(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
27 September 2012 (27.09.2012)

WIPO | PCT

(10) International Publication Number
WO 2012/127513 A1

(51) International Patent Classification:
A61M 1/14 (2006.01) *A61M 39/22* (2006.01)

(21) International Application Number:
PCT/IT2011/000093

(22) International Filing Date:
24 March 2011 (24.03.2011)

(25) Filing Language: Italian

(26) Publication Language: English

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(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PE, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

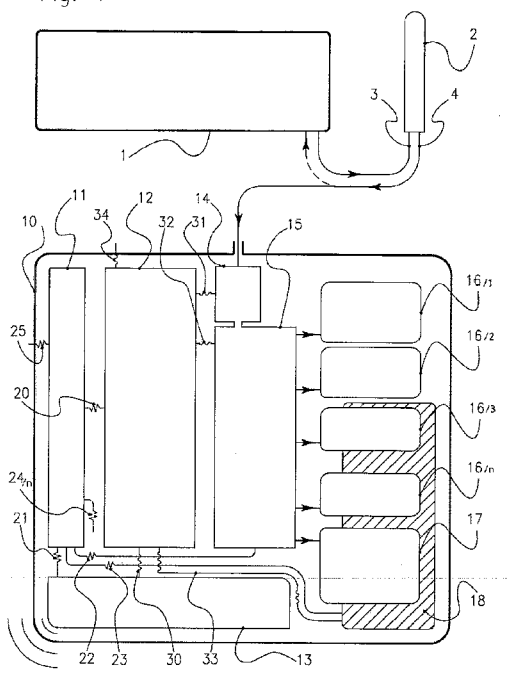
Declarations under Rule 4.17:

— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*

[Continued on next page]

(54) Title: DEVICE FOR MANAGEMENT AND SAMPLING OF DIALYSIS FLUIDS FOR USE WITH SYSTEMS OF THE CGMS TYPE (CONTINUOUS GLUCOSE MONITORING SYSTEMS) AND THE LIKE

Fig. 1



(57) Abstract: Device for management and sampling of dialysis fluids, for use with systems of the. CGMS type (Continuous Glucose Monitoring Systems) and the like, capable of complete management of operations relating to the management of dialysis collection and/or return fluids either in "multi-task" (or "multi-collector") mode or in "multi-day" mode so that it can adapt to all the various requirements for sampling and analysis both in a hospital setting and in the context of laboratory operations.

WO 2012/127513 A1

Published:

— *with international search report (Art. 21(3))*

DEVICE FOR MANAGEMENT AND SAMPLING OF DIALYSIS FLUIDS FOR USE WITH SYSTEMS OF THE CGMS TYPE (CONTINUOUS GLUCOSE MONITORING SYSTEMS) AND THE LIKE

Field of the invention

The present invention relates to the field of multi-task and multi-day programming and management of spent dialysis fluids, for use in CGMS systems (Continuous Glucose Monitoring Systems) and/or in systems of a similar type that envisage transducers for measuring the concentration of specific molecules (among which we may mention, for purposes of illustration and non-exhaustively: lactate, pyruvate, cortisol, calcium, magnesium etc.) for use in therapy and/or in intensive care.

Prior art

In existing CGMS systems, used for example for multi-day monitoring and control of glucose in patients with diabetes both of type 1 and of type 2, there is an opportunity for diverting and collecting the fluids taken and/or recycled in dialysis for use in subsequent laboratory analyses for identifying various analytes (for example lactate and pyruvate etc.), hormones (for example cortisol, glucagon etc.) and ions (for example magnesium, calcium, potassium etc.). This possibility of using dialysis fluids is particularly interesting with regard to hospital patients in intensive care, for whom dialysis tubes are generally inserted in veins. The aforementioned activity of dialysis sampling is usually programmed, timed and executed manually, and exclusively on hospitalized patients.

Also in laboratories for basic medical research that utilize both subcutaneous and venous dialysis tubes implanted in guinea pigs, systems are used that collect spent fluids (which can then be treated using measuring transducers for finding the concentration of specific molecules or hormones), fractionable in various amounts and at various limited times and attributable to physiological phenomena of various kinds, both natural (such as wakefulness, sleep, muscular activity etc.) and induced (such as feeding, administration of drugs etc.)

These systems, which envisage the use of dialysis for a limited time, are normally operated manually or controlled by standard or standardizable management programs.

Recently, especially in the area of intensive care, there has been further extension of the use of both subcutaneous and venous probes that envisage the use of measuring systems with multi-day management programs for the real-time analysis of specific analytes, such as in the case of CGMS systems for determination of glycaemia; the dialysis recovery received from a CGMS system can in fact be used advantageously for preparing samples for subsequent laboratory analysis.

Based on the requirements in the area of research and in the hospital context, a new generation of CGMS systems has recently been developed, equipped with systems for remote communication – based for example on the Bluetooth communication protocol – capable of transmitting and/or receiving data acquired and/or processed by the microprocessors of their management system.

In view of the foregoing, the purpose of the present invention is to introduce a device for automating the management of dialysis collection and/or return fluids received from systems of the CGMS type.

The device according to the present invention, preferably comprising a microprocessor-based electronic control unit, is capable of completely managing the operations relating to the aforementioned management of dialysis collection and/or return fluids and can advantageously be programmed so as to operate in "multi-task" (or "multi-collector") and "multi-day" mode for adapting to all the various requirements for sampling and analysis both in the hospital setting and in the context of laboratory operations.

The innovative characteristics introduced by the present invention include, among others:

- minimizing the time delay between sampling and separation of the samples achieved by the use of an internal hydraulic circuit for sorting of the dialysis collection and/or return fluids received from the CGMS system of minimum

length;

- optimized management of sorting of the dialysis collection and/or return fluids received from the CGMS system and storage thereof in one or more collecting units;
- communication, through a bidirectional interface, with external management and control systems with the possibility of altering the internal programming;
- processing of the data received from said external systems and the possibility of requesting adjustment thereof to the processes under development;
- management of hybrid systems for processing external data, such as sampling timetables, volumes of the various samples, multiple reading barcodes for sample identification;
- storage of multi-day programs for dialysis collection and/or return received from the CGMS system;
- management of programs for periodical maintenance and automatic cleaning of the hydraulic system.

Brief description of the drawings

Fig. 1 shows a functional block diagram of the device according to the present invention.

Fig. 2 shows a first preferred embodiment of the blocks: hydraulic actuator (15), flow transducer (14) and respective connections to said collection modules (16/1-16/n) and discharge unit (17).

Fig. 3 shows possible timing profiles for controlling the microvalves of the electrically-operated hydraulic actuator (15) of the device according to the present invention.

Fig. 4 shows a second preferred embodiment of the blocks: hydraulic actuator (15), flow transducer (14) and respective connections to said collection modules (16/1-16/n) and discharge unit (17).

Summary of the invention

The device for management and sampling of dialysis fluids for use with systems of the CGMS type (Continuous Glucose Monitoring Systems) and the like according to the present invention can provide complete management of operations relating to the management of dialysis collection and/or return fluids and can advantageously be programmed to operate in "multi-task" (or "multi-collector") and "multi-day" mode so as to be able to adapt to all the various requirements for sampling and analysis both in the hospital setting and in the context of laboratory operations.

Detailed description of the invention

Referring to the appended Fig. 1, the device for management of dialysis fluids for use with CGMS systems and the like according to the present invention comprises: a sampling device (10) that can be interfaced with a CGMS system or the like (1) by means of return fluid line (4) to the discharge bag of dialysis tube (2) of said CGMS system (1); an electronic control module (12) for controlling the operations of said sampling device; a wireless bidirectional communication module (13) able to manage the flow of input/output data according to the required protocol; a flow transducer (14) able to supply an electrical signal proportional to the flow rate of the collection and/or return dialysis fluid arriving from the connected CGSM; an electrically-operated hydraulic actuator (15) for controlling the flow of the separate dialysis collection and/or return fluids to the individual outlet tubes; a refrigeration and/or conditioning module (18) able to regulate the temperature of the optional separate fractions, subject to biological alteration of a thermal origin; at least one collecting module (16/1-16/n) for receiving the separated dialysis collection and/or return fluids; a discharge unit (17) for receiving the dialysis collection and/or return fluids that have not been separated, and a power module (11) able to supply the required electric currents and voltages to said modules of said sampling device (10).

In detail, said electrically-operated hydraulic actuator (15) preferably comprises a plurality of microvalves (50, 51/1–51/n, 52) for managing the sampling of said dialysis collection and/or return fluids, separating them and sending them to the individual outlet tubes based on suitable operating signals, as shown for example in the appended Figs. 3a and 3b.

In more detail, said power module (11) is of the independent, autonomous type and comprises batteries of the replaceable or rechargeable type. It can moreover be equipped with a battery charging unit with possibility of connection to the mains by a suitable isolating transformer. Still referring to the appended Fig. 1, said power module comprises suitable electrical connections to said control module (12) (20), to said module for bidirectional communication (13) (21), to said electrically-operated hydraulic actuator (15) (22) and to said refrigeration and/or conditioning module (18) (23).

Said electronic control unit (12) is preferably provided with a microprocessor of sufficient size for management of software, resident or receivable from the outside via said bidirectional communication unit (13), capable of real-time operation, and of executing – for example – the following functions: management of units for calculating and processing data detectable by the internal functions of said sampling system; management and processing of the data received from units external to said sampling system such as systems of the CGMS type (1); storage and management in simple or combinatorial mode of the data received from the flow transducer (14); production of multi-day and multi-collection / multi-separation (multi-task) combinatorial programs for management of spent dialysis fluids; storage and management, in simple or combinatorial mode, of the combining of recognition data (typologically identifiable as barcodes or similar systems normally employed in the clinic/hospital setting and/or in the clinic/laboratory setting) with said collection modules (16/1,...16/n); management, storage and processing of data received from systems of measuring transducers (60) usable in said sampling system (10).

Said bidirectional communication unit (13) can be equipped, as a non-limiting example for purposes of illustration, with communication equipment of the wireless Bluetooth and/or RF type (WiFi or similar), or alternatively with equipment of the optical IR type or similar.

The appended Fig. 2 shows in more detail a first preferred embodiment of the following blocks: the electrically-operated hydraulic actuator (15), the flow transducer (14) and the connections to said collection modules (16/1-16/n) and said discharge

unit (17). Typically, the return fluid line (4), received from the dialysis tube (2), has one end (4a) provided with a connector for connection to the discharge system of the CGMS system. The sampling device according to the present invention is equipped with a fluid intake (40) connected to said flow transducer (14) and compatible with the terminal connector (4a) of said dialysis tube (2). Said electrically-operated hydraulic actuator (15) preferably comprises a miniature three-way solenoid valve (50) provided with two outlets, one normally open connected to a first fluid line (42) that supplies said discharge unit (17), by means of a connection preferably of the Luer lock type (43, 17/a), and the other normally closed connected to a second fluid line (44). In a further preferred embodiment of the present invention, said miniature solenoid valve (50) can be replaced with a pair of two-way micro-solenoid valves actuated alternately in opposite conditions of opening, inserted before the fluid line (44) (not shown in the drawing) which supply a plurality of microvalves (51/1- 51/n and 52), downstream of which the containers for collection (16/1- 16/n) of the fractions of collected analyte are connected.

The appended Fig. 4 shows a second preferred embodiment of the aforementioned blocks: hydraulic actuator (15), flow transducer (14) and connections to said collection modules (16/1-16/n) and discharge unit (17). In this second preferred embodiment, which is provided for allowing continuous measurement of the concentration of another specific molecule, a measuring transducer (60), enzymatic or of some other type, is used, which is capable of carrying out the real-time determination of another analyte, and is connected to said first fluid line (42) via a micropump (61) and a microvalve (62). Another microvalve (63) is inserted in said first fluid line (42), immediately before the discharge connector (43).

The operation of the device according to the present invention is as follows:
As described previously, said device can be interfaced with the dialysis tube (2) of the measuring unit, for example of the CGMS type or similar, by means of the connection of the return fluid line (4), received from dialysis tube (2) to the fluid feed inlet (40) of the sampling device (10). This connection, for purposes of illustration and non-

exhaustively, can envisage the use of a connector of the Luer lock type, to be provided depending on the type of probe used by the CGMS system.

Said fluid feed inlet (40) is connected to the flow transducer (14), which is able to supply, as output, an electrical signal proportional to the measured instantaneous flow rate, which in the field of application of the present invention is between 0.3 µl/min and 10 µl/min. Said signal is sent, via a suitable electrical connection (31), to the internal microprocessor of said electronic control unit (12).

Downstream of the flow transducer (14), and connected to it by a hydraulic connector, there is said electrically-operated hydraulic actuator (15), which comprises a miniature three-way solenoid valve (50) (for example similar to the model LHDA1211111H 3-way valve from LEE Co. - Westbrook - CN USA), preferably installed on a multifunctional support (manifold) (41) provided with two outlets, one normally open (N.O. port) and one normally closed (N.C. port), which supply fluid tube (42) and fluid tube (44) respectively.

Fluid tube (42) supplies in its turn the discharge container (17) – which can be in the form of an ampoule, a bag etc. - to which it is connected by means of, for example, a connector of the Luer lock type; male (43) and female (17/a).

For its part, fluid tube (44) supplies various branch connectors to said containers (16/1.....16/n) for differential collection and separation of the spent dialysis fluids. Each branch is provided with a microvalve (51/1- 51/n) preferably of the two-way type (for example similar to the model Type1 from Bartels Microtechnik GmbH – Dortmund, Germany).

Said fluid tube (44) additionally supplies, after the aforementioned branches, another two-way microvalve (52) operated by a logic control element, the state of which is a function of the state of closure of the microvalves (51/1- 51/n). Said microvalve connects fluid line (44) to line (45), connected in its turn directly to tube (42), which feeds the discharge container (17).

It is known that various parameters identifiable in dialysis fluids are subject to circadian variations - for example the alternation of day and night, the administration of drugs, physical activity etc. - characterized by a maximum speed of response of the

concentrations of the order of minutes: the time program for sampling that controls the device according to the present invention must therefore take this speed of circadian modulation into account and must therefore permit sampling of the various fractions with the appropriate accuracy.

This objective can be achieved by suitable modulation of the pulses of the aforementioned microvalves (50, 51/1-51/N, 52), as shown in Fig. 3a and Fig. 3b.

To obtain greater time precision, it is necessary to use microvalves that are characterized by a high speed of response, typically less than a millisecond, which make it possible to work with overall sampling times of the order of a few seconds for all of the microvalves, thus achieving differential separation of the spent dialysis fluids.

Moreover, the device according to the present invention will have to make it possible to collect various amounts of the individual fractions, to satisfy the requirements of the laboratories carrying out the analyses on said fractions: these requirements can be met by modulating the temporal duration of the various microvalves, as shown in Fig. 3b in the case of microvalve (51/2).

More precisely, Fig. 3a shows the time sequence of operation of solenoid valves (50), (51/1), (51/2) and (52) in continuous mode, and Fig. 3b shows the time sequence of operation of solenoid valves (50), (51/1), (51/2), (51/3) and (52) in pulsed mode.

The great flexibility of the device according to the present invention and of the microprocessor-based architecture of its control module (12) makes it possible to update the time program for sampling, utilizing the "real-time" time base for re-synchronizing the operations so as to provide automatic repetition of the same operations extended to several days, even non-consecutive.

Still referring to the appended Fig. 3a, solenoid valves (51/1), (51/2) and (52) operate in succession, in the time intervals from T0 to T1, from T1 to T2, and from T2 to Tn, and the dialysis stream arriving at the system will be stored in containers (16/1), (16/2) and (17) respectively.

Referring to the appended Fig. 3b, solenoid valves (51/1), (51/2), (51/3) and (52) are operated simultaneously by time pulses of equal or different amplitude, for time from

T0 to T1, while they still operate in time sequence from T1 to Tn, and the dialysis stream arriving at the system will be stored in container (16/1), (16/2), (16/3) and (17) respectively: in this mode it is possible to separate the same sample over several containers and with different volumes owing to the modulation of pulse duration.

This operating mode is provided for taking account of the physiological time distribution of the contents of the samples, for example, night-day, post-prandial, during physical activity, etc.

CLAIMS

1. Device for management and sampling (10) of dialysis fluids adapted to be interfaced with a CGMS system or similar (1) by means of the return fluid line (4) to the discharge bag of the dialysis tube (2) of said CGMS system or similar (1) comprising: an electronic control module (12) for controlling the operations of said sampling device; a module for wireless bidirectional communication (13) adapted to manage the flow of input/output data according to a suitable communication protocol; a flow transducer (14) adapted to supply an electrical signal proportional to the flow rate of the collection and/or return dialysis fluid arriving from said CGMS system or similar (1); an electrically-operated hydraulic actuator (15) for controlling the flow of the separate dialysis collection and/or return fluids, to the individual outlet tubes; at least one collecting module (16/1-16/n) for receiving the separate dialysis collection and/or return fluids; a discharge unit (17) for receiving dialysis collection and/or return fluids that have not been separated, and a power module (11) adapted to supply the required electric currents and voltages to said modules of said device for management and sampling (10), characterized in that said electrically-operated hydraulic actuator (15) comprises a plurality of microvalves (50, 51/1-51/n, 52) for managing the sampling of said dialysis collection and/or return fluids, separating them and sending them to the individual outlet tubes based on suitable operating signals.
2. Device according to Claim 1, characterized in that said power module (11) is of the independent, autonomous type, and comprises batteries of the replaceable type.
3. Device according to Claim 1, characterized in that said power module (11) is of the independent, autonomous type and comprises batteries of the rechargeable type, together with a battery charging unit adapted to be connected to the mains by a suitable isolating transformer.
4. Device according to Claims 1-3, characterized in that said electronic control unit (12) comprises a microprocessor capable of operating in real time, and of

managing units for calculating and processing the data acquired by the internal functions of said device for management and sampling (10), managing and processing data received from units external to said device for management and sampling (10) such as systems of the CGMS type or similar (1), storing and managing, in simple or combinatorial mode, the data received from said flow transducer (14), elaborating multi-day and multi-collection / multi-separation (multi-task) combinatorial programs for management of spent dialysis fluids, storing and managing, in simple or combinatorial mode, the combining of the recognition data associated with said collection modules (16/1,...16/n), managing, storing and processing data received from systems of measuring transducers (60) that can be installed in said device for management and sampling (10).

5. Device according to Claims 1-4, characterized in that said bidirectional communication unit (13) comprises communication equipment of the wireless type.
6. Device according to Claim 5, characterized in that said communication equipment of the wireless type is selected from the group comprising devices of the Bluetooth type, of the RF type (WiFi or similar), or of the IR optical type or similar.
7. Device according to Claims 1-6 comprising a fluid intake (40) connected to said flow transducer (14) and compatible with the terminal connector (4a) of said dialysis tube (2) of said CGMS system or similar (1).
8. Device according to Claims 1-7, characterized in that said electrically-operated hydraulic actuator (15) comprises a miniature three-way solenoid valve (50) provided with two outlets, one normally open connected to a first fluid line (42) that supplies said discharge unit (17), and the other normally closed connected to a second fluid line (44).
9. Device according to Claims 1-7, characterized in that said electrically-operated hydraulic actuator (15) comprises a pair of two-way micro-solenoid valves, actuated alternately in opposite conditions of opening, installed upstream of

said fluid line (44) and adapted to feed a plurality of microvalves (51/1- 51/n and 52), downstream of which said collection containers (16/1- 16/n) of the fractions of collected analyte are connected.

10. Device according to Claims 1-9 comprising a refrigeration and/or conditioning module (18) adapted to regulate the temperature of the separate fractions, which are subject to biological alterations of a thermal origin.

11. Device according to Claims 1-10 comprising a measuring transducer (60), enzymatic or of some other type, capable of carrying out real-time determination of a specific analyte, connected to said first fluid line (42) by means of a micropump (61) and a microvalve (62), a further microvalve (63) being inserted on said first fluid line (42), upstream of the discharge connector (43).

Fig. 1

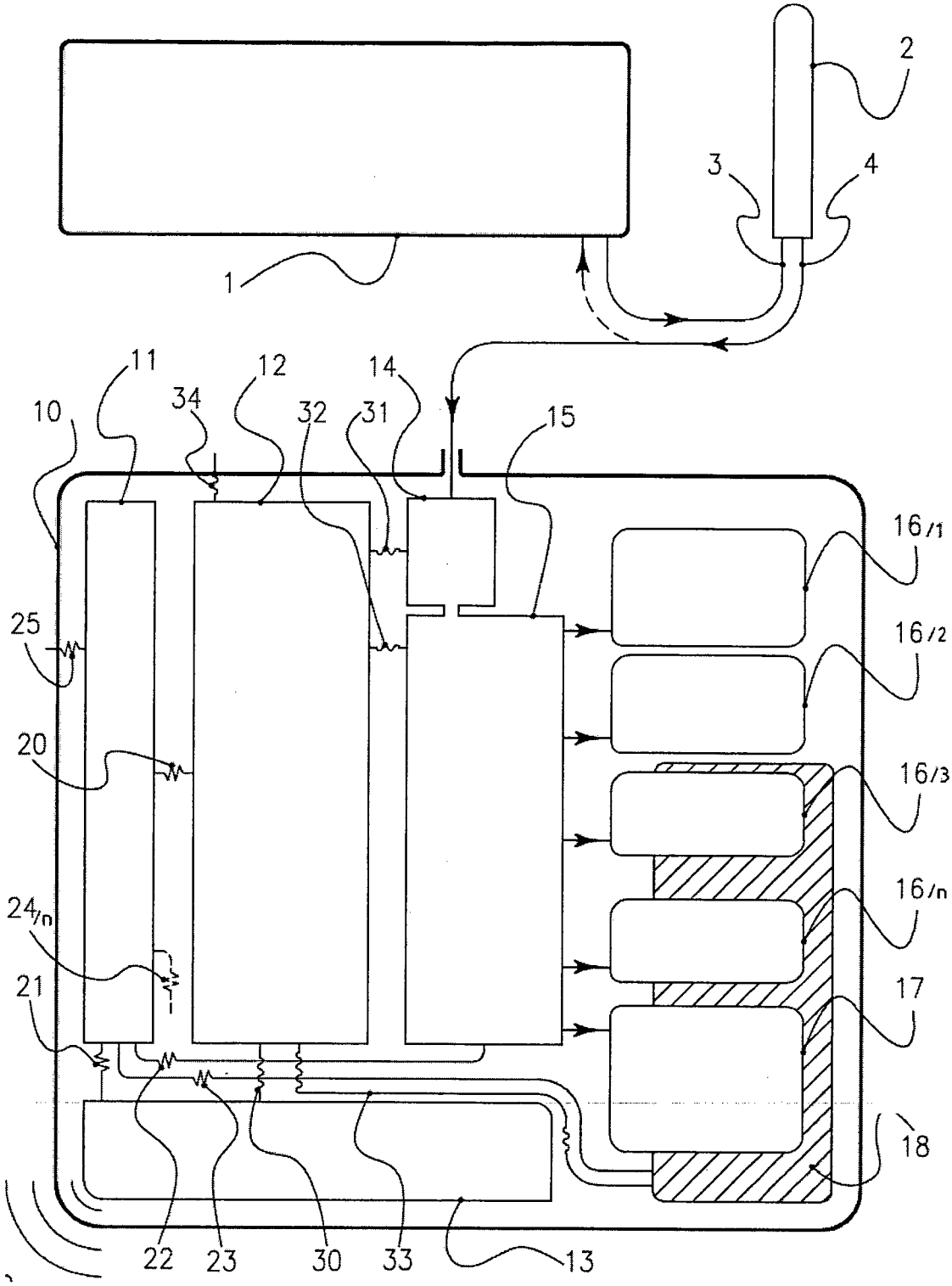

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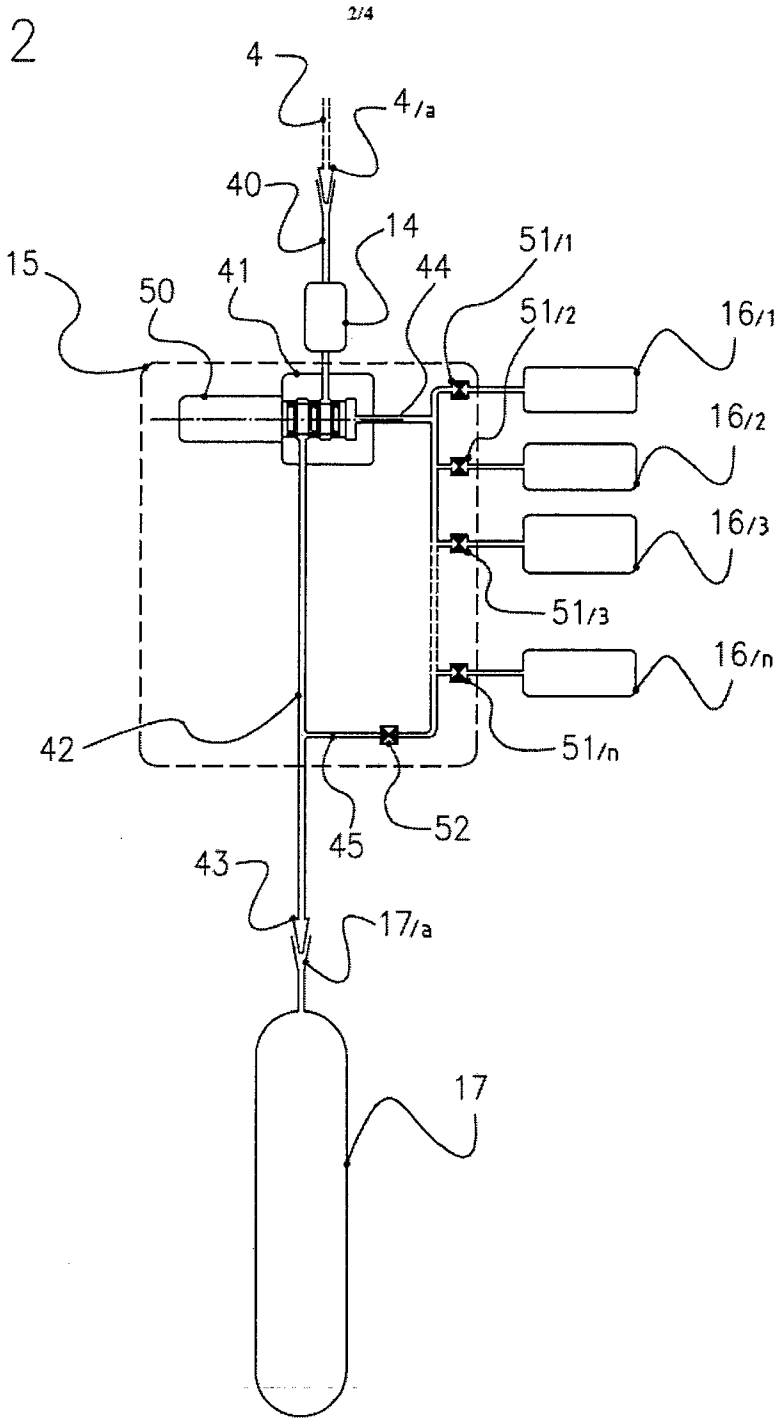
Fig. 2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44
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51/2
16/1
16/2
16/3
51/3
16/n
42
51/n
45
52
43
17/a
17

Fig. 3a

continuous valve commands (tube 44)

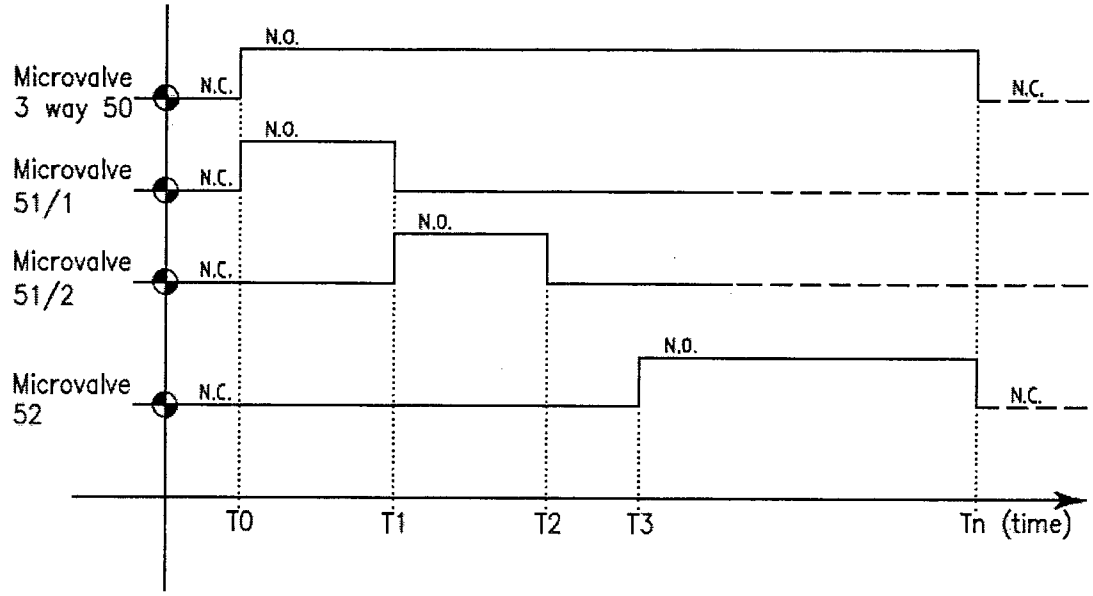


Fig. 3b

pulsed valve commands (tube 44)

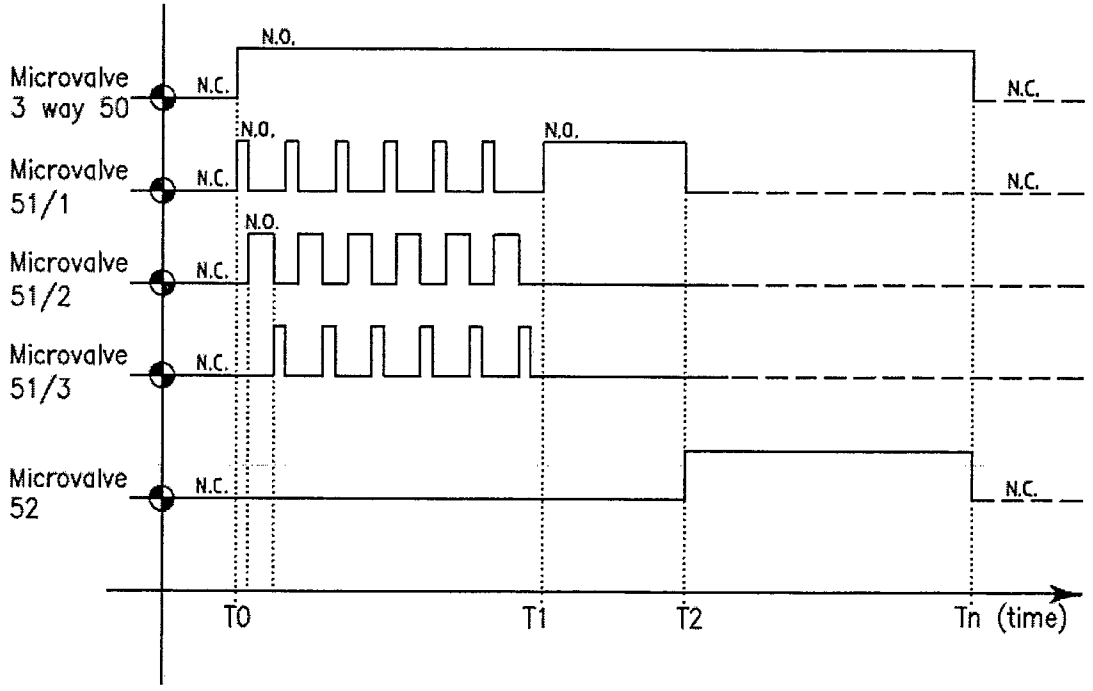
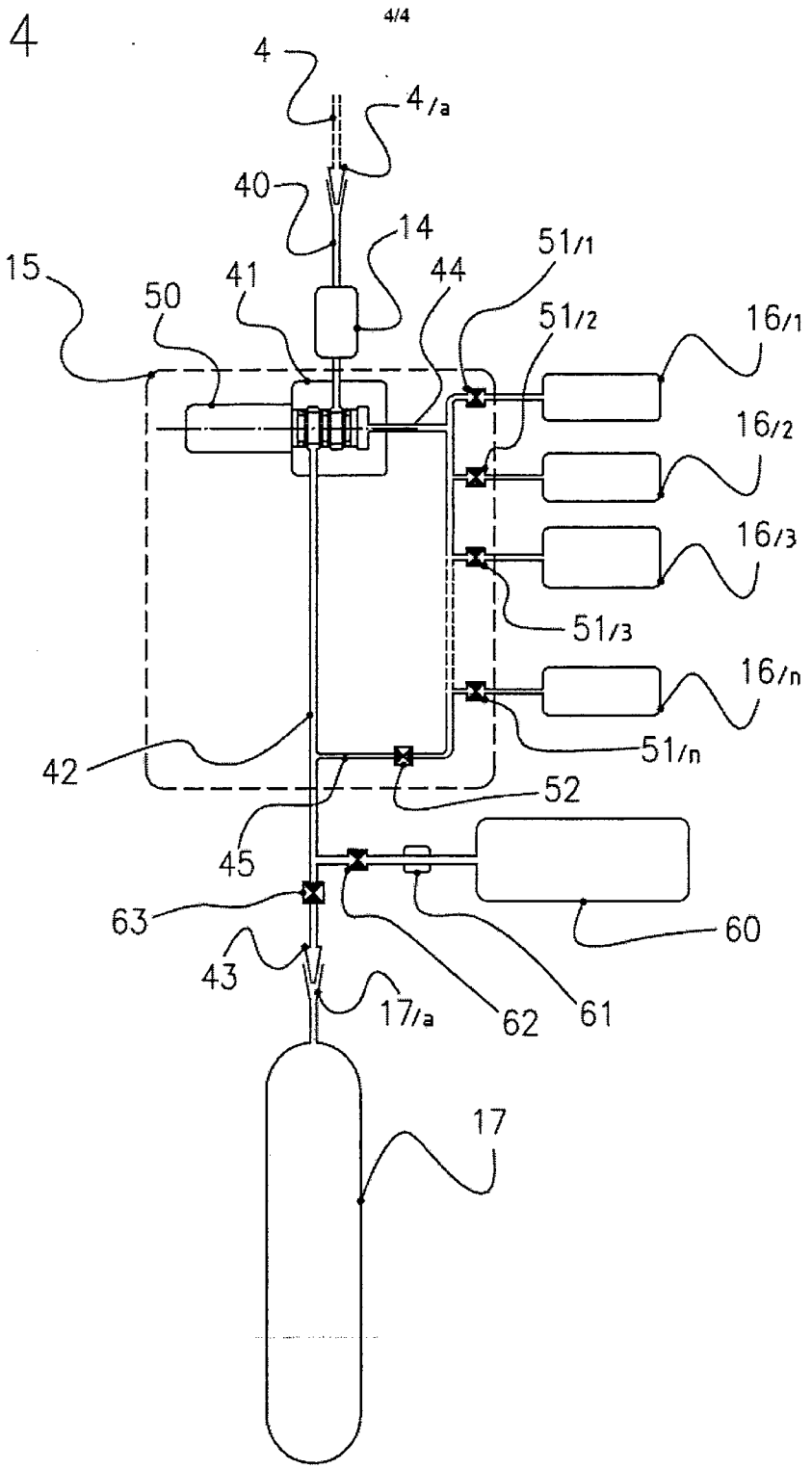


Fig. 4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51/3
16/n
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INTERNATIONAL SEARCH REPORT

International application No
PCT/IT2011/000093

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M1/14 A61M39/22
ADD.

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)
A61M A61B G06F G01N

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	US 2005/255442 A1 (BRASSIL JOHN [US] ET AL) 17 November 2005 (2005-11-17) paragraphs [0085] - [0097], [0110] - [0114], [0147] - [0163], [0170], [0177] - [0201]; claims; figure 32	1-11 1-11
Y	US 2005/089994 A1 (NEFTEL FREDERIC [CH]) 28 April 2005 (2005-04-28) the whole document	1-11
Y	US 2004/262203 A1 (NISHIMURA TAKAYUKI [JP] ET AL) 30 December 2004 (2004-12-30) the whole document	1-11
Y	US 2004/019312 A1 (CHILDERS ROBERT W [US] ET AL) 29 January 2004 (2004-01-29) paragraphs [0132] - [0194]; claims; figures	1-11

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[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
8 November 2011	17/11/2011

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INTERNATIONAL SEARCH REPORT

International application No
PCT/IT2011/000093

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	EP 1 029 554 A2 (FRESENIUS MEDICAL CARE DE GMBH [DE]) 23 August 2000 (2000-08-23) the whole document	1-11
Y	EP 1 053 759 A2 (FRESENIUS MEDICAL CARE DE GMBH [DE]) 22 November 2000 (2000-11-22) the whole document	1-11
Y	US 4 530 759 A (SCHAEL WILFRIED [DE]) 23 July 1985 (1985-07-23) column 4, line 64 - column 5, line 41 column 6, line 11 - column 7, line 58 column 11, lines 17-29; claims; figures	1-11

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/IT2011/000093

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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