United States Patent [19]

Sayer

[11] **3,742,939**

[45] **July 3, 1973**

[54] **METHOD AND APPARATUS FOR DETERMINING RESPIRATORY AIRWAY RESISTANCE**

[76] Inventor: **William J. Sayer,** 1618 Willow Road, Palo Alto, Calif. 94304

[22] Filed: **Feb. 24, 1971**

[21] Appl. No.: **118,280**

[52] **U.S. Cl.** **128/2.08**

[51] **Int. Cl.** **A61b 5/08**

[58] **Field of Search** ..... 128/2.08, 2.07, 2 C, 128/2 R, 2.08

[56] **References Cited**

UNITED STATES PATENTS

3,410,264	11/1968	Frederik	128/2.08 X
3,516,401	6/1970	Dell'Aira	128/2.08
3,621,833	11/1971	Crane	128/2.08
3,036,569	5/1962	Clements et al.	128/2.08

FOREIGN PATENTS OR APPLICATIONS

1,508,303	11/1967	France	128/2.08
1,915,959	10/1970	Germany	128/2 C

OTHER PUBLICATIONS

Gulesian, P.J., IEEE Trans on Bio-Med Engineering, Sept., 1971,pp.378–382, (copy in GR.335, 128/2.08)

Jaeger, J.J., et al, Journ. of Applied Physiology, Vol. 19, No. 4, July,1964, pp.813–820, (Copy in GR.335,128/2.08)

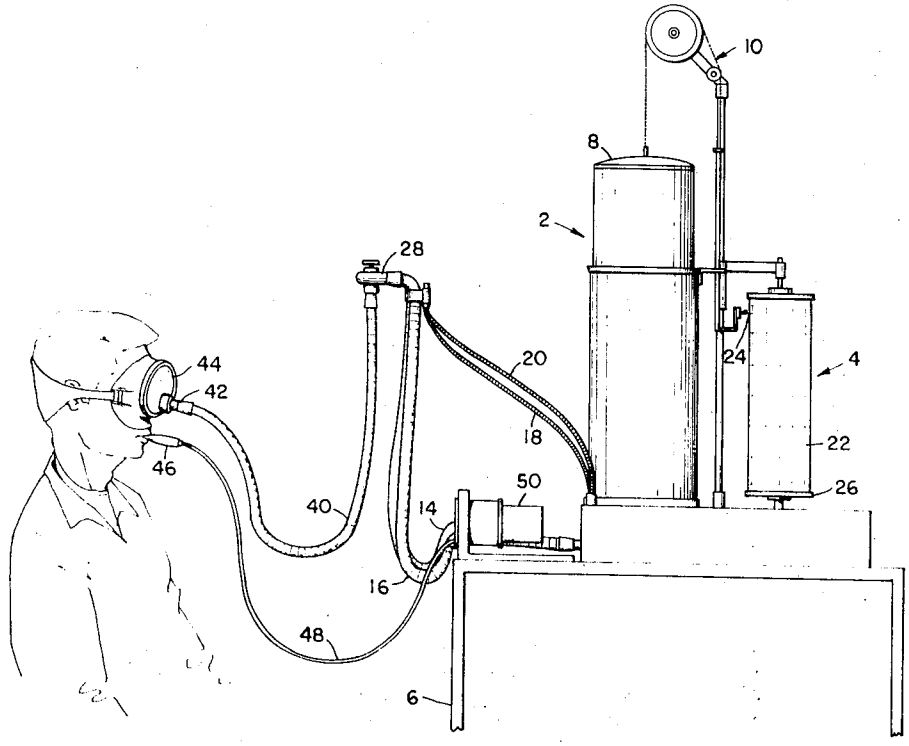
Primary Examiner—Kyle L. Howell

Attorney—Limbach, Limbach & Sutton

[57] **ABSTRACT**

A method and apparatus for determining nasal or tracheobronchial respiratory airway resistance in a person. The volume of freely breathed air, pharyngeal pressure, and time duration of a breath are measured or recorded. Preferably, a narrow pharyngeal pressure range is chosen to optimize the validity of the data. Further, the choice of data in which the volume of air breathed per unit time is substantially constant enhances the validity of the data.

8 Claims, 10 Drawing Figures



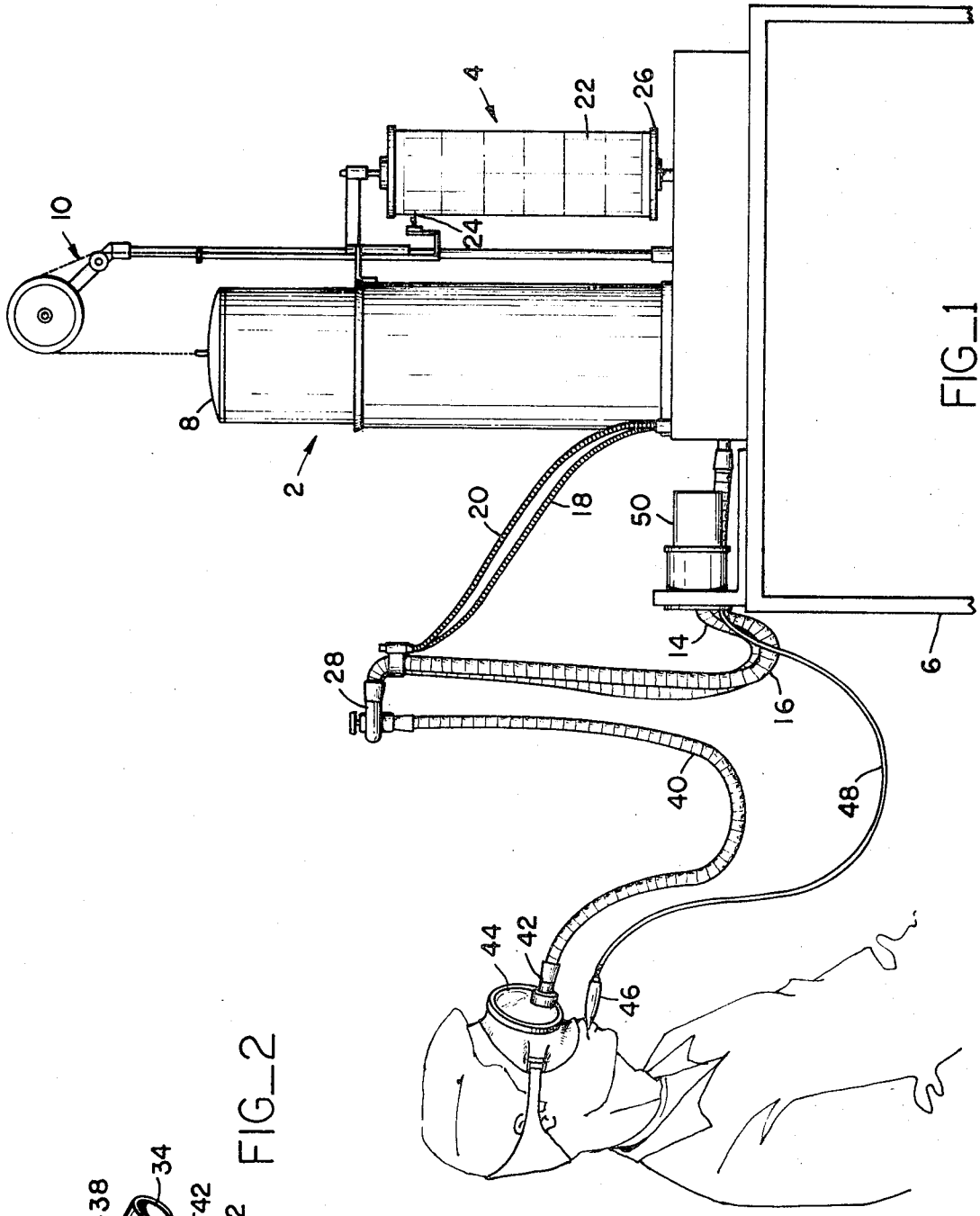


FIG_1

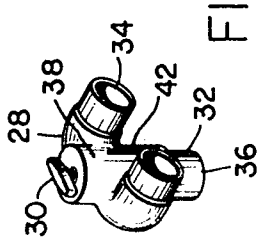
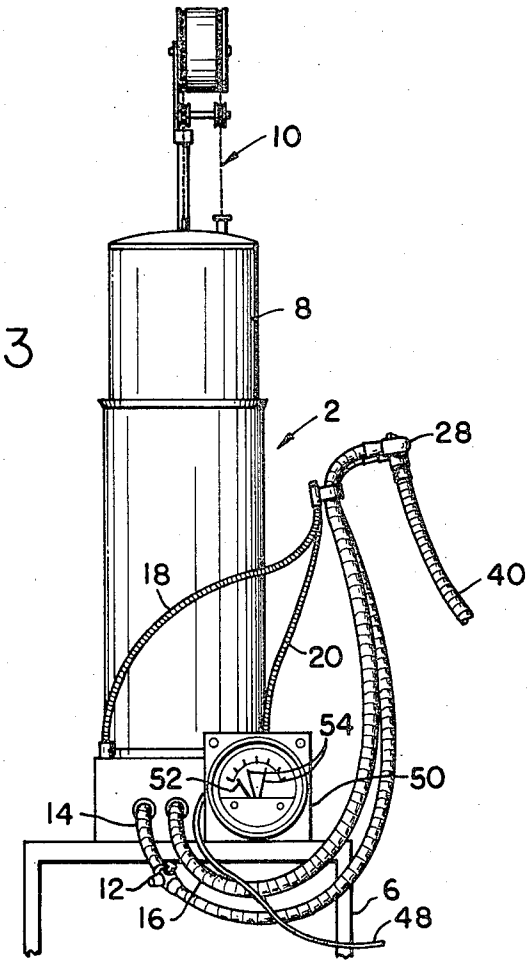


FIG_2

INVENTOR.
WILLIAM J. SAYER
BY Lindsey, Lindsey & Sutton

ATTORNEYS

FIG_3



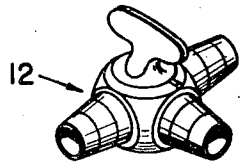


FIG_4

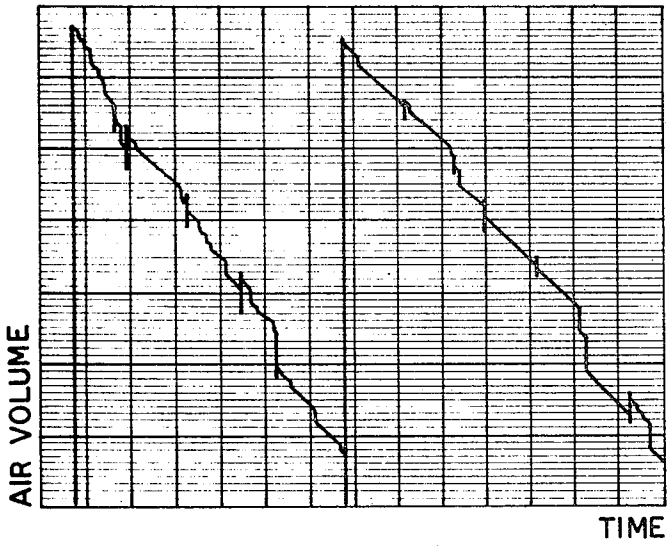
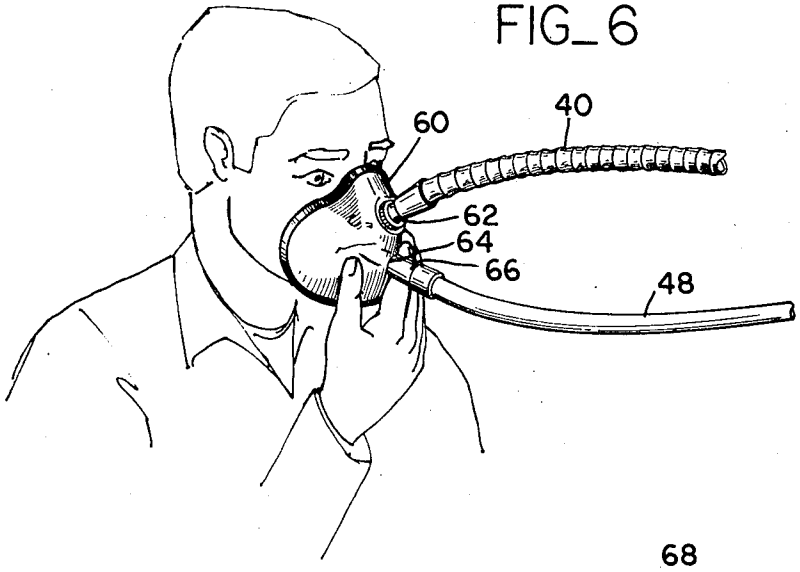


FIG_5

INVENTOR.
WILLIAM J. SAYER
BY Limbach, Limbach & Sutton

ATTORNEYS

FIG_6



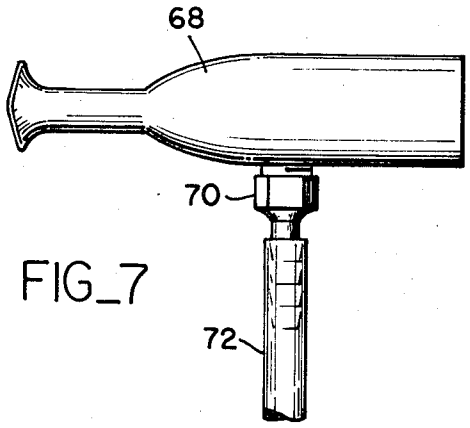


FIG_7

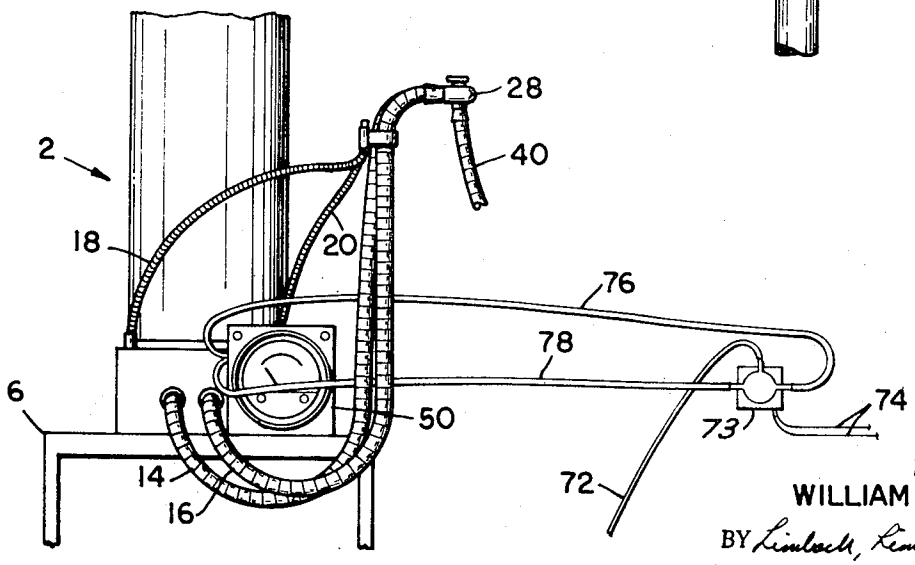


FIG_8

INVENTOR.
WILLIAM J. SAYER
BY Limbach, Limbach & Sutter
ATTORNEYS

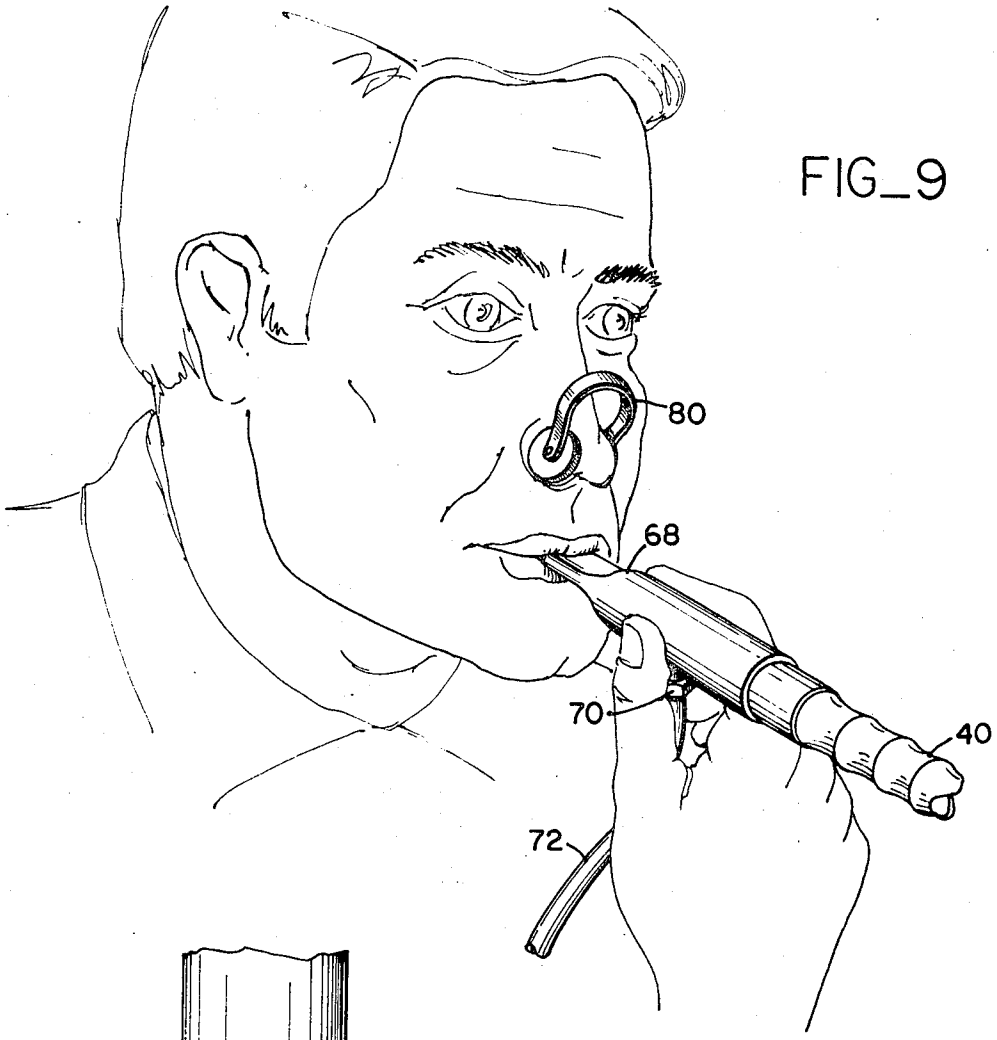


FIG_9

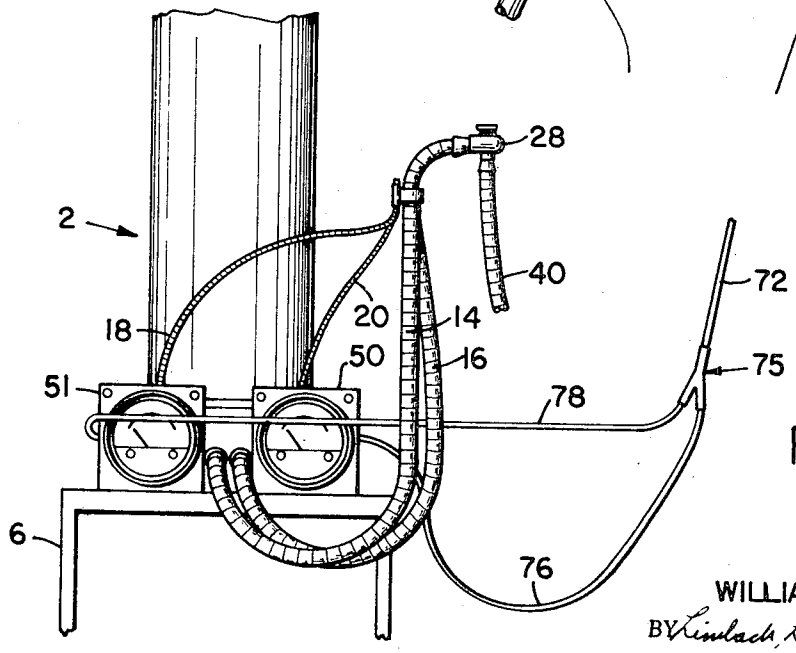


FIG_10

INVENTOR.
WILLIAM J. SAYER
BY Kinlach, Kinlach & Sutton

ATTORNEYS

METHOD AND APPARATUS FOR DETERMINING RESPIRATORY AIRWAY RESISTANCE

BACKGROUND OF THE INVENTION

Medical attempts to evaluate nasal airway capacity or "nasal congestion" date back at least to 1889 when Zwaardemeker wrote about his cold mirror test. It is accepted that a patient's own observations about his nose are not determinative and looking in the nose also fails to yield the complete picture. Therefore, an accurate measurement of nasal and/or tracheobrochial airway capacity is important to both the clinical practitioner and medical researchers.

The condition of the nasal passages affects the resistance to air flow through the nostrils in the same way that air flow in any tube depends on its structure (length, diameter, shape) according to Poiseuille's Law. In his text *Physiology of Respiration* by Julius H. Comroe, Jr., M.D. Year Book Medical Publishers, Inc., 1965, air flow in patients' is compared to air flow in tubes. Dr. Comroe points out that air flow resistance is a calculated dimension and that resistance across the nasal or tracheobronchial airways is equal to:

Atmospheric pressure—pressure in the oropharynx/flow.

The determination of nasal or tracheobronchial airway resistance has been a difficult task, particularly because the pharyngeal pressure (pressure in the nasopharynx) varies substantially during the inspiration-respiration cycle. Also, the simple linear relationship between pressure and flow to yield the airway resistance has been proven invalid as hysteresis occurs at very low and very high pressures.

One prior art method was originally presented in 1939. In that approach a transducer is used to measure the difference in pressure between the nasopharynx and a nasal mask. The air flow is measured and plotted opposite the pressure at each instant of time to obtain a plot of resistance. This method provides results of questionable validity because it attempts to apply the simple first order relationship of pressure divided by flow values for all pressure encountered, whereas this relationship holds true only for a common pipe having a laminar flow therein.

Another prior art approach, recognizing the diminished significance of testing over a wide pressure range, eliminates completing the pressure measurement and relies solely on a measurement of air flow through the nasal airway. This method is described in an article "Nasal Spirometry" by Murray D. Morrison, M.D., in *Arch Otolaryng*, Vol. 90, Nov. 1969.

In a further prior art approach, a mask with selected inlet members measures pharyngeal pressure and pressure at the inlet to the nostrils during breathing, but without measuring volume.

One prior art U.S. Patent provides a rather complex instrument for measuring nasal airway resistance. Air flow is indirectly measured by looking at a pressure differential. The device appears to be an elaborate successor to the 1939 method, and because it tests over a wide pressure range it suffers from the same inaccuracies.

SUMMARY OF THE INVENTION

The apparatus and method of the present invention overcome the shortcomings of the prior art by measuring parameters from which nasal or tracheobronchial airway resistance may be calculated in a narrow pharyngeal pressure range, allowing selection of that range in which the linear relationship between pressure and air flow volume is most nearly valid. In one embodiment of the invention, the pharyngeal pressure is monitored during a patient's expiratory or inspiratory phase and when the pressure fits within prescribed limits the nasal or tracheobronchial air flow is measured and recorded. The nasal or tracheobronchial airway resistance may then be calculated by dividing the difference between atmospheric pressure and the selected pharyngeal pressure by the air flow. The details of the apparatus and method of the present invention along with further advantages thereof will become evident as the detailed description of the preferred embodiment is read and understood.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a schematic side view of the apparatus of the present invention as used with a patient.

FIG. **2** is a perspective view of a two-way valve forming a portion of the apparatus of the present invention.

FIG. **3** is a schematic end view of a portion of the apparatus of the present invention.

FIG. **4** is a perspective view of a three-way stop-cock valve forming a portion of the apparatus of the invention.

FIG. **5** is a graph of air volume per unit of time (air flow) generated by the kymograph and pen that forms a portion of the apparatus of the invention.

FIG. **6** is a schematic view of a portion of the apparatus having a modified face mask as used with a patient.

FIG. **7** is a side elevation view of a mouthpiece adapted for use in measuring tracheobronchial airway resistance.

FIG. **8** is a schematic end view of a portion of the apparatus of FIG. **3** modified for measurement of tracheobronchial airway resistance.

FIG. **9** is a schematic view of the mouthpiece of FIG. **7** as used with a patient to measure tracheobronchial airway resistance.

FIG. **10** is a schematic end view of the apparatus of FIG. **8** modified to include a pair of gauge switches.

DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring now particularly to FIGS. **1** and **3** of the drawings, a conventional spirometer **2** and kymograph **4** is shown supported on suitable base means **6.** A suitable spirometer and kymograph is the Warren E. Collins, Inc., "Respirometer" No. P-900 described in that company's 1966 catalog. For use in this invention the Collins "Respirometer" may be used virtually as provided or if less resistance to air flow is desired it is modified by removing the inner soda lime cannister and rubber flutter valve. Either device, for which any suitable equivalent means may be substituted, is essentially a source of air, the volume of which can be accurately measured with respect to time. Thus, the bell **8** is filled with air when it is raised by the chain and counterbalance **10.** The three-way stop-cock valve **12** is rotated to permit room air to be drawn through tube **14** to fill the bell **8.** Tube **16** is in parallel to tube **14** and could be eliminated if desired. Tubes **14** and **16** are supported by a pair of flexible goose-neck supports **18** and **20.**

The kymograph **4** has a removable paper chart **22** mounted on a motor-driven cylinder **26** and a moving

pen 24 for marking thereon. As described hereinafter, the cylinder 26 is driven only when the patient's pharyngeal pressure is within the prescribed limits, thus creating a chart record only during those time periods.

Tubes 14 and 16 are joined in a two-way valve 28, shown in greater detail in FIG. 2. When the lever 30 is in the position shown, openings 32, 24 and 36 are connected in a closed system, thus connecting tubes 14 and 16 together to tube 40. When the lever is rotated 90°, tubes 14 and 16 are connected together in a closed system and tube 40 at opening 36 is open to the room air via slot 42. Tube 40 is attached via a coupling 42 to a scuba-type face mask 44 that fits over the patient's nose in an air-tight manner. A disposable mouthpiece 46 is placed into the patient's mouth, over his tongue, and is connected to a tube 48 that may be of relatively small diameter because its purpose is to conduct the pharyngeal pressure, as present in the mouth, to a combination meter and switching device 50. Device 50 has a pressure reading needle 52 and a pair of adjustable needles 54 for setting the desired pressure range. When the patient's pharyngeal pressure read by needle 52 is within the limits as set by needles 54, then device 50 closes a switch to activate the kymograph motor. As the motor turns cylinder 26, the volume of air present in spirometer 2 is recorded by pen 24. As will be explained below, the record on chart 22 will provide the data necessary to calculate the nasal airway resistance of the patient. Device 50 is a commercially available product marketed as a photohelic gauge switch by Dwyer Instruments, Inc., of Michigan City, Ind., as described in U.S. Pat. No. 3,397,319 to J.P. Locke. The device 50 has both positive and negative pressure inputs.

In inspiratory nasal airway measurement operation, valve 28 is rotated to connect tubes 14 and 16 together and to open tube 40 to the room air. Mask 44 may be placed on the patient at this time since room air is available at the mask. Valve 12 is rotated to open tube 12 to the room air. Bell 8 is raised to fill the spirometer 2 with room air and then valve 12 is rotated to provide a closed path between the spirometer 2 and valve 28. The patient is instructed to breath in through his nostrils while at the same time holding mouthpiece 46 in his mouth with his mouth closed around it. He is instructed to exhale through his mouth around the mouthpiece, holding the mouthpiece in place with his teeth. The patient is allowed to practice this before the actual recording procedure is begun. The patient is also instructed to practice inhaling so as to provide a pharyngeal pressure falling within the limits set on device 50. Since the meter face of device 50 is visible to the patient he may watch it until he achieves the desired pressure. In actual practice it has been found that patients can achieve the desired pressure after a relatively brief period of practice. The linear relation-ship between pressure and flow expressed in the equation. $R = Po - Pp/V/t$, where R is the nasal airway resistance, Po is the atmospheric pressure, Pp is the pharyngeal pressure, and V/t is the volume of air per unit of time, is most valid in the range of about 15 to 35 mm H_2O. It has been found that substantially all of the patients tested can achieve a pressure in this range for a duration of 1½ seconds or more. A typical pressure achievable by patients is on the order of 25 mm H_2O. After the patient has succeeded in achieving the desired pressure after practice, the valve 28 may be rotated to connect the spirometer air supply to the patient's face mask via tubes 14, 16 and 40. As the patient inhales a chart of the spirometer volume level will be recorded whenever the pharyngeal pressure measured by device 50 through tube 48 and mouthpiece 46 is within the prescribed range.

Alternatively, expiratory nasal airway measurements may be made, although most patients find the inspiratory measurements to be more comfortable. Also, there is less air leakage around the face mask during inspiratory measurements. Expiratory nasal airway measurements are made in a manner identical to the taking of inspiratory measurements except that the patient breathes out through his nostrils while holding mouthpiece 46 in his mouth with his mouth closed around it. The patient breathes in by holding the mouthpiece between his teeth and inhaling through his mouth around the mouthpiece. Tube 48 must be connected to the positive pressure input of pressure gauge 50 during expiratory measurements.

An actual reproduction of a patient's chart of spirometer air volume versus time is shown in FIG. 5. The longest straight lines indicate periods in which the patient achieved continuous inhalation within the prescribed pharyngeal pressure limits for the longest times. To convert the chart data to nasal airway resistance, the longest straight line is chosen, preferably lasting 1½ seconds or more, and the angle to the horizontal is measured to derive the slope of the line from which the volume per unit time can be calculated. The nasal resistance is then the average pressure between the two limits set on device 50 divided by the volume per unit time taken from the chart. Thus, for constant settings of pressure limits on device 50, the practitioner need only deal with the volume per unit time since it will be related to nasal resistance by a constant.

Further techniques employed with the invention include plugging each nostril in turn to provide resistance data for the nasal airway with both nostrils uncovered, the left covered, and the right covered. The nostrils may be covered by using cellophane tape or the like, being careful not to deform the nostril. In addition, it is convenient to employ a clock in conjunction with the apparatus so that the operator may record the times at which the data was taken. It will be apparent that in a computerized version of the invention that time could be included along with the data taken.

FIG. 6 shows a modified face mask 60 that may be used with the apparatus of FIGS. 1 and 3. Mask 60 is hand-held by the patient and is advantageously used with patients who wear glasses or who feel uneasy with the mask strapped to their head. Tube 40 as in FIG. 1 is connected via a coupling 62 to the mask 60. Tube 48 as in FIG. 1 is connected to a mouthpiece 66 that passes through an air-tight fitting 64 in the mask 66. In operation, the mask 60 is held firmly by the patient over his nose and mouth with mouthpiece 66 in his mouth. The assembly functions in like manner to mask 44 and mouthpiece 46 of FIG. 1. Tube 40 carries air to or from the nose just as it does with mask 44. In order to breath out through the mouth during inspiratory nasal airway measurements or to breath in through the mouth during expiratory nasal airway measurements the patient simply moves the mask away from his face. Alternatively, a relief valve (not shown) could be incorporated in the mask so that the patient could continually hold the mask against his face.

FIGS. 7–10 relate to an embodiment of the invention adapted for measuring tracheobronchial airway resistance.

FIG. 7 shows a side elevation view of a mouthpiece 68 adapted for measuring tracheobronchial airway resistance. An air hose such as tube 40 (in FIG. 8) is connected to the right end of the mouthpiece. A tube 72 (see also FIG. 8) for measuring pressure is connected to a tap 70 in the periphery of the mouthpiece.

FIG. 8 shows a modification of FIGS. 1 and 3 adapted for tracheobronchial measurements. The mouthpiece 68 of FIG. 7 is employed with the apparatus of FIG. 8. Pressure gauge 50 has two inputs: for measuring negative and positive pressures. Tube 78 connects to one input and tube 76 connects to the other input. A solenoid operated electric switch 73 connects the pressure measuring line 72 to one of the tubes 76 or 78 depending on whether or not electric leads 74 are energized. Thus the apparatus can measure pressure during expiration (positive pressure) or inspiration (negative pressure).

FIG. 9 shows a patient using the mouthpiece of FIG. 7 as it is used for tracheobronchial airway measurements. A nose clamp 80 is placed over the patient's nose to prevent any nasal airflow. For inspiratory measurements, the switch 73 is selected to connect tube 72 to the negative input of gauge 50. The patient breathes in through his mouth and attempts to maintain a pressure within the preselected range on gauge 50 in a manner analogous to the taking of nasal measurements. The pressure measured by tube 72 is the pharyngeal pressure as in the nasal measurements and the measurement is still a differential pressure; the other pressure being the atmospheric pressure that surrounds the lungs, against which the lungs must work. Thus the same equations and computations are used to calculate the tracheobronchial airway resistance.

If it is desired to measure the expiratory airway resistance, the switch 73 is changed to connect pressure tube 72 to the positive pressure input of gauge 50 and the patient attempts to maintain the preset pressure on gauge 50 when he breathes out.

As in the nasal measurements, the patient breathes around the mouthpiece while holding it in place with his teeth when a measurement is not being taken.

FIG. 10 shows a further modification of the embodiment of FIG. 8. A pair of "photohelic" pressure gauge switches 50 and 51 are used in conjunction with a Y connection 75 and tubes 76 and 78. Gauge 50 has tube 76 connected to its negative input and gauge 51 has tube 78 connected to its positive input. This arrangement is desirable in taking tracheobronchial measurements when the pressures achievable by the typical patient are different for expiration and inspiration. By using two gauges, the pressure range need not be reset when changing from expiration to inspiration measurements. It has been found that when using two photohelic gauge switches, a simple Y connection may be used in lieu of a manual or solenoid switch in the pressure measuring line. When a single photohelic gauge switch is used, the pressure lines must be switched from the negative to positive input.

It will be recognized by those of ordinary skill in the art that the apparatus of the present invention may be substantially modified and yet provide the same function and results provided the teachings of the invention are followed. For example, any means providing a measurable source of air supply such as a pneumotachograph may be substituted for the spirometer 2. Also, the recordation of the air supply volume with respect to time can be achieved by devices other than the kymograph 4. For example, such recordation could be done on an X–Y plotter, a storage-type oscilloscope, or the data could be stored in an analog or digital memory device. Likewise, the photohelic switch could be replaced by another pressure measuring arrangement and apparatus wherein a selected pressure range provides a control signal. In addition, it will be apparent that the computation of the nasal resistance may be carried out by a programmed machine such as an analog or digital computer. Therefore, the invention is to be limited only by the scope of the appended claims.

I claim:

1. A method of deriving data for use in calculating nasal or tracheobronchial airway resistance of a person comprising the simultaneous steps of

measuring and recording the volume of air freely inspired or expired during a breath through either the mouth or nasal passages of a person,

measuring and recording time during the breath,

measuring the pharyngeal pressure of the person during the breath, and selecting the data for calculation only when the volume of air per unit time is substantially constant during the breath.

2. The method of claim 1 wherein said volume of air and time duration are measured only when the pharyngeal pressure of the person is within a limited pressure range where the volume of air per unit time is substantially constant during the breath.

3. Apparatus for deriving data for use in calculating nasal or tracheobronchial airway resistance of a person comprising

means for measuring and recording the volume of air freely inspired or expired during a breath through either the mouth or nasal passages of a person,

means for measuring and recording the time during said breath, means responsive to said means for measuring the pharyngeal pressure to actuate said means for measuring and recording the volume of air and said means for measuring and recording time only when the volume of air per unit time is substantially constant.

means for measuring the pharyngeal pressure of the person during said breath.

4. Apparatus according to claim 3 wherein the means for measuring and recording the volume of air includes:

substantially air-tight mask means adapted to fit over the nostrils or mouth of the person,

spirometer means, and

tube means connecting said spirometer means to said mask means.

5. Apparatus according to claim 4 wherein the means for measuring pharyngeal pressure comprises:

a hollow mouthpiece insertable into the mouth of the person,

pressure measuring means, and

tube means for connecting said mouthpiece to said pressure measuring means.

6. Apparatus according to claim 5 wherein the means for measuring and recording time during the breath comprises a kymograph pen and ink chart recorder.

7. A method of determining the nasal or tracheobronchial airway resistance of a person comprising the simultaneous steps of

measuring and recording the volume of air freely inspired or expired during a breath through either the mouth or nasal passages of a person,

measuring and recording time during the breath,

measuring the pharyngeal pressure of the person during the breath, selecting the measured volume and time where the volume of air per unit time is substantially constant, followed by the step of calculating the nasal airway resistance of the patient using only the data where the volume of air per unit time is substantially constant according to the relationship

$$R = Po - Pp/V/t$$

where R is the nasal airway resistance, Po is the atmospheric pressure, Pp is the average pharyngeal pressure during the breath and V/t is the volume of air per unit time inspired during the breath.

8. The method of claim **7** wherein said volume of air and time duration are measured and recorded only when the pharyngeal pressure of the person is within a limited pressure range during the breath.

* * * * *