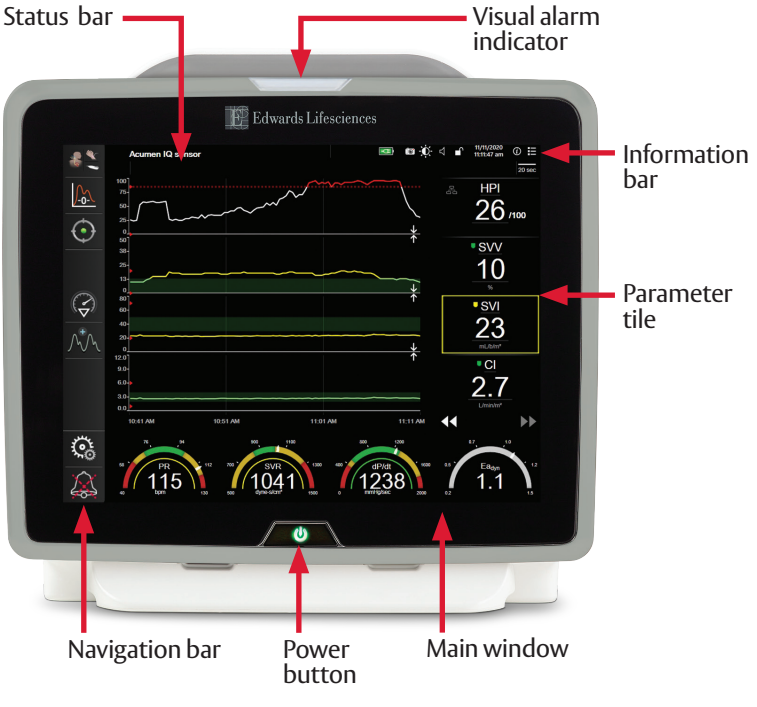
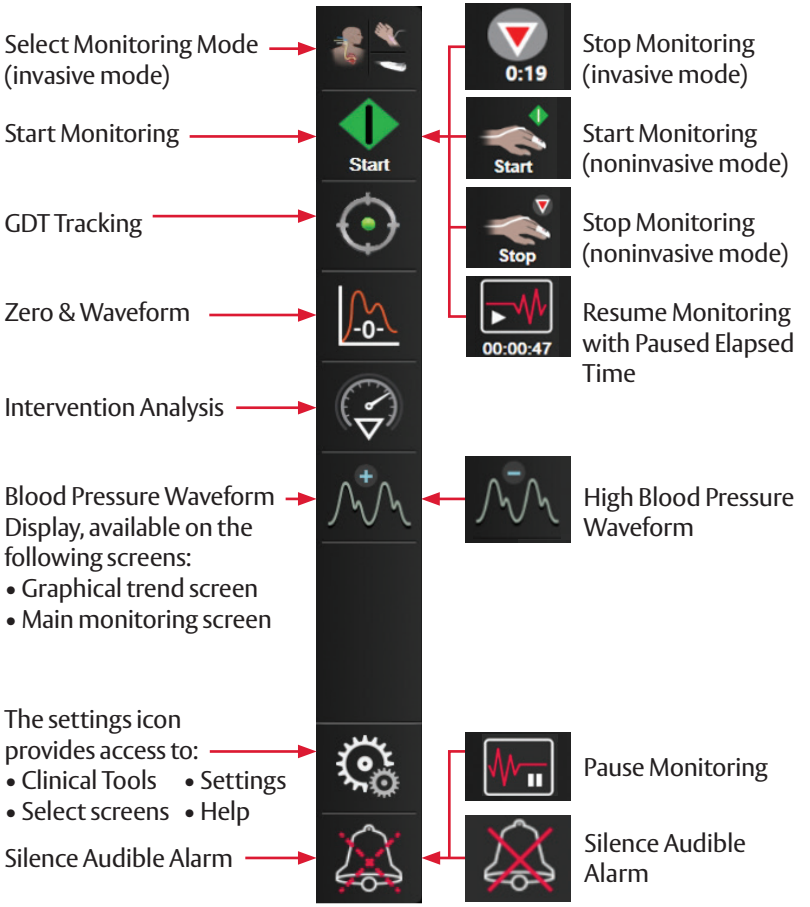
HemoSphere Advanced Monitoring Platform
Setup guide

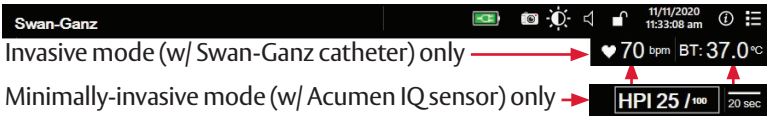


Edwards

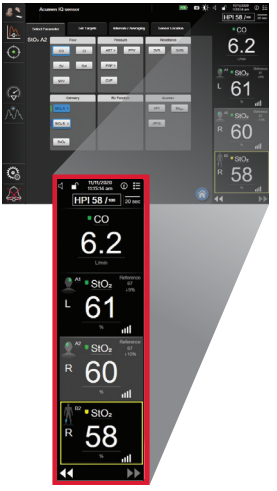
HemoSphere advanced monitor screen features



Information bar (located at the top of the screen)

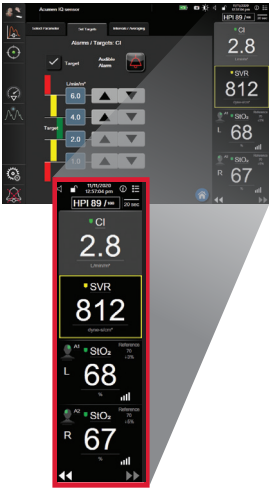


Clinical actions



Changing parameters

1. Touch the displayed parameter label located inside the parameter tile to change it to a different parameter.
2. The tile configuration menu will show the selected parameter highlighted and other parameters currently being displayed outlined. Available parameters appear on the screen without highlight.
3. Select desired parameter to display.

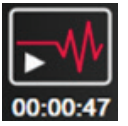


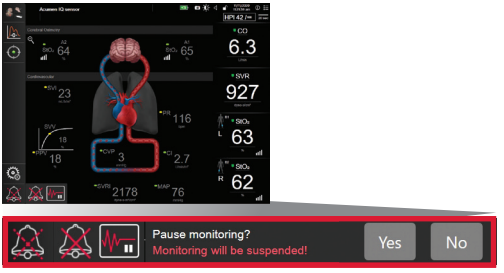
Changing targets and alarms

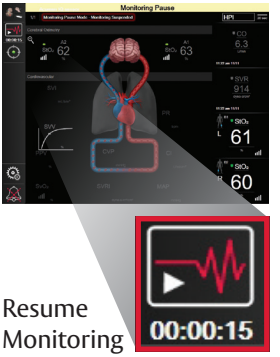
1. Touch the parameter value on a parameter tile.
2. Adjust target values using arrows or select value and type in parameter target.
3. Select **Target** to disable or enable colors in target ranges.
4. To silence parameter alarms, select **Audible Alarm** button.

Monitoring Pause

1. Touch the silence audible alarms icon continuously for five seconds to show additional alarm silencing options.
2. Touch this icon to pause monitoring. A monitoring pause confirmation banner will appear to confirm suspension of monitoring operations. Exception: Tissue oximetry monitoring and associated alarms will remain active during a monitoring pause.
3. After monitoring pause confirmation, a resume monitoring icon and elapsed time will appear on the navigation bar. A “Monitoring Pause” banner will be displayed. To return to monitoring, touch the resume monitoring icon.







Resume Monitoring

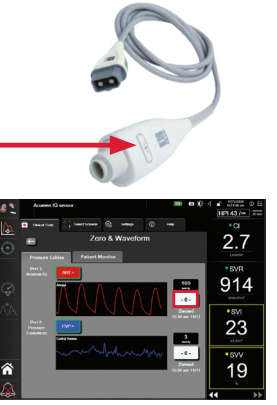
Zeroing

Open the sensor stopcock valve to measure atmospheric conditions.

1. Press and hold the physical zero button directly on the pressure cable.
2. When zeroing is complete, a tone sounds, and the message “Zeroed” appears with the time and date.

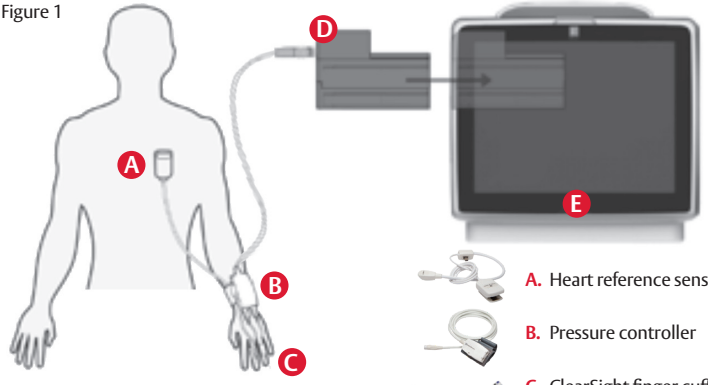
   Or

Touch the zero button located on the screen.



ClearSight System
Setup guide

Figure 1



A. Heart reference sensor

B. Pressure controller

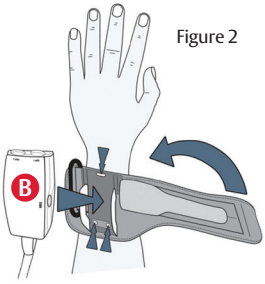
C. ClearSight finger cuff(s)

D. HemoSphere ClearSight module

E. HemoSphere advanced monitor

- Step 1: Verify that you have all equipment as noted in Figure 1, then turn on HemoSphere advanced monitor
- Step 2: Select the "new patient" button and enter patient data, and then select the "non-invasive" button on the "monitoring mode selection" window
- Step 3: Connect the pressure controller B to the HemoSphere ClearSight module D followed by wrapping the pressure controller band around the patient's wrist (either wrist can be used), attaching the pressure controller to the band (Figure 2)

Figure 2

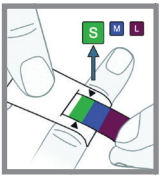


Edwards

ClearSight Module

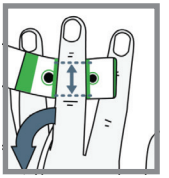
- Step 4: Select the proper size finger cuff by using the ClearSight finger sizing aid; best results are obtained from the middle, ring, or index finger (Figure 3)

Figure 3



- Step 5: Open the finger cuff and place the finger between the lines, with the finger cuff centered between the knuckles (Figure 4)

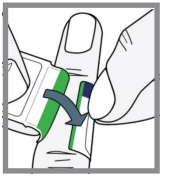
Figure 4



- Step 6: Gently lead the cuff cable between the two fingers (Figure 4)

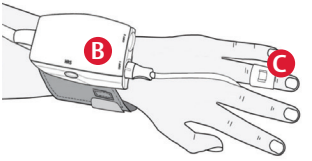
- Step 7: Tightly wrap the cuff around the finger; do not rotate the cuff after application (Figure 5)

Figure 5



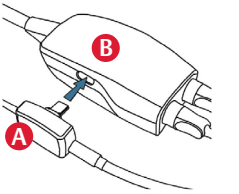
- Step 8: Connect finger cuff C to pressure controller B (Figure 6)

Figure 6



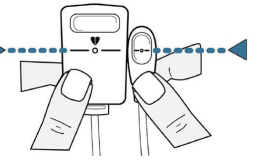
- Step 9: Connect heart reference sensor (HRS) A to pressure controller B (Figure 7)

Figure 7



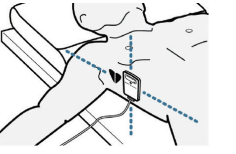
- Step 10: Vertically align the line on both ends of the HRS and touch the on-screen “zero” button and wait for on screen indication that the HRS has been zeroed (Figure 8)

Figure 8



- Step 11: Apply the heart end of the HRS to the patient at the phlebostatic axis level by using an HRS clip (Figure 9) and attach the other end of the HRS to the finger cuff (Figure 10)

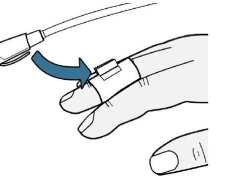
Figure 9



- Step 12: Touch the start monitoring icon 

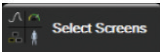
on the navigation bar to begin monitoring

Figure 10



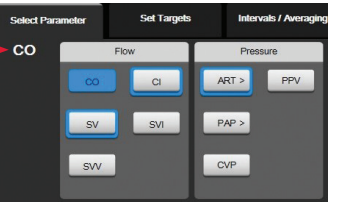
- Step 13: Touch the home icon  to return to the main monitoring screen

HemoSphere advanced monitoring platform:
System navigation

- Step 1: Touch the settings icon  and choose "Select Screens" tab 

to select the desired monitoring screen view

- Step 2: Parameter tiles are located on the right side of the monitoring screen. To change the parameter, touch the displayed parameter label. The tile configuration menu will show the selected parameter highlighted in color. Available parameters appear on the screen without highlights; touch any parameter to select the replacement parameter



- Step 3: To adjust alarms/targets, touch the settings icon  advanced setup -> parameter settings -> alarms and targets *(this step will require the advanced setup password)*

- Step 4: If desired, HemoSphere advanced monitor outputs can be connected to a bedside monitor and a second pressure cable can be added *(see General Troubleshooting setup guide)*

ForeSight Elite Tissue Oximetry System
Setup guide

HemoSphere advanced monitor setup

1. Slide the HemoSphere tissue oximetry module into the monitor.
2. Connect the ForeSight Elite tissue oximetry module cable into the HemoSphere tissue oximetry module (Figure 1). ***Note: ForeSight Elite module LED illuminates green when connected to port A, and blue when connected to port B.***
3. Select **Continue Same Patient** or **New Patient**, enter patient data. Select corresponding patient mode. ***Note: Tissue oximetry works with invasive, minimally-invasive, and noninvasive modes.***
4. Touch the displayed parameter label located inside of any parameter tile to select StO_2 <Ch> as a key parameter.

Figure 1

ForeSight Elite sensor setup

Note: Refer to the HemoSphere Operator's Manual, Table 13-2, for sensor selection guidelines based on patient monitoring mode, patient weight, and body location.

1. Open ForeSight Elite sensor packaging and inspect for damage (Figure 2).
2. Clean patient's skin and ensure area is dry prior to sensor application.
3. Remove protective liner and apply sensors.
4. Connect sensors to ForeSight Elite tissue oximetry module cable. Ensure each sensor is connected with a tactile click (Figure 3).

Figure 2

Figure 3

Edwards

Sensor location setup

1. If StO_2 is not a current key parameter, touch the displayed parameter label located inside of any parameter tile to select StO_2 <Ch> as a key parameter from the Select Parameter tab of the tile configuration menu, where <Ch> is the sensor channel. The channel options are A1 and A2 for ForeSight Elite module A and B1 and B2 for ForeSight Elite module B.
2. The channel will appear in the upper left corner of the parameter tile. Touch the patient figure (Figure 4a) to access Sensor Location tab.
3. Select the patient monitoring mode: adult or pediatric
4. Select the anatomical location of the sensor (Figure 4b)
5. Touch the home icon to return to the monitoring window.

Figure 4a

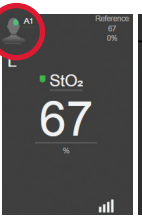


Figure 4b

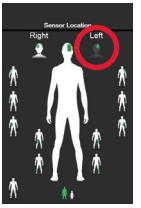
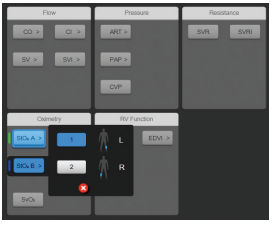


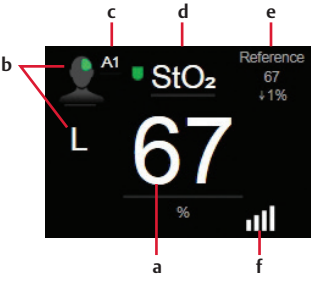
Figure 5



Parameter tile area (Figure 6)

1. **StO$_2$** reading displays current StO$_2$% level (a).
2. **Sensor Location** displays location and side of body sensor is placed (b).
3. **Channel Location** displays which channel each sensor is connected (c).
4. **Parameter** displays which parameter is being monitored (d).
5. **Reference Value** displays the reference value from timepoint which menu selection is made (e).
6. **Signal Quality Indicator** displays the quality of the signal (f).

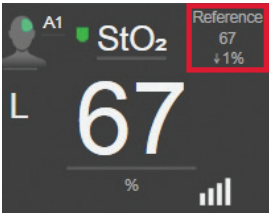
Figure 6



Display reference value

1. Select parameter tile, then select **Intervals/Averaging** tab (Figure 7).
2. Select **Change Interval** tab and select **Reference.**
3. Select **% Changed** or **Value Difference** in **Change Display** button.

Figure 7



Skin check assessment

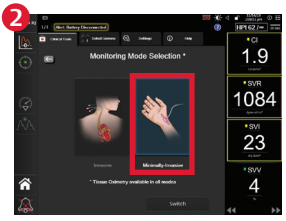
1. Select parameter tile, then select **Sensor Location** tab.
2. Select **Skin Check Reminder** button to choose a time interval between skin check notifications.
3. When performing skin check assessment lift the sensor to assess the skin integrity under the sensor.

Acumen IQ Sensor
Setup guide

1. Turn on the monitor and connect the HemoSphere pressure cable to the HemoSphere monitoring platform.

2. Select **minimally-invasive** technology then select **Start Monitoring**.

3. Open the Acumen IQ sensor packaging and inspect contents. Mount the Acumen IQ sensor on an IV pole using the appropriate holder.



4. To remove air from the IV flush bag, first invert the IV bag. Spike the bag and keep drip chamber upright. Ensure all air has been removed. Insert IV bag into the pressure bag and hang on the IV pole (do not inflate).

5. To prime the Acumen IQ sensor: With gravity only (with no pressure in pressure bag), flush the Acumen IQ sensor by pulling the Snap-Tab device, while holding pressure tubing in an upright position until the column of fluid reaches the end of the tubing.

6. Replace all caps with non-vented caps and ensure that all connections are tight.

Acumen IQ sensor

Edwards

7. Pressurize the IV bag until it reaches 300 mmHg, then fast-flush the sensor per hospital policy and tap on tubing and stopcocks to remove any residual bubbles.

8. Plug green connector from the Acumen IQ sensor to the HemoSphere pressure cable.

9. Plug red connector from the Acumen IQ sensor to the bedside cable.

10. Connect tubing to the arterial catheter.

11. Level the Acumen IQ sensor to the phlebostatic axis. **Note: It is important to keep the Acumen IQ sensor level to the phlebostatic axis at all times to ensure accuracy of cardiac output.**

12. Open the sensor stopcock valve to measure atmospheric conditions.
    1. Press and hold the physical zero button directly on the pressure cable.
    2. When zeroing is complete, a tone sounds, and the message "Zeroed" appears with the time and date.

    Or

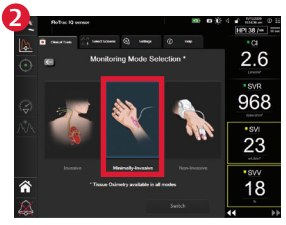
    Touch the zero button located on the screen.

For instructions on configuring a second pressure cable for use with a TruWave pressure transducer, refer to section "Dual HemoSphere pressure cables."

FloTrac Sensor
Setup guide

1. Turn on the monitor and connect the HemoSphere pressure cable to the HemoSphere monitoring platform.

2. Select **minimally-invasive** technology then select **Start Monitoring**.



3. Open the FloTrac sensor packaging and inspect contents. Mount the FloTrac sensor on an IV pole using the appropriate holder.

4. To remove air from the IV flush bag, first invert the IV bag. Spike the bag and keep drip chamber upright. Ensure all air has been removed. Insert IV bag into the pressure bag and hang on the IV pole (do not inflate).

5. To prime the FloTrac sensor: With gravity only (with no pressure in pressure bag), flush the FloTrac sensor by pulling the Snap-Tab device, while holding pressure tubing in an upright position until the column of fluid reaches the end of the tubing.

6. Replace all caps with non-vented caps and ensure that all connections are tight.

Edwards

FloTrac sensor

7. Pressurize the IV bag until it reaches 300 mmHg, then fast-flush the sensor per hospital policy and tap on tubing and stopcocks to remove any residual bubbles.

8. Plug green connector from the FloTrac sensor to the HemoSphere pressure cable.

9. Plug red connector from the FloTrac sensor to the bedside cable.

10. Connect tubing to the arterial catheter.

11. Level the FloTrac sensor to the phlebostatic axis. **Note: It is important to keep the FloTrac sensor level to the phlebostatic axis at all times to ensure accuracy of cardiac output.**

12. Open the sensor stopcock valve to measure atmospheric conditions.
    1. Press and hold the physical zero button directly on the pressure cable.
    2. When zeroing is complete, a tone sounds, and the message “Zeroed” appears with the time and date.

    Or

    Touch the zero button located on the screen.

For instructions on configuring a second pressure cable for use with a TruWave pressure transducer, refer to section “Dual HemoSphere pressure cables.”

Connecting a second HemoSphere pressure cable for use with a TruWave pressure transducer

When a ClearSight finger cuff, Acumen IQ sensor, or FloTrac sensor is paired with a central venous pressure (CVP) measured by a TruWave pressure transducer, systemic vascular resistance (SVR) and systemic vascular resistance index (SVRI) are also available. The FastCCO algorithm, second flow parameters are also available in when monitoring with the HemoSphere Swan-Ganz module and a PA (pulmonary artery) pressure signal.

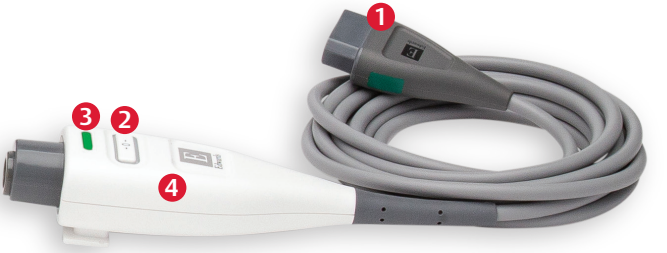
HemoSphere pressure cable

1. Pressure transducer/sensor connection
2. Zero button/status LED
3. Color insert for pressure type
4. HemoSphere advanced monitor pressure cable connection

1. Steps to add in a pressure cable

- Step 1: Connect monitor connection end of the pressure cable 1 to the HemoSphere advanced monitor platform
- Step 2: Connect a primed TruWave pressure transducer to the second HemoSphere pressure cable, once connected the LED that surrounds the zero button 2 on the pressure cable will flash green indicating that the pressure sensor is detected 3
- Step 3: Touch the zero and waveform icon located on the navigation bar

Edwards



- Step 4: Select the pressure type button for the connected pressure cable port (1 or 2) to select the type/location of pressure sensor being used; the waveform color will match the pressure type selected; the choices for the pressure transducer are: central venous pressure (CVP) or pulmonary artery pressure (PAP)

- Step 5: Level the stopcock valve (vent port) just above the TruWave transducer to the patient's phlebostatic axis position and open the stopcock valve to measure atmospheric conditions; the pressure should display as flatline

- Step 6: Press the physical zero button 4 directly on the pressure cable and hold for three seconds or touch the zero button located on the HemoSphere monitor screen; when zeroing is complete, a tone sounds, and the message "zeroed" appears with the time and date; the zero button 4 will stop blinking and turn off once zeroing is completed successfully

- Step 7: Touch the home icon to begin monitoring

Swan-Ganz Module
Setup guide

1. Ensure the HemoSphere Swan-Ganz module is inserted into the monitor. The module will click when properly engaged.

2. Connect the patient CCO cable to the HemoSphere Swan-Ganz module.

3. Attach the thermistor and thermal filament catheter connections to the patient CCO cable by aligning arrows.

4. Touch the **Start** monitoring icon.

   A countdown timer will appear indicating CO data is being collected.

   After approximately 5 to 12 minutes, when sufficient data has been obtained, a CO value will appear.

   For longer time spans between calculations, select STAT CO (sCO) as a key parameter. Estimate of the CO value updated every 60 seconds.

   For instructions on the FastCCO algorithm, 20-second flow parameters (CO20s/CI20s and SV20s/SVI20s), refer to section Swan-Ganz with FastCCO algorithm. Please contact your local Edwards representative for more information on enabling this advanced feature.

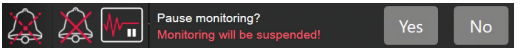
Edwards

Venous Oximetry (SvO_2 / $ScvO_2$) connection overview

Note: Swan-Ganz catheter should not be primed prior to in vitro calibration.

1. Connect the HemoSphere oximetry cable to the HemoSphere advanced monitor.
2. Connect the HemoSphere oximetry cable to the oximetry port of the Swan-Ganz catheter.
3. Select **Settings** on navigation bar.
4. Select **Venous Oximetry Calibration**.
5. Select **In Vitro Calibration** or **In Vivo Calibration** as desired and follow prompts.

Monitoring pause



1. Touch the silence audible alarms icon continuously for five seconds to show additional alarm silencing options.
2. Touch this icon to pause monitoring. A monitoring pause confirmation banner will appear to confirm suspension of monitoring operations. Exception: Tissue oximetry monitoring and associated alarms will remain active during a monitoring pause.
3. After monitoring pause confirmation, a resume monitoring icon and elapsed time will appear on the navigation bar. A "Monitoring Pause" banner will be displayed. To return to monitoring, touch the resume monitoring icon. 

EDV/RVEF monitoring

Right ventricular end diastolic volume (EDV) monitoring is available in conjunction with CO monitoring mode when using a Swan-Ganz CCOmbo V catheter and ECG signal input.

1. Ensure patient CCO cable is connected to Swan-Ganz catheter.
2. Connect the ECG interface cable's 1/4 inch miniature phone plug to the ECG monitor input on the rear panel of the HemoSphere advanced monitor.
3. Change parameter tiles to reflect EDV/RVEF parameters as desired.

Swan-Ganz with FastCCO Algorithm
Setup guide

The 20-second flow parameters are available when monitoring with the HemoSphere Swan-Ganz module and a PA (pulmonary artery) pressure signal is also monitored through a connected CCO cable, HemoSphere pressure cable, TruWave DPT, and CCOmbo V catheter (models 777F8 and 774F75).

1. Attach the thermistor and thermal filament Swan-Ganz CCO catheter connections to the patient CCO cable.

2. Connect the HemoSphere “smart” pressure cable to HemoSphere advanced monitor port 1 or 2.

3. Connect the HemoSphere smart pressure cable to the Truwave disposable pressure transducer (DPT) connected to the PA port on the Swan-Ganz catheter to provide pulmonary artery pressure (PAP).

4. Plug the HemoSphere pressure-out cable into the rear panel of the monitor at the pressure out port

FastCCO™

Edwards

5. Connect the Edwards PX1800 pressure cable for PAP monitoring into the compatible patient monitor. Connect the opposite end to the yellow pressure out cable on the HemoSphere advanced monitor.

6. Go to the Zero & Waveform screen and follow steps to zero the PA pressure. Transmit PAP signal to the bedside monitor by following the steps at the bottom of the Zero & Waveform screen.

7. When the system is properly connected, touch the start monitoring icon to begin CO monitoring.

8. The 20 second parameters will display and continue to update every 20 seconds once the CO countdown timer has finished and sufficient time averaging data is obtained.

Fluid Responsiveness Test
Setup guide

1. Touch the Settings icon, Clinical Tools tab, then touch Fluid Responsiveness Test.
2. On the New Test tab, touch the desired test type: Passive Leg Raise or Fluid Bolus.

Passive Leg Raise

1. Touch and highlight Passive Leg Raise under the New Test tab.
2. Select the Parameter to be analyzed:
   a. SV, SVI, CO, or CI (Minimally-Invasive and Noninvasive monitoring modes)
   b. $SV_2$0s, $SVI_2$0s, $CO_2$0s, or $CI_2$0s (Invasive monitoring mode with PAP signal)

3. Select the Challenge Duration: 1 minute, 1 minute 30 sec, or 2 minutes (Minimally-Invasive and Noninvasive monitoring modes) or 3 minutes (Invasive monitoring mode).
4. Place the patient in a semi-recumbent position. Touch the Start Baseline button to begin the baseline measurement.
5. The baseline value will appear below the trend graph. (To remeasure the baseline value, touch RESTART.)
6. To continue to the Passive Leg Raise Measurement, place the patient in supine position and touch the START button, Passively raise the patient's legs to a 45 degree angle within five seconds. A five second countdown clock will appear to indicate time remaining until the start of the challenge measurement.
7. A new countdown timer will appear starting at the selected Challenge Duration time. Ensure that the patient remains still during the measurement period.
8. The change in the selected Parameter value as a response to the fluid challenge will be displayed.

Edwards

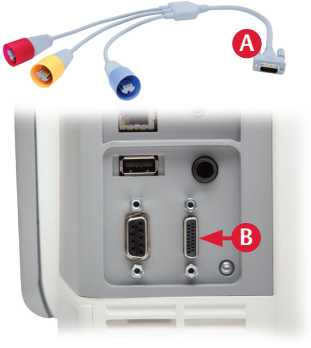
Fluid Bolus

1. Touch and highlight Fluid Bolus under the New Test tab. The New Test tab displays test configuration menu options.
2. Select the Parameter to be analyzed:
   a. SV, SVI, CO, or CI (Minimally-Invasive and Noninvasive monitoring modes)
   b. SV_20s, SVI_20s, CO_20s, or CI_20s (Invasive monitoring mode with PAP signal)
3. Select the Challenge Duration: 5 minutes, 10 minutes, or 15 minutes.
4. Touch the Start Baseline button to begin the baseline measurement.
5. The baseline value will appear below the trend graph. (To remeasure the baseline value, touch RESTART.)
6. To continue to the Fluid Bolus Measurement, administer the fluid bolus and touch START when the bolus begins.
7. A new countdown timer will appear starting at the selected Challenge Duration time. Ensure that the patient remains still during the measurement period.
8. The change in the selected Parameter value as a response to the fluid challenge will be displayed.

Output signal to a bedside patient monitor
The Zero & Waveform screen provides the user with the option to send the waveform signal(s) to a patient monitor.

- Step 1: Touch the Zero & Waveform icon located on the navigation bar

- Step 2: Plug the HemoSphere advanced monitor pressure out cable A into the rear panel of the monitor at the pressure out port B



- Step 3: Connect the pressure signal plug(s) into a compatible patient monitor
- Step 4: Touch the patient monitor tab on the zero and waveform screen and zero patient monitor and confirm 0 mmHg is displayed on the patient monitor

Step 4

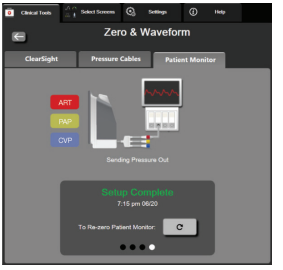
Edwards

- Step 5: Touch the transmit waveform icon  to begin pressure signal output to the patient monitor

Step 5

- Step 6: A “setup complete” message will be displayed when the live waveform is being transmitted to the connected patient monitor

Step 6



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).

Edwards devices placed on the European market meeting the essential requirements referred to in Article 3 of the Medical Device Directive 93/42/EEC bear the CE marking of conformity.

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