



(43) International Publication Date
6 February 2014 (06.02.2014)

(51) International Patent Classification:
A61F 2/00 (2006.01)

(21) International Application Number:
PCT/EP2012/065260

(22) International Filing Date:
3 August 2012 (03.08.2012)

(25) Filing Language: English

(26) Publication Language: English

(71) Applicant (for all designated States except US):
FRAUNHOFER-GESELLSCHAFT ZUR FÖRDERUNG DER ANGEWANDTEN FORSCHUNG E.V. [DE/DE]; Hansastraße 27c, 80686 München (DE).

(72) Inventors; and

(75) Inventors/Applicants (for US only): RICHTER, Martin [DE/DE]; Brahmstrasse 6, 81677 München (DE). KIBLER, Sebastian [DE/DE]; Maria-Eich-Straße 57, 81243 München (DE).

(74) Agents: STÖCKELER, Ferdinand et al.; P.O. Box 246, 82043 Pullach (DE).

(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, BN, 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, QA, RO, RS, RU, RW, SC, SD, 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, RW, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, 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))

(54) Title: APPARATUS FOR CLOSING AND OPENING A FLOW PATH HAVING A FLEXIBLE FLOW PATH WALL

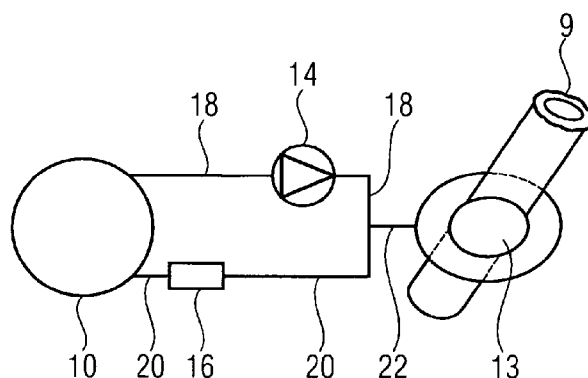


FIG 1

(57) Abstract: An apparatus for closing and opening a flow path (9) having a flexible flow path wall, comprises a fluid reservoir (10), an inflatable closing device (12) arrangeable at least partially around the flow path (9) and having an interior space, a pump (14) fluidically coupled between a fluid reservoir (10) and the interior space of the inflatable closing device (12), and a passive flow restriction (16) fluidically coupled between the fluid reservoir (10) and the interior space of the inflatable closing device (12) in parallel to the pump (14). The pump (14) is actuatable to increase the pressure within the interior space of the inflatable closing device (12) to close the flow path (9), and the flow restriction (16) is configured to permit a reduction of the pressure within the interior space to open the flow path (9) when the pump (14) is not actuated or the pump rate of the pump is set to be smaller than a flow rate through the flow restriction.



Apparatus for Closing and Opening a Flow Path having a Flexible Flow Path Wall

Description

5

The present invention relates to an apparatus for closing and opening a flow path having a flexible flow path wall, and, in particular, such an apparatus suitable to be used as an artificial mechanism for closing and opening a flow path within a human or animal body, such as the rectum or the urethra.

10

So called “sphincters” are artificial sphincter muscles for the rectum or the urethra, which replace the natural sphincter muscles, such as following a tumor surgery to remove the natural sphincter muscle, or such as in case of incontinence. An important part of the artificial sphincter is a member called “cuff”, which is a expandable torus which may be inflated by pumping an inert salt solution into the torus and which may be deflated or collapsed by removing the inert salt solution from the torus. The torus is arranged so that the rectum or the urethra extend through the opening thereof, wherein the rectum or urethra may be closed by pumping inert salt solution into the interior space of the torus and wherein the rectum or the urethra may be opened by emptying the interior space of the torus. Filling and emptying the torus may be achieved by means of a pump, such as a micropump, transporting a liquid, such as an inert salt solution, between the cuff and a reservoir.

15

20

It is the object of the invention to provide for an apparatus for closing and opening a flow path having a flexible flow path wall which has a simple construction and which permits opening of the flow path in case of a power failure.

25

This object is achieved by an apparatus according to claim 1.

30

Embodiments of the invention provide for an apparatus for closing and opening a flow path having a flexible flow path wall, comprising:

a fluid reservoir;

35

an inflatable closing device arrangeable at least partially around the flow path and having an interior space, wherein the flow path is closable by inflating the inflatable closing

device by increasing the pressure within the interior space and openable by deflating the inflatable closing device by reducing the pressure within the interior space;

5 a pump fluidically coupled between a fluid reservoir and the interior space of the inflatable closing device; and

a passive flow restriction fluidically coupled between the fluid reservoir and the interior space of the inflatable closing device in parallel to the pump,

10 wherein the pump is actuatable to increase the pressure within the interior space of the inflatable closing device to close the flow path, and

15 wherein the flow restriction is configured to permit a reduction of the pressure within the interior space to open the flow path when the pump is not actuated or the pump rate of the pump is set to be smaller than a flow rate through the flow restriction.

According to embodiments of the invention, the apparatus comprises a pump and a passive flow restriction so that the number of active fluidic elements may be reduced. Accordingly, embodiments of the invention permit for an apparatus for closing and opening a flow path
20 having a flexible flow path wall, which has a simple construction and which is power saving. A passive flow restriction is fluidically coupled between the fluid reservoir and the interior space of the inflatable closing device to permit a fluid flow from the interior space of the inflatable closing device to the fluid reservoir and, thereby, a reduction of the pressure within the interior space so that the inflatable closing device is deflatable via the
25 passive flow restriction when the pump is not actuated and, therefore, the flow path is opened in case of a power failure. For example, this is important in case the apparatus is to be used as an artificial sphincter for a rectum or a urethra. The inflatable closing device is deflated as long as the flow rate through the flow restriction exceeds the flow rate provided by the pump. Thus, in embodiments of the invention, the flow restriction is configured to
30 permit a fluid flow in the direction from the interior space of the inflatable closing device to the fluid reservoir and, thereby, a reduction of the pressure within the interior space of the inflatable closing device when the pump rate of the pump is set to be smaller than a flow rate through the flow restriction.

35 In embodiments of the invention, the apparatus is configured so that there is a continuous leakage flow in a return path from the interior space of the inflatable closing device to the fluid reservoir while the apparatus is operated to close the flow path. The fluid amount escaping by this leakage flow may be compensated for by actuating the pump in an

appropriate manner, such as by refilling the inner space of the inflatable closing device periodically. In embodiments of the invention, there is not any element restricting the leakage flow in the return path in addition to the passive flow restriction even during times the pump is driven to generate a pressure within the interior space of the inflatable closing device to close the flow path.

In embodiments of the invention, the inflatable closing device is adapted to be arranged at least partially around a rectum and the apparatus is configured to act as an artificial sphincter for the rectum. In embodiments of the invention, the inflatable closing device is adapted to be arranged at least partially around a urethra and the apparatus is configured to act as an artificial sphincter for the urethra. To be more specific, the size of the inflatable closing device and the pressures and flow rates provided by the pump and the passive flow restriction may be adapted to permit for opening and closing the rectum or the urethra to enable emptying the rectum or the bladder in an appropriate manner. In such embodiments, the invention may be implemented as a sphincter implant in a manner compliant with a patient as it is obvious for those skilled in the art.

In embodiments of the invention, the pump is configured to provide a maximum counter pressure of at least 10 kPa, 20 kPa or 50 kPa and to provide a flow rate of at least 0.5 ml/s, 1 ml/s or 1.5 ml/s without counter pressure, i.e. maximum flow rate. In embodiments of the invention, the passive flow restriction is configured to provide a flow resistance between the interior space of the inflatable closing device and the reservoir which, upon stopping actuation of the pump, permits opening of the flow path within a period of 10 sec, 5 sec, 2 sec or less by means of a corresponding fluid flow through the flow restriction. Such embodiments may be appropriate to be used as an artificial sphincter for the rectum or for the urethra of a patient.

In embodiments of the invention, the pump and the passive flow restriction are configured so that a flow rate through the flow restriction is between 15 % and 45 %, between 20 % and 40 % or between 25 % and 35 % of a maximum pump rate of the pump without counter pressure. It turned out that configuring the pump and the passive flow restriction in this manner is a beneficial tradeoff permitting enough pressure to be generated within the interior space of the inflatable closing device (to sufficiently close the flow path such as the rectum or the urethra) and a sufficient flow rate through the flow resistance permitting opening the flow path within an acceptable time period.

In embodiments of the invention, the pump is a unidirectional pump configured to pump a fluid in a direction from the reservoir to the interior space of the inflatable closing device.

In other words, the pump is configured to pump a fluid in a single direction only, to permit a fluid flow in this direction when not being actuated and to prevent a fluid flow in the opposite direction when not being actuated. In embodiments of the invention, the pump may be provided with a safety valve such that a fluid flow in a direction contrary to the pumping direction is prevented. Accordingly, the pump may be implemented as a high power pump providing for the required flow rate and maximum counter pressure.

In embodiments of the invention, a further pump is fluidically coupled between the interior space of the inflatable closing device and the reservoir in series to the passive flow restriction, wherein the further pump is actuatable to increase a flow rate from the interior space of the inflatable closing device to the reservoir. By making use of such a further pump, the time required to open the flow path may be reduced.

In embodiments of the invention, an actuatable fluidic element, such as a normally closed valve or a pump, is coupled in parallel to the flow restriction. The actuatable fluidic element is configured to prevent a fluid flow from the interior space of the inflatable closing device if not actuated (supplied with power) and to enable a fluid flow from the inflatable closing device to the reservoir if actuated. The actuatable fluidic element may be configured to empty the inner space such that the flow path is opened in a short time, such as in 30s or below. In such embodiments, the flow restriction may be configured to empty the inner space of the inflatable closing device such that the flow path is opened within a longer time period, such as between 20 and 30 minutes. Such a period is believed to be sufficient in case of a power failure, while the flow path (such as the rectum or the urethra) may be opened in a short time period by actuating the fluidic element. In such embodiments, the resistance of the passive flow restriction may be higher when compared to a case in which the actuatable fluidic device is not provided, so that the leakage flow which has to be compensated for by the pump in the forward path may be reduced. With that the ratio between ON time (actuated time) and OFF time (non actuated time) of the pump can be reduced to a very small value, saving significant energy to operate the pump. Another advantage of this embodiment is that a possible disturbance of the patient due to noise or vibrations of the pump is reduced to the short ON time of the pump.

Embodiments of the invention permit for an apparatus for closing and opening a flow path comprising an inflatable closing device without the necessity to provide for a normally open valve in a reflow path between the inflatable closing device and the fluid reservoir,

while it is still ensured that a reflow path from the inflatable closing device to the fluid reservoir is open (to permit opening of the flow path having the flexible flow path wall) in case of a power failure.

5 Embodiments and further details of the invention are described referring to the enclosed figures, in which:

Fig. 1 shows a schematic diagram of an embodiment of the invention;

10 Fig. 2 shows a schematic diagram of another embodiment of the invention:

Fig. 3 shows a diagram illustrating the relationship between the counter pressure and the pump rate of a pump;

15 Fig. 4 shows a schematic diagram of an embodiment of the invention having an actuatable fluidic element coupled in parallel to the flow restriction;

20 Figs. 5a and 5b show a schematic top view and a schematic side view of an example of a inflatable closing device;

Fig. 6a and 6b show schematic views of an inflatable closing device in an open state and a closed state; and

25 Fig. 7 shows a schematic view of a comparative example not falling under the scope of the claims.

Fig. 1 shows an embodiment of an inventive apparatus comprising a fluid reservoir 10, an inflatable closing device 12, a pump 14 and a passive flow restriction 16.

30

The inflatable closing device 12 has an internal space hermetically sealed by inflatable closing device walls (except for at least one inlet/outlet enabling inflating and deflating the inflatable closing device). In the embodiment shown, the inflatable closing device has an annular shape having a central opening 13. A flow path 9 having a flexible flow path wall extends through the central opening 13.

35

In embodiments of the invention, flow path 9 may be the rectum or the urethra of a patient and the inflatable closing device 12 may form an artificial sphincter adapted to be arranged

around the rectum or the urethra of the patient. Such artificial sphincters as such are known to those skilled in the art. An important component of the artificial sphincter is the so called cuff, i.e. a torus inflatable and deflatable by means of a liquid, such as a salt solution. The cuff representing an inflatable closing device 12 is arranged around the
5 rectum or the urethra so that the rectum or the urethra extends through the opening of cuff 12 and can be closed and opened by inflating and deflating cuff 12. As such, cuff may be of a conventional design, wherein embodiments of the invention relate to the approach how this artificial sphincter muscle is activated and deactivated.

10 It is, however, clear to those skilled in the art that in other embodiments of the invention, the inflatable closing device may be configured to be used in connection with other flexible flow paths such as any hoses or tubes for administering drugs or the like. Generally, the invention may be used in connection with any flexible flow path that is to be switched between a closed state and an open state.

15

Pump 14 is fluidically connected between reservoir 10 and inflating closing device 12 by means of appropriate fluidic lines, such as tubes/hoses or such as fluid channels formed in a substrate. Likewise, passive flow restriction 16 is fluidically coupled between reservoir 10 and inflatable closing device 12 by means of appropriate fluidic lines. Fluidic lines 18
20 form a forward path between reservoir 10 and inflatable closing device 12, while fluidic lines 20 form a return path from inflatable closing device 12 to reservoir 10 in parallel to the forward path. As shown in Fig. 1, fluidic lines 18 and fluidic lines 20 may lead into a common fluidic line 22, which is fluidically coupled to the interior space of inflatable closing device 12.

25

In embodiments of the invention, fluidic reservoir 10 is configured to include any suitable pumpable fluid, i.e. a liquid or a gas. In embodiments of the invention, the fluid may be a liquid such as an inert salt solution (e.g., for medical applications) or simply water. In other embodiments, the fluid may be a gas, such as air.

30

In operation, pump 14 pumps pumping fluid from reservoir 10 into the interior space of inflatable closing device 12 so that the pressure within the interior space is increased. Thus, the inflatable closing device is inflated and a flexible flow path extending through the opening 13 is closed. Pump 14 is configured to prevent a flow of the pumping fluid in the
35 direction from the inner space of device 12 to the reservoir upon stopping actuation thereof. At the same time, there is a leakage flow through passive flow restriction 16 in the direction from device 12 to reservoir 10. Pump 14 is configured to provide the pressure necessary to inflate the inflatable closing device while this leakage flow is present, i.e. is

configured to compensate for this leakage flow. In embodiments of the invention, pump 14 may be controlled to periodically refill the interior space of the inflatable closing device with fluid from fluid reservoir 10 in order to compensate for the leakage flow through passive flow restriction 16. Thus, flow path 9 can be closed by appropriately controlling pump 14.

In case flow path 9 is to be opened, actuation of pump 14 is stopped and, therefore, the inner space of inflatable closing device 12 is emptied through flow restriction 16. In embodiments of the invention, flow restriction 16 is configured such that the interior space of the inflatable closing device 12 is emptied in a limited time period so that flow path 9 is opened. Thus, embodiments of the invention permit for emptying the cuff of an artificial sphincter and, therefore, opening the urethra or the rectum, within a time period acceptable to a patient.

In embodiments of the invention, pump 14 is a unidirectional pump, i.e. a pump configured to pump a fluid in a single direction and to prevent a fluid flow in the opposite direction even if the pump is not actuated. Accordingly, any fluid flow from the inflatable closing device back to the reservoir 10 takes place through flow restriction 16. Any such pump which is able to provide the required flow rates and counter pressures for a desired application can be used according to the invention. Generally, a pump may be described by means of two characteristic parameters thereof, the pump rate Q_{0p} without counter pressure, and the maximum achievable counter pressure p_{max} . Specific implementations of pumps and passive flow restrictions can be found by those skilled in the art without undue burden having the following considerations in mind.

The characteristic of a pump and, in particular, a high power pump is as follows:

$$Q_p = Q_{0p} \left(1 - \frac{p}{p_{max}} \right), \quad (1)$$

wherein p is the counter pressure against which the pump has to pump, p_{max} is the maximum counter pressure of the pump, Q_p is the pump rate which depends on the counter pressure, and Q_{0p} is the pump rate of the pump without a counter pressure.

Examples of pumps suitable for the invention may be configured to provide a maximum counter pressure p_{max} of at least 10 kPa, 20 kPa or 50 kPa. Examples of pumps suitable for the invention may provide a flow rate Q_{0p} of at least 0.5 ml/s, 1 ml/s or 1.5 ml/s. For

example, a micropump may comprise a pump rate Q_{0p} of 1.5 ml/s and a maximum counter pressure p_{\max} of 50 kPa.

5 A diagram showing an exemplary dependency of the flow rate from the counter pressure for a number of micro pumps is shown in Fig. 3. The curves in Fig. 3 have been determined making use of water and a number of similar micropumps. Fig. 3 shows that there is a substantially linear dependency of the flow rate from the counter pressure.

10 In embodiments of the invention, a flow channel having a defined internal cross sectional area and having a defined length may be used as the passive flow restriction. For example, a circular capillary channel, such as a glass capillary, may be used as a passive flow restriction. The flow rate in a capillary channel is (according to the law of Hagen Poiseuille):

$$15 \quad Q_{HP} = \frac{\pi r^4 \Delta p}{8\eta l}, \quad (2)$$

wherein Q_{HP} represents the flow rate through the capillary channel, r represents the radius of the capillary channel, Δp represents the pressure drop across the capillary channel, η 20 represents the viscosity of the fluid in the capillary channel, and l represents the length of the capillary channel.

The pump (micropump) can achieve the maximum counter pressure $p_{\text{cuff,max}}$ in the inflatable closing device (cuff) if the pump rate equals the leaking loss (through the passive 25 flow restriction):

$$Q_{HP} = Q_p \quad (3)$$

30 Combining Eqs. 1 and 3 results in:

$$p_{\text{cuff,max}} = p_{\max} \frac{Q_{HP}}{Q_{0p}} \quad (4)$$

35 The following table shows the results for different radii r of the capillary channel.

Table 1

r	9,50E-05	1,50E-04	1,75E-04	2,00E-04	2,25E-04	2,50E-04	3,00E-04	radius of glass capillary
η	0,001	0,001	0,001	0,001	0,001	0,001	0,001	viscosity of water
l	3,0E-02	3,0E-02	3,0E-02	3,0E-02	3,0E-02	3,0E-02	3,0E-02	length of glass capillary
p	1,5E+04	1,5E+04	1,5E+04	1,5E+04	1,5E+04	1,5E+04	1,5E+04	pressure in cuff
Q_p	1,6E-08	9,9E-08	1,8E-07	3,1E-07	5,0E-07	7,7E-07	1,6E-06	m ³ /s
Q_{HP}	0,02	0,10	0,18	0,31	0,50	0,77	1,59	ml/s
V20	0,32	1,99	3,68	6,28	10,06	15,34	31,81	ml in 20 sec

Pcuff,max	49,20	45,03	40,79	34,29	24,84	11,65	-29,52	maximum counter pressure kPa
-----------	-------	-------	-------	-------	-------	-------	--------	------------------------------

5

The results in Table 1 have been obtained making use of a pump having a maximum counter pressure of 50 kPa and a pump rate Q_{op} of 1.5 ml/s.

10 It can be seen from Table 1 that the maximum counter pressure within the interior space of the inflatable closing device (cuff) approaches the maximum pressure of the pump at small radii of the capillary of the passive flow restriction. However, the flow rate through the flow restriction and, therefore, the volume flowing through the restriction, such as within 20 s, is very low. On the other hand, the higher the radius of the capillary channel of the
 15 passive flow restriction is, the lower the maximum pressure within the interior space of the inflatable closing device is. Above a specific radius of the capillary (when Q_{HP} becomes equal or greater than Q_{op}), it is no longer possible to generate a pressure within the interior space of the inflatable closing device.

20 Accordingly, the dimensions of the pump and the flow restriction have to be chosen such that sufficient pressure can be generated within the interior space of the inflatable closing device to open the flow path by actuating the pump and such that the flow rate through the flow restriction to deflate the inflatable closing device is sufficient to close the flow path within an acceptable time period.

25

In exemplary embodiments of the invention, the dimensions of the pump and the flow restriction may be chosen such that a flow rate through the flow resistance is between 15 % and 54 %, between 20 % and 40 % or between 25 % and 35 % of a maximum flow rate of the pump without a counter pressure. In the embodiment described with respect to Table 1,
5 a radius of the capillary of the flow restriction of 200 μ m corresponds to a leakage flow of 31 % of the maximum pump rate.

In the above considerations, the flow resistance of the fluidic lines 18, 20 and 22 have been neglected since same may be by orders lower than the flow resistance of the passive flow
10 restriction 16. In alternative embodiments, the return flow path as a whole may represent a flow restriction in an apparatus for closing an operating flow path.

According to the embodiment shown in Fig. 1, a single active element, i.e. pump 14, is provided. In an alternative embodiment, an additional pump 24 may be coupled in the
15 return path in series with the flow restriction 16 as shown in Fig. 2. In embodiments of the invention, pump 24 is a unidirectional pump allowing for a fluid flow in the direction from the inflatable closing device 12 to the reservoir 10, but not in the opposite direction, even if pump 24 is not actuated. Pump 24 may be actuated in order to increase a flow rate through the return path, i.e. through the fluidic lines 20 and the flow restriction 16. Thus, the time
20 period required to empty the interior space of the inflatable closing device and, therefore, to open the flow path, can be further reduced.

Fig. 4 shows an embodiment, in which an actuatable fluidic element 38 is fluidically coupled in parallel to a flow restriction 36 by corresponding fluidic lines 21. Flow
25 restriction 36 may be configured to permit a fluid flow between the interior space of the inflatable closing device 12 and the reservoir, which is sufficient to open the flow path within a time period of 20 to 40 min. Actuatable fluidic element 38 is configured to prevent a fluid flow from the interior space of the inflatable closing device 12 to the fluid reservoir 10 if not actuated and to enable a fluid flow from the inflatable closing device 12
30 to the fluid reservoir 10 if actuated. As used herein, actuated means that power is applied to a device, while non actuated means that no power is applied to the device. Accordingly, fluidic element 38 is in a closed state without consuming power. Fluidic element 38 may be formed by a normally closed valve, i.e. a valve which is closed when no power is applied. In alternative embodiments, the fluidic element 38 may be formed by a normally
35 closed pump to enable an increased fluid flow from the interior space of the inflatable closing device 12 to the reservoir. The actuatable fluidic element may be configured to

empty the inner space such that the flow path is opened in a short time, such as in 30s or below. Flow restriction 36 may be configured with a higher flow resistance to empty the inner space of the inflatable closing device such that the flow path is opened within a longer time period, such as between 20 and 30 minutes. Thus, the leakage flow which has
5 to be compensated for by pump 14 may be reduced.

In Fig. 4, the passive flow restriction is shown separately from the actuatable fluidic element. In different embodiments, the passive flow restriction may be implemented integrated with the actuatable fluidic device. For example, the passive flow restriction may
10 be implemented as a small opening or a defined gap in the valve seat or as a parallel fluid path in the normally closed valve forming the actuatable fluidic element, the pump forming the actuatable fluidic element or a safety valve of the pump forming the actuatable fluidic element. In either case, the passive flow restriction provides for a return path from the inner space of the inflatable closing device if the actuatable fluidic element is closed.

15

An example of an inflatable closing device in the form of a cuff 42 is now described referring to Figs. 5a to 6b. Figs. 5a and 5b show cuff 42 in an initial state. Cuff 42 comprises a flexible support 44 and an inflatable body 46 attached to the support 42. A tube 48 is attached to the support 44 and/or the inflatable body 46 and fluidically coupled
20 to an interior space of inflatable body 46 by means of a fluidic connector 47. Tube 48 may represent common fluid line 22 shown in Figs. 1, 2 and 4, for example.

Support 44 comprises an opening 50 and a strap 52. To bring cuff 42 into a working position, support 44 is bent in a direction indicated by arrow 54 in Fig. 5b. Strap 52 is
25 drawn through opening 50 and fixed in any suitable manner, such as by a clamping means, by an adhesive or the like. Thus, cuff 42 has a structure as shown in Fig. 6a. In Fig. 6a inflatable body 46 of cuff 42 is deflated so that a fluid path (such as a rectum or a urethra) extending through an inner opening 56 formed by cuff 42 is open. In Fig. 6b, inflatable body 46 is inflated so that a fluid path extending through the inner opening 56 is closed.

30

In embodiments of the invention, the inflatable closing device extends around the flow path, wherein a small portion of the flow path is not surrounded. In other embodiments of the invention, the inflatable closing device is arranged around the flow path completely. Any amount of being arranged around the flow path suitable to close and opening the flow
35 path is regarded as falling under the definition that the inflatable closing device is arranged or arrangeable at least partially around the flow path. In this regard, an inflatable closing

device surrounding a flow path in an angle of between 180° and 360° may be regarded as at least partially surrounding the flow path.

5 In embodiments of the invention, pump 14 (and optionally any further pump) may be implemented by a pump as described in WO 2009/065427 A1. In embodiments, the pump may be implemented by any suitable pump, wherein such a pump may be provided with a safety valve as described in DE 10048376 C2. In embodiments, the pump may be implemented as described by M. Herz et. al., “Entwicklung einer energieeffizienten piezoelektrischen Hochfluss-Mikropumpe für Methanol-Brennstoffzellen”,
10 Mikrosystemtechnik Kongress 2011, Oktober 10 to 12, Darmstadt, ISBN 978-3-8007-3367-5 © VDE Verlag GmbH, Berlin, Offenbach.

According to embodiments of the invention, the pump 14 coupled between the reservoir and the inflatable closing device is operated to compensate for the continuous leaking flow
15 through the return path. An appropriate controller for controlling pump 14 may be provided. For example, the controller may control pump 14 to periodically refill the interior space of the inflatable closing device 12 to compensate for a liquid escaping through the return path including passive flow restriction 16. Thus, sufficient pressure to keep the flow path having the flexible flow path wall closed can be maintained within the
20 interior space of the inflatable closing device. In embodiments of the invention, a pressure sensor may be provided, which is configured to determine the pressure within the interior space of the inflatable closing device. The controller may include a feedback control to control pump 14 based on the output of the pressure sensor.

25 In case of substantially stationary environmental conditions, the leakage flow through the passive flow restriction may be known or may be estimated so that refilling the inflatable closing device in order to maintain sufficient pressure within the interior space thereof may be possible without feedback control. In alternative embodiments, a feedback control may be provided.

30 Accordingly, embodiments of the invention do not require a fluidic element consuming power to close a return path from the inner space of the inflatable closing device to the reservoir during times at which the closing device closes the fluid path, and which automatically opens in case of a power failure. Rather, according to embodiments of the
35 invention, a fluid flow from the inner space of the inflatable closing device to the reservoir may take place through the passive flow restriction in case of a power failure.

Accordingly, embodiments of the invention do not require a bidirectional peristaltic micropump, the pump rate of which is typically too low. Moreover, embodiments of the invention do not require a normally open valve or micro valve in the return path. A normally open valve, as this term is understood by those skilled in the art, is a valve which is open if no power is applied. A comparative example of an apparatus for closing and opening a flow path is shown in Fig. 7. The comparative example comprises a fluid reservoir 10', a fill pump 14', a back pump 24', an inflatable closing device (sphincter) 12' and a normally open valve 70. The normally open valve 70 is closed when the inflatable closing device 12' is driven to close the flow path extending through the opening 13'. Valve 70 is opened in case of a power failure so that the inflatable closing device is opened in case of a power failure. However, valve 70 represents an additional active component consuming power during the normal operation. An additional normally open valve as shown in Fig. 7 is not necessary according to the invention and, accordingly, consumption of the power necessary to keep the normally open valve closed during the normal operation can be avoided. The saved power can be used to drive the pump in the forward path to compensate for the leakage flow through the flow restriction.

Claims

1. An apparatus for closing and opening a flow path (9) having a flexible flow path
5 wall, comprising:
- a fluid reservoir (10);
- an inflatable closing device (12) arrangeable at least partially around the flow path
10 (9) and having an interior space, wherein the flow path (9) is closable by inflating
the inflatable closing device (12) by increasing the pressure within the interior
space and openable by deflating the inflatable closing device (12) by reducing the
pressure within the interior space;
- 15 a pump (14) fluidically coupled between a fluid reservoir (10) and the interior space
of the inflatable closing device (12); and
- a passive flow restriction (16) fluidically coupled between the fluid reservoir (10)
and the interior space of the inflatable closing device (12) in parallel to the pump
20 (14),
- wherein the pump (14) is actuatable to increase the pressure within the interior
space of the inflatable closing device (12) to close the flow path (9), and
- 25 wherein the flow restriction (16) is configured to permit a reduction of the pressure
within the interior space to open the flow path (9) when the pump (14) is not
actuated or the pump rate of the pump is set to be smaller than a flow rate through
the flow restriction.
- 30 2. The apparatus of claim 1, wherein the inflatable closing device (12) is adapted to be
arranged at least partially around a rectum and the apparatus is configured to act as
an artificial sphincter, or wherein the inflatable closing device (12) is adapted to be

arranged at least partially around a urethra and the apparatus is configured to act as an artificial mechanism for closing and opening the urethra.

3. The apparatus of claim 1 or 2, wherein the pump (14) is configured to provide a maximum counter pressure of at least 10 kPa, 20 kPa or 50 kPa and to provide a flow rate of at least 0,5 ml/s, 1 ml/s or 1,5 ml/s without counter pressure.
4. The apparatus of one of claims 1 to 3, wherein the passive flow restriction (16) is configured to provide a flow resistance between the interior space of the inflatable closing device (12) and the reservoir (10), which, upon stopping actuation of the pump (14), permits opening of the flow path (9) within a period of 10s, 5s, 2s or less.
5. The apparatus of one of claims 1 to 4, wherein the pump (14) and the passive flow restriction (16) are configured so that a flow rate through the flow resistance is between 15% and 45%, between 20% and 40% or between 25% and 35% of a maximum pump rate of the pump (14) without counter pressure.
6. The apparatus of one of claims 1 to 5, wherein the pump (14) is a unidirectional pump (14) configured to pump a fluid in a direction from the reservoir (10) to the interior space of the inflatable closing device (12).
7. The apparatus of one of claims 1 to 6, wherein a further pump (24) is fluidically coupled between the interior space of the inflatable closing device (12) and the reservoir (10) in series to the passive flow restriction (16), wherein the further pump (24) is actuatable to increase a flow rate from the interior space of the inflatable closing device (12) to the reservoir (10).
8. The apparatus of one of claims 1 to 6, comprising an actuatable fluidic element (38) coupled in parallel to the flow restriction (16) and configured to prevent a fluid flow from the interior space of the inflatable closing device if not actuated and to enable a fluid flow from the inflatable closing device (12) to the reservoir if actuated.

9. The apparatus of one of claims 8, wherein the actuatable fluidic element (38) is a normally closed valve or a pump.
- 5 10. Implant comprising an apparatus according to one of claims 1 to 9.

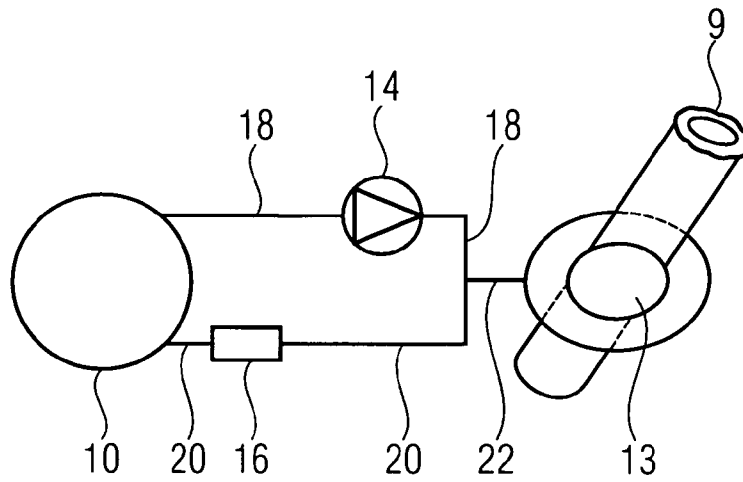


FIG 1

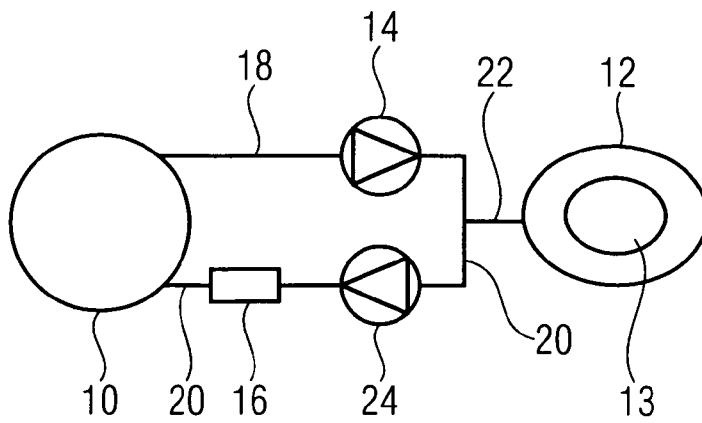


FIG 2

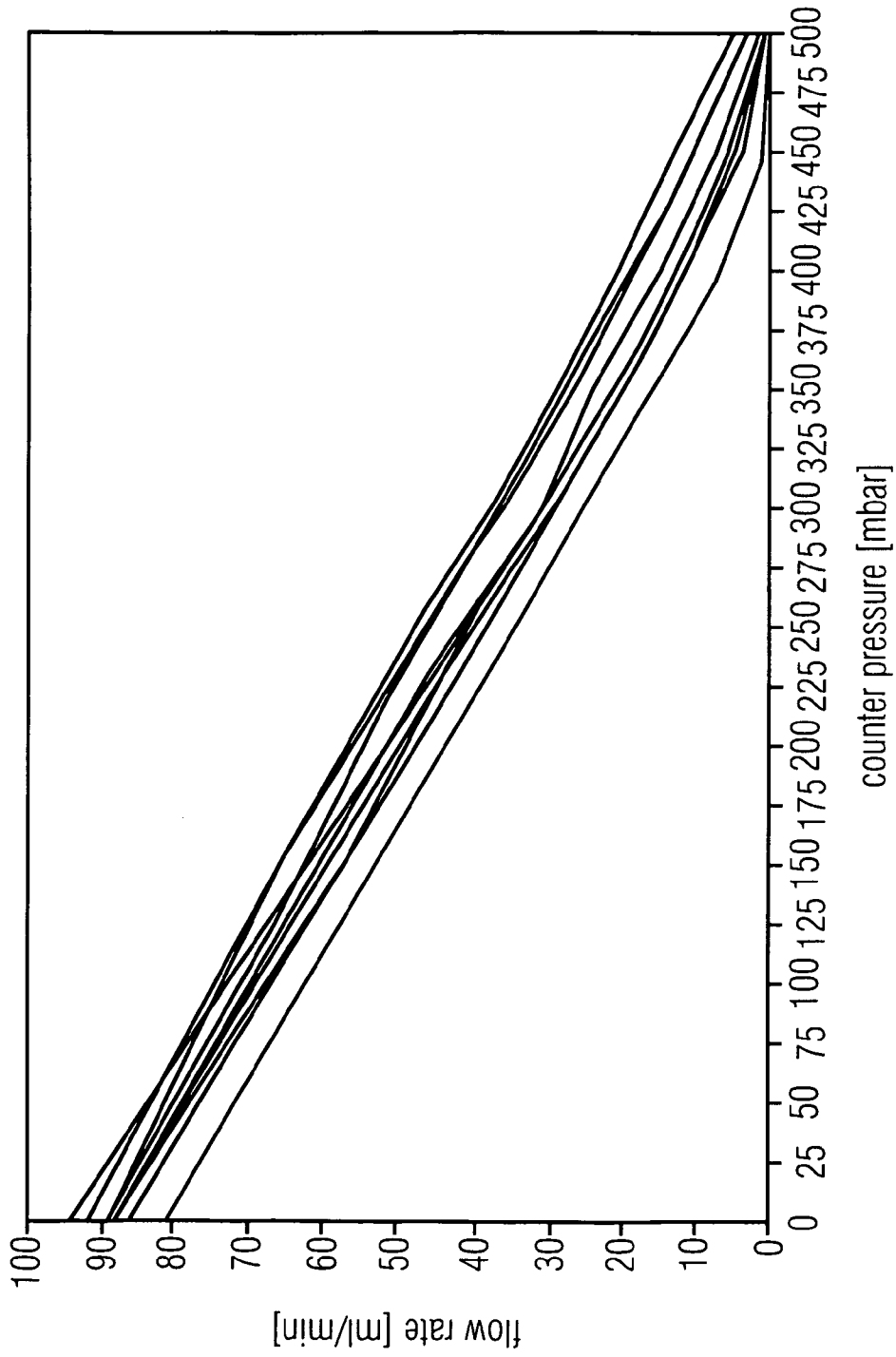


FIG 3

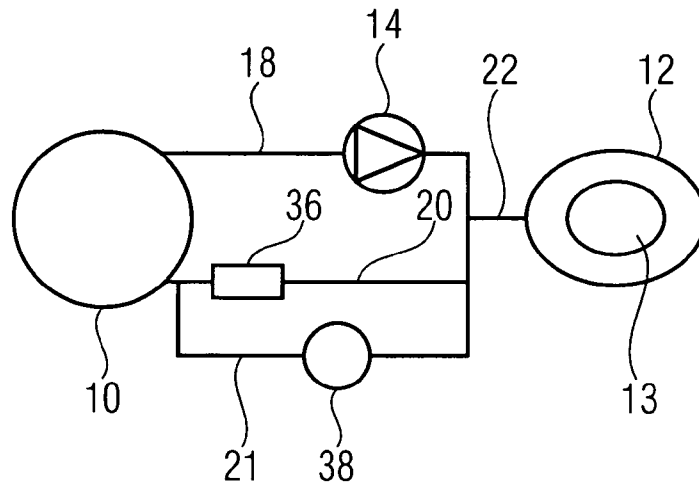


FIG 4

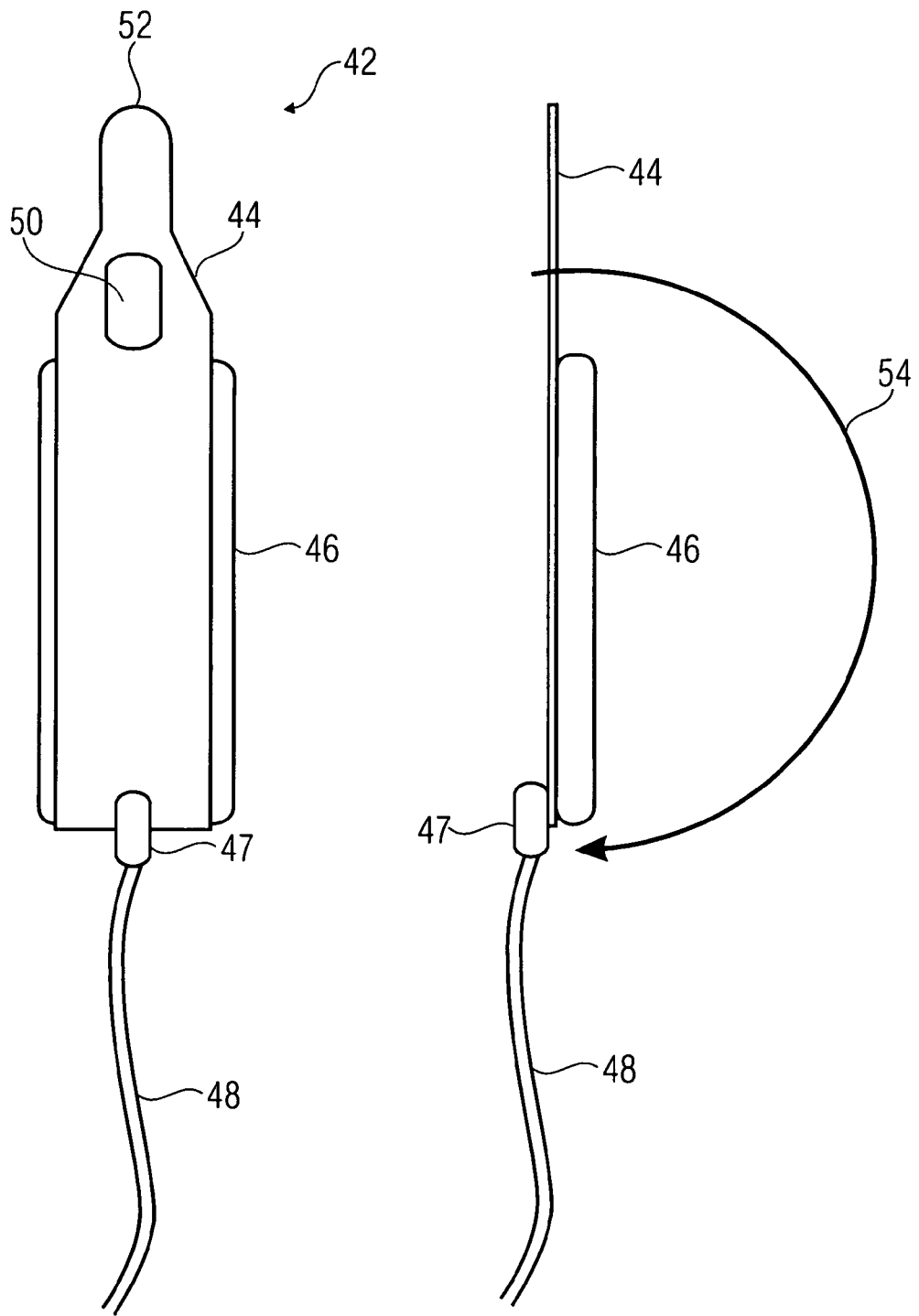


FIG 5A

FIG 5B

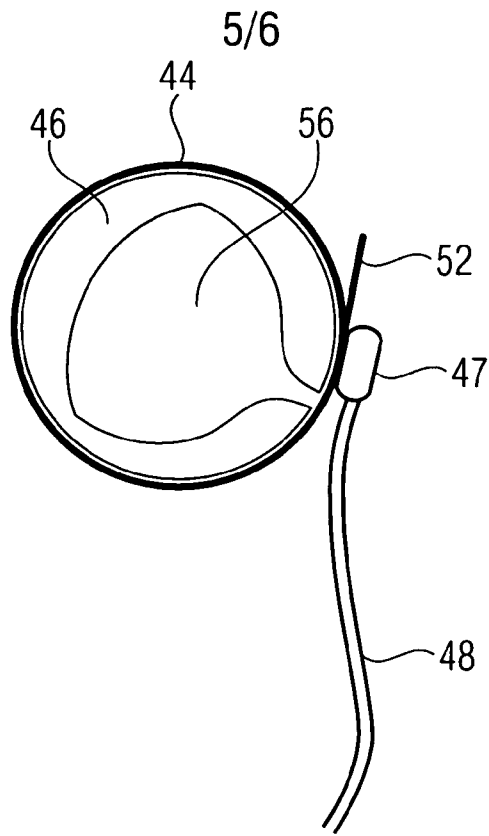


FIG 6A

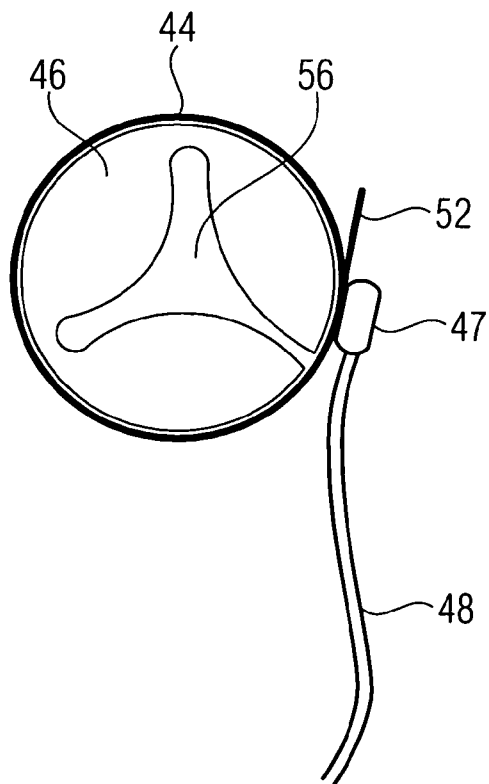


FIG 6B

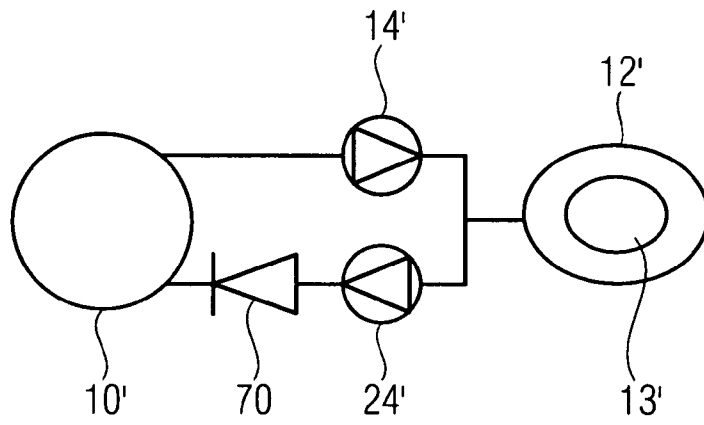


FIG 7

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2012/065260

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F2/00
ADD.

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)
A61F

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)
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 2003/028076 A1 (KUYAVA CHARLES C [US] ET AL) 6 February 2003 (2003-02-06) paragraphs [0033] - [0041]; figures 1-4 -----	1-10
X	DE 102 39 309 A1 (WASSERMANN HELMUT [DE]; SCHOSTEK SEBASTIAN [DE]) 11 March 2004 (2004-03-11) paragraphs [0051] - [0056]; figure 11 -----	1-10
X	WO 90/04368 A1 (UNIV CALIFORNIA [US]) 3 May 1990 (1990-05-03) page 16, lines 14-23; figure 15 -----	1-10
A	US 4 441 491 A (EVANS SR ALVIN S [US]) 10 April 1984 (1984-04-10) column 3, line 10 - column 4, line 20; figures 1,6 -----	1-10

Further documents are listed in the continuation of Box C.

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 27 February 2013	Date of mailing of the international search report 06/03/2013
--	---

Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Authorized officer Chevalot, Nicolas
--	--

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No PCT/EP2012/065260

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2003028076	A1	06-02-2003	US 2003028076 A1
			US 2006083848 A1

DE 10239309	A1	11-03-2004	NONE

WO 9004368	A1	03-05-1990	CA 2000844 A1
			EP 0444063 A1
			JP H04501372 A
			US 4982731 A
			WO 9004368 A1

US 4441491	A	10-04-1984	NONE
