31 December 1961

STUDIES ON RESUSCITATION AND ARTIFICIAL RESPIRATION

Progress Report

1 November 1960 - 31 December 1961

Contract DA-49-007-MD-507

Health Research, Inc.
Buffalo 3, New York

James O. Elam, M.D., John L. Evers, Ph.D.

Supported by: Research and Development Command, Office of the Surgeon General, Department of the Army, Washington 25, D.C.

ABSTRACT

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   XI. Anatomical Dynamics of the Upper Airway (film report).

   XII. Training Medical and Lay Personnel in Heart-Lung Resuscitation.

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I. A NEW MANUAL AIR BAG INFLATOR (MABI)

Since 1957, the bag and mask resuscitator (Ambu) designed and introduced by Dr. Henning M. Ruben of Denmark has become a recognized and valuable field emergency unit. Its well-known advantages include:

a. Independence from power sources such as compressed gas and electricity;

b. Conventional components of proven merit readily accepted by anesthesiologists;

c. Visible performance of non-rebreathing valve by operator;

d. Optional oral and/or nasal routes of inflation and expiration.

However, among the several available versions of the Ambu resuscitator, a number of criticisms and disadvantages have been noted by various users:

a. General

1. Lack of standardized technic of use, especially for training beginners. This has resulted in poor performances with the unit by lay trainees in the studies of some investigators while others have demonstrated excellent results when the technic taught insured proper continual positioning of the victim's head and proper fit of the face mask.

2. Inability of neophytes to simultaneously prevent upper airway obstruction and maintain position of the mask.

3. Non-adaptability of certain Ambu-type units to inhalator usage for high-oxygen % administration to the adequately breathing patient (non-rebreathing valve's neutral position allowing patient to inspire atmospheric air through expiratory part instead of only the bag content).

b. Mask

1. Lack of universal mask size which fits a wide variety of facial contours (edentulous, micrognathic, or craggy-featured patients).

2. Deterioration of inflatable face cushion.

c. Valves

1. Deterioration or distortion of latex valves in certain Ambu-type units.
2. Sticking of moving parts as a result of neglected cleaning of mucus, etc.
3. Difficulty in cleaning and removing dried secretions in some units as a result of difficult disassembly.

d. Bag

1. Deterioration of latex (solved by use of neoprene in some units).
2. Conflicting recommendations regarding size of bag (adult sizes range from one to 3.3 liters). Some feel the size of the bag is one aspect of the safety requirement to preclude excessive pressure. Others feel higher volume is necessary to compensate against leaks at the mask.
3. Variations in the compression compliance and in the recoil characteristics of sponge liner (foam rubber or polyether) interfering with detection of changes in patient's resistance and compliance.

In recent years, the Ambu and similar units have been adapted for use with ether and Fluothane vaporizers for emergency anesthesia apparatus (EMO and PUFFA). Thus the Ambu device promises to serve the dual purpose of emergency respiratory resuscitation and a simple practical apparatus for inhalation anesthesia. Our modifications of the Ambu unit have attempted to overcome the several criticisms and, thereby, extend the utility and acceptance of this ingenious contribution to simple effective resuscitation.

Description and Features of a Manual Air Bag Inflator (MABI):

MASK: The folding vinyl mask previously developed in this department was further modified with a soft, sponge-rubber-filled, wide perimeter cuff (Figure 1). The unique features of this mask are its compact shape and size, its built-in tendency to fold inward from the lateral margins to form a snug seal against the face of both normal and elderly edentulous patients. Trials in anesthetized patients by both experts and neophytes have demonstrated the ease of obtaining and maintaining a pneumatic seal. The configuration of the mask permits maintenance of this seal without excessive

pressure with only the rescuer's thumb and forefinger holding the mask around the ferrule. As in all other mask-holding technics, the other three fingers are placed along the body and symphysis of the mandible. A standardized 1-2-3 maneuver of simple steps permits efficient and adequate training of beginners (illustrated in this report in the section on training):

1. Applying mask with patient's mouth open;
2. Establishing head-tilt position;
3. Compressing bag against patient's head until chest rises.

NON-REBREATHING VALVE: A new simple Sphere Valve was developed by which the inspiratory-expiratory action is based on aerodynamics (Bernoulli's principle and differential diameters) rather than spring-loaded design (Figure 2). This valve has acceptable resistance characteristics (Table I), performs reliably during both positive pressure and spontaneous breathing, and therefore meets the ancillary requirement of delivering oxygen from the bag during spontaneous breathing (inhalator function). An incidental safety feature of this non-rebreathing valve allows the sphere to reverse its normal cycle and permit the patient to inhale through the expiratory port when the oxygen supply to the bag fails. The reversal occurs at less than 1 cm. H_2O pressure. The delicate balance of the sphere, positioned to move between the inspiratory and expiratory seats during weak spontaneous breathing, permits the rescuer to observe minimal inspiratory effort by the patient. Inspiratory movement of the sphere serves as a convenient aid for both detecting and teaching manually assisted respiration. A similarly visible Sphere Valve is employed at the intake opening of the bag (Figure 2). The outside diameter of this valve housing is 15/16 inch to provide direct coupling of a standard anesthesia breathing tube leading from a vaporizer of liquid anesthetic agent or anesthetic gas reservoir. The cleaning of all valve parts with soap and water with or without disassembly is simple.

BAG: A new neoprene bag has been developed by Air Shields Incorporated (Figure 3). This bag is superior to its predecessors in all of the characteristics and criticisms previously listed. It provides adequate sensing by "feel" of patient's resistance because of (1) high compliance of a foam rubber (butyl-dipped) liner without sacrificing adequate recoil characteristics, and (2) the loose state of the bag surrounding the liner unlike the stretched state of one of the five liter Ambu-type bags

lined with polyether sponge. The volume of the new neoprene bag is 2400 cc. providing both a safe maximal tidal volume for all adult patients while preserving the safe-pressure feature emphasized by Ruben. The 2400 cc. volume is sufficient to compensate for mask leakage (Table II). A schematic view of MABI showing operating range of motion of the Sphere Valves and cross sectional view of the neoprene bag is shown in Figure 4. An important feature of the bag is the use of specially formed end bushings which are glued both to the bag and liner, preventing the openings in the sponge liner to shift and partially occlude the end openings, thereby causing sluggish refilling as a result of increased resistance.

GENERAL: 1. Our experience with MABI suggests that standardized technic of use may be achieved.

2. The cuffed folding mask extends the fitting over a wide range of facial sizes and contours.

3. Substitution for the mask with a nasopharyngeal tube, described in another section of this report, eliminates the difficulties of training in mask-holding technics and improves the reliability of the neophyte to maintain an unobstructed upper airway in the unconscious subject.

4. The Sphere Valve provides versatility for the manual inflator to include:

   a. manually-operated resuscitator employing ambient air;

   b. manually-operated resuscitator using oxygen;

   c. non-rebreathing apparatus for anesthetic vaporizers and anesthesia circuits;

   d. manually-operated assistor employing detection of minimal patient effort assuring simple technic for assisting inadequate ventilation;

   e. improvised visual inspection of valves, both sphere, non-rebreathing, and intake, during use;

   f. simple disassembly, cleaning, and reassembly - usually flushing the intact non-rebreathing valve with soap and water suffices;

   g. rugged design of sphere valves provides long life; the lack of delicate valve parts and springs simplifies care of unit.

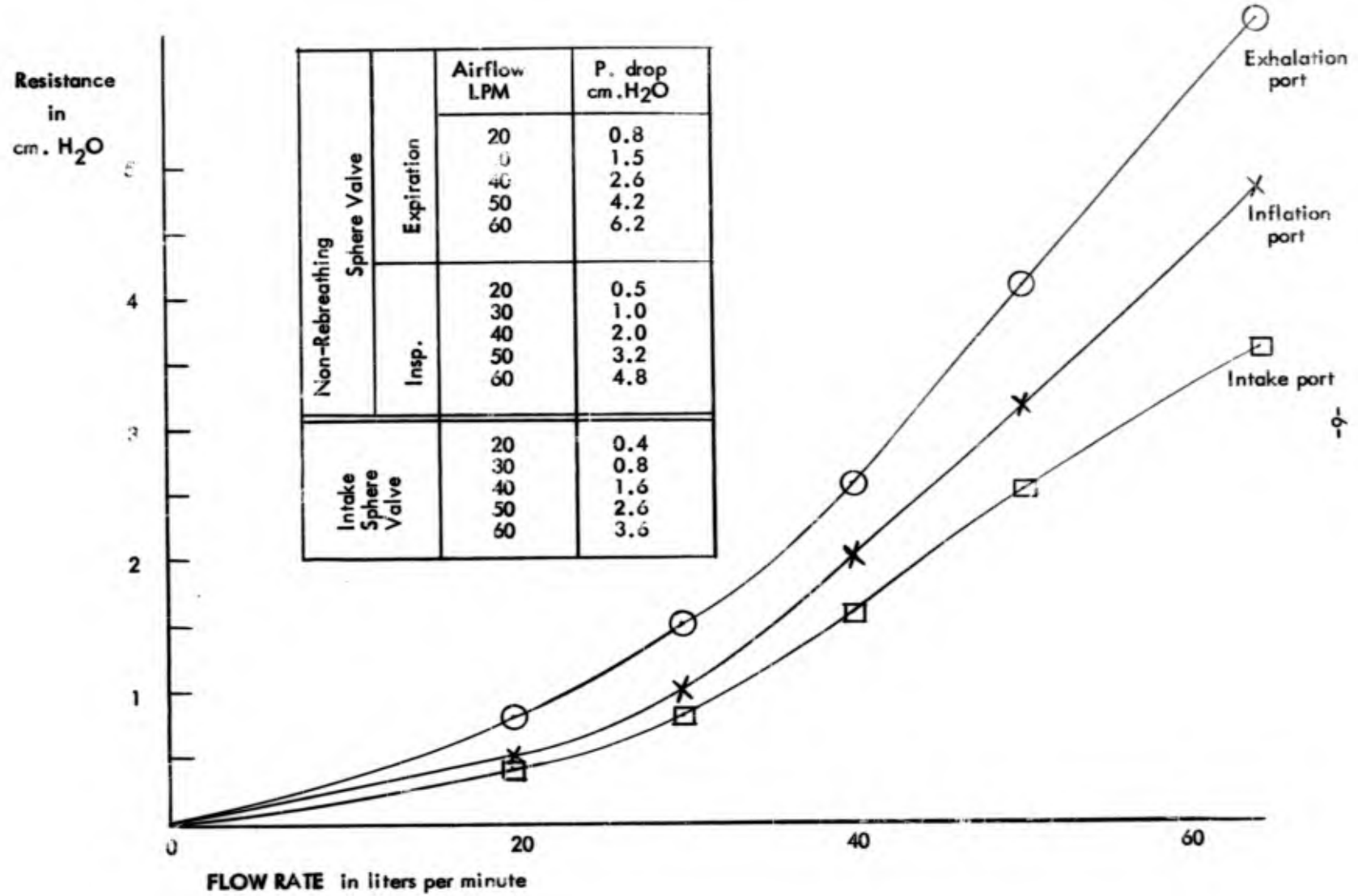
Figure 5 and accompanying chart illustrates and lists the five Ambu or Ambu-type units and MABI. All have standard size adaptors to anesthesia masks (outside diameter of NRB valves) and to standardized tracheal tube adaptors (inside diameter of NRB valves).

COMMENT: Comparison of performance of the five manual bag inflators shown in Figure 5 by one operator ventilating the "normal" lung model yielded tidal volumes of 875 to 1400 cc. This range was reduced to 650 - 850 cc. with a calibrated 4 mm. leak at the "mask" (coupling between non-rebreathing valve and "lung").

The pressures produced by these test inflations ranged from 28 to 37.5 cm. H_2O without leak and from 20 to 23.5 cm. H_2O with the 4 mm. leak.

The maximal possible rate of manual compressions showed greater variations, 25 to 38 per minute. Although the largest bag, (Pulmonator), obviously had a more brisk recoil from the action of its polyether liner, the minute volume performance with this unit was equivalent to that of MABI and Ambu (Air Shields). The fully expanded resting state of the Pulmonator, its stiff compliance on compression, and its brisk recoil deny the operator of being able to feel and sense the pressure required to inflate the lungs. It appears therefore, that the oversize Pulmonator bag affords no advantage in performance and a disadvantage from a clinical standpoint. Since no operator's hand is large enough to surround the large Pulmonator bag or gather it in his hand to empty it, its large size is unwarranted. Another defective operation occurred in the Pulmonator tests: The Lewis-Liegh non-rebreathing valve tended to "lock" in the position obstructing passive exhalation frequently, thereby causing undesirable increases in sustained positive pressure applied to the "lung" and rebreathing. This valve locking and all of the performances of these units are reproduced (Figures 6 - 11) in the next section of this report.

MABI is not commercially available but may be obtained for field trials in limited quantity. The Sphere Valve assemblies are applicable for the non-rebreathing technics commonly employed in anesthesia.



		Airflow LPM	P. drop cm.H_2O
Non-Rebreathing Sphere Valve	Expiration	20	0.8
		30	1.5
		40	2.6
		50	4.2
		60	6.2
	Insp.	20	0.5
		30	1.0
		40	2.0
		50	3.2
		60	4.8
Intake Sphere Valve		20	0.4
		30	0.8
		40	1.6
		50	2.6
		60	3.6

TABLE I. RESISTANCE CHARACTERISTICS OF SPHERE VALVES (MABI)

Resuscitator	Maximum Bag Volume in Liters	Tidal Volume* in cc.		Pressure in cm.H_2O		Rate of Manual Compression per min.		Minute Volume in LPM	
		No Leak	Leak**	No Leak	Leak	No Leak	Leak	No Leak	Leak
	A	B	C	D	E	F	G	B x F	C x G
1 MABI 5	2.4	1400	850	37.5	22.0	25	25	35.0	21.25
2 Ambu (Air Shields) 6	1.5	1200	750	32.5	22.5	29	33	34.8	24.75
3 Pulmonator (DuPaCo) 7	3.3	1200	800	37.5	23.5	29	30	34.8	24.0
4 Ambu (Danish S & W) 8	1.5	875	650	28.0	20.0	38	38	33.25	24.70

*Ventilating lung model of compliance 0.04 L/cm.H_2O and resistance of 2 cm.H_2O/liter/second.
**Standardized leak of 4 mm. diameter opening at coupling of NRB valve to lung model.

TABLE II. PERFORMANCE OF MABI AND AMBU - TYPE RESUSCITATORS

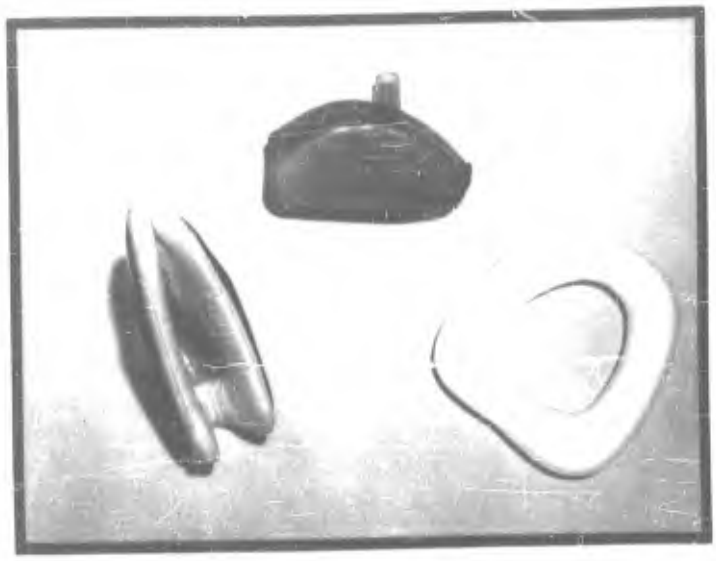


Figure 1. Folding Vinyl Mask with soft wide-perimeter cuff (sponge).

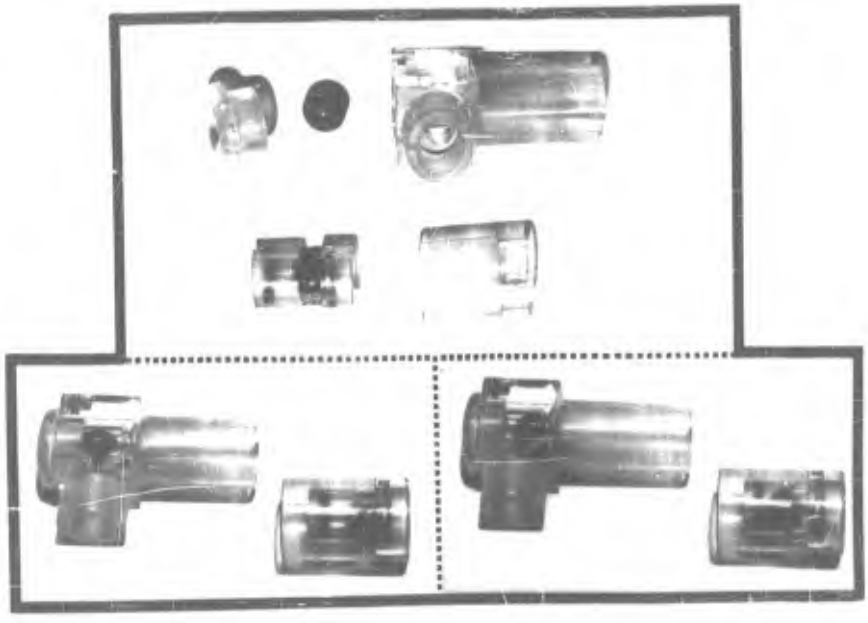


Figure 2. Sphere Valves for Intake and Non-Rebreathing with MABI. Polyethylene spheres of 1/2 inch diameter are removable for cleaning (upper). Spheres move aerodynamically with inflation (lower left) and exhalation (lower right).

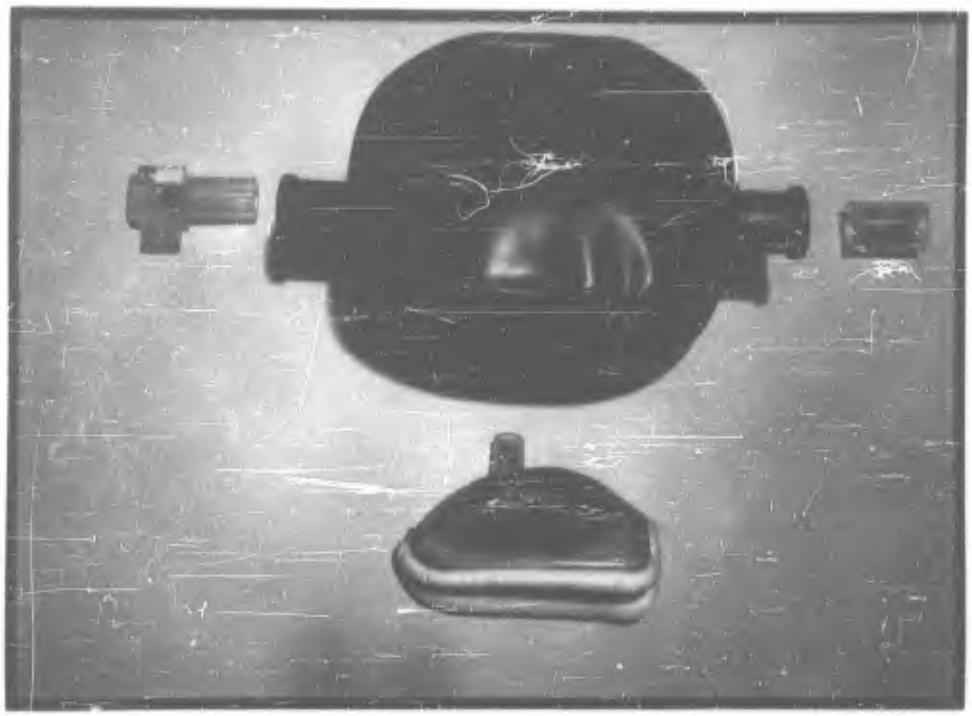


Figure 3. Neoprene 2.4 liter bag (sponge-lined) with Sphere Valves and Folding Mask (Complete MABI).

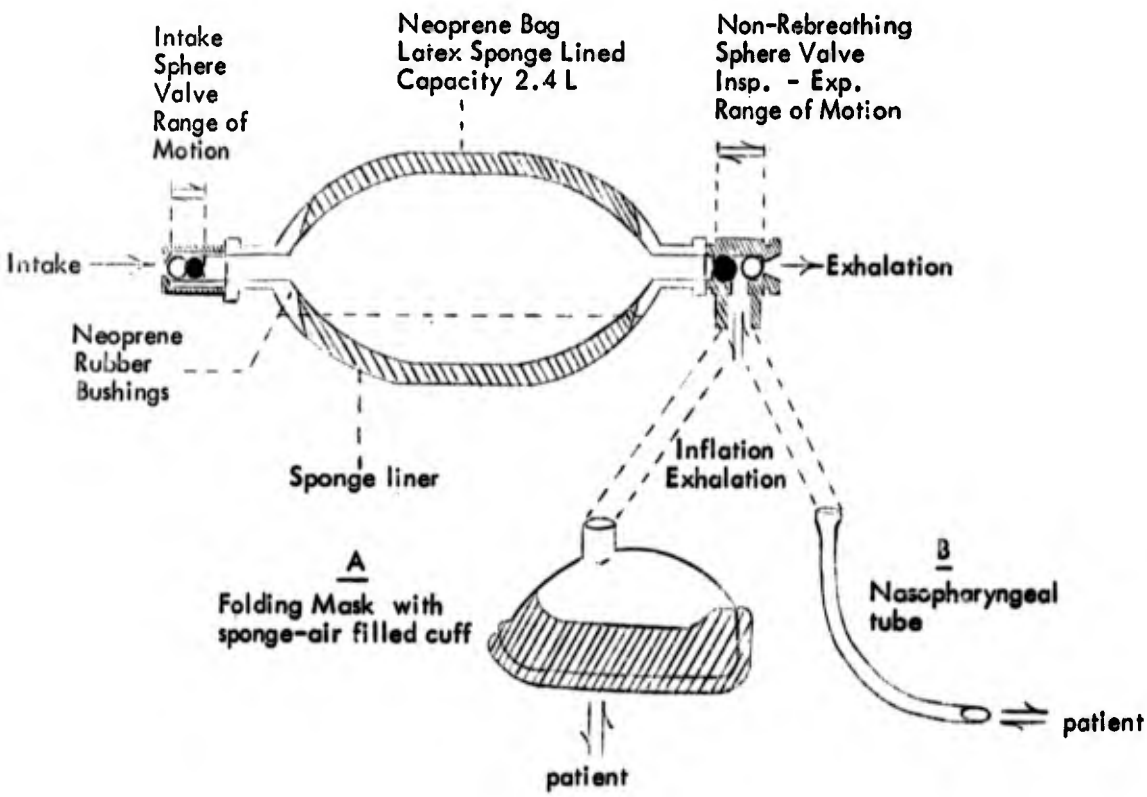


Figure 4. Schematic view of MABI with Sphere Valves for positive pressure inflation through Folding Mask (A) or Nasopharyngeal Tube (B). Sponge liner is secured to Neoprene Bag and to Neoprene end bushings.

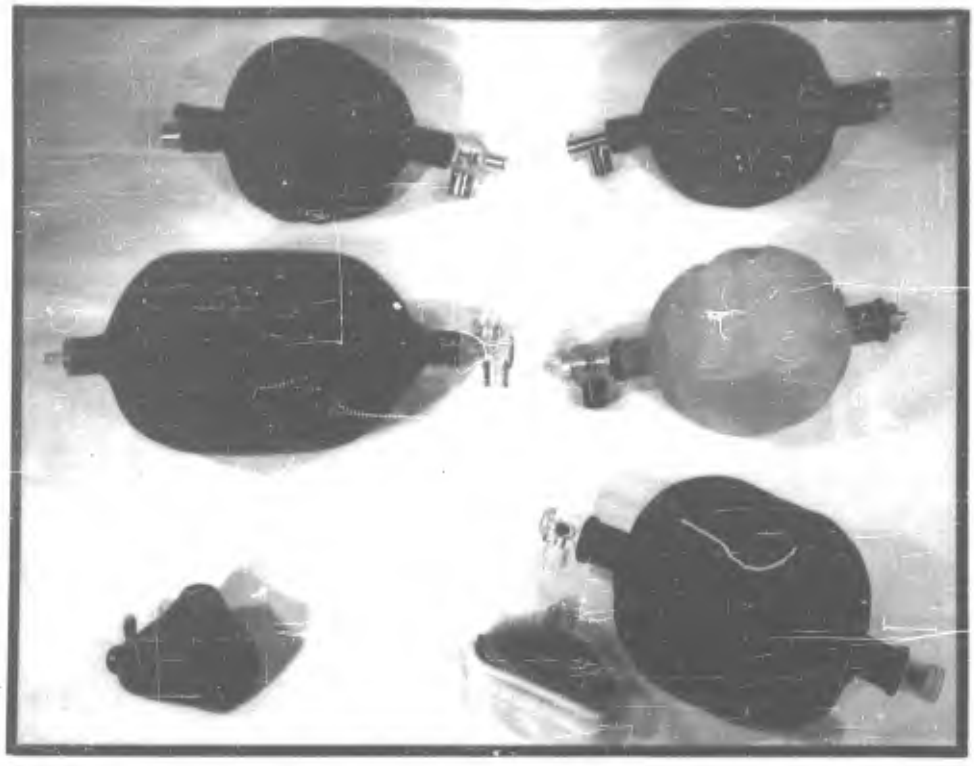


Figure 5.

		bag material	bag liner	valve material	valve part
Ambu Danish (S & W)	upper left	Latex	Latex	clear plastic	plastic spool
Ambu Danish (Testa)	upper right	Latex	Latex sponge	brass	metal spool
Pulmonator U.S. (DuPaCo)	middle left	Neoprene	Polyether	clear plastic	latex flap
Ambu U.S. (Airshields)	middle right	Latex	Latex sponge	clear plastic	plastic disc
MABI with Folding Mask	lower right	Neoprene	Latex sponge	clear plastic	sphere plastic
WARNE Mask (UK)	lower left				

II. LUNG MODEL FOR EVALUATION OF VENTILATORY DEVICES

The lung models used for analysis of several units reported this year have been set up as follows (see Figure 26, page 48):

1. The device is coupled to:
   a. Differential pneumotachograph to record inspiratory and expiratory flow.
   b. Statham strain gage to record pressure.
   c. Tracheal tube, either size 40 or size 22 (shortened), providing resistances of a "normal" or of a "bronchoconstricted" patient.
   d. Lung P-V Analogue, consisting of either a 40 liter glass reservoir, of a 20 liter glass reservoir, providing the compliances of a "normal" or of a "rigid" unconscious patient.
2. The VOLUME delivered to the lung was recorded by means of a strain gage calibrated by delivering known volume increments with a super syringe. Use of suitable amplifier attenuations permitted identical recorded excursions for identical volumes delivered to 1-d above.
3. Airway PRESSURE was recorded with another strain gage referred to under 1-b above calibrated with a water manometer.
4. Inspiratory and Expiratory FLOW were recorded from the pneumotachograph and a third strain gage calibrated with suitable rotameters.

The characteristics of the lung model may be summarized in terms of resistance and compliance:

	Compliance in $\frac{\text{liters}}{\text{cm.H}_2\text{O}}$	Resistance in $\frac{\text{cm.H}_2\text{O/liter/second}}{}$
NORMAL	0.04	2.0
ABNORMAL	0.02	30.0

The lung analogue was further refined for evaluation of assistors by the addition of a volume displacement system, operated pneumatically. The latter, called a "triggering" device produced the small inspiratory flow pattern of a near-curarized patient at a predetermined respiratory rate. The coupling from the triggering device into the lung reservoir permitted recording and analysis of the sensitivity of different assistor ventilators arranged to ventilate normal, abnormally resistive, or non-compliant, or near-curarized patients. The triggering device, called the triggerometer is schematically represented in Figure 26 for simultaneous testing of an Assistor's sensitivity and compensation against changes in mechanical properties of the pulmonary system. To further analyze the performance of an Assistor in relation to the opening of the inspiratory check valve, the pressure measurements, P_o, P_1, and P_2 are recorded as shown in Figure 27, page 49.

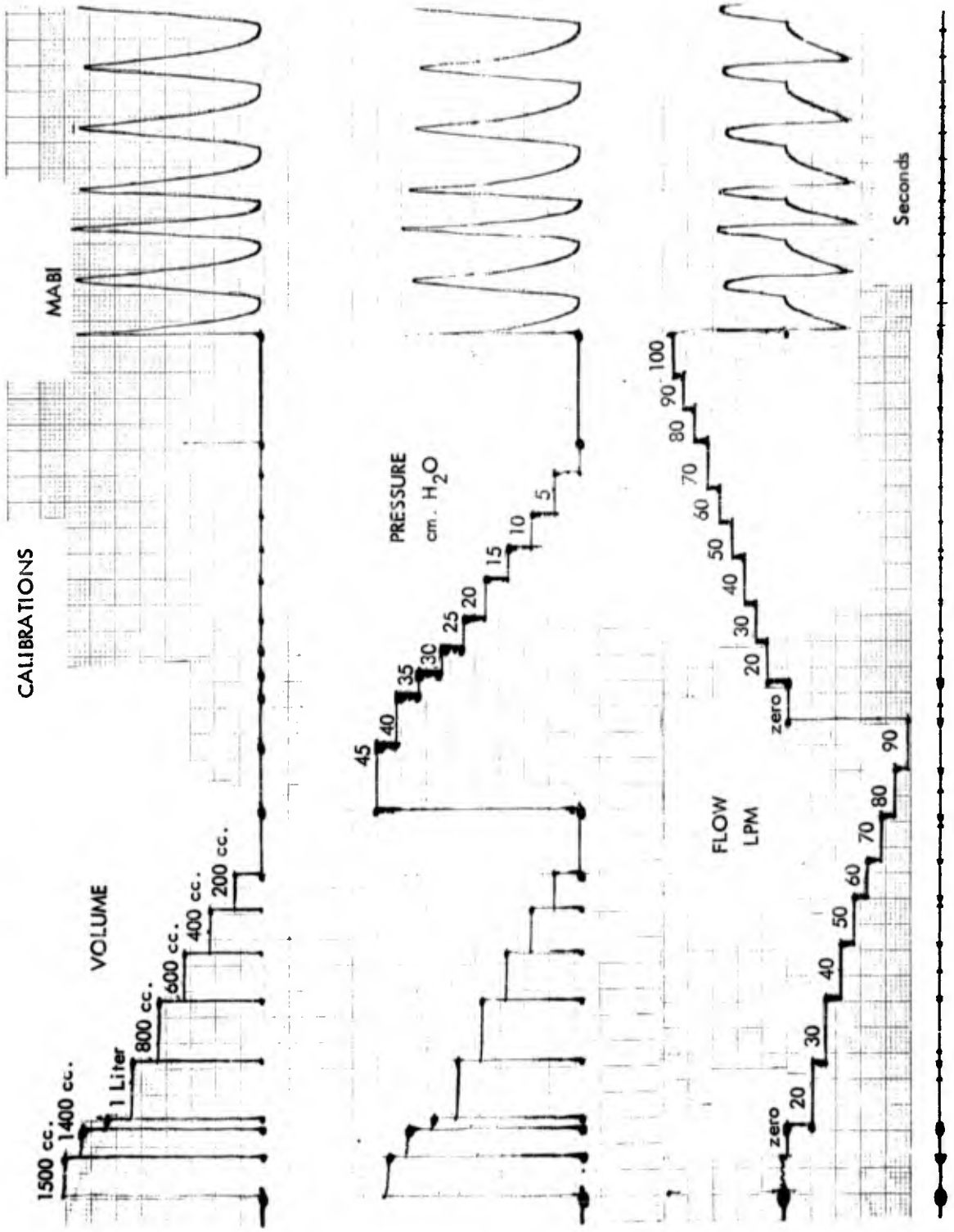


Figure 6. Calibration of lung model and performance of MABI.

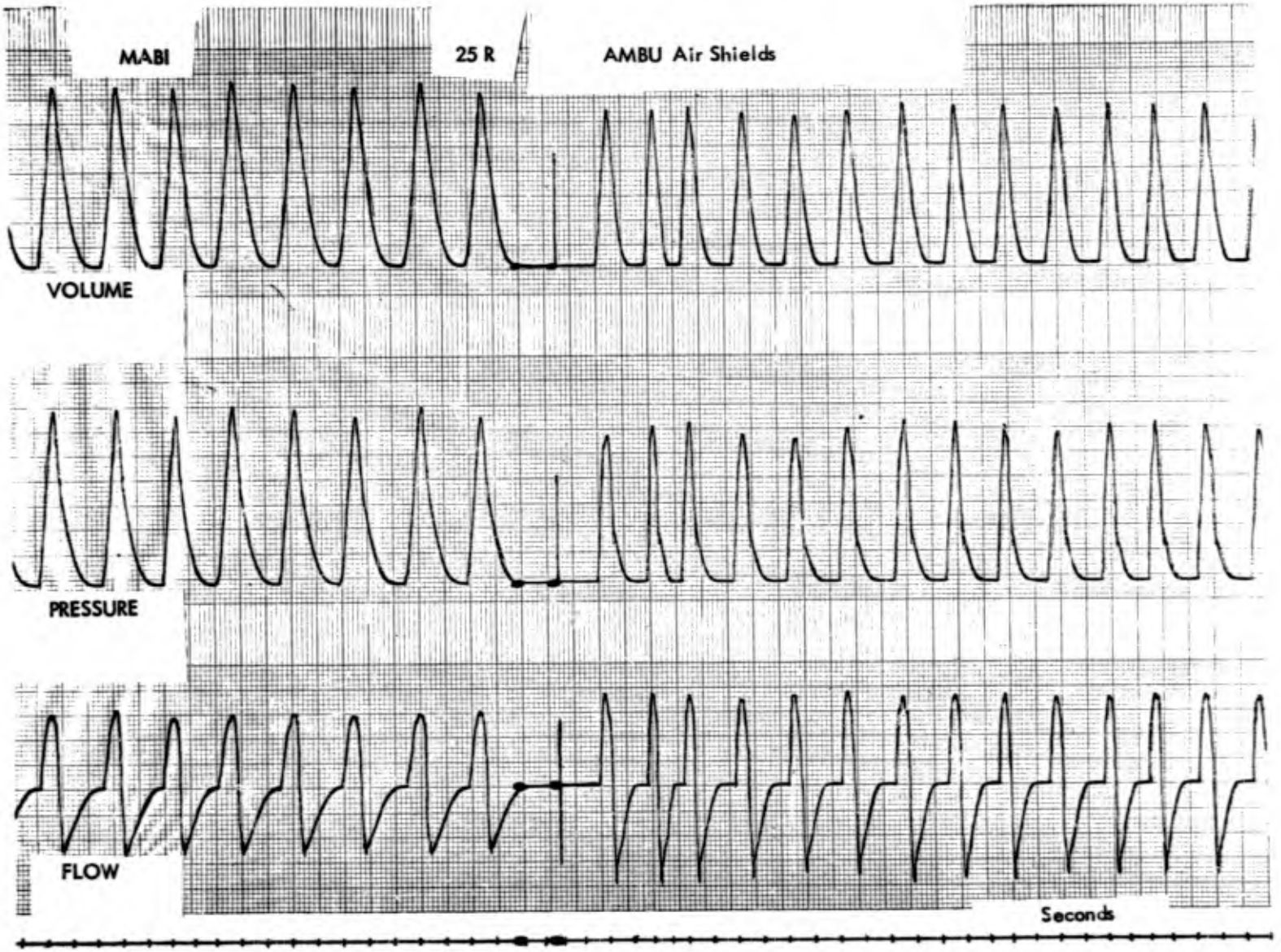


Figure 7. Performance of MABI and Ambu (Air Shields).

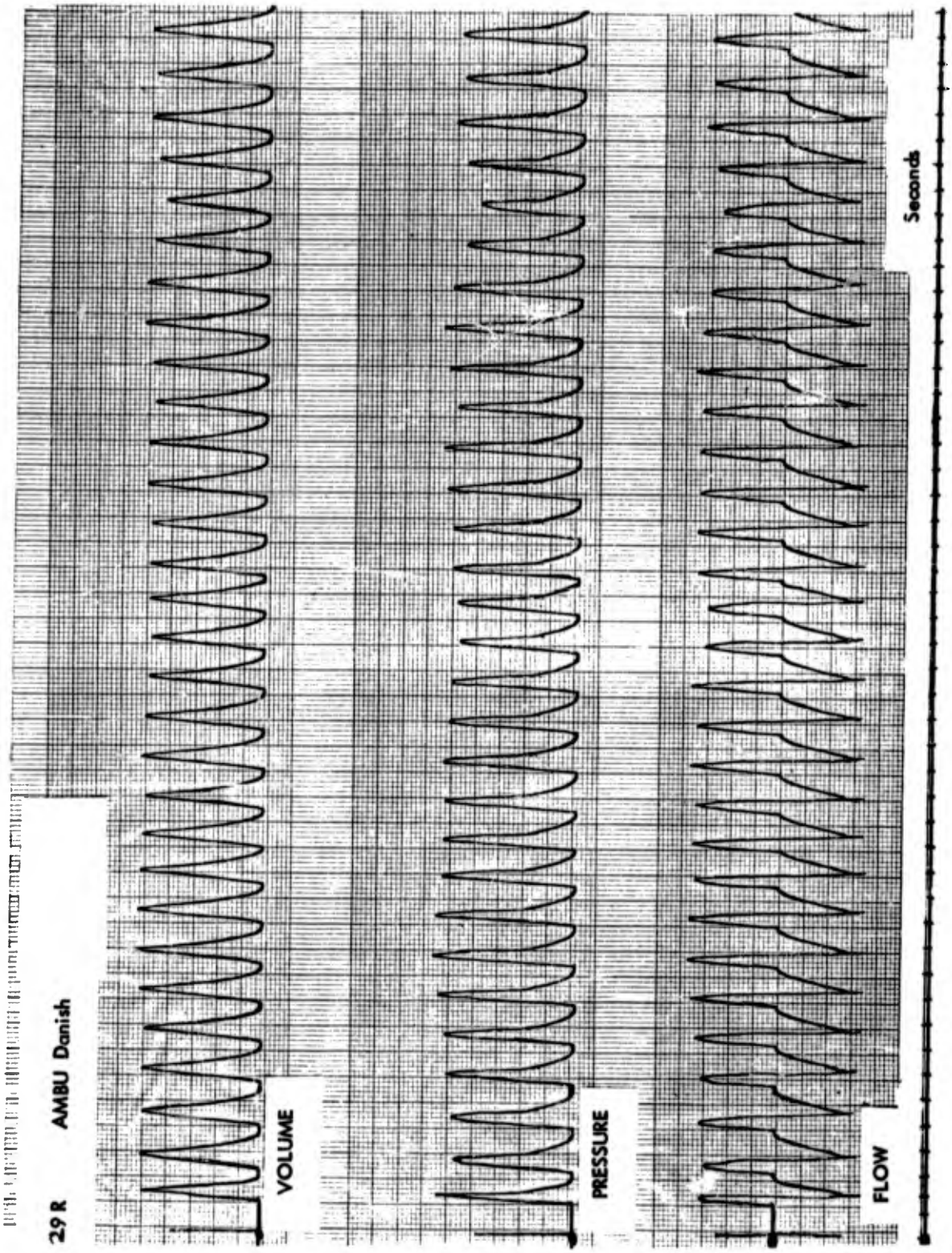


Figure 8. Performance of Ambu (Danish).

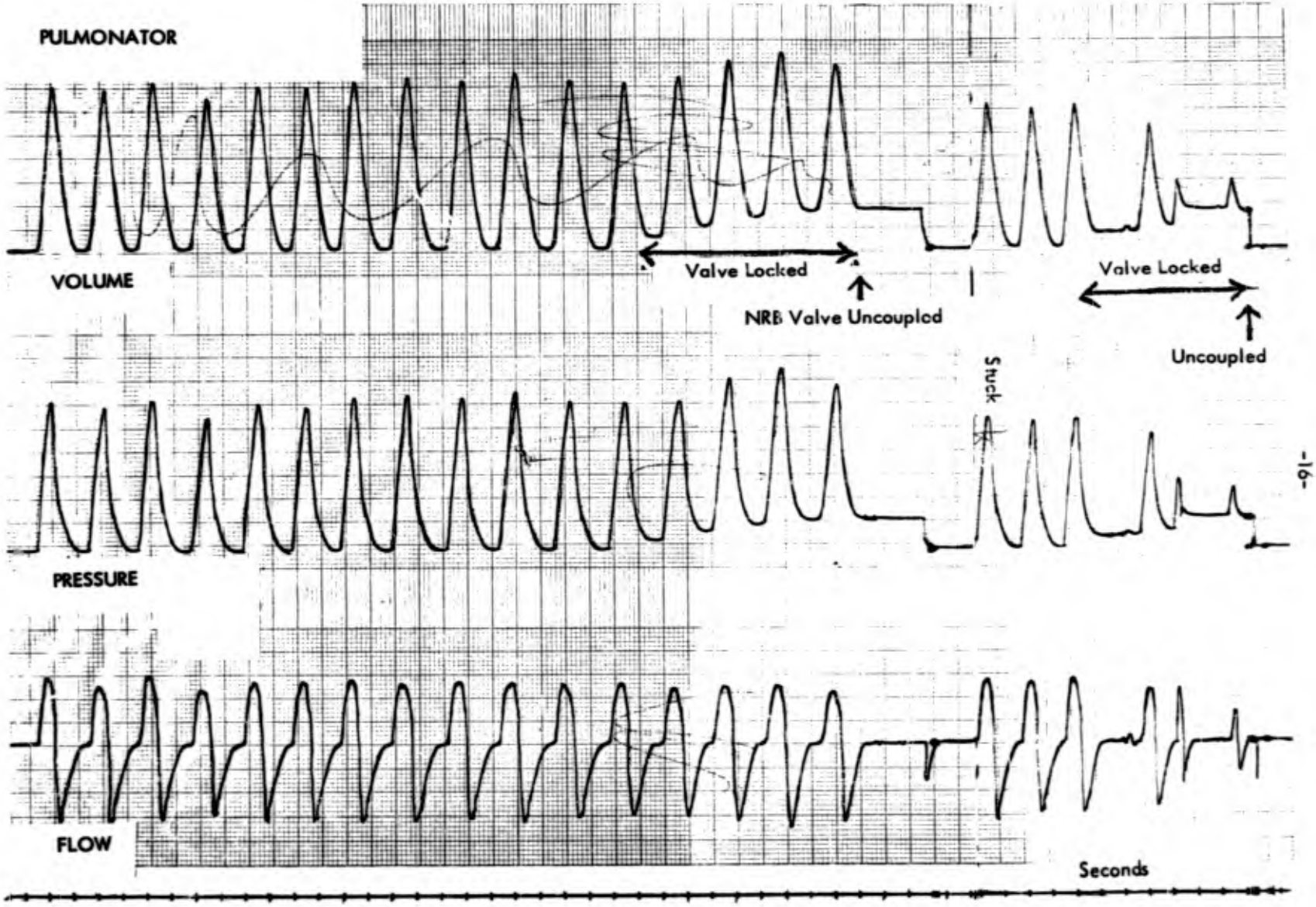


Figure 9. Performance of Pulmonator. (Note: "pressure lock" sticking of rubber flap valve.)

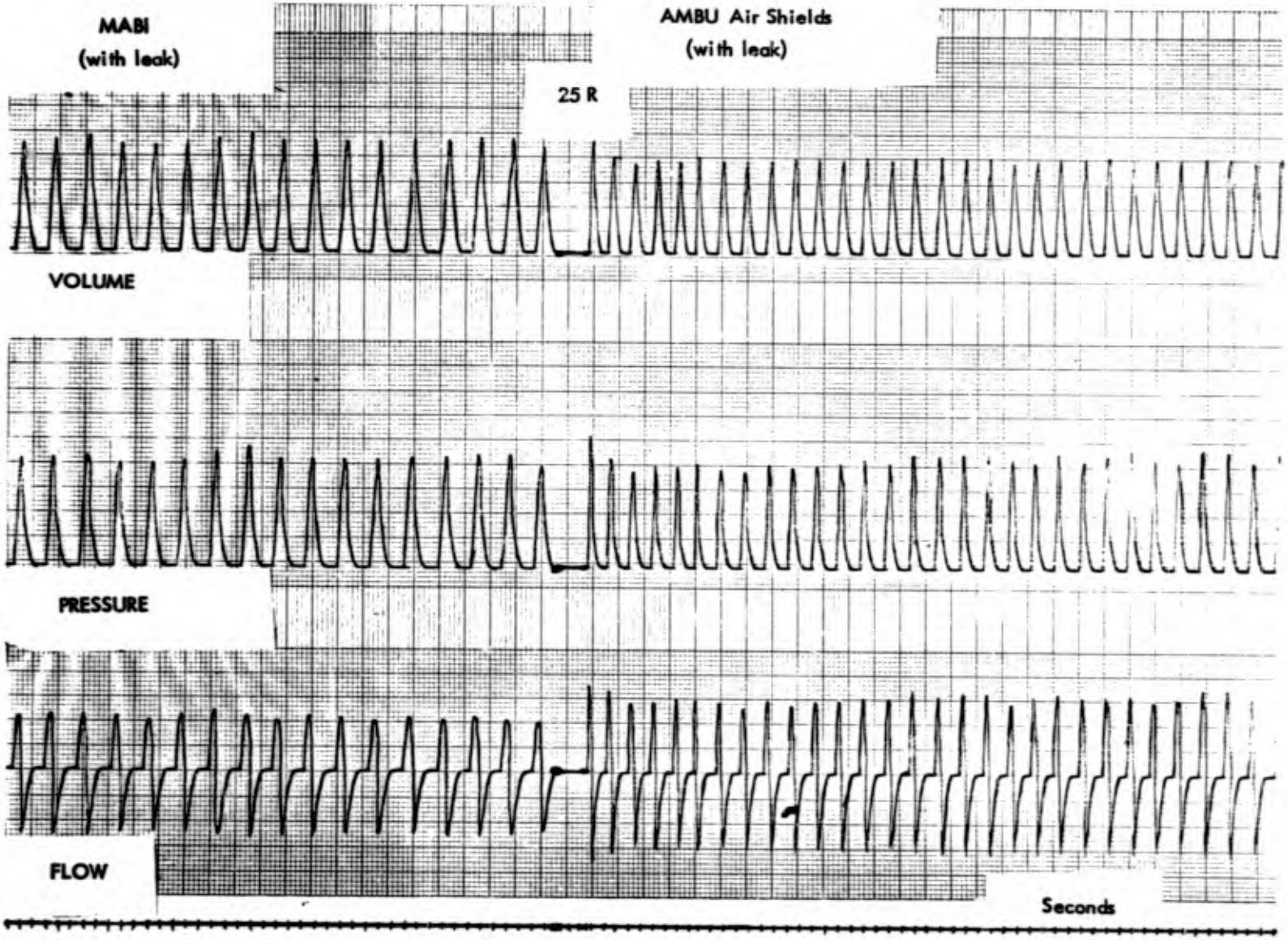


Figure 10. Performance of MABI & Ambu (Air Shields) with 4 mm. "mask leak".

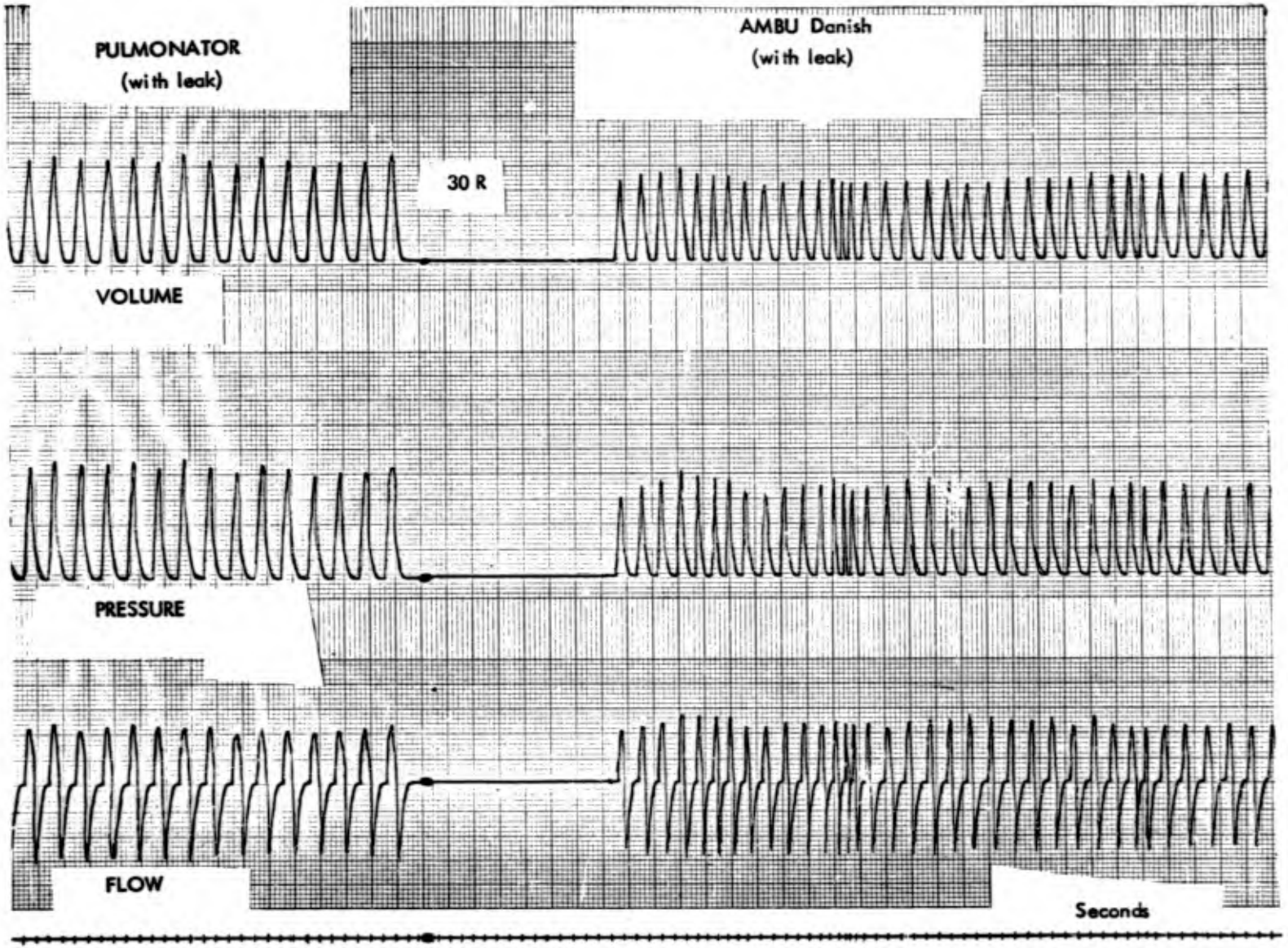


Figure 11. Performance of Pulmonator & Ambu (Danish) with 4 mm. "mask leak".

III. PORTABLE HEART-LUNG OXYGEN RESUSCITATOR (PHLO)

In 1954, Dr. John Clements at the Army Chemical Center suggested the idea of a simple field resuscitator designed to ventilate nerve-gas casualties, have very compact dimensions, and only one adjustable control labeled for the size of the casualty (tidal volume). This idea is not to be confused with the Edgewood and MEDL Resuscitators subsequently developed by Dr. Hustead, Dr. Clements, and Mr. Aaron Ismach of Fort Totten.

During 1961, our group decided to evaluate Dr. Clements' simple approach and obtain a prototype to evaluate its possibilities. The following design features were set forth by Dr. Elam in consultation with Dr. Hustead:

1. Power source: compressed air or oxygen regulated to 35 lbs/inch^2
2. Fixed timing control to give:
   a. inspiratory interval of 2 seconds,
   b. expiratory interval of 2 seconds, fixing the respiratory rate at 15 cycles per minute.
3. Variable flow control to result in the delivery to the patient of inflation volumes ranging from zero to 1.5 liters. Thus, to deliver the following tidal volumes within two seconds, the calibrated points on this single control would result in:

Dial Setting		Tidal Volume in cc.	Inspiratory Flow Rate in LPM	Minute Volume LPM
1	Infants	100	3	1.5
2	Children	400	12	6
3	Small Adults	700	21	10.5
4	Large Adults	1000	30	15
5	Adults (when mask leakage is excessive)	1500	45	22.5

These flow rates and the inspiratory time of two seconds were selected in part to minimize the inflation pressure applied to the pharynx and larynx of patients wearing a face mask or nasopharyngeal tube. Excessive pressures cause reflex laryngospasm in semiconscious patients and gastric inflation in comatose or anesthetized patients.

Trial of these parameters in flow rate and inspiratory time were carried out with the Janney Ventilator. Results were excellent in ventilation, independence from patient variables in resistance and compliance. The approach appeared to warrant fabrication of a compact unit. At this juncture, the E & J Resuscitator was being criticized for its failure to perform during closed chest cardiac massage (CCCM).*

We then evaluated the performance of all resuscitators available in patients receiving CCCM and found that the cycling of all pressure-cycled designs (E & J, Emerson, Stephenson, Globe) is accelerated by the excursions applied manually to the sternum, resulting in the interruption of lung inflation about every two seconds (with a rate of CCCM of one compression per second). Although the airway-pressures resulting from CCCM appear on an aneroid manometer to be less than the resuscitator cycling pressure of 20 cm. H_2O, the undamped recording of instantaneous airway pressure during CCCM showed values which consistently attained 20 cm. H_2O (Figures 12 and 13).

In contrast, ventilators of the volume-limited or time-limited type provided adequate tidal volumes during CCCM since their inspiratory cycles were not interrupted by CCCM airway pressure fluctuations. These data served as an impetus to develop a simple resuscitator specifically designed to be used during heart-lung resuscitation. Its applicability should be limited to the post-emergency maintenance of ventilation during the "therapeutic plateau" designated by Jude as an established oxygen supply system. Such a device has ideal application in conjunction with tracheal intubation but our evaluation has primarily combined its use with a face mask and/or a nasopharyngeal tube. Obviously the use of oxygen is preferable to atmospheric or expired air in patients with marginal circulation.

The Flow-Limited Resuscitator (PHLO), is shown in Figure 14. This PHLO prototype weighs 33 lbs., including the oxygen supply. A "D" cylinder of oxygen (lasting 63 minutes

*The Ohio Chemical and Surgical Equipment Company requested our advice on this problem. We proposed in July 1961 that a resuscitator as specified above be designed by their engineers and fabricated for our evaluation. The prototype unit was built without government support in Madison, Wisconsin, and shipped to our department in December 1961.

at 400 cc. tidal and 36 minutes at 700 cc. tidal volume settings) is coupled to a pressure regulator to supply the inspiratory system and, in parallel, a pneumatic timer (Figure 15). The timer controls the on-off valve which allows a constant flow for 2 seconds and then turns off all flow for 2 seconds. Delivery to the patient is adjusted as a resistance on the tubing leading to a high-flow capacity relief valve (48 liters per minute which may be internally pre-set at 30-60 cm. H_2O) and then to the non-rebreathing valve. The latter is a diaphragm arranged to permit the patient to inspire atmospheric gas when his inspiratory flow exceeds the flow delivered from the resuscitator, a novel feature in such appliances but one which is contrary to use in toxic atmospheres. The family of performance curves obtained in a normal lung model is shown in Figure 16.

The airflow patterns, airway pressures, and tidal volumes obtained in a normal and abnormal lung-airway model are shown in Figure 17. The performance resembles the volume-limited ventilator. The PHLO compensates against transient bronchoconstriction.

Records taken in curarized anesthetized patients before and during CCCM during ventilation by PHLO are shown in Figure 18. Although the fluctuations in airway pressure and airflow indicate the effects of CCCM, ventilation is not impaired. Moreover, the somewhat prolonged inspiratory cycle to two seconds should theoretically improve the mechanical effect of CCCM on the heart. This speculation has been confirmed recently by Jude and others.

Preliminary clinical trial of the Flow-Limited Resuscitator demonstrates:

1. Satisfactory ventilation despite patient changes in resistance and compliance.
2. Low airway pressures as a result of the low flow rates employed at adequate tidal volumes for adult patients.
3. Satisfactory performance with either a fitting face mask or nasopharyngeal tube without incidence of laryngospasm in recovering semiconscious patients or of gastric inflation.
4. Longest performance of any commercially available resuscitator as a result of low consumption of oxygen.
5. Satisfactory performance during CCCM.
6. Simplicity in operation with only one adjustment (labeled either as "tidal volume" or for size of the patient).
7. Compact portable unit.
8. At present, the pre-set adjustments of the PHLO resuscitator are applicable to adults but would produce an unsuitable cycle for infants (prolonged low flow at 200 and 400 cc. tidals would not overcome small mask leaks) at the currently fixed 2 second inspiratory phase.

Further trials with a variety of fixed parameters are underway.

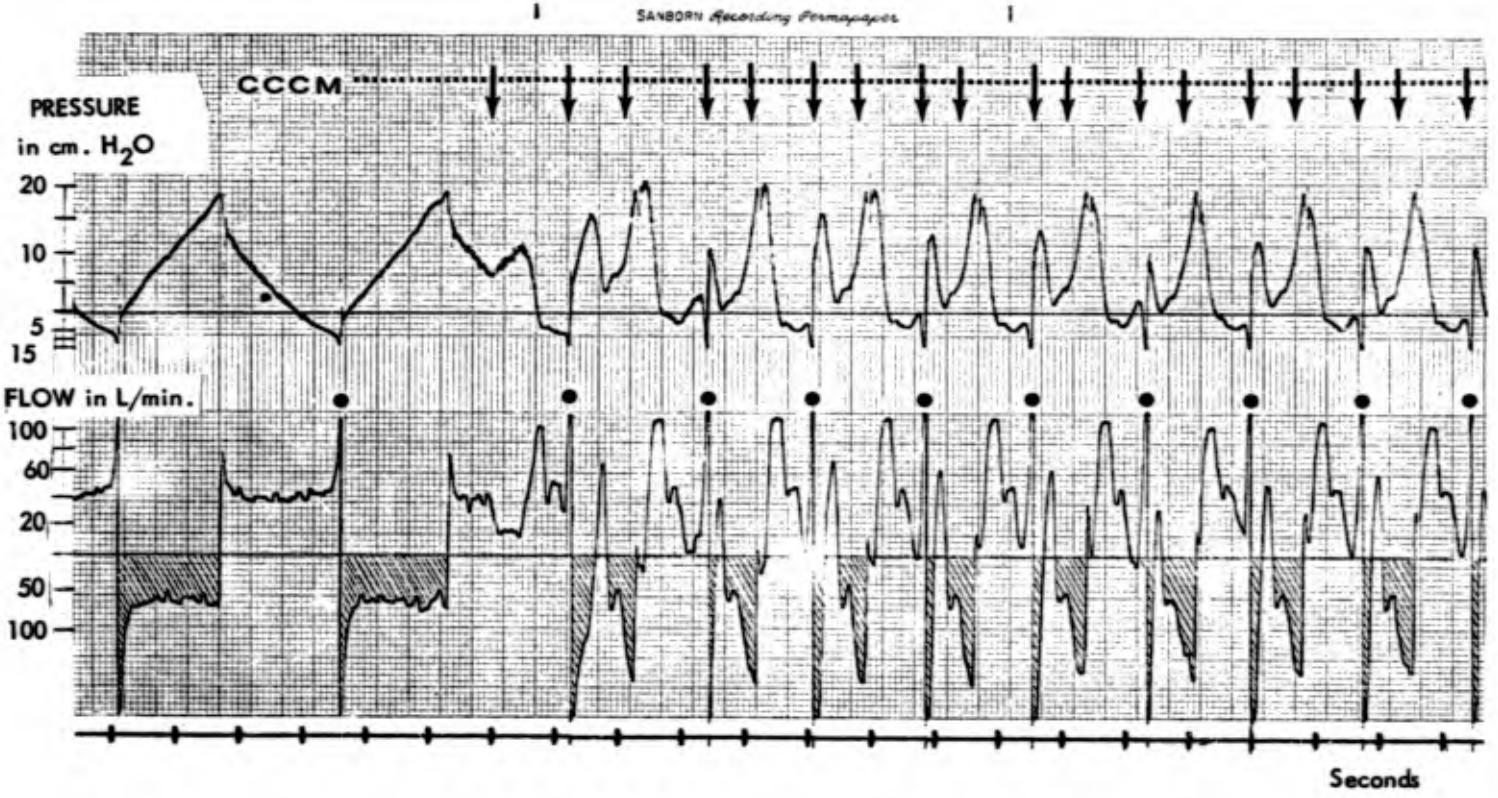


Figure 12. E & J Resuscitator. Anesthetized curarized patient. Pressure and Flow tracing before and during Closed Chest Cardiac Massage.
Note increased frequency of triggering of resuscitator as a result of CCCM (one sternal compression at each arrow). Each inspiratory phase of resuscitator is indicated by back circle. The E & J is artificially triggered with every other chest compression.

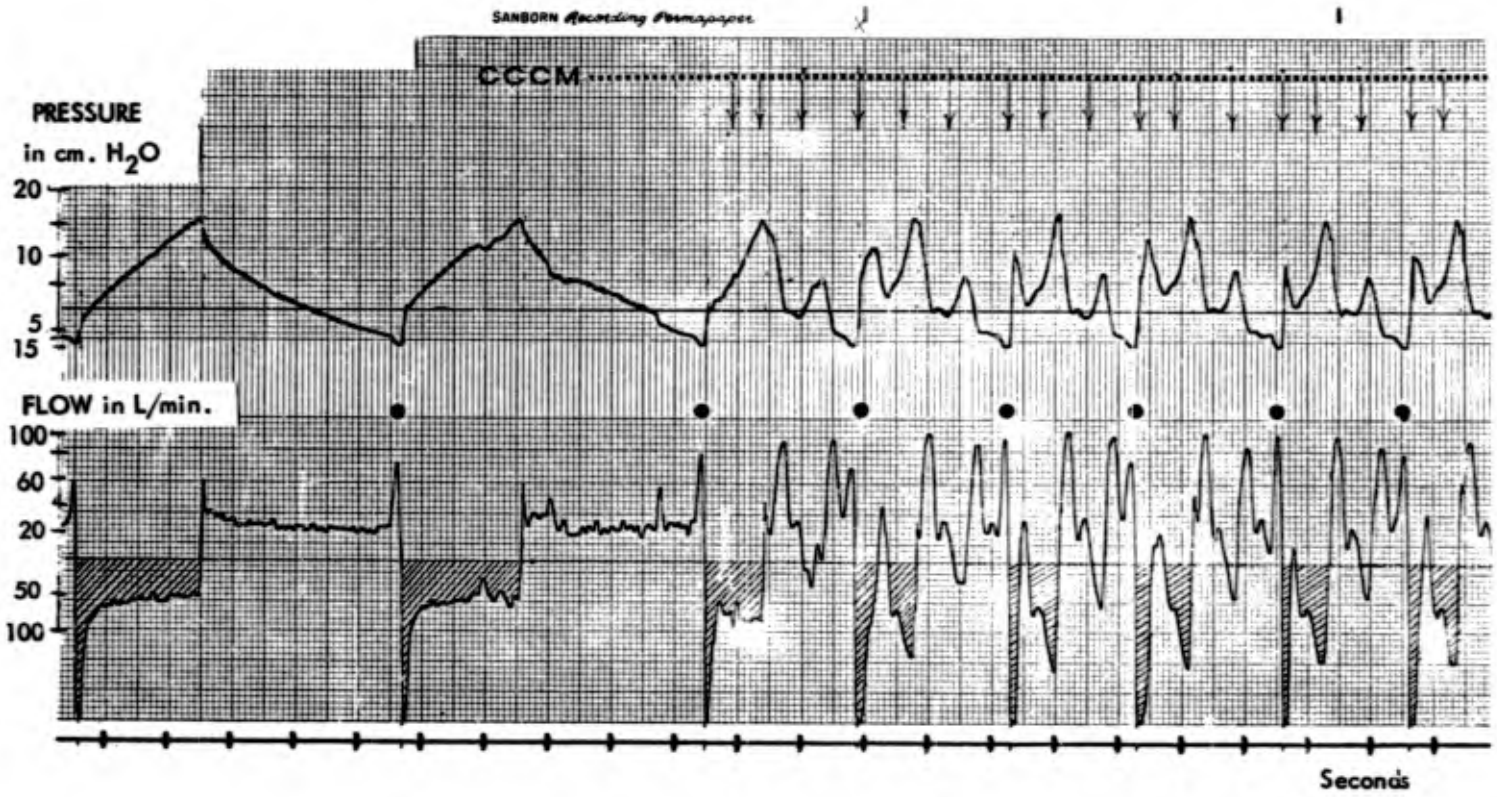


Figure 13. Emerson military model resuscitator. Anesthetized curarized patient. Pressure and Flow tracing before and during CCCM.
Note that the inspiratory phase of the resuscitator is triggered by every third CCCM compression, unlike the E & J, apparently since the Emerson is producing a greater negative pressure during the expiratory phase. However, CCCM accelerates both the inspiratory and expiratory phases of any pressure-cycled resuscitator, thereby producing too shallow ventilation.

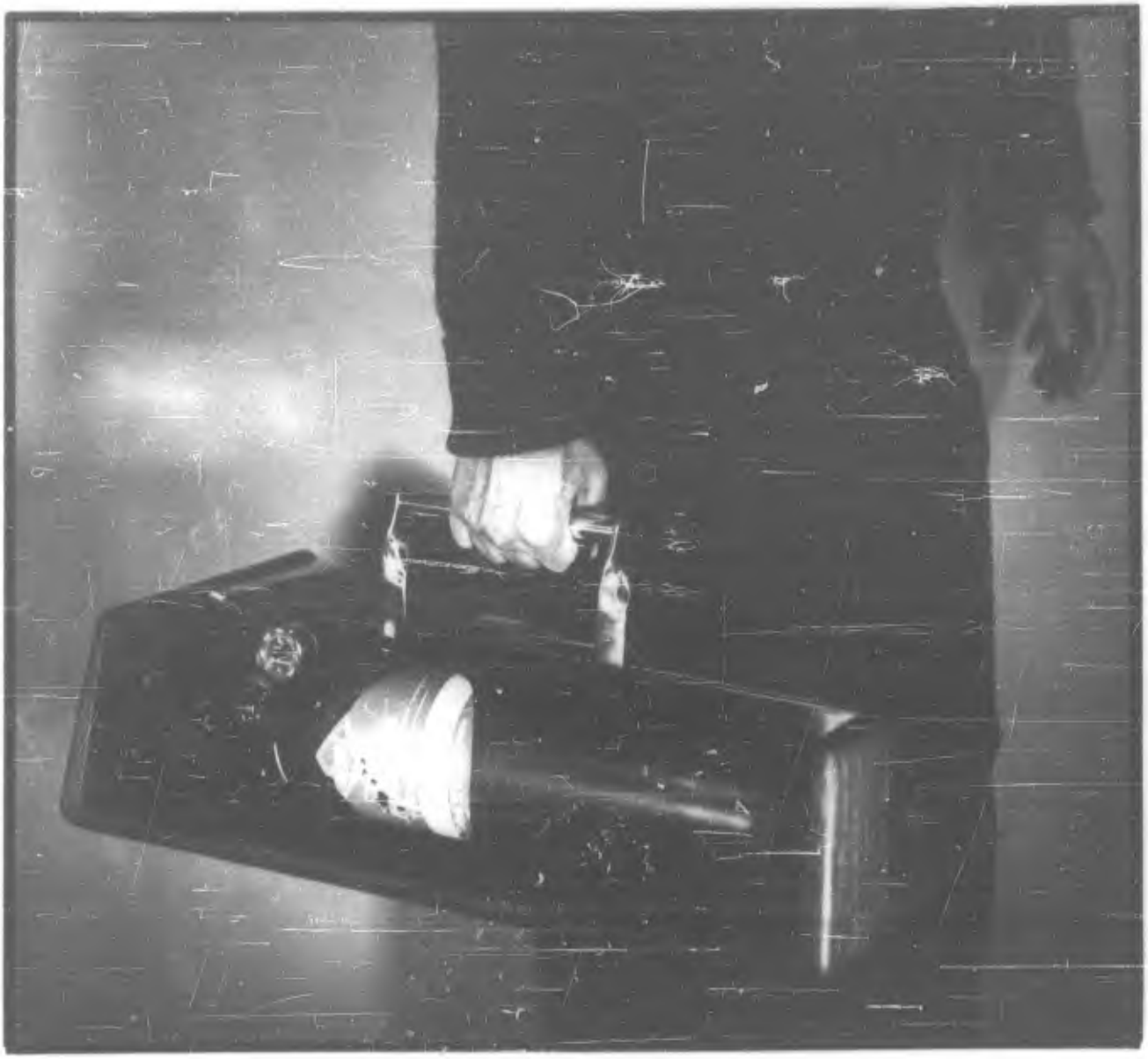
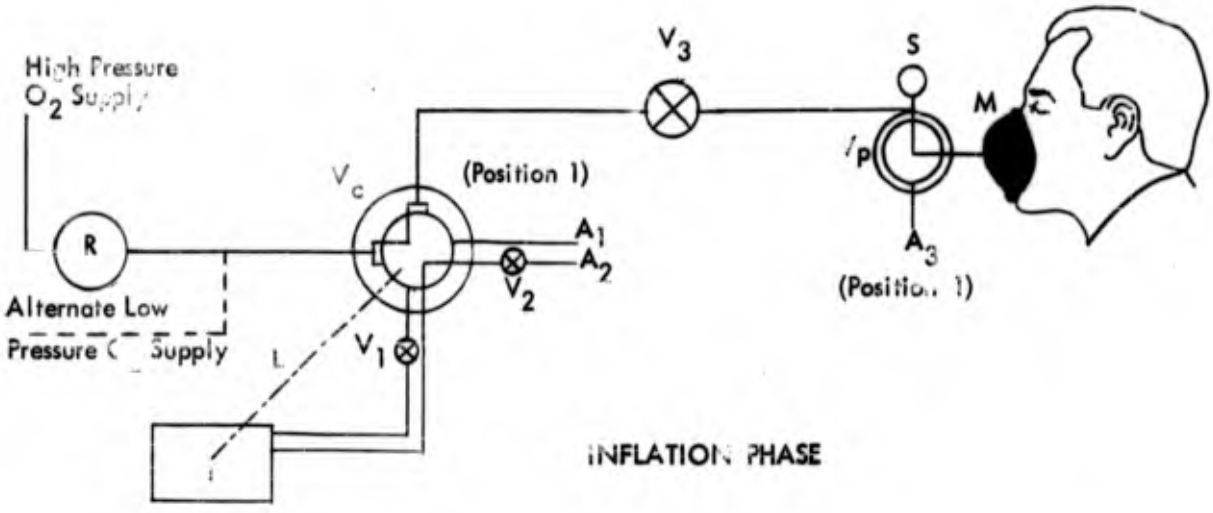
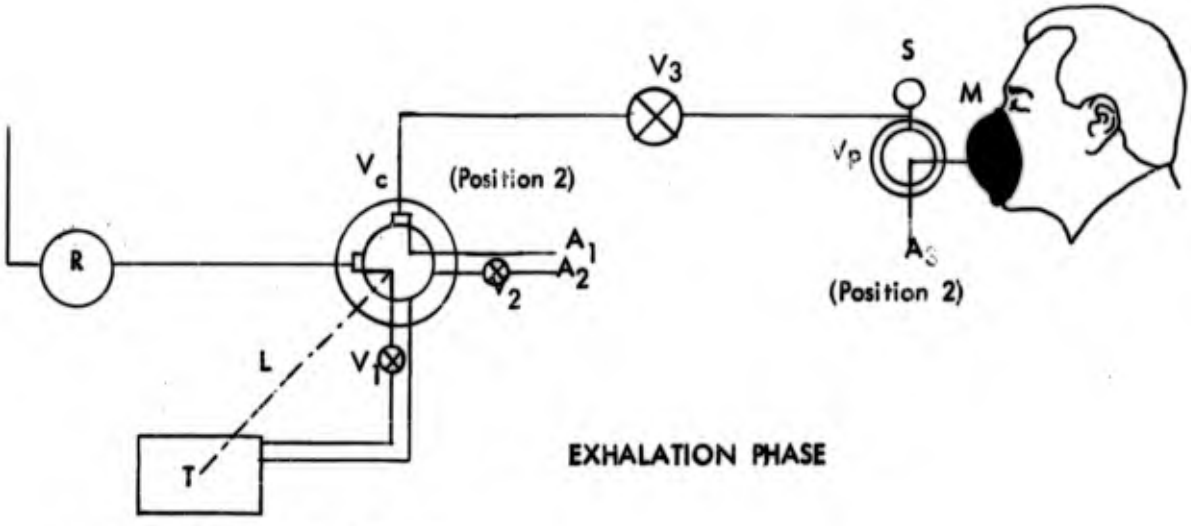


Figure 14. PHLO Resuscitator with D cylinder. Weight 33 pounds.

Figure 15. SCHEMATIC DIAGRAM - PHLO RESUSCITATOR





R - Pressure Reducing Regulator

T - Pneumatic Timer

L - Mechanical Inter Connection with Toggle

V_c - Cycling Valve

V_p - Patient Inhaler Valve (pneumatically actuated by diaphragm)

S - Pressure Safety Valve (pre-set)

A_1, A_2, A_3 - Atmospheric Vents (internally pre-set)

V_1, V_2 - Timing Adjustment Valves (interval)

V_3 - Tidal Volume Adjustment Valve, the single external adjustment.

OPERATION OF PHLO RESUSCITATOR

LEGEND TO FIGURE 15

The primary elements of the PHLO Resuscitator are the pneumatic timer (T), the cycling valve (V_c), the tidal volume adjustment valve (V_3), and the patient inhaler valve (V_p). The cycling valve and patient inhaler valve are depicted as having rotary elements so as to simplify graphic illustration of function. In these illustrations, the inner circle represents a rotary stator and the outer circle, the corresponding valve body.

The pneumatic timer is mechanically interconnected with the operating element of the cycling valve so that this element will automatically assume positions 1 and 2 , as shown in the schematic diagram. The rate of operation of the pneumatic timer and subsequently the cycling valve element is adjusted by virtue of the timing adjustment valves (V_1 and V_2). Timing adjustment valve V_1 adjusts the time interval of the expiratory phase and timing adjustment valve V_2 adjusts the time interval of the inspiratory phase.

The tidal volume adjustment valve is a throttling type device which restricts gas flow from the cycling valve to the patient inhaler valve during the inspiratory phase.

The patient inhaler valve is pneumatically actuated and selects position 1 during the inspiratory phase so as to route gas flow from the cycling valve to the patient. Position 2 of the patient inhaler valve is assumed upon cessation of flow from the cycling valve at the end of the inspiratory phase. When in position 2, the patient inhaler valve vents the patient mask circuit to atmosphere, allowing passive exhalation by the patient.

The pressure safety valve (S) is located in the resuscitative circuit so as to prevent mask pressures from exceeding a predetermined pressure during the inspiratory phase. This valve is located in the circuit so as not to be exposed to the patient's expiration, minimizing the possibility of safety valve failure in the event that fluid materials from the patient are present in the mask circuit.

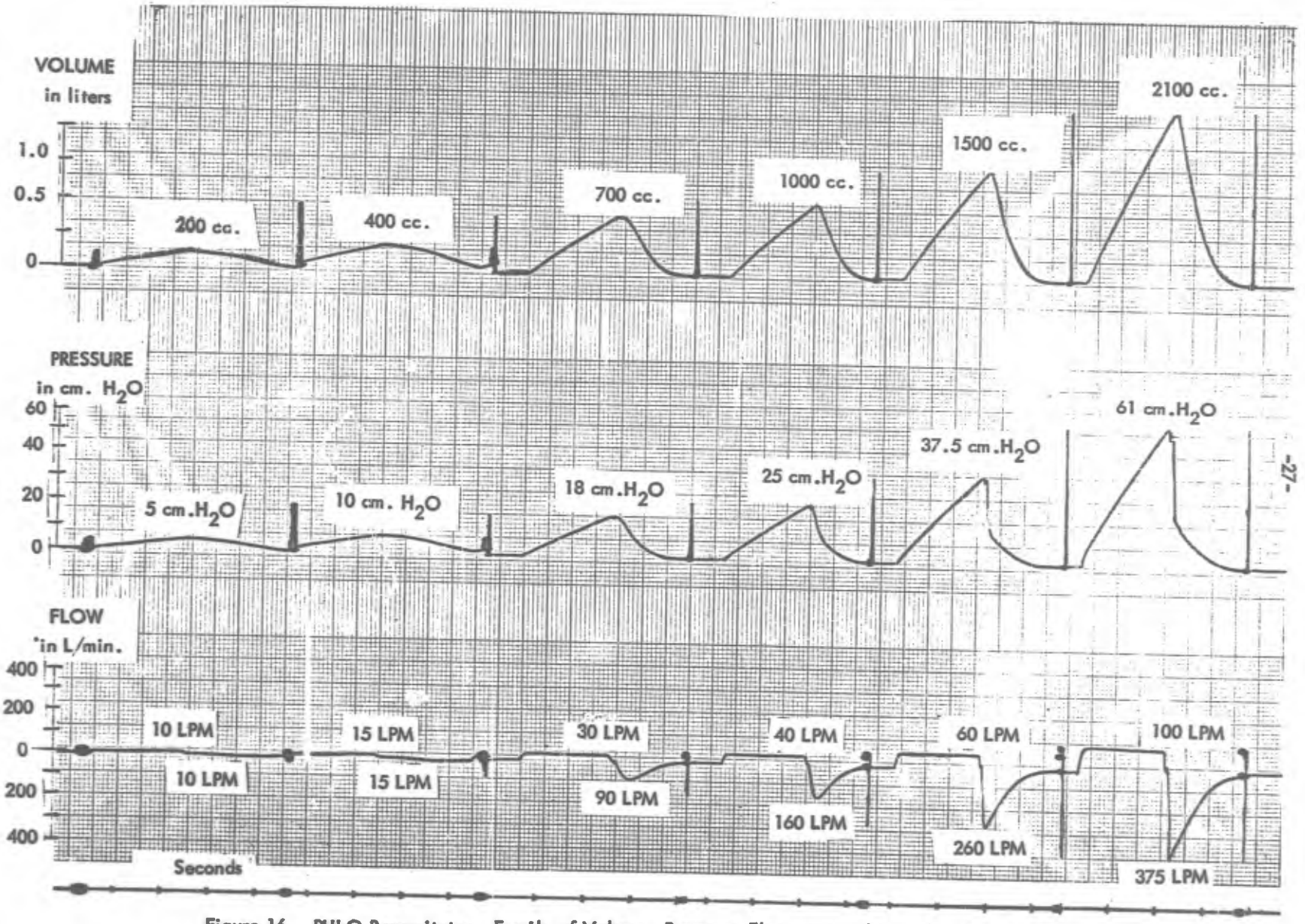


Figure 16. PHLC Resuscitator. Family of Volume, Pressure, Flow curves obtained in normal lung model with adjustments of the single variable control, V_3 (Figure 15).

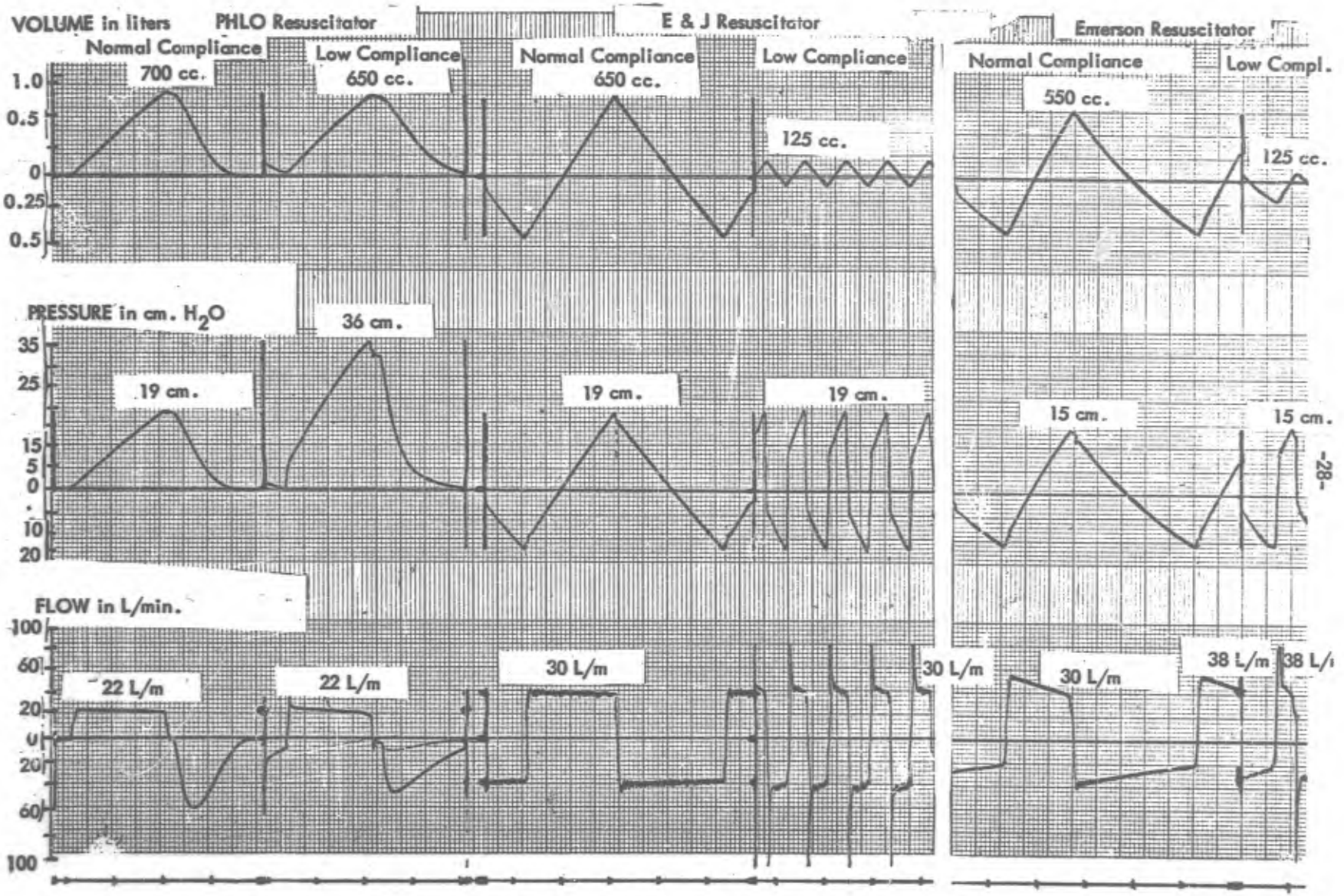
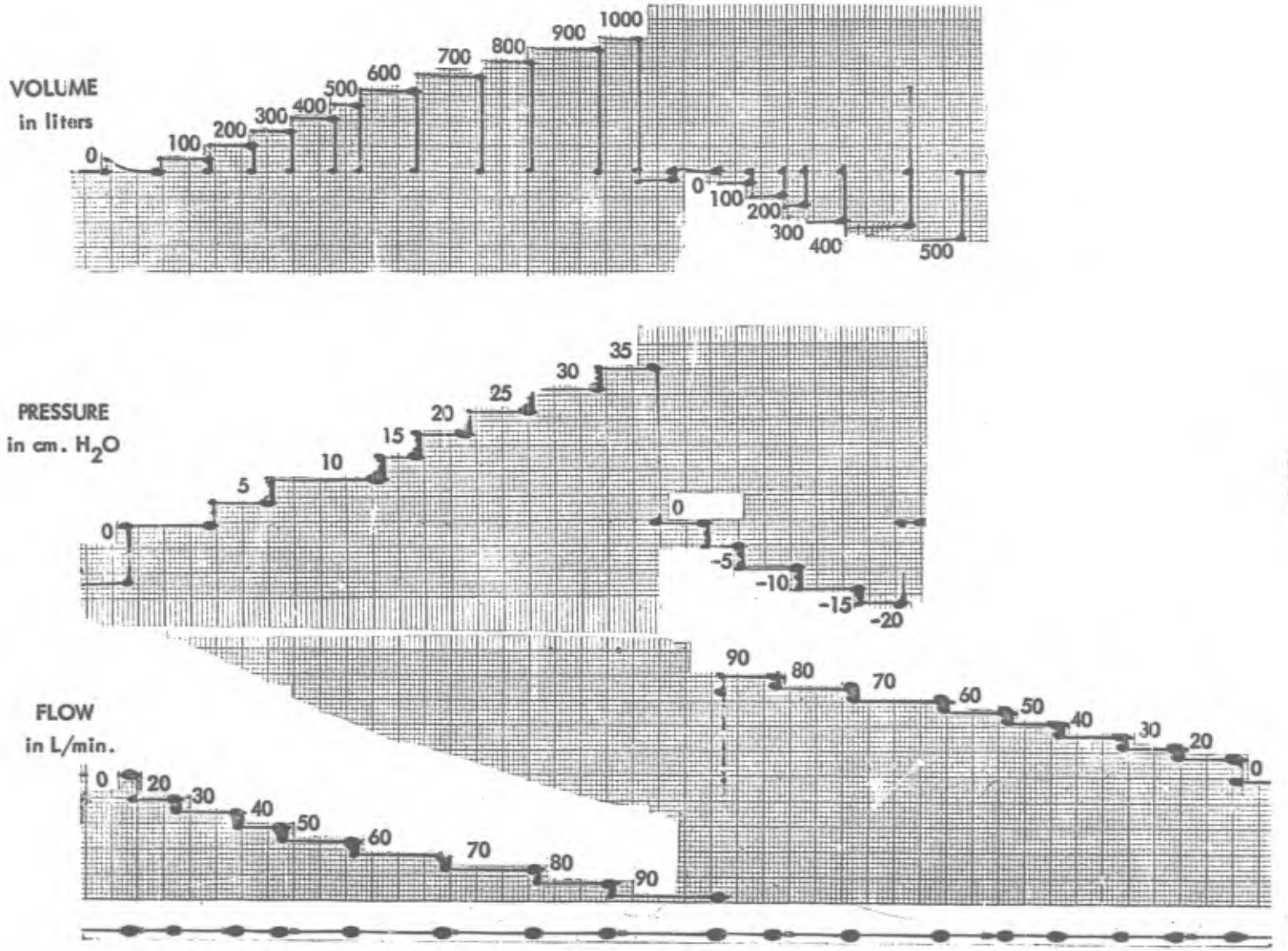


Figure 17. Comparative Performance of PHLO, E & J, and Emerson Resuscitators against "normal" and "bronchoconstricted", low-compliant lung models.



CALIBRATIONS: Rigid versus Normal Lung Model (low-compliance, high-resistance).
PHLO, E & J, and Emerson Resuscitators.

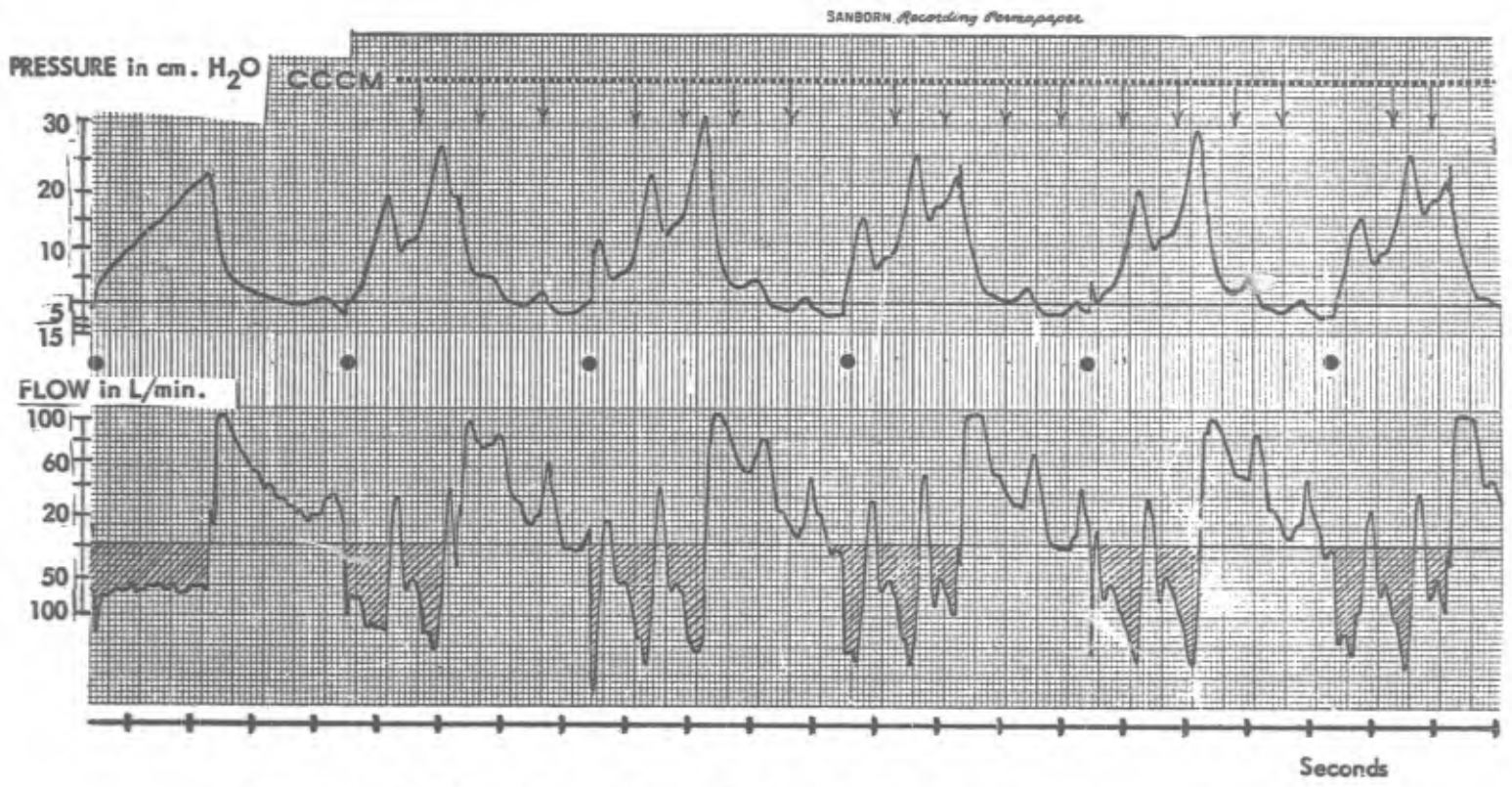


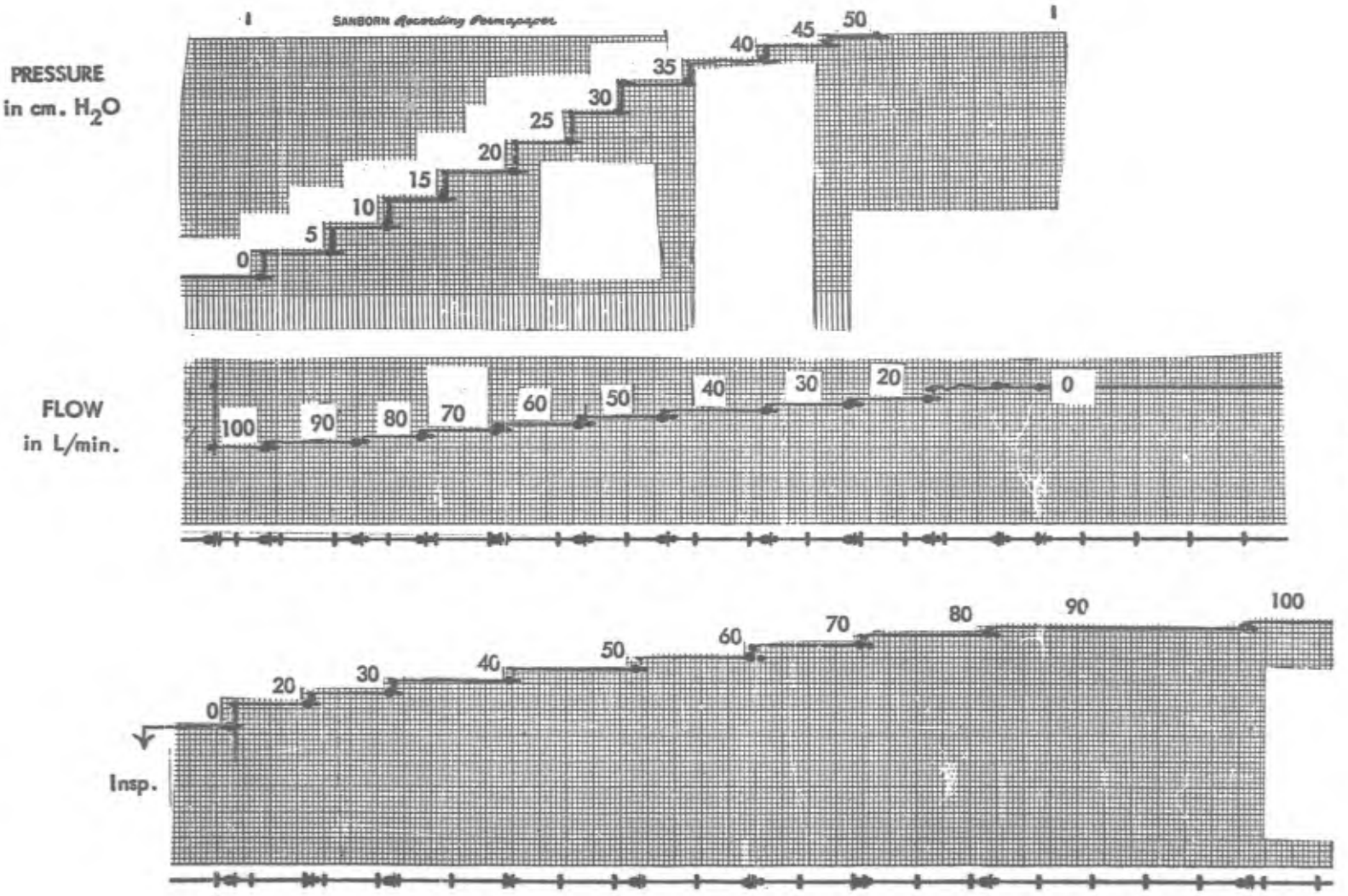
Figure 18. PHLO Resuscitator. Anesthetized curarized patient. Pressure and Flow tracing before and during Closed Chest Cardiac Massage. Note resuscitator does not change frequency of ventilation. The shaded areas showing the volumes with each inflation have equivalent total areas for each cycle before or during CCCM.

COMMENT ON FURTHER TRIALS: The flow rates of the PHLO Resuscitator are about 120% the pre-design specifications. However, no reflex "bucking" has been noted thus far when the PHLO Resuscitator is used in semi-conscious patients.

These are two clinical characteristics of this approach to a flow-limited resuscitator which necessitate a wise compromise based on usage in patients:

1. The low flow needed for getting small enough tidal volumes in infants (100 - 200 cc) over 2 seconds make for difficulty when there is mask leakage.
2. The high-flow desirable for the adult in coma is poorly tolerated by the semi-conscious patient with laryngo-bronchial reflexes. Therefore, considerable versatile clinical trials will be necessary to arrive at the compromise of variable flow adjustment in relation to the fixed inspiratory time.

Another difference from the specified parameters of the PHLO Resuscitator is the maximal setting of the flow adjustment for adults when mask leakage is excessive. The PHLO Resuscitator delivers 100 liters per minute and 2100 cc. at the maximal adjustment. For the small adult without mask leakage, the inflating pressure peak would exceed the 60 centimeters of water specified for the MEDL unit's maximum. One would speculate that the above maximum of the PHLO should be revised downward. However, until more data are collected in the context of mask leakage under "field" conditions (beard stubble and greasy skin), the selection of maximal available flow, time, and delivered volume is a rather arbitrary contemplation.



CALIBRATIONS: Pressure, Flow. CCCM – PHLO, E & J, Emerson, and MEDL Resuscitators.

IV. THE DESIGN AND EVALUATION OF A TIME-LIMITED VENTILATOR FOR CONSCIOUS AND UNCONSCIOUS APNEIC PATIENTS

Heretofore, the two categories of classified functions for Assistor-Controller ventilators have been the pressure-limited and the volume-limited devices. In the pressure-limited device the operator pre-sets the maximal positive pressure for a fixed time of inspiration; the resulting tidal volume inflated varies with the patient's resistance and compliance. In the volume-limited device, the operator pre-sets the maximal volume for a fixed time of inspiration; the resulting inspiratory pressure varies with the patient's resistance and compliance. Thus the pressure-limited ventilator is volume-variable and the volume-limited ventilator is pressure-variable, so far as the patient's ventilation is concerned.

During 1959-1961, a time-limited device has been developed which forms a third basic category.* As reported here, the time-limited device is pressure-variable and performs similarly to the volume-limited device. A fourth basic category would be a flow-limited ventilator.

Existing examples of the pressure-limited or volume-limited Assistor-Controllers are the Bird, Bennett, Emerson, Jefferson, and Stephenson devices. Several of these may be modified by appropriate adjustments to operate either as pressure-limited or volume-limited devices. None of the contemporary ventilators incorporate the fixed-flow, time-limited features described here for the experimental ventilator. In this design, the tidal volume is directly proportional to the

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* In 1956, an elaborate experimental Assistor-Controller was designed and constructed by C.D. Janney and used in anesthetized patients for two years. Since this ventilator could be operated with choice of parameters, the trial of time-limited operation was explored daily for three months. After the advantages of this approach were recognized, it was decided to undertake the design of a simplified small practical ventilator to be operated exclusively as a time-limited, fixed-flow, pressure-activated Assistor-Controller. Since Dr. Janney left our group, we were unable to proceed with this project until Air-Shields, Inc. agreed to work on this project with us in 1959. This collaborative effort has been continued without the support of government funds to Air-Shields, Inc. Our role in the project has been the recommendation of specifications while Air-Shields has supplied entirely the engineering design and fabrication of the ventilator. A commercial design has not been reached and, because of the specialized purposes of our experimental work, it is questionable that the ventilator as described will be marketed. Probably certain features of the experimental ventilator will be incorporated into a more comprehensive device to be marketed by Air-Shields. Without the help of Air-Shields, this investigation of a new principle in ventilators would have been impossible.

period of inspiration which is pre-set by the operator. Pressure developed during inspiration is a variable depending upon the patient's resistance and compliance.

DESIGN: The basic functional design of this ventilator is represented in Figures 19 and 20. The power source, compressed gas regulated to 35 pounds per square inch, is delivered through a Venturi into a chamber surrounding the bellow's reservoir. The flow rate characteristics of the Venturi are fixed at 0.7 liters per second (Figure 22) Thus, the displacement of gas (tidal volume) from the bellows is a function of the period of time gas flows through the Venturi to compress the bellows. Therefore, adjustment of this variable, designated either inspiratory time or tidal volume, is pre-set for each patient by the operator using an adjustment on the timer component. This timer also regulates the intervals of zero flow through the Venturi (permitting passive expiration) between each recurring cycle. Thus a second control adjustment on the timer determines expiratory time or the effective respiratory rate. When this rate control is pre-set to produce cycles at a frequency faster than the patient's spontaneous respiratory rate, the ventilator operates as a Controller. Conversely, when the rate control is pre-set to cycle slower than the patient's spontaneous frequency, the ventilator operates as an Assistor in which the timer operation is overriden by a sensing mechanism which activates gas flow through the Venturi with minimal inspiratory effort by the patient.

The ventimeter principle was incorporated into the design of the experimental ventilator to permit continuous direct visual monitoring of all ventilation (spontaneous and assisted and controlled) on the same bellows. Whether the anesthetist compresses the bag or turns on the ventilator, he observes each tidal volume and may compare it with the patient's unassisted breathing.

The experimental ventilator is shown in Figure 21, mounted on an anesthesia machine and on a stand for use in ward patients. The bellows is the same as that used in the Ventimeter. The compact enclosed unit includes all the pneumatic components diagrammed in Figures 19 and 20. The controls include the:

1. selector between bag and ventilator;
2. selector between Controller only and Assistor-Controller operation;
3. on-off ventilator;

4. tidal volume;
5. respiratory rate;
6. sensitivity of Assistor.

Inspiratory flow rate may be altered but is usually left maximal (0.7 liters per second). Tidal volume may be varied between 300 cc. and 1400 cc., respiratory rate between 6 and 50 per minute, and sensitivity between 0.1 and 4.0 cm. H_2O.

Another innovation in the experimental ventilator is the location of the detection of patient effort at the tracheal tube on the patient's side of the breathing check valves. The sensing mechanism, which triggers the timer and thereby the Venturi flow, is sensitive only to a relative decrease in pressure and is thereby, essentially unaffected by varying flow rates of anesthetic gas into the breathing circuit. An exquisite sensitivity to weak inspiratory efforts has been achieved by the use of a pneumatic amplifier in the sensing component. The result is stable performance of the detector and a lesser tendency for pneumatic oscillation. However, because of the high level of detection of weak negative pressure, care must be taken to be sure that the Assistor is not triggered by the small fluctuations in airway pressure due to the heart beat, instead of those of inspiratory effort by the near-curarized patient. Since the check valves which are situated near the tracheal tube have an appreciable opening pressure (0.45 - 0.75 cm. H_2O when valve leaflets are wet), the detection system and the anesthesia breathing circuit have the following unique features:

a. The initial weak inspiratory effort is detectable as negative pressure within 0.15 seconds after it becomes sufficient to open the inspiratory check valve. A pressure drop of only 0.2 cm. H_2O triggers the Assistor after the inspiratory valve opens.
b. The inherent resistance of the check valves favors the early detection of the patient's effort and damps the transmission of spurious pressure signals resulting from accordian-like recoil of the corrugated breathing tubes following inflation. Thus the oscillations common with assistor ventilators of high sensitivity are minimized by the location of the detection point at the tracheal tube.
c. Effects on the assistor's sensitivity by the changing pressures in the breathing circuit resulting from high versus low inflow rates of anesthetic gas are minimized by 1.) a high capacity flow through the overflow valve, 2.) the relative locations of inflow and overflow ports, and, 3.) the isolation of the sensing point by the check valves from the rest of the breathing circuit. Accordingly, readjustments in gas flow from a closed circuit (300 cc.) to a high flow semi-closed circuit (12 liters) require minimal or no readjustments in the sensitivity of the Assistor.

Tests of the simultaneous sensitivity and stability of the five assistors available for comparison demonstrated definite superiority of the experimental ventilator. See next section of report.

PERFORMANCE: The family of pressure, flow, and volume curves illustrated in Figure 22 shows the performance of the experimental ventilator operating as a Controller at a frequency of 20 cycles per minute to ventilate a lung model simulating an average healthy anesthetized apneic adult (compliance 0.04 liters per cm. H_2O and resistance of 2 cm. H_2O per liter per second provided by a MacGill size 10 tracheal tube). The tidal volumes range from 300 to 1350 cc. as a result of adjusting one control on the ventilator, thereby changing the duration of inspiration from 0.4 sec. to 2.4 sec.

Analysis of the performance of the experimental ventilator to changes in airway resistance of the patient and to changes in pulmonary-thoracic compliance revealed a similarity to that of volume-limited devices with one notable exception (Figure 23). While the experimental time-limited ventilator maintains the delivered alveolar ventilation comparable to the volume-limited device, it does not prolong the post-inspiratory pressure plateau in patients with minimal airway resistance and maximal compliance. This effect is illustrated in Figure 23 which compares the Jefferson AC-6, operated as a volume-limited device, with that of the experimental time-limited ventilator. Note that when both ventilators are adjusted to deliver comparable tidal volume (500 cc.) to the lung model arranged for high resistance and low compliance, a significant difference was observed in their pressure curves when the lung model is converted to normal resistance and compliance. The volume-limited AC-6 prolonged the airway pressure of 23 cm. H_2O without flow in the rigid model and sustained a continuous positive pressure of 12.5 cm. H_2O upon the normal lung model for more than a second after inspiratory flow had ceased. In the less compliant model with simulated bronchoconstriction, the sustained positive pressure of 23 cm. H_2O for more than a second without significant airflow served no purpose to ventilation but would be very undesirable in the hypovolemic-hypotensive patient. In contrast the mean pressures following zero airflow for the time-limited ventilator were both less than 5 cm. H_2O for about 0.5 seconds. This test comparison assumes that the anesthetist is using only 500 cc. tidal volume in the relaxed or non-compliant patient. If he adjusts the ventilator to deliver 500 cc. to the low-compliant, high resistance patient and does not readjust the ventilator after these impedances are returned to normal by relaxant drug or by subsequent

bronchodilatation, the positive pressure plateau effects are more exaggerated (Figure 24). In this instance, the sustained pressure without flow decreased from 28 cm.H_2O to 17 cm.H_2O for 1.5 seconds as the patient relaxed. While the time-limited ventilator similarly delivers a larger tidal volume, the sustained pressure without flow is less than a mean value of 8 cm.H_2O for 1 second or less.

These comparisons in the lung model demonstrate that the time-limited ventilator will almost eliminate the undesirable feature of the volume-limited ventilator, namely, prolonged pressure plateau with no flow which decreases right heart filling without benefitting the ventilation, especially important in the intermittently relaxed hypotensive patient. Therefore, the experimental ventilator is an improvement functionally over the volume-limited ventilator without the sacrifice of any of the advantages which both designs share in comparison with the pressure-limited devices. In other words, unlike the pressure-limited devices, the experimental time-limited ventilator does not compromise ventilation when the patient increases resistance or decreases compliance, and this compensation does not require diagnosis and readjustment of the device. Such compensation is attained with a pressure-limited ventilator only after the operator diagnoses the alteration in the patient's respiratory system and then manually readjusts the ventilator controls (either flow or pressure).

MONITORING: Unlike conventional ventilators, the monitoring features of the experimental ventilator provide information about the patient's respiratory status and thereby about the level of maintenance of anesthesia.

Airway Pressure is indicated at the tracheal tube rather than at some distal point in the larger reservoir of the breathing circuit (Figures 19 and 20). This location of pressure measurement on the patient's side of the breathing valves reflects more closely both the pressure applied to the tracheal tube and the expiratory resistance of the anesthesia breathing circuit, heretofore neglected in aneroid indicators on ventilators. Further, the small negative pressures of 0.2 to 1.0 cm.H_2O of weak inspiratory effort by the patient, may be visually followed.

Volume delivered and exhaled is similarly monitored continuously. The dimensions of the reservoir bellows and its position at eye level provides the operator with a convenient means of

watching the tidal volumes during spontaneous respiration whether the bag or ventilator is employed. The same bellows meters the patient's tidal volumes from induction of anesthesia through emergence, permitting the anesthetist to compare and equate the pattern of respiration applied by positive pressure with the patient's spontaneous breathing. This matching is possible in light anesthesia before the anesthetic depresses respiration. During recovery from anesthesia, after the ventilator has been turned off, the anesthetist is informed by the Ventimeter excursions whether the patient has residual respiratory depression and still needs assisted ventilation.

THE PATIENT'S SPONTANEOUS INSPIRATORY EFFORT is monitored by means of a flowmeter 1 3/8 inches high (the "Assist Indicator" labeled in Figures 19 and 20). The bobbin of this miniature flowmeter, a steel ball of 1/8 inch diameter, is deflected from its resting seat when the patient's effort triggers the Assistor.* This detection permits observation of residual respiratory activity in clinically curarized patients which defies detection by any clinical sign. To evaluate the reliability of this simple negative pressure detector, diaphragmatic electromyography (EMG) and airflow have been recorded (Figure 25). Results confirm the validity of apnea monitoring with only the assist indicator, provided the anesthetist understands oscillation and how to rule it out.

CLINICAL TRIAL: In our clinical work, the most important parameter of a ventilator is its ability to follow, with simple adjustments, the patient's apneic carbon-dioxide sensitive threshold. Our clinical anesthesia routines for establishing and maintaining this operation of a ventilator are called servo-cycling. We have practiced servo-cycling with four of the aforementioned commercially available ventilators in our department since 1957.

MAINTENANCE OF ADEQUATE VENTILATION: Previous investigations have been reported which demonstrate a precise maintenance of arterial pCO_2 in a large series of surgical patients

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* or when other pressure fluctuations in the circuit trigger the sensing device even when the patient is apneic, an artifact we call oscillation. To differentiate these spurious oscillations from weak inspiratory triggering (displacements as low as 10 cc.), the assistor is turned off, the anesthetic gas inflow minimized temporarily, and the bellows is observed to determine if small tidal excursions confirm or deny the presence of inspiratory activity by the near-curarized patient. If the assistor had not been oscillating, the rate would revert to the slower one set on the controller.

given the common anesthetic agents. The experimental ventilator is ideally suited to servo-cycling operation, not only because of its constancy of tidal volume, but also beccuse of its feed-back of information by its built-in monitors.

Since each delivered tidal volume is relatively constant, the recurring intervals of hyper- and hypoventilation of servo-cycling during the respective assist and control phases are purely the result of changes in the rate of ventilation. For example, a patient receiving 600 cc. tidal volume at a spontaneous rate of 14 per minute is given an alveolar ventilation of 7.0 liters (600 - 100 cc. dead space x 14). During the interval of apnea, with the ventilator timer set at 10 cycles per minute, his tidal volume remains the same, resulting in an alveolar ventilation of 5.0 liters per minute (600 - 100 x 10). This alternation between a ventilation of 7 liters per minute and 5 liters per minute occurs in response to alternating periods of apnea and spontaneous effort, each of which lasts from 1/2 to 5 minutes. The corresponding fluctuations in arterial pCO_2 vary only 4 millimeters and the accompanying shifts in arterial pH, by the precise methods of Dr. Lowe of this department, are within 0.02 pH units.

During the past 15 months in clinical experience with four experimental ventilators in routine use, the advantages of the servo-cycling technic in surgical patients have frequently been demonstrated. Dr. Lowe's pH and pCO_2 studies have shown that not only the respiratory acidosis of hypoventilation, but also the metabolic acidosis attending excessive hyperventilation have been avoided during Fluothane-O_2 anesthesia. Depending upon the anesthetic agent, pH maintenance has been within normal limits or insignificantly reduced. Abdominal relaxation has been noteworthy and sufficient to greatly reduce doses of relaxant drugs.

MANAGEMENT OF HYPOTENSION: Prediction of hypotension with continuous slow surgical hemorrhage has again preceded the appearance of tachycardia or of lowered blood pressure (as measured by arm cuff and auscultation). As reported previously, the normotensive patient, who is to later develop peripheral hypotension, departs from the servo-cycling pattern and exhibits continuous respiratory drive as a premonitored event.(indicated on Assistor, not the blood pressure).

Hypothesis: With the attending metabolic acidosis of reduced circulation, there is a slight elevation in pCO_2 at the brain stem. This rise in carbon dioxide at the respiratory center

sustains inspiratory activity despite the hyperventilation of the lung maintained by the ventilator. Thus, the patient who had been alternating between assist and control on the ventilator, reverts to continuous triggering of the assistor. In other words, the previous recurring apneas disappear. The resulting pattern of continuous respiratory drive may precede the detection of hypotension (cuff and stethoscope) by 10 - 20 minutes.

Further evidence for this hypothesis is the series of events after the peripheral hypotension is reversed by appropriate therapy (whole blood, vasopressors, or $NaHCO_3$). Then the patient returns to the recurring apnea of servo-cycling. Several minutes later, the blood pressure returns to normal. Thus the clinical use of the servo-cycling responses with the information afforded by the assist indicator forewarns of impending shock. An earlier diagnosis and confirmation of therapy is provided by these simple means than is attainable by any other conventional signs. Whether central aortic pressure tracings would reveal this early information has not been determined but is doubtful. Presumably, the important differences in these respiratory responses depend upon changes of a few millimeters in the pCO_2 at the respiratory centers. It is doubtful that the transient "loss" of the patient's CO_2 threshold and its subsequent restoration could be correlated with measurable changes in arterial blood pressure.

ASSISTOR OPERATION AND CURARIZING DRUGS: As reported previously, the technic of servo-cycling is practical in the curarized patient since the Assistor is able to follow minimal inspiratory effort. In such patients, the anesthetist judges him by clinical signs to be apneic since he cannot discern the patient's very small efforts which trigger the Assistor. Accordingly, the assist indicator refines further the servo-cycling technic by informing the anesthetist of the recurring onset and recovery from apnea, a cycle which occurs every few minutes.

USE OF ASSISTOR FOR INDUCING GENERAL ANESTHESIA: Since the interpretation of the assist indicator allows the anesthetist to follow the patient's respiratory depression, the induction of anesthesia in a conscious patient with potent inhalation agents is efficient and safe. For 15 months in this department, lightly premedicated or unmedicated patients have been induced (cyclopropane or Fluothane) in conscious patients triggering the assistor of the experimental ventilator. As the patient triggers the assistor, cyclopropane or Fluothane rapidly anesthetized him to

first plane anesthesia (2 - 3 minutes). These inductions by face mask are smooth, safe, and reassuring since oxygenation and CO_2 elimination are continuously assured by the ventilator. The patient activates the assistor with minimal effort. He relaxes his abdominal muscles. The continuous triggering of the assist indicator assures the anesthetist that he has not overdosed the patient.

USE OF THE VENTILATOR DURING MAINTENANCE OF ANESTHESIA: After tracheal intubation employing curare or succinylcholine, the transient apnea interferes for only a few minutes with establishing the servo-cycling pattern (Figure 25). This is accomplished by incremental adjustments every 2 - 3 minutes in tidal volume until apnea supervenes, noted by the anesthetist as failure of the assist indicator to cycle. At this juncture, the rate of the controller is set at 80% of the patient's previous spontaneous rate. This slightly elevates the reduced pCO_2, terminating the apnea. From this moment, the ventilator controls are left alone. The servo-cycles of relative hyperventilation during respiratory effort, alternating with relative hypoventilation during apnea, are self-perpetuating in the uneventful case.

This individualizing of the ventilation to match the patient's threshold requirements is made by adjustments of the ventilator's volume and rate during first plane anesthesia. Continued maintenance of the servo-cycle (or recurring apnea) depends upon:

1. The level of anesthesia in relation to surgical stimulation
    a. If the patient's level becomes lighter, he continuously triggers the assistor, usually at a faster rate.
    b. If his anesthesia becomes deeper, he stops triggering the assistor in apnea. The concentrations of cyclopropane or Fluothane are changed accordingly, until servo-cycling reappears.
2. The circulation (as discussed above).
3. The use of discrete doses of relaxant drugs to avoid gross overdose and prolonged total apnea.
4. The performance of all the components in the breathing circuit which influence CO_2 removal (absorbers, valves, leaks and kinks).

USE OF VENTILATOR TO HASTEN RECOVERY FROM ANESTHESIA: At the termination of surgery, the ventilator is switched to "controller only" operation (Figure 19 and 20) to hasten elimination of anesthetic gases and emergence to conscious breathing. The patient wakes up from inhalation anesthesia quickly and the "recovery room slump" is avoided. Although this interval of hyperventilation lowers his pCO_2 and would produce apnea during light or deep anesthesia, no apnea is observed since the patient returns to consciousness. Then his pCO_2 becomes only one of many factors in the CNS regulation of his breathing. The anesthetist's command,

control, and assessment of ventilation has been extended by the experimental ventilator to cover the entire period of the patient's journey through unconsciousness. In contrast, the conventional use of ventilators today is only during maintenance of anesthesia. The assist indicator allows the use of potent agents with continual mechanical ventilation without sacrificing the observation of the patient's spontaneous respiratory activity as a sign of anesthetic level or overdose. Anesthetists who have become experienced with the experimental ventilator do not fear overdose with potent agents nor do they insist upon spontaneous breathing during closed system oxygen-Fluothane anesthesia. Fortunately, the common clinical doses of curare or succinylcholine produce total apnea for only a few minutes (despite the widespread idea that such apneas last 20 minutes). The EMG as well as the assist indicator of the experimental ventilator prove that significant motor function of the inspiratory muscles sufficient to trigger the assistor returns within 2-3 minutes (Figure 25). Such information is useful in deciding either intermittent doses or continuous rates of infusion of relaxant.

The experimental ventilator has been used for approximately 15 months in clinical anesthesia in the surgical procedures performed at the Institute. It is useful for the short case done with a face mask or the 12 hour resection when the trachea is intubated. The simplicity of its operation by clinicians has been a real advantage. The only two adjustments required are: tidal volume and rate. Occasionally the variable sensitivity control is readjusted for an infant or a 90 year old adult.

An improved set of clinical signs for judging the effect of premedication, anesthetic planes, the requirements for relaxant drug, as well as the patient's circulatory status have been developed through experience with the feed-back responses between the patient and the ventilator. These refinements have extended the safety of anesthesia especially to poor-risk surgical patients.

USE OF VENTILATOR IN CONSCIOUS PATIENTS: Trial of the experimental ventilator in tracheotomized pulmonary cripples has been started. In this application, the bellows is removed from the unit. Oxygen flow through the Venturi is delivered directly to the patient, a feature which simplifies operation and conserves oxygen. The simple compact unit for ventilating the patient in his hospital room or on the ward is illustrated in Figure 21. The breathing circuit is converted to a non-rebreathing of oxygen or compressed air. The non-rebreathing valve is activated by pressure from the ventilator to close the expiratory port during inflation. High humidification of the inspired gas is being evaluated.

Tracheotomized patients are comfortable on the ventilator. The Assistor components are sufficiently sensitive that a cuffed tracheotomy is not required to trigger inspiration. The flow rate of 0.7 liters per second provides the patient with the feeling that he is "getting enough air".

Several of these prototype experimental ventilators can be made available for trials by anesthesiologists designated by the Research and Development Command. Trial periods should be limited to six weeks. Assessment by other groups is invited.

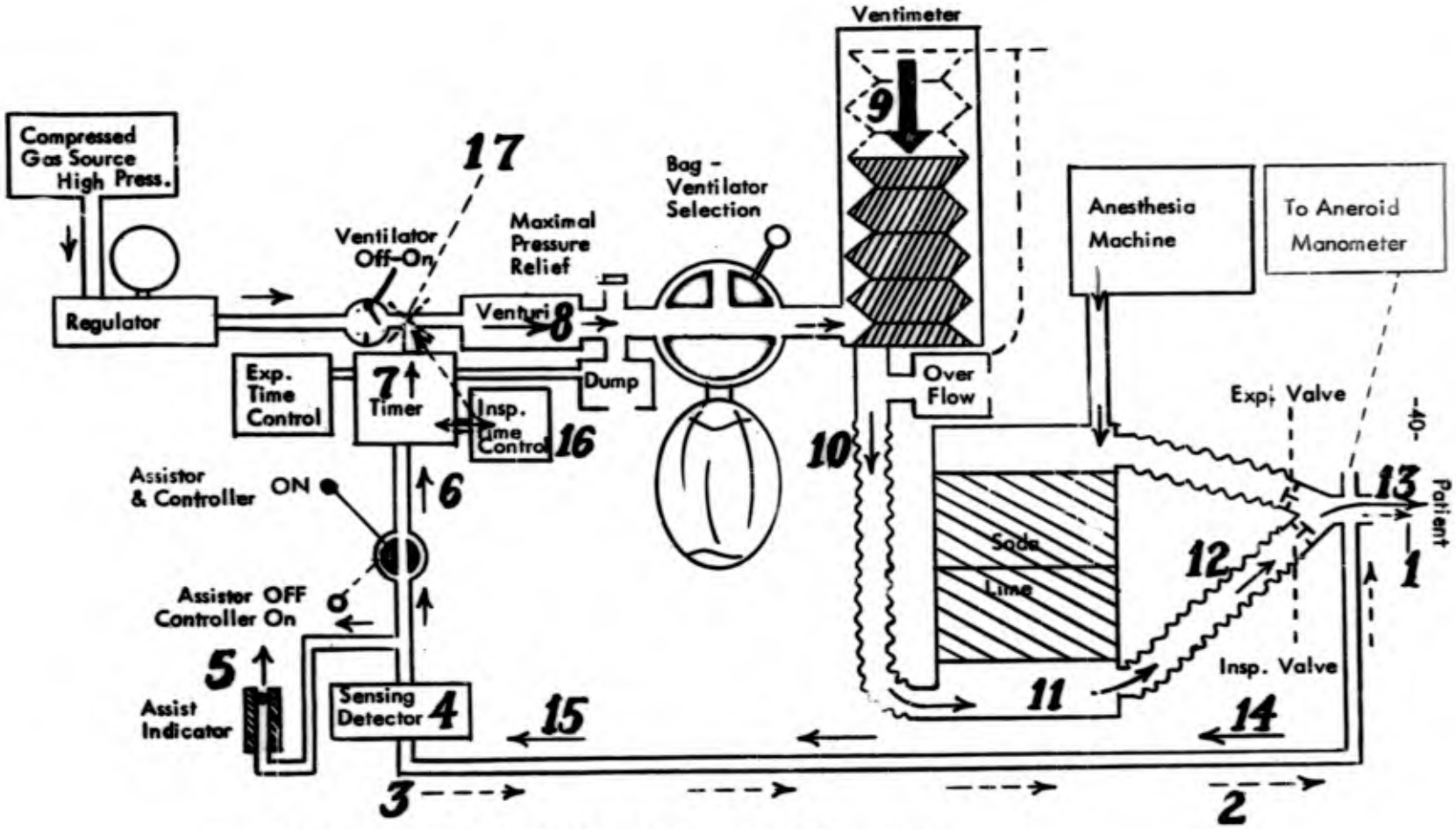


Figure 19. FUNCTIONAL DIAGRAM OF EXPERIMENTAL VENTILATOR

INFLATION PHASE (activated by patient)

Sensing detector opens gas source to Venturi for interval pre-set on timer.

Numbers 1 - 17 show sequence.

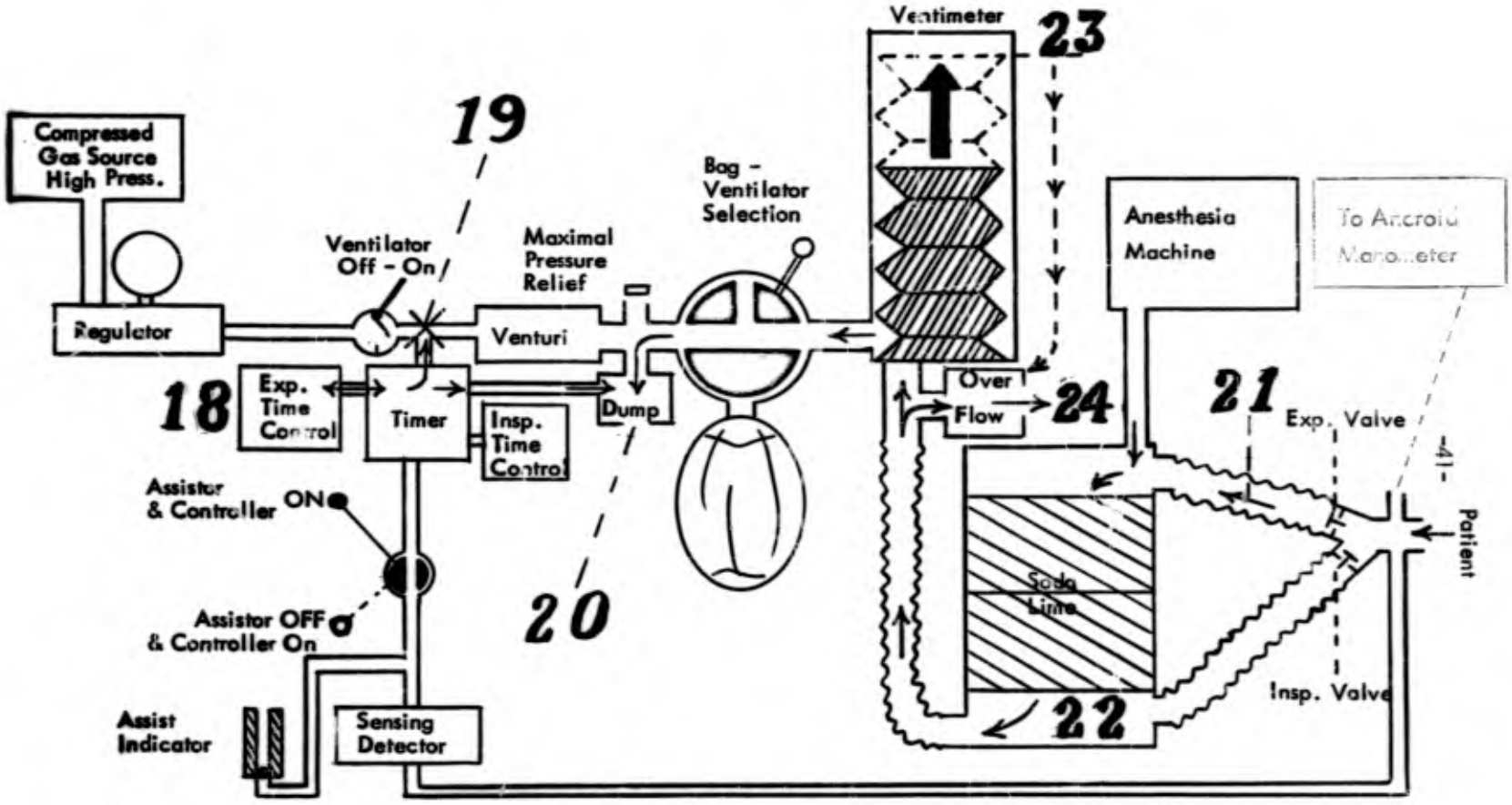


Figure 20. FUNCTIONAL DIAGRAM OF EXPERIMENTAL VENTILATOR

EXPIRATORY PHASE

Timer stops Venturi flow, opens dump valve. Full bellows opens overflow valve. Numbers 18 - 24 show sequence.

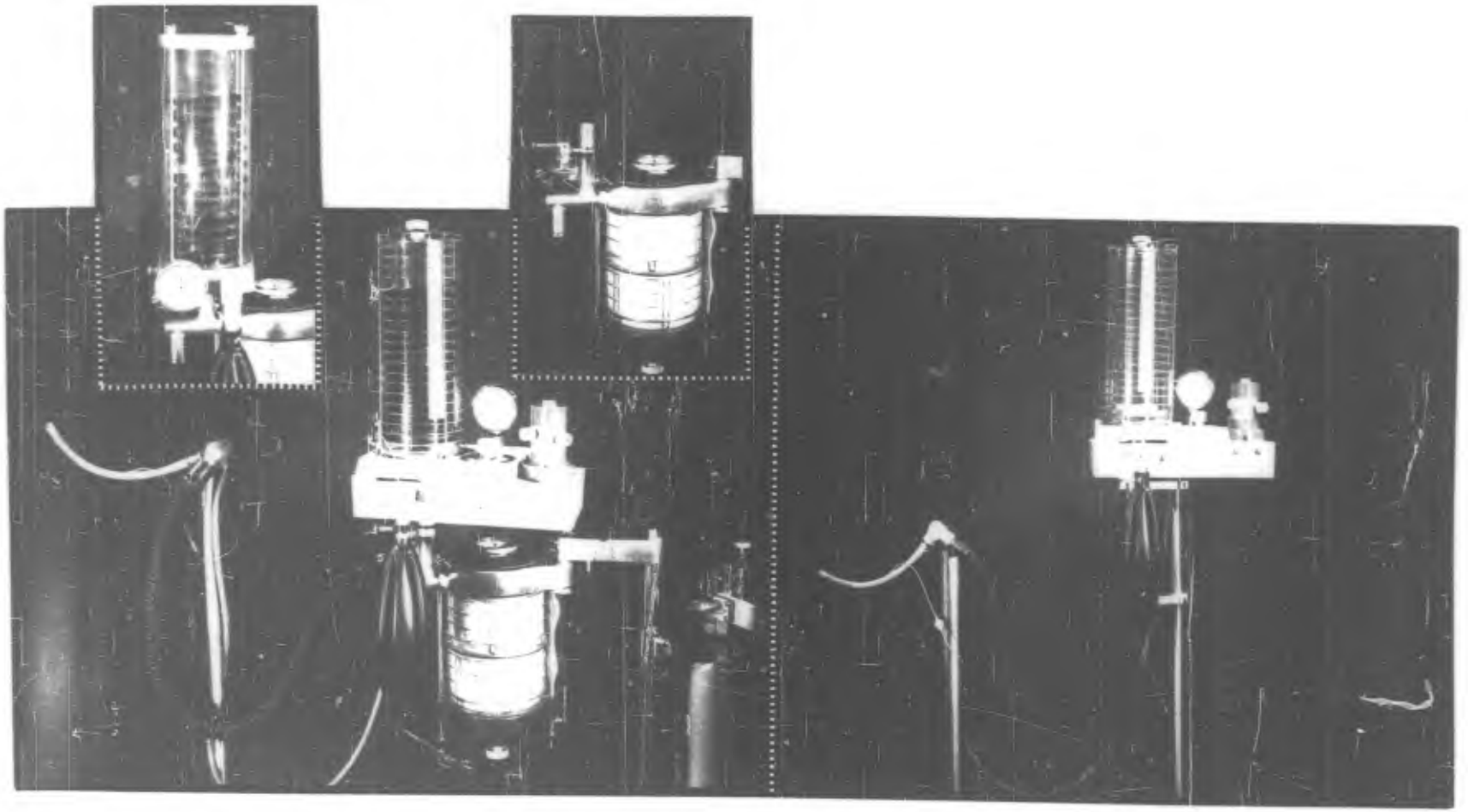


Figure 21. TIME LIMITED VENTILATOR.

The ventilator is designed for mounting on the anesthesia machine at the expiratory outlet (right inset) in the same manner as the ventimeter (left inset). The slot above the bag is the selector switch permitting optional use of bag or ventilator, both of which connect to outside of bellows (left). Bellows is removed for use of ventilator in ward patient permitting the driving gas (O_2 or compressed air) to be used also as the ventilating gas (right).

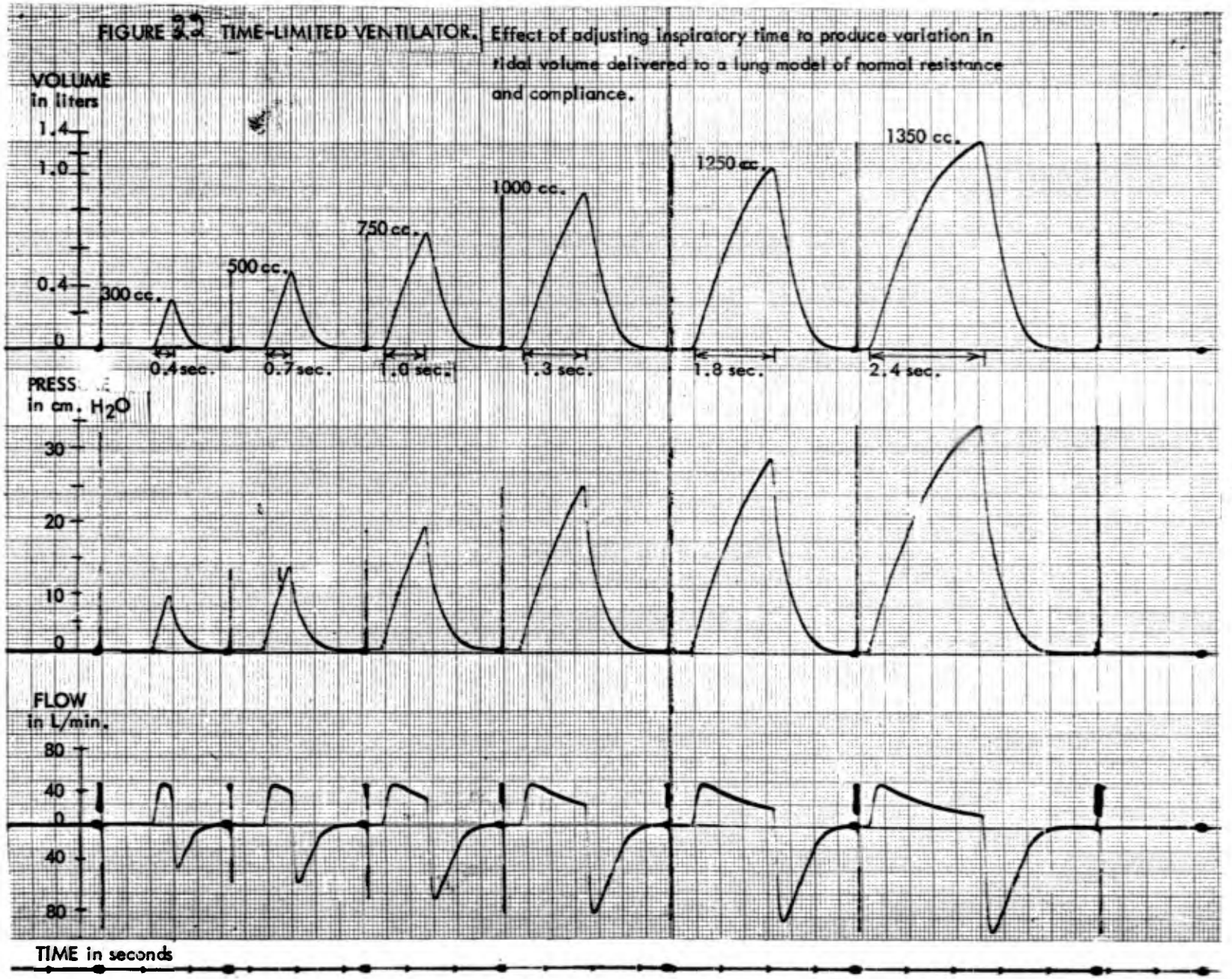


FIGURE 2.2 TIME-LIMITED VENTILATOR. Effect of adjusting inspiratory time to produce variation in tidal volume delivered to a lung model of normal resistance and compliance.

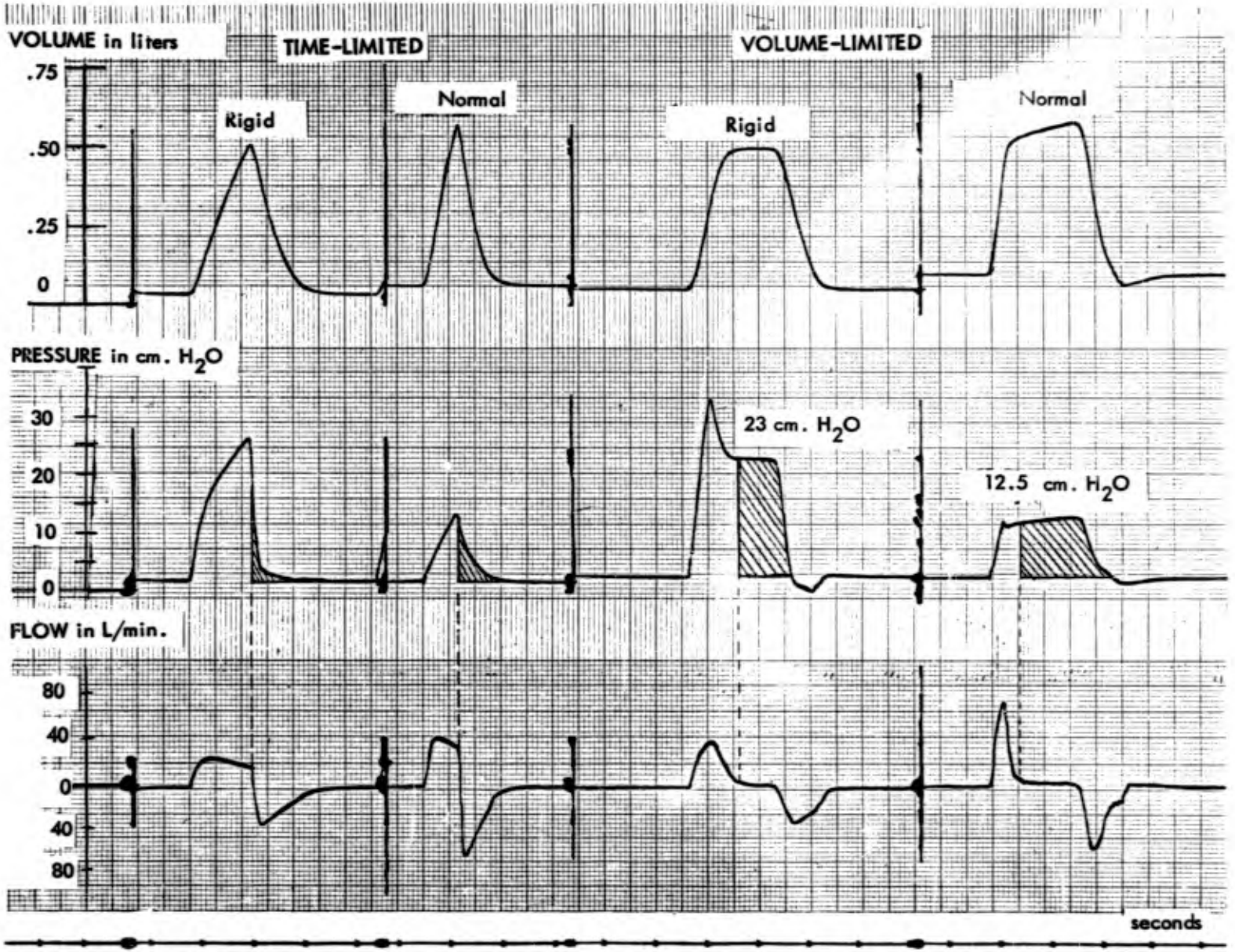


Figure 23. Comparison of time-limited and volume-limited (AC-6) ventilators. Response to relaxation of patient. Ventilator controls optimally readjusted by anesthesiologist.

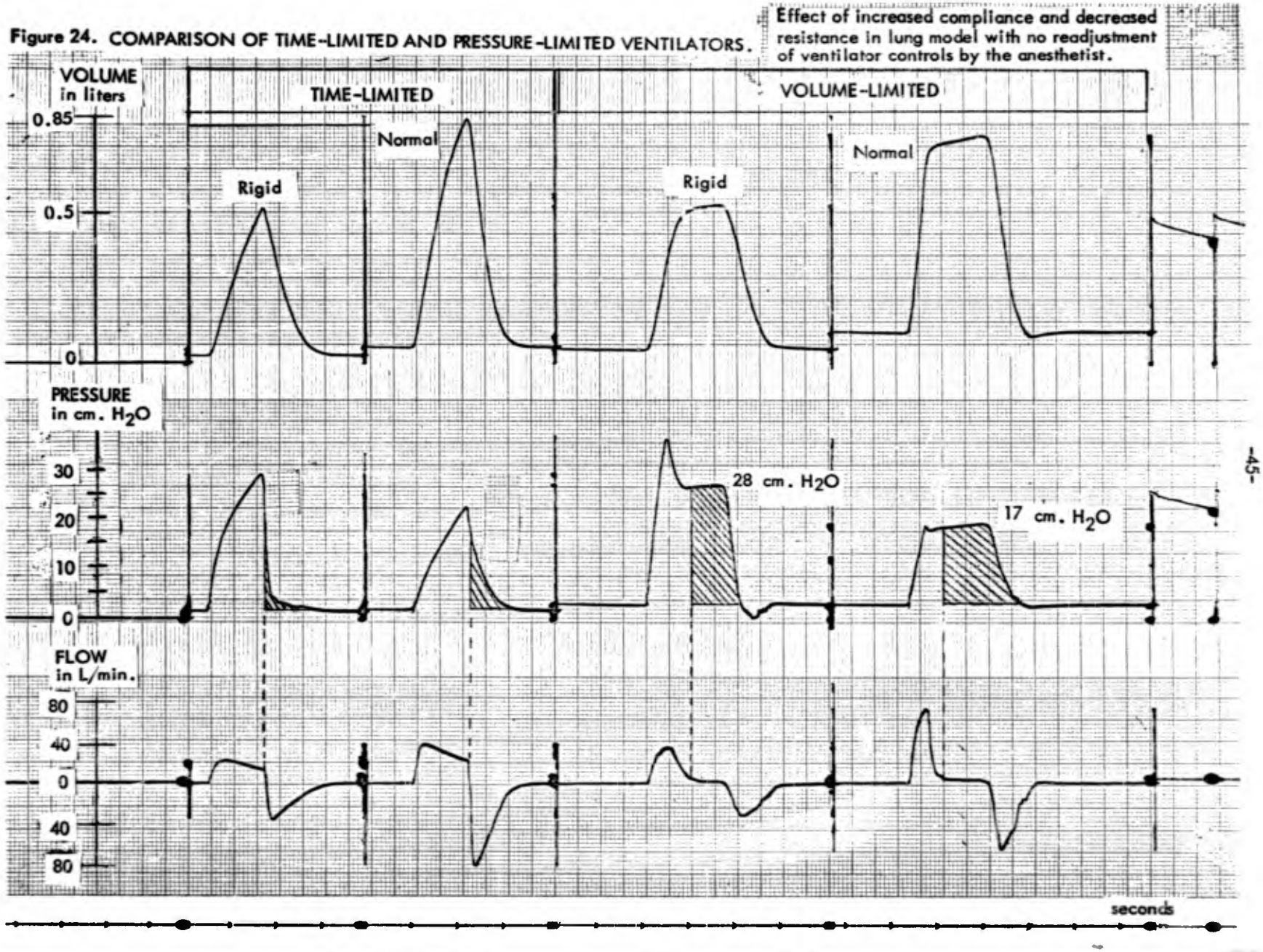


Figure 24. COMPARISON OF TIME-LIMITED AND PRESSURE-LIMITED VENTILATORS.

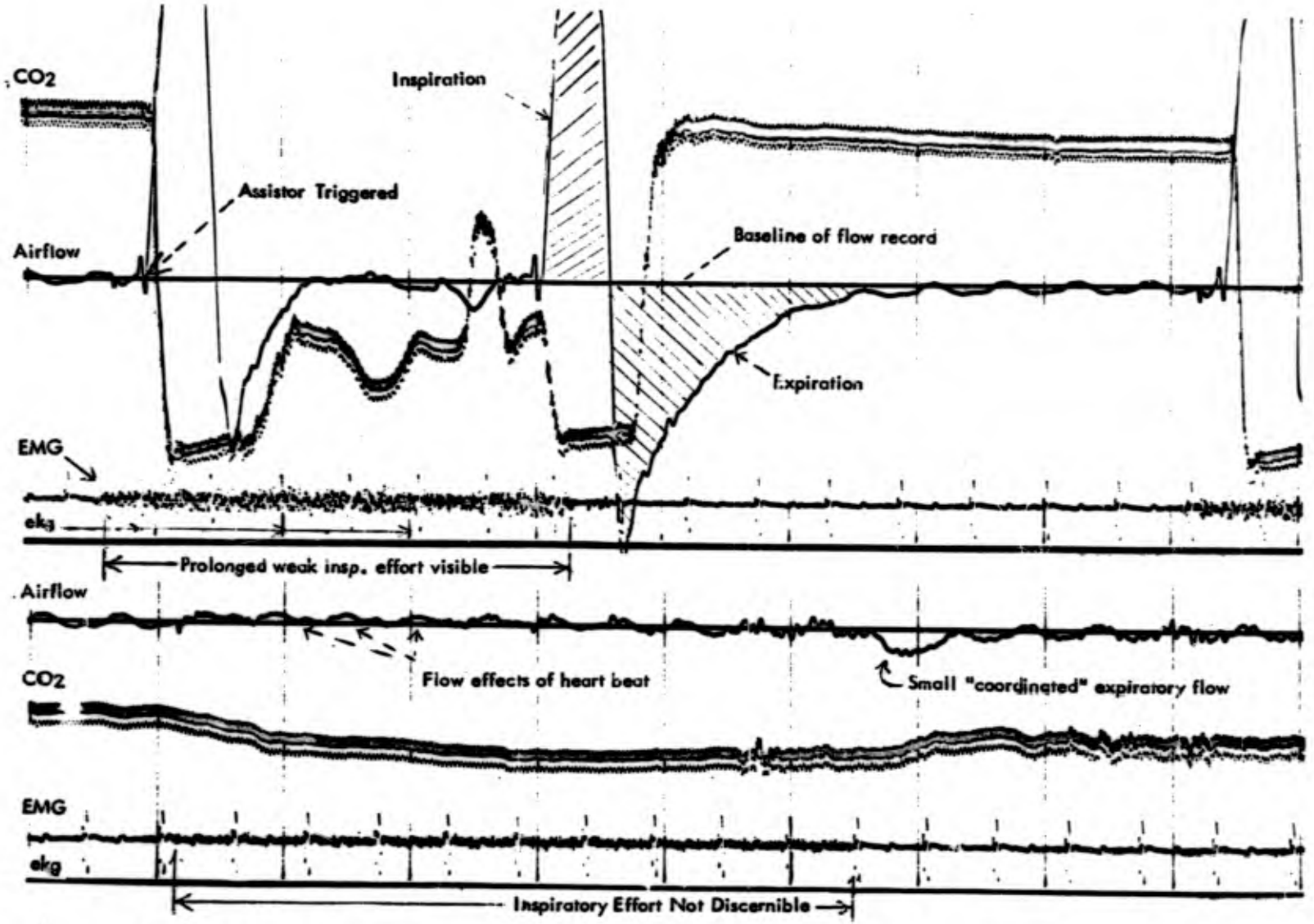
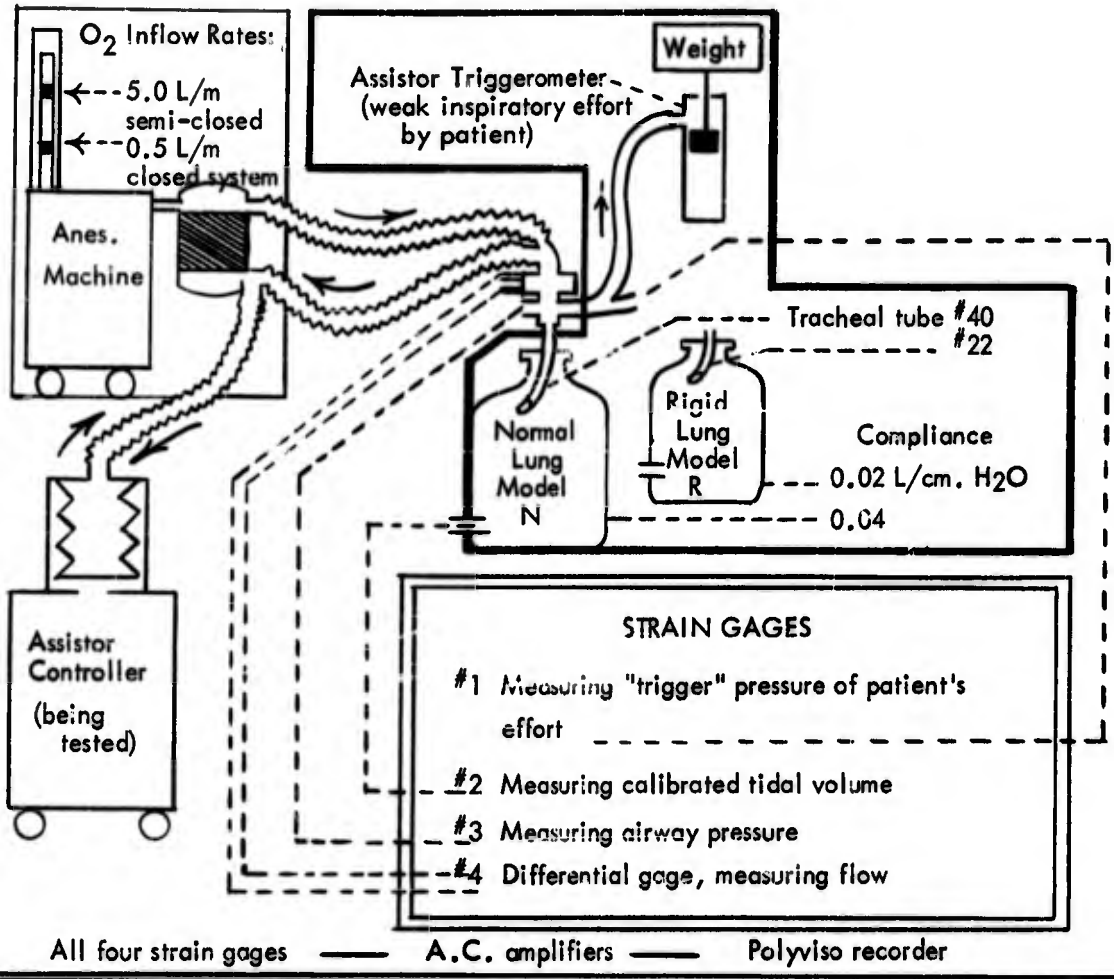


Figure 25. SIMULTANEOUS EMG diaphragm, CO_2, AIRFLOW during C_3H_6 anesthesia. Upper tracing before succinylcholine. Lower tracing 3 minutes later showing early recovery of paralysis on EMG while "clinical apnea" persists.

V. COMPARATIVE TESTS OF ASSISTORS

The design and clinical use of assistors poses several difficulties which are poorly understood and generally neglected. To date, this problem has not been submitted to objective analysis in anesthesia research. While it is well recognized that such assistors as the Bird, Emerson, and Bennett have remarkable sensitivity to respond to the patient's effort and synchronize inflation with his pattern of breathing, there are several pitfalls in clinical interpretation of the action of these devices:

1. The near-curarized patient inspires 5 to 50 cc. without assistance.
    a. During the interval of this small inspiration, he takes gas from the circuit while the anesthetic gas is entering the circuit. The inflow rate of anesthetic gas amounts to:
        1. About 10 cc. with a closed system during the patient's spontaneous inspiration.
        2. About 100 cc. with a semi-closed system.
        3. As much as 250 cc. with a high flow system.
    b. These inflow rates damp or obscure the withdrawal of small volumes by the patient's weak inspiration.
    c. Therefore, the design of assistors must necessarily include an adjustment to vary the sensitivity with which the inspiratory signal is detected.
2. If maximal sensitivity (intended for the high flow circuit) is employed with a closed system, the detector responds not to inspiratory effort but to unrelated events:
    a. Pressure changes produced by recoil of the corrugated breathing tubes following inflation trigger the Assistor.
    b. The curarized patient's heart beat produces small rapid volume displacements from 5 to 40 cc. which easily trigger the Bird, Bennett, and Emerson assistors.



PARAMETER COMBINATIONS		COMPLIANCE (Liters per cm. H_2O)	RESISTANCE (cm. H_2O per liter per second)	SIMULATED STATUS OF PATIENT
closed system	semi-closed system			
Normal lung model & size 40 trach. tube		0.04	2.0	Relaxed apneic anesthetized adult
Normal lung model & size 22 trach. tube		0.04	30.0	Apneic adult with severe bronchoconstriction
Rigid lung model & size 40 trach. tube		0.02	2.0	Chest muscles contracted, apnea
Rigid lung model & size 22 trach. tube		0.02	30.0	Chest muscles in tonus, severe bronchoconstriction
Any of above four groups & trigger operating		0.04 or 0.02	2.0 or 30.0	Near-paralyzed with weak insp. effort

Figure 26. DIAGRAM OF CIRCUITS AND MEASUREMENTS FOR RECORDING OBJECTIVE PERFORMANCE OF ASSISTOR-CONTROLLERS

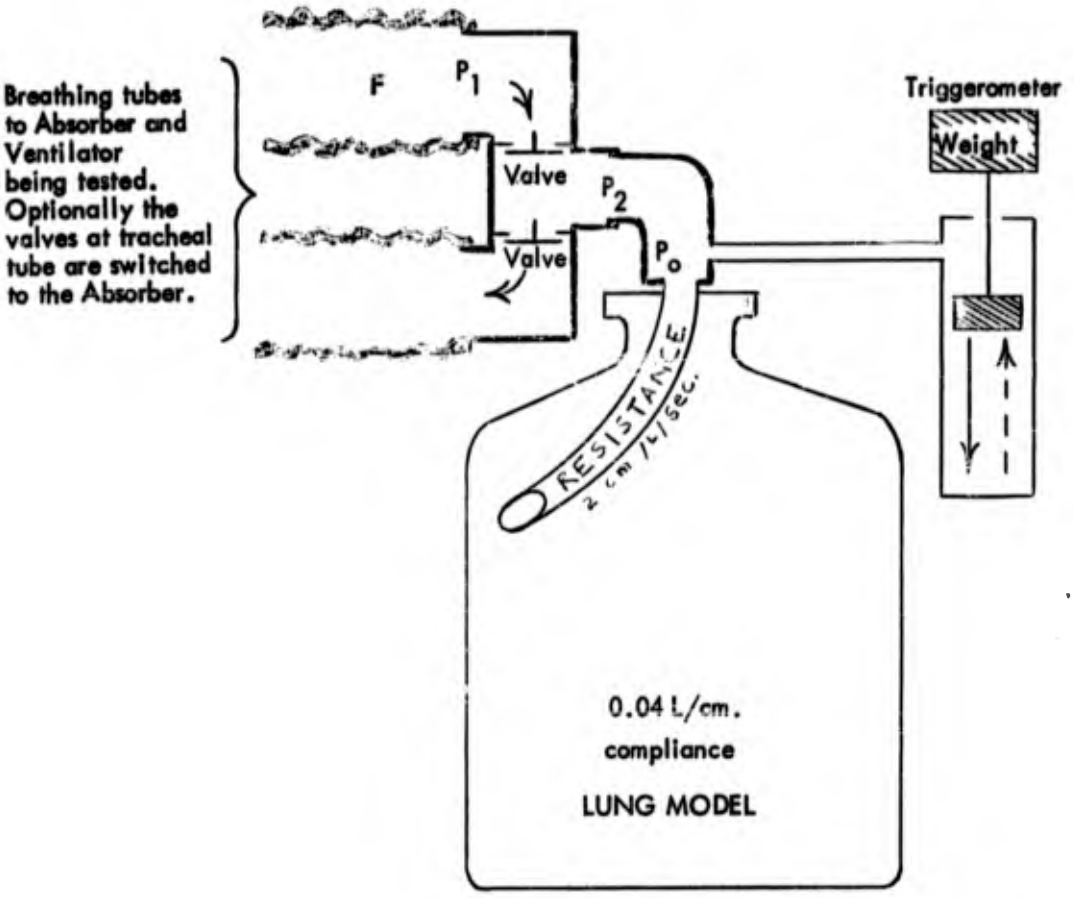


Figure 27. ANALOGUE FOR TESTING ASSISTOR TRIGGERING IN RELATION TO THE DYNAMIC RESISTANCE OF THE CIRCUIT CHECK VALVES:

- P_o - Pressure in cm. H_2O developed by triggerometer (showing inspiratory effort by patient).
- P_1 - Pressure transmitted across inspiratory valve (shows moment of opening of valve).
- P_2 - Pressure developed by patient to open inspiratory valve.
- F - Flow through inspiratory breathing tube.

c. The non-specific small pressure fluctuations transmitted into the breathing circuit by

1. External manipulations of the breathing tubes,
2. Changes in tension upon the thorax or diaphragm during surgical manipulation (moving packs, retractors, or leaning intermittently on the lower thoracic cage).

3. Pneumatic oscillation of the triggering of an overly sensitive Assistor is difficult to rule out because

a. The patient has "clinical apnea" (although an EMG of the diaphragm shows significant inspiratory activity).

b. No simple devices are available to detect weak inspiratory effort.

c. In some assistors, the triggering sensitivity progressively increases during the post expiratory period as a result of the gas inflow. The trigger point is not attained until the reservoir bellows refills and the system reaches an equilibrium. Then the patient's heart beat triggers the Assistor's detector. These events result in a frequency of inflation by the assistor which appears grossly to resemble the patient's previous respiratory rate (15 to 25 per minute). In other assistors, this effect is opposite. The sensing mechanism is unstable when the reservoir is underfilled but then becomes stable and "insensitive" when the bellows reservoir reaches equilibrium position.

d. The equilibrium states of the Assistor and breathing circuits not only vary with gas flow, but also

1. with the overflow valve characteristics of different ventilators,
2. leaks in the breathing system, weight and mounting arrangement of the reservoir bellows, and
3. the amplitude of the cardio-pneumographic displacement of different patients.

These complex interrelationships confound anesthesiologists and ventilator manufacturers. Accordingly, assistors are regarded by many clinicians as tricky, unreliable devices. On the contrary, our experience with such ventilators has been fortified by the ancillary use of pneumatic sensing devices or EMG observations which clarify much of this confusion. Further, the remarkable clinical advantages of ventilation technics such as servo-cycling demonstrate that further work is justified to better understand the interrelated pneumatics of delicate assistors. Both their rational use and basic design could be improved. For example, as a result of what we have learned from experimental observations, we can now do clinical anesthesia with an assistor AND NO MONITORING EQUIPMENT and manage the patient's ventilation to maintain his arterial pH and pCO_2 constant and normal. However, to demonstrate this practice to others, monitors must be used to demonstrate weak inspiratory effort.

Therefore, this project has been underway for several years to objectively test the complicated parameters of Assistors.

The test analogue we have developed is shown diagrammatically in Figures 26 & 27. A piston from the Jefferson ventilator has been modified to simulate the weak inspiratory effort of a near-curarized adult, withdrawing about 50 cc. within 1.0 second from the breathing circuit at the tracheal tube.

RESULTS: Preliminary data confirm the impression that the dynamic resistance and opening pressure of the circuit check valves (inspiratory and expiratory) influence the operation of the various Assistors. It was also evident that the location of these valves in the breathing circuit and the relative position of the inflow and overflow points are critical.

The analysis and interpretation of these data on all the ventilators would inordinarily lengthen this report. Results are therefore limited to studies on one assistor in popular use, the Bird, Mark 4. The performance of the experimental ventilator is also reported.

The Sierra Y-piece valves required an opening pressure of 0.8 cm. H_2O and 0.57 seconds using the same triggerometer signal (Figure 28). Although these values are relatively low in comparison with other competent Y-piece valves, they are relatively high in comparison with the gravity lift Ohio Model 20 absorber check valves.

Typical tracings of the performance of the BIRD assistor are shown in Figures 29 and 30. These records resolve the pneumatic events in relation to the action of check valves at the tracheal tube (Figure 29) and at the absorber (Figure 30).

The BIRD was operated as a volume-limited device with the following adjustments:

FLOW and INSP. TIME: Maximum, dial reading 40.

PRESSURE: dial reading 22.

EXP. TIME: off.

SENSITIVITY: dial reading 5.

The effect of inflow rates of 500 cc. per minute and 5 liters per minute is shown in Tables III & IV. For these trials, the check valves were at the tracheal tube (Figure 29, Table III) or the absorber (Ohio Model 20) (Figure 30, Table IV). The triggering pressures and delay times were comparable of the order of 0.25 cm. H_2O and just over a half second.

When the check valves were changed to the Y-piece at the tracheal tubes, these values were decreased for the semi-closed system but unchanged for the closed system (Table IV).

Performances of the Bird and experimental ventilator is shown in Figures 32 and 33. Following the start of simulated weak inspiratory effort, the Bird responds within 0.7 seconds, the experimental ventilator within 0.5 seconds. Both respond to a relative decrease in existing system pressure of the order of 0.25 cm. H_2O with a semi-closed system and the check valves at the tracheal tube. The BIRD ventilator opens the inspiratory valve for the patient.

COMMENT: Therefore, for stable uniform sensitivity and reliable performance for both closed and semi-closed systems, this Assistor should always be used with the check valves at the Absorber. If use is to be limited to the semi-closed system, the Y-valves at the tracheal tube render the detection of patient effort twice as sensitive and three times more rapid.

BIRD, MARK 4	GAS INFLOW RATE per minute	
	500 cc.	5 liters
Pressure difference in cm. H_2O required to trigger Assistor	0.8 cm. H_2O	0.2 cm. H_2O
Time lapse from start of simulated weak inspiratory effort to triggering	0.57 seconds	0.3 seconds

TABLE III. Effect of Gas Inflow Rates. BIRD ASSISTOR. Check valves (Sierra) at tracheal tube.

BIRD, MARK 4	GAS INFLOW RATE per minute	
	500 cc.	5 liters
Pressure difference in cm. H_2O required to trigger Assistor	0.3 cm. H_2O	0.2 cm. H_2O
Time lapse from start of simulated weak inspiratory effort to triggering	0.54 seconds	0.57 seconds

TABLE IV. Effect of Gas Inflow Rates. BIRD ASSISTOR, MARK 4. Check values at Absorber (Ohio Model 20).

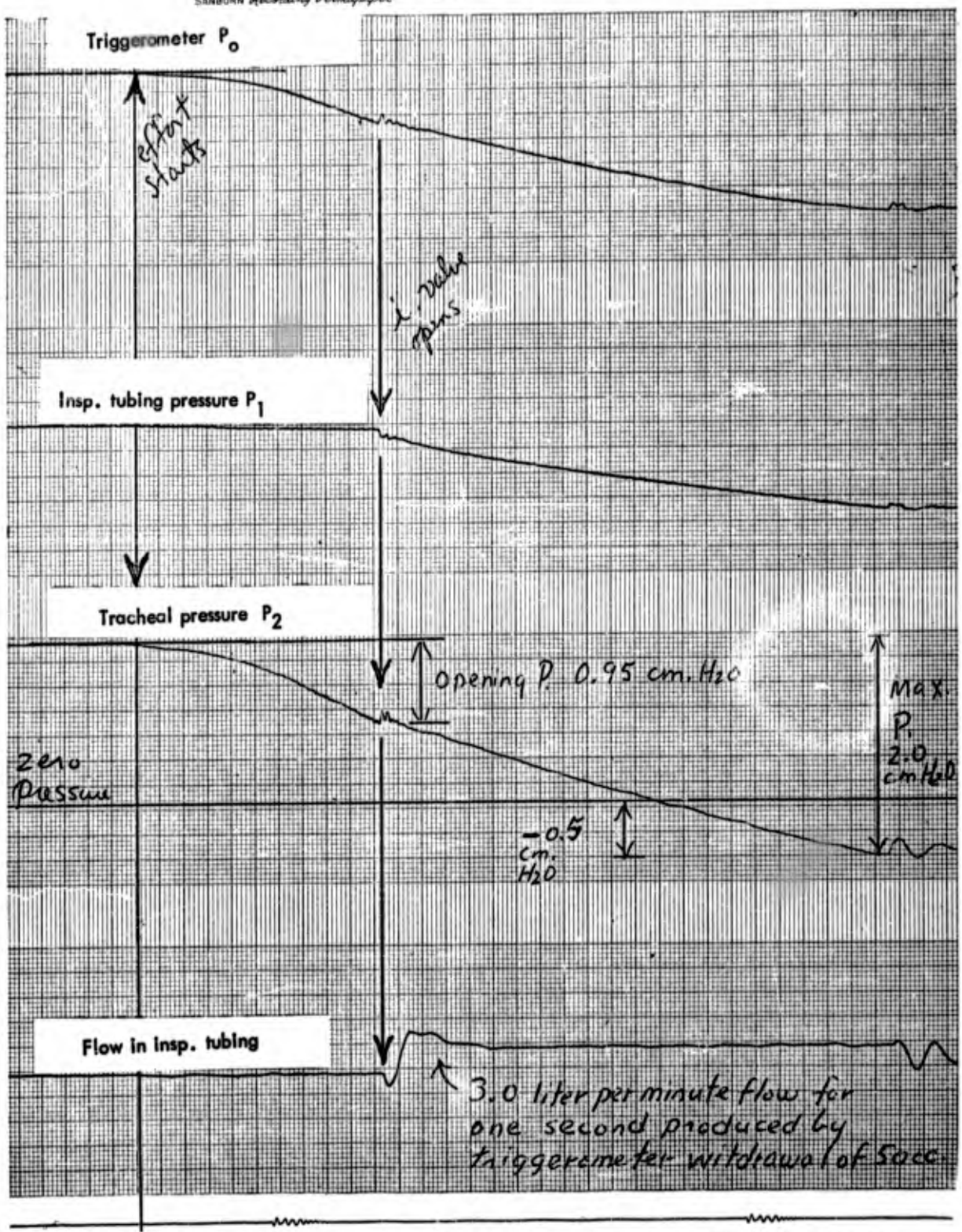


Figure 28. Pressure and Flow Curves obtained from Analogue shown in Figure 27. BIRD Ventilator turned off. Patient's "effort" opens inspiratory Sierra check valve and develops 2 cm. pressure change.

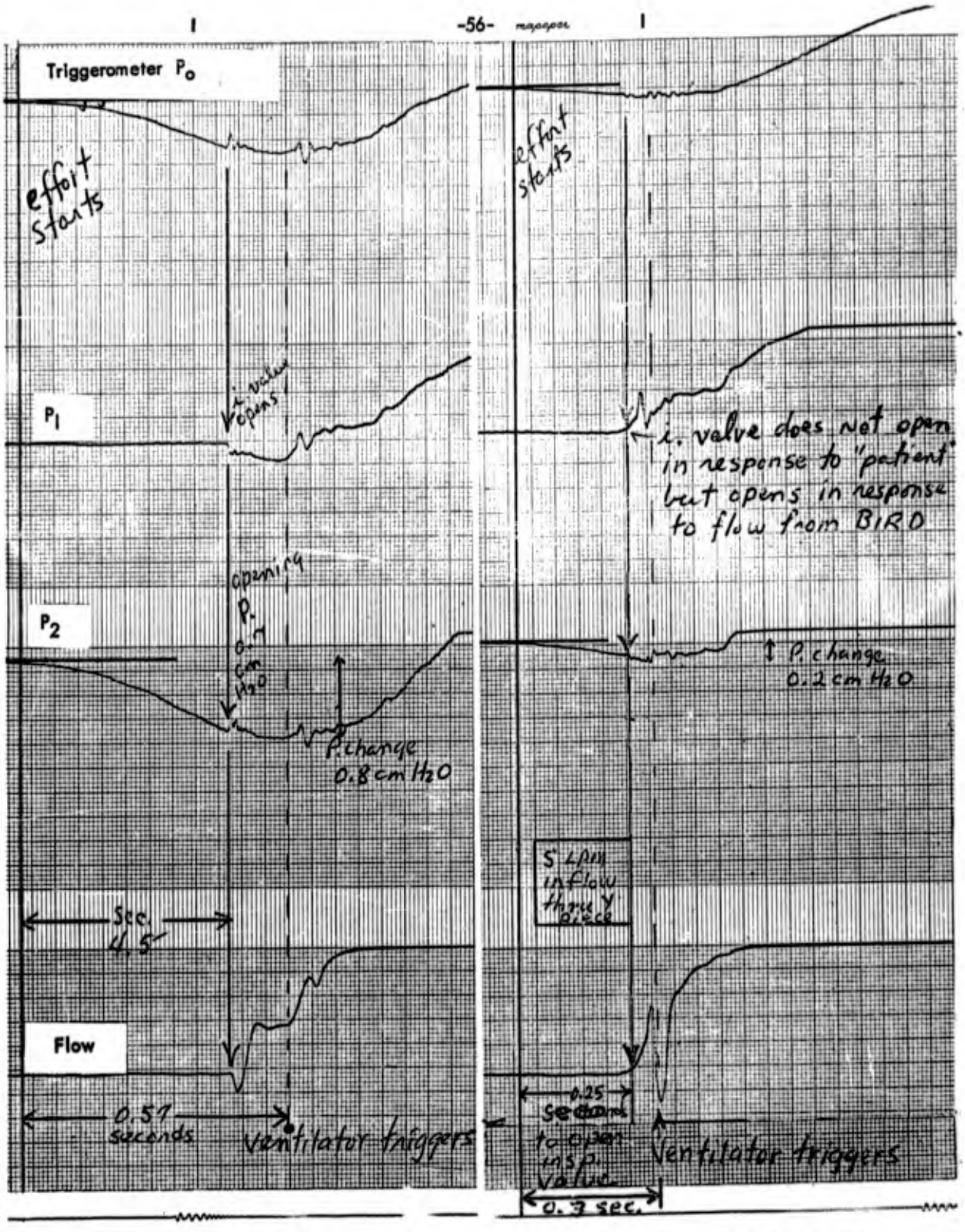


Figure 29. BIRD, Mark 4. 500 cc. and 5 liters gas inflow. Sierra check valves at tracheal tube improve semi-closed system.

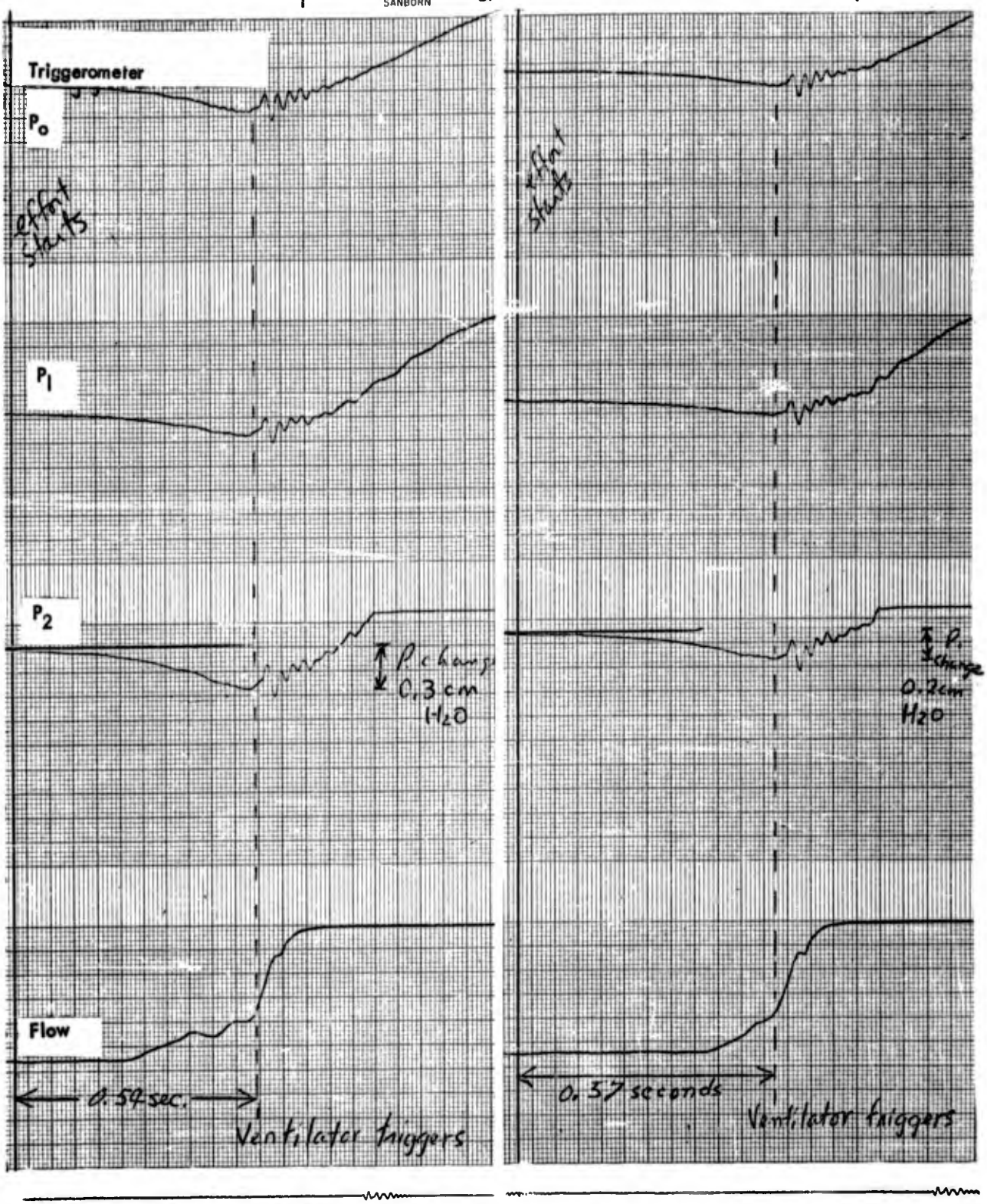
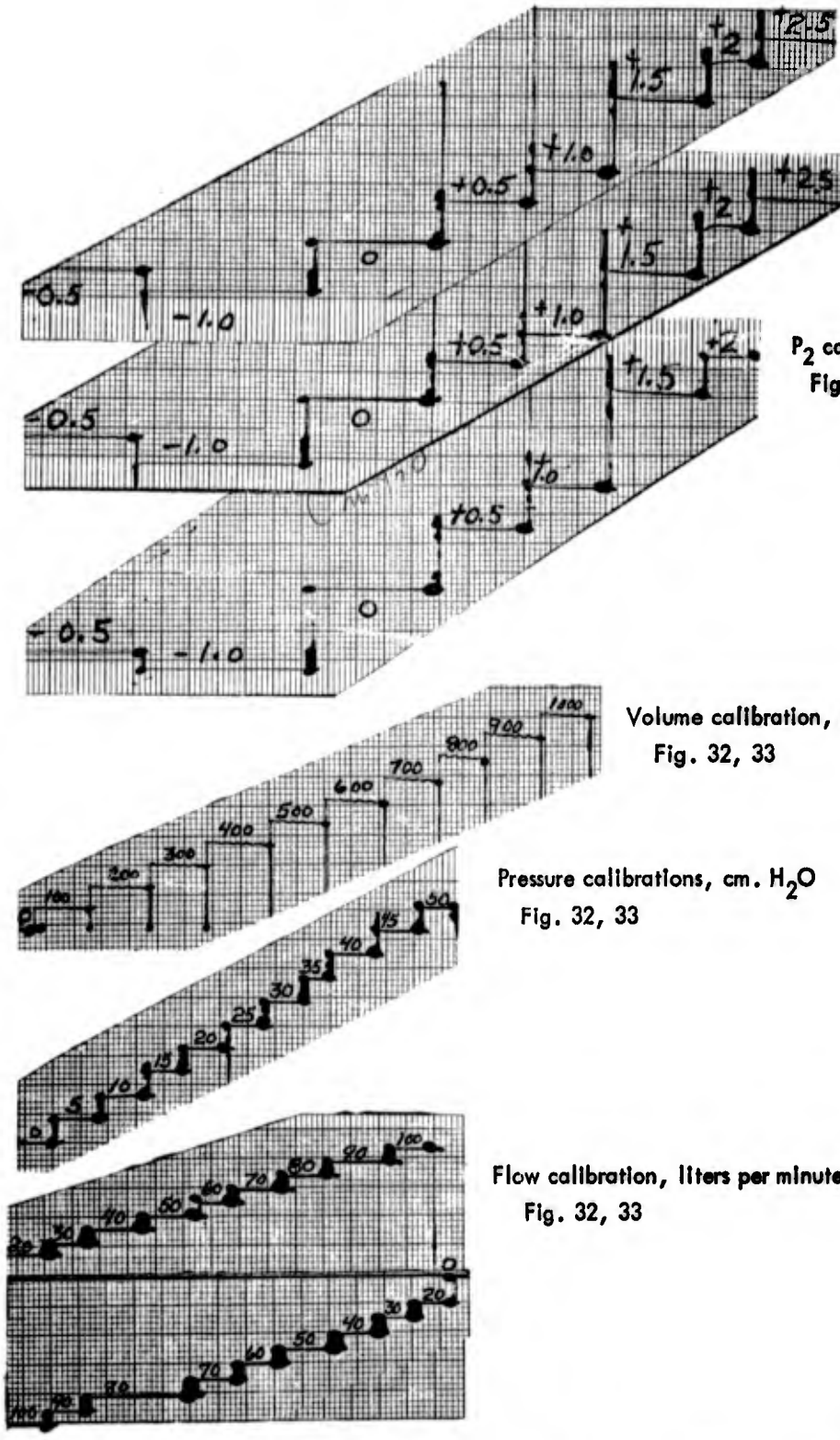


Figure 30. BIRD, Mark 5. 500 cc. and 5 liters gas inflow. Ohio check valves at Absorber. Comparable performance.



Triggerometer calibration cm. H_2O
Fig. 28, 29, 30, 32, 33

P_1 calibration, cm. H_2O
Fig. 28, 29, 30

P_2 calibration, cm. H_2O
Fig. 28. 29. 30

Volume calibration, cubic centimeters
Fig. 32, 33

Pressure calibrations, cm. H_2O
Fig. 32, 33

Flow calibration, liters per minute
Fig. 32, 33

Figure 31. CALIBRATIONS. Lung Model and Analogue of Figures 26 and 27.

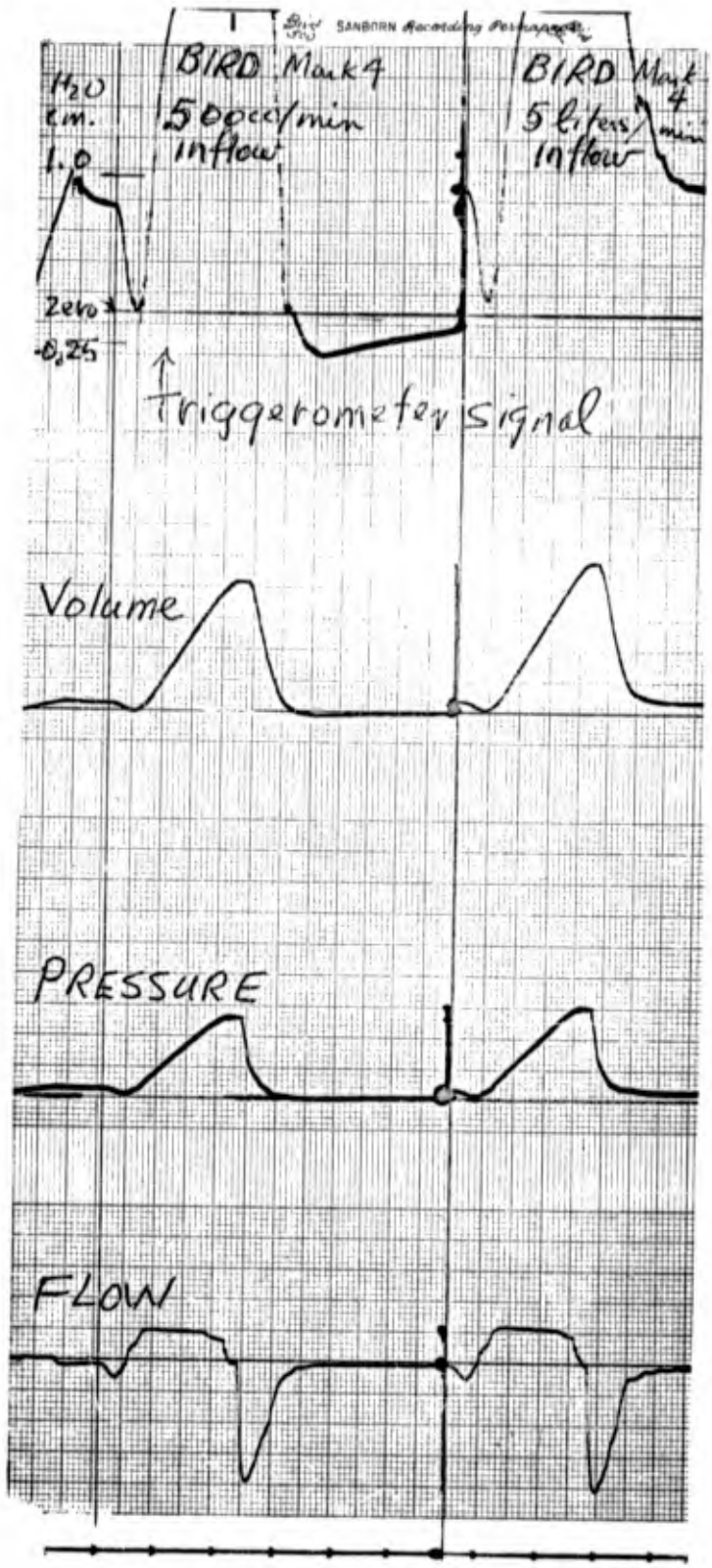


Figure 32. Performance of Bird, Mark 4 Assistor–Controller in Lung Model of Figure 26.

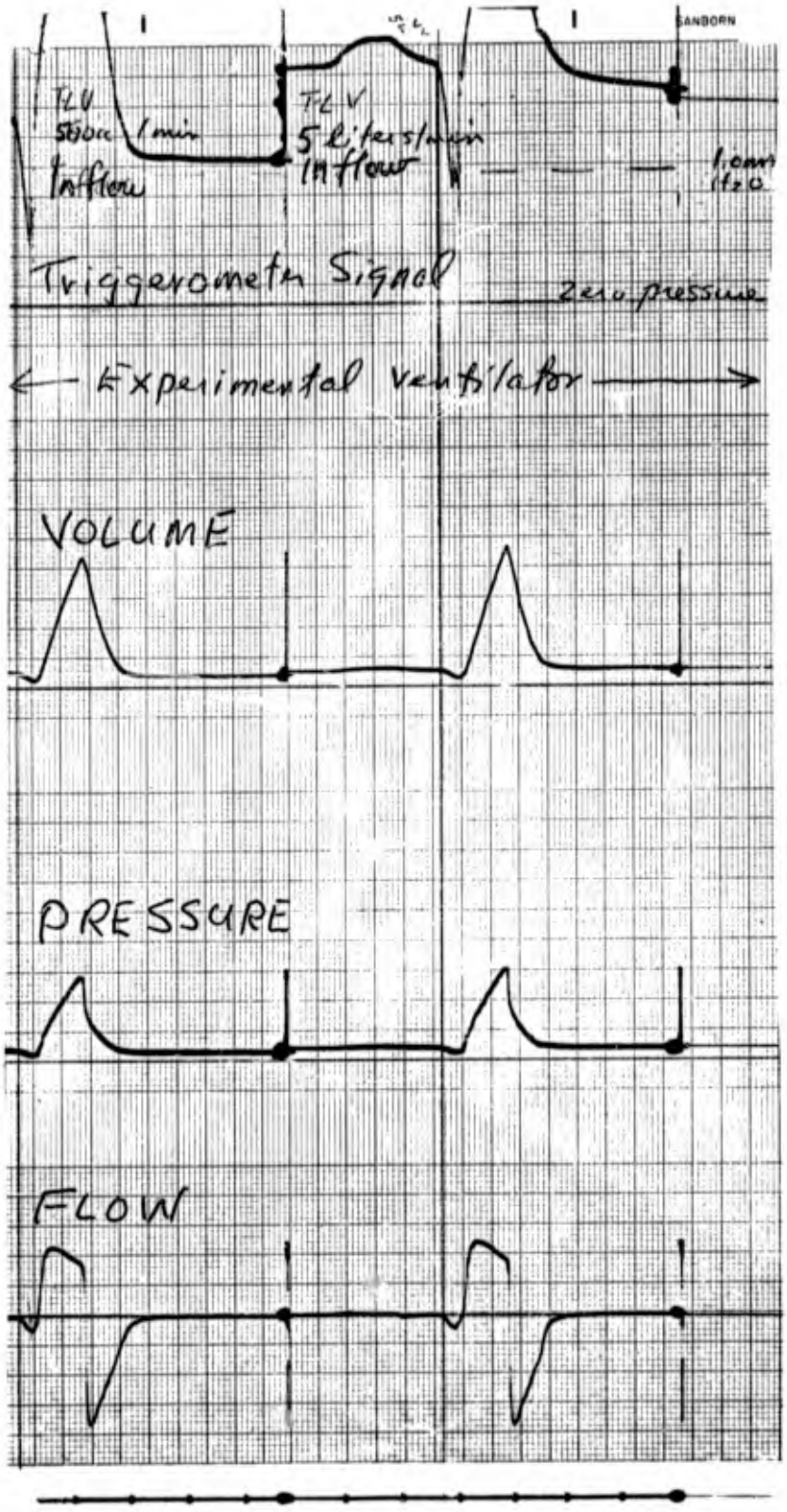


Figure 33. Performance of Experimental Ventilator in Lung Model of Figure 26.

VI. ELECTROMYOGRAPHY DURING SURGICAL ANESTHESIA

Previous sections of this report have referred to electromyographic recordings from the diaphragm during anesthesia. These experiments have been pursued to determine:

1. The carbon-dioxide-sensitive threshold during surgical anesthesia.
2. The maintenance of acid-base balance in patients ventilated with an assistor-controller using the servo-cycling technic. The EMG detects whether an Assistor responds properly to weak inspiratory efforts during "clinical apnea".
3. The relative merits of different ventilators in the practice of servo-cycling.
4. The validity of simplified pneumatic detectors designed to detect and amplify weak inspiratory efforts by patients in a "clinically curarized" state.

These studies are still in progress. This introductory presentation concerns the significant respiratory parameters which have been correlated with arterial blood determinations of pH, pCO_2, and buffer base. Conclusions are unwarranted until the current series is completed.

METHOD: Following or during celiotomy, an EMG electrode of 38 gage enameled copper is placed in the right lateral muscle fibers of the diaphragm. The muscle fibers are identified visually. A suitable preamplifier transmitter has been constructed with semi-conductors (Figure 34) in this department. The FM signals of the EMG and EKG are transmitted to an FM tuner. This signal is fed into a DC amplifier, a tape recorder and oscilloscope. Records are made on photographic paper on the E for M oscillograph. EMG signals are simultaneously displayed on a 7 inch oscilloscope for visual monitoring and with a loud speaker which provides ideal auditory discrimination of the characteristic spike potentials of contracting muscles.

Preliminary records were made to correlate the diaphragmatic EMG with respiratory airflow (Figures 35 - 40). The persistence of inspiratory flow throughout the period of EMG activity is shown in Figure 35 during spontaneous breathing during light C_3H_6 anesthesia. No electrical activity except the EKG is recorded during expiration.

When the experimental ventilator is turned on, spontaneous inspiration triggered inflation (Figure 36). However, instead of a 200 cc. inspiration of 1 3/4 second's duration (Figure 35) the ventilator delivered 300 cc. in a half second (Figure 36) and passive expiration could not occur until the diaphragm relaxed, after 1 3/4 seconds. This illustrates the requirement of an ideal ventilator in which inflation should extend through the duration of contraction and match the period of EMG activity.

The effect of deeper anesthesia is shown in Figure 37. The rate has now slowed to a breath every eight seconds (in first plane the rate was one breath per 4 seconds). Accordingly, the volume has been increased to 400 cc. to maintain an adequate alveolar ventilation until the C_3H_6 level of anesthesia could be lightened. Despite the reduced frequency of respiration in deep anesthesia, the duration of diaphragmatic contraction remained 1 3/4 seconds. Note however that the activity (number of spikes) was about 20% of that in light anesthesia (Figure 36) and that the 2/3 of this contraction took place before the subject triggered the assistor, signifying the weaker state of the muscle and the few units contracting.

Within a few minutes, the servo-cycle pattern was established. The apneic phase of which is illustrated in Figure 38 in which the EMG had disappeared. The ventilator is now operating as a controller at a rate of 17 per minute. With the next return of spontaneous effort (EMG activity) the controller was turned off to determine the patient's spontaneous rate. The first discernible diaphragmatic contraction (EMG) triggered the Assistor (Figure 39) while the second effort did not. However, the subsequent efforts were sufficient to activate the Assistor (Figure 40) until apnea again supervened. The rate of 12 spontaneous efforts per minute with a tidal volume of 400 was sufficient to hyperventilate the subject to apnea. The rate of the controller was then set at 10 per minute. Servo-cycling persisted then for two hours when the anesthesia was concluded.

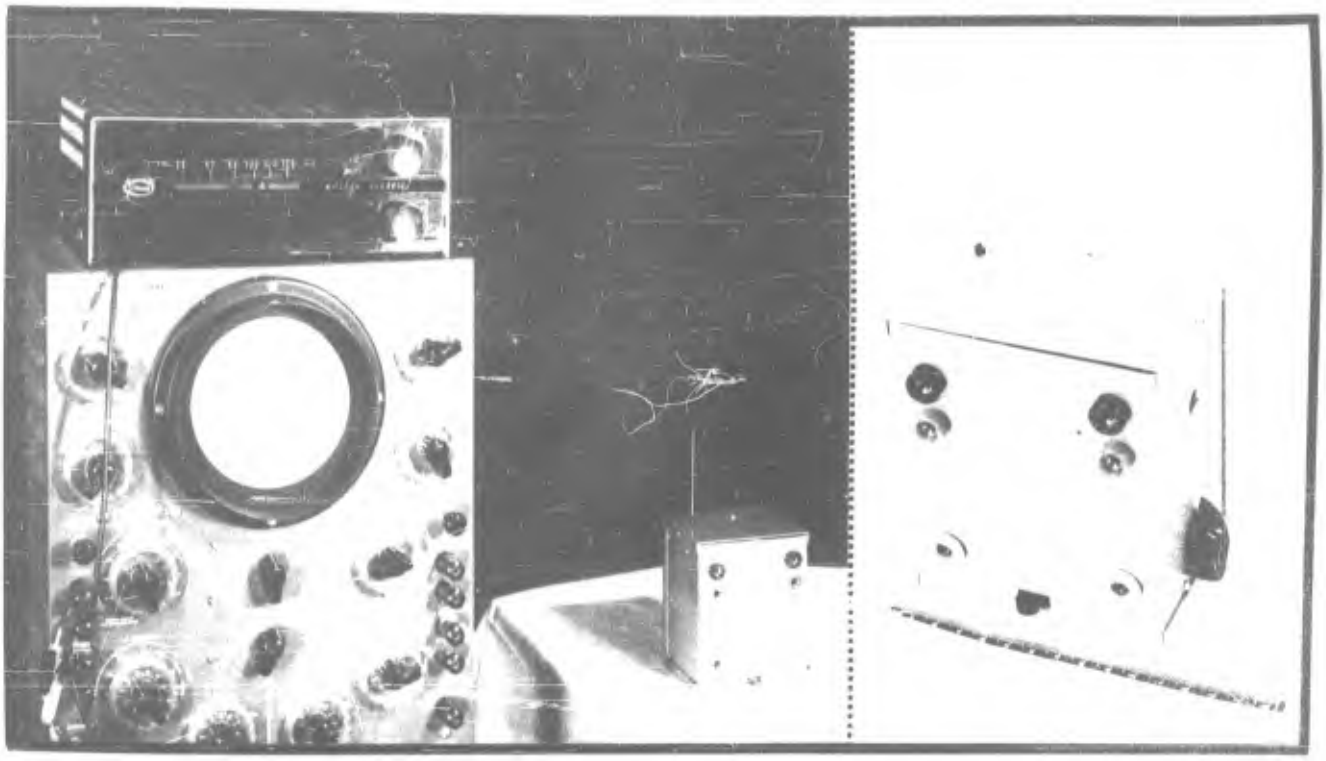
Another study is illustrated in Figures 41 - 47. In addition to EMG and airflow, the respired CO_2 concentration was recorded and arterial samples were taken during servo-cycling to define the threshold and compare it with the blood values during slight anesthesia and spontaneous breathing. The events and blood values were correlated in the anesthetized patient in relation to spontaneous breathing and servo-cycling (Table V).

COMMENT: Several similar experiments have demonstrated:

1. The CO_2 apneic threshold is normal during light cyclopropane or Fluothane anesthesia.
2. An assistor-controller, although by no means ideally developed, is easily capable (with appropriate simple adjustments based on enlightened clinical observation) of maintaining normal and relatively constant arterial pH and pCO_2.
3. Assistors can be used as effectively as an EMG to "track" the patient's CO_2 apneic threshold.
4. Unreported observations suggest that the EXPIRATORY muscles potentials of the external oblique provide the same information regarding apnea, hyperventilation, curare or succinylcholine block, deep anesthesia, and carbon-dioxide retention. Of greater surgical interest is the additional information the external oblique EMG provides, namely, the state of contracting tone or flaccid relaxation, apart from any respiratory phasing. It would appear that the EMG should become the most practical useful monitor for surgery as well as anesthesia, providing a simple objective tool which depicts both the EKG and the EMG on one loud speaker.

Figure 41.	First plane C_3H_6 anesthesia. Spontaneous breathing. Tidal volume 250 cc. Respiratory rate 17 per minute. Duration of diaphragmatic contraction 1 3/4 seconds. The arterial pH 7.32, pCO_2 58 mm.
Figure 42.	Servo-cycling has been established. This is the end of the first assist phase. Tidal volume 450 cc. Rate 17 per minute. The EMG was not perceptible on loud speaker but faintly discernible on the oscilloscope. Alveolar CO_2 has decreased with the larger tidal volume but not as much as would be expected (tidal was increased from 250 to 450 cc.). The small notches at the start of the inflation flow curves show that the Assistor is still being triggered. Arterial pH 7.34, pCO_2 54.
Figure 43.	Apnea is now reached. The controller is shut off to determine the duration of apnea and the patient's new rate of respiration when spontaneous effort reappears on the EMG. The four tracings of this figure, Figures 42 and 43, are the continuous record.
Figure 44.	After 36 seconds, the EMG reappeared. Although the small inspiratory effort slightly diluted the previous alveolar sample which had been static in the CO_2 analyzer, it was not sufficient to trigger the Assistor.
Figure 45.	However, the next effort, 6 seconds later, triggered the Assistor and an arterial sample was drawn. pH 7.32, pCO_2 58 mm.
Figure 46.	Subsequent efforts continuously triggered the Assistor although the 3/4 of the duration of diaphragmatic contraction was required indicating the weak state of the muscle (only a few units contracting).
Figure 47.	To demonstrate the effect of CO_2 on the EMG activity of the diaphragm, the subject was allowed to partially rebreathe CO_2 (the CO_2 absorber was bypassed in the closed system breathing circuit). Within 5 minutes, the inspired CO_2 concentration had reached 1% (compare with Figure 61), although the alveolar CO_2 level remained unchanged. Note that the EMG is increased in number of spikes, is 50% longer in duration, and it now triggers the Assistor early in the contraction and persists to retrigger it again to produce two inflations for one EMG inspiratory phase.
Figure 48.	The phenomenon of two ventilator cycles for each diaphragmatic contraction continued for several minutes of CO_2 rebreathing. This result is interesting in that it demonstrates that 450 cc. inflations in this patient under cyclopropane does not elicit the vagal stretch inhibitory reflex. Otherwise, the first inflation by the Assistor would not have caused the EMG to disappear. If such reflexes occur in man anesthetized with cyclopropane, they are overriden by relatively small elevations in pCO_2.

TABLE V. Respiratory Events, Ventilator Performance, and Acid-Base Values During Cyclopropane Anesthesia.



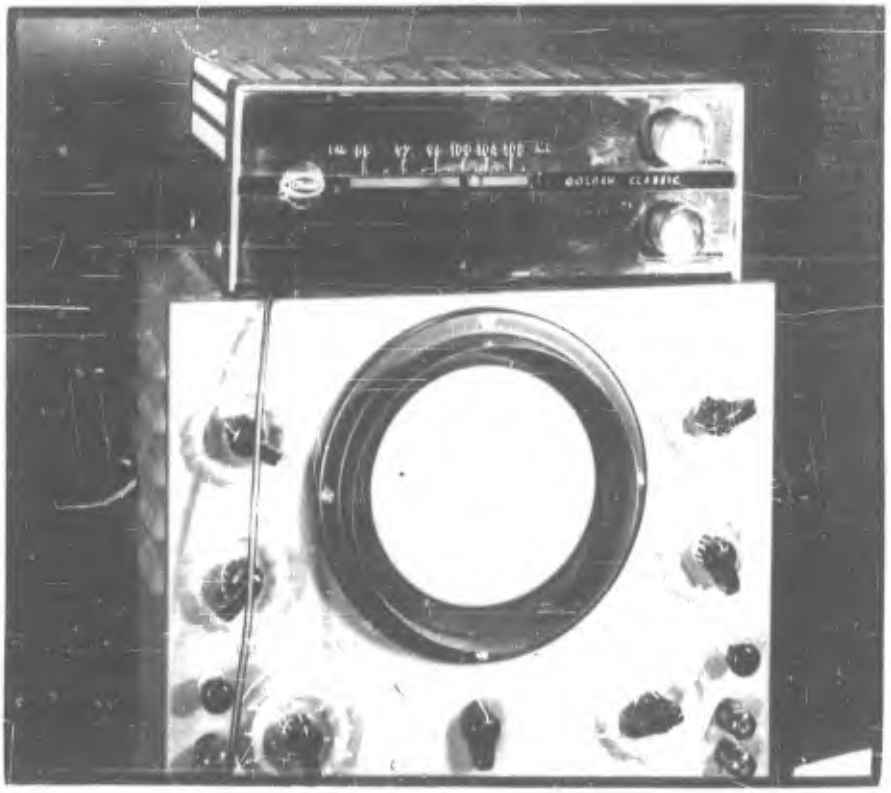


Figure 34.

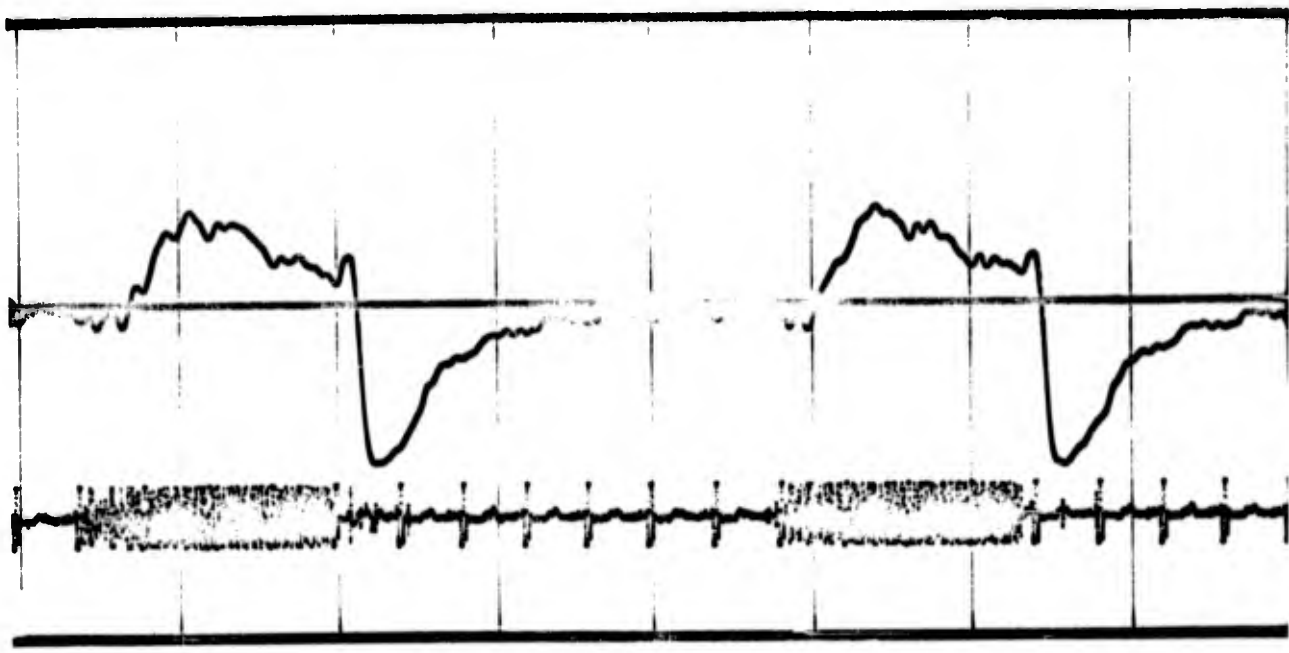


Figure 35. EMG and Airflow Record. Spontaneous breathing. C_3H_6 anesthesia.

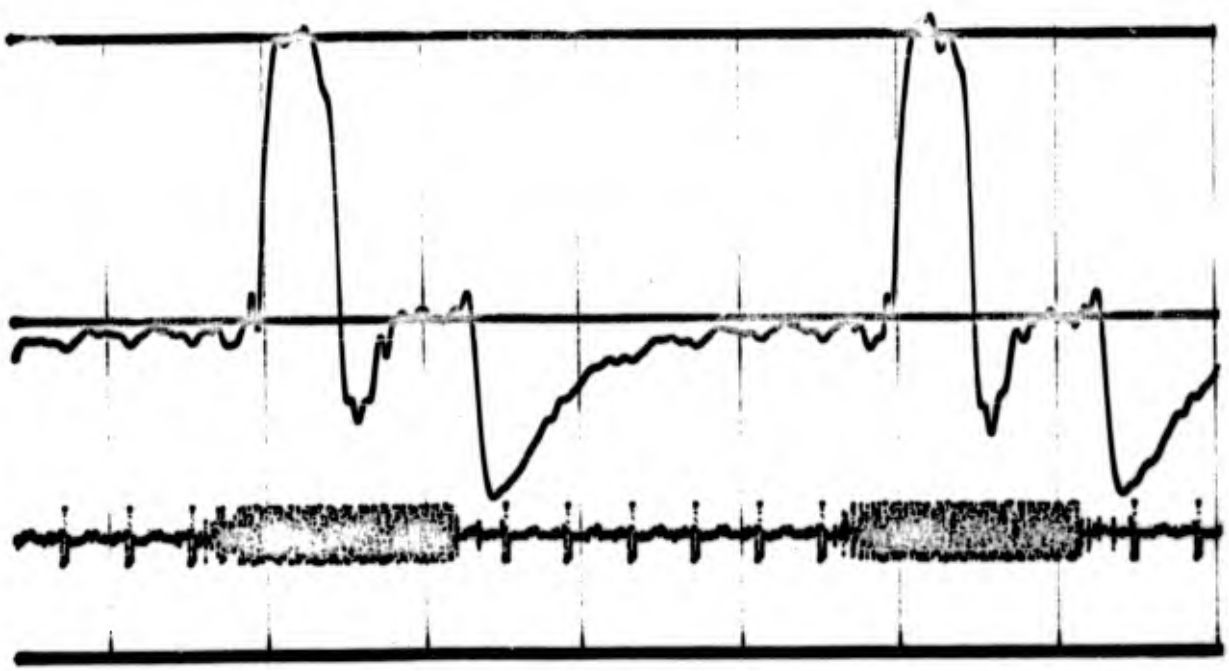


Figure 36. Experimental ventilator turned on to assist inspiration. The inflation by the Ventilator is too rapid to match duration of patient's effort. Triggering is early in the long period of diaphragmatic contraction.

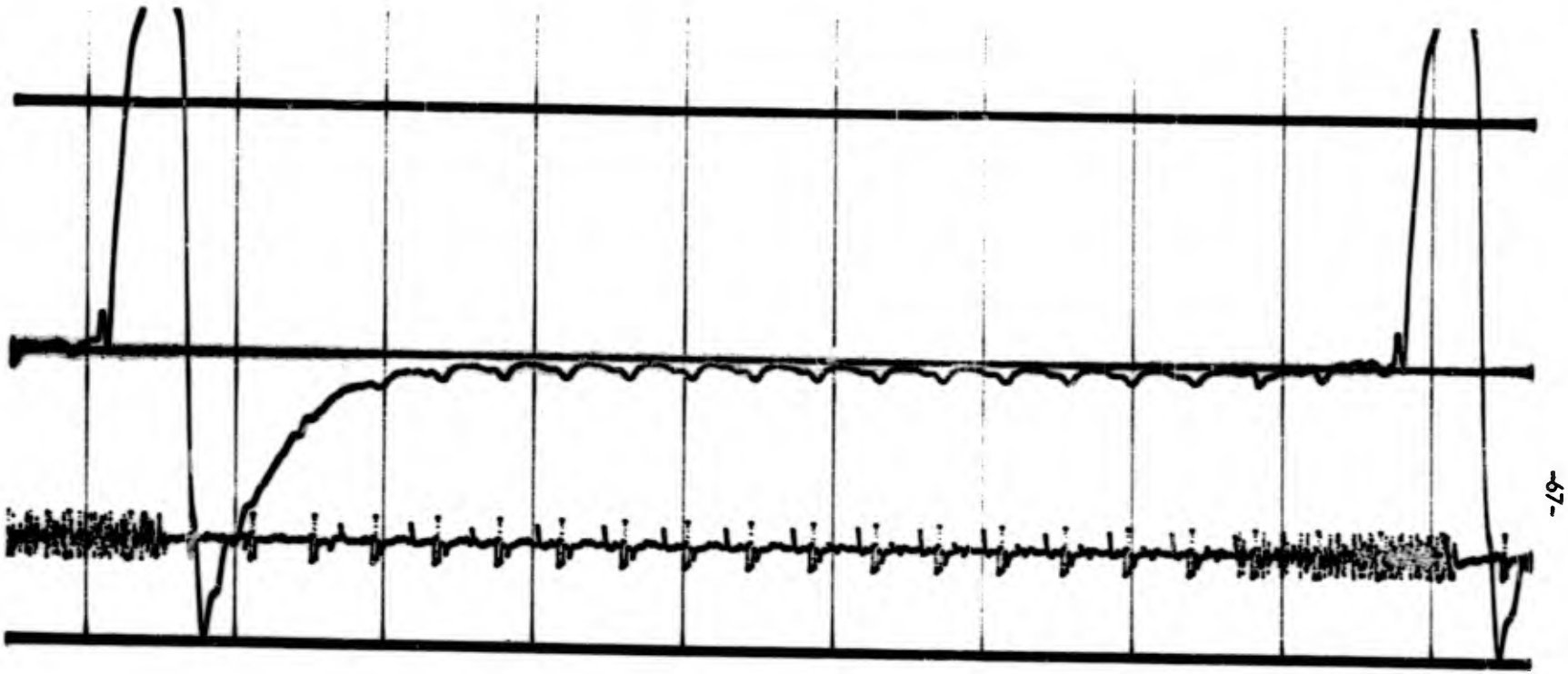


Figure 37. Deeper anesthesia. Slower rate of breathing. The Controller rate is off, only the Assistor is operating. The EMG activity is reduced and diaphragmatic contractions are weak. Now the patient triggers the ventilator quite late in the period of diaphragmatic contraction.

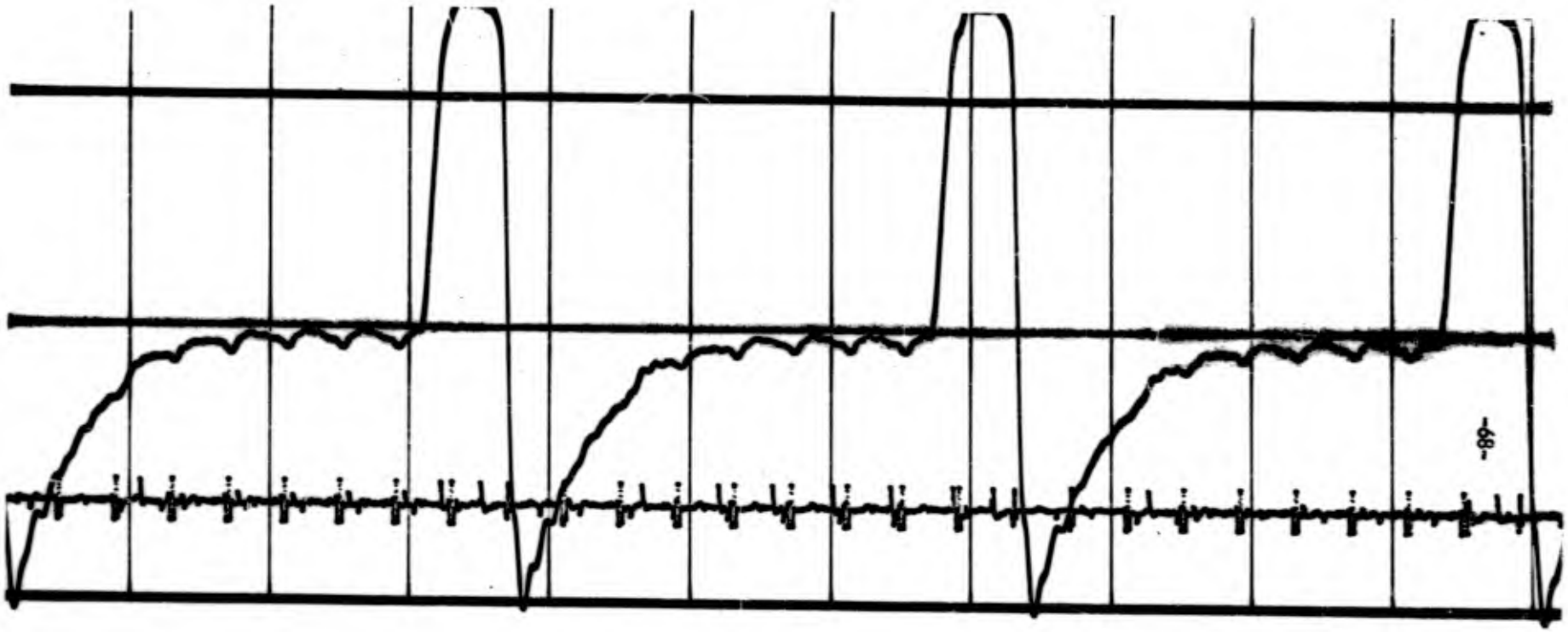


Figure 38. The Controller is now on at a rate of 16/min. Absence of notching at start of ventilator's inflation pressure shows that the patient is not triggering the Assistor, but that the controller alone is operating (compare with Figures 35, 36, and 39). The diaphragm EMG is absent, and only the EKG is recorded.

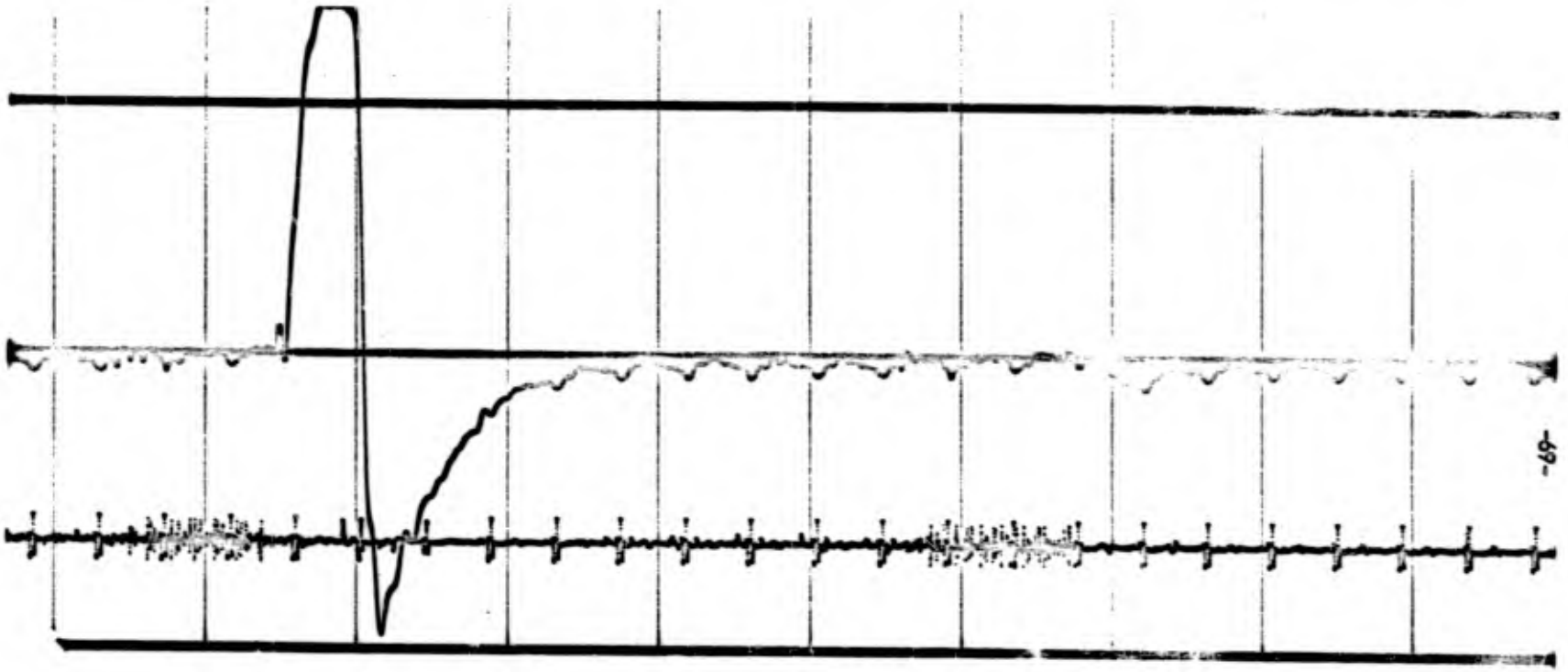


Figure 39. First breath following EMG apnea of Figure 38 triggers the Assistor. The second effort does not (see Figure 40 for third and fourth efforts). Frequency of diaphragm contractions is slower than controller frequency of Figure 39, indicating no "adaptation" of patient to the previous rate of lung inflation.

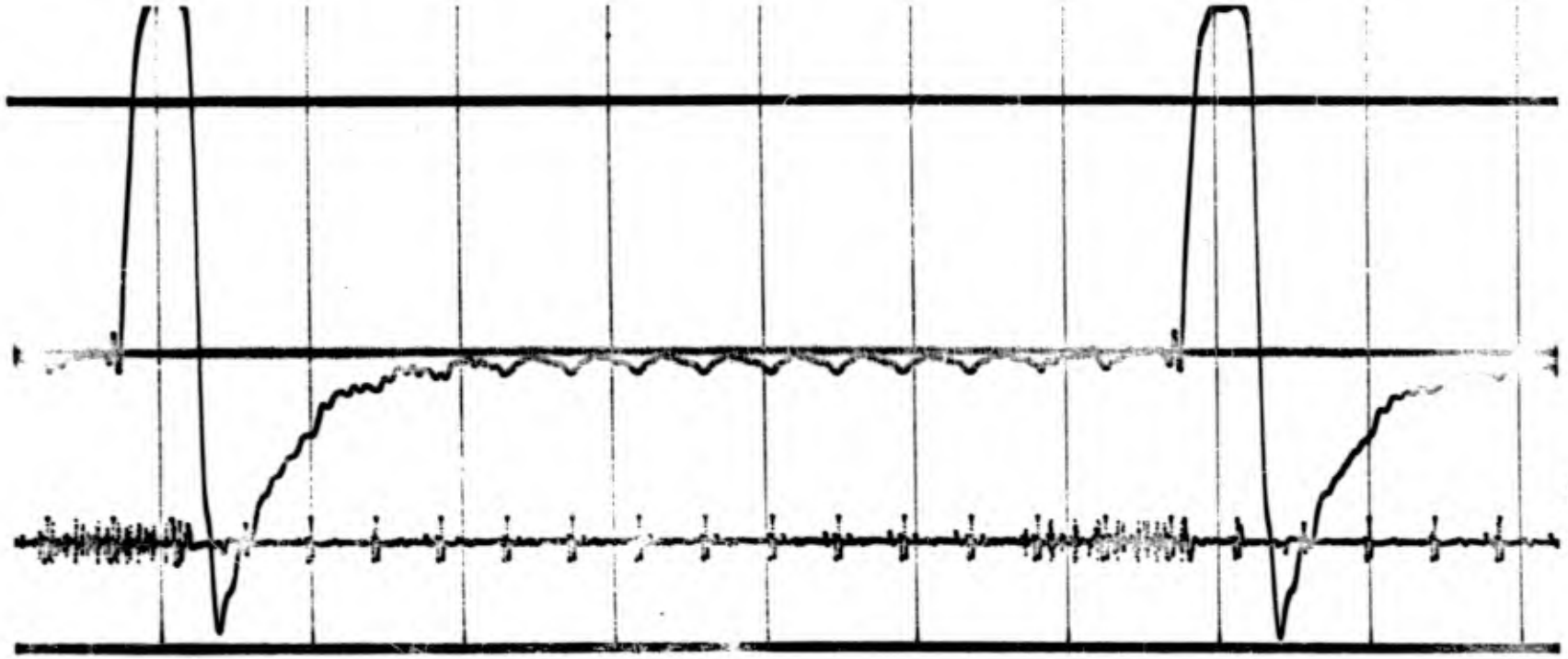


Figure 40. Third and fourth breaths after apnea (Figure 39) trigger ventilator's assistor. The lessened EMG activity suggests near-threshold status in ventilation and pCO_2. The loud speaker displaying the characteristic high-frequency potentials of the EMG could be heard easily. This simpler form of monitoring is probably sufficient for clinical differentiation of such EMG activity as in Figures 37 and 39. From such audible signals, the anesthetist can tell whether the ventilation is adjusted to maintain pCO_2 at or near the patient's threshold. Or he may, without an EMG, obtain the same assessment by watching the Assist Indicator on the experimental ventilator.

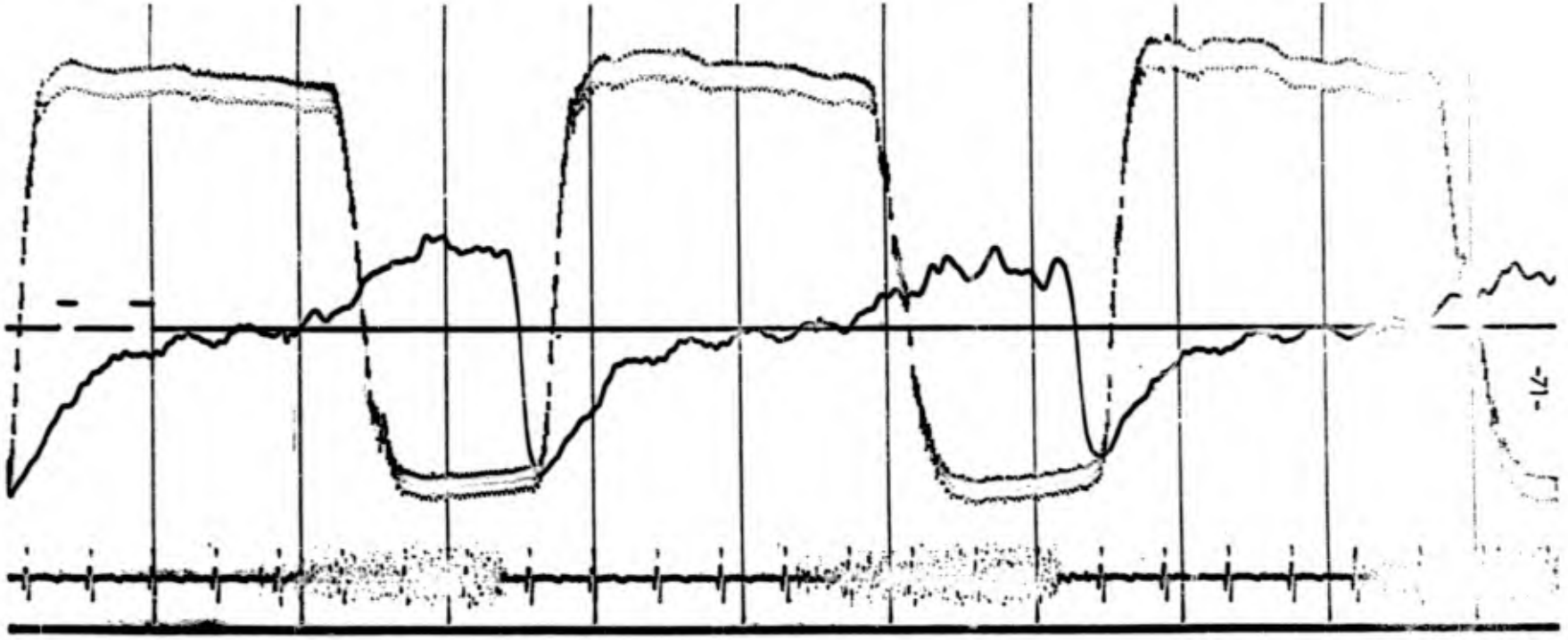


Figure 41. Spontaneous breathing. Light C_3H_6 anesthesia. Another parameter is recorded, the respired CO_2 concentration. An arterial blood sample taken showed pH 7.32, pCO_2 58, BP 47. This study is continued through Figure 49.

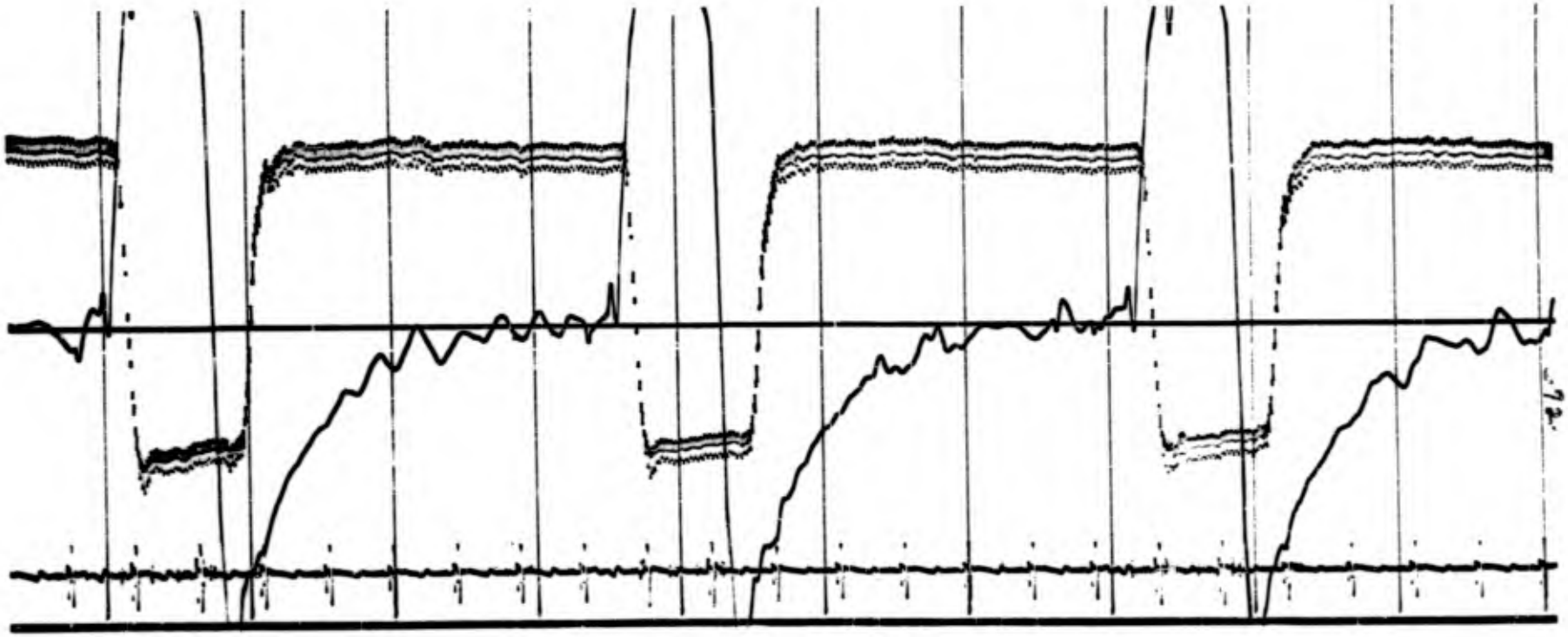


Figure 42. Servo-cycling has been established within 4 minutes of record in Figure 41. The EMG was barely perceptible on the oscilloscope but could not be heard on the loud speaker. However, the Ventilator is still being triggered (see notches at start of inflation pressure). Alveolar CO_2 is down 2 mm. (compare with Figure 41). The pH is now 7.34, the pCO_2 54.

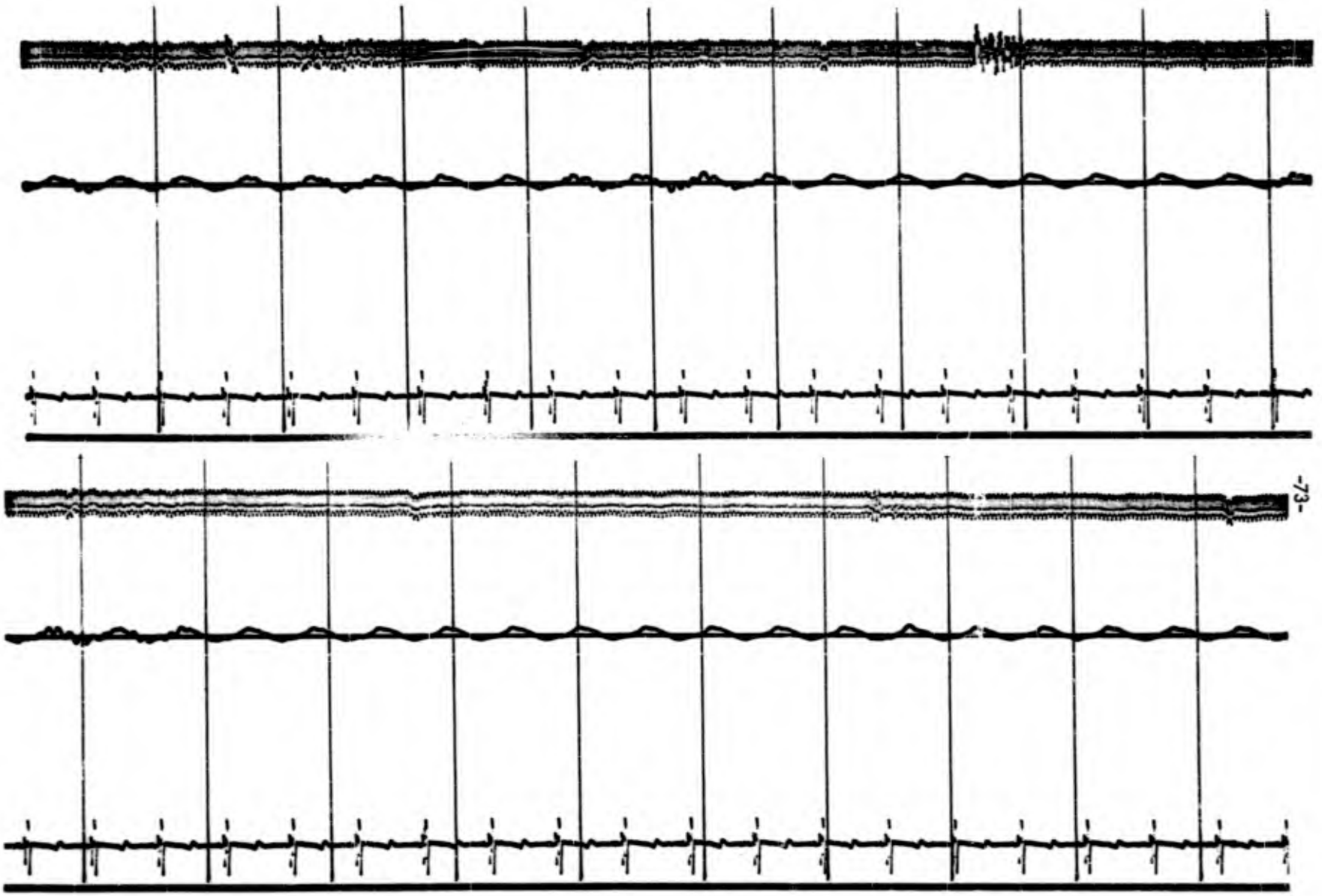


Figure 43. Following Figure 42, the controller was shut off to demonstrate the expected EMG apnea. Here it is: duration 36 seconds before Figure 44.

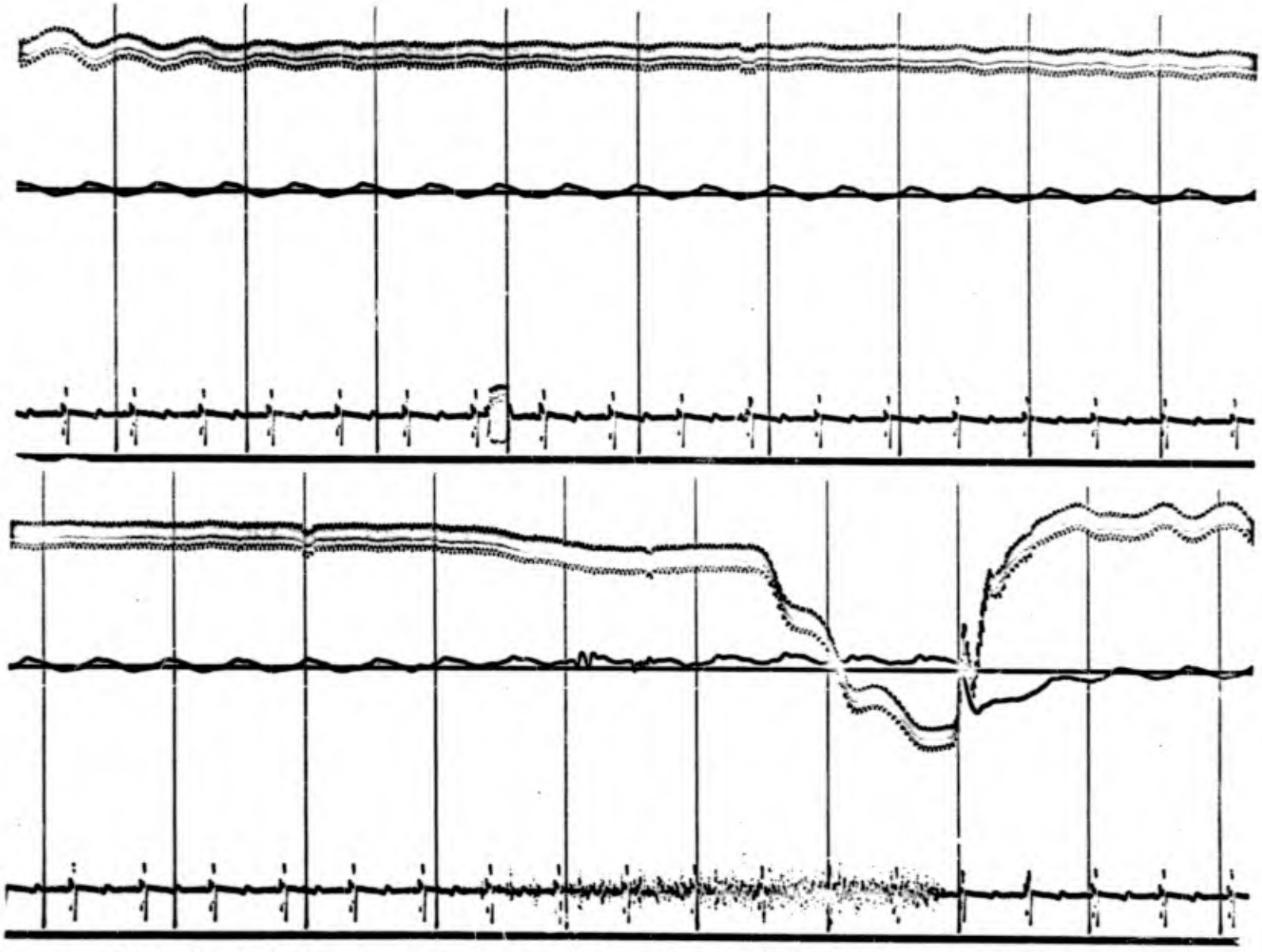


Figure 44. Termination of apnea (continuation of Figure 43). First effort does not trigger ventilator but moves a few cc's through the CO_2 analyzer.

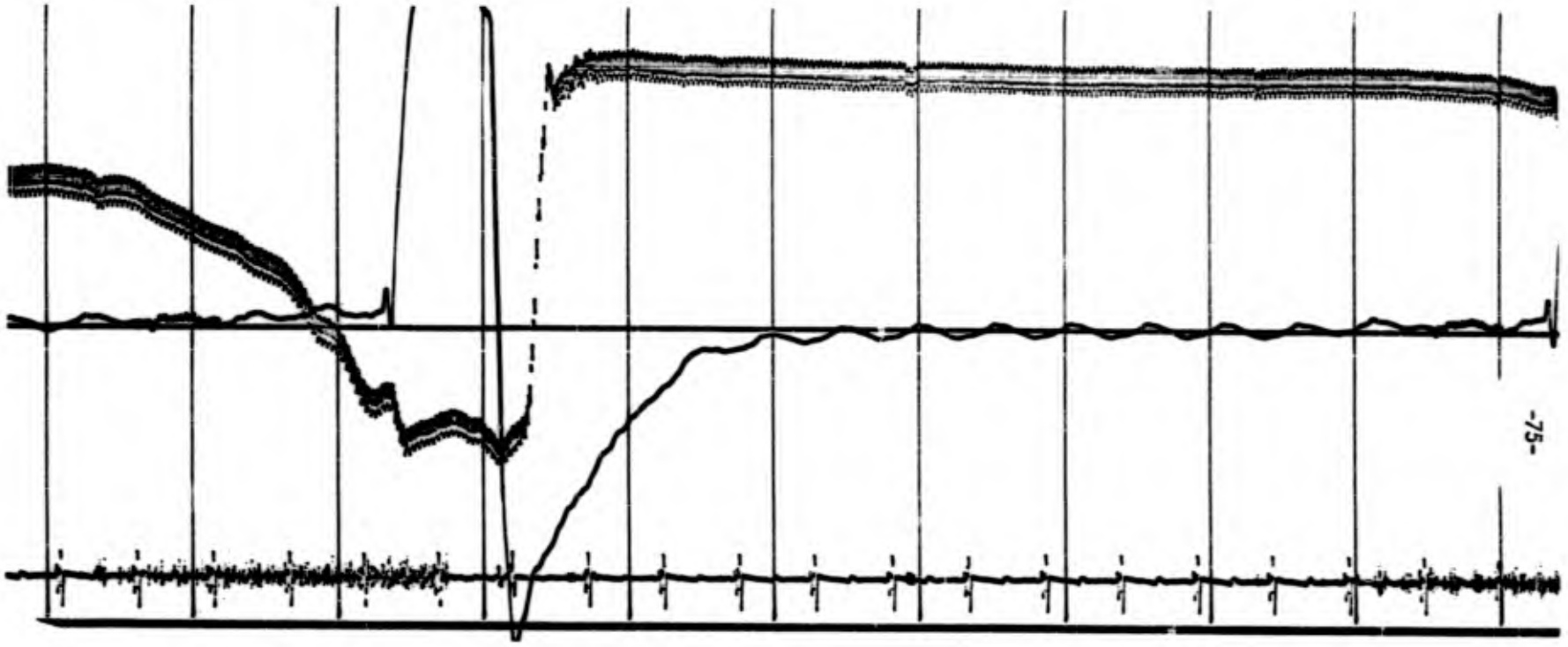


Figure 45. (continuation from Figure 44) However, the next effort and each subsequent contraction of the diaphragm (see each EMG) does trigger the Assistor. The pH has now returned to 7.32, the pCO_2 to 58 mm. Now the Assistor must hyperventilate (by volume) the patient to pH 7.34 again to cause the next short apnea and accomplish the next servo-cycle.

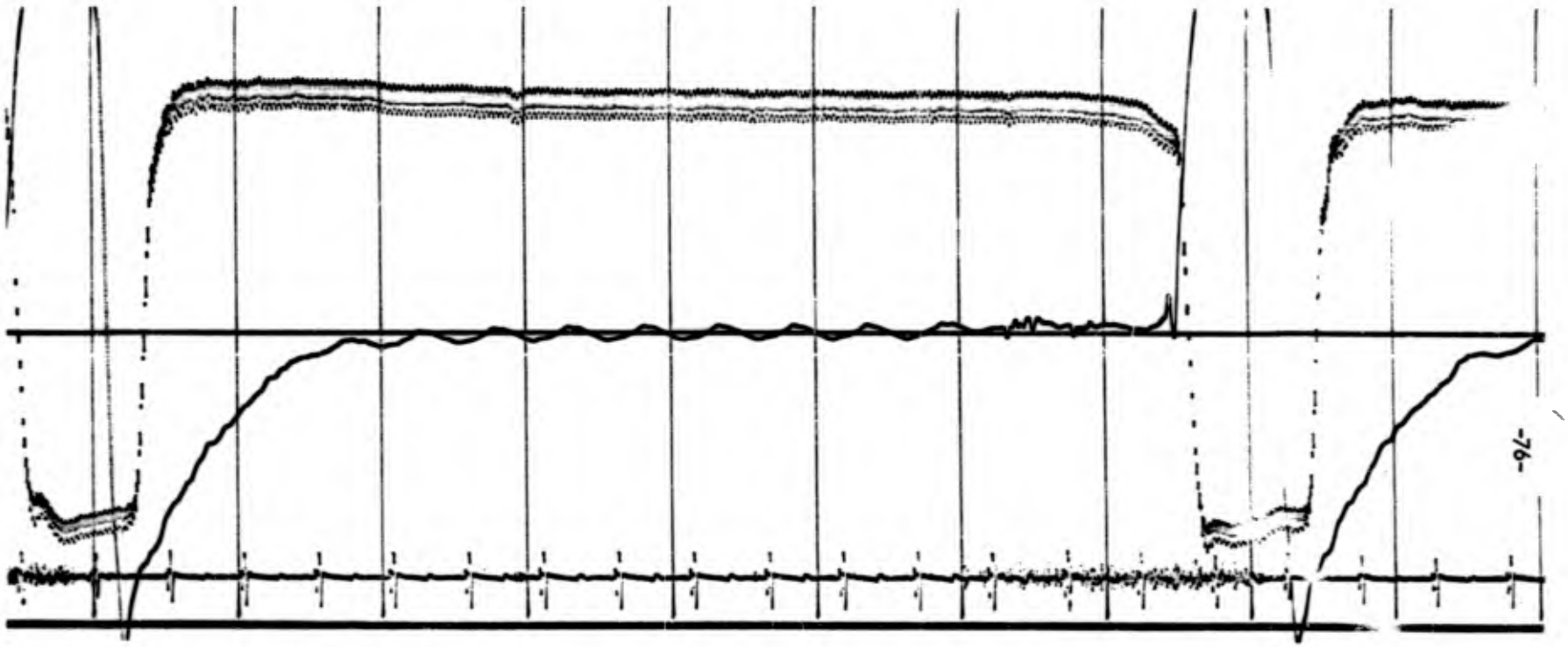


Figure 46. (continuation of Figure 45) The respiratory rate is now slower than the patient's previous spontaneous rate (compare with Figures 41 and 42). Anesthesia has become stable at a surgical plane so the controller rate is now set to 80% of the above rate. The constant tidal volume must be sufficient to hyperventilate the patient at 100% of his own spontaneous rate to perpetuate servo-cycling.

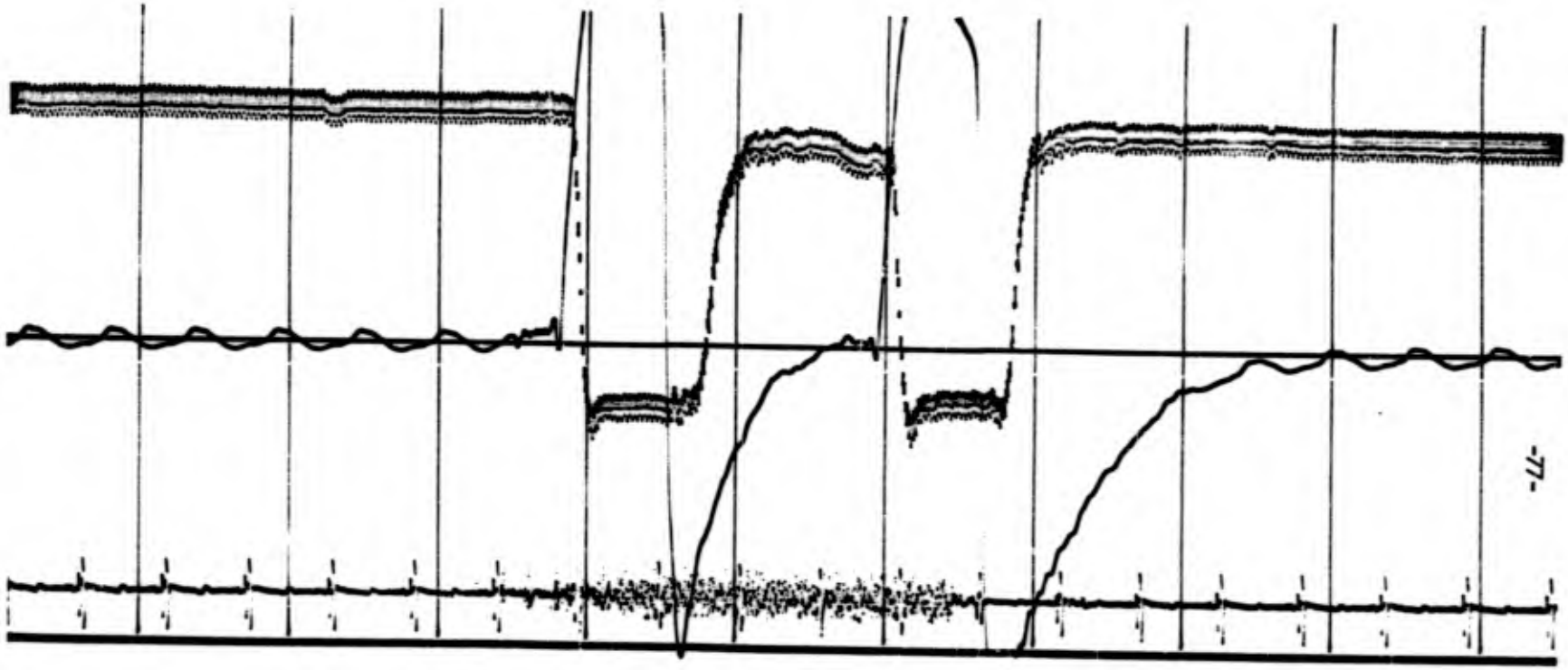


Figure 47. Rebreathing with CO_2 absorber cut out. Alveolar CO_2 is up (compare with Figure 46). Diaphragmatic EMG activity is increased and prolonged. In fact, it persists beyond the period of inflation and "passive" exhalation and the patient re-triggers the second inflation with the same contraction that triggered the first one. If the vagus stretch inhibitor reflex were operative, the first inflation should have terminated the EMG.

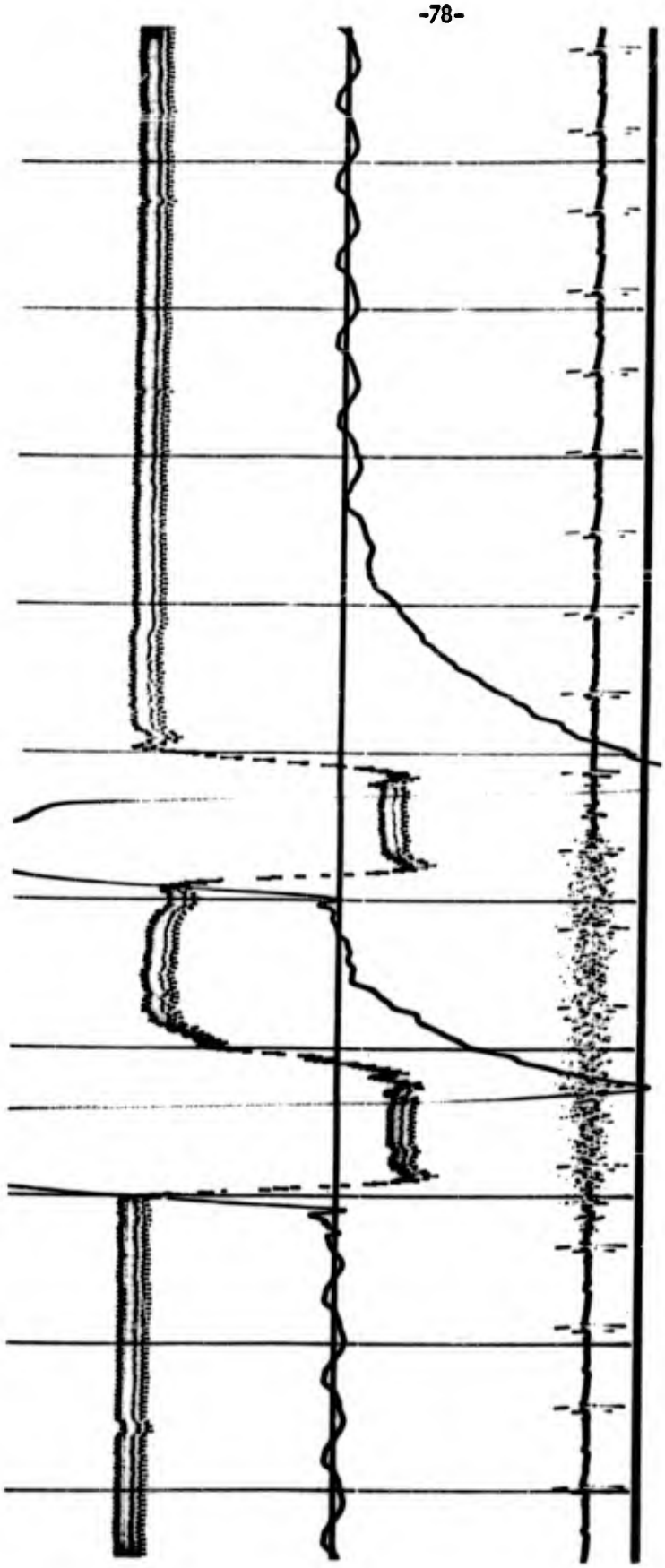


Figure 48. (continuation of Figure 46) This phenomenon of double inflations for each effort persisted until the inspired CO_2 level returned to zero.

VII. PRELIMINARY EVALUATION OF MEDL RESUSCITATOR

To date, the physiological evaluation of this device has consisted of

a. Trial use in lightly anesthetized adults using a face mask as the coupling to the patient's airway.

b. Trial in anesthetized patients during heart-lung resuscitation using a cuffed tracheal tube as the coupling to the patients airway.

This series of studies will not be completed until March 20, 1962. At this time, the reportable observations cannot represent a comprehensive trial. Certain comments may be of interest however.

Figure 49 shows airflow and airway pressure during CCCM in the same patient of previous figures 12, 13, and 18 in this report. The volumes of inflation during CCCM were comparable to the ventilation by MEDL prior to heart resuscitation. An increase in the frequency of cycling did not result from the sternal compression. In fact, the inflation pressures became elevated significantly in contrast to the results with conventional pressure-cycled resuscitators (E & J and Emerson, Section III of this report).

These results are similar to the performance of the Portable Heart-Lung Oxygen Resuscitator described in Section III.

Accordingly, it was of interest to compare the performances of MEDL and the "PHLO" resuscitators in the context of compensation against bronchoconstriction and rigid compliance. The two devices gave very similar performances (Figure 50). Both maintained the inflation volume to the abnormal lung model within 10% of that delivered to the normal lung model. Contrary to the implication in MEDL interim report 61-13, September 18, 1961, the MEDL decreased the frequency of cycling and inspiratory flow to the rigid model in contrast to the performance of the PHLO Resuscitator. This result suggests that the patient who developed

an increased resistance or reduced compliance or both would be relatively hypoventilated with the MEDL. With the PHLO resuscitator, his ventilation would be unchanged except for the rate of his expiratory flow. The increment of pressure delivered to his lung is identical for a range of 15 fold change in lung-airway resistance and 2 fold change in compliance.

Whether the slight differences in the performances of the MEDL and PHLO are of clinical significance is difficult to predict.

We have found no difficulty in using the MEDL resuscitator in well anesthetized patients with tracheal tube in place. However, five semi-conscious or lightly anesthetized patients without tracheal intubation have not tolerated the inflation pressure or flow rates. They developed reflex bronchospasm and "backing". From our previous experience, we would recommend a reduced inspiratory flow rate if the MEDL is to be used with a face mask (with or without an oral airway or a nasal airway) in other than areflexic comatose patients.

Further observations will be reported in March, 1962.

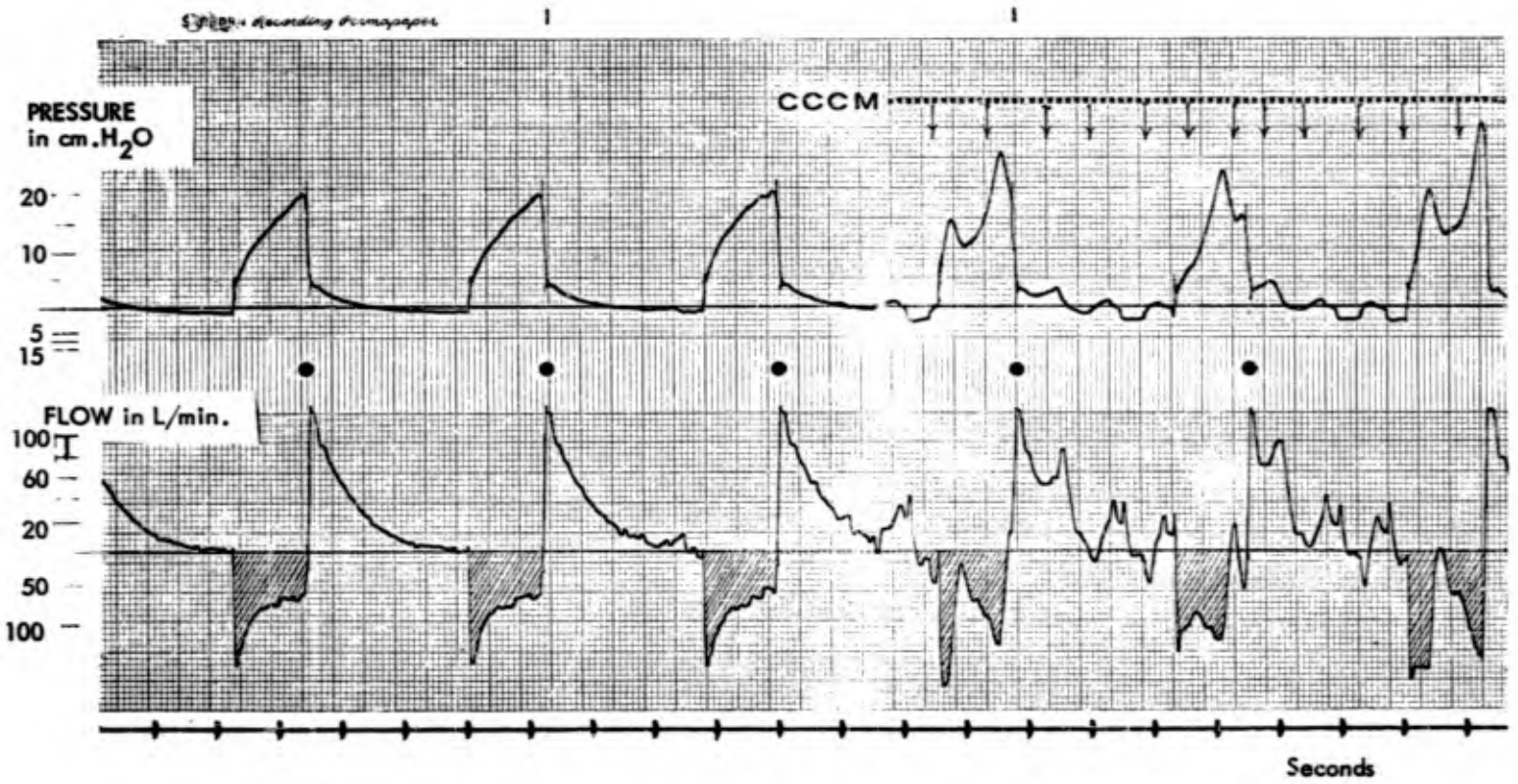


Figure 49. MEDL Resuscitator. Pressure and Flow tracing before and during Closed Chest Cardiac Massage. The areas within the flow curves indicate that inflation volumes are comparable whether or not the sternum is compressed. Each inspiratory phase of the resuscitator is indicated by a black circle. The rate of cycling is not significantly affected.

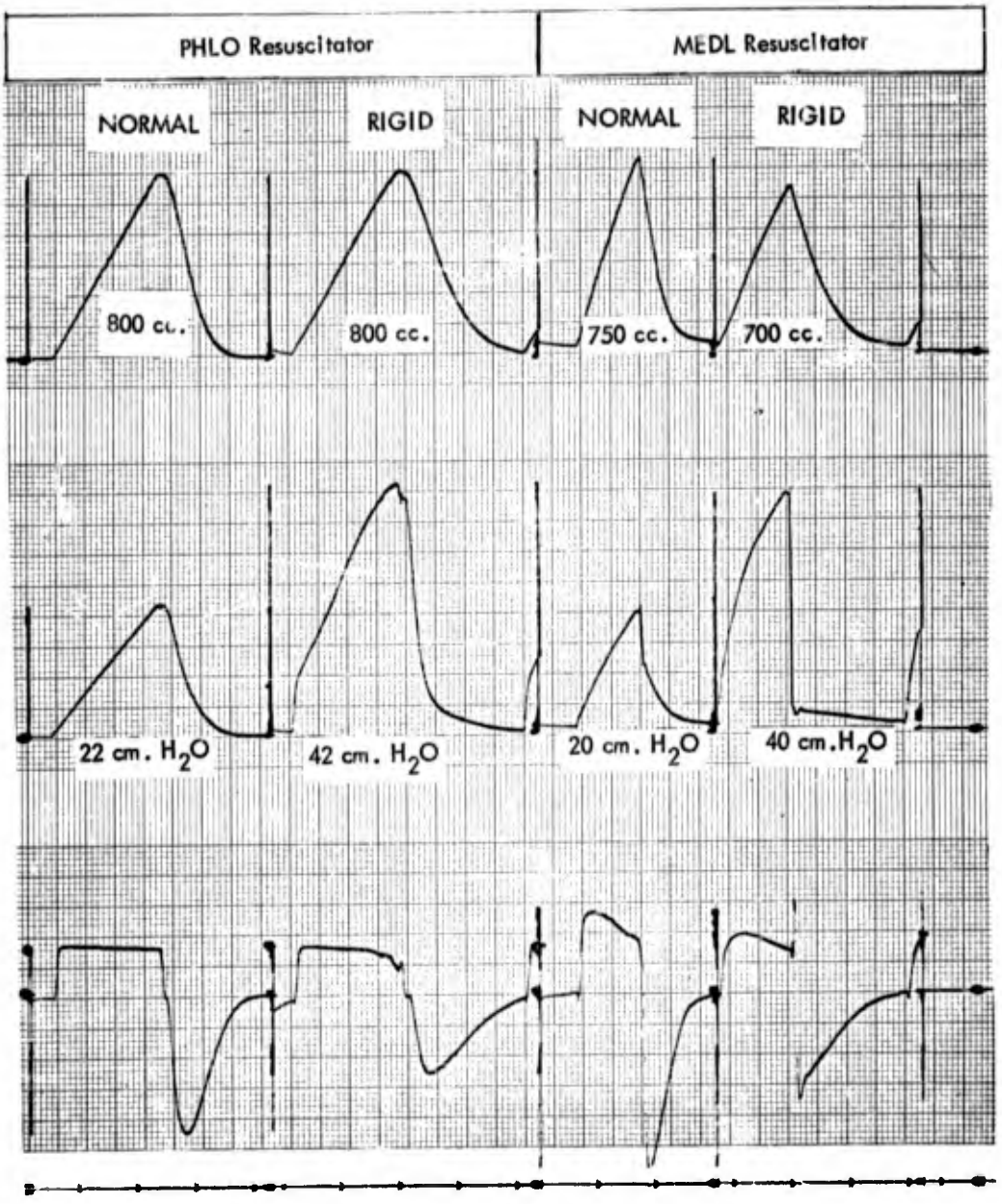


Figure 50. Comparative performances of PHLO and MEDL Resuscitators with NORMAL and RIGID lung models.

VIII. EVALUATION OF NASOPHARYNGEAL (NP) TUBES

During 1961, we have evaluated nasal intubation of the hypopharynx of anesthetized and semi-conscious patients. Many anesthesiologists place the NP tube in patients during emergence and recovery from anesthesia. The semi-conscious patient quickly adjusts to the presence of a tube in the nose and pharynx at a time when he will not tolerate an oropharyngeal airway. Apparently, NP tubes are currently employed only in spontaneously-breathing patients. However, the NP tube has not previously been considered as the coupling to the patient for positive pressure inflation to produce artificial respiration. Our interest in this possibility arises from the difficulties of training lay personnel in the conventional methods of coupling a resuscitator to the patient (tracheal tube or a face mask with or without an oral airway). The nasal route of airway management might provide several advantages:

A. Bilateral access to both sides of the nasopharynx for:
   1. Ventilation via one nostril
      a. Spontaneous breathing, or
      b. Positive pressure inflation.
   2. Aspiration and removal of secretions through the other nostril with minimal interruption of ventilation.

Results have shown other advantages:

B. Relative ease of insertion of two NP tubes and their fixation with adhesive tape despite trismus or convulsions.

C. Adjusting the length of insertion of NP tubes accommodates any adult patient's dimensions from nostril to epiglottis.

D. Length of NP tube and the funneled end prevents intubation of esophagus or larynx to produce unwanted laryngospasm.

E. The semi-conscious patient cannot "spit out", dislocate, or occlude the NP tubes which are securely taped in place as he can an oropharyngeal airway.

F. Tolerance of NP tubes by semi-conscious patient.

Disadvantages of NP tubes should be recognized:

A. Occasional hemorrhage by traumatic insertion.

B. NP tubes require vigilance by trained personnel for presence of secretions and their removal before inflations drive secretions into the trachea. Mucous plugs or clots occluding the NP tube must be removed to insure patency.

C. Effective inflation through NP tube requires occlusion of victim's lips.

D. Excessively high flow of positive pressure inflation causes gastric dilatation.

This evaluation concerned:

1. The tolerance of surgical patients to nasopharyngeal intubation during recovery from anesthesia and,
2. an assessment of the NP tube for maintaining unobstructed breathing, both spontaneous and by positive pressure,
3. the technical difficulty of insertion,
4. the incidence of hemorrhage caused by insertion of the NP tube,
5. the possible insertion of an NP tube in each nostril,
6. removal of secretions via suction applied to NP tube.

Although we prefer the Robertazzi soft NP latex tube with a bevelled end opening, these were not available in 8 x 15 cm. size. Accordingly, these preliminary trials were conducted with the R or L Saklad polyvinyl tubes of the chosen diameter and length. This arbitrary choice was based on cinefluorographic measurements of the nasopharyngeal dimensions in 34 adults and upon the presumption that a standard single size tube would offer an advantage for a field procedure. The hard rounded whistle tip of the Saklad NP tube was not suitable for some patients with narrow nasopharyngeal clearance. However, a single Robertazzi tube could be inserted in such patients because of its softer bevelled tip. Whether such insertions would result in sufficient intraluminal patency as a result of narrow clearances remains to be determined.

PROCEDURES: The NP tube(s) were inserted following the induction of general anesthesia whether or not the trachea was intubated. In only one patient, hemorrhage was observed which interferred with the patency of the NP tube(s). Seventeen patients had both right and left NP

tubes inserted. In three patients a deviated septum caused too much tissue resistance to the insertion of a second NP tube. During spontaneous breathing, tidal volumes and respired airflow rates were recorded prior to tracheal extubation. These curves served as controls for judging the subsequent airflow through the NP tubes. A nasal cuffed mask was fitted over the distal end of the NP tube(s) for measuring ventilation. In patients whose trachea had not been intubated, spontaneous ventilation was recorded before and after NP extubation through a nasal mask and a face mask respectively. The latter comparisons showed the proportions of oral and nasal breathing with and without nasal tubes in place.

Tidal volumes were recorded by integration of air flow on an Electronics for Medicine oscillograph and simultaneously read visually and written down by direct observation of a Ventimeter, connected as a closed oxygen-filled system to the patient's tube or mask through an 8 x 13 to-and-fro absorber. Oxygen flow was turned off during the trial to provide accurate direct reading of the Ventimeter to within 25 cc. Only Ventimeter values are reported here (tidal volumes may be more quantitatively determined by planimetry of the flow tracing or by inspection of the recorded integrated record).

RESULTS: Tables VI & VII report these data in 27 patients ranging in age from 27 to 74 years. Figures 51 - 56 show reproductions of airflow patterns measured during spontaneous breathing through the NP tube(s) to be compared with control tracings of airflow through a conventional cuffed tracheal tube (Table VI). In 11 other patients, the ventilation through NP tube(s) was also compared with ventilation through a face mask and with the NP tube left in place (Table VII). If obstruction occurred after removing the NP tube(s), a Geudel oropharyngeal airway was inserted. However, most patients were sufficiently awake to resist leaving the oropharyngeal airway in place.

The tidal volume data demonstrate satisfactory ventilation through the NP tube(s). In many patients, the airflow tracings showed lower peak flow rates with the NP tube(s) than with the tracheal tubes suggesting a slightly increased resistance with the NP tube(s). However, some patients produced higher peak flow rates through the NP tube(s) than through the tracheal

tube. Since the NP tubes used had a blunt rounded tip with the apertures in the side of the tube near the tip (Saklad type), one would expect a greater resistance in situ than would be encountered with the bevelled open ended tubes of the Robertazzi type. Another factor in the difference between the airway resistance of the NP and tracheal tubes is the aerodynamic effect of the epiglottis and larynx.

COMMENT: The most important finding in this series of nasopharyngeal intubations is that of patency of the upper airway in every patient. This clinical fact confirms the prediction from cinefluorography in 1960 that a tube of 15 centimeters reaches sufficiently into the hypopharynx of any adult to bypass the common site of airway obstruction in the flaccid patient, namely, the base of the tongue.

Standardization of the external diameter of the NP tube at 8 mm. for adults appears feasible provided a soft material is used, preferably latex. The variable dimensions in adults between nostril and larynx may be accommodated by the length of the NP tube inserted. Fortunately, the snug fit of this size NP tube tends to stabilize it at the point it is placed. It may be that a sliding fitting to fix the tube at the nostril at the optimal insertion point may be desirable to prevent esophageal intubation in very small adults. Should inadvertent tracheal intubation occur, the result would be favorable in the areflexic patient.

The tolerance of the NP tube(s) in patients awake and able to swallow and cough has been noteworthy. We consider this feature of the NP tube superior to the tolerance of oral airways in semi-conscious patient. From a military usage standpoint, the nasopharyngeal airway affords:

1. Access to the pharyngeal pool for the suctioning of mucus, either by inserting the nasal catheter directly through the tube or by attaching the suction adapter directly to the nasopharyngeal tube.
2. Stability of position in the pharynx in hyperactive patients thereby minimizing reaction on the NP tube.
3. Inability of the patient to occlude the tube voluntarily as compared with biting the tracheal tube or soft oral airway.

Only patients with marked deviation of the septum presented difficulty in the insertion of two Saklad nasopharyngeal airways and many of these patients could be intubated through both nostrils with the Robertazzi-type nasopharyngeal airway.

As soon as improved NP tubes can be obtained, we plan to evaluate the results of nasopharyngeal intubation in anesthetized or recovering patients by neophytes. The problem of the 15 millimeter length NP tube in very small adults may be, we believe, solved by the trainee learning the simple criteria of noise-free breath sounds with the proper level of insertion immediately following intubation. While the NP tube is obviously less desirable than the ideal of tracheal cuffed tube, it does afford a compromise solution as to how minimally trained personnel might apply a field resuscitator. Figure 57 shows the idea of such field management. One nasal tube couples the resuscitator, the other is placed and ready for use of suction to allow quick removal of secretions.

Patient	TIDAL VOLUMES IN CC				Patient's Tolerance of NP tube(s)	Evidence of Blood on NP tube or in pharynx
	Through NP tube			Through Nose* & Mouth With or Without Oropharyngeal Airway		
	Rt.	Lt.	Both R & L			
2		400		400	S	-
7			500	600	S	-
10		300		300	S	-
15			400	300	S	-
19			425	500	S	-
20	500			450	S	trace
21	300			400	S	-
22			400	600	S	trace
23			300	300	S	trace
26			500	600	S	trace
27	200			200	S	-

*without NP tube(s).

TABLE VI. COMPARISON OF VENTILATION WITH AND WITHOUT NP TUBES IN 11 PATIENTS

Patient	Mucus	TIDAL VOLUMES IN CC					Patient's Tolerance of NP tube(s)	Evidence of Blood on NP tube or in pharynx
		Tracheal Tube	Nasal Pharyngeal Tube			Nose and Mouth Without Artificial Airways		
			Rt.	Lt.	Both			
1		425			475		S	-
3		300			315		S	-
4		300	550				Poor (awake)	-
5		500			600		S	-
6		500			900	700	S	tinge
8		400			400		S	-
9		475			450	500	S	-
11		300			300		S	-
12		300			150		S	plug
13	+	-			-		S	-
14	slight	200			200		S	-
16	slight	200			300	350	S	-
17		350	300				S	-
18		350		400		400	S	-
24	plug removed by suction	550			550	600	S	-
25		200		300		300	S	-

TABLE VII. COMPARISON OF VENTILATION THROUGH TRACHEAL AND NP TUBE(S) IN 16 PATIENTS.

Route of Spontaneous Breathing	Tidal Volume in cc. as read on Ventimeter
Tracheal tube with cuff inflated	500 450 450
NP tubes R & L and Berman oral airway	600 700 600
Both NP tubes alone	900 600 500

TABLE VIII. Tidal Volumes read on Ventimeter during Spontaneous Breathing through Tracheal Tube and through Nasopharyngeal Tubes with and without an Oral Airway.

COMMENT: Since this study was carried out as the patient recovered from N_2O anesthesia, one cannot assume that these 9 breaths represent a steady state of respiratory drive or work of breathing. However, it is clearly demonstrated that the large volumes via NP tubes are accompanied by the highest peak airflows during inspiration, indicating that resistance was not critical.

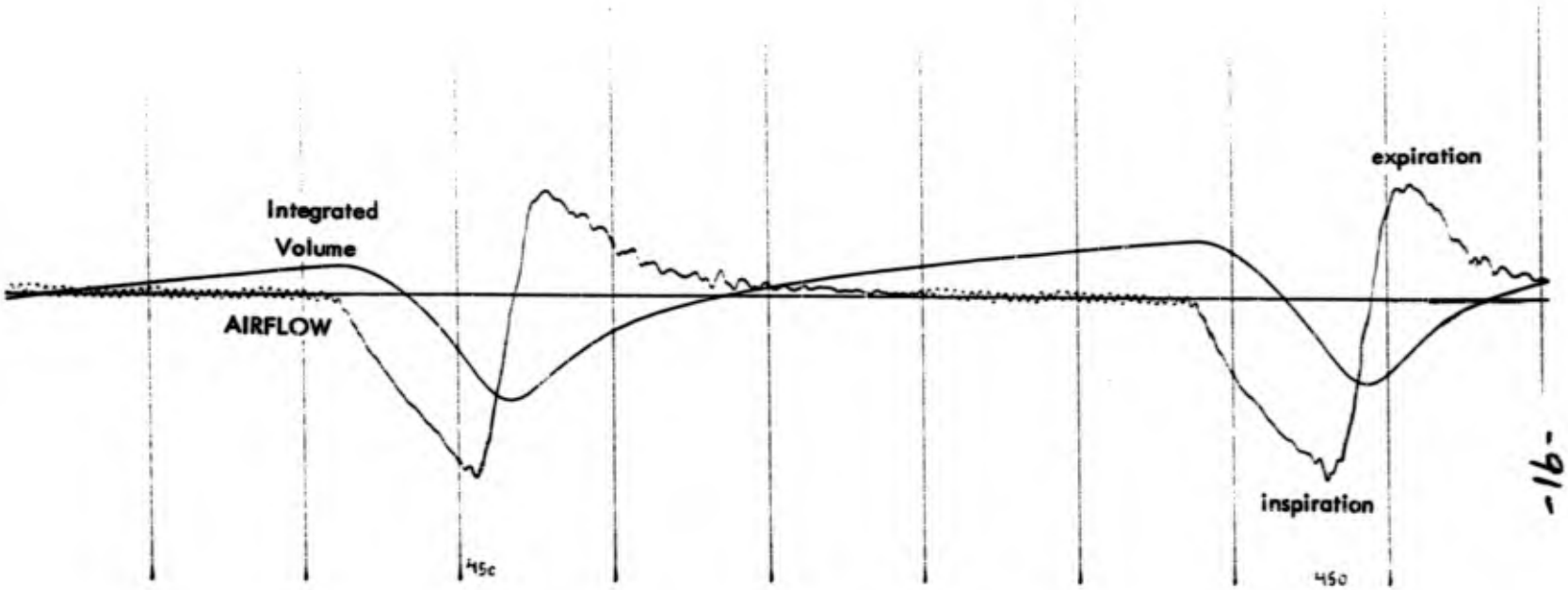


Figure 51. Airflow and integrated volume through tracheal tube. Spontaneous breathing. Sixty year old female recovering from N_2O anesthesia. Inspiratory excursions are below base lines. The peak flow rate of 30 liters per minute during inspiration is characteristic of minimal lung-airway resistance. Second intervals are horizontal. The 450 cc. tidal volumes were read from the ventimeter to facilitate data work-up. The patient weighed 224 pounds.

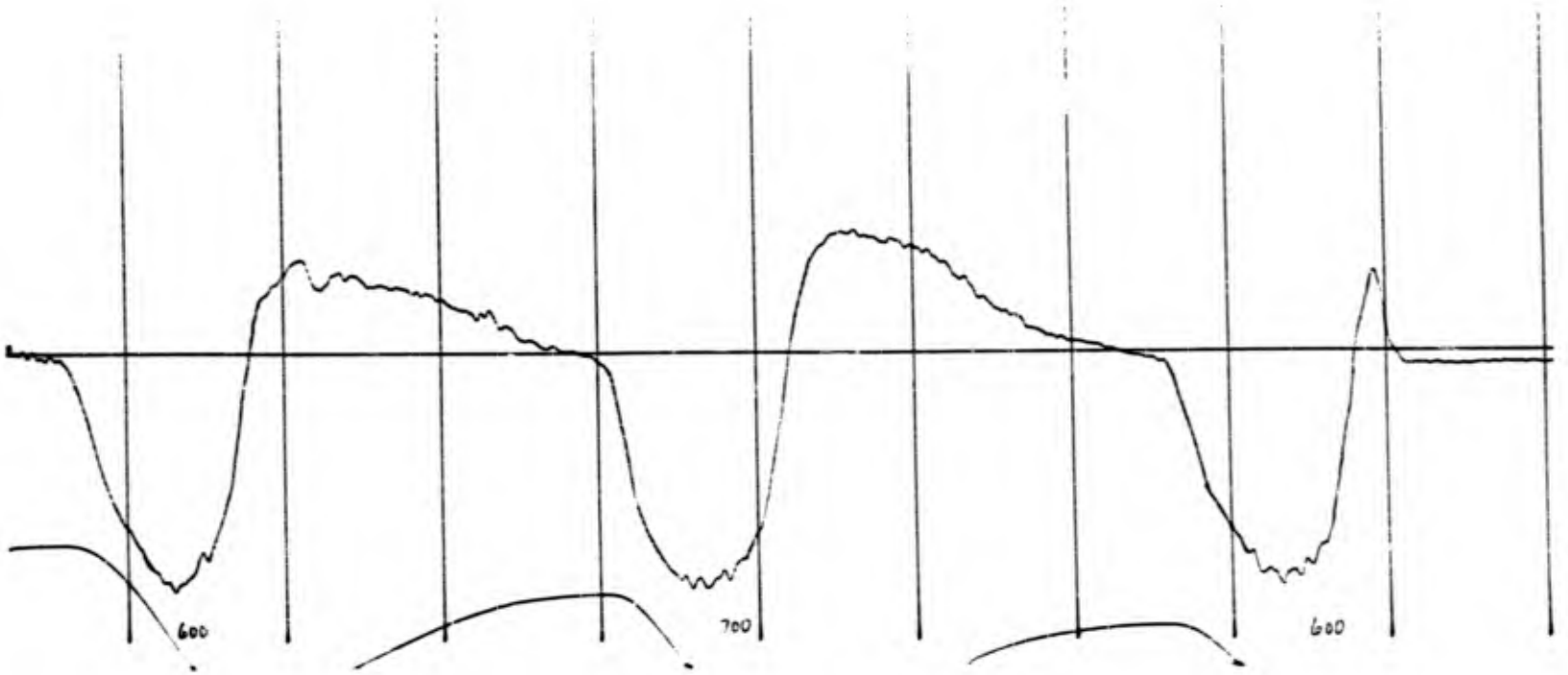


Figure 52. Same patient as Figure 51. Airflow and Volume through nasopharyngeal tubes in right and left nostril plus an oral airway, immediately following tracheal extubation. Both tidal volumes and inspiratory flow rates are increased. The inspiratory and expirarory flow peaks are no longer sharp, suggesting slight resistive effects, perhaps of the epiglottis or larynx.

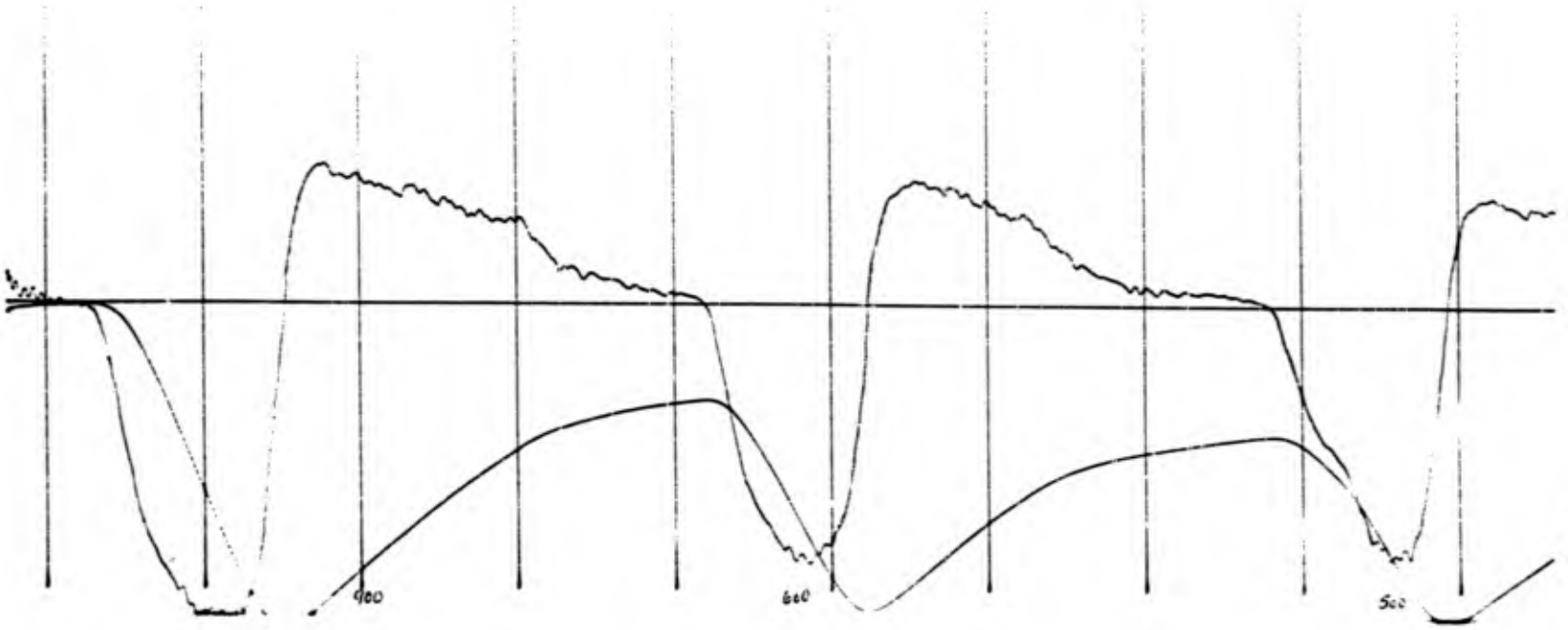


Figure 53. Same patient as Figures 51 and 52. Airflow and Volume through the two nasopharyngeal tubes with the lips occluded. The NP tubes accommodate even greater volumes and flow rates without the contribution of oral breathing. The consecutive tidal volumes monitored and recorded for tracheal, oro-nasal, and nasal breathing are tabulated in Table VIII.

Route of Spontaneous Breathing	Tidal Volume in cc. as read on Ventimeter
Tracheal tube	400 700 300 400 475
Both NP tubes covered by nose mask	450 400 400 450 350 400 450 450 300 400
Mouth breathing with NP tubes in place. Oronasal mask covering NP tubes and mouth (no oral airway).	450 450 500

TABLE IX. Tidal volumes read on Ventimeter during spontaneous breathing through tracheal tube and through nasopharyngeal tubes, with and without mouth open.

COMMENT: During his recovery from cyclopropane anesthesia, all but one of this patient's spontaneous breaths showed evidence of partial obstruction (seecirflow records Figures 54, 55, and 56), even through the tracheal tube. Thick mucous in trachea or bronchi might explain these findings. When his mouth was opened, he breathed slightly larger tidal volumes spontaneously but the airflow records did not show any less resistance than through the NP tubes alone.

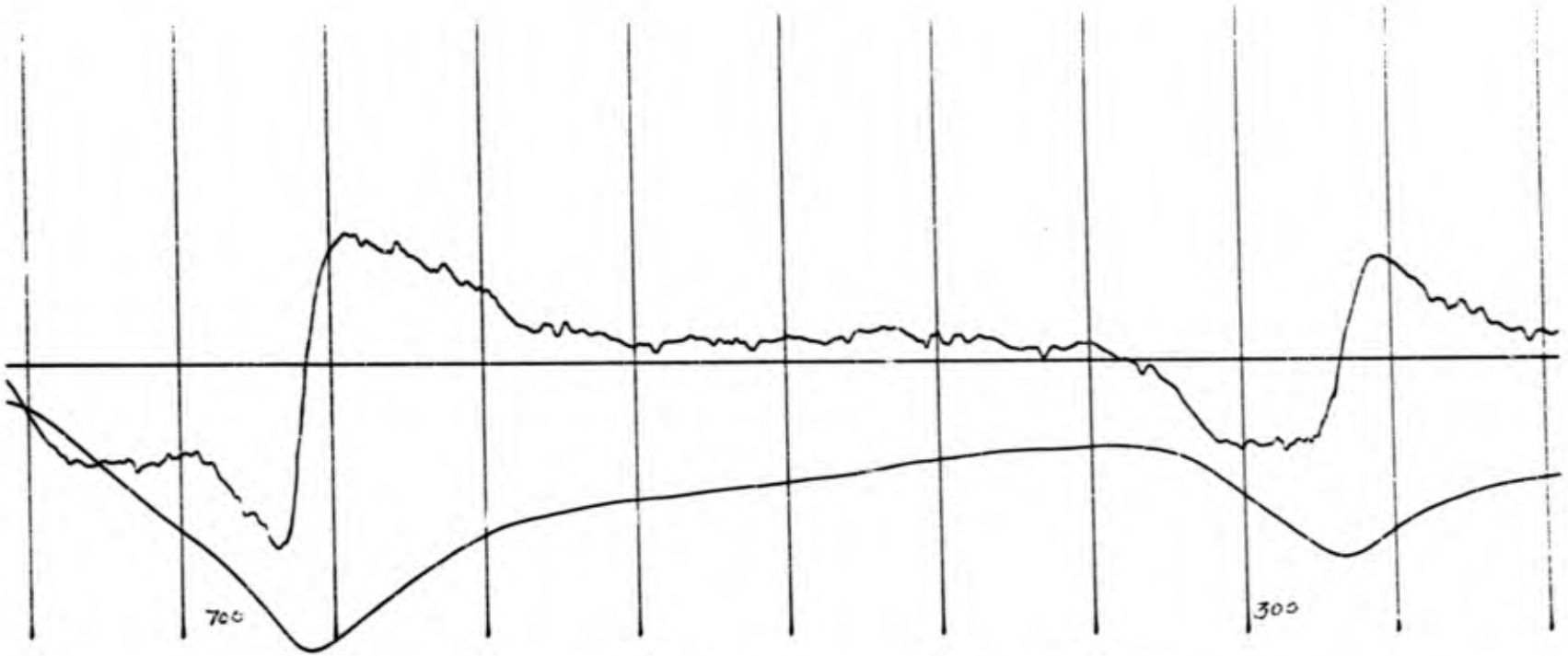


Figure 54. Airflow and Volume through tracheal tube of 54 year old patient (weight 130 pounds), recovering from cyclopropane anesthesia. The first spontaneous breath recorded shows 30 LPM peak inspiratory flow, the second only 15 LPM. Further, the reduced volume suggests the effect of appreciable resistance. Other volumes are tabulated in Table IX during tracheal, nasal, and oronasal breathing.

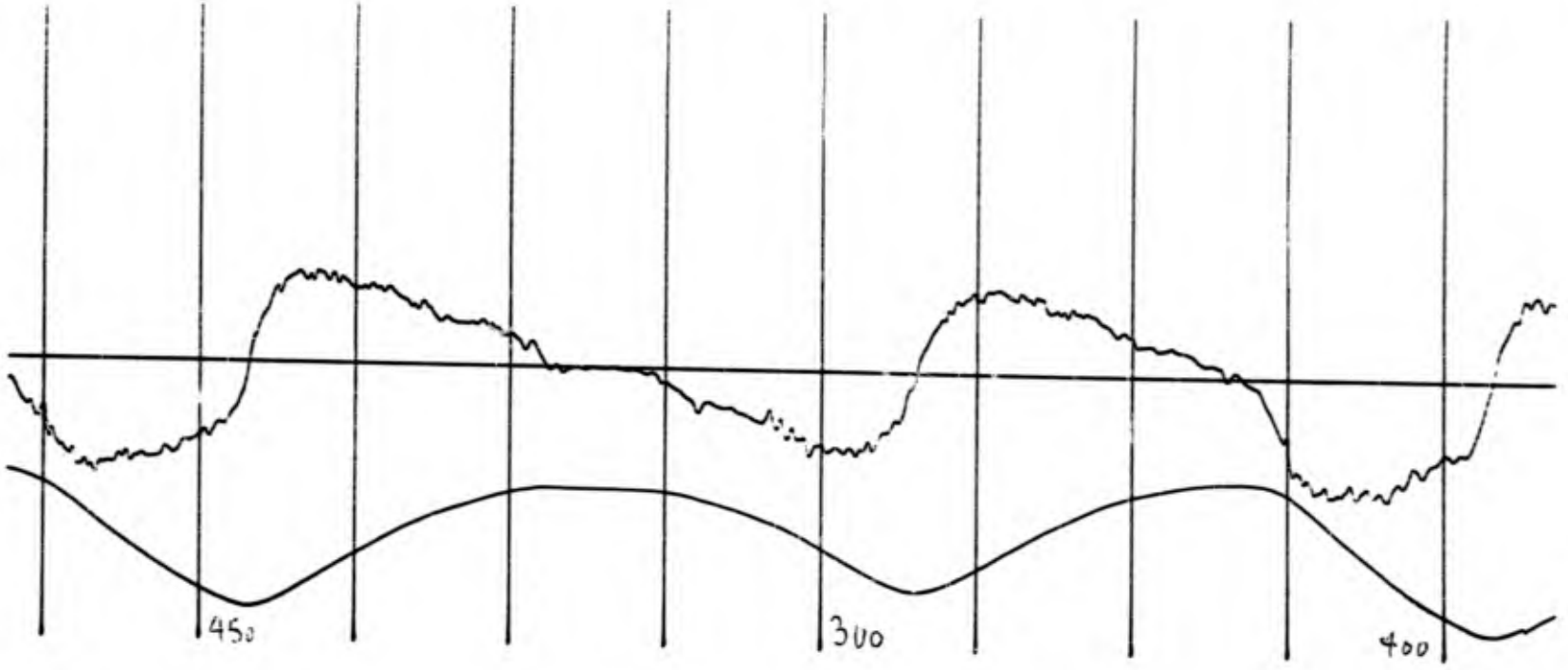


Figure 55. Same patient as Figure 54. Airflow and Volume through bilateral NP tubes covered by a nasal mask (dental). These values are comparable to the tracheal airflow in which evidence of some resistance appeared. One explanation could be thick mucous in the trachea or bronchi. In any event, adequate spontaneous respiration occurred through the NP tubes.

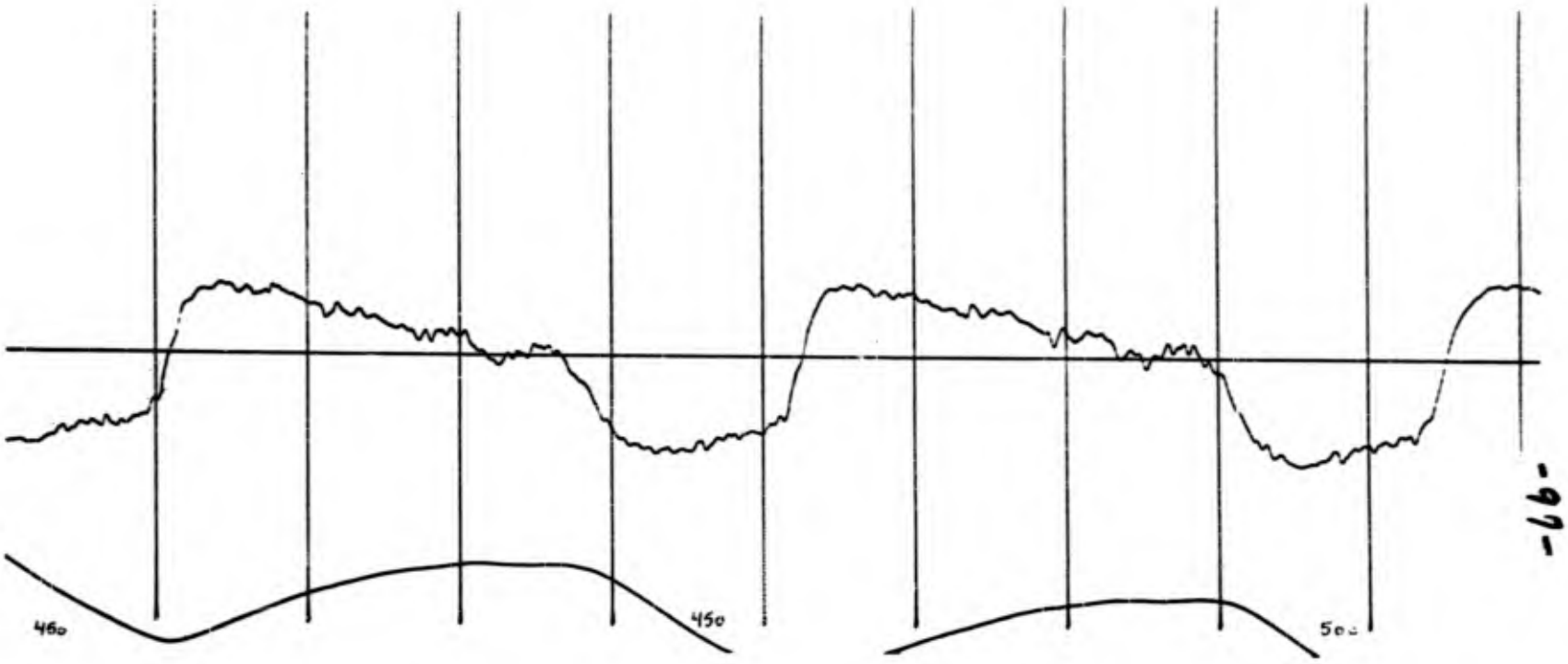


Figure 56. Same patient as Figure 54. Airflow and Volume through NP tubes and the patient's opened mouth (oro-nasal mask). The volumes are slightly increased with the addition of mouth breathing. The airflow peaks remain damped.

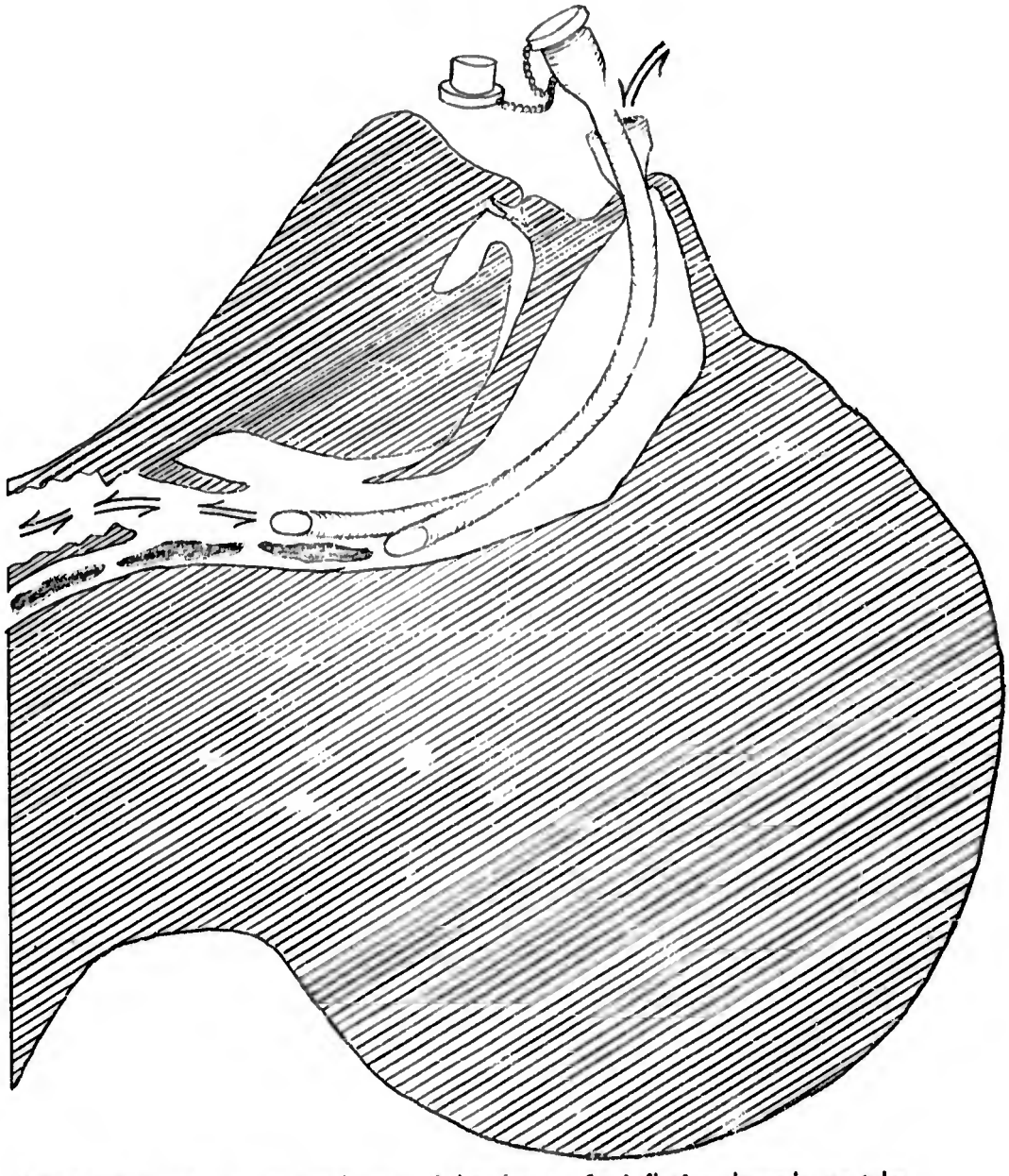


Figure 57. Scheme of bilateral nasal intubation of the pharynx for inflation through one tube (while the other is occluded) and intermittent suction through the other for rapid removal of secretions. The lips must also be occluded for positive-pressure inflation. This scheme minimizes interruption of ventilation for removal of mucous, affords convenience, and reduces the trauma of repeated insertions for suction. Tubes are well tolerated and provide excellent upper airway patency in the reactive, irrational semi-conscious patient whether breathing is spontaneous, assisted, or controlled.

IX. TREATMENT OF PROTRACTED SURGICAL HYPOTENSION WITH SODIUM BICARBONATE (15 Patients)

During 1961, we observed that there was an apparent relationship between (1) the onset of hypotension (following blood loss) and (2) the servo-cycling of the patient. Dr. Lowe observed that during stable planes of anesthesia, the patient departed from the established recurring apnea pattern and continuously triggered the assistor even before the blood pressure had begun to fall. He noted further that whole blood replacement was heralded by a return to servo-cycling as the blood pressure was restored to the previous control value.

This observation stimulated our clinical group to apply this special pre-monitoring to determine whether the respiratory drive of the patient consistently preceded hypotension. Within 10 months we have collected a series of 15 patients who exhibited the above sequence (Table X).

More remarkable than the early detection of impending hypotension was the therapy devised by Dr. Lowe to reverse a protracted hypotension.

Frequently we find that with prolonged extensive resections (in elderly patients suffering from long standing malignancy) the replacement, however prompt, of surgical blood loss does not restore the blood pressure. Nor does the additional administration of vasopressor amine, solu-cortef (R), or atropine correct the hypotension in a number of these patients.

During 1961, Dr. Lowe reasoned that during the period of compromised circulation, the onset of metabolic acidosis would be inevitable. He then began studying pH, pCO_2, and buffer base of the arterial blood in several hundred cases, especially patients receiving 3 or 4 units of blood during surgery. The results confirmed, as several other investigators have reported (Gesell, 1930; Campbell, 1958; Meyer, 1961), that not only was pH reduced (range 7.34 to 6.9) but the buffer base, or available binding cation was consistently reduced (by 1 to 15 milli-equivalents per liter).

Campbell treated such metabolic acidosis with intravenous sodium lactate. We decided to try sodium bicarbonate instead since we reasoned that either the lactate or bicarbonate has

its result on buffer base and pH by virtue of the sodium ion elevation. With lactate, this sodium is balanced by lactate until the patient can metabolize the lactate. By then his kidneys will have excreted much of this sodium. Besides these events would take several hours and the patient in metabolic acidosis has an elevated lactate level before therapy.

In contrast, the bicarbonate could be made promptly effective by following the administration of sodium bicarbonate with an interval of hyperventilation to blow off the liberated CO_2 and thereby effecting a prompt elevation in sodium ion level.

Therefore, sodium bicarbonate was used. The patients showed the respiratory drive of the transient elevation in blood CO_2, they were hyperventilated, usually with an assistor-controller, and the response in blood pressure was prompt (within 2-3 minutes). If the blood pressure did not remain at the control level, another ampule (44 mEq) was given, and one patient required 7 ampules before blood pressure, pH, and buffer base were stabilized at his previous control values.

COMMENT:

1. The administration of intravenous sodium bicarbonate is indicated in surgical hypotensive episodes accompanied by metabolic acidosis. The inciting causes may be:
    a. massive blood loss accompanied by rapid replacement of ACD blood.
    b. anesthetic agents which result in metabolic acidosis (ether, cyclopropane, pentothal).
    c. peripheral ischemia (pump oxygenator).
2. The readjustments of the pH following sodium bicarbonate and hyperventilation produces a sustained vasopressor action.
3. Respiratory responses immediately following the administration of sodium bicarbonate are a transient tachypnia with deep respirations. The patient triggers an assistor at a faster rate.
4. No untoward reactions including renal suppression have been noted.

The surgical patient who develops hypotension for half an hour is benefited by one or two ampules of intravenous sodium bicarbonate. Preferably, this therapy should always precede the use of pressor amines because the blood pressure response often excludes the need for ephedrine, neosynephrine, vasoxyl (R), or levophed (R). We recommend that sodium bicarbonate (1 ampule for every 2 units of ACD blood) be given during transfusion for blood loss.

For the patient who suffers cardiac arrest or severe sudden failure or adequate circulation, the use of sodium bicarbonate is indicated. When the circulation has been markedly deficient for only 5 minutes, the explosive onset of severe metabolic acidosis (pH below 7.0) requires as many as 4 ampules of sodium bicarbonate to restore the pH to a normal range. As soon as possible during closed chest cardiac massage, several ampules of bicarbonate should be given. We recommend that it be given prior to epinephrine.

Case No.	Pre-operative or control Blood Pressure	Hypotension	No. of ampules (50 cc, 0.89 molar) Bicarbonate IV	Immediate Response Blood Pressure
1	150/80	85/60	1	150/85
2	130/80	90/70	1	120/60
3	140/80	80/50	2	130/70
4	130/50	90/50	2	130/90
5	130/80	70/40	7	130/80
6	130/80	80/?	2	140/80
7	120/80	60/?	1	100/80
8	170/80	100/70	2	140/80
9	?	80/70	3	120/80
10	150/90	70/50	2	160/80
11	120/70	80/60	1	110/90
12	180/100	80/50	2	120/90
13	140/90	70/?	1	120/80
14	130/80	90/50	1	90/50*
15	160/80	80/60	1	120/90

*Fluothane anesthesia.

TABLE X. Correlation of Blood Pressures with Sodium Bicarbonate Therapy.

X. CO_2 ELIMINATION FROM REBREATHING CIRCUITS WITHOUT SODA LIME

Since large two-chambered transparent reversible carbon-dioxide absorbers, developed in this department, have become available for anesthesia, considerable reduction in soda lime consumption has been achieved. While these absorbers reduce waste of soda lime in closed circle systems, Dr. Brown of this department found an enormous lifetime in clinical practice where semi-closed technic was employed. These clinical impressions were confirmed in laboratory tests using an "artificial patient" lung analogue. In a semi-closed system with an inflow of 4 liters, an absorber lasted 60 hours instead of 15 hours when a closed circuit was tested.

The theoretically predicted effect of the 4 liters dilution was extension to only 30 hours. The 60 hours performance showed that the outflow of gas from the breathing circuit was undiluted expired air. Thus the system appeared to approach the completeness of CO_2 removal of a non-rebreathing circuit but with a gas flow rate of only half the minute volume.

To simulate the usual aerodynamics within the absorber, canisters filled with popcorn were used instead of soda lime. Various inflow rates of gas were tested. The lowest inspired CO_2 concentration in the various systems tested with spontaneous ventilation was the Magill where the patient inspires through a corrugated breathing tube from a bag and gas is exhausted at the mask after the bag refills to a pre-set pressure on exhalation. In this study, the Model 20 Ohio canister performed better than the older Forreger Adriani or the Model 9 B Ohio circle absorbers (Figure 58).

When the "patient's" ventilation was converted from spontaneous to controlled positive-pressure inflations, the Magill system was poorest (Figure B). The other systems had values of inspired CO_2 below 1% when the inflow rate was 5 liters or more. Using a pop-off valve at the yoke was nearly as detrimental to the circle systems as it was in the Magill on controlled ventilation.

A comparison was made of the effect of changing the valves from near the canister to near the patient and moving the pop-off similarly, using spontaneous ventilation (Figure C). Only minor

differences were observed except that when the valves and pop-off were both at the patient, results were poor. Tests with spontaneous breathing to determine the hours of performance* of the absorber filled with soda lime were made on the analogue. Results showed no effect on life of the absorber when the position of the bag was changed from the expiratory to the inspiratory side of the canister. Changing the pop-off to near the patient made no difference in life with spontaneous breathing. However, the life was reduced from 60 to 35 hours when the inflow of gases was between the inspiratory valve and the patient, and the pop-off was also at the patient. If, under the same circumstances, the pop-off was placed between the expiratory valve and the absorber, the life was reduced to 30 hours. With the pop-off on the inspiratory side of the canister, the life was no better than with the closed circle, 15 hours.

Similar studies are projected for controlled ventilation to determine the best arrangement of components. From the present information, the pop-off and reservoir bag should be between the expiratory valve and the canister and the inflow gas should enter between the inspiratory valve and the canister.

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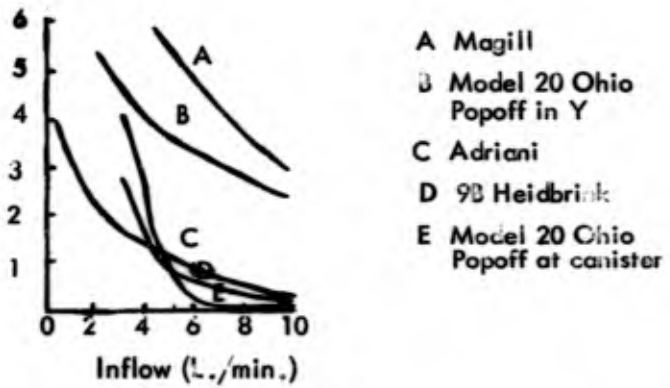
*Period for depletion of lime in upper half of absorber, judged by change of indicator.

Figure 58. LOWEST INSPIRED CO_2 CONCENTRATION



XI. ANATOMICAL DYNAMICS OF THE UPPER AIRWAY

This film entitled AIRWAY OBSTRUCTION: CAUSE AND PREVENTION was undertaken jointly by Dr. David Greene and our department with the support of contracts DA-49-007-MD-507 and DA-49-007-MD-209*.

The first part of this film consists of manipulative sequences performed in an anatomical sagittal hemi-section of the head and neck of a cadaver. This dissection was carried out to expose the soft parts of the human upper airway. For differentiation, colored paint was applied to the several structures. The action sequences demonstrate the effects of all the airway-clearing manual maneuvers and the insertion of catheters, tubes, and artificial airways.

A bilateral sagittal model is shown which is constructed in wood and plastic to simulate the effect of head and jaw positions upon upper airway patency and to permit a demonstration of the dynamic behavior of the airway. The model permits the airway-clearing maneuver to be demonstrated by essentially the same technique which would be used on a victim. The dimensions of airway parts, the action of the important joints, and the tension produced by pertinent muscle groups are mimicked in the design of this airway model.

The second part of this film consists of a demonstration with cinefluorography of two maneuvers: (1) hyperextension of the head with upward traction on the chin, and (2) the insertion of oral airways of various lengths. These x-ray movies relate the pharyngeal clearance with the degree of extension of the victim's head and jaw (Figures 59 - 62) similarly with the length or oral airway being used. These films were taken in adult male volunteers during thiopenthal induced apnea without additional drugs (no relaxants). The film shows upper airway dynamics not previously described such as the marked expansion of the entire pharynx during expired air inflation. The results demonstrate in these subjects that an oral tube does not need to enter the hypopharynx in order to establish a patent airway since hyperextension with upward chin traction uniformly achieved a wide open pharynx.

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*The editing and sound track were handled by American Film Producers, 1600 Broadway, New York.

The combined results of the anatomical dissection and x-ray studies indicated the following conclusions:

1. The pharynx and hypopharynx undergo marked dilation during positive pressure inflation.

2. The base of the tongue acts like a ball-valve which is closed by contact with the posterior pharyngeal wall. This ball-valve action depends upon either or both of the following: (a) extension of the head at the atlanto-occipital joint; and (b) forward displacement of the mandible. Ball-valving of the tongue base was also found to be influenced by inflation pressure. Thus obstructed unconscious subjects with complete occlusion between tongue base and pharynx showed a transient opening of this occlusion when inflation pressures exceeded 20 ($\pm$ 7) cm. H_2O. Therefore this form of flaccid obstruction may be converted by strong inflation to a partial expiratory obstruction and is often associated with gastric dilatation. This ball-valve obstruction uniformly disappeared when the subject's head or jaw were properly positioned. This finding appears to explain why some laymen have been able to achieve successful rescues with several quick inflations in spite of an incorrect position of the victim's head.

3. A flap-valve action of the soft palate was found to be of negligible significance unless, as in the ball-valving of the tongue, the head was in the neutral or slumped position. Under these conditions the force of inflation was easily able to move the soft palate passively. Undoubtedly, the tendency to obstruct during expiration as a result of the palate flapping into contact with the posterior pharyngeal wall varies among individuals and is most common in subjects with long pendulous soft palates. So far as a patent airway is concerned, such individuals need to have their oral pathway opened for exhalation. Expiratory obstruction is no problem in such subjects unless there is concomitant occlusion of the lips preventing exhalation through the mouth.

4. Gastric inflation is influenced not only by excessive inflation pressure, but also the clearance between the tongue and posterior pharyngeal wall. Thus, a strong

inflation can temporarily reverse tongue base obstruction but an equal force cannot be passively exerted during exhalation. Therefore, the expiratory pressure in the apneic subject is always a small fraction of the inflating pressure since the compliance and volume of the oronasopharynx transmit exerted pressure to lift the tongue during inflation. With passive exhalation, however, this pressure is reduced because of the larger compliance and volume of the thorax, so that too little force is exerted to lift the tongue and permit free expiration. Since the opening of the esophagus requires less pressure than that required to lift the tongue base from contact with the posterior pharynx, the tendency of air to enter and dilate the esophagus and stomach is readily apparent. The soft-part mechanics of this relationship between partial obstruction and gastric inflation, although very simple, have not been previously elucidated.

5. The Geudel length of oral airway of 90 millimeters (size No. 4) is somewhat long for the small adult as it may be lodged in the valleculae.

6. An oral tube of 20 to 30 millimeter length projects just beyond the teeth is sufficient as an adjunct for expired air inflation provided the rescuer either hyperextends the patient's head or displaces the mandible forward.

7. The commonly used manual maneuvers of extending the head and/or displacing the mandible forward all resulted in equivalent and satisfactory elimination of airway obstruction by the tongue. Displacement of the mandible, however, did not eliminate the tendency of the palate to produce expiratory obstruction in individuals who show this valving with neutral head position.

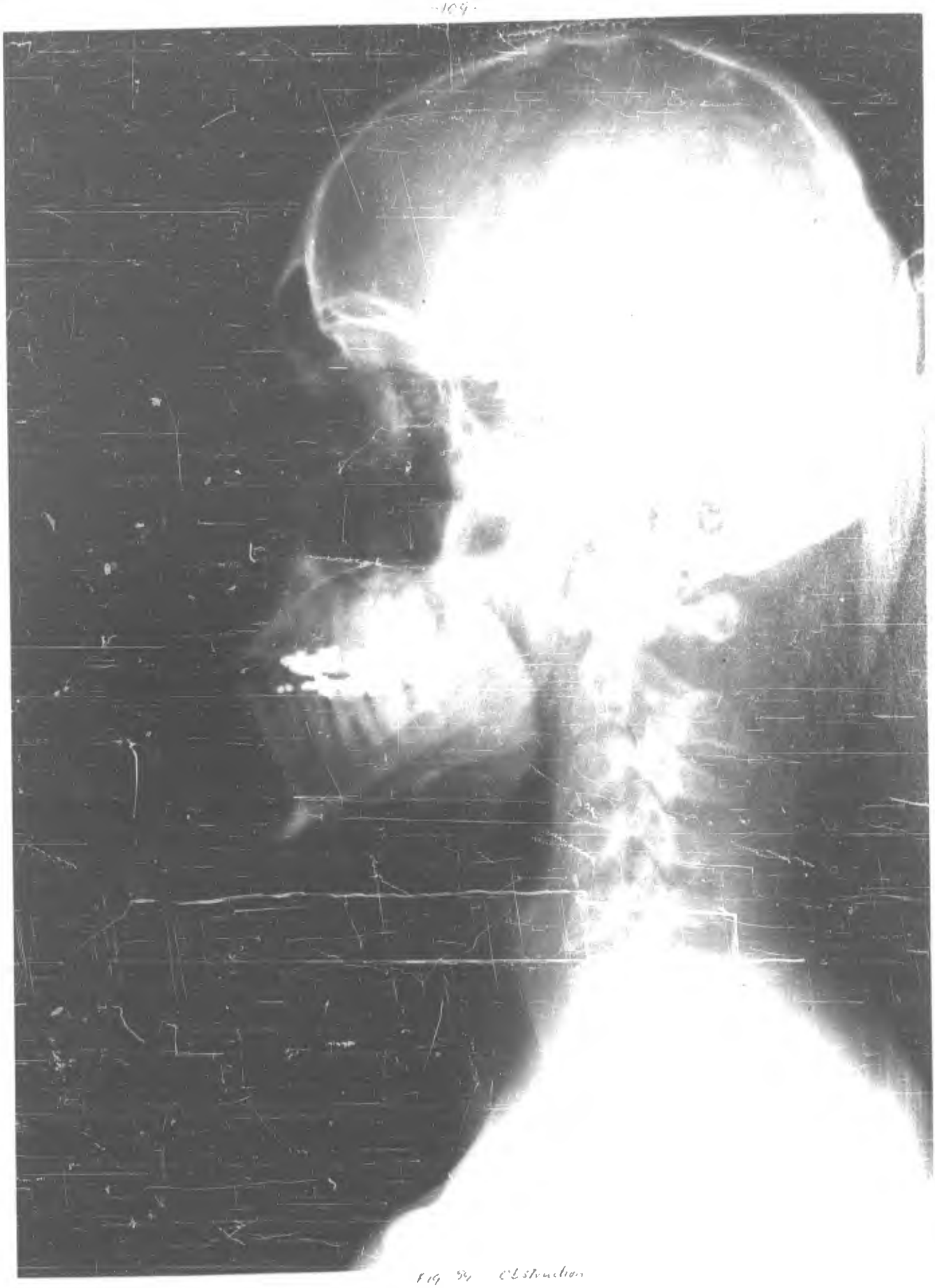
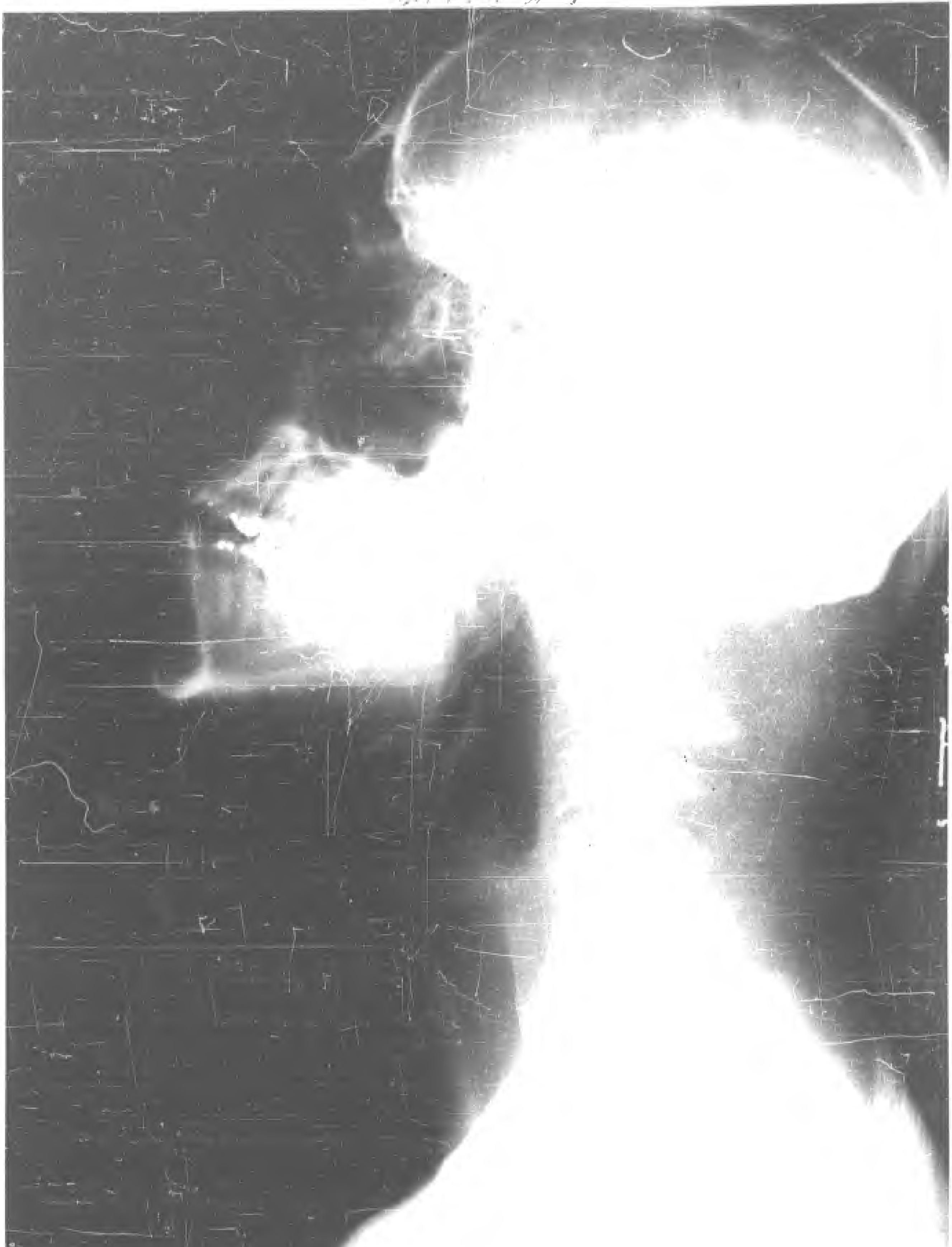
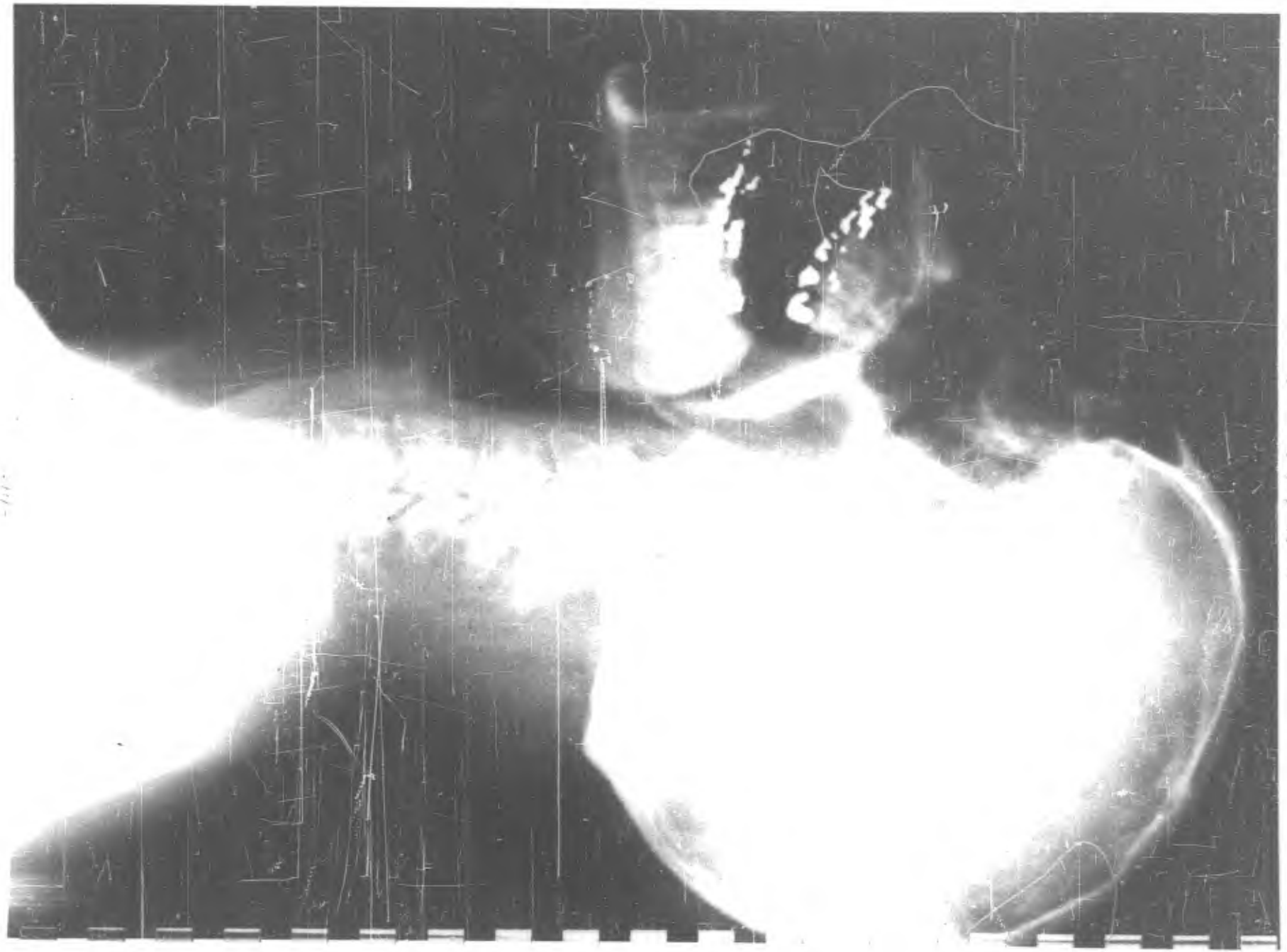


Fig 54 Obstruction





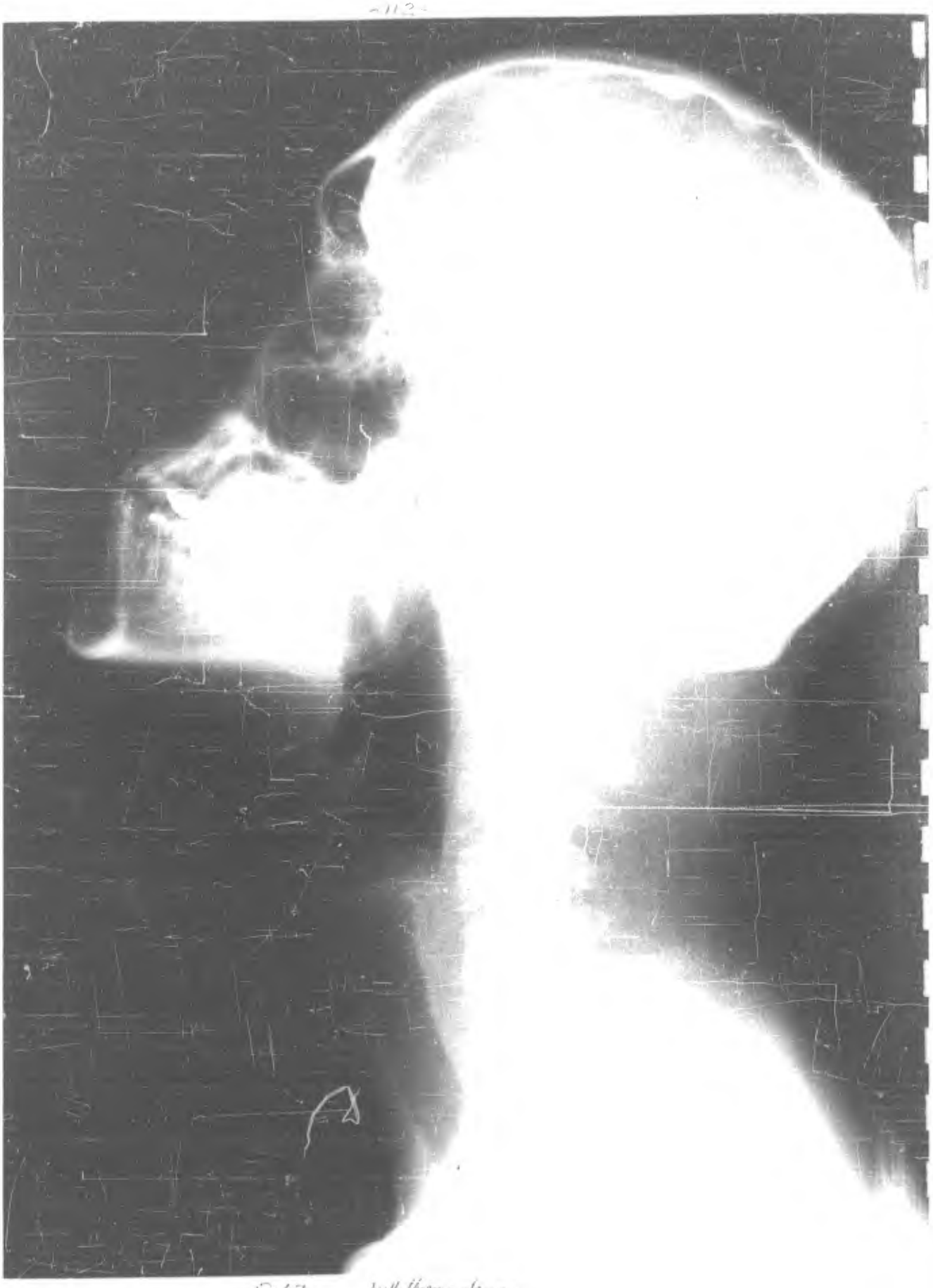


Fig 6.2 Skull (Upper view)

XII. TRAINING MEDICAL AND LAY PERSONNEL IN HEART-LUNG RESUSCITATION

A. Experiences at Roswell Park Memorial Institute and in New York State:

During 1961, our group personally trained or sponsored programs for approximately 5,000 medical and lay personnel. This experience is reported here briefly.

Emphasis Upon Simultaneous Heart-Lung Resuscitation: All medical groups have been taught simultaneously how to perform expired air resuscitation and closed chest massage as a co-ordinated system to be applied together unless the patient has obviously adequate circulation. Instruction in heart resuscitation is currently excluded only from the training programs we are sponsoring in New York State public schools. For many adult lay groups, we are convinced that sufficient caution can be learned in applying the proper technic of sternal compression to permit any intelligent able adult to perform this closed chest cardiac massage effectively. We stress the potential hazards of excessive pressure applied off the sternum, emphasize the need for precise careful technic, but encourage the trainee to accept and use the technic without hesitation, provided he understand these hazards.

Preference for Practice on Full-Size Manikin Over Use of Training Films Alone: The time previously spent reviewing propaganda or technic films is now more profitably devoted to having all trainees practice on manikins. We are convinced this change in instruction from passive audiovisual learning to live performance of the actual procedure imparts the details in technic which the trainee will remember. The average trainee, whether medical or lay, learns only by doing the maneuvers himself, for example: how wide he must open his mouth, with what force he must blow air, and how to depress the sternum 1 1/2 inches. Only after he has performed, will he gain confidence as a rescuer.

We employ the Norwegian "Resusci-Anne" manikin with several modifications:

1. The plastic face shields are wetted with 1:1000 zephiran solution prior to application on the manikin's face to facilitate a quick pneumatic seal of the shield, insure continual sanitation, and eliminate tedious sterilization of the manikin airway, trachea, and lung. Cultures taken from the manikin after several hundred training performances have been reported as sterile.

2. An aneroid manometer is connected to a side arm at the trachea of the manikin so that the instructor may independently monitor the rescuer's efforts. The instructor above monitors both the mouth-to-mouth breathing on the aneroid and blood pressure excursions produced by closed chest cardiac massage on a mercury manometer.
3. To obtain a more realistic action for sternal compression, the body cavity is filled with water instead of air.

Training groups are teamed in pairs. One trainee performs mouth-to-mouth breathing while the other does closed chest compression at the same time; then they alternate. The remaining trainees watch to benefit from the individual instruction given the first few pairs who then become instructors for the rest of the group. A group of 20 medical or para-medical trainees may be adequately instructed in these technics in 30 minutes.

Medical installations could use a similar training program for all clinical personnel (physicians, nurses, aidmen) to that developed at Roswell Park Institute during November, 1961. Non-physician personnel are instructed in the importance of noting only that the patient is suddenly apneic and/or pulseless. The importance of frequent observation of the dilatation or constriction of the pupils should be emphasized.

Physicians should hold separate conferences to become familiar with the important steps in heart-lung resuscitation following the emergency institution of artificial respiration and artificial circulation. Practicing external defibrillation on dogs is the best procedure to convince the surgeon of the indications for:

A. Reversal of acidosis

B. Cardiotonic drugs

C. External defibrillation

D. Electrocardiographic evaluation

We distribute a summary of Jude's procedures which we have reduced to 12 basic steps in Heart-Lung Resuscitation (appended).

The anesthesia service of the hospital installation is best suited and equipped to co-ordinate the training of all medical personnel in the clinic or hospital. A concerted effort at indoctrination of all personnel within a few weeks results in better general acceptance, actual use of heart-lung resuscitation in subsequent emergencies and contributes to an understanding of an organized plan of action for such emergencies for all personnel who become involved.

During October - December, 1961, our group has loaned manikins for pilot training programs in the public schools of New York State. We instruct the Physical Education Department head for 10 minutes. In 3 such pilot programs over 4,000 trainees, age 12 to 18, have been indoctrinated in mouth-to-mouth breathing.

12 STEPS IN

HEART - LUNG RESUSCITATION

(For any patient who suddenly develops apnea, pulselessness, pupil dilation, or BP less 70 mm. Hg.)

1.	5 seconds		MOUTH-TO-MOUTH VENTILATION
2.	10 seconds		EXTERNAL HEART COMPRESSION
3.	2 minutes		INTRACARDIAC EPINEPHRINE 0.5 mg.
4.	5-10 minutes		EKG, EXTERNAL DEFIBRILLATOR, BP CUFF
5.	within 10 - 15 minutes		IV CUTDOWN - 3 way
6.			IV SODIUM BICARBONATE (inject 3.75 gm. ampule every 5 minutes)
7.			IV NEOSYNEPHRINE (20 mg/500 cc by IV drip)
8.			IV CALCIUM CHLORIDE (inject 0.5 gm. when EKG shows weak, slow activity)
9.		ASSESS ELECTROCARDIOGRAM	
10.		EXTERNAL DEFIBRILLATION	
11.		TRACHEAL INTUBATION & VENTILATION WITH O_2	
12.			IV QUINIDINE GLUCONATE (inject 240 mg. slowly until EKG shows depression)

DURATION OF RESUSCITATION - 1 to 90 minutes

B. AN ANATOMICAL RESUSCITATION TRAINING AID: Head-Chest Model for Instruction of Medical Personnel in Upper Airway Dynamics and Positive-Pressure Lung Inflation, MR. VICTIM

Practical instruction in the manual maneuvers of airway management and the emergency methods of lung inflation for groups of medical students, physicians, and nurses is difficult because unconscious patients are frequently not available during scheduled lectures. A realistic anatomical manikin would solve this problem. We have, therefore, designed and developed a training aid for demonstrating the important anatomical principles involved in the behavior of the upper airway and in the positive-pressure inflation of the lungs. This training aid, nicknamed MR. VICTIM, simulates for teaching purposes the head, neck, and anterior chest of a supine unconscious adult. MR. VICTIM provides for:

1. Demonstration and practice of the deliberate manual manipulations which, without adjuncts, establish and maintain a patent upper airway in the unconscious or paralyzed human being.
2. Performance of positive pressure lung inflation, including the expired air methods of resuscitation, with or without equipment.

Only a prototype MR. VICTIM possessing these functional characteristics has been completed. Unlike the other manikins recently designed for laymen (Respertrain (R), Resusci-Anne (R), Brook Manikin (R)) this training aid duplicates the specific anatomical relationships which are particularly needed to educate medical personnel, such as:

a. The two distinctly different effects upon pharyngeal airspace of:
   1. Protrusion of the mandible anteriorly (the jaw-lift maneuver).
   2. Hyperextension of the head (the head-tilt maneuver).
b. The upper airway resistance to airflow produced by:
   1. Jaw-lift: 25.6 cm. H_2O/L/sec.
   2. Head-tilt: 25.6 cm.H_2O/L/sec.
   3. Both maneuvers: 10.6 cm. H_2O/L/sec.

The simulated upper airway resistances have never been measured in the context of emergency resuscitation (thick mucous and flaccid soft parts - epiglottis and tongue - partially obstructing the pharynx). These present values which represent an estimate of an appropriate resistance may be varied by substituting different sizes of rubber tubing for that now in the manikin.

c. The lung-thorax compliance of

1. .036 L/cm.H_2O

This value of compliance is approximately the average for unconscious adults with relaxed chest musculature. The compliance may be altered by selection of the sac (Figure 65) which receives the inflation air.

DESCRIPTION OF THE MANIKIN. The general features and external appearance of MR. VICTIM are shown in Figure 63. The head is a modified form of MR. AMERICA, one of the head models used at the Army Chemical Center which represents the composite dimensions of an average male of military age. The chest of MR. VICTIM was derived from a plaster impression of a 24 year old male volunteer. The rigid chest wall and head were vacuum formed in sheet Royalite (R), a hard and durable plastic. In the present version of MR. VICTIM, the lung is fabricated from sheet rubber and mounted as a bladder over the rigid chest wall, and the "flesh and skin" of the head are made of a cold-molding compound. The soft face is molded to fit the rigid Royalite (R) skull. In subsequent versions of MR. VICTIM, these soft parts should be fabricated of durable vinyl plastic, similar to that used in Resusci-Anne (R).

The soft head covering may be removed to show mandibular action (Figure 64). The range of mandibular motion permits about 1 cm. forward displacement. Obviously, an accurate simulation of this mandibular motion depends upon the anatomical location of the temporo-mandibular

joints. Similarly, accurate simulation of the range of head extension depends upon the location and action of the atlanto-occipital articulation. These dimensions and relationships in MR. VICTIM were based on the cinefluorographic & x-ray studies reported under this contract in 1960.

The internal structural and functional features of MR. VICTIM are shown schematically in Figure 65. Some of these features are also shown in Figure 66. A unique feature of design is the isolation of inflated air from the thoracic parts of the manikin. Air blown through the mouth or nose fills and expands a sac within the pneumatically sealed skull, displacing an equal volume of air through the "pharynx" and "trachea" into the "lungs". The inflated air is isolated from the pharynx, trachea, and lungs by a disposable sac. This feature simplifies decontamination. The only parts of MR. VICTIM to become contaminated when expired air methods are taught would be:

1. a relatively inexpensive, disposable sac , and
2. the face (with mouth and nasal passages) which may be washed in Zephiran (R) for re-use.

Another unique design feature of MR. VICTIM is the definite separation of two airway-clearing actions:

1. head-extension, and
2. forward displacement of the mandible.

When the head is hyperextended, a mechanical linkage between the head and the cervical spine actuates a battery-powered solenoid valve to open half of the "pharynx" and convert 100% obstruction to partial obstruction (50%). When the mandible is displaced anteriorly, another solenoid opens the other 50% of the pharynx. Thus the degree of airway patency, as well as the magnitude of airway resistance, is determined by two separate actions (jaw elevation and head-extension) as was found in x-ray studies on anesthetized adults. With these actions, the "click" of the solenoid valves tells both the instructor and the student whether the airway is: 1) obstructed, 2.) 50% obstructed, or 3.) 100% patent.

USE OF MR. VICTIM IN TEACHING AIRWAY MANAGEMENT: The construction of an anatomical manikin with both structural and functional anatomic accuracy would be an unjustified undertaking, because the behavior of the soft parts in the pharynx would be hidden from view of the trainee. Therefore, a functionally anatomical manikin such as MR. VICTIM should be used in conjunction with a sagittal head model such as MR. AIRWAY, reported under this contract in 1960. A knowledge and understanding of the anatomy of airway obstruction and its management can be learned from MR. AIRWAY. The performance of technics of airway management and of positive pressure lung inflation can be learned and practiced on MR. VICTIM.

In an unconscious or paralyzed human being, the upper airway usually is obstructed by the tongue's collapsing against the posterior pharyngeal wall. If MR. VICTIM'S head is slumped or neutral, such airway obstruction is mimicked as total obstruction by the two closed solenoid valves. As in unconscious patients, this obstruction can be relieved by either of two manual maneuvers: (1) hyper-extension of the head at the atlanto-occipital articulation (Figure 67) and/or the jaw-lift maneuver of forward displacement of the mandible (Figure 68). Use of both manipulations results in maximum relief of this obstruction.

Foreign matter or vomitus, both fluid and solid, should be anticipated as a likely complication in resuscitation. Drainage by lateral tilting of the head and the use of the fingers are indicated (Figure 69).

USE OF MR. VICTIM IN TEACHING POSITIVE-PRESSURE LUNG INFLATION: With a patent upper airway maintained by head-tilt or jaw-lift, positive-pressure inflation of the apneic patient's lungs can be accomplished via the oral or nasal routes (Figure 70). Adequacy of pulmonary inflation can be judged by observation of the chest rise (compare anterior chest wall in Figures 69 and 70).

Technics for using mechanical respirators and the Manual Air Bag Inflator (Figures 71 and 72) can be learned and practiced on MR. VICTIM. Important features of these technics again include hyper-extension of the head at the atlanto-occipital joint and lifting the mandible at the

chin, as well as proper technic of fitting the face mask, obtaining a good seal between the border of the mask and the patient's face, and judging adequacy of inflation by observation of the chest-rise. Since chest-rise serves as a check on all other details of technic, regardless of the ventilating procedure, the realistic anatomical simulation of the chest-rise per unit volume of air inflated completes the necessary features of the training aid, MR. VICTIM.

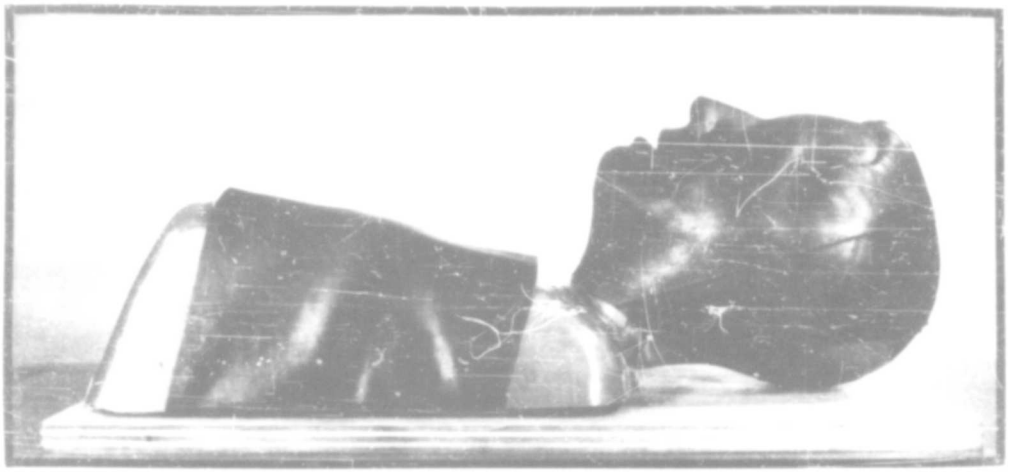


Figure 63. Lateral view of MR. VICTIM in neutral position with 100% airway obstruction.

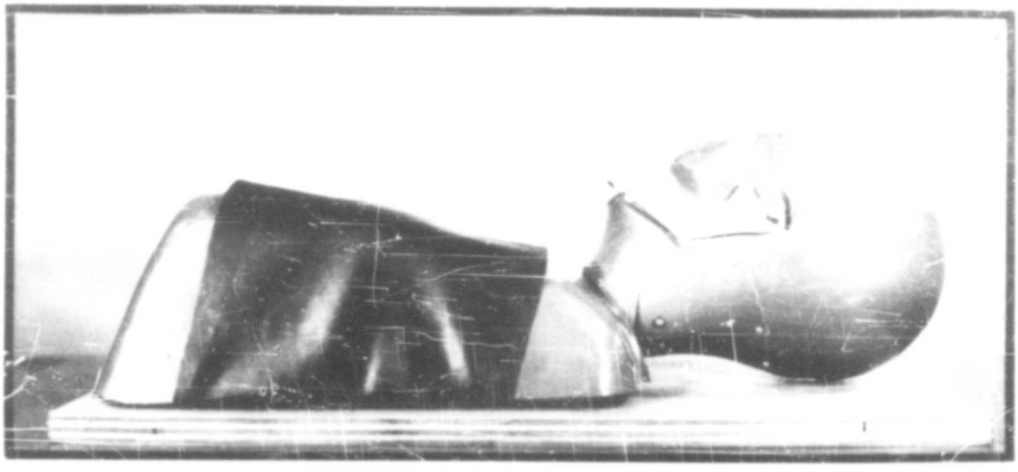


Figure 64. Lateral view with "soft tissues" removed to expose mandible.

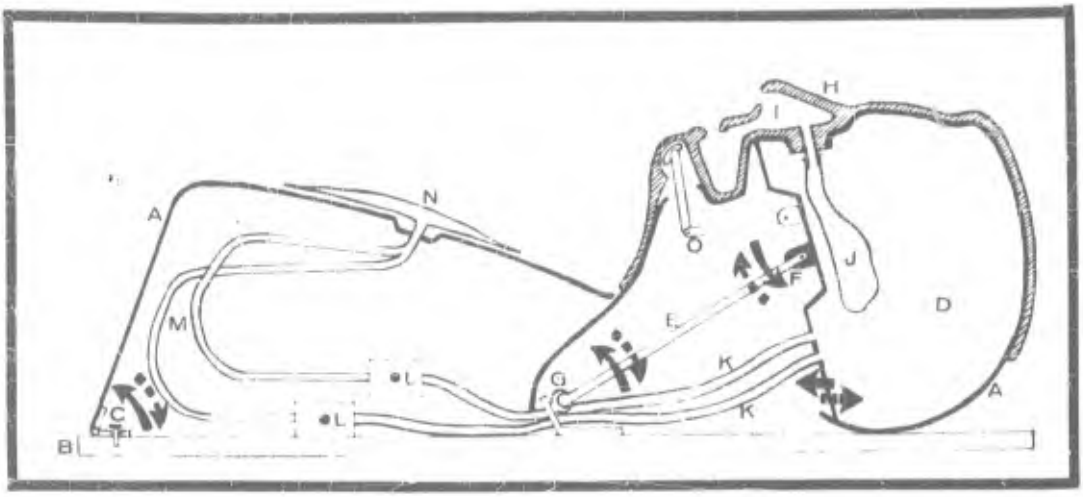


Figure 65. Schematic Sagittal Section of Training Aid

A chest wall and skull (Royalite)
B plywood base
C hinge and pivot attachment of chest to base
D pneumatically sealed skull cavity
E cervical spine
F "atlanto-occipital articulation"
G ball and socket joint
H "soft tissues" of face
I oro-nasal cavity
J sac, which relieves inflation air
K two rubber tubes representing the pharynx
L two solenoid valves which operate to obstruct and to relieve obstruction
M two rubber tubes representing the trachea
N lung
O switching linkage between skull and mandible

Solid arrows show motion of head extension, dotted arrows are motions of flexion.

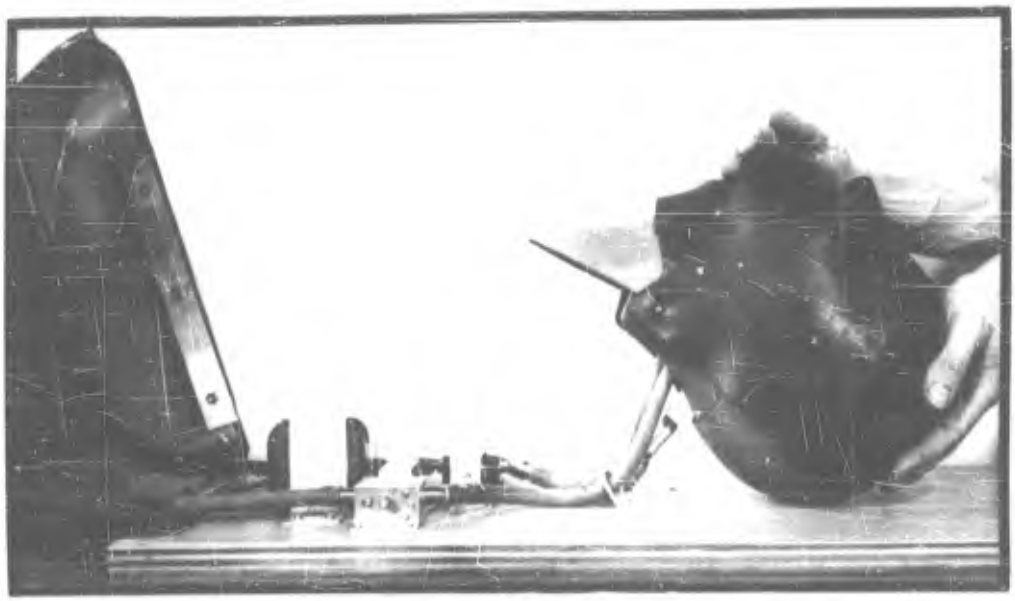


Figure 66. Head hyperextended and chest opened on hinge to expose the spine, two pharyngeal tubes, solenoid valves, and battery.

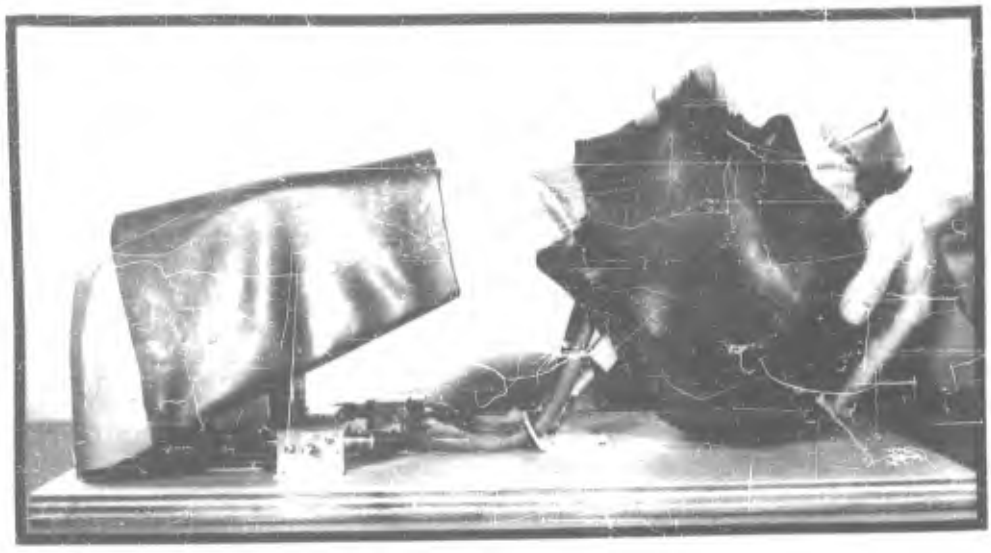


Figure 67. Head-tilt maneuver showing full hyperextension of head at atlanto-occipital joint.

Figure 68. Jaw-lift maneuver. Mandible is displaced forward in comparison with resting position.

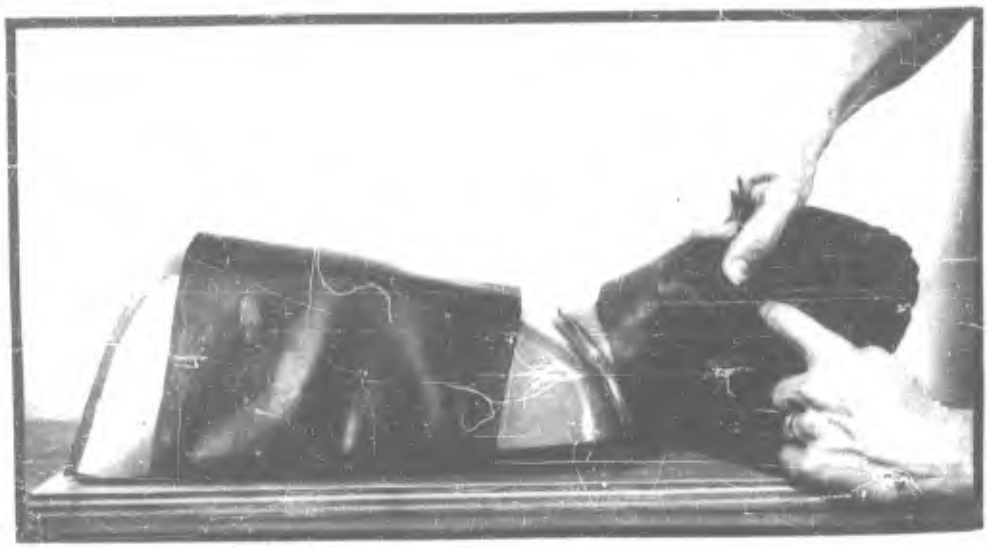


Figure [illegible] Demonstration simulating cleansing of mouth and throat with fingers.

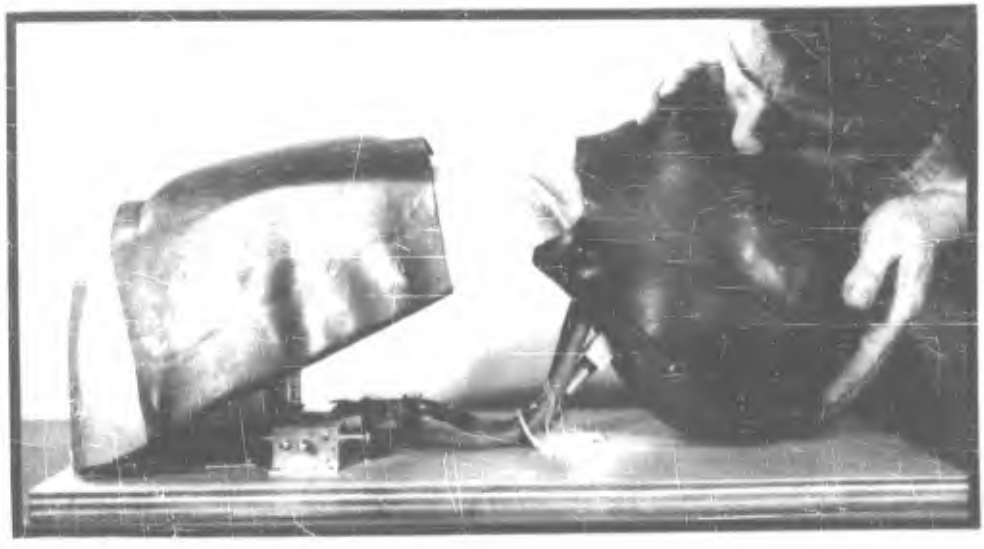


Figure 70. Head-tilt position and mouth-to-nose inflation is illustrated. Mouth is closed by rescuer's thumb. Note chest expansion in comparison with resting chest (Figure 69).

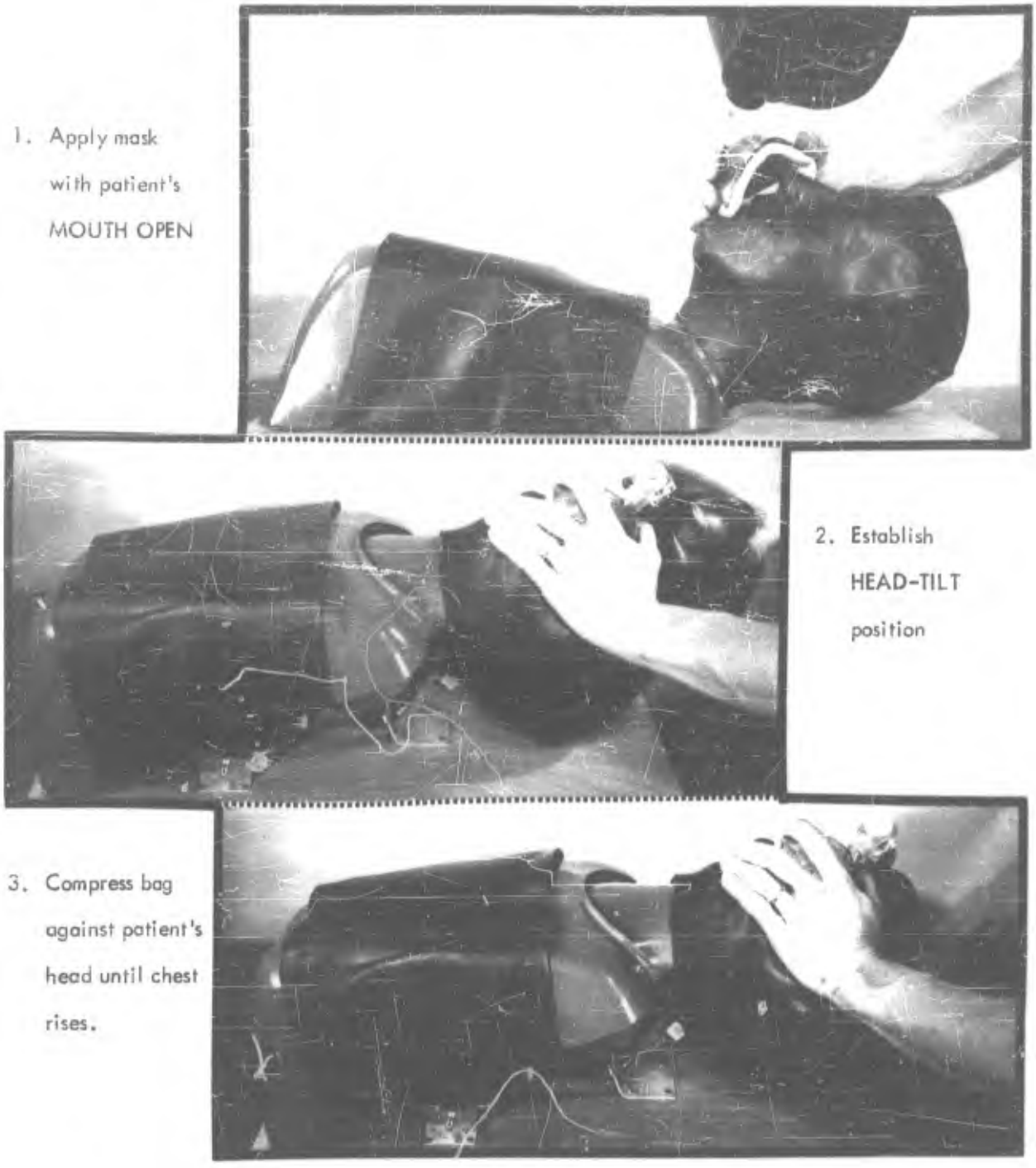


Figure 71. Recommended 1-2-3 Procedure for Using MR. VICTIM to Learn MABI

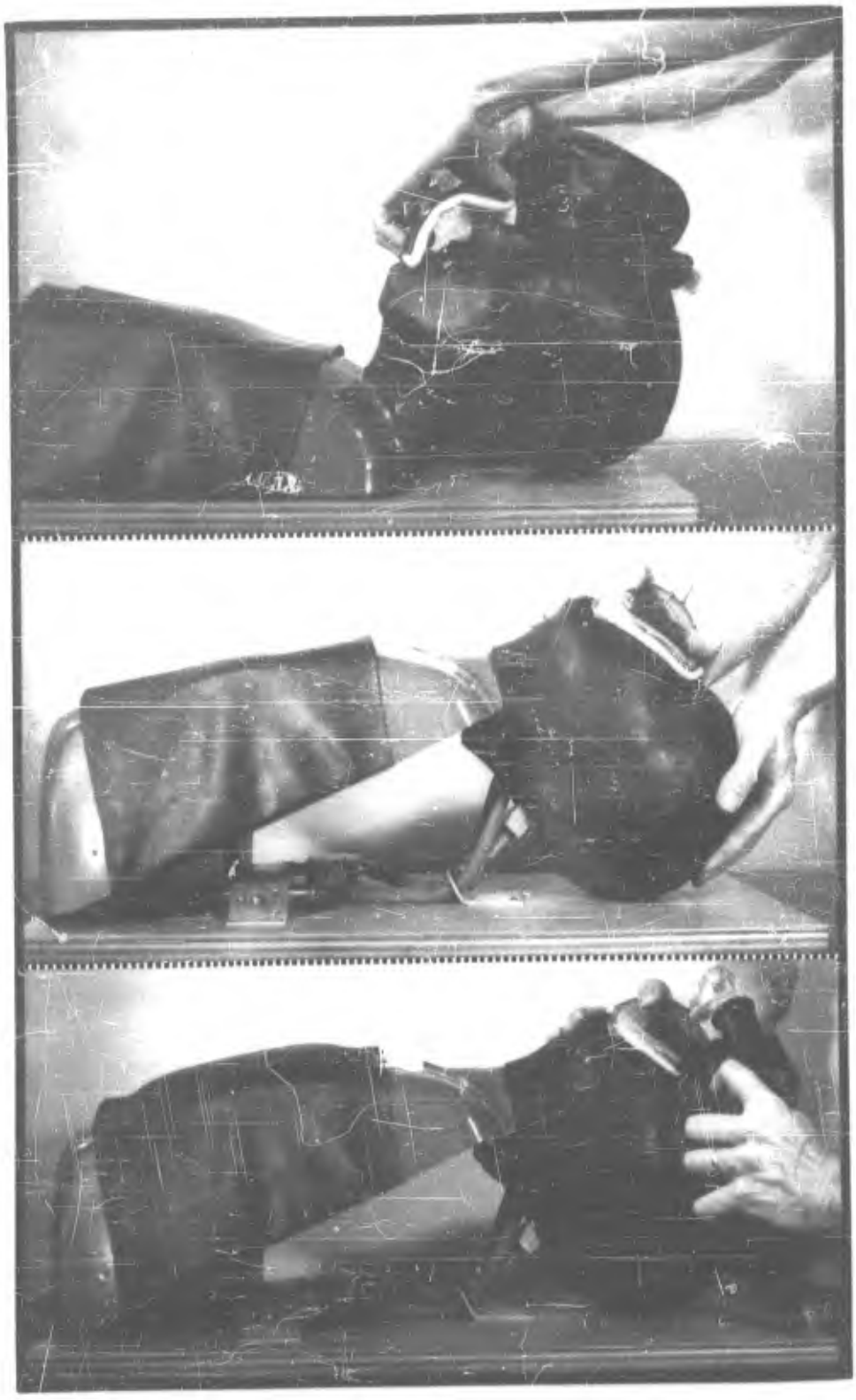


Figure 72. Similar steps with MABI as Figure 71, showing profile and chest inflation. Middle view indicates recommended technic of holding FOLDING MASK.

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PATENT STATEMENT

Several devices are described in this report which may raise questions regarding patents. This statement is inserted to clarify pertinent facts.

The MABI, PHLO Resuscitator, experimental ventilator, and semi-conductor EMG transmitter are reported here for the first time.

The design of the new Air Shields neoprene bag, the Ohio Chemical PHLO Resuscitator, and the experimental ventilator was not performed under or with the support of the contract. Instead, these represent the activities of several commercial firms to develop and fabricate devices according to our suggestions and general specifications. Nor do we claim credit for much of the improvements in these devices.

The descriptions and performances of these units are herein reported as clinical investigations.

Work on the Sphere Valves, the Folding Mask, and the EMG unit has been the exclusive undertaking of our group over several years and these specific projects were supported by the contract. Of these items, the Sphere Valve is similar to one patented by Warren E. Collins of Cambridge, Massachusetts many years ago. (This was a ping-pong ball valve used with a Drinker respirator).

The folding mask was patented August 8, 1961, by J.O. Elam and J.L. Evers. The question of interest in this patent was considered in 1958 by lawyers in the Department of the Army and the decision was that the Army would not seek a patent. The patent application was filed July 3, 1958. Health Research, Inc. is currently monitoring the manufacture of the mask and its distribution to recognized rescue organizations.

Two copyrights have been granted during 1961 to Health Research, Inc.: (1) MR. AIRWAY, the training aid sagittal model, January 10, 1961, and (2) the accompanying instruction manual, October 23, 1961, Library of Congress Cat. No. 61-18595.

UNCLASSIFIED