Operator's Manual

Edwards Critical-Care Division

Vigilance®

Continuous Cardiac Output (CCO) Monitors and
Continuous Cardiac Output/Oximetry (CCO/SvO$_2$)
Monitors

Baxter

Table of Contents

TROUBLESHOOTING GUIDE

Appendix A: VIGILANCE® MONITOR SPECIFICATIONS

Appendix B: EQUATIONS FOR CALCULATED PATIENT PARAMETERS

Appendix C: VIGILANCE® MONITOR DEFAULT SETTINGS

Appendix D: COMPUTATION CONSTANTS

Appendix E: PERFORMANCE CHECK

Appendix F: SERVICE AND SUPPORT

Appendix G: WARRANTY

GLOSSARY

INDEX

Figures

Tables

Preface

❖ **WARNING:** CAREFULLY READ THIS OPERATOR'S MANUAL BEFORE ATTEMPTING TO USE THE *Vigilance®* MONITOR.

Purpose and Scope

The purpose of this manual is to provide the operator of the *Vigilance®* Monitor with setup and operating instructions, device applications, limitations, and routine performance verification procedures. The *Vigilance®* Monitor Operator's Manual provides instructions for all *Vigilance®* Monitor configurations*. To achieve satisfactory results, the operator should read this manual thoroughly before attempting to use the monitor.

Audience

This manual has been prepared for use by trained critical care clinicians, nurses, and physicians in any hospital environment where critical care is administered (for example, emergency rooms, operating rooms, intensive care units, etc.).

*Vigilance Monitors may be configured to perform CCO/ICO measurements only or CCO/ICO and SvO_2 measurements. For Vigilance monitors with SvO_2 capabilities removed disregard all references to SvO_2 capabilities in this manual.

1

INTRODUCTION

1. Introducing the Vigilance® Monitor

The *Vigilance®* Monitor is an advanced patient monitor which measures cardiac output both continuously and by the intermittent bolus thermodilution method. The *Vigilance®* Monitor may also be configured to measure continuous mixed venous oxygen saturation (SvO_2). In addition, the *Vigilance®* Monitor calculates hemodynamic and oxygenation parameters. The *Vigilance®* Monitor is designed for use by trained clinicians in a variety of critical care settings including operating rooms, intensive care units, and recovery rooms, as well as hospital emergency rooms, cardiac care, and burn units.

The *Vigilance®* Monitor measures cardiac output continuously by introducing small pulses of energy into the blood and recording blood temperature via a pulmonary artery catheter. Cardiac output is computed using a conservation of heat equation, and indicator dilution curves are obtained by cross-correlation of the energy input and blood temperature waveforms. After initialization, the monitor continuously displays the patient's cardiac output without the need for user calibration or intervention.

To measure cardiac output intermittently using the bolus thermodilution technique, a small amount of indicator of a known volume and temperature is injected through the catheter injectate port, and the resultant decrease in blood temperature is measured by the thermistor in the Pulmonary Artery (PA). The *Vigilance®* Monitor plots a curve representing the decrease in blood temperature over time and integrates the data based on the Stewart-Hamilton indicator dilution equation. The area beneath the thermodilution curve is calculated and displayed in numeric form (in liters per minute).

Vigilance® Monitors measure mixed venous oxygen saturation by a spectrophotometric technique that uses light emitting diodes (LEDs) to transmit light in the red and infrared spectra through an optical fiber in a PA catheter to the blood. The light is reflected back through a separate optical fiber to an optical module. The amount of light reflected is primarily dependent on the color and amount of red blood cells present. The reflected light is electrically measured by the *Vigilance*® Monitor and analyzed to determine SvO_2 by detecting color changes in the red blood cells.

The *Vigilance*® Monitor derives parameter values related to hemodynamics and oxygenation with appropriate user input.

2

QUICK-START GUIDE
TO OPERATION

**2.
Quick-Start
Guide to
Operation**

This *Quick-Start Guide to Operation* is intended only as a checklist for operating the *Vigilance®* Monitor. The user should thoroughly read this manual before attempting to use this instrument.

Vigilance® Monitor is for use only as an adjunct in patient assessment. This instrument should be used in conjunction with other clinical indicators.

Before using the *Vigilance®* Monitor, the user should thoroughly read the directions for catheter use provided with each catheter for complete description, instructions, warnings, cautions, and specifications.

❖ **WARNING: IMPROPER USE OF THE *Vigilance®* MONITOR COULD PRESENT A HAZARD TO THE PATIENT. CAREFULLY READ THE "WARNINGS" SECTION OF THIS MANUAL (Section 3.8) BEFORE USING THE INSTRUMENT.**

1. Attach one end of the power cord securely to the *Vigilance®* Monitor and connect the other end to an AC power outlet.

2. Turn the *Vigilance®* Monitor on by pressing the green power switch located at the lower left on the front of the monitor. The small green LED will light up and the video screen will display a self-test message. The monitor will then proceed with initialization.

3. Carefully align the instrument end of the catheter interface cable with the corresponding receptacle located at the bottom right of the monitor. Push the connector straight in until fully seated.

4. In order to acquire SvO_2 measurements, connect the optical module to the SvO_2 connector on the front of the *Vigilance®* Monitor. **Allow 20 minutes for optical module warm up.**

5. Following the internal self-test and initialization, the **HOME** screen is displayed.

6. If SvO_2 monitoring is desired:

   i.   Connect the catheter to the optical module.

   ii. Press **SvO$_2$** on the touch bar.

   iii. Select **IN VITRO CALIBRATION** on the touch bar.

   iv. Use the **CURSOR** key to select Hgb (hemoglobin) or Hct (hematocrit). Enter lab value using touch bar.

        If the lab value is not available or unknown, the default values can be used until the lab value is available. (When the lab value is available, see the HGB Update instructions in section 3.4.6.)

   v.   Press the **CAL** key. The following message will be displayed:

        In Vitro Calibration in progress.

        Upon completion of a successful calibration, the monitor will display the following message:

        In Vitro Calibration OK. Insert catheter then press Start SvO2.

7. Prepare the catheter for insertion (see package insert that accompanies the catheter).

8. If SvO_2 monitoring is desired and the catheter is properly positioned in the patient, press **START SvO$_2$** on the touch bar. The following message will be displayed:

   Optical Module Update in progress.

   The **HOME** screen will automatically be displayed with an SvO_2 value.

9. If CCO monitoring is desired, press the **CCO** key to begin the continuous cardiac output monitoring process.

10. The five function keys **(CCO (STOPPED/RUNNING), TREND, PATIENT DATA, SETUP, and ALARMS)**, located vertically to the right of the screen, provide access to optional screens which will, in turn, change the functions and labels of individual keys. The blue touch bar located below the display screen allows for operating mode changes and data entry based upon the function selected.

3

OPERATING THE VIGILANCE® MONITOR

3.

Overview

The *Vigilance®* Monitoring System consists of the following components: monitor, detachable catheter patient interface cable, optical module*, flow-through temperature probe, and power cord. The monitor is principally intended for use with Edwards Critical-Care catheters designed to continuously measure cardiac output and mixed venous oxygen saturation. Alternatively, the monitor can be used to measure cardiac output intermittently, through the BOLUS CO mode, using compatible thermodilution pulmonary artery catheters.

➡ **NOTE:** User entered values are shifted into the selected field from the right-most digits. The first digit entered will cause the decimal point and any necessary 0's (place holders between the right most position and the decimal point) to appear. Additional digits shift in from the right.

*Optical modules are only provided with those *Vigilance®* Monitors that are going to be used for SvO_2 measurement.

3.1
Controls
and Basic
Operation

3.1.1 CONTROLS

Figure 3-1 *Vigilance*® Monitor, Front Panel
For Vigilance monitors not configured with SvO₂, SvO₂ display items
will not appear.
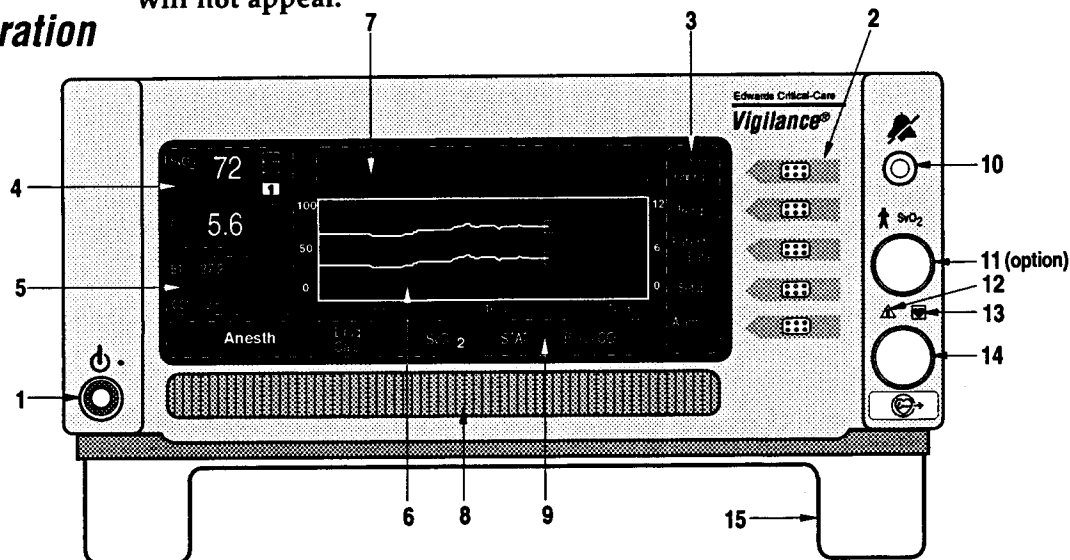
1. **POWER SWITCH**
Green button turns the instrument power
ON and OFF.

2. **FUNCTION KEYS**
Five keys provide direction to general
operating functions:

   • **CCO (STOPPED/RUNNING) key:** Starts
   or stops the chosen mode of cardiac out-
   put measurement — either continuous
   or bolus.

   • **TREND key:** Allows the user to vary
   the time scale duration (30 minutes to 24
   hours). Also allows the user to select pa-
   tient parameters to graph, to change the
   vertical scale, and to mark events.

   • **PATIENT DATA key:** Provides for
   review of calculated hemodynamic and
   oxygenation parameters and manual
   entry of patient data.

   • **SETUP key:** Provides for selection of
   display units, audio level, setting inter-
   nal clock, and auxiliary functions.

   • **ALARMS key:** Allows the user to control
   the alarm monitoring function by select-
   ing patient parameters to be monitored
   and by establishing alarm limits.

3. **FUNCTION KEY LABELS**

4. **LARGE NUMERIC DISPLAY AREA**

5. **SMALL NUMERIC DISPLAY AREA**

6. **GRAPH OR MENU AREA**

7. **MESSAGE WINDOW FOR FAULTS,
ALARMS, ALERTS**

8. **TOUCH BAR**
The blue bar is used to select options for
touch pad functions and allows for oper-
ating mode changes and numeric data entry.

9. **TOUCH BAR LABELS**

10. **ALARM SILENCE KEY**
The orange button silences the audible
alarm for two minutes or until all alarm
conditions are cleared, whichever
occurs first.

11. **OPTICAL MODULE CONNECTOR**
This provides the interface for the
OM-2 cable. (On monitors equipped with
SvO₂ Capabilities)

12. **CAUTION**
Before connecting cable, refer to
Operator's Manual.

13. **CAUTION**
Connections are electrically isolated from
earth ground.

14. **CATHETER CABLE CONNECTOR**
This connector provides the interface for
the patient cable.

15. **TILT STAND**
Pulls down to raise monitor screen
for viewing.

Figure 3-2 *Vigilance®* Monitor, Rear Panel
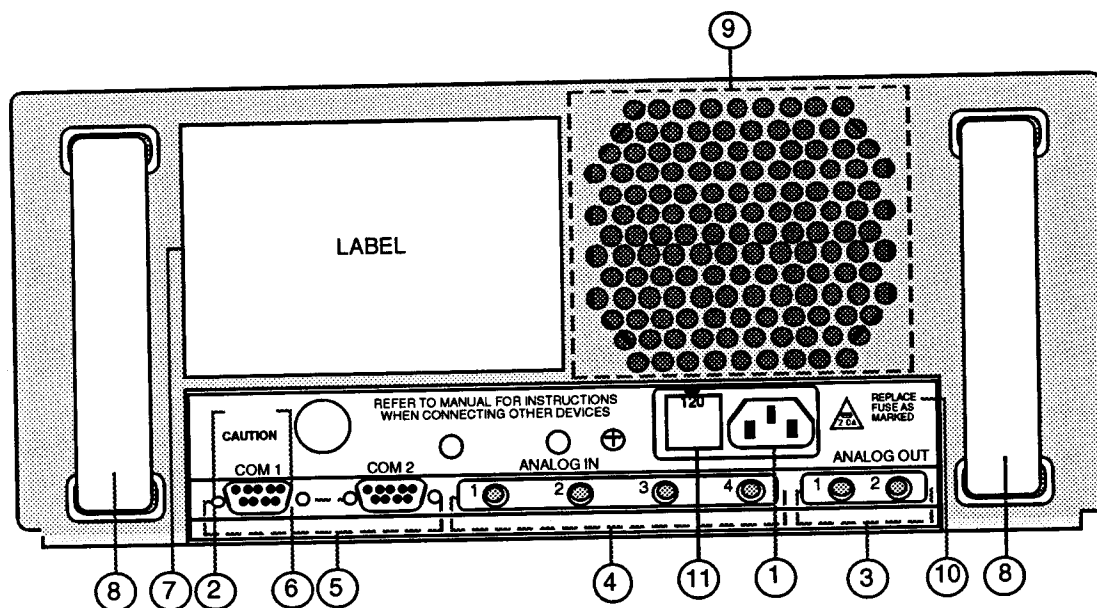
1. **AC POWER INPUT**
   Use only the power cord supplied with the monitor. This connector accepts AC power ranging from 100 to 240 VAC, 50/60 Hz.

2. **CAUTION**
   For safe operation, see Section 3.7 for instructions before connecting other devices.

3. **ANALOG OUT**
   These 2 connectors provide the user with selectable analog signals for output to a chart recorder or other instruments via a 1/8 inch miniature phone plug.

4. **ANALOG IN**
   These 4 connectors provide the instrument with input signals from other equipment via 1/8 inch miniature phone plugs.

5. **COM1/COM2**
   These 2 connectors allow for connecting the instrument to a printer, or other clinical instrument, or other manufacturer's instruments, via 9-pin RS-232 connectors.

6. **CAUTION**
   To reduce the risk of electric shock, DO NOT remove back. Refer servicing to qualified service personnel.

7. **INSTRUMENT SERIAL NUMBER**
   Numerical identification required when contacting Edwards Technical Support.

8. **HANDLES**
   The plastic handles provide convenient portability for the instrument.

9. **FAN OUTPUT**
   Opening allows for air output from the instrument fan.

10. **CAUTION**
    Replace fuse as marked.

11. **FUSE HOLDER**
    Should be positioned so that arrow points to desired voltage setting.

3.1.2 PREPARING INSTRUMENT FOR BASIC OPERATION

The following procedure describes the steps to be performed in setting up the *Vigilance®* Monitor for basic operation:

1. Attach one end of the power cord securely to the *Vigilance®* Monitor and connect the other end to an AC power outlet.

2. Turn the *Vigilance®* Monitor on by pressing the green power switch located at the lower left on the front of the monitor. The small green LED will light up and the video screen will display a self-test message. The monitor will then proceed with initialization.

▲ CAUTION: Ensure that the ventilation fan is operating properly through the fan output on the instrument rear panel.

➡ NOTE: If the power has been off for less than 8 hours, the *Vigilance®* Monitor will prompt the user to confirm that a new patient is being connected. If new patient is confirmed, all previously recorded patient and trend data will be deleted. Otherwise, the data will be saved. If the monitor power is off for more than eight hours, patient data is automatically deleted and no new patient confirmation is required.

3. To prepare the *Vigilance®* Monitor for CCO monitoring, carefully align the instrument end of the catheter interface cable with the corresponding receptacle located at the bottom right of the monitor. Push the connector straight in until fully seated.

4. If SvO_2 monitoring is desired, connect the optical module to the SvO_2 connector on the front of the instrument to prepare for monitoring.

➡ NOTE: If the optical module is being connected for the first time or the system has been turned off with the optical module connected, **allow 20 minutes for optical module warm up.** The catheter need not be connected to the optical module for it to warm up.

5. Following the internal self-test and initialization, the **HOME** screen is displayed. The instrument will emit a beep and display a message to check the catheter connection, for example:

FAULT: Check Catheter and Cable Connections

The following message will be displayed during SvO_2 initialization:

SvO2 Initializing, Please Wait

The following message will be displayed when SvO_2 initialization is complete:

Optics Module Not Calibrated

The above message will be displayed until a calibration (in vitro or in vivo) or TRANSPORT function is performed (see Section 3.4).

If the SvO_2 functions are attempted prior to completion of self-initialization, the following message will be displayed upon pressing the **SvO₂** key:

SvO2 Not Ready. Please Wait.

6. To set time and date, press the **SETUP** key and use the **CURSOR** key to scroll to the time format. Select either non-military or military (12 or 24 hour) clock using the **CHANGE** key. Press **SET TIME** on the touch bar and use the **CURSOR** key to select time or date. Input the current information using the touch bar. Press **HOME** to return to the **HOME** screen.

➡ **NOTE:** If the military clock is selected, the time must be input in the military format (i.e. 11:00pm must be input as 23:00). Date must be input as month/date/year.

➡ **NOTE:** If power is lost for any reason, for less than 60 seconds, the *Vigilance®* will attempt to start CCO data collection if CCO was running when power was lost and will attempt to recall SvO_2 calibration data from the optical module if SvO_2 was calibrated when power was lost.

3.1.3 FUNCTION KEY FEATURES

3.1.3.1 CCO (stopped/running) Key

Pressing **CCO** initiates or terminates continuous cardiac output (CCO) monitoring. The key gives the status of the CCO at all times. It indicates CCO running during operation and CCO stopped when CCO is off. Once CCO monitoring is terminated, the large CCO display in the upper left corner will be removed, but time continues to be noted on the graph. The last CCO value is displayed with the time when monitoring was stopped. Once CCO monitoring is resumed, the trend graph will start displaying CCO trend data, and a break in the trend line indicates when monitoring was interrupted.

3.1.3.2 TREND Key

The **TREND** key allows for configuration of the graph display area as well as allowing the user to mark the time of occurrence of clinically and functionally significant events.

To set the trend graph time interval displayed on the screen, press **TREND**, then select from the various time intervals from 30 minutes to 24 hours by pressing the touch bar.

To view trend data in time periods outside the current trend screen, press the <----- and -----> touchbar keys. The time period displayed will be adjusted by the currently selected time interval.

To select the parameters to be plotted (two maximum), press **SELECT GRAPH** on the **TREND** screen and scroll through selections by using the touch bar.

➡ **NOTE:** To select indexed parameters for trending (i.e. CCI), you must first select the INDEXED option for the desired parameter on the **SETUP** screen (see Section 3.1.3.4, SETUP).

To display the selected parameters, press the **HOME** key. The curve for the right axis parameter is displayed using a lower intensity curve. Information regarding parameter range and alarm limits is displayed on the axis of the respective graph. Only CCO, CCI, and SvO_2 can be plotted on the trend graph.

➡ **NOTE:** When selecting a parameter for a particular graph, the user may select the vertical scale from the following ranges:

Parameter	Ranges					
CCO (L/min)	0-20	0-16	0-12	0-6	0-4	2-8
CCI (L/min/m^2)	0-20	0-16	0-12	0-6	0-4	2-8
SvO_2 (%)	0-100	50-80	50-100	30-60	20-90	

The *Vigilance*® Monitor logs and displays certain user selectable (manually entered) and automatically recorded events. Event labels are displayed in the trend area on the **HOME** screen at the time the event occurs or is entered. If two or more events occur simultaneously, the first manually entered event selected is displayed. A manually entered event is always displayed before an automatic event, while automatic events are displayed by priority (as listed below). To manually mark an event, access the **EVENTS** menu by pressing the **TREND** key and then the **EVENTS** key. Select the appropriate event label by pressing

the touch bar. Press the touch bar a second time prior to pressing the **HOME** key if that event is not to be recorded. Events and their labels are as follows:

Manually Entered Events	Label
Drug	D
Arrhythmia	A
Ventilator	V
Fluid	F
Nurse	N
Suction	S
Miscellaneous	M

Automatic Events	Label
In Vitro Calibration	I
In Vivo Calibration	C
Update Calibration	U
Recall Data from OM	R
Auto Zero Error	Z
Light out of Range	L
Draw Blood	d
OM Disconnect	O
Bolus TD	B

Pressing the **HOME** key or **EVENT REVIEW** key will save the selected events and mark the trend graph. Once saved, an event cannot be erased or changed. When events occur simultaneously or such that the event markers would occupy the same space on the trend graph, only the oldest occurring event will be displayed.

All events are recorded in the **EVENT REVIEW** screen, 32 of which can be stored for review at any one time. When 32 events have occurred, the most recent event will replace the oldest event. To review the stored events, press the **EVENT REVIEW** key, then press **PAGE UP** or **PAGE DOWN** on the touch bar to scroll through the event listing.

3.1.3.3 PATIENT DATA Key

Specific patient parameters may be entered to obtain derived hemo-dynamic and oxygenation measurements. Pressing the **PATIENT DATA** key displays the cardiac profile parameters. To enter data for the oxygenation profile, press the **OXYGEN PROFILE** key.

Table 3-1 Patient Data Calculations

By Manually Entering:	The Monitor Will:
• Height (in. or cm) • Weight (lbs or kg)	Calculate body surface area, display cardiac index (L/min/m2) on the **HOME** screen, and allow other indexed parameters to be computed.
• Mean Arterial Pressure (MAP) • Central Venous Pressure (CVP)	Calculate and display systemic vascular resistance (SVR). SVR WILL NOT be automatically updated as CO changes.
• Mean Pulmonary Artery Pressure (MPAP) • Pulmonary Artery Wedge Pressure (PAWP) • Heart Rate	Calculate and display other hemodynamic parameters.
• Arterial Oxygen Saturation	Calculate and display oxygen delivery, oxygen consumption and other oxygenation parameters.

➡ **NOTE:** For hemodynamic and oxygenation equations, refer to Appendix B.

To enter or change a patient parameter, press **EDIT** and move the cursor by pressing the **CURSOR** key. Use the touch bar to enter a new value. To recalculate the derived parameters, press the **CALC** key and the monitor will update the displayed profile. Pressing the **HOME** key will also update the information if the values are manually entered, and return you to the **HOME** screen. The time and date displayed on the top line of the patient profile indicate the time when the information was last updated. Unlike parameters displayed on the left side of the **HOME** screen, the profile parameters are not automatically updated as the values change.

The *Vigilance* allows editing of CCO, CCI, MAP, CVP, SaO_2 and HR while in the Patient Data Screen. Derived parameters using edited data are updated when the **CALC** key is pressed. An asterisk indicates the current data field was edited. The asterisk remains on the screen until the data field is cleared. Clear the current data field by pressing the **CLEAR** key on the touchbar. After the data field is cleared, derived parameters are calculated using the continuous or slaved data. New data will only be entered into calculations by pressing the **CALC** key.

The *Vigilance®* allows editing of BSA while in the Patient Data screen. When BSA is edited, the patient's height and weight is cleared from the screen.

Derived parameters sent to the analog output ports use the continuous and slaved data. Derived parameters using edited data are not sent to the analog output ports.

➡ NOTE: If you access the patient profile and do not change (EDIT) any values or the values are imported from external devices, pressing the HOME key will not update the derived parameters.

➡ NOTE: Input parameters common to the CARDIAC PROFILE and OXYGENATION PROFILE screens are automatically updated when input on either of the two screens.

➡ NOTE: The CURSOR key moves to parameters that can be edited.

➡ NOTE: Refer to Appendix A for high and low limits of patient parameters.

➡ NOTE: Selecting NEW PATIENT provides you with the option to erase all historic profile, trend, event and bolus average data, and reset alarm limits to default settings. New patient parameters for each profile may then be entered.

3.1.3.4 SETUP Key

The SETUP key allows for changes in the HOME screen display format. The SETUP key also allows you to set the system time and date, and to configure the monitor for input and output functions, diagnostics, and demonstration functions.

Table 3-2 Setup

Variable:	May be displayed as:
Temperature Units	°F or °C
International Units	No - mmHg, dn-s/cm^5, g/dL Yes - kPa, kPa-s/L, mmol/L
Time Format	Military or non-military
Speaker Volume	Varies from low to high
Patient Parameters: CCO, SVR	Measured variable or indexed to body surface area

To make a change in any of the variables, press **SETUP** then use the **CURSOR** key to scroll through the variables. Press **CHANGE** to toggle between the choices. The current time and date may also be entered by selecting **SET TIME** using the touch bar.

Selecting **SET TIME** on the **SETUP** screen allows you to change the monitor's time and date (month/date/year). Using the **CURSOR** key to select the desired variable, the current information can be entered via the touch bar. The *Vigilance* Monitor will continue to store time and date when power is off.

➡ **NOTE:** If a patient parameter that is indexed to body surface area has been selected for display and body surface area is not available, the indexed patient parameter will not be displayed. To display an indexed patient parameter, the patient's height and weight must be entered using the **PATIENT DATA** screen or the **PATIENT INFORMATION** screen during setup.

The **PATIENT INFORMATION** screen is displayed when CO/CCO or SVR is selected for **INDEXED** and BSA is not available when **HOME** is pressed on the **SETUP** screen. Press **CURSOR** to select the patient's height and weight or BSA. Use the touchbar to enter the new value.

To calculate BSA, the patient's height and weight must be entered. Patient BSA can be manually entered without height and weight. Press **CURSOR** to select BSA and use the touchbar to enter the new value. Press **RETURN** to return to the **HOME** screen.

➡ **NOTE:** Any height, weight or BSA information will appear in the Patient Data screen the next time the **CALC** key is pressed.

If height and weight or BSA information is not entered into the **PATIENT INFORMATION** screen, indexed patient parameters will not be displayed. To enter the patient's height and weight or BSA at a later time, press the **PATIENT DATA** key from the **HOME** screen. Use the **CURSOR** key to select the desired parameter and input the new values using the touchbar.

Selecting **SYSTEM CONFIG** on the **SETUP** screen displays the monitor's software versions. Catheter model and serial numbers for the last catheter connected are also displayed.

- **ANALOG INPUT**
  To configure the Analog Input Ports to receive signals from an optional instrument, select the touchbar keys: **PORT 1, PORT 2, PORT 3** or **PORT 4**. When any of these touchbar keys are pressed the corresponding port information is displayed. The

order of the input fields are as follows: Parameter, Voltage Range, Low Voltage Value, and High Voltage Value. The SET A/D calibrates these voltage settings, if necessary.

➡ **NOTE:** The SET A/D key should only be used by properly trained personnel. See Section 3.7.1 for a detailed description of connecting the *Vigilance*® Monitor to analog input devices.

- **ANALOG OUTPUT**
  To configure the Analog Output Ports to send signals to an optional instrument, select **PORT 1** or **PORT 2** touchbar keys. When any of these touchbar keys are pressed the corresponding port information is displayed. See Section 3.7.2 for a detailed description of connecting analog output devices to the *Vigilance*® Monitor.

- **DIGITAL PORTS**
  The touchbar keys **COM 1** and **COM 2** are for use with selected optional devices (for example: Printer). Other serial port parameters can be changed by using the **CURSOR** to select them. Default settings are already programmed. See Section 3.7.3 for a detailed description of connecting digital devices to the *Vigilance*® Monitor.

- **DEFAULTS**
  This key allows you to set the selectable alarm limits, display settings and communication port settings to original factory conditions. Patient data and trend information will be erased when these settings are re-established. See Appendix C for factory default settings.

- **DIAGS**
  This key provides access to the Diagnostics Screen that displays the cross correlation curves of the CCO run data. It also displays the STAT value and SNR (signal-to-noise ratio) value for the run data.

- **DEMO**
  With a password, this key allows the operator to configure the instrument for demonstration purposes. The monitor will not operate in this mode with a catheter attached. A "DEMO" label will appear above the **CCO** key when the monitor is in this mode.

❖ **WARNING:** DO NOT USE THE DEMO MODE IN A PATIENT CARE SETTING TO AVOID POSSIBLE CONFUSION WITH PATIENT MEASUREMENTS.

3.1.3.5 ALARMS Key

To change the limits, press **ALARMS** and select the desired parameter via the touch bar. Using the **Hi/Low** key, select the limit to be changed and enter the desired value using the touch bar. To change the other limit, use the same procedure (see Appendix C for default alarm settings).

➡ **NOTE:** The high and low alarm limits cannot be set to the same value.

To turn an alarm off, select the **ON/OFF** key while displaying the appropriate parameter. **OFF** disables both the audible and visual alarm signals. In situations where the alarm is turned OFF for all parameters, a "No Alarms" icon (shown below) will appear on all screens while the alarms are suspended.

"No Alarms" icon: 𝕏

When the alarm function is ON and the monitored parameter is outside the desired limits, audible and visual indicators will be activated. The audible indicator can be temporarily disabled for two minutes using the orange **ALARM SILENCE** button. The **ALARM SILENCE** icon (shown below) will continue to be displayed until the alarm condition is corrected, the limits are changed, or the alarm function is turned OFF for that parameter.

ALARM SILENCE icon: ⬚

3.1.4 STANDARD OPERATING KEYS

3.1.4.1 HOME

This key returns the monitor to the initial or **HOME** screen from any existing screen. In most situations, the **HOME** key will save the data or instrument configuration at the time it is pressed. The **HOME** key is similar to the **ENTER** key on a personal computer.

3.1.4.2 CURSOR

This key allows you to select from the available choices in any chosen operating mode. It generally moves downward and/or to the right, and highlights the chosen entry. Highlighted entries can then be modified using other keys.

3.1.4.3 CHANGE

This key cycles among options for a highlighted function that has been previously selected using the **CURSOR** key.

Edwards Critical-Care Division

3.1.4.4 RETURN

This key allows you to return to the first screen of a selected function. For example, in the BOLUS CO mode, the **RETURN** key returns you to the initial BOLUS CO screen.

3.2 Continuous Cardiac Output Monitoring

3.2.1 STANDARD CCO MONITORING

1. Attach the catheter end of the patient cable to the color-coded catheter connectors.

2. Verify that the catheter is properly inserted into the patient.

▲ CAUTION: Prior to catheter insertion, refer to directions for use provided with each catheter for complete description, instructions, warnings, cautions, and specifications.

When the system is properly connected, the following message will be displayed:

Press CCO Key to begin CCO monitoring

3. Press the **CCO** key. The instrument will begin the measurement process as indicated by the status of 'running' underneath CCO and by displaying the following screen message:

Collecting CCO data . . .

After approximately three to six minutes, when sufficient data have been obtained, a CCO value will appear on the left of the display.

4. CCO data will be plotted on the trend graph. A flashing box indicates the most recent CCO value. As new CCO values become available, the digital display will be updated (every 30 - 60 sec), and a point will be plotted on the graph.

5. If you choose to stop CCO monitoring, press the **CCO** key. The status will indicate the stopped mode of operation. The large digital value for CCO will be removed from the display. The digital value will be replaced by the last CCO value computed with a time stamp indicating when monitoring was stopped. If CCO monitoring is resumed, a gap will appear in the plotted trend indicating the time period when monitoring was interrupted.

6. In some situations where patient conditions create large changes in pulmonary artery blood temperature over several minutes, the monitor may take longer than 6 minutes to obtain an accurate CCO measurement. In these cases, the following alert message will appear 6 minutes after monitoring has commenced:

   ALERT CCO: Signal Adapting — Continuing

   If the condition has not cleared in 9 minutes (a total of 15 minutes after monitoring began), the following message will appear:

   ALERT CCO: Unstable Blood Temp. — Continuing

   In either case, the monitor will continue to function and no operator action is required. When CCO measurements are obtained, the alert message will be removed and the current CCO value will be displayed and plotted.

   In cases where a CO measurement takes longer than 30 minutes to obtain after monitoring was initiated, the following message will appear:

   FAULT CCO: Thermal Signal Loss

   CCO monitoring will then be terminated. This condition could result from migration of the catheter tip into a small vessel preventing the thermistor from accurately sensing the thermal signal. Check catheter position and reposition the catheter, if necessary. After verifying patient status and catheter position, CCO monitoring may be resumed by pressing the **CCO** key.

7. When CCO monitoring is in progress, updating of the CCO measurement may be delayed by unstable PA blood temperature. If the CCO value is not updated for 6 minutes, the following message will appear:

   ALERT CCO: Unstable Blood Temp. — Continuing

   The last CCO value and measurement time will be displayed in place of the large digital CCO value in the upper left of the display. No operator action is required. When sufficient data are available, the CCO value will again be displayed.

   If the above condition has not cleared in 14 minutes (a total of 20 minutes from the time the CO value was last updated), the following message will appear:

   FAULT CCO: Thermal Signal Loss

CCO monitoring will then be terminated. This condition could result from migration of the catheter tip into a small vessel preventing the thermistor from accurately sensing the thermal signal. The operator should check catheter position and reposition the catheter, if necessary. After verifying patient status and catheter position, CCO monitoring may be resumed by pressing the **CCO** key.

8. While in operation, the monitor will store up to 72 hours of trend data. If monitoring continues beyond 72 hours, the most recent data will be added to the trend, and the oldest data removed.

   When power is lost, the monitor retains the last eight (8) hours of information. If power is immediately restored, those eight hours of information will be retained and displayed. As time passes without power, however, an equal amount of data is lost (i.e. after 8 hours, all 8 hours of retained data is lost). The monitor will also store any specific selections made regarding graph selections, etc., as well as user-entered patient data.

   If power is restored within 60 seconds, the *Vigilance®* will attempt to start CCO data collection if CCO was running when power was lost. It will also attempt to recall SvO_2 calibration data from the optical module if SvO_2 was calibrated when power was lost.

❖ **WARNING:** CCO MONITORING SHOULD ALWAYS BE DISCONTINUED WHEN BLOOD FLOW AROUND THE THERMAL FILAMENT IS STOPPED OR REDUCED. CLINICAL SITUATIONS WHERE CCO MONITORING SHOULD BE DISCONTINUED INCLUDE, BUT ARE NOT LIMITED TO: TIME PERIODS WHEN A PATIENT IS ON CARDIOPULMONARY BYPASS, PARTIAL WITHDRAWAL OF THE CATHETER SO THAT THE THERMISTOR IS NOT IN THE PULMONARY ARTERY, CARDIAC ARREST, OR REMOVAL OF THE CATHETER FROM THE PATIENT.

3.2.2 STAT MODE OPERATION

When monitoring continuous cardiac output, a hemodynamically unstable thermal signal may delay the *Vigilance®* Monitor from displaying a CCO or CCI value after the **CCO** key has been pressed. In this event, the STAT mode may be used to present fast estimates of CCO/CCI values until such time that the thermal signal has stabilized.

1. After CCO monitoring has commenced, press **STAT** on the blue touch bar. Ten boxes used for displaying CCO/CCI run data will appear.

2. Each box displays a fast CCO/CCI estimate. The most recent run is displayed in the top left box (highlighted with a double box) and the oldest run is displayed in the bottom right box. The most recent esti-

mate is accompanied by a time stamp. All other values are accompanied by the duration of time that has passed since that value and the most current value were first displayed. These numbers are indicated in parenthesis. A countdown timer in the middle of the screen indicates when the next fast CCO/CCI estimate is expected (in seconds). If the fast estimate for a CCO/CCI run is unavailable, a blank box will be displayed.

➡ **NOTE:** The *Vigilance*® Monitor must be configured such that CCO is an indexed parameter in order to display CCI values. If the monitor is configured for CCI and no BSA is available, the boxes will be blank. See SETUP for monitor configuration.

➡ **NOTE:** No trend CCO or CCI value will be displayed in the large numeric display area on the left side of the screen until sufficient, time-averaged data is available.

➡ **NOTE:** When the **PATIENT DATA** softkey is pressed, the **CARDIAC PATIENT DATA** screen is displayed. **STAT** mode data may be manually entered in this area.

3. To return to the trend screen, press the **HOME** key.

3.2.3 ANESTHESIA MODE OPERATION

The Anesthesia Screen is a useful tool for viewing the trend screen and the diagnostic screen at the same time. The screen provides the trend graph as configured in the **HOME** screen, and directly below, a graph of the diagnostic CCO curves. The two diagnostic graph curves provide specific information about the process of CCO generation. They represent the time averaged SNR (signal-to-noise ratio) data. The darker curve is the actual representation of the patient data for CCO calculation. The lighter curve is the calculated ideal curve that represents a good SNR. The curves should be nearly superimposed when the signal is adequate. The curves are updated approximately every 30-60 seconds.

The following information can be obtained from the Anesthesia Screen:

BT - Blood Temperature
ST - Surface Temperature of the thermal filament
CO or CI STAT - The STAT mode value of CO or CI updated every 30-60 seconds.
SNR - The signal-to-noise ratio indicating the level of thermal noise being experienced with each updated CCO. (Range -10 to +20)

1. To access the Anesthesia screen from the HOME screen or STAT screen, press **ANESTH**.

2. To return to the HOME screen, press **HOME**.

3. To return to the STAT screen, press **STAT**.

4. To print the displayed Anesthesia screen, press **PRINT**.

3.3 Bolus Cardiac Output Measurement

You can choose the **BOLUS CO** option for cardiac output (CO) or cardiac index (CI) measurement from the **HOME** screen via the touch bar. There are two modes for intermittent bolus CO measurement — AUTOMATIC and MANUAL.

The monitor factory default setting is the AUTOMATIC mode, which is generally the most convenient configuration. In this mode, the monitor automatically flashes an INJECT message upon achieving a baseline blood temperature. When an injection is completed, the instrument computes a value and is again ready to process another bolus injection. Up to six bolus injections can be completed in one sequence.

To change the mode of operation to MANUAL, press **MODE AUTOMATIC** on the touch bar, then select **MODE MANUAL**. Press **RETURN** to return to the main **BOLUS CO** screen. The MANUAL mode operation is similar to the AUTOMATIC mode except that the instrument indicates that it is in the READY state prior to an injection. You must press **START BOLUS** prior to each injection in the MANUAL mode.

Either cardiac output (CO) or cardiac index (CI) can be computed, displayed, and averaged in the BOLUS CO mode. To alternate between CO and CI, press **CO DISPLAY** when CI values are displayed and **CI DISPLAY** when CO values are displayed.

As a factory default setting, the monitor calculates the computation constant based on the following input variables: catheter size and injectate volume. The default catheter size for computation constant selection is 8 French. Alternatively, the computation constant may be entered manually.

▲ CAUTION: Refer to the computation constant chart in Appendix D to verify that the computation constant used by the *Vigilance* Monitor is the same as the computation constant specified in the catheter package insert. If the constant specified by the catheter package insert does not match that used by the monitor, manually enter the desired computation constant according to the following instructions.

To manually enter the computation constant, select **BOLUS SETUP**, press **CHANGE** to select YES for the COMPUTATION CONSTANT manual entry, then press **RETURN** to return to the main **BOLUS CO** screen. To change the computation constant value, press below the label on the touch bar. Use the touch bar to enter desired constant, and press **RETURN** to effect the change.

➟ **NOTE:** The *Vigilance*® Monitor does not recognize probe type (e.g. bath or in-line) when the user chooses to manually enter the computation constant (i.e. in the Computation Constant YES mode). If the probe type is changed when manual selection has been chosen, the computation constant must be changed for the corresponding probe type. If the monitor is set for automatic selection (i.e. in the Computation Constant NO mode), the computation constant is automatically determined by the monitor when the user selects the appropriate catheter size and injectate volume.

All bolus averages are recorded in the **BOLUS REVIEW** screen, 32 of which can be stored for review at any time. When 32 averages have occurred, the most recent average will replace the oldest average. To review the stored bolus averages, press the **BOLUS REVIEW** key, then press **PAGE UP** or **PAGE DOWN** on the touch bar to scroll through the bolus average listing.

3.3.1 AUTOMATIC MODE

Perform the following to measure CO or CI in the AUTOMATIC mode:

1. Press the touch bar beneath the **BOLUS CO** label displayed on the **HOME** screen. Injectate temperature (IT) is displayed beneath blood temperature (BT) in the lower left corner of the screen. Note the specific measurement variables (**INJECTATE VOLUME, CATHETER SIZE**) in the touch bar display area and change if necessary. To change a selected variable, press the touch bar beneath the appropriate label, select the correct choice, and press **RETURN**.

   If a manually entered computation constant is to be used instead of catheter size and injectate volume, select **BOLUS SETUP** to configure the monitor to display a computation constant. The touch bar may then be used to enter the desired constant. Select **RETURN** to effect the change.

2. When a stable baseline blood temperature is obtained by the monitor, the INJECT message will flash, and you may proceed with a bolus injection.

▲ CAUTION: Sudden changes in PA blood temperature such as those caused by patient movement or bolus drug administration may cause a CO or CI value to be computed. To avoid falsely triggered curves, you should inject as soon as possible after the INJECT message appears.

➡ NOTE: The **STOP BOLUS** key may be used to interrupt baseline blood temperature monitoring in the event that bolus measurements are discontinued. To resume baseline monitoring and bolus cardiac output measurement, press the **START BOLUS** key.

3. Once a bolus is injected, the thermodilution washout curve appears, a COMPUTING message is displayed, and the resultant CO measurement is displayed on the left side of the screen.

➡ NOTE: If a bolus measurement is compromised, as indicated by an alert message, an "a" will appear next to the value displayed on the **BOLUS CO** screen.

4. Subsequent determinations can be performed as desired when the INJECT message reappears.

➡ NOTE: The maximum time allowed between the appearance of the INJECT message and injection of the bolus is four minutes. If no injection is detected within this time interval, the screen returns to READY until you press **START BOLUS** to begin the inject cycle again.

5. When sufficient determinations have been made, you can press the **EDIT BOLUS** key to obtain an average value. The average CO or CI is displayed in the upper left corner of the screen. CO or CI is automatically averaged if the **HOME** key or the **PATIENT DATA** key is pressed. This average is indicated on the **HOME** screen with a dot representing the value and the time as reflected by the position on the trend.

➡ NOTE: Any bolus measurement that was accompanied by an alert message will have an "a" displayed above the value on the **EDIT BOLUS** screen.

➡ NOTE: Only information displayed on the **BOLUS** screen will be transferred to the **PATIENT DATA** screen when the **PATIENT DATA** key is pressed. If CI is selected and BSA is not available then the CI data is not transferred.

6. All curves resulting from bolus injections are automatically utilized in determining an average value. To remove individual measurements from the displayed average, press the touch bar beneath the values to be eliminated. Only highlighted values are used to calculate the average CO. Pressing the touch bar beneath a previously eliminated measurement will again include this measurement in the average.

7. Press **RESUME SERIES** to return to the **BOLUS CO** screen and press **REDO SERIES** to begin a new series of injections. To return to the **HOME** screen and display the trend graph, press **HOME**. Press **CCO STOPPED** to resume continuous monitoring, if desired.

3.3.2 MANUAL MODE

Perform the following to measure CO or CI in the MANUAL mode:

1. Press the touch bar beneath the **BOLUS CO** label displayed on the **HOME** screen. Injectate temperature (IT) is displayed beneath blood temperature (BT) in the lower left corner of the screen. Note the specific measurement variables (**INJECTATE VOLUME, CATHETER SIZE**) in the touch bar display area and change if necessary. To change a selected variable, press the touch bar beneath the appropriate label, select the correct choice, and press **RETURN**.

   If a manually entered computation constant is to be used instead of catheter size and injectate volume, select **BOLUS SETUP** to configure the monitor to display a computation constant. The touch bar may then be used to enter the desired constant. Select **RETURN** to effect the change.

2. When a baseline blood temperature is obtained by the monitor, the READY message will appear. When you are ready to inject, press the **START BOLUS** key, and the INJECT message will flash. You may then proceed with a bolus injection.

➡ NOTE: You have a maximum of 30 seconds in which to inject following **START BOLUS**. If no injection is detected within this time interval, the screen returns to READY until you choose to resume the sequence by pressing **START BOLUS**.

3. Once a bolus is injected, the thermodilution washout curve appears, a COMPUTING message is displayed, and the resultant CO or CI measurement is displayed on the left side of the screen.

Edwards Critical-Care Division

➡ **NOTE:** If a bolus measurement is compromised, as indicated by an alert message, an "a" will appear next to the value displayed on the **BOLUS CO** screen.

4. Subsequent determinations can be performed as desired when the READY message reappears.

5. When sufficient determinations have been made, you can press the **EDIT BOLUS** key to obtain an average value. The average CO or CI is displayed in the upper left corner of the screen.

➡ **NOTE:** Any bolus measurement that was accompanied by an alert message will have an "a" displayed above the value on the **EDIT BOLUS** screen.

6. All curves resulting from bolus injections are automatically utilized in determining an average value. To remove individual measurements from the displayed average, press the touch bar beneath the values to be eliminated. Only highlighted values are used to calculate the average. Pressing the touch bar beneath a previously eliminated measurement will again include this measurement in the average.

7. Press **RESUME SERIES** to return to the **BOLUS CO** screen and press **REDO SERIES** to begin a new series of injections. To return to the **HOME** screen and display the trend graph, press **HOME**. Press **CCO** to resume continuous monitoring, if desired.

Up to six bolus injections can be completed in one sequence. If additional injections are desired (more than 6), you will be prompted to obtain an average. Then press the **REDO SERIES** key to return to the **BOLUS CO** screen and begin a new series of injections. If an average is not taken, the **HOME** screen will be displayed and the previous series of injections will be cleared.

If the **HOME** key is pressed before an average is obtained, the bolus CO data will be averaged and the **HOME** screen will be displayed. The bolus CO value will be plotted on the trend graph.

After resuming continuous monitoring, an event marker (B) will denote the change to BOLUS CO mode on the graph. The average measurement that is obtained while in BOLUS CO mode will be plotted on the graph.

3.3.3 OPTIMIZING BOLUS CO/CONTINUOUS CO CORRELATION

To optimize correlation of Bolus CO and CCO measurements, you should:

1. Verify correct catheter French size and injectate volume, or computation constant.

2. Verify proper catheter position by ensuring:
   a) PA tracing on distal lumen port
   b) RA tracing on proximal injectate port
   c) 1.25 - 1.5 cc of air are required to obtain PAWP
   d) correct placement by X-ray

3. Purge system of air.

4. Use correct injectate port.

5. Inject 3cc of injectate into patient for temperature equalization and ensure that there are no leaks in the system.

6. Inject correct volume in rapid (10cc within 4 seconds), smooth motion.

7. Ensure injectate temperature is appropriate for setup.

8. Wait 1 minute between injections.

9. Inject randomly throughout the respiratory cycle.

10. Edit erroneous values from average.

3.4 Mixed Venous Oxygen Saturation Monitoring (SvO$_2$)

3.4.1 SvO$_2$ SETUP

1. Press **SvO$_2$** on the touch bar.

2. Select a calibration method (IN VITRO or IN VIVO) by pressing the corresponding key. See calibration instructions below.

There are two types of calibration that can be performed:

- **IN VITRO:** performed before the catheter is inserted into the patient by using the calibration cup provided in catheter packaging.

- **IN VIVO:** performed after the catheter has been inserted into the patient.

➡ **NOTE:** For optimal accuracy, it is recommended that an in vivo calibration be performed at least every 24 hours.

➡ **NOTE:** The **TRANSPORT** function (see Section 3.4.4) may be used to recall previous calibration data from the optical module and start SvO_2 monitoring without performing a system calibration.

❖ **WARNING:** DO NOT DISCONNECT THE OPTICAL MODULE WHILE CALIBRATION AND PATIENT DATA ARE BEING TRANSFERRED FROM THE *Vigilance®* MONITOR.

3.4.2 IN VITRO CALIBRATION

▲ **CAUTION:** The catheter and the calibration cup must be dry for an accurate in vitro calibration. Flush the catheter lumens only after the in vitro calibration has been completed.

▲ **CAUTION:** Performing an in vitro calibration after the catheter has been inserted into the patient will yield an erroneous calibration.

1. Remove section of tray lid to expose optical module connector, thermal filament connector, and thermistor connector.

2. Insert the optical connector, "TOP" side up, into the optical module.

3. Press SvO_2 key on the touch bar.

4. Press **IN VITRO CALIBRATION** on the touch bar.

5. If the default values of 11.5 g/dL (7.2 mmol/L) for hemoglobin and 35% for hematocrit are to be used, press the **CAL** key.

6. If new (lab) hemoglobin or hematocrit values are to be entered, press **CURSOR** to select the desired value (either Hgb or Hct) and use the touch bar to input the new value.

7. After the correct value has been entered, press **CAL**. The following message will appear:

       In Vitro Calibration In Progress

The monitor will indicate when the calibration has been successfully completed by displaying the following message:

       In Vitro Calibration OK. Insert catheter
       then press Start SvO2

➡ NOTE: If the system is unable to perform an in vitro calibration, the following message will be displayed:

IN VITRO CALIBRATION ERROR

The operator may press **CANCEL** to return to the **HOME** screen or press the **IN VITRO CALIBRATION** key and the *Vigilance®* Monitor will restart the calibration sequence. If the error message persists, refer to the Troubleshooting Guide for further instructions.

➡ NOTE: Once a calibration has been performed, the **IN VITRO CALIBRATION** key is replaced by the **NEW CATHETER** key. When the **NEW CATHETER** key is pressed, the user will be asked to confirm that a new catheter is being connected. Upon confirmation, the **NEW CATHETER** key will revert to the **IN VITRO CALIBRATION** key permitting a new in vitro calibration. If the **NEW CATHETER** key is used but the old catheter is not disconnected and replaced, SvO_2 will continue to be trended if monitoring had been previously commenced.

After the in vitro calibration has been successfully completed, prepare and insert the catheter to begin SvO_2 monitoring.

1. Remove section of catheter tray lid to expose the distal and injectate lumen hubs.

2. Flush catheter.

3. Grasp body of the catheter at the finger depressions in the tray and lift catheter to release it from the calibration cup. Avoid pulling the catheter tip and balloon straight through the silicon gripper.

4. Check balloon integrity.

5. Insert catheter into the patient as described in the catheter package insert.

6. After the catheter is correctly positioned, press **START SvO₂**. The optical module will be updated with the new calibration parameters, and the *Vigilance®* Monitor will return to the **HOME** screen.

3.4.3 IN VIVO CALIBRATION

An in vivo calibration is performed using mixed venous blood samples drawn from the distal lumen of the catheter.

1. After the catheter is properly inserted and positioned, press **SvO₂** on the touch bar.

2. Press **IN VIVO CALIBRATION** on the touch bar. The screen will then read:

    IN VIVO BASELINE SETUP IN PROGRESS.

    After the baseline has been established, the SQI bar will display signal quality.

➡ **NOTE:** The user should not attempt to access another screen while the baseline setup is in progress. This will cause the calibration to be invalidated.

➡ **NOTE:** If **UNSTABLE SIGNAL** or **WALL ARTIFACT** or **WEDGE** messages appear during the calibration sequence, attempt to troubleshoot the problem and press **IN VIVO CALIBRATION** to attempt calibration again. To continue with the calibration despite the **UNSTABLE SIGNAL** or **WALL ARTIFACT** or **WEDGE** messages, select **CONTINUE** on the touch bar. The monitor will prompt the user to draw blood samples for calibration. If the calibration is to be discontinued, press **CANCEL** on the touch bar to return to the **HOME** screen. Refer to the Troubleshooting Guide (Chapter 4) for a description of causes and remedies for these particular alerts.

3. Press **DRAW** on the touch bar.

4. Draw waste blood sample slowly from distal lumen.

5. Draw laboratory blood sample slowly (2 cc over 30 seconds).

6. Put blood sample on ice and send for analysis by co-oximeter.

➡ **NOTE:** While waiting for the hemoglobin/hematocrit and SvO_2 laboratory values, other modes may be accessed by pressing the **HOME** key. To return to the **IN VIVO CALIBRATION** screen from the **HOME** screen, press SvO_2 on the touch bar.

7. After the co-oximeter SvO_2 and hemoglobin/hematocrit values are obtained, press **CURSOR** to select the value to be entered. Enter lab HGB or Hct and SvO_2 values using the touch bar. The parameter ranges are as follows:

    HGB .... 4 - 20 g/dL (2.5 - 12.4 mmol/L)
    Hct .... 12 - 60%
    SvO_2 .... 10 - 99%

➡ NOTE: Upon entry of either a hemoglobin or hematocrit value, the *Vigilance®* Monitor will automatically calculate the other value. If both hemoglobin and hematocrit values are input, the system will accept the last value entered.

➡ NOTE: When **DRAW** is selected, the SvO_2 value and the SQI value at the time the sample is drawn is displayed in the **DRAW SvO_2** box on the **IN VIVO CALIBRATION** screen. This value is for reference only, and cannot be changed by the user. However, if no prior calibration has been performed, the **DRAW SvO_2** box will not contain a value and a " - " will be displayed for SQI.

8. Press CAL to begin SvO_2 monitoring. The following message will appear:

    Optical Module Update in Progress.

➡ NOTE: If the operator presses **CAL** before entering an SvO_2 value and no previous in vivo calibration was performed, the user will be prompted to enter an SvO_2 value within the established range. If the operator presses **CAL** before entering HGB or Hct, the monitor will use values from an in vitro calibration if a previous in vitro calibration was performed.

3.4.4 TRANSPORT FUNCTION: RECALLING OPTICAL MODULE DATA

In the event that a patient needs to be transported while the SvO_2 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 re-calibrate the monitor.

1. With the catheter connected to the optical module, unplug the optical module cable from the *Vigilance®* Monitor and transport it with the patient. The catheter should not be disconnected from the optical module.

➡ NOTE: The monitor does not need to be transferred with the patient. Another *Vigilance®* Monitor may be used.

2. If the optical module is being connected to a new *Vigilance®* Monitor, press the **PATIENT DATA** key, then select **NEW PATIENT** and confirm that data is to be deleted.

3. Once the patient has been transferred, re-connect the optical module cable to the *Vigilance®* Monitor.

4. To start monitoring SvO_2, return to the **HOME** screen and press SvO_2 then **TRANSPORT** on the touch bar. The *Vigilance*® Monitor will display the calibration data stored in the optical module.

5. Press **RECALL** on the touch bar and the optical module calibration data will be used to continue monitoring SvO_2. If a new calibration is desired, return to the **HOME** screen and follow the in vivo instructions in Section 3.4.3.

➥ **NOTE:** If the optical module calibration data is greater than 24 hours old, the optical module data cannot be recalled and a new calibration will have to be performed.

➥ **NOTE:** If the system is to be re-calibrated, allow 20 minutes for the optical module to warm up.

6. To review patient data that was transported with the optical module, go to the **PATIENT DATA EDIT** screen and press **CALC**.

3.4.5 SIGNAL QUALITY INDICATOR (SQI)

A four level signal quality indicator (SQI) is provided to assist in proper catheter placement. The SQI level is updated every 2 seconds after SvO_2 calibration is complete. Signal Quality is displayed during IN VIVO CALIBRATION and UPDATE functions. It is recommended that calibrations be performed only when the SQI is < 3.

The SQI displays four signal levels. Those levels are:

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

Signal quality may be compromised by the following:

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

It is recommended that the user troubleshoot the SvO_2 signal whenever SQI ≥ 3. See the Troubleshooting Guide (Chapter 4) for further assistance.

➥ NOTE: The SQI signal is sometimes affected by the presence of electrosurgical units. Attempt to distance electrocautery equipment and cables from the *Vigilance®* system and plug the power cords into separate AC circuits if possible. If signal quality problems persist, call Edwards Technical Support for assistance.

➥ NOTE: To achieve optimal accuracy, it is recommended that the entered hemoglobin and hematocrit values be updated 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. A change in hemoglobin may also affect SQI. Use the UPDATE function to remedy signal quality problems (see Section 3.4.6).

3.4.6 UPDATE FUNCTION

The update function can only be used if a previous calibration has been performed, or if the calibration data has been recalled from the optical module. To update calibration data:

1. Press **SvO$_2$** on the touch bar

2. Press the **HGB UPDATE** key

3. The displayed HGB and Hct values may be used or new values entered.

4. Once the proper HGB and Hct values are entered, press the **CAL** key.

3.4.7 OPTICAL RESET

When the SQI level is continuously high, an optical reset may stabilize the signal quality. To perform an optical reset, do the following:

1. Press **SvO$_2$** on the touch bar.

2. Press **OPTICAL RESET**. The following message will be displayed:

   Optical Module Update in Progress

3. After the intensity calibration is complete, the *Vigilance®* Monitor will return to the **HOME** screen.

➥ NOTE: An optical reset should only be performed after other actions to resolve the high SQI as defined in the Troubleshooting Guide (Chapter 4) has been performed.

➡ **NOTE:** The monitor will not permit an optical reset prior to performing a calibration or prior to recalling calibration data from the optical module.

3.4.8 DISABLING SvO$_2$

If an optical module is not used with the *Vigilance*®, the SvO$_2$ information may be removed from the display. The displayed SvO$_2$ information may be removed by de-selecting SvO$_2$ in the **TREND** screen. When SvO2 is de-selected as one of the trend graphs, the SvO$_2$ value, the SQI and the graphical data is removed from the display. All SvO$_2$ faults, alerts, notify messages and alarms are disabled when SvO$_2$ is de-selected. All other information, such as CCO and SVR, is displayed in the usual manner. The SvO$_2$ touchbar remains displayed when SvO$_2$ is de-selected. If the SvO$_2$ touchbar is pressed, the following help message will appear:

**SvO$_2$ processing unavailable.
Please configure on TREND graph.**

SvO$_2$ information may be displayed by selecting SvO$_2$ as a trend graph in the **TREND** screen. Select SvO$_2$ to reconfigure SvO$_2$ on the **HOME** display, when SvO$_2$ is re-selected, the SvO$_2$ information is re-displayed. All SvO$_2$ faults, alerts, notify messages and alarms are re-enabled when SvO$_2$ is re-selected.

3.5 Drug Calculation

In this mode, the *Vigilance*® system can calculate infusion rate, dosage, drug amount or solution volume from the parameters which are entered.

3.5.1 DRUG TITRATION

Derived parameters for drug titration are calculated from data which is entered by the user. The *Vigilance*® system will calculate the desired values based on one of the following formulas:

$$r = \frac{(dw)\,(W)\,(V)}{Rx} \qquad \text{Formula 1}$$

$$r = \frac{(d)\,(V)}{Rx} \qquad \text{Formula 2}$$

where:

r	=	Infusion Rate
dw	=	Drug Administration by Weight
d	=	Drug Administration
W	=	Body Weight
V	=	Solution Volume
Rx	=	Drug Quantity

The following unit table identifies the units that are available for selection.

Weight	Dosage	Drug Amount	Volume	Rate
kg	mcg/kg/min	mg	ml	ml/hr
lbs	mcg/min			

Note: mcg = microgram
       mg = milligram

3.5.2 USING THE DRUG CALCULATION MODE

To access the drug titration screen, press the **DRUG CALC** touchbar key on the **HOME** screen, the **DRUG CALCULATION** screen will appear.

Select the parameter to input by pressing **CURSOR**. When the desired parameter is highlighted, enter the necessary data. Input the data by selecting the number using the numeric touchbar keys.

➡ NOTE: Hard decimal points exist in the fields.

➡ NOTE: If the weight has previously been entered to determine BSA, the weight in kilograms and pounds will appear in the screen.

Continue to input all parameters in this manner. Press **CURSOR** after each input. When all data has been input, the desired parameter will be calculated automatically.

➡ NOTE: Updating the patient weight in the **DRUG CALCULATION** screen will not update the weight in the **PATIENT DATA** screen and the Optics Module will not be updated. The patient's weight will revert back to the **PATIENT DATA** weight upon leaving and re-entering the **DRUG CALCULATION** screen.

➡ NOTE: If the **CLEAR** touchbar key is pressed, the current selected value field will be cleared and only the decimal point, if one exists in the field, will be displayed.

3.6 Compatible Catheters

Compatible catheters include Edwards Critical-Care CCO/ SvO$_2$ TD catheters, oximetry TD catheters, CCO TD catheters, and thermodilution catheters.

▲ CAUTION: For continuous cardiac output measurement, only Edwards Critical-Care CCO catheters should be used with the *Vigilance®* Monitor to ensure safe operation.

3.7 Connecting to Other Instruments

The *Vigilance®* Monitor may be connected to a variety of other instruments to exchange patient data and print reports. Two digital communication ports (9-pin RS-232) are provided to exchange physiological data with other monitors and to export report information to a printer. Two analog output ports are provided for sending analog signals to a chart recorder. Four analog input ports are provided to import physiological signals from other monitors.

For complete information on connecting other devices to the *Vigilance®* Monitor (analog input, analog output, digital interface), please contact Edwards Technical Support at 1.800.8BAXTER.

▲ CAUTION: When connecting the *Vigilance®* Monitor to external devices, refer to the external device's instruction manual for complete instructions. Verify proper operation of the system before clinical use.

❖ WARNING: THE ANALOG AND DIGITAL COMMUNICATION PORTS OF THE MONITOR SHARE A COMMON GROUND THAT IS ISOLATED FROM THE CATHETER ELECTRONIC COMPONENTS AND FROM EARTH GROUND. WHEN CONNECTING MULTIPLE DEVICES TO THE *Vigilance®* MONITOR, ALL DEVICES SHOULD BE PROVIDED WITH ISOLATED POWER TO AVOID COMPROMISING THE ELECTRICAL ISOLATION OF ANY OF THE CONNECTED DEVICES.

3.7.1 ANALOG INPUT DEVICES

Perform the following procedure to connect analog input devices to the *Vigilance®* Monitor:

1. To connect a device that provides an analog signal to the *Vigilance®* Monitor, select one of the four analog input connectors and plug in the cable from the analog device.

2. Press the following keys in sequence: **SETUP, SYSTEM CONFIG,** and **ANALOG INPUT.**

3. Use the touchbar key to select the correct analog port.

4. Use the **CHANGE** key to select the parameter label that the external device will be providing (MAP, CVP, SaO$_2$, HR or NONE).

5. Select the voltage range (0–1, 0–5, or 0–10 volts) based on the particular device that you have connected. (Refer to the device manufacturer's manual.)

6. When the parameter has been selected, you will be able to see the low and high values which are the default settings for the monitor. If the actual values are different from the default values, the high and low values must be changed.

7. To ensure accurate operation, calibrate the *Vigilance* Monitor's analog port. Press the **SET A/D** button to see the low value and the current value (A/D reading) that is received from the external device.

▲ **CAUTION: Only properly trained personnel should calibrate the *Vigilance* Monitor analog ports using the SET A/D function.**

8. Send out a low voltage from the external device to the *Vigilance* Monitor (refer to the device manufacturer's manual).

9. When the A/D reading is stable, press **ENTER**.

10. Repeat steps 8 and 9 to calibrate the high voltage level.

➡ **NOTE:** Connecting to external input devices allows additional information to be displayed. For example, when MAP and CVP are available continuously from another monitor, SVR is displayed on the **HOME** screen as a large number. MAP and CVP are also displayed on the **HOME** screen, but as small numbers below all the large number parameters.

➡ **IMPORTANT:** The accuracy of continuous SVR, VQI, and O$_2$EI depends upon the quality and accuracy of the MAP, CVP, and SaO$_2$ data transmitted from the external monitors. Since the MAP, CVP and SaO$_2$ analog signal quality from the external monitor cannot be validated by the *Vigilance* Monitor, actual values and the values displayed by the *Vigilance* Monitor may not be consistent. The accuracy of continuous SVR, VQI and O$_2$EI measurement, therefore, cannot be guaranteed. To aid in determining the quality of the analog signals, regularly compare the MAP, CVP and SaO$_2$ values displayed on the external monitor to the values displayed on the *Vigilance* Monitor. Refer to the manufacturer's operator's manual for detailed information regarding accuracy,

calibration, and other variables which may impact the analog output signal from the external monitor.

3.7.2 ANALOG OUTPUT DEVICES

Perform the following procedure to connect analog output devices to the *Vigilance*® Monitor:

1. To connect the *Vigilance*® Monitor to a device that can accept an analog signal, select one of the two analog output ports and plug in the connector.

2. Press the following keys in sequence: **SETUP, SYSTEM CONFIG,** and **ANALOG OUTPUT.**

3. Use the touchbar key to select the appropriate analog port.

4. Use the **CHANGE** key to select the patient parameter that you want to export from the *Vigilance*® Monitor (CCO, CCI, SvO_2, BT, IT, ΔBT, SVR, SVRI or NONE).

5. Use the **CURSOR** key, then the **CHANGE** key to select the voltage range: 0–1 or 0–10 volts.

6. If the device you are connecting allows for calibration, the monitor will continuously send out a low or high voltage when either the **CALIBRATE LOW** or **CALIBRATE HIGH** key is pressed.

3.7.3 DIGITAL DEVICES

Perform the following procedure to connect digital devices to the *Vigilance*® Monitor:

1. The *Vigilance*® Monitor Data Terminal Equipment (DTE) digital ports are provided by two 9-pin connectors. If the device that you are connecting to the monitor is also a DTE, then a null modem cable or adapter is required. To connect another digital device to the monitor, select one of the two digital connectors (COM 1 or COM 2) and plug in the cable from the device.

2. Press the following keys in sequence: **SETUP, SYSTEM CONFIG,** and **DIGITAL PORTS.**

3. Use the touchbar key to select the correct port (COM 1 or COM 2). The cursor should be positioned on the device label for that port.

4. Use the **CHANGE** key to select the device that has been connected (Printer, IFMout, or Flexport®). Press the **HOME** key when completed.

5. All device selections are listed with standard communication protocol parameters already set to default values. To change these parameters, press **CURSOR** to select the parameter that you wish to change and use the **CHANGE** key.

➠ NOTE: Flexport® parameters cannot be changed by the user.

6. The *Vigilance®* Monitor supports the following communication parameters:

Baud rate:	1200	2400	9600	19200
Parity:	None	Odd	Even	
Data Bits:	7	8		
Stop Bits:	1	2		
Flow Control:	None	XON/XOFF		

3.7.3.1 PRINTER FUNCTION

When **PRINT** appears as a touch bar label, the current *Vigilance®* screen may be printed. Once **PRINT** is selected, allow entire screen to print prior to pressing any other keys.

For a Canon BJ-30 Bubble Jet Printer to function properly when connected to the *Vigilance®* Monitor, execute the following procedure.

1. Power on the printer

➠ IMPORTANT: The *Vigilance®* Monitor must already be powered, the printer interface cable must already be attached, and the digital port must be configured prior to powering on the printer. Failure to perform these items first will cause the printer to perform poorly.

2. Press and hold down both the **ON LINE** and **CLEANING** buttons until the printer beeps.

3. All items in the display appear for a moment the same way as when the printer was powered on. Then the printer's settings return to the factory default settings and the printer returns to ON-LINE.

4. Press the **MENU** button once - the printer beeps once as it enters Menu mode.

5. Press the **MENU** button again - the display shows the possible Reduction modes. Press the **CARTRIDGE** button once to select the 2/3 Mode.

6. Press the **MENU** button again - the display shows the two control modes. Press the **CARTRIDGE** button once to select the LQ Mode.

7. When the LQ Mode is blinking, press the **ON LINE** button and the ON LINE LED comes on.

➡ **NOTE:** On the very first printout after the printer setup, a "-+k" will appear in the top left corner of the page. This will not occur on subsequent printouts as long as both units remain powered up.

3.7.3.2 IFMOUT FUNCTION

To export parameter values to any Patient Monitor or PC that accepts the *Vigilance®* IFMout protocol, select the device to be IFMout. For assistance in selecting the proper communication parameter settings contact Edwards Technical Support (see Appendix F).

3.7.3.3 FLEXPORT® FUNCTION

To export parameter values to a Space Labs Medical Patient Care Management System select the device to be Flexport. Communication parameter settings are pre-set and cannot be changed. For assistance in connecting to a Space Labs Monitor contact Edwards Technical Support (see Appendix F).

3.8 Warnings

❖ **WARNING:** CAREFULLY READ THIS OPERATOR'S MANUAL BEFORE ATTEMPTING TO USE THE EDWARDS CRITICAL-CARE *Vigilance®* MONITOR.

❖ **WARNING:** REFER TO THE CATHETER PACKAGE INSERT PROVIDED WITH EACH CATHETER FOR SPECIFIC INSTRUCTIONS ON CATHETER PLACEMENT AND USE, WARNINGS, CAUTIONS, AND SPECIFICATIONS.

❖ **WARNING:** DO NOT USE A DAMAGED CATHETER OR ONE WITH EXPOSED ELECTRICAL CONTACTS.

❖ **WARNING:** INACCURATE CARDIAC OUTPUT MEASUREMENTS MAY BE CAUSED BY:
  • Incorrect placement or position of the catheter
  • Excessive variation in pulmonary artery blood temperature
  • Clot formation on the thermistor
  • Anatomical abnormalities (for example, cardiac shunts)
  • Excessive patient movement
  • Repeated intermittent flushes of cold fluid through the fluid lumens of the catheter

- Use of a manual pump such as the Abbott Blood Set with Pump and CAIR Clamp
- Electrocautery or electrosurgical unit interference
- Rapid changes in cardiac output

❖ **WARNING:** IN SITUATIONS WHERE MONITORED PATIENT PARAMETERS ARE OUTSIDE THE DESIRED ALARM LIMITS, THE AUDIO ALARM WILL NOT SOUND IF THE ALARM HAS BEEN TURNED OFF OR TEMPORARILY SILENCED. DO NOT TURN OFF THE ALARMS IN SITUATIONS IN WHICH PATIENT SAFETY COULD BE COMPROMISED.

❖ **WARNING:** CCO MONITORING SHOULD ALWAYS BE DISCONTINUED WHEN BLOOD FLOW AROUND THE THERMAL FILAMENT IS STOPPED OR REDUCED. CLINICAL SITUATIONS WHERE CCO MONITORING SHOULD BE DISCONTINUED INCLUDE BUT ARE NOT LIMITED TO: TIME PERIODS WHEN A PATIENT IS ON CARDIOPULMONARY BYPASS, PARTIAL WITHDRAWAL OF THE CATHETER SO THAT THE THERMISTOR IS NOT IN THE PULMONARY ARTERY, OR REMOVAL OF THE CATHETER FROM THE PATIENT.

❖ **WARNING:** EXPLOSION HAZARD! DO NOT USE THE *Vigilance®* MONITOR IN THE PRESENCE OF FLAMMABLE ANESTHETICS.

❖ **WARNING:** TO AVOID COMPLICATIONS CAUSED BY KNOTTING, THE CATHETER SHOULD NOT BE USED SIMULTANEOUSLY WITH ANOTHER PULMONARY ARTERY CATHETER.

❖ **WARNING:** DO NOT USE THE DEMO MODE IN A PATIENT CARE SETTING TO AVOID POSSIBLE CONFUSION WITH PATIENT MEASUREMENTS.

❖ **WARNING:** IMPROPER USE OF THE *Vigilance®* MONITOR COULD PRESENT A HAZARD TO THE PATIENT. CAREFULLY READ THE WARNINGS SECTION OF THIS MANUAL BEFORE USING THE INSTRUMENT.

❖ **WARNING:** THE ANALOG AND DIGITAL COMMUNICATION PORTS OF THE MONITOR SHARE A COMMON GROUND THAT IS ISOLATED FROM THE CATHETER INTERFACE ELECTRONICS AND FROM EARTH GROUND. WHEN CONNECTING MULTIPLE DEVICES TO THE *Vigilance®* MONITOR, ALL DEVICES SHOULD BE PROVIDED WITH ISOLATED POWER TO AVOID COMPROMISING THE ELECTRICAL ISOLATION OF ANY OF THE CONNECTED DEVICES.

❖ **WARNING:** THE *Vigilance*® MONITOR CONTAINS NO USER-SERVICEABLE PARTS. REMOVAL OF THE COVER OR DISASSEMBLY WILL EXPOSE HAZARDOUS VOLTAGES. TO AVOID INJURY OR INSTRUMENT DAMAGE, DO NOT DISASSEMBLE OR SERVICE THE INSTRUMENT UNLESS YOU ARE QUALIFIED TO DO SO.

❖ **WARNING:** FOR PROTECTION AGAINST FIRE, REPLACE THE FUSE WITH ONLY ONE OF THE SAME TYPE AND RATING.

❖ **WARNING:** THE *Vigilance*® MONITOR IS INTENDED FOR USE ONLY AS AN ADJUNCT IN PATIENT ASSESSMENT. THIS INSTRUMENT MUST BE USED IN CONJUNCTION WITH PATIENT CLINICAL SIGNS AND SYMPTOMS.

❖ **WARNING:** TO AVOID SHOCK OR FIRE HAZARD, DO NOT SOAK OR IMMERSE THE *Vigilance*® MONITOR, PROBES, OR CABLES IN ANY LIQUID SOLUTION. DO NOT ALLOW ANY FLUIDS TO ENTER THE INSTRUMENT.

❖ **WARNING:** CONDUCT PERIODIC INSPECTIONS OF ALL CABLES FOR DEFECTS. DO NOT STORE CABLES TIGHTLY COILED.

❖ **WARNING:** TREAT THE OPTICAL MODULE WITH EXTREME CARE.

❖ **WARNING:** DO NOT OBSTRUCT THE *Vigilance*® MONITOR'S VENTILATION OPENINGS.

❖ **WARNING:** DO NOT EXPOSE THE *Vigilance*® MONITOR TO EXTREME TEMPERATURES.

❖ **WARNING:** DO NOT USE THE *Vigilance*® MONITOR DURING MRI SCANNING.

❖ **WARNING:** DO NOT DISCONNECT THE OPTICAL MODULE WHILE CALIBRATION AND PATIENT DATA ARE BEING TRANSFERRED FROM THE *Vigilance*® MONITOR.

4

TROUBLESHOOTING GUIDE

4. Resolving Monitoring Problems

This section discusses possible monitoring difficulties, their possible causes, and suggested resolutions. Table 4-1 on the next page contains a troubleshooting checklist to assist you in identifying and correcting possible problems. The checklist is followed by a section that describes displayed fault and alert messages, and alarm conditions.

If a problem persists after following the indicated suggestions, you should discontinue operation and contact Edwards Technical Support at 1.800.8BAXTER or 949.756.4400.

4.1
Troubleshooting
Checklist

Table 4-1 General Troubleshooting Checklist

Problem	Possible Cause	Solution
Instrument does not power on	• AC power not connected, Defective fuse	• Connect to AC power • Replace fuse as marked
Monitor screen is blank	• System malfunction	• Turn power off and on again • If problem persists contact Edwards Technical Support at 1.800.8BAXTER or 949.756.4400
Monitor displays message: **Main processor not responding** or **Please recycle power to restore system**	• System malfunction	• Turn power off and on again • If problem persists contact Edwards Technical Support at 1.800.8BAXTER or 949.756.4400
Monitor displays message: **SvO2 processing unavailable**	• SvO_2 subsystem malfunction	• Turn power off and on again • If problem persists contact Edwards Technical Support at 1.800.8BAXTER or 949.756.4400
Monitor displays message: **CCO processing unavailable**	• CCO subsystem malfunction	• Turn power off and on again • If problem persists contact Edwards Technical Support at 1.800.8BAXTER or 949.756.4400
Monitor displays message: **Bolus CO processing unavailable**	• Bolus CCO subsystem malfunction	• Turn power off and on again • If problem persists contact Edwards Technical Support at 1.800.8BAXTER or 949.756.4400

Table 4-1 General Troubleshooting Checklist *(continued)*

Continuous Cardiac Output (CCO) measurements do not agree with Bolus Cardiac Output measurements	• Instrument configured incorrectly • Faulty thermistor or injectate probe connection • Unstable baseline temperature affecting bolus CO measurements	• Verify that computation constant, injectate volume, and catheter size have been correctly selected • Use "iced" injectate and/or 10cc injectate volume to create large signal
Analog port connections with peripheral monitoring equipment produce questionable communications	• Incomplete connections • External monitor needs calibration	• Check cable connections • Check analog port setup (analog port calibration) • Check external monitor's output signals
Digital port connections with peripheral monitoring equipment produce questionable communications	• Incomplete connections • External monitor needs calibration	• Check cable connections • Check serial port setup, Check external monitor's calibration

4.2 Displayed Messages

The message display area is located in the top center of the screen. Three types of messages that may be displayed in this area are: Faults, Alarms, and Alerts. Messages appear in the following order of priority: 1) Faults, 2) Alarms, 3) Alerts.

A message is cleared from the screen if:

• The condition has been resolved.

• The user presses **CCO** key and the condition is no longer in effect.

• Another message of higher priority or a new message of the same priority needs to be displayed.

In the last situation, the older message will not be shown due to limited display space. Once the new condition has been cleared, if the original condition still exists, the older message will reappear.

In addition, SvO_2 calibration warning messages may be displayed in the trend graph area. These warnings indicate difficulties with SvO_2 calibration.

4.2.1 FAULT MESSAGES

Fault messages indicate situations in which the system cannot operate properly and are accompanied by a single beep tone. Fault messages will terminate CO or SvO_2 monitoring. Correction of a fault condition is necessary to resume CO or SvO_2 monitoring in the present mode. In some cases, fault conditions that prevent CCO monitoring will not prevent bolus CO or SvO_2 monitoring. For example, **Check Thermal Filament Connection** is a fault message in CCO mode, but will not affect BOLUS CO or SvO_2 mode operation.

4.2.2 ALARM CONDITIONS

Alarm conditions occur for selected patient parameters when the calculated value is outside the range determined by the high and low limits. The alarm function must be ON to generate the audible and visual indicators. The audible indicator consists of a repeating sequence of three rapid tones. Numerical values of the alarming patient parameter are repeatedly flashed to provide a visual indicator. The alarm will continue until the condition is cleared, the **ALARM SILENCE** key is pressed, the limits are changed, or the alarms are turned off.

Edwards Critical-Care Division

4.2.3 ALERT MESSAGES

Alert messages are intended to provide help in qualifying the measurement results. These messages appear on the screen without auditory notification. In most cases, no corrective action is required by the operator when an alert message is displayed.

4.2.4 SvO$_2$ CALIBRATION WARNING MESSAGES

Warning messages pertaining to SvO$_2$ system calibration are displayed in the trend graph area when SvO$_2$ monitoring is available and system calibration may be compromised. Depending on the nature of the warning condition, the user may continue with the calibration sequence, troubleshoot the problem and attempt another system calibration, or cancel the calibration and return to the **HOME** screen.

4.3 Fault Message Summary

The following summaries provide a quick-reference to the displayed messages. Refer to Tables 4-2 to 4-8 for detailed information of Fault, Alert, and Warning messages that include possible causes and suggested corrective actions.

4.3.1 CCO MODE *(see Table 4-2 for detail)*

1. Thermal Filament, Use Bolus Mode
2. Catheter Memory, Use Bolus Mode
3. Catheter Verification, Use Bolus Mode
4. Check Catheter and Cable Connections
5. Blood Temp Out of Range (< 31 or > 41)
6. Check Thermal Filament Connection
7. Check Thermal Filament Position
8. Check Thermistor Connection
9. Intermittent Thermistor Connection
10. CO is less than 1.0 L/min
11. Thermal Signal Loss
12. CCO Signal Processor, Use Bolus Mode
13. CCO Not Available, Use Bolus Mode
14. CCO Thermal Filament, Use Bolus Mode

15. CO: Not Responding

16. Thermal Element, Use Bolus Mode

4.3.2 MIXED VENOUS OXYGEN SATURATION MODE
(see Table 4-3 for detail)

1. OM2 Memory

2. Auto Zero

3. Light Range

4. Out of Range

5. Red/IR Transmit

6. OM Disconnected

7. EPROM

8. RAM

9. Offset

10. Gain

11. SvO_2 Not Responding

12. SvO_2 Processing Unavailable

4.3.3 BOLUS CO MODE *(see Table 4-4 for detail)*

1. Check Thermistor Connection

2. Injectate Too Warm, Check Probe

3. Intermittent Thermistor Connection

4. Bolus CO Processing Unavailable

4.4 Alert Message Summary

4.4.1 CCO MODE *(see Table 4-5 for detail)*

1. Signal Adapting — Continuing

2. Unstable Blood Temp. — Continuing

3. Electrical Interference

4.4.2 MIXED VENOUS OXYGEN SATURATION MODE
(see Table 4-6 for detail)

1. SQI = 4

4.4.3 BOLUS CO MODE *(see Table 4-7 for detail)*

1. Curve Not Detected

2. Extended Curve

3. Irregular Curve

4. Warm Injectate

5. Unstable Baseline

6. Electrical Interference

4.5
Warning
Message
Summary

4.5.1 MIXED VENOUS OXYGEN SATURATION MODE
(see Table 4-8 for detail)

1. In Vitro Calibration Error

2. Wedge or Wall Artifact

3. Unstable Baseline

Table 4-2 Fault Messages, CCO Mode

Displayed Message	Possible Cause	Suggested Action
1. Thermal Filament, Use Bolus Mode	• Thermal filament measurement error	• Use BOLUS CO mode • Contact Edwards Technical Support • Replace catheter for CCO measurement
2. Catheter Memory, Use Bolus Mode	• Poor catheter connection • Cable malfunction • Thermal filament error	• Check catheter and cable connections • Change patient cable • Replace catheter for CCO measurement • Use BOLUS CO mode
3. Catheter Verification, Use Bolus Mode	• Cable malfunction • Thermal filament error • Catheter connected is not an Edwards catheter	• Change patient cable • Use BOLUS CO mode • Verify that catheter is an Edwards catheter for CCO measurement
4. Check Catheter and Cable Connections	• Catheter connections (thermal filament and thermistor) not detected	• Check catheter cable and catheter connections • Disconnect thermistor and thermal filament connection and check for bent pins, etc.
5. Blood Temp Out of Range (< 31 or > 41)	• Blood temperature is less than 31° C or greater than 41° C	• Verify that catheter is properly positioned in the pulmonary artery • Wait for blood temperature to be within range
6. Check Thermal Filament Connection	• Monitor cannot sense the thermal filament • Catheter connected is not an Edwards CCO catheter	• Verify that catheter is connected to patient cable • Verify that catheter is an Edwards catheter for CCO measurement • Use BOLUS CO mode

Table 4-2 Fault Messages, CCO Mode *(continued)*

Displayed Message	Possible Cause	Suggested Action
7. Check Thermal Filament Position	• Flow around thermal filament may be reduced • Blood temperature too warm • Catheter not in patient	• Verify proper catheter position • Wait for blood temp. to decrease • Verify that catheter tip is properly positioned in the pulmonary artery
8. Check Thermistor Connection	• Loose thermistor connection • Invalid blood temperature measurements	• Verify that catheter thermistor is connected securely • Verify that thermistor temperature is between 15–45° C
9. Intermittent Thermistor Connection	• Blood temperature measurements are intermittent	• Verify that catheter thermistor is connected securely • Replace catheter for CCO measurement
10. CO is less than 1.0 L/min	• Measured CO less than 1.0 L/min	• Wait for CO to increase
11. Thermal Signal Loss	• Signal detected by monitor is too small to process	• Verify proper catheter position • Press **CCO** key to resume CCO monitoring, as indicated
12. Signal Processor, Use Bolus Mode	• Electrical interference (e.g., electrocautery device)	• Power off and restart • Use BOLUS CO mode
13. CCO Not Available, Use Bolus Mode	• CCO Subsystem has malfunctioned	• Turn monitor off and restart • If problem persists, call Edwards Technical Support at 1.800.8BAXTER or 949.756.4400.
14. CCO Thermal Filament, Use Bolus Mode	• CCO Subsystem has malfunctioned	• Turn monitor off and restart • If problem persists, call Edwards Technical Support at 1.800.8BAXTER or 949.756.4400.

Table 4-2 Fault Messages, CCO Mode *(continued)*

Displayed Message	Possible Cause	Suggested Action
15. CO: Not Responding	• Electrocautery interference has been continuous for 5 minutes	• Turn monitor off and restart • Disconnect CCO cable during continuous electrocautery use at more than 5 minutes • If problem persists, call Edwards Technical Support at 1.800.8BAXTER or 949.756.4400.
16. Thermal Element, Use Bolus Mode	• CCO Subsystem has malfunctioned	• Turn monitor off and restart • If problem persists, call Edwards Technical Support at 1.800.8BAXTER or 949.756.4400.

Edwards Critical-Care Division

Table 4-3 Fault Messages, Mixed Venous Oxygen Saturation Mode

Displayed Message	Possible Cause	Suggested Action
1. OM2 Memory	• Optical Module memory is dysfunctional	• Replace optical module
2. Auto Zero	• Electrocautery interference • Bright light into optical module or catheter tip	• Wait until electrocautery use is discontinued. If problem persists, call Edwards Technical Support at 1.800.8BAXTER or 949.756.4400. • Check optical module/ catheter connections
3. Light Range	• Loose connections • Optical module failure • Catheter kinked or damaged	• Check optical module connections • Check for obstructed optical surface; replace optical module • Perform in vivo calibration; replace catheter if damage is suspected and recalibrate the *Vigilance®* monitor
4. Out of Range	• Calculated value outside of 0 - 99% range	• Recalibrate the *Vigilance®* Monitor
5. Red/IR Transmit	• Optical module is damaged	• Replace optical module. If problem persists, contact Edwards Technical Support at 1.800.8BAXTER or 949.756.4400
6. OM Disconnected	• Loose connections	• Check optical module/catheter connection
7. EPROM	• SvO$_2$ smart module EPROM test failed	• Turn monitor off and restart
8. RAM	• SvO$_2$ optical module RAM test failed	• Turn monitor off and restart
9. Offset	• Internal electrical problem	• Contact Edwards Technical Support at 1.800.8BAXTER or 949.756.4400

Table 4-3 **Fault Messages, Mixed Venous Oxygen Saturation Mode** *(continued)*

10. Gain	• Internal electrical problem	• Contact Edwards Technical Support at 1.800.8BAXTER or 949.756.4400
11. SvO2 Not Responding	• No communication between SvO$_2$ module and mainframe	• Turn monitor off and restart • If problem persists, contact Edwards Technical Support at 1.800.8BAXTER or 949.756.4400

Table 4-4 **Fault Messages, Bolus CO Mode**

Displayed Message	Possible Cause	Suggested Action
1. Check Thermistor Connection	• Loose thermistor connection • Invalid blood temperature measurements	• Verify that catheter thermistor is connected • Verify that thermistor temperature is between 15–45° C
2. Injectate Too Warm, Check Probe	• Injectate temperature > 30° C or > BT	• Use cooler injectate fluid • Replace injectate temperature probe
3. Intermittent Thermistor Connection	• Blood temperature measurements are intermittent	• Verify that catheter thermistor is connected securely • Replace catheter for CO measurement

Table 4-5 Alert Messages, CCO Mode

Displayed Message	Possible Cause	Suggested Action
1. **Signal Adapting - Continuing**	• Patient's respiratory pattern may have changed	• Allow more time for the monitor to measure and display CCO
2. **Unstable Blood Temp. - Continuing**	• Large blood temperature variations detected	• Wait for CO measurement to be updated • Minimizing patient discomfort may reduce temperature variations
3. **Electrical Interference**	• Electrocautery interference	• Wait until electrocautery use is terminated

Table 4-6 Alert Messages, Mixed Venous Oxygen Saturation Mode

Displayed Message	Possible Cause	Suggested Action
1. **SQI = 4**	• Low blood flow at catheter tip or catheter tip against vessel wall • Change in HGB/Hct values • Catheter kinked or damaged	• Reposition and/or flush catheter • Update HGB/Hct values using UPDATE function • Check catheter for kinking and recalibrate; replace catheter if required and recalibrate

Table 4-7 Alert Messages, Bolus CO Mode

Displayed Message	Possible Cause	Suggested Action
1. Curve Not Detected	• Greater than 4 minutes (AUTOMATIC mode) or 30 seconds (MANUAL mode) has passed without detection of injection	• Press START and begin injections
2. Extended Curve	• Thermodilution curve slow to return to baseline • Injectate port in introducer • Possible cardiac shunt	• Use correct injection technique • Verify thermistor location • Ensure injectate port location is outside introducer • Verify accuracy of CO measurement
3. Irregular Curve	• Thermodilution curve has multiple peaks	• Check injection technique • Check thermistor location • Possibly eliminate value from CO average
4. Warm Injectate	• Injectate temperature within 8°C of blood temperature	• Use cooler injectate fluid • Replace injectate temperature probe
5. Unstable Baseline	• Unable to compute cardiac output	• Make more injections • Use MANUAL mode
6. Electrical Interference	• Electrocautery interference	• Wait until electrocautery use is terminated

Table 4-8 Warning Messages, Mixed Venous Oxygen Saturation Mode

Displayed Message	Possible Cause	Suggested Action
1. In Vitro Calibration Error	• Loose connections • Calibration cup wet • Catheter kinked or damaged • Optical module failure	• Check optical module connections • Perform in vivo calibration • Perform in vivo calibration and straighten out visible kinks; replace catheter if damage is suspected • Replace optical module
2. Wedge or Wall Artifact	• Low blood flow at catheter tip • Catheter tip clotted • Catheter tip wedged in vessel or against vessel wall	• Reposition catheter and recalibrate by performing in vivo calibration • Try to aspirate distal lumen; if able to aspirate, flush lumen with extreme caution and reposition catheter • Reposition catheter, and if SQI > 2, recalibrate monitor by performing in vivo calibration
3. Unstable Baseline	• Changing SvO_2, HGB/Hct, or unusual hemodynamic values	• Stabilize patient and recalibrate monitor by performing in vivo calibration

4.6 Cleaning the Monitor

The surface of the *Vigilance®* Monitor may be cleaned with a cloth dampened with 70% isopropyl alcohol or a non-abrasive, liquid commercial cleaner or spray disinfectant. Stronger institutional disinfectants such as chlorhexidine gluconate or glutylaldehyde may also be used. The top, bottom and front surfaces may be lightly wiped with the cloth, but the monitor screen and its accessories SHOULD NOT have liquid poured or sprayed directly on them.

- DO NOT allow any liquid to come in contact with the power connector, fuse holder, or switches, nor to penetrate connectors or openings in the chassis. If any of the foregoing does occur, DO NOT attempt to operate the monitor. Disconnect power immediately and call Edwards Technical Support at 1.800.8BAXTER or 949.756.4400.

- DO NOT attempt to clean the rear panel of the monitor.

A

VIGILANCE® MONITOR SPECIFICATIONS

A.1
General

Product Description: The *Vigilance®* Monitor measures continuous cardiac output (CCO) and mixed venous oxygen saturation (SvO_2) when used with an Edwards Continuous Cardiac Output and Oximetry Catheters.

Weight		23 lbs
Dimensions	Height Width Depth	6.2 in. 12.9 in. 14.7 in.
Patient Cable	Length	8.5 ft
CRT Display System	Display Area	7.9 in. by 2.8 in.
Trend Display	Length	30 minutes to 24 hours
	Parameters (2 max.)	SvO_2, CCO, CCI

A.2 Measurement Specifications

CCO Mode	Range Reproducibility* Response Time**	1 to 20 L/min ±6% or 0.1 L/min, whichever is greater 3–6 minutes
Mixed Venous Oxygen Saturation Mode	Range Precision†	0 to 99% ± 2% at 30 to 99%
Bolus CO Mode	Range Reproducibility*	1 to 20 L/min ±3% or 0.1 L/min whichever is greater
Blood Temperature Range		15 to 45°C, ±0.3°C (59 to 113 °F)
Injectate Temperature Range		0 to 30°C, ±0.3°C (32 to 86°F)
Patient Data Profiles	Calculates derived hemodynamic and oxygenation parameters based upon entered data	

* Coefficient of variation — measured using electronically generated data

** 10% to 90% change, under conditions of stable blood temperature

† Precision was tested under laboratory conditions

A.3 Patient Data Profiles

Parameter Ranges	SaO$_2$	0 - 100%
	SvO$_2$	10 - 99%
	HGB	4 - 20 g/dL (2.5 - 12.4 mmol/L)
	PaO$_2$	0 - 1520 mmHg (0.0 - 202.6 kPa)
	PvO$_2$	0 - 1520 mmHg (0.0 - 202.6 kPa)
	MAP	0 - 500 mmHg (0.0 - 66.6 kPa)
	CVP	0 - 100 mmHg (0.0 - 13.3 kPa)
	MPAP	0 - 100 mmHg (0.0 - 13.3 kPa)
	PAWP	0 - 100 mmHg (0.0 - 13.3 kPa)
	HR	1 - 250 bpm
	Height	12 - 98 in. 30 - 250 cm
	Weight	2 - 880 lbs 0.9 - 400 kg
	BSA	0.08 - 5.02 m^2

A.4
Technical

System Interface	Analog Inputs (4)	Selectable span 0–1 volt, 0–5 volts, 0–10 volts >100kΩ input impedance, 1/8 in. phone jack Bandwidth = 5 Hz Resolution = 12 bits
	Analog Outputs (2)	Selectable span 0–1 volt 0–10 volts, 1/8 in. phone jack Bandwidth = 10 Hz Resolution = 8 bits
	Digital I/O (2)	RS-232, programmable DE9 serial ports Maximum data rate = 19.2 Kilobaud
	Touch Bar	Pressure-sensitive switch to enter numeric data and select menu items.
	Keypad	Five push buttons to select menu items.
Electrical	Voltage	100 to 240 volts ac, 50/60 Hz
	Power Consumption	180 watts, maximum
	Fuse (Model VGS)	UL and CSA approved 2.0 amps, 250 volts, fast-acting F 2A/250V

A.5 Environmental Requirements

Operating Temperature	10 to 35°C (50 to 95°F)
Storage Temperature	-40 to 65°C (-40 to 149°F)
Operating and Storage Relative Humidity	10% to 95% non-condensing
Operating and Shipping Pressure	0 to 10,000 ft (equivalent pressure)

A.6 Accessories

A.6.1 Model VGS *Vigilance®* Monitors

The following accessories are available for use with Model VGS *Vigilance®* Monitors.

Catheters	*
Power Cord	Model COM-2-PC
Operator's Manual	Model VGS-OM
Catheter Interface Cable	Model 70-CC1 or 70-CC2
Optical Module**	Model OM-2
In-Line Temperature Probe	Model 93-522
Bath Temperature Probe	Model 9850A
Canon BJ-30 Bubble Jet Printer	Model 70-PRT-CN
Canon BJ-30 Printer Interface Cable	Model 70-RS-CN
Pressure Slave Cables	*
Nellcor Pulse Oximeter Slave Cables	*

* Please contact your Baxter representative, or call Edwards Customer Service at 800.424.3278 (in the US and Canada) or 949.250.2500 (outside the US and Canada).

** For models configured with S_vO_2 only.

A.7 International Symbols

The following table shows the international medical equipment symbols used on the *Vigilance®* Monitor with their respective meanings:

	TYPE B EQUIPMENT - Equipment protected against electric shock.
	TYPE BF EQUIPMENT - Equipment protected against electric shock, having an F-type isolated (floating) applied part.
	TYPE CF EQUIPMENT - Equipment protected against electric shock, having an F-type isolated (floating) applied part and intended for direct cardiac application.
	ATTENTION: Consult accompanying documents.
	WARNING: Risk of fire. Replace fuse as marked.
	ALTERNATING CURRENT
	DANGEROUS VOLTAGE
	CAUTION: Refer servicing to qualified personnel.
	EQUIPOTENTIALITY
	DANGER: Risk of explosion if used in the presence of flammable anesthetics.
	REMOTE START
	FUSE

B

EQUATIONS FOR CALCULATED PATIENT PARAMETERS

This section describes the equations used to calculate patient parameters displayed on the Cardiac Profile and the Oxygenation Profile screens.

➡ **NOTE:** Calculated patient parameters contain more decimal places of accuracy than are displayed on the screen (e.g., a CO of 2.4 may be a CO of 2.4492). Consequently, attempts to verify the accuracy of the monitor's display using the following equations may produce results that are slightly different from the data computed by the monitor.

➡ **NOTE:** SI - Standard International Units

B.1 CARDIAC PROFILE EQUATIONS

1. $CI = CO/BSA$ (L/min/m^2)

   where: CI   – Cardiac Index
             CO   – Cardiac Output, L/min
             BSA – Body Surface Area, m^2

2. $SVR = \{(MAP - CVP) \times 80\} / CO$ (dynes-sec/cm^5)
   $SVR = \{(MAP_{SI} - CVP_{SI}) \times 60\} / CO$ (kPa-sec/L)

   where: SVR   – Systemic Vascular Resistance
             MAP   – Mean Arterial Pressure, mmHg
             MAP$_{SI}$ – Mean Arterial Pressure, kPa
             CVP   – Central Venous Pressure, mmHg
             CVP$_{SI}$ – Central Venous Pressure, kPa
             CO   – Cardiac Output, L/min

B.1 CARDIAC PROFILE EQUATIONS *(continued)*

3. $\text{SVRI} = \{(\text{MAP} - \text{CVP}) \times 80\}\,/\text{CI}$ (dynes-sec-m^2/cm^5)
   $\text{SVRI} = \{(\text{MAP}_{SI} - \text{CVP}_{SI}) \times 60\}\,/\text{CI}$ (kPa-sec-m^2/L)

   where: SVRI   – Systemic Vascular Resistance Index
          MAP   – Mean Arterial Pressure, mmHg
          MAP$_{SI}$ – Mean Arterial Pressure, kPa
          CVP   – Central Venous Pressure, mmHg
          CVP$_{SI}$ – Central Venous Pressure, kPa
          CI   – Cardiac Index, L/min/m^2

4. $\text{PVR} = \{(\text{MPAP} - \text{PAWP}) \times 80\}\,/\text{CO}$ (dynes-sec/cm^5)
   $\text{PVR} = \{(\text{MPAP}_{SI} - \text{PAWP}_{SI}) \times 60\}\,/\text{CO}$ (kPa-sec/L)

   where: PVR   – Pulmonary Vascular Resistance
          MPAP   – Mean Pulmonary Artery Pressure, mmHg
          MPAP$_{SI}$ – Mean Pulmonary Artery Pressure, kPa
          PAWP   – Pulmonary Artery Wedge Pressure, mmHg
          PAWP$_{SI}$ – Pulmonary Artery Wedge Pressure, kPa
          CO   – Cardiac Output, L/min

5. $\text{PVRI} = \{(\text{MPAP} - \text{PAWP}) \times 80\}\,/\text{CI}$ (dynes-sec-m^2/cm^5)
   $\text{PVRI} = \{(\text{MPAP}_{SI} - \text{PAWP}_{SI}) \times 60\}\,/\text{CI}$ (kPa-sec-m^2/L)

   where: PVRI   – Pulmonary Vascular Resistance Index
          MPAP   – Mean Pulmonary Artery Pressure, mmHg
          MPAP$_{SI}$ – Mean Pulmonary Artery Pressure, kPa
          PAWP   – Pulmonary Artery Wedge Pressure, mmHg
          PAWP$_{SI}$ – Pulmonary Artery Wedge Pressure, kPa
          CI   – Cardiac Index, L/min/m^2

6. $\text{SV} = (\text{CO}/\text{HR}) \times 1000$ (mL)

   where: SV   – Stroke Volume
          CO   – Cardiac Output, L/min
          HR   – Heart Rate, beats/min

7. $\text{SVI} = (\text{CI}/\text{HR}) \times 1000$ (mL/m^2)

   where: SVI   – Stroke Volume Index
          CI   – Cardiac Index, L/min/m^2
          HR   – Heart Rate, beats/min

B.1 CARDIAC PROFILE EQUATIONS *(continued)*

8. $LVSWI = SVI \times (MAP - PAWP) \times 0.0136$ $(g\text{-}m/m^2/beat)$
   $LVSWI = SVI \times (MAP_{SI} - PAWP_{SI}) \times 0.0136 \times 7.5$ $(g\text{-}m/m^2/beat)$

   where: LVSWI – Left Ventricle Stroke Work Index
           SVI   – Stroke Volume Index, mL/m^2
           MAP   – Mean Arterial Pressure, mmHg
           MAP_{SI} – Mean Arterial Pressure, kPa
           PAWP – Pulmonary Artery Wedge Pressure, mmHg
           $PAWP_{SI}$– Pulmonary Artery Wedge Pressure, kPa

9. $RVSWI = SVI \times (MPAP - CVP) \times 0.0136$ $(g\text{-}m/m^2/beat)$
   $RVSWI = SVI \times (MPAP_{SI} - CVP_{SI}) \times 0.0136 \times 7.5$ $(g\text{-}m/m^2/beat)$

   where: RVSWI – Right Ventricle Stroke Work Index
           SVI   – Stroke Volume Index, mL/m^2
           MPAP – Mean Pulmonary Artery Pressure, mmHg
           $MPAP_{SI}$– Mean Pulmonary Artery Pressure, kPa
           CVP   – Central Venous Pressure, mmHg
           CVP_{SI} – Central Venous Pressure, kPa

10. $BSA = 71.84 \times (WT^{0.425}) \times (HT^{0.725}) / 10{,}000$ (m^2)

    where: BSA   – Body Surface Area (DuBois formula)
            WT   – Patient Weight, kg
            HT   – Patient Height, cm

B.2 OXYGENATION PROFILE EQUATIONS

1. $O_2EI = \{(SaO_2 - SvO_2) / SaO_2\} \times 100$ (%)

     where: O_2EI –   Oxygen Extraction Index
                SaO_2 –   Arterial O_2 Saturation
                SvO_2 –   Venous O_2 Saturation

2. $DO_2 = CaO_2 \times CO \times 10$ (mL O_2/min)

     where: DO_2 –   Oxygen Delivery
                CaO_2 –   Arterial Oxygen Content, mL/dL
                CO   –   Cardiac Output, L/min

3. $CaO_2 = (0.0138 \times HGB \times SaO_2) + (0.0031 \times PaO_2)$ (mL/dL)
   $CaO_2 = (0.0138 \times (HGB_{SI} \times 1.611) \times SaO_2) +$
             $(0.0031 \times (PaO_{2SI} \times 7.5))$ (mL/dL)

     where: CaO_2 –   Arterial Oxygen Content
                HGB   –   Total Hemoglobin, g/dL
                HGB_{SI} –   Total Hemoglobin, mmol/L
                SaO_2 –   Arterial O_2 Saturation
                PaO_2 –   Partial Pressure of Arterial Oxygen, mmHg
                PaO_{2SI} –   Partial Pressure of Arterial Oxygen, kPa

4. $CvO_2 = (0.0138 \times HGB \times SvO_2) + (0.0031 \times PvO_2)$ (mL/dL)
   $CvO_2 = (0.0138 \times (HGB_{SI} \times 1.611) \times SvO_2) +$
             $(0.0031 \times (PvO_{2SI} \times 7.5))$ (mL/dL)

     where: CvO_2 –   Venous Oxygen Content
                HGB   –   Total Hemoglobin, g/dL
                HGB_{SI} –   Total Hemoglobin, mmol/L
                SvO_2 –   Venous O_2 Saturation
                PvO_2 –   Partial Pressure of Venous Oxygen, mmHg
                PvO_{2SI} –   Partial Pressure of Venous Oxygen, kPa

5. $Ca - vO_2 = CaO_2 - CvO_2$ (mL/dL)

     where: CaO_2 –   Arterial Oxygen Content, mL/dL
                CvO_2 –   Venous Oxygen Content, mL/dL

6. $DO_2I = CaO_2 \times CI \times 10$ (mL O_2/min/m^2)

     where: DO_2I –   Oxygen Delivery Index
                CaO_2 –   Arterial Oxygen Content, mL/dL
                CI   –   Cardiac Index, L/min/m^2

B.2 OXYGENATION PROFILE EQUATIONS *(continued)*

7. $VO_2 = Ca\text{-}vO_2 \times CO \times 10 \quad (mL\ O_2/min)$

   where: VO_2 – Oxygen Consumption
   $Ca\text{-}vO_2$ – Arteriovenous Oxygen Content Difference, mL/dL
   CO   – Cardiac Output, L/min^2

8. $VO_2I = Ca\text{-}vO_2 \times CI \times 10 \quad (mL\ O_2/min/m^2)$

   where: VO_2I – Oxygen Consumption Index
   $Ca\text{-}vO_2$ – Arteriovenous Oxygen Content Difference, mL/dL
   CI   – Cardiac Index, $L/min/m^2$

9. $O_2ER = (Ca\text{-}vO_2\ /\ CaO_2) \times 100 \quad (\%)$

   where: O_2ER – Oxygen Extraction Ratio
   CaO_2 – Arterial Oxygen Content, mL/dL
   $Ca\text{-}vO_2$ – Arteriovenous Oxygen Content Difference, mL/dL

10. $VQI = \dfrac{\{1.38 \times HGB \times (1.0 - (SaO_2/100)) + (0.0031 \times PAO_2)\}}{\{1.38 \times HGB \times (1.0 - (SvO_2/100)) + (0.0031 \times PAO_2)\}} \times 100 \quad (\%)$

$$VQI = \dfrac{\{1.38 \times HGB_{SI} \times 1.611344 \times (1.0 - (SaO_2/100)) + (0.0031 \times PAO_2)\}}{\{1.38 \times HGB_{SI} \times 1.611344 \times (1.0 - (SvO_2/100)) + (0.0031 \times PAO_2)\}} \times 100 \quad (\%)$$

   where: VQI   – Ventilation Perfusion Index
   HGB   – Total Hemoglobin, g/dL
   HGB_{SI} – Total Hemoglobin, mmol/L
   SaO_2 – Arterial O_2 Saturation
   SvO_2 – Venous O_2 Saturation
   PAO_2 – Alveolar O_2 Tension

   and:

$$PAO_2 = ((PBAR - PH_20) \times FiO_2) - PaCO_2 \times (FiO_2 + (1.0 - FiO_2)/0.8)$$

where: FiO$_2$ -   Fraction of Inspired Oxygen
       PBAR = 760 mmHg
       PH$_2$0   = 47 mmHg
       PaCO$_2$ = 40 mmHg

C

VIGILANCE® MONITOR DEFAULT SETTINGS

The information in this section defines the factory default settings for the *Vigilance®* Monitor that includes: Alarm Limits, Display Settings, Patient Data Screen Defaults, and Communication Port Settings. Also included in this section is information about supported digital devices.

C.1 ALARM LIMITS

Parameter	High Limit	Low Limit	Status	Units
CCO	14.0	2.0	On	L/min
SvO_2	99.0	10.0	On	
CCI	7.0	1.0	On	$L/min/m^2$

C.2 DISPLAY SETTINGS

Trend Time Scale	2 hours
Graph 1	SvO_2 (scale 0–100)
Graph 2	CCO (scale 0–12)
Temperature Units	°C
International Units	No
Time Format	non-military (12-hour)
CCO	Not indexed to body surface area
SVR	Not indexed to body surface area

C.3 PATIENT DATA SCREEN DEFAULTS

PvO_2 = 40 mmHg
PaO_2 = 100 mmHg

C.4 COMMUNICATION PORT SETTINGS

	Parameter Device
Analog Input Ports (1, 2, 3, 4)	None
Analog Output Ports (1, 2)	None
Digital Port — COM 1	None
Digital Port — COM 2	None

C.5 SUPPORTED DIGITAL DEVICES

- Canon BJ-30 Printer

- Patient Monitors that use the *Vigilance®* Standard Communication Protocol (IFMout). For more information on this communication protocol, contact Edwards Technical Support (see Appendix F).

- Space Labs Medical Patient Care Management Systems (PCMS™) that use the Space Labs Universal Flexport® Communications Protocol (Flexport®).

A P P E N D I X

D

COMPUTATION CONSTANTS

The computation constants listed in the following tables are used by the *Vigilance®* Monitor in the BOLUS CO mode to compute cardiac output employing either a bath probe setup or in-line temperature probe. The *Vigilance®* Monitor automatically senses the type of injectate temperature probe being used, and the corresponding injectate temperature, catheter size and injectate volume define the computation constant. When a bath temperature probe is used, the computation constant is determined before sensing an injection. When an in-line temperature probe is used, the computation constant is determined after sensing an injection.

➧ **NOTE:** The computation constants given below are nominal and generally applicable to the specified catheter sizes. For computation constants specific to the catheter being used, refer to the catheter package insert. Model specific computation constants can be manually entered in the BOLUS CO mode after pressing the **BOLUS SETUP** key.

Table D-1 Computation Constants
for use with a Bath Temperature Probe

Injectate Temperature Range*	Injectate Volume	Catheter Size, French				
		8	7.5	7	6	5.5
Room Temp. 22.5–27°C	10	0.612	0.594	0.595	0.607	0.616
	5	0.301	0.283	0.287	0.304	0.304
	3	0.177	0.159	0.165	0.180	0.180
Room Temp. 18-22.5°C	10	0.588	0.582	0.578	0.597	0.606
	5	0.283	0.277	0.274	0.297	0.298
	3	0.158	0.156	0.154	0.174	0.175
Cold (Iced) 5-18°C	10	0.563	0.575	0.562	0.573	0.581
	5	0.267	0.267	0.262	0.278	0.281
	3	0.148	0.150	0.144	0.159	0.161
Cold (Iced) 0–5°C	10	0.564	0.564	0.542	0.547	0.555
	5	0.262	0.257	0.247	0.259	0.264
	3	0.139	0.143	0.132	0.144	0.148

Edwards Critical-Care Division

Table D-2 Computation Constants
for use with an In-Line Temperature Probe

Injectate Temperature	Injectate Volume Range*	Catheter Size, French				
		8	7.5	7	6	5.5
Room Temp. 22.5–27°C	10	0.601	0.599	0.616	0.616	0.624
	5	0.294	0.301	0.311	0.307	0.310
Room Temp. 18-22.5°C	10	0.593	0.593	0.603	0.602	0.612
	5	0.288	0.297	0.295	0.298	0.304
Cold (Iced) 5-18°C	10	0.578	0.578	0.570	0.568	0.581
	5	0.272	0.286	0.257	0.276	0.288
Cold (Iced) 0–5°C	10	0.562	0.563	0.537	0.533	0.549
	5	0.267	0.276	0.217	0.253	0.272

*To optimize cardiac output measurement, it is recommended that the temperature of the injectate corresponds to one of the temperature ranges listed in the catheter inserts.

A P P E N D I X

E

PERFORMANCE CHECK

E.1 Introduction

This section provides a performance test of the operation of the *Vigilance®* Continuous Cardiac Output Monitor. This procedure is designed to be followed in the order it is presented here. Perform these tests in the order presented to assure the user that the monitor is functioning properly. If the monitor does not perform these tests as specified, please contact Technical Support at 1-800-8-BAXTER (1-800-822-9837).

E.2 Equipment Required

This procedure requires the following items:

Item:	Model Number	Description
	OM-2	Optics Module
	9511A	Field Tester
	93A-741H-7.5F	Oximetry catheter (unopened)
	or	
	93A-780H-7.5F	Oximetry catheter (unopened)
	70-CC1 or 70-CC2	Catheter Interface Cable

E.3 Power On Self Test (POST)

Perform the following steps for the Power On Self Test.

1. Place the *Vigilance®* monitor on a table.

2. Check for loose hardware by tilting the unit to the left side, the right side, to the back, and to the front.

3. Connect the monitor to an appropriate AC power source.

4. Turn the monitor ON by pressing the power switch.

5. If any power up system fault messages appear, carefully record the exact message and call Technical Support at 1-800-8-BAXTER.

E.4 System Setup for Performance Check

1. If the patient data is less than 24 hours old, the trend screen will then appear with the following message:

   Clear patient data profiles?

   Press **YES**.

2. Press **SETUP**.

3. Make sure both CO/CCO and SVR display non-indexed values. If they are set for indexed values, move the cursor to that field and press change so non-indexed is displayed.

4. Press **SYSTEM CONFIG**.

5. Select Analog Input from the touch bar.

6. Press **CURSOR** until Parameter is backlit. Press change until -none- appears.

7. Press **PORT2**. Repeat steps 5 and 6 to set all four analog ports to -none-.

8. Press **HOME**.

9. Connect the OM-2 to the monitor.

10. Connect the catheter optical connector to the OM-2.

11. Select SvO2 from the touch bar.

12. Select In Vivo Calibration. A warning will be displayed because the catheter is still in the package and not in a patient. Select Continue from the touch bar.

13. Select Draw from the touch bar.

14. Enter the following values:

    SvO_2:   70.0
    HGB: 11.5
    Hct: 35

15. Press **CAL**

16. After the Optical Module Update is complete, the screen should revert to the Home screen, and SvO2 should begin to trend at 70.

E.5
Bolus CO
Performance
Check

➡ NOTE: Make sure an injectate Temperature probe is not connected to the cable.

1. Connect the 70-CC1 or 70-CC2 cable to the Catheter Cable Connector on the front panel.

2. Connect the 9511A Field Tester to the white thermistor connector on the end of the 70-CC1 or 70-CC2.

3. Select Bolus CO from the touch bar.

4. Select Bolus Setup. Computation Constant should read **Yes**. Press **RETURN**.

5. Select Comp Const.

6. Using the touch bar at the bottom of the screen, enter 0247. The computation constant should be displayed as 0.247. Press **RETURN**.

7. Press **START BOLUS** if in the manual mode, or just continue if in the automatic mode. Press and hold the red button on the 9511A field tester for 10 seconds. The cardiac output should be between 6.5 and 7.9 liters per minute (lpm).

8. Repeat step 6 to obtain a total of three cardiac output values.

9. Press **EDIT BOLUS**. If any curves are outside the specified range, touch the touch bar just below the value to delete it from the calculation. Press **RESUME SERIES** to obtain a total of at least three good cardiac output values.

10. From the Edit Bolus screen, press **PATIENT DATA**.

E.6
Cardiac
Profile
Performance
Check

1. Press **EDIT**

2. Enter the following values:

MAP:	85	mmHg
CVP:	8	mmHg
MPAP:	24	mmHg
PAWP:	14	mmHg
HR:	60	mmHg
Height:	72	inches
Weight:	160	pounds

3. Press **CALC**.

4. The calculated values should be within the following ranges:

CO:	6.5 - 7.9	CI:	3.3 - 4.0
SVR:	780 - 948	SVRI:	1513 - 1839
PVR:	101 - 123	PVRI:	196 - 239
LVSWI:	53 - 65	RVSWI:	12 - 14
SV:	108 - 132	SVI:	55 - 67

E.7 Oxygen Profile Performance Check

1. Press **OXYGEN PROFILE**.

2. Press **EDIT**.

3. Enter the following values:

SaO_2:	81	%
SvO_2:	70	%
HGB:	11.5	g/dL
PvO_2:	37	mmHg
PaO_2:	95	mmHg
FiO_2:	1.00	

4. Press **CALC**.

5. The calculated values should be within the following ranges:

VO2:	115 - 152	VO2I:	59 - 78
DO2:	855 - 1039	DO2I:	441 - 535
CO:	6.5 - 7.9	CI:	3.3 - 4.0
		VQI:	75%

F

SERVICE AND SUPPORT

❖ **WARNING:** THE *Vigilance®* MONITOR CONTAINS NO USER-SERVICABLE PARTS. REMOVAL OF THE COVER OR DISASSEMBLY WILL EXPOSE HAZARDOUS VOLTAGES. TO AVOID INJURY OR INSTRUMENT DAMAGE, DO NOT DISASSEMBLE OR SERVICE THE INSTRUMENT. REFER SERVICING TO THE MANUFACTURER.

❖ **WARNING:** FOR PROTECTION AGAINST FIRE, REPLACE THE FUSE WITH ONE OF THE SAME TYPE AND RATING.

F.1 Service and Support

The *Vigilance®* Monitor does not need routine servicing to maintain its optimum performance level. See Section 4, "Troubleshooting Guide," of this manual for potential difficulties, causes of those difficulties, and suggested solutions.

Baxter provides a technical services support department for user support. Telephone inquiries for service, technical support, supplies, or miscellaneous questions are made by calling Edwards Technical Support at the telephone numbers listed below.

To respond to questions, this department will need the serial number of the unit and, if possible, the version of software. The serial number is found on the back panel of the *Vigilance®* Monitor. Press the following keys in sequence to display the software version: **SETUP, SYSTEM CONFIG.**

* Monitor Problem Troubleshooting, call Edwards Technical Support:

Inside the U.S. and Canada (24 hours):   1.800.8BAXTER
Outside the U.S. and Canada (24 hours):   949.756.4400

- Return address for repair of electronic items (in the U.S.) - Please contact Edwards Technical Support prior to returning any electronic equipment:

  Edwards Critical-Care Division
  1402 East Alton Avenue
  Irvine, CA 92714

  Attention: Service Operations
  RGA#_____

- Sales and nontechnical questions should be directed to the Customer Service Department at 1.800.4.A-HEART or 949.250.2500.

- Return address for the evaluation of non-electronic items (e.g. catheters) - Please contact Edwards Customer Service prior to returning any non-electronic items:

  Edwards Critical-Care Division
  1402 East Alton Avenue
  Irvine, CA 92714

  Attention: Returned Goods
  RGA#_____

GLOSSARY

ALARMS
Audible and visual indicators that notify operator that a measured patient parameter is outside the alarm limits.

ALARM LIMITS
Maximum and minimum values for monitored patient parameters.

ARTERIAL OXYGEN CONTENT (CaO$_2$)
The amount of oxygen carried in the arterial blood, both in the dissolved state and the amount bound to hemoglobin. Content of oxygen (CO$_2$) can be expressed as milliliters of oxygen per deciliter (mL/dL) of blood or as volume percent (vol %).

ARTERIAL OXYGEN SATURATION (SaO$_2$)
Percentage of hemoglobin saturated with oxygen in the arterial blood.

ARTERIOVENOUS OXYGEN CONTENT DIFFERENCE (Ca-vO$_2$)
The difference between the content of oxygen in the arterial and venous side. This difference is expressed as milliliters of oxygen per deciliter (mL/dL) of blood or as volume percent (vol %).

BASELINE BLOOD TEMPERATURE
Blood temperature that serves as the basis for cardiac output measurements.

BLOOD TEMPERATURE (BT)
Temperature of the blood in the pulmonary artery when the catheter is properly positioned.

BODY SURFACE AREA (BSA)
Surface area of a patient's skin.

BOLUS CO MODE
Functional state of the *Vigilance®* Monitor in which cardiac output is measured by the bolus thermodilution method.

BOLUS INJECTION
A known volume of iced or room temperature fluid, which is injected into a port on the pulmonary artery catheter and serves as the indicator for measuring cardiac output.

CARDIAC INDEX (CI)
Cardiac output adjusted for body size.

CARDIAC OUTPUT (CO)
Volume of blood ejected per minute from the heart into systemic circulation.

CENTRAL VENOUS PRESSURE (CVP)
Mean pressure in the superior vena cava (right atrium). Indicates venous return to the right side of the heart.

COMPUTATION CONSTANT
A constant used in the cardiac output equation that accounts for density of blood and injectate, injectate volume, and indicator loss in the catheter.

CONTINUOUS MODE
Functional state of the *Vigilance®* Monitor in which cardiac output is trended on a continuous basis.

CURSOR
Highlighted portion of monitor screen used to indicate choices of variables which can be entered.

DEFAULT SETTINGS
Initial operating conditions assumed by the monitor.

DRUG CALCULATION
The *Vigilance®* system calculates the desired values based on data entered by the user.

EVENT
An episode during monitoring that the operator wishes to mark on the trend graph.

FRACTION OF INSPIRED OXYGEN (FiO_2)
The fraction of oxygen in the inspired air.

HEART RATE (HR)
Number of ventricular contractions per minute.

HEMOGLOBIN (HGB)
Oxygen carrying component of red blood cells.

ICON ⊠
The "No Alarms" icon appears on all screens when alarms are suspended.

INJECTATE
Fluid used for bolus thermodilution cardiac output measurement.

INJECTATE TEMPERATURE (IT)
Measured temperature of the injectate used for bolus thermodilution cardiac output measurement.

INTELLICATH™ CATHETER
Edwards Critical-Care thermodilution pulmonary artery catheter used to measure cardiac output continuously.

LEFT VENTRICULAR STROKE WORK INDEX (LVSWI)
A measure of the amount of work the left ventricle exerts during systole, adjusted for body size.

MEAN ARTERIAL PRESSURE (MAP)
Average systemic arterial blood pressure.

MEAN PULMONARY ARTERY PRESSURE (MPAP)
Average blood pressure measured in the pulmonary artery.

MIXED VENOUS OXYGEN SATURATION (SvO_2)
Percentage of hemoglobin saturated with oxygen in the venous blood as measured in the pulmonary artery.

OXYGEN DELIVERY (DO_2)
Amount of oxygen in milliliters per minute (ml/min) delivered to the tissues.

OXYGEN DELIVERY INDEX (DO_2I)
Amount of oxygen in milliliters per minute (ml/min) delivered to the tissues, adjusted for body size.

OXYGEN CONSUMPTION (VO_2)
Amount of oxygen in milliliters per minute (ml/min) used by the tissues.

OXYGEN CONSUMPTION INDEX (VO_2I)
Amount of oxygen in milliliters per minute (ml/min) used by the tissues, adjusted for body size.

OXYGEN EXTRACTION INDEX (O_2EI)
O_2EI is determined by using dual oximetry, SaO_2 and SvO_2 and evaluates the ratio of oxygen extracted to the amount of oxygen supplied.

OXYGEN EXTRACTION RATIO (O_2ER)
O_2ER is the ratio of oxygen content difference to the amount of oxygen supplied.

PULMONARY ARTERY WEDGE PRESSURE (PAWP)

Pressure obtained from the pulmonary artery catheter when balloon is inflated and catheter tip progresses into a more distal branch of the pulmonary artery. Reflects left atrial pressure when there is no mechanical obstruction (e.g. left atrial tumors, or pulmonary vein obstruction) between the balloon tip and the left atrium.

PULMONARY VASCULAR RESISTANCE (PVR)

A derived measure of impedance to blood flow from right ventricle (afterload).

PULMONARY VASCULAR RESISTANCE INDEX (PVRI)

Pulmonary vascular resistance adjusted for body size.

RIGHT VENTRICULAR STROKE WORK INDEX (RVSWI)

A measure of the amount of work the right ventricle exerts during systole, adjusted for body size.

SIGNAL

Induced temperature change which is used to measure cardiac output.

STAT MODE

Presents fast trend estimates of CCO/CCI values.

STROKE VOLUME (SV)

Amount of blood ejected from the ventricles with each contraction.

STROKE VOLUME INDEX (SVI)

Stroke volume adjusted for body size.

SYSTEMIC VASCULAR RESISTANCE (SVR)

A derived measure of impedance to blood flow from left ventricle (afterload).

SYSTEMIC VASCULAR RESISTANCE INDEX (SVRI)

Systemic vascular resistance adjusted for body size.

THERMAL FILAMENT

Area on the CCO thermodilution catheter that transfers small amounts of energy into the blood to serve as indicator for trending cardiac output continuously.

THERMISTOR

Temperature sensor near the tip of the pulmonary artery catheter.

THERMODILUTION

A variant of the indicator dilution technique using temperature change as the indicator.

TREND

A collection of historical data points.

VENOUS OXYGEN CONTENT (CvO$_2$)

The amount of oxygen carried in the venous blood, both in the dissolved state and the amount bound to hemoglobin. Content of oxygen (CO_2) can be expressed as milliliters of oxygen per deciliter (mL/dL) of blood or as volume percent (vol %).

VENOUS OXYGEN SATURATION (SvO$_2$)

Percentage of hemoglobin saturated with oxygen in the venous blood.

VENTILATION PERFUSION INDEX (VQI)

VQI is determined by using dual oximetry, SaO$_2$ and SvO$_2$. This value is a derivation of the intrapulmonary shunt equation and provides an estimate of intrapulmonary shunt value.

WASHOUT CURVE

Indicator dilution curve produced by a bolus injection. Cardiac output is inversely related to the area under this curve.