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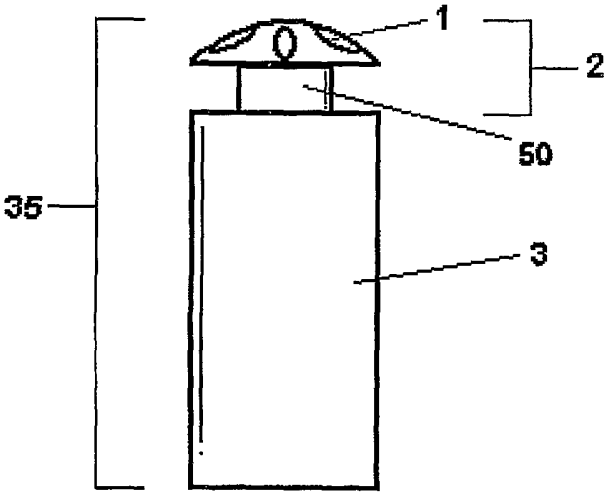
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(54) Title: SYSTEM AND METHOD FOR MODIFYING A FLUID FOR ORAL ADMINISTRATION



(57) Abstract: Methods and system are provided for modifying a fluid for oral administration. Typical systems include a reservoir which contains or may be filled with water or other aqueous components. The system also include a container or retention pocket which is integral with or mountable on or in the reservoir. The container holds a soluble beneficial agent, typically an electrolyte or a medicament. The container is adapted to selectively combine a measured amount of the beneficial agent with the aqueous component based upon patient need.

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SYSTEM AND METHOD FOR MODIFYING A FLUID FOR ORAL ADMINISTRATION

CROSS-REFERENCES TO RELATED APPLICATIONS

[0001] This application claims the benefit and priority of U.S. Provisional Patent Application No. 60/603,949 (Attorney Docket 022337-000200US), filed August 23, 2004, the full disclosure of which is hereby incorporated by reference for all purposes.

STATEMENT AS TO RIGHTS TO INVENTIONS MADE UNDER FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

[0002] NOT APPLICABLE

REFERENCE TO A "SEQUENCE LISTING," A TABLE, OR A COMPUTER PROGRAM LISTING APPENDIX SUBMITTED ON A COMPACT DISK.

[0003] NOT APPLICABLE

BACKGROUND OF THE INVENTION

[0004] This application relates to a method and system for modifying a fluid for oral administration and, further, to a method and system for providing a hydration fluid to a patient.

[0005] Certain populations are particularly at risk for developing various fluid and electrolyte disorders—among them, hypernatremia (elevated blood sodium levels), hyponatremia (depleted blood sodium levels), volume depletion, and edema (volume overload)—including independent seniors (for whom dehydration ranks among the top five most frequent causes for hospitalization), institutionalized seniors (of whom over 50 percent acquire hypo- or hypernatremia in any given 12-month period), young children (for whom dehydration resulting from gastroenteritis accounts for 10 percent of pediatric hospital admissions), post-surgical hospital patients (of whom between 5 percent and 15 percent develop hyper- or hyponatremia), professional and non-professional athletes (for whom dehydration of as little as 2 percent (dehydration of between 5 and 10 percent is common) can

reduce athletic performance by as much as 20 percent), chronically-ill individuals (a number of chronic conditions, or medications for such conditions, including diabetes and hypertension, precipitate dehydration), military personnel (the Military Operational Medical Research Program characterizes fluid and electrolyte imbalances and dehydration as "among the highest non-adversarial threats to U.S. superiority in the battlespace" and states that "moderate dehydration degrades physical and mental performance by as much as 50%"), and mining and forestry personnel. Dehydration can lead to a number of serious medical complications, including renal failure, heart failure, brain damage, heat stroke, and death. If not treated in a timely fashion, mortality rates may exceed 50 percent. In 2000, the costs associated with dehydration-related hospitalizations among the 65+ demographic alone totaled $3.8 billion.

[0006] Dehydration, or risk thereof, is extraordinarily difficult to monitor. First, severe dehydration can occur very rapidly, in just a couple of hours. Second, many of the symptoms associated with dehydration (e.g. fatigue, confusion, dry mouth) do not appear until substantial fluids have been lost and medical complications take hold. Finally, many of the symptoms of dehydration may be present among normally-hydrated, at-risk individuals (among seniors, for example, a number of chronic conditions, and medications for such conditions, cause confusion; among athletes, anaerobic exercise often causes dry mouth and/or fatigue). The implication of the latter is that individuals at risk for dehydration, or their health care providers, often attribute classic signs of dehydration to non-hydration-related conditions and do not seek to correct the condition as a result.

[0007] Even more importantly, perhaps, fluid and electrolyte disorders are extraordinarily difficult to correct, as fluid loss and the ratio of water-to-electrolyte loss—both critical to understanding the amount, and concentration, of the oral or intravenous hydration solution required to correct these disorders—are unknown. Individuals are left to formulate their own "best-guess" estimates of fluid and electrolyte replacement needs. These best-guess estimates are rarely accurate, as the type and degree of fluid and electrolyte loss depends on a number of different variables, including heat, humidity, altitude, management of various chronic conditions, diet, fluid consumption, weight, sex, race, age, and height, among other variables. Comprehensive diets and frequent fluid administration may provide an acceptable degree of metabolic control, but often fall short of preventing the onset of various fluid and electrolyte disorders in at-risk populations. Cynthia Lucero, for example, a two-time Boston Marathon finisher, died from medical complications resulting from hyponatremia shortly after

completing her third Boston Marathon in 2002, throughout which she followed the exact diet and rehydration regime of the previous two years.

[0008] The field of hydration monitoring and rehydration therapy is active. Its importance lies in facilitating early detection and correction. Ideally, hydration monitoring would be near continuous and non-invasive. Information would be available to direct and enable a closed loop system in which electrolytes would be automatically delivered to an aqueous solution for oral administration so as to keep serum fluid and electrolyte levels close to normal physiological levels. Such a system would reduce medical complications and provide obvious increases in quality of life for at-risk patients.

[0009] It is known that information derived from biometric data, for example analyte levels in body fluids, may be employed to reliably predict the onset of, or to indicate the presence of, a fluid or electrolyte disorder in a human patient. For example, for patients presenting symptoms of fluid or electrolyte disorders, physicians will often order lab tests which measure any of a number of different clinical parameters in body fluids—most often in blood or urine—including, among others: sodium concentrations, osmolality, blood urea nitrogen (BUN) levels, creatinine levels, BUN/creatinine ratios, hematocrit levels, protein levels, glucose levels, keytone levels, amylase levels, calcium levels, urate levels, chloride levels, albumin levels, and urine specific gravity. Other non-analyte measures used to improve the accuracy of diagnosis and to guide rehydration therapy include weight change, mucous membrate moistness, reported renal function, urine volume, urine color, tissue turgor, venous pressure, postural change in heart rate, postural change in blood pressure, body temperature, respiratory rate, heat rate, blood pressure, medication and medical history, recent environmental conditions (e.g. heat, exercise, etc.), recent change in functional ability (e.g. cognitive function, continence, etc.), fever/diarrhea/vomiting, and recent fluid intake. Most systems designed to determine the concentration of one or multiple analytes in body fluids employ electronic, chemical or electrochemical methods such as disclosed in U.S. Patent Nos. 6,752,927; 6,743,597; 6,689,618; 6,635,491; 6,602,719; 6,503,198; 6,403,384, 6,149,865; 6,087,088; 6,068,971; 5,837,546; and 5,766,870.

[0010] A major drawback of such systems is that they require medically trained personnel to interpret the results and to translate the results of the clinical tests into fluid replacement recommendations. Even if a medical professional is available to provide such recommendations based on clinical lab data, patients operating in an outpatient setting cannot

easily translate clinical guidelines into fluid compositions that adhere to such guidelines. That is, commercially-available oral rehydration solutions fix the concentrations of beneficial agents at the time of manufacture. The latter means that while some consumers of such commercially-available rehydration solutions are ingesting too high a concentration of electrolytes given their serum analyte concentrations (thereby risking hypernatremia), other consumers are ingesting too low a concentration of electrolytes given their serum analyte concentrations (thereby risking hyponatremia).

[0011] Prior art discloses various drug delivery systems, and beverage containers, which recognize the need for separating beneficial agents from liquid components until just prior to oral administration including, among others, U.S. Patent Nos. 6,685,692; 6,652,134; 6,541,055; 6,382,411; 6,354,190; 6,269,973; 5,921,955; and 5,125,534. However, such systems combine substantially all of the beneficial agents with the liquid component, thereby providing no means for controlling the amount of the beneficial agent to be delivered, or the concentration of the resulting mixture.

[0012] Prior art discloses liquid dosing devices for beverage or liquid chemical manufacture, whereby the amount of beneficial agents to be delivered to the liquid component is variable and based upon measured parameters of the combined beneficial agent and component mixture, including U.S. Patent Nos. 6,387,424; 6,129,104; 5,816,448; 5,234,134; 5,154,319; and 5,058,780. In contrast, the disclosed invention varies the amount of beneficial agents to be delivered based upon measured patient biometric data.

[0013] Prior art discloses drug delivery systems, which vary the beneficial agent to be delivered based upon patient biometric data including, among others, U.S. Patent Nos. 6,572,542; 6,558,351; 6,309,373; 6,024,090, which describe insulin delivery systems, among others, that control insulin dosage based upon measured blood glucose levels. The aforementioned patents, among others, describe methods of delivery including inhalation, injection/infusion and subcutaneous administration, whereas the present invention describes delivery via oral administration.

[0014] It will now be seen that there exists a need for a system that receives patient biometric data indicative of a patient's condition, for a method for rapidly processing this data to determine a patient's need with respect to a beneficial agent, and for a system that delivers a controlled amount of the agent in response to such need. Furthermore, there exists a need for a system that receives data indicative of a patient's current fluid and/or electrolyte

levels, for a method for rapidly processing this data to determine fluid and/or electrolyte replacement needs, and for a system that delivers a controlled amount of at least one beneficial agent in response to such replacement needs. At least some of these objectives will be fulfilled by the present invention.

BRIEF SUMMARY OF THE INVENTION

[0015] The present invention provides both methods and systems for providing soluble beneficial agents to patients, particularly including providing electrolytes or other hydration agents in water and other aqueous solutions for drinking. Apparatus according to the present invention comprise drinking systems which include a reservoir which contains or may be filled with water or other aqueous components. The systems also include a container or retention pocket which is mounted on or may be mountable on or in the reservoir. The container holds a soluble beneficial agent, typically an electrolyte or other hydration agent or a medicament. The container is adapted to selectively combine a measured amount of the beneficial agent with the aqueous component.

[0016] The reservoir of the drinking system may have any form suitable for holding the aqueous component and subsequently mixing the aqueous component with the beneficial agent. Usually, the reservoir will permit sealing and storage of the aqueous component for extended periods of time. Exemplary reservoirs include cups, bottles, bladders, tubes, boxes, cans, pouches, covered children's cups, and the like. The container will usually be formed as part of the reservoir or be selectively attachable to, or detached from, the reservoir. For example, the container may comprise a plurality of dosage or dose-releasing receptacles which are formed as part of the reservoir. The patient or other user may then selectively release the doses of beneficial agent into the aqueous component from the receptacles in the reservoir. More commonly, however, the container will be removably attached to the reservoir, typically being attached to a spout or other component or feature on the reservoir from which the patient or other user may drink. For example, the spout may form a typical threaded connector of the type found on plastic water bottles. The container may then comprise a holder having a complementary threaded end for attachment to the reservoir. Typically, the container will also include a mechanism for selectively delivering a measured or calibrated amount of the beneficial agent within the container. After releasing the beneficial agent from the container, the container may be removed and the patient or other user may then drink from the bottle through the spout.

[0017] A number of different mechanisms may be provided for selectively combining the contents of the container with the aqueous component within the reservoir. For example, a mechanical element, such as a pusher plate or a pusher bar, can be mounted on the container to selectively advance and dispense a calibrated amount of the beneficial agent from the container. Alternatively, a mechanical element, such as a blister mechanism which can be depressed against a pierceable material to release measured amounts of the beneficial agent from the container, can be employed. In such instances, the beneficial agent may be in the form of a powder or granulated solid, a plurality of encapsulated pellets or dissolvable tablets or other discrete dosage forms, a liquid, a gel, or any other form of the agent which may be selectively released in measured amounts. Alternatively, the beneficial agent may be held in a pouch, osmotic device, or other holder from which it may be squeezed or otherwise pushed. The selective amount may then be released based on the amount of the pouch which is squeezed or the osmotic gradient. Other systems may be employ dials, levers, measuring receptacles, or any other variety of mechanisms which can release dosages of the beneficial agent based on user input.

[0018] The present invention further provides methods for hydrating patients. The methods rely on determining a level of hydration in the patient and preparing a hydration fluid by combining an amount of the soluble hydration agent with an aqueous component. It may be appreciated that level of hydration may include level of dehydration and level of overhydration. Particularly, the methods provide that the amount of the hydration agent to be combined is selected based on the determined level of hydration. The patient's hydration may be measured by any conventional technique, typically being based upon measured sodium concentration or osmolality, or markers therefor, in saliva, oral fluids, sweat, tears, breath, urine, or blood. Additional patient data, including the presence or absence of a medical condition, the level of other disease biomarkers, medication history, age, weight, and prior fluid consumption, among many others parameters, may be used to refine the calculation of hydration level. The hydration fluid is then prepared by mechanically releasing the calibrated amount of the hydration agent into the aqueous component, typically in a drinking vessel as described above. That is, usually, the hydration agent will be in a container attached to the drinking vessel. After dispensing the selected amount of the hydration agent into the drinking vessel, the container may be removed. Most typically, removal of the container will leave a drinking spout on the drinking vessel which is available for the patient or other user to drink from.

[0019] The present invention fulfills many objects. That is, the present invention provides solutions to problems existing in the prior art. The present invention provides a system for titrating beneficial-agent delivery based on actual beneficial-agent needs, thus combining oral delivery therapies for administering beneficial agents with monitoring technologies so as to effect tight control over the analyte level of a patient. More specifically, the present invention provides a system for titrating fluid and electrolyte delivery based on actual fluid and electrolyte replacement needs, thus combining oral delivery therapies for administering fluid and electrolytes with monitoring technologies so as to effect tight control over the fluid and electrolyte level of a patient. The optimal hydration solution concentration varies widely from patient to patient, and inter-patient over time, and may be based on a number of different factors. The system of the present invention can deliver all or any proportional amount of the beneficial agents contained in the at least one container, enabling the oral delivery of controlled amounts of beneficial agents based on the particular needs of the patient as determined by measured patient biometric data, or as determined by the latter in combination with patient preferences and additional patient data. The present invention also controls the fluid and/or electrolyte state of the patient by determining dosage at the point of consumption, rather than at the point of manufacture, thereby decreasing the incidence of electrolyte disorders resulting from the oral consumption of a solution too high or too low in electrolytes relative to the patient's replacement needs.

[0020] Various embodiments of the present invention have advantages, including one or more of the following: (a) improving the direct or indirect control that may be exercised over the fluid and electrolyte levels of a patient; (b) quickly delivering the required number and amount of beneficial agents to a patient before a hypernatremic, hyponatremic, volume depleted, or edemic state develops or becomes dangerous; (c) overcoming the deficiencies of relying on "best guess" estimates of fluid and electrolyte replacement requirements, either or both of which are often under- or overestimated by patients and formal and informal health care providers; (d) reducing the number and severity of medical complications, thereby increasing patient safety and lowering health care costs due to better control of patient fluid and electrolyte levels.

[0021] Various embodiments of the present invention have certain features. In one embodiment of the present invention, the patient or healthcare provider measures, and then manually inputs into the system of the present invention, saliva sodium concentrations, for example, and the information derived from such concentrations is used to determine the

patient's fluid and electrolyte replacement needs. The patient or health care provider may input additional patient data or preferences—including patient height, weight, sex, age, or fitness level, among other parameters included in the claims herein—to further inform the calculation of replacement needs. In this embodiment, the control strategy of the system is mechanically based, whereby the patient or health care provider manually manipulates the system based on the patient's current fluid and electrolyte levels, such manipulation causing the delivery of controlled amounts of beneficial agents to the container's reservoir based on the patient's replacement needs.

[0022] Alternatively, the present invention may comprise a closed loop system in which a diagnostic or monitoring device either external, or integral, to the system of the present invention wirelessly or electronically transmits measured patient biometric data to the first receiving system, which in turn generates a set of commands for the delivery system. In the case of the latter, for example, a saliva-based diagnostic device may be built into the mouthpiece of the container for drinking. A patient activates the system by placing his lips on the mouthpiece of the container, such action generates a saliva sodium concentration reading, such reading is transmitted to the first receiving system which, based on the data transmitted from the diagnostic device, in combination with other data entered manually by the patient, sends a series of commands to the delivery system, which then releases a proportional amount of the beneficial agents contained in the container into the reservoir.

[0023] In this embodiment, the control strategy of the system is preferably microprocessor based and/or implemented using dedicated electronics. Such a control strategy would enable the delivery system to generate patient data, such as fluid and/or electrolyte delivery trends, which data may be used to further refine future calculations of fluid and/or electrolyte replacement needs.

[0024] Based on the information disclosed herein in combination with what is known about fluid and electrolyte administration, computer software can be readily developed which can be used in connection with the receiving and delivery systems of the present invention. More specifically, a microprocessor can be programmed so as to deliver precise doses of fluids and electrolytes which correspond to the particular needs of the patient based on manually input or wirelessly or electronically transmitted patient biometric data supplied to the microprocessor. Furthermore, the dosing information contained within the microprocessor

can be fed to a separate computer and/or diagnostic or monitoring device in order to calculate the best treatment and dosing schedule for the particular patient.

[0025] Optimal control of patients' fluid and electrolyte levels implies reducing the long-term threats of renal and cardiovascular complications. The system and method of the present invention constitute a reliable fluid and electrolyte control system that permits enhanced, tight control of patient fluid and electrolyte levels.

[0026] Additional objects, advantages, and embodiments of the invention will be realized by the method and system described in the written description and claims hereof, as well as from the appended drawings. It is to be understood that both the foregoing general description and the following detailed description are exemplary and are intended to provide further explanation of the invention claimed.

BRIEF DESCRIPTION OF THE DRAWINGS

[0027] FIG. 1 illustrates an embodiment of a system of the present invention having a reservoir and a container including a spout structure and cap.

[0028] FIGS. 2A-2D illustrate embodiments of a portion the container of FIG. 1.

[0029] FIGS. 3A-3B illustrate several embodiments of a reservoir.

[0030] FIG. 4 illustrates a cross-sectional view of an embodiment of a container having a one-way valve, wherein the container is attachable to a reservoir.

[0031] FIG. 5 provides a cross-sectional view of an embodiment of an encapsulated beneficial agent embodiment.

[0032] FIG. 6 provides a cross-sectional view of an embodiment of a pierceable vapor barrier.

[0033] FIG. 7A-7B illustrate embodiments of a blister package.

[0034] FIG. 8 provides a cross-sectional view of the blister package embodiments of FIG. 7A-7B.

[0035] FIG. 9 illustrates a cross-sectional view of a pierceable vapor barrier embodiment.

[0036] FIGS. 10A-10H illustrate various embodiments of the system of the present invention wherein the container has a variety of positions.

[0037] FIG. 11 illustrates a sliding/pusher bar dispensing apparatus.

[0038] FIG. 12 illustrates a rotating dial dosing embodiment.

[0039] FIG. 13 is a flow chart illustrating an embodiment of a method of the present invention.

[0040] FIG. 14 illustrates an embodiment of a rotating dial calibrated as a function of a biometric data type.

[0041] FIG. 15 provides a top view of the rotating dial of FIG. 14.

DETAILED DESCRIPTION OF THE INVENTION

[0042] FIG. 1 illustrates an embodiment of a system **35** comprising a reservoir **3** and a container **2** mounted on the reservoir **3**. In this embodiment, the container **2** comprises a rotational cap **1** which sits atop a structure **50**, wherein the structure **50** attaches to the reservoir **3** by a threaded interface. The container **2** has a spout structure adapted for drinking therethrough.

[0043] FIGS. 2A-2D provide various views of embodiments of the structure **50** of FIG. 1. FIG 2A provides a top view of a structure **50** having protrusions **4** radially outwardly, and FIG. 2B illustrates a side view of the structure **50** of FIG. 2A. Embodiments of the structure **50** may have a variety of cross-sectional shapes, including round, oval, square, polygonal, to name a few. FIG. 2C illustrates an embodiment of a structure **50** having a non-circular cross section and FIG. 2D illustrates a side view of the structure **50** of FIG. 2C.

[0044] FIG. 3 illustrates various embodiments of reservoirs **3** having gripping features **6** or gripping contoured shapes **7** which give the user a more secure hold on the reservoir **3**. This may be particularly useful when agitating the rotational cap **1** or when mixing the dispensed beneficial agents with the aqueous component stored in the reservoir **3**.

[0045] FIG. 4 illustrates an embodiment of a system **35** of the present invention including a container **2** and a reservoir **3**. The container **2** includes a rotational cap **1** attached to a threaded protrusion **8**, which in turn interfaces with inner diameter threads **17** within structure **50**. A barrier component **10** is attached to an end of the thread protrusion **8** distal to the rotational cap **1**. When the rotational cap **1** is turned, the barrier component **10** moves axially away from the rotational cap **1**, thereby forcing an amount of the beneficial agent **11**—proportional to the amount the rotational cap is turned—through a one-way valve **12**. When

the structure **50** is mounted on the reservoir **3**, such as with the use of inner threads **9**, the beneficial agent **11** passes into the reservoir **3**. When the reservoir **3** holds an aqueous component, the measured amount of agent is selectively combined with the aqueous component.

[0046] A variety of beneficial agents **11** may be used. Examples of beneficial agents **11** include electrolytes, rehydration solutions, carbohydrates, nutrients, ergogenic supplements, medicaments, probiotics, diagnostic agents, and clinically and physiologically compatible combinations thereof. When the beneficial agent **11** comprises an electrolyte, the electrolyte may be selected from the group consisting of: particularly sodium and salts of chloride, potassium, calcium, magnesium, bicarbonate, phosphate and sulfate. When the beneficial agent **11** comprises a medicament, the medicament may be selected from the group consisting of: medications for diabetic conditions; chemotherapy agents; gastrointestinal drugs such as antacids; antibiotics; probiotic medications; prokinetic medications; bioactive peptides; antihistamine drugs; anti-infective agents, such as antibiotics, antivirals and urinary tract anti-infectives; antineoplastic agents; autonomic drugs such as adrenergic agents and skeletal muscle relaxants; blood formation and coagulation drugs; cardiovascular drugs; central nervous system agents; diagnostic agents; electrolytic, caloric and water balance agents; enzymes; antitussive, expectorant and mucolytic agents; gold compounds; hormones and synthetic substitutes; smooth muscle relaxants; H.sub.2 blockers like Tagamet.RTM.; consistency-altering agents; unclassified therapeutic agents; and any other medication intended for oral administration.

[0047] Another embodiment of a container **2** is illustrated in FIG. 5. Here, the beneficial agent **11** is encapsulated into individual portions, such as capsules **13**. The capsule **13** may be coated in a material that would prevent clumping of the beneficial agent **11** due to vapors from the aqueous component stored in the reservoir **3**. Encapsulation also provides a means of dividing the beneficial agent **11** into discrete doses.

[0048] FIG. 6 illustrates a method for separating the beneficial agent **11** from vapors generated by the aqueous component stored in the reservoir **3**. A foil or otherwise pierceable barrier **16** confines the vapor to the reservoir **3**. When the rotational cap **1** is turned, the beneficial agent **11** forces a cannulated barrier component **14** toward the pierceable barrier **16**. When a cannula **15** extending from the cannulated barrier component **14** pierces the

pierceable barrier **16**, a channel is created through which the beneficial agent **11**—illustrated here in a liquid or gel form, can flow.

[0049] FIGS. 7A, 7B, and 8 illustrate a methods and devices for storage and administration of the beneficial agent **11** with the use of a blister mechanism **18**. The beneficial agent **11** is stored in a cavity formed by a pierceable material **19** on one side and a deformable material **21** on the other. When the deformable material **21** is depressed, the beneficial agent **11** is forced against the pierceable material **19**, which then bursts open, thereby opening a path between the beneficial agent **11** and the aqueous component stored in the reservoir **3**. The blister mechanism may be located on or in the container, as in FIG. 7A, or on or in the reservoir, as in FIG. 7B

[0050] FIG. 9 illustrates another embodiment of a pierceable barrier. An elastic component **22** is positioned over a moveable piercing mechanism **23**. The beneficial agent **11** is located between the moveable piercing mechanism **23** and a pierceable barrier **25**. When the elastic component **22** is depressed, it moves the moveable piercing mechanism **23** forward, piercing the pierceable barrier **25**, and enabling the beneficial agent **11** to mix with the aqueous components in the reservoir **3**.

[0051] FIGS. 10A-10H illustrate several embodiments of systems of the present invention having the container **2** disposed in various positions. The container **2** holds a soluble beneficial agent **11**, and may optionally include other elements including a cap **1**, as illustrated in FIG. 10A. Here, the container **2** is separate from the reservoir **3** and attachable to the reservoir **3** with the use of threads **51** on the reservoir **3**. FIG. 10B illustrates the container **2** by itself holding a soluble beneficial agent **11**. FIG. 10C illustrates the container **2** inside of a reservoir **3**. FIG. 10D illustrates a container **2** integral (or attached) to a stand-alone open reservoir **3**. FIG. 10E illustrates a container **2** positionable between a cap **1** and a reservoir **3**, wherein the container **2** forms a spout structure. FIG. 10F illustrates a container **2** that is advanceable into a reservoir **3**, as indicated by an arrow. FIG. 10G illustrates an embodiment wherein the container **2** is integral to the reservoir **3**. And, FIG. 10H illustrates an embodiment wherein the container **2** is mounted on or integral with a component or fluid conduit **31**.

[0052] FIG. 11 illustrates a sliding control mechanism for the dispensing of the beneficial agent **11** from a container **2**. Here, the sliding control mechanism comprises a sliding bar **32** having a portion that protrudes such that a user can move the sliding bar **32** relative to the

container **2**. The movement of the sliding bar **32** pushes the beneficial agent **11** from an exit orifice **34**, which allows the beneficial agent **11** to then mix with the aqueous component.

[0053] FIG. 12 illustrates a rotating dial dosing mechanism. The rotating dial **37** has external markings, which enable the user to determine how much rotation has been applied to the rotating dial **37**. The rotating dial **37** has a series of external protrusions **38**, which occlude the beneficial agent channel formed by the rotating dial **37** and the feeder ramp **36**. The feeder ramp **36** forces the discrete units **39** of the beneficial agent into a single column. When the rotating dial **37** is turned, a path is temporarily opened for at least one discrete unit **39** to then drop into the reservoir **3**.

[0054] FIG. 13 uses a flowchart to illustrate an embodiment of a method of the present invention. Here, a patient's biometric data is received and this data is used as an input to automatically adjust the beneficial agent concentration of the aqueous solution to be consumed by the patient.

[0055] FIG. 14 describes a cap **40** with a twist dial **42** that is used to control the amount of beneficial agent released to the reservoir **3**. The twist dial **42** has a protruding pointer **41** that will give the user feedback as to how much beneficial agent is being released.

[0056] FIG. 15 describes the relationship of the twist dial **42**, the pointer **41**, and the calibrations **43**. In this embodiment, such calibrations take a numerical form (e.g. the analyte concentration in a bodily fluid in milli-equivalents per liter). As the twist dial **42** is turned, an increasingly proportional amount of the beneficial agent contained in the container is released, and the pointer **41** points to the appropriate corresponding calibration **43**.

[0057] An example system for modifying a patient's water and/or electrolyte levels as a function of measured patient biometric data includes a reservoir containing at least one aqueous component, at least one beneficial agent being in a form adapted to be taken up in the aqueous component for oral administration, and at least one container capable of storing the at least one beneficial agent and of separating the at least one beneficial agent from the aqueous component or from vapors of the aqueous component contained in the reservoir. In addition, the system includes a first receiving system configured for receiving a patient's measured biometric data, said receiving system calibrated as a function of at least one biometric data type; a processor which calculates a quantity of the at least one beneficial agent that is to be released to the reservoir utilizing the received measured biometric data;

and a delivery system configured to release the quantity of the at least one beneficial agent into the reservoir to form a mixture for oral administration.

[0058] The reservoir may have a variety of forms including a bottle, a cup, a bottle, a tube, a box, a can, a sack, a rehydration container, a thermos, a canister, a soft gu-like container, a pouch, a drinking-straw-type tube, a nursing bottle, a covered children's cup, a sippy cup, an on-demand drinking apparatus, or a backpack, to name a few. Typically, the reservoir is comprised of a hard material, a soft material, plastic, glass, aluminum, stainless steel, rubber, or a combination thereof. Further, the reservoir may include a cover, cap and/or a straw. The at least one aqueous component may have a variety of forms including a liquid or semi-liquid medium.

[0059] The container may be removably attached to, formed integrally with, appended to, or detached from the reservoir. In some of these embodiments, the reservoir includes a spout-like or cap-like structure and the container is integral with or appended to the spout-like or cap-like structure. In some embodiments, the container is configured to move unrestrained within the reservoir. The container may store the at least one beneficial agent in one or multiple doses. In some embodiments, the container comprises a barrier that separates the beneficial agents from the reservoir, such as a mechanical barrier, an electrical or magnetic field barrier, or a material barrier that changes states. In a mechanical embodiment, the mechanical barrier may comprise a mechanical door, a capsule, a one-way valve, or a pierceable material that is impenetrable to liquid, moisture, or vapors when unpierced. Typically, the mechanical barrier is comprised of plastic, rubber, or aluminum. It may be appreciated that the at least one beneficial agent may alternatively or in addition be contained in an osmotic device or in controlled release dosage form units.

[0060] The at least one beneficial agent may take a variety of forms including a granulated solid, powder, coated or uncoated granules, an encapsulated tablet, a compressed tablet, a dissolvable tablet, a capsule, a gel, or a liquid. In some embodiments, the at least one beneficial agent is selected from the group consisting of an electrolyte, a rehydration solution, a carbohydrate, a nutrient, an ergogenic supplement, a medicament, a probiotic, a diagnostic agent, and combinations of these. In some embodiments, the system further includes a flavoring or coloring agent disposed in the at least one container.

[0061] In some embodiments, the biometric data includes at least one of: a measured sodium concentration in a body fluid, a measured osmolality in a body fluid, a presence of at

least one analyte in a body fluid, an absence of at least one analyte in a body fluid, a quantity of at least one analyte in a body fluid, a concentration of at least one analyte in a body fluid, a body temperature, a saliva flow rate, a sweat rate, a urine volume, a capillary refill time, a mucous moistness, a respiratory rate, a heart rate, a postural change in heart rate, a blood pressure, a postural change in blood pressure, a venous pressure, a osmolality, a urine specific gravity, or any combination of these. The said body fluid may include saliva, sweat, tears, breath, urine, blood, or other transudates or exudates.

[0062] Typically, the first receiving system comprises an electronic-, chemical-, or electrochemical-based diagnostic or monitoring device. In some embodiments, the receiving system is calibrated according to a level having a numerical form, a quantitative form, or a combination of these. The system may further comprise a second receiving system for receiving a patient's preference data wherein the processor calculates the quantity of the at least one beneficial agent that is to be released to the reservoir utilizing the received measured biometric data and the patient's preference data, wherein said patient preference data includes color, flavor, or inclusion or exclusion of a type of the at least one beneficial agent. The system may further comprise a third receiving system for receiving a patient's additional patient data wherein the processor calculates the quantity of the at least one beneficial agent that is to be released to the reservoir utilizing the received measured biometric data, the patient's preference data, if applicable, and the patient's additional patient data, wherein said additional patient data includes the presence or severity of a particular medical condition, history of medical procedures, weight, weight gain, body mass index, weight loss, height, sex, age, fitness level, illness, environmental data, heat, humidity, behavioral data, frequency of fluid or electrolyte consumption, amount of fluid or electrolyte consumption, diet, medication history; or trends in patient biometric data.

[0063] In any case, the receiving systems may receive manually input patient data. In such instances, the system may include a pressable button, pressable arrows, a pushable or pullable lever or a turnable wheel for manually inputting the patient data. In other embodiments, the receiving systems are configured to receive the biometric data from a diagnostic or monitoring device via electronic or wireless transmission. The processor may generate at least one electronic command which actuates the delivery system.

[0064] In some embodiments, the processor calculates the quantity utilizing known patient averages. For example, the known patient average may includes total body water as a

percentage of total body weight. In other embodiments, the processor calculates the quantity utilizing a patient's selection of a stock keeping unit (SKU).

[0065] It may be appreciated that the delivery system may includes a door, lever, sieve or syringe-like device which is manipulated to release the beneficial agent. Further, the at least one beneficial agent contained in the container may be separated into discrete doses, and the delivery system may be configured to release one or more discrete doses. In other embodiments, the delivery system may be configured to release the quantity all at once or in stages over time.

[0066] In some embodiments, the reservoir is configured to orally administer the aqueous component and quantity of the at least one beneficial agent to the patient directly, through a spout structure mounted onto the reservoir or through a straw-like device.

[0067] Although the foregoing invention has been described in some detail by way of illustration and example, for purposes of clarity of understanding, it will be obvious that various alternatives, modifications and equivalents may be used and the above description should not be taken as limiting the scope of the invention which is defined by the appended claims.

[0068] All publications and patent applications cited in this specification are herein incorporated by reference as if each individual publication or patent application were specifically and individually indicated to be incorporated by reference.

WHAT IS CLAIMED IS:

1. A drinking system comprising:

a reservoir containing an aqueous component;

a container mounted or mountable on or in the reservoir, said container holding at least one soluble beneficial agent; and

means for selectively combining a measured amount of the agent with the aqueous component.

2. A drinking system as in claim 1, wherein the reservoir comprises a cup, bottle, bladder, tube, box, can, sack, thermos or canister, soft gu-like pouch, nursing bottle, covered children's cup, rehydration container, drinking-straw-type tube, or an on-demand drinking apparatus.

3. A drinking system as in claim 1, wherein the reservoir is comprised of a hard material, a soft material, plastic, glass, aluminum, stainless steel, rubber, or a combination thereof.

4. A drinking system as in any of the above claims, wherein the reservoir includes a drinking spout, wherein the drinking spout is configured for drinking through by a patient.

5. A drinking system as in claim 4, wherein the container is removably attached to the reservoir or drinking spout.

6. A drinking system as in claim 4, wherein the container is formed integrally with the reservoir or drinking spout.

7. A drinking system as in claims 4, wherein the container is detached from the reservoir or drinking spout.

8. A drinking system as in any of the above claims, wherein the container stores the at least one beneficial agent in one or multiple doses and wherein the one or multiple doses can be individually released into the aqueous component.

9. A drinking system as in any of the above claims, wherein the means for selectively combining comprises a pusher plate or bar which can be selectively advanced to dispense a calibrated amount of the at least one beneficial agent.

10. A drinking system as in any of the above claims, wherein the means for selectively combining comprises a dial which can be turned to selectively release measured amounts of the at least one beneficial agent.

11. A drinking system as in any of the above claims, wherein the means for selectively combining comprises a mechanical action.

12. A drinking system as in any of the above claims, wherein the means for selectively combining comprises a blister mechanism which can be depressed against a pierceable material to release measured amounts of the at least one beneficial agent.

13. A drinking system as in claim 1, wherein the at least one beneficial agent comprises a powder or granulated solid.

14. A drinking system as in claim 1, wherein the at least one beneficial agent comprises a plurality of dissolvable tablets.

15. A drinking system as in claim 1, wherein the at least one beneficial agent comprises a plurality of encapsulated pellets.

16. A drinking system claim 1, wherein the at least one beneficial agent comprises a liquid or gel.

17. A drinking system as in any of the above claims, wherein the at least one beneficial agent is disposed in a pouch or osmotic device.

18. A drinking system as in claim 1, wherein the at least one beneficial agent comprises controlled release dosage form units.

19. A drinking system as in any of the above claims, wherein the at least one beneficial agent comprises electrolytes, rehydration solutions, carbohydrates, nutrients, ergogenic supplements, medicaments, probiotics, diagnostic agents, and any combination of these.

20. A drinking system as in claim 1, wherein the at least one beneficial agent comprises an electrolyte.

21. A drinking system as in claim 20, wherein the electrolyte is selected from the group consisting of sodium, potassium, calcium, magnesium, salts of chloride, bicarbonate, phosphate, and sulfate.

22. A drinking system as in claim 1, wherein the at least one beneficial agent comprises a carbohydrate.

23. A drinking system as in claim 22, wherein the carbohydrate comprises a simple carbohydrate selected from the group consisting of sucrose, glucose, and fructose.

24. A drinking system as in claim 22, wherein the carbohydrate comprises a complex carbohydrate selected from the group consisting of glucose polymers and maltodextrins.

25. A drinking system as in claim 1, wherein the at least one beneficial agent comprises a nutrient.

26. A drinking system as in claim 25, wherein the nutrient comprises glutamine, hydrolysates, vitamins, minerals, proteins, amino acids, combinations of amino acids, polyamines, arginine, oligosaccharides, short chain fatty acids, enzymes, soluble fibers, fermentable fibers, nonfermentable fibers, phytochemicals, pyruvamide, pyruvyl-amino acids, amides of pyruvyl-amino acids, pyruvates, esters, salts, structured lipids, fats, d-chiroinositol, lactoferrin, marine oils, acidulents, ascorbic acid, anti-oxidants, or any combination of these.

27. A drinking system as in claim 1, wherein the at least one beneficial agent comprises an ergogenic supplement.

28. A drinking system as in claim 27, wherein the ergogenic supplement comprises creatine, carbohydrates, caffeine, carnitine, bicarbonate, glycerol, antioxidant vitamins, colostrums, glutamine, amino acids, inosine, coenzyme Q10, herbs, beta-Hydroxy-beta-MethylButyrate, chromium, choline, GHB, vanadyl sulphate, hydroxymethylbutyrate or any combination of these.

29. A drinking system as in claim 1, wherein the at least one beneficial agent comprises a medicament.

30. A drinking system as in claim 29, wherein the medicament comprises medications for diabetic conditions, chemotherapy agents, gastrointestinal drugs, antacids, antibiotics, probiotic medications, prokinetic medications, bioactive peptides, antihistamine drugs, anti-infective agents, antivirals, urinary tract anti-infectives, antineoplastic agents, autonomic drugs, adrenergic agents, skeletal muscle relaxants, blood formation drugs, coagulation drugs, cardiovascular drugs, central nervous system agents, diagnostic agents, electrolytic balance agents, caloric balance agents, water balance agents, enzymes, antitussive agents, expectorant agents, mucolytic agents, gold compounds, hormones, synthetic substitutes, smooth muscle relaxants, H.sub.2 blockers, consistency-altering agents, or any combination of these.

31. A drinking system as in claim 1, wherein the at least one beneficial agent comprises a probiotic.

32. A drinking system as in claim 31, wherein the probiotic comprises Lactobacillus reuteri, Lactobacillus acidophilus, Lactobacillus animalis, Lactobacillus salivarius, or a live or dead microbial food supplement which affects the host's microbial balance in the gastrointestinal tract.

33. A drinking system as in claim 1, wherein the at least one beneficial agent includes a flavoring agent.

34. A method for providing a hydration fluid to a patient, said method comprising:

determining a level of hydration in the patient; and

preparing a hydration fluid by combining an amount of a soluble hydration agent with an aqueous component,

wherein the amount of hydration agent is selected based on the determined level of hydration.

35. A method as in claim 34, wherein determining the level of hydration comprises utilizing measured sodium concentration of a bodily fluid or biomarkers for measured sodium concentration of a bodily fluid.

36. A method as in claim 35, wherein the bodily fluid comprises saliva or oral fluids.

37. A method as in claim 35, wherein the bodily fluid comprises sweat, tears, breath, urine, transudates, exudates, or blood.

38. A method as in claim 34, wherein determining the level of hydration comprises utilizing measured osmolality of a bodily fluid, or biomarkers for measured osmolality of a bodily fluid.

39. A method as in claim 38, wherein the bodily fluid comprises saliva or oral fluids.

40. A method as in claim 38, wherein the bodily fluid comprises sweat, tears, breath, urine, transudates, exudates or blood.

41. A method as in claim 34, wherein determining the level of hydration comprises utilizing one or a combination of measured biomarkers for dehydration in a bodily fluid.

42. A method as in claim 41, wherein the bodily fluid comprises saliva or oral fluids.

43. A method as in claim 41, wherein the bodily fluid comprises sweat, tears, breath, urine, transudates, exudates or blood.

44. A method as in claim 35, 38, or 41, wherein determining the level of hydration further comprises utilizing at least one known patient average.

45. A method as in claim 44, wherein the at least one known patient average comprises total body water as a percentage of total body weight, a rate of fluid loss or a rate of electrolyte loss.

46. A method as in claim 35, 38, 41 or 44, wherein determining the level of hydration further comprises utilizing additional patient data.

47. A method as in claim 46, wherein said additional patient data comprises presence of one or more particular medical conditions, absence of one or more particular medical conditions, severity of one or more particular medical conditions, history of medical procedures, medication history, behavioral data, diet, fluid consumption, electrolyte consumption, weight; weight gain, weight loss, body mass index, height, sex, age, race, fitness level, physical appearance, cognitive capability of the patient, environmental data, environmental temperature, humidity, altitude, and any combination f these.

48. A method as in claim 35, 38, 41, 44 or 46, wherein determining the level of hydration further comprises utilizing previously-recorded patient biometric data and/or trends in previously-recorded patient biometric data.

49. A method as in claim 34, wherein preparing the hydration agent comprises releasing the amount of soluble rehydration agent from a container which is mounted or mountable on a reservoir which holds the aqueous component.

50. A method as in claim 49, wherein the reservoir comprises a cup, bottle, bladder, tube, box, can, sack, thermos, canister, soft gu-like pouch, nursing bottle, covered children's cup, rehydration container, drinking-straw-type tube, or an on-demand drinking apparatus.

51. A method as in claim 50, wherein the reservoir includes a drinking spout, wherein the drinking spout is configured for drinking through by a patient.

52. A method as in claim 34, wherein the container stores at least one hydration agent in one or multiple doses and wherein the one or multiple doses can be individually released into the aqueous component.

53. A method as in claim 34, wherein preparing the hydration fluid comprises mechanically releasing a calibrated amount of a hydration agent into the aqueous component held in a reservoir.

54. A method as in claim 53, wherein mechanically releasing a calibrated amount of agent is accomplished by advancing a pusher plate or bar, turning a dial, or depressing a blister mechanism.

55. A method as in claim 34, wherein preparing the hydration fluid comprises pouring a measured amount of the hydration agent into the aqueous component held in a reservoir.

56. A method as in claim 34, wherein the hydration agent comprises a powder or granulated solid.

57. A method as in claim 34, wherein the hydration agent comprises a dissolvable tablet.

58. A method as in claim 34, wherein the hydration agent comprises a plurality of encapsulated pellets.

59. A method as in claim 34, wherein the hydration agent comprises a liquid or gel.

60. A method as in claim 34, wherein the hydration agent is disposed in a pouch or osmotic device.

61. A method as in claim 34, wherein the hydration agent is in controlled release dosage form units.

62. A method as in claim 34, wherein the hydration agent comprises electrolytes, rehydration solutions, carbohydrates, nutrients, ergogenic supplements, medicaments, and any combination of these.

63. A method as in claim 34, wherein the hydration agent comprises an electrolyte.

64. A method as in claim 63, wherein the electrolyte is selected from the group consisting of sodium, potassium, calcium, magnesium, salts of chloride, bicarbonate, phosphate, and sulfate.

65. A method as in claim 34, wherein the hydration agent comprises a nutrient.

66. A method as in claim 65, wherein the nutrient comprises glutamine, hydrolysates, vitamins, minerals, proteins, amino acids or combinations of amino acids, polyamines, arginine, oligosaccharides, short chain fatty acids, enzymes, soluble fibers, phytochemicals, pyruvamide, pyruvyl-amino acids, amides of pyruvyl-amino acids, pyruvates, esters, salts, structured lipids, fats, d-chiroinositol, lactoferrin, marine oils, acidulents, ascorbic acid, anti-oxidants, or any combination of these.

67. A method as in claim 34, wherein the hydration agent comprises an ergogenic supplement.

68. A method as in claim 67, wherein the ergogenic supplement is selected from the group consisting of creatine, carbohydrates, caffeine, carnitine, bicarbonate, glycerol, antioxidant vitamins, colostrums, glutamine, amino acids, inosine, coenzyme Q10, herbs, beta-Hydroxy-beta-MethylButyrate, chromium, choline, GHB, vanadyl sulphate, and hydroxymethylbutyrate.

69. A method as in claim 34, wherein preparing the hydration fluid comprises positioning a flavoring agent along with the hydration agent.

70. A method for modifying a fluid for oral administration, said method comprising:

measuring biometric data of the patient; and

preparing the fluid by combining an amount of a soluble beneficial agent with an aqueous component,

wherein the amount of beneficial agent is selected based on the measured patient biometric data.

71. A method as in claim 70, wherein the beneficial agent is in a container mounted or mountable on or in a reservoir configured to hold the aqueous component.

72. A method as in claim 71, wherein the reservoir comprises a cup, bottle, bladder, tube, box, can, sack, thermos, canister, soft gu-like pouch, nursing bottle, covered

children's cup, rehydration container, drinking-straw-type tube, or an on-demand drinking apparatus.

73. A method as in claims 71, wherein the reservoir is comprised of a hard material, a soft material, plastic, glass, aluminum, stainless steel, rubber, or a combination thereof.

74. A method as in claims 71, wherein the reservoir includes a drinking spout, wherein the drinking spout is configured for drinking through by a patient.

75. A method as in claim 70, wherein the beneficial agent is stored in one or multiple doses and wherein the one or multiple doses can be individually released into the aqueous component.

76. A method as in claim 70, wherein preparing the fluid comprises mechanically releasing a calibrated amount of the beneficial agent into the aqueous component held in a reservoir.

77. A method as in claim 76, wherein mechanically releasing the calibrated amount of agent comprises advancing a pusher plate or bar, turning a dial, or depressing a blister mechanism.

78 A method as in claim 70, wherein preparing the fluid comprises pouring a measured amount of the beneficial agent into the aqueous component held in the reservoir.

79. A method as in claim 70, wherein the beneficial agent comprises a powder or granulated solid.

80. A method as in claim 70, wherein the beneficial agent comprises a dissolvable tablet.

81. A method as in claim 70, wherein the beneficial agent comprises a plurality of encapsulated pellets.

82. A method as in claim 70, wherein the beneficial agent comprises a liquid or gel.

83. A method as in claim 70, wherein the beneficial agent is disposed in a pouch or osmotic device.

84. A method as in claim 70, wherein the beneficial agent is in controlled release dosage form units.

85 A method as in claim 70, wherein the beneficial agent comprises electrolytes, rehydration solutions, carbohydrates, nutrients, ergogenic supplements, medicaments, probiotics, diagnostic agents, or any combination of these.

86. A method as in claim 70, wherein the beneficial agent comprises an electrolyte.

87. A method as in claim 86, wherein the electrolyte is selected from the group consisting of sodium, potassium, calcium, magnesium, salts of chloride, bicarbonate, phosphate, and sulfate.

88. A method as in claim 70, wherein the beneficial agent comprises a carbohydrate.

89. A method as in claim 88, wherein the carbohydrate comprises a simple carbohydrate selected from the group consisting of sucrose, glucose, and fructose.

90. A method as in claim 88, wherein the carbohydrate comprises a complex carbohydrate selected from the group consisting of glucose polymers and maltodextrins.

91. A method as in claim 70, wherein the beneficial agent comprises a nutrient.

92. A method as in claim 91, wherein the nutrient is selected from the group consisting of glutamine, hydrolysates, vitamins, minerals, proteins, amino acids, combinations of amino acids, polyamines, arginine, oligosaccharides, short chain fatty acids, enzymes, soluble fibers, phytochemicals, pyruvamide, pyruvyl-amino acids, amides of pyruvyl-amino acids, pyruvates, esters, salts, structured lipids, fats, d-chiroinositol, lactoferrin, marine oils and acidulents, ascorbic acid, anti-oxidants, and any combination of these.

93. A method as in claim 70, wherein the beneficial agent comprises an ergogenic supplement.

94. A method as in claim 93, wherein the ergogenic supplement is selected from the group consisting of creatine, carbohydrates, caffeine, carnitine, bicarbonate, glycerol, antioxidant vitamins, colostrums, glutamine, amino acids, inosine, coenzyme Q10, herbs, beta-Hydroxy-beta-MethylButyrate, chromium, choline, GHB, vanadyl sulphate, and hydroxymethylbutyrate.

95. A method as in claim 70, wherein the beneficial agent comprises a medicament.

96. A method as in claim 95, wherein the medicament comprises medications for diabetic conditions, chemotherapy agents, gastrointestinal drugs, antacids, antibiotics, probiotic medications, prokinetic medications, bioactive peptides, antihistamine drugs, anti-infective agents, antibiotics, antivirals, urinary tract anti-infectives, antineoplastic agents, autonomic drugs, adrenergic agents, skeletal muscle relaxants, blood formation and coagulation drugs, cardiovascular drugs, central nervous system agents, diagnostic agents, electrolytic balance agents, caloric balance agents, and water balance agents, enzymes, antitussive agents, expectorant agents, mucolytic agents, gold compounds, hormones, synthetic substitutes, smooth muscle relaxants, H.sub.2 blockers, Tagamet.RTM., consistency-altering agents, or any combination of these.

97. A method as in claim 70, wherein the beneficial agent comprises a probiotic.

98. A method as in claim 97, wherein the probiotic is selected from the group consisting of Lactobacillus reuteri, Lactobacillus acidophilus, Lactobacillus animalis, Lactobacillus salivarius, and live or dead microbial food supplements which affect a host's microbial balance in its gastrointestinal tract.

99. A method as in claim 70, further comprising positioning a flavoring agent along with the beneficial agent.

100. A drinking system comprising:

at least one reservoir containing an aqueous component;

at least one container mounted or mountable on or in the at least one reservoir, the at least one container holding a soluble beneficial agent;

a first receiving system configured for receiving a patient's measured biometric data, said receiving system calibrated as a function of at least one biometric data type;

a processor which calculates a quantity of the agent that is to be released to the reservoir utilizing the received measured biometric data; and

a delivery system configured to release the quantity of the agent into the reservoir to form a mixture for oral administration.

101. A drinking system as in claim 100, wherein the at least one reservoir comprises a cup, bottle, bladder, tube, box, can, sack, thermos, canister, soft gu-like pouch, nursing bottle, covered children's cup, rehydration container, drinking-straw-type tube, or an on-demand drinking apparatus.

102. A drinking system as in claims 100, wherein the at least one reservoir is comprised of a hard material, a soft material, plastic, glass, aluminum, stainless steel, rubber, or a combination thereof.

103. A drinking system as in claims 100, wherein the at least one reservoir includes a drinking spout, wherein the drinking spout is configured for drinking through by a patient.

104. A drinking system as in claims 100, wherein the at least one container is removably attached to the reservoir or drinking spout.

105. A drinking system as in claims 100, wherein the at least one container is formed integrally with the reservoir or drinking spout.

106. A drinking system as in claims 100, wherein the at least one container is detached from the at least one reservoir or drinking spout.

107. A drinking system as in claims 100, wherein the at least one container comprises one or multiple doses of beneficial agent, and wherein the one or multiple doses can be individually released into the aqueous component

108. A drinking system as in claim 100, wherein the means for selectively combining comprises a pusher plate or bar which can be selectively advanced to dispense a calibrated amount of the beneficial agent.

109. A drinking system as in claim 100, wherein the means for selectively combining comprises a dial which can be turned to selectively release measured amounts of the beneficial agent.

110. A drinking system as in claim 100, wherein the means for selectively combining comprises a mechanical action.

111. A drinking system as in claim 100, wherein the means for selectively combining comprises a blister mechanism which can be depressed against a pierceable material to release measured amounts of the beneficial agent.

112. A drinking system as in claim 100, wherein the beneficial agent comprises a powder granulated solid.

113. A drinking system as in claim 100, wherein the beneficial agent comprises a dissolvable tablet.

114. A drinking system as in claim100, wherein the beneficial agent comprises a plurality of encapsulated pellets.

115. A drinking system as in claim 100, wherein the beneficial agent comprises a liquid or gel.

116. A drinking system as in claim 100, wherein the beneficial agent is disposed in a pouch or osmotic device.

117. A drinking system as in claim 100, wherein the beneficial agent is in controlled release dosage form units.

118. A drinking system as in claim 100, wherein the beneficial agent is selected from the group consisting of electrolytes, rehydration solutions, carbohydrates, nutrients, ergogenic supplements, medicaments, probiotics, diagnostic agents, and combinations thereof.

119. A drinking system as in claim 100, wherein the beneficial agent comprises an electrolyte.

120. A drinking system as in claim 119, wherein the electrolyte is selected from the group consisting of sodium, potassium, calcium, magnesium, salts of chloride, bicarbonate, phosphate, and sulfate.

121. A drinking system as in claim 100, wherein the beneficial agent comprises a carbohydrate.

122. A drinking system as in claim 121, wherein the carbohydrate comprises a simple carbohydrate selected from the group consisting of sucrose, glucose, and fructose.

123. A drinking system as in claim 121, wherein the carbohydrate comprises a complex carbohydrate selected from the group consisting of glucose polymers and maltodextrins.

124. A drinking system as in claim 100, wherein the beneficial agent comprises a nutrient.

125. A drinking system as in claim 124, wherein the nutrient is selected from the group consisting of glutamine, hydrolysates, vitamins, minerals, proteins, amino acids, combinations of amino acids, polyamines, arginine, oligosaccharides, short chain fatty acids, enzymes, soluble fibers, phytochemicals, pyruvamide, pyruvyl-amino acids, amides of pyruvyl-amino acids, pyruvates, esters, salts, structured lipids, fats, d-chiroinositol, lactoferrin, marine oils, acidulents, ascorbic acid, anti-oxidants, or combinations thereof.

126. A drinking system as in claim 100, wherein the beneficial agent comprises an ergogenic supplement.

127. A drinking system as in claim 126, wherein the ergogenic supplement is selected from the group consisting of creatine, carbohydrates, caffeine, carnitine, bicarbonate, glycerol, antioxidant vitamins, colostrums, glutamine, amino acids, inosine, coenzyme Q10, herbs, beta-Hydroxy-beta-MethylButyrate, chromium, choline, GHB, vanadyl sulphate, and hydroxymethylbutyrate.

128. A drinking system as in claim 100, wherein the beneficial agent comprises a medicament.

129. A drinking system as in claim 128, wherein the medicament comprises medications for diabetic conditions, chemotherapy agents, gastrointestinal drugs, antacids, antibiotics, probiotic medications, prokinetic medications, bioactive peptides, antihistamine drugs, anti-infective agents, antivirals, urinary tract anti-infectives, antineoplastic agents, autonomic drugs, adrenergic agents, skeletal muscle relaxants, blood formation drugs, coagulation drugs, cardiovascular drugs, central nervous system agents, diagnostic agents, electrolytic balance agents, caloric balance agents, water balance agents, enzymes, antitussive agents, expectorant agents, mucolytic agents, gold compounds, hormones, synthetic substitutes, smooth muscle relaxants, H.sub.2 blockers, Tagamet.RTM, consistency-altering agents, or any combination of these.

130. A drinking system as in claim 100, wherein the beneficial agent comprises a probiotic.

131. A drinking system as in claim 130, wherein the probiotic is selected from the group consisting of Lactobacillus reuteri, Lactobacillus acidophilus, Lactobacillus animalis, Lactobacillus salivarius, and a live or dead microbial food supplement which affects the host's microbial balance in the gastrointestinal tract.

132. A drinking system as in claim 100, wherein a flavoring agent is positioned along with the beneficial agent.

133. A drinking system as in claim 100, wherein the first receiving system comprises an electronic-, chemical-, or electrochemical-based diagnostic or monitoring device.

134. A drinking system as in claim 100, wherein said biometric data is selected from the group consisting of a measured sodium concentration of a bodily fluid, a measured osmolality of a bodily fluid, a presence or absence of at least one analyte in a body fluid, a quantity or concentration of at least one analyte in a body fluid, and any combination of these.

135. A drinking system as in claim 134, wherein the bodily fluid comprises saliva or oral fluids.

136. A drinking system as in claim 134, wherein the bodily fluid comprises sweat, tears, breath, urine, transudates, exudates, or blood.

137. A drinking system as in claim 100, wherein said receiving system is calibrated as a function of a data type taking a numerical form, a qualitative form, a quantitative form, or any combination thereof.

138. A drinking system as in claim 100, further comprising a second receiving system for receiving a patient's preference data wherein the processor calculates the quantity of the at least one beneficial agent that is to be released to the reservoir utilizing the received measured biometric data and the patient's preference data.

139. A drinking system as in claim 138, wherein said patient preference data comprises color, flavor, or inclusion or exclusion of a type of the at least one beneficial agent.

140. A drinking system as in claim 138, further comprising a third receiving system for receiving additional patient data wherein the processor calculates the quantity of the at least one beneficial agent that is to be released to the reservoir utilizing the received measured biometric data, patient preference data, or additional patient data.

141. A drinking system of claim 140, wherein said additional patient data comprises presence of one or more particular medical conditions, absence of one or more particular medical conditions, severity of one or more particular medical conditions, history of medical procedures, medication history, behavioral data, diet, fluid consumption, electrolyte consumption, patient biometric data, trends in patient biometric data, weight; weight gain, weight loss, body mass index, height, sex, age, race, fitness level, or environmental data.

142. A drinking system as in claim 100, wherein said receiving systems receive manually input patient biometric data, patient preference data, and additional patient data.

143. A drinking system as in claim 100, wherein said receiving systems receive patient biometric data, patient preference data, and additional patient data electronically or wirelessly.

144. A drinking system as in claim 100, wherein the processor calculates the quantity utilizing known patient averages.

145. A drinking system as in claim 100, wherein the processor calculates the quantity utilizing a patient's selection of a stock keeping unit.

146. A drinking system as in claim 100, wherein the processor generates at least one electronic command which actuates the delivery system.

147. A drinking system as in claim 100, wherein the delivery system includes a door, lever, sieve or syringe-like device which releases the beneficial agent.

148. A drinking system as in claim 100, wherein the delivery system can individually release doses of the beneficial agent into the aqueous component.

149. A drinking system as in claim 100, wherein the delivery system is configured to release the quantity all at once or in stages over time.

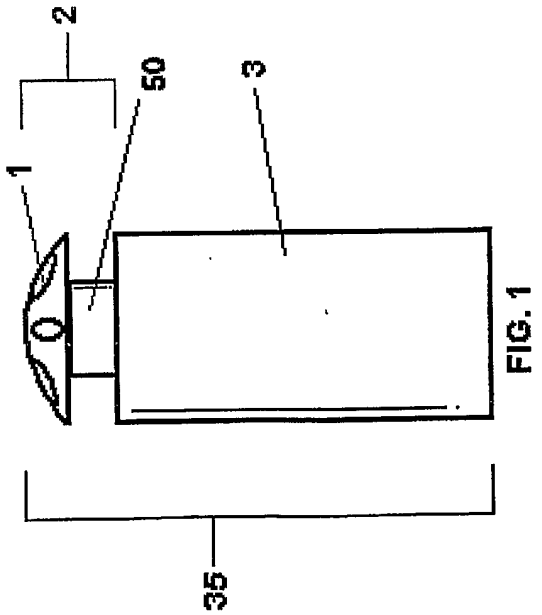


FIG. 1

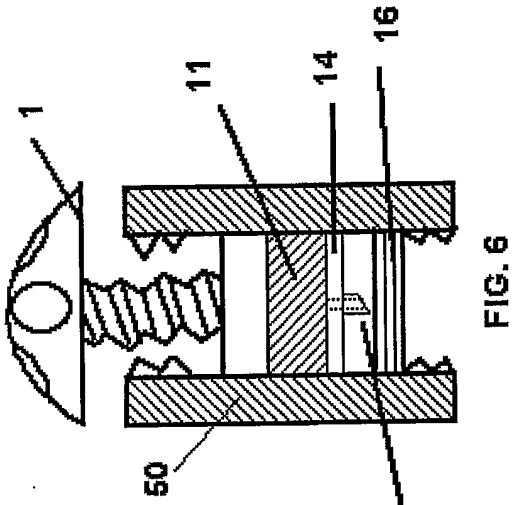


FIG. 6

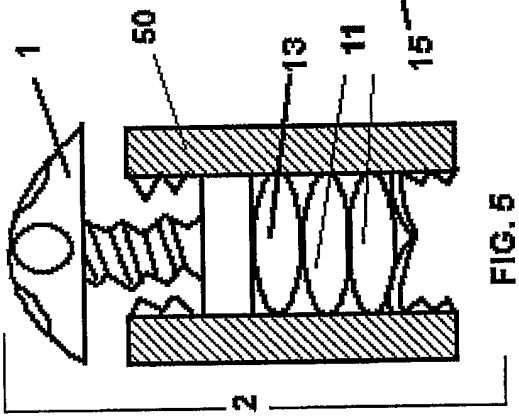


FIG. 5

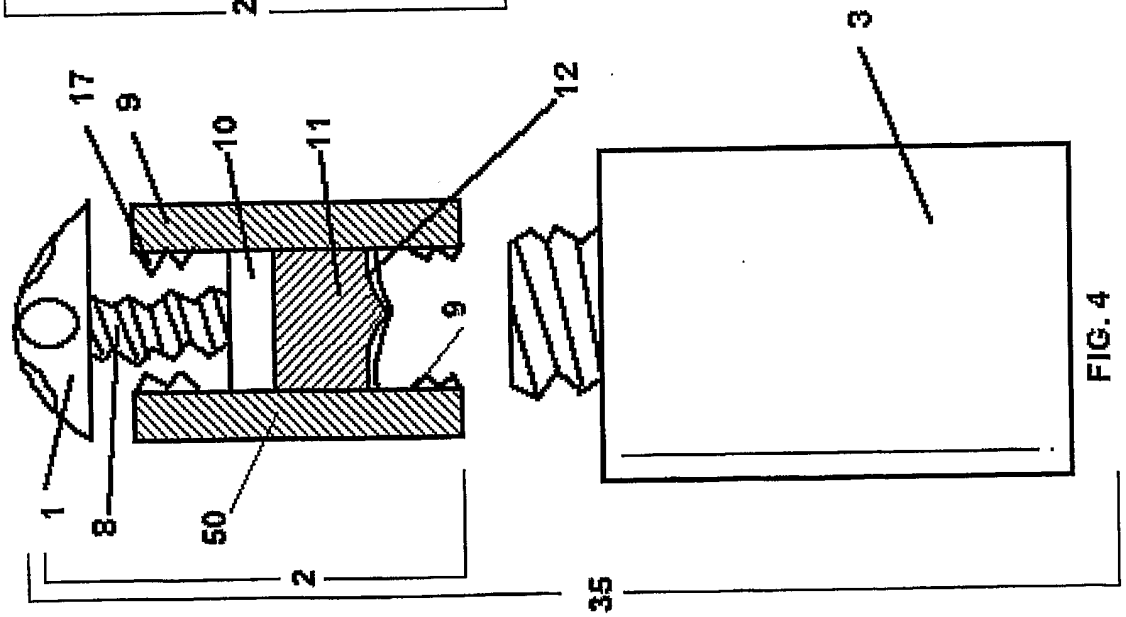


FIG. 4

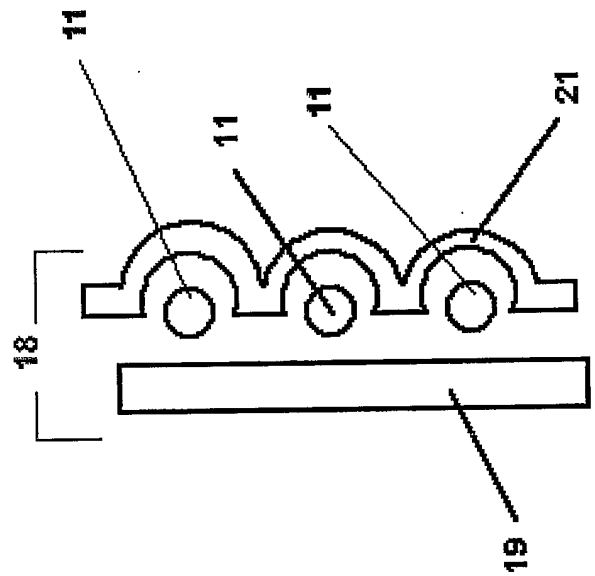


FIG 8

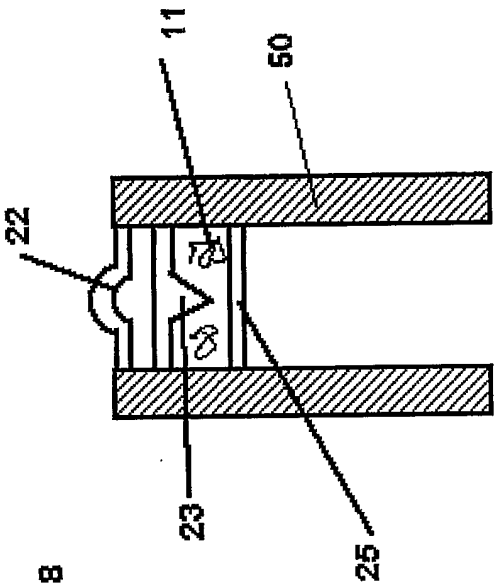


FIG. 9

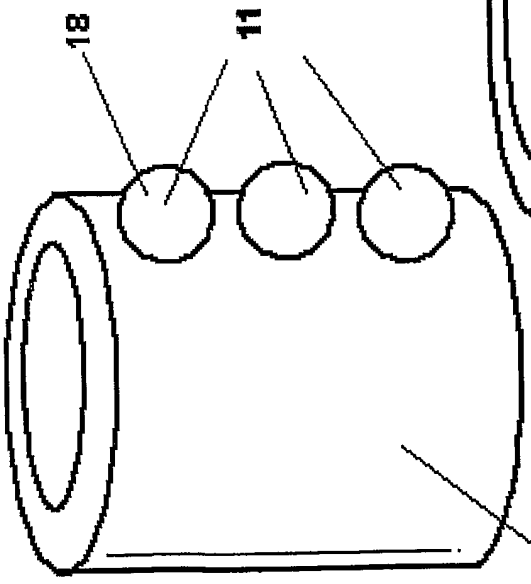


FIG. 7A

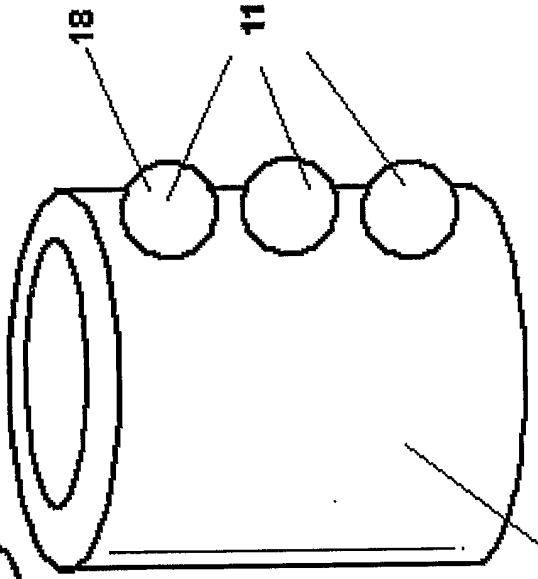
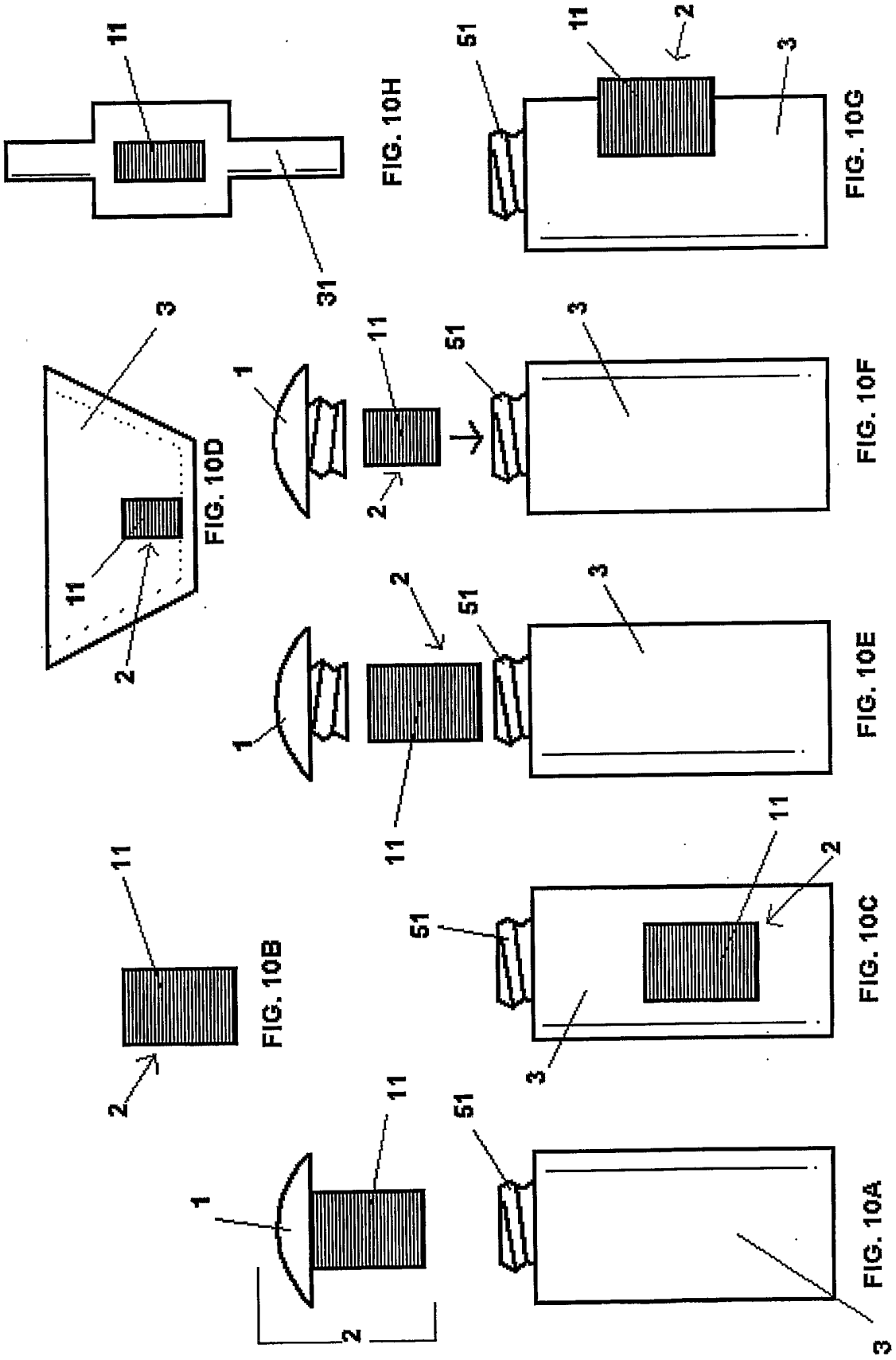


FIG. 7B


11
31
FIG. 10H
51
11
2
3
FIG. 10G
3
11
2
FIG. 10D
1
11
51
2
3
FIG. 10F
2
51
3
1
11
FIG. 10E
11
2
51
3
FIG. 10C
11
2
FIG. 10B
1
11
2
51
3
FIG. 10A

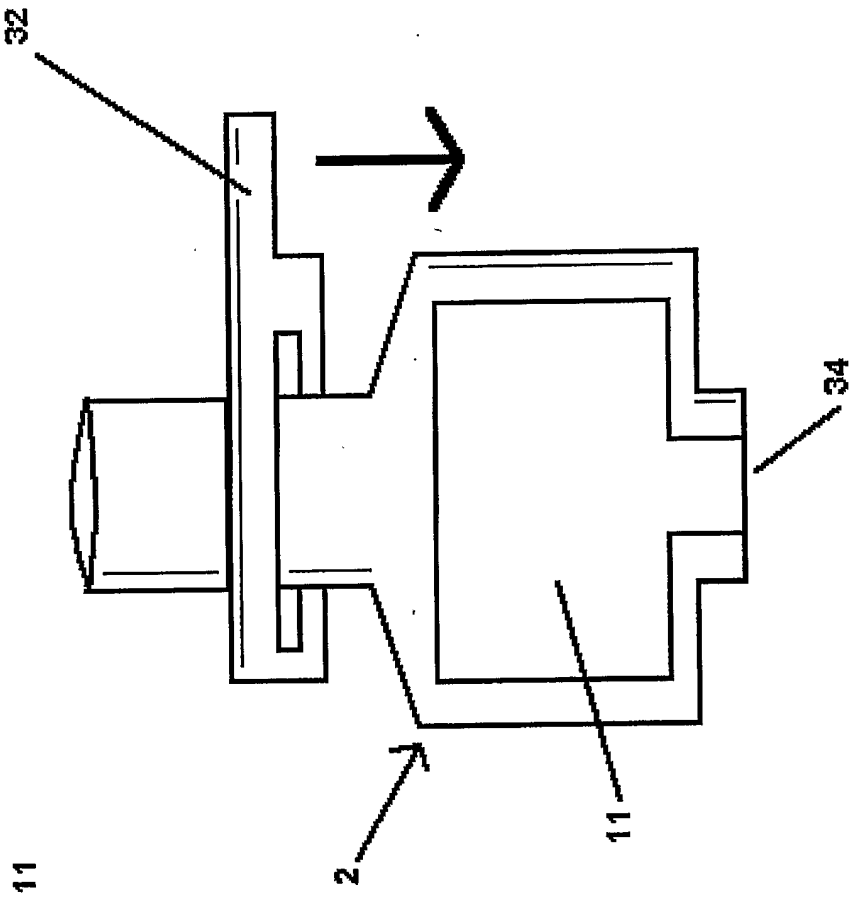


FIG. 11

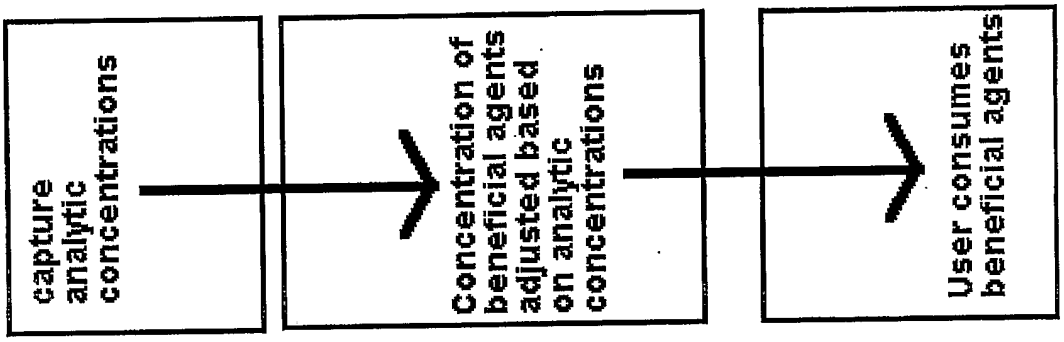
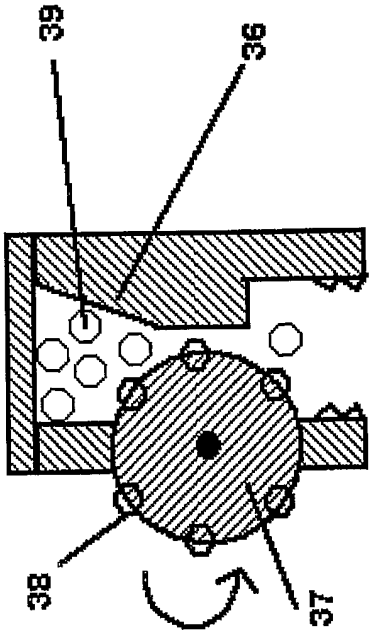

capture analytic concentrations
Concentration of beneficial agents adjusted based on analytic concentrations
User consumes beneficial agents

Fig. 13


39
36
38
37

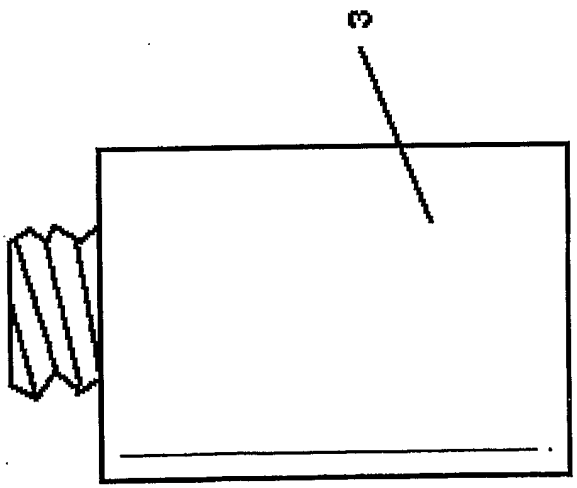

3

Fig. 12

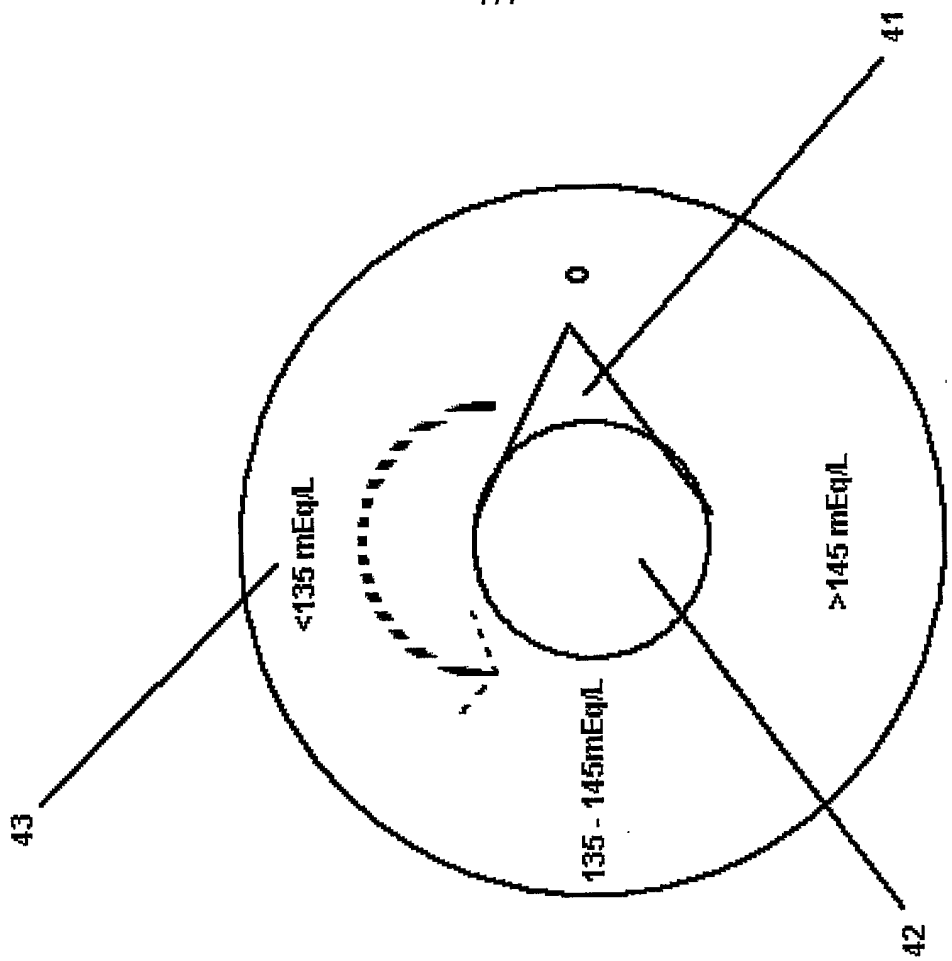


Fig. 15

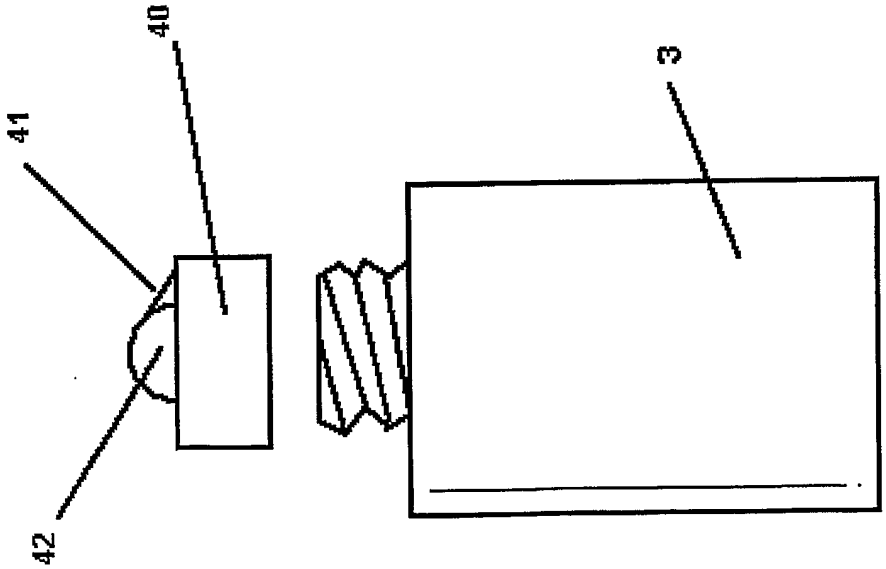


Fig. 14