

(12) **United States Patent**
Delnevo et al.

(10) **Patent No.:** **US 7,314,554 B2**
(45) **Date of Patent:** **Jan. 1, 2008**

(54) **EXTRACORPOREAL BLOOD TREATMENT MACHINE**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 383 days.

(21) Appl. No.: **10/771,377**

(22) Filed: **Feb. 5, 2004**

(65) **Prior Publication Data**

US 2005/0011823 A1 Jan. 20, 2005

Related U.S. Application Data

(60) Provisional application No. 60/469,839, filed on May 13, 2003.

(30) **Foreign Application Priority Data**

Feb. 7, 2003 (IT) MI03A0212

(51) **Int. Cl.**

B01D 61/28 (2006.01)

B01D 61/24 (2006.01)

B01D 61/32 (2006.01)

A61M 1/14 (2006.01)

(52) **U.S. Cl.** **210/258**; 210/85; 210/87; 210/90; 210/96.1; 210/97; 210/134; 210/143; 210/252; 210/257.1; 210/258; 210/321.6; 210/321.65; 210/416.1; 210/436; 210/472; 604/4.01; 604/5.01; 604/6.07; 604/6.09; 604/6.1; 604/6.11; 604/65; 604/67

(58) **Field of Classification Search** 210/85, 210/87, 90, 96.1, 97, 134, 143, 252, 257.1, 210/257.2, 258, 321.6, 321.65, 321.71, 416.1, 210/433.1, 436, 472; 604/4.01, 5.01, 6.07, 604/6.09, 6.1, 6.11, 65, 66, 67
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

3,909,045 A 9/1975 Meagher 285/22
(Continued)

FOREIGN PATENT DOCUMENTS

AU 744404 1/1999
(Continued)

OTHER PUBLICATIONS

International Search Report for International Application No. PCT/IB2004/000104.

(Continued)

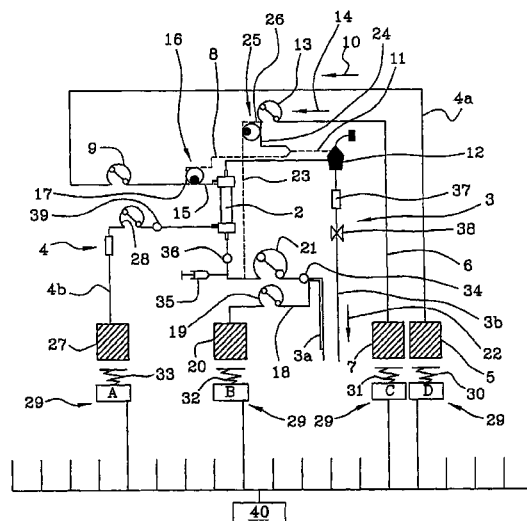
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(57) **ABSTRACT**

The invention relates to an extracorporeal blood treatment machine in which a blood circuit (3) is equipped with an inlet line leading to a filtration unit (2) and with an outlet line (3b) from the filtration unit; a fluid circuit comprises an inlet line (4a) leading to the filtration unit and an outlet line (4b) from the filtration unit so as to allow a fluid taken from a primary container (5) to circulate within the filtration unit, thus enabling the treatment of the patient's blood. There is further an infusion line (6) acting on the outlet line of the blood circuit, which is supplied by an auxiliary fluid container (7). The inlet line of the fluid circuit is equipped with at least an infusion branch (8) acting on the outlet line of the blood circuit so as to enable the intensive therapy machine to manage therapies with large exchange of fluids.

48 Claims, 3 Drawing Sheets



U.S. PATENT DOCUMENTS

4,009,107	A	2/1977	Miller et al.	210/321 B
4,263,808	A	4/1981	Bellotti et al.	73/714
4,379,452	A	4/1983	DeVries	604/6
4,424,009	A	1/1984	van Os	417/394
4,436,620	A	3/1984	Bellotti et al.	210/90
4,526,515	A	7/1985	DeVries	417/63
4,637,813	A	1/1987	DeVries	604/6
4,844,810	A	7/1989	Richalley et al.	
4,871,012	A	10/1989	Kuo	165/41
4,886,431	A	12/1989	Soderquist et al.	417/477
4,950,245	A	8/1990	Brown et al.	604/153
5,311,908	A	5/1994	Barone et al.	
5,366,630	A	11/1994	Chevallet	210/645
5,427,509	A	6/1995	Chapman et al.	417/477.2
5,462,416	A	10/1995	Dennehey et al.	417/477.2
5,482,440	A	1/1996	Dennehey et al.	417/63
5,641,144	A	6/1997	Hendrickson et al. .	248/292.13
5,698,090	A *	12/1997	Bene et al.	210/85
5,714,060	A	2/1998	Kenley et al.	210/194
5,722,399	A *	3/1998	Chevallet et al.	600/485
5,910,252	A *	6/1999	Truitt et al.	210/645
5,983,947	A	11/1999	Utterberg	138/89
6,277,277	B1	8/2001	Jacobi et al.	210/240
6,308,721	B1	10/2001	Bock et al.	134/166 R
6,325,775	B1	12/2001	Thom et al.	604/6.02
6,730,233	B2 *	5/2004	Pedrazzi	210/739
6,814,864	B1 *	11/2004	Favre et al.	210/321.65

FOREIGN PATENT DOCUMENTS

AU	199870078	A1	1/1999
AU	199870078	B2	1/1999
EP	0 134 436	B1	1/1988
EP	0 256 956	B1	2/1988
EP	0 116 596	B1	11/1990
EP	0 282 539	B1	1/1992
EP	0 611 227	A1	8/1994

EP	0 643 808	B1	1/1998
EP	0 695 397	B1	9/1998
EP	0 887 100	A1	12/1998
EP	0 893 603	A2	1/1999
EP	0 694 125	B1	2/1999
EP	0 686 237	B1	5/1999
EP	0 992 256	A2	4/2000
EP	0 679 099	B1	7/2001
EP	0 852 953	B1	11/2001
GB	2 076 476	A	12/1981
GB	2 110 564		6/1983
GB	2 208 896	A	4/1989
WO	WO 80/02376		11/1980
WO	WO 88/01895		3/1988
WO	WO 95/17597		6/1995
WO	WO 95/17598		6/1995
WO	WO 95/17599		6/1995
WO	WO 95/17600		6/1995
WO	WO 95/17601		6/1995
WO	WO 95/17602		6/1995
WO	WO 95/17603		6/1995
WO	WO 95/17604		6/1995
WO	WO 97/02056		1/1997
WO	WO 97/10436		3/1997
WO	WO 98/22163		5/1998
WO	WO 99/13926		3/1999
WO	WO 00/06292		2/2000
WO	WO 01/08722		2/2001
WO	WO 01/08772	A2	2/2001
WO	WO 02/26288	A2	4/2002
WO	WO 02/062454		8/2002

OTHER PUBLICATIONS

English language abstract of EP 0 877 100 A1, Thomson Derwent.
International Search Report for International Application No. PCT/
IB2004/000062.

* cited by examiner

FIG 1

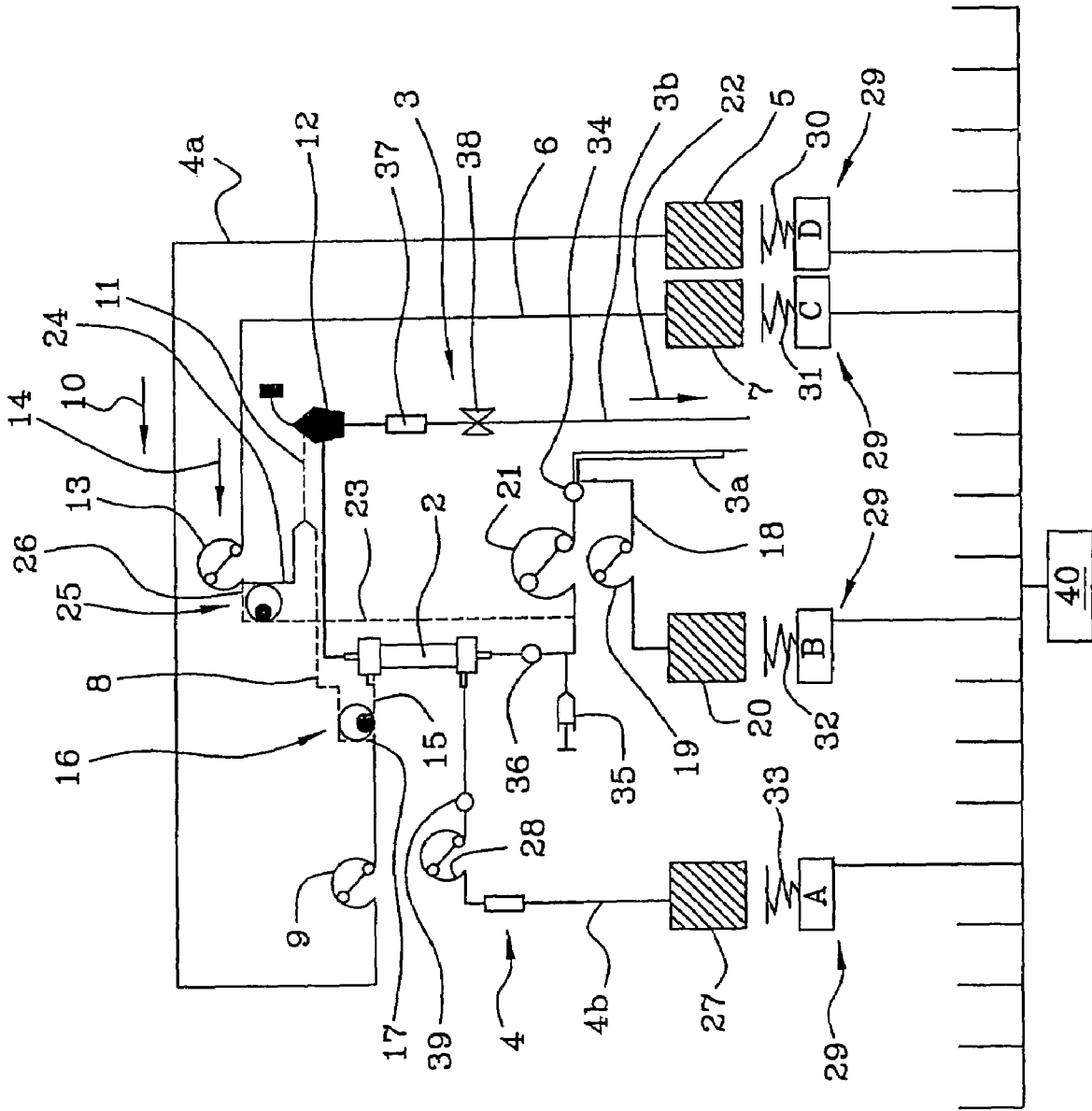


FIG 2

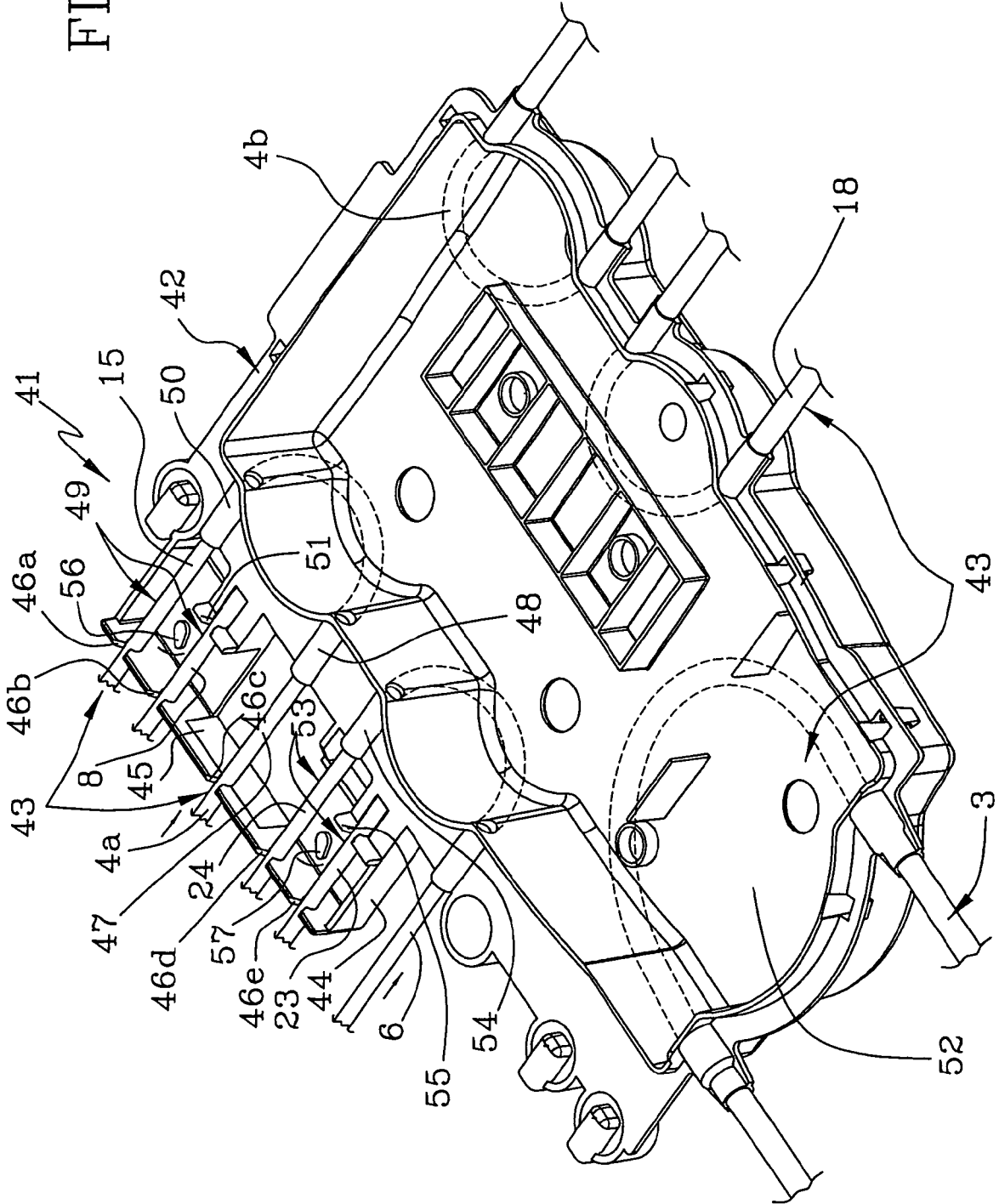
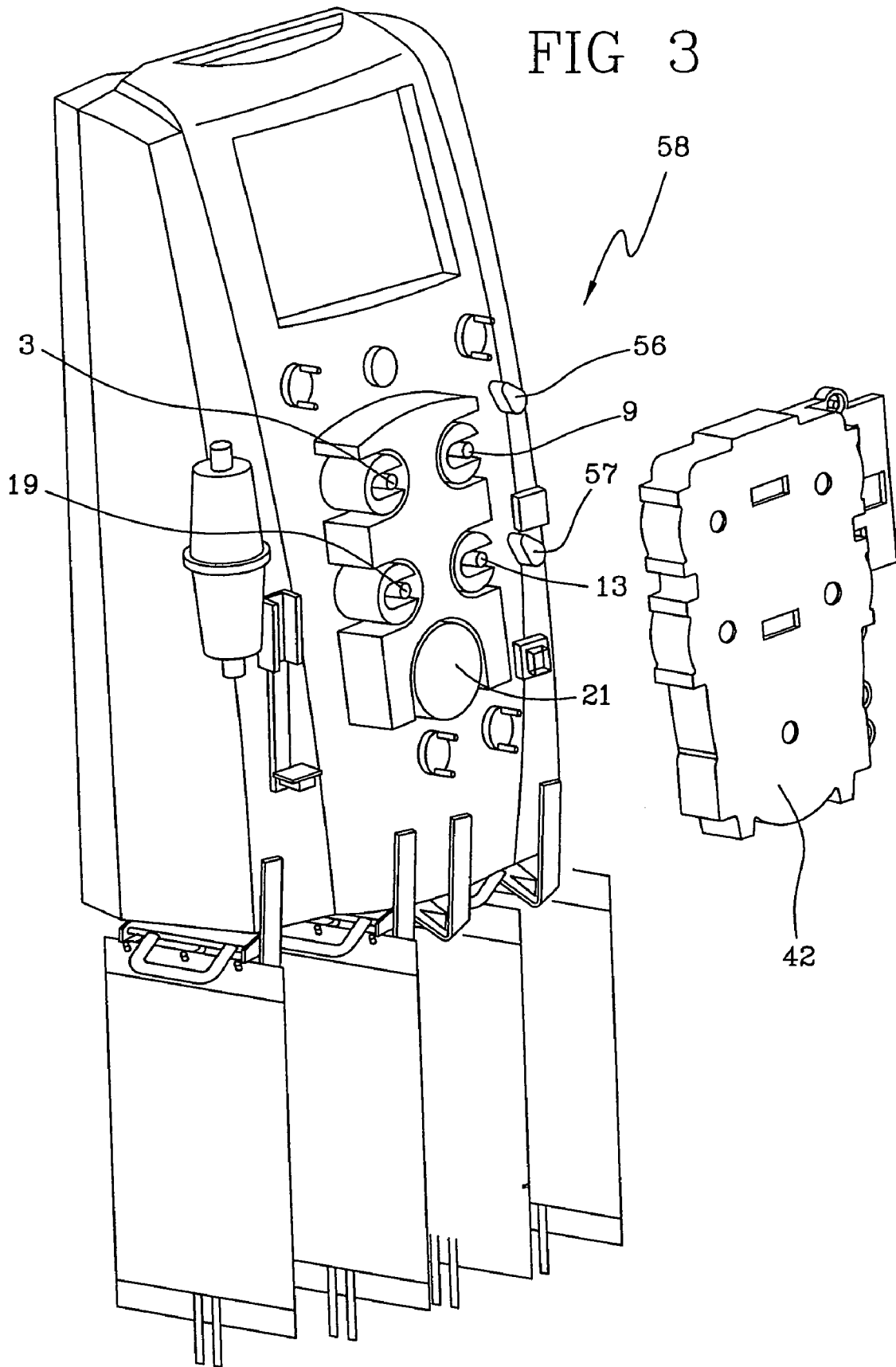


FIG 3



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EXTRACORPOREAL BLOOD TREATMENT MACHINE

CROSS REFERENCE TO RELATED APPLICATIONS

This application claims the priority of Italian Patent Application No. MI2003 A 000212, filed on Feb. 7, 2003, and the benefit of U.S. Provisional Application No. 60/469,839, filed May, 13, 2003, the contents of which are incorporated herein by reference.

BACKGROUND OF THE INVENTION

The present invention relates to an extracorporeal blood treatment machine and to an integrated treatment module that can be used on said machine.

The object of the invention can be used for instance in intensive therapy machines which can carry out a plurality of different blood treatments.

Extracorporeal treatments generally consists in taking blood from the patient, in treating said blood when it is outside the patient's body and then in re-circulating the blood thus treated.

The treatment typically consists in removing from the blood unwanted and/or dangerous substances, as well as excess liquid in patients who cannot autonomously carry out said operations, such as for instances patients suffering from temporary or permanent kidney problems.

For instance, it may be necessary to add or remove substances from blood, to keep a correct acid/base ratio or also to remove fluid excess from the body.

The extracorporeal treatment is generally obtained by removing blood from the patient, by letting the blood flow within a filtration unit where a semipermeable membrane ensures the exchange of suitable substances, molecules and fluids.

Generally though not necessarily, said exchange is carried out by letting a given biological fluid ensuring the aforesaid exchanges pass in counter-current and within a secondary chamber of the filtration unit.

It should be noted that currently used machines can enable different types of blood treatment.

In the ultrafiltration treatment the substances and fluids to be eliminated are removed by convection from the blood, pass through the semipermeable membrane and are led towards the aforesaid secondary chamber.

In hemofiltration treatments part of the molecules, substances and fluids present in the blood pass through the membrane by convection as in the ultrafiltration treatment, although further necessary elements are added to the blood; typically a suitable fluid is infused directly into the blood before or after the latter passes through the filtration unit and anyhow before it is carried back into the patient.

In haemodialysis treatments a fluid containing material to be transferred into the blood is introduced into the secondary chamber of the filtration unit. The unwanted material flows through the semipermeable membrane from the blood into the secondary fluid and the desired substances/molecules from the secondary fluid can pass through the membrane as far as the blood.

In hemodiafiltration treatments the blood and the secondary fluid exchange their respective substances/molecules as in haemodialysis and, in addition, a fluid is infused into the blood as in hemofiltration treatments.

Obviously, in order to carry out each of said extracorporeal blood treatments, the blood has to be removed from a

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patient's vein or artery, suitably circulated in the machine and then re-introduced into the patient.

As is also known, blood treatment machines for intensive therapy have to be ready as fast as possible for an immediate use for any possible emergency.

Obviously, to this purpose the machine must not require either preliminary sanitizing operations or long pre-assembling operations of the various components for the various therapies.

As is known, intensive therapy machines are present on the market and are currently used, in which a blood circuit comprises a line for taking blood from the patient, which carries said blood to a filtration cartridge, and an outlet line from the filtration cartridge, which carries the treated blood back into the patient's body.

The machine is then equipped with a circuit for the passage of dialysis fluid; also said circuit has an intake line leading into the filtration unit, which is supplied by a sterile bag containing the dialysis liquid, and has also an outlet line enabling the passage of a fluid which has received by convection/diffusion the dangerous substances and molecules from the blood towards a collection bag for their subsequent removal.

Said machine is further equipped with an infusion line allowing with suitable doses—to transfer directly into the blood upstream from the filtration unit the content of another liquid bag, thus adding the necessary products into the blood.

A known intensive therapy machine is further equipped with a suitable syringe containing for instance heparin as blood anticoagulant, the latter being added to the blood taken from the patient so as to avoid the creation of dangerous clots within the circuit.

The structure and circuitry mentioned above are generally defined by a single integrated module attached to the machine body.

It is evident that in order to enable the immediate use of the machine, the fluid bags referred to above have to be present and already sterile, so as to be directly and easily connected to their respective tubes, the latter also being sterile and disposable.

The machine is further equipped with a suitable control unit managing the flow of fluids by means of suitable peristaltic pumps and respective sensors associated to the circuit.

It is evident that by suitably setting the control unit said machine can selectively carry out one or more of the extracorporeal blood treatments described above (i.e. ultrafiltration, haemofiltration, haemodialysis and haemodiafiltration).

The machine described above, though being today quite a vanguard device for extracorporeal blood treatments in intensive therapies, has proved to be susceptible of several improvements.

In particular, a first intrinsic drawback in intensive therapy machines is related to the limited availability of fluids for operations involving the exchange of substances by convection/diffusion within the filter and for pre- or post-infusions into the blood line.

Said limitation is obviously related to the necessary use of prepackaged sterile fluid bags typically containing 6 kg of dialysis liquid.

It is evident that the pre-established fluid amount to be used imposes some limitations, in particular in the case of therapies with large exchange of fluids, which would sometimes be extremely suitable in emergency cases.

On the other hand, it is not possible to use larger fluid amounts in intensive therapies since suitably treated water taken from the water network cannot be used as exchange fluid in short times; indeed, this would involve long operations for installing the devices for in-line preparation of sterile liquids; moreover, it is not possible to use bags with higher amounts of liquids due to the obvious problems involving transport and management of said containers by the personnel.

Another problem of known intensive therapy machines consists in achieving an optimal management of the administration of anticoagulant substances which are necessary for a good working of the machine.

In particular, today known intensive therapy machines cannot manage effectively the use of regional anticoagulation methods, such as for instance citrate-based methods, since the use of said techniques requires the administration of further solutions recovering the blood ion balance before carrying the treated blood back into the patient's body.

SUMMARY OF THE INVENTION

Under these circumstances the present invention aims at solving basically all the drawbacks referred to above.

A first technical aim of the invention is to provide physicians with the possibility to manage therapies with large exchange of fluids using an intensive therapy machine where, in any case, fluids are housed in small-size containers.

A further aim of the present invention is to be able to manage intensive therapies by using regional anticoagulation techniques, i.e. acting on the blood only in the extracorporeal circuit, without having to limit pre-infusion upstream from the filtration unit.

Moreover, an aim of the present invention is to enable the substantial separation of the use of regional anticoagulation techniques from the infusion of fluids for carrying out the necessary therapeutic exchange (by convection or diffusion).

Finally, an auxiliary aim of the present invention is to provide an machine ensuring quite simple and reliable loading and installing operations, further enabling the complete control of the therapy cycles that are carried out.

These and other aims, which shall be evident in the course of the present description, are basically achieved by an extracorporeal blood treatment machine as described in the appended claims.

Further characteristics and advantages will be clearer from the detailed description of a preferred though not exclusive embodiment of an extracorporeal blood treatment machine according to the present invention.

BRIEF DESCRIPTION OF THE DRAWINGS

This description will be given below with reference to the appended tables, which are provided as a mere guidance and are therefore not limiting, in which:

FIG. 1 shows schematically a hydraulic circuit to be used in an intensive therapy machine in accordance with the present invention;

FIG. 2 shows an integrated module comprising a support element and a portion of the fluid distribution circuitry, to be used in intensive therapy machines in accordance with the present invention; and

FIG. 3 shows an machine body in accordance with the invention.

DETAILED DESCRIPTION

With reference to the figures mentioned above, the numeral **1** globally refers to a machine for extracorporeal blood treatment, in particular for intensive therapies.

As can be inferred from the appended table **1**, the machine consists of a blood circuit **3**, which takes blood from a patient, for instance by means of a catheter introduced into a vein or artery of said patient, and through at least an inlet line **3a** takes said blood, for instance continuously, to a filtration unit **2**.

Then the blood passes through a primary chamber of said filtration unit **2** and through an outlet line **3b** the treated blood is carried back to the patient.

The connection with an auxiliary pre-infusion line **18** is provided immediately downstream from the blood collecting zone on the inlet line **3a**.

In particular, the machine is equipped with at least a secondary fluid container or bag **20** for supplying the pre-infusion line **18**; by using corresponding means for conveying fluid, in the example shown comprising an auxiliary pre-infusion pump **19**, for instance a peristaltic pump, it is possible to control the fluid flow within said line by introducing said fluid directly into the blood by means of a direct connection to the inlet line **3a**.

Generally, the secondary fluid container **20** can house a suitable biological fluid for a pre-infusion, however said bag **20** can also contain an anticoagulant, generally causing a regional anticoagulation so as to ensure a particular working of the machine as shall be explained below in further detail.

After defining a direction of blood circulation **22** from the inlet line **3a** towards the filtration unit and from the latter through the outlet line **3b** towards the patient, a known blood pressure sensor **34**, which shall not be described in further detail, is placed immediately downstream from the auxiliary pre-infusion line **18**.

The blood circuit **3** therefore comprises means for conveying fluid, i.e. in this particular case at least a blood pump **21** for controlling and managing the suitable blood flow in the circuit. Also the blood pump **21** is generally a peristaltic pump.

Following the direction of blood circulation **22**, there is then a device **35** for administering an anticoagulant, for instance a syringe containing suitable doses of heparin.

The blood then passes through another pressure sensor **36** controlling the correct flow within the blood circuit.

After passing through a main chamber of the filtration unit **2**, where the suitable exchanges of substances, molecules and fluids occur by means of a semipermeable membrane, the treated blood enters the outlet line **3b** first passing through a gas separating device (generally air) **12** commonly known as "bubble trap", designed so as to ensure the detection and removal of substances or air bubbles present in the blood.

The treated blood getting out of the separating device **12** then passes through an air bubble sensor **37** verifying the absence of said dangerous formations within the treated blood that has to be re-introduced in the patient's blood circulation.

Immediately downstream from the bubble sensor **37** there is an element **38** which, in case of alarm, can block the blood flow towards the patient.

In particular, should the bubble sensor **37** detect the presence of anomalies in the blood flow, the machine through the element **38** (be it a tap, a clamp or similar) would be able to block immediately the passage of blood so as to avoid any consequence to the patient.

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Downstream from said element **38** the treated blood is then carried back to the patient undergoing therapy.

The extracorporeal blood treatment machine shown above is then equipped with a fluid circuit **4**, which is also provided with at least an inlet line **4a** leading into the filtration unit **2** and with an outlet line **4b** from the filtration unit.

At least a primary fluid container **5** is designed to supply the inlet line **4a** of the fluid circuit **4** (generally the primary fluid container **5** shall consist of a bag containing a suitable dialysis liquid).

The inlet line **4a** then comprises means for conveying fluid such as at least a pump **9** (in the embodiment shown a peristaltic pump) for controlling the flow of liquid from the bag **5** and for defining a direction of circulation **10**.

Downstream from the pump **9** in the direction of circulation **10** there is a branching **17** splitting the fluid circuit **4** up into an intake branch **15** and an infusion branch **8**.

In particular, the infusion branch **8** is connected to the outlet line **3b** of the blood circuit **3**.

In other words, by means of said infusion branch **8** it is possible to obtain a post-infusion directly in the blood line using the content of the primary fluid container **5**.

Conversely, the intake branch **15** conveys the fluid directly to the filtration unit and in particular to a secondary chamber of said unit.

The fluid circuit **4** is further equipped with selecting means **16** for determining the percentages of fluid flow within the infusion branch **8** and the intake branch **15**.

Generally said selecting means **16**, usually placed near the branching **17**, can be positioned at least between a first operating condition in which they allow the passage of fluid in the intake branch **15** and block the passage in the infusion branch **8**, and a second operating condition in which they allow the passage of fluid in the infusion branch **8** and block the passage in the intake branch **15**.

In other words, said selecting means **16** can consist of a valve element operating on the fluid circuit **4** by alternatively blocking the passage of fluid in either branch.

It is also evident that it might be provided for suitable selectors, which are able to establish a priori the amount of liquid that has to pass through both branches simultaneously.

It will also be possible to vary the percentages of fluid in either branch as a function of time and of the pre-established therapies.

The dialysis liquid through the intake branch **15** gets into a secondary chamber of the filtration unit **2**.

In particular, the primary chamber through which the blood flow passes is separated from the secondary chamber through which the dialysis liquid passes by means of a semipermeable membrane ensuring the suitable passage of the dangerous substances/molecules and of fluid from the blood towards the dialysis liquid mainly by means of convection and diffusion processes, and also ensuring through the same principles the passage of substances/molecules from the dialysis liquid towards the blood.

The dialysis fluid then gets into the outlet line **4b** and passes through a suitable pressure sensor **39** whose function is to control the working of said line.

Then there are means for conveying fluid, for instance a suction pump **28** controlling the flow in the outlet line **4b** within the fluid circuit **4**. Also said pump will generally be a peristaltic pump.

The fluid to be eliminated then passes through a blood detector and is conveyed into a collection container or bag **27**.

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Further analyzing the particular circuit of the machine according to the invention, note the presence of at least another infusion line **6** acting on the outlet line **3b** of the blood circuit **3**.

In particular, the infusion fluid is taken from at least an auxiliary container **7** and is sent directly to the outlet line **3b** of the blood circuit **3** through means for conveying fluid, generally an infusion pump **13** controlling its flow (in the example a peristaltic pump).

In particular and as can be observed in the appended figure, the infusion liquid can be introduced directly into the gas separating device **12**.

As can also be inferred, the infusion branch **8** of the fluid circuit **4** and the infusion line **6** are equipped with a common end length **11** letting into the blood circuit **3**.

Said intake end length **11** is placed downstream from the infusion pump **13** with respect to a direction of infusion **14** and carries the fluid directly into the bubble trap device **12**.

Further referring to the diagram in FIG. 1, one can notice the presence within the infusion line **6** of at least a pre-infusion branch **23** connected to an inlet line **3a** of the blood circuit **3**.

In further detail, downstream from the infusion pump **13** with respect to the direction of infusion **14**, there is a branching **26** splitting the infusion line **6** up into pre-infusion branch **23** and post-infusion branch **24**.

The pre-infusion branch **23**, in particular, carries the fluid taken from the bag **7** on the inlet line **3a** of the blood circuit downstream from the blood pump **21** with respect to the direction of circulation **22**.

Conversely, the post-infusion branch **24** is connected directly to the common end length **11**.

The infusion line **6** further comprises selecting means **25** for determining the percentage of liquid flow to be sent to the post-infusion branch **24** and to the pre-infusion branch **23**.

The selecting means **25** placed near the branching **26** can be positioned between at least a first operating condition in which they allow the passage of fluid in the pre-infusion branch **23** and block the passage in the post-infusion branch **24**, and at least a second operating condition in which they allow the passage of fluid in the post-infusion branch **24** and block the passage in the pre-infusion branch **23**.

Obviously, as in the case of the selecting means **16** present on the fluid circuit **4**, also the other selecting means **25** will be able to determine the percentage of fluid that has to pass in each of the two branches and to possibly vary it in time in accordance with the planned therapies. Moreover, the selecting means **16** and the other selecting means **25** will generally though not necessarily be of the same nature.

The machine is then equipped with means **29** for determining at least the weight of the primary fluid container **5** and/or of the auxiliary fluid container **7** and/or of the secondary fluid container **20** and/or of the collection container **27**.

In particular, said means **29** comprise weight sensors, for instance respective scales **30**, **31**, **32** and **33** (at least an independent one for each fluid bag associated to the machine).

In particular, there will be at least 4 of said scales, each pair being independent from the other, and each one measuring the respective weight of a bag.

It should then be pointed out that there is a processing unit or CPU **40** acting on the blood circuit **3** and in particular on the pressure sensor **34**, on the blood pump **21**, on the device **35** for heparin infusion, on the other pressure sensor **36**, and

on the device for detecting the presence of air bubbles **37** and on its respective closing element **38**.

Said CPU **40** has also to control the fluid circuit **4** and, in particular, shall be input with the data detected by the scales **30** and concerning the weight of the bag **5** and shall act on the pump **9**, on the selecting means **16**, on the pressure sensor **39**, then on the suction pump **28** and shall eventually receive the data detected by the scales **33** whose function is to determine the weight of the collection container **27**.

The CPU **40** shall also act on the infusion line **6** checking the weight of the auxiliary container **7** (checked by the scales **31**) and will be able to control both the infusion pump **13** and the other selecting means **26**.

Eventually, the CPU **40** shall also act on the auxiliary pre-infusion line **18** detecting the weight of the secondary fluid container **20** by means of the scales **32** and suitably controlling the pump **19** according to the treatments to be carried out.

Reminding that the above description has been made with the sole purpose of describing the whole of the hydraulic circuit of the extracorporeal blood treatment machine, here is a short description of the working of the device.

Once the whole hydraulic circuit and the filtering unit **2** have been correctly associated to the machine so that the various peristaltic pumps engage the respective lengths of tubes and that all the sensors have been suitably positioned, and the various bags containing the various fluids have been associated to the corresponding liquid supply/intake lines, and the blood circuit has been connected to a patient's artery/vein, the initial circulation of blood within its circuit is enabled.

Therefore, according to the kind of therapy that has been set, the extracorporeal blood treatment machine is automatically started and controlled by the processing unit **40**.

If the patient undergoes an ultrafiltration treatment, as well as the blood pump **21** the suction pump **28** connected to the outlet line of the fluid circuit **4** is started, so as to take by convection a fluid excess in the patient by means of the filtration unit.

Conversely, if the therapy that has been set comprises a haemofiltration treatment, as well as the blood pump **21** and the suction pump **28** for taking fluids by convection also the pump **9** on the inlet line of the fluid circuit **4** and the selecting means **16** placed so as to enable a post-infusion are started.

Also the infusion line **6** shall be used so as to enable a further addition of liquids to the post-infusion or to enable a suitable pre-infusion.

Conversely, if the treatment involves haemodialysis, the pumps **9** and **28** of the fluid circuit **4** shall be started and the selecting means **16** shall be positioned so as to ensure the passage of the dialysis liquid only towards the filtration unit **2** so as to take substances and/or molecules and/or liquids by diffusion and possibly by convection if the transmembrane pressure through the filtration unit is other than zero.

Eventually, if a haemodiafiltration treatment has to be carried out, beyond the blood pump **21** the fluid circuit and therefore the pumps **9** and **28** shall be started, so as to ensure a circulation of the liquid within the filtration unit **2** and also the pump **14** of the infusion line **6** shall be started so as to ensure a pre- or post-infusion.

It will be possible to set up therapies comprising one or more of the treatments referred to above.

In all the treatments described above, possibly except the ultrafiltration treatment, it will be possible to use the auxiliary pre-infusion line for introducing an anticoagulant and/or a suitable infusion liquid into the blood.

The anticoagulant can also be administered by means of the suitable device **35** designed for the introduction of heparin into blood.

Concerning this it should be pointed out that the machine according to the invention is designed to receive various kinds of syringes according to the amount of anticoagulant to be administered.

Obviously, it is the control unit **40** that, being connected to the various devices, sensors, pumps and being input with the data on weight from the scales, is able—once it is set—to control and automate the whole working of the machine.

In further detail, it is possible to set the flows of the various pumps present on the machine in accordance with the therapy or therapies to be started.

Obviously, the setting of said flows results in an amount of fluid taken from the patient (weight loss), which will generally be given by the difference between the weight of the liquid that has been collected in the bag **27** and of the liquid circulated in the circuit through the primary fluid container **5**, the auxiliary fluid container **7** and the secondary fluid container **20**.

In particular, in accordance with the data received by the control unit coming from the various scales (and the theoretical flow rates fixed on each pump of therapy/treatment carried out) the control unit **40** shall control the means for circulating fluid in the various lines by suitably varying the thrust exerted by the various pumps **9**, **13**, **19**, **21** and **28**.

In particular, the signals coming from the scales referred to above **30**, **31**, **32**, **33** are used by the control unit **40** for determining the weight of the particular fluid introduced into the line or collected.

In order to determine the amount of fluid released or collected in a particular bag or container the control unit **40** compares at regular intervals (the greater the flows the smaller the intervals) the actual weight of the container with the desired weight (which is a direct function of the desired flow for each pump and of the time interval between each control step $\Delta W = Q \Delta t$).

The desired weight can be calculated as a function of the required flow (stored in a suitable storage unit of the computer) and of the time elapsed from the beginning of the treatment.

If the actual weight and the desired weight differ from each other, the control unit acts on the corresponding pump so as to reduce, and possibly cancel, said difference. In other words, during each cycle not an absolute weight variation, but only the variation in the time interval is taken into consideration to correct the latter.

The control unit takes into consideration variations in the difference starting from the last comparison, so as to avoid oscillations of the actual flow around the desired flow.

Reminding that the above description has been carried out with the sole purpose of providing a general view of the blood treatment machine and of the hydraulic circuit thereto associated, it should be noted that generally the whole machine shall comprise a body **58** (see in particular FIG. 3) designed to integrate all instruments and devices to be used several times in different treatments on one or more patients.

In particular, the machine body **58**, beyond the whole electronic control circuitry (processing unit **40**, data input and reading display, pressure sensors **34**, **36**, **39**, . . .) shall also have on its front surface the blood pump **21**, the fluid pump **9**, the infusion pump **13** and the auxiliary pre-infusion pump **19**.

Conversely, the parts of the machine that are designed to be used only once for each treatment on the patient, generally in the course of an intensive therapy, shall be housed in

a corresponding disposable integrated module **41** to be attached directly onto the machine body **58**.

As shown in FIG. 2, the integrated module **41** for blood treatment has a support element **42** consisting of a main body **52** and of a supporting structure **44** associated, for instance as one piece, to the main body and placed laterally with respect to the latter.

Said integrated module further comprises a fluid distribution circuitry **43** (represented only partially in the appended FIG. 2) associated to said support element **42** and cooperating with the filtration unit **2** so as to carry out the hydraulic circuit previously described.

In particular, it is possible to note how the main body **52** defines a housing compartment designed to receive the respective U-arranged lengths of tubes of the circuitry, which are kept in position so as to be ready to cooperate with the respective peristaltic pumps housed by the machine body **58**.

As can be observed, the blood circuit **3** and in general the inlet line **3a** of the blood circuit **3** is fastened by means of connectors to a side wall of the main body **52**, in the same way as also the inlet line **4a** of the fluid circuit **4** and the outlet line **4b** of the fluid circuit **4** are secured to the main body **52**.

Also the infusion line **6** and the auxiliary pre-infusion line **18** are secured to the main body **52** (see again FIG. 2).

All the portions of lines referred to above are secured to the support element **42** so as to define at least a corresponding U-arranged length of tube with respect to said support element **42** and so that each of said U-lengths can cooperate with the corresponding peristaltic pump housed in the machine body.

Going into further constructive details, it can be noted how the support structure **44** comprises a positioning fin **45** provided with a given number of main seats **46a**, **46b**, **46c**, **46d** and **46e** suitably placed so that respective tubes of the fluid distribution circuit **43** associated to the support element can be engaged therein.

As can be further observed, the inlet line **4a** of the fluid circuit **4** is fastened to the main body **52** on the support structure **44**.

As a matter of fact, at least an inlet length **47** is kept in position by the support structure **44** by means of a main seat **46c** of the positioning fin **45** and by a corresponding connector **48** defined on the main body.

The outlet length **49** of the fluid circuit **4** is engaged in its turn with the respective engagement connector **50** and with the main seat **46a** of the positioning fin **45**.

As can be noted from the arrangement shown, the inlet and outlet lengths **47** and **49** engaged to their respective connectors **48**, **50** and with the main seats **46c** and **46a** are placed in a substantially rectilinear arrangement and are parallel one to the other.

It should then be pointed out that the outlet length **49** has a branching **17** splitting up into intake branch **15** designed to convey the fluid to the filtration unit, and infusion branch **8** designed to convey the fluid to the blood circuit **3**.

Said branching **17** cannot be seen in FIG. 2 since it is defined by the engagement connector **50** on the opposite side with respect to the one shown in said figure.

In other words, the connector **50** has a basically T shape, whose two outlets are connected to the intake branch **15** and to the infusion branch **8**.

The infusion branch **8** is further secured to an auxiliary seat **51** of the support structure and to another main seat **46b**.

When engaged the infusion branch **8** and the intake branch **15** are placed in a rectilinear arrangement and are parallel one to the other.

Also the infusion line **6** is fastened to the main body **52** on the support structure **44**.

At least an outlet length **53** of the infusion line **6** is engaged to a main seat **46d** of the positioning fin and to a respective engagement connector **54**.

Analogously to the above description, also the outlet length **53** of the infusion line **6** has a branching **26** splitting up into pre-infusion branch **23** designed to convey the fluid to the inlet line **3a** of the blood circuit **3**, and post-infusion branch designed to convey the fluid to the outlet line **3b** of the blood circuit **3**.

Here again the branching **26** is not shown in FIG. 2 since it is defined by the T-shaped connector **54**, one of whose outlets can be seen only on the opposite side with respect to the one shown.

The pre-infusion branch **23** is secured to an auxiliary seat **55** of the support structure and to another main seat **46e** of the fin **45**.

Said arrangement enables to have pre-infusion branch **23** and post-infusion branch **24** in rectilinear configuration and parallel one to the other.

It should now be observed that the selecting means **16** previously defined act by enabling or blocking the passage of fluid in the infusion branch **8** and/or in the intake branch **15** exactly on the rectilinear lengths defined on the support structure **44**.

In particular, said selecting means **16** can be defined by suitable cams or clamps.

The example of embodiment shown provides for a moving element **56**, which as a result of its movement blocks either the infusion branch **8** or the intake branch **15**.

Said moving element **56** is generally mounted directly onto the machine body **58** and has been shown with a mere explicative purpose and with a hatched line in the appended FIG. 2.

Wholly similarly, the other selecting means **25** can comprise a moving element **57** acting on the pre-infusion branch **23** or on the post-infusion branch **24** for selectively blocking or enabling the passage of fluid.

Here again said moving element **57** has been shown by way of example in FIG. 2; however, it should be noted that generally said element is mounted directly onto the machine body **58**.

The invention has important advantages.

It is obvious that the use of a hydraulic circuit enabling a passage of the dialysis fluid within the filtration unit or selectively towards a post-infusion by using the same liquid coming from the primary fluid bag **5**, allows to manage therapies with a large volume of fluids, particularly in intensive therapy machines where anyhow said fluids are housed in small bags.

As a matter of fact, it will be possible to carry out a pre-and/or post-infusion into the blood line using the fluid of the primary container **5** and of the auxiliary container **7**, thus carrying out for instance a more intense ultrafiltration.

Moreover, the presence of a branching also on the infusion line allows to manage therapies with regional anticoagulation techniques without limiting the possibilities of dialysis pre-filter infusion in any way.

When regional anticoagulation techniques are used, such as for instances the use of citrates, it is always necessary, before carrying the treated blood back into the patient, to administer to the latter suitable substances (for instance calcium) for recovering the ion balance in the blood.

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It is obvious that the elimination/balance of the anticoagulant substances should be carried out downstream from the filtration unit, for instance by means of the post-infusion line.

In the machine according to the invention, however, in order to balance the ions in the returned blood it will be possible to use directly the fluid circuit by introducing a suitable reagent into the primary fluid bag **5** and by using the inlet line **4a** for carrying out the post-infusion through the infusion branch **8**.

The infusion line **6** shall thus enable to carry out pre-infusions, ensuring the optimal working of the machine also during this kind of treatments.

Therefore, the particular arrangement of the pre- and post-infusion lines and of the dialysis lines enables—also in intensive therapy machines where all the various fluids are contained in small bags—to carry out all the necessary therapies/treatments, thus eliminating the operational limits present in known machines.

The invention claimed is:

1. An extracorporeal blood treatment machine comprising:

- at least one filtration unit;
- a blood circuit having an inlet line leading to the filtration unit and an outlet line from the filtration unit;
- a fluid circuit having at least one inlet line leading to the filtration unit and one outlet line from the filtration unit;
- at least one infusion line comprising at least a pre-infusion branch connected to the inlet line of the blood circuit and a post-infusion branch connected to the outlet line of the blood circuit;
- an auxiliary pre-infusion line connected to the inlet line of the blood circuit
- at least one primary fluid container connected so as to supply the inlet line of the fluid circuit;
- at least a secondary fluid container for supplying said auxiliary pre-infusion line;
- at least one auxiliary fluid container for supplying said at least one infusion line,

wherein the inlet line of the fluid circuit comprises an intake branch leading to the filtration unit and at least one infusion branch connected to the outlet line of the blood circuit, wherein said at least one infusion branch of the fluid circuit line has at least a length which is separate from said post-infusion branch of the at least one infusion line;

said fluid circuit further comprising selecting means for determining percentages of a flow of a fluid within said length of the infusion branch and the intake branch, said at least one infusion line further comprising other selecting means for determining the percentage of flow within the post-infusion branch and the pre-infusion branch.

2. A machine according to claim **1**, wherein the inlet line of the fluid circuit comprises means for conveying fluid, said means for conveying fluid including at least one inlet line pump, for controlling the fluid flow.

3. A machine according to claim **2**, wherein the infusion branch of the fluid circuit is placed downstream from said inlet line pump with respect to a direction of circulation of the fluid.

4. A machine according to claim **1**, wherein the infusion branch of the fluid circuit and the infusion line are equipped with a common end length letting into the blood circuit.

5. A machine according to claim **4**, further comprising a gas separating device engaged on the outlet line of the blood circuit.

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6. A machine according to claim **5**, wherein the common end length infuses the fluid directly into said gas separating device.

7. A machine according to claim **1**, further comprising means for conveying the fluid, said means for conveying fluid including an infusion pump, for controlling the fluid flow in the infusion line.

8. A machine according to claim **4**, wherein the common end length is placed downstream from the infusion pump with respect to a direction of infusion.

9. A machine according to claim **1**, wherein the selecting means are placed near a branching of the fluid circuit splitting into the intake branch and the infusion branch.

10. A machine according to claim **1**, wherein the selecting means is positioned at least between a first operation condition in which said selecting means allow the passage of fluid in the intake branch and block the passage in the infusion branch, and a second operating condition in which said selecting means allow the passage of fluid in the infusion branch and block the passage in the intake branch.

11. A machine according to claim **1**, wherein the auxiliary pre-infusion line comprises means for conveying fluid, said pre-infusion line including at least one auxiliary pre-infusion pump, for controlling the fluid flow.

12. A machine according to claim **1**, wherein the blood circuit comprises means for conveying fluid, said blood circuit including at least one blood pump, for controlling the flow of blood in the circuit.

13. A machine according to claim **12**, wherein the auxiliary pre-infusion line operates upstream from the blood pump with respect to a direction of blood circulation.

14. A machine according to claim **1**, wherein the secondary fluid container supplying the auxiliary pre-infusion line is configured to contain an anticoagulant.

15. A machine according to claim **12**, wherein the pre-infusion branch operates downstream from the blood pump with respect to a direction of blood circulation.

16. A machine according to claim **7**, wherein the pre-infusion branch is placed downstream from the infusion pump with respect to a direction of infusion.

17. A machine according to claim **1**, wherein the other selecting means are placed near a branching of the infusion line splitting up into the pre-infusion branch and the post-infusion branch.

18. A machine according to claim **1**, wherein the other selecting means can be positioned at least between a first operation condition in which said selecting means allow the passage of fluid in the pre-infusion branch and block the passage in the post-infusion branch, and at least a second operating condition in which said selecting means allow the passage of fluid in the post-infusion branch and block the passage in the pre-infusion branch.

19. A machine according to claim **4**, wherein the pre-infusion branch starts from the post-infusion branch upstream from the common end length with respect to a direction of infusion.

20. A machine according to claim **1**, further comprising a collection container engaged to the outlet line of the fluid circuit.

21. A machine according to claim **1**, wherein the outlet line of the fluid circuit further comprises means for circulating fluid, said outlet line of the fluid circuit including an outlet line pump, for controlling a flow within the fluid circuit.

22. A machine according to claim **1**, further comprising means for determining a weight of at least said primary fluid container.

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23. A machine according to claim 22, further comprising means for determining a weight of at least said auxiliary fluid container.

24. A machine according to claim 23, further comprising means for determining a weight of at least said secondary fluid container.

25. A machine according to claim 24, further comprising means for determining a weight of at least a collection container engaged to the outlet line of the fluid circuit.

26. A machine according to claim 25, wherein said means for determining the weight of at least said primary fluid container, of at least said auxiliary fluid container, of at least said secondary fluid container, and of at least said collection container each comprise at least a respective scale for each one of said collection container, said primary fluid container, said secondary fluid container, and said auxiliary fluid container.

27. A machine according to claim 26, further comprising a processing unit acting on the blood circuit, on the fluid circuit, and on the infusion line, thus allowing respective flows of the blood circuit, fluid circuit, and infusion line to be controlled.

28. A machine according to claim 27, wherein the processing unit acts on the auxiliary pre-infusion line.

29. A machine according to claim 27, wherein the processing unit acts by controlling an inlet line pump operating on the inlet line of the fluid circuit, an infusion pump operating on the infusion line, a blood pump operating on the blood circuit, an outlet line pump operating on the outlet line of the fluid circuit, or the auxiliary pre-infusion pump operating on the auxiliary pre-infusion line.

30. A machine according to claim 27, wherein the processing unit acts on the selecting means, or on the other selecting means.

31. A machine according to claim 27, wherein the processing unit is input with a signal concerning weights detected by the means for determining the weight.

32. A machine according to claim 1, incorporating an integrated module for blood treatment comprising:

- a support element carrying the filtration unit; and
- a fluid distribution circuit associated to the support element and cooperating with the filtration unit, the fluid distribution circuit including the blood circuit, the fluid circuit, the infusion line, and the auxiliary pre-infusion line, wherein the selecting means comprises a moving element acting on the infusion branch or on the intake branch on a support structure connected to a main body for selectively blocking or allowing a passage of said fluid in said infusion branch or intake branch.

33. A machine according to claim 32, wherein said moving element is mounted directly onto a machine body.

34. A machine according to claim 32, wherein the other selecting means comprises a moving element acting on said pre-infusion branch and/or on said post-infusion branch for selectively blocking or enabling the passage of said fluid in said pre-infusion branch or in said post-infusion branch.

35. A machine according to claim 34, wherein said moving element is mounted directly onto a machine body.

36. A machine according to claim 32, wherein the support element comprises a main body and a support structure associated to the main body, said support structure being placed laterally with respect to the main body.

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37. A machine according to claim 36, wherein the support structure comprises a positioning fin having at least one main seat configured to connect to respective tubes of the fluid distribution circuit to be associated to the support element.

38. A machine according to claim 37, wherein the inlet line of the fluid circuit is fastened to the support element so as to define at least a U-shaped tube length with respect to said support element, said U-shaped tube length being configured to cooperate operationally with a respective pump.

39. A machine according to claim 38, wherein the inlet line is fastened to the main body on the support structure, at least an inlet length of the fluid circuit being connected to a first main seat of the positioning fin and to a first respective engagement connector, at least an outlet length of the fluid circuit being connected to a second main seat of the positioning fin and to a second respective engagement connector.

40. A machine according to claim 39, wherein the inlet and outlet lengths connected to the first and second engagement connectors and to the first and second main seats are placed in a rectilinear arrangement and are parallel to one another.

41. A machine according to claim 39, wherein the outlet length has a branching splitting into the intake branch conveying the fluid to the filtration unit, and into the infusion branch conveying the fluid to the blood circuit.

42. A machine according to claim 41, wherein said branching, splitting into the intake branch and the infusion branch, is defined on an engagement connector.

43. A machine according to claim 40, wherein the infusion branch and the intake branch, when engaged to the support structure, are placed in a rectilinear arrangement and are parallel to one another.

44. A machine according to claim 37, wherein the infusion line is secured to the support element so as to define at least one U-shaped tube length with respect to said support element, said at least one U-shaped tube length being configured to cooperate operationally with a respective pump.

45. A machine according to claim 44, wherein the infusion line is fastened to the main body on the support structure, at least an outlet length of the infusion line being connected to a main seat of the positioning fin and to a respective engagement connector.

46. A machine according to claim 45, wherein the outlet length has a branching splitting up into the pre-infusion branch conveying fluid to an inlet line of the blood circuit, and into the post-infusion branch conveying fluid to an outlet line of the blood circuit.

47. A machine according to claim 46, wherein the branching, splitting into the pre-infusion branch and the post-infusion branch, is defined on an engagement connector.

48. A machine according to claim 46, wherein the pre-infusion branch and the post-infusion branch, when connected to the support structure, are placed in a rectilinear arrangement and are parallel to one another.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 7,314,554 B2
APPLICATION NO. : 10/771377
DATED : January 1, 2008
INVENTOR(S) : Annalisa Delnevo et al.

Page 1 of 1

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In claim 1, column 11, line 33, "circuit" should read --circuit;--.

Signed and Sealed this

Twenty-ninth Day of April, 2008

A handwritten signature in black ink that reads "Jon W. Dudas". The signature is written in a cursive style with a large, looped initial "J".

JON W. DUDAS
Director of the United States Patent and Trademark Office