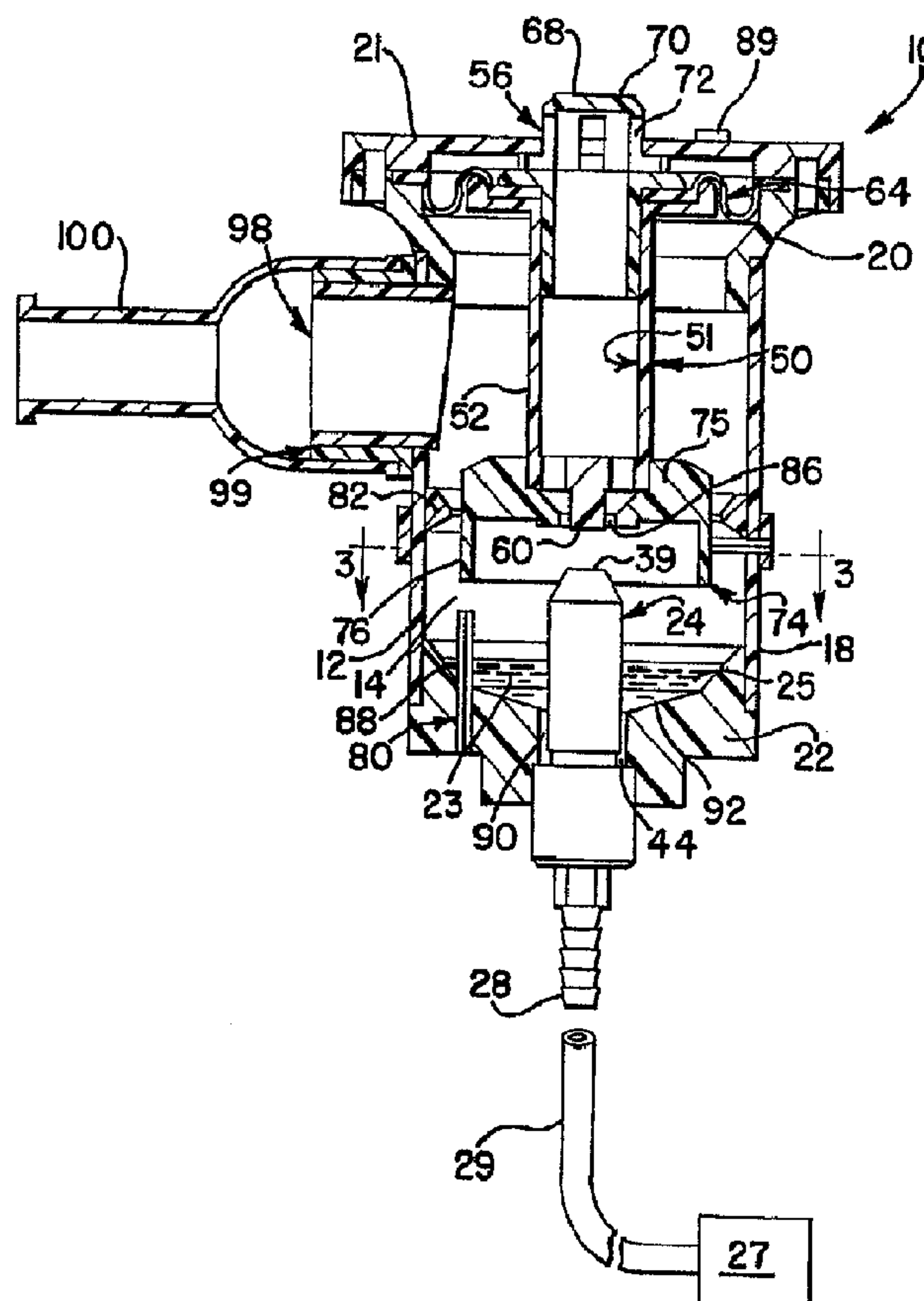




(86) Date de dépôt PCT/PCT Filing Date: 1997/02/13
(87) Date publication PCT/PCT Publication Date: 1997/08/21
(45) Date de délivrance/Issue Date: 2005/02/22
(85) Entrée phase nationale/National Entry: 1998/08/11
(86) N° demande PCT/PCT Application No.: CA 1997/000096
(87) N° publication PCT/PCT Publication No.: 1997/029799
(30) Priorité/Priority: 1996/02/13 (08/600,419) US

(51) Cl.Int.⁶/Int.Cl.⁶ A61M 11/06
(72) Inventeurs/Inventors:
GRYCHOWSKI, JERRY R., US;
BARAN, GEORGE, CA;
FOLEY, MARTIN P., CA
(73) Propriétaire/Owner:
TRUDELL MEDICAL INTERNATIONAL, CA
(74) Agent: BENNETT JONES LLP

(54) Titre : PROCEDE ET DISPOSITIF DE NEBULISATION
(54) Title: NEBULIZER APPARATUS AND METHOD



(57) Abrégé/Abstract:

An apparatus and method for providing a nebula or aerosol to a patient. In one aspect, a nebulizer is pressure sensitive so that nebulization is coordinated with a breathing cycle of the patient. The nebulizer includes a movable gas diverter that diverts pressurized gas across a liquid outlet. The diverter is moved in response to the patient's breathing cycle. In one aspect, a biasing



(57) Abrégé(suite)/Abstract(continued):

member moves the diverter. According to another aspect of the nebulizer, an annular liquid orifice disperses an aerosol in a radial direction in response to a pressurized gas flow from an orifice located concentrically thereto. Multiple liquid orifices may be provided. In a further aspect of the nebulizer, a reservoir includes an upper, wide portion and a lower narrow portion to apply relatively uniform pressure at a liquid orifice.

PCTWORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61M 11/06	A3	(11) International Publication Number: WO 97/29799 (43) International Publication Date: 21 August 1997 (21.08.97)
--	-----------	---

(21) International Application Number: PCT/CA97/00096

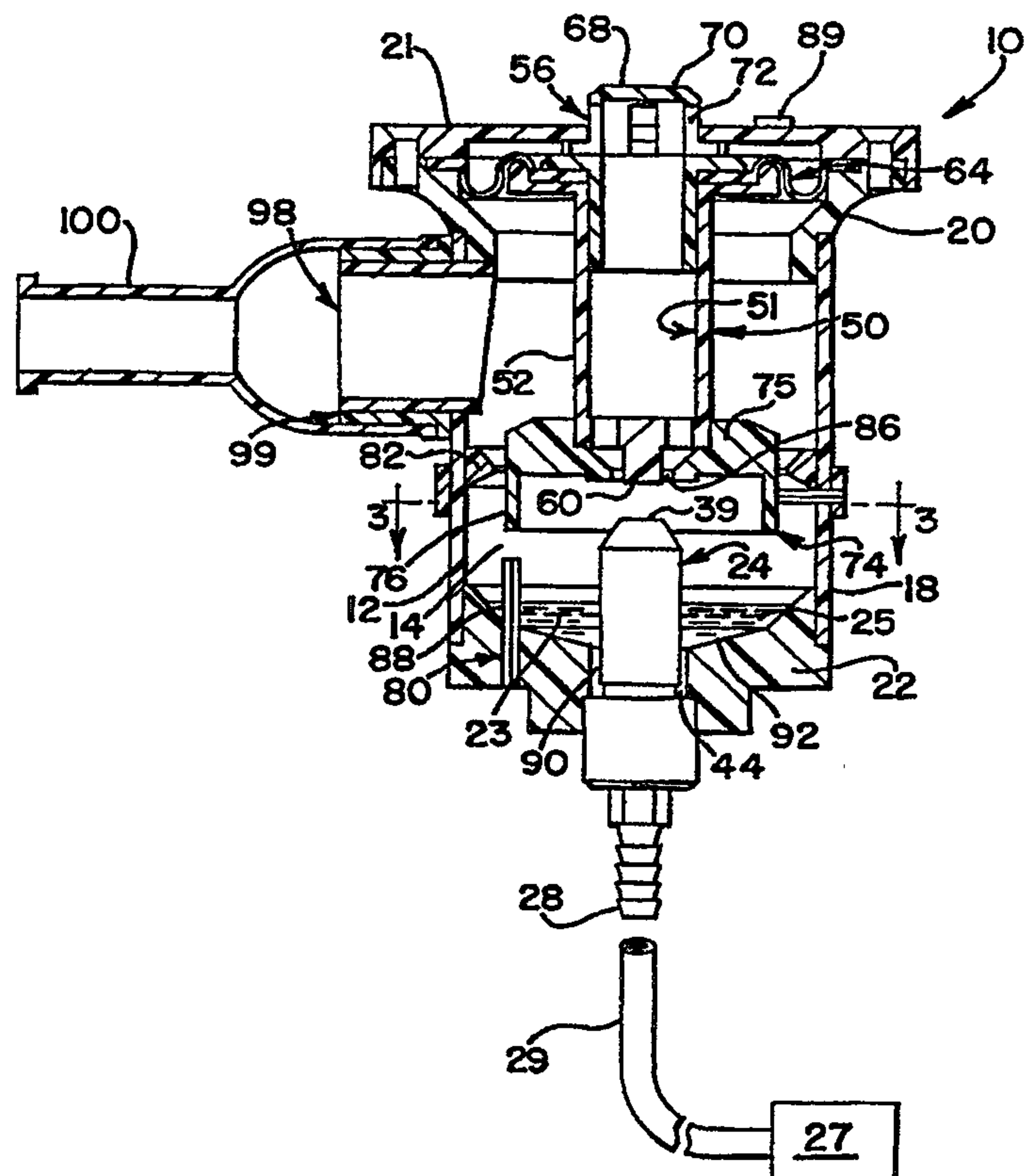
(22) International Filing Date: 13 February 1997 (13.02.97)

(30) Priority Data:
08/600,419 13 February 1996 (13.02.96) US(71) Applicant: TRUDELL MEDICAL LIMITED [CA/CA]; 926
Leathorne Street, London, Ontario N5Z 3M5 (CA).(72) Inventors: GRYCHOWSKI, Jerry, R.; 535 Waterford Drive,
Lake Zurich, IL 60047 (US). BARAN, George; 233 Colette
Drive, London, Ontario N6E 3S9 (CA). FOLEY, Martin, P.;
381 Grangeover Avenue, London, Ontario N6G 3V8 (CA).(74) Agents: MACLEAN, P., Scott et al.; Barrigar & Moss, 7th
floor, 81 Metcalfe Street, Ottawa, Ontario K1P 6K7 (CA).(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR,
BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE,
HU, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS,
LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL,
PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TR, TT, UA,
UG, UZ, VN, YU, ARIPO patent (KE, LS, MW, SD, SZ,
UG), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ,
TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR,
GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF,
BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).**Published***With international search report.*(88) Date of publication of the international search report:
23 October 1997 (23.10.97)

(54) Title: NEBULIZER APPARATUS AND METHOD

(57) Abstract

An apparatus and method for providing a nebula or aerosol to a patient. In one aspect, a nebulizer is pressure sensitive so that nebulization is coordinated with a breathing cycle of the patient. The nebulizer includes a movable gas diverter that diverts pressurized gas across a liquid outlet. The diverter is moved in response to the patient's breathing cycle. In one aspect, a biasing member moves the diverter. According to another aspect of the nebulizer, an annular liquid orifice disperses an aerosol in a radial direction in response to a pressurized gas flow from an orifice located concentrically thereto. Multiple liquid orifices may be provided. In a further aspect of the nebulizer, a reservoir includes an upper, wide portion and a lower narrow portion to apply relatively uniform pressure at a liquid orifice.



1 NEBULIZER APPARATUS AND METHOD

2 BACKGROUND OF THE INVENTION

3 The present invention relates to a method and
4 apparatus for delivering an aerosol, nebulized liquid
5 or solid medicine or a vapor to a patient's respiratory
6 tract, and more particularly, the present invention
7 relates to an improved nebulizer that provides an
8 aerosol more efficiently and with improved particle
9 size uniformity.

10 Medical nebulizers for generating a fine spray or
11 nebula of a liquid medicine that can be inhaled by a
12 patient are well known devices commonly used for the
13 treatment of certain conditions and diseases.
14 Nebulizers have applications in treatments for
15 conscious, spontaneously-breathing patients and for
16 controlled ventilated patients.

17 In some nebulizers, a gas and a liquid are mixed
18 together and directed against a baffle. As a result,
19 the liquid is aerosolized, that is, the liquid is
20 caused to form into small particles that are suspended
21 in the air. This aerosol of the liquid can then be
22 inhaled into a patient's respiratory tract. One way to
23 mix the gas and liquid together in a nebulizer is to
24 pass a quickly moving gas over a liquid orifice tip of
25 a tube. The negative pressure created by the flow of
26 pressurized gas is a factor that contributes to drawing

1 the liquid out of the liquid orifice tip into the
2 stream of gas and nebulize it.

3 Some of the considerations in the design and
4 operation of nebulizers include regulation of dosages
5 and maintenance of consistent aerosol particle size.
6 In conventional nebulizer design, pressurized gas may
7 entrain a liquid against a baffle on a continuous basis
8 until the liquid in a reservoir is depleted.
9 Continuous nebulization may result in a waste of
10 aerosol during a patient's exhalation or during a delay
11 between a patient's inhalation and exhalation. This
12 effect may also complicate regulation of dosages
13 because the amount of wasted aerosol may be difficult
14 to quantify. Also, continuous nebulization may affect
15 particle size and/or density. In addition, there may
16 be excess medication lost to condensation on the
17 nebulizer or mouthpiece during periods of non-
18 inhalation. On the other hand, interrupted
19 nebulization may also affect particle size and density
20 as the nebulization is turned on and off.

21 There are several other considerations that relate
22 to the effectiveness of nebulizer therapies. For
23 example, it has been suggested that nebulization
24 therapy is more effective when the generation of
25 aerosol particles is relatively uniform, for example,
26 producing particles of a particular size, particles
27 within a range of sizes, and/or particles a substantial
28 percentage of which are within a range of sizes. One
29 particle size range that has been considered to be
30 appropriate for inhalation therapy includes a particle
31 size range of approximately 0.5 to 2 microns. Other
32 particle size ranges may be suitable or preferable for
33 particular applications. Generally, large and small
34 size droplets should be minimized. It has also been
35 considered desirable for some inhalation therapies that
36 a substantial percentage, e.g. over 75%, of the aerosol
37 particles be less than approximately 5 microns

1 depending on the desired area of particle deposition in
2 the respiratory tract. In addition, it may be
3 advantageous for a nebulizer to be able to generate a
4 large amount of aerosol quickly and uniformly so that a
5 proper dosage can be administered.

6 Accordingly, with these considerations taken into
7 account, there is a need for an improved nebulizer.

8 SUMMARY OF THE INVENTION

9 The present invention provides a method and
10 apparatus for delivering nebulized liquid or solid
11 medication or vapor to a patient. According to one
12 aspect, the present invention includes a nebulizer that
13 generates an aerosol during inhalation, and sometimes
14 during both inhalation and exhalation, and that can be
15 used both by ventilated patients and spontaneously
16 breathing patients.

17 According to another aspect of the invention,
18 there is provided a nebulizer that is pressure
19 sensitive so that nebulization is coordinated with a
20 natural physiological cycle of the patient, such as the
21 patient's breathing cycle. The nebulizer includes a
22 movable gas diverter that diverts pressurized gas
23 across a liquid outlet. The diverter is moved in
24 response to the patient's breathing cycle. In one
25 embodiment, a biasing member such as membrane, moves
26 the diverter.

27 According to still another aspect of the
28 invention, a nebulizer is provided having an annular
29 liquid orifice that disperses an aerosol in a radial
30 direction in response to a pressurized gas flow from a
31 gas orifice located concentrically thereto.

32 In yet another aspect of the invention, a
33 nebulizer is provided having a chamber with multiple
34 liquid orifices and/or gas orifices located therein.
35 The multiple orifices may be annular orifices. A

1 diverter may be provided to direct gas across the
2 multiple liquid orifices.

3 In a further aspect of the invention, a nebulizer
4 reservoir includes an upper, wide portion and a lower
5 narrow portion to apply relatively uniform pressure at
6 a liquid orifice that draws liquid from the reservoir.

7 BRIEF DESCRIPTION OF THE DRAWINGS

8 Figure 1 is a partial cross-sectional side view of
9 a first embodiment of a nebulizer according to the
10 present invention.

11 Figure 1A is a cross-sectional view of the
12 nebulizer of Figure 1 shown in an inspiration cycle.

13 Figure 2 is a cross-sectional view of the nozzle
14 assembly of the nebulizer of Figure 1.

15 Figure 3 is a cross-sectional top view of the
16 nebulizer of Figure 1 taken along line 3-3' (without
17 the baffle for clarity).

18 Figure 4 is perspective view of the top portion of
19 the nebulizer of Figure 1.

20 Figure 4A is perspective view of the top of the
21 nebulizer shown in the inspiration cycle of Figure 1A.

22 Figure 5 is a cross sectional view of a second
23 embodiment of the nebulizer of the present invention.

24 Figure 6 is a cross sectional view of the bottom
25 of the chimney of the embodiment of Figure 5.

26 Figure 7 is a cross sectional view similar to
27 Figure 6 showing an alternative embodiment the bottom
28 of the chimney of the nebulizer shown in Figure 5.

29 Figure 8 is a cross-sectional view of a portion of
30 the nebulizer of Figure 5 showing the diverter ring.

31 Figure 9 is a cross sectional view similar to
32 Figure 8 showing an alternative embodiment of the
33 diverter ring arrangement for the embodiment of the
34 nebulizer of Figure 5.

1 Figure 10 is a cross sectional view similar to
2 Figure 8 showing another alternative embodiment of the
3 diverter ring arrangement.

4 Figure 11 is a cross sectional view of a third
5 embodiment of the nebulizer of the present invention.

6 Figure 12 is a top view of the embodiment nozzle
7 assembly of Figure 11.

8 Figure 13 is a cross sectional view of the
9 embodiment of Figure 11 taken along line 13-13'.

10 Figure 14 is a cross sectional view of a fourth
11 embodiment of the nebulizer of the present invention.

12 Figure 15 is a cross sectional view of a fifth
13 embodiment of the nebulizer of the present invention.

14 Figure 16 is a cross sectional view of a sixth
15 embodiment of the nebulizer of the present invention.

16 Figures 17A and 17B shows cross sectional views of
17 a seventh embodiment of the present invention.

18 DETAILED DESCRIPTION OF THE
19 PRESENTLY PREFERRED EMBODIMENTS

20 I. First Embodiment

21 A first preferred embodiment of a nebulizer 10 is
22 illustrated in Figure 1. The nebulizer 10 is a small
23 volume nebulizer and includes a housing or container 12
24 defining an internal chamber 14. The housing 12 is
25 formed of a cylindrically-shaped side wall portion 18,
26 a top portion 20, and a bottom portion 22. The
27 component parts of the housing 12 may be formed of
28 separate, multiple pieces of material that are
29 connected together by welding, adhesives, etc., or more
30 preferably, some of the component parts may be formed
31 together of a single piece of material formed by an
32 injection molding process. For example, the bottom,
33 and side portions 22 and 18 may be formed of separate
34 pieces that are connected together, or preferably,
35 these parts may be formed of one piece of molded
36 plastic. Any of a number of plastics may be suitable,
37 including polycarbonate, or polycarbonate blends. A

1 cover 21 is removably mounted on the upper portion of
2 the housing 12, such as by means of a snap-on cover
3 arrangement, twist-lock threads, screws or other types
4 of fasteners. The housing 12 is approximately 6 cm
5 (2.36 in) in height and has a diameter of approximately
6 4 cm (1.57 in).

7 A lower portion 23 of the chamber 14 serves as a
8 reservoir for holding a fluid 25 for nebulizing, such
9 as a solution containing a medication. Located in the
10 lower portion 23 of the housing 12 is a nozzle assembly
11 24. Referring to Figures 1-3, the nozzle assembly 24
12 extends downward from the chamber 14 of the housing 12
13 to a fitting 28 located external of the chamber 14 on a
14 bottom side 22 of the housing 12. The fitting 28 is
15 sized to connect to a supply 27 of pressurized gas
16 provided through conventional tubing 29. The
17 pressurized gas may be supplied by any suitable source,
18 such as a conventional gas supply used in hospitals, a
19 pump, compressor, cartridge, canister, etc.

20 The nozzle assembly 24 is comprised of an outer
21 tubular member 30 and an inner tubular member 32. The
22 inner tubular member 32 has a passageway 34 that
23 extends from an opening 36 in the bottom end of the
24 fitting 28 to a gas outlet orifice 38 located at a top
25 end 39 of the nozzle assembly 24. The inner tubular
26 member 32 is located in an inner passageway 40 of the
27 outer tubular member 30. The inner tubular member 32
28 is sized to slide into the inner passageway 40 of the
29 outer tubular member 30 so that it is aligned therein.
30 A passageway 42 is formed by grooves or slots on the
31 outer surface of the inner tubular member 32 and/or the
32 inner surface of the outer tubular member 30. The
33 passageway 42 extends from an opening 44 located at the
34 reservoir 23 of the lower portion of the chamber 14 to
35 a liquid outlet orifice 46 located at the top end 39 of
36 the nozzle assembly 24. The passageway 42 serves to
37 convey liquid medicine from the reservoir 23 at the

1 bottom of the chamber 14 to the liquid outlet orifice
2 46 at the top of the nozzle assembly 24. (In an
3 alternative embodiment, the passageway 42 may be formed
4 by spaces or regions between fins located on the outer
5 surface of the inner tubular member 32 and/or the inner
6 surface of the outer tubular member 30.)

7 As shown in Figure 3, the liquid outlet orifice 46
8 has an annular shape defined by the top ends of the
9 outer tubular member 30 and the inner tubular member 32
10 of the nozzle assembly 24. The gas outlet orifice 38
11 has a circular shape and is located concentrically of
12 the annular liquid orifice. In one embodiment, the gas
13 outlet orifice 38 is approximately 0.022 inches in
14 diameter and the liquid outlet orifice 46 has an outer
15 diameter of approximately 0.110 to 0.125 inches and an
16 inner diameter of approximately 0.084 inches. These
17 dimensions are provided by way of example and the
18 nebulizer may be made in other sizes with different
19 dimensions as desired.

20 The top end 39 of the nozzle assembly 24 is formed
21 by the top ends of the outer and inner tubular members
22 30 and 32. In a present embodiment, the top end 39 is
23 a generally flat surface having a diameter of
24 approximately 0.18 inches. In alternative embodiments,
25 the top end 39 may have an other-than-flat shape, for
26 example, the inner tubular member 32 may be spaced
27 above the outer tubular member 30 so that the liquid
28 orifice 46 is located below the gas orifice 38.

29 The nozzle assembly 24, or a portion thereof, may
30 be formed as part of the housing 12 as a single piece
31 of material in an injection molding process. For
32 example, the inner tubular member 32 may be formed of
33 the same piece of injected molded plastic as the bottom
34 of the housing 12.

35 Referring again to Figure 1, the nebulizer 10 also
36 includes a chimney assembly 50. The chimney assembly
37 50 is located in an upper portion of the chamber 14

1 above the liquid reservoir 23. The chimney assembly 50
2 includes a tubular body 51 that defines an internal
3 passageway 52 that extends from an inlet opening 56 in
4 the housing cover 21 to an outlet opening 58 at a
5 bottom end of the tubular body 51. Thus, the chimney
6 assembly 50 serves as an inlet channel for ambient air
7 to enter into the chamber 14. The inlet opening 56
8 communicates with ambient air (through ports of an
9 actuator button, as described below) and the outlet
10 opening 58 communicates with the chamber 14.

11 Located on the lower end of the chimney assembly
12 50 is a diverter 60. The diverter 60 may be formed of
13 the same piece of molded plastic material as the
14 chimney 50 or alternatively, the diverter 60 may be
15 formed of a separate piece of material that is attached
16 by suitable means to the rest of the chimney assembly
17 50. (The diverter may also be provided pneumatically,
18 for example by an opposing gas source located directly
19 opposite the nozzle.) The diverter 60 is located
20 directly opposite from the gas outlet orifice 38 and
21 the liquid outlet orifice 46 located at the top end 39
22 of the nozzle assembly 24. The diverter 60 is movable
23 so that the distance between the diverter 60 and the
24 top surface 39 of the nozzle assembly 24 can be varied.
25 The diverter 60 has of a flat circular shape with a
26 diameter of approximately 0.18 inches so that it
27 extends over both the gas and liquid orifices 38 and 46
28 out to approximately the edge of the top surface 39 of
29 the nozzle assembly 24.

30 The chimney assembly 50 is connected to the
31 housing 12. Specifically, the chimney assembly 50 is
32 attached to the top portion 20 of the housing 12 by
33 means of a membrane or diaphragm 64. The membrane 64
34 is a ring-shaped piece of a flexible, resilient
35 material, such as silicone rubber. An outer rim or
36 bead of the membrane 64 is secured in a groove in the
37 top portion 20 of the housing 12 and/or the cover 21.

1 An inner rim of the membrane 64 is secured in a slot
2 formed by two parts of the chimney assembly 50. The
3 membrane 64 has a rolled cross-sectional profile as
4 shown in Figure 1. This permits the membrane 64 to act
5 as a rolling diaphragm. The membrane 64 permits
6 limited movement of the chimney assembly 50. The
7 chimney assembly 50 is connected to the membrane 64 so
8 that the membrane 64 biases the chimney assembly 50
9 away from the nozzle assembly 24 as shown in Figure 1.
10 When installed in the manner shown in Figure 1, the
11 bottom of the chimney assembly 50 is approximately 0.15
12 inches away from the top surface of the nozzle assembly
13 24.

14 Located at the top end of the chimney assembly 50
15 is an actuator 68. The actuator 68 connects to the
16 tubular body 51 of the chimney assembly 50 and extends
17 through the opening 56 at the top of the housing 12 in
18 the cover 21. The actuator 68 includes a closed top
19 side 70 with one or more side opening ports 72.

20 Referring to Figure 4, located on the sides of the
21 body of the actuator 68 are indicators 69A and 69B.
22 The indicators 69A and 69B may be formed of colored
23 markings or parallel rings on the sides of the actuator
24 68. In a preferred embodiment, the indicator 69A is
25 red and is located next to the top side 21 of the
26 nebulizer body 12. The indicator 69B is preferably
27 green and is adjacent to and above the indicator 69A.

28 Located in the chamber 14 at the bottom end of the
29 chimney assembly 50 is a bell-shaped baffle 74. The
30 baffle 74 extends from the opening 58 at the bottom of
31 the chimney passageway 51 outward toward the inside
32 wall of the cylindrical portion 18 of the housing 12.
33 The baffle 74 includes a horizontal portion 75 and a
34 vertical portion 76 that extends downward from the
35 horizontal portion 75 toward the top of the nozzle
36 assembly 24. The baffle 74 has an open bottom side

1 providing an air passageway around the bottom side of
2 the cylindrical vertical wall 76.

3 As mentioned above, the diverter 60 is movable
4 relative to the nozzle assembly 24. The present
5 embodiment provides a means to limit the travel of the
6 diverter relative to the nozzle assembly 24. This may
7 be accomplished in any of several suitable ways. In a
8 present embodiment, the movement of the diverter 60
9 toward the nozzle assembly 24 is limited by one or more
10 stop pins 80. The stop pins 80 extend up from the
11 bottom portion 22 of the housing. In a present
12 embodiment, there are three stop pins. The top ends of
13 the stop pins 80 are spaced away from the bottom end of
14 the vertical wall 76 of the baffle 74. Because the
15 chimney assembly 50 is movable vertically due to its
16 connection to the housing 12 by means of the flexible
17 membrane 64, the stop pins 80 provide a lower limit to
18 the movement of the chimney assembly 50. In a present
19 embodiment, the stop pins 80 are spaced so that when
20 the lower edge of the vertical wall 76 of the baffle 74
21 is brought into contact with the stop pins 80, a space
22 'h' is provided between the diverter 60 and the upper
23 surface 39 of the nozzle assembly 24. In a preferred
24 embodiment, the space 'h' is approximately between
25 0.025 and 0.045 inches, or more preferably
26 approximately between 0.030 and 0.040 inches, and most
27 preferably approximately 0.033 inches.

28 In alternative embodiments, movement of the
29 diverter 60 toward the nozzle assembly 24 may be
30 limited by means other than stop pins. For example, if
31 the housing were formed by an injection molding
32 process, steps, shoulders, fins, or other structures,
33 may be provided along the walls of the housing in order
34 to limit the downward travel of the chimney and/or
35 diverter.

36 Also located in the chamber 14 is a diverting ring
37 82. The diverting ring 82 is located on the inner wall

1 of the cylindrical portion 18 of the housing 12.
2 Specifically, the diverting ring 82 is positioned
3 adjacent to the baffle 74. The diverting ring 82 is
4 sized to define a gap 86 around the baffle 74. The
5 diverting ring 82 serves to impede large droplets of
6 liquid that might form on the inner wall of the housing
7 12 and divert large droplets back down into the
8 reservoir 23 at the bottom of the housing 12. In
9 addition, the diverting ring 82 serves to provide a
10 relatively tortuous path for the flow of aerosol
11 particles from the lower portion of the chamber 14 to
12 the upper portion. This tortuous path also serves to
13 reduce the presence of larger particles and helps to
14 make the particle size distribution more uniform.

15 As mentioned above, the bottom of the chamber 14
16 serves as a reservoir 23 for a liquid to be nebulized.
17 In a present embodiment, the reservoir has a funnel-
18 like shape to direct the liquid to be nebulized in a
19 downward direction toward the inlet 44. The reservoir
20 portion of the chamber 14 is formed of at least two
21 portions or stages. In a present embodiment, an upper
22 portion 88 of the reservoir is relatively wide having a
23 diameter approximately the same as that of the
24 cylindrical portion 18 of the housing 12 (e.g. 2.36
25 in). The upper portion 88 is relatively shallow (e.g.
26 0.3125-0.25 in). The upper portion 88 of the reservoir
27 tapers in a funnel-like manner toward a lower portion
28 90 (or secondary well) of the reservoir. The lower
29 portion 90 is relatively narrow, but relatively deep
30 (e.g. 0.25 in). The lower portion 90 of the reservoir
31 is slightly wider (e.g. 0.625 in) than the outer
32 diameter of the nozzle assembly 24. The opening 44
33 from which the liquid is drawn is located at the bottom
34 of the lower portion 90 of the reservoir. In a present
35 embodiment, the reservoir 23 also includes an
36 intermediate portion 92 located between the upper
37 portion 88 and the lower portion 90. The intermediate

1 portion 92 of the reservoir 23 has a height and a width
2 between that of the upper and lower portions.

3 In the embodiment of the nebulizer shown in
4 Figure 1, the relative sizes and dimensions of the
5 upper, lower and intermediate portions of the reservoir
6 23 contribute to the generation of an aerosol wherein
7 the aerosol particle size and output is relatively
8 uniform overall. As described more below, the liquid
9 in the reservoir 23 is drawn through the opening 44 and
10 up the liquid passageway 42 in part by the negative
11 pressure caused by the flow of gas across the liquid
12 orifice 46. The suction force provided by the gas flow
13 both draws the liquid up out of the reservoir to the
14 top of the nozzle and entrains the liquid with a
15 certain velocity in the air flow. As the liquid is
16 nebulized, the surface level of the liquid in the
17 reservoir goes down, thereby directly increasing the
18 distance that the liquid has to be drawn up out of the
19 reservoir to the orifice at the top of the nozzle. As
20 the distance of the top of the nozzle over the liquid
21 surface increases, more energy is required to draw the
22 liquid up to the liquid orifice at the top of the
23 nozzle assembly 24. Assuming a relatively constant gas
24 pressure, this increasing distance may have the effect
25 of decreasing liquid flow through the liquid orifice
26 which in turn may affect the uniformity of the aerosol
27 particle size and rate.

28 The embodiment of the nebulizer in Figure 1
29 reduces this possible adverse effect. With the
30 embodiment of Figure 1, a relatively large portion of
31 the liquid is stored in the upper portion 88 of the
32 reservoir and a relatively smaller portion of the
33 liquid is stored in the lower portion 90 of the
34 reservoir. Since the large portion 88 of the reservoir
35 is wide and relatively shallow, the surface level of
36 the liquid in the reservoir changes relatively slightly
37 as the liquid in this portion of the reservoir is drawn

1 down. Therefore, there is little change in the energy
2 needed to draw this amount of liquid up from the
3 reservoir to the liquid orifice 46 as this portion of
4 the liquid is depleted. When all the liquid in the
5 upper portion 88 of the reservoir is nebulized, the
6 remaining liquid in the lower portion 90 of the
7 reservoir is drawn into the liquid passageway 42 and
8 the height of the top surface of the liquid falls
9 rapidly. However, since the lower portion 90 of the
10 reservoir is relatively narrow, it contains only a
11 small portion of the liquid being nebulized so there is
12 relatively little overall effect on aerosol particle
13 size and output from this portion of the liquid.

14 Another advantage provided by the funnel shape of
15 the reservoir is that the relatively narrow size of the
16 lower portion 90 of the reservoir has less surface area
17 thereby directing the liquid toward the opening 44.
18 This causes most or all of the liquid to be directed to
19 opening 44 with little waste.

20 The nebulizer 10 of Figures 1-3 may also include a
21 sensor 89. The sensor 89 may be attached to the
22 housing 12 at any suitable location, such as on the
23 cover 21, as shown in Figure 1. The sensor 89 monitors
24 the operating cycles of the nebulizer 10. The sensor
25 89 may monitor operating cycles by monitoring the
26 movement of the chimney portion 50 relative to the
27 housing body 12. The sensor 89 may utilize any
28 suitable technology, such as electronic, pneumatic, or
29 mechanical. For example, the sensor may be responsive
30 to a change in local capacitance as the chimney moves
31 closer and further from the top of the housing.
32 Alternatively, the sensor may be responsive to a
33 embedded magnet, or may measure an optical parameter,
34 etc. The sensor 89 monitors the cycles of operation
35 and provides a count that can be observed by the user
36 or a medical care provider. This enables the user or
37 care provider to estimate how much medication has been

1 delivered. The sensor 89 includes a display or similar
2 device for this purpose. In addition, the sensor may
3 also include appropriate programming to report on the
4 duration, frequency, speed, etc. of nebulizer
5 operation. These parameters may also be provided to
6 inform the patient or care provider about the delivery
7 of medication. This embodiment of the nebulizer may
8 also include appropriate programming to limit the
9 amount of medication or drugs that can be administered.
10 For example, if the nebulizer is used to deliver drugs
11 for pain control, such as morphine, the nebulizer can
12 be programmed to limit the amount of such drugs that
13 can be delivered to the patient.

14 The embodiment of the nebulizer shown in Figures
15 1-3 is adapted for use by a spontaneously breathing
16 patient, so the aerosol from the nebulizer is output to
17 a mouthpiece or mask that can be used by the
18 spontaneously breathing patient. Accordingly, located
19 in an upper portion of the chamber 14 is an adapter 99
20 having an outlet 98 that connects to a mouthpiece 100.
21 In alternative embodiments, as described further below,
22 the nebulizer may be used with ventilator systems and
23 instead of the mouthpiece 100, the adapter 99 would
24 connect the outlet 98 to the ventilator circuit.

25 To operate the nebulizer 10, a suitable amount of
26 a liquid such as a medicine or water is placed in the
27 reservoir of the chamber 14. The liquid may be placed
28 in the reservoir by first removing the cover 21,
29 membrane 64, and chimney 50, filling an appropriate
30 amount of liquid into the reservoir, and replacing the
31 cover 21, membrane 64, and chimney 50 onto the housing
32 12. In a preferred embodiment, the cover, membrane and
33 chimney are assembled together and would be removable
34 together as a unit. (Alternatively, the liquid may be
35 placed into the reservoir through the mouthpiece 100,
36 or further, the nebulizer may be provided pre-filled
37 with the appropriate amount of medicine from the

1 manufacturer, or in yet another alternative, the
2 nebulizer may be provided with a resealable fill port.)
3 The source of pressurized gas 27 is connected to the
4 fitting 28. The source of pressurized gas 27 may be an
5 external source that provides gas at a rate of 4 to 10
6 liters per minute in a range from 35 p.s.i to 50 p.s.i,
7 although other rates and pressures could also be
8 suitable. Gas is delivered through the passageway 34
9 and is expelled from the gas outlet orifice 38 into the
10 chamber 14. However, at this stage, prior to
11 inhalation by the patient, the gas travels upward from
12 the gas outlet orifice 38 and nebulization does not
13 occur since the diverter 60 is in the non-nebulizing
14 position. The membrane 64 holds the chimney assembly
15 50, including the diverter 60, away from the nozzle 24.
16 When in the non-nebulizing position, the distance
17 between the diverter 60 and the top of the nozzle is
18 approximately 0.15 inches. At this distance, the gap
19 between the diverter 60 and the nozzle 24 is such that
20 the flow of gas does not create sufficient negative
21 pressure over the liquid orifice 46 to draw out the
22 liquid.

23 To generate an aerosol with the nebulizer, the
24 patient places the mouthpiece 100 to his/her mouth.
25 When the patient inhales, air is withdrawn from the
26 chamber 14 reducing the pressure inside the housing 12.
27 The lower pressure in the chamber 14 causes the
28 membrane 64 to flex drawing the chimney 50 down. The
29 lower position of the chimney 50 is shown in Figure 1A.
30 Downward movement of the chimney 50 is limited by the
31 stop pins 80. When the stop pins 80 limit the downward
32 movement of the chimney 50, the diverter 60 is spaced a
33 predetermined distance 'h' from the top surface 39 of
34 the nozzle assembly 24. In a present embodiment, the
35 gap 'h' is approximately 0.033 inches.

36 The pressurized gas, which may be continuously
37 injected into the nebulizer through the fitting 38, is

1 diverted sideways approximately 90° by the diverter 60.
2 Since the gas outlet orifice 38, diverter 60 and nozzle
3 top 39 are generally circular, gas exiting the orifice
4 38 is dispersed evenly in an approximately 360° or
5 radial pattern. The liquid medicine in the reservoir
6 is then drawn up the passageway 42 and out of the
7 liquid outlet orifice 46 in part by the negative
8 pressure caused by the moving gas passing over the
9 liquid outlet orifice. The liquid drawn into the
10 diverted gas stream is aerosolized at least by the time
11 it reaches the larger volume space of the chamber. In
12 a present embodiment, the liquid medicine drawn out of
13 the liquid orifice 46 has little or no impaction
14 against the diverter 60. However, in an alternative
15 embodiment, the liquid drawn into the gas stream may be
16 directed against the diverter 60.

17 As the liquid is nebulized it travels into the
18 chamber 14 along a path around the lower edge of the
19 baffle 74. As the patient inhales, the nebulized
20 liquid travels upward through the gap 86 between the
21 baffle 74 and the diverting ring 82, and out through
22 the mouthpiece 100 to the patient's respiratory tract.

23 When the patient ceases to inhale, the pressure in
24 the chamber 14 rises. The biasing of the membrane 64
25 is again sufficient to move the chimney 50 upward,
26 increasing the distance between the diverter 60 and the
27 top surface 39 of the nozzle assembly 24, and causing
28 nebulization of the liquid to cease. In alternative
29 embodiments, a spring, pneumatic valve, or other
30 biasing device may be utilized, alone or in combination
31 with each other and the membrane, to move the diverter
32 60 into a non-nebulizing position. Thus, the nebulizer
33 automatically cycles aerosol generation in time with
34 the breathing cycle of the patient.

35 If the patient exhales into the nebulizer, no
36 nebulization occurs since the diverter 60 is in the
37 non-nebulizing position due to the biasing of the

1 membrane 64. Upward travel of the chimney 50 is
2 limited by the cover 21.

3 During inhalation, some air flow may be provided
4 through the nebulizer in a path through the chimney 50.
5 This air flow into the chamber 14 may be provided from
6 ambient in a path provided through the ports 72, the
7 chimney inlet 56, the chimney passageway 52, and the
8 chimney outlet 58. This air flow may continue during
9 both inhalation when the chimney 50 is in the lower
10 position and exhalation when the chimney is in the
11 higher position. Alternatively, the air flow through
12 the chimney 50 may be stopped or reduced during
13 inhalation when the chimney 50 is in the lower
14 position. Control of the airflow through the nebulizer
15 during inhalation or exhalation may be effected by
16 suitable selections of the dimensions of the chimney
17 inlet 56, the chimney outlet 58, the actuator ports 72,
18 the diverter ring 82, and other components that affect
19 airflow through the chamber, such as any filters.

20 In the embodiment described above, the membrane 64
21 provides an elastic triggering threshold that permits
22 cyclical nebulization to occur that coincides with the
23 breathing of the patient. This threshold is set to
24 fall within normal human breathing parameters so that
25 the diverter moves into and out of proximity with the
26 nozzle top as a result of the patient's normal
27 breathing. In one embodiment, this level may be
28 approximately less than or equal to 3.0 cm of water.
29 It can be appreciated that the threshold may be
30 established at different levels to account for
31 different classes of patients. For example, if the
32 nebulizer is designed to be used with infants or neo-
33 nats, the elastic threshold of the membrane may be
34 lower than the threshold used for adults. Similarly, a
35 different threshold may be used for geriatric patients.
36 The nebulizer may be used also for veterinary
37 applications, such as equine or canine. In veterinary

1 applications, there may be a relatively wide range of
2 thresholds related to the various sizes of animals.
3 Nebulizers having suitably chosen operating thresholds
4 can be designed for veterinary uses. It is also
5 recognized that the openings into the chamber, such as
6 the opening 56, may affect the operating threshold for
7 nebulization. Thus, the operating threshold of the
8 nebulizer may be made readily adjustable by making the
9 actuator 68 adjustable. Alternatively, the operating
10 threshold may be adjusted by selection of the size of
11 the openings 56 and 72 into the chamber which would
12 also control air entrainment. This would permit the
13 user to adjust the thresholds, if desired. By
14 appropriate adjustment of the operating thresholds,
15 flow control through the nebulizer can be provided.
16 For example, it may be desirable that the patient not
17 inhale or exhale too quickly or too deeply. For
18 adults, a suitable flow rate may be approximately 30-60
19 liters/minute. The openings into and out of the
20 chamber may be suitably adjusted to provide for these
21 rates.

22 The nebulizer may be operated manually instead of
23 relying on the breath-actuated feature. To operate the
24 nebulizer manually, the actuator 70 is pressed down
25 toward the cover 21. As mentioned above, the actuator
26 70 is connected to the chimney 50. Pressing the
27 actuator 70 brings the diverter 60 down into the
28 nebulizing position close to the nozzle 24. Release of
29 the actuator 70 causes the chimney 50 to rise due to
30 the biasing of the membrane 64 thereby causing
31 nebulization to cease.

32 Referring to Figures 4 and 4A, the indicators 69A
33 and 69B provide a convenient way to confirm the
34 operation of the nebulizer. As mentioned above, when
35 the diverter 60 is spaced away from the top of the
36 nozzle 24, no aerosol is being generated. When the
37 diverter 60 is spaced away the actuator 68, the

1 actuator 68, which is connected to the diverter 60
2 through the chimney 50, is in an upper position and the
3 red indicator 69A on the side of the actuator 68 is
4 visible along the top side 21 of the nebulizer 10, as
5 shown in Figure 4. When the patient inhales
6 sufficiently to bring the diverter 60 into a lower
7 position, the red indicator 69A on the side of the
8 actuator 68 is withdrawn through the opening 56 in the
9 top side 21 of the nebulizer 10. The red indicator 69A
10 is no longer visible, however, the green indicator 69B,
11 which is located above the red indicator 69A, remains
12 visible at the top 21 of the nebulizer. Thus, a
13 patient or medical attendant can readily determine
14 whether the nebulizer is operating. In embodiments of
15 the nebulizer for children, the actuator and/or
16 indicators can be designed with comic figures.

17 The breath actuation of the nebulizer is
18 convenient and efficient. By cycling the nebulization
19 of the liquid, the nebulizer can be more efficient
20 thereby reducing the cost of the therapy.

21 An important advantage follows from the feature of
22 this nebulizer that nebulization can be cycled so as to
23 occur in coordination with a physiological cycle of the
24 patient. Specifically, by nebulizing only during an
25 inhalation, for example, the dosage of medication
26 delivered to the patient can be more accurately
27 delivered and monitored. This enables this embodiment
28 of the nebulizer to provide for dosimetric medication
29 delivery to an extent that has been otherwise
30 unavailable. By limiting the medication delivery to
31 the inhalation cycle of the patient, a dosimetric
32 portion of the medication can be provided.

33 In addition, the nebulizer 10 provides for high
34 output and uniform nebulization due to the arrangement
35 of the gas and liquid orifices 38 and 46 relative to
36 the diverter 60. The annular configuration of the
37 liquid orifice 46 relative to the gas orifice provides

WO 97/29799

PCT/CA97/00096

1 for aerosol generation in a approximately 360°
2 direction. This enables a relatively high and uniform
3 rate of nebulization. The uniformity is enhanced
4 because the nebulization is formed with little or no
5 impaction of liquid against the diverter.

6 In alternative embodiments of the nebulizer, the
7 cover 12 may include an air filter that covers the air
8 inlet 56. The filter would serve to keep contaminants
9 out of the chamber and deter the escape of nebulized
10 liquid. Such a filter may be removable to permit
11 simple, inexpensive replacement.

12 In a still further embodiment, the nebulizer may
13 be used in conjunction with an aerosolization spacer,
14 such as an Aerochamber® sold by Trudell Medical
15 Partnership of London, Ontario. The Aerochamber spacer
16 is described in U.S. Pat. No. 4,470,412.

17 In this alternative embodiment, the output of
18 the nebulizer would be directed into the inlet of the
19 Aerochamber from which the patient inhales the aerosol
20 through an outlet of the Aerochamber.

21 Another advantage provided by this embodiment of
22 the nebulizer is that less aerosol is likely to escape
23 to the surrounding environment. This potentially
24 benefits attending care providers who would otherwise
25 be exposed to aerosol medication that is released from
26 nebulizers that generate on a continuous basis.

27 In a present embodiment, the membrane 64 is biased
28 to keep the chimney in an upper, non-nebulizing
29 position except during inhalation. Thus, in the
30 periods of time between inhalations and exhalations, or
31 if the patient pauses and removes the mouthpiece,
32 nebulizing does not take place. In alternative
33 embodiments, the membrane 64 may bias the chimney
34 downward so that the nebulizer generates an aerosol or
35 nebula except during exhalation. This alternative may
36 not be as efficient as the prior alternative, but may
37

1 still provide significant advantages over nebulizers
2 that generate aerosol continuously.

3 In further alternative embodiments of the
4 nebulizer, the gas orifice 38, the gas passageway 34,
5 or a portion thereof, may have a shape that modifies
6 the force of the pressurized gas against the diverter
7 60. For example, the gas orifice 38 may have a conical
8 shape that facilitates the change of direction of the
9 gas when it is directed against the diverter, so that
10 the force of the gas would not move the diverter away
11 during inhalation thereby helping to direct the gas out
12 into the chamber. In other embodiments, the conical
13 geometry may be varied to tailor gas force and flow.

14 As mentioned above, the membrane 62 serves as a
15 biasing member that moves the diverter. Preferably,
16 the membrane is constructed of a silicone rubber
17 material. Other materials capable of repetitive
18 flexing, compression or expansion in response to the
19 force of inhaled or exhaled air, such as a spring, or
20 elastic bellows, may also be used. The biasing member
21 is constructed so that it will move the diverter a
22 predetermined distance away from or toward the nozzle
23 during the course of a patient's spontaneous or
24 ventilated breathing.

25 In a present embodiment, the diverter moves up and
26 down in response to the patient's breathing. However,
27 in alternative embodiments, the nozzle 24 can move
28 instead of the diverter, or alternatively, both the
29 nozzle and the diverter can move. Also, in a present
30 embodiment, the diverter movement is up and down, but
31 in alternative embodiments, the movement can be side to
32 side, rotating, or pivoting. Alternatively, instead of
33 moving diverter into proximity with a gas outlet, in
34 alternative embodiments, the liquid jet or orifice can
35 be moved toward the gas jet or orifice, or is otherwise
36 directed toward the gas jet or orifice, or vice versa.
37 In effect, alternative embodiments contemplate various

1 means of bringing or diverting the gas and liquid
2 streams into proximity in a cyclical basis.

3 In alternative embodiments of the nebulizer, the
4 liquid orifice may have shapes other than annular. For
5 example, the liquid orifice may be located adjacent to
6 the gas orifice. Alternatively, the liquid orifice may
7 be formed of a series of orifices positioned adjacent
8 or annularly around the gas orifice.

9 The nebulizer 10 may also be provided with a
10 plurality of support legs (not shown) that are
11 connected around the exterior of the housing 12 and
12 provide support therefor.

13 In this embodiment, the diverter 50 moves into
14 proximity with the nozzle 24 due to a negative pressure
15 in the chamber 14. However, the pressure variance may
16 also be created by a variance in positive pressure, or
17 a combination of positive and negative pressures.

18 II. Second Embodiment

19 A second embodiment of a nebulizer is shown in
20 Figure 5. According to this embodiment, a nebulizer
21 110 has a housing 112 that defines a chamber 114. A
22 lower portion of the chamber 114 serves as a reservoir
23 123 for holding a liquid to be nebulized. Located in a
24 lower portion of the housing 112 is a nozzle assembly
25 124. The nozzle assembly 124 may be similar or
26 identical to the nozzle assembly of the first
27 embodiment, described above. Like the first
28 embodiment, a bottom of the nozzle
29 assembly 124 has a fitting 128 that can be connected to
30 a supply of pressured gas 127 by means of conventional
31 tubing 129. Located in the nozzle assembly 124 are
32 inner and outer tubular members that define gas and
33 liquid passageways that exit at gas and liquid orifices
34 at the top of the nozzle assembly 124, as in the first
35 embodiment. Like the first embodiment, the gas and
36 liquid orifices preferably have a concentric

1 arrangement with the liquid orifice having an annular
2 shape encircling the gas outlet orifice. Also, like
3 the first embodiment, in the embodiment of Figure 5 the
4 reservoir 123 includes a relatively wide, but shallow,
5 primary or upper portion 188 and a relatively narrow,
6 but deep, lower or secondary portion 190.

7 Although this embodiment is shown without a bell-
8 shaped baffle similar to baffle 74 of the first
9 embodiment, a baffle may be provided in this
10 embodiment. If a baffle were provided in this
11 embodiment, it would have a construction similar to
12 that of the baffle 74 of Figure 1.

13 In the embodiment of Figure 5, a chimney 150 is
14 located in an upper portion of the housing 112. The
15 chimney includes a first internal passageway 152. In
16 this embodiment, the internal passageway 152 of the
17 chimney assembly 150 serves as an outlet 198 from the
18 chamber 114. The outlet connects to a mouthpiece 199,
19 or other suitable means of delivering an aerosol to a
20 patient, such as a mask. A diverter 160 is located at
21 and connected to a lower end of the chimney 150. The
22 diverter 160 is located a predetermined distance from
23 the top of the nozzle assembly 124. In this
24 embodiment, this distance is approximately 0.033
25 inches. Unlike the first embodiment, the chimney
26 assembly 150 in this embodiment 110 is not movable
27 between upper and lower positions. Instead, the
28 chimney assembly 150 is fixed in position so that the
29 diverter 160 is maintained a suitable distance from the
30 top of the nozzle assembly 124 to generate an aerosol.

31 In this embodiment, at least one second air
32 passageway 153 is provided. The second air passageway
33 153 is located adjacent to the first air passageway 152
34 in the chimney assembly 150. The second air passageway
35 153 communicates with an inlet opening 161 and a
36 suction chamber 163. The suction chamber 163 is
37 located around a lower end of the chimney assembly 150

1 and specifically, around the perimeter of the diverter
2 160. An opening 158 communicates between the suction
3 chamber 163 and the chamber 114. As pressurized gas
4 and nebulized liquid flow past the perimeter of the
5 diverter 160, a pressure variance is created that draws
6 air from ambient through the inlet opening 161 through
7 the second passage way 153 into the suction chamber
8 163. In one embodiment, the pressure variance is a
9 negative pressure, however, the pressure variance may
10 also be created by a variance in positive pressure, or
11 a combination of positive and negative pressures. The
12 suction provided at the opening 158 serves to enhance
13 generation of the aerosol.

14 A nebulizing enhancement feature provided by the
15 nebulizer 110 relates to the shape of wall 171 around
16 the opening 158. As shown in Figures 5 and 6, the
17 shape of the wall 171 includes a first region 173 and a
18 second region 175. The first region 173 is separated
19 from the second region 175 by a step or shoulder 177.
20 The first region 173 and the second region 175 are
21 preferably horizontal, flat surfaces and the shoulder
22 177 is preferably a vertical surface. The wall 171
23 also includes a third region 179. The third region 179
24 is located around the second region 175. The third
25 region 179 is a sloped or angled surface that extends
26 from the second region 175 to a gap 186 formed adjacent
27 to a diverting ring 182.

28 The shapes of the first, second and third regions
29 173, 175 and 177 affect the air flow in the chamber
30 from the diverter. The relative sizes and shapes may
31 be varied to enhance particle size generation and
32 uniformity. An alternative embodiment of the wall 171
33 and regions 173, 175, and 177 is shown in Figure 7. In
34 the embodiment of the wall 171A shown in Figure 7, the
35 relative sizes of the first region 173A, second region
36 175A, and third region 177A are modified relative to
37 those in the embodiment of Figure 6. These sizes are

1 varied to affect the size and uniformity of the
2 particle distribution of the nebula or aerosol.

3 Referring again to Figure 5, located in a wall of
4 the chimney 150 is at least one, and preferably a
5 plurality of openings 185. Openings 185 communicate
6 between the chamber 114 and the first air passageway
7 152 of the chimney assembly 150.

8 Referring to Figures 5 and 8, a diverting ring 182
9 may be provided in the chamber 114 to reduce the
10 presence of large droplets and help make the aerosol
11 delivered to the patient more uniform. As mentioned
12 above in connection with the first embodiment, the
13 diverting ring provides this function, in part, by
14 limiting the migration of droplets on the inside wall
15 of the nebulizer housing. In addition, by forming a
16 barrier on the inside wall of the housing, the
17 diverting ring forces the nebulized aerosol to travel
18 along a relatively non-linear path to move from the
19 lower part to the upper part of the chamber and out the
20 mouthpiece.

21 Referring to Figure 5, to operate the nebulizer
22 110, a suitable amount of liquid medicine is placed in
23 reservoir of the chamber 114. The outlet 198 is
24 connected to the mouthpiece 199 in a suitable manner.
25 The source of pressurized gas 127 is connected to the
26 fitting 128. The flow of gas from the top of the
27 nozzle assembly 124 is directed by the diverter 160
28 across the annular liquid orifice surrounding the gas
29 orifice causing the generation of an aerosol from the
30 liquid in the reservoir. The aerosol is generated in a
31 360° direction into the chamber 114 around the nozzle
32 124 and diverter 160.

33 An air flow path is established into the chamber
34 114 from the inlet 161. The gas provided by the source
35 127 also supplements the air supply into the chamber
36 114. Air flows into the chamber through the second
37 passageway 153 through the suction chamber 163 and

1 opening 158. Air flow laden with aerosolized liquid
2 from the chamber 114 travels past the gap 186, through
3 the opening 185, into the first air passageway 152, and
4 out from the outlet opening 198 to the mouthpiece 199
5 or face mask. In this embodiment, nebulization may
6 proceed continuously, or may be cycled by other means,
7 such as cycling of the gas supply.

8 Alternative embodiments of the diverting ring
9 arrangement are shown in Figures 9 and 10. In Figure
10 9, the diverting ring 182A extends further toward the
11 chimney 150 almost overlapping an edge 183A at the
12 bottom 150A of the chimney 150. This arrangement
13 provides an even more tortuous pathway for the aerosol
14 than the embodiment shown in Figure 8. The embodiment
15 of Figure 8 may provide an even more uniform particle
16 distribution. In Figure 10, the passageway between the
17 diverting ring 182B and the bottom 150B of the chimney
18 is extended thereby providing a longer pathway of a
19 narrow dimension. The embodiment of Figure 10 may
20 provide an even more uniform particle distribution than
21 the embodiments of Figures 8 or 9.

22 III. Third Embodiment

23 A nebulizer 210 according to another embodiment of
24 the invention is shown in Figures 11-13. The nebulizer
25 210 is similar to the previous embodiments of the
26 nebulizers discussed above. The nebulizer 210 includes
27 a housing 212 defining a chamber 214. In the
28 embodiment of Figure 11, the housing 212 is relatively
29 larger than the housings of the previous embodiments.
30 For example, the housing 212 may have a height of
31 approximately 11 cm (4.33 in.) and a diameter of
32 approximately 9 cm (3.54 in.). This enables the
33 nebulizer 210 to hold a correspondingly larger volume
34 of liquid and aerosol. A large size nebulizer, such as
35 shown in Figure 11, may be suitable for certain
36 veterinary applications such as for horses, cattle,

1 dogs, etc. A larger size nebulizer may also be used
2 with humans for uses such as sputum induction.

3 A fitting 238 connects to a pressurized gas supply
4 (not shown) and an outlet 298 provides nebulized
5 medicine from the chamber 214 to the patient. The
6 outlet 298 may connect to a mouthpiece, mask, or
7 ventilator, as appropriate. Like the first described
8 embodiment, the nebulizer 210 has a movable chimney
9 250. In the chamber 214 of the nebulizer 210, there
10 are a plurality of nozzle assemblies 224A, 224B, and
11 224C. Each of these nozzle assemblies may be similar
12 to the nozzle assembly 24 of the first embodiment.
13 Each of the nozzle assemblies includes a gas supply
14 passageway, such as 234A, and an annular liquid supply
15 passageway, such as 242A. At the top ends of each of
16 the nozzles 224A, 224B, and 224C, the gas passageways
17 of each communicate with gas outlet orifices 238A,
18 238B, and 238C, respectively and the liquid passageways
19 of each communicate with liquid outlet orifices 246A,
20 246B, and 246C. The liquid inlets 244 into each of the
21 nozzles assemblies communicate in common with a
22 reservoir 223 formed at the bottom of the chamber 214.

23 Located at the bottom of chimney is a diverter
24 260. The diverter 260 may be formed of a single face
25 or surface, or may be formed of multiple faces or
26 surfaces that are aligned with the multiple nozzle
27 assemblies 224A-224C, or alternatively, the diverter
28 may be formed as a ring. Further, there may be
29 provided multiple diverters. In a preferred
30 embodiment, there is a space or gap 261 formed
31 centrally in the bottom of the diverter 260 to permit
32 aerosol generation in 360° around each of the nozzles.

33 A membrane 264 may be located at the top of the
34 chimney 250 to provide a biasing function as in the
35 embodiment of Figure 1. Due to the larger size and
36 weight of the chimney assembly 250 in the embodiment of
37 Figure 11 relative to the embodiment of Figure 1, a

1 biasing member 265 such as a spring may be provided in
2 substitution for or in addition to the membrane 264.
3 The spring or other biasing member 265 may be connected
4 to the top of the chimney assembly 250.

5 The nebulizer 210 is operated in a manner similar
6 to the nebulizer shown in Figure 1. Like the nebulizer
7 shown in Figure 1, the nebulizer 210 in Figure 11 is
8 breath- or pressure-actuated. After a suitable liquid
9 is stored in the housing 212, the generation of a
10 nebula or aerosol will cycle with the cyclic decrease
11 of pressure in the chamber 214. The decrease of
12 pressure may be caused by inhalation by the patient, or
13 by action of ventilator. As in the first embodiment,
14 nebulization will cease upon exhalation or in the
15 absence of inhalation.

16 Because the nebulizer 210 has multiple nozzles
17 224A-C, a large amount of liquid can be nebulized
18 quickly. Since the single diverter or connected
19 multiple diverters move in unison toward the multiple
20 nozzles with the patient's inhalation, the cycling of
21 nebulization is coordinated among all the nozzles.

22 As in the previous embodiments, the annular shape
23 of each of the liquid orifices provides for a high
24 nebulization generation rate. Although the embodiment
25 of Figures 11-13 shows three nozzles, there can be any
26 number of multiple nozzles, such as two, four, five,
27 etc.

28 In an alternative embodiment, the diverter 260 is
29 rotatable relative to the body 252 of the chimney 150.
30 The diverter 260 may include appropriate vanes,
31 channels or a propeller, that captures some of the
32 pressurized gas flow and causes the diverter 260 to
33 rotate inside the housing 212. Rotation of the
34 diverter 260 may be used to improve mixing of the
35 aerosol inside the chamber.

36 This embodiment may also include a bell-shaped
37 baffle as shown in the first embodiment.

1 IV. Fourth Embodiment

2 Figure 14 shows a fourth embodiment of a nebulizer
3 of the present invention. This embodiment 310 of the
4 nebulizer is adapted for use with a ventilator circuit
5 301. The ventilator circuit 301 includes an
6 inspiratory airflow passageway 302 that delivers air
7 from the ventilator to the patient. This embodiment of
8 the nebulizer 310 is located in the inspiratory airflow
9 passageway 302 connected between a first length of
10 inspiratory tubing 303 that delivers air from the
11 ventilator circuit 301 and a second length 304 that
12 delivers air to the patient. The second length of
13 inspiratory tubing 304 may connect to the patient by
14 means of a mask, endotracheal tube, etc.

15 Like the embodiment of Figure 1, the embodiment of
16 the nebulizer in Figure 14 is pressure- or breath-
17 actuated. Accordingly, the nebulizer 310 produces an
18 aerosol in a cyclical manner in coordination with the
19 breathing or ventilation of the patient. The nebulizer
20 310 has a housing 312 defining a chamber 314. A nozzle
21 assembly 324 extends up from the bottom of the chamber
22 314. Pressurized gas is delivered from a gas orifice
23 at the top end of the nozzle assembly 324 and liquid
24 from a reservoir 323 at the bottom of the chamber 314
25 is drawn up to a liquid orifice also located at the top
26 end of the nozzle assembly 324 as in the first
27 embodiment. A chimney assembly 350 extends down from a
28 top of the housing 312. The chimney 350 connects to
29 the housing by means of a flexible, resilient membrane
30 364. A diverter 360 is located at the bottom of the
31 chimney assembly 350 directly opposite from the gas and
32 liquid orifices at the top of the nozzle assembly 324.
33 An inlet 356 of the chimney 350 connects to the length
34 of inspiration tubing 303 from the ventilator circuit
35 301. The inlet 356 communicates with an internal
36 passageway 352 of the chimney assembly 350.
37 Inspiratory gas from the ventilator 301 enters the

1 nebulizer 310 via the chimney inlet 356, passes through
2 the passageway 352 of the chimney assembly 350, and
3 passes into the nebulizer chamber 314 through the
4 openings 385 located in the wall of the chimney 350.
5 The inspired gas exits the nebulizer chamber 314 via an
6 outlet 398. The outlet 398 connects to the second
7 length of inspiratory tubing 304 which in turn connects
8 to an endotracheal tube, a mask, or other means (not
9 shown). This embodiment may also include a bell-shaped
10 baffle as shown in the first embodiment.

11 In the embodiment of Figure 14, the normal
12 operation of the ventilator circuit 301 causes a
13 sufficient change in the pressure in the nebulizer 310
14 to induce the chimney assembly 350 to move into and out
15 of proximity with the nozzle assembly 324.
16 Accordingly, during an inspiration cycle, the chimney
17 assembly 350, including the diverter 360, will be
18 brought into proximity with the top of the nozzle
19 assembly 324 causing nebulization of the liquid (as
20 described above in connection with the first
21 embodiment). During an expiratory phase of the
22 ventilator 301, the diverter 350 is positioned away
23 from the nozzle assembly 324 thereby causing
24 nebulization to stop. Nebulization cycles
25 automatically in synchronism with the operation of the
26 ventilator. No extra connection is required beyond
27 that necessary to withdraw the aerosol from the chamber
28 314 of the nebulizer 310 into the inspiratory tubing of
29 the ventilator circuit.

30 V. Fifth embodiment.

31 Figure 15 shows a fifth embodiment 410 of the
32 nebulizer of the present invention. Like the previous
33 embodiment, the nebulizer 410 in Figure 15 is adapted
34 for use in a ventilator circuit and produces an aerosol
35 in a cyclical manner in coordination with operation of
36 the ventilator and/or the breathing of the patient.

1 A ventilator circuit 401 has an inspiratory
2 passageway 402 that is formed of a first length of
3 tubing 403 that connects to the ventilator 401 and a
4 second length of tubing 404 that connects to a mask
5 405, or endotracheal tube, and so on, associated with
6 the patient. The ventilator circuit 401 also includes
7 an exhalation valve pressure line 406. This exhalation
8 valve pressure line 406 connects to an exhalation valve
9 407 associated with an expiratory passageway 408.
10 During ventilation of the patient, pressured gas is
11 delivered in the exhalation valve pressure line 406 to
12 the exhalation valve 407 to assist in the cycling of
13 ventilation of the patient.

14 The nebulizer 410 has a housing 412 defining a
15 chamber 414, and includes a nozzle assembly 424, a
16 flexible, resilient membrane 462, and a diverter 460,
17 arranged generally as in the previously described
18 embodiment. Instead of a chimney, the nebulizer 410
19 has a post 450 to which the diverter 460 is connected.
20 Unlike a chimney, the post 450 does not include air
21 openings or an internal air passageway. The diverter
22 460 is connected to a bottom side of the post directly
23 adjacent from the top of the nozzle assembly 424. The
24 embodiment of Figure 15 also differs from the previous
25 embodiment in the manner that the ventilator circuit
26 401 is connected to the nebulizer 410 and the manner
27 that the ventilator circuit 401 causes the nebulizer
28 410 to cycle nebulization. This embodiment may also
29 include a bell-shaped baffle as shown in the first
30 embodiment.

31 In Figure 15, the nebulizer housing 412 includes
32 an inlet 456 into the chamber 414. The inlet 456
33 connects to the first section 403 of inspiratory tubing
34 402 from the ventilator circuit 401. The nebulizer
35 housing 412 also includes an outlet 498 from the
36 chamber 414. The outlet 498 connects to the second
37 section 404 of inspiratory tubing that leads to a

1 conventional device 405, e.g. an endotracheal tube or
2 mask, from which the patient receives the inspiratory
3 flow from the ventilator 401 including the aerosol from
4 the nebulizer 410.

5 Located across the membrane 462 from the
6 nebulization chamber 414 is a passageway 483. The
7 passageway 483 connects to the exhalation valve
8 pressure line 406 of the ventilator circuit 401 by a
9 suitable means, such as a tee 487. Because the
10 ventilator 401 cycles air to and from the patient, air
11 flows in the exhalation valve pressure line 406 in a
12 cyclic manner to operate the exhalation valve 407.
13 This air flow in the exhalation valve pressure line 406
14 causes a pressure differences with the air in the
15 chamber 414. The membrane 462 is positioned across the
16 inspiratory flow passageway 402 and the exhalation
17 valve pressure line 406 and therefore senses the
18 pressure differential across these two passageways. As
19 in the previous embodiment, the diverter 460 is brought
20 into proximity with the top of the nozzle assembly 424
21 during the inspiratory phase of the ventilator and
22 brought out of proximity with the top of the nozzle
23 assembly 424 during the expiratory phase of the
24 ventilator. Accordingly, nebulization occurs during
25 the inspiratory phase and not during the expiratory
26 phase.

27 VI. Sixth embodiment.

28 Figure 16 shows a sixth embodiment 510 of the
29 nebulizer of the present invention. This embodiment is
30 similar to the embodiment of the nebulizer 110 in
31 Figure 15. The nebulizer 510 includes a housing 512
32 defining a chamber 514. The chamber 514 has an inlet
33 528 connected to a source of pressurized gas 527 and an
34 outlet 598 connected to a tubing 599, or similar
35 structure, such as a mouthpiece, etc., that leads to
36 the patient 596 and from which the patient can inhale

1 air and aerosol. Like the embodiment of Figure 5, the
2 nebulizer 510 of Figure 16 may also include an inlet
3 for air entrainment 562. As in the other embodiment,
4 liquid and gas outlets (not shown) located at the top
5 of a nozzle 524 directly adjacent a diverter 560
6 dispense an aerosol into the chamber 514.

7 The embodiment of the nebulizer 510 includes a
8 breath-actuation feature that enables the nebulizer to
9 generate a nebula in cyclic manner in coordination with
10 a physiological cycle of the patient. In the
11 embodiment of Figure 15, the breath-actuation feature
12 is external of the nebulizer housing 512. The breath-
13 actuation feature includes a valve 569 or other
14 metering device located in-line with the inlet tubing
15 529 that provides the pressurized gas from the source
16 527 to the nebulizer inlet 528. A tubing 567 connects
17 from the outlet tubing 599 to the inlet tubing 529.
18 The tubing 567 enables the valve 569 to sense the
19 pressure in the outlet tubing 599. In one embodiment,
20 the tubing 567 may be conventional tubing and the valve
21 569 senses the pressure through the tubing 567. The
22 valve 569 is adapted to open and close the delivery of
23 pressurized gas to the nebulizer 510 in coordination
24 with the changes in the pressure in the outlet 599 as
25 sensed via the tubing 567. Specifically, upon
26 inhalation, the pressure in the inlet 599 and the
27 connecting tubing 567 will be lower, and the valve 569
28 will open to allow pressurized gas to be delivered to
29 the nebulizer 510 thereby causing nebulization to
30 occur. After inhalation, the pressure in the patient
31 outlet 599 and the connecting tubing 567 rises, and the
32 valve closes thereby causing nebulization to cease. In
33 this manner, the embodiment of Figure 16 can provide
34 similar breath-actuation features as the other
35 embodiments discussed above. The tubing 567 and valve
36 569 may be either re-usable or disposable and may be
37 used with a nebulizer 510 as shown in Figure 16, or may

1 be used with other types of nebulizers. The tubing 567
2 and valve 569 could also be used with vaporizers that
3 are used for providing humidification for ventilated
4 patients. Such vaporizers are used with prefilled bags
5 of sterilized water, and the tubing 567 and valve 569
6 would provide adjustable air entrainment of vapor.

7 VII. Seventh embodiment.

8 Figures 17A and 17B show a seventh embodiment 610
9 of the nebulizer of the present invention. This
10 embodiment is similar to the previous embodiments
11 wherein a housing 612 defines a chamber 614 for holding
12 and aerosolizing a liquid 625 by means of a pressured
13 gas supply 627. In this embodiment, a top end of a
14 diverter assembly post 650 is connected to the top side
15 of the housing so that the bottom surface 660 of the
16 diverter post 650 is located at a fixed distance, e.g.
17 0.033 inches, from a top 639 of a nozzle assembly 624.
18 As in the previous embodiments, a gas orifice and a
19 liquid orifice (not shown) are located at the top of
20 the nozzle assembly 624. The liquid orifice may be
21 ring-shaped and concentric with the gas orifice, or
22 alternatively, the orifices may be side by side. A
23 mouthpiece 700 permits the withdrawal of aerosol and
24 air from the chamber 614. A flexible diaphragm 664 is
25 located in an upper region of the nebulizer chamber 614
26 and forms a boundary between the inside of the chamber
27 and the ambient outside. One or more air inlet ports
28 656 are located on a top side of the housing 612. A
29 filter 639 is located at the top of the diverter post
30 650.

31 A cylindrical shield or collecting surface 633 is
32 connected to the flexible diaphragm 664 and extends
33 downward into the chamber 614 over the lower portion of
34 the diverter post 650 and the upper portion of the
35 nozzle assembly 624. The shield 633 has an inside
36 diameter larger than the outside diameters of the

1 diverter post 650 and the nozzle assembly 624 so that
2 it can readily shift relative to these parts. One or
3 more windows 637 are located in the wall of the shield
4 633. The windows 637 are located in the wall of the
5 cylindrical shield 633 such that when the diaphragm 664
6 is in an upper position (as shown in Figure 17B) the
7 window 637 is not aligned with the gap between nozzle
8 624 and the diverter 660. When the shield 633 is in
9 this upper position, aerosol particles generated by the
10 flow of pressured gas across the liquid orifice impact
11 upon the inside wall of the cylindrical shield 633 and
12 tend to form into droplets that fall back into the
13 reservoir. In addition or alternatively, depending on
14 the specific dimensions, the shield 633 may impede the
15 flow of gas from the pressurized gas orifice across the
16 liquid orifice to the extent that there is insufficient
17 vacuum to draw the liquid out of the liquid orifice.
18 In any event, the production of aerosol particles into
19 the chamber 614 is reduced. However, when air is
20 withdrawn from the chamber 614, such as when a patient
21 inhales through the mouthpiece 700, a decrease in
22 pressure inside the chamber 614 causes the diaphragm
23 664 to flex downward (as shown in Figure 17A). This
24 causes the cylindrical shield 633 to shift into a lower
25 position. When the shield 633 is in a lower position,
26 the window 637 is aligned with the gap between the
27 nozzle 624 and the diverter 660 thereby permitting
28 aerosol generated from the liquid orifice to escape
29 into the chamber 614 from which it can be inhaled by
30 the patient.

31 The above embodiments of the nebulizer have been
32 described for use in medical or therapeutic
33 applications. It is noted that the principles of the
34 invention disclosed herein may have applicability to
35 other usages, such as industrial, manufacturing, or
36 automotive (e.g. carburetors).

1 It is intended that the foregoing detailed
2 description be regarded as illustrative rather than
3 limiting, and that it be understood that the following
4 claims, including all equivalents, are intended to
5 define the scope of this invention.

WE CLAIM:

1. A nebulizer comprising:

a housing having a chamber for holding an aerosol;

an air outlet communicating with said chamber for permitting said aerosol to be withdrawn from said chamber;

a liquid outlet located in said chamber;

a pressurized gas outlet located in said chamber adjacent to said liquid outlet;

a diverter located in said chamber and relative to said pressurized gas outlet and said liquid outlet so as to divert pressurized gas from said gas outlet across said liquid outlet to produce said aerosol in cycles in coordination with a patient's breathing; and

a biasing member connected to said diverter wherein said biasing member comprises a flexible membrane.

2. The nebulizer of Claim 1 wherein said diverter discontinues nebulization during patient exhalation.

3. The nebulizer of Claim 1 wherein said nebulizer comprises multiple liquid outlets located in said chamber.

4. The nebulizer of Claim 1 further comprising:

an air inlet communicating with ambient air connected to said air outlet located in said chamber.

5. The nebulizer of Claim 1 comprising a suction chamber communicating with said chamber.

- 38 -

6. The nebulizer of Claim 1 further comprising: a means for limiting movement of said diverter.

7. The nebulizer of Claim 1 wherein during an inhalation, said gas diverter is moved towards said gas outlet and forms a gap therewith such that said pressurized gas is directed in a radial direction away from said gas outlet into said chamber, said pressurized gas drawing liquid from said liquid outlet.

8. The nebulizer of Claim 1 wherein said diverter is movable into a non-nebulizing position away from said gas outlet.

9. The nebulizer of Claim 1 wherein said liquid outlet has an annular shape surrounding said gas outlet.

10. A nebulizer for nebulizing a medication during a patient's inhalation stage comprising:

a housing having a chamber, an air outlet connected to said chamber, and a liquid reservoir;

a biasing member attached to said housing;

an air passageway connecting said chamber to an air supply, said air passageway having a hollow tube, an ambient air opening, and an internal opening;

a variable height nebulizing gap defined at a first boundary by a movable breath-sensitive gas diverter and defined at a second boundary by a fixed nozzle, said gas diverter movable to a nebulizing position by said patient's inhalation, said gas diverter movable to a non-nebulizing position by said patient's exhalation; and

said nozzle positioned inside said housing opposite said movable gas diverter, said nozzle having a pressurized gas

- 39 -

outlet and a liquid outlet, said liquid outlet connected to said liquid reservoir; and

wherein said nebulizer comprises multiple liquid outlets located in said chamber.

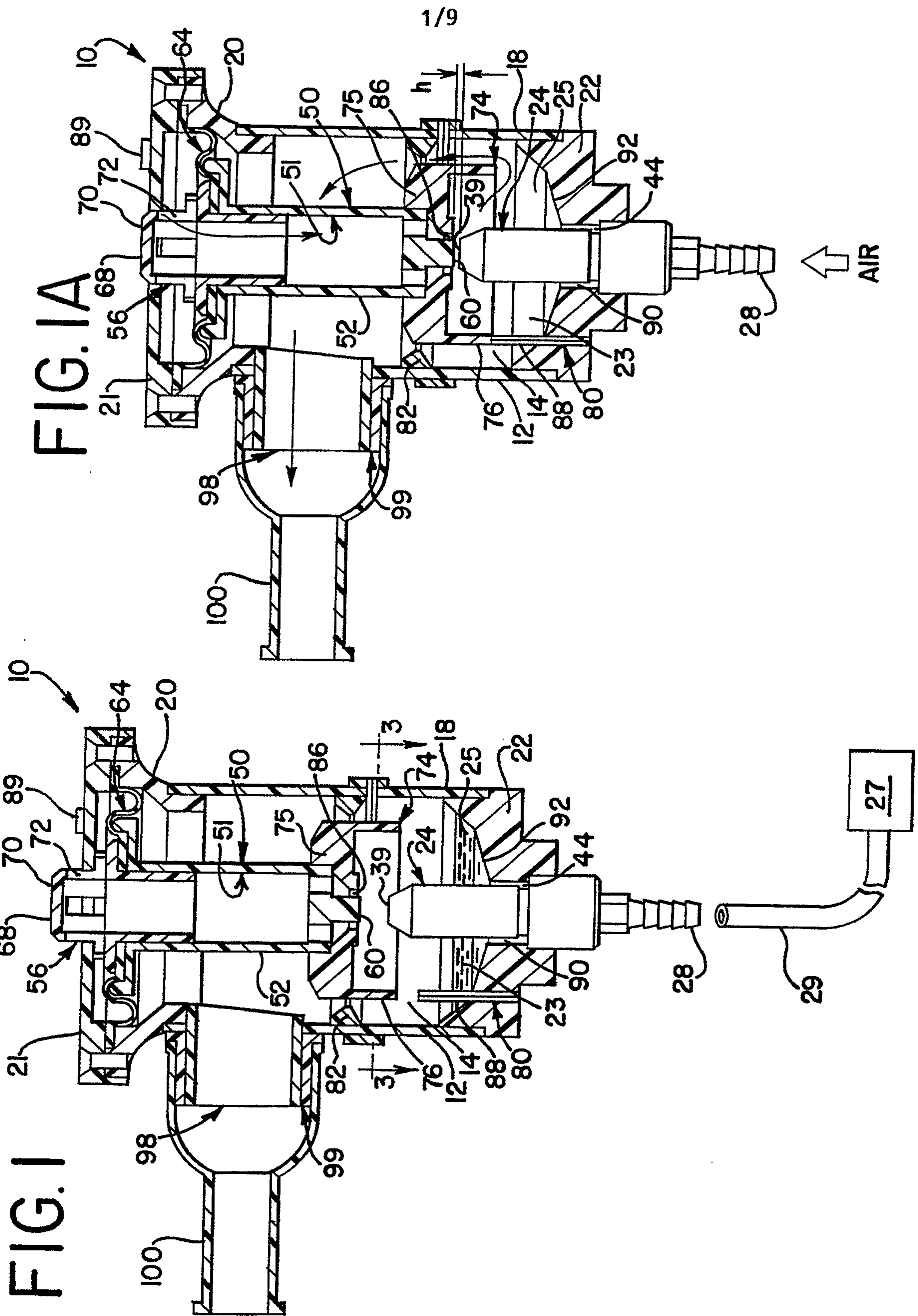


FIG.2

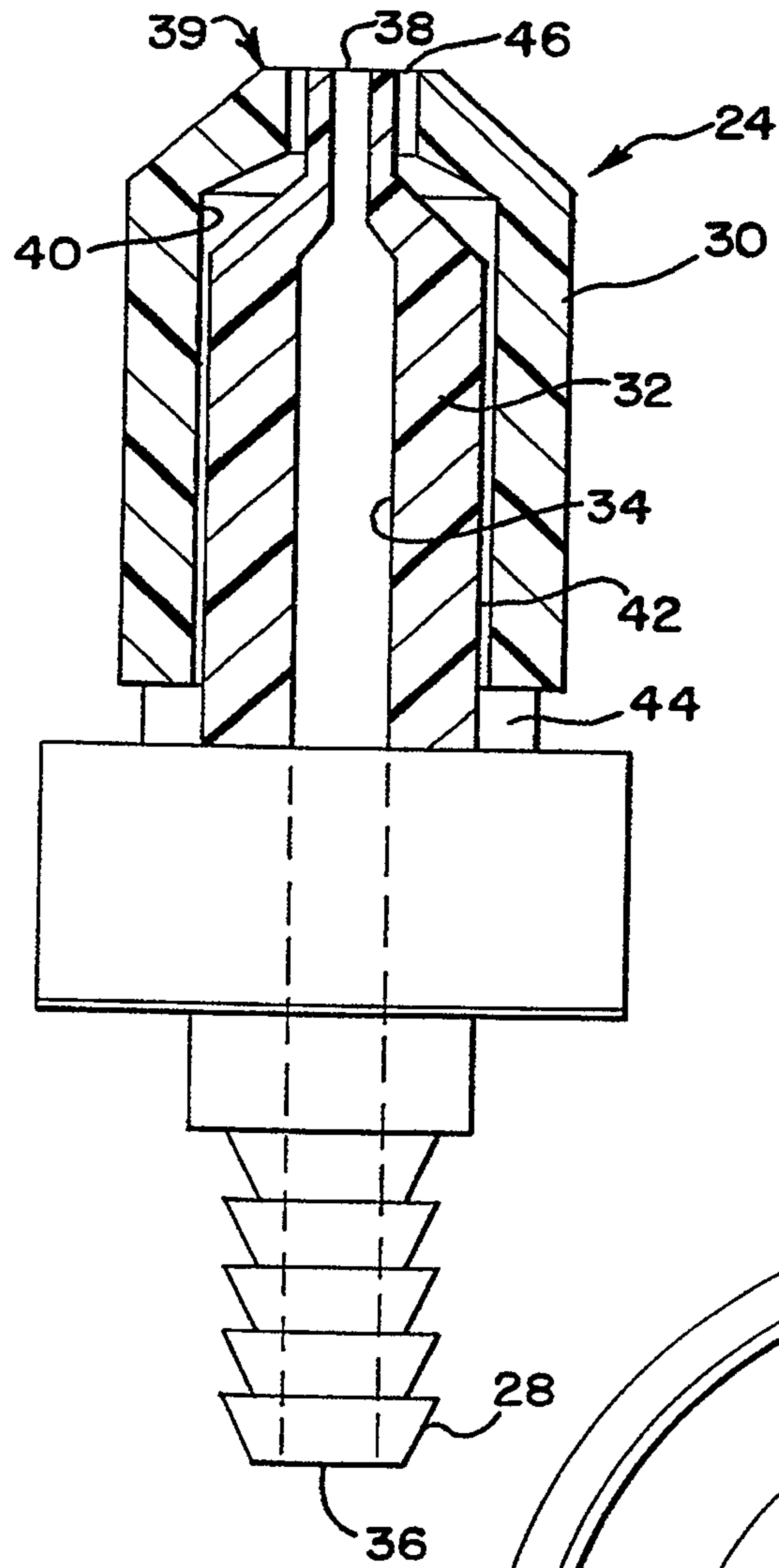
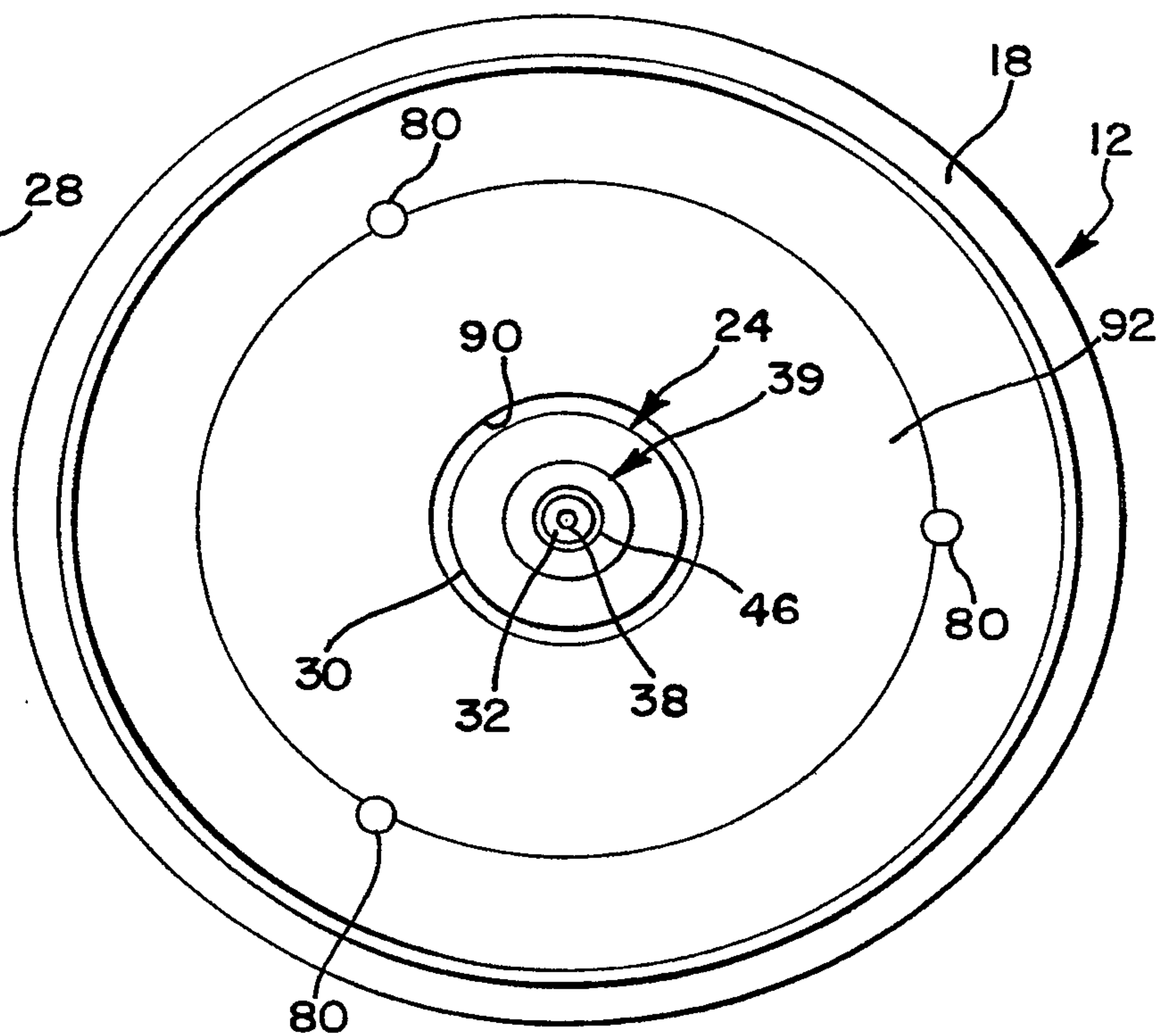


FIG.3



3/9

FIG.5

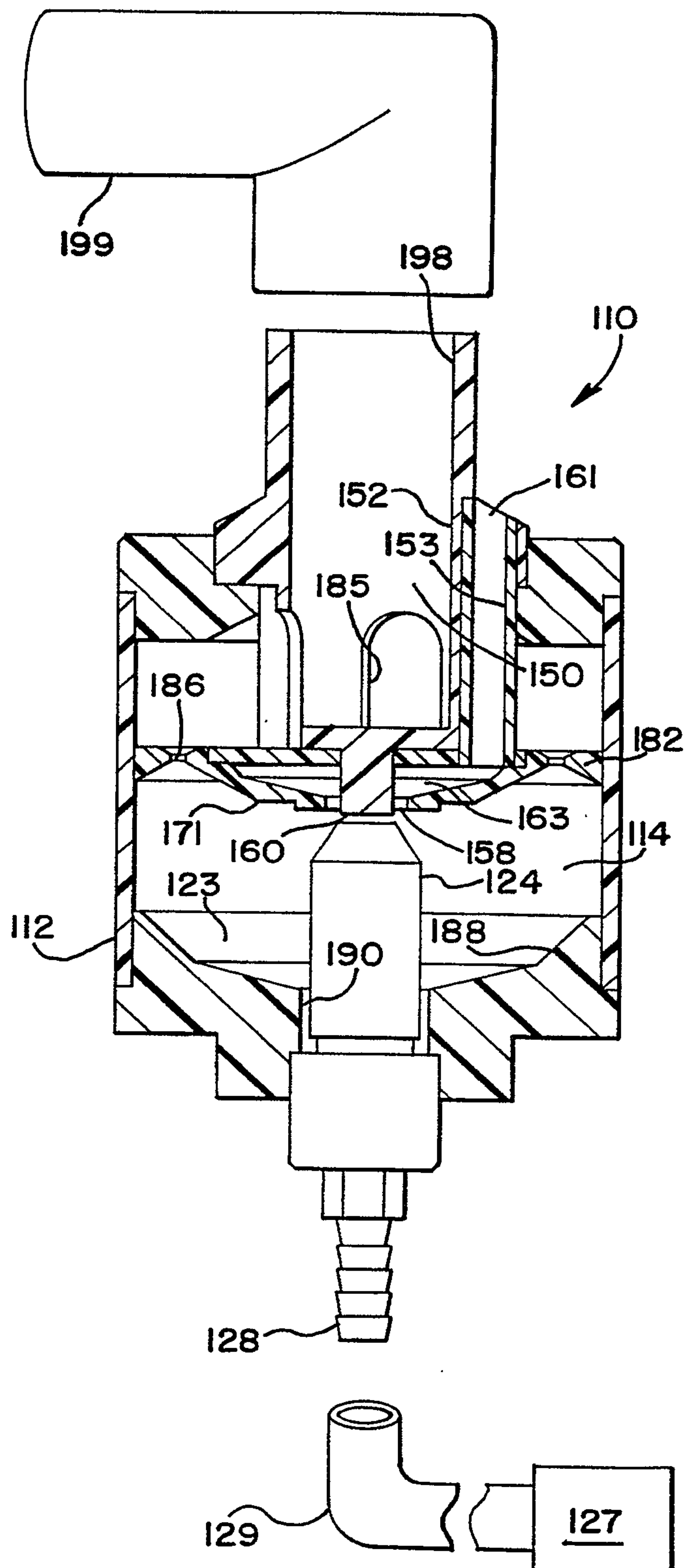
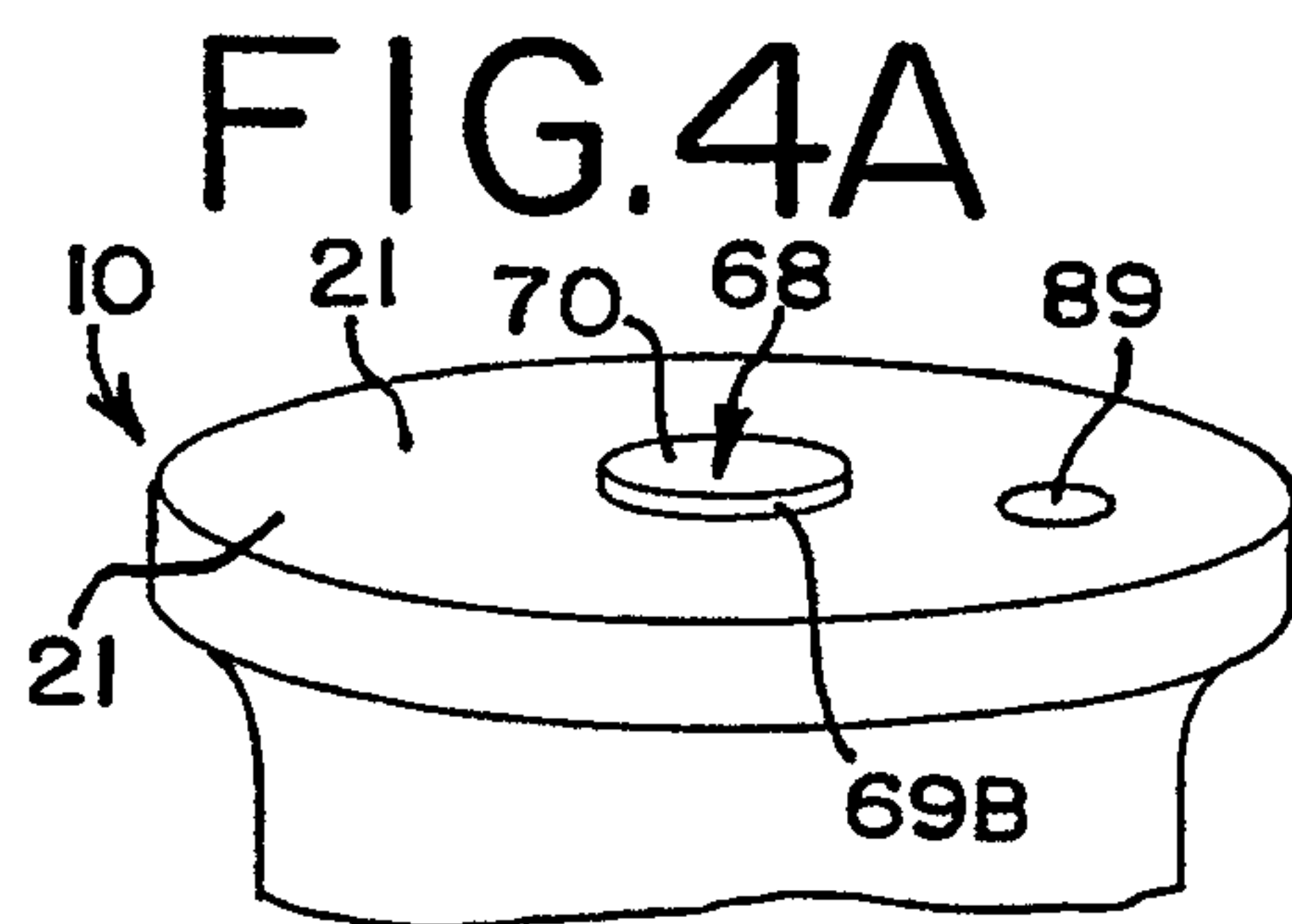
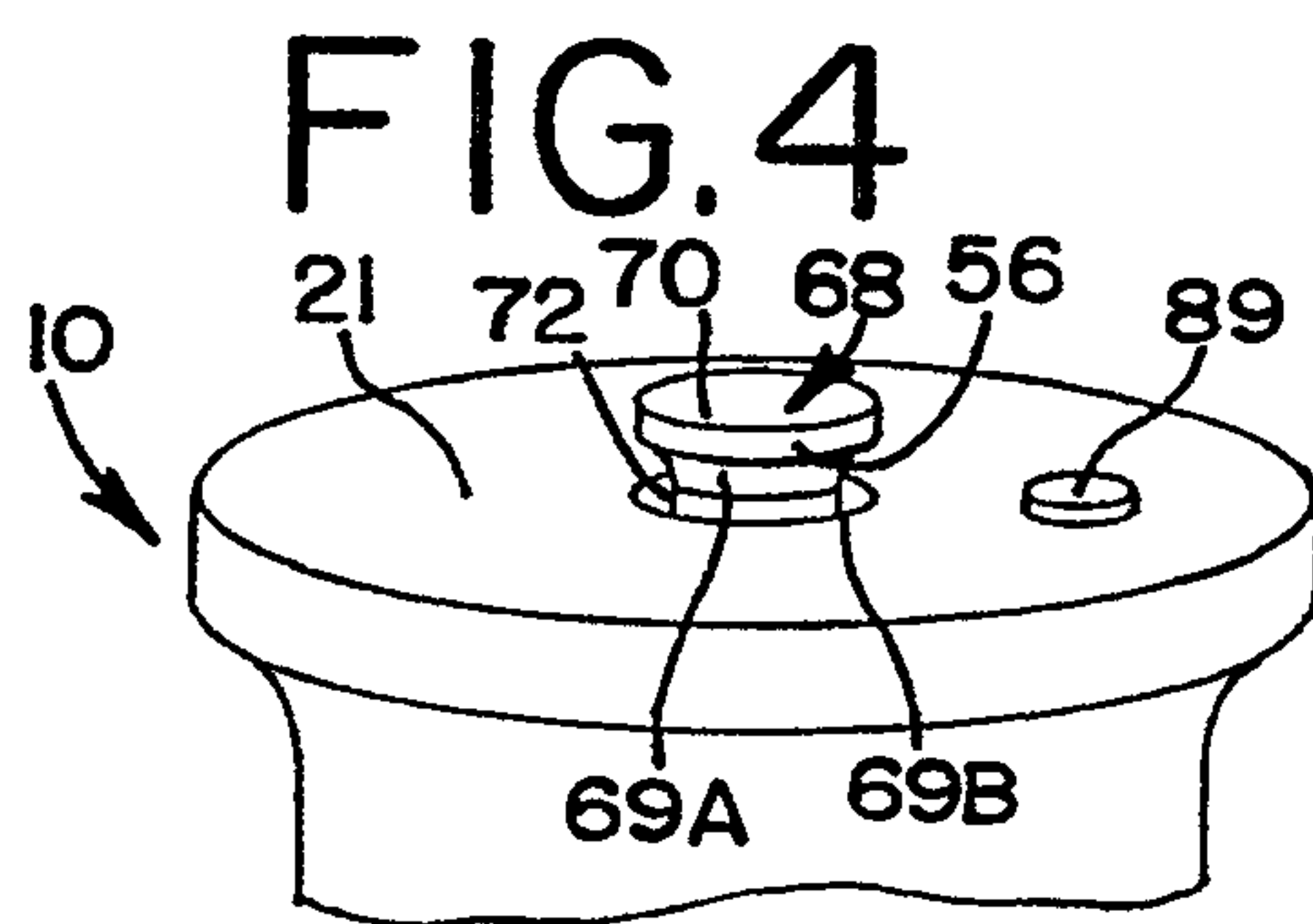


FIG.6

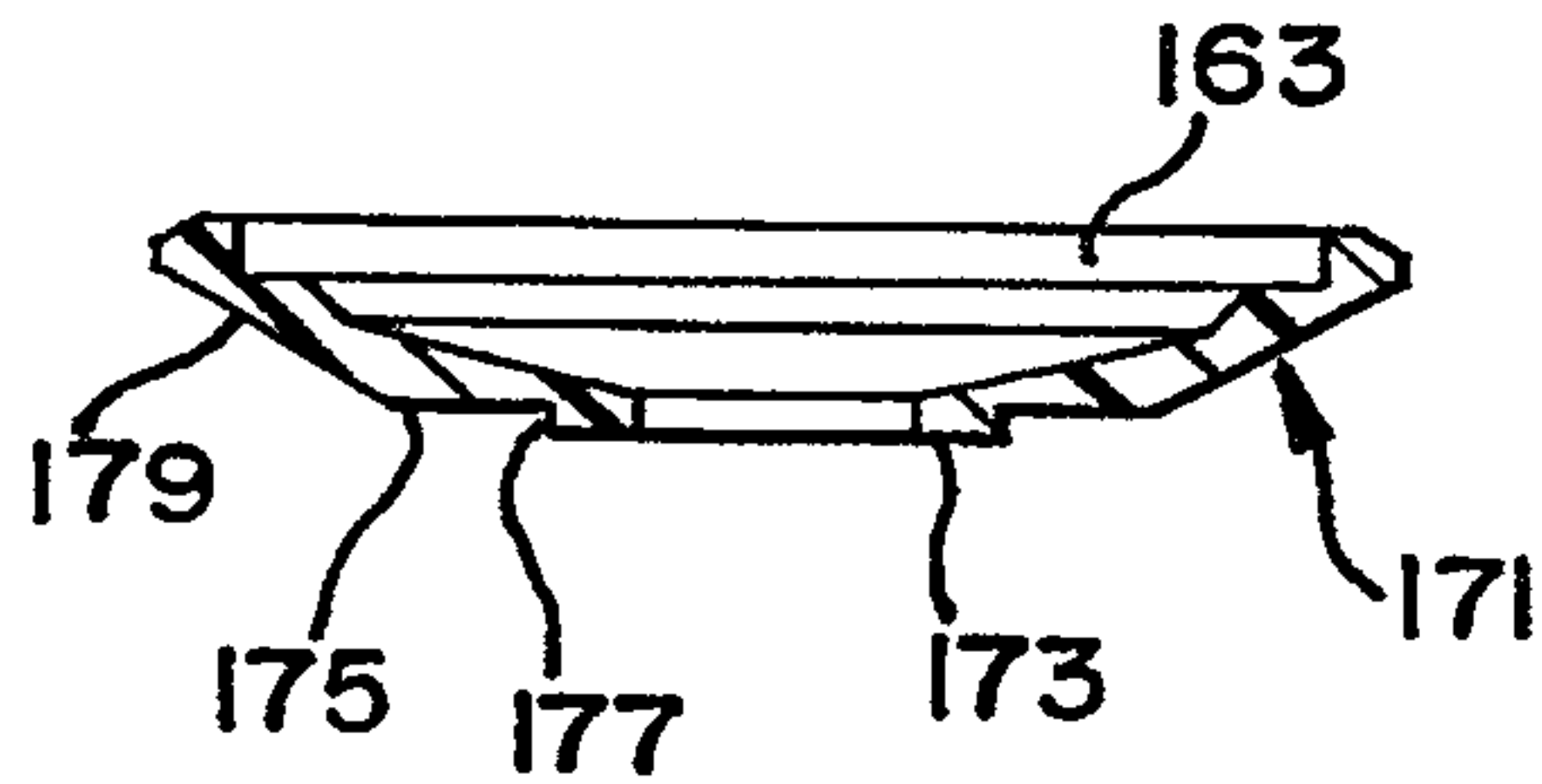


FIG.7

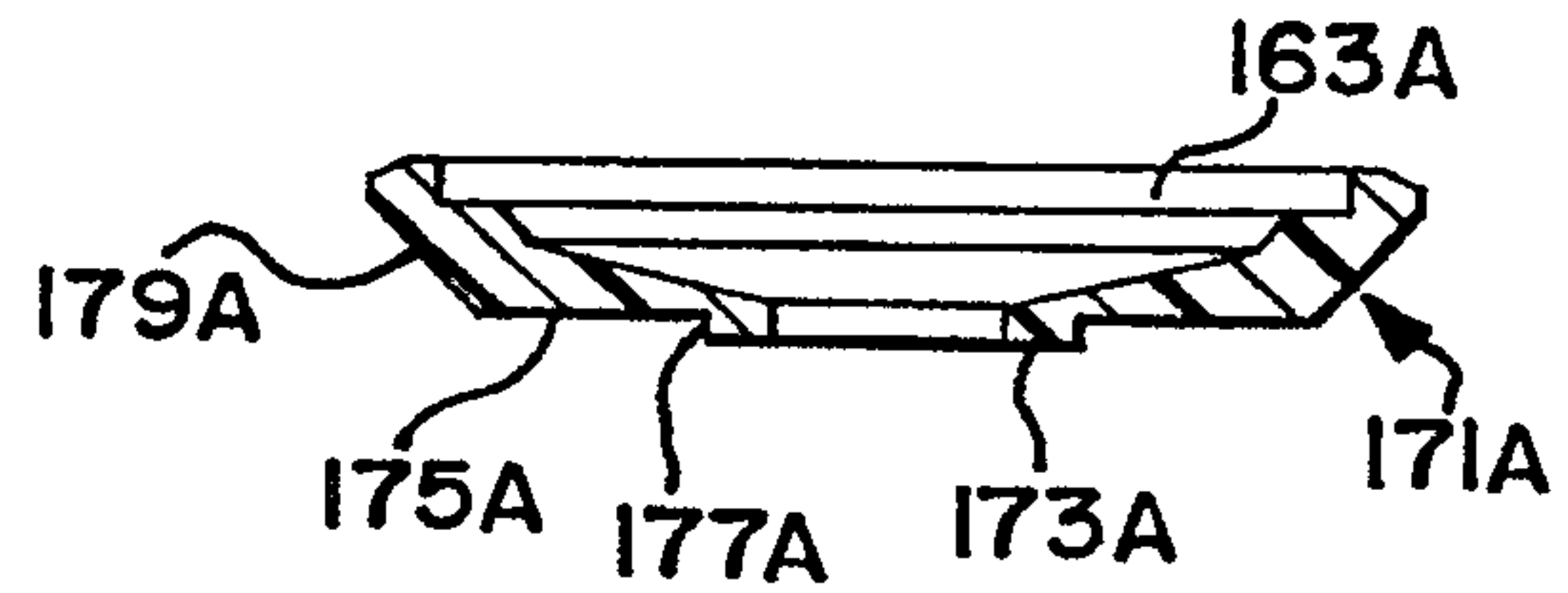


FIG.8

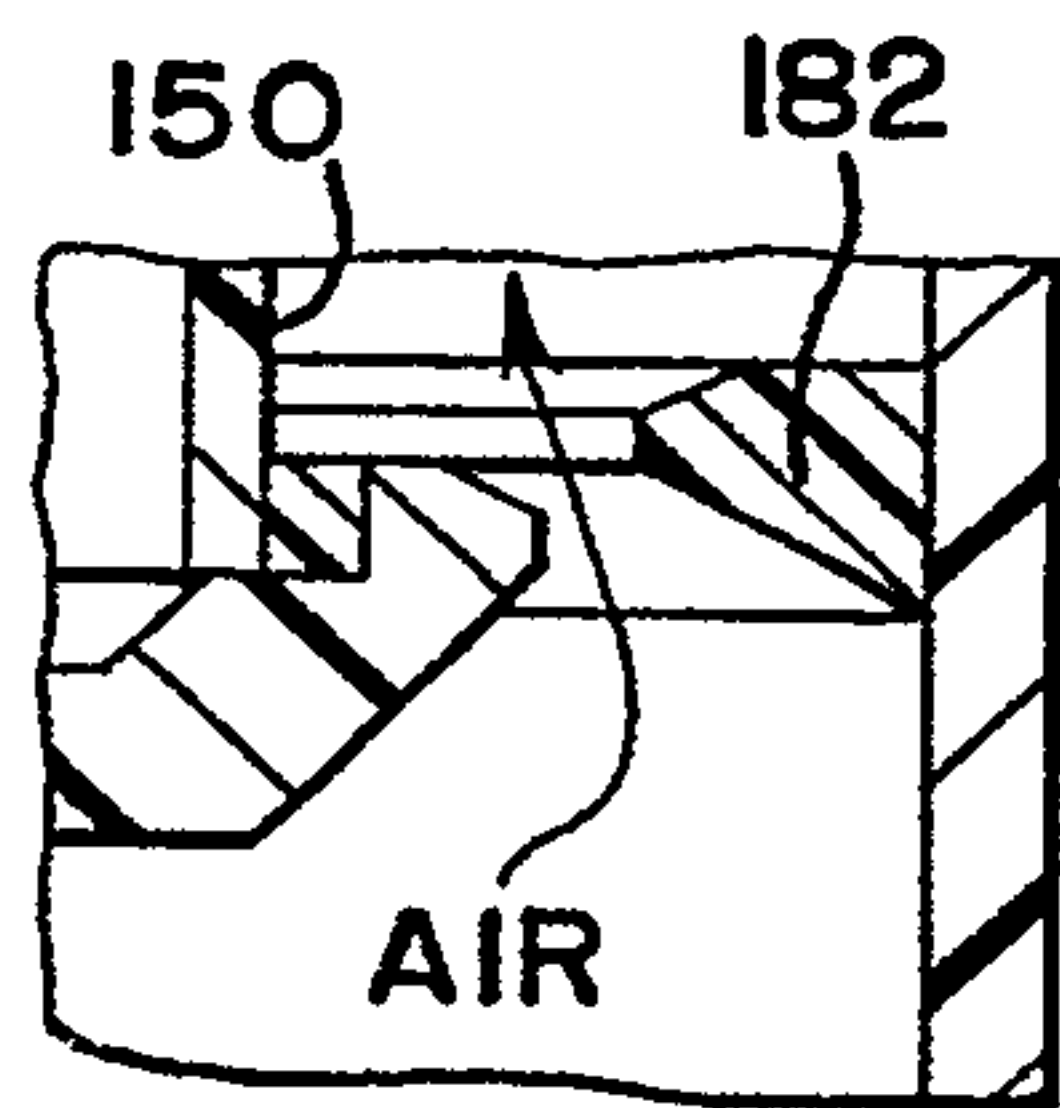


FIG.9

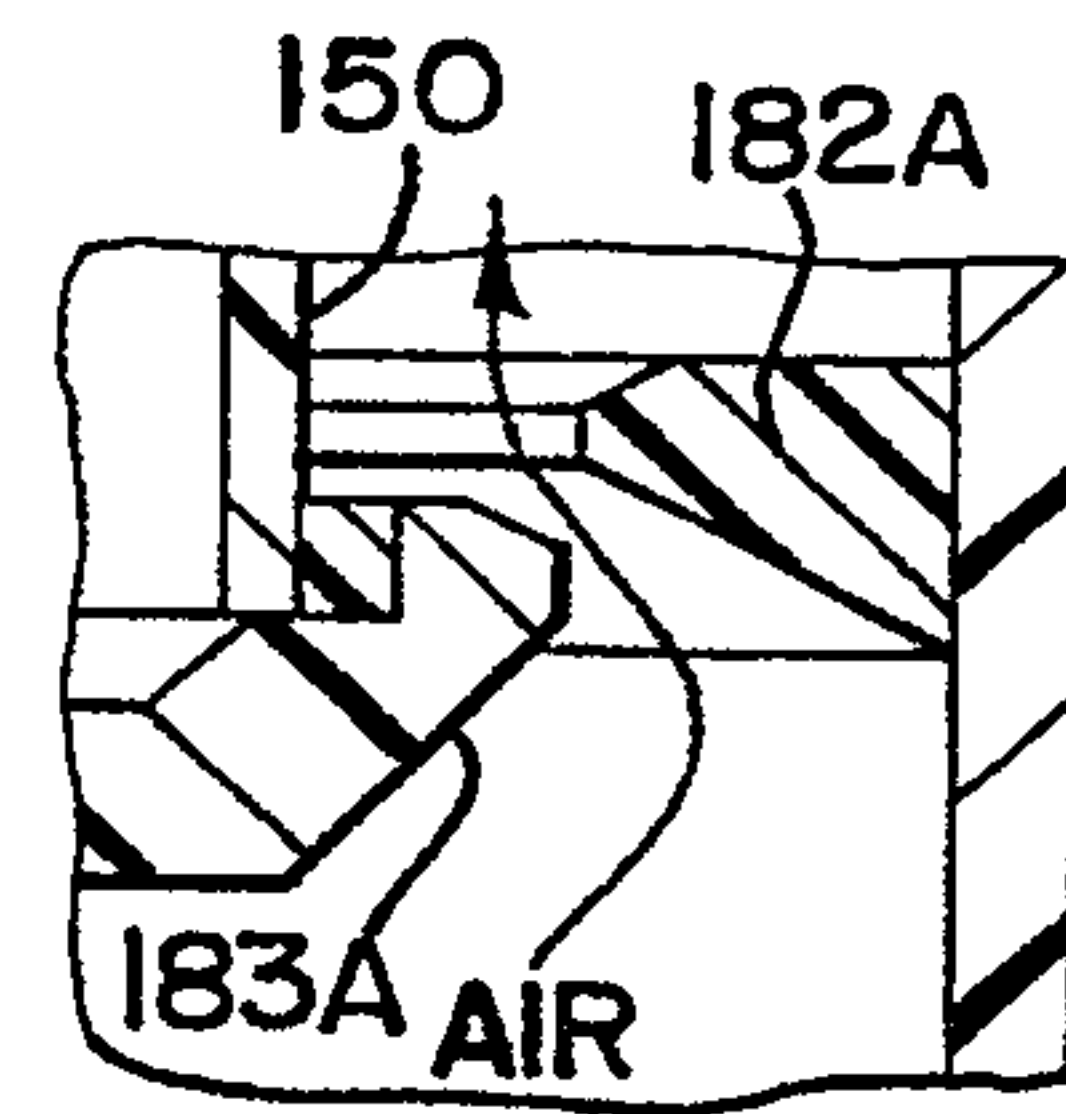
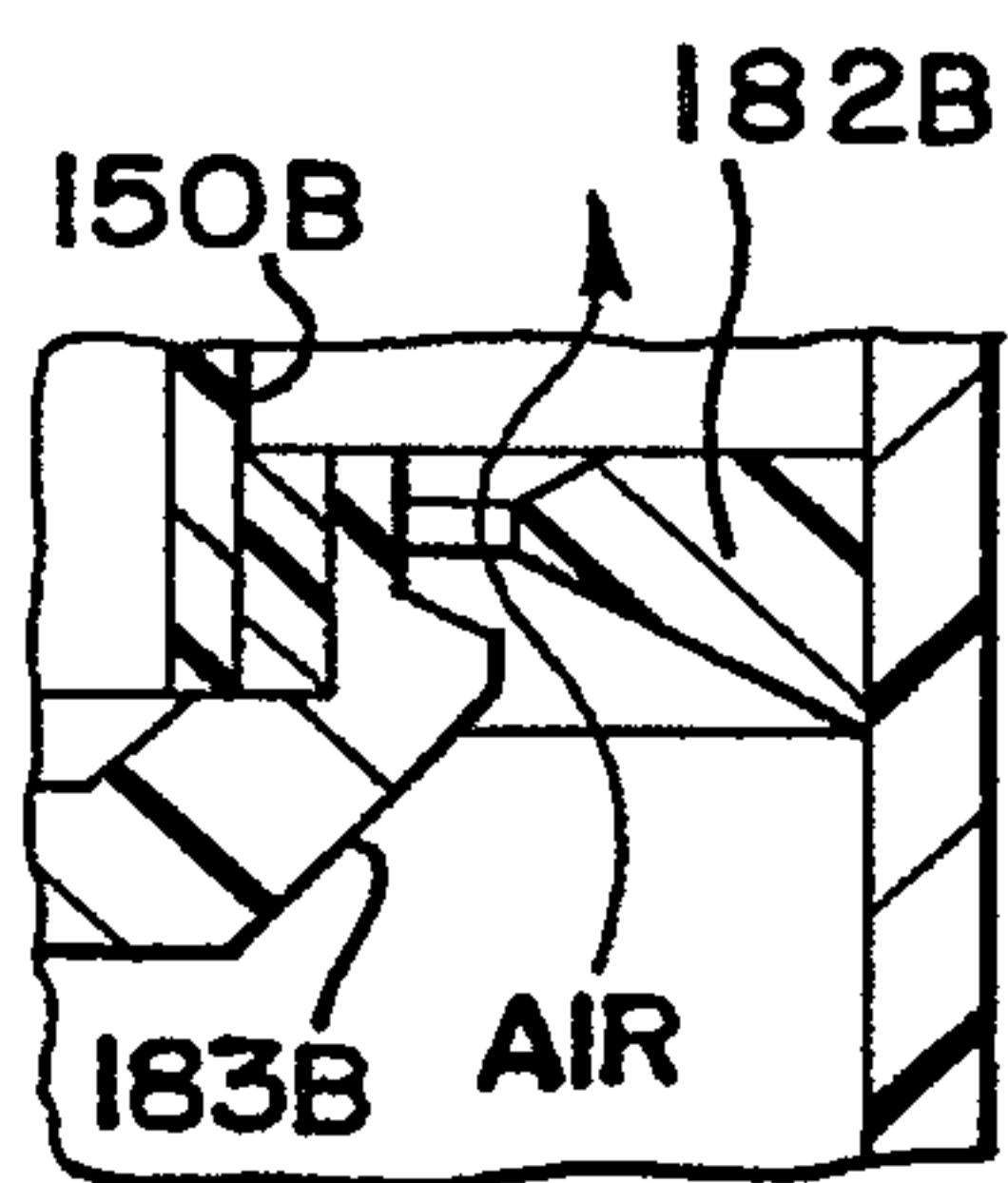


FIG.10



5/9

FIG. II

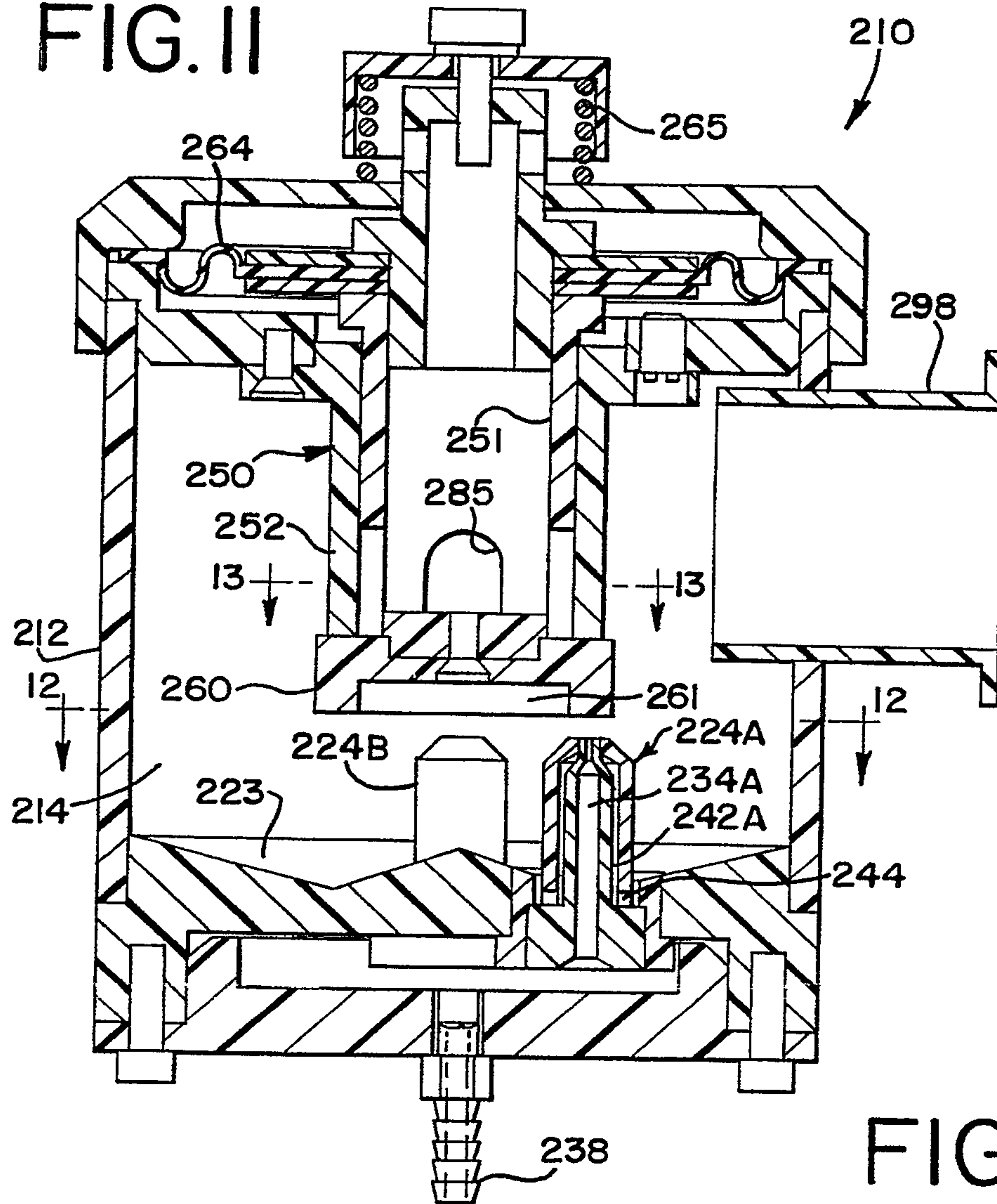


FIG. 12

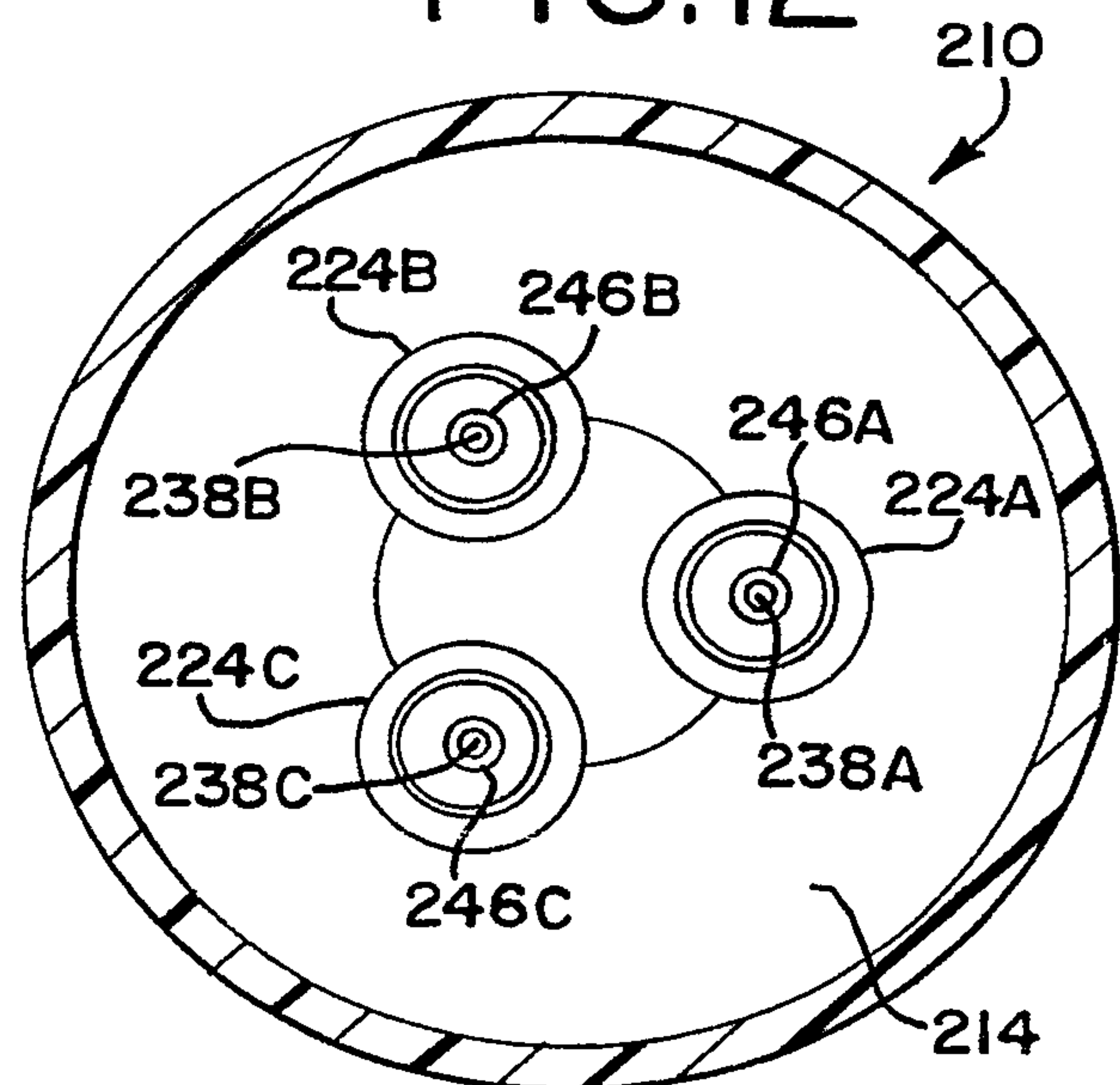


FIG. 13

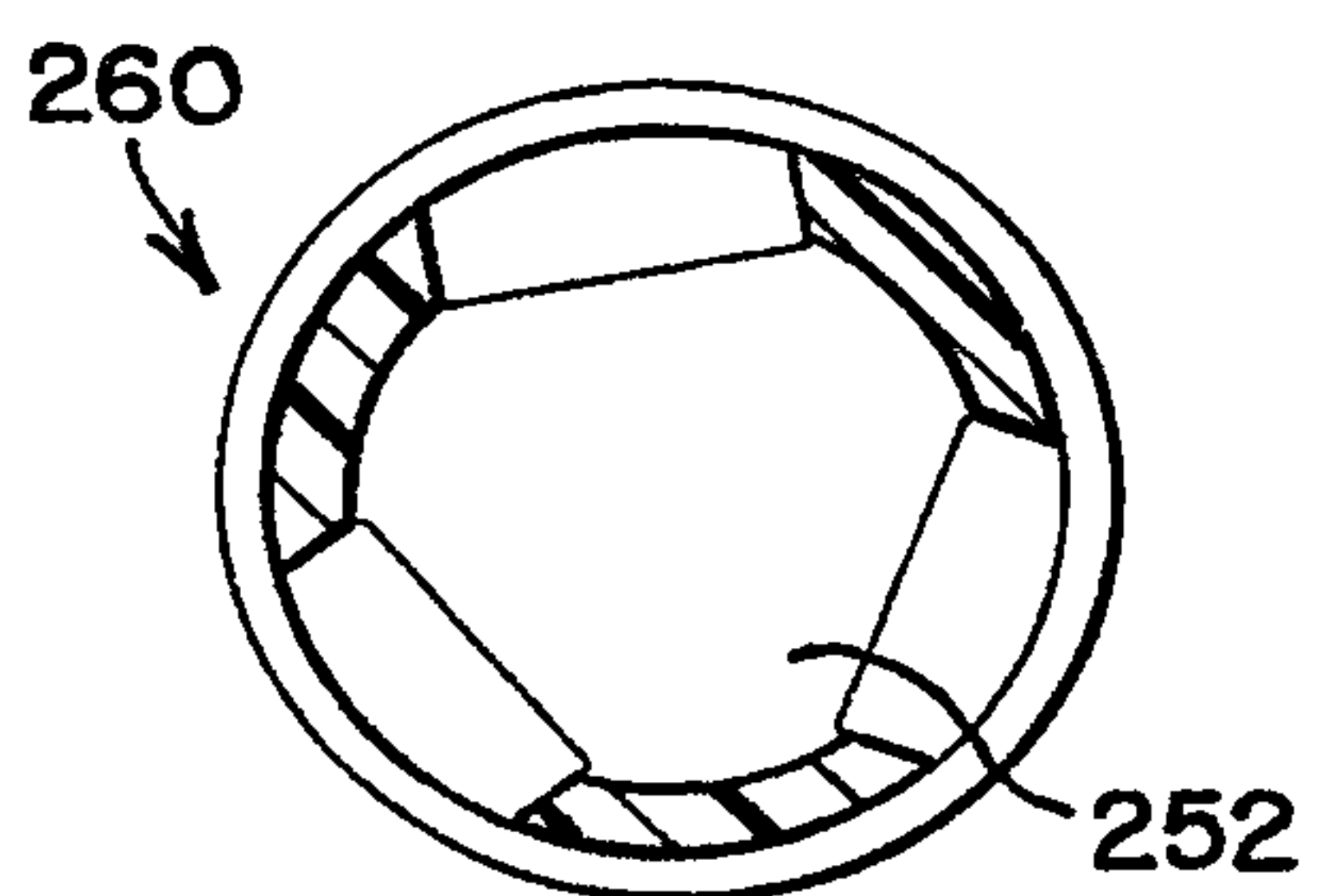
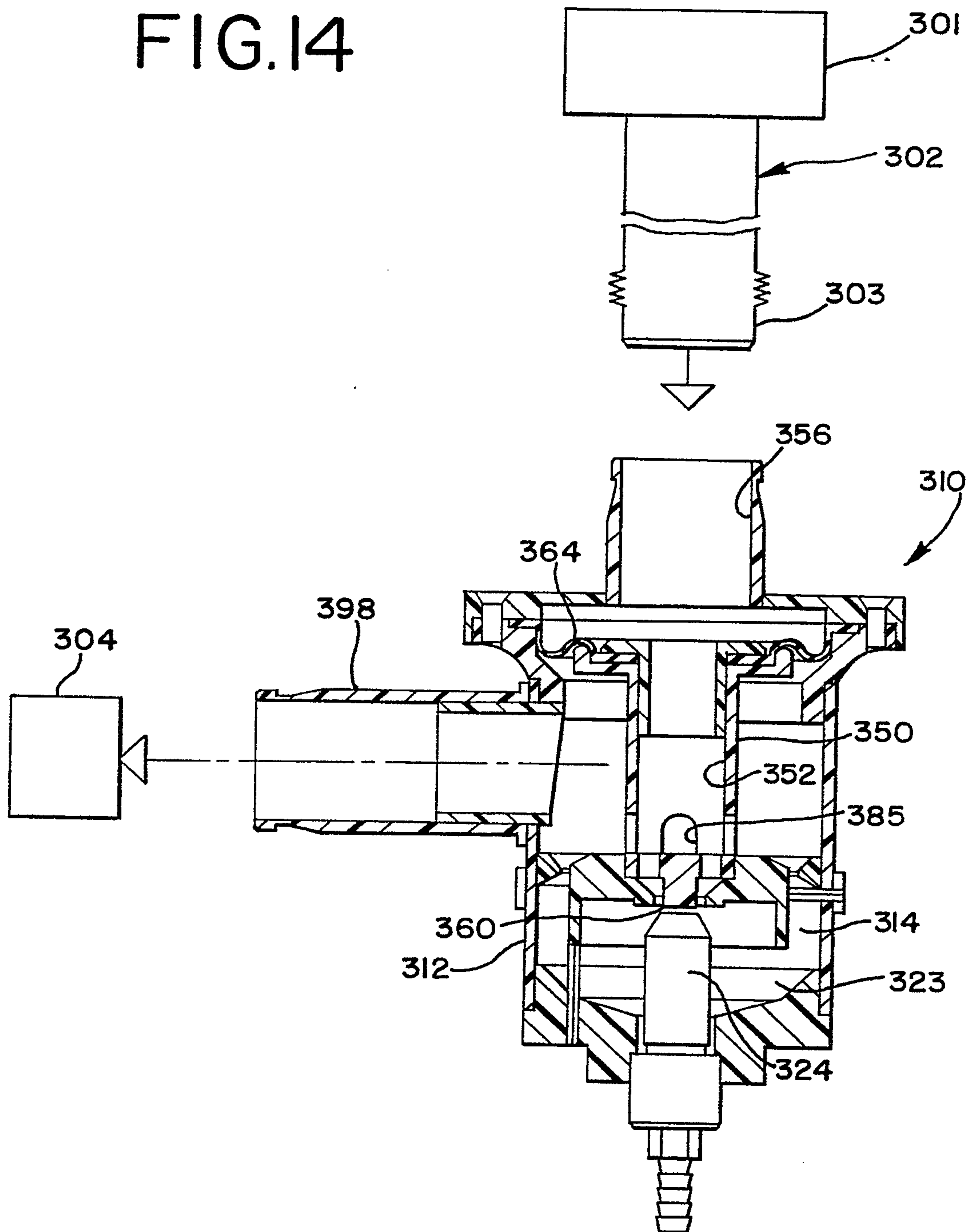
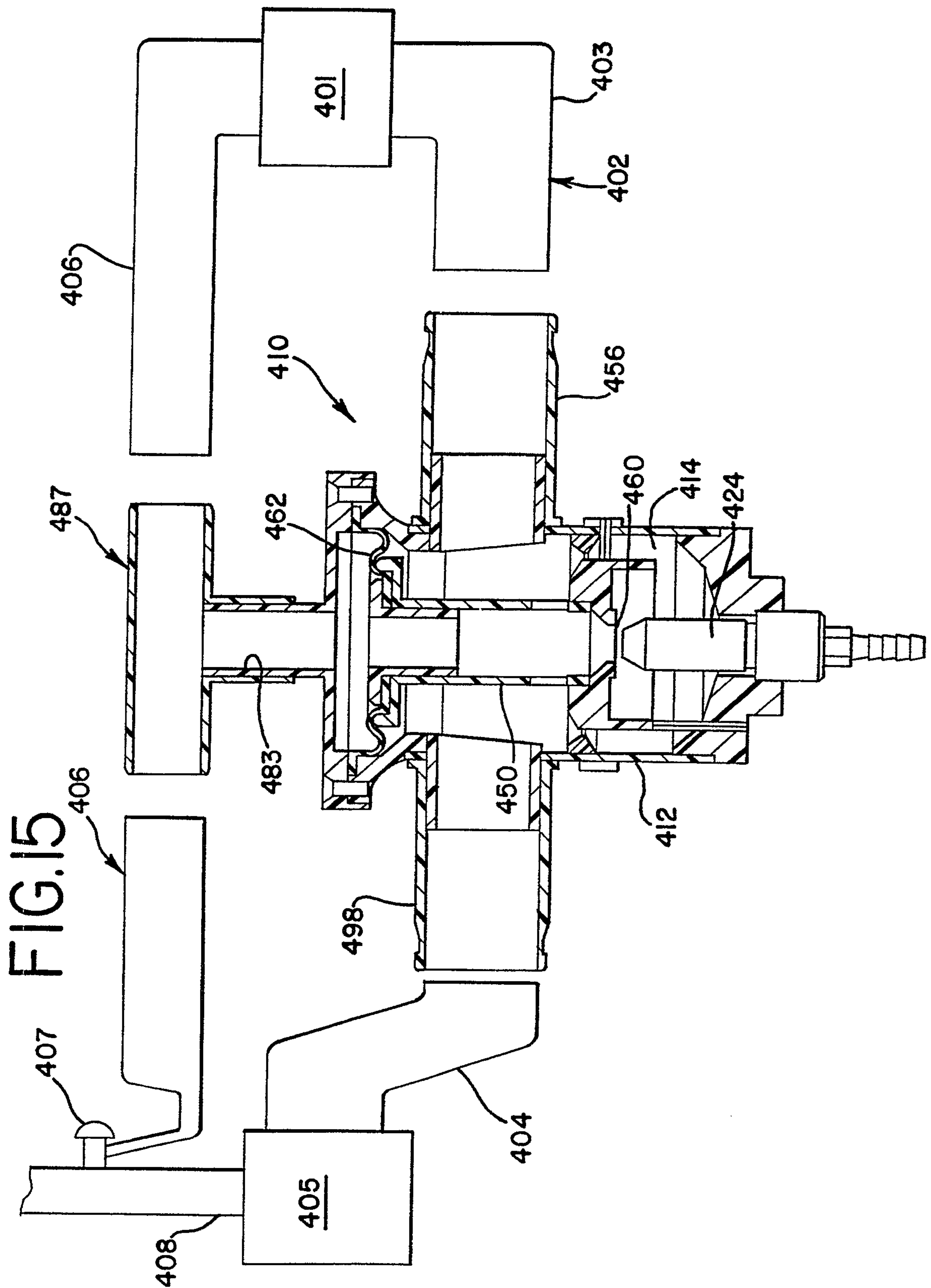


FIG.14



7/9



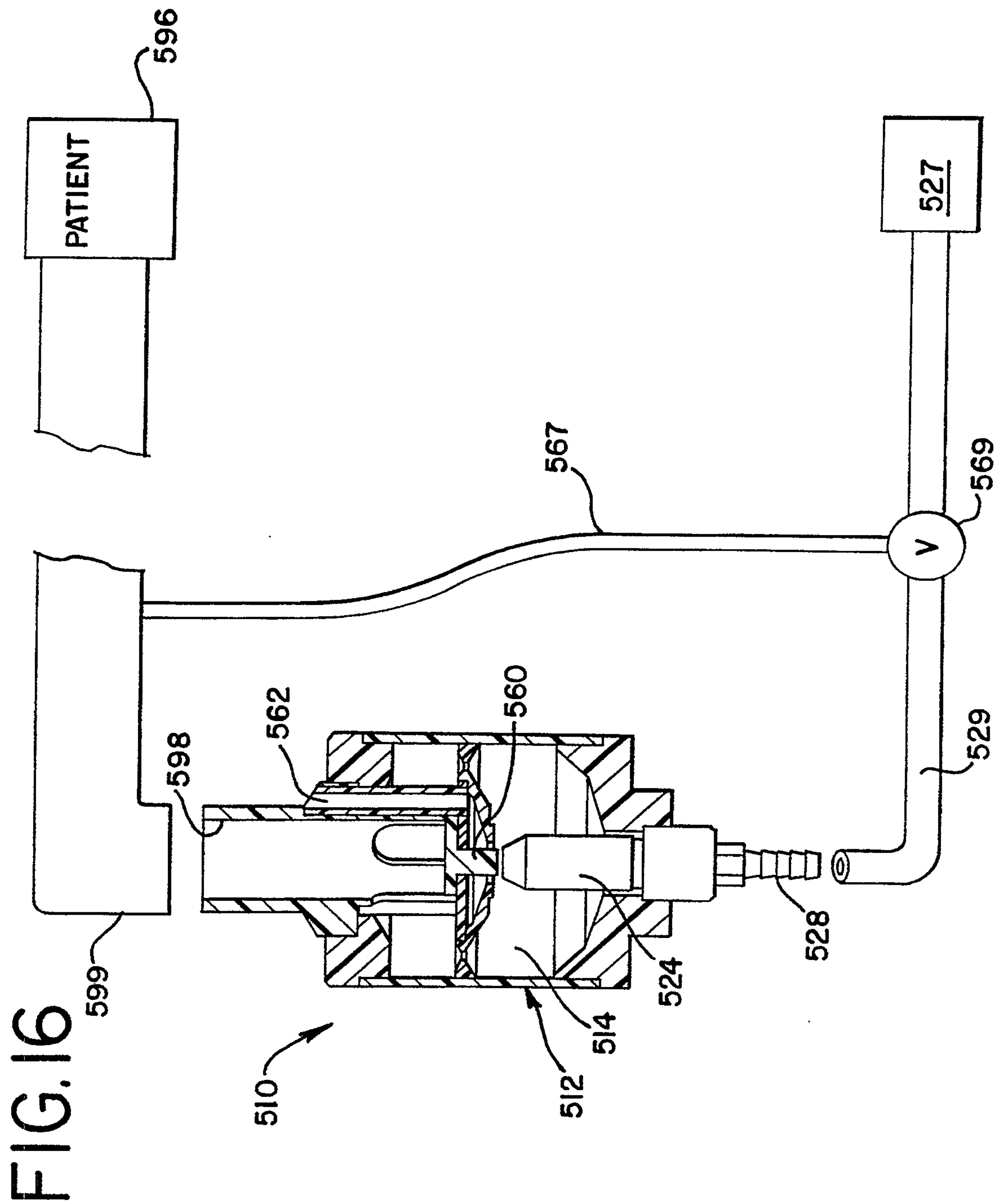


FIG.17B

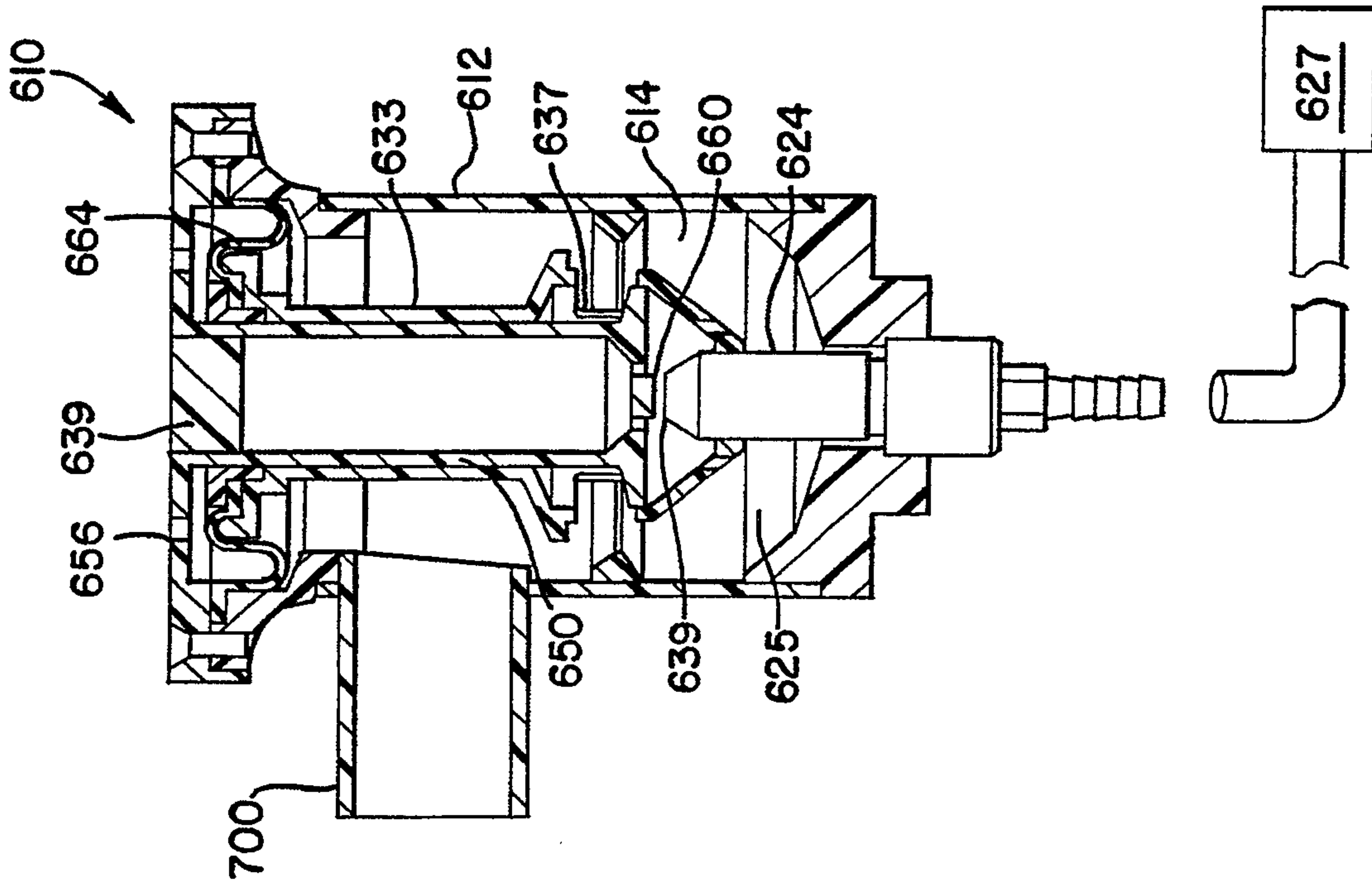


FIG.17A

