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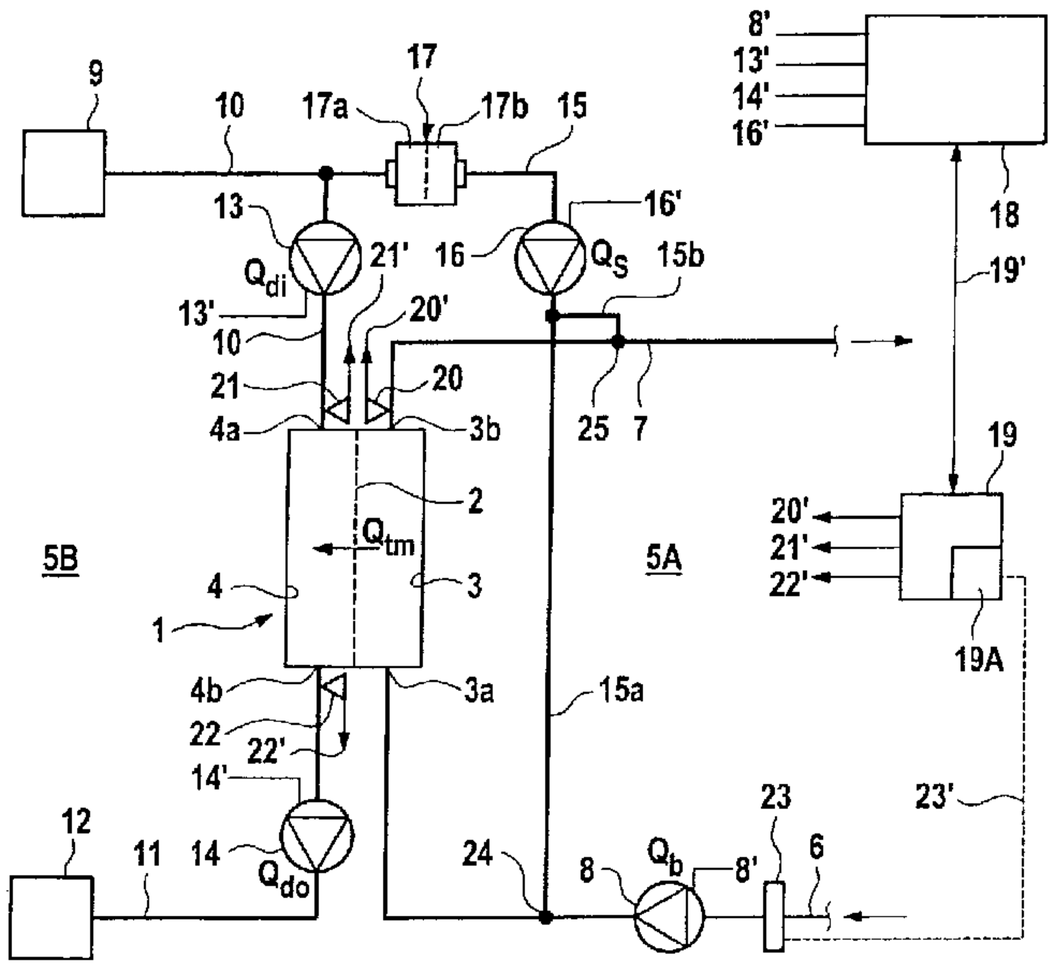

(57) Abrégé/Abstract:
The invention relates to a method for determining the transmembrane pressure during an extracorporeal blood treatment in which blood flows at a defined blood flow rate through an arterial blood conduit 6 of an extracorporeal blood circuit 5A into the inlet of a first chamber 3 of a dialyzer 1, which is divided by a semipermeable membrane 2 into the first chamber and a second chamber 4, and flows through a venous blood conduit 7 from the outlet of the first chamber 3 of the dialyzer 1, while dialysis liquid flows through a dialysis liquid supply conduit 10 into the inlet of the second chamber of the dialyzer and flows through a dialaysis liquid discharge conduit 11 from the outlet of the second chamber of the dialyzer. The method according to the invention and the device according to the invention for determining the transmembrane pressure are such that the pressure on the blood side and on the dialysis liquid side of the dialyzer is measured with relatively little technical outlay, specifically with fewer than four pressure sensors 20, 21, 22, and a preliminary uncorrected value is calculated for the transmembrane pressure and is thereafter corrected by a correction variable that is dependent on a variable correlating with the viscosity of the blood.

Abstract

The invention relates to a method for determining the transmembrane pressure during an extracorporeal blood treatment in which blood flows at a defined blood flow rate through an arterial blood conduit 6 of an extracorporeal blood circuit 5A into the inlet of a first chamber 3 of a dialyzer 1, which is divided by a semipermeable membrane 2 into the first chamber and a second chamber 4, and flows through a venous blood conduit 7 from the outlet of the first chamber 3 of the dialyzer 1, while dialysis liquid flows through a dialysis liquid supply conduit 10 into the inlet of the second chamber of the dialyzer and flows through a dialaysis liquid discharge conduit 11 from the outlet of the second chamber of the dialyzer. The method according to the invention and the device according to the invention for determining the transmembrane pressure are such that the pressure on the blood side and on the dialysis liquid side of the dialyzer is measured with relatively little technical outlay, specifically with fewer than four pressure sensors 20, 21, 22, and a preliminary uncorrected value is calculated for the transmembrane pressure and is thereafter corrected by a correction variable that is dependent on a variable correlating with the viscosity of the blood.

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Method and device for determining the transmembrane pressure in an extracorporeal blood treatment

The invention relates to a method for determining the transmembrane pressure during an extracorporeal blood treatment, in which blood flows at a specific blood flow rate via an arterial blood supply line of an extracorporeal blood circuit into the inlet of a first chamber of a dialyser divided by a semipermeable membrane into the first chamber and a second chamber and flows via a venous blood return line from the outlet of the first chamber of the dialyser, whilst dialysing fluid flows via a dialysing fluid supply line into the inlet of the second chamber of the dialyser and flows via a dialysing fluid discharge line out of the outlet of the second chamber of the dialyser, fluid being withdrawn from the blood at a specific flow rate via the membrane of the dialyser. Moreover, the invention relates to an extracorporeal blood treatment in which the transmembrane pressure is determined. Furthermore, the invention relates to a device for determining the transmembrane pressure for a blood treatment apparatus for performing an extracorporeal blood treatment and an extracorporeal blood treatment apparatus with a device for determining the transmembrane pressure.

Various methods for extracorporeal blood treatment or cleaning are used for the purpose of removing substances usually eliminated with urine and for the purpose of withdrawing fluid. In the case of haemodialysis, the patient's blood is cleaned outside the body in a dialyser. The dialyser has a blood chamber and a dialysing fluid chamber, which are separated by a semipermeable membrane. During the treatment, the patient's blood flows through the blood chamber. In order to clean the blood effectively from substances usually eliminated with urine, fresh dialysing fluid continuously flows through the dialysing fluid chamber.

Whereas the transport of the smaller molecular substances through the membrane of the dialyser is essentially determined by the concentration differences (diffusion) between the dialysing fluid and the blood in the case of haemodialysis (HD), substances dissolved in

the plasma water, in particular higher molecular substances, are effectively removed by a high fluidic flow (convection) through the membrane of the dialyser in the case of haemofiltration (HF). In haemofiltration, the dialyser acts as a filter, which is therefore referred to in the following as a dialyser. Haemodiafiltration (HDF) is a combination of the two methods.

In the case of haemo(dia)filtration (HDF), a part of the serum withdrawn via the membrane of the dialyser is replaced by a sterile substitution fluid, which is supplied to the extracorporeal blood circuit upstream and/or downstream of the dialyser. The supply of substitution fluid upstream of the dialyser is referred to as pre-dilution and the supply downstream of the dialyser as post-dilution.

In an extracorporeal blood treatment, the ultrafiltration rate (UF rate) is of interest, which is a measure of the amount of fluid withdrawn from the patient within a time interval. The ultrafiltration rate is dependent on transmembrane pressure TMP in the extracorporeal blood treatment, the ultrafiltration rate increasing with increasing transmembrane pressure.

Transmembrane pressure TMP is defined as the pressure difference between the mean blood-side pressure and the mean dialysate-side pressure on the dialyser. In principle, four pressure measurements are required for an exact determination of the transmembrane pressure, the pressure being measured at the inlet and outlet of the blood chamber and inlet and outlet of the dialysing fluid chamber of the dialyser. For this purpose, a pressure sensor is required in each case at the blood-side inlet and outlet and at the dialysate-side inlet and outlet of the dialyser.

In practice, however, the measurement of the transmembrane pressure by means of four pressure sensors proves to be relatively expensive. For reasons of technical simplification, therefore, the determination of the transmembrane pressure by means of four pressure sensors is generally refrained from in practice.

For the determination of the transmembrane pressure, it is known to determine the pressure solely by means of two pressure sensors, whereof one pressure sensor is disposed on the blood side and the other pressure sensor on the dialysate side. For reasons of handling and cost, it is proposed, for example in the article by H. D. Polaschegg "Methods and history of

ultrafiltration control in haemodialysis (Aktuelle Nephrologie, vol. 1/1985, page 135 and following), to restrict the measurement to the venous backflow pressure and the pressure at the dialysing fluid outlet.

Apart from the determination of the transmembrane pressure by means of two pressure sensors, the determination of the membrane pressure by means of three pressure sensors is also known. For the determination of the transmembrane pressure, EP 0 212 127 for example proposes measuring the pressure in the dialysing fluid supply line and discharge line and the pressure in the blood return line, in particular the drip chamber disposed in the blood return line, and calculating the transmembrane pressure on the basis of the measured pressures. The calculated transmembrane pressure is compared with a predetermined set-point value for the mean transmembrane pressure, in order to adjust the dialysing fluid pump disposed in the dialysing fluid discharge line. The suction pump on the dialysing fluid side is regulated in such a way that the transmembrane pressure in the dialyser is kept at the setpoint value.

In practice, the determination of the transmembrane pressure on the basis of only two or three pressure measurements, whereof one pressure measurement takes place on the blood side and the other measurement on the dialysate side in each case, has been considered to be sufficiently accurate. The inventors have found, however, that under certain treatment conditions limiting factors have to be placed on the determination of the transmembrane pressure with a high degree of accuracy.

The problem underlying the invention is to provide a method for determining the transmembrane pressure in an extracorporeal blood treatment, which on the one hand requires only a relatively small technical outlay for the measurement and on the other hand guarantees a high degree of accuracy under all treatment conditions.

Moreover, it is a problem of the invention to provide a device for determining the transmembrane pressure for an extracorporeal blood treatment apparatus, which permits a determination of the transmembrane pressure with a high degree of accuracy with less than four pressure sensors under all treatment conditions.

Further problems of the invention are a method for extracorporeal blood treatment and an extracorporeal blood treatment apparatus, wherein the determination of the transmembrane pressure takes place with a high degree of accuracy with a relatively low technical outlay.

The method according to the invention and the device according to the invention for determining the transmembrane pressure are based on the fact that the pressure on the blood side and dialysing fluid side of the dialyser is measured with less than four pressure sensors with a relatively low technical outlay and a preliminary uncorrected value for the transmembrane pressure is calculated, which is then corrected with a correcting quantity which is dependent on a variable correlating with the viscosity of the blood. Consequently, a variable correlating with the viscosity of the blood, in particular the haematocrit of the blood, is taken into account in the determination of the transmembrane pressure.

The inventors have found that, especially in the case of marked thickening or thinning of the blood, such as can occur during haemodiafiltration treatment or haemofiltration treatment, deviations can occur between the actual transmembrane pressure and the value for the transmembrane pressure which results from the measurement of the pressure at less than four measuring points, for example in the case of a measurement of the pressure only at the inlet or outlet, but not at the inlet and outlet of the respective chambers of the dialyser.

With the method according to the invention, the determination of the transmembrane pressure is also particularly accurate when erythropoietin (EPO) is administered to the patient, as a result of which the haematocrit increases and the viscosity of the blood rises.

In a preferred embodiment of the method according to the invention and the device according to the invention, the pressure on the blood side is measured in the blood return line at the outlet of the first chamber of the dialyser, whilst on the dialysing fluid side the pressure is measured in the dialysing fluid supply line at the inlet of the second chamber and in the dialysing fluid discharge line at the outlet of the second chamber of the dialyser. It is

therefore not necessary to measure the pressure on the blood side in the blood supply line at the inlet of the first chamber of the dialyser, so that the pressure measurement can take place with only three pressure sensors.

It is however also possible that, on the blood side, the pressure is measured not at the outlet, but at the inlet of the first chamber of the dialyser. Likewise, it is possible that the pressure on the blood side is measured both at the inlet and outlet of the first chamber of the dialyser, whilst the pressure on the dialysing fluid side is measured only either at the inlet or at the outlet of the second chamber of the dialyser. The decisive factor is that at least one pressure measurement takes place both on the blood side and the dialysing fluid side of the dialyser.

When mention is made of a measurement of the pressure at the inlet or outlet of one of the two chambers of the dialyser, this does not necessarily have to be understood to mean that the measurement has to take place directly at the point at which the lines are connected to the dialyser. On the contrary, it is also possible to carry out the measurement upstream or downstream of the inlet or outlet, whereby it is to be assumed that the pressure increase or pressure decrease between the actual measuring point and the inlet or outlet of the respective chamber of the dialyser is small.

The correcting quantity for the transmembrane pressure is preferably a parameter characteristic of the flow resistance of the dialyser in the longitudinal direction, said parameter in turn being dependent on a parameter correlating with the viscosity of the blood, in particular on the haematocrit.

It has been shown that the deviations between the transmembrane pressure that is calculated on the basis of a measurement with less than four pressure sensors and the actual transmembrane pressure increases with increasing flow resistance of the dialyser in the longitudinal direction. Since, in the determination of the transmembrane pressure by the method according to the invention and the device according to the invention, the flow resistance of the dialyser in the longitudinal direction is taken into account, the actual transmembrane pressure can be calculated with a high degree of accuracy.

The flow resistance of the dialyser in the longitudinal direction, which is dependent on a parameter correlating with the viscosity of the blood, in particular the haematocrit, can in principle be calculated at the start of the blood treatment or during the blood treatment.

A particularly preferred embodiment of the invention provides for a continuous determination of the parameter correlating with the viscosity of the blood, in particular the haematocrit, during the blood treatment, whereby the haematocrit is measured on-line.

The dependence of the longitudinal resistance of the dialyser on the variable correlating with the viscosity of the blood, in particular on the haematocrit, is preferably described by a polynomial approach, the parameters of which are determined from individual measurement data for each relevant type of dialyser on the assumption of a pre- or post-dilution.

The inventors have found that the flow resistance in the longitudinal direction of the dialyser is essentially dependent on the design of the dialyser, which is characterised by a specific membrane area or length and a specific diameter of the capillaries, on the type of treatment, for example an HD treatment or H(D)F treatment with pre-dilution or post-dilution, on the substitution rate and on the ultrafiltration rate and the blood constituents. In a preferred embodiment of the invention, therefore, the aforementioned quantities are taken into account in the polynomial approach for the determination of the longitudinal resistance of the dialyser.

The correcting quantity for the transmembrane pressure is preferably determined on the basis of the product of the parameter characteristic of the flow resistance in the longitudinal direction of the dialyser and the blood flow rate in the extracorporeal blood circuit. The correcting quantity is therefore also dependent on the blood flow.

The method according to the invention and the device according to the invention therefore proceed on the basis that the deviations between the transmembrane pressure calculated on the basis of the measured pressures and the actual transmembrane pressure increase with increasing viscosity of the blood and with increasing blood flow.

The device according to the invention for determining the transmembrane pressure, which is determined for a blood treatment apparatus for performing an extracorporeal blood

treatment, comprises means for measuring the pressure on the blood side and the dialysing fluid side and means for calculating the transmembrane pressure taking account of the correcting quantity. The means for measuring the pressure on the blood side and the dialysing fluid side of the dialyser comprise, in a preferred embodiment, means for measuring the pressure in the blood return line at the outlet of the first chamber of the dialyser as well as means for measuring the pressure in the dialysing fluid supply and return line at the inlet and outlet of the second chamber of the dialyser. Means for measuring the pressure in the blood supply line at the inlet of the first chamber of the dialyser are not therefore required.

The means for measuring the pressure can be conventional pressure sensors, which are in any case present in the case of the known blood treatment apparatuses. The means for calculating the transmembrane pressure can be a conventional microprocessor or suchlike, which is also in any case present in the known blood treatment apparatuses.

According to one aspect of the present invention, there is provided a method for determining the transmembrane pressure during an extracorporeal blood treatment, in which blood flows at a specific blood flow rate via an arterial blood supply line of an extracorporeal blood circuit into the inlet of a first chamber of a dialyser divided by a semipermeable membrane into the first chamber and a second chamber and flows via a venous blood return line from the outlet of the first chamber of the dialyser, and dialysing fluid flows via a dialysing fluid supply line into the inlet of the second chamber of the dialyser and flows via a dialysing fluid discharge line out of the outlet of the second chamber of the dialyser, fluid being withdrawn from the blood at a specific flow rate via the membrane of the dialyser, with the flowing method steps: measurement of the pressure on the blood side at the inlet or outlet of the first chamber of the dialyser and on the dialysing fluid side at the inlet and/or outlet of the second chamber of the dialyser, or measurement of the pressure on the blood side at the inlet and/or outlet of the first chamber of the dialyser and on the dialysing fluid side at the inlet or outlet of the second chamber of the dialyser, and calculation of the transmembrane pressure on the basis of the pressure measured on the blood side and dialysing fluid side, wherein a variable correlating with the viscosity of the blood is determined, a correcting quantity for the

transmembrane pressure is determined, which is dependent on a variable correlating with the viscosity of the blood, and the transmembrane pressure is calculated on the basis of the pressure measured on the blood side and the dialysing fluid side and the correcting quantity for the transmembrane pressure.

According to another aspect of the present invention, there is provided a device for determining the transmembrane pressure for a blood treatment apparatus for performing an extracorporeal blood treatment, in which blood flows at a specific blood flow rate via an arterial blood supply line of an extracorporeal blood circuit into the inlet of a first chamber of a dialyser divided by a semipermeable membrane into the first chamber and a second chamber and flows via a venous blood return line from the outlet of the first chamber of the dialyser, and dialysing fluid flows via a dialysing fluid supply line into the inlet of the second chamber of the dialyser and flows via a dialysing fluid discharge line out of the outlet of the second chamber of the dialyser, fluid being withdrawn from the blood at a specific flow rate via the membrane of the dialyser, whereby the device for determining the transmembrane pressure comprises: means for measuring the pressure on the blood side at the inlet or outlet of the first chamber of the dialyser and on the dialysing fluid side at the inlet and/or outlet of the second chamber of the dialyser, or for measuring the pressure on the blood side at the inlet and/or outlet of the first chamber of the dialyser and on the dialysing fluid side at the inlet or outlet of the second chamber of the dialyser, and means for calculating the transmembrane pressure on the basis of the pressure measured on the blood side and the dialysing fluid side, wherein the means for calculating the transmembrane pressure are configured to determine a correcting quantity for the transmembrane pressure, said correcting quantity being dependent on a variable correlating with the viscosity of the blood, and that the transmembrane pressure is calculated on the basis of the pressure measured on the blood side and dialysing fluid side and the correcting quantity for the transmembrane pressure.

According to another aspect of the present invention, there is provided an apparatus for extracorporeal blood treatment with a device as described herein.

An example of embodiment of the method according to the invention and the device according to the invention will be described in detail below by reference to the appended figure.

The figure shows only the main components of a blood treatment apparatus for an extracorporeal blood treatment together with a device for determining the transmembrane pressure in a greatly simplified schematic representation.

The device according to the invention for measuring the transmembrane pressure can be a component of a conventional blood treatment apparatus or a separate device unit which cooperates with the blood treatment apparatus.

The present blood treatment apparatus is a haemo(dia)filtration apparatus, which comprises a dialyser 1, which is divided by a semipermeable membrane 2 into a first chamber 3 through which blood flows and which will be referred to in the following as a blood chamber, and a second chamber 4 through which dialysing fluid flows which will be referred to as a dialysing fluid chamber. First chamber 3 is incorporated into an extracorporeal blood circuit 5A, whilst second chamber 4 is incorporated into dialysing fluid system 5B of the haemo(dia)filtration apparatus.

Extracorporeal blood circuit 5A comprises an arterial blood supply line 6 which leads to inlet 3a of chamber 3, and a venous blood return line 7 which departs from outlet 3b of blood chamber 3 of dialyser 1. The patient's blood is conveyed through blood chamber 3 of dialyser 1 by an arterial blood pump 8, in particular a roller pump, which is disposed on arterial blood return line 6. The blood pump delivers blood at a specific blood flow rate Q_b to blood chamber 3 of the dialyser. In order to eliminate air bubbles, an air separator (drip chamber) can be incorporated into the arterial and venous blood line.

Blood lines 6, 7 of the blood treatment apparatus are tube lines which are placed into the roller pumps for one-off use. In principle, therefore, the tube lines are not a component of the blood treatment apparatus. In principle, the dialyser is also not a component of the blood treatment apparatus, but rather is connected for one-off use to the tube lines.

The fresh dialysing fluid is made available in a dialysing fluid source 9. A dialysing fluid supply line 10 leads from dialysing fluid source 9 to inlet 4a of dialysing fluid chamber 4 of dialyser 1. A dialysing fluid discharge line 11 leads from outlet 4b of dialysing fluid chamber 4 to a drain 12. A first dialysing fluid pump 13 is incorporated into dialysing fluid supply line 10 and a second dialysing fluid pump 14 is incorporated into dialysing fluid discharge line 11. First dialysing fluid pump 13 delivers dialysing fluid from the dialysing fluid source at a specific dialysing fluid supply rate Q_{di} to inlet 4a of dialysing fluid chamber 4, whilst second dialysing fluid pump 14 delivers dialysing fluid at a specific dialysing fluid discharge rate Q_{do} from outlet 4b of dialysing fluid chamber 4 to drain 12.

During the dialysis treatment, dialysing fluid from dialysing fluid system 5B can be fed as a substitution fluid via a substitution fluid line 15 to extracorporeal circuit 5A, which branches off from dialysing fluid supply line 10 upstream of first dialysing fluid pump 13.

Substitution fluid line 15 comprises two line sections 15a and 15b, whereof one line section 15a leads to arterial blood line 6 and the other line section 15b leads to venous blood line 7.

The substitution fluid is delivered by means of a substituate pump 16, in particular a roller pump, into which substitution fluid line 15 is inserted. A sterile filter 17 divided into two

chambers 17a, 17b is incorporated into substitution fluid line 15 upstream of the substituate pump. The substituate pump together with the accompanying lines and the sterile filter form the substitution device of the dialysis apparatus. For the clamping of the two line sections 15a, 15b of substitution fluid line 15, shut-off elements, for example hose clamps, can be provided, which however are not represented for the sake of greater clarity.

Blood pump 8, first and second dialysing fluid pump 13 and 14 and substituate pump 16 are connected via control lines 8', 13', 14', 16' to a central control and computing unit 18, from which the pumps are controlled taking account of the preselected treatment parameters. Control and computing unit 18 also controls the shut-off elements (not shown), in order to perform the blood treatment with pre-dilution or post-dilution.

For the operation of the haemo(dia)filtration apparatus as a haemodialysis apparatus, blood pump 8 and first and second dialysing fluid pumps 13 and 14 are operated, dialysing fluid flowing through dialysing fluid chamber 4 of dialyser 1. For the operation of the haemo(dia)filtration apparatus as a haemodiafiltration apparatus, substituate pump 16 is operated, so that sterile dialysing fluid as a substitution fluid flows via sterile filter 17 optionally to arterial supply point 24 downstream of blood pump 8 and upstream of blood chamber 3 (pre-dilution) or to venous supply point 25 downstream of the blood chamber (post-dilution). In principle, however, an operation of the haemo(dia)filtration apparatus is also possible solely as a haemofiltration apparatus, if first dialysing fluid pump 13 is not operated and the supply of dialysing fluid into the dialysing fluid chamber of the dialyser is thus interrupted.

The processing of the treatment parameters characteristic of the blood treatment takes place in central control and computing unit 18 of the blood treatment apparatus. These characteristic variables can either be inputted by the operator of the machine, be measured during the treatment and/or be calculated from measured and/or preselected variables. In the following, it is assumed that all of the variables of relevance here are made available by the central control and computing unit, since they are inputted by the operator via a keyboard (not shown) and/or measured by measuring units (not shown) and/or calculated from the inputted and/or measured variables.

The device according to the invention for determining the transmembrane pressure can form an independent module or component of central control and computing unit 18 of the blood treatment apparatus. In the present example of embodiment, the relevant components of the device for determining the transmembrane pressure form a separate module which will be described in detail below.

The device for determining the transmembrane pressure comprises a central computing unit 19, for example a microprocessor, which may also be the microprocessor which is provided in central control and computing unit 18 of the treatment apparatus. Moreover, the device for determining the transmembrane pressure can comprise a total of three pressure sensors 20, 21, 22, whereof the first pressure sensor measures the pressure at outlet 3b of first chamber 3 of dialyser 1, second pressure sensor 21 measures the pressure at inlet 4a of second chamber 4 and pressure sensor 22 measures the pressure at outlet 4b of second chamber 4 of dialyser 1. These pressure sensors do not have to be disposed directly at the inlet and outlet of the dialyser. The decisive factor is that the pressure is measured with sufficient accuracy at the blood-side outlet and at the dialysate-side inlet and outlet of the dialyser.

Computing unit 19 receives the measured values of pressure sensors 20, 21, 22 via data lines 20', 21' and 22'. Moreover, computing unit 19 communicates via a further data line 19' with central control and computing unit 18 of the blood treatment apparatus in order to receive the variables of relevance here, which are inputted by the operator and/or are measured by sensors (not shown) and/or are calculated.

In a preferred embodiment, the device for determining the transmembrane pressure also comprises a measuring unit 23 for measuring the haematocrit of the blood flowing in extracorporeal blood circuit 5A, which can change in the course of the extracorporeal blood treatment. On account of the ultrafiltration, the haematocrit generally increases during the blood flow treatment. Computing unit 19 is connected via a data line 23' to measuring unit 23 for determining the haematocrit. Measuring units for determining the haematocrit are known to the person skilled in the art from the prior art.

The theoretical principles of the determination of the transmembrane pressure and the device according to the invention for determining the transmembrane pressure and the

method according to the invention, according to which the device for determining the transmembrane pressure works, are described in detail below.

Four pressure sensors are in principle required for the exact determination of mean transmembrane pressure TMP. After the measurement of the pressure at blood-side inlet $P_{b,in}$, the pressure at blood-side outlet $P_{b,out}$, the pressure at dialysate-side inlet $P_{d,in}$ and the pressure at dialysate-side outlet $P_{d,out}$, transmembrane pressure P_{TM} (TMP) can be calculated according to the following equation

$$TMP = P_{TM} = \frac{P_{b,in} + P_{b,out}}{2} - \frac{P_{d,in} + P_{d,out}}{2} \quad (1)$$

where

P_{TM}	transmembrane pressure TMP
$P_{b,in}$	pressure at the blood-side inlet of the dialyser
$P_{b,out}$	pressure at the blood-side outlet of the dialyser (= venous pressure P_{ven})
$P_{d,in}$	pressure at the dialysate-side inlet of the dialyser
$P_{d,out}$	pressure at the dialysate-side outlet of the dialyser

In the present example of embodiment, however, the pressure is measured not by means of four pressure sensors at the aforementioned measuring points, but only by means of three pressure sensors 20, 21, 22, which measure pressure $P_{b,out}$ at blood-side outlet 3b of blood chamber 3 of dialyser 1, $P_{d,in}$ at dialysate-side inlet 4a and $P_{d,out}$ at dialysate-side outlet 4b of dialysing fluid chamber 4 of dialyser 1.

The differences between the determination of the transmembrane pressure on the basis of a measurement at three measuring points and a measurement at four measuring points result from pressure drop ΔP_b on the blood side of the dialyser, which increases with increasing viscosity of the blood, increasing blood flow Q_b and smaller capillary diameter with identical membrane area. Smaller or larger differences between the two measurements may result according to the possible combinations of the boundary conditions.

Moreover, the viscosity of the blood in the dialyser can be changed by the treatment process. In the case of an H(D)F treatment, for example, the mean blood viscosity in the dia-

lyser (filter) diminishes in the case of pre-dilution, whereas the mean blood viscosity increases in the case of post-dilution. Post-dilution therefore leads to greater differences in the two measurements. This can be traced back to the different transmembrane flow via the membrane of the dialyser, which is withdrawn from blood flow Q_b. Total transmembrane flow $Q_{tm} = Q_{uf} + Q_{sub}$ is composed of ultrafiltration rate Q_{uf} and substitution rate Q_{sub}. In practice, however, substitution rate Q_{uf} can often be neglected.

The invention is based on calculating transmembrane pressure P_{TM3} on the basis of the pressure measured with three pressure sensors 20, 21, 22 and determining a correcting quantity for the calculated transmembrane pressure, in order to ascertain actual transmembrane pressure P_{TM} = TMP.

By transforming equation (1), the following results:

$$P_{TM} = P_{b.out} - \frac{P_{d,in} + P_{d,out}}{2} + \frac{P_{b,in} - P_{b,out}}{2} \qquad (2)$$

Uncorrected transmembrane pressure P_{TM3} is contained therein:

$$P_{TM3} = P_{b,out} - \frac{P_{d,in} + P_{d,out}}{2} \qquad (3)$$

The correction term results from a comparison of equation (3) and equation (2) from the last term of equation (2). It reflects the blood-side pressure drop on the longitudinal side of blood chamber 3 of dialyser 1:

$$\frac{P_{b,in} - P_{b,out}}{2} = \frac{\Delta P_b}{2} \qquad (4)$$

where: ΔP_b pressure drop on the longitudinal side of the dialyser (blood side).

The pressure drop on the blood side of the dialyser chiefly depends on blood flow Q_b. This relationship can generally be described by a polynomial approach

$$\Delta P_b = \sum_{i=0}^{n} c_i * Q_b^i \qquad (5)$$

As a rule, linear dependences between pressure drop ΔP_b and blood flow Q_b result with sufficient accuracy in practice. The pressure drop on the blood side ΔP_b can thus be split up into a flow resistance R_b in the longitudinal direction of the dialyser, which is independent of blood flow Q_b, and current blood flow Q_b. The following thus results:

$$P_{TM} = P_{TM3} + \frac{1}{2} * R_b * Q_b \qquad (6)$$

where: R_b longitudinal resistance of the dialyser on the blood side

Q_b blood flow

In the present example of embodiment, a polynomial approach with parameters α_0, α_1, α_2, α_3, α_4 ... is used to calculate flow resistance R_b in the longitudinal direction of blood chamber 3 of dialyser 1. An example of a possible polynomial approach is:

$$R_b\,(Hkt, Q_{tm}) = a_0 + a_1 * Hkt + a_2 * \frac{Q_{tm}}{Q_{tm,\max}} + a_3 * Hkt * \frac{Q_{tm}}{Q_{tm,\max}} + a_4 * \left(Hkt * \frac{Q_{tm}}{Q_{tm.\max}} \right)^4 \qquad (7)$$

$Q_{tm,max}$ can be determined for the case of post-dilution or pre-dilution as follows:

$$Q_{tm,Post,\max} = Q_b * (1 - Hkt) * \left(1 - k * \frac{TP}{100} \right) \qquad (8)$$

or

$$Q_{tm,\Pr ae,\max} = Q_{tm,Post,\max} \left(k * \frac{TP}{100g/dl} \right) \qquad (9)$$

where k is a factor, for example $k = 7$, and where:

H*kt*	haematocrit [0.10...0.69]
TP	total protein content [5.0...9.0 g/dl]
Q_{tm}	current flow rate via the dialyser membrane [ml/min]; where: $Q_{tm} = Q_{sub} + Q_{uf}$
Q_{sub}	substitution rate [ml/min];
Q_{uf}	ultrafiltration rate [ml/min];

$Q_{tm,max}$ maximum flow rate [ml/min] where

- post-dilution: $Q_{tm,post,max}$ according to equation (8), or where
- pre-dilution: $Q_{tm,pre,max}$ according to equation (9)

Instead of the polynomial approach according to equation (7), a general approach is also possible, which takes account of higher powers for haematocrit H*kt*, for transmembrane flow Q_{tm} and the product of haematocrit and transmembrane flow.

$$R_b\left(Hkt, Q_{tm}\right) = \sum_{i=0}^{n} b_{1,i} * Hkt^i + \sum_{j=1}^{m} b_{2,j} * \left(\frac{Q_{tm}}{Q_{tm,\max}}\right)^j + \sum_{k=1}^{p} b_{3,k} * \left(Hkt * \frac{Q_{tm}}{Q_{tm,\max}}\right)^k \qquad (10)$$

The device according to the invention determines transmembrane pressure TMP as follows.

Computing unit 19 of the device for determining the haematocrit first calculates, according to equation (7), longitudinal resistance R_b of the dialyser as a function of haematocrit H*kt* and flow rate Q_{tm} of the fluid withdrawn via membrane 2 of dialyser 1. For this purpose, the computing unit makes use of a memory 19A, in which the parameters of the polynomial approach $\alpha_0, \alpha_1, \alpha_2, \alpha_3, \alpha_4$ are stored, which have been obtained by an offsetting calculation from individual measured data for a specific type of dialyser. The parameters for various types of dialyser can be stored in memory 19A of computing unit 19, whereby the computing unit then takes recourse to the parameters applicable to the type of dialyser currently being used.

Computing unit 19 communicates with central control and computing unit 18 of the blood treatment apparatus in order to exchange the data of relevance here. For example, the computing unit may receive a data record which indicates the type of dialyser which has previously been inputted by the user, for example by means of a keyboard. Moreover, computing unit 19 receives substitution rate Q_{sub} and ultrafiltration rate Q_{uf} from central control and computing unit 18, in order to calculate, from the sum of the substitution rate and the ultrafiltration rate, flow rate $Q_{tm} = Q_{sub} + Q_{uf}$ of the fluid withdrawn via membrane 2 of dialyser 1. Furthermore, computing unit 19 receives from central control and comput-

ing unit 18 haematocrit H*kt*, which can lie between 0.10 and 0.69, and total protein content TP, which can lie between 5.0 and 9.0 g/dl. Furthermore, the computing unit receives from the central control and computing unit a signal which indicates whether a pre-dilution or post-dilution is present.

According to equations (8) and (9), computing unit 19 calculates maximum flow rate $Q_{tm,.max}$ from haematocrit H*kt* and total protein content TP for the case where a pre-dilution or a post-dilution is carried out.

In a simplified embodiment, longitudinal resistance R_b of the dialyser is calculated only once before or during the dialysis treatment. An improved embodiment makes provision, however, such that longitudinal resistance R_b of the dialyser is calculated at specific times in the blood treatment or is even calculated continuously during the blood treatment. The improved embodiment proves to be particularly advantageous when one of the variables of relevance here, for example the substitution rate or ultrafiltration rate, but also the haematocrit of the patient's blood, changes during the dialysis treatment. A recalculation of longitudinal resistance R_b also comes into question if a changeover is to be made from pre-dilution to post-dilution or vice versa.

A further alternative embodiment provides for a calculation of longitudinal resistance R_b not according to equation (7), but according to equation (10), which describes a general polynomial approach. In principle, however, other polynomial approaches are also possible.

A particularly preferred embodiment makes provision such that a constant value for haematocrit H*kt*, inputted for example by means of a keyboard or measured only once, is not taken as a basis. In this embodiment, the haematocrit is continuously measured during the blood treatment by measuring unit 23. Data line 23' for transmitting the measured values for the haematocrit is represented by a broken line in the figure, since the measurement of the haematocrit is not absolutely essential during the blood treatment and is provided only in the case of the particularly preferred embodiment.

During the blood treatment, moreover, pressure $P_{b,out}$ at the blood-side outlet, pressure $P_{d,in}$ at the dialysate-side inlet and pressure $P_{d,out}$ at the dialysate-side outlet are preferably

measured continuously or at least at different times by means of pressure sensors 20, 21 and 22. Computing unit 19, which receives the measured values for the pressures via data line 20', 21', 22', calculates uncorrected transmembrane pressure P_{TM3} from the pressures according to equation (3). As a further variable, computing unit 19 receives from control and computing unit 18 blood flow rate Q_b, which can be inputted by the operator. Computing unit 19 then calculates the corrected value for transmembrane pressure P_{TM} = TMP according to equation (6) from blood flow rate Q_b, calculated longitudinal resistance R_b of the dialyser and uncorrected transmembrane pressure P_{TM3}.

Corrected transmembrane pressure TMP can be displayed on a display unit (not shown) and/or be used for controlling or regulating the blood treatment apparatus.

CLAIMS:

1. A method for determining the transmembrane pressure

during an extracorporeal blood treatment, in which blood flows at a specific blood flow rate via an arterial blood supply line of an extracorporeal blood circuit into the inlet of a first chamber of a dialyser divided by a semipermeable membrane into the first chamber and a second chamber and flows via a venous blood return line from the outlet of the first chamber of the dialyser, and dialysing fluid flows via a dialysing fluid supply line into the inlet of the second chamber of the dialyser and flows via a dialysing fluid discharge line out of the outlet of the second chamber of the dialyser, fluid being withdrawn from the blood at a specific flow rate via the membrane of the dialyser,

with the flowing method steps:

measurement of the pressure on the blood side at the inlet or outlet of the first chamber of the dialyser and on the dialysing fluid side at the inlet and/or outlet of the second chamber of the dialyser, or measurement of the pressure on the blood side at the inlet and/or outlet of the first chamber of the dialyser and on the dialysing fluid side at the inlet or outlet of the second chamber of the dialyser, and

calculation of the transmembrane pressure on the basis of the pressure measured on the blood side and dialysing fluid side,

wherein

a variable correlating with the viscosity of the blood is determined,

a correcting quantity for the transmembrane pressure is determined, which is dependent on a variable correlating with the viscosity of the blood, and

the transmembrane pressure is calculated on the basis of the pressure measured on the blood side and the dialysing fluid side and the correcting quantity for the transmembrane pressure.

2. The method according to claim 1, wherein the variable correlating with the viscosity of the blood is the haematocrit of the blood.

3. The method according to claim 1 or 2, wherein the pressure on the blood side is measured in the blood discharge line at the outlet of the first chamber of the dialyser and the pressure on the dialysing fluid side is measured in the dialysing fluid supply line at the inlet of the second chamber of the dialyser and in the dialysing fluid discharge line at the outlet of the second chamber of the dialyser.

4. The method according to any one of claims 1 to 3, wherein, for the determination of the correcting quantity for the transmembrane pressure, a parameter characteristic of the flow resistance of the dialyser is determined, said parameter being dependent on the parameter correlating with the viscosity of the blood.

5. The method according to claim 4, wherein the parameter characteristic of the flow resistance of the dialyser is determined on the basis of the parameter correlating with the viscosity of the blood and the flow rate of the fluid withdrawn via the membrane of the dialyser.

6. The method according to claim 5, wherein the parameter characteristic of the flow resistance of the dialyser is calculated according to the following polynomial approach with parameters α_0, α_1, α_2, α_3, α_4:

$$R_b\,(Hkt, Q_{tm}) = a_0 + a_1 * Hkt + a_2 * \frac{Q_{tm}}{Q_{tm,\max}} + a_3 * Hkt * \frac{Q_{tm}}{Q_{tm,\max}} + a_4 * \left(Hkt * \frac{Q_{tm}}{Q_{tm,\max}} \right)^4$$

Hkt : haematocrit

Q_{tm} : flow rate via the dialyser membrane

$Q_{tm,max}$: maximum flow rate via the dialyser membrane.

7. The method according to any one of claims 1 to 6, wherein the correcting quantity is determined on the basis of the product of the parameter characteristic of the flow resistance and the blood flow rate.

8. The method according to any one of claims 3 to 7, wherein the transmembrane pressure is calculated from the pressure measured on the blood side and on the dialysing fluid side and the correcting quantity according to the following equation:

$$P_{TM} = P_{TM3} + \frac{1}{2} * R_b * Q_b$$

where: R_b longitudinal resistance of the dialyser on the blood side

Q_b blood flow

and

$$P_{TM3} = P_{b,out} - \frac{P_{d,in} + P_{d,out}}{2}$$

9. The method according to any one of claims 1 to 8, wherein the variable correlating with the viscosity is continuously measured during the blood treatment.

10. A device for determining the transmembrane pressure for a blood treatment apparatus for performing an extracorporeal blood treatment, in which blood flows at a specific blood flow rate via an arterial blood supply line of an extracorporeal blood circuit into the inlet of a first chamber of a dialyser divided by a semipermeable membrane into the first chamber and a second chamber and flows via a venous blood return line from the outlet of the first chamber of the dialyser, and dialysing fluid flows via a dialysing fluid supply line into the inlet of the second chamber of the dialyser and flows via a dialysing fluid discharge line out of the outlet of the second chamber of the dialyser, fluid being withdrawn from the blood at a specific flow rate via the membrane of the dialyser,

whereby the device for determining the transmembrane pressure comprises:

means for measuring the pressure on the blood side at the inlet or outlet of the first chamber of the dialyser and on the dialysing fluid side at the inlet and/or outlet of the second chamber of the dialyser, or for measuring the pressure on the blood side at the inlet and/or outlet of the first chamber of the dialyser and on the dialysing fluid side at the inlet or outlet of the second chamber of the dialyser, and

means for calculating the transmembrane pressure on the basis of the pressure measured on the blood side and the dialysing fluid side,

wherein

the means for calculating the transmembrane pressure are configured to determine a correcting quantity for the transmembrane pressure, said correcting quantity being dependent on a variable correlating with the viscosity of the blood, and that the transmembrane pressure is calculated on the basis of the pressure measured on the blood side and dialysing fluid side and the correcting quantity for the transmembrane pressure.

11. The device according to claim 10, wherein the variable correlating with the viscosity of the blood is the haematocrit of the blood.

12. The device according to claim 10 or 11, wherein the means for measuring the pressure on the blood side and on the dialysing fluid side comprise:

means for measuring the pressure in the blood discharge line at the outlet of the first chamber of the dialyser,

means for measuring the pressure in the dialysing fluid supply line at the inlet of the second chamber of the dialyser and means for measuring the pressure in the dialysing fluid discharge line at the outlet of the second chamber of the dialyser.

13. The device according to any one of claims 10 to 12, wherein the means for calculating the transmembrane pressure are configured to determine, for the determination of

the correcting quantity for the transmembrane pressure, a parameter characteristic of the flow resistance of the dialyser, which is dependent on the parameter correlating with the viscosity of the blood.

14. The device according to claim 13, wherein the means for calculating the transmembrane pressure are configured to determine the parameter characteristic of the flow resistance of the dialyser on the basis of the parameter correlating with the viscosity of the blood and the flow rate of the fluid withdrawn via the membrane of the dialyser.

15. The device according to claim 14, wherein the means for calculating the transmembrane pressure are configured to calculate the parameter characteristic of the flow resistance of the dialyser according to the following polynomial approach with parameters α_0, α_1, α_2, α_3, α_4:

$$R_b\,(Hkt, Q_{tm}) = a_0 + a_1 * Hkt + a_2 * \frac{Q_{tm}}{Q_{tm,\max}} + a_3 * Hkt * \frac{Q_{tm}}{Q_{tm,\max}} + a_4 * \left(Hkt * \frac{Q_{tm}}{Q_{tm,\max}} \right)^4$$

H*kt* : haematocrit

Q_{tm} : flow rate via the dialyser membrane

$Q_{tm,max}$: maximum flow rate via the dialyser membrane.

16. The device according to any one of claims 10 to 15, wherein the means for calculating the transmembrane pressure are configured to determine the correcting quantity on the basis of the product of the parameter characteristic of the flow resistance and the blood flow rate.

17. The device according to any one of claims 12 to 16, wherein the means for calculating the transmembrane pressure are configured to calculate the transmembrane pressure from the pressure measured on the blood side and the dialysing fluid side and the correcting quantity according to the following equation:

$$P_{TM} = P_{TM3} + \frac{1}{2} * R_b * Q_b$$

where:

R_b longitudinal resistance of the dialyser on the blood side

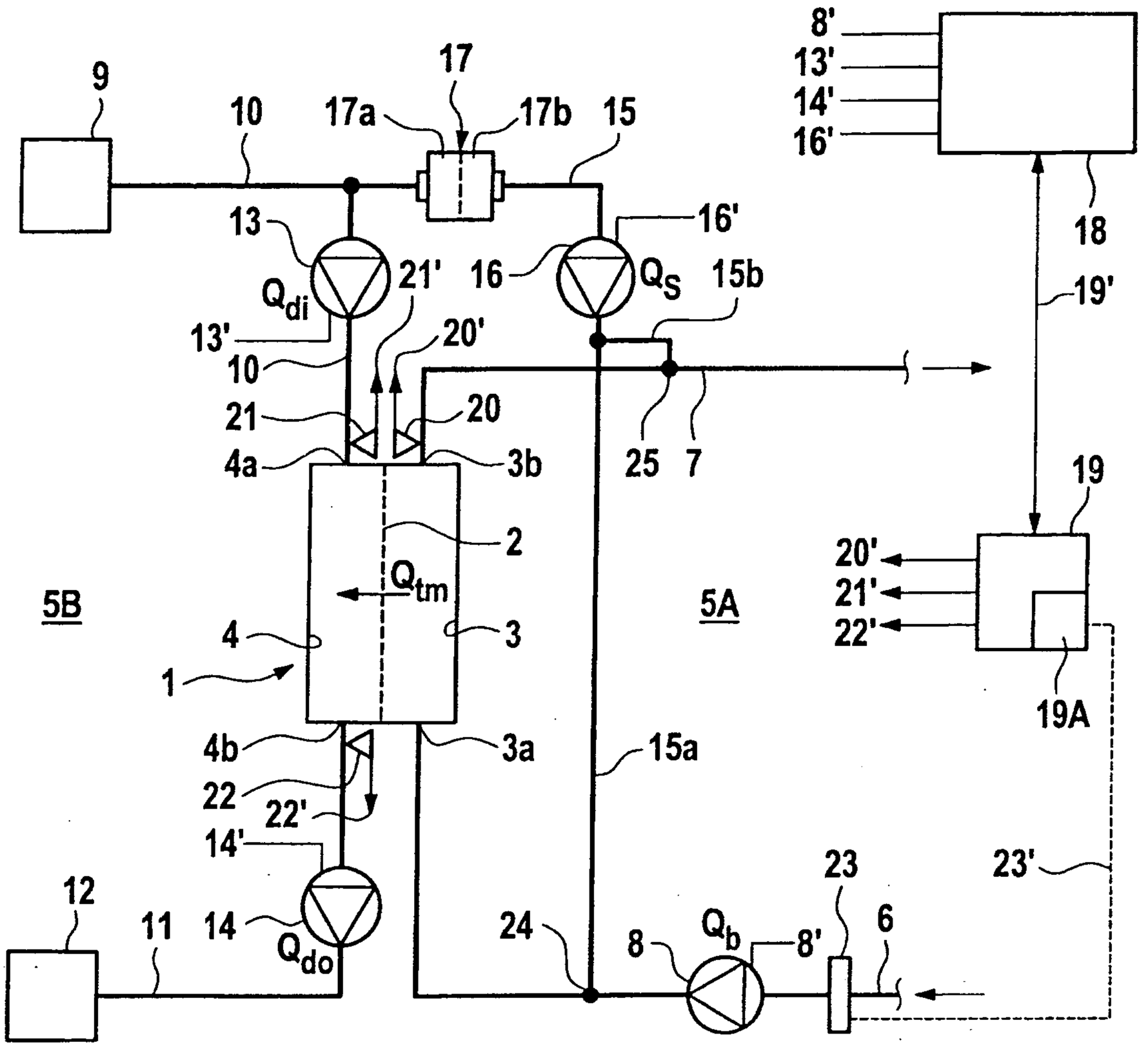
Q_b blood flow

and

$$P_{TM3} = P_{b,out} - \frac{P_{d,in} + P_{d,out}}{2}$$

18. The device according to any one of claims 10 to 17, wherein the device for determining the transmembrane pressure comprises means for measuring the variable correlating with the viscosity of the blood, means for calculating the transmembrane pressure being configured to take, as a basis for the calculation of the transmembrane pressure, the variable which correlates with the viscosity and is measured continuously during the blood treatment.

19. An apparatus for extracorporeal blood treatment with a device according to any one of claims 10 to 18.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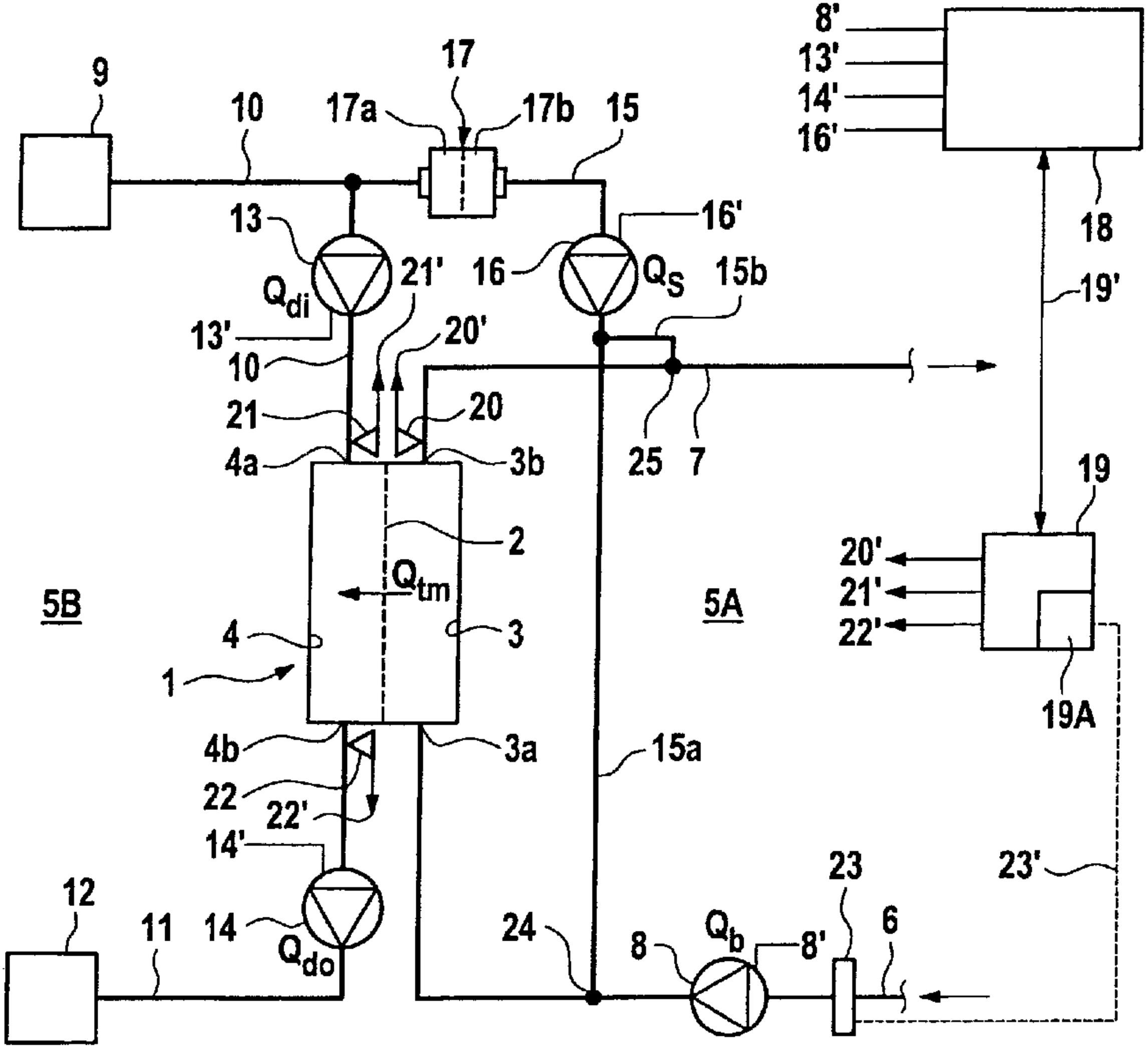
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