

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
27 December 2002 (27.12.2002)

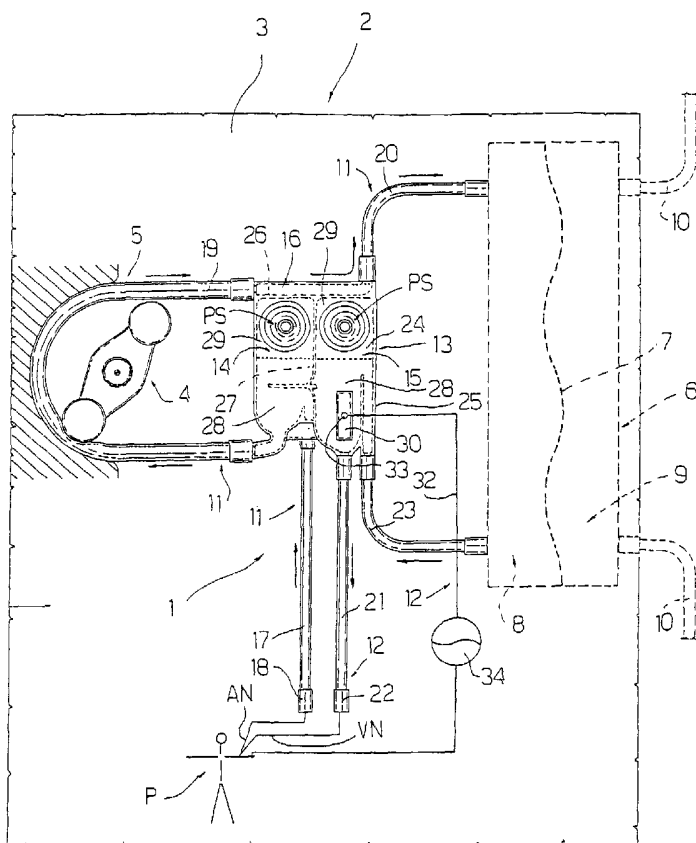
PCT

(10) International Publication Number
WO 02/102440 A1

- (51) International Patent Classification⁷: **A61M 1/36** (74) Agent: **SUTTO, Luca**; Gambro Patent Department, 61, avenue Tony Garnier, F-69007 Lyon (IT).
- (21) International Application Number: PCT/IB02/01953
- (22) International Filing Date: 30 May 2002 (30.05.2002) (81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZM, ZW.
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
TO01A000583 15 June 2001 (15.06.2001) IT
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- (84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

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(54) Title: BLOOD CIRCUIT FOR A DIALYSIS MACHINE AND CORRESPONDING DIALYSIS MACHINE



(57) Abstract: A blood circuit (1) for a dialysis machine is made from plastic material and is provided with a metallic plate (30), which is applied to an external face of the blood circuit (1) and is connectable to a voltage generator (34) in such a way as to form a capacitor, in which the plate (30) and the blood act as the capacitor plates and the plastic material acts as the dielectric.



Published:

— with international search report

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

BLOOD CIRCUIT FOR A DIALYSIS MACHINE AND CORRESPONDING DIALYSIS MACHINE

DESCRIPTION

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The present invention relates to a blood circuit for a dialysis machine.

As is known, blood consists of a liquid component, called the blood plasma, and a corpuscular component formed by the blood cells, including the red corpuscles among other types. In renal insufficiency, the blood contains, in addition to the aforesaid
10 components, particles of low molecular weight (referred to below as the solute), which have to be eliminated by a dialysis treatment carried out by means of a dialysis machine.

A dialysis machine of a known type generally comprises a blood circuit, a dialysate circuit, and a filter which is connected to the aforesaid circuits and comprises a blood compartment and a dialysate compartment, which are separated from each other
15 by a semi-permeable membrane, and through which pass, respectively, the blood to be treated and the dialysate, generally flowing in counter-current mode, when the machine is in operation.

During the dialysis treatment, the unwanted particles contained in the blood migrate from the blood compartment to the dialysate compartment both by diffusion
20 and by convection, as a result of the passage of some of the liquid contained in the blood towards the dialysate compartment. The patient will therefore have lost some weight by the end of the dialysis process.

The blood circuit is connected to the patient by means of an arterial needle and a venous needle, which are inserted into a fistula formed in the patient's cardiovascular
25 system, and are used, respectively, to collect the blood to be treated and to return the treated blood to the patient's cardiovascular system. The blood circuit comprises two expansion chambers (or droppers), one located in the arterial branch and one in the venous branch.

In a known method for detecting the detachment of the venous needle from the
30 patient and preventing blood loss due to the detachment of the venous needle, an electric

current is injected into the blood circuit in such a way that the detachment of the venous needle is comparable to the opening of a circuit. Thus, by measuring the variation of electric current flowing in the blood circuit it is possible to detect the detachment of the venous needle.

5 For example, patent application WO 99/12588 describes a method in which the blood circuit is connected to an electrical circuit to inject a current into a closed circuit consisting of the blood circuit and the patient's cardiovascular system, and to measure, by means of a measuring instrument located in the aforesaid blood circuit, the variations of current caused by the detachment of one or both of the needles. In this method, the
10 current injection and the measuring of the variation of current are carried out by means of inductive couplings located in the blood circuit, in other words by means of windings formed around the extracorporeal blood circuit at specified points of this circuit.

 The placing of the windings around the blood circuit gives rise to problems of a practical nature, since the coupling between the blood circuit and the electrical circuit is
15 laborious to set up and requires a certain amount of the operator's time.

 The object of the present invention is to provide a blood circuit which can be coupled in a simple and practical way to an electrical circuit.

 According to the present invention, a blood circuit is provided for a dialysis machine, the blood circuit being made from plastic material and being characterized in
20 that it comprises a metallic plate applied to an external face of the said blood circuit, the said plate being connectable to a voltage generator in such a way as to form a capacitor, in which the said plate and the blood act as the capacitor plates and the plastic material acts as the dielectric.

 The advantages of the present invention are due to the replacement of the
25 inductive coupling by a capacitive coupling, which can be formed simply by applying a metallic plate to the blood circuit at the point of the blood circuit where the electrical connection is to be made.

 The present invention also relates to a dialysis machine for providing dialysis treatment to patients.

According to the present invention, a dialysis machine is made for carrying out dialysis treatments on patients, the machine comprising a blood circuit according to any one of the preceding claims, an electrical cable and the said voltage generator for supplying, when in use, an electric current through a preferential current-carrying circuit comprising the blood circuit, the electrical cable and a patient connected to the said blood circuit.

The present invention will now be described with reference to the attached drawings, which show a non-restrictive example of its embodiment, in which

- Figure 1 is a schematic view, with parts removed for clarity, of a blood circuit associated with a dialysis machine; and
- Figure 2 is a view, on an enlarged scale, of a detail of the circuit of Figure 1.

In Figure 1, the number 1 indicates the whole of a blood circuit for a dialysis machine 2.

The machine 2 is provided with a machine casing 3, which supports a rotor 4 which, in conjunction with a circuit 1, forms a peristaltic pump 5; a filter 6, which is shown in broken lines and comprises a semi-permeable membrane 7 which separates a blood compartment 8 from a dialysate compartment 9; and a dialysate circuit 10, which is shown in broken lines and is connected to the dialysate compartment 9 of the filter 6.

The circuit 1 has an arterial branch 11, a venous branch 12 and a box 13, which comprises an expansion chamber 14 in the arterial branch 11, an expansion chamber 15 in the venous branch 12, and a channel 16 located above the expansion chambers 14 and 15. The arterial branch 11 comprises a portion 17, which extends between the expansion chamber 14 and a connector 18 for connecting the arterial branch 11 to an arterial needle AN, a portion 19, which is bent into a U-shape around the rotor 4 to form the peristaltic pump 5, and whose ends are connected to the expansion chamber 14 and to the channel 16, and a portion 20 which connects the channel 17 to the blood compartment 8 of the filter 6. The venous branch 12 has a portion 21, which extends between the expansion 15 and a connector 22 for connecting the venous branch 12 to a venous needle VN, and a portion 23, which extends between the expansion chamber 15 and the blood compartment 8 of the filter 6.

In operation, the arterial needle AN and the venous needle VN are connected to a fistula of a patient P, in order, respectively, to collect the blood from the patient P and return it to him.

The box 13 is made from rigid transparent material, while the arterial branch 11
5 and the venous branch 12 are made from transparent flexible plastic material.

With reference to Figure 2, the box 13 comprises two principal opposed walls 24 (only one of which is shown in the attached figures), a perimetric wall 25 located between the principal walls 24, a partition 26 for separating the channel 16 from the expansion chambers 14 and 15, and a partition 27 for separating the expansion chambers
10 14 and 15 from each other.

During dialysis treatment, the blood occupies lower portions 28 of the corresponding expansion chambers 14 and 15, while the upper portions 29 are occupied by air. In practice, the division of each of the chambers 14 and 15 into a lower portion 28 and an upper portion 29 is marked by the level L of the blood in each of the
15 expansion chambers 14 and 15. During the dialysis treatment, the level L is kept essentially constant by means of known control devices which are associated with the dialysis machine 2 and are not illustrated.

Each chamber 14 and 15 has a corresponding pressure sensor PS located in the upper portion 29, while the expansion chamber 15 has a conductive element in the form
20 of at least a metallic plate 30, which is fixed to the lower portion 28 of the box 13.

Note that the conductive element may alternatively be a plastic element having conductive properties, such as a plastic element embedding conductive particles and/or conductive fibres and/or conductive filaments. Suitable materials for the particles, fibres, filaments can be Aluminium or Carbon.

25 The plate 30 is a strip of metallic material, and has a face in direct contact with the external face of the wall 24 and a face which is opposite the preceding one and supports an electrical connector 31. The number 32 indicates an electrical cable provided with an electrical connector 33 which can be joined to the connector 31 to connect the plate 30 to a voltage generator 34. With reference to Figure 1, the electrical cable 32 also
30 connects the voltage generator 34 to the patient P.

During the dialysis treatment, the blood is directed along the arterial branch 11 and the venous branch 12 in the direction shown by the arrows in Figure 1, and passes through the blood compartment 8 of the filter 6 and the expansion chambers 14 and 15 of the box 13. The blood accumulates in the lower portions 28 of the expansion chambers 14 and 15.

In order to detect the detachment of the venous needle VN, the cable 32 is connected to the plate 30 through the connectors 31 and 33, and is connected to the patient P and is supplied by the generator 34.

Since blood and the plate 30 are conductors of electric current, and the plastic material from which the box 13 is made is an insulating material, the presence of the plate 30 on the portion 28 of the expansion chamber 15 effectively forms a capacitor, in which the plate 30 and the blood are the opposing plates and the wall 24 is the dielectric.

The applicant has found that the connections shown in Figure 1 between the cable 32, the patient P and the blood circuit 1 provide a preferential circuit for the flow of the electric current, comprising the cable 32, the patient P, the portion 21 of the venous branch 12 and the lower portion 28 of the expansion chamber 15.

Consequently, any discontinuity between the venous branch 12 and the patient P causes a significant variation of the current in the aforesaid preferential electrical circuit. This variation can be measured, for example, by measuring the variation of voltage across the terminals of an impedance located in the branch 32.

The detachment of the venous needle VN is therefore comparable to the opening of the aforesaid preferential electrical circuit, and is easily detectable by measuring the voltage.

The applicant has also found that the preferential electrical circuit does not differ from that described above when the end of the cable 32 connected to the patient P is connected to earth and the current flowing in the preferential circuit exceeds 10 kHz. In this case, the preferential electrical circuit is completed via the earth, regardless of whether the patient P is connected directly to earth or is not connected directly to earth. In the second case, the patient P in conjunction with the earth forms a capacitor, and, in electric terms, behaves in an essentially equivalent way to a patient P directly connected

to earth when the frequency of the current flowing in the preferential circuit exceeds 10 kHz.

In a variant which is not shown, both of the expansion chambers 14 and 15 are provided with corresponding plates 30 for coupling both the arterial branch 11 and the
5 venous branch 12 to the cable 32 by means of corresponding electrical connectors 33.

In a further variant which is not shown, the plate 30 can be located in any one of the portions of the venous branch 12 and the arterial branch 12, and can have an annular shape.

The present description implies that one or more plates 30 can be located at any
10 point of the blood circuit 1 to electrically connect an electrical cable to the blood circuit 1 by means of a capacitive coupling.

The example which is described and illustrated is particularly advantageous, since it simplifies the electrical coupling between the electrical circuit and the blood circuit, while requiring only a single electrical connection.

CLAIMS

1. Blood circuit for a dialysis machine, the blood circuit (1) being made from plastic material and being characterized in that it comprises an electrically conductive element
5 (30) applied to an external face of the said blood circuit (1), the said conductive element (30) being connectable to a voltage generator (34) in such a way as to form a capacitor, in which the said conductive element (30) and the blood act as the capacitor plates and the plastic material acts as the dielectric.
2. Circuit according to Claim 1, characterized in that the said conductive element is
10 a metallic plate (30) and has one face placed in contact with the said blood circuit (1).
3. Circuit according to Claims 1 or 2, characterized in that the said conductive element comprises a first electrical connector (31), the generator (34) having an electrical cable (32) provided with a second electrical connector (33) which can be coupled to the said first electrical connector (31).
- 15 4. Circuit according to any one of Claims 1 to 3, characterized in that it comprises an arterial branch (11) and a venous branch (12) made from flexible plastic material and a box (13) made from transparent plastic material.
5. Circuit according to Claim 4, characterized in that the said conductive element (30) is placed in contact with an external face of the said venous branch (11).
- 20 6. Circuit according to Claim 4, characterized in that the said conductive element (30) is placed on an external face of the said box (13).
7. Circuit according to Claim 6, characterized in that the said box (13) comprises two principal walls (24) and a perimetric wall (25); the said wall (30) being located along an external face of one of the said principal walls (24).
- 25 8. Circuit according to Claim 6 or 7, characterized in that the said box (13) comprises an arterial expansion chamber (14) connected to the arterial branch (11) and a venous expansion chamber (15) connected to the venous branch (11); the arterial expansion chamber (14) and venous expansion chamber (15) being provided with corresponding portions (28) which are occupied by blood when in use, the conductive

element (30) being applied to an external face of the said venous chamber (15) in the area of the said portion (28).

9. Circuit according to Claim 8, characterized in that it comprises a further electrically conductive element (30), the said further electrically conductive element (30) being applied to an external face of the said arterial expansion chamber (14) in the area of the said portion (28).

10. Circuit according to claim 9, characterized in that said further electrically conductive element is a metallic plate.

11. Circuit according to claim 1 or to claim 9, characterized in that said electrically conductive element and/or said further electrically conductive elements are made of plastics embedding electrically conductive bodies.

12. Circuit according to claim 11, characterized in that said electrically conductive bodies comprise electrically conductive fibers.

13. Circuit according to claim 11, characterized in that said electrically conductive bodies comprise electrically conductive particles.

14. Circuit according to claim 11, characterized in that said electrically conductive bodies comprise electrically conductive filaments.

15. *Dialysis machine for carrying out dialysis treatments on patients (P), the machine comprising a blood circuit (1) according to any one of the preceding claims, an electrical cable (32) and the said voltage generator (34) for supplying, when the machine is in use, an electrical current through a preferential electrical circuit comprising the blood circuit (1), the electrical cable (32) and a patient (P) connected to the said blood circuit (1).*

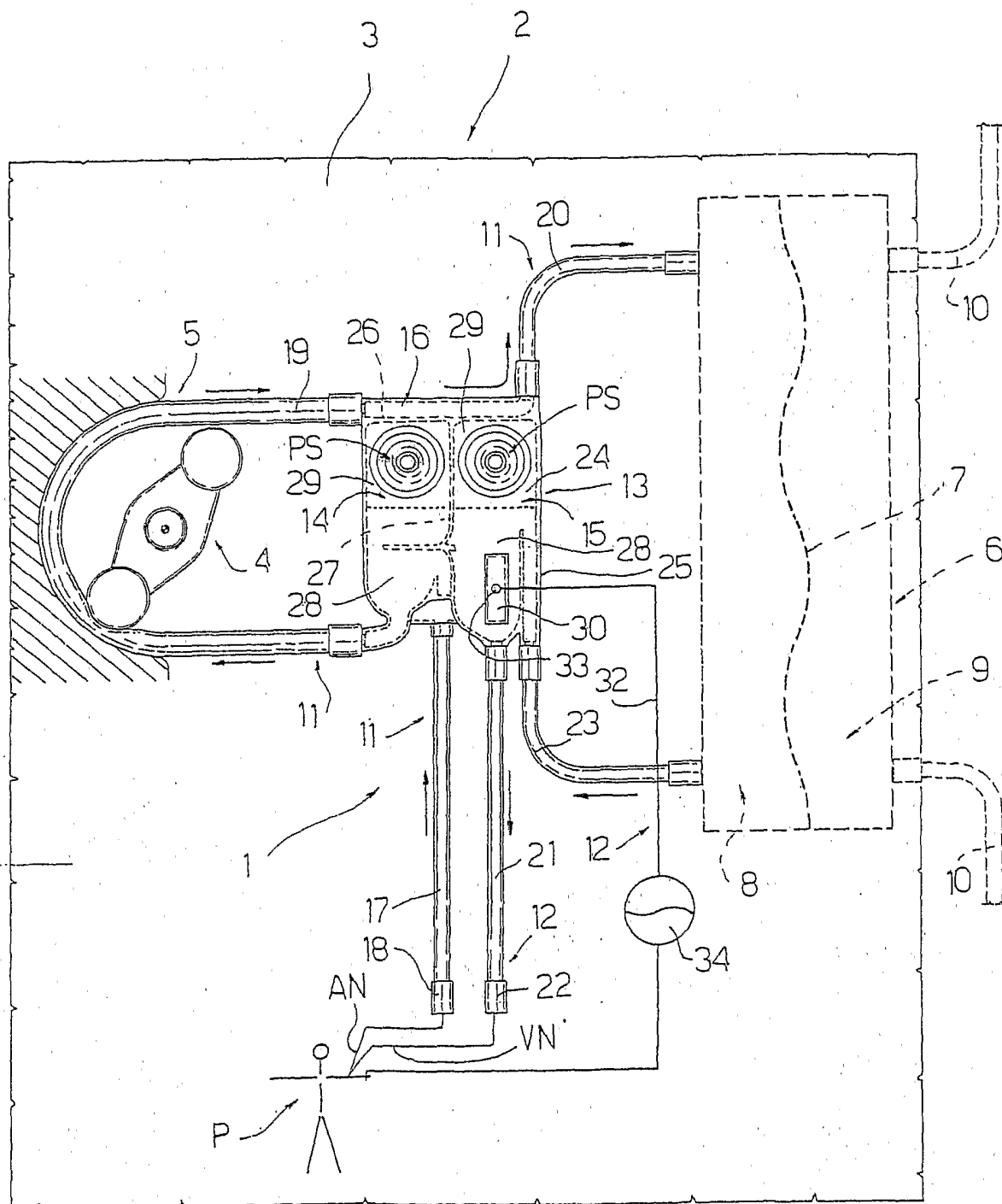


Fig.1

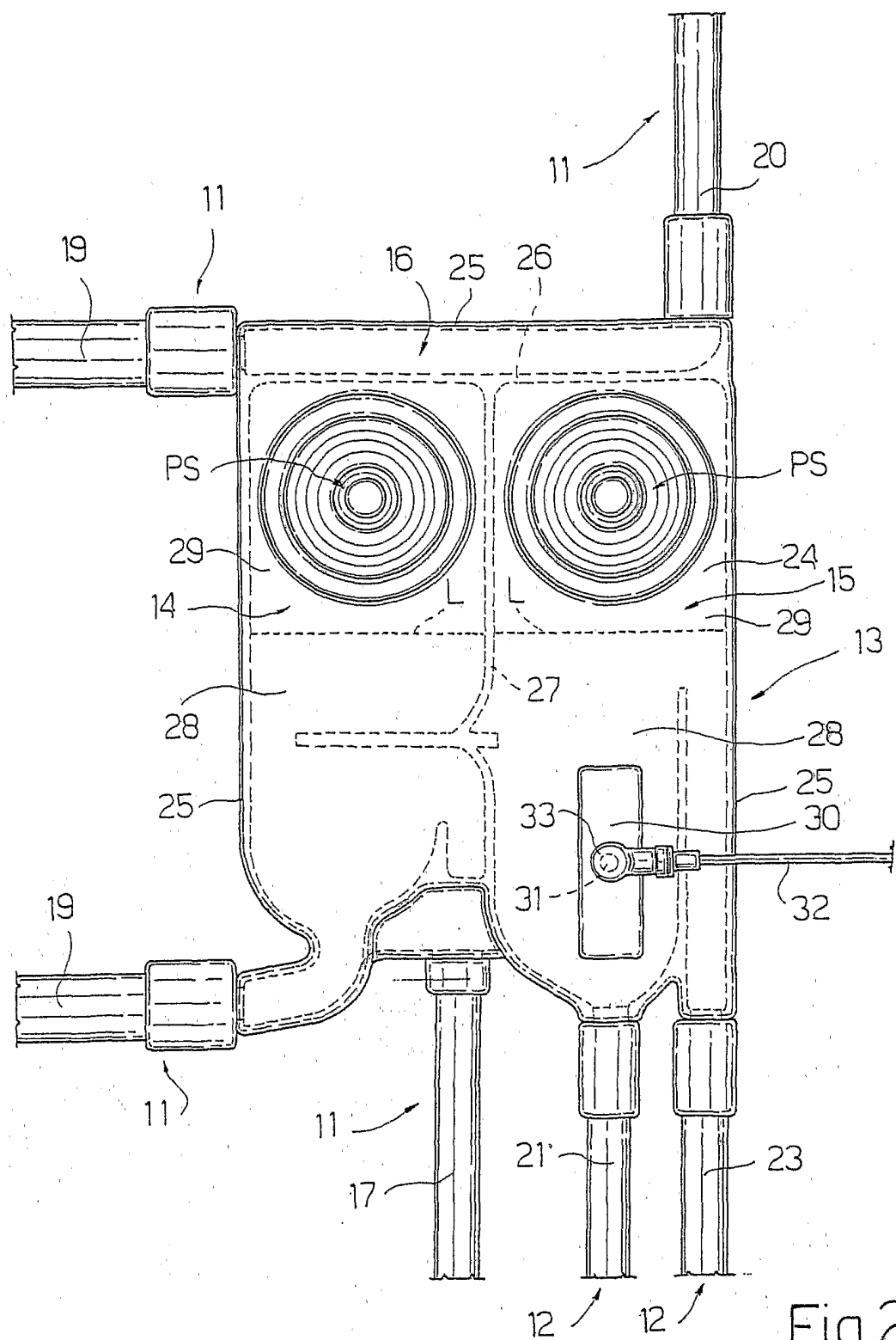


Fig. 2

INTERNATIONAL SEARCH REPORT

International Application No

PCT/IB 02/01953

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61M1/36

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	FR 2 067 572 A (AURA) 20 August 1971 (1971-08-20) page 1, line 35 -page 2, line 20 page 5, line 9 - line 27 figures	1-15
A	WO 99 24145 A (AKSYS LTD ;KJELLSTRAND CARL M (US)) 20 May 1999 (1999-05-20) abstract; figure 2	1, 15
A	WO 99 12588 A (ENDER HELMUTH ;FRESENIUS MEDICAL CARE DE GMBH (DE)) 18 March 1999 (1999-03-18) cited in the application page 7, paragraph 2 -page 8, paragraph 2; figure 1	1, 15
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☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

° Special categories of cited documents :

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

& document member of the same patent family

Date of the actual completion of the international search

29 August 2002

Date of mailing of the international search report

06/09/2002

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INTERNATIONAL SEARCH REPORT

International Application No
PCT/IB 02/01953

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/IB 02/01953

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