TM-66-20

# ENGINEERING EVALUATION OF THE ARMY VOLUME-CYCLED RESPIRATOR, MODEL 2

by

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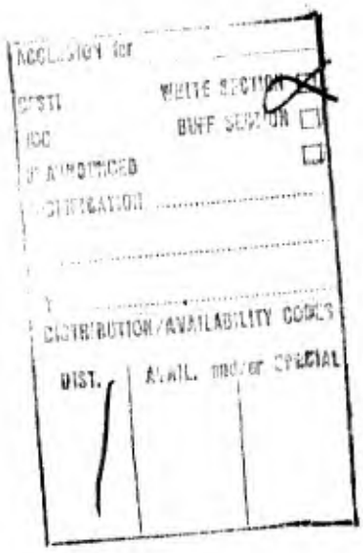
U.S. ARMY MATERIEL COMMAND
HARRY DIAMOND LABORATORIES
WASHINGTON, D.C. 20438

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ABSTRACT

The Army volume-cycled respirator is designed to assist or control the ventilation of patients; it must necessarily operate in military environments. Medical evaluation of the Model 1 prototype of this respirator demonstrated insufficiencies in the assist mode of operation and a need to expand the functional capabilities. This report describes the engineering tests performed on the Model 2 prototype of the respirator which is powered and controlled by two bistable fluid amplifiers (the Model 1 version used only one amplifier). The newer model can also be pressure-cycled.

The tests performed indicate that the Model 2 prototype satisfies the expanded set of requirements established for it with two exceptions. The exceptions pertain to the requirements for inspiratory times and minute volumes. Medical evaluation is now underway to determine the respirator's acceptability as a clinical tool.

## 1. INTRODUCTION

The Army volume-cycled respirator (figure 1) is a joint development of the Harry Diamond Laboratories (HDL) and the Walter Reed Army Institute of Research (WRAIR). An earlier prototype of this respirator, using a single fluid amplifier and having somewhat different control logic, was determined to be inadequate, particularly for the assist operation. This resulted from an incomplete definition of original requirements for clinical use (ref 1).* The requirements were reviewed thoroughly and then revised by the responsible WRAIR-HDL team. The respirator was then redesigned to meet the updated requirements.

The redesigned unit uses two bistable fluid amplifiers to power and control it. In addition to the normal volume-cycled mode of operation, this respirator can be pressure-cycled. As in the case of the original respirator, this unit can be used as either an assistor or a controller, and the power circuit is separated from the patient circuit to permit the use of contaminated power sources.

## 2. DESIGN REQUIREMENTS

The current functional and packaging requirements for this respirator are based on the premise that the respirator will be used primarily on adult patients. Further, these requirements have been generated with emphasis on the needs of Army medicine.

* Joyce, J. W., "The Development of a Volume-Cycled Respirator," HDL TM-65-14, Harry Diamond Laboratories, Washington, D. C., 20438, 24 Mar 1965.

## 2.1 Functional Requirements

The functional requirements for this respirator are as follows:

(1) The respirator should be able to assist or control the ventilation of a patient, and the change from one mode of operation to the other should take place automatically.

(2) In the assist mode of operation, the respirator should be able to sense an inspiratory effort by the patient of 1.0 cm $H_2O$ negative pressure. Sensitivity of the inspiration initiation trigger should, in addition, be variable at least to 4 cm $H_2O$ of negative pressure.

(3) The respirator should have pressure-cycling capabilities. The switching pressures for the pressure-cycled mode of operation should be continuously variable between 10 and 60 cm $H_2O$.

(4) The respirator should have a continuously variable tidal volume capability from 300 to 2500 cc.

(5) The respirator should be able to deliver minute volumes from 5 to 20 L/min.

(6) When operating in the control mode, the respirator should be able to cycle from 6 to 60 cpm. Requirements 4 through 6 are summarized graphically in figure 2.

(7) The inspiratory period of the respirator should be continuously variable from 0.4 to 1.3 sec.

(8) Expiratory periods achieved by the device should be compatible with the requirements for inspiratory times and cycling rates stated above.

(9) The respirator must be able to administer pure oxygen as well as room air to the patient.

(10) The respirator should have a gas canister to filter contaminated incoming air when room air is used as the breathing gas.

(11) Provisions must be made to humidify the breathing gases being administered to the patient.

(12) The pulmonary loads against which the respirator must function possess compliances from 0.010 to 0.230 L/cm $H_2O$ and airway resistances to 20 cm $H_2O$/L/sec. Airway resistances are to be calibrated at a flow rate of 0.5 L/sec.

## 2.2 Packaging Requirements

The packaging requirements for this respirator include the following:

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

(2) The respirator should be capable of operating continuously for three months with a minimum of maintenance.

(3) Interdependence of controls should be minimized or eliminated if possible.

(4) The respirator should be able to use either contaminated or uncontaminated gases as its power source. This necessitates the isolation of the power circuit from the patient circuit.

(5) In general, the respirator should be small, light weight, portable (can be carried by one person), and rugged. It should be able to withstand the environmental conditions imposed on it by military applications.

# 3. OPERATIONAL DESCRIPTION

A schematic diagram of the respirator is shown in figure 3. The two fluid amplifiers are operated through a common pressure regulator. At the beginning of a cycle, the output of amplifier A (located on the front of the respirator) is flowing into the lower piston chamber, pushing the piston upward, while the output of amplifier B (located on the back of the respirator) is exhausting to the surroundings. As the piston is driven upward, the rubber bellows is compressed, and breathing gas in the bellows is forced into the patient's lungs via the breathing valve. In the normal volume-cycled mode of operation, the upward motion of the piston is terminated when a striker attached to the bottom of the bellows activates an adjustable mechanical (upper excursion) trigger. Activation of this trigger opens feedback lines to both

fluid amplifiers and switches them simultaneously, so that the output of amplifier B is now flowing into the upper piston chamber, driving the piston down, and the output of amplifier A exhausts to the surroundings. In the pressure-cycled mode of operation, piston upstroke is terminated when a predetermined pressure has been reached in the patient circuit. This pressure activates the pressure-cycle trigger (a spring-loaded diaphragm arrangement), and as in the case of volume-cycled operation, feedback lines to both amplifiers are opened to admit switching air flow, and the amplifiers are switched to begin the downstroke.

As the piston descends, the bellows refills with fresh breathing gas through a one-way valve in the gas intake at the top of the respirator. The patient, meanwhile, exhales to the surroundings through the breathing valve. None of the exhaled gases are allowed to reenter the bellows where they could be breathed again. At the bottom of the downstroke, the bottom of the bellows strikes a fixed mechanical (lower excursion) trigger, and in so doing, opens the left feedback line to amplifier B. This action switches the amplifier's power stream to the right receiver where it exhausts to the surroundings. Amplifier A is not affected by this trigger, and its output continues to exhaust. At the instant the bellows comes to rest at the bottom of the downstroke (but not until such time), the rate of entrainment out of the lower piston chamber produced by the exhausting amplifier A is sufficient to produce negative pressure in this chamber. The negative pressure operates the delay mechanism by exerting a force on one side of a piston. The rate of motion of this piston is controlled by a variable atmospheric bleed (a needle valve) on the opposite side of the piston, which determines the magnitude of the retarding force; as a consequence, a variable time delay is achieved. In the control mode of operation, at the end of its travel, the delay piston strikes a mechanical trigger which opens the right feedback line to amplifier A, thus switching its power stream back into the piston chamber to begin a new cycle. In the assist mode of operation, an inspiratory attempt by the patient, in the form of a small negative pressure, initiates a new cycle by activating the inspiration initiation trigger before the delay mechanism trigger is activated. The inspiration initiation trigger is also a spring-loaded diaphragm arrangement which, when activated, uncovers the right feedback line to amplifier A to switch it and begin a new cycle.

The second fluid amplifier was added on the Model 2 version to provide a sufficiently rapid piston downstroke so that assist efforts by the patient can be sensed after, and only after, the bellows has returned to the reset position. In this manner of

operation, a constant volume of breathing gas is always delivered to patient during assist. In contrast, the Model 1 version allowed the patient to initiate a cycle during the piston downstroke, which downstroke was considerably slower than in the present unit. The subsequent volumes delivered to the patient were not necessarily constant. Moreover, it was possible to reach a condition of instability during assist because of the variable volumes delivered. If the patient received too small a volume on a given cycle, he would most likely attempt to breath even sooner on the next cycle, and a still smaller volume would be delivered. This condition would progress to the point where the patient would be panting in an effort to get more volume. In the Model 2 respirator, such a condition cannot exist.

The functions of the various controls in altering the parameters involved will be discussed later.

## 4. TEST EQUIPMENT AND PROCEDURE

In order to determine the performance capabilities of the respirator, it was necessary to simulate lung compliance and airway resistance. Lung compliance was simulated by tanks of known volumes. The tanks used in these tests were equivalent to lung compliances of 0.011 and 0.230 L/cm $H_2O$, which closely approximate the two extremes of compliance set forth in the requirements. A perforated disk with a flow resistance of 20 cm $H_2O$/L/sec (calibrated at a flow of 0.5 L/sec) was inserted in the tubing connecting the respirator to the tank (compliance) to simulate maximum airway resistance.

A pressure transducer (±1 psid range) was used to sense pressures in the tanks and ahead of the airway resistance. The latter measurement represents face mask pressure—the pressure monitored by most respirators. A second transducer (50 psia range) was used to monitor pressures in the right feedback line of amplifier B in order to determine the downstroke time and the delay time. These two durations cannot be determined from tank pressures which indicate only the total expiratory time (the sum of downstroke time and delay time). The outputs of the transducers were displayed on an oscilloscope, and the data was recorded from photographs of the oscilloscope traces.

## 5. PERFORMANCE RESULTS

The respirator was tested under four different loading conditions using the compliances and resistances described earlier. These conditions were as follows:

(1) Low compliance, no resistance

(2) Low compliance, maximum resistance

(3) High compliance, no resistance

(4) High compliance, maximum resistance

## 5.1 Calibration of Tidal Volumes

Before testing the respirator against these loads, however, it was first necessary to calibrate the tidal volumes delivered by the respirator. This was done in the following manner. The respirator was connected to a tank representing a compliance of 0.074 L/cm $H_2O$ (considered to be about the normal adult compliance) with no airway resistance. The volumes delivered to the tank were then calculated from the pressures in the tank using Boyle's Law (pV = constant). In this manner, strokes corresponding to tidal volumes at 100-cc intervals, up to a maximum of 2300 cc, were marked on the bellows housing of the respirator (fig. 1); these calibrated settings of tidal volume were used in all subsequent tests. The maximum tidal volume available (2300 cc) is limited by the maximum allowable piston stroke. Although the requirements call for a maximum tidal volume of 2500 cc, the difference is not enough to warrant a design change to recover the extra 200 cc. The tidal volumes delivered for other values of compliance, and with airway resistance present, will vary somewhat from the calibrated values because of compressibility effects and losses from the system, for example, through the breathing valve. These effects will be discussed further later.

## 5.2 Inspiratory Times

Inspiratory times for the respirator can be varied by adjusting the input pressure to the fluid amplifiers. Inspiratory time decreases as input pressure increases. To determine the limits of such operation, the respirator was operated against each of the four loading conditions described above for two different input pressures at each of the various tidal volume settings. The two input pressures were 30 psig, the upper design limit of input pressure, and the lowest pressure necessary to cycle the unit against the particular load. Figures 4 and 5 indicate that for the low compliance, the respirator cannot be operated at the upper limit of inspiratory time. This effect is due mostly to the high pressures developed in the 0.011 L/cm $H_2O$ compliance, as a result of which the minimum input pressure to cycle the respirator is raised to such a level that the slower inspiratory

times cannot be achieved. Figures 6 and 7 show that for the high compliance, both limits of inspiratory time are achieved over the range of tidal volumes. At small tidal volumes, however, the upper limit is not achievable, while at large tidal volumes, the lower limit cannot be reached. These are limitations of the respirator inasmuch as even at the lowest possible input pressures, the strokes for small tidal volumes are so short that they will always be completed in less than 1.3 sec. Similarly, for large tidal volumes, the stroke cannot be completed in 0.4 sec, even for the maximum input pressure of 30 psig. It remains to be seen whether this limitation is in practice a serious one, or whether the real problem is a lack of adequate definition of the requirements for inspiratory times. It seems reasonable that the range of inspiratory times would be a function of tidal volume—the faster times being associated with the smaller tidal volumes, and the slower times with larger tidal volumes. In other words, constant inspiratory times regardless of tidal volumes appear to be unrealistic.

It should be mentioned that if the respirator's inspiratory time during assist is not fast enough to meet the patient's flow demands, he will not be starved for air to breathe. Negative pressures of approximately 4 cm $H_2O$ will open the intake valve at the top of the respirator (fig. 3) and allow the patient to supplement the air already in the bellows with air drawn in from the surroundings.

### 5.3 Cycling Rates

The cycling rates produced by the respirator are shown in figures 8 through 10. As before, the respirator was tested against the extreme loading conditions of lung compliance and airway resistance. The lower limit of cycling rates in all cases was obtained for the lowest input pressure to cycle the respirator (maximum inspiratory time) and maximum delay time (maximum expiratory time). The upper limit in each case was obtained at the upper limit of input pressure (30 psig), corresponding to the minimum inspiratory time. For the small compliance (0.011 L/cm $H_2O$), the delay control was adjusted for minimum delay time, so that expiratory time was also minimized. The resulting cycling rates for the small compliance (fig. 8) provide a wide enough range of operation to satisfy the imposed requirements. These results also show that the 20-cm $H_2O$/L/sec airway resistance has very little effect on the cycling rates for this case.

For the large compliance (0.230 L/cm $H_2O$), the delay control was adjusted so that the total expiratory time was just equal to the time required for the tank pressure to return to

atmospheric. The results shown in figure 9 indicate that the range of cycling rates with no airway resistance is not as great for the high compliance as for the small compliance, but is still adequate to meet the requirements. For the large compliance with maximum airway resistance (fig. 10), the range of cycling rates is quite narrow. This limited performance is not, however, the fault of the respirator. It is caused by the long expiratory time required for the tank to exhaust completely and return to atmospheric pressure, thereby greatly lowering the upper limt of cycling rates attainable. Shorter expiratory times would result in air "trapping" within the tank; that is, a residual volume of air (and a corresponding residual positive pressure) would remain in the lungs, causing an increase in mean pulmonary pressure and a decrease in effective ventilation capacity. Since this limitation for large compliance is not a respirator deficiency, the cycling requirements may still be considered as having been met.

### 5.4 Pressures Developed

The pressures developed in the tank and ahead of the airway resistance for the extreme conditions of operation are shown in figures 11 through 14. For the low compliance and no airway resistance (fig. 11), the pressures in the tank vary slightly with input pressure. This effect is probably caused by losses through the breathing valve during the inspiratory phase. At the lower input pressures, the valve does not completely seal as rapidly, and some of the breathing gases are lostto the surroundings. The differences produced are not great enough to cause concern. The results for the low compliance with maximum airway resistance (fig. 12) show that the airway pressure (ahead of the resistance) is higher at the 30-psig input pressure than at the lower input pressures. This effect is to be expected because the higher input pressure is associated with faster inspiratory times, and hence, greater inspiratory flow rates that result in increased pressure drops across the resistance. The tank pressures in this case are relatively independent of input pressure.

For the large compliance, the results for the case of no airway resistance (fig. 13) show no variation of tank pressure with changes in input pressure. For maximum resistance (fig. 14), the pressures ahead of the resistance become quite large at the upper input pressure. The pressure drops across the resistance for 30 psig input pressure are anywhere from 1 to 3 times the tank pressures developed. The interesting point to be observed here is that a pressure-cycled respirator would be switching on these elevated airway pressures, whereas the pressure in the lungs might be only one-half (or less) of that value. Unless the

operator is aware of this fact and increases the switching pressure of the respirator, the patient may not be adequately ventilated.

### 5.5 Minute Volumes

The actual minute volumes delivered to the tanks are shown in figures 15 through 17. The minute volumes were determined by first calculating the actual tidal volumes delivered to the tank from the pressures developed in the tank (using Boyle's Law), and then multiplying these volumes by the corresponding respirator cycling rates. The minute volumes for the low compliance are shown in figure 15, which indicates that the upper limit cannot always be reached, especially for the case of maximum airway resistance. The reason for this is twofold. First, the actual tidal volumes delivered to the 11-L tank are only about 50 percent of the calibrated values because of compressibility and losses through the breathing valve. Secondly, the high tank pressures developed create a large back load to the respirator and thereby restrict the upper limit of cycling rates that can be achieved. This effect is most noticeable for the case of maximum airway resistance.

Figure 16 shows that the minute volume requirements are satisfied for all operating conditions for the case of high compliance and no airway resistance. For high compliance and maximum airway resistance, figure 17 shows that once again the upper limit of minute volumes cannot be reached. This result is to be expected because of the limitations imposed on the cycling rates for this loading condition (see section 5.3). Therefore, the failure of the respirator to meet the upper limit of minute volumes under these conditions, as in the case of its failure to meet the cycling rate requirements, is not a shortcoming of the respirator, but is instead a limitation imposed by the load itself as explained in section 5.3.

### 5.6 Pressure Cycling

The switching pressure for pressure-cycled operation is controlled by the spring force acting on the diaphragm of the pressure-cycle trigger as described earlier. Figure 18 shows the effects of input pressure to the respirator and compliance on the switching pressure for a given spring setting. Even for the extremes of loading and operating conditions involved, the range of switching pressure variation is only 5 cm $H_2O$. The same range of variation occurs at higher switching pressures (higher spring forces) also. Therefore, once the spring force has been set, the switching pressure will not change by more than 5 cm $H_2O$

with a change in lung compliance or input pressure to the respirator. The spring was selected so that switching pressures from 10 to 60 cm $H_2O$ could be achieved. This range of pressures is in accord with the requirements for pressure-cycled operation.

### 5.7 Assist Sensitivity

The sensitivity of the inspiration-initiation trigger to inspiratory efforts by the patient is also controlled by a spring force adjustment. Increasing the spring force by rotating the control knob in a clockwise direction decreases the sensitivity; i.e., the patient must exert a stronger inspiratory effort to initiate a new cycle. Because of the small pressures involved, this trigger is somewhat dependent upon input pressures to the respirator. Therefore, the maximum sensitivity is obtained as follows: Once the input pressure has been selected, the sensitivity control knob is turned counterclockwise until the respirator begins to free run; i.e., when it starts to cycle without an effort from the patient (and before the delay time has elapsed). The knob is then turned clockwise until the free run is just eliminated. Under these conditions, the sensitivity is about 0.5 cm $H_2O$ of negative pressure. With the control knob turned clockwise until it bottoms, the sensitivity is about 4 cm $H_2O$ of negative pressure. These sensitivities are within the limits set forth in the requirements.

### 5.8 Air Consumption

The input air flows to the respirator as a function of input air pressure are shown in figure 19. This curve sums the input flows to both fluid amplifiers. The peak consumption rate is 61 L/min of free air at an input pressure of 30 psig. In normal use, it is anticipated that the respirator would be operated at input pressures between 10 and 20 psig; the corresponding flows under these conditions are 33 to 47 L/min of free air.

The maximum pressure developed in the piston chamber (the pressure recovery of either fluid amplifier) is 30 to 35 percent of the input pressure to the respirator.

## 6. DISCUSSION AND CONCLUSION

The performance results show that with the exceptions noted previously, the respirator satisfies the performance requirements imposed on it. The respirator also has provisions for the administration of pure oxygen as the breathing gas and for a standard Army gas canister to filter incoming room air. Presently under

consideration is a method of mixing pure oxygen with room air to achieve an oxygen-enriched breathing gas. The only remaining functional requirement to be solved is that of providing humidification. Several types of commercially available humidifiers are now being investigated to determine their applicability to this respirator.

Medical evaluation of the first engineering prototype of this respirator (fig. 1) is now underway at WRAIR. The early results have been encouraging, although one minor difficulty arose. At times, the breathing valve malfunctioned in such a way that the respirator could not sense an inspiratory effort by the patient. The valve presently in use was designed at HDL because available commercial valves fell far short of acceptable performance. Their main shortcoming was failure to prevent gross leaking of breathing gases from the patient circuit during inspiration. The HDL valve was successfully modified to satisfy the earlier criticisms that had been made pertaining to its performance.

Three more prototypes of this respirator are presently being fabricated for field evaluation. The combined results of all evaluations (medical and engineering) will establish the clinical acceptability of this respirator.

## GLOSSARY OF MEDICAL TERMS

| | |
|---|---|
| Airway resistance | The pressure difference across the airway (between the mouth and the lungs) per unit flow, usually expressed as centimeters of water per liter of flow per second (cm $H_2O$/L/sec). |
| Assisted respiration | Artificial respiration which is synchronized with the inspiratory effort of the patient. |
| Compliance | The volume increase produced by a unit pressure increase in the lungs, 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 air delivered to the patient circuit per minute. It equals the product of tidal volume and breathing rate. |
| Patient circuit | That part of the respiratory circuit in communication 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. |
| Tidal volume | The amount of gas delivered to or breathed by the patient per breath. |

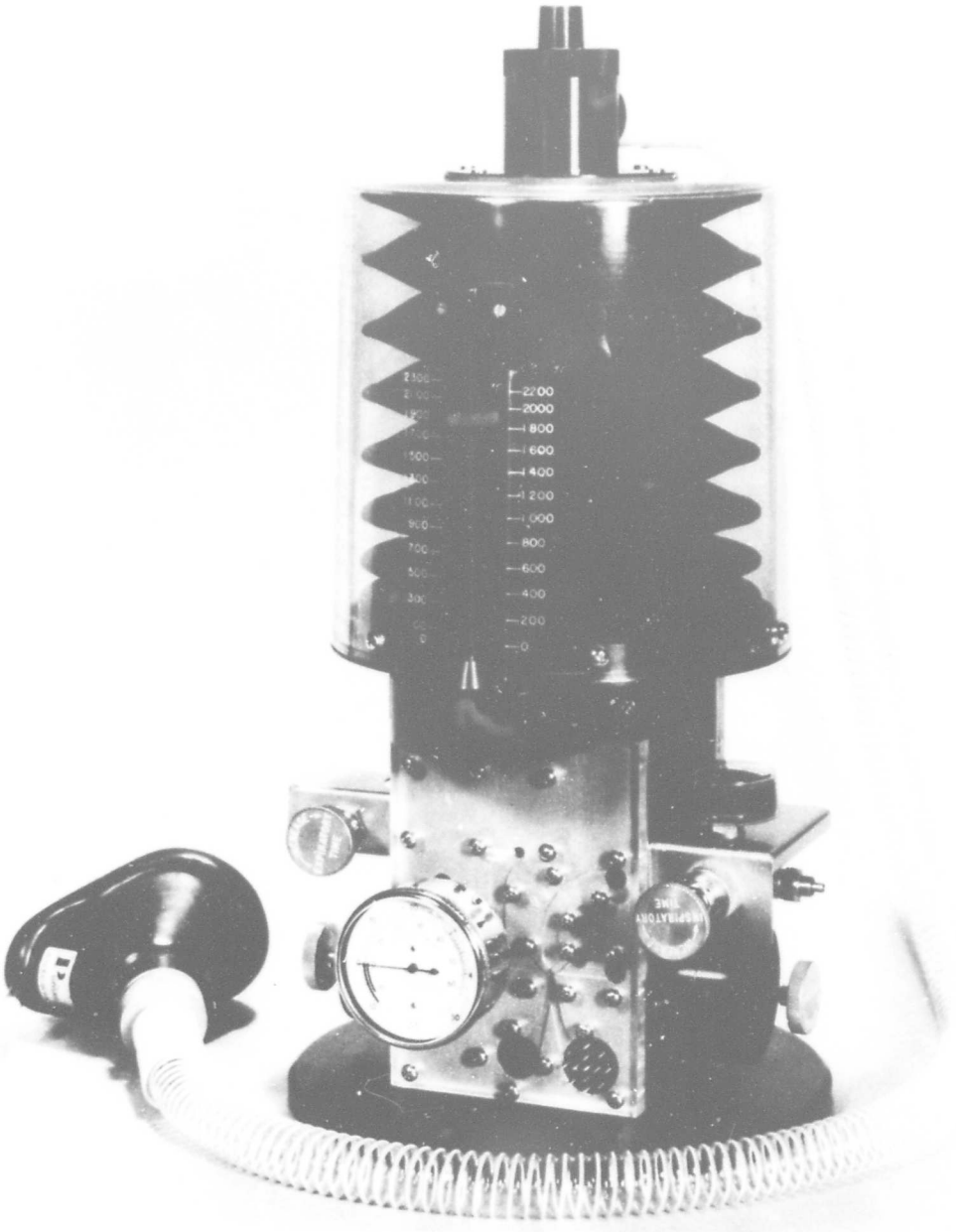


Figure 1. Army volume-cycled respirator.

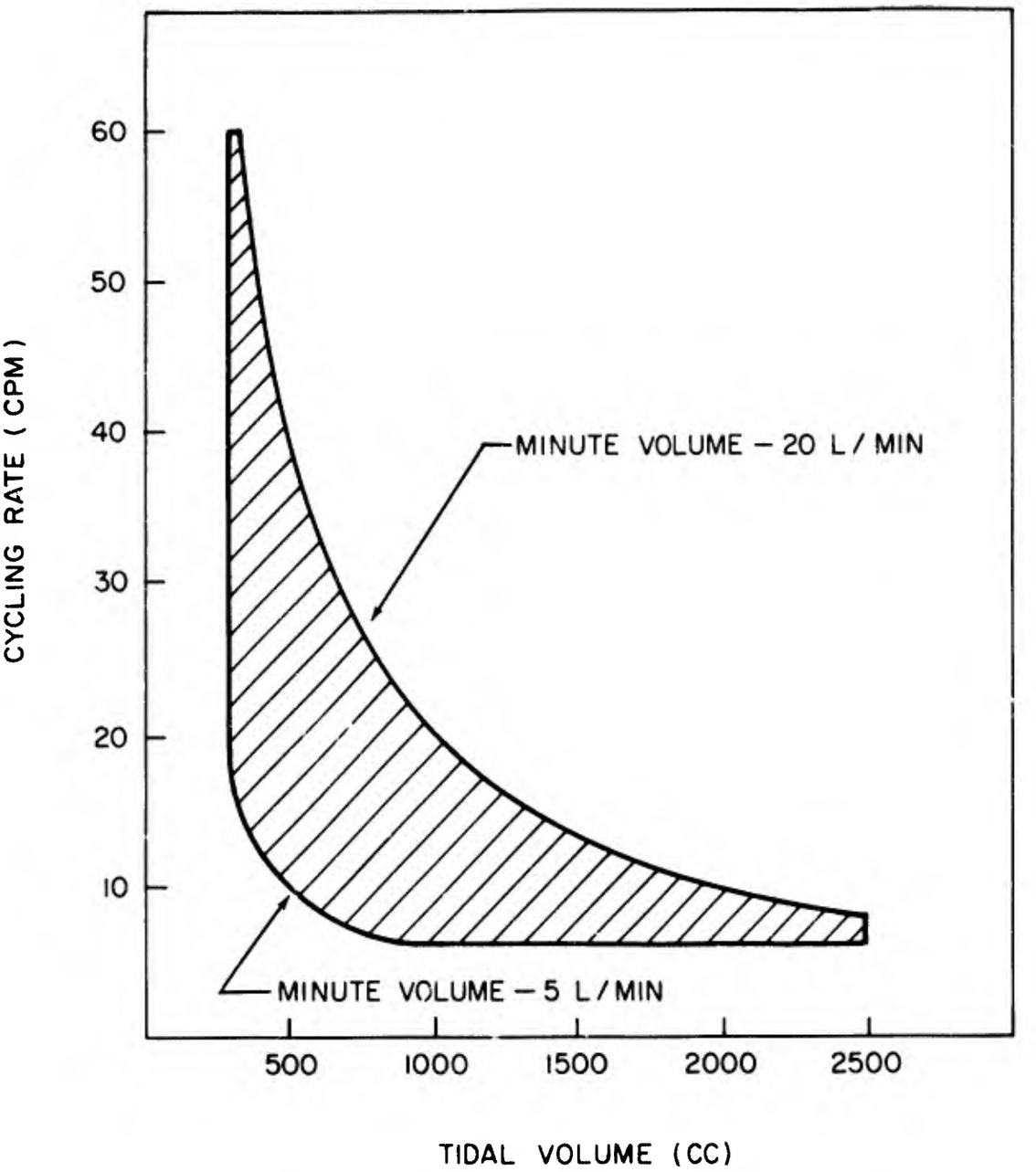


Figure 2. Requirements for cycling rate as a function of tidal volume.

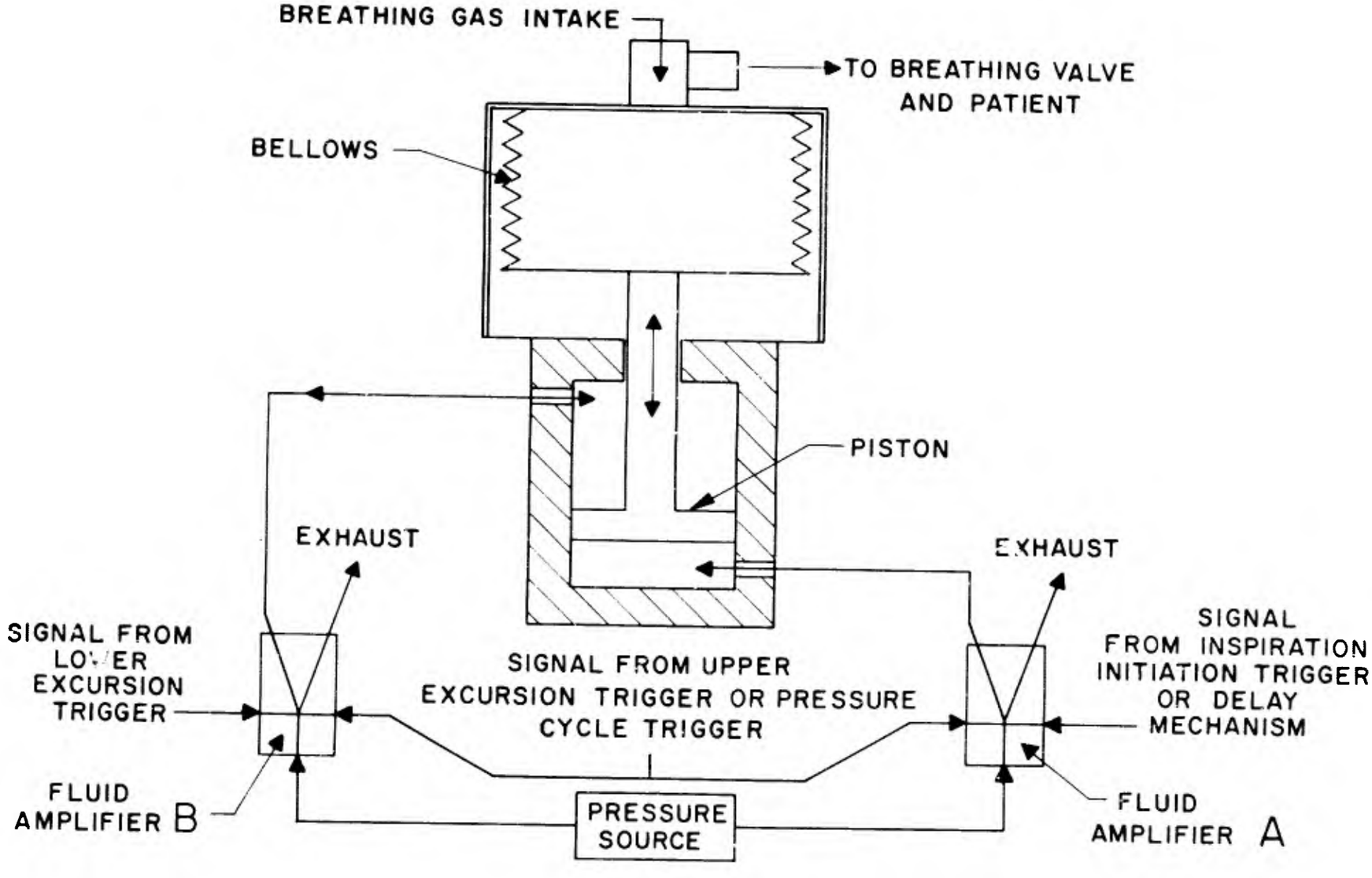


Figure 3. Volume-cycled respirator schematic.

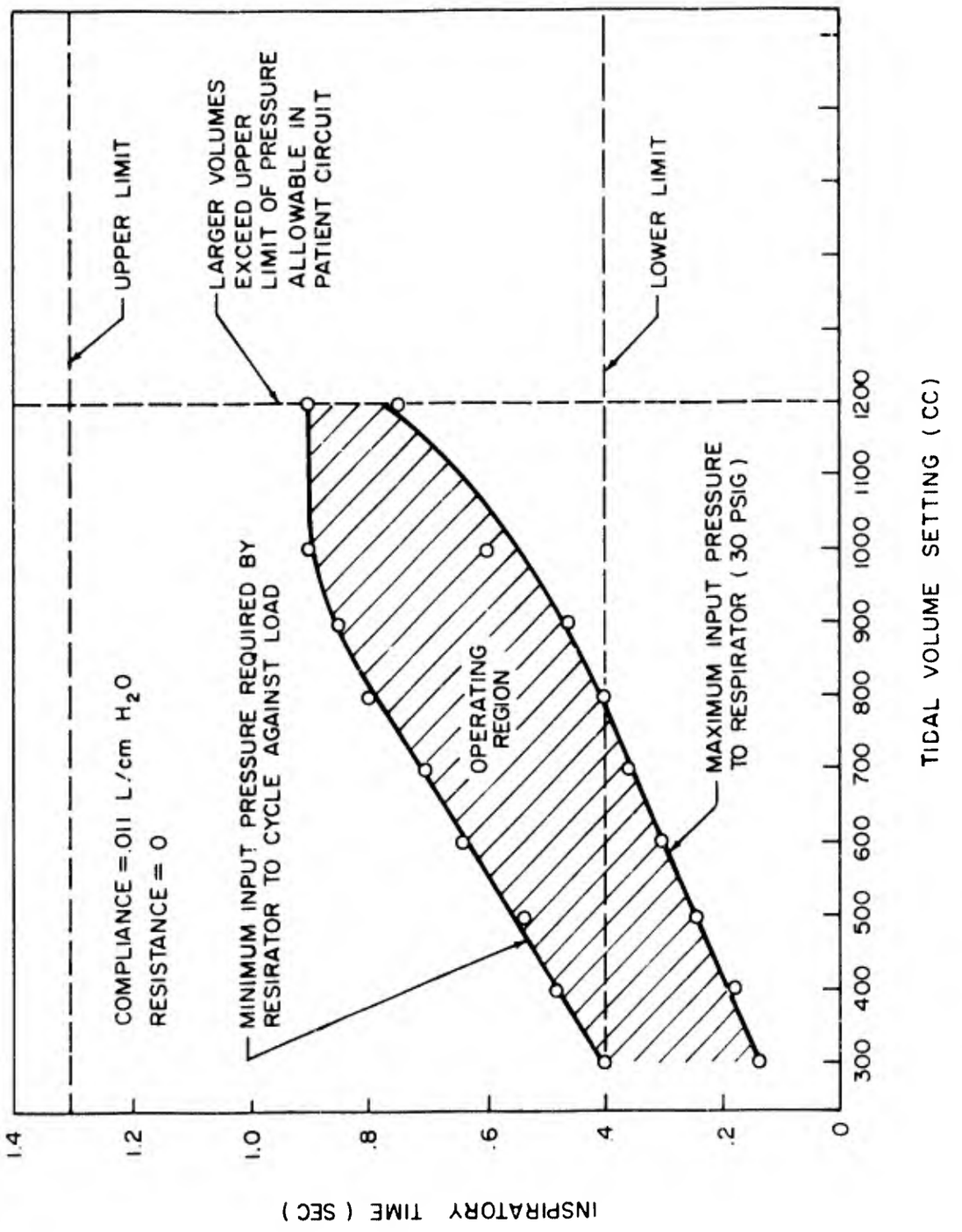


Figure 4. Inspiratory times—low compliance, no resistance.

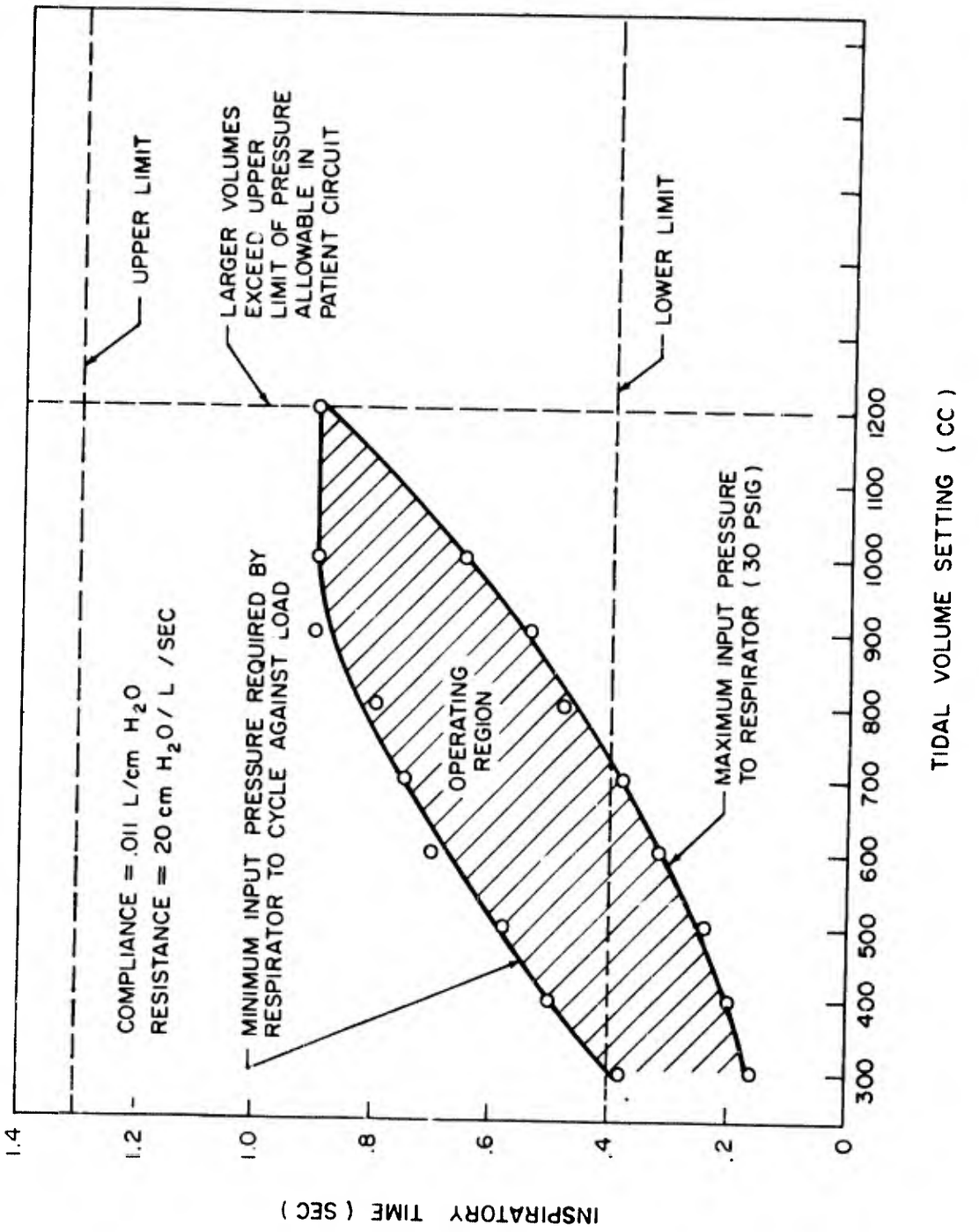


Figure 5. Inspiratory times--low compliance, maximum resistance.

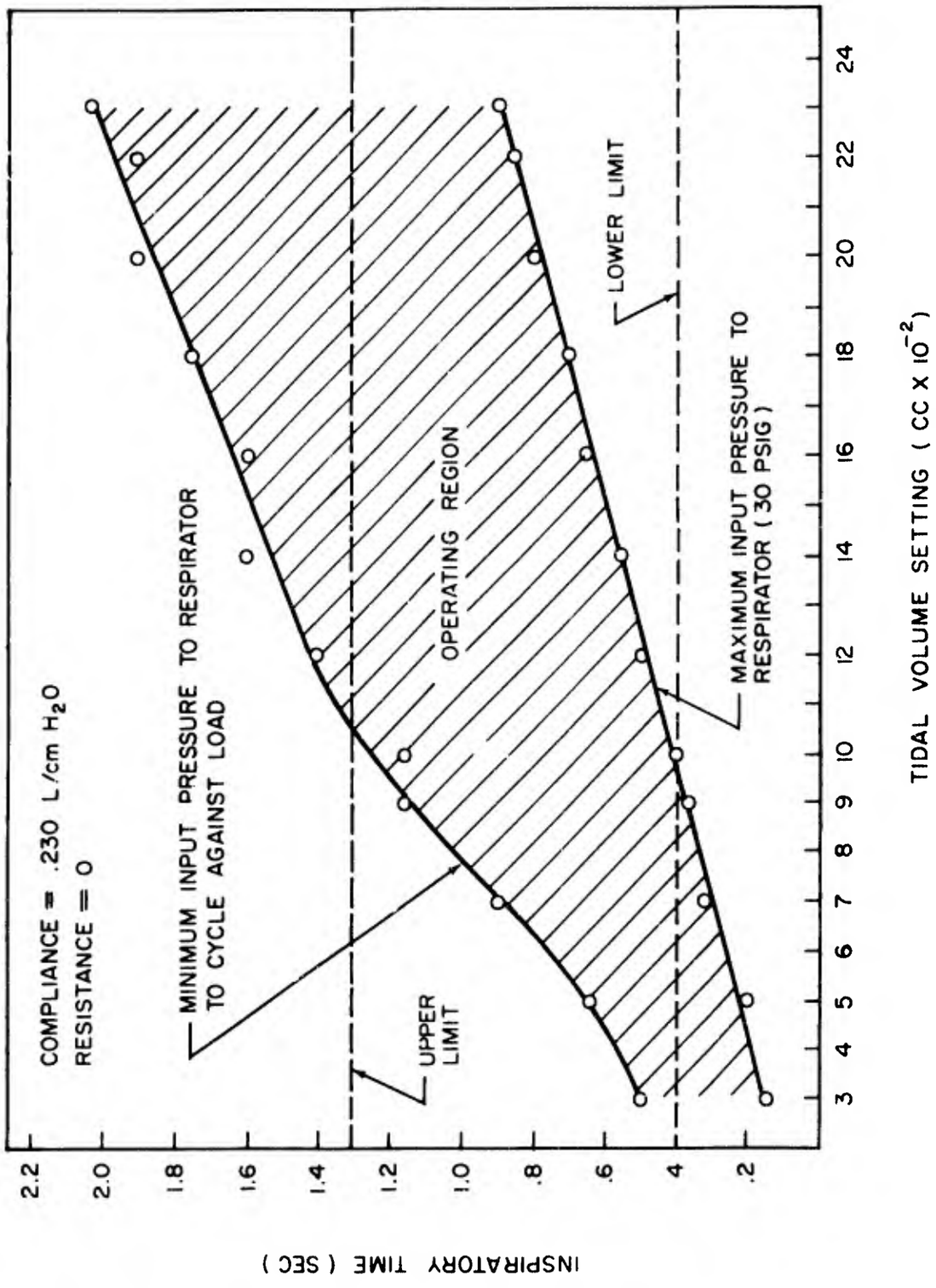


Figure 6. Inspiratory times—high compliance, no resistance.

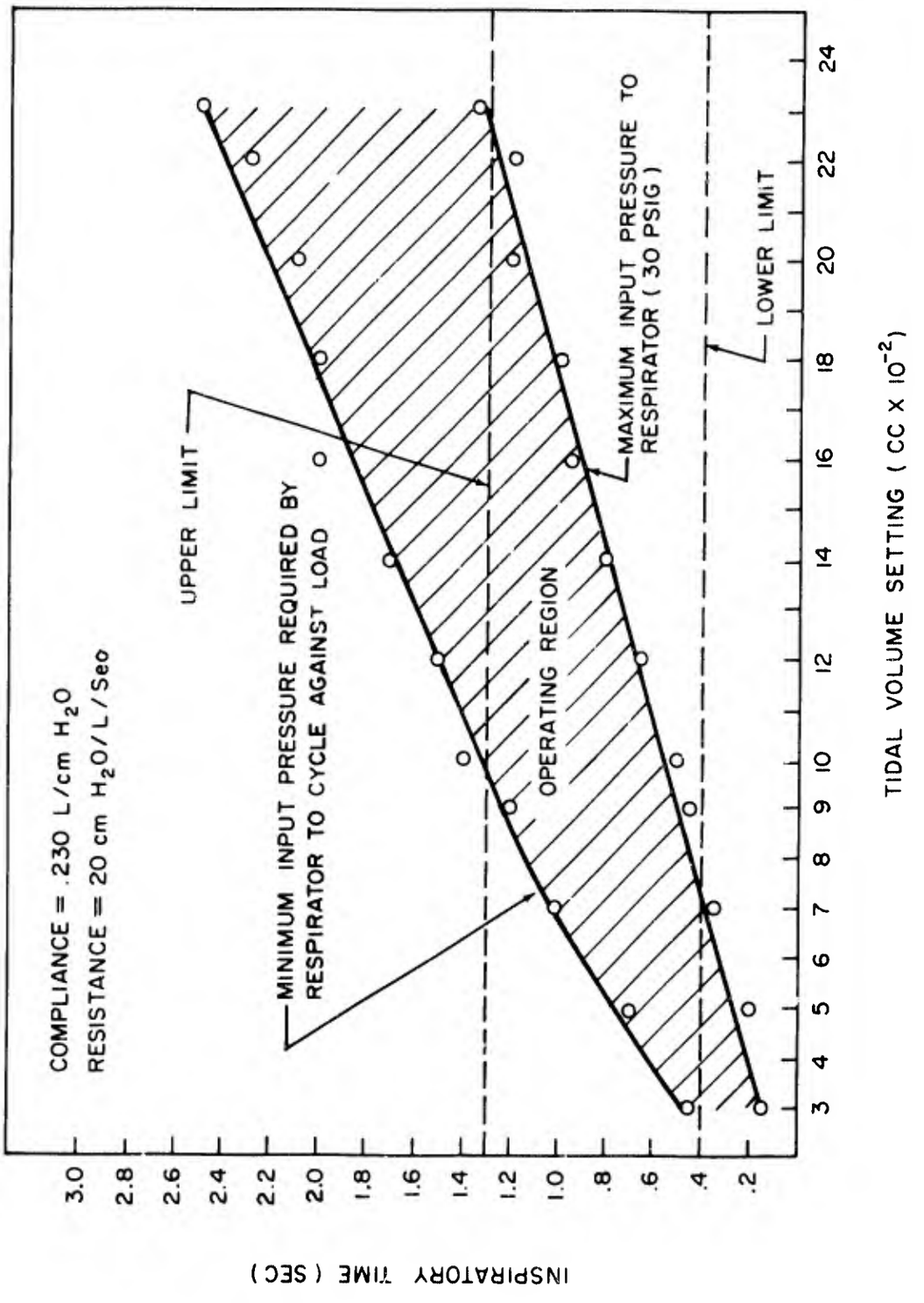


Figure 7. Inspiratory times—high compliance, maximum resistance.

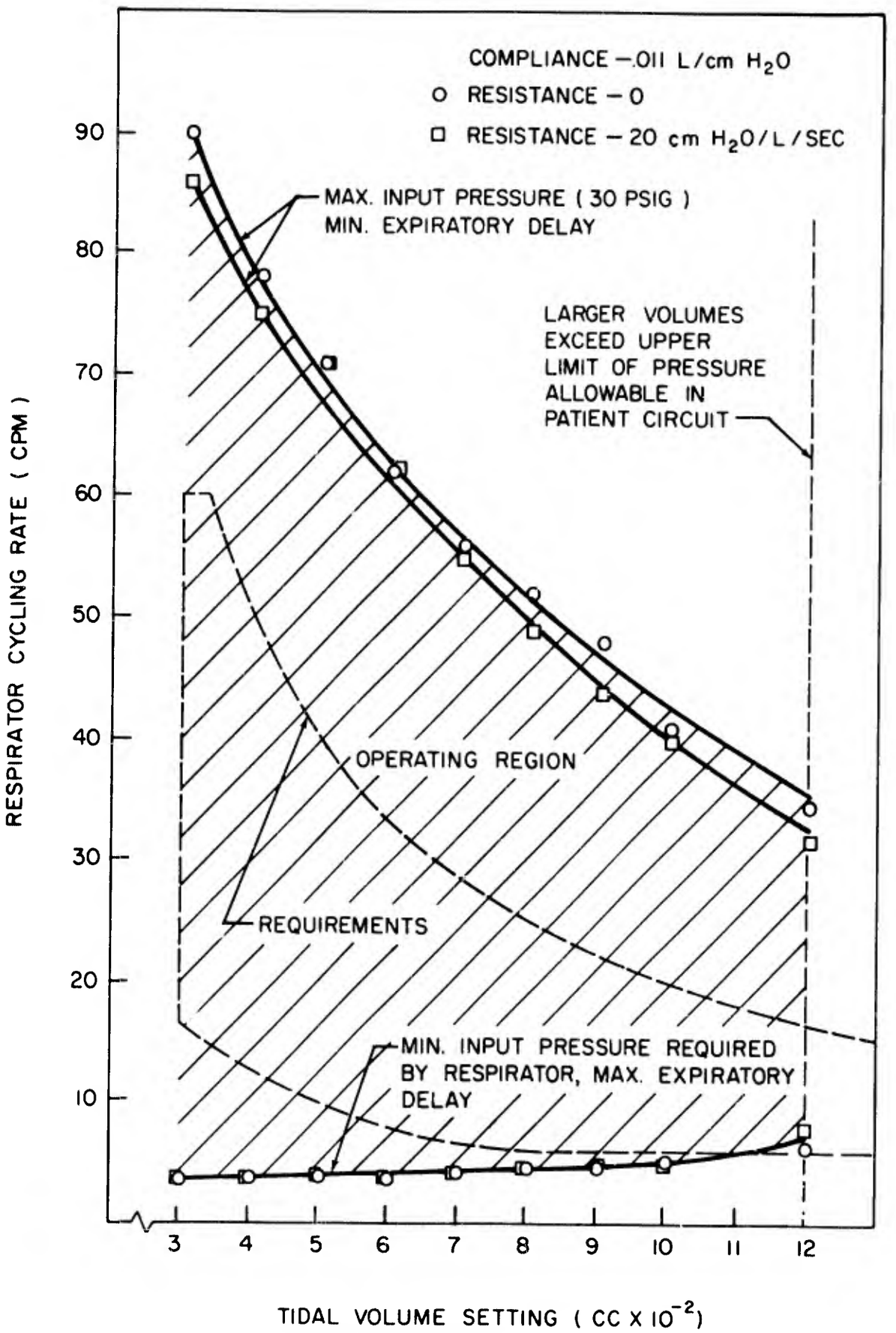


Figure 8. Cycling rates—low compliance.

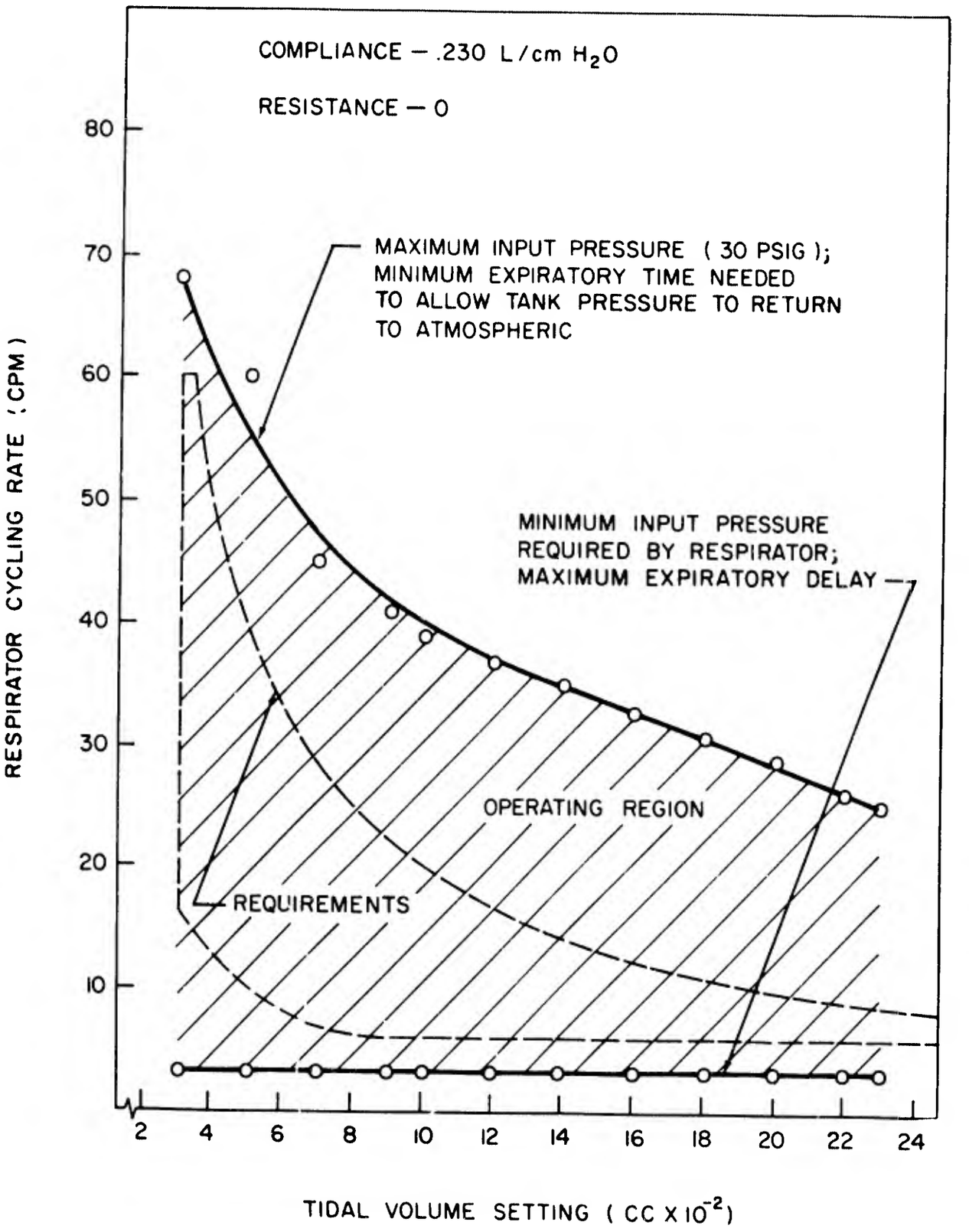


Figure 9. Cycling rates—high compliance, no resistance.

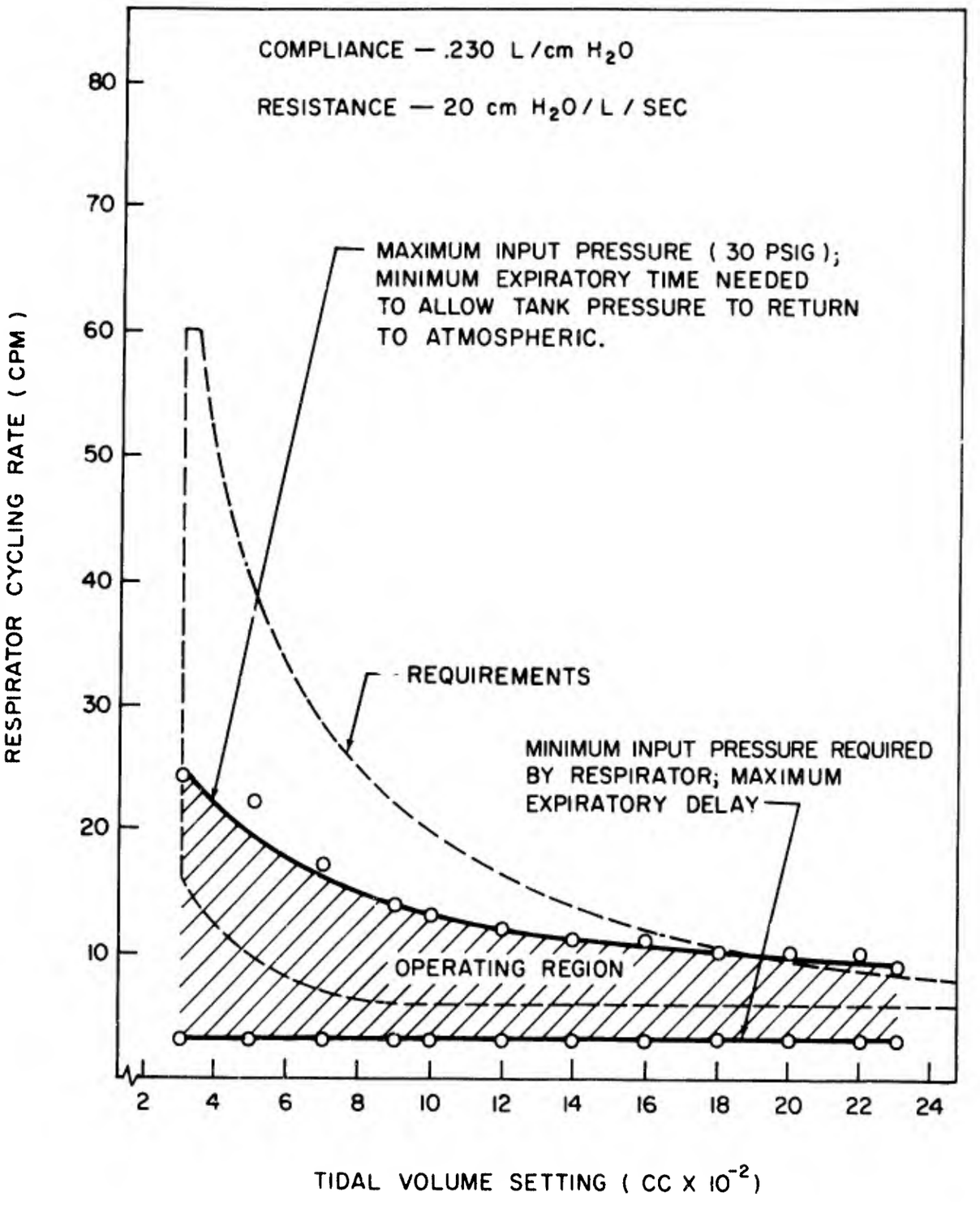


Figure 10. Cycling rates—high compliance, maximum resistance.

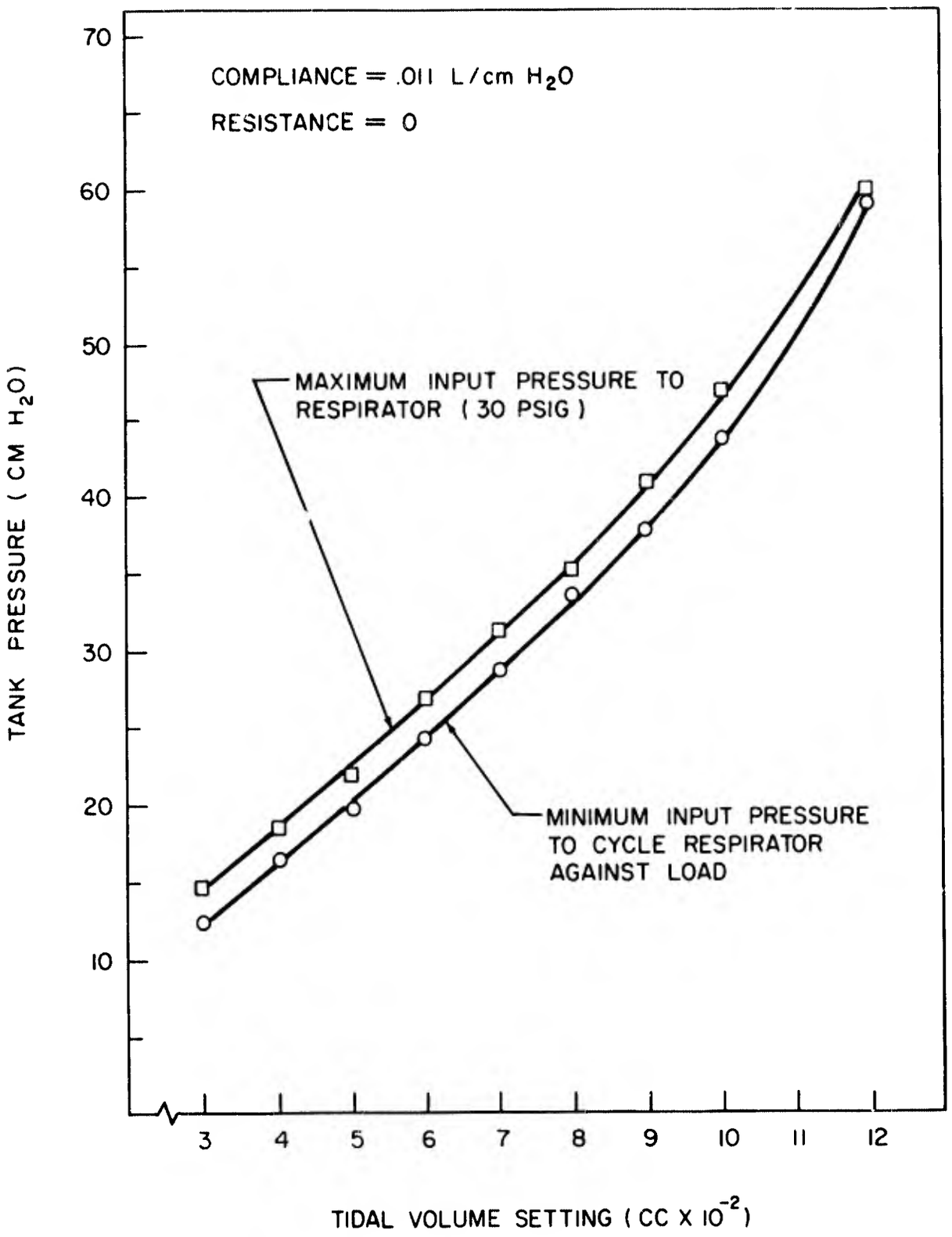


Figure 11. Pressures developed—low compliance, no resistance.

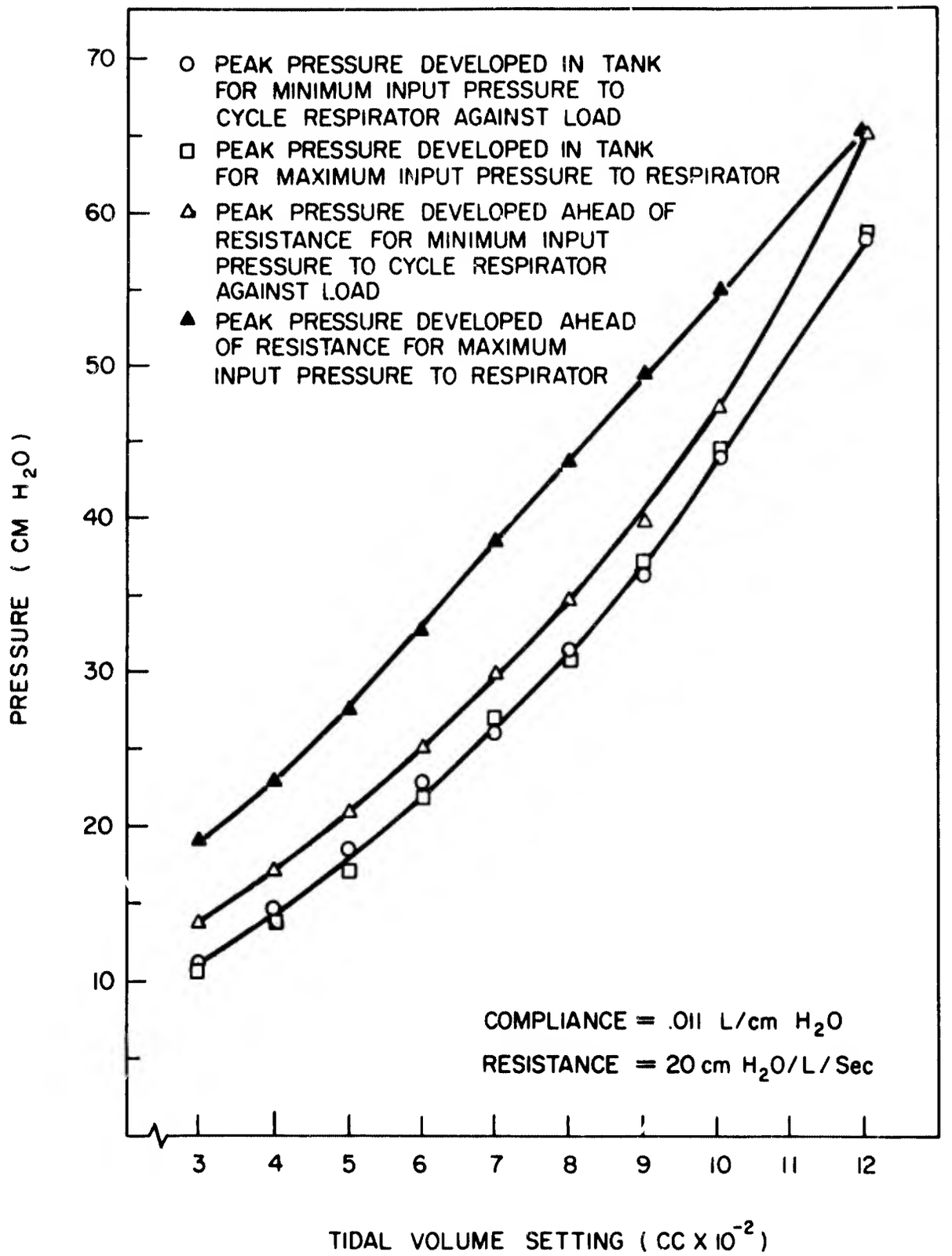


Figure 12. Pressures developed—low compliance, maximum resistance.

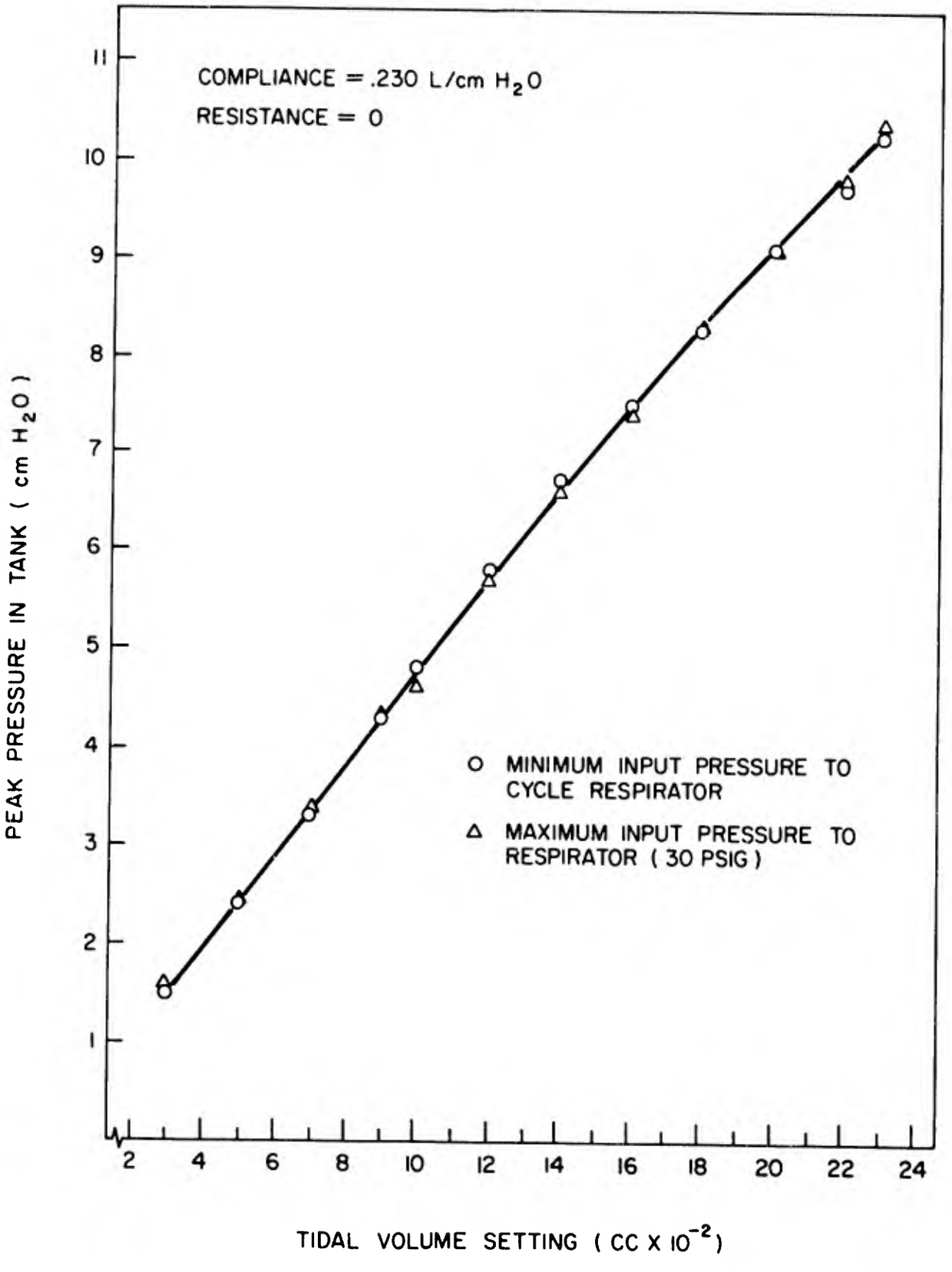


Figure 13. Pressures developed—high compliance, no resistance.

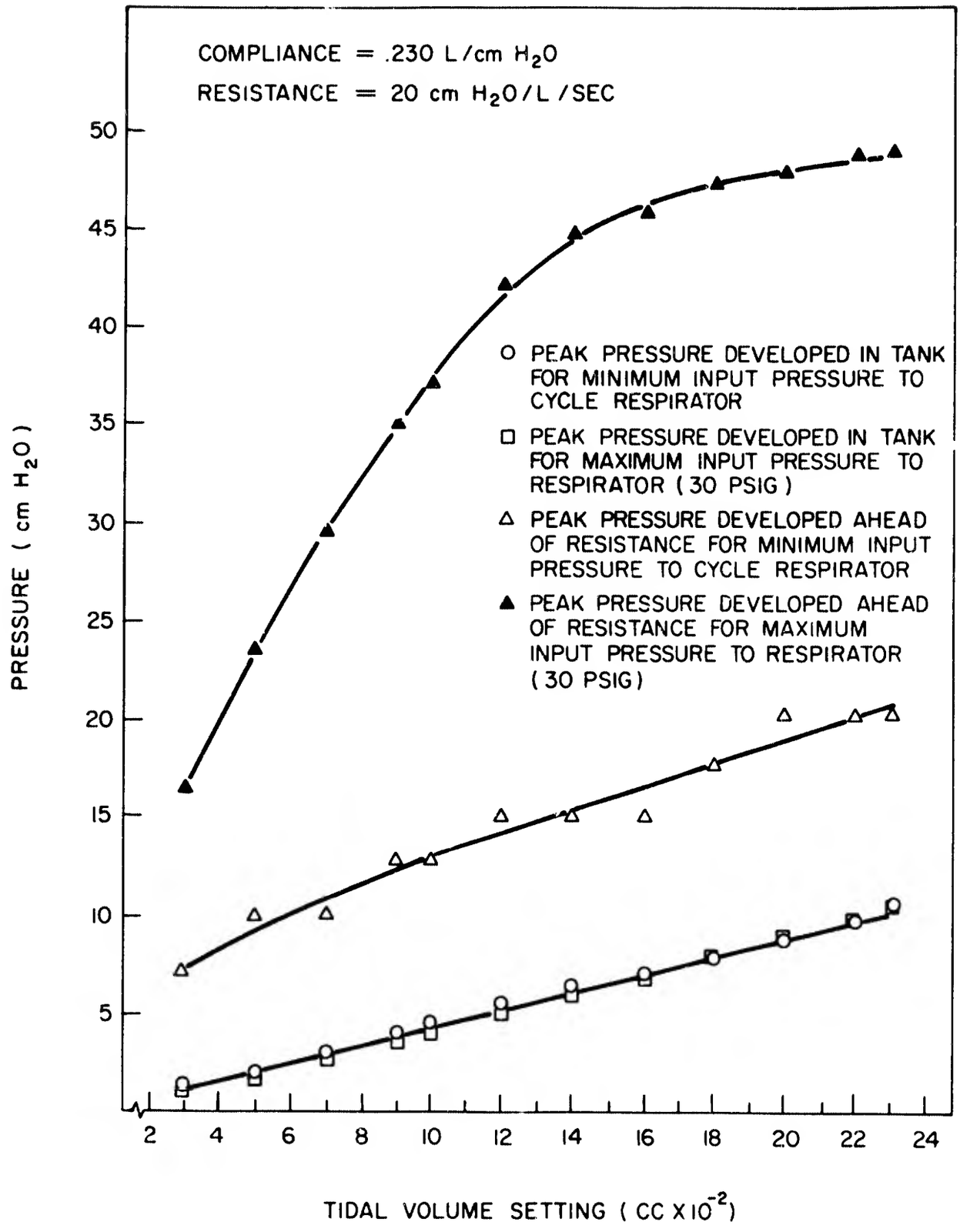


Figure 14. Pressures developed—high compliance, maximum resistance.

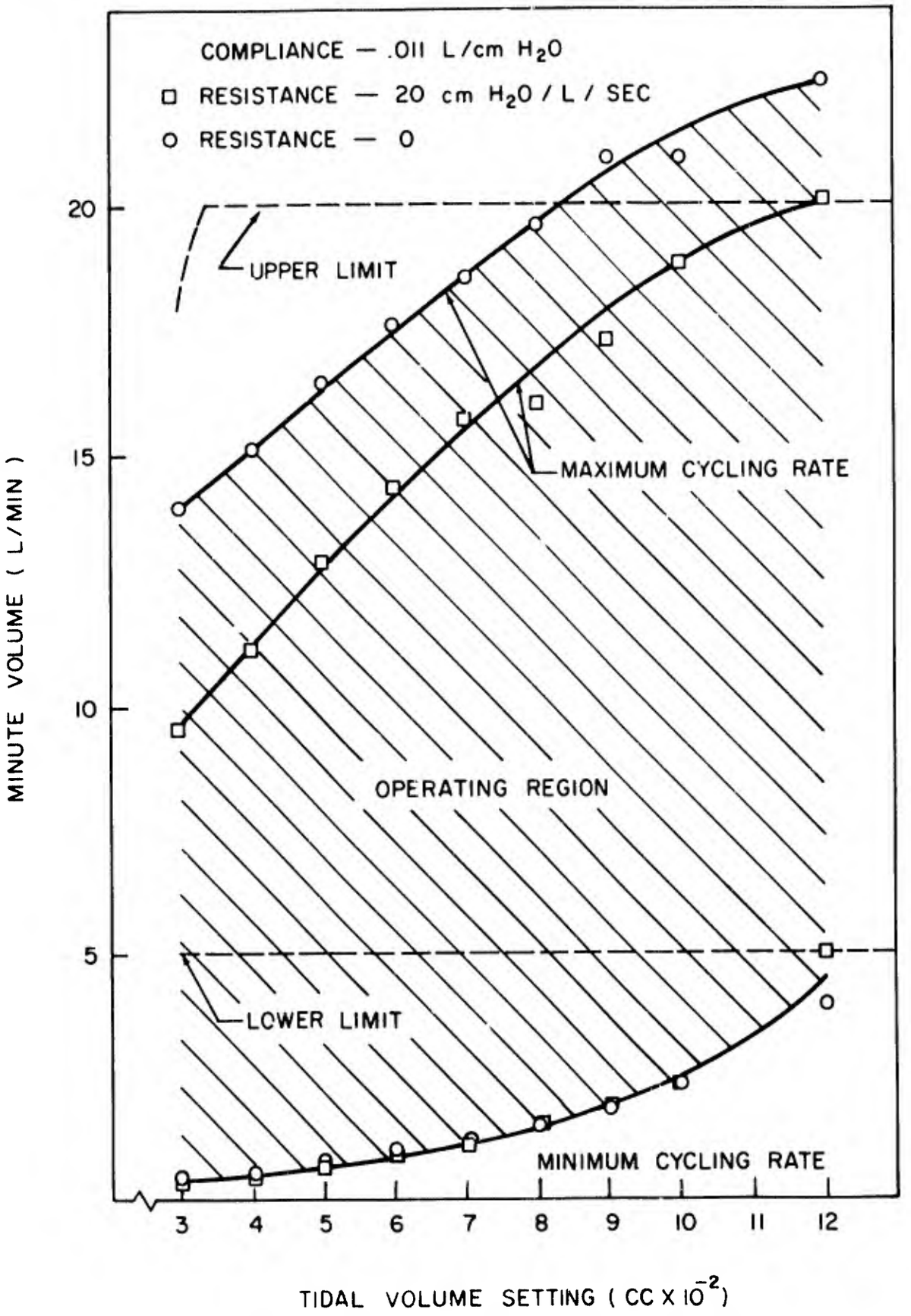


Figure 15. Minute volumes—low compliance.

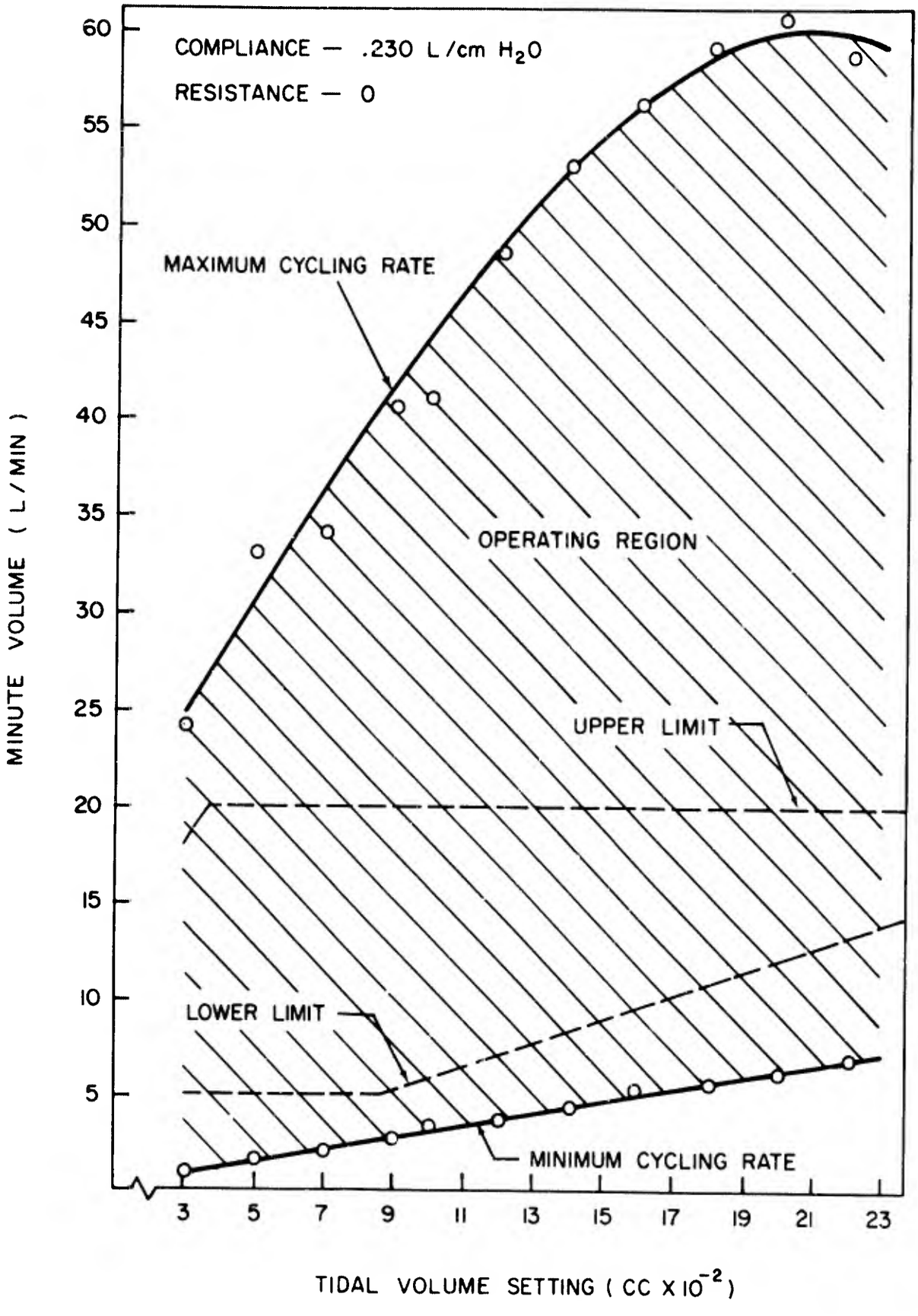


Figure 16. Minute volumes—high compliance, no resistance.

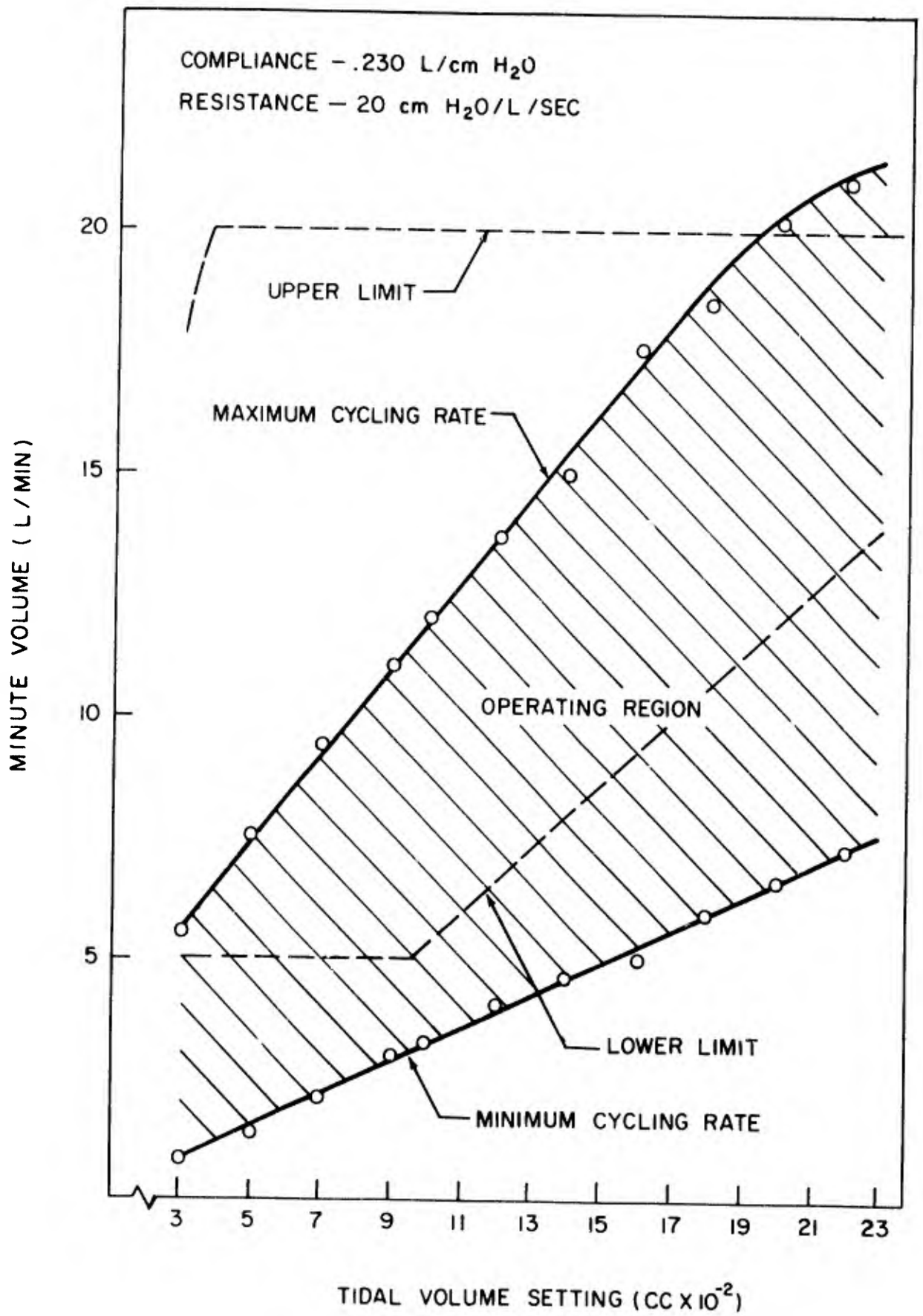


Figure 17. Minute volumes—high compliance, maximum resistance.

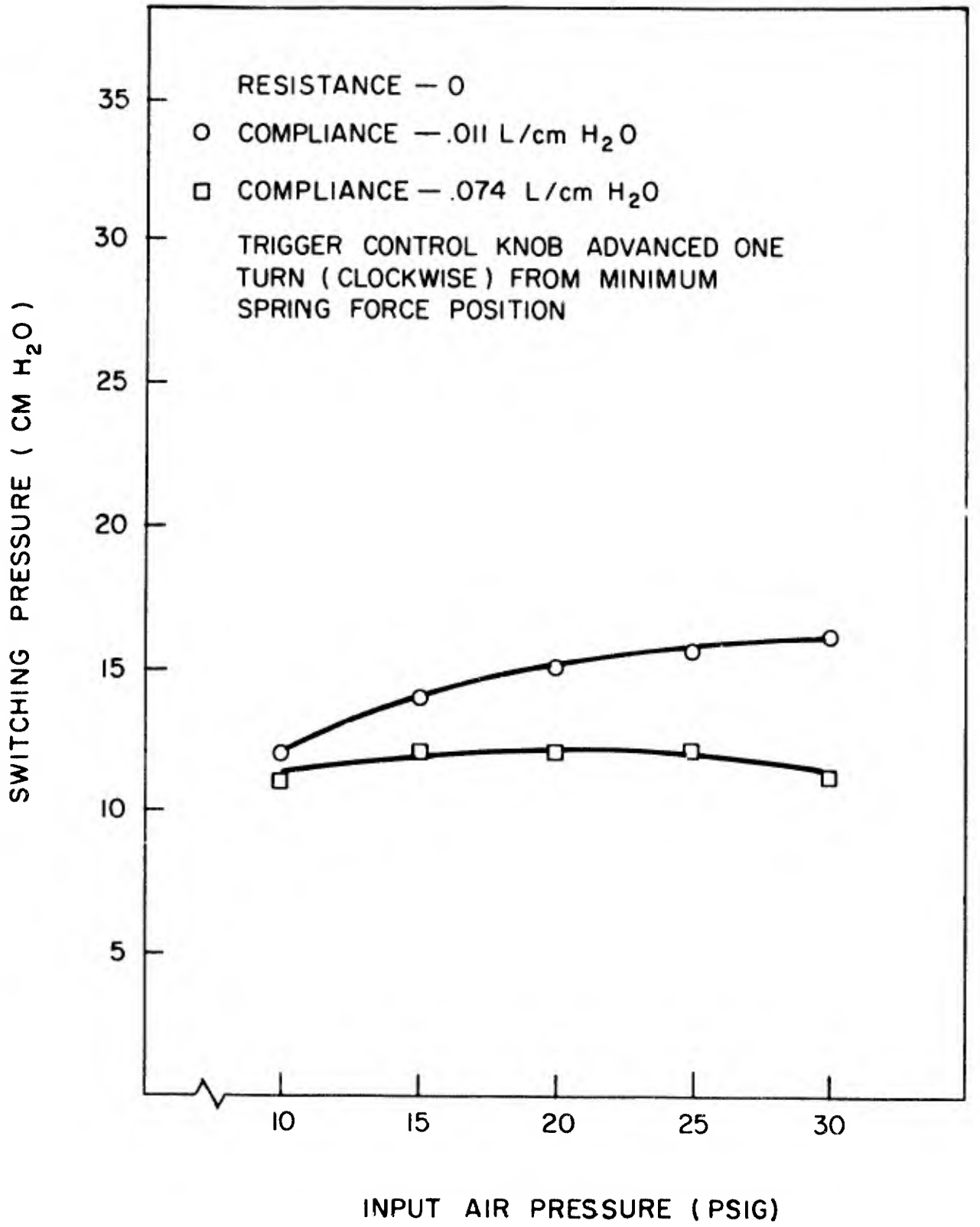


Figure 18. Dependence of pressure-cycling on input pressure and loading.

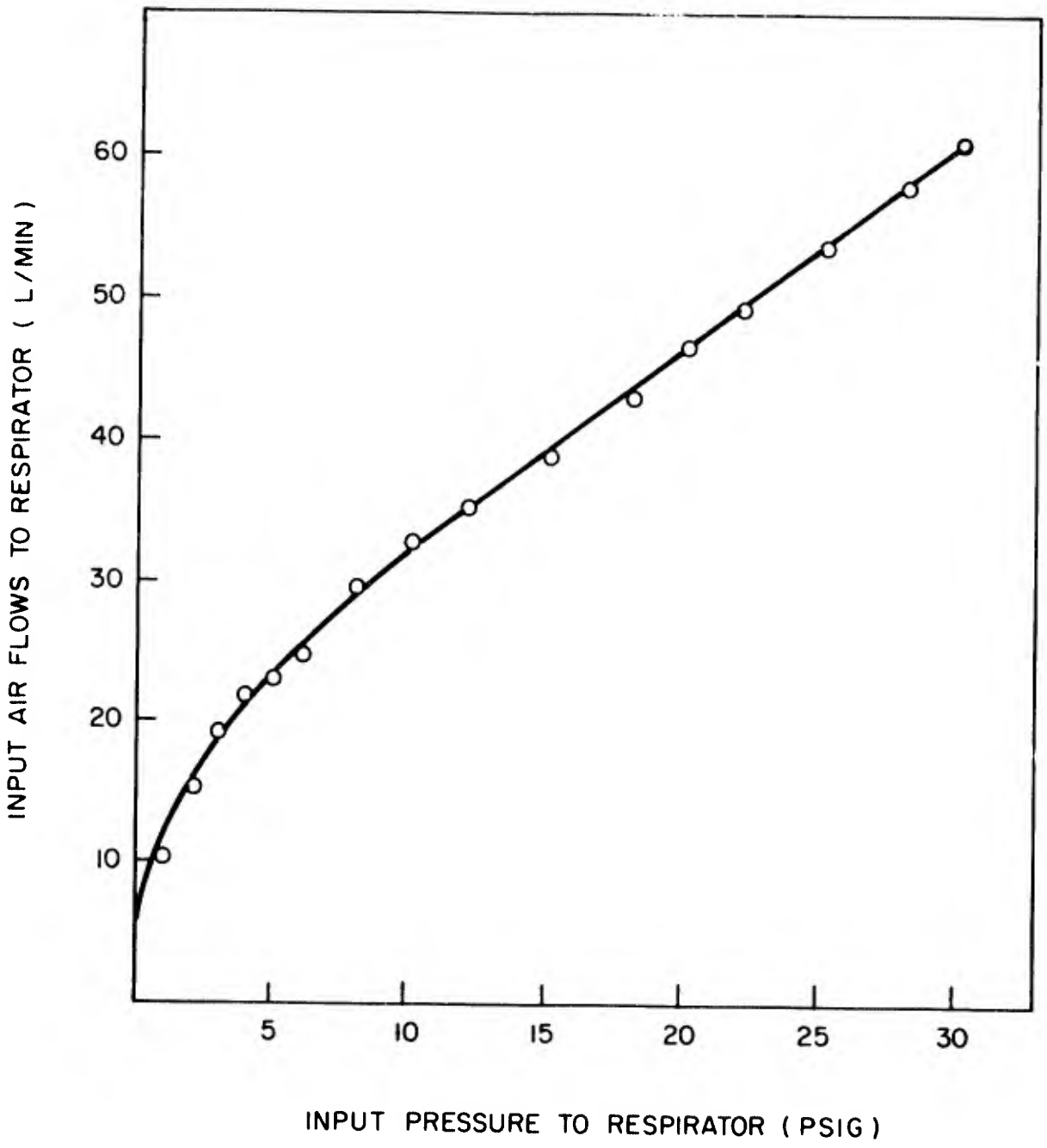


Figure 19. Air consumption rate.

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4. DESCRIPTIVE NOTES *(Type of report and inclusive dates)*

5. AUTHOR(S) *(Last name, first name, initial)*

Joyce, James W., Jr.

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13. ABSTRACT

The Army volume-cycled respirator is designed to assist or control the ventilation of patients; it must necessarily operate in military environments. Medical evaluation of the Model 1 prototype of this respirator demonstrated insufficiencies in the assist mode of operation and a need to expand the functional capabilities. This report describes the engineering tests performed on the Model 2 prototype of the respirator which is powered and controlled by two bistable fluid amplifiers (the Model 1 version used only one amplifier). The newer model can also be pressure-cycled.

The tests performed indicate that the Model 2 prototype satisfies the expanded set of requirements established for it with two exceptions. The exceptions pertain to the requirements for inspiratory times and minute volumes. Medical evaluation is now underway to determine the respirator's acceptability as a clinical tool.

DD FORM 1 JAN 64 1473

| 14. KEY WORDS | LINK A | | LINK B | | LINK C | |
|---|---|---|---|---|---|---|
| | ROLE | WT | ROLE | WT | ROLE | WT |
| Fluidic respirator | | | | | | |

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