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.

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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

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 hypovolemic and hypervolemic states 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:
17. Patent WO 2011/094487 A2, Elimination of the Effects of Irregular Cardiac Cycles in the Determination of Cardiovascular Parameters

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