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Wise et al.

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[54] **DISPOSABLE ANESTHESIA DEVICE**

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[73] Assignee: **Will Ross, Inc.,** Milwaukee, Wis.

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[52] **U.S. Cl.** **128/188,** 137/478

[51] **Int. Cl.** **A61m 17/00**

[58] **Field of Search** .128/188, 191; 55/387; 137/525, 137/533, 533.19, 532, 534, 469, 478, 471, 528; 257/332, 324

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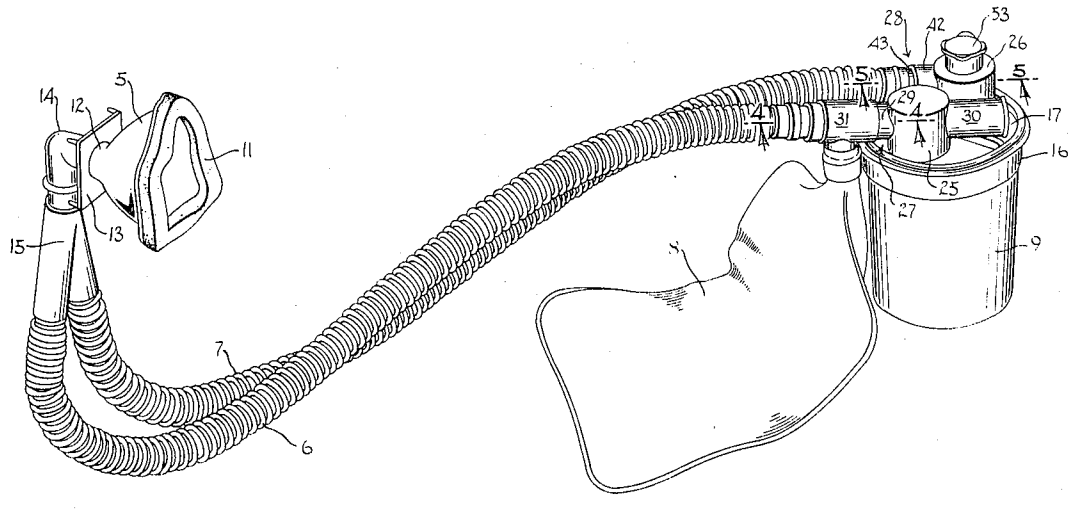
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[57] **ABSTRACT**

A disposable anesthesia device that is completely assembled and ready to use in administering anesthetic gas from a source thereof to a patient. The device provides a closed circuit connectable with a conventional anesthesia machine and consisting of a face mask, a rebreathing bag, a canister containing granular carbon dioxide absorbing material, flexible inhalation and exhalation tubes connecting the face mask with the canister and the rebreathing bag, and flap-like inhalation and exhalation valves, all parts of the device, with the exception of the granular canister contents, but including the valves, being molded or otherwise made of plastic and hence economically disposable after one use thereof to preclude the danger of patient cross contamination.

15 Claims, 13 Drawing Figures



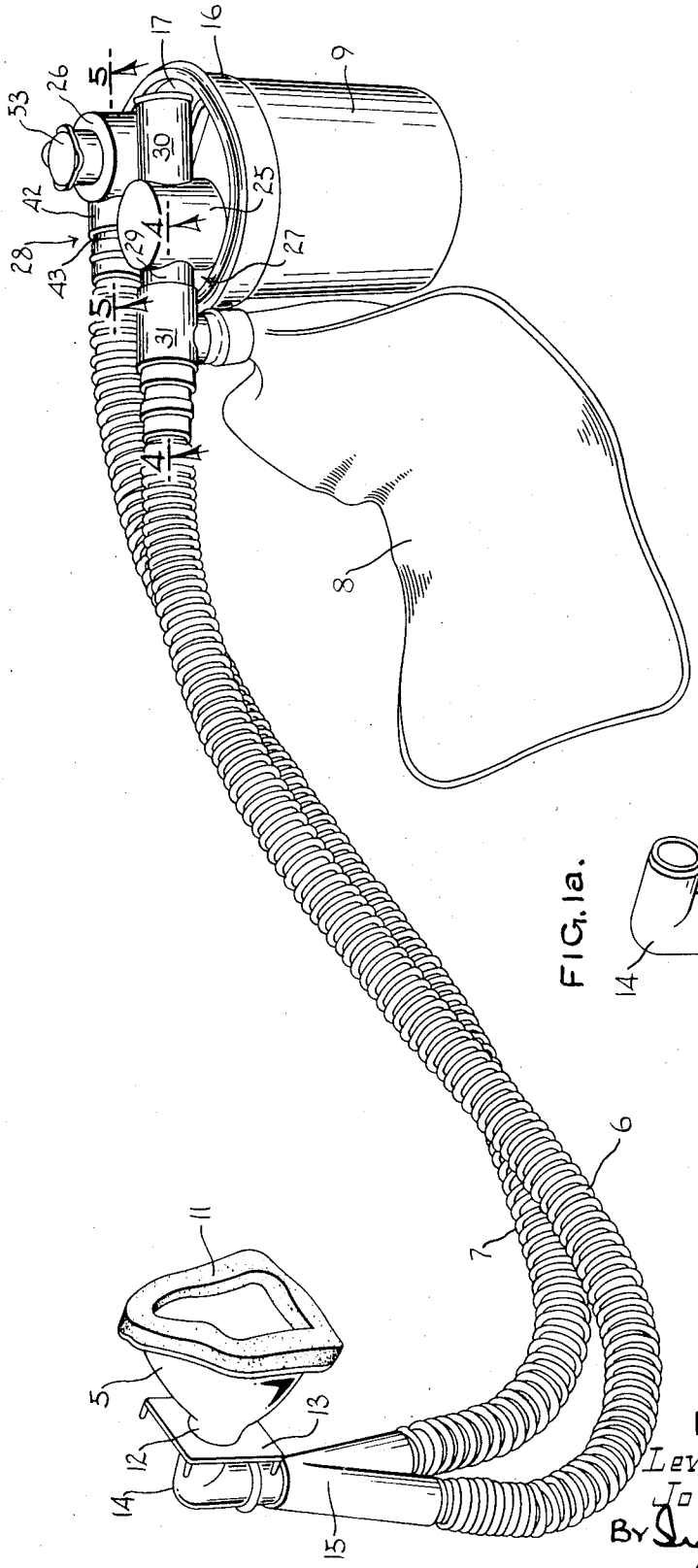


FIG. 1.

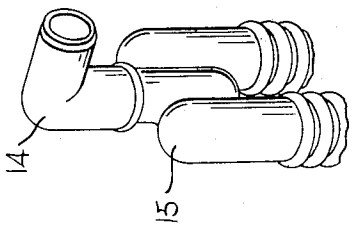


FIG. 1a.

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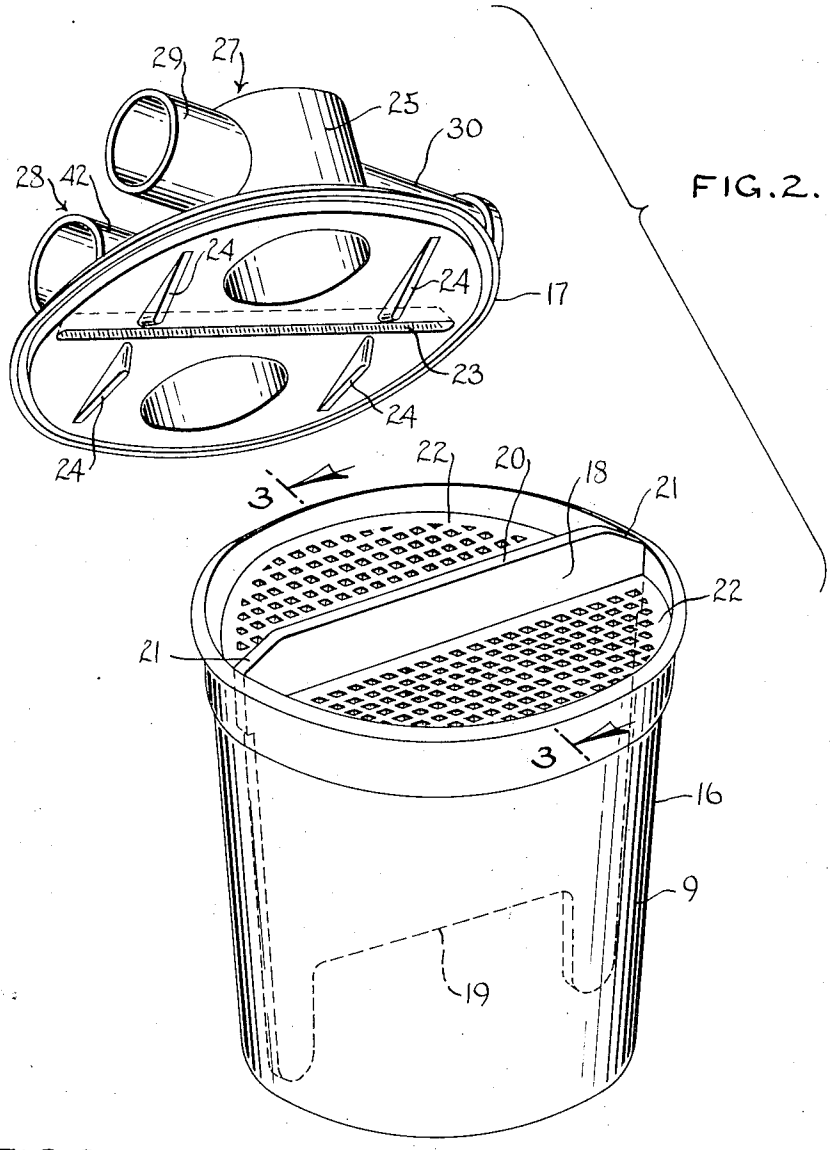
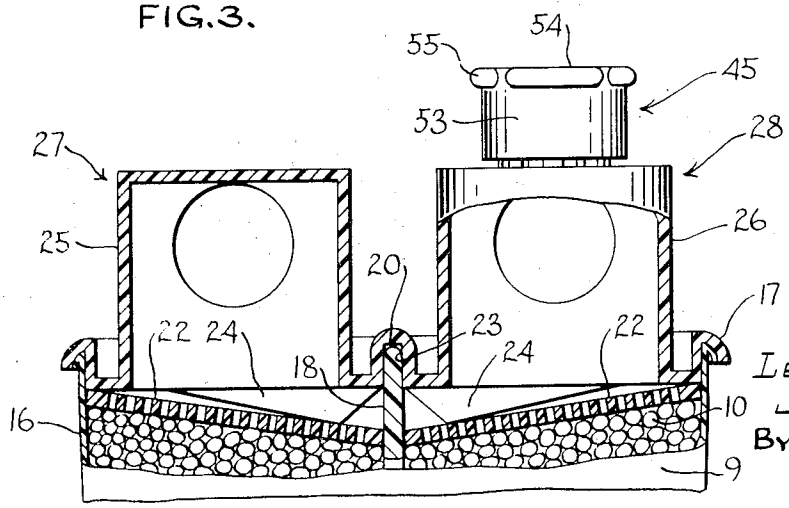


FIG. 2.

FIG. 3.



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FIG. 4.

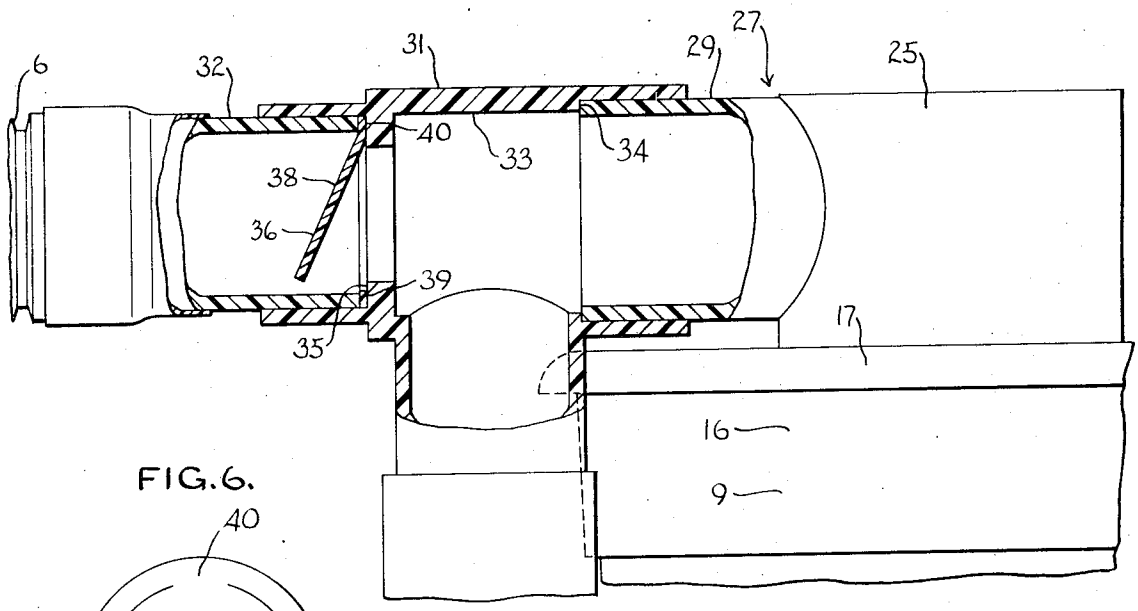


FIG. 6.

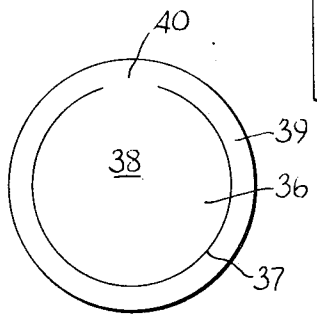
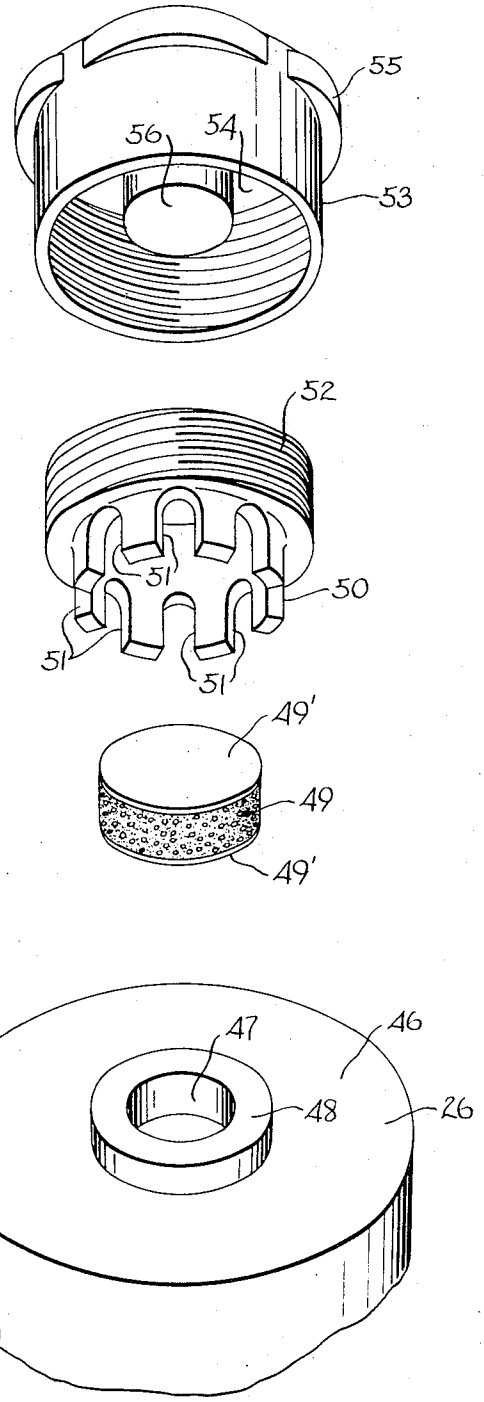


FIG. 5.

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FIG. 7.



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FIG. 8.

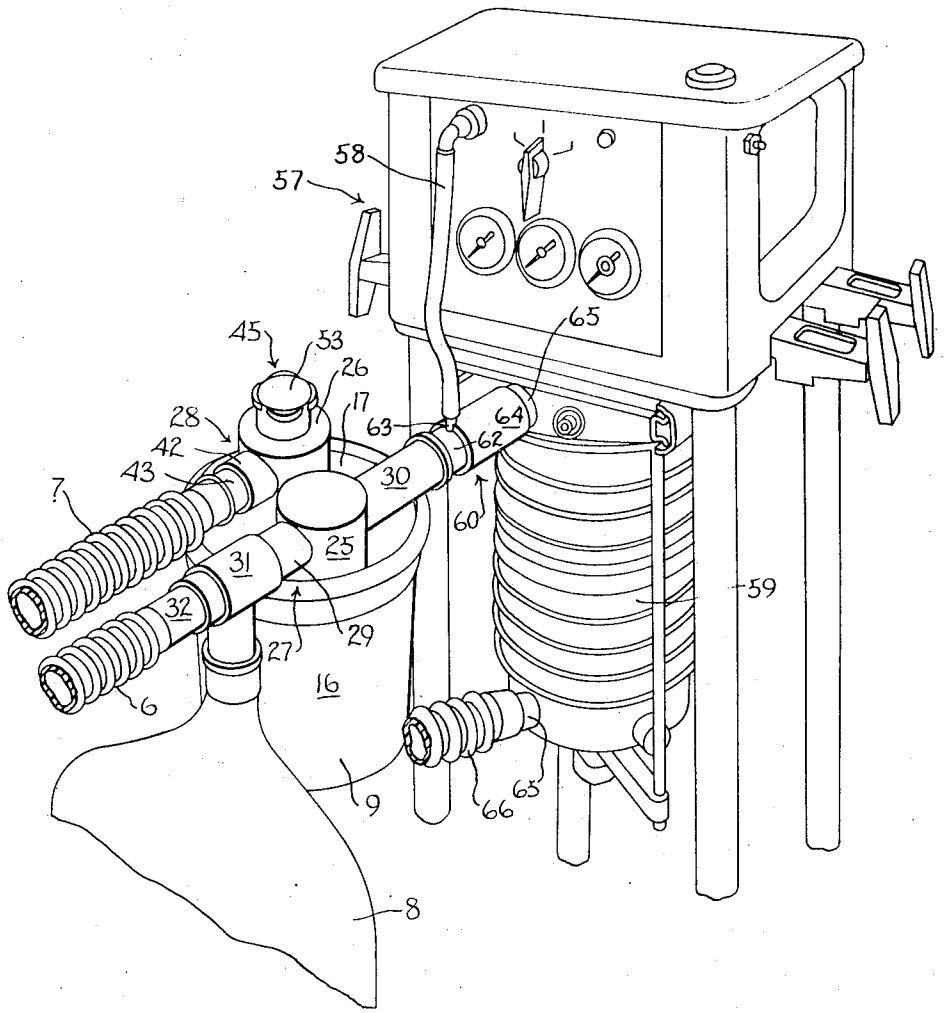
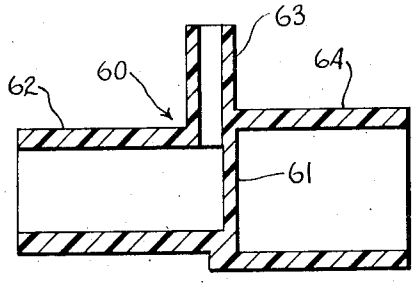


FIG. 9.



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FIG. 10.

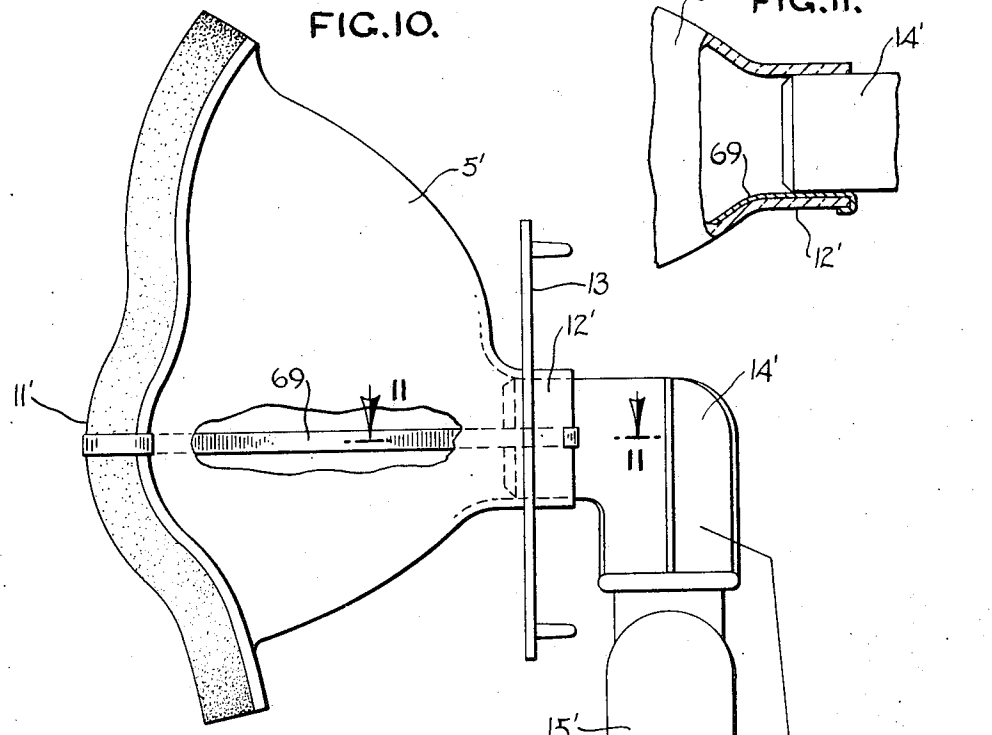
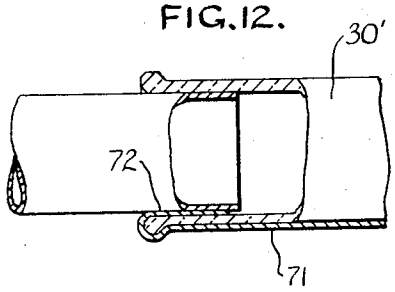
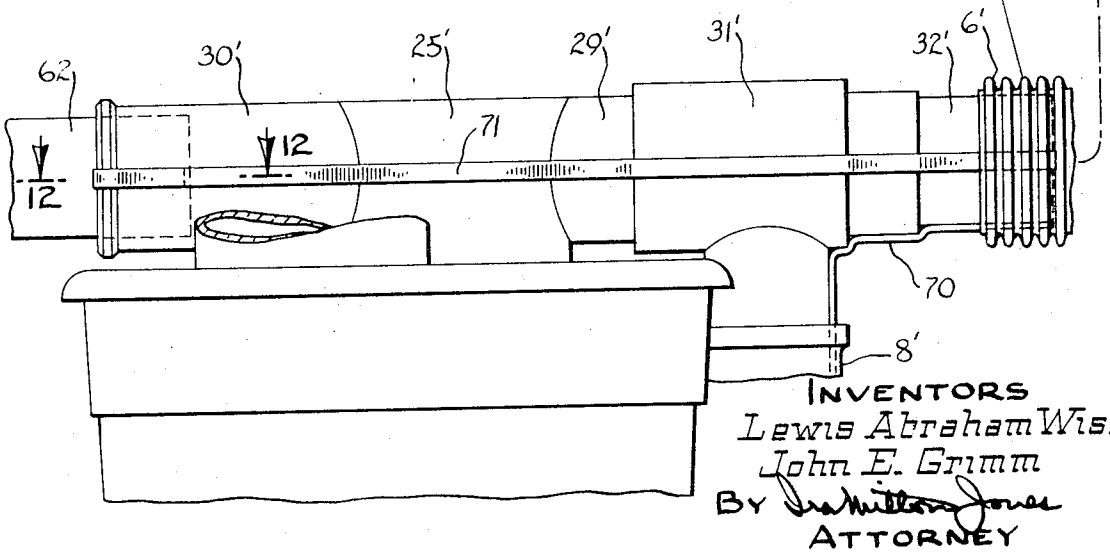


FIG. 11.

FIG. 12.





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DISPOSABLE ANESTHESIA DEVICE

This invention relates generally to anesthesia apparatus and, more particularly, to that part thereof which may be considered its delivery system, by which anesthetic gases coming from an anesthesia machine in predetermined volume and mixture, are fed to the patient under the control of either an anesthesiologist or an anesthetist. Hereinafter, for sake of brevity, where the term anesthetist is used it will be understood to include anesthesiologist as well. This delivery system forms a closed circuit or circle, as it is referred to by anesthetists, and consists of a canister containing granular carbon dioxide absorbing material, a face mask, a rebreathing bag, flexible inhalation and exhalation tubes connecting the face mask with the canister and the rebreathing bag, check valves that control flow to and from the mask, and an adjustable pressure relief valve by which the anesthetist can control the pressure in the system.

Closed circuit anesthesia devices are of course not new in concept, but heretofore they have been relatively expensive, costing between three and four hundred dollars. More significantly, though, they were intended for and designed to be reused. This confronted hospitals with a very disconcerting dilemma. If a reusable system or apparatus was used on a patient with a communicable respiratory disease, the entire apparatus could become infected. Subsequent use of the infected apparatus on other patients could, and often did, infect those patients.

The likelihood of cross infection from unsterile and contaminated circle systems was understood and appreciated by the hospitals, but it was most difficult to clean and sterilize the available reusable systems. They had to be completely taken apart and washed thoroughly with germicidal solutions just to clean them. This was a time consuming bother, and sterilization of the reusable equipment was an even greater problem. The materials — rubber and metal — of which the conventional reusable circle systems were made, were deleteriously affected if steam pressure autoclaves were used, and if ethylene oxide gas sterilizers were employed the long aeration time required to get rid of the highly toxic ethylene oxide gas that was absorbed into the rubber parts forced hospitals to have a very large number of the reusable circle systems on hand — or run the risk of patient cross contamination.

The obvious answer to this dilemma was an anesthetic delivery apparatus that would be inexpensive enough to be entirely disposable, but heretofore no such thing existed.

It is the purpose and object of this invention to fill that need, and — to do so — significant innovations have been made in the component parts of the system. As a result of these improvements, all of the components of the entire system — except the granular carbon dioxide absorbing material which fills the canister — are relatively inexpensive molded or otherwise formed plastic parts. The net result is a fully assembled, highly efficient closed circuit system that not only is completely reliable and easy to use, and readily disposable, but also exceptionally attractive in appearance, as evidenced by U.S. Design Pat. No. 215,982, issued Nov. 11, 1969, to the instant applicants.

With these observations and objectives in mind, the manner in which the invention achieves its purpose will be appreciated from the following description and the accompanying drawings, which exemplify the invention, it being understood that such changes in the specific apparatus disclosed herein may be made as come within the scope of the appended claims.

The accompanying drawings illustrate a physical embodiment of the invention constructed according to the best mode so far devised for the practical application of the principles thereof, and in which:

FIG. 1 is a perspective view of the complete anesthetic device of this invention;

FIG. 1*a* is a perspective view of a portion of the anesthetic device shown in FIG. 1, illustrating a varient of one of the elements thereof;

FIG. 2 is a perspective view of the canister which contains the carbon dioxide absorbing material, and its cover shown lifted from the canister;

FIG. 3 is a sectional view through the canister on the plane of the line 3—3 in FIG. 2;

FIG. 4 is a detail sectional view through the inhalation port structure of the canister, said view being taken on the plane of line 4—4 in FIG. 1;

FIG. 5 is a detail sectional view through the exhalation port structure of the canister, taken on the plane of the line 5—5 in FIG. 1;

FIG. 6 is a plan view of the valve disc employed in both the inhalation and exhalation valves;

FIG. 7 is an exploded perspective view of the pop-off or pressure relief valve of the device;

FIG. 8 is a perspective view of a conventional gas machine showing the device of this invention supported therefrom;

FIG. 9 is a detail view of the adapter used to supportingly connect the device of this invention with the gas machine shown in FIG. 8;

FIG. 10 is a side view of the face mask, a part of the canister and of one of the tubes connecting the face mask with the canister, to illustrate how all parts of the device may be electrically grounded despite the fact that portions thereof, notably the face mask and the canister, are molded of non-conducting plastic;

FIG. 11 is a detail sectional view through FIG. 10 on the plane of the line 11; and

FIG. 12 is a detail sectional view through FIG. 10 on the plane of the line 12—12.

Referring to the accompanying drawings, in which like numerals designate like parts throughout the several views, the numeral 5 designates the face mask of the closed circuit or circle device of this invention and which is connected by flexible inhalation and exhalation tubes 6 and 7, respectively, with a rebreathing bag 8 and a canister 9 containing granular carbon dioxide absorbing material 10.

The face mask is a cupped plastic molding having a suitably shaped and cushioned edge 11 defining its face-engaging opening, and a cylindrical rearwardly projecting nipple 12 onto which a head strap plate 13 is fitted, to provide for the attachment of straps (not shown) by which the mask may be held in place on a patient. An elbow 14, which is inserted into the nipple 12, and a Y-shaped coupling 15 connect the mask with the inhalation and exhalation tubes. The elbow and the Y fitting are molded plastic parts.

As shown in FIG. 1a, the Y-shaped coupling 15 can have its branches parallel to one another and to its trunk portion to facilitate molding the same.

The canister 9 comprises a tub-shaped molded plastic open-topped container 16 with a straight slightly inwardly sloping side wall, and a cover 17, also a plastic molded part, closing the top of the container. A partition wall 18 extending diametrically across the interior of the container divides the same into two compartments that are connected only at the bottom through an opening 19 in the partition wall. The upper edge 20 of the partition wall extends horizontally straight across the container at an elevation somewhat above the top edge of the container, but slopes downwardly at its ends as at 21.

Both compartments of the canister are filled with the granular carbon dioxide absorbing material 10, and to hold this material in place and prevent internal shifting thereof which, if permitted, might objectionably pulverize some of the material, perforated inner covers 22 are tightly fitted into the tops of the container compartments. The perforations of these inner covers are smaller than the particle size of the absorbent material 10.

The cover 17, which will be referred to as an outer cover to distinguish it from the perforated inner covers 22, has a downwardly opening groove 23 extending diametrically thereacross to snugly receive the upper edge portion of the partition wall 18 including its downwardly sloping ends 21. Accordingly, the spaces in the upper portions of the two canister compartments above the perforated inner covers are sealed from one another except by passage through the interstice between the particles of the granular carbon dioxide absorbing material.

The underside of the outer cover 17 also has spacer ribs 24 depending therefrom to engage and firmly hold the perforated inner covers in place. These spacer ribs extend at right angles to the groove 23 and hence do not interfere with open communication of the spaces above the perforated inner covers with open bottomed hollow protuberances 25 and 26 which rise from the top of the outer cover 17 at opposite sides of the groove 23.

Being open bottomed, the hollow protuberances have unrestricted communication with the spaces above the perforated inner covers 22 and form part of inlet and outlet ports, designated generally by the numerals 27 and 28, respectively, and through which the canister is connected with the inhalation and exhalation tubes. The inlet port 27, in addition to the protuberance 25, comprises short and long tubular stubs 29 and 30, respectively, extending in diametrically opposite directions from the hollow protuberance 25. The long stub 30 provides an inlet for fresh gas which may be fed thereto from a conventional anesthesia gas machine in any suitable manner, one of which will be described hereinafter.

Mounted on the shorter stub 29 is a T-coupling 31, the stem of which has the rebreathing bag 8 attached thereto. The T-coupling is mounted on the stub 29 by fitting one end of its head into the stub. The opposite end of the head of the T receives a short rigid tube 32 which projects from and is secured to the adjacent end of the flexible inhalation tube 6. As shown in FIG. 4, the bore 33 through the head of the T is slightly enlarged at its end into which the stub 29 fits, to provide a locating shoulder 34 that bears against the end of the stub, and at the opposite end of the bore 33 there is another shoulder 35 which not only limits insertion of the tube 32 into the bore, but coacts with the end of the tube to hold a valve member 36 in place.

The valve member 36 is a disc of thin air-impervious pliable plastic material of a diameter very slightly smaller than the bore 33 outwardly of the shoulder 35, so that the valve disc may be easily inserted into the bore and against the shoulder. At a short distance in from its periphery, the disc 36 has an arcuate slit 37 that extends concentrically along nearly all of the circumference of the disc, to define a central flap 38 and an encircling ring 39 hingedly connected at a small localized zone 40. The radial width of the ring 39 is less than the width of the shoulder 35 but at least as great as the wall thickness of the coupling tube 32. Hence, with the parts assembled, the ring 39 is tightly clamped between opposing shoulders, one of which is provided by the end of the tube 32 and the other being the shoulder 35 upon which the flap 38 seats. A very simple but highly reliable inhalation valve is thus provided to open upon inspiration and close upon expiration.

A similar exhalation valve is located adjacent to the protuberance 26 but, in this case, the shoulders between which the ring 39 of the valve disc is clamped are provided by an outwardly facing rather narrow shoulder 41 in the bore of a short tubular stub 42 that projects from the side of the protuberance 26, and the end of a short rigid coupling tube 43 that is secured to and projects from the adjacent end of the flexible exhalation tube 7. As shown in FIG. 5, the wall thickness of the coupling tube 43 at least at the end thereof received in the tubular stub 42 is greater than the radial width of the ring 39 and hence provides a seat against which the flap 38 bears in the closed condition of the exhalation valve.

As will be readily apparent, the inhalation and exhalation valves, being entirely self-contained and devoid of springs, are the epitome of simplicity but, more significantly, the manner in which they are oriented makes them completely reliably and instantly responsive to inspiration and expiration of a patient undergoing anesthesia.

This most important advantage of the anesthesia device of this invention stems from the fact that the shoulders between which the valve discs are confined are vertically disposed when the canister is in its normal position of use; and the discs are so placed that their hinge portions 40 are at the top. The flaps thus hang freely in their closed or seated positions, and since they are practically weightless, they respond to the most minute pressure differential. The anesthetist can therefore proceed with utmost assurance that, at even the lowest level of breathing, only cleaned air from which carbon dioxide has been removed by its passage through the contents of the canister, and fresh gas coming directly from the gas machine can enter the patient's lungs.

During use, the rebreathing bag, which is as much a part of the closed circuit as any other portion thereof, enables the anesthetist to assist the patient in his breathing. Since the pressure is uniform in all parts of

the closed circuit, the pressure in the rebreathing bag is exactly the same as the pressure in the patient's lungs. This then provides the anesthetist with the indication needed to tell him whether or not to assist the patient's breathing by rhythmically squeezing the bag. His feel of the bag will also indicate to him if the pressure in the system is correct.

To enable regulation of the pressure in the system, an adjustable pressure relief or "pop off" valve **45** is provided. This valve is mounted on the protuberance **26**, the top wall **46** of which has a hole **47** encircled by an upstanding rim **48**, the top of which provides a seat for a light button-like valve disc **49**. The valve disc is guided for movement to and from its seat by a cylindrical valve cage **50** that rises from the top wall **46** of the protuberance and circumscribes the rim **48**.

The lower portion of the valve cage has a plurality of openings **51** through which its interior is communicated with atmosphere. The upper portion of the cage is externally threaded, as at **52**, to adjustably mount a cap **53** that has a top wall **54** with a scalloped edge **55** to facilitate turning the cap, and a downwardly projecting central stem **56** to overlie and limit the extent the valve disc can lift off its seat. Hence, by screwing the cap further onto or off the valve cage, the pressure in the system can be regulated.

The button-like valve disc **49** is formed of light foam or cellular plastic material, preferably polyurethane foam, with a veneer **49'** of thin non-adherent sheet plastic on its opposite flat faces, "Mylar" being especially well adapted for the purpose.

With the exception of the granular carbon dioxide absorbing material, all parts of the entire device are molded or otherwise formed of plastic, and where the separate components or parts thereof are secured together, this is done by closely interfitting the joined portions and permanently bonding them with an appropriate plastic solvent. The entire device therefore reaches the hospital and the anesthetist in a completely assembled ready-to-use condition, and after being used once is discarded, its disposal presenting no problems.

For use with non-flammable gases there is no need for the device to be electrically conductive. Hence the selection of the plastic from which the component parts of the device are molded can be based upon esthetic considerations and, in the case of the face mask, upon the need for transparency. However, a very simple modification renders the device entirely safe for use with flammable gas. That modification is illustrated in FIGS. **10**, **11** and **12**.

In this modification, the inhalation and exhalation tubes (only the inhalation tube **6'** appears), the elbow **14'**, the Y-shaped coupling **15'** and the rebreathing bag **8'** are electrically conductive, being made so by the incorporation of carbon black in the plastic material of which they are made. Of course, any other suitable expedient may be employed to render these parts electrically conductive.

The non-conductive face mask **5'** has a grounding strip **69** adhered to its inner surface to extend from the outer end of its nipple **12'** to and across its cushioned edge **11'**. Since the grounding strip extends across the cushioned edge of the mask it of course makes contact with the patient's face and, by virtue of the end portion of the strip that is in the nipple **12'** being in contact with the elbow **14'**, the patient is electrically connected with the tubes.

Another grounding strip **70** is adhered to the exterior surface of the T-coupling **31'** to provide an electrically conductive path connecting the rebreathing bag **8'** with the inhalation tube **6'**; and still another grounding strip **71** is adhered to the canister, and — more particularly — to the side of the protuberance **25'**, the short and long stubs **29'** and **30'** which extend in diametrically opposite directions from the protuberance, the head of the T-coupling **31'**, and the tube **32'** which is secured to the adjacent end of the inhalation tube **6'**. The strip **71** thus has physical and electrical connection with the inhalation tube **6'**; and by virtue of the opposite end portion **72** of the strip being turned in around the edge of the mouth of the stub **30'** which constitutes a duct by which the device is connectible with a gas machine, the attachment of the stub **30'** to the gas machine effectively grounds the entire device — it being understood that the gas machine is suitably grounded.

The grounding strips are preferably formed of thin metallic foil which is easily adhered to the plastic parts along which the strips extend, and to meet code requirements, these strips — as well as the parts that are formed of conductive material — should have a resistance to the flow of electric current of no less than 25 thousand ohms and no more than 1 million ohms.

The manner in which the device of this invention is connected with a gas machine to receive fresh gas therefrom, may take any one of several forms. For instance, as shown in FIG. **8**, the canister **9** may be supported from some portion of a gas machine **57** of the type now generally found in hospitals, with the gas delivery line or hose **58** that leads from the gas machine suitably connected with the gas inlet **30** — or **30'** in the case of the electrically conductive form of the device. For this purpose, an adapter **60**, illustrated in FIG. **9**, is provided. By means of this adapter, the canister **9** and the various other components of the disposable system that are mounted thereon can be supportingly connected with the existing reusable canister **59** that is associated with the gas machine **57**, without in anywise risking the danger of infection from the reusable canister.

The adapter is simply a rigid tube **60** with a partition wall **61** closing its bore medially of its two ends to isolate one end portion thereof from the other. One end portion **62** of the tube has a nipple **63** projecting laterally therefrom, and has an outside diameter to snugly fit into the tubular inlet stub **30** which, as shown, is rigidly connected with the canister. The other end portion **64** of the tube **60** is of a size to snugly telescope onto one or the other of the inlet or outlet stubs **65** that project from the gas machine, and to which flexible rubber tubes **66** are ordinarily connected. In this manner, the disposable anesthesia device of this invention is suitably supported in close proximity to the gas machine **57** so that the gas delivery line or hose **58** leading from the gas machine may be attached to the nipple **63** to supply fresh anesthetic gas to the delivery system provided by this invention. For the electrically conductive device, the adapter may be formed of metal or be provided with a grounding strip similar to the strips **70** and **71**.

Those skilled in the art will appreciate that the invention can be embodied in forms other than as herein disclosed for purposes of illustration.

The invention is defined by the following claims:

1. An anesthesia device for administering anesthetic gas, having inhalation and exhalation hoses connected to a face mask and attachable to a canister containing granular material capable of absorbing carbon dioxide gas, characterized in that said canister comprises:

A. a hollow upright container;

B. a partition in said hollow container dividing the same into two laterally adjacent compartments connected with one another only at the bottom of the hollow container;

C. a cover sealingly closing the top of the hollow container and having a groove in its underside to sealingly receive the upper edge portion of the partition;

D. a pair of hollow protuberances integral with said cover and rising therefrom, one over each of said compartments and having its interior connected therewith;

E. tubular coupling means fixed to and projecting laterally from one side of each protuberance and opening to its interior; each said coupling means having a coupling tube which provides for attachment of one of said hoses to the canister;

each said coupling tube being telescoped into and fixed within an adjoining tubular portion of its coupling means;

F. an annular shoulder on each tubular portion axially opposing the end of the tube therein; and

G. a check valve in said tubular portion of the coupling means on each protuberance, said check valve comprising a single thin pliable disc having an annular peripheral rim portion which is clamped between the shoulder in said tubular portion and the adjacent end of the coupling tube, and a central flap which is integrally joined to said peripheral rim portion at a localized zone of the latter, the check valve associated with one of said protuberances opening away from the same to serve the inhalation hose, and the other check valve opening towards the other protuberance to serve the exhalation hose.

2. The anesthesia device of claim 1, further characterized in that the canister body, the partition therein, the cover with its hollow protuberances, and the coupling means being molded plastic parts so that the entire anesthesia device is economically disposable.

3. The anesthesia device of claim 1, further characterized by:

A. the shoulder in the coupling means on said one protuberance providing a valve seat which is engageable by the flap of the associated check valve upon motion of said flap toward said one protuberance;

B. and the end of the tube in the coupling means on the other of said protuberances providing a valve seat which is engageable by the flap of the other check valve upon motion of said flap away from said other protuberance.

4. The anesthesia device of claim 1, wherein the coupling means on one of said protuberances has a tubular side outlet which projects therefrom and provides for attachment of a rebreathing bag to the canister.

5. The anesthesia device of claim 4, further characterized by:

A. said side outlet being on that coupling means having the inhalation check valve which opens away from its associated protuberance;

B. and said last named protuberance having tubular means thereon which projects from another side thereof and provides an inlet for fresh gas which may be fed thereto from an anesthesia gas machine.

6. The anesthesia device of claim 1, wherein a pressure relief valve is mounted in said other protuberance.

7. The anesthesia device of claim 6, wherein said pressure relief valve which is mounted in said other protuberance has a cap at the top thereof which provides a readily accessible adjusting means for varying the relief setting of the valve.

8. The anesthesia device of claim 6, wherein said pressure relief valve comprises:

A. an annular valve seat on the top wall of said other protuberance;

B. a valve cage fixed with respect to the top wall of said other protuberance and encircling the valve seat, the interior of said cage having open communication with the atmosphere;

C. a cap adjustably mounted on and covering the top of said valve cage;

D. and a light-weight valve disc held in the cage by said cap, and movable over said seat to and from a closed position engaging the same to prevent ingress of air into the canister while being freely movable off of its seat by very slight positive pressure exerted thereon from under the seat.

9. The anesthesia device of claim 8, wherein said valve disc comprises a cylindrical body of foam plastic having opposite flat faces covered by thin plastic non-adherent film.

10. The anesthesia device of claim 1, further characterized by the provision of an adjust-able pressure relief valve comprising:

A. a valve seat encircling a hole in a top portion of the hollow upright container and opening to one of said compartments;

B. a valve cage fixed with respect to said top portion of the hollow upright container and encircling the valve seat, the interior of said cage having open communication with the atmosphere;

C. a light-weight valve disc loosely received in said cage and freely movable to and from a closed position seated upon the valve seat to close said hole and prevent ingress of air into said one compartment while being free to move off of its seat in response to very slight positive pressure in said one compartment;

D. and a cap adjustably mounted on said valve cage and having means thereon to engage and limit the extent the valve disc may be lifted off of its seat.

11. The anesthesia device of claim 1, further characterized by:

A. said granular material filling said compartments to a level below the top edge of the partition; and

B. perforated cover means covering the top of each compartment and engaging the surface of the granular material therein to confine the same against displacement.

12. The anesthesia device of claim 11, further characterized by downwardly projecting spacers on the underside of the cover bearing upon said perforated cover means to hold the latter down on the granular material in the compartments.

13. The anesthesia device of claim 1, further characterized in that it is of the closed circuit type and has a pressure relief valve comprising: a wall defining part of the closed circuit of the anesthesia device, said wall having a hole encircled by a valve seat; a valve cage member projecting from said wall and encircling said valve seat; said valve cage member being externally threaded; a light-weight valve disc in the valve cage member to engage said valve seat and close the hole against ingress of air into the closed circuit while being free to leave the valve seat to relieve pressure in the closed circuit; a cap member threaded onto the hollow valve cage member, said cap member having an end wall and a cylindrical internally threaded skirt depending therefrom to fit the threads on the valve cage member, and the cap member also having a central stem depending from its end wall to be engageable with the valve disc and limit displacement thereof off its seat to an amount dependent upon the extent the cap member is threaded onto the valve cage member; and one of said members having an opening through which the interior of the valve cage member is at all times open to the atmosphere, all of said structure with the exception of the light weight valve disc being molded plastic parts.

14. The pressure relief valve of claim 13, wherein the valve disc is a piece of foam plastic with flat opposite faces covered with a thin pliable veneer of plastic sheet material.

15. An anesthesia device for administering anesthetic gas from a source thereof to a patient, which device comprises

1. a canister containing carbon dioxide absorbent material, and having inlet and outlet ports communicating with the canister interior, the inlet port being connectable with a source of fresh gas,
2. a face mask,
3. flexible inhalation and exhalation tubes connected with the face mask,
4. and tubular coupling members connecting said tubes with the inlet and outlet ports of the canister so that the canister, face mask, and the flexible tubes form a closed circuit,

said device being characterized by:

A. flap-type inhalation and exhalation valves controlling air flow through said closed circuit,
   each of said valves comprising a circular disc of thin pliable sheet material arcuately slit a short distance in from its periphery to define a circular flap encircled by and having a narrow localized highly flexible hinge connection with an uninterrupted annular rim portion;
B. means mounting said valves in the tubular coupling members, comprising opposing annular shoulders in said coupling members between which the annular rim portion is clamped, the downstream shoulder in each instance being no wider than the annular rim portion of the valve disc but the upstream shoulder being wider so as to form a seat for the hinged flap; and
C. an adjustable pressure relief valve for controlling the pressure in said closed circuit, comprising
   1. a valve seat encircling a hole in a wall which defines part of said closed circuit,
   2. a valve cage fixed with respect to said wall and encircling said valve seat, the interior of the cage having open communication with the atmosphere,
   3. a light-weight disc loosely received in said cage and freely movable to and from a closed position seated upon said valve seat to close said hole and prevent ingress of air into the closed circuit while being freely movable off of the valve seat by very slight positive pressure in the closed circuit,
   4. said valve disc comprising a cylindrical body of foam plastic having opposite flat faces covered by thin plastic non-adherent film material,
   5. and a cap adjustably mounted on said valve cage and having an abutment to engage and limit the extent the valve disc may be lifted off the valve seat.

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