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(54) **Title:** INSUFFLATION OF BODY CAVITIES

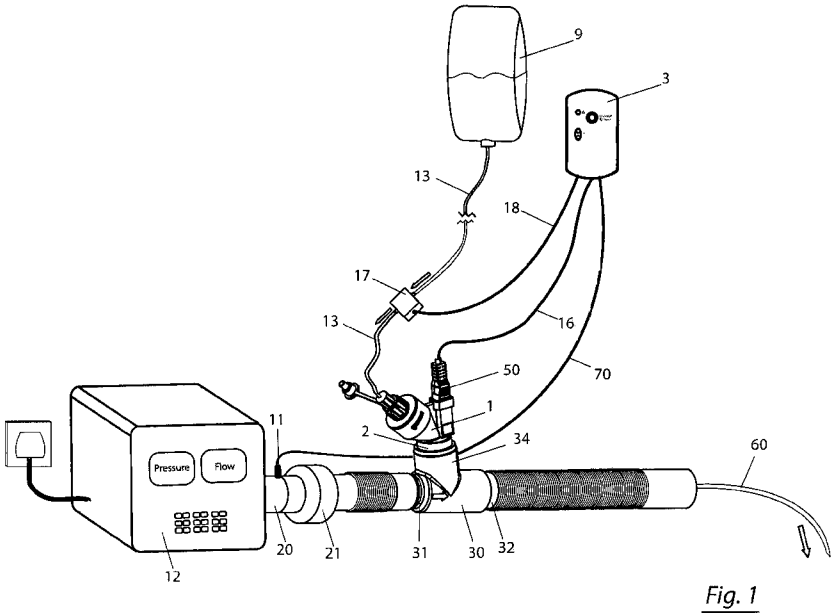

Fig. 1

(57) **Abstract:** Apparatus used in insufflation comprises an insufflator 12 for generating an insufflation gas such as carbon dioxide and an aerosol generator 2 for aerosolising a fluid and entraining the aerosol with the insufflation gas. The aerosol generator 2 comprises a vibratable member 40 having a plurality of apertures extending between a first surface and a second surface. The fluid may comprise a therapeutic or prophylactic agent. A controller 3 is used to control the operation of the aerosol generator 2. The controller 3 controls operation of the aerosol generator 2 responsive to the flow of insufflation gas such as detected by a flow sensor 11.

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'Insufflation of body cavities'

Background of the Invention

Laparoscopic surgery, also called minimally or less invasive surgery (MIS or LIS) or keyhole surgery is a modern surgical technique in which operations in the body are performed through small incisions as compared to the larger incisions needed in traditional surgical procedures. Gas such as carbon dioxide is delivered, via an insufflator, into a body cavity such as the abdomen leading to the formation of a pneumoperitoneum, thereby providing sufficient space for the surgeon to operate. The insufflator maintains the pneumoperitoneum and acts to renew the gas when leaks occur.

Gas such as carbon dioxide that is used for insufflation is both cold and dry and it is not surprising therefore those patients undergoing laparoscopic procedures often suffer a significant drop in core body temperature, which can result in considerable post-surgical pain and significant complications, such as cardiac stress, immunological and clotting problems, for the patient. By using standard thermo physical principles it has been shown that the major cause of patient heat loss is due to evaporation from the body acting to humidify the large volumes of dry insufflated gas at ATPD (Ambient Temperature Pressure Dry) passing into the body which is at BTPS (Body Temperature Pressure Saturated). If such heat loss could be minimised, post-operative pain and the significant side effects suffered by the patient could be considerably alleviated.

Various attempts have been made to condition insufflation gas by heating, humidifying and or filtering the gas. However in general, known insufflation gas conditioning systems suffer from one or more disadvantages including complexity

of construction involving expensive monitoring devices, inaccurate control and/or difficulties in using them in a controlled working environment.

Some systems employ heat moisture exchangers (HME). These operate directly in the flow path of the insufflation gas and are therefore inherently susceptible to affecting pressure or flow, dependent upon their level of saturation and condition. Other systems require manual intervention to respond to patients needs by the adding of moisture. Other prior art devices require the cumbersome procedure of passing gas over and through non-heated or heated liquid containers. Such devices present the major drawback of impeding pressure measurement in the insufflation cavity.

Systems using conventional jet nebulisers or nebulisation catheters exhibit one or more of the following disadvantages: impaction of larger particles, fogging in the body cavity thus reducing the surgeon's visibility, interference with insufflator settings increasing flow/pressure in the system.

This invention is directed towards providing a method and an apparatus that will address at least some of these problems.

Statements of Invention

According to the invention there is provided an apparatus for use in laparoscopic surgery comprising:

an insufflator for generating an insufflation gas;

an aerosol generator for aerosolising a fluid and entraining the aerosol with the insufflation gas wherein the aerosol generator comprises a

vibratable member having a plurality of apertures extending between a first surface and a second surface; and

a controller to control the operation of the aerosol generator.

In one embodiment the controller is configured to control operation of the aerosol generator responsive to the insufflation gas.

The controller may be configured to control operation of the aerosol generator responsive to the flow rate of the insufflation gas. The controller may be configured to control the flow rate of the fluid to be aerosolised.

In one case the apparatus comprises a device to determine the fluid flow rate of the insufflation gas. The determining device may comprise a flow sensor such as a flowmeter.

In one embodiment the first surface of the vibratable member is adapted to receive the fluid to be aerosolised.

The aerosol generator is configured to generate an aerosol at the second surface of the vibratable member.

In one embodiment the vibratable member is dome-shaped in geometry.

In one case the vibratable member comprises a piezoelectric element.

The apertures in the vibratable member are sized to aerosolise the first fluid by ejecting droplets of the first fluid such that the majority of the droplets by mass have a size of less than 5 micrometers. The apertures in the vibratable member

may be sized to aerosolise the first fluid by ejecting droplets of the first fluid such that the majority of the droplets by mass have a size of less than 3 micrometers.

In one case the controller is configured to control the pulse rate at a set frequency of vibration of the vibratable member.

The controller may be impedance matched to the aerosol generator.

In one embodiment the apparatus comprises means to determine whether the fluid is in contact with the aerosol generator.

The determining means may be configured to determine at least one electrical characteristic of the aerosol generator. The determining means may be configured to determine at least one electrical characteristic of the aerosol generator over a range of vibration frequencies.

In one case the determining means is configured to compare the at least one electrical characteristic against a pre-defined set of data.

The invention also provides a method for carrying out a procedure involving insufflation comprising the steps of:-

generating an insufflation gas;

aerosolising a fluid using an aerosol generator wherein the aerosol generator comprises a vibratable member having a plurality of apertures extending between a first surface and a second surface; and

entraining the aerosol with the insufflation gas.

The method may comprise the step of controlling the aerosolisation of the fluid.

In one case the method comprises controlling aerosolisation of the fluid responsive to the insufflation gas.

In one case the method comprises controlling aerosolisation of the fluid responsive to the flow rate of the insufflation gas.

The method may comprise controlling the flow rate of the fluid.

In one embodiment the method comprises the step of determining the flow rate of the insufflation gas.

In another embodiment the method comprises the step of determining if the fluid is in contact with an aerosol generator. This may involve determining at least one electrical characteristic of the aerosol generator. Electrical characteristics of the aerosol generator may be determined over a range of vibration frequencies.

In one case the method comprises the step of comparing the at least one electrical characteristic against a pre-defined set of data.

In one embodiment the method comprises the step of delivering the entrained fluid and insufflation gas into a body to insufflate at least part of the body.

In one case the fluid is an aqueous solution.

The aqueous solution may be saline having a salt concentration in the range of from 1μM to 154mM.

In one embodiment the fluid contains a therapeutic and/or prophylactic agent. The agent may be one or more selected from the group comprising an analgesic, and anti-inflammatory, an anti-infective, an anaesthetic, and an anti-cancer chemotherapy agent.

In one case the procedure is a laparoscopic procedure.

Brief Description of the Drawings

The invention will be more clearly understood from the following description of some embodiments thereof, given by way of example only, with reference to the accompanying drawings, in which:-

Fig. 1 is a perspective view of an apparatus according to the invention for use in a procedure involving insufflation of a body cavity, such as laparoscopic surgery;

Fig. 2 is a schematic illustration of a part of an apparatus according to the invention;

Fig. 3 is a schematic illustration of a part of the apparatus of Fig. 1;

Fig. 4 is an exploded isometric view of an aerosol generator used in the invention;

Fig. 5 is a cross-sectional view of the assembled aerosol generator of Fig. 4;

Fig. 6 is a perspective view of a controller housing used in the apparatus of the invention;

Figs. 7(a) and 7(b) are graphs of DC voltage versus time and AC voltage versus time respectively to achieve a 100% aerosol output;

Figs. 8(a) and 8(b) are graphs of DC voltage versus time and AC voltage versus time respectively to achieve a 50% aerosol output - Fig 8(a) illustrates the waveform output from a microprocessor to a drive circuit and Fig 8(b) illustrates the waveform output from a drive circuit to a nebuliser;

Figs. 9(a) and 9(b) are graphs of DC voltage versus time and AC voltage versus time respectively to achieve a 25% aerosol output - Fig 9(a) illustrates the waveform output from a microprocessor to a drive circuit and Fig 9(b) illustrates the waveform output from a drive circuit to a nebuliser;

Fig 10 is a graph of AC voltage versus time; and illustrates an output waveform from a drive circuit to a nebuliser;

Fig. 11 is a graph of frequency versus current for another apparatus according to the invention;

Fig. 12 is a view similar to Fig. 1 of another apparatus of the invention; and

Fig. 13 is a view similar to Fig. 1 of a further apparatus of the invention.

Detailed Description

Referring to Fig. 1 there is illustrated an apparatus according to the invention for use in insufflation of a body cavity. One such application is laparoscopic surgery. The device is also suitable for use in any situation involving insufflation of a body cavity such as in arthroscopies, pleural cavity insufflation (for example during thoracoscopy), retroperitoneal insufflations (for example retroperitoneoscopy), during hernia repair, during mediastinoscopy and any other such procedure involving insufflation.

The apparatus comprises a reservoir 1 for storing an aqueous solution, an aerosol generator 2 for aerosolising the solution, and a controller 3 for controlling operation of the aerosol generator 2. The aqueous solution is fed from a reservoir 9 to the aerosol generator 2 along a delivery tube 13. In the invention aerosolised aqueous solution is entrained with insufflation gas. The gas is any suitable insufflation gas such as carbon dioxide. Other examples of suitable insufflation gases are nitrogen, helium and xenon.

The insufflation gas is delivered into an insufflation gas tubing 15 by an insufflator 12. The insufflator 12 may be of any suitable type such as those available from Karl Storz, Olympus and Stryker. The insufflator 12 has an outlet 20 through which insufflation gas is delivered. A bacterial filter 21 may be provided within the insufflator or, as illustrated, downstream of the insufflator outlet 20.

In this case a flow rate sensor/meter 11 is located in the flow path of the insufflation gas from an insufflator 12 to the aerosol generator 2. The flow rate sensor/meter 11 is connected by a control wire 70 to the controller 3, and the aerosol generator 2 is connected to the controller 3 by a control wire 16. The flow

rate sensor/meter 11 may be a hot wire anemometer, or in the case where the flow is laminar or can be laminarised, a differential pressure transducer.

Sterile water may be used. In the case of an aqueous solution any suitable solution may be used. Solutions with a salt concentration in the range 1μM (micro molar) to 154mM (milli molar) (0.9% saline) are optimum as they cover the majority of medical applications. In addition, such saline concentrations can be readily nebulised using the aerosolisation technology used in the invention.

Aqueous solution may be stored in the reservoir 1 container of the nebuliser or the aqueous solution may be delivered to the reservoir 1 of the aerosol generator 2 in this case from the supply reservoir 9 along the delivery line 13. The flow of aqueous solution may be by gravity and/or may be assisted by an in-line flow controlling device 17 such as a pump and/or a valve which may be positioned in the delivery line 13. The operation of the flow controlling device 17 may be controlled by the controller 3 along a control wire 18 to ensure that the aerosol generator 2 has a supply of aqueous solution during operation. The device 17 may be of any suitable type.

The apparatus comprises a connector 30, in this case a T-piece connector 30 having an insufflation gas conduit inlet 31 and an outlet 32. The connector 30 also comprises an aerosol supply conduit 34 for delivering the aerosol from the aerosol generator 2 into the insufflation gas conduit 15 to entrain the aerosol with the insufflation gas, passing through the gas insufflation conduit 15. The entrained aerosol/insufflation gas mixture passes out of the connector 30 through the outlet 32 and is delivered to the body cavity along a line 60.

The aerosol supply conduit 34 and the insufflation gas conduit meet at a junction. Referring particularly to Figs. 4 and 5, in the assembled apparatus the aerosol

supply conduit of the connector 30 may be releasably mounted to a neck 36 of the aerosol generator housing by means of a push-fit arrangement. This enables the connector 30 to be easily dismounted from the aerosol generator housing 36, for example for cleaning. The neck 36 at least partially lines the interior of the aerosol supply conduit 34.

The nebuliser (or aerosol generator), has a vibratable member which is vibrated at ultrasonic frequencies to produce liquid droplets. Some specific, non-limiting examples of technologies for producing fine liquid droplets is by supplying liquid to an aperture plate having a plurality of tapered apertures extending between a first surface and a second surface thereof and vibrating the aperture plate to eject liquid droplets through the apertures. Such technologies are described generally in U.S. Pat. Nos. 5,164,740; 5,938,117; 5,586,550; 5,758,637; 6,014,970, 6,085,740, and US2005/021766A, the complete disclosures of which are incorporated herein by reference. However, it should be appreciated that the present invention is not limited for use only with such devices.

In use, the liquid to be aerosolised is received at the first surface, and the aerosol generator 2 generates the aerosolised first fluid at the second surface by ejecting droplets of the first fluid upon vibration of the vibratable member. The apertures in the vibratable member are sized to aerosolise the liquid by ejecting droplets of the liquid such that the majority of the droplets by mass have a size of less than 5 micrometers. The vibratable member 40 could be non-planar, and may be dome-shaped in geometry.

Referring particularly to Figs 4 and 5, in one case the aerosol generator 2 comprises a vibratable member 40, a piezoelectric element 41 and a washer 42, which are sealed within a silicone overmould 43 and secured in place within the

housing 36 using a retaining ring 44. The vibratable member 40 has a plurality of tapered apertures extending between a first surface and a second surface thereof.

The first surface of the vibratable member 40, which in use faces upwardly, receives the liquid medicament from the reservoir 1 and the aerosolised medicament, is generated at the second surface of the vibratable member 40 by ejecting droplets of medicament upon vibration of the member 40. In use the second surface faces downwardly. In one case, the apertures in the vibratable member 40 may be sized to produce an aerosol in which the majority of the droplets by weight have a size of less than 5 micrometers.

The complete nebuliser may be supplied in sterile form, which is a significant advantage for a surgical device.

Referring particularly to Fig 3, the controller 3 controls operation of and provides a power supply to the aerosol generator 2. The aerosol generator has a housing which defines the reservoir 1. The housing has a signal interface port 38 fixed to the lower portion of the reservoir 1 to receive a control signal from the controller 3. The controller 3 may be connected to the signal interface port 38 by means of a control lead 39 which has a docking member 50 for mating with the port 38. A control signal and power may be passed from the controller 3 through the lead 39 and the port 38 to the aerosol generator 2 to control the operation of the aerosol generator 2 and to supply power to the aerosol generator 2 respectively.

The power source for the controller 3 may be an on-board power source, such as a rechargeable battery, or a remote power source, such as a mains power source, or an insufflator power source. When the remote power source is an AC mains power source, an AC-DC converter may be connected between the AC power source and the controller 3. A power connection lead may be provided to connect a power socket of the controller 3 with the remote power source.

Referring particularly to Fig. 6 the controller 3 has a housing and a user interface to selectively control operation of the aerosol generator 2. Preferably the user interface is provided on the housing which, in use, is located remote from the aerosol generator housing. The user interface may be in the form of, for example, an on-off button. In one embodiment a button can be used to select pre-set values for simplicity of use. In another embodiment a dial mechanism can be used to select from a range of values from 0-100%.

Status indication means are also provided on the housing to indicate the operational state of the aerosol generator 2. For example, the status indication means may be in the form of two visible LED's, with one LED being used to indicate power and the other LED being used to indicate aerosol delivery. Alternatively one LED may be used to indicate an operational state of the aerosol generator 2, and the other LED may be used to indicate a rest state of the aerosol generator. 2.

A fault indicator may also be provided in the form of an LED on the housing. A battery charge indicator in the form of an LED may be provided at the side of the housing.

Referring particularly to Fig 1, the aqueous solution in the reservoir 9 flows by gravitational action towards the aerosol generator 2 at the lower medicament outlet. The controller 3 may then be activated to supply power and a control signal to the aerosol generator 2, which causes the piezoelectric element 41 to vibrate the non-planar member 40. This vibration of the non-planar member 40, causes the aqueous solution at the top surface of the member 40 to pass through the apertures to the lower surface where the aqueous solution is aerosolised by the ejection of small droplets of solution.

Referring particularly to Figs 4 and 5, the aerosol passes from the aerosol generator 2 into the neck 36 of the aerosol generator housing, which is mounted within the aerosol supply conduit of the connector 30 and into the gas conduit of the connector 30 (flow A). The aerosol is entrained in the insufflation gas conduit with gas, which passes into the gas conduit through the inlet 31 (flow B). The entrained mixture of the aerosol and the insufflation gas then passes out of the gas conduit through the outlet 32 (flow C) and on via an insufflator line 60 to a patient, for example into the abdomen of the patient.

In use during laparoscopic surgery the flow of the insufflation gas into the abdomen of a patient is commenced to insufflate the abdomen. The flow rate sensor/meter 11 determines the flow rate of the insufflation gas. In response to the fluid flow rate of the insufflation gas, the controller 3 commences operation of the aerosol generator 2 to aerosolise the aqueous solution. The aerosolised aqueous solution is entrained with the insufflation gas, and delivered into the abdomen of the patient to insufflate at least part of the abdomen.

In the event of alteration of the fluid flow rate of the insufflation gas, the flow rate sensor/meter 11 determines the alteration, and the controller 3 alters the pulse rate of the vibratable member of the nebuliser accordingly.

The controller 3 is in communication with the flow rate sensor/meter 11. The controller 3 is configured to control operation of the aerosol generator 2, responsive to the fluid flow rate of the insufflation gas and also independent of the fluid flow rate of the insufflation gas as required.

In one case, the controller 3 is configured to control operation of the aerosol generator 2 by controlling the pulse rate at a set frequency of vibration of the vibratable member, and thus controlling the fluid flow rate of the aqueous solutions.

The controller 3 may comprise a microprocessor 4, a boost circuit 5, and a drive circuit 6. Fig. 2 illustrates the microprocessor 4, the boost circuit 5, the drive circuit 6 comprising impedance matching components (inductor), the nebuliser 2, and the aerosol. The inductor impedance is matched to the impedance of the piezoelectric element of the aerosol generator 2. The microprocessor 4 generates a square waveform of 128KHz which is sent to the drive circuit 6. The boost circuit 5 generates a 12V DC voltage required by the drive circuit 6 from an input of either a 4.5V battery or a 9V AC/DC adapter. The circuit is matched to the impedance of the piezo ceramic element to ensure enhanced energy transfer. A drive frequency of 128 KHz is generated to drive the nebuliser at close to its resonant frequency so that enough amplitude is generated to break off droplets and produce the aerosol. If this frequency is chopped at a lower frequency such that aerosol is generated for a short time and then stopped for a short time this gives good control of the nebuliser's flow rate. This lower frequency is called the pulse rate.

The drive frequency may be started and stopped as required using the microprocessor 4. This allows for control of flow rate by driving the nebuliser 2 for any required pulse rate. The microprocessor 4 may control the on and off times to an accuracy of milliseconds.

The nebuliser 2 may be calibrated at a certain pulse rate by measuring how long it takes to deliver a know quantity of solution. There is a linear relationship between the pulse rate and the nebuliser flow rate. This may allow for accurate control over the delivery rate of the aqueous solution.

The nebuliser drive circuit consists of the electronic components designed to generate output sine waveform of approximately 100V AC which is fed to nebuliser 2 causing aerosol to be generated. The nebuliser drive circuit 6 uses

inputs from microprocessor 4 and boost circuit 5 to achieve its output. The circuit is matched to the impedance of the piezo ceramic element to ensure good energy transfer.

The aerosol generator 2 may be configured to operate in a variety of different modes, such as continuous, and/or phasic, and/or optimised.

For example, referring to Fig 7(a) illustrates a 5V DC square waveform output from the microprocessor 4 to the drive circuit 6. Fig 7(b) shows a low power, ~100V AC sine waveform output from drive circuit 6 to nebuliser 2. Both waveforms have a period p of 7.8μS giving them a frequency of 1/7.8μs which is approximately 128KHz. Both waveforms are continuous without any pulsing. The aerosol generator may be operated in this mode to achieve 100% aerosol output.

Referring to Figs 8(a) in another example, there is illustrated a 5V DC square waveform output from the microprocessor 4 to the drive circuit 6. Fig 8(b) shows a low power, ~100V AC sine waveform output from the drive circuit 6 to the nebuliser 2. Both waveforms have a period p of 7.8μS giving them a frequency of 1/7.8μs which is approximately 128KHz. In both cases the wavefoms are chopped (stopped/OFF) for a period of time x. In this case the off time x is equal to the on time x. The aerosol generator may be operated in this mode to achieve 50% aerosol output.

In another case, referring to Figs 9(a) there is illustrated a 5V DC square waveform output from microprocessor 4 to drive circuit 6. Fig 9(b) shows a low power, ~100V AC sine waveform output from the drive circuit 6 to the nebuliser 2. Both waveforms have a period p of 7.8μS giving them a frequency of 1/7.8μs which is approximately 128KHz. In both cases the wavefoms are chopped

(stopped/OFF) for a period of time x. In this case the off time is 3x while the on time is x. The aerosol generator may be operated in this mode to achieve 25% aerosol output.

Referring to Fig 10, in one application pulsing is achieved by specifying an on-time and off-time for the vibration of the aperture plate. If the on-time is set to 200 vibrations and off-time is set to 200 vibrations, the pulse rate is 50% (½ on ½ off). This means that the flow rate is half of that of a fully driven aperture plate. Any number of vibrations can be specified but to achieve a linear relationship between flow rate and pulse rate a minimum number of on-time vibrations is specified since it takes a finite amount of time for the aperture plate to reach its maximum amplitude of vibrations.

The drive frequency can be started and stopped as required by the microprocessor; this allows control of flow rate by driving the nebuliser for any required pulse rate. The microprocessor can control the on and off times with an accuracy of microseconds.

A nebuliser can be calibrated at a certain pulse rate by measuring how long it takes to deliver a known quantity of solution. There is a linear relationship between the pulse rate and that nebuliser's flow rate. This allows accurate control of the rate of delivery of the aerosolised aqueous solution.

The pulse rate may be lowered so that the velocity of the emerging aerosol is much reduced so that impaction rain-out is reduced.

Detection of when the aperture plate is dry can be achieved by using the fact that a dry aperture plate has a well defined resonant frequency. If the drive frequency is swept from 120kHz to 145kHz and the current is measured then if a minimum

current is detected less than a set value, the aperture plate must have gone dry. A wet aperture plate has no resonant frequency. The apparatus of the invention may be configured to determine whether there is any of the first fluid in contact with the aerosol generator 2. By determining an electrical characteristic of the aerosol generator 2, for example the current flowing through the aerosol generator 2, over a range of vibration frequencies, and comparing this electrical characteristic against a pre-defined set of data, it is possible to determine whether the aerosol generator 2 has any solution in contact with the aerosol generator 2. Fig. 11 illustrates a curve 80 of frequency versus current when there is some of the solution in contact with the aerosol generator 2, and illustrates a curve 90 of frequency versus current when there is none of the solution in contact with the aerosol generator 2. Fig. 11 illustrates the wet aperture plate curve 80 and the dry aperture plate curve 90.

If an application requires a constant feed from a drip bag then a pump can be added in line to give fine control of the liquid delivery rate which can be nebulised drip by drip. The rate would be set so that liquid would not build up in the nebuliser. This system is particularly suitable for constant low dose delivery. Referring now to Fig. 12 there is illustrated another insufflation apparatus which is similar to the apparatus of Fig. 1 and like parts are arranged the same reference numerals. In this case the controller 3 is integrated into the insufflator 12. The insufflator 12 would have information on the rate of flow that it is producing and using an integrated circuit board may directly communicate with the nebuliser 2. This would eliminate the need for the separate flowmeter 11 and the stand-alone controller 3 to be present.

In another case there may be a common information bus between the insufflator 12 and the controller 3. The insufflator 12 would have information on the rate of flow that it is producing and would communicate this to the controller 3 and on to

the nebuliser 2, thereby eliminating the need for the flowmeter 11. This would allow the invention to be backward compatible with a variety of types of insufflator.

Referring to Fig. 13 there is illustrated another insufflation apparatus which is similar to the apparatus of Fig. 1 and like parts are again identified by the same reference numerals. In this case the insufflation gas flow signal is provided directly from the insufflator along a lead 71. One advantage of this arrangement is that no separate meter/sensor required.

Humidity may be generated via the aerosolisation of any aqueous solution. Relative humidity in the 50-100% range would be optimum. The control module can generate a nebuliser output of any defined relative humidity percentage based on the insufflator flow. These solutions include any aqueous drug solution. Solutions with salt concentrations in the range 1μM–154mM would be optimum.

The use of the nebulizer to humidify the insufflation gas prior to entering the body will eliminate the need for the body to humidify the gas once it is inside the body, thereby minimizing body heat loss by internal evaporation.
The control in nebulizer output allows proportional delivery of the required amount of humidity according to the amount of insufflation gas entering the body. In addition this control of aerosolization rate will prevent overloading of the insufflation gas with aerosol which would obscure the surgeons view.

In addition to acting as a humidifying agent the nebulizer can also act to deliver any agent presented in an aqueous drug solution. The system facilitates delivery of, for example, pain-relief medications, anti-infectives, anti-inflammatory and/or

chemotherapy agents in aerosol form to the body cavity. These therapeutic agents could also act as humidifying substances in their own right.

The liquid entrained in the insufflation gas may contain any desired therapeutic and/or prophylactic agent. Such an agent may for example be one or more of an analgesic, an anti-inflammatory, an anaesthetic, an anti-infective such as an antibiotic, or an anti-cancer chemotherapy agent.

Typical local anaesthetics are, for example, Ropivacaine, Bupivacaine and Lidocaine.

Typical anti-infectives include antibiotics such as an aminoglycoside, a tetracycline, a fluroquinolone; anti-microbials such as a cephalosporin; and anti-fungals.

Anti-inflammatories may be of the steroidal or non-steroidal type.

Anti-cancer chemotherapy agents may be alkylating agents, antimetabolites anthracyclines, plant alkaloids, topoisomerase inhibitors, nitrosoureas, mitotic inhibitors, monoclonal antibodies, tyrosine kinase inhibitors, hormone therapies including corticosteroids, cancer vaccines, anti-estrogens, aromatase inhibitors, anti-androgens, anti-angiogenic agents and other antitumour agents.

The system of the invention can be used for precise controlled delivery of drug and/or humidity during insufflation. No heating is required. Consequently there is no risk of damage to drugs due to heating The system may be used to provide precise control over aerosol output can be exercised by utilising pulse rate control. The system may be used for targeted delivery of a range of drugs, thereby

reducing systemic side effects. In addition the system provides alleviation of post-surgical pain experienced by the patient.

The system need not be located in the direct flow path of insufflation gas. In addition, minimal caregiver intervention during laparoscopic procedure is required. The system is small and compact and allows for integration with an insufflator.

The device of the invention can be used throughout the procedure carried out by a surgeon. The device ensures that humidity is actively controlled during the procedure and thus ensures that a surgeon's view is clear as fogging is avoided.

All parts of the device (except the controller and associated leads) are autoclavable which provides a significant advantage for a device used in surgery.

The invention is not limited to the embodiments hereinbefore described, with reference to the accompanying drawings, which may be varied in construction and detail.

Claims

1. Apparatus for use in insufflation comprising:

an insufflator for generating an insufflation gas;

an aerosol generator for aerosolising a fluid and entraining the aerosol with the insufflation gas wherein the aerosol generator comprises a vibratable member having a plurality of apertures extending between a first surface and a second surface; and

a controller to control the operation of the aerosol generator.

2. An apparatus as claimed in claim 1 wherein the controller is configured to control operation of the aerosol generator responsive to the insufflation gas.

3. An apparatus as claimed in claim 1 or 2 wherein the controller is configured to control operation of the aerosol generator responsive to the flow rate of the insufflation gas.

4. An apparatus as claimed in any of claims 1 to 3 wherein the controller is configured to control the flow rate of the fluid to be aerosolised.

5. An apparatus as claimed in any of claims 2 to 4 wherein the apparatus comprises a device to determine the fluid flow rate of the insufflation gas.

6. An apparatus as claimed in claim 5 wherein the determining device comprises a flow sensor.

7. An apparatus as claimed in claim 6 wherein the flow sensor comprises a flowmeter.

8. An apparatus as claimed in any of claims 1 to 7 wherein the first surface is adapted to receive the fluid to be aerosolised.

9. An apparatus as claimed in any of claims 1 to 8 wherein the aerosol generator is configured to generate an aerosol at the second surface.

10. An apparatus as claimed in any of claims 1 to 9 wherein the vibratable member is dome-shaped in geometry.

11. An apparatus as claimed in any of claims 1 to 10 wherein the vibratable member comprises a piezoelectric element.

12. An apparatus as claimed in any of claims 1 to 11 wherein the apertures in the vibratable member are sized to aerosolise the first fluid by ejecting droplets of the first fluid such that the majority of the droplets by mass have a size of less than 5 micrometers.

13. An apparatus as claimed in any of claims 1 to 12 wherein the apertures in the vibratable member are sized to aerosolise the first fluid by ejecting droplets of the first fluid such that the majority of the droplets by mass have a size of less than 3 micrometers.

14. An apparatus as claimed in any of claims 1 to 13 wherein the controller is configured to control the pulse rate at a set frequency of vibration of the vibratable member.

15. An apparatus as claimed in any of claims 1 to 14 wherein the controller is impedance matched to the aerosol generator.

16. An apparatus as claimed in any of claims 1 to 15 wherein the apparatus comprises means to determine whether the fluid is in contact with the aerosol generator.

17. An apparatus as claimed in claim 16 wherein the determining means is configured to determine at least one electrical characteristic of the aerosol generator.

18. An apparatus as claimed in claim 17 wherein the determining means is configured to determine at least one electrical characteristic of the aerosol generator over a range of vibration frequencies.

19. An apparatus as claimed in claim 17 or 18 wherein the determining means is configured to compare the at least one electrical characteristic against a pre-defined set of data.

20. A method for carrying out a procedure involving insufflation comprising the steps of:-

generating an insufflation gas;

aerosolising a fluid using an aerosol generator wherein the aerosol generator comprises a vibratable member having a

plurality of apertures extending between a first surface and a second surface; and

entraining the aerosol with the insufflation gas.

21. A method as claimed in claim 20 comprising the step of controlling the aerosolisation of the fluid.

22. A method as claimed in claim 21 comprising controlling aerosolisation of the fluid responsive to the insufflation gas.

23. A method as claimed in claim 21 or 22 comprising controlling aerosolisation of the fluid responsive to the flow rate of the insufflation gas.

24. A method as claimed in any of claims 21 to 23 comprising controlling the flow rate of the fluid.

25. A method as claimed in any of claims 21 to 24 wherein the method comprises the step of determining the flow rate of the insufflation gas.

26. A method as claimed in any of claims 21 to 25 wherein the method comprises the step of determining if the fluid is in contact with an aerosol generator.

27. A method as claimed in claim 26 comprising determining at least one electrical characteristic of the aerosol generator.

28. A method as claimed in claim 27 comprising determining at least electrical characteristics of the aerosol generator over a range of vibration frequencies.

29. A method as claimed in claim 27 or 28 wherein the method comprises the step of comparing the at least one electrical characteristic against a pre-defined set of data.

30. A method as claimed in any of claims 20 to 29 wherein the method comprises the step of delivering the entrained fluid and insufflation gas into a body to insufflate at least part of the body.

31. A method as claimed in any of claims 20 to 30 wherein the fluid is an aqueous solution.

32. A method as claimed in claim 31 wherein the aqueous solution is saline having a salt concentration in the range of from 1μM to 154mM.

33. A method as claimed in any of claims 20 to 32 wherein the fluid contains a therapeutic and/or prophylactic agent.

34. A method as claimed in claim 33 wherein the agent is one or more selected from the group comprising an analgesic, and anti-inflammatory, an anti-infective, an anaesthetic, and an anticancer chemotherapy agent.

35. A method as claimed in any of claims 20 to 24 wherein the procedure is a laparoscopic procedure.

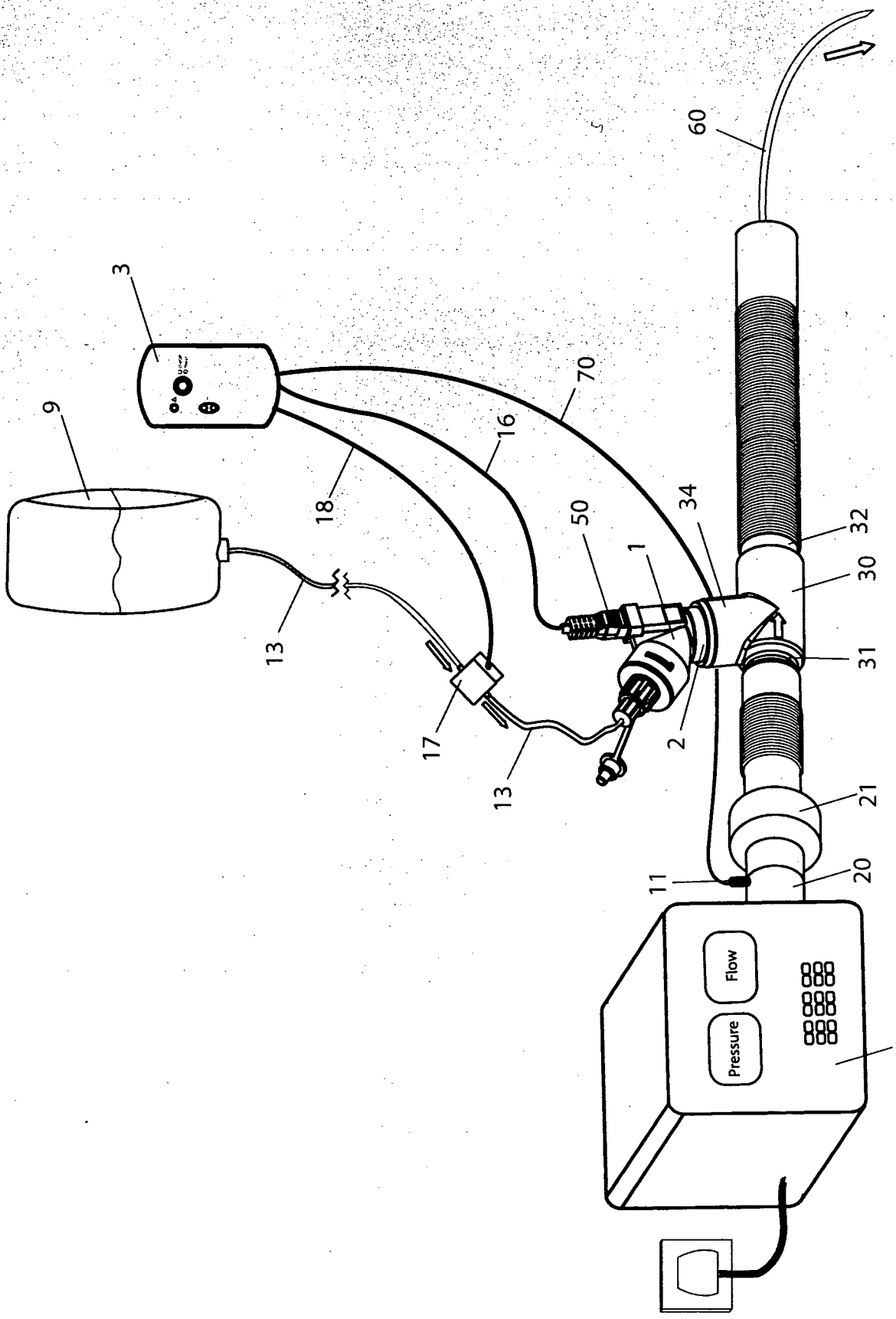


Fig. 1

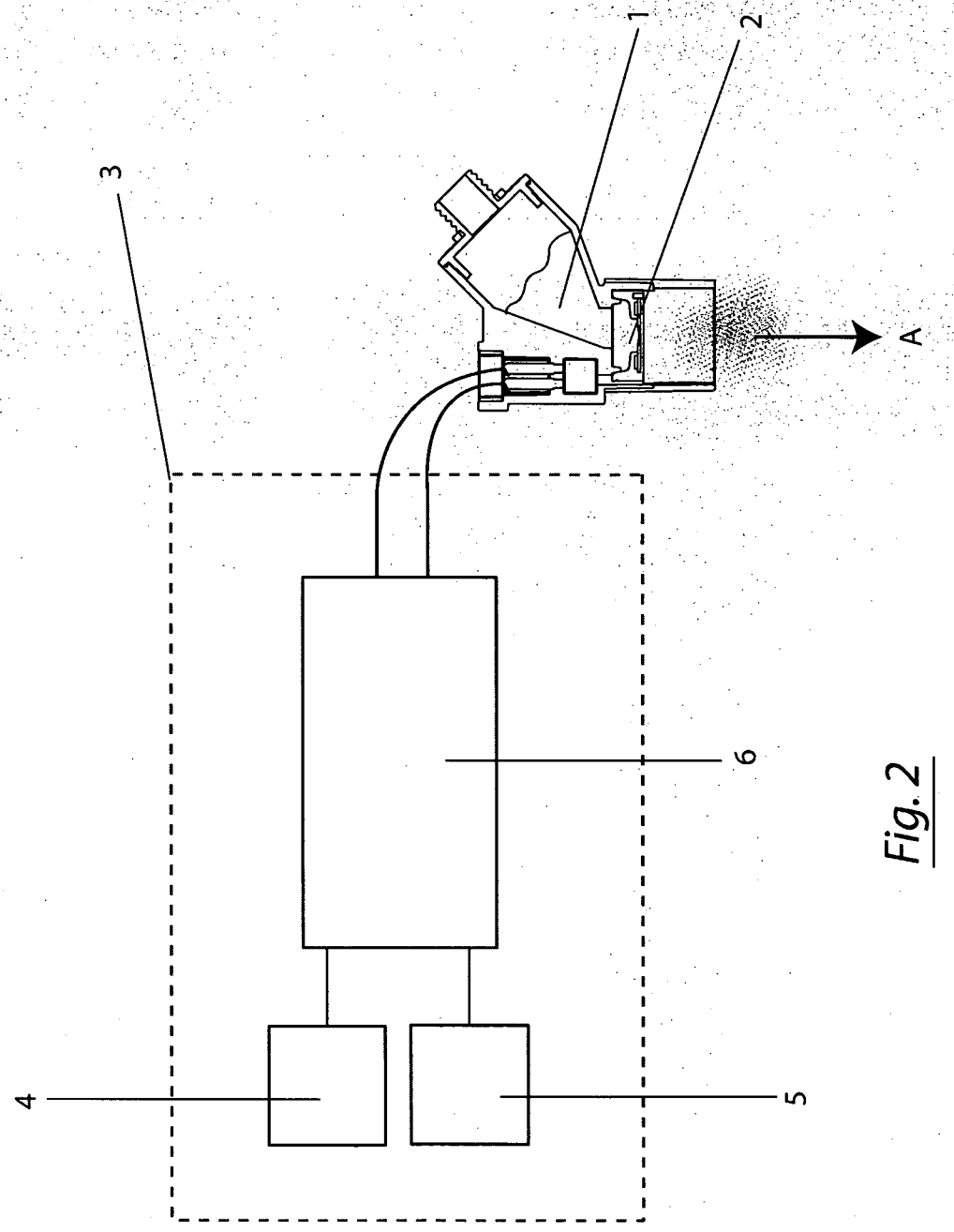


Fig. 2

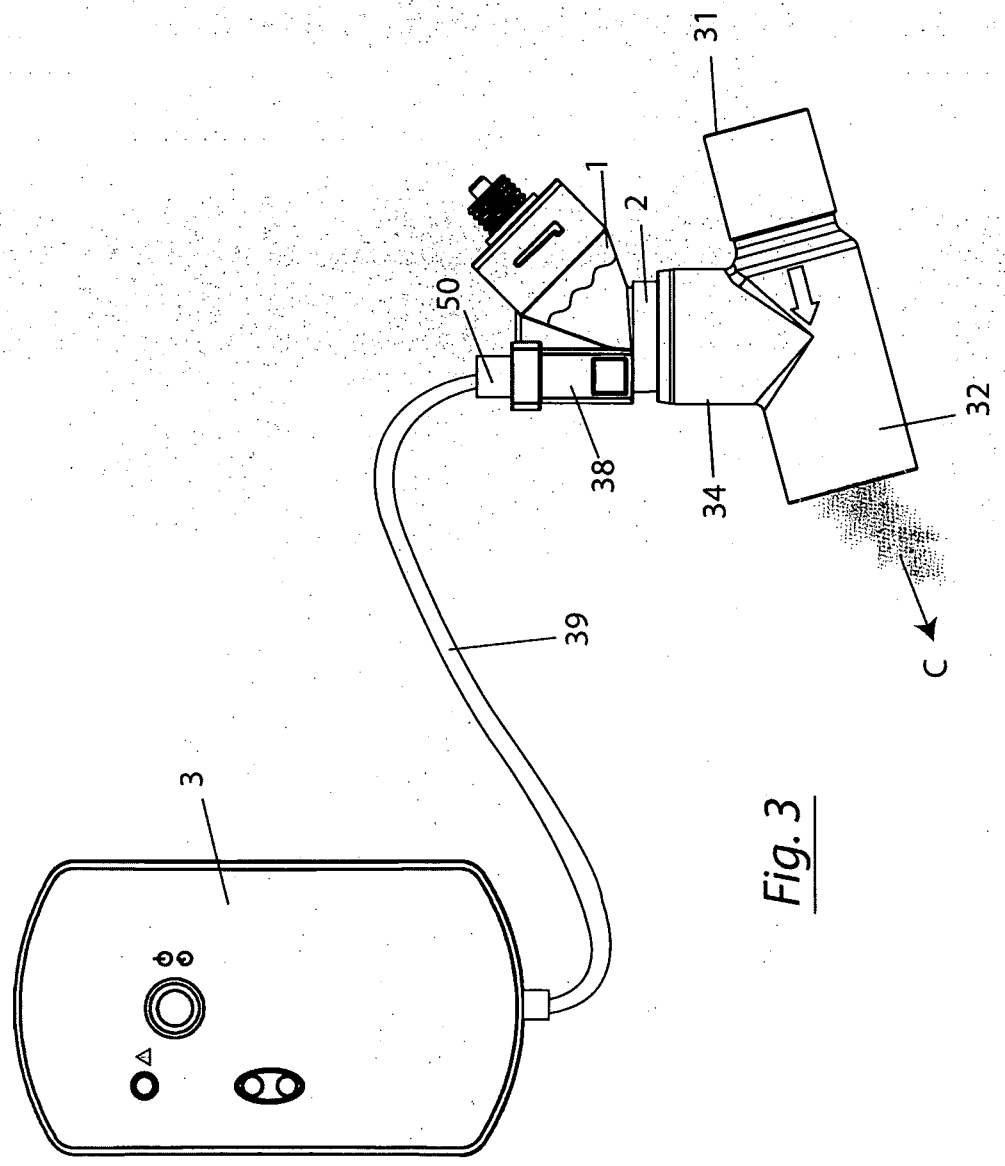


Fig. 3

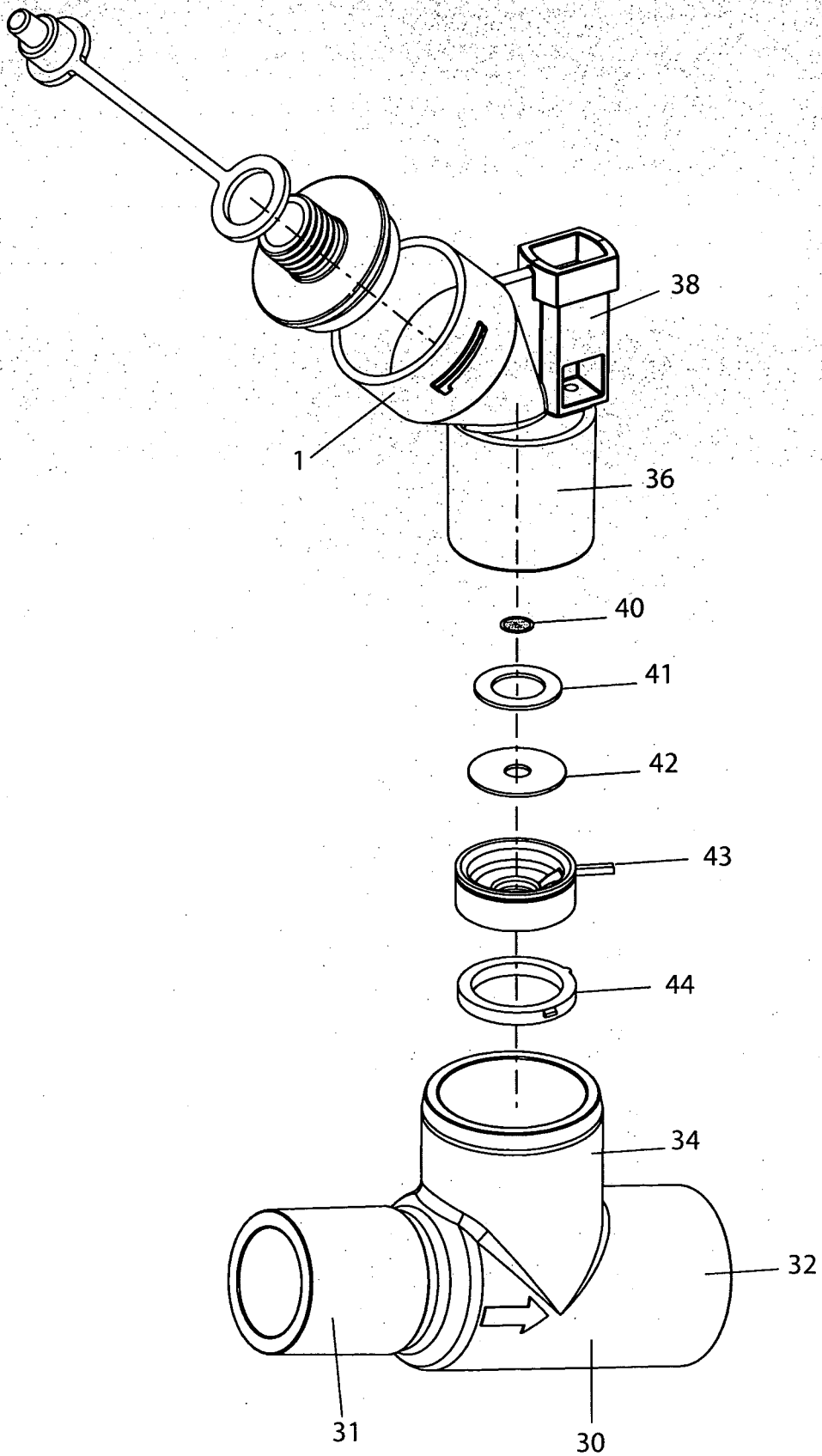


Fig. 4

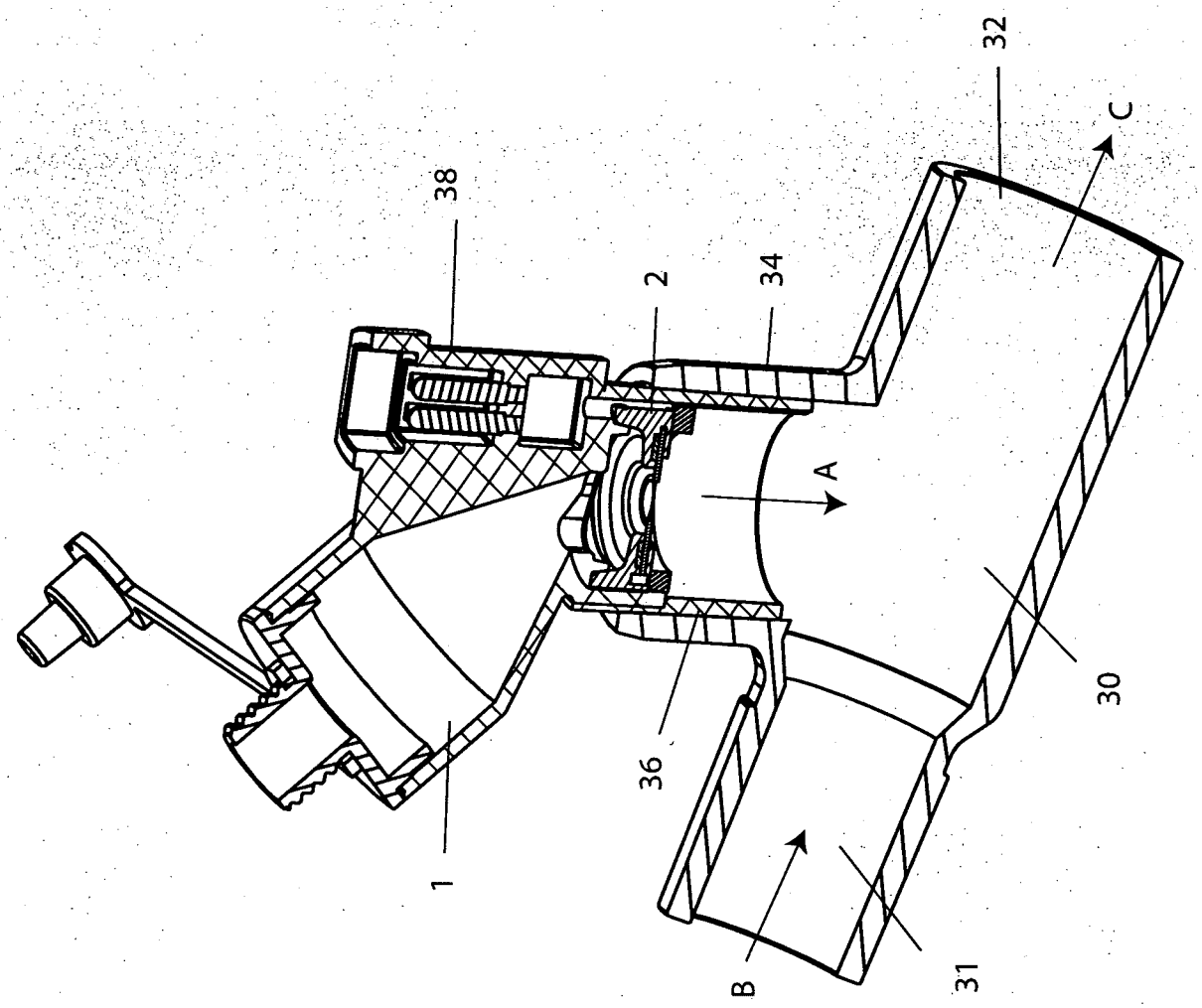


Fig. 5

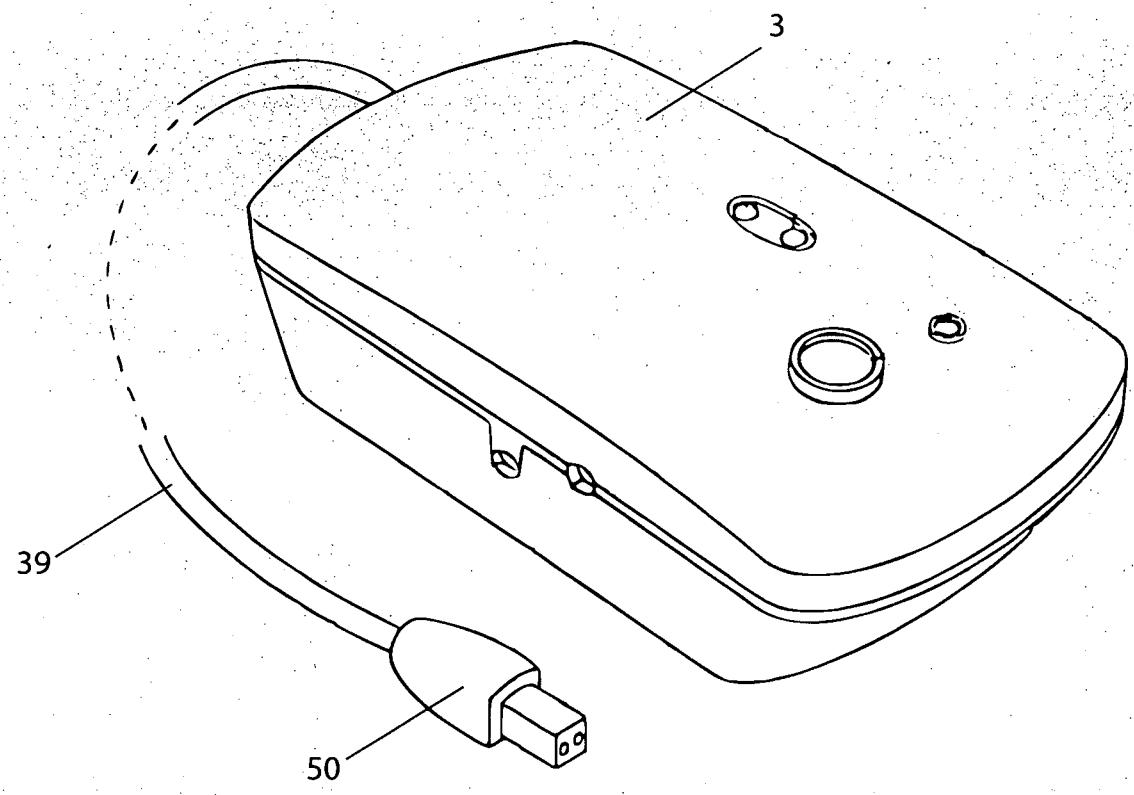


Fig. 6

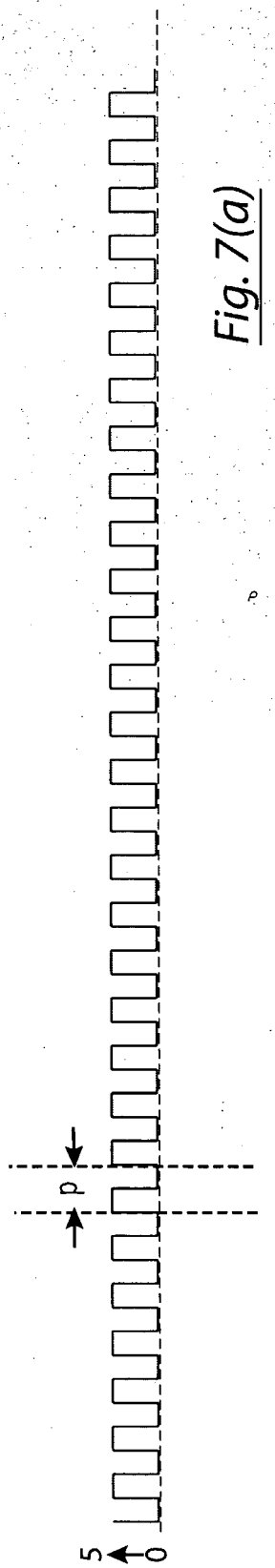


Fig. 7(a)

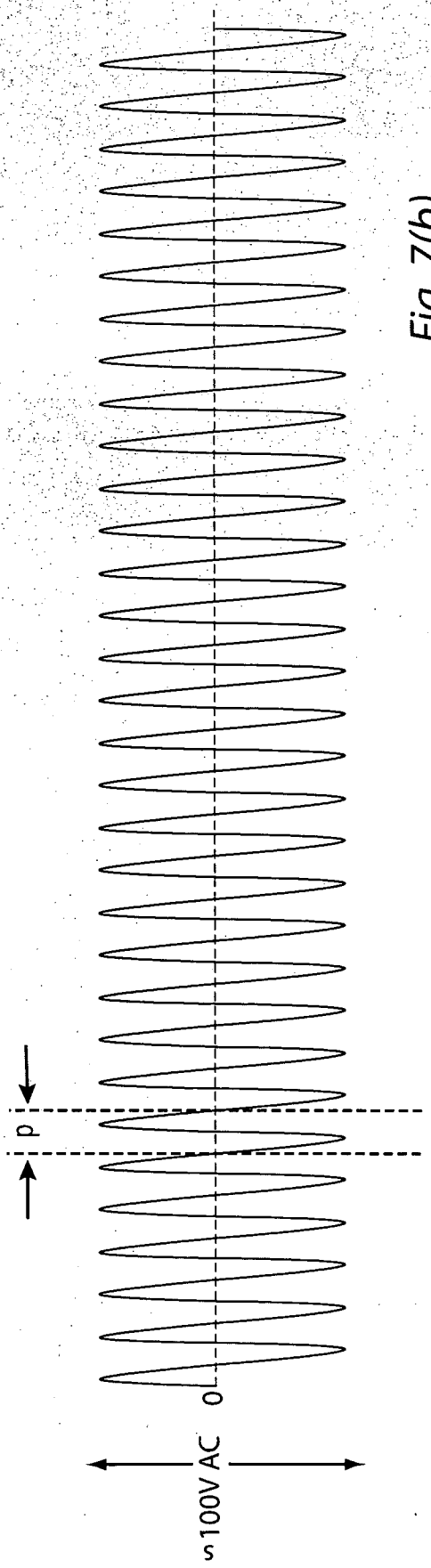
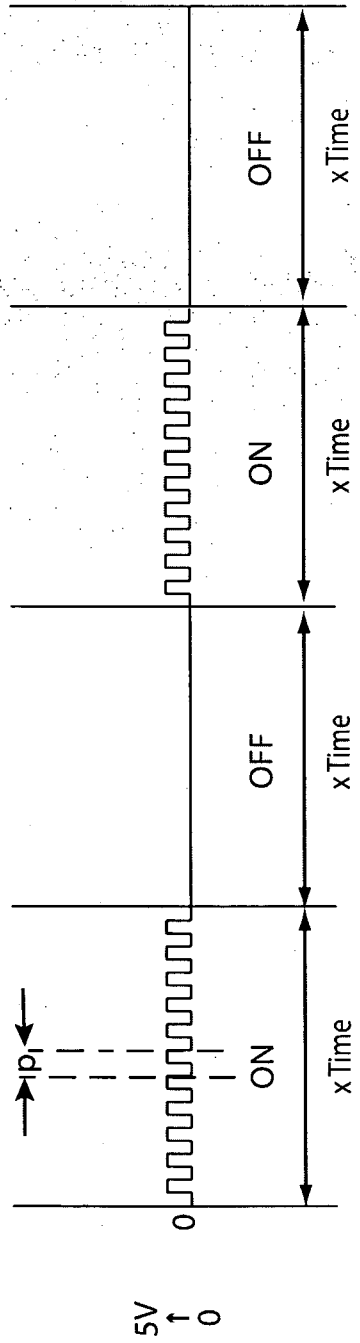


Fig. 7(b)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ON
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OFF
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ON
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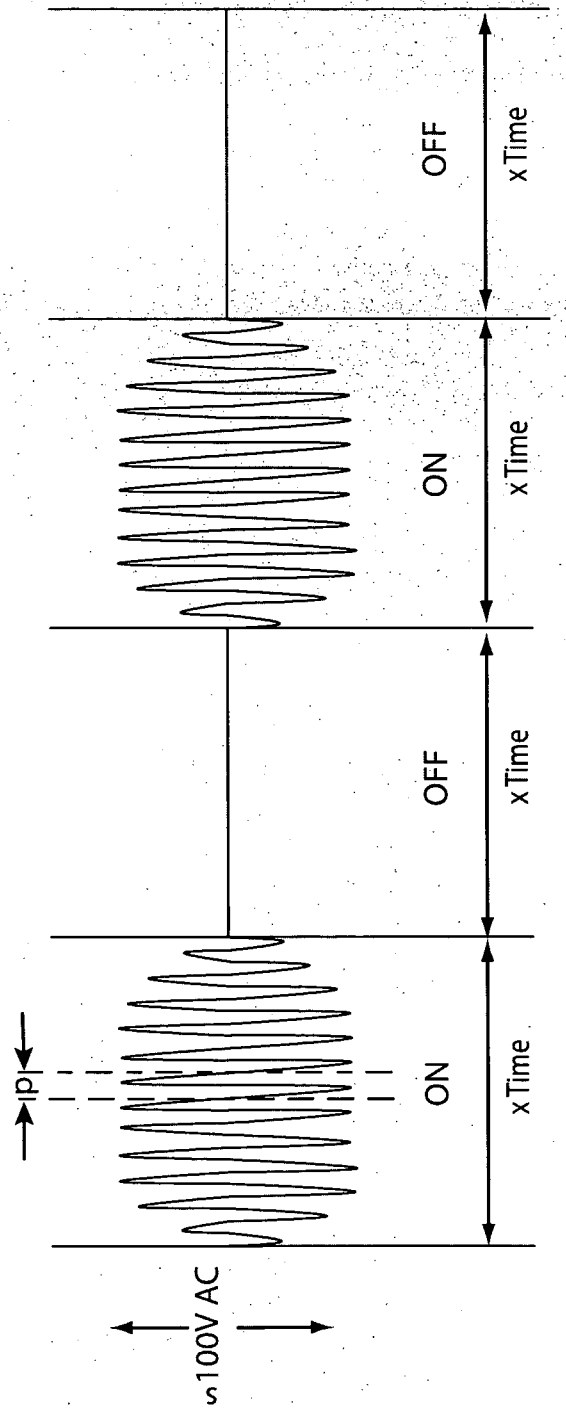
P
5V
0

Fig. 8(a)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ON
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P
100V AC

Fig. 8(b)

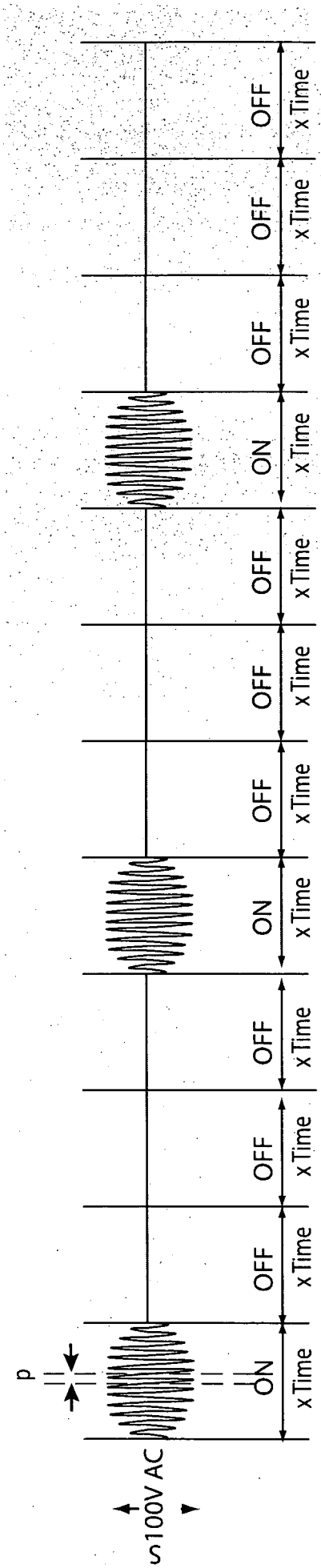

Fig. 9(a)

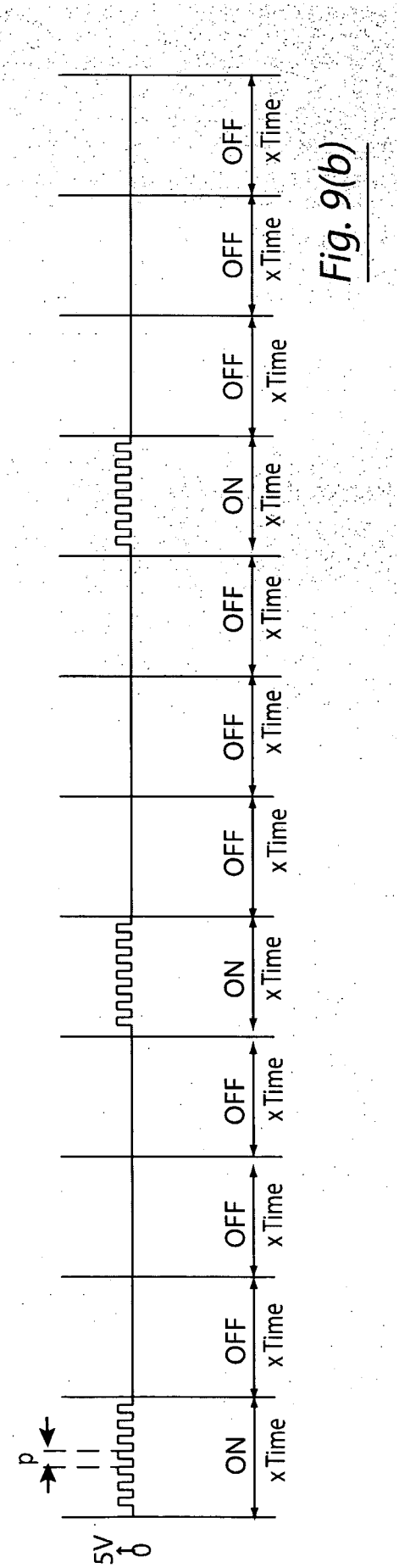

Fig. 9(b)

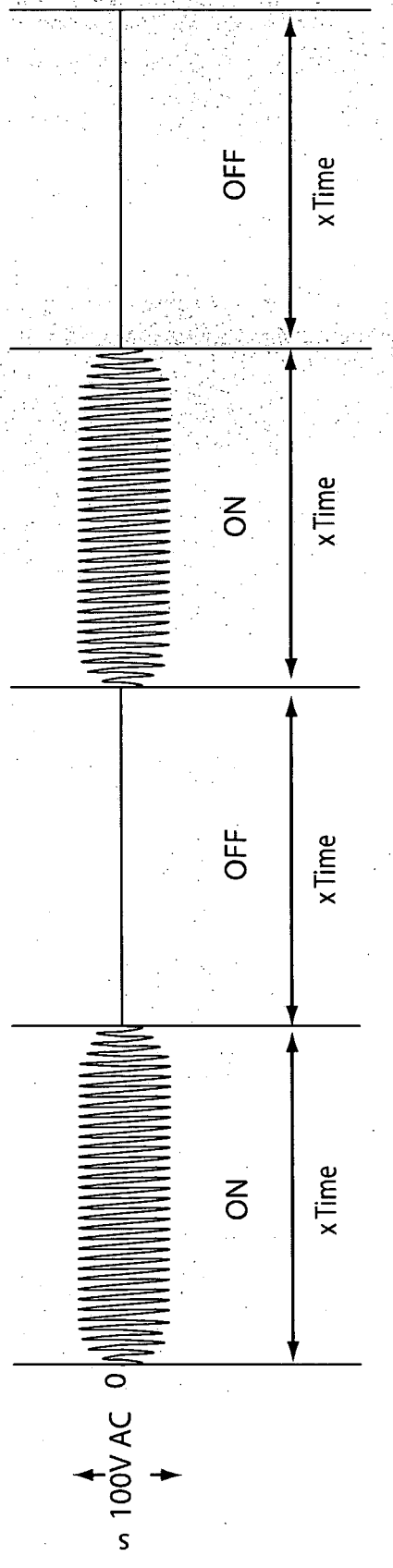

Fig. 10

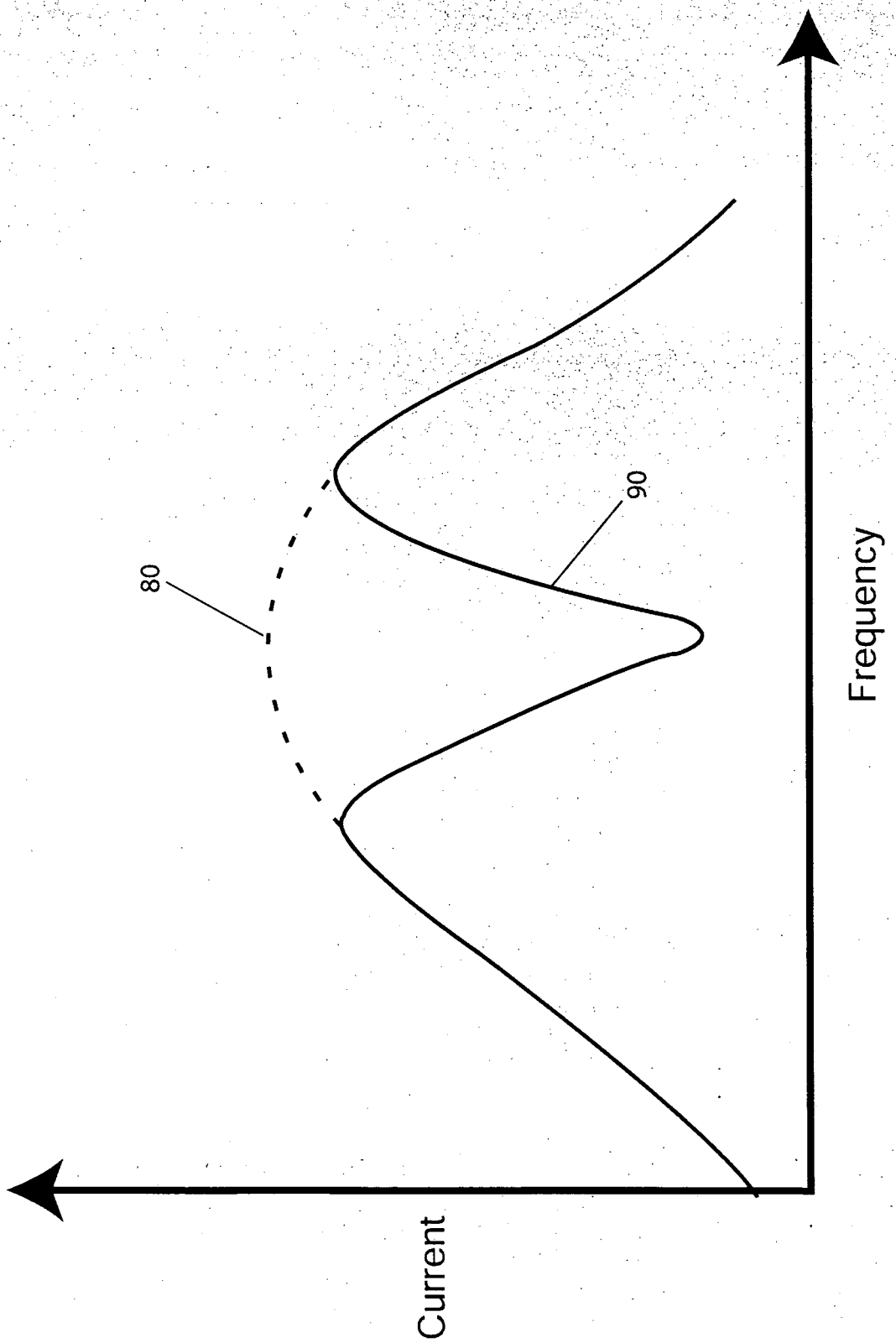

Fig. 11

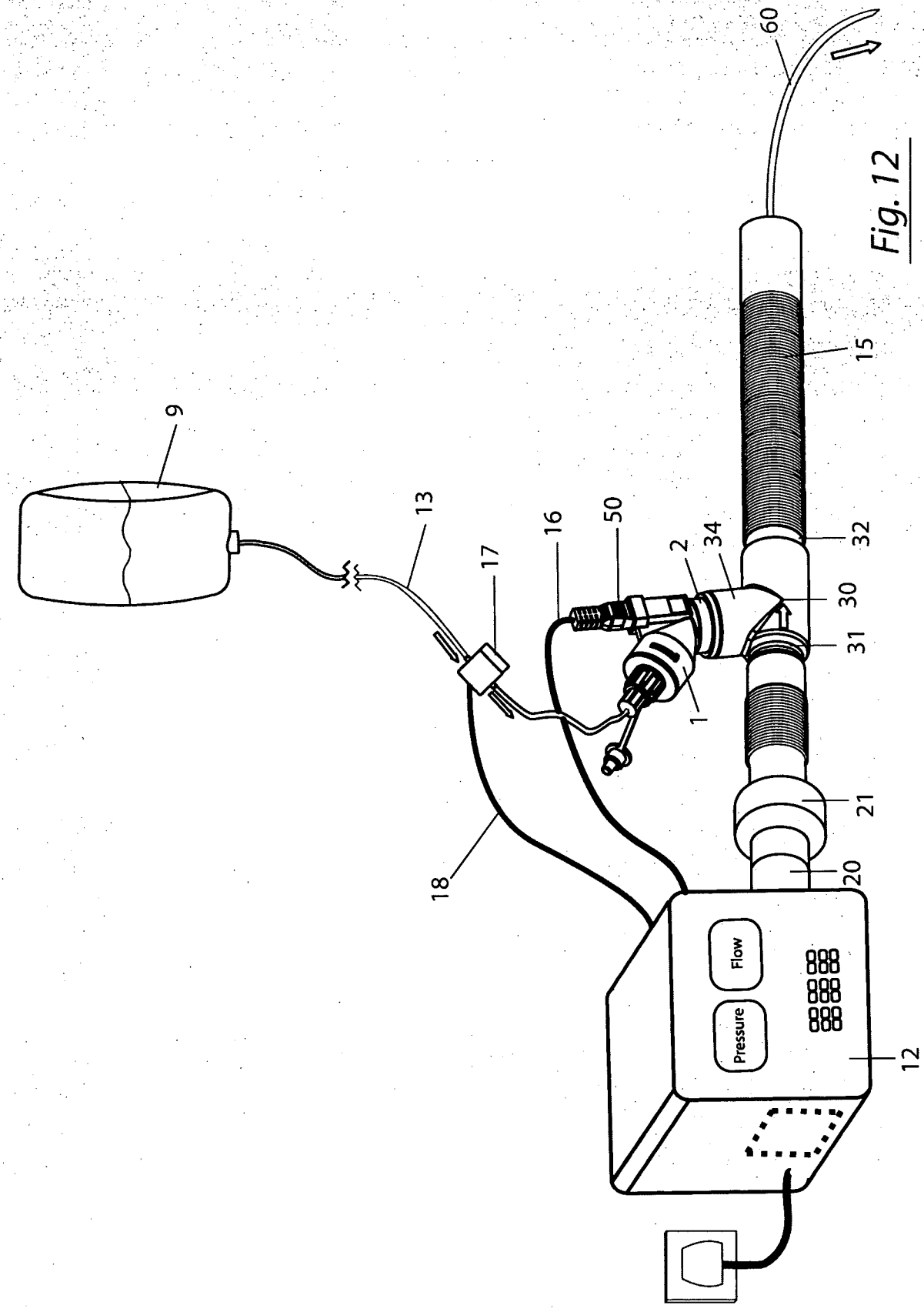

Fig. 12

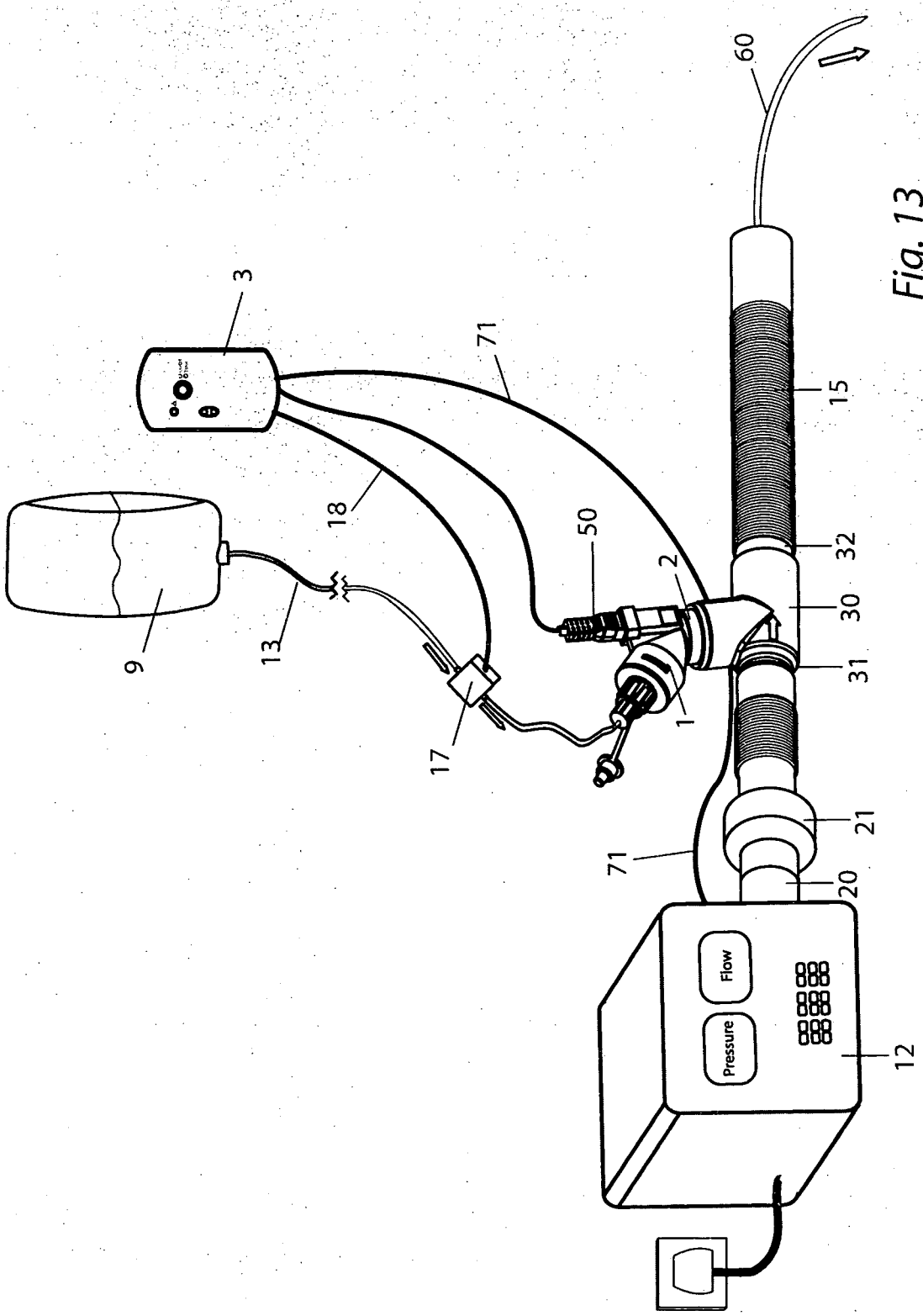

Fig. 13

INTERNATIONAL SEARCH REPORT

International application No
PCT/IE2008/000031

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/34 A61M16/16 B05B17/06 A61M15/00

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)
A61B A61M B05B

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 practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2004/043274 A (GASIN VIACHESLAV [IL]; FREEDMAN ZEEV VLADIMIR [IL]; TARAN DAVID [IL]) 27 May 2004 (2004-05-27) page 3, paragraph 4 - page 5, paragraph 2; figure 1	1-19
A	US 2005/107766 A1 (OTT DOUGLAS E [US] ET AL) 19 May 2005 (2005-05-19) paragraph [0158] - paragraph [0166]; figures 16,20,29 paragraph [0184]	1
A	US 6 014 970 A (IVRI YEHUDA [US] ET AL) 18 January 2000 (2000-01-18) cited in the application column 7, line 57 - column 8, line 39; figures 1,3	1

-/--

[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
4 July 2008	11/07/2008

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Moers, Roelof

INTERNATIONAL SEARCH REPORT

International application No
PCT/IE2008/000031

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 938 117 A (IVRI YEHUDA [US]) 17 August 1999 (1999-08-17) cited in the application column 7, line 13 - line 55; figures 1,2,9,18 -----	1

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IE2008/000031

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 20-35
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers allsearchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search reportcovers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/IE2008/000031

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2004043274 A	27-05-2004	AU 2003279504 A1	03-06-2004
US 2005107766 A1	19-05-2005	US 7250035 B1	31-07-2007
		US 2005113795 A1	26-05-2005
		US 2005113797 A1	26-05-2005
		US 2005107767 A1	19-05-2005
US 6014970 A	18-01-2000	NONE	
US 5938117 A	17-08-1999	US 2003226906 A1	11-12-2003

专利名称(译)	吹入体腔		
公开(公告)号	EP2139409A1	公开(公告)日	2010-01-06
申请号	EP2008719889	申请日	2008-03-28
申请(专利权)人(译)	STAMFORD器件有限公司		
当前申请(专利权)人(译)	STAMFORD器件有限公司		
[标]发明人	POWER JOHN SYLVESTER SMITH NIALL SCOTT DUFFY CONOR PAUL GIBBONS KEITH DIEMUNSCH PIERRE AUGUSTE		
发明人	POWER, JOHN, SYLVESTER SMITH, NIALL, SCOTT DUFFY, CONOR, PAUL GIBBONS, KEITH DIEMUNSCH, PIERRE, AUGUSTE		
IPC分类号	A61B17/34 A61M16/16 B05B17/06 A61M15/00		
CPC分类号	A61B17/3474 A61M11/005 A61M13/00 A61M13/003 A61M2202/0225 A61M2202/025 A61M2202/0266 A61M2202/0291 B05B12/081 B05B17/0646 B05B17/0669		
优先权	60/907311 2007-03-28 US		
外部链接	Espacenet		

摘要(译)

用于吹气的装置包括用于产生吹入气体（例如二氧化碳）的吹入器12和用于雾化流体并用吹入气体夹带气雾剂的气溶胶发生器2。气溶胶发生器2包括可振动构件40，其具有在第一表面和第二表面之间延伸的多个孔。流体可包含治疗剂或预防剂。控制器3用于控制气溶胶发生器2的操作。控制器3响应于诸如由流量传感器11检测到的吹入气体的流动来控制气溶胶发生器2的操作。