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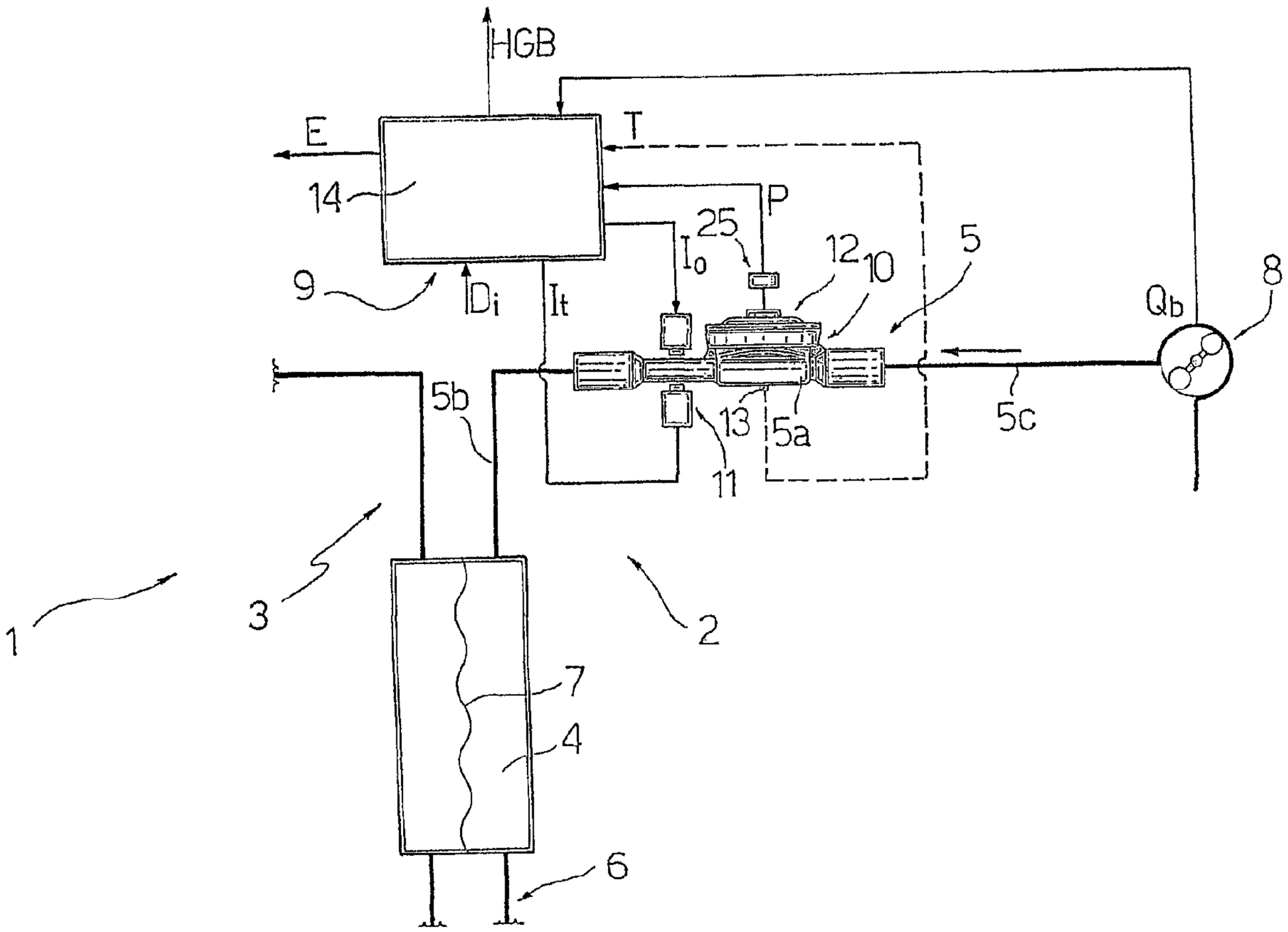
(54) Titre : PROCEDE DE MESURE DE LA CONCENTRATION DE L'HEMOGLOBINE (HGB) DANS LE SANG DANS UN CIRCUIT DE MACHINE A DIALYSE, APPAREIL DE MESURE ET CIRCUIT D'APPLICATION DU PROCEDE

(54) Title: A METHOD FOR MEASURING HEMOGLOBIN CONCENTRATION (HGB) IN THE BLOOD IN A CIRCUIT OF A DIALYSIS MACHINE, MEASURING DEVICE AND CIRCUIT FOR THE APPLICATION OF THE METHOD



(57) Abrégé/Abstract:
A method for measuring the hemoglobin concentration (HGB) in the blood in a circuit (2) of a dialysis machine (1), the method comprising the measurement of the values of absorption (A) of electromagnetic waves by the blood conveyed along a specified

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(57) Abrégé(suite)/Abstract(continued):
section (5a) of the said circuit (2), the measurement of the values of a physical quantity from the group comprising the blood pressure (P), the blood temperature (T) and the rate of flow (Q_b) of the blood along the aforesaid section (5a), and the calculation of the hemoglobin concentration (HGB) as a function of the values of absorption (A) and of the aforesaid physical quantity.

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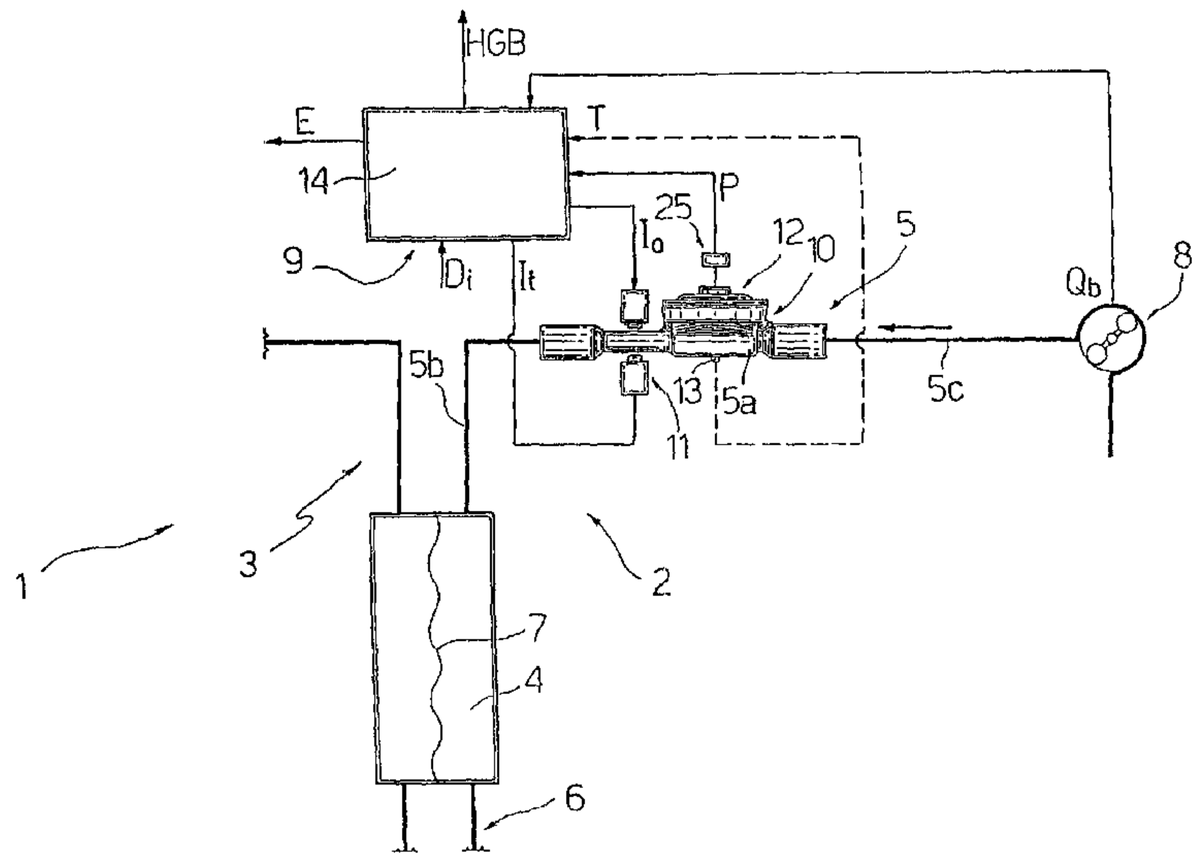
(54) Title: A METHOD FOR MEASURING HEMOGLOBIN CONCENTRATION (HGB) IN THE BLOOD IN A CIRCUIT OF A DIALYSIS MACHINE, MEASURING DEVICE AND CIRCUIT FOR THE APPLICATION OF THE METHOD



(57) Abstract: A method for measuring the hemoglobin concentration (HGB) in the blood in a circuit (2) of a dialysis machine (1), the method comprising the measurement of the values of absorption (A) of electromagnetic waves by the blood conveyed along a specified section (5a) of the said circuit (2), the measurement of the values of a physical quantity from the group comprising the blood pressure (P), the blood temperature (T) and the rate of flow (Q_b) of the blood along the aforesaid section (5a), and the calculation of the hemoglobin concentration (HGB) as a function of the values of absorption (A) and of the aforesaid physical quantity.

WO 02/071039 A1

A METHOD FOR MEASURING HEMOGLOBIN CONCENTRATION (HGB) IN THE BLOOD IN A CIRCUIT OF A DIALYSIS MACHINE, MEASURING DEVICE AND CIRCUIT FOR THE APPLICATION OF THE METHOD

DESCRIPTION

The present invention relates to a method for measuring hemoglobin concentration in the blood in a circuit of a dialysis machine.

Generally, a dialysis machine of the known type comprises a first circuit for blood circulation, connected, when in use, to the circulatory system of a patient, a second circuit for the circulation of dialysate, and a filter, through which the first circuit passes the blood and the second circuit passes the dialysate. The filter comprises a semi-permeable membrane which, when in use, separates the dialysate from the blood and permits an exchange of ions between the dialysate and the blood and the transfer of some of the blood plasma through the membrane. The first circuit comprises an arterial branch located up-line from the filter and a venous branch located down-line from the filter, while the machine comprises a peristaltic pump located in the arterial branch to convey the blood extracted from the patient to the filter. The first and second circuits are made from transparent flexible material, such as PVC, to ensure the asepsis of the circuit. The flexibility of the circuits facilitates their packaging and enables the flow to be blocked by a simple constriction of a section of the circuit, while the transparency makes it possible to visually inspect the liquids being conveyed in the circuit during use.

There is a known way of determining the concentration of hemoglobin in the red corpuscles during the dialysis treatment, by means of highly accurate measurements of an intrusive kind, which require the laboratory examination of blood samples. Other dialysis machines enable non-intrusive measurements of the hemoglobin concentration to be made within the machine. The non-intrusive measurements made within the machine are markedly less accurate than laboratory

measurements, but have the advantage of being provided in real time in such a way that the operating parameters of the dialysis machine can be corrected instantaneously.

The patent IT 1,240,489 discloses a method of measuring the hemoglobin concentration within the machine and in a non-intrusive way, by measuring the absorption of electromagnetic waves of the blood flowing in the arterial branch of the first circuit.

Hemoglobin is a protein contained in the red corpuscles, and its concentration modifies the pigmentation of the red corpuscles; the concentration of hemoglobin in the blood therefore depends on the quantity of red corpuscles contained in the blood and on the quantity of hemoglobin contained in the red corpuscles. To measure the absorption of electromagnetic waves by the blood, an emitter is used to emit a beam of electromagnetic waves having an emission intensity correlated with an emission signal, the beam of electromagnetic waves is made to strike a section of the circuit, and a beam of electromagnetic waves is detected by means of a receiver which emits a signal correlated with the reception intensity. The difference between the emitted intensity and the received intensity corresponds to the absorption, which is correlated with the hemoglobin concentration by a specific function.

Although the described method has been shown to provide an accurate measurement, laboratory tests conducted by the applicant have demonstrated that, in some cases of operation of the dialysis machine, the measurement made according to the method described above supplies values of hemoglobin concentration which deviate from the concentration values measured in the laboratory for the same type of blood.

The object of the present invention is to provide a method for measuring the hemoglobin concentration in the blood in a circuit of a dialysis machine in a non-intrusive way, and with a level of accuracy which is as close as possible to the level of accuracy of laboratory measurement.

According to the present invention, a method is provided for measuring the hemoglobin concentration in the blood in a

circuit of a dialysis machine, the method comprising the measurement of the absorption of electromagnetic waves by the blood along one section of the said circuit, the values of the said absorption being correlated with the values of the said hemoglobin concentration; the method being characterized in that the values of at least one physical quantity of the blood, from the group comprising blood pressure, blood temperature and the rate of flow of blood along the said section, are measured, and the values of hemoglobin concentration in the blood are calculated as a function of the values of absorption and of the said physical quantity.

The present invention also relates to a circuit for the application of the aforesaid method.

According to the present invention, a blood circulation circuit for dialysis machine, comprises a connection forming a section of the circuit, the said connection comprising a tube for subjecting the blood to the measurement of the absorption of electromagnetic waves and a chamber for subjecting the blood to the measurement of pressure.

The present invention relates to a device for measuring a characteristic of the blood in a circuit of a dialysis machine.

According to the present invention, a device is provided for measuring the hemoglobin concentration in a circuit of a dialysis machine comprising a connection forming a section of the said circuit, the said connection comprising a tube along which a measurement is made by means of beams of electromagnetic waves to determine the absorption of the blood, the hemoglobin concentration being correlated with the said absorption, the device being characterized in that it comprises at least one further sensor for measuring one of two quantities, namely the blood pressure and the blood temperature; the hemoglobin concentration being a function of the absorption and of the said quantity.

The present invention will now be described with reference to the attached drawings, which show, without restrictive intent, an example of embodiment in which

- Figure 1 is an experimental graph showing the hemoglobin concentration as a function of the received intensity;
- Figure 2 is an experimental graph showing the error of measurement of the hemoglobin concentration as a function of the blood temperature;
- Figure 3 is an experimental graph showing the error of measurement of the hemoglobin concentration as a function of the blood pressure;
- Figure 4 is an experimental graph showing the error of measurement of the hemoglobin concentration as a function of the blood flow;
- Figure 5 is a schematic view of a dialysis machine for implementing the method according to the present invention;
- Figure 6 is a side elevation of an element of the device for implementing the present invention;
- Figure 7 is a plan view of the element of Figure 6;
- Figure 8 is a graph of received intensity as a function of time in a first operating condition of the machine of Figure 5; and
- Figure 9 is a graph of received intensity as a function of time in a second operating condition of the machine of Figure 5.

With reference to Figure 5, the number 1 indicates the whole of a dialysis machine for carrying out dialysis treatments on patients suffering from kidney failure. The machine 1 comprises a blood circuit 2, a dialysate circuit 3, and a filter 4. In use, the circuit 2 is connected to the circulatory system of a patient and supplies the blood taken from the patient to the filter 4 along an arterial branch 5 and returns the blood to the patient along a venous branch 6. The filter 4 comprises a semi-permeable membrane 7, which separates the blood from the dialysate and permits an exchange of ions between the blood and the dialysate and the extraction of some of the blood plasma from the blood circuit 2. The machine 1 comprises a peristaltic pump 8, which is

located on the arterial branch 5 and, in use, extracts the blood from the patient and conveys the blood to the filter 4, and a measuring device 9 for measuring hemoglobin concentration (HGB) in the blood along the arterial branch 5 in a non-intrusive way.

The measuring device 9 comprises a connection 10 located between the peristaltic pump 8 and the filter 4, a sensor 11 of the optical type, a pressure sensor 12, a temperature sensor 13 and a calculation unit 14 connected to the sensors 11, 12 and 13. With reference to Figure 1, the connection 10 forms a section 5a of the arterial branch 5 and is interposed between two flexible sections 5b and 5c of the arterial branch 5.

With reference to Figures 6 and 7, the connection 10 comprises a tube 15 and a chamber 16 rigidly connected to the tube 15; the tube 15 is integral with the chamber 16 and both are made from transparent rigid plastic. The chamber and/or the tube may integrally carry a radial element protruding from the surface of connection 10 in the form of a little fin (not shown) that may serve to easily handle the connector and as positioning device to easily mount and fix the connector onto a machine. The tube 15 comprises an opening 17 for connection to the section 5b, an opening 18 for connection to the section 5c, a portion 19 adjacent to the chamber 16 and a portion 20, which has an internal diameter Di and is located between the opening 17 and the portion 19. The chamber 16 comprises a container 21, a cover 22 provided with a central hole 23 and an elastic membrane 24, which is gripped between the container 19 and the cover 22 and is deformed as a function of the blood pressure. In other words, the pressure sensor 12 comprises the chamber 16 and an electric device 25 for measuring the extent of deformation of the membrane 24 in the form of an electrical signal acquired by the calculation unit 14.

The sensor 11 comprises an emitter 26 for emitting a beam of electromagnetic waves in the visible, or "NIR", spectrum, and for guiding the beam of electromagnetic waves along the portion 20 of the tube 15 and a detector 27 for receiving a beam of electromagnetic waves on the opposite side of the tube 14. The sensor 11 is described in detail in the patent IT 1,240,489, whose content is included by reference in the present description.

The temperature (T) sensor 13 is a sensor of electromagnetic waves which are outside the visible or NIR spectrum.

In use, the peristaltic pump 8 provides a flow of blood Q_b along the circuit 2 as indicated by the arrow in Figure 1 and through the connection 10. The peristaltic pump 8 supplies the values of the flow Q_b to the calculation unit 14 at successive instants.

The sensor 12 transmits electrical signals correlated to the pressure values P at successive instants to the calculation unit 14, while the sensor 13 supplies electrical signals correlated with the values of temperature T to the calculation unit 14. The blood flowing along the portion 20 of the tube 15 forms an optical path which is correlated with the internal diameter Di of the portion 20, while the detector 27 receives a beam of electromagnetic waves on the opposite side of the portion 20. The emitted beam is correlated with a signal of emitted intensity I_0 and the received beam generates a signal of received intensity I_R. The calculation unit 14 receives, in a time sequence with constant intervals, the values of the received intensity I_R for a constant emitted intensity I_0. In practice, the absorption A is equal to the emitted intensity I_0 minus the received intensity I_R.

The measurement of the hemoglobin concentration HGB is based on studies carried out by the applicant, who, by means of experimental tests, has correlated the hemoglobin

concentration HGB with the absorption A, in other words with the received intensity signal I_R for a constant emitted intensity signal I_0, as shown in the graph of Figure 1.

The applicant has determined the error of measurement of the hemoglobin concentration HGB as a function of the blood pressure P as shown in Figure 3, as a function of the blood

flow Q_b as shown in Figure 4, and as a function of temperature T as shown in Figure 2.

The applicant's studies have demonstrated that the blood flow Q_b, the pressure P, and the temperature T modify the blood's capacity for absorption (A) of electromagnetic radiation, in other words the absorption A, and cause a deviation between the values of hemoglobin concentration HGB found in the machine and those found in laboratory tests. In other words, the physical quantities acting on the blood during the operation of the machine 1 cause structural modifications of the red corpuscles, which, although small, are sufficient to alter the measurement of the hemoglobin concentration HGB. In particular, when the pressure P increases the red corpuscles are flattened, while the flow Q_b causes an orientation of the red corpuscles and the temperature T causes a change in the dimensions of the corpuscles.

Measurements were made on the basis of the studies carried out by the applicant, and by means of the measuring device 9, and their accuracy was found to increase with an increase in the allowance made for the physical quantities which modify the structure of the red corpuscles.

The value of the internal diameter Di is set in the calculation unit 14, which receives the value of the flow Q_b and calculates the hemoglobin concentration HGB as a function of the values of absorption A of electromagnetic waves, of the pressure values P measured by the sensor 12, of the flow Q_b of the pump 8, and of the values T measured by the sensor 13.

In practice, the following function relating the hemoglobin concentration to the aforesaid quantities was calculated on the basis of the studies which were carried out:

$$HGB = \left(\ln \frac{I_R}{I_0} \right) \cdot f(Q_b, P, Di, T) = \left[\ln \left(1 - \frac{A}{I_0} \right) \right] \cdot f(Q_B, P, Di, T)$$

This function can also be simplified, since eliminating the dependence on one or two of the measured physical quantities, consisting of the pressure P, the flow Q_b and the

temperature T, will provide a measurement of the hemoglobin concentration HGB which is less accurate than the measurement in which the function takes into account all three of the measured physical quantities, but is still more accurate than a measurement based solely on the absorption A, and is closer to the laboratory measurements.

The structure and functional working of the connection 10 is important in order to properly compensate the measurement of HGB as a function of the pressure. Indeed the amplitude, period and variable components of pressure in the tube 15 (the pressure is constantly modulated by the blood pump 8) influence the HGB measurement. Since the tube 15 and the chamber 16 are directly engaged one another and both made of rigid material the pressure detection in the chamber 16 is very precise and strictly related to the pressure and to the pressure variations in tube 15. Moreover, given the close proximity between tube 15 and chamber 16 and the rigidity of connection 10, it is practically impossible to deform the blood conduit between the section where the optical detection is carried out and the section where the pressure detection is obtained. The axial distance between the cross section of the portion 20 of tube 15 where the optical detection is carried out and the cross section of chamber 16 where the pressure detection is obtained shall be less than 50 mm; in the embodiment shown in the figures 6 and 7 such a distance is equal to 25 mm. The portion 20 of tube 15 shall present an internal diameter Di less than 10mm.

With reference to Figures 8 and 9, the graphs show a curve of the intensity I_R received by the detector 27 as a function of time t and a curve of the values of the variance VAR of the curve of received intensity I_R as a function of time t.

With reference to Figure 8, the curve of the values of I_R comprises a first section 28, which is characterized by a cyclical variation of the values of I_R caused by the flow Q_b provided by the peristaltic pump 8 and corresponds to a normal stage of operation of the dialysis machine 1, and a section 29 which corresponds to a stage in which a blockage

of the circuit has occurred up-line from the sensor 11. Although the divergence between the values of I_R of the section 28 and those of the section 29 is significant in graphic terms, it is difficult, in terms of the signal, to establish a threshold which clearly distinguishes the section 28 from the section 29. Conversely, the variance VAR shows a peak tending towards infinity at the point of the change from the section 28 to the section 29, in other words at the instant when the blockage of the circuit 2 occurs.

With reference to Figure 9, the curve of the received intensity I_R comprises a first section 30 which corresponds to a stage of normal operation of the machine 1, and a section 31 which corresponds to a stage in which a blockage of the circuit has occurred down-line from the sensor 11, which does not cause a significant variation of the received intensity I_R. Conversely, the down-line blockage causes a significant variation of the variance VAR as a function of time t.

The calculation unit 14 constantly compares each value of the variance VAR with a range of acceptability in the region of a mean value of the values of variance VAR corresponding to the normal operation of the machine 1, in other words without blockages of the circuit 2. If the value of the variance VAR diverges significantly from the range of acceptability, the calculation unit 14 emits an error signal E.

Consequently, the measurement of the absorption A is used not only to measure the hemoglobin concentration HGB, but also to discover whether a blockage has occurred up-line or down-line from the sensor 11 in the arterial branch 5.

CLAIMS

1) Method of measuring the hemoglobin concentration (HGB) in the blood in a circuit (2) of a dialysis machine (1), the method comprising the measurement of the values of absorption (A) of electromagnetic waves by the blood along one section (5a) of the said circuit (2), the values of the said absorption (A) being correlated with the values of the said hemoglobin concentration (HGB); the method being characterized in that the values of at least one physical quantity of the blood, from the group comprising blood pressure (P), blood temperature (T) and the rate of flow (Q_b) of blood along the said section (5a), are measured, and the values of hemoglobin concentration (HGB) in the blood are calculated as a function of the values of absorption (A) and of the said physical quantity.

2) Method according to Claim 1, characterized in that the values of the hemoglobin concentration (HGB) are calculated as a function of the values of absorption (A) and the values of pressure (P) measured along the said section (5a).

3) Method according to Claim 1, characterized in that the values of the hemoglobin concentration (HGB) are calculated as a function of the values of absorption (A) and the values of flow rate (Q_b) along the said section (5a).

4) Method according to Claim 1, characterized in that the values of the hemoglobin concentration (HGB) are calculated as a function of the values of absorption (A) and the values of temperature (T) measured along the said section (5a).

5) Method according to Claim 1, characterized in that the said section (5a) is located down-line from a peristaltic pump (8) providing a specified rate of flow (Q_b) of blood, the values of hemoglobin concentration (HGB) being calculated as a function of the values of absorption (A), the values of pressure (P) and the values of flow rate (Q_b).

6) Method according to Claim 1, characterized in that the said section (5a) is located down-line from a peristaltic pump (8) providing a specified rate of flow (Q_b) of blood, the values of hemoglobin concentration (HGB) being calculated

as a function of the values of absorption (A), the values of pressure (P) and the values of flow rate (Q_b) and the values of temperature (T).

7) Method according to one of claims 1 to 6, characterized in that the said section (5a) comprises a portion (20) of a tube (15), said electromagnetic waves passing through the said portion (20) along a specified path.

8) Method according to claim 7, characterized in that the said path is correlated with the internal diameter (Di) of the said portion (20).

9) Method according to claim 8, characterized in that the said characteristic (HGB) of the blood is calculated as a function of the internal diameter (Di) of the said portion (20).

10) Method according to one of claims 1 to 9, characterized in that the absorption (A) is measured by means of a sensor (11) located in the said section (5a), comprising an emitter (26) for emitting a beam of electromagnetic waves with a specified emission intensity (I_o) and a detector (27) which can detect a received intensity (I_R), the said absorption (A) being equal to the difference between the emission intensity (I_o) and the received intensity (I_R).

11) Method according to claim 10, characterized in that a variance (VAR) of the received intensity (I_R) is calculated, and the variance (VAR) is compared with a range of acceptability to detect an interruption up-line or down-line from the said section (5a).

12) Method according to claim 11, characterized in that an error signal (E) is emitted if the value of the variance (VAR) is outside the said range of acceptability.

13) Blood circulation circuit for a dialysis machine, characterized in that it comprises a connection (10) forming a section (5a) of the circuit (2), the said

connection comprising a tube (15) for subjecting the blood to the measurement of the absorption (A) of electromagnetic waves and a chamber (16) for subjecting the blood to the measurement of pressure (P).

14) Circuit according to claim 13, characterized in that the said chamber (16) is covered by a deformable membrane (24).

15) Circuit according to claim 13 or 14, characterized in that it comprises an arterial branch (5) and a venous branch (6), the said connection (10) being located along the arterial branch (5).

16) Circuit according to claim 13, characterized in that the tube (15) and the chamber (16) are directly engaged one another.

17) Circuit according to claim 13, characterized in that the tube (15) and the chamber (16) are both made of rigid material.

18) Circuit according to claim 13, characterized in that the tube (15) presents a portion (20) defining a first measurement cross section where the absorption measurement is carried out, and the chamber (16) presents a second measurement cross section where pressure detection is obtained, the distance between said measurement cross sections being less then 50 mm.

19) Circuit according to claim 13, characterized in that the portion (20) presents an internal diameter Di less than 10mm.

20). Device for measuring the hemoglobin concentration in a circuit (2) of a dialysis machine (1) comprising a connection (10) forming a section (5a) of the said circuit (2), the said connection (10) comprising a tube (15) along which a measurement is made by means of beams of electromagnetic waves to determine the absorption (A) of the blood, the hemoglobin concentration (HGB) being

correlated with the said absorption (A), the device being characterized in that it comprises at least one further sensor (12, 13) for measuring one of two quantities, namely the blood pressure (P) and the blood temperature (T); the hemoglobin concentration (HGB) being a function of the absorption (A) and of the said quantity.

21) Device according to claim 20, characterized in that the pressure sensor (12) comprises a chamber (16) fitted with a deformable membrane (24) to measure the variations of pressure (P) of the blood by means of an electrical device (25) in the said section (5a), the hemoglobin concentration (HGB) of the blood being a function of the absorption (A) of the blood and of the pressure (P).

22) Device according to claims 20 and 21, characterized in that it comprises a temperature sensor (13) located in the said connection (10).

23) Device according to one of claims 20 to 22, characterized in that the said connection (10) is located down-line from a peristaltic pump (8) providing a specified rate of flow (Q_b) of blood, the hemoglobin concentration (HGB) being calculated as a function of the rate of flow (Q_b) of the blood.

24) Device according to claim 21, characterized in that the said tube (15) and the said chamber (16) are made from transparent rigid material.

25) Device according to claim 21, characterized in that it comprises a sensor (11) located on the said tube (15), the sensor (11) comprising an emitter (26) for emitting a beam of electromagnetic waves with a specified emission intensity (I_o) and a detector (27) which can detect the received intensity (I_R), the said absorption (A) being equal to a difference between the emission intensity (I_o) and the received intensity (I_R).

26) Device according to claim 25, characterized in that it comprises a calculation unit (14) connected to the said sensors (11, 12, 13) and to the said peristaltic pump (8).

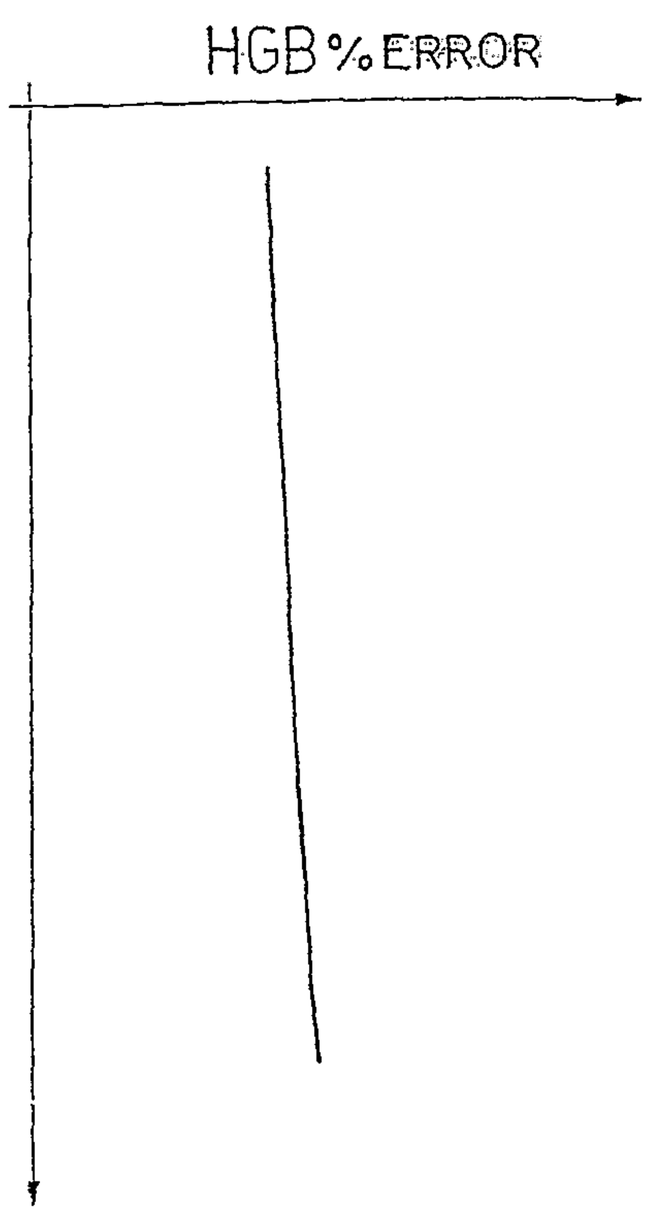


Fig.3

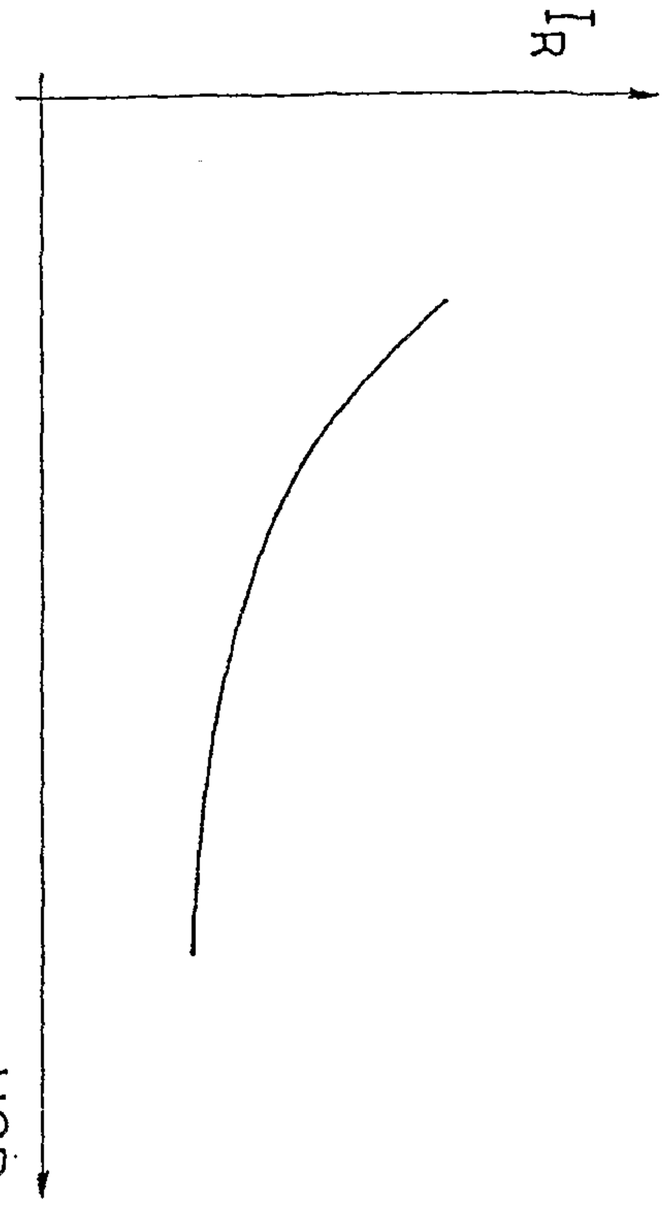


Fig.1

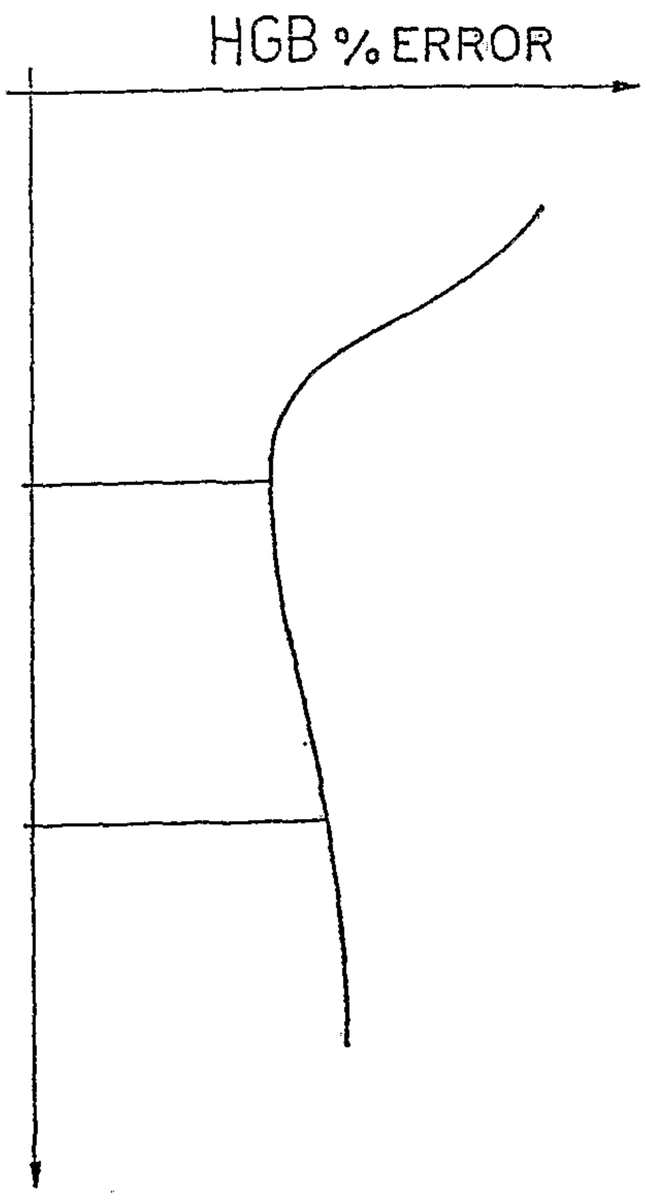


Fig.4

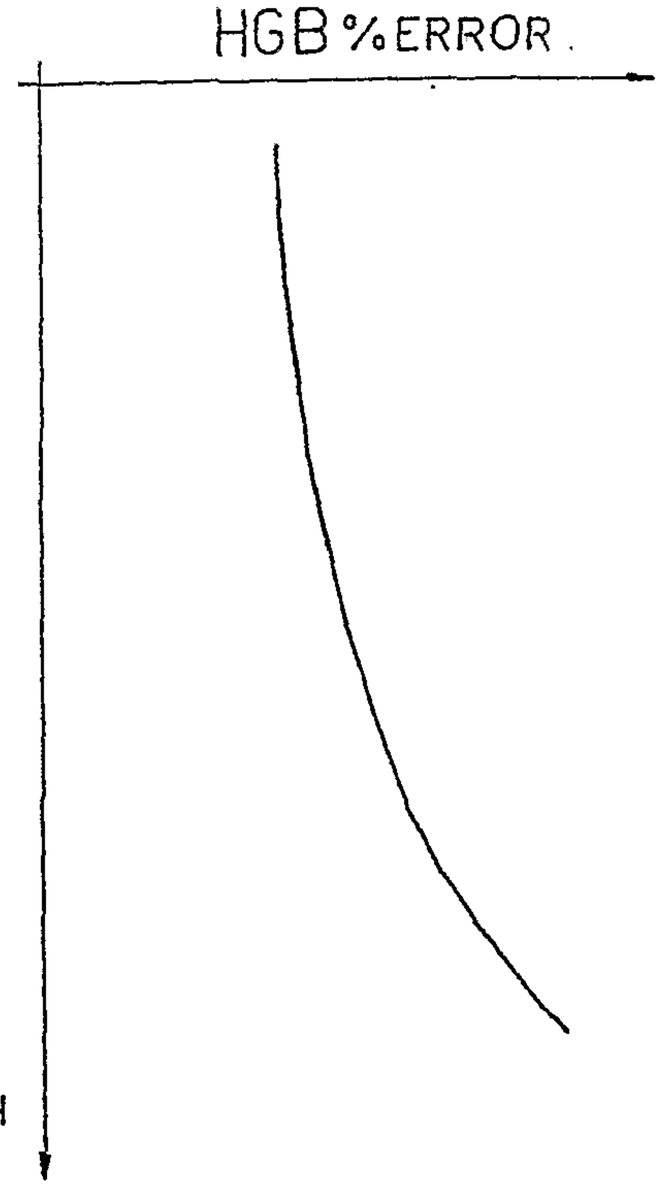


Fig.2

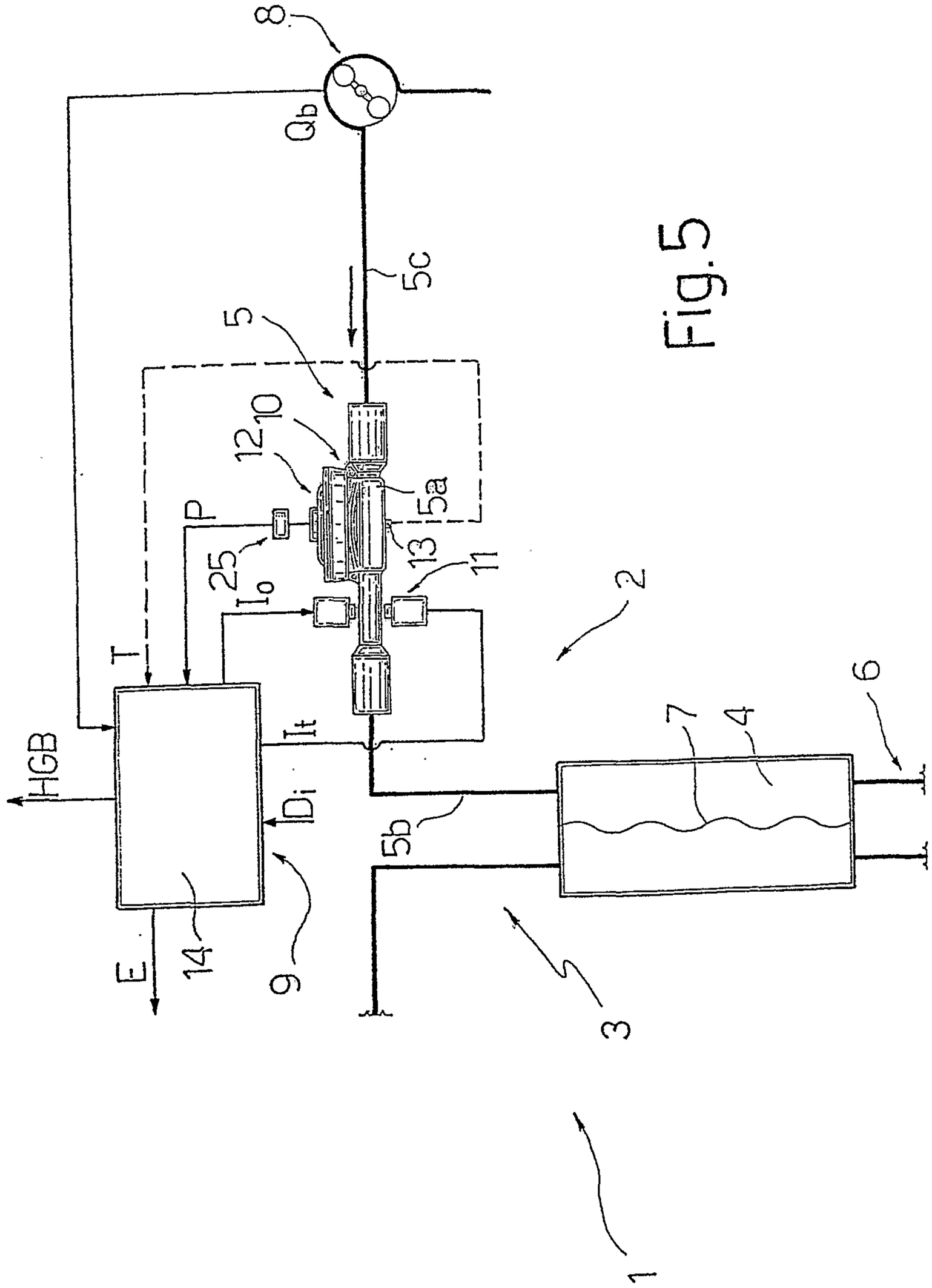


Fig.5

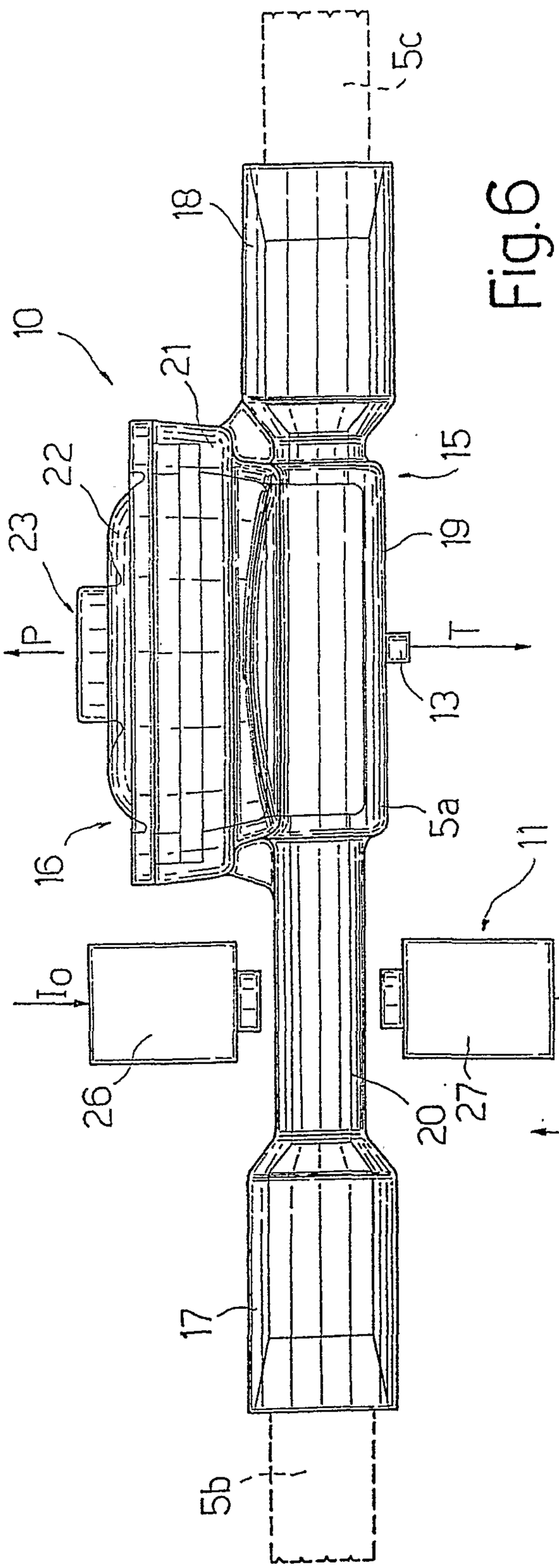

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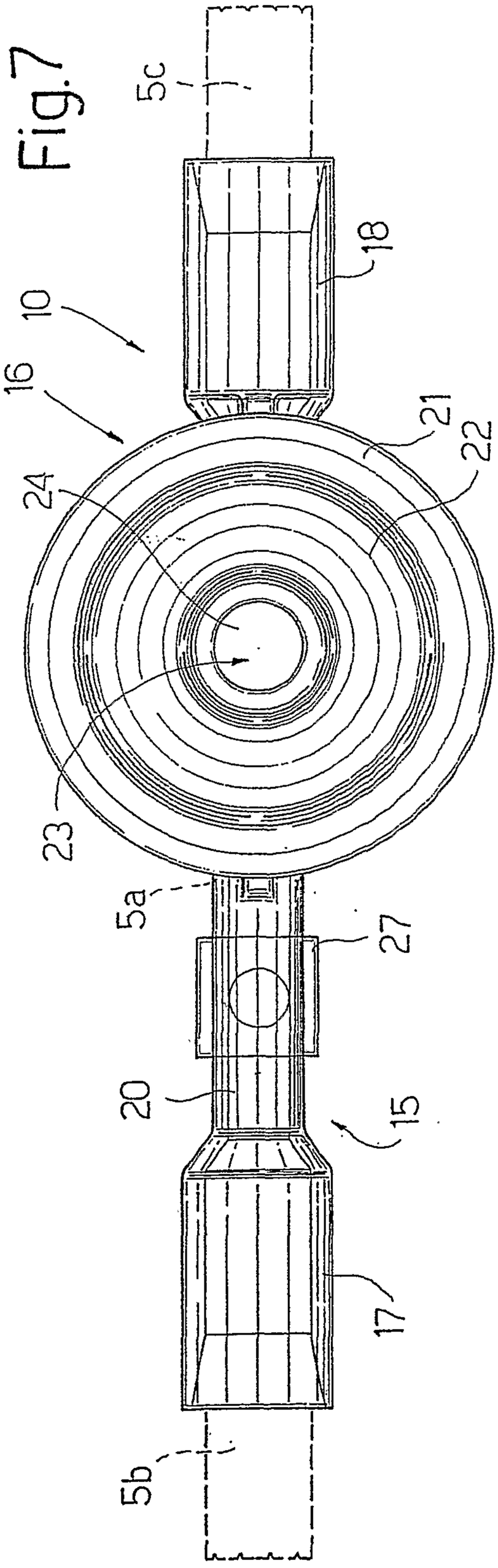
Fig.6

Fig.7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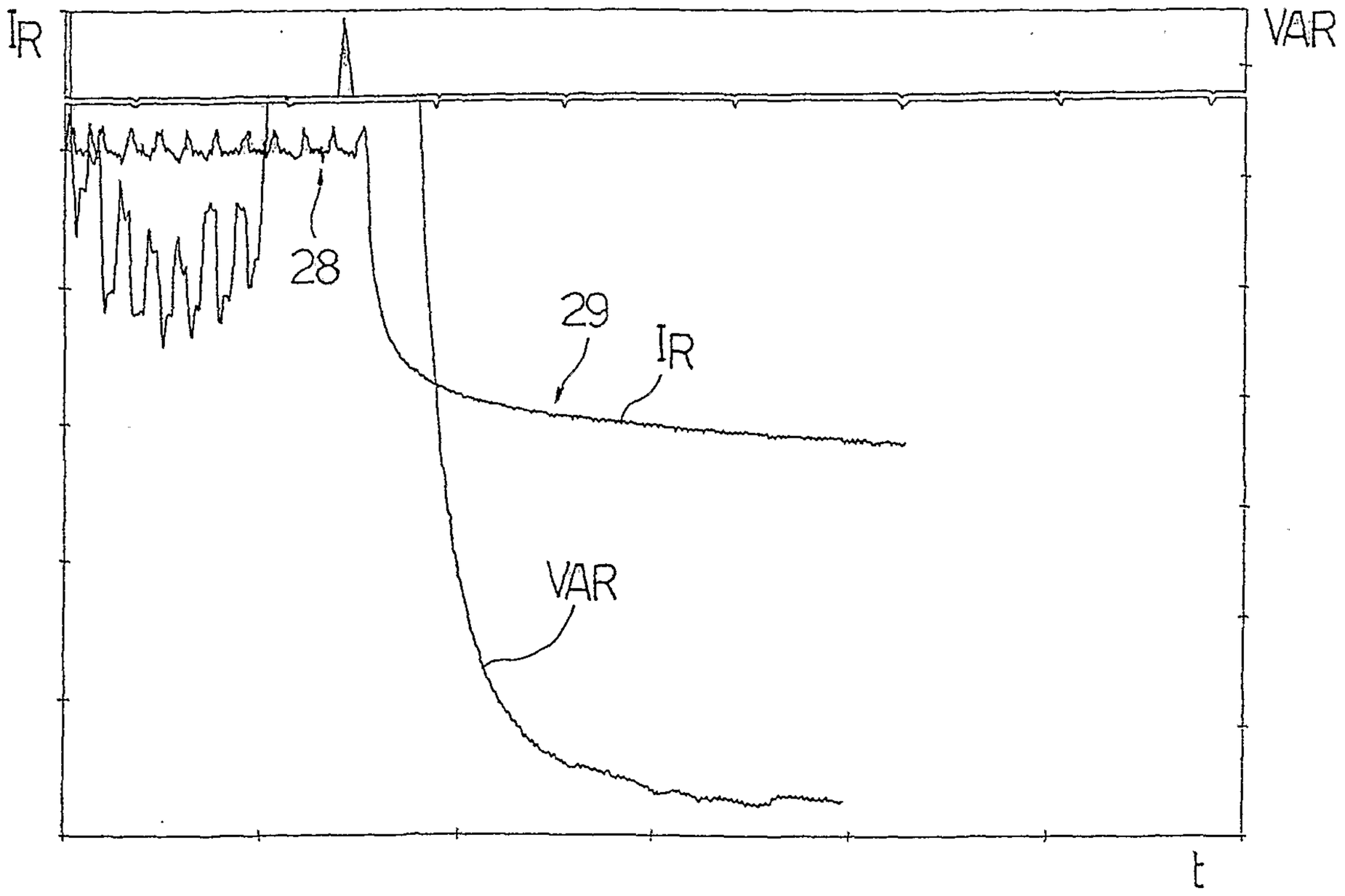
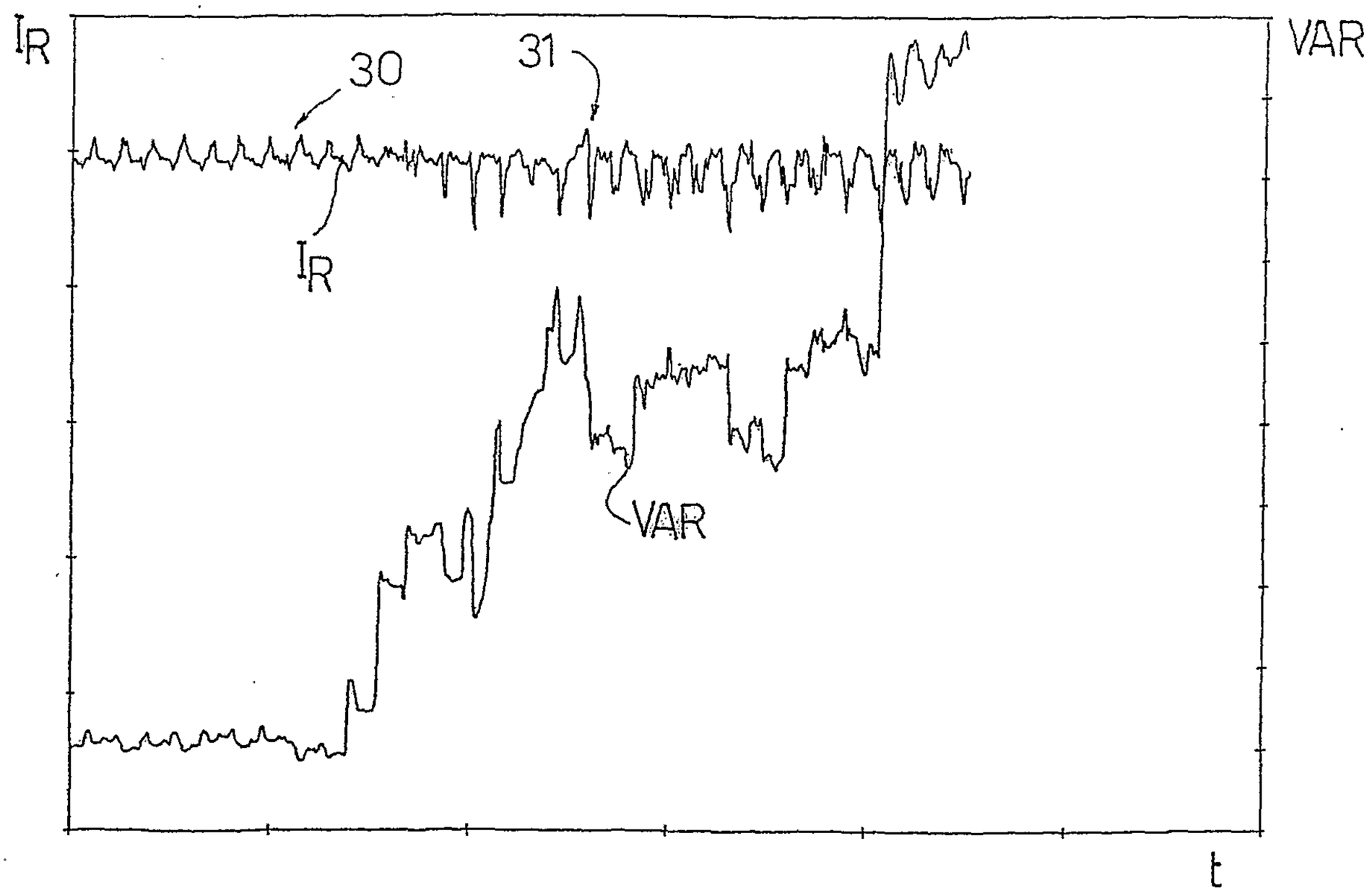
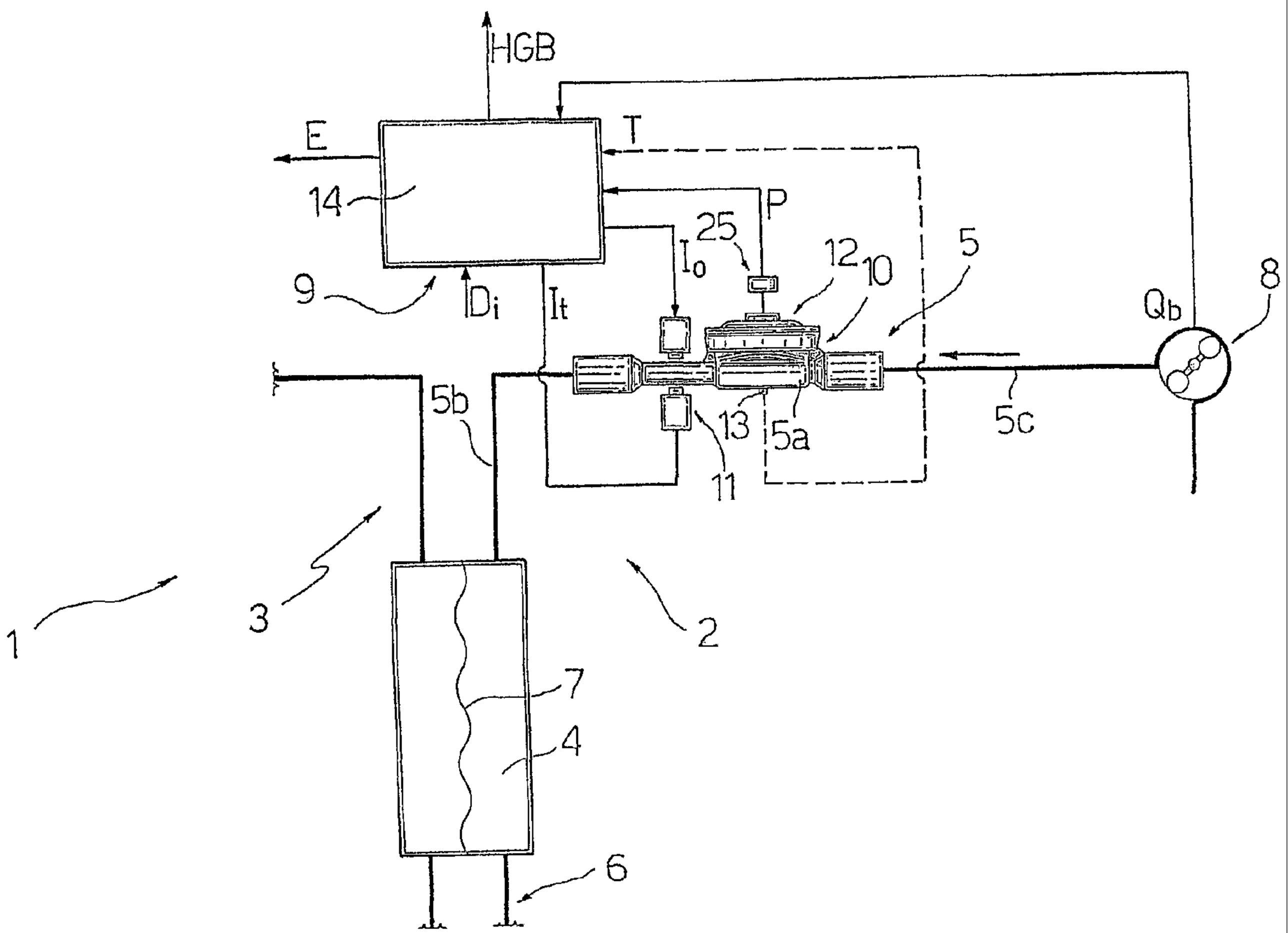


Fig.8

Fig.9

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