CLOSED-CYCLE RESPIRATOR DEVELOPMENT PROGRAM

CONTRACT N00014-69-C-0329

ANNUAL REPORT
(JUNE 1969 - JUNE 1970)

DOCUMENT RDP-019

June 24, 1970

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PREPARED FOR:

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1.0 INTRODUCTION

The General Electric Company, Re-entry and Environmental Systems Division, has developed a unique medical respirator based on the technology of closed cycle life support systems. Under contract to the Office of Naval Research (Contract N00014-69-C-0329), four prototype units were designed, fabricated and delivered to the National Naval Medical Center, Bethesda, Maryland for laboratory and clinical evaluation.

System performance requirements were selected to meet the needs of military use and the overall design was bounded by the requirement for portability and extended autonomous operation. An eleven month program starting in June, 1969, translated these requirements to prototype hardware which underwent comprehensive performance testing at the component, sub-system and system levels prior to delivery. This testing amply demonstrated the capability of the prototype systems to satisfy the performance requirements. This report summarizes the design and development efforts addressed to defining the prototype configuration and presents a complete physical description of the system. In addition, system calibration and test procedures, along with typical results, are presented.

2.0 BACKGROUND

Recent advances in the technology of closed cycle life support systems in the ocean technology area led the General Electric Company to the design of a respirator system which combined the versatility and diagnostic capabilities of existing volume controlled console units with light weight and portability. Specifically, a portable, electrically powered system which incorporates both volume and pressure controlled cycling as well as oxygen partial pressure control and other critical operating features was devised. The original concept consisted of a suitcase type unit weighing about 40 pounds and capable of providing 8 hours of autonomous operation.

Discussions with military medical personnel in January, 1968 indicated that this type of device, if successfully developed, would provide a capability for which there is an immediate need and is currently not satisfied by existing equipment. As a result, the General Electric Company built an operating system breadboard which satisfied the basic functional requirements identified as important in improving the capability to provide emergency as well as therapeutic respiration. The features incorporated in this breadboard system were as follows:

- Volume Control
- Pressure Control
- Controlled or Assist Cycling
- Oxygen Partial Pressure Control
- Inspiratory Flow Rate Control
- Passive Exhalation with Adjustable Time Delay
- Open Cycle (Ambient Air) Operation
- Operation from Battery or External Power

To substantiate the performance of the design, tests were conducted on selected components as well as on the entire breadboard system.

- Extensive testing of the carbon dioxide scrubber had shown that over a wide range of environmental conditions, exit gas CO_2 level could readily be held to less than 0.5 percent over the entire design life of eight hours.

- The oxygen partial pressure control system, originally developed for other uses had demonstrated the accuracy, stability, and response required for this application.

- Total system performance had been verified by an animal test conducted at the Albert Einstein Medical Center. The test consisted of maintaining the respiratory function of a paralyzed canine for approximately four hours and evaluating the various control features of the system. Test results confirmed the effectiveness of tidal volume control, oxygen partial pressure control, and carbon dioxide removal.

Subsequent to the conclusion of the breadboard evaluation tests, studies were initiated to evaluate the feasibility of packaging the system in a unit which could meet various mission and functional requirements. In June, 1969, a contract for the development of four prototype respirators configured to meet Military requirements was awarded by the Office of Naval Research. The work performed under that contract is summarized herein.

3.0 SYSTEM DESCRIPTION

Design of the respirator was based on the requirements set forth in Document RDP-001, Closed Cycle Respirator Development Program - System Requirements, a copy of which is included as Appendix I of this report. These requirements and performance parameters were selected to satisfy military mission profiles, and environmental considerations are based on projected usage on board aircraft, ships and motor vehicles. The design is compatible with existing military medical equipment and hospital facilities and provides the capability of sophisticated pulmonary therapy at remote locations and during transport of injured personnel.

The complete respirator is packaged in a suitcase sized container whose dimensions are 8" x 18" x 28". Weight of the unit, including a rechargeable battery power supply and expendables, is approximately 75 pounds. Drawings of the respirator showing the external configuration and locations of the various features are presented in Figure 3.1.

KEY TO FIGURE 3.1

A - Access Panel for Oxygen Cylinder and Power Cords

B - Primary Control Panel

C - Secondary Control Panel

D - Electronic Compartment Access Panel

E - Scrubber Access Panel

F - Airways, Masks, Adaptors and Battery Charging Switch Access Panel

G - Bacterial Filter Access Panel

H - External Oxygen Connector

I - AC Power Inlet

KEY TO FIGURE 3.1 (Cont'd.)

J - DC Power Inlet

K - Battery Pack

L - Compressor Filter

M - Carrying Handle

Figure 3.2 schematically illustrates the basic concept of a closed cycle breathing system. The principal elements are the carbon dioxide removal system, the oxygen partial pressure controller, flow check valves, and a variable volume accumulator. In this simple system energy required for gas circulation is provided by the user of the system. In the event the user, or patient, were not capable of providing the necessary circulation, a mechanical device could be provided which would alternately compress and release the accumulator to provide a means of forcing the gas into the lung. Upon releasing the accumulator, the natural elasticity of the lungs and the patient's muscular contraction will return the gas to the accumulator. The check valves ensure the flow of gas leaving the accumulator, passes through the scrubber where the carbon dioxide level is reduced to an acceptable value, and to the oxygen controller where the oxygen partial pressure is increased to the desired value by adding oxygen from an external supply. Ideally, there are no leaks to the surrounding atmosphere and the inert gases in the system are continually recirculated without replenishing.

While this simple system obviously does not satisfy the functional requirements of a complete respirator system, it does represent the basic building block to which the various flow control and flow conditioning elements are added to achieve the final system design. Figure 3.3 presents a schematic illustration of the complete system. Table 3.1 defines the numbered components of Figure 3.3 and includes a brief description of the component functions.

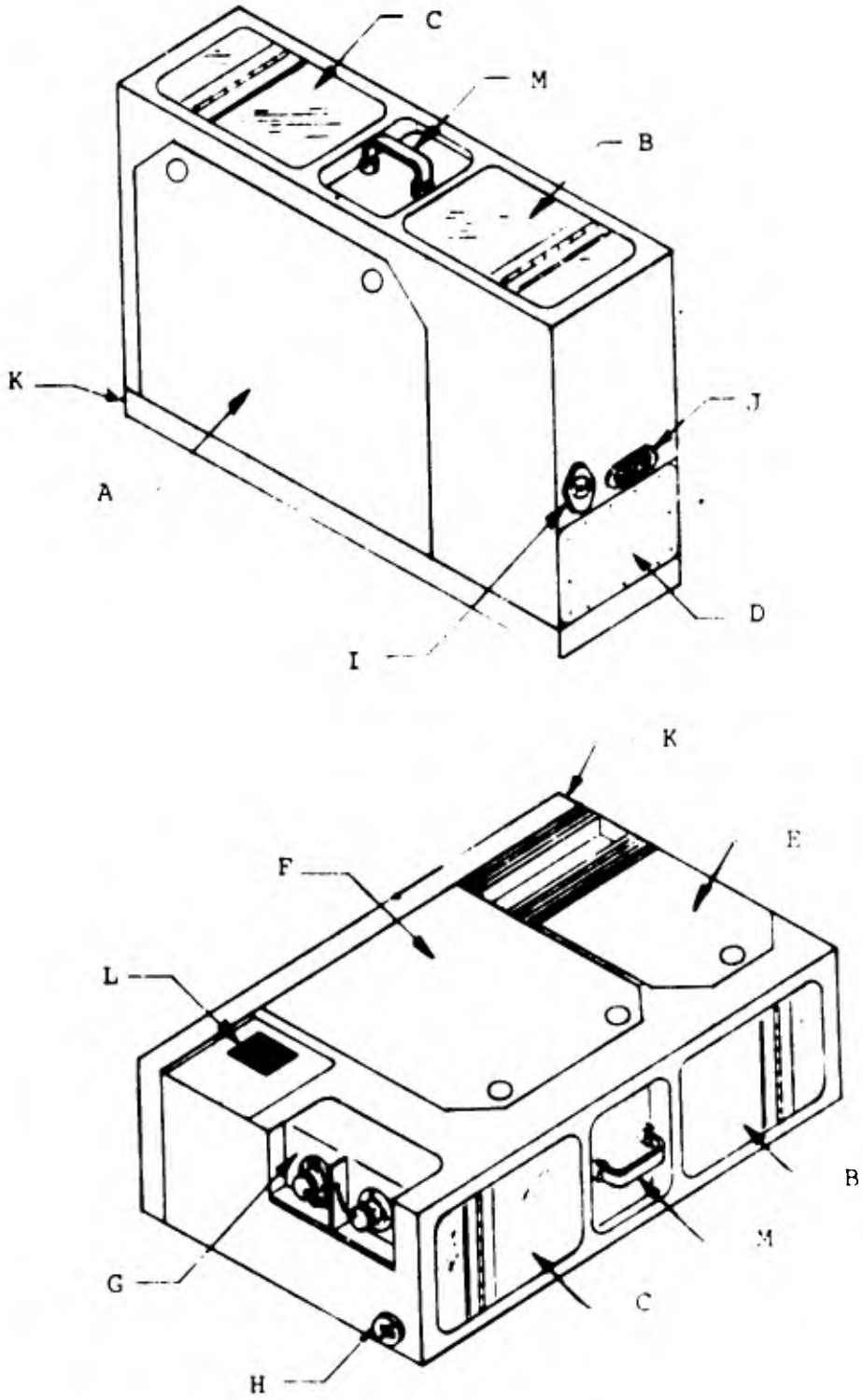


FIGURE 3.1 - PROTOTYPE RESPIRATOR CONFIGURATION

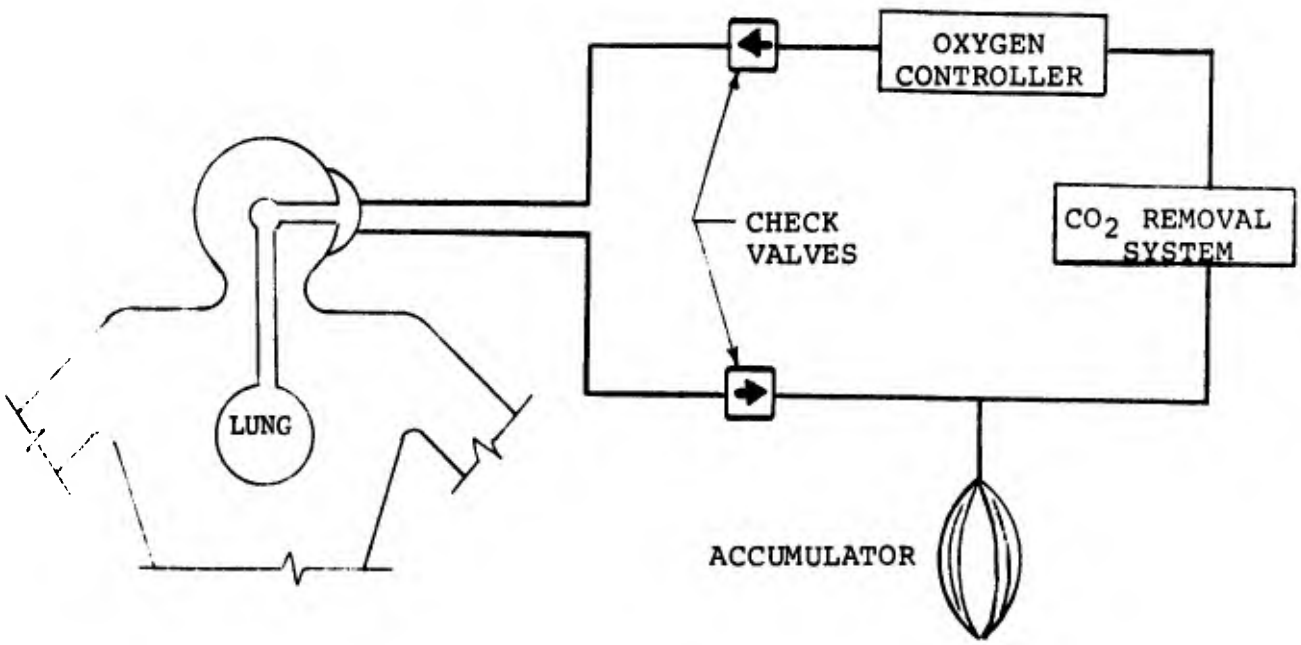


FIGURE 3.2 - BASIC CLOSED-CYCLE BREATHING SYSTEM

System performance is most readily explained by following the operation of one complete breathing cycle. Consider first, operation in the closed cycle mode. On the inhalation portion of the cycle, ambient air is drawn through the filter (21), pressurized by the compressor (22) and directed to the accumulator (17) through the compressor manifold (23). The flow control valve (24) at this time is positioned to connect the compressor manifold to the diaphragm pump (25). Air leaving the compressor manifold passes directly into the ambient side of the diaphragm pump. At high flow rate settings, pressurized air stored in the accumulator is used to supplement the compressor output to meet the flow rate requirements. The pressurized

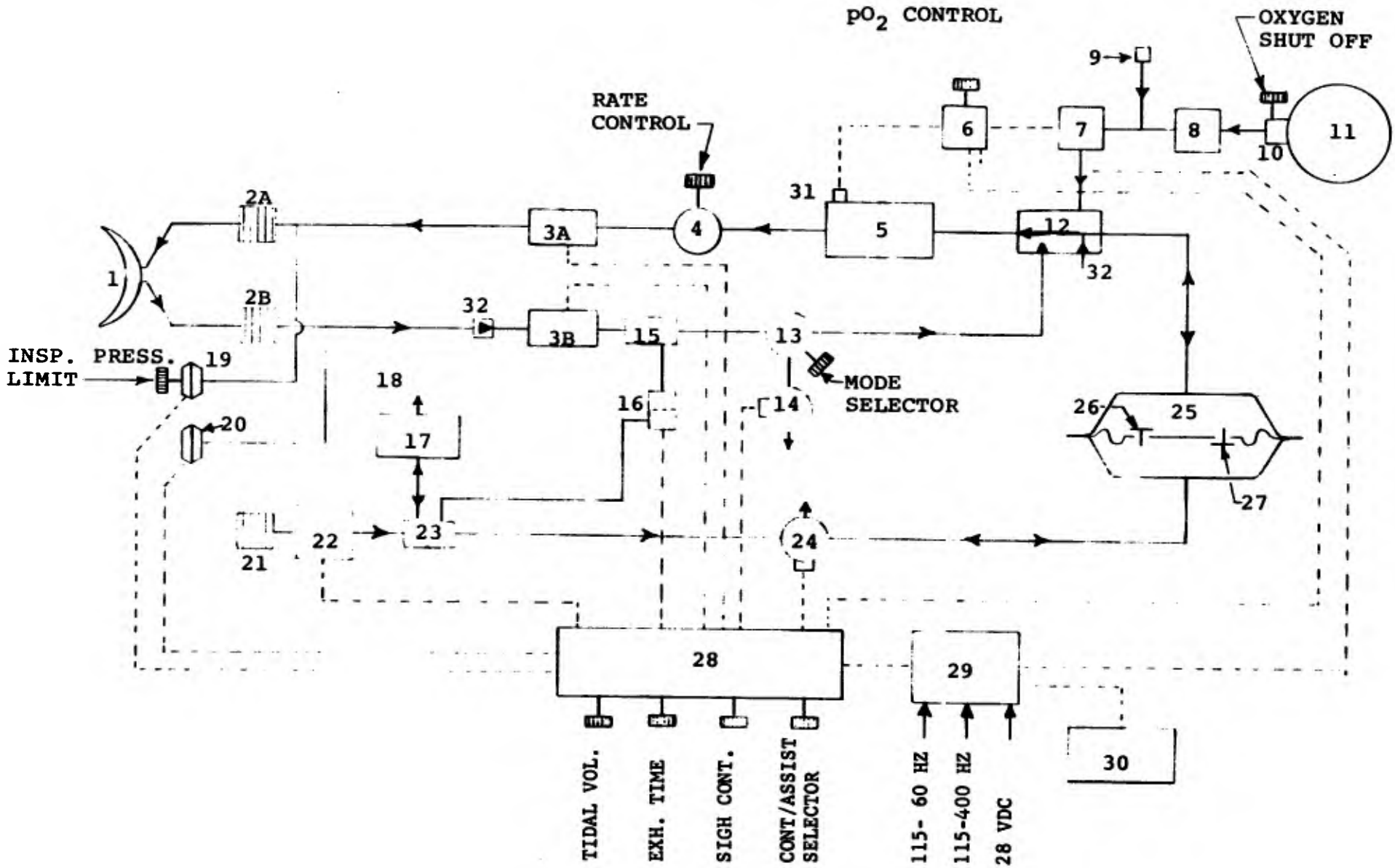


FIGURE 3.3 - RESPIRATOR SYSTEM SCHEMATIC

TABLE 3.1 SYSTEM COMPONENTS

PART NUMBER	DESCRIPTION	FUNCTION
1	Patient Interface Kit (Mask, Tracheal Adapter, etc.)	Adapts system to patient.
2	Filter	Bacterial filter to cleanse closed loop gases.
3	Flowmeter - Inhalation - Exhalation	Measures gas flow in closed loop and generates an electrical signal proportional to the flow rate.
4	Rate Control Valve	Manually operated variable flow impedance device which controls the rate at which air is delivered to the patient.
5	Carbon Dioxide Scrubber	Removes carbon dioxide gas from closed loop.
6	Oxygen Controller	Electronic controller compares sensor output to valve selected by operator. Controls oxygen solenoid valve operation.
7	Oxygen Solenoid Valve	On signal from oxygen controller, valve admits oxygen from the low pressure side of regulator to closed loop.
8	Oxygen Pressure Regulator	Reduces high pressure oxygen (2000 psig to 50 psig)
9	External Oxygen Connector	Provides recepticle for external 50 psig oxygen supplies.

TABLE 3.1 (Cont'd.) SYSTEM COMPONENTS

PART NUMBER	DESCRIPTION	FUNCTION
10	Oxygen Shut-Off Valve	Closed-off oxygen supply when system is not operating or when changing oxygen cylinders.
11	Oxygen Storage Cylinder	Storage of high pressure oxygen for autonomous operation.
12	Check Valve Manifold	Controls flow direction of gases in closed loop.
13	Mode Selector Valve	Manually operated valve which selects either closed cycle or open cycle modes of operation.
14	Exhale Valve	Allows exhale gases to pass to the ambient during open mode of operation.
15	Vent Valve Manifold	Provide common connection point for vent valve and sensor points.
16	Vent Valve	Protects patient from suffocation in the event of a power failure.
17	Accumulator	Stores air pressurized by compressor at a constant pressure.
18	Accumulator Vent	Protects system from becoming over pressurized.
19	High Pressure	Senses positive gage pressures in closed loop. When internal pressure exceeds value preset by operator, a signal is sent to flow controller to terminate inspiration.

TABLE 3.1 (Cont'd.) SYSTEM COMPONENTS

PART NUMBER	DESCRIPTION	FUNCTION
20	Low Pressure Switch	Senses negative gage pressures in closed loop. When internal pressure falls below ambient, a signal is sent to flow controller to start inspiration in the assist mode of operation.
21	Air Filter	Filters ambient air supplied to compressor.
22	Compressor	Provides supply of pressurized ($\sim$1 psig) ambient air for system operation.
23	Compressor Manifold	Provides common connection point for compressor, accumulator and flow control valve.
24	Flow Control Valve	Solenoid actuated valve which controls flow of air to and from the open loop side of diaphragm pump. Operates on command from flow controller.
25	Diaphragm Pump	Provides circulation of gas in closed loop. Flexible diaphragm is actuated by compressed ambient air.
26	Exhalation By-Pass Valve	Allows gas in closed loop to escape to ambient when diaphragm reaches lower limit of travel.

TABLE 3.1 (Cont'd.) SYSTEM COMPONENTS

PART NUMBER	DESCRIPTION	FUNCTION
27	Inhalation By-Pass Valve	Allows ambient air to be added to closed loop when diaphragm reaches upward limit of travel.
28	Flow Controller	Electronic controller which integrates flow-meter output to determine volume flow, processes signals from pressure switches and commands flow control valve to establish cycle rate.
29	Power Conditioning Unit	Conditions input power to proper levels for system use. Incorporates battery recharging circuitry.
30	Internal Battery Pack	Internal power supply for autonomous operation.
31	Oxygen Partial Pressure Sensor	Senses partial pressure oxygen in gas delivered to patient.
32	Under-Pressure Relief Valve	Allows ambient air to be drawn into closed loop when pressure drops below ambient.

air moves the flexible diaphragm to force the gas out of the closed loop side of the diaphragm pump. If the diaphragm is positioned near the end of its stroke at the start of the inhalation phase, as might be the case when the system is first put into use, the inhalation by-pass valve (27) is opened and ambient air passes the diaphragm into the closed loop. Gas leaving the closed loop side of the diaphragm pump passes through the check valve manifold (12) and is directed through the scrubber (5) where the carbon dioxide is removed. Leaving the scrubber, the gas passes through the rate control valve (4), the inhalation flowmeter (3A), the bacterial filter (2A) and to the patient via the mask or tracheal adaptor (1). Gas flow is analyzed by the pO_2 sensors (31) for oxygen content while passing through the scrubber and the measured partial pressure is fed to the oxygen controller (6) where it is compared to the value preselected by the operator. To insure extremely high reliability of this critical function, two sensors are incorporated. When the measured value of oxygen partial pressure is less than that selected by the operator, the solenoid valve (7) is activated to admit a pre-set quantity of oxygen to the system.

Termination of the inhalation stroke occurs when either the preselected volume has passed through the inhalation flowmeter (3A) or when the pressure in the closed loop has reached the limit set on the inspiratory pressure limit switch (19). When either limit has been reached, the flow controller (28) indexes the flow control valve (24) to the exhale position. In this position, the port connecting to the compressor manifold (23) is blocked and the remaining two ports are connected to allow air from the ambient side of the diaphragm pump (25) to be direct to the atmosphere. Throughout the exhale portion of the cycle, the compressor continues to operate and its output is stored in the accumulator for use during the following inhalation stroke.

Circulation of the closed loop gases during exhalation is provided by the patient as negative pressures are not produced. For closed cycle operations, the mode selector valve (13) connects the vent valve manifold (15) to the check valve manifold (12) and blocks gas flow to the exhale valve (14).

Exhaled gases travel to the diaphragm pump by way of the exhalation flowmeter (3B) and mode selector valve (13). Volume of the exhaled gas is measured and compared to the preset tidal volume. If found to be less than a value consistent with the selected volume, an alarm is activated to warn the operator. As the closed cycle side of the diaphragm pump is filled, air on the ambient side is forced through the flow control valve to the atmosphere. If the volume of gas entering the closed loop side of the diaphragm pump exceeds the chamber capacity, the exhalation by-pass valve (26) is opened allowing the closed system gases to cross the flexible diaphragm and exit to the atmosphere. In normal operation, the inhalation and exhalation by-pass valves (27) and (26) automatically establish that the proper amount of gas is contained in the closed portion of the system and are generally activated only during the first few cycles of operation. Duration of the exhalation period is controlled by an adjustable electronic timer within the flow controller. A pressure sensing element (20) monitors the closed loop pressure and is activated (if the assist/control switch is set in the assist position) if the patient begins inhalation before the preset exhalation time has elapsed. Since both inhalation and exhalation can be initiated by pressure switches (19 and 20), the system cycling rate can be established by the patient.

For open cycle operation, the mode selector valve (13) is positioned to direct the exhaled gas flow from the vent valve manifold (15) to the exhale valve (14) while blocking the return of gases to the diaphragm pump (25). After the exhaled gas volume has been measured by the exhale flowmeter (3B), they are vented to the ambient via the mode selector valve (13) and the exhale valve (14). During the inhalation phase of open cycle operation, the solenoid operated exhale valve (14) blocks the flow of gases to the ambient and ambient air pressurized by the compressor (22), passes through the flexible diaphragm of the diaphragm pump (25) by way of the inhalation by-pass valve (26), is enriched with oxygen to the desired partial pressure, and supplied to the patient via the same path used in closed cycle operation. Since exhaled gases are not returned to the diaphragm pump, a fresh charge of ambient air must be enriched with oxygen and delivered to the patient in each succeeding breath. This eliminates the need for an

active chemical charge in the scrubber during open cycle operation and increases the amount of oxygen consumed. This mode is provided for operation when the system is to be used for extensive periods with auxiliary oxygen and electrical power sources.

To provide a path for gas exchange between the patient and the ambient in the event of power interruption or system malfunction, a safety vent valve (16) is provided. Closure of this valve requires both electrical power and a supply of gas from the compressor. The valve is spring-loaded in the closed position to give a high degree of reliability to this critical component.

4.0 DESIGN APPROACH

The system, as described in the preceding section, had been fairly well defined as a result of the breadboard testing performed at General Electric. However, a considerable amount of detailed design effort remained on the individual components and the overall system to minimize weight, enhance packaging and improve performance characteristics and reliability. This section describes the major design activities and the results obtained in the development of the prototype units.

4.1 Weight Trade-Offs

Weight of the overall system could be minimized by observing the following guidelines.

- Minimize the number of components in the system.
- Design essential components for minimum weight by minimizing size and selecting light weight materials of construction.
- Minimize the electrical requirements thereby reducing the battery requirements.

The system shown schematically in Figure 3.3 represents the minimum component system. When designing the individual components and when selecting the materials of construction, the lightest weight system was not always a feasible selection since the tooling and/or manufacturing costs for limited quantity production could not be justified. As a result, a weight penalty was actually incurred. Notable examples of component designs in which consideration of cost instead of weight was paramount are:

- The scrubber which is constructed of stainless steel instead of plastic.
- The chassis and case which is a dip brazed aluminum structure instead of a plastic sheathed aluminum frame.

- The battery case which consists of a built-up aluminum structure instead of a plastic shell.

The only major area in which significant weight savings could be realized then was in the conservation of electric power and only two areas of significant import were identified -- compressor power consumption and autonomous operation duration.

4.1.1 Use of an Accumulator

The primary purpose of the accumulator is to supplement the compressor output during the inhalation stroke, thereby reducing the output requirements of the compressor and minimizing electrical demands. Without the use of an accumulator, the compressor would have to be designed for intermittent operation (on during the inhale stroke, off during the exhale stroke) or would have to run continuously with the compressor discharge being vented to the atmosphere during the exhale stroke. In the former case, response times to start the compressor and bring it to operating speed were considered too long to achieve the type of response desired. In addition, the large starting currents necessary to start the compressor motor would result in greater power usage, bulkier electronics and ultimately increased battery requirements. Analyses showed the most favorable arrangement from the viewpoints of total weight and reliability was to run the compressor continuously and to provide an accumulator for compressor discharge storage during the exhale stroke.

Maximum minute volume was established as 30 liters per minute, therefore, the compressor was sized to provide a 30 liter/minute flow against a receiver pressure of 90 cm H_2O, which represented the maximum system working pressure. While the compressor is sized for average flow rates, actual delivery of the gas takes place only on the inhalation stroke, which is typically one third the duration of the breathing cycle, or, about 20 seconds of each minute. The flow distribution for the inhale pulse varies with application and may readily exceed twice the average value. To meet these maximum flow rate requirements, the system must be capable of providing instantaneous flow

rates as high as 180 liters/minute. If a compressor were to be used singly as the source of compressed air, the required flow rate would be 180 liters/minute. On the other hand, if an accumulator was used and properly sized, the compressor could be sized to supply the average quantity of compressed air or 30 liters/minute.

Figure 4.1 relates battery weight to compressor flow rate for the compressor type used in the system and assuming continuous operation against a 90 cm H_2O head. Battery weight is based on the use of rechargeable nickel-cadmium sealed cells and the weights shown are for one hour's operation. At the 30 liter/minute flow rate, approximately 1.5 pounds of batteries are required for each hour's running as opposed to the 9.0 pounds which would be required if no accumulator were used and the flow rate of 180 liters/minute were supplied by the compressor. Design studies showed that an accumulator of the appropriate size and configuration could be fabricated with a total weight less than 10 pounds. In a system which is capable of autonomous operation for periods up to four hours, a total weight saving of greater than 20 pounds is realized.

4.1.2 Duration of Autonomous Operation

Total weight of the respirator system is affected by the period of time it must operate without benefit of external services or refurbishment. Three factors are involved, namely, the oxygen supply, the CO_2 scrubber chemical inventory and the battery power supply. The choice of oxygen supply is largely dictated by the availability of cylinders for 2000 psi oxygen storage. The original intent was to use a cylinder already in the Federal Stock System to facilitate replacement. While an appropriate cylinder was identified, it was found to be not available and a standard commercial cylinder purchased from the Kidde Company was used. This cylinder stores 0.62 pounds of oxygen at 2000 psig and weighs approximately 5 pounds when fully charged. Under normal closed cycle operating conditions, this amount of oxygen is sufficient for at least four hours.

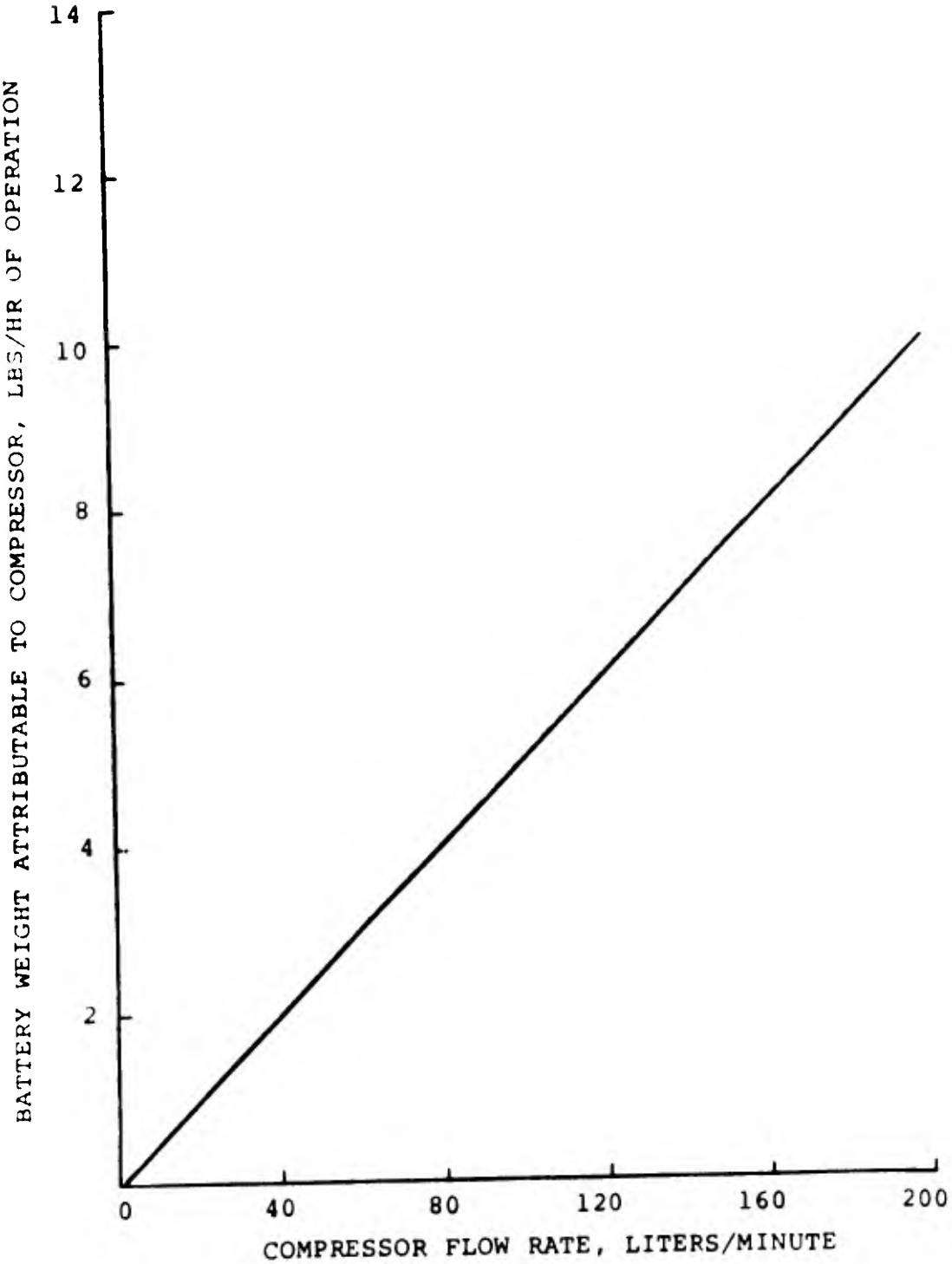


FIGURE 4.1 - COMPRESSOR BATTERY WEIGHT

Carbon dioxide removal is accomplished by means of a chemical scrubber which uses Sodalime granules as the absorbing agent. Five pounds of chemical provide ample CO_2 removal capacity for a minimum of eight hours closed cycle operation. Other chemicals such as lithium hydroxide could have been employed to reduce the weight of the scrubber; however, Sodalime is readily available in the military supply system and the potential weight savings did not justify a departure from the routine at this time.

Battery weight is the parameter which was identified as being most sensitive to duration of autonomous operation. In addition to power required for compressor operation, an additional electrical load exists in the form of alarms, flowmeter and other electronic controls. Experience from the development of the breadboard system indicated that about 1 pound of batteries per hour of operation would be required for all functions other than compressor operation. Total electrical requirement for the system requires about 2.5 pounds of batteries for each hours operation. A review of the potential use of the respirator, coupled with the fact that it is operable from external sources of AC and DC power commonly found in transport vehicles, led to the selection of four hours duration for the battery pack. Weight of the batteries, excluding the structural elements of the battery case, is approximately 15 pounds.

Two of the three expendable elements, therefore, have a minimum life of four hours, while the third, the carbon dioxide scrubber, is sized to provide at least eight hours safe operation. This selection is consistent with good safety practice since alarm systems and usage displays are available for the oxygen and electrical power inventories while the CO_2 scrubber depends on routine servicing to assure safe operation.

A summary of the various component weights is presented in Table 4.1. These weights reflect measured values for the prototype hardware.

TABLE 4.1 - RESPIRATOR WEIGHT SUMMARY

COMPONENT	WEIGHT Lbs.	Ozs.
Battery Pack	15	10
Manifolds	1	5
CO_2 Scrubber	5	13
Compressor	2	1
O_2 Cylinder (charged)	4	5
O_2 Subsystem (regulator, solenoid, lines)	2	1
Accum. Diaphragm Pump Assembly	8	9
Pressure Switches		13
Case (without harness brackets, protective covers)	16	3
Filters	1	4
Patient Interfaces (hoses, masks, etc.)	1	10
Flow Control & Exhale Valves	2	2
Internal Hoses	2	8
Electrical Harness	3	0
Power Cords	1	5
Electronics	7	2
Miscellaneous	2	0
TOTAL----------	77 Lb.	11 Oz.

4.2 Mechanical Compo..nt Designs

Mechanical components in the respirator may be divided into two general categories; those which were commercially available and those which required design, development and fabrication. Whenever possible, commercially available components were selected to minimize engineering and manufacturing costs. However, in many instances, the performance requirements for the specific component were such that commercially available components were not suitable. Those components which required the majority of the engineering design effort are discussed further in the following paragraphs.

4.2.1 Accumulator/Diaphragm Pump Assembly

Both the diaphragm pump and the accumulator are components unique to the respirator. Experience with the breadboard respirator indicated these elements were the largest of the system, hence, would dominate the overall packaging arrangement. Considerable effort was expended evaluating various design approaches to arrive at the most favorable configureation for integration with the system.

Of these two components, the diaphragm pump is the least demanding with regard to physical arrangements. Its principal function, that of providing circulation of gases in the closed loop while maintaining these gases separate from the open loop side of the system, could be satisfied with a number of configurations. The most salient factor in the design of this element is that the work required to move the membrane separating the closed loop and open loop sides be held to a minimum. This is most readily accomplished by using a configuration which results in minimal movement of the diaphragm. A large diameter short stroke arrangment best satisfies this need. Total volume of the diaphragm pump must be adequate to allow delivery of the maximum tidal volume, 1.5 liters, without adding ambient air to the closed loop. A volume of 1.8 liters was selected to give a 20% margin.

The accumulator is a multi-functional device in that it stores the compressor output during exhalation, smoothes the pulsating flow of the compressor and regulates the maximum pressure in the

system. Ideally, the gas stored in the accumulator is maintained at a constant pressure independent of the amount of gas in the accumulator. Conceptually, this can be accomplished with a flexible bellows mounted between two plates connected with loading system designed to amintain a constant force.

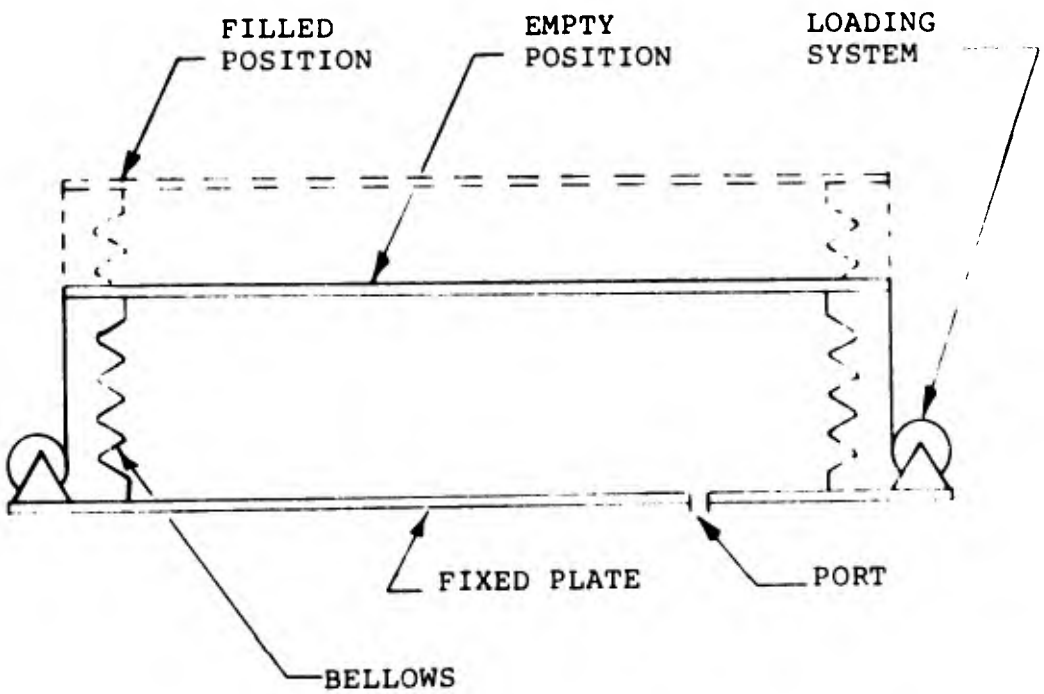


FIGURE 4.2 - ACCUMULATOR CONCEPT

Figure 4.2 shows one such concept which employs a type of loading system known as Negator springs. These springs have the unique characteristic of producing a constant force independent of displacement, a quality perfectly suited to this application. Detailed design studies based on this loading concept showed

that an accumulator using these springs required a small diameter bellows acting over a large stroke. This arrangement was necessitated by consideration of the fatigue life of the Negator springs which are required to cycle with each breath. To assure adequate margin of design, a large number of springs, each producing a relatively small force, are required. One million cycles was considered the minimum acceptable life for the accumulator and the appropriate Negator springs produced an unmanageable configuration which compromised the entire packaging concept.

The next most favorable arrangement involved the use of helical compression springs. Unlike negator springs, the helical compression springs develop a force which is a function of the stroke length. However, a fairly constant delivery force can be achieved if the spring (or springs) are designed so that their active stroke length is small with respect to their free length. Designing the accumulator bellows with a large diameter and short stroke is compatible with the use of helical springs and results in a reasonable packaging arrangement. A parametric study relating accumulator displacement and pressure requirements to the spring parameters was performed and a suitable spring design was developed. The resulting system consisted of a 12 inch diameter bellows with a stroke length of 1 inch. The selected spring system consisted of one 4 inch diameter spring with a free length of 14.1 inches and a spring constant of 11 pounds per inch. Variations in gas storage pressure resulting from the force change of the helical spring ranges from 82 cm H_2O in the empty position to 90 cm H_2O in the full position. The effect of this pressure variation on operating performance is noticeable only at very high minute volume rates. As the minute volume approaches 30 liters/minute, the maximum inhalation pressure approaches 82 cm H_2O. During lower minute volumes, the system can be operated at 90 cm H_2O inhalation pressures. This compromise of design is considered to be of minimal significance since in practical application, the need for inhalation pressure as high as 90 cm H_2O is not usually accompanied by minute volumes as high as 30 liters/-minute.

Offsetting this performance variation, the use of a helical spring offers several important engineering advantages. First, it is a simple and lightweight approach which is economical to produce and reliable in operation. With a small amount of internal hysteresis, the helical spring is excellent for cyclic operation and a design life of one million cycles is readily achieved. High forces can be developed from a relatively compact spring which allows the use of a large diameter short stroke accumulator and provides a convenient packaging arrangement. These factors were considered to far outweigh the less than ideal performance characteristics and a helical spring design was selected for the accumulator.

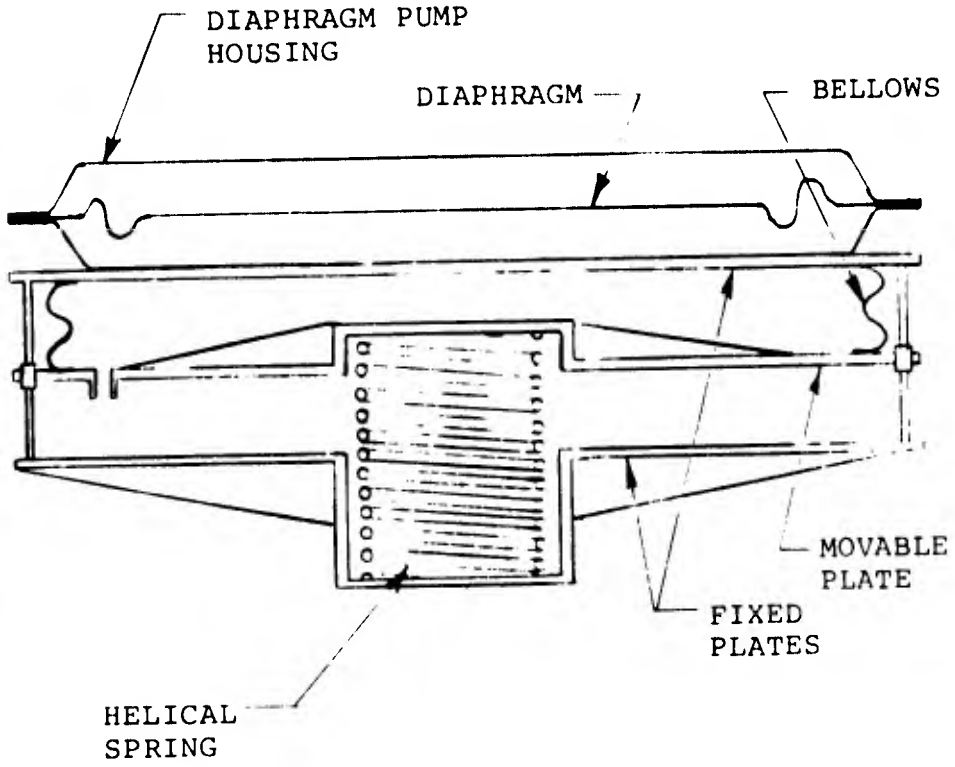


FIGURE 4.3 - ACCUMULATOR/DIAPHRAGM PUMP ASSEMBLY

Figure 4.3 illustrates the diaphragm pump/-accumulator arrangement finally selected for use in the prototype respirators. A nominal 12 inch diameter accumulator and diaphragm pump allowed the total assembly thickness to be held to 7 1/2 inches which is compatible with the overall system geometric constraints. With a working stroke of 1 inch, a total volume of 1.2 liters can be stored in the accumulator. This volume was determined from a parametric study of the gas storage values which are required over the entire performance range. A displacement actuated vent valve is incorporated in the accumulator to allow excess compressor output to be vented thereby preventing over-fill and damage to the accumulator. Storage pressures within the accumulator can be varied over a fairly wide range to suit special application by adjusting the initial compression of the helical spring. Provision for this adjustment is incorporated in the design.

4.2.2 Compressor

The concept of a long life portable respirator hinges on closed cycle technologies for conservation of the breathing gases and an efficient means of gas circulation. In the common open cycle resuscitator, power for gas circulation is provided from the compressed gases. In closed cycle systems, gas consumption is only that required for metabolic purposes and consequently, the rate of energy release is not sufficient to provide circulation. A compact means of energy storage which is far superior to compressed gas energy storage is that of batteries. The form of this energy must, of course, be transformed from electrochemical to an appropriate means of gas circulation, and if the benefits of the high energy storage capability of batteries are to be realized, an efficient means of energy conversion must be used. An electrically driven compressor was the obvious choice and the design requirements for the device are as follows:

- Overall efficiency (electric to hydraulic) must be greater than 20%.
- Design life of 4,000 hours.

- Fit within a 4" x 6" x 6" compartment.
- Weight not to exceed 2 pounds.
- Noise level to be minimized.
- Deliver 30 liters/minute air flow at a pressure of 90 cm H_2O.

A review of the commercially available air compressors and rotodynamic pump showed that no device suitable for this application was available and a compressor would have to be designed specifically to meet the needs of the respirator. The commercially available rotodynamic pumps (centrifugal and vane pumps, axial flow and squirrel cage fans, etc.) serve primarily to move large volumes of air; they do not develop the relatively high pressure head of 90 cm of water at the desired low flow rate of 30 LPM. One type of rotodynamic pump - the discontinuous discharge centrifugal pump - can develop the desired flow rate at the high pressure head. Such a pump was designed. The theoretical pump efficiency (not including motor efficiency) of this pump, however, was only 17%. The low efficiency is attributable to the excessive wheel friction developed when the impeller rotates at 20,000 RPM, the speed necessary to develop the desired pressure head.

A positive displacement compressor can move small volumes of fluid against a high head pressure; their rate of discharge depends almost entirely on the speed of rotation and hardly at all upon the working pressure. Because of the performance advantages, a positive displacement compressor was selected for the respirator. However, it was recognized that noise would be a problem.

Motor selection was also of paramount importance to the overall compressor design. Both AC and DC motors were considered. AC motors had a distinct advantage in that the brushless design feature made them inherently more reliable than DC motors. However, use of an AC motor would require the addition of electronics to convert the DC power from the battery

to AC. Although possible, this conversion is highly inefficient and was considered impractical since the compressor motor was already the largest single drain on the battery and was the primary factor in sizing of the battery. Thus, a DC motor was selected for the compressor. To increase the reliability of the motor, the compressor speed was reduced and a high quality motor was selected. At the design operating point, the motor life expected to satisfy the 4,000 hour requirement and subsequent life tests verified this prediction.

An engineering prototype compressor was built and tested to obtain an accurate measure of performance of this critical components. Tests showed that total efficiency of the motor/pump assembly was 26% and identified several areas where modifications could yield even higher efficiencies. This prototype compressor was also used to develop an acoustic map to evaluate the noise generation problem. The principal sources of mechanical noise were found to be the bearings and gears. A slapping noise was also identified and attributed to the check valves and the piston diaphragm. It was found that both types of noise were dependent on operating speed and significant reductions in noise output would result if pump speed was kept below 1,000 RPM. Further improvements were attained by using a pre-molded cone shaped diaphragm made from 10 mil thick nylon reinforced neoprene rubber and check valves of latex rubber of similar thickness. The DC motor selected for use with the pump, an Indiana General PM1509-P32, was found completely satisfactory.

A performance characteristic of the permanent magnet motor at a constant voltage of 24 volts was obtained so that a more efficient pump could be designed. These curves showed that a motor efficiency of 59% can be obtained for an applied torque of 2 to 3 in-oz. and for motor speeds between 4,000 add 5,000 RPM. The compressor was then redesigned. Ball bearings and linear bearings were incorporated into the final design, whereas a teflon guide and brass bushings were used in the prototype; an overall pump efficiency of 30% could therefore be anticipated. The dead volume was

made as small as possible in order to minimize pump weight and volume. The following assumptions were made in the pump design:

Pressure Head	90 cm H_2O
Flow Rate	30 LPM
Operating Voltage	24 volts
Overall Pump Efficiency	30%
Motor Efficiency	59%
Volumetric Efficiency	78%
Stroke	1/2 inch
Pinion Gear	.625" PD, 20 teeth, 3/16" face width
Mating Gear	3.50" PD, 112 teeth, 1/8" face width

With these assumptions, a compressor was designed. The resulting unit was 2.71 inches in diameter and weighed 2.1 pounds. The compressor with motor and gears attached fit within the allocated space with only minor alteration of one compartment wall. Performance testing of the final design showed that an overall efficiency of 35% had been achieved. After the compressor assembly had been operated for a period of 500 hours and all elements of the system had properly seated, the overall efficiency increased to 41%. Subsequent to the performance testing, a life test was begun. Efficiency was monitored at discrete points throughout the life test and found to remain above 35% at all times. At 4,000 hours, the test was terminated due to a failure of the brushes in the electric motor. This was the predicted failure mode and all other elements of the compressor assembly showed little sign of wear.

The most technically difficult problem to overcome in the compressor design was that of noise generation without compromising efficiency. The approach taken was to design for maximum performance efficiency then modify the design as appropriate to minimize noise output. The use of a pre-molded diaphragm and thin latex check valves minimized the internal slapping noise. Gear ratios were selected to give an operating speed of 900 RPM and sound absorbing material was used to line the compress or compartment. In its present configuration, the noise level of the operating system is estimated as 60 db.

4.2.3 CO_2 Scrubber

In the closed cycle operational mode, gases exhaled by the patient are returned to the respirator to conserve the residual oxygen. The gas contains carbon dioxide which results from the metabolic processes and which must be removed from the circulating system. This function is readily accomplished by passing the gas mixture through a dry chemical bed which reacts with and removes the CO_2 in the mixture. Table 4.2 lists some of the common materials used for CO_2 removal and presents their performance characteristics relative to CO_2 absorption.

TABLE 4.2 - SCRUBBER CHEMICAL CHARACTERISTICS

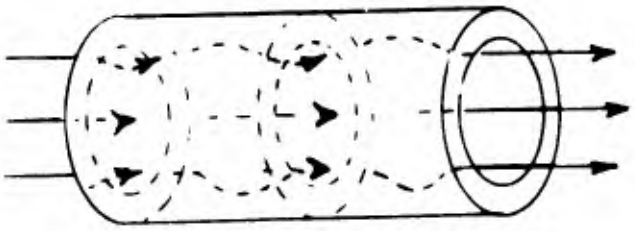
Chemical	Theoretical Absorbtion	Typical Utilization Efficiency %	Experimental Absorption #Chem.-#CO_2
Baralyme	2.20	40	5.5
Barium Hydroxide	3.80	40	9.5
Lithium Hudroxide	1.10	75	1.5
Lithium Peroxide	1.00	80	1.3
Sodium Hydroxide	1.80	50	3.6
Sodalime	2.05	50	4.1

Barium Hydroxide was not considered becasue of the extremely high weight penalty. Lithium Hydroxide, lithium peroxide and sodium hydroxide, although being very light in weight, are extremely caustic, difficult to handle and not in common use except as scrubbing chemicals aboard submarines. Of the remaining two commonly used chemicals, Baralyme and Sodalime, Sodalime has about a 20% weight advantage and is commonly used in hospitals. As a result, it was selected for use in the closed cycle respirator.

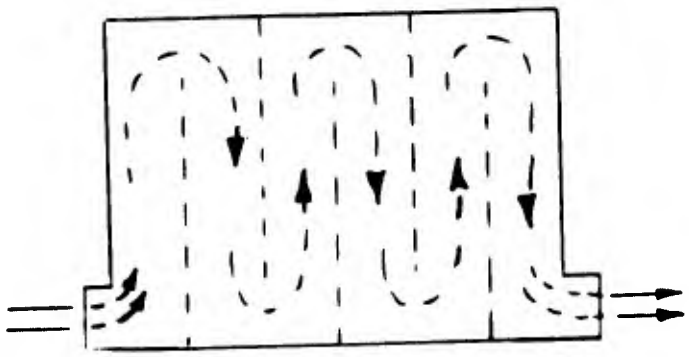
A second important consideration in design of the scrubber is the configuration of the chemical. The most simple and widely used arrangment is the linear flow scrubber which consists of a cylinder containing the active chemical with gas flowing axially through the bed. Though simple to manufacture and convenient to maintain and service, this type of scrubber does not effectively utilize the chemical contained within. To prevent channeling of the gas through the bed, which results in premature breakthrough, these scrubbers must be designed with long flow path lengths. The resulting high pressure drop requires increases in flow area which further increases the amount of chemical involved and reduces efficiency. Figure 4.4a schematically illustrates this basic scrubber arrangement.

Another familiar design is the tortuous path concept shown in Figure 4.4b. This design effectively utilizes the chemical inventory and can be packaged in a compact arrangement. Its major disadvantages are inherently high pressure loses, complexity of manufacture and inconvenience of loading. The latter factor is most important since improper filling can result in large amounts of by-pass flow.

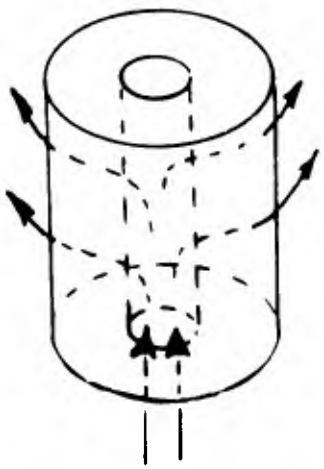
The third concept is the radial flow scrubber shown in Figure 4.4c. This design offers several advantages over both of the other types. In the radial flow scrubber, CO_2 laden gas is fed up the center of the scrubber bed and allowed to flow radially outward. With a large cross-section to flow, pressure drops are minimized. At the same time, the gas velocity through the bed is minimized resulting in more efficient utilization of the scrubber chemical. The concept also is less



a) LINEAR FLOW SCRUBBER



b) TORTUOUS PATH SCRUBBER



c) RADIAL FLOW SCRUBBER

FIGURE 4.4 - SCRUBBER CONCEPTS

susceptible to channeling. Based on experimental results which showed efficiency of this configuration to be as much as 20% higher than those published for other designs, the radial flow scrubber concept was selected.

Although the battery pack and oxygen bottles for the respirator were sized to provide autonomous operation for a period of four hours, the scrubber is sized to provide safe operation for at least eight hours. Based on data taken from the Bioastronautics Data Book average CO_2 production for eight hours by a man at rest is 1.1# CO_2. From table 4.2, it can be seen that approximately 4.5# of sodalime is required to absorb this amount of CO_2. Using a theoretical packing density of .8 gm/cc for sodalime, the scrubber was sized for the 4.5# of chemical. Once the volume had been defined, selection of the L/D was simply a function of the packaging scheme. To facilitate servicing, the scrubber was installed across the width of the respirator case. In this way, charging could occur through a cover at one end of the scrubber and access to the cover could be achieved through a door on the side of the respirator case.

Figure 4.5 shows a cross-section of the scrubber. Gas from the patient enters Port A, flows upward through the center and then radially outward. The center core of the basket is made of a stainless steel screen material which offers resistance to flow. In this way, gas has a tendency to flow up the core and then radially outward over the entire length of the core. If this feature were not incorporated, more gas would tend to flow through the lower portions of the chemical bed thereby reducing the efficiency of the scrubber. After leaving the chemical bed, the gas is collected in the annulus between the basket and the canister from which it flows to the pO_2 sensor manifold and exits to the inhalation side of the closed loop. The exit plenum is such that the gas must flow over the pO_2 sensors thereby providing the accurate reading necessary for pO_2 control.

Proper sealing of the canister and the basket in the canister is essential to safe operation. The first seal, located at the bottom of the basket,

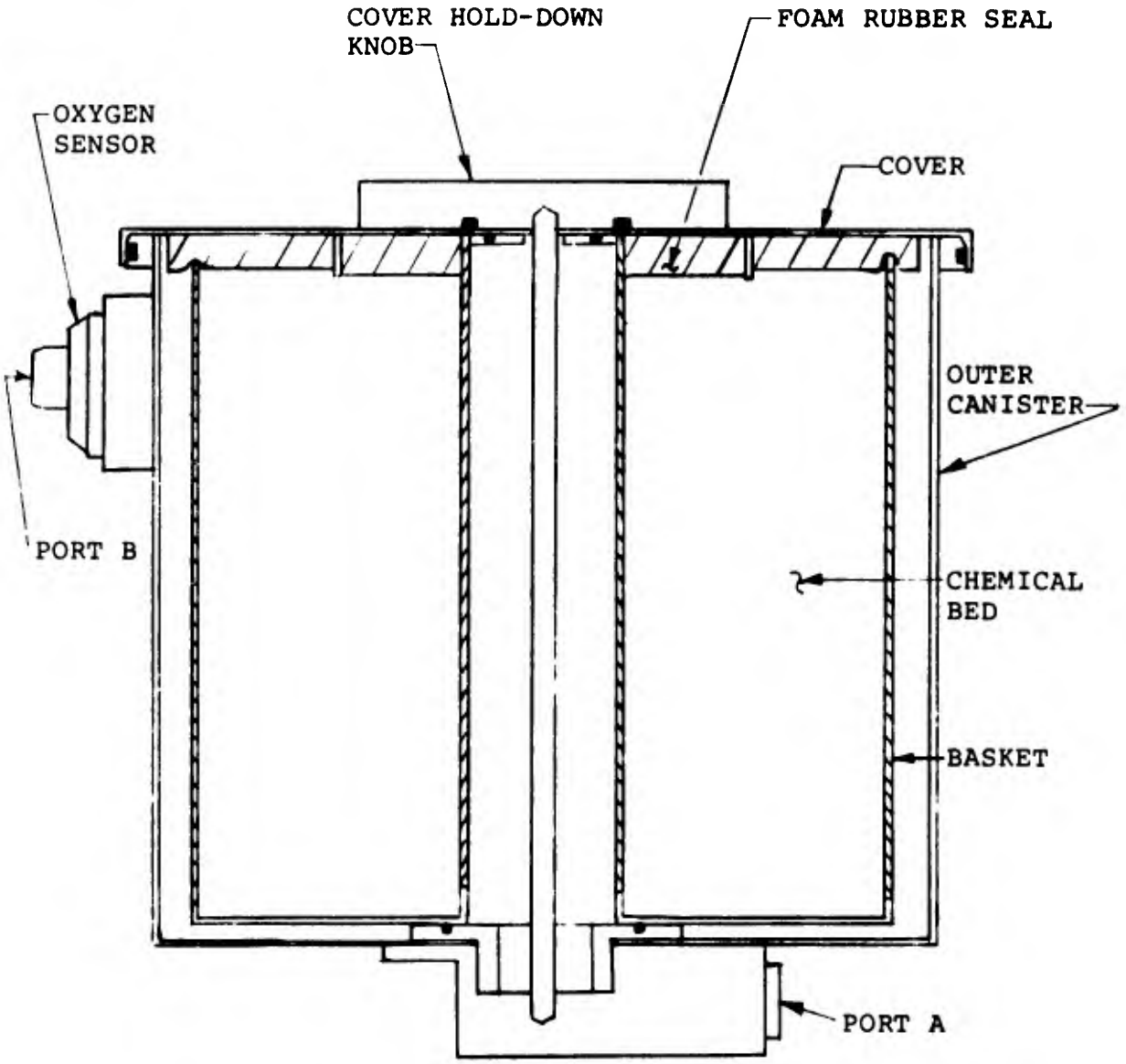


FIGURE 4.5 - RADIAL FLOW SCRUBBER DESIGN

prevents gas from channeling under the basket. A second seal at the top of the basket between the core and the cover prevents the same occurrence at the top. The cover is lined with a foam rubber gasket. This gasket serves two purposes. First, it prevents channeling across the top of the scrubber and secondly, if any settling of the chemical occurs in the basket, the foam rubber expands keeping the bed compact. Two seals located in the cover knob and the outer perimeter of the cover prevent leakage from the canister to the environment.

The basket is readily removed from the scrubber by removing the lid and lifting the basket out. The basket can be cleaned and recharged external to the respirator and then simply inserted into the canister. Whenever the scrubber is serviced or charged, it is important that the operator check all seals and gaskets for proper placement or damage. Improperly placed seals can result in by-pass flow rendering the scrubber ineffective.

Scrubber performance was verified using a mechanical test facility which allows variation of tidal volume, respiratory rate, gas and ambient temperatures and controls the concentration of CO_2 in the inlet gas. Table 4.3 simmarizes the tests which were performed. In all tests, breakthrough was considered to have occurred when outlet CO_2 concentrations exceeded 0.5% standard atmosphere (3.8 mm Hg). The gas mixture, prior to entering the scrubber, was passed through a water bath at 95°F to assure saturation at that temperature thereby simulating the exhaled breath. Test results indicate that considerable design margin exists at normal and low ambient temperatures. At extremely high ambient temperatures, the reaction is somewhat impeded; however, the design goal of 8 hours duration is satisfied.

4.2.4 Flow Control and Exhale Valves

One of the most critical components in the respirator pneumatic system is the flow control valve. This valve controls the flow of pressurized air from the compressor and accumulator to the ambient side of the diaphragm pump thereby

TABLE 4.3 - SCRUBBER TEST SUMMARY

TEST	AMBIENT TEMP. (°F)	TIDAL VOLUME (liters)	CHEMICAL WEIGHT (lbs.)	RESPIRATION RATE (cycle/min)	INLET CO_2 CONCENTRATION (% std atm)	CO_2 ABSORBED (lbs.)	LBS. CO_2 ABSORBED / LBS. CHEMICAL
1	70	1.5	5.1	15.0	4.5	1.48	.294
2	70	1.5	5.1	7.5	4.5	1.76	.345
3	70	1.5	5.25	20.0	2.0	1.90	.362
4	32	1.5	5.25	15.0	4.5	1.90	.362
5	125	1.5	5.31	15.0	4.5	1.09	.205
6	125	1.5	5.25	15.0	4.5	1.16	.220

establishing the duration of the inhalation and exhalation phases of the breathing cycle. During open cycle operations, when exhaled gases are vented to the ambient the exhale valve operates simultaneously with the flow control valve. These valves are identical from the design and operational viewpoints and the discussion here will be limited to the flow control valve.

Figure 4.6 presents a drawing of the flow control valve. It consists of a cylindrical plunger which slides inside a rectangular valve body and two linear solenoids mounted on either end of the body to actuate the plunger. Ports leading to the various elements of the system are machined in the valve body and adaptors, not hsown in the drawing, provide the transition to the interconnecting tubing. The plunger is cylindrical and has a single angular shaped port cut through the center with magnets mounted at both ends. These magnets, when in contact with a solenoid body, provide a detent action to prevent accidental shifting of the valve during operation. The plunger slides freely back and forth in the body, within the limits imposed by the two solenoids. When in operation, the plunger is stable only in either one of two extreme positions. In the first position, the plunger is up against solenoid A and the magnet holds the plunger against the solenoid. In this position, the compressor port is aligned with the diaphragm pump port and the vent port is blocked. The valve is now positioned for the inhale stroke of the cycle. At the end of the inhalation period, an electrical pulse is sent to solenoid A. This solenoid, when energized, pushes the plunger until it contacts solenoid B. The magnet in the plunger now latches to solenoid B, the port from the diaphragm pump is aligned to the atmosphere and the compressor port is blocked. The valve is now in the exhale position. When the preset time on the exhale timer is elapsed, solenoid B will be pulsed to reposition the valve back into the inhale position.

Leakage from the valve is controlled by closely held diametrical clearance between the plunger and the bore of the body. Diametrical clearance for the respirator valves are held at

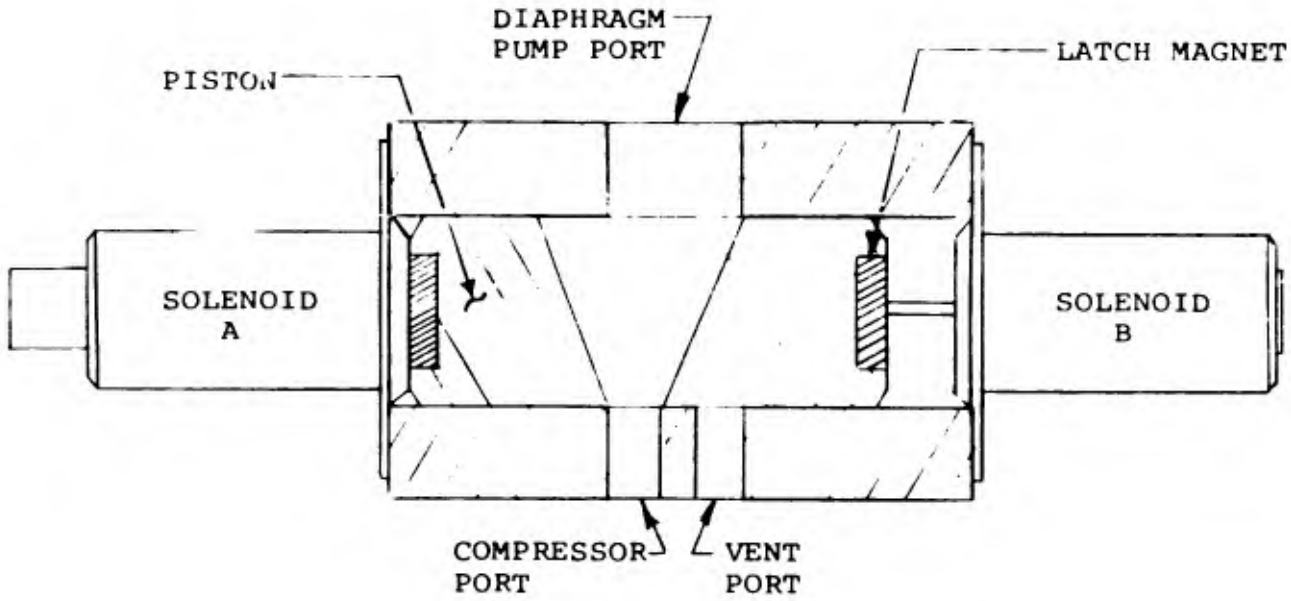


FIGURE 4.6 - FLOW CONTROL VALVE DESIGN

.001". The leakage has been measured to be 300 cc/min. Excessive leakage is determental to the operation of the unit, but 300 cc/min. which represents only 1% of the total compressor output is considered acceptable. This concept allows the use of very low powered solenoids and thereby minimizes the consumption of electrical power.

Lexan plastic was originally selected as the material for the valves. Selection was based on light weight, strength, and transparency. Machining tests were performed to determine if diametrical clearances of .001" could be held, and initial indications were promising. However, after the first valve was built, repeated cycling of the valves caused inconsistent operation due to binding of the piston in the bore. This failure was traced to deformation of the plastic piston which was caused by the high inertia loads occurring during actuation. An aluminum valve was then built and tested. After a relatively few cycles, this valve also malfunctioned in a similar manner; however, the cause of the piston seizure was traced to galling of the sliding surfaces rather than deformation of the piston. On a second aluminum valve, hard anodizing was applied to both piston surface and the bore of the valve body. This valve was placed on test at an accelerated operating rate and accumulated more than 125,000 cycles without failure or malfunction. This number of cycles is equivalent to 25% of the design life. The valve was disassembled and inspected for wear. Results of the inspection were extremely promising in that no galling or scuffing had occurred and clearances had not changed a measurable amount. This design approach was therefore considered satisfactory and selected for use in the prototype hardware. As a further measure of precaution, each valve used in the prototype respirators was tested for at least 10,000 cycles, disassembled and inspected prior to installation. Each valve was also checked for leakage. At 90 cm H_2O internal pressure, leak rates were found to range from 230 to 370 cc/min. of air. Resistance to air flow-through the valve was also measured for each unit. Table 4.4 shows typical pressure loss readings measured with air flowing from the diaphragm port to the vent port as occurs during exhalation.

TABLE 4.4 PRESSURE DROP THROUGH FLOW CONTROL VALVE (TYPICAL)

(Air Flow from Diaphragm to Vent Port)

Flow Rate (CFM)	Pressure Drop (cm H_2O)
1.0	0.5
2.0	2.0
3.0	5.7
4.0	9.7
5.0	15.0
6.0	20.0

4.2.5 Vent Valve

The vent valve is a safety device incorporated into the pneumatic system of the respirator which connects the closed circuit to the ambient to allow free breathing in the event of a power failure or inadvertent shut down. To assure safety under all probable modes of failure, this component must perform its critical function when there is (1) an interruption of electrical power and/or (2) when the supply of compressed air from the compressor/-accumulator diminishes as would occur in the case of a compressor failure. It is obvious the energy required to perform the necessary operation must not rely on electrical power or compressed air and a logical selection for the energy storage element is a mechanical spring. In concept, any device which requires both electrical power and a source of compressed air to close a port would be satisfactory. In this application electrical power is at a premium, and operating power must be held to a minimum. Figure 4.7 illustrates the safety valve design employed in the respirator. The concept centers around a differential area diaphragm valve which amplifies the pressure sensed at port A to seal flow from port B. An orifice in port A restricts gas flow into the chamber so that a pressure buildup cannot occur if the spring loaded plunger valve is opened. Power to the solenoid is required to hold the plunger valve closed hence both electrical power and air pressure are necessary to seal port B.

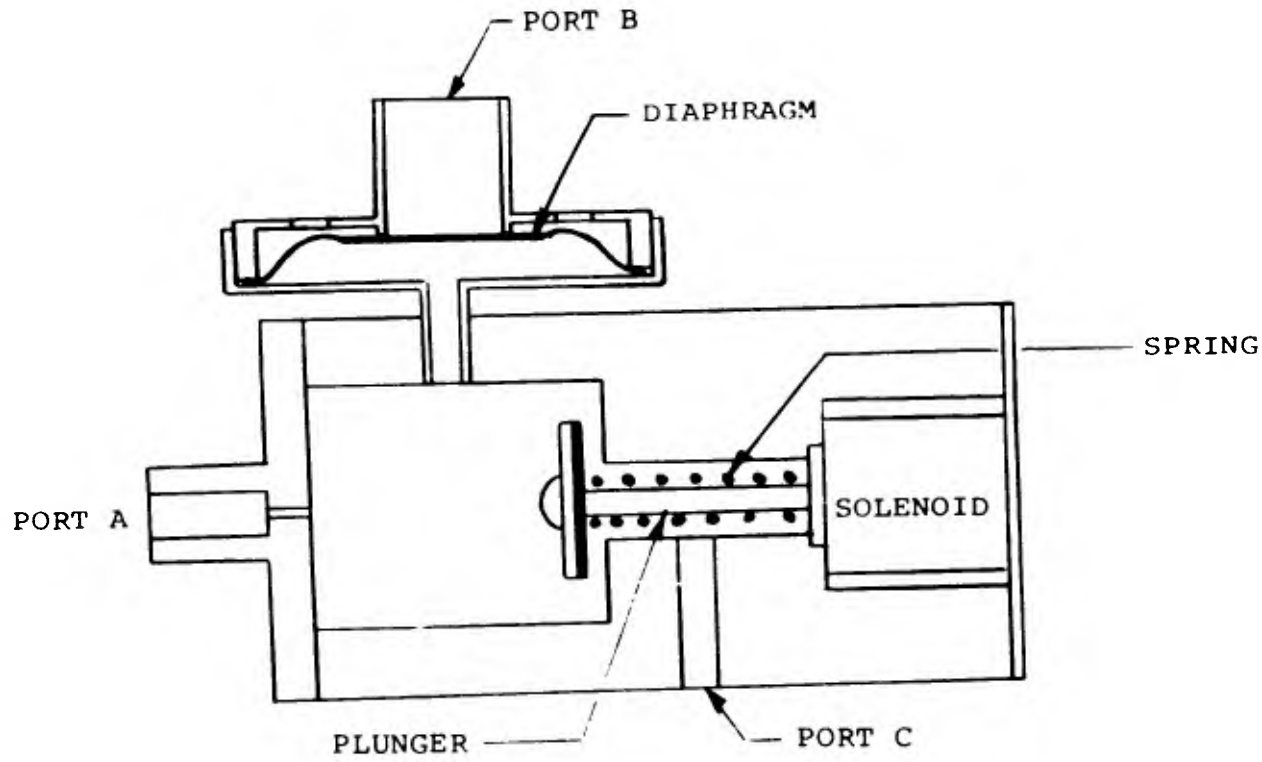


FIGURE 4.7 - VENT VALVE DESIGN

Numerous tests were performed to verify the reliability of operation over the entire range of air pressures and electrical voltage found in operation in the respirator system. An engineering test was placed on life test and cycled 2,000 times without failure. Teardown and inspection indicated no signs of wear. Subsequent operations and tests further substantiated the design.

4.2.6 Miscellaneous Mechanical Components

The remainder of the mechanical elements of the system are not unique in design and most items were procured from commercial sources. In some instances the items were manufactured specifically for this application; however, these were relatively insignificant from a design viewpoint and will not be discussed in detail. A summary of the remaining mechanical components, along with the source from which they were procured, is presented in Table 4.5.

4.3 Electrical Subsystem

The electrical subsystem of the respirator was designed to comply with the general system requirements of low weight and volume, environmental immunity, and maximized reliability. Integrated circuit technology was implemented throughout to provide the necessary accuracy with increased packaging density. Fail-safe measures were provided in many cases to ensure continued system operation under circumstances of partial damage or failure. In addition, breadboard testing was conducted on a complete operating mock-up of the electrical subsystem before design finalization to determine compliance with total system performance requirements.

On a functional basis, the electrical subsystem may be divided into five sections:

Power Distribution
Hot Wire Flowmeter
Flow Control
pO_2 Control
Alarm

Block diagrams and schematics accompany the explanation of each in the following paragraphs.

TABLE 4.5 - MECHANICAL COMPONENT SOURCES

	Component	Source	Manufacturer
1.	Intake Filter	purchased	Foamade Industries
2.	Compressor Manifold	manufactured	-
3.	Check Valve Manifold	manufactured	-
4.	Check Valves	purchased	U.S. Divers
5.	O_2 Cylinder	purchased	Walter Kidde, Inc.
6.	O_2 Shut-Off Valve	purchased	Lif-O-Gen
7.	O_2 Regulator	purchased	Lif-O-Gen
8.	External O_2 Connector	purchased	Oxequip Health Industries
9.	O_2 Solenoid	purchased	Skinner Corp.
10.	Rate Control	manufactured	-
11.	Biomedical Filters	purchased	Puritan-Bennett
12.	Patient Interface Kit	purchased	Puritan-Bennett
13.	High Pressure Limit Switch	purchased	United-Electronics
14.	Low Pressure Limit Switch	purchased	Fairchild Instruments
15.	Vent Valve Manifold	manufactured	-
16.	Mode Select Valve	manufactured	-

4.3.1 Power Distribution Circuitry

A block diagram of the power distribution network is presented by Figure 4.8. The major component in the power distribution system is the power supply unit produced by the General Electric Specialty Transformer Department, Fort Wayne, Indiana. It incorporat s an AC-DC converter to supply the -10 to +14 volt primary DC potential and a number of voltage regulators to generate the intermediate potentials of -5, 0, and +10 volts. These voltage levels are necessary to accommodate the various integrated circuits in the electrical subsystem design. The convenience of operating with unregulated DC or battery power was easily implemented by inputing these external sources to the +14 and -10 volt lines. All external power and battery inputs are internally isolated by the power select switch so that it is not necessary to disconnect one before selecting another. The system will operate on a battery voltage of from 22.5 to 30 volts, an external DC source of 24-32 volts, or an AC source of 110 to 130 volts and 50-400 cycles. While operating from AC power, a grounded outlet must be used to prevent electrical shock or fire hazard.

The power supply also contains a battery charging circuit providing a continuous 400 milliampere charging current up to a cut-off voltage of 30 volts at which it would maintain a fully charged battery. This charging may be done from either standard AC or an external DC source of over 30 volts, and will occur automatically during normal operation. If battery charging is desired exclusive of system operation, there is an internal switch to accomplish this, but only from external AC power.

The power select switch allows system operating from external AC or DC power sources or autonomous operation from battery power. The voltmeter indicates the primary DC voltage appropriate to the power source selected. In the case of battery or off position, it reads battery voltage, in DC position it reads the external DC voltage, and in AC position it reads the rectified AC, +14 to -10 volt DC potential.

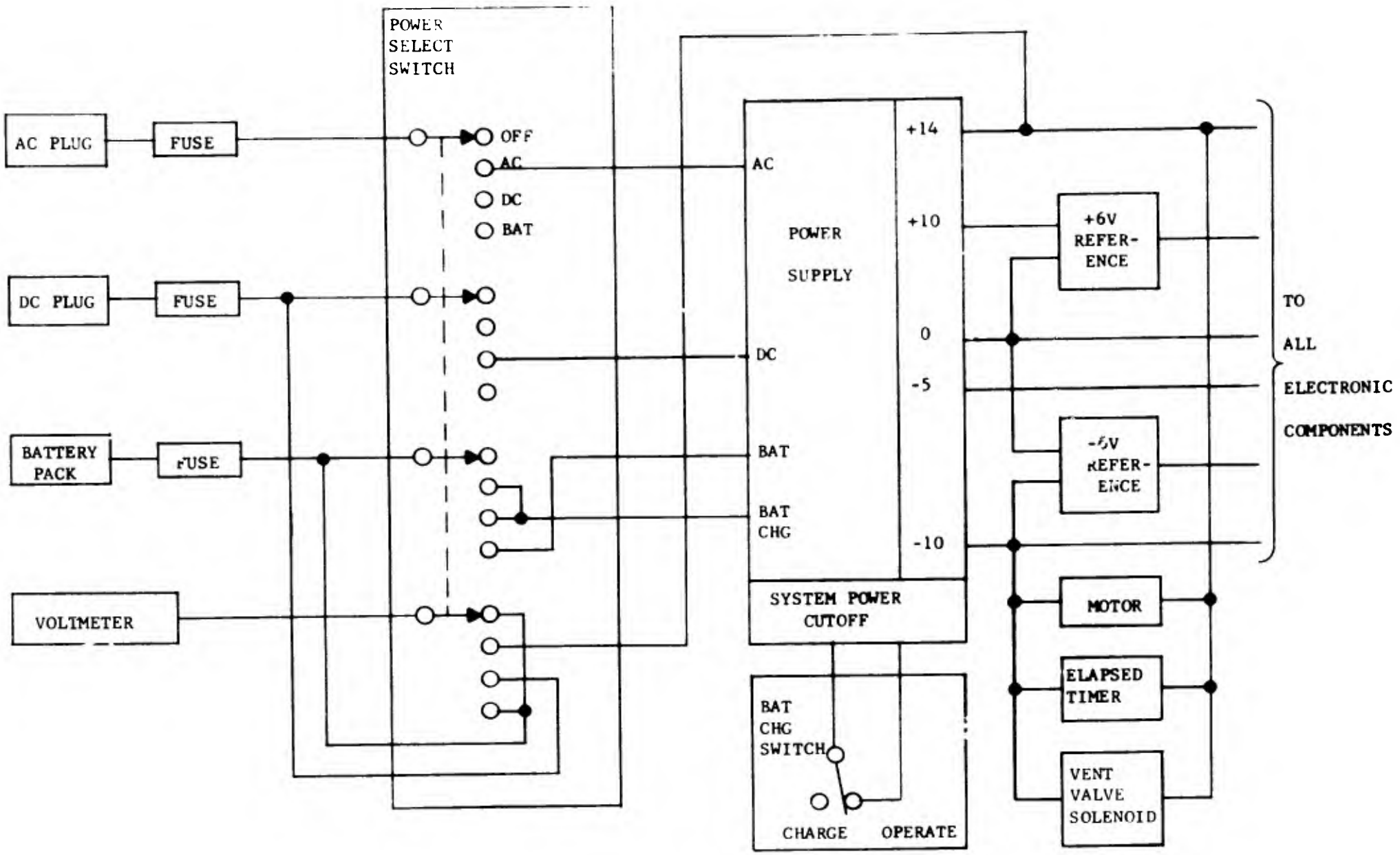


FIGURE 4.8 - POWER DISTRIBUTION CIRCUITRY

The +14 to -10 volt DC potential is used to power the motor, elapsed time, alarm lights, vent valve solenoid and other internal circuitry not requiring closely regulated DC sources. The intermediate DC potentials are sufficiently stable to power the integrated circuits. All the above voltage levels are internally adjustable for calibration purposes. Finally, two ultra-stable +6 and -6 volt potentials are generated about the 0 volt (ground) level to provide accurate and stable reference voltages.

4.3.2 Hot Wire Flowmeter

The gas flow measuring device in the respirator is based on the principles of hot wire anemometry and provides the signal which controls cycling operations in the volume controlled mode. Hot wire anemometry was chosen for this application because of its adaptability to problems of very low gas velocities with good accuracy both in the steady and transient states and because it imparts minimum resistance to the flow of gases being measured. While some power is required for its operation, the electrical demands of the sensor used is minimal in comparison with other system elements. Also, the device can be compensated for variations in environmental temperatures and is not sensitive to humidity in the gas mixture.

A schematic diagram of the flowmeter bridge network is presented in Figure 4.9. Those elements enclosed by the broken line are physically contained in the sensor housing and exposed to the airstream. The sensor element is a 0.0003 inch diameter platinum wire mounted normal to the air flow. The temperature compensating resistor is also exposed to the gas flow but is designed to be insensitive to flow velocity and only dependent on the temperature of the flowing gases. In this arrangement, changes in the temperature of the gas being measured cause a resistance change in temperature compensating resistor which offsets the variation in cooling of the sensor element and effectively make accuracy of measurement independent of gas temperature. Other elements of the circuit are mounted external to the sensor for convenience of service and fabrication.

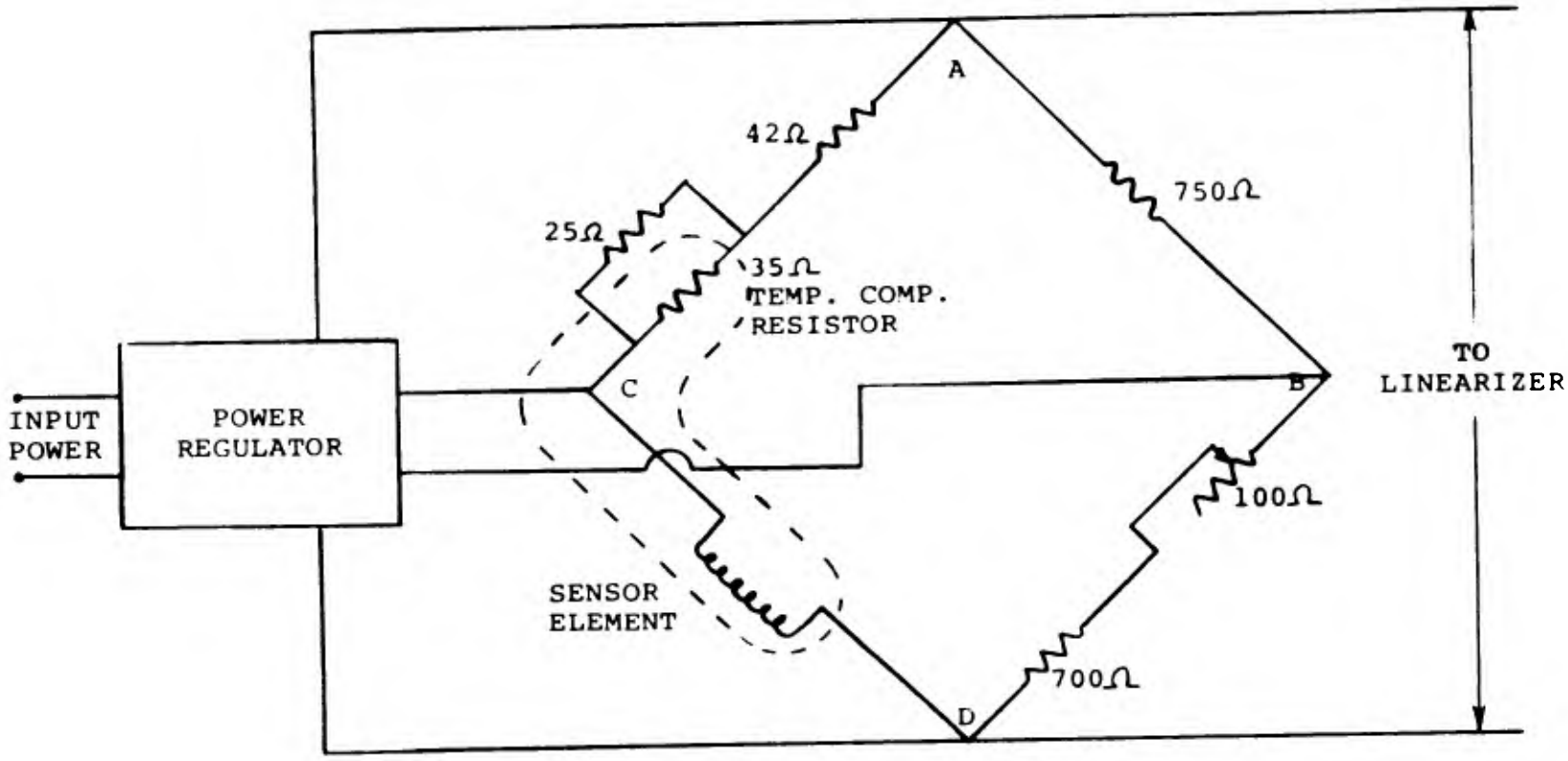


FIGURE 4.9 - FLOWMETER BRIDGE NETWORK

Operation of the hot wire flowmeter is based on convective cooling of the heated sensor element when exposed to a gas flow and the corresponding change in resistance of the element as its temperature changes. As gas flow increases, convective cooling increased according to an exponential relation. With a fixed power input to the sensor, the increases cooling causes the sensor temperature to drop and the resistance to change linearly with temperature. When mounted in a bridge circuit, this small change in resistance can be detected in the form of bridge unbalance which is used to control a power regulator which stabilizes the sensor temperature and provides the basis for a signal which is a measure of flow velocity. In operation, the bridge voltage is initially selected so that the temperature of the sensor element is about 300°F. This temperature is selected to minimize power requirements and provide insensitivity to moisture in the gas. Other resistances in the bridge are trimmed to provide an essentially zero offset voltage between points B and D, and the bridge is said to be balanced. An increase in gas flow causes increased cooling of the sensor element which changes its temperature and resistance. Since the other resistances remain fixed, the bridge is unbalanced and a voltage differential exists between points B and D. This offset is used to drive a differential amplifier which applies more voltage to the bridge across points A and C until the sensor temperature again reaches 300°F and the resistance returns to its nominal value and the bridge is balanced. The applied voltage, across points A and C, is now a measure of the flow velocity. Unfortunately, the heat transfer correlations for convective cooling are not linear with velocity, rather, they vary in an exponential fashion. Figure 4.10 graphically illustrates this relation, as measured values of bridge voltage are plotted against flow rate. To obtain a measure of volume flow it is necessary to integrate this signal and this requires a linear relation between voltage and flow rate. A signal conditioning device which linearizes this signal is added to the circuit to provide the nearby linear output shown by Figure 4.11.

FIGURE 4.10 - UNCONDITIONED FLOWMETER OUTPUT

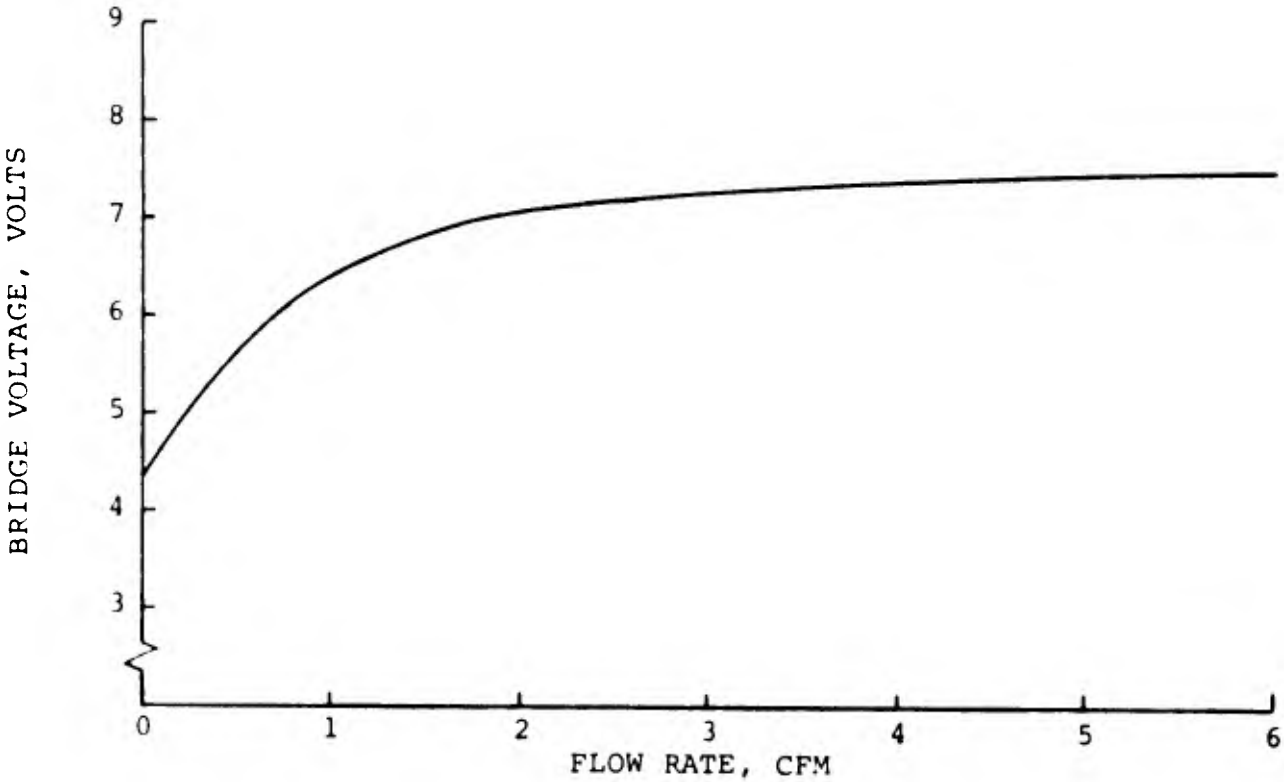
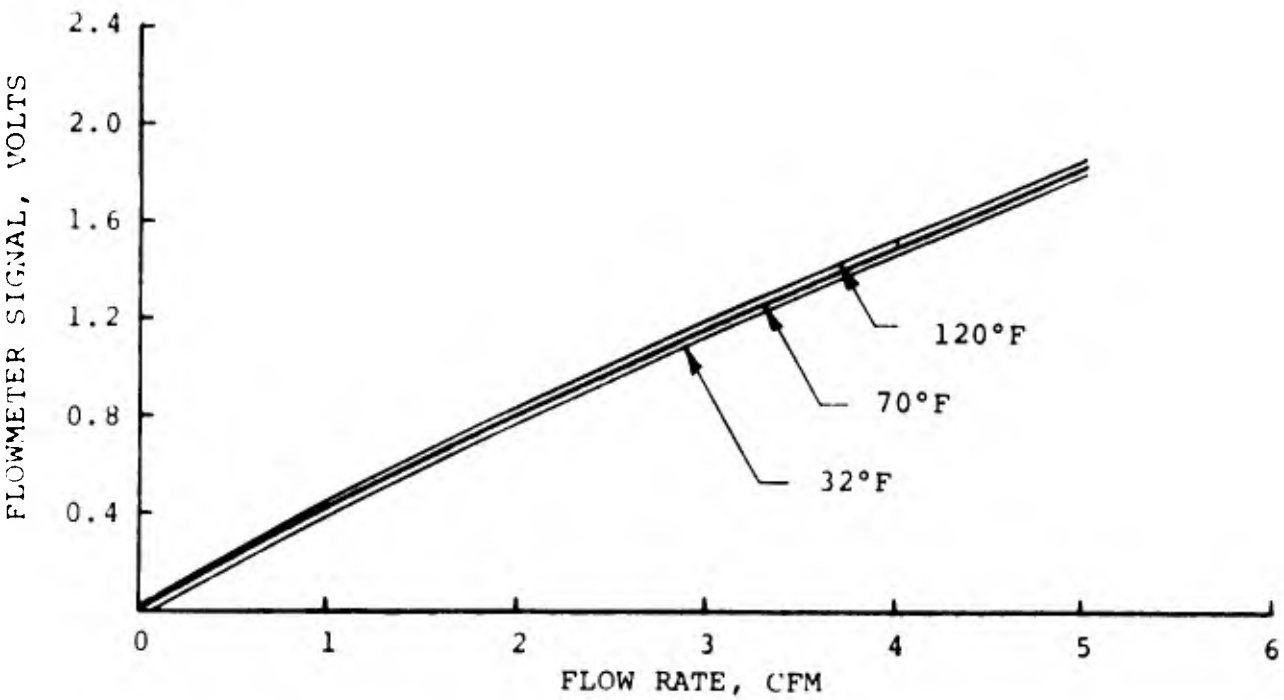


FIGURE 4.11 - CONDITIONED FLOWMETER SIGNAL



A temperature compensating resistor must be included in the bridge to offset the affects of ambient air temperature on the convective cooling rate. Air flowing at 32°F would cool the sensor at a much faster rate than air at 120°F. For the same flow rate the net result on the system would be lower volume deliveries at cold temperatures and excessive deliveries at high temperatures. By placing another resistor in the bridge which is sensitive to the ambient temperature but not to the convective currents, dependency of the sensor response on ambient temperature can be minimized. While the effects of ambient temperature cannot be totally eliminated, they can be minimized to the point where they are inconsequental to the operation. In Figure 4.11, linearized and temperature compensated sensor output are shown for the extreme ranges of operation. Considering that the system is calibrated at 70°F, these variations are obviously negligible.

4.3.3 Flow Controller

The electronic flow control can be considered the "heart" of the respirator circuitry and most vital to the system operation. It interprets the patients demands or requirement and governs the functional operation of respirator accordingly. A block diagram is presented in Figure 4.12. Its operation is most easily understood by tracing the course of a single breathing cycle electronically.

At the beginning of inhalation, the gas to be inhaled passes through the flowmeter, which in conjunction with the power regulator, generates a signal that is a function of the mass flow rate. The linearizer transforms this signal to one directly proportional to flow rate. During exhalation and until the beginning of inhalation, the integrator is initialized to zero output. During inhalation, its output rises as the flow signal is integrated. When the comparator senses that the output of the integrator, which is in direct proportion to total volume inhaled, has reached the preset tidal volume level (0.2 to 1.5 liters) it fires the 50-millisecond pulse generator through the "OR" gate. Had the high pressure level set for the system been exceeded

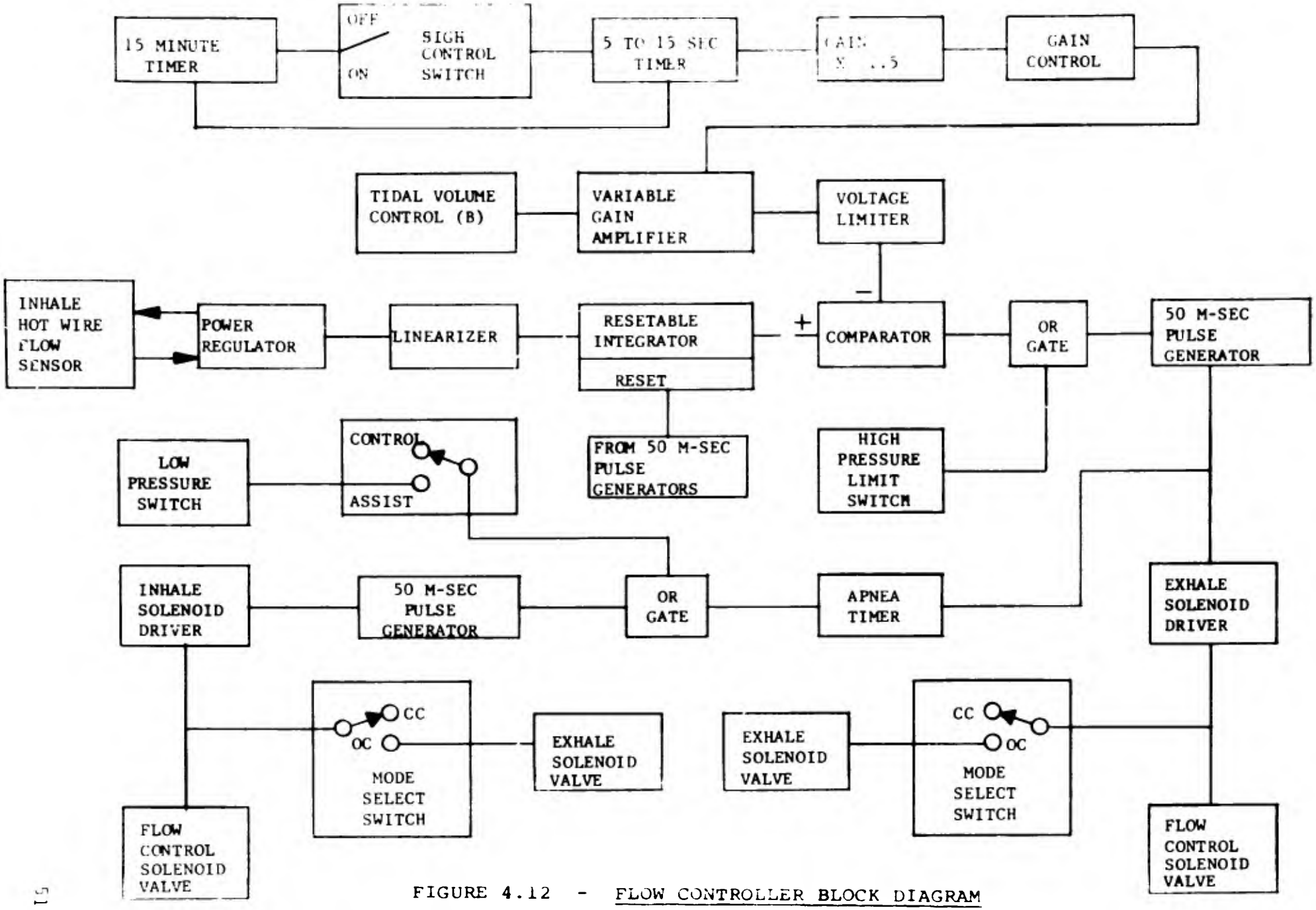


FIGURE 4.12 - FLOW CONTROLLER BLOCK DIAGRAM

during inhalation, this would have independently fired the 50-millisecond pulse generator. The resulting pulse moves the solenoids into position for exhalation, and starts the exhalation timer. In open cycle mode both solenoid valves are powered, while in closed cycle mode only one, the flow control valve is powered.

The sigh control is comprised of a pair of continuously cycling timers: one of duration 15 minutes, and the other of adjustable 5-15 second duration. While the latter is operating, the preset tidal volume is increased by a factor of 1.5 up to a maximum of 1.5 liters, cut-off being provided by the voltate limiter. The sigh control may be suppressed by turning off the sigh control switch which interrupts the firing of 5-15 second timer. If the switch is returned to the "On" position, a sigh will occur 15 minutes after the most previous sigh or immediately if the switch has been off for more than 15 minutes.

The exhalation timer sets the duration of the exhalation period from 1 to 15 seconds. Either the completion of the exhalation time or the tripping of the low pressure switch will fire the second 50-millisecond pulse generator which will in turn move the solenoid valves into position for inhalation and start the inhale volume integrator, initiating inhalation. If desired, the low pressure switch may be prevented from terminating exhalation by putting the assist-control switch in the control position.

4.3.4 Oxygen Partial Pressure Controller

The pO_2 control electronics serves to maintain the internal gas mixture at the preset level. It allows a quantity of oxygen necessary to raise the internal mixture to the desired pO_2 level to pass through the oxygen solenoid. As the solenoid contains a flow limiting orifice and is preceded by a pressure regulator, the amount of oxygen fed to the system is directly proportional to the time the solenoid is held open by the electronic driver.

The pO_2 control electronics determines this time interval and delivers the required pulse duration to the solenoid driver at the beginning of each inhalation. A block diagram of this subsystem is presented in Figure 4.13.

In open cycle operation, the amount of oxygen added to the inspired gas mixture on each breath is a function of the desired oxygen level and the volume being delivered. It is therefore necessary to combine these factors by means of a variable gain amplifier so that the duration of the solenoid pulse is a function of both. When open cycle operation calls for the use of 100% oxygen, the entire volume delivered on each cycle must pass through the solenoid valve. In closed cycle operation, pulse duration is a function of only one variable, namely, the desired pO_2 level. In this case, the oxygen sensors provide the signal for control. The output of the sensor is compared to the preset value and the solenoid pulse duration varied until these two quantities are within the prescribed tolerance. For added reliability the system pO_2 level is monitored by two oxygen sensors, the signals from which are amplified and calibrated. The higher reading is selected for use in the control system and for display on the panel meter as sensor degredation results in a decreased output and the higher reading is more accurate. This is fed into the negative input of the adder so that the amplifier input is (pO_2 control setting) - (pO_2 sensed). The gain of the amplifier in closed cycle is the fixed value of tidal volume described above, and the amplifier output is then a voltage proportional to the oxygen deficiency, i.e., that necessary to raise the system level to that set on the control.

In both open cycle and closed cycle operation, the voltage from the amplifier, proportional to O_2 pulse duration, is compared with a voltage ramp regenerated at the beginning of each inhalation. This comparator holds the oxygen solenoid open as long as the ramp voltage is below the amplifier output. When the ramp rises above the amplifier output, the solenoid is allowed to close. Thus, the oxygen released into the system is directly proportional to the amplifier output as is required in both open and closed cycle operation.

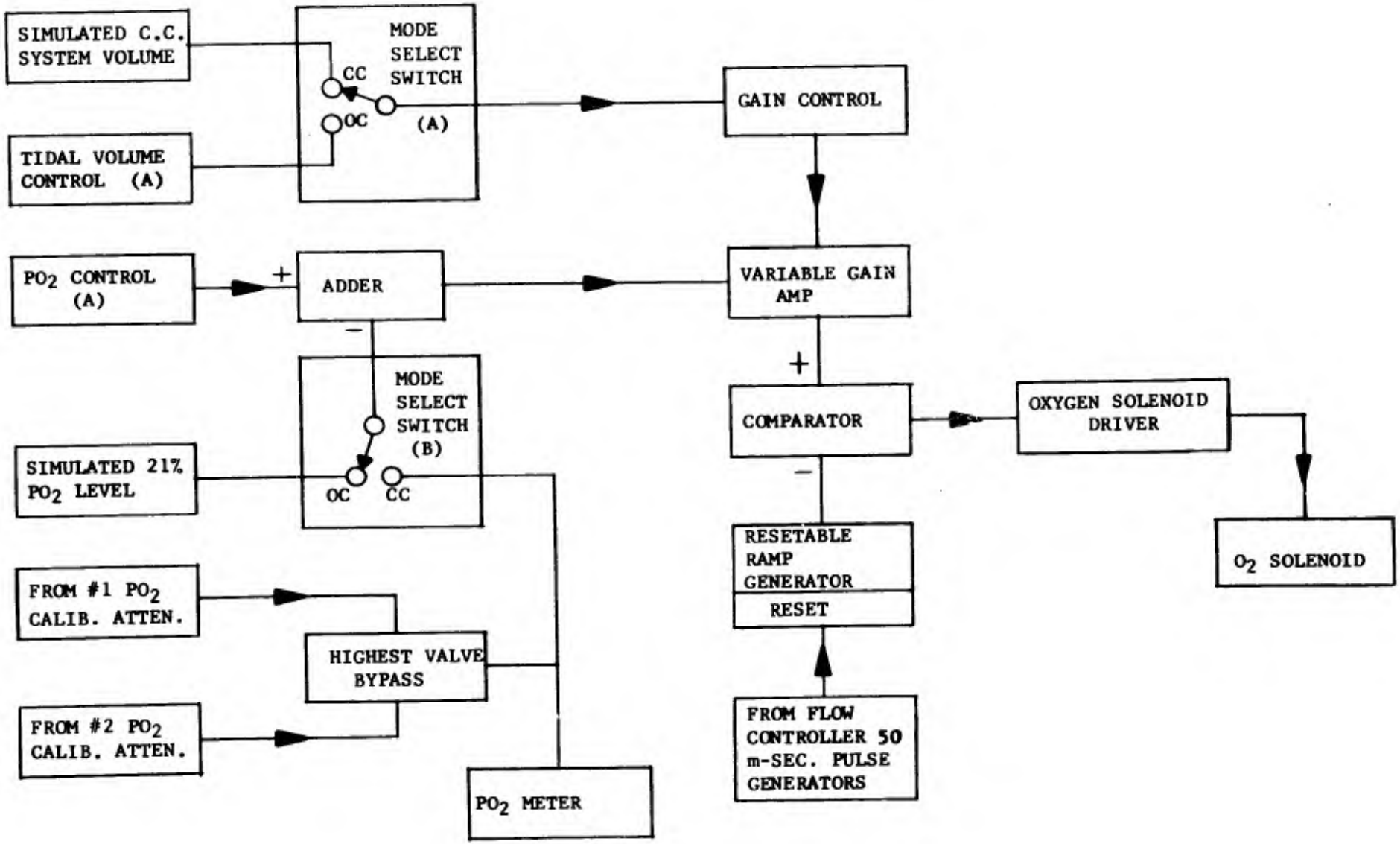


FIGURE 4.13 - OXYGEN CONTROL SYSTEM BLOCK DIAGRAM

4.3.5 Alarm System

The alarm system continuously monitors three vital system parameters and gives both visual and audible warnings of malfunction. The parameters monitored are battery voltage, pO_2 level, and exhaled volume, each of which are further provided with quantitative displays. A block diagram of the alarm system is given by Figure 4.14. Separate visual alarms are provided for each alarm function. A common audible alarm is actuated after a 10 second delay. A combination of one or more of the above alarms occurring continuously for 10 seconds or more will actuate the audible alarm. Loss of the alarm condition will interrupt the audible alarm and reset the delay timer. The audible signal may be halted by placing the alarm disable switch to the "Off" position thereby removing power from the audible alarm. The visual light alarms have no delay action or cut-out switch and are an instantaneous indication of the monitored function.

The battery alarm circuit monitors the primary DC voltage in the system and will actuate whenever this voltage falls below 22.5 volts. This is accomplished by comparing half of the appropriate voltage with an internally generated voltage reference which is independent of the supply voltage.

The partial oxygen pressure of the system is monitored by a pair of oxygen sensors contained in the scrubber, the signals from which are amplified and calibrated. The higher signal is read on the pO_2 meter. Each calibrated signal is compared with 85% of the pO_2 control setting. A signal lower than this level indicates a low system oxygen level. The oxygen control setting is further compared with 87% of each of the calibrated oxygen signals. The latter greater indicates a high system oxygen level. This provides for a $\pm$15% tolerance in system oxygen level about the control setting. An oxygen level outside of this tolerance triggers the alarm.

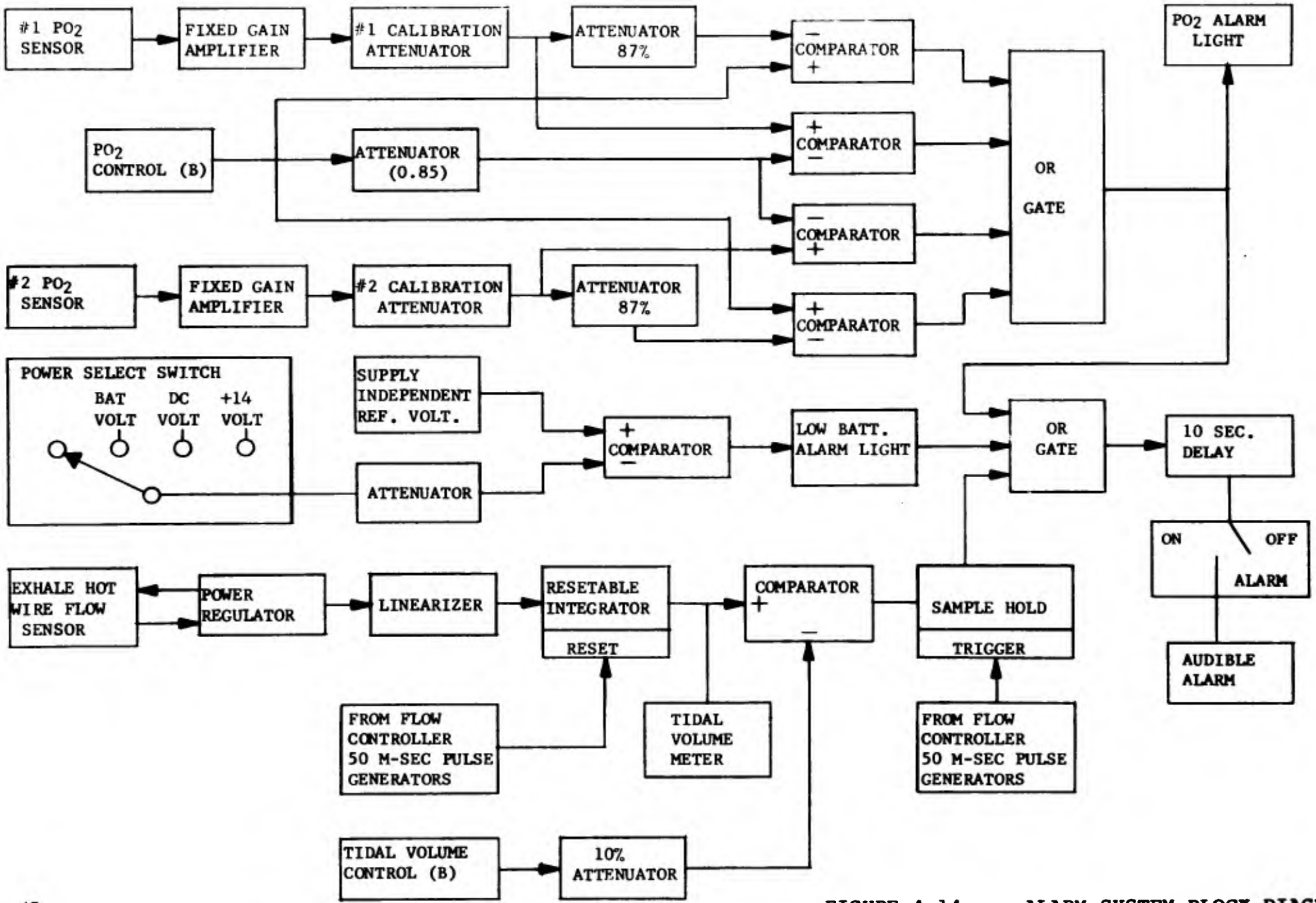


FIGURE 4.14 - ALARM SYSTEM BLOCK DIAGRAM

The exhale volume alarm circuitry continuously compares the exhaled volume with 90% of the tidal volume control setting. If the expired volume fails to reach 90% of the control setting by the end of exhalation, the tidal volume alarm will actuate and remain on until a satisfactory exhale occurs. The expiratory flow is sensed by a second flow sensor in the exhalation flow path. The measurement of exhaled volume is also displayed on the instrument panel enabling the operator to visually observe the integration of exhaled flow.

All amplifiers and integrators in the electronics are provided with nulling adjustments to insure accurate zeroing and minimum drift, and with adjustable output attenuators to fine tune the gain. These are set during the calibration procedures of the internal electronics, and sealed in the electronics compartment. Only the calibration attenuators for the oxygen sensor readout are located on the front panel.

5.0 TEST PROGRAM

Testing activities on the program were divided into two phases. The first phase was associated with the development testing of the components and subsystems to verify adequacy of performance and conformance to design specifications. On certain critical components, life tests were performed; however, duration and scope of the program did not permit conclusive testing in this area. The second phase of testing relates to the calibration and performance measurements of the assembled respirators. Discussions of the tests performed and typical results are presented in this section.

5.1 Component Testing

All functional elements of the respirator system, whether manufactured specifically for this application or purchased as a piece of commercially available hardware, were subjected to component tests. The degree of testing varied considerably and was designed to reflect the relative criticality of the element. In the case of commercially available components whose designs are well proven, only performance checks were made. For those components which were more developmental in nature, complete performance characteristics were measured. A summary of the component tests is given in Table 5.1.

5.2 System Testing

Each respirator unit, at various stages of its assembly, was subjected to tests to evaluate subsystem performance as the various components were mated and assembled into working systems. While this approach does involve redundant testing on certain components, it allows a step-by-step elimination of problems as they are introduced. The following paragraphs discuss some of the major tests performed during assembly as well as the final system checkout which is designed to verify total system operation.

TABLE 5.1 - COMPONENT TEST SUMMARY

Component	Test Performed	Test Results
1. Compressor	a. efficiency determination	a. Efficiency was found to be 35%.
	b. compressor output	b. Compressor output was 34 liters at 90 cm.
	c. compressor life	c. Life expectancy of motor was found to be approximately 4000 hrs. Compressor showed no signs of excessive wear.
2. Accumulator	a. leak checks	a. Units were leak tight.
	b. storage volume	b. Storage volume was found to be 1.2 liters.
	c. pressure range	c. Low pressure point was between 76-78 cm. High pressure point was set at 90 cm.
3. Flow Control	a. leak rate	a. Leak rates ranged from 220 to 370 cc/min.
	b. ΔP across valves	b. Typical pressure drop is 7 cm H_2O at 100 liters/-minute air flow.

TABLE 5.1 (Cont'd.) - COMPONENT TEST SUMMARY

Component	Test Performed	Test Results
3. (Cont'd.)	c. minimum pulse width	c. Minimum pulse width to activate solenoids was 29-33 msec.
4. Diaphragm Pump	a. leak rate b. volume displacement c. bladder valve actuation pressure	a. Units were leak tight. b. Units had a total displaced volume per stroke of 1.8 liters. c. Valves required 2-3 cm H_2O to open.
5. Scrubber	a. leak tightness b. CO_2 absorption capability	a. Units were leak tight. b. Scrubbers absorbed a minimum of 1.1 lbs. of CO_2 under all conditions.
6. Manifolds	a. leak rates checks	a. Units were made leak tight.
7. Rate Control Valve	a. leak rate b. control linearity	a. Valves were leak tight. b. Deviations from linearity were less than 10% with a 90 cm H_2O pressure applied to the valve.

TABLE 5.1 (Cont'd.) - COMPONENT TEST SUMMARY

Component	Test Performed	Test Results
8. Mode Select Valve	a. leak checks b. switch continuity	a. Valve was leak tight in both positions. b. Switches were activated or closed when required.
9. Vent Valve	a. leak check b. pressure holding capability c. response time	a. Valves were leak tight. b. Valve could hold 1 1/2 times reference pressure. c. All valves opened in less than 1 second.
10. High Pressure Limit Switch	a. activation Point b. dead band	a. Actuation points were not coincident with set points. Variations up to 10% were measured. b. Dead band varied from 6 cm H_2O to 12 cm H_2O.
11. Low Pressure Switch	a. actuation point	a. Actuation point was found to be approximately 1 cm H_2O with a movement of less than 10 cc of gas.

TABLE 5.1 (Cont'd.) - COMPONENT TEST SUMMARY

Component	Test Performed	Test Results
12. Inspiratory Pressure Gage	a. Calibration check	a. All gages read 10% higher than actual pressure.
13. Oxygen Pressure Regulator	a. leak check	a. Regulators had leaks, leaks were repaired.
	b. 2nd stage pressure set point	b. Set point varied from 53 to 57 psi. However, pressure was 50 psi for all units under maximum flow rate.
	c. maximum flow rate	c. 60 liters per minute
14. Oxygen Solenoid	a. leak check	a. No leakage observed in closed position
	b. maximum flow rate	b. 40 liters per minute with 50 psi supply pressure

5.2.1 System Leak Tests

Leak checks were performed on all units to insure integrity of the pneumatic system and that leak rates were within specified limits. Leak checks were performed individually for the following system areas:

- open loop side
- closed loop side in closed cycle mode
- closed loop side in open cycle mode
- vent valve subsystem
- oxygen subsystem

To measure the open loop leak rate, the compressor discharge line was interrupted at the inlet to the compressor manifold and an external air supply with an inline flowmeter was connected. The diaphragm pump discharge line was removed and plugged. With the flow control valve in the inhale position, the loop was then pressurized to 90 cm H_2O. The inline flowmeter indicated the leak rate from all components in the open loop. A second reading was then made with the flow control valve in the exhale position. Maximum leak rate acceptable in either position was established as 1000 cm/min. Leaks resulting in higher rates were repaired. The finally measured leak rates were as follows:

	Leak Rate, cc/min. (90 cm H_2O Pressure)	
Respirator S/N	Exhale Position	Inhale Position
6549725	300	270
6549726	325	325
6549727	270	220
6549728	270	230

To measure leakage in the closed loop portion of the system while in the closed cycle mode, the vent valve was removed from the vent valve manifold and the port plugged. The exhale filter port was plugged as was the line disconnected from the diaphragm pump in the previous tests. The air supply was connected to the inhalation filter port and the system pressurized to 90 cm H_2O. Leak rates greater than 50 cc/min were considered unacceptable. The final leak rates for the four units were as follows:

Respiration S/N	Leak Rate, cc/min (90 cm H_2O Pressure)
6549725	5
6549726	50
6549727	45
6549728	5

This test was repeated with the mode select valve in the open cycle position and the exhale valve in the inhale position. In the open cycle mode, a higher leak rate can be tolerated since oxygen consumption is not as critical. A leak rate of 500 cc/min is considered acceptable. Measurement determined the leakage in this portion of the system to be as follows:

Respirator S/N	Leak Rate, cc/min (90 cm H_2O Pressure)
6549725	300
6549726	410
6549727	270
6549728	170

The fourth leak check consisted of repeating the closed loop-closed cycle test with the vent valve installed in the vent valve manifold. The vent valve solenoid was energized and the pressure port connected to the air supply and leak rates recorded. In all cases the deviations from the previous test with vent valve removed were negligible indicating the vent valve itself was not contributing to leakage.

The high pressure oxygen system was tested for leaks using liquid detection methods. After gross leaks had been isolated and repaired, the system was pressurized to its maximum rated value and sealed. A pressure loss of 100 psi per hour was considered acceptable. All units satisfied this requirement.

5.2.2 Pressure Drop Measurements

Low impedance to the flow of gases in the breathing loop is critical to satisfactory operation of the system and measurements of various portions of the airway system were made. The three flow paths which are considered most important are:

a) Exhale path in closed cycle mode

b) Exhale path in open cycle mode

c) Exhale/inhale path through vent valve

Minor differences were noted from one unit to another due to variations in the routing of airways; however, the following data is typical of the values recorded for all units:

Flow Rate	Pressure Drop, cm H_2O		
LPM	Path A	Path B	Path C
30	3.2	1.9	2.4
60	8.7	6.5	6.9
90	19.6	13.2	12.9
120	32.4	19.8	17.1
150	44.3	26.3	23.2
180	58.8	35.1	31.8

5.2.3 Compliance Measurements

An inherent problem associated with the accuracy of volume measurement is that of airway compliance. Ideally, the flow measuring device would be located as near as possible to the patient interface to minimize this effect. In practice this would require electrical cables to extend from the respirator to the patient thereby complicating the application of the device. A more practical arrangement is to locate these sensitive components within the respirator and minimize the extent of

flexible tubing between the flowmeter and the patient. This latter approach was selected and the flowmeters located as near to the airway attachment ports as possible to minimize effects of elastic deformation of tubing and compression of the gas.

System compliance was determined by pressurizing that portion of the system between the inhalation flowmeter and the patient, including that segment of the exhale path which is exposed to high pressure, and measuring the amount of gas necessary to raise the pressure to a known level. In all four systems, it was found that approximately 360 standard cubic centimeters of gas are required to increase the pressure to 90 cm H_2O. The compliance is linear over the operating range and the effective system compliance can be stated as 4 cc/cm H_2O. Of this total value, approximately 50% is due to air compression while airway expansion accounts for the remainder.

5.2.4 Tidal Volume Calibration

Prior to assembly in the system, each flowmeter and its associated power regulator were calibrated against a laboratory flowmeter by triming the resistances of the bridge circuit and the flowmeter power regulator. After installation in the respirator, a system calibration is performed utilizing the apparatus shown in Figure 5.1. Illustrated schematically here, this device consists of a light weight graduated column inverted in a water reservoir with a tube communicating to a trapped volume of air. The respirator airways are connected to this tube. Air delivered by the respirator raises the graduated column and gives an accurate measure of the quantity of gas delivered. A plastic graduate is used so the weight is minimal and the trapped air is, for practical purposes, at standard conditions. Calibration was accomplished by selecting a tidal volume setting of 1.0 liters and adjusting the trim potentiometer of the flowmeter power regulator to give the desired delivery. Because of compliance effects discussed previously, the flowmeters were set to deliver 1.16 liters of gas when working against a zero back pressure receiver.

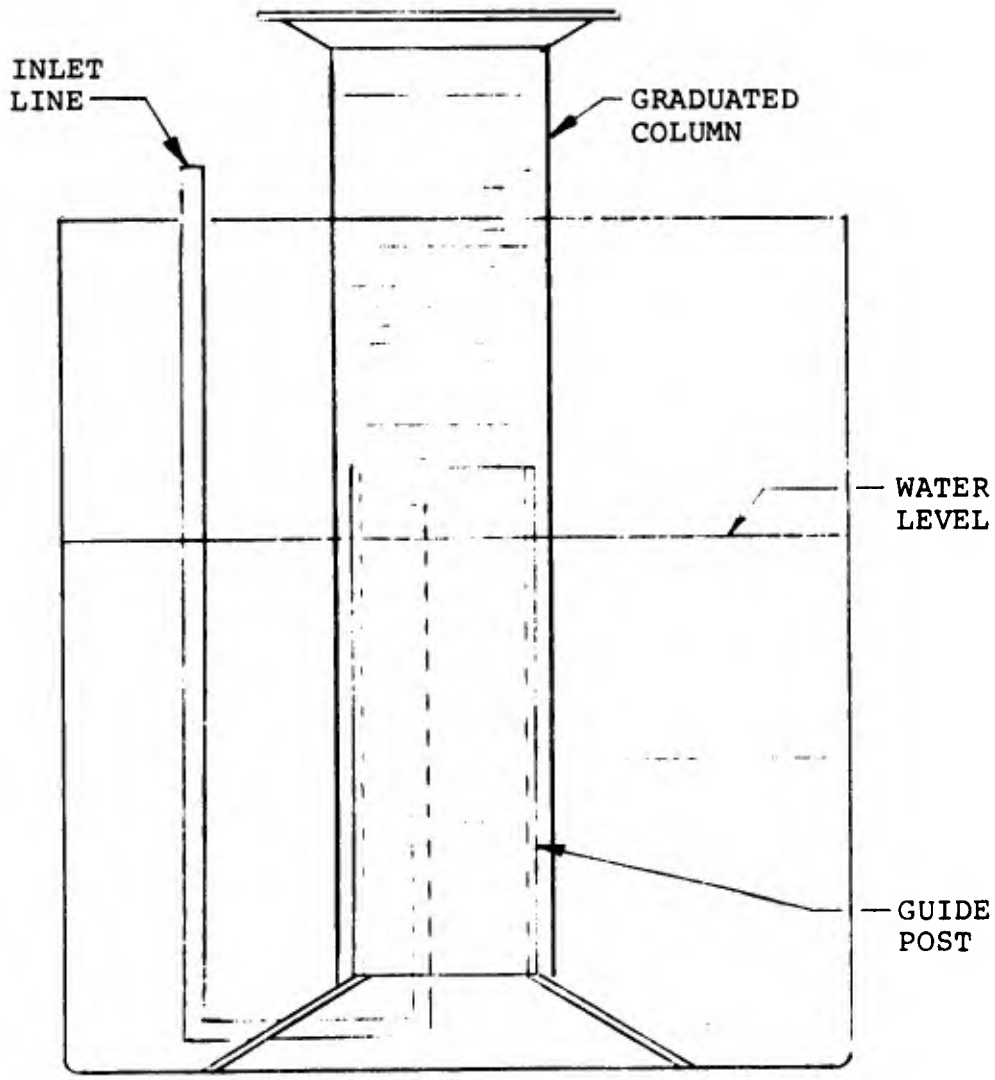


FIGURE 5.1 - TIDAL VOLUME CALIBRATION TEST FIXTURE

This corresponds to accurate delivery at the 35 cm H_2O pressure level which was considered to be an average operating point.

With the electronic calibration complete, the tidal volume control performance was mapped. Figure 5.2 shows results of these tests when the system is operated against back pressures of 0 and 35 cm H_2O. The effect of delivery rate on tidal volume control accuracy was also measured. Figure 5.3 shows that low rate control valve settings cause an under delivery of gas. This results from non-linearities in the flowmeter output at low flow rates. In practice, this factor is of little concern since a very small fraction of each breathing cycle is spent in this regime and the integration further minimizes the effect of the error.

5.2.5 Oxygen Partial Pressure Control Calibration

Two separate oxygen partial pressure control systems are incorporated for the open and closed cycle modes. In the closed cycle mode, the key element is the oxygen partial pressure sensor which provides an electrical signal proportional to the oxygen content of the gas in closed system. Characteristics of the sensor are fixed by design so that calibration requires only the adjustment of the sensor amplifier gain to give the desired output signal for known gas mixture. During the system test, a three point calibration is performed. This involves exposing the sensor to an inert gas such as nitrogen to check the zero point output, pure oxygen to measure the output at the 100% level and a final check of the calibration on air. An operational check of the control system is then made by selecting a partial pressure of 60% and allowing the system to operate into a closed volume. After equilibrium has been reached, the gas concentration is measured and compared to the preset value. Proper operation will maintain the level within 10% of the set point.

The open cycle control system does not rely on the sensor signal as the basis for control but is accomplished by timed pulses of the oxygen solenoid valve. The oxygen sensors continue to

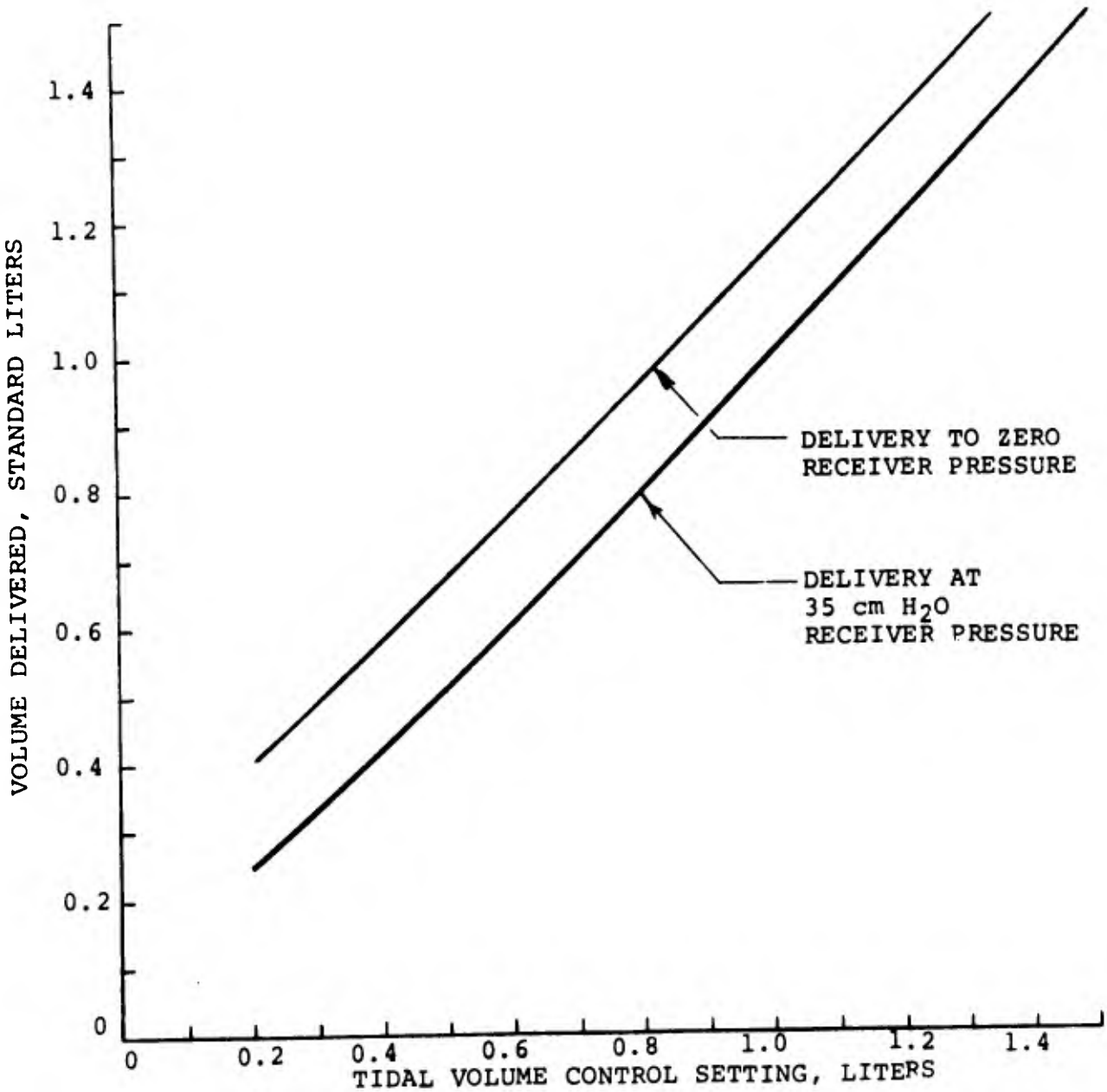


FIGURE 5.2 - TIDAL VOLUME CALIBRATION CURVE

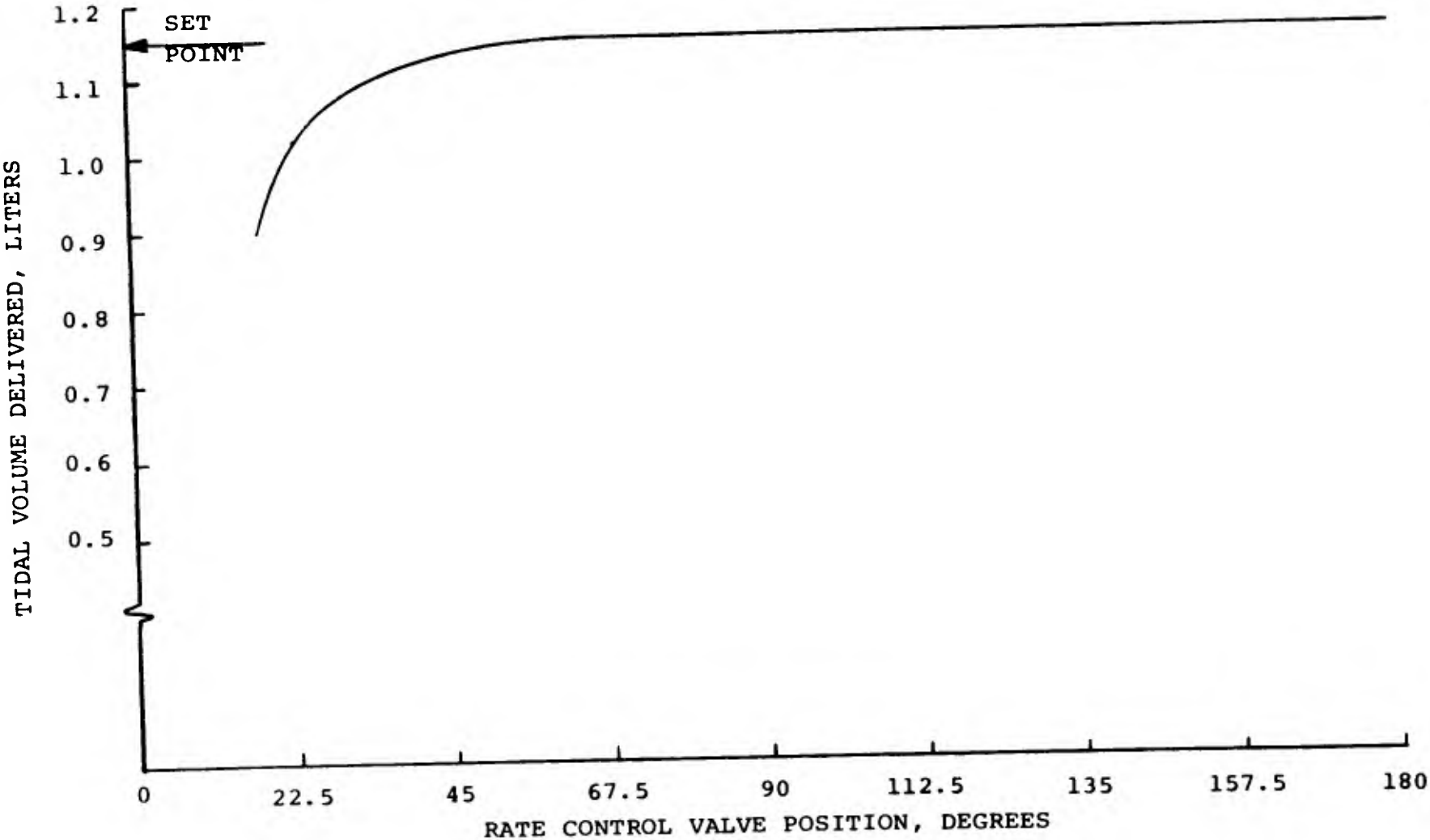


FIGURE 5.3 - EFFECT OF DELIVERY RATE ON TIDAL VOLUME ACCURACY

operate during open cycle operations; however, and their output is used in the alarm system and to operate the panel meter. Duration of the solenoid valve pulse is dependent on the selected settings for oxygen partial pressure and tidal volume. The amount of oxygen to be added on each breathing cycle is proportional to the product of these parameters and calibration consists only of modifying the constants in this relation. This is accomplished by adjusting an amplifier gain which controls the solenoid pulse duration. A single point calibration at 60% oxygen is all that is required.

After initial calibration is complete, testing over the entire operating range is performed. Characteristic performance curves for open and closed cycle operation are developed as shown by Figure 5.4 and 5.5 respectively. In Figure 5.4 it can be seen that the entire range of performance could not be attained. This is the result of an orifice restriction in the solenoid valve. Valves with larger orifices would readily rectify this limitation; however, such components were not available within the time span of this development program.

5.2.6 Final System Check

Upon satisfactory completion of all calibration procedures and tests, the units were completely assembled and connected to the test apparatus used in tidal volume calibration and allowed to ventilate this divice for a minimum of four hours. After completion of this period of operation, the system was again checked for proper operation of all functions and prepared for delivery.

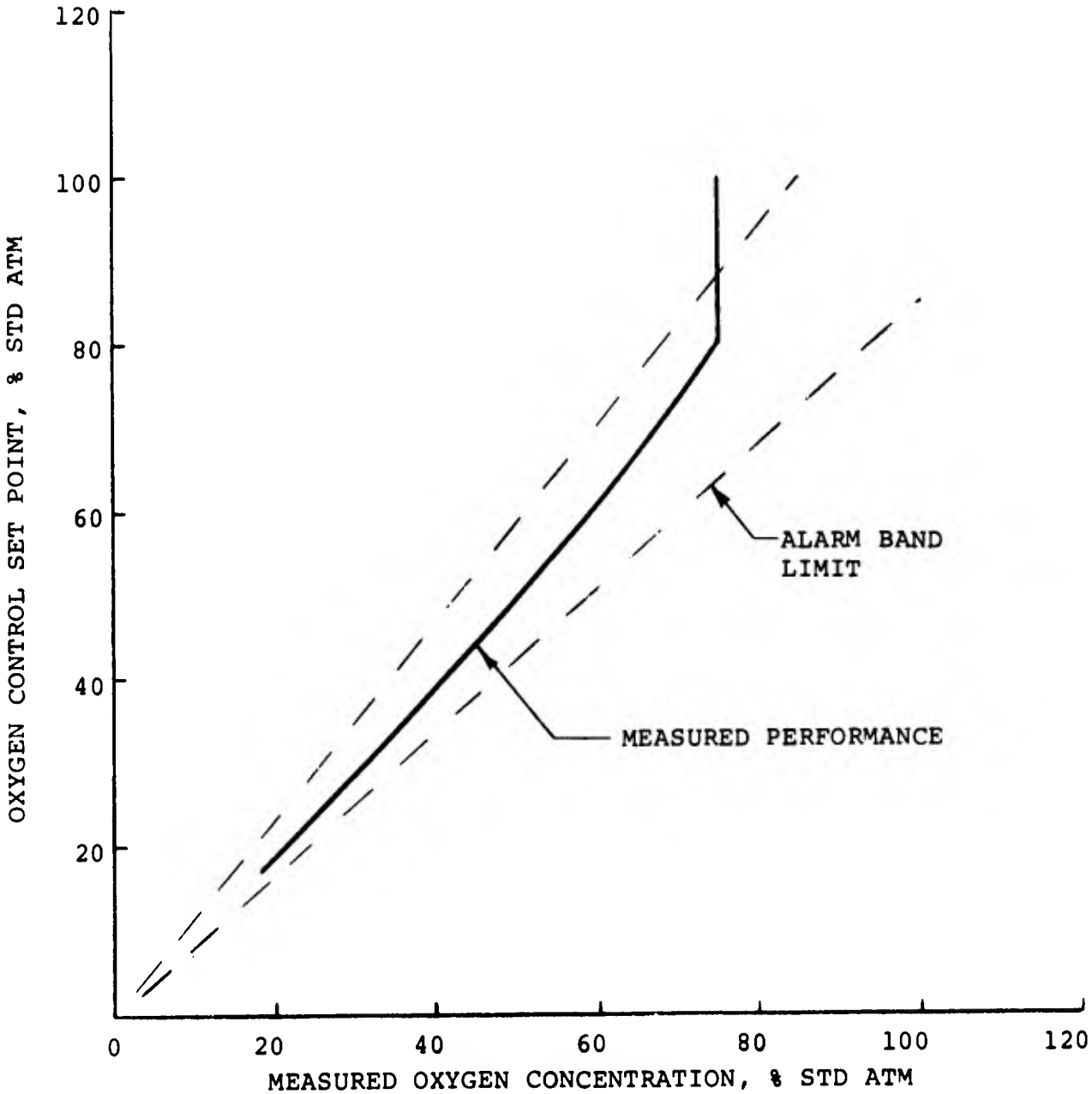


FIGURE 5.4 - OXYGEN CONTROLLER PERFORMANCE
OPEN CYCLE MODE

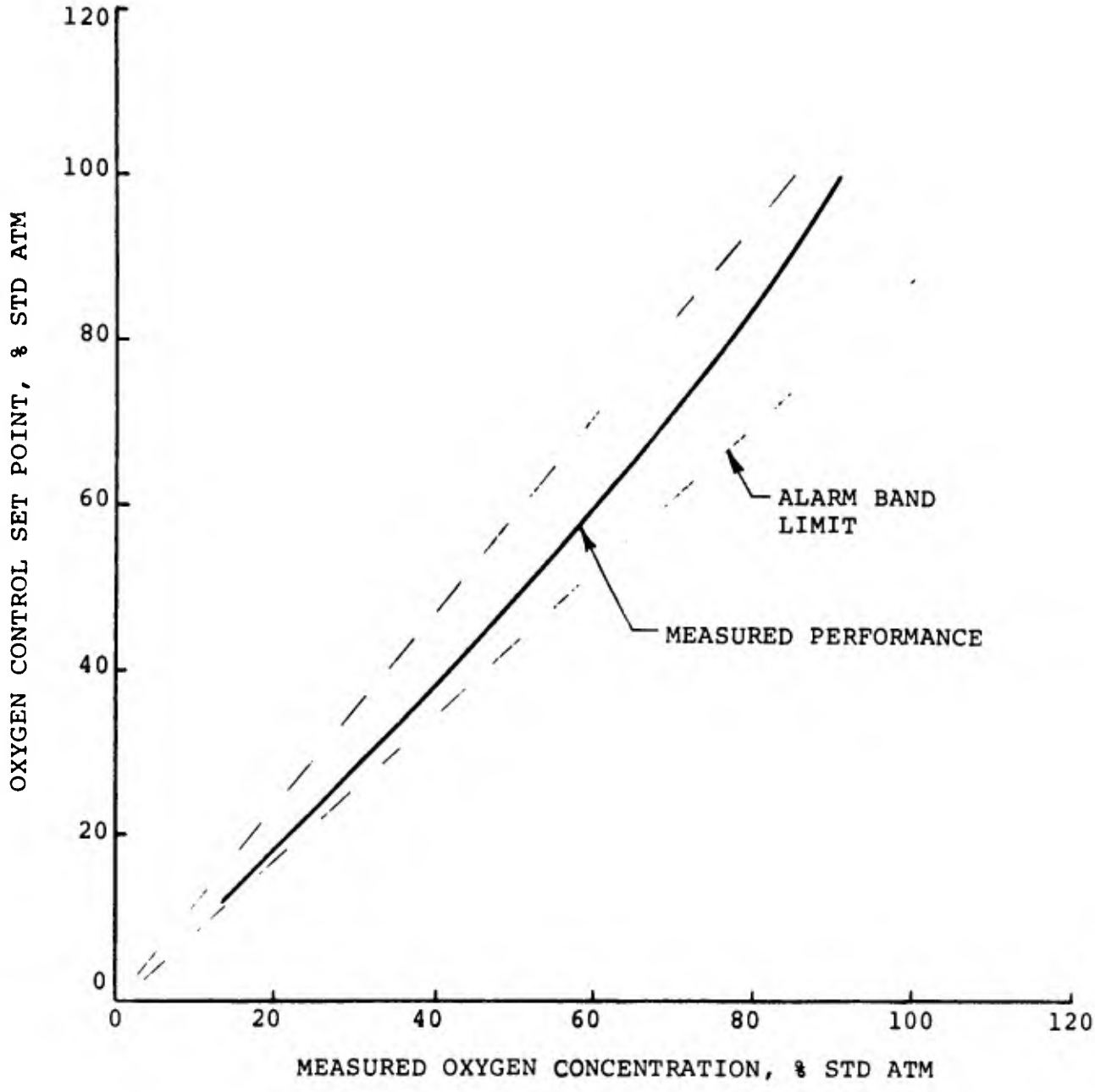


FIGURE 5.5 - OXYGEN CONTROLLER PERFORMANCE CLOSED CYCLE MODE

6.0 CONCLUSIONS

At the outset of this development program, specific objectives and design goals were established and form the basis for the system requirements. The great majority of these objectives were satisfied and in some cases even exceeded. In several instances; however, the goals were not met. In all cases, these deficiencies are the result of conscious compromises and were permitted because they have little or no effect on functional performance. Most of these compromises were necessitated by considerations of cost and schedule as limited production precludes the use of certain manufacturing techniques and necessitates the use of existing commercial components.

The greatest deviations from the design goals are related to the final physical configuration and servicability of the unit. Weight of the completed respirators approached 80 pounds while the target weight was 60 pounds. At least half of this difference can be attributed to the fact that metals were used in place of light weight plastics because of the limited quantities involved. In production quantities, appropriate tooling would eliminate these penalties and a weight of 65 pounds seems realistic. A great deal of emphasis was placed on minimizing the overall dimensions to enhance portability. In retrospect, further relaxation of the envelope would have resulted in a net improvement of the design. The present configuration has been compacted beyond practicality and non-routine maintenance requires excessive time and effort.

It was recognized at the start of the program that operational noise level was a definite problem area due to the types of compressors which could be considered for a portable device. Compressor design was strongly influenced by this consideration and careful attention was given to acoustic insulation in the compressor compartment. The final result showed substantial improvements in this area compared to the previous breadboard system; however, the operational noise level is still greater than is normally accepted for hospital use. Further development effort in minimizing generated noise as well as application of acoustic insulations would doubtlessly improve conditions beyond the present state. The necessity

for a high efficiency compressor makes it unlikely that the elevated operational noise level can be completely eliminated. Refinements in the application of acoustic insulation offer the greatest promise for improvement but the cost will be increased volume to accommodate this material.

The scope of this development program did not include gathering of sufficient data to verify the reliability of the design for extended operation and for operations under all environmental conditions. This data will have to be developed during subsequent tests and evaluations. Continued use of the prototype respirators will most certainly identify areas for improvement. The production of additional units, even if in limited quantity as appropriate for field evaluation, should be preceded by a redesign effort to incorporate these findings and to allow an interation on the packaging arrangement.

APPENDIX A

SYSTEM REQUIREMENTS DOCUMENT

DOCUMENT RDP-001

July 3, 1969

CLOSED-CYCLE RESPIRATOR DEVELOPMENT PROGRAM

CONTRACT N00014-69-C-0329

SYSTEM REQUIREMENTS

REVISION: 0

J. T. Keiser, Program Manager
RESPIRATOR DEVELOPMENT PROGRAM

Dr. M. Mills, Principal Investigator
RESPIRATOR DEVELOPMENT PROGRAM

RESPIRATOR SYSTEM REQUIREMENTS

1.0 GENERAL

The respirator system shall be designed to satisfy general Military Mission requirements in the areas of operational characteristics, environmental considerations, logistics, and configuration. It shall operate primarily as a volume controlled system with controls to set tidal volume and duration of the passive exhalation period. The system shall not generate negative pressures. Pressure sensing elements shall be incorporated to provide an adjustable upper limit on inspiration pressure and a fixed low pressure limit which overrides the tidal volume and exhalation timer controls. The system shall also include a sigh control which activates automatically at fixed intervals and overrides the primary tidal volume control but not the inspiration pressure control.

Two modes of operation shall be incorporated into the design, namely, open cycle and closed cycle. Oxygen partial pressure control shall be provided in both modes. A rechargeable chemical scrubber shall be incorporated to remove carbon dioxide from the system when operating closed cycle. An oxygen supply and rechargeable battery pack shall be designed integral with the unit to allow completely autonomous operation for edtended periods.

2.0 SYSTEM CHARACTERISTICS

2.1 Performance

The following performance characteristics are applicable to both open and closed cycle modes of operation. These requirements are to be satisfied for the environmental conditions listed in Paragraph 3.5.1.

PARAMETER	RANGE	TOLERANCE
Tidal Volume	0.2 to 1.5 liters	$\pm$10% of set point
Exhalation Time	1 to 10 sec.	$\pm$10% of set point
Inspiration Pressure Limit	10 to 90 cmH_2O	$\pm$2 cmH_2O
Minute Volume	Up to 30 LPM	
Oxygen Partial Pressure	160 to 760 mmHg	$\pm$ 5% of set point
Subpressure to Terminate Exhalation	-3 cmH_2O	$\pm$1 cmH_2O

2.2 Inventory of Expendable Items

The following expendable items shall be integrated with the respirator system in a manner which allows convenient refurbishing.

2.2.1 Oxygen supply - selection of storage cylinders is limited to those which are currently available in the Federal Stock System. The storage cylinder will contain at least 0.7 pounds of oxygen when fully charged (at 70°F) and maximum storage pressure shall not exceed 2250 psig. No provision will be made to allow charging of the storage cylinder while attached to the respirator system.

2.2.2 Scrubber - a rechargeable scrubber, using a carbon dioxide absorbing chemical, will be designed integral with the respirator system. The chemical inventory will be sufficient to remove 1.1 lbs. of carbon dioxide in continuous operation without exceeding an exit gas CO_2 concentration of 0.5%. The scrubber will be designed to satisfy these requirements using Soda Lime (Federal Stock No. 6505-153-8515) as a scrubbing agent.

2.2.3 Batteries - the internal battery pack will use rechargeable, sealed nickel-cadmium cells arranged to provide a 24 volt source. The number and size of cells will be compatible with peak current requirements and of sufficient capacity to provide 4 hours autonomous operation.

2.2.4 Filters - two bacteria filters (Bennett 3790 or equivalent) will be used in the closed loop portion of the system. One filter will be placed in the inhalation line and one in the exhalation line. These are to be located as near to the interface with the external airways as is possible to minimize the portions of the system subject to contamination.

2.3 Configuration

2.3.1 Size - the respirator system, complete with all expendable items necessary for autonomous operation, shall be packaged in a suitcase type portable carrying case. The case size shall be the minimum consistent with practical packaging and service considerations. A design goal for the overall package is 7 inches, by 18 inches by 27 inches.

2.3.2 Weight - total weight of the system shall be minimized. A target weight of 60 pounds has been set for the entire system, including carrying case and expendables.

3.0 DESIGN CONSIDERATIONS

3.1 Controls

Operation of the respirator system will be governed by the following controls. For convenience, these are grouped in two categories: primary controls which regulate the system performance and secondary controls which select operational modes and/or are used for calibration.

3.1.1 Primary Controls

a) Tidal Volume - continuously adjustable over 270° sweep (calibrated 0.2 to 1.5 liters)

b) Exhalation Time - continuously adjustable over 270° sweep (calibrated 1 to 10 seconds)

c) Oxygen Partial Pressure - continuously adjustable over 270° sweep (calibrated 160 to 760 mmHg)

d) Inspiration Pressure Limit - continuously adjustable over 270° sweep (calibrated 10 to 90 cmH_2O)

e) Inhalation Flow Rate - continuously adjustable over 90° sweep (uncalibrated).

f) Sigh Control - two position on-off switch. When engaged, the tidal volume is increased to 150% of the preset value for two consecutive breaths at 15 minute intervals. The maximum sigh volume is 1.5 liters.

g) Control/Assist Selector - two position switch with "control" and "assist" positions. In the "control" position, the signal from the low pressure override switch is interrupted so that patient cannot initiate inspiratory phase. In the "assist" position, this signal circuit is completed.

3.1.2 Secondary Controls

a) Power Selector - a 5-position switch which selects power source for operation; off, batt, 115-60~ , 115-400~ , 28 vdc.

b) Mode Selector - a 2-position control which selects either open - or closed cycle operational modes.

c) pO_2 Sensor Selector - a 3-position switch used to engage sensor calibration circuits.

d) pO_2 Sensor Gain Controls - two continuously adjustable controls for sensor calibration.

e) Oxygen Shut-off - standard high pressure shut-off valve to control flow of oxygen from internal storage cylinder.

3.2 Displays

The following displays will be provided:

a) Tidal Volume - a real-time reading of the integrated output of the exhalation flowmeter. Calibrated from 0 to 1.5 liters.

b) Oxygen Partial Pressure - a reading of the partial pressure of oxygen in the inspired gas mixture. Calibrated from 0-760 mmHg.

c) Inspiration Pressure - a reading of gage pressure in the closed loop. Calibrated in cmH_2O; 0 to 100 cmH_2O.

d) Oxygen Storage Pressure - pressure of gas in internal oxygen storage cylinder; 0-2500 psig.

e) Battery Voltage - voltage of internal battery pack; 0-30 V.

f) Elapsed Time - records total operating time and includes a resettable timer to measure duration of each use.

3.3 Alarms

The following alarms will be provided. An alarm condition will be indicated by a separate warning light for each function in addition to a common audible alarm (buzzer) which will sound for any of the alarm conditions. A delay circuit which postpones the buzzer operation for 10 seconds after the alarm condition is recognized will be incorporated.

a) Oxygen Partial Pressure - when the pO_2 in the system, as measured by the sensors, is less than the value preselected, the alarm is activated.

b) Expiratory Volume - the volume of gas exhaled by the patient into the system is measured and compared to the preset tidal volume; if less than 90% of the preset value, the alarm signal is given.

c) Battery Voltage - when voltage of the internal battery pack drops below a prescribed limit, an alarm condition will be indicated.

3.4 Electrical System

The respirator system shall be electrically powered and capable of operating with the following power inputs:

a) Self-contained battery power (nominally 24 vdc)

b) External 115 volt - 60 Hz

c) External 115 volt - 400 Hz

d) External 28 vdc

3.5 Environmental Requirements

3.5.1 Operational - the respirator must be capable of operating in the following environments:

a)	Temperature:	32°F to 120°F (note: system operation can be sustained to 0°F by selecting the open cycle operational mode which does not rely on the oxygen sensors for control of oxygen partial pressure).
b)	Humidity:	0% to 95% relative humidity including cycling over the temperature range specified above.
c)	Altitude:	Sea level to 5,000 ft.
d)	Salt:	20% by weight NaCl salt fog for 48 hrs. with an average fog mean density such that 3.0cc of condensation will collect on an 80 sq. cm surface in one hour.
e)	Vibration:	Simple harmonic vibration from 55 to 2,000 cps under constant peak acceleration of 10g.
f)	Shock:	Equivalent to a one foot free fall to a hard surface.

3.5.2 Transportation and Storage

a)	Temperature:	-65°F to 160°F with batteries and oxygen sensors removed. 0°F to 135°F with batteries and oxygen sensors installed.
b)	Humidity:	0% to 95% relative humidity including cycling over the temperature range specified above.
c)	Altitude:	Sea level (14.7 psia) to 60,000 ft. (1.7 psia)

d) Salt: 20% by weight NaCl salt fog for 48 hrs. with an average fog mean density such that 3.0cc of condensation will collect on an 80 sq. cm surface in one hour.

e) Vibration: Simple harmonic vibration from 55 to 2,000 cps under constant peak acceleration of 10g.

f) Shock: Equivalent to a one foot free fall to a hard surface.

Additionally, the electrical system shall incorporate a charging network which will allow the internal battery pack to be charged while the system is operating from any of the above specified external power sources. The system will be adequately fused, grounded and otherwise protected to ensure minimum risk of electrical shock to operator and/or patient in the event of malfunction in the electrical system.

3.6 Pneumatic Sub-System Arrangement

Several features in the design of the pneumatic sub-system are critical to the development of a safe and practical respirator system. These are as follows:

3.6.1 The system must incorporate a valve arrangement which, in the event of intentional or unintentional power interruption, vents the closed loop to the atmosphere to allow the patient to breathe freely.

3.6.2 Internal flow resistance in the closed loop must be held to a minimum. This is particularly critical in the exhalation phase where the patient provides pressure to sustain flow. Total pressure loss in this path should not exceed 3 cmH_2O at a flow rate of 60 liters/minute.

3.6.3 A quick disconnect fitting will be provided to allow operation from an external oxygen supply. This fitting will be connected to the oxygen supply line at the low pressure side of the oxygen pressure regulator where pressure has been reduced to 50 psig.

UNCLASSIFIED
Security Classification

DOCUMENT CONTROL DATA - R & D

(Security classification of title, body of abstract and indexing annotation must be entered when the overall report is classified)

1 ORIGINATING ACTIVITY (Corporate author)	2a. REPORT SECURITY CLASSIFICATION
GENERAL ELECTRIC COMPANY RE-ENTRY & ENVIRONMENTAL SYSTEMS DIVISION OCEAN SYSTEMS PROGRAMS DEPARTMENT	UNCLASSIFIED
	2b. GROUP

3 REPORT TITLE

CLOSED CYCLE RESPIRATOR DEVELOPMENT PROGRAM

4 DESCRIPTIVE NOTES (Type of report and inclusive dates)

ANNUAL REPORT - JUNE 1969-JUNE 1970

5. AUTHOR(S) (First name, middle initial, last name)

John T. Keiser

Richard Bingmann

6 REPORT DATE	7a. TOTAL NO. OF PAGES	7b. NO. OF REFS
June 24, 1970	83	none

8a. CONTRACT OR GRANT NO.	9a. ORIGINATOR'S REPORT NUMBER(S)
N00014-69-C-0329	RDP-019
b. PROJECT NO.	
c.	9b. OTHER REPORT NO(S) (Any other numbers that may be assigned this report)
d.	

10 DISTRIBUTION STATEMENT

11 SUPPLEMENTARY NOTES	12. SPONSORING MILITARY ACTIVITY
	DEPARTMENT OF THE NAVY OFFICE OF NAVAL RESEARCH

13 ABSTRACT

The General Electric Company, Re-entry and Environmental Systems Division, has developed a unique medical respirator based on the technology of closed cycle life support systems. Under contract to the Office of Naval Research (Contract N00014-69-C-0329), four prototype units were designed, fabricated and delivered to the National Naval Medical Center, Bethesda, Maryland for laboratory and clinical evaluation.

System performance requirements were selected to meet the needs of military use and the overall design was bounded by the requirement for portability and extended autonomous operation. An eleven month program starting in June, 1969, translated these requirements to prototype hardware which underwent comprehensive performance testing at the component, sub-system and system levels prior to delivery. This testing amply demonstrated the capability of the prototype systems to satisfy the performance requirements. This report summarizes the design and development efforts addressed to defining the prototype configuration and presents a complete physical description of the system. In addition, system calibration and test procedures, along with typical results, are presented.

DD FORM 1 NOV 65 1473

UNCLASSIFIED
Security Classification

14. KEY WORDS	LINK A		LINK B		LINK C	
	ROLE	WT	ROLE	WT	ROLE	WT
VOLUME CONTROLLED RESPIRATOR						
CLOSED CYCLE RESPIRATOR						
MEDICAL RESPIRATOR						