A PERFUSION SYSTEM WITH MONITORING DEVICES

FOR OPEN-HEART SURGERY

A Thesis Submitted to
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in Partial Fulfilment of the Requirements for
the Degree of Master of Science
in Electrical Engineering
in the Department of
Electrical Engineering

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by

Walter Steve Stachuk

Saskatoon, Saskatchewan

1965

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ABSTRACT

The recent efforts on improving the physiological aspects of heart-lung perfusion techniques concern mainly two areas connected with the extracorporeal system. These are the reduction of priming volume required in the oxygenator and the requirement for a monitored control of the blood's gas-exchange parameters to maintain a more physiological perfusion during bypass. This thesis presents a contribution in these areas.

First, this thesis presents a heart-lung system specifically designed to operate in conjunction with an improved Kay Cross disc oxygenator. This oxygenator requires exclusive control features, not generally available in commercial units, since it performs the dual function of heat-exchanging and oxygenating the blood. This dual function provides an overall reduction in the systems priming volume. Secondly, a unique Rotating Cylinder oxygenator design, demonstrating a 1/3 priming volume requirement over the equivalent Kay Cross model, is presented and evaluated for clinical suitability.

Finally, this thesis describes a constant withdrawal system, employing commercially available electrodes, whereby simultaneous and continuous monitoring of the blood gas-exchange parameters can be monitored. Specific tests were performed whereby the performance of the electrodes in the system were evaluated under the constant withdrawal conditions required to continuously monitor a heart-lung bypass.
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GLOSSARY OF TERMS

PCO₂ = carbon dioxide tension (mm. Hg.)
PO₂ = oxygen tension (mm. Hg.)
PH = degree of acidity or alkalinity
PaO₂ + PvO₂ = oxygen tension in arterial and venous blood
P I O₂, P O₂, P E O₂ = tension of O₂ in influent, chamber, effluent gases
CO₂ = O₂ content in blood (vols. %)
V O₂ + V CO₂ = rates of O₂ consumption and CO₂ consumption
Vc = rate of total gas flow through oxygenator
Q B = cardiac output or pump flow rate
PB = barometric pressure
SO₂ = % saturation of hemoglobin with O₂
R = ratio which CO₂ exchanges with O₂
R B = respiratory exchange ratio
R.Q. = ratio of CO₂ production to oxygen consumption
= the respiratory quotient
1. INTRODUCTION

To repair internal defects of the heart, the normal cardio-pulmonary functions of the heart and lung must be temporarily performed extra-corporeally by a mechanical device.22 The technology of extra-corporeal circulation has developed in the last decade to the extent that it is now possible to bypass the heart and lungs for many hours. This technique has enabled the cardiac surgeon to perform many corrective operations on the heart which had previously been impossible.

The history of the development of artificial heart-lung equipment extends back to the early 1930's.21,22 This history is an extremely interesting one but will not be discussed since it is adequately covered in the references. However, it should be noted that the first successful 'open-heart' operation on a human using an artificial heart-lung apparatus was not performed until 1953.23 This belated success had to await the advancements in biologic technology which removed a number of obstacles to the progressive development of better machines. In particular, a better understanding of the effects and proper administration of anti-coagulants such as heparin and protamine and improved anaesthetics were necessary for prolonged perfusion. In addition, the development of plastics and stainless steel provided the materials necessary for the design of oxygenators and blood pumps which could operate efficiently with minimal blood damage. (1)
Figure 1 Heart-Lung Bypass.
The generally accepted open-heart bypass technique is as follows:\textsuperscript{24,25} (see figure 1).

An incision is made into the right auricle and cannulae are securely implanted to drain the venous blood from the inferior and superior vena cavae. The blood flows by gravity into a reservoir and then into an oxygenating unit. The oxygenated blood is then moved by a simple pump through a filtering system into the femoral artery. The blood flows to the heart in the reverse to normal direction but is prevented from entering the main chambers of the heart by the aortic tricuspid valve. In this manner the aorta and all branches leading to the body and the coronary arteries of the heart are supplied with blood. The blood supplied to the heart through the coronary arteries returns to the right auricle and must be collected by an auxiliary "sucker" system.

When the aortic semi-lunar valve requires repair (due to stenosis, as one example), the aorta must be "clamped off". However, by clamping the aorta, the blood supply to the coronary arteries feeding the heart tissue is also cut off. At normal body temperature the supply to the coronaries may be but off for only two minutes without permanent damage. An auxiliary supply to the coronaries must therefore be started immediately following "clamp-off" and carefully maintained. However, by lowering the body temperature, cellular metabolism is reduced, thereby increasing the time that the blood supply may be cut off to any organism. One of the techniques of
lowering body temperature (Hypothermia)\textsuperscript{24,25} is to cool the blood by placing a heat exchanger in the external flow circuit. The body may be cooled to any desired temperature (above freezing), thereby decreasing the blood flow required from the heart-lung machine and providing an additional degree of safety in the event of blood flow interruption.

Thus, a well designed heart-lung apparatus should incorporate the following facilities:\textsuperscript{29}

(a) An oxygenator with sufficient gas-exchange capacity and control to maintain the blood-gas equilibration within physiologically normal limits, with a minimum amount of blood.

(b) An easily controlled, non-traumatic pump to provide the blood flow rates required.

(c) A heat exchanger and associated temperature regulating equipment to maintain normal or below normal body temperatures.

(d) A non-traumatic blood recovery system to remove blood from the coronary return and operating field, as required.

(e) A filtering system to remove air emboli.

(f) A venous reservoir to control the aspiration pressure.

(g) Auxiliary reservoirs for emergency blood supplies in maintaining blood levels during perfusion.

The system should be simple, compact, and easily operated. In addition, the system must be fail safe with standby manual emergency control in the event of power failure. Section 2 of this thesis describes a heart-lung system which incorporates
these features. The design uses commercially available components integrated into a compact versatile system.

A variety of oxygenating devices have been developed. However, the main objection of the majority of these devices has been the necessity for a large 'priming volume'. This requirement is a problem, not only in securing donors for this blood, but also of the increased risk of human error in checking blood types and of complications resulting from incompatible characteristics of the donor blood. This problem has been alleviated to a large extent in recent years by using 5% dextrose and water to make up the necessary priming volume. In this way 'transfusionless' open-heart operations have been successfully performed. At the time this thesis project was undertaken this technique had not been established. Thus a study was undertaken to investigate various oxygenator designs to reduce priming volume requirements. Section 3 of this thesis describes a rotating cylinder oxygenator design which resulted from this study. The design features a novel method of introducing the blood between the cylinders whereby identical oxygenating capacity is achieved as for the disc oxygenator but with 1/3 to 1/4 priming volume requirement.

During an open-heart operation, the oxygenator and pump speed parameters are set and maintained, by the operator, according to a set of data empirically established from accumulated clinical experience for a particular classification of patient. Recently, some authors have felt that this reliance
on empirical data of perfusion parameters is insufficient to adequately control the perfusion within physiological limits. To maintain blood-gas relationships within normal values it is necessary to continuously monitor the partial pressures of oxygen and carbon dioxide in the blood, and its pH.\textsuperscript{6,7,8,9} A monitoring system was designed to provide a continuous measurement of these parameters, and is described in Section 4 of this thesis. The design incorporates commercially available amplifiers and electrodes. The particular feature of the design is the adaptation of the electrodes into a single cuvette, facilitating continuous and simultaneous measurement of the blood parameters.
2. A UNIFIED HEART-LUNG SYSTEM

The essential function of the heart-lung system is to safely provide regulated control of the gas exchange efficiency in the oxygenator unit, and regulate blood flows at a controlled temperature.¹

There are many commercially available heart-lung machines which meet most of the requirements of a good system as outlined in the introduction. However, besides being overly expensive, none of these units incorporate all of the features considered essential. As an example, to avoid additional priming volumes, it was considered desirable to use the rotating disc heat exchanger developed at the University of Saskatchewan.²⁰ This unit performs the dual function of oxygenating and cooling the blood. Although this heat exchanger may be safely operated with a coolant pressure of 30 psi, it was considered that to provide an additional factor of safety the coolant should be under negative pressure. Thus, if a leak did occur in the heat exchanger, blood would flow harmlessly into the coolant.

In addition, commercially available heart machines have separate hypothermia and perfusion control units. This results in the complete system taking up more floor space than a fully integrated system.
2.1 Normothermia-Hypothermia Unit

The temperature regulation of extracorporeal circulation is achieved via a heat exchanger through controlled heating or cooling of the heat exchanger media (i.e., water). Normal body temperatures are sustained by warming the perfusion flow to body temperature (37.5°C). This is denoted as the normothermia technique of perfusion. In certain heart repairs, however, it is necessary to temporarily interrupt the blood flow to certain organs in the body in order to facilitate the repair procedure. In these circumstances the allowable period of blood flow interruption may be prolonged by decreasing the oxygen requirements of the organism. This may be achieved by lowering the temperature of the blood (and thus the body temperature) by controlled external cooling in a heat exchanger. This is called the hypothermia technique of perfusion.

A normothermia-hypothermia control unit should have sufficient cooling capacity to lower the esophageal temperature of a man from 37.5°C to 10°C as rapidly as possible. In addition, the unit should provide for rapid rewarming where the coolant temperature range does not exceed 0°C to 44°C.

An accepted means of providing rapid cooling has been the use of crushed ice in an "ice bucket" which furnished an ice water flow to the heat exchanger. Also, a simple means of rewarming and attaining accurate control of the temperature range (i.e., 44°C) is to mix tap water to the required temperature, and allowing it to circulate through the heat exchanger.
The temperature control system was designed as a separate unit, and is illustrated in the left hand portion of figure 3. The essential features of this normothermia-hypothermia temperature regulating unit are:

1. Provision for the precise control of mixing hot and cold tap water to maintain blood temperatures within the range of 44°C to 20°C.
2. Facilities for deep hypothermia (20°C to 0°C) are provided by means of an ice bucket.
3. Provision for maintaining a negative pressure condition in the heat exchanger to guard against heat exchanger media leakage into the blood stream.
4. Provision for direct observation of the water temperature and the resultant pressure within the heat exchanger.
5. Provision for rapid and reliable connection to the heat exchanger, taps and pump from the regulation unit, through 'quick disconnect' connections.

The operation of the normothermia-hypothermia regulating unit is described below, referring to figure 2.

For normothermia, hot and cold tap water is introduced via rubber hoses to the temperature control valve. The temperature control valve automatically mixes the hot and cold water to maintain the temperature of the resulting mixture at a preset value. If the three-way valve (A) is positioned so that 3-1 is closed, the tap water flows entirely through the one-way check valve to the sump. Thus the maximum possible
Figure 3 Photograph illustrating the heart-lung apparatus currently in use at the University of Saskatchewan Hospital. (a) venous reservoir, (b) emergency reservoir, (c) disc oxygenator (with heat exchanger), (d) normothermia-hypothermia unit, (e) oxygenator and pump control unit, (f) coronary sucker control unit, (g) coronary sucker reservoir, (h) hot and cold water mixing control, (i) hot water inlet, (j) cold water inlet, (k) heat exchanger inlet, (l) heat exchanger outlet, (m) pressure indicator, (n) temperature indicator, (o) roller pump (blood flow), (p) foot pedal sucker control, (q) a.c. rectifier control boxes, (r) disc drive shaft.
Figure 2 Normothermia-Hypothermia Layout.
pressure on the heat exchanger is the pressure drop from A to the sump. If the three-way valve is positioned so that 3-1 is open, pump No. 1 is used to suck the water through the heat exchanger and then forces it through the three-way valve (B) to the sump. At normal coolant flow rates a negative pressure (0 to -10 mm. Hg.) is maintained within the heat exchanger by this means.

During the cooling phase of hypothermia the three-way valve is rotated to close 3-1 and open 2-1. Ice water is then pumped by a low pressure pump No. 2 through openings 2-1 into the heat exchanger. From the heat exchanger the water is again drawn by pump No. 1 and pumped through the three-way valve (B) back into the ice bucket.

The unit is totally encased in stainless steel, presenting the finished appearance shown in figure 3. The top of the unit is removable for easy access for motor maintenance purposes.

2.2 Oxygenator and Pump Control Unit

Control of oxygenator disc speed and blood pumping rate is achieved by the regulating unit illustrated in the right hand portion of figure 3. In addition to providing the essential oxygenator and pump regulation controls, the unit also incorporates the essential safety features for maintaining safe blood levels in the oxygenator, and provides for manual operation in case of power failure. These regulating
and safety features are briefly described below.

(1) "Single-roller" pumps, made by Perfusion Associates Limited, were used for both the main blood pump and the "sucker" pump. The particular advantages of this type of pump over other commercially available pumps are its small size (8 inch diameter by 6 inch depth), silent operation, and lower traumatic effect on blood.

(2) The oxygenator and pumps are driven by 1/8 H.P. d.c. motors. The a.c. rectifier and voltage control (speed control) units for the oxygenator and main pump motors are of the plug-in type which insert in the front panel facing the pump operator (see figure 3). Voltmeters are directly calibrated in terms of disc speed (rpm) and blood pump speed (rev./min.) for their respective applications. In the event of rectifier failure, the plug-in control box may be quickly replaced.

Mechanical clutches are placed between the motor and drive shaft to facilitate manual operation of the pump and oxygenator in the event of power failure.

(3) Temperature telethermometer indicators (made by Yellowsprings Telethermometer Inc.) are provided for continuous monitoring of the blood and patient rectal and esophageal temperatures.

(4) A blood level indicator is provided which continuously monitors the level of blood in the oxygenator. At a specified low level of blood, a relay is activated which opens a solenoid
valve allowing an emergency volume of blood to flow into
the oxygenator. If the blood level continues to fall, the
pump motor is stopped. In this manner a safe level of blood
is always maintained in the oxygenator to prevent the possi-
bility of air entering the arterial system.

2.3 Coronary Sucker System

To complete any perfusion control system, a means must
be provided for removing blood from the chest cavity to main-
tain a clear operating field for the surgeon. In addition
blood returned through the coronary sinus must be collected
and returned to the system. A conventional manner of achiev-
ing this blood removal is by suction at a negative pressure
of 1 atmosphere. The blood is then collected, allowed to
settle, and if necessary, introduced back into the extra-
corporeal system. However, recent studies have indicated
that high negative pressures result in considerable damage to
the blood. Since the volume of blood to be returned by the
sucker system varies considerably, control of suction should
also be provided.

A single roller pump driven by a 1/8 H.P. Bodine motor
is used to provide the suction pressure. The maximum degree
of suction is controlled by a vacuum regulator which may be
set between the range of 0 to -60 mm. Hg. The pump speed
and, hence, suction pressure is controlled by means of a foot-
pedal located near the surgeon.
The "sucked blood" is deposited on the apex of a stainless steel cone as it enters the collecting reservoir (see figure 4). The spreading effect along the cone facilitates the removal of air bubbles and provides an additional oxygenating surface. Oxygenating gas may be introduced into the collecting reservoir, thus increasing the saturation of the blood before it is emptied into the emergency reserve supply.
Figure 4  Scavenger Reservoir.
3. ROTATING CYLINDER OXYGENATOR

3.1 Development of Oxygenators

It was stated in the introduction that during open-heart surgery the normal oxygenation function is performed extracorporeally by a mechanical device. The adequacy of this oxygenation depends on a sufficiently large gas exchange capacity to meet the minimal requirements of the organism at rest.

Gas exchange in the artificial device relies on the creation of a large surface area between the blood and the oxygenating gas. Mechanical simulation of such a surface may be obtained principally by two methods: The first is the dispersion of gas in the blood (i.e. "bubble oxygenator")\(^\text{17}\). A huge gas-blood interface is created in a relatively small volume by bubbling the gas through the blood. With this method, it is the size and quantity of bubbles which determine the oxygenating surface. The second is the dispersion of blood in the gas ("film oxygenator")\(^\text{21}\). This is accomplished by maintaining a thin film of blood in an atmosphere of the oxygenating gas. The film is produced on either a fixed\(^\text{15}\) (e.g. stationary screen oxygenator)\(^\text{19,23,27}\) or moving (e.g. rotating disc oxygenator)\(^\text{1,21}\) support.

The stationary screen oxygenator produces a film by allowing blood to flow over a vertical surface of stainless steel or wire mesh. Satisfactory, steady conditions of gas transfer are obtained by mechanical mixing due to flow recirculation.
The rotating disc oxygenator achieves a film on a series of discs by rotating these discs in a pool of blood. This rotation provides the rapid renewal of the blood film yielding a large surface of gas exchange per unit of time. The speed of rotation of the discs and the depth of immersion of the discs into the blood are critical in achieving optimal oxygenation in the shortest time.

Finally, a membrane permeable to the oxygenating gas can be interposed between the blood and gas phases to avoid the trauma to blood associated with a large free blood-gas interface (membrane oxygenator)\textsuperscript{1}.

Since 1953, the three major mechanical oxygenators (i.e. bubble, stationary screen and rotating disc oxygenators) have evolved into dependable pieces of clinical equipment. However, due to the traumatic effect of the bubbling mechanism on blood, for the bubble oxygenator, and the large physical size of the stationary screen oxygenator required in achieving the oxygenating capacity, the rotating disc oxygenator has been the most popular design. In particular the "Kay Cross" rotating disc oxygenator has been perfected to provide the adequate oxygenating capacity in a relatively small unit with minimal blood damage. However, this was done at the expense of an increase in priming volume required. This priming volume ranges from 400 to 3000 ml\textsuperscript{1} depending on the application (see figure 6).
In recent years the popular thought on oxygenator design improvement has been the reduction or elimination of the priming volume. This would result in decreased dependence on an abundant reserve blood supply and increased physiological effectiveness of the bypass system. This prompted a study of various oxygenator designs whereby the priming volume requirements could be held to a minimum. As a result of this study, (which was conducted on a comparative basis with the Kay Cross disc oxygenator), a rotating cylinder oxygenator design evolved which is discussed in the following sections.

3.2 Prototype Rotating Cylinder Oxygenator Design

The filming surface required for different flow rates using the Kay Cross disc oxygenator was used as the basis of design for a prototype rotating cylinder oxygenator (see Table 2). Since the Kay Cross oxygenator was used as the basis for the initial design and as a basis for evaluating the final cylindrical oxygenator, a description of its operation will be given.

The Kay Cross disc oxygenator (illustrated in figure 5) consists of a number of stainless steel discs (12 cm. diameter) spaced 1/4 inch apart and held rigidly to a central shaft which is supported at the end plates of a pyrex glass cylinder. The discs are immersed in a volume of blood to a depth of 4 cm. The discs are normally rotated at 120 rpm, continuously replenishing a film of blood which is exposed to the oxygenating
Figure 5  Disc Oxygenator.
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<th>Maximum Blood Flow (120 rpm) (l/min.)</th>
<th>Oxygen Consum. (ml.)</th>
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</table>

Figure 6  Surface Area And Priming Volume Of The Disc Oxygenator.
gas. It is this exposed film which constitutes the equilibrating surface area required to maintain an adequate and stable oxygenating capacity. This capacity is directly dependent on the number of discs contained within the pyrex cylinder. Thus, standard oxygenator 'lengths' have been established which have been found by experience to provide the oxygenation capacity for a range of human requirements (see table 1). An attempt was made to achieve the same filming surface for the same flow rates using cylinders instead of discs. A diagram of the basic cylindrical model is presented in figure 8. A number of concentric cylinders supported by the inner cylinder and central shaft are stacked one upon the other and rigidly held to the inner cylinder by means of bolted spacers. The spacing between the cylinders is maintained at 1/8 inch. This particular spacing was selected as a safe limit when considering the aspect of drawover of blood volume at high rotational speeds (120 rpm). A low volume of blood is contained within the cylinder annulli. Thus, upon rotation of the cylinders, the surface of the annulli collects a blood film which is exposed to the oxygenating gas. It is this exposed area of the annulli which provides the equilibrating surface area. The dimensions and number of cylinders then determine the oxygenating capacity requirements. Table 2 shows the cylindrical dimensions, the resulting surface area and the priming volume for the proposed design.
Table 2

<table>
<thead>
<tr>
<th>Cylinder Diameter (in)</th>
<th>Cylinder Length (in)</th>
<th>Surface Area (in^2)</th>
<th>Priming Vol. Annuli (ml)</th>
<th>Reservoir Priming Volume (ml)</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td>19</td>
<td>200</td>
<td></td>
<td>60</td>
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<td>4.25</td>
<td>19.5</td>
<td>215</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.50</td>
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<td>220</td>
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<td>60</td>
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<td>4.75</td>
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<td>235</td>
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<td>5.0</td>
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<td>240</td>
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<td>60</td>
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<tr>
<td>5.75</td>
<td>21</td>
<td>265</td>
<td></td>
<td>60</td>
</tr>
</tbody>
</table>

Figure 7 Surface Area And Priming Volume Of The Cylinder Oxygenator.
It is evident from the calculations that a simpler design (by virtue of the fewer parts required) and lower priming volume is obtained with the cylinder oxygenator. It remains, then, to establish the compatability of the design under actual flow conditions.

The complexity of the nature of blood made theoretical analysis of blood flow difficult. For this reason a prototype oxygenator was built of transparent plexiglass material, whereby actual flow patterns and surface filming could be physically observed. In addition, the prototype was used to study:

(1) the type of cylinder spacer and its position relative to the flow so as to cause minimal blood turbulence,
(2) the type of blood inflow tube, which could be used to direct and control the flow to any of the cylinder annuli,
(3) the design of a collection reservoir to provide smooth outflow conditions.

Initial fluid flow studies were conducted using a fluid with simulated blood viscosity (i.e. 400 gms. sugar per 1000 c.c. water). The flow patterns in each cylinder annulus were individually observed and photographed for varying flow rates and rotational speed.

Satisfactory and stable flow patterns were maintained for flow rates from 500 to 1000 c.c./minute per annulus at rotational speeds up to 140 rpm. However, the tests indicated that the spacers caused considerable turbulence and should be
eliminated if possible in the final design. Figure 9 illustrates the typical flow behaviour.

These initial tests also indicated that for the above flow rates and rotational speeds, both surfaces of each annulus tested was completely filmed. However, in order to determine whether the filming properties of the rotating cylinder design achieved the required gas exchange capability for the equivalent surface area of a corresponding disc oxygenator, a quantitative measure of the oxygenating efficiency (i.e. gas exchange capacity) was required.

Oxygenating capacity of an oxygenator (or efficiency) is defined as the maximum blood flow rate whereby blood entering at a venous saturation of 65% is raised to an arterial saturation of 95% under normal physiological conditions (i.e. pH, PCO₂, hematocrit, temperature, etc. - normal values of these parameters are presented in Section 3.4).

An efficiency test was performed on the prototype, modified to eliminate the spacers at the outlet and to provide independent control of the gas and blood flows to each annulus. Only the innermost cylinder annuli was used for these tests. As such, the oxygenator has a surface area equivalent to a 5 inch disc oxygenator (see figure 6).

In determining the efficiency of the cylinder oxygenator a constant supply of venous blood was required at approximately 65% saturation. To provide this, a bubble oxygenator was placed in a closed-loop circuit with the cylinder oxygenator,
Figure 9  Flow Pattern In The Cylinder Oxygenator.
and served as a "deoxygenating" device ventilated with 95% nitrogen and 5% CO₂ gas. Thus the pH and PCO₂ blood parameters were also maintained within physiological limits in conjunction with the oxygenating gas (97% CO₂ and 3% CO₂).

In addition a heat exchanger was also provided in the circuit to maintain the blood temperature at 37°C.

The parameters of blood flow rate and rotational speed of the cylinder oxygenator were varied to establish the optimum conditions and maximum blood flow rate for oxygenation. For the low blood flows required by the single annulus cylinder oxygenator, the bubble oxygenator provided just adequate deoxygenating capacity.

Three such tests were performed for a range of blood flows extending from 500 to 1000 ml per minute, and rotational speeds from 60 to 120 rpm. These results are indicated in figure 10. The maximum blood flow possible to maintain 95% saturation was in the order of 1000 c.c. per minute for a fixed rotational speed of 120 rpm. The corresponding 6 inch disc oxygenator maintains this capacity of 95% arterial saturation to a maximum flow rate of 700 ml per minute at 120 rpm. (see also figure 6).

Despite the crudeness of this initial prototype design, wherein the cylinder tolerances were at best within ± 1/32 inch, these results presented a quantitative indication of the practicality of the design and prompted the decision for further and more extensive investigation. Thus, a stainless
Blood - Bovine
Flow - 500 to 1000 c.c./min.
P H - 7.19

Figure 10: Plot Of Saturation Efficiency Versus Cylinder Speed.
The stainless steel model was designed for the equivalent surface area of a 13 inch disc oxygenator, whereby the design specifications and materials employed were based on clinical standards.

3.3 Stainless Steel Model of the Cylinder Oxygenator

The stainless steel model is illustrated in figure 11. The essential features of this model which differ from the plexiglass prototype are:

(1) Stainless steel cylinders were constructed with tolerances of ± 0.01 inch throughout, thus minimizing mechanical turbulence by providing a smooth surface to blood flow. In addition the stainless steel cylinders can be repeatedly sterilized by autoclave (i.e. temperature of 200°F) for clinical applications.

(2) Provision was made for three blood flow and gas flow inlets to the individual annulli surfaces. These flows are directed to the respective annulli by means of a flow piece built into the retaining face-plate (see figure 12a). The blood flow is sustained from a venous reservoir attached to the flow piece (see figure 12b), and was brought through the respective channels of the flow piece by means of rubber tubing (3/8 inch inner diameter). The volume and rate of blood and gas flows can be controlled by means of the 'screw clamping' adjustments indicated (figure 12a).

In addition the flows were restricted solely to the individual annulli since the extended cylinder lips mount on the flow piece and ride on ribbon teflon bearings, facilitating cylinder rotation.
Figure 12a. Construction Features Of The Stainless Steel Cylinders.
thick tygon tubing 2" I.D. acts as venous reservoir

nickel plated brass reservoir sleeve
venous inflow
emergency reservoir inflow
three flexible rubber tubes 1/8" I.D. feeding blood to each cylinder annulus
recirculation inflow

CROSS-SECTIONAL VIEW OF THE VENOUS RESERVOIR

Figure 12a. (continued)
Figure 12b. Construction Of The Stainless Steel Cylinders.
Rolled lip of cylinder

Bearing shoe fitted to cylinder and soldered at break point shown

Join of rear lip to cylinder body

Figure 12b. (continued.)
The face-plate and flow piece, as well as the venous-reservoir attachment were constructed of nickel-plated brass in order to meet clinical requirements of non-toxicity to blood and repeated sterilization by autoclave.

(3) An arterial reservoir was designed which allowed for the gentle outflow collection in a sufficient volume to permit the "settling-out" of any air bubbles.

(4) The spacers were eliminated from the flow path of the annuli. The spacing was maintained by the arrangement of the rear flanges (see figure 11) and the cylinder mounting on the flow piece.

The construction of the stainless steel cylinders, with extended lips and rear flanges, involved a different construction approach. The major difficulty lay in the requirement of + 0.01 inch tolerance of cylinder surface. Such a tolerance was demanded to provide a minimum of turbulence to blood flow between cylinder faces. The stainless steel model is illustrated in figure 13).

3.4 Evaluation of the Rotating Cylinder Oxygenator

The qualities of an ideal oxygenator are usually described in terms of the efficient performance of the human lung as a gas exchanger and of the gentleness of the normal circulatory system in handling blood. Most authors agree on the following requirements:1,15,31
(1) The artificial lung must be able to oxygenate venous blood to 95% saturation for blood flow rates which are greater than the organism requirement.

(2) Simultaneously, the gas exchange device must remove carbon dioxide in appropriate amounts so as to avoid either CO₂ retention or CO₂ depletion.

(3) A suitably large gas exchange capacity must be provided while keeping the blood content (i.e. priming volume) of the artificial lung within reasonable limits.

(4) The mechanical process of gas exchange must be gentle enough to avoid destruction of formed elements of the blood or desaturation of plasma proteins.

(5) The artificial lung must be of simple and dependable construction so as to permit safe oxygenation over prolonged periods, easy cleaning and assembly, and reliable sterilization.

On the basis of satisfying the above requirements to an adequate degree, the rotating cylinder was evaluated on the basis of a comparison with the accepted 13 inch disc oxygenator as regards to oxygenator performance in hemolysis and efficiency.

3.4.1 Hemolysis Comparison

Hemolysis pertains to the measure of damaged red blood cells or caused by traumatic influences or non-physiological conditions. The degree of hemolysis in blood can be measured by a number of techniques; however, the most accepted method
is by spectrophotometry. The units of hemolysis express the hemoglobin of damaged red cells contained in the plasma in mg. (of damaged cells) /100 mg. of plasma.

In order to obtain a comparative relationship between oxygenating systems for the degree of hemolysis produced, "in vitro" tests must be conducted (i.e. excluding the animal from the bypass), since each animal may compensate for the blood damage at different rates. Physiological conditions of pH, PCO₂, etc. are, however, necessary.

Hemolysis comparison tests were performed with the two-annulli rotating cylinder oxygenator and the 13 inch disc oxygenator. The closed-circuit test setup for the oxygenators is illustrated in figure 14. Identical circuits were employed for each oxygenator as follows:

(1) A roller pump, calibrated for blood, working at a pressure of 120 mm. Hg.

(2) The plastic tubing employed was of clinical standard (i.e. siliconized).

(3) All adaptors and connectors were of equal size and tapered to minimize turbulence.

(4) Sufficient priming volume, as clinically required during bypass procedures, was used in each oxygenator.

(5) The oxygenator operating parameters of blood flow rate and rotational speed were set for normal operation. These settings were identical for both oxygenators.
Figure 14  Hemolysis Test Circuit.
The 13 inch disc oxygenator circuit was primed with 1.3 liters of fresh bovine blood and the rotating cylinder oxygenator circuit was primed with 0.6 liters of an identical sample of bovine blood. For a fixed common rotational speed of 120 rpm and blood flow rate of 1.4 liters/minute, the blood samples were allowed to circulate for two hours. Samples were withdrawn every 15 minutes and spectrophotometrically analyzed.

The resulting hemolysis figures were very low and identical for both oxygenators, starting at 12 mg % and at end of run 16 mg %. This indicates the superior performance of the rotating cylinder oxygenator since the number of blood passages through the system was twice that for the disc oxygenator, due to the lower priming volume.

3.4.2 Efficiency Test

In establishing a quantitative rotating cylinder oxygenating performance for the parameters of flow rate and rotational speed, an unlimited supply of venous blood is required, this blood being of standardized hemoglobin content, oxygen saturation, carbon dioxide content, pH and temperature. These requirements are dictated by a few basic physiologic considerations1,30,31

(1) in terms of overall gas transfer, it is not equivalent to saturate diluted blood or concentrated blood;
(2) due to the shape of the oxygen dissociation curve depicting affinity of hemoglobin for oxygen, it is much easier to raise oxygen saturation in the lower range (55-80%) than in the upper range (80-100%);

(3) a drop in pH, an increase in CO₂ pressure or an increase in temperature brings about a decrease in the affinity of hemoglobin for oxygen;

(4) conversely, a rise in pH, a decrease in CO₂ pressure or a decrease in temperature increases the affinity of hemoglobin for oxygen.

It is not practical to collect the exceedingly large amounts of fresh blood needed for measurement of oxygenator performance by "one-passage" techniques. Further, determination of performance while perfusing a laboratory animal, meets with only partial success due to the homodynamic and metabolic fluctuations of the organism, making it difficult to maintain steady perfusion conditions for different test oxygenator parameters. Thus, closed circuit methods have to be devised. The most promising technique is to couple to the test oxygenator another oxygenating unit used as a "deoxygenator" or source of venous blood (as used in the prototype tests). In such a circuit, the same venous blood is continuously arterialized in the test unit, then deprived of oxygen and loaded with CO₂ in the deoxygenating unit, which is ventilated with an appropriate CO₂ - N₂ mixture (maintaining normal blood conditions).
Figure 15 illustrates the closed-circuit test arrangement successfully utilized in measuring the performance of the cylinder oxygenator.

The cylinder oxygenator was provided with a supply of constant venous blood from the venous reservoir. This saturation was monitored by an oximeter measurement for fast determination. The blood, once arterialized, was pumped to the arterial reservoir. A 26 inch disc oxygenator was used as the deoxygenation device, providing the larger equilibrating capacity necessary for the process. In the deoxygenator the arterial blood was exposed to a mixture of 92% nitrogen and 8% carbon dioxide. The oxygen and carbon dioxide contents of the venous blood were regulated by varying the blood flow, disc speed and gas flow.

Fresh heparinized beef blood was utilized in determining cylinder oxygenator efficiency. The blood was maintained at 37°C by the heat exchanger contained within the deoxygenator.

The parameters of blood flow rate and cylinder rotational speed of the test unit were varied. For each parameter change a corresponding regulation was made on the deoxygenator to maintain a constant venous saturation (within the normal limits of 60 ± 5%) and CO2 content (which determines normal pH and PCO2). Adjusted conditions were allowed to reach and sustain stability for a period of 15 to 20 minutes before several venous and arterial samples were taken at 10 minute intervals for accurate Van Slyke determination of the blood conditions.
Figure 15 Efficiency Test Circuit.
A measure of the cylinder oxygenator efficiency was thus obtained as a function of the flow and rotational speed for fixed conditions of gas flow rate with the oxygenator horizontally level.

The results of this controlled experiment are plotted in figure 16. The arterial saturation resulting from a fixed range of venous saturation and oxygen uptake are plotted against blood flow rate. Physiological conditions of the blood (i.e. pH, PCO₂, hematocrit and temperature) were maintained.

The determining factor in establishing the oxygenating efficiency is the maximum flow rate at which an arterial saturation of 95% is obtained from a venous saturation of 65%. This point corresponds to an oxygen uptake of 6 vols. %, which reflects the lower allowable limit of O₂ consumption in the perfused organism at rest (i.e. human requirements). Thus, from the graph this situation results in the two annulli cylinder oxygenator at a maximum flow in the order of 1,150 to 1,200 c.c./min. at a fixed rotational speed of 120 rpm. The two annulli cylinder oxygenator corresponds in surface area to a 9 inch disc oxygenator. In figure 7, it is noted that the 9 inch disc oxygenator achieves this lower bound of oxygenating efficiency for a maximum flow rate of 1,200 c.c./minute for a fixed disc speed of 120 rpm.

Further, in extrapolating the results to a three annulli cylinder oxygenator, the expected maximum flow rate for the
oxygenating efficiency is then 1700 c.c./min. (i.e. 575 to 600 c.c./min. flow/annulus), which is equivalent to the 13 inch disc oxygenator.
Figure 16 Cylinder Oxygenator Efficiency As A Function Of Flow Rate.
4. AN ELECTRODE MONITORING DEVICE

4.1 Need for Monitoring Devices

In the control of heart-lung bypass procedures a choice exists between the technical difficulty of obtaining complete biologic information and the common sense observation that the more numerous the monitoring devices, the greater is the likelihood of instrumental and human failure. Since all vital signs, hemodynamic as well as metabolic, are interdependent, not all need be measured. One practical solution to the control problem is to monitor only those parameters which empirically have been found useful in the operating room, such as arterial, superior vena cava and inferior vena cava pressures, the electrocardiogram, the electroencephalogram, the blood and body temperatures. In addition, it is ascertained that quantities of well oxygenated blood in excess of body requirements are distributed to the organism. This approach has been the most popular, whereby perfusion conditions are preset and maintained from empirical data obtained from clinical experience for particular patient classification.

Another approach to the control problem, 6,7,8,9 which has received attention, is based on the principle that normal oxygen and carbon dioxide partial pressures (i.e. PO₂ and PCO₂) and pH in arterial and venous blood reflect normal tissue gas exchange. Thus, by continually monitoring these parameters the perfusion can be maintained in physiologically normal limits, whereby blood flow rate, gas flow rate and efficiency
of extracorporeal gas exchange are adjusted accordingly.

This latter approach prompted the design of a continuous monitoring system to be used in conjunction with the bypass procedures at the University of Saskatchewan Hospital. The design incorporates commercially available electrodes and amplifiers adapted to provide simultaneous and continuous recordings of the three parameters (i.e., \( P_O_2 \), \( P_CO_2 \), \( \text{pH} \)).

In addition to the perfusion control application for the monitoring system, the continuous and instantaneous recording of the gas exchange parameters indicates extensive application in post-operative observation of recovery, and in pre-operative test diagnoses. Also, such a system might be used as a laboratory instrument for fast determinations of \( P_O_2 \), \( P_CO_2 \), and \( \text{pH} \), which could replace the meticulous and time consuming Van Slyke and Astrup techniques.

4.2 Monitoring System Requirements in Maintaining Perfusion Control Within Physiologically Normal Limits

It is the purpose of this section to describe how normal conditions of the blood parameters are obtained in the respiratory-blood phase of the oxygenator.

The graph of figure 17 relates the partial pressures of oxygen and carbon dioxide (\( P_O_2 \) and \( P_CO_2 \)) of the oxygenating gas at barometric pressure (which will vary depending on locality). The line between 100% \( P_O_2 \) and 100% \( P_CO_2 \) (slope at \(-1\)) indicates all possible combinations of the two pressures.
Figure 17 Graph Relating The Blood Parameters Of $P_{O_2}$ And $P_{CO_2}$ To The Normal Arterial Point.
at barometric pressure. For the standard oxygenating gas used, 95% O₂ and 5% CO₂, the corresponding pressure point is indicated by slope \( I \) (i.e. the influent gas point).

When gas at \( I \) is equilibrated from gas phase to blood phase by molecular diffusion, O₂ and CO₂ diffuse at different rates. The diffusion of oxygen occurs twenty times faster than for CO₂ due to the lower molecular weight. The diffusion line is indicated in the graph as the \( R \) line at a slope \(-1/20\).

The handbook of biological data states that the normal values of oxygenated blood are 80 to 100 mm. Hg. \( P_{O₂} \) and 35 to 45 mm. Hg. \( P_{CO₂} \) for arterial blood; 25 to 45 mm. Hg. \( P_VO₂ \) and 38 to 58 \( P_VCO₂ \) for venous blood. Referring to the graph again, it is noted that the point representing the mean arterial point in the acceptable range is contained within the original \(-1\) slope relating \( P_{O₂} \) and \( P_{CO₂} \).

The partial pressure of the oxygen in the alveolar air in the human lungs is less than 125 mm. Hg. At normal blood flow rates the partial pressure of oxygen in the blood becomes approximately equal to that of the alveolar air during the time of exposure. For a given blood flow rate through an external oxygenator the resulting partial pressure of oxygen in the blood will be largely a function of the disc speed. Thus 'the efficiency' of the oxygenator for a particular gas composition and pressure may be controlled by varying the disc speed. The line shown in figure 17 at slope \(-1\) may therefore represent an oxygenator operating at 100% efficiency. The
blood-gas relationships in an oxygenator less efficient may thus be represented by lines of increasing negative slope (as shown). For example, an oxygenator efficiency of 0.18 is required to achieve the blood-gas relationships indicated at point $\bar{a}$ in the figure.

The normal venous point ($\bar{V}$) is determined by the arterial-venous oxygen difference or the volume of oxygen consumed by the body.

$$\dot{V}_O_2 = \frac{C_{aO_2} - C_{vO_2}}{\dot{Q}_B} \quad (1)$$

where $C_{aO_2} = $ quantity of arterial $O_2$, expressed in volumes % (e.g. 14 c.c. $O_2$ per 100 c.c. blood = 14 vols. %).

$C_{vO_2} = $ quantity of venous blood.

$\dot{Q}_B = $ blood flow rate.

Similarly for $CO_2$ production by the body,

$$\dot{V}CO_2 = \frac{C_{vCO_2} - C_{aCO_2}}{\dot{Q}_B} \quad (2)$$

Thus, assuming that one can control the position of the $\bar{a}$ point, and assuming fixed oxygen consumption, one can control the position of the $\bar{V}$ point by varying the blood flow rate.

Since the partial pressure of oxygen and carbon dioxide of the blood can be expressed in terms of oxygen saturation (at a constant pH and temperature 37°C), the relationships shown in the graph (figure 17) may be represented in the composite graph of figure 18. The normal ranges of the arterial and venous parameters are indicated by the dotted boxes.
in the figure. It may be seen from the graph that a number of parameters may be monitored to control the arterial and venous points within normal limits. The arterial point can be monitored and fixed by observing the PaO\textsubscript{2} and PaCO\textsubscript{2} or the PaO\textsubscript{2} and pH, or the SaO\textsubscript{2} and pH.

By monitoring PaO\textsubscript{2} and PaCO\textsubscript{2}, an accuracy of measurement of ± 20% is required to maintain the indicated arterial point midway between the limits of the acceptable values. However, if PaO\textsubscript{2} and pH are monitored, the pH parameter must be measured to an accuracy of ± 0.05 pH units. Finally, if SaO\textsubscript{2} and pH are monitored, the values of the parameters must be measured within a very close accuracy. The latter technique is generally used for non-continuous monitoring (i.e. Van Slyke technique). However, this procedure is not applicable to continuous monitoring. Fortunately electrodes are commercially available which measure PO\textsubscript{2}, PCO\textsubscript{2} and pH 10,14,28,32 within the accuracy required.

4.3 The Monitoring System

The oxygenator blood-gas relationship (i.e. the \( \overline{a} \) and \( \overline{v} \) points) can be adequately maintained within the required limits by specifically monitoring arterial PO\textsubscript{2} and pH (thus controlling the \( \overline{a} \) point) and venous PO\textsubscript{2} (controlling the \( \overline{v} \) point, since the pH lines are nearly linear in the range of interest). In addition, by monitoring the arterial PCO\textsubscript{2}, the respiratory condition of the post-operative patient can be determined so as to avoid CO\textsubscript{2} retention or depletion. From these consider-
Figure 18 Graph Relating PO₂, Pco₂, pH and So₂ for the Normal Arterial and Venous Ranges.
ations it was decided to design a four channel system to con-
tinuously monitor these parameters. This system is briefly
described in the block diagram of figure 19.

Since the \( \overline{V} \) point is determined by the single of \( P_\text{O}_2 \),
an electrode can be placed directly in the oxygenator
flow path to provide a continuous measurement. However, two
parameters are required to establish the \( \overline{A} \) point (i.e. arterial
\( P_\text{O}_2 \), \( P_\text{CO}_2 \) and \( \text{pH} \)). To facilitate a continuous measurement
of these parameters it was decided to adapt the electrodes
required into a single cuvette of very low priming volume
and use a 'continuous withdrawal and waste' technique.
In this manner, major sterilization and leakage problems
can be avoided. This type of system design lends itself not
only to the application of perfusion control, but equally
to postoperative and pre-operative observation and as a lab-
oration measuring instrument for either arterial or venous
\( P_\text{O}_2 \), \( P_\text{CO}_2 \) and \( \text{pH} \).

The basic elements of the designed monitoring system
were two polarographic oxygen electrodes, a Severinghaus
carbon dioxide electrode and a miniature pH reference and
glass electrode with their corresponding chopper stabilized,
high gain amplifiers (with recorder outputs) purchased from
Beckman Instruments Inc. The individual amplifier channels
and readout meters for the four parameters were enclosed in
a single cabinet. This cabinet also facilitates the storage
Figure 19 Block Schematic of A Continuous Withdrawal Monitoring Unit.
of the water bath and calibration gases for the electrodes. Thus, a compact, easily transportable unit is achieved (the final assembly is pictured in figure 20).

The particular electrodes, the principle of measurement and the cuvette design for the arterial withdrawal system are briefly discussed in the following subsections.

4.3.1 The Measuring Electrodes

(a) The Polarographic Oxygen Electrode

Two methods are presently available for achieving continuous measurement of $PO_2$ within an accuracy of $\pm 20\%$. The first is oximetry$^{28}$ which utilizes the principle of spectrophotometry to measure the quantity of oxygen in the sample. The second available method is polarography$^4,5,12,13$ which is better suited to continuous monitoring applications due to its principle of operation.

Figure 21 illustrates the Beckman polarographic cell purchased for the monitoring tests. As indicated, both sensing and reference elements (platinum cathode and silver anode) are contained in a single teflon unit. Electrical communication between the two electrodes is maintained via the potassium chloride (KCl) electrolyte gel surrounding the electrodes. The gel and membrane separate the electrodes from the blood to prevent contamination of electrode surface.

A simplified illustration of the oxygen electrode is presented in figure 22 which illustrates the operating principle.
Figure 20  The Monitoring Unit.
Figure 21 (a) Diagramatic Illustration Of The Po₂ Electrode. (b) Diagramatic Illustration Of The Ph Electrodes.
Figure 22 Simplified PO₂ Measurement.

Figure 24 Simplified PCO₂ Measurement.

Figure 25 Simplified pH Measurement.
The platinum wire and the silver wire are attached to a battery so the platinum wire forms the negative pole and the silver wire the positive pole from a constant polarizing source of -0.68 volts. The platinum cathode and silver wire are connected via an electrolyte solution of potassium chloride and water. Oxygen molecules migrate from the pressure gradient in the sample through the membrane and into the electrolyte region of no pressure gradient, and contact the platinum cathode. Each oxygen atom gains two electrons, forming $O^{2-}$ ions. These ions then combine with hydrogen ions, $H^+$, to form $OH^-$. To balance the reduction of oxygen at the cathode, atoms in the anode are oxidized and lose an electron. The silver ions, $Ag^+$, combine with $Cl^-$ in the electrolyte, forming silver chloride which is deposited on the anode. In this simplified electrode, reduction of oxygen at the cathode and oxidation of silver at the anode allow a direct current to flow. The flow of current is directly proportional to the rate of oxygen reduction at the cathode. Thus the current flow provides a continuous measurement of the partial pressure of oxygen in the blood.

(b) The Carbon Dioxide Electrode

An electrode within the +25% accuracy required for measuring PCO$_2$ has been developed by Severinghaus$^{10}$ and brought to a high degree of development. It is illustrated in figure 23.
Figure 23  Severinghaus PCO Electrode Assembly

NOTE: entire assembly fits into water bath housing.
The principle of operation is described through the simple illustration of figure 24. The PCO₂ electrode is essentially a pH glass electrode arranged to measure the pH of a very thin film of aqueous sodium bicarbonate solution. The solution is separated from the gas or blood sample by a teflon membrane permeable to CO₂ molecules only. The aqueous bicarbonate layer, referring to figure 23, is maintained between the glass and teflon membrane by a matrix consisting either of very thin cellophane, glass wool or nylon. This matrix is mounted on the end of a lucite tube using a siliconized 'O' ring electrical seal. Teflon is an electrical insulator; in this manner the inside of the CO₂ electrode is completely insulated from the adjoining cuvette and water bath.

As CO₂ molecules dissolve into the aqueous bicarbonate layer, the CO₂ reacts with water producing carbonic acid, thus lowering the pH. The pH falls nearly 1 pH unit for a tenfold increase in PCO₂ giving a linear function of the log of pH. The pH of the film is determined by measuring the potential between the glass electrode and calomel reference cell, the electrical contact being maintained via the KCl electrolyte.

(c) The pH Electrodes

The pH electrode requirements are stricter than for the PO₂ and PCO₂ electrodes. It must be capable of measuring the degree of acidity or alkalinity of blood to an accuracy of ± 0.05 pH units. Fortunately these electrodes
have existed as standard laboratory measuring devices for many years.

The principle of pH measurement is described in conjunction with the simplified illustration of figure 25.

The active element of a glass electrode is a membrane of special glass. The membrane forms a partition between two liquids of differing hydrogen ion concentration. One liquid is a known pH sample contained in the membrane while the other is the unknown sample external to the membrane. An electrostatic potential develops across the membrane proportional to the pH difference, represented by the H⁺ ion activity. Due to inherent potentials in the glass from manufacture it is thus necessary to standardize the electrode against a known pH buffer first.

A saturated calomel electrode is used as a reference electrode (figure 21) and provides an independent potential to which the glass potential can be compared. Electrical connection between the two electrodes is maintained via the KCl solution.

4.3.2 Electrode Cuvette Design

The above mentioned electrodes were selected because of their suitability for direct, continuous parameter measurement. In considering the electrode holder and cuvette design, it was necessary not only to provide a small flow path connecting the three electrodes but also to maintain the temperature of the blood volume contained and the electrodes
Figure 26  The Carbon Dioxide Electrode Assembly.
Figure 27 The Designed Three Electrode Flow Cuvette.
themselves at a constant 37°C as required. This assembly is illustrated in figure 28. The carbon dioxide electrode is mounted within a metal cuvette (as shown in figure 26), which in turn is contained within a plexiglass water-bath. The blood sample enters the metal cuvette via flow tubes contained in the water-bath. The oxygen tension and pH reference and glass electrodes are also mounted so as to be in contact with the blood flow path, as shown in figure 27.

4.4 Electrode System Evaluation

In order to assign the monitoring system for use in any or all of the applications suggested, it is necessary to ascertain whether reliable results are achieved in each situation. This involves an investigation of the accuracy of the electrode system under the required circumstances of measurement. From the data, system performance can be adequately predicted and appropriate correction factors derived, where applicable.

In evaluating the performance of the electrode monitoring system, for specific anaerobic spot sample and continuous withdrawal measurement conditions, selected experiments were performed with the following aims in view:

1) to compare the values obtained with the electrode system on blood equilibrated with gases of different concentrations of O2 and CO2, to the known partial pressures of the gases;
(2) to compare estimations of blood $P_{O_2}$, $P_{CO_2}$ and pH obtained by the electrode system with values made on samples of the same blood by the Van Slyke manometric method;
(3) to obtain a measure of electrode response time;
(4) to obtain a measure of electrode sensitivity to flow for different withdrawal speeds;
(5) to check electrode response for withdrawal duration.

4.4.1 Test Procedure

The monitoring system was prepared for measurement daily by allowing the amplifiers, the electrodes and the recorder to stabilize for a period of one hour. During this time the electrodes, mounted in the adaptor cuvette, stabilize to the water bath temperature of $37^\circ C \pm 1^\circ C$. When measurements are not being performed, distilled water was always maintained in the cuvette flow path to prevent water vapor loss in the $P_{O_2}$ and $P_{CO_2}$ membranes. Thus deterioration of the membrane was prevented permitting a long membrane life and little variation from day to day in its electrical characteristics.

The initial electrode calibrations were performed with fixed gas samples of known concentration (for the $P_{O_2}$ and $P_{CO_2}$ electrodes) and with a buffer solution (for the pH electrode) in conjunction with the electrode system setup depicted in figure 29.

The oxygen tension electrode was calibrated for a linear readout span on the meter and recorder output with
Figure 29  Electrode Setup For Measuring Equilibrated Blood Samples
And The Equilibrating Gases.
sequential (continuous) flows of nitrogen and compressed air. The actual concentration oxygen contained was analyzed with the Scholander technique and the tension setting calculated for the ambient pressure. The identical calibration may be accomplished with equilibrated distilled water.

The carbon dioxide tension electrode was calibrated with a single gas mixture. The gas contained a 5.83% concentration CO₂ in oxygen, which provided a calculated tension setting for the ambient pressure in the midrange of the readout scale.

The pH electrodes were calibrated with a pH buffer of 7.4, providing a mid-range calibration. However, when the buffer solution was introduced, on occasion an erratic meter reading resulted. This condition was due to trapped air bubbles, resulting from the previous gas calibration in the V mounting arrangement of the pH reference and glass electrodes in the cuvette path. When this occurred it was necessary to withdraw the reference electrode, agitating it to free any bubbles, while continuing to flush the cuvette with buffer. When the air bubbles were eliminated, the electrode (reference) was reseated in its 'O'-ring seal and the calibration completed. Finally, the buffer was flushed from the cuvette with distilled water and scaled within the cuvette (position c of inlet stopcock); thus prepared for measurement.

The repeatability of electrode measurements was first examined with specific known samples of blood equilibrated with gases of different concentrations of O₂ and CO₂ mixtures...
(as analyzed by the Scholander technique) in conjunction with the known tensions of the gas itself.

The blood utilized in equilibration was outdated red cross reserve blood (i.e. 4 weeks old) to which sodium bicarbonate was added to adjust the pH of the blood within the normal range (i.e. 7.35 to 7.45) to allow complete equilibration of the blood to the gas tensions.

Separate 20 ml. blood samples contained in a small erlenmeyer flask were equilibrated for one hour with different gases of known O₂ and CO₂ concentrations at a maintained temperature of 37°C ± 0.1° in a water-bath. At this temperature, the solubility of the blood for the gases is controlled to reflect the tensions of the equilibration at normal body temperature. For different temperatures the solubility varies. The anaerobic samples were drawn from the equilibrating flask and measured immediately to maintain the temperature of the blood and to avoid any metabolic alteration of the parameters due to a time lapse prior to measurement. Each sample was then measured to determine O₂ and CO₂ tensions with a corresponding measurement of the equilibrating gas itself.

Each anaerobic blood sample had to be flushed into the cuvette three successive times before the measured value was recorded due to the equilibrating properties of the PO₂ electrode membrane. The first flushing produced a higher value of measured tension. On the two succeeding flushings reproducible and stable values were maintained (over a 'still'
period of five minutes).

Several such tension measurements of the equilibrating gases and equilibrated blood samples were performed successively over several days. The recorded measured tensions were compared against the derived tensions of the equilibrating gases in figures 30a and 30b. These measurements were performed following initial electrode calibrations and demonstrate a consistent response within a deviational error (see figure 5). However, two blood samples were measured after one hour and a half had lapsed between initial calibration and measurement. The deviational error increased, as shown in figure 5. This increase can be attributed to a "drift" in the diffusive properties of the membrane when they are not "primed" for measurement.

In conjunction with the measurements of known blood samples, unknown patient samples were measured and the values compared against the corresponding values of the identical samples obtained by an accepted laboratory standard method. The comparison standard was the Van Slyke manometric technique which provides derived values of PO₂, PCO₂ and pH.

Eight samples of arterial and venous blood were obtained from patients undergoing rest and exercise tests. The withdrawn samples were split into two separate 10 c.c. syringes and immediately measured by the electrode system with a simultaneous Van Slyke determination. In this manner solubility and metabolic changes resulting in blood parameter
Figure 30a: Measured Values of PO₂ of Blood and Gas Samples As Compared To The Known Gas Partial Pressures.
Figure 30b Measured Values of Pco₂ of Blood and Gas Samples As Compared To The Known Gas Partial Pressures.
changes were eliminated.

An electrode calibration was performed prior to sample measurements. Three sample flushings provided the stabilized response of the O₂ and CO₂ tensions and pH, which were recorded. The results are plotted against the derived Van Slyke values in figures 31, 32 and 33 respectively. The measured electrode values were determined within a mean deviational error of .02 pH units, 2 mm. Hg. PCO₂ and 2 mm. Hg. PO₂ in respect to the Van Slyke values.

Under the initial gas calibrations and established measurement technique an electrode measurement repeatability was established regarding anaerobic still sample determination of known and unknown blood samples. In the situation of continuous measurement of the blood parameters the additional factors of electrode response and sensitivity to flow are important considerations in evaluating the electrode system performance.

In determining the electrodes' response time, separate anaerobic samples of patient arterial and venous blood were flushed alternately into the electrode cuvette at regular intervals (as illustrated in figure 34). The PO₂, PCO₂ and pH electrode response from a stable sample reading to 95% of the new sample reading were recorded for the conditions of distilled water (initial condition) to venous, venous to arterial and arterial to venous. The mean response time of several such tests is illustrated in figure 34 for the PO₂,
Figure 31 Measured \( P_{O_2} \) Of Patient Blood Samples As Compared To The Derived \( P_{O_2} \) Of A Van Slyke Analysis Of The Same Samples.
Figure 32 Measured Pco₂ of Patient Blood Samples as Compared to the Derived Pco₂ of a Van Slyke Analysis of the Same Samples.
Figure 33 Measured pH of Patient Blood Samples as Compared to a Standard pH Analysis of the Same Samples.
PCO\textsubscript{2} and pH electrodes.

The pH electrode responds practically instantaneously to changes in either direction, whereas the O\textsubscript{2} and CO\textsubscript{2} tension electrode responses suffered a time lag due to their respective membrane permeability and equilibrating time-constant in achieving steady state diffusion, which in turn is determined by the membrane thickness. Since the diffusion field of the measured sample is confined in the membranes, the direction of change in the diffusion gradient influences the equilibration time-constant (as demonstrated).

A measure of electrode sensitivity to flow rates was obtained for a known blood sample in conjunction with the test setup depicted in figure 35.

A 300 ml. sample of red cross reserve blood was equilibrated with gas (of concentration 20.3% O\textsubscript{2} - 2.0% CO\textsubscript{2}) under a maintained temperature of 37°C. The blood was equilibrated for two hours prior to measurement to achieve stable conditions and continued throughout the experiment to maintain constant blood parameters.

After stable conditions of the blood had been reached (after approximately two hours), an anaerobic sample value was recorded. This value was rechecked for repeatability with an additional anaerobic sample at the termination of the experiment.

In conjunction with the anaerobic measured value, the measured response of the electrodes was recorded for different
Figure 34  Electrode Response Times To Changes In Blood Sample Parameters.
Figure 35  Electrode Setup For Measuring Flow Variations For Different Withdrawal Speeds.
constant withdrawal speeds. A Harvard withdrawal unit (Model 600-910/920) with 30 c.c. storage syringe was used. Each withdrawal speed was maintained for a duration of 5 to 10 minutes to assure a stabilized electrode measurement under the prevailing condition of flow. Figure 36 illustrates the measured values of P02, PCO2 and pH obtained as a percentage of the initial anaerobic value as a function of flow rate.

The variations in the measured values for the different flow rates is a result of pressure effects. These effects are due to hydrostatic pressure changes in the blood caused by the particular force of withdrawal, which causes the thin film of electrolyte between the respective P02 and PCO2 membrane and electrode to be 'squeezed out', thus influencing the reading. It can be noted in figure 36 that the PCO2 electrode sensitivity to flow is less pronounced than for the P02 electrode. This is due to the greater thickness of the PCO2 membrane and longer equilibrating time-constant which significantly retards the hydrostatic effects.

From two such tests performed, reproducible results were obtained (as shown in figure 36). This indicates that the flow effects maintain a consistent plateau of actual measured values to actual still sample value.

Coincident with the electrode sensitivity to flow is the stability of the electrode response as a function of time for a prolonged period of withdrawal. In obtaining a measure of this factor the test setup was identical to the arrangement.
Figure 36 Electrode Response As A Function Of Withdrawal Speed.
illustrated in figure 35.

300 ml. of red cross blood was equilibrated with a gas (concentration of 20.3% O₂ and 2.0% CO₂) at a maintained temperature of 37°C. Under stabilized equilibration conditions (after 2 hours of equilibration), an anaerobic sample value was recorded. The blood sample was then drawn continuously through the electrode cuvette for a period of three hours at a flow rate of 0.494 c.c./min. Actual measured values were recorded at 15 minute intervals. Figure 37 illustrates the measured values of the pH, PCO₂ and PO₂ parameters as a percent of the initial anaerobic value, as a function of time.

At the end of the run the anaerobic sample measurements were rechecked in conjunction with an electrode recalibration and the electrode deviational errors were noted (as shown in the figure).
5. CONCLUSION

Part 2 of this thesis presented a unified heart-lung control system which was designed for the rotating disc heat exchanger oxygenator used at the University of Saskatchewan hospital. The system employs commercially available components incorporated so as to achieve a compact and versatile unit, providing safe and reliable oxygenator and temperature regulation. The reliability of this system has been substantiated by two years of continued trouble-free use. In addition, those who have worked with the equipment have commented on its very satisfactory overall performance.

Part 3 of this thesis has described a rotating cylinder oxygenator design of equivalent surface area to a corresponding Kay Cross disc oxygenator, requiring only one-third of the priming volume of the latter. The complexity of the nature of blood made theoretical analysis of flow effects, surface tension effects for cylinder rotation, filming and the associated diffusion phenomenon of the design difficult. In this respect, the approach adopted was to establish the equivalence in surface areas in the design to the standard disc oxygenator '"lengths"'. Then, through prototype testing the compatibility and merits of the design are determined and the adequacy of oxygenating performance is achieved by a direct comparison to the known disc oxygenator performance/disc oxygenator '"length"'.

From the preliminary prototype experiments a clinical model evolved containing two annulli (equivalent to a 9 inch disc oxygenator). Evaluation of the design in conjunction with this two annulli rotating cylinder oxygenator model indicated that identical gas exchange capacity as for the corresponding 9 inch disc oxygenator is achieved. In addition the hemolysis per passage of blood in the rotating cylinder oxygenator is lower than in the disc oxygenator.

From these indications this particular design appears to be practical, particularly in the lower oxygenating capacity ranges. However, by extending the number of cylinders to incorporate the larger standard disc oxygenator ranges (i.e. 13, 18, 21, 25 inch disc oxygenators), a number of design problems become apparent. For example, a rotating cylinder oxygenator corresponding to the 25 inch disc oxygenator would require 6 annulli (i.e. seven cylinders) to provide the equivalent oxygenating capacity. As such, the unit would be very bulky and would present engineering design problems in providing reliable constant flow blood inlets and achieving adequate rotational support for the cylinders.

It is also considered desirable to incorporate heat exchange facilities within the rotating cylinders in order to maintain the low prime conditions of the design. To provide these facilities presents a further design problem.

These design restrictions greatly limit the practicality of the device as a piece of clinical equipment. However, if
the oxygenating capacity of the unit could be increased for a given surface area, a fewer number of cylinders would be required, easing the design restrictions. In this manner, the rotating cylinder oxygenator would have considerable merit.

To achieve a greater oxygenating capacity, not only for the cylinder oxygenator, but for any future oxygenator design, requires an extensive study into the properties of blood when filmed over various surfaces. In particular, in the resultant film the factors influencing the diffusion phenomenon from the oxygenating atmosphere to the blood film and from the oxygenated blood film into the venous reservoir contained between the oxygenating surfaces, are important. From this understanding a more scientific approach can be followed in the design of the oxygenator to provide the necessary factors.

Part 4 of this thesis presented an electrode monitoring system designed for perfusion control. The system incorporates commercially available electrodes (i.e. pH, PO₂, PCO₂) adapted into a single cuvette, facilitating continuous blood flow measurement by means of a withdrawal and waste procedure.

Evaluation of this system under continuous withdrawal conditions pointed out the dependence of the system response to the individual electrodes' sensitivity to blood sample parameter changes (i.e. response time), blood flow rate and internal electrode consistences as a function of time. Thus, perfusion monitoring, or post-operative monitoring, becomes a
multi-variable problem. These considerations are discussed below.

The blood sample withdrawal rates to three electrode cuvette is restricted to low flows in these applications. At these lower flows the $P_{O_2}$ and $P_{CO_2}$ electrodes exhibit a response plateau which is a percentage of the actual value for a specific flow rate. However, since the readout scale for the $P_{O_2}$ and $P_{CO_2}$ parameters is linear, this response can be compensated or pre-adjusted to the right value by calibrating the electrodes with a known sample of blood at the flow rate used. Also, for the lower flows, a time problem exists between a sample insertion until electrode indication. This time is made up of the transit time of the flow path to the electrodes and the electrode response time. In order to limit the transit time, it is desirable to connect the measuring unit via a stopcock to the perfusion flow, or via a small needle to the patient during post-operative monitoring, thus restricting the flow path (and transit time) to the cuvette path itself. In this manner, the time remaining is greatly a function of the electrode response. The $P_{O_2}$ electrode can respond to within 4 to 6 secs. (from a low $P_{O_2}$ value to a higher one, or 12 to 10 secs. in the reverse direction), $pH$ can respond instantly, and the $P_{CO_2}$ can respond within 45 to 60 secs. (in either direction).

In addition to the above factors, the $P_{O_2}$ $pH$ and $P_{CO_2}$ electrodes suffer a "drift" in response over a period of time, necessitating recalibration. The $P_{CO_2}$ electrode is the worst
offender, requiring recalibration every 15 minutes in order to maintain a response accuracy of ±10%, whereas the PO₂ and pH require recalibration every hour to maintain an accuracy within approximately ±5% and ±.03 pH units respectively.

In view of the above considerations, the electrode system can provide a continuous measurement of PO₂ and pH for perfusion control of the arterial point within the required ±20% accuracy with a minimum time lag and a minimum requirement for recalibration. (The PCO₂ response, in this case, can be ignored or a separate PO₂ and pH adapter can be designed). However, in post-operative monitoring, the PCO₂ electrode limits the period of measurement to 15 minute intervals, in addition to its long response time. A means whereby this situation can be overcome with the present electrodes and system is to continuously monitor the PO₂ and the pH, providing only spot samples for the PCO₂ electrode in a separate adaptor external to the continuous flow path.
6. BIBLIOGRAPHY


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CALCULATIONS OF SURFACE AREA AND PRIMING VOLUME FOR A TWENTY-ONE INCH DISC OXYGENATOR.

The 21 inch disc oxygenator represents the surface area required by an average adult.

Figure A-L. CALCULATIONS.
In a 21 inch disc oxygenator there are 84 discs (1 disc every .25 inches.)

The surface area of a single disc (the submerged area) is:

\[ \sin \alpha = \frac{2 \text{ cm.}}{6} \]
\[ \cos \alpha = \frac{\text{cm.}}{6} \]

Surface area (1 disc) = total disc area - area of submerged segment + 2 area of triangle remaining - area of spacer.

Surface area = \(\pi r^2 - \pi r^2 \cdot \frac{\theta}{360^\circ} + 2 \cdot \frac{1}{2} b h - \pi r^2\).

\[ \text{Surface area} = \pi \left( \frac{6}{2.54} \right)^2 - \pi \left( \frac{6}{2.54} \right)^2 \cdot \frac{144^\circ}{360^\circ} + 2 \cdot \frac{1}{2} \cdot 5.65 \cdot 2 - \pi (2)^2 \]

Surface area = 10.45 inches\(^2\).

There are two sides to the disc, therefore the total surface area of the 21 inch oxygenator = \(2 \cdot (10.45)(84) = 1750 \) inches\(^2\).

The priming volume required is;

Area of the submerged portion of a single disc.

\[ = \pi r^2 \cdot \left( \frac{\theta}{360^\circ} \right) - 2 \left(\frac{1}{2}\right) b h. \]
\[ = \pi \left( \frac{6.65}{2.54} \right)^2 \cdot \frac{144^\circ}{360^\circ} - 2 \left(\frac{1}{2}\right) \frac{6.65}{2.54} (2) \]
\[ = 6.8 \text{ inches}^2. \]

TOTAL PRIMING VOLUME = 6.8 inches\(^2\) (21 inches) = 120 inches\(^3\).
CALCULATIONS OF SURFACE AREA AND PRIMING VOLUME FOR THE CYLINDER OXYGENATOR.

(Equivalent to the 21 inch disc oxygenator.)

Figure A-2 CALCULATIONS.
Surface area of a cylinder = circumference x length.

\[ A = \pi(d)(\frac{\theta}{360}) L \]

(This is for the flooded situation shown - for complete filming.)

ANGLES:

- Outer cylinder (5\(\frac{1}{2}\) inch O.D.)
  \[ \sin\alpha = \frac{1.75}{2.625} \]
  \[ \theta = \frac{42^\circ}{2} \]
  \[ \phi = 90^\circ - 42^\circ = 48^\circ, \phi = 90^\circ - 42^\circ = 48^\circ \]

- 5 inch (O.D.) cylinder
  \[ \sin\alpha = \frac{1.75}{2.5} \]
  \[ \theta = \frac{44.5}{2} \]
  \[ \phi = 90^\circ - 44.5^\circ = 45.5^\circ, \phi = 90^\circ - 44.5^\circ = 45.5^\circ \]

- 4.75" (I.D.) cylinder
  \[ \sin\alpha = \frac{1.75}{2.38} \]
  \[ \theta = \frac{47.5}{2} \]
  \[ \phi = 90^\circ - 47.5^\circ = 42.5^\circ, \phi = 85^\circ \]

- 4.5" (O.D.) cylinder
  \[ \sin\alpha = \frac{1.75}{2.25} \]
  \[ \theta = \frac{51}{2} \]
  \[ \phi = 90^\circ - 51^\circ = 39^\circ, \phi = 76^\circ \]

- 4.25" (I.D.) cylinder
  \[ \sin\alpha = \frac{1.75}{2.125} \]
  \[ \theta = \frac{60.5}{2} \]
  \[ \phi = 90^\circ - 60.5^\circ = 29.5^\circ, \phi = 68^\circ \]

- 4" (O.D.) cylinder
  \[ \sin\alpha = \frac{1.75}{2.00} \]
  \[ \theta = \frac{60.5}{2} \]
  \[ \phi = 90^\circ - 60.5^\circ = 29.5^\circ, \phi = 59^\circ \]

Cylinder Surface Areas:

1. Surface area 4 inch (o.d.) = \( \frac{4\pi(301^\circ)(19)}{360^\circ} = 200 \) inches

2. Surface area 4.25 inch (i.d.) = \( \frac{4.25\pi(292^\circ)(19\frac{3}{8})}{360^\circ} = 215 \) inches

3. Surface area 4.5 inch (o.d.) = \( \frac{4.5\pi(282^\circ)(19\frac{3}{8})}{360^\circ} = 220 \) inches

4. Surface area 4.75 inch (i.d.) = \( \frac{4.75\pi(275^\circ)(20)}{360^\circ} = 235 \) inches

5. Surface area 5 inch (o.d.) = \( \frac{5\pi(269^\circ)(20)}{360^\circ} = 240 \) inches
(6) Surface area 5.25 inch (i.d.) = $5.25 \pi (26.6^2)(20\frac{1}{2}) = 250$ inches$^2$

(7) Surface area 5.5 inch (o.d.) = $5.5 \pi (25.5^2)(20\frac{1}{2}) = 255$ inches$^2$

(8) Surface area 5.75 inch (i.d.) = $5.75 \pi (25.5^2)(21) = 260$ inches$^2$

TOTAL SURFACE AREA = 1850 inches$^2$

PRIMING VOLUME REQUIRED:

Volume of a cylinder = $\frac{\pi}{4} r^2 h = 0.0796 \pi r^2 h$

Volume of a segment of a cylinder = $0.0796(\pi d \cdot \theta)^2 h$

(submerged sections)

Total Volume = $0.0796(\pi 5.25 \cdot 96^o) \frac{20.5}{360} - 0.0796(\pi 5 \cdot 21^o)^2 \frac{20}{360} - 2\frac{1}{2}(0.33)(1.75) + 0.0796(\pi 4.75 \cdot 85^o)^2 \frac{20}{360} - 0.0796(\pi 4.75 \cdot 78^o)^2 \frac{19.5}{360} - 2 \frac{1}{2} (1.75)(0.1) + 0.0796(\pi 4 \cdot 68^o)^2 \frac{19.5}{360} - 0.0796(\pi 5.75 \cdot 108^o)^2 \frac{20.5}{360} - 2\frac{1}{2} (1.75)(0.05) + 0.0796(\pi 5.5 \cdot 102^o)^2 \frac{20.5}{360} - 0.0796(\pi 5.5 \cdot 102^o)^2 \frac{20.5}{360} - 2\frac{1}{2} (1.75)(0.5) = 20$ inches$^3$

This volume, however, is only that between the cylinders. A reservoir volume is required to mix the arterial blood and to provide a "settling action" on minute air bubbles. Therefore, a minimum volume of 250 c.c. reservoir volume was adopted (i.e. 10 inches$^3$)

TOTAL PRIMING VOLUME = 30 inches$^3$