

**Original Article**

***Clinical Evaluation of the CDI-100 In-Line Hematocrit/  
Saturation Monitor***

Howard G. Walton, BA, CCP; David Boucher, BS, CCP; Dan Linne, CCP

Memorial Medical Center, Modesto, California

Keywords: cardiopulmonary bypass, saturation meter/monitor, blood gas analyzer, recalibration

**ABSTRACT**

This study was undertaken to evaluate the accuracy, reliability, consistency and biases of the CDI-100 saturation monitor when compared with a blood gas analyzer. The advantage of continuous in-line monitoring is that the perfusionist has continuous updates as to the patient's changing physiologic state. During this study, if the sample readout of the CDI-100 was off by greater than 10% from that of the Gem-Premier, the CDI-100 parameter was recalibrated. The accuracy of the CDI-100 was fair (greater than 10% of the samples needed recalibration) with regards to the initial sample comparisons. Recalibration was needed 67% of the time for the hematocrit and 35% for the saturation. The reliability of the CDI-100 was good (no equipment failure). The CDI-100 was consistent. It consistently overestimated both the hematocrit and saturation. This overestimation is the bias of the monitor. We recommend recalibration of the CDI-100 during clinical use to insure greater accuracy.

Address correspondence to:  
Howard G. Walton, CCP  
Department of Surgery  
Memorial Medical Center  
1700 Coffee Road  
Modesto, CA 95355

**Table 1: Summary of patient data**

Variable			
Sex	Male = 40	Female = 9	Total = 49
Age (years)	Mean = 65.4 ± 10	Max = 85	Min = 42
Weight (Kg)	Mean = 83.5 ± 14.5	Max = 121	Min = 56
Procedures	ACB = 46	Valves = 2	Valve + ACB = 1
Time between samples (minutes)	Mean = 63 ± 26.7	Max = 137	Min = 22

Note: Where applicable, all data are shown as the mean ± standard deviation. ACB = Aorto-coronary bypass.

## 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 (1–7). For the most part, the correlations between the saturation meters and laboratory blood analyzers have been excellent (1–3). Baris, et al, concluded that the meters “may be useful for trending” during cardiopulmonary bypass (4). 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.

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. Svenmarker et al concluded that the CDI-400 blood gas monitor makes cardiopulmonary bypass a procedure based on trend information, rather than a scattered feedback from a laboratory blood gas analyzer (8). Whereas most authors find the correlations acceptable, none suggest the total replacement of routine off-line use of a blood gas machine.

The new generation of venous saturation monitors also measure hematocrit. These monitors have demonstrated acceptable correlations and precision (9–11). Niles et al found that the Cobe monitor was the most accurate among the units tested (9). Whereas, Yaskulka et al, concluded that the CDI-100 “to be more accurate, reliable, and consistent” than the other devices tested (10). Others have gone as far as to even suggested that these devices should be the “standard of care” (12) and “essential” (13) for the perfusionist.

How accurate are the results displayed on the monitors, and can the perfusionist depend on these results? The accuracy of the equipment has always been a concern for the perfusionist. This study was undertaken to evaluate the accuracy, reliability, consistency and biases of the CDI-100<sup>c</sup> when compared with the Mallinckrodt Gem-Premier<sup>d</sup> blood gas analyzer.

a Baxter Healthcare Corp., Mill Valley, CA 94941

b Radiometer, DK-2400, Copenhagen, Denmark

c CDI, 3M Health Care, Irvine, CA 92714

d Mallinckrodt Sensor System Inc., Ann Arbor, MI 48108

## MATERIALS AND METHODS

This study consisted of 49 open heart procedures with two samples taken during each of the 49 procedures. The CDI-100 has the capability of storing data for later recalibration of the monitor should that be necessary. During our study the saturation (Sat) and hematocrit (Hct) values were internally stored and simultaneously charted for later recalibration upon the draw of a blood gas sample to be analyzed by the Gem-Premier blood gas analyzer. 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 5 minutes) (14). One sample was drawn after cooling and one sample was taken after the patient was warm. The mean time between the drawing of the cool sample and the drawing of the warm sample was 63 minutes. The samples collected for analysis were run immediately in the operating room (OR) suite by the perfusionist using the Gem-Premier analyzer. The results reported are uncorrected for temperature (i.e., Alpha-Stat technique). If the first sample readout of the CDI-100 was off by greater than 10% from that of the Gem-Premier results, that particular parameter of the CDI-100 was recalibrated and noted.

The data was analyzed using a statistical package developed for microcomputers<sup>e</sup>. The p-value and Standard Deviation (SD) was used to compare the CDI-100 Hct and Sat data with that of the GemPremier values (Table 2).

## RESULTS

A paired T-test was used to analyze the 98 Hct samples (49 after cooling and 49 after warming) of the CDI-100 and Gem-Premier. There was statistical difference ( $p < 0.001$ ) between the Hct values of the CDI-100 when compared with those of the GemPremier. The Hct values of the CDI-100 were consistently higher (over estimated).

Of the 49 initial samples taken after cooling, 67% ( $n = 33$ )

e Number Cruncher Statistical System, Kaysville, UT 84037

**TABLE 2: Comparison of the CDI-100 and Gem-Premier values**

Variable	CDI-100	Gem-Premier	n/% of Total	p-Value
Hematocrit	25.03 ± 3.9	22.83 ± 3.6	98/100%	p < 0.001
Saturation	74.60 ± 8.1	68.85 ± 8.6	98/100%	p < 0.001
Re-cal Hct.	21.90 ± 2.9	21.93 ± 2.6	33/67%	NS
Re-cal Sat.	60.26 ± 16.3	63.47 ± 5.8	17/35%	NS
No-cal Hct.	24.94 ± 3.1	22.38 ± 2.9	16/33%	p < 0.001
No-cal Sat.	71.0 ± 4.0	63.06 ± 6.6	32/65%	p < 0.001

Note: Where applicable, all data are shown as the mean ± standard deviation. Re-cal Hct. = CDI-100 hematocrit values that were recalibrated; Re-cal Sat. = CDI-100 saturation values that were recalibrated; No-cal Hct. = CDI-100 hematocrit values that were not recalibrated; No-cal Sat. = CDI-100 saturation values that were not recalibrated.

of the Hct values were off by greater than 10% and were recalibrated. Of the warm samples taken after recalibration, 90.9% (n = 30) of the Hct values were within the 10% accuracy range. There was no significant difference between the recalibrated (re-cal) CDI-100 Hct and the GemPremier Hct. Sixteen Hct samples (33%) needed no recalibration. The warm samples in this group had only 31.2% (n = 5) that fell within the 10% accuracy range.

A paired T-test was used to analyze the 98 Sat (49 after cooling and 49 after warming) samples of the CDI-100 and GemPremier. There was statistical difference (p < 0.001) between the Sat values of the CDI-100 when compared with those of the Gem-Premier. The Sat values of the CDI-100 were consistently higher (over estimated).

Of the 49 initial samples taken after cooling, 35% (n = 17) of the Sat values were off by greater than 10% and were recalibrated. After recalibration, all 17 warm values (100%) were within the 10% accuracy range. There was no statistical difference between the re-cal Sat samples of the CDI-100 and the Sat values of the Gem Premier. Of those Sat samples (n = 32) that needed no initial recalibration, only 43.8% (n = 14) were within 10% accuracy range upon remeasurement after warming. There were 56.2% (n = 18) that fell out of the 10% accuracy range after measurement. Although there was no statistical significance in the data that was out by greater than 10%, we felt that greater than 10% accuracy range was not acceptable in our practice and chose to recalibrate the probe/monitor. Of those samples that needed no re-cal initially (cool sample), there was significant difference at the end of bypass when comparing the warm samples. This was true of both the Hct and Sat.

## DISCUSSION

The greatest advantage to continuous in-line monitoring is that the perfusionist has continuous updates as to the patient's

rapidly changing physiologic state. These devices can help the perfusionist make appropriate decisions regarding patient management. The monitors have not attained the level of accuracy to base clinical decisions on. They can, however, alert the perfusionist of rapid trends in the patient's physiologic condition. For example, if the patient's Hct, according to the in-line monitor, has been falling, and volume is anticipated, a blood sample can be drawn and blood sent for before the volume is actually needed. This allows the perfusionist to look beyond the immediate situation and plan his course of action ahead of time.

The combination of a Sat and Hct reading allows the perfusionist to balance oxygen delivery with tissue demands, and blood bank utilization. This is extremely helpful during difficult cases when metabolic fluctuations, oxygen demand, and fluid changes become a challenge to the perfusionist.

As mentioned in the introduction of this report, it was our purpose to study the accuracy, reliability, consistency, and biases of the CDI-100. The accuracy of the CDI-100 was fair (>10% of the initial samples needed recalibration). By our protocol, the Hct needed re-cal 67% of the time, but the results after re-cal were accurate 91% of the time when the warm sample was compared. Of the Hct samples that did not require initial re-cal, only 31.2% were accurate by the warm sample. The same trend was seen with the Sat measurements. All re-cal Sat values were within accuracy range. If no re-cal was needed, only 43.8% were within range. The samples that needed no initial re-cal were significantly different upon remeasurement toward the end of bypass.

The reliability of the CDI-100 was good. We did not experience any failed or damaged cubets that prevented us from using the CDI-100 monitor. There were no failed in-vitro calibrations or down time. The equipment performed as specified by the manufacturer.

The CDI-100 was consistent in that it always overestimated both the Hct and Sat. The Hct was overestimated to a greater extent and more often than the Sat. This demonstrates the bias of the monitor. The CDI-100 bias is to overestimate the Hct by greater than 10%, and to do that 67% of the time. Niles et al. found in their study that, on the average, the Hct was overestimated and that this tendency is exaggerated at Hct below 15% (9). The Sat is overestimated by greater than 10% only 35% of the time. In contrast to our study, Yaskulka et al. found that both Hct and Sat stayed within a +/-5% range about the zero line over all evaluated parameters that they measured (10).

It is interesting to note that after re-cal the accuracies of both the Hct and Sat greatly improve (91% and 100% respectfully). It is also interesting to note that if the initial reading falls within the 10% accuracy range, the final reading is only accurate 31% of the time for Hct, and only 44% of the time for Sat. Our recommendation is, therefore, to recalibrate the CDI-100 monitor after a stable by-pass is established. Recalibration will insure greater accuracy with the use of the CDI-100 monitor.

**REFERENCES**

1. Iatridis A, Heinemann S, DeRocher R, Osborn R. Continuous monitoring of blood oxygen saturation during extracorporeal circulation. *J Extra-Corpor Technol.* 1981;13: 233–236.
2. Riley JB, Young MR, Kauffman JN, et al. In line oxygen saturation monitor. *J Extra-Corpor Technol.* 1983;15:54–58.
3. Harloff M and Palen S. Bentley Gas-Sat: Our clinical experience. *Proceedings, Am Soc Extra-Corpor Technol.* 1986;18:46–48.
4. Baris RR, Wilt SL, Schiavo J, Klobus JJ, Mcafee T. Clinical evaluation of the Oxysat 2 monitoring system. *Proceedings, Am Soc Extra-Corpor Technol.* 1988;52–55.
5. Bash JW, Sternlieb JJ, Bjork VO, et al. Clinical evaluation of Cardiomet 4000 continuous on-line blood gas analyzer. *Proceedings, Am Soc Extra-Corpor Technol.* 1988;48–51.
6. Hill AG, McNair E, Vinansky RP, et al. Blood gas monitoring—Current status. *Proceedings, Am Acad Cardiovasc Perfusion.* 1987;8:120–126.
7. Gefke K, Waaben J, Andersen LI, et al. An investigation of the Bentley Gas-Sat monitoring system GSM-100. *J Extra-Corpor Technol.* 1988;20;59–62.
8. Svenmarke S, Lindholm R, Haggmark S, et al. Clinical evaluation of the CDI System 400 blood gas monitor. *Perfusion.* 1994;9:71–76.
9. Niles S, Cronbaugh R, Engle J, et al. Evaluation of Five In-line hematocrit monitors. *J Extra-Corpor Technol.* 1995;27:24–28.
10. Yaskulka S, Burnside J, Bennett D, et al. Accuracy of In-line venous saturation and hematocrit monitors in pediatric perfusion. *J Extra-Corpor Technol.* 1995;27:132–136.
11. Miller M. Clinical Evaluation of a New Saturation/Hematocrit Monitor. *J Extra-Corpor Technol.* 1992;24: 55–57.
12. Ferries L. Standards of care in perfusion: Should not continuous In-line blood gas monitoring be one? *J Extra-Corpor Technol.* 1992;24:45–48.
13. Rubsamen D. Continuous blood gas monitoring during cardiopulmonary bypass—how soon will it be the standard of care? (Editorial). *J CardioThor Anes.* 1990;4:1–4.
14. Riley JB, Fletcher RW, Jenusaitis M, et al. Comparison of the response time of various sensors for continuous monitoring of blood gases, pH and O<sub>2</sub> saturation during cardiopulmonary bypass. *Proceedings, Am Acad Cardiovasc Perfusion.* 1987;8:1–5.