Clinical Evaluation of Cardiomet 4000 Continuous On-Line Blood Gas Analyzer

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Abstract

PURPOSE: Clinically evaluate a new, continuous, on-line blood gas analyzer, Cardiomet 4000, for accuracy, safety, user friendliness.

METHOD: 32 patients undergoing cardiopulmonary bypass were randomly selected. Approximately 105 blood samples were drawn and analyzed by the hospital blood-gas laboratory. The Bentley Gas Stat was used as an on-line reference. The parameters of the C4000 and BGS were recorded simultaneous to the drawing of blood samples. Calibration times and sensor insertion procedures were noted. Lab results were evaluated for bias and precision (B/P). The bias of both in-line systems was subject to a student's t-test analysis for significance.

RESULTS: Significant level = 0.001

Device	pH Bias/Precision	pCO_2 B/P	pO_2B/P
C4000	0.003/0.028	0.059/2/8 mmHg	−7.1/43.7 mmHg
BGS	**0.28/0.505	*0.13/4.4 mmHg	**29.5/44.7 mmHg

*not significant **significant

Daily cal. time C4000 5 min. Full cal. time 15 min. (apx. once/wk.) Design of C4000 connector allows for sensor insertion and removal during CPB.

CONCLUSION: The C4000 demonstrated a clinically acceptable bias and precision in the measured parameters pH, pCO_2, pO_2 and required minimal calibration and set-up time during daily use. The C4000 stainless steel reinforced gas/ion window design provides a pressure barrier (17PSI) thus: A) allows for sensor calibration verification at any time, B) allows for sensor insertion after onset of CPB in emergency applications, C) eliminates sensor placement as requirement for membrane integrity.

Introduction

The need for automating and centralizing the extracorporeal circuit has been well documented.[1,2] One such level of automation/centralization is the use of continuous on-line blood gas analysis. (CLBGA)[3,4,5,6]

Currently available CLBGA systems have several disadvantages: A) they do not provide the user a means to verify the calibration during operation, B) are sensitive to acetate containing priming solutions at low pH and high pCO_2 levels, causing permanent offset of the pCO_2 sensor values,[7] and C) pose a potential safety hazard in that proper sensor placement is a requirement for gas ion permeable membrane integrity.*

A new CLBGA system, the Cardiomet 4000[a] (C 4000) from Biomedical Sensors Incorporated was evaluated in the clinical setting for accuracy, safety, reliability and ease of operation. The C4000 pH and pCO_2 system is based on absorbance technology. The indicator dye phenol red behaves as a weak acid and exists in two tautomeric forms, each having a different light absorption spectrum. As the pH varies, the relative size of each tautometer's optical absorption peaks varies in proportion to the changing concentrations of the acid and base forms of the dye. Therefore, changes in the optical absorption of the phenol red dye measure changes in pH or pCO_2.[8] The pO_2 sensor of the C4000 uses electrochemical technology (Clark type electrode).[9,3]

Materials and Methods

Thirty-two patients undergoing cardiopulmonary bypass (CPB) for myocardial revascularization were randomly selected. Patient population consisted of 21 males, 11 females with an average age of 72 (range 63–81) and average weight of 73 kilograms (ranges 47–

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Table 1.

Patient Population

32 PATIENTS	
MALES	21
FEMALES	11
AVG. AGE (RANGE 63 - 81 YRS.)	72 YRS.
AVG. WT. (RANGE 47 - 92 kg.)	73 kg.

92) (Table 1). The Bentley Gas Stat[b] (BGS) was used as an on-line reference. The C4000 and BGS connectors were placed sequentially in the arterial line just proximal to the arterial line filter. Samples sent to the hospital laboratory were drawn from the purge of the arterial line filter (Diagram 1) and measured on the Corning 178.[c] All results were reported at 37.0°C. Simultaneous to drawing the samples n = 112, values from both systems were recorded. Samples were drawn at predetermined intervals that divide into four groups: stable at 37.0°C., cooling,** warming,*** and stable at less than 32°C. The results were evaluated for bias and precision,[10] and the bias of both systems subjected to a student's t-test analysis for significance. The bias is defined as the mean difference between the CLBGA values and the laboratory reported values.

Results

The recorded values from the C4000 system for pH, pO_2 and pCO_2 are illustrated in Figure 1. Notably, the bias and precision of the C4000 values for pH, pCO_2 and pO_2 were within clinically acceptable ranges in all of the subdivided temperature groups, with no intra-group significant variation. Figure 2 reports the cumulative data for the C4000 and BGS. The collective values for pH and pO_2 showed statistically significant differences (significance level 0.001) in the C4000 and BGS values, with a significantly lower bias shown by

b Bentley Labs, Irvine, CA 92714.

c Corning Medical Instruments, Palo Alco, CA 94306.

**Cooling defined as an active reduction in blood temperature.

***Warming defined as an active increase in blood temperature.

Diagram 1.

C4000 and BGS Connectors In-Line and Sampling Site

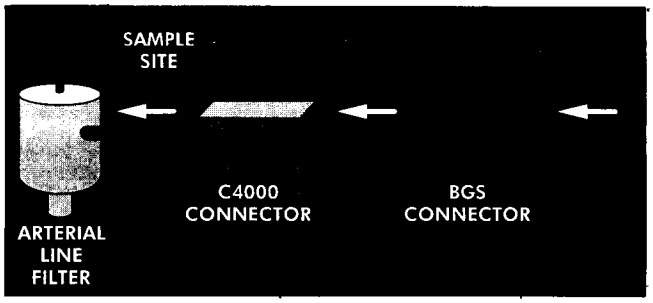
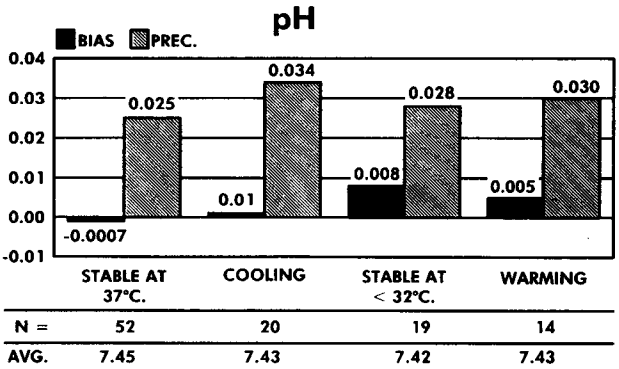
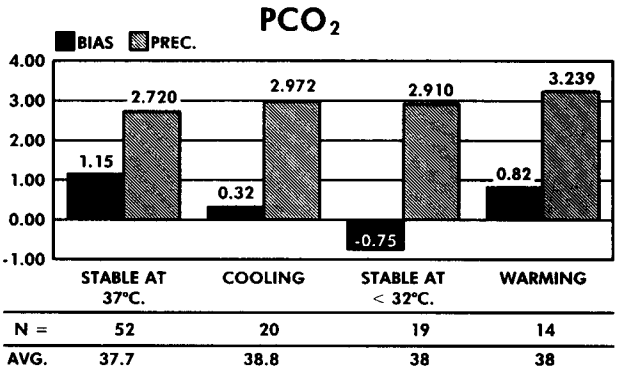


Figure 1.

pH, pCO_2 and pO_2 Values of C4000 at Four Temperature Groups





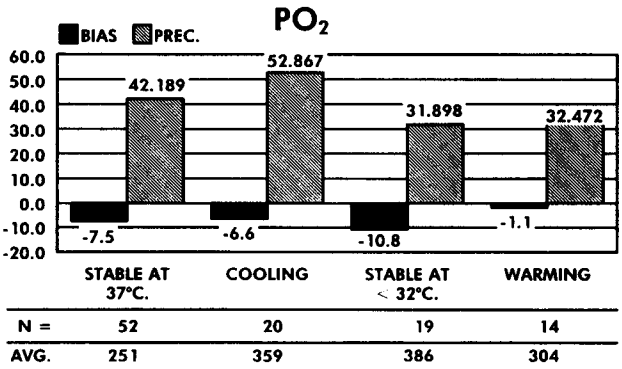
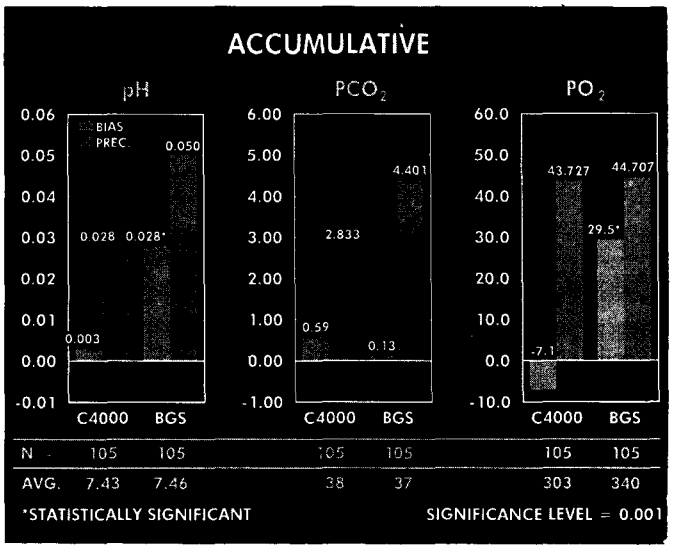


Figure 2.

Accumulative Data for C4000 and BGS



the C4000. Six cases were omitted from the study: two cases the battery of the BGS was discharged, two cases of pCO_2 sensor failure, one case the BGS could not be calibrated to specification and one emergency procedure where time constraints did not allow for BGS calibration. However, the C4000 was used relying on the previous day's calibration and the values for that case are presented in Table 2.

Remarkably, the values contained in Table 2 are all within clinically acceptable ranges, indicating that the C4000's memory stored calibration constants allow for clinically acceptable monitoring based on the previous day's calibration. Additionally, calibration of the C4000 required minimal time, approximately five minutes for a daily calibration and approximately 15 minutes per week for a full calibration. The C4000 does not require case-to-case full calibration and has no other associated hardware. Instead, calibration solution is stored in (CALPODS). The sensors can be inserted into the (CALPODS) at any time, and single sensor calibration or calibration verification can be performed.

Additionally, the C4000 incorporates a nonvolatile memory allowing the system to be turned off without loss of calibration constants and can be operated on battery or line power. The connector of the C4000 (Diagram 2) has three chambers for insertion of the sensors. The gas/ion windows provide a pressure barrier of 17 psi allowing for insertion and removal of the sensors at any time during the procedure.

This feature is paramount in emergency applications, or when single sensor calibration verification is desired. Sensor placement is not necessary for maintenance of gas/ion window integrity during either priming or CPB. The 4000 connectors have a shelf life of two years limited by sterilization and are not sensitive to light, acidic priming solutions or exposure to high pCO_2 commonly found in CO_2 primed systems.[7]

Table 2.

Emergency Procedure C4000 Calibrated 24 Hours

EMERGENCY PROCEDURE				
	SAMPLE 1		SAMPLE 2	
	CARDIOMET 4000	HOSP. LAB	CARDIOMET 4000	HOSP. LAB
pH	7.48	7.48	7.44	7.42
PCO_2	40.7	40	41.8	38.5
PO_2	208	262	277	273
TEMP	37	37	37.5	37.5
	SAMPLE 3		SAMPLE 4	
	CARDIOMET 4000	HOSP. LAB	CARDIOMET 4000	HOSP. LAB
pH	7.46	7.44	7.48	7.48
PCO_2	41.8	39	40.7	40
PO_2	323	313	208	262
TEMP	38	38	37	37

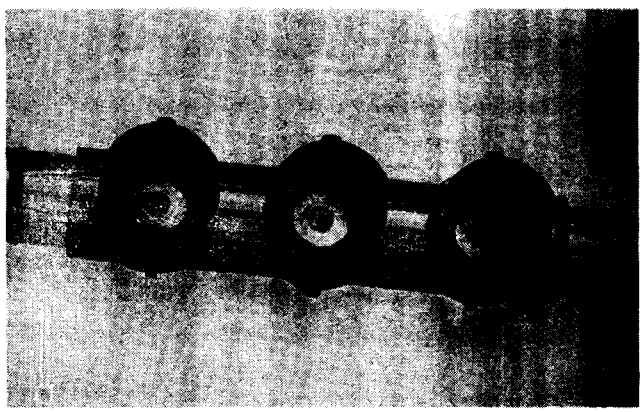
Discussion

It has been described that even with a highly trained staff using blood gas analyzers meeting quality control standards, intermittent errors of clinical significance occur, at times frequently.[11]

In review, CLBGA provides the perfusionist with real time, on-line, continuous information, thereby eliminating the potential for laboratory analysis error, and circumvents unnecessary, unwanted time delays in obtaining clinical parameters.[6] Additionally, CLBGA

Diagram 2.

C4000 Connector—Gas/Ion Windows



allows the perfusionist to maintain blood gas parameters at physiologic levels and avoids the risks of sampling error, contamination of the sampling site, handling error, and receipt of erroneous results.

The data presented in this evaluation shows that the C4000 CLBGA system has a clinically acceptable bias and precision for the measured parameters PH, pCO_2 and pO_2 within the dynamic environment of CPB. The C4000's unique connector design provides stainless steel reinforced gas/ion windows pressure tested to 17 psi. Therefore, single or multi-sensor calibration verification can be performed at any time, and the need for one point calibration to the external laboratory deleted, helping bring complete consolidation of the CPB circuit in view.

Acknowledgement

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Questions from the Audience

Mike Dunaway, San Diego, CA: Question: Could you explain the precision bias to us again and tell us how that is significant to us on a daily basis?
Answer: The bias is the standard deviation of the values being compared and the precision is the spread of those differences. Neither one alone means anything, however an ideal situation is to have a very low bias combined with a low or statistically insignificant precision. I would refer you to a reference in the article by Altman, D.G., Statistics and Ethics in Medical Research, *British Medical Journal*, 1987, Vol. 33 page 1538.
Question: Did you feel that Gas Stat was acceptable or unacceptable?
Answer: Well, I think it is unfair whether the Gas Stat was acceptable or unacceptable–I think it would be better to evaluate this system solely on its own merit. I believe that the ability to remove the sensor from the connector to verify calibration is a key plus to this particular system. The other system in this case is not able to do that. The recommendation of a one point calibration to the external lab, I think, defeats the whole purpose of what we are trying to accomplish. We all have experienced multiple problems with the external lab . . . lost blood gases, blood gas results that seemed completely out of proportion to what we expected, etc. So when you want to consolidate a cardiopulmonary bypass circuit, I see no need to be drawing blood to send away.