TM-65-14

THE DEVELOPMENT OF A VOLUME-CYCLED RESPIRATOR

by
James W. Joyce, Jr.

24 March 1965

U.S. ARMY MATERIEL COMMAND
HARRY DIAMOND LABORATORIES
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ABSTRACT

A volume-cycled respirator, powered and controlled by a bistable fluid amplifier, was designed and developed to satisfy a set of predetermined requirements. A working prototype was tested in the laboratory to evaluate its performance on an engineering basis. The results indicate that this device generally satisfies the requirements imposed on it. Medical evaluation of the unit will provide the final decision as to its usefulness.

1. INTRODUCTION

Respirators are devices capable of supplementing or completely assuming human respiratory functions as well as performing other related functions. These devices provide the necessary ventilation by forcing a breathing gas into the patient's lungs during the inspiratory phase. During the expiratory phase, the respirator actively or passively allows the lungs to expel the expiratory products. While there are a number of respirators currently in use that function adequately,* most of these are complex in design and construction (ref 1). Since reliability is improved, environmental ruggedness increased, and cost reduced by simplicity in design, there is an army need for a respirator of simpler design--one with fewer moving parts.

A recent study (ref 2) suggested the possibility of developing simpler and more reliable respirators through the application of fluid amplification techniques. One such device proposed in this study was a volume-cycled respirator expressly designed for Army needs. It is the purpose of the present study to develop this volume-cycled respirator using fluid amplification techniques. The results of engineering evaluation tests of the prototype are presented. Based on these results, the limitations of the device are discussed.

This volume-cycled respirator was designed and developed at the Harry Diamond Laboratories in cooperation with the Walter Reed Army Institute of Research. The work was funded by the Army Medical Corps.

2. DESCRIPTION OF THE PROBLEM

The main purpose of a respirator is to supply the right amounts of air to the patient's lungs during inspiration. Most respirators are passive during expiration; that is, they do not affect the rate

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*None totally satisfy the army's demands for respirators as related to conditions of function, transportation, and use.

at which the patient exhales. Some of these devices, however, are capable of supplying suction to aid in emptying the lungs during the expiratory phase. Respirators are generally categorized according to the manner in which they cycle. A brief description of the three basic categories follows.

The pressure-cycled respirator is so named because it terminates the inspiratory phase of the cycle when a specific pressure is reached in the patient circuit. This switching pressure can be preset to the desired value within a defined operating range. The impedance of the patient circuit affects the output of these devices; i.e., inspiratory time and inspiratory flow rate are load dependent.

Respirators that complete inspiration when a preset volume of breathing gas has been delivered to the patient circuit are volume-cycled respirators. Most of these devices are insensitive to loads presented by the patient circuit. Hence, an obstruction in the airway leading to the lung could produce excessive pressure harmful to the patient. Therefore, a pressure-sensitive safety valve is generally incorporated in the patient circuit.

The third type of respirator is the time-cycled unit in which the duration of inspiration and expiration are preset by controls. Flow rates and pressures delivered are set according to the demands of the patient circuit. Such devices may be driven either electrically or pneumatically.

Each of the three categories of respirators has a number of general advantages and disadvantages associated with it (ref 1). Most of the respirators in each category, however, have the common disadvantage of relatively complex design. In order to perform a variety of functions, they have a large number of moving parts, which degrade their reliability.

One possible solution to reducing the number of moving parts is through the application of fluid amplification techniques (ref 2). In general, the function of a fluid amplifier is one of controlling high-energy fluid jet streams with low-energy streams. The basic pneumatic circuit for the proposed volume-cycled respirator, powered and controlled by a bistable fluid amplifier with memory, is shown schematically in figure 1 (ref 2). The fluid amplifier causes the piston to move up and down. The rubber bellows, attached to the piston, forces air into the patient circuit on the upstroke and refills with fresh air on the downstroke. The inspiratory time can be varied by changing the input pressure to the amplifier. Expiratory time is controlled by limiting the rate at which air enters to refill the bellows. The volume of air delivered to the patient circuit depends upon the stroke of the piston. A breathing valve in the patient circuit allows the patient to exhale to the surroundings, and at the same time, precludes the return of exhaled air to the bellows.

During inspiration, this same valve insures that air going to the patient does not leak to the surroundings.

The components that directly affect system performance are the fluid amplifier, the piston, the bellows, the expiratory control, the feedback controls, and the breathing valve. These components must be properly selected and matched to enable the device to operate satisfactorily.

3. REQUIREMENTS

Before the components of the volume-cycled respirator can be selected, it is necessary to define certain requirements that the device must meet. Such a set of requirements has been generated (ref 2) with emphasis on the demands of military medicine. These requirements can be divided into two types--functional and packaging.

The functional requirements, obtained in a joint effort of engineers and medical doctors, were established on the premise that the respirator will be used primarily on adult patients. These requirements are as follows (ref 2):

(1) The respirator should be able to control or assist the ventilation of a patient. When operating in the assist mode, the change from expiration to inspiration shall be triggered by the inspiratory effort of the patient. The inspiration trigger circuit should be sensitive to relatively weak inspiratory attempts by the patient (approximately 2 cm H_2O of negative pressure).

(2) The respirator should be capable of delivering tidal volumes ranging from 300 to 1000 cc, regardless of the loads encountered in the patient circuit.

(3) The minute volume delivered by the respirator should be variable between 5 and 15 L/min.

(4) When operating in the control mode, the respirator should be able to cycle between 6 and 40 times a minute to achieve adequate minute volumes. Requirements 2 through 4 can be related graphically as shown in figure 2.

(5) To achieve adequate control of ventilation, inspiratory times should range from 0.4 to 1.3 sec.

(6) Expiratory times for the respirator must be compatible with inspiratory time and cycling rate limits as stated above.

(7) The maximum positive pressure built up in the patient circuit during inspiration should never exceed 50 cm H_2O.

(8) The proposed respirator will, because of its method of operation, be load dependent, as this is an inherent property of such pneumatically operated devices. It is therefore necessary to describe the pulmonary loads presented to the device and to assign values to the extremes that can be anticipated. The pulmonary load presented to the respirator may be considered as being composed of lung compliance and airway resistance. Inertance is considered negligible. The extremes of compliances anticipated are 0.010 and 0.250 L/cm H_2O. Airway resistance has a normal value of 2.5 cm H_2O/L/sec and ranges from 0.5 to 20 cm H_2O/L/sec. All resistances are calibrated at a flow rate of 0.5 L/sec (ref 2).

Finally, there are requirements imposed on the packaging of the respirator. These include the following (ref 2):

(1) Operation of the respirator should be simple enough to enable its use by individuals with a minimum of training. Little or no interdependence of control functions is desirable.

(2) The respirator should be constructed so that parts that might become contaminated can be easily cleaned and/or sterilized. In normal use, only the face mask, breathing valve, and connecting tubing would be sterilized.

(3) The respirator should be capable of operating continuously for three months with as little maintenance as possible.

(4) The respirator should be operable using either contaminated or uncontaminated gases as the power source. Driving pressures below 50 psig combined with low flow rates are preferable so that the device can be operated using customary compressors or bottled compressed gas as the power source.

(5) In general, the respirator should be small, lightweight, portable, and rugged. The respirator should be able to withstand the environmental conditions imposed on it by military applications.

4. DESIGN OF THE BASIC RESPIRATOR

Based on the requirements set forth in section 3, the components of the system can now be selected. The first item to be considered is the rubber bellows since its volume capacity must be sufficient to enable it to meet the requirements for tidal volumes. In addition, it must be sturdy enough not to collapse when the pressure inside drops slightly below atmospheric. The need for this feature will become apparent later.

The commercial bellows chosen has a total capacity of 2400 cc, an outside diameter of 7 in. and an inside diameter of 5-7/8 in. at

the bottom. This latter dimension determines the downward force exerted by the pressure developed inside the bellows and will be a factor in choosing the piston. When incorporated in the respirator, its capacity is about 1800 cc. The construction of this bellows is rigid enough to prevent collapsing for the range of negative bellows pressures anticipated.

The next component to be considered is the piston to drive the bellows. To minimize the power necessary to operate the device, the internal resistance of the respirator must be kept as low as possible. To accomplish this, the weight of the piston and the bearing friction between piston and cylinder must be minimized. In addition, the diameter of the piston must be carefully selected to match the maximum anticipated loads on the basis of known available pressures recovered from the fluid amplifier. The length of the piston is not critical except that it must be greater than the maximum stroke needed to deliver 1000 cc to the patient circuit. The piston selected to meet these requirements is $4\frac{1}{2}$ in. long, has a $2\frac{1}{4}$ in. diameter, and is made of Delrin* AF (acetal-fluorocarbon), a plastic material with self-lubricating properties.

A 3-in. piston stroke was determined experimentally to be capable of producing tidal volumes slightly in excess of 1000 cc with the selected bellows. The piston length $4\frac{1}{2}$ in. was chosen on the basis that the extra $1\frac{1}{2}$ in. would be sufficient to aid in guiding the motion of the piston. The $2\frac{1}{4}$-in. piston diameter was finally chosen on the basis of the maximum pressures anticipated in the bellows, the inside diameter at the bottom of the bellows, and the available driving pressures and flows. (A detailed explanation of this selection is given in appendix A.) Delrin AF was selected for its low weight (specific gravity of 1.59), low moisture absorption (0.6 percent by weight for total immersion in water), and low coefficient of static and dynamic friction (as low as 0.02).** To reduce bearing friction further, a clearance of 0.002 in. on the diameter between the piston and cylinder was specified.

Once the bellows and piston have been designated, the next item to be considered is the fluid amplifier. Fluid amplification is a relatively new concept, and as a result, its application to particular use is still more an art than a science. Sufficient mathematical description does not exist to calculate the amplifier's performance in detail. Therefore, the selection of a bistable amplifier

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*duPont trademark

**Values obtained from manufacturer

configuration to be used for the respirator was based on the author's own experience with such units. A schematic of the configuration chosen is shown in figure 3. The location of the splitter insures that the unit will possess good memory characteristics. The optimum operating range for the configuration selected is for input air pressures up to approximately 30 psig, a figure well within the specified power requirements. Further it is known that about 30 percent of the input pressure can be recovered in a receiver.

With the basic geometry thus fixed, the amplifier output can be altered to obtain the desired performance by varying the depth of the channels. In effect, changing the channel depth changes the power nozzle area, and hence affects the air flows both into and out of the amplifier, while the static pressure recovery, which depends primarily on splitter location, will remain virtually unchanged. Final choice of channel depth is based on the amplifier's ability to power the piston upstroke at speeds compatible with the inspiratory time requirements. A channel depth of 0.034 in. was determined experimentally to provide the best respirator performance. The actual performance data are presented graphically in section 5.

Still to be discussed are the controls for varying expiratory time and tidal volume. As mentioned previously, inspiratory time for any given loading of the respirator is controlled by the input pressure to the amplifier.

Expiratory time depends on two factors, assuming that all other parameters are held constant. The first factor is the loading of the right output receiver of the amplifier. If this receiver is properly loaded, the exhausting air (when the power jet is locked in the right side) helps the descent of the piston by entraining air out of the cylinder at a rate sufficient to maintain ambient or slightly negative pressure in the cylinder. For simplicity, this loading was achieved in the form of a fixed bleed, which was designed to minimize the noise produced by the exhausting air.

The second factor in determining expiratory time is the rate at which air is allowed to enter to refill the bellows. If this rate is limited, the pressure in the bellows drops below atmospheric, and the bellows is slowed up by the drag produced by this negative pressure. The more limited the rate of entering air, the greater the suction inside the bellows and the slower the descent. To control this, the simple device shown in figure 4 was designed to vary the expiratory time of the respirator. The rubber flapper prevents leakage of air out through the control during the inspiratory phase.

To control tidal volume, the stroke of the piston must be effectively limited. To accomplish this task, two excursion triggers were devised. The lower trigger (fig. 5a), when struck by the

bellows at the bottom of the stroke, opens the right control of the amplifier to atmosphere. The right control is now able to entrain sufficient flow to switch the power jet from the right receiver to the left receiver, where it pushes the piston upward. As the piston is driven upward, the bellows compresses until an arm, attached to the bottom of the bellows, strikes the knob on the upper excursion trigger (fig. 5b). This action pulls the trigger rod up, and the left control of the amplifier is opened to receive the positive feedback flow provided by the pressure in the cylinder. This feedback flow switches the jet back to the right receiver, and a new cycle begins. The knob on this trigger, which is adjustable, permits varying the stroke of the piston, and hence the tidal volume.

Finally, there is one more component which will have a marked effect on respirator performance. This item is the breathing valve. The specific functions of the breathing valve have already been described. To achieve these functions, the breathing valve* shown schematically in figure 6 was selected for use with the respirator.

A schematic diagram of the assembly of all components of the basic respirator is shown in figure 7. The fluid amplifier is mounted on the cylinder block, and the amplifier cover plate (which must be employed to seal the channels of the amplifier) contains the fixed bleed for the right receiver of the amplifier. The bleed consists of thirteen 0.039-in.-diameter holes. The two excursion triggers and expiratory control are positioned as illustrated.

5. ENGINEERING EVALUATION OF THE BASIC RESPIRATOR

The basic respirator design has been established by the selection of the various components described in section 4. At this point, an engineering evaluation of the respirator will best describe its operation. Of primary interest are the output capabilities of the respirator. Since output performance depends on the load, the device was tested under the following load conditions:

(1) High compliance, high resistance

(2) High compliance, no resistance

(3) Low compliance, high resistance

(4) Low compliance, no resistance

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*Fink modified Stephen-Slater Non-Rebreathing Valve, a product of Ohio Chemical & Surgical Equipment Co., Madison, Wisconsin.

To simulate compliance, tanks of known volumes were used. The particular tanks used represented compliances of 0.230 L/cm H_2O and 0.011 L/cm H_2O, which closely approximate the maximum and minimum compliances set forth in the requirements. The relationship between tank capacity and compliance is developed in appendix B.

To simulate maximum airway resistance, a perforated disk with a flow resistance of 20 cm H_2O/L/sec (calibrated at a flow of 0.5 L/sec as specified in the requirements) was inserted in the tubing connecting the breathing valve and the tank. The minimum resistance as stated in the requirements is so small that it was assumed to be negligible.

The tidal volumes to be delivered by the respirator were calibrated by operating the unit into a 34-L tank (0.033 L/cm H_2O compliance) with no airway resistance. The pressures developed in the tank were used to determine the volume of air delivered to it by the respirator. For a given piston stroke, this volume varies somewhat with input pressure to the amplifier and setting of the expiratory control (for reasons to be explained later). Therefore, for each tidal volume (in 100-cc intervals) the maximum and minimum strokes were determined and the average of these was then used for calibration purposes. These calibrated tidal volumes were used throughout subsequent tests.

In performing the evaluation tests, traces of pressures developed in the tanks and sensed by appropriate transducers were obtained from a pen recorder. From these traces, inspiratory time, cycling rate, and maximum tank pressure developed were determined for various combinations of input pressure to the fluid amplifier, tidal volume, and expiratory control setting. A typical pressure trace is shown in figure 8.

Figures 9 through 12 show that for the extremes of loading conditions, the inspiratory times fall within the limits set forth in the requirements. The maximum amplifier input pressure used was 30 psig (the upper limit of the optimum amplifier operating range), although in some cases, the lower limit of 0.4 sec inspiratory time was achieved at a considerably lower pressure, especially for the smaller tidal volumes. The maximum times were obtained at the minimum input pressure necessary to operate the device for the particular load conditions.

The cycling capabilities of the respirator are shown in figures 13 through 16. The maximum cycling rates are associated with 30-psig input pressure or the minimum inspiratory time of 0.4 sec, whichever occurs first. Minimum cycling rates are associated with the lowest input pressure necessary to operate the respirator. For the small compliance, with and without resistance, and the large compliance

with no resistance, the range of respirator cycling rates appears adequate. The combination of high compliance and maximum resistance, however, imposes severe limitations on cycling rates (fig. 13). The limitations are imposed by the time required for the pressure developed in the tank during inspiration to return to atmospheric during expiration and are not due to inadequacies of the respirator. The expiratory time of the respirator should always be equal to or greater than the time required for the lung (tank) pressure to reach atmospheric. Because of the large compliance, the pressures developed in the tank are quite low (less than 10 cm H_2O), and the high resistance impedes the exhaust to atmosphere, thus causing abnormally long expiratory times. Therefore, the narrow range of possible cycling rates is not the result of inadequate respirator capability, but rather a limit imposed by the very nature of the loading (the condition of the patient).

In describing the calibration of respirator tidal volumes, mention was made that an exact calibration was not possible. One reason for variation is the suction produced in the bellows during expiration, the magnitude of which is a function of input pressure and expiratory control setting (fig. 17). The reduced pressure persists in the bellows until inspiration is initiated. Thus the initial pressure at the beginning of inspiration is in fact not atmospheric, but some value slightly below atmospheric. The result is a loss of tidal volume, since in effect the first portion of the stroke is one of compressing the air in the bellows until atmospheric conditions are achieved.

Another cause of tidal volume discrepancy is the performance of the breathing valve. At lower input pressures (longer inspiratory times) the response time of the diaphragm in sealing the expiratory port is slower than at higher pressures. This delay results in air leaking out through the breathing valve at the start of inspiration. The tendency for air to escape through the breathing valve is increased as pressures developed in the tank are increased.

One more source of error concerning tidal volumes is the dead space in the respirator itself. The initial volume of the respirator, including connecting tubing, is approximately 2 L. If the bellows is compressed by 500 cc, there still remains 1500 cc of dead space, which effectively adds to the compliance of the system. The effect of respirator volume is greatest for small compliance and high resistance. It also increases as tidal volume decreases. For the minimum compliance (11-L tank), the error in tidal volume caused by the added compliance of the respirator is between 9 and 13 percent. For the 34-L tank (used for calibration), the error is only about 3 percent, and for the high compliance, the error is negligible.

The various causes for loss of tidal volume suggest that the greatest discrepancy between calibrated tidal volume and actual volume delivered to the tank will occur for the small compliance. Figure 18 substantiates that the losses are indeed very great for the small compliance, inasmuch as the pressure is a direct indication of volume delivered to the tank. For the large compliance, figure 19 shows that although variations in delivered tidal volumes are evident, the average values would be much closer to the calibrated volumes than for the small compliance.

In addition to the respirator output performance, the characteristics of the fluid amplifier are essential in an evaluation of the system. In describing a bistable fluid amplifier, the most common curves presented are the load curves (ref 3), which describe how the pressure varies with the flow at the output. For the respirator amplifier, these are shown in figure 20. Also of interest is the power required to drive the amplifier. The input air flows as a function of input pressure to the amplifier used for the respirator are presented in figure 21. The maximum air flow of 0.9 scfm* is judged to be in accord with low power requirements.

6. ADDITIONAL COMPONENTS

In an effort to satisfy several of the requirements not considered in the basic respirator design, two additions to the respirator, an inspiration trigger and a safety valve, were necessary. The purpose of the first is to enable the respirator to switch from the expiratory to the inspiratory phase of the cycle when the patient makes an inspiratory effort. The safety valve will prevent the pressure in the patient circuit from exceeding 50 cm H_2O.

In the basic respirator, switching from expiration to inspiration is accomplished by the bellows striking the lower excursion trigger, thus opening the right control of the amplifier to the atmosphere. It is therefore possible to enable this switching to be patient initiated by incorporating a pressure-sensitive trigger in parallel with the lower excursion trigger. The patient effort will be manifested in the form of a slightly negative pressure, and the requirements dictate that the triggering device be sensitive to weak signals.

The simple piston arrangement shown schematically in figure 22 was designed to satisfy this need. Negative pressure exerted by the patient lifts the piston, thereby exposing the right control of the amplifier to atmospheric pressure. The small area in contact with the amplifier control minimizes the effects of fluctuating pressures within the control line. The pressure in this line is negative during the expiratory phase, but the actual magnitude of suction depends

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* Standard cubic feet per minute

on input pressure to the amplifier and, to some extent, on the setting of the expiratory control. The large ratio of area in contact with the patient circuit to area in contact with the amplifier control enables the trigger to be activated by weak respiratory attempts on the part of the patient regardless of the magnitude of suction in the control line of the amplifier. The sensitivity is also enhanced by the light weight of the piston.

The inspiration trigger was connected to the basic respirator and tested to determine its sensitivity. The tests showed that the trigger could be successfully activated by 2 cm H_2O of negative pressure for all operating conditions. If, however, the setting of the expiratory control was such that more than the five small holes were open (fig. 4), the amplifier was not able to switch on flow entrained from the atmosphere. For such settings of the expiratory control, then, the respirator cannot be inspiration controlled.

The inability of the amplifier to switch under these conditions can be explained by referring to figure 23 (ref 3). When five or less small holes are open in the expiratory control, the descent of the piston is impeded to the extent that the pressure in the cylinder drops below atmospheric due to entrainment. Under these conditions the switching point is between points A and B. If the expiratory control is now opened further, the piston descent increases sufficiently to prevent the cylinder pressure from becoming less than atmospheric. In the extreme case, the weight of the piston may even allow it to descend rapidly enough to maintain a slightly positive pressure in the cylinder. For the case of atmospheric or slightly positive pressure in the cylinder, the switching point is moved to the right of point B; i.e., the pressure needed to switch the amplifier is greater than atmospheric. Therefore, the inspiration trigger, when opened, cannot interrupt the expiratory time of the respirator under these conditions.

The addition of the safety valve to the basic mechanism is to prevent more than 50 cm H_2O from developing in the patient circuit during inspiration. Two general approaches were considered. One was to use a simple relief valve, which would be set for an opening pressure of 50 cm H_2O so that excess air would be bled off. The other approach was to modify the relief valve concept so that when the valve opened, the air escaping would switch the amplifier, thus terminating the inspiratory phase of the cycle. The latter method was considered superior because it results in a lower mean lung pressure than the first method.

The safety valve thus designed is very similar to the inspiration trigger and is shown schematically in figure 24. As in the case of the inspiration trigger, the piston area in contact with the patient circuit was purposely made much larger than the area in contact with the amplifier to reduce the effects of the pressure signals in that leg of the amplifier. The spring holds the piston in place

until 50 cm H_2O develops in the patient circuit. This pressure produces sufficient force to overcome the spring force. As the piston is moved, the positive pressure is transmitted to the left control of the amplifier, thus switching the amplifier. In effect, then, the safety valve allows the respirator to pressure cycle, rather than volume cycle, whenever pressures in the patient circuit reach 50 cm H_2O.

Once the proper spring was selected, the safety valve described was connected to the basic respirator and permitted to operate continuously for periods up to ten days. During these periods, observations were made of the patient circuit pressures for which the valve was opening. The opening pressures observed varied between 49 and 52 cm H_2O over a total time of 640 hr. During this time, all other parameters were held constant.

7. DISCUSSION

The volume-cycled respirator developed has generally satisfied the functional requirements established for it. It is capable of operating against the extremes of loading conditions mentioned, although increased losses in tidal volumes delivered were observed for the small compliance. Fortunately, this extremely small compliance would not be encountered frequently in actual applications of the respirator. For more normal compliances, these losses are not so great. The only real weakness is the extent of interdependence of controls. As explained in section 6, the effects of the expiratory control on tidal volume and on the functioning of the inspiration trigger are the most noticeable examples of this interdependence.

In an effort to satisfy the remaining requirements, the respirator was packaged as shown in figure 25. The inspiration trigger and safety valve are incorporated in the aluminum base block, and the fluid amplifier is mounted on the front of the block as shown. The plastic dome serves as both support and protection for the rubber bellows. A pressure regulator is mounted in the right side of the block to control the input pressure to the amplifier. In addition, a relief valve in the input line is set to open when the input pressure exceeds 30 psig.

In its present form, the device satisfies most of the packaging requirements. The noise produced by the respirator is audible, but not objectionable. The prototype has operated in the laboratory for 30 days without malfunctioning. The more general requirements for size, weight, and ruggedness appear to be adequately satisfied. The respirator is now ready to undergo medical evaluations.

8. SUMMARY AND RECOMMENDATIONS

The first engineered prototype of a volume-cycled respirator has been developed and tested in the laboratory. The unit has

successfully met most of the requirements established for it from an engineering point of view. The next step will be to have this device medically evaluated. The acceptance of the respirator as a medical device will be determined by the results of the medical evaluations. These results could conceivably necessitate a number of modifications to the present model.

Based on the problems encountered in the development of this volume-cycled respirator, the following recommendations are made:

(1) There appears to be a need for more specific and also more extensive requirements. In the present requirements, the parameters involved need to be correlated in some fashion where possible. For example, the specified inspiratory times are 0.4 to 1.3 sec. No mention is made as to whether the two extremes must be met under all conditions of loading, etc, or whether the longer times should be associated with the larger tidal volumes. More extensive requirements have already been formulated by the medical team at WRAIR following their preliminary evaluation of the respirator. These additional requirements are as follows:

(a) The respirator should be capable of being pressure cycled as well as volume cycled, especially when used in the assist mode.

(b) The respirator should have a tidal volume capacity of 2500 cc.

(c) The respirator should be able to assist a panting patient; i.e., it should be able to operate at cycling rates of 50 to 60 cpm in the assist mode.

(d) Provision should be made for the administration of pure oxygen to the patient. It presently administers only room air.

(e) A gas canister should be added to filter contaminated air.

(f) A humidifier is needed for the breathing gas being administered to the patient.

(2) In an effort to eliminate problems connected with the present expiratory control design, it is recommended that a variable time delay circuit, preferably pneumatic, be considered as a replacement for the lower excursion trigger presently used. With such a circuit the bellows could be returned to the starting position as quickly as possible, and the setting of the time delay would control the expiratory duration. In this manner, the problem of variable suction in the bellows is eliminated, and the variations between calibrated and delivered tidal volumes are thereby reduced. In addition, once the bellows has returned to the starting position, the

amplifier can be switched back into the cylinder by flow from the atmosphere. Therefore, the inspiration trigger would not be restricted as it presently is.

(3) The material used in the plastic dome presently in use is polystyrene. This material is not rugged enough to be compatible with the requirements. It is therefore recommended that a more rugged plastic (such as Lexan*, a polycarbonate resin) or metal be used in constructing the dome.

Further medical evaluation of the present device may substantiate the need for accepting some or all of these recommendations. A second prototype will be designed and built to incorporate the additional requirements and other changes suggested. As the need for further changes becomes apparent, the prototype will be modified to reflect these changes.

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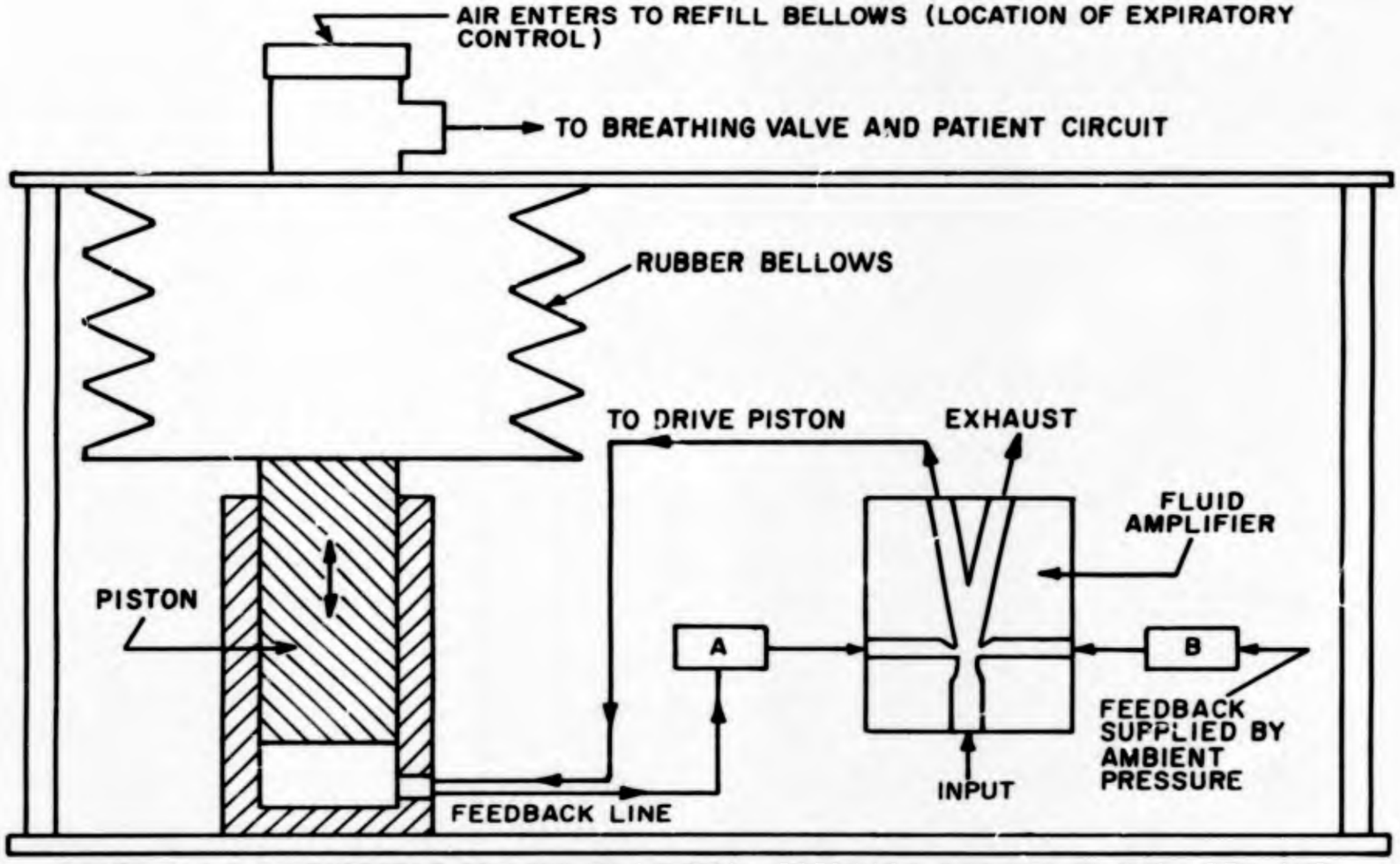
*A General Electric trademark



BOXES A AND B REPRESENT DEVICES TO CONTROL FEEDBACK SIGNALS TO THE LEFT AND RIGHT CONTROL PORTS OF THE FLUID AMPLIFIER

Fig. 1. SCHEMATIC OF PNEUMATIC CIRCUIT FOR PROPOSED VOLUME-CYCLED RESPIRATOR

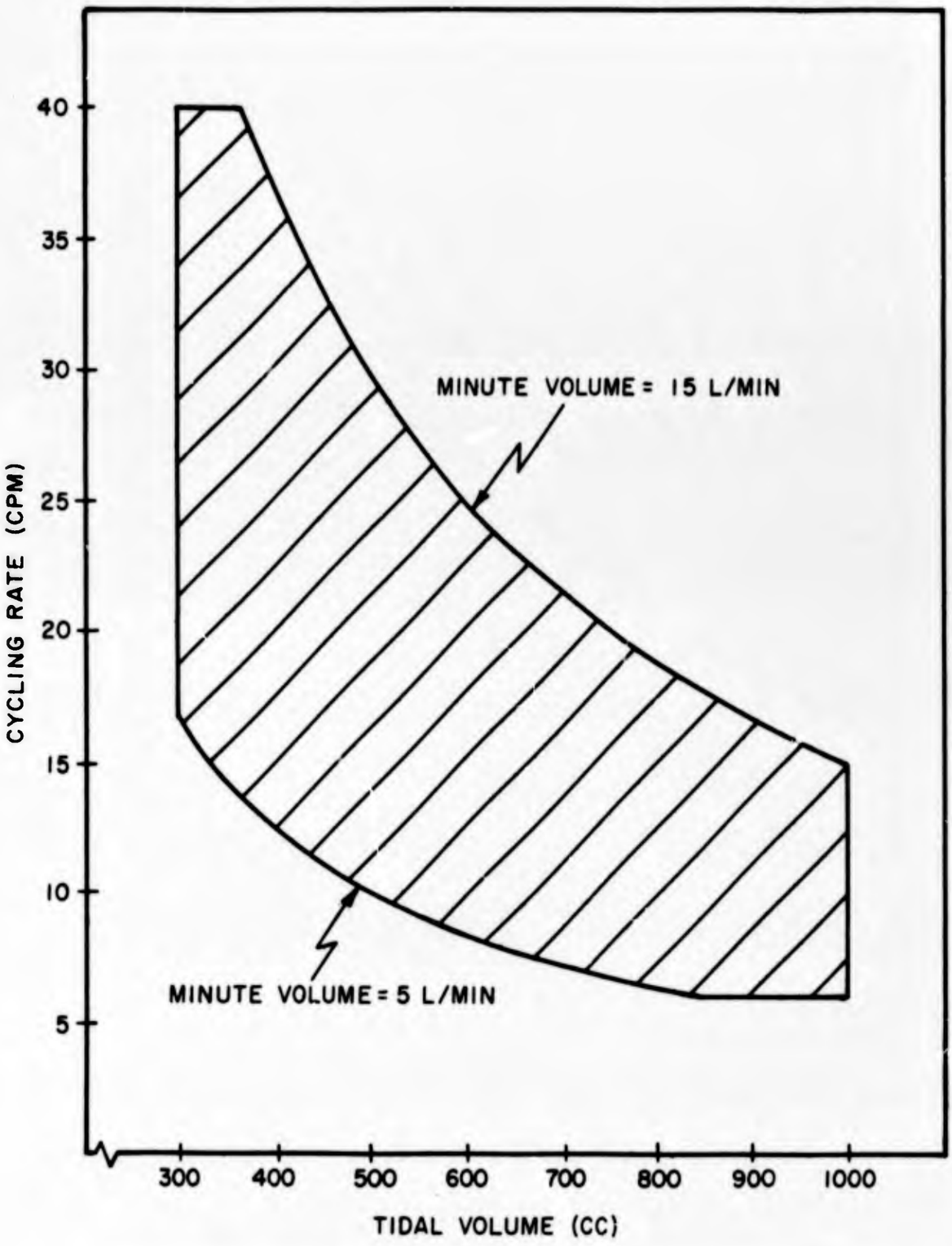


Fig. 2. REQUIREMENTS FOR CYCLING RATES AS A FUNCTION OF TIDAL VOLUME

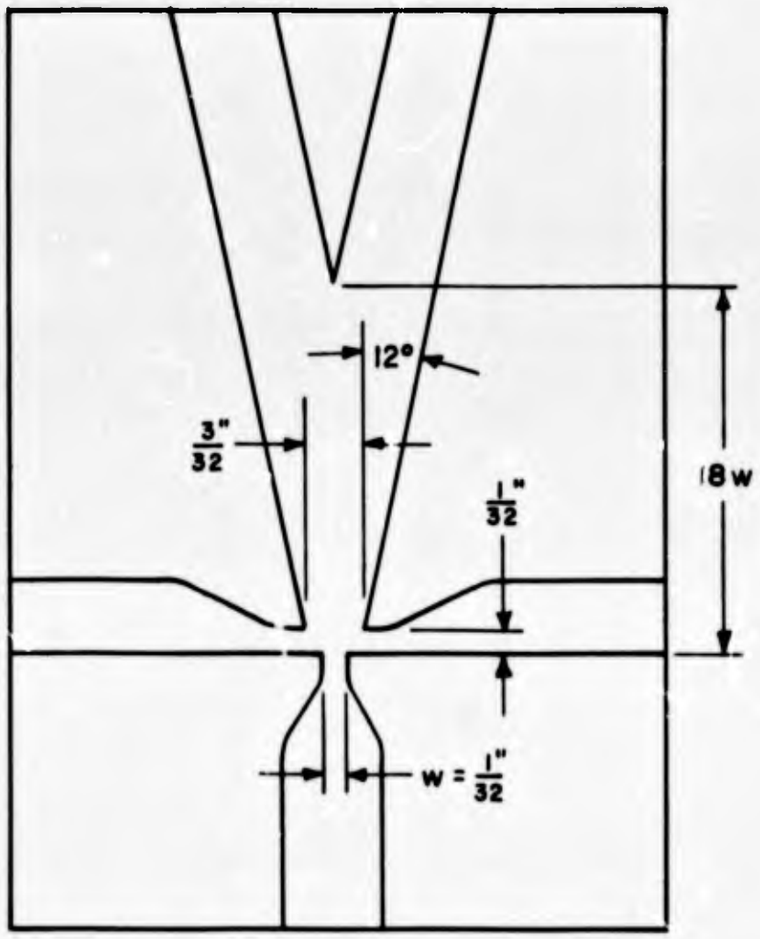


Fig. 3. SCHEMATIC OF BISTABLE AMPLIFIER CONFIGURATION FOR RESPIRATOR

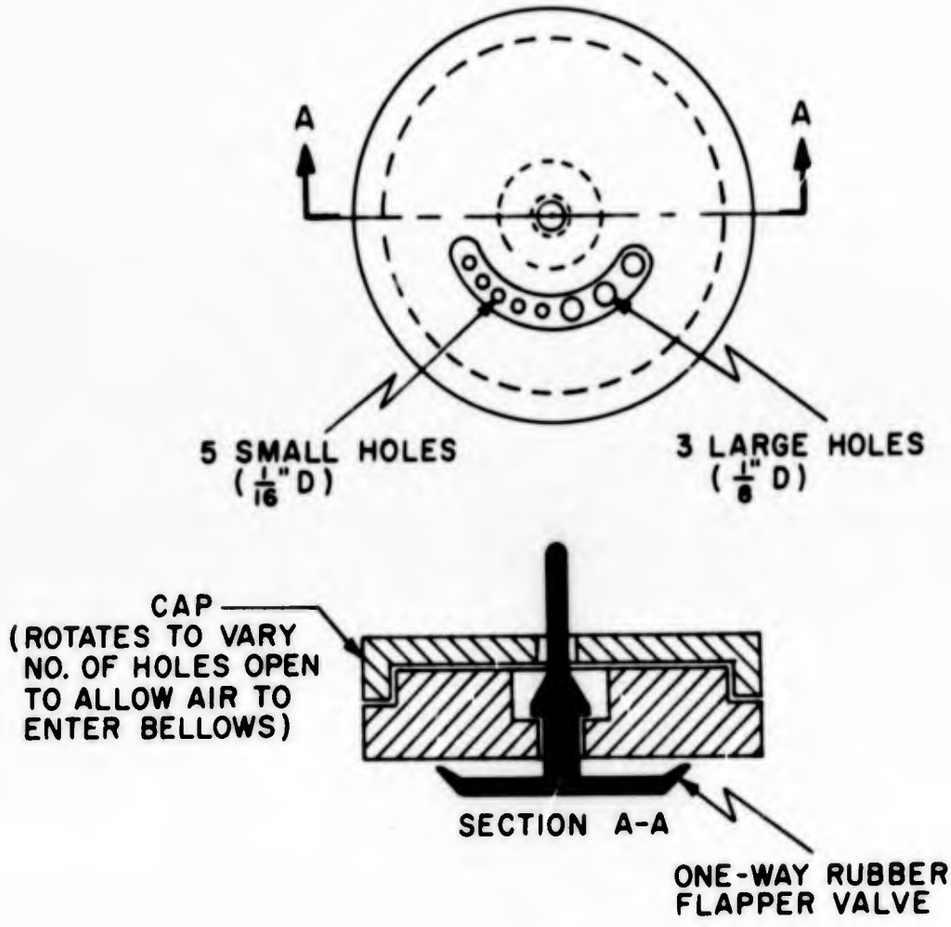
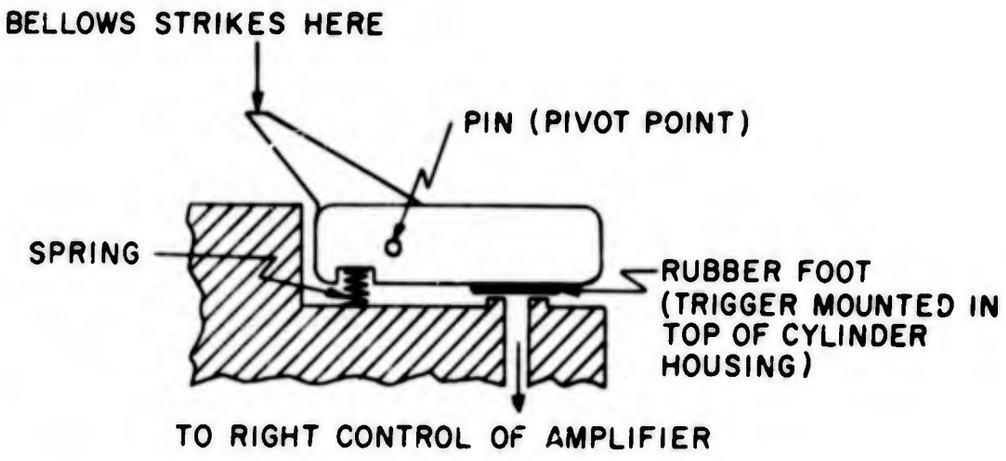
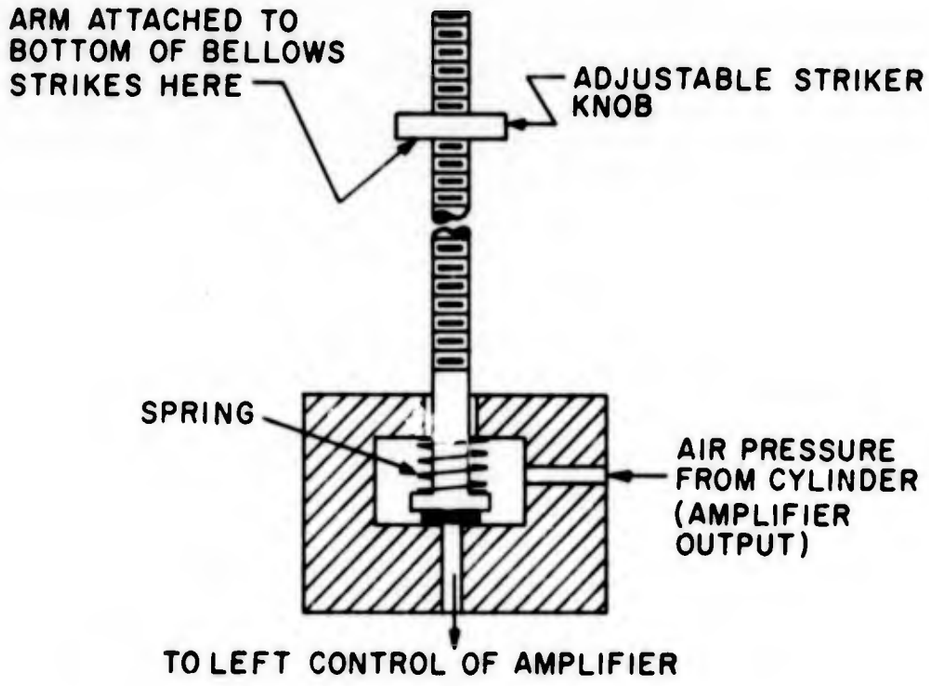


Fig. 4. EXPIRATORY CONTROL



a. LOWER EXCURSION TRIGGER



b. UPPER EXCURSION TRIGGER

Fig. 5. SCHEMATIC OF EXCURSION TRIGGERS

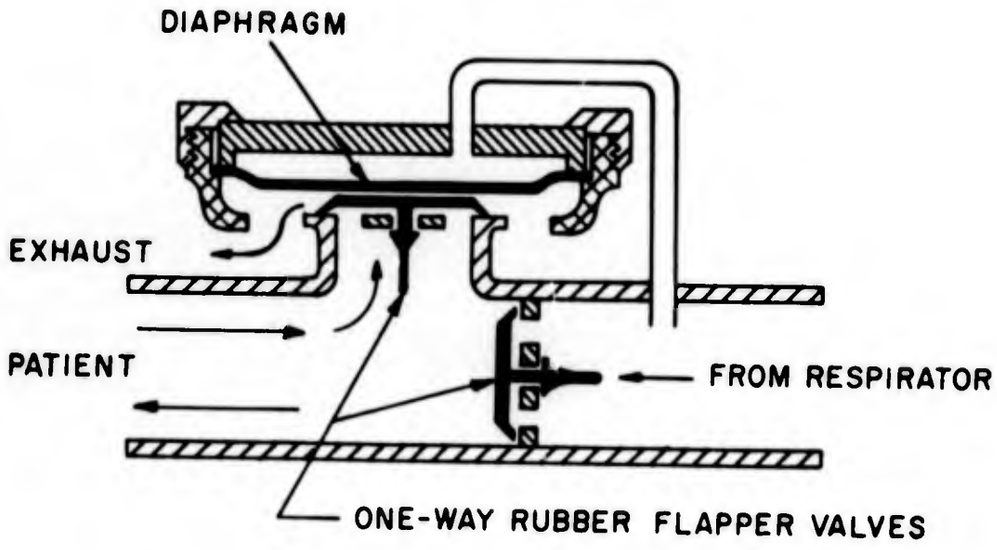


Fig. 6. SCHEMATIC OF RESPIRATOR BREATHING VALVE

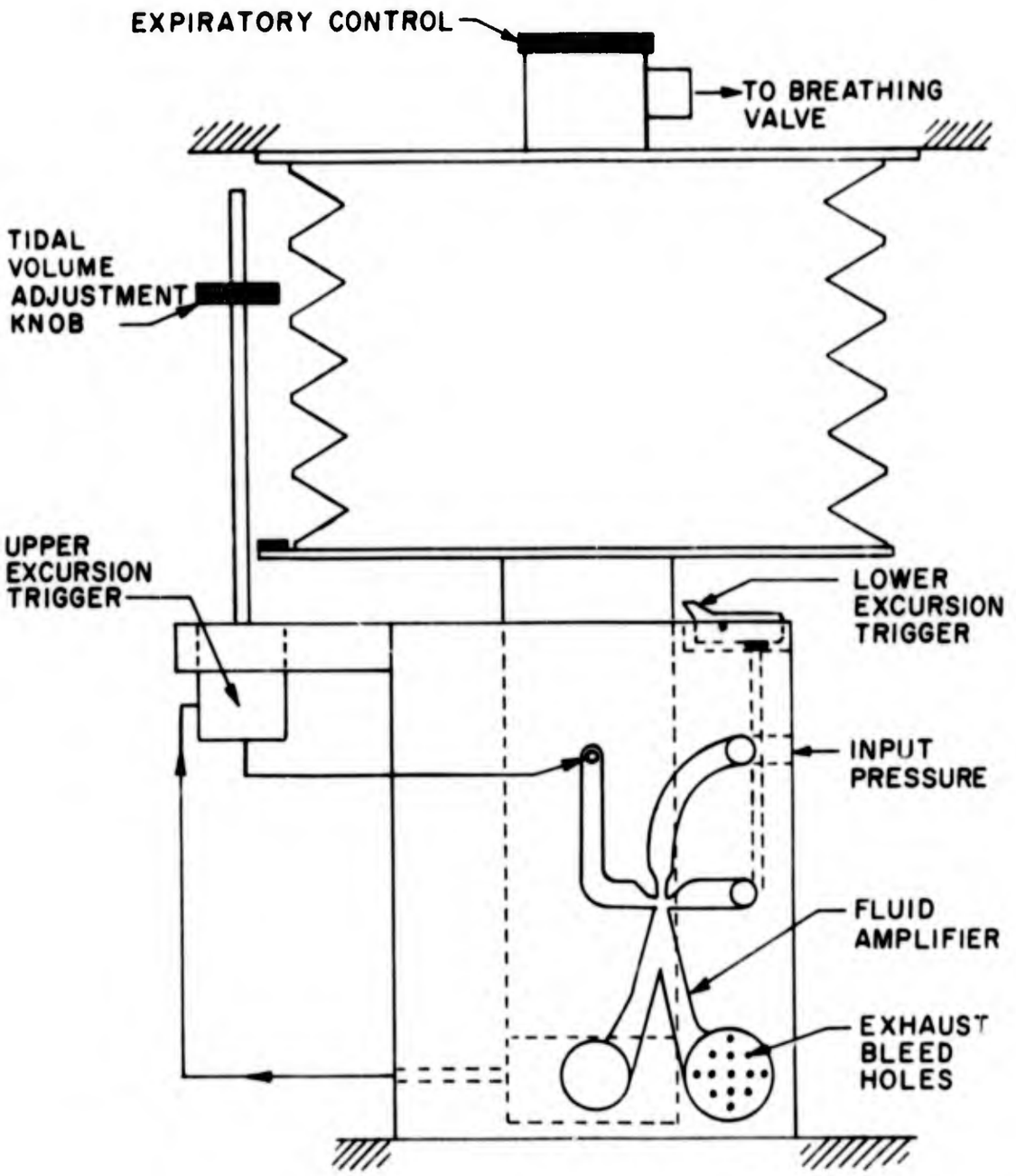
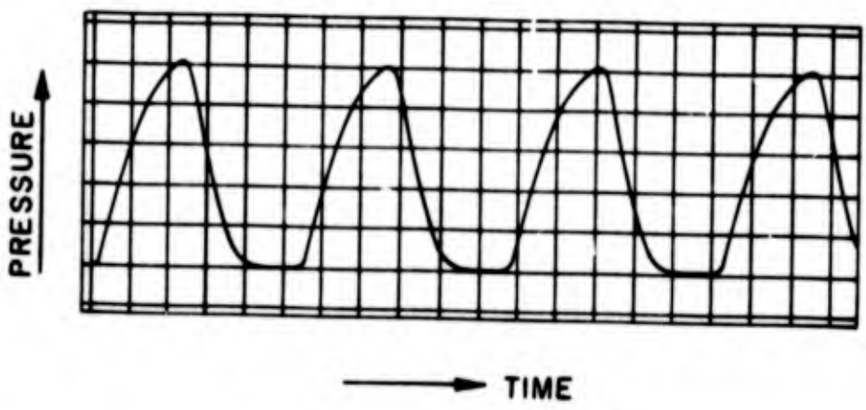


Fig. 7. SCHEMATIC OF ASSEMBLY OF COMPONENTS OF BASIC MECHANISM



COMPLIANCE = 0.011 L/cm H_2O

RESISTANCE = 20 cm H_2O/L/sec

INPUT PRESSURE TO AMPLIFIER = 30 psig

PAPER RATE = 10 DIVISIONS/sec

ORDINATE SCALE: 10 DIVISIONS = 20 cm H_2O

Fig. 8. TYPICAL PRESSURE TRACE PRODUCED BY RESPIRATOR

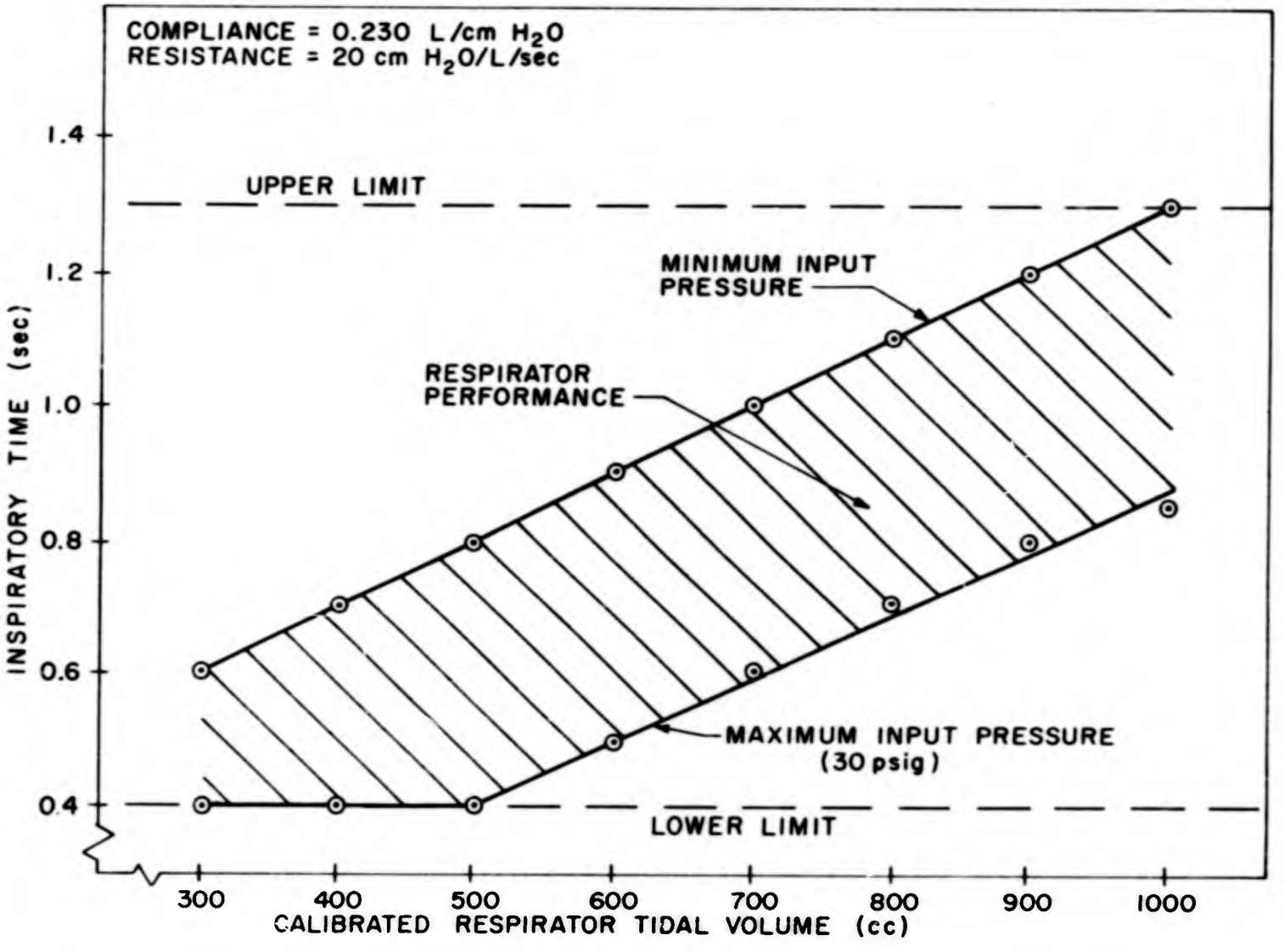


Fig. 9. INSPIRATORY TIMES-HIGH COMPLIANCE, HIGH RESISTANCE

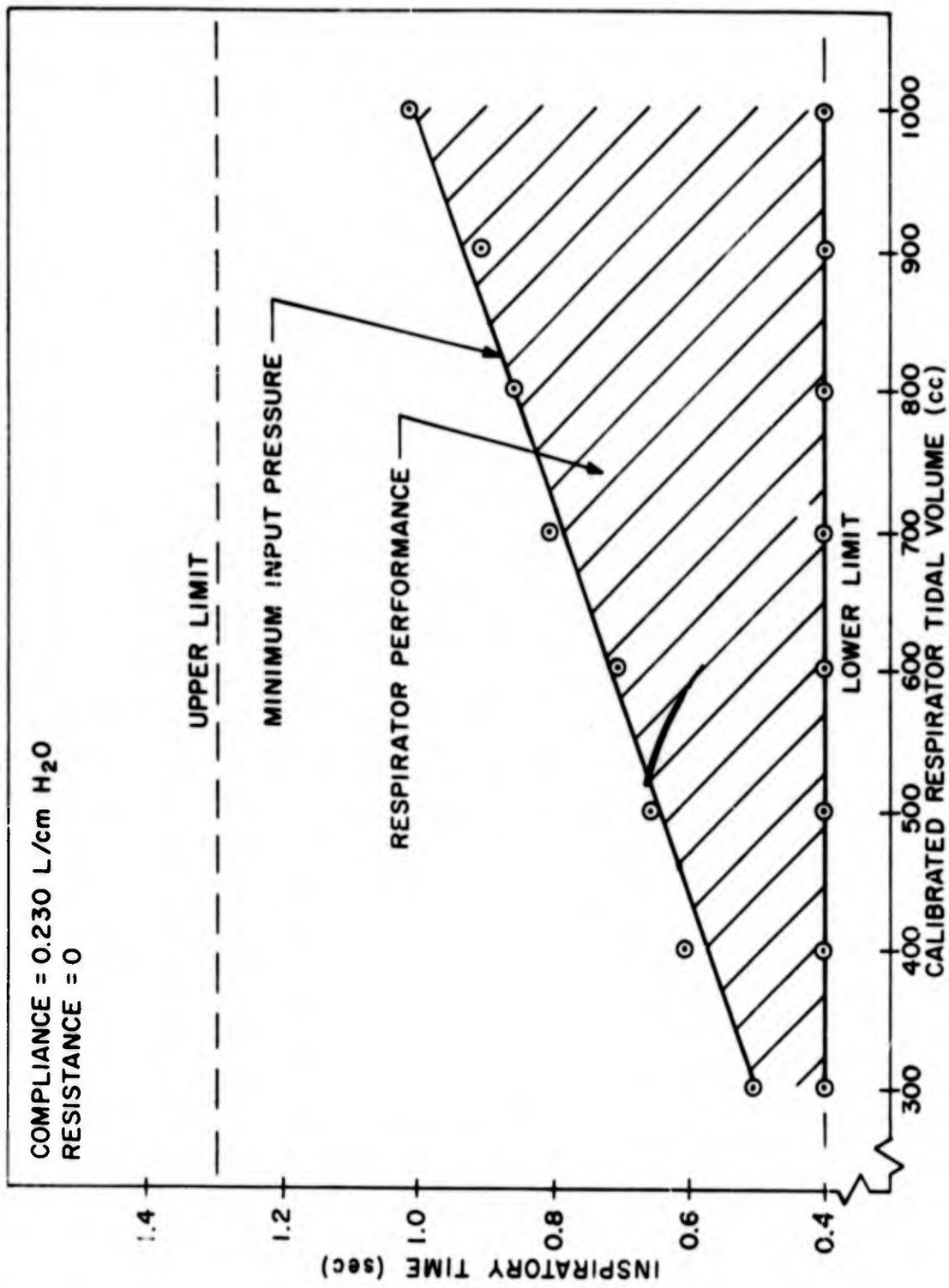


Fig. 10. INSPIRATORY TIMES–HIGH COMPLIANCE, NO RESISTANCE

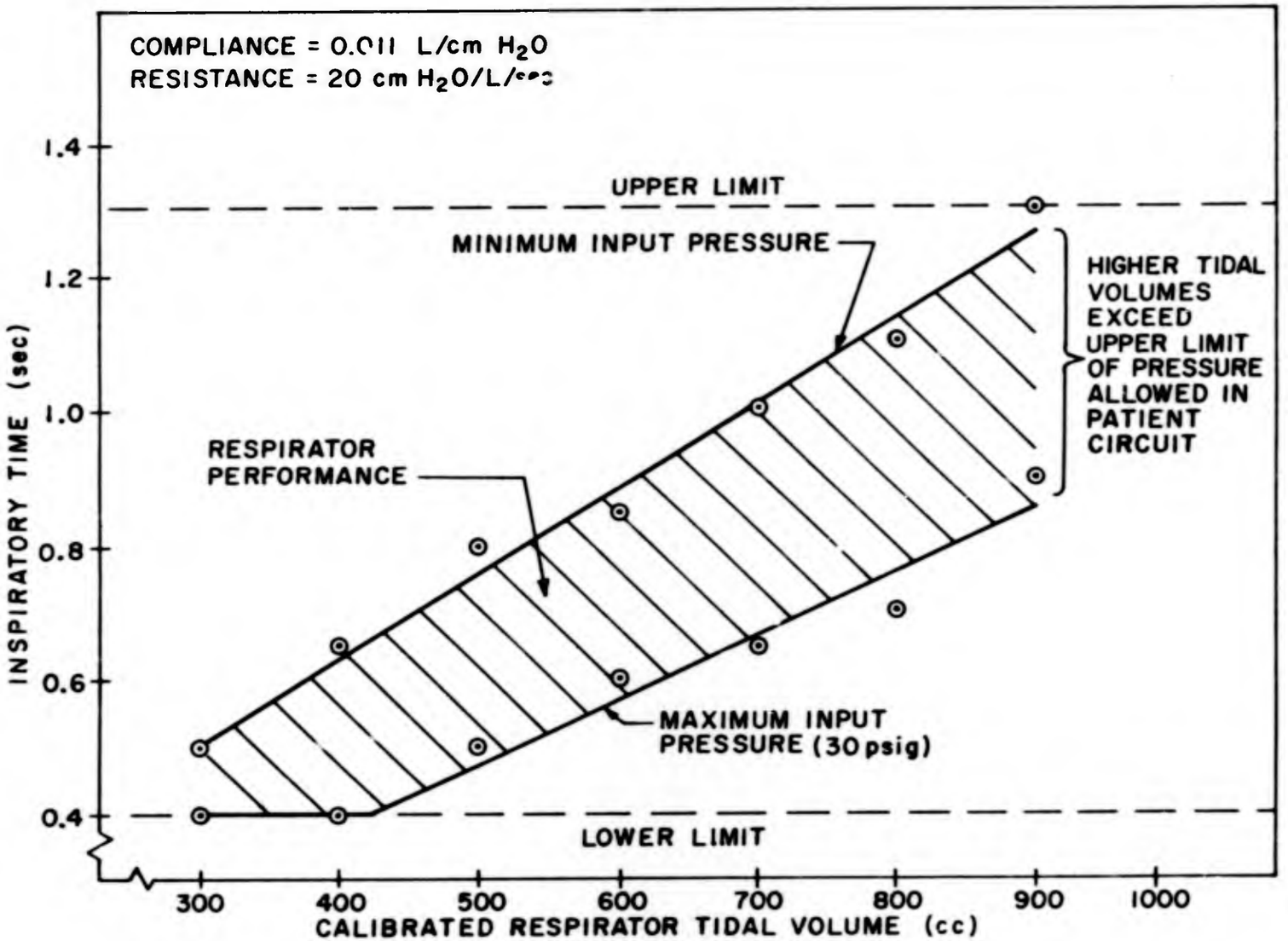


Fig. 11. INSPIRATORY TIMES-LOW COMPLIANCE, HIGH RESISTANCE

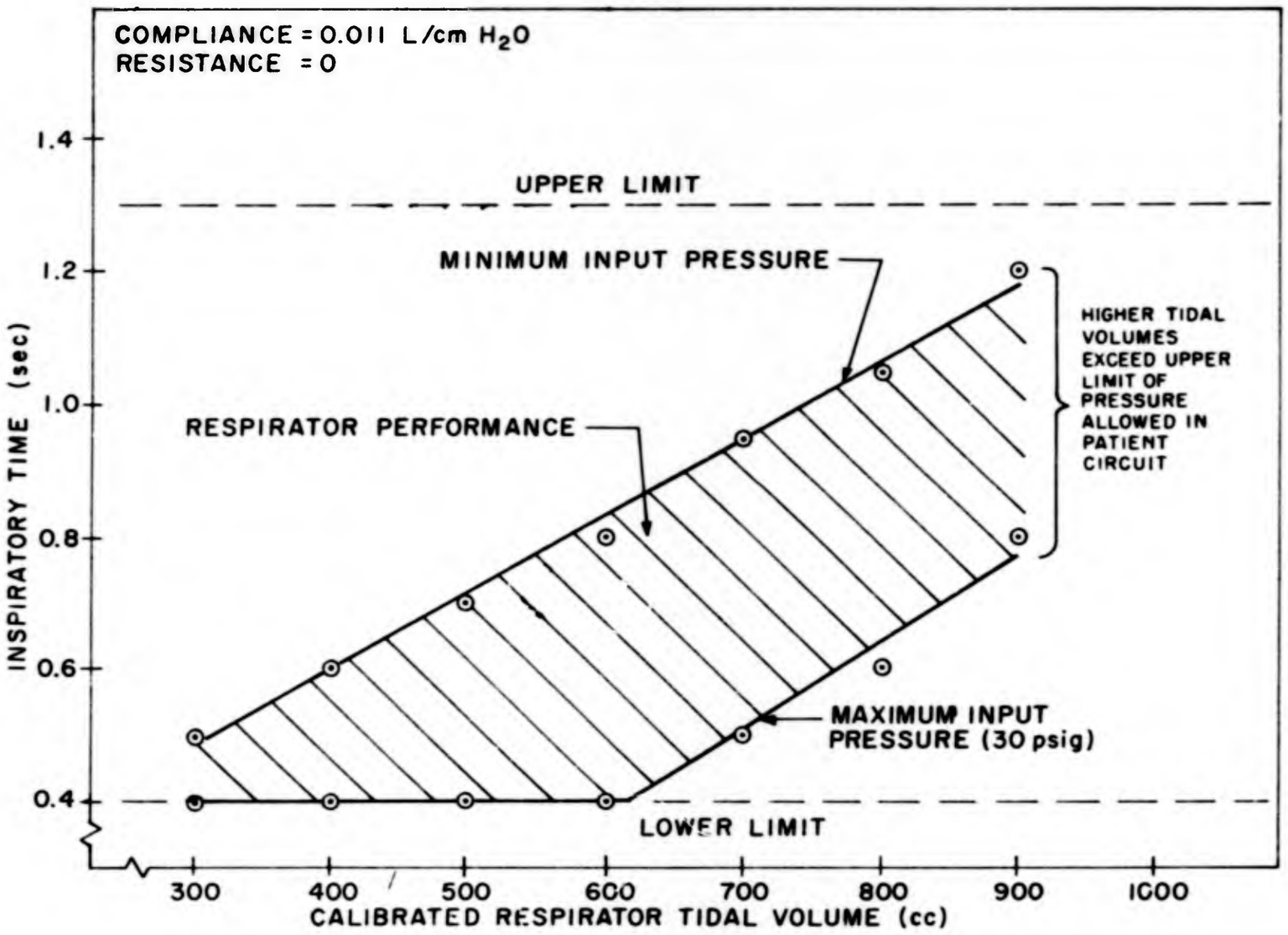


Fig. 12. INSPIRATORY TIMES-LOW COMPLIANCE, NO RESISTANCE

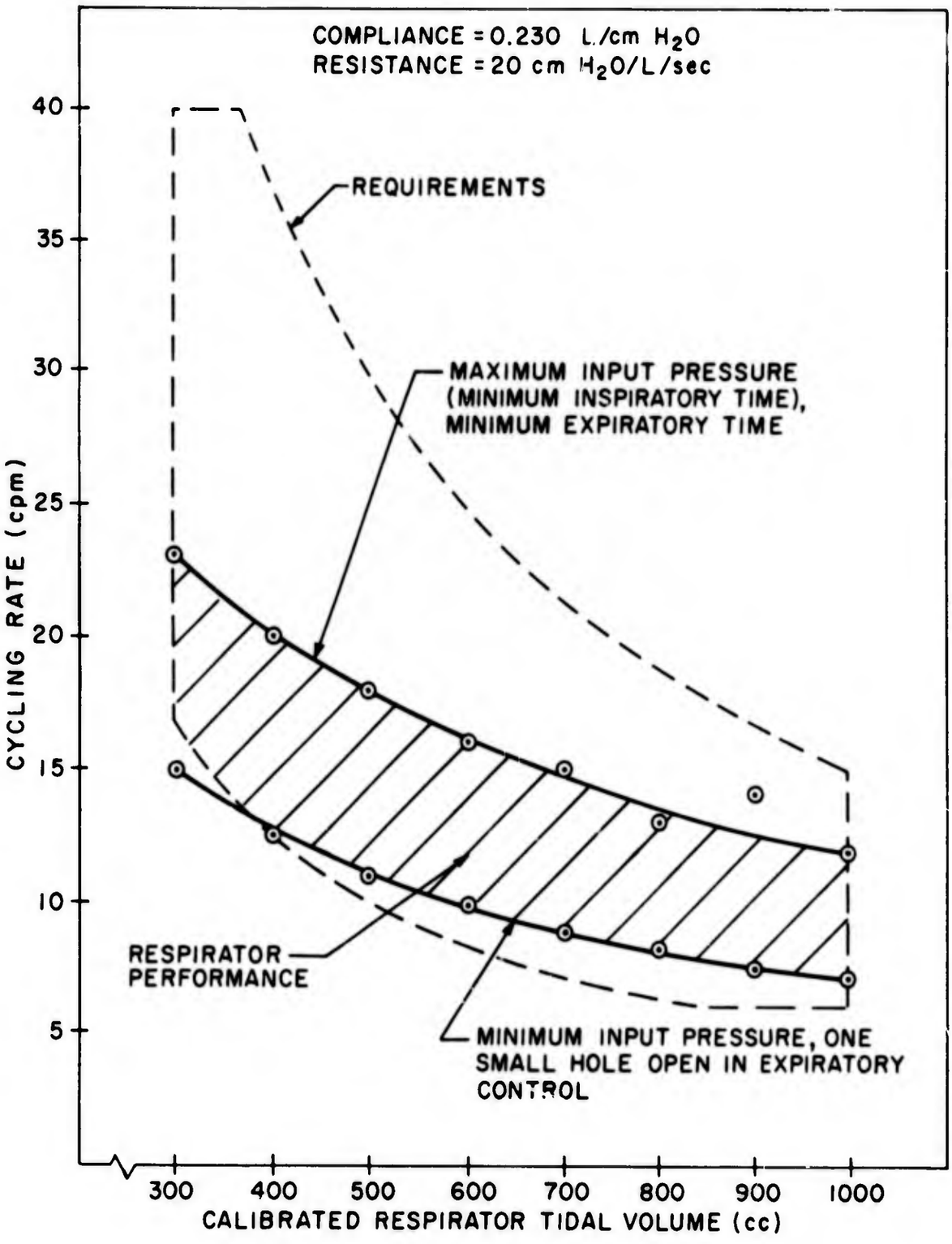


Fig. 13. CYCLING RATES - HIGH COMPLIANCE, HIGH RESISTANCE

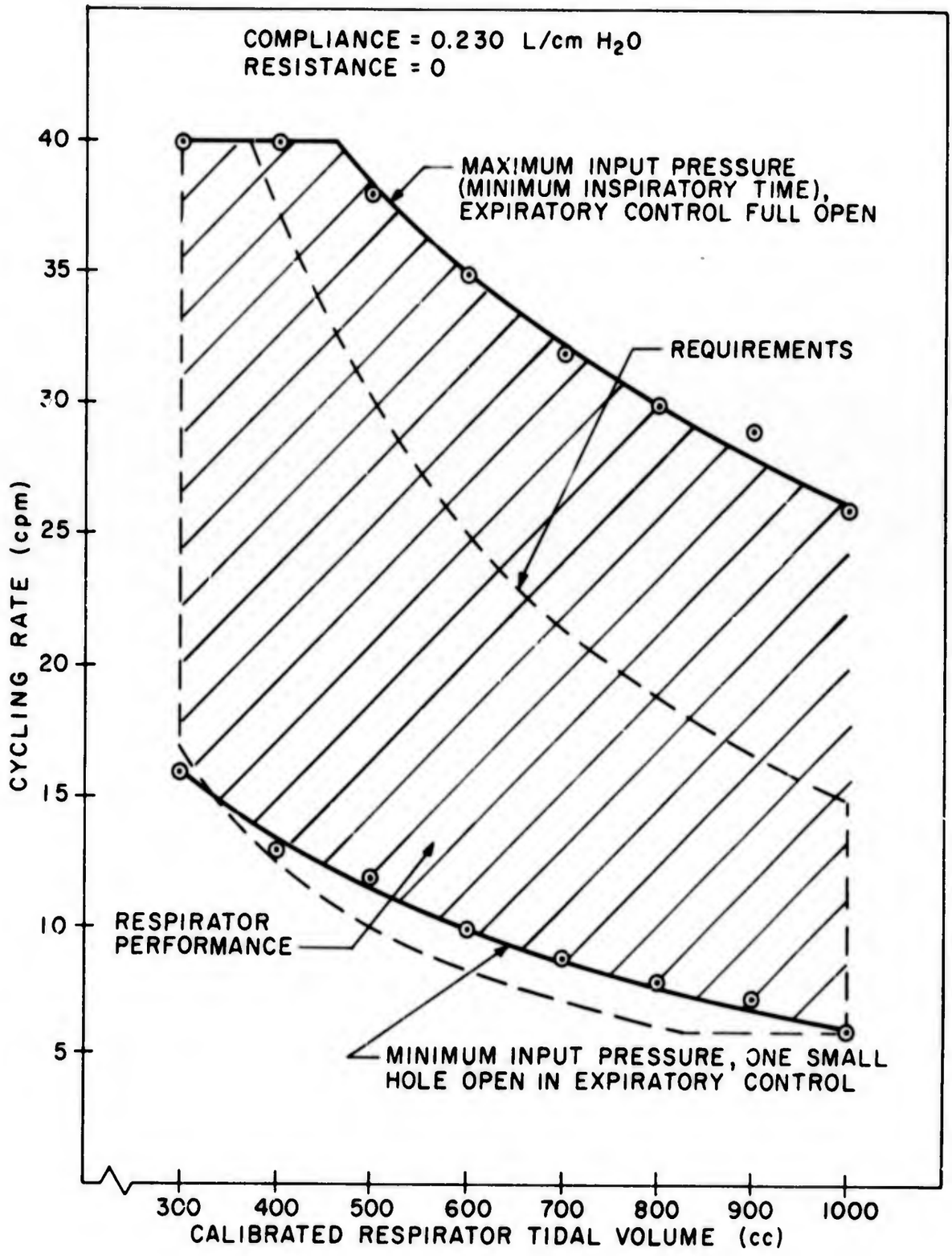


Fig. 14. CYCLING RATES - HIGH COMPLIANCE, NO RESISTANCE

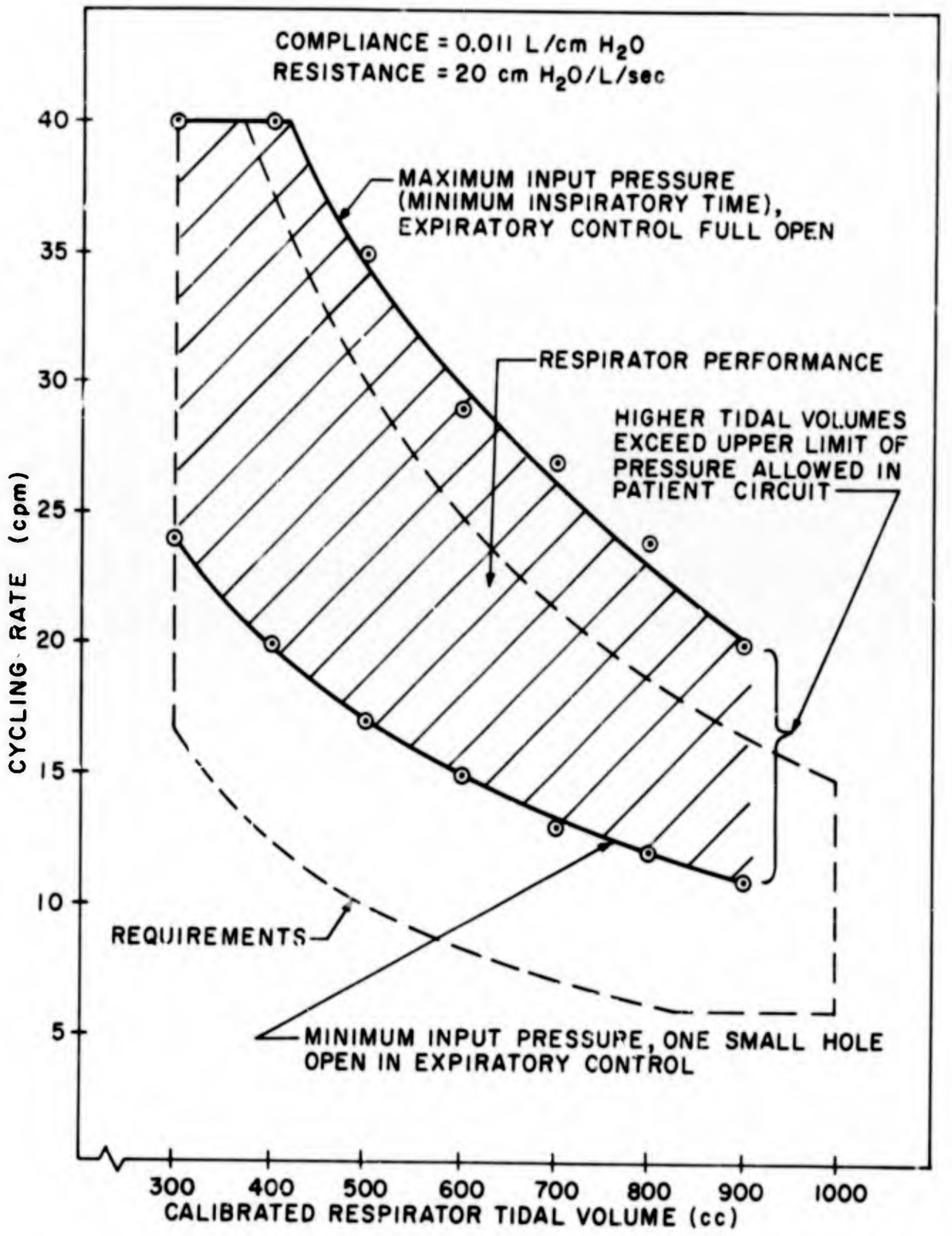


Fig. 15. CYCLING RATES - LOW COMPLIANCE, HIGH RESISTANCE

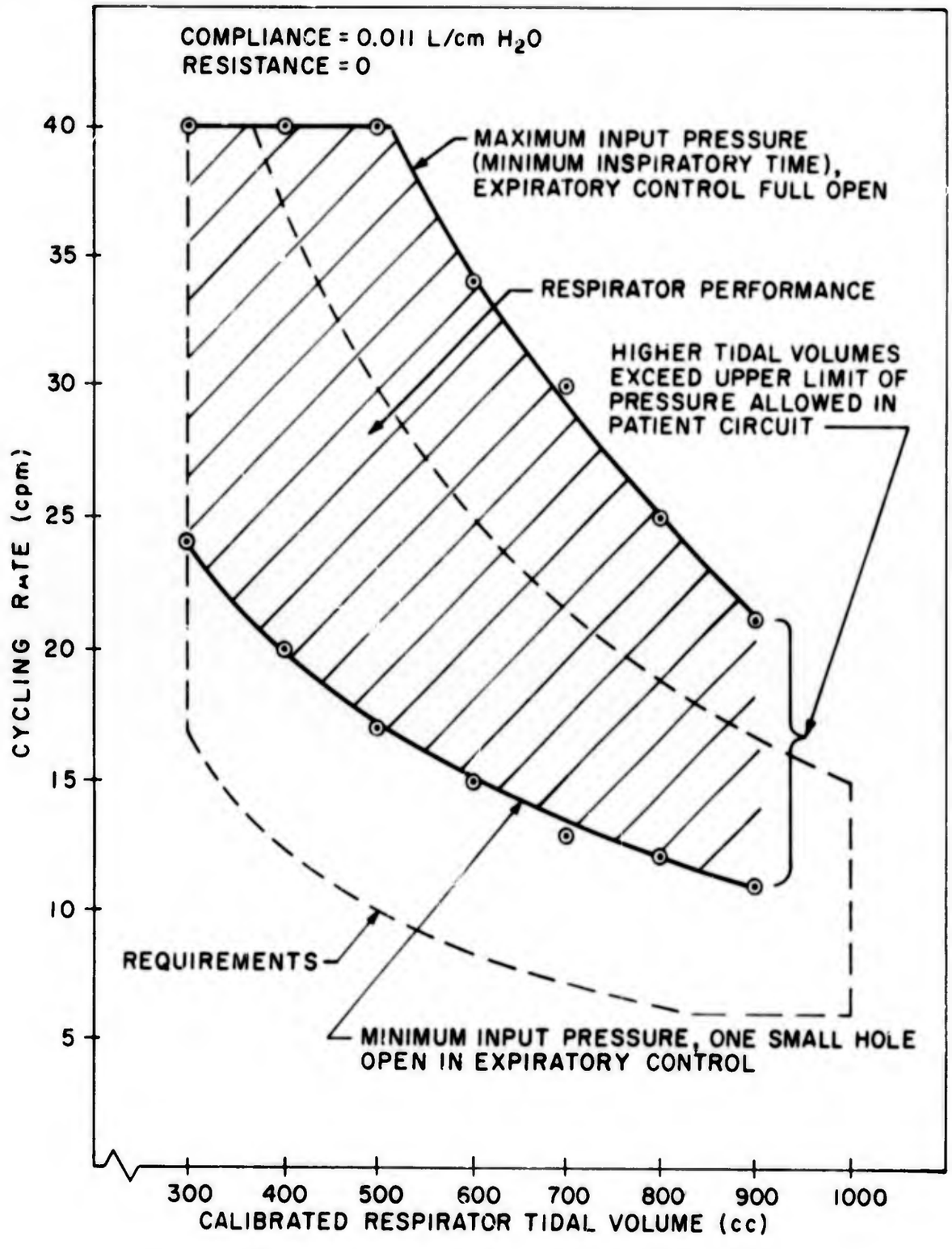


Fig. 16. CYCLING RATES - LOW COMPLIANCE, NO RESISTANCE

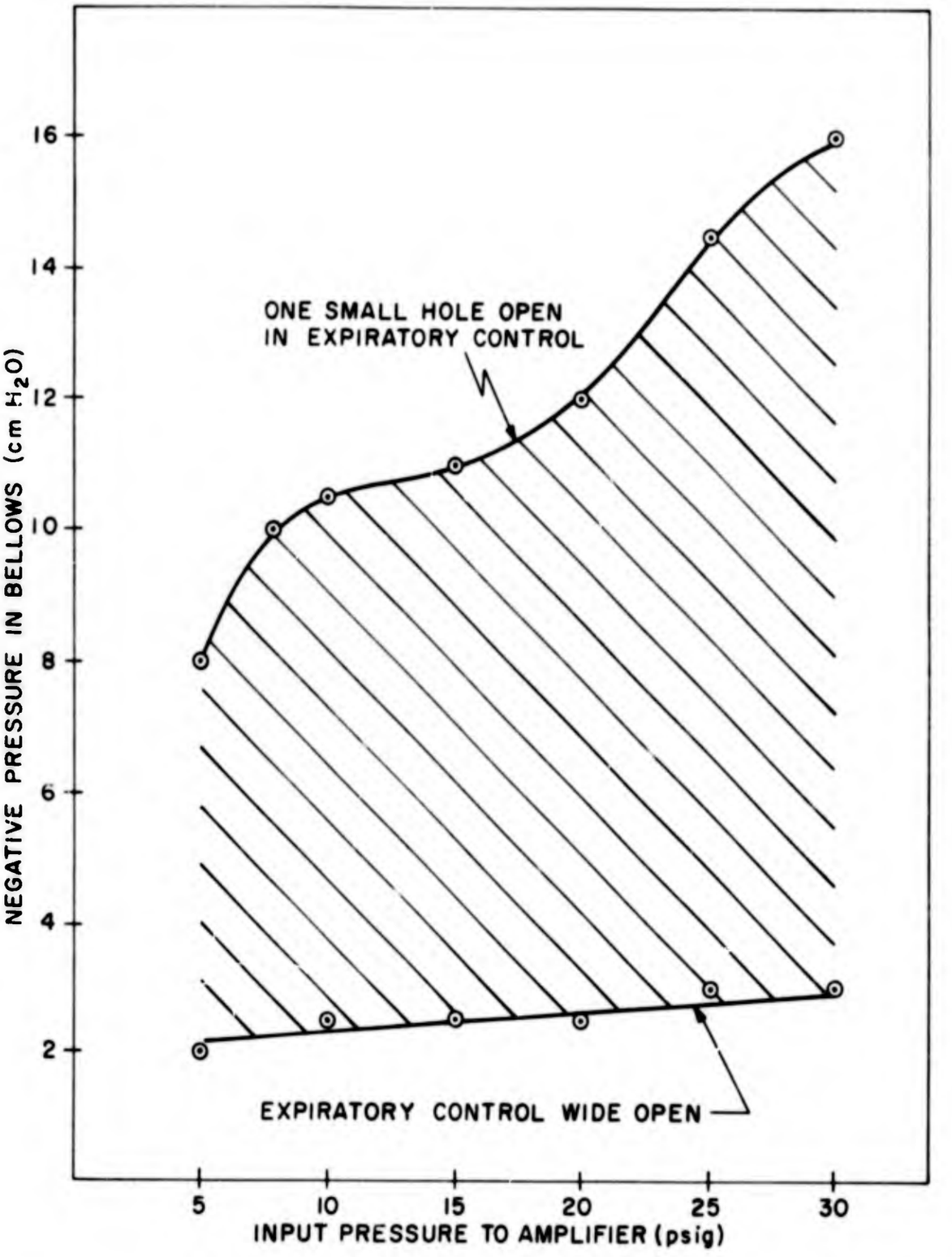


Fig. 17. SUCTION DEVELOPED IN BELLOWS DURING EXPIRATORY PHASE

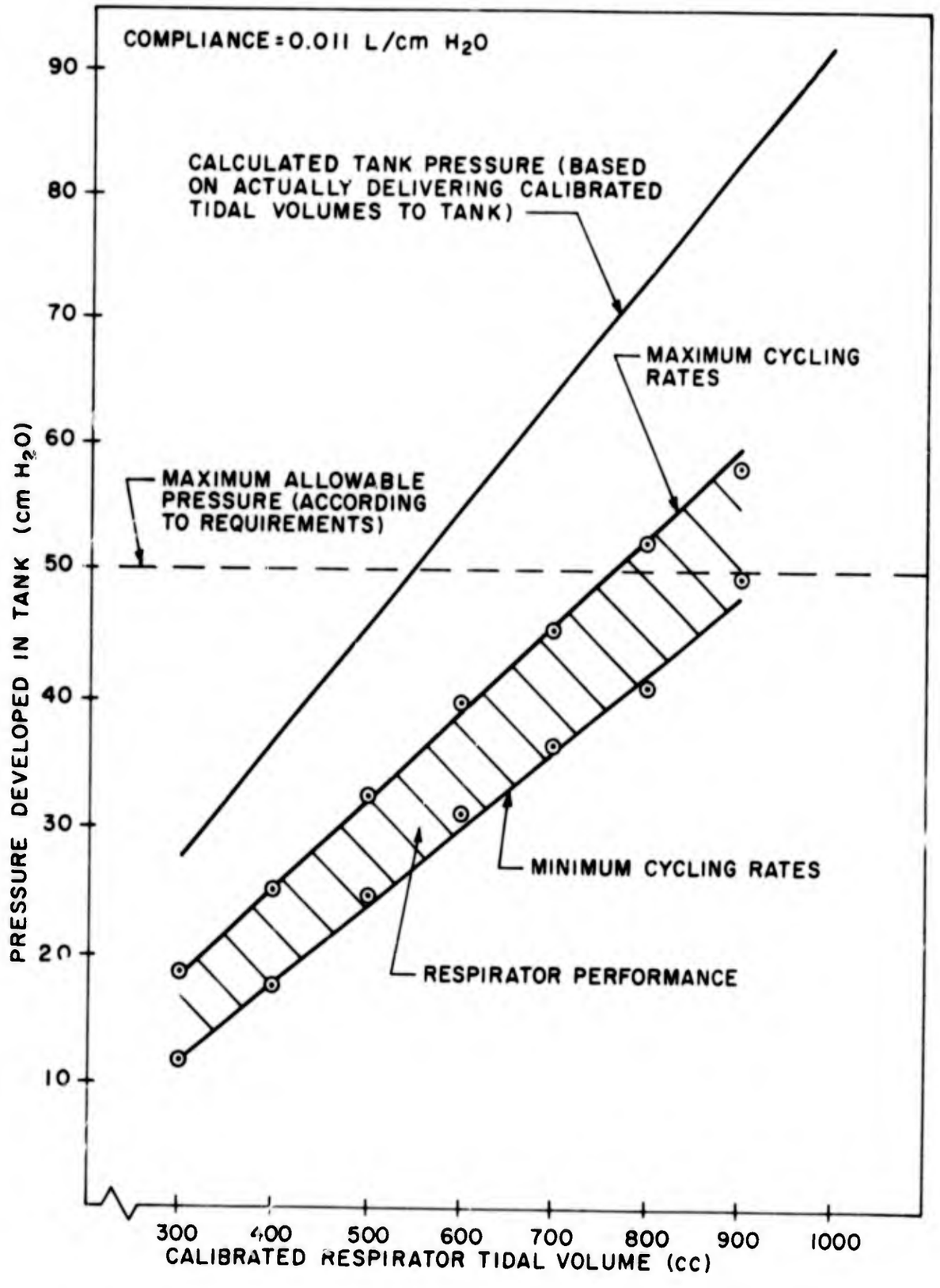


Fig. 18. TANK PRESSURES DEVELOPED-LOW COMPLIANCE

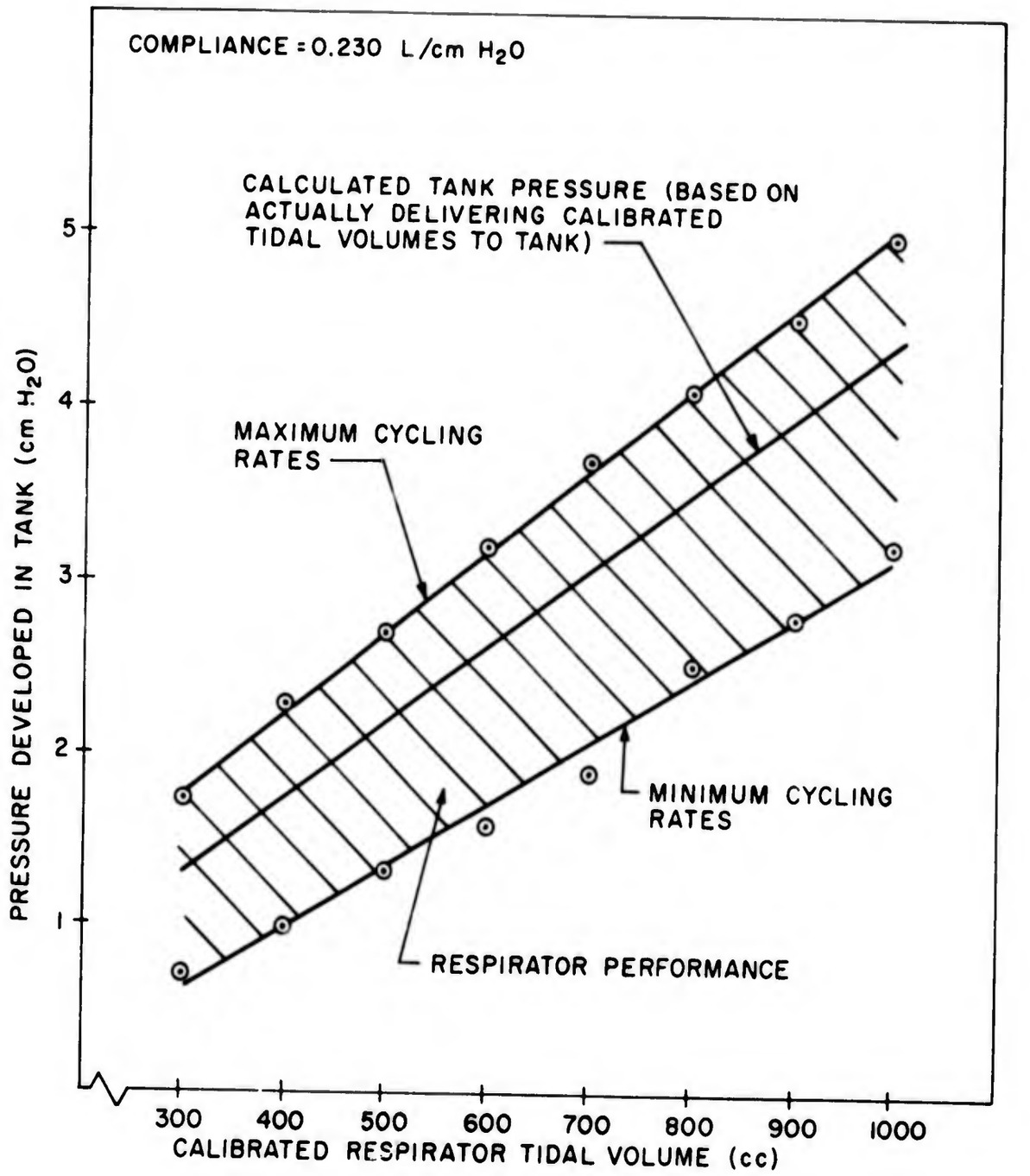


Fig. 19. TANK PRESSURES DEVELOPED-HIGH COMPLIANCE

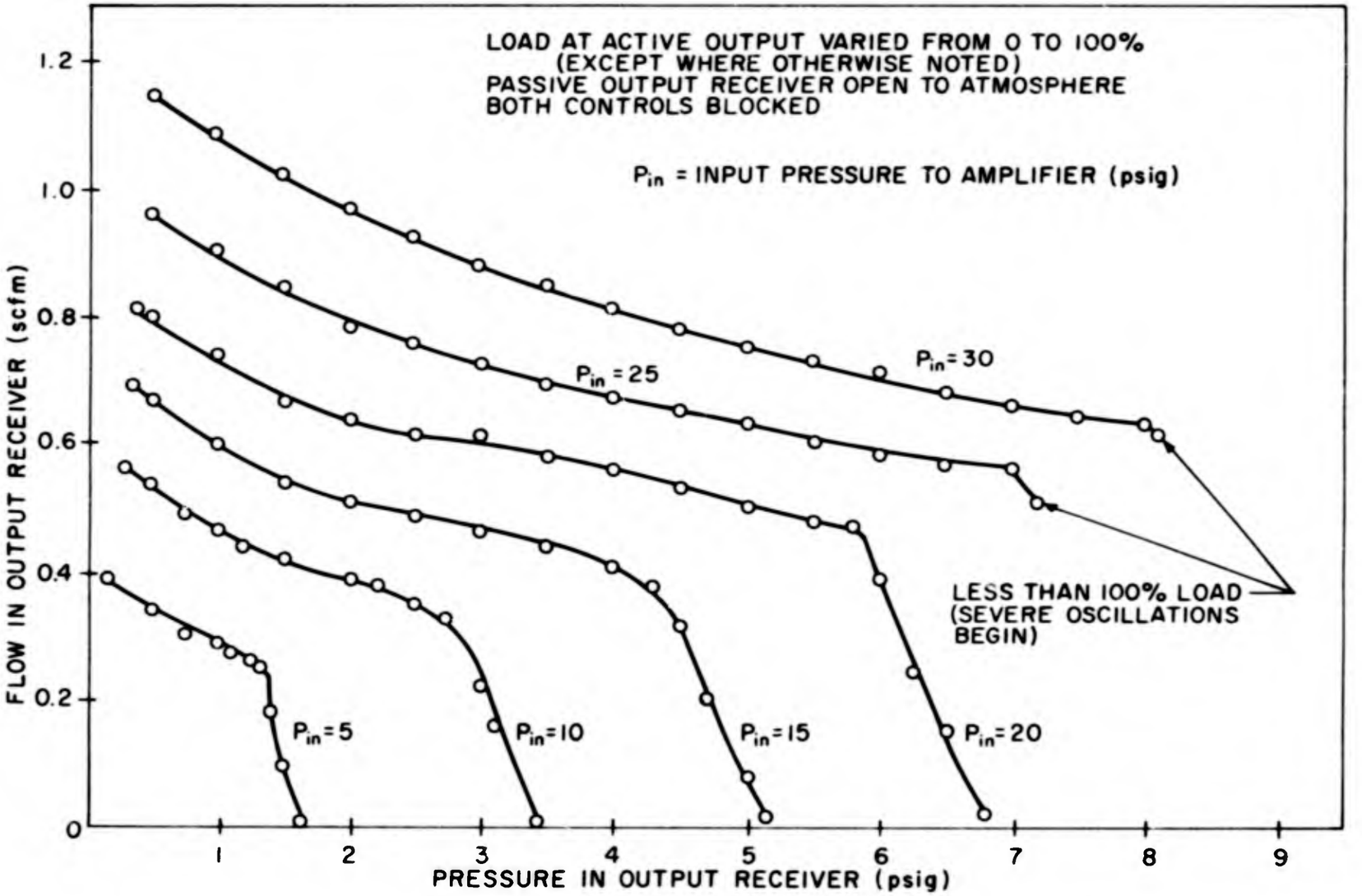


Fig. 20. LOAD CURVES FOR RESPIRATOR FLUID AMPLIFIER

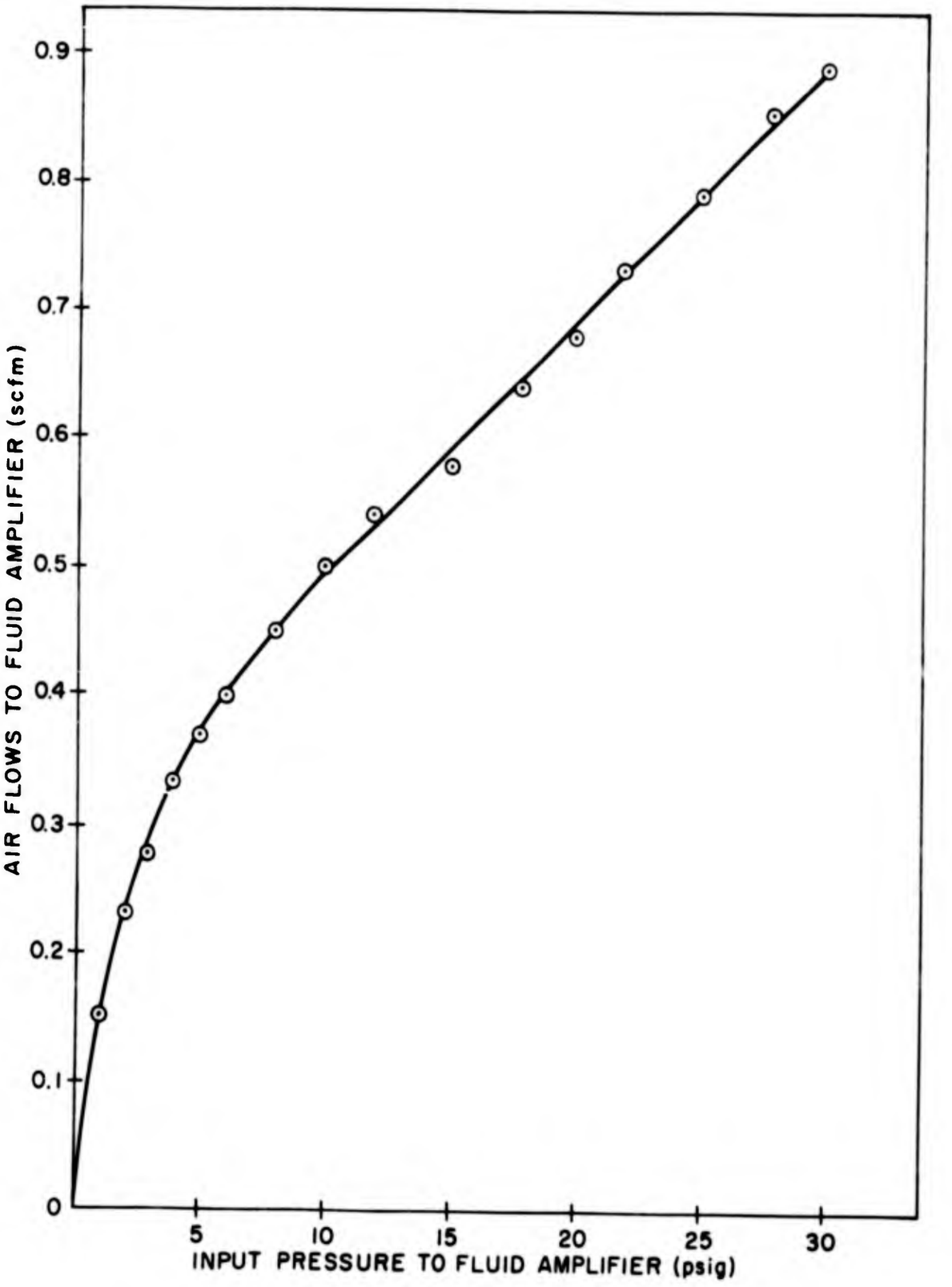


Fig. 21. INPUT AIR FLOWS FOR FLUID AMPLIFIER

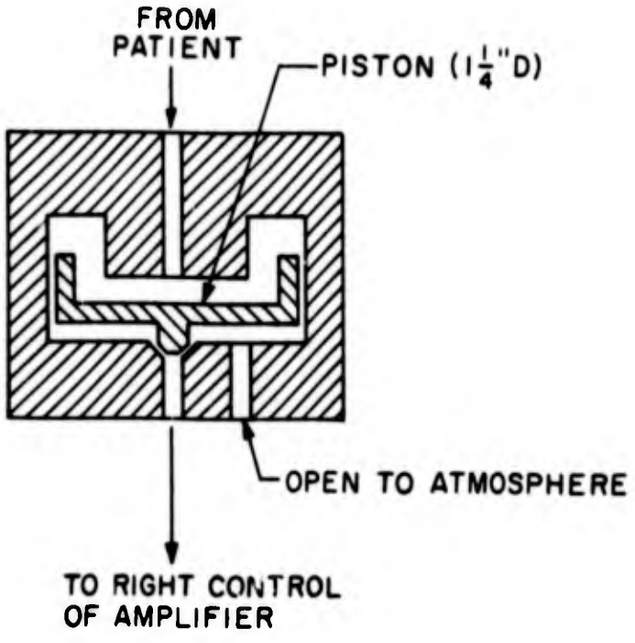


Fig. 22. SCHEMATIC OF INSPIRATION TRIGGER

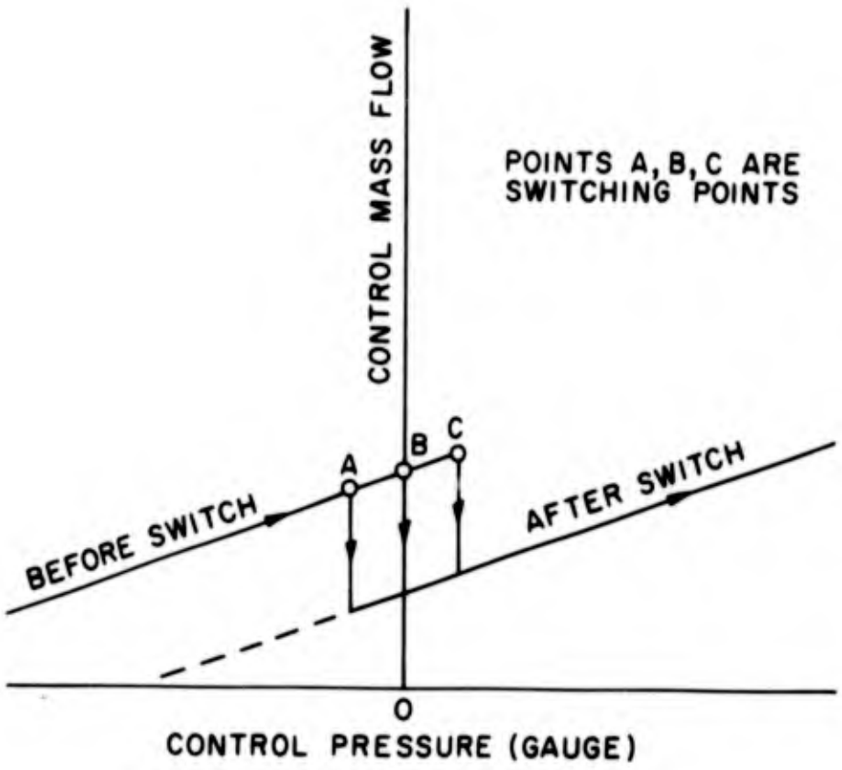


Fig. 23. SWITCHING CHARACTERISTICS FOR RIGHT CONTROL OF RESPIRATOR AMPLIFIER

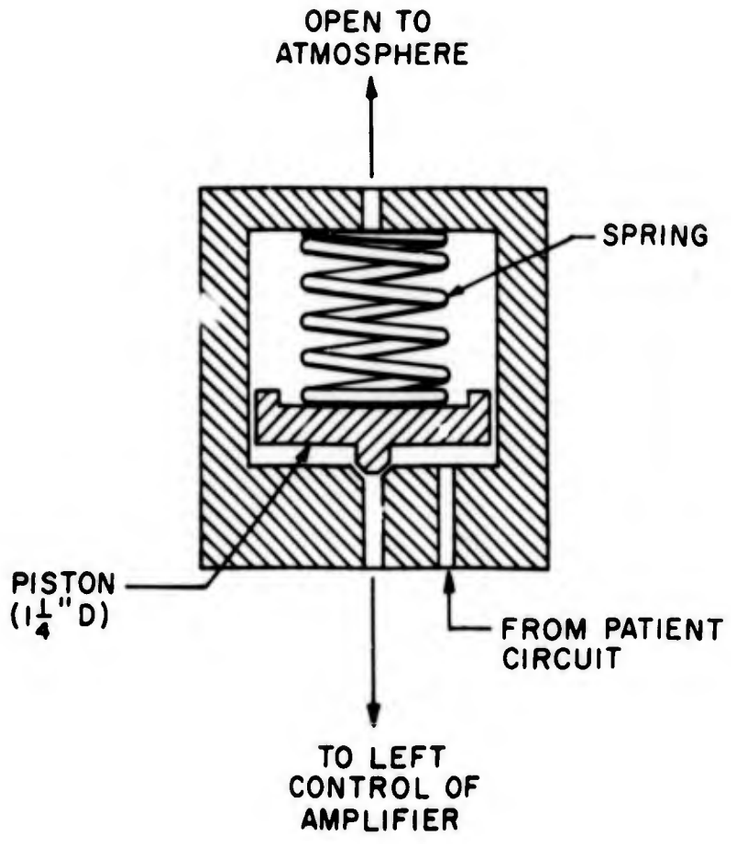


Fig. 24. SCHEMATIC OF SAFETY VALVE

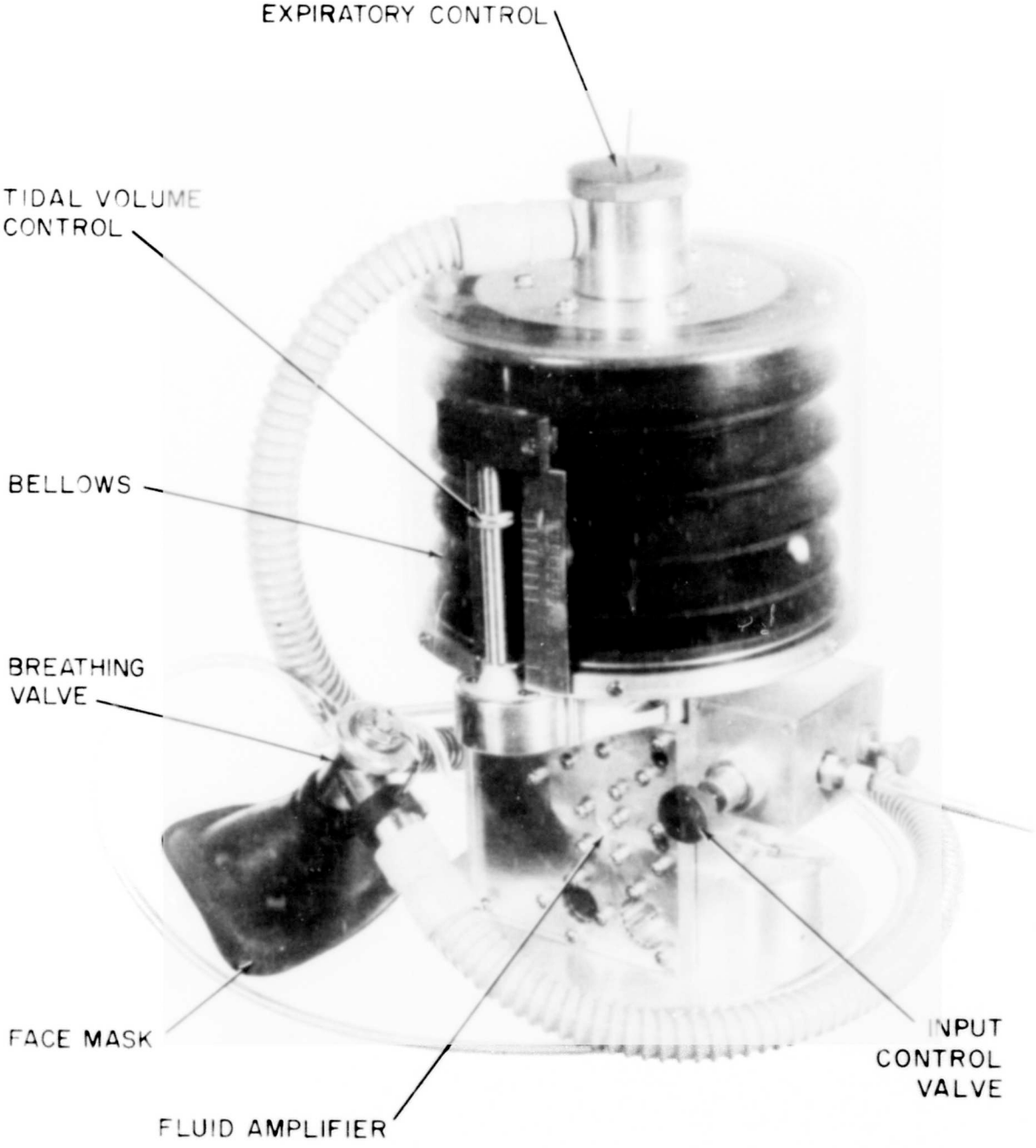


Fig. 25 The Volume-Cycled Respirator Prototype

GLOSSARY OF MEDICAL TERMS (Ref 4)

Airway resistance- The pressure difference across the airway (between the mouth and the alveoli) per unit flow, usually expressed as centimeters of water pressure per liter of flow per second (cm H_2O/L /sec).

Alveoli- The air cells of the lung.

Assisted respiration- A form of artificial respiration, which is synchronized with the inspiratory effort of the patient.

Compliance- The volume increase produced by a unit pressure increase in the alveoli, usually expressed as L/cm H_2O.

Controlled respiration- Any form of intermittent artificial inflation of the lungs, but not necessarily synchronous with any respiratory effort of the patient.

Expiratory phase- That part of the respiratory cycle which includes exhalation and expiratory pause (period of complete respiratory inactivity).

Inspiratory phase- That part of the respiratory cycle during which the lungs are inflated.

Minute volume- The total volume of gas delivered to the patient circuit per minute. It equals the product of tidal volume and breathing rate.

Patient circuit- That part of the circuit in contact with the patient's lungs, here considered to be everything to the patient side of the breathing valve.

Power circuit- A pneumatic circuit in a ventilator used to drive gases to the patient's lungs.

Pulmonary- Pertaining to the lungs.

Tidal volume- The amount of gas delivered to or breathed by the patient per breath.

APPENDIX A—DETERMINATION OF PISTON DIAMETER

In an effort to minimize the power needed to drive the respirator, the piston diameter should be matched to the loads anticipated in the patient circuit. As a first approximation, the use of static equilibrium will be considered. For the piston to be in static equilibrium, the following force balance must exist:

$$F_B + W + F_f = F_p \qquad \text{(A-1)}$$

where

F_B = force produced by pressure in bellows (lb)

W = weight of piston (lb)

F_f = friction force (lb)

F_p = force produced by pressure in cylinder pushing piston up (amplifier output) (lb)

The force F_B can be calculated by multiplying the inside diameter at the bottom of the bellows by the bellows pressure. Assuming the maximum bellows pressure will be 50 cm H_2O (0.714 psig),

$$F_B = \frac{\pi(.5 \frac{7}{8})^2}{4} (0.714) = 19.3 \text{ lb} \qquad \text{(A-2)}$$

The weight of the piston can be expressed in terms of its diameter D as

$$W = \frac{\pi D^2}{4} L\gamma \text{ lb} \qquad \text{(A-3)}$$

where

L = piston length

γ = specific weight of piston

For a piston length of 4-1/2 in. and using Delrin (specific gravity =1.59) as the piston material, equation (A-3) becomes

$$W = \frac{\pi D^2}{4} (4.5) \frac{(1.59 \times 62.4)}{1728}$$

$$= 0.203 D^2 \text{ lb} \qquad \text{(A-3a)}$$

The upward force, produced by the output of the fluid amplifier, can also be expressed in terms of D if the pressure is known. The amplifier chosen for the respirator has a pressure recovery of approximately 30 percent (ref 5) and an optimum operating range for input pressures up to 30 psig. Assume that the condition of static equilibrium under consideration must be achieved for an input pressure of no more than 20 psig, so that the remaining range (21-30 psig) is available for adjusting the dynamic performance. At 20 psig input pressure, the cylinder (amplifier output) pressure therefore cannot exceed 6 psig. The upward force can now be written as

$$F_p = \frac{\pi D^2}{1}(6) = 4.71\ D^2 \text{ lb} \qquad \text{(A-4)}$$

The remaining term in the force balance equation is the friction force. The piston material chosen was selected in part for its low coefficient of friction. In addition, a clearance of 0.001 in. on the radius between the piston and the cylinder wall was specified. For these reasons, the friction force will be assumed negligible.

The expressions for the individual forces can now be substituted into equation (A-1) to yield

$$19.3 + 0.203\ D^2 = 4.71\ D^2 \qquad \text{(A-5)}$$

Equation (A-5) can be solved for D to yield

$$D = 2.08 \text{ in.} \qquad \text{(A-6)}$$

This diameter is just sufficient to satisfy the conditions described. To provide a safety factor, a piston diameter of 2-1/4 in. was finally selected for the respirator. Experimental results verify the selection of this diameter.

APPENDIX B—RELATIONSHIP BETWEEN COMPLIANCE AND TANK VOLUME

The use of a tank of known volume to represent lung compliance is based on the following:

Consider a closed system, shown schematically in figure B-1, initially composed of the volume of the tank and tidal volume to be delivered to it. The pressure is initially atmospheric. After completion of inspiration, the volume has been compressed to the volume of the tank only, and the pressure has risen above atmospheric. The temperature throughout this process is that of the surroundings (an infinite reservoir). Assume that the perfect gas law holds true. Therefore

$$p_\infty(V + V_t) = (p_\infty + p_t)\, V \qquad \text{(B-1)}$$

where

p_∞ = atmospheric pressure, psia

p_t = pressure developed in tank, psig

V = volume of tank, L

V_t = tidal volume, L

Equation (B-1) can be simplified and rewritten as

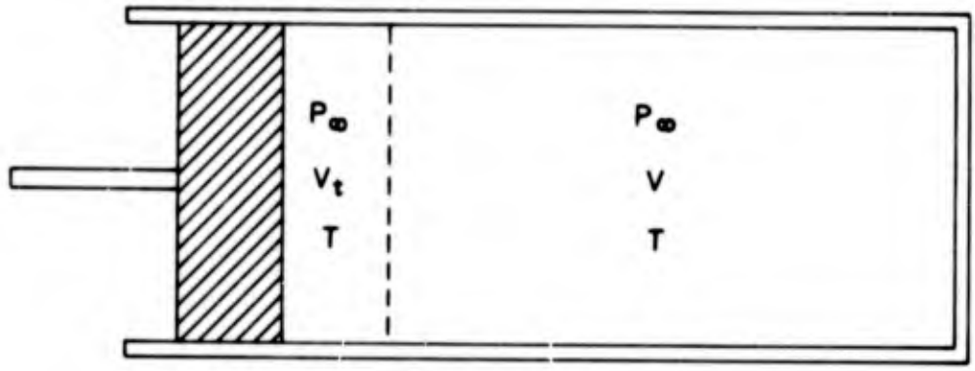
$$\frac{V_t}{p_t} = \frac{V}{p_\infty} \qquad \text{(B-2)}$$

But compliance is defined as the ratio of volume increase (tidal volume) to pressure increase; i.e.,

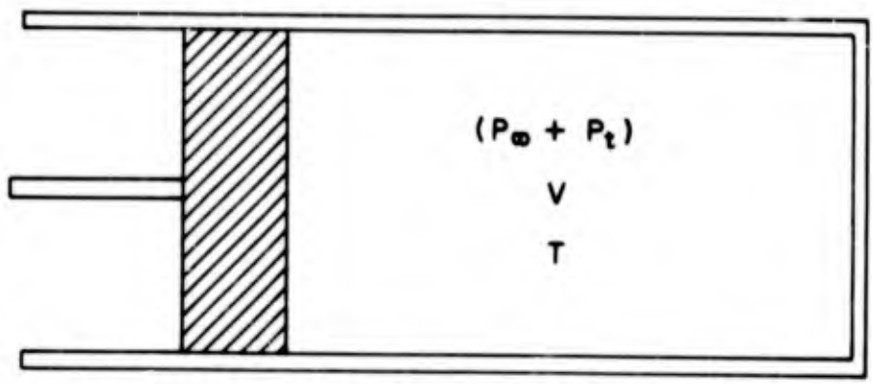
$$\text{compliance} = \frac{V_t}{p_t} \qquad \text{(B-3)}$$

Hence from equations B-2 and B-3

$$\text{compliance} = \frac{V}{p_\infty} \qquad \text{(B-4)}$$



a. INITIAL STATE



b. FINAL STATE

Fig. B-1. SCHEMATIC OF BREATHING GAS CIRCUIT