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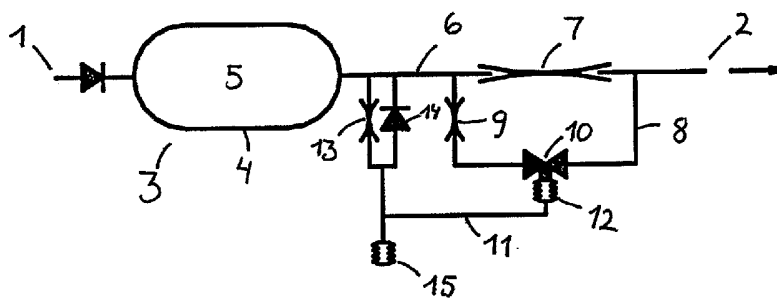
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(54) Title: A PUMPING SYSTEM AND A METHOD FOR CONTROLLING A FLUID FLOW IN A PUMPING SYSTEM



(57) Abstract: A pumping system for providing a steady flow rate as well as a bolus flow rate when needed. The bolus function is controlled in a self-regulating and simple manner. A fluid reservoir in fluid contact with a pump causes a valve in a bolus flow path to be closed when the reservoir is full and open when the reservoir is empty. The bolus function is activated by emptying the reservoir, and the open time of the valve is controlled by the fluid flow to the reservoir. May also comprise a similar system for providing a flush function to the pumping system. May comprise a preventing function for preventing activation of the bolus function during a specific time interval following a previous activation. Comprises a valve preventing that the reservoir is emptied during the time interval.

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A PUMPING SYSTEM AND A METHOD FOR CONTROLLING A FLUID FLOW IN A PUMPING SYSTEM

FIELD OF THE INVENTION

The present invention relates to a pumping system for pumping fluid. More particularly, the present invention relates to a pumping system which is
5 capable of providing various flow rates, such as a 'basal flow rate' and a 'bolus flow rate' being larger than the 'basal flow rate'.

The system of the present invention is particularly suited for being inserted into an infusion system, such as an implantable infusion system, e.g. for
10 providing insulin for diabetes patients. It is also well suited for providing fluid to an analysis probe.

BACKGROUND OF THE INVENTION

EP 0 039 124 A1 discloses an implantable infusion apparatus having a first flow path establishing a fluid connection between a reservoir and a
15 fluid outlet. It further comprises a second flow path having a valve inserted therein and establishing a fluid connection between the reservoir and the fluid outlet when the valve is in an open position. The first flow path provides a steady fluid flow ('basal flow rate') while the second flow path provides an additional fluid flow when needed ('bolus flow rate'). A fluid
20 chamber is positioned in fluid connection with the second flow path.

Opening and closing of the valve is controlled by an electrical controller which is connected to a switch button which may be manually activated.

During normal operation the valve is closed. Fluid is pumped from the reservoir to the fluid outlet via the first flow path. Fluid is also pumped via
25 the second flow path from the reservoir to the fluid chamber which is

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thereby filled. However, the fluid is prevented from reaching the fluid outlet via the second flow path due to the closed valve.

When a bolus infusion is desired, the switch button is activated causing the valve to open. The pressure built up in the fluid chamber in return
5 presses fluid collected in the fluid chamber towards the fluid outlet via the second flow path. The valve closes after a predetermined time.

It is a disadvantage of the infusion apparatus of EP 0 039 124 A1 that the valve needs to be controlled by an electrical controller in order to ensure a correct bolus infusion, since correct functioning of an electrical controller
10 requires correctly functioning electronics and power supply. Thus, in case any of these fails, the bolus infusion can not be delivered correctly. Furthermore, it is desirable to make the controlling of the bolus infusion more simple.

SUMMARY OF THE INVENTION

15 It is an object of the present invention to provide a pumping system capable of providing a 'basal flow rate' as well as a 'bolus flow rate', and wherein the provision of the 'bolus flow rate' is controlled in a simple and self-regulating manner.

It is a further object of the present invention to provide a pumping system
20 as defined above, wherein the 'bolus flow rate' is controlled without the need for external or internal electronical control system.

According to a first aspect of the present invention, the above and other objects are fulfilled by providing a pumping system comprising:

- a fluid inlet and a fluid outlet,

- a pump positioned at or near the fluid inlet,
- a first flow path having a first flow restrictor with a first flow restriction inserted therein, said first flow path establishing a fluid connection between the pump and the fluid outlet,
- 5 – a second flow path having a first valve inserted therein, said second flow path establishing a fluid connection between the pump and the fluid outlet when said first valve is in an open position,
- a third flow path establishing a fluid connection between the pump and a first fluid reservoir, said first fluid reservoir causing the first valve to be in a closed position when the first fluid reservoir is full and in an open position when the first fluid reservoir is empty, and
- 10 – first switching means being adapted to cooperate with the third flow path in controlling the amount of fluid in the first fluid reservoir, thereby controlling the first valve.

15 According to a second aspect of the present invention, the above and other objects are fulfilled by providing a method for controlling a fluid flow in a pumping system, the pumping system comprising a fluid inlet, a fluid outlet, a pump, and a flow path having a valve inserted therein and establishing a fluid connection between the pump and the fluid outlet when

20 the valve is in an open position, the method comprising the steps of:

1. leading fluid from the pump to a fluid reservoir, thereby filling the fluid reservoir,
 2. switching the valve to a closed position when the fluid reservoir is full, thereby preventing fluid from passing from the pump to the fluid outlet via the flow path,
- 25

3. emptying the fluid reservoir in response to a control signal,
4. switching the valve to an open position when the fluid reservoir is empty, thereby allowing fluid to pass from the pump to the fluid outlet via the flow path, and
5. repeating steps 1-4.

It will be clear to a skilled person that elements described in connection with the first aspect of the invention may also be combined with the second aspect of the invention, and vice versa.

In the present context the term 'fluid' should be interpreted as either a liquid or a gas. It may be a drug to be delivered to a patient, e.g. insulin to a person suffering from diabetes, in which case the pumping system of the present invention preferably forms part of an infusion apparatus for continuously providing the drug to the patient. Alternatively, the fluid may be a gas or a liquid which needs to be analysed by an analysis probe. In this case the pumping system of the present invention leads the fluid to the analysis probe. The fluid outlet may, thus, be connected to a catheter for insertion into a patient, or it may be connected to an analysis apparatus or probe.

The first flow restrictor preferably has the property of providing a specific desired flow rate for each pressure difference between its upstream and downstream sides. Thus, a given flow restrictor inserted into the first flow path will ensure a specific corresponding flow rate through the first flow path. This may be achieved by a piece of capillary tube, e.g. made from glass. By choosing a capillary tube of a suitable length and inner diameter, the desired flow parameters may easily be obtained. This also applies to any of the other flow restrictors mentioned below.

The first valve may, e.g., be a pinch valve or a valve of the type comprising a diaphragm which closes against a seat.

During normal operation the first valve is in a closed position, and the pumping system will provide fluid to the fluid outlet via the first flow path only. When a bolus flow is desired, the first switching means is activated causing the first fluid reservoir to be emptied, which in turn causes the first valve to switch to an open position, thereby allowing fluid to pass through the second flow path. This will increase the overall flow rate of the pumping system, thereby providing more fluid to the fluid outlet. As the first fluid reservoir is refilled the first valve will again be switched to a closed position, thereby again preventing fluid from flowing through the second flow path.

Since the first fluid reservoir is in fluid contact with the pump it will automatically be filled during operation. The first valve is therefore controlled in a self-regulating manner and without the need for external or internal electrical control systems. This is a great advantage because the controlling of the first valve is thereby very simple.

In a preferred embodiment the first reservoir is positioned adjacent to the first valve. Thus, when the first reservoir is full, it will press onto the first valve which is thereby closed. On the other hand, when the first reservoir is empty, it will not press onto the first valve which will therefore be open. It should be understood that there will normally be a level of fluid in the first reservoir between 'completely full' and 'completely empty', where the position of the first valve will shift from open to closed or vice versa.

The second flow path may further have a second flow restrictor with a second flow restriction inserted therein. The second flow restrictor controls the flow rate through the second flow path when the first valve is in an open position.

The second flow restriction is preferably smaller than the first flow restriction. In this case the flow rate through the second flow path will be larger than the flow rate through the first flow path when the first valve is in an open position. Thus, the overall flow rate of the pumping system will be on a stable, relatively low level during normal operation when the first valve is in a closed position, and will increase to a higher level when the first valve is switched to an open position.

In one embodiment of the present invention the first fluid reservoir may comprise a bellow which is in fluid connection with the third flow path, so that the bellow is being filled with fluid via the third flow path, thereby causing the first valve to be closed, and wherein the bellow is operatively connected to the first switching means in such a way that activation of the first switching means causes the bellow to be emptied, thereby causing the first valve to be opened. The bellow may form part of a bellow arrangement where the bellow is positioned in a chamber containing a compressible fluid. When the bellow is being filled, the compressible fluid is compressed. When the first switching means is subsequently operated in order to allow passage of fluid via the second flow path, the compressed fluid in the chamber will press fluid out of the bellow and into the second flow path, thereby emptying the bellow, and consequently switching the first valve to an open position.

Alternatively, the first fluid reservoir may comprise a cylinder and a piston for pressing fluid out of the cylinder, or it may comprise a cavity and a diaphragm for pressing the fluid out of the cavity.

The first switching means may be mechanical, such as means for squeezing the reservoir, thereby pressing the fluid out of the reservoir, or a bellow arrangement as described above. Alternatively, the switching

means may be electrical, magnetic, or any other suitable kind of switching means.

The pump may comprise a container adapted to contain a fluid and means for pressing the fluid out of the container and into the first flow path. The
5 fluid is provided to the container from the fluid inlet.

The container may have walls which are made from an elastomeric material, and the pressing means may in this case be adapted to compress the walls of the container in order to press the fluid out of the container. The pressing means may be very simple mechanical means, or
10 it may be electrical, magnetic or any other suitable kind of means.

Alternatively, the pump may comprise a compressible bellow positioned within the container, in which case the pressing means may be adapted to compress the bellow in order to press the fluid out of the container. This may be a bellow arrangement as the one described above.

15 In any of the embodiments described above, the pressing means may comprise a spring for compressing the container walls or the bellow.

Alternatively, the pump may be any other suitable kind of pump, such as a pump comprising a compressed fluid for providing the drive pressure.

The third flow path may comprise a third flow restrictor having a third flow
20 restriction. The third flow restrictor may control the amount of time used for filling the first fluid reservoir. Thus, if the third flow restriction is relatively large, the first fluid reservoir will fill relatively slowly, and if the third flow restriction is relatively small, the first fluid reservoir will fill relatively quickly. However, the third flow restriction should be chosen relatively to the first
25 flow restriction, and optionally the second flow restriction, in such a way that fluid will be led to the first fluid reservoir when the first valve is in an

open position. Thereby it is ensured that the first fluid reservoir is refilled, thereby ensuring that the first valve is switched to a closed position after a certain time has elapsed.

5 The third flow path may comprise a check valve for allowing fluid from the first fluid reservoir to enter the first flow path via the third flow path. In this case, when first fluid reservoir is emptied, the fluid contained therein will pass via the third flow path and through the check valve into the first flow path or back into the pump. Furthermore, the check valve prevents fluid from flowing in the opposite direction. In a preferred embodiment the
10 check valve is positioned in parallel to a third flow restrictor. In this case fluid will flow from the pump via the third flow restrictor and the third flow path to the first fluid reservoir while filling the first fluid reservoir. When the first fluid reservoir is subsequently emptied, the fluid from the first fluid reservoir will pass through the check valve rather than through the third
15 flow restrictor, since the flow restriction in the third flow restrictor will typically be substantially larger than in the check valve. Thereby the first fluid reservoir is emptied much faster than it is filled.

The pumping system may further comprise one or more additional flow paths being adapted to provide a flush function to the pumping system. In
20 some cases the first flow restriction is so large that it will take a relatively long time to obtain a full throughput through the first flow path. In such cases it may be advantageous to provide a quick flush function in order to obtain a full throughput shortly after the pumping system has been turned on.

- 25 In one embodiment the one or more additional flow paths comprises:
- a fourth flow path having a second valve inserted therein, said fourth flow path establishing a fluid connection between the pump and the fluid outlet when the second valve is in an open position,

- a fifth flow path establishing a fluid connection between the pump and a second fluid reservoir, said second fluid reservoir causing the second valve to be in a closed position when the second fluid reservoir is full and in an open position when the second fluid reservoir is empty, and
- second switching means being adapted to cooperate with the fifth flow path in controlling the amount of fluid in the second fluid reservoir, thereby controlling the second valve.

Thus, the additional flow paths may constitute a system which is more or less identical to the system providing the bolus function, except for the chosen flow restrictors. Thus, the remarks set forth above are equally applicable here.

The pumping system may further comprise means for preventing opening of the first valve during a predetermined time interval following a previous opening of the first valve. In some cases it is desirable to be able to prevent that bolus flows are provided at too close time intervals. For instance, in case the pumping system forms part of an infusion system for delivering insulin to a diabetes patient, the patient needs a steady dose of insulin constantly, and on top of that a bolus dose around a meal time. The patient may, therefore, manually activate the switching means in connection with the consumption of a meal. However, if the patient accidentally activates the switching means twice within a short time interval, e.g. because the patient forgets that he/she has already activated the switching means and therefore erroneously activates it again, it should be prevented that the additional bolus dose is delivered, because taking too much insulin may lead to hyperglycemia, a condition which should preferably be avoided. It is therefore desirable to be able to prevent that a bolus dose is provided shortly after the previous bolus dose was provided.

The preventing means may comprise

- a third valve inserted into the third flow path, the third valve preventing fluid from the third flow path from entering the first flow path when the third valve is in a closed position, and
- 5 – means for controlling the third valve.

Thus, when the third valve is in a closed position, it is not possible to empty the first fluid reservoir, because the fluid contained therein is prevented from flowing via the third flow path into the first flow path. As long as the first fluid reservoir can not be emptied, the first valve will
10 remain in a closed position, thereby preventing a bolus dose from being delivered to the fluid outlet. Thus, the third valve should be controlled to be in a closed position for a suitable time following the delivery of a bolus dose. As soon as it is again considered suitable or safe to deliver a new bolus dose, the third valve can be switched to an open position, thereby
15 allowing the first fluid reservoir to be emptied upon activation of the first switching means.

The means for controlling the third valve may comprise a third fluid reservoir which is in fluid connection with the first fluid reservoir, the third fluid reservoir thereby receiving fluid when the first fluid reservoir is
20 emptied. In this case the third fluid reservoir is adapted to cause the third valve to be in a closed position when the third fluid reservoir is full and in an open position when the third fluid reservoir is empty. In this embodiment the third valve is automatically switched to a closed position when the first fluid reservoir is emptied.

25 As mentioned above, the pumping system of the present invention may advantageously form part of an infusion system, preferably an implantable infusion system. Alternatively, it may form part of an analysis system.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will now be described with reference to the accompanying drawing in which

Fig. 1 shows a pumping system with a bolus function,

- 5 Fig. 2 shows a pumping system with a bolus function and a flush function, and

Fig. 3 shows a pumping system with a bolus function, a flush function and a preventing function.

DETAILED DESCRIPTION OF THE DRAWINGS

- 10 Fig. 1 shows a pumping system according to the present invention. The pumping system comprises a fluid inlet 1, a fluid outlet 2, and a pump 3. The pump 3 comprises compressible walls 4 made from an elastomeric material and defining a container 5 adapted to contain a fluid to be pumped by the pumping system. A first flow path 6 connects the pump 3
15 and the fluid outlet 2 via a first flow restrictor 7. The pumping system further comprises a second flow path 8 having a second flow restrictor 9 and a first valve 10 inserted therein. When the first valve 10 is in an open position, the second flow path 8 establishes a fluid connection between the pump 3 and the fluid outlet 2. The second flow path 8 is positioned in
20 parallel to the part of the first flow path 6 having the first flow restrictor 7 inserted therein. If the flow restriction of the second flow restrictor 9 is smaller than the flow restriction of the first flow restrictor 7, a fluid will prefer the second flow path 8 to the first flow path 6 when the first valve 10 is on an open position, and the resulting fluid flow to the fluid outlet 2 will
25 accordingly increase when the first valve 10 is opened.

The first valve 10 is operated by means of a third flow path 11 having a first fluid reservoir 12 inserted therein. The first fluid reservoir 12 is positioned adjacent to the first valve 10. Thus, when the first fluid reservoir 12 is full it presses against the first valve 10, thereby closing it. On the other hand, when the first fluid reservoir 12 is empty, it does not press against the first valve 10, which is consequently open.

The third flow path 11 further has a third flow restrictor 13 and a first check valve 14 positioned in parallel to each other, and each connecting the third flow path 11 to the first flow path 6. Thus, fluid may enter the third flow path 11 via the third flow restrictor 13, and it may leave the third flow path 11 via the first check valve 14.

The pumping system of Fig. 1 is preferably operated in the following manner.

During normal operation the first fluid reservoir 12 is full and the first valve 10 is in a closed position. Consequently, fluid is pumped from the pump 3 to the fluid outlet 2 via the first flow path 6. When a bolus dose is desired, a first switching means 15 is activated which causes the first fluid reservoir 12 to be emptied, thereby switching the first valve 10 to an open position. The fluid from the first fluid reservoir 12 enters the first flow path 6 via the third flow path 11 and the first check valve 14. Thus, fluid is now pumped from the pump 3 to the fluid outlet 2 via the second flow path 8 as well as via the first flow path 6, thereby increasing the total fluid flow to the fluid outlet 2. Simultaneously, fluid is pumped via the third flow path 11 and the third flow restrictor 13 to the first fluid reservoir 12, thereby refilling the first fluid reservoir 12. When the first fluid reservoir 12 is full it once again presses against the first valve 10, thereby switching the first valve 10 to a closed position. Fluid is thereby again prevented from reaching the fluid

outlet 2 via the second flow path 8, and the system has, thus, returned to normal operation.

Fig. 2 shows a pumping system like the one shown in Fig. 1, and the corresponding parts have been provided with the same reference
5 numerals. The pumping system of Fig. 2 is further provided with a flush function for quickly flushing the system.

The flush function is provided by a system of flow paths which is identical to the system of flow paths shown in Fig. 1 and providing the bolus function. Thus, the pumping system of Fig. 2 further comprises a fourth
10 flow path 16 having a second valve 17 and a fourth flow restrictor 18 inserted therein. When the second valve 17 is in an open position, the fourth flow path 16 establishes a fluid connection between the pump 3 and the fluid outlet 2. The pumping system of Fig. 2 also comprises a fifth flow path 19 having a second fluid reservoir 20 inserted therein. The fifth flow
15 path 19 also has a fifth flow restrictor 21 and a second check valve 22 positioned in parallel to each other, and each establishing a fluid connection between the first flow path 6 and the fifth flow path 21. Finally, the pumping system comprises a second switching means 23 adapted to cause the second fluid reservoir 20 to be emptied upon activation.

20 The fifth flow path 19, the second fluid reservoir 20 and the second switching means 23 cooperate in operating the second valve 17 in the same way as the third flow path 11, the first fluid reservoir 12 and the first switching means 15 cooperate in operating the first valve 10.

Thus, the flush function of the pumping system of Fig. 2 is preferably
25 operated in the following manner.

During normal operation the second fluid reservoir 20 is full and the second valve 20 is in a closed position, thereby preventing fluid from

reaching the fluid outlet 2 via the fourth flow path 19. When a flush function is desired, the second switching means 23 is activated. This has the effect that the second fluid reservoir 20 is emptied, thereby causing the second valve 17 to be switched to an open position. The fluid from the second fluid reservoir 20 enters the first flow path 6 via the fifth flow path 19 and the second check valve 22. Thus, fluid is allowed to reach the fluid outlet 2 via the fourth flow path 16 as well as via the first flow path 6, thereby increasing the total fluid flow to the fluid outlet 2.

A flush function will typically be desirable during a start-up process where it is advantageous that the possible tubing of the system is filled with the liquid relatively fast. This is particularly useful when the pumping system forms part of an infusion apparatus for delivering a drug to a patient.

By choosing flow restrictors 7, 18 with a right flow restriction it is possible to provide a quick flush of the system. Thus, if the flow restriction of the fourth flow restrictor 18 is substantially lower than the flow restriction of the first flow restrictor 7, the fluid will prefer to go towards the fluid outlet 2 via the fourth flow path 16 rather than via the first flow path 6 when the second valve 17 is in an open position. Furthermore, the fluid flow to fluid outlet 2 is relatively large if only the flow restriction of the fourth flow restrictor 18 is chosen to be sufficiently low. Thereby the pumping system is flushed when the second valve 17 is switched to an open position.

Fig. 3 shows a pumping system like the one shown in Fig. 2, and corresponding parts have been provided with the same reference numerals. The pumping system of Fig. 3 further comprises a preventing function for preventing that a bolus dose is delivered within a specific time interval following a previous bolus dose.

The preventing function is provided by a system of flow paths inserted in connection with the third flow path 11. Thus, the pumping system of Fig. 3

further comprises a third valve 24 inserted in the third flow path 11 in series with the first check valve 14 and in parallel with the third flow restrictor 13. When the third valve 24 is in an open position, fluid is allowed to flow from the first fluid reservoir 12, via the third flow path 11, the third valve 24 and the second check valve 14 and into the first flow path 6. When the third valve 24 is in a closed position, such a flow is prevented. Therefore, the first fluid reservoir 15 can not be emptied when the third valve 24 is in a closed position, and it is therefore not possible to open the first valve 10 and provide a bolus dose as long as the third valve 24 is in a closed position.

The third valve 24 is controlled by means of a fluid chamber 25 positioned adjacent to the third valve 24. The fluid chamber 25 is of a kind which will attempt to push any fluid which is in the fluid chamber 25 out of the fluid chamber 25. The fluid chamber 25 acts on the third valve 24 in such a way that when the fluid chamber 25 is full it causes the third valve 24 to be in a closed position, and when the fluid chamber 25 is empty it causes the third valve 24 to be in an open position. The fluid chamber 25 is in fluid connection with the third flow path 11 via a sixth flow restrictor 26 and a third check valve 27 arranged in parallel to each other. The third check valve 27 allows fluid to pass from the fluid chamber 25 to the third flow path 11, while fluid passing from the third flow path 11 to the fluid chamber 25 must pass via the sixth flow restrictor 26.

The preventing function of Fig. 3 is preferably operated in the following manner.

When a bolus dose is desired and the first fluid reservoir 12 is therefore emptied in order to switch the first valve 10 to an open position, some of the fluid contained in the first fluid reservoir 12 enters the fluid chamber 25 via the sixth flow restrictor 26. This causes the third valve 24 to be

switched to a closed position, thereby preventing further fluid from the first fluid reservoir 12 from leaving the first fluid reservoir 12, which in turn prevents a new bolus dose from being provided. Since the fluid chamber 25 is now full, it will attempt to push the fluid out of the fluid chamber 25 as
5 described above. The fluid from the fluid chamber 25 enters the third flow path 11 via the third check valve 27. After a while the fluid chamber 25 is again empty, and the third valve 24 will accordingly be switched to an open position. Thus, it will again be possible to activate the bolus function. However, the bolus function has been prevented from being activated for
10 as long as it takes to empty the fluid chamber 25.

CLAIMS

1. A pumping system comprising:

- a fluid inlet and a fluid outlet,
- a pump positioned at or near the fluid inlet,
- 5 – a first flow path having a first flow restrictor with a first flow restriction inserted therein, said first flow path establishing a fluid connection between the pump and the fluid outlet,
- 10 – a second flow path having a first valve inserted therein, said second flow path establishing a fluid connection between the pump and the fluid outlet when said first valve is in an open position,
- 15 – a third flow path establishing a fluid connection between the pump and a first fluid reservoir, said first fluid reservoir causing the first valve to be in a closed position when the first fluid reservoir is full and in an open position when the first fluid reservoir is empty, and
- 20 – first switching means being adapted to cooperate with the third flow path in controlling the amount of fluid in the first fluid reservoir, thereby controlling the first valve.

2. A pumping system according to claim 1, wherein the first reservoir is positioned adjacent to the first valve.

20 3. A pumping system according to claim 1 or 2, wherein the second flow path further has a second flow restrictor with a second flow restriction inserted therein.

4. A pumping system according to claim 3, wherein the second flow restriction is smaller than the first flow restriction.
5. A pumping system according to any of the preceding claims, wherein the first fluid reservoir comprises a bellow which is in fluid connection with the third flow path, so that the bellow is being filled with fluid via the third flow path, thereby causing the first valve to be closed, and wherein the bellow is operatively connected to the first switching means in such a way that activation of the first switching means causes the bellow to be emptied, thereby causing the first valve to be opened.
- 10 6. A pumping system according to any of the preceding claims, wherein the first switching means is mechanical.
7. A pumping system according to any of the preceding claims, wherein the pump comprises a container adapted to contain a fluid and means for pressing the fluid out of the container and into the first flow path.
- 15 8. A pumping system according to claim 7, wherein the container has walls which are made from an elastomeric material, and wherein the pressing means is adapted to compress the walls of the container in order to press the fluid out of the container.
9. A pumping system according to claim 7, wherein the pump comprises a compressible bellow positioned within the container, and wherein the pressing means is adapted to compress the bellow in order to press the fluid out of the container.
- 20 10. A pumping system according to any of claims 7-9, wherein the pressing means comprises a spring.

11. A pumping system according to any of the preceding claims, wherein the third flow path comprises a third flow restrictor having a third flow restriction.

12. A pumping system according to any of the preceding claims, wherein
5 the third flow path comprises a check valve for allowing fluid from the first fluid reservoir to enter the first flow path via the third flow path.

13. A pumping system according to any of the preceding claims, further comprising one or more additional flow paths being adapted to provide a flush function to the pumping system.

10 14. A pumping system according to claim 13, wherein the one or more additional flow paths comprises:

- a fourth flow path having a second valve inserted therein, said fourth flow path establishing a fluid connection between the pump and the fluid outlet when the second valve is in an open position,
- 15 – a fifth flow path establishing a fluid connection between the pump and a second fluid reservoir, said second fluid reservoir causing the second valve to be in a closed position when the second fluid reservoir is full and in an open position when the second fluid reservoir is empty, and
- 20 – second switching means being adapted to cooperate with the fifth flow path in controlling the amount of fluid in the second fluid reservoir, thereby controlling the second valve.

15. A pumping system according to claim 14, wherein the second fluid reservoir is positioned adjacent to the second valve.

16. A pumping system according to any of the preceding claims, further comprising means for preventing opening of the first valve during a predetermined time interval following a previous opening of the first valve.

17. A pumping system according to claim 16, wherein the preventing means comprises
- a third valve inserted into the third flow path, the third valve preventing fluid from the third flow path from entering the first flow path when the third valve is in a closed position, and
 - means for controlling the third valve.

18. A pumping system according to claim 17, wherein the means for controlling the third valve comprises a third fluid reservoir which is in fluid connection with the first fluid reservoir, the third fluid reservoir thereby receiving fluid when the first fluid reservoir is emptied, and wherein the third fluid reservoir is adapted to cause the third valve to be in a closed position when the third fluid reservoir is full and in an open position when the third fluid reservoir is empty.

19. An infusion system comprising a pumping system according to any of the preceding claims.

20. An infusion system according to claim 19, said infusion system being implantable.

21. An analysis system comprising a pumping system according to any of claims 1-18.

22. A method for controlling a fluid flow in a pumping system, the pumping system comprising a fluid inlet, a fluid outlet, a pump, and a flow path

having a valve inserted therein and establishing a fluid connection between the pump and the fluid outlet when the valve is in an open position, the method comprising the steps of:

- 5 1. leading fluid from the pump to a fluid reservoir, thereby filling the fluid reservoir,
2. switching the valve to a closed position when the fluid reservoir is full, thereby preventing fluid from passing from the pump to the fluid outlet via the flow path,
3. emptying the fluid reservoir in response to a control signal,
- 10 4. switching the valve to an open position when the fluid reservoir is empty, thereby allowing fluid to pass from the pump to the fluid outlet via the flow path, and
5. repeating steps 1-4.

23. A method according to claim 22, further comprising the step of flushing
15 the pumping system prior to performing steps 1-5.

24. A method according to claim 22 or 23, further comprising the step of preventing performance of step 3 during a predetermined time interval following a previous performance of step 3.

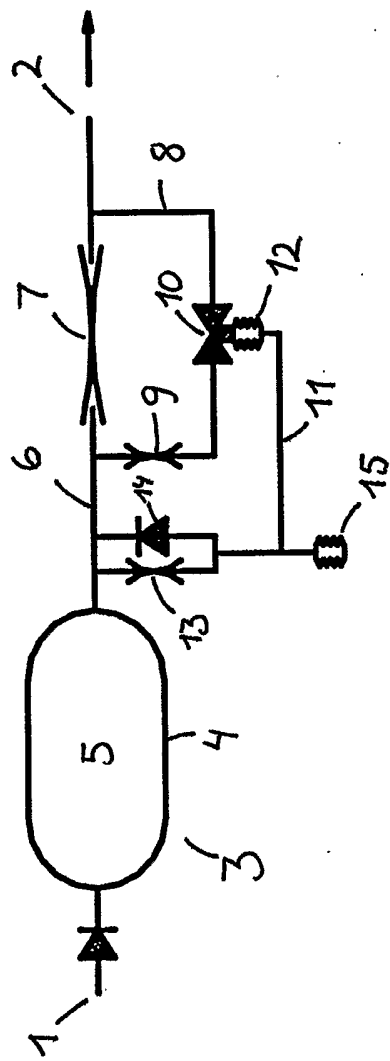


Fig. 1

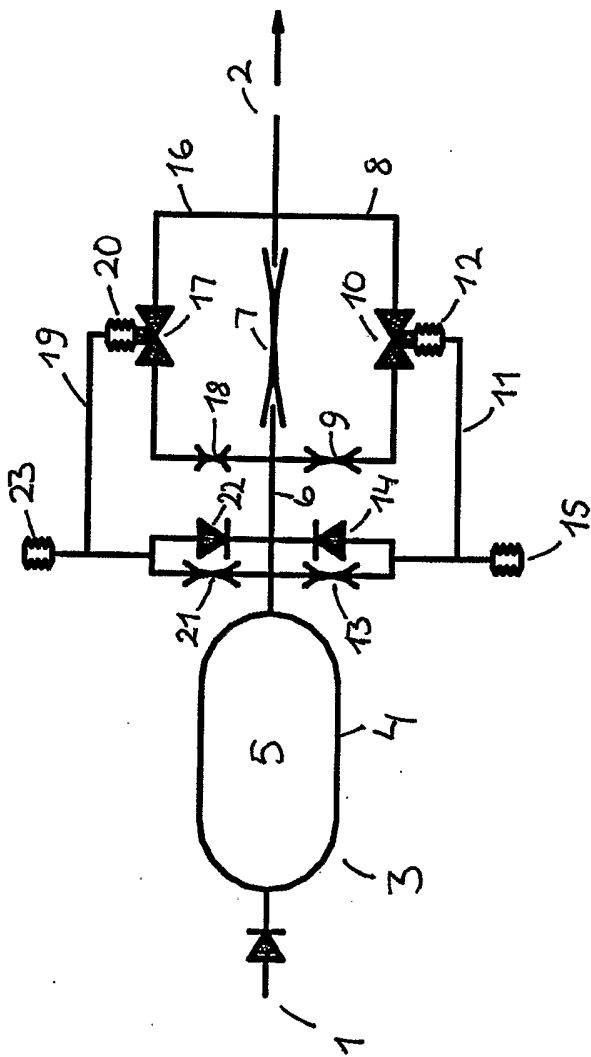


Fig. 2

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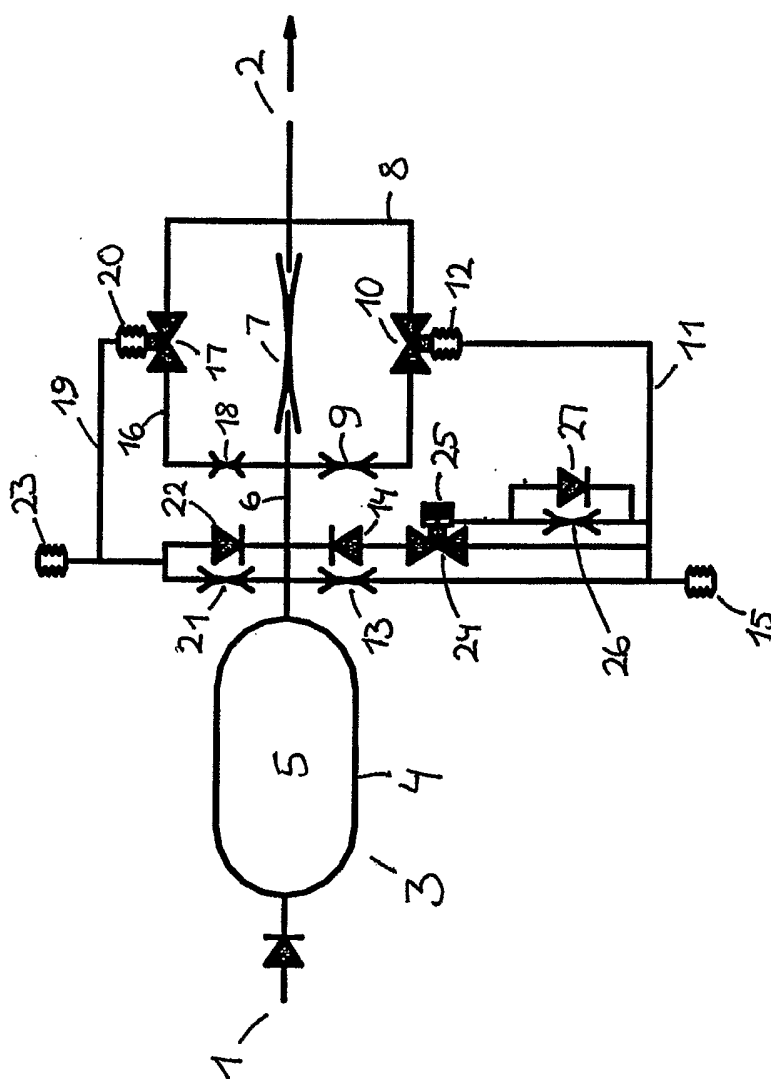


Fig. 3

INTERNATIONAL SEARCH REPORT

Internal Application No
PC/LK2005/000634

A. CLASSIFICATION OF SUBJECT MATTER
A61M5/142 F16K7/07 F16K31/126

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)
A61M F16K F04B

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 practical, search terms used)

EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0 039 124 A (INFUSAID CORPORATION) 4 November 1981 (1981-11-04) page 8, line 6 - page 13, line 28 -----	1-21
A	US 3 738 430 A (LIVINGSTON W,US) 12 June 1973 (1973-06-12) column 2, line 36 - column 4, line 18 -----	22-24
A	WO 03/068294 A (DANFOSS A/S; GRAVESEN, PETER; RASMUSSEN, PER, BRANDT; DIRAC, HOLGER) 21 August 2003 (2003-08-21) the whole document -----	1-24
A	US 6 283 944 B1 (MCMULLEN RAY ET AL) 4 September 2001 (2001-09-04) the whole document -----	1-24

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Date of the actual completion of the international search

8 December 2005

Date of mailing of the international search report

22/12/2005

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PC 1, UK/2005/000634

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
EP 0039124	A	04-11-1981	CA 1154345 A1	27-09-1983
			DE 3166247 D1	31-10-1984
			DK 104581 A	08-09-1981
			JP 56136562 A	24-10-1981
US 3738430	A	12-06-1973	NONE	
WO 03068294	A	21-08-2003	AU 2003208305 A1	04-09-2003
			CN 1642588 A	20-07-2005
			EP 1476209 A2	17-11-2004
			JP 2005517472 T	16-06-2005
			US 2005165384 A1	28-07-2005
US 6283944	B1	04-09-2001	DE 69918545 D1	12-08-2004
			DE 69918545 T2	28-07-2005
			EP 1075291 A1	14-02-2001
			WO 9956803 A1	11-11-1999