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**Edwards *FloTrac* Sensor  
&  
Edwards *Vigileo* Monitor**

*Performance Assessments of the  
FloTrac Sensor and Vigileo Monitor*

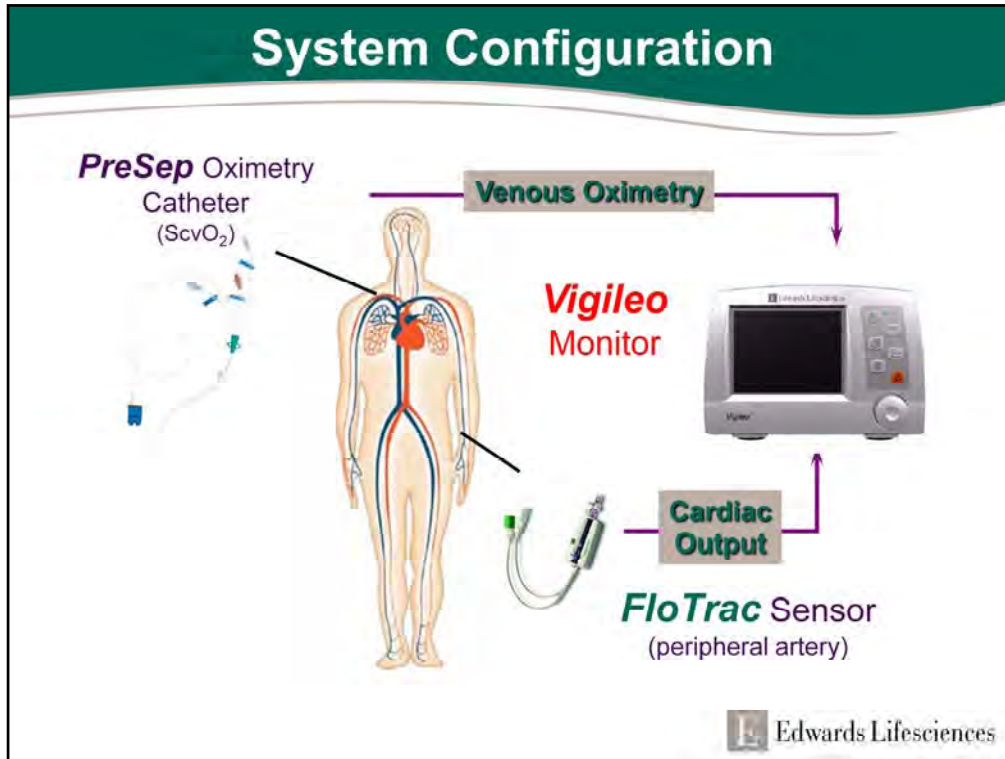
**Edwards FloTrac System**

  
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The image shows a white medical monitor on the left with a screen displaying a large number '82' and a waveform. To the right is a white FloTrac sensor connected to a white tube. The background is a light, neutral color with a decorative green wavy line separating the top and bottom sections.

## Topics

- **System configuration**
- **Performance and Validation**
  - Dr. William T. McGee, “Validation of a Continuous Cardiac Output Measurement Using Arterial Pressure Waveforms”
  - Dr. Gerard R. Manecke, “Cardiac Output Determination Using the Arterial Pulse Wave: A Comparison of a Novel Algorithm Against Continuous and Intermittent Thermodilution”
  - Dr. Jeffrey L. Horswell, “Arterial Pressure-Based Method of Continuous Cardiac Output Monitoring Accurately Follows Trends in Cardiac Output During and After Surgery”



The Vigileo monitor by Edwards Lifesciences supports both the FloTrac Sensor for continuous cardiac output and the PreSep oximetry catheter for continuous central venous oximetry (ScvO<sub>2</sub>)

## Vigileo Monitor

- **Continuously computes stroke volume from the patients arterial pressure signal**
- **Displays key hemodynamic parameters on a continuous basis (every 20 sec)**
- **Essentially NO calibration necessary**
  - The user simply enters patient age, gender, height and weight to initiate monitoring
  - Advanced waveform analysis compensates for:
    - Patient-to-patient differences in vasculature
    - Real time changes in vascular tone
    - Differing arterial sites
- **Venous oximetry available when used with appropriate Edwards oximetry technology**



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The Vigileo monitor continuously displays and updates Continuous Cardiac Output, Cardiac Index, Stroke Volume, Stroke Volume Index, Systemic Vascular Resistance\*, Systemic Vascular Resistance Index\*, and Stroke Volume Variation every 20 seconds when used with the FloTrac Sensor. DO<sub>2</sub> and DO<sub>2</sub>I are also available for intermittent calculation.\*\* These parameters help guide the clinician in optimizing stroke volume through precision guided management of preload, afterload, and contractility.

Vascular tone = vessel compliance and resistance

Vigileo then helps identify the adequacy of cardiac output by monitoring central venous (ScvO<sub>2</sub>) or mixed venous (SvO<sub>2</sub>) oxygen saturation when used with Edwards venous Oximetry technologies.


*\* These parameters require the CVP value to be slaved from bedside monitor for continuous monitoring. SVR/SVRI can also be assessed on the Derived Value Calculator for intermittent calculations using either slaved or manually entered MAP, CVP, and CO values.*

*\*\* These parameters require the SpO<sub>2</sub> and PaO<sub>2</sub> values to be manually entered. If CO is being continuously monitored, the calculator will default to the existing CO value. Otherwise, the user may override the continuous value to manually enter CO.*

## FloTrac Sensor



The specially designed *FloTrac* Sensor provides the high fidelity arterial pressure signal required by the *Vigileo* monitor to calculate the stroke volume.

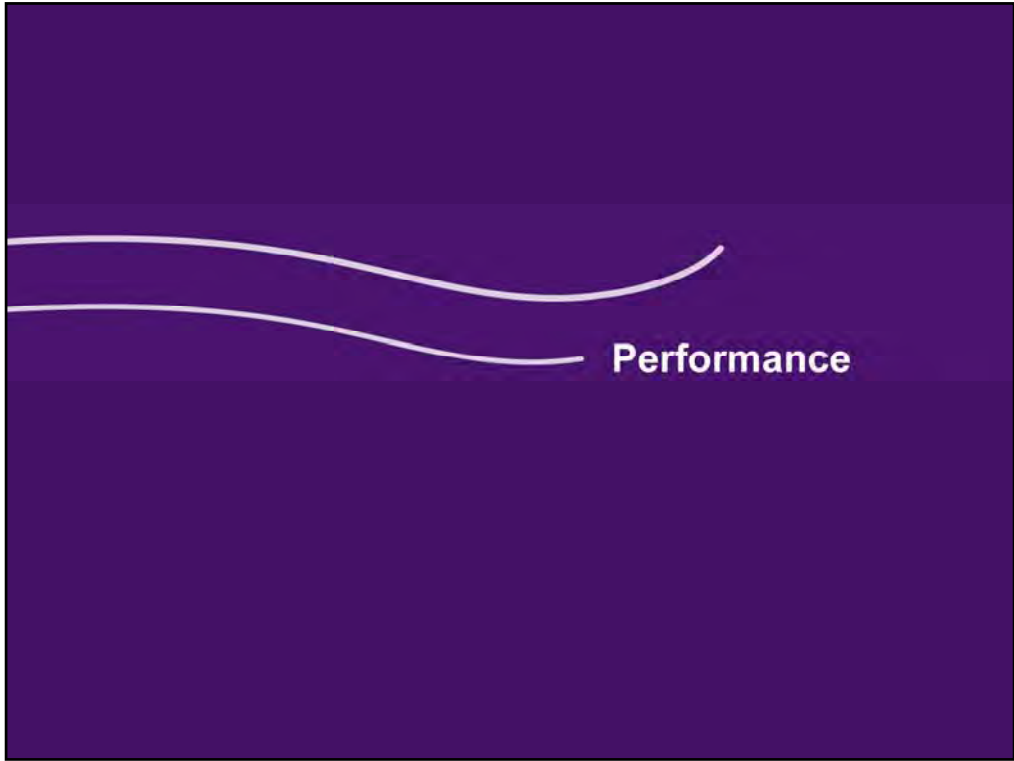
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The *Vigileo* monitor uses the patient's arterial pressure waveform to continuously measure cardiac output. With inputs of height, weight, age and gender, patient-specific vascular compliance is determined.

The *FloTrac* Sensor measures the variations of the arterial pressure which is proportional to stroke volume. Vascular compliance and changes in vascular resistance are internally compensated for.

Cardiac output is displayed on a continuous basis by multiplying the pulse rate and calculated stroke volume as determined from the pressure waveform.

The *FloTrac* Sensor is easily setup and calibrated at the bedside using the familiar skills used in pressure monitoring.





***“Validation of a Continuous Cardiac  
Output Measurement Using Arterial  
Pressure Waveform”***

***William T. McGee, MD, MHA, et al.***

# Validation of a Continuous Cardiac Output Measurement Using Arterial Pressure Waveforms

## Validation of a Continuous Cardiac Output Measurement Using Arterial Pressure Waveforms

William T. McGee, MD, MHA, et al.

**Methods**

- APCO, ICO, CCO data collected from 84 patients
  - (69 OR and in ICU, 15 ICU only)
  - 2 US, 2 European centers
  - Average age 67.7 (+/- 12.0) years, 65.5% male
- Grouped measurements (562 data points) for APCO, ICO and CCO were analyzed for bias, precision and correlation via Bland-Altman analysis

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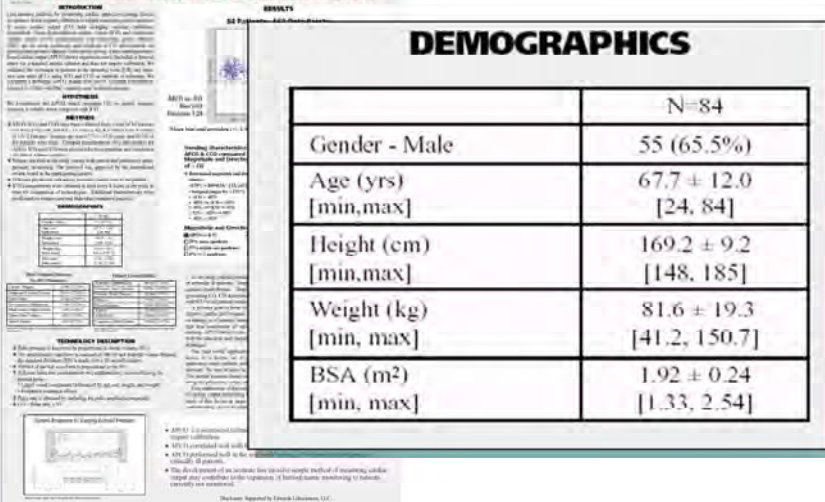
“Validation of a continuous cardiac output measurement using arterial pressure waveform”, *Critical Care*, Mar 05 supplement (abstract)

Dr McGee’s study is the largest validation study of its kind. The study was conducted in 4 centers, 2 American and 2 European, in both ORs and ICUs, over a wide range of ages. This study presents a “real life” validation as patient sample bias often caused by homogeneous demographics and the effect of a limited number of participating clinical sites has been minimized.

# Validation of a Continuous Cardiac Output Measurement Using Arterial Pressure Waveforms

## Validation of a Continuous Cardiac Output Measurement Using Arterial Pressure Waveforms

William T. McGee, MD, MHA, et al.



**DEMOGRAPHICS**

	N=84
Gender - Male	55 (65.5%)
Age (yrs) [min,max]	67.7 ± 12.0 [24, 84]
Height (cm) [min,max]	169.2 ± 9.2 [148, 185]
Weight (kg) [min, max]	81.6 ± 19.3 [41.2, 150.7]
BSA (m <sup>2</sup> ) [min, max]	1.92 ± 0.24 [1.33, 2.54]

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A wide variety of patient demographics were included in this study with broad age and BSA ranges.

# Validation of a Continuous Cardiac Output Measurement Using Arterial Pressure Waveforms

## Validation of a Continuous Cardiac Output Measurement Using Arterial Pressure Waveforms

William T. McGee, MD, MHA, et al.

### Most Frequent Reasons for PAC Placement

Cardiac Surgery	23/84 (27.38%)
Diagnosed Cardiac Disease	23/84 (27.38%)
Fluid Shifts	21/84 (25.00%)
Peri-operative Monitoring	17/84 (20.24%)
Multi-system Organ Failure	8/84 (9.52%)
Acute Heart Failure	6/84 (7.14%)
Severe Sepsis	4/84 (4.76%)

Totals may be more than 100 because each patient may have more than one diagnosis.

### Patient Co-morbidities

Systemic Hypertension	48/84 (57.14%)
Coronary Artery Disease	29/84 (34.52%)
Valvular Heart Disease	28/84 (33.33%)
Diabetes	27/84 (32.14%)
Hyperlipidemia	23/84 (27.38%)
Angina	22/84 (26.19%)
Arrhythmia	20/84 (23.81%)
Congestive Heart Failure	18/84 (21.43%)

Totals may be more than 100 because each patient may have more than one pre-existing condition.

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**CONCLUSIONS**

- The study demonstrated that the pulse contour method is a valid method for measuring cardiac output in patients with a variety of cardiac and non-cardiac conditions.
- The study also demonstrated that the pulse contour method is a valid method for measuring cardiac output in patients with a variety of cardiac and non-cardiac conditions.

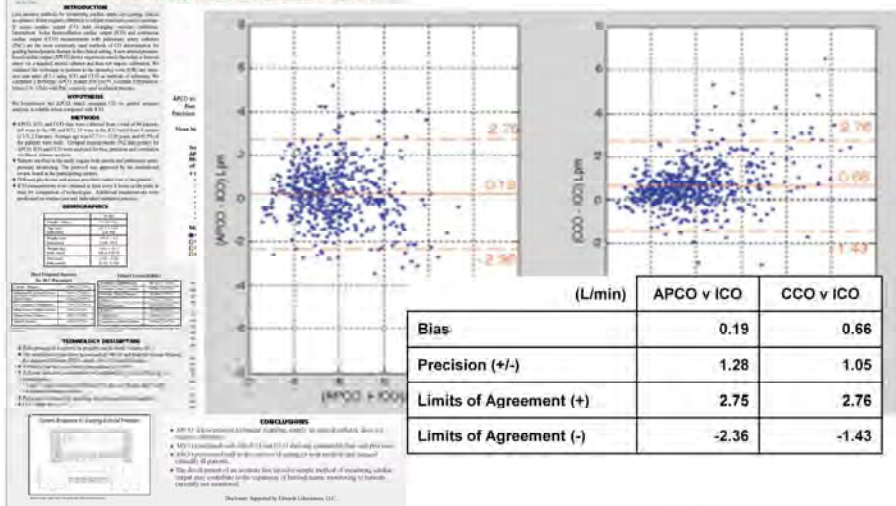
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All patients recruited had an existing PAC as required for their particular therapies. Many were cardiac patients or had a history of cardiac disease. Important to note is the high prevalence of arrhythmias in the patient sample, as many pulse contour or pulse power based devices tend to have technical difficulties calculating CO through dysrhythmias.

# Validation of a Continuous Cardiac Output Measurement Using Arterial Pressure Waveforms

## Validation of a Continuous Cardiac Output Measurement Using Arterial Pressure Waveforms

William T. McGee, MD, MHA, et al.



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Bland-Altman analysis indicates comparable variance amongst CO methods.

APCO vs ICO had a lower bias as compared to the CCO vs ICO analysis. Precision (1SD) showed only a difference of <.25 Liters/min. Limits of agreement, as shown above, indicate comparable variances against ICO. The most likely factor impacting variance is the difference in calculation timing associated with arterial pressure-based technology and thermodilution based technology respectively. The abstract presented at SCCM in 2006 by Dr Jeffrey Horswell, a participant in this study whose work is referenced later in this presentation, better illustrates this factor.

## Validation of a Continuous Cardiac Output Measurement Using Arterial Pressure Waveforms

**Validation of a Continuous Cardiac Output Measurement Using Arterial Pressure Waveforms**

**INTRODUCTION**


**RESULTS**

54 Patients, 142 Data Points

William T. McGee, MD, MHA, et al.


### CONCLUSIONS

- ◆ APCO, a less invasive technique requiring simply an arterial catheter, does not require calibration.
- ◆ APCO correlated well with ICO and CCO showing comparable bias and precision.
- ◆ APCO performed well in the real world setting of both medical and surgical critically ill patients.
- ◆ The development of an accurate less invasive simple method of measuring cardiac output may contribute to the expansion of hemodynamic monitoring to patients currently not monitored.




FloTrac, associated with APCO, is:

- \* Less invasive, requiring only an existing arterial catheter
- \* Correlates well with ICO and CCO
- \* Performs well in a real world setting
- \* Could be used to help monitor a population of patients who currently are not monitored with a PAC but could benefit from its most basic parameters (i.e., CO, CI, SV, SVI, SVV)



***“Cardiac Output Determination using the  
Arterial Pulse Wave:  
A Comparison of a Novel Algorithm Against  
Continuous and Intermittent Thermodilution”***


***Gerard Manecke, MD, et al.***



## Cardiac Output Determination using the Arterial Pulse Wave: A Comparison of a Novel Algorithm Against Continuous and Intermittent Thermodilution

*Gerard R. Manecke Jr., M.D., Mathew Peterson, M.D., William R. Auger, M.D.*

*UCSD Medical Center, San Diego, CA*



**Introduction**  
Assessment of cardiac output using the arterial pulse wave has been accomplished with varying success, usually requiring calibration with another method(1). We tested a new algorithm based on arterial pulsatility that does not require such calibration. Comparisons were made against standard thermodilution techniques using a pulmonary artery catheter.

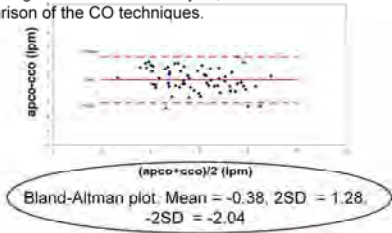
**Methods**  
In 11 cardiothoracic surgery patients (7 men and 4 women) cardiac output (CO) was monitored immediately after surgery. An arterial pressure based algorithm calculated cardiac output from arterial pressure (APCO) in real time while a pulmonary artery (PA) catheter (777HF8 CCO Catheter, Edwards Lifesciences, Irvine, California) was used to measure continuous (CCO) and intermittent bolus thermodilution cardiac output (ICO). A laptop-based data acquisition system provided continuous calculation and storage of APCO, as well as storage of the PA-based CO determinations. Each bolus cardiac output was calculated as the average of four measurements taken over approximately 5 minutes. APCO values were determined by averaging the individual values (3 per minute) over a 5 minute interval surrounding the time of bolus determination. CCO values were taken immediately prior to the bolus determinations, and represent a 5 minute average. Bland-Altman analysis, based on 65 comparison points, was used to determine bias and precision in the comparison of the CO techniques.

**Results**  
The CCO range was 2.77-9.60 L/min, with the mean being  $6.02 \pm 1.58$  L/min. The mean bias between APCO and CCO was  $-0.38 \pm 0.83$  L/min (figure 1), and the mean bias between APCO and ICO was  $0.04 \pm 0.99$  L/min.


**Conclusion**  
This APCO algorithm provides a reliable, minimally invasive method for measuring CO that requires neither dilution nor CO reference for calibration. It shows strong correlation and minimal bias with both traditional intermittent bolus thermodilution and continuous cardiac output over a wide range of values.

**References**  
1. J Cardiothoracic Vasc Anesth 18:185-189. 2004

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Bland-Altman plot. Mean = -0.38, 2SD = 1.28, -2SD = -2.04



Critical Care Medicine. 32(12) Supplement:A43, December 2004.

Dr Manecke's study was the first FloTrac validation. Again, the comparison is with thermodilution PAC but with a smaller more homogeneous patient population. The structure of this study is more comparable to validation studies conducted for other devices as it is a small, homogeneous sample in a single center.

In this study, the range of CCO data collected was between 2.77 L/min and 9.60 L/min. Variance between APCO and CCO was analyzed, resulting with Limits of Agreement of 1.28 and -2.04. Precision between APCO:CCO and APCO:ICO are shown in the Results section, indicating little difference in variance between the two data sets. Thus, **"It (the study) shows strong correlation and minimal bias with both traditional intermittent bolus thermodilution and continuous cardiac output over a wide range of values (when compared with APCO)."**



***“Arterial Pressure-Based Method of  
Continuous Cardiac Output Monitoring  
Accurately Follows Trends in Cardiac  
Output During and After Surgery”***

***Jeffrey L. Horswell, MD, et al.***

## Validation of a Continuous Cardiac Output Measurement Using Arterial Pressure Waveforms

Jeffrey L. Horswell, MD and Christina M. Worley, RN



### Methods

- **APCO, ICO, CCO data collected from 23 cardiovascular surgery patients**
  - Average age 63 (+/- 12.0) years, 65% male
  - All ASA class III or IV
- **Grouped simultaneous measurements (164 data points) of APCO, ICO and CCO were analyzed and compared for magnitude and direction of trends**

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Critical Care Medicine. Society of Critical Care Medicine 35th Critical Care Congress San Francisco, California, USA January 7-11, 2006. 33(12)

Abstract Supplement:A60, December 2005.

This study was presented at the 2006 SCCM to show comparisons between FloTrac and the clinical gold standard Swan-Ganz catheter's CCO and ICO. The focus of this study was to compare the direction and magnitude change in trends between data sets: APCO vs ICO and CCO vs ICO. The patients had high ASA classifications and required monitoring with a PAC.

# Validation of a Continuous Cardiac Output Measurement Using Arterial Pressure Waveforms

Jeffrey L. Horswell, MD and Christina M. Worley, RN

Medical City  
 Arterial Pressure-Based Method of Continuous Cardiac Output Monitoring  
 Accurately Follows Trends in Cardiac Output During and After Surgery (0220-S)

Table 1: Patient Demographics

	Mean	Std Dev	Minimum	Maximum
Age (yrs. old)	63.3	11.56	44	84
Height (cm)	172.2	9.07	155	183
Weight (kg)	89.0	22.64	55.0	150.7
Body Surface Area (m <sup>2</sup> )	2.01	0.23	1.59	2.54
Heart Rate (bpm)	73.2	10.04	56	95
Systolic Blood Pressure	136.3	20.78	99	190
Diastolic Blood Pressure	70.0	11.68	48	98

Table 2: Surgical Description

Surgical Procedure	N
CABG	13 (56.5%)
Valve	5 (21.7%)
CABG/Valve	2 ( 8.7%)
Maze	2 ( 8.7%)
Valve/Maze	1 ( 4.4%)

Table 3: Patient Co-morbidities

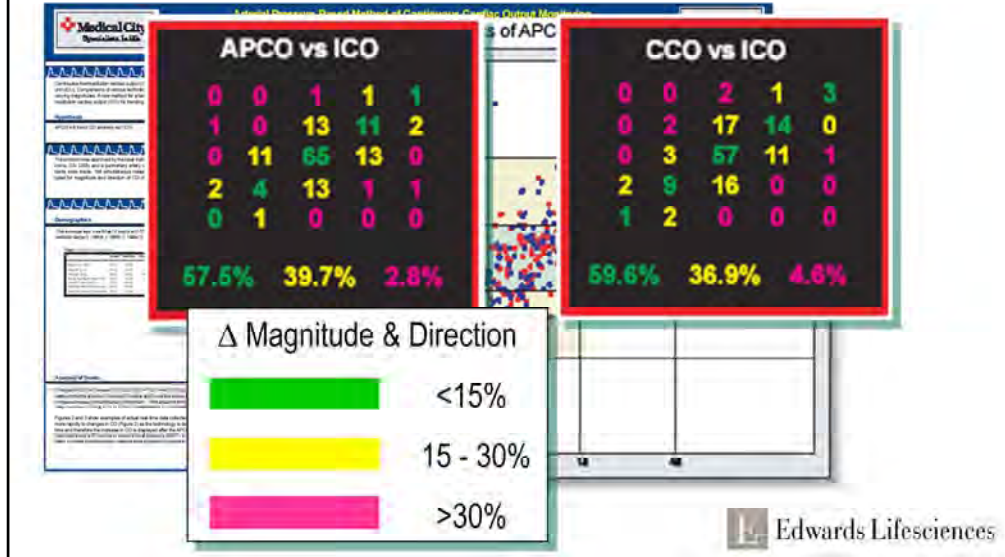
Co-morbidities	N
Systemic Hypertension	11 (47.8%)
Hyperlipidemia	9 (39.1%)
Diabetes	6 (26.1%)
Atrial Fibrillation	5 (21.7%)
Myocardial Infarction	4 (17.4%)
Obesity	4 (17.4%)
Smoker (Past)	4 (17.4%)
Congestive Heart Failure	3 (13.0%)
Smoker (Current)	3 (13.0%)
COPD	2 ( 8.7%)
Renal Insufficiency	2 ( 8.7%)
Hemodialysis	1 ( 4.4%)

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The procedures conducted on this sample primarily were CABG, valve therapy, or a combination of the two. Patient demographics were broad, with patient ages ranging from 44 to 84 and a broad range of BSAs, from 55 kgs to 151 kgs.

# Validation of a Continuous Cardiac Output Measurement Using Arterial Pressure Waveforms

Jeffrey L. Horswell, MD and Christina M. Worley, RN



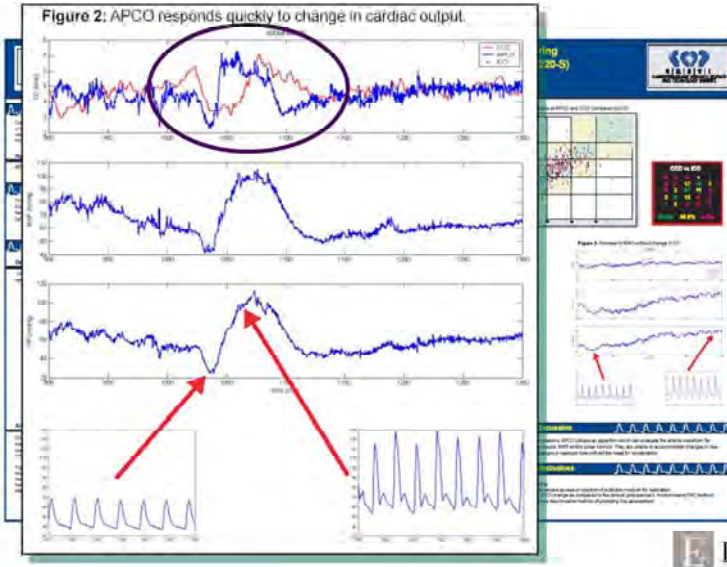
The above show the differences between the comparison data being very little in terms of differences in magnitude and direction of trends.

The green figures represent pairs of data with less than 15% difference in magnitude and direction; the yellow figures represent pairs of data with a 15% - 30% difference; and the light red figures represent pairs with more than a 30% difference.

The differences between the two comparisons, APCO vs ICO and CCO vs ICO, were comparable.

## Validation of a Continuous Cardiac Output Measurement Using Arterial Pressure Waveforms

Jeffrey L. Horswell, MD and Christina M. Worley, RN



APCO responds quickly to changes in cardiac output.

One of the most significant factors affecting differences in the magnitude and timing of changes in trends between the two continuous technologies, APCO and CCO, is the averaging time.

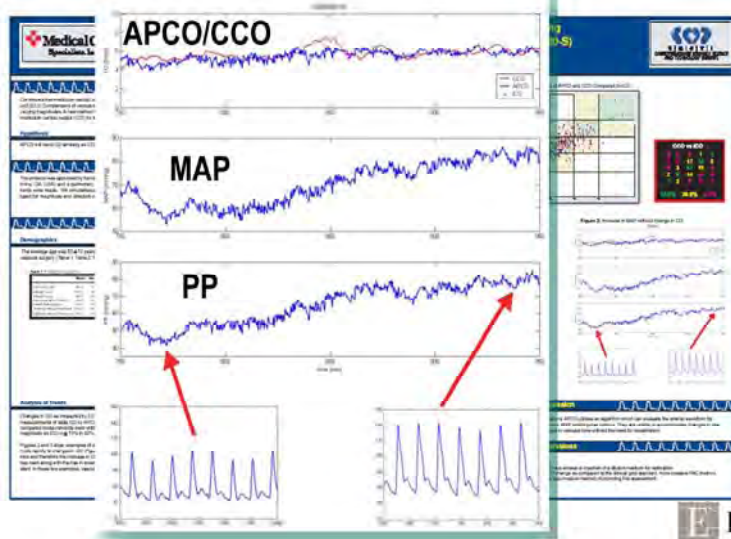
As FloTrac has trends based on a 20 second averaging time, the response to changes in hemodynamics will be evident earlier than with CCO Swan-Ganz, which could have averaging times ranging from 3 to 6 minutes\*, depending upon signal noise. The differences in averaging time results in time phasing of trends.

- Stat mode

## Validation of a Continuous Cardiac Output Measurement Using Arterial Pressure Waveforms

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Figure 3: Increase in MAP without change in CO



In this example, the patient's CO and HR remain relatively constant over the time, as shown in the APCO/CCO trend. Both MAP and PP increased over the same time span. The constant CO (and HR) with increasing MAP and PP indicates there has been a change in vascular tone.

The APCO algorithm detects changes in vascular tone via analysis of waveform characteristics. CO systems based upon an indicator dilution method of calculating CO require regular calibration because they do not compensate continuously for changes in vascular tone.

APCO does not require a manual method of recalibration.

## Validation of a Continuous Cardiac Output Measurement Using Arterial Pressure Waveforms

Jeffrey L. Horswell, MD and Christina M. Worley, RN

### CONCLUSIONS

- **APCO is a new, less invasive method for continuous cardiac output monitoring.**
- **APCO requires only arterial catheterization and does not necessitate central venous access or injection of a dilution medium for calibration.**
- **APCO compares favorably with trending both the direction and magnitude of CO change as compared to the clinical gold-standard, more invasive-PAC method.**
- **Patients who currently are not monitored with a PAC for CO may benefit from a less invasive method of providing this assessment.**

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## Summary

- **APCO is a new, less invasive method for continuous cardiac output monitoring**
- **APCO requires only arterial catheterization and does not necessitate central venous access or injection of a dilution medium for calibration**
- **APCO compares favorably with trending both the direction and magnitude of CO change as compared to the clinical gold-standard, more invasive-PAC method**
- **Patients who currently are not monitored with a PAC for CO may benefit from a less invasive method of providing this assessment**
- **APCO algorithm automatically accommodates for changes in vascular tone (without a manual method of calibration)**

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