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(54) **AEROSOL GENERATOR AND METHODS OF MAKING AND USING AN AEROSOL GENERATOR**

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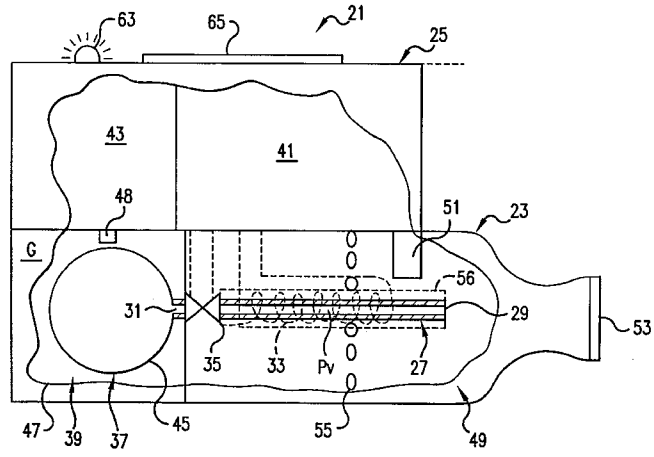
(57) **ABSTRACT**

An aerosol generator includes a tube having a first and a second end, a heater arranged relative to the tube for heating the tube, a source of material to be volatilized, the second end of the tube being in communication with the source of material, a valve operatively located between the source of material and the tube, the valve being openable and closeable to open and close communication between the source of material and the first end of the tube, and a pressurization arrangement for causing material in the source of material to be introduced into the tube from the source of material when the valve is in an open position. The aerosol generator further includes a source of power for operating the heater and the valve, and a control device for controlling supply of power from the source of power to the heater and the valve. A method of making and a method of using an aerosol generator are also disclosed.

68 Claims, 6 Drawing Sheets



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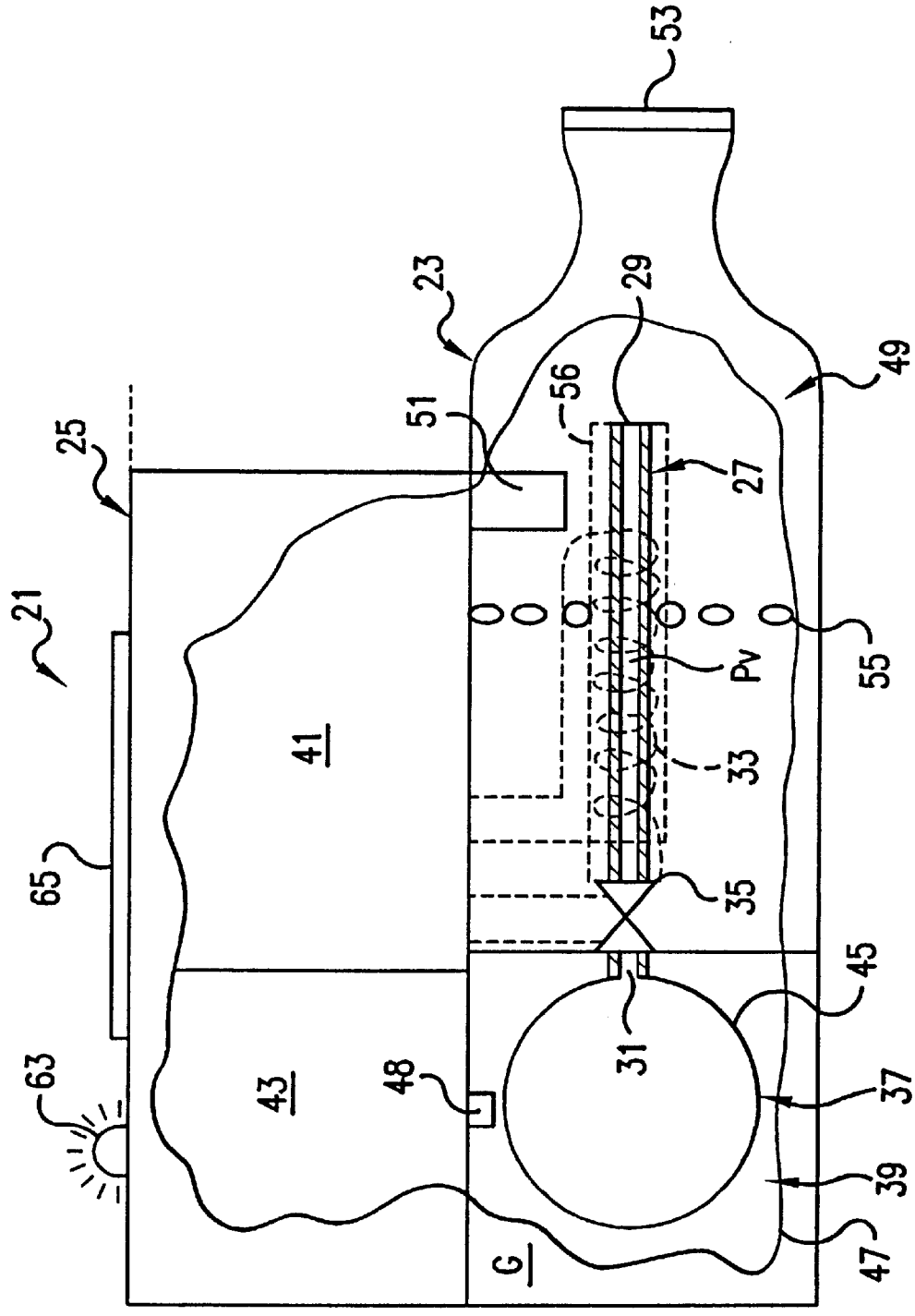

FIG. 1

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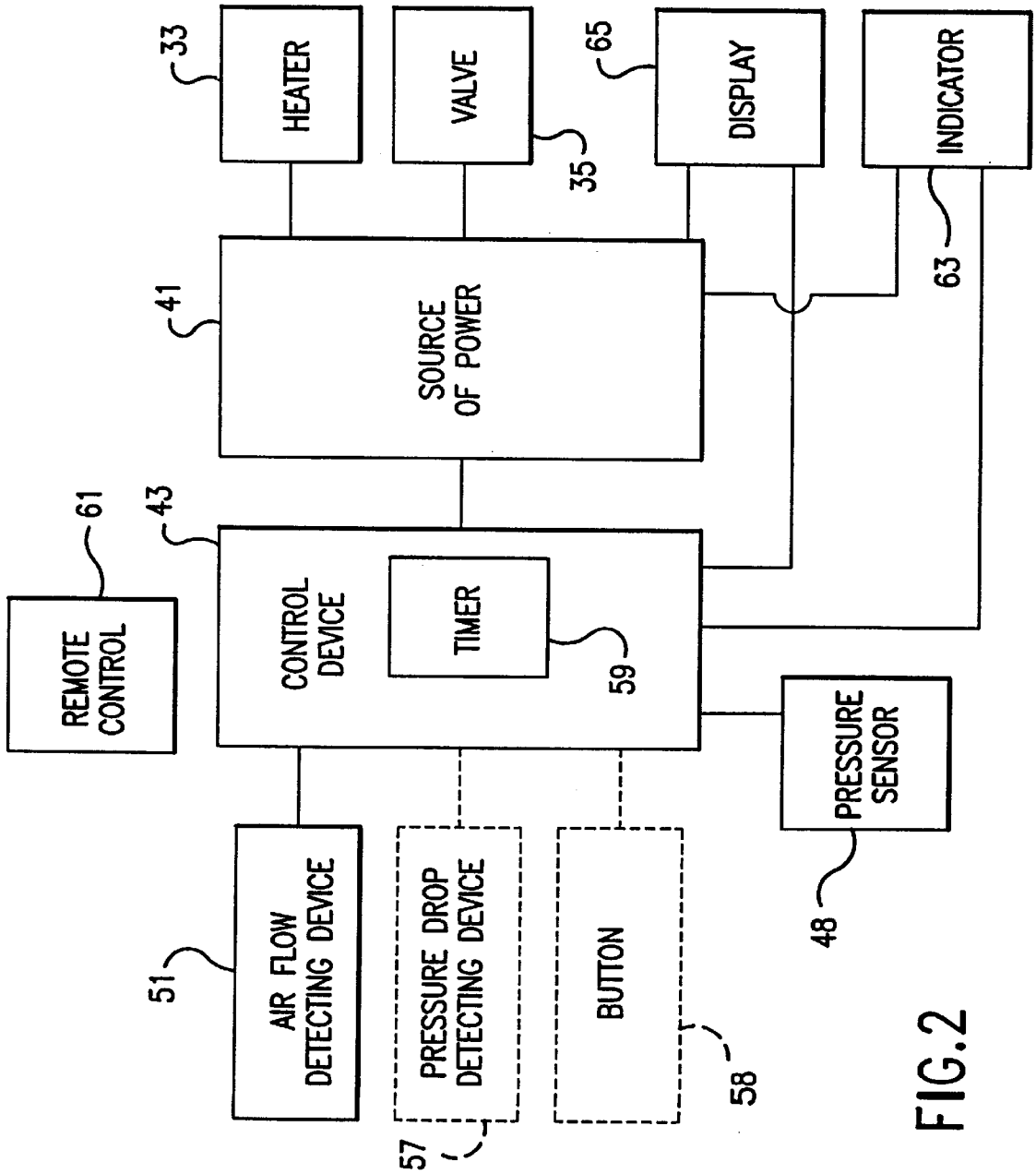

FIG.2

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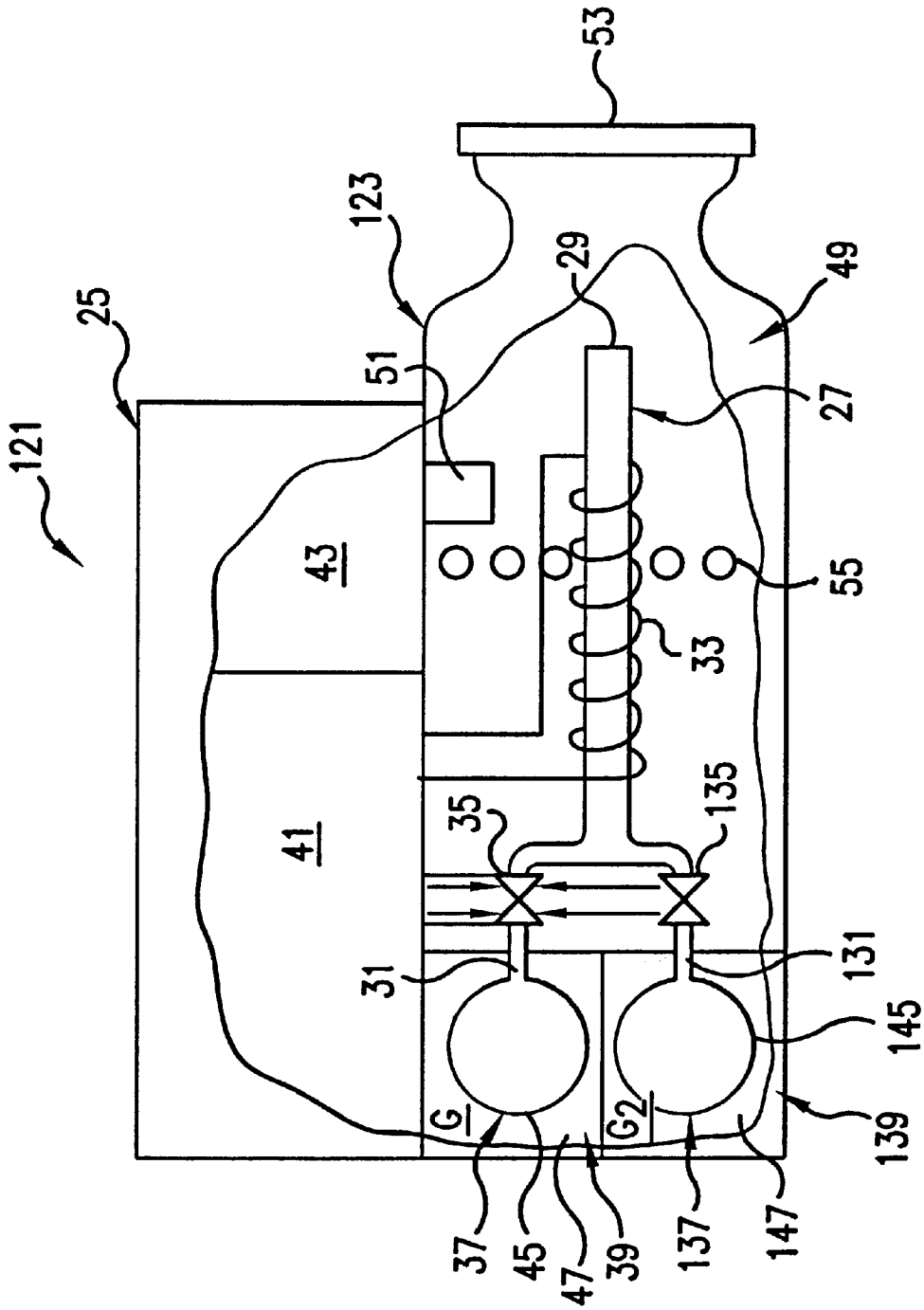

FIG.3

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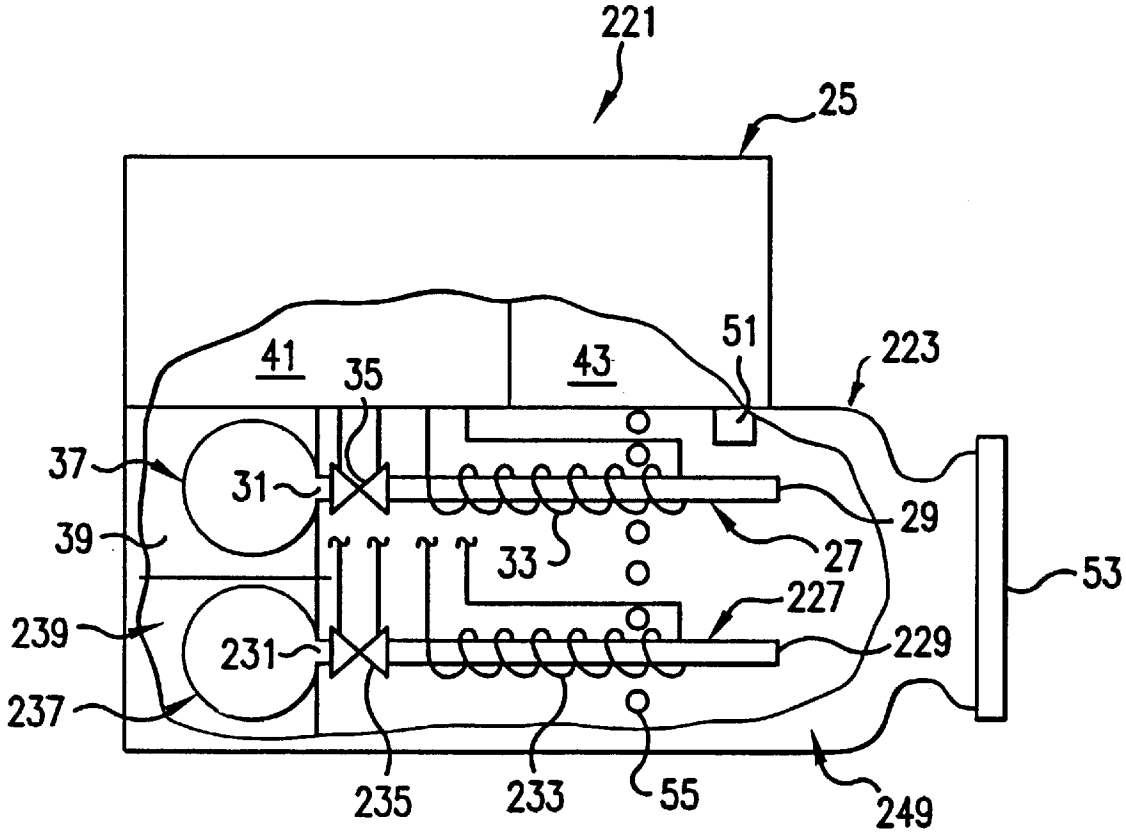

FIG.4

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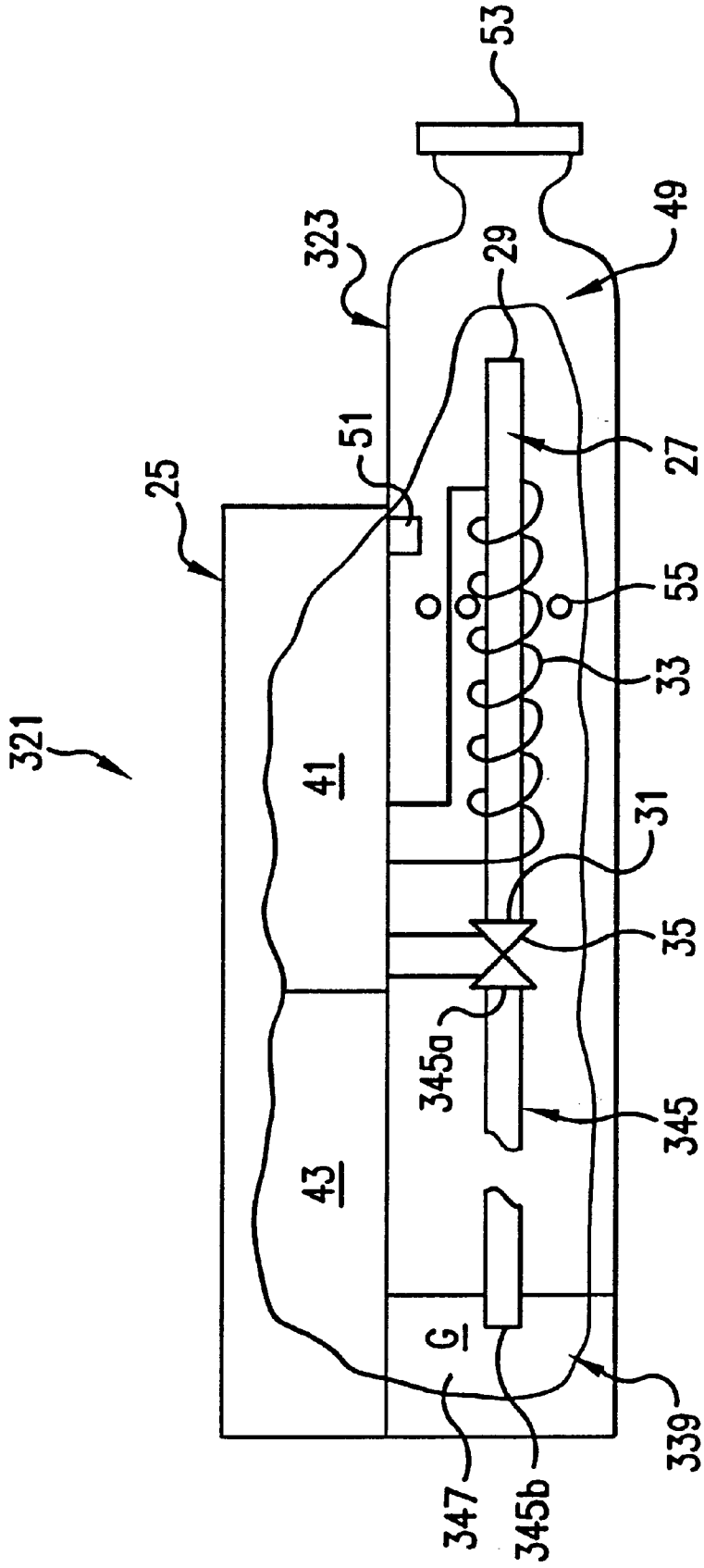

FIG.5

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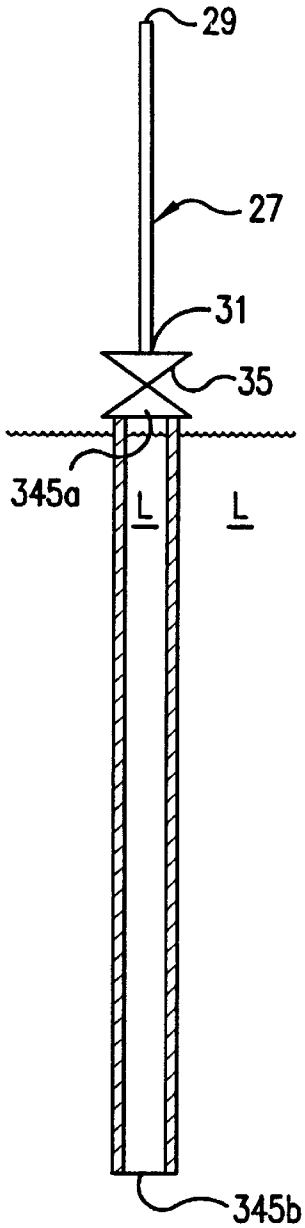

FIG. 6A

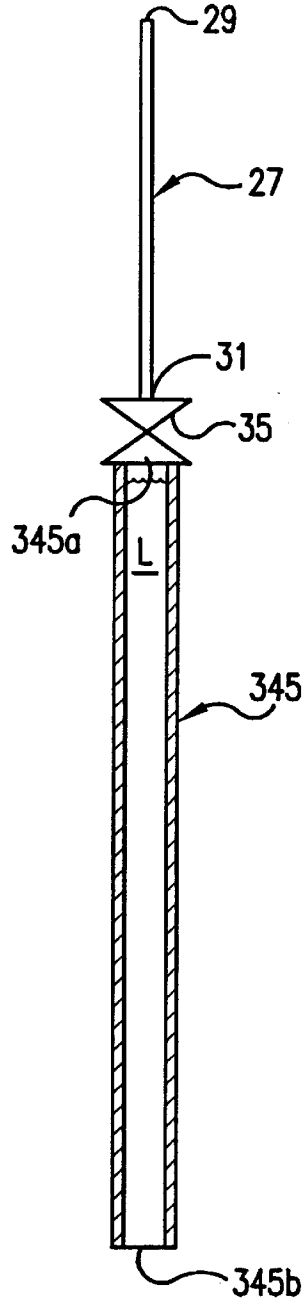

FIG. 6B

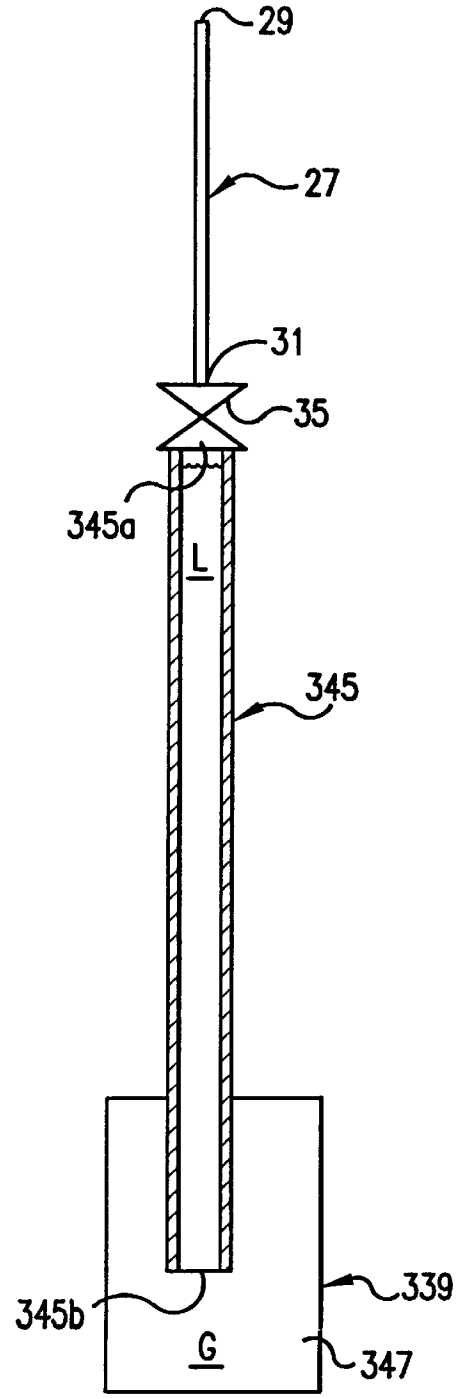

FIG. 6C

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AEROSOL GENERATOR AND METHODS OF MAKING AND USING AN AEROSOL GENERATOR

BACKGROUND AND SUMMARY OF THE INVENTION

The present invention relates generally to aerosol generators and, more particularly, to aerosol generators able to generate aerosols without compressed gas propellants and methods of making and using such aerosol generators.

Aerosols are useful in a wide variety of applications. For example, it is often desirable to treat respiratory ailments with, or deliver drugs by means of, aerosol sprays of finely divided particles of liquid and/or solid, e.g., powder, medicaments, etc., which are inhaled into a patient's lungs. Aerosols are also used for purposes such as providing desired scents to rooms, applying scents on the skin, and delivering paint and lubricant.

Various techniques are known for generating aerosols. For example, U.S. Pat. Nos. 4,811,731 and 4,627,432 both disclose devices for administering medicaments to patients in which a capsule is pierced by a pin to release a medicament in powder form. A user then inhales the released medicament through an opening in the device. While such devices may be acceptable for use in delivering medicaments in powder form, they are not suited to delivering medicaments in liquid form. The devices are also, of course, not well-suited to delivery of medicaments to persons who might have difficulty in generating a sufficient flow of air through the device to properly inhale the medicaments, such as asthma sufferers. The devices are also not suited for delivery of materials in applications other than medicament delivery.

Another well-known technique for generating an aerosol involves the use of a manually operated pump which draws liquid from a reservoir and forces it through a small nozzle opening to form a fine spray. A disadvantage of such aerosol generators, at least in medicament delivery applications, is the difficulty of properly synchronizing inhalation with pumping. More importantly, however, because such aerosol generators tend to produce particles of large size, their use as inhalers is compromised because large particles tend to not penetrate deep into the lungs.

One of the more popular techniques for generating an aerosol including liquid or powder particles involves the use of a compressed propellant, often containing a chlorofluoro-carbon (CFC) or methylchloroform, to entrain a material, usually by the Venturi principle. For example, inhalers containing compressed propellants such as compressed oxygen for entraining a medicament are often operated by depressing a button to release a short charge of the compressed propellant. The propellant entrains the medicament as the propellant flows over a reservoir of the medicament so that the propellant and the medicament can be inhaled by the user. Since the medicament is propelled by the propellant, such propellant-based arrangements are well-suited for those who might have difficulty inhaling. Nonetheless, aerosols generated by propellant-based arrangements have particles that are too large to ensure deep lung penetration.

In propellant-based arrangements, however, a medicament may not be properly delivered to the patient's lungs when it is necessary for the user to time the depression of an actuator such as a button with inhalation. Moreover, such arrangements tend to be poorly suited for delivery of materials in large quantities. Although propellant-based aerosol generators have wide application for uses such as antiperspirant and deodorant sprays and spray paint, their use is often limited because of the well-known adverse environmental effects of CFC's and methylchloroform, which are among the most popular propellants used in aerosol generators of this type.

In drug delivery applications, it is typically desirable to provide an aerosol having average mass median particle diameters of less than 2 microns to facilitate deep lung penetration. Most known aerosol generators are incapable of generating aerosols having average mass median particle diameters less than 2 to 4 microns. It is also desirable, in certain drug delivery applications, to deliver medicaments at high flow rates, e.g., above 1 milligram per second. Most known aerosol generators suited for drug delivery are incapable of delivering such high flow rates in the 0.2 to 2.0 micron size range.

U.S. Pat. No. 5,743,251, which is hereby incorporated by reference in its entirety, discloses an aerosol generator, along with certain principles of operation and materials used in an aerosol generator, as well as a method of producing an aerosol, and an aerosol. The aerosol generator disclosed according to the '251 patent is a significant improvement over earlier aerosol generators, such as those used as inhaler devices. It is desirable to produce an aerosol generator that is portable and easy to use.

According to one aspect of the present invention, an aerosol generator includes a tube having a first and a second end, a heater arranged relative to the tube for heating at least a portion of the tube, a source of material to be volatilized, the second end of the tube being in communication with the source of material, and a valve operatively located between the source of material and the tube, the valve being openable and closeable to open and close communication between the source and the first end of the tube. A pressurization arrangement is provided for causing material in the source of material to be introduced into the tube from the source of material when the valve is in an open position. A source of power is provided for operating the heater and for the valve, and a control device is provided for controlling supply of power from the source of power to the heater and the valve.

According to a further aspect of the present invention, a method of making an aerosol generator is disclosed. According to the method, a heater is arranged relative to a tube for heating of the tube, the tube having first and second ends. The second end of the tube is connected to a source of material to be volatilized. An openable and closeable valve is provided between the source of material and the tube. A pressurization arrangement is provided for causing material in the source of material to be introduced into the tube from the source of material when the valve is in an open position. The valve is connected to a source of power for opening and closing the valve. The heater is connected to the source of power. The source of power is connected to a control device for controlling a supply of power from the source of power to the heater and the valve.

According to yet another aspect of the present invention, a method of using an aerosol generator is disclosed. According to the method, a first signal, indicative of a user's intention to use the aerosol generator, is provided to a control device. With the control device and in response to the first signal, a second signal is sent to a source of power to cause the source of power to open an openable and closeable valve, the valve being disposed between a source of material to be volatilized and a tube, opening of the valve permitting material from the source of material to flow from

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the source of material and into the tube. Material from the source of material is caused to flow from the source of material and into the tube. With the control device and in response to the first signal, a third signal is sent to the source of power to supply power to a heater disposed relative to the tube to heat the tube. Material from the source of material is heated in the tube with the heater to a vaporization temperature such that the material volatilizes and expands out of an open end of the tube.

BRIEF DESCRIPTION OF THE DRAWINGS

The features and advantages of the present invention are well understood by reading the following detailed description in conjunction with the drawings in which like numerals indicate similar elements and in which:

FIG. **1** is a schematic, partially broken, side view of an aerosol generator according to an embodiment of the present invention;

FIG. **2** is a logic diagram of powered components of an aerosol generator according to an embodiment of the present invention;

FIG. **3** is a schematic, partially broken, side view of an aerosol generator according to a second embodiment of the present invention;

FIG. **4** is a schematic, partially broken, side view of an aerosol generator according to a third embodiment of the present invention;

FIG. **5** is a schematic, partially broken, side view of an aerosol generator according to a fourth embodiment of the present invention;

FIGS. **6**A–**6**C show steps according to a method, according to a further aspect of the present invention, of manufacturing an aerosol generator according to the fifth embodiment of the present invention.

DETAILED DESCRIPTION

An aerosol generator **21** according to the present invention is shown in FIG. **1**. The principles of operation of the aerosol generator **21** and, where applicable, materials used in the aerosol generator are preferably similar to the principles of operation and materials used in the aerosol generator disclosed in U.S. Pat. No. 5,743,251, which is hereby incorporated by reference in its entirety.

A preferred application for the aerosol generator **21** is as an inhaler device, such as an inhaler for medicaments, such as asthma medication and pain killers. The aerosol generator **21** preferably includes a first component **23**, which preferably includes, for example, the material to be turned into an aerosol and which is preferably disposable after one or a predetermined plurality of uses, removably attached to a second component **25**, which preferably includes, for example, power source and logic circuitry structures and which is preferably permanent in the sense that it is reusable with successive ones of the first components. The first and second components **23** and **25** can be attachable to one another in end to end or side by side relationships. If desired or necessary, however, the aerosol generator can be a one-piece device.

The first component **23** preferably includes a tube **27** having a first and a second end **29**, **31**, and a heater **33** arranged relative to the tube for heating the tube. A valve **35** is provided either on the tube **27** or between the second end **31** of the tube and a source **37** of material, the valve preferably being openable and closeable to open and close communication between the first end **29** of the tube and the source of material. The valve **35** may define the second end **31** of the tube. The valve **35** is preferably electronically openable and closeable, preferably a solenoid-type valve. The first component **23** preferably further includes the source **37** of material to be volatilized. The first component **23** preferably also includes a pressurization arrangement **39** for causing material in the source **37** of material to be introduced into the tube **27** from the source of material when the valve **35** is in an open position.

The second component **25** is preferably attachable and detachable to the first component **23** and includes a source **41** of power for the heater **33** and for the valve **35**, and a control device **43**, such as a microchip, for controlling supply of power from the source of power to the heater and the valve. The source **41** of power is preferably a battery, more preferably a rechargeable battery, however, the source of power may, if desired or necessary, be a non-depleting source of power, such as a conventional power line. International Publication No. WO 98/17131 discloses a power controller and a method of operating an electrical smoking system that discloses a power source and a control device, particularly for heaters, the principles of operation and features of which are transferrable to the present invention, and is hereby incorporated by reference.

General operation of the aerosol generator **21** involves a user providing a signal, such as by compressing a button or performing some other action such as inhaling near the first end **29** of the tube **27** to actuate a flow sensing detector or a pressure drop sensing detector, which is received by the control device **43**. In response to the signal, the control device **43** preferably controls the supply of power from the power source **41** such that the valve **35** is opened and power is supplied to the heater **33** to cause it to heat up to its desired operating temperature. It may be desired or necessary, depending upon the application and the equipment employed, to open the valve **35** before or after supplying power to the heater **33**.

Upon opening the valve **35**, the pressurization arrangement **39** causes material in the source **37** of material to be introduced into the tube **27**. The material in the tube **27** is heated to a vaporization temperature in the tube, volatilizes, and expands out of the free first end **29** of the tube. Upon exiting the tube **27**, the volatilized material contacts cooler air and condenses to form an aerosol. Preferably, after a predetermined period of time, the control device **43** automatically closes the valve **35** and shuts off the supply of power to the heater **33**. After one or a plurality of uses, the first component **23** is preferably separated from the second component **25** and is disposed of, and a new first component is attached to the second component for further use.

Because presently preferred applications for the aerosol generator **21** include use as an inhaler, the aerosol generator is preferably as small as possible. The valve **35** is preferably a microvalve. More preferably, the valve **35**, the heater **33**, and the tube **27** are a single micoelectronic machine formed on a single chip. To the extent that other components of the aerosol generator **21** disclosed in the present application are subject to production as microelectronic devices, they may also be formed on a single chip with the valve **35**, the heater **33**, and the tube **27**, or on another chip.

According to the preferred embodiment, the source **37** of material includes a flexible container **45**, and the pressurization arrangement **39** includes a chamber **47** in which the flexible container is disposed. A pressurized gas G is preferably sealed in the chamber **47** and surrounds the flexible container **45**. The pressurization arrangement **39** is prefer-

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ably a so-called sepra container of the type used for dispensing, for example, gel shaving creams, caulking compounds, and depilatories, although other pressurization arrangements for delivering the material, such as propellants and manual or automatic pumps, may be used if desired or necessary. The sepra container pressurization system is particularly preferred, however, particularly due to its capacity for resistance to surrounding temperature variations, as well as to variations in pressure of the gas G because the gas is not depleted. When it is desired to dispense material from the source **37** of material, and the valve **35** is opened, the pressure of the gas G, which is preferably about two atmospheres (about 30 psi) greater than ambient pressure, compresses the flexible container **45**, causing material to enter the tube **27** through the second end **31** of the tube in communication with the source of material. A preferred gas G is nitrogen because of its ready availability and comparatively low cost, although various other gases are also suitable and may be preferred for particular applications.

Displacement of material from the flexible container **45** means that there is more room in the chamber **47**, which means that the gas G enclosed in the chamber occupies a greater volume. Preferably, the size of the flexible container **45** relative to the size of the chamber **47** is selected such that pressure of the gas G is about ten percent lower when the flexible container is empty than when the flexible container is full.

A pressure sensor **48** may be provided to sense the pressure of the gas G in the chamber **47**. As seen in FIG. **2**, the pressure sensor **48** is preferably arranged to send a signal representative of the pressure in the chamber **47** to the control device **43**. The control device **43**, in turn, is preferably arranged to control the power source **41** to adjust a length of time that power is supplied to the valve **35**, and if desired or necessary, to the heater **33**, in response to the signal from the pressure sensor. In this way, pressure drops in the chamber **47**, which may result in a decrease in the rate at which material in the flexible container **45** is dispensed, can be compensated for by dispensing material for somewhat longer periods of time, i.e., by keeping the valve **35** open longer and, if desired or necessary, maintaining a supply of power to the heater **33**.

A signal to the control device **43** to supply power to the valve **35** and the heater **33** and, where provided, other features of the aerosol generator **21**, is preferably provided by a user of the aerosol generator. While the signal may be provided by, for example, pressing a button, turning a knob, or switching a switch, a preferred arrangement for providing a signal is based on a user causing some manner of air flow in the proximity of the free first end **29** of the tube **27**, such as by inhaling on a mouthpiece section **49** of the aerosol generator. The aerosol generator **21** preferably includes an air flow detecting device **51** for determining when a predetermined air flow rate exists proximate the first end **29** of the tube **27**. The air flow detecting device **51** is preferably arranged to send a signal to the control device **43** to indicate that the predetermined air flow rate exists, which may be indicative that a user is drawing on the open end **53** of the mouthpiece **49** section, and the controller is preferably arranged to control the power source to supply power to the valve **35** and the heater **33**, and any other components, in response to the signal from the air flow detecting device. As seen in FIG. **1**, the air flow detecting device **51** is preferably disposed transversely to and upstream of the first end **29** of the tube **27** so that the air flow detecting device will assist in ensuring that an adequate supply of air flow exists to produce and effectively deliver an aerosol from the volatilized material as it expands out of the first end of the tube.

Where the aerosol generator **21** is a multi-piece device, the air flow detecting device **51** is preferably permanently attached to the second component **25** and is, thus, preferably a permanent component, i.e., it is not disposed of. If desired or necessary, however, the air flow detecting device **51** can be a disposable component forming part of the first component **23** and can be removably connected, such as through an electrical connection, to the control device **43**.

The mouthpiece section **49** preferably has an open end **53**. The tube **27** is preferably disposed in the mouthpiece section **49** and the first end **29** of the tube is preferably disposed inside of the mouthpiece section at a distance from the open end **53** to permit complete mixing of volatilized material expanding out of the first end of the tube with surrounding air to form an aerosol. To ensure an adequate supply of air for mixing with the volatilized material, as well as to ensure an adequate supply of air for permitting a user to draw on the mouthpiece section and actuate the air flow detecting device **51**, the mouthpiece section **49** preferably has a plurality of vent holes **55**. To facilitate the flow of air past the first end **29** of the tube **27** and thereby facilitate formation of an aerosol, the first end of the tube is preferably disposed in the mouthpiece section **49** between the vent holes **55** and the open end **53** of the mouthpiece section. The vent holes **55** are preferably located relative to the tube **27**, preferably close to the end **29**, such that air passing through the vent holes has no or minimal cooling effect on the tube. The tube **27** may, of course, be insulated from air flowing through the vent holes **55**, such as by providing insulation material or a concentric tube **56** (shown in phantom) or the like around the tube to channel air away from the tube.

As an alternative to, or in addition to, using an air flow detecting device **51** to send a signal to the control device **43**, as seen in FIG. **2** in phantom, a pressure drop detecting device **57** for determining when a predetermined pressure drop occurs proximate the first end **29** of the tube **27** may be used. The pressure drop detecting device **57** is preferably arranged to send a signal to the control device **43** to indicate that the predetermined pressure drop is occurring, which may be indicative of a user drawing on the open end **53** of the mouthpiece section **49**, and the control device is arranged to control the power source **41** to supply power to the valve **35** and the heater **33**, and any other electrically powered components, in response to the signal from the pressure drop detecting device.

A suitable pressure drop detecting device is a puff-actuated sensor in the form of a Model 163PC01D35 silicon sensor, manufactured by MicroSwitch division of Honeywell, Inc., Freeport, Ill., or an SLP004D 0-4" H_2O Basic Sensor Element, manufactured by SenSym, Inc., Milpitas, Calif. Other known flow-sensing devices, such as those using hot-wire anemometry principles, are also believed to be suited for use with the aerosol generator **21**. The use of an air flow detecting device **51**, as compared to a pressure drop detecting device, is presently preferred for inhaler-type applications because it is anticipated that an air flow detecting device will be easier for users to actuate as compared to a pressure drop detecting device.

Presently anticipated applications for the aerosol generating device **21** include drug delivery applications. For such applications, as well as in other applications to which the aerosol generating device **21** might be applied, the control device **43** may include a timer **59** for controlling a frequency with which the control device controls the power supply **41** to supply power to the valve **35** and the heater **33** and other components. In this way, the aerosol generating device **21** can automatically limit the frequency with which a user can

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operate the aerosol generating device, thereby facilitating in preventing accidental misuse and overdosages. Moreover, to assist caregivers in treating their patients, the aerosol generator **21** can be associated with a remote control device **61** remote from the control device **43**. The remote control device **61** is preferably capable of adjusting the timer **59** to adjust the frequency with which the control device **43** controls the power supply **41** to supply power to the valve **35** and the heater **33**, and other components. In this way, when a caregiver desires to increase or decrease the frequency with which the user is able to operate the aerosol generator, the caregiver can do so in situations where the caregiver and the user are separated by some distance. In this way, users who might otherwise be required to personally see their caregivers to have their treatment schedules adjusted have greater mobility.

The control device **43** and, if provided, the remote control device **61**, may also be configured to permit adjustment or remote adjustment of other powered components of the aerosol generator **21**, such as the length of time that the valve **35** is open, and the length of time that power is supplied to the heater from the power source **41**. In this manner, it is possible to adjust dosages up or down, as well as to adjust operating conditions of the aerosol generator **21** to maintain the same operation where, for example, pressure of the gas G in the chamber **47** drops or the rate at which power is supplied from the power source **41** reduces, such as where the aerosol generator is used in different temperatures, material in the flexible container **45** is used up, or the charge of a battery forming the power source diminishes.

The timer **59** of the control device preferably is associated with an indicator **63**, such as a beeper or light forming part of the timer or, for example, electrically connected to the timer, for indicating that the control device **43** is available to control the power supply **41** to supply power to the valve **35** and the heater **33** and other components. Where, for example, the aerosol generator **21** is used to dispense medication, the indicator **63** serves to remind the user that it is time for the medication. The indicator **63** may also, if desired or necessary, be operable by the remote control device **61**. The indicator **63** may also be used to indicate to a user a length of time since the aerosol generator **21** was actuated, such as where the aerosol generator is used as an inhaler, and the user is supposed to hold his or her breath for a length of time after inhaling, with the indicator **63** indicating when a period of time has elapsed.

The aerosol generator **21** may also include a display device **65**, such as an LCD display, for displaying information such as a number of times that the control device **43** controls the power supply **41** to supply power to the valve and the heater. The display device **65** may display, for example, a number of times that the aerosol generator **21** has been operated, e.g., 1 or 2 or 3, or a number of operations remaining, which may be based on, for example, the size of the source **37** of material and the amount of material dispensed each time that the valve **35** is opened and closed, or the life of the power supply **41**, such as the remaining life of a battery. The same or additional display devices can be provided to display other information, such as pressure in the pressure chamber **47** and power level of the power source **41**. Further, the aerosol generator **21** may be equipped with various sensors and displays to provide feedback to be displayed in a display device **65** to, for example, assist a user in learning how to use the aerosol generator properly as an inhaler, such as sensors to measure the volume and duration of an inhalation after completion of an inhalation, and even to provide feedback during an inhalation to assist the user in employing an optimum inhalation profile. The display device **65** is preferably controlled by the control device **43** and powered by the power supply **41**.

The control device **43** may be individually programmable, such as by a pharmacist, to control the aerosol generator **21** to dispense medications according to a prescription, i.e., quantity of medication, frequency, etc., as well as programming in the information that would prevent improper use of the aerosol generator. In this manner, fewer types of aerosol generators **21** may be useful for a wide range of medications. The particular aerosol generator **21** would preferably be optimized for different classes of medications and then "fine tuned" by, for example, the pharmacist, for a specific drug or prescription.

The aerosol generator **21** may also be programmed to permanently prevent use after a set period of time. In this way, it would be possible to prevent the use of expired medications. This may be accomplished by, for example, having a battery power source **41** be non-replaceable, or by incorporating a battery and/or control device that keeps track of date and time and prevents operation past a particular date and time.

While not wishing to be bound by theory, depending upon selection of factors presently understood to primarily include a rate of power supplied from the source of power **41** to the heater **33**, a diameter of the tube **27**, and the material to be volatilized and delivered as an aerosol, the aerosol generator **21** is preferably specifically designed to generate an aerosol having certain desired characteristics. For many applications, particularly for medication delivery applications, the aerosol generator **21** according to the present invention is preferably designed to produce an aerosol having a mass median particle diameter of less than 3 microns, more preferably less than 2 microns, still more preferably between 0.2 and 2 microns, and still more preferably between 0.5 and 1 microns. While not wishing to be bound by theory, depending upon selection of factors presently understood to primarily include a length of the tube **27**, a pressure with which the pressurization arrangement **39** supplies the material from the source **37** of material, and a rate at which power is supplied from the source **41** of power, the rate at which the material is supplied and volatilized in the tube is established. The aerosol generator **21** is preferably designed to supply and volatilize material at a rate greater than 1 milligram per second.

It may be desirable to produce an aerosol formed from different liquid components that, for a variety of reasons, may be best kept separated until the moment that it is desired to form the aerosol. As seen in FIG. **3**, another embodiment of the aerosol generator **121** may, in addition to the features described with respect to the aerosol generator **21**, include, preferably as part of a modified first component **123**, a source **137** of a second material in liquid form that is supplied to the tube **27** together with the material from the first source of material **37**. The source **137** of second material preferably communicates with the tube **27** at a point **171** before the heater **33**. A separate valve **135** is preferably powered by the power source **41** and controlled by the control device **43** to permit the pressurization arrangement **39** to cause material in the source **137** of second material to be introduced into tube **27** from the source of second material when the valve **35** is in an open position. If desired or necessary, the valve **35** and the valve **135** can be opened and closed at different times.

The source **137** of second material preferably includes a second flexible container **145**. The pressurization arrange-

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ment **39** preferably includes a second chamber **147** in which the second flexible container **145** is disposed, and a second pressurized gas G_2 sealed in the second chamber and surrounding the second flexible container. The pressurized gas G and the second pressurized gas G_2 may be pressurized to different pressures to facilitate delivery of the material and the second material to the tube **27** at different rates. If desired or necessary, the flexible container **45** and the second flexible container **145** may be disposed in the same pressurized chamber. Additional sources of material and other components may be provided to produce an aerosol having still further components.

As seen with respect to FIG. **4**, a third embodiment of the aerosol generator **221** may include, preferably as part of a modified first component **223**, a structure, or several structures, that is substantially entirely parallel to the structure of the first component to permit generation of an aerosol formed from two or more components. The aerosol generator **221** preferably includes a second tube **227** having a first and a second end **229**, **231**. A second heater **233** is preferably arranged relative to the second tube **227** for heating the second tube. A second valve **235** is preferably provided on the second tube **227** and is openable and closeable to open and close communication between the first and the second ends **229** and **231** of the second tube. A source **237** of second material to be volatilized is provided and the second end **231** of the second tube **227** communicates with the source of second material. A second pressurization arrangement **239** is provided for causing material in the source **237** of second material to be introduced into the second tube **227** from the source of second material when the second valve **235** is in an open position. If desired or necessary, the pressurization arrangement **39** can be used to cause material in the source **237** of second material to be introduced into the second tube **227**. Preferably, the source **41** of power supplies power for the second heater **233** and for the second valve **235**, as well as to any other electrically powered components of the aerosol generator, and the control device **43** controls supply of power from the source of power to the second heater and the second valve.

The aerosol generator **221** preferably includes a chamber **249**, such as a mouthpiece section. The first ends **29** and **229** of the tube **27** and the second tube **227** are preferably disposed in the chamber **249** proximate each other. The chamber **249** is preferably of sufficient size and configuration to permit mixture of volatilized material and volatilized second material that expands out of the tube **27** and the second tube **227** together with ambient air such that the volatilized material and the volatilized second material form first and second aerosols, respectively, the first and second aerosols being mixed with each other to form a combination aerosol including the first and second aerosols.

In the embodiment described with reference to FIG. **1**, a combination aerosol can be formed by providing material in the source **37** of material that includes two or more components mixed together before the material is volatilized. While the components in the source **37** of material may be two or more liquids, it is also possible to suspend solid particles in solution in a liquid material, or to dissolve solid particles in a liquid material. If desired or necessary, the solid particles, when suspended in solution, may be of a larger average diameter than particles of the material in aerosol form. The solid particles, when they form a part of the aerosol, may be of a larger average diameter than particles of the material in aerosol form. Solid particles can, of course, also be suspended in solution in liquid materials in the embodiments described with reference to FIGS. **3** and **4**.

As noted, a preferred pressurization arrangement **39** for the aerosol generator **21** includes a sepra container type of arrangement. An aerosol generator **321** having an alternative pressurization arrangement **339** is shown in FIG. **5**. In this embodiment, the source **337** of material preferably includes a second tube **345** having first and second ends **345***a*, **345***b*. The first end **345***a* of the second tube **345** is connected to the second end **31** of the tube **27**. The pressurization arrangement **339** includes a chamber **347** filled with a pressurized gas G. The second end **345***b* of the second tube **345** is disposed in the chamber **347** and is open to the chamber. The source **337** of material, the second tube **345**, and the tube **27** preferably form part of a modified first component **323**.

As seen in FIGS. **6A–6C**, the source **337** of material is preferably filled with material by first opening the valve **35** in the tube **27**, then immersing the open second end **345***b* of the second tube **345** in liquid material L (FIG. **6A**). After the liquid material in which the second tube **345** is immersed fills the second tube, the valve **35** is then shut. The second tube **345** is withdrawn from the liquid material, with the liquid material that filled the second tube remaining in the second tube due to closure of the valve (FIG. **6B**), i.e., air is unable to get behind the liquid material in the second tube. The second tube **345** is then positioned in the chamber **347** and the chamber is pressurized (FIG. **6C**). When the valve **35** is opened, the pressure in the chamber forces the liquid material in the second tube **345** to enter the tube **27** where it can be volatilized by the heater **27**.

In a method of making the aerosol generator **21** described with reference to the embodiment shown in FIG. **1**, the heater **33** is arranged relative to the tube **27** to permit heating of the tube. The second end **31** of the tube **27** is connected to the source **37** of material to be volatilized. The openable and closeable valve **35** is provided to allow and stop communication between the source **37** of material and the tube **27**.

The pressurization arrangement **39** for causing material in the source **37** of material to be introduced into the tube **27** from the source of material when the valve **35** is in an open position is provided. The valve **35** is connected to the source **41** of power for opening and closing the valve. The heater **35** is connected to the source **41** of power. The source **41** of power is connected to the control device **43** for controlling the supply of power from the source of power to the heater **33** and the valve **35**, as well as to any other components of the aerosol generator.

The step of providing the pressurization arrangement **39** preferably includes positioning the source **37** of material in a chamber **47** and pressurizing the chamber, preferably to about two atmospheres. The source **37** of material preferably includes a flexible container **45**. However, other embodiments are also possible. For example, as described with reference to FIGS. **5** and **6A–6B**, the source **337** of material may include a second tube **345** having first and second ends **345***a*, **345***b*, the first end of the second tube being connected to the second end **31** of the tube **27** and the second end **345***b* of the second tube being positioned in the chamber **345**.

In making the aerosol generator **21** according to the present invention, it is particularly preferred that the heater **33**, the tube **27**, the valve **35**, the source **37** of material, and the pressurization arrangement **39** are arranged relative to each other to form a first component **23**, and that the source **41** of power and the control device **43** are arranged relative to each other to form a second component **25**, and that the second component is attachable to and detachable from the first component. In this way, the second component **25** can

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be made as a permanent device, with most or all of the more expensive features of the aerosol generator being associated with the second component, and the first component **23**, which preferably includes the depletable or less expensive components of the aerosol generator, can be disposable. The different features of the aerosol generator **21** can be provided on whichever one of the components **23** and **25** seems appropriate for a particular application. However, according to the presently envisioned preferred application of the aerosol generator as a medical inhaler device, it is believed that the arrangement of features on the components **23** and **25** properly distributes the more and less disposable features.

The aerosol generator **21** is preferably used by a user providing a first signal, indicative of a user's intention to use the aerosol generator, to the control device **43**. The first signal may be provided by the user pressing a button **58** (FIG. **2**, in phantom) but, particularly where the aerosol generator **21** is intended to be used as an inhaler device, it is preferred that the first signal be provided by some form of draw-actuated device, such as a pressure drop detecting sensor **53** or, more preferably, an air flow detecting sensor **51**.

The control device **43**, in response to the first signal, sends a second signal to the source of power **41** to cause the source of power to open the openable and closeable valve **35**. The valve **35** is preferably disposed between the tube **27** and the source **37** of material. Opening of the valve **35** permits material from the source **37** of material to flow from the source of material and into the tube **27**.

Material from the source **37** of material is caused to flow from the source of material and into the tube **27**, preferably by means of the pressurization arrangement. The source **37** of material preferably includes the flexible container **45**, and material in container is caused to flow from the source of material by a pressurization arrangement **39**. The pressurization arrangement **39** preferably includes the chamber **47** filled with gas G under pressure and in which the flexible container **45** is disposed. In an alternative embodiment, as described with reference to FIGS. **5** and **6**A–**6**C, the source **337** of material includes the second tube **345** having first and second ends **345***a*, **345***b*. The first end **345***a* of the second tube **345** is connected to the second end **31** of the tube **27**, and material in the source **337** of material is caused to flow from the source of material by the pressurization arrangement **339**. The pressurization arrangement **339** includes a chamber **347** filled with gas G under pressure and in which the second end **345***b* of the second tube **345** is disposed.

A third signal is sent by the control device **43** and in response to the first signal to the source **41** of power to supply power to the heater **33** disposed relative to the tube **27** to heat the tube. Material from the source **37** of material is heated in the tube **27** with the heater **35** to a vaporization temperature such that the material volatilizes and expands out of the first end **29** of the tube.

The aerosol generator according to the present invention is preferably constructed in accordance with certain design principles that the inventors have recognized. These design relationships permit design of the aerosol generator with a certain robustness, particularly with respect to ambient temperature and container pressure variations, such that it is possible to ensure that the rate of aerosol delivery is substantially constant. While not wishing to be bound by theory, one relationship involves the rate at which aerosol is delivered (D), which is understood to be substantially linearly related to the power delivered to the liquid to be volatilized, i.e., the power (P), according to the relationship: $D=k_1P$, where k_1 is substantially constant and depends upon design factors peculiar to the particular aerosol generator.

While not wishing to be bound by theory, the amount of aerosol delivered (d), or the aerosol delivery rate D multiplied by the time that the aerosol is delivered, is understood to be substantially linearly related to the pressure drop (p) of the liquid material through the tube **27**, which is usually the difference between whatever pressure at which the liquid is maintained in the source **37** of material (e.g., container pressure) and atmospheric pressure, and substantially linearly related to the inverse of the length (L) of the tube from the beginning of the tube to the point PV along the tube where the liquid material has completely volatilized, according to the relationship: $D=k_2p/L$, where k_2 is substantially constant and, like k_1, depends upon factors peculiar to the particular aerosol generator.

Further to the foregoing relationships, and while not wishing to be bound by theory, the value L will tend to increase with increasing pressure drop p or, conversely, decreases with decreasing pressure drop p. Accordingly, the capillary aerosol generator tends to maintain delivery rate D despite changes in p, which might result from, for example, changes in ambient temperature or pressure or container pressure or other causes, at least over a usable range.

The aerosol generator **21** according to the present invention is preferably designed according to the relationships discovered by the inventors. For example, while not wishing to be bound by theory, when a desired delivery amount and a delivery rate are known beforehand, such as where the aerosol generator **21** is to be used as an inhaler for predetermined dosages of medication, a designer can provide an appropriately sized battery as the power source **41** and can allow for a certain pressure drop of the gas G in the chamber **47** as material is depleted from the container **45** and still be certain that the desired delivery amount is achieved. If the pressure is too low, the consequence will be too low a delivery rate. If the pressure is too high, the consequence is that material emerges from the tube **27** as a liquid.

According to one potential sequence of events in a design process, and while not wishing to be bound by theory, the pressure drop p of the material prior to complete volatilization is a function of factors such as the diameter of the tube **27**, and the nature of the material to be volatilized. Changing tube diameter can affect where the point P_v occurs, i.e., affect the the length L. If it is desired to have a tube with a certain length, and to accommodate changes in battery power, e.g., due to the battery losing its charge, and changes in pressure of the gas G, the length of the tube **27** can be designed with certain factors of safety in view of calculations for the length L involving different tube diameters that affect the pressure drop p. Similarly, if it is known that a particular battery loses a charge at a certain predetermined rate, the length of the tube **27** can be selected to ensure that volatilization of the material occurs in the tube at all intended operating levels of the battery.

According to another potential sequence of events in a design process, and while not wishing to be bound by theory, for a given delivery rate D, tube diameter d should be chosen taking into account the effect of tube diameter upon particle size. Tube length and the pressure in the container should then be adjusted to ensure that P_v occurs prior to the first end **29** of the tube **27**, particularly in view of the likelihood of some variation in container pressure p.

Moreover, the control device **43** can be programmed to ensure that, as the pressure of the gas G drops, or the power

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level of the source **41** of power drops, certain changes in operation to accommodate these changes will take place. For example, as power levels drop, delivery of the same amount of material will take a longer time. Accordingly, the control device **43** can be programmed to, for example, keep the valve **35** open for a longer time as drops in power levels are detected.

While this invention has been illustrated and described in accordance with a preferred embodiment, it is recognized that variations and changes may be made therein without departing from the invention as set forth in the claims. For instance, the aerosol generator could include arrangements for manually operating the valve **35**, i.e., instead of actuation by detection of air flow or pressure drop, with the controller **43** being configured to execute a scheduled heating cycle upon receipt of a signal indicating actuation of the valve. Such arrangements might further include devices (electrical or mechanical) to maintain the valve **35** in an opened position for a predetermined amount of time once it is mechanically actuated.

What is claimed is:

1. An aerosol generator, comprising:

a tube having a first and a second end;

a heater arranged relative to the tube for heating at least a portion of the tube;

a source of material to be volatilized, the second end of the tube being in communication with the source of material;

a valve operatively located between the source of material and the tube, the valve being openable and closeable to open and close communication between the source and the first end of the tube;

a pressurization arrangement for causing material in the source of material to be introduced into the tube from the source of material when the valve is in an open position;

a source of power for operating the heater and for the valve; and

a control device for controlling supply of power from the source of power to the heater and the valve.

2. The aerosol generator as set forth in claim **1**, wherein the source of material includes a flexible container, and the pressurization arrangement includes a chamber in which the flexible container is disposed, and a pressurized gas sealed in the chamber and surrounding the flexible container.

3. The aerosol generator as set forth in claim **2**, wherein the gas is nitrogen.

4. The aerosol generator as set forth in claim **2**, wherein the gas is pressurized to about 2 atmospheres.

5. The aerosol generator as set forth in claim **2**, wherein pressure of the gas is about ten percent lower when the flexible container is empty than when the flexible container is full.

6. The aerosol generator as set forth in claim **2**, further comprising a pressure sensor arranged to sense pressure in the chamber, the pressure sensor being arranged to send a signal representative of the pressure in the chamber to the control device, and the control device being arranged to control the power source to adjust a length of time that power is supplied to the valve in response to the signal from the pressure sensor.

7. The aerosol generator as set forth in claim **1**, further comprising an air flow detecting device for determining when a predetermined air flow rate exists proximate the first end of the tube, the air flow detecting device being arranged to send a signal to the control device to indicate that the predetermined air flow rate exists, and the control device being arranged to control the power source to supply power to the valve and the heater in response to the signal from the air flow detecting device is disposed in a position transverse to and upstream of the first end of the tube.

8. The aerosol generator as set forth in claim **7**, wherein the air flow detecting device includes a flow sensor.

9. The aerosol generator as set forth in claim **7**, further comprising a mouthpiece section, the mouthpiece section having an open end, the tube being disposed in the mouthpiece section and the first end of the tube being disposed inside of the mouthpiece section at a distance from the open end.

10. The aerosol generator as set forth in claim **9**, wherein the mouthpiece section has a plurality of vent holes.

11. The aerosol generator as set forth in claim **10**, wherein the first end of the tube is disposed in the mouthpiece section between the vent holes and the open end of the mouthpiece.

12. The aerosol generator as set forth in claim **1**, further comprising a pressure drop detecting device for determining when a predetermined pressure drop occurs proximate the first end of the tube, the pressure drop detecting device being arranged to send a signal to the control device to indicate that the predetermined pressure drop is occurring, and the control device being arranged to control the power source to supply power to the valve and the heater in response to the signal from the pressure drop detecting device.

13. The aerosol generator as set forth in claim **12**, further comprising a mouthpiece section, the mouthpiece section having an open end, the tube being disposed in the mouthpiece section and the first end of the tube being disposed inside of the mouthpiece section at a distance from the open end.

14. The aerosol generator as set forth in claim **1**, wherein the control device includes a timer for controlling a frequency with which the control device controls the power supply to supply power to the valve and the heater.

15. The aerosol generator as set forth in claim **14**, further comprising a remote control device remote from the control device, the remote control device being adapted to adjust the timer to adjust the frequency with which the control device controls the power supply to supply power to the valve and the heater.

16. The aerosol generator as set forth in claim **14**, wherein the timer includes an indicator for indicating that the control device is available to control the power supply to supply power to the valve and the heater.

17. The aerosol generator as set forth in claim **1**, further comprising a display device, the display device being controlled by the control device and being adapted to display a number of times that the control device controls the power supply to supply power to the valve and the heater.

18. The aerosol generator as set forth in claim **17**, wherein the control device includes a timer for controlling a frequency with which the control device controls the power supply to supply power to the valve and the heater.

19. The aerosol generator as set forth in claim **18**, further comprising a remote control device remote from the control device, the remote control device being adapted to adjust the timer to adjust the frequency with which the control device controls the power supply to supply power to the valve and the heater.

20. The aerosol generator as set forth in claim **18**, wherein the display indicates when the timer will permit the control device to control the power supply to supply power to the valve and the heater.

21. The aerosol generator as set forth in claim **1**, wherein the control device is arranged to permit adjustment of at least

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one of an amount of time that the valve is in an open condition and an amount of time that power is supplied to the heater.

22. The aerosol generator as set forth in claim **21**, further comprising a remote control device remote from the control device, the remote control device being adapted to adjust at least one of the amount of time that the valve is in an open condition and the amount of time that power is supplied to the heater.

23. The aerosol generator as set forth in claim **22**, wherein the control device includes a timer for controlling a frequency with which the control device controls the power supply to supply power to the valve and the heater.

24. The aerosol generator as set forth in claim **23**, wherein the remote control device is adapted to adjust the timer to adjust the frequency with which the control device controls the power supply to supply power to the valve and the heater.

25. The aerosol generator as set forth in claim **1**, wherein a rate of power supplied from the source of power to the heater and a diameter of the tube are selected to cause the aerosol generator to produce an aerosol having a mass median particle diameter of less than 3 microns.

26. The aerosol generator as set forth in claim **25**, wherein the aerosol has a mass median particle diameter of less than 2 microns.

27. The aerosol generator as set forth in claim **25**, wherein the aerosol has a mass median particle diameter of between 0.2 and 2 microns.

28. The aerosol generator as set forth in claim **25**, wherein the aerosol has a mass median particle diameter between 0.5 and 1 microns.

29. The aerosol generator as set forth in claim **1**, wherein a length of the tube, a pressure with which the pressurization arrangement supplies the material from the source of material, and a rate at which power is supplied from the source of power are selected so that the material is supplied and volatilized in the tube at a rate greater than 1 milligram per second.

30. The aerosol generator as set forth in claim **1**, further comprising a source of a second material in liquid form to the tube together with the material, the source of second material communicating with the tube at a point before the heater, the pressurization arrangement causing material in the source of second material to be introduced into the tube from the source of material when the valve is in an open position.

31. The aerosol generator as set forth in claim **30**, wherein the source of material includes a flexible container and the source of second material includes a second flexible container, and the pressurization arrangement includes a chamber in which the flexible container is disposed, and a pressurized gas sealed in the chamber and surrounding the flexible container, and a second chamber in which the second flexible container is disposed, and a second pressurized gas sealed in the chamber and surrounding the second flexible container.

32. The aerosol generator as set forth in claim **31**, wherein the pressurized gas and the second pressurized gas are pressurized to different pressures.

33. The aerosol generator as set forth in claim **1**, further comprising

a second tube having a first and a second end,

a second heater arranged relative to the second tube for heating at least a portion of the second tube,

a source of second material to be volatilized, the second end of the second tube being in communication with the source of second material, and

a second valve operatively located between the source of second material and the second tube, the second valve being openable and closeable to open and close communication between the source of second material and the first end of the second tube,

a second pressurization arrangement for causing material in the source of second material to be introduced into the second tube from the source of second material when the second valve is in an open position, and

wherein the source of power supplies power for operating the second heater and the second valve, and the control device controls supply of power from the source of power to the second heater and the second valve.

34. The aerosol generator as set forth in claim **33**, further comprising a chamber, the first ends of the tube and the second tube being disposed in the chamber proximate each other, the chamber being of sufficient size and configuration to permit mixture of volatilized material and volatilized second material that expands out of the tube and the second tube together with ambient air such that the volatilized material and the volatilized second material form first and second aerosols, respectively, the first and second aerosols being mixed with each other to form a combination aerosol including the first and second aerosols.

35. The aerosol generator as set forth in claim **1**, wherein material in the source of material includes two or more components mixed together before the material is volatilized.

36. The aerosol generator as set forth in claim **35**, wherein solid particles are suspended in solution in the material.

37. The aerosol generator as set forth in claim **36**, wherein the solid particles, when suspended in solution, are of a larger average diameter than particles of the material after the material is volatilized and is in aerosol form.

38. The aerosol generator as set forth in claim **37**, wherein the solid particles, when they form a part of the aerosol, are of a larger average diameter than particles of the material after the material is volatilized and is in aerosol form.

39. The aerosol generator as set forth in claim **36**, wherein the solid particles, when they form a part of the aerosol, are of a larger average diameter than particles of the material after the material is volatilized and is in aerosol form.

40. The aerosol generator as set forth in claim **1**, wherein the valve is a microvalve.

41. The aerosol generator as set forth in claim **1**, wherein the valve, the heater, and the tube are a single microelectronic machine formed on a single chip.

42. The aerosol generator as set forth in claim **1**, wherein the aerosol generator includes a first component and a second component, the second component being attachable and detachable to the first component, the first component including the tube, the heater, the valve, the source of material, and the pressurization arrangement, and the second component including the source of power and the control device.

43. The aerosol generator as set forth in claim **42**, further comprising an air flow detecting device for determining when a predetermined air flow rate exists proximate the first end of the tube, the air flow detecting device being arranged to send a signal to the controller to indicate that the predetermined air flow rate exists, and the controller being arranged to control the power source to supply power to the valve and the heater in response to the signal from the air flow detecting device.

44. The aerosol generator as set forth in claim **43**, wherein the air flow detecting device is permanently attached to the second component.

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45. The aerosol generator as set forth in claim 43, further comprising a mouthpiece section forming part of the first component, the mouthpiece section having an open end, the tube being disposed in the mouthpiece section and the first end of the tube being disposed inside of the mouthpiece section at a distance from the open end.

46. The aerosol generator as set forth in claim 45, wherein the mouthpiece section has a plurality of vent holes.

47. The aerosol generator as set forth in claim 45, wherein the first end of the tube is disposed in the mouthpiece section between the vent holes and the open end of the mouthpiece.

48. The aerosol generator as set forth in claim 42, further comprising a pressure drop detecting device for determining when a predetermined pressure drop occurs proximate the first end of the tube, the pressure drop detecting device being arranged to send a signal to the controller to indicate that the predetermined pressure drop is occurring, and the controller being arranged to control the power source to supply power to the valve and the heater in response to the signal from the pressure drop detecting device.

49. The aerosol generator as set forth in claim 48, further comprising a mouthpiece section forming part of the first component, the mouthpiece section having an open end, the tube being disposed in the mouthpiece section and the first end of the tube being disposed inside of the mouthpiece section at a distance from the open end.

50. The aerosol generator as set forth in claim 42, wherein the first component includes

a second tube having a first and a second end,

a second heater arranged relative to the second tube for heating the second tube,

a second valve operatively located between the source of second material and the second tube, the second valve being openable and closeable to open and close communication between the source of second material and the first end of the second tube,

a source of second material to be volatilized, the second end of the second tube being in communication with the source of second material, and

a second pressurization arrangement for causing material in the source of second material to be introduced into the second tube from the source of second material when the second valve is in an open position, and

wherein the source of power supplies power for operating the second heater and the second valve, and the control device controls supply of power from the source of power to the second heater and the second valve.

51. The aerosol generator as set forth in claim 50, further comprising a chamber, the first ends of the tube and the second tube being disposed in the chamber proximate each other, the chamber being of sufficient size and configuration to permit mixture of volatilized material and volatilized second material that expands out of the tube and the second tube together with ambient air such that the volatilized material and the volatilized second material form first and second aerosols, respectively, the first and second aerosols being mixed with each other to form a combination aerosol including the first and second aerosols.

52. The aerosol generator as set forth in claim 1, wherein the source of material includes a second tube having first and second ends, the first end of the second tube being connected to the second end of the tube, and wherein the pressurization arrangement includes a chamber filled with a pressurized gas, the second end of the second tube being disposed in the chamber.

53. A method of making an aerosol generator, comprising the steps of:

arranging a heater relative to a tube for heating of the tube, the tube having first and second ends;

connecting the second end of the tube to a source of material to be volatilized;

providing an openable and closeable valve between the source of material and the tube;

providing a pressurization arrangement for causing material in the source of material to be introduced into the tube from the source of material when the valve is in an open position;

connecting the valve to a source of power for opening and closing the valve;

connecting the heater to the source of power;

connecting the source of power to a control device for controlling a supply of power from the source of power to the heater and the valve.

54. The method as set forth in claim 53, wherein the step of providing a pressurization arrangement includes positioning of the source of material in a chamber and pressurizing the chamber.

55. The method as set forth in claim 54, wherein the chamber is pressurized to about two atmospheres.

56. The method as set forth in claim 54, wherein the source of material includes a flexible container.

57. The method as set forth in claim 54, wherein the source of material includes a second tube having first and second ends, the method comprising the further steps of connecting the first end of the second tube to the second end of the tube and positioning the second end of the second tube in the chamber.

58. The method as set forth in claim 53, wherein the source of power is selected such that it is adapted to deliver power at a sufficient rate to the heater and the tube is selected to have an appropriate diameter such that the aerosol generator produces an aerosol having a mass median particle diameter of less than 3 microns.

59. The method as set forth in claim 53, wherein a length of the tube, a pressure with which the pressurization arrangement supplies the material from the source of material, and a rate at which the source of power is adapted to supply power to the heater are selected so that the material is supplied and volatilized in the tube at a rate greater than 1 milligram per second.

60. The method as set forth in claim 53, wherein the heater, the tube, the valve, the source of material, and the pressurization arrangement are arranged relative to each other to form a first component, and the source of power and the control device are arranged relative to each other to form a second component, the second component being attachable and detachable to the first component.

61. A method of using an aerosol generator, comprising the steps of:

providing a first signal, indicative of a user's intention to use the aerosol generator, to a control device;

sending, with the control device and in response to the first signal, a second signal to a source of power to cause the source of power to open an openable and closeable valve, the valve being disposed between a source of material to be volatilized and a tube, opening of the valve permitting material from the source of material to flow from the source of material and into the tube;

causing material from the source of material to flow from the source of material and into the tube;

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sending, with the control device and in response to the first signal, a third signal to the source of power to supply power to a heater disposed relative to the tube to heat the tube; and

heating material from the source of material in the tube with the heater to a vaporization temperature such that the material volatilizes and expands out of an open end of the tube.

62. The method as set forth in claim **61**, wherein the first signal is provided by a user pressing a button.

63. The method as set forth in claim **61**, wherein the first signal is provided by a user drawing on a mouthpiece in such a manner as to operate an air flow detecting device disposed proximate the first end of the tube.

64. The method as set forth in claim **61**, wherein the first signal is provided by a user drawing on a mouthpiece in such a manner as to operate a puff actuated sensor disposed proximate the first end of the tube.

65. The method as set forth in claim **61**, wherein the source of material includes a flexible container, and wherein material in the source of material is caused to flow from the source of material by a pressurization arrangement.

66. The method as set forth in claim **65**, wherein the pressurization arrangement includes a chamber filled with gas under pressure and in which the flexible container is disposed.

67. The method as set forth in claim **61**, wherein the source of material includes a second tube having first and second ends, the first end of the second tube being connected to the second end of the tube, and wherein material in the source of material is caused to flow from the source of material by a pressurization arrangement.

68. The method as set forth in claim **67**, wherein the pressurization arrangement includes a chamber filled with gas under pressure and in which the second end of the second tube is disposed.

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UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 6,234,167 B1
DATED : May 22, 2001
INVENTOR(S) : Kenneth A. Cox et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Title page,
Item [56], **References Cited**, FOREIGN PATENT DOCUMENTS delete the references "EP 358114 issued 3/1990" and "EP 642802 issued 3/1995", first occurrence of each;

Column 12,
Line 13, delete "PV" and insert therefor -- P_v --;

Column 16, claim 43,
Line 60, delete "controller" and insert therefor -- control device --;

Column 17, claim 48,
Lines 17 and 18, delete "controller" and insert therefor -- control device --.

Signed and Sealed this

Sixteenth Day of April, 2002

Attest:

Attesting Officer

JAMES E. ROGAN
Director of the United States Patent and Trademark Office

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