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(54) Title: A DUAL-PURPOSE DEVICE FOR DRUG DELIVERY AND SECRETION COLLECTION AND METHODS FOR USING THE SAME

(57) Abstract: A dual-purpose medical device for drug delivery and secretion collection and methods for using the device are disclosed. The device for drug delivery and secretion collection upper airway treatment includes two primary components. The first component is a cassette connectable to an airflow generator. The second component is the airflow generator. The airflow generator is manually operable and relies upon ambient air to create a flow of air. The airflow generator is capable of generating airflow through the cassette for either aerosol delivery of a drug or for suction of samples or unwanted secretions. Further disclosed is a method for aearosol delivery of a drug using the disclosed device. The method includes at least two steps. In the first step, the airflow generator is connected to the cassette. In the second step, air is caused to flow through the cassette so that aerosol delivery of a drug in the cassette is accomplished. Further disclosed is a method for suction of samples or unwanted secretions from a bodily orifice. The method includes at least two steps. In the first step, the airflow generator is connected to the cassette. In the second step, air is caused to flow through the cassette so that suction of samples or unwanted secretions from a bodily orifice is accomplished and so that the samples or unwanted secretions accumulate in the cassette.

A DUAL-PURPOSE DEVICE FOR DRUG DELIVERY AND SECRETION COLLECTION AND METHODS FOR USING THE SAME

FIELD AND BACKGROUND OF THE INVENTION

The present invention relates to a medical device. More particularly, the present invention relates to a device capable of both delivery of drugs and removal of fluids, for therapeutic or diagnostic purposes. Specifically, the present invention relates to the delivery of substances, such as drugs and other medicaments, through a bodily orifice (mouth, nose, ear, eye, rectum, vagina, et al.) and removal of fluid samples or secretions therefrom.

Medical disorders of the upper airway are common. Asthma affects approximately 10% of the adult population. Asthmatic patients, together with those suffering from cystic fibrosis, bronchitis, smoking related disorders and infants with difficulty maintaining adequate oral ventilation are probably found in 20-50% of households. Patients with these disorders are generally treated with drugs delivered as an aerosol suspension, or with suction to remove samples or unwanted secretions, or with both aerosol drugs and suction.

Aerosol delivery of drugs to the upper airway is typically accomplished by either a stream of air created by a motorized pump, or by use of a pressurized propellant gas (e.g. aerosol canister).

Aerosol delivery devices, which include a motorized pump, are typically heavy, noisy and expensive. A typical device may cost a consumer between $70 and $200. In addition, use of devices of this type often requires measuring and mixing of components of the aerosol. This provides an opportunity for patient error and may lead to delivery of an incorrect dose of medication.

Devices, which rely upon a pressurized propellant gas, are typically configured to deliver a pre-measured dose of medication with each actuation. However, medication packaged in this way is relatively expensive. In addition, patients with poor co-ordination (e.g. young children, geriatric patients) often have difficulty using these devices. These patients typically employ a spacing chamber that allows them to draw in medication by inhaling after actuation of the device. Such a spacing chamber typically costs approximately $30. While devices of this type are often small enough to be easily portable (pocket size), the spacing chambers employed with these devices are generally too large to be conveniently portable (typically 6cm by 15 cm).

Suction of unwanted secretions such as mucous from the upper airway (e.g. nose, pharynx) is often performed using devices with electric vacuum pumps. These devices are

typically found primarily in hospitals and medical facilities. They are heavy, noisy and expensive. Currently, the primary solution for home suction is a portable device, disclosed in British Pat. No. 2,245,833. This patent does not teach the use of a disposable mucous trap. A re-usable mucous trap is a potential source of infection and represents a serious limitation in practicing of the teachings of the patent.

There is thus a widely recognized need for, and it would be highly advantageous to have, a device for upper airway treatment devoid of the above limitation. Ideally, such a device would be a dual-purpose device capable of performing both aerosol delivery and suction treatments, specifically, delivery of substances, such as drugs and other medicaments, through a bodily orifice (mouth, nose, ear, eye, rectum, vagina, et al.) and removal of samples or unwanted secretions therefrom.

SUMMARY OF THE INVENTION

The device and the methods of the present invention successfully addresses the shortcomings of the presently known configurations by providing a dual-purpose medical device for drug delivery and secretion collection and methods for using same, which facilitates both drug delivery and hygienic removal of fluid samples or secretions from a bodily orifice.

According to the teachings of the present invention there is provided a first device, useful for the removal of fluids (such as blood, mucous, pus and other secretions for example, for therapeutic or diagnostic purposes) through a bodily orifice (mouth, nose, ear, eye, rectum, vagina, et al.), comprising a cassette having a first opening, a second opening and an air-filled interior volume. The cassette is configured to allow the air to be evacuated by the application of suction at the first opening consequently producing suction at the second opening.

According to a feature of the first device of the present invention, there is provided a manually operable airflow generator, configured to create the suction at the first opening. At least part of the airflow generator is a reversibly deformable air-filled compressible container. The airflow generator is configured to create the suction at the first opening upon expansion of the container, after the container has been compressed. It is important to emphasize that when the term "reversibly deformed" is used herein, the meaning is that once the container has been compressed with a force and the force is released, the container has a property (such as elasticity) or there exists a mechanism (such as a spring) to cause the container to return to substantially the pre-compression shape and configuration.

According to a different feature of the first device of the present invention, the source of suction at the first opening is a mechanical air pump, including for example, a household vacuum cleaner.

According to a further feature of the first device of the present invention, there is a tube, connectable or attached to the second opening, where the tube is configured to be insertable into a bodily orifice and to remove fluids therefrom.

According to still further feature of the present invention, the cassette is configured to contain a fluid entering the cassette through the second opening. Once the fluid is contained in the cassette, the cassette is configured to prevent the fluid from escaping through the first opening.

There is also provided according to the teachings of the present invention a second device, useful for the delivery of drugs (in the form of an aerosol, a liquid, a gas or a dry powder) through a bodily orifice, made up of a cassette having a first opening, a second opening and an interior volume, and configured to allow air to flow from the first opening, through the interior volume and out through the second opening. When the air flows through the cassette, the flow of air causes delivery of a drug confined within the internal volume. Two examples of drugs deliverable by the second device of the present invention are antihistamines or an aqueous saline solution.

According to a feature of the first device of the present invention, there is provided a manually operable airflow generator, configured to create the flow of air at the first opening. At least part of the airflow generator is a reversibly deformable air-filled compressible container. The airflow generator is configured to create the flow of air at the first opening upon compression of the container. The container is configured to fill up with ambient air during the expansion subsequent to the compression.

According to a different feature of the second device of the present invention, the source of air flow at the first opening is a mechanical air pump.

According to a further feature of the second device of the present invention, there is a tube, connectable or attached to the second opening, where the tube is configured to be insertable into a bodily orifice and to deliver drugs into the bodily orifice.

According to a still further feature of the second device of the present invention, there is an aerosol jet, connectable or attached to the second opening, where the aerosol jet is configured to deliver the confined drug as a plurality of micro-droplets.

According to a further feature of the second device of the present invention, the dosage and the nature of the drug contained within the cassette is identifiable by marks on the external surface of the cassette. Such marks can include but are not limited to a specific coloration or pattern of coloration for visual identification of the dosage or nature of the drug or to some palpable structure such as ridges or incised pattern for tactile identification of the dosage or nature of the drug.

According to a still further feature of the second device of the present invention, a mask is provided, operatively connected to the second opening of the cassette. Such a mask is configured to sealingly fit over the bodily orifice, usually the mouth, nose or both simultaneously to increase the efficiency of drug delivery. When the drug exits the second opening it is dispersed inside the volume defined by the mask and the bodily orifice. It is preferable that the inside surface of the mask is made of or coated with a material that has the property to reject aerosol particles, for example by modifying the electrostatic properties of the mask.

According to a further feature of the second device of the present invention there is provided a multi-diameter orifice mechanism. Such a mechanism has substantially three openings. One opening, the inlet, is functionally connected to the source of airflow. The second opening is the drug-delivery outlet and is functionally connected to the first opening of the cassette. The third opening is the pressure-release outlet. The ratio of the diameters of the two outlets is determined so that of an amount of air flowing in through the first opening of the cassette, a certain proportion flows out through the pressure release outlet and the remainder flows out through the drug delivery outlet into the internal volume to carry the drug confined therein through the second opening of the cassette. In such a way the amount of drug transported to the bodily orifice as a result of each application of airflow ("puff") can be varied. This allows delivery of the drug dose with one or multiple puffs, as decided by the patient or other person.

According to a still further feature of the second device of the present invention with a multi-diameter orifice mechanism, the drug-delivery outlet has a fixed diameter whereas the pressure-release outlet has a variable user-defined diameter. This allows the number of "puffs" necessary for drug delivery to be decided upon use.

According to a further feature of the second device of the present invention, the cassette is also configured to be useful for the removal of fluids in analogy to the first device of the present invention, described hereinabove. In some cases it may be useful to add a mechanism

that allows the user to select either from two or from three modes: a drug delivery mode (actuation of the airflow generator delivers the drug through the second opening), fluid removal mode (actuation of the airflow generator removes fluid through the second opening) and combined mode (the airflow generator first delivers the drug and thereafter removes fluid, both through the second opening).

Ideally, the same device which produces the airflow to deliver the drug contained within the interior volume is also configured to produce the suction necessary to remove the fluids. For example, the expansion of the manually operated elastic air-filled compressible container can be configured to create the suction at the first opening upon expansion of the container.

According to a feature of both the first and the second device of the present invention, the cassette is placed within a reusable holder for use. The reusable holder can be optionally configured to hold for storage at least one cassette for increased convenience. When held for storage, any seals a cassette may have are not compromised and activation of the airflow according to the invention does not lead to the passage of air through a stored cassette.

According to a further feature of both the first and second device of the present invention, the first opening is sealed with a removable first opening seal. The first opening seal can be manually removed or be automatically removed when the cassette is attached to the source of air flow.

According to a further feature of both the first and second device of the present invention, the second opening is sealed with a removable second opening seal. The second opening seal can be manually removed or can be removed as a result of pressure accumulating in the interior volume of the cassette as a result of the flow of air.

According to a further feature of both the first and second device of the present invention, there is a pressure activated valve operatively attached to the second opening, effectively sealing it, but allowing drug exit, fluid entrance, or both when the respective device is activated.

According to a still further feature of both the first and second device of the present invention, the cassette has a partition dividing the interior volume into at least two separate chambers and on the partition is an openable region, sealed with a removable partition seal and where at least one of the chambers contains at least one component of a drug. According to a feature of the invention, the partition seal is removed by the act of connecting the airflow source. According to a further feature of the present invention the partition seal is removed with

the use of a mechanism configured for that purpose. The seals can be perforated to ease removal of the partition seal.

It is clear that it is most advantageous to design the casettes of both the first and second device of the present invention to be disposable.

There is also provided according to the teachings of the present invention a first method for delivery of a drug (in the form of an aerosol, a liquid, a gas or a dry powder) through a bodily orifice (mouth, nose, ear, eye, rectum, vagina, et al.) by: (a) providing a cassette having a first opening, a second opening and an interior volume. When air flows through the cassette from the first opening, through the interior volume and out through the second opening, a drug confined inside the interior volume of the cassette is delivered through the second opening. (b) connecting a source of airflow to the first opening and (c) causing air to flow into the internal volume via the first opening and outward from the internal volume via the second opening towards a bodily orifice of a patient so that drug contained within the internal volume of the cassette is accomplished.

According to a feature of the first method of the present invention the source of airflow includes a manually operable airflow generator configured to generate the required airflow from ambient air. Such an airflow generator can have a reversibly deformable compressible container and at least one air outlet. In order to operate such an airflow generator, the container is compressed, creating the required airflow.

According to a different feature of the first method of the present invention, the source of airflow includes a mechanical pump, such as is well known in the art.

According to a further feature of the first method of the present invention, the cassette has a partition dividing the interior volume into at least two separate chambers and on the partition is an openable region, sealed with a removable partition seal and where at least one of the chambers contains at least one component of a drug. According to a feature of the invention, the partition seal is removed by the act of connecting the airflow source.

According to a still further feature of the first method of the present invention, the cassette is placed within a reusable holder for use.

According to a still further feature of the first method of the present invention, an aerosol jet is attached to the second opening so that the drug exiting the cassette through the second opening is made into an aerosol. The aerosol jet is either removably attached or permanently fixed.

According to a still further feature of the first method of the present invention, a drug delivery tube is connected on one end to the second opening and the other end of the tube is inserted into whatever bodily orifice it is required to deliver the drug. It is clear that the tube is designed in accordance with the nature of the drug and the identity and size of the bodily orifice into which it is inserted. When present, the drug delivery tube is either removably attached or permanently fixed.

According to a still further feature of the first method of the present invention, either the first opening or the second opening or both are sealed with removable seals. It is clear that to perform all steps of the first method of the present invention it is necessary to remove the opening seals.

There is also provided according to the teachings of the present invention a second method for the removal of a fluid (such as blood, mucous, pus and other secretions for example, for therapeutic or diagnostic purposes) from a bodily orifice (mouth, nose, ear, eye, rectum, vagina, et al.) by: (a) providing a cassette having a first opening, a second opening and an interior volume, the cassette configured to produce suction at the second opening when suction is applied to the first opening. The cassette is configured so that the suction at the second opening causes removal of fluid from the bodily orifice into the internal volume; (b) applying suction to the first opening; (c) removing fluids from the bodily orifice.

According to a feature of the second method of the present invention the source of suction at the first opening includes a manually operable airflow generator configured to generate the required suction. Such an airflow generator can have a reversibly deformable compressible container. In order to operate such an airflow generator, the container is compressed. When released, the container expands generating, the required suction.

According to a different feature of the second method of the present invention, the source of suction at the first opening includes a mechanical pump, for example, a household vacuum cleaner.

According to a still further feature of the second method of the present invention, the cassette is placed within a reusable holder for use.

According to a still further feature of the second method of the present invention, a suction tube is connected on one end to the second opening and the other end of the tube is inserted into whatever bodily orifice sction is required. It is clear that the tube is designed in accordance with the identity and size of the bodily orifice into which it is inserted. When present, the suction tube is either removably attached or permanently fixed.

According to a still further feature of the second method of the present invention, the fluids removed are retained inside of the cassette and the cassette with the fluids therein is discarded.

According to a still further feature of the second method of the present invention, either the first opening or the second opening or both are sealed with removable seals. It is clear that to perform all steps of the first method of the present invention it is necessary to remove the opening seals.

The opening seal of the first opening can be configured to be manually removable or to be automatically removed when the cassette is attached to a source of air. The opening seal of the second opening can be configured to be manually removable or removable by the action of excess air pressure in the interior volume of the cassette when air is allowed to flow therein.

According to a still further feature of the second method of the present invention, there is an air-pressure actuated valve covering the second opening. In such a case, escape of the contents of the cassette is prevented by the valve. When the airflow is actuated, the valve is configured to open in the appropriate fashion to allow proper functioning of the device.

There is also provided according to the teachings of the present invention a method of easing breathing of a patient having nasal congestion by: (a) providing a cassette having a first opening, a second opening and an interior volume, wherein: i) the cassette is configured so that air flowing from the first opening, through the interior volume and out through said second opening causes delivery of a drug confined within the internal volume via the second opening; and wherein ii) the cassette is further configured to produce suction at the second opening when air is evacuated from the cassette through the first opening, so that the suction draws fluid into the internal volume via the second opening; (b) placing the second opening in proximity of a nasal cavity of the patient; (c) causing air to flow through the internal volume via the first opening and outward from the internal volume via the second opening towards a bodily orifice of a patient such that delivery of a drug is accomplished. If the drug is an aqueous saline solution, this renders any mucous that congests the nasal passages more fluid and easier to remove. Subsequently, air is evacuated through the first opening, causing suction at the second opening which is used to remove the fluid causing the nasal congestion.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention is herein described, by way of example only, with reference to the accompanying drawings. With specific reference now to the figures in detail, it is stressed

that the particulars shown are by way of example and for purposes of illustrative discussion of the preferred embodiments of the present invention only, and are presented in the cause of providing what is believed to be the most useful and readily understood description of the principles and conceptual aspects of the invention. In this regard, no attempt is made to show structural details of the invention in more detail than is necessary for a fundamental understanding of the invention, the description taken with the drawings making apparent to those skilled in the art how the several forms of the invention may be embodied in practice.

In the drawings:

FIG. 1 is a side view of an airflow generator according to the present invention;

FIG. 2 is a side view of the airflow generator of figure 1 in a collapsed state;

FIG. 3 is a transparent view of a disposable cassette according to the present invention;

FIG. 4 shows insertion of a disposable cassette of the present invention in a re-usable holder according to the present invention;

FIGS. 5a and 5b depict opening of an openable region according to the present invention;

FIGS. 6a and 6b depict opening of an openable region according to an alternate preferred embodiment of the present invention;

FIGS. 7a, 7b, and 7c show details of one preferred embodiment of an openable region and a mechanism for opening same according to the present invention;

FIG. 8 is schematic diagram of a device according to the present invention configured for aerosol delivery of a drug;

FIG. 9 is a cut away view of a suction tube according to the present invention;

FIG. 10 is a side view of a device according to the present invention configured for suction of samples or unwanted secretions from a bodily orifice; and

FIG. 11 is a view in perspective of an embodiment of a device of the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention is of a device and of methods for using the device. The present invention can be used to both deliver a drug as an aerosol, a liquid, a gas or a dry powder and to hygienically remove fluid samples and secretions from the body of the patient. Specifically, the invention is useful for the delivery of substances, such as drugs and other medicaments, through

a bodily orifice (mouth, nose, ear, eye, rectum, vagina, et al.) and removal of samples or unwanted secretions therefrom.

The principles and operation of a device and of methods for using the device according to the present invention may be better understood with reference to the drawings and accompanying descriptions.

Before explaining at least one embodiment of the invention in detail, it is to be understood that the invention is not limited in its application to the details of construction and the arrangement of the components set forth in the following description or illustrated in the drawings. The invention is capable of other embodiments or of being practiced or carried out in various ways. Also, it is to be understood that the phraseology and terminology employed herein is for the purpose of description and should not be regarded as limiting.

For purposes of this specification and the accompanying claims, the term "drug" refers to any material that is delivered for prophylactic or therapeutic purposes. The term drug therefore specifically includes, but is not limited to, water, saline solutions, vasoconstrictors, antihistamines, steroid compounds, decongestants, aroma-therapy agents, plant extracts, oils, anti-inflammatory compounds and antibiotics as well as any combination thereof. A drug may take many physical forms, including but not limited to, a liquid, a powder, a gel, an emulsion, a gas, and a solid. It will be appreciated that those solids that have a high vapor pressure at room temperature, i.e. those which tend to sublimate, are more suited for use as a drug in the context of the present invention than those solids with a low vapor pressure at room temperature.

For purposes of this specification and the accompanying claims, the term "patient" refers to any person or animal using the device of, or practicing a method of, the present invention.

Referring now to the drawings, a narrative description of the component parts of a device **20**, and their workings, will be presented. As an example, device **20** described is specifically configured for the treatment of upper airways, typically accessible through the mouth or nose of the patient. For treatments that require access through other bodily orifices, a suitable modified device, operating in a substantially similar way is provided. The necessary modifications are clear to one skilled in the art.

Device **20** for upper airway treatment (figure 8) includes a disposable cassette **30** (figure 3) having a first opening **32** or **67**, a second opening **34** or **67** and an interior volume **36.** In some cases, one first and second opening may be used for delivery of a drug (e.g. **32** and **34**) as an aerosol, a liquid, a gas or a dry powder and a second first and second opening may be used for suction of samples or unwanted secretions from a bodily orifice (e.g. pair of **67**). Cassette **30**

typically is supplied as a sealed unit containing a pre-measured dose of a drug. In order to reduce risk of infection during use, cassette **30** is often supplied in a sterile wrapper that serves also to seal openings **32, 34**, and **67** prior to use. This insures that the pre-measured dose of drug remains in cassette **30**. Alternatively or additionally, each of openings **32, 34**, and **67** may be sealed with an openable region and perforations as described hereinbelow for partitions **40** and **41**. Alternatively or additionally, mechanism **64** (see Figure 4) for opening may seal one or more of holes **32, 34**, and **67**. Alternatively or additionally, mechanism **64** for opening may be employed to break a seal on one or more of holes **32, 34**, and **67**. Alternatively or additionally, valves **88** or **90** may be employed to break a seal on one or more of holes **32, 34**, and **67** as cassette **30** is connected to airflow generator **80**.

Cassette **30** is connectable to an airflow generator **80** (figures 1, 2, 8 and 10) by means of first opening **32** or **67**. Airflow generator **80** is manually operable and relies upon ambient air to create a flow of air. Compression of a compressible elastic container **82** causes the flow **54** of air to be in a first direction, outwards via outlet valve **88**. When cassette **30** is attached to airflow generator **80** during compression, this causes airflow **54** through interior volume **36** of cassette **30** via first opening (e.g. **32**, as pictured in figure 3) allowing delivery of a drug through second opening **34** as an aerosol, as a liquid, a gas or as a dry powder.

Subsequent expansion of compressible elastic container **82** causes the flow **56** of air to be in a second direction, inwards via intake valve **90**. If cassette **30** is connected to valve **90** during this expansion, airflow will be in a second direction **56**, facilitating suction of samples or secretions from a bodily orifice. Although pictured as separate valves, valves **88** and **90** may be a single variable direction valve according to some embodiments of the invention. According to some preferred embodiments, valve **90** takes in air only when external pressure is applied, for example by a finger or by spring holders **83**. According to preferred embodiments of the present invention, airflow generator **80** may include a flattened cassette-accommodating portion **79**. According to additional preferred embodiments of the present invention, airflow generator **80** may be equipped with one or more springs **85**. These may be either externally mounted on mounting arms **81** containing spring holders **83** or inside elastic container **82**. Compressible elastic container **82** may be divided into an elastic portion **84** and an inelastic portion **86**. Elastic portion **84** may be strengthened by rigid rings **92**.

When airflow generator **80** is connected to disposable cassette **30**, it is capable of generating a flow of air through disposable cassette **30** in at least two directions. This means that delivery of a drug residing in internal volume **36** of cassette **30** as an aerosol, a liquid, a gas

or a dry powder may be accomplished if the flow of air is in a first direction into internal volume **36** of cassette **30** via a first opening (e.g. **32**) and outward from the internal volume via a second opening (e.g. **34**) towards a bodily orifice of a patient. Further, suction of fluid samples or secretions may be accomplished if the flow of air is in a second direction into internal volume **36** of cassette **30** via a first opening (for example **32, 34** or **67**) and outward from internal volume **36** via a second opening (for example **32, 34** or **67**) towards the airflow generator. Openings (for example **32, 34** or **67**) may be covered, for example by a finger, during use of device **20** for suction.

In a not-illustrated embodiment of the present invention, the airflow is generated remote from cassette **30**, by any one of the methods known to one skilled in the art and directed into the first opening **32** or **67** of cassette **30**. The operation of such an embodiment is, in analogy to an embodiment equipped with airflow generator **80**, clear to one skilled in the art and is therefore not discussed further in detail. It is clear to one skilled in the art that such an embodiment may require that means for regulation of the rate and direction of the airflow be part of the embodiment.

According to some preferred embodiments, device **20** further includes a re-usable holder **58** (figures 4, 5a, 5b, 6a and 6b) for cassette **30**. Holder **58** may be supplied either as a separate unit, or constructed as an integral portion of airflow generator **80,** or supplied with cassette **30** inside. Holder **58** has fixed sides **53** and may have an openable top **57**, at least one openable side **59**, or both. Openable top **57** and side **59** may be equipped with, for example, hinges **61** in order to facilitate opening of holder **58.** Re-usable holder **58** may be equipped with a mechanism for opening the openable region.

According to some preferred embodiments, cassette **30** may further include at least one partition (two are pictured **40** and **42**) dividing interior volume **36** into at least two chambers (three are pictured **44, 46** and **48**). Each partition (**40** and **42**) includes therein an openable region **52** (figures **7a** and **7b**). Perforations **50** may surround at least a portion of each openable region **52** in partition (**40** and **42**) such that opening thereof is facilitated by perforations **50**. In some cases, a mechanism for opening **64** openable region **40** and **42** is further provided. In other cases, increased air pressure in cassette **30** may be used to open openable region **52.**

Mechanism for opening **64** may include, for example, (Figure 7c) a moveable plate **66** capable of translational motion along rails **68** within interior **36** of cassette **30** (figure 7c). As shown in figures 5a and 5b, translational motion of moveable plate **66,** for example by pressing on a widened end **63** of a piston protruding from holder **58,** causes openable region **52** to be

opened by breaking perforations **50**. This creates channels of fluid communication between chambers **44, 46,** and **48** of interior **36** of cassette **30**. This fluid communication may facilitate, for example, mixing of components of a drug to be delivered as an aerosol, as a liquid, or as a gas as air flows through interior **36.**

Alternatively, or additionally, mechanism for opening **64** (dashed oval) may include (figures 4, 6a and 6b), for example, pistons **72** having widened ends **63** and being moveable against spring tension of springs **70**. Pistons **72** move within holes **67** ends thereof **71** are capable of contacting openable regions **52** and opening them by breaking perforations **50**.

Device **20** may further include additional features, including but not limited to, an aerosol jet **60** (figure 8) connectable to second opening **34** of cassette **30.** Aerosol jet **60** is capable of delivering the drug as a plurality of micro-droplets. Aerosol jet **60** may discharge into a spacer, such as an aerosol cloud enhancer and face mask (e.g. one produced by DHD Health Care Corporation, Canastota, NY, USA or DEY, Napa, CA, USA), or to any tube used for endoscopy (e.g. bronchoscope, gastroscope).

Device **20** may further include additional features, including but not limited to, a suction tube **62** (figures 9 and 10) connectable to an opening (for example **32, 34** or **67**) of cassette **30** via widened end **104** and insertable into a bodily orifice of a patient (mouth, nose, ear, eye, rectum, vagina, et al.) for removal of samples or secretions therefrom via end **108.**

The present invention is further embodied by a method for delivery of a drug as an aerosol, as a liquid, a gas or as a dry powder. The method includes at least two steps. The first step includes connecting a source of airflow, such as airflow generator **80,** to disposable cassette **30** via first opening **32** of cassette **30.** Cassette **30** includes first opening **32,** second opening **34** and interior volume **36**. The second step includes causing air to flow into internal volume **36** of cassette **30** via first opening **32** and outward from internal volume **36** via second opening **34** towards a bodily orifice of a patient. In this way, delivery of a drug residing in internal volume **36** of cassette **30** as an aerosol, as a liquid, a gas or as a dry powder is accomplished. Airflow generator **80** is manually operable and relies upon ambient air to create a flow of air. Airflow generator **80** can be, for example, a compressible elastic container **82** (as described hereinabove) such that the step of causing air to flow into internal volume **36** of cassette **30** is effected by compression of elastic container **82**. According to some preferred embodiments, the method includes the additional step of placing cassette **30** within a re-usable holder **58.**

According to some preferred embodiments, the method includes an additional step of providing additional items associated with cassette **30**. These items may include, but are not

limited to, at least one partition (**40** or **42**) dividing interior volume **36** into at least two chambers (**44, 46,** and **48**) and an openable region **52** in each of partitions (**40** or **42**). At least one of the chambers (**44, 46,** and **48**) contains at least one component of the drug. Alternatively, the drug may have several components, each component being stored separately in chambers **44, 46,** and **48** and mixed after opening of openable regions **52** in partitions **40** and **42.** In some cases, perforations **50** surrounding a portion of openable region **52** in each partition (**40** or **42**) such that opening thereof is facilitated by perforations **50**. In some cases the method further includes an additional step which includes opening openable region **52** by means of mechanism for opening **64** openable region **52** as described hereinabove.

According to some preferred embodiments, the method includes the additional step of aerosolizing the drug to form a plurality of micro-droplets. This step may be accomplished, for example, by means of an aerosol jet **60** connected to second opening **34** of cassette **30**. Aerosol jet **60** may be one of many commercially available devices, for example a Microsprayer™ (PennCentury, Inc., Philadelphia, PA, USA).

The present invention is further embodied by a method for removal of fluid samples or secretions from a bodily orifice through suction. The method includes two steps. The first step includes connecting a source of airflow, such as airflow generator **80,** to disposable cassette **30** via a first opening (for example **32, 34** or **67**) of cassette **30**. The second step includes causing air to flow into internal volume **36** of cassette **30** via a second opening (for example **32, 34** or **67**) and outward from internal volume **36** via first opening (for example **32, 34** or **67**) towards the source of the airflow or airflow generator **80**. In this way, the suction of samples or unwanted secretions from a bodily orifice is accomplished and the samples or unwanted secretions accumulate in cassette **30**. According to preferred embodiments of the present invention, airflow generator **80** is manually operable and relies upon ambient air to create a flow of air.

According to preferred embodiments of the invention, the method includes an additional step which includes drawing samples or unwanted secretions through a suction tube **62** (described hereinabove) connected to a second opening (for example **32, 34** or **67**) of cassette **30** and inserted into a bodily orifice of a patient.

Dimensions of cassette **30** are preferably within the following ranges although other sizes are within the scope of the invention:

Height:

0.5 to 3 cm, more preferably 0.7 to 2 cm, most preferably approximately 1 cm.

Width:

0.5 to 3 cm, more preferably 0.7 to 2 cm, most preferably approximately 1 cm.

Length:

0.5 to 7 cm, more preferably 1 to 5 cm, most preferably approximately 3 cm.

The volume of air delivered by a single compression of elastic container **82** of airflow generator **80** is preferably in the range of 0.5 to 100 ml, more preferably 1 to 20 ml, still more preferably 2 to 4 ml, most preferably approximately 2.5 ml although other volumes are within the scope of the invention. It will be appreciated that similar volumes will be vacuumed into cassette **30** during practice of the disclosed method for suction of fluid samples or secretions from a bodily orifice.

In an additional embodiment of the present invention device **84**, many of the important features of the invention can be seen. Device **84** is made up of a re-usable holder **86** with an integrated airflow generator **88**. Cassette **90** is suspended over cutout **92** in holder **86**. Once casette **90** is placed within cutout **92**, mask **94** can be attached to second opening **96** of cassette **90** through nipple **98**. Spare cassette **100** is held inside a specially designed port **102** of holder **86**.

Although the invention has been described in conjunction with specific embodiments thereof, it is evident that many alternatives, modifications and variations will be apparent to those skilled in the art. Accordingly, it is intended to embrace all such alternatives, modifications and variations that fall within the spirit and broad scope of the appended claims.

All publications, patents and patent applications mentioned in this specification are herein incorporated in their entirety by reference into the specification, to the same extent as if each individual publication, patent or patent application was specifically and individually indicated to be incorporated herein by reference. In addition, citation or identification of any reference in this application shall not be construed as an admission that such reference is available as prior art to the present invention.

WHAT IS CLAIMED IS:

1. A device, useful for the removal of fluids through a bodily orifice, comprising a cassette having a first opening, a second opening and an interior volume, said interior volume filled with air, said cassette configured to allow said air to be evacuated by the application of suction at said first opening, wherein said evacuation of air produces suction at said second opening.

2. The device of claim 1 further comprising a manually operable airflow generator, configured to create said suction at said first opening.

3. The device of claim 2, wherein at least part of said airflow generator is a reversibly deformable air-filled compressible container.

4. The device of claim 3, wherein said airflow generator is configured to create said suction at said first opening upon expansion of said container, said expansion subsequent to a compression of said container.

5. The device of claim 1 further comprising a mechanical air pump configured to create said suction at said first opening.

6. The device of claim 1, further comprising a tube connectable to said second opening, said tube insertable into the bodily orifice and configured for removal of fluids therefrom.

7. The device of claim 1, further comprising a tube attached to said second opening, said insertable into the bodily orifice and configured for removal of fluids therefrom.

8. The device of claim 1, wherein said cassette is further configured to contain a fluid entering said cassette through said second opening.

9. The device of claim 8, wherein said cassette is further configured to prevent a contained fluid from exiting said cassette through said first opening.

10. A device, useful for the delivery of drugs through a bodily orifice, comprising a cassette having a first opening, a second opening and an interior volume, said cassette configured to allow air to flow from said first opening, through said interior volume and out through said second opening, said cassette further configured so that said flow of air causes delivery of a drug confined within said internal volume.

11. The device of claim 10 further comprising a manually operable airflow generator, configured to create said flow of air at said first opening.

12. The device of claim 11, wherein at least part of said airflow generator is a reversibly deformable air-filled compressible container.

13. The device of claim 12, wherein said airflow generator is configured to create said flow of air upon compression of said container.

14. The device of claim 13, wherein said airflow generator is configured to fill with ambient air upon expansion of said container, said expansion subsequent to said compression.

16. The device of claim 10 further comprising a mechanical air pump configured to create said flow of air at said first opening.

17. The device of claim 10, further comprising a tube connectable to said second opening, said tube insertable into the bodily orifice and configured for delivery of said confined drug thereinto.

18. The device of claim 10, further comprising a tube attached to said second opening, said tube insertable into the bodily orifice and configured for delivery of said confined drug thereinto.

19. The device of claim 10, further comprising an aerosol jet connectable to said second opening, said aerosol jet configured to deliver said confined drug as a plurality of micro-droplets.

20. The device of claim 10, further comprising an aerosol jet attached to said second opening, said aerosol jet configured to deliver said confined drug as a plurality of micro-droplets.

21. The device of claim 10 wherein said confined drug is identifiable by markings on an external surface of said cassette.

22. The device of claim 21 wherein said markings comprise a color of said external surface.

23. The device of claim 21 wherein said markings comprise a palpable structure on said external surface.

24. The device of claim 10 wherein a dosage of said confined drug is identifiable by markings on an external surface of said cassette.

25. The device of claim 24 wherein said markings comprise a color of said external surface.

26. The device of claim 24 wherein said markings comprise a palpable structure on said external surface.

27. The device of claim 10 further comprising a mask operatively attachable to said second opening, said mask configured to sealingly fit over the bodily orifice.

28. The device of claim 27 wherein an internal surface of said mask is configured to reject aerosol particles.

29. The device of claim 10 wherein a rate of said flow of air into said internal volume from said first opening is controllable by means of a multi-diameter orifice mechanism.

30. The device of claim 10 wherein said confined drug is substantially an aqueous saline solution.

31. The device of claim 10 wherein said confined drug is substantially an antihistamine.

32. The device of claim 10 wherein said cassette is further configured to allow air confined in said internal volume to be evacuated by the application of suction at said first opening, wherein said evacuation of air produces suction at said second opening.

33. The device of claim 32 further comprising a manually operable airflow generator, configured to create said flow of air and said suction at said first opening.

34. The device of claim 33, wherein at least part of said airflow generator is a reversibly deformable air-filled compressible container.

35. The device of claim 34, wherein said airflow generator is configured to create said flow of air upon compression of said container and to create said suction at said first opening upon expansion of said container, said expansion subsequent to said compression.

36. The device of claim 32,wherein said cassette is further configured to contain a fluid entering said cassette through said second opening.

37. The device of claim 36, wherein said cassette is further configured to prevent a contained fluid from exiting said cassette through said first opening.

38. The device of claim 1 and claim 10, further comprising a re-usable holder for said cassette.

39. The device of claim 38 wherein said re-usable holder is configured to store at least one said cassette.

40. The device of claim 1 and claim 10 wherein said first opening is sealed with a removable first opening seal.

41. The device of claim 40 wherein said first opening seal is manually removable.

42. The device of claim 40 wherein said first opening seal sealing said is configured to be automatically removed by attachment of said cassette to a source of air flow.

43. The device of claim 1 and claim 10 wherein said second opening is sealed with a removable second opening seal.

44. The device of claim 43 wherein said second opening seal is manually removable.

45. The device of claim 43 wherein said second opening seal is removable by pressure accumulating in said interior volume of said cassette as a result of said flow of air.

46. The device of claim 1 and claim 10 comprising a pressure activated valve operatively attached to said second opening.

47. The device of claim 1 and claim 10, wherein said cassette further comprises:

(i) at least one partition dividing said interior volume into at least two chambers; and

(ii) a removable partition seal in each one of said at least one partition.

48. The device of claim 47 wherein at least one of said chambers contains at least one component of a drug.

49. The device of claim 47, further comprising perforations surrounding at least a portion of said partition seal, said perforations configured to facilitate removal of said partition seal.

50. The device of claim 47, further comprising:

(c) a mechanism for removing said partition seal.

51. The device of claim 1 and claim 10 wherein said cassette is disposable.

52. A method for delivery of a drug into a bodily orifice comprising:

(a) providing a cassette having a first opening, a second opening and an interior volume, said cassette configured to allow air to flow through said cassette from said first opening, through said interior volume and out through said second opening, said cassette further configured so that said flow of air causes delivery of a drug confined within said internal volume via said second opening;

(b) connecting a source of airflow to said first opening;

(c) causing air to flow through said internal volume via said first opening and outward from said internal volume via said second opening towards a bodily orifice of a patient such that delivery of said drug is accomplished.

53. The method of claim 52 wherein said source of airflow includes a manually operable airflow generator configured to generate said airflow from ambient air.

54. The method of claim 53, wherein at least part of said airflow generator is a reversibly deformable compressible container and said flow of air is created by compression of said container.

55. The method of claim 54, further comprising:

d) compressing said elastic container.

56. The method of claim 52 wherein said source of airflow includes a mechanical air pump.

57. The method of claim 52, further comprising:

(d) providing within said cassette:

(i) at least one partition dividing said interior volume into at least two chambers; and

(ii) an openable region in each of said at least one partition, said openable region sealed with a removable partition seal

wherein at least one of said chambers contains at least one component of said drug.

58. The method of claim 57 wherein said connecting removes said partition seal.

59. The method of claim 52, further comprising:

d) placing said cassette within a re-usable holder.

60. The method of claim 52, further comprising

d) connecting an aerosol jet to said second opening.

61. The method of claim 52 further comprising

d) providing a drug delivery tube with a first end and a second end;

e) connecting said first end to said second opening; and

f) inserting said second end into the bodily orifice.

62. The method of claim 52, further comprising

d) sealing said first opening and said second opening with opening seals;

e) removing said opening seals.

63. A method for removal of a fluid from a bodily orifice comprising:

(a) providing a cassette having a first opening, a second opening and an interior volume, said cassette configured to produce suction at said second opening when suction is applied to said first opening, said cassette further configured so that said suction at said second opening causes removal of fluid from the bodily orifice into said internal volume;

(b) applying suction to said first opening;

(c) removing fluids from the bodily orifice.

64. The method of claim 63 wherein said suction at said first opening is applied by a manually operable airflow generator.

65. The method of claim 64, wherein at least part of said airflow generator is a reversibly deformable compressible container, and said suction at said first opening occurs upon expansion of said container.

66. The method of claim 65, further comprising:

d) compressing said container; and

e) allowing said container to expand

67. The method of claim 63 wherein said airflow generator includes a mechanical pump.

68. The method of claim 63, further comprising:

d) placing said cassette within a re-usable holder.

69. The method of claim 63, further comprising

d) providing a suction tube with a first end and a second end;

e) connecting said first end to said second opening; and

f) inserting said second end into the bodily orifice.

70. The method of claim 69 further comprising:

d) retaining said fluid in said cassette; and

e) discarding said cassette.

71. The method of claim 63 wherein said first opening is sealed with a removable first opening seal further comprising:

d) removing said first opening seal.

72. The device of claim 71 wherein said removing of said first opening seal occurs concurrently with said connecting.

73. The method of claim 63 wherein said second opening is sealed with a removable second opening seal further comprising:

d) removing said second opening seal.

74. A method of easing breathing of a patient having nasal congestion comprising:

(a) providing a cassette having a first opening, a second opening and an interior volume, wherein:

i) said cassette is configured so that air flowing from said first opening, through said interior volume and out through said second opening causes delivery of a drug confined within said internal volume via said second opening;

ii) said cassette is further configured to produce suction at said second opening when air is evacuated from said cassette through said first opening, so that said suction drawing fluid into said internal volume via said second opening;

(b) placing said second opening in proximity of a nasal cavity of the patient;

(c) causing air to flow through said internal volume via said first opening and outward from said internal volume via said second opening towards a bodily orifice of a patient such that delivery of a drug is accomplished.

(c) subsequent to said causing air to flow, evacuating air through said first opening;

(d) removing fluids causing the nasal congestion.

75. The method of claim 74 wherein said drug is is substantially an aqueous saline solution.

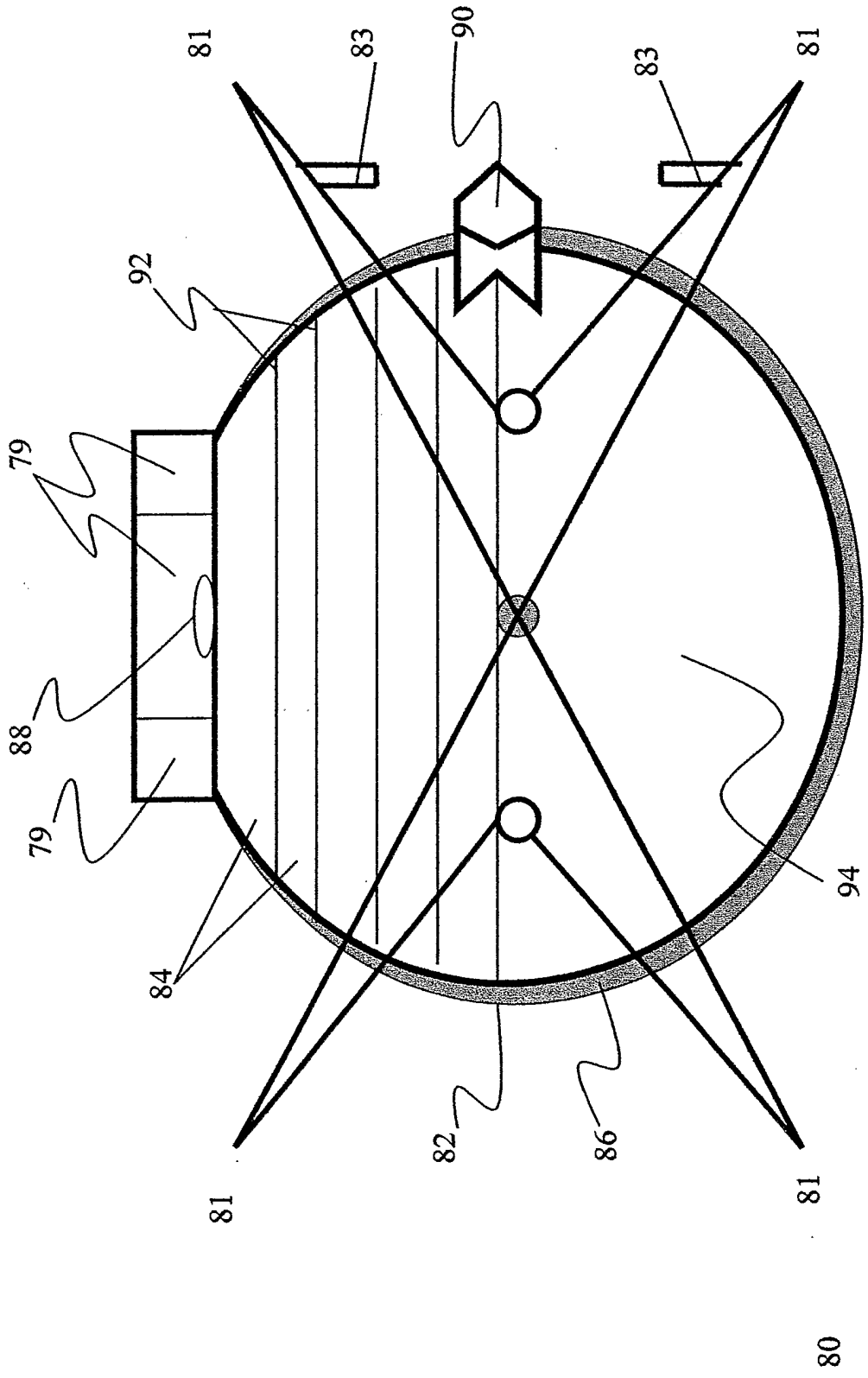

Fig. 1

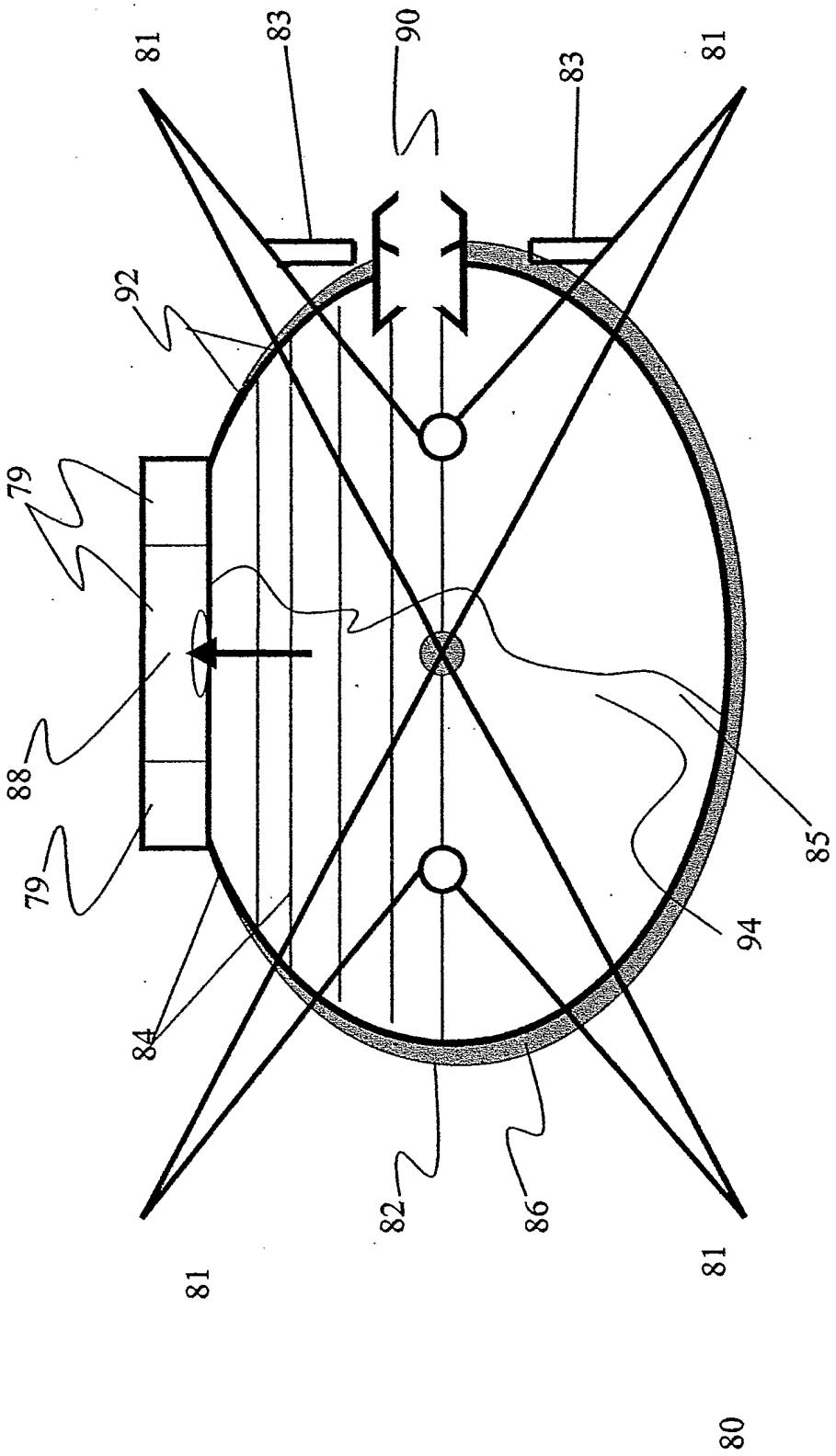

Fig. 2

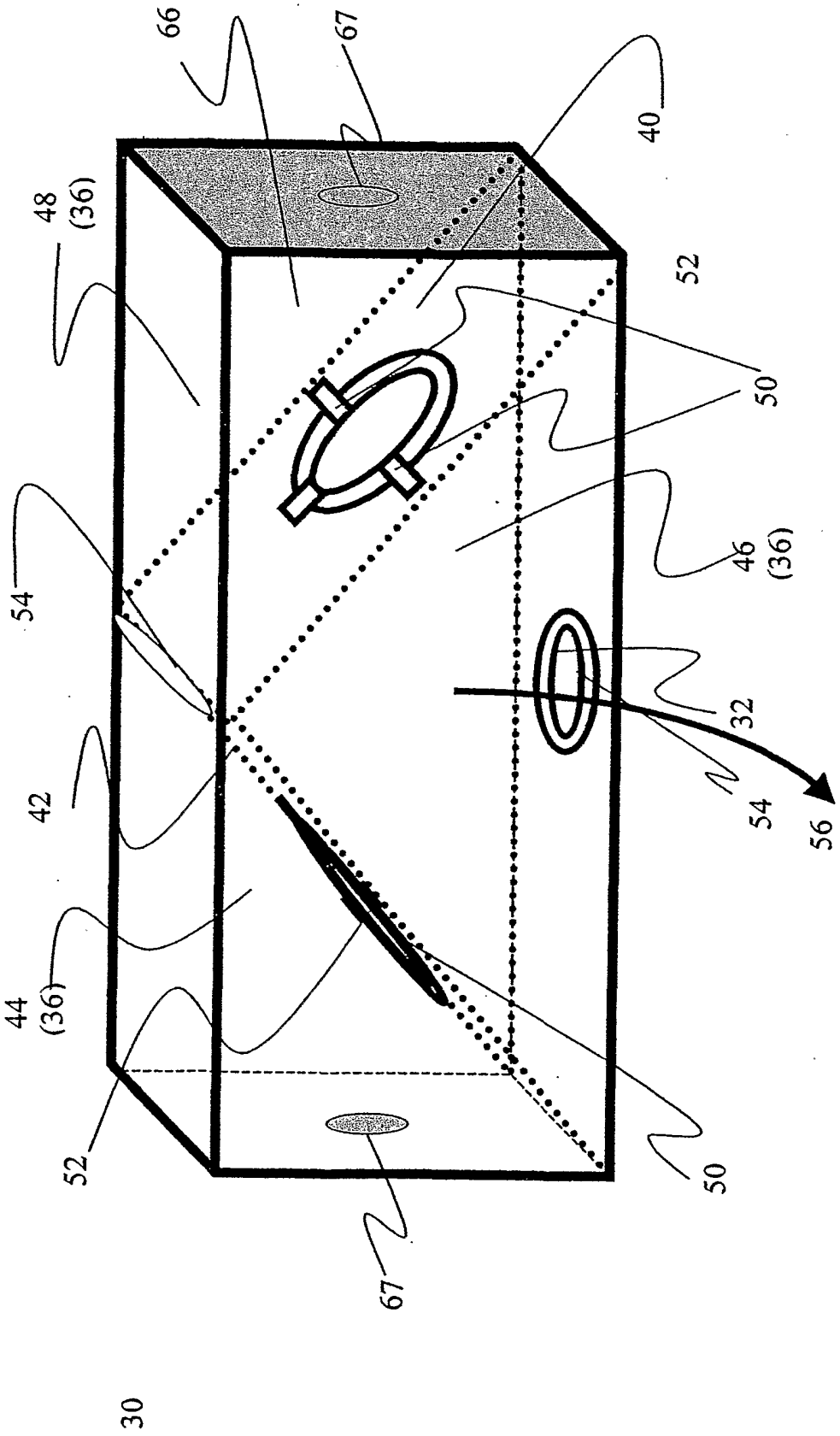

Fig. 3

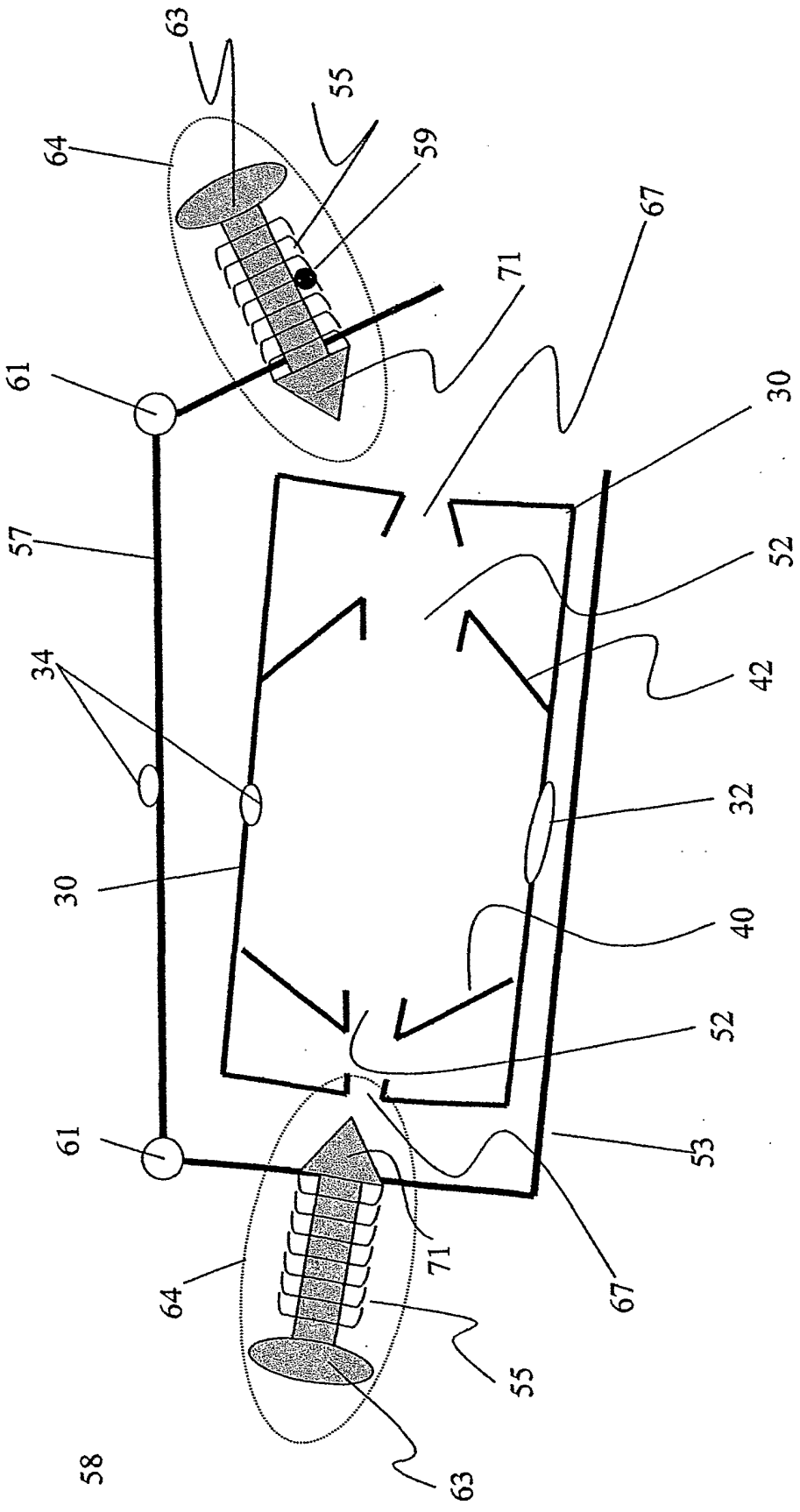

Fig. 4

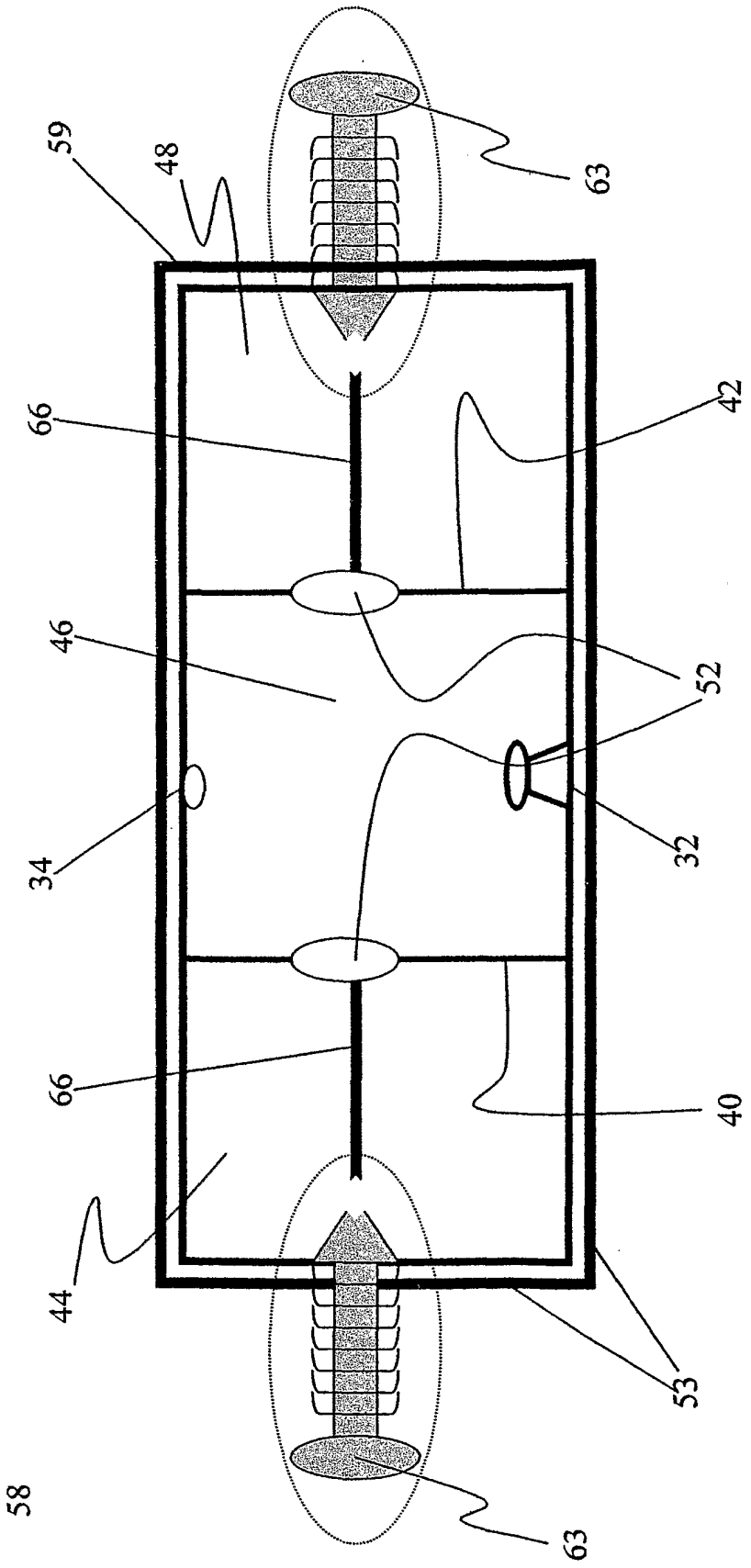

Fig. 5A

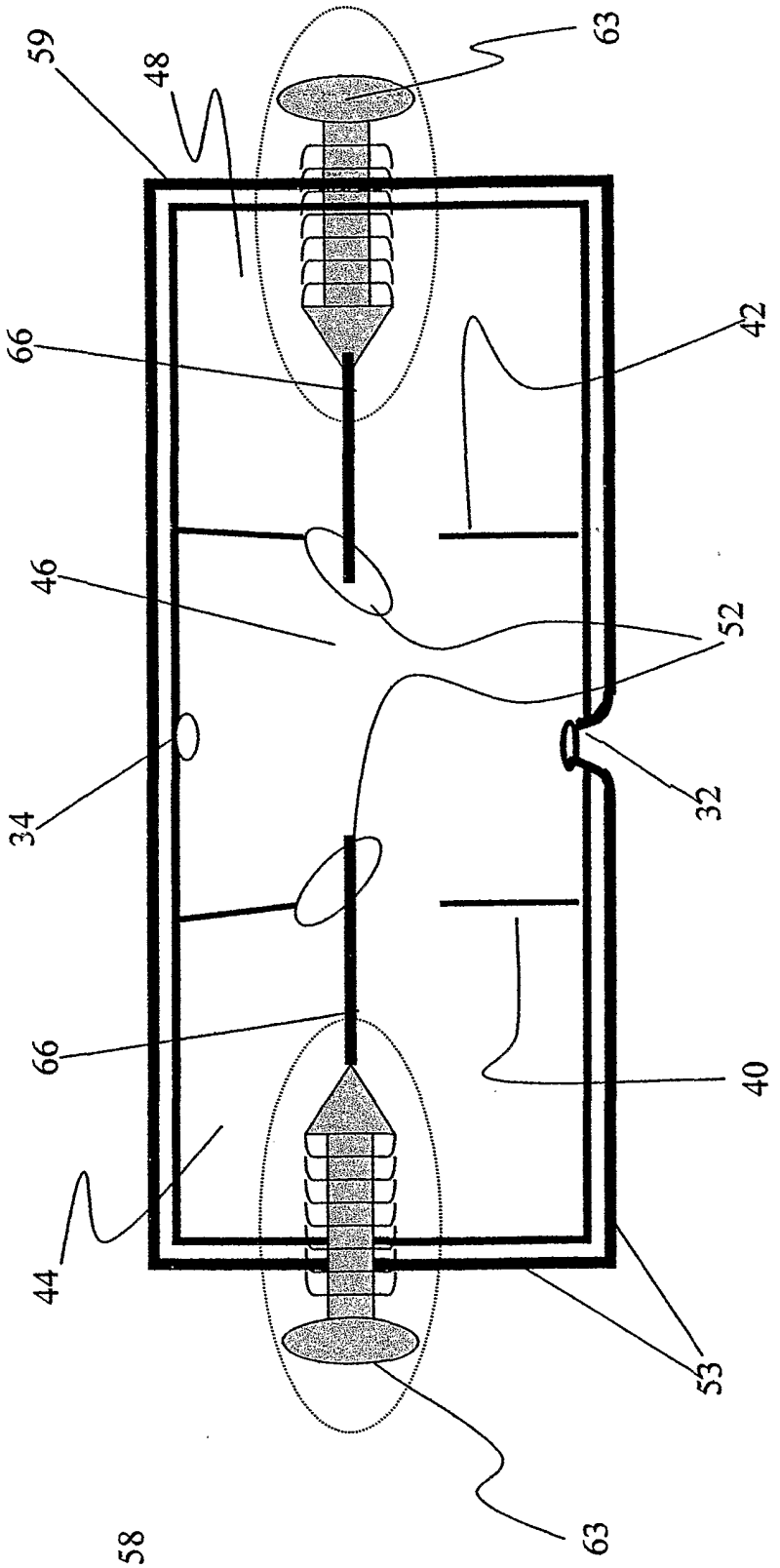

Fig. 5B

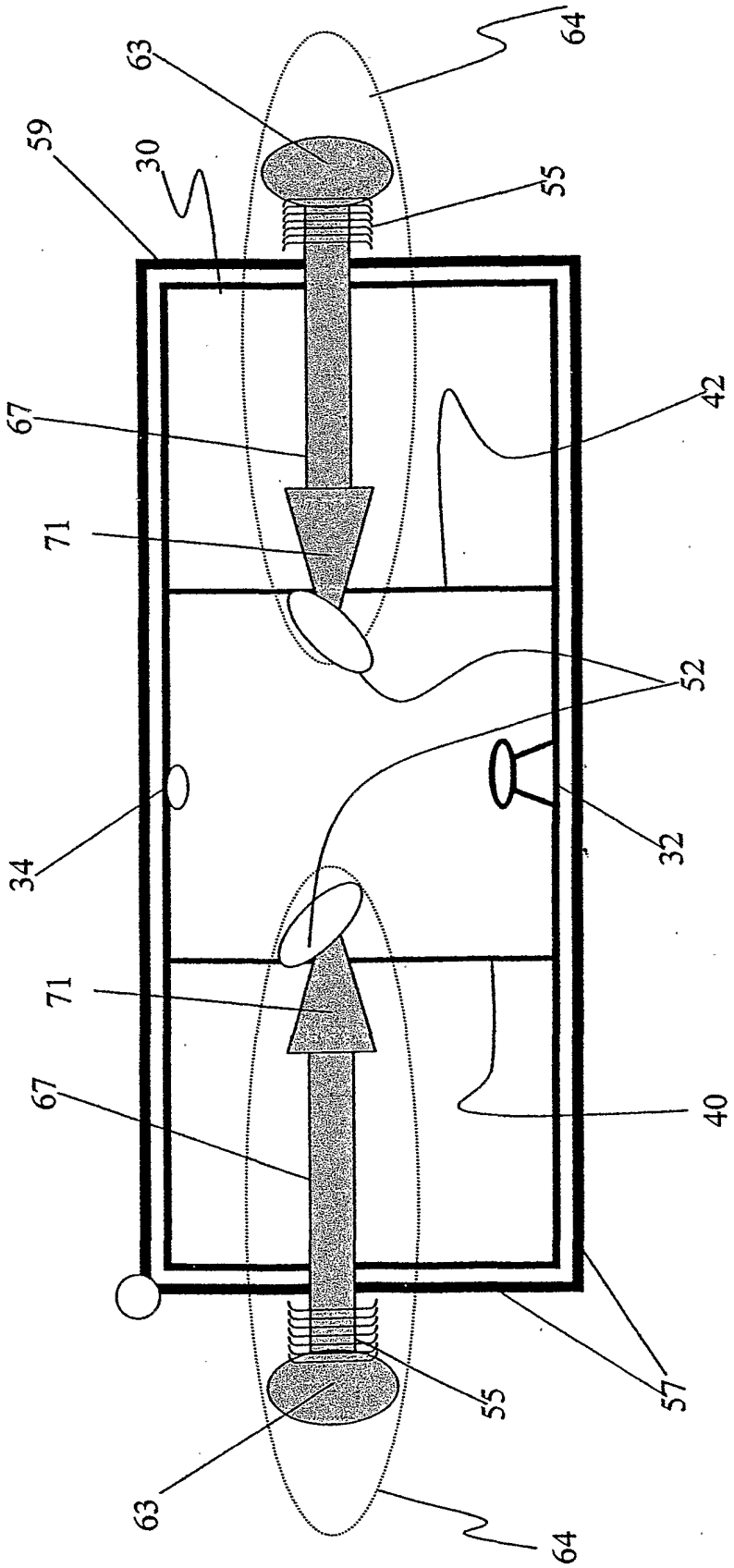

Fig. 6A

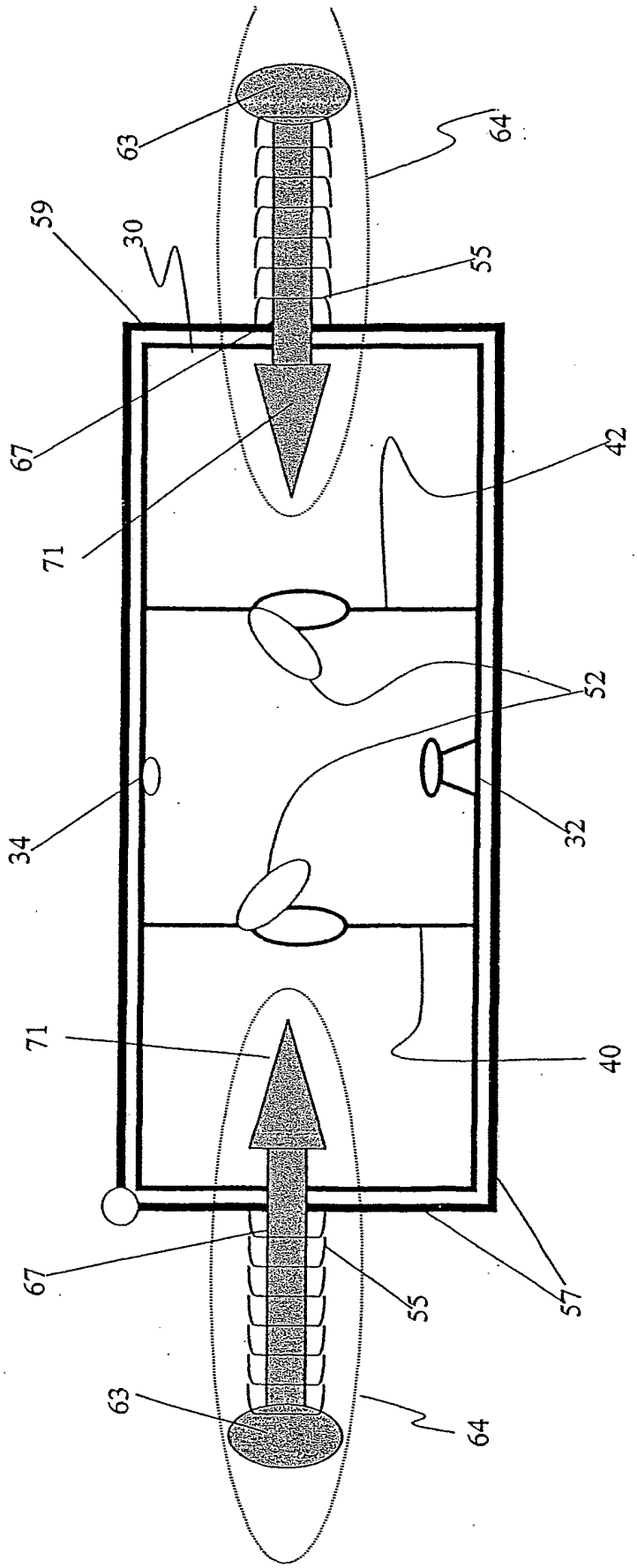

Fig. 6B

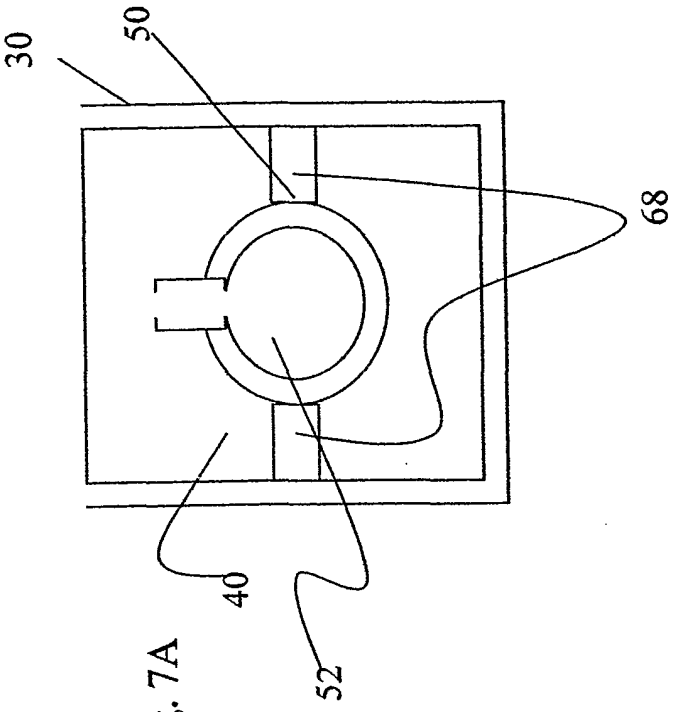

Fig. 7A

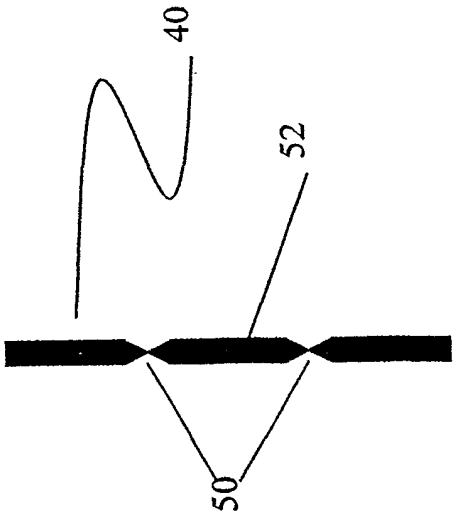

Fig. 7B

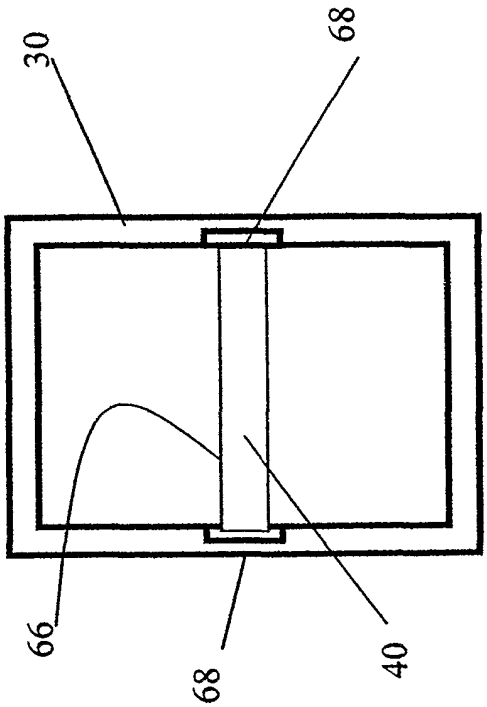

Fig. 7C

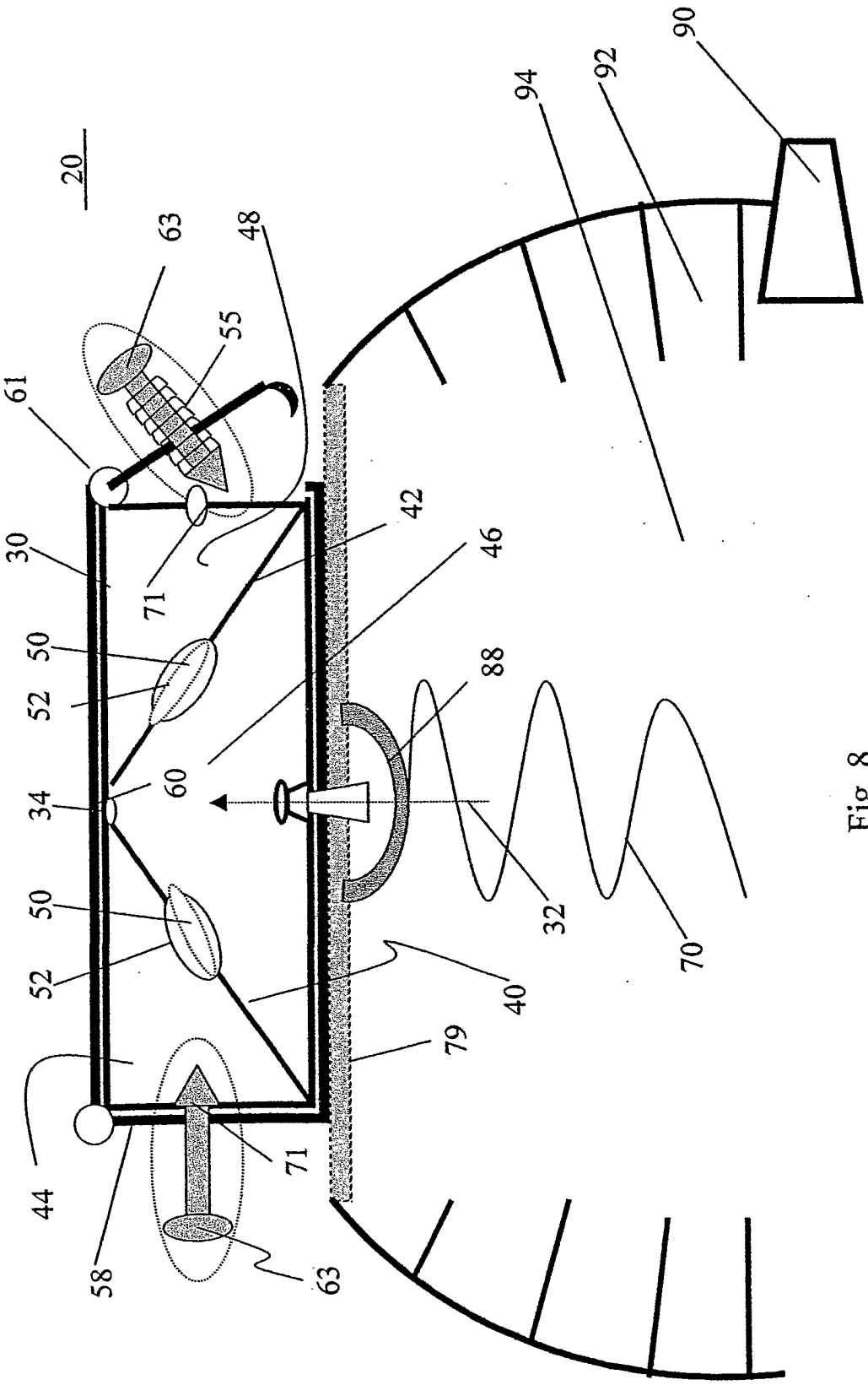
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Fig. 8

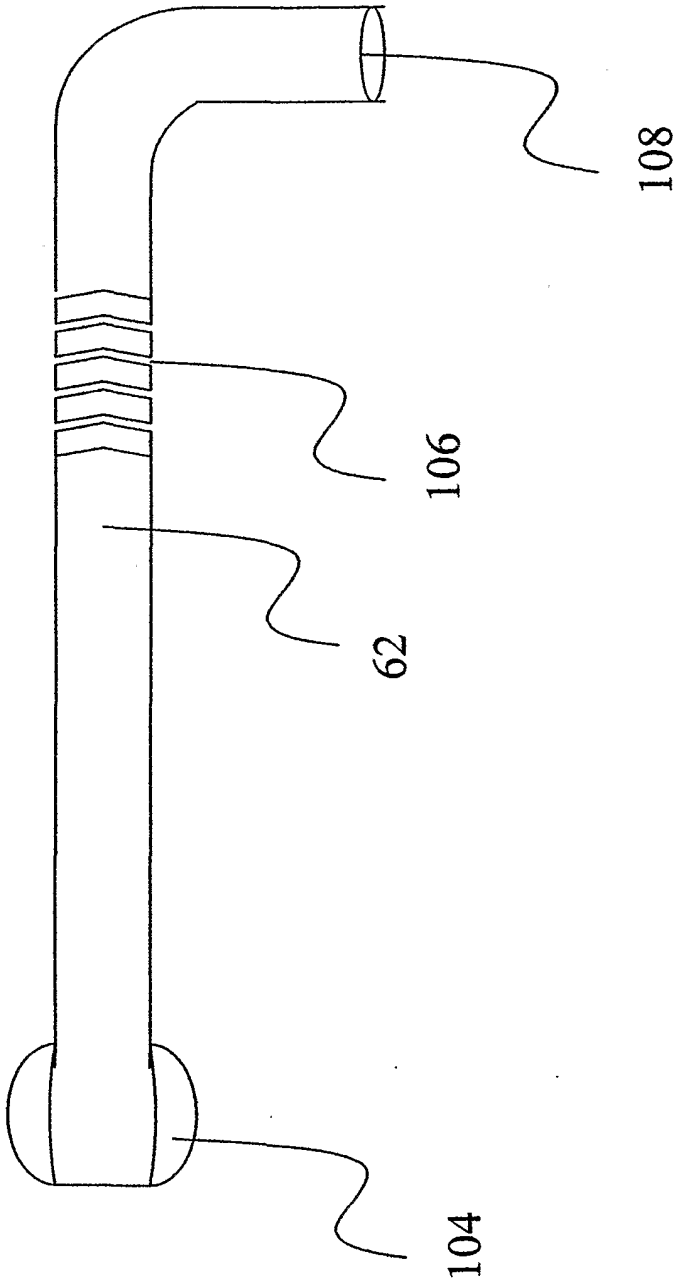

Fig. 9

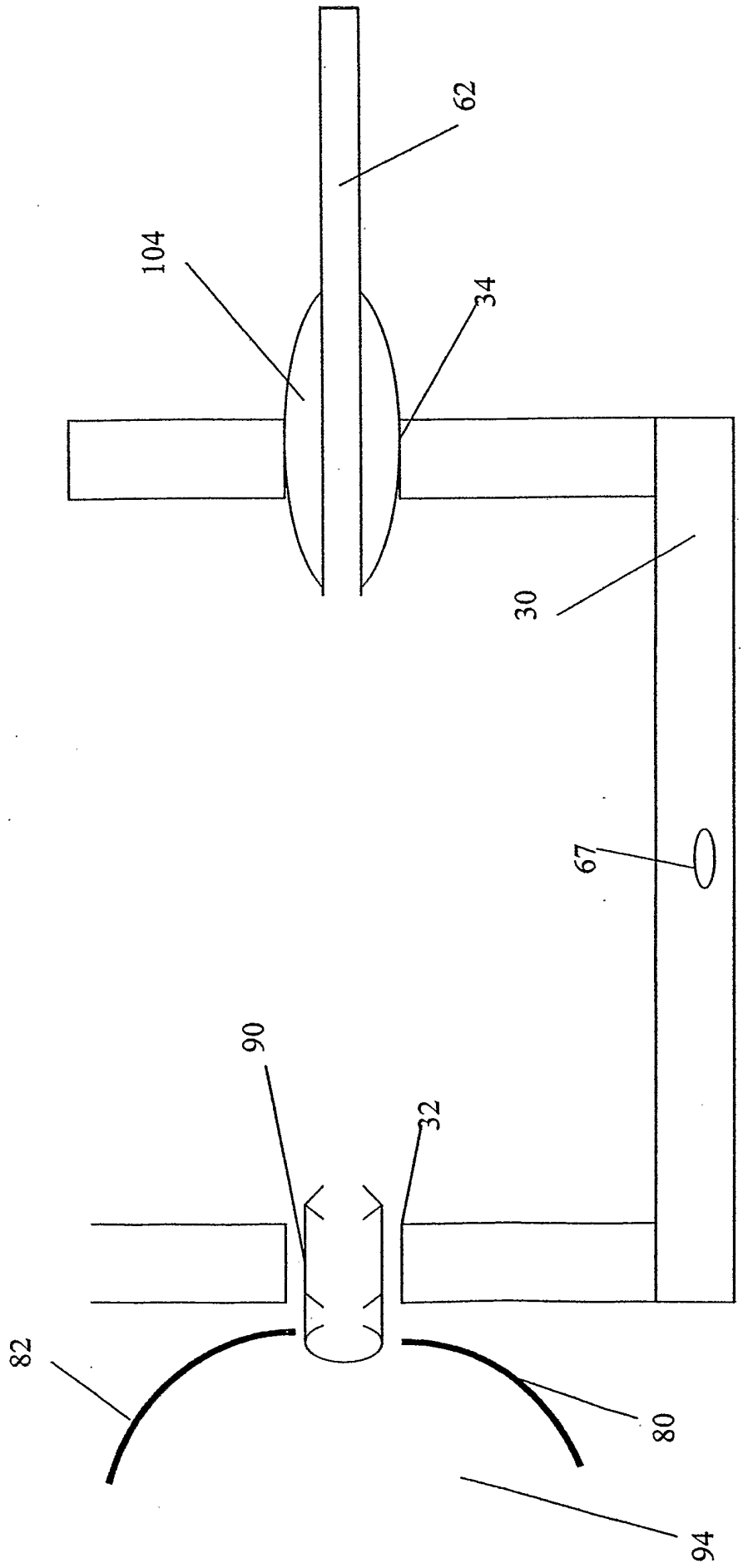

Fig. 10

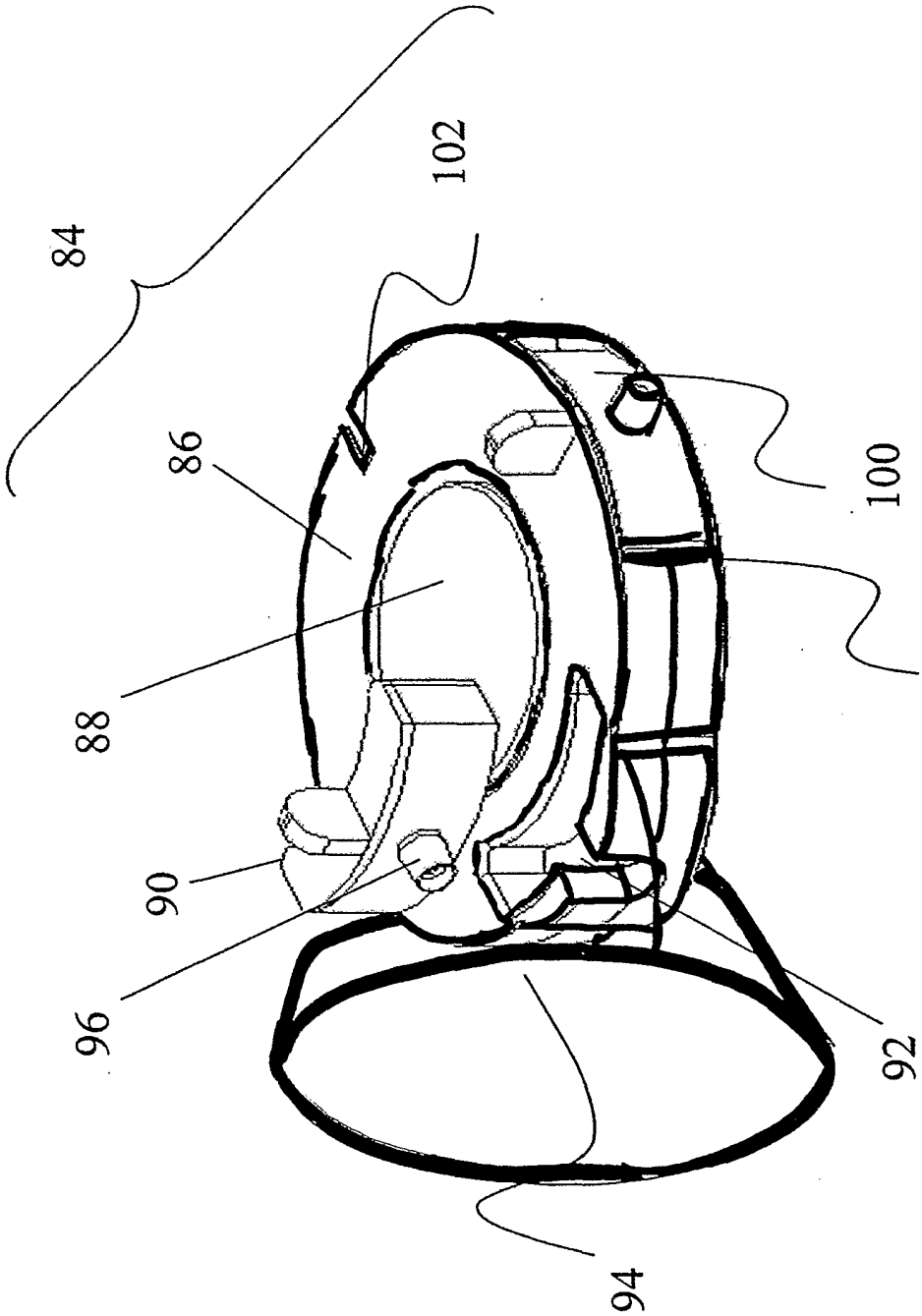

Fig. 11