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(54) METHOD AND APPARATUS FOR BLOOD PURIFICATION

(71) We, INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE, a French body corporate, of 3 rue leon bonnat, 75016 Paris, France, do hereby declare the invention, for which we pray that a patent may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement:—

This invention relates to a method and apparatus for purification of blood by extra-corporeal haemodialysis. More specifically, This invention is concerned with regulating haemodialysis conditions in effecting purification of blood extra-renally so that the dangers of accidents are reduced.

To overcome chronic renal insufficiency, use is made of artificial kidneys or haemodialysers. Apparatus of this type achieves purification of blood by circulation of the blood of the patient and of a solution, separated by a diaphragm, circulation preferably being in counter-current. The purification which occurs utilises the phenomena of diffusion, osmosis and usually ultrafiltration.

Three types of dialyser have found common use, these dialysers differing basically in respect of the arrangement of the blood compartment and solution compartment and being termed: coil dialysers, plate dialysers and capillary dialysers. Reference is here made to an article by A. Baglin and J. P. Fendler "L'hemodialyse periodique", Revue de Medicine, No. 4, 28th January, 1974, pages 107 to 111, which describes in detail the principles of haemodialysis and artificial kidneys which are used therein.

During a haemodialysis session, which may, for example, last for 6 to 8 hours, patients often exhibit hypotension. This phenomenon can quickly lead to serious consequences for the patient and, for this reason, must be remedied as soon as it is noticed. Various procedures have been proposed for noting the fluid loss responsible for blood pressure drop and remedying it.

Of particular interest in this connection is an article entitled "Automatic Fluid Replacement and blood Pressure Control During Dialysis", Vol. XVI, Trans. amer. Soc. Artif. Int. Organs, 1970, J. A. Miller, E. Prescott and C. Carpenter which describe the automatic adjustment of haemodialysis conditions with the object of raising blood pressure when hypotension occurs, by comparison of the weight of a patient with a theoretical weight which he should have so that a perfusion or intravenous drip is actated to replenish body fluid lost when the actual weight is lower than the normal body weight of the patient thereby causing the hypotension. This perfusion is stopped when the weight has re-assumed the desired value. The automatic adjustment of haemodialysis conditions also includes the modification of the transmembrane pressure gradient so that the speed of ultrafiltration increases when the body weight becomes too high and the further adjustment of this pressure gradient when the desired weight has been reached, comparison of the blood pressure of the patient with a pre-determined alarm point, reduction of the transmembrane pressure gradient to a minimum value when the blood pressure falls below the alarm point and immediate initiation of a perfusion, triggering of an alarm circuit indicating to the staff that the blood pressure has fallen and stopping of perfusion and returning to its previous value the transmembrane pressure gradient when the blood pressure has returned to above the alarm point.

In this article by Miller et al, it is proposed that the arterial pressure be measured by a sensor placed on the arterial channel of the haemodialyser. In the event of a fall in arterial pressure, the apparatus operates to reduce the transmembrane pressure to a minimum value and immediately starts a perfusion. It simultaneously triggers an

external alarm. When the pressure rises again to above the alarm point, the apparatus terminates the perfusion and increases the transmembrane pressure.

It has now been discovered that an automatic haemodialysis apparatus should satisfy a condition which is not fulfilled by apparatus described in the aforsaid article by Miller et al. This is a condition whereby the patient can be allowed to undergo weight change during haemodialysis, provided that this weight change is in accordance with a weight/time curve which can be calculated and which is based upon certain initial values of dialysis parameters and the desired final body weight and which lies within predetermined acceptable limits. More particularly it has been found that the hypotension phenomenon which is particularly dangerous is not the cause of the established incidents but is a simple result thereof. In this connection, it is the variation in weight loss over a period of time which is the main parameter to take into consideration and this has to be controlled very precisely during haemodialysis.

According to one aspect of the present invention, there is provided a method of regulating haemodialysis conditions while simultaneously subjecting a patient to ultrafiltration of the blood, in which method ultrafiltration of the blood to achieve such haemodialysis is effected by simultaneous circulation of the blood and a dialysis solution on either side of a haemodialyser membrane and control of the weight of a patient, his arterial pressure and at least one parameter determining the course of ultrafiltration, said parameter being regulated to maintain said control by ensuring that change in the body weight of the patient with time during haemodialysis follows a curve which lies within a validity zone defined by two weight/time curves.

According to a second aspect of this invention, there is provided an automatic haemodialysis apparatus for effecting dialysis of blood by ultrafiltration, comprising a haemodialyser having membrane means separating a blood compartment from a dialysis solution compartment, means for causing the circulation of the blood of a patient and a haemodialysis solution on either side of said membrane, a perfusion arrangement for a patient whose blood is to undergo haemodialysis and a plurality of sensors comprising at least one sensor of a parameter related to the weight of the patient for providing a signal representing variations in the weight of the patient; at least one sensor of arterial pressure adapted to provide a signal indicating the magnitude of arterial pressure and at least one sensor of a parameter determining the course of ultrafiltration, this sensor being adapted to provide at least one ultrafiltration signal, the sensors being associated with means for comparing the signal of variations in weight with an area of weight values defined by plotting maximum and minimum acceptable weights of the patient against time with a haemodialysis period during which the haemodialyser is to be employed, to give a deficiency signal when the signal of weight variation in not within said area.

It is particularly preferred that the arterial pressure be read in the method of this invention by a bloodless procedure, in the form of the systolic and/or diastolic pressure and apparatus according to this invention accordingly preferably comprises a sensor for effecting measurement of arterial pressure by a bloodless procedure. The measurement of arterial pressure in this manner is preferably carried out by detection of the korotkoff sounds or by Doppler effect.

The apparatus of this invention preferably additionally comprises an alarm indicator controlled by the aforesaid deficiency signal and adapted to indicate an alarm condition. Morever, the apparatus may comprise means for indicating supplementary alarm conditions when one of the parameters affecting ultradialysis deviates from a predetermined variation range. The apparatus is also preferably adapted to effect the automatic modification of said one parameter when an alarm condition is indicated.

The parameter affecting the course of ultrafiltration which is monitored can be one of a number, including the weight of liquid withdrawn by ultrafiltration, the pressures of the blood inlet and outlet of the haemodialyser, the pressures of the solution at the inlet and outlet of the haemodialyser, the rate of flow of blood in the haemodialyser and the rate of perfusion.

It is a characteristic feature of the present invention that the permitted range of values within which the body weight of a patient undergoing haemodialysis may lie is defined at any moment by two curves on a weight-time diagram which enclose an ideal curve of weight variation with haemodialysis time, this curve being calculated before the haemodialysis. If the actual curve of weight variation with haemodialysis time recorded during the haemodialysis undergoes deviation from this ideal curve, then the curve may be modified to return it to the ideal curve. Thus, the apparatus of the invention will comprise a curve control means designed for modifying one of the parameters in the presence of an alarm condition, for example the speed of perfusion to return the weight-time curve to within the validity zone and will preferably

operate at all times to ensure that the weight-time curve is returned to the ideal curve if it deviates therefrom. The apparatus may also comprise a display console designed to show the actual weight variation curve during haemodialysis, the curves defining the ranges of variation in weight, the initial data concerning the patient and the value at a particular time of the at least one parameter.

For a better understanding of the invention and to show how the same can be carried into effect, reference will now be made to the accompanying drawings, in which:

Figures 1 and 2 are weight-time diagrams showing examples of ideal weight variation curves during haemodialysis;

Figure 3 is another weight-time diagram showing the variation in weight of a patient with time during haemodialysis and the curves which indicate the acceptable limits of weight variation at any particular time during haemodialysis;

Figure 4 is a schematic representation of a haemodialysis apparatus according to the invention;

Figure 5 represents the screen of the display console of the apparatus of Figure 4, during a haemodialysis; and

Figure 6 is a schematic diagram of an artierial pressure sensor operating by a bloodless procedure as required by the process according to the invention.

The adjustment of the haemodialysis conditions in the practice of this invention requires, firstly, the calculation of an ideal weight curve from the initial values of the dialysis parameters and the desired final weight and, secondly, the determination of the best manner of achieving the desired final values with the assistance of the dialysis parameter values determined at any instant.

The determination of the ideal weight curve will be dependent upon the nature of the contents of the haemodialyser which is used. For example, the curve may comprise three parts corresponding to a first dialysis period, a second dialysis period and a restoration period indicated in Figures 1 and 2 by the reference numerals 1, 2 and 3 respectively. During the first dialysis period, the rate of loss of weight is low when the artificial kidney contains an isotonic saline solution. The ideal ultrafiltration gradient is, in this case, low in relation to the mean gradient during the remainder of the dialysis. When the dialyser contains a macromolecular solution and not an isotonic saline solution, the rate of loss in weight may be constant during the two dialysis periods.

In this first dialysis period, five to ten minutes are devoted to checking the properties of the membrane of the dialyser before haemodialysis is commenced. Moreover, the rate of flow of blood on the counter pressure outlet pressure of the blood) are set at low values so as to avoid the risk of rupture of blood vessels with the commencement of dialysis. This testing time is too short for it to have an appreciable influence on the theoretical curve and it may be disregarded.

During the second dialysis period, the loss in weight varies linearly with time.

The restoration period which commences when the dialysis proper is terminated, lasts for five minutes, during which the blood content of the haemodialyser and a connection tube between patient and haemodialyser is restored to the patient, possibly with addition of a volume of liquid (isotonic saline solution or macromolecular solution). The desired weight is determined after this restoration.

The calculation of the ideal curve before commencing a haemodialysis requires knowledge of a certain number of parameters. Certain of these parameters may undergo modification during the dialysis, for example, the desired final weight, the duration of the haemodialysis, the total weight of the perfusions and the provided perfusion time, this time being less than or equal to the dialysis time.

Fixed parameters to consider are the initial weight, the initial contents of the haemodialyser and the restoration volume on completion of dialysis. The restoration volume is equal to the sum of the volume of the dialyser which is constant and the volume of fluid used for emptying it when this fluid is a solution.

Referring next to Figures 1 to 3, these are curves in which body weight, P, is plotted on the ordinate axis against time t. In Figures 1 and 2, typical curves calculated in the manner set out hereinafter are shown, whereas in Figure 3, two calculated and acceptable curves of the type shown in Figure 2 are indicated by broken lines and between them lies a solid curve showing the actual change in bodyweight encountered during a haemodialysis during which tendency for body weight to increase has to be compensated for.

When the dialyser is initially filled with an isotonic saline solution, the ideal curve may have the form shown in Figure 1, that is to say, it comprises three straight segments, namely a segment of negative slope a/n during the first dialysis period 1, a segment of negative slope a during a second dialysis period 2 and a segment of positive slope during the third period of restoration period 3.

Figure 2 shows an ideal curve for a haemodialysis carried out when the

apparatus is filled with a macromolecular solution. It is noted that in this case, the curve comprises a single straight segment of negative slope *a* during the two dialysis periods. The curves of Figures 1 and 2, given by way of example,correspond to the equations:

$$a = \frac{Pd - Vr - Pt}{Td - T1(1-b) - bt}$$

$$u = -ab + \frac{Vp - Vt}{Tp - t}$$

in which

Vp is the total weight of perfusion liquid provided,

Vt is the weight of liquid perfused at any time,

Vr is the weight of the restoration liquid,

Pt is the initial weight of the patient,

Pd is the desired weight,

Td is the duration of the haemodialysis,

T1 is the duration of the first haemodialysis period,

Tp is the time during which perfusion is effected,

t represents the time calculated from the commencement of dialysis,

u represents the desired ultrafiltration rate,

a is the rate of loss of weight during the second dialysis period, and

b is a calculation parameter.

The total volume of the perfusion liquid provided is equal to the volume already perfused when Vp is greater than Vt or when t is greater than Tp. *b* represents the coefficient of slope or gradient reduction when *t* is smaller than T1 and when the dialyser is filled with saline solution. In other cases, b is equal to 1. Moreover, it should be noted that the fraction in the expression giving *u* has a zero value when t is greater that or equal to Tp.

In fact, during haemodialysis, it is not the rate of ultrafiltration which is followed, but the mean difference in pressures in the dialyser, that is to say, the difference between the mean of the inlet and outlet pressures of dialysate. The relationship between this difference, p, in pressures and the rate of ultrafiltration *u* is given by the equation:

$$P = \alpha u + \beta$$

α and β being constants determined by the construction of the haemodialysis apparatus.

The curves thus calculated permit the haemodialysis conditions to be regulated.

The general organisation of preferred apparatus according to this invention will now be described with reference to Figure 4. A patient 10 is placed on a bed 12. He is connected to a blood compartment 16 of a haemodialyser 14 which comprises the blood compartment and a dialysate compartment 18 through a blood circuit which comprises a pump 20 which is optional and may be dispensed with, pressure sensors 22 and 24 positioned at the inlet and outlet respectively of the dialyser and a flow rate sensor 26. For dialysate there is a circuit which comprises an inlet pressure sensor 28 and an outlet pressure sensor 30, or an ultrafiltration sensor 32 which is also shown. When the return of the dialysate circuit is at atmospheric pressure, the sensor 30 may obviously be omitted. A control unit 34 is provided for regulation of the rate of perfusion of the patient.

The bed 12 of the patient is mounted on an electronic balance 36 of the analog type, which is connected to an analog-digital converter 38. In addition, the patient carries on his arm an arterial pressure sensor 40 which will be hereinafter described in greater detail by reference to Figure 6.

The sensors 22, 24, 26, 28, 30 and 40, the control unit 34 and the converter 38 all transmit signals to data processing unit or to a cabled or microprogrammed logic unit 42 which exchanges data with a display console 44, which may comprise a data input keyboard.

The various elements of the apparatus shown in Figure 4 will now be described in greater detail. The sensors 22, 24, 28 and 30 may be of the type No. 8 805 marketed in France by Endevco, having an area of use of ±500 mmHg. These sensors comprise a part which is to be sterilised or discarded after use and a fixed part.

The blood flow sensor 26 may be a Doppler effect flow meter designed to measure the flow rate in the blood circulation tube. It will generally have a range of measurements from 30 to 500 cc/min, supplying a continuous analog voltage which can be transformed into numerical form for direct treatment by the data processing unit 42.

The ultrafiltration sensor 32 may take the form of an overflow dripping into a test tube positioned on a balance transmitting an analog signal in the case of certain haemodialysers, such as model "RP6" of Rhone-Poulenc. The sensitivity of this signal is preferably at least 50 g, the maximum weight to be measured being of the order of 8 Kg.

The control unit 34 for regulating the perfusion may comprise an automatic perfuser or drip known as the Braun "Infusomat". This apparatus comprises a peristaltic pump driven by a stepping motor, which is itself piloted by a pulse generator.

The rate of perfusion is for example adjustable continuously between 5 and 1000 cc/hour.

The balance 36 may be of the "Fresenius" electronic type, comprising a movable platform connected by a cable to a monitor. Its sensitivity will need to be 50 g up to a total load of 200 Kg. It enables variations of ±10 Kg relative to the initial weight to be followed and it transmits an analog signal to the converter 38.

As can be seen from Figure 6, The sensor 40 for determining arterial pressure comprises a sphygmanometer 46, for example of the Siemens "Diasyst" type, a control unit 48 and an inflation valve 50. The control unit 48 regulates the inflation and the deflation of the arm of the sphygmanometer in response to signals from the data processing unit 42 and is unable to permit the measurement of the pulse, the systolic pressure and the diastolic pressure to be effected in the manner of a conventional sphygmanometer. This apparatus is preferably of a completely automatic type.

The data processing unit 42 receives all the signals from the sensors and exchangers the data with the display console 44 to be hereinafter described. In addition, it transmits the orders indicated by the arrows provided with a small circle on Figure 4 to provide control of regulation of dialysis. The console 44 has, for example, a screen whose appearance is indicated in Figure 5. The screen comprises a first zone 52, designed to indicate the name of the patient, the number of the session, the number of the bed, the hour and other such administrative particulars. Zone 54 indicates the initial data in relation to the haemodialyser, the provided time for the session in relation to the haemodialyser, the provided time for the session, the initial weight of the patient, the desired weight of the patient and various risk factors. Zone 56 indicates data pertained to the haemodialysis such as difference in weight, blood pressure, pulse, rate of flow of blood and ultrafiltration rate. Zone 58 provides an area in which an alarm condition for the patient can be indicated or warning can be given of an alarm condition for another bed to which the apparatus is connected to allow a full display of information pertaining to that bed to be presented on the console. Zone 60 is a dialogue zone.

A major part of the screen is occupied by a screen 62 which shows the actual variation in weight of the patient as a function of time. This curve 64 lies between two curves 66 and 68 which define accessible maximum and minimum weight ranges and are calculated as previously described.

During a haemodialysis operation, an operator introduced through the keyboard associated with the console the file number of the patient, in the form of seven alpha-numerical characters, his name or his shortened name, the date, etc. All these parameters may or may not be arranged on a sequential mass periphery for use during each operation to which a patient is subject.

Certain parameters, such as initial weight and arterial pressure are directly recorded by means of the sensors. Others are asked for by means of the console, then arranged in a memory for the duration of the supervision, these parameters being, for example, the desired weight, the type of haemodialyser being used and its contents, the restortion volume, the duration of the session, the frequency of supervision, the degree of supervision, that is to say the spacing of the curves which define the ranges, and the provided volume and speed of the perfusions.

The apparatus indicates alarm conditions. It is possible initially to classify them as minor alarms and major alarms. The minor alarms do not necessitate any immediate action and, for example, do not modify the frequency of utilisation of the data. They are indicated by a visual signal, for example, a flashing arrow on the console.

The major alarms necessitate immediate action by the medical staff and they can cause a modification in the frequency of acceptance of the data. In addition, they cause the appearance of data in the alarm zone 58 of the console.

The different forms of alarm are concerned, for example, with the weight, the arterial blood pressure and the pulse, the rate of flow of the blood, the pressures in the different circuits of the haemodialyser and control of the ultra-filtration conditions. For example, the data processing unit may verify the fact that the weight at the time falls within the range as provided and possibly indicate an alarm condition. However, it is able to disregard a too large variation in weight between the two acceptances of data, for example subsequent to a book being placed on the bed of a patient.

Minimum and maximum values of the arterial pressure, depending on the arterial pressure at the commencement of the dialysis, are calculated at the commencement of the session, as a function of the degree of risk, and then with each change in the degree of risk.

Provision can also be made for an alarm range in respect of the pulse to be given when too greater a variation from the initial value of the pulse occurs.

The extreme values of the rate of flow of blood are constant parameters which can be

stored in the memory and can also lead to the establishment of an alarm condition.

Four pressure readings of the haemodialyser can lead to establishment of an alarm condition. These four pressures are the inlet and outlet pressures of the blood and of the dialysate. In coil dialysers, the inlet and outlet pressures of the dialysate are both practically zero. The ranges of these values for actuating the alarm are stored in a memory so that each time the difference in pressures inside the dialyser is spaced from a calculated value, an alarm condition is indicated, this difference in internal pressures in the dialyser is equal to the difference between the mean of the inlet and outlet pressures of the blood circuit and that of the inlet and outlet pressures of the dialysate circuit.In the event of an alarm signal being given to indicate that parameters being monitored are outside valves at which automatic control of perfusion and dialysis can be achieved in accordance with this invention, a doctor is able to increase the difference in pressures by increasing the counter pressure, that is to say, the pressure of the blood, or by increasing the rate of flow of blood.

In the case of the artificial kidney "RP6", this difference in pressures does not apply and the control parameter is the rate of variation of the ultrafiltration rate, measured with respect to the recommended values.

The acceptance of the data can be effected at different frequencies. For example, the weight can be measured every minute, whatever may be the conditions. On the other hand, the arterial pressure and the pulse which are measured every fifteen minutes under normal conditions, can be measured every five minutes or even every minute. The parameters relating to blood flow, the perfusion flow, pressures and the ultrafiltration flow rate are normally measured every five or ten minutes, but can be measured every minute under alarm conditions.

Although the heaemodialyser apparatus of the invention has been described hereinabove primarily with respect to its use as an artificial kidney, it is pointed out that the method and apparatus of the invention are not limited in their application to the treatment of chronic renal deficiency. Haemodialysers are also utilised as "artificial pancreases". What is then involved is a treatment wherein a dosage of insulin is supplied to the blood of a diabetic and the amount of insulin present is compared automatically with a reference value and further insulin is supplied to the blood of the diabetic if necessary. The apparatus according to the invention permits the automatic correction of the insulin supply as a function of the operation of the artificial pancreas. Consequently, data can be made available for calculating a haemodialysis curve, because these data are correlated to the variations in weight.

Although an apparatus has been described herein which ensures the control of a large number of parameters, it must be noted that varations in weight constitute the fundamental parameter on which is based the control of haemodialysis. These variations in weight are preferably determined accurately, measurements being to within 50 g.

WHAT WE CLAIM IS:—

1. A method of regulating haemodialysis conditions while simultaneously subjecting a patient to ultrafiltration of the blood, in which method ultrafiltration of the blood to achieve such haemodialysis is effected by simultaneous circulation of the blood and a dialysis by perfusion solution on either side of a haemodialyser membrane while supplying physiologically acceptable fluid to the patient and control of the weight of the patient, his arterial pressure and at least one parameter determining the course of ultra-filtration, said parameter being regulated to maintain said control by ensuring that change in the body weight of the patient with time during haemodialysis follows a curve which lies within a validity zone defined by two weight/time curves.

2. A method as claimed in claim 1, wherein arterial pressure is determined by a bloodless procedure.

3. A method as claimed in claim 2, wherein the arterial pressure is determined by the detection of Korotkoff sounds.

4. A method as claimed in claim 2, wherein arterial pressure is measured by determination of Doppler effect

5. A method as claimed in any one of the preceding claims, wherein the parameter determining the course of ultrafiltration is the weight of liquid withdrawn by ultrafiltration.

6. A method as claimed in any one of claims 1 to 4, wherein the parameter determining the course of ultrafiltration is the pressures of the blood at the inlet and the outlet of the haemodialyser.

7. A method as claimed in any one of claims 1 to 4, wherein the parameter determining the course of ultrafiltration is the pressures of the dialysis solution at the inlet and outlet of the haemodialyser.

8. A method as claimed in any one of claims 1 to 4, wherein the parameter defining the ultrafiltration is the rate of flow of the blood in the haemodialyser.

9. A method as claimed in any one of claims 1 to 4, wherein the parameter

determining the course of ultrafiltration is the rate of perfusion which is effected.

10. A method as claimed in any one of the preceding claims, wherein said parameter is regulated to maintain said control by ensuring that change in the body weight of the patient with time during haemodialysis follows an ideal curve calculated to lie within said validity zone.

11. A method as claimed in claim 10, wherein said calculated curve is plotted in accordance with the formula:

$$a = \frac{Pd - Vr - Pt}{Td - T1(1-b) - bt}$$

$$u = -ab + \frac{Vp - Vt}{Tp - t}$$

in which

Vp is the total weight of perfusion liquid provided,

Vt is the weight of liquid perfused at any time,

Vr is the weight of the restoration liquid,

Pt is the initial weight of the patient,

Pd is the desired weight,

Td is the duration of the haemodialysis,

T1 is the duration of the first haemodialysis period,

Tp is the time during which perfusion is effected,

t represents the time calculated from the commencement of dialysis,

u represents the desired ultrafiltration rate,

a is the rate of loss of weight during the second dialysis period, and

b is a calculation parameter.

12. A method as claimed in any one of the preceding claims, wherein an indication is given of an alarm condition when the weight of the patient at a particular instant during the course of haemodialysis lies outside said validity zone.

13. A method as claimed in any one of the preceding claims, wherein an alarm signal is given when at least one said parameter lies outside a predetermined range of values within which said parameter is expected to lie.

14. A method as claimed in claim 13, wherein, on said deviation of said least one parameter, haemodialysis conditions are altered to return said parameter to within said predetermined range of values.

15. A method as claimed in any one of the preceding claims, which is employed to compensate for chronic renal insufficiency.

16. A method as claimed in any one of claims 1 to 14, which is carried out to monitor and control insulin supply to the blood of a diabetic.

17. A method of regulating haemodialysis conditions while simultaneously subjecting a patient to ultrafiltration of the blood, substantially as hereinbefore described with reference to the accompanying drawings.

18. An automatic haemodialysis apparatus for effecting dialysis of blood by ultrafiltration, comprising a haemodialyser having membrane means separating a blood compartment from a dialysis solution compartment, means for causing the circulation of the blood of a patient and a haemodialysis solution on either side of said membrane, a perfusion arrangement for a patient whose blood is to undergo haemodialysis and a plurality of sensors comprising at least one sensor of a parameter related to the weight of the patient for providing a signal representing variations in the weight of the patient; at least one sensor of arterial pressure adapted to provide a signal indicating the magnitude of arterial pressure and at least one sensor of a parameter determining the course of ultrafiltration, this sensor being adapted to provide at least one ultrafiltration signal, the sensors being associated with means for comparing the signal of variations in weight with an area of weight values defined by plotting maximum and minimum acceptable weights of the patient against time within a haemodialysis period during which the haemodialyser is to be employed, to give a deficency signal when the signal of weight variation is not within said area.

19. Apparatus as claimed in claim 18, wherein the sensor for determining arterial pressure operates by detecting arterial pressure by a bloodless procedure.

20. Apparatus as claimed in claim 19, wherein said sensor is adapted to detect Korotkoff sounds.

21. Apparatus as claimed in claim 19, wherein said sensor is adapted to measure Doppler effect as a means of indicating arterial pressure.

22. Apparatus as claimed in any one of claims 18 to 21, which comprises means adapted to cause variations in the limits of the said area as a function of time during haemodialysis.

23. Apparatus as claimed in claim 22, wherein the means adapted to cause variations in the limits of said area modifies this area so that it always incorporates an ideal curve of which the variations as a function of time are predetermined.

24. Apparatus as claimed in claim 23, wherein said means is operative to modify said ideal curve during the haemodialysis.

25. Apparatus as claimed in claim 24, which comprises a manual control means permitting the modification of the ideal curve during a haemodialysis.

26. Apparatus as claimed in any one of

claims 18 to 25, which additionally comprises an alarm indicator controlled by the deficiency signal and adapted to indicate an alarm condition.

27. Apparatus as claimed in any one of claims 18 to 26, which comprises a means for comparing at least one signal of a parameter determining the course of ultrafiltration with a second area defined by plotting maximum and minimum acceptable areas of said parameter against time within a haemodialysis period during which the haemodialyser is to be employed, to give a second deficiency signal when the signal of said parameter variation is not within said second area.

28. Apparatus as claimed in claim 27, and comprising a second alarm-indicating device controlled by the second deficiency signal and adapted to indicate an alarm condition.

29. Apparatus as claimed in any one of claims 18 to 28, further comprising a control means adapted to modify the value of one said parameter defined in the course of ultrafiltration, when a said deficiency signal is given, in use.

30. Apparatus as claimed in any one of claims 18 to 29, wherein the sensor adapted to provide at least one ultrafiltration signal is adapted to indicate the weight of liquid withdrawn by ultrafiltration.

31. Apparatus as claimed in any one of claims 18 to 29, wherein the sensor of a parameter determining the course of ultrafiltration is adapted to indicate the pressures of the blood at the inlet and outlet of the haemodialyser.

32. Apparatus as claimed in any one of claims 18 to 29, wherein the sensor adapted to provide at least one ultrafiltration signal is adapted to determine the pressures of the dialysis solution at the inlet and outlet of the haemodialyser.

33. Apparatus as claimed in any one of claims 18 to 29, wherein the sensor adapted to provide at least one ultrafiltration signal is adapted to indicate the rate of flow of the blood in the haemodialyser.

34. Apparatus as claimed in any one of claims 18 to 29, wherein the sensor adapted to provide at least one ultrafiltration signal is adapted to indicate the rate of perfusion which is effected.

35. Apparatus as claimed in claim 28 or any one of claims 29 to 34 when appended to claim 28, wherein the control means is adapted to modify the rate of perfusion.

36. Apparatus as claimed in any one of claims 18 to 29, which further comprises a display console adapted to receive signals representing the variations in weight of the patient and signals representing the said area and adapted to display curves which represent the limits of said area of weight values and the variations in the weight of the patient during the haemodialysis.

37. A haemodialysis apparatus for effecting dialysis of blood by ultrafiltration, substantially as hereinbefore described with reference to the accompanying drawings.

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1580916 COMPLETE SPECIFICATION

3 SHEETS *This drawing is a reproduction of the Original on a reduced scale*

Sheet 1

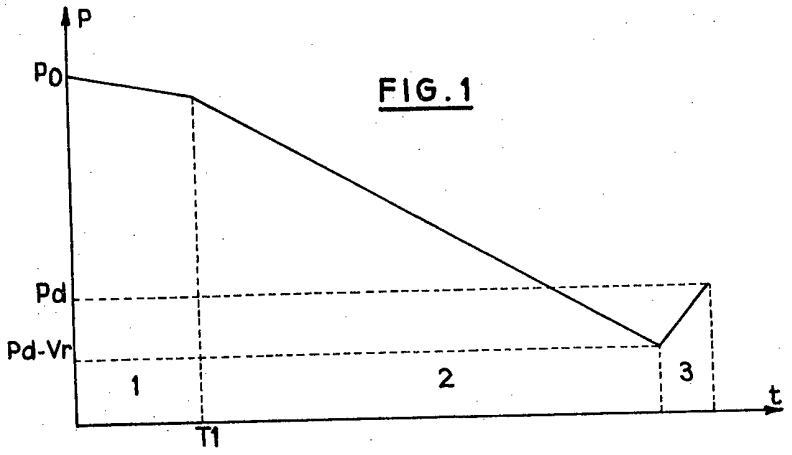

FIG. 1

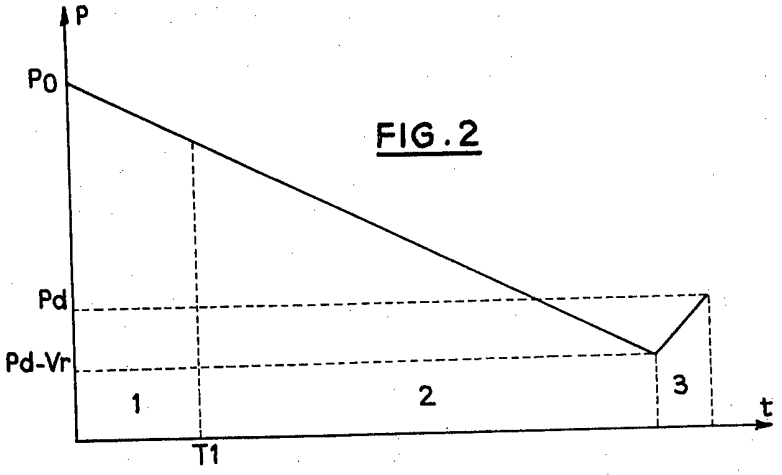

FIG. 2

FIG.3

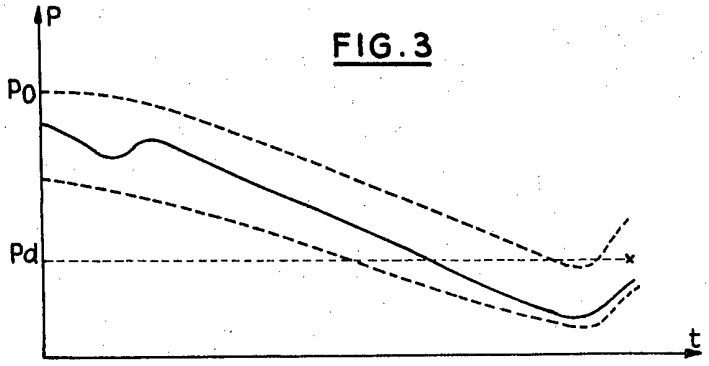

FIG.4

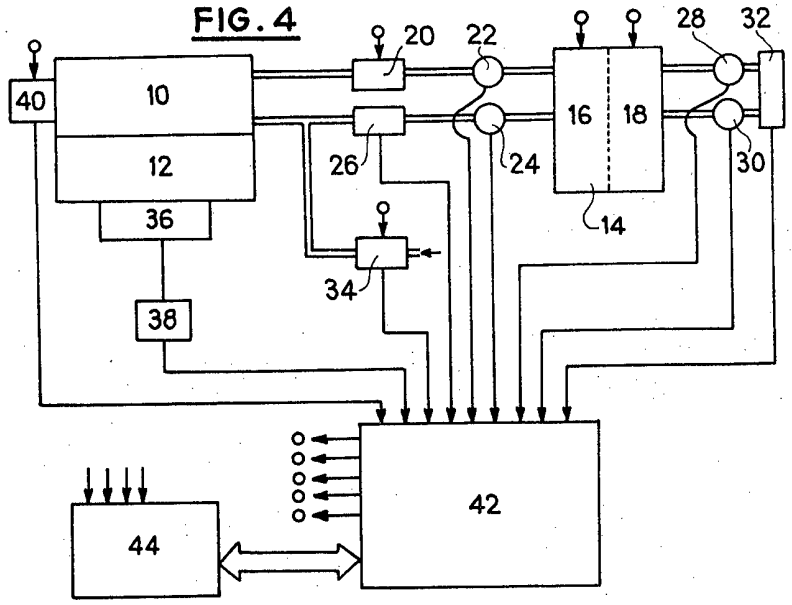

FIG. 5

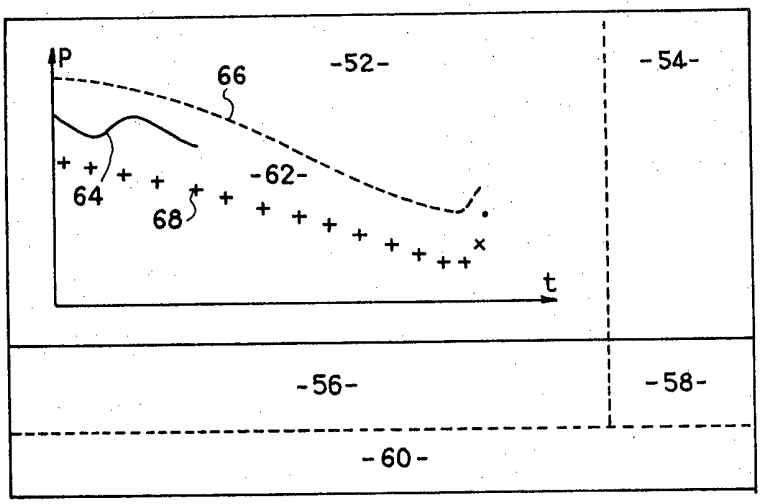

FIG. 6