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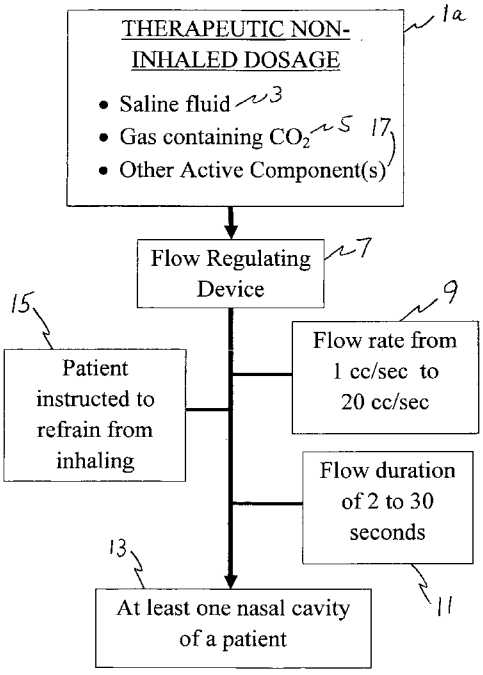
— *as to the identity of the inventor (Rule 4.17(i))*

[Continued on next page]

(54) **Title**: CARBON DIOXIDE AND SALINE NASAL DELIVERY METHODS AND DELIVERY DEVICES

FIGURE 1a



(57) **Abstract**: Methods for treating ailments in a patient in need thereof includes the step of directing a therapeutic, non-inhaled dosage to at least one nasal cavity of the patient through a flow regulating device while the patient refrains from inhaling. The dosage includes a saline fluid and a gas containing carbon dioxide, and, in some dosages, additional active component(s) wherein the therapeutic, non-inhaled dosage is delivered at a specified flow rate; the delivery devices are also included.

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CARBON DIOXIDE AND SALINE NASAL DELIVERY METHODS AND DELIVERY DEVICES

Attorney Docket No. GTI-131PCT

REFERENCES TO RELATED APPPLICATIONS

[0001] This application is based on previously filed United States Patent Applications, as follows: USSN 13/506,425, filed on April 18, 2012, titled "Carbon Dioxide, Saline and Additional Active Nasal Delivery Methods and Treatments" (Docket No. GTI-132A), same inventor as herein; USSN13/506,426, filed on April 18, 2012, titled "Carbon Dioxide and Saline Nasal Delivery Methods and Treatments" (Docket No. GTI-131A) same inventor as herein; and USSN13/507,112, filed on June 4, 2012, titled "Nasal Treatment Delivery Device For Carbon Dioxide and Saline " (Docket No. GTI-131A) same inventor as herein. No priority is claimed.

BACKGROUND OF THE INVENTION

a. Field of Invention

[0002] This invention relates generally to healthcare, and specifically to the treatment of head ailments. More specifically, the present invention relates to intranasal delivery methods and treatments with carbon dioxide and saline; and with carbon dioxide, saline and other active components, as well as to devices used in these methods. These treatment methods and devices result in reduction of nasal passage swelling and congestion and treatment of causes of such swelling and congestion.

b. Description of Related Art

[0003] The following patents and applications are representative of various types of nasal medicine delivery devices:

[0004] United States Patent No. 8,007,842 B2 to Rau describes a composition for providing aromatherapy, and in particular, symptomatic relief of nasal and sinus congestion in unit dosage format. The composition includes a penetrating aromatic vapor whose release from a preparation of warm water is augmented by an effervescent component which reacts in the warm water to promote release of the aromatic fragrance, or sustained over time by tableting or gelatin encapsulation. As the fragrance is inhaled, symptomatic relief is obtained. The composition of matter may be rendered ingestible, so that the warm water containing the composition is consumed following inhalation. In preferred embodiments, the release of the penetrating aromatic fragrance persists over time.

[0005] United States Patent No. 7,959,597 B2 to Baker et al. describes an irrigation and aspiration system. The system can be configured to aspirate and irrigate alone, sequentially or concurrently. The system can be configured to aspirate and irrigate the nasal cavity. The system can be manually controlled. The system can have removable and easily cleanable reservoirs for aspirant and irrigant.

[0006] United States Patent No. 7,858,650 B2 to Yamamoto et al. describes a medicinal composition for inhalation containing a continuous-release type prodrug of an EP2 agonist which topically exhibits a prolonged bronchodilating and antiinflammatory effects. Namely, the medicinal composition for inhalation containing a continuous-release type prodrug of an EP2 agonist is useful as a safe preventive and/or a remedy for respiratory diseases (for example,

asthma, pulmonary injury, pulmonary fibrosis, pulmonary emphysema, bronchitis, chronic obstructive pulmonary disease, adult respiratory distress syndrome, cystic fibrosis, pulmonary hypertension or the like) without causing any systemic effect such as lowering blood pressure. Thus, a safe and useful remedy for respiratory diseases is provided.

[0007] United States Patent No. 7,845,348 B2 to Rasor et al. describes apparatus, methods, and kits for treating symptoms associated with common ailments, such as headaches, rhinitis, asthma, epilepsy, nervous disorders and the like. The apparatus comprises dispensers for carbon dioxide and other therapeutic gases. The methods comprise delivering small volumes of these gases to patients in a manner where the gas infuses into a body region in order to bathe the mucous membranes therein. It has been found that even very short exposure of patients to small volumes and high concentrations of such gases can provide significant relief from symptoms.

[0008] United States Patent No. 7,836,883 B2 to Rasor et al. describes apparatus, methods, and kits for treating symptoms associated with common ailments, such as headaches, rhinitis, asthma, epilepsy, nervous disorders and the like. The apparatus comprises dispensers for carbon dioxide and other therapeutic gases. The methods comprise delivering small volumes of these gases to patients in a manner where the gas infuses into a body region in order to bathe the mucous membranes therein. It has been found that even very short exposure of patients to small volumes and high concentrations of such gases can provide significant relief from symptoms.

[0009] United States Patent No. 7,827,986 B2 to Rasor et al. describes apparatus, methods, and kits for treating symptoms associated with common ailments, such as headaches, rhinitis, asthma, epilepsy, nervous disorders and the like. The apparatus comprises dispensers for carbon dioxide and other therapeutic gases. The methods comprise delivering small volumes of these gases to patients in a manner where the gas infuses into a body region in order to bathe the

mucous membranes therein. It has been found that even very short exposure of patients to small volumes and high concentrations of such gases can provide significant relief from symptoms.

[00010] United States Patent Application No. 2008/0169047 A1 to Connolly et al. describes a hand-held, low-flow dispenser which comprises an enclosure holding a gas cartridge. A spring-biased needle is advanced to puncture a septum on the gas cartridge, and a separate spring-biased ball valve is used to turn the resulting gas flow off and on as well as to control the flow rate.

[00011] United States Patent Application No. 2008/0078382 A1 to LeMahieu et al. describes systems and methods for delivery of a drug to the respiratory system of a patient in a stream of purified air are provided. In particular, the drugs are delivered to the respiratory system of the patient at a positive air pressure relative to atmospheric pressure. With the systems and methods of the present disclosure, medication available in a variety of forms is introduced in a controlled fashion into the air stream in aerosol, nebulized, or vaporized form.

[00012] United States Patent Application No. 2008/0066741 A1 to LeMahieu et al. describes systems and methods for delivery of a drug to the respiratory system of a patient, where the drug is supplied in purified air at a positive pressure relative to atmospheric pressure. With the systems and methods of the present disclosure, medication available in a variety of forms is introduced in a controlled fashion into the purified air stream in aerosol, nebulized, or vaporized form.

[00013] United States Patent Application No. 2008/0066739 A1 to LeMahieu et al. describes systems and methods for delivery of a drug to the respiratory system of a patient where the drug is supplied at a positive pressure relative to atmospheric pressure. In particular, the drugs are delivered to the respiratory system of a patient who is capable of unassisted breathing. With the systems and methods of the present disclosure, medication available in a variety of forms is introduced in a controlled fashion into the air stream in aerosol, nebulized, or vaporized form.

[00014] United States Patent Application No. 2006/0172017 A1 to Rasor et al. describes an apparatus and methods to deliver vasoconstrictive agents simultaneously with capnic gases. The capnic gases can enhance the effectiveness of the vasoconstrictive agent, lower the dosage of drug or concentration of agent necessary to achieve a therapeutic result, or both. Exemplary capnic gases include carbon dioxide, nitric oxide, nitrous oxide, and dilute acid gases.

[00015] United States Patent Application No. 2004/0009126 A1 to Pilkiewicz et al. describes an inhalation system comprising an anti-infective agent in particle form, the anti-infective agent being directed toward prevention and treatment of intracellular infection, and an inhalation device, and a method of use of the system.

[00016] United States Patent Application No. 2002/0040205 A1 to Rasor et al. describes methods and devices for transcutaneous and transmucosal application of carbon dioxide in the form of gas and in the form of a capnic solution (such as carbonated water) for the relief of pain, including musculoskeletal disorders, neuralgias, rhinitis and other ailments. Gaseous carbon is applied to the skin for at least three minutes, and the capnic solution may be held on the skin for at least three minutes, which provides relief of symptoms. The capnic solution may be sprayed onto mucous membranes such as the nose for relief of symptoms such as allergic rhinitis.

[00017] Casale, et al., "Nasal Carbon Dioxide for the Symptomatic Treatment of Perennial Allergic Rhinitis," Ann Allergy Asthma Immunol., Oct. 2011, pp. 364–370, examines the safety and efficacy of nasal carbon dioxide on the symptoms of perennial allergic rhinitis.

[00018] Baroody et al., "The Effect of Intranasal Carbon Dioxide on the Acute Response to Nasal Challenge with Allergen," Allergy Asthma Proc., May–Jun. 2011, pp. 206–212 describes a study in which intranasal carbon dioxide (CO(2)) was shown to reduce symptoms of seasonal allergic rhinitis (SAR). This study was designed to evaluate the effect of CO(2) on nasal allergen

challenge. We conducted a randomized, controlled, crossover trial in 12 subjects with SAR outside their pollen season. Thirty minutes after a 20-second exposure to CO(2) or no exposure, subjects underwent a unilateral, localized, nasal allergen challenge. Filter paper disks were placed on the nasal septum to deliver a sham challenge followed by 2 increasing doses of either grass or ragweed allergen. Secretions were collected from both sides of the septum to evaluate the nasonasal reflex and were assayed for histamine. Nasal and eye symptoms were recorded. The primary outcome measure was the contralateral, reflex, secretory response to allergen as measured by secretion weights. Secondary outcome measures included ipsilateral nasal secretion weights, nasal and eye symptoms, levels of histamine in nasal secretions, and eosinophils in nasal scrapings. Subjects reported a transient burning sensation during exposure to CO(2). Compared with no treatment, active treatment resulted in a significant reduction in sneezes ($p = 0.05$), contralateral secretion weights ($p = 0.04$), and bilateral runny nose symptoms ($p = 0.01$). Ipsilateral secretion weights were numerically reduced. Histamine levels in ipsilateral nasal secretions increased significantly when the subjects received sham treatment but did not increase after pretreatment with CO(2). Treatment with nasal CO(2) resulted in partial reduction of the acute response to allergen challenge. Reflex responses were reduced, supporting an effect on neuronal mechanisms, which predict usefulness in the treatment of allergic rhinitis.

[00019] Pagani et al., "Carbon Dioxide-Enriched Water Inhalation in Patients With Allergic Rhinitis and its Relationship with Nasal Fluid Cytokine/Chemokine Release," Arch Med Res, May 2011, pp. 329–333 investigates a possible in vivo effect of carbon dioxide-enriched water inhalation in patients with allergic rhinitis.

[00020] Casale, Romero, and Spierings, "Intranasal Noninhaled Carbon Dioxide for the Symptomatic Treatment of Seasonal Allergic Rhinitis," J Allergy Clin Immunol., Jan. 2008, pp.

105–109, studies whether noninhaled intranasal CO2 would be effective in the treatment of seasonal allergic rhinitis.

[00021] Notwithstanding the prior art, the present invention is neither taught nor rendered obvious thereby.

SUMMARY OF INVENTION

[00022] The present invention is directed to a method for treating ailments in a patient in need thereof. It includes the step of directing a therapeutic, non-inhaled dosage to at least one nasal cavity of the patient through a flow regulating device. The dosage includes a saline fluid and a gas containing carbon dioxide, and I some embodiments, at least one additional active component, wherein the therapeutic, non-inhaled dosage is delivered at a flow rate from 1 cc/sec to 20 cc/sec for a duration of 2 to 30 seconds. The invention includes the step of having the patient substantially refrain from inhaling while the fluid is being released.

[00023] In some preferred embodiments of the present invention method for treating ailments in a patient in need thereof, the head ailment is rhinitis.

[00024] In some preferred embodiments of the present invention method for treating ailments in a patient in need thereof, the head ailment is conjunctivitis.

[00025] In some preferred embodiments of the present invention method for treating ailments in a patient in need thereof, the head ailment is the common cold.

[00026] In some preferred embodiments of the present invention method for treating ailments in a patient in need thereof, the head ailment is sinusitis.

[00027] In some preferred embodiments of the present invention method for treating ailments in a patient in need thereof, the head ailment is a headache.

[00028] In some preferred embodiments of the present invention method for treating ailments in a patient in need thereof, the flow regulating device is a single dose dispenser with a pressure control valve for released flow regulation.

[00029] In some preferred embodiments of the present invention method for treating ailments in a patient in need thereof, the flow regulating device is a multiple dose dispenser with a pressure control valve for released flow regulation. In some of these preferred embodiments of the present invention method for treating ailments in a patient in need thereof, the multiple dose dispenser further includes a dosage amount control mechanism and activator to limit dosage release amount for each activation.

[00030] In some preferred embodiments of the present invention method for treating ailments in a patient in need thereof, the duration is 5 to 10 seconds per nasal cavity.

[00031] In some preferred embodiments of the present invention method for treating ailments in a patient in need thereof, the duration is 2 to 15 seconds per nasal cavity.

[00032] In some preferred embodiments of the present invention method for treating ailments in a patient in need thereof, the dose is repeated from 1 to 10 times.

[00033] In some preferred embodiments of the present invention method for treating ailments in a patient in need thereof, the method is for treating rhinitis and the rhinitis is allergic rhinitis.

[00034] In some preferred embodiments of the present invention method for treating ailments in a patient in need thereof, the flow rate is from 2 cc/sec to 10 cc/sec.

[00035] In some preferred embodiments of the present invention method for treating ailments in a patient in need thereof, the flow rate is from 1 cc/sec to 5 cc/sec.

[00036] In some preferred embodiments of the present invention method for treating ailments in a patient in need thereof, the flow rate is from 4 cc/sec to 5 cc/sec.

[00037] In some preferred embodiments of the present invention method for treating ailments in a patient in need thereof, the gas includes at least 50% carbon dioxide.

[00038] In some preferred embodiments of the present invention method for treating ailments in a patient in need thereof, the gas includes at least 70% carbon dioxide.

[00039] In some preferred embodiments of the present invention method for treating ailments in a patient in need thereof, the gas includes at least 95% carbon dioxide.

[00040] In some preferred embodiments of the present invention method for treating ailments in a patient in need thereof, the gas includes at least 100% carbon dioxide.

[00041] The present invention is directed to a nasal treatment delivery device for mixed carbon dioxide and saline for treating head ailments in a patient in need thereof, comprising: a) a main housing having a proximal and a distal end and having a hollow central area containing a dosage that includes a saline fluid and a gas containing carbon dioxide; b) a dosage dispenser head located at the distal end of the main housing, the dosage dispenser head having at least one flow channel for movement of the dosage from the main housing through the dosage dispenser head and to external of the dosage dispenser head; c) a dosage release control component located between the main housing and the dosage dispenser head adapted to permit flow of the dosage from the main housing and through the dosage dispenser head in response to increased pressure against the dosage; and d) a pressure-changing moveable component located on the main housing. When the dosage dispenser head of the device is placed in a nasal cavity and the pressure-changing moveable component is activated by movement toward the dosage, the dosage is at least partially forced through the dosage release control component and through the dosage dispenser head for application of the dosage to a nasal cavity wall.

[00042] In some embodiments of the present invention, the nasal treatment delivery device for mixed carbon dioxide and saline for treating head ailments in a patient in need thereof, the dosage release control component is selected from the group consisting of a frangible member, a puncturable member and a one-way valve.

[00043] In some embodiments of the present invention, the nasal treatment delivery device for mixed carbon dioxide and saline for treating head ailments in a patient in need thereof, the main housing is an open ended tube with the dosage release control component and the dosage dispenser located at the distal end of the main housing and the pressure-changing moveable component is located at the proximal end of the main housing.

[00044] In some embodiments of the present invention, the nasal treatment delivery device for mixed carbon dioxide and saline for treating head ailments in a patient in need thereof, the pressure-changing moveable component is a flexible squeeze member and a seal float.

[00045] In some embodiments of the present invention, the nasal treatment delivery device for mixed carbon dioxide and saline for treating head ailments in a patient in need thereof, the pressure-changing moveable component is a push-up piston.

[00046] In some embodiments of the present invention, the nasal treatment delivery device for mixed carbon dioxide and saline for treating head ailments in a patient in need thereof, the dosage release control component is selected from the group consisting of a frangible member, a puncturable member and a one-way valve.

[00047] In some embodiments of the present invention, the nasal treatment delivery device for mixed carbon dioxide and saline for treating head ailments in a patient in need thereof, the main housing is a tube having an open distal end and a closed proximal end, with the dosage release control component and the dosage dispenser head being located at the distal end of the main

housing, and at least a portion of the tube is flexible and constitutes the pressure-changing moveable component.

[00048] In some embodiments of the present invention, the nasal treatment delivery device for mixed carbon dioxide and saline for treating head ailments in a patient in need thereof, the dosage release control component is selected from the group consisting of a frangible member, a puncturable member and a one-way valve.

[00049] In some embodiments of the present invention, the nasal treatment delivery device for mixed carbon dioxide and saline for treating head ailments in a patient in need thereof, the dosage dispenser head has a plurality of flow channels.

[00050] In some embodiments of the present invention, the nasal treatment delivery device for mixed carbon dioxide and saline for treating head ailments in a patient in need thereof, the dosage dispenser head has a circular shape from a top viewpoint.

[00051] In some other embodiments of the present invention, the nasal treatment delivery device for mixed carbon dioxide and saline for treating head ailments in a patient in need thereof, the nasal treatment delivery device for mixed carbon dioxide and saline for treating head ailments in a patient in need thereof, comprising: a) a main housing having a proximal and a distal end and having a hollow central area containing a dosage that includes a saline fluid and a gas containing carbon dioxide; b) a dosage dispenser head located at the distal end of the main housing, the dosage dispenser head having at least one flow channel for movement of the dosage from the main housing through the dosage dispenser head and to external of the dosage dispenser head; c) a nose guard flange connected to and extending from at least one of the main housing and the dosage dispenser head; d) a dosage release control component located between the main housing and the dosage dispenser head adapted to permit flow of the dosage from the main

housing and through the dosage dispenser head in response to increased pressure against the dosage; e) a pressure-changing moveable component located on the main housing; wherein, when the dosage dispenser head of the device is placed in a nasal cavity and the pressure-changing moveable component is activated by movement toward the dosage, the dosage is at least partially forced through the dosage release control component and through the dosage dispenser head for application of the dosage to a nasal cavity wall. In this particular embodiment with the nose guard flange, all of the other details and features set forth in the previous paragraphs, may be included.

[00052] Additional features, advantages, and embodiments of the invention may be set forth or apparent from consideration of the following detailed description, drawings, and claims. Moreover, it is to be understood that both the foregoing summary of the invention and the following detailed description are exemplary and intended to provide further explanation without limiting the scope of the invention as claimed.

BRIEF DESCRIPTION OF THE DRAWINGS

[00053] The accompanying drawings, which are included to provide a further understanding of the invention and are incorporated in and constitute a part of this specification, illustrate preferred embodiments of the invention and together with the detail description serve to explain the principles of the invention. In the drawings:

[00054] Figure 1a and Figure 1b are block diagrams of embodiments of the present invention carbon dioxide and saline nasal delivery methods and treatments, with and without one or more additional active components;

[00055] All of the following Figures are described as carbon dioxide and saline solutions, it being understood that this means with and without at least one additional active component;

[00056] Figure 2 is a block diagram showing head ailments treated by various embodiments of the present invention carbon dioxide and saline nasal delivery methods and treatments;

[00057] Figure 3 is a block diagram showing durations for therapeutic non-inhaled dosage in some preferred embodiments of the present invention carbon dioxide and saline nasal delivery methods and treatments;

[00058] Figure 4 is a block diagram of another embodiment of the present invention carbon dioxide and saline nasal delivery methods and treatments, showing the additional step of repeating the other steps;

[00059] Figure 5 is a block diagram showing flow rates in some additional preferred embodiments of the present invention carbon dioxide and saline nasal delivery methods and treatments;

[00060] Figure 6 is a block diagram showing the percentage of carbon dioxide present in the gas in some preferred embodiments of the present invention carbon dioxide and saline nasal delivery methods and treatments;

[00061] Figure 7 illustrates a block diagram showing monodose and multidose dispensers that may be used in the present invention methods;

[00062] Figure 8 illustrates a front partially cut view of one embodiment of a present invention nasal treatment delivery device with a pressure release mechanism;

[00063] Figure 9 illustrates a view of one embodiment of a present invention nasal treatment delivery device that is a squeeze to release device;

[00064] Figure 10 shows a front partially cut view of a present invention nasal treatment delivery device with a piercing channel, with the device being held in a hand using two fingers and a thumb to activate release of the medicinal treatment;

[00065] Figures 11, 12 and 13 illustrate front partially cut views of one embodiment of a present invention nasal treatment delivery device with a frangible internal medicine capsule that may be used for a monodose or multidose using replacement cartridges. The three Figures show the device in different stages of use; and,

[00066] Figures 14 and 15 show alternative types of dosage dispenser heads that may be used in present invention devices, one showing multiple release ports and the other showing multiple release ports with a soft contact sheath.

DETAILED DESCRIPTION OF THE EMBODIMENTS

[00067] "Saline" and "saline solution" as used herein means water containing salt. Saline solutions are used in a wide variety of medical applications. For example, "normal saline" is the commonly used term for a solution of 0.90% w/v of sodium chloride (NaCl). Normal saline is frequently used in intravenous drips for patients unable to take fluids orally to prevent dehydration. Normal saline is also used to flush wounds and skin abrasions. Another application of saline solution is as a rinse for contact lenses.

[00068] Saline solution also is frequently used in nasal washes to treat some of the symptoms of the common cold or other ailments adversely affecting the nasal cavities. By irrigating the nasal passages with saline, inflammation can be reduced. Also, more concentrated ("hypertonic") solutions of NaCl, can have therapeutic uses. For example, 7% NaCl/water

solutions are considered mucoactive agents and as such are used to hydrate thick secretions (mucous) in order to make it easier to cough up and out (expectorate).

[00069] Another chemical substance useful in medical treatments is carbon dioxide. One example is the use of diluted carbon dioxide by inhalation for treating symptoms related to headaches, allergies, asthma, nervous disorders, and other common ailments, which was demonstrated in the 1940s and 1950s. Another example is the use of high-concentration, non-inhaled carbon dioxide, delivered to the nasal passages locally. This type of treatment may provide fast relief without the adverse side effects of systemic drugs that are inhaled, ingested, or injected.

[00070] By combining the beneficial therapeutic effects of saline treatment and carbon dioxide treatment, an improved therapy is created. In this way, the beneficial effects of the saline, such as reduced inflammation and expectoration of mucous, are combined with the beneficial effects of carbon dioxide therapy, such as relief from headaches, allergies, asthma, nervous disorders, and other common ailments. Further, the saline moisturizes the nasal cavities and acts as a base host for the carbon dioxide as it acts on the nasal cavity walls. (It is hypothesized that at least some of the carbon dioxide is adsorbed by the saline.) In addition, the saline reduces any slight burning that might otherwise be felt from the carbon dioxide. The benefits of saline treatment are supplemented by the benefits of carbon dioxide treatment, and the benefits of carbon dioxide treatment are supplemented by the benefits of saline treatment. This combination of utilizing the saline to perform at least moisturizing and other beneficial affects while carrying and enhancing the delivery of the carbon dioxide is an unexpected synergistic result thereof.

[00071] In addition to the benefits listed above, the present invention carbon dioxide and saline nasal delivery methods and treatments have other synergistic benefits that are not available from

either saline treatment or carbon dioxide treatment alone. For example, the presence of dissolved carbon dioxide in the saline solution means that the solution will be carbonated; the effervescent effect of the carbon dioxide helps the saline solution to mix more energetically against the interior surface of the nasal cavity or cavities. This improved mixing allows the saline treatment to be more effective. Another potential advantage of combining carbon dioxide and saline treatments is that in some embodiments, with sufficient pressure and a proper nozzle, the carbon dioxide can act as a carrier gas for the saline, allowing the saline solution to be aerosolized.

[00072] To summarize the advantages and benefits of the present invention, the combination of controlled delivery carbon dioxide and saline provides the following: it cleanses the nasal cavity removing allergens and particulates that cause inflammation and congestion; its special formula shields nasal mucosa from viruses; it soothes and moisturizes irritated mucosa; its unique buffering system neutralizes inhaled irritants such as oxidative free radicals and endogenous cytotoxins which cause inflammation and damage to the sensitive mucosa and muco-cillary hairs in the nasal cavity; it enhances mucous clearance and flow by reducing mucus viscosity; its superior safety profile gives it broader application than corticosteroids and decongestants and can be used safely in children 6 months of age and adults, even with co-morbidities such as diabetes, hypertension, suppressed immune systems and pregnant and nursing females; and its exceptional safety profile allows for flexible dosing.

[00073] In addition to the beneficial carbon dioxide and saline, as described above, in some preferred embodiments of the present invention, there is further included at least one additional active component. These active components may be any of one or more beneficial additions that are compatible with saline and have some medicinal, curative, pain relieving or moisturizing effect on the sinus cavity walls, vascular system or upper respiratory system. These include, but

are not limited to, moisturizers, humectants, over the counter drugs and prescription drugs. Such drugs may be antihistamines, infection treatments, antioxidants, cell growth accelerators, anti-inflammatories, vasoconstrictors, nasal decongestants, or other nasal cavity, wall or upper respiratory treatments. Preferred actives are moisturizers, decongestants, antihistamines, infection treatments and anti-inflammatories. Examples of moisturizers and humectants are: glycerin, propylene glycols (MW 400 to 8000), maltodextrins (liquid), honey, pectin, hydroxypropyl methylcellulose, and carboxymethylcellulose. Examples of topical decongestants are: ephedrine, levomethamphetamine, naphazoline, oxymetazoline, phenylephrine, pseudoephedrine, tramazoline, and xylometazoline. The actives may also be fragrance sensations or fragrance with other benefits, such as eucalyptus, menthol or lavender.

[00074] Referring now to the drawings, like reference numerals designate corresponding parts throughout the several views, various embodiments of the present invention are shown.

[00075] Figure 1a is a block diagram of an embodiment of the present invention carbon dioxide, saline and additional active component(s) nasal delivery methods and treatments. However, because the present invention includes the dosages with and without other actives, the additional additives in this Figure 1a are excluded in Figure 1b, and both Figure 1a and 1b are to be taken as discussed together as Figure 1a, it being understood that Figure 1b illustrates a the invention without additional additives, but the Figures are otherwise the same, and the discussion below of Figure 1a, except for the additional actives, applies also to Figure 1b.

[00076] Figure 1a illustrates a therapeutic non-inhaled dosage 1, containing saline fluid 3, a carbon dioxide-containing gas 5 and at least one additional active 17. The saline fluid 3 contains water and at least one salt. In some preferred embodiments of the present invention, the salt is sodium chloride. In other embodiments of the present invention, other salts may be used, but it is

important that any salt used in the saline fluid 3 must be safe for intranasal use. In some preferred embodiments of the present invention, the concentration of salt in the saline fluid is approximately isotonic with the salt concentration of bodily fluids. In other preferred embodiments, the concentration of salt in the saline fluid is less than the concentration of salt in bodily fluids. In still other preferred embodiments, the concentration of salt in the saline fluid is hypertonic, meaning that it has a salt concentration higher than that of bodily fluids. In still other preferred embodiments, the saline solution is saturated with salt.

[00077] The gas 5 contains some portion of carbon dioxide. When the gas 5 containing carbon dioxide is added to the saline fluid 3, the saline fluid 3 becomes carbonated. If the therapeutic non-inhaled dosage 1 containing saline fluid 3 and the gas 5 is kept under pressure, the pressure can later be released (for example by opening a valve), which causes some of the carbon dioxide to bubble out of the solution. This sudden release of carbon dioxide creates effervescence in the therapeutic non-inhaled dosage.

[00078] The therapeutic non-inhaled dosage travels through a flow-regulating device 7. In preferred embodiments, the flow-regulating device 7 controls the flow rate 9 of the therapeutic non-inhaled dosage 1 at a rate that is safe and comfortable for the patient. In the embodiment shown in Figure 1a, the flow rate 9 of the therapeutic non-inhaled dosage is between 1 cubic centimeter per second (cc/sec) and 20 cc/sec. In preferred embodiments of the present invention shown in Figure 1a, the flow rate is adjustable to any value between 1 cc/sec and 20 cc/sec.

[00079] The therapeutic non-inhaled dosage 1 has a flow duration 11. The flow duration 11 is the length of time during which the therapeutic non-inhaled dosage flows through the flow regulating device into at least one nasal cavity 13 of a patient. In the embodiment shown in Figure 1a, the flow duration 11 is shown as lasting between 2 and 30 seconds. In preferred

embodiments of the present invention, the flow duration is adjustable to any value between 2 and 30 seconds.

[00080] After the therapeutic non-inhaled dosage 1 leaves the flow regulating device 7, it enters at least one nasal cavity 13 of a patient. The therapeutic non-inhaled dosage 1 is adsorbed by the nasal tissue and subsequently absorbed by the body. This adsorption and subsequent absorption can have a beneficial effect on many head ailments, some of which are shown in Figure 2. The effervescent effect of the gas 5 containing carbon dioxide causes better contact between the salt in the saline solution 3 and the nasal tissue.

[00081] The additional step 15 of instructing the patient to refrain from inhaling protects the patient from accidently inhaling the therapeutic non-inhaled dosage 1. This is important, even critical, when the therapeutic non-inhaled dosage 1 contains a gas 5 that is substantially 100% carbon dioxide to prevent carbon dioxide poisoning (hypercapnia). Even mild hypercapnia can cause uncomfortable mental and physical effects. Also, when the concentration of salt in the saline solution 3 is greater than isotonic (particularly if salts other than sodium chloride are used), it is desirable to limit the patient's exposure to the salts. The step 15 of instructing the patient not to breathe accomplishes these goals.

[00082] Turning now to Figure 2, a block diagram, block 20, shows some of the medical conditions that can be treated using the present invention carbon dioxide and saline (with and without additional actives) nasal delivery methods and treatments. In some embodiments of the present invention, the carbon dioxide and saline nasal delivery methods and treatments treat rhinitis 17, a swelling of some internal parts of the nose. In other embodiments, the present invention treats allergic rhinitis 19. In still other embodiments, the present invention treats conjunctivitis 21, an inflammation of the conjunctiva also known as pink-eye. In still other

embodiments of the present invention, the common cold 23 is treated. In other embodiments of the present invention, sinusitis 25, an inflammation of the sinuses, is treated. In yet other embodiments, the present invention is used to treat headaches 27. It is important to recognize that in some embodiments of the present invention carbon dioxide and saline nasal delivery methods and treatments, multiple conditions can be treated simultaneously. For example, a patient may be suffering from both sinusitis and headache simultaneously; the present invention can alleviate both conditions at the same time. The present invention can treat any ailment shown in Figure 2 or any combination of those ailments. It should also be recognized that the present invention may be useful in treating other ailments, particularly head ailments. The treatment of other ailments on which the present invention carbon dioxide and saline nasal delivery methods and treatments is effective are considered to be within the scope of the invention.

[00083] Turning now to Figure 3, a block diagram, block 30, shows the durations of therapeutic non-inhaled dosage used in some embodiments of the present invention carbon dioxide and saline nasal delivery methods and treatments. The durations listed in Figure 3 are ranges, so the actual duration can be any value between the low end of the range and the high end of the range, inclusive. In some embodiments of the present invention, the duration 29 lasts between 2 and 30 seconds. In other embodiments of the present invention, the duration 31 lasts between 2 and 15 seconds. In still other embodiments of the present invention, the duration 33 lasts between 5 and 10 ten seconds. Durations of less than 2 seconds and more than 30 seconds are also considered to be within the scope of the invention.

[00084] Turning now to Figure 4, another embodiment of the present invention carbon dioxide and saline nasal delivery methods and treatments is shown. Figure 4 is a block diagram of an

embodiment of the present invention carbon dioxide and saline nasal delivery methods and treatments that incorporates many aspects shown in Figures 1a and 1b, and identical blocks are identically numbered. Figure 4 illustrates a therapeutic non-inhaled dosage 1 containing saline fluid 3 and a gas 5. The saline fluid 3 contains water and at least one salt. In some preferred embodiments of the present invention, the salt is sodium chloride. In other embodiments of the present invention, other salts may be used, but it is important that any salt used in the saline fluid 3 must be safe for intranasal use. In some preferred embodiments of the present invention, the concentration of salt in the saline fluid is approximately isotonic with the salt concentration of bodily fluids. In other preferred embodiments, the concentration of salt in the saline fluid is less than the concentration of salt in bodily fluids. In still other preferred embodiments, the concentration of salt in the saline fluid is hypertonic, meaning that it has a salt concentration higher than that of bodily fluids. In still other preferred embodiments, the saline solution is saturated with salt.

[00085] The gas 5 contains some portion of carbon dioxide. When the gas 5 containing carbon dioxide is added to the saline fluid 3, the saline fluid 3 becomes carbonated. If the therapeutic non-inhaled dosage 1 containing saline fluid 3 and the gas 5 is kept under pressure, the pressure can later be released (for example by opening a valve), which causes some of the carbon dioxide to bubble out of the solution. This sudden release of carbon dioxide creates effervescence in the therapeutic non-inhaled dosage.

[00086] The therapeutic non-inhaled dosage travels through a flow-regulating device 7. In preferred embodiments, the flow-regulating device 7 controls the flow rate 9 of the therapeutic non-inhaled dosage 1 at a rate that is safe and comfortable for the patient. In the embodiment shown in Figure 1a, the flow rate 9 of the therapeutic non-inhaled dosage is between 1 cubic

centimeter per second (cc/sec) and 20 cc/sec. In preferred embodiments of the present invention shown in Figure 1a, the flow rate is adjustable to any value between 1 cc/sec and 20 cc/sec.

[00087] The therapeutic non-inhaled dosage 1 has a flow duration 11. The flow duration 11 is the length of time during which the therapeutic non-inhaled dosage flows through the flow regulating device into at least one nasal cavity 13 of a patient. In the embodiment shown in Figure 1a, the flow duration 11 is shown as lasting between 2 and 30 seconds. In preferred embodiments of the present invention, the flow duration is adjustable to any value between 2 and 30 seconds.

[00088] After the therapeutic non-inhaled dosage 1 leaves the flow regulating device 7, it enters at least one nasal cavity 13 of a patient. The therapeutic non-inhaled dosage 1 is adsorbed by the nasal tissue. This adsorption can have a beneficial effect on many head ailments, some of which are shown in Figure 2. The effervescent effect of the gas 5 containing carbon dioxide causes better contact between the salt in the saline solution 3 and the nasal tissue.

[00089] The additional step 15 of instructing the patient to refrain from inhaling protects the patient from accidently inhaling the therapeutic non-inhaled dosage 1. This is important, even critical, when the therapeutic non-inhaled dosage 1 contains a gas 5 that is substantially 100% carbon dioxide to prevent carbon dioxide poisoning (hypercapnia). Even mild hypercapnia can cause uncomfortable mental and physical effects. Also, when the concentration of salt in the saline solution 3 is greater than isotonic (particularly if salts other than sodium chloride are used), it is desirable to limit the patient's exposure to the salts. The step 15 of instructing the patient not to breathe accomplishes these goals.

[00090] In the embodiment shown in Figure 4, after the therapeutic non-inhaled dosage 1 passes through the flow regulating device 7 and into the at least one nasal cavity 13 of a patient,

the dose is repeated 35. In some preferred embodiments, the dose is repeated 35 between one and ten times. In still other embodiments, the dose is repeated more than ten times. The step 35 of repeating the dose can be used if a single application of the therapeutic non-inhaled dosage 1 is insufficient to alleviate the head ailment or ailments from which the patient suffers.

[00091] Turning now to Figure 5, a block diagram, block 50, shows flow rates used in some embodiments of the present invention carbon dioxide and saline nasal delivery methods and treatments. The flow rates used in Figure 5 are shown as ranges, and the actual rate of the flow may any value between the low end of the range and the high end of the range, inclusive. In some embodiments, a rate 37 between 1 cc/sec and 20 cc/sec is used. In other embodiments, a flow rate 39 between 2 cc/sec and 10 cc/sec is used. In other preferred embodiments, a flow rate 41 between 1 cc/sec and 5 cc/sec is used. In still other preferred embodiments, a flow rate 43 between 4 cc/sec and 5 cc/sec is used. In still other preferred embodiments, a flow rate 45 of approximately 10 cc/sec is used. Embodiments with flow rates of less than 1 cc/sec or more than 20 cc/sec are also considered to be within the scope of the invention.

[00092] Turning now to Figure 6, a block diagram, block 60, shows levels of carbon dioxide in the gases used in some embodiments of the present invention. The levels of carbon dioxide are expressed as a percentage of the gas (3 in Figures 1 and 4) used in the therapeutic non-inhaled dosage (1 in Figures 1 and 4). In some embodiments of the present invention carbon dioxide and saline nasal delivery methods and treatments, the amount of carbon dioxide 47 in the gas is at least 50%. In other embodiments, the amount of carbon dioxide 49 in the gas is at least 70%. In still other embodiments, the amount of carbon dioxide 51 in the gas is at least 95%. In other preferred embodiments, the amount of carbon dioxide 53 in the gas is substantially 100%. Gases

with a percent composition of less than 50% carbon dioxide are also considered to be within the scope of the invention.

[00093] Figure 7 illustrates a block diagram showing nasal treatment delivery devices that may be used in the present invention methods. Here, block 71 illustrates the caption of the Figure, namely, nasal treatment delivery devices. Block 73 shows that the flow regulating device used in the present invention methods may be a single dose dispenser (monodose) with a pressure control valve for flow rate regulation. The rate of flow is set in accordance with the ranges set forth above. In the case of a monodose dispenser, the entire dose is dispensed, so that time of dispensing does not need to be controlled- it is just the controlled flow rate over time it takes to unload the dose. Thus, a monodose dispenser may controllably release a pressurized mixture of the carbon dioxide and the saline, until it stops flowing. The various types of mechanisms for driving the contents from the container to the nasal cavity are also exemplified. These include squeeze mechanisms where the squeeze component or bulb is below the content so that external squeeze pressure forces out the content, much like a turkey baster; squeeze mechanisms where the squeeze component is the actual dose holding aspect of the container, like a nasal decongestant squeeze spray container; push mechanisms that physically operate much like syringes but may have more complex internal aspects, such as piercers or counter-biased valving; and others, referring to any known controlled flow mechanism available to the artisan.

[00094] On the other hand, a plural or multidose dispenser may be used, and needs dispensing on/off control, otherwise the entire contents could be unnecessarily released in one shot. Thus, block 75 illustrates the use of a multidose dispenser with a pressure control valve for flow rate regulation. The rate of flow is set in accordance with the ranges set forth above. Block 77 shows one multidose dispenser option wherein the user controls the release time, so that there is variable

dosage. For example, there may be an activator, such as a push button or a squeeze mechanism to release the dosage, and the user may be directed to dispense for a time, e.g., dispense for eight to ten seconds. Alternatively, as shown in block 79, an auto-controlled release mechanism may be used, e.g., a spring return release that closes a valve based on set timing, or a dual spring device with one being reverse spring mechanism that returns a lever to control the time of release. Timed valving is well known in the field of medicine dispensing and any available multidose fixed time dispensing mechanism may be utilized.

[00095] In Figure 7, block 73 shows the main housing and dosage. It contains a dosage of saline fluid and carbon dioxide gas according to parameters as more specifically set forth above. Block 79 shows that the main housing 73 may have two open ends or one open end. In the case of one open end, the top end would include the release control and dispenser head mechanisms, with a closed bottom. In the case of a main housing with two open ends, one end would have the release control and dispenser head mechanisms and the other end would contain a moveable drive mechanism such as a pressure release mechanism, a piercer or a plunger (drive piston). Block 81 shows that the main housing 73 may be at least partially flexible or it may be inflexible. If the driver is the squeezing of the main housing, it must be flexible. If the driver a moveable component attached to the main housing 71 (a push or squeeze mechanism), then the main housing 71 is preferably inflexible.

[00096] Block 83 shows the dosage release control component. Block 85 illustrates the options for the dosage release control component, which are: frangible, puncturable, one-way valve, or gate. Block 87 shows the dosage dispenser head, which Block 89 then shows the options for, which are: perforated, hard, soft, or delivery cover (sponge, foam, cotton batting, or other). Block 74 shows the optional nose guard flange for the nasal treatment delivery device 71.

[00097] Figure 8 illustrates a front partially cut view of one embodiment of a present invention nasal treatment delivery device 90. It includes a main housing 91 with a top 93 having a hollow central area containing a dosage of the present invention medicine. This storage area may be the inside of the main housing, or it may be one or more subunits- compartments, capsules, tanks, pouches, etc, within the main housing.

[00098] In this embodiment, the main housing 91 has attached to its distal end a dosage control component that is a spray release nozzle 95 that is set for prescribed flow rates within the ranges set forth in the present invention claims and as described above. Internal bag container 105 contains the liquid/ gas mixture of the present invention and external pressure on bag 105 is created by pressurized gas located in space 107 inside main housing 91. At top 93 is a dosage dispenser head, in this case, a push dispenser mechanism 97 that includes release orifice 101, actuation tube 99 and push pad 103. A user inserts push dispenser mechanism 97 into a nasal cavity at its distal end (orifice 101) while holding nasal treatment delivery device 90 and then pressing push pad 103 to release the contents. The flow regulation is set to an acceptable range so as to be relatively gentle to the user. This may include ranges in the order of 1 cc/sec to 10 cc per second. Typically this is a multidose device wherein the user is given instructions to dispense for a specified time period while not breathing, e.g., three seconds at full depression per nostril twice a day as needed. Alternatively, a built-in timer could automatically control the dose. For example, the device could have a slow spring closure that would require reset and re-push to reactivate.

[00099] Figure 9 shows an alternative nasal treatment delivery device 110. This is an insert and squeeze device that includes a main body 111 with flexible walls and a dispensing nozzle 115 at its top 113. There is a stop 117 and threads 109 and a tapered dispensing tip 119 designed for

nasal cavity insertion. There is a flow control valve 112 that regulates the rate of delivery. Additional valving, such as a duck bill valve, may also be included. The present invention liquid/gas mixture is contained within the main housing 111 and is dispensed by a user inserting and squeezing while holding his/her breath.

[000100] Figure 10 shows a front partially cut view of a present invention nasal treatment delivery device 120 being held in a hand using two fingers and a thumb, as shown. There is a main housing 121 and a vertically moveable piston 131. A rigid, semi-flexible or flexible container or pouch 123 contains the liquid/gas mixture of the present invention and piercing tube 125 is connected to flow control valve 127. A user holds nasal treatment delivery device 120 as shown, inserts it into a nasal cavity, and while not breathing, pushes piston 131 upwardly to force pouch 123 to rupture via piercing tube 125 for medicine release through valve 127 to the nasal cavity walls.

[000101] Figures 11, 12 and 13 illustrate front partially cut views of one embodiment of a present invention nasal treatment delivery device 150 with a frangible internal medicine capsule 171 containing medicine 175-the gas and liquid mixtures described above. Device 150 may be used for a monodose or multidose using replacement capsules. The three Figures show the device in different stages of use. Identical number is used for all three of the figures and the device 150 is described collectively for all of these figures.

[000102] Device 150 is a push device that relies upon a frangible capsule 171 to deliver the medicine 175 by breaking open the top 173 of the frangible capsule 171. Device 105 includes a main housing 151 designed with both an open top and an open bottom, as shown. Permanently inserted into the open top of main housing 151 is a dosage dispensing head 161, with release tube 165 and control valve 153. Dosage dispensing head 161 has a downward hemispherical end 163

for puncturing the top 173 (e.g., a foil top) of capsule 171. A circular platform or dual protrusions, such as platform 167, serves as a finger grip and is attached to main housing 151. Capsule 171 may be permanently installed in main housing 151, or it may be removably placed therein so that subsequent capsules may be inserted, the former being a monodose and the latter being a multidose device.

[000103] Further, capsule 171 may be fully frangible, but is preferably so only at its top 173. Capsule 171 could have different shape, such as a heminspherical bottom to correspond to the shape of the end 163 of the dosage dispensing head 161. Or both could have other shapes and be the same or different, e.g., a chisel shaped end/bottom. Plunger 157 has a sealed piston159 at its distal end and a widened finger rest at its proximal end. Plunger 157 may be inserted at its distal end permanently or removably, and its piston 159 may be any shape, but is preferably the same or similar to the bottom of the capsule. The piston 159 is used to drive the capsule 171 into breaker end 163, as shown sequentially in Figures 11, 12 and 13. In Figure 11, a user's thumb and first two fingers are shown embracing the plunger 157 and the platform 167, respectively. By placing the device 150 in a desired nasal cavity and pushing plunger 157 upwardly while holding the device steady, and while the user holds his/her breathe, the frangible top 173 is broken and the gas/liquid medicine begins release from the device 150 (Figure 12). The medicine is nearly fully expended by the time the plunger 157 is pushed maximally and the top 163 is near or at the bottom of the capsule 171 (Figure 13), to deliver the medicine to the user effectively.

[000104] Figures 14 and 15 show alternative types of dosage dispenser heads that may be used in present invention device one has multiple release ports and the other has multiple release ports with a soft contact sheath. Figure 14 shows a cut front view of one dosage dispenser head 180 that may be used in conjunction with a present invention device. It includes a control valve 181

to regulate release of medicine to be within the proscribed ranges set forth above. Upstream from control valve 181 is a main flow channel 183 with branches 185, 187, 189, 191,193 and 195 to show a diverse multiport manifold head for diverse. This dosage dispensing head will direct the gas/liquid medicine in many directions simultaneously to more evenly and quickly coat the sinus cavity wall.

[000105] Figure 15 shows a similar present invention dosage dispensing head 200, but with a soft pad for nasal wall comfort. This pad does not cover the ports and may be made of soft pervious or impervious materials such as various foams or skins. Alternatively, they may be previous and cover the parts so as to create wetting foams or sponges to effect broad based medicine placement in the nasal cavity.

[000106] Although particular embodiments of the invention have been described in detail herein with reference to the accompanying drawings, it is to be understood that the invention is not limited to those particular embodiments, and that various changes and modifications may be effected therein by one skilled in the art without departing from the scope or spirit of the invention as defined in the appended claims.

Patent Claims

What is claimed is:

1. A method for treating head ailments in a patient in need thereof, said method comprising:

directing a therapeutic, non-inhaled dosage to at least one nasal cavity of said patient through a flow regulating device, said dosage including: (a) a saline fluid and (b) a gas containing carbon dioxide, wherein the therapeutic, non-inhaled dosage is delivered at a flow rate from 1 cc/sec to 20 cc/sec for a duration of 2 to 30 seconds, while said patient is substantially refraining from inhaling.

2. The method of claim 1, wherein said treated head ailment is selected from the group consisting of rhinitis, conjunctivitis, common cold and sinusitis.

3. The method of claim 1, wherein said method is for treating rhinitis and the rhinitis is allergic rhinitis.

4. The method of claim 1, wherein said head ailment is headache.

5. The method of claim 1, wherein said flow regulating device is a single dose dispenser with a pressure control valve for released flow regulation.

6. The method of claim 5, wherein said flow regulating device is a multiple dose dispenser with a pressure control valve for released flow regulation.

7. The method of claim 1, wherein multiple dose dispenser further includes a dosage amount control mechanism and activator to limit dosage release amount for each activation.

8. The method of claim 1 wherein the gas comprises at least 70% carbon dioxide.

9. The method of claim 1 wherein the gas comprises substantially pure carbon dioxide.

10. The method of claim 1 wherein the dosage further includes: (c) at least one additional active component.

11. A nasal treatment delivery device for mixed carbon dioxide and saline for treating head ailments in a patient in need thereof, comprising:

a) a main housing having a proximal and a distal end and having a hollow central area containing a releasable nasal treatment dosage that includes a saline fluid and a gas containing carbon dioxide;

b) a dosage dispenser head located at said distal end of said main housing, said dosage dispenser head having at least one flow channel for movement of said dosage from said main housing through said dosage dispenser head and to external of said dosage dispenser head;

c) a dosage release control component located between said main housing and said dosage dispenser head adapted to permit flow of said dosage from said main housing and through said dosage dispenser head in response to increased pressure against said dosage;

d) a pressure-changing moveable component located on said main housing;

wherein, when said dosage dispenser head of said device is placed in a nasal cavity and said pressure-changing moveable component is activated by movement toward said dosage, said dosage is at least partially forced through said dosage release control component and through said dosage dispenser head for application of said dosage to a nasal cavity wall.

12. The nasal treatment delivery device for mixed carbon dioxide and saline for treating head ailments in a patient in need thereof of claim 11, wherein said dosage release control component

is selected from the group consisting of a frangible member, a puncturable member and a one-way valve.

13. The nasal treatment delivery device for mixed carbon dioxide and saline for treating head ailments in a patient in need thereof of claim 11, wherein said main housing is an open ended tube with said dosage release control component and said dosage dispenser located at said distal end of said main housing and said pressure-changing moveable component is located at said proximal end of said main housing.

14. The nasal treatment delivery device for mixed carbon dioxide and saline for treating head ailments in a patient in need thereof of claim 11, wherein said pressure-changing moveable component is a flexible squeeze member and a seal float.

15. The nasal treatment delivery device for mixed carbon dioxide and saline for treating head ailments in a patient in need thereof of claim 11, wherein said pressure-changing moveable component is a push-up piston.

16. The nasal treatment delivery device for mixed carbon dioxide and saline for treating head ailments in a patient in need thereof of claim 11, wherein said device further includes e) a nose guard flange connected to and extending from at least one of said main housing and said dosage dispenser head.

17. The nasal treatment delivery device for mixed carbon dioxide and saline for treating head ailments in a patient in need thereof of claim 11, wherein said main housing is a tube having an open distal end and a closed proximal end, with said dosage release control component and said dosage dispenser head being located at said distal end of said main housing, and at least a portion of said tube is flexible and constitutes said pressure-changing moveable component.

18. The nasal treatment delivery device for mixed carbon dioxide and saline for treating head ailments in a patient in need thereof of claim 11, wherein said dosage further includes at least one additional active component.

19. A method of treating head ailments in a patient in need thereof utilizing a nasal treatment delivery device for mixed carbon dioxide and saline, which comprises:

a) providing a nasal treatment delivery device having a flow regulating device and a releasable nasal treatment dosage contained therein that includes a saline fluid and a gas containing carbon dioxide; and,

b) directing at least a portion of said nasal treatment dosage to at least one nasal cavity of said patient through said flow regulating device.

20. The method of claim 19 wherein said dosage further includes at least one additional active component.

FIGURE 1a

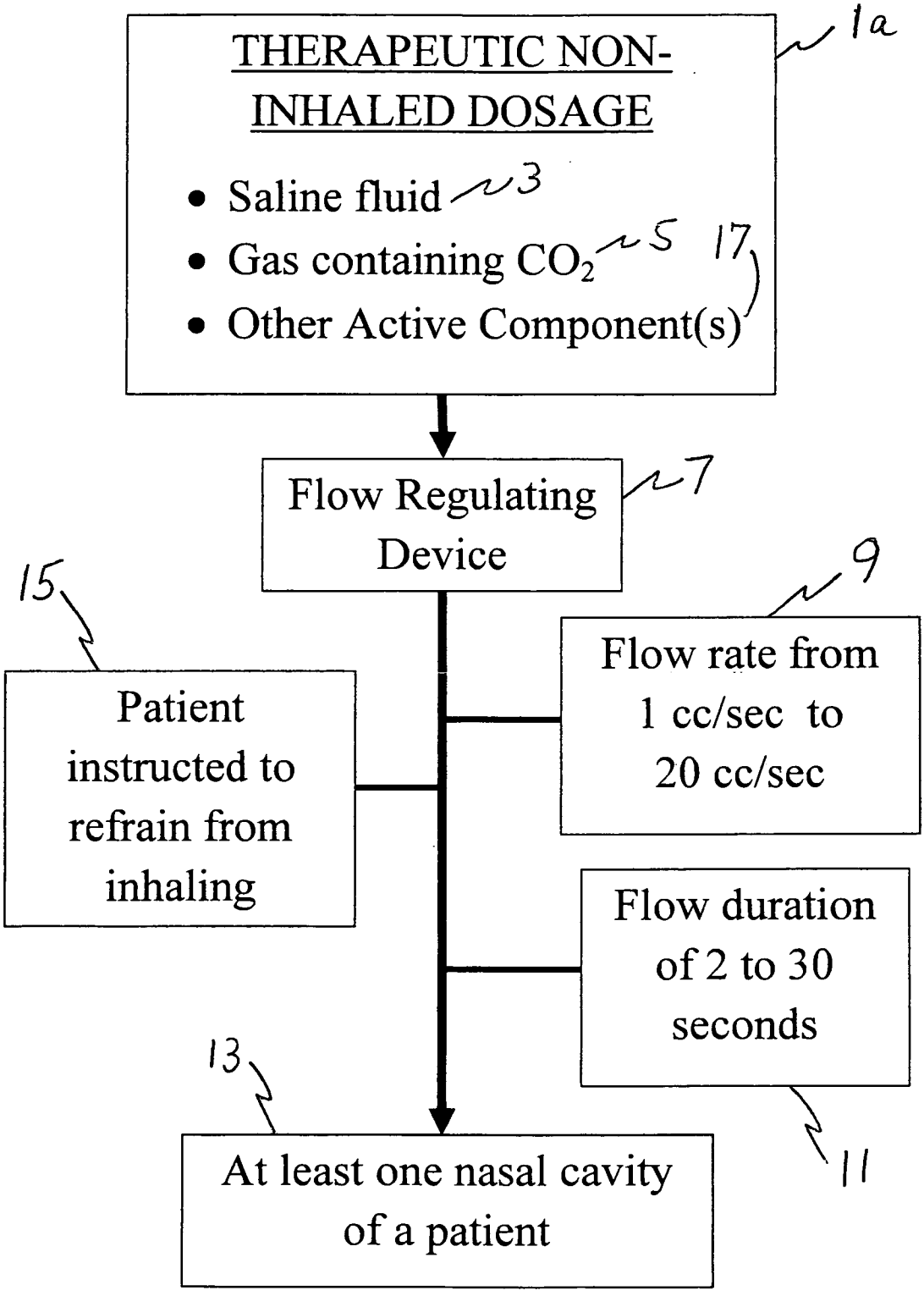

THERAPEUTIC NON-INHALED DOSAGE
1a
Saline fluid
3
Gas containing CO_2
5
17
Other Active Component(s)
Flow Regulating Device
7
15
Patient instructed to refrain from inhaling
9
Flow rate from 1 cc/sec to 20 cc/sec
Flow duration of 2 to 30 seconds
11
13
At least one nasal cavity of a patient

FIGURE 1b

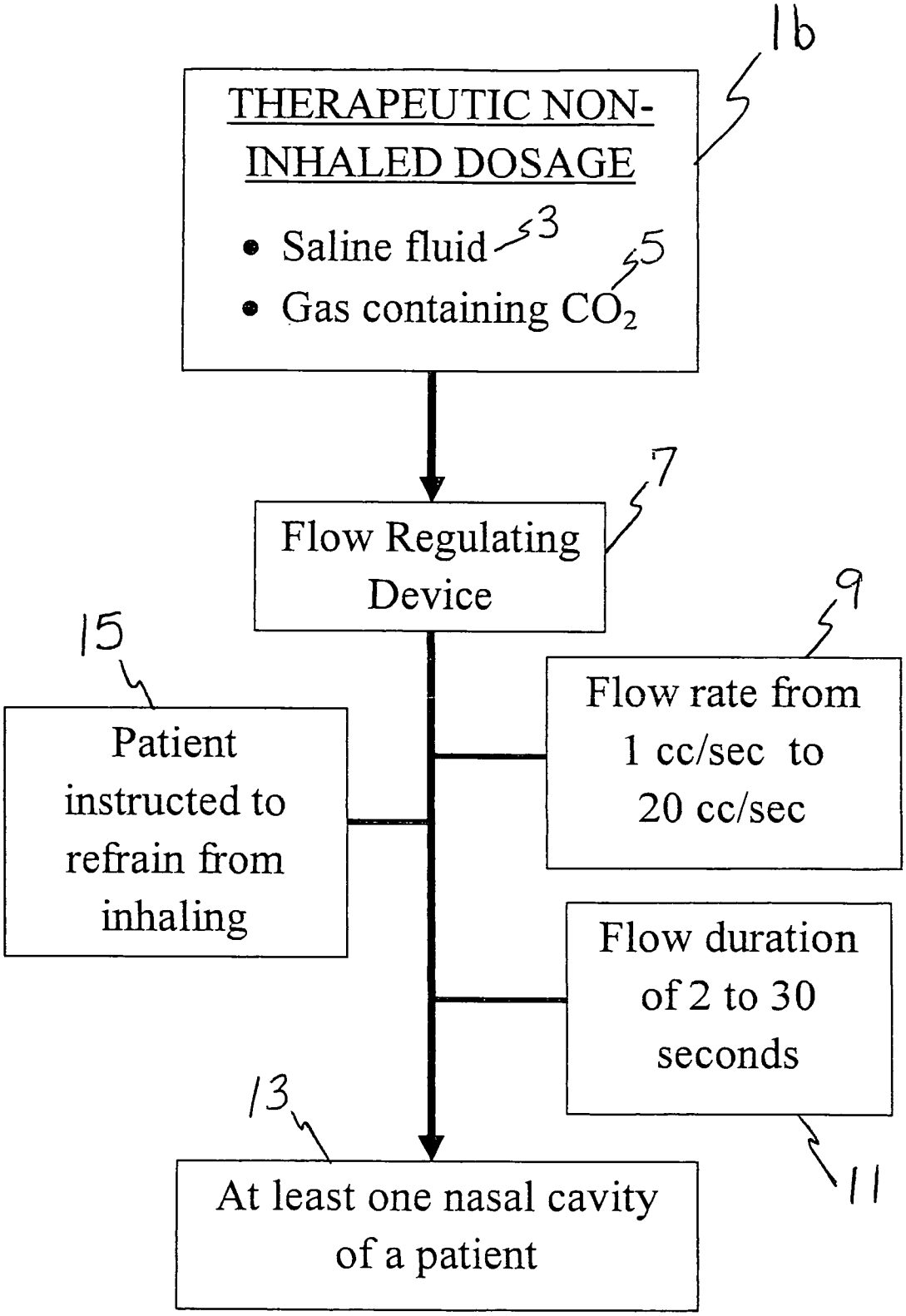

1b
THERAPEUTIC NON-INHALED DOSAGE
• Saline fluid
3
5
• Gas containing CO_2
7
Flow Regulating Device
9
Flow rate from 1 cc/sec to 20 cc/sec
15
Patient instructed to refrain from inhaling
Flow duration of 2 to 30 seconds
11
13
At least one nasal cavity of a patient

FIGURE 2

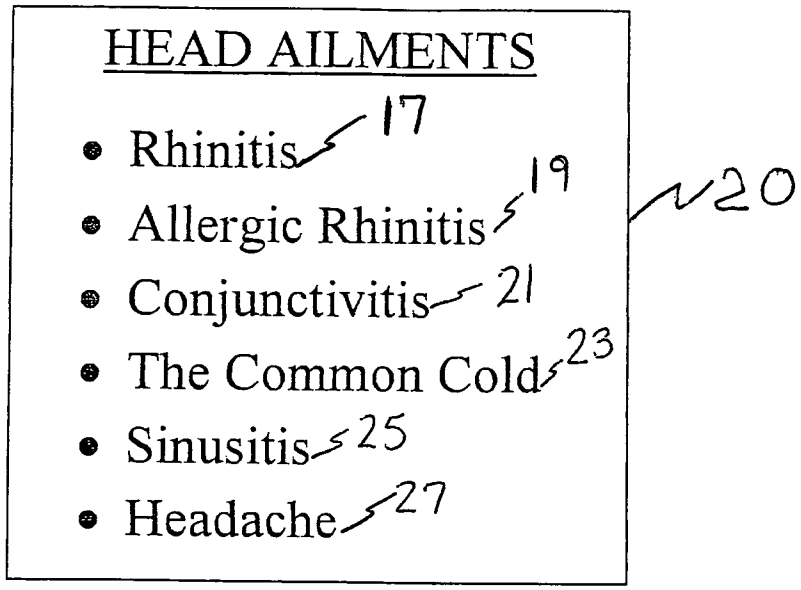


FIGURE 3

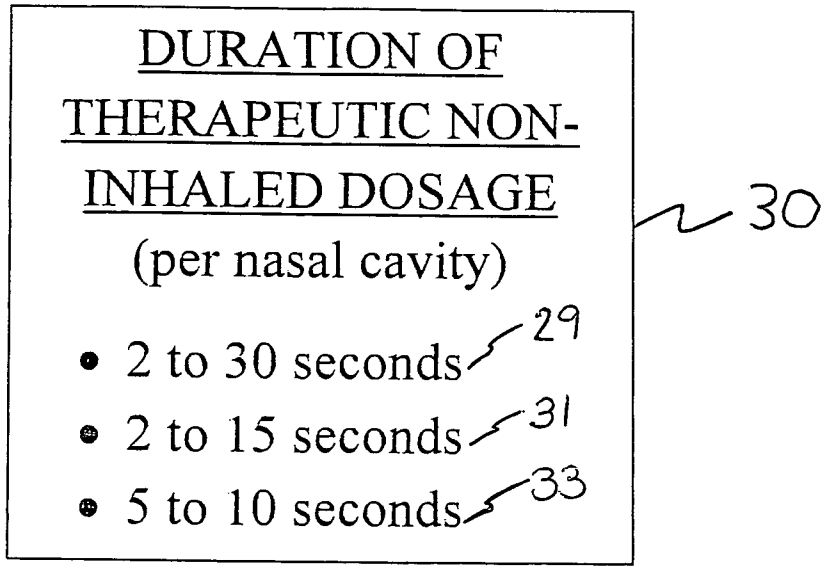


FIGURE 4

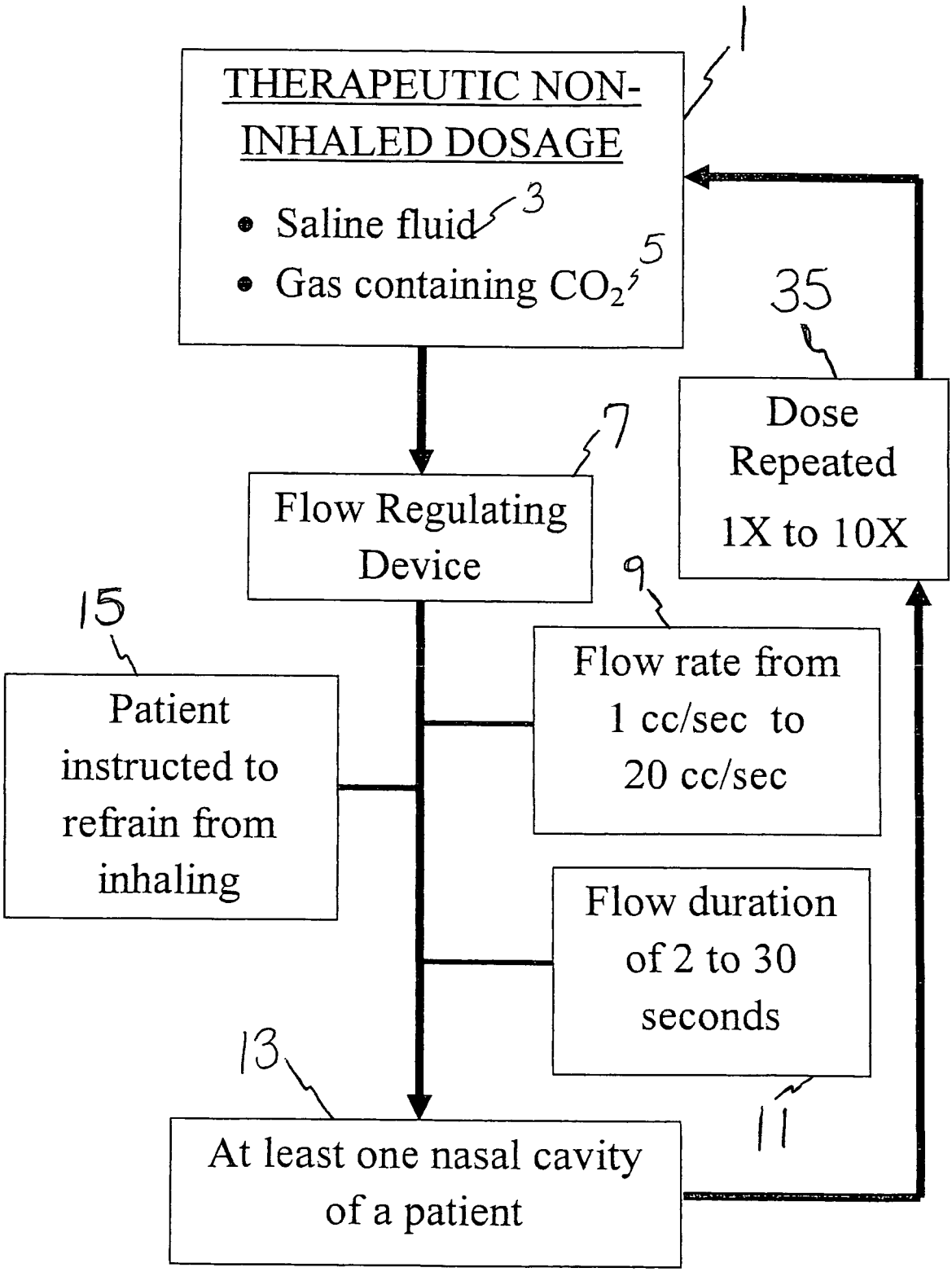

1
THERAPEUTIC NON-INHALED DOSAGE
• Saline fluid 3
• Gas containing CO_2 5
35
Dose Repeated 1X to 10X
7
Flow Regulating Device
9
Flow rate from 1 cc/sec to 20 cc/sec
15
Patient instructed to refrain from inhaling
Flow duration of 2 to 30 seconds
13
11
At least one nasal cavity of a patient

FIGURE 5

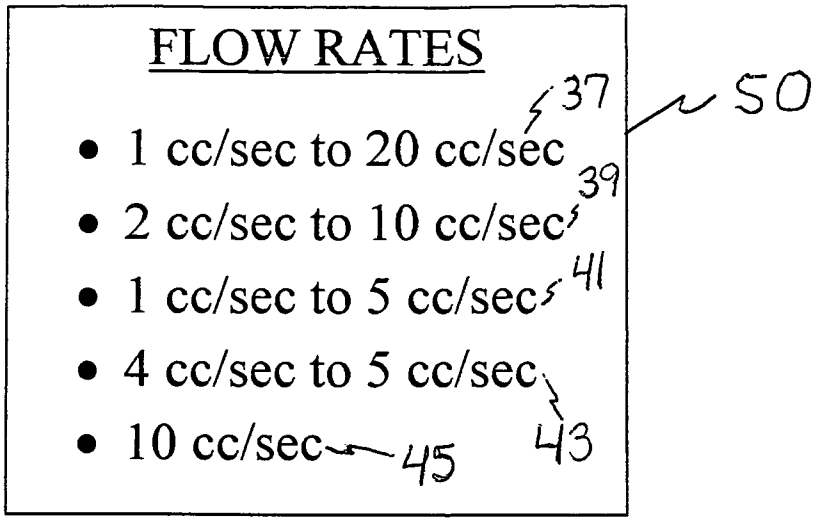
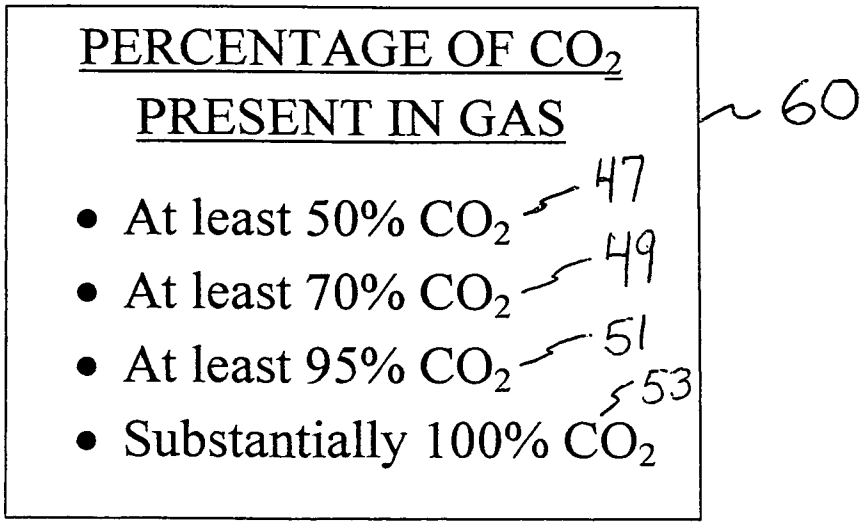


FIGURE 6



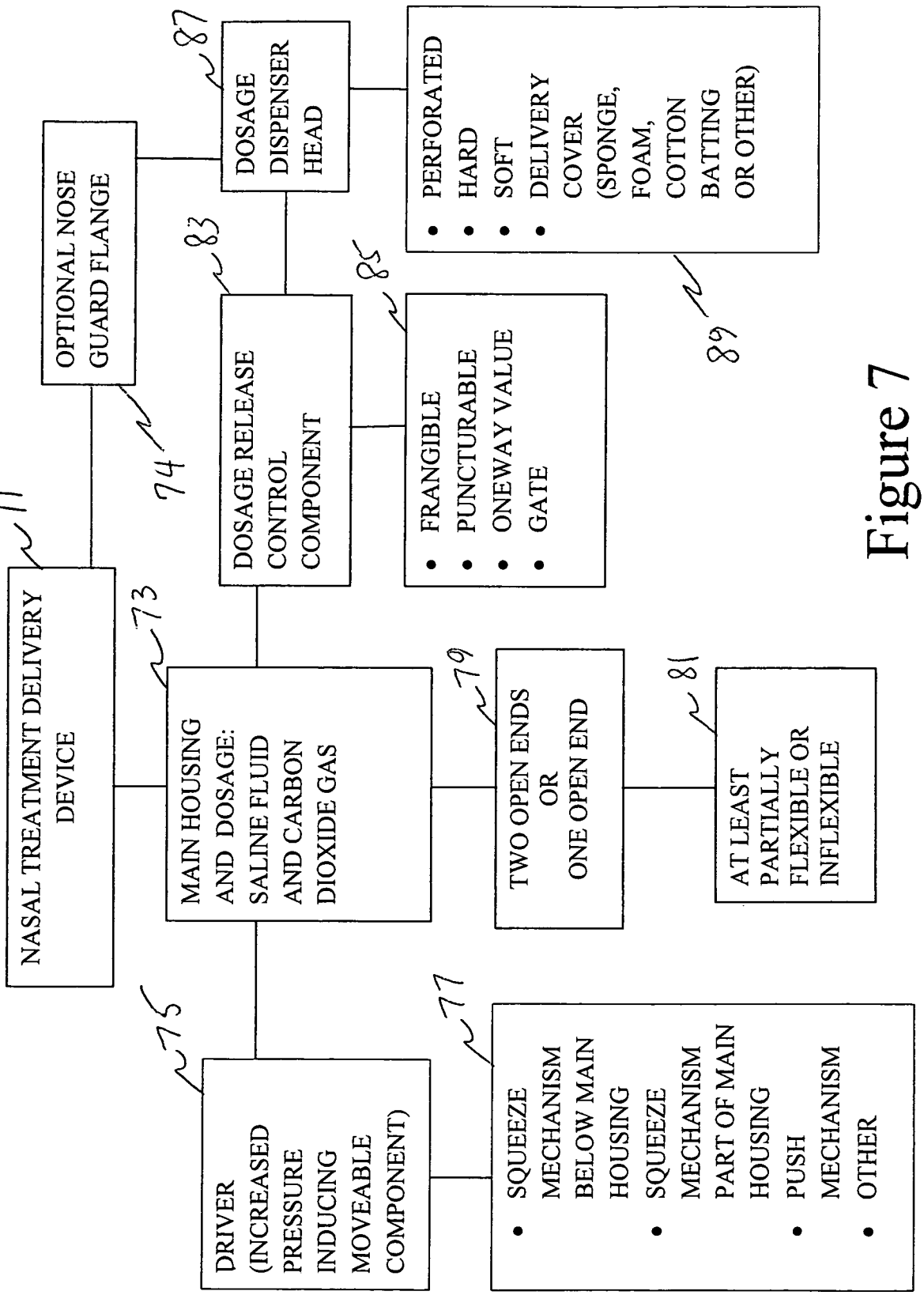

NASAL TREATMENT DELIVERY DEVICE
71
OPTIONAL NOSE GUARD FLANGE
74
DOSAGE DISPENSER HEAD
87
DOSAGE RELEASE CONTROL COMPONENT
83
FRANGIBLE
PUNCTURABLE
ONEWAY VALVE
GATE
85
PERFORATED
HARD
SOFT
DELIVERY COVER (SPONGE, FOAM, COTTON BATTING OR OTHER)
89
MAIN HOUSING AND DOSAGE: SALINE FLUID AND CARBON DIOXIDE GAS
73
TWO OPEN ENDS OR ONE OPEN END
79
AT LEAST PARTIALLY FLEXIBLE OR INFLEXIBLE
81
DRIVER (INCREASED PRESSURE INDUCING MOVEABLE COMPONENT)
75
SQUEEZE MECHANISM BELOW MAIN HOUSING
SQUEEZE MECHANISM PART OF MAIN HOUSING
PUSH MECHANISM
OTHER
77

Figure 7

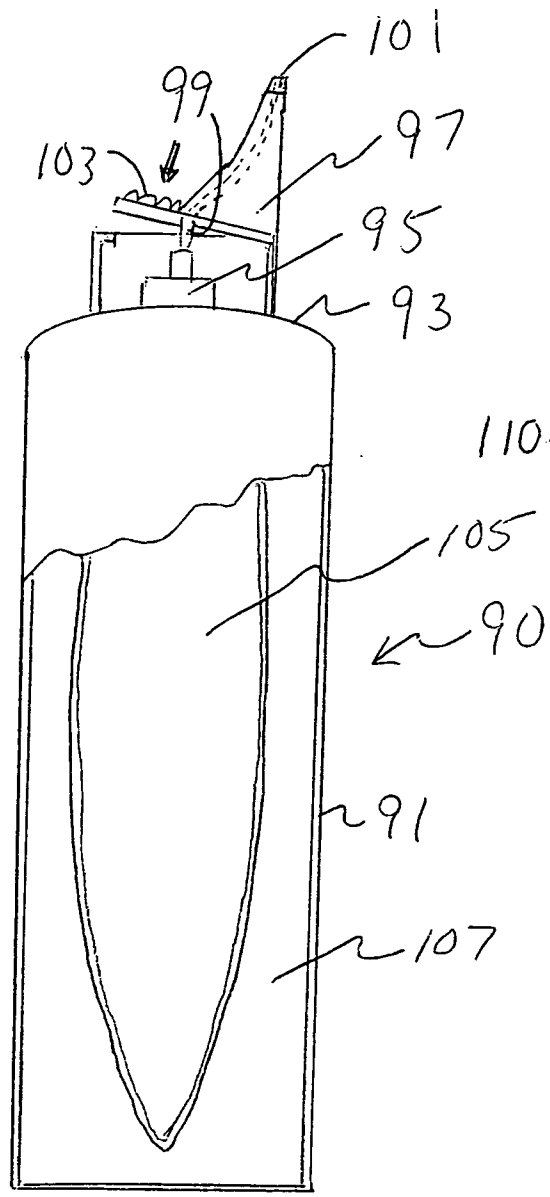


Figure 8

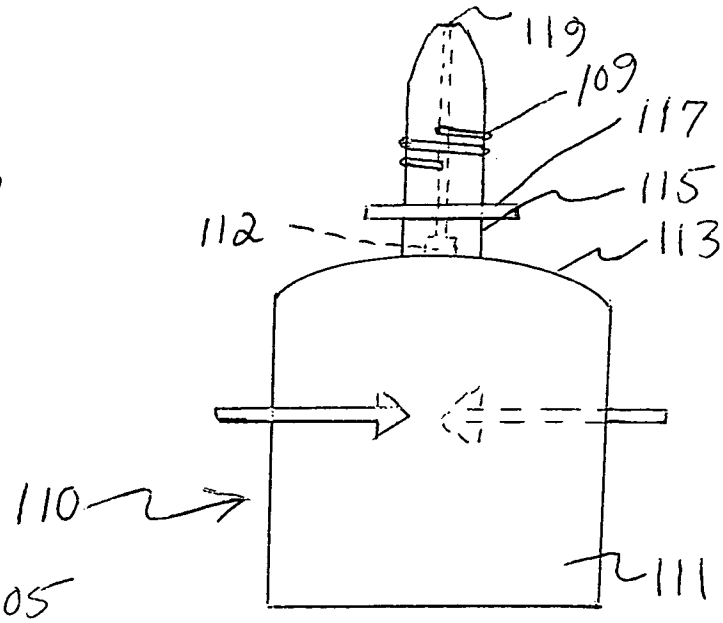


Figure 9

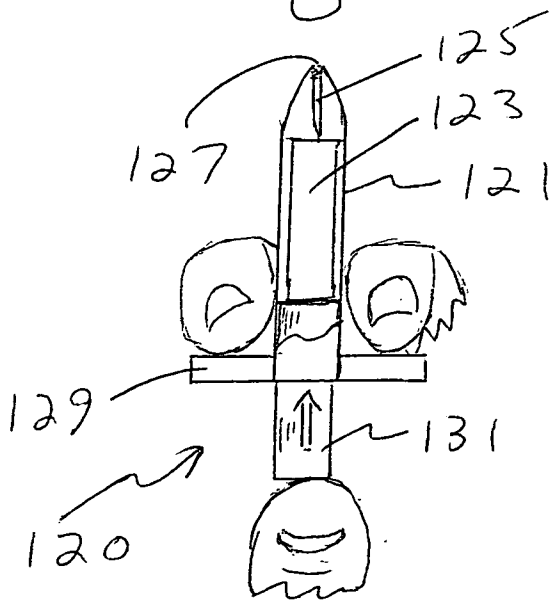


Figure 10

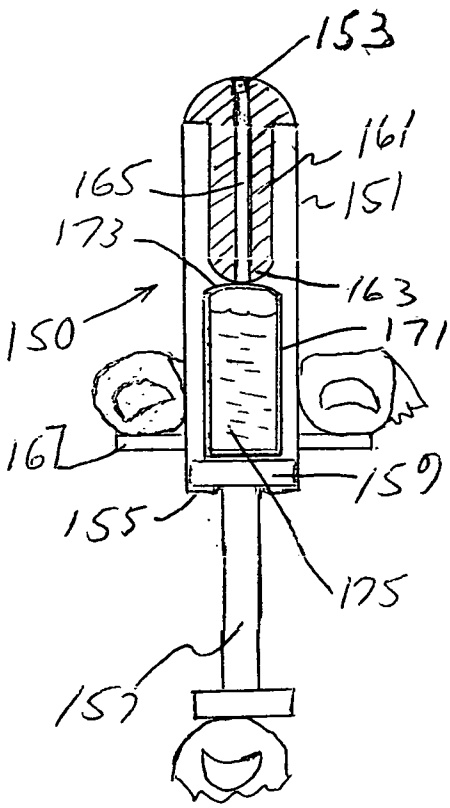


Figure 11

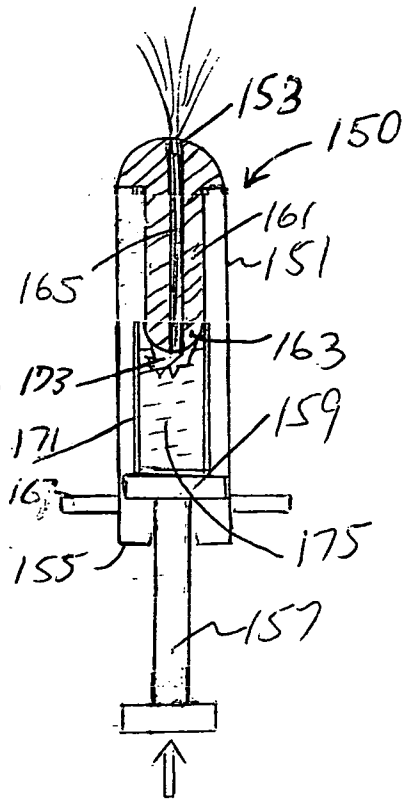


Figure 12

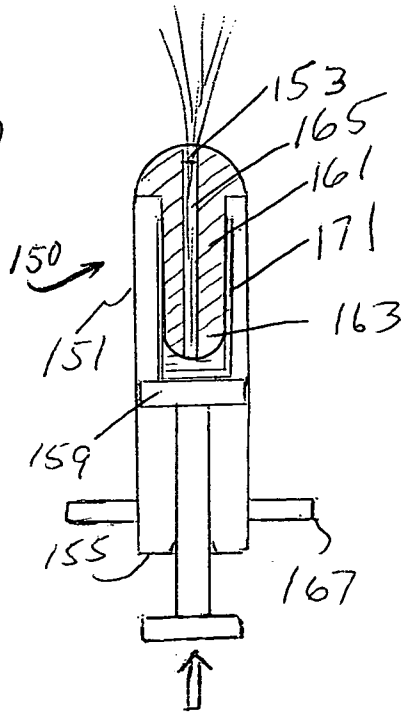


Figure 13

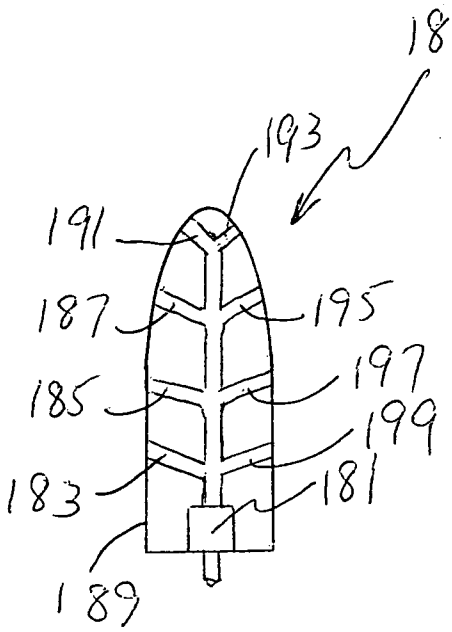


Figure 14

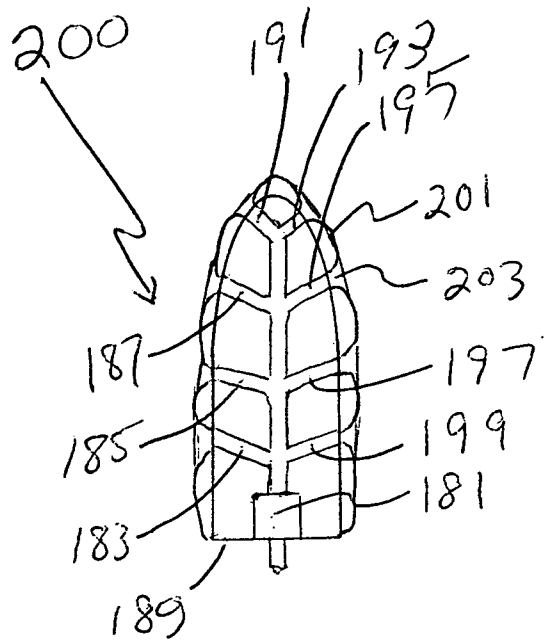


Figure 15