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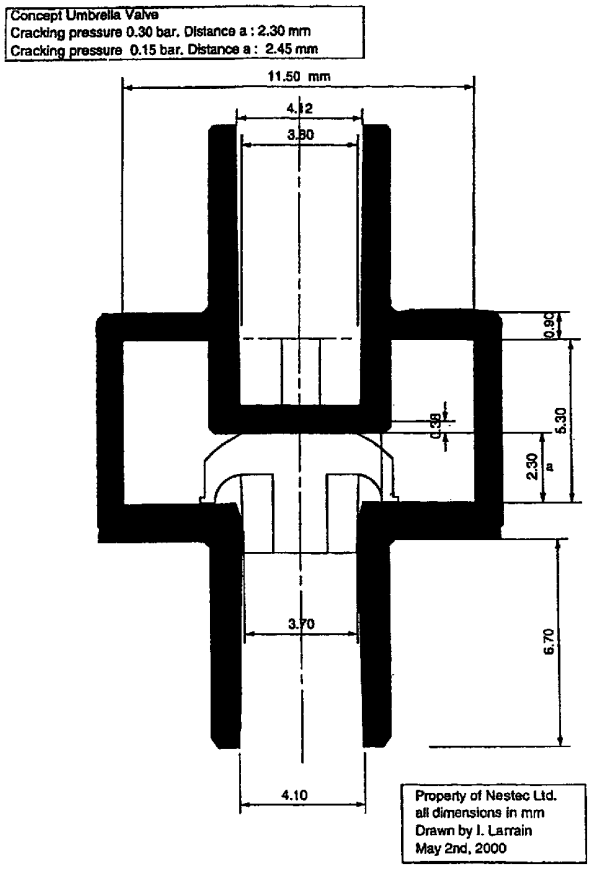
(54) Title: MEDIUM CRACKING PRESSURE VALVE ARRANGEMENT



(57) Abstract: A valve arrangement is described for providing clinical nutrition. The valve arrangement is suitable for use with a rotary peristaltic pump and is capable of allowing flow of fluid in a first direction and capable of preventing flow of fluid in a second direction, wherein the valve arrangement comprises a valve having a cracking pressure of about 0.10 to about 0.20 bar. Also described are a method of production of the valve arrangement, use of the valve arrangement in providing nutrition to a patient and a method of treatment of a patient that comprises administering an effective amount of a composition via the valve arrangement.

WO 02/00291 A1

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

Medium Cracking Pressure Valve Arrangement

The present invention relates to a valve arrangement for providing clinical nutrition, a flow set comprising the valve arrangement, a method of production of the valve arrangement, use of the valve arrangement in providing nutrition and a method of treatment of a patient that comprises administering an effective amount of a nutritional composition through the valve arrangement.

Within the context of this specification the word "comprises" is taken to mean "includes, among other things". It is not intended to be construed as "consists of only".

"Flow back" is taken to mean flow of fluid in a direction away from a patient.

"Free flow" is taken to mean flow of fluid which occurs passively by gravity, generally without the intervention of a mechanical device such as a pump. It is characterised by a state of inactive pump operation. Free flow can be very harmful to patients as it can lead to aspiration of fluid into lungs.

"Cracking Pressure" is taken to mean the threshold pressure at which flow is allowed to occur. If the pressure of fluid across a valve is below this threshold, flow is not permitted.

Hospital patients are routinely provided fluids for maintaining a good state of hydration. Furthermore, fluid can act as a carrier for nutrients in order to provide a patient with adequate nutrition, for example, following surgery.

Systems for administration of fluids to a patient are widely known. The manner of propelling the fluid to a patent may be by gravitation; by means of pressure applied on a deformable container; or by means of a pump. In pump- operated administration systems, the pump must be capable of administering the fluid in a controlled, generally continuous manner.

Pumps are employed to meet the need for a high degree of accuracy in the administration of fluids, to protect the patient and to maximise the effectiveness of medication.

An example of a pump presently used for pumping fluid along a tube to a patient is a rotary peristaltic pump. This type of pump suffers from the problem that if a flow set is not connected properly or disconnected from the pump, free-flow can occur. Furthermore, in general, this type of pump does not have antifree-flow protection. Uninhibited free flow of fluid to a patient can be dangerous for the patient - it can lead to drowning.

Another example of a pump presently used is a linear peristaltic pump. This type of pump suffers from the problem that if a flow set is not connected properly, it is subject to (pumped) back flow of liquid in a direction opposite to the intended direction of flow to a patient. It is clear that if free flow or back flow proceeds unchecked, it can be dangerous for a patient.

To cope with the problem of free flow, a piece of apparatus known as an occluder has been employed. This piece of medical apparatus operates by folding a length of resilient tubing, thereby pinching the tubing and causing its internal diameter to be reduced, thereby inhibiting flow through it. This arrangement works, but it has been found that it suffers from the problems that, if an elastic part of the occluder (for keeping a resilient tube folded) is over stretched, it can be broken easily. Therefore, if an operator disconnects the pump, but fails to close the tubing, for example with a roller clamp, free flow may occur.

Therefore, a need exists for an apparatus which permits a good flow of fluid to a patient, but which addresses the problems presented by uninhibited free flow and flow back.

The present invention addresses the problems set out above.

Remarkably, it has now been found that a valve having a critical narrow range of cracking pressure can prevent flow of fluid from a patient and restrict free flow in the opposite direction. This can provide a high level of safety for a patient. Suprisingly, it has been found that this can be achieved by reducing free flow to a level which is not dangerous. In contrast, previous attempts were made to eliminate free flow entirely. It has now been found that this is not necessary.

Consequently, in a first aspect, the present invention provides a valve arrangement which is suitable for use with a rotary peristaltic pump and which is capable of allowing flow of fluid in a first direction and capable of preventing flow of fluid in a second direction, wherein the valve arrangement comprises a valve having a cracking pressure of about 0.10 to about 0.20 bar.

In a second aspect the invention provides a flow set for the administration of at least one fluid to a patient which comprises a valve arrangement according to an embodiment of the invention; an inlet tube for connecting a container to an inlet port of the valve; and an outlet tube for connecting to an outlet of the valve for the delivery of a fluid to a patient.

In a third aspect the invention provides a method of production of the valve arrangement which comprises producing a chamber, making ports including an inlet port and an outlet port, fixing a one way valve between the inlet port and the outlet port for allowing fluid to flow in only one direction, wherein the cracking pressure of the valve is about 0.10 to 0.20 bar.

In a forth aspect the invention provides use of a valve arrangement according to an embodiment of the invention for providing nutrition to a patient.

In a fifth aspect the invention provides a method of treatment of a patient that comprises administering an effective amount of a fluid via a valve arrangement according to an embodiment of the invention.

A valve arrangement according to an embodiment of the invention provides the advantage of permitting simple and safe administration of a fluid from a container to a patient. If the pressure of fluid across the valve assembly exceeds a predetermined cracking pressure, flow is permitted, but unless the cracking pressure is exceeded, for example by a pump, flow of fluid is not permitted through the valve assembly. During normal use, the height of the container may be such so as to generate a static pressure that slightly exceeds the cracking pressure of the valve. If, in addition, the set has been disconnected from the pump,flow of fluid through the valve assembly is restricted – ie free flow is inhibited to a degree so that any leakage by the valve presents no risk for a patient. In contrast, known valve arrangements have suffered from the problem

that they have allowed a high flow rate of free flow to occur from a container to a patient if the set is misloaded or unloaded from the associated pump. .

Another advantage provided by the present invention is that the volume of programmed flow by the pump is not affected by the valve arrangement. This is a result of a reduction of impedance of the valve arrangement.

Another advantage of the present invention is that no disconnection of tubing, no manual adjustment of valves or use of other equipment for blocking flow is required. Therefore, the flow of fluid from the valve arrangement can be accurately controlled. Furthermore, in view of the fact that no disconnection of tubing is required during use, the risk of contamination is lowered.

In addition, no special software or mechanical modification of a known pump is required.

Yet another advantage of the present invention is that it provides an arrangement that is easy and inexpensive to make. A simple construction method can be carried out comprising a simple housing and piston or membrane and this increased simplicity adds to the speed at which production can be achieved. Furthermore, if a valve arrangement according to the invention is employed, fewer pieces of commercially available apparatus (such as a pinch-clip occluder or roller clamp) are required.

Furthermore, although a valve arrangement in accordance with the present invention is suitable for use with a rotary peristaltic pump, it is not limited to use with only this type of pump or any particular type of flow set. In contrast, known arrangements have been limited in this way.

Preferably, an embodiment of a valve arrangement according to the present invention includes a valve having a cracking pressure of about 0.12 bar to about 0.18 bar. Most preferably the cracking pressure is about 0.15 bar.

Remarkably, it has now been found that the specific cracking pressure of a valve according to an embodiment of the invention is critical. It is not merely a result of optimisation of known apparatus. Indeed, the specific cracking pressure could

not have been arrived at logically without first making an inventive step by realising that a cracking pressure could be important specifically in the administration of a fluid to a patient.

It has been found that these cracking pressures provide the advantage that, if a pump is disconnected from the valve arrangement fluid is not able to pass through the outlet valve to a patient (or only a small amount of fluid). Therefore, uncontrolled flow to a patient is prevented. It has also been found that these cracking pressures provide the advantage that they do not alter a pump's operation, as they are sufficiently low to avoid any slippage in a peristaltic mechanism.

Preferably, an embodiment of a valve arrangement according to the present invention includes a valve which comprises a flexible membrane which is deformable under pressure in a desired flow direction. The flexible membrane has perforations through it which open at a selected extent of deformation of the flexible membrane to permit flow. The valve assembly may be provided with a support associated with the flexible membrane for preventing the flexible membrane from deforming sufficiently in a direction opposite the flow direction for preventing back flow. In accordance with a preferred embodiment of the invention, the membrane of the valve deforms at a predetermined cracking pressure.

Preferably, an embodiment of a valve arrangement according to the present invention is obtained by modification of known apparatus. Suitable starting materials are for example: a housing manufactured of metal or plastics material, preferably rigid plastics material including ABS, polycarbonate, PVC, acrylic or MABS; and a valve membrane manufactured of a resilient material including polyurethane, silicone or rubber.

Preferably, a method of treatment according to the present invention includes the steps of administering a fluid from a container to a patient using a pump to propel the fluid and a valve arrangement according to an embodiment of the invention.

Additional features and advantages of the present invention are described in, and will be apparent from, the description of the presently preferred embodiments which are set out below with reference to the drawings in which:

Figure 1 shows a valve arrangement in accordance with the invention.

A valve arrangement according to an embodiment of the invention comprises a channel and a chamber. Fluid passes through the channel via the chamber. The chamber has an annular inlet and an annular outlet. A resilient piston having a stem and a mushroom shaped head is located in the chamber. The piston is of flexible material, typically a sterilisable material such as silicon, rubber or any other suitable material.

In a rest state, the mushroom shaped head blocks the channel at the inlet of the chamber. When the pressure of fluid at the inlet exceeds the pressure in the chamber by a cracking pressure of at least about 0.15 bar (15 kPa), the head deforms and/or the piston deforms and/or shifts axially in the channel. This unblocks the channel at the inlet of the chamber and allows flow of fluid. Movement of the piston relative to the channel is restricted by a stopper which engages the apex of the mushroom shaped head. In contrast, where the pressure differential is lower than 0.15 bar or negative, the head of the piston blocks flow of fluid. This prevents undesired free flow of the fluid from the container.

The cracking pressure can be predetermined by setting the degree of compression of the mushroom shaped head or by setting the tension in the stem which exists during the rest state.

A pump of a pump unit is coupled to valve arrangement via tubing. The pump is preferably a peristaltic pump but any pump which is able to pump fluid at controlled flow rates and which is suitable for clinical applications may be used. The pump unit may include a control unit. The control unit typically comprises a control panel which has a display and a key pad. The key pad may be used for manual control of the pump, data entry, and the like. The control unit may include a microprocessor for controlling and activating the pump. A memory may be associated with, or be incorporated in, the microprocessor. If desired, the control unit may include an audio, visual or dual alarm signalling means.

A flow set comprising the valve arrangement is typically mounted on a stand with a container for fluid being held by an arm at the top of the stand. Drip chambers may be provided adjacent the outlet of the valve arrangement or between the container and the inlet of the valve arrangement.

In use, a pump pumps fluid from a container to a patient. Prior to pumping by the pump, the piston is in a rest state. When fluid is pumped through the inlet tube and a selected threshold pressure differential is reached, the piston is stretched and/or moved axially in the channel and/or the head of the piston deforms. This unblocks the inlet of the chamber and flow of fluid through the valve arrangement from the inlet tube into the outlet tube is permitted.

An alternative valve arrangement according to an embodiment of the invention comprises a housing having a channel and a chamber. A flexible membrane is held across the channel. The flexible membrane is made of a resilient flexible material, typically a sterilisable material such as silicon, rubber or any other suitable material. The membrane has a plurality of slits (for example two) which, in the rest state, are closed and do not permit flow of fluid. Typically, the membrane is designed so that its slits will open only when the pressure differential over the membrane exceeds about 0.15 bar (15 kPa). This prevents undesired free flow of the fluid from the container.

In use, a pump pumps fluid from a container to a patient. Prior to pumping by the pump, the flexible membrane is in a rest state. When fluid is pumped through the inlet tube, the flexible membrane is stretched. Once a selected threshold pressure differential is reached and the flexible membrane is sufficiently stretched, it deforms and slits in the membrane widen and open to allow flow of fluid from the inlet tube into the outlet tube.

The system provides a safe and rapid means of administering a fluid to a patient which is extremely simple to operate.

It will be appreciated that numerous modifications may be made to the preferred embodiments without departing from the spirit and scope of the invention as set out in the claims.

Claims

1. A valve arrangement which is suitable for use with a rotary peristaltic pump and which is capable of allowing flow of fluid in a first direction and capable of preventing flow of fluid in a second direction, wherein the valve arrangement comprises a valve having a cracking pressure of about 0.10 to about 0.20 bar.

2. A valve arrangement according to claim 1wherein the cracking pressure is about 0.15 bar.

3. A valve arrangement according to claim 1 or 2 wherein the valve comprises a flexible membrane which is deformable under pressure in a desired flow direction and the flexible membrane has perforations through it which open at a selected extent of deformation of the flexible membrane to permit flow.

4. A valve arrangement according to claim 3 wherein the valve has a support associated with the flexible membrane for preventing the flexible membrane from deforming sufficiently in a direction opposite the flow direction for preventing back flow.

5. A flow set for the administration of at least one fluid to a patient which comprises a valve arrangement according to any preceding claim; an inlet tube for connecting a container to an inlet port of the valve arrangement; and an outlet tube for connecting to an outlet of the valve arrangement for the delivery of a fluid to a patient.

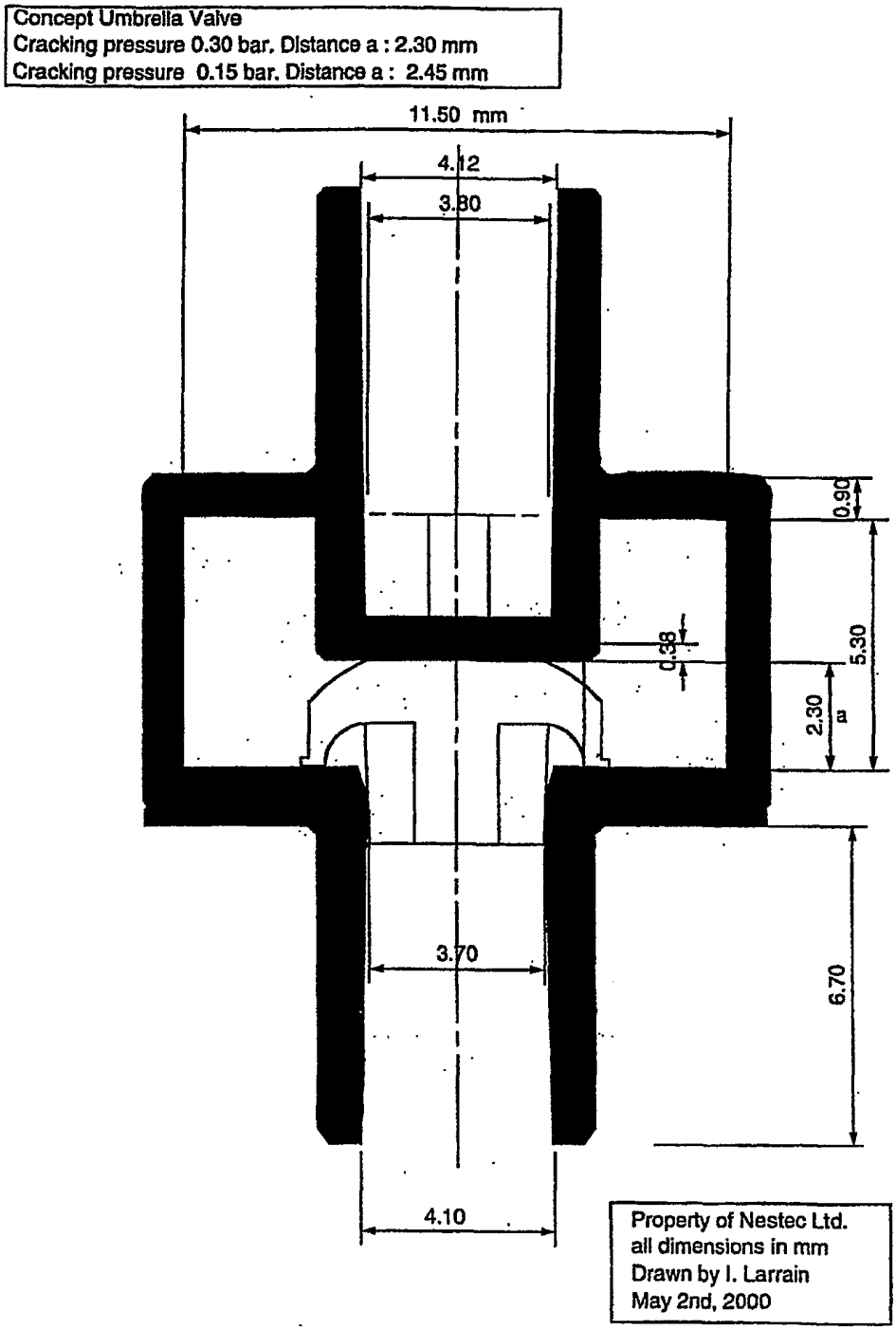
6. A method of production of a valve arrangement according to any one of claims 1 to 4 which comprises producing a chamber, making ports including an inlet port and an outlet port, fixing a one way valve between the inlet port and the outlet port for allowing fluid to flow in only one direction, wherein the cracking pressure of the valve is about 0.10 to 0.20 bar.

7. A valve arrangement according to any one of claims 1 to 4 for providing enteral nutrition to a patient.

8. A method of treatment of a patient that comprises administering an effective amount of a fluid via a valve arrangement according to any one of claims 1 to 4.

9. A method of treatment according to claim 8 which includes the steps of administering a fluid from a container to a patient using a pump to propel the fluid via a and a valve arrangement according to any one of claims 1 to 4.

Figure 1


Concept Umbrella Valve
Cracking pressure 0.30 bar. Distance a : 2.30 mm
Cracking pressure 0.15 bar. Distance a : 2.45 mm
11.50 mm
4.12
3.80
0.90
5.30
0.38
2.30
a
3.70
6.70
4.10
Property of Nestec Ltd.
all dimensions in mm
Drawn by I. Larrain
May 2nd, 2000

INTERNATIONAL SEARCH REPORT

International Application No
PCT/EP 01/06432

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M39/24 F16K15/00

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)
IPC 7 A61M F16K

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6 059 747 A (BEAUFORE SPENCER W ET AL) 9 May 2000 (2000-05-09) the whole document ---	1,2,5,6
P,X	EP 1 099 455 A (BORLA IND) 16 May 2001 (2001-05-16) the whole document ---	1-4,6
P,X	EP 1 093 828 A (BORLA IND) 25 April 2001 (2001-04-25) the whole document ---	1,2,6
X	US 5 738 662 A (KOENIG DONALD HENRY ET AL) 14 April 1998 (1998-04-14) the whole document ---	1,2
	-/--	

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
28 August 2001	06/09/2001

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Jameson, P

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0 934 757 A (3BY LIMITED) 11 August 1999 (1999-08-11) the whole document	1,3-7
A	US 5 617 897 A (MYERS JAN W M) 8 April 1997 (1997-04-08) the whole document	1,3,5-7
A	US 5 660 205 A (EPSTEIN ALAN B) 26 August 1997 (1997-08-26) abstract; figures 1-3	1,5,6

INTERNATIONAL SEARCH REPORT

Information on patent family members

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