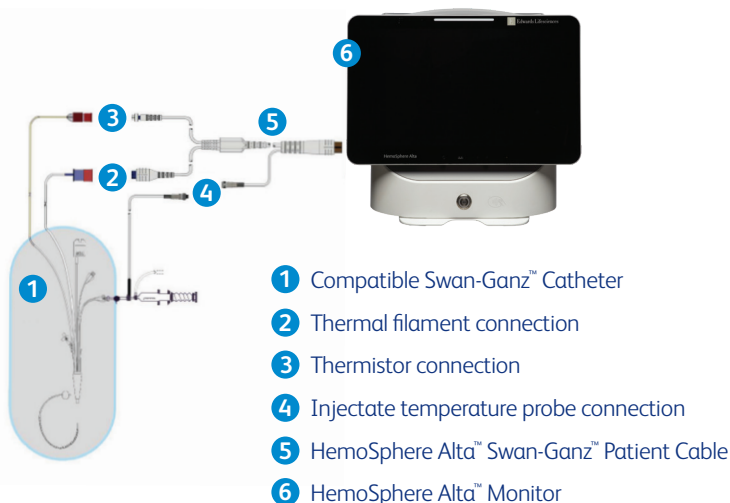




Swan-Ganz™ and Swan-Ganz IQ™ Pulmonary Artery Catheters

Setup Guide

Swan-Ganz™ Pulmonary Artery Catheter Setup for Continuous Cardiac Output Monitoring



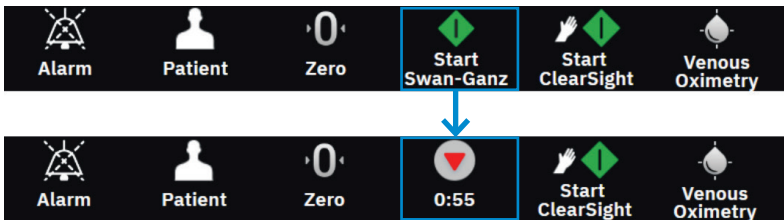
- 1 Plug the HemoSphere Alta™ Swan-Ganz™ CCO into the HemoSphere Alta™ Advanced Monitor.
- 2 Press the **Power** button to turn on the HemoSphere Alta™ Advanced Monitoring Platform and follow steps for entering patient data.
- 3 Connect the compatible Swan-Ganz™ Catheter to the HemoSphere Alta™ Swan-Ganz™ Patient Cable.
- 4 Attach the catheter end of the patient cable to the thermistor and thermal filament connectors on the Swan-Ganz™ CCO Catheter. 2 3
- 5 Verify that the CCO catheter is properly inserted into the patient.





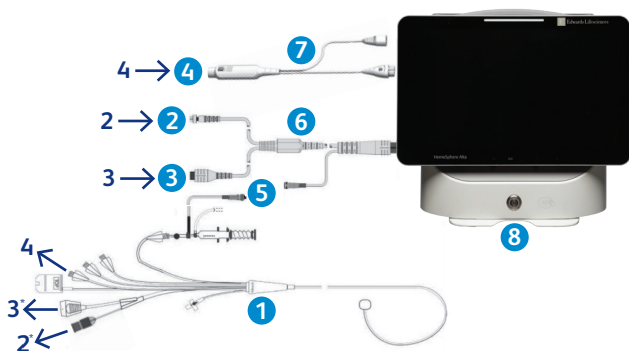
- 6 When the system is properly connected, touch the start monitoring icon on the navigation bar to begin CO monitoring. The CO countdown timer will appear on the **Stop Monitoring** icon. After approximately 5 to 12 minutes, when sufficient data has been obtained, a CO value will appear in the parameter tile. The CO value displayed on the screen will be updated approximately every 60 seconds.

NOTE: No CO value will be displayed until sufficient time-averaged data is available.





Swan-Ganz IQ™ Pulmonary Arterial Catheter Setup



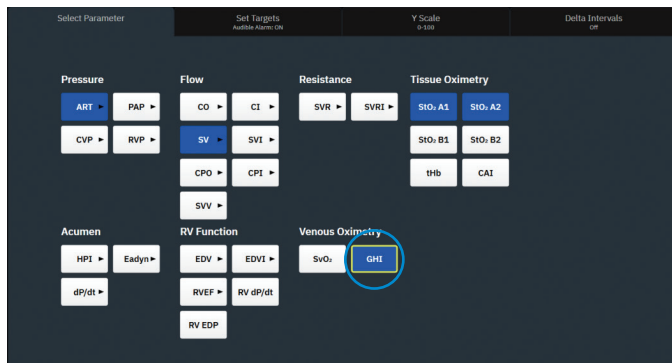
- | | |
|---|--|
| 1 Swan-Ganz IQ™ Catheter | 5 Injectate temperature probe connection |
| 2 Thermistor connection* | 6 HemoSphere Alta™ Swan-Ganz™ Patient Cable |
| 3 EEPROM connection to HemoSphere Alta™ Swan-Ganz™ Patient Cable | 7 Pressure cable |
| 4 Catheter RV post to TruWave™ Transducer / Pressure Cable | 8 HemoSphere Alta™ Advanced Monitor |
| | *optional |

- 1 Plug the HemoSphere Alta™ Swan-Ganz™ Patient Cable into the HemoSphere Alta™ Advanced Monitor.
- 2 Connect EEPROM connector of the catheter to the thermal filament connection of the HemoSphere Alta™ Swan-Ganz™ Patient Cable. **3**
- 3 Connect the RV port of the Swan-Ganz IQ™ Catheter to TruWave™ Transducer and pressure cable. **4**
- 4 (Optional for iCO thermodilution): Attach the catheter end of the patient cable to the thermistor connector on the Swan-Ganz IQ™ Catheter. **2**
- 5 (Optional for iCO thermodilution): Connect the injectate temperature probe (in-line or bath) to the injectate temperature probe connector on the patient CCO cable. **5**
- 6 Verify that the catheter is properly inserted into the patient. Refer to details in catheter IFU.



Global Hypoperfusion Index (GHI)

The GHI algorithm can be activated in invasive monitoring mode with a connected Swan-Ganz™ Catheter and oximetry cable. The GHI algorithm provides hemodynamic instability correlates to when mixed venous oxygen saturation (SvO₂) drops to 60% or less for one minute.



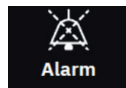
Configure GHI parameter by selecting GHI under the venous oximetry title

Parameter status colors for GHI

Parameter status color	Lower limit	Upper limit
Gray	Fault condition	
White	0	74
Red/Gray Flashing	75	100

Silence Audible GHI Alarm

The GHI alarm will be silenced for 15 minutes when silence audible alarm icon on the navigation bar is touched. A countdown timer will appear on the parameter tile. Alarms will resume sounding after the pause period has elapsed. If GHI drops below 65 before 15 minutes have elapsed, the alarm pause will end and the alarm can be re-activated if GHI alarms again.





GHI Value graphical and audible display elements

GHI value	Graphical display elements	Audible	General interpretation	Recommended user action
GHI < 75	White	None	Patient hemodynamics indicate that there is a low to moderate likelihood of a hypoperfusion event occurring. A low GHI value does not exclude a hypoperfusion event from occurring in the future	Continue monitoring patient hemodynamics. Remain vigilant with respect to changing patient hemodynamics using the primary monitoring screen, GHI, and trends in parameters and vital signs.
GHI ≥ 75	Red (flashing)	None	Surgical patient has a high likelihood of experiencing a future hypoperfusion event within the next 15 minutes	Check patient hemodynamics and blood flow in order to investigate the potential cause of the high likelihood of hypoperfusion in order to inform a potential course of action
GHI ≥ 75 and persists for three continuous readings (6 seconds)	Red (flashing)	Medium priority alarm tone	Surgical patient has a high likelihood of experiencing a future hypoperfusion event	Check patient hemodynamics using the other primary screen parameters in order to investigate the potential cause of the high likelihood of hypoperfusion in order to inform a potential course of action
GHI = 100	Red (flashing)	Medium priority alarm tone	Patient is experiencing hypoperfusion and at risk for ischemia	Check patient hemodynamics and other primary screen parameters in order to investigate the potential cause of the hypoperfusion in order to inform a potential course of action

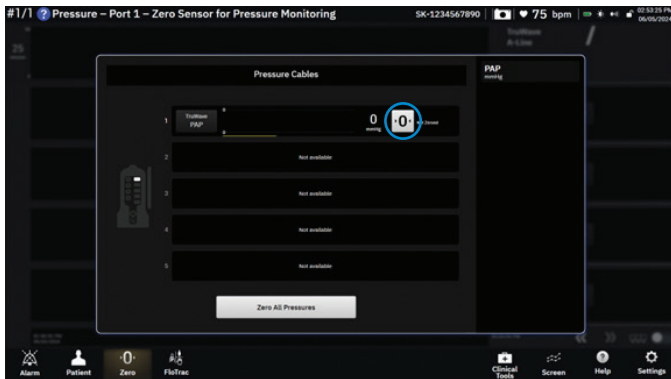


Smart Wedge™

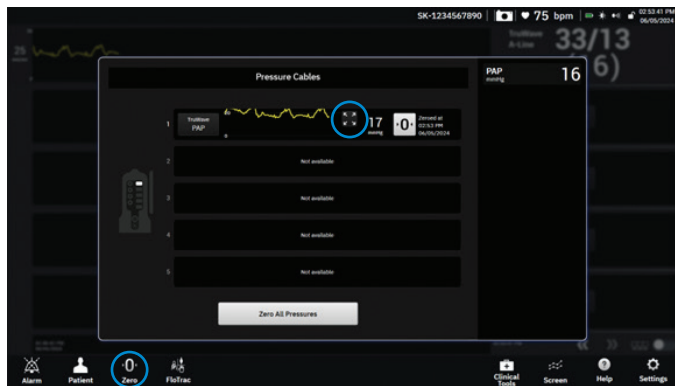
The Smart Wedge™ algorithm is designed to provide the value at end-expiration of the pulmonary artery occlusion pressure (PAOP) signal, also called pulmonary wedge pressure, pulmonary capillary wedge pressure (PCWP), or pulmonary artery wedge pressure (PAWP), and to assess the quality of the pulmonary artery occlusion pressure measurement.

To start the PAOP measurement procedure

- 1 Ensure the Swan-Ganz™ Catheter is properly set up and zero the Swan-Ganz™ Catheter pulmonary pressure line.



- 2 Touch the **Expand** icon  on the zero screen  (located on the navigation bar) to view and evaluate the PAP waveform. The current pressure waveform along with a graphic aid of example waveforms for various catheter tip positions is displayed. Check that the Swan-Ganz™ Catheter balloon is not in a wedged position.

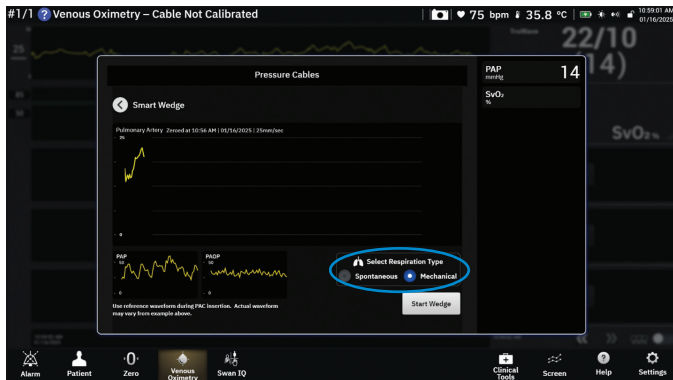


3 Touch the **Smart Wedge** button to initiate the Smart Wedge™ Algorithm.

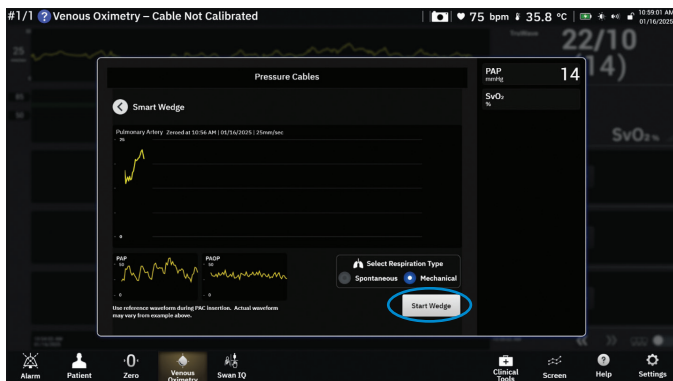




- 4 Select the respiration type: mechanical ventilation or spontaneous respiration and press **Smart Wedge** button.



- 5 When prompted by the algorithm, touch the **Start** button and inflate the balloon. Hospital policy and the catheters' Instructions for Use (IFU) should guide balloon inflation technique.





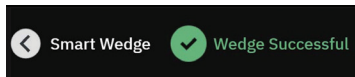
- 6 A timer will appear with the inflation time. The waveform changes from the PAP to the PAOP wave. The measurement takes approximately 1-2 respiration cycles (5-15 seconds).



WARNING: Do not leave the catheter in a permanent wedge position. Furthermore, avoid lengthy balloon inflation while the catheter is in a wedge position; this occlusive maneuver may result in pulmonary infarction.

NOTE: Detection of a wedge waveform is limited to 60 seconds. Wedges longer than 60 seconds will automatically take user to the “Edit Wedge” screen. Smart Wedge™ requires at least 60 seconds of PAP waveform data before Smart Wedge™ can be engaged.

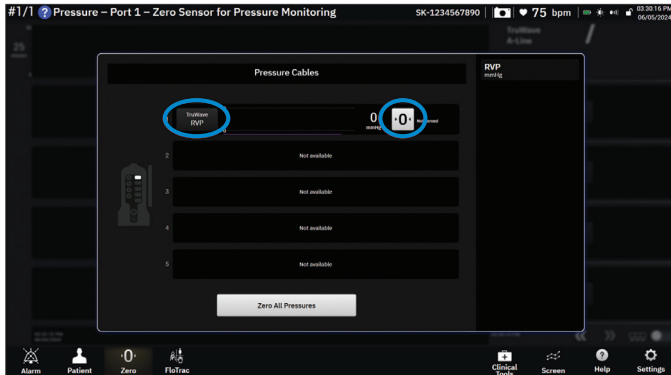
- 7 Deflate the balloon once a measurement is obtained/after two attempted respiratory cycles and verify that the waveform returns to pulmonary artery shape.
- 8 Once deflation is successfully completed, the PAOP value is provided and a **“Wedge Successful”** message appears. Successful PAOP measurements can be viewed on the **Events & Intervention** side panel at any point.



Touch the **Clinical Tools** icon  → **Events & Intervention** button. Scroll through the events to find any completed Smart Wedge™ Events.



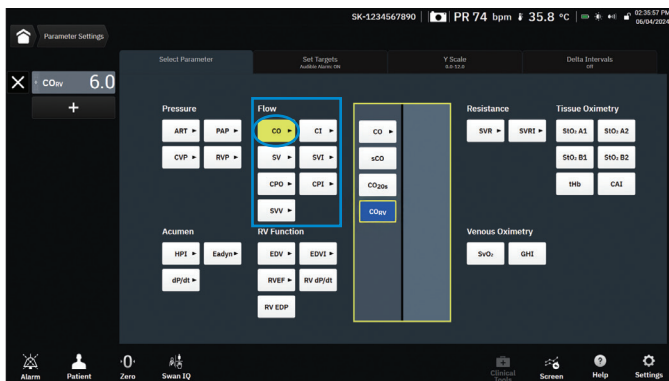
RV Cardiac Output (CO_{RV}) and other RV parameters



Connect TruWave™ Transducer designated to Swan-Ganz IQ™ RVP Lumen, configure channel to RVP, level, and zero transducer.



The RV waveform as well as the RV pressures will be displayed.



The screenshot displays the TruWave medical device interface. At the top, it shows the patient's heart rate (PR 87 bpm) and temperature (35.8 °C). The main display area is divided into two columns. The left column shows five stacked waveforms: a purple arterial pressure waveform (PR) with a scale from 0 to 25 mmHg, and four green venous pressure waveforms (RVP, CO, RV EDP, RV dP/dt, and PR RVP) with scales from 0 to 10.6, 1.8, and 1.8 mmHg respectively. The right column displays the corresponding numerical values for each parameter, along with the TruWave logo and a 'Scan IQ' button. The bottom of the screen features a navigation bar with icons for Alarms, Patient, Zero, Venous, and Scan IQ, and a status bar at the very bottom showing the time (01:13:14 PM) and date (01/26/2025).

Parameter	Value	Unit
PR	87	bpm
Temp	35.8	°C
TruWave	44/9	mmHg
RVP	(23)	mmHg
CO	4.5	L/min
RV EDP	14	mmHg
RV dP/dt	372	mmHg/s
PR RVP	76	mmHg

Once RVP pressure channel is zeroed, RV pressures, CO_{RV}, and other derived RV parameters will be displayed.



Venous Oximetry Connection Overview

NOTE: The HemoSphere™ Oximetry Cable must be calibrated before monitoring.

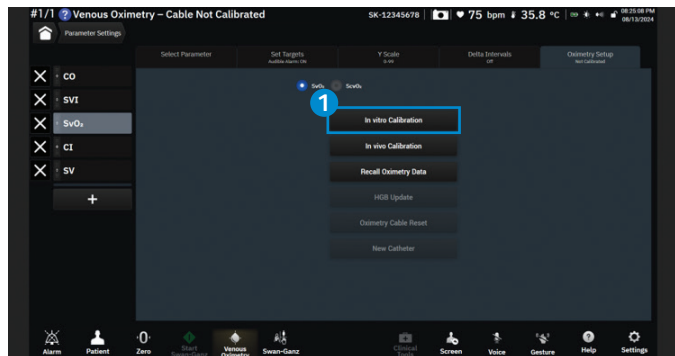
- 1** Connect the HemoSphere™ Oximetry Cable to the HemoSphere Alta™ Advanced Monitor. The following message will appear: **Oximetry Cable Initializing, Please Wait**
- 2** If the HemoSphere Alta™ Advanced Monitor is not on, turn on the power switch and follow steps for entering patient data.
- 3** Remove a section of the catheter tray lid to expose the optical connector.
- 4** Insert the optical connector of the catheter "TOP" side up into the oximetry cable and snap the enclosure shut.



Venous Oximetry Monitoring: In Vitro Calibration

In vitro calibration is performed before the catheter is inserted into the patient, using the calibration cup provided in the catheter packaging.

CAUTION: The catheter tip or calibration cup must not get wet before an in vitro calibration is performed. The catheter and the calibration cup must be dry for an accurate oximetry in vitro calibration. Flush the catheter lumen only after the in vitro calibration has been completed. Performing an in vitro calibration after the oximetry catheter has been inserted into the patient will yield an inaccurate calibration.

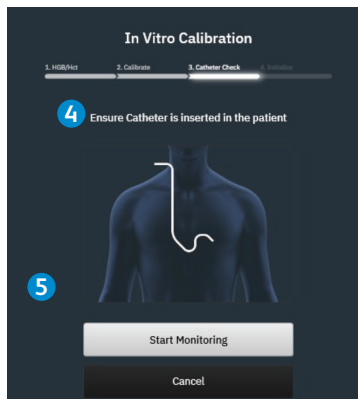
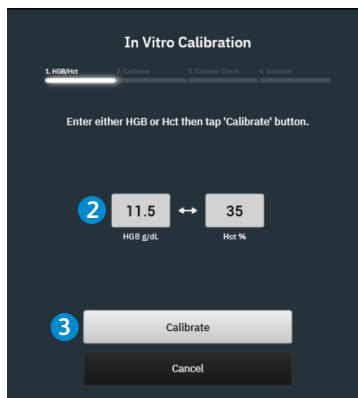


1 Touch the **Oximetry Calibration** icon  on the **ScvO₂/SvO₂** parameter tile or touch the **Venous Oximetry** icon  on the navigation bar to show the **Oximetry Setup** screen.

2 Touch **In Vitro Calibration** button. **1**



- 3 On the **In Vitro Calibration** screen, enter either the patient's hemoglobin (**HGB**) or hematocrit (**Hct**). Hemoglobin may be entered in either g/dL or mmol/L on the keypad. 2
- 4 Touch **Calibrate** button to start the calibration process. 3
- 5 When the calibration successfully completes, step 3, **Catheter Check** will illuminate and the following message appears: **Ensure Catheter is inserted in the patient.** 4
- 6 Insert the catheter as described in the catheter instructions for use.
- 7 Touch **Start Monitoring** button. 5





Venous Oximetry Monitoring: In Vivo Calibration

Use in vivo calibration to perform a calibration after the catheter has been inserted into the patient.

NOTE: For optimal accuracy, in vivo calibration should be performed at least every 24 hours. Signal quality is displayed during in vivo calibration. It is recommended that calibration be performed only when the SQI level is 1 or 2.



1 Touch the **Oximetry Calibration** icon  on the **ScvO₂/SvO₂** parameter tile or touch the **Venous Oximetry** icon  on the navigation bar to show the **Oximetry Setup** screen.

2 Touch **In Vivo Calibration** button. **1**

If setup is unsuccessful, one of the following messages will be displayed:

Warning: Wall Artifact or Wedge Detected.
Reposition catheter.

OR

Warning: Unstable Signal.



3 If a **“Wall Artifact or Wedge Detected,”** or **“Unstable Signal”** message appears, attempt to troubleshoot the problem as instructed in table 14-30, “Venous oximetry general troubleshooting,” on page 352 in the HemoSphere Alta™ Advanced Monitoring Platform operator’s manual and Touch **Recalibrate** button to restart the baseline setup.

OR

Touch **Continue** button to proceed to the draw **2** operation.

4 When baseline calibration is successful, touch **Draw** button and then draw the blood sample.

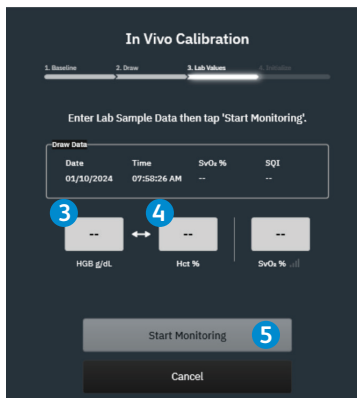
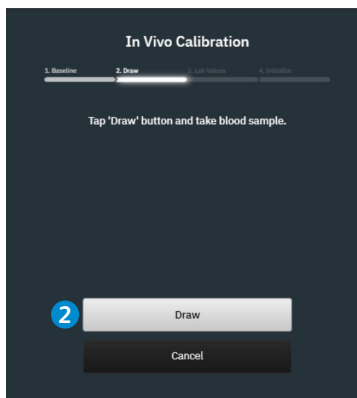
5 Draw the blood sample slowly (2 mL or 2 cc over 30 seconds) and send the blood sample to the lab for measured analysis by co-oximeter.

6 When lab values are received, touch **HGB** **3** button to enter the patient’s hemoglobin and touch g/dL or mmol/L or **Hct** **4** button to enter the patient’s hematocrit.

NOTE: When an HGB or Hct value is entered, the system automatically calculates the other value. If both values are selected, the last value entered is accepted.

7 Enter the lab oximetry value (ScvO₂/SvO₂).

8 Touch **Start Monitoring** button. **5**





Medical device for professional use. For a listing of indications, contraindications, precautions, warnings, and potential adverse events, please refer to the Instructions for Use (consult eifu.edwards.com where applicable).

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