



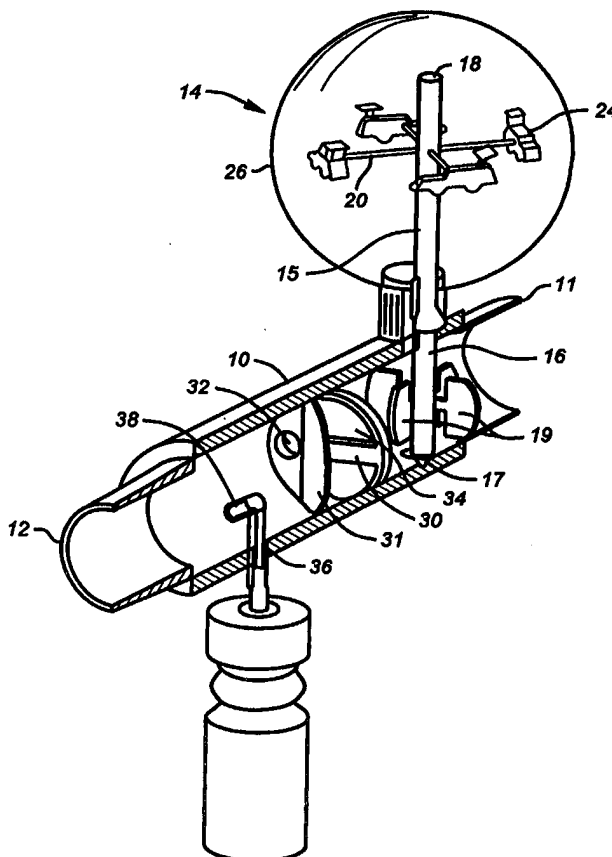
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(21) International Application Number: PCT/US98/06778 (22) International Filing Date: 6 April 1998 (06.04.98) (30) Priority Data: 08/841,937 8 April 1997 (08.04.97) US (71) Applicant: THE BOARD OF REGENTS OF THE UNIVERSITY OF TEXAS SYSTEM [US/US]; 201 West 7th Street, Austin, TX 78702-2981 (US). (72) Inventors: BUTLER, Bruce, D.; 1609 Milford, Houston, TX 77006 (US). WARTERS, R., David; 321 Pinehaven, Houston, TX 77024 (US). (74) Agent: REDANO, Richard, T.; Rosenblatt & Redano, P.C., Suite 500, One Greenway Plaza, Houston, TX 77046 (US).		(81) Designated States: CA, JP, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>

(54) Title: METHOD AND APPARATUS FOR INDUCTION OF INHALED PHARMACOLOGICAL AGENT BY A PEDIATRIC PATIENT

(57) Abstract

This invention relates to an apparatus for inducing a pediatric patient breathing gas through a face mask to inhale a fluid pharmacological agent. The apparatus comprises a fluid conduit (10) through which fluid pharmacological agent may be inhaled, a sensory patient stimulator (14) coupled to said conduit (10), and actuated by inspiratory or expiratory flow through said conduit.



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**TITLE: METHOD AND APPARATUS FOR INDUCTION OF INHALED
PHARMACOLOGICAL AGENT BY A PEDIATRIC PATIENT**

**INVENTORS: Bruce D. Butler
R. David Warters**

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates to an apparatus for inducing a pediatric patient to inhale a fluid pharmacological agent through a face mask. The apparatus comprises a fluid conduit through which fluid pharmacological agent may be inhaled, and a sensory patient stimulator coupled to said conduit and actuatable by inspiratory or expiratory flow through said conduit.

2. Description of the Prior Art

In the medical arts, it is customary to deliver pharmacological agents to a patient. For instance, it is common to induce anesthesia in patients prior to many surgical procedures. A common method of inducing anesthesia is through the inhalation of pharmacological fluids through a face mask. The delivery of pharmacological agents through a face mask to a pediatric patient, particularly to a preschool age child, is often difficult. This difficulty is a result of many factors, including but not limited to a child's short attention span, fear, and/or an inability to comprehend the importance of inhaling pharmacological fluids.

The lack of cooperation exhibited by many pediatric patients during the course of attempting to administer pharmacological agents in fluid form can result in increased anxiety on the part of the patient, the patient's parents or guardians, and the anesthetist. There is also a risk of bodily injury to an uncooperative or combative patient. Such increased anxiety and lack of cooperation result in an

increase in the time required to induce anesthesia in an uncooperative pediatric patient.

Common prior art procedures for inducing a pediatric patient to inhale pharmacological fluids for anesthesia are to allow the patient to first play with a face mask prior to the induction of pharmacological gas, so that the child becomes familiar and comfortable with mask ventilation.

The process of administering a fluid pharmacological agent comprises both inhalation or inspiration and exhalation or expiration by the patient. It is desirable to motivate the pediatric patient to maximize his breathing rate and volume of inhaled or inspired gases. The present invention provides an apparatus for inducing a pediatric patient to inhale pharmacological agent by providing a sensory stimulus to the pediatric patient which induces the patient to maximize his inhalation of a pharmacological agent. An advantage of the present invention is the potential for decreased dosage or necessity of preoperative sedation.

The sensory stimulus provided by the present invention is simple and inexpensive, requiring no electrical or electronic parts. This is one major advantage of the present invention over the inhaler devices of the prior art which involve complex and expensive electronics. Such prior art devices are disclosed in U.S. Patent No. 5,363,842 to Mishelovich et al. and U.S. Patent No. 5,167,506 to Killis et al. Certain of these prior art devices, such as that disclosed in U.S. Patent No. 5,167,506, use display screens which display text messages. Such text message screens are of little or no value with pediatric patients who have not yet learned to read.

Another advantage of the present invention is that the sensory stimulus is easily visible to a pediatric patient breathing gas through a face mask. Prior art inhalation devices comprise indicator means that are visible to a party dispensing drugs to a patient, but which provide insufficient visual or sensory stimulus to directly induce the patient to maximize his breathing. One such prior art device is disclosed in U.S. Patent No. 4,832,015 to Nowacki et al.

SUMMARY OF THE INVENTION

The present invention is directed toward an apparatus for inducing a pediatric patient to inhale a fluid pharmacological agent through a face mask. The invention comprises a fluid conduit having a first end and second end. The first end is capable of being coupled to a source of fluid pharmacological agent and the second end is capable of being coupled to a face mask sized to fit a pediatric patient such that fluid pharmacological agent flowing through the conduit can enter the face mask. The conduit has sufficient diameter to allow fluid pharmacological agent to flow through the conduit at a sufficient flow rate to be inhaled by a pediatric patient.

The invention further comprises a sensory patient stimulator coupled to the conduit such that the inspiratory or expiratory flow through the conduit activates the stimulator. The stimulator is positioned such that when it is activated, it can be seen by a pediatric patient breathing gas through a face mask connected to the second end of the conduit. The activation of the stimulator may be dynamic, such as by visible movement, or the activation may be static, such as by a visible color change.

DESCRIPTION OF THE DRAWINGS

Figure 1 is an isometric view of a first embodiment of the present invention.

Figure 2 is a side view of a second embodiment of the present invention being used by a pediatric patient.

Figure 3 is a top view of a third embodiment of the rotor and arm assembly of the present invention.

Figure 4 is a top view of a fourth embodiment of the fluid conduit of the present invention.

Figure 5 is a side view of a fifth embodiment of the present invention.

Figure 6 is a side view of a sixth embodiment of the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

The invention comprises a fluid conduit 10 having a first end 11 and a second end 12. The first end is capable of being coupled to a source of fluid pharmacological agent. The second end is capable of being coupled to a face

mask sized to fit a pediatric patient, such that fluid pharmacological agent flowing through the conduit can enter a face mask. The conduit has a sufficient diameter to allow fluid pharmacological agent to flow through it at a sufficient flow rate to be inhaled by a pediatric patient.

5 In another embodiment, as shown in Figure 4, the fluid conduit comprises a rotor housing 40 comprising a first port 44 and a second port 42. The first and second ports are positioned on opposite sides of the rotor housing and are offset from the center of the rotor housing. This offset provides unidirectional rotation of a rotor in said housing.

10 The invention further comprises a sensory patient stimulator 14, coupled to the conduit such that inspiratory or expiratory flow through the conduit activates the stimulator. The stimulator is positioned such that when it is activated, it provides a stimulus that is visible to a pediatric patient breathing gas through a face mask connected to the second end of the conduit.

15 In one preferred embodiment, the sensory patient stimulator 14 is a rotating visual stimulator as shown in Figures 1 and 2. The visual stimulator may comprise arcuate members 13, as shown in Figure 2. In this embodiment, the stimulator may comprise a rotatable turbine 15 whose rotation is actuatable upon the patient's exhalation or inhalation, as shown in Figures 1 and 2.

20 In another preferred embodiment, the stimulator comprise a material that changes color in response to temperature changes as shown in Figure 6. In this embodiment, the portion of the stimulator not positioned in the fluid conduit may be coated with a thermal liquid crystal paint 9 that changes color in response to temperature changes. Such paints are available from Cole-Parmer® Instrument
25 Company. The inspiration and expiration of a pediatric patient through the fluid conduit cause air temperature changes which result in a visible color change in the stimulator.

 In another preferred embodiment, the rotatable turbine comprises a turbine driven rotor 16 having a first end 17 in said fluid conduit, a second end 18 extending

outside said fluid conduit, and at least two turbine blades **19** affixed to the first end. As shown in Figure 1, the turbine blades are positioned in the stream of ventilatory gases. In this embodiment, the second end of the rotor comprises at least one arm **20** extending radially outward, such that when the rotor rotates, the rotation of the arm is visible to a patient inhaling or exhaling ventilatory gases through a face mask. The visual stimulation may also comprise a spherical element located on the second end of said rotor.

The arm comprises a near end **21** attached to the rotor, a far end **22** opposite the near end, and a visual object **24** affixed to the far end. In a preferred embodiment, each of the visual objects is of sufficient size to capture the attention of the patient inhaling or exhaling ventilatory gases through a face mask when the rotor is rotating, as depicted in Figures 1 and 2. In preferred embodiments, the visual object may be shaped to represent things that young children readily associate with motion, such as a car, truck or an animal.

In one embodiment of the present invention, the rotor comprises at least three arms spaced apart radially by at least 90° , as shown in Figure 3. In Figure 3, the spacing angle between adjacent arms is denoted by the symbol θ .

In another embodiment of the present invention, the rotor comprises four arms spaced apart radially by at least 60° , as shown in Figure 1. In a preferred embodiment, the second end of the rotor and the arms are housed within a transparent housing **26**, as shown in Figure 1.

In another embodiment of the present invention, a flow control device **30** is installed in the conduit. In a preferred embodiment, the flow control device comprises a check valve **31**. The check valve may be a flapper valve, as shown in Figure 1.

In another preferred embodiment, the visual stimulator **14** is inflatable in response to a patients' exhalation and deflatable in response to a patient's inhalation, as shown in Figure 5.

In another preferred embodiment, the flow control device comprises an inhalation port **34**, an exhalation port **32**, and a check valve, as shown in Figure 1. In a preferred embodiment, the exhalation port and inhalation port are positioned on the flow control device to produce rotation of the turbine driven rotor in the same direction upon the patient's inhalation and exhalation.

In a preferred embodiment, the invention further comprises a fluid injection port **36** positioned in the fluid conduit between the second end of the fluid conduit and the flow control device. In a preferred embodiment, the invention further comprises a flow diverter **38** positioned in the fluid conduit, such that fluid injected into the fluid injection port is directed toward the second end of the fluid conduit.

The foregoing disclosure and description of the invention are illustrative and explanatory thereof, and various changes in the size, shape and materials, as well as in the details of the illustrated construction, may be made without departing from the spirit of the invention.

WHAT IS CLAIMED IS:

1 1. An apparatus for inducing a pediatric patient to inhale a fluid
2 pharmacological agent through a face mask, comprising:

3 a. a fluid conduit having a first end and a second end, said first end
4 capable of being coupled to a source of fluid pharmacological agent
5 and said second end capable of being coupled to a face mask sized
6 to fit a pediatric patient such that fluid pharmacological agent flowing
7 through said conduit can enter a face mask, said conduit having
8 sufficient diameter to allow fluid pharmacological agent to flow
9 through said conduit at a sufficient flow rate to be inhaled by a
10 pediatric patient; and

11 b. a sensory patient stimulator coupled to said conduit such that
12 inspiratory or expiratory flow through said conduit activates said
13 stimulator, said stimulator being positioned such that when it is
14 activated, it provides a stimulus that is visible to a pediatric patient
15 breathing through a face mask connected to said second end of said
16 conduit.

1 2. The apparatus of claim 1, wherein said stimulator comprises a
2 rotatable turbine whose rotation is actuatable by a pediatric patient's exhalation or
3 inhalation, and further comprising a flow control device installed in said conduit.

1 3. The apparatus of claim 2, wherein said rotatable turbine comprises a
2 turbine driven rotor comprising a first end in said fluid conduit, a second end
3 extending outside said fluid conduit and at least two turbine blades affixed to said
4 first end.

1 4. The apparatus of claim 3, wherein said second end of said rotor
2 comprises at least one arm extending radially outward, such that when said rotor

3 rotates, the rotation of said arm is visible to a pediatric patient inhaling or exhaling
4 ventilatory gases through a face mask.

1 5. The apparatus of claim 4, wherein each of said arms comprises a near
2 end attached to said rotor, a far end opposite said near end, and a visual object
3 affixed to said far end.

1 6. The apparatus of claim 5, wherein each of said visual objects is of
2 sufficient size to capture the attention of a pediatric patient inhaling or exhaling
3 ventilatory gases through a face mask, when said rotor is rotating.

1 7. The apparatus of claim 6, wherein said second end of said rotor
2 comprises at least two arms spaced apart radially by at least 150 degrees.

1 8. The apparatus of claim 6, wherein said second end of said rotor and
2 said arms are housed within a transparent housing.

1 9. The apparatus of claim 2, wherein said flow control device comprise
2 a check valve.

1 10. The apparatus of claim 9, wherein said check valve is a flapper valve.

1 11. The apparatus of claim 1, wherein said stimulator is inflatable in
2 response to a patient's exhalation and deflatable in response to a patient's
3 inhalation.

1 12. The apparatus of claim 1, wherein said stimulator comprises a
2 material that changes color in response to temperature changes.

1 13. An apparatus for inducing a pediatric patient to inhale a fluid
2 pharmacological agent through a face mask, comprising:

- 3 a. a fluid conduit having a first end and a second end, said first end
4 capable of being coupled to a source of fluid pharmacological agent
5 and said second end capable of being coupled to a face mask sized
6 to fit a pediatric patient such that fluid pharmacological agent flowing
7 through said conduit can enter a face mask, said conduit having
8 sufficient diameter to allow fluid pharmacological agent to flow
9 through said conduit at a sufficient flow rate to be inhaled by a
10 pediatric patient;
11 b. a visual patient stimulator coupled to said conduit such that
12 inspiratory or expiratory flow through said conduit activates said
13 stimulator, said stimulator being positioned such that when it is
14 activated, it can be seen by a pediatric patient breathing gas through
15 a face mask connected to said second end of said conduit; and
16 c. a flow control device installed in said conduit, said flow control device
17 comprising an inhalation port, an exhalation port, and a check valve.

1 14. The apparatus of claim 13, wherein said stimulator comprises a
2 turbine driven rotor comprising a first end in said fluid conduit, a second end
3 extending outside said fluid conduit, and at least two turbine blades affixed to the
4 first end and wherein the second end of said rotor comprises at least one arm
5 extending radially outward such that when said rotor rotates, the rotation of said
6 arm is visible to a patient breathing the ventilatory gases through a face mask.

1 15. The apparatus of claim 14, wherein said exhalation port and said
2 inhalation port are positioned on said flow control device to produce rotation of said
3 turbine driven rotor in the same direction upon inhalation or exhalation by a
4 pediatric patient.

1 16. The apparatus of claim 15, further comprising a fluid injection port
2 positioned in said fluid conduit between said second end of said fluid conduit and
3 said flow control device.

1 17. The apparatus of claim 16, further comprising a flow diverter
2 positioned in said fluid conduit such that fluid injected into said fluid injection port
3 is directed toward said second end of said fluid conduit.

1 18. An apparatus for inducing a pediatric patient to inhale a fluid
2 pharmacological agent while breathing gas through a face mask, comprising:

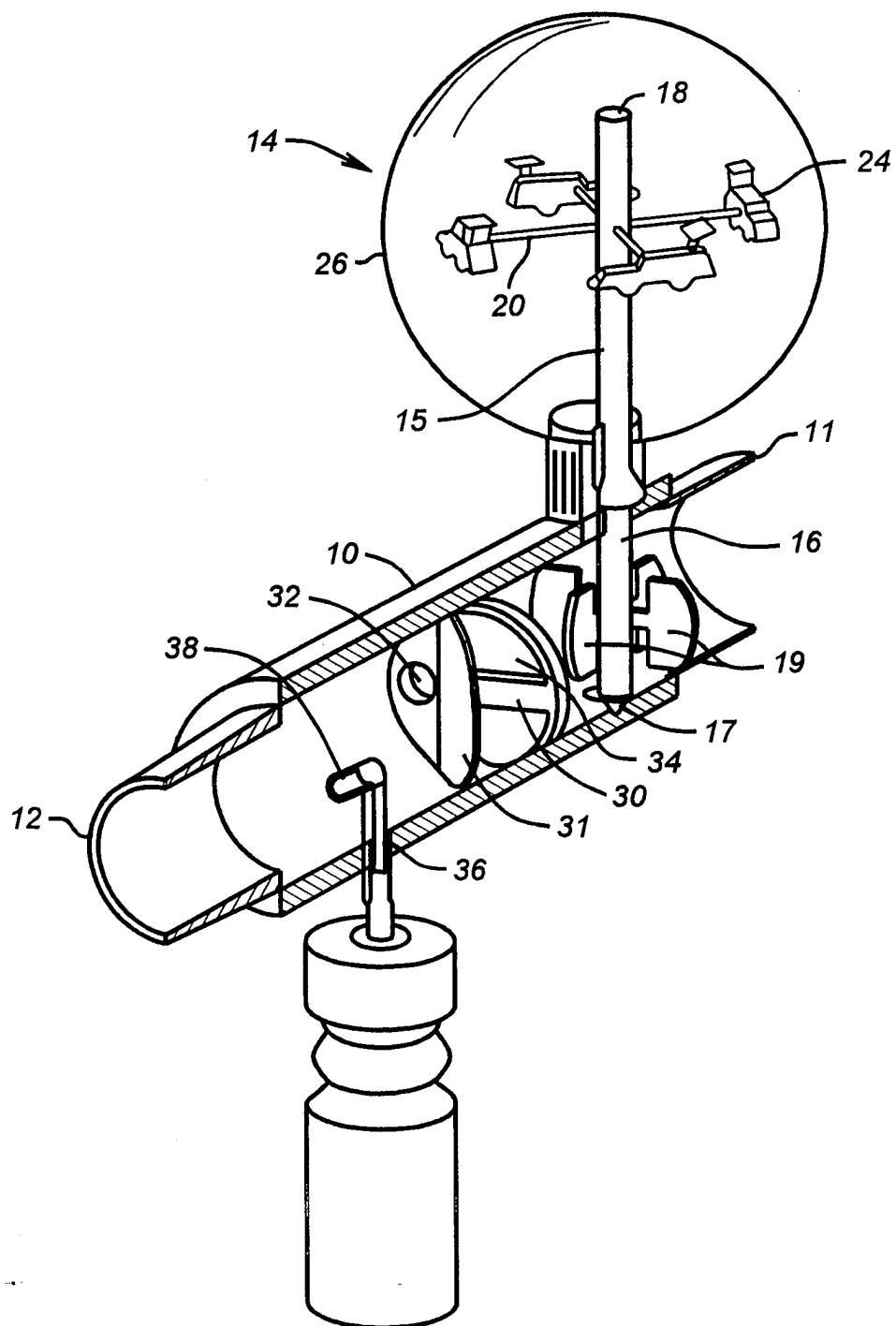
- 3 a. a fluid conduit having a first end, a second end, and a rotor housing,
4 said first end capable of being coupled to a source of fluid
5 pharmacological agent and said second end capable of being coupled
6 to a face mask sized to fit a pediatric patient such that fluid
7 pharmacological agent flowing through said conduit can enter a face
8 mask, said rotor housing comprising first port and a second port
9 positioned on opposite sides of said housing and offset from the
10 center of said housing; said conduit having sufficient diameter to allow
11 fluid pharmacological agent to flow through said conduit at a sufficient
12 flow rate to be inhaled by a pediatric patient;
- 13 b. a turbine driven rotor in said rotor housing, said rotor comprising a
14 first end in said fluid conduit, a second end extending outside said
15 fluid conduit, and at least two turbine blades affixed to the first end;
16 and
- 17 c. a visual stimulator affixed to the second end of said rotor such that
18 said stimulator moves when said rotor rotates, and said stimulator
19 being of sufficient size such that its movement is visible to a pediatric
20 patient breathing ventilatory gases through a face mask.

1 19. The apparatus of claim 18, wherein said stimulator rotates when said
2 rotor rotates.

1 20. The apparatus of claim 18, wherein said rotor housing is cylindrical.

1 21. The apparatus of claim 18, wherein said visual stimulator is housed
2 within a transparent housing.

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**FIG. 1**

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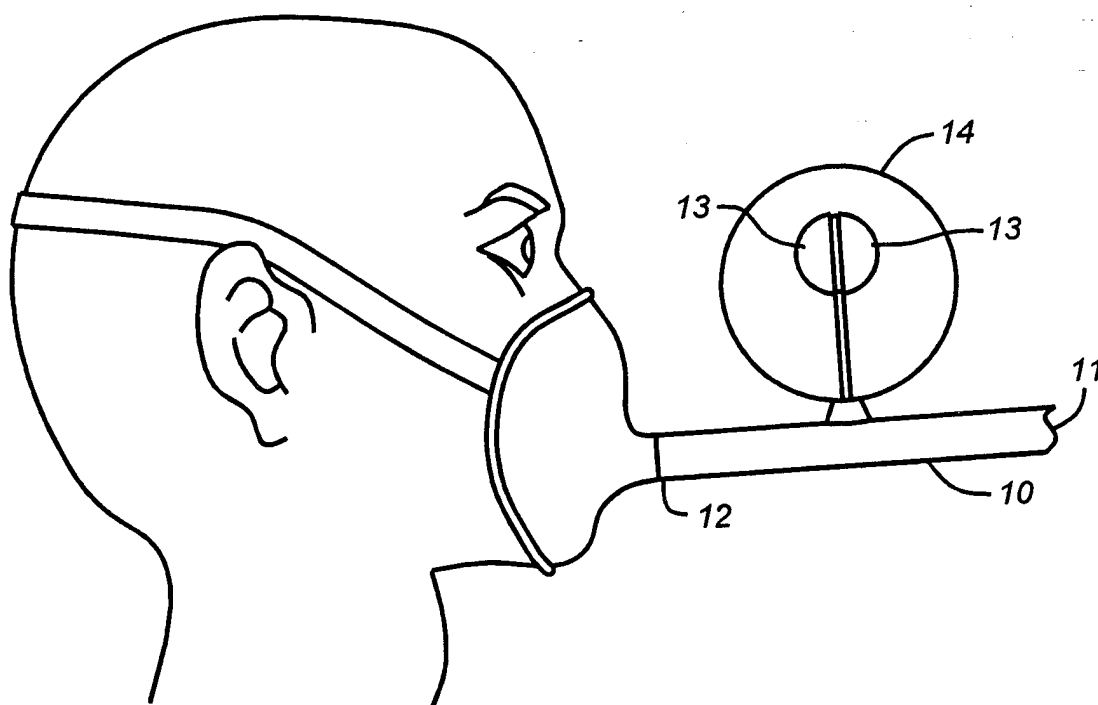


FIG. 2

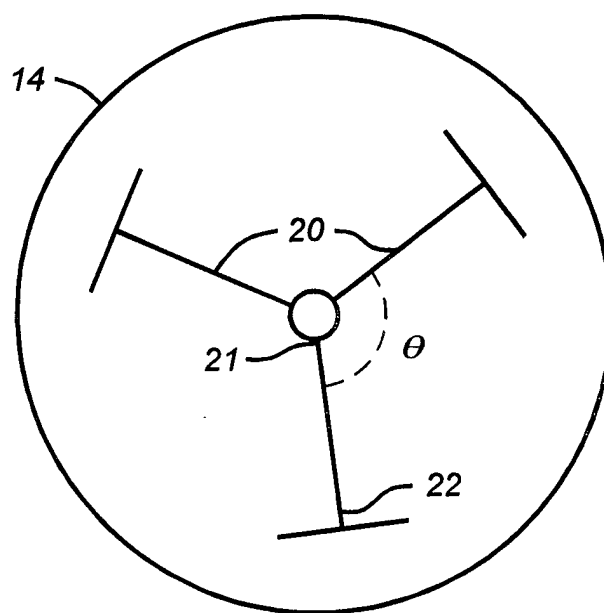


FIG. 3

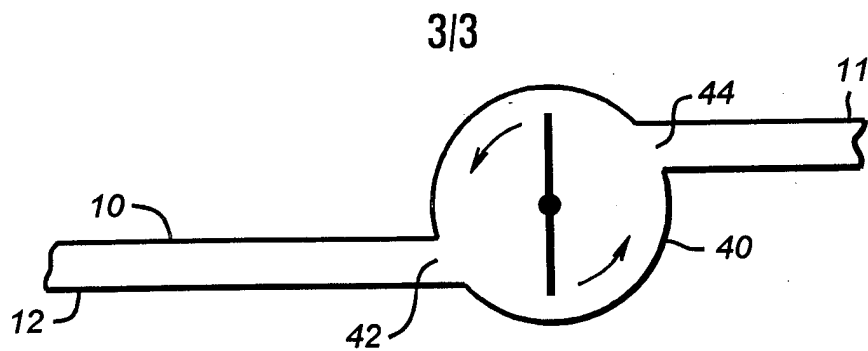


FIG. 4

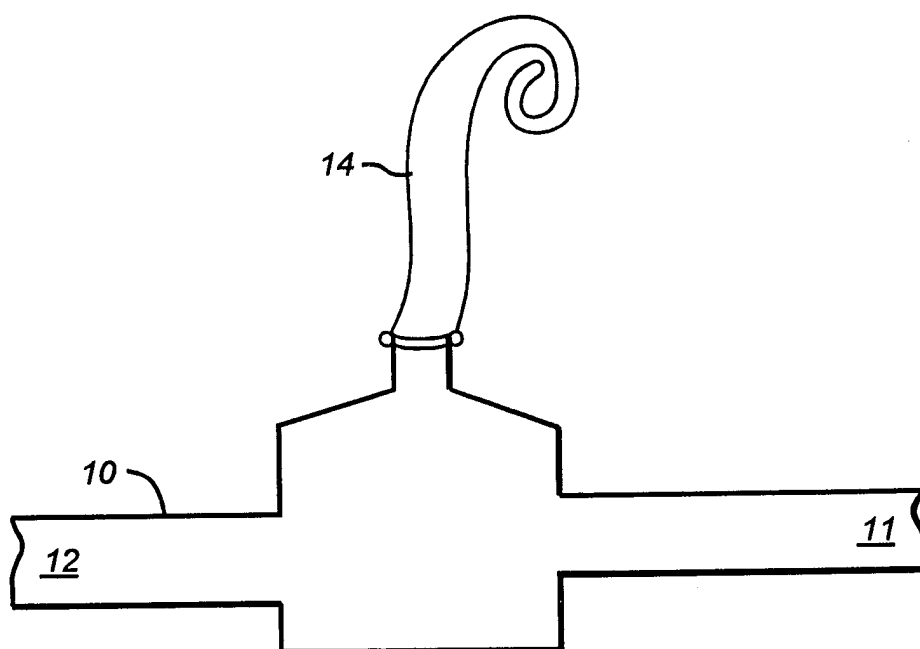


FIG. 5

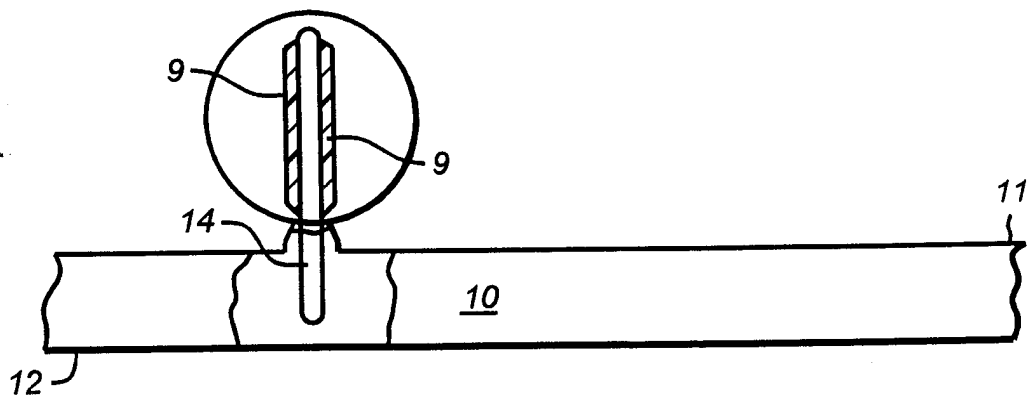


FIG. 6

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US98/06778

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61M 15/00

US CL :128/203.12

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/200.14, 200.23; 203.28, 205.11, 205.13

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5,363,842 A (MISHELEVICH ET AL) 11 NOVEMBER 1994,SEE ENTIRE DOCUMENT	1-21
Y	US 5,613,489 A (MILLER ET AL) 25 MARCH 1997,SEE ENTIRE DOCUMENT.	1-21
Y	US 5,522,380 A (DWORK) 04 JUNE 1996,SEE ENTIRE DOCUMENT.	1-21



Further documents are listed in the continuation of Box C.



See patent family annex.

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Date of the actual completion of the international search

10 AUGUST 1998

Date of mailing of the international search report

03 SEP 1998

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