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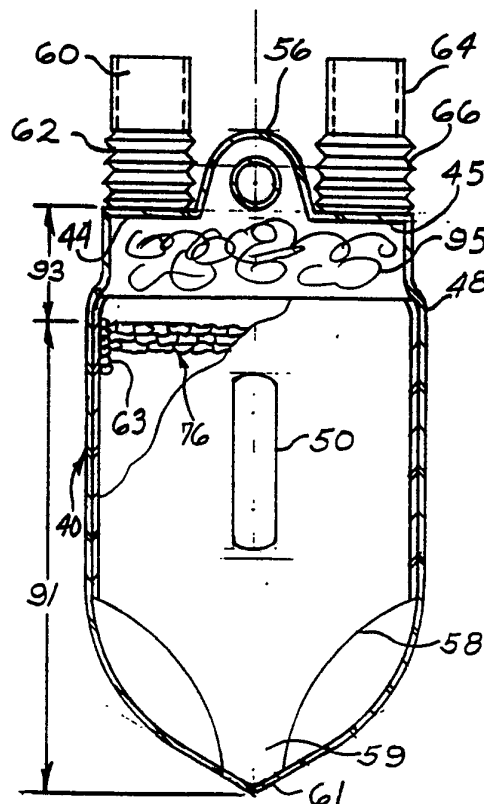
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(54) Title: SINGLE PATIENT USE DISPOSABLE CARBON DIOXIDE ABSORBER

(57) Abstract

A single-patient-use disposable carbon dioxide absorbing and air treatment device (40) which avoids use of any moving parts. The invention includes an air impervious container (48) having at least two openings (44, 45) for fluid communication between the inside and outside of the container (48). The container (48) includes granular, carbon dioxide absorbing material (63), and may also include a bacteria filter (97). The airstream enters the container (48) and is dispersed into the granular material (63), where it is heated, humidified, and carbon dioxide in the airstream is absorbed. The size, shape of the container (48), and amount of absorbent material (63) are preselected to provide immediate, optimal heating, humidifying effect and carbon dioxide removal. The airstream is delivered to the patient without contacting regulator valves, pumps and the like thereby, avoiding heat loss and condensing of water vapor before the treated air reaches the patient.



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DESCRIPTION
SINGLE PATIENT USE
DISPOSABLE CARBON DIOXIDE ABSORBER

BACKGROUND OF THE INVENTION

5 The present invention relates to carbon dioxide absorption devices used in breathing assistance systems and more particularly to recirculatory aided respiration systems for surgical or other medical applications, usually involving anesthesia.

10 In using recirculating breathing assistance systems, particularly with patients who are experiencing breathing difficulty because of trauma, surgical procedures, anesthesia, or other reasons, it is generally desirable to provide heated and
15 humidified air to the patient. Warm, humidified air prevents "drying out" of the mucocilliary tissues of the patient's respiratory system, and reduces patient heat loss that results from evaporation of water vapor from the lungs. It is also desirable
20 that the air provided to the patient be relatively free of any contamination, especially contamination which may result from previous use of the system by another patient.

 Complicated, proven hazardous, and relatively expensive apparatus have often, been employed
25 to condition the air supplied to a patient in a recirculatory aided respiration system. Where such a system is in use for a surgery or other operating room procedure, anesthesia gases or other conditioning agents are often introduced into the stream
30 of air inhaled by the patient. Also, any recirculation system requires the removal of carbon dioxide from the air exhaled by the patient.

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Such prior art systems for warming and humidifying air supplied to a patient often require the use of water reservoirs, heaters, and complicated delivery systems including complex electrical/electronic controls. Those systems may require complex hose connections and knowledge of the control systems; they may also require a significant amount of space in the operating room. Setup of these prior art systems can be quite complicated, and the systems may require substantial capital outlay as well as costly supplies. In such previous applications, the use of heated humidifiers is prevalent in order to provide proper conditioning for the air and entrained gases supplied to the patient.

CROSS REFERENCE TO RELATED APPLICATION

This application is a continuation-in-part of pending U.S. Patent Application Serial No. 07/699,485 filed 5/31/91 by Charles A. Smith, inventor of the present invention.

SUMMARY OF THE INVENTION

By proper utilization of the heat typically generated by the reaction of carbon dioxide with a granular absorbent material, such as soda lime, and by effective insulation, the typically expensive and often troublesome arrangements of a heated humidifier, water supply, reservoir, hose connection system, electronic monitoring and control, bulky mounting apparatus, and other generally complicated arrangements as employed in the prior art can be much simplified or eliminated. The carbon dioxide removal, heating, and humidifying functions

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can also be isolated from an associated anesthesia machine in disposable fashion to prevent cross contamination between patients. The capability of a single-use disposable device to warm, humidify and
5 filter the air stream recirculated to the patient, and to provide great flexibility and convenience to medical personnel utilizing such a device is highly advantageous. One device providing some of these features and advantages is the subject matter of a
10 pending United States Patent Application, Serial No. 590,967, filed on October 1, 1990 by the inventor of the present invention. This invention is another device that achieves the same fundamental objects in a different manner with yet additional advantages.

15 The present invention relates to the heating and humidification of air to be supplied to a patient which eliminates electrical/electronic humidifiers, heaters, and other related apparatus, previously listed and generally required by previous
20 procedures, to properly condition the air before it returns to the patient. In general, a device within the scope of the present invention absorbs carbon dioxide from recirculated air mixed with anesthesia gases, and simultaneously warms and humidifies the
25 air. The device can also include means for filtering out dust, virus and/or bacteria.

Nevertheless, the devices of the invention are simple and inexpensive enough such that the complete carbon dioxide absorbing unit can be
30 disposed of after only a single patient use.

The single patient use device of the present invention does not require the flow control valves normally included in conventional carbon dioxide absorption devices. Rather, any of the
35 devices of the present invention may be utilized

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together with the elements of a conventional recirculatory aided respiration system having flow control valves, air bag, hoses, etc., to provide a carbon dioxide absorption capability for the "life" of the soda lime or other CO₂ absorption material, after which disposal of the single use unit of the present invention and replacement by a new disposable unit ensues.

An important feature of the present invention is that the only portion of the aided respiration system which is discarded is that portion which ceases to be operational, i.e., the carbon dioxide absorbing material itself and the container and hoses. Moreover, the device provides all of the features of a conventional aided respiration system having a carbon dioxide absorber with the additional feature that replacement of the spent soda lime granules is performed quickly and easily with the disconnection and reconnection of only two hoses.

The disposable device according of the present invention is thermally self regulating; as more air is circulated, the air heating and humidification increases. That is, the amount of heat generated in the exothermic reaction associated with CO₂ absorption correspondingly increases because of the increased quantity of carbon dioxide produced by the patient.

Specifically the self-regulating aspect of the present invention derives from the fact that the source of heat and humidity is a direct consequence of the exothermic chemical reaction of carbon dioxide and the soda lime. Carbon dioxide is derived from the metabolic reaction at the biologic cell level and is delivered to the ventilating gas stream

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at the alveolar area of the patients lung. The amount of CO₂ produced is dependant on the patient's body weight and activity, which is minimal during surgery. Consequently it can be seen that CO₂ is
5 delivered in a metered dose as part of a tidal volume of gas passing from the patient to the respiratory system 10 and then on to the unit 40 at a rate controlled by the anesthesiologist. The reaction between CO₂ and soda lime produces 13,500
10 calories per gram molecular weight (mole) of CO₂ (22.4 liters). Thus a known tidal volume of known CO₂ content combines with a pre-selected amount of soda lime at a known reaction rate. Consequently the device can be considered to be self-regulating.

15 Insulation is preferably disposed around the device, the hoses, and other elements of the system to reduce heat loss. One such insulating device for hoses is described and taught in U.S. Patent Application Serial No. 07/019,248 filed
20 2/26/87 by the inventor Charles A. Smith and incorporated herein by reference.

Accordingly, the invention relates to a single-patient-use disposable device for removing carbon dioxide from, and increasing the moisture
25 content and temperature of, air delivered to a patient connected in a recirculatory aided respiration system which system includes an anesthesia machine having an inlet flow control valve and an outlet flow control valve. The system also includes
30 an exhalation conduit through which a stream of air exhaled by the patient flows to the inlet valve of the anesthesia machine, and an inhalation conduit through which a stream of air from the outlet valve of the anesthesia machines flows to be inhaled by
35 the patient.

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The device in its preferred form comprises a sealed, transparent, air impervious container having an inlet opening and an outlet opening, and a mass of granular soda lime or other carbon dioxide
5 absorbing material whereby air passing through the material to remove the carbon dioxide will be warmed, humidified and filtered.

Specifically the invention includes in a recirculatory aided respiration system for patients,
10 the improvement of a disposable single-patient use apparatus for conditioning air administered to a patient under anesthesia including an air impervious container located in immediate proximity to the patient having an inlet opening and an outlet
15 opening, a mass of granular carbon dioxide absorption material disposed within the container in flow communication with the inlet opening and outlet opening whereby air laden with carbon dioxide entering the container contacts the carbon dioxide
20 absorption material and whereupon carbon dioxide is absorbed therein with the resultant generation of heat and water vapor. The size of the container and the amount of carbon dioxide absorption material is selected such that the normal breathing of a patient
25 causes air to be freed of carbon dioxide and thus available to be recirculated to the patient at a desirable humidification level and temperature. The function of the container and material is self regulating such that air at an acceptable tempera-
30 ture and humidity and carbon dioxide level will be delivered compatible to the patient's breathing rate and tidal volume.

The amount of carbon dioxide absorbant material disposed within the container could be as
35 much as 3,000 grams. However, the preferred amount

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is in the range of 500 to 800 grams with 550 grams being the amount most preferred within the above range. Moreover, the air impervious container is sized in the range of 1250cc. to 1500 cc. of free
5 air space. However, most preferred is a container size such that when it contains the absorbant material it has a free air space in the range of between 470 cc. and 1000 cc. The most preferred free air space in the container within the above range is
10 750 cc.

Generally the container shape is preferred to be rectangular in planar cross section with the ratio of length to width being about 2 to 1. Moreover, the container shape in the vertical
15 direction (ie. its depth) is determined most advantageously to terminate in a rounded bottom or distal end, most conveniently the rounded bottom is semi-circular in nature. The diameter of the circular portion is equal to the larger of the two planar
20 dimensions, ie. the length of the container such that the container has in essence a rounded bottom. Moreover, it has been found to be advantageous that the depth of the container be greater than the length of the container, generally a ratio of depth
25 to width of 1.25 to 1 being preferred. Moreover, advantageously the container can be sized such that the ratio of planar cross section internal surface area to the depth of the container is approximately 2 to 1 thus, providing optimal absorbant utili-
30 zation, space utilization, and optimal heat and water vapor output.

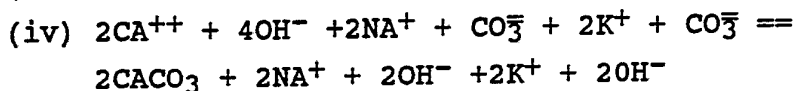
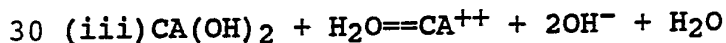
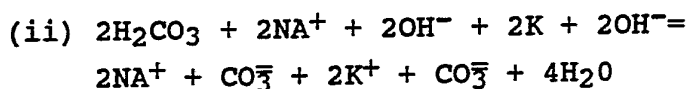
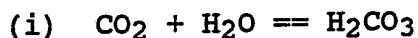
The air impervious container of the present invention also is preferrably constructed of a rigid deformation resistant material. Many of the
35 clear polymeric resinous materials have been found

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to be suitable. Examples include polystyrene, polypropylene, ABS plastics, polycarbonates and the like. The advantage of using such deformation resistant material is that the sidewalls are re-
 5 strained from bowing out and providing dimensional changes in the bed of absorbant material and also avoiding channeling along the sidewalls of said container. In addition, channeling along the side-
 10 walls of the container can be avoided by adhesively affixing a layer of carbon dioxide absorbant material thereto. The result is that the sidewall is coated with the absorbent material and the remainder of the bed interfaces with such coating to provide air passageways similar to those present throughout
 15 the bed as will be seen from the drawing.

The carbon dioxide absorbant material can be selected from any one of those commercially available. One such carbon dioxide absorption material is produced by Dewey and Almy Chemical
 20 Division of W.R. Grace & Co. and is sold under the tradename "SODASORB". Generally the material includes active ingredients of sodium hydroxide and hydrated lime.

The chemical neutralization of CO₂ with
 25 resultant production of heat and water vapor is taught in the literature as follows:



In (i) the CO₂ dissolves at a rate governed by a number of physical chemical factors. The
 35 rate is not proportional to the partial pressure of

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the CO₂ which is in contact with the film of moisture coating the soda lime granules, but greater - because some of the CO₂ combines chemically with the water to form carbonic acid. The rate is directly
5 proportional to the rate of removal of dissolved CO₂, or H₂CO₃, from solution, by reaction with hydroxyl ion (reaction ii). Thus the rapidity of removal of dissolved CO₂ is directly related to the availabiltiy of hydroxyl ions. Since the reaction
10 between H + and OH- is instantaneous, forming water, reaction (iii) and (iv) must supply additional hydroxyl ions to keep the absorption of CO₂ progressing. The latter two reactions are therefore rate limiting.

15 DESCRIPTION OF THE PRIOR ART

It has long been known that it is desirable to use a recirculatory respiratory system for anesthetizing patients. Such a system however, demands that carbon dioxide be removed from the
20 patient's exhaled gases before they are recycled. Moreover, ideally the gas should be readministered to the patient in a warm humid condition to prevent drying of the mucus membranes and other post-operative complications. Several authors have identified
25 this need as will be mentioned hereinafter.

One such author/inventor is Wayne W. Hay, inventor of the invention of U.S. Patent 3,088,810 issued May 7, 1963. The invention of the '810 Patent is a conventional carbon dioxide absorber found in
30 operating rooms throughout the country. The apparatus is not directed toward humidification and heating of the air although, admittedly the chemical reaction disclosed above is taking place in the carbon dioxide absorber of the invention.

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Another prior art reference is entitled "Humidification of Anesthetic Gases", by Chalon et. al. published by Carl C. Thomas, publisher Bannerstone House, 301-327 East Lawrence Ave., Springfield IL, U.S.A. 1981, Library of Congress, Catalogue Card No. 8027492.

Of particular interest is figure 8.7 on page 76 and also figures 10-2 and 11-3 showing prior art carbon dioxide removal and heating and humidification of anesthetic gases.

Similarly are D'ery et. al. have addressed the subject matter of heat and moisture in air streams in an article entitled, "Humidity in Anesthesiology II. Evolution of Heat and Moisture in the Large Carbon Dioxide Absorbers", at page 205 of The American Anesthesiology Society Journal Volume 14, No. 3, May 1967. Also Krister Nelson has addressed humidification of the airways in a presentation at the Gibeck Meeting in Stockholm, March 1991 as a member of the department of Pediatric Anesthesia and Intensive Care, Ostra Sjukhuset, Gotenberg, Sweden.

Other references include an article entitled "Health Devices" published by ECRI, a non-profit agency, May 1983, Volume 12, No. 7 and U.S. Patent 3,752,654.

Lastly, applicant is aware of "The Sodasorb Manual of Carbon Dioxide Absorption", published by W.R. Grace & Co., Dewey and Almy Chemical Division, copyright 1962.

The above references and the references disclosed in U.S. Patent Application Serial No. 07/699,485 of which the present application is a continuation-in-part and all of the references cited in any of the foregoing constitute all of the

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relevant prior art known to the inventor. It should be noted that none of this prior art teaches or suggests the novel features of applicants invention which will be hereinafter more fully described and
5 claimed.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a schematic diagram of a recirculatory aided respiration system, constituting an anesthesia system, in which the present invention
10 is incorporated;

Fig. 2 is an elevation view, on an enlarged scale, of a single-use disposable carbon dioxide absorption device that comprises one embodiment of the invention;

15 Fig. 3 is a detail sectional view taken approximately as indicated by line 3-3 in Fig. 2;

Fig. 4 is a detail sectional view taken approximately as indicated by line 4-4 in Fig. 2;

20 Fig. 5 is a sectional elevation view of the carbon dioxide absorber device of Figs. 2-4;

Fig. 6 is a detail view, on an enlarged scale, partly in cross-section, of a portion of the device of Figs. 2-5; and

25 Fig. 7 is an elevation view, similar to Fig. 2 of another embodiment of the invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

The recirculatory aided respiration system
10 illustrated in Fig. 1, which is actually and anesthesia system, includes a conventional anesthesia or "gas" machine 11. Machine 11 is utilized to
30 provide a desired mix of anesthetic gases through a hose 12 to a fitting 13 that is a part of the casing 14 of a device 15 that would normally serve system 10 as a carbon dioxide "absorber", which is not

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needed when employing the present invention. Device 15 may be mounted upon anesthesia machine 11 by suitable means such as a bracket 16, as shown schematically in Fig. 1. There are two other 5 tubular fittings 17 and 18 at the top of the housing or canister 14 of device 15. A pressure relief valve 19 is connected by a hose 21 to fitting 17 and a manometer or other pressure indicator 22 is connected by a hose 23 to fitting 18.

10 The three fittings 13, 17, and 18 each communicate with an outlet chamber 24 located, in the illustrated system, in the top of device 15. Device 15 has a unidirectional outlet flow control valve 27 mounted in chamber 24 to permit only 15 outward flow of air from chamber 24 through an outlet port 26 into an inhalation hose or conduit 28, sometimes referred to as a rebreathing hose. A face mask 31 included in system 10 is connected to conduit 28 so that a patient wearing the mask can 20 receive air, mixed with anesthetic gases, flowing to the patient in the direction indicated by arrow 29.

System 10 includes another conduit or hose 32, sometimes referred to as an exhalation or exhaust conduit. Hose 32 extends from the patient's 25 mask 31 to a T-fitting 33 that is connected to an inlet port 34 for device 15. Port 34 is in turn connected, by a unidirectional valve 38, to an inlet chamber 36 in the bottom of device 15. A rebreathing bag 37 is also connected to the T-fitting 33. The 30 flow of air through conduit 32 and into the inlet chamber 36 of device 15 is in the direction indicated by arrow 39.

Device 15 includes a central chamber 41 separated from the outlet chamber 24 by a wall 42 35 and separated from the inlet chamber 36 by another

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transverse wall 43. Wall 42 is provided with a plurality of apertures (not shown) to permit the flow of air from chamber 41 to chamber 24. Similarly, wall 43 includes a multiplicity of 5 apertures (not shown) to allow the flow of air from inlet chamber 36 into central chamber 41. In a conventional system the central chamber 41 would be filled with an absorption material; the CO₂ absorption material typically comprises granular soda 10 lime, though some other proprietary carbon dioxide absorption materials are occasionally used. In system 10, however, the chamber 41 of device 15 is empty.

As thus far described, system 10 would be 15 quite conventional if the canister, device 15, were filled with soda lime or some other CO₂ absorber material. When the patient wearing mask 31 exhales, the exhaled air passes through conduit 32 to the inlet port 34 that leads into the inlet chamber 36 20 of the carbon dioxide absorption device 15 through inlet flow control, check valve 38. A part of the air exhaled by the patient may pass into the re-breathing bag 37.

When the patient wearing mask 31 inhales, 25 air is drawn from the outlet chamber 24 of device 15 through the outlet flow control valve 27 and outlet port 26 into the inhalation hose or conduit 28. Additional air or oxygen anesthetic gases may be introduced into chamber 24 from machine 11 to pass 30 to the patient. The pressure in the system is held to an acceptable level by relief valve 19. Other controls may be provided, usually in the anesthesia machine 11.

A major problem with the recirculatory 35 aided respiration systems, such as the anesthesia

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system 10, is that the amount of carbon dioxide absorption material that they utilize is very large and acts as a heat sink and a water vapor trap. For example, device 15 would present such a problem if
5 its chamber 41 were filled with soda lime. Moreover, the absence of filter means leads to the entrainment of dust and even larger granules of soda lime or other carbon dioxide absorption material into the air stream. This action is decidedly undesirable,
10 particularly with respect to possible effects upon the respiratory tract of the patient wearing mask 31.

Another problem of major proportions is that device 15, in the conventional system, should
15 be replaced for each new patient to avoid inter-patient spread of contamination. Device 15 may be treated as a single use device of this purpose, but it is really too expensive and complex for such use. Consequently, hospital and other service personnel
20 are inclined to sterilize and recharge the device 15 with carbon dioxide absorption material and use it repeatedly. This is a poor practice. Sterilization is difficult and adds to the expense of system operation. It may also be ineffective, to the
25 decided detriment of the next patient. And the service personnel may simply neglect to sterilize or even re-charge device 15, with potentially disastrous results.

Moreover, if such units are left standing
30 for prolonged periods of time after an initial use unacceptably high levels of carbon monoxide are generated within the soda lime units which have a very deleterious effect on subsequent patients. In addition the absorption bed is so remote from the
35 patient that any heat produced by the reaction

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between carbon dioxide and the absorbant material is completely dissipated into the downstream hoses, valves and equipment. Similarly, humidity transmitted to the air flowing through the
5 absorption material is lost to downstream hoses, valves and equipment or condenses in conduit 28 before reaching the patient.

To minimize and eliminate these problems the recirculatory breathing assistance system is
10 properly sized and located in the immediate proximity of the patient to take full advantage of the CO₂ absorption process. The present invention includes a simple inexpensive, single-patient-use, disposable device 40 for removing carbon dioxide, heating,
15 filtering and humidifying the air delivered to the patient wearing mask 31. This device 40 is shown interposed in series in the inhalation conduit 28.

The CO₂ absorption device 40 includes container 48 having an air inlet 44 and an air
20 outlet 45, through which the air enters and exits while passing through the recirculation circuit. Container 48 is preferably made from two pieces of transparent rigid deformation resistant material which are sealed together, the seal providing
25 openings 44 and 45 for communication between the outside and inside of the container.

The CO₂ absorption receptacle or device 40 includes an air inlet 44 and an air outlet 45, through which the air enters and exits while passing
30 through the recirculation circuit. Shown in Fig. 1, and in phantom in Fig. 2, device 40 includes a styrofoam or polyfoam bag 46, which fits snugly around, and acts as a pouch for the container 48, shown in Fig. 2, and in phantom in Fig. 1. Con-
35 tainer 48 is also referred to as sac 48, and

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comprises a sac made from two transparent flexible walls which are sealed together, the seal providing openings 44, 45 and 47 for communication between the outside and inside of the sac. The bag 46 insulates 5 to the container 48, the requirement for which will be explained below. The bag 46 also includes a viewing aperture 50 which provides a view into the container 48 to a viewer who may wish to inspect the contents of the container 48.

10 Container 48 further includes a flexible holder 56 for supporting it in an upright position from a hook or other means (not shown). Suspension of the container 48 is desirable so that it does not weigh down the conduit 28. Avoidance of weighing 15 down of the conduit is desirable because any weight on conduit 28 pulls at mask 31 and causes discomfort to the patient or may cause container 48 to become disconnected from conduit 28. Referring now to Figs. 2, 3, and 4, the container 48 is shown in 20 greater detail. Flexible holder 56 can be formed as a consequence of the formation of container 48 by providing excess material in the two sheets adhesively secured together or by a single projection or strap attached later. The flexible holder 56 can be 25 disposed between the arms formed by air inlet 44 and air outlet 45, or can be attached at other suitable locations on container 48.

Fig. 4 shows in cross section an insulating layer 58 disposed on the inside of container 48.

30 Insulating layer 58 is preferably disposed on the inside of container 48, but could be located on the outside thereof. Very typically insulating layer 58 is made up of a closed cell foamed polymeric resinous material examples of which 35 are foamed polyethylene, polypropylene, ABS, or

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polystyrene. Although any suitable insulating material could be used. Preferably it may be desirable to adhesively secure insulating material 58 to the interior side of container 48 under conditions where the insulating layer is positioned continuous around the inner diameter of container 48 to block any potential air path between the insulating layer and the container wall which may form or exist during construction or use of the disposable device or unit 40. Insulating layer 58 may also include a layer of reflective foil, between the insulating layer and the container wall (not shown) which would tend to minimize radiant heat loss from unit 40 hereby serving to additionally maintain heat within unit 40.

Insulating material 58 advantageously includes a viewing aperture or slot 50 for observing the color change in the CO₂ absorbant as it is consumed. The slot may have champhored internal edges to avoid forming an air flow path when unit 40 is filled with CO₂ absorbing material. In a preferred embodiment shown in figure 7, insulating layer 58 terminates at a point above the bottom most part of container 40, but includes one or more tabs 59 which extend from opposite sides of container 48 and project downwardly along the side walls thereof in a butting relationship at the center line of container 48 to form stabilizing and locating means 61 which prevent insulating layer 58 from sliding downwardly in container 48 when insulating layer 58 is not adhesively secured to the sidewalls of container 48.

It is important that insulating layer 58 not be permitted to extend downwardly to the full depth of container 48 since insulating layer 58 by

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virtue of its presence may foster an air path either on its outside surface or its inside surface. The consequence of the formation of such an air path generally leads to less effective air treatment and
5 detrimental downstream effects on the patient.

To further avoid the formation of such an air path granular carbon dioxide absorbant material can be affixed to the inside surface of the insulation layer 58 as shown in Fig. 7 at 63. Several
10 commercially available non-toxic adhesive materials are available which are suitable for such purpose. One such adhesive is manufactured by Ross Chemical Corp. and sold under the tradename Wellbond. It should be understood that although it is desirable
15 to affix the absorbant material on the entire inside surface of the insulating layer 58, only portions may be so treated.

Air inlet 44 includes a female joining member 60 attached to the air inlet 44 by a corrugated hose section 62, which may be a conventional
20 22 mm. hose. Similarly, air outlet 45 includes a male joining member 64, attached to the air outlet 45 by a section of corrugated hose 66, which may also be a conventional 22 mm. hose. Corrugated hoses
25 62, 66 provide flexibility to the connection of the joining members 60, 64 to the conduit 28 or 32.

As will be shown below, it is important that the air inlet 44 and air outlet 45 be differentiated. Accordingly, disposing a female joining
30 member 60 at air inlet 44 and a male joining member 64 at air outlet 45 ensures only proper connection will be made of the device 40 into the conduit 28 of system 10. For example, to connect a device 40 into a system 10, a conduit hose 28 includes a connection
35 (not shown) within its length of a male member

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within a female member, shown in Fig. 1 as 70 and 72, respectively. The connection of members 70, 72 provides a continuous passageway for an airstream through conduit 28. That connection is first broken, and the male member 70 is inserted into female joining member 60 and the female member 72 is disposed over male joining member 64, thus once again completing the air flow circuit through conduit 28. A connection of the separate sections of conduit 28 to each other may thus be temporarily broken for insertion of device 40 without creating stress to the breathing cycle of the patient.

Male and female joining members 64, 60 are thus associated with each section of conduit 28. Each of these can only be fitted onto the joining members 72, 70 in one way, thus ensuring that the connection of the device is made properly. Such a system also provides flexibility in that use of the device 40 in system 10 may be omitted if air purification is not desirable.

Moreover such a system permits very rapid error free disconnection of a spent unit and replacement with a fresh unit during an operation. It is not required that a female joining member 60 be associated with the air inlet 44 and a male joining member 64 be associated with the air outlet 45. The opposite relationship may be used even though such an arrangement may be contrary to conventional practice; the only important consideration being the consistency of the connections to ensure correct operation of the device 40, as will be explained below.

Referring now to Figs. 4 and 5, detail sectional views of the device 40 are shown, partially illustrating the passively operating parts of

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the device 40. Similar elements shown in greater detail or in full configuration will be identified by identical numerals between the respective Figures. Fig. 4 is a detail sectional view taken along
5 line 4-4 of Fig. 3, and showing in cross section the wall 74 of container 48, insulating layer 58, and air impervious hose means or corrugated hoses 62, 66. Disposed between the corrugated hoses 62 and 66 are granules 76 of an absorbant material which
10 absorbs carbon dioxide from the airstream flowing through the device 40. The CO₂ absorbant material may be soda lime or the like as is described above.

Referring now to Fig. 5, a partial sectional elevational view of the carbon dioxide
15 absorber device 40 is illustrated, showing both ends of each of the corrugated hoses 62, 66. Female joining member 60 defines one end of corrugated hose 62 and provides an air inlet 44 into the device 40. Similarly, the male joining member 64 defines one
20 end of the corrugated hose 66 which provides for an air outlet 45 from the device 40. An airstream outflow opening 80 defines the other end of corrugated hose 66.

As shown in Fig. 5, corrugated hose 66
25 extends well into the space bounded by the container 48, and the airstream outflow opening 80 is disposed as far as possible from the airstream inflow opening 78. Arrows 84 indicate the flow of air into and through the granular material 76. The construction
30 of nonwoven fiber material 96 is set forth in greater detail in U.S. Patent Application No. 07/674,682, filed on March 21, 1991, having common inventorship with the present invention. The disclosure of that application is incorporated herein
35 by reference.

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Outflow opening means 80 has outflow apertures 92 which permit the outflow of the airstream from the granular material 76 into the opening means 80 as indicated by arrows 94. A filter
5 means 96 covers outflow opening means 80 and is held in place by means of rubber bands 98.

As the arrows 84 and 94 indicate, the airstream must flow into and between the granular material 76 and must flow from the container 48 and
10 into corrugated hose 66 through outflow apertures 92. As will be explained below, container 48 is a hermetically sealed enclosure in which the inlet 44 and outlet 45 are sealed to the corrugated hoses 62 and 66 as is the edge 100 of the container 48. The
15 airstream path, as shown by arrows 84 and 94, requires that the air pass through as much as possible of the granular material 76 in container 48. This expends as much as possible of the carbon dioxide absorbent capability of the granular mate-
20 rial 76 because most of the material 76 comes into contact with the passing airstream.

As a preferred embodiment the present invention contemplates that hose 66 may terminate in a bacteria filter 97 which is in flow communication
25 therewith. Several bacteria filters can be utilized as is are common in the art. One such filter, commercially available is identified as model 5000, manufactured by ARTEC Inc.

There are several advantages to locating a
30 bacteria filter 97 within the container 48 surrounded by granular material 76. One of those advantages is that the bacteria filter 97 is kept at the surrounding temperature of the granular material which may exceed 110°. Consequently, the bacteria
35 filter is positioned so the condensation of water in

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the filter is eliminated and its life thereby, prolonged. Moreover, the filter can be selected such that its size and mass do not constitute a significant heat sink and thereby, do not disadvantageously affect the temperature and humidity of the treated gas passing therethrough. In many applications it is advisable to provide for a screen across the end of the filter to prevent any fine particles of the granular material from passing into the bacteria filter and causing it to become plugged and thereby shortening its life. If the above filter and screen system are used filter means 96 may be eliminated.

Granular material 76 is comprised of large granules of soda lime or the like. Soda lime changes color after its CO₂ absorbant capacity has been expended. Thus viewing aperture or slot 50 in insulating layer 58 provides a view of the granules 76 through a clear wall portion of the container 48. If the color change is sufficient to indicate that the granules no longer can absorb a sufficient amount of CO₂, then the complete container 48 may be removed from the system 10 by disconnecting male and female adjoining members 60 and 64 and replacing the container 48 with a new container containing fresh CO₂ absorbing material 76.

In the operation of the unit of the present invention, it can be seen that there are several advantageous features which constitute an improvement over the prior art. Specifically, as described earlier it becomes very simple to interpose the unit 40 in a conduit carrying air to the patient. Because the unit is sized in volume and soda lime content it is observed that initial charges of CO₂ containing gas into the unit cause

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immediate heat and moisture evolution. This heat quickly brings the CO₂ absorbant material to temperature and thereafter, heats the through flowing airstream to a desirable level. In addition, water vapor evolving from the reaction within unit 40 as well as water vapor coming from water added to the absorbant material during its manufacture and water of hydration all contribute to the through flowing gas stream being humidified to approximately 95%. This is contrasted to the normal humidification level between 50% and 60% for conventional apparatus of standard operating conditions. Thus drying of the mucus membranes is significantly reduced since humidification begins instantly after the unit is interposed in conduit 28. As described earlier, if approximately 650 grams of soda lime are used in unit 40 ample reserve for CO₂ removal is afforded since approximately 100 grams of absorbant material is required per hour for a normal operation with the average operation lasting for approximately two to three hours.

Referring again to Fig. 7, it should be noted that ideally, the absorbant material 76 advantageously does not fill the entire container 48, but rather divides the container into an upper portion and a lower portion 91 and 93, respectively. The lower portion contains the carbon dioxide absorbant material while the upper portion remains empty or may advantageously be filled with an air pervious flow dispensing material or air distribution means 95. The concept of having a manifold or air dispersing area above the carbon dioxide absorbant material plays a significant role inasmuch as the air entering conduit 62 is more evenly dispersed across the entire bed thereby, causing a more

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uniform penetration and utilization of the material 76. This air distribution means 95 in the upper portion 91 is but one way by which air flow is evened through the bed.

5 Other means to distribute the air relates to the fact that flow volume is greater near the peripheral wall of container 48 than through the center of bed 76. This is true even if a free air space is provided above the entire surface of the
10 granular bed. The result is uneven use of the granular bed material due to the "wall effect".

The "wall effect" stems from the fact that gas flows more evenly over a smooth wall surface than through the tortuous channels formed by the
15 carbon dioxide absorbant granules. Normally the container wall constitutes a smooth surface, thus the interface between the smooth surface of the wall and the rough granular bed offers less resistance to flow than the paths between the granules.

20 To even the flow volume through the bed, methods are some times employed such as ridges and baffles along the peripheral wall to retard or extend the flow path, thus promoting volume flow through the central portion of the granular bed.
25 While somewhat effective in providing more uniform gas volume penetration over the bed surface, there still exists a differential in flow between the center and edges of the granular bed. The maximum flow rate differential between center and edge flow
30 increases in the container with a short depth and large circumference. Proper sizing of container 48 suggests that to remedy the problem one should advantageously change the wall circumference and depth. This change can be expressed in terms of a
35 depth to surface area ratio. In effect, deepening

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the container and decreasing the surface area results in more even penetration of the entire granular bed and better utilization of the material while minimizing the effect of any sidewall channeling.

In the case of course granular material such as the soda lime 76, intergranular space is quite large compared to the granule size so a relatively insignificant increase in flow resistance results when the container surface is decreased and container 40 is made deeper. The surface area to depth ratio of approximately 2 to 1 has been determined to be advantageous in the present invention, thereby providing optimum granule utilization, best space utilization, and optimal heat and water vapor output. Most preferred is a surface area to depth ratio in the range of 2.3 to 1, although other ratios have been found to be effective. In the alternative to the earlier suggestion of adhesively secured granules 76 to the inner surface of the insulation layer it is possible to texture the inner surface of container 48 or insulating layer 58 as the case may be, thereby eliminating the smooth surface present in prior art devices.

In summary then, utilization of the present invention by interposing it in a conduit 28 permits the elimination of carbon dioxide absorbant material in central chamber 41. Thereafter all of the air passing to the patient passes through container 40. Since the average tidal volume of an adult patient is approximately 750cc and normally the time sequence for a complete inhalation and exhalation is in the ratio of one third of the time elapsed for inhalation and two thirds of the time elapsed for exhalation. Container 40 can be

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optimally sized to take advantage of several simultaneously occurring events, for example, if container 40 begins with approximately 750cc. of intergranular volume and free air space, upon the first inhalation this treated air is transmitted to the patient. Residual air in the device 15 is immediately drawn into the absorber bed whereupon the carbon dioxide contained therein causes the evolution of heat and humidity. This heat and humidity serves to saturate and heat unit 40 and its contents such that upon the second inhalation and those subsequent thereto, the humidity and temperature of the air passing to the patient begins to rise. Subsequent inhalations of treated air continue to provide the patient with warmer humidified air as the unit 40 approaches equilibrium. The insulating material prevents heat loss to aid the process of heating and humidifying the air supply to the patient. Moreover, because the unit itself is compact it does not in and of itself constitute a large heat sink. Also because the bacteria filter 97 is located inside container 40, it is kept at the temperature of the granular bed therein, for optimal efficiency by elimination of condensation.

It should be noted that if the patient's tidal volume is greater than 750cc., additional air will be drawn into unit 40 through conduit 28 from the device 15 and since the outlet conduit 62 extends well within unit 40 to the bottom portion thereof, any air drawn from conduit 28 will most assuredly be treated before it is inhaled by the patient. Thus the unit is termed self regulating since the greater the patient's tidal volume the more heat and humidity that is provided and the more air that is treated.

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It should be further noted that every effort is made to avoid downstream valves and metal components which would serve as heat sinks. Moreover, advantageously the insulated hoses disclosed
5 and claimed in Patent Application U.S. Serial No. 07/593,555 can be employed.

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CLAIMS

1. In a recirculatory aided respiration system for patients, the improvement comprising: a disposable, single patient use apparatus, 5 for conditioning air administered to a patient under anesthesia including an air impervious container located in immediate proximity to the patient having an inlet and an outlet opening a mass of granular carbon dioxide absorption material disposed within 10 said container in flow communication with said inlet and outlet openings, whereby air laden with carbon dioxide entering said container contacts said carbon dioxide absorption material and whereupon carbon dioxide is absorbed therein with resultant genera- 15 tion of heat and water vapor, the size of the container and amount of carbon dioxide absorption material being selected such that the normal breathing of a patient causes air to be freed of carbon dioxide and available to be recirculated to 20 the patient at a desirable humidification level and temperature and wherupon the function of said container and material is self regulating such that air at an acceptable temperature and humidity and carbon dioxide level will be delivered, compatible 25 to the patient's breathing rate and tidal volume.

2. The apparatus of claim 1, wherein the amount of granular carbon dioxide absorbant material disposed within said container is about 650 grams.

30 3. The apparatus fo claim 1, wherein the amount of free air space in said container is between 470cc. and 750cc.

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4. The apparatus of claim 1, wherein said container is generally rectangular in planar cross section with the ratio of length to width being about two to one.

5 5. The apparatus of claim 1, wherein ratio of internal surface area to depth of said container is approximately two to one, thereby providing optimal absorbant utilization, space utilization, and optimal heat and water vapor
10 output.

6. The apparatus of claim 1, wherein the volume of said air impervious container is approximately 1000-1500cc.

7. The apparatus of claim 1 in-
15 cluding at least two flexible air impervious hose means exterior of said container one of which is in flow communication with said inlet opening and the other in flow communication with said outlet opening, whereby flexible connection with the re-circu-
20 latory system is facilitated.

8. The apparatus of claim 1, wherein said air impervious container includes flexible holding means for supporting said container in operating position as a part of said re-circu-
25 latory aided respiration system.

9. The apparatus of claim 1, wherein said air impervious container is constructed of a rigid deformation resistant material thereby resisting flexing, and dimension change of said
30 container.

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10. The apparatus of claim 9,
wherein said air impervious container includes
connector means connecting opposed portions of said
container whereby dimensional stability is facili-
5 tated.

11. The apparatus of claim 1,
wherein, said air impervious container is made up of
an upper portion and a lower portion wherein, said
carbon dioxide absorption material is disposed
10 within said lower portion and said upper portion
contains an air pervious dispersing material.

12. The apparatus of claim 11,
wherein said air pervious dispersing material is
comprised of a non-woven web and wherein, said
15 dispersing material also functions to hold said
granular carbon dioxide absorption material in
position in said air impervious container.

13. The apparatus of claim 1,
wherein an air impervious hose means is in fluid
20 communication with said outlet opening and extends
inwardly into the interior of said air impervious
container.

14. The apparatus of claim 13,
wherein said air impervious hose means extends into
25 the lower portion of said air impervious container
thereby, insuring air passage through said granular
material prior to said air proceeding through said
outlet opening.

15. The apparatus of claim 14,
30 wherein said hose means contains therewith a filter

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means for filtering bacteria and other unwanted materials from the air exiting said air impervious container.

16. The apparatus of claim 15,
5 wherein said bacteria filter is located within said air impervious container surrounded by carbon dioxide absorption material, whereby, the bacteria filter is warmed thereby improving its efficiency and whereby condensation of water vapor is avoided
10 thereby providing for longer bacteria filter life.

17. The apparatus of claim 6, wherein a screen is attached in fluid communication with said bacteria filter for pre-screening particles from said air.

15 18. The air impervious container of claim 1, having an insulating layer thereby preventing heat loss from said container.

19. The apparatus of claim 18, wherein said insulating layer is disposed adjacent
20 the outside surface of said air impervious container.

20. The apparatus of claim 18, wherein said insulating layer is disposed against the inner sidewall of said container.

25 21. The apparatus of claim 20, wherein said insulating layer includes an inwardly facing surface coated with carbon dioxide absorption material.

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22. The air impervious container of claim 2, wherein said insulating layer includes a slot for viewing the granular carbon dioxide absorption material contained within said container
5 surrounded by said insulating material.

23. The apparatus of claim 22, wherein, said slot in said insulation layer has chamfered edges thereby avoiding formation of air channels when said granular material is disposed
10 within said container.

24. The container of claim 23, having upper and lower portions, wherein, the lower portion of said container is rounded to conform to the general direction of flow air to be treated and
15 whereby, said insulating layer extends along the side walls of the container from the upper portion to the lower portion, said insulating layer including tab projections extend downwardly from said insulation layer to form insulation layer stabilizing and locating means.
20

25. The apparatus of claim 24, wherein said insulation material extends from the upper portion of the air impervious container into the lower portion of said air impervious container
25 but terminates at a point remote from the bottom of said air impervious container thereby insuring that air flowing through said air impervious container from said inlet opening to said outlet opening could possibly follow continuously along a side wall
30 without at some point contacting granular carbon dioxide absorption material.

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26. In a recirculating aided respiration system for patients a single-patient-use readily insertable device connectable in flow-through relationship in said respiration system, 5 said system including an anesthesia machine, an exhalation conduit through which a stream of air exhaled by the patient flows to the anesthesia machine, and an inhalation conduit through which a stream of air from the anesthesia machine flows to 10 be inhaled by the patient, the device comprising:

a sealed, transparent, container having an inlet opening and an outlet opening;

a mass of granular soda lime or other carbon dioxide absorption material that reacts with carbon 15 dioxide in gas passing through the material to remove the carbon dioxide from the gas while increasing the temperature and the moisture content of the gas, in the container;

an inlet tube in flow communication with the 20 inlet opening of the container, the inlet tube having a connection end located outside of the container and connectable to either the inhalation or exhalation conduit; and

an outlet tube in flow communication with the 25 outlet opening of the container, the outlet tube having a connection end located outside of the container and connectable to the other of the inhalation or exhalation conduits, the outlet tube further having an air flow end extending into the 30 container, through which air flows from the carbon dioxide absorption material into the outlet tube.

27. The single-patient-use disposable carbon dioxide absorption device of Claim 26 wherein said container includes flexible holding means for

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supporting said container in operating position while connected as a part of said recirculatory aided respiration system.

28. The device of Claim 26 having an
5 outer container thereby defining an insulating layer therebetween preventing heat loss from said inner container.

29. The outer container of Claim 28
10 comprising a bag which fits snugly around the inner container.

30. The container of Claim 26 having an insulating layer therearound, thereby preventing heat loss from said container.

31. The container of Claim 30 wherein
15 said insulating layer includes a heat reflective film.

32. The device of Claim 28 wherein said
outer container includes a window through which the mass of carbon dioxide absorption material is
20 visible to permit visual monitoring of the operating condition of said material.

33. The single-patient-use device according to Claim 26 in which each of the inlet and outlet tubes is a corrugated, flexible plastic tube.

25 34. The single-patient-use disposable carbon dioxide absorption device according to Claim 26 in which the air flow end of the outlet tube is covered by a dust filter to preclude migration of dust or granules from the sac into the outlet tube.

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FIG. 1

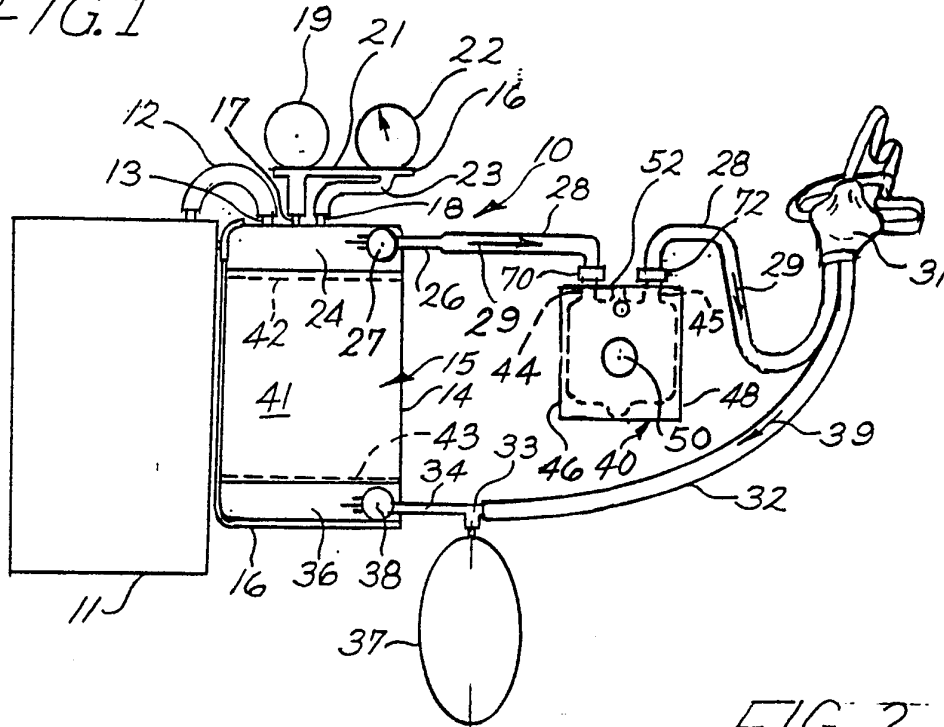


FIG. 3

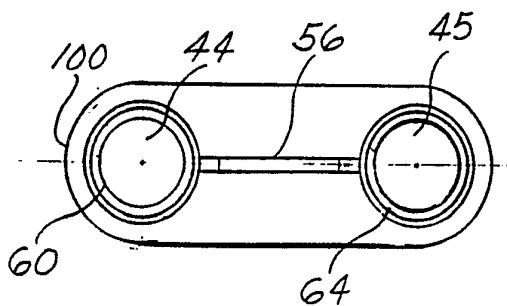


FIG. 4

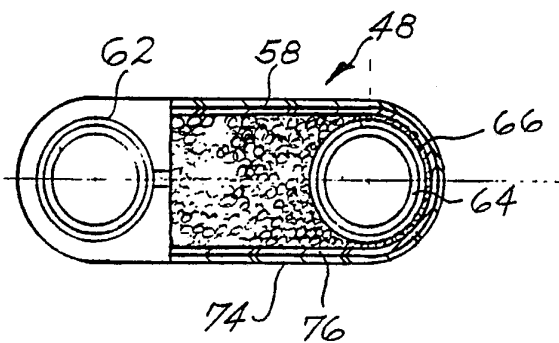


FIG. 2

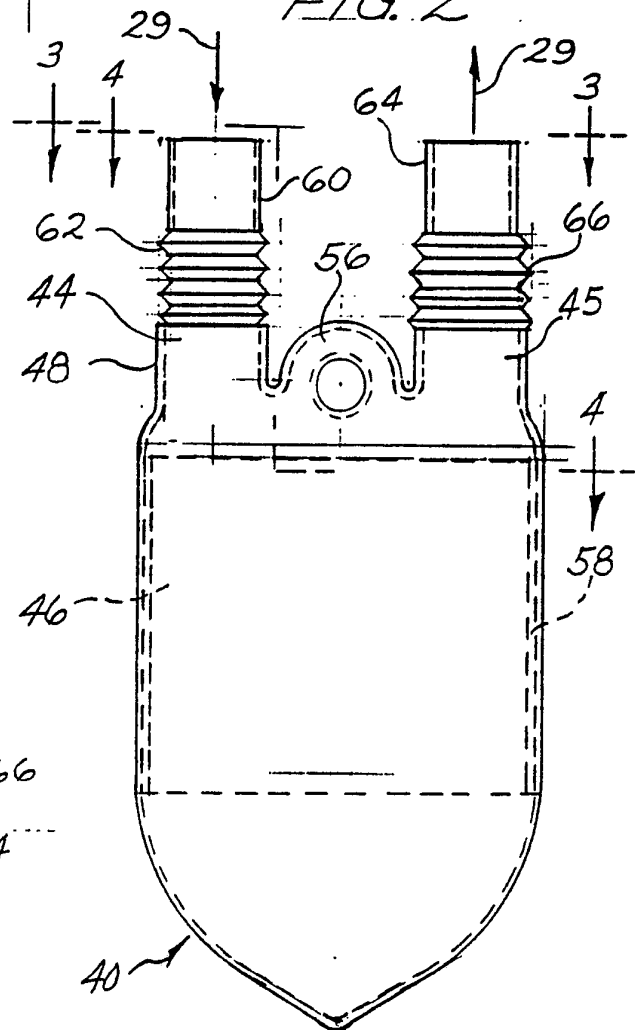
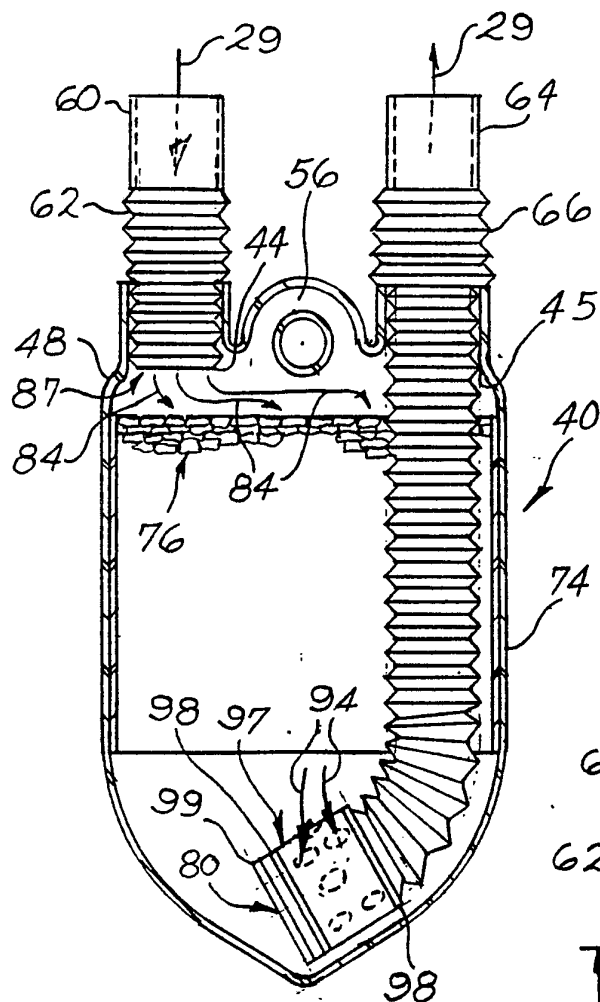


FIG. 5



F/G. 6

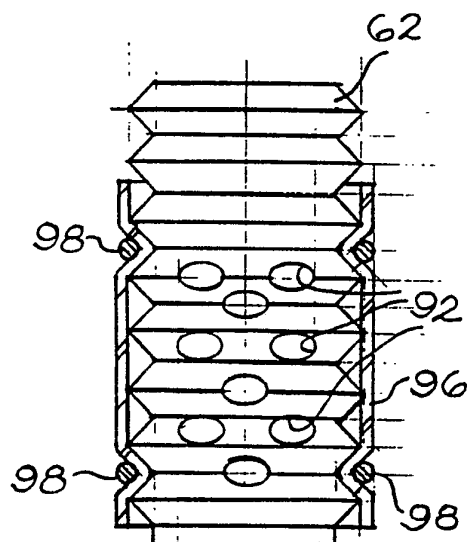
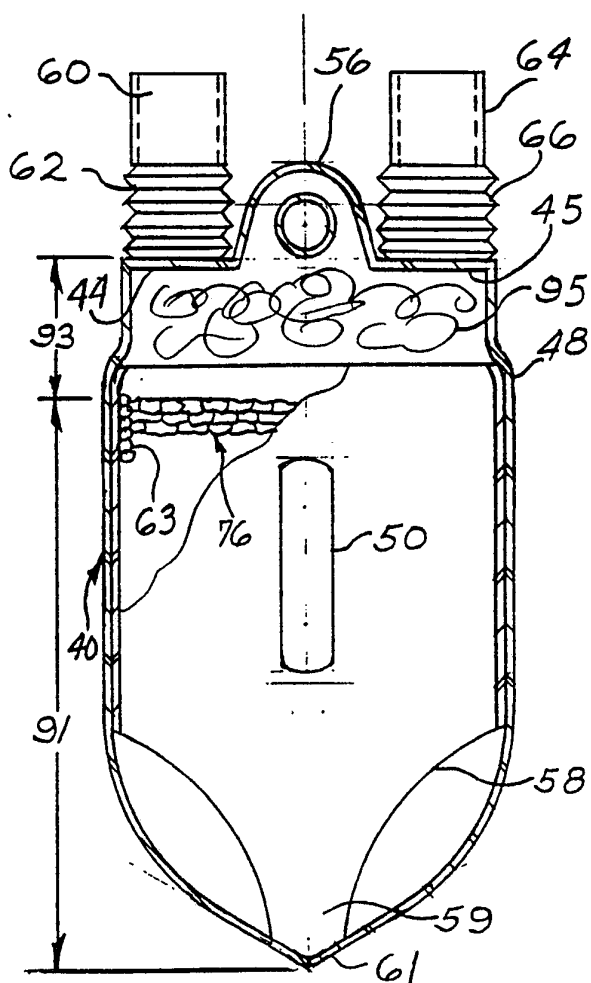


FIG. 7



INTERNATIONAL SEARCH REPORT

International application No.

PCT/US92/04060

A. CLASSIFICATION OF SUBJECT MATTER

IPC(5) :A62B 7/10,23/02

US CL :128/205.28

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : Please See Extra Sheet.

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

Please See Extra Sheet.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US, A, 3,240,567 (CAPARRELI ET AL.) 15 March 1966, See entire document.	1-14,18-22, 26-34
Y	US, A, 2,090,358 (REITER) 17 August 1937, See entire document.	4,13,14, 26-34
Y	US, A, 1,424,623 (STEINERT ET AL.) 11 February 1976, See entire document.	13,14,26-34
Y,P	US, A, 5,016,628 (LAMBERT) 21 May 1991, See entire document.	18-21,28-32
Y,P	US, A, 5,038,768 (McGOFF ET AL.) 13 August 1991, See entire document.	22,32
Y	US, A, 4,750,485 (BARTOS) 14 June 1988, See entire document.	34

☐ Further documents are listed in the continuation of Box C.
 ☐ See patent family annex.

* Special categories of cited documents:	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be part of particular relevance	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E" earlier document published on or after the international filing date	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&" document member of the same patent family
"O" document referring to an oral disclosure, use, exhibition or other means	
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

08 JULY 1992

Date of mailing of the international search report

11 SEP 1992

 Name and mailing address of the ISA/
 Commissioner of Patents and Trademarks
 Box PCT
 Washington, D.C. 20231

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US92/04060

B. FIELDS SEARCHED

Minimum documentation searched

Classification System: U.S.

128/201.22,201.24-201.26,201.29,202.22,203.16,
203.17,203.26,203.27,204.17,205.12,205.13,205.23,
205.27-205.29,205.17,909,DIG. 24

B. FIELDS SEARCHED

Electronic data bases consulted (Name of data base and where practicable terms used):

APS/USPAT-Search Terms: 128/CLAS, (CO2 OR CARBON(1W)DIOXIDE), (MOIST? OR HUMID?), (HEAT? OR WARM?), SODA)1W)LIME, INSULAT?, FOIL#, SCRUB?, EXOTHERM?, DUST, FILTER###, (BAG OR SAC OR SACK), FLEXIBLE, TRANSPARENT, (POLYFOAM## OR STYROFOAM## OR FOAM##), (BACTERIA OR VIRUS)(3W)(FILTER###), DISPOSABLE ANESTHES?, HEAT(3W)LOSS OR HEAT(3W) INSULAT?, REFLECT?(3W)FOIL##