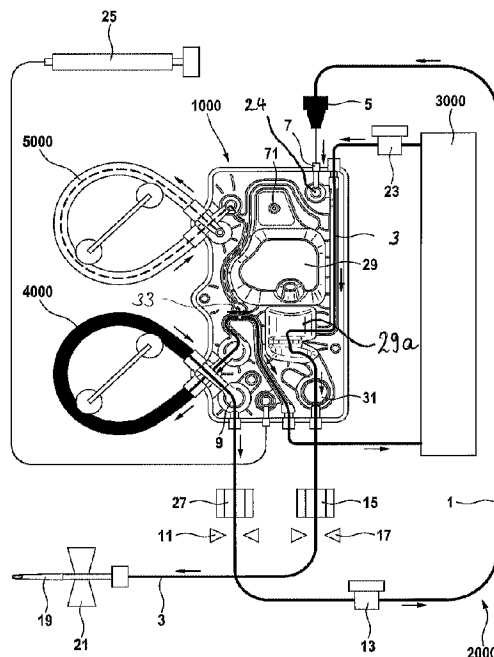




(86) Date de dépôt PCT/PCT Filing Date: 2015/04/16
(87) Date publication PCT/PCT Publication Date: 2015/10/22
(45) Date de délivrance/Issue Date: 2022/10/04
(85) Entrée phase nationale/National Entry: 2016/09/19
(86) N° demande PCT/PCT Application No.: EP 2015/058298
(87) N° publication PCT/PCT Publication No.: 2015/158843
(30) Priorité/Priority: 2014/04/16 (DE10 2014 105 473.3)

(51) Cl.Int./Int.Cl. *A61M 1/36* (2006.01)
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(54) Titre : METHODE D'EXTRACTION DU SANG D'UN CIRCUIT SANGUIN EXTRACORPOREL CONTROLE PAR LA
PRESSION ET APPAREILLAGE
(54) Title: METHOD FOR REMOVING BLOOD FROM AN EXTRACORPOREAL BLOOD CIRCUIT UNDER PRESSURE
CONTROL AND APPARATUSES



(57) **Abrégé/Abstract:**

The present invention relates to a method for removing blood from an extracorporeal blood circuit and/or a functional device, each of which is connectable with a blood treatment apparatus for performing a blood treatment of a patient, after concluding a blood treatment session. The blood treatment apparatus comprises or is connected with at least one extracorporeal blood circuit with a line interior, the extracorporeal blood circuit comprising at least one blood pump for conveying blood within the line interior. The method encompasses the step of operating the blood pump in a second conveying direction which is opposite to the first conveying direction of this pump which is customary during the blood treatment. A first section of an arterial line section of the line interior is or will be connected with a second section of a venous line section of the line interior of the extracorporeal blood circuit.

Abstract**Method for removing blood from an extracorporeal blood
5 circuit under pressure control as well as apparatuses**

The present invention relates to a method for removing blood from an extracorporeal blood circuit and/or a functional device, each of which is connectable with a blood treatment
10 apparatus for performing a blood treatment of a patient, after concluding a blood treatment session. The blood treatment apparatus comprises or is connected with at least one extracorporeal blood circuit with a line interior, the extracorporeal blood circuit comprising at least one blood
15 pump for conveying blood within the line interior. The method encompasses the step of operating the blood pump in a second conveying direction which is opposite to the first conveying direction of this pump which is customary during the blood treatment. A first section of an arterial line
20 section of the line interior is or will be connected with a second section of a venous line section of the line interior of the extracorporeal blood circuit.

**METHOD FOR REMOVING BLOOD FROM AN EXTRACORPOREAL BLOOD CIRCUIT
UNDER PRESSURE CONTROL AND APPARATUSES**

Description

5

Not least for hygienic reasons, blood remaining in the blood circuit is regularly removed from the extracorporeal blood circuit after use of the latter.

10

An object of the present invention is to provide a further method for removing blood from an extracorporeal blood circuit or from a functional means after the conclusion of a blood treatment session.

15

Further, a blood treatment apparatus by means of which the method according to the present invention is feasible as well as a control unit provided for executing the method according to the present invention, a suitable digital storage medium, a
20 suitable computer program product and a suitable computer program are to be specified.

The object according to the present invention is solved by means of a method as described herein.

25

All advantages achievable by means of the method according to the present invention may in certain embodiments according to the present invention undiminished also be achieved by the apparatuses according to the present invention.

30

The method according to the present invention is suited and intended for removing blood from an extracorporeal blood circuit which comprises at least one arterial line section and at least one venous line section, and/or for removing blood
5 from a functional device which is or are connectable or connected with a blood treatment apparatus for the purpose of a blood treatment of a patient, or each from sections hereof.

The method according to the present invention encompasses
10 conveying the fluid present in the extracorporeal blood circuit after the conclusion of the treatment by means of a blood pump which was already being used for the blood treatment. While the blood pump has conveyed fluid in a first conveying direction during the blood treatment, in the method according to the
15 present invention conveying takes place by means of the blood pump in a second conveying direction which is opposite to the first conveying direction. For executing the method according

20

25

to the present invention, a first section of the arterial line section is or will be connected with a second section of the venous line section of the extracorporeal blood circuit.

5 Thereby, the feed rate of the blood pump in certain embodiments according to the present invention is or will be adapted, at least at a certain point or during at least a period of time continuously or until reaching the pre-determined maximum value of the feed rate to which the feed rate of the blood pump is
10 limited, to be between 75% and 90%, preferably between 80% and 84%, particularly preferred is 82% of the feed rate of a second conveying device of the employed blood treatment apparatus. This may take place optionally under reserve taking into consideration a specified limitation.

15

The blood treatment apparatus that is employed for executing the method according to the present invention comprises next to the blood pump at least a second conveying device, in particular a substitute pump for bringing a second fluid, in
20 particular a substitute fluid, into the interior of a line of the extracorporeal blood circuit and/or for the conveyance of a line contents inside of the line interior of the extracorporeal blood circuit.

25 The blood treatment apparatus according to the present invention is provided and embodied and/or equipped for executing the method according to the present invention.

The control unit according to the present invention is suitable
30 and provided and/or arranged and/or configured for executing the method according to the present invention in interaction

with each required device thereto, as described in the following by way of example.

A digital, particularly a non-volatile storage medium according to the present invention, particularly in the form of a machine-readable data storage device, particularly in the form of a disk, CD, EPROM or DVD, with electrically readable control signals may interact with a programmable computer system such that the mechanical steps of a method according to the present invention are prompted.

In doing so, all or some of the mechanically executed steps of the method according to the present invention may be prompted.

A computer program product according to the present invention comprises a program code that is volatile or saved on a machine-readable medium for prompting the mechanical steps of the method according to the present invention when the computer program product runs on a computer. According to the present invention a computer program product can be understood as, for example, a computer program which is stored on a storage device, an embedded system as a comprehensive system with a computer program (e.g. an electronic device with a computer program), a network of computer-implemented computer programs (e.g. a client-server system, a cloud computing system, etc.), or a computer on which a computer product is loaded, executed, saved or developed.

The term *machine-readable medium* as used herein denotes in certain embodiments of the present invention a medium containing data or information which is interpretable by

software and/or hardware. The medium may be a data medium, like a disk, a CD, DVD, a USB stick, a flashcard, an SD card or the like.

5 A computer program according to the present invention comprises a program code for prompting the mechanical steps of a method according to the present invention when the computer program runs on a computer. A computer program according to the present invention can be understood as, for example, a physical, ready-
10 for-distribution software product which comprises a computer program.

It also applies for the computer program product according to the present invention and the computer program according to the
15 present invention that all or some of the mechanically executed steps of the method according to the present invention are prompted.

Embodiments according to the present invention may comprise
20 some or all of the following features in arbitrary combination as long as this is not realized by the skilled person to be technically impossible.

In all of the following embodiments, the use of the expression
25 *may be* or *may have* and so on, is to be understood synonymously with *preferably is* or *preferably has*, respectively, and so on, and is intended to illustrate exemplary embodiments according to the present invention.

30

Whenever a numerical word is mentioned herein, the skilled person understands this as an indication of a numerically lower limit. As long as it does not lead to any discernible contradiction for the skilled person, the skilled person, therefore, implicitly reads for example in the indication "one" at all times "at least one". This understanding is also encompassed by the present invention as well as the interpretation that, for example, "one" can alternatively be meant as "exactly one", as long as this is technically possible in the view of the skilled person. Both of which are encompassed by the present invention and apply to all used numerical words herein.

In some exemplary embodiments according to the present invention, a feed rate of the blood pump is limited, particularly by the user, to a pre-determined value, preferably to a value between 90 and 110 ml/min.

The extracorporeal blood circuit is in certain embodiments of the present invention a tube set. In any case, the extracorporeal blood circuit is provided for extracorporeally conducting blood of a patient, e.g., during hemodialysis, hemofiltration, hemodiafiltration or the like.

In some embodiments according to the present invention, the extracorporeal blood circuit is at least in sections embodied as an integral and, where appropriate, permanent part of the functional device, in others it is not. A freely movable tube section of the extracorporeal blood circuit may therefore continue in one piece or integrally on or in the functional device, e.g., a blood cassette, and vice versa.

A functional device is in certain embodiments of the present invention a device which is used in a blood treatment. Examples of functional devices include internal and external functional devices, medical disposables, in particular blood cassettes such as a disposable blood cassette, or other blood-conducting devices.

Exemplary embodiments of a blood cassette are in particular disclosed in the application of the Applicant with the publication number DE 10 2009 018 664 A1 having the title *Externe Funktionseinrichtung, Blutbehandlungsvorrichtung zum Aufnehmen einer erfindungsgemäßen externen Funktionseinrichtung, sowie Verfahren*, which was submitted to the German Patent and Trademark Office on 23.04.2009, and in the application of the Applicant with the publication number DE 10 2009 024 468 A1 of the same title, which was submitted to the German Patent and Trademark Office on 10.06.2009. The respective disclosures are herewith fully incorporated by way of reference.

In certain embodiments according to the present invention, the functional device as external functional device is not a part of the blood treatment apparatus, i.e. no integral element thereof. In other embodiments, the functional device may be a part of the blood treatment apparatus.

A blood treatment apparatus is provided and/or embodied for performing or prompting a medical treatment, in particular a blood treatment of the patient, e.g., a dialysis. For this purpose, the blood treatment apparatus is connected with or

comprises at least one extracorporeal blood circuit which comprises a line interior.

5 The arterial line section of the extracorporeal blood circuit is in certain embodiments of the present invention the line section in which the patient blood that leaves the body of the patient for the purpose of the extracorporeal blood treatment flows and in which it is present before it enters the blood treatment device, e.g., a dialyzer.

10

In certain embodiments of the present invention, the first section of the arterial line section is or encompasses the arterial needle connection to the patient, e.g. the arterial needle connection in a double-needle dialysis method.

15

The venous line section of the extracorporeal blood circuit is in some embodiments of the present invention the line section from which the extracorporeally treated patient blood flows towards or back into the body of the patient after its treatment in a blood treatment device, e.g., a dialyzer.

20

In certain embodiments of the present invention, the second section of the venous line section is or encompasses a venous port, for example a venous addition port or a venous addition point. It may, where appropriate, be used or provided for the addition of substitute liquid, calcium citrate heparin or the like to the patient blood flowing in the line section of the extracorporeal circuit.

25 30 In certain embodiments of the present invention, the venous addition point of the venous line section of the extracorporeal

blood circuit leads, optionally directly or indirectly, into the venous line section upstream from a blood chamber and upstream from a clot catcher.

- 5 In some embodiments of the invention, the venous addition point is an integral part of a blood cassette.

The blood treatment apparatus comprises a blood pump for conveying blood within the line interior of the extracorporeal
10 blood circuit.

In certain embodiments of the present invention, the first conveying direction -as customary during the blood treatment- corresponds to a conveying direction from an arterial access
15 (blood withdrawal point) of a patient to a blood treatment device, for example a blood filter or a dialyzer and subsequently through the venous line section of the extracorporeal circuit to the venous access (blood return point).

20

The second conveying direction which is opposite to the first conveying direction therefore proceeds in such embodiments from venous to arterial.

- 25 "Removing blood" denotes in certain embodiments of the present invention completely -or basically or nearly completely- or partially removing blood from an extracorporeal blood circuit after conclusion of a blood treatment session.

- 30 Reinfusing the blood removed from the extracorporeal blood circuit into the vascular system of the patient itself is in

some embodiments of the present invention not a part of the method according to the present invention, in others however, it is.

5 The blood treatment apparatus comprises at least one second conveying device. The second conveying device serves to introduce at least a second fluid which is different from the blood, for example a substitute liquid, into the line interior of the extracorporeal blood circuit and/or to convey the fluid
10 herein.

Introducing the second fluid, hereafter simply -but not restrictively- denoted as substitute liquid, into the line interior of the extracorporeal blood circuit by operating the
15 second conveying device, hereafter simply -but not restrictively- denoted as substitute pump, takes place in certain embodiments of the present invention after connecting the first section of the arterial line section with the second section of the venous line section.

20

In some embodiments according to the present invention, the blood pump is operated in the second conveying direction such that the flow of the substitute liquid which is introduced into the line interior of the extracorporeal blood circuit is
25 separated into at least a first and a second partial flow. The first partial flow of the substitute liquid moves towards a blood treatment device, the second partial flow of the substitute liquid moves into the second conveying direction.

In certain embodiments according to the present invention, the method according to the present invention encompasses disconnecting the first section.

5 In some embodiments of the present invention, the method according to the present invention encompasses connecting the first section with a venous addition point of the venous line section of the extracorporeal blood circuit or with a venous addition point of the functional device (for example the blood
10 cassette).

In certain embodiments of the present invention, the second conveying device and the blood pump are started, in particular basically or nearly or completely, at the same time.

15

The feed rates of the second conveying device and the blood pump in some embodiments of the present invention are or will be set such that a section of the venous line section, e.g., from a pre-dilution point or from a pre-dilution valve to the
20 venous addition point or to a point at which fluid from the venous line section and fluid from the arterial line section are joined or meet, are not emptied of blood before a section of the arterial line section, e.g., until its connection with the venous addition point or up to the point at which fluid
25 from the venous line section is joined with fluid from the arterial line section or both fluids meet.

In certain embodiments of the present invention, the feed rate of the blood pump is (initially, always, or on average) lower
30 than the feed rate of the second conveying device or is adjusted accordingly.

In some embodiments of the present invention, the feed rates of the blood pump and/or of the second conveying device are monitored and/or controlled or regulated by means of pressure monitoring and/or pressure measurement and/or pressure limitation during the removal of the blood.

In some embodiments of the present invention, the feed rates of the blood pump and the second conveying device during the removal of the blood are monitored and/or controlled or regulated by means of pressure monitoring and/or pressure measurement and/or pressure limitation, in particular by means of multiple measurements of an actual feed pressure of the blood pump, for example in a timely connection with the mesh or position or the tilt angle of a roll of a blood pump, as long as it is embodied as a roll pump, by determining the control difference between the measured feed pressure of the blood pump and a target value and by raising the feed rate of the blood pump according to the control difference.

In some embodiments of the present invention, the actual feed pressure is gripped, measured or calculated when the pre-determined tilt angle or tilt angle area of a pump rotor of the blood pump has been reached.

In some embodiments of the present invention, the actual feed pressure is measured by means of the arterial pressure sensor.

In some embodiments of the present invention, the feed rate of the blood pump and/or the feed rate of the second conveying device are set or limited with the intention to reach a target

pressure $P_{art,soll}$ and/or not to exceed it. The target pressure is set according to the formula (I):

$$P_{art,soll} = a \cdot P_{art,max}$$

5

wherein the following applies:

$P_{art,soll}$ is the pressure measured by means of an arterial pressure gauge;

10

a is a constant; it is preferably between 0,85 and 0,95. Particularly preferred is 0,9;

15

$P_{art,max}$ is a pre-set or pre-determined measurement range limit or a maximum allowable value for the pressure which is measured by an arterial pressure measurement and it is preferably an alarm-release range.

20

In some embodiments of the present invention, the method encompasses the increase of the feed rate of the second conveying device according to the formula (II):

$$Q_{5000_künftig} = Q_{5000_aktuell} + ((P_{art,soll}) - (P_{art,scan})) \cdot b$$

25

The following applies thereby:

$Q_{5000_künftig}$ is a future feed rate of the second conveying

device which is to specified $t_{\text{künftig}}$ at a point of time by means of the formula (II) respectively.

5 $Q_{5000_aktuell}$ is an actual feed rate of the second conveying device that is at a point of time t_{aktuell} , which is to be replaced by $Q_{5000_künftig}$ and precedes this temporally, respectively, wherein t_{aktuell} comes before $t_{\text{künftig}}$; $t_{\text{künftig}}$ may
10 be denoted as $t(x+1)$ and t_{aktuell} as $t(x)$.

$P_{\text{art,soll}}$ is a pre-set or identified target value, which is to be measured as a target value by means of an arterial pressure measurement, it corresponds
15 to a "Soll-Wert" ("target value");

$P_{\text{art,scan}}$ is a pressure value which is measured at the arterial pressure measurement during the adapting of the actual feed rate $Q_{5000_aktuell}$
20 of the second conveying device; it corresponds therefore to an actual value or to a value $P_{\text{art,aktuell}}$; and

25 b is a constant; it is preferably between 0,10 and 0,15. Particularly preferred is 0,12.

In certain embodiments of the present invention, the method encompasses the decrease of the feed rate of the second
30 conveying device according to formula (III):

wherein the following applies:

5 Q5000_künftig is a feed rate of the second conveying device which is to be set henceforth to a point of time t_künftig, respectively;

10 Q5000_aktuell is an actual feed rate of the second conveying device that is at a point of time t_aktuell, which is to be replaced by Q5000_künftig and preceeds this temporally, respectively, wherein t_aktuell comes before t_künftig; t_künftig may be denoted as t(x+1) and t_aktuell as t(x);

15 P_art,soll is a pre-set target value which should suit the arterial pressure measurement

20 P_art,scan is a pressure value which is measured at an arterial pressure measurement during the adapting of the actual feed rate Q5000_aktuell; and

c is a constant; it is preferably between 0,20 and 0,30. Particularly preferred is 0,24.

25 In certain embodiments of the present invention, the feed rate of the second conveying device is determined such that at the venous addition point - or at a point at which fluid from the venous line section is joined with or meets fluid from the arterial line section - blood (from a line) and substitute
30 liquid (from a different line) of the same degree of dilution meet.

In certain embodiments of the method according to the present invention, the intention is to stop the blood pump or reduce its feed speed or feed rate, before substitute liquid downstream (with regard to the second conveying direction or to the method according to the present invention) reaches the venous addition point or the point at which fluid from the venous line section and fluid from the arterial line section are joined or meet.

10

This may in certain embodiments of the present invention advantageously contribute to a stronger and/or improved flushing of the blood treatment device.

15 The time for stopping the blood pump or for reducing its feed rate is in certain embodiments of the present invention determined with the aid of the arterial air bubble detector/optical detector (also known as ABD/OD) which is integrated in the extracorporeal blood circuit. This may
20 advantageously increase the accuracy of determination of the time for stopping.

In other embodiments of the present invention, the method according to the present invention encompasses stopping the
25 second conveying device or reducing the speed or the feed rate of the second conveying device before substitute liquid downstream (with regard to the second conveying direction or to the method according to the present invention) reaches the venous addition point or the point at which fluid from the
30 venous line section and fluid from the arterial line section are joined or meet. This may advantageously contribute to a

stronger and/or improved flushing of the arterial line section of the extracorporeal blood circuit. The blood pump is further operated in such embodiments, or it is not further operated.

- 5 In certain embodiments of the present invention, the method according to the present invention encompasses checking the connection of the first section, e.g., of the arterial needle connection, of the extracorporeal blood circuit at the venous addition point of the venous line section of the extracorporeal
10 blood circuit (connection test).

In certain embodiments of the present invention, checking encompasses creating a pressure balance.

- 15 In such embodiments the intention may be to stop the blood pump and/or the second conveying device. Further, the intention may be to open or keep the arterial clamp open.

- In certain further embodiments of the present invention,
20 checking encompasses determining a diastolic patient pressure. A minimum value of the diastolic patient pressure may be saved over a time period of, e.g., 2.5s. Subsequently, a negative pressure is created by means of the blood pump which conveys in the first conveying direction, i.e. forwards, wherein the
25 venous clamp is opened or is already open. In certain embodiments of the present invention, it is defined that the vascular pressure of the patient has to drop by 50mmHg within a time period of 2.1s in order for the connection test to be considered as passed. Alternatively, other values for pressure
30 drop and/or times than the ones named here may be considered. If the desired and/or required pressure reduction has not taken

place at all or not within the pre-determined time, the connection test may be considered as failed.

In some embodiments according to the present invention, the method encompasses a step for the free rinsing of the pre-dilution valve. For this purpose, the feed rate of the second conveying device is increased, e.g. in a bore manner, e.g. on a short notice, from preferably 0 ml/min until a specified value. This may optionally be 100 ml/min. In addition or alternative to the feed rate with the aforementioned specified values, a specified quantity of the conveyance is conveyed during the free rinsing. This is based on 0 ml/min by way of example. The free rinsing takes place preferably based on 0 ml/min. After reaching the specified value of the feed rate and/or after conveying the specified volume, the feed rate may optionally be dropped to 0 ml/min.

The functional device according to the present invention is in some embodiments according to the present invention embodied as disposable.

In certain embodiments according to the present invention, the venous addition point of the functional device is embodied to create a fluid connection by simply clamping, attaching or screwing together an arterial needle connection or another section of the arterial line section of the extracorporeal blood circuit. A corresponding embodiment and/or corresponding arrangements may be provided according to the present invention.

In some embodiments according to the present invention, the venous addition point of the functional device and the arterial needle connection or another section of the arterial line section of the extracorporeal blood circuit are from the same connector system, e.g., Luer connectors, or female and male connector.

In certain embodiments according to the present invention, the connection geometry of the venous addition point is embodied the same as or corresponds to the connection geometry of an arterial needle by means of which the extracorporeal blood circuit is connected for its use.

The control device according to the present invention is in some embodiments according to the present invention embodied as a regulating device.

The blood treatment device according to the present invention is in some embodiments according to the present invention embodied as a hemodialysis apparatus or hemofiltration apparatus or hemodiafiltration apparatus.

The blood treatment device according to the present invention comprises in certain embodiments according to the present invention at least one control device according to the present invention.

Some or all embodiments according to the present invention may comprise one, more or all of the advantages named above and/or hereafter.

The present invention provides a simple and not very elaborate method for removing blood from an extracorporeal blood circuit after a blood treatment session as well as corresponding apparatuses. By removing blood at the end of the treatment, the risk of contamination may advantageously be reduced during further use or disposing of the blood circuit.

During a blood treatment, blood clots may be formed on construction-related unevenness. During an utmost precautionary free rinsing, as described herein, the second conveying device conveys such blood clots with a specified free rinsing rate, e.g. by bringing ca. 10 ml volume, from pre-dilution valve in direction of the blood entry filter. Thereby, the pre-dilution valve is liberated from blood clots. Due to the herein described relation between the feed rate of the blood pump and the feed rate of the second conveying device (preferably 82%), it is advantageously guaranteed that such blood clots are not brought in direction of the venous line section until the venous needle, rather, they accumulate at the blood entry side of the blood filter from which, by adapting the aforementioned relation between the feed rate of the blood pump and the feed rate of the second conveying device (preferably 82%), they are not further moved upstream and subsequently they may not reach the venous line section or not even the venous needle and from here further to the vascular system of the patient. This advantageous state is not achievable with other or other precise relations. Moreover, even when the patient due to a user error is mistakenly still connected to the arterial needle during reinfusion, no blood clot may advantageously be infused. Furthermore, the venous addition point and the check valve may

not be blocked by such blood clots which contributes to a rapid and trouble-free process.

5 The user may in certain embodiments according to the present invention adjust the maximum flow allowed, desired or determined for removing blood out of an extracorporeal blood circuit at the blood treatment apparatus and does not have to submit any further inputs.

10 In some embodiments according to the present invention, it is guaranteed due to the proposed regulation that there shall be no exceeding in the measurement range in the arterial pressure sensor. Therefore, the patient and the user are spared the avoidable interruption of the treatment.

15

In specific embodiments according to the present invention, the greatest possible feed rate via the arterial line section and/or the blood treatment apparatus is conveyed, which contributes to keeping a low sedimentation (and therewith also
20 the remaining blood quantity in the blood filter and/or the extracorporeal blood circuit).

In some of the embodiments according to the present invention, the greatest possible feed rate of the second conveying device
25 is ensured, by means of which the blood is removed as soon as possible out of the entire blood treatment apparatus.

In specific embodiments according to the present invention, a dynamic control of the feed rate from the blood pump as well as
30 the second conveying device depending on the outcome of the viscosity of the blood and the decreasing viscosity of the

increasingly diluted blood during the reinfusion is advantageously possible due to the proposed pressure control according to the present invention.

For functional or constructive requirements, the arterial line
5 section comprises a comparatively low cross section in the area
of the venous addition point to which it is connected for the
reinfusion of blood and/or for emptying the blood filter or the
extracorporeal blood circuit. The cross section is needed so
that a dosage of medicine may be given as intended (typically
10 for example $Q > 1\text{ml/min}$) through it - and particularly through
the venous addition point - Due to the low cross section of the
venous addition point, the latter has in comparison with the
arterial or venous line section a relatively high flow
resistance. For this reason, the use of the apparatus, for
15 example according to WO 2013/017240 A2, for the reinfusion is
uncomfortable and/or physically unfavourable. The user would
like to prevent the increase of pressure on the pressure sensor
until its upper measurement range which may lead to warning the
user and to an interruption of the treatment. Therefore, the
20 user shall specify a corresponding low feed rate (typically 70
ml/min.) for the second conveying device. The low feed rate has
consequently the disadvantage of a low efficiency of blood
return. This is due to fact that at the end of the reinfusion
or emptying the blood treatment device, e.g. of the blood
25 filter, more blood rest remains in the blood treatment
apparatus. Another disadvantageous consequence of the low feed
rate is a sedimentation of the blood within the blood treatment
device which again leads to a low efficiency of blood return
due to the fact that at the end of the reinfusion or emptying
30 of the blood treatment device,

for example of the blood filter, more blood rest remains in the blood treatment device. A further disadvantageous consequence of the low rate is that the procedure of reinfusion takes a long time due to the low feed rate. These disadvantageous
5 consequences do not advantageously occur in some embodiments of the invention.

However, also a high feed rate set by the user has disadvantageous consequences in proceeding with the state of
10 the art. As the high feed rate (typically 150 ml/min) leads according to experience to regular alarming due to measurement range excess on the pressure sensor. This makes it necessary for the user to intervene. The process of emptying or reinfusion takes a longer time due to herethrough related
15 interruptions which again leads to sedimentation in the arterial line section and in the blood treatment device. These disadvantages of the state of the art are preventable according to the present invention.

20 In certain embodiments according to the present invention, the method allows for completely returning blood present in the extracorporeal blood circuit at the end of the blood treatment session to the vascular system of the patient via a venous connection with the vascular system of the patient. Infusing
25 substitute liquid or another fluid to the patient at the same time is hereby preventable.

The method according to the present invention may advantageously be implemented in treatment apparatuses already
30 known from practice just by means of a simple-to-perform

software update. The blood treatment apparatuses known from practice often already comprise the required machine elements.

Hereafter, the present invention is exemplarily described with
5 reference to the appended figures. It applies that:

Fig. 1 shows in simplified illustration a medical functional device with an extracorporeal blood circuit, which may be cleared of blood by means of the method
10 according to the present invention.

Fig. 2 shows the progress of pressure and volume over a period of time which may occur or that may be measured while performing an exemplary embodiments
15 according to the present invention of the method according to the present invention by means of an arrangement shown in Fig. 1.

Fig. 1 shows a schematically simplified functional device 1000
20 with an extracorporeal blood circuit 2000 connected herewith.

The extracorporeal blood circuit 2000 comprises or is connected with a blood treatment device 3000, e.g., a blood filter or dialyzer.
25

A blood treatment apparatus represented in Fig. 1 only by means of some of its devices, by means of which the method described here is automatically completely or mostly executed by means of reinfusing blood contained in the extracorporeal blood
30 circuit 2000, comprises a blood pump 4000 and a second conveying device 5000. Both the blood pump 4000 and the

conveying device 5000 convey fluid through sections of the functional device 1000 and of the extracorporeal blood circuit 2000. The functional device 1000 is exemplarily a blood cassette.

5

Indicated is a connection diagram as well as flow direction, specified by arrows, of blood and substitute (as an example a second fluid) during removal of blood with a simultaneous reinfusion of the blood. The sole double arrow describes a
10 split of the substitute flow in two partial flows

The extracorporeal blood circuit 2000 comprises an arterial line section 1 as well as a venous line section 3.

15 The arterial line section 1 comprises a first section. The first section is in the example of Fig. 1 exemplarily embodied as an arterial needle connection 5.

The venous line section 3 comprises a second section. The
20 second section 3 is embodied in Fig. 1 as a venous addition point 7 of the functional device 1000.

The arterial line section 1 comprises an arterial pressure sensor which is coupled to the functional device 1000 at the
25 location denoted with reference numeral 9 without being itself part of the functional device 1000. This pressure sensor serves, amongst others, to measure the pressure or to determine pressure drop during an optional connections test. It is arranged in the arterial line connection 1 of the
30 extracorporeal blood circuit 2000.

The arterial line section 1 comprises an arterial clamp 11.

The arterial line section 1 comprises an arterial septum 13, here, optionally in the shape of an addition device.

5

The venous line section 3 comprises a venous air bubble detector/optical sensor 15.

The venous line section 3 comprises a venous clamp 17.

10

The venous line section 3 comprises a venous needle 19 on a venous patient connector 21.

15 A venous septum 23, here optionally in the shape of an addition device, is arranged between the blood treatment device 3000 and the location of its connection with the section of the extracorporeal blood circuit 2000 present on the functional device 1000.

20 The functional device 1000 comprises a check valve 24 which allows a fluid supply in a direction shown by means of an arrow in Fig. 1 through the venous addition point 7 into the functional device 1000 and into the venous line section 3, however it prevents a flow out of the venous line section 3
25 through the venous addition point out of the functional device 1000.

For adding heparin into the line interior of the extracorporeal blood circuit 2000 during an extracorporeal blood treatment,
30 the extracorporeal blood circuit 2000 is connected with a

heparin syringe 25 via a corresponding port of the functional device 1000.

The arterial line section 1 comprises an arterial air bubble
5 detector/optical sensor 27.

During the blood treatment, the extracorporeal blood circuit 2000 is, e.g., as is shown in Fig. 1 in the form of a tube system, connected with the vascular system of the patient
10 via two needles (in the case of a double-needle dialysis). For performing the blood treatment, the extracorporeal blood circuit 2000 is filled with blood of the patient and this blood flows through the extracorporeal blood circuit 2000 during the treatment.

15 Hereafter, removal of blood according to the present invention from the extracorporeal blood circuit by using the venous addition point 7 of the functional device 1000 is described. In the herein described example of an embodiment of the method
20 being executed by the machine, while removing blood there is a concurrent reinfusion of this blood.

The method according to the present invention may be started automatically, or manually by the doctor.

25 For this purpose, in certain embodiments of the invention, the arterial patient connector is disconnected from the arterial needle connection 5 after the conclusion of the blood treatment and connected in fluid connection with a port of the blood
30 cassette, here the venous addition point 7. As may be taken from the blood cassette shown in Fig. 1, the venous addition

point 7 may lead directly (in other embodiments also indirectly, however) into the venous line section 3 of the extracorporeal blood circuit 2000 upstream from a blood chamber 29 and from a clot catcher 31.

5

In the example of Fig. 1, the functional device 1000 comprises at the location of the clot catcher 31 or near the latter, in any case downstream thereof, however upstream of the venous air bubble sensor 15, a venous pressure sensor not shown in Fig. 1, which may measure the pressure of the flow of venous blood or fluid passing by. In other embodiments of the invention the venous pressure sensor is provided at another suitable location of the functional device 1000 or of the extracorporeal blood circuit 2000.

10

The venous addition point 7 is in the above-named applications of the Applicant with the publication numbers DE 10 2009 018 664 A1 and DE 10 2009 024 468 A2.

20 The user may be prompted towards the end of the blood treatment to disconnect the arterial needle connection 5 from the arterial patient connector (not shown in Fig. 1) and screw the arterial needle connection 5 onto the Luer connector of the venous addition point 7 of the functional device 1000. In order to check whether the connection is made correctly, a connection test may be performed by the blood treatment apparatus automatically or upon request. In doing so, the correct connection of the arterial line section 1 with the venous line

25

section 3 is checked. Directly conveying the blood via the arterial line section 1 into the vascular system of the patient may therefore advantageously be prevented.

- 5 The venous line section 3 is in certain embodiments provided with a check valve, which is why the blood pump 4000 cannot draw in liquid from the venous line section 3 in the first conveying direction. It may therefore be expected that during performance of the connection test the pressure in the arterial
10 line section 1 decreases. If the arterial pressure decreases as expected, it can be assumed that the patient is no longer arterially connected, at least that the (manual) arterial (tube) clamp 11 is closed.
- 15 If, as is the case in certain embodiments of the present invention, an arterial pressure alarm during conveying is provided in this stage of the method, an error would advantageously be detected also early on, even without a connection test. Thus, it may advantageously be possible to
20 forego explicitly testing the connection state.

The connection test for detecting whether the arterial line section 1, e.g., by means of the arterial needle connection 5, is connected with the venous line section 3, e.g., the venous
25 addition point 7, may hereby take place in detail as described hereafter: At first, a pressure balance is created, wherein the blood pump 4000 and the second conveying device 5000 are stopped. The arterial clamp 11 is open.

- 30 By means of a pressure sensor 9, the diastolic patient pressure is detected. Hereby, a minimum value is saved over 2.5s, for

example. Subsequently, a negative pressure is built up, whereby the venous clamp 17 is opened and by means of the blood pump 4000 conveyed in the first conveying direction. The pressure has to drop because of the check valve 24 below the diastolic patient pressure as detected before, e.g., by 50mmHg within 2.1s, otherwise the connection test is considered to be failed.

A predilution valve or predilution connection, provided for introducing substitute liquid into the blood line between the blood treatment device 3000 and the blood pump 4000 is opened for removing blood according to the present invention. The substitute line is connected with the pre-dilution connection, so that the second conveying device 5000 can introduce substitute solution into a section of the extracorporeal blood circuit 2000 which is located between the blood pump 4000 and the blood treatment device 3000.

In the embodiment illustrated here, the blood pump 4000 starts, at the same time (simultaneously) at which conveying begins by means of the second conveying device 5000, conveying backwards, i.e. in the second conveying direction at a lower feed rate than the second conveying device 5000. In doing so, the substitute flow is split due to the different feed speeds of the two pumps - in the example of Fig. 1 - one partial flow of the substitute solution moves towards the blood pump 4000, another partial flow of the substitute solution moves in the direction towards the blood treatment device 3000.

The occurring venous and/or arterial pressures are monitored during this process. The set pump rates or feed rates of the

conveying devices (blood pump 4000 and second conveying device 5000) may have a considerable effect on the removal of the blood.

- 5 In certain embodiments of the present invention, it is ensured that the feed rate of the blood pump 4000 is not selected to be too high. Thus, it may advantageously be ensured that the blood is not damaged when it flows through the point of introduction - e.g., provided with a thinner tube and a check valve. For
10 this, a limitation of the maximum feed rate, for example based on experience from *in vitro* tests or *in vivo* tests, is possible or provided.

In some embodiments of the present invention, a limitation
15 and/or monitoring the pressure drop across the addition point and/or the addition line and the check valve is possible with the aid of the arterial pressure sensor 9 during reinfusion.

When setting the venous reinfusion rate, i.e. the speed by
20 means of which the blood which is extracorporeally present is conveyed towards the patient via the venous line section 3 of the extracorporeal blood circuit 2000, it is in some embodiments according to the present invention ensured that the part of the extracorporeal blood circuit 2000 which extends
25 from the pre-dilution point or the pre-dilution valve to the venous addition point is not emptied earlier than or before the arterial line section 1 of the extracorporeal blood circuit 2000 is also emptied.

30 Hereby, in certain embodiments of the present invention, a further commingling of blood (arterial) and substitute liquid

(venous) and, along with this, an unnecessary increase of the reinfusion volume with the known unpleasant consequences for the patient may advantageously be prevented.

5 As the volumes of the individual line sections of an extracorporeal blood circuit (also denoted as tube set) are known, it is in certain embodiments of the present invention provided to calculate the maximum possible or permissible
10 the extracorporeal blood circuit 2000. The calculation may be carried out as described above.

The venous feed rate is in some embodiments of the present invention set by means of the feed rate Q5000 of the second
15 conveying device 5000 (*substitute pump*) deducting the feed rate Q4000 of the blood pump 4000. For this purpose, reference is made to the formulas above.

As with such a fixed specification of the volume of the blood
20 treatment device 3000 the arterial line section 1 of the extracorporeal blood circuit 2000 may be emptied earlier or faster than the venous line section 3, it is in certain embodiments of the present invention suggested to stop the blood pump 4000 before substitute liquid is conveyed across
25 the venous addition point 7.

Such stopping of the conveying by means of the blood pump 4000 is in certain embodiments possible by means of the corresponding adjustment of the feed rate of the blood
30 pump 4000, if the above-mentioned volume is known. Waiting for the moment in which the blood pump 4000 may be stopped - where

applicable advantageously more precise - is also possible considering the signals of the arterial air bubble detector or optical sensor 11 - if existent.

- 5 In some embodiments according to the present invention, the feed rate of the second conveying device 5000 is increased from the time of stopping the blood pump 4000 with the advantage of saving time.
- 10 If the volume of the utilized blood treatment device 3000 is known, the feed rate is advantageously set individually to the maximum possible feed rate with each reinfusion. This shortens the period of time the patient and the operating personnel have to spend at the blood treatment apparatus until the completion
- 15 of this measure, due to the faster removal of blood from the extracorporeal blood circuit 2000.

The type of the utilized blood treatment device 3000 may be set by the operating personnel. Alternatively, the utilized type

20 may be automatically determined by means of certain parameters which can be observed when filling the blood treatment device 3000.

If the volume of the blood treatment device 3000 is known, in

25 some embodiments according to the present invention, the feed rate of the second conveying device 5000 is set such that at the point of introduction of the venous addition point 7 (or at a comparable point in the blood circuit) substitute and blood of the same dilution degree from both line sections 1, 3 meet

30 at the same time. The blood pump 4000 may subsequently either be stopped; alternatively, it continues to run.

In embodiments in which the blood pump 4000 continues to run, the arterial line section 1 of the extracorporeal blood circuit 2000 is advantageously comparatively flushed better; in
5 embodiments in which the blood pump 4000 is stopped, the blood treatment device 3000 is advantageously comparatively flushed better.

In certain embodiments, the individual setting of the feed
10 rates takes place according to the above-named formula (II) and (III) if necessary.

Fig. 2 shows pressure and volume progresses (y-axis, vertical) over the time (x-axis, horizontal), which may occur or may be
15 measured by means of the arrangement shown in Fig. 1 while performing an embodiment according to the present invention of the method according to the present invention.

The scale on the left indicates a volume in ml/min for curves
20 Q4000 and Q5000, the scales on the right indicate pressure in mmHg and apply for curves P_art for the arterial pressure progress and P_ven for the venous pressure progress, as well as for P_ven_sm, the calculated smoothed progress of the curve P_ven.

25

Fig. 2 shows a curve Q5000 which is indicated by the conveying volume of the second conveying device 5000 over the time t or the feed rate Q5000. The curve Q5000 is composed of several curve sections Q5000-1 to Q5000-5.

30

Q5000 shows the conveying line of the second conveying device 5000 during an optional, so-called free rinsing of the pre-diluted valve 33. The conveying line of the second conveying device 5000 which is applied for this purpose, is, based on 0
5 ml/min, e.g. 100 ml/min. After completion of this free rinsing, the feed capacity may optionally drop to 0 ml/min. The volume conveyed thereby may be 10 ml for example.

Q5000 indicates the feed capacity during the blood-return or
10 emptying according to the present invention. Q5000 has a purely exemplary increasing course in the form of staircase, which however must not be neither in a form of a staircase nor must it comprise the pitches and heights. Q5000-2 shows the gradually increasing conveying capacity Q5000_aktuell of the
15 second conveying device 5000 which is being successively increased by the control device according to the above formula II.

The increase of Q5000, i.e. the section Q5000-2, starts at the
20 time $t=0$.

The progress section Q5000 goes in the present example at a time $t=1$ over a section Q5000-3 presently further increasing. The duration of the section Q5000-3 is thus $T = (t=1) - (t=0)$.

25

The feed capacity Q5000 of the second conveying device 5000 increases from the time $t=1$ until reaching a specified maximum feed capacity Q5000-4, presently for example 300 ml/min, again in a staircase form.

30

The maximum feed capacity Q5000-4 may again be reached in steps or staircase form, as exemplary shown in Fig. 2. It may however be reached in a vertical increase (with reference to Fig. 2) or in some other way.

5

Starting from the time $t=1$, an increase of Q5000 without considering the arterial pressure is undertaken. The formulas II and III are not considered any further starting from $t=1$. The increase takes place from $t=1$ regardless of the arterial pressure.

10

After the maximum feed capacity Q5000-4 has been reached and held, the curve Q5000 drops in its section Q5000-5 at the time $t=2$ to 0 ml/min. The method according to the present invention is concluded at $t=2$.

15

Fig. 2 shows further a curve Q4000 which indicates the feed volume of the blood pump 4000 through the time or the feed rate Q4000. The curve Q4000 is formed of several curve sections Q4000-1 to Q4000-4.

20

Q4000 shows the set feed capacity and - duration during an optional connection test. The applied feed capacity is, based on 0 ml/min, e.g. 25 ml/min. After completion of this connection test the feed capacity may optionally drop to 0ml/min.

25

Q4000-2 shows the feed capacity during the blood return or emptying according to the present invention. Q4000-2 shows an exemplary increasing progress in a form of a staircase which however must not be neither in a form of a staircase nor must

30

it comprise the indicated width and heights of the steps. Q4000-2 shows the gradually increasing feed capacity of the blood pump 4000 which stands in fixed relation to the feed capacity of the second conveying device 5000.

5

The increase of Q4000, i.e. its section Q4000-2, begins at the time $t=0$.

10 The progress section Q4000-2 passes over at a time $t=1$ which is between $t=0$ and $t=1$ into a plateau, the section Q4000-3. This plateau may correspond to a specified maximum feed capacity of 100 ml/min by way of example.

15 The feed capacity of the blood pump 4000 drops at the time $t=1$ to 0 ml/min. The drop is denoted with Q4000-4. Fig. 2 shows further a pressure progress P_{art} , its scaling is represented on the right edge of Fig. 2 and namely on the left of both adjacent scales.

20 The pressure P_{art} , e.g. measured by means of the arterial pressure sensor 9 of Fig. 1 increases by begin of the conveyance by means of the blood pump 4000 starting from the time $t=0$. The local maximum values P_{art-1} , P_{art-2} and so on denote, respectively, highest pressure which is measured in
25 certain rotary angle by conveyance with the blood pump 4000 which is embodied as a roller pump. This maximum pressure occurs during the intrusion of the roll of the blood pump 4000 with the pump tubing segment. The maximum value is adjustable as Fig. 2 also shows. The last measured maximum value P_{art-1} ,
30 P_{art-2} , and so on, respectively, enter into controlling. In this way, a first maximum value P_{art-1} which occurs

immediately after the begin of the method according to the present invention is initially measured and used in the following example as basis for the calculation as $P_{art,scan}$.

- 5 The blood pump 4000 generates, design-limited, two pressure pulses per rotation (may be more than two in other designs) which are measured at the arterial pressure sensor 9. An algorithm present in the control device determines, by means of the rotation angle of the pump rotor and of the actual pressure
10 present at the pressure sensor, these maximum pressures P_{art-1} , P_{art-2} and so on respectively, and provides this pressure for further processing as $P_{art,scan}$ as described above.

- The blood return begins at $t=0$, when the second conveying
15 device 5000 preferably at the same time as the blood pump 4000 begins with conveying, optionally with the lowest possible rate (the downward limitation is hereby design-limited), in this case 25 ml/min.

- 20 Until the time $t=1$ both the second conveying device 5000 as well as the blood pump 4000 convey.

- Thereby the blood pump 4000 is always regulated such that to convey with only a fraction of the feed rate Q_{5000} of the
25 second conveying device 5000. The exemplary selected relation in this case is $Q_{4000} = Q_{5000} \cdot 0,82$. This value has proven itself particularly advantageous due to the fact that with it, the passing of blood clots from the entry of the blood treatment device, here as a dialyser, on its blood side in the
30 arterial line section 1 is prevented.

It may therefore be intended that starting from a conveyance Q5000 of the second conveying device 5000 of e.g. more the 122 ml/min, the feed rate Q4000 of the blood pump 4000 is limited to e.g. 100 ml/min.

5

Following each created positive pressure pulse $P_{art,scan}$ by the blood pump 4000 which is measured in the pressure sensor 9, the feed rate Q5000 of the second conveying device 5000 is increased. It is increased to an upper point which is
10 determined by the user by means of the maximum measurement range limit of the pressure sensor where a specified pressure limit $P_{art,soll}$ is reached.

Therefore, the pressure in the pressure sensor 9 shall reliably
15 not exceed its upper measurement range $P_{art,max}$, here 455 mmHg in the present example. $P_{art,max}$ is in this example, the pressure value starting from which the pressure sensor releases an alarm due to high pressure. Hence, the regulation target $P_{art,soll}$ for the pressure in the pressure sensor 9 is
20 specified to be 90% of the measurement range $*0,9$, i.e. around 410 mmHg.

In the example of Fig. 2, the first maximum value for the pressure, namely P_{art-1} is about 260 mmHg. If measured to the
25 target value $P_{art,soll}$ of about 410 mmHg (corresponds to 455mmHg.* 0,9), the control difference in this example is now about 150 mmHg.

The feed rate Q5000 of the second conveying device 5000 is
30 increased in the section Q5000-2 as follows:

$$Q5000_künftig = Q5000_aktuell + ((P_art, soll) - (P_art, scan)) * 0,12 \text{ *ml/min}$$

Q5000_künftig is thereby the new feed rate to be determined.
 5 Q5000_aktuell is the last determined. Q5000_künftig might therefore also be denoted as $Q5000(t=x+1)$ and Q5000_aktuell might be denoted as $Q5000(t=x)$.

Should the pressure in the pressure sensor 9 exceed the
 10 regulation target $P_art, soll$, the following countermeasures are taken:

$$Q5000_künftig = Q5000_aktuell + ((P_art, soll) - (P_art, scan)) * 0,24 \text{ *ml/min}$$

15

Starting from the time $t=1$ of Fig. 2, the blood pump 4000 ceases to convey, only the second conveying device 5000 still conveys.

Starting from the time $t=1$ of Fig. 2, the feed rate Q5000 of
 20 the second conveying device 5000, presently purely by way of example, is increased each 0,5s of 10ml/min until the maximum flow which is determined by the user in the device is reached. Other values are of course encompassed by the present invention as well.

25

The progress P_ven is measured by means of the venous pressure sensor, the course P_ven_sm corresponds to the smoothing of the first-mentioned.

Reference Numerals List

<u>Reference numerals</u>	<u>Description</u>
1000	functional device
2000	extracorporeal blood circuit
3000	blood treatment device
4000	blood pump
5000	second conveying device
1	arterial line section
3	venous line section
5	arterial needle connection
7	venous addition point
9	(arterial) pressure sensor or pressure measurement
11	arterial clamp
13	arterial septum
15	venous air bubble detector/optical sensor
17	venous clamp
19	venous needle
21	venous patient connector
23	venous septum
24	check valve
25	heparin syringe
27	arterial air bubble detector/optical sensor
29	single needle chamber
29a	blood chamber or bubble chamber
31	clot catcher
33	pre-dilution valve
P _{art}	
P _{art} -1, -2, -3	maximum value P _{art} , scan
P _{ven}	venous pressure
P _{ven sm}	smoothed progress of the curve P _{ven}

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ENGLISH TRANSLATION

Q4000	feed rate of the blood pump
Q4000-1 to Q4000-4	sections of curve Q4000
Q5000	feed rate of the second conveying device
Q5000-1 to Q5000-5	sections of curve Q5000

Claims

1. A method of removing blood from an extracorporeal blood circuit and/or a functional device, each of which is connected with a blood treatment apparatus for the purpose of a blood treatment of a patient, after concluding the blood treatment session,

wherein the blood treatment apparatus comprises or is connected with:

 - at least one extracorporeal blood circuit with a line interior, wherein the extracorporeal blood circuit comprises at least one arterial line section and at least one venous line section;
 - at least one blood pump for conveying blood within the line interior in a first conveying direction;
 - at least a substitute pump, for introducing a substitute liquid into the line interior of the extracorporeal blood circuit and for conveying a line content within the line interior of the extracorporeal blood circuit;

wherein the method encompasses the step:

 - while operating the substitute pump to introduce the substitute liquid into the extracorporeal blood circuit, operating the blood pump in a second conveying direction which is opposite to the first conveying direction of this pump which is customarily operated during the blood treatment;

wherein a first section of the arterial line section is in fluid connection with a second section of the venous line section of the extracorporeal blood circuit and

wherein a feed rate (Q_{4000}) of the blood pump is or will be determined in order to, at least at a point of time or during at least a time period ($t=1-t=0$) or until reaching a specified maximum feed rate (Q_{4000-3}), to which the feed rate (Q_{4000}) of the blood pump is limited or is supposed to be user-limited, to be between 75% and 90% of a feed rate (Q_{5000}) of the substitute pump,

wherein the feed rates (Q_{4000} , Q_{5000}) of the blood pump and the substitute pump during the removal of blood are monitored or controlled or regulated by at least one of a means of pressure control, a means of pressure measurement and a means of pressure limitation, wherein the feed rates (Q_{4000} , Q_{5000}) are monitored or controlled or regulated by means of multiple measurement of an actual feed pressure ($P_{art,scan}$) of the blood pump, by determination of control difference between the measured feed pressure of the blood pump and a target value ($P_{art,soll}$) of the feed pressure, and by raising the feed rate (Q_{4000}) of the blood pump according to the control difference, and

wherein the actual feed pressure ($P_{art,scan}$) is measured or calculated when a pre-determined rotation angle or rotation angle range of a pump rotor of the blood pump is reached.

2. The method according to claim 1, wherein the feed rate (Q4000) of the blood pump is limited to a value, specified by the user of between 90 and 110/ml/min.
3. The method according to claim 1 or 2, wherein at least one of the feed rate (Q4000) of the blood pump and the feed rate (Q5000) of the substitute pump is limited to not be increased further when the actual feed pressure (P_{art,scan}) has reached or exceeded the target value (P_{art,soll}), wherein the target value (P_{art,soll}) is as follows:

$$P_{art,soll} = a \cdot P_{art,max}$$

wherein the following applies:

P_{art,soll} is the target value of the feed pressure measured by a means of the arterial pressure measurement;

a is a first constant with a value of between 0,85 and 0,95;

P_{art,max} is a pre-set or specified measurement range limit or an admissible maximum value for the pressure measured by means of the arterial pressure measurement.

4. The method according to claim 3 with the step:
 - increasing of the feed rate (Q5000) of the substitute pump according to the formula:

$$Q5000_künftig = Q5000_aktuell + ((P_art,soll) - (P_art,scan)) * b;$$

wherein the following applies:

$Q5000_künftig$ is a feed rate of the substitute pump which is to be set henceforth to a point of time $t_künftig$, respectively;

$Q5000_aktuell$ is an actual feed rate of the substitute pump at a point of time $t_aktuell$, which is to be replaced by $Q5000_künftig$ and precedes this temporally, respectively, wherein $t_aktuell$ comes before $t_künftig$; $t_künftig$ being denoted as $t(x+1)$ and $t_aktuell$ as $t(x)$;

$P_art,soll$ is a pre-set target value which should be applied or detected by the means of arterial pressure measurement

$P_art,scan$ is a pressure value which is measured by the means of arterial pressure measurement during the adapting of the actual feed rate $Q5000_aktuell$; and

b is a second constant with a value of between 0,10 and 0,15, or is 0,12.

5. The method according to claim 3 with the step:

- decreasing the feed rate ($Q5000$) of the substitute pump when the feed pressure ($P_art,scan$) reaches the target pressure ($P_art,soll$) or exceeds it, according to the formula:

$$Q5000_künftig = Q5000_aktuell + ((P_art,soll) - (P_art,scan)) * c;$$

wherein the following applies:

$Q5000_künftig$ is a feed rate of the substitute pump which is to be set henceforth to a point of time $t_künftig$, respectively;

$Q5000_aktuell$ is an actual feed rate of the substitute pump at a point of time $t_aktuell$, which is to be replaced by $Q5000_künftig$ and precedes this temporally, respectively, wherein $t_aktuell$ comes before $t_künftig$; $t_künftig$ being denoted as $t(x+1)$ and $t_aktuell$ as $t(x)$;

$P_art,soll$ is a pre-set target value which should suit the means of arterial pressure measurement

$P_art,scan$ is a pressure value which is measured by the means of künftig measurement during the adapting of the actual feed rate $Q5000_aktuell$; and

c is a third constant with a value of between 0,20 and 0,30, or is 0,24.

6. The method according to any one of claims 1 to 5, with the step:
 - stopping the blood pump before the substitute liquid is introduced into the venous line section of the

extracorporeal blood circuit at a venous addition point, or before the substitute liquid reaches a point or place at which fluid from the venous line section and fluid from the arterial line section are joined or meet;

or

- stopping the substitute pump before the substitute liquid is introduced into the venous line section of the extracorporeal blood circuit at the venous addition point, or before the substitute liquid reaches a point or passage at which fluid from the venous line section and fluid from the arterial line section are joined or meet.
7. The method according to any one of claims 1 to 6, further encompassing the step:
- checking the connection of the first section of the arterial line section of the extracorporeal blood circuit with the second section of the venous line section of the extracorporeal blood circuit.
8. The method according to claim 7, wherein checking encompasses:
- creating a pressure balance or compensation;
 - detecting a diastolic patient pressure; and
 - building up a negative pressure by means of the blood pump which is conveying in the first conveying direction or forwardly.

9. The method according to any one of claims 1 to 8, wherein the venous addition point of the venous line section of the extracorporeal blood circuit leads into the venous line section upstream from a blood chamber and upstream from a clot catcher.
10. A control device or regulating device, suitable and arranged for executing the method according to any one of claims 1 to 9.
11. A blood treatment apparatus embodied as a hemodialysis apparatus, hemofiltration apparatus or hemodiafiltration apparatus, provided and embodied for executing the method according to any one of claims 1 to 9.
12. A digital storage medium in the form of a disk, CD or DVD or EPROM, with electrically readable control signals, configured for interacting with a programmable computer system such that the mechanical steps of the method according to any one of the claims 1 to 9 are prompted.
13. A computer program product with a program code saved on a machine-readable medium for prompting the mechanical steps of the method according to any one of claims 1 to 9 when the computer program product runs on a computer.
14. A computer program with a program code for prompting the mechanical steps of a method according to any one of claims 1 to 9 when the computer program product runs on a computer.

15. The method according to any one of claims 1 to 6,
wherein said checking step is:
- checking the connection of the arterial needle
connection of the extracorporeal blood circuit with
the venous addition point of the extracorporeal blood
circuit.

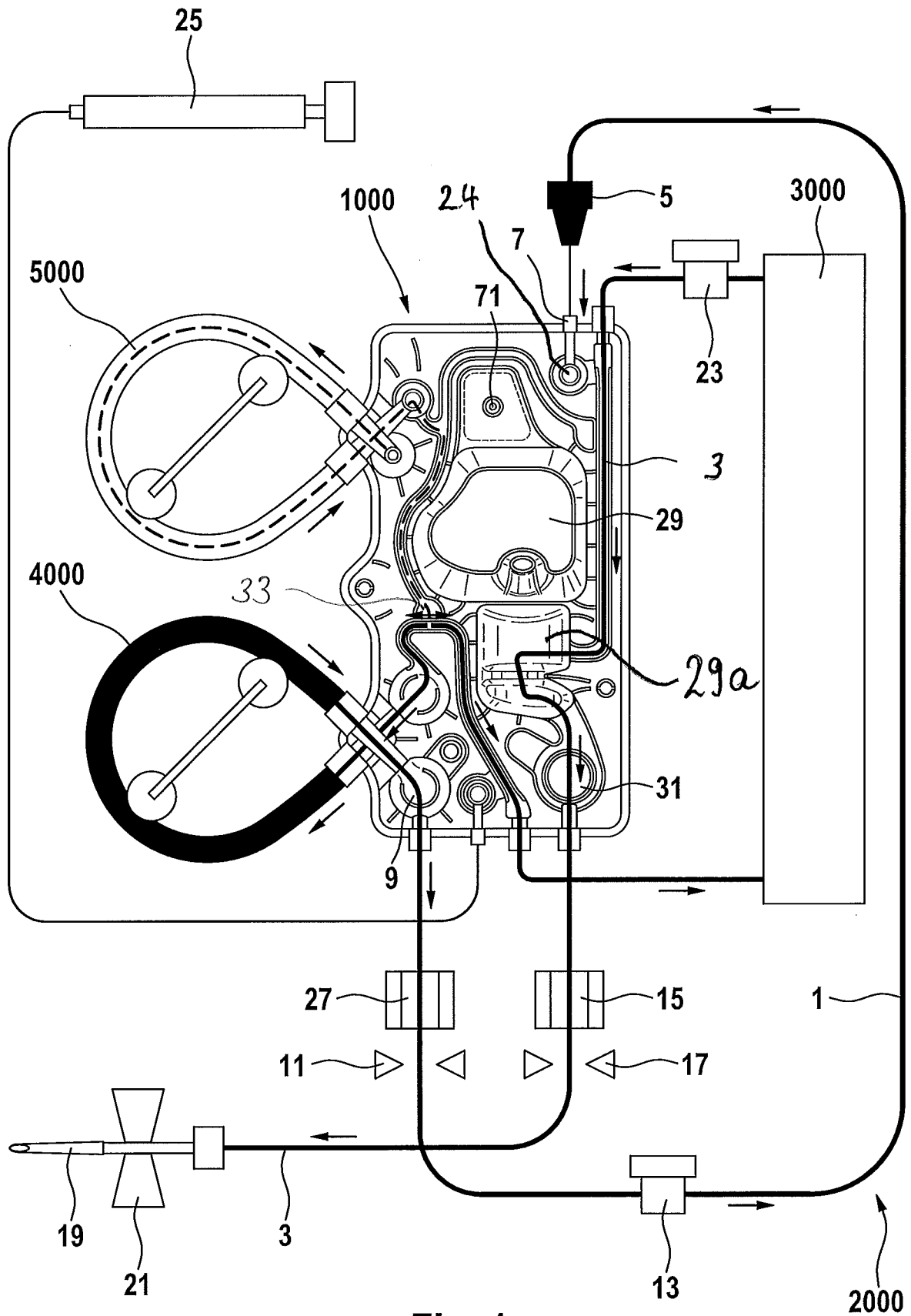


Fig. 1

