The FloTrac System 4.0

Continuously Evolving to Meet Your Clinical Needs

The Latest Evolution of the FloTrac System Algorithm Provides Increased Reliability Under More Clinical Conditions

Offers more specific monitoring of a broader range of changing patient conditions

- This update to the FloTrac system algorithm uses expanded patient data to include more diverse clinical situations and high-risk surgical procedures, such as gastrointestinal, pancreaticoduodenectomy (whipple), kidney transplant, nephrectomy, hip replacement and esophagectomy

Provides reliable, continuous Stroke Volume Variation (SVV) in expanded situations

- Clinicians can now monitor and utilize SVV as a reliable indicator of preload responsiveness in most patients despite significant arrhythmias, even multiple premature atrial or ventricular contractions (PACs and PVCs)

I. Algorithm Overview

Trusted by more clinicians and used on over 1 million patients worldwide, the FloTrac system from Edwards Lifesciences connects to any existing arterial line to provide real-time measurement of advanced hemodynamic parameters:

- Continuous Cardiac Output (CCO)
- Stroke Volume (SV)
- Stroke Volume Variation (SVV)
- Systemic Vascular Resistance (SVR)

The reliable FloTrac system is operator independent and minimally invasive. It helps hemodynamically optimize moderate to high-risk surgical and critically ill patients, enabling the clinician to make a differential diagnosis leading to either a volume or cardiovascular intervention.

The FloTrac sensor updates key flow-based parameters such as Stroke Volume every 20 seconds, more accurately reflecting physical changes during use in high-risk surgery (HRS). Measurements are based on patient arterial pressure data and expanded patient demographics. The FloTrac system continuously monitors changes in vascular tone (compliance and resistance) and adjusts automatically, eliminating the need for manual calibration.

II. The FloTrac System Algorithm Development and Evolution

The continuously evolving FloTrac system algorithm is based on cardiovascular hemodynamic principles, advanced signal processing of the arterial pressure waveform, and comparative analysis with the clinical gold standard – thermodilution Cardiac Output. To recognize and adjust for more patient conditions, the next-generation version 4.0 algorithm is modeled and compared across a wide range of hemodynamic values, patient profiles, pathologies and hemodynamic conditions.

III. Arterial Pressure-Based Cardiac Output (APCO) and Stroke Volume

An important component of global oxygen delivery, Cardiac Output is the variable most often manipulated to improve oxygen delivery. Traditionally, Cardiac Output is calculated by multiplying heart rate by Stroke Volume (CO = HR x SV). The evolved FloTrac system algorithm uses similar components, but substitutes heart rate with Pulse Rate (PR), capturing only truly perfused beats. Pulse Rate is multiplied by a calculated Stroke Volume.

The FloTrac system algorithm analyzes the arterial pressure waveform at 100 times per second over 20 seconds, capturing 2,000 data points for analysis. Together with expanded patient demographic information, these data points are used to calculate the standard deviation of the arterial pressure, which is multiplied by a conversion factor that incorporates the effects of resistance and compliance. The system adjusts automatically and independently for up-to-the-minute access to valuable hemodynamic information under more patient conditions.

The FloTrac System Cardiac Output

Formula for Cardiac Output = Heart Rate x Stroke Volume

The FloTrac System Cardiac Output = Pulse Rate x [std(BP)*x]

Pulse Rate (PR)
- Measured as beats per minute
- Beats identified by upslope of waveforms
- Advanced beat detection differentiates fully perfused beats
- Computed from 20-second time period of beats

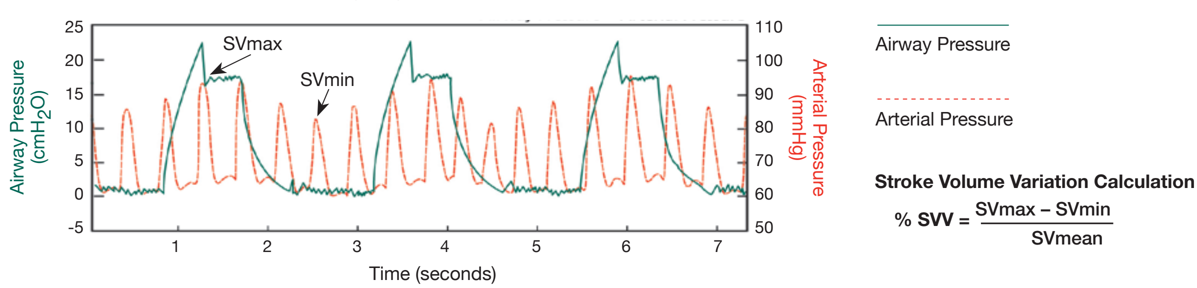
Standard deviation of arterial Blood Pressure [std(BP)]
- Pulse pressure ∞ SV ∞ std(BP)
- Measured as mmHg
- Computed on a beat-by-beat basis

The x factor compensates for differences in vascular compliance and resistance
- Patient-to-patient differences estimated from biometric data
- Dynamic changes estimated by waveform analysis (skewness, kurtosis of the waveform)
- Measured as mL per beat/mmHg
- 20 second average updates

IV. Sensitive, Specific Stroke Volume Variation Guides Volume Administration

Traditional hemodynamic monitoring parameters (HR, MAP, CVP and PAOP) are often insensitive and sometimes misleading in the assessment of circulating blood volume. Stroke Volume Variation has been shown to have a high sensitivity and specificity compared with conventional indicators of volume status and their ability to determine fluid responsiveness.[1-3] Optimization of intravascular volume based on real-time changes in Stroke Volume Variation may be an appropriate strategy for patients in whom tighter control of fluid replacement is beneficial.[8,18]

Figure 1: Stroke Volume Variation and Fluid Optimization
On Control Ventilated Patients[4]



Several requirements with Stroke Volume Variation[4]

Although it is a powerful tool in managing volume administration, Stroke Volume Variation has several limitations, including:

- **100% Mechanical ventilation –** Currently, literature supports the use of Stroke Volume Variation only on patients who are 100% mechanically (control mode) ventilated with tidal volumes of more than 8 cc/kg and fixed respiratory rates (see Figure 1).
- **Spontaneous breathing –** Due to the irregular nature of rate and tidal volumes, the literature does not support the use of Stroke Volume Variation with patients who are spontaneously breathing.
- **Severe arrhythmias –** Atrial fibrillation can dramatically affect Stroke Volume Variation values due to the severe irregular rhythm. For this reason, the use of Stroke Volume Variation as a guide for volume resuscitation is not recommended in patients with atrial fibrillation.

Note: Limitations associated with SVV are not limitations of the FloTrac system in calculating CO or SV.

V. The FloTrac System 4.0

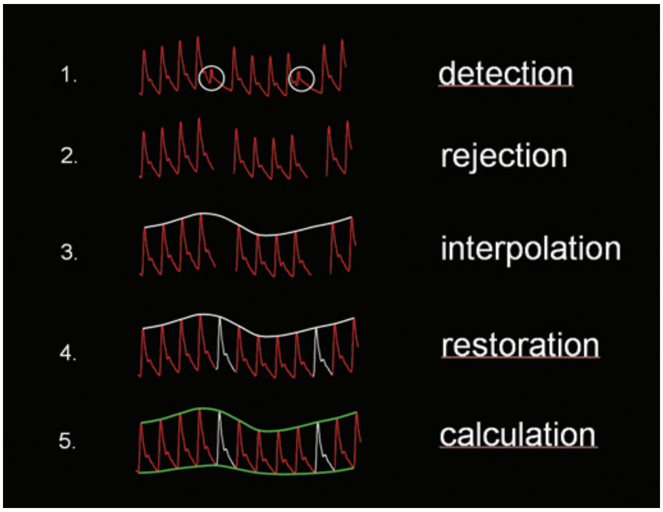
Expanded monitoring of broader range of patient conditions

This latest evolution (version 4.0) of the FloTrac system algorithm expands the patient database to include a more diverse surgical patient population. Specifically, more of the following high-risk surgical patients were added (but not limited to) gastrointestinal, pancreaticoduodenectomy (whipple), kidney transplant, nephrectomy, hip replacement and esophagectomy. As a result, the upgraded algorithm now recognizes and adjusts to more patient conditions, allowing the FloTrac system to provide valuable insights to clinicians for making critical decisions earlier and more effectively than for patients monitored with vital signs alone.

Delivers continuous SVV even in patients with PACs and PVCs

Through continuous beat detection and analysis, the updated algorithm allows for the ongoing use of Stroke Volume Variation as a reliable indicator of preload responsiveness. The FloTrac system algorithm enables the display and use of SVV in patients with multiple premature atrial or ventricular contractions and allows the clinician to guide volume resuscitation despite most arrhythmias (see Figure 2). At least eight clinical studies published in leading medical journals have validated the SVV FloTrac system algorithm as an accurate predictor of preload responsiveness.[2,6-14] And, Benes and Cecconi have demonstrated that a perioperative goal-directed therapy strategy based on optimization of Stroke Volume Variation and cardiac output can improve patient outcomes.[15,16]

Figure 2: Estimation of Stroke Volume Variation by the SVVxtra algorithm is based on detection of abnormal beats, rejection of abnormal beats, interpolation of remaining beats, restoration of missing beats, and calculation of Stroke Volume Variation[17]



Greater Insight for Making Clinical Decisions

Key hemodynamic parameters provided by the FloTrac system deliver greater clarity, to ensure the appropriateness of interventions and avoid the harmful effects of excessive, insufficient, and inappropriate volume administration.[18,19] Providing volume administration in the optimal range is important because both hypo- and hypervolemia may deleteriously affect organ function.[18]

Hemodynamic optimization through the use of advanced hemodynamic parameters within protocols such as Perioperative Goal-Directed Therapy (PGDT) can ensure the patient is maintained in the optimal range.[18] The updated algorithm provides a more reliable solution for use in PGDT protocols in more diverse surgical procedures and patient types.

Trusted globally by more clinicians than any other fluid management solution

Edwards has transformed the complexity and invasiveness traditionally associated with continuous hemodynamic monitoring into the practicality of utilizing an arterial catheter. The FloTrac system provides clinicians the option to monitor Cardiac Output, Stroke Volume Variation, Stroke Volume and other advanced hemodynamic parameters on any patient who requires an arterial line.

This latest evolution of the FloTrac system algorithm is an example of the never-ending Edwards commitment to continuously engage with clinicians to understand and meet expanding clinical needs.

References:

1. Berkenstadt H, Margalit N, Hadani M, et al. Stroke volume variation as a predictor of fluid responsiveness in patients undergoing brain surgery. *AnesthAnalg.* 2001;92:984–989.
2. Michard F. Changes in arterial pressure during mechanical ventilation. *Anesthesiology.* 2005;103:419-428.
3. Reuter D, Kirchner A, Felbinger T, et al. Usefulness of left ventricular stroke volume variation to assess fluid responsiveness in patients with reduced cardiac function. *Crit Care Med.* 2003;31:1300–1404.
4. McGee, W., A Simple Physiologic Algorithm for Managing Hemodynamics Using Stroke Volume and Stroke Volume Variation: Physiologic Optimization Program. *J Intensive Care Med.* 2009; 24; 352 originally published online Sep 6, 2009.
5. Maas J, Pinsky M, de Wilde R, Jonge E. Cardiac Output Response to Norepinephrine in Postpoperative Cardiac Surgery Patients: Interpretation with Venous Return and Cardiac Function Curves. *Critical Care Medicine,* Jan 2013, Volume 41, Number 1.
6. Biais M, Bernard O, Ha J, Degryse C, Sztark F. Abilities of pulse pressure variations and stroke volume variations to predict fluid responsiveness in prone position during scoliosis surgery. *Br J Anaesth.* 2010;104:407–413.
7. Biais M, Nouette-Gaulain K, Cottenceau V, Revel P, Sztark F. Uncalibrated pulse contour-derived stroke volume variation predicts fluid responsiveness in mechanically ventilated patients undergoing liver transplantation. *Br J Anaesth.* 2008;101:761-768.
8. Biais M, Nouette-Gaulain K, Quinart A, Roullet S, Revel P, Sztark F. Uncalibrated stroke volume variations are able to predict the hemodynamic effects of positive and end-expiratory pressure in patients with acute lung injury or acute respiratory distress syndrome after liver transplantation. *Anesthesiology.* 2009;111:855-862.
9. Cannesson M, Musard H, Desebbe O, et al. The ability of stroke volume variations obtained with Vigileo/FloTrac system to monitor fluid responsiveness in mechanically ventilated patients. *Anesth Analg.* 2009;108:513-517.
10. Derichard A, Robin E, Tavernier B, et al. Automated pulse pressure and stroke volume variations from radial artery: evaluation during major abdominal surgery. *Br J Anaesth.* 2009;103:678-684.
11. Hofer C, Senn A, Weibel L, Zollinger A. Assessment of stroke volume variation for prediction of fluid responsiveness using the modified FloTrac and PiCCOplus system. *Crit Care.* 2008;12.
12. Kungys G, Rose D, Fleming N. Stroke volume variation during acute normovolemic hemodilution. *Anesth Analg.* 2009;109:1823–1830.
13. Monge Garcia M, Gil Cano A, Diaz Monrove J. Brachial artery peak velocity variation to predict fluid responsiveness in mechanically ventilated patients. *Crit Care.* 2009;13:R142.
14. Zimmermann M, Feibicke T, Keyl C, et al. Accuracy of stroke volume variation compared with pleth variability index to predict fluid responsiveness in mechanically ventilated patients undergoing major surgery. *Eur J Anaesthesiology.* 2010;27:555–561.
15. Benes J, Chytra I, Altmann P, et al. Intraoperative fluid optimization using stroke volume variation in high risk surgical patients: results of prospective randomized study. *Crit Care.* 2010;14:R118.
16. Cecconi M, Fasano N, Langiano N, et al. Goal directed haemodynamic therapy during elective total hip arthrosplasty under regional anaesthesia. *Crit Care.* 2011;15:R132.
17. Patent WO 2011/094487 A2, Elimination of the Effects of Irregular Cardiac Cycles in the Determination of Cardiovascular Parameters
18. Bellamy MC. Wet, dry or something else? *Br J Anaesth.* 2006;97(6):755-757.
19. Cannesson M. Arterial pressure variation and goal-directed fluid therapy. *J Cardiothorac Vasc Anesth.* 2010;24(3):487-497.

For professional use. CAUTION: Federal (United States) law restricts this device to sale by or on the order of a physician. See instructions for use for full prescribing information, including indications, contraindications, warnings, precautions and adverse events.

Edwards Lifesciences 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.

Edwards Lifesciences | edwards.com
One Edwards Way | Irvine, California 92614 USA
Switzerland | Japan | China | Brazil | Australia | India

Edwards