SUMMARY
Edwards Lifesciences has led the field of cardiac output measurement with the Edwards Swan-Ganz thermodilution cardiac output catheter. Edwards has now developed the FloTrac algorithm, an arterial pressure-based cardiac output (APCO) method in which cardiac output can be continuously measured real time using an arterial catheter. This new technology is based on the basic principles of physics and the application of a sophisticated algorithm.

PHYSICS AND PHYSIOLOGY
Flow is determined by a pressure gradient along a vessel and the resistance to that flow \( F = \Delta P/R \). The FloTrac algorithm uses a similar principle to measure pulsatile flow by incorporating the effects of both vascular resistance and compliance through a conversion factor known as Khi \( (\chi) \).

Cardiac output is an important component of global oxygen delivery \( (DO_2) \) and is the most often manipulated variable when improving oxygen delivery. Cardiac output is calculated by multiplying heart rate by the stroke volume. The FloTrac algorithm uses these same components but substitutes heart rate with the pulse rate \( (PR) \), capturing only truly perfused beats, and multiplies PR by a calculated stroke volume. Stroke volume is calculated from the patient’s arterial pressure using a specially designed system, the FloTrac sensor and the Edwards Vigileo monitor, to analyze the arterial pressure waveform using the unique FloTrac algorithm. The FloTrac algorithm analyzes the pressure waveform at one hundred times per second over 20 seconds, capturing 2,000 data points for analysis. These data points are used along with patient demographic information to calculate the standard deviation of the arterial pressure \( (\sigma_{AP}) \). This \( (\sigma_{AP}) \) is proportional to pulse pressure \( (PP) \). The \( \sigma_{AP} \) is multiplied by a conversion factor known as Khi \( (\chi) \) which incorporates both the effects of resistance and compliance (vascular tone) and also converts \( \sigma_{AP} \) in \( (\text{mmHg}) \) into \( \text{ml/beat} \). Therefore, with the variables \( \sigma_{AP} \) and vascular tone \( (\chi) \) flow or stroke volume can be calculated.

**Traditional:** \( \text{CO} = \text{HR} \times \text{SV} \)

**FloTrac system:**
\[
\text{APCO} = \text{PR} \times (\sigma_{AP} \times \chi)
\]

Where \( \chi = M (\text{HR}, \sigma_{AP}, C(P), \text{BSA}, \text{MAP}, \mu_{3ap}, \mu_{4ap},...) \)

\( \sigma_{AP} = \) standard deviation of arterial pulse pressure in \( \text{mmHg} \) is proportional to pulse pressure.

\( \chi = \) scaling multivariate parameter proportional to the effects of vascular tone on pulse pressure.

\( M = \) multivariate polynomial equation.

\( \text{BSA} = \) body surface area calculated by Dubois’ equation for body surface area.

\( \text{MAP} = \) mean arterial pressure calculated by taking sum of sampled pressure point values over 20 seconds and dividing it by the number of pressure points.

\( \mu = \) statistical moments determined by skewness (symmetry) and kurtosis (distinctness of a peak) calculated along several mathematical derivatives.
**ARterial Pressure-based Cardiac Output**
The FloTrac algorithm is based on the principle that aortic pulse pressure is proportional to stroke volume (SV) and inversely related to aortic compliance.

**Standard Deviation of Arterial Pressure**
Initially, the FloTrac algorithm assesses pulse pressure by using the standard deviation of the arterial pressure ($\sigma_{AP}$) around the MAP value, measured in mmHg, making it independent of the effects of vascular tone. This standard deviation of the pulse pressure is proportional to the volume displaced or the stroke volume. This is calculated by analyzing the arterial pressure waveform over 20 seconds at 100 times per second, creating 2,000 data points from which $\sigma_{AP}$ is calculated.

**Khi and the Conversion of mmHg to ml/beat**
The conversion of standard deviation of arterial pressures (mmHg) into ml/beat is performed by multiplying it by a conversion factor known as Khi ($\chi$). Khi is a multivariate polynomial equation which assesses the impact of the patient’s ever-changing vascular tone on pulse pressure. Khi is calculated by analyzing the patient’s pulse rate, mean arterial pressure, standard deviation of mean arterial pressure, large-vessel compliance as estimated by patient demographics, and skewness and kurtosis of the arterial waveform. Khi is updated and applied to the FloTrac algorithm on a rolling 60-second average.

- **Pulse rate**: The patient’s pulse rate is calculated by counting the number of pulsations in a 20 second period and extrapolated to a per minute value.

- **Mean arterial pressure (MAP)**: An increase in average pressure often indicates an increase in resistance, and vice versa.

- **Standard deviation of arterial pressure ($\sigma_{AP}$)**: Pulse pressure is proportional to $\sigma_{AP}$ and to stroke volume. Increases and decreases in the standard deviation also provide information on pressure amplitude. When this pressure amplitude is correlated with kurtosis, it compensates for differential compliance and wave reflectance that vary from one arterial location to another. This then allows the monitoring of cardiac output from different arterial locations.

**Large vessel compliance**: Work reported by Langewouters found a direct correlation among age, gender, and MAP with respect to aortic compliance. An equation was derived from these studies by which a patient’s compliance could be estimated with the inputs of age and gender. According to Langewouters et al, the arterial compliance ($C$), as a function of pressure, could be estimated using the following equation:

$$C(p) = L \cdot \frac{A_{max}}{\pi \cdot P_1} \cdot \frac{1}{1 + \left(\frac{P - P_0}{P_1}\right)^2}$$

$L$ = estimated aortic length.

$A_{max} =$ aortic root cross sectional area maximum.

$P =$ arterial pressure.

$P_0 =$ pressure at which compliance reaches its maximum.

$P_1 =$ the width of compliance curve at half of maximum compliance. Additional measures of weight and height (BSA) were also found to correlate with vascular tone and were added to enhance the calculation of aortic compliance.

**Skewness (a measure for lack of symmetry, $\mu_3_{ap}$)**: Symmetry characteristics on arterial pressure can indicate a change in vascular tone and/or resistance. Two different functions may have the same mean and standard deviation but will rarely have the same skewness. For example, an arterial pressure waveform in which the data points increase quickly in systole and fall slowly can result as an increase in vasoconstriction and would have increased skewness.
Kurtosis (a measure of how peaked or flat the pressure data points are distributed from normal distribution, $\mu_{AP}$): Pressure data with high kurtosis has the pressure rise and fall very quickly relative to the normal pulse pressure and can be directly associated with large vessel compliance. 1) A high kurtosis value will indicate a distinct peak near the mean, with a drop thereafter, followed by a heavy “tail”. 2) A low kurtosis value will tend to indicate that the function is relatively flat in the region of its peak and suggests decreased central tone, as is often seen, for example, in the neonatal vasculature.

Taking all of these variables into consideration, the FloTrac algorithm continuously assesses the impact of vascular tone on pressure every 60 seconds. The result of the analysis is a conversion factor known as Khi ($\chi$). Khi is then multiplied by the standard deviation of the arterial pressure to calculate stroke volume in milliliters per beat. This stroke volume is multiplied by the pulse rate to obtain cardiac output in liters per minute.

Stroke Volume (ml/beat) = $\sigma_{AP}$ (mmHg)* $\chi$ (ml/mmHg)

DEVELOPED WITH THE CLINICAL GOLD STANDARD

The vascular tone factor (Khi) was developed based on cardiovascular hemodynamics principles, advanced signal processing of the arterial pressure waveform, and comparative analysis with the clinical gold standard thermodilution cardiac output.

Khi ($\chi$) was modeled and compared across a wide range of cardiac output values, patient profiles, pathologies, and hemodynamic conditions.

Since clinically available, the FloTrac system has been validated against various cardiac output technologies including thermodilution cardiac output.

NO MANUAL CALIBRATION NEEDED

Other arterial pressure cardiac output devices (pulse contour or pulse power) require calibration as they cannot auto correct for the patient’s changing vascular tone. Since the FloTrac algorithm continuously adjusts for the patient’s ever changing vascular tone, it does not require manual calibration. As a component of the calibration, Khi auto corrects for changes in vascular tone through a complex waveform analysis. This feature also eliminates the need for a central or peripheral venous line, required for indicator dilution methods used in manual calibration.

TECHNICAL CONSIDERATIONS

The FloTrac algorithm is dependent upon a high fidelity pressure tracing. Attention to best practice in pressure monitoring is important by; priming with gravity, pressure bag kept to 300mmHg, adequate I.V. bag flush volume, sensor stopcock is kept level to phlebostatic axis, and periodic testing of optimal dampening with a square wave test. FloTrac sensor kits are especially configured to optimize frequency response therefore adding additional pressure tubing or stopcocks is highly discouraged.

LIMITATIONS

As of this publication, the FloTrac sensor is only indicated for adult use and has not been validated in patients with ventricular assist devices or intra aortic balloon pumps. Absolute values during aortic regurgitation may be affected although trending may be appropriate. Severe peripheral constriction during shock states or hypothermic episodes may influence values with radial arterial locations, consideration to femoral sites during these episodes or insertion of a pulmonary artery catheter may be considered.

CONCLUSION

Edwards has converted the complexity and invasiveness traditionally associated with continuous cardiac output monitoring into the simplicity of utilizing only an arterial catheter. The ease of use of the FloTrac system allows for earlier implementation of flow monitoring in critically ill patients. Clinicians now have the option to monitor cardiac output on any patient who currently requires an arterial line.
For further information on the FloTrac sensor and the Vigileo monitor, please visit www.Edwards.com/FloTrac

REFERENCES


Prepared by:
John Frazier, RN, RRT
Clinical Marketing
Edwards Lifesciences

Feras Hatib, PhD
Technology & Discovery
Edwards Lifesciences

Rx only. See instructions for use for full prescribing information.

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 is a trademark of Edwards Lifesciences Corporation. Edwards Lifesciences, the stylized E logo, FloTrac, Swan-Ganz and Vigileo are trademarks of Edwards Lifesciences Corporation and are registered in the United States Patent and Trademark Office.

© 2008 Edwards Lifesciences LLC. All rights reserved. AR03192