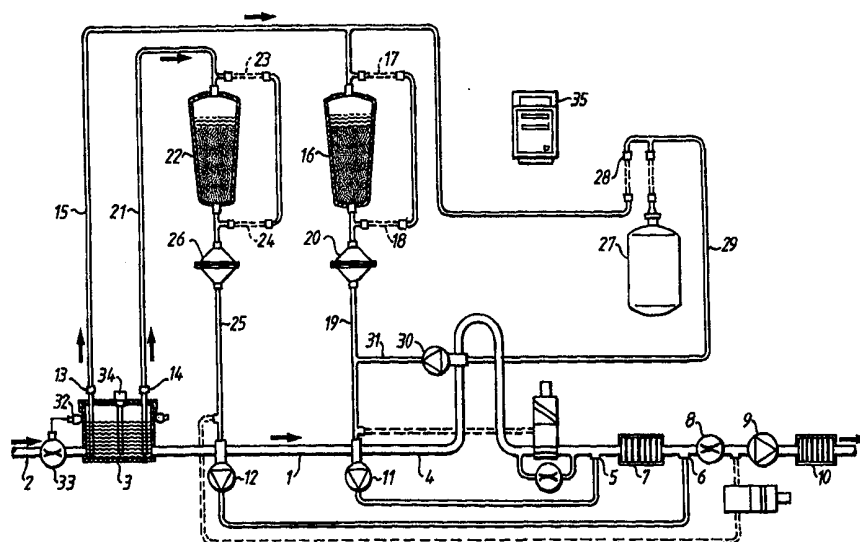


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(54) Title: SAFETY ARRANGEMENT FOR A DIALYSIS MACHINE AND METHOD OF ACTIVATING THE SAFETY ARRANGEMENT

**(57) Abstract**

Safety arrangement for a dialysis machine and method of activating the safety arrangement, comprising a holder with upper (17) and lower (18) holder arms for a sodium chloride cartridge (16). When the sodium chloride cartridge is coupled-in via the holder arms (17, 18), water is supplied via a separate conduit (51) to the upper end of the cartridge and concentrated solution is taken from the lower end of the cartridge via a conduit (19) to a concentrate pump (11). When the dialysis machine is used for preparing a dialysis solution from an A-canister with concentrate in liquid form, an A-rod (13) is used which via a conduit (15) leads to the lower holder arm (18) and via the holder arm to the conduit (19) and the concentrate pump (11). By this arrangement the possibility is avoided of using both a sodium chloride cartridge (16) and an A-canister via the A-rod (13) at the same time.

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TITLE

5 SAFETY ARRANGEMENT FOR A DIALYSIS MACHINE AND METHOD OF
ACTIVATING THE SAFETY ARRANGEMENT

FIELD OF THE INVENTION

10 The invention relates to a holder for a powder cartridge
in a dialysis machine and in particular to safety
considerations in connection with such a holder and the use of
such a powder cartridge. More precisely, the invention relates
to an improved conduit layout in connection with the holder in
15 order to increase safety.

The term "dialysis machine" is intended to cover not only
a machine intended for haemodialysis but also machines for
haemofiltration and for haemodiafiltration, as well as for
peritoneal dialysis.

20

BACKGROUND ART

EP-B1-278 100 describes a dialysis machine of the type to
which the present invention may be applied. This describes a
dialysis machine which includes a preparation unit for dialysis
25 solutions where the preparation occurs on-line starting from
concentrates in liquid and powder form positioned in separate
cartridges or vessels.

A dialysis machine comprises basically two parts, a first
blood part for transport of blood from a patient through an
30 extracorporeal circuit comprising a dialyser, and a second
liquid part for preparing a dialysis solution and transporting
this to the dialyser and further to a drain.

The dialyser comprises a semi-permeable membrane which divides the dialyser into a blood-containing part and a dialysate-containing part. A transport of molecules and substances occurs through the membrane for conditioning the blood, in order to replace the function of the kidney.

The present invention relates to the liquid part of the dialysis machine which prepares the dialysis solution. In this part of the dialysis machine, purified water is supplied from an external source such as an RO-unit and is mixed with concentrate in suitable proportions so that a dialysis solution is prepared. The dialysis solution comprises sodium-, bicarbonate-, potassium-, calcium-, magnesium-, chloride- and acetate ions in suitable concentrations, as well as possibly glucose and other ions, all dissolved in water. The concentrations of the ions in the dialysis solution are generally mirror-images of the concentrations in blood, where the mirror line is the normal concentration in blood of the ions. Thus, if an ion concentration is increased in the blood over the normal concentration, the ion concentration in the dialysis solution is decreased in relation to the normal concentration. The pH of the solution is adjusted to about 7.1-7.4.

With the most common form of treatment occurring today, bicarbonate dialysis, the dialysis solution is prepared by mixing two liquid concentrates into the main flow of water, a B-concentrate comprising substantially bicarbonate and an A-concentrate comprising the remaining components. The B-concentrate can also contain sodium chloride. These concentrates are metered in ratios of between 1:25 and 1:40 depending on the concentration and the desired content of the dialysate, respectively. The metering occurs either volumetrically or by measuring the conductivity and controlling

metering pumps so that the correct conductivity is obtained, i.e. feedback control of the metering pumps.

The reason for the division into A- and B-concentrates is that calcium precipitates to calcium carbonate in the presence of bicarbonate, meaning that these two substances cannot be mixed until immediately before use and then only in low concentrations. Magnesium also causes similar problems.

EP-B1-278 100 describes the use of one or more powder cartridges as a replacement for the aforementioned concentrate. The powder cartridges are coupled into the dialysis machine and water is allowed to pass through the cartridges in order to form substantially saturated solutions of the powder contents at the outlets. These saturated solutions are metered into the main flow of water instead of the above-mentioned concentrates. For a little less than 10 years, there has been a bicarbonate cartridge on the market which is sold under the trademark BiCart[®] by GAMBRO AB, as a replacement for the B-concentrate. The B-concentrate was the concentrate which was the most difficult to handle, since the bicarbonate solution was close to its saturation limit and when storing in cold spaces easily formed precipitates. Additionally, containers were required which were sealed against carbon dioxide, since otherwise decomposition into sodium carbonate occurred with subsequent pH increase.

Now there is also another type of cartridge on the market which contains sodium chloride. This cartridge replaces the larger amount of ions in the A-concentrate. The remaining ions and substances are contained in a little bag of only about half a litre, called an ion bag.

A dialysis machine which is adapted to use these three components must also have the possibility of using the still generally occurring liquid-formed concentrates. For this

purpose there are two hollow rods which are removable and can be fitted into an A-concentrate canister or a B-concentrate canister respectively. The machine then includes sensors which detect if the rods are positioned in the machine or not. Also
5 there are separate holders for the above-mentioned cartridges. If the holders are folded out and contain a cartridge, this condition is detected by sensors.

One problem which arises with dialysis machines of this type, which are intended to be used for a plurality of
10 different types of concentrate, is that it is possible to mix up the rods and to put the rod for the B-concentrate into the A-concentrate canister and vice versa. This error condition is detected by the electronics in the dialysis machine in that the conductivity value which is expected after the mixing-in does
15 not occur. Thus the conductivity for the A-concentrate is significantly higher than the conductivity for the B-concentrate.

Another error case is where the dialysis machine is provided with both cartridges of the powder type and the
20 corresponding rod is put into a container with concentrate. In order to resolve this error condition, the liquid is taken to the bicarbonate cartridge via the rod, to the upper end of the cartridge. If the rod is put into a container with bicarbonate this has no great practical significance, and the only thing
25 that happens is that an additional amount of bicarbonate is dissolved in the cartridge so that the outgoing solution is substantially saturated. Normally the machine detects this in that the rotational speed for the B-metering pump is lower than when using normal B-concentrate. If however A-concentrate comes
30 into a bicarbonate cartridge, gas formation, carbon dioxide, occurs which rapidly results in an alarm condition.

The same or similar conditions exist with the use of a sodium bicarbonate cartridge. If the corresponding A- rod is put into a B-canister, gas formation occurs, carbon dioxide, which rapidly results in an alarm condition.

5 However, the situation is different if the A-rod corresponding to the A-cartridge is put into a concentrate container containing A-concentrate. The A-concentrate contains substantially sodium chloride and in this respect the situation is the same as with bicarbonate. The A-concentrate however also
10 contains magnesium, potassium, calcium, acetic acid and possibly glucose. Magnesium, potassium and calcium are present in only relatively small amounts, so small that they do not have a noticeable effect on the conductivity measurements. If the machine is now adjusted for dialysis with a bicarbonate
15 cartridge, a sodium chloride cartridge and a little bag containing other ions, the machine meters the necessary amount of ions from the little bag, i.e. magnesium, potassium and calcium. This means that the dialysis solution in principle contains double the amount of magnesium, potassium and calcium
20 than was intended. Apart from the fact that this gives rise to incorrect treatment, it can be life-threatening for certain patients. A construction which makes this error condition impossible would be desirable.

25 SUMMARY OF THE INVENTION

A first object of the present invention is to provide a dialysis machine having improved safety.

A second object of the present invention is to arrive at a dialysis machine intended for use of both liquid concentrate as
30 well as at least one powder cartridge for sodium chloride, where it is impossible to unintentionally supply A-concentrate and at the same time use the powder cartridge.

These objects are fulfilled by a safety arrangement for a dialysis machine comprising at least one holder for a container or cartridge containing a substance in powder form. According to the invention, the arrangement comprises a first supply
5 conduit, which leads from a water source to a supply end of the cartridge holder, a delivery conduit for delivering solution from a delivery end of the cartridge holder to a concentrate pump, and a second supply conduit, which is connectable to the delivery end of the cartridge holder and further to the
10 delivery conduit and the concentrate pump.

Preferably, the cartridge holder includes an upper holder arm intended to cooperate with an upper end of the cartridge and a lower holder arm intended to cooperate with the lower end of the cartridge, and in that at least one of the holder arms
15 is manoeuvrable between a first position where it cooperates with said second supply conduit in order to connect the A-rod to the concentrate pump, and a second position where it cooperates with the delivery end of said cartridge. The second holder arm of the cartridge holder cooperates, in a first
20 position, with a flush and disinfection conduit. The dialysis machine may further comprise at least one additional cartridge holder and a holder for an ion bag. Moreover, the supply end of the cartridge holder is constituted by an upper supply arm and said delivery end of the cartridge holder is constituted by a
25 lower delivery arm.

In another aspect of the invention, there is provided a method of activating a safety arrangement for a dialysis machine comprising at least one holder for a cartridge containing a substance in powder form. The invention comprises
30 the steps of: activating a first holder arm for cooperation with the supply end of the cartridge; activating a second holder arm for cooperation with the delivery end of the

cartridge; supplying of substantially water from a water source to the supply end of the cartridge via a separate first supply conduit; and delivering of solution from the delivery end of the cartridge via a delivery conduit to a concentrate pump.

5 Preferably, said second holder arm is folded in for connection with an A-rod for feeding of concentrate via a second supply conduit directly to the delivery conduit and the concentrate pump. The supply end is the upper end of the cartridge and the delivery end is the lower end of the
10 cartridge.

Further problems, objects, features and advantages of the present invention are disclosed below in the detailed description of preferred embodiments of the invention with reference to the drawings.

15

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a schematic diagram of a preparation part for the dialysis solution in a dialysis machine according to the state of the art.

20 Fig. 2 is a schematic diagram similar to Fig. 1 but modified in order to achieve improved safety in accordance with the present invention.

Fig. 3 is a perspective view of a holder for the powder cartridges according to the state of the art, which can be used
25 in the present invention.

DETAILED DESCRIPTION OF THE INVENTION

The invention is described below in more detail with reference to a preferred embodiment intended to be used on the
30 dialysis machine GAMBRO AK 200 which is sold by GAMBRO AB. The principles of the invention can be used on other types of

dialysis machine without modification, this being obvious for a skilled person.

Fig. 1 is a flow diagram of the above-mentioned dialysis machine, where only the part of the machine is shown which is relevant to the present invention, namely the part where the preparation of the dialysis solution occurs.

The dialysis machine is connected via tubes to an outlet for purified water which is normally found in a dialysis clinic. The water normally comes from a RO-unit and is, practically speaking, free of ions and other impurities.

The water enters a main conduit 1 in a dialysis machine according to Fig. 1 via an inlet conduit 2. The inlet conduit 2 opens into a water vessel 3 where the water is heated to the temperature of use, normally about 37°C. During a normal dialysis treatment which continues over four hours, about 120 l of water is used. Thus 1/2 litre of dialysis solution has to be prepared per minute (500 ml/minute). Other speeds of dialysis solution preparation can be used, but the normal range is 300-700 ml/minute.

The heated water from the water vessel 3 passes further through a conduit 4 and reaches a first metering point 5 where a first concentrate is metered into the main flow, normally the A-concentrate. Additionally there is a second metering point 6 where a B-concentrate is metered in. Between the metering locations there is a first conductivity sensor 7. After the second metering point 6 there is a restrictor valve 8, a powerful pump 9 and a second conductivity sensor 10. The inverse metering order can equally be used.

A first metering pump 11 is connected to the first metering point 5 and a second metering pump 12 is connected to the second metering point 6.

In the heating vessel there are two rods 13, 14. These rods pass through holes in the front of the machine and through holes in the water vessel and extend down below the water level in the water vessel 3 as shown in Fig. 1. The rods are removable and the rod 13 is marked with a red colour and is intended to be put into a canister with A-concentrate. The rod 14 is marked with a blue colour and is intended to be put into a canister with B-concentrate.

When the machine is used for preparation of dialysis solution starting from concentrate in powder form, the rods 13 and 14 are positioned in the water vessel as shown in Fig. 1. Additionally, one or two cartridges are arranged in separate cartridge holders. In Fig. 1 the dialysis machine is shown arranged for preparing dialysis solution starting from two powder cartridges and an ion bag.

A conduit 15 extends from the rod 13 and opens into the upper end of a sodium chloride cartridge 16 inserted in a holder 17, 18 which is described in more detail below. The lower end of the sodium chloride cartridge 16 is connected via a conduit 19 to the suction side of the first metering pump 11. The conduit 19 suitably includes a particle filter 20 for preventing powder from passing out of the cartridge 16 and reaching the pump.

In the same way, a conduit 21 leads from the B-rod 14 and opens into the upper end of a bicarbonate cartridge 22 arranged in a second holder 23, 24. From the lower end of the bicarbonate cartridge 22 there is a conduit 25 which leads to the second concentrate pump 12. The conduit 25 preferably contains a particle filter 26.

Finally there is a little bag 27, below referred to as an ion bag, which contains about 1/2 litre of liquid with other components which are not provided via the powder cartridges.

The ion bag 27 is arranged in a third holder 28. A conduit 29 leads from the ion bag and opens into a third concentrate pump 30. The concentrate pump 30 pumps the contents via a conduit 31 which opens into the conduit 19. The degree of concentration in the ion bag is for example 1:400 or at least 1:150.

The function of the dialysis machine according to Fig. 1 is the following.

Water enters via the inlet 2 to the water vessel 3. A level sensor 32 ensures that the water level in the vessel is substantially constant via an inlet valve 33 controlled by the level sensor 32. The water vessel is open to atmosphere. Water passes from the water vessel into the main conduit 1, and via the main conduit 4 to the mixing points 5 and 6 and further through the restrictor arrangement 8 and the pump 9. The water flow is thus controlled by the powerful pump 9 so that the desired amount of dialysis solution is produced, normally 500 ml/minute.

Water passes via the rod 13, which is in the water vessel 3 with its tip lowered into the water, via the conduit 15 to the upper end of the first holder 17, 18. The water enters into the upper end of the sodium chloride cartridge 16 and passes through the sodium chloride powder therein and out via the particle filter 20 to the conduit 19. The conduit 19 thus contains water substantially saturated with sodium chloride. This saturated sodium chloride solution in the pump 19 is pumped via the first metering pump 11 to the first metering point 5 in the main conduit 1, 4. Thereafter the mixture of concentrate and water in the conduit 4 passes to the first conductivity sensor 7 where the conductivity is measured. The conductivity is substantially proportional to the concentration of sodium chloride and the pump 11 is controlled by the conductivity cell 7 so that the desired conductivity is

obtained after the dilution of the sodium chloride, normally about 12 mS/cm.

The control takes place by a control processor comprised in a computer 35 and connected to the respective sensors and actuators. Moreover, the computer 35 comprises a supervisory processor or portion, that supervises the control processor and the dialysis machine operation, as is conventional in the art.

The second rod 14 is similarly put into the water container 3 with the tip positioned in the water. The water thus passes via the rod 14 and the conduit 21 to the upper part of a cartridge 22 with bicarbonate powder, the cartridge 22 being arranged in the second holder. The water passes through the powder and out through the bottom of the cartridge via the filter 26 to the conduit 25. The conduit 25 thus contains water substantially saturated with sodium bicarbonate, which by means of the second concentrate pump is metered into the second metering point 6. By this second metering of substantially saturated sodium bicarbonate, the conductivity in the solution rises from about 12 mS/cm to about 15 mS/cm, which is measured with the second conductivity sensor 10. The increase in conductivity controls the metering pump 12 so that the correct amount of bicarbonate is metered in.

Normally the metering pumps are controlled so that the concentration of bicarbonate ions in the finally prepared dialysis solution is about 35 mmol/l and that of the sodium ions about 140 mmol/l.

In the manner described above, sodium chloride and sodium bicarbonate have been metered into the main conduit, these being the two main ingredients in the dialysis solution, i.e. the substances which are present in the highest concentration.

The remaining ions and substances which are to be included in the final dialysis solution are metered in with a third

metering pump 30. An ion bag 27 is positioned in a third holder 28. The contents in the ion bag 27 is fed out via the holder to the conduit 29 which leads to the third metering pump 30 and via the conduit 31 to the conduit 19. In this way, the solution which reaches the inlet of the first concentrate pump 11 will have about the same composition as the contents in an A-concentrate, although normally with another dilution. In principle it is possible to let the third concentrate pump 30 and its outlet conduit open wherever into the main conduit 1, or even after the metering pump 11. The addition of the conductivity from the contents in the ion bag is relatively small. An example of the contents in the ion bag is described below.

Fig. 3 shows a holder for one of the cartridges 16 and 22. The holder consists of an upper bracket 17, 23 and a lower bracket 18, 24. The brackets are pivotable between a folded-out position, as shown in Fig. 3, where the brackets cooperate with a powder cartridge, and a folded-in position which is shown in dashed lines in Fig. 3, where the brackets cooperate with separately arranged connection tubes 41, 42 arranged on the side surface of the dialysis machine. The connection tubes 41 and 42 may be joined with one another via a conduit 43.

During normal operation water enters through the conduit 15, 21 to the pivotal holder and reaches the upper end of the cartridge holder. Water is supplied with a speed of about 10-20 ml/min, which is controlled by the output metering pump. The water drips down into the upper end of the container and reaches the water level 44 which is shown in Fig. 3. The container is filled with powder or particles consisting of sodium chloride or sodium bicarbonate (or some other substance). The powder level is shown by the dashed line 45. The powder level sinks during the treatment from an upper level

just below the water level 44 until the powder has run out and is near to the bottom surface of the cartridge. The water which is fed into the cartridge thus has to pass through the powder bed 45 in order to reach the outlet 46. The solution thereby becomes saturated, or substantially saturated, when it reaches the outlet 46 and is led further through the conduit 19, 25 to the respective concentrate pump.

When the dialysis machine is adapted for treatment by using liquid concentrates, the brackets 17, 23 and 18, 24 are pivoted inwardly to the positions 47, 48 shown in dashed lines. The water is then led directly from the conduit 15, 21 via the connection tube 41, the conduit 43, the connection tube 42 to the outlet conduit 19, 25. This is shown in Fig. 1 by means of the dashed lines marked 17, 23 and 18, 24. Additionally Fig. 3 shows a position sensor 49 which detects when the brackets 47 and 48 are close to the sensor 49. The sensor 49 can be a magnetic relay which is actuated by small permanent magnets 50, 51 arranged in the brackets so that when the permanent magnets 50, 51 are close to the sensor 49 an electrical contact is made. If both the holder arms 47, 48 are pivoted inwardly the sensor 49 is thus activated. Other forms of sensor can of course be used such as mechanical, electrical etc. The sensor 49 can consist of two discrete sensors which are connected in parallel or in series.

If the dialysis machine according to Fig. 1 is to be used only with liquid concentrates, the holder arms 23, 24 and 17, 18 are thus inwardly pivoted. The rod 13 is placed in an A-concentrate container and the rod 14 is placed in a B-concentrate container. The contents in the containers is sucked via the conduit 15, the holder 17, the holder 18 and the conduit 19 to the pump 11. The contents in the B-concentrate canister is sucked via the rod 14, the conduit 21, the holder

arms 23, 24 and the conduit 25 to the pump 12. In this position of operation the pump 30 is not in motion.

If the dialysis machine is now by mistake applied for dialysis with powder cartridges 16, 22 and an ion bag 27 and
5 then the second (blue-marked) rod 14 is lowered into a concentrate container, there will be no direct difficulties which are not immediately detected by the dialysis machine. Firstly it will be noted that the rods are not positioned in their respective holders. If however this mechanical detection
10 for any reason does not work, the following possible situations will occur.

If the B-rod 14 is placed in an A-concentrate container the conductivity sensor 10 will detect a high conductivity, whereby the pump 12 reduces its speed to the point where it
15 lies outside the set predetermined range. In this condition a rotational speed alarm is given. The reason is that the A-concentrate container contains concentrate with sodium chloride in high concentration which gives a high conductivity. Since the A-concentrate has a low pH-value, a large build-up of
20 carbon dioxide gas will occur in the bicarbonate cartridge which soon leads to an alarm.

If the B-rod 14 by mistake would be put into a B-canister containing sodium bicarbonate solution with a concentration of 840 g/10 l, which is a normal concentration, there will be no
25 great problem. The bicarbonate solution from the canister will of course pass through the cartridge 22, but only receives a minimal addition of bicarbonate so that the outgoing solution will be saturated in the conduit 25, which depending on the temperature can be an extra addition of 10-20%. The mixing of
30 the dialysis solution occurs entirely satisfactorily. It also occurs that the B-canister contains bicarbonate with a concentration of 660 g/10 l, and moreover sodium chloride with

a concentration of about 350 g/10 l. The conductivity for this solution is however so large that the same happens as if the rod 14 is put into an A-canister, i.e. the conductivity sensor 10 detects such a high conductivity that the pump 12 is driven
5 with such a low speed that it lies outside its normal operating range and a rotational speed alarm is given.

When the holders 23, 24 and 17, 18 are open, it is indicated for the dialysis machine that the machine is arranged for preparing a dialysis solution starting from powder
10 cartridges for sodium chloride and sodium bicarbonate as well as an ion bag. For this, it is programmed into the dialysis machine that the conductivity values for the conductivity sensors 7 and 10 are to control the pumps 11, 12 at a predetermined speed in the range of 10-20 ml/min, e.g. 16
15 ml/min for the bicarbonate cartridge. Since the concentration in the conduit 25 can vary somewhat depending on temperatures and other factors, there is an allowable variation range for the pump 12, normally +/- 20%. If the pump goes outside this range, an alarm signal is given. The same is true for the pump
20 11 but with correspondingly different values.

Thus it is clear from the above that no large problems are present concerning the B-rod 14 which leads to the B-concentrate pump 12 and which are not taken care of by the normal safety system of the dialysis machine.

25 If the red A-rod 13 is mistakenly put into a B-concentrate canister the conductivity sensor 7 and the pump 11 will lie outside their predetermined ranges, whereby an alarm signal is given. Moreover, gas formation occurs since the acidic solution from the ion bag meets bicarbonate solution in the conduit 19
30 after the connection to the conduit 31, leading to an alarm situation.

If however the A-rod 13 is put into an A-concentrate canister, the following situation will occur. The A-concentrate contains substantially sodium chloride with a concentration of 200 g/l. Furthermore there is magnesium, potassium and calcium and acetic acid in lower concentrations. When this solution reaches the cartridge 16, additional sodium chloride is added until the solution becomes saturated with sodium chloride. The saturated sodium chloride solution reaches the conduit 19. Also the pump 30 meters in magnesium, potassium and calcium from the ion bag 27 via the conduit 31 to the conduit 19. The conduit thus contains magnesium, potassium and calcium both from the A-canister and from the ion bag 27.

The conductivity sensor 7 thus detects a somewhat higher conductivity than normal and the pump 11 reduces speed slightly. This reduction is however moderate and within the error tolerance of this pump of +/- 10%. The machine thus accepts the obtained solution without giving any alarm signal. However the content of potassium, magnesium and calcium is about 50% higher than originally set, since the contribution from the ion bag 27 consists of 100% and the contribution from the A-concentrate container, depending on its degree of concentration, is up to at least 50%. Such an increase of, in particular, the content of potassium ions can be life-threatening for the patient.

In order to solve this problem it is possible to use ion-selective meters which measure the concentration of potassium, magnesium and/or calcium. Such meters are however expensive and complicated to use.

Since the calcium content is raised, it may be possible to indicate this error since calcium carbonate might precipitates. This however takes a long time and is difficult to measure.

In accordance with the present invention the above problem is solved in the following way. The problem occurs due to the fact that the dialysis machine has to be adapted for using both liquid concentrate for the A-concentrate and a combination of powder-formed and liquid-formed concentrate by means of the powder cartridge 16 and the ion bag 27. Thus there have to be two conduit paths which fulfil this need.

In accordance with the present invention, the conduit 15 from the rod 13 is moved to connect to the lower pivotal arm 18 of the first holder at a connection tube 50 corresponding to tube 42 of Fig. 3. The upper holder arm's 17 connection to the cartridge 16 is joined with a separate conduit 51 to the main conduit 1 or the water vessel 3, as shown in Fig. 2. Due to this coupling, the characteristic is obtained that when the powder cartridge 16 is coupled-in, the water transport occurs through the separate conduit 51 to the upper end of the cartridge 16 and out through the lower end of the cartridge to the conduit 19. Even if the rod 13 is put into a container, there is no transport through the rod 13 since the conduit 15 ends in the connection tube 50, which is open to the atmosphere. When the cartridge 16 is not located in the holder 17, 18 the holder is closed, whereby the connection tube 50 is connected to the conduit 19. If the rod 13 is therefore in an A-canister, the contents is led from the A-canister via the rod 13, the conduit 15, the connection tube 50 and the holder arm 18 to the conduit 19 and the pump 11. In this way the possibility is obtained of using both liquid-formed concentrate and powder cartridges also for the A-concentrate, whereby at the same time the above-mentioned risk of possible incorrect operation is completely removed.

The reason for the present arrangement in respect of the holders and the rod 14 in connection with the bicarbonate

cartridge is that the holders must be able to be disinfected and flushed between treatments. This occurs simply by folding-in of the holder brackets 23, 24 and the use of the short circuiting conduit 43 in the arrangement of Fig. 1. As a result of the different coupling of the holder arms 17, 18 in connection with the sodium chloride cartridge 16 according to the present invention, there is no longer this possibility and a new disinfection construction has to be achieved.

In order to allow flushing of the holder arms 17 and 18, special measures have therefore been taken as shown in Fig. 2. The lower holder arm 18 is flushed automatically via the rod 13, the conduit 15, the holder arm 18, the conduit 19, the pump 11. The upper holder arm is connected via a flush conduit 52 with a connection tube 53, which in turn is connected with the conduit 29 when the ion bag 27 is not in the third holder, as is shown by the dashed line 54. Thus, the upper holder arm 17 of the first holder is flushed by water passing via the conduit 51 to the upper holder arm 17 and from there via the conduit 52 to the connection tube 53 and to the conduit 29 as well as via the pump 30 to the conduit 31. By means of this special arrangement of the flush conduit 52 it is made possible to flush the upper holder arm 17 and the holder 28 at the same time with the aid of the pump 30. The same flow path is used for disinfection.

As an example, the following composition is given for the contents in the ion bag 27 per 500 ml:

KCl about 30g

CaCl₂·2H₂O about 44g

MgCl₂·6H₂O about 20g

Acetic acid about 36g

The above substances are dissolved in water so that the volume is about 500 ml.

The sodium chloride cartridge contains about 1200 g of sodium chloride in powder form. The bicarbonate cartridge 22 contains about 650 g of sodium bicarbonate in powder form.

The contents in the ion bag 27 can be varied within wide
5 limits in order to be adapted to the particular needs of the patient. Since the bag is as small as 1/2 litre, a larger number of different compositions can be stored at the hospital or the dialysis clinic without the storage space becoming too large. In this way, individualised treatment can be carried out
10 more easily. Since sodium chloride and sodium bicarbonate are taken from the powder cartridges under control of the pumps 11 and 12 with the aid of the conductivity sensors 7 and 10, individualisation of the concentration of bicarbonate ions and sodium ions is made possible as well as profiling the
15 concentration of these ions during operation.

A dialysis machine contains many more components than have been described above, such as a number of valves, pumps, sensors and measurement devices. These arrangements are however not described in the present application since they are not
20 required for understanding the invention.

The present invention can also be used in connection with other types of holders for powder cartridges.

The ion bag 27 can for example be replaced by an arrangement as disclosed in EP-B1-443 324, where the contents
25 of the ion bag 27 are prepared on-line.

The invention has been described above with reference to a preferred embodiment of the invention. The various features of the invention can be combined in different ways and be adapted to different types of dialysis machines, as is obvious for a
30 skilled person reading this description. Such modification are intended to be encompassed by the invention. The invention is only limited by the appended claims.

CLAIMS

5

1. Safety arrangement for a dialysis machine comprising at least one holder (17, 18) for a container or cartridge (16) containing a substance in powder form, **characterized** by

10 a first supply conduit (51), which leads from a water source (3) to a supply end (17) of the cartridge holder,

a delivery conduit (19) for delivering solution from a delivery end (18) of the cartridge holder to a concentrate pump (11), and

15 a second supply conduit (15), which is connectable to the delivery end (18) of the cartridge holder and further to the delivery conduit (19) and the concentrate pump (11).

2. Safety arrangement according to claim 1, **characterized** by an A-rod (13) which via the second supply conduit (15) is connectable to the delivery end (18) of the cartridge holder
20 and further to the delivery conduit (19) and the concentrate pump (11).

3. Safety arrangement according to claim 2, **characterized** in that the cartridge holder includes an upper holder arm (17) intended to cooperate with an upper end of the cartridge (16)
25 and a lower holder arm (18) intended to cooperate with the lower end of the cartridge, and in that at least one of the holder arms (17, 18) is manoeuvrable between a first position where it cooperates with said second supply conduit (15) in order to connect the A-rod (13) to the concentrate pump (11),
30 and a second position where it cooperates with the delivery end of said cartridge (16).

4. Safety arrangement according to claim 3, **characterized** in that the second holder arm of the cartridge holder, in a first position, cooperates with a flush and disinfection conduit (52).

5 5. Safety arrangement according to any one of the preceding claims, **characterized** in that the dialysis machine comprises at least one additional cartridge holder (23, 24) and a holder (28) for an ion bag (27).

10 6. Safety arrangement according to any one of the preceding claims, **characterized** in that said supply end of the cartridge holder is constituted by an upper supply arm (17) and said delivery end of the cartridge holder is constituted by a lower delivery arm (18).

15 7. Method of activating a safety arrangement for a dialysis machine comprising at least one holder (17, 18) for a cartridge (16) containing a substance in powder form, **characterized** by

activating a first holder arm (17) for cooperation with a supply end of the cartridge,

20 activating a second holder arm (18) for cooperation with a delivery end of the cartridge,

supplying of substantially water from a water source (3) to the supply end of the cartridge via a separate first supply conduit (51),

25 delivering of solution from the delivery end of the cartridge via a delivery conduit (19) to a concentrate pump (11).

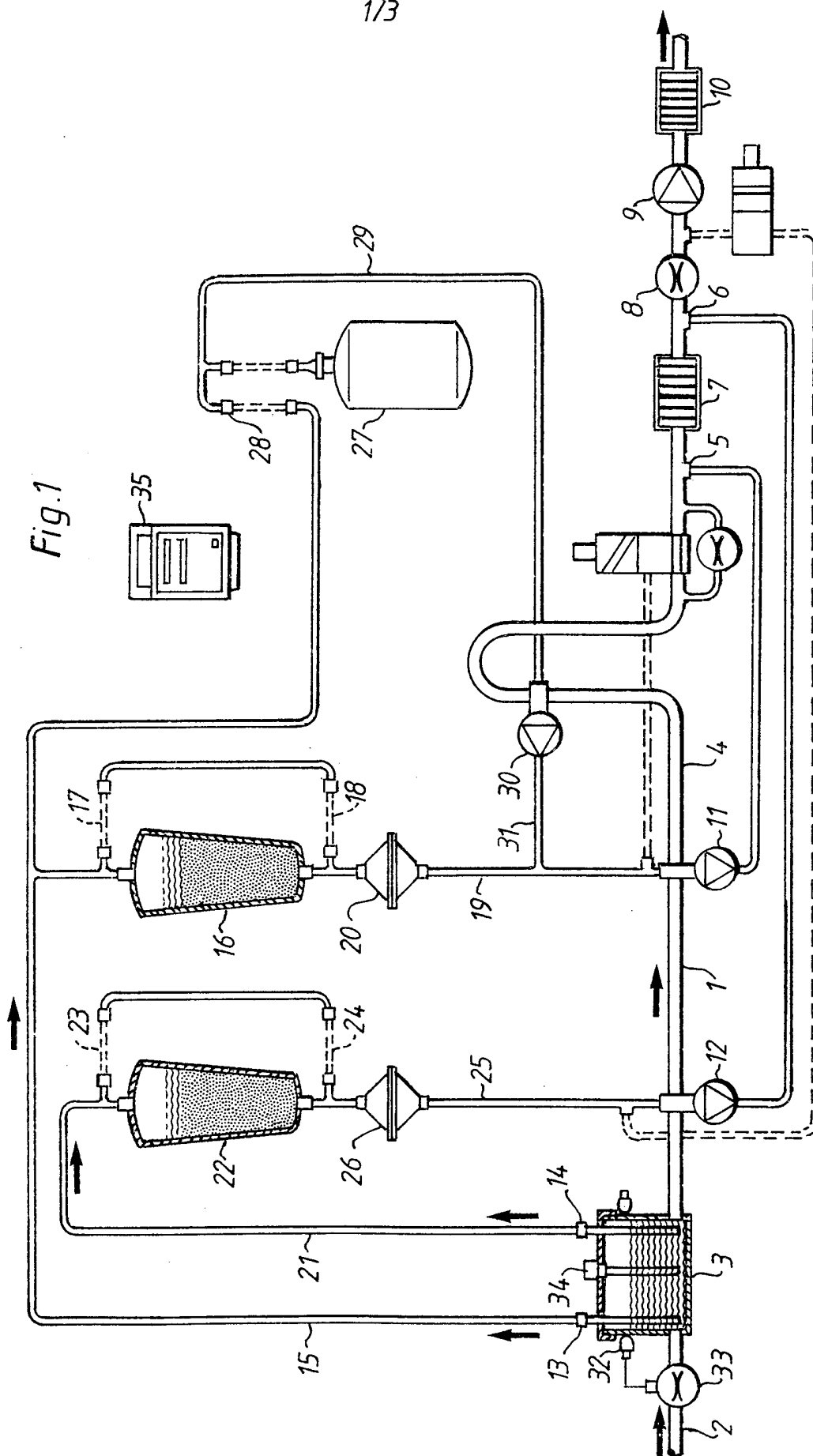
8. Method according to claim 7, **characterized** by

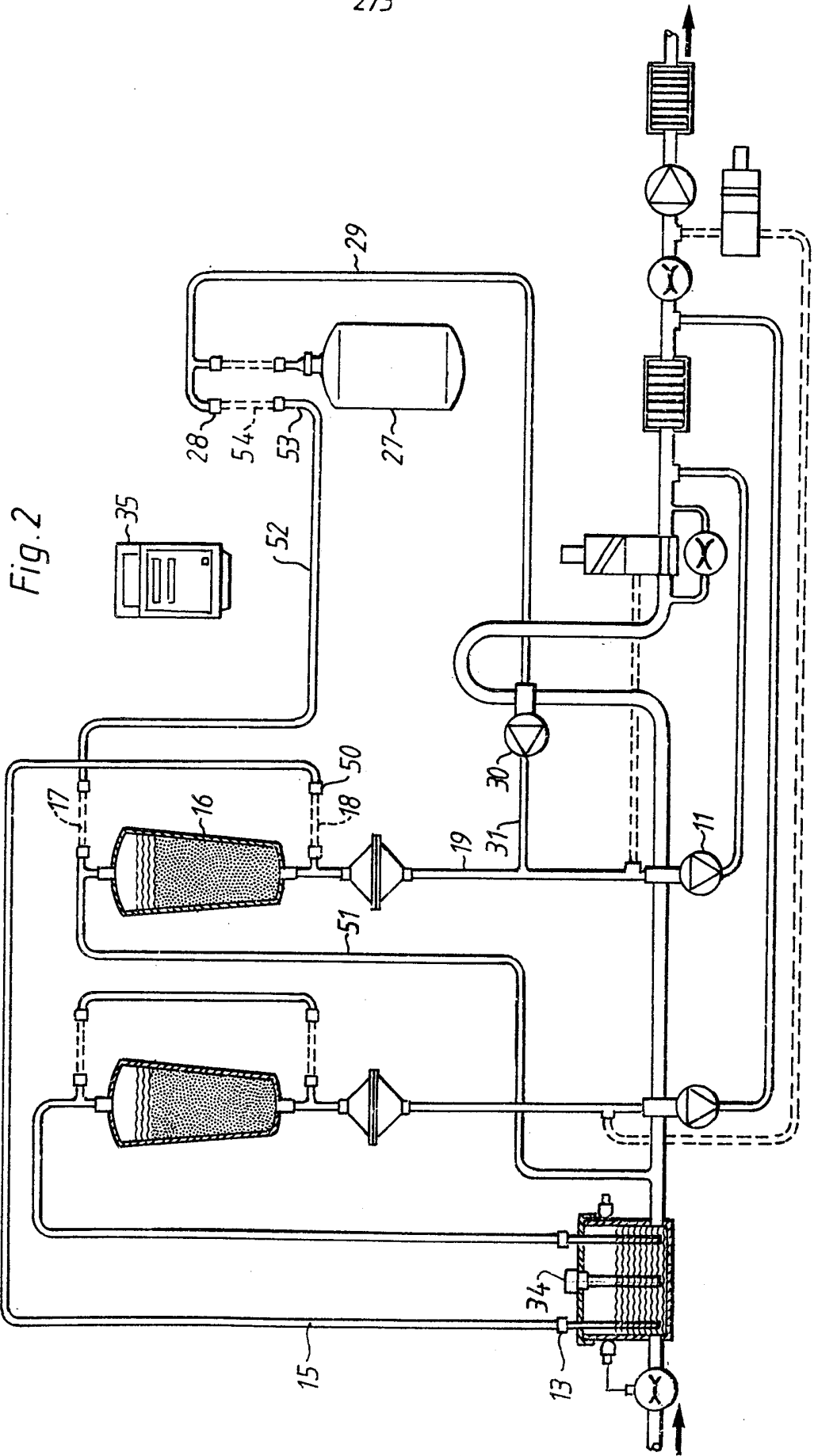
30 folding in said second holder arm (18) for connection with an A-rod (13) for feeding of concentrate via a second supply conduit (15) directly to the delivery conduit (19) and the concentrate pump (11).

9. Method according to claim 7 or 8, **characterized** in that said supply end is the upper end of the cartridge and said delivery end is the lower end of the cartridge.

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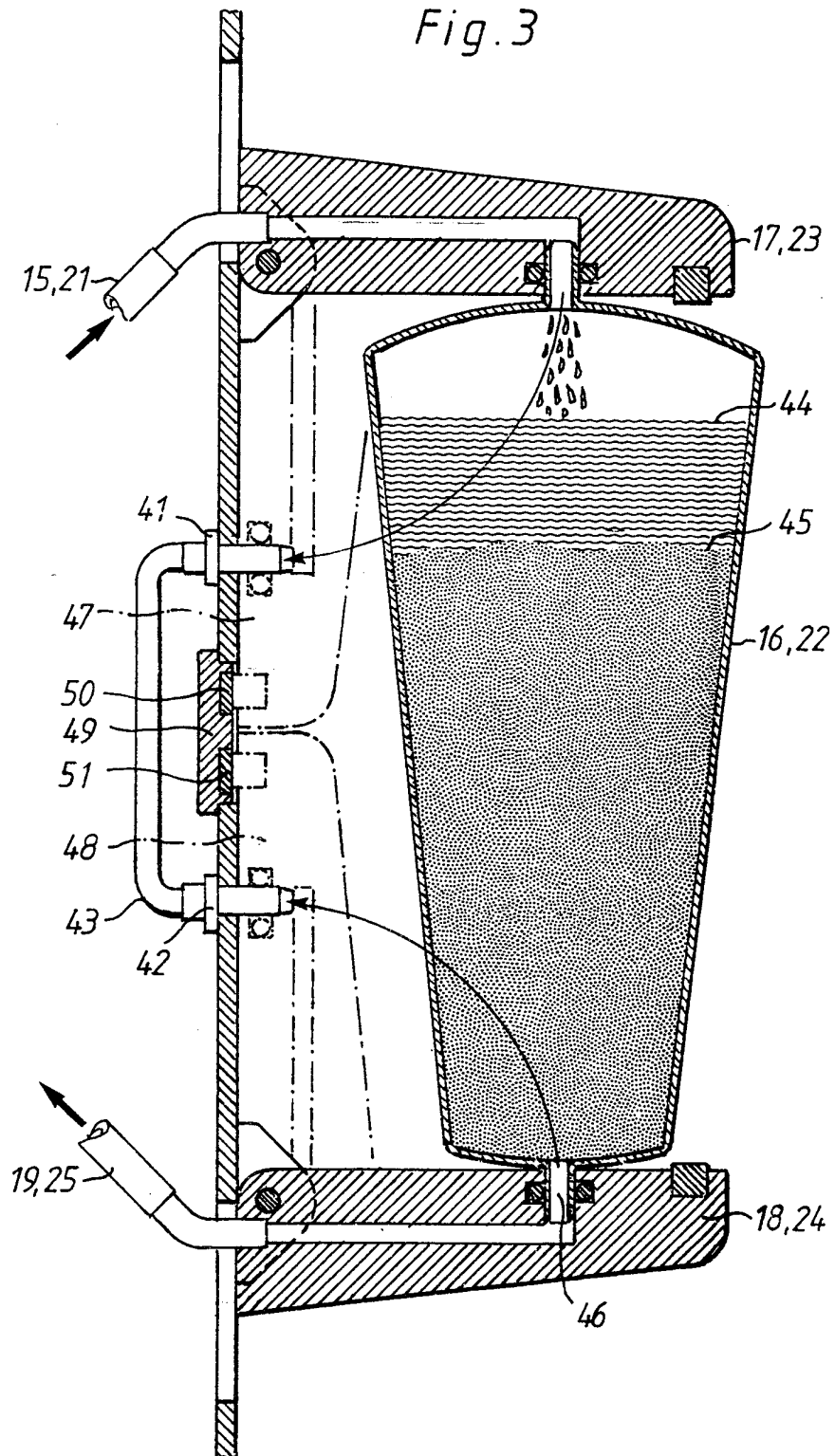
Fig.1





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Fig. 3



INTERNATIONAL SEARCH REPORT

International application No.

PCT/SE 99/00062

A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61M 1/16

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)

IPC6: A61M, B01F

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

SE,DK,FI,NO classes as above

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

WPI

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 9702056 A1 (ALTHIN MEDICAL AB), 23 January 1997 (23.01.97), page 9, line 17 - line 30, figures 10-14	7-9
A	--	1-6
A	WO 9738743 A1 (GAMBRO AB), 23 October 1997 (23.10.97), figure 1, abstract -----	1-9

☐ Further documents are listed in the continuation of Box C.☒ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"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

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INTERNATIONAL SEARCH REPORT

Information on patent family members

02/03/99

International application No.

PCT/SE 99/00062

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		SE 9502397 A	04/01/97

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