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(54) Ventilator apparatus.

(57) Ventilator apparatus for treating a patient has a ventilator enclosure to which oscillating air flow is controlled via a valve connected to the enclosure and to sources of positive and negative pressure. The valve (A) comprises a main chamber (812) separated via a valve seat and a shutter member (810) from subsidiary chambers (816, 817) which are isolated from one another. Rotation of the shutter member by a stepper motor (B) connects each subsidiary chamber to the main chamber in turn to produce oscillating gas flow through a main port (812a) connected to the enclosure.

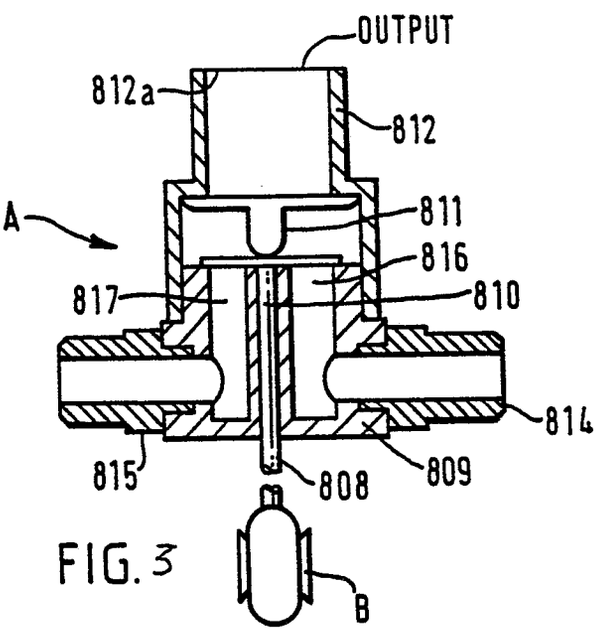

FIG. 3

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VENTILATOR APPARATUS

The present invention relates to ventilator apparatus incorporating fluid control valves, for controlling air flow in such ventilator apparatus.

The present invention provides apparatus for use in ventilation of the lungs of a patient, comprising a ventilator enclosure for receiving at least the chest region of the patient's body, and means for varying the pressure in the enclosure to produce ventilation, said pressure varying means comprising a source of positive gas pressure, a source of negative gas pressure, and valve means connected between said sources and said housing, said valve means comprising a valve body, a main chamber and at least two subsidiary chambers in said valve body, a main port connected for gas flow to said housing and communicating with the main chamber in said valve body, at least two subsidiary ports, one subsidiary port being connected for gas flow to said source of positive pressure and the other said port being connected for gas flow to said source of negative pressure and each said port communicating with a respective said subsidiary chamber in said valve body, a valve seat in said valve body, said subsidiary chambers being mutually isolated and opening into the main chamber at respective openings in said valve seat, a rotary shutter member having a sealing face overlying said valve seat openings which controls fluid flow between said main and subsidiary chambers, and an electronic stepper motor connected to said shutter member for selectively rotating the shutter member, the shutter member having an opening so disposed in relation to the said chambers that the shutter member is rotatable between a range of positions for each subsidiary chamber at which fluid flow is permitted through the shutter opening only between that subsidiary chamber and the main chamber, and through a range of positions in which the subsidiary chambers and main chamber are all mutually isolated.

The enclosure for the patient may be as described and claimed in European Patent Application No. 0258302 from which the present Application is divided.

The means for varying the pressure in the enclosure, alternatively referred to as "the oscillator", is preferably adapted to establish a sub-ambient pressure in the enclosure and to vary the pressure in the enclosure so as to superimpose on the sub-ambient pressure a cyclic variation, preferably having a frequency of above 1 Hz.

Preferably, the oscillator is adapted to produce a negative base line pressure of at least 196 Pa (2 cm H_2O), e.g. from 196 Pa to 2940 Pa (30 cm H_2O) more preferably from 196 Pa (2 cm H_2O) to 1961 Pa (20 cm H_2O).

Preferably, the oscillator is adjustable to provide a desired sub-ambient pressure and as the most preferred mean enclosure pressure is about -980 Pa (-10 cm H_2O), preferably at least a range of from -490 Pa (5 cm H_2O) to -1470 Pa (15 cm H_2O) is available.

Preferably, the oscillator is adapted to produce a pressure variation amplitude of from 392 Pa (4 cm H_2O) to 3136 Pa (32 cm H_2O).

Preferably, the oscillator is adjustable to produce a desired amplitude of pressure variation such as from 785 Pa (8 cm H_2O) to 1570 Pa (16 cm H_2O).

Preferably, the oscillator is adjustable to provide a desired shape of waveform for said cyclic pressure variation. It may for instance be possible to vary the I/E ratio, to choose between two or more of a sine wave pattern, a square wave pattern or a saw tooth wave pattern for the whole of the pressure variation, or for parts of the wave form or to choose other wave forms.

The source of positive pressure of gas may be, for example a pressurised air line in a hospital ward, or a locally-provided air compressor. Where a vacuum suction line is provided, for example adjacent the pressurised air source, the suction line may serve as the source of negative pressure. Alternatively, the vacuum source may be a vacuum pump, which pump may be driven by the source of air under pressure.

Suitably, the means for varying the pressure in the enclosure is adapted to produce cyclic variations in said pressure at a frequency of from 3 to 12 Hz.

The frequencies most advantageously used are from 4 to 8 Hz, e.g. about 5 Hz.

Isolation of the subsidiary chambers of the valve means from one another prevents air flow from the source of pressurised air to the vacuum source. The rate of flow between the main port and each subsidiary port preferably varies with the position of the shutter opening within the range of positions for that subsidiary port. This enables the fluid flow to be controlled cyclically in accordance with any desired flow sequence. For example to vary the I/E ratio, to choose between two or more of a sine wave pattern, a square wave pattern or a saw tooth pattern, for the whole of the pressure variation, or for parts of the wave form or to choose other wave forms.

The shutter member preferably consists of a plate, the shutter opening being an aperture therein. Preferably, the plate is a disc, the aperture being off-set from the centre of the disc, and the

shutter member further comprising a spindle connected to the disc for controlled rotation of the aperture about an axis.

The first and second subsidiary chambers are preferably spaced, e.g. parallel, bores in a body portion of the valve means, whose respective ends lie in said common plane sealing against the disc. The said bores are preferably shaped as spaced sectors of an annulus, when viewed in cross-section, the arrangement being such that the disc aperture overlaps successive sector-shaped ends of the bores as the disc is rotated. The minimum cross-section of the first subsidiary chamber is preferably substantially larger than that of the second subsidiary chamber. The valve is then capable of compensating for differences in the fluid pressures applied to the first and second subsidiary ports.

Preferably, the motor is controlled by an electronic processor in accordance with a predetermined program whereby the first and second subsidiary chambers are periodically and alternately connected to the main chamber.

Preferably, accumulator reservoirs are connected to either or to each of said first and second subsidiary ports, the or each accumulator reservoir being for connection to a source of gas pressure or vacuum.

Preferably, the apparatus includes a pressure sensor for sensing gas pressure at or adjacent said main port or in said ventilator enclosure.

Preferably, the apparatus includes electronic circuitry for controlling the movement of said shutter member to provide a desired pattern of pressure changes at or adjacent said main port or in said ventilator.

Preferably, said circuitry makes use of signals from said pressure sensor to control said shutter member.

The invention will be further illustrated by the following description of a specific embodiment with reference to the accompanying drawings in which:-

Figure 1 is a perspective view of a patient enclosure of ventilator apparatus according to the invention in use;

Figure 2 is a schematic diagram of a pressure oscillator incorporating a fluid control valve apparatus of the present invention;

Figure 3 is a schematic axial section through the fluid control valve of Figure 2;

Figure 4 is a view from the output end of a bearing disc incorporated in the fluid control valve of Figure 3;

Figure 5 is a side elevation of the bearing disc of Figure 4;

Figure 6 is a view of a shutter disc of the fluid control valve of Figure 3, taken along the axis of the valve from the input end thereof;

Figure 7 is a side elevation of the shutter disc of Figure 6;

Figure 8 is an elevation of the valve body of the fluid control valve of Figure 3, taken along the axis from the output end thereof; and

Figure 9 is a side elevation of the valve body of Figure 8.

As shown in Figure 1, a ventilator enclosure according to the invention includes a base member 10 providing a patient receiving upper surface 11 upon which is shown an infant patient being provided with artificial respiration by the ventilator.

The ventilator further comprises a cover member 12 of a generally flattened U-shaped defining a tunnel over the trunk of the patient. The cover member comprises open ends provided with apertures 13 through which pass the body of the patient. Each aperture 13 is provided with a sealing member 14 in the form of a pleated rubber curtain attached along all three sides of the end of the cover member 12.

The cover member is detachable from the base by releasing quick release latches 15 positioned one on each longitudinally running edge of the cover member.

A pair of air inlet/outlet ports 16 are provided lying one either side of the longitudinal mid-line of the cover member and above an upper chest region of the patient. The ports 16 are connected to an oscillator for producing pressure changes in the enclosure via flexible tubes 17 meeting at a T-junction before being connected to the oscillator.

The ports 16 are provided in a detachable hatch portion 18 of the cover member which is removable to provide access to the chest of the patient.

An oscillating pressure source is shown in Figure 2. This pressure oscillator is capable of producing oscillations in the pressure within the ventilator, and can be arranged to provide a negative mean enclosure pressure.

The pressure oscillator 800 comprises a fluid control valve A whose output is connected to the ventilator enclosure by way of an output pipe 804. The valve A has two alternative inputs, connected respectively to a pressure chamber C and a vacuum enclosure D. The valve A is controlled by means of an electronic stepper motor B to connect the output either to the pressure chamber C or to the vacuum enclosure D.

The pressure chamber C receives pressurised air through an air pipe 801, for example from a source located in the wall W of a hospital. The vacuum enclosure D may be connected, through an air pipe 802, to a suction pipe, for example in the hospital wall W. However, if such a suction pipe is not available, the vacuum in the vacuum enclosure D can alterntively be provided by means of a

vacuum pump E connected thereto, the vacuum pump E being driven by means of pressurised air conveyed to the vacuum pump E by way of a further air pipe 803 which is connected to the source of pressurised air.

The electronic stepper motor B is controlled by a microprocessor M through a control line 807. The microprocessor M monitors the output air pressure, i.e. the pressure in the ventilator enclosure, by means of a pressure gauge F whose input is connected by way of a pressure line 805 to the interior of the ventilator enclosure, and whose output is connected by way of control line 806 to the microprocessor M. The pressure line 805 conveniently passes through the output air pipe 804 which links the fluid control valve A and the ventilator enclosure.

The fluid control valve A will now be described in greater detail with reference to Figures 3 to 9. The valve A comprises a valve body 809, an output port 812a leading to an output chamber 812 in screw-threaded engagement with the valve body 809, a pressure port 815 at one side of the valve body, a vacuum port 814 at the opposite side of the valve body, and a shutter disc 810 retained by a bearing disk 811 and drivingly connected by a spindle 808 to the stepper motor B. The "output port" and "output chamber" will be so referred to for convenience but it will be apparent that the flow of gas therethrough is in fact oscillating and not solely or predominantly in the outward direction. The valve body 809 and output chamber 812 are coaxial, and the valve body 809 has an axial bore which receives the spindle 808 of the shutter disc 810.

As shown in Figures 6 and 7, the shutter disc 810 consists of a circular disc from which depends axially the spindle 808. A shutter aperture 813 is formed in the disc off the centre thereof. The shutter aperture 813 subtends an angle of approximately 70°, and has the shape of a sector of an annulus.

As shown in Figures 4 and 5, the bearing disc 811 35 consists of a circular disc 824 from which depends axially a short bearing shaft 825 on whose end is mounted a ball bearing 826. The disc 824 is formed with three large apertures, shaped as sectors of an annulus, to enable air to flow through the bearing disc 811. As shown in Figure 3, the bearing disc 811 is mounted coaxially within the output chamber 812. The upper peripheral surface of the disc 824 abuts against an annular shoulder between two sections of the output chamber of different internal diameters. The ball bearing 826 engages the centre of the upper surface of the shutter disc 810, ensuring that the shutter disc remains in its seating within the valve body 809, but allowing the shutter disc to rotate.

As shown in Figures 3 and 8, the valve body 809 has a pressure input chamber 817 and a vacuum input chamber 816, these chambers being mutually isolated and communicating respectively with the pressure input and vacuum input ports 815, 814. The input chambers 816, 817 are formed as paraxial bores in the valve body 809, each having the shape of a sector of an annulus, when viewed in cross-section. The lower end of each input chamber is closed, while the upper ends, at the interface with the shutter disc 810, lie in a plane which is common to the disc of the shutter disc 810.

The pressure input and vacuum input chambers 817, 816 are arranged relative to the shutter disc 810 such that the shutter aperture 813 registers with either or neither of the input chambers but never with both of them at the same time. As the shutter disc 810 rotates, passes through a first range of positions, at which flow is permitted only through the shutter opening between the pressure input chamber and the output chamber and at a variable rate dependant on a precise position within the first range, and a second range at which flow is permitted only between the vacuum input chamber and the output at a variable rate dependent on the precise position within the second range at which the input and output chambers are all mutually isolated.

The cross-sectional area of the vacuum input chamber 816 is approximately twice the cross-sectional area of the pressure input chamber 817. This is to provide an extra constriction in the flow of pressurised air to the output chamber, to compensate for the fact that there is a greater pressure difference between the pressure chamber C and the mean output pressure than between the vacuum enclosure D and the mean output pressure.

As shown in Figures 8 and 9, the valve body 809 has a base portion 819, shaped as an irregular triangle with rounded vertices, from which depends from its centre an externally-threaded, cylindrical portion 820, for screw-threaded engagement with the output chamber 812. A shallow lip is cut into the upper surface of the cylindrical portion 820 of the valve body, at the interface with the shutter disc 810. The ledge 823 subtends an angle of approximately 140°, and is divided from the remainder 822 of the upper surface of the cylindrical portion 820 by a ridge 821. The purpose of the ledge 823 is to reduce friction between the undersurface of the shutter disc 810 and the adjacent upper surface of the cylindrical portion 820 of the body member, against which the shutter disc slides in use.

The cyclic pressure oscillations applied to the ventilator enclosure are produced as follows.

The valves of the maximum and minimum

pressures are determined by selecting the precise angular position of the shutter disc 810, so that the required proportion of the total area of the relevant input chamber 816 or 817 is opened by the shutter 813. This is achieved by the electronic stepping motor B, controlled by the microprocessor M. Further, the variation of pressure with time is controlled by precise timing of the movement of the shutter disc 810. For example, the shutter opening 813 could be moved rapidly or more slowly over the appropriate input chamber, and the dwell time could be small or a large proportion of the overall cycle.

The electronic stepping motor B is preferably capable of moving the shutter disc back and forth in a reciprocating motion alternately over the two input chambers, at a frequency of from 1 to 1800 times per minute, thus causing air pressure oscillations in a corresponding frequency. The wave shape of the pressure oscillations can be controlled as required, for example to a saw tooth, square or sine wave.

It has been found that the regime of pressure changes and mean enclosure pressure described above enables the ventilation of patients whose lungs are not healthy, for instance neonates with IRDS, whereas previous proposals for external high frequency ventilation have proved effective only for brief periods in animals with healthy lungs in laboratory tests.

Moreover, it has been found that the delivery of air into the enclosure through apertures 16 positioned directly over the chest, as opposed to simply opening a connection between the enclosure and atmosphere or locating the apertures in the sides of the enclosure, has important consequences.

The jet of air into the chamber impinging upon the chest wall serves to start downward movement of the chest wall before the resulting increase of pressure in the enclosure as a whole takes effect. The suction produced by the outflow of air at the commencement of the falling-pressure phase of the cycle serves to start chest inflation before the resulting drop in pressure in the enclosure as a whole would do so.

Thus, the coupling between the air flow to and from the chamber and chest wall movement can be much improved by disposing the air inlet/outlet ports so as to produce these local pressure effects.

To this end, the pressure oscillator is preferably capable of delivering through the connection to the enclosure an air flow of at least twice the velocity that would be obtained by connecting the inlet port to atmosphere through an equivalent flow path, preferably 3 or more times the velocity.

Compared to existing methods and apparatus for assisted ventilation the apparatus described above has susbtantial advantages. Intubation is avoided and with it all of the associated complications.

As compared to negative pressure ventilators of prior designs, the ventilator described with reference to the drawing is of low cost since it does not seek to replace the incubator and allows the use of conventional incubator.

The head, shoulders and arms and the lower part of the patients body are left accessible for routine or emergency procedures. There is therefore no need to interfere with the process of ventilation to keep the infant clean and dry or to install or maintain drips or other lines.

Because it can be arranged that the air moving in and out of the ventilator is drawn from the incubator, the temperature of the infant can be controlled satisfactorily and this is made even easier by the fact that a substantial part of the patients body is not involved in the ventilator but is simply in the atmosphere of the incubator.

Whilst the invention has been described with particular reference to infant patients, methods and apparatus of the invention constructed on a suitable scale may be employed with adult patients also.

Whilst the invention has been described with reference to specific characteristics of the embodiment described, many modifications and variations thereof are possible within the scope of the invention.

For example, it is envisaged that the fluid control valve could take other forms than that illustrated. The cross-sectional areas of the two input chambers 816, 817, for example, could be of any relative size, and these chambers could be formed at any circumferentially-spaced positions in the valve body. Further, the valve could be provided with three or more inputs, with corresponding separate input chambers, each of which may be brought separately into communication with the output chamber.

Claims

1. Ventilator apparatus for use in ventilation of the lungs of a patient, comprising a ventilator enclosure (10,12) for receiving at least the chest region of the patient's body, and means for varying the pressure in the enclosure to produce ventilation, said pressure varying means comprising a source of positive gas pressure (801), a source of negative gas pressure (802), and valve means (A) connected between said sources and said housing, said valve means comprising a valve body (809), a main chamber (812) and at least two subsidiary chambers (816, 817), in said valve body, a main port (812a) connected for gas flow to said housing

and communicating with the main chamber in said valve body, at least two subsidiary ports (814, 815), one subsidiary port being connected for gas flow to said source of positive pressure and the other said port being connected for gas flow to said source of negative pressure and each said port communicating with a respective said subsidiary chamber in said valve body, a valve seat in said valve body, said subsidiary chambers being mutually isolated and opening into the main chamber at respective openings in said valve seat, a rotary shutter member (810) having a sealing face overlying said valve seat openings which controls fluid flow between said main and subsidiary chambers, and an electronic stepper motor (B) connected to said shutter member for selectively rotating the shutter member, the shutter member having an opening so disposed in relation to the said chambers that the shutter member is rotatable between a range of positions for each subsidiary chamber at which fluid flow is permitted through the shutter opening only between that subsidiary chamber and the main chamber, and through a range of positions in which the subsidiary chambers and main chamber are all mutually isolated.

2. Apparatus as claimed in Claim 1, wherein there are two (first and second) subsidiary ports and respective subsidiary chambers.

3. Apparatus as claimed in Claim 2, wherein the shutter member comprises a plate, the shutter opening being an aperture (813) therein.

4. Apparatus as claimed in Claim 3, wherein the plate is a disc, the aperture being off-set from the centre of the disc, and the shutter member further comprises a spindle connected to the disc for controlled rotation of the apertures about an axis.

5. Apparatus as claimed in Claim 4, wherein the first and second subsidiary chambers (816, 187) are spaced bores in a body portion (809) of the valve, whose respective ends lie in a common plane sealing against the disc.

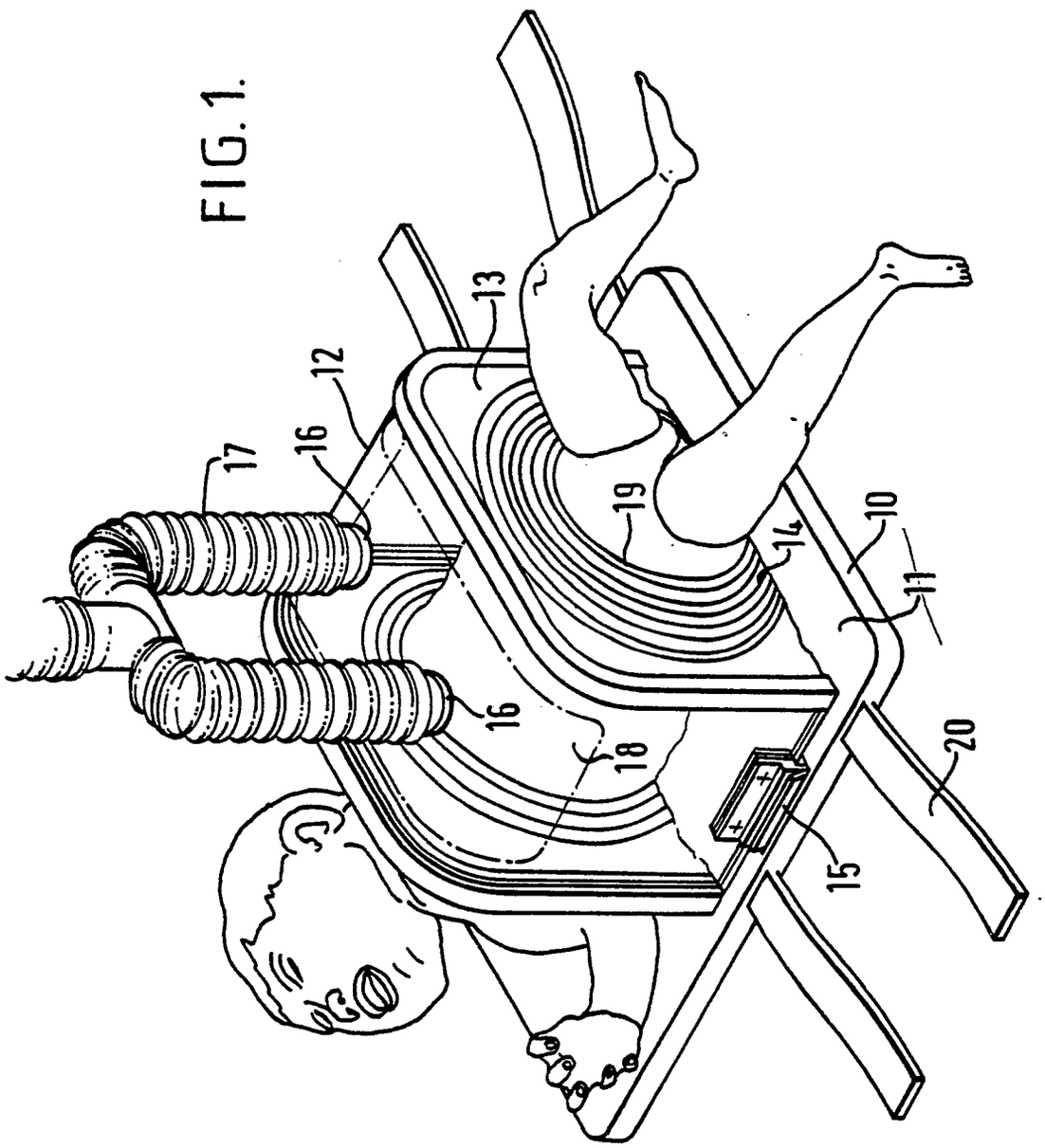
6. Apparatus as claimed in any one of Claims 2 to 5, wherein the minimum cross-section of the first subsidiary chamber (816) is substantially larger than that of the second subsidiary chamber (817).

7. Apparatus as claimed in any preceding claim, further comprising at least one accumulator reservoir (C,D) connected between one of said first and second subsidiary ports (814, 815) and its respective source of gas pressure.

8. Apparatus as claimed in any preceding claim, wherein the apparatus includes a pressure sensor (805,F) for sensing gas pressure at or adjacent said main port or in said ventilator enclosure.

9. Apparatus as claimed in any preceding claim, which includes electronic circuitry (M) for controlling said stepper motor (B) to produce movement of said shutter member to provide a desired pattern of pressure changes at or adjacent said main port or in said ventilator.

FIG. 1.



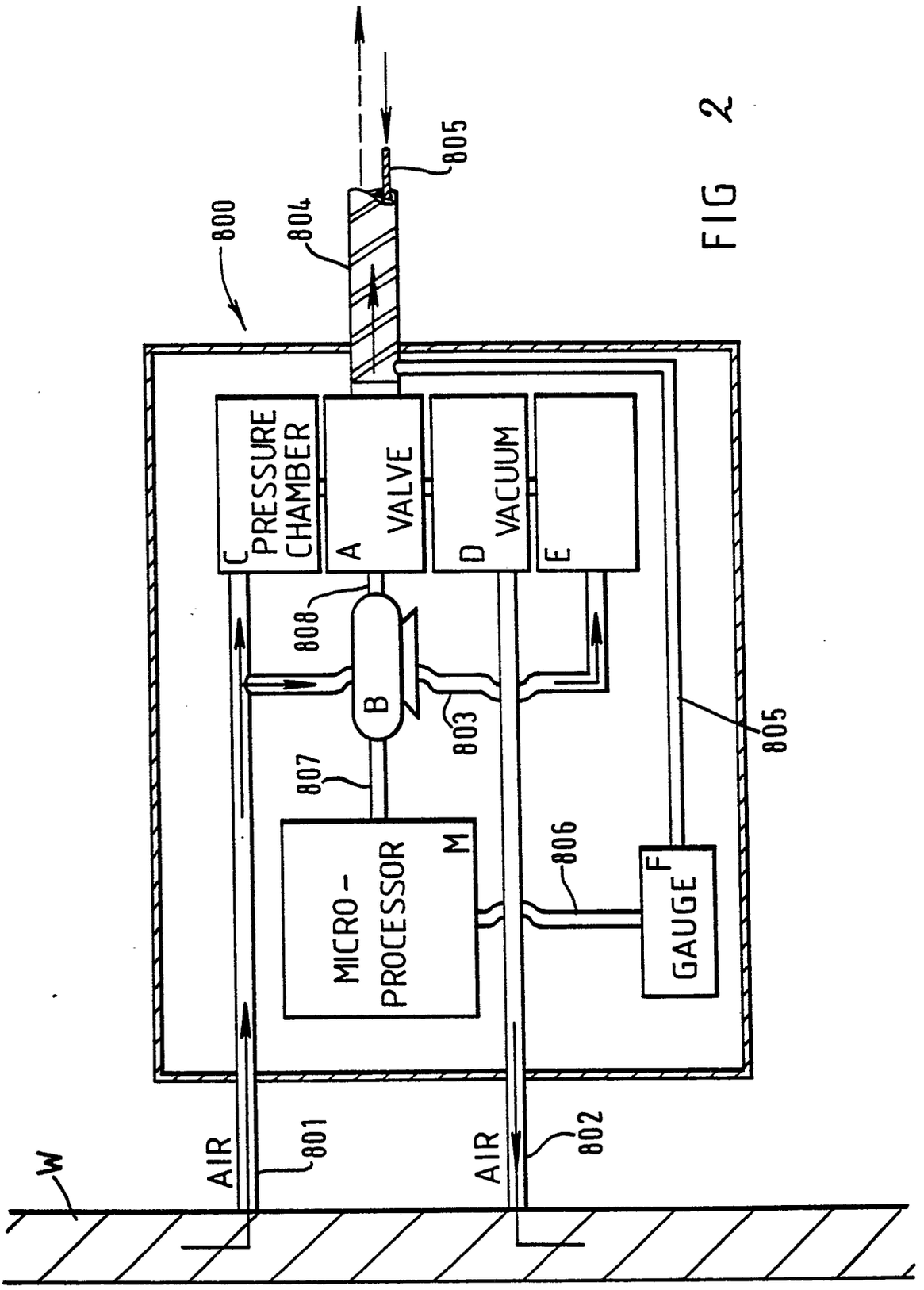

800
804
805
C PRESSURE CHAMBER
A VALVE
D VACUUM
E
808
B
803
805
807
M MICRO-PROCESSOR
806
F GAUGE
AIR
801
AIR
802
W

FIG 2

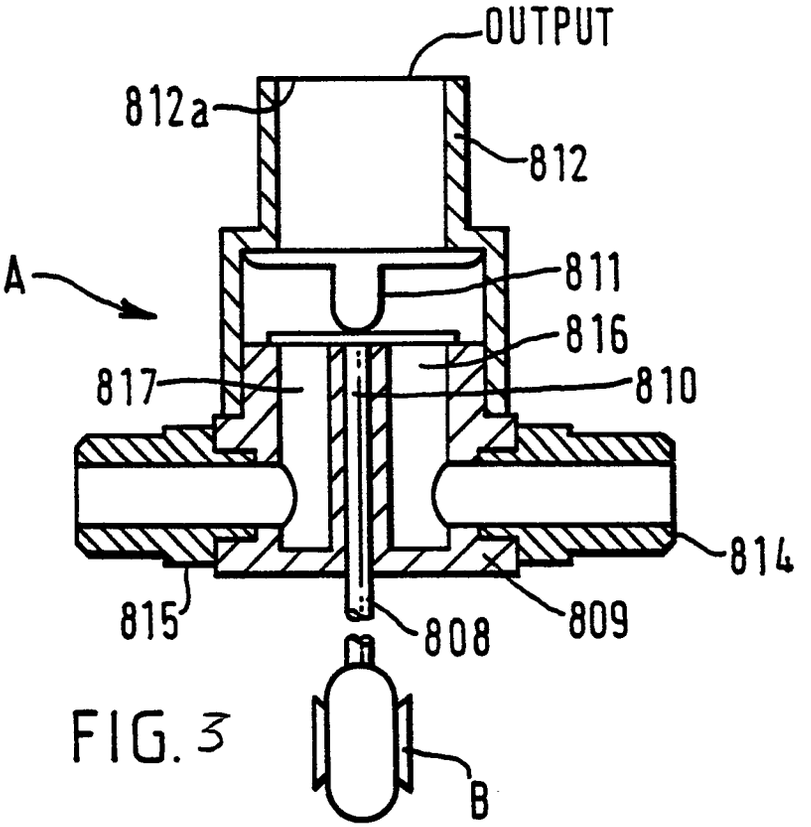


FIG. 3

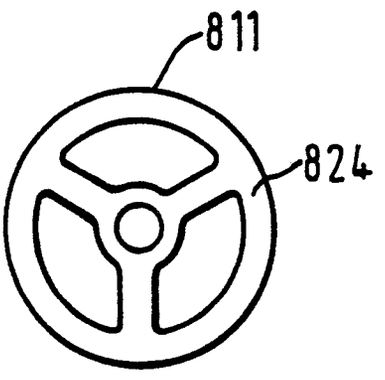


FIG. 4

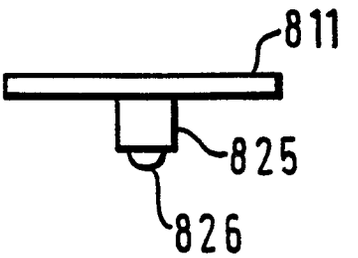


FIG. 5

FIG. 6

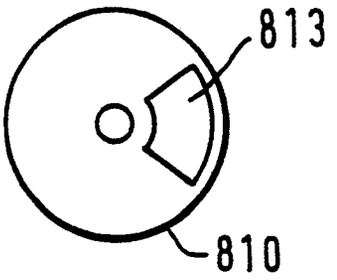


FIG. 7

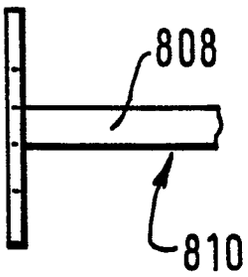
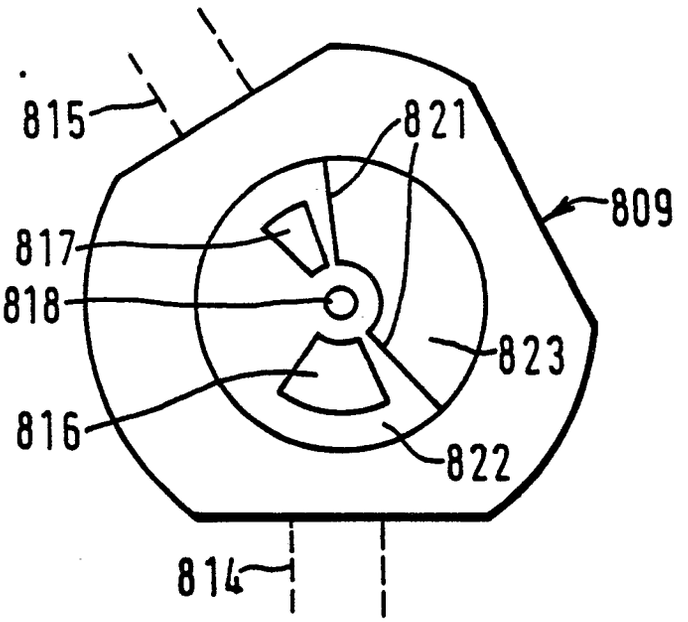


FIG. 8



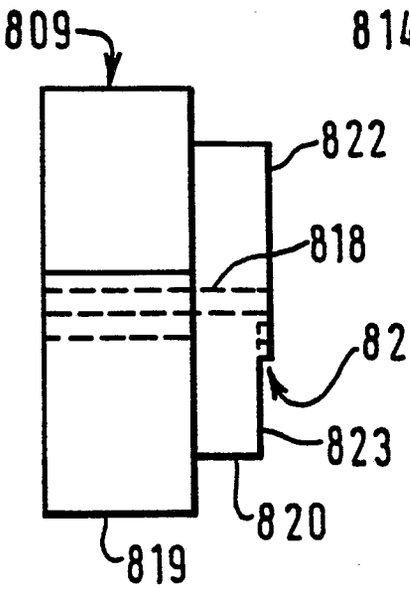


FIG. 9