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(54) **Title**: APPARATUS AND METHOD FOR ELECTRICALLY ISOLATED PATIENT COOLING

(57) **Abstract**: Apparatuses and methods for electrical isolating a fluid loop in a patient cooling system and other items touching the patient allows the remainder of the cooling and monitoring system to be electrically grounded without providing a ready path to ground for current passing through the patient.

DESCRIPTION

APPARATUS AND METHOD FOR ELECTRICALLY ISOLATED PATIENT COOLING

BACKGROUND

1. Field of the Invention

[0001] The present invention relates to an apparatus and method for delivering chilled fluid to a patient. More particularly, the present invention relates to a method and apparatus which delivers electrically isolated chilled fluid.

2. Description of Related Art

[0002] When a patient is in contact with caregivers or medical equipment, particularly multiple caregivers or pieces of equipment, it is often desirable to electrically isolate the patient so that in the event the patient's electrical potential is elevated by any means (intentional or un-intentional) a large electric current will not flow through the patient to ground.

[0003] It is often simultaneously desirable to cool the patient to control fever or induce therapeutic hypothermia. One method of doing so is through the use of chilled fluid. Ideally, the chilled fluid is biocompatible, in direct contact with the patient, i.e. not contained in a balloon or gel pad, and can be delivered continuously for several hours at a time. Several cooling systems exist where cooling fluid is not in direct contact with the patient, such as the QuickCool product, available from QuickCool SE of Lund, Sweden, or the Arctic Sun system, available from Medivance, Inc. of Louisville, Colorado. However, putting aqueous biocompatible fluid in direct contact with the patient can make electrical isolation difficult if not impossible, because thermal energy must be continuously removed from the electrically conductive irrigating fluid without making electrical contact. Two methods currently exists which electrically isolate the fluid but preclude continuous removal of energy. These methods involve phase change of the cooling fluid. One phase change based method, employed in the RhinoChill device available from BeneChill, Inc. of San Diego, California, uses non-conductive, nebulized fluorocarbon liquid spray, which removes energy from the patient as the nebulized liquid turns to vapor. A second phase change based method would be to use an electrically isolated ice bath that is continuously replenished as ice melts. The "Thermosuit" from Life Recovery Systems HD, LLC of Kinnelon, New Jersey uses this method. While feasible, these methods are undesirable for this application because a large amount of ice or fluorocarbon chemical would be required to complete the treatment, particularly when treatment times can be 6 hours, 12, hours or even in some cases more than 24 hours.

[0004] Accordingly, there is a need for improved apparatuses and methods for cooling a patient.

SUMMARY

[0005] Apparatuses and methods which enable thermal exchange between a patient and a refrigeration or other cooling system, while maintaining a high degree of electrical isolation from the environment, for extended period of time are disclosed herein. Additionally, apparatuses and methods for electrically isolating a fluid loop in a patient cooling system and other items touching the patient allows the remainder of the cooling and monitoring system to be electrically grounded without providing a ready path to ground for current passing through the patient are disclosed herein.

[0006] In accordance with an embodiment of the present invention, an apparatus for providing electrically isolated cold irrigation fluid, comprises a chilled fluid source for providing a first chilled fluid, wherein the first chilled fluid is non-electrically conductive, a primary heat exchanger having a first fluid flow path for receiving the first fluid and a second fluid flow path for circulating a second fluid, wherein the first and second fluid flow paths are thermally linked, and at least one pump for delivering the second fluid to a target site.

[0007] The chilled fluid source may comprise a chiller.

[0008] The apparatus may further comprise a reservoir for receiving the second fluid from the target site, and the reservoir may be non-electrically conductive. The apparatus may further comprise a regulated vacuum source connected to the reservoir to create a negative pressure within the reservoir. A head space may be formed above a level of the second fluid in the reservoir, and the vacuum source may be in communication with the head space so that no electrical connection is formed between the vacuum source and the second fluid.

[0009] The first chilled fluid may be selected from the group consisting of perflouro compounds, hydrocarbons, and poly alpha olefin fluids, and the first chilled fluid may have an electrical resistivity greater than about $1x10^8$ Ohm-Meters. The first chilled fluid may have a viscosity of less than about 100 centipoise at temperatures between -10°C and 10°C.

[0010] The primary heat exchanger is an indirect contact type heat exchanger, and allows fluid streams to exchange thermal energy, but prevents mixing of the fluid streams. The primary heat exchanger may comprise a shell and tube heat exchanger or a plate heat exchanger.

[0011] The chilled fluid source may comprises a chiller for providing a third chilled fluid, a secondary heat exchanger having a first fluid flow path for receiving the third chilled fluid and a second fluid flow path for circulating the first fluid, wherein the first and second fluid flow paths are thermally linked, and a circulation pump for circulating the third chilled fluid.

[0012] In accordance with another embodiment, an apparatus for providing electrically isolated irrigation fluid comprises a chilled fluid source for providing a first chilled fluid, a heat exchanger having a first fluid flow path for receiving the first fluid and a second fluid flow path for circulating a second fluid, wherein the first and second fluid flow paths are thermally linked, and wherein the heat exchanger is non-electrically conductive so that the first and second fluid flow paths are electrically isolated.

[0013] The heat exchanger may comprise a polymer or the heat exchanger may be coated to be non-electrically conductive.

[0014] In accordance with another embodiment, an apparatus for providing electrically isolated irrigation fluid comprises 2 main loops that are electrically isolated from each other and exchange thermal energy by transfer of fluid between the loops as controlled by valves. A first loop comprises a reservoir of biologically compatible fluid in contact with a pump and heat exchanger. The heat exchanger is in contact with a cooling unit – such as a refrigerating chiller, thermoelectric device, cold flowing fluid, or other cold source. The first loop circulates continuously and the fluid in the reservoir decreases in temperature as heat flows from the fluid in the loop to the cooling unit. The second loop comprises a reservoir of biologically compatible fluid, a pump, may include filters and sensors, and includes the patient and a return line. The second loop circulates continuously and removes heat from the patient, however, because there is no heat exchanger in the loop the fluid warms in response to the heat coming from the patient. The operator may, however, replace the warm fluid reservoir of the second loop with the cold fluid reservoir of the first loop by actuating valves to 'swap' the reservoirs between loops. The valves may also be placed under automatic control so that this swap is done when the first 'cold' reservoir reaches a pre-defined temperature, or when the second 'warm' reservoir reaches a pre-defined temperature, or when a certain temperature differential is established between the two reservoirs.

[0015] In accordance with another embodiment, a method of providing an electrically isolated cold irrigation fluid for treating a patient, comprises providing a first chilled fluid, wherein the first chilled fluid is non-electrically conductive, circulating the first chilled fluid through a heat exchanger to chill a second biologically compatible fluid, and delivering the chilled biologically compatible fluid to a patient.

[0016] The method may further comprise recirculating the biologically compatible fluid after delivery to the patient back to the heat exchanger, and the method may further comprise storing the biologically compatible fluid in a reservoir prior to delivery to the heat exchanger.

[0017] In accordance with another embodiment, the reservoir and heat exchanger may be combined. Where cold fluid is circulated through a 'cooling coil' made of an electrically non-conductive material through which is circulated an electrically conductive fluid or an electrically conductive material through which is circulated an electrically non-conductive fluid. The coil may be immersed partially or fully in the reservoir serving the patient.

[0018] The term "coupled" is defined as connected, although not necessarily directly. The terms "a" and "an" are defined as one or more unless this disclosure explicitly requires otherwise.

[0019] The terms "substantially," "approximately," and "about" are defined as largely but not necessarily wholly what is specified (and includes what is specified; e.g., substantially 90 degrees includes 90 degrees and substantially parallel includes parallel), as understood by a person of ordinary skill in the art. In any disclosed embodiment, the terms "substantially," "approximately," and "about" may be substituted with "within [a percentage] of" what is specified, where the percentage includes 0.1, 1, 5, and 10 percent.

[0020] The terms "comprise" (and any form of comprise, such as "comprises" and "comprising"), "have" (and any form of have, such as "has" and "having"), "include" (and any form of include, such as "includes" and "including") and "contain" (and any form of contain, such as "contains" and "containing") are open-ended linking verbs. As a result, a system, or a component of a system, that "comprises," "has," "includes" or "contains" one or more elements or features possesses those one or more elements or features, but is not limited to possessing only those elements or features. Likewise, a method that "comprises," "has," "includes" or "contains" one or more steps possesses those one or more steps, but is not limited to possessing only those one or more steps. Additionally, terms such as "first" and "second" are used only to differentiate structures or features, and not to limit the different structures or features to a particular order.

[0021] A device, system, or component of either that is configured in a certain way is configured in at least that way, but it can also be configured in other ways than those specifically described.

[0022] Any embodiment of any of the systems and methods can consist of or consist essentially of – rather than comprise/include/contain/have – any of the described elements, features, and/or steps. Thus, in any of the claims, the term "consisting of" or "consisting essentially of" can be substituted for any of the open-ended linking verbs recited above, in order to change the scope of a given claim from what it would otherwise be using the open-ended linking verb.

[0023] The feature or features of one embodiment may be applied to other embodiments, even though not described or illustrated, unless expressly prohibited by this disclosure or the nature of the embodiments.

[0024] Details associated with the embodiments described above and others are presented below.

BRIEF DESCRIPTION OF THE DRAWINGS

[0025] Figure 1 is a flow diagram of a patient cooling device using one heat exchanger with an electrically non-conductive fluid circulating between the chiller and heat exchanger;

[0026] Figure 2 is a flow diagram of a patient cooling device using two heat exchangers and a non-conductive fluid to electrically isolate the patient from the chillers;

[0027] Figure 3 is a chart illustrating the performance of the patient cooling device of Figure 2;

[0028] Figure 4 is a flow diagram of a patient cooling device using a non-electrically conductive heat exchanger;

[0029] Figure 5 is a flow diagram of a patient cooling device using a discontinuous flow path;

[0030] Figure 6 is a flow diagram of a patient cooling device using a discontinuous flow path with automatic switching; and

[0031] Figure 7 is a flow diagram of a patient cooling device where the non-conductive heat exchanger has been immersed in the reservoir.

DESCRIPTION OF ILLUSTRATIVE EMBODIMENTS

[0032] In the following detailed description, reference is made to the accompanying drawings, in which are shown exemplary but non-limiting and non-exhaustive embodiments of the invention. These embodiments are described in sufficient detail to enable those having skill in the art to practice the invention, and it is understood that other embodiments may be used, and other changes may be made, without departing from the spirit or scope of the invention. The following detailed description is, therefore, not to be taken in a limiting sense, and the scope of the invention is defined only by the appended claims. In the accompanying drawings, like reference numerals refer to like parts throughout the various figures unless otherwise specified.

[0033] Referring to Figure 1, in accordance with an illustrative embodiment, a device for patient cooling 100 comprises a chilled fluid source, such as a recirculating chiller 102, for producing a non-electrically conductive chilled heat transfer fluid 108 and a primary heat exchanger 110. The primary heat exchanger 110 has a first fluid flow path for circulating the non-electrically conductive chilled heat transfer fluid 108 and a second fluid flow path for circulating an aqueous fluid 104. The first and second fluid flow paths are thermally linked so that heat may be transferred between the non-electrically conductive chilled heat transfer fluid 108 and the aqueous fluid 104.

[0034] Examples of suitable non-electrically conductive heat transfer fluids are perflouro compounds, such as 3M's fluorinert family of compounds, hydrocarbons and hydrocarbon mixtures such as mineral oil, or poly alpha olefin (PAO) fluids, or other fluids with electrical resistivity of greater than about $1x10^8$ Ohm*Meters. Preferably, the fluids also have a viscosity of less than 100 centipoise at the temperatures of interest – typically between -10° C and to 10° C so that they can be readily driven by pumping.

[0035] The non-electrically conductive heat transfer fluid 108 is thermally linked to the aqueous stream of fluid 104 through the heat exchanger 110. One suitable type of heat exchanger 110 is an indirect contact heat exchanger such as a shell and tube heat exchanger that comprises a first fluid flow path through a first side of the heat exchanger and a second fluid flow path through a second side of the heat exchanger. Other indirect contact heat exchangers, such as a plate heat exchanger, may also be used. The non-electrically conductive heat transfer fluid 108 is circulated through the first fluid flow path using non-electrically conductive coolant lines 112. The aqueous stream of fluid 104, which may be a more conductive fluid such as water or another biologically compatible fluid, is circulated through the second side of the heat exchanger. In this way, heat is transferred between the aqueous stream of fluid 104 and the non-electrically conductive heat transfer fluid 108. Since the coolant lines 112 and heat transfer fluid 108 are non-electrically conductive, the heat exchanger and the aqueous stream of fluid 104 are electrically isolated from the chiller, and the aqueous fluid entering the patient is kept within the desired temperature range by using the heat exchanger to compensate for the heat load due to the patient.

[0036] One or more pumps 116, 118 may be provided to deliver the aqueous fluid 104 from the heat exchanger 110 to the patient 106. The aqueous fluid 104 may be recirculated through the heat exchanger 110. To accomplish this, a reservoir 114 may be provided which is in fluidic communication with the patient through a return line 120 and the heat exchanger through supply line 122. The reservoir may be made of a non-electrically conductive material, such as plastic, and the reservoir may be sized so as to leave a gas head space 128 above a volume of the aqueous liquid 104. A vacuum source 124, such as a vacuum pump, and an associated regulator 126 are in communication with the gas head space 122 of the reservoir 114 to generate a negative pressure (i.e., below ambient pressure). No electrical connection is made between the vacuum source 124 and the fluid 104 since the vacuum source is only in communication with the gas head space. Any exposed metal along the flow path may be covered with insulation (i.e., a non-electrically conductive material) or isolated from grounded metal so that accidental grounding is unlikely to occur.

[0037] In operation, the chiller 102 is used to chill (i.e., remove thermal energy from) the non-electrically conductive heat transfer fluid 108. The non-electrically conductive heat transfer fluid 108 is circulated through the first flow path of the heat exchanger 108. The circulation may be accomplished through pumps included in the chiller or through separate circulation pumps.

[0038] The biologically compatible fluid 104 is circulated through the second flow path of the heat exchanger 108. The first and second flow paths are thermally linked so that heat energy is transferred from the biologically compatible fluid 104 to the non-electrically conductive heat transfer fluid 108.

[0039] The chilled biologically compatible fluid 104 is delivered to the patient 106 through delivery lines 130. In one embodiment, the aqueous fluid 104 is used to irrigate the aerodigestive tract, such as disclosed in U.S. Patent No. 8,308,787, which is hereby incorporated by reference in its entirety. The fluid may be recovered for recirculation through the return line 120, which is under negative pressure due to the vacuum source 124 and vacuum regulator 126.

[0040] Figure 2 shows another embodiment of a patient cooling system 200 in accordance with the present invention. In this embodiment, the source of a chilled fluid comprises a chiller 202 and a secondary heat exchanger 204. The secondary heat exchanger has a first fluid flow path for receiving a secondary chilled fluid 206 from the chiller 202 and a second fluid flow path for circulating a non-electrically conductive fluid 208. The first and second fluid flow paths are thermally linked to transfer heat between the secondary chilled fluid 206 and the non-electrically conductive fluid 208. A circulation pump 212 circulates the non-electrically conductive fluid 208, which is delivered through non-electrically conductive fluid lines 214 to the primary heat exchanger 210. The remainder of the apparatus is substantially similar in other aspects to the previously described embodiment and includes a primary heat exchanger 210, a reservoir 218 and associated circulation pumps 220 and circulation lines 222. A vacuum source 224 and regulator 226 may also be provided.

[0041] This embodiment may be utilized when the particular chiller 202 utilized is incompatible with non-electrically conductive heat transfer fluids. That is, the secondary chilled fluid 206 may be an electrically conductive fluid, such as propylene glycol. However, by utilizing the secondary heat exchanger 204 with the non-electrically conductive fluid 208, the patient 228 remains electrically isolated.

[0042] Figure 3 is a chart showing test data comparing performance of the 'oil loop' system in Figure 2 to that of a system where the chilling unit uses a 50:50 propylene glycol water mixture to cool the heat exchanger that directly cools the biologically compatible fluid (in this case water) to be introduced to the patient. Note that the water-glycol system has been used to generate brain-body differentials in 80 Kg pigs as high as 10.8° C. The metric of performance was the time needed for the system to return to steady-state after being perturbed by the addition of 900ml of 37° C water to the reservoir. The heat removed in this return to steady state is the heat required to cool the 900 ml of water added to the reservoir from about 37° C to about 2° C, and the average cooling power may be determined by dividing this amount of heat by the amount of time required for return to steady state. The data show that the addition of an intermediate non-electrically conductive fluid loop—in this case the fluid was light mineral oil of 70 Saybolt viscosity—does indeed impair heat transfer. The chart shows that the increased heat transfer resistance incurred by introduction of the electrically isolating oil loop can be overcome through a combination of reasonably high oil flow rate and increasing the area of the heat exchangers, this is illustrated by the results for the CP1-1 and the Duda 2 configurations of the system. The 'oil less' curve was not obtained with the configuration of Fig 2, but is included to provide a benchmark of the performance appropriate for inducing brain hypothermia in an animal model.

[0043] Referring now to Figure 4, a patient cooling system 400 includes a chiller 402 and a heat exchanger 404 for circulating a first fluid 418 through a first flow path of the heat exchanger 404. Circulation pumps 406, 408, circulation lines 410, reservoir 412, vacuum source 414 and vacuum regulator 416 circulate a second, biologically compatible fluid 420 through a second flow path of the heat exchanger 402 and deliver chilled fluid to the patient 422.

[0044] The heat exchanger 402 is an indirect contact type heat exchanger, as previously described. The heat exchanger is non-electrically conductive to isolate the first and second fluids 418, 420. A non-electrically conductive heat exchanger may be formed of plastic or a metal heat exchanger with an electrically insulating coating, such as PTFE. The use of plastic or non-electrically conductive coating will generally decrease the effectiveness of the heat exchanger (i.e., reduced watts per square meter for a given temperature difference) so a larger area is needed for heat exchange than would have been needed with an uncoated metal exchanger. Examples of non-electrically conductive heat exchangers are shell and tube and immersion heat exchangers available from Flourotherm Polymers Inc. of Parsippany, New Jersey, which are made of fluoropolymers, or a polypropylene or polyethylene shell and tube exchanger, or plate heat exchanger. Many examples are possible, so long as the heat exchanger 402 is an indirect contact exchanger and the materials or coatings used prevent electric current (at least no more than a few micro amperes) to be exchanged between the two fluids in the heat exchanger.

[0045] Referring now to Figure 5, a patient cooling system 500 in accordance with another exemplary embodiment provides electrical isolation even though heat exchanger 506 and all fluids used are conductive. The embodiment uses 2 or more fluid flow loops. The fluid loops are configured to be selectively connected to the heat exchanger so that one loop is in contact with the patient and the other in contact with the chiller units and the heat exchanger. In this arrangement, 3 way valves may be used to switch reservoirs between the loops.

[0046] The chiller 508 circulates cold fluid 507 into one side of the heat exchanger 506. The other side of the heat exchanger is in fluidic communication with a first pump 504, the pump 504 is in fluidic communication with a first 3-way valve 512 on the outlet of a first reservoir and a second 3 way valve 516 on the outlet of a second reservoir. Fluid 501 is circulated through a circuit comprising first reservoir 502, first outlet valve 512, first pump 504, heat exchanger 506, and finally first inlet valve 514. Circulation continues until all the liquid in the first reservoir has been brought to a desired temperature. Note that in some cases some freezing of the fluid may be desired. Freezing may provide additional thermal storage due to the large heat of fusion of water and other liquids. After reaching the desired temperature, the first 3 way valves 512, 514 and second 3 way valves 516 and 518 are switched from position 1 to position 2 and the fluid from the second reservoir 510 is circulated through the circuit comprising second reservoir 510, second outlet valve 516, first pump 504, first heat exchanger 506, and second inlet valve 518. The switching also serves to put the first reservoir and its first outlet valve 512 into fluidic communication with a second pump 520, an optional array of filters and sensors 522, the patient 524, and the first inlet valve 514. When the cooling fluid in the first reservoir 502 is no longer cold enough it is switched back into communication with the chiller 508, and the fluid form the second reservoir 510 is supplied to the patient.

[0047] A vacuum source 526 may be fluidically connected to the head space in the first and second reservoirs to return fluid from the patient 524.

[0048] Referring now to Figure 6, a patient cooling system 600 is similar to the patient cooling system 500 of Figure 5, except with temperature sensors 630 and 632 placed in both the first reservoir 602 and second reservoir 610, respectively, to provide temperature measurement data to an automated control unit 628 that can actuate the valves 612, 614, 616 and 618 based on temperature measurements.

[0049] Referring now to Figure 7, a patient cooling system 700 comprises a non-conductive heat exchange element 704, such as a cooling coil made of a non-electrically conductive material, such as plastic, glass, or ceramic. Alternatively, the heat exchange element 704 may be made of a conductive material but contain a circulating cold, non-conductive fluid. The coil is immersed or partially immersed in the fluid to be cooled 720. In this way the reservoir and coil together comprise an indirect contact heat exchanger. Chiller 702 circulates cold fluid though cooling coil 704, which chills fluid 720 in reservoir 712. Fluid is drawn from the reservoir by pumps 706 and 708 and provided to the patient 722. Fluid returns in line 710, driven by the fact that the reservoir is held under vacuum by vacuum source 714 and regulator 716.

[0050] The above specification and examples provide a complete description of the structure and use of exemplary embodiments. Although certain embodiments have been described above with a certain degree of particularity, or with reference to one or more individual embodiments, those skilled in the art could make numerous alterations to the disclosed embodiments without departing from the scope of this invention. As such, the various illustrative embodiments of the present devices are not intended to be limited to the particular forms disclosed. Rather, they include all modifications and alternatives falling within the scope of the claims, and embodiments other than the one shown may include some or all of the features of the depicted embodiment. For example, components may be combined as a unitary structure, and/or connections may be substituted. Further, where appropriate, aspects of any of the examples described above may be combined with aspects of any of the other examples described to form further examples having comparable or different properties and addressing the same or different problems. Similarly, it will be understood that the benefits and advantages described above may relate to one embodiment or may relate to several embodiments.

[0051] The claims are not intended to include, and should not be interpreted to include, means-plus- or step-plus-function limitations, unless such a limitation is explicitly recited in a given claim using the phrase(s) "means for" or "step for," respectively.

CLAIMS

1. An apparatus for providing electrically isolated cold irrigation fluid, comprising:
a chilled fluid source for providing a first chilled fluid, wherein said first chilled fluid is non-electrically conductive;
a primary heat exchanger having a first fluid flow path for receiving said first fluid and a second fluid flow path for circulating a second fluid, wherein said first and second fluid flow paths are thermally linked; and
at least one pump for delivering said second fluid to a target site.

2. The apparatus according to claim 1, wherein said chilled fluid source comprises a chiller.

3. The apparatus according to claim 2, further comprising a reservoir for receiving said second fluid from said target site.

4. The apparatus according to claim 3, wherein said reservoir is non-electrically conductive.

5. The apparatus according to claim 3, further comprising a regulated vacuum source connected to said reservoir to create a negative pressure within said reservoir.

6. The apparatus according to claim 5, wherein a head space is formed above a level of the second fluid in the reservoir, and said vacuum source is in communication with said head space so that no electrical connection is formed between said vacuum source and said second fluid.

7. The apparatus according to claim 1, wherein said first chilled fluid is selected from the group consisting of perflouro compounds, hydrocarbons, and poly alpha olefin fluids.

8. The apparatus according to claim 1, wherein said first chilled fluid has an electrical resistivity greater than about 1x108 Ohm-Meters.

9. The apparatus according to claim 8, wherein said first chilled fluid has a viscosity of less than about 100 centipoise at temperatures between -10° C and 10° C.

10. The apparatus according to claim 1, wherein the primary heat exchanger comprises a shell and tube heat exchanger.

11. The apparatus according to claim 1, wherein the primary heat exchanger comprises a plate heat exchanger.

12. The apparatus according to claim 1, wherein said chilled fluid source comprises:

a chiller for providing a third chilled fluid;

a secondary heat exchanger having a first fluid flow path for receiving said third chilled fluid and a second fluid flow path for circulating said first fluid, wherein said first and second fluid flow paths are thermally linked; and

a circulation pump for circulating said first fluid.

13. The apparatus according to claim 12, further comprising a reservoir for receiving said second fluid from said target site.

14. The apparatus according to claim 13, further comprising a regulated vacuum source connected to said reservoir to create a negative pressure within said reservoir.

15. An apparatus for providing electrically isolated irrigation fluid, comprising:

a chilled fluid source for providing a first chilled fluid; and

a heat exchanger having a first fluid flow path for receiving said first fluid and a second fluid flow path for circulating a second fluid, wherein said first and second fluid flow paths are thermally linked, and wherein said heat exchanger is non-electrically conductive so that the first and second fluid flow paths are electrically isolated.

16. The apparatus according to claim 15, wherein said heat exchanger comprises a polymer.

17. The apparatus according to claim 15, wherein said heat exchanger is coated to be non-electrically conductive.

18. An apparatus for providing electrically isolated irrigation fluid, comprising:

a source of chilled first fluid;

a heat exchanger having a first fluid flow path for receiving said chilled fluid and a second fluid flow path, wherein said first and second fluid flow paths are thermally linked;

a first fluid loop comprising at least one first pump and a first reservoir for supplying a biologically compatible fluid to be introduced into a patient and a first recovery line that returns fluid to said first reservoir;

a second fluid loop comprising at least one second pump and a second reservoir for supplying a biologically compatible fluid to be introduced into a patient and a second recovery line that returns fluid to said second reservoir;

wherein said first and second reservoirs are configured to be selectively coupled to said second fluid flow path of said heat exchanger.

19. The apparatus of claim 18, further comprising:

a plurality of valves coupled to said first and second fluid loops for selectively coupling said first and second reservoirs to said second fluid flow path of said heat exchanger.

20. The apparatus of claim 19, further comprising:

first and second temperature sensors associated with said first and said second reservoirs, respectively; and

a controller for operating said plurality of valves based on temperature measurements from the first and second temperature sensors.

21. An apparatus for providing electrically isolated cold irrigation fluid, comprising:

a chilled fluid source for providing a first chilled fluid;

a reservoir for containing a second fluid for delivery to a target site;

a non-conductive indirect heat exchanger having a fluid flow path for circulating said first fluid, wherein said heat exchanger is located within said reservoir and in communication with said second fluid to transfer heat energy from said second fluid to said first fluid.

22. An apparatus for providing electrically isolated cold irrigation fluid, comprising:

a chilled fluid source for providing a first chilled fluid, wherein said first chilled fluid is non-electrically conductive;

a reservoir for containing a second fluid for delivery to a target site;

an indirect heat exchanger having a fluid flow path for circulating said first fluid, wherein said heat exchanger is located within said reservoir and in communication with said second fluid to transfer heat energy from said second fluid to said first fluid.

23. A method of providing an electrically isolated cold irrigation fluid for treating a patient, comprising:

providing a first chilled fluid, wherein said first chilled fluid is non-electrically conductive;

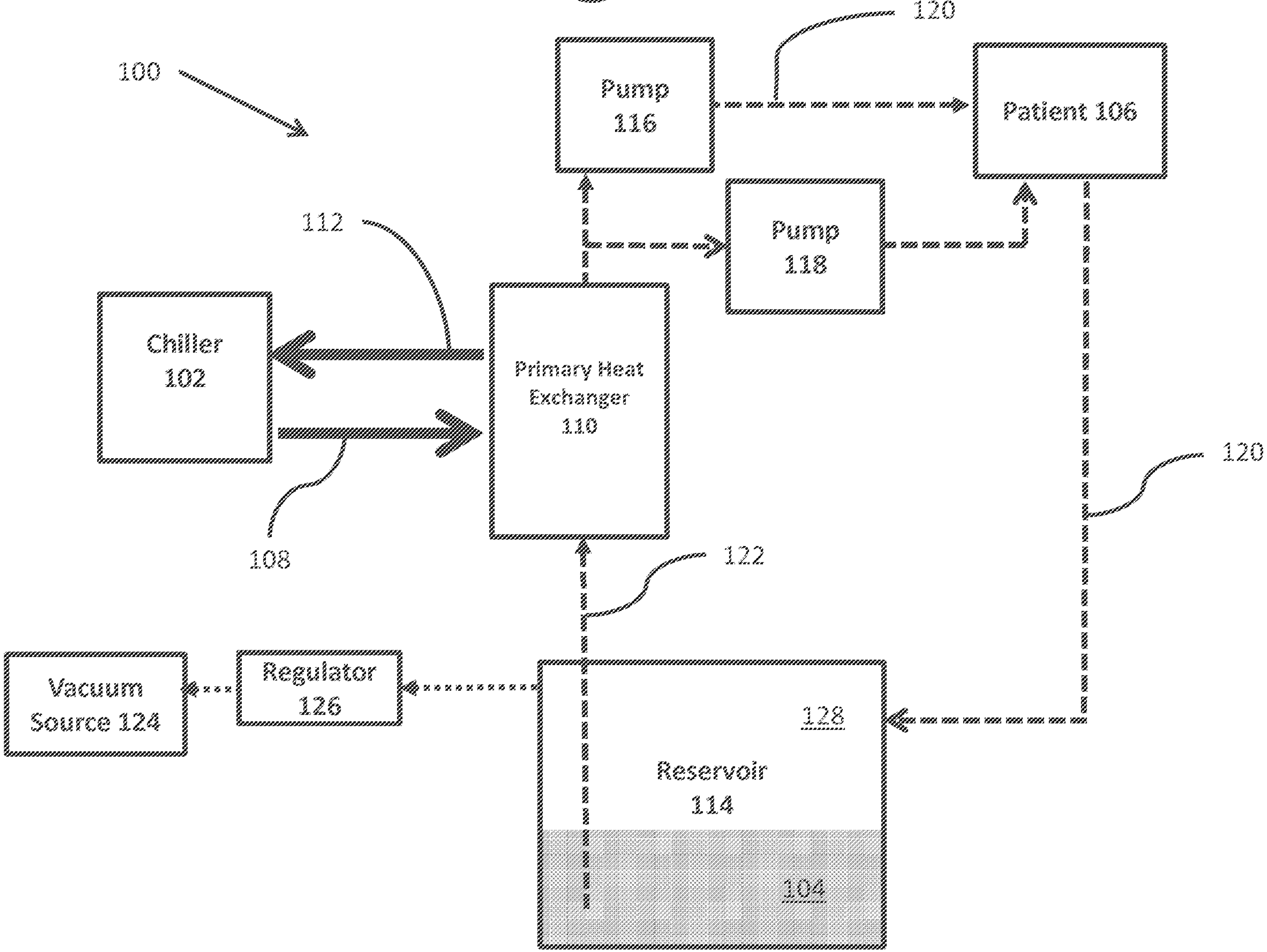
circulating said first chilled fluid through a heat exchanger to chill a second biologically compatible fluid; and

delivering said chilled biologically compatible fluid to a patient.

24. The method according to claim 19, further comprising recirculating the biologically compatible fluid after delivery to said patient back to said heat exchanger.

25. The method according to claim 20, further comprising storing said biologically compatible fluid in a reservoir prior to delivery to said heat exchanger.

Figure 1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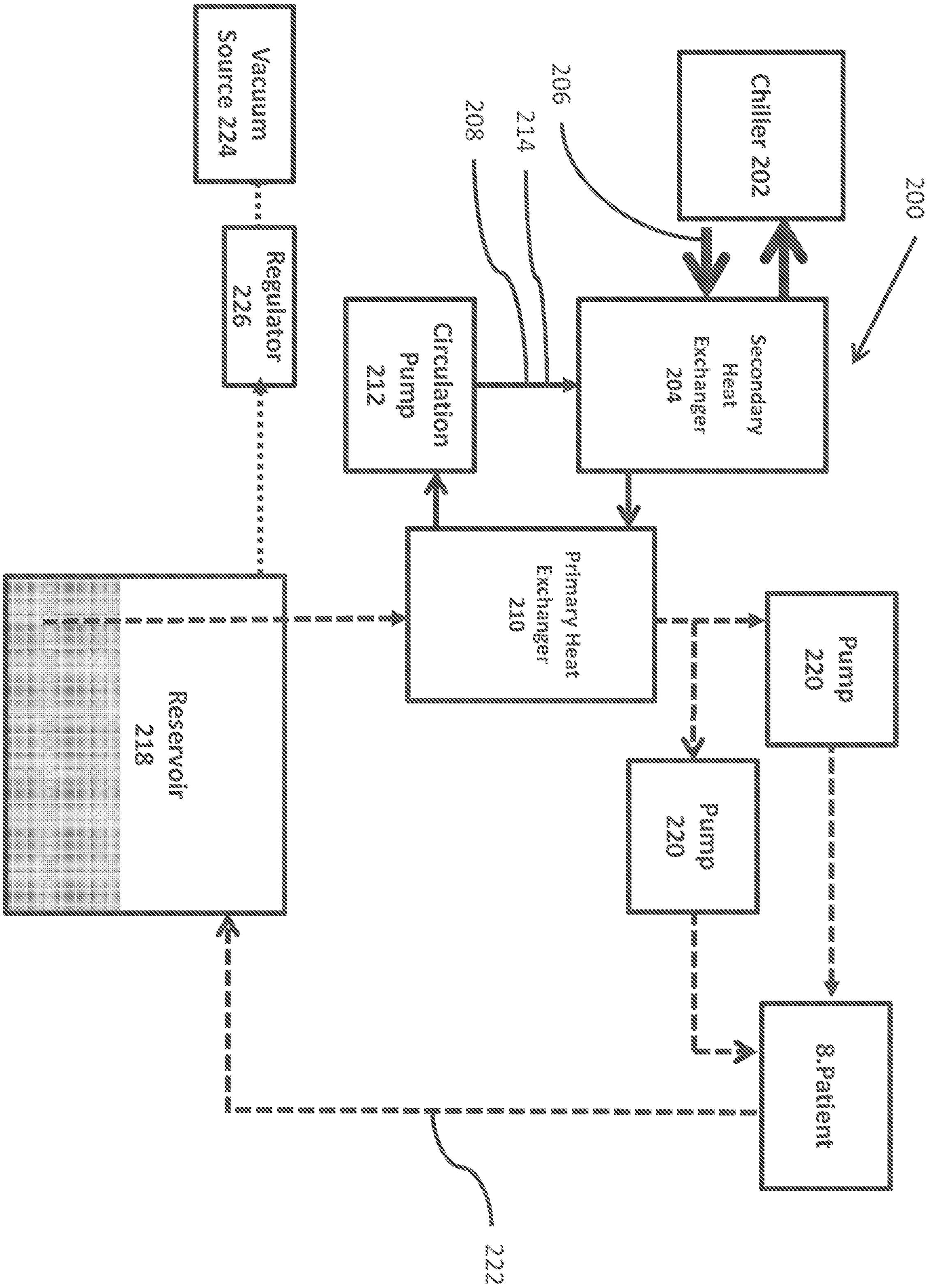
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Regulator 226
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206
214
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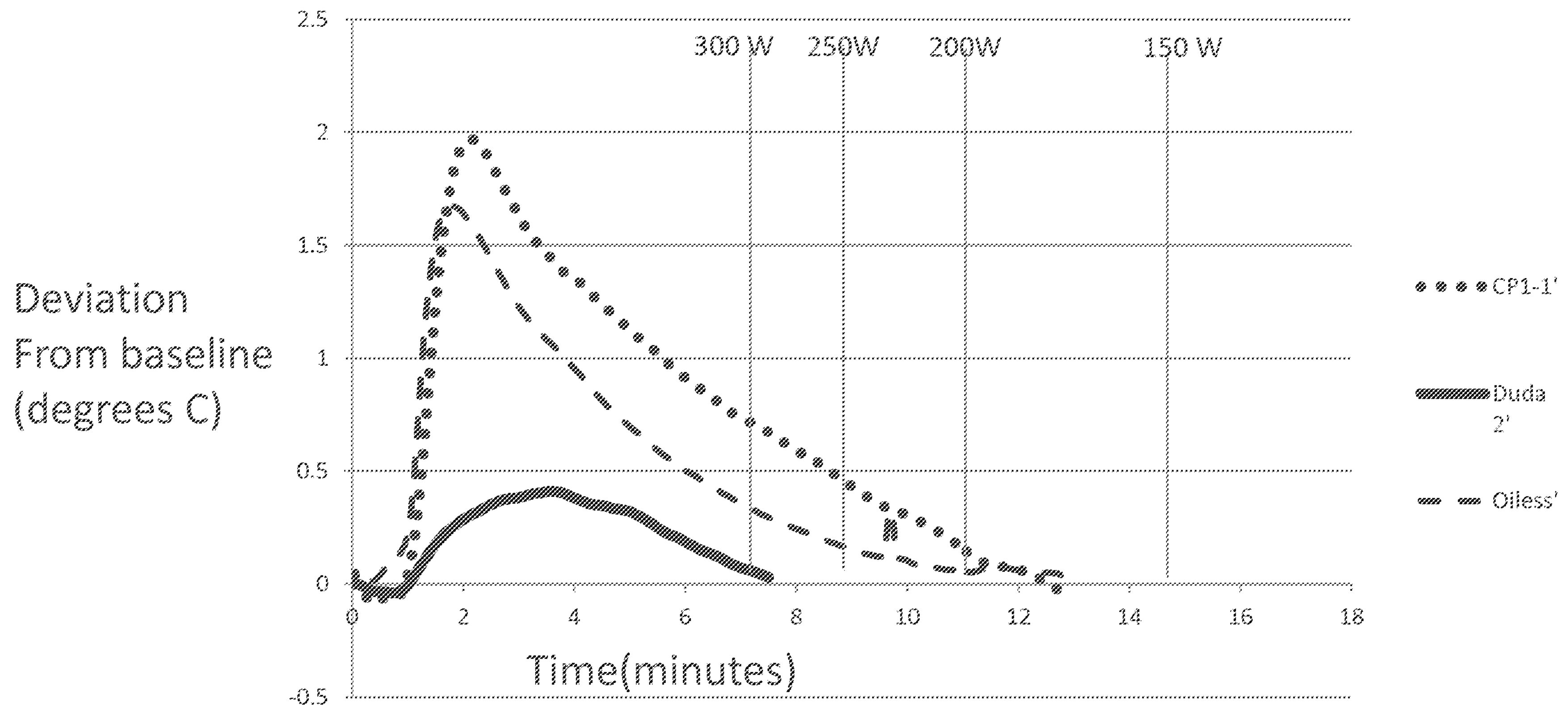
Primary Heat Exchanger 210
Reservoir 218
Pump 220
Pump 220
8.Patient
222

Figure 2

Figure 3



- CP1-1 are large heat exchangers and centrifugal pump (about 15 l/min)
- Duda 2 are the large exchangers and gear pump (about 80 l/min)
- Oiless denotes the original water/glycol only system with small heat exchangers

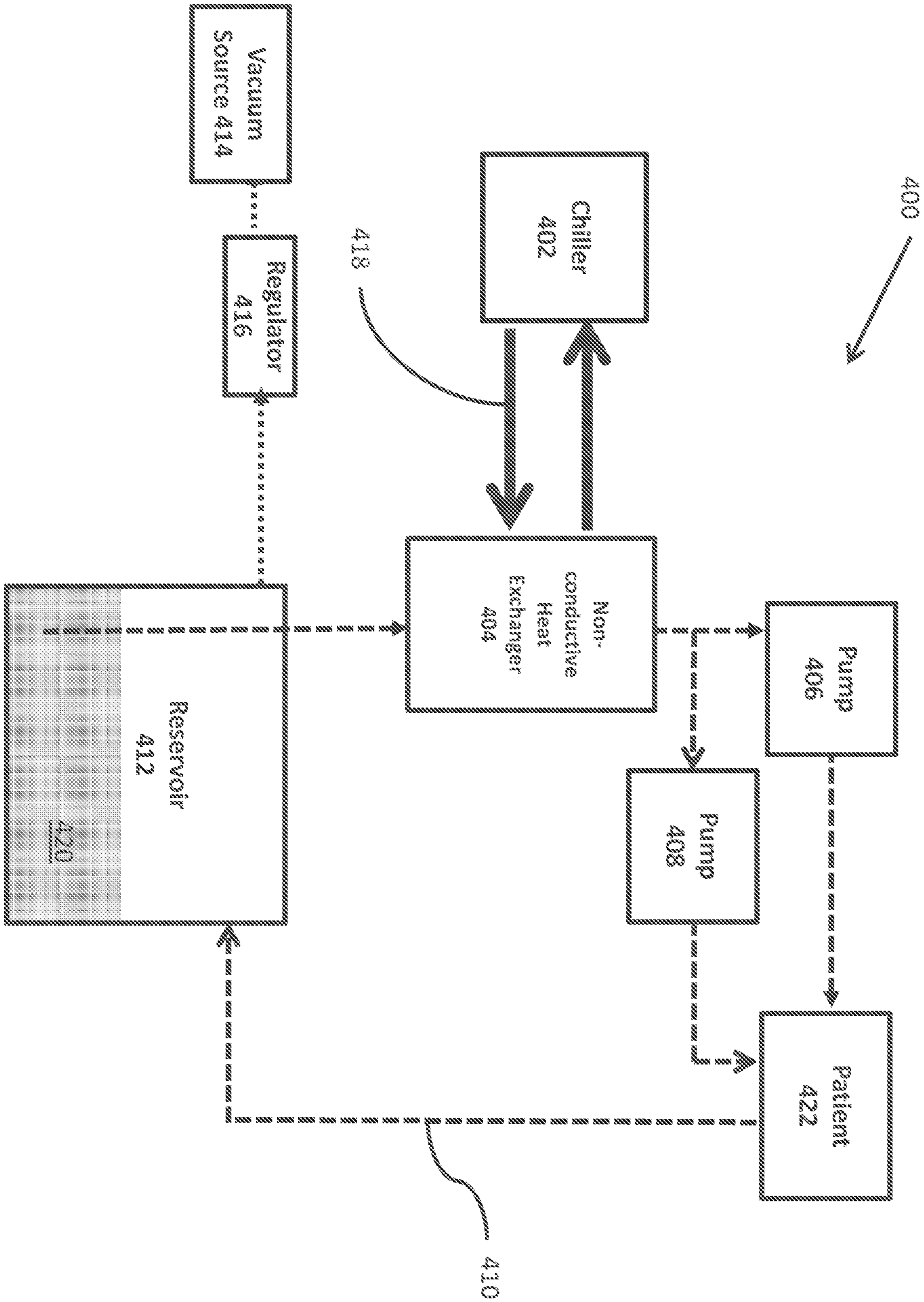

400
Vacuum Source 414
Regulator 416
418
Chiller 402
Non-conductive Heat Exchanger 404
Pump 406
Pump 408
Reservoir 412
420
Patient 422
410

Figure 4

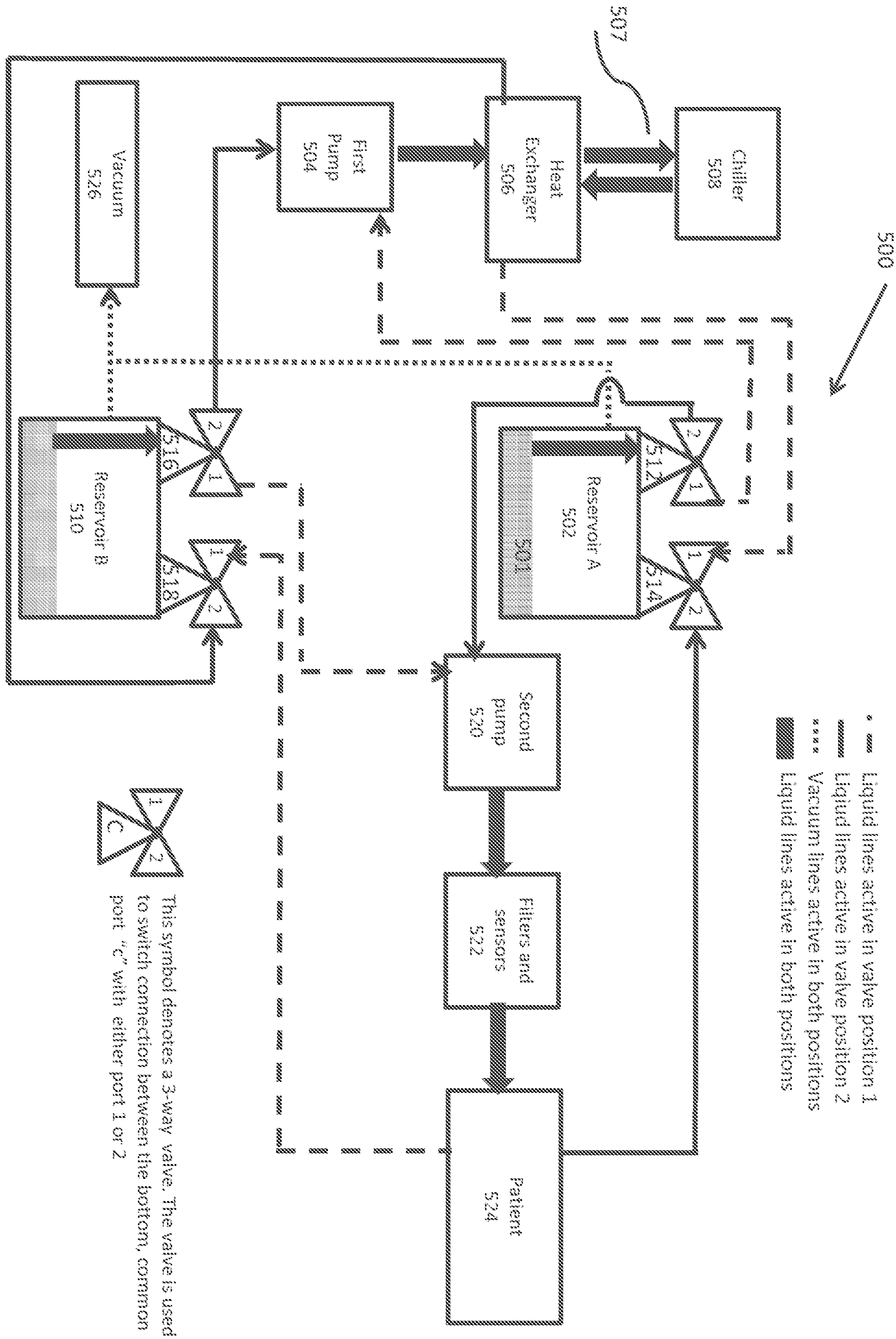

500
507
Chiller
508
Heat
Exchanger
506
First
Pump
504
Vacuum
526
Reservoir A
502
501
512
514
Reservoir B
510
516
518
Second
pump
520
Filters and
sensors
522
Patient
524
Liquid lines active in valve position 1
Liquid lines active in valve position 2
Vacuum lines active in both positions
Liquid lines active in both positions
C
This symbol denotes a 3-way valve. The valve is used to switch connection between the bottom, common port "c" with either port 1 or 2

Figure 5

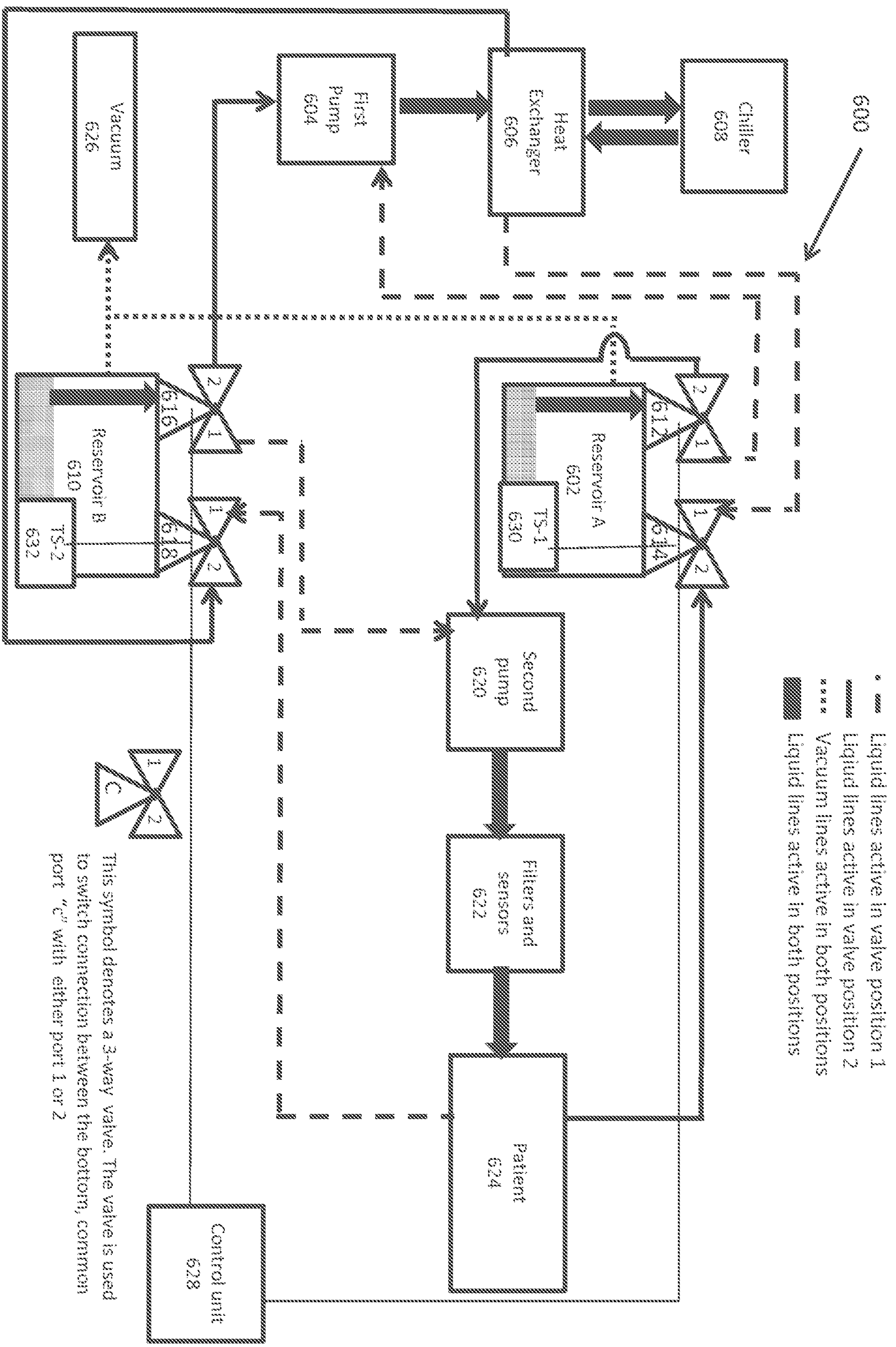
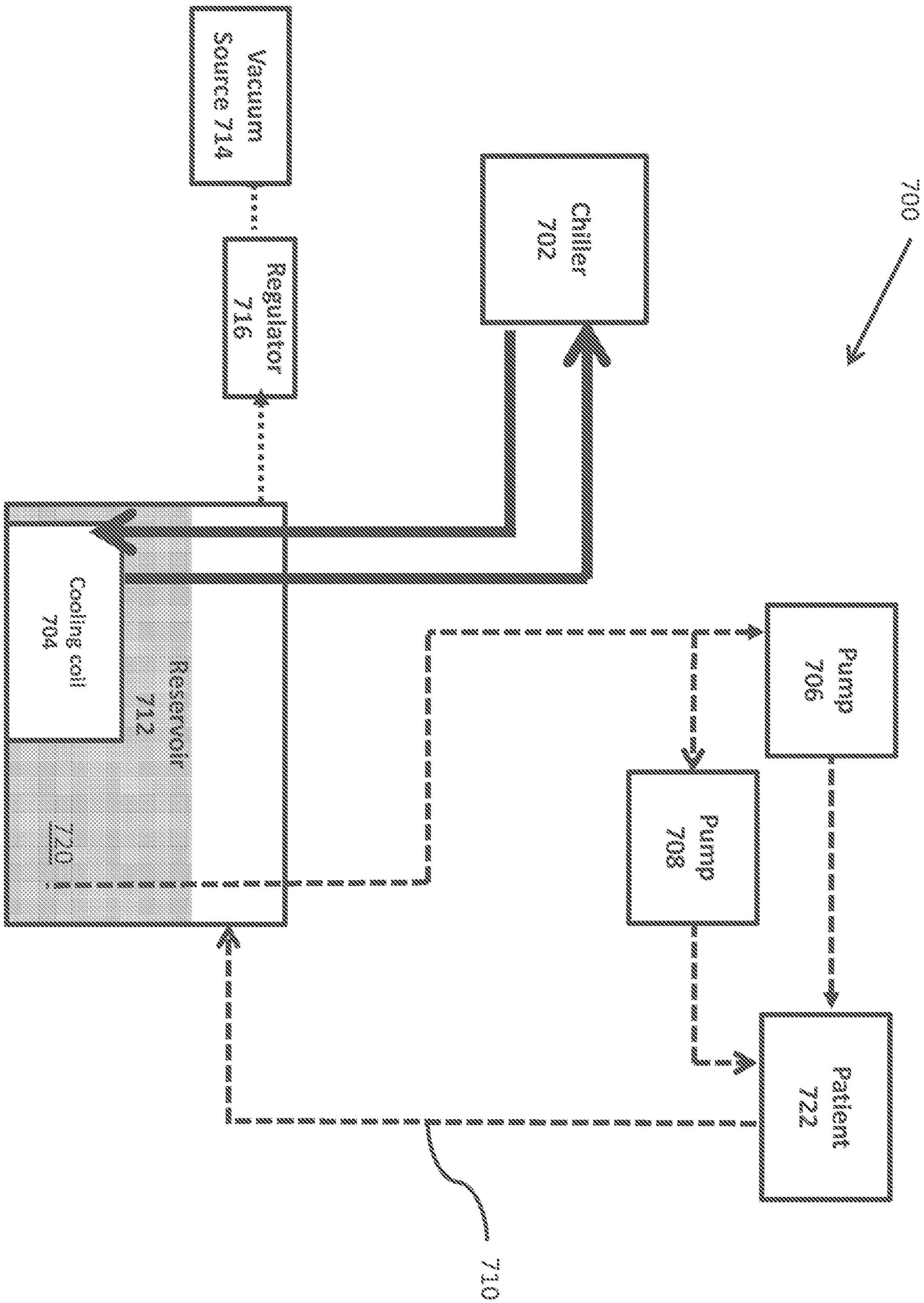

600
Chiller
608
Heat
Exchanger
606
First
Pump
604
Vacuum
626
Reservoir A
602
TS-1
630
612
614
Reservoir B
610
TS-2
632
616
618
Second
pump
620
Filters and
sensors
622
Patient
624
Control unit
628
Liquid lines active in valve position 1
Liquid lines active in valve position 2
Vacuum lines active in both positions
Liquid lines active in both positions
This symbol denotes a 3-way valve. The valve is used to switch connection between the bottom, common port "c" with either port 1 or 2

Figure 6



700
Vacuum Source 714
Regulator 716
Chiller 702
Reservoir 712
Cooling coil 704
720
Pump 706
Pump 708
Patient 722
710

Figure 7

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2014/040005

A. CLASSIFICATION OF SUBJECT MATTER

A61F 7/00(2006.01)i

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)
A61F 7/00; A61N 5/06; A61M 5/00; A61F 7/12; A61B 18/02

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
Korean utility models and applications for utility models
Japanese utility models and applications for utility models

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
eKOMPASS(KIPO internal) & keywords: heat exchange, chilled, pump, reservoir

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 03-030790 A1 (MEDIVANCE INCORPORATED) 17 April 2003 See abstract; page 18, line 15; claims 11, 22, 53; and figure 1.	1-4,8-11,15-21
Y		5-6,12-14,22
A		7
Y	US 2010-0057064 A1 (BAUST, J. M. et al.) 4 March 2010 See abstract; paragraph [0025]; claim 1; and figure 1.	5-6,14
A		1-4,7-13,15-22
Y	KR 10-2010-0054097 A (KOREA ELECTROTECHNOLOGY RESEARCH INSTITUTE) 24 May 2010 See abstract; claim 16; and figure 3-4.	12-14
A		1-11,15-22
Y	US 2007-0244434 A1 (NODA, W. et al.) 18 October 2007 See abstract; paragraph [0038]; claim 1; and figure 1.	22
A		1-21
A	US 6042559 A (DOBAK, III, J. D.) 28 March 2000 See abstract; claim 1; and figure 1.	1-22

☒ 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 application or patent 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
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
16 September 2014 (16.09.2014)	**16 September 2014 (16.09.2014)**

Name and mailing address of the ISA/KR
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Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 23-25
because they relate to subject matter not required to be searched by this Authority, namely:
Claims 23-25 pertain to methods for treatment of the human and thus relate to a subject-matter which this International Searching Authority is not required to search under PCT Article 17(2)(a)(i) and PCT Rule 39.1(iv).

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required addtional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of any additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 7806915 B2 (SCOTT, D. J. et al.) 5 October 2010 See abstract; claim 1; and figures 6-8.	1-22

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/US2014/040005

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 03-030790 A1	17/04/2003	EP 1158941 A1	05/12/2001
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		US 2003-0114903 A1	19/06/2003
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		WO 00-40185 A1	13/07/2000
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KR 10-2010-0054097 A	24/05/2010	GB 2465245 A	19/05/2010
		GB 2465245 B	22/06/2011
		KR 10-1117198 B1	07/03/2012
		US 2010-0121418 A1	13/05/2010
US 2007-0244434 A1	18/10/2007	US 2005-0028551 A1	10/02/2005
		US 2007-0240447 A1	18/10/2007
		US 2007-0244531 A1	18/10/2007
		US 7287398 B2	30/10/2007
		US 7640768 B2	05/01/2010
US 6042559 A	28/03/2000	None	
US 7806915 B2	05/10/2010	EP 1885306 A2	13/02/2008
		EP 1885306 A4	09/12/2009
		EP 2305188 A1	06/04/2011
		JP 2008-539034 A	13/11/2008
		US 2006-0293734 A1	28/12/2006
		US 2011-0022136 A1	27/01/2011
		WO 2006-116603 A2	02/11/2006
		WO 2006-116603 A3	25/10/2007