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(72) Inventor; and
(71) Applicant : **POLASCHEGG, Hans-Dietrich** [AT/AT]; Malerweg 12, A-9231 Koestenberg (AT).

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(54) **Title**: DEVICE AND METHOD FOR AN EXTRACORPOREAL TREATMENT OF A BODILY FLUID

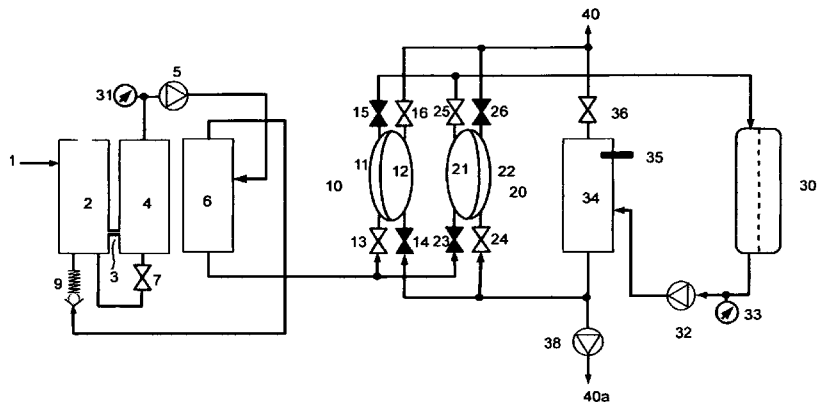

Fig. 1a

(57) **Abstract**: The invention provides a device for an extracorporeal treatment of a bodily fluid comprising a filter means arranged in a filter circuit (50) for exchanging solute substances between the fluid and a liquid and at least one degassing means arranged in a degassing (60, 60', 60") circuit for the liquid. Furthermore, the device comprises a control means that is configured to control the degassing means according to at least one operational parameter of the device. Furthermore, the invention provides a method for an extracorporeal treatment of a bodily fluid where such a device is used.

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Device and method for an extracorporeal treatment of a bodily fluid

Description:

The present invention generally relates to a device for an extracorporeal treatment of a bodily fluid comprising a filter means arranged in a filter circuit for exchanging solute substances between the fluid and a liquid and at least one degassing means arranged in a degassing circuit for the liquid.

Furthermore the invention relates to a method for an extracorporeal treatment of a bodily fluid, wherein such a device is used.

Today's dialysis machines are the result of a development that began with home hemodialysis machines in the 1960's. The first machines already comprised pumps for mixing dialysate, warming the dialysate and removing fluid by ultrafiltration. Eschbach et al. (Eschbach Jr JW, Wilson Jr WE, Peoples RW, Wakefield AW, Babb AL, Scribner BH. Unattended Overnight Home Hemodialysis. Trans Am Soc Artif Intern Organs 1966/12, pages 346-356) observed gas bubbles in the venous drip chamber of the extracorporeal circuit and found out that they originated from dialysate over saturated with air. Consequently a degassing stage was added to the flow path of the dialysate circuit.

The physical background of the degassing phenomenon is well known. Water used for hemodialysis may have a temperature between approximately 5 and 20°C and is usually saturated with air. When this water is mixed with electrolytes and heated to approximately 37°C, it becomes over saturated with air because the saturation limit decreases when the water is heated and when electrolytes are added. Over saturation means that the air is not immediately released when the water is heated but remains in solution and a simple passage through a heating system may not reduce over saturation sufficiently with the risk that excess gas will be released in the dialyser circulation loop. In this form the air may also diffuse through a dialyser

membrane. The over saturated water or dialysate will degas spontaneously when the fluid comes into contact with nucleation points. As described by Eschbach et.al., this may occur in the venous drip chamber or it may already occur in the dialysate circuit with the result that gas bubbles may accumulate in the dialyser and reduce the efficiency of the solute exchange.

During dialysis not only uremic solutes are removed but also excess fluid. This is done by creating a pressure gradient from the blood side to the dialysate side called transmembrane pressure. Up to the beginning of the 1980's the membranes used for hemodialysis were almost 100% 'low-flux' membranes, characterized by an ultrafiltration coefficient of <5ml/(h*mmHg). Machines were designed to remove up to 2l of fluid per hour by ultrafiltration which resulted in transmembrane pressures of about 500mmHg. Because the positive pressure on the blood side is only 150-250mmHg, a negative pressure down to -300mmHg or more had to be created on the dialysate side.

The early machines did not allow a precise prediction or control of the fluid removed by ultrafiltration. In the 1980's machines allowing for ultrafiltration control became available. Various systems were developed. The most popular system uses balancing chambers, balancing the fresh versus the spent dialysate as described ,e.g., in the US patent 4,770,769. In these machines it was very important to remove all air bubbles in fresh and spent dialysate. For this reason not only the fresh dialysate was degassed, but a secondary degassing stage was inserted into the flow path downstream of the dialyser and before the balancing chamber in case additional gas was released or entered the circuit through leaks in the connectors. Most dialysis machines still rely on balancing chambers and primary and secondary degassing.

In the recent years so called 'high-flux' dialysers with ultrafiltration coefficients of about 20–80ml/(h*mmHg) became available. Because these dialysers allow the efficient removal of larger molecules they became more popular than 'low-flux' dialysers. When high-flux dialysers are used, dialysate pressure will be above atmospheric pressure in the majority of cases.

Another more recent development is on-line hemodiafiltration or on-line hemofiltration which is, e.g., described in the US patent 4,702,829 as well as in a recent paper (Polaschegg HD, Roy T. Technical aspects of online hemodiafiltration. Contrib Nephrol 2007/158, pages 68-79). This method enhances the removal of larger molecules by ultrafiltering a large quantity of fluid from blood which is replaced by filtered fresh dialysate. In order to achieve the necessary high ultrafiltration rates low pressures or high negative pressures must be applied on the dialysate side.

In order to achieve the necessary degree of degassing for low-flux dialysers or on-line hemodiafiltration/hemofiltration, dialysate is exposed to a very low pressure of -500mmHg or less. Because degassing is not spontaneous, dialysate is recirculated as described in the US patent 4,770,769. The lowest pressure in this degassing loop is in the degassing pump, usually a gear pump. Because of the low pressure cavitation occurs which causes an accelerated erosion of the gears.

Experience has shown that the gear pump used for degassing wears out far more rapidly compared to the gear pump used for circulating dialysate through the dialyser. As mentioned above, the reason is the much higher flow rate necessary for recirculation of the dialysate to be degassed and the cavitation taking place inside the gear pump.

So one purpose of this invention is to provide a device for an extracorporeal treatment of a bodily fluid which is configured to adjust the speed of a degassing pump of a degassing means according to the degassing requirements of the extracorporeal treatment.

One further purpose of the invention is to provide a method for an extracorporeal treatment of a bodily fluid in which such a device is used.

This problem is to be solved by a device with the features of the independent claim 1. Advantageous embodiments of the device are shown in the dependent claims 2-9. Furthermore, this problem is to be solved by a method with the features of the independent claim 10. Advantageous embodiments of the method are shown in the dependent claims 11-15.

The invention provides a device for an extracorporeal treatment of a bodily fluid comprising a filter means arranged in a filter circuit for exchanging solute substances between the fluid and a liquid and at least one degassing means arranged in a degassing circuit for the liquid. Furthermore, the device comprises a control means that is configured to control the degassing means according to at least one operational parameter of the device.

Extracorporeal treatments of bodily fluids might incorporate hemodialysis, hemofiltration, hemodiafiltration and similar systems, e.g., systems able to treat blood or other bodily fluids extracorporeally by removing toxins by diffusion or convection and so the term dialysis machine is used exemplarily hereinafter.

A liquid incorporates water and aqueous solutions, e.g., dialysate for dialysis machines and the term dialysate is used exemplarily hereinafter.

Bodily fluids might incorporate not just blood but also other bodily fluids.

One embodiment of the device shows that the device is configured to determine the operational parameter comprising an ultrafiltration coefficient of the filter means, an ultrafiltration rate of an ultrafiltration pump arranged in the filter circuit and/or a pressure of the liquid.

Another embodiment of the device indicates that the degassing means comprises at least one flow restrictor comprising at least one orifice or at least one capillary, a degassing pump with an adjustable pump speed and at least one degassing valve operationally positioned parallel to the flow restrictor.

This positioning allows a degassing free operation during rinse and sterilize operation of the degassing and filter circuit.

In an advancement of the device the flow restrictor is configured as variable flow restrictor means and the device comprises at least two flow restrictor means which are configured as parallel flow restrictor circuits each comprising a flow restrictor and

at least one of these flow restrictor circuits comprising a valve being arranged in series with the flow restrictor.

A variable flow restrictor allows the adjustment of the negative degassing pressure independently of the pump speed of the degassing pump. So the degassing pump could operate at constant speed.

Another advancement of the device shows that the degassing valve comprises a degassing pump with an adjustable pump speed and at least one combined degassing valve that is configured to restrict the flow of the liquid and to degas the liquid comprising a movable plunger with a seal on one end as well as a stator with an axial bore for liquid outflow and with a slot on a sealing surface of the stator allowing a substantially reduced liquid pressure downstream of the combined degassing valve, if the plunger seal is in close contact with the sealing surface of the stator. Furthermore the combined degassing valve is provided with a first operational position allowing flow of the liquid through the combined degassing valve with a low flow resistance and with a second operational position allowing flow of the liquid through the combined degassing valve with a high flow resistance.

A further embodiment is characterized in that the device further comprises a degassing pressure sensor arranged between the flow restrictor and the degassing pump or between the combined degassing valve and the degassing pump.

The degassing pressure sensor controls the degassing pump in order to achieve a required negative pressure in the degassing circuit.

Another embodiment of the device indicates that the device comprises a primary degassing means arranged upstream of the filter means and a secondary degassing means arranged downstream of the filter means, and that the secondary degassing means comprises at least one air release chamber and at least one air release valve.

In an advancement of the device the air release chamber is so configured that a gas release volume of the air release chamber is derivable by the device and is usable as one of the operational parameters to control the primary degassing means.

In another advancement the air release valve is so configured that an operation frequency of the air release valve is derivable by the device and is usable as one of the operational parameters to control the primary degassing means.

Furthermore, the invention provides a method for an extracorporeal treatment of a bodily fluid using a device comprising a filter means arranged in a filter circuit for exchanging solute substances between the fluid and a liquid and at least one degassing means arranged in a degassing circuit for the liquid. This method comprises the step that a control means of the device controls the degassing means using at least one operational parameter of the device.

One embodiment of the method shows that the control means controls the degassing means in such a way that no substantial degassing might occur in the filter circuit while operating the degassing means at a minimum pump speed and/or power consumption of a degassing pump of the degassing means with an adjustable pump speed.

An advancement of the method indicates that the control means processes a function using an ultrafiltration coefficient of the filter means and an ultrafiltration rate of an ultrafiltration pump arranged in the filter circuit as operational parameters to pre-determine a function controlling the pump speed of the degassing pump.

Another advancement of the method indicates that the control means processes a function using a pressure of the liquid as operational parameter to pre-determine a function controlling the pump speed of the degassing pump.

A further advancement of the method indicates that the control means processes a function using an operational frequency derived from an air release valve of a secondary degassing means arranged downstream of the filter means to pre-determine a function controlling a pump speed of a degassing pump with an adjustable pump speed of a primary degassing means arranged upstream of the filter means.

Yet another advancement of the method indicates that the control means processes a function using a degassing gas release volume derived from an air release chamber of a secondary degassing means arranged downstream of the filter means to pre-determine a function controlling a pump speed of a degassing pump with an adjustable pump speed of a primary degassing means arranged upstream of the filter means.

The invention makes extracorporeal treatment of bodily fluids easier and more affordable. In the following the word hemodialysis is used for any of the above mentioned methods.

All advantages mentioned before as well as further advantages, specific characteristics and appropriate advancements of the invention will be obvious by means of exemplary embodiments which will be described hereinafter with reference to the figures.

The figures show:

Fig. 1a Degassing and dialysate or filter circuit;

Fig. 1b Alternative degassing circuit with multiple degassing valve circuits;

Fig. 1c Alternative degassing circuit with a combined degassing valve;

Fig. 2a Combined degassing valve in a closed or degassing position;

Fig. 2b Top of the stator of the combined degassing valve;

Fig. 2c Stator of the combined degassing valve in a 90° rotated view compared to fig. 2a;

Fig. 3 Combined degassing valve in an open or rinse position and

Fig. 4 Solubility of air as function of the temperature

Figure 1a shows exemplarily the relevant components of a degassing circuit (60) and a dialysate or filter circuit (50) of a dialysis machine utilizing balancing chambers 10, 20 for fluid balancing. Not shown are the extracorporeal circuit, the dialysate mixing components (i.e. the concentrate pumps), heating components and monitors not relevant for degassing control.

The degassing and dialysate circuit (50, 60) comprises a line 1, the chambers 2, 4, 6 usually having a cylindrical form, a flow restrictor 3 comprising an orifice or a capillary with a high flow resistance, a degassing pump 5 usually being a gear pump, a degassing valve 7, a check valve 9, the balancing chambers 10, 20 which are separated by a membrane (not numbered) into the compartments 11, 21 for fresh dialysate and the compartments 12, 22 for spent dialysate and the chamber valves 13, 14, 15, 16, 23, 24, 25 and 26. The degassing and dialysate circuit (50, 60) further comprises a dialyser or filter 30, a degassing pressure sensor 31, a flow pump 32 usually being a gear pump, a dialysate pressure sensor 33, an air release chamber 34 usually having a cylindrical form, a level sensor 35, an air release valve 36, a metering or ultrafiltration pump 38 usually being a membrane or piston pump and the drains 40, 40a.

The line 1, chambers 2, 4, 6, the flow restrictor 3, the degassing pump 5, the degassing valve 7, the check valve 9 as well as the degassing pressure sensor 31 form together the degassing circuit 60.

The balancing chambers 10, 20 with the compartments 11, 12, 21, 22 and the chamber valves 13-16, 23-26 the dialyser 30, the flow pump 32, the dialysate pressure sensor 33, the air release chamber 34, the level sensor 35 the air release valve 36, the ultrafiltration pump 38 and the drains 40, 40a form together the filter circuit 50.

The sensors 31, 33, 35, the pumps 5, 32, 38 as well as the valves 7, 9, 13, 14, 15, 16, 23, 24, 25, 26, 36 are active components of the degassing and dialysate circuit (50, 60). All these active components are connected to a control means (not shown) that takes input from external sources, e.g., a user interface or a central computer

(also not shown), that receives signals from the sensors 31, 33, 35 and that controls the active components. This control means may also comprise a storage means with data of available dialysers 30.

Fig. 1b shows exemplarily a degassing circuit 60' with two parallel degassing circuits each comprising a flow restrictor 3a, 3b and a degassing valve 7a, 7b arranged in series with the flow restrictors 3a, 3b. Both of these parallel degassing circuits are arranged in parallel with a degassing valve 7.

Using a dialysis machine a user either chooses a dialyser 30 from a list stored in the storage means of the control means or treatment data including the chosen type of dialyser is transferred from an external computer to the dialysis machine. If neither option is available the user can enter the dialyser data on-site through conventional means attached or integrated to/into the dialysis machine, e.g., a touch panel or a key board. A control program looks up the ultrafiltration coefficient of the dialyser (30) and the chosen ultrafiltration rate for the treatment and estimates the dialysate pressure. Based on this estimate the control program will adjust the degassing pump 5 to a pre-determined speed. The dialysate pressure – degassing pump speed function can be pre-determined by tests.

Alternatively to the degassing valve 7 and the flow restrictor 3 a combined degassing valve 100 for varying the degree of degassing is usable which incorporate the function of the degassing valve 7 and the flow restrictor 3. Fig. 1c shows exemplarily a degassing circuit 60" with a combined degassing valve 100 which replaces the degassing valve 7 and the flow restrictor 3 of the degassing and dialysate circuit (50, 60) as shown in Fig. 1a.

Figure 2a shows exemplarily the combined degassing valve 100 in a closed or degassing position. The combined degassing valve 100 comprises a housing 102 with an inlet 104 and an outlet 106 for fresh dialysate. Inside the housing 102 there is a stator 120 with an axial bore 122 and a small slot 124 at the top of the stator 120. A movable plunger 110 carries a seal 112 which, in the closed position, seals the stator bore 122 with the exception of the small slot 124 at the top of the stator 120.

Figure 2b shows exemplarily the top of the stator 120 of the combined degassing valve 100 with the slot 124.

Figure 2c shows exemplarily the stator 120 of the combined degassing valve 100 with the slot 124 in a 90° rotated view compared to figure 2a.

Figure 3 shows exemplarily the combined degassing valve 100 in an open or rinse position. The mechanism by which the plunger 110 is moved is not shown. Any conventional mechanism can be used. Typically used is a magnetic drive where the body of the plunger 110 consists of a magnetizable material and a coil is positioned outside the housing 102. The magnet is used to open the combined degassing valve 100 while the closed position is achieved with the help of a spring (not shown) between plunger 110 and housing 102.

By moving the plunger 110 from the closed position to the open position and back, the degree of degassing can be varied from maximum degassing to no degassing. The combined degassing valve 100 is designed such that it comprises a small passageway that serves as flow restrictor in the closed position of the valve. The combined degassing valve 100 can be opened whenever no degassing is required or wanted, e.g., during the cleaning cycle of the dialysate circuit (50). The combined degassing valve 100 can also be opened when the flow restricting passage is obstructed by a particle.

For persons skilled in the art and familiar with the design of valves it will be obvious that the principle can be applied to other designs.

Now, for a better understanding why degassing is necessary, figure 4 shows exemplarily the solubility of air as function of the temperature. Tap water used with dialysis machines is usually saturated with air. When the tap water is heated, air is not released immediately although the solubility decreases. Such water is called over saturated. It will degas spontaneously if it comes into contact with hydrophobic surfaces or with already existing gas nuclei. In a dialysate circuit (50) a dialyser 30 is the preferred point of degassing because of the large surface area and because most

modern membranes in dialysers 30 comprise hydrophobic and hydrophilic domains on the surface.

If air saturated water at 10°C is heated to 37°C, approximately 10Ncm³/l air (cm³ of air as measured at sea level per litre of water) are released at equilibrium and may be released in the dialysate circuit (50) if no degassing is done. At 37°C air saturated water contains approximately 14Ncm³/l air. The saturation volume in dialysate is about 5% lower. At 37°C the vapour pressure of water is approximately 50mmHg and the saturation pressure of air is approximately 700mmHg. When dialysate is exposed to negative pressure of -500mmHg the vapour pressure is still approximately 50mmHg which leaves approximately 200mmHg for the air with the result that only about 30% of the air remains in water or dialysate under equilibrium condition and 70% or 10Ncm³/l air is released.

The process of degassing, using the degassing and dialysate circuit 50, 60 as shown in Fig. 1a starts if water or fresh dialysate flows through the line 1 into the chamber 2. The degassing pump 5 sucks dialysate from the chamber 2 through the flow restrictor 3 into the chamber 4 by creating a negative pressure which causes partial degassing of the dialysate. During the filling of chamber 4 the degree of degassing depends on the position of the plunger 110 of the degassing valve 7 and might vary from maximum degassing to no degassing, whereby a maximum degassing is preferred. Gas bubbles rise in chamber 4 and are pumped together with the dialysate into chamber 6 in which the gas bubbles rise to the top. After this, degassed dialysate flows to the pair of balancing chambers 10, 20. While one of these chambers 10, 20 is filled with fresh dialysate, the dialysate from the other chamber 10, 20 is circulated through the dialyser 30.

The degassing pump 5, the flow restrictor 3 as well as the degassing valve 7 together form a primary degassing means.

In this example fresh dialysate may flow through the chamber valve 13 into the compartment 11 of the balancing chamber 10. This moves the separating membrane in this balancing chamber 10 expelling spent dialysate in the compartment 12 through the chamber valve 16 to the drain 40. When the compartment 11 is

completely filled, the pressure in the chamber 6 rises, the check valve 9 opens and dialysate from the chamber 6 including gas bubbles is recirculated back to the chamber 2 where the gas rises to the top and is released through an opening at the top of the chamber 2. Typically fresh dialysate is recirculated three times through this loop in order to achieve a gas pressure equivalent to a saturation pressure at –500mmHg.

While the balancing chamber 10 is filled with fresh dialysate, dialysate from the already filled balancing chamber 20 is circulated by the flow pump 32 from the compartment 21 through the chamber valve 25, the dialyser 30, an air release chamber 34 and the chamber valve 24 back to the compartment 22 of the balancing chamber 20. The Ultrafiltration pump 38 pumps spent dialysate from this closed circuit resulting in a negative pressure relative to the blood side of the dialyser 30 which causes ultrafiltration of blood water through the membranes of the dialyser 30 to the dialysate side of the dialyser 30.

The ultrafiltration pump rate of the ultrafiltration pump 38 is chosen by an operator of the dialysis machine and is typically between 300 and 1000ml/h depending on the intradialytic weight gain of the patient. If gas is set free in this circuit, gas bubbles will rise to the top of the air release chamber 34 and accumulate there. The decreasing fluid level in the air release chamber 34 is detected by the level sensor 35 and the control unit opens the air release valve 36 for a short period of time to release gas to the drain 40. The pressure downstream of the dialyser 30 is measured by the dialysate pressure sensor 33. During a treatment the dialysate pressure is recorded continuously so that the degassing pump 5 is controllable accordingly.

The air release chamber 34, the level sensor 35 and the air release valve 36 together form of a secondary degassing means.

According to the invention the degassing pump 5 is controlled such that the saturation pressure of the dialysate is always somewhat lower (typically 10 to 100mmHg lower) than the dialysate pressure measured by dialysate pressure sensor 33. This is done by calculating the expected dialysate pressure from the ultrafiltration

coefficient of the dialyser 30, the adjusted ultrafiltration rate of the ultrafiltration pump 38 and the expected blood pressure on the blood side of the dialyser 30.

While the ultrafiltration coefficient is a feature of the used dialyser 30 and can be taken from the manufacturers data sheet, the ultrafiltration rate is prescribed for the specific treatment. The blood side pressure is a function of the blood pump rate, the type of blood access device used and the patients hematocrit. It is measured in the extracorporeal circuit (not shown) and usually called 'venous pressure'. The blood side pressure changes very little from treatment to treatment for a specific patient. For a first estimate before start of dialysis it can be taken from the log sheet of the previous treatment.

A typical example of a low-flux dialyser (a dialyser with a low ultrafiltration coefficient) has following specification:

Blood side pressure BSP	= 200 mmHg
Ultrafiltration coefficient UFK	= 5 ml/(hr*mmHg)
Ultrafiltration rate UFR	= 1000 ml/hr

Now, to calculate the transmembrane pressure TMP following formula is used:

$$TMP = UFR/UFK \text{ [mmHg]}$$

and to calculate the dialysate pressure DP following formula is used:

$$DP = BSP - TMP \text{ [mmHg]}$$

So, based on the parameters above, the resulting transmembrane pressure TMP amounts to 1000/5 = 200 mmHg and the resulting dialysate pressure DP amounts to 200 – 200 = 0 mmHg.

Using a high-flux dialyser (a dialyser with a high ultrafiltration coefficient) with an ultrafiltration coefficient UFK = 40 ml/(hr*mmHg), the calculation results in a

transmembrane pressure TMP = 1000/40 = 25 mmHg and in a dialysate pressure DP = 200 – 25 = 175 mmHg.

The degassing pump 5 is controlled according to a predetermined function which is evaluated for every type of degassing system and which is stored in the control means. In a popular dialysis machine degassing to a saturation pressure of -500mmHg (at sea level) is achieved by recirculating the dialysate twice.

To achieve a net dialysate flow of 500ml/min it is necessary to operate the degassing pump 5 at approximately 1500 ml/min flow. For the high-flux dialyser example no degassing of the incoming dialysate below the saturation point at 37°C is required. Nevertheless some recirculation will be required in the embodiment used in the most popular machines and described here in order to release the accumulated gas. At this point the degassing pump 5 will be operated typically 1.2 times faster than the flow pump 32.

Instead of using a calculated dialysate pressure the pressure measured by the dialysate pressure sensor 33 can be used to control the degassing pump 5. The degassing pump 5 could be controlled according to a pre-determined function or, if a degassing pressure sensor 31 is used, the degassing pump 5 will be controlled such that the degassing pressure is always lower than the dialysate pressure (typically 20-100 mmHg). Because it takes a while until the dialysate pressure reaches its equilibration value, the degassing control could start with the estimated pressure first.

In order to get the maximum savings in energy and pump lifetime the speed of degassing pump 5 could be set to the lowest level if the dialysate pressure is above atmospheric pressure which is always the case if high-flux dialysers are used. In this case it may happen that the dialysate is still over saturated especially in winter when the water temperature is low and the water is very cold and saturated with air in some regions of the world. Degassing will occur inside the dialyser 30 because of the large surface area providing nuclei for degassing. This gas will be collected in the air release chamber 34 and will eventually be detected by the level sensor 35 and subsequently released to the drain 40.

But, in order to avoid degassing of the dialysate in the degassing and dialysate circuit (50, 60) at start, the system may start with the maximum speed of the degassing pump 5 and allow control of the degassing pump 5 only after the dialysate pressure has stabilised which is usually the case a few minutes after the blood flow and ultrafiltration have been established.

The amount of gas released is a function of the geometry of the air release chamber 34, especially of the volume between top of the air release chamber 34 and the level sensor 35, and the pressure in the air release chamber 34. Gas release per hour can be estimated by multiplying the amount released by a single gas release event multiplied by the number of gas releases. This amount can be used as input parameter for controlling the degassing pump 5. For a known geometry the frequency of gas release, e.g., more often than ones per half hour, can be used. If this happens, degassing will be set to a higher level by increasing the speed of the degassing pump 5. If another system is used for gas release downstream of the dialyser 30 a different parameter appropriate for indicating secondary degassing quantity might be used.

Now, if a user wants to use a dialysis machine, he either chooses a dialyser 30 from a list stored in the storage means or treatment data including the chosen type of dialyser 30 is transferred from an external computer to the dialysis machine. If neither option is available the user can enter the dialyser data on-site through conventional means attached or integrated to/into the dialysis machine, e.g., a touch panel or a key board. A control program looks up the ultrafiltration coefficient of the dialyser 30 and the chosen ultrafiltration rate for the treatment and estimates the dialysate pressure. Based on this estimate the control program will adjust the degassing pump 5 to a pre-determined speed. The dialysate pressure – degassing pump speed function can be pre-determined by tests.

For persons skilled in the art it will be obvious that the above described principle for the filter and degassing circuit 50, 60 can be applied to a degassing circuit 50, 60' as shown in Fig. 1b as well as a degassing circuit 50, 60" as shown in Fig. 1c, too.

Although the invention was described in the figures as well as in the preceding description in detail, all embodiments are illustrative respectively exemplarily and are not understandable restrictively. In particular the invention is not limited to the explained embodiments. Further variations of the invention and its embodiments are obvious to a person skilled in the art based on the above disclosure, the figures as well as the patent claims.

Used terms in the patent claims like comprise, consist, contain, include and the like do not exclude further elements, components or steps. Furthermore, the use of indefinite articles does not exclude plural. One single means might be able to carry out the functions of several means mentioned in the patent claims.

Declared reference numerals in the patent claims are not to be seen as a limitation of the used means and steps.

Reference numerals:

1 line
2 chamber
3, 3a, 3b flow restrictor
4 chamber
5 degassing pump
6 chamber
7, 7a, 7b degassing valve
9 check valve
10 balancing chamber
11, 12 compartments
13, 14, 15, 16 chamber valves
20 balancing chamber
21, 22 compartments
23, 24, 25, 26 chamber valves
30 dialyser or filter
31 degassing pressure sensor
32 flow pump
33 dialysate pressure sensor
34 air release chamber
35 level sensor
36 air release valve
38 ultrafiltration or dialysate pump
40, 40a drain
50 degassing circuit
60, 60', 60" filter or dialysate circuit

100 combined degassing valve
102 housing
104 inlet
106 outlet
110 plunger
112 seal

120 stator

122 axial bore

124 slot

Claims:

1. A device for an extracorporeal treatment of a bodily fluid comprising a filter means (30) arranged in a filter circuit (50) for exchanging solute substances between the fluid and a liquid and at least one degassing means arranged in a degassing circuit (60, 60', 60") for the liquid,
characterized in,
that the device further comprises a control means that is configured to control the degassing means according to at least one operational parameter of the device.

2. The device according to Claim 1, whereby the device is configured to determine the operational parameter comprising an ultrafiltration coefficient of the filter means (30), an ultrafiltration rate of an ultrafiltration pump (38) arranged in the filter circuit (50) and/or a pressure of the liquid.

3. The device according to Claim 1 or 2, whereby the degassing means comprises at least one flow restrictor (3) comprising at least one orifice or at least one capillary, a degassing pump (5) with an adjustable pump speed and at least one degassing valve (7) operationally positioned parallel to the flow restrictor (3).

4. The device according to Claim 3, whereby the flow restrictor (3) is configured as variable flow restrictor means and whereby the device comprises at least two flow restrictor means which are configured as parallel flow restrictor circuits each comprising a flow restrictor (3) and at least one of these flow restrictor circuits comprising a valve being arranged in series with the flow restrictor (3).

5. The device according to Claim 1 or 2, whereby the degassing means comprises a degassing pump (5) with an adjustable pump speed and at least one combined degassing valve (100) that is configured to restrict the flow of the liquid and to degas the liquid comprising a movable plunger (110) with a seal (112) on one end as well as a stator (120) with an axial bore (122) for liquid outflow and with a slot (124) on a sealing surface of the stator (120) allowing a substantially reduced liquid pressure downstream of the combined degassing

valve (100), if the plunger seal (124) is in close contact with the sealing surface of the stator (120) and that is provided with a first operational position allowing flow of the liquid through the combined degassing valve (100) with a low flow resistance and with a second operational position allowing flow of the liquid through the combined degassing valve (100) with a high flow resistance.

6. The device according to one of the previous Claims, whereby the device further comprises a degassing pressure sensor (31) arranged between the flow restrictor (3) and the degassing pump (5) or between the combined degassing valve (100) and the degassing pump (5).

7. The device according to one of the previous Claims, whereby the device comprises a primary degassing means arranged upstream of the filter means (30) and a secondary degassing means arranged downstream of the filter means (30), and whereby the secondary degassing means comprises at least one air release chamber (34) and at least one air release valve (36).

8. The device according to Claim 7, whereby the air release chamber (34) is so configured that a gas release volume of the air release chamber (34) is derivable by the device and is usable as one of the operational parameters to control the primary degassing means.

9. The device according to Claim 7, whereby the air release valve (36) is so configured that an operation frequency of the air release valve (36) is derivable by the device and is usable as one of the operational parameters to control the primary degassing means.

10. A method for an extracorporeal treatment of a bodily fluid using a device comprising a filter means (30) arranged in a filter circuit (50) for exchanging solute substances between the fluid and a liquid and at least one degassing means arranged in a degassing circuit (60, 60', 60") for the liquid,
characterized in,
that a control means of the device controls the degassing means using at least one operational parameter of the device.

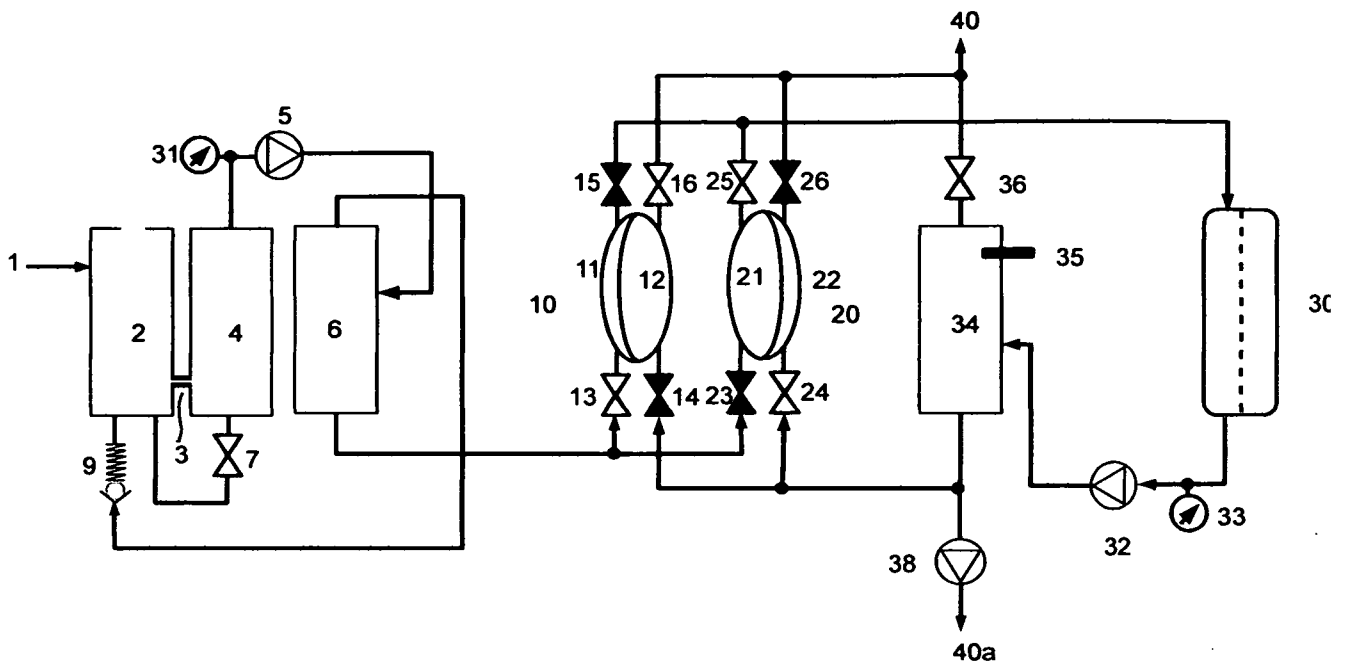
11. The method according to Claim 10, whereby the control means controls the degassing means in such a way that no substantial degassing might occur in the filter circuit while operating the degassing means at a minimum pump speed and/or power consumption of a degassing pump (5) of the degassing means with an adjustable pump speed.

12. The method according to Claim 11, whereby the control means processes a function using an ultrafiltration coefficient of the filter means (30) and an ultrafiltration rate of an ultrafiltration pump (38) arranged in the filter circuit (50) as operational parameters to pre-determine a function controlling the pump speed of the degassing pump (5).

13. The method according to Claim 11, whereby the control means processes a function using a pressure of the liquid as operational parameter to pre-determine a function controlling the pump speed of the degassing pump (5).

14. The method according to Claim 11, whereby the control means processes a function using an operational frequency derived from an air release valve of a secondary degassing means arranged downstream of the filter means (30) to pre-determine a function controlling a pump speed of a degassing pump (5) with an adjustable pump speed of a primary degassing means arranged upstream of the filter means (30).

15. The method according to Claim 11, whereby the control means processes a function using a degassing gas release volume derived from an air release chamber of a secondary degassing means arranged downstream of the filter means (30) to pre-determine a function controlling a pump speed of a degassing pump (5) with an adjustable pump speed of a primary degassing means arranged upstream of the filter means (30).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32
38
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Fig. 1a

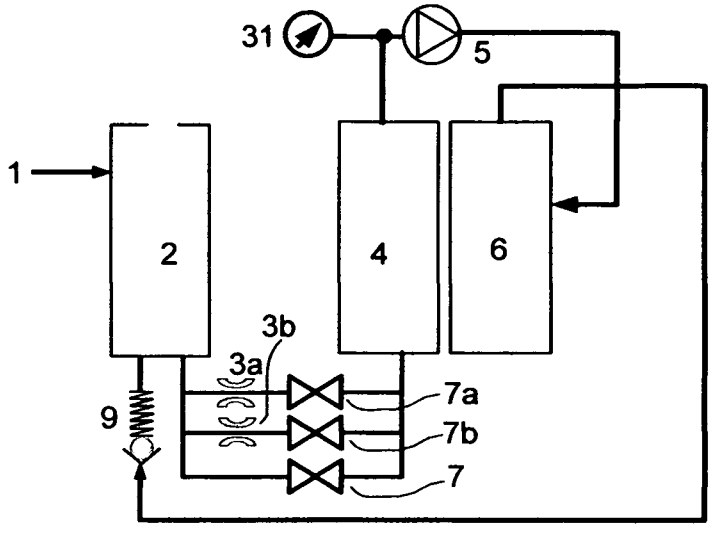

Fig. 1b

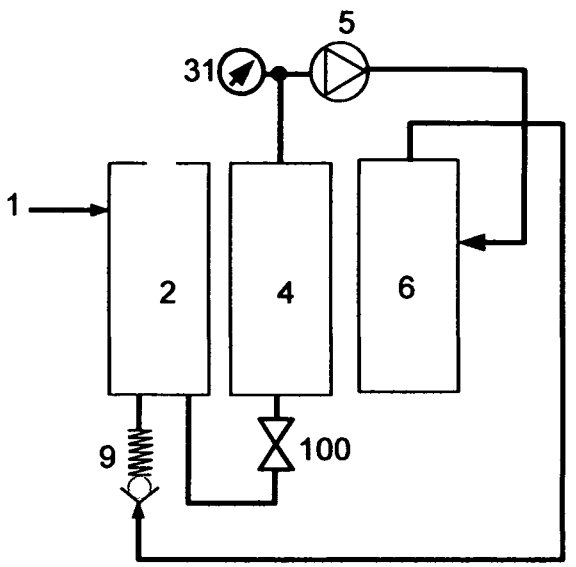

Fig. 1c

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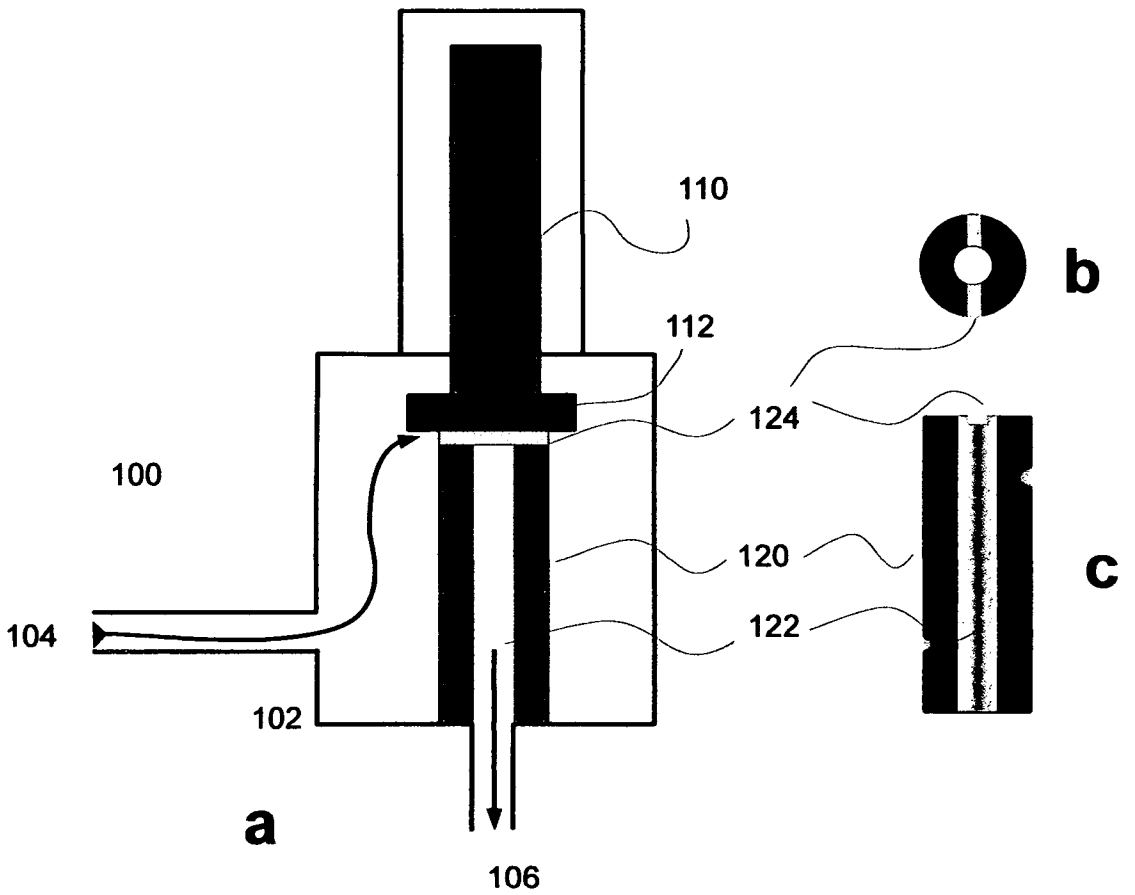

Fig. 2a, 2b, 2c

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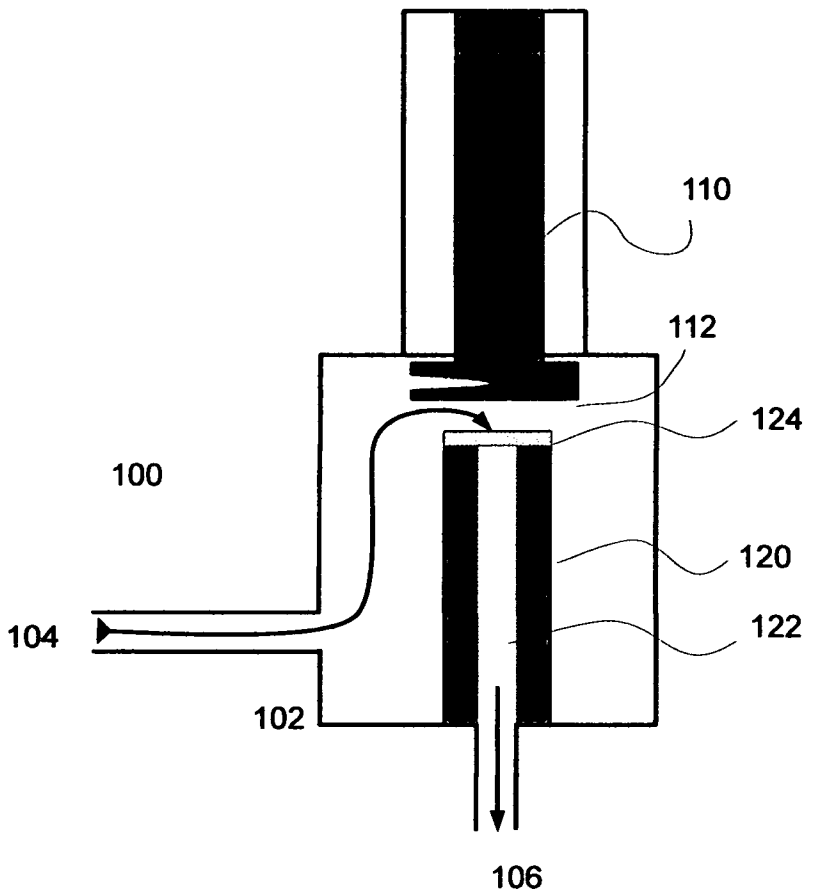

Fig. 3

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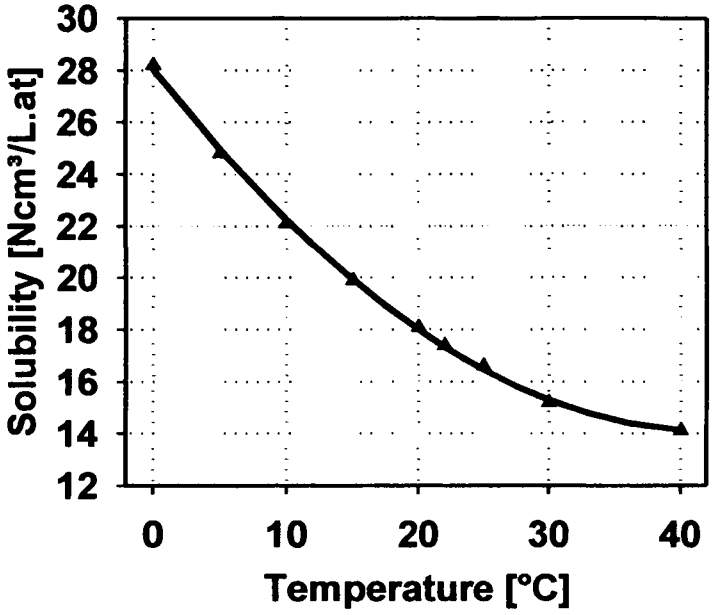
Solubility [Ncm³/L.at]
30
28
26
24
22
20
18
16
14
12
0
10
20
30
40
Temperature [°C]

Fig. 4

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2011/005222

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M1/36 F04C15/00
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)
F04C A61M A61B

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2008/125893 A1 (GAMBRO LUNDIA AB [SE]; FAVA MASSIMO [IT]; SUFFRITTI MAURO [IT]; SCAGLI) 23 October 2008 (2008-10-23) paragraphs [0023] - [0024]; figure 1	1-9
X	US 5 584 806 A (AMANO NOBUHIKO [JP]) 17 December 1996 (1996-12-17) column 3, lines 28-39; figures 1,6	1-9
X	US 2004/084371 A1 (KELLAM BENJAMIN A [US] ET AL) 6 May 2004 (2004-05-06) paragraph [0062]; figures 1-3	1-9
X	DE 100 11 208 C1 (FRESENIUS MEDICAL CARE DE GMBH [DE]) 27 September 2001 (2001-09-27) column 7, lines 38-49; figure 1	1-9

☐ 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 document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
16 February 2012	06/03/2012

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, Fax: (+31-70) 340-3016	Westsson, David

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/EP2011/005222

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2008125893 A1	23-10-2008	AU 2007350967 A1	23-10-2008
		CA 2683051 A1	23-10-2008
		CN 101678161 A	24-03-2010
		EP 2142234 A1	13-01-2010
		WO 2008125893 A1	23-10-2008
US 5584806 A	17-12-1996	NONE	
US 2004084371 A1	06-05-2004	AU 2003284063 A1	03-06-2004
		US 2004084371 A1	06-05-2004
		WO 2004043520 A1	27-05-2004
DE 10011208 C1	27-09-2001	NONE	

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP2011/005222

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

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

1. [X] Claims Nos.: 10-15
because they relate to subject matter not required to be searched by this Authority, namely:

see FURTHER INFORMATION sheet PCT/ISA/210

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

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

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

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

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

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

Remark on Protest

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

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

[ ] No protest accompanied the payment of additional search fees.

Continuation of Box II.1

Claims Nos.: 10-15

Claims 10-15 refer to a method for treatment of the human or animal body by therapy and surgery, which is against Rule 39.1(iv) PCT and Rule 67.1(iv). The reason is that although not explicitly mentioned in the claims, it is clear from the description [p.13 paragraph 2] that the method is intended to be performed on a patient, implicitly comprising steps of withdrawing and treating blood from said patient.