

- [54] **DISPOSABLE PULMONARY FUNCTION KIT**
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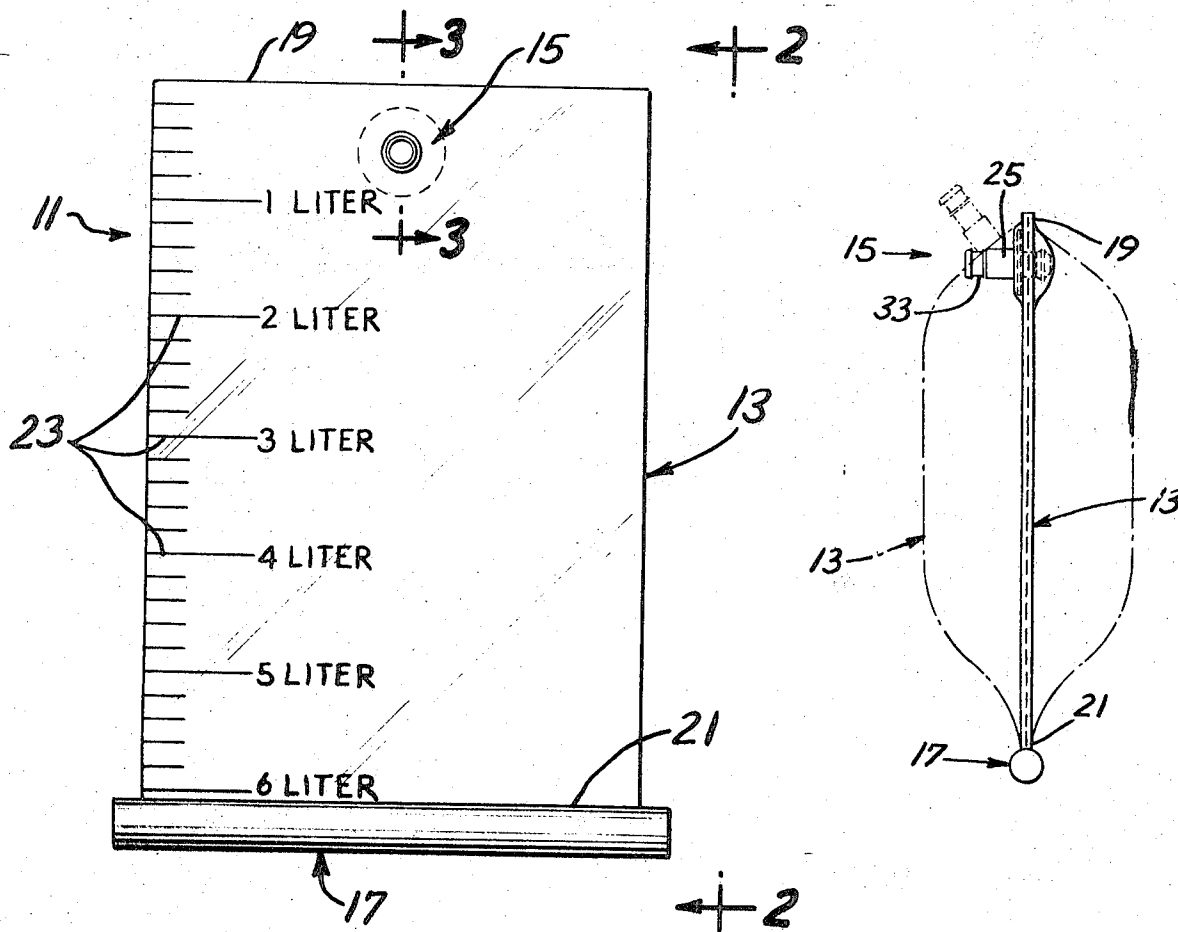
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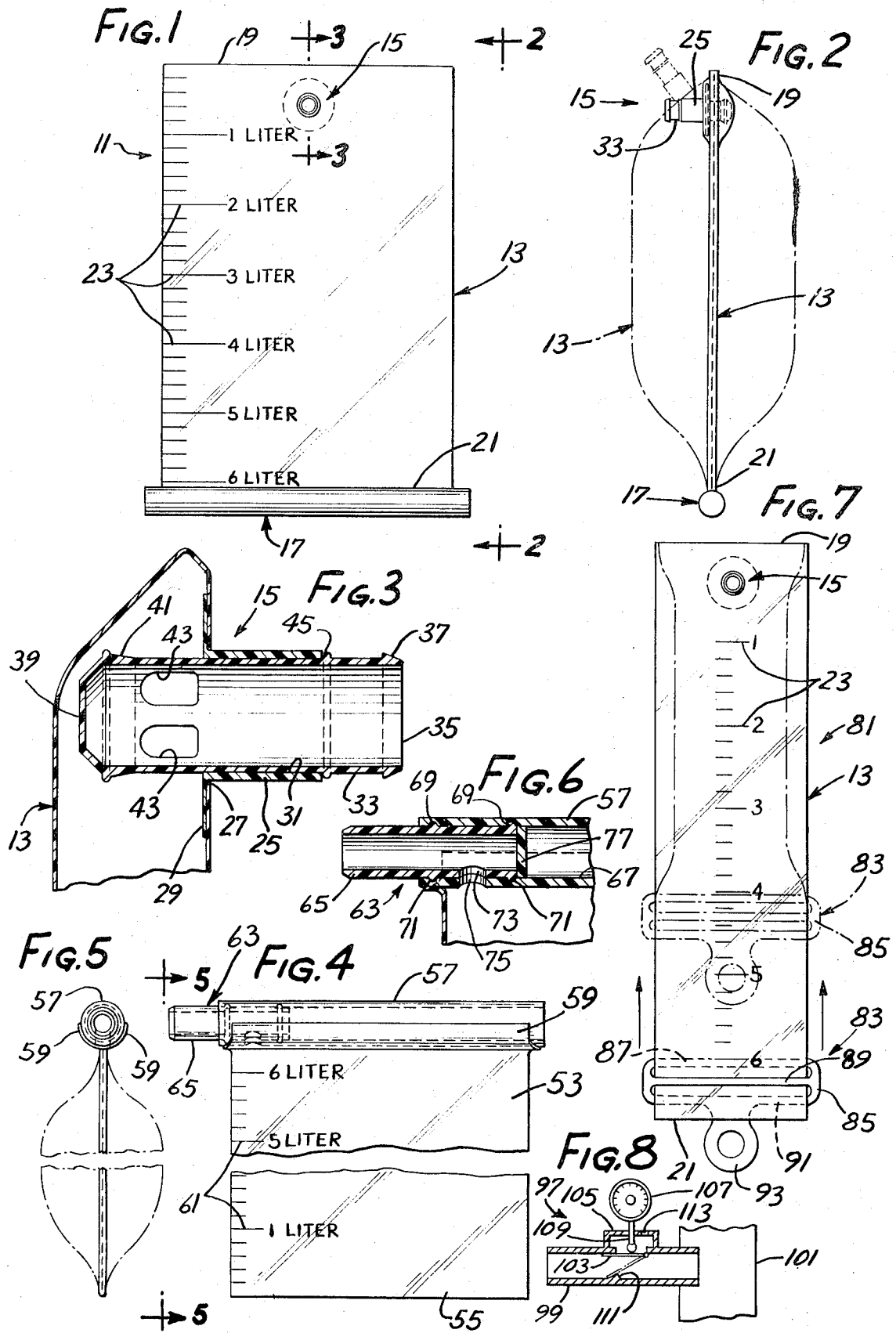
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ABSTRACT

A disposable pulmonary function kit for use in post-surgical lung exercise and in testing lung capacity by exhaling into an inflatable bag having an input tube with valve means which, in one embodiment, is manually operable to close off the bag. The bag may then be rolled from one end, or separate means moved along the length of the bag, until the portion of the bag retaining the gas therein is taut whereupon the volume of gas within the bag may be read from calibrations on the bag.

6 Claims, 8 Drawing Figures





DISPOSABLE PULMONARY FUNCTION KIT

The present invention relates generally to pulmonary function apparatus, and more particularly, to a novel disposable pulmonary function kit for use in post-operative lung exercise and lung capacity testing, which kit is efficient and easy to operate and is economical to manufacture.

It is known to test human lung capacity by apparatus having means to receive and register the volume of exhaled gases from one's lungs. However, the known apparatus for testing human lung capacity are highly complex, costly to manufacture, and require trained personnel to operate. In one known lung capacity testing apparatus, the patient is required to place a mask-like device over his mouth and breathe a known gas. After a predetermined period, the patient must take a deep breath and hold it while an attendant closes off a line to the known input gas and opens a line from the mask to a gas receiving chamber. The patient then exhales his lungs into the gas receiving chamber which is then closed off and the volume of exhaled gas received in the chamber is measured. Such testing is time consuming and, because of the expensive apparatus required, costly to the person being tested. Additionally, apparatus of the aforescribed type requires purging with pure oxygen or other pure gases prior to, and preferably immediately following, each test to minimize bacterial contamination. The present invention overcomes the disadvantages found in the known lung capacity testing apparatus by providing a simple and economical, yet highly efficient, disposable pulmonary function kit which finds application in lung capacity testing.

In addition to lung capacity testing, it is generally known that post-surgical lung exercise is beneficial to the recuperating patient. For example, daily lung exercise serves to assist in preventing postoperative collapse of the lung tissue and other complications. Moreover, it is known that exhaling into and inhaling from a generally closed receptacle increases the CO₂ concentration within one's lungs, stimulates respiration and deepens the respiratory effort. The present invention also provides an improved means for postoperative lung exercise.

Accordingly, one of the primary objects of the present invention is to provide a novel pulmonary function kit which is highly efficient in operation and which is disposable after use so as to preclude possible bacterial contamination.

Another object of the present invention is to provide a novel disposable pulmonary function kit which employs an inflatable bag which may be conveniently wrapped about a roll tube to facilitate storage and packaging of the kit prior to test use.

Another object of the present invention is to provide a pulmonary function kit as described wherein an input tube is provided at one end of the inflatable bag, the input tube including a mouth piece fitment and having valve means operable to close off the bag after exhaling into the bag.

A further object of the present invention is to provide a pulmonary function kit as described which in one embodiment provides a roll tube at the end of the bag opposite the input tube, the roll tube being rotated about its longitudinal axis after closing the valve means to make the bag taut such that the volume of gas in the

bag may be directly determined from calibrations on the bag.

Still another object of the present invention is to provide a pulmonary function kit which in one embodiment includes valve means in the input tube to close off the bag after exhaling into the bag for a predetermined time period.

Another object of the present invention is to provide a pulmonary function kit for use in postoperative lung exercise and lung capacity testing, which kit employs an inflatable bag to allow a person to exhale into and inhale from the bag whereby to increase the CO₂ concentration and stimulate the respiration system, the bag having means associated therewith to measure the person's lung capacity and provide an indication of progressive lung capacity increase.

Other objects and advantages of the present invention, together with the organization and manner of operation thereof, will become apparent from the following detailed description of the invention when taken in conjunction with the accompanying drawing wherein like reference numerals designate like elements throughout the several views, and wherein:

FIG. 1 is a front elevational view of one embodiment of a pulmonary function kit in accordance with the present invention;

FIG. 2 is a side elevational view taken generally along the line 2—2 of FIG. 1, with the inflatable bag being shown in an inflated condition in phantom;

FIG. 3 is an enlarged partial sectional view of the inlet valve means of FIG. 1, taken generally along the line 3—3 of FIG. 1 looking in the direction of the arrows;

FIG. 4 is a foreshortened front elevational view of a disposable pulmonary function kit in accordance with another embodiment of the present invention;

FIG. 5 is a foreshortened side elevational view of the pulmonary function kit of FIG. 4, being taken generally along the line 5—5 of FIG. 4;

FIG. 6 is an enlarged partial longitudinal sectional view of the input valve means of the pulmonary function kit shown in FIG. 4;

FIG. 7 is a front elevational view of a pulmonary function kit in accordance with still another embodiment of the present invention; and

FIG. 8 schematically illustrates a time delay closing valve as may be employed with the pulmonary function kit of the present invention.

Referring now to the drawing, and in particular to FIGS. 1-3, one embodiment of a disposable pulmonary function kit in accordance with the present invention is indicated generally at 11. The pulmonary function kit 11 finds primary utility in post-surgical lung exercise and in testing lung capacity, and particularly, the lung capacity of humans. The pulmonary function kit 11 includes inflatable bag means, indicated generally at 13; input means, indicated generally at 15, to facilitate exhaling the gas contents of one's lungs into the inflatable bag means 13; and roll tube means, indicated generally at 17, operable to place the inflatable bag means in a taut condition after closing the input means 15 to facilitate direct reading of the volumetric contents of the inflatable bag means.

More particularly, the inflatable bag means 13 is made of a suitable gas and liquid impervious material having a generally tubular configuration closed at its upper and lower ends, 19 and 21, respectively. The in-

inflatable bag means 13 may be made of a suitable transparent plastic material having dimensional stability, such as one of the polyester or polyolefins. The bag means 13 has a generally rectangular configuration when deflated, as shown in FIG. 1, and has a series of gradation calibration markings 23 provided thereon which indicate the volumetric content of the bag when inflated as will become more apparent herein below. The calibration markings 23 preferably indicate the volumetric content of the inflated bag means in liters, with intermediate milliliter gradation markings therebetween. It will be understood that the gradation calibration markings 23 are provided on the bag means 13 so as to provide an accurate indication of the volumetric gas content of the inflatable bag means even though not completely filled, taking into account that the bag will not assume a true cylindrical configuration when inflated thereby precluding a pure linear gradation scale.

The input means 15 provides access to the interior of the inflatable bag means 13 and to this end includes a first generally tubular member 25 received through a suitable opening 27 in the inflatable bag means. The tubular member 25 may be made of a suitable plastic material and has a generally radial flange 29 which is secured to the bag means adjacent the opening 27 therein in a known manner. The tubular member 25 communicates with the interior of the bag means 13 through its cylindrical bore 31. The input means 15 includes a second tubular member 33 which is longitudinally slidable within the bore 31 of the first tubular member 25, the outer cylindrical peripheral surface of the tubular member 33 forming a snug sliding fit with the member 25 to provide a substantially air-tight seal therebetween.

The second tubular member 33 is open at its outer end 35 and has a slight tapered portion 37 to facilitate assembly of the tubular member 33 within the tubular member 25 and also provide a mouth piece fitment. The end of the tubular member 33 opposite the open end 35 is closed at 39, while the peripheral surface of the second tubular member has a rearwardly and outwardly inclined peripheral surface portion 41 which serves to provide a wedged seal engagement with the inner peripheral surface 31 of the first tubular member 25 when the second tubular member 33 is moved longitudinally to the right, as considered in FIG. 3. The second tubular member 33 of the input means 15 has four circumferentially equidistantly spaced openings in the annular wall thereof, two of which are shown at 43. The openings 43 provide communication between the open end 35 of the member 33 and the interior of the inflatable bag means 13 when the tubular member 33 is in its inward position as shown in FIG. 3. The extent of inward longitudinal movement of the second tubular member 33 is limited by an annular ridge or projection 45 thereon which is spaced longitudinally from the open end 35, the ridge 45 being of sufficient radial extent to abut the outer end of the tubular member 25. It can be seen that with the second tubular member 33 of the input means 15 disposed in its inward position as shown in FIG. 3, one could place the member 33 in his mouth and exhale into and inhale from the interior of the bag means 13 through the openings 43 in the annular wall of the second tubular member. Moving the tubular member 33 to its outermost position, from left-to-right in FIG. 3, will move the openings 43 to within

the first tubular member 25 with the tapered peripheral surface 41 abutting and sealing against the inner peripheral surface 31 of the first tubular member 25 to retain any gases within the inflatable bag means 13. The cooperating first and second tubular members 25 and 33 thus provide valve means for the input means 15 to selectively close off the interior of the inflatable bag 13. It has been found that the pulmonary function kit provides particularly satisfactory performance when the inner diameter of the tubular member 33 is a minimum of $\frac{3}{4}$ inch.

The lower closed end 21 of the bag means 13 is suitably affixed to the roller means 17 as by a suitable adhesive bonding. The roller means 17 preferably comprises a cylindrical roller having a longitudinal length equal to or slightly greater than the width of the bag means 13, considered in FIG. 1, so that the roller means 17 may be rotated about its longitudinal axis to roll the bag means 13 about the peripheral surface of the roller when the bag means 13 is deflated. In this manner, storage and handling of the pulmonary function kit 11 is greatly facilitated.

In operation, the bag means 13 is unrolled from the roller means 17 to substantially the position as shown in FIG. 1. The input means 15 is prepared for exhaling into the inflatable bag means 13 by moving the second tubular member 33 to its inward position as shown in FIG. 3. The open end 35 of the second tubular member 33 is then placed within the user's mouth after taking a deep breath and the lungs are then exhausted into the bag 13. Thereafter, the user may repeatedly inhale from and exhale into the inflatable bag means 13 to exercise his lungs. The repeated breathing into the bag means 13 increases the CO_2 concentration within the user's lungs, and serves to stimulate respiration and deepen the respiratory effort. This is particularly beneficial in recovery during postoperative periods to prevent collapse of the lung tissue. The bag means 13 may be used repeatedly for such lung exercises.

When employing the pulmonary function kit 11 for purposes of measuring lung capacity, the user may exhaust his lungs into the bag means 13 either with or without preliminary breathing into the bag means as above described. It will be understood that if repeated breathing into the bag means 13 is practiced prior to testing lung capacity, the bag means should be completely exhausted before exhaling into the bag during the lung capacity test.

When the lungs have been exhausted, the first tubular member 25 of the input means 15 is slid longitudinally along the length of the second tubular member 33 while the open end 35 remains in the user's mouth to close off the input openings 43 and seal the interior of the inflatable bag means 13 which has assumed a configuration generally similar to that shown in phantom in FIG. 2. Thereafter, the roller means 17 is rotated about its longitudinal axis until the bag becomes taut at which time the calibration marking 23 disposed at the position where the roller means 17 is stopped indicates the volume of gas exhaled into the inflatable bag 13. This volumetric measurement is an accurate measurement of the volumetric lung capacity of the person exhaling into the bag. After use of the bag as aforescribed, it may be readily disposed of or may be used again by the same person as in the lung exercise usage.

FIGS. 4-6 illustrate another embodiment of a pulmonary function kit, indicated generally at 51, in accordance with the present invention. The pulmonary function kit 51 is generally similar to the above-described pulmonary function kit 11 except that it does not employ a lower roller means such as shown at 17 in FIGS. 1-3, and further in that the pulmonary function kit 51 employs a different type of input means. The pulmonary function kit 51 includes inflatable bag means 53 which is closed at its lower end 55 and is secured to the peripheral surface of an elongated tubular roller member 57 at its upper marginal edge portions 59. The inflatable bag means 53 is preferably made of a suitable transparent material such as used for the afores-described bag means 13 and has gradation calibration markings 61 provided thereon, such as along the left-hand vertical marginal edge portion thereof. The calibration markings 61 are positioned so as to accurately indicate the volume of gas within the inflatable bag means after the roller means 57 is rotated about its longitudinal axis to roll the bag 53 thereon until the bag is taut in similar fashion to the above-described pulmonary function kit 11.

The pulmonary function kit 51 includes input means, indicated generally at 63, which provides communication with the interior of the inflatable bag means 53 for effecting the introduction of a gas therein. Noting FIG. 6, the input means 63 includes a tubular member 65 which is received within the cylindrical bore 67 of the tubular roller member 57. The tubular member has a pair of longitudinal spaced peripheral ridges or projections 69 thereabout which are sealingly received within corresponding annular grooves 71 provided in the internal bore 67 of the tubular member 57. The roller member 57 and the tubular member 65 of the input means 63 preferably are made of a suitable plastic material, and the annular ridges 69 cooperate with the grooves 71 to provide seal means to prevent leakage of gas between the tubular member 65 and the bore 67.

The tubular member 65 is provided with at least one opening 73 in the annular wall thereof which is adapted, upon selective rotation of the tubular member 65 about its longitudinal axis, for alignment with a similarly shaped opening 75 in the tubular member 57. The opening 75 opens into the interior of the inflatable bag 53. The end of the tubular member 65 opposite its open outer end is closed at 77. In this fashion, it can be seen that when the tubular member 65 of the input means 63 is rotated about its longitudinal axis to effect alignment of the opening 73 with the opening 75 in the tubular member 57, the interior of the bag is adapted to receive the gas exhaled from the user's lungs. The cooperation of the tubular member 65 with the tubular roller member 57 serves as valve means for the input means 63. The interior bore of the tubular member 65 preferably has a minimum diameter of $\frac{3}{4}$ inch.

To operate the pulmonary function kit 51 as a lung exercise device, the tubular member 65 of the input means 63 is positioned as shown in FIG. 6 to provide communication between the outer open end of the tubular member 65 and the interior of the inflatable bag means 53. The user may then exhale into and inhale from the inflatable bag means 53 to increase the CO_2 concentration within the user's lungs and stimulate respiration. Breathing into the bag means 53 may be re-

peated as desirable to deepen the respiratory effect and assist in postoperative recovery.

When the pulmonary function kit 51 is used to test lung capacity, the outer end of extended member 65 is placed in the user's mouth after the bag means 53 has been deflated and the user has taken a deep breath, or after the last inhale from the bag means 13. The gas content of the user's lungs is then exhausted into the interior of the inflatable bag means 53. After exhausting the lungs, and with the end of the tubular member 65 still within the user's mouth, the tubular roller 57 is manually rotated to move the opening 73 to a position out of registry with the opening 75 so that the interior of the inflatable bag means 53 is closed off. Thereafter, the tubular member 57 may be rotated about its longitudinal axis to effect rolling of the inflatable bag means 53 about the peripheral surface of the roller 57 until the bag means is taut. The volumetric contents of the inflatable bag means 53 may then be read at the gradation marking 61 disposed adjacent the roller member 57 in similar fashion to reading the volumetric measurement of the above-described pulmonary function kit 11. After a single use, the pulmonary function kit 51 may be disposed of, or may be used again on the same person as in the lung exercise.

FIG. 7 illustrates another embodiment of a pulmonary function kit, indicated generally at 81, in accordance with the present invention. The pulmonary function kit 81 is generally similar to the pulmonary function kit 11 illustrated in FIGS. 1-3 in that the kit 81 includes an inflatable bag means, indicated generally at 13, having a generally rectangular configuration, when deflated, and having closed upper and lower end portions 19 and 21, respectively. The inflatable bag means 13 has input means 15 provided generally intermediate the vertical side edges thereof and adjacent the upper closed end 19, the input means 15 being substantially identical to the input means 15 described above with respect to the pulmonary function kit 11. Similarly, the bag means 13 of the pulmonary function kit 81 has calibration gradation markings 23 along the vertical length thereof which are disposed to indicate the volumetric content of the inflatable bag means 13 when either fully or partially filled with a gas such as the gas content of one's lungs, as will become apparent below.

The pulmonary function kit 81 differs primarily from the above described pulmonary function kit 11 in that it includes means, indicated generally at 83, slidable along the length of the inflatable bag means 13 for forcing the gas content captured within the bag means toward the upper closed end 19 of the inflatable bag means. The means 83 comprises a sweeper member 85 having three generally parallel spaced leg portions 87, 89 and 91 which are integrally interconnected to each other at their ends as shown. The three spaced leg portions 87, 89 and 91 are generally planar and are spaced sufficiently to receive the inflatable bag means 13 therethrough such that the intermediate leg portion 89 cooperates with the upper and lower leg portions 87 and 91 to prevent the passage of a gas confined within the inflatable bag means 13 past the sweeper member 85. The sweeper member is normally disposed at the lower end of the inflatable bag means 13 and is slidable upwardly along the length of the inflatable bag means after partially filling the inflatable bag means with a gas and closing the valve means 15. To this end, the lower horizontal leg 91 of the sweeper member 85 includes

a depending portion 93 which may be grasped between one's thumb and fingers to move the sweeper relative to the inflatable bag means 13.

When employing the pulmonary function kit 81 to test a person's lung capacity, the input valve means 15 is opened and the gas content of the user's lungs is exhausted into the inflatable bag means 13. Thereafter, the valve means 15 is closed and the sweeper member 85 is moved upwardly along the length of the inflatable bag means while grasping the depending portion 93 of the sweeper member with one hand and pulling or securing the lower end 21 of the inflatable bag means with the other hand. The sweeper member 85 is moved upwardly until the gas captured within the inflatable bag means 13 causes the portion of the bag means above the sweeper member to become taut. The gradation calibration marking 23 adjacent the intermediate leg portion 89 of the sweeper member 85 then indicates the volumetric content of the gas within the inflatable bag means 13, and thereby the volumetric content of the gas exhausted from the user's lungs.

While the input means 15 of the pulmonary function kit 11, and the input means 63 of the pulmonary function kit 53 have been described as being manually closeable to close off the inflatable bag means 13 and 53, respectively, it is contemplated that a suitable commercially available time limit valve means may be readily incorporated into either of the pulmonary function kits 11, 53 or 81 so that the interior of the inflatable bag means may be automatically closed off after a predetermined time period, such as two or three seconds, after commencing exhausting of the user's lungs into the inflatable bag means. With reference to FIG. 8, one such time limit valve means is shown schematically at 97 and includes an input tube 99 of square cross section which is suitably secured to an inflatable bag 101 of similar construction to the aforescribed inflatable bag means 13 and 53. The input tube 99 provides selective communication with the interior of the inflatable bag means 101. The square tube 99 may be made of a suitable polypropylene material and has a flapper valve 103 moveable between a first position, as shown in solid lines, which allows the passage of air into the interior of the inflatable bag means 101, and a closed position, as indicated in phantom, wherein the flapper valve 103 prevents inward flow of air into the inflatable bag means 101. The square tubular input tube 99 has an upwardly directed portion 105 which serves to support a conventional time delay device 107 having a depending actuator member 109 moveable to effect movement of the flapper valve 103 between its opened and closed positions. An abutment or sealing member 111 is provided on the lower internal surface of the input tube 99 for cooperation with the flapper valve 109 when moved to its closed position to assist in preventing the inflow of air into the inflatable bag means 101. A suitable exhaust vent or port 113 is provided in the raised portion 105 of the input tube 111 to allow the escape of air when the flapper valve 103 is in its lowered closed position.

When employing a time limit valve means as indicated schematically at 97, the timer 107 may be set to close the flapper valve 103 after a predetermined time period following commencement of the passage of air into the inflatable bag means 101. For example, the timer 107 may be set to close the flapper valve 103 after two or three seconds following the beginning of

exhausting the user's lungs into the inflatable bag means 101, whereupon the flapper valve 103 will prevent further air input into the inflatable bag means 101. Thereafter, gas exhausted from the user's lungs will pass outwardly through the exhaust port or opening 113 in the raised portion 105 of the input tube 99. In this fashion, standards or norms may be established for lung capacity based upon a fixed time period of exhaling one's lungs into an inflatable bag whereby to allow direct comparison between individuals. The time period of exhaling into the inflatable bag means 101 through the time limit valve means 99 would provide an indication of the condition of one's lungs.

While preferred embodiments of the present invention have been illustrated and described, it will be obvious to those skilled in the art that changes and modifications may be made therein without departing from the invention in its broader aspects. Various features of my invention are set forth in the accompanying claims.

What is claimed is:

1. A disposable pulmonary function kit for use in testing lung capacity, comprising, in combination, inflatable bag means, input means connected to the interior of said bag means and providing means for exhaling gas from one's lungs into said bag means, said input means comprising an elongated tubular member secured to said bag means generally adjacent one end thereof, said elongated member having a mouth actuated slidable and closable valve means supported thereon and adapted for selectively closing said bag means after at least partially inflating said bag means, said bag means having calibration gradations thereon beginning with zero at the end of said bag means opposite said elongated member, said elongated member being rotatable about its longitudinal axis to roll said bag means thereon until the portion of said bag means having gas entrapped therein is taut such that the volume of gas within said bag means may be determined by observing the calibration gradation adjacent the rolled elongated member.

2. A pulmonary function kit as defined in claim 1, wherein said elongated tubular member comprises a roller member secured to said bag means at said one end thereof, said tubular roller member having at least one opening in the annular wall thereof communicating with the interior of said bag means, and wherein said valve means comprises an input tube member coaxially supported within said tubular roller member and rotatable relative thereto, said input tube member having an open end providing a mouthpiece fitment and having an opening in the annular wall thereof adapted for registry with said opening in said roller member, said input tube being rotatable about its longitudinal axis between a first position establishing registry of said openings for introducing a gas into said bag means and a second position sealing the gas within said bag means.

3. A pulmonary function kit as defined in claim 2 wherein said tubular roller member extends across the full width of said bag means.

4. A disposable pulmonary function kit for use in testing lung capacity, comprising, in combination, inflatable bag means, calibration gradations on said bag means positioned to indicate the volume of gas entrapped in said bag means when selectively disposed in a taut condition, input means secured to said bag means and comprising a mouth actuated slidable and

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closable valve means including a tubular mouthpiece fitment movable between a first position wherein one may exhale therethrough into said bag means and a second position while in the person's mouth to close off said bag means and entrap the exhaled gas therein, and air gathering means mounted on said bag means and movable along the length of said bag means to force the entrapped gas therein toward one end of said bag means until said bag means is taut whereupon the volume of gas within said bag means may be determined by observing the calibration gradation adjacent said gathering means.

5. A pulmonary function kit as defined in claim 4 wherein said calibration gradations begin with zero at one end of said bag means, and wherein said air gathering means includes a sweeper member supported on said bag means normally adjacent the end thereof opposite the zero calibration gradation, said sweeper

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member being slidable along the length of said bag means until any gas entrapped therein causes said bag means to become taut whereupon the calibration gradation adjacent said sweeper member indicates the volume of gas within said bag means.

6. A disposable pulmonary function kit as defined in claim 5 wherein said sweeper member comprises a generally flat sweeper element having three leg portions defining a pair of spaced slots therebetween of sufficient length to receive said bag means therethrough such that said sweeper element may be slid along the length of said bag means with the intermediate leg portion cooperating with the remaining leg portions to prevent the passage of gas entrapped within said bag means past said sweeper element as it is moved longitudinally along said bag means.

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