(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
3 November 2011 (03.11.2011)

PCT

(10) International Publication Number
WO 2011/136667 A1

(51) International Patent Classification:
A61M 5/168 (2006.01) *F16K 7/06* (2006.01)
A61M 39/28 (2006.01)

(21) International Application Number:
PCT/NZ2011/000063

(22) International Filing Date:
29 April 2011 (29.04.2011)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
585067 30 April 2010 (30.04.2010) NZ

(72) Inventors; and
(71) Applicants : **AVERY, Raymond John** [GB/NZ]; 17 Matipo Street, Mt Eden, Auckland (NZ). **HUMAN, Neil** [ZA/NZ]; 19 Ponderosa Drive, Oteha, Auckland (NZ).

(74) Agents: **ELLIS | TERRY** et al.; PO Box 10 932, The Terrace, Wellington, 6143 (NZ).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PE, PG, PH, PL, PT, RO, RS, RU, SC, SD,

[Continued on next page]

(54) Title: FLOW CONTROL SYSTEM

(57) Abstract: A flow control system includes a controller that receives an elastomeric flow conduit. The controller compresses the conduit to adjust the flow rate through the conduit. The conduit may be secured to the controller to prevent deformation or stretching of the conduit and consequent undesirable effects on the operation of the flow control system.

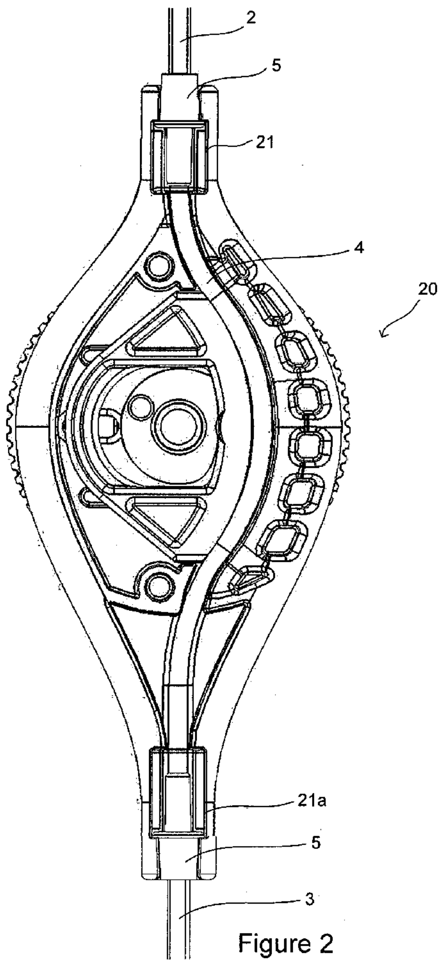


Figure 2

WO 2011/136667 A1

SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report (Art. 21(3))*

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*

FLOW CONTROL SYSTEM

FIELD OF THE INVENTION

The invention relates to flow control systems, particularly but not exclusively to flow control systems for control of administration of fluids to patients.

BACKGROUND TO THE INVENTION

To date, it is largely electromechanical devices (EMDs) such as infusion and syringe pumps that have been able to provide infusion therapy accuracy over an extended period of time. These are however extremely expensive and largely beyond the reach of countries and patients particularly in the developing world.

Gravity Infusion Systems (e.g. IV drip systems) suffer from two major problems that inhibit their accuracy. First, as the infusion bag empties the hydrostatic pressure falls. Generally this will cause the flow rate to decrease, which is undesirable for ongoing flow rate accuracy. Second, management and control of the fluid flow rate by a controller mechanism is generally inaccurate and drifts over time.

The effect of Hydrostatic Pressure will depend on the infusion volume and IV bag size (150ml/250ml/500ml/1000ml) with change in flow rate of between 5% and 20%.

There are two broad groups of flow control devices: inline devices where the medication flows through the device (i.e. from a first length of conduit into the device, through the device and then into a second length of conduit; in these devices, the fluid contacts the device); and external devices that compress the IV Set tubing, so fluid flows through the tubing without contacting the device.

Inline devices include various mechanical devices such as the Exadrop from B Braun and the Abbott Dial-a-Flow devices which function as a tap or faucet to control the flow rate. These are disposable devices and the medication that is being delivered flows through them. They do however not provide for different viscosities of fluid and the drop rates as indicated on the devices will therefore vary accordingly. These controllers are also more expensive than the current standard for infusion delivery flow control where EMDs are not used, namely the roller clamp.

The roller clamp in various embodiments is the standard external device that is used for low cost infusion therapy. There are however, significant inaccuracies and problems that are associated with standard roller clamp devices and they require constant adjustment to deliver accurate and consistent results over an extended period of time. If not closely monitored the flow rate can change in an uncontrolled manner, and the devices can even either stop fluid delivery altogether or go into free-flow, both with significant adverse impact on the patient.

The problems of roller clamps are generally due to one or more of the following of factors.

First, cold flow creep of tubing materials changes the behaviour of the tubing over time. The tubing commonly used in gravity IV sets continues to deform over an extended period of time thereby changing the cross-sectional area and consequently the flow rate.

Second, a mechanical relationship is required between the tubing and the roller clamp to maintain the clamp position. The roller of the roller clamp requires the pressure from the tubing to maintain its position – without this pressure it will roll free. This problem is of course exacerbated by the cold flow creep of the tubing material.

Third, roller clamps have wide tolerance levels which allows for significant movement of the wheel in a direction perpendicular to the tubing. This has a significant effect on the accuracy and consistency of flow rate. Furthermore, the axle of the roller clamp wheel in almost all instances is small, and under pressure can easily deform.

Fourth, a significant level of energy is required to compress the tubing to achieve a desired flow rate. Standard tubing requires large amounts of energy and force to be compressed, and this energy will dissipate and be absorbed by all the components of the system over a period of time, resulting in a change in flow rate. This energy will be released predominantly in the form of cold flow creep, but also through the clamping mechanism itself, e.g. the housing and the wheel axle.

Temperature also has a significant effect on the force and energy required to compress standard IV tubing and at lower temperatures greater force will be required, injecting greater levels of energy into the system and therefore the possibility of greater variances in flow rate.

The tolerances of prior clamps are also not sufficiently fine to provide accurate control.

Gravity feed IV sets use a standard tubing with high levels of cold flow creep. Constant adjustment is required to maintain a set delivery rate, so that without proper care, attendance and management these sets result in poor administration and morbidity at best, and mortality at worst.

Thus patients in the developing world are unable to receive the care and treatment that they need because existing fluid administration systems are either too expensive (e.g. EMDs) or not sufficiently reliable and accurate (e.g. roller clamps).

The Mondiale Technologies Limited clamp design published in WO2008/079023 goes some way towards addressing this problem. However, the Applicant has found that still further improvements can be made to improve the quality of flow control.

An object of the invention is to provide a flow control system at a reasonable/low cost and which operates with a high level of accuracy.

A further object of the invention is to provide improved infusion therapy for patients in developing countries.

Each object is to be read disjunctively with the object of at least providing the public with a useful choice.

SUMMARY OF THE INVENTION

In a first aspect the invention provides a flow control system including: a flow conduit; a flow controller configured to receive a section of the flow conduit and including a clamp to compress the conduit in a compression region so as to control fluid flow through the conduit, at least that part of the flow conduit in the compression region being formed from an elastomeric material; and one or more securing arrangements to secure the flow conduit to the flow controller on at least one side of the compression region.

Preferably the flow control system includes two or more securing arrangements to secure the flow conduit to the flow controller on each side of the compression region.

Preferably the flow control system is configured as a gravity fed flow control system, wherein the securing arrangements reduce the weight forces acting on the part of the flow conduit in the compression region.

Preferably the securing arrangements include cooperating elements on the flow conduit and the flow controller.

Preferably the cooperating elements include lugs on the flow conduit cooperating with surfaces on the flow controller.

Preferably the elastomeric material has a compression set of less than 40% at 22hrs / 347°F (175°C). Preferably the elastomeric material has a compression set of less than 15% at 22hrs / 158°F (70°C). Preferably the elastomeric material has a compression set of less than 5% at 22hrs / 30°C.

Preferably the elastomeric material is a silicone material.

Preferably the elastomeric material is a tubing with a wall thickness in the range 0.5mm to 1mm. Preferably the elastomeric material is a tubing with an internal diameter in the range 1mm to 5mm. Preferably the elastomeric material is a tubing with an external diameter in the range 2.3 to 7mm.

Preferably the elastomeric material is a tubing with a ratio of internal diameter: external diameter: wall thickness of around 4:6:1 (+/- 15%).

Preferably the clamp is biased away from the conduit. Alternatively the clamp may be biased towards the conduit, with an adjustment mechanism moving the clamp to open the flow path.

Preferably the bias is provided by one or more biasing elements formed from an elastic material. Alternatively the biasing elements may be provided by one or more springs.

Preferably the flow control system includes a device which reduces the effect of hydrostatic pressure.

Preferably the flow control system is configured to provide fluid flow in the range 5 drops per minute to free flow.

Preferably the clamp has a clamp surface with a shape which co-operates with the shape of a compression surface so as to compress the flow conduit substantially uniformly along a section of its length.

Preferably the clamp surface and compression surface cooperate to compress a conduit along a section of its length such that flow rate is substantially controlled by interactions of fluid with the conduit walls.

Preferably the clamp surface and compression surface cooperate to compress a conduit along a section of its length such that fluid flow through the compressed conduit is laminar.

Preferably the clamp surface and compression surface cooperate to compress a conduit along a section of its length which is greater than 2mm in length.

Preferably the clamp surface and the compression surface are opposing substantially flat surfaces.

Preferably the flow control system includes a cam driven by an actuator and configured to adjust the clamp.

Preferably the flow control system is configured to control delivery of fluids to a human or animal patient.

Preferably fluid is contained within the flow conduit and does not contact the flow controller.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will now be described by way of example only, with reference to the accompanying drawings, in which:

Figure 1	shows a tube set forming part of one embodiment of flow control system;
Figure 1A	shows a joiner from the tube set of Figure 1;
Figure 1B	is a perspective view of the joiner of Figure 1A;
Figure 2	is a rear view of a flow controller fitted with the tube set of Figure 1;
Figure 3	is an expanded view of part of the flow controller of Figure 2;
Figure 4	is a perspective view of a further flow controller;
Figure 5	is a further perspective view of the flow controller of Figure 4;
Figure 6	is an exploded view of the flow controller of Figure 4;
Figure 7	is a further exploded view of the flow controller of Figure 4;
Figure 8	is a rear view of the flow controller of Figure 4, before installation of a back plate;
Figure 9	is a chart showing compression forces for different types of tubing;
Figure 10	shows a tube set forming part of one embodiment of flow control system;
Figure 10A	shows a joiner from the tube set of Figure 10;
Figure 10B	is a perspective view of the joiner of Figure 10A;
Figure 11	is a rear view of a flow controller fitted with the tube set of Figure 10;
Figure 12	shows a further embodiment of flow control system; and
Figure 13	shows yet a further embodiment of flow control system.

DETAILED DESCRIPTION

The Applicant has devised an accurate and low cost mechanical flow control system, typically for use in infusion therapy. The Applicant's system is particularly suited for controlling the flow of fluid through a tube, where the accurate control of fluid flow is essential to the correct delivery of medication to a patient receiving infusion therapy. This system relies on the synergistic design of the flow controller and mechanism, and the design and characteristics of the tubing needed to achieve accurate control, including, but not limited to the connection of the elastomeric tubing to the flow controller. The system is particularly suited to flow control in gravity fed flow systems, such as IV drip systems.

The system includes a variably adjustable mechanical flow controller which controls the cross-sectional area of a section of elastomeric tubing passing through the clamp, with the tubing securely gripped between the distal ends of the clamp, thereby preventing or at least reducing stretching of the elastomeric tubing.

The flow controller may be similar to Mondiale Technologies' flow controller described in WO2008/079023, the entire contents of which are incorporated by reference herein. However, in that device tubing simply passes through the flow controller, without any mechanism for gripping the tubing. Furthermore, a standard tubing is used, which suffers from the problems described above.

The flow controller preferably maintains a set position as set by the operator, in order to prevent drift of the flow rate over time.

The tubing used in the Applicant's device includes at least a section of elastomeric tubing with excellent memory characteristics. While the entire tubing set could be formed from such a material, the relatively high cost associated with suitable materials can be minimised by using a short length of high cost material, with standard tubing connected to each end of that section.

The elastomeric tubing may be made from silicone or a material with similar characteristics, including platinum or peroxide cured silicone. The material should preferably be chemically inert, or otherwise suitable for use in flow control of fluids which will pass into the human body. In particular a suitable material is R4305/60 WACKER silicone.

Preferably the material is resistant to the fluid flowing through the flow control system.

"Compression set" is a measure of deformation or permanent deflection at given temperatures as defined by ASTM D395-85 (a standard from ASTM International). The material used for the elastomeric material preferably may have a compression set of less than 40% at 22hrs / 347°F (175°C), and less than 15% at 22hrs / 158°F (70°C).

At room temperature such a material is expected to exhibit extremely low levels of deformation. Preferably the elastomeric material has a compression set of less than 5% at 22hrs / 30°C.

The elastomeric tubing requires only a low level of energy in order to compress the tubing. The chart of Figure 9 shows that significant additional levels of force/energy are required to compress standard IV tubing when compared with the elastomeric tubing – nearly 800% more.

The elastomeric tubing also has a stable response under variable temperature range.

The elastomeric tubing may have a wall thickness in the range 0.5mm to 1mm. The elastomeric tubing may have an internal diameter in the range 1mm to 5mm. The elastomeric tubing may have an external diameter in the range 2.3 to 7mm.

The elastomeric tubing may have a ratio of internal diameter: external diameter: wall thickness of around 4:6:1 (+/- 15%).

The use of the elastomeric tubing provides a significant improvement in flow control accuracy. The excellent memory properties of the tubing mean that the characteristics of the flow control system as a whole remain substantially constant over time, i.e. the effects of the tubing are predictable and constant. This means that flow rates can be accurately set over the life of the flow control system. A low level of force is required to compress the tubing, so the effects of the tubing on operation of the clamping mechanism are reduced.

The section of elastomeric material is preferably gripped or retained at the distal ends of the flow controller. This prevents any stretching of the tubing under the weight of the tube set and/or flow controller, so provides a stable section of tubing within the clamp. The adjustable cross-section of the tubing is controlled by the flow controller which preferably has a mechanism with extremely fine tolerances and adjustability. Preferably the flow controller is configured to clamp the tubing uniformly along a section of the tubing length, rather than at a single point. This helps to achieve flow control using cross-sectional area as well as wall effect. A suitable device is the re-usable Acuset Flow Controller from Mondiale Technologies, the subject of WO2008/079023. However, other controllers, including controllers that compress at a point rather than uniformly over a length, may be used. The Applicant's system is expected to improve performance for many different types of flow controller.

Figures 1 to 1B show one mechanism for gripping or securing the tube with respect to the flow controller. The tube set includes first and second sections 2, 3 of standard tubing. A section of high memory elastomeric tubing 4 is joined to the standard tubing sections 2, 3 by a joiner 5 at each end.

A suitable joiner is shown in Figures 1A and 1B. A first section 6 has an internal diameter suitable to receive the standard tubing 2, 3, the end of which will sit against the shoulder 7 when inserted into the joiner 5. Preferably the standard tubing and the internal diameter of joiner section 6 are dimensioned to form a secure fit.

A second section 8 of the joiner has an external diameter such that the elastomeric tubing 4 can be pushed over that section, again forming a secure fit. The end of the elastomeric tubing will sit against the shoulder 9. Thus the standard tubing can be joined to the elastomeric tubing. In the assembled tubing set the end surface 10 of the joiner will sit proud of the standard tubing.

The tubing set of Figure 1 may be installed in a suitable flow controller 20 (Figures 4 to 8). The flow controller includes retention members 24, 25, which when the device is used with standard tubing serve to retain the tubing in the flow controller, as described in WO2008/079023.

However, when used with the Applicant's tubing set, the retention members 24, 25 interact with the proud surface 10 of the joiner to secure the tubing set to the flow controller. In particular, the end surface 10 of the upper joiner sits against the lower surface 12 of the upper retention member, such that the weight of the flow controller is taken by the first length of standard tubing extending above the flow controller, not by the elastomeric tubing. Similarly, the end surface 10 of the lower joiner sits against the upper surface 13 of the lower retention means, such that the weight of the second length of standard tubing extending below the flow controller (and any equipment attached to that tubing) is taken by the flow controller and then passed to the first length of standard tubing.

Figures 2 and 3 show a modified form of the Medicine Mondiale's flow controller, in which the retention members have been replaced by shaped recesses 21, 21a. The shaped recesses receive a cooperating element 5 attached to or mounted on the tubing, whether in the form of a joiner or otherwise.

Thus the retention members and joiners, or the shaped recesses and cooperating elements, together form one or more securing arrangements which secure the tubing to the flow controller on one or preferably both sides of a region where the tubing is to be compressed.

In a further embodiment the retention members and joiners, or the shaped recesses and cooperating elements are configured to prevent movement of the tubing relative to the flow controller in both directions. For example, the joiner may fit into a precisely shaped recess, possibly with an interference fit, or may have a protrusion which engages with a groove. This not only reduces the tension forces acting on the elastomeric tubing within the flow controller but also exactly positions the tubing and prevents compression or bunching of the tubing within the flow controller. This means that the flow control system is easily assembled exactly as designed, such that operation is also as designed.

Therefore, no, or at least minimal, weight is taken by the section of elastomeric tubing within the flow controller. That is, the securing arrangements reduce the weight forces acting on the part of the flow conduit in the compression region. As discussed above, this prevents stretching of the elastomeric material and associated effects on the accuracy of the flow rate. Furthermore, the effects of other influences, such as patient movement, are minimised. Any tension exerted by a patient on the flow conduit is taken by the joiners and retention means and is not passed to the length of elastomeric tubing within the flow controller.

In one embodiment a linear braid may be wrapped around the elastomeric tubing section thereby further reducing any linear stretching of the tubing. However, this is likely to increase the cost and could influence the compression of the tubing.

Many other mechanisms may be suitable for gripping or securing the tubing at the ends of the flow controller. For example, small clamps could be mounted on the flow controller to clamp around the tubing or the joiner. Cooperating elements could be built into or attached to the tubing and clamp device. For example, lugs at either end of the elastomeric section would allow for retention within the clamp.

The flow controller preferably includes a clamp which compresses the conduit against an opposed compression surface. The clamp is preferably biased away from the compression surface. A suitable biasing element is a spring or a length of elastic material to pull the clamp away from the conduit. Alternatively, the mechanism could work against a pressure point to bias the clamp away from the compression surface. This helps to maintain correct orientation and operation of the clamp, and also helps to move the clamp away from the compression surface when the flow rate is to be increased.

In an alternative embodiment the clamp may be biased towards the flow conduit. The clamp is then moved against the bias to allow insertion of the flow conduit. This movement may be independent of the flow rate adjustment mechanism such that the clamp can be moved without altering the adjustment. The clamp can be held in this open, retracted position, either manually or by a simple lock mechanism. The tubing can be inserted between the retracted clamp and the compression surface. When released the biased clamp will move from the retracted position towards the compression surface to close the flow path up to the point where it reaches the setting of the flow rate adjustment mechanism. The adjustment mechanism then operates as a stop on movement of the clamp, i.e. to move the clamp to open the flow path against the bias or to allow further compression of the tubing by the bias. In this embodiment the bias applied to the clamp is preferably sufficient to completely compress the tubing so as to block any flow of fluid through the tubing. This allows for very fine adjustment of flow rates by the adjustment mechanism with compression forces provided by a separate biasing device. This is expected to reduce the minimum controllable flow rate to under 5 mL per hour.

Figure 12 illustrates one example of such a configuration. This system is similar to the flow controller and tube set described above, but the clamping arrangement has been altered. The compression surface 100 is now formed as a flattened region opposing a flat clamp surface 101 on a clamp 102. The clamp 102 is carried by a shaft or plunger 103 which rides in a cooperating hollow housing 104 formed in the body of the flow controller. The shaft 103 extends through the housing 104 and a knob or handle 106 may be provided on the end of the shaft 103. Preferably the shaft 103 and the bore of the housing 104 are shaped to prevent rotation movement of the shaft within the housing. For example the shaft and housing may be of square cross-section, or the shaft may be formed with a spline that rides in a groove in the housing bore.

The shaft 103 and clamp 102 are biased towards the compression surface 100 by a biasing device 107, which may be a spring as shown or any other suitable biasing arrangement. As discussed above, the spring 107 preferably provides sufficient force to completely compress the conduit 4 within the compression region. A user, by grasping the knob 106 and pulling, may retract the clamp 102 to allow insertion or removal of the flow conduit from the flow controller.

An adjustment mechanism in the form of a collar 110 is mounted on a threaded portion 111 of the shaft 103. Cooperating threads in the interior bore of the collar 110 allow the collar to be rotated and thereby moved along the length of the shaft 103. When the use releases the plunger 103, the biased plunger moves towards the compression surface until the surface 112 of the collar 110 meets the end surface 113 of the housing 104. This stop limits further movement of the plunger. In this way the level of compression and therefore the flow rate through the device can be adjusted by adjustment of the position of the collar 110.

The mechanism may also include a clicker 115 to provide an audible indication of adjustment. The clicker may also assist to prevent flow rate creep by resisting creep of the adjustment mechanism. Some form of locking mechanism may also be provided to prevent accidental adjustment and/or to prevent full retraction of the plunger after the conduit has been installed. A flow rate scale may be provided, preferably on the shaft 103, housing 104 or on a combination of the two.

Figure 13 shows a further embodiment in which the flow controller body has been replaced by an alternative body in a generally triangular form. The device is otherwise similar to that of Figure 12.

The clamping mechanism is preferably made with very tight tolerances (less that 0.01mm) in order to provide very accurate flow control. The clamp mechanism preferably holds its position independent of pressure exerted by the tubing and has an extremely fine method of adjustment.

Adjustment of the clamp may be provided by a single adjustment mechanism, as shown in the drawings, or by an adjustment mechanism including both coarse adjustment and fine adjustment (for example using separate dials, knobs, levers or any combination of actuators). Here the coarse adjustment can be used to set an approximate flow rate, or in one embodiment simply to close the flow path. The fine adjustment can then be used for accurate selection of the desired flow rate. Where coarse adjustment closes the flow path, fine adjustment accurately opens the flow path to provide a desired flow rate.

In order further to enhance accuracy of the system, a device may be included which reduces or even eliminates the effect of hydrostatic pressure. This ensures that the pressure of fluid flowing into the flow controller is constant, so that the flow controller can operate as designed at al times providing an accurate and predictable flow rate. A suitable device is the IV^2 Flow regulator from Varori International Ltd. That device is described in the specification of US Patent No. 7,001,365, the entire contents of which are incorporated by reference herein. Such a device is inserted into the flow conduit between the fluid source (usually an IV bag) and the flow controller and ensures that the pressure of fluid received by the flow controller remains substantially constant despite the decreasing level of fluid in the IV bag. Other hydrostatic pressure control or compensation devices may also be suitable.

The Applicant's system provide a flow control system which maintains a flow rate within +/-5% of the desired level at a given level of hydrostatic pressure. This system minimises the amount of force/energy that is required to clamp the elastomeric tubing to deliver the flow rate that is desired and prevents gravity from having an influence on the flow rate through stretching of the tubing.

This current invention provides a simple, low cost, yet accurate system, which has application in a multiplicity of markets, but particularly in the developing nations where such accuracy is currently not available at an affordable cost.

Returning to Figures 4 to 8, these figures show a flow controller 20 in more detail. This controller is substantially as described in the Mondiale Technologies' WO2008/079023. Many other types of flow controller may be used as part of the Applicants' system and are intended to fall within the scope of the invention. However, the flow controller shown has a number of desirable features as described in WO2008/079023 and below which contribute to the excellent results provided by the Applicants' system.

The flow controller 20 has a controller chassis 22 which is adapted to retain a deformable flow conduit in a conduit channel 23. In use, a conduit is inserted into the conduit channel 23 and engages with the retention members 24, 25 at the top and bottom ends of the controller. There is no need to disassemble the flow controller in order to insert the flow conduit.

The flow controller 20 includes an actuator 26, which may be a dial. Alternatively, a sliding actuator, lever or any other suitable actuator may be used. The actuator may be equipped with a scale 27. A pointer 28 may be provided on the controller chassis 22, such that a user can read a value from the scale 27. Of course, the pointer could be provided on the actuator, with a scale on the controller chassis.

The scale may provide an indication of actuator position, or flow rate or any other useful parameter. Different fluids (including IV fluids and drug formulations) have slightly different viscosities and may flow at slightly different rates through a flow conduit. Therefore, the scale may be a scale associated with a particular fluid. The scale could also be associated with a particular drug treatment regime (e.g. a chemotherapy regime) making clinical treatment easier and reducing the possibility of operator error. The scale could be supplied on a sticker suitable for attachment to the flow controller, and the flow controller could be supplied with a number of different stickers suitable for different fluids and/or treatment regimes. Alternatively the sticker could contain a numerical scale which in combination with a reference chart can be used to calculate flow rates in drops per minute and/or millilitres per hour.

Figures 6 and 7 show exploded views of the flow controller 20. The flow controller 20 includes a controller chassis 22 (described above), which retains the flow conduit, and also provides a body to which the other elements of the controller are mounted.

The dial 26 mounts to the front surface of the controller chassis 22 and also engages with a clicker 40. The clicker 40 is mounted to the controller chassis in a slot 41 and engages with a series of grooves and projections 42 (Figure 7) formed on the back face of the dial 26. The clicker mechanism formed by the combination of the clicker 40 and the grooves and projections 42 allows the position of the dial to be accurately set in one of the positions where the clicker 40 engages with a groove. Furthermore, the projections restrict movement of the dial out of these positions, such that drift of the dial position over time is prevented. This also decreases the chance of the dial setting being accidentally altered by its being knocked etc.

Although the clicker 40 as shown engages with the dial 26, it could also engage with the cam or clamp (both described below). The important feature of the clicker mechanism is that it should operate to allow the clamp (and therefore the flow rate) to be accurately adjusted and to be retained in a particular setting, intermediate a maximum setting and a minimum setting.

The dial also includes a dial shaft 43 (Figure 7) which engages with the internal bore 44 (Figure 6) of a cam 45. The dial shaft 43 and the bore 44 may have cooperating non-circular cross-sections. The cam 45 and the dial shaft 43 are secured to each other using a pin 46 which passes through the cam and into a hole 47 provided in the dial shaft 43. The cam is also provided with a cylindrical cam shaft 48 which is seated in a bore 49 in the controller chassis, such that the cam is free to rotate within the bore 49. Thus, the dial and the cam are rotatably secured to the controller chassis, with the dial driving rotation of the cam.

The flow controller 20 also includes a clamp 50. The clamp 50 includes a pin 51 which rides in a slot 52 in the controller chassis 22. The slot 52 is sufficiently long to allow adjustment of the clamp 50 over a desired range. The clamp 50 is secured to the controller chassis 22 by a backing plate 53 having two pins 54 which engage with holes 55 in the controller chassis 22. In addition, the backing plate 53 includes a cylindrical bearing member 56 (Figure 6) which engages with a hole 57 (Figure 7) in the back of the cam 45, providing further stability in rotational movement of the cam 45.

The various components may be joined where appropriate using self tapping screws. Alternatively, screws in threaded holes or adhesives or a welding process (such as sonic welding) or simply a friction fit could be used (although this may not last well). However, gluing may be problematic where a number of different materials are used, since a glue is unlikely to bond well to different materials. Sonic welding may suffer from similarly poor bonding where different materials are welded.

When assembled, the cam 45 engages with the inner surface 58 of the clamp 50. When rotated, the eccentric shape of the cam 45 adjusts the lateral position of the clamp 50, and in particular of the clamp surface 59 which, in use, presses against the outside of a flow conduit passing through the flow controller 20. The other side of the flow conduit presses against a compression surface 60 formed by one wall of the conduit channel 23. The clamp surface 59 is shaped with substantially the same profile as the compression surface 60 on the controller chassis 22. When the controller is adjusted to compress a flow conduit, the clamp surface 59 and the compression surface 60 cooperate to provide substantially uniform compression along a section of the conduit's length. The substantially uniform compression and the large operative surface areas of the clamp surface and compression surface provide an increase in flow rate accuracy over prior devices. In contrast, prior devices generally compress a tube at a point, or in a non-uniform manner. This does not allow the flow rate to be adequately controlled.

The large surface areas used in the Applicant's device control flow through interactions of the fluid with the walls of the tube and the size of the flow passage, rather than simply the size of a point constriction. In general, when fluid flows through a tube it flows more quickly at the centre of the tube, and at a minimum speed at the tube walls. The actual flow rate is an average of the flow rate gradient across the cross section of the tube. In the Applicant's device, as the tubing is compressed the effect of the tubing walls on the flow rate increases and the flow rate is slowed. The longer the length of compressed tubing, the greater the effect.

Furthermore, where a point constriction is used, the fluid flow through the constriction is turbulent and satisfactory control of such turbulent flow is difficult to achieve. In contrast, the Applicant's device provides laminar flow through the compressed region, allowing satisfactory control of fluid flow. Again, this laminar flow is achieved through compression of the tubing along a section of its length, rather than at a point.

Therefore, it is desirable to compress the tubing over a section of its length rather than simply at a point. The length of the compressed section may be at least 2mm, preferably greater than 1cm, preferably greater than 2.5cm and more preferably about 5cm. Similarly, the length of the compressed section may be in the range 0.5cm to 10cm, or 1cm to 10cm, preferably 2.5cm to 6cm and more preferably about 5cm. The 5cm length has also been found suitable for ergonomic reasons – a device with this length compression fits well in the hand and can be operated one-handed.

The clamp surface 59 and compression surface 60 may be substantially flat surfaces, or may be formed with any suitable pattern of grooves. However, large grooves have been found to cause instability in the change of flow rate with clamp adjustment, while smaller grooves produce approximately the same result as flat surfaces. So, for simplicity of manufacture and best results, flat surfaces are preferred. (The term "flat surface" as used in this specification, including the claims, means a surface free of surface features such as grooves, projections etc. However, a "flat surface" may be a curved surface, such as the clamp surface or the compression surface shown in the drawings.)

An IV tube generally deforms into a figure 8 shape between flat plates, forming two channels of flow. It may be possible to use a clamp surface and a compression surface at a slight angle to each other in order to create a single flow channel.

However, the most desirable surface shape is one that causes the tube to adopt a generally rectangular cross-section. The change in flow rate with adjustment of the clamp mechanism is then more linear, since (if the width of the rectangle is assumed to be constant) the area of the flow passage varies linearly with the height of the rectangle and therefore with adjustment of the clamp mechanism. In contrast where the cross-section is approximately circular the area of the flow passage varies with the square of the radius. The flat surfaces described above provide a generally rectangular flow-passage for most flow rates.

In a further embodiment the two opposing surfaces may be convex to the extent that the tubing can still be compressed to prevent flow. One of the two surfaces may have a concave surface and the other a convex surface. In a further embodiment, a system which is so designed as to specifically generate a figure-of-eight shape, thereby creating two lumens through which the fluid will flow. In this embodiment, at least one of the opposing surfaces which clamp the tubing may have a longitudinal rib at a position so as to match the centre line of the tubing. The rib should not be so deep as to prevent the tubing from being clamped to a closed position.

The shape of the cam 45 is shown most clearly in Figure 8, which shows the flow controller 20 from the back, before attachment of the backing plate 53. The operating surface 62 of the cam 45 contacts the inner surface 58 of the clamp 50, driving it laterally when the dial and cam are turned by a user.

The profile of the cam's operating surface 62 may be designed such that the cam radius increase continuously with rotation (where the cam radius is the distance from its axis to the operating surface 62). The profile may be designed to provide a linear or near linear relationship between actuator position and flow rate. Different portions of the profile may have different shapes. For example, the profile may be designed to provide a first rate of adjustment of clamp position with rotation of the cam over a first portion, and a second rate of adjustment of clamp position with rotation of the cam over a second portion. For example, the cam may be designed to provide fine adjustment of clamp position (and therefore flow rate) at low flow rates and slightly coarser adjustment of clamp position at high flow rates. The cam may have a first region covering about 90° of rotation and providing a total increase in cam radius of about 3mm, allowing the tube to be loaded after it has been fitted to the flow controller. A second region covering about 135° of rotation may provide a total increase in cam radius of about 1mm, allowing fine adjustment of flow rate. Accurate adjustment of flow rates requires the cam to be fabricated with tight tolerances.

Figure 8 also shows two biasing elements 66 in the form of elastomeric threads. These threads are stretched between one end attached to the clamp 50 and the other end attached to the controller chassis 22. Thus, the threads bias the clamp 50 away from an installed flow conduit, or in other words away from the compression surface. Other biasing elements such as springs or the like could be used instead of elastomeric threads.

The various components of the flow controller may be formed from plastic materials such that they can be formed by known moulding techniques. Polycarbonate, polysulphone and acetal may be suitable materials. As accuracy is paramount, the low shrinkage of polycarbonate components during fabrication is advantageous, since accurate moulds can be fabricated and the finished part will match the mould closely. However, movement of polycarbonate against polycarbonate creates wear, which will reduce accuracy over time. Therefore, adjacent moving parts should not both be made of polycarbonate. In particular, the dial and the cam should be formed from different materials.

The following combination of materials has been found suitable. The controller chassis 22, dial 26 and back plate 53 are formed from polycarbonate. The clamp 50 may be formed from either polycarbonate or polysulphone. The cam 45 and the clicker 40 are preferably formed from acetal or similar lubricating type materials, such as nylon, that have low shrinkage characteristics (less than 1%) during the injection moulding process.

Figure 10 shows a further embodiment of mechanism for gripping or securing the tube with respect to the flow controller. The tube set includes first and second sections 2, 3 of standard tubing. A section of high memory elastomeric tubing 4 is joined to the standard tubing sections 2, 3 by a joiner 5 at each end.

A suitable joiner is shown in Figures 10A and 10B. A first section 6 has an internal diameter suitable to receive the standard tubing 2, 3, the end of which will sit against an internal shoulder (similar to that shown in Figure 1A) when inserted into the joiner 5. Preferably the standard tubing and the internal diameter of joiner section 6 are dimensioned to form a secure fit.

A second section 8 of the joiner has an external diameter such that the elastomeric tubing 4 can be pushed over that section, again forming a secure fit. The end of the elastomeric tubing will sit against the shoulder 9. Thus the standard tubing can be joined to the elastomeric tubing. In the assembled tubing set the lug 10 of the joiner will sit proud of the standard tubing as is clear in Figure 10.

The tubing set of Figure 1 may be installed in any of the flow controllers discussed herein. One suitable flow controller is shown in Figure 11 and includes a groove 70 for receiving the lug 10 in order to grip or secure the tubing set to the flow controller, providing the advantages discussed herein. This flow controller also has a slightly altered path for the flow conduit, including a flat section 72 where the clamp and compression surfaces have been machined to provide straight, parallel walls. This more accurately provides for uniform compression along a section of tube length than the curved walls. This flow controller is otherwise similar to that described above with reference to Figures 2 to 8.

The flow controllers of Figures 2 to 8 and 10 to 11 are reusable, clipping onto a deformable flow conduit. The controller can be easily attached to and removed from the conduit. Fluid never contacts the flow controller, being confined to the inside of the flow conduit. The flow rate can be accurately and simply adjusted. The large compression area formed by the cooperating shapes of the clamp surface 59 and the compression surface 60 provides accurate and precise adjustment of flow rate. The clicker mechanism allows that flow rate to be accurately set and retains the dial, cam and clamp in a set position, preventing creep or accidental adjustment of flow rate. The cam may be shaped to provide substantially linear adjustment of flow rate with rotation of the dial, or may be shaped to provide any other desired relationship between flow rate and dial rotation.

The simple operation of this device makes it possible to set flow rate accurately with minimal training. Once the flow rate at a given flow controller setting has been established for a given IV fluid or drug preparation, there is no need for operators to count drops over a period of time in order to set that flow rate; the desired flow rate can simply be set using the dial. The average accuracy of flow rate setting is at a similar level to many state-of-the-art microprocessor controlled IV devices, which currently cost around US$1500.

The controller provides an accurate and simple means of adjusting flow rate at a reasonable/low cost. The flow controller is expected to cost about the same as existing dial-a-flow controllers. However, while those controllers are single use devices, the Applicant's device is reusable and designed to have an operating life of at least 10 years. This makes the Applicant's flow controller a viable option for use in cost-sensitive applications, including health care in the developing world and other cost-sensitive applications worldwide.

When the Applicant's flow control system includes a device which further reduces the effect of hydrostatic pressure, variations over time caused by changes in hydrostatic pressure are extremely small.

The flow controller, when used with the elastomeric tubing described above has been found suitable for accurate setting of any flow rate between 5 drops per minute up to free flow. Other suitable flow ranges may be available by altering the tubing used and the parameters of the device, such as length of the clamp and compression surfaces. For example, a flow controller having a flow rate range of 1 to 500 ml/hour, or 0.5 to 250ml/hour could be provided.

The invention may be useful in many applications where it is necessary to control fluid flows, including: administration of fluids to human patients, including IV fluids such as rehydration fluids, drug therapy regimes, anaesthetics and palliative care treatments; administration of fluids to animals (i.e. by veterinarians); administration of fluids in a remote setting or by paramedics; and controlling flow of chemicals in various settings, including controlling chemical flow for treatment of water, such as drinking water or sewage.

The flow controller may be provided in kit form. For example, the flow controller may be provided in a kit including a flow controller and two or more stickers each marked with a scale. Each sticker may be marked with a scale suitable for flow control of a particular fluid or administration of a particular treatment regime. A sticker could be marked with two or more such scales. In this specification, "particular fluid" includes a particular class of fluids, for example fluids with a viscosity in a particular range. Similarly, the flow controller could be supplied marked with a single scale, but with a conversion chart allowing conversion of the scale reading to a flow rate, or a flow rate for a particular fluid, or two or more different fluids. The flow controller could also be supplied in a kit including two or more cams, each with a different cross-section, so as to provide different relationships between flow rate and actuator position. Each cam could be suitable for flow control of a particular fluid or administration of a particular treatment regime.

While the invention has been described with reference to one form of flow controller as shown in the figures, other types of flow controller may instead be used as part of the flow control system.

While the flow controllers described are generally manually adjusted, electromechanical adjustment mechanisms may be used in some embodiments. Controllers may be used to drive such electromechanical adjustment mechanisms. Display screens, speakers and other suitable output or user interface devices can be provided to allow user interactions with the system and to allow alerts or warnings to be issued.

While the present invention has been illustrated by the description of the embodiments thereof, and while the embodiments have been described in detail, it is not the intention of the Applicant to restrict or in any way limit the scope of the appended claims to such detail. Additional advantages and modifications will readily appear to those skilled in the art. Therefore, the invention in its broader aspects is not limited to the specific details, representative apparatus and methods, and illustrative examples shown and described. Accordingly, departures may be made from such details without departure from the spirit or scope of the Applicant's general inventive concept.

CLAIMS:

1. A flow control system including:

   a flow conduit;

   a flow controller configured to receive a section of the flow conduit and including a clamp to compress the conduit in a compression region so as to control fluid flow through the conduit, at least that part of the flow conduit in the compression region being formed from an elastomeric material; and

   one or more securing arrangements to secure the flow conduit to the flow controller on at least one side of the compression region.

2. A flow control system as claimed in claim 1 including two or more securing arrangements to secure the flow conduit to the flow controller on each side of the compression region.

3. A flow control system as claimed in claim 1 or 2 configured as a gravity fed flow control system, wherein the securing arrangements reduce the weight forces acting on the part of the flow conduit in the compression region.

4. A flow control system as claimed in any preceding claim wherein the securing arrangements include cooperating elements on the flow conduit and the flow controller.

5. A flow control system as claimed in claim 4 wherein the cooperating elements include lugs on the flow conduit cooperating with surfaces on the flow controller.

6. A flow control system as claimed in any preceding claim wherein the elastomeric material has a compression set of less than 40% at 22hrs / 347°F (175°C).

7. A flow control system as claimed in any preceding claim wherein the elastomeric material has a compression set of less than 15% at 22hrs / 158°F (70°C).

8. A flow control system as claimed in any preceding claim wherein the elastomeric material has a compression set of less than 5% at 22hrs / 30°C.

9. A flow control system as claimed in any preceding claim wherein the elastomeric material is a silicone material.

10. A flow control system as claimed in any preceding claim wherein the elastomeric material is a tubing with a wall thickness in the range 0.5mm to 1mm.

11. A flow control system as claimed in any preceding claim wherein the elastomeric material is a tubing with an internal diameter in the range 1mm to 5mm.

12. A flow control system as claimed in any preceding claim wherein the elastomeric material is a tubing with an external diameter in the range 2.3 to 7mm.

13. A flow control system as claimed in any preceding claim wherein the elastomeric material is a tubing with a ratio of internal diameter: external diameter: wall thickness of around 4:6:1 (+/- 15%).

14. A flow control system as claimed in claim 1 wherein the clamp is biased away from the conduit.

15. A flow control system as claimed in claim 1 wherein the clamp is biased towards the conduit.

16. A flow control system as claimed in claim 14 or 15 wherein the bias is provided by one or more biasing elements in the form of springs or elements made of an elastic material.

17. A flow control system as claimed in claim 1 further including a device which reduces the effect of hydrostatic pressure.

18. A flow control system as claimed in claim 1 configured to provide fluid flow in the range 5 drops per minute to free flow.

19. A flow control system as claimed in any preceding claim wherein the clamp has a clamp surface with a shape which co-operates with the shape of a

compression surface so as to compress the flow conduit substantially uniformly along a section of its length.

20. A flow control system as claimed in claim 19 wherein the clamp surface and compression surface cooperate to compress a conduit along a section of its length such that fluid flow through the compressed conduit is laminar.

21. A flow control system as claimed in claim 19 or 20 wherein the clamp surface and compression surface cooperate to compress a conduit along a section of its length which is greater than 2mm in length.

22. A flow control system as claimed in any one of claims 19 to 21 wherein the clamp surface and the compression surface are opposing substantially flat surfaces.

23. A flow control system as claimed in any preceding claim including a cam driven by an actuator and configured to adjust the clamp.

24. A flow control system as claimed in any preceding claim, for controlling delivery of fluids to a human or animal patient.

25. A flow control system as claimed in any preceding claim wherein fluid is contained within the flow conduit and does not contact the flow controller.

26. A flow controller configured to receive a deformable fluid flow conduit and having:

i) a clamp having a clamp surface opposing a compression surface;

ii) a biasing device configured to bias the clamp towards the compression surface to compress a conduit between the clamp surface and the compression surface; and

iii) an adjustment mechanism configured to adjustably limit movement of the clamp under the bias, thereby allowing adjustment of the level of compression of the conduit and the flow rate of fluid through the conduit.

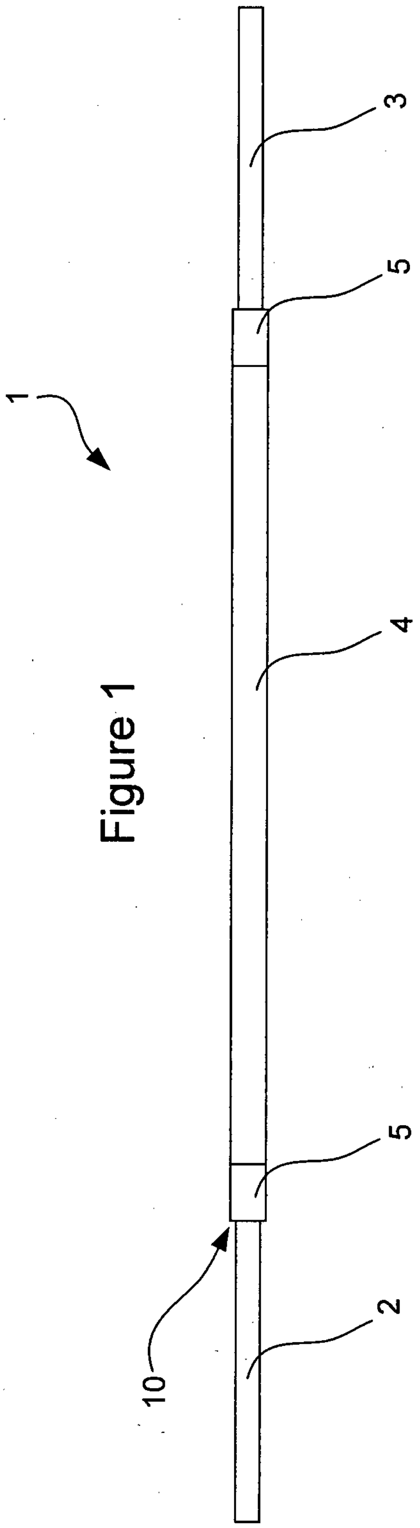


Figure 1

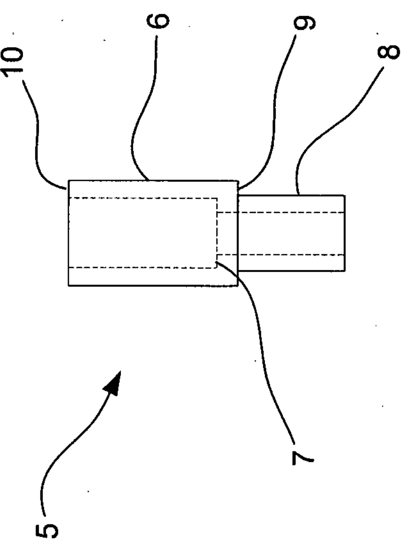


Figure 1A

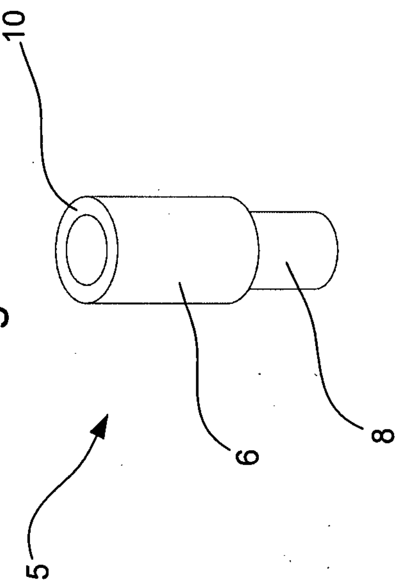


Figure 1B

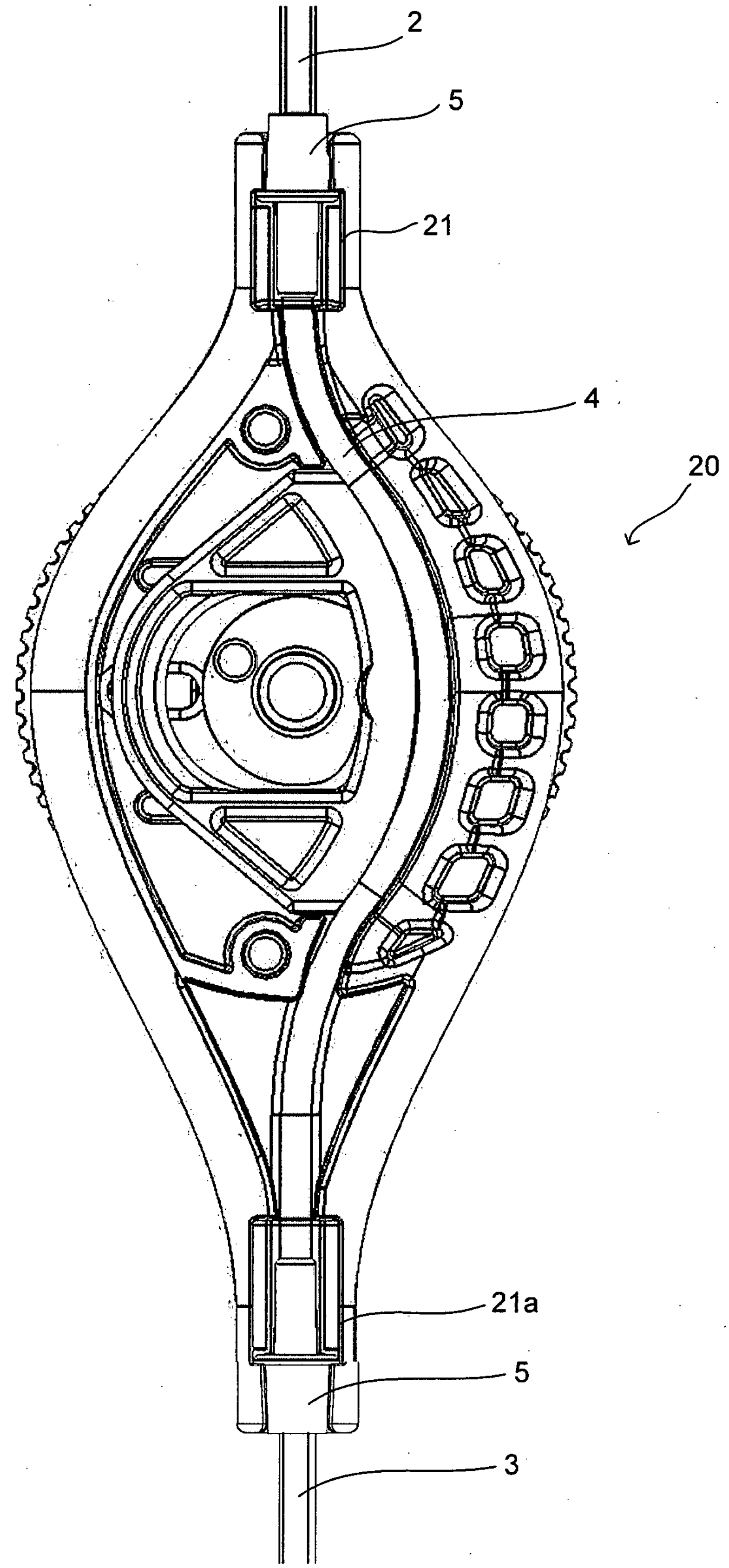


Figure 2

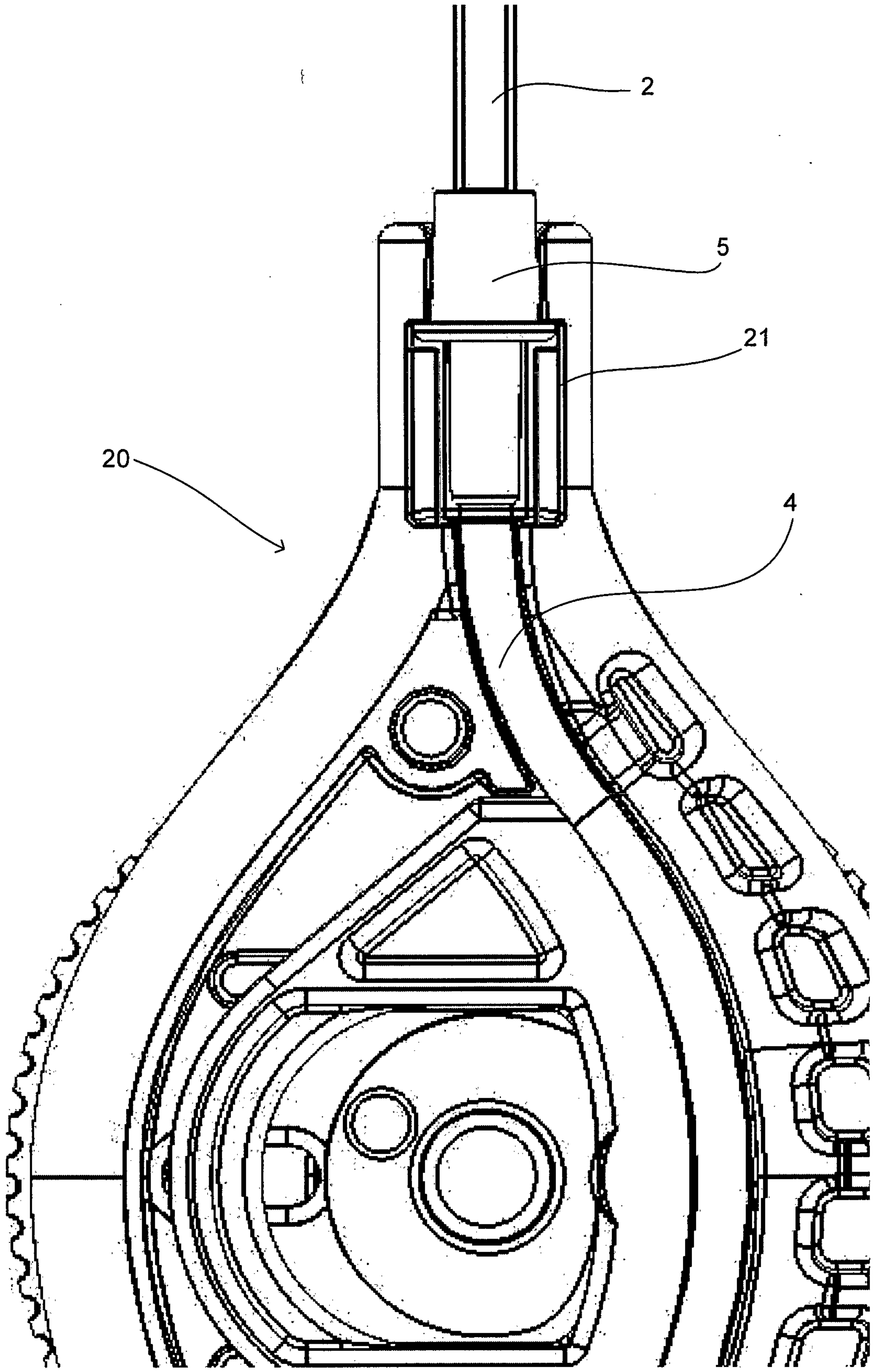
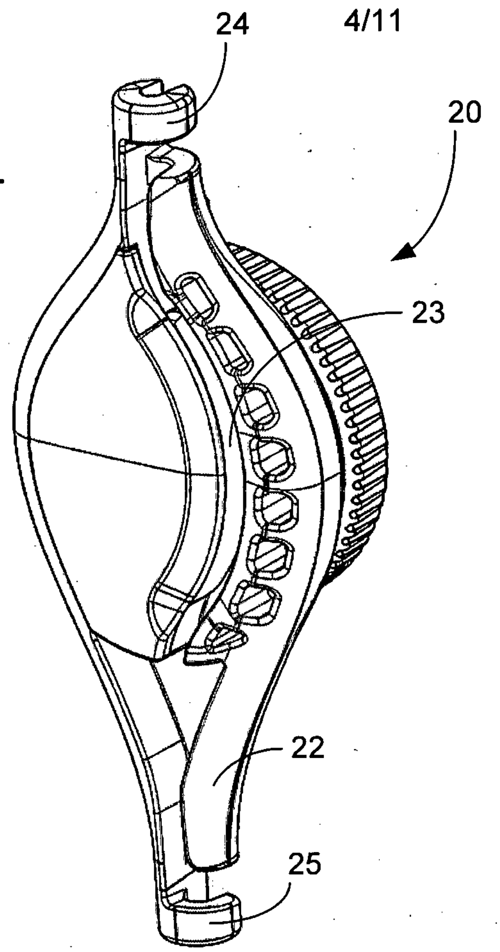


Figure 3

Figure 4



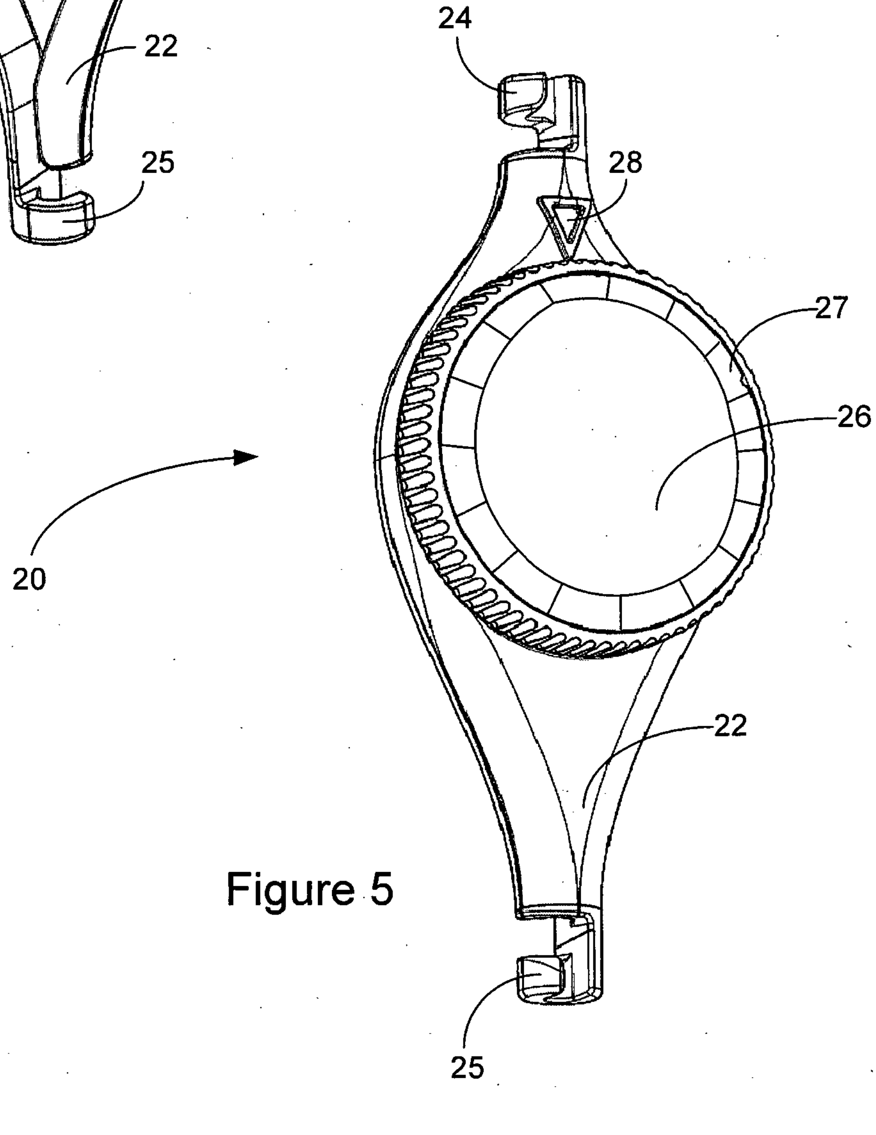


Figure 5

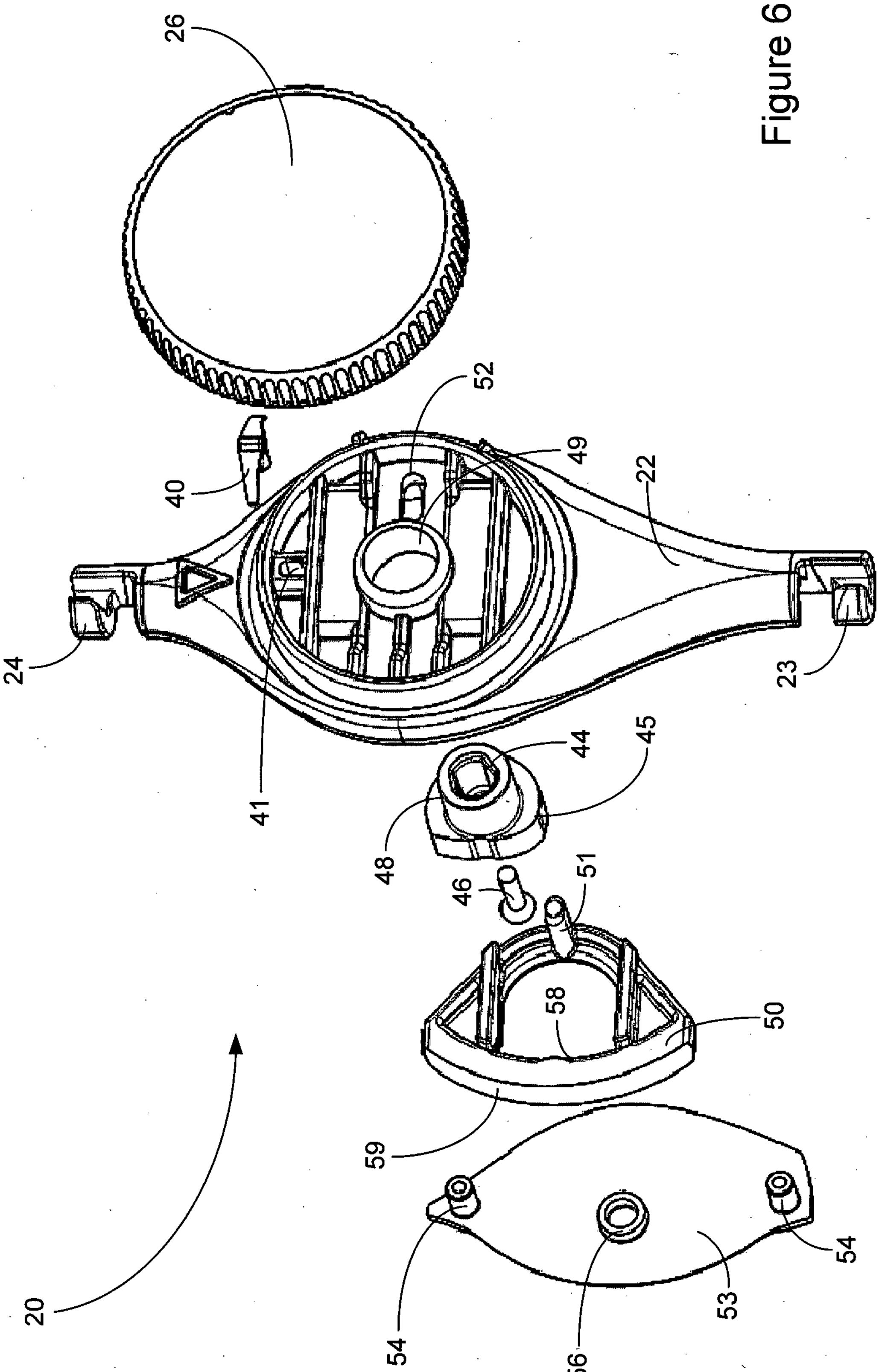


Figure 6

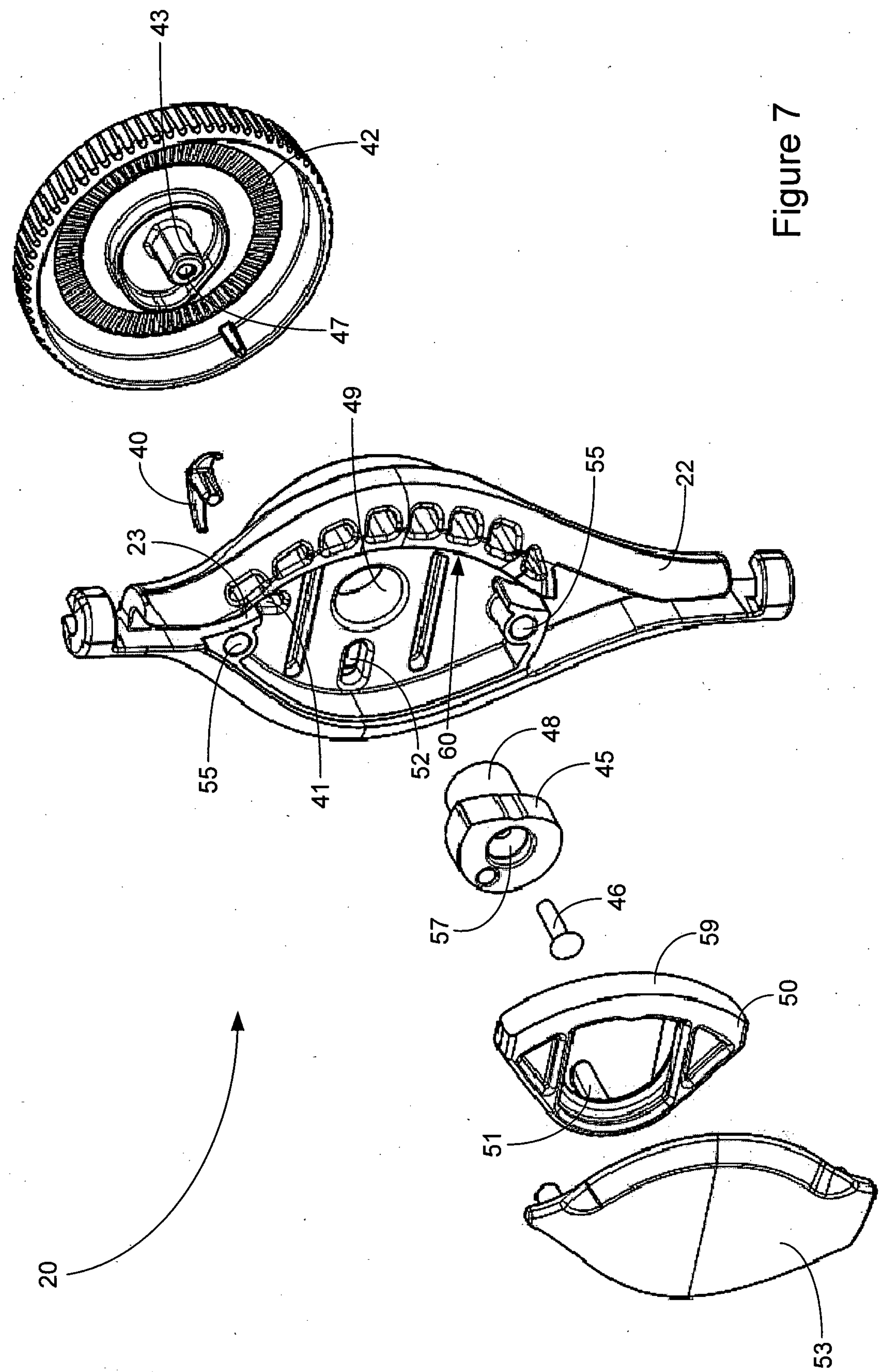


Figure 7

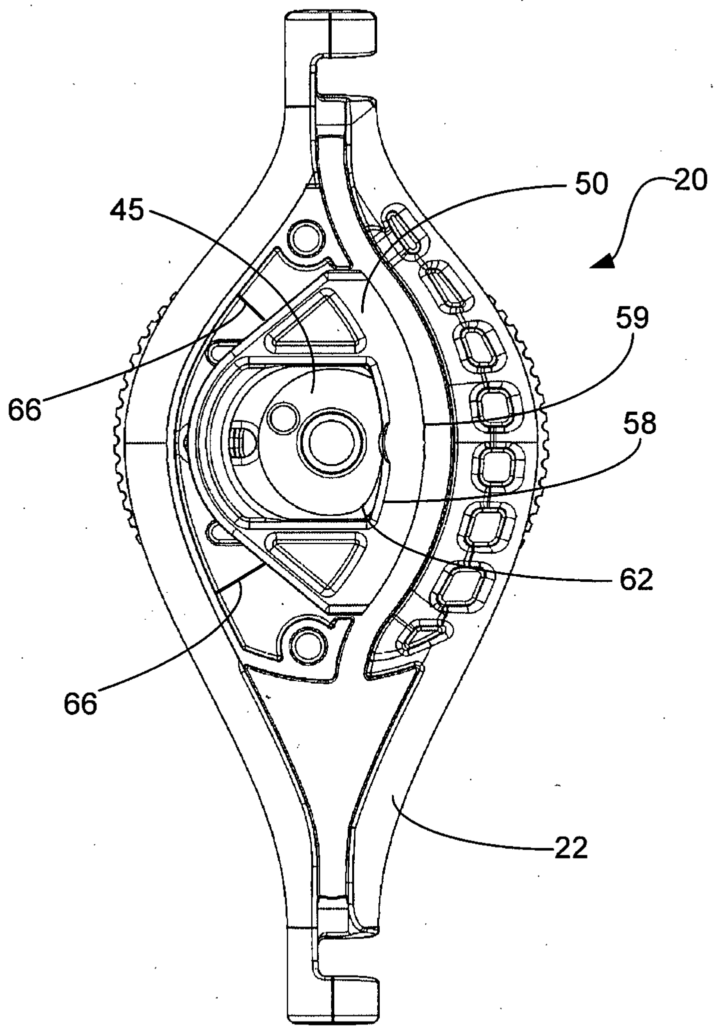
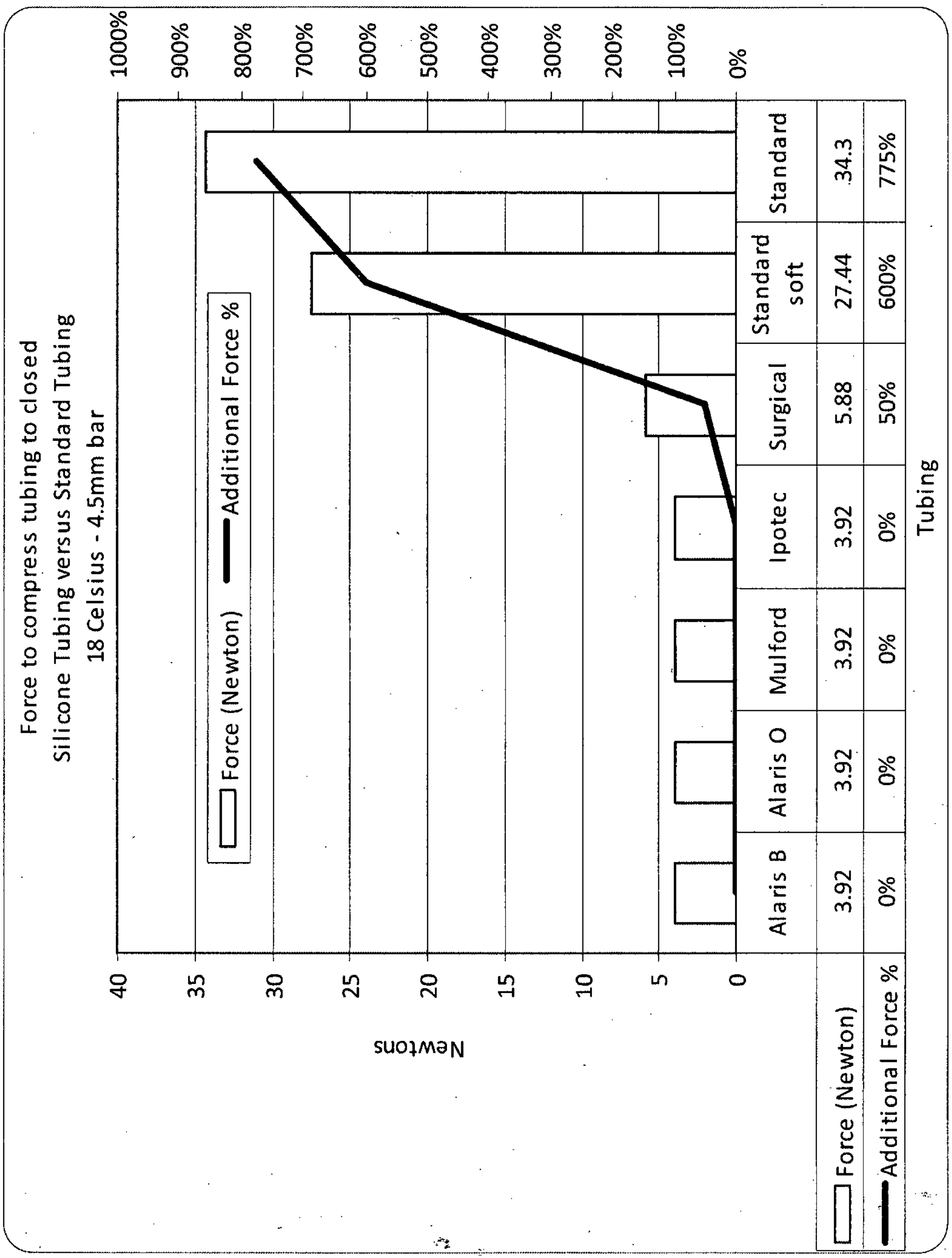


Figure 8



Force to compress tubing to closed
Silicone Tubing versus Standard Tubing
18 Celsius - 4.5mm bar
Force (Newton)
Additional Force %
Newtons
40
35
30
25
20
15
10
5
0
1000%
900%
800%
700%
600%
500%
400%
300%
200%
100%
0%
Alaris B
Alaris O
Mulford
Ipotec
Surgical
Standard soft
Standard
Force (Newton)
3.92
3.92
3.92
3.92
5.88
27.44
34.3
Additional Force %
0%
0%
0%
0%
50%
600%
775%
Tubing

Figure 9

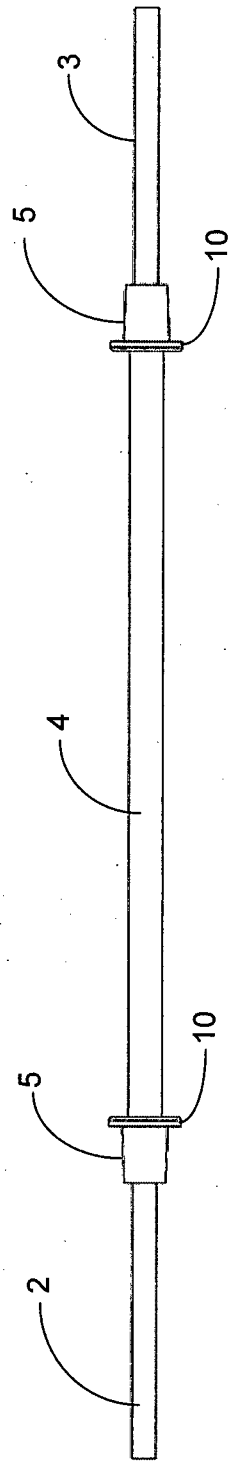


Figure 10

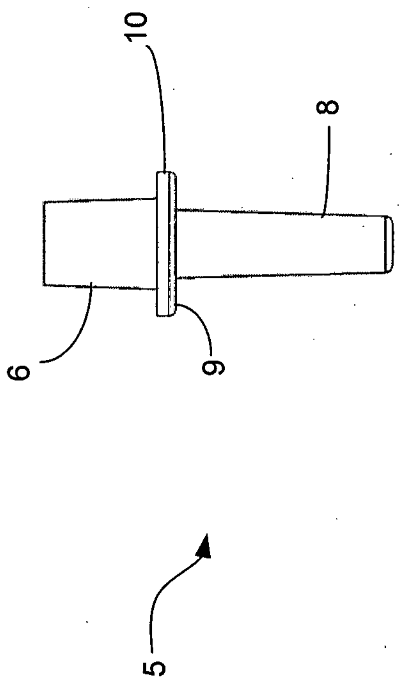


Figure 10A

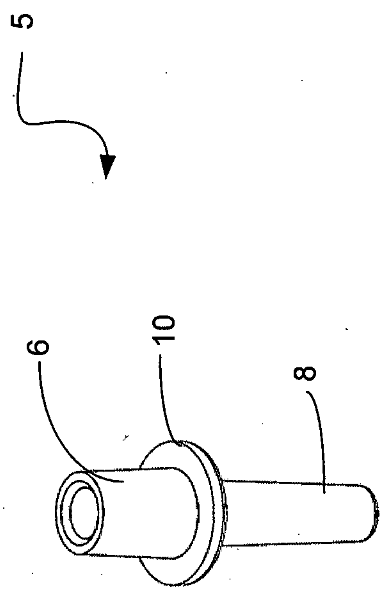


Figure 10B

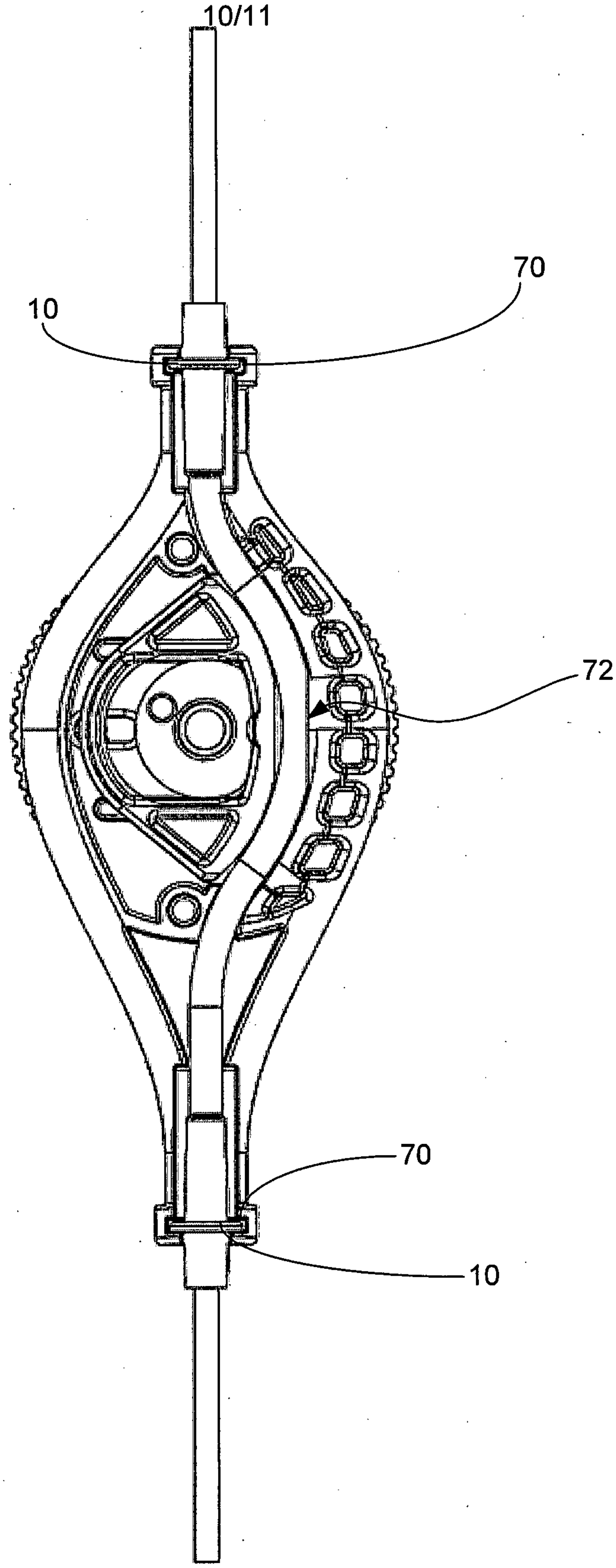


Figure 11

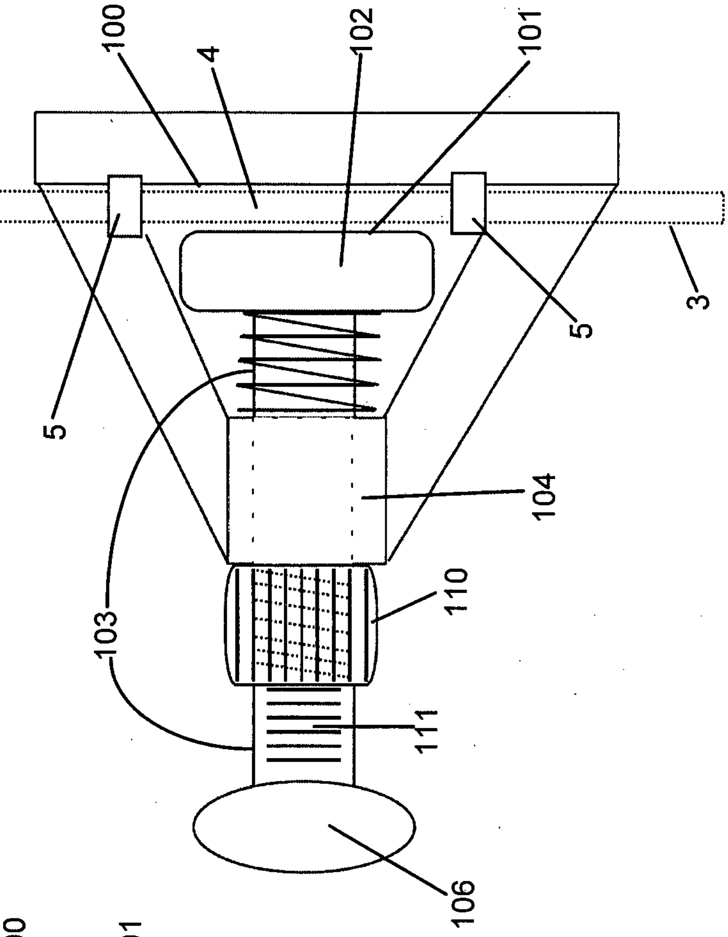


Figure 13

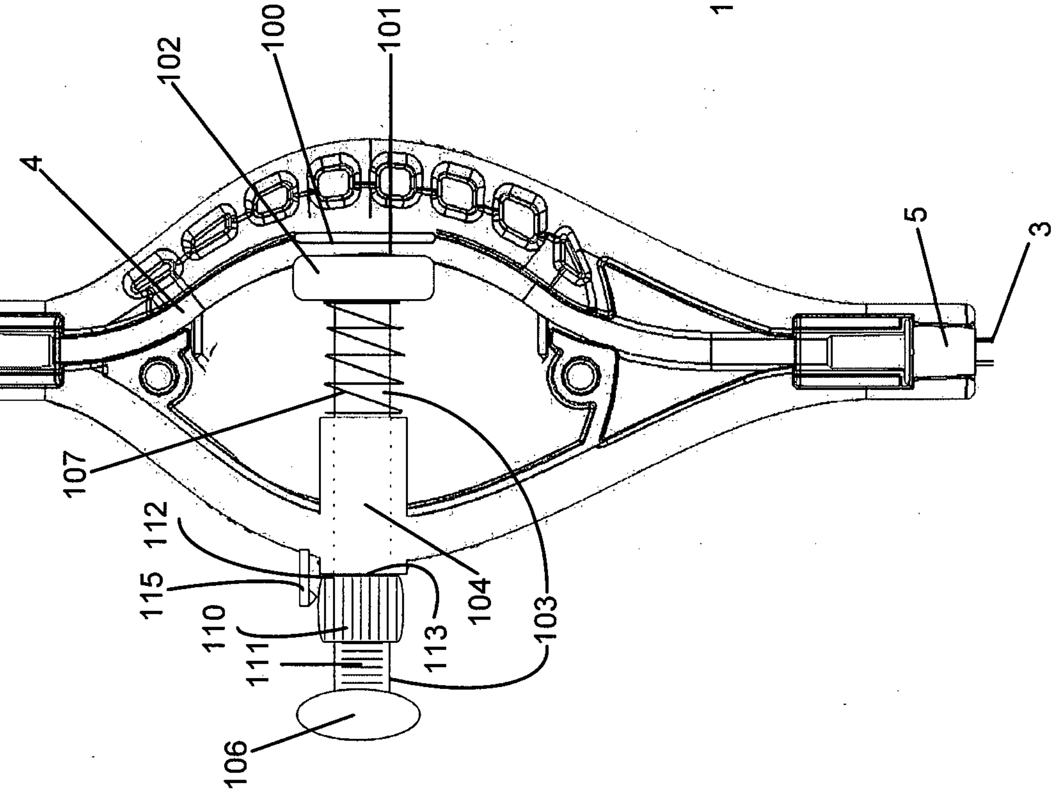


Figure 12

INTERNATIONAL SEARCH REPORT

International application No.
PCT/NZ2011/000063

A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl.

A61M 5/168 (2006.01) ***A61M 39/28*** (2006.01) ***F16K 7/06*** (2006.01)

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)

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)
EPODOC, WPI: IPC and EC A61M 5/-, A61M 39/-, F16K 7/- and Keywords: control, adjust, regulate, clamp, compress, deform, memory, elastomeric, rubber, silicone, conduit, tubing, bias, spring, flow controller, infusion; and like terms
ESP@CENET, PATENT LENS, GOOGLE PATENTS keywords: flow, control, elastomeric, clamp, compress, conduit, infusion, deform; and like terms

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
	WO 1981/002770 A1 (BAXTER TRAVENOL LABORATORIES, INC.) 1 October 1981	
X	Abstract; column 5, line 19-column 6, line 34; figures 1-4	1, 3, 4, 6-9, 19, 20, 22, 24, 25
Y		2, 5, 10-18, 21, 23
	WO 2008/079023 A1 (MONDIALE TECHNOLOGIES LIMITED) 3 July 2008	
Y	See entire document	2, 5, 10, 12, 13, 18, 21, 23

[X] Further documents are listed in the continuation of Box C [X] See patent family annex

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"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)

"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

"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

"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

"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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
29 July 2011	01.09.2011

Name and mailing address of the ISA/AU	Authorized officer
AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. +61 2 6283 7999	**A. ALI** AUSTRALIAN PATENT OFFICE (ISO 9001 Quality Certified Service) Telephone No : +61 2 6283 2607

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
	US 5154704 A (ARCHIBALD) 13 October 1992	
X	Figures 2, 3; column 3, line 25-column 5, line 7	26
	US 3384336 A (PULMAN) 21 May 1968	
X	Figures 1, 2; column 1, line 38-column 3, line 10	26
Y	Figures 1, 2; column 2, lines 35-55	14-16
	US 7001365 B2 (MAKKINK) 21 February 2006	
Y	Column 4, lines 14-20, lines 42-44	17
	US 3831600 A (YUM et al.) 27 August 1974	
Y	Figure 1; column 2, line 6-column 4, line 16	11
	GB 2328982 A (BAXTER INTERNATIONAL, INC.) 10 March 1999	
A	Abstract; Figures 1-7	
	US 3685787 A (ADELBERG) 22 August 1972	
A	Abstract; Figure 2	

INTERNATIONAL SEARCH REPORT	International application No. PCT/NZ2011/000063

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
   because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
   because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
   because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

See Supplemental Box

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☒ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

Supplemental Box
(To be used when the space in any of Boxes I to IV is not sufficient)

Continuation of Box No: III

This International Application does not comply with the requirements of unity of invention because it does not relate to one invention or to a group of inventions so linked as to form a single general inventive concept.

This Authority has found that there are different inventions based on the following features that separate the claims into distinct groups:

- Claims 1-25 are directed to a flow control system. The feature of at least part of the flow conduit in the compression region being formed from an elastomeric material is specific to this group of claims.
- Claim 26 is directed to a flow controller. The feature of a biasing device and an adjustment mechanism is specific to this claim.

PCT Rule 13.2, first sentence, states that unity of invention is only fulfilled when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features. PCT Rule 13.2, second sentence, defines a special technical feature as a feature which makes a contribution over the prior art.

When there is no special technical feature there is no unity of invention.

In the above groups of claims, the identified features may have the potential to make a contribution over the prior art but are not common to all the claims and therefore cannot provide the required technical relationship. The only feature common to all of the claims and which provides a technical relationship among them is a flow controller configured to receive a section of flow conduit including a clamp to compress the conduit in a compression region. However this feature does not make a contribution over the prior art because it is disclosed in:

WO 2008/079023 A1 (MONDIALE TECHNOLOGIES LIMITED) 3 July 2008 (see page 8, line 26; flow controller 1 and clamp 30 in the figures)

Therefore in the light of this document this common feature cannot be a special technical feature. Therefore there is no special technical feature present in the claims and the requirements for unity of invention are consequently not satisfied *a posteriori*.

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member					
WO	2008/079023	AU	2007338948	CA	2673517	CN	101687076
		EP	2101846	JP	2010512941	NZ	552376
		US	2010114041				
WO	1981/002770	BE	888098	CA	1145315	EP	0048268
		US	4406440				
US	5154704	NONE					
US	3384336	DE	1425693	GB	977818		
US	3831600	AU	70650/74	BE	817673	CH	582387
		DE	2431805	FR	2278026	GB	1416856
		NL	7409012				
US	7001365	AP	1582	AU	63532/01	BG	107401
		BR	0111105	CA	2410635	CN	1434731
		CZ	20023628	EP	1286711	HR	20021016
		HU	0302236	JP	2003534059	MA	26050
		MX	PA02011599	NO	20025616	NZ	523225
		PL	360883	SK	18302002	US	2003163112
		WO	0189608	ZA	200004569		
GB	2328982	BR	9806161	CA	2269842	EP	0935709
		JP	2000508406	WO	9911932		
US	3685787	BE	888889	CA	926371	CH	535915
		DE	2043551	ES	383303	FR	2061049
		GB	1319090	IL	35241	NL	7013172

Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.

END OF ANNEX