FLOW CONTROLLING OR METERING DEVICE

Inventors: Howard R. Bierman, 152 N. Robertson Blvd., Beverly Hills, Calif. 90211; John G. Mast, 7934 Kirkland Dr., Cincinnati, Ohio 45224

Filed: Mar. 16, 1973

Appl. No.: 341,915

U.S. Cl. 138/43, 138/46

Int. Cl. F15d 1/00

Field of Search 138/41, 42, 43, 46

References Cited

UNITED STATES PATENTS

340,696 4/1886 Caldwell 138/46
1,734,027 10/1929 Bijur 138/41 UX
2,486,133 10/1949 Egger 138/41
2,576,610 11/1951 Kunzog 138/41
2,635,641 4/1953 Kasten 138/43 X

3,042,079 7/1962 Swift et al. 138/42
3,738,392 6/1973 Veach et al. 138/46

Primary Examiner—Charles A. Ruehl
Attorney, Agent, or Firm—Herzig & Walsh

ABSTRACT

A device for controlling or metering a relatively small flow of liquid which may be a gravity flow such as in intravenous introduction of liquids into human veins. The controller, referred to as a flow rater in one form is a cylindrical ceramic filter element of a predetermined length capable of maintaining a uniform, metered flow without monitoring. Adjustable forms of the flow rater are provided in which two resistance materials are provided in series, one of which is adjustable by compressing it to provide rates between zero and a very small flow. In another form, the effective length of the cylindrical ceramic filter element is adjustable.

8 Claims, 12 Drawing Figures
FLOW CONTROLLING OR METERING DEVICE

SUMMARY OF THE INVENTION

The invention relates to a liquid flow controller or metering device typically referred to as a flow rater. The device is particularly adapted for use in the medical field for control of the supply of liquids other than orally with respect to the body of a patient.

For example, in intravenous feeding, liquids are administered through a needle introduced into a vein. Further at times, in the treatment of diseases, solutions are introduced in concentrated form locally at the site of the diseased condition. Other situations may call for the infusion or introduction of liquids in the body of a patient such as well known to the medical profession. Such infusion is necessary or desirable flow rate of the liquid is known and prescribed by the doctor must be held at the desired rate and controlled or regulated for a substantial period of time. Typically, the flow is a relatively small one at a pressure rate which usually would be quite low as described more in detail hereinafter.

Typically, the problem exists of giving a patient a certain volume of fluid over a period of six, eight, twelve, or twenty four hours in the usual amount of about 1,000 cc's of fluid. The rate must be monitored, since the body reserve over a prescribed amount is only about twenty percent. That is to say, twenty percent more than the prescribed amount might prove seriously injurious or even fatal to the patient. Therefore, a ten percent change is extreme over the prescribed rate. As the rate or amount of fluid injected increases, the venous pressure tends to rise and so does the diastolic pressure.

Experience indicates that approximately one-third of the nurse's time is expended in adjusting the flow rate of the flow controller. Since this occurs on each shift, a considerable amount of the nurse's time is thereby saved if the flow rate does not vary sufficiently to require constant attention and adjustment. In practice, the intravenous bottle is suspended a sufficient distance above a patient so that the difference in pressure drop due to the lowering of the fluid in the bottle during the transfusion or injection is inconsequential. It is noted that the distance the fluid level lowers is generally only a distance of about five inches. The resulting drop in pressure head is generally less than a ten percent drop. For example at 180 cc's of fluid in a bottle and the bottle 6 feet about the patient's heart, a drop of as much as 6 inches would amount to less than a ten percent drop in the head of pressure.

With conventional commercial installations, the drop varies from manufacturer to manufacturer; and whereas some equipment yields 15 drops per cubic centimeter of fluid, others yield 22 drops per cubic centimeter. Also, the fluid level varies depending upon the amount of fluid remaining in the bottle.

With respect to the fibrous or porous flow controller as described herein, the higher the column, the lower degree of pressure difference between the delivery when the bottle is full and when the bottle is empty. That is, if the bottle can be raised to eight feet above the heart level of the patient, it is so much the better. It is desirable to keep the difference in pressure from full to empty bottle to approximately one to two percent.

A primary object of the invention is to realize and make available a flow controller which will meet and solve the problem described in the foregoing paragraphs, and more specifically, one which will not require monitoring by the nurse, but rather one which will dependably deliver the fluid consistently at a rate within specifications as set out. Realization of this objective contemplates provision of a controller which is not adjustable that will provide dependably a set flow rate and does not require monitoring by the nurse.

A further object is to provide a controller as described taking the form of a member having a through bore and made of an appropriate material, such as ceramic having the required characteristics.

A further object of the invention is to provide and make available a control device or flow rater as described having the necessary characteristics to adapt it to the service described above and particularly, that it will be capable of metering a controlled, uniform flow of liquid at a low rate for a long period of time.

A further object is to provide a simple, nonadjustable flow rater for conventional intravenous systems which will permit flow of for example 42, 83, or 125 cc per hour.

Another object is to provide and make available a flow rater which enables the user to make adjustments in flow rates in the area of 42, 83, and 125 cc per hour of flow. More specifically, an object is to provide such a flow rater using a tubular ceramic filter element as a resistance means, the device providing mechanism to be able to vary the effective length of the tubular element. A more specific object is to provide such a flow rater wherein two resistance materials are provided in a flow rater in series, one of them having a very uniform characteristic and the other being variable by being subjected to pressure.

BRIEF DESCRIPTION OF THE DRAWINGS

Further objects and additional advantages of the invention will become apparent from the following detailed description and annexed drawings, wherein:

FIG. 1 is a sectional view of a nonadjustable flow controller;
FIG. 2 is a schematic view of a test set up for the flow controllers;
FIG. 3 is a chart of flow rate versus length of filter, i.e., flow resistance element;
FIG. 4 is a sectional view of an adjustable form of flow controller;
FIG. 5 is a perspective view illustrating utilization of the flow controller of the invention in association with gravity feed from a bottled liquid;
FIG. 6 is a cross sectional view of a preferred form of adjustable flow controller of the invention;
FIG. 7 is a perspective view of two of the components of the assembly of FIG. 6;
FIG. 8 is a sectional view taken along the line 8—3 of FIG. 6;
FIG. 9 is a sectional view of a modified form of adjustable flow controller;
FIG. 10 is a sectional view taken along the line 10—10 of FIG. 9;
FIG. 11 is a sectional view of another modified form of adjustable flow controller; and
FIG. 12 is a sectional view taken along line 12—12 of FIG. 11.
DESCRIPTION OF THE PREFERRED EMBODIMENTS

FIG. 1 shows a 0.12 micron ceramic filter 14 in a plastic holder 10. Ceramic filters as manufactured by Flowtronics are made in cylindrical shape as shown in various lengths for product uniformity reasons. In the flow rate shown, one end of the filter is plugged at 16 by a plug of suitable material, and the drug-carrying solution is forced to flow into open end 17 of the filter and through the side walls. Thus, the filter area becomes the inside circumference of the cylinder times the filter length, \( A = \pi l \). However, \( c \) is fixed by the manufacturer. Thus, the flow rate is determined by the filter length only. The tubular filter material is fitted within an assembly of molded polyethylene or similar material comprising tube 20 and standard medical male and female luer fittings 22 and 24 fitted together as shown.

The incoming fluid containing the desired drug comes in at high pressure (530 to 600 mm hg) and drops to a lower arterial blood pressure (90 mm hg) through the filter material. Since the filter material is linear, that is, the flow rate through the filter is linearly proportional to the pressure differential between the two sides of the filter, the flow rate permitted by the flow rate is proportional only to the filter area available to transmit flow. Mathematically, \( F = KA \) (Pin Pout). Since \( P_1 - out \) is fixed and \( k \) is fixed by filter material choice (in this case, 0.12 micron ceramic filters manufactured by Flowtronics, Inc.), it is left only to adjust the filter area to get the desired flow rate.

To choose appropriate lengths and filter porosities, a test setup is shown in FIG. 2 may be used. Balloon 30, valve 32, and flow rate 10 are set in their usual configuration, but instead of connecting to a catheter or needle, it connects to a tube 34 leading to a column of water 36. The water column height is chosen to be 48.2 in (1,224 mm) which produces a pressure of 1,224 mm water (90 mm hg) or arterial pressure. To the pressure generator and flow rate, the column of water is equivalent to a human venous system. The feed tube (0.035 I.D. polyethylene tubing) and graduated bottle (10 cc syringe barrel) were used and were large enough to not restrict flows or cause a considerable pressure drop at these low flow rates. Using this system, the data generated is shown in FIG. 3.

FIG. 2 also illustrates a typical installation or set-up including infusion means 33 adapted for insertion into the human body. Since a 0.40 length is long enough to be manufacturable easily and that 0.01 in manufacturing length errors do not cause a significant error in flow rate (only 0.01/0.40 = 2.5 percent), this material was chosen. If a low standard porosity filter material manufactured by Flowtronics, such as 0.10 micron is used, then the filter would be lengthened and thus lengthen the overall product making it more cumbersome to the user and more fragile (although this might be a reasonable second choice material). If a 0.27 micron or 0.8 micron filter material were chosen, the filter element would become extremely short (about 1/5 and 1/50 as long, respectively) resulting in flow rates which were shorter but extremely sensitive to manufacturing error.

Once the desired filter material is chosen and \( kc \) (material constant times inside circumference) is fixed, it becomes an easy matter to use the curve as shown in FIG. 3 to choose the desired curve to choose the desired filter length.

Running a horizontal line at the desired flow rate (1 cc per hour) until it intersects the flow line and then read downward, it is found that the 0.12 micron filter should be 0.40 inch long. Once this dimension is found, the remainder of the flow rate's dimensions are chosen simply to allow adequate flow in and out of the filter to avoid interfering with or damaging the filter and to fit standard luer (medical connector) dimensions into which the filter must fit.

With a standard intravenous bottle hung at 72 inches above the patient's heart and assuming that the flow rate's back pressure is negligible (venous pressure is very low relative to a pressure of 72 inches of water), a test stand using a standard McGaw 500 ml intravenous bottle and McGaw No. V140 L.V. set can be arranged similar to FIGS. 2 and 5.

Using the graduations on the bottle and a watch to measure flow rate, filter elements of various lengths can be tested for flow rates they permit. Using this data, a flow rate curve similar to the one appearing in FIG. 3 for the balloon and 0.12 micron filter element can be generated.

When the desired flow rates are known, the desired lengths are easily found. The 0.8 micron filter material was selected because it is the highest porosity of Flowtronics standard filter material. If the lower porosity, 0.27 micron filter material were chosen, the resulting filter element would be roughly ten times longer which would result in an undesirably long flow rate. If a slightly lower porosity filter material were developed by Flowtronics, a new slightly longer filter element length could be found. This might be desirable because the 0.19 length is slightly short but acceptable. If a higher porosity material became available, the filter lengths could be adjusted shorter accordingly.

Once the filter length is selected including the plug length, the remainder of the flow rate dimensions are designed to house the filter and allow unrestricted flow in and out of the filter.

The following describes the approaches undertaken to give some adjustability to the flow as described. The primary advantage of ceramic materials as made by Flowtronics is uniformity. However, this property negates adjustability of the ceramic material short of filters with adjustable effective element lengths which can be done as illustrated in FIG. 4. Body 40 has extending nozzle part or luer 42. It has bore 44 and bore 46 in the nozzle part. It has external threads 45 to receive internally threaded knop 50 having bore 52 and threaded counterbore 54. Numerical 60 indicates the tubular ceramic filter element. Body 40 has internal flange 64 which seals to element 60, the end of which is closed by plug 68. Only the part of element 60 beyond the sealing flange is effective to control flow, which is adjustable by turning knob 50.

As pointed out in the foregoing, a primary objective is to make available a flow controller for controlled rates of flow which is readily capable of having fine adjustments made in the flow rate. Basically, the controller of the preferred form of the invention embraces the concept of having two flow resistances in series so that an advantage can be taken of the desirable positive qualities of each. The first resistance is in the form of a ceramic filter, fixed length and density. This element may be one which is readily commercially available.
Specifically, the material of this resistance is chosen for its high resistance, chemical stability, large pore size, and its filter-to-filter batch-to-batch uniformity. In typically available commercial materials, uniformity can be expected to be no worse than ±5 percent of the flow rate.

The desired filter element lengths may be determined experimentally by supplying known pressure to a filter element of known length and then measuring the flow rate through the filter. It was found that in the case of the 0.010 micron ceramic material pressure of 47 inches of water produced a flow rate of 299 cc/hour for every inch of element. Thus, for any specific flow rate in cc's per hour taken pressure the length of the filter can be readily calculated.

It can be pointed out that for the first resistance, any filter material can be used, although materials as described have preferred characteristics. Filters made of uniform ceramic material are preferred so that advantage can be taken of the uniformity.

The second element in the series is a low density pressure drop unit. Low density material is necessary because it is to be expected that there will be considerable uniformity in acceptable materials for this element. If this material were twice its desired density, the element supplies only 5 percent of the total pressure drop through the flow controller and only 5 percent will be introduced into the overall system. Thus, a 100 percent nonuniformity produces a 5 percent error in the flow controller acceptable level.

The preferred material in the second element is polyurethane foam, although it could be polyethylene or other comparable material. Any relatively uniform, non-wettable, chemically inert, compressible material may be used. Some further examples of materials which can be used include plastic, rubber, paper (cellulose), of chemical fibers, electrostatically charged or chargeable particles, or possibly fragments of any inert, slightly compressible material such as plastic spheres. However, for handling convenience, foam type material is preferred.

Properties of plastic foams and fibrous material include typically low pressure drop flow rate constants; hence, it takes a great thickness of fibrous material to get the same properties as the ceramic and extreme sensitivity to changing through flow rate properties with compression as well as manufacturing variations. Thus, it is practical to use the ceramic filter for gross fixed flow rating and fibrous material for fine adjustments.

Polyethylene foam is preferred because it is easy to handle, inexpensive, and can be made in a desired thickness. A particular foam density will give a 5 to 10 percent change in flow rate with varying compression on the foam. The ceramic filter length is the same as nonadjustable units except it is roughly two percent longer to make up for the pressure drop through the polyethylene foam.

The series resistances can be set up in various ways. The preferred embodiment or set up is shown in FIGS. 6 through 8, and modified forms are shown in FIGS. 9, 10, 11, and 12. In the typical preferred embodiment, only one of the resistances in series has adjustable flow resistance. That is the low density nonuniform one. In each form of the invention, means are provided to slowly or variably compress the foam material to variably control its resistance.
forms a knob 144. At the inner end of plug 142, there is a flange 150 which fits inside cap 134. It has external threads as shown which thread into threaded bore 140. Plug 142 has a bore 152 and a larger counterbore 154 adapted to receive a tubular connection. At the inner end of plug 142, it has a counterbore 156. Received in this counterbore is tubular filter or flow resistance member 104. Interposed between flange 132, body 120, and flange 150 on plug 142, there is a compressible sealing ring member 160.

At the end of flow resistance member 104 is a disc 162 having apertures in it as shown at 164. This disc presses against the compressible flow resistance material 96 which engages against taper 126. As may be seen from FIGS. 9 and 10, when the knob of threaded plug 142 is rotated, flange 150 pushes against the sealing ring, compressing it, and a flow resistance element 104 pushes against disc 162 which in turn pushes on the compressible material 96 causing its resistance to be varied, making it possible to make fine adjustments in the flow rate of the unit as a whole.

FIGS. 11 and 12 show another modified form of the invention. In these figures, numeral 170 designates a tubular barrel having a bore 172 and a nozzle or luer end 174 with bore 176. Numerals 180 designates a knob part having a bore 182 which is shown schematically associated with the barrel part 170. This association may be like that of FIGS. 6 or 9. The tubular flow resistance element seats in a counterbore 184 in knob part 180 which has an annular groove or depression 186 at the bottom thereof. The end of the flow resistance, element 104 is closed by disc 190. Variable resistance material 96 is between this disc and taper 171 at the end of bore 172. Numerals 192 designates a circular element having holes 195 through it and bevel or slanting wedge surface 193, its flat end positioned against resistance material 96. Numerals 194 designates a threaded element or screw having a head 196 and an end part 198 of smaller diameter which engages the top of a wedge member 199 having wedge surface 200 engaging surface 193. The wedge member is between element 192 and disc 190. Thus, by turning screw 194, wedge 199 can be caused to push down against surface 200 to urge element 192 against resistance material 96 to change its flow resistance characteristic by compression to thus change the overall resistance to flow through the unit as in the previous embodiments. Screw 194 makes it possible to make very fine adjustments in the flow resistance.

From the foregoing disclosure, those skilled in the art will readily understand the nature and the characteristics of the invention and the manner in which it achieves and realizes all of the objects as set forth in the foregoing.

The foregoing disclosure is representative of preferred forms of the invention and it is to be interpreted in an illustrative rather than a limiting sense, the invention to be accorded the full scope of the claims appended hereto.

What is claimed is:

1. A flow controller for controlling a small, slow flow of liquid comprising in combination: structure means forming a tubular body, said tubular body defining a longitudinal tubular cavity and having an inlet formed in one end and an outlet formed in its other end; a first flow resistance member tubularly shaped to fit within said tubular cavity in a spaced apart relationship from its inner peripheral wall, said first tubularly shaped flow resistance member being mounted at one end within said tubular cavity with one of its ends in communication with said inlet and its other end closed whereby liquid flowing into said inlet flows into said tubular cavity by passing through the flow restriction defined by the portion of the tubular wall of said first flow resistance member extending into said tubular cavity, said first flow resistance member being made of a material having a fixed resistance to flow characteristic; a second flow resistance member mounted within said tubular cavity across said outlet so that liquid flowing into said tubular cavity through said first flow resistance member must pass through said second flow resistance member to flow out said outlet, said second flow resistance member being made of a resilient compressible material having a resistance to flow characteristic which varies directly with its compression; and means for selectively compressing said second flow resistance member for selectively controlling and adjusting the flow of liquid through said flow controller.

2. A flow controller as in claim 1, wherein the density of the material making up said second flow resistance member is substantially less even when compressed than the material making up said first flow resistance member whereby selective compression of said second flow resistance member operates to make a fine adjustment in the flow rate through said flow controller.

3. A flow controller as in claim 1, wherein said means for selectively compressing said second flow resistance member is formed by making said body a threaded adjustable member which is movable axially to compress said second flow resistance member.

4. A flow controller as in claim 1, wherein said means for selectively compressing said second flow resistance member comprises means positioned to be radially adjustable with respect to said body for compressing the material making up said second flow resistance member.

5. A flow controller for controlling a small, slow flow of liquid and having the capability of making fine adjustments in the resistance to flow comprising, in combination: a body defining a channel therethrough, a first flow resistance material having uniform flow resistance characteristics positioned within said channel so that liquid flowing therein passes through said first flow resistance material; a second flow resistance material in said body arranged and positioned in said channel for a series flow through the two resistance materials, said second resistance material having an adjustable flow resistance characteristic; and means for selectively adjusting the resistance characteristic of said second flow resistance material for selectively controlling and adjusting the flow of liquid through said flow controller, the density of said second flow resistance material being substantially less than said first flow resistance material even when adjusted to provide greatest flow resistance whereby selective adjustment of the resistance characteristic of said second resistance material operates to make a fine adjustment in the flow rate through said flow controller.

6. A flow controller for controlling a small, slow flow of liquid and having the capability of making fine adjustments in the resistance to flow comprising, in combination: a body defining a channel therethrough, a first flow resistance material having uniform flow resistance characteristics positioned within said channel so
that liquid flowing therein passes through said first flow resistance material; a second flow resistance material in said body arranged and positioned in said channel for a series flow through the two resistance materials, said second resistance material having an adjustable flow resistance characteristic; and means for selectively adjusting the resistance characteristic of said second flow resistance material for selectively controlling and adjusting the flow of liquid through said flow controller, said second flow resistance material being a resilient compressible material and having a resistance to flow characteristic which varies directly with its compression and said means for selectively adjusting the resistance characteristic of said second flow resistance material being operable to apply compressive force to said second material for the purpose of making fine adjustments in its resistance characteristic, the density of said second flow resistance material being substantially less even when compressed than said first flow resistance material whereby selective compression of said second flow resistance material operates to make a fine adjustment in the flow rate through said flow controller.

7. A flow controller as in claim 6, wherein said means for selectively adjusting the resistance characteristic of said second flow resistance material comprises axial adjustable threaded means capable of being rotated relatively for applying axial compressive force to said second material.

8. A flow controller as in claim 6, wherein said means for selectively adjusting the resistance characteristic of said second flow resistance material comprises means within said body positioned to be movable radially for applying pressure to said second material and means for adjusting said radially movable means to make fine adjustments in the flow resistance of said second material.