How does this technology work?
The FloTrac system, consisting of the Edwards Vigileo monitor and the FloTrac sensor, uses a clinically validated algorithm to provide continuous cardiac output (CCO), stroke volume (SV) and stroke volume variation (SVV) in real-time. The FloTrac algorithm utilizes arterial pressure, age, gender, and body surface area to calculate SV. The patient-specific SV is then multiplied by pulse rate to provide CCO. Patient-specific SV is updated as fast as every 20 seconds.

How can I rely on the data from this system with no manual calibration?
One of the variables in the FloTrac algorithm accounts for changes in compliance and resistance (vascular tone). The conversion factor Khi is a multivariate polynomial equation which incorporates factors such as the standard deviation of mean arterial pressure, skewness and kurtosis of the arterial waveform, and large vessel compliance as estimated by patient demographics to assess peripheral vascular tone. Khi’s robust and dynamic nature makes manual calibration unnecessary. Validation studies confirm the accuracy of the FloTrac system against both bedside thermodilution cardiac output (CO) and continuous thermodilution CO.¹² These studies were performed against a range of patient demographics, pathologies and CO values.

How does the FloTrac sensor compare to bolus cardiac output?
The FloTrac algorithm correlates well with intermittent bolus cardiac output (ICO), showing a similar bias and precision as the Edwards Swan-Ganz CCO catheters do to ICO.²

What is required to obtain accurate readings?
The FloTrac system is dependent upon good intra-arterial pressure monitoring practices. Accuracy and fidelity of the arterial pressure tracing are important.

- Compromised waveforms due to dampened lines, kinked catheters, non-leveled transducers, etc. may also compromise CO values.

- The FloTrac algorithm is sensitive to signal quality and frequency response. Thus, the FloTrac sensor must be used with the Vigileo monitor. Modification of the sensor kit configuration (i.e., changing or adding tubing) is not advised and may compromise performance.

- Accuracy of input parameters (age gender, height, weight) is important to the FloTrac algorithm - incorrect values may affect CO values.
What are the limitations of the FloTrac sensor?
- The system has not been validated in artificial hearts and ventricular assist devices (VAD).
- Inaccurate CO measurements can be caused by intra-aortic balloon pumps (IABP).
- Severe, persistent arrhythmias may affect accuracy.
- Severe, persistent peripheral vasoconstriction or arterial spasm, such as in shock states, may dampen the arterial waveform resulting in erroneously low CO values. Central arterial access (e.g., femoral access) is recommended in such conditions.
- The FloTrac sensor is currently not validated or labeled for use in pediatric patients.

What is stroke volume variation (SVV)?
Stroke volume variation is a naturally occurring phenomenon in which the arterial pulse pressure falls during inspiration and rises during expiration due to changes in intra-thoracic pressure secondary to negative pressure ventilation (spontaneously breathing). Variations over 10mmHg have been referred to as pulsus paradoxus. Reverse pulsus paradoxus is the same phenomenon with controlled mechanical ventilation, however, in reverse. Arterial pressure rises during inspiration and falls during expiration due to changes in intra-thoracic pressure secondary to positive pressure ventilation. Normal SVV values are less than 10-15% on controlled mechanical ventilation.  

$$SVV = \frac{SV_{\text{max}} - SV_{\text{min}}}{SV_{\text{mean}}}$$

What does SVV tell me? Why is SVV important?
SVV is not an indicator of actual preload but of relative preload responsiveness. SVV has been shown to have a very high sensitivity and specificity when compared to traditional indicators of volume status (HR, MAP, CVP, PAD, PAOP), and their ability to determine fluid responsiveness. Volume is one of the first therapeutic interventions clinicians turn to when optimizing DO2. The question often difficult to answer is: “Can we use fluid to improve hemodynamics?” and one might add, “Is it the appropriate intervention?” SVV as displayed on the Vigileo monitor when used with the FloTrac sensor may help answer such questions.

What is normal SVV?
Normal SVV values are less than 10-15% on controlled mechanical ventilation. SVV below 10-15% indicates that the patient is not likely to increase CO through fluid infusion.

Will CO measurement be accurate when you see a change in vessel compliance or resistance?
Yes, the FloTrac sensor accounts for changes in compliance and resistance (vascular tone) and therefore does not require manual calibration to account for these changes. The FloTrac algorithm incorporates determination of larger vessel compliance via a Langewouters relationship, which is impacted by age, gender and body surface area. Peripheral vascular resistance changes are assessed by a robust waveform analysis in the algorithm.
Can I display data from the Vigileo monitor on a bedside monitor?

Yes, analogue and digital communication ports are featured, similar to those of the Edwards Vigilance monitor and the Edwards Vigilance II monitor and can be interfaced with various bedside monitoring systems (Example: GE, Nihon Kohden, Philips Spacelabs). The Vigileo monitor also provides digital communications that can be directly interfaced with a data management system. Check with Edwards Lifesciences technical support or your bedside monitor provider for details.

Can I use a Philips VueLink module with the Vigileo monitor?

Yes, software for the VueLink module is validated in the Vigileo monitor. Not all parameters (e.g. SVV) may be displayed on the bedside monitor using the VueLink module.

Can I use my Vigilance monitor cables with my Vigileo monitor?

Edwards optical module cables are compatible with all Edwards oximetry technology monitors, including the Vigileo monitor. The continuous cardiac output cable (70CC2) for the Vigilance monitors are specific for Edwards’ advanced technology Swan-Ganz catheters and are not compatible with the Vigileo monitor or FloTrac sensor.

What about the link between the Vigileo monitor and central monitoring or data management systems?

Typical connection to central monitoring and data management systems is through the patient monitor. The Vigileo monitor can be connected in the same manner as the Vigilance monitor. The Vigileo monitor also provides digital communications that can be directly interfaced with a data management system. Check with your data management software provider for details.

Can the FloTrac sensor be used on radial or femoral arterial sites?

Yes, it is accurate at both of these sites without calibration as the algorithm automatically compensates for differential compliance and wave reflectance from one location to another.

How is this different from the pulse contour analysis or the pulse power technologies?

In short, both of these technologies require manual calibration to initiate and/or maintain monitoring because they correlate CO with the area under the pressure waveform while the FloTrac system does not.

Pulse contour correlates the area under a portion of the arterial waveform with CO. This method requires calibration to initiate monitoring and to detect the dicrotic notch for analysis. Pulse power analysis requires calibration by the introduction of an accurate CO value, typically a lithium based indicator, every 12 to 24 hours.

The FloTrac algorithm does not calculate the area under the pressure waveform. Instead, CO is correlated with the variance between systolic and diastolic pressure. Real-time analysis of waveform characteristics is also integrated, compensating for changes in vascular physiology affecting the pressure waveform.
Contraindications:
There are no absolute contraindications for using the FloTrac sensor in patients requiring invasive pressure monitoring.

Complications:

Sepsis/Infection -
Positive cultures can result from contamination of the pressure setup. Increased risks of septicemia and bacteremia have been associated with blood sampling, infusing fluids, and catheter related thrombosis.

Air Emboli -
Air can enter the patient through stopcocks that are inadvertently left open, from accidental disconnection of the pressure setup, or from flushing residual air bubbles into the patient.

Clotted Catheter and Bleed-Back -
If the flush system is not adequately pressurized relative to the patient’s blood pressure, blood bleed-back and catheter clotting may occur.

Overinfusion -
Excessive flow rates may result from pressures greater than 300 mmHg. This may result in a potentially harmful increase in blood pressure and fluid overdose.

Abnormal Pressure Readings -
Pressure readings can change quickly and dramatically because of loss of proper calibration, loose connection, or air in the system.

REFERENCES
1. Manecke, G: Poster SCCM 2005