

Original Article***Clinical Evaluation of a New In-Line Continuous Blood Gas Monitor***

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ABSTRACT

Two methodologies for obtaining accurate blood gas and electrolyte values during cardiopulmonary bypass (CPB) are traditional laboratory analyzers, which use an electrochemical technology, and continuous in-line monitoring systems, which use a fluorometric and/or spectrophotometric technology. The purpose of the present study was to evaluate the accuracy of a new continuous in-line monitor, the 3M™ CDI™ Blood Parameter Monitoring System 500, which provides continuous in-line measurements of pH, PCO₂, PO₂, potassium (K⁺), oxygen saturation, hematocrit, hemoglobin, and temperature, during partial or complete CPB. Study parameters included arterial pH, PCO₂, PO₂, and K⁺ values. Overall performance was analyzed by calculating the mean difference (expressed as the bias) between the CDI system 500 and the laboratory analyzer for each parameter. The accuracy of the arterial pH, PCO₂, and K⁺ values provided by the CDI system 500 was then evaluated using target values established in the acceptable performance standards for laboratory analyzers from the Clinical Laboratory Improvement Act of 1988 (CLIA '88). The accuracy of the PO₂ value provided by the CDI system 500 was evaluated using a target value of $\pm 10\%$ of the reference, or laboratory analyzer, value.

A prospective multi-center trial was conducted following Institutional Review Board approval. A total of 75 cases was included in the analyses, with over 200 data points from 4 clinical locations. Results for pH, PCO₂, and K⁺ were within the target values established by CLIA '88. pH bias was 0.00 ± 0.02 pH units. PCO₂ bias was -0.3 ± 3.3 mm Hg. K⁺ bias was approximately $+0.12 \pm 0.31$ mmole/l. Results for PO₂ were within 10% of the reference value. PO₂ bias was 7.5 ± 13.8 mm Hg.

The results of this clinical trial show that the CDI System 500 continuous in-line monitoring system provides values that meet the accuracy standards for laboratory analyzers for arterial pH, PCO₂, PO₂, and K⁺.

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INTRODUCTION

Obtaining accurate blood gas and electrolyte values has always been critically important to the clinician during cardiopulmonary bypass (CPB), thereby prompting the investigation of different methodologies to obtain them. The traditional laboratory analyzer, using an electrochemical technology to provide intermittent samples and/or on demand, has long been considered a "gold standard" for accuracy. Continuous in-line monitoring systems, by contrast, are based on a fluorometric and/or spectrophotometric technology that continuously monitor and display results.

One reservation about the acceptance of continuous in-line monitors is the perception that they do not meet the same accuracy standards for measuring blood gas and electrolyte parameters as laboratory analyzers. Because continuous in-line monitors use a different technology from that of conventional laboratory analyzers, comparing the accuracy of the two methods is more complicated than if both used the same technology. In both systems, however, the goal is the same: to provide clinically useful values for the blood gas parameters being measured to ensure the best available patient care will be delivered in a cost-effective way (1,2).

The purpose of the present study was to evaluate the accuracy of a new continuous in-line monitor, the 3M™ CDI™ Blood Parameter Monitoring System 500^a, by comparing it with the laboratory analyzers used at 4 clinical locations.

MATERIALS AND METHODS

CLINICAL SITES

Four clinical sites participated in a prospective 2 month clinical trial using the CDI System 500 to monitor blood parameter values during CPB procedures. The pH, PCO₂, PO₂, and K⁺ values for the CDI System 500 were compared with the values recorded by the standard laboratory analyzer used at each site. The 4 sites were St. Mary's Hospital, Mayo Clinic, Rochester, MN; Medical University of South Carolina, Charleston, SC; University of Nebraska Medical Center, Omaha, NE; and the University of Iowa Hospital and Clinics, Iowa City, IA.

MONITOR AND ANALYZERS

The following analyzers were used at the 4 sites: Nova Stat Profile 5^b, Instrumentation Laborato-

ries 1620^c, and Chiron 865^d.

The CDI system 500 is an AC-powered, microprocessor-based monitor which uses optical fluorescence technology with microsensors to measure pH, PCO₂, PO₂, and K⁺. The microsensors are contained in a disposable shunt sensor that can be placed in any shunt or purge line with continuous flow (Figure 1). A minimum blood flow of 35 ml/min is recommended for optimal performance of the shunt sensor. Blood gas parameters are displayed at either actual temperature or adjusted to 37°C.

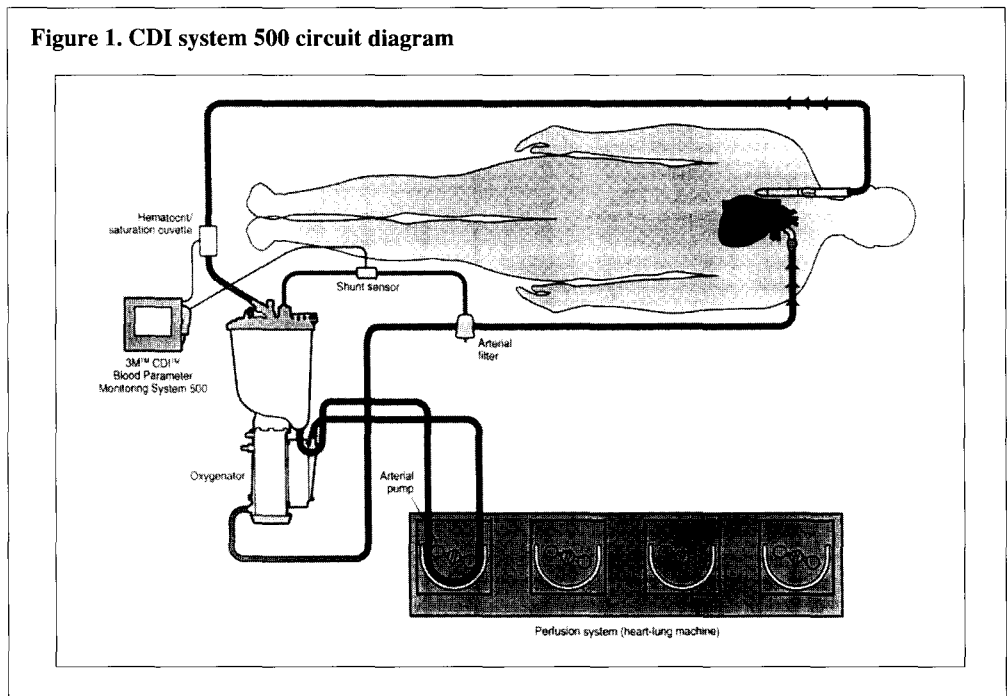
STUDY PROTOCOL

Following Institutional Review Board approval, and obtainment of informed patient consent where necessary, a prospective study was performed. Adult patients (18 years or older) undergoing cardiac surgery with CPB expected to last 1 hour or more were included. A minimum of 3 blood samples were collected with each patient serving as his or her own control.

The microsensors were calibrated according to the manufacturer's instructions. The pH, PCO₂, and PO₂ microsensors were automatically calibrated before each case using tonometered 2-point gases. The K⁺ microsensor was calibrated using the patient's blood K⁺ value as measured by the laboratory analyzer. This first K⁺ measurement was not included as a data point in the study results. When a blood sample was withdrawn, the blood parameter values displayed by the CDI System 500 were recorded. These recorded values were then com-

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- b Nova Biomedical Corporation, Boston Massachusetts 02154
- c Instrumentation Laboratories, Lexington, Massachusetts 02173
- d Chiron Diagnostics, Medfield, Massachusetts 02052

Figure 1. CDI system 500 circuit diagram



pared with the laboratory analyzer values.

STATISTICS

The overall performance of the CDI System 500 was analyzed by calculating the mean difference between the CDI System 500 values and the laboratory analyzer values. This difference is expressed as the bias. All data is expressed, unless otherwise specified, as the mean \pm the standard deviation of the mean. Clinically useful target values for the parameters were established using the acceptable performance standards from the Clinical Laboratory Improvement Act of 1988 (CLIA '88).

established in CLIA '88 (Table 2). The CLIA standards represent a commonly recognized method to monitor the proficiency of laboratory analyzers (3).

To date, no acceptable standard has been published for comparing the variance between a laboratory analyzer and a con-

Table 1: Statistical results of blood gas values for the CDI System 500 compared with laboratory analyzers

	pH (units)	PCO ₂ (mm Hg)	PO ₂ (mm Hg)	K+ (mmole/l)
Mean Difference (Bias)	0.00	-0.3	7.5	0.12
Standard Deviation	0.02	3.3	13.8	0.31
Number of Data Points	263	263	262	190

RESULTS

A total of 75 patients from the 4 clinical sites was included in the analyses. Data from all 4 sites, which included over 200 data points, were analyzed together. Table 1 shows a statistical summary of the data: the mean differences and standard deviations for pH, PCO₂, PO₂, and K+ of the CDI System 500 compared with the laboratory analyzers. Figures 2 through 5 display the results of the CDI System 500 blood parameter values compared with the lab analyzers for all 4 clinical sites.

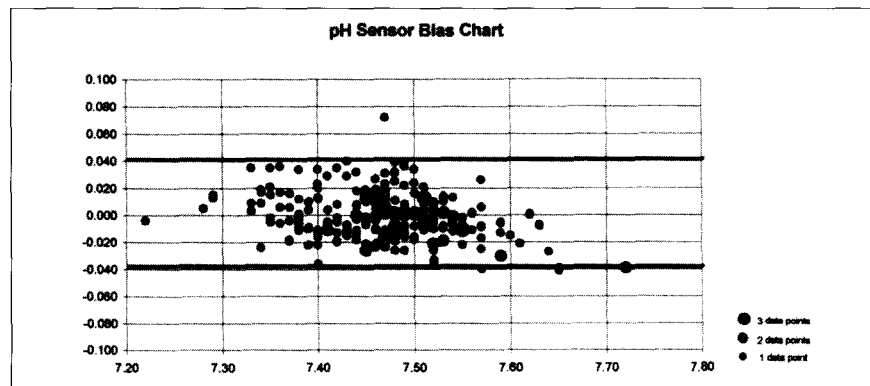
The CDI System 500 value for pH showed no bias when compared with the laboratory analyzer. The standard deviation was 0.02. The bias for PCO₂ was -0.3 mm Hg, with a standard deviation of 3.3. The bias for K+ was approximately + 0.12 mmole/l, with a standard deviation of 0.31. The bias for PO₂ was 7.5 mm Hg, with a standard deviation of 13.8.

DISCUSSION

The results of this clinical trial show that the CDI System 500 continuous in-line monitoring system provides values that meet the accuracy standards for laboratory analyzers for arterial pH, PCO₂, PO₂, and K+.

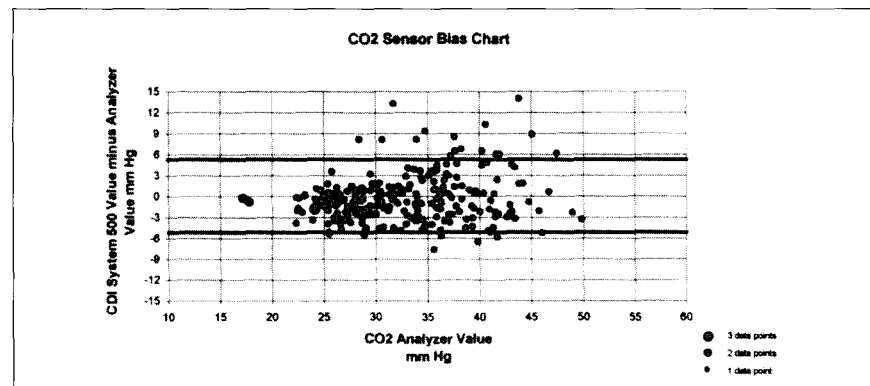
The bubbleplots for pH, PCO₂, and K+ (Figures 2-4) display clinically useful target values, based on standards es-

Figure 2: pH sensor bias chart



Each point represents the difference between the CDI system 500 value and the laboratory analyzer value (y-axis) referenced against the laboratory analyzer value (x-axis). Upper and lower limits of CLIA mean target values are represented by the pair of parallel lines across the data field.

Figure 3: CO₂ sensor bias chart



Each point represents the difference between the CDI system 500 value and the laboratory analyzer value (y-axis) referenced against the laboratory analyzer value (x-axis). Upper and lower limits of CLIA mean target values are represented by the pair of parallel lines across the data field.

tinuous in-line monitor. The CLIA '88 standards provide an industry-acceptable method to evaluate the variance between two laboratory analyzers. Therefore, we chose these standards as clinically useful target values with which to evaluate the CDI System 500 performance for pH, PCO₂, and K+. For pH, PCO₂, and K+, the variance between the CDI System 500 values and the laboratory analyzer values was within the target values established by CLIA '88.

For PO₂ values, the CLIA target value (see Table 2) could not be used because it represents a variable range (± 3 standard deviations) as opposed to a fixed interval (eg. ± 5 mm Hg). We therefore used $\pm 10\%$ of the reference, or laboratory analyzer, value to evaluate the performance of the PO₂ sensor. This value is based on information from the study by Mark et al, who concluded that a bias as high as 15% above arterial PO₂ values is of minor clinical importance (4). A bias of 7.5 mm Hg at typical arterial PO₂ values is less than 10% of the reference value.

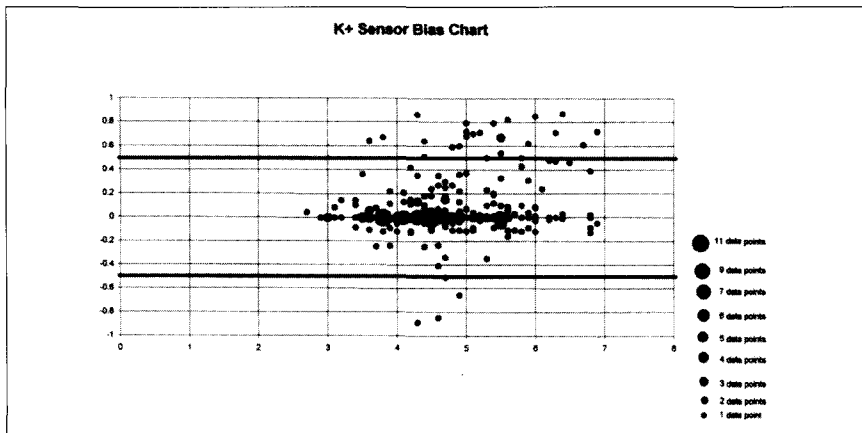
The overestimation in the PO₂ results is apparent. In earlier studies, it has been shown that at higher PO₂ values, the laboratory analyzer tends to underestimate PO₂ values (4,5). Therefore, in our study, the overestimation of PO₂ results may have less to do with the accuracy of the CDI System 500 than with the methodology used by the laboratory analyzer.

In conclusion, the results of this study provide evidence that values obtained by continuous in-line monitoring of the CDI System 500 are comparable in accuracy with those obtained by traditional laboratory analyzers. This study may therefore provide clinically useful comparisons of the two methodologies for clinicians evaluating the utility of continuous in-line monitoring during CPB.

ACKNOWLEDGEMENTS

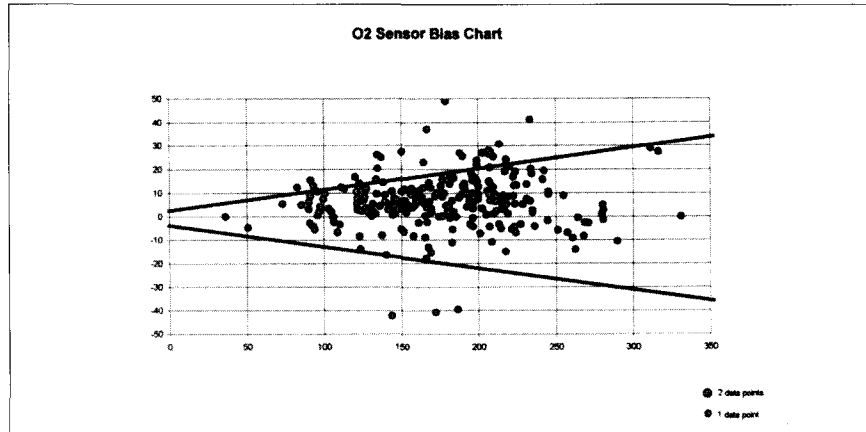
This study was funded in part by 3M Health Care Cardiovascular Systems, Ann

Figure 4: K+ sensor bias chart



Each point represents the difference between the CDI system 500 value and the laboratory analyzer value (y-axis) referenced against the laboratory analyzer value (x-axis). Upper and lower limits of CLIA mean target values are represented by the pair of parallel lines across the data field.

Figure 5: O₂ sensor bias chart



Each point represents the difference between the CDI system 500 value and the laboratory analyzer value (y-axis) referenced against the laboratory analyzer value (x-axis). The range of target values, defined by 10% of the laboratory analyzer value, is represented by the diverging lines across the data field; as PO₂ increases, the acceptable variance from the laboratory analyzer value increases.

Table 2: Comparison between CLIA '88 standards for laboratory analyzers and CDI System 500 results

Blood Gas Parameters	CLIA '88 Mean Target Values	CDI System 500 Bias ^a
pH	$\pm .04$ pH units	0.00 pH units
PCO ₂	± 5 mm Hg	-0.3 mm Hg
PO ₂	± 3 standard deviations	NA ^b
K+	± 0.5 mmole/l	0.12 mmole/l

^aSee Table 1.

^bNot applicable. See text for explanation of the comparable target value used for PO₂.

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