OPIC
Office de la propriété intellectuelle du Canada

CIPO
Canadian Intellectual Property Office

(12) (19) (CA) **Demande-Application**

(21) (A1) **2,292,011**

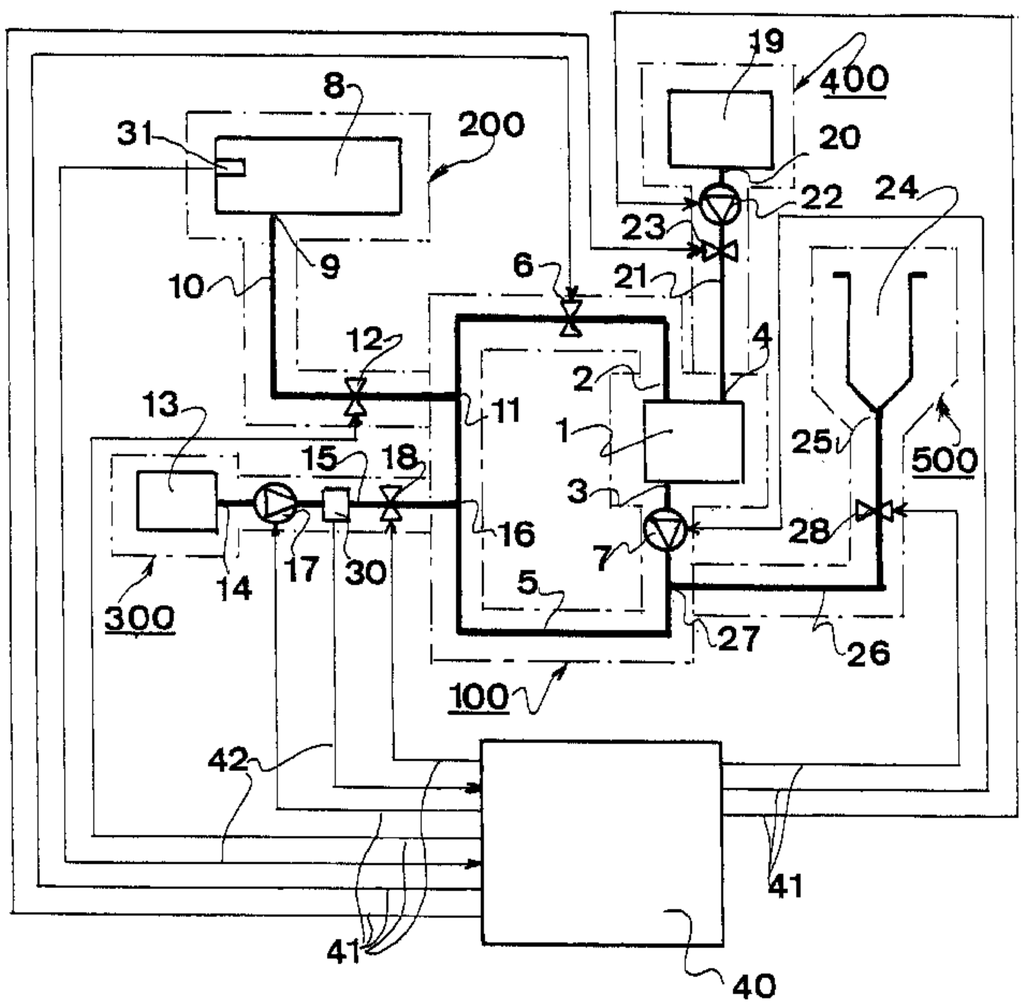
(22) 1999/12/09
(43) 2001/06/09

(72) VINCENT, ERIC, FR
(72) MATHIS, JEAN-FRANÇOIS, FR
(71) A.A.S., FR

(51) Int.Cl.[7] A61M 1/14

(54) **METHODE ET DISPOSITIF PERMETTANT LA PREPARATION D'UNE SOLUTION D'AU MOINS UN PRODUIT EN POUDRE DANS UN LIQUIDE**

(54) **METHOD AND DEVICE WHICH PERMIT THE PREPARATION OF A SOLUTION OF AT LEAST ONE POWDERED PRODUCT IN A LIQUID FLUID**



(57) The present invention relates to methods and devices which permit the preparation of a solution of at least one powdered product in a liquid fluid. The method and the device according to the invention are characterised by the fact that, in a first phase, a specific quantity of powdered product is dissolved in a dissolution volume 13 by means of a dissolution liquid coming from a source 8 in order to obtain an intermediate solution; in a second phase, a specific quantity of the intermediate solution is introduced into a mixture volume 1 by means of a volumetric pump 17, with a given quantity of the liquid fluid via pump 22, in order to obtain a primary mixture of the intermediate solution and of the liquid fluid; in a third phase, the primary mixture is circulated in a loop circuit 100 in order to obtain a final mixture, and in a fourth phase, at least a portion of the final mixture is diverted towards a utilisation volume 24, this diverted portion of the final mixture constituting the solution to be obtained. Application, in particular, to the preparation of solutions for carrying out dialysis.

ABSTRACT

The present invention relates to methods and devices which permit the preparation of a solution of at least one powdered product in a liquid fluid.

The method and the device according to the invention are characterised by the fact that, in a first phase, a specific quantity of powdered product is dissolved in a dissolution volume 13 by means of a dissolution liquid coming from a source 8 in order to obtain an intermediate solution; in a second phase, a specific quantity of the intermediate solution is introduced into a mixture volume 1 by means of a volumetric pump 17, with a given quantity of the liquid fluid via pump 22, in order to obtain a primary mixture of the intermediate solution and of the liquid fluid; in a third phase, the primary mixture is circulated in a loop circuit 100 in order to obtain a final mixture, and in a fourth phase, at least a portion of the final mixture is diverted towards a utilisation volume 24, this diverted portion of the final mixture constituting the solution to be obtained.

Application, in particular, to the preparation of solutions for carrying out dialysis.

FIGURE 1

METHOD AND DEVICE WHICH PERMIT THE PREPARATION OF A SOLUTION OF AT LEAST ONE POWDERED PRODUCT IN A LIQUID FLUID

The present invention relates to methods of preparing a solution of at least one powdered product in a liquid fluid, as well as to devices making it possible to obtain such a solution, which find particularly advantageous application for the preparation of a medical solution for dialysis.

Methods of preparing a solution of at least one powdered product in a liquid fluid are already known, as are devices making it possible to obtain such a solution which find an application, in particular, in the medical field for preparing solutions for dialysis.

However, all the currently known methods and devices of this type do not give entire satisfaction, since either they are very complex and thus have a high cost price, or they are too simple to offer the reliability and the precision which are desirable in the medical field, in particular that of dialysis.

Thus the object of the present invention is to implement a method of preparing a solution of at least one powdered product in a liquid fluid, and to realise a device making it possible to obtain a solution according to the method, finding an advantageous application in the medical field for preparing a solution for dialysis which overcomes the above-mentioned disadvantages of the methods and devices of prior art.

More precisely, the subject matter of the present invention is a method of preparing a solution of at least one powdered product in a liquid fluid, characterised by the fact that it consists in:

- in a first phase, dissolving said powdered product in a dissolution volume by means of a dissolution liquid in order to obtain an intermediate solution,
- in a second phase, sending a specific quantity of the intermediate solution into a mixture volume with a given quantity of the liquid fluid in order to obtain a primary mixture of the intermediate solution and the liquid fluid,
- in a third phase, circulating said mixture in a loop in order to obtain a final mixture, at
- in a fourth phase, diverting at least a portion of the final mixture towards a utilisation volume, this said portion of the final mixture diverted into the utilisation volume constituting the solution to be obtained.

The subject matter of the present invention is also a device making it possible to prepare a solution of at least one powdered product in a liquid fluid, characterised by the fact that it comprises:

- a loop circuit comprising a mixture volume including three first, second and third inlet ports, a first conduit connecting the first and second inlet ports, a first controllable valve connected in series in the first conduit upstream of the first inlet port, and a first volumetric pump connected in series in the first conduit,
- a circuit for supplying dissolution liquid comprising a source capable of delivering dissolution liquid to a first outlet, a second

conduit connecting the first outlet to a first point of the first conduit, this first point being situated between the first controllable valve and the second inlet port, and a second controllable valve connected in series in the second conduit,

- a circuit for supplying powdered product comprising a source of powdered product including a second outlet, a third conduit connecting the second outlet to a second point of the first conduit, this second point being situated between the first controllable valve and the second inlet port, a second volumetric pump and a third controllable valve connected in series on the third conduit,

- a circuit for supply liquid fluid comprising a source capable of delivering the liquid fluid to a third outlet, a fourth conduit connecting the third outlet to the third inlet port of the mixture volume, a third volumetric pump and a fourth controllable valve connected in series in the fourth conduit, and

- a utilisation circuit comprising a sampling volume of the solution to be obtained including a feed inlet, a second conduit connecting a third point of the first conduit to the feed inlet of the sampling volume, this third point being situated between the first controllable valve and the second inlet port, and a fifth controllable valve connected in series in the fifth conduit.

The subject matter of the present invention is also a device making it possible to prepare a solution of a plurality of powdered salts, i.e. calcium, potassium, magnesium and sodium salts, in a liquid fluid such as acetic acid.

Other characteristics and advantages of the present invention will appear in the course of the following description given with regard to the annexed drawings by way of non-restrictive illustration, in which:

Figure 1 represents the functional diagram of a device according to the invention making it possible to prepare a solution of at least one powdered product in a liquid fluid, and

Figure 2 represents the functional diagram of a device according to the invention making it possible to prepare a solution of a plurality of products, such as powdered salts in a liquid fluid such as acetic acid, to be applied to the realisation of a medical solution for dialysis.

Although the two figures represent two different embodiments of a device according to the invention, the same reference numerals on them designate the same elements, whichever figure they appear on.

The Applicant is anxious to state that the two figures represent two examples of embodiment of the object according to the invention, but other embodiments can exist which correspond to the definition of this invention.

The Applicant states furthermore that, when, according to the definition of the invention, the object of the invention comprises "at least one" element having a given function, the embodiment described can include a plurality of these elements.

The Applicant also states that, if the embodiment of the object according the invention as illustrated comprises a plurality of elements of identical function and if, in the description, it is not specified that the object according to this invention must necessarily include a particular number of these elements, it will be possible to define the object of the invention as including "at least one" of these elements.

The present invention relates to a method of preparing a solution of at least one powdered product in a liquid fluid, which method comprises the four following phases.

In a first phase, the powdered product is dissolved in a dissolution volume by means of a dissolution liquid in order to obtain an intermediate solution.

In a second phase, a specific quantity of the intermediate solution is sent into a mixture volume with a given quantity of the liquid fluid in order to obtain a primary mixture of the intermediate solution and the liquid fluid.

In a third phase, the process consists in circulating the primary mixture in a loop in order to obtain a final mixture.

Finally, in a fourth phase, at least a portion of the final mixture is diverted towards a utilisation volume, this portion of the final mixture diverted into the utilisation volume constituting the solution sought for a given use, for example in the medical field for carrying out dialysis.

The method described above is advantageously implemented by means of a device such as the one which is represented schematically on Figure 1.

The device schematically illustrated on Figure 1 comprises a loop circuit 100, a circuit for supplying dissolution liquid 200, a circuit for supplying powdered product 300, a circuit for supplying liquid fluid 400 and a utilisation circuit 500.

The loop circuit 100 comprises a mixture volume 1 including three first 2, second 3 and third 4 inlet ports, a first conduit 5 connecting the first 2 and second 3 inlet ports, a first controllable valve 6 connected in series in the first conduit 5 upstream of the first inlet port 2, and a first volumetric pump 7 connected in series in this first conduit.

The circuit for supplying dissolution liquid 200 comprises a source 8 capable of delivering dissolution liquid to a first outlet 9, a second conduit 10 connecting the first outlet 9 to a first point 11 of the first conduit 5, this first point 11 being situated between the first controllable valve 6 and the second inlet port 3, and a second controllable valve 12 connected in series in the second conduit 10.

The circuit for supplying powdered product 300 comprises a source of powdered product 13 including a second outlet 14, a third conduit 15 connecting the second outlet 14 to a second point 16 of the first conduit 5, this second point 16 being situated

between the first controllable valve 6 and the second inlet port 3, a second volumetric pump 17 and a third controllable valve 18 connected in series on the third conduit 15.

The circuit for supplying liquid fluid 400 comprises a source 19 capable of delivering the liquid fluid to a third outlet 20, a fourth conduit 21 connecting this third outlet to the third inlet port 4 of the mixing volume 1, a third volumetric pump 22 and a fourth controllable valve 23 connected in series in the fourth conduit.

As for the utilisation circuit 500, it comprises a utilisation volume 24 of the solution sought, including a feed inlet port 25, a fifth conduit 26 connecting a third point 27 of the first conduit 5 to the feed inlet port 25 of the sampling volume 24, this third point 27 being situated between the first controllable valve 6 and the second inlet port 3, and a fifth controllable valve 28 connected in series in the fifth conduit 26.

It is made clear that, within the framework of this description, the expression "volumetric pump" refers to any means which make it possible, following a specific control command, to circulate, in a conduit, a quantity of fluid with a perfectly determined flow rate. Moreover, according to the control command, the fluid can be circulated in the conduit in one direction or in the other. A particular value of this control command is even provided so that the volumetric pump prevents the circulation of the fluid at least in one direction.

As for the valves, they can be of any type, for example the stop or sliding type, all controllable by any means, for example with electromagnetic control.

These means are well known per se and, solely in a desire to simplify this description, they will not therefore be described more fully here.

In a preferred embodiment, the device comprises in addition means 30 capable of delivering a first signal, the value of which is representative of the concentration of the product dissolved in the intermediate solution flowing in the third conduit 15. These means 30 comprise, for example, a conductivity sensor, for example an electrical Wheatstone bridge, one of the four branches of which is mounted in conduit 15 in contact with the fluid which can flow there.

For use in automatic mode, the device comprises in addition means 31 for delivering a second signal representative of the temperature of the dissolution liquid, for example a temperature sensor such as a thermistor or similar situated in contact with the dissolution liquid in source 8 or in the second conduit 10.

As mentioned above, the device can function in a quasi-automatic manner. To this end, it comprises a processing unit 40 of the microprocessor type or similar which includes outputs 41 respectively to control the first, second and third volumetric pumps and the first, second, third, fourth and fifth

controllable valves, and inputs 42 to receive and process the first and second signals defined above.

This processing unit 40 is programmed to generate command signals to control the volumetric pumps and the controllable valves according to a specific process as a function of the needs of the users of the solution obtained in the utilisation volume 24, as described below. A person skilled in the art will easily know how to realise the programming of this processing unit 40 depending on the structural description given above and the functional description made below.

The device described above functions and is used in the following manner:

It is first of all assumed that all the controllable valves are in their closed state and that the volumetric pumps are stopped. The dissolution volume 13 contains a specific quantity of powdered product, such as a salt or similar, soluble in the dissolution liquid, such as water, which is capable of being delivered to outlet 9 of source 8.

The control unit 40 can be programmed to realise the following commands:

In the first place, the controllable valves 12 and 18 are open and volumetric pump 17 is actuated to suck up a specific quantity of dissolution liquid, from source 8 into the dissolution volume 13 via conduits 10, 5(in part) and 15.

As soon as all the quantity of powdered product is dissolved, i.e. as soon as the intermediate solution defined above in the method is obtained, controllable valve 12 is closed and controllable valve 6 is opened.

At this moment, volumetric pump 17 is actuated to send, into the mixture volume 1, a specific quantity of this intermediate solution via conduits 15 and 5 (in part).

Then, controllable valve 23 is opened and volumetric pump 22 is actuated to send, into the mixture volume 1, a quantity of liquid fluid determined in correlation with the quantity of intermediate solution which has been sent into this mixture volume by volumetric pump 17, in order to obtain in this mixture volume the primary mixture defined before in the method.

In fact, knowing the concentration Cs of the powdered product dissolved in the intermediate solution and the volume V of the quantity of this solution introduced into the mixture volume, the processing unit 40 determines the real quantity Qr of powdered product present in this mixture volume, according to the relationship Qr = V.Cs. Knowing this quantity Qr of powdered product and the concentration of the liquid fluid delivered to outlet 20, the processing unit 40 will be able to actuate volumetric pump 22 in order to introduce, into the mixture volume 1, a quantity of liquid fluid in correlation with the quantity Qr of powdered product defined above, in order to obtain the desired primary mixture.

When this primary mixture is obtained, all the controllable valves are closed with the exception of valve 6 and volumetric pump 7 is actuated in order to obtain continuous circulation in circuit 100.

Volumetric pump 7 is actuated until the concentration of the mixture in the loop circuit 100 is constant. This concentration can be controlled by a concentration detector placed on conduit 5 at outlet 3 of the mixture volume, as represented in 70 on Figure 2. When the concentration of the mixture is constant, the mixture obtained is the final mixture defined previously.

Controllable valve 28 is then opened and controllable valve 6 is closed, volumetric pump 7 being kept in operation. In this manner, the final mixture circulating in conduit 5 is diverted towards the utilisation volume 24, in order to fill it up by a specific quantity determined according to a control command received by the volumetric pump 7.

When the utilisation volume 24 contains the desired quantity of final mixture, the device is returned to its initial state as defined previously, in order to be able to function again as described above, it being understand that the filling up of the utilisation volume 24 can be carried out several times until the quantity of final mixture contained in the mixture volume 1 is exhausted.

The device described above finds a particularly advantageous application for the preparation of solutions for dialysis. A device more particularly

intended to be used in this application is illustrated schematically on Figure 2.

This device comprises, like the one illustrated on Figure 1, a loop circuit 100, a circuit for supplying dissolution liquid 200, a circuit for supplying powdered product 300, a circuit for supplying liquid fluid 400 and a utilisation circuit 500.

However, in the application defined above, the circuit for supplying dissolution liquid 200 comprises a source 8 capable of delivering, to the first outlet 9, pure water with PH 7.

The circuit for supplying powdered product 300 comprises four primary supply circuits 300/1-4 connected in parallel and all connected to conduit 5, for example at the same point 16 defined previously.

These four primary supply circuits each comprise a dissolution volume 13 each containing a powdered product, respectively a calcium (Ca) salt, a magnesium (Mg) salt, a potassium (K) salt and a sodium (Na) salt.

In a possibility due to the particular nature of the sodium salts, the dissolution volume 13 which is associated with them can be connected, at its upper level, via another second conduit 10', to another outlet 99 of the source 8 of dissolution liquid, in order to be able to introduce water according to a specific process.

In addition, the circuit for supply liquid fluid 400 is a circuit for supplying acetic acid, for example a commercial type termed "at 25%".

In an advantageous manner, the device according to the invention can also comprise means 50 for flushing out at least the five conduits 5, 10, 15, 21, 26. This realisation illustrated on Figure 2 shows the possibilities of flushing out conduits 5, 10, 10, 15, 21, and 26, but also volumes 1 and 24, valves 30 etc. These means of flushing out possibly comprise a buffer volume 51, making it possible, if necessary, to store the residues of the flushing processes and to evacuate them via outlet 52 towards statutory means of elimination.

The device can also comprise means 60 for detecting the minimal safety level of the solution in the utilisation volume 24 so as to be able to control its replenishment again.

CLAIMS

1. Method of preparing a solution of at least one powdered product in a liquid fluid, **characterised by the fact** that it consists in:

- in a first phase, dissolving said powdered product in a dissolution volume (13) by means of a dissolution liquid in order to obtain an intermediate solution,
- in a second phase, sending a specific quantity of the intermediate solution into a mixture volume (1) with a given quantity of the liquid fluid in order to obtain a primary mixture of the intermediate solution and the liquid fluid,
- in a third phase, circulating said mixture in a loop (100) in order to obtain a final mixture, and
- in a fourth phase, diverting at least a portion of the final mixture towards a utilisation volume (24), this said portion of the final mixture diverted into the utilisation volume constituting the solution to be obtained.

2. Device making it possible to prepare a solution of at least one powdered product in a liquid fluid, **characterised by the fact** that it comprises:

* a loop circuit (100) comprising a mixture volume (1) including three first (2), second (3) and third (4) inlet ports,
- a first conduit (5) connecting the first (2) and second (3) inlet ports,
- a first controllable valve (6) connected in series in the first conduit (5) upstream of the first inlet port (2),

- and a first volumetric pump (7) connected in series in the first conduit (5),

* a circuit for supplying dissolution liquid (200) comprising:
- a source (8) capable of delivering dissolution liquid to a first outlet (9),
- a second conduit (10) connecting the first outlet (9) to a first point (11) of the first conduit (5), this first point (11) being situated between the first controllable valve (6) and the second inlet port (3), and
- a second controllable valve (12) connected in series in the second conduit (10),

* a circuit for supplying powdered product (300) comprising:
- a source of powdered product (13) including a second outlet (14),
- a third conduit (15) connecting the second outlet (14) to a second point (16) of the first conduit (5), this second point (16) being situated between the first controllable valve (6) and the second inlet port (3), and
- a second volumetric pump (17) and a third controllable valve (18) connected in series on the third conduit (15),

* a circuit for supplying liquid fluid (400) comprising:
- a source (19) capable of delivering the liquid fluid to a third outlet (20),
- a fourth conduit (21) connecting the third outlet (20) to the third inlet port (4) of the mixture volume (1), and

- a third volumetric pump (22) and a fourth controllable valve (23) connected in series in the fourth conduit,

and

* a utilisation circuit (500) comprising:
- a utilisation volume (24) capable of containing the solution to be obtained, including one feed inlet port (25),
- a fifth conduit (26) connecting a third point (27) of the first conduit (5) to the feed inlet (25) of the utilisation volume, this third point (27) being situated between the first controllable valve (6) and the second inlet port (3), and
- a fifth controllable valve (28) connected in series in the fifth conduit (26).

3. Device according to claim 2, **characterised by the fact that** it comprises in addition means (30) capable of delivering a first signal representative of the concentration of the product dissolved in the solution flowing in the third conduit (15).

4. Device according to claim 3, **characterised by the fact that** the means (30) capable of delivering a first signal representative of the concentration of the product dissolved in the solution flowing in the third conduit (15) comprise at least one conductivity sensor.

5. Device according to one of claims 2 to 4, **characterised by the fact that** it comprises means (31) for delivering a second signal representative of the temperature of the dissolution liquid.

6. Device according to claims 4 and 5, **characterised by the fact that** it comprises a processing unit (40) including outputs (41) respectively to control first (7), second (17) and third (22) volumetric pumps and first (6), second (12), third (18), fourth (23) and fifth (28) controllable valves and inputs (42) for receiving and processing the first and second signals, said processing unit (40) being capable of generating command signals to control according to a specific process said volumetric pumps and controllable valves in order to prepare the said solution.

7. Device according to one of claims 2 to 6, **characterised by the fact that** it comprises means (50) for flushing out at least the five conduits (5,10,15,21,26).

8. Device according to one of claims 2 to 7, **characterised by the fact that** it comprises in addition means (60) for detecting a fluid level in the utilisation volume (24).

9. Device according to one of claims 2 to 8, **characterised by the fact that** it comprises in addition means (70) for determining the concentration of the solution flowing in the first conduit (5).

10. Device making it possible to prepare a medical solution for dialysis, **characterised by the fact that** it includes:

* a loop circuit (100) comprising:

- a mixture volume (1) including three first (2), second (3) and third (4) inlet ports,
- a first conduit (5) connecting the first (2) and second (3) inlet ports,
- a first controllable valve (6) connected in series in the first conduit (5) upstream of the first inlet port (2),
- and a first volumetric pump (7) connected in series in the first conduit (5),

* a circuit for supplying dissolution liquid (200) comprising:
- a source (8) capable of delivering water to a first outlet (9),
- a second conduit (10) connecting the first outlet (9) to a first point (11) of the first conduit (5), this first point (11) being situated between the first controllable valve (6) and the second inlet port (3),
- and a second controllable valve (12) connected in series in the second conduit (10),

* circuits for supplying four powdered products (300), respectively a calcium salt, a magnesium salt, a potassium salt and a sodium salt, each supply circuit comprising:
- a source of one of the four powdered products (13), said source including a second outlet (14),
- a third conduit (15) connecting the second outlet (14) to a second point (16) of the first conduit (5), this second point (16) being situated between the first controllable valve (6) and the second inlet port (3), and

- a second volumetric pump (17) and a third controllable valve (18) connected in series on the third conduit (15),

* a circuit for supplying acetic acid (400) comprising:
- a source (19) capable of delivering acetic acid to a third outlet (20),
- a fourth conduit (21) connecting the third outlet (20) to the third inlet port (4) of the mixture volume (1), and
- a third volumetric pump (22) and a fourth controllable valve (23) connected in series in the fourth conduit (21), and

* a utilisation circuit (500) comprising:
- a utilisation volume (24) capable of containing the solution for dialysis, including a feed inlet (25),
- a fifth conduit (26) connecting a third point (27) of the first conduit (5) to the feed inlet (25) of the utilisation volume (24), this third point (27) being situated between the first controllable valve (6) and the second inlet port (3), and
- a fifth controllable valve (28) connected in series in the fifth conduit (26).

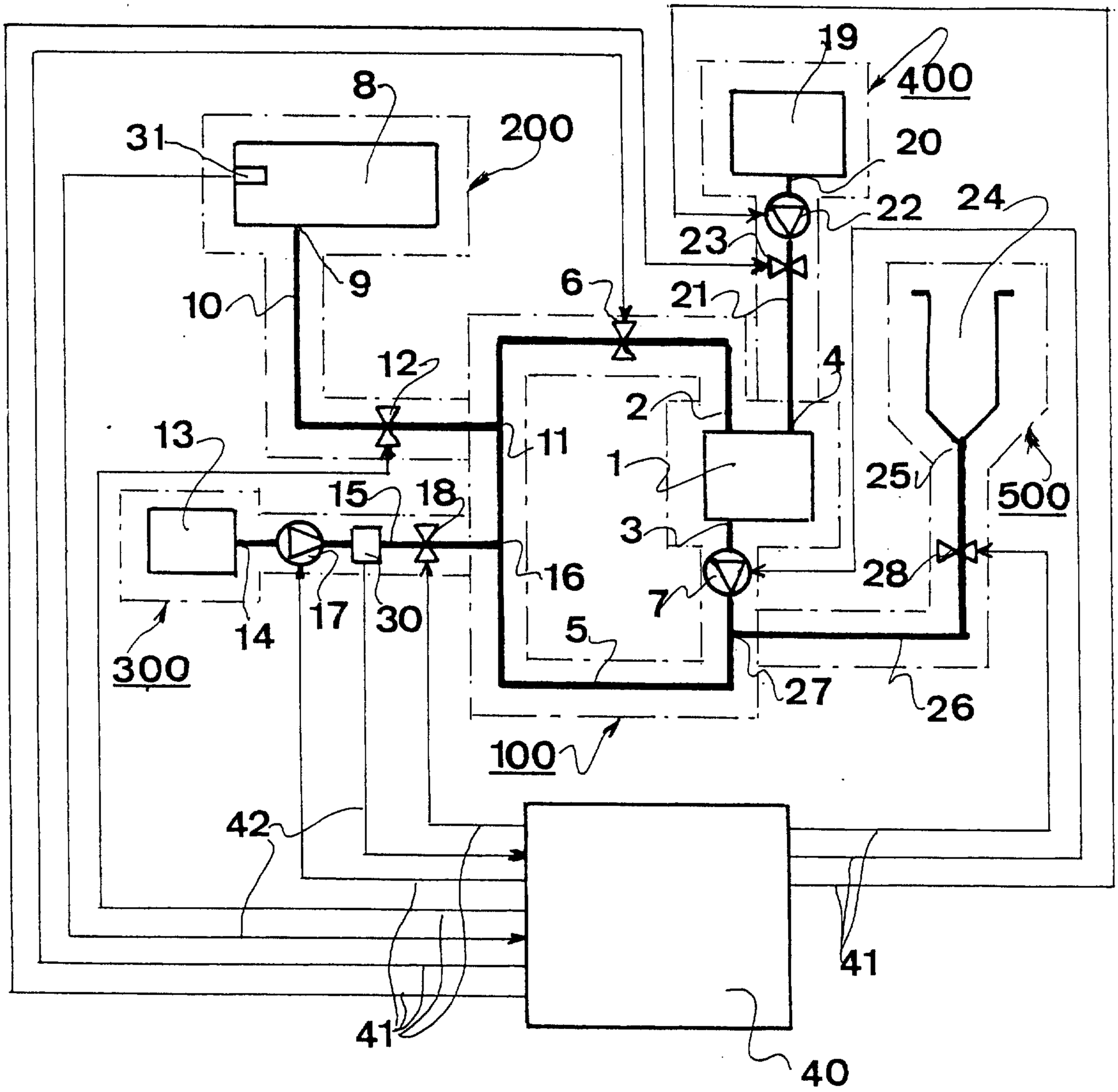

19
400
8
200
31
20
22
24
23
9
6
21
10
12
4
2
13
11
1
25
500
15
18
3
16
28
7
14
17
30
5
27
26
300
100
42
41
41
40

fig.1

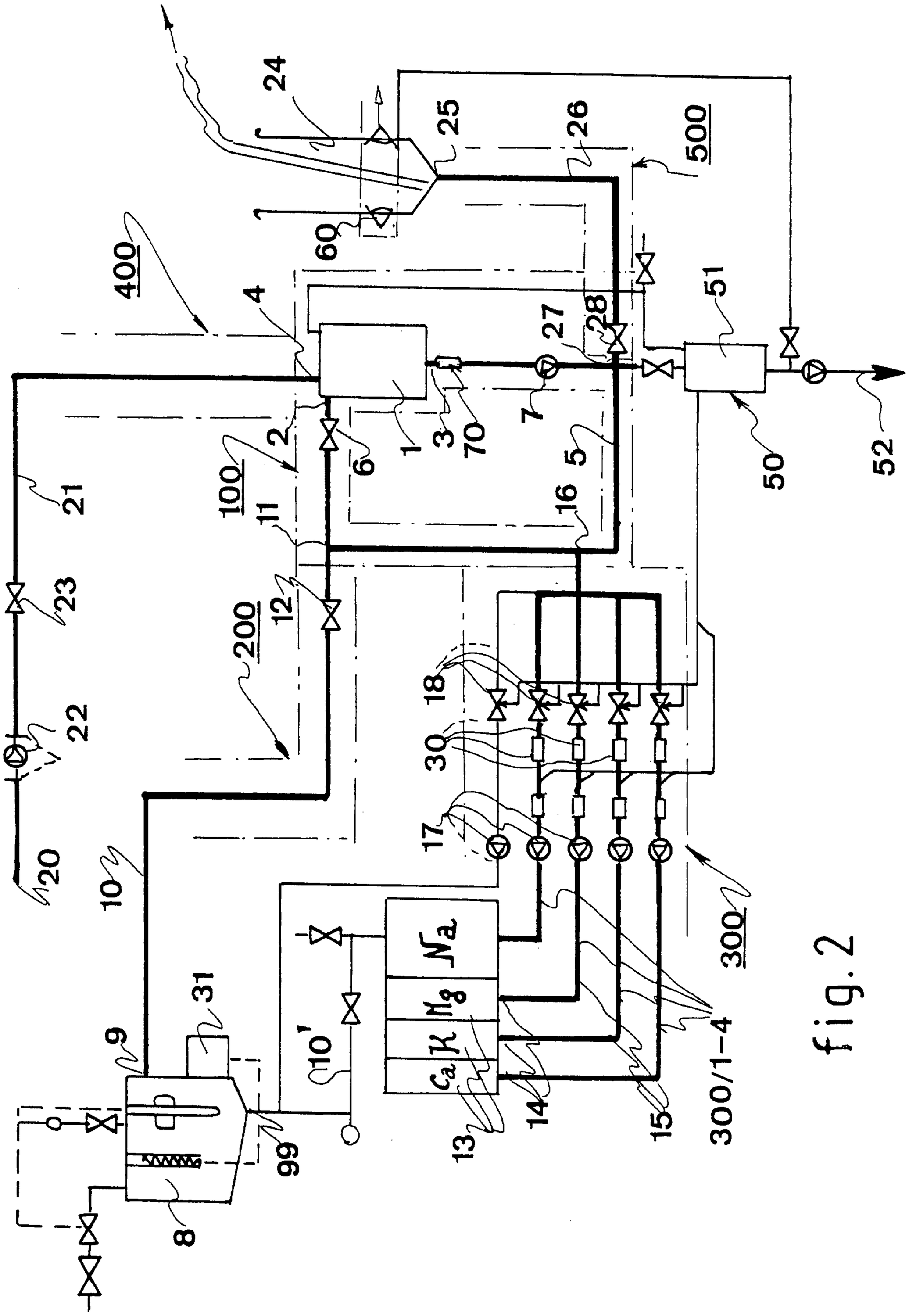
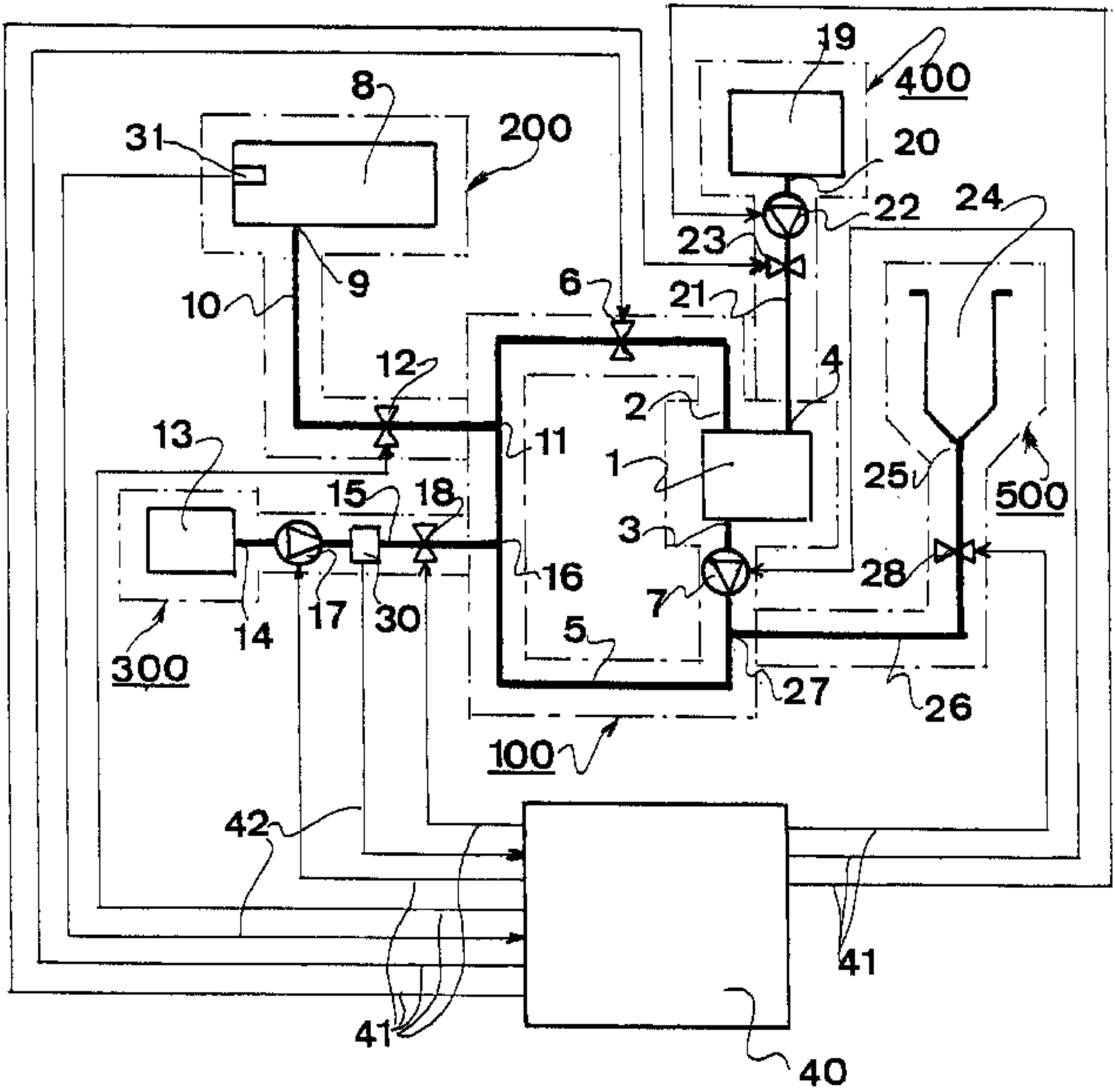

24
25
26
500
60
400
4
27
28
51
7
2
6
1
3
70
5
50
52
21
100
11
16
23
22
200
12
18
30
20
10
17
Na
Mg
Ca
K
31
9
10'
99
8
300
13
14
15
300/1-4

fig. 2


19
400
8
200
31
20
22
24
23
9
6
21
10
12
4
2
13
11
1
25
500
15
18
3
16
28
7
14
17
30
5
27
26
300
100
42
41
41
40