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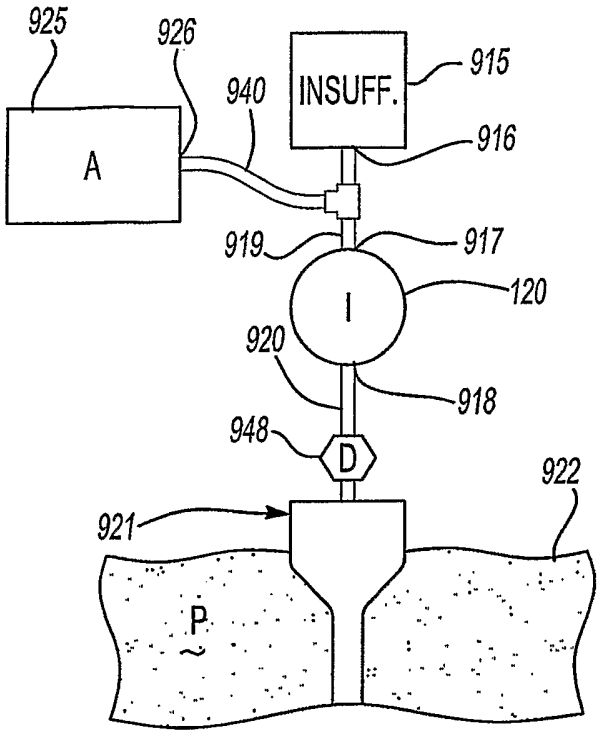
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(54) Title: METHOD AND APPARATUS FOR DELIVERING AN AGENT TO THE ABDOMEN



(57) Abstract: A method and apparatus for treating gas (915) for delivery into a body cavity, body space or body surface of an animal (P). The apparatus comprises a housing defining a chamber, an entry port and an exit port. One or more agents are released into the gas stream that flows through the chamber so that the gas stream carries the agent to the animal (P). Also, shown for use with or without, the chamber is an agent chamber (925) adapted to be coupled to at least one structure defining at least one fluid flow path (940) extending at least a portion of the distance between an insufflation device (915) and the body cavity, body space or body surface (P).

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TITLE

METHOD AND APPARATUS FOR DELIVERING AN AGENT TO THE ABDOMEN

BACKGROUND OF THE INVENTION

FIELD OF THE INVENTION

This invention relates to treating gases delivered into body cavities, spaces or body surfaces of an animal. More specifically, it relates to a device for, and method of, treating gases with one or more agents to be carried by the gas stream to an animal.

RELATED ART

The delivery of gas into the body of a patient is well known for many purposes. Gas is delivered into a body cavity, such as the abdomen, to distend a compliant surface or create pressure for a specific purpose. Distention of the abdomen using gas creates a pneumoperitoneum that achieves a space in which one can examine, repair, remove and surgically manipulate. The space created by gas insufflation is a basic component of laparoscopic surgery. Within the space of the body created by the gas flow and pressure, tissue surfaces and organs can be visualized safely and instruments placed that are used for diagnostic and therapeutic purposes. Examples of such uses include, but are not limited to, coagulation, incision, grasping, clamping, suturing, stapling, moving, retracting and morcelizing. The quality of the gas stream can be modified and conditioned by filtering, heating and hydrating. U.S. Patent No. 5,411,474 and the aforementioned U.S. patent application disclose methods for conditioning gas in this matter.

There is room for further improvement and advancement. During a procedure that instills gas to a body cavity, body space or body surface, the addition of pharmacologically active or inert materials (organic or inorganic) can enhance tissue healing, reduce infection, reduce adhesion formation, modify the immunologic response, treat neoplasm, treat specific disease processes, reduce pain and assist in diagnosis. It is desirable to provide an apparatus and method suitable for treating gas in such a manner.

SUMMARY OF INVENTION

Briefly, the present invention is directed to a method and apparatus for treating gas with one or more agents for delivery to a body cavity, body space or body surface. The gas is received into the apparatus from a gas source. The apparatus comprises a housing defining at least one chamber having an entry port and an exit port, the entry port for receiving a gas stream from a gas source. A quantity of one or more agents is released into the chamber to be admixed in the gas stream that is delivered to the animal by a delivery device. The gas stream is optionally humidified and/or heated in the housing.

The above and other objects and advantages of the present invention will become more readily apparent when reference is made to the following description taken in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a schematic view of an apparatus according to the present invention.

Figure 2 is a cross-sectional view of the gas treater of the apparatus according to the present invention.

Figure 3 is schematic diagram of a gas treater housing according to an embodiment of the present invention comprising a plurality of distinct chambers.

Figure 4 is an end view of the gas treater housing according to the embodiment of Figure 3.

Figure 5 is an internal view of the gas treater housing according to another embodiment featuring one or more bag members inside the housing.

Figure 6 is an internal view of the gas treater housing according to still another embodiment featuring one or more bag members outside the housing.

Figure 7 is an internal view of the gas treater housing according to yet another embodiment featuring a tube member disposed within the housing and having a restrictive opening at a distal end thereof.

Figure 8 is an internal view of the gas treater housing according to another embodiment featuring a tube member disposed within the housing and having a plurality of openings on a length portion thereof.

Figure 9 is a schematic diagram of still another embodiment featuring an inkjet printhead for controllably releasing a quantity of one or more agents into the chamber of the gas treater housing.

Figure 10 is a schematic diagram of a heating element used in the gas treater.

Figure 11 is a cross-sectional view of the gas treater chamber and showing the fluted gas inlet and outlet of the chamber.

Figure 12 is an internal view of a gas treater housing showing a container for releasing a quantity of a solid phase agent into the chamber.

Figure 13 is a view of a gas treater housing, similar to Figure 12, but showing the container positioned outside of the chamber.

Figure 14 is a schematic diagram showing a circuit for controlling the temperature of the gas and for monitoring the humidity of the gas.

Figure 15 is a schematic diagram showing a circuit for monitoring humidity of the gas according to an alternative embodiment.

Figure 16 is a schematic diagram of an alternative embodiment of the present invention, which can deliver treated or untreated gas and an agent into body cavities, spaces, or surfaces.

Figure 17 is a schematic diagram of a further alternative embodiment of the present invention which can deliver treated or untreated gas and an agent into body cavities, spaces, or surfaces.

Figure 18 is a schematic diagram of a further alternative embodiment of the present invention which can deliver treated or untreated gas and an agent into body cavities, spaces, or surfaces.

Figure 19 is a schematic diagram of a further alternative embodiment of the present invention which can deliver treated or untreated gas and an agent into body cavities, spaces, or surfaces.

Figure 20 is a schematic diagram of a further alternative embodiment of the present invention which can deliver treated or untreated gas and an agent into body cavities, spaces, or surfaces.

Figure 21 is an elevational view showing how an agent may be introduced into the agent chamber used in some embodiments of the invention.

Figure 22 is an elevational view showing another way in which an agent may be introduced into an agent chamber.

Figure 23 is an elevational view showing still another way in which an agent may be introduced into an agent chamber.

Figure 24 is an elevational view showing still another way in which an agent may be introduced into an agent chamber.

Figure 25 is an elevational view showing how a syringe may be used as an agent chamber in the present invention.

Figure 26 is an elevational view showing how a pump may be used as an agent chamber in the present invention.

Figure 27 is an elevational view showing how a pressurized chamber may be used as an agent chamber in the present invention.

Figure 28 is an elevational view showing how a bag may be used as an agent chamber in the present invention.

Figure 29 is an elevational view showing how a piezoelectric chamber may be used as an agent chamber in the present invention.

Figure 30 shows a further embodiment of the present invention.

Figure 31 is an elevational view of a two inlet trocar forming part of the present invention.

Figure 32 is a modification of the construction shown in Figure 31

Figure 33 is a further modification of the construction shown in Figure 31.

Figure 34 is a flow chart showing a series of steps that may be used in operating various embodiments of the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

DEFINITIONS

As used in the claims, "a" can mean one or more.

As used herein, "a predetermined temperature" or "a predetermined temperature range" is one that has been preset or programmed by the user during a procedure. For example, a desirable temperature range may be physiological body temperature, i.e., approximately 35-40°C. As explained hereinafter, the temperature of the gas may be adjusted by a "dial" type or other similar adjustment.

As used herein, the term "humidifying solution" means water, normal saline, lactated Ringers, any buffered liquid or solution, an aqueous solution, a non-water

based solution, a combination of water or non-water solutions and other substances, or a gel substance containing water or non-water solutions and other substances.

As used herein, the term "agent" means any organic substance, inorganic substance, inert or biologically active substance of pharmacologic material, that may effect or enhance tissue healing, reduce infection, reduce adhesions formation, modify the immunologic response, treat specific disease processes, reduce pain or be used for any therapeutic or diagnostic purpose. This includes materials in solid, liquid or gas phase, and materials that are water (aqueous) based, colloid and non-colloid suspensions, mixtures, solutions, hydrogels, lyophilized materials, hydrophobic, hydrophilic, anionic, cationic, surface active agents, surgical adjuvants, anticoagulants, antibiotics, immunologic stimulators, immunologic suppressants, growth inhibitors, growth stimulators, diagnostic materials, anesthetic agents, analgesic agents, and materials by themselves or dissolved or based in other materials, such as, but not limited to, alcohols, ethers, esters, lipids and solvents. The agent can be dry, such as in a power form. Any material that can be carried by the flow of gas into a body cavity or onto a surface for therapeutic or diagnostic purposes can be delivered in accordance with this invention. It is not intended to limit the present invention to the above examples of agents. Furthermore, the gas stream may be treated with any type or combination of agents in accordance with the present invention. An example is to treat the gas stream with a humidifying solution for hydration to prevent desiccation, an antibiotic to reduce infection, an anti-inflammatory to reduce inflammation and an anti-adhesive to reduce adhesions and improve healing. Agents such as those sold under the trademarks Adept manufactured by ML Laboratories, Adcon manufactured by Gliatech and Atrisol manufactured by Atrix Laboratories can be used to reduce adhesions.

As used herein, the term "gas" includes any gas or combination or mixture of gases in any proportion that occurs naturally or can be manufactured or placed or created in a container.

The term "treating" used in connection with treating of the gas stream means to inject or release one or more agents into the gas stream so that the gas stream is a fume or dust in the case of a solid phase agent, or a mist or spray in the case of a liquid phase agent. In some embodiments, such as where the agent is in liquid form, the agent is wicked off or dislodged from a container. In other cases, the agent is injected or

released into the gas stream. In general, the gas stream to be treated with one or more agents is also humidified.

The terms "cavity" or "space" mean any body cavity or space including the interthoracic cavity, the pericardium, the peritoneal cavity or abdomen, plural cavity, knee space, shoulder space, eyeball, stomach and lung.

The term "aerosol" means a suspension of liquid or solid particles in a gas.

The term "spray" means a jet of liquid dispersed by a sprayer.

The term "mist" means liquid in the form of particles suspended in a gas.

The term "fog" means vapor condensed to fine particles of liquid suspended in a gas.

The term "vapor" means a gas dispersion of molecules of a substance.

The basic tenet of the present invention is to treat a flowing gas stream with one or more agents so that the agent(s) actively or passively are injected into the gas stream and are made part of the gas stream as a result of the dynamics of flow, vapor pressure and/or rate of evaporation. The gas stream thereby is modified to contain additives that are determined desirable by the user for purposes of enhancing the outcome of a gas delivery event in connection with, for example, a particular treatment or diagnostic procedure or prevention.

The term "body surface" means any surface of the body, whether internal or external, and whether exposed naturally or by way of surgical procedure.

Referring to Figure 1, the apparatus for treating or conditioning gas is shown generally at reference numeral 100. The apparatus 100 is adapted to receive gas from a gas regulator 10 (high or low pressure, high or low flow rate), such as an insufflator. The apparatus comprises a gas treater 120, an optional filter 110 and an optional control module 140. Tubes are provided to connect the various components of the apparatus together. Specifically, a first tube segment 160 connects the outlet of the gas regulator 10 to the inlet tubing of the filter 110 via a male Luer lock 166 or any appropriate adapter compatible with the insufflator outlet port. A second tube segment 162 connects the outlet of the filter 110 to the inlet of the gas treater 120. A third tube segment 164 connects the outlet of the gas treater 120 by a male Luer lock 168 (or other appropriate fitting adapter) to a gas delivery device (not shown), such as a trocar, Veres needle, endoscope or a tube that enters a body cavity or space that delivers the treated gas into the body of an animal. Alternatively, if the gas is to be delivered to a

body surface, the gas delivery device may be shaped, formed or otherwise configured to direct or spread the flow of gas onto a surface.

The tubing of the tube segments 160, 162 and 164 is preferably flexible and sufficiently long to permit the gas regulator 10 and control module 140 to be placed at a convenient distance from an animal undergoing procedure requiring gas delivery. For applications of the apparatus 100 where the temperature of the gas stream should be within a desired range when delivered, the gas treater 120 is preferably placed immediately adjacent to that location where the gas is to be delivered.

The filter 110 is an optional element and consists of a high efficiency, hydrophobic filter (for example Gelman Sciences Metricel M5PU025, having a pore size preferably small enough to exclude all solid particles and bacterial or fungal agents that may have been generated in a gas supply cylinder or the gas regulator 10 (i.e., 0.5 micron or less and preferably about 0.3 micron). A preferable filter is a hydrophobic filter, such as a glass fiber-type filter, e.g., Metrigard by Gelman Sciences or Porous Media Ultraphobic filter, Model DDDF 4700 M02K-GB. Other suitable filters include polysulfone (Supor, HT Tuffrin, Gelman Sciences) and mixed cellulose esters (GN-6 Metricel, Gelman Sciences), for example. Decreasing the pore size of filter 110 below 0.1 micron causes a concomitant increase in pressure drop of gas, and thus flow rate is reduced significantly. If the procedure to be performed requires a relatively high pressure and/or flow rate of gas to the animal, such as laparoscopy, the pore size should preferably not decrease below 0.2 micron. A hydrophobic filter is preferable to a hydrophilic one, as a hydrophobic filter is less likely to tear under water pressure caused by accidentally suctioning or siphoning peritoneal or irrigation fluids.

In some applications, it is desirable that the gas treater 120 be connected immediately adjacent to a gas delivery device so that the gas travels a minimum distance from the outlet of the gas treater 120 to the conduit or connection to the interior of an animal. The purpose of this arrangement is to allow gas to be delivered to the animal while still at a temperature and water content sufficiently close to the physiological interior body temperature or other body surface. That is, for some applications, the apparatus according to the invention prevents thermodynamic cooling of gases in transit to the animal, because it provides a highly efficient treatment chamber that, as a result of its efficiency, can be quite compact and thus be positioned very near to the animal.

The control module 140 is contained within an electrical housing 210 and is connected to the gas treater 120 by several wire pairs contained within an insulated electrical cable 170. In particular, the cable 170 has a connector 172 at one end that electrically connects into a circuit connector 212 of the housing 210 for the control module 140, and at the other end it is electrically connected to the gas treater 120 by a sealed electrical feed through 174. The cable 170 is attached to the tube segment 162 by a plastic tape or clip 176. Alternatively, the cable 170 is attached to the tube segment 162 by heat seal, extrusion, ultrasonic welding, glue or is passed through the interior of tube segment 162.

The control module 140 and associated components in the gas treater 120 are preferably powered by an AC-DC converter 180. The AC-DC converter 180 has an output that is connected by a plug connector 182 into a power receptacle 214 of the circuit within the control module 140, and has a standard AC wall outlet plug 184 that can be plugged into standard AC power outlets. For example, the AC-DC converter 180 is plugged into an AC power strip that is provided on other equipment in an operating room. Alternatively, electrical power for the apparatus is provided by a battery or photovoltaic source. Another alternative is to provide circuitry in the control module 140 that operates on AC signals, as opposed to DC signals, in which case the control module 140 could be powered directly by an AC outlet. The control module 140 and the heating and hydrating components inside the gas treater 120 will be described in more detail hereinafter.

In some embodiments, the gas treater 120 has a charging port 190 that is capable of receiving a supply of an agent and/or humidifying solution. For example, a syringe 200 containing a predetermined volume of liquid-based agent is introduced into the charging port 190 to inject it into the gas treater 120 for an initial charge or re-charge thereof. The apparatus 100 may be sold with the gas treater 120 pre-charged with a supply of an agent and/or humidifying solution such that an initial charge is not required for operation.

Turning to Figure 2, the gas treater 120 will be described in greater detail. The gas treater 120 comprises a housing 122 having an (entry port) gas inlet 124 and an (exit port) gas outlet 126. The housing 122 defines a chamber 128 that contains a treatment subchamber for treating the gas supplied through the inlet with an agent, and in some embodiments, contains elements for substantially simultaneously heating and

hydrating (humidifying), as well as means 136 for sensing the temperature of the gas and means 138 for sensing the relative humidity of the gas as it exits the chamber 128.

Specifically, in the embodiment of Figure 2, within the chamber 128, there is provided a subchamber that comprises of one or more layers of liquid-retaining or absorbing padding or sponge material, shown at reference numerals 130, 131 and 132. It should be understood that the number, spacing and absorbency of the liquid-retaining layers 130, 131 and 132 varies according to specific applications. Three layers are shown as an example. The material of the layers 130, 131 and 132 can be any desirable liquid retaining or absorbent material, such as a rayon/polyester formed fabric (e.g., NU GAUZE™, manufactured and sold by Johnson & Johnson Medical, Inc.). The pore size of the selected material should be chosen according to a balance of liquid-retaining capabilities and low pressure drop considerations. The larger the pore size, the greater the liquid retention capability for gas contact for aerosolizing the gas.

Other forms of the treatment subchamber may consist of an empty chamber, a subcontainer or subchamber of liquid within the chamber 128 (without absorbent layers) having a semi-permeable membrane on opposite ends to allow gas to pass there through. The agent in the chamber is optionally heated by a heating jacket placed around the chamber.

The heating means in the gas treater 120 consists of at least one heating element 134 positioned in the housing, such as between the absorbent layers 130 and 131. The heating element 134 is an electrically resistive wire, for example. The heating element 134 is placed preferably between absorbent layers or en-meshed within the layers of material (in the fabric). The heating element 134 heats the gas supplied through the inlet, under control of a heat control signal supplied by the control module 140, substantially simultaneous with the treatment of the gas as the gas passes through the chamber 128. Additional heating elements may be disposed within the chamber.

In order to sense the temperature and humidity of the gas as it exits the gas treater 120, a temperature sensor 136 and a relative humidity sensor 138 are provided. The temperature sensor 136 may be provided anywhere within the flow of gas in the chamber 128, but is preferably positioned on the downstream side of the heating element 134 between liquid-retaining layers. The temperature sensor 136 is a thermistor (for example, Thermometrics MA100 Seres chip thermistor, or Thermometrics Series BR23, Thermometrics, Inc., Edison, New Jersey). It is

preferable that the temperature sensor 136 be accurate to within about 0.2°C. In the present invention, the temperature of the gas is preferably sensed after the gas has been treated (and optionally humidified) so that any change in the temperature of the gas as it is treated is corrected at that point in the apparatus, thereby compensating for enthalpy changes.

The humidity sensor 138 is positioned in the flow path of gas exiting the chamber 128, preferably downstream from the heating element 134 either between liquid-retaining layers or on the downstream side of the absorbent layers, proximate the exit port 126 of the housing 122. The humidity sensor 138 is preferably not in contact with a layer. Figure 2 shows the humidity sensor 138 distal to the absorbent layers, separated from the liquid-retaining layer 132 by a porous mesh (plastic or metal) layer 133 that extends across the interior of the housing 122. The humidity sensor 138 actually is generally not in contact with the porous mesh layer 133, but is spaced there from as well. The humidity sensor 138 is, in one embodiment, a humidity-sensitive capacitor sensor, such as a capacitive humidity sensor manufactured by Philips Corporation, which changes capacitance in response to humidity changes. The humidity sensor 138 measures the relative humidity of the gas as it passes through the chamber 128 to enable monitoring of the gas humidity, and in order to provide an indication of the amount of humidifying solution remaining in the gas treater 120, i.e., in layers 130, 131 and 132. As will be explained hereinafter, in one embodiment, a timer/divider integrated circuit (IC) 145 (Figure 5), is connected to the humidity sensor 138 and is preferably disposed within the housing 122 together and substantially co-located with the humidity sensor 138. Other means of determining the humidity of the gas are well within the scope of the present invention.

One way to treat a gas stream with one or more agents using the embodiment of the gas treater 120 shown in Figure 2 is to inject from a syringe 200 a liquid-based agent into the chamber 128 through the charging port 190 for absorption onto one of the layers 130-132. When the gas stream flows over the layers 130-132, the gas stream will become treated with agent and thereby carry the agent out of the gas treater 120 into an animal. Depending on the dimensions and type of absorbent pad or pads used, there is a capacity to the amount of agent that can be introduced into the chamber 128. The size of the chamber 128 can be increased to allow for larger pads, and therefore greater capacity.

Several additional embodiments of the invention will now be described in conjunction with Figures 3-9, and 12-15. In these embodiments, other configurations of the housing 122 of the gas treater 120 are described that are useful to treat the gas stream flowing through the gas treater housing 122 with one or more agents. These embodiments show different types of containers for containing an agent and releasing it into the gas stream in a chamber of the gas treater 120.

Figures 3 and 4 illustrate an embodiment for the gas treater housing 122 featuring multiple chambers, for example, three chambers 128A, 128B and 128C that extend a certain length portion (not necessarily all) of the housing 122. These chambers are separated by walls or partitions 202, 204 and 206. Associated with each chamber 128A, 128B and 128C is a charging port 190A, 190B and 190C, respectively to receive a supply of agent from a respective source, such as an external bag, syringe, etc. The agent is delivered under pressure into a chamber through its respective charging port, or is wicked off from a small opening of a bag (Figs. 5 and 6) placed through the charging port into a chamber. Alternatively, within each chamber 128A, 128B and 128C is one or more absorbent pads or layers similar to that shown in Figure 2, onto which a quantity of an agent is absorbed. Still a further alternative is to provide a separate semi-permeable membrane in each chamber filled with a different agent.

Each of the chambers can be charged with a different agent. For example, chamber 128A may be charged with a humidifying solution, chamber 128B may be charged with agent A and chamber 128C may be charged with agent B. Though not shown in Figures 3 and 4, it should be understood that the heating elements, temperature sensor and humidity sensor shown in Figure 2 may optionally be included in their various configurations in the embodiment of the housing shown in Figures 3 and 4. In the embodiment of Figures 3 and 4, when the gas stream flows through the housing 122, the gas stream wicks off or dislodges the humidifying solution from chamber 128A, is mixed with agent A from chamber 128B and is mixed with agent B from chamber 128C. Thus, the gas stream that exits the housing 120 is hydrated and treated with the agents, for delivery to an animal.

Figures 5 and 6 illustrate another embodiment where the agents to be carried by the gas stream are contained within bags. In Figure 5, there are, for example, two bags 220 and 230 each of which are to contain a quantity of an agent. The apparatus may be shipped with the bags 220 and 230 pre-loaded or pre-charged with a quantity of agents,

or they may be filled with a quantity of agents prior to use. The bags 220 and 230 are formed of flexible material such as, polyethylene or other similar material. In one configuration, the bags 220 and 230 are formed of semi-permeable membrane material such that the agent contained therein can be wicked off by the flowing gas stream over the surface of the bags through the housing 122. In another configuration, at the end of each bag 220 and 230 inside the housing 122 is a restrictive orifice, nozzle or hole 222 and 232, respectively, such as a spray hole or atomizer hole to allow for contact with the gas stream to be admixed therewith. At the other end of each bag 220 and 230 is an optional charging port 224 and 234, respectively, to allow the introduction of a quantity of an agent into the bags 220 and 230. Openings are made in the housing 122 to allow a length of the bags 220 and 230 to pass there through and into the chamber.

As the bags are filled, they expand inside the chamber 128. The pressure of the quantity of agent in the bags 220 and 230 and/or capillary action at the holes 222 and 232 forces the agent to drip out of the holes 222 and 232 to be wicked off or dislodged by the flowing gas stream through the chamber 128 and carried out of the exit port of the housing 122. In the configuration where the bags 220 and 230 are formed of a semi-permeable membrane material, the pressure of the quantity of agent in the bags facilitates the wicking off of the agent through the membrane. The bags 220 and 230 are deployed within the chamber 128 so that when they are filled, they expand and are substantially confined to a predetermined region of the chamber so as not to interfere with gas flow over the other bag. For example, a heating coil 124 or an absorbent pad can be used to separate the bags 220 and 230 in the chamber 128.

Figure 5 shows only two bags 220 and 230, but it should be understood that one or any number of bags may be suitable depending on the number of agents to be carried by the gas stream.

Figure 6 shows a variation of the embodiment of Figure 5 wherein the bags 220 and 230 are located on the outside or exterior of the housing 122. In this configuration, openings are made in the housing 122 and the holes 222 and 232 of the bags are located just inside the housing 122 at these openings. The agents bead out of the holes 222 and 232 and are wicked off or dislodged by the flowing gas stream through the chamber 128. In addition, there will be a natural tendency for the agent in the bags 220 and 230 to enter the flowing gas stream from the holes 222 and 232 due to the change in vapor pressure. Because the gas stream is relatively dry and by contrast, the agent in the bags

220 and 230 may have some degree of moisture, a natural mechanism occurs by which the moist agent will wick out of the bags in an attempt to reach a vapor pressure equilibrium. The greater the rate of flow of the gas stream, the less of the agent in the bags 220 and 230 that will bead into the gas stream. The same theory of operation applies to the embodiment of Figure 5.

Even if deployed on the outside of the housing 122, the bags 220 and 230 can be filled through their respective charging ports 224 and 234 in the same manner as described in conjunction with Figure 5. The number of bags may vary on a particular application, and two are shown in Figures 5 and 6 only as an example. All other features concerning the heating, humidification and sensing in the housing 122 are applicable to the embodiments shown in Figures 5 and 6.

A still further variation on the embodiments of Figures 5 and 6 is to provide the optional tubing member 250 that extends from a bag to an optional absorbent pad 130 that is positioned within the housing 122.

Further embodiments for deploying one or more agents into the gas stream are shown in Figures 7 and 8. Figure 7 shows an elongated tubing member 300 that is disposed in the chamber 128 of the housing 122. The tubing member 300 is extremely long and winds throughout the chamber 128; Figure 7 is over-simplified in this respect. The tubing member 300 is, for example, a polyamide tubing product manufactured by MicroLumen of Tampa, Florida. The important characteristics of the tubing material are that the sides or walls of the tubing member 300 are as thin as possible so that the volume of agent that the tubing member 300 can carry is maximized. At the tip or end of the tubing member 300 is a restrictive orifice or hole 310 through which the agent may bead and be wicked off or dislodged into the gas stream, then multiple tubing members each containing a different agent is provided. A charging port 312 is also provided on the proximal end of the tubing member 300 just outside the housing 122 to supply a quantity of the agent into the tubing member 300.

Figure 8 illustrates a variation of the embodiment shown in Figure 7, wherein a tubing member 400 is provided that includes one or a plurality of holes or perforations 410 along the length of the tubing member 400 through which the agent is allowed to release into the chamber 128. The gas stream flowing through the chamber 128 will wick off or dislodge the agent from the holes 410 and carry the agent in the gas stream. The tubing member 400 has a charging port 412 similar to charging port 300 for tubing

member 300. Also, multiple tubing members 400 may be provided in the chamber to release multiple types of agents into the gas stream. The length of each tubing member 400 and the quantity and size of the holes 412 therein may be selected to control the rate at which different agents from different tubing members 400 are wicked off or dislodged by the gas stream flowing through the chamber 128.

In the embodiments shown in Figures 2-8, the size of the chamber 128 of the gas treater housing 122 may vary depending on the intended use, gas flow, type of agent, whether and how many absorbent pads are provided, etc. There is no limit, either relative small, or relatively large, to the size of the chamber for purposes of carrying out the present invention.

Turning to Figure 9, yet another embodiment is shown wherein an inkjet printhead cartridge 500 is used to release vapor bubbles containing a quantity of one or more agents into the chamber 128 of the housing 122. The inkjet printhead cartridge 500 may be one of any known inkjet printheads such as those used in inkjet printers sold by Hewlett-Packard, Canon, etc.

As is well known in the art, an inkjet printhead cartridge, such as that shown at reference numeral 500, comprises a reservoir 510, a printhead 520 and a plurality of contact pads 530. Conductive traces in the cartridge 500 are terminated by the contact pads 530. The contact pads are designed to normally interconnect with a printer so that the contact pads 530 contact printer electrodes that provide externally generated energization signals to the printhead 520 to spray ink onto paper. Thermal inkjet printheads create vapor bubbles by elevating the ink temperature, at the surface of a plurality of heaters, to a superheat limit. This same process can be used to create vapor bubbles of one or more agents. The printhead 520 comprises a plurality of nozzles 522 from which the vapor bubbles are released when heaters are energized to heat the quantity of agent contained in the reservoir.

According to the present invention, the inkjet printhead cartridge 500 is connected to a control circuit 600 by way of connector 610 having contacts to match the contact pads 530. The control circuit 600 may be contained within the control module 140 shown in Figure 1 and coupled to the cartridge 500 by one or more electrical conductors contained in the electrical cable 170. The reservoir 510 is filled with a quantity or volume of one or more agents to be released into the chamber 128. For example, a color inkjet printhead cartridge contains multiple chambers or reservoirs

for each of three colors of ink. Using this same type of device, an inkjet printhead cartridge may contain a quantity or volume of several different agents to be separately or simultaneously delivered into the chamber in controlled amounts. The control circuit 600 generates appropriate control signals that are coupled to the cartridge 500 via the connector 610 to drive the heaters in the printhead 520 and release vapor bubbles of one or more agents into the chamber from the nozzles 522.

When the one or more agents are released into the chamber 128, the gas stream that flows through the chamber and carries the agent out the exit port of the housing 122 and into the animal. Each of the different agents can be released into the chamber 128 at different rates or volumes. Furthermore, it is possible that a different inkjet printhead cartridge is provided for each of separate subchambers inside chamber 128 to keep the agents from mixing for a period of time before delivered into the animal.

Referring back to Figure 2, electrical connections to the components inside the housing 122 of the gas treater 120 are as follows. A ground or reference lead (not specifically shown) is provided that is connected to each of the temperature sensor 136, heating element 134 and humidity sensor 138-timer/divider 145. A wire 175 (for a positive lead) electrically connects to the hearing element 134 and a wire 176 (for a positive lead) electrically connects to the temperature sensor 136. In addition, three wires 177A, 177B and 177C electrically connect to the humidity sensor 138-timer/divider circuitry, wherein wire 177A carries a DC voltage to the timer/divider 145, wire 177B carries an enable signal to the timer/divider 145, and wire 177C carries an output signal (data) from the timer/divider 145. All of the wires are fed from the insulated cable 170 into the feedthrough 174 and through small holes in the housing 122 into the chamber 128. The feedthrough 174 is sealed at the opening 178 around the cable 170.

The charging port 190 is attached to a lateral extension 139 of the housing 122. The charging port 190 comprises a cylindrical body 192 containing a resealable member 194. The resealable member 194 permits a syringe or similar device to be inserted there through, but seals around the exterior of the syringe tip. This allows a volume of liquid agent or humidifying solution to be delivered into the chamber 128 without releasing the liquid already contained therein. The resealable member 194 is, for example, Baxter InterLink™ injection site 2N3379. Alternatively, the charging port may be embodied by a one-way valve, a sealable port, a screw cap, a cap with a slit to

permit the introduction of a syringe or other device, such as a Safeline™ injection site, part number NF9100, manufactured by B. Braun Medical Inc., or any other covering material or member capable of permitting the introduction of a syringe and preventing the backflow of contained liquid or gas. The control module 140 will issue a warning when the humidity of the gas being treated by the gas treater 120 drops below a predetermined or user programmable relative humidity, as explained hereinafter.

As an alternative, or in addition to the sensing and monitoring features described above, a backup or reserve supply container for liquid agent and/or humidifying solution is provided. Referring back to Figure 1, one form of a backup supply container is a container 800 that hangs free of the apparatus 100 and is connected with an access tubing 810 to the charging port 190. The container 800 is, for example, a bag such as an intravenous fluid bag and the access tubing 810 is an intravenous type tubing.

Another form of a backup supply container is a container 850 that attaches to a portion of the apparatus 100. For example, the container 850 is a reservoir tube, bag, syringe or tank that is attached to the tubing segment 162 or is strapped or fastened to the tubing segment 162 close to the gas treater 120. Another alternative would be to strap or fasten it to the outside of the housing 122 of the gas treater 120. The container 850 is connected to an access tubing 860 that connects into the charging port 190, similar to access tubing 810 described above.

Access tubing 810 and 860 have a penetrating member (not shown) at their distal ends to penetrate the charging port 190 to gain access to the chamber 128 of the gas treater housing 122. Alternatively, instead of the access tubing 860, the container 850 has at the end proximate the charging port 190 a tip member similar to that of the syringe 200 to penetrate and directly couple to the charging port 190.

The containers 800 and 850 can be pre-charged or charged prior to use according to techniques well known in the art. For example, container 850 has an injection site 862 to enable injection of liquid into the container 850.

Preferably, the access tubing 810 or 860 of the backup supply containers 800 and 850, respectively, (or the integral penetrating tip of the container 850) extend far enough through the charging port 190 so as to make contact with one of the layers 130-132 so that the liquid therein is wicked off on to one of the layers 130-132 due to capillary forces. Alternatively, the access tubing 810 or 860 (or integral penetrating tip

of the container 850) stops short of one of the layers 130-132, and the pressure differential created by the flowing gas stream through the housing 122 will wick off the liquid agent and/or humidifying solution from the end of these members to contribute to the treatment of the gas.

With reference to Figure 2, another variation is to provide an extension tube 870 that leads from the charging port 190 where the access tubing 810 or 860 (or the integral penetrating tip member of the container 850) terminates, to the treatment subchamber inside the chamber 128, i.e., to contact one or more of the layers 130-132. Liquid agent and/or humidifying solution is continuously wicked out from the end of the extension tube 870 onto one of the layers 130-132.

In either form of the backup supply container, the basic principle is the same. The backup supply container provides is coupled through the charging port 190 to the treatment subchamber inside the chamber 128 to constantly replenish the treatment subchamber, e.g., one or more of the layers 130, 131 or 132. Consequently, the treatment subchamber will have an initial amount of liquid agent and/or humidifying solution (pre-charged or charged prior to use) and a backup supply from the backup supply container is constantly supplied to the treatment subchamber to constantly replenish it as gas flows through the chamber. The overall time of sufficient gas humidification and/or treatment is thereby lengthened to a duration that is suitable for all or nearly all gas delivery applications. As a result, there is no need to be concerned about decreasing humidity of the gas delivered. The backup supply container acts as a backup to provide gas humidification and/or treatment for an entire procedure. Therefore, some forms of the apparatus 100 need not include the humidity and temperature sensing and monitoring features, or the recharge alert, described herein. The features provide another type of backup that may be useful in certain applications, instead of, or in addition to the backup supply container.

The desirable width and diameter of the gas treater is dependent upon many factors, including the intended use, the rate of gas flow from the gas source and the pressure desired to be maintained, which is affected more by the diameter of chamber 128 than by its length. A person of ordinary skill in the art, given the teachings and examples herein, can readily determine suitable dimensions for chamber 128 without undue experimentation. It should also be noted, however, that upon activating the apparatus or changing the demand on the apparatus (e.g., flow rate or pressure), there is

a lag time of only several tenths seconds for sensing the temperature of gas and adjusting the hearing element to achieve the proper gas or desired temperature. Such a fast start-up time is extremely beneficial.

Referring to Figure 10, the heating element 134 is shown in more detail. The heating element 134 is an electrically resistive wire that is disposed in the housing 128 in a concentrical coil configuration having a number of turns, such as 6-8 turns. Alternatively, a second heating element 134' is provided that is arranged with respect to the heating element 134 such that its coils are offset from those of the first heating element, relative to the direction of gas flow through the chamber. If two or more heating elements are employed, they are preferably spaced from each other in the chamber of the gas treater by approximately 3-4 mm. The first and second heating elements 134 and 134' can be coiled in opposite directions relative to each other. This arrangement allows for maximum contact of the gas flowing through the chamber with a heating element. Other non-coiled configurations of the heating element 134 are also suitable.

Turning to Figure 11, another feature of the gas treater 120 is illustrated. At the inlet and/or outlet of the housing 122, fluted surfaces 123 may be provided to facilitate complete dispersion of gas as it is supplied to the gas treater 120. This improves the fluid dynamics of the gas flow through the chamber 128 to ensure that the gas is uniformly heated and humidified as it flows through the chamber 128.

Figures 12 and 13 illustrate embodiments of the apparatus to treat the gas stream with a solid phase agent. Figure 12 shows a container 700 of a solid phase agent, such as in power form, that is positioned in the chamber 128 of the gas treater housing 122. The container 700 includes a check valve 710 and a pressurizer 720, such as a carbon dioxide cartridge. When the pressurizer 720 is activated, pressure inside the container 700 is caused to rise, such that the bias of the check valve 710 is overcome, releasing the agent into the chamber 128. A button 730 on the exterior of the housing 122 is coupled by a wire or other means to pressurizer 720 to activate it remotely.

Figure 13 shows a container 700 of solid phase agent positioned outside of the housing 122. The check valve 710 of the container 700 is fed through an opening in the housing 122 into the chamber 128. The button 730 for activating the pressurizer is

optionally positioned on the exterior of the container 700. Operation of the configuration shown in Figure 13 is similar to that of Figure 12.

In the embodiment of Figures 12 and 13, the rate at which the solid phase agent is released into the chamber 128 is dependent upon the pressure created in the container 700 by the pressurizer 720 and the size of the check valve 710. It may be desirable to deliver short bursts of the solid phase agent into the gas stream, or to deliver it into the gas stream on a continuous basis. If necessary, a separate backup source of pressure may be coupled to the container 700 to provide for longer term treatment of the gas stream. In any case, the gas stream flowing through the housing 122 will carry the solid phase agent with through the exit port.

Referring to Figure 14, the control module 140 will be described in detail. The control module 140 contains monitoring circuitry and control circuitry for the apparatus 100. It is understood that some forms of the apparatus 100 need not include the humidity (and heating) sensing, monitoring, temperature control and recharge alert functions. The control module 140 comprises a voltage regulator 141, a microcontroller 142, an A/D converter 143, a dual operational amplifier (hereinafter "op-amp") module 144, and a timer/divider 145. The monitoring circuit portion of the control module 140 consists of the combination of the microcontroller 142 and timer/divider 145. The control circuit portion of the control module 140 consists of the microcontroller 142, A/D converter 143 and op-amp module 144. The monitoring circuit monitors the relative humidity of gas exiting the chamber based on a signal generated by the timer/divider 145. The control circuit monitors the temperature of the gas exiting the chamber and in response, controls electrical power to the heating element to regulate the temperature of the gas to a user programmable or fixed temperature or temperature range. While the temperature of the gas exiting the chamber is actively controlled, the relative humidity of the gas in the chamber is not actively controlled; rather it is monitored and an alert is generated when it drops below a corresponding threshold so that appropriate action can be taken, such as replenishing the gas treater 120 with liquid agent or humidifying solution.

Figure 14 shows that several components are preferably located within the electrical housing 210 (Figure 1), whereas other components are located within the housing of the gas treater 120 (Figure 2). In particular, the timer/divider 145 and the associated resistors R4 and R5 are preferably located inside the housing 122 of the gas

treater 120, together with the humidity sensor 138 in a circuit package that includes the humidity sensor 138 exposed on one or more surfaces thereof. More specifically, the timer/divider 145 is co-located with humidity sensor 138. This configuration minimizes timing error by stray wiring inductance and capacitance (sensor kept close to active circuits of timer/divider 145). In addition, by co-locating the timer/divider 145 and humidity sensor 138, the need for interconnecting wires is eliminated, thereby avoiding undesirable signal radiation.

The voltage regulator 141 receives as input the DC output of the AC-DC converter 180 (Figure 1), such as for example, 9V DC, that is suitable for use by the analog components of the control module. The voltage regulator 141 regulates this voltage to generate a lower voltage, such as 5V DC, for use by the digital components of the control module. The capacitor C1 at the output of the voltage regulator 141 serves to filter out any AC components, as is well known in the art. Alternatively, a suitable DC voltage is provided by a battery or photovoltaic source shown at reference numeral 149.

The microcontroller 142 is a PIC16C84 integrated circuit microcontroller that controls system operation. A ceramic resonator 146 (4 MHz) is provided to supply a raw clock signal to pins 15 and 16 of the microcontroller 142, which uses it to generate a clock signal for the signal processing functions explained hereinafter.

The op-amp 144 module is coupled (by wire 176) to the temperature sensor 136 (thermistor) mounted in the housing of the gas treater. The op-amp module 144 is, for example, a LTC1013 dual low-input-offset-voltage operational amplifier integrated circuit that includes two op-amps, referred to hereinafter as op-amp A and op-amp B. The non-inverting input of the op-amp A of the op-amp module 144 is pin 3, and pin 2 is the inverting input. The output of op-amp A is pin 1. Op-amp A of the op-amp module 144 is used to buffer the output voltage of the voltage divider formed by resistors R1 and R2. The buffered output voltage, referred to as Vx in Figure 5, is applied to op-amp B in the op-amp module 144. Op-amp B is configured as a non-inverting-with-offset amplifier with a gain of 21.5, and also receives as input the output of the temperature sensor 136, adjusted by resistor R3, shown as voltage Vy in the diagram. The output voltage of op-amp B is at pin 7, referred to as Vo in Figure 5. The output voltage Vo is equal to 21.5Vy - 20.5Vx, which is inversely proportional to

the gas temperature in the housing of the gas treater. The output voltage Vo ranges between 0-5V DC, depending on the temperature of the gas in the chamber.

The A/D converter 143 is an ADC 0831 integrated circuit analog-to-digital converter that receives as input at pin 2, the output Vo of the op-amp module 144. The A/D converter 143 generates a multi-bit digital word, consisting of 8 bits for example, that represents the output voltage Vo, and is supplied as output at pin 6, which in turn is coupled to I/O pin 8 of the microcontroller 142. The microcontroller 142 commands the A/D converter 143 to output the digital word by issuing a control signal on I/O pin 10 which is coupled to the chip select pin 1 of the A/D converter 143. Moreover, the microcontroller 142 controls the rate at which the A/D converter 143 outputs the digital word by supplying a sequence of pulses on pin 9 applied to clock input pin 7 of the A/D converter 143. The "unbalanced bridge" values of resistors R1, R2 and R3 are chosen to produce a 0-5V DC output over gas temperatures from approximately 20°C to approximately 45°C. Since the bridge and the reference for the A/D converter 143 are provided by the same 5V DC source, error due to any reference voltage shift is eliminated.

The timer/divider 145 is, for example, a MC14541 precision timer/divider integrated circuit. The humidity sensor 138 is connected to pin 2 and to resistors R4 and R5 as shown. In response to an enable signal output by the microcontroller 142 on pin 12 that is coupled to timer/divider pin 6, the timer/divider 145 generates an output signal that oscillates at a rate determined by the value of the resistor R4, the capacitance of the humidity sensor 138 (which varies according to the relative humidity of the gas inside the gas treater housing) and a predetermined divider constant. For example, the divider constant is 256. Specifically, the output signal of the timer/divider 145 is a square wave oscillating between 0V ("low") and 5V ("high") at a frequency of approximately $1/[256*2.3*R4_t*C_t]$Hz, where $R4_t$ is, for example, 56 kOhms, and C_t is the capacitance at some time (t) of the relative humidity sensor 138 depending on the relative humidity of the gas in the chamber. For example, the humidity sensor manufactured by Phillips Electronics, referred to above, can measure between 10-90%RH (relative humidity), where C_t at 43%RH is 122 pF (+/- 15%), with a sensitivity of 0.4 +/- 0.5 pF per 1%RH. The output signal of the timer/divider 145 appears at pin 8, which is coupled to the I/O pin 13 of the microcontroller 142. Thus, the timer/divider 145 is essentially an oscillator circuit connected to the humidity sensor

that generates an output signal with a frequency dependent on a capacitance of the humidity sensor. Any oscillator circuit that can generate as output a signal whose frequency is dependent on a variable capacitance may be suitable for the timer/divider 145.

The microcontroller 142 computes a measure of the relative humidity of the gas inside the gas treater housing by timing or measuring a characteristic of the output signal of the timer/divider 145. Specifically, microcontroller measures the time duration of one of the phases of the output signal of the timer/divider 142, such as the "high" phase which is approximately $\frac{1}{2}*[256*2.3*R4_t*C_t]$. This time duration is indicative of the relative humidity of the gas in the chamber of the gas treater since the rate of the oscillation of the timer/divider depends on the capacitance of the humidity sensor 138, as explained above. For example, for a change in RH of 10-50% and/or 50 to 90%, there is a 13% change in the duration of the "high" phase of the timer/divider output signal. The microcontroller 142 monitors the relative humidity of the gas exiting the chamber in this manner and when it drops below a predetermined relative humidity threshold (indicated by a corresponding predetermined change in the oscillation rate of the timer/divider 145), the microcontroller 142 generates a signal on pin 17, called a recharge signal, that drives transistor Q3 to activate an audible alarm device, such as buzzer 147. The buzzer 147 generates an audible sound which indicates that the relative humidity of the gas in the gas treater has dropped below the predetermined threshold and that it is necessary to recharge the gas treater with liquid. The predetermined relative humidity threshold corresponds to a minimum level for a desirable relative humidity range of the gas exiting the gas treater, and may be 40%, for example. The predetermined relative humidity threshold is an adjustable or programmable parameter in the microcontroller 142. Optionally, the microcontroller 142 may generate another warning signal at the output of pin 7 to illuminate a light emitting diode (LED) 148A, thereby providing a visual indication of the humidity dropping below the predetermined relative humidity threshold in the gas treater, and the need to recharge the gas treater 120 with liquid. Further, the microcontroller 142 generates a trouble or warning signal output at pin 6 to drive LED 148B (of a different color than LED 148A, for example) when there is either a "code fault" in the microcontroller 142 (an extremely unlikely occurrence) or when the relative humidity of the gas in the gas treater is less than a critical relative humidity threshold (lower than

the predetermined relative humidity threshold), such as 10%. In either case, power to the heating element 134 is terminated in response to the warning signal.

The microcontroller 142 also controls the heating element 134 in order to regulate the temperature of the gas inside the gas treater. Accordingly, the microcontroller 142 processes the digital word supplied by the A/D converter 143 to determine the temperature of the gas inside the gas treater housing. In response, the microcontroller 142 generates a heat control signal on the output pin 11 that drives transistor Q1, which in turn drives the MOSFET power transistor Q2, that supplies current to the heating element 134. The temperature of the gas inside the gas treater is regulated by the microcontroller 142 so that it is within a predetermined temperature range as it exits the gas treater for delivery into the body of a patient. The predetermined temperature range that the gas is regulated to is approximately 35°-40°C, but preferably is 37°C. As mentioned above, when the relative humidity inside the gas treater falls below a critical threshold as determined by the monitoring circuit portion of the control module 140, the control circuit portion in response terminates power to the heating element 134 to prevent the delivery of warm gas that is extremely dry.

The circuitry for monitoring the relative humidity of the gas can be embodied by other circuitry well known in the art. In addition, while the control module 140 has been described as having a single microcontroller 142 for monitoring signals representing temperature and relative humidity of the gas exiting the chamber, and for controlling the heating element to control the temperature of the gas, it should be understood that two or more microcontrollers could be used dedicated to the individual functions. In addition, the functions of the microcontroller 142 could be achieved by other circuits, such as an application specific integrated circuit (ASIC), digital logic circuits, a microprocessor, or a digital signal processor.

Figure 15 illustrates an alternative embodiment for monitoring relative humidity of the gas, in which a humidity sensitive resistor is used, instead of a humidity sensitive capacitor 138. The humidity sensing scheme employing a resistive humidity sensor does not require the timer/divider circuit 145 shown in Figure 14. The humidity sensitive resistor 900 is located inside the gas treater housing in a suitable location for sensing the relative humidity of the gas stream flowing through the gas treater 120. A suitable humidity sensitive resistor is a model UPS600 resistor by Ohmic, which at

45% RH is approximately 30.7 k Ohms. A resistor R10 is coupled in a voltage divider configuration with the humidity sensitive resistor 900. Three pins of the microcontroller 142 couple to the voltage divider formed by resistor R10 and humidity sensitive resistor 900.

Pin 910 of the microcontroller 142 is coupled to one terminal of the resistor R10, pin 912 is coupled to one terminal of the humidity sensitive resistor 900 and pin 914 is coupled to the terminal between the resistor R10 and the humidity sensitive resistor 900. The humidity sensitive resistor 900 may be a type that requires AC excitation. Accordingly, the microcontroller 142 excites the humidity sensitive resistor 900 by applying an alternating pulse, such as a 5-volt pulse, to pins 910 and 912, such that pin 912 is "high" for a period of time and pin 910 is low. As a result, the average excitation voltage to the humidity sensitive resistor 900 is zero. During the time period when pin 910 is "high", the microcontroller 142 senses the humidity of the gas by determining if the tap voltage pin 914 is a logic "zero" or a logic "one". If it is a logic zero (low voltage), the resistance of the humidity sensitive resistor 900 is low, indicating that the relative humidity of the gas is still high. If it is a logic one (high voltage), then the resistance of the humidity sensitive resistor 900 is high, indicating that the relative humidity of the gas is low. The value of the resistor R10 is chosen to yield a transition at pin 914 at a desired humidity threshold, such as 45% RH, with a 2.5 V transition from a low voltage to a high voltage. For example, resistor R10 is a 30k ohm resistor. In the embodiment employing a resistive humidity sensor, a microcontroller that is suitable is a PIC 16C558 in place of the microcontroller model referred to above in conjunction with Figure 14. This sensing scheme can be simplified even further if a relative humidity sensor that allows DC excitation is used. In this case, only one pin of the microcontroller 142 need be associated with humidity sensing.

A resistive humidity sensor has certain advantages over a capacitive humidity sensor. It has been found that the specific type of resistive humidity sensor referred to above can tolerate immersion in water in the gas treater 120 if a user accidentally over-fills the gas treater 120. In addition, the sensing scheme using a resistive sensor does not require a relatively high frequency square wave signal, which may be undesirable in some environments where the apparatus is used. Finally, the resistive sensor affords better accuracy for relative humidity sensing in some applications.

Other variations or enhancements to the circuitry shown in Figure 14 are possible. The type of microcontroller used can be one, such as the PIC16C715, that incorporates the functions of the A/D converter 143. The PIC16C715 microcontroller incorporates a multichannel A/D converter. In addition, a more feature rich microcontroller of this type will allow for the addition of a display, such as a liquid crystal display (LCD) or LED display. The microcontroller could generate information on a periodic basis to be displayed to the user, such as gas temperature and relative humidity. In addition, the microcontroller may directly drive an audible alert device, rather than indirectly driving it through a transistor as shown in Figure 14. These are examples of the types of modifications or variations that are possible depending on the type of microcontroller that is selected for use in the control module 140.

With reference to Figures 1 and 2, the setup and operation of the apparatus 100 will be described. The AC/DC converter 180 is plugged into a 110V AC power source, such as a wall outlet or a power strip. The control module 140 is connected to the AC/DC converter 180. Alternatively, the apparatus 100 may be powered by a battery or photovoltaic source. The heater/hydrating tubing set is then installed by attaching one end of the tube segment 160 to the outlet of the insufflator 10 by the Luer lock 166. The tube segments 160, 162 and 164 may be pre-attached to the filter 110 and the gas treater 120 for commercial distribution of the apparatus 100. The cable 170 is installed into the electrical housing 210 of control module 140 by the connector 172.

The gas treater 120 is charged with a supply of liquid agent and/or humidifying solution by the syringe 200. The syringe 200 is then inserted into the charging port 190 so that a needle or cannula of the syringe 200 penetrates the resealable member 194 (Figure 2) and the liquid is injected into the gas treater 120 to be absorbed by the absorbent layers. The syringe 200 is then removed from the charging port 190, and the charging port 190 seals itself. The free end of the tube segment 164 is attached to a gas delivery device by the Luer lock 168 or other appropriate connector. Alternatively, the gas treater 120 may be pre-charged with liquid, thus not requiring a charge prior to operation.

If the embodiment of Figure 5 or 6 is employed, then the bags 220 and 230 are charged (unless they are pre-charged) with a quantity of one or more agents. Likewise, if the embodiment of Figure 7 or 8 is employed, the tube member 300 or tube member 400 is charged (unless it is pre-charged) with a quantity of one or more agents. The

nozzles 522 of the printhead 520 are positioned in alignment with an opening to the housing 122. Finally, if the embodiment of Figures 12 or 13 is employed, the container 700 is prepared for use as described above in conjunction with Figures 12 and 13.

Once the gas regulator 10 is activated, it receives gas from a gas supply cylinder and regulates the pressure and flow rate of the gas, both of which can be adjusted by the operator. The pressure and volumetric flow rate are controlled by adjusting controls (not shown) on the gas regulator 10. Gas then flows through the tube segment 160 into the optional filter 110 where it is filtered, and then through tube segment 162 into the gas treater 120. In the gas treater 120, gas comes into contact with the optional electrical heating element 134 and the optional humidifying liquid-retaining layer(s) 130-132 which are positioned within the flow path of the gas, as shown in Figure 2.

Depending on which gas treater embodiment of Figures 2-9, 12, or 13 is employed, the gas stream is treated with a quantity of one or more agents so that the one or more agents is carried out of the gas treater 120 for delivery to an animal. For some applications and temperature range requirements, it may be desirable to position the gas treater 120 immediately adjacent the location to which the treated gas is to be delivered.

In the event that heating and humidification of the gas is also desired and the appropriate components are also deployed in the gas treater 120, then in chamber 128, the gas is also simultaneously heated and humidified to the proper physiological range by regulation of the heating element 134 and liquid content of the layers 130-132 such that the temperature of gas exiting chamber 128 is within a preselected physiological temperature range (preferably 35° to 40°C, though any desired temperature range can be preselected), and within a preselected range of relative humidity (preferably above 40% relative humidity, such as in the range of 80-95% relative humidity). If the apparatus is operated with the gas treater 120 not charged with liquid agent and/or humidifying solution either because the user forgot to manually charge it before initiating operation, or the apparatus was sold without a pre-charge of liquid (i.e., in a dry state), the relative humidity of the gas in the chamber of the gas treater 120 will be detected to be below the predetermined threshold and the alarm will be activated, alerting the user that the gas treater 120 requires charging of liquid. The apparatus will automatically issue an alarm to alert a user to the need for charging the gas treater 120

with liquid agent and/or humidifying solution, thereby avoiding further delivery of unhydrated gas into an animal.

With further reference to Figure 5, the control module 140 monitors the relative humidity of the gas exiting the chamber and further regulates the temperature of the gas in the chamber 128. In particular, the microcontroller 142 generates a recharge signal when the relative humidity of the gas in the chamber drops below the predetermined relative humidity threshold, indicating that the liquid supply in the gas treater 120 requires replenishing. An audible alarm is issued by the buzzer 147 and/or a visual alarm is issued by LED 148A to warn the medical attendant or user that the gas treater 120 requires recharging. Preferably, the microcontroller 142 continues the alarm until the humidity in the chamber returns to a level above the predetermined relative humidity threshold, which will occur when the gas treater 120 is recharged with liquid. Moreover, the microcontroller 142 will issue a second alarm, such as by energizing LED 148B, when the relative humidity level of gas in the gas treater 120 drops below the critical relative humidity threshold, at which point electrical power to the heating element 134 is terminated. In addition, the microcontroller 142 controls the temperature of the gas by controlling electrical power supplied to the heating element 134.

In some cases, the controlled humidity of the gas stream is more important than controlled heating. For those applications, the apparatus would include only those components necessary to treat the gas stream with one or more agents (according to the embodiments of Figures 7-13) and to humidify the gas stream. Furthermore, monitoring the humidity of the gas stream is also optional for certain applications. For example, treating the gas stream with a dry agent may not normally require heating or humidification.

The method and apparatus of this invention can be utilized for many medical procedures requiring the provision of heated and humidified gas. The optional filtration may also be utilized according to the sterility of gas required for the procedure. The gas is chosen according to the procedure to be performed and can be any medically useful gas, such as carbon dioxide, oxygen, nitrous oxide, argon, helium, nitrogen and room air and other inert gases. Preferable gases for endoscopy are carbon dioxide and nitrous oxide. A combination of the above gases can also be used, i.e., 100% of a single gas need not be used. The procedure is preferably endoscopy such as

laparoscopy, colonoscopy, gastroscopy, bronchoscopy, and thoracoscopy. However, it may also be utilized for providing heated and humidified oxygen or any anesthetic gases or combination of gases for breathing, for example, or to administer anesthesia or breathing therapy. In particular, the compact size of the apparatus make the invention portable and thus suitable for uses requiring portability. The gas delivery device that provides the direct contact to the patient should be selected according to the medical procedure to be performed as known to those skilled in the art. The gas that is conditioned by the apparatus may be pressure controlled, volumetrically controlled or both.

In some cases, it is desired to supply some agents of pharmacologic material, separate from other agents (which, as discussed above, could be pharmacologic agents) which may be supplied by the heater/hydrator 120. Depending upon the agent, it may be desirable to use the heater/hydrator to humidify and heat the insufflation gas, and supply the agent separately. Alternatively, one or more agents could be supplied using a heater/hydrator while one or more additional agents could be supplied into the gas stream separately.

Agents can be supplied through a gas stream, for example, during a laparoscopy, colonoscopy, gastroscopy, and/or thoracoscopy, or any other procedure that requires distention. For example, while these procedures are presently done under general anesthesia, where uses of therapeutic doses of anesthesia administered, by way of example, and not of limitation, into the abdomen during surgery, less, or no general anesthesia may be needed, making for faster surgeries, and quicker patient recovery. For example, an appendectomy, cholycysectomy, or tubal ligation might be done without general anesthesia.

While any type of agent could be delivered using the invention, examples of particular agents that might be delivered in a gas stream during a procedure include anesthetic agents, analgesic agents, chemotherapy agents, anti-infective agents, and anti-adhesion agents.

Anesthetic agents include, but are not limited to, alcohol, Bupivacaine, Chloroprocaine, Levobupivacaine, Lidocaine, Mepivacaine, Procaine, Ropivacaine and Tetracaine.

Analgesic agents may include, but are not limited to, respiratory agents such as Excedrin, Tylenol, DayQuil, NyQuil; centrally acting analgesics such as, Duraclon,

Ultrocet and Ultram; miscellaneous analgesics agents such as, Carbatrol, Hyalgan, Lidoderm, Nuropin, Neurontin, Phenegran, and Tegretol; as well as narcotics such as, Nubain, Darvocet, Dilaudid, Lortab, OxyContin, Percocet, and Vicodin.

Chemotherapy agents, also known as antineoplastic agents, may include, but not be limited to, Altretamine, Asparaginase, BCG, Bleomycin sulfate, Busulfan, Carboplatin, Carmustine, Chlorambucil, Cisplatin, Cladribine, Cyclophosphamide, Cytarabine, Decarbazine imidazole carboxamide, Dactinomycin, Daunorubicin-daunomycin, Dexamethasone, Doxorubicin, Etoposide-epipodophyllotoxin, Floxuridine, Fluorouracil, Fluoxymesterone, Flutamide, Fludarabine, Goserelin, Hydroxyurea, Idarubicin HCL, Ifosfamide-Isophosphamide, Interferon alfa, Interferon alfa 2a, Interferon alfa n3, Irinotecan, Leucovorin calcium, Leuprolide, Levamisole, Lomustine, Megestrol, Melphalan-L-phenylalanine mustard, L-sarcolysin, Melphalan hydrochloride, MESNA, Mechlorethamine, nitrogen mustard, Methylprednisolone, Methotrexate-Amethopterin, Mitomycin-Mitomycin C, Mitoxantrone, Mercaptopurine, Paclitaxel, Plicamycin-Mithramycin, Prednisone, Procarbazine, Streptozocin-Streptozotocin, Tamoxifen, 6-thioguanine, Thiotepa-triethylene thiophosphoramide, Vinblastine, Vincristine and Vinorelbine tartrate.

Anti-infective agents include those agents classed as antihelminics and antibiotics. Antibiotics may be further classified as aminoglysosides, anti-fungal antibiotics, cephalosporins, b-lactam antibiotics, chloramphenical, macrolides, penicillins, tetracyclines, miscellaneous antibiotics, antituberculosis agents, anti-virals, anti-retrovirals, antimalarials, ouinolones, sulfonamides, sulfones, urinary anti-infectives and miscellaneous anti-infectives.

Antihelminics may include by way of example, but not of limitation to, Thiabendazole.

Aminoglycosides may include by way of example, but not of limitation to, Amikacin, Gentamicin, Neomycin, Streptomycin and Tobramycin.

Antifungal antibiotics may include by way of example, but not of limitation to, Amphotericin B, Amphotericin B, Lipid formulation T.E., Fluconazole, Flucytosine, Griseofulvin, Itraconazole, Ketoconazole, Nystatin, and Terbinafine.

Cephalosporins may include by way of example, but not of limitation to, Cefaclor, Cefazolin, Cefepime, Cefixime, Cefonicid, Cefotaxine, Cefpodoxine, Cefprozil, Ceftazidine, Ceftriaxone, Cefuroxime, Cephalexin, and Cephradine.

B-Lactam antibiotics may include by way of example, but not of limitation to, Aztreonam, Cefotetan, Cefoxitin, and Imipenem/Cilastatin.

Chloroamphenicol may include by way of example, but not of limitation to, Chloramphenicol, Chloramphenicol Palmitate, and Chloramphenicol Succinate.

Macrolides may include by way of example, but not of limitation to, Azithromycin, Clarithromycin, Erythromycin, Erythromycin Ethyl Succinate and Erythromycin Lactobionate.

Tetracyclines may include by way of example, but not of limitation to, Demeclocycline, Doxycycline, Minocycline and Tetracycline.

Miscellaneous antibiotics may include by way of example, but not of limitation to, Bacitracin, Clindamycin, Polymyxin B, Spectinomycin and Vancomycin.

Antituberculosis agents may include by way of example, but not of limitation to, Ethambutol, Isoniazid, Pyrazinamide, Rifabutin and Rifampin

Antivirals may include by way of example, but not of limitation to, Acyclovir, Amantadine, Famciclovir, Foscarnet, Ganciclovir, Ribavirin, Valacyclovir and Valganciclovir.

Antiretrovirals may include by way of example, but not of limitation to, Abacavir, Amprenavir, Didanosine, Efavirenz, Indinavir, Lamivudine, Loopinavir, Nelfinavir, Nevirapine, Ritonavir, Saquinavir, Stavudine, Zalcitabine and Zidovudine.

Antimalarials may include by way of example, but not of limitation to, Chloroquine, Hydroxychloroquine, Pyrimethamine and Quinine.

Quinolones may include by way of example, but not of limitation to, Gatifloxacin, Levofloxacin and Ofloxacin.

Sulfonamides may include by way of example, but not of limitation to, Sulfadiazine, Sulfamethoxazole, Sulfasalazine and Sulfisoxazole.

Sulfones may include by way of example, but not of limitation to, Dapsone.

Urinary anti-infectives may include by way of example, but not of limitation to, Nitrofurantoin.

Miscellaneous anti-infectives may include by way of example, but not of limitation to, Clofazamine, Co-trimoxazole, Metronidazole and Pentamidine.

Anti-adhesions agents may include by way of example, but not of limitation to, Aspirin, Calcium channel blockers, Carboxymethylcellulose, Chondroitin sulfate, Corticosteroids, Chymase inhibitors, Dextran, Dialysis solution, Diphenhydramine,

Fibrin glue, Haparin, Hyaluronic acid, L-Arginine, Methylene blue, Mifepristone, Mitomycin C, NSAIDs, Octreotide, Pentoxifylline, Peritoneal transplant, Photopolymerized hydrogel, Polyethylene glycol, Polyoxamer, Ringers lactate, Saline, Surfactant and tissue plasminogen activator.

Also known are solutions or gels such as Hyaluronic acid, Hyalutronate-carboxymethylcellulose, Carboxymethylcellulose, Polyethylene glycol, Dextran 70 and Icodextrin 4%.

The preceding are liquids, solutions or gels which it is believed within the skill of those in the art to use in the present invention. Also known are commercial anti-adhesion barriers such as hyaluronate-carboxymethylcellulose, oxidized regenerated cellulose, polyethylene oxide-oxidized regenerated cellulose, expanded polytetrafluoroethylene and pericardial patch.

The use of these in the present invention may require shredding, pulverizing or powdering together with mixing them with a liquid to make them usable in the present invention.

The present invention contemplates use of yet to be invented agents of the above classes, as well as any of those drugs of the above classes which have not been listed.

Referring to Figures 16-20, there are shown embodiments of the present invention which are thought to be particularly useful in providing agents to be delivered, along with insufflation gas, whether treated or not, to the abdomen of a patient. There is shown an insufflation device, at least one structure defining at least one fluid flow path extending at least a portion of the distance between the insufflation device and the abdomen of a patient, and a chamber adapted to be coupled to the at least one structure and adapted to supply an agent to the interior of the abdomen through the at least one structure.

Figure 16 shows an apparatus comprising an insufflation device 915, which may be such as the Stortz Model 26012 mentioned above, or any other insufflation device that supplies insufflation gas to a surgical site. The insufflation device 915 has an outlet 916 through which it supplies insufflation gas.

There is optionally provided downstream of the insufflation device 915, and in fluid communication therewith, the heater/hydrator 120 of the present invention. The heater/hydrator 120 has an inlet 917 and an outlet 918. A first conduit 919 connects the

insufflation device outlet 916 with the inlet 917 of the heater/hydrator 120, thus placing the insufflation device 915 in fluid communication with the heater/hydrator 120.

In any of the embodiments set forth herein, conduits may be short or long, wide or narrow. In some cases, the conduits may be separate pieces from devices they are in fluid communication with, while in other cases the conduit may be formed together with such devices. In some cases, various devices may be connected or coupled together without conduits between them. In some cases, various devices may be formed as a single device with multiple chambers. All such embodiments are within the scope of the invention.

The addition of an agent into the gas stream which is going into the patient's abdomen may be beneficial whether or not the insufflation gas is dry or humidified, or warm or cold. The scope of the present invention covers the addition of an agent under any conditions. The preferred method is one in which the insufflation gas is heated and humidified.

A second conduit 920 is connected at its first end 920A to the outlet 918 of the heater/hydrator 120, and is open at its second end 920B. Either end may include one or more connectors, such as, for example, a Luer lock. During surgery, the second conduit may be connected to, or placed in fluid communication with trocar assembly 921 which has previously been placed into the abdomen 922 of the patient P, thus placing the heater/hydrator in fluid communication with the patient's abdomen. A Veres needle or other device could also be used to provide access to the abdomen without departing from the scope of the present invention. The first conduit 919, or second conduit 920, may have a filter attached thereto.

In this embodiment of the present invention, an agent chamber 925 is provided external and separate of the heater/hydrator 120. The agent chamber 925 has at least an outlet 926. A third conduit 927 is connected at its first end 927A to the outlet 926 of the agent chamber. The third conduit 927, at its other end 927B, may be in flow communication with the trocar assembly 921 (or could be in flow communication with conduit 920 if an appropriate connector was used).

A two-inlet trocar assembly 930 (Figure 31) may be provided. Or, if desired, a modified trocar 933 (Figure 32) may be provided. Since the third conduit is open to atmosphere, some pressure source, other than the insufflation device 915, is employed

to drive the agent in the agent chamber 925 into the insufflation gas stream. An example pressure source is described below.

A dispersion device 948 may be used to promote the entry of the agent into the abdomen 922 of the patient P as an aerosol spray, mist, fog or vapor. It is believed that the dispersion device will promote the effectiveness of the agent.

The dispersion device placement may depend on where and how the agent is introduced to the insufflation gas stream. It is believed that when the agent chamber 925 is not connected in line, the dispersion device may be anywhere in the third conduit 927 or in the trocar 921.

Referring now to Figure 17, a modification of the construction shown in Figure 16 is provided. In this embodiment, the insufflation device 915 having outlet 916 is again provided. The heater/hydrator 120 has its inlet 917 connected to the outlet 916 of insufflation device 915 by the first conduit 919. However, in this embodiment, the modified agent chamber 935 (referred to as modified because of having an inlet and an outlet), having an inlet 936, and an outlet 937, is placed in-line with the heater/hydrator 120 and connected thereto by second conduit 920. Therefore, the pressure of the insufflation gas may be used to drive the agent, if desired. The term "modified agent chamber" is used for convenience and is not meant to create a special definition of either "agent chamber" or "modified agent chamber" in the claims. As used in the claims, the term "agent chamber" is meant to refer broadly to any chamber that may contain an agent.

A fourth conduit 938 is connected to the outlet 937 of agent chamber 935. The fourth conduit 938 may be used to place the agent chamber 935 in fluid communication with the trocar assembly 921 in the abdomen 922 of a patient P during a surgical procedure. The dispersion device 948 may be anywhere downstream of the modified agent chamber 935, such as interposed or connected to the fourth conduit 938. As discussed above, a device other than a trocar 921 could be used to provide access to the abdomen, such as, for example, a Veres needle.

One skilled in the art will appreciate that, depending on the nature of the dispersion device 948, it may be placed in the conduits described herein, with the fluid flowing through the dispersion device 948, or around it, or, the dispersion device 948 could surround the conduit. Depending on the application, for any particular conduit, there may be a dispersion device both, in a conduit, and external to it.

In Figure 18, the agent chamber 925 is connected upstream of the heater/hydrator 120. It is connected in flow communication with the heater/hydrator 120 by fifth conduit 940. Fifth conduit 940 may be connected anywhere between the outlet 916 of the insufflation device 915 and the inlet 917 of the heater/hydrator 120 to place the agent chamber 925 in flow communication with the heater/hydrator 120. As before, second conduit 920 is connected to the outlet 918 of the heater/hydrator 120, and places the heater/hydrator 120 in fluid communication with the patient's abdomen through trocar assembly 921. As discussed above, a device other than a trocar 921 could be used to provide access to the abdomen, such as, for example, a Veres needle.

Since the agent chamber 925 is connected in parallel with the insufflation device 915, the dispersion device 948 may be connected or placed anywhere downstream of the agent chamber 925, for example, in the second conduit 920.

The embodiment shown in Figure 19 is similar to that shown in Figure 17, except that the modified agent chamber 935 having inlet 936 and outlet 937 is placed upstream of the heater/hydrator 120, instead of downstream thereof. First conduit 919 may now be connected between the outlet 916 of the insufflation device 915 and the inlet 936 of the modified agent chamber, thus placing the modified agent chamber 935 in fluid communication with the insufflation device 915.

A sixth conduit 941 connects the outlet 937 of the modified agent chamber 935 to the inlet 917 of the heater/hydrator 120. A seventh conduit 942 is connected to the outlet 918 of the heater/hydrator 120. Seventh conduit 942 may be placed in fluid communication with a trocar 921 assembly which has previously been placed in the abdomen 922 of a patient P during a surgical procedure. As discussed above, a device other than a trocar 921 could be used to provide access to the abdomen, such as, for example, a Veres needle. When gas is flowing from the insufflation device 915, and there is agent remaining in the modified agent chamber 935, the agent may be delivered into the abdomen 922 of the patient P. As before, dispersion device 948 may be placed anywhere downstream of the agent chamber, such as interposed in, or connected to seventh conduit 942.

The embodiment shown in Figure 20 is similar to the embodiment shown in Figure 18, except that the agent chamber 925, having outlet 926 is connected downstream of the heater/hydrator 120, instead of upstream. First conduit 919 is connected between the outlet 916 of the insufflation device 915 and the inlet 917 of the

heater/hydrator, thereby placing heater/hydrator 120 in fluid or flow communication with the insufflation device 915.

Second conduit 920 is connected to the outlet 918 of the heater/hydrator 120. As before, second conduit 920 may be placed in flow communication with a trocar assembly 921 that has been placed into the abdomen 922 of a patient P during a surgical procedure. As discussed above, a device other than a trocar 921 could be used to provide access to the abdomen, such as, for example, a Veres needle. The outlet 926 of the agent chamber 925 has an eighth conduit 943 connected thereto. The other end of eighth conduit 943 may be connected in flow communication with the gas stream coming from the heater/hydrator anywhere between the outlet 918 of the heater/hydrator 120 and the trocar assembly 921. Dispersion device 948 may be placed anywhere downstream of the agent chamber 925, such as being interposed in, or connected to, second conduit 920. When pressure is applied to the agent in the agent chamber 925, whether or not gas is flowing from the insufflation device 915, agent may be supplied into the abdomen 922 of the patient P.

Depending on the application, the constructions shown in Figs. 1-20 may be combined or duplicated to achieve the desired results. For example, one or more agents may be introduced through the heater/hydrator 120, and one or more agents may be introduced through one or more agent chambers (925,935). Also, any of the chambers shown may be single or multiple chambers, so as to provide for the addition of multiple agents. The gas may be heated and/or humidified, as desired. The chambers may be empty chambers, or have various means to absorb or adsorb liquid in them.

Referring now to Figure 21, there is shown one way in which agent may be introduced into an agent chamber (925,935). Although modified agent chamber 935 is illustrated in Figure 21, the apparatus shown will also work with agent chamber 925. An external port 950 is provided, which may have a closure member 968 to regulate flow through the port 950, into which syringe 951 containing the desired amount of agent may be inserted. At the proper time, the surgeon, anesthetist, or other medical personnel, will open the closure member 968, if present, and depress the plunger 952 of syringe 951 to inject the agent into the agent chamber (925,935), where it will travel to the patient's abdomen in the manner previously described.

Referring now to Figure 22, there is shown another device that may serve to introduce agent into an agent chamber (925,935) in various embodiments of the present

invention. In this embodiment, pump 954 is used to deliver the agent to the agent chamber (925,935). An external port 950 is provided to which pump 954, such as a peristaltic or other suitable type pump, is connected. A closure member 968 may be provided to regulate the flow into the port 150. A reservoir (not shown) containing at least the desired amount of agent is provided.

At the proper time, the surgeon, anesthetist, or other medical personnel, will open the closure member 968, if present, activate the pump 954 to supply the desired amount of the agent into the agent chamber (925, 935), where it will travel to the patients abdomen in the manner previously described. Note that in any of the embodiment discussed herein, closure member 968 could be an adjustable valve.

Referring now to Figure 23, there is shown a still further device that may serve to introduce agent into an agent chamber (925, 935) in embodiments of the present invention. In this embodiment, a pressurized cylinder 956 which has been pre-charged with a desired amount of agent is used to deliver the agent to the agent chamber (925, 935). An external port 950 is provided to which pressurized cylinder 956 is connected. A closure member 968 is interposed between cylinder 956 and port 950. The pre-charged cylinder, in addition to having a desired amount of agent contained therein, may have a predetermined amount of a pressurizing agent, such as an inert gas, contained therein, and may have apparatus (e.g. an electronically controlled valve) to cause the release of the agent at the desired time. At the proper time, the surgeon, anesthetist, or other medical personnel, may open the closure member 968, if present, and activate the release apparatus to supply the desired amount of the agent into the agent chamber, where it will travel to the patients abdomen in the manner previously described.

Referring now to Figure 24, there is shown yet another device which may serve to introduce agent into an agent chamber (925, 935) of the present invention. In this embodiment, a flexible bag 958 containing a desired amount of agent is connected by tubing 959 to the external port 950. Apparatus (e.g. an adjustable valve) to control the release of the agent from the flexible bag 958 may, or may not, be provided, depending on the application. The closure member 968 may serve as the release apparatus. At the desired time in the surgery, the flexible bag 958 will be squeezed, the release apparatus, if present, will be operated, and the agent will be forced into the agent chamber (925, 935).

It should be understood that all of the ways of introducing the agent into the agent chamber (925, 935) shown in Figures 21-24 will work with any of the embodiments of the invention shown in Figures 16-20. It should further be understood that other methods of introducing agent into the chamber (925, 935) may be used without departing from the scope of the invention.

Referring now to Figures 25-28, if a separate agent chamber is not desired for whatever reason, the syringe 951, pump 954, pressurized cylinder 956 and flexible bag 958 may be used by themselves to supply agent to the embodiments of the invention shown in Figures 16-20. An appropriate external port or connector 965 may be placed in line in the appropriate conduit so that the external port or connector 965 will be in the flow path of the insufflation gas. The operation of the various devices will be as just described with regard to Figures 21-24.

Referring now to Figure 29, there is shown an additional device that may serve as the agent chamber (925, 935) of the present invention. Piezoelectric chamber 961 comprises a hollow chamber 962 having an inlet 963 and an outlet 964. The piezoelectric chamber is connected in flow communication with the appropriate conduit to place it in the stream of the insufflation gas 970 when the insufflation device is in operation. In the hollow chamber 962 is placed a desired quantity of agent 966 in liquid form. The agent 966 will be placed in the chamber with the piezoelectric crystal 965. Piezoelectric crystal 965 may then be energized to activate the crystal.. Activation of the crystal 965 may cause the molecules of the agent to vibrate at such speeds as to produce an agent fog 967, which may be drawn into the insufflation gas stream 970 and delivered to the patient's abdomen.

With reference to Figure 30, there is shown a further alternative embodiment of the invention which is believed useful for the administration of agent into the abdomen of a patient. This embodiment of the invention involves the use of a modified syringe 971 being used with a trocar 972. The trocar 972 has a tubular portion 973 and an enlarged top portion 974. The modified syringe 971 has a normally sized hollow body portion 978 which sealingly accepts the plunger 979 for reciprocal movement in the body portion 978. Attached to, or integral with, the body portion 978 is an elongated, hollow, tubular, lower portion 980 having a dispersion device 948 mounted at the distal end thereof.

In use, agent is drawn into the modified syringe assembly 971, either through a needle, or the lower tubular portion 980. If not already attached, the lower tubular portion 980 is attached, and the modified syringe 971 is placed into the trocar assembly 972, with the lower tubular portion 980, and the dispersion device 948, slidably fitting in the tubular portion of the trocar 972.

The elongated tubular portion 980 of the modified syringe should be long enough so that when the modified syringe 971 is inserted in the trocar, the distal end 980A of the lower tubular portion 980 extends past the end of the tubular portion 973 of the trocar 972. In this manner, during surgery, when it is desired to add agent to the abdomen, and the modified syringe 971 is fully inserted into the trocar 972, the dispersion device 948 may actually be inside the pneumoperitoneum. Therefore, when the plunger 979 is depressed, the agent that has previously been drawn into the modified syringe 971 may be forced through the dispersion device 948, and may directly enter the abdomen as an aerosol, spray, mist, fog or vapor, depending on the dispersion device 948 used, and the agent. Some agents may not be capable of being dispersed in all forms.

Referring now to Figure 31, there is shown a two-inlet trocar 930. Two-inlet trocar 930 is similar in some respects to trocars known in the art in that it has a tubular body portion 975, having an enlarged top portion 975A and has a single inlet 976 for the admission of insufflation gas, such as that which may be supplied from insufflation device 915. Due to the potential desirability of introducing the agent into the insufflation gas stream right at the trocar, two-inlet trocar 930 with second inlet 977 may be desirable. When desired, the insufflation gas stream may enter the two-inlet trocar 930 through first inlet 976, and the agent gas stream may enter the trocar through the second inlet 977 (or vice versa).

A modification of the trocar construction shown in Figure 31 is shown in Figure 32. Modified trocar 933 is shown. Modified trocar 933 has a tubular body portion 975 and enlarged top portion 974 as before. In addition, it has inlet 976. However, instead of having a second inlet 977, it has a branch inlet 934 which branches off the inlet 976 to provide for the agent stream to be connected directly to the modified trocar 933, but without the provision of an entirely separate second inlet. A dispersion device 948 is optionally provided at the distal end of the branch outlet 934. Closure members 968 are optionally provided.

Referring now to Figure 33, a further embodiment of the invention, which is, in some respects similar to the embodiment shown in Figure 32, is shown. This embodiment of the invention uses most of the construction of Figure 32 in that the modified trocar 933 having a lower tubular portion 975 and enlarged top portion 974 is used with a single inlet 976 and a branch outlet 934. In this modification, the branch inlet is sized and shaped to accommodate a pressurized aerosol spray can 981which has a desired amount of agent and propellant contained therein.

The pressurized container or spray can 981 has a nozzle 982 with an orifice that should be chosen, depending on the agent being used, to create an aerosol spray, mist, fog, or vapor, if possible. The nozzle 982 may be adapted to be press fit onto the branch inlet 934. Because the nozzle may create the desired dispersion, dispersion device 948 may be omitted in this embodiment of the invention, but could also be included, if desired.

Referring now to Figure 34, there is shown a flow chart illustrating a series of steps in which various embodiments of the invention may be used. At Box 1000, the first step is to gain access to the abdomen 922 of the patient P. This may be done by any of several well known surgical techniques known to those skilled in the art of surgery, and will usually involve making a surgical incision in the patient's abdomen and inserting a trocar therein.

Next (Box 1010) a gas stream of insufflation gas may be introduced into the patient's abdomen 922. This will involve the steps of providing an insufflation device 120, creating a flow path between the insufflation device and the trocar, and initially inflating the patient's abdomen with about 2-3 liters of insufflation gas. After the initial inflation of the patient's abdomen, insufflation gas may continue to flow into the abdomen at the desired rate or may cease to flow depending upon the particular circumstances.

The agent, or agent stream may then be introduced into the pneumoperitoneum along with the insufflation gas (Box 1020). A predetermined concentration suitable for a particular procedure may be chosen.

Once the desired concentration of agent has been determined for the surgical procedure being performed, there are several ways the agent may be introduced into the pneumoperitoneum, as described above.

Regardless of the method used, when the desired amount of agent has been introduced, the flow of agent or agent stream will be shut off (Box 1030).

Throughout this application, various patents publications are referenced. The disclosures of these publications in their entireties are hereby incorporated by reference into this application in order to more fully describe the state of the art to which this invention pertains.

Although the present process has been described with reference to specific details of certain embodiments thereof, it is not intended that such details should be regarded as limitations upon the scope of the invention except as and to the extent that they are included in the accompanying claims.

CLAIMS

1. An apparatus for introducing chemotherapy agent into the abdomen of a patient comprising:
   a) an insufflation device;
   b) at least one structure defining at least one fluid flow path extending at least a portion of the distance between the insufflation device and the abdomen; and
   c) a chamber adapted to be coupled to the at least one structure and adapted to supply chemotherapy agent to the interior of the abdomen through the at least one structure.

2. The apparatus of Claim 1, further comprising a dispersion device configured to cause dispersion of the chemotherapy agent.

3. The apparatus of Claim 1, wherein the chamber is pre-charged.

4. The apparatus of Claim 1, wherein the chamber has an external port to accept a charging device.

5. The apparatus of Claim 4, wherein the charging device is a syringe.

6. The apparatus of Claim 1, wherein the chamber is a syringe.

7. The apparatus of Claim 1, wherein the chamber is a bag.

8. The apparatus of Claim 1, wherein the chamber is a pump.

9. The apparatus of Claim 2, wherein said dispersion device produces an aerosol.

10. The apparatus of Claim 2, wherein said dispersion device produces a spray.

11. The apparatus of Claim 2, wherein said dispersion device produces a mist.

12. The apparatus of Claim 2, wherein said dispersion device produces a fog.

13. The apparatus of Claim 2, wherein said dispersion device produces a vapor.

14. A chemotherapy agent delivery system for use with an insufflation device capable of providing a gas stream to the abdomen of a patient comprising:
a) at least one structure defining at least one fluid flow path extending at least a portion of the distance between the insufflation device and the abdomen; and
b) a chamber adapted to be coupled to the at least one structure and adapted to supply chemotherapy agent to the interior of the abdomen through the at least one structure.

15. The apparatus of Claim 14, comprising a dispersion device in fluid communication with the chamber and downstream thereof.

16. The apparatus of Claim 14, comprising a dispersion device interposed between the chamber and the trocar.

17. The apparatus of Claim 14, wherein the chamber is pre-charged.

18. The apparatus of Claim 14, wherein the chamber has an external port to accept a charging device.

19. The apparatus of Claim 1, wherein the chamber is a piezoelectric chamber.

20. A trocar having a first inlet for insufflation gas, and a separate, second, inlet for a chemotherapy agent.

21. A trocar having a first inlet for insufflation gas, and a branch inlet in fluid communication with the first inlet for chemotherapy agent.

22. The apparatus of Claim 21, wherein an aerosol can comprising a pressurized source of chemotherapy agent is connected to the branch inlet.

23. A method of medicating a patient with a chemotherapy agent, comprising:
a) supplying a gas stream from an insufflator;
b) injecting at least one chemotherapy agent into the gas stream to produce a chemotherapy agent gas stream; and
c) delivering the chemotherapy agent gas stream into the patient's body during an endoscopy procedure.

24. The method of Claim 19, wherein the chemotherapy agent is injected by passing the gas stream through a chamber containing an absorbent material which has absorbed at least a first quantity of the chemotherapy agent.

25. The method of Claim 20, wherein the chamber further comprises a port in fluid communication with the chamber.

26. The method of Claim 20, further comprising heating the gas stream within the chamber.

27. The method of Claim 20, further comprising heating and humidifying the gas stream within the chamber wherein the humidifying step employs a humidifying agent separate from the chemotherapy agent.

28. The method of Claim 20, further comprising humidifying the gas stream within the chamber wherein the humidifying step employs a humidifying agent separate from the chemotherapy agent.

29. The method of Claim 19, further comprising heating the gas stream.

30. The method of Claim 19, further comprising heating and humidifying the gas stream.

31. The method of Claim 19, further comprising humidifying the gas stream.

32. The method of Claim 19, further comprising heating the chemotherapy agent gas stream.

33. The method of Claim 19, further comprising heating and humidifying the chemotherapy agent gas stream.

34. The method of Claim 19, further comprising humidifying the chemotherapy gas stream.

AMENDED CLAIMS

[received by the International Bureau on 23 May 2005 (23.05.05);
original claims 1 and 14 amended; claims 2-13, 15-34 remain unchanged (2 pages)]

1. An apparatus for introducing chemotherapy agent into the abdomen of a patient comprising:
   a) an insufflation device;
   b) at least one structure in fluid communication with the insufflation device and defining at least one fluid flow path extending at least a portion of the distance between the insufflation device and the abdomen; and
   c) a chamber adapted to be coupled to the at least one structure and adapted to supply a chemotherapy agent to the interior of the abdomen through the at least one structure.

2. The apparatus of Claim 1, further comprising a dispersion device configured to cause dispersion of the chemotherapy agent.

3. The apparatus of Claim 1, wherein the chamber is pre-charged.

4. The apparatus of Claim 1, wherein the chamber has an external port to accept a charging device.

5. The apparatus of Claim 4, wherein the charging device is a syringe.

6. The apparatus of Claim 1, wherein the chamber is a syringe.

7. The apparatus of Claim 1, wherein the chamber is a bag.

8. The apparatus of Claim 1, wherein the chamber is a pump.

9. The apparatus of Claim 2, wherein said dispersion device produces an aerosol.

10. The apparatus of Claim 2, wherein said dispersion device produces a spray.

11. The apparatus of Claim 2, wherein said dispersion device produces a mist.

12. The apparatus of Claim 2, wherein said dispersion device produces a fog.

13. The apparatus of Claim 2, wherein said dispersion device produces a vapor.

14. An anti-adhesion agent delivery system for use with an insufflation device capable of providing a gas stream to the abdomen of a patient comprising:
a) at least one structure in fluid communication with an insufflation device and defining at least one fluid flow path extending at least a portion of the distance between the insufflation device and the abdomen; and
b) a chamber adapted to be coupled to the at least one structure and adapted to supply a chemotherapy agent to the interior of the abdomen through the at least one structure and the gas stream.

15. The apparatus of Claim 14, comprising a dispersion device in fluid communication with the chamber and downstream thereof.

16. The apparatus of Claim 14, comprising a dispersion device interposed between the chamber and the trocar.

17. The apparatus of Claim 14, wherein the chamber is pre-charged.

18. The apparatus of Claim 14, wherein the chamber has an external port to accept a charging device.

19. The apparatus of Claim 1, wherein the chamber is a piezoelectric chamber.

20. A trocar having a first inlet for insufflation gas, and a separate, second, inlet for a chemotherapy agent.

21. A trocar having a first inlet for insufflation gas, and a branch inlet in fluid communication with the first inlet for chemotherapy agent.

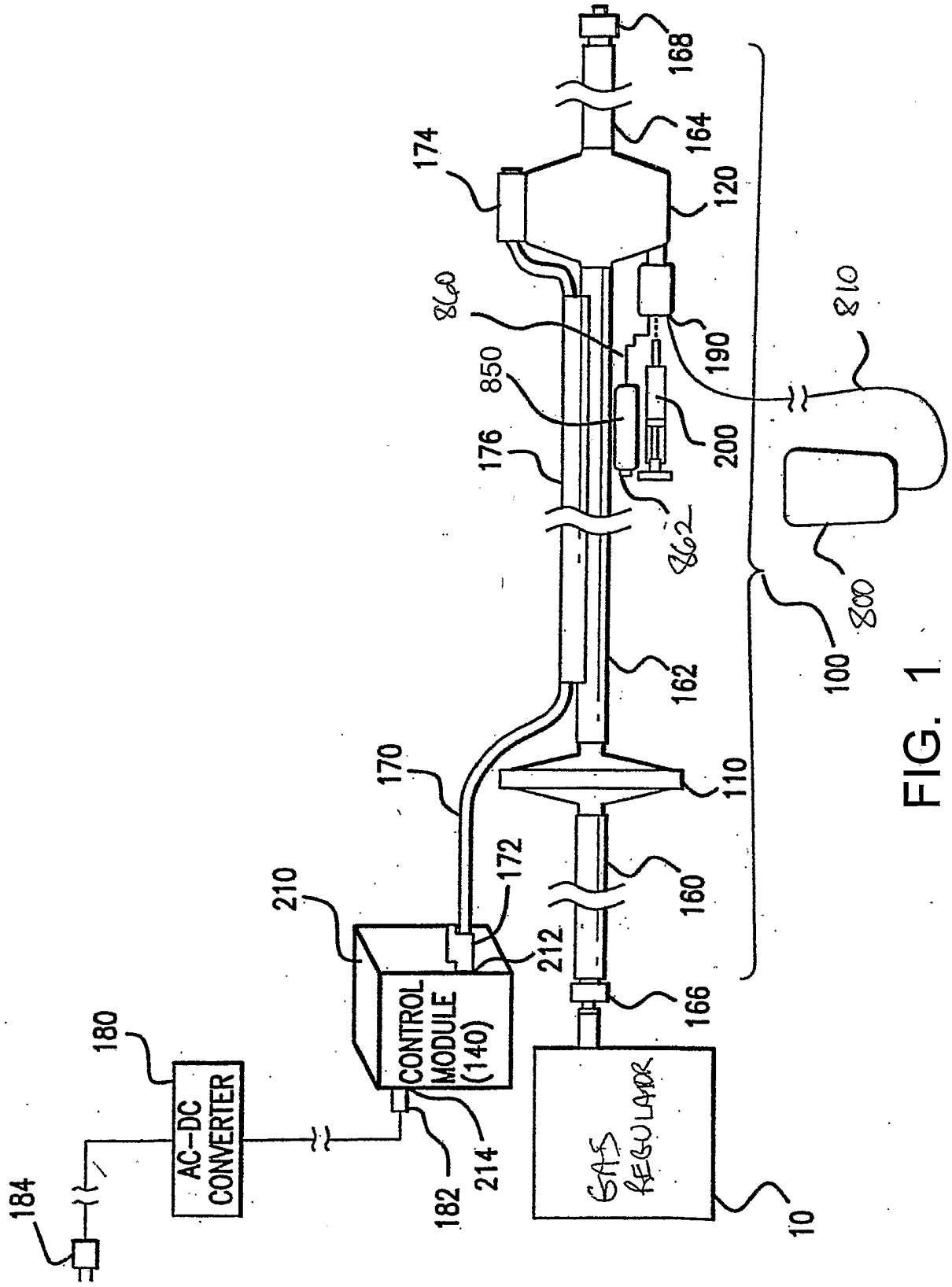

168
164
174
120
860
810
850
190
176
200
862
800
100
162
170
110
160
210
172
212
166
CONTROL MODULE (140)
180
AC-DC CONVERTER
184
182
214
GAS REGULATOR
10

FIG. 1

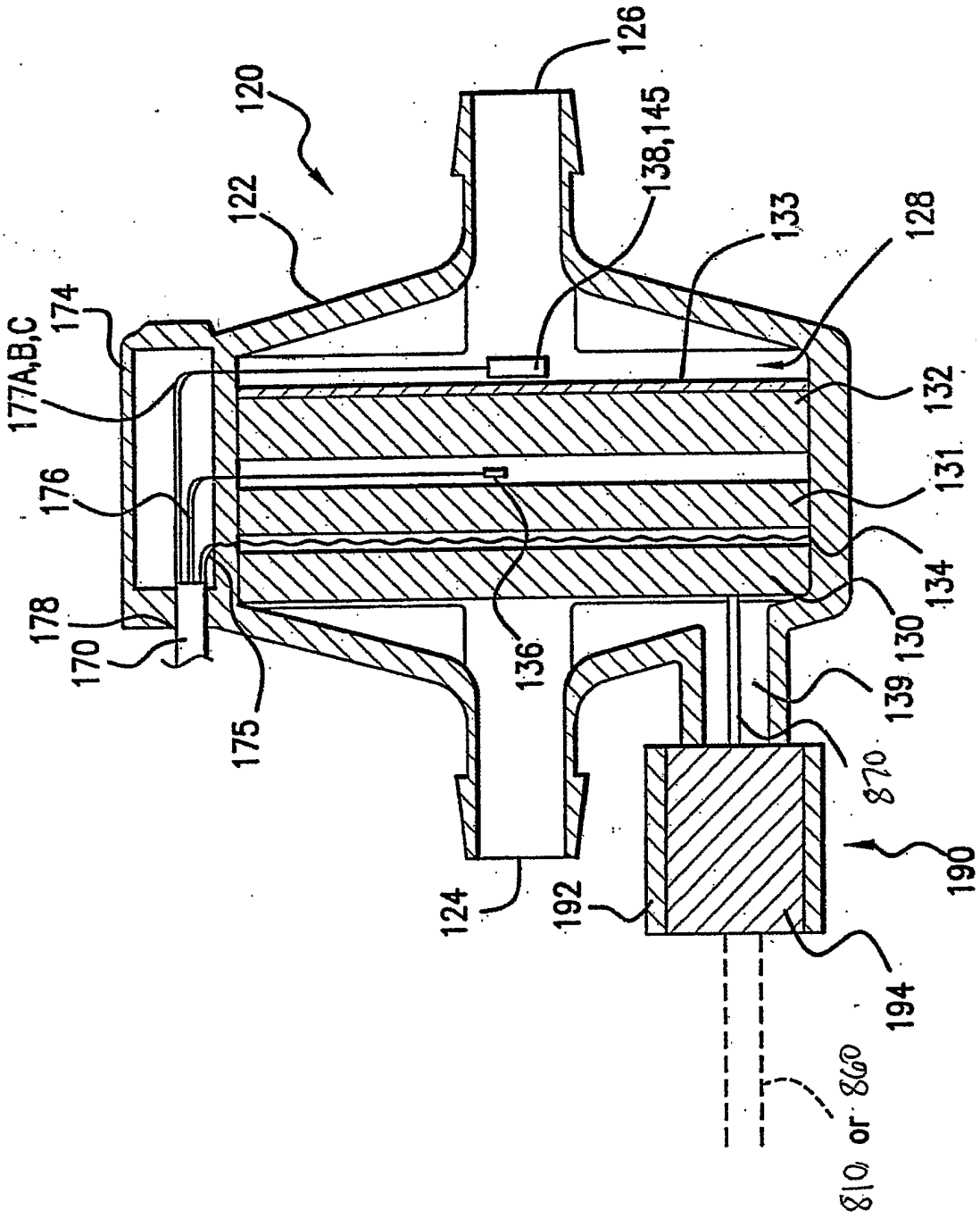

120
122
126
138,145
133
128
174
177A,B,C
176
178
170
175
136
132
131
134
130
139
870
190
124
192
194
810 or 860

FIG. 2

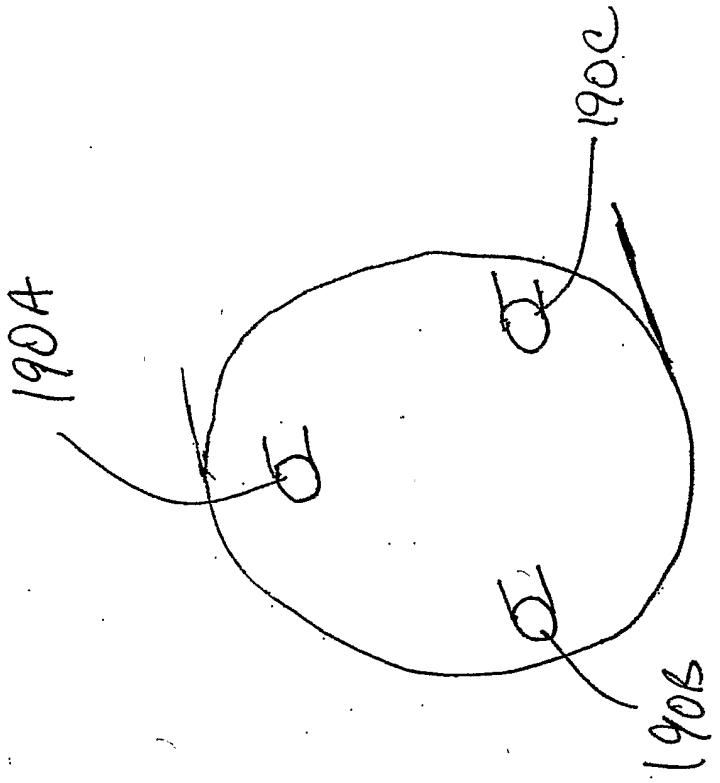


FIG. 4

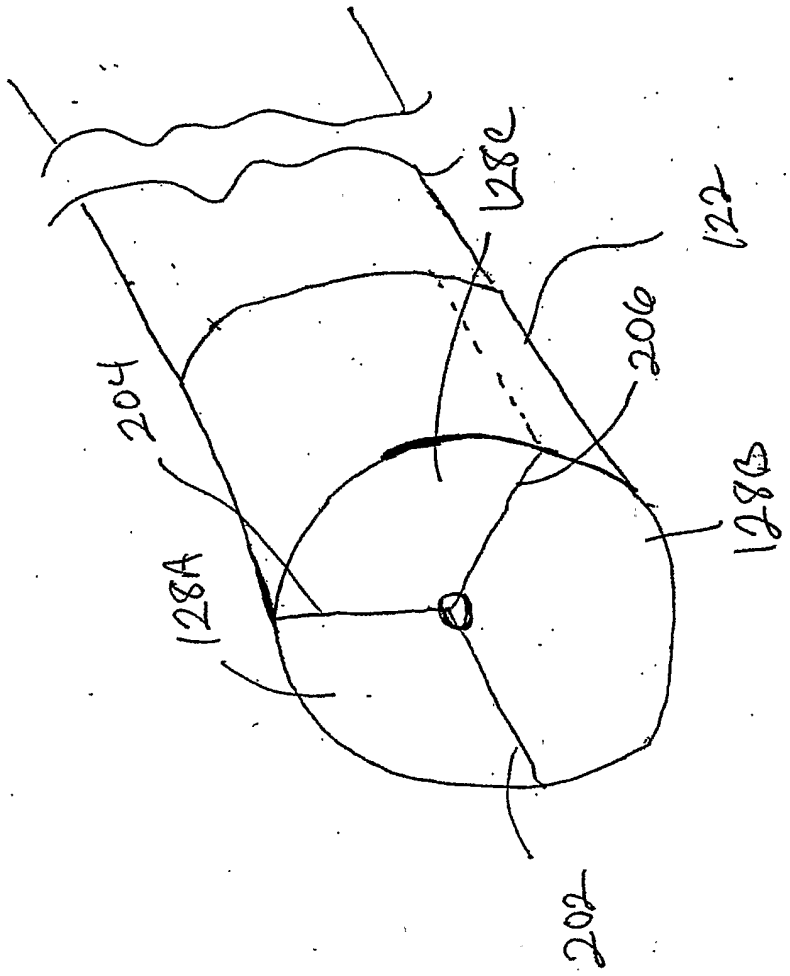


FIG. 3

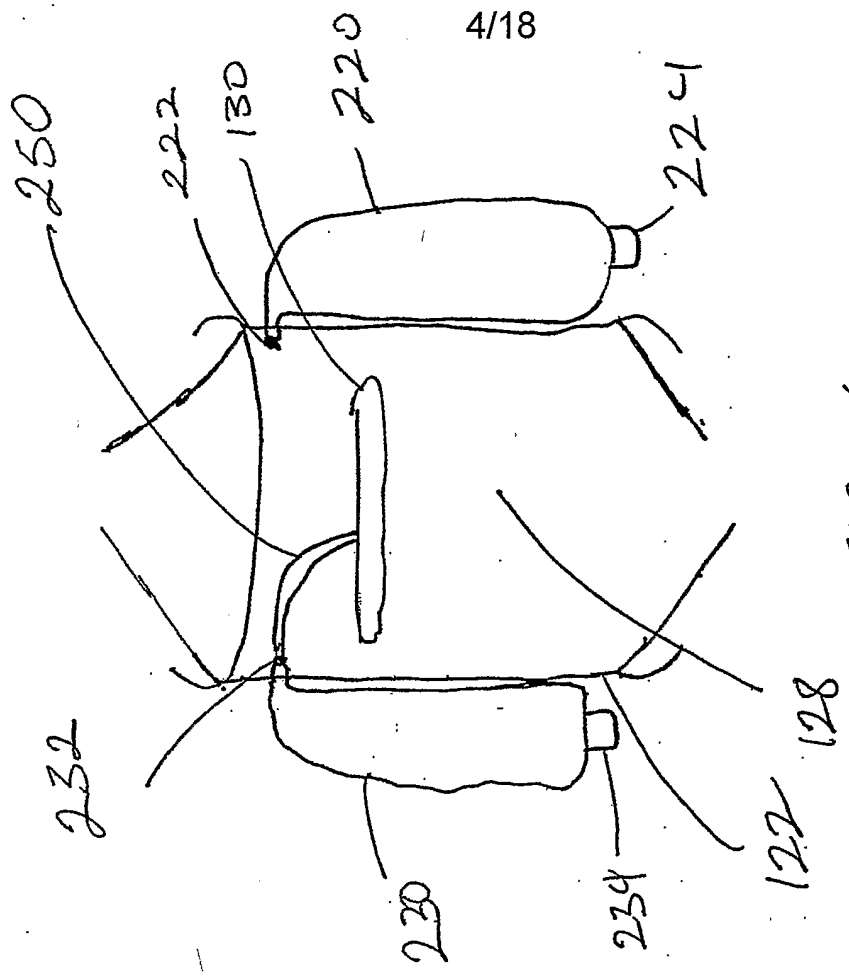

250
222
130
220
224
232
128
122
234
220

FIG. 6

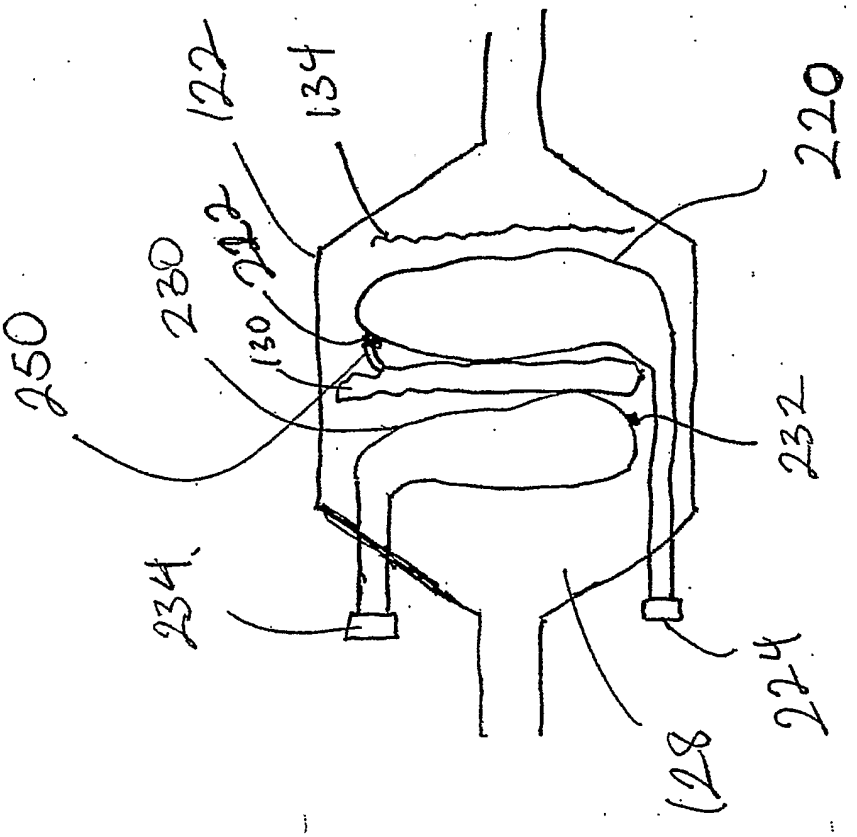

122
134
220
230
222
130
250
232
234
224
128

FIG. 5

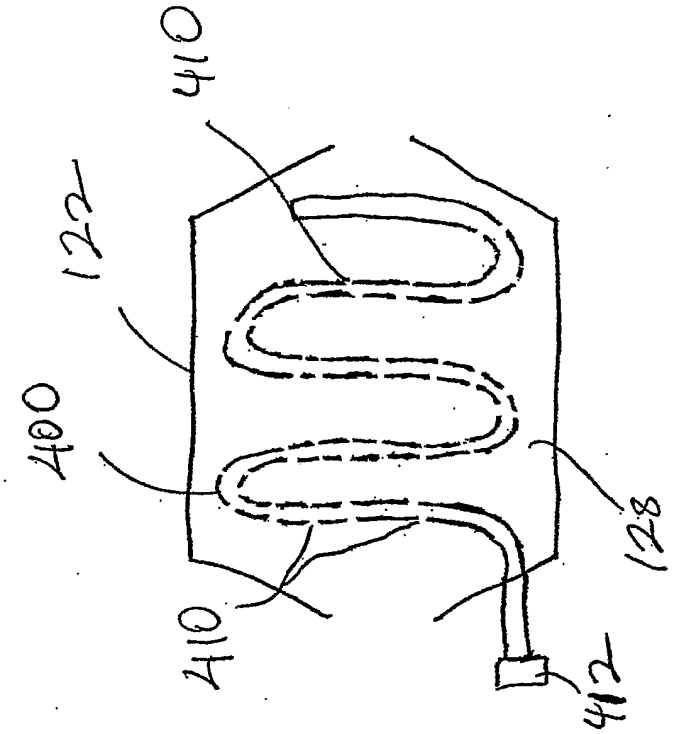


FIG. 8

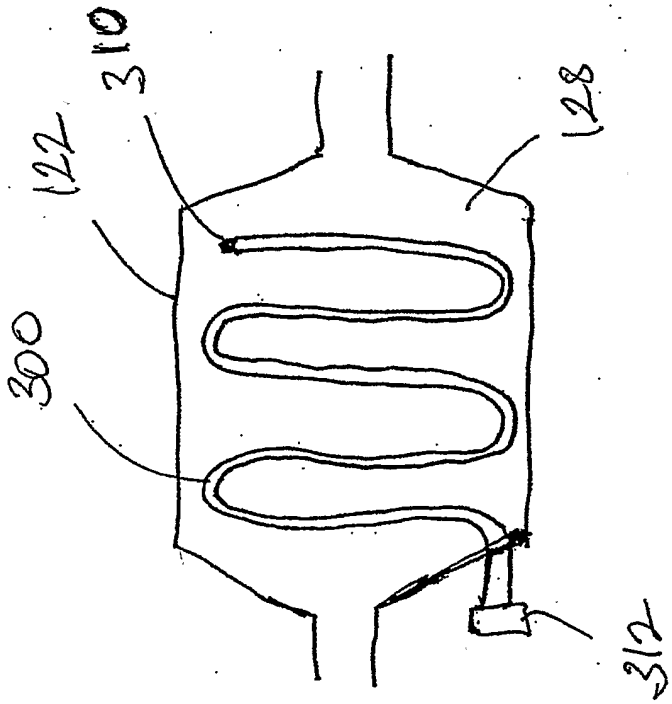


FIG. 7

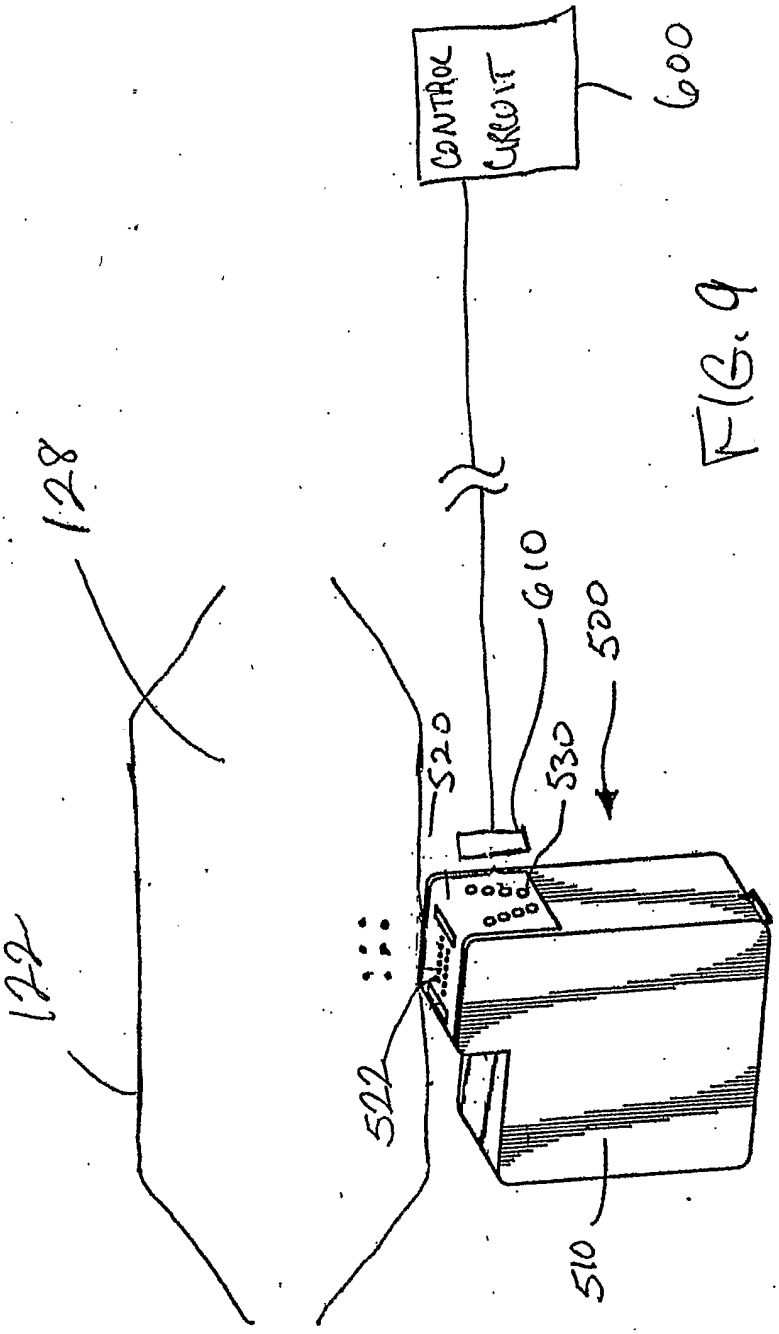


FIG. 9

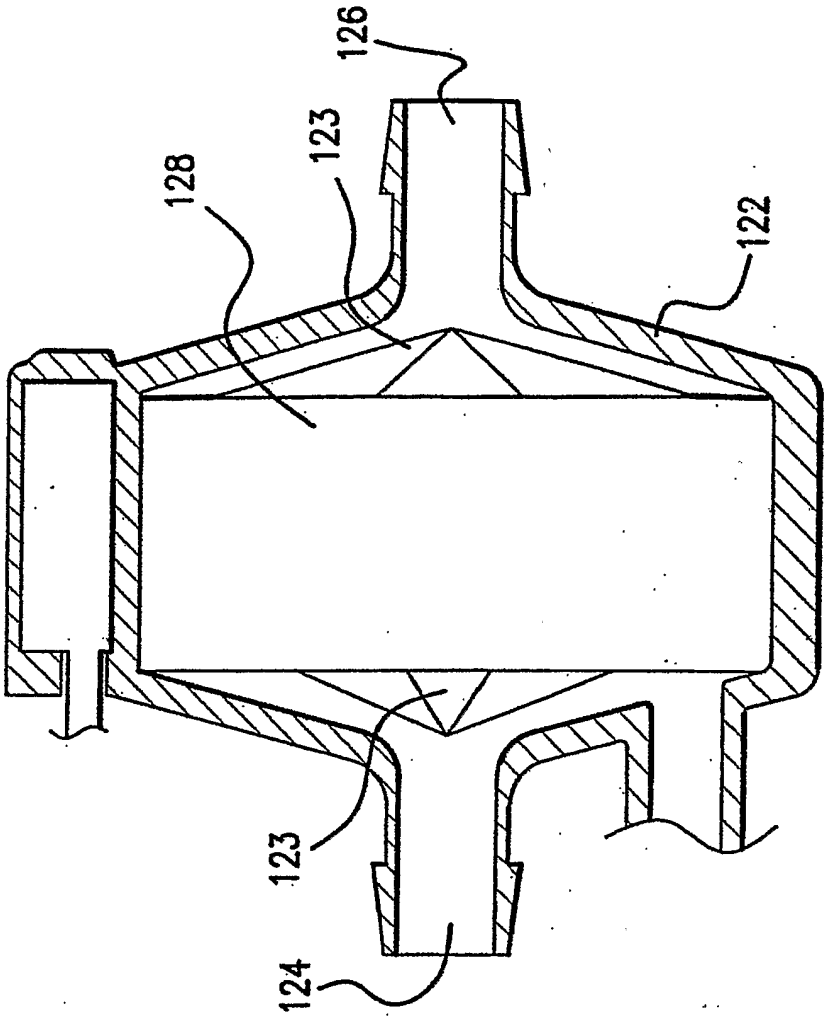


FIG. 11

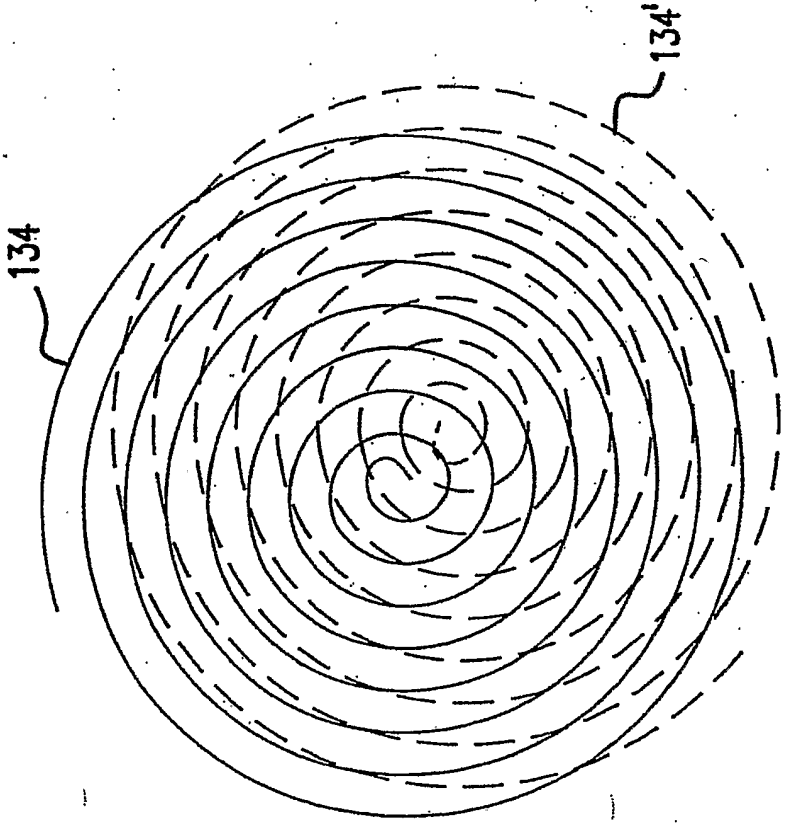


FIG. 10

FIG. 12

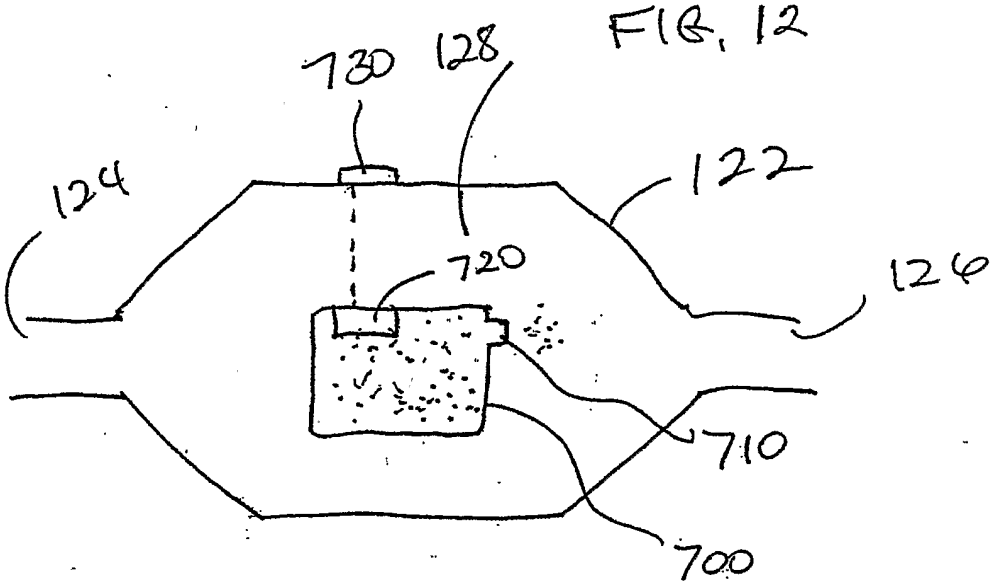
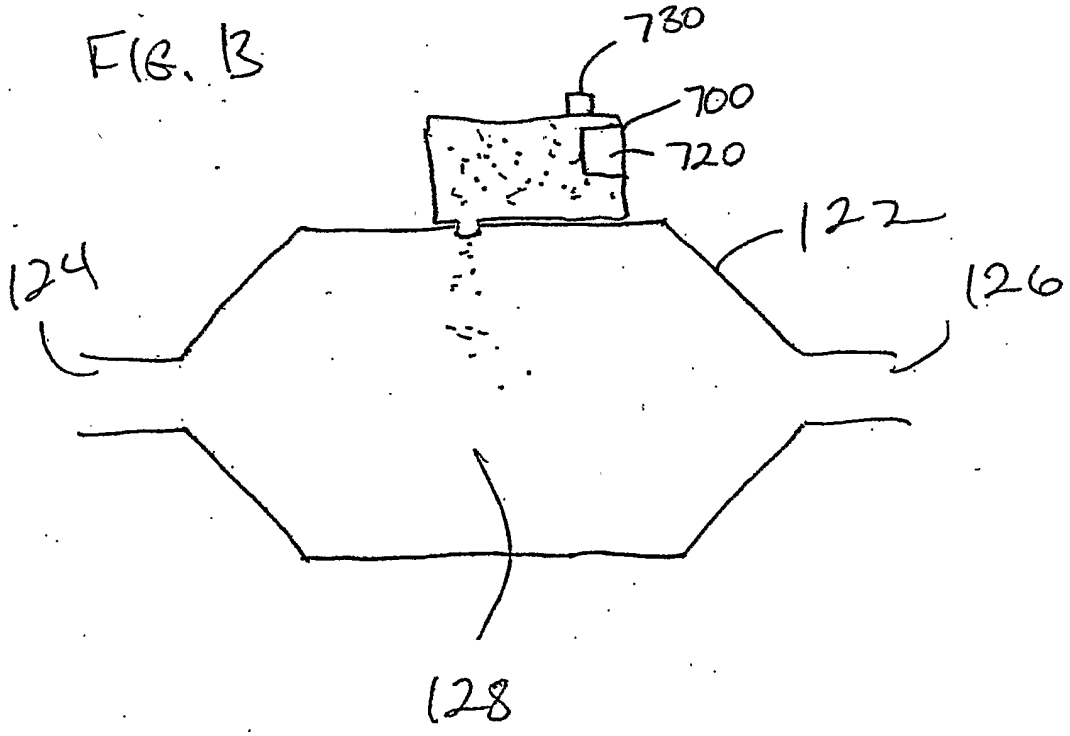


FIG. 13



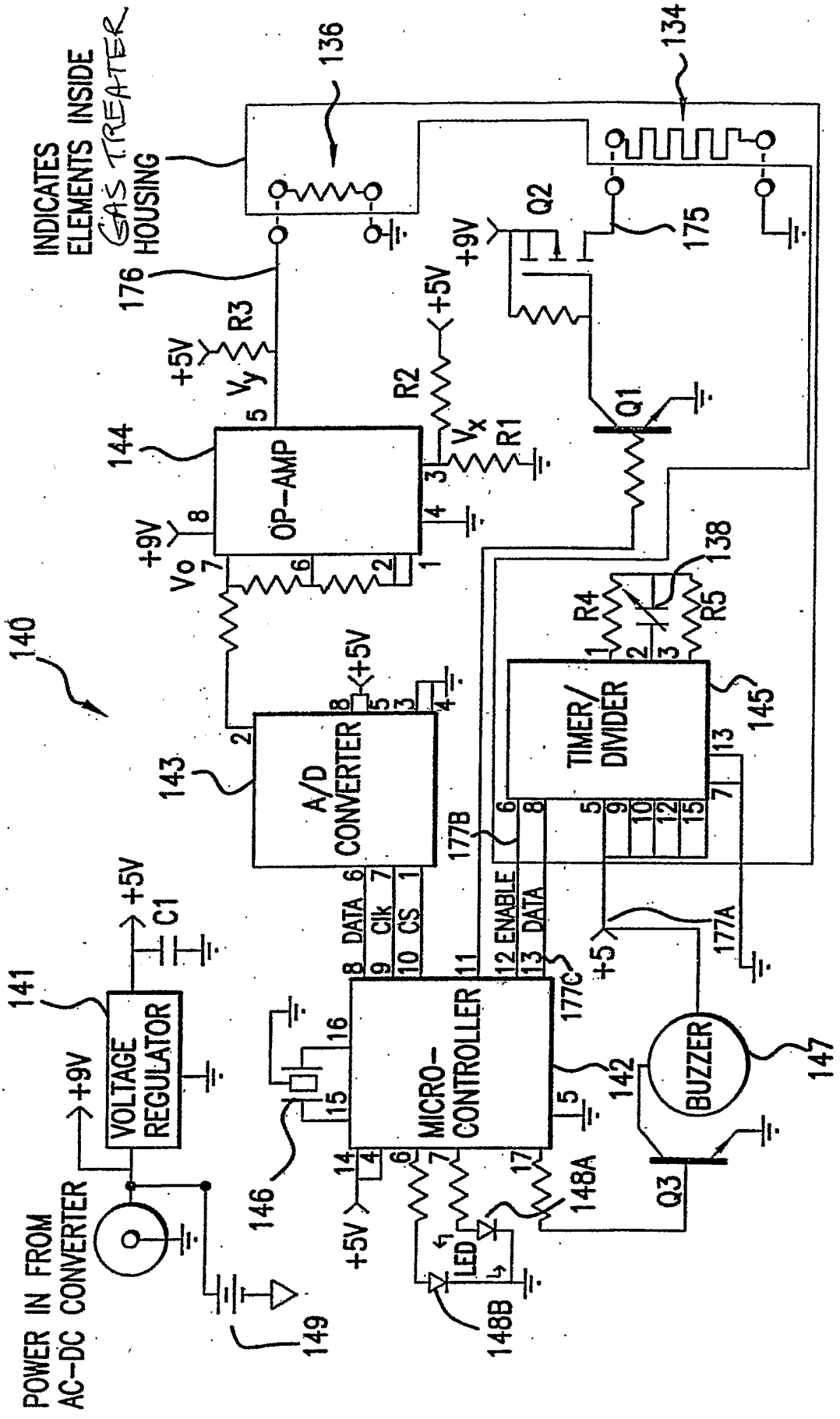

INDICATES ELEMENTS INSIDE GAS TREATER HOUSING
136
134
176
+5V
R3
Vy
+5V
R2
Vx
R1
+9V
Q2
175
Q1
144
OP-AMP
+9V
Vo
138
R4
R5
140
+5V
143
A/D CONVERTER
TIMER/ DIVIDER
145
177B
DATA
Clk
CS
ENABLE
DATA
+5
177A
177C
+5V
C1
141
+9V
VOLTAGE REGULATOR
MICRO-CONTROLLER
142
BUZZER
147
POWER IN FROM AC-DC CONVERTER
146
+5V
LED
148A
Q3
148B
149

FIG. 14

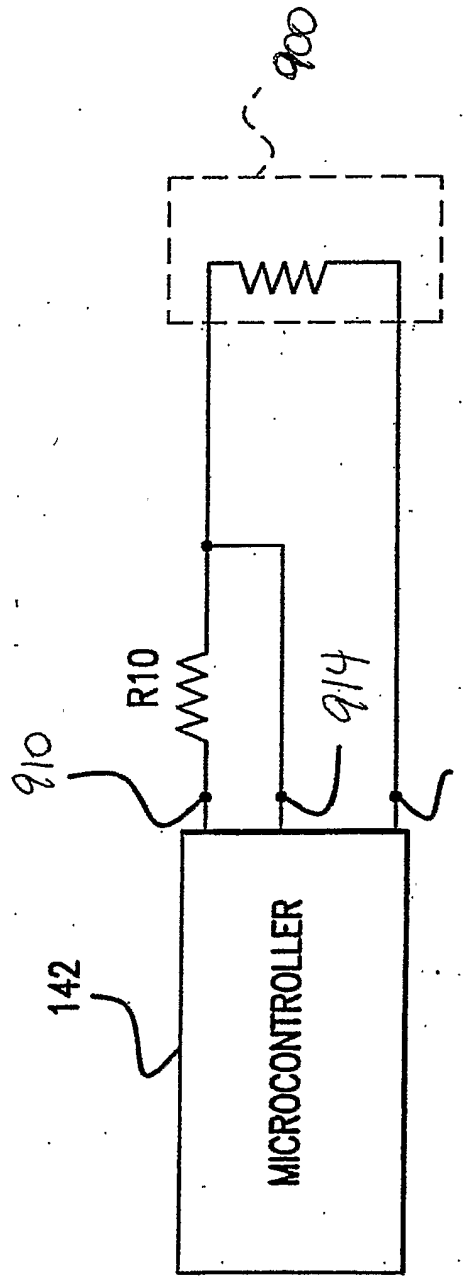
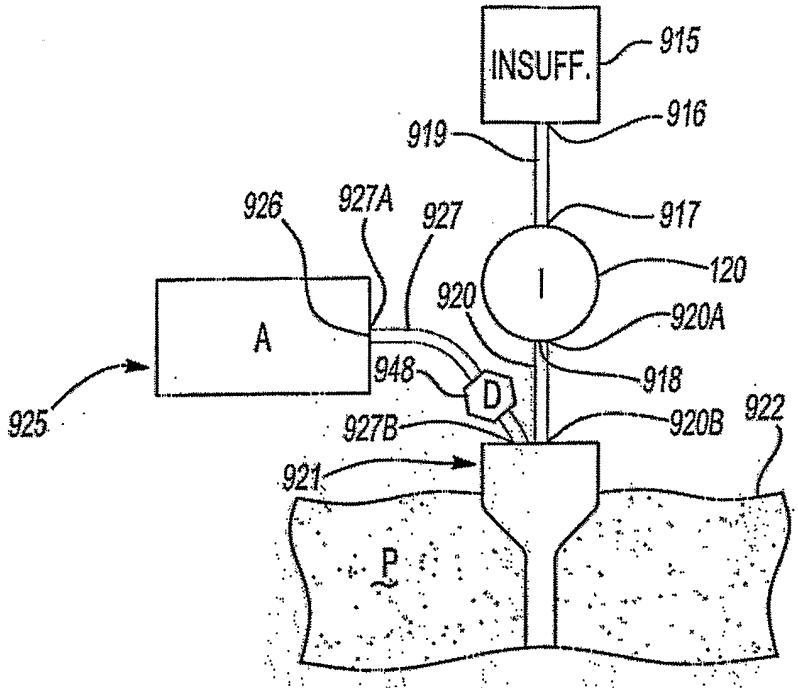


FIG. 15

Fig-16


INSUFF.
915
916
919
917
926
927A
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120
I
920
920A
A
948
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918
925
927B
920B
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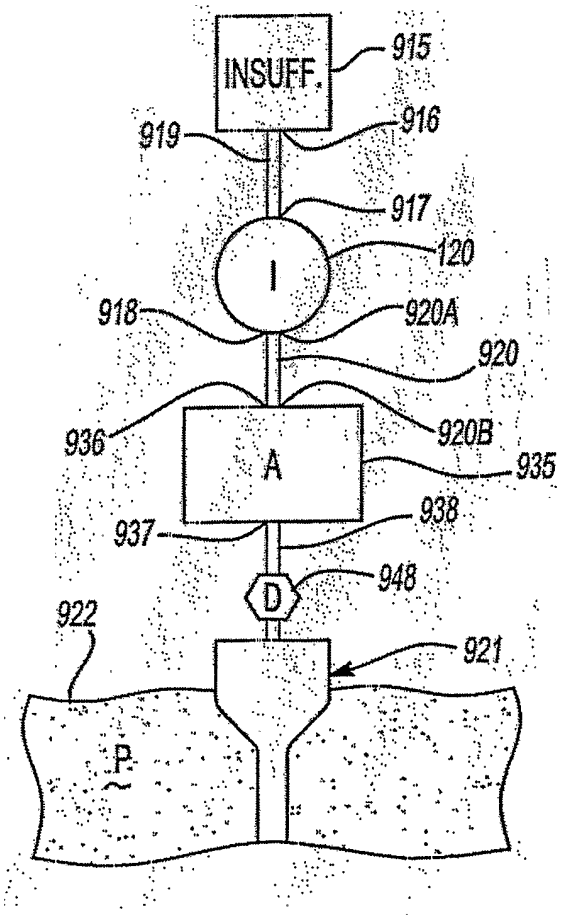

INSUFF.
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P

Fig-17

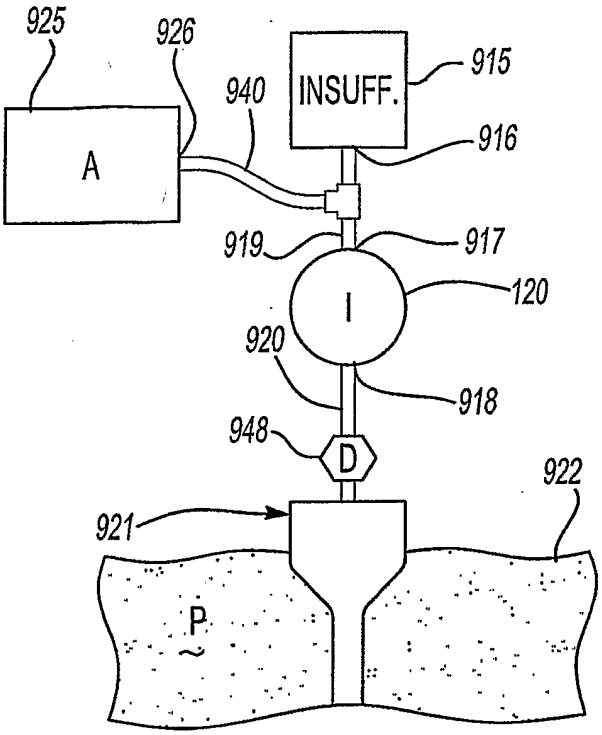

925
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940
INSUFF.
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P

Fig-18

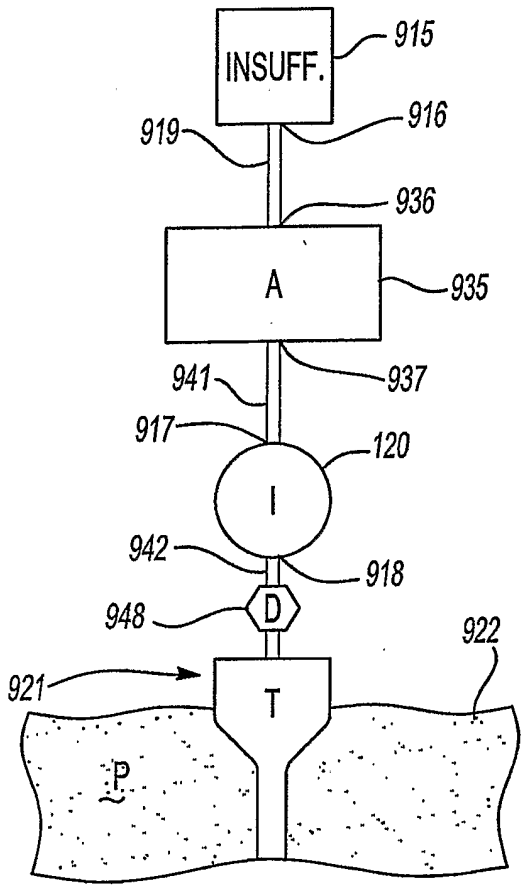

INSUFF.
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Fig-19

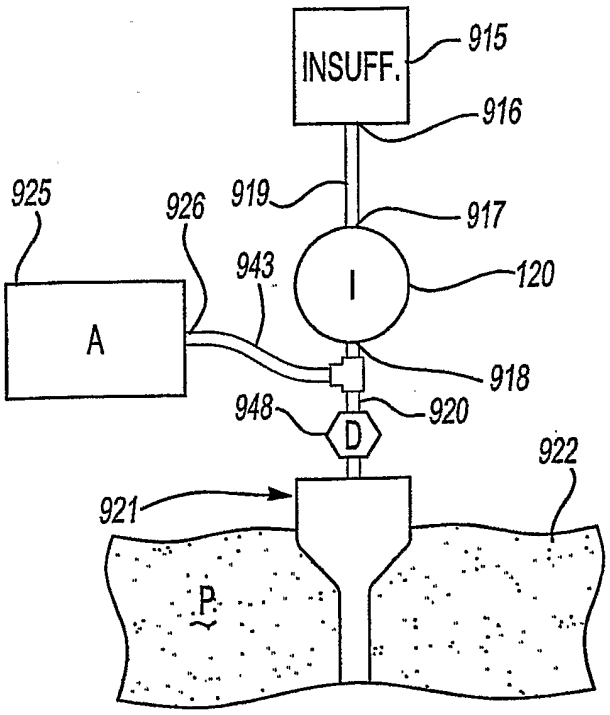

INSUFF.
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D
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922
921
P

Fig-20

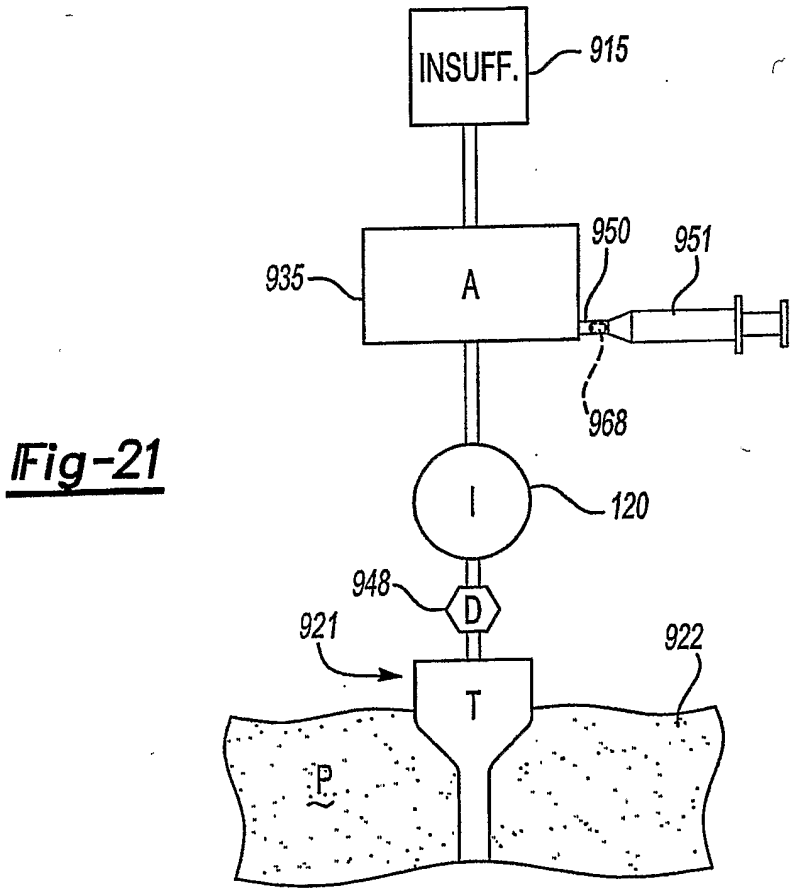

INSUFF.
915
950
951
935
A
968
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D
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T
P

Fig-21

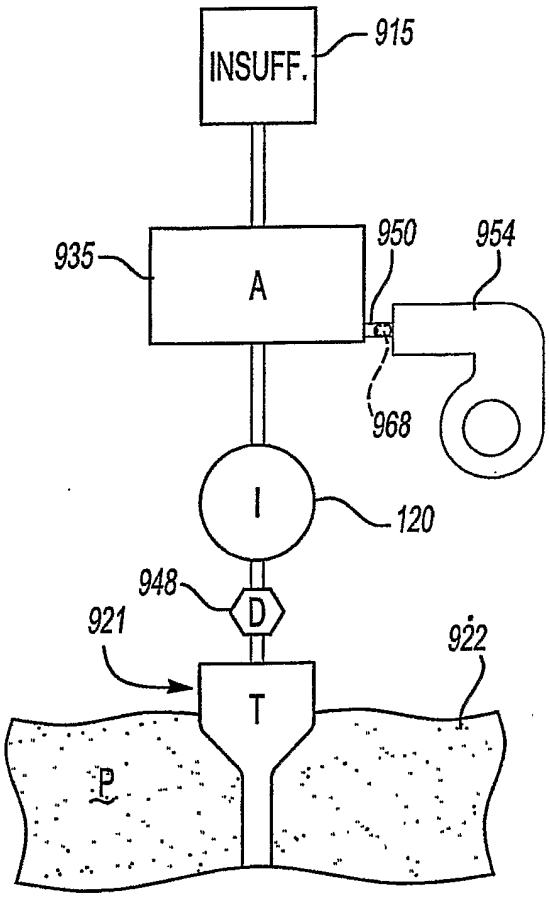

INSUFF.
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Fig-22

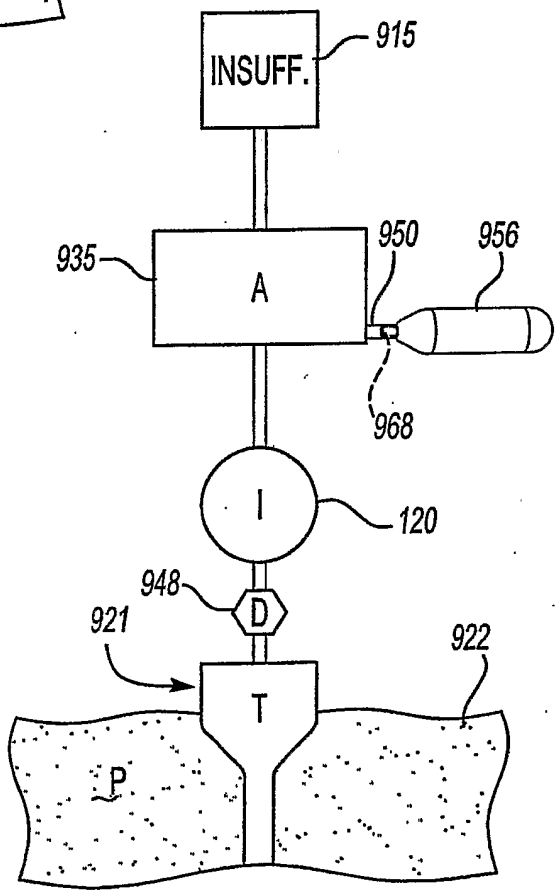

INSUFF.
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Fig-23

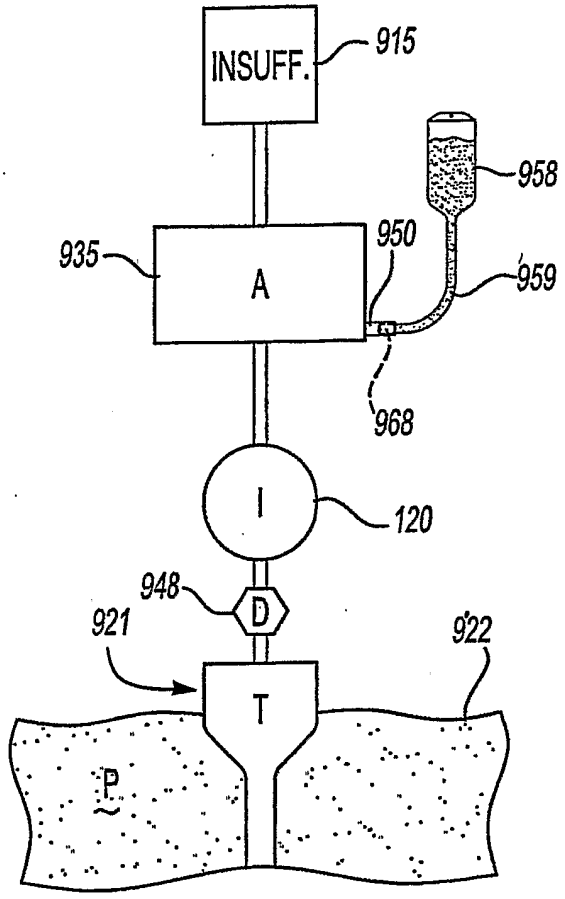


Fig-24

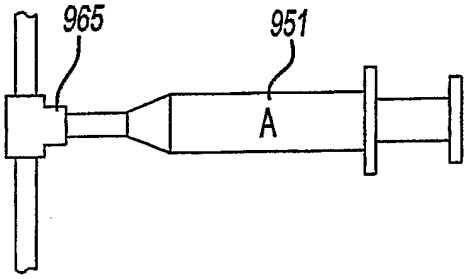


Fig-25

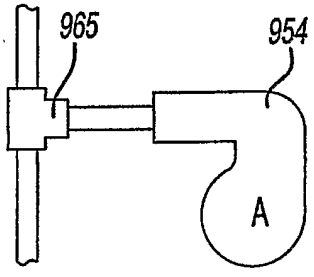


Fig-26

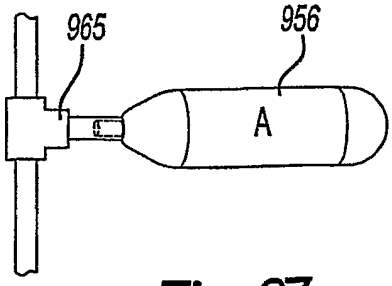


Fig-27

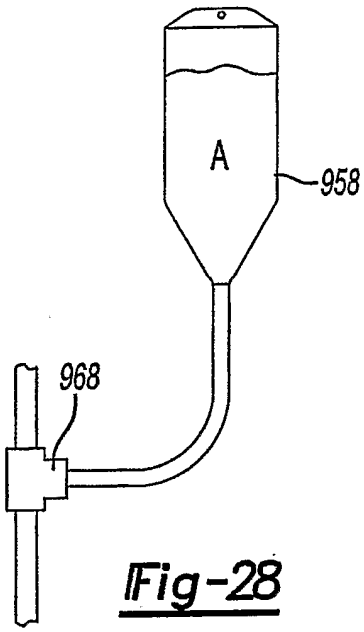


Fig-28

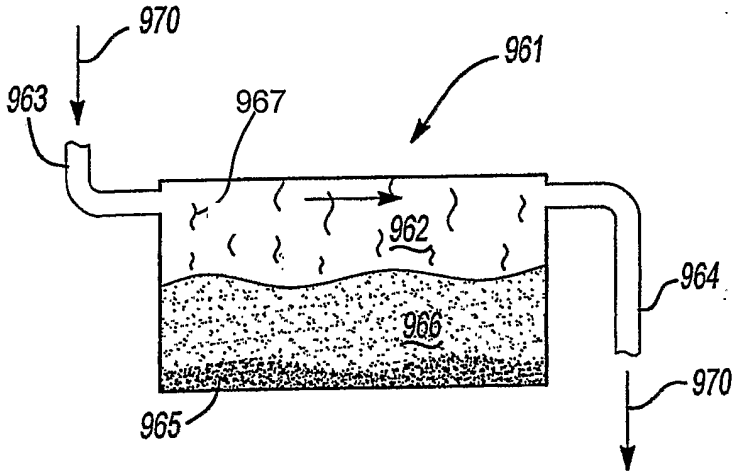


Fig-29

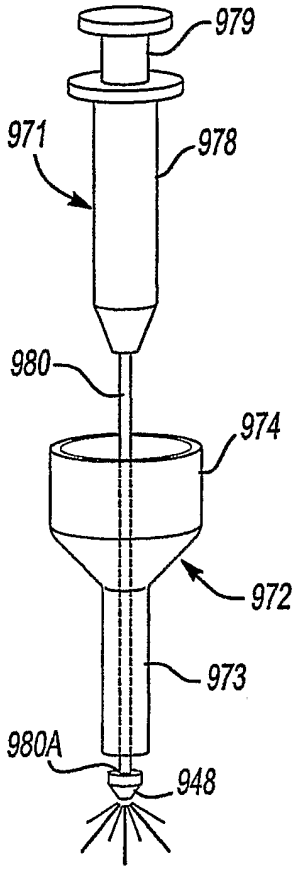


Fig-30

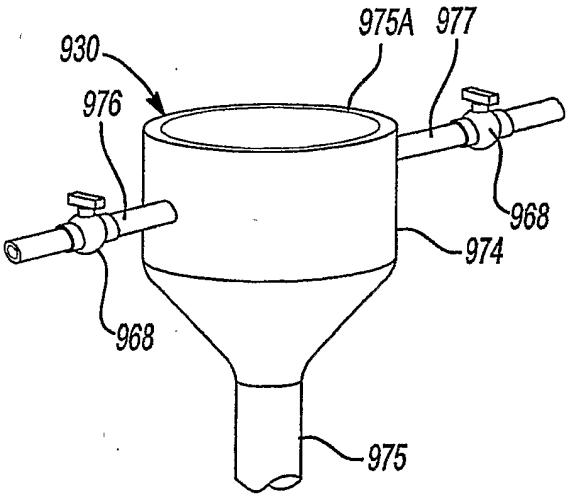


Fig-31

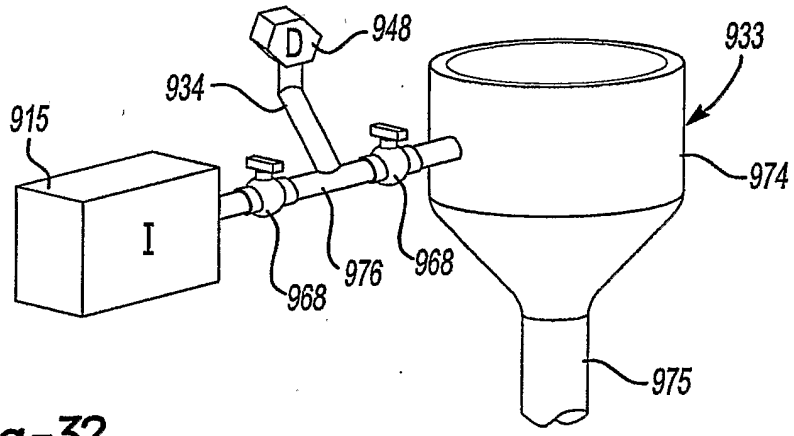


Fig-32

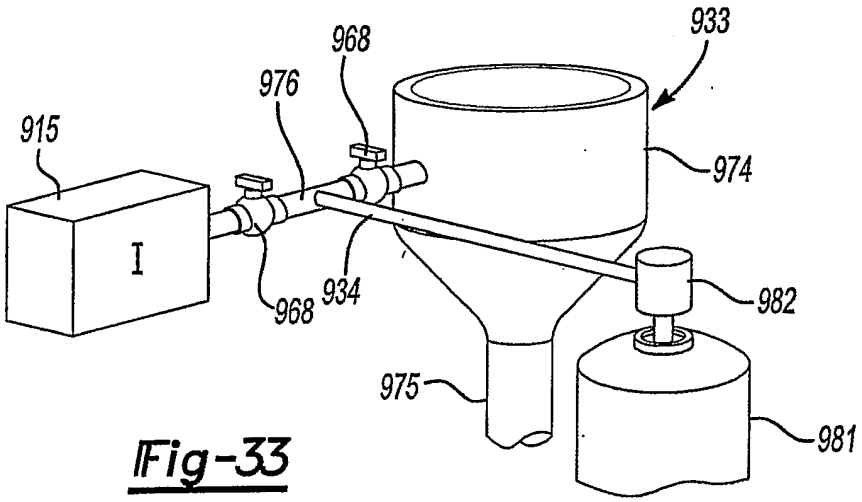


Fig-33

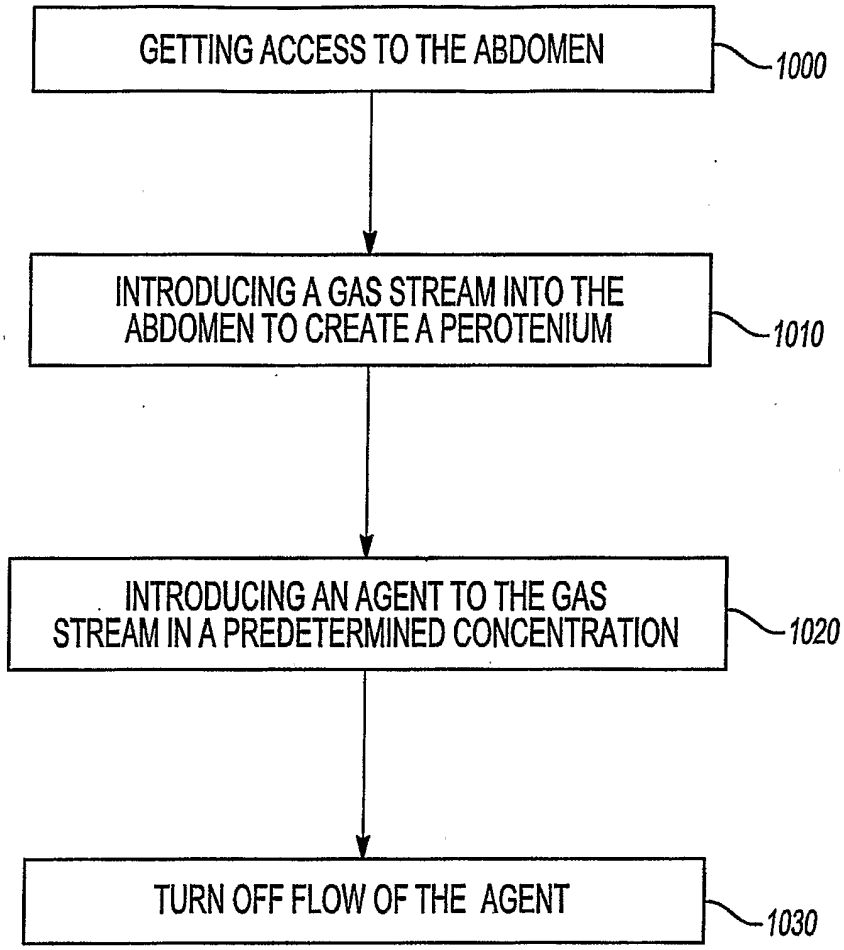

GETTING ACCESS TO THE ABDOMEN
1000
INTRODUCING A GAS STREAM INTO THE ABDOMEN TO CREATE A PEROTENIUM
1010
INTRODUCING AN AGENT TO THE GAS STREAM IN A PREDETERMINED CONCENTRATION
1020
TURN OFF FLOW OF THE AGENT
1030

Fig-34

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US04/32865

A. CLASSIFICATION OF SUBJECT MATTER
IPC(7) : A61M 37/00
US CL : 604/26
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 604/26, 23, 500

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EAST BRS ; insufflat$, trocar, chemohterapy

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 4,230,116 A (WATSON) 28 October 1980, see abstract, columns 1-2,7--10, and figures 1,8-16.	1-6,9-18,20-26 --- 7-8
A	US 6,203,517 B2 (SHIPP et al.) 20 March 2001, see abstract, columns 2-9 and figures 1,6-10.	1-34
Y	US 5,411,474 A (OTT et al.) 02 MAY 1995. see abstract, columns 1-5, and figures 1-2.	19,27-34

☐ Further documents are listed in the continuation of Box C. ☐ 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 application or patent 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
07 March 2005 (07.03.2005)	31 MAR 2005
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer LoAn H. Thanh Sharon N. Greene for Telephone No. (703) 308-0858

Form PCT/ISA/210 (second sheet) (January 2004)