Evaluation of a Noninvasive Continuous Cardiac Output Monitoring System Based on Thoracic Bioreactance

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Running Head: Non-invasive cardiac output monitoring system

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ABSTRACT

Noninvasive cardiac output measurement (NICOM) can be useful in many clinical settings where invasive monitoring is not desired. Bioimpedance (intrabeat measurement of changes in transthoracic voltage amplitude in response to an injected high frequency current) has been explored for this purpose, but is limited in some clinical settings due to inherently low signal-to-noise ratio. Since changes in fluid content also induce changes in thoracic capacitive and inductive properties, we tested whether a NICOM could be obtained through measurement of the relative phase shift of an injected current (i.e., bioreactance). We constructed a prototype device that applies a 75 kHz current and determines the relative phase shift ($d\Phi/dt$) of the recorded transthoracic voltage. Cardiac output (CO) was related to the product of peak $d\Phi/dt$, heart rate, and ventricular ejection time. The pre-clinical study was done in nine open chest pigs put on right heart bypass so that CO could be varied at known values. This was followed by a feasibility study in 27 post operative patients who had a Swan-Ganz Catheter (SGC). The measurements of NICOM and cardiopulmonary bypass pump correlated to each other ($r=0.84$) despite the large variation in CO and temperatures. Similarly, in patients, mean CO was 5.18 L/min and 5.17 L/min as measured by SGC and NICOM system, respectively, and were highly correlated over the range of values studied ($r=0.90$). Preclinical and clinical data demonstrate the feasibility of using blood flow related phase shifts of transthoracic electric signals to perform noninvasive continuous CO monitoring.

Key words: cardiac output, thoracic bioreactance, non-invasive monitoring
INTRODUCTION:

The development of an accurate, simple, cost effective, non-invasive technique of measuring cardiac output (CO) can be important for clinical decision making and research in many inpatient and outpatient clinical settings. The recent emphasis on the uncertain risk-benefit ratio of invasive CO monitoring by pulmonary artery catheterization (PAC) with a Swan-Ganz catheter (SGC) further highlights the clinical imperative of developing non-invasive alternatives (15). A number of non-invasive methods of assessing CO have been studied in the past, with transoesophageal Doppler echocardiography, impedance cardiography, and carbon dioxide breath analysis currently available (11).

Thoracic bioimpedance was the first and currently, the most widely used non-invasive method for CO monitoring (2, 3, 17). Standard bioimpedance systems apply a high frequency electrical current of known amplitude and frequency across the thorax and measure changes in voltage. The ratio between voltage and current amplitudes is a measure of transthoracic direct current resistance (more generically referred to as impedance, Zo) and this varies in proportion to the amount of fluid in the thorax. The instantaneous rate of change of Zo therefore relates to instantaneous blood flow in the aorta. Since the aortic blood flow pulse contour is roughly triangular in time (Fig. 1), stroke volume (SV, the integral of flow over time) is proportional to the product of peak flow and the ventricular ejection time (VET). Thus, SV is also proportional to the product of maximal rate of change of Zo (dZo/dt_{\text{max}}) and VET.

Although clinical utility has been increasingly recognized in some clinical settings (13, 14), bioimpedance has been found to be inaccurate in intensive care units and other settings where significant electrical noise and body motion exists (5, 9). Also, the technique is sensitive to placement of the electrodes on the body, variations in patient body size and other physical
factors which impact on electrical conductivity between the electrodes and skin (e.g., temperature and humidity).

In addition to changing resistance to blood flow ($Z_0$), changes in intrathoracic volume also produce changes in electrical capacitive and inductive (i.e., bioreactance) properties which result in phase shifts of the received signal relative to the applied signal. Techniques for detecting relative phase shifts are inherently more robust and less susceptible to noise (e.g., the comparison between AM and FM radio). We therefore hypothesized that in contrast to analysis of changes in transthoracic voltage used in standard bioimpedance based systems, analysis of relative phase shifts would yield a system with improved accuracy and less susceptibility to ambient conditions.

To test this hypothesis, we developed a bioreactance-based system of noninvasive cardiac output measurement (NICOM) and tested its accuracy in two settings: 1) an animal model in which cardiac output can be controlled and measured accurately, and 2) in preliminary clinical studies by comparing its performance to that of thermodilution.
METHODS:

**Bioreactance-based noninvasive cardiac output measurement: principle of operation**

The bioreactance-based NICOM system is based on an analysis of relative phase shifts of an oscillating current that occur when this current traverses the thoracic cavity, as opposed to traditional bioimpedance-based systems, which rely only on measured changes in signal amplitude. This NICOM system (NICOM™, Cheetah Medical Inc, Delaware) is comprised of a high frequency (75 kHz) sine wave generator and four dual electrode “stickers” that are used to establish electrical contact with the body (Fig. 2). Within each sticker, one electrode is used by the high frequency current generator to inject the high frequency sine wave into the body, while the other electrode is used by the voltage input amplifier. Two stickers are placed on the right side of the body and two stickers are placed on the left side of the body. The stickers on a given side of the body are paired, so that the currents are passed between the outer electrodes of the pair and voltages are recorded from between the inner electrodes. A NICOM signal is thus determined separately from each side of the body, and the final NICOM signal is obtained by averaging of these two signals.

The system’s signal processing unit detects the relative phase shift ($\Delta \Phi$) of the input signal (picked up by the receiving electrodes) relative to the injected signal. As discussed above, the phase shift between the injected current and output signal received from the thorax is due to changes in blood flow in the aorta. With standard bioimpedance, $SV \propto (L/Z_o)^2 \cdot VET \cdot dZ_o/dt_{max}$, where $VET$ is ventricular ejection time, $dZ_o/dt_{max}$ is the maximal rate of rise of $Z_o$, and $L$ is the distance between the electrodes on the body surface (Fig. 1) (18). Similarly, we found that there is also a tight correlation between the blood flow rate and the rate of change in the relative phase shift ($d\Phi/dt$). Thus, $SV$ can also be expressed as:
SV = C \cdot \text{VET} \cdot \frac{d\Phi}{dt_{\text{max}}}

[Equation 1]

where C is a constant of proportionality. CO is then calculated using the relation:

CO = SV \cdot HR

[Equation 2]

where HR is the heart rate. Unlike bioimpedance, bioreactance-based NICOM does not use the static impedance $Z_o$ and does not depend on the distance between the electrodes $L$ for the calculations of SV and CO, which significantly reduces the uncertainty in the result.

The signal processing unit is comprised of a limiter which eliminates amplitude variations in the input signal using an amplitude saturation technique but maintains the information contained in its frequency and phase modulation. The saturated amplitude reference input signal and the output signal are both sent to a mixer-multiplier which subtracts these two high frequency signals to allow determination of the relative phase shift variation, $d\Phi/dt$. To enhance signal-to-noise ratio, a low pass filter is applied to the mixed output signal. The resulting signal is used to calculate $d\Phi/dt$ which is converted from the original analog signal to digital data for processing at a sampling frequency of 500 Hz. The device also records and digitizes a three lead electrocardiogram (ECG). This is used to identify the start and end of each beat for determination of HR. Within each beat defined by these start and end time marks, the system determines $d\Phi/dt_{\text{max}}$ that is used in Equation 1. Finally, the ECG is also used in determination of VET which is determined with a standard algorithm that uses information from the ECG and the $d\Phi/dt$ signal. Specifically, the peak of the QRS complex of the ECG is used as the timing mark of the start of each beat. VET is then calculated as the time interval between the start of ejection, defined by the first zero crossing of the $d\Phi/dt$ signal, and the end of ejection, defined as the second zero crossing the $d\Phi/dt$ signal. These zero crossings are readily identified on the $d\Phi/dt$ tracings shown in Fig. 3.
**Animal Studies:**

Nine pigs were used in the pre-clinical phase of the validation study. In each case, the chest was opened by midline thoracotomy after establishment of deep anaesthesia with katanine (10mg/Kg i.v.) and azaperon (2mg/Kg, i.v.). Each animal was put on right heart bypass as follows. The inferior and superior vena cavae were cannulated and connection to the atrium was completely blocked by bivacal ligation. These cannulae were connected to a cardiopulmonary bypass pump (CPB) that was used to regulate blood flow. Following oxygenation, blood was reinfused into the right atrium via a third cannula. In this manner, flow in the pulmonary artery and aorta were pulsatile and with a mean value that was controlled. Four NICOM™ electrodes were placed on the thorax (two on the upper thorax, two on the lower thorax) and these were connected to the NICOM™ signal processor. A Transonic flow probe was held in place over the pulmonary artery in some of the experiments in order to record the blood flow velocity profile. After completion of the surgery and stabilization of the preparation, CO was varied in small increments by adjusting the speed of the CPB pump. In a second sequence, CO was varied in large increments and temperature of the blood was varied between 38° and 36° Celsius. Changes in temperature induce significant changes in electrical conductivity and thus impose a relatively rigorous test on the independence of system performance of physical factors.

A single calibration factor was determined retrospectively for each animal by dividing the value obtained with the NICOM™ system and the known value of CPB pump flow at each pump setting and then taking the average of all measurements; this average value was then applied to all data for that individual experiment. Standard correlation analysis was performed between the readings obtained from preset CPB output and NICOM™ system.
The study conformed to the *Guide for the Care and Use of Laboratory Animals* published by the US National Institutes of Health (NIH Publication No. 85-23, revised 1996) and the protocol was approved by the Institutional Animal Care and Use Committee of the IMM Recherche Institut Mutualiste Montsouris, Paris.

**Clinical Study**

27 patients admitted into the ICU following valve replacement or coronary artery bypass graft (CABG) surgery were included from two centers, Clinque Ambroise Pare and IMM Recherche Hospital, France. All patients underwent CO measurement invasively by the continuous thermodilution technology using the SGC and non-invasively by the NICOM™ system. This study was approved by the ethics committee of the hospitals and each patient provided written informed consent prior to participation.

Following the induction of anaesthesia in the operating room, a SGC (Arrow 7.5 Fr) was inserted via the jugular or subclavian vein as is routine during cardiac surgery. This pulmonary artery catheter provided CO measurements that were time averaged over the preceding five minutes. Upon admission to the ICU after cardiac surgery, the pulmonary arterial catheter was connected to a continuous thermodilution CO device (Baxter Medical, Inc., USA) and proper positioning of the catheter was confirmed on a chest X-ray. NICOM™ electrodes were placed on the patient’s chest and connected to the NICOM™ controller. No special attention was given to sticker location, only that the upper electrodes were to be positioned in the subclavian region and the lower stickers were placed in the lower costal margin. The clock times of the NICOM™ controller and the continuous thermodilution device were synchronized immediately before starting the acquisition of the measurements. Thus, timing of data acquisition by both devices
was synchronized so as to obtain simultaneous reading by the two devices from each patient. For purposes of analysis, data obtained from each individual patient were averaged over the entire recording, which ranged from 1 to 2 hours. Selected patients underwent the evaluation of the NICOM system in response to positive end expiratory pressure (PEEP) tests in which the lungs are inflated by increased air pressure (typically to the equivalent of 15-20 cm of water), which in turn reduces venous return and CO.

Statistical analysis was carried out with the SPSS statistical software. The null hypothesis was to demonstrate that there was no statistically significant difference between cardiac output determined by thermodilution and NICOM measurements. For each pair of measurements, Pearson’s correlation coefficient was calculated.

RESULTS

Animal Studies

Examples of the original pulmonary blood flow velocity signals, 2 electrocardiograms, the NICOM relative phase signal (Φ) and its first derivative (dΦ/dt) are shown in Fig. 3. The triangular contour of the flow velocity pattern is evident. The NICOM™ relative phase signal shows a periodic signal in synchrony with the QRS complexes. Note the approximately triangular contour of the dΦ/dt signal that is in phase with the pulmonary blood flow velocity signal.

Results from one animal in which CPB flow was varied gradually are shown in Fig. 4A. As seen, NICOM™ closely tracked the cardiac output imposed by CPB. Fig. 4B summarizes the correlation between individual measurements from all the measurements confirming the consistency of this finding. Fig. 5 shows the overall results from all animals in this series.
the whole, there was a strong correlation between the cardiac output set by the CPB pump and that detected by the NICOM \( (y=0.85+0.81x; r=0.87) \). As noted, there is a relatively large offset in the regression equation, which may suggest that at very low values of CO, the assumptions underlying the NICOM estimation of CO may not be fully valid. Nevertheless, if the regression line is forced through the origin (line not shown on the graph), the correlation coefficient remains at 0.87 and the slope increases to 1.09.

An example in which large variations of cardiac output were imposed by the CPB flow with superimposed changes in blood temperature is shown in Fig. 6A. As shown in the example, the close match between NICOM\(^\text{TM}\) and imposed CPB flow was retained, despite abrupt, large changes in flow and despite changes in temperature (Fig. 6B). The overall correlation between CPB flow and NICOM\(^\text{TM}\) for all points measured in all animals is summarized in Fig. 7A; data obtained at 38 °C shown by black circles, data obtained at 36 °C shown by red triangles. Overall, the correlation between CPB flow and NICOM\(^\text{TM}\) measurement was not impacted by temperature. When data from both temperatures are pooled, the overall correlation between CPB flow and NICOM\(^\text{TM}\) measurement was \( y=0.13+0.95x \) \( (r=0.84) \) which was not significantly different than the line of identity.

Within this last protocol, imposed changes in CO ranged from approximately -1.5 to +2.0 L/min in 0.5 L/min increments. The correlation between imposed changes in CO and changes detected by NICOM are summarized in Fig. 7B (data from both temperatures and all animals included). The regression between imposed and measured CO changes was not different than the line of identity \( (y=1.06x-0.03, r=0.88) \).
Clinical Data

The baseline characteristics of the patients are summarized in Table 1. No adverse events were noted in any patients and monitoring with the NICOM™ system was found to be safe. The mean CO for the group was 5.17 L/min and 5.18 L/min as measured by the NICOM™ system and by the SGC, respectively. An example of an hour and a half of simultaneously recorded NICOM™ and SGC data is shown in Fig. 8. There is generally good agreement between the techniques, both of which show a gradual increase in CO from ~4.5 to ~5.5 L/min. These recordings are typical in that because of the difference in time averaging (1 minute for NICOM™ vs. 5 minutes for SGC) there was slightly more variability in the NICOM™ signals. The regression plot of mean CO measured from the NICOM™ system versus mean CO measured from the SGC system for all patients showed a good correlation (r=0.90) which didn’t differ statistically from the line of identity (y=0.59+0.89x, Fig. 9).

Data showing the responsiveness of the SGC and NICOM™ systems to episodes of PEEP is shown in Fig. 10. As shown, the NICOM™ system was found to be highly reactive to variations in PEEP. In this example, NICOM™ indicated an initial CO of ~6.6 L/min. Upon application of 15 cm H₂O PEEP, the NICOM™ signal decreased within the first one minute to ~4.1 L/min, with additional small amount reduction over the ensuing 4 minutes. PEEP was then reduced stepwise (in steps of 5 cm H₂O) back to 0 cm H₂O, during which time the NICOM™ signal returned towards normal. With abrupt reintroduction of 15 cm H₂O PEEP, the NICOM™ signal immediately reduced back towards 4.0 L/min with even an additional small reduction. When PEEP was removed 10 minutes later, the NICOM™ signal returned to the original starting level. It is noteworthy that in comparison to the NICOM™ signal, the SGC signal (data not shown) was significantly less responsive (a consequence of the 5 minute running averaging done
by that system). So, there was high concordance between the NICOM™ and SGC during the
hemodynamically stable periods, but differences emerged during these rapid periods due to the
differences in filtering. The NICOM™ proved to be similarly responsive in other patients
subjected to PEEP test.

DISCUSSION

Preclinical and clinical data from this pilot study validate the safety and feasibility of
using a bioreactance-based system for tracking CO in animals and humans. The study also
established that the device can work even in the experimental laboratory and the intensive care
setting, environments that are rich in ambient electrical noise. It is in such settings in which
traditional bioimpedance-based systems are known to exhibit poor performance (1, 5, 9).
Nevertheless, NICOM™ performed well in comparison to the SGC, which is currently
considered to be the gold standard for CO determination in the clinical setting.

Measurement of CO and, sometimes more importantly, changes in CO can be extremely
useful when assessing circulatory function. A simple and reliable method of measuring CO is
frequently required both clinically and for research purposes. However, the thermodilution
technique using a PAC is invasive and recently the use for hemodynamic monitoring has been
increasingly criticized because of its uncertain risk–benefit ratio and cost (15). As a result, there
is a continuing search for a method of CO measurement that is less invasive than its
predecessors. In this respect, impedance cardiography, which calculates SV and CO from
changes in the instantaneous mean resistance (i.e., impedance) of a small electrical current
 transferred through the body, has received much attention in the last four decades because it is
non-invasive, easy to use and adapted for continuous monitoring of CO and related parameters (16).

In order to investigate the validity of thoracic bioimpedance, numerous studies have compared the results obtained from thoracic bioimpedance with values obtained from reference methods in different research settings. Some studies have reported very good correlations (6) while others have reported relatively poor correlations (8). In contrast, the NICOM™ system uses an approach based on bioreactance to estimate CO. This bioreactance approach is based on an analysis of relative phase shifts of oscillating currents that occur when this current traverses the thoracic cavity as opposed to the traditional bioimpedance, which relies only on the measured changes in signal amplitude. Use of amplitude is theoretically a suboptimal approach compared to phase shift related changes because it is impacted more by patient movement, variable environment, humidity, sticker location and is patient dependent. Unlike bioimpedance technologies, NICOM™ offers the theoretical advantages of little to no performance variability related to inter-patient body variance and electrode positioning.

No major adverse events were observed in the animals or human subjects throughout the course of the study when NICOM™ system was used. This can be expected, the system being non-invasive in nature. The event free experiments thus point to the safety of the NICOM™ device. The preliminary right heart bypass study in animals provided consistent results, allowing comparison tests to be performed. The NICOM™ system provided very good correlation with the pre-set CPB pump. Moreover, the NICOM™ system showed comparable performance with both small and large abrupt increments in CO. Importantly, there was no variation in the correlation of NICOM™ system with the pre-set CPB at either temperature.
**Limitations.** Like several other noninvasive techniques, NICOM is based on the assumption that the area under the flow pulse is proportional to the product of peak flow and ventricular ejection time. However, there may be situations, especially during periods of low flow, when the this assumption may not be valid. A second limitation is that in the animal studies employing right heart bypass, great cardiac vein and azygous vein flows are left intact. The flow through these structures are not controlled, so that the correlation between pump flow and NICOM estimates of CO do not account for these, which combined amount to a small percentage of the total flow. Finally, for the clinical studies, SGC was taken as a gold standard in the clinical study because it is the best available reference for continuous CO monitoring (4, 7, 10, 12). Our interest was comparing the NICOM™ system with an automatic and continuous monitoring tool. In this regard, the data shows that there is good correlation between NICOM™ and SGC derived measurements of CO. However, thermodilution technique may not actually provide an accurate value for comparison.

**Conclusions:**

In conclusion, the results of this study show the feasibility of using a bioreactance-based system for noninvasive measurement of CO. The system is safe and can work in challenging environments where there is a lot of electrical noise. Further testing and validation of this approach is required to support use of the system in the clinic. In particular, the theoretical claims of improved accuracy and less susceptibility to ambient factors and patient physical characteristics require testing in a relatively large number of patients. In addition, derivation and validation of an algorithm for assigning a patient specific proportionality constant (for Eq.1) will be important for broad clinical applicability. If this is not possible, this technique might only be
useful as a qualitative index of changes in cardiac output. The current feasibility study shows
that the first generation device can perform well in open chest animals in a laboratory setting and
in humans in the intensive care unit, which is very encouraging.

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Disclosures:

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Hanan Keren is the founder and employee of Cheetah Medical, Inc. Daniel Burkhoff and Pierre
Squara are consultants to Cheetah Medical, Inc.
REFERENCES:


FIGURE LEGENDS

Figure 1
Schematic representation of aortic flow as a function of time underlying the basic principle for estimation of SV from changes in bioimpedance (dZ_{max}/dt) or changes in relative phase shifts (d\Phi/dt_{max}, bioreactance). Since the aortic flow pulse is relatively triangular in time, stroke volume (SV) is proportional to the product of peak flow (F_{max}) and ventricular ejection time (VET).

Figure 2
The NICOM^{TM} system and its connection to the body. Four double electrode stickers are placed around the thorax. A high frequency current is passed between the two outer electrodes and the resulting voltages are recorded between the two inner electrodes. The relative phase shift (\Phi) and rate of change of phase (d\Phi/dt) between these signals are determined and used in the calculations of stroke volume.

Figure 3
Original recordings of aortic flow (AoF), 2 electrocardiograms, the signal of relative phase (\Phi) and its first derivative (d\Phi/dt). See text for further details.

Figure 4
Cardiac output (CO) measurements in animals on cardiopulmonary bypass (CPB) by NICOM^{TM} system during gradual changes in CPB pump flow. A. Comparison between CPB flow and
NICOM measurements from a typical experiment. B. Data from panel A plotted to show the correlation between the CO measurements by NICOM and CPB.

Figure 5
Cardiac output (CO) measurements in animals on cardiopulmonary bypass (CPB) by the NICOM™ system during gradual changes in CPB pump flow. Summary data from all animals studied.

Figure 6
A: CO measurements by NICOM™ when large variation imposed by CPB and superimposed temperature variation in a typical animal experiment. B: Data from panel A plotted to show the correlation between the CO measurements by NICOM™ and CPB.

Figure 7
A. Overall correlation between CO measurements by NICOM™ and cardiopulmonary bypass pump (CPB) when large variation imposed in all the animals at two different blood temperatures. Black circles, 38°C; red triangles: 36 °C. B. Correlation between changes in CO imposed by CPB and those measured by NICOM™. Points are mean±SD derived from data at both blood temperatures and all animals. Line of regression: y=1.06x-0.03 (r=0.88).

Figure 8
Simultaneous CO monitoring from NICOM™ system (1 minute running time average) and continuous thermodilution from Swan-Ganz catheter (5 minute running time average) from a
patient during a 100 minute period of time when there was ~1 L/min increase in mean CO. Trends in NICOM™ nicely track those of the thermodilution technique.

Figure 9
Correlation between mean values of CO measured from NICOM™ system and thermodilution in 27 post operative patients.

Figure 10
Recording of NICOM™ in an intubated patient during an episode of positive end expiratory pressure (PEEP) showing the responsiveness of the NICOM™ system to an intervention that reduces CO. The results of the continuous output thermodilution system showed much less variation, owing the long filtering time (5 minutes) employed in that system (data not shown).
Table 1:

Patient Characteristics

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<th>Mean ± SD or N</th>
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<th>Minimum value</th>
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<td>Weight in Kg</td>
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<tr>
<td>Height in cm</td>
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<td>CO from NICOM (Ltr/min)</td>
<td>5.17 ± 1.14</td>
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<td>CO from SGC (Ltr/min)</td>
<td>5.18 ± 1.15</td>
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</table>
FIGURE 1

Aortic Blood Flow ($F$)

$F_{\text{max}} \propto \frac{dZ}{dt_{\text{max}}} \propto \frac{d\Phi}{dt_{\text{max}}}$

Time

VET

Copyright Information
FIGURE 2

RF Generator 75kHz, fixed amplitude signal

Input Amplifier

Phase Shift dΦ/dt

Image of human torso with annotations for circuit components.
FIGURE 5

\[ Y = 0.85 + 0.81X \]
\[ r = 0.87 \]
FIGURE 6

A

Cardiac Output (L/min)

B

B

CO by NICOM (L/min)

CO by CPB (L/min)
FIGURE 7

A

B

CO by NICOM (L/min)

CO by CPB (L/min)

ΔCO by CPB (L/min)

ΔCO by NICOM (L/min)
FIGURE 8

Thermodilution (5min Avg)

NICOM (1min Avg)

CO (L/min)

Time (min)
FIGURE 9

\[ Y = 0.59 + 0.89X \]
\[ r = 0.90 \]
FIGURE 10

Cardiac Output (L/min)

Time (min)

PEEP