

In Vitro Measurement of the Accuracy of a New Patient Side Blood Gas, pH, Hematocrit and Electrolyte Monitor

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Abstract

(*J. Extra-Corpor. Technol.* 19[3] p. 322-329 Fall 1987, 34 ref.) An In Vitro human blood circuit was brought to equilibrium with five analyzed gases and at varied electrolyte concentrations to determine the accuracy of the GEM-6 analyzer with respect to current market standard analyzers.

Diamond Sensor Systems GEM-6	Radiometer A/S ABL-4 Blood Gas and pH Analyzer	Nova Stat Electrolyte Monitor	Becton Dickman Readacrit Centrifuge
Correlation Coefficient (r)			
pH	.9988	—	—
pCO ₂	.99864	—	—
pO ₂	.9933	—	—
Hct %	—	—	.79205
K ⁺	.99695	.99553	—
Ca ⁺⁺	—	.98399	—
[HCO ₃ ⁻]	.9738	—	—
B.E.	.8022	—	—
%Hb-O ₂	.9546	—	—

(n = 60, all r values are significant at p < .001)

The GEM-6 is equivalent to current analyzers that measure the same parameters.

Introduction

A new patient side monitor, the Diamond Sensor Systems GEM-6^a, is now available for use in the oper-

a GEM-6 Analyzer, Diamond Sensor Systems, Ann Arbor, MI 48104

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ating room and intensive care unit. The monitor directly measures hematocrit (HCT), ionized calcium (Ca⁺⁺), ionized potassium (K⁺), pH, pCO₂, and pO₂. In addition, bicarbonate ion concentration ([HCO₃⁻]), percent O₂ saturation of hemoglobin (%SO₂), Base Excess (BE), and oxygen transfer are estimated from the arterial and venous blood gas, temperature, hematocrit, and pH values.

The perfusionist connects the automatic sampler tubing set to arterial and venous ECC blood sites and initializes the sampling frequency and logic (that is: arterial or venous samples only, or both; "temperature corrected," or not). The analyzer features two-point recalibration every hour.

In the advent of new perfusion ventilation techniques such as "alpha stat" and the greater usage of calcium channel blocker agents and similar cardiovascular drugs, the need for more frequent and timely blood gas, pH, and ionized electrolyte activity measurements is increasing.^{2,3,5,15,19,22,23,33,34} The debate to weigh the cost of online monitoring against the potential gain in patient care benefits is undecided to date.^{2,6,22,24,34} Patient side monitoring does not always replace stat laboratories in cardiovascular care areas and therefore occasionally introduces new expenses that can be justified only by demonstrating improved patient care and safety.

The desired frequency of sampling of blood gas, pH, and electrolyte parameter values for optimal patient monitoring during cardiopulmonary bypass has not been established. Inline, online, continuous trending, and intermittent discrete sampling techniques are available. All blood gas, pH, and electrolyte activity sensors or electrodes have response times that prevent sampling at frequencies great enough to accurately reproduce a CPB procedure minute-by-minute.

Many well-documented sources of error are presently incorporated in the current standard of intermittent CPB sampling and measuring blood gases and pH. Some of the sources of error in the agreement between patient side monitors and tabletop analyzers include inaccurate temperature correction, air bubbles in blood sample syringes, time delay and blood metabolism while the sample awaits processing. Inaccurate assumptions regarding patient hemoglobin P₅₀ and the patient's pK of the first dissociation of carbonic acid lead to errors in calculated BE and percent O₂ saturation of hemoglobin. Nonlinearity in electrode performance outside of the limits of calibration and outside the intended temperature use limits.^{1-3,9,10,17,20,27-31}

The GEM-6 monitor employs a disposable cartridge that contains the high and low calibrating solutions, a waste compartment, and the ion selective sensors (ISS) that measure ionic activity in the sample blood. The cartridge ISS card assembly is maintained at 37°C for analysis. Recirculated ECC line blood is diverted to the sample chamber according to the programming by the user. The blood sample is diverted to the ISS sample chamber, the blood is equilibrated to 37°C, and ionic activity is measured and reported within 130 seconds.

An *in vitro* circuit was employed to tonometer human blood with different known O₂ and CO₂ concentrations of gas. Electrolytes were varied and pH followed CO₂ content and bicarbonate ion activity. The purpose of this investigation was to evaluate the accuracy of the GEM-6 ISSs compared to current market standard measurement devices.

Materials and Methods

The *in vitro* circuit illustrated in Figure 1 was assembled and primed with heparinized, washed, human red blood cells suspended in normal saline to a hematocrit of about 37%, and a low protein concentration. Figure 1 presents the ideal circuit to test ion selective sensors. However, this method did not employ a dialyzer to control ion activities.

A bubble oxygenator is employed to tonometer the human blood prime with the five calibrated gases listed in Table 2 similar to the method reported by Reeder and Hood, and others.^{1,10,17} During the test, hemodilution was achieved by the addition of a pH balanced isotonic, non-blood solution. Bicarbonate, calcium and potassium ion activity was altered by the addition of NaHCO₃, CaCl₂ and KCl solutions.

Six cartridges were tested in 6 GEM-6 analyzers. Six automatic sampling tubing sets were connected in close proximity to the arterial line of the test blood circuit and led to each of the cartridges.

Simultaneous sampling results were entered into a computer file created by software that allowed the

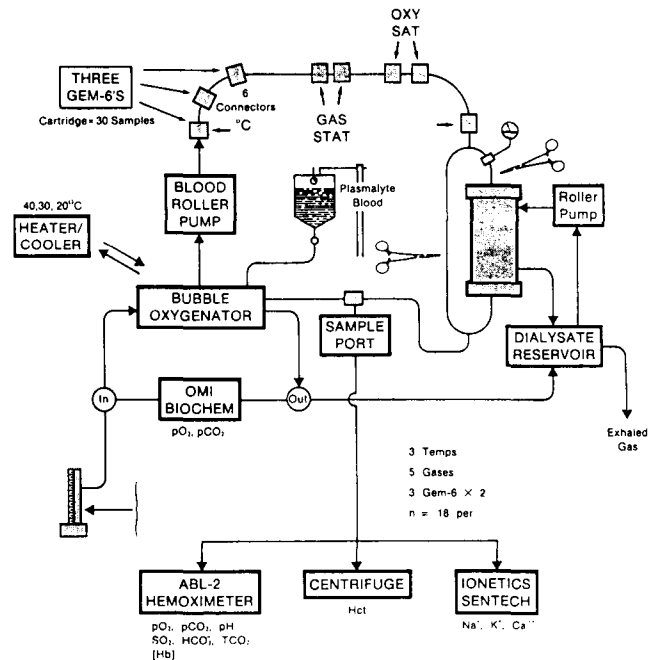


Figure 1: Ideal *in vitro* test circuit to vary and control blood gases, pH, electrolyte activity, temperature, and hematocrit

Table 1

Correlation Coefficients for GEM-6 Parameters Compared to Market Standard Instrument Measurements

	DIAMOND SENSOR SYSTEMS GEM-6	RADIOMETER A/S ABL-4 BLOOD GAS AND PH ANALYZER	NOVA STAT ELECTROLYTE MONITOR	BECTON DICKMAN READACRIT CENTRIFUGE
	Correlation Coefficient (r)			
pH	.9988	----	----	----
pCO ₂	.99864	----	----	----
pO ₂	.9933	----	----	----
Hct %	----	----	----	.79205
K ⁺	.99695	----	.99553	----
Ca ⁺⁺	----	----	.98399	----
[HCO ₃ ⁻]	.9738	----	----	----
B. E.	.8022	----	----	----
%Hb·O ₂	.9546	----	----	----

(n=60, all r values are significant at p<.001)

rapid graphic and statistical analysis of the paired GEM-6 and market standard analyzer data sets^b. Correlation coefficients and paired hypothesis tests between means^c were employed to evaluate the consistency in measurement values from the GEM-6 compared to the simultaneous market standard analyzer values.

Results

Figures 2 through 4 demonstrate the agreement between the GEM-6 ISE blood gases and pH measurements compared to the current standard for

^b Lotus 1-2-3, Lotus Development Corporation, Boulder, CO 80321

^c Microstat Release 4.1, Ecosoft, Inc., Indianapolis, IN 46220

Table 2

Calibration Gases Oxygen and Carbon Dioxide Concentration and Expected Gas Partial Pressures.

ANALYZED GAS COMPOSITION				
GAS NUMBER	%O ₂	%CO ₂	pO ₂	pCO ₂
#1	57.9	1.5	430	11
#2	35.7	2.9	265	22
#3	21.4	5.7	159	42
#4	18.7	8.6	79	64
#5	2.9	11.4	22	85

Barometric Pressure = 742 mmHg Dry Gas

Accuracy of the GEM-6 pH Ion Selective Sensor Compared to the ABL-4 pH Electrode

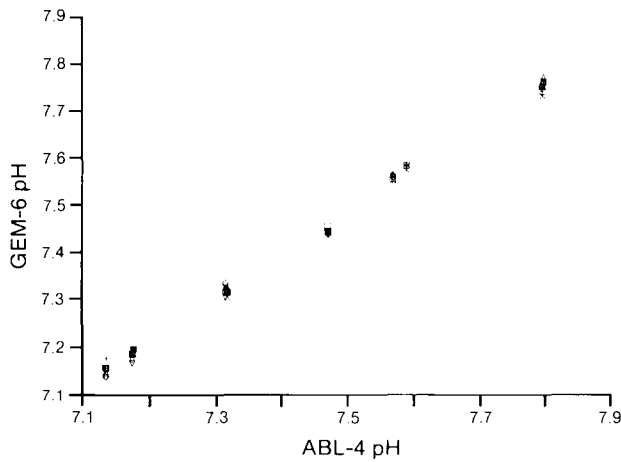


Figure 2: Accuracy of the GEM-6 pH ion selective sensor compared to the ABL-4 pH electrode

Accuracy of the GEM-6 pO₂ Ion Selective Sensor Compared to the ABL-4 pO₂ Electrode

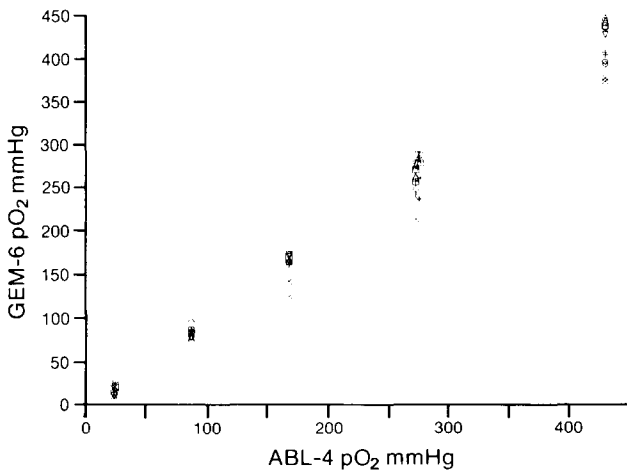


Figure 3: Accuracy of the GEM-6 pO₂ ion selective sensor compared to the ABL-4 pO₂ electrode

standing in vitro blood gas and pH analyzers^d. Table 1 lists the acceptable correlation coefficients for each ABL-4 directly measured parameter.

Figures 5 and 7 illustrate the high correlation between the GEM-6 electrolyte ISSs compared to the Nova^e potassium and calcium electrodes.

Figure 8 presents the GEM-6 hematocrit electrode borderline correlation with centrifuge hematocrits. The blood was deplete of protein and the GEM-6 hematocrit electrode read false low compared to centrifuge values.²⁵ Figure 9 presents the same GEM-6 hematocrit

Accuracy of the GEM-6 pCO₂ Ion Selective Sensor Compared to the ABL-4 pCO₂ Electrode

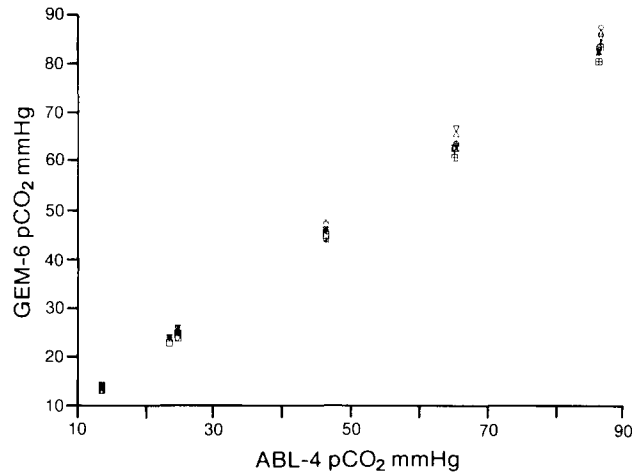


Figure 4: Accuracy of the GEM-6 pCO₂ ion selective sensor compared to the ABL-4 pCO₂ electrode

Accuracy of the GEM-6 K⁺ Ion Selective Sensor Compared to the the ABL-4 K⁺ Electrode

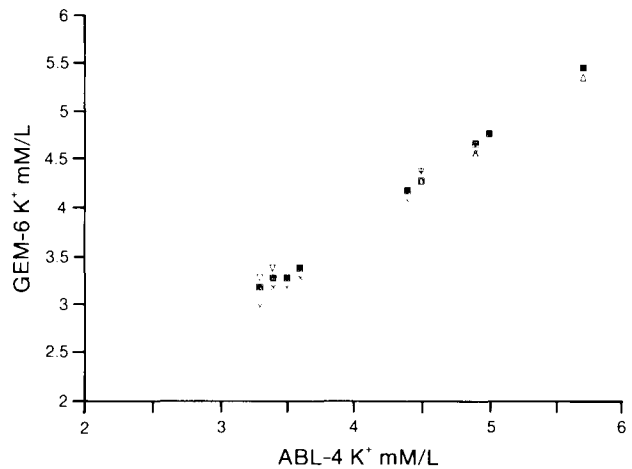


Figure 5: Accuracy of the GEM-6 K⁺ ion selective sensor compared to the Nova 6 K⁺ electrode

^d Model ABL-4, Radiometer/Copenhagen, DK 2400, Copenhagen NV, Denmark

^e Nova 6 Electro Analyzer, Nova Instruments, Waltham, MA 02154

values corrected for the effect of plasma protein concentration on the resulting hematocrit electrode signal. The presence of normal CPB diluted protein concentrations affects the hematocrit electrode substantially. At a hematocrit at 24%, the presence of an albumin concentration is approximately 3. Gm/dL results in an increase of about 4 hematocrit percent in the GEM-6 reading.

Figures 10 through 12 present the acceptable agreement between GEM-6 and ABL-4 derived patient management parameters; bicarbonate ion concentration, Base Excess, and hemoglobin O₂ saturation, respectively.

The temperature in the in vitro circuit was changed from 23 to 37°C in 23 minutes and the blood allowed to equilibrate with a dramatic step change in pH, pCO₂, and pO₂. Figure 13 depicts the response of the automatic sample tubing set content blood to the dramatic change in the ECC blood gases and pH. The tubing set blood gas and pH values lagged about a minute and a half behind the ECC tubing blood values.

Accuracy of the GEM-6 K⁺ Ion Selective Sensor Compared to the Nova 6 K⁺ Electrode

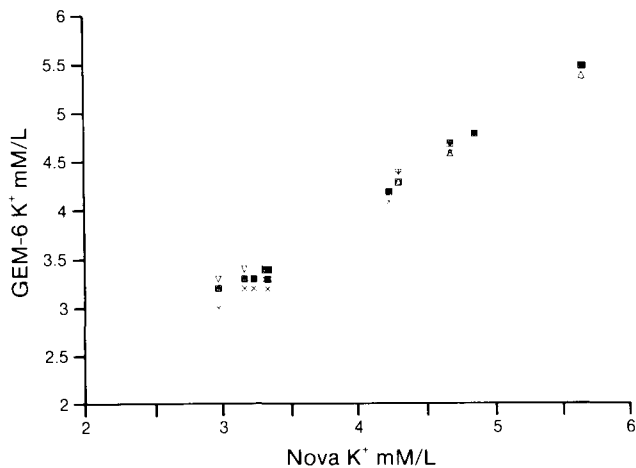


Figure 6: Accuracy of the GEM-6 K⁺ ion selective sensor compared to the ABL-4 K⁺ electrode

Accuracy of the GEM-6 Ca⁺⁺ Ion Selective Sensor Compared to the Nova 6 Ca⁺⁺ Electrode

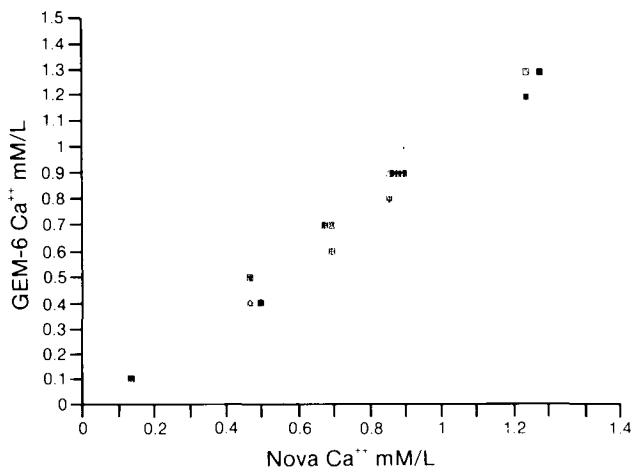


Figure 7: Accuracy of the GEM-6 Ca⁺⁺ ion selective sensor compared to the Nova 6 Ca⁺⁺ electrode

Accuracy of the GEM-6 Hematocrit Sensor Compared to the Centrifuge Hematocrit

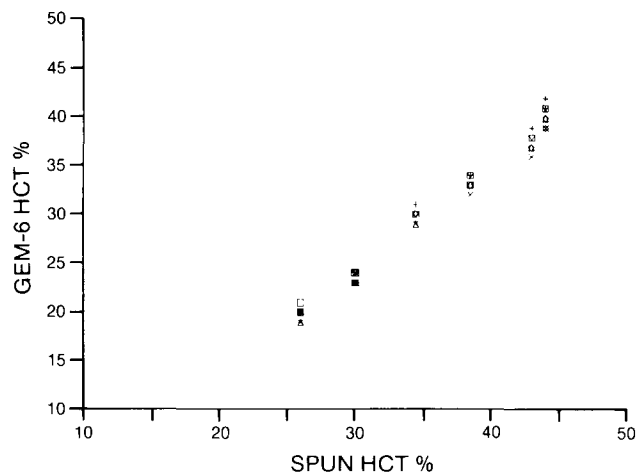


Figure 8: Accuracy of the GEM-6 hematocrit sensor compared to the centrifuge hematocrit

Discussion

The correlation coefficients and the square of the correlation coefficient were acceptable for the GEM-6 ISS directly measured parameters. The current trend by blood gas and electrolyte analyzer manufacturers is to report the mean and the deviation of a specific sensor's or cartridge ISS's deviations in percent error from expected values. The deviation of the population of sensors' deviations in the percent agreement is a measurement of reliability and reproducibility of the manufacturing process.

The figures presenting the borderline agreement in derived parameters (bicarbonate ion concentration, Base Excess, and saturation) exemplify the effect that the small differences between input parameters values of the ABL-4 and GEM-6 have on the result of the calculation in a complicated estimating equation.

Estimates of saturation from pH, pO₂, pCO₂, Base Excess, and temperature assume a normal patient hemoglobin P₅₀ = 26 mmHg which is not true in about half of the population of open heart patients.²⁰ It is desirable to directly measure hemoglobin O₂ saturation during CPB, especially in the mixed venous

Data Illustrating the Hematocrit Sensor Response Corrected for the Normal Diluted Presence of Albumin Compared to Centrifuge Hematocrits

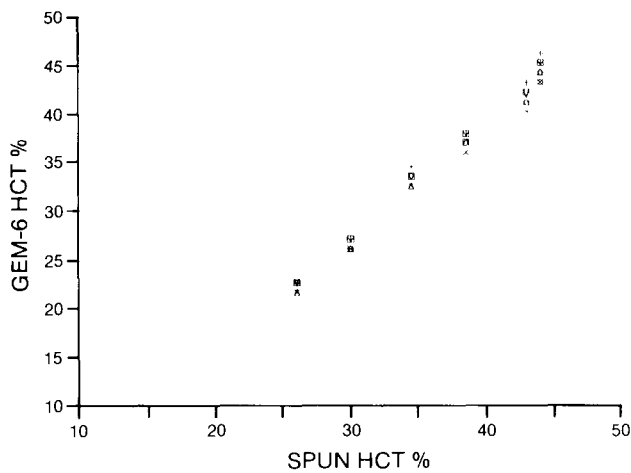


Figure 9: Data illustrating the hematocrit sensor response corrected for the normal diluted presence of albumin compared to centrifuge hematocrits

Accuracy of the GEM-6 Bicarbonate Ion Concentration Calculation Compared to the ABL-4 HCO₃⁻ Estimate

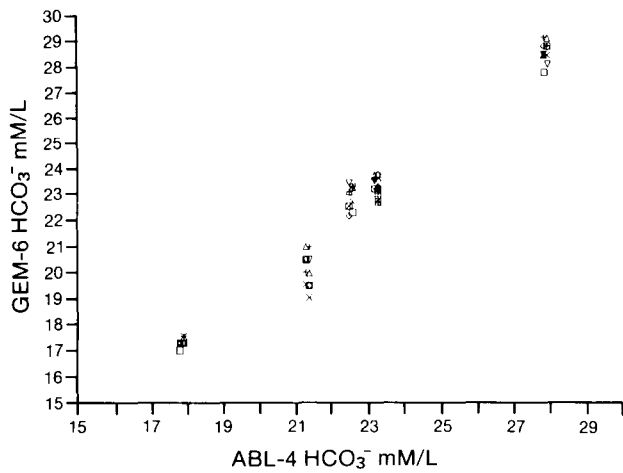


Figure 10: Accuracy of the GEM-6 bicarbonate ion concentration calculation compared to the ABL-4 HCO₃⁻ estimate

line.^{4,16,19,20} The pK of the first dissociation of carbonic acid is not always 6.1 and estimates of bicarbonate ion activity, Base Excess, and "reverse temperature correction" are not always accurate.¹⁵ For example, the only true test for "alpha stat" is to warm the cold patient blood to 37°C and the analyzed pH will = 7.4; reverse temperature correction to predict alpha stat is not always accurate.^{15,33}

The GEM-6 hematocrit electrode performance is dependent on plasma protein concentration and the

Accuracy of the GEM-6 Base Excess Estimate Compared to the ABL-4 Calculated Base Excess

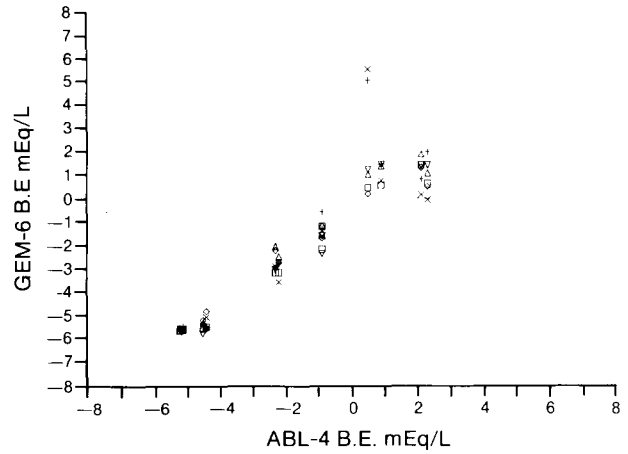


Figure 11: Accuracy of the GEM-6 Base Excess estimate compared to the ABL-4 calculated Base Excess

type of pH balanced non-blood priming solution employed during preparation for CPB. Clinical trials with the current hematocrit electrode design and algorithm track normal dilutional changes in hematocrit.³⁴

Many current tabletop in vitro blood gas analyzers are being calibrated at the high end at a pO₂ value less than 175 mmHg.^{1,10,17} Blood samples that have pO₂ values above the high calibration point will evaluate low and lead the observer to possibly judge that the online device is reading false high. However, the non-linearity of older model tabletop in vitro analyzers not designed for cold blood samples is well established.

Accuracy of the Hemoglobin Oxygen Saturation Estimation Compared to the ABL-4 Saturation Calculation

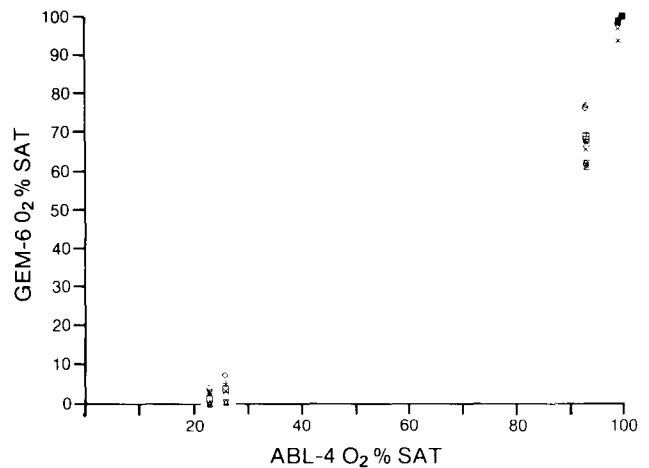


Figure 12: Accuracy of the hemoglobin oxygen saturation estimation compared to the ABL-4 saturation calculation

Response of the GEM Tube Set to a Rapid Change in ECC Blood Line Temperature, pCO₂, pO₂, and pH During Simulated CPB Warming

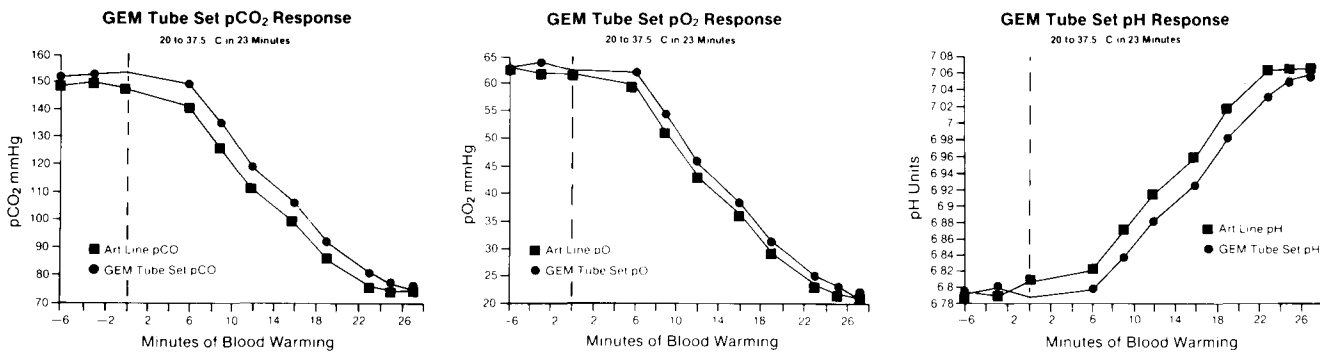


Figure 13: Response of the GEM Tube Set to a rapid change in ECC bloodline temperature, pCO₂, pO₂, and pH during simulated CPB warming

Potential gaseous microembolization at high pO₂ values, or more importantly, high ventilation rates in direct blood gas interface devices is to be avoided. The use of an online blood gas analyzer may certainly allow the perfusionist to avoid excessive arterial blood pO₂s and gas flow rates during CPB.^{7,8,12,14,18,21}

The GEM-6 blood gas, pH, and electrolyte ISS performance measured in this study is comparable to current analyzer performance and accuracy.³²

The GEM-6 patient side monitor is equivalent to current day, bench top technology, and, conveniently, provides the most important patient management parameters to the open heart team during the entire preoperative period.

Acknowledgment

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Questions from the Audience

Question: Tom Utsey, Mount Pleasant, SC: The hematocrit area about this machine is what I'm skeptical about. Can you tell us about the particular technology? Just clarify again for me the albumin or the protein business.

Response: There are two species in blood that affect the resistivity of blood. The phenomenon that the resistivity of blood changes with hematocrit and protein concentration was described in the 1960s by Geddes, who was at Purdue University. It turns out that the resistivity or conductivity of blood is directly proportional to hematocrit or protein concentration over the range of normal hematocrit and protein concentrations. So theoretically, one could build a well to place blood in, and just pass a small current through it and measure the resistance in that current flow and predict hematocrit. This is what has been accomplished in this device. Yellow Springs Instruments had a device that accomplished this also. It's been available for 15 years. The problem is that there is a disproportion between the change in albumin and the change in hematocrit as we use different solutions to dilute patients. Then we looked at the effect of changing protein on the electrode, and the algorithm that's in the GEM-6 blends the effect of changing protein and changing hematocrit as it is normally expected during bypass. But if one primes with a lot of albumin in the circuit, the electrode will read a false high of about one percent on the average.

Question: Nancy Achorn, San Francisco, CA: When you were comparing the oxygen saturations of the Diamond versus the ABL-4, you found there was a discrepancy. But that really means that the error could have been in either machine. That didn't exactly correlate. But it's hard to know in which the errors you describe could have occurred. How did it compare with the Oxysat?

Response: Neither agreed with the Oxysat. I didn't report it here, but in studies in the past where we used the Oxysat, which is probably the most accurate direct measurement by oximetry that we have available today, neither of the estimates agree well or even acceptably with the Oxysat. I strongly recommend that you measure saturation directly, especially on the venous side. I think that is pretty much the standard of care in perfusion today. Probably 70% of the institutions in the country use direct measurement saturation on the venous side. And you're right. Estimates should not be trusted.

Question: Dick Slessor, Riverside, PA: It is my understanding that each cartridge is capable of testing 50 samples. In light of cost containment, can more than one patient be used on one cartridge?

Response: I think that if you did bypass very rapidly, you could probably use one cartridge to work on four or five patients. The device has a sleep mode now and I'm really not well informed enough about the logic in it to make any kind of statement about how many samples you can get, and of what condition. But I think the devices that we've tested and the logic that we've tested to date—if you work really

quickly and use the device as it may be used, not as it is recommended, you probably could do several patients with one cartridge.

Question: Brian Murphy, Irvine, CA: I would recommend that you avoid using correlation coefficient for these kinds of studies. Correlation coefficient can be very misleading, because the numbers are generally always very high and they don't give anybody looking at the data a real feel for what the percentage mean difference in error is. And I suggest that to improve your study, you could use mean difference in reading between the two instruments that you're comparing. It would give us a much better idea as to where there are some errors.

Response: I agree exactly. How would you organize the data? Would you do a paired t test at each sample point for each parameter of value or would you gather all the data together into a large group and do a paired t test on it? What would you recommend?

Comment: The best way is to present all the data. I realize there are tremendous interpretation difficulties that you get into if you try to boil down the data to a single number—such as mean error or correlation coefficient. And the best way to allay any concerns that a reader might have in these kind of studies is to tabulate all of the readings. It doesn't take up too much space on a general page and it gives you a much higher degree of confidence about what's really going on.

Response: Agreed 100%. That's the objective of diagrams such as the scattergrams that include all the points that were measured. Each point pairs them. When one looks at these scattergrams one should look for Y intercept errors, and how close you are to where the points are, to the line of identity—which is an indication of the standard error of the mean. The distance of each of these points falls away from the line of identity.

Comment: That's right, but I had trouble knowing how far away it is compared to the height. I have to visually estimate. It looks to me as if there is 10 to 15% error on some of those points. If you tabulate the data I can just get that number right away.

Response: I've done that. The test always fails. No matter how close those points are to the line of identity, you fail to get a P value that shows that the populations come from a different population. So I've always assumed that I was misapplying the statistics. Thank you for your point.

Question: Aaron Hill, Falls Church, VA: You have a very interesting presentation. You've touched on hematocrit differences. I have looked at the GEM as well, except not on the bench, but in a clinical situation. I was able to get better correlation with the hematocrit that you've achieved on the bench. I'm not exactly sure why that was. We've compared that to NOVA STAT and to spun hematocrit as well. The other thing is that my calciums were not as good in correlation as yours—which may have been a function of our individual machines, possibly. How about hematocrit differences? You've talked about it a little bit before?

Response: I've tried to explain. Here we do not have protein in the prime. And then we looked separately at the effect of protein on the hematocrit electrode. I think probably the differences between our two studies is that ours is well controlled and yours is subject to clinical variables. Also, when you compare calcium analyzers from different manufacturers, the variability is great from manufacturer to manufacturer. And one of the problems that any sensor developer has is in picking which one they are going to agree best with. With the advent of microprocessors, you can make these sensors do anything you want. You can change the shape of these curves any way you wish, but the question is: What is the best standard for measurement of an ion activity?