

[54] **CONTROLLED POSITIVE END PRESSURE
EXPIRATORY DEVICE**

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[56] **References Cited**

UNITED STATES PATENTS

1,672,394	6/1928	Sargent	137/533.13
1,965,333	7/1934	Connell	73/209
3,720,202	3/1973	Cleary	128/2.08

FOREIGN PATENTS OR APPLICATIONS

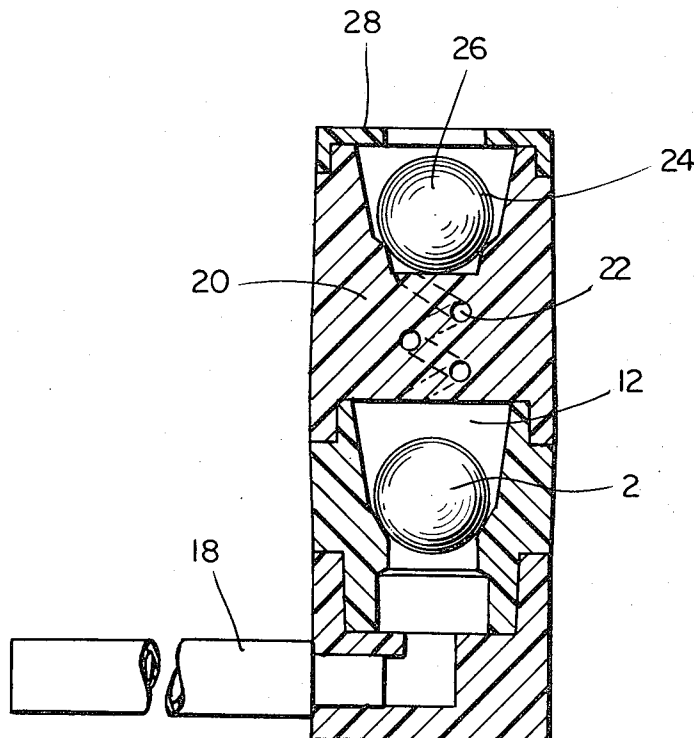
776,172	1935	France	137/533.13
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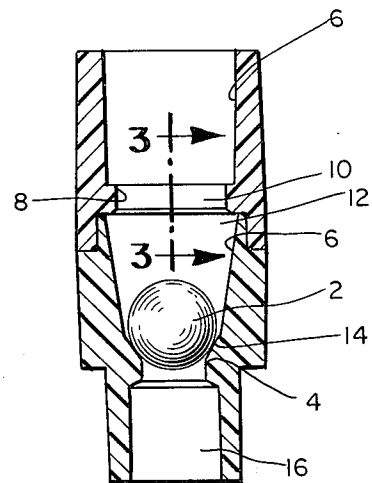
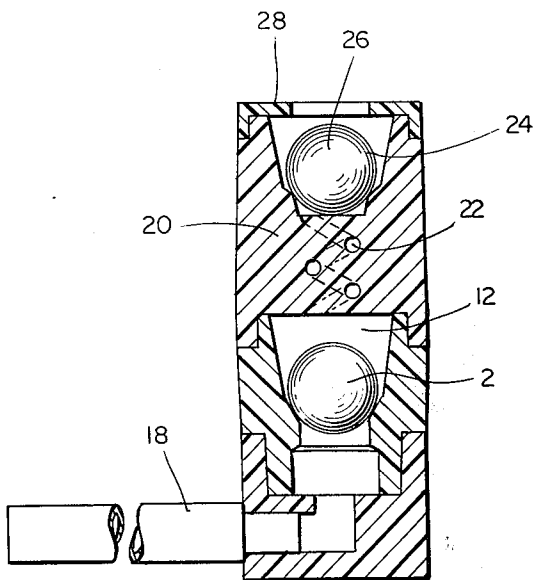
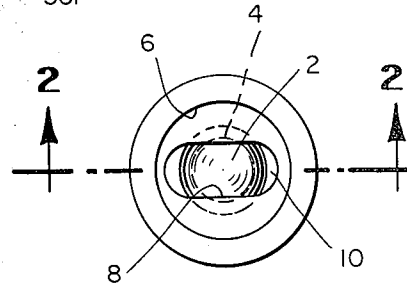
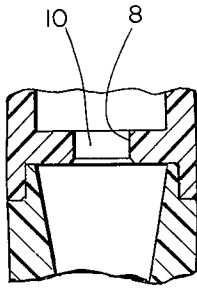
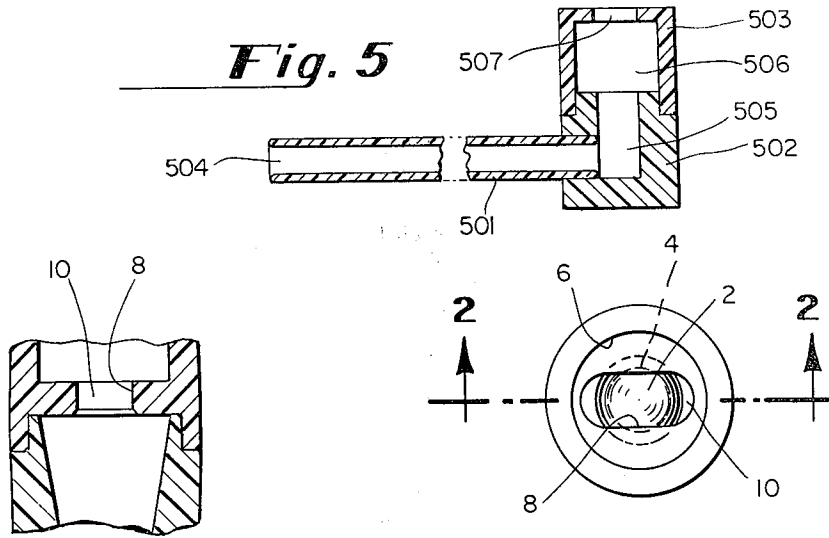
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[57] **ABSTRACT**

A controlled positive end expiratory pressure device comprises a vertically disposed passageway having a frustoconical segment at its lower end in which is supported a ball. The bottom of the passageway is adapted to communicate with a source of expiratory air such that the expiratory air tends to raise the ball off its support at the bottom of the passageway in order to provide a path for flow of the expiratory air around the ball. In this manner, the device acts as a calibrated end pressure means for providing a positive end expiratory pressure for the test subject or patient, thereby providing for enhanced pulmonary function. The device is designed to be universal in that it can be used intraoperatively on common anesthesia machines or post operatively on common ventilator machines. In one form, it is a hand held, self-controlled, lung exerciser.

16 Claims, 5 Drawing Figures





CONTROLLED POSITIVE END PRESSURE EXPIRATORY DEVICE

This invention pertains to a controlled positive pressure expiratory device, and more particularly to a convenient, sanitary means for providing a controlled positive pressure of known calibration and relatively free flow characteristics for use in the protocol known as positive end expiratory pressure or "PEEP" either during surgery intraoperatively or on ventilator machines used to support or to assist breathing.

A person's ability to inspire and expire a sufficient quantity of air is usually seriously impaired by many diseases of the respiratory system. Therapeutically, it is often desirable forceably to increase the lung effectiveness and capacity of such patients by providing them with a means or device providing an end expiratory pressure against which the lungs of the patient must be actuated to provide for enhanced pulmonary function.

It is therefore the general object of the present invention to provide a simple, sanitary, aesthetically pleasing, controlled positive end expiratory pressure device which is economical to manufacture, easy to use, and reasonably precise in providing a predetermined level of positive end expiratory pressure for a patient.

It is a more specific object of this invention to provide a relatively simple, disposable, easily useable, controlled positive end expiratory pressure device dependent totally on gravity and not easily susceptible to mechanical malfunction or calibration error.

These objects, and others which will become apparent in the course of the subsequent discussion, are met, briefly, by a device consisting of a vertically disposed passageway terminated at its lower end with a frusto-conical segment in which is supported (or which is adapted to support) a spherical ball which is freely movable within the passageway above the point of its support. The passageway at its bottom communicates with a source of expiratory air from the test subject to patient. The dimensions of the passageway and frusto-conical segment, as well as the dimensions and mass of the ball are calibrated to provide a predetermined positive end expiratory pressure for pulmonary patients.

In one preferred form of this invention, the device communicates at its bottom end with a horizontally disposed air passageway adapted to be held in the mouth of a user such that the overall configuration of the device resembles a conventional smoke pipe and may be used as such by the respiratory patient to exercise and thereby to enhance his lung function in a convenient and aesthetically pleasing manner.

The invention may be better understood by reference to the following detailed description taken in conjunction with the subjoined claims and the attached drawings, in which:

FIG. 1 is a top view of the preferred form of the invention;

FIG. 2 is a sectional view, in the plane 2—2, of the device shown in FIG. 1;

FIG. 3 is a partial sectional view of the device shown in FIG. 3, the section taken along the plane 3—3 of FIG. 2; and

FIG. 4 is a sectional view of another form of the present invention.

FIG. 5 shows still another alternative embodiment.

Referring more specifically to FIG. 1, there is shown a top view of one particular preferred form of the positive end expiratory pressure device of the present in-

vention. More particularly, this device consists of spherical ball 2 supported above the smaller lower circumference 4 of a frusto-conical lower segment of a vertically disposed passageway defined by sidewall 6 and covered by a top closure 8 having an opening 10 therein of shape and size to retain spherical ball 2 within the passageway defined by sidewall 6 and ensuring an air passageway around spherical ball 2 with spherical ball 2 forced against top closure 8. In the configuration of top closure 8 shown in FIG. 1, opening 10 is an elongated oval. It could as easily be any of a variety of other shapes or forms, including a plurality of circular holes or, in fact, any shape other than a simple circle located on the axis of the vertically disposed passageway. The reason such a simple axially disposed circle would not be acceptable is that it would be susceptible to being closed by forcing spherical ball 2 against, and seated within, such a circular opening during a forceable expiration such as a cough. Furthermore, this design is foolproof in that if installed upside down, it disables itself. In the commercial embodiment of the device shown in FIG. 1, there is a large arrow on the side of the body showing proper flow direction.

The details of top closure 8 and opening therein 10 may be better seen in the sectional view, FIG. 2, of the device shown in FIG. 1 taken along the plane 2—2, and in the sectional view of FIG. 3 taken along the plane 3—3 of FIG. 2.

As best seen in FIG. 2, the device shown in FIG. 1 includes a vertically disposed passageway 12 with a lower frusto-conical segment 14 in which spherical ball 2 is supported, and through which passageway 12 is adapted to communicate through passageway 16 with a source of expiratory air from a test subject or patient.

As shown in FIG. 2, in the preferred form of the present invention, lower frusto-conical segment 14 is inclined, with respect to the vertical, at an angle of about 37°–41°; this angle depends more specifically on the weight and diameter of the ball 2 and the diameter of the lower circumference 4. Vertical passageway 12 is also defined by an upper frusto-conical section vertically adjacent the lower conical section 14, the upper frusto-conical section terminating at its lower end with a circumference coinciding with the upper circumference of lower frusto-conical section 14, the upper frusto-conical section extending to the top closure 8 of the device, and having an angular inclination, with respect to the vertical, on the order of 8°–12°, most preferably about 10° for the commercial embodiment previously referred to.

While this preferred form of the invention includes a double frusto-conical segment, vertically disposed passageway 12 may consist of a continuous frusto-conical section of constant angular inclination, with respect to the vertical, on the order of 5°–20°. Preferably, however, a lower frusto-conical section of greater annular inclination acts as a throat for vertically disposed passageway 12, as well as a support for spherical ball 2 and provides for a number of improved functions, i.e., prevents jamming, promotes sealing, provides a massive surface not able to chip, etc.

By carefully manufacturing the device, the taper of passageway 12 urges the ball to float in an air stream at or below the pressure at which the ball will seat thus giving a valve which will have simultaneously in one design low resistance to high flow (such as a cough) but accurate sensitivity to pressure to lift the ball from the

seat. The low resistance to high pressure is important to prevent rupture of lung tissue and pneumothorax which might be caused by a forced exhalation, such as a cough, through a flow dependent resistance.

In another form of the present invention, as shown in FIG. 4, vertical passageway 12 communicates at its lower end with a horizontally extended member 18 adapted to be held in the mouth by a patient or user, the overall configuration of horizontally disposed member 18 and the housing of vertically disposed passageway 12 resembling that of an ordinary hand held smoke pipe so that the user can be encouraged to exercise his lung function using the device in the manner of a conventional smoke pipe.

While the device of the present invention, as described and illustrated, generally includes a lower frusto-conical segment in a vertically disposed passageway supporting a spherical ball, the spherical ball may instead rest simply in a circular opening not including a frusto-conical segment. Because calibration of such devices is more difficult and functioning of the device is not as effective as that with the frusto-conical segment, this is a non-preferred form of the present invention. While, such a simple circular opening is used in a commercial embodiment of the smoke pipe lung exerciser of the present invention, it is probably not suitable for other applications because it is not inherently safe in that the ball may stick in the opening since the angle of the sidewall of the opening on which the ball is seated is generally below the angle of repose of the materials in question. Similarly, another, though much less preferred, form of the present invention is that in which the shape of the ball is changed. For example, a vertically guided rod (to which a variable amount of weight may be attached) with a specifically designed lower seating surface may be used. A simple spherical ball, however, provides a constant mass regardless of orientation and has less of a tendency to stick than other non-spherical shapes. The spherical ball shape is therefore preferred.

In the preferred forms of the present invention, expiratory air passes up through the bottom of a vertically disposed chamber, as shown in both FIGS. 2 and 4, and, in order to escape upwardly therethrough, raises spherical ball 2, of predetermined size and mass to provide a controlled amount of positive end pressure against which the expiratory air must act in order to raise spherical ball 2 off its supporting surface within vertically disposed passageway 12.

The expiratory air then raises spherical ball 2 off its support in the lower end of the vertically disposed passageway 12, the amount by which the ball is raised being determined by the weight and size of the ball, the dimensions of the passageway and the air (or gas) flow present. The passageway may be vertically calibrated so that the distance the ball is raised can be used as an indication of the expiratory flow. More normally, the device is used as an end expiratory pressure regulator to encourage and to develop lung function and no such vertical calibration is required.

In one particular form of the present invention, a device such as that shown in FIG. 2, has a diameter at the lower circumference of the lower frusto-conical section 14 of 0.591 inch and a diameter at the upper circumference of frusto-conical section segment 14 of 0.615 inch with the angular inclination of the sidewalls of frusto-conical section 14, with respect to vertical, being 39°.

The angular inclination of the upper frusto-conical segment is 10°, and the spherical ball 2 supported therein, which is composed of stainless steel, has a diameter of 0.625 inch and a weight of 16.33 grams.

The basic variation in end pressure is obtained by varying ball material (glass, nylon, stainless steel), and varying orifice diameters to suit. The ball may also be hollowed out to change its effective weight or mass may be added above the ball to increase its effective weight, but these are not preferred embodiments.

The devices of this invention may be configured such that the valves can be stacked one on another (as in FIG. 4) to give addition of pressures such as 2.5 plus 5 give 7.5 cm H₂O total end pressure. In the commercial embodiments of this invention, the devices are clearly labeled with large color coded one-half inch high numbers on the side of the body placed so that the adaptor system does not interfere with it.

The devices of this invention are generally designed so that they can be disabled by turning them 90° from the vertical. A side port version is produced which makes the valve a suitable device for drawing samples of expired gas conveniently into a sample container.

In order further to enhance the utility of embodiments of the present invention other modifications may also be made. For example, increased flexibility may result if the ball 2 is provided with an adaptable weight facility. That is, it may be recognized that variation of the force with which the ball 2 bears down in the passageway 16 proportionally varies the resistance of the ball 2 to input air flow. Thus, this force, or "effective weight" of the ball may be changed either by directly altering the mass of the ball, or by exerting forces such as magnetic force upon the ball 2. One manner in which the mass of the ball 2 may be altered directly is to connect to the ball 2 a shaft which protrudes upwardly and out of the device. If such a shaft is conditioned for attachment of weights, any desired mass variation of the ball 2 may result.

While this invention has been described with respect to particular forms thereof, it should not be interpreted as limited thereto. Instead, the appended claims are intended to cover all such equivalent modifications of the present invention as would be obvious to those skilled in the art, and within the true spirit and scope of the present invention. For example, the sidewall 6 may be cylindrical in shape and terminated by a hemispherical surface, rather than the frusto-conical shape shown. Similarly, variation of the orifice, diameter of the ball, and specific gravity of the ball will have a predictable effect on the back pressure produced during zero flow and during flow conditions. Likewise, the device may be modified as shown in FIG. 5 for a simpler exerciser. In that embodiment, a stem 501 defines a mouthpiece part 504 which communicates with a cavity 505 in a body segment 502. Segment 502 is shown connected with a cap 503 defining a cavity 506 which exhausts via part 507. The size of the cavities 505 and 506 and parts 504 and 507, together with the orientation of the stem 501 relative to the air flow path, provide an inherent flow resistance function which, although less severe than foregoing embodiments, does provide a useful exerciser configuration.

I claim:

1. A controlled positive end pressure expiratory device comprising a vertically disposed passageway terminated at the lower end by a frustoconical segment

adapted to communicate at the bottom thereof with a source of expiratory air, and a spherical ball having a calibrated size and effective weight, said passageway being adapted to receive said spherical ball, said ball being freely movable vertically within said passageway above said segment and supportable by said segment between the top and bottom thereof, said ball defining means for exerting a substantial predetermined back pressure function to said source of expiratory air, in order to provide significant resistance to the expiration of air by a user.

2. A device, as recited in claim 1, wherein the angular displacement, from vertical, of the sidewalls of said frusto-conical segment is 10°.

3. A device, as recited in claim 1, wherein said passageway includes a top cover having an opening therein, said cover and opening being adapted to retain said ball in said passageway and to assure an escape of air from said passageway.

4. A device, as recited in claim 1, further including means for directing air entering said lower segment from the bottom thereof in a stream aimed generally outwardly and tangentially with respect to said frusto-conical segment and entering said segment off-center with respect thereto.

5. A device, as recited in claim 1, wherein said passageway communicates through the bottom thereof with a horizontally disposed member adapted to be held in the mouth of a test subject, the overall configuration of said device being substantially similar to that of a hand held smoke pipe.

6. A device as recited in claim 1 wherein said segment comprises a first portion having sidewalls disposed at 5°-20° from vertical, and a second section having substantially greater disposition to vertical to support said ball in nonjamming fashion.

7. A device as described in claim 1 wherein said passageway defines a plurality of cavities, each including a spherical ball defining means for exerting a predetermined back pressure function to expiratory air in said passageway.

8. A device as described in claim 7 wherein said housing means comprises a plurality of separate interlocking portions, each such portion defining one of said cavities and input and exhaust ports therefor, whereby

a plurality of portions may be stacked upon one another to produce aggregate devices having variable back pressure devices.

9. A device, as recited in claim 7 wherein each of said cavities includes a frustoconical segment above and vertically adjacent the next successive cavity, said segments each having a first circumference at its upper end and a second circumference at its lower end, said second circumference being smaller than said first circumference and communicating with and being smaller than the top circumference of the next lower cavity.

10. A device, as recited in claim 9, wherein the angular inclination, from vertical, of said second frusto-conical segment is the same as that of said first or lower segment.

11. A device, as recited in claim 9, wherein the angular inclination, from vertical, of said second frusto-conical segment is less than that of said first or lower segment.

12. A device, as recited in claim 9, wherein the angular inclination, from vertical, of said first segment is 37°-41° and that of said second segment is 8°-12°.

13. A controlled positive end pressure expiratory device comprising a vertically disposed passageway with a circular opening at its lower end adapted to communicate with a source of expiratory air, and a spherical ball having a calibrated size and effective weight, said passageway being adapted to receive said spherical ball having a diameter greater than that of said opening and being freely movable vertically within said passageway and above said opening, said ball defining means for exerting a substantial predetermined back pressure function to said source of expiratory air, in order to provide significant resistance to the expiration of air by a user.

14. A device as described in claim 13 wherein said means for exerting operates responsively to the specific gravity of said ball, the diameter of said ball, and the size of said opening.

15. A device as described in claim 14, and further including means for varying force exerted by said ball against flow of expiratory air from said opening.

16. A device as described in claim 14, wherein said device is provided with means for sampling the expiratory air flowing in said passageway.

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