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Comparison of the Response Time of Various Sensors for Continuous Monitoring of Blood Gases, pH and O_2 Saturation During Cardiopulmonary Bypass

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Abstract

The rise times and decay times of the currently available, continuous blood gas and pH monitors' sensors were evaluated at 37°C and 25°C.

An INVITRO human blood circuit was employed to apply step functions in pH, pCO_2, pO_2 and SO_2 to the monitor sensors. The 10% and 90% response and the time to respond (reach 10% response) for the sensors are as follows:

Continuous and discrete monitors for cardiopulmonary bypass have inherent measureable response delays. The inherent delays in the sterile diffusion barriers of the sensor flow-through connectors for the continuous monitors is probably the greatest source of interference in accuracy studies involving discrete sampling versus continuous monitoring techniques during CPB.

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Table 1

Results of average sensor decay time (DT in sec.), rise time (RT), time to respond (TR) during rise time study, and sensors conditions not studied (NS).

Device:	Sensor:	25°C			37°C		
		DT	RT	TR	DT	RT	TR
Oxy SAT 1	sO_2		NS		45	45	10
Oxy-SAT 2	sO_2	45	45	10	45	45	10
GEM-6			all times = 30-220 (discrete)				
Gas STAT	pH	164	344	65	145	263	65
	pCO_2	283	186	35	184	133	30
	pO_2	165	172	40	132	131	65
CDI 300	pH	155	252	58	169	283	62
	pCO_2	279	230	59	208	184	41
	pO_2	162	252	33	195	190	19
Orange Medical pO_2			NS		72	110	21
Cardiomet 4000	pH	132	265	45	99	207	42
	pCO_2	150	139	28	124	98	6
	pO_2	129	133	17	159	120	8

Where: DT = decay time (sec.), RT = rise time, TR = time to respond during RT, and NS = conditions not studied

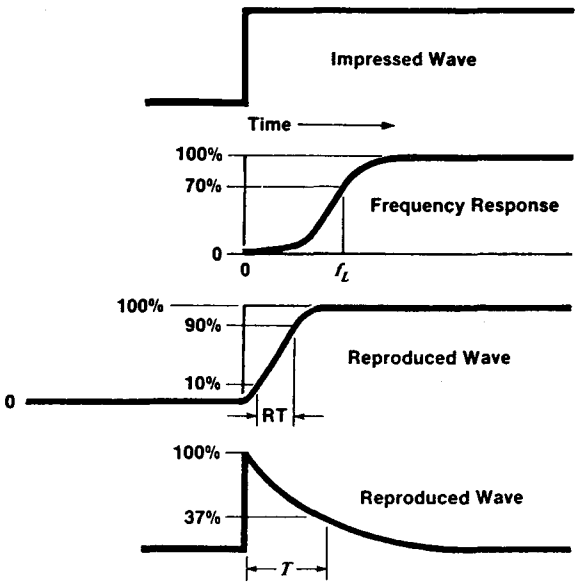
Background

Continuous monitors for pO_2, pCO_2, pH, SO_2 and other parameters have been available for use for CPB and have demonstrated varied, yet acceptable accuracy compared to INVITRO analyzers.[1-11]

The greatest source of error during these accuracy studies may be the inherent response delay in the monitors' blood line sensors and the connectors with sterile barriers. A method was developed to expose continuous monitor sensors to a negative and positive step function in pO_2, pCO_2, pH, and hemoglobin O_2 saturation.

Figure 1 illustrates the typical on-line monitor sensor response to a step function.[12] The concepts of a step function, lag response and the time constant are evident. One may simply assume that the response of the perfusionist controlled, oxygenator—patient arterial blood pO_2 response system is a first order equation (Figure 1). The response time of a first order sensor is independent of the amplitude of the step change. This method employs rise time and decay times of 10 to

TYPICAL BLOOD SENSOR RESPONSE TO STEP FUNCTION

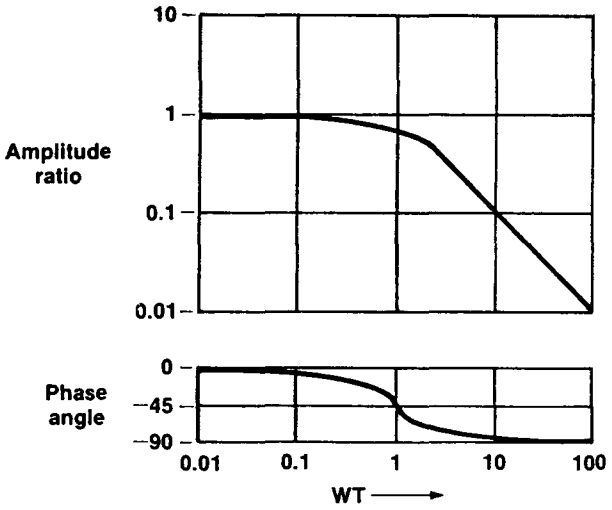


f_L = Frequency on sine-wave @70%
T = Time constant (sec.)
RT = Rise time

After Geddes and Baker

Figure 1: A step function, first order response, one time constant, and low frequency response. Redrawn from Geddes and Baker.[12]

BODE DIAGRAM



After Coughanour

Figure 2: Bode Diagram. Two logarithmic plots of both amplitude response and phase angle versus the product of the fundamental frequency (w) and time constant (t). Redrawn after Coughanowr and Koppel.[13]

90% response as opposed to the traditional time constant (100 to 37% response during decay).

It may be assumed that oxygenator—patient pO_2 control is basically proportional. For example, if the pO_2s are greater than desired, the FiO_2 may be decreased proportionally to attempt to gain control. As the blood parameter is changing, the blood sensor is attempting to come to equilibrium with the blood value. The sensor readout is lagging behind the true blood value as it changes. The sensor readout has a discrete phase lag angle compared to the actual blood value.

In order to assess the ramifications of the phase lag on sensor amplitude response during control of the extra-corporeal circuit, The Bode Diagram may be employed. The Bode Diagram relates the amplitude ratio response and the phase angle for a first order system.[13]

The phase angle (Ø) of an in-line sensor may be calculated for a specific sensor time constant (w) and measured, changing parameter periodic frequency (t) (personal communication with Matthew Jenusaitis, December 24, 1987):

$$\phi = \tan^{-1}(-wt) \qquad \text{Eq. 1}$$

The Bode Diagram relates the product of the time constant (100–37% response during decay) and the

fundamental frequency of the blood gas value change to the phase angle and amplitude error between the sensor readout and the absolute blood value of the parameter.

Parameter sensors will be the most accurate when the time delay of the measuring sensor system is less than the periodic frequency of the input event. If the product of the time constant and the frequency (wt) is about equal to 1., the monitor would read −45° out of phase and will read only 75% of the true blood peak to peak value deviation. The sensor phase lag might lead the perfusionist to increase or decrease FiO_2 or sweep rate, or perform some other compensatory action after the fact, and possibly at a time when the action may not be entirely appropriate.

The sensor time lag may defeat any attempt to accomplishing an acceptable accuracy protocol when the blood gas or pH values are changing at periodic frequencies that approach the response time of the in-line sensors. The following method was undertaken to observe the response time of several on-line sensors to assess the effect of lag time on the accuracy of the sensor during rise time and decay time at normothermia and 25°C.

Materials and Methods

The INVITRO circuit in Figure 3 was assembled and primed with human packed red cells diluted with isotonic saline to a hematocrit of 17–21%. With the sensor loop clamped out, the oxygenator FiO_2 and $FiCO_2$ were varied to alter the blood gases, pH, and hemoglobin O_2 saturation in the sensor bypass loop. The newly equilibrated blood was then exposed to the sensor loop to cause a step function in blood parameters on the sensors.

The circuit sensor loop contained the sensors for the Gas-STAT[a], CDI 300[b], Orange Medical Cardiomet 1000[c], Cardiomet 4000[c], Oxy-SAT 1[a] and Oxy-SAT 2[a]. The GEM-6[d] automatic sample tube set was connected to the sensor loop and the GEM-6 was programmed to sample as frequently as possible. Several negative and positive step function observations at each of two temperatures, 25°C and 37°C, were performed to observe decay and rise times.

Sensor decay and rise time observations were adjusted to a scale of 0.0 to 100.0%, full scale. A response curve for each device sensor was created for each temperature by plotting the mean % full scale response versus elapsed time of the applied step function. The rise time and decay times were defined graphically as 10% to 90% response to the step function and the time to respond as 0% to 10% elapsed time during the rise time observation.

Results

Figure 4 presents a typical sensor group decay comparison at 37°C. Each pH and pCO_2 sensor exhibits a similar shape. The times reported in Table 1 were collected graphically from comparison curves for the pH and pCO_2 sensors at the two test temperatures.

Figure 5 illustrates the effect of temperature on the rise time and decay time observations for the SO_2 and pO_2 sensors. The pH and pCO_2 sensors follow similar temperature effect patterns. Table 1 lists the mean

INVITRO TEST CIRCUIT TO APPLY STEP FUNCTION TO MONITOR SENSORS

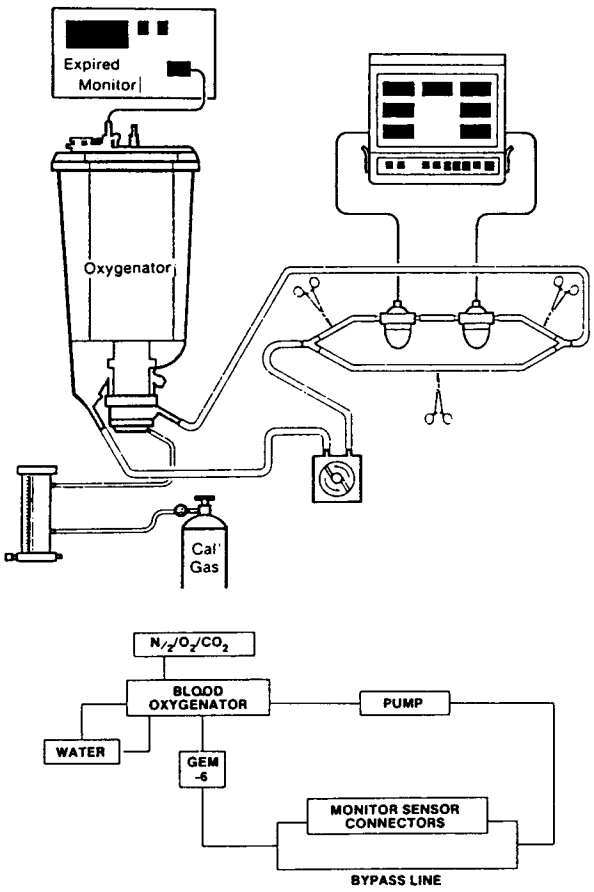


Figure 3: INVITRO test circuit to apply negative and positive step functions in blood gas, pH, and hemoglobin O_2 saturation to on-line sensors

a Baxter, Bentley Laboratories, Inc., Irvine, CA 92714
b Cardiovascular Devices, Inc., Irvine, CA 92714
c Biomedical Sensors, Inc., Kansas City, MO 64153
d Diamond Sensor Systems, Ann Arbor, MI 48104

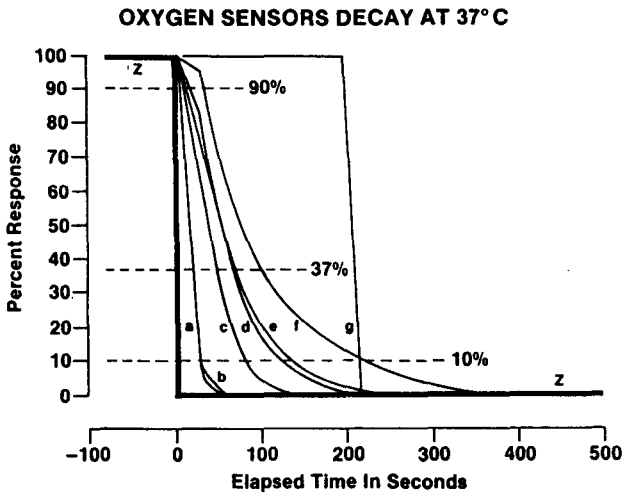


Figure 4: Hemoglobin O_2 saturation and pO_2 sensor decay time observations for 37°C. The sensors ranked as followed (shortest decay time first); a = OxySAT I, b = OxySAT II, c = CM 1000, d = CM 4000, e = GasSTAT, f = CDI 300, and g = GEM-6.

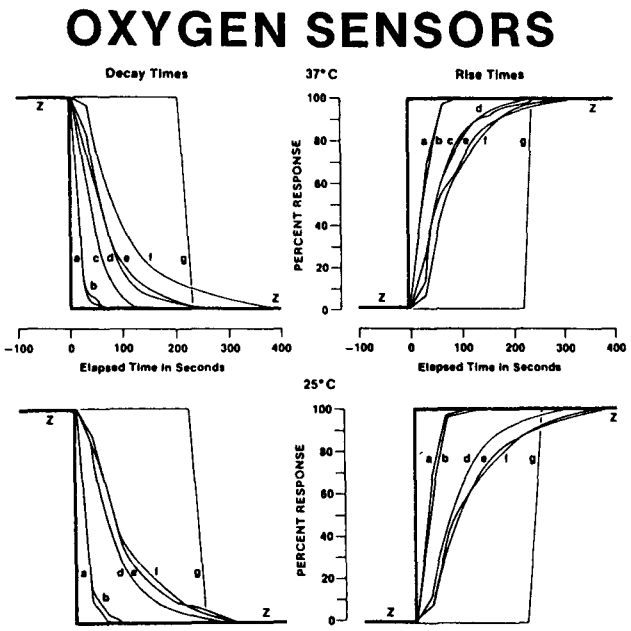


Figure 5: Hemoglobin O_2 saturation and pO_2 sensor decay time and rise time observations for 37°C and 25°C, where a = OxySAT I, b = OxySAT II, c = CM 1000, d = CM 4000, e = GasSTAT, f = CDI 300, and g = GEM-6.

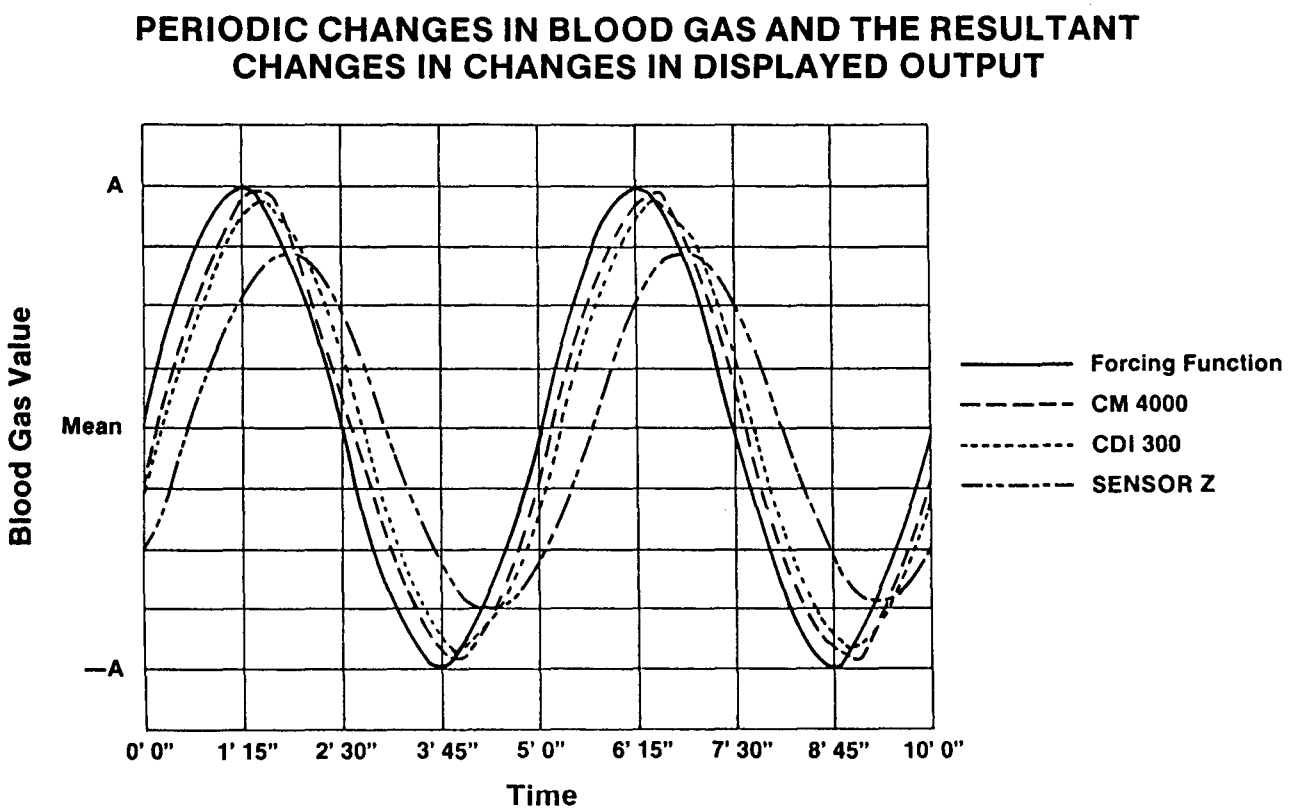


Figure 6: First order system response for CDI 300 (time constant = 104 sec.) and Cardiomet 4000 (time constant = 74 sec.) pO_2 sensors for an input parameter (arterial blood pO_2) forcing function with a fundamental frequency period = 5 minutes. Sensor Z has a time constant = 7 minutes, a phase angle of −23°, an amplitude error of at least 25% and the sinusoidal period of the input function is 15 minutes.

times found graphically for each manufacturer device sensor and the condition studied.

Figure 6 compares the Cardiomet 4000 and CDI 300 pO_2 sensors' first order response to a sinusoidally changing arterial blood pO_2 that has a period of five minutes. The CDI 300 exhibits a phase angle equal to $-12°$ and the Cardiomet 4000 exhibits a phase angle equal to $-8°$. The CDI pO_2 sensor will understate peak values by about 4% and the Cardiomet pO_2 sensor will understate peak values by about 3%. Sensor Z is the 'worst-case' and has a time constant = 7 minutes, exhibits a phase angle of $-23°$, demonstrates an amplitude error of at least 15% at peak values (given that the forcing function sinusoidal period is 15 minutes).

Discussion

Figure 6 illustrates that the two blood gas sensors with the lowest observed time constants in this method will exhibit about a 7 to 12% error when compared to the results of a simultaneous sample with a discrete analyzer while the actual blood parameter (pO_2) is changing. The other blood gas and pH sensors will exhibit greater phase lag angles than the two pO_2 sensors and not accurately reflect the highest and lowest actual peak to peak blood values.

The Bode Diagram may be employed to discover the phase angle (Eq. 1) and amplitude error for a specific sensor response at a given temperature by solving for the mathematical product of the input function periodic frequency and the sensor time constant. The time constant is approximately equal to the sum of the time to respond (TR) plus about 66% of the decay time (DT) from Table One.

Continuous on-line monitors serve as the front end transducers to computer assisted monitoring systems that maintain the open heart patient's operative CPB database. The database manager and the clinician must be aware of the inherent phase lag in the continuous sensors and the effect of the equilibrium time lag on the accuracy of the database parameter entry. The construction and programming of microprocessor based direct feedback FiO_2, ECC blood flow, or gas sweep rate control devices must account for the sensor negative phase angle.

Sensor manufacturers may employ the processor capability of the monitor to calculate and report the rate of change in the sensor readout to alert the user to the direction and rate of change of the blood parameter. Mathematical techniques could be employed to adjust the sensor reading on the monitor readout to more accurately reflect the actual blood values.

CPB continuous monitor accuracy comparison study samples should only be drawn in CPB steady-state conditions. Generally, changing blood or gas flow rate, and/or water or blood temperature will lead to changing blood gas and pH values.

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Questions from the Audience

Question: How far are we from continuous control of the flow and how significant are these changes between devices if we used them as controllers?
Answer: It is very interesting. You can set up experiments and define exactly the response of each of the sensors under specific conditions. If one piece of data is missing, to understand controllers, it is how fast the blood values actually change on bypass when you are trying to control situations. We don't know how fast the pO_2 changes in the blood and the normal conditions on bypass for a routine case. So it is very important to look at the rate of change or for information on the front of the monitor to tell us what approximately is going on in the blood.
Question: Are you saying we can do it now?
Answer: Yes.
Question: Without the experience?
Answer: The issue, as I know it, is the liability to build a controller to replace the human person controlling it.
Question: The automatic device ought to be better is the assumption?
Answer: For consistency.
Al Stammers, Ann Arbor, MI: Question: These changes that you had in the in vitro laboratory were rather dramatic at best. I presume in a more controlled environment such as on bypass, say, after the initiation and things have stabilized, do you expect to see a dramatic reduction in the lag time. Of course all your sensors perhaps with the on-line monitoring approach the single point method of determination for any of your parameters—Do you again see a drop in delay time?
Answer: One of the things that continuous monitors have given us is the ability to see how fast something is changing and stop it from changing. The perfusionist can actually get in a feedback loop with the monitor. If we start the pO_2 going up and we turn the FIO_2 down, we see the monitor come down and we turn the FIO_2 back up and we try to hit a value. We can get into this feedback loop and be out of phase. You are right, the step changes we used here are dramatic. The trial assumption is not a clinical assumption other than they just change like that clinically. But, what we did discover was, in a peak change were the pO_2 is rising and going from 150 up to 300, the monitors are going to understate it by 6 or 7 percent. So, if you are on CPB and draw a blood sample, and there is a change in the actual blood value, we cannot expect an accuracy protocol to be successful. You are automatically going to have 6 percent accuracy from the start.
Question: But, after you have reached the stabilization, you expect the time to decrease substantially.
Answer: Well, there is no change. If it is stable, there is no change in it and there is no discrepancy. It will come to equilibrium and that time is 5 to 7 minutes, generally for sensors.