

## Original Article

# *Comparison of Blood Gas and Electrolyte Test Results From the Gem-Stat and CDI-300 Versus a Conventional Laboratory Analyzer*

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### ABSTRACT

Continuous blood gas monitoring devices have been an aid to the perfusionist since the introduction of the oxygen saturation meters of the early 1980s. Since that time, the perfusionist has had to decide between continuous versus intermittent sampling, and on-line (an analyzer that can automatically sample either at prescribed intervals and/or on demand) versus in-line devices (monitors that continuously sample and display results). This report compares the continuous, in-line CDI-300 blood gas monitor and the Mallinckrodt Gem-Stat blood gas analyzer using intermittent sampling with the Corning 278 blood gas analyzer and 2500 Co-Oximeter. Thirty samples were taken, one per 30 patients, for comparison. Five samples were disqualified from the study. When comparing the remaining 25, the Gem-Stat results to the Corning 278 blood gas analyzer results, all measured values (arterial pH, pCO<sub>2</sub>, pO<sub>2</sub>, venous pO<sub>2</sub>, Na, K and Hct) correlated >0.5000 with a p value of <0.001. The exception was the ionized calcium value which had a correlation of 0.2473 with a p value of <0.232. When comparing the CDI-300 results to the Corning 278 blood gas machine results, all measured values (pH, pO<sub>2</sub>, pCO<sub>2</sub> and venous pO<sub>2</sub>) correlated >0.5000 with a p value of <0.003 or better. When comparing the Gem-Stat results to the CDI results, all measured values (pH, pCO<sub>2</sub>, pO<sub>2</sub> and venous pO<sub>2</sub>) correlated >0.5000 with a p value of <0.002 or better.

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## INTRODUCTION

Since the introduction of the oxygen saturation meter, continuous, in-line blood gas monitors and intermittent or discrete sampling blood gas analyzers, many authors have reported the reliability and clinical outcome of using such devices. (1-6) For the most part, the correlations between the saturation meters and the laboratories' blood gas analyzers have been excellent ( $r > 0.8500$ ). (1-3) Baris, et al, concluded that the meters "may be useful for trending" (4) during cardiopulmonary bypass. One notable exception is a study done by Kaj Gefke, et al. (7) Dr. Gefke reported only fair agreement between the Bentley Gas-STAT<sup>a</sup> monitoring system GSM-100 and an ABL-2<sup>b</sup> blood gas analyzer with respect to  $pO_2$  and  $pCO_2$ . He found a poor correlation of pH values between the GSM-100 and the ABL-2.

The studies done with in-line, continuous blood gas monitors, comparing their results against laboratory blood gas machines, have likewise seen acceptable bias and precision in the measured parameters of pH (0.003/0.028),  $pCO_2$  (0.059/2.8) and  $pO_2$  (-7.1/44.7) (5) and favorable correlations ( $r > 0.9000$ ) for pH,  $pCO_2$  and  $pO_2$ . (6) When comparing the use of on-line blood gas analyzers with that of a laboratory blood gas analyzer, the reported correlations have been excellent ( $r > 0.9000$ ). (8)

The accuracy of the equipment measuring blood gases and electrolytes has always been a concern of the perfusionist. Are the results accurate and can the perfusionist depend on the results from these machines? This study was undertaken to evaluate the accuracy, reliability, consistency and biases of the CDI-300<sup>c</sup> and the Mallinckrodt Gen-Stat<sup>d</sup> when compared with the Corning 278 blood gas analyzer and 2500 Co-Oximeter<sup>e</sup>. The aforementioned study (8) compared the Gem-6<sup>d</sup> with the laboratory blood gas analyzers. This study utilizes the Gem-Stat analyzer. The only operational difference between the two is the sample size and time it takes to measure the sample. The Gem-6 uses 2.5 ml of blood and takes 2 minutes and 20 seconds to analyze, while the Gem-Stat uses 0.5 ml of blood and takes one minute and 50 seconds to analyze. The electrode system is exactly the same for both units.

## MATERIALS AND METHODS

This study consisted of 30 open heart procedures with one sample taken during each of the 30 procedures. Cases were disqualified from the study for the following reasons: one, if the CDI-300 sensor cell was not functioning and/or if it needed recalibration during bypass; two, the Corning 278 blood gas machine was not operational, and the samples sent to the laboratory were analyzed on a different model blood gas machine. Five cases were disqualified for one or both of the above reasons, which left us with 25 cases to be analyzed.

Each of the 25 cases included in the analysis utilized a roller pump<sup>f</sup> and custom tubing pack<sup>f</sup>, with an arterial filter<sup>g</sup>, which was continuously purged into the top of the oxygenator's filtered cardiomy<sup>f</sup>. Depending on the size of the patient, either

the Cobe Excell or Ultra membrane oxygenator<sup>f</sup> was used and primed with 2000 ml or 1600 ml of Normosol-R and 5% Dextrose<sup>h</sup>, respectively. Added to the prime was 2500 U of heparin, 25 mEq of  $NaHCO_3$  and 1.5 mg of phenylephrine per 1000 ml. Packed cells were added to the prime if the post-dilutional hematocrit was anticipated to be less than 20%, or if the hematocrit fell below 20% during bypass.

Blood gas data was charted from the CDI-300 simultaneously with the collection of blood gas samples to be analyzed by the Gem-Stat and Corning blood gas machines. There is an inherent phase lag in continuous monitoring sensors and this equilibrium time lag could affect the accuracy of reporting results. Therefore, samples were drawn in a cardiopulmonary bypass steady-state condition (i.e., no changes being made in gas or blood flow, or temperature within the past five minutes). (9) Two samples each of arterial and venous blood were drawn immediately one after the other during this steady bypass state. The samples collected for analysis by the Gem-Stat analyzer were run immediately in the operating room (OR) suite by the perfusionist. The samples collected for analysis by the Corning 278 blood gas analyzer were placed on ice and sent to the laboratory by runner. All samples were analyzed within five minutes upon delivery to the laboratory, and reported within five minutes by phone to the OR suite. The results reported are uncorrected for temperature (i.e., Alpha-stat technique).

The data was analyzed using a statistical package developed for micro-computers<sup>i</sup>. A correlation and p-value was used to compare: 1) the Corning 278 blood gas and electrolyte values with the Gem-Stat values, 2) the Corning 278 values with the CDI-300 values, and 3) the Gem-Stat data with the CDI-300 data.

## RESULTS

Of the 30 patients studied, five were disqualified from the study because recalibration of the CDI sensors was necessary. Recalibration of the pH value was needed four times during this study when the pH value was off by  $> 0.05$  pH units. Recalibration was necessary one other time when the venous  $pO_2$  reading was  $> 100$  mmHg. This left 25 patients in the study; 12 patients were male, 13 patients were female. Twenty-three patients underwent aorto-coronary bypass. Of the two remaining patients, one underwent aortic valve replacement and the other received a mitral valve replacement. The average age of the patients was 66.76 years, with a minimum of 38 years and a maximum of 82 years. The average weight of the patients was 74.32 kg, with a minimum

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- a American Bentley, Irvine, CA 92714
  - b Radiometer, DK-2400, Copenhagen, Denmark
  - c CDI, 3M Health Care, Irvine, CA 92714
  - d Mallinckrodt Sensor Systems Inc., Ann Arbor, MI 48108
  - e Corning Medical and Scientific, Medfield, MA 02052
  - f Cobe Laboratories Inc., Arvada, CO 80004
  - g Pall Biomedical Inc., Fajardo, Puerto Rico 00648
  - h Abbott Laboratories, North Chicago, IL 60064
  - i Number Cruncher Statistical System, Kaysville, UT 84037

**Table 1**  
**Comparison of the Corning 278 and the Gem-Stat Values**

SD=Standard Deviation; N=Number of events; pCO<sub>2</sub>, pO<sub>2</sub>, venous pO<sub>2</sub> (VpO<sub>2</sub>) and venous saturation (Vsat) are expressed in mmHg; bicarbonate (HCO<sub>3</sub>), Sodium (Na), Potassium (K) and ionized calcium (Ca) are all expressed in mmol/L; hematocrit (Hct) is expressed as a percent.

	<b>Corning 278 Mean ± SD</b>	<b>Gem-Stat Mean ± SD</b>	<b>p value</b>	<b>Correlation</b>	<b>N</b>
pH	7.39 ± .05	7.39 ± .05	p<0.001	0.8993	25
pCO2	37.6 ± 3.0	35.8 ± 3.1	p<0.001	0.9302	25
pO2	212.4 ± 34	204.3 ± 37	p<0.001	0.9604	25
VpO2	43.5 ± 5.2	39.7 ± 5.8	p<0.001	0.8673	25
Vsat	77.9 ± 6.4	71.5 ± 8.6	p<0.001	0.9260	25
HCO3	22.8 ± 1.7	21.9 ± 2.1	p<0.001	0.7954	25
Hct	23.0 ± 4.7	22.5 ± 3.7	p<0.001	0.6895	25
Na	128.7 ± 3.5	131.9 ± 4.0	p<0.001	0.6223	25
K	3.8 ± .77	4.1 ± .65	p<0.001	0.6226	25
Ca	.82 ± .07	.97 ± .09	p<0.232	0.2473	25

**Table 2**  
**Comparison of the Corning 278 and the CDI-300 Values**

SD=Standard Deviation; N=Number of events; pCO<sub>2</sub>, pO<sub>2</sub>, venous pO<sub>2</sub> (VpO<sub>2</sub>) and venous saturation (Vsat) are expressed in mmHg; bicarbonate (HCO<sub>3</sub>) is expressed in mmol/L

	<b>Corning 278 Mean ± SD</b>	<b>CDI-300 Mean ± SD</b>	<b>p value</b>	<b>Correlation</b>	<b>N</b>
pH	7.39 ± .05	7.42 ± .06	p<0.001	0.8916	25
pCO2	37.6 ± 3.0	34.4 ± 3.1	p<0.001	0.7087	25
pO2	212.4 ± 34	218.1 ± 50	p<0.001	0.8960	25
VpO2	43.5 ± 5.2	49.0 ± 6.2	p<0.001	0.8188	25
Vsat	77.9 ± 6.4	83.0 ± 5.2	p<0.001	0.7480	25
HCO3	22.8 ± 1.7	22.5 ± 2.6	p<0.003	0.5716	25

**Table 3****Comparison of the Gem-Stat and the CDI-300 Values**

SD=Standard Deviation; N=Number of events; pCO<sub>2</sub>, pO<sub>2</sub>, venous pO<sub>2</sub> (VpO<sub>2</sub>) and venous saturation (Vsat) are expressed in mmHg; bicarbonate (HCO<sub>3</sub>) is expressed in mmol/L

	<b>Gem-Stat Mean ± SD</b>	<b>CDI-300 Mean ± SD</b>	<b>p value</b>	<b>Correlation</b>	<b>N</b>
pH	7.39 ± .05	7.42 ± .06	p<0.001	0.8625	25
pCO <sub>2</sub>	35.8 ± 3.1	34.4 ± 3.1	p<0.002	0.5932	25
pO <sub>2</sub>	204.3 ± 37	218.1 ± 50	p<0.001	0.9101	25
VpO <sub>2</sub>	39.7 ± 5.8	49.0 ± 6.2	p<0.001	0.7755	25
Vsat	71.5 ± 8.6	83.0 ± 5.2	p<0.001	0.6804	25
HCO <sub>3</sub>	21.9 ± 2.2	22.5 ± 2.6	p<0.011	0.4961	25

of 53 kg and a maximum of 106 kg.

Table 1: The pH, pCO<sub>2</sub>, pO<sub>2</sub>, VpO<sub>2</sub> and Vsat all showed good correlations (>0.8000) with a p value of <0.001. The correlation for HCO<sub>3</sub>, Hct, Na and K all were fair (>0.5000) with p values of <0.001. The ionized Ca showed a poor correlation (0.2473) and a p value of <0.232.

Table 2: The pH, pO<sub>2</sub> and VpO<sub>2</sub> all showed good correlations (>0.8000) with a p value of <0.001. The pCO<sub>2</sub> and the Vsat showed fair correlations (>0.5000) with p values of 0.001. The correlation value for the HCO<sub>3</sub> was 0.5716 with a p value of <0.003.

Table 3: The pH and pO<sub>2</sub> showed a good correlation (>0.8000) with a p value of <0.001. The pCO<sub>2</sub>, VpO<sub>2</sub> and Vsat showed a fair correlation (>0.5000) with a p value of <0.001. The HCO<sub>3</sub> bordered on a fair correlation of 0.4961 with a p value of <0.011.

## DISCUSSION

As stated in the introduction of this paper, the purpose of this study was to determine the accuracy, reliability, consistency and biases of the Gem-Stat and CDI-300 when evaluated with the Corning 278 blood gas analyzer. Accuracy has been discussed in the above results section of this paper, and has been summarized in table form (see Tables 1-3).

The reliability of the Gem-Stat was excellent. There was no down time during this evaluation, nor did we experience any failed cartridges. Quality control tests (QC) at all three levels were done every day according to the recommendations of the manufacturer, and all of the QC results fell into the expected ranges for all measurements.

The reliability of the CDI-300 was not as good as that of the Gem-Stat. During this study there were four times that the pH electrode failed and needed to be recalibrated, and once the venous pO<sub>2</sub> electrode failed and needed recalibration. At this point we felt that we could not make a valid clinical decision regarding the acid/base or venous pO<sub>2</sub> status of the patient, the cell was recalibrated, and the case was disqualified from the study. It was obvious when the CDI monitor was not working properly and could not be relied upon to give accurate results. The times that the cells are not functioning accurately and were in need of recalibrations were obvious to us, and we would verify the readout of the monitor with a sample drawn and sent for analysis. Based on our experience with this equipment, we know what range to expect from the CDI-300 monitor. When the accuracy is questionable, then a sample is drawn and analyzed on a blood gas machine.

The Gem-Stat blood gas values and hematocrit were consistently lower than the Corning 278. The Gem-Stat electrolyte measurements were consistently higher than the Corning 278. This is what we called the bias of the analyzer. The Gem-Stat was consistently biased, lower in the areas of blood gases and hematocrit and higher in the area of electrolytes, without exception. We could depend on this bias. If the Gem-Stat K value was in the low end of normal (3.5 - 3.7 mmol/L) we felt that this warranted the administration of KCl. The Gem-Stat results for K are, on the average, 0.3 mmol/L higher than the Corning 278.

The CDI-300 blood gas values were consistently higher than the results from the Corning 278 (higher than the Gem-Stat also). The exception was the pCO<sub>2</sub>. The CDI-300 pCO<sub>2</sub> values were consistently lower than those of the Corning 278 (lower than the Gem-Stat also). Again, this bias was consistent through-

out this study. We adjusted our  $\text{FiO}_2$  and gas flows to give us a  $\text{pCO}_2$  of 35-40 mmHg and a  $\text{pO}_2$  of 200 mmHg  $\pm$  10 mmHg as monitored by the CDI-300. On the average, the CDI-300  $\text{pCO}_2$  values were consistently 3.2 mmHg lower than the Corning 278 and the  $\text{pO}_2$  values were consistently 6 mmHg higher. Since the venous  $\text{pO}_2$  ( $\text{VpO}_2$ ) and the venous saturations ( $\text{Vsat}$ ) are the only venous values that were used to make adjustments in our perfusion parameters, these were the only values analyzed in this study.

Currently, we are using both the Gem-Stat and the CDI-300 in our OR. We feel comfortable using the CDI-300 for trending and making adjustments in our  $\text{FiO}_2$  and gas flows using the results from the readout on the monitor. Since the  $\text{HCO}_3^-$  results of the CDI-300 monitor demonstrated only a fair correlation (0.5716) with the Corning 278, we confirm the patient's acid/base status with a sample analyzed by the Gem-Stat. When the Gem-Stat hematocrit measurement reads  $<20\%$  we will administer a unit of packed red blood cells. By using the CDI-300 we are able to minimize the necessity of drawing and analyzing samples on a blood gas machine. When drawing and analyzing a sample is warranted, we use the Gem-Stat blood gas analyzer in the OR. Although it has not been necessary to do so, if we have reason to question the results we get from the Gem-Stat, we are free to send a sample to the laboratory to confirm its accuracy. Knowing the accuracy, reliability, consistency and bias of these machines is invaluable information for the safe conduct of cardiopulmonary bypass.

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