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(54) **Title**: IMPROVED MEDICAL PAD AND SYSTEM FOR THERMOTHERAPY

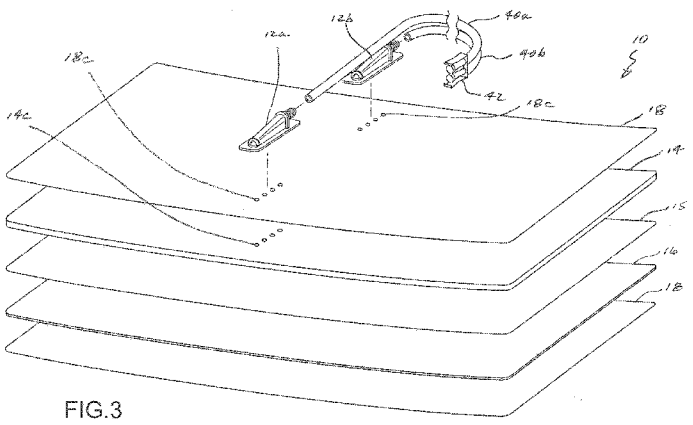


FIG.3

(57) **Abstract**: An improved medical pad for contact thermal exchange with a patient includes a fluid circulation layer for containing a thermal exchange fluid circulatable therethrough, a first port and a second port for circulating the thermal exchange fluid in to and out of the fluid circulation layer, and a hydrogel layer interconnected to and extending across one side of the fluid circulation layer to define an adhesive surface for adherence to a patient's skin. The hydrogel layer comprises an ultra violet light-cured composition that includes a cross-linking copolymer in an amount of between about 15% to 30% by weight of the composition, water in an amount of between about 15% to 40% by weight of the composition, and glycerol in an amount of between about 25% to 35% by weight of the composition. The hydrogel layer is provided to have a thermal conductivity of at least about 1.9 ca//hr-cm-°C.

WO 2016/123500 A1

IMPROVED MEDICAL PAD AND SYSTEM FOR THERMOTHERAPY

FIELD OF INVENTION

The present invention relates an improved medical pad and system for use in patient temperature control, and in particular, for therapeutic patient temperature cooling to induce hypothermia and optionally patient warming to achieve normothermia.

BACKGROUND OF THE INVENTION

There are a number of medical conditions for which systemic cooling is an effective therapy. For example, rapid systemic cooling of stroke, head-trauma, cardiac arrest, and myocardial infarction patients has significant therapeutic benefits.

In that regard, stroke is a major cause of neurological disability, but research has established that even though a stroke victim's brain cells may lose their ability to function during the stroke, they do not necessarily die quickly. Brain damage resulting from a stroke may take hours to reach a maximum level. Neurological damage may be limited and the stroke victim's outcome improved if a cooling neuroprotectant therapy is applied during that timeframe.

Similar possibilities exist with victims of trauma, such as may result from vehicle crashes, falls, and the like. Such trauma may impart brain injury through mechanisms that have overlap with elements in the genesis of neurologic damage in stroke victims. Delayed secondary injury at the cellular level after the initial head trauma event is recognized as a major contributing factor to the ultimate tissue loss that occurs after brain injury.

Further, corresponding possibilities exist with cardiac arrest and myocardial infarction patients. Again, rapid cooling of such patients may limit neurological damage. In addition, rapid

cooling may provide cardio protection. Further in that regard, rapid heart cooling of myocardial arrest patients prior to reperfusion procedures (e.g., carotid stenting) may significantly reduce reperfusion-related injuries.

Additionally, patients having a neurological disease may often have accompanying fever. Cooling such patients has been recently proposed to yield therapeutic benefits, but may entail cooling over an extended period of time.

Various approaches have been developed for applying cooling therapy. In one non-invasive approach, one or more contact pad(s) may be placed on a patient's body (e.g. the torso and/or legs of a patient) and a cooled fluid, such as cooled water or air, circulated through the pad(s). In turn, thermal energy is exchanged between the patient and the circulated fluid to cool the patient.

SUMMARY OF THE INVENTION

An objective of the present invention is to provide a medical pad for thermal exchange with a patient that facilitates the realization of pad production efficiencies and the reduction of pad production facility requirements.

Another objective of the present invention is to provide a medical pad for thermal exchange with a patient yields rapid thermal exchange with a patient.

A further objective of the present invention is to provide a medical pad for thermal exchange with a patient that provides stable mechanical properties to facilitate continued use on a patient over an extended time period.

An additional objective of the present invention is to provide a medical pad for thermal exchange with a patient that is bio-compatible and otherwise comfortable.

Yet a further objective of the present invention is to provide a medical pad for thermal exchange with a patient that is relatively easy to remove and does not require extensive hygienic patient clean-up after removal.

In one embodiment, an improved medical pad for contact and thermal exchange with a patient comprises a fluid circulation layer for containing a thermal exchange fluid circulatable therethrough, a first port fluidly interconnected to the fluid circulation layer for circulating the fluid into the fluid circulation layer, and a second port fluidly interconnected to the fluid circulation layer for circulating the fluid out of the fluid circulation layer. Further, the medical pad includes a hydrogel layer interconnected to and extending across one side of the fluid circulation layer to define an adhesive surface for adherence to a patient's skin.

Uniquely, the hydrogel layer comprises an ultra violet light-cured composition that includes a cross-linking copolymer in an amount of between about 15% to 30% by weight of the composition, and preferably in an amount of between about 25% to 30% by weight of the composition; water in an amount of between about 15% to 40% by weight of the composition, and preferably in an amount of between about 25% to 35% by weight of the composition; and glycerol in an amount of between about 25% to 35% by weight of the composition, and preferably in an amount of between about 27.5% to 32.5 % by weight of the composition. Surprisingly, the water content utilized in the hydrogel layer facilitates the utilization of ultra violet light-cured compositions for facility-friendly and production-scale manufacturing, while also yielding a hydrogel layer having desirable mechanical properties, i.e. desirable degrees of thermal conductivity, shelf life stability, and tack strength.

In some embodiments, the hydrogel layer may be provided to have a thermal conductivity of at least about 1.9 cal/hr-cm-°C. More particularly, the hydrogel layer may have a thermal conductivity of between about 1.9 cal/hr-cm-°C and 2.37 cal/hr-cm-°C.

In some implementations, the adhesive surface of the hydrogel layer may be provided to have a tack strength of between about 20g and 65g, as determined according to ISO 9665:1998(E).

In contemplated embodiments, the hydrogel layer may have a thickness of between about .018" and .04". More particularly, the hydrogel layer may have a thickness of between about .022" and .032".

Further, in contemplated embodiments, the fluid circulation layer may define an internal volume having an average or substantially equal geometric height, or thickness, across the fluid circulation layer of at least about .06", and preferably between about .06" and .1". In medical pad applications where fluid is circulated, or drawn, through the fluid circulation layer at a negative pressure, the fluid containing layer may have an effective internal volume height of between about .04" and .08" during circulated fluid flow therethrough.

In contemplated arrangements, the fluid circulation layer may comprise a flexible film layer and a flexible base member interconnected to the film layer for containing the circulatable thermal exchange fluid therebetween. In such arrangements, the hydrogel layer may have a thermal conductivity as indicated above.

In a system embodiment for contact thermal exchange with a patient, a medical pad having a fluid circulation layer, a hydrogel layer, and optional additional features as described above may be employed in combination with a controller and a fluid conditioning assembly that is fluidly interconnectable to an inlet port and outlet port of the pad. The fluid conditioning assembly may include a fluid pump for circulating a thermal exchange fluid through the pad and a heat exchanger for use in controlling a temperature of the circulated fluid (e.g. for cooling and optionally rewarming the cooled fluid). In the later regard, the controller may provide output signals for controlling operation of the heat exchanger to provide for temperature control of the circulated thermal exchange fluid in a predetermined manner.

In system embodiments, a patient temperature sensor may be provided for sensing a patient temperature (e.g. a patient core body temperature) and providing a patient temperature signal indicative thereof, wherein the controller may be provided to utilize the patient temperature signal in providing the output signals to the heat exchanger. Further, the fluid conditioning assembly may include a fluid temperature sensor for sensing the temperature of the circulated thermal exchange fluid and for providing a fluid temperature signal indicative thereof, wherein the controller may be provided to utilize the fluid temperature signal in providing the output signals to the heat exchanger.

Additional features and advantages will be recognized by those skilled in the art upon consideration of the further description that follows.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a perspective view of a medical pad embodiment.

Fig. 2 is a perspective view of a corner of the medical pad embodiment of Fig. 1 with various layers of the medical pad embodiment separated for purposes of illustration.

Fig. 3 is a perspective exploded view of the medical pad embodiment of Fig. 1.

Fig. 4 is a bottom view of a base member of the medical pad embodiment of Fig. 1.

Fig. 5 is a schematic illustration of a system embodiment that includes the medical pad embodiment of Fig. 1.

Fig. 6 is a schematic illustration of a fluid conditioning assembly of the system embodiment of Fig. 5.

Fig. 7 is a schematic illustration of an embodiment of a controller of the system embodiment of Fig. 5.

Fig. 8 illustrates steps of a method embodiment utilizing the system embodiment of Figs. 5-7.

DETAILED DESCRIPTION

One embodiment of a medical pad 10 for contact and thermal exchange with a skin region of a patient is illustrated in Figs. 1 - 4. As shown in Fig. 1, the pad 10 may include an inlet port 16a and an outlet port 16b for circulating a thermal exchange fluid (e.g. a liquid such as water) in to and out of a fluid circulation layer of the pad 10. For such purposes, the inlet port 12a and outlet port 12b may have corresponding first ends that fluidly communicate with the fluid containing layer of the pad 10, respectively. The inlet port 12a and outlet port 12b may further

include corresponding second ends that extend laterally outside of the fluid containing layer in a common direction. As illustrated, the second ends of inlet port 12a and outlet port 12b may be provided for fixed interconnection with fluid circulation lines 40a and 40b, respectively. In one approach, the fluid circulation lines 40a and 40b may be defined by lengths of flexible tubing. The fluid circulation lines 40a, 40b may be provided with a connector 42 for use in selective interconnection to and disconnection from a fluid conditioning assembly, wherein a thermal exchange fluid may be circulated through the pad 10, as will be further described hereinbelow.

As best illustrated in Figs. 2 - 4, the pad 10 may include a flexible base member 14 and a flexible film layer 15 that are interconnected to define the fluid circulation layer of pad 10, wherein the fluid circulation layer has an internal volume between the base member 14 and film layer 15. Further, pad 10 may comprise a flexible hydrogel layer 16 interconnected to the film layer 15. As will be further described, the hydrogel layer 16 provides for thermal conduction between the circulated thermal exchange fluid and a patient, and further presents an adhesive surface 16a to establish and maintain intimate contact with a skin region of a patient so as to optimize thermal exchange. The hydrogel layer may extend across a portion, a majority, or substantially the entirety of one side of the fluid circulation layer.

A removable liner layer 17 may be provided to cover the adhesive surface 16a prior to use. Further, an optional outer layer 18 may be provided on another side of the fluid containing layer.

As illustrated in Figs. 2 and 4, the base member 14 may have two sets of one or more holes 14c extending therethrough, wherein one set is disposed in aligned relation with inlet port 12a and the other set is disposed in aligned relation with outlet port 12b. Similarly, optional layer 18 may have two sets of one or more holes 18c extending therethrough, wherein one set is

disposed in aligned relation with inlet port 12a and the other set is disposed in aligned relation with outlet port 12b. In turn, circulated fluid may flow from inlet port 12a through the first sets of the holes and into the fluid circulation layer, then out of the fluid containment layer via the second sets of holes and outlet port 12b.

As shown in Figs 2 and 4, the fluid circulation layer may comprise one or a plurality of fluid channels to direct fluid flow between the inlet port 12a and outlet port 12b. In that regard, the base member 14 may include one or a plurality of rib members 14a that project from a base portion 14d and are interconnected to the film layer 15. The fluid channels may extend between adjacent rib members 14a and/or between sealed edges of the pad 10 and/or between rib members 14a and sealed edges of the pad 10.

The fluid channels may be configured to provide for fluid flow across the lateral extent of the pad 10. In some embodiments, the inlet port 12a and fluid channels may be spaced to define a staging region within the fluid containing layer that is adjacent to and fluidly interconnected to a first end of each of a plurality of channels. Further, the outlet port 12b and fluid channels may be spaced to define another staging region within the fluid containing layer that is adjacent to and fluidly interconnected to a second end of each of a plurality of channels.

The rib members 14a may be provided to project from the base portion 14d a distance that defines a geometric height, or thickness, of the internal volume of the fluid circulation layer. As may be appreciated, the rib members 14a may be provided to not only define fluid channels but also to support the film layer 15.

In the later regard, the base member 14 may also comprise a plurality of offset projections 14b that project from the base portion 14d a distance that is substantially the same or different

from the projection distance of rib members 14a. In contemplated arrangements, the rib members 14a and projections 14b all may projection the same distance from base portion 14d, wherein the common distance is between about .06" to .10" from base portion 14d. As such, an internal volume having a geometric height, or thickness, of between about .06" and .10" is provided. In turn, medical pad applications where fluid is circulated, or drawn, through the fluid circulation layer at a negative pressure, the fluid containing layer may maintain an effective internal volume height of at least between about .04" and .08" during circulated fluid flow therethrough. In short, the rib members 14a and projections 14b may be provided to supportably engage the film layer 15 to define and maintain fluid flow passageways through the fluid circulation layer by keeping the film layer 15 from collapsing across the base member 14.

The hydrogel layer 16 may comprise an ultra violet light-cured composition that includes a cross-linking copolymer in an amount between about 15% to 30% by weight of the composition, and preferably in an amount between about 25% to 30% by weight of the composition; water in an amount between about 15% to 40% by weight of the composition, and preferably in an amount of between about 25% to 35% by weight of the composition; and glycerol in an amount between about 25% to 35% by weight of the composition, and preferably in an amount of between about 27.5% to 32.5% by weight of the composition. Further, the composition may comprise potassium chloride, e.g. in an amount between about 1.75% to 2.25% by weight of the composition, and/or (poly)vinyl pyrrolidone, e.g. in an amount between about 1.25% to 1.75% by weight of the composition.

In one implementation, the hydrogel layer 16 may comprise an ultra violet light-cured composition having a formulation as set forth in Table 1 below.

TABLE 1

Material	Percentage by Weight
Glycerin	30±.25%
Water	34±.25%
NaAMPS*/AA co-polymer	28±.25%
Potassium chloride	2±.25%
(Poly)vinyl pyrrolidone	1.5±.25%

* AMPS is a trademark of The Lubrizol Corporation

In such formulation, the cross-linking copolymer comprises sodium 2-acyrylamido–2-methylpropanesulfonate and acrylic acid.

In contemplated embodiments, the hydrogel layer 16 may be provided to have a thermal conductivity of at least about 1.9 cal/hr-cm-°C, and preferably between about 1.9 cal/hr-cm-°C and 2.37 cal/hr-cm-°C. Further, in various arrangements film layer 15 may be provided to have a thermal conductivity of between about 3.44 cal/hr-cm-°C and 4.3 cal/hr-cm-°C.

In some implementations, the adhesive surface of the hydrogel layer may have a tack strength of between about 20g and 65g, as determined according to ISO 9665:1998(E).

In contemplated embodiments, the hydrogel layer may have a thickness of between about .018" and .04". More particularly, the hydrogel layer may have a thickness of between about .022" and .032".

In some implementations, the base member 14 may be defined by a closed foam material (e.g. a polymer foam material) that is heat pressed to form the rib members 14a and projections

14b. The film layer 15 may comprise a heat activatable film (e.g. a polymer material) that may be sealably bonded via a heat lamination process about its periphery to the periphery of the base member 14. Further, the heat lamination process may bond the film layer 15 to interfacing top surfaces of the rib members 14a, and optionally to interfacing top surfaces of the projections 14b.

In some embodiments, the removable liner layer 17 may be provided to peel away from adhesive surface 16a. In that regard, successive portions of the liner layer 17 may be pulled away from adhesive surface 16a to allow for successive adhesive positioning of different portions of adhesive surface 16a at a patient skin region.

Fig. 5 schematically illustrates one embodiment of a system 1 for patient temperature control. The system 1 may include a controller 50 for providing output signal 52 for use in the operation of a fluid conditioning assembly 20, so as to cool, optionally warm, and circulate thermal exchange fluid through one or more medical pad(s) 10.

The fluid conditioning assembly 20 may include a fluid pump 21 for circulating the thermal exchange fluid to a heat exchanger 23 for passage to a fluid coupling interface 30 and pad(s) 10. In one implementation, the controller 50, fluid conditioning assembly 20, and fluid coupling interface 30 may be supportably interconnected to a first support structure 100.

As noted, controller 50 may provide output signals for use in the operation of fluid conditioning assembly 20. More particularly, output signals 52 may include a signal for use in controlling the speed and/or duty cycle of the fluid pump 21 and a signal for controlling a cooling rate of the heat exchanger 23, and optionally, for controlling a warming rate of the heat exchanger 23. For example, the output signals 52 may include a signal for controlling a duty cycle of heat

exchanger 23 and/or for controlling a magnitude of fluid thermal exchange provided by heat exchanger per time unit of operation.

In turn, the output signals 52 may be provided to control thermal exchange between the circulated fluid and a patient P via pad(s) 10. For example, the rate of thermal exchange between the circulated fluid and the patient P may be controlled so as to achieve a desired degree of patient temperature cooling for induced hypothermia and optional patient temperature warming to achieve normothermia.

To generate the output signals 52, the controller 50 may be provided to utilize one or a number of signals provided by one or more sensors comprising system 1. In particular, system 1 may include at least a first fluid temperature sensor 24 for sensing a temperature of the circulated fluid and providing a first fluid temperature signal 25 indicative thereof to controller 10. The first fluid temperature sensor 24 may be provided as part of the fluid conditioning assembly 20 and disposed to sense a temperature of the circulated fluid to be supplied through fluid coupling interface 30 to pad(s) 10. Additionally, controller 10 may be further provided to receive a patient temperature signal 82 from a patient temperature sensor 80, wherein the patient temperature signal is indicative of a sensed temperature of a patient P (e.g., a patient core body temperature).

Optionally, the fluid conditioning system 20 may also include a flow meter sensor 22 for measuring a flow rate of the circulated fluid (e.g., between the pump 21 and heat exchanger 22) and providing a flow rate signal 26 indicative thereof to controller 10, and a second fluid temperature sensor (not shown in Fig. 1) for sensing a temperature of the circulated fluid returning from thermal exchange module 40 (e.g., upstream of pump 21) and providing a second fluid temperature signal indicative thereof to controller 10. The flow rate signal 26 and/or second fluid

temperature signal may also be utilized by controller 10 to generate one or more of the output signals 12a.

As shown, the fluid coupling interface 30 may be provided for selective fluid interconnection with one or more medical pad(s) 10 that may be utilized for thermal exchange with a patient P. For purposes of fluidly interconnecting fluid circulation lines 40a, 40b with fluid conditioning assembly 20, the connecter 42 may be configured for selective connection to and disconnection from a compatible connecter 70 provided on a reusable hose assembly that is interconnectable to and disconnectable from fluid at interface 30. In that regard, connectors may be employed as taught in U.S. Patent No. 6,802,855, hereby incorporated by reference in its entirety.

Fig. 6 illustrates an embodiment of a fluid conditioning assembly 20 for use in the system embodiment of Fig. 5. As shown, fluid conditioning assembly 20 includes fluid pump 21 for pumping fluid through a flow meter 22 in to heat exchanger 23. Upon operation of fluid pump 21, fluid may be drawn from heat exchanger 23 through outlet line 27, through an outlet port 34 of fluid coupling interface 30, through the fluidly interconnected medical pad(s) 10, through inlet port 33 of fluid coupling interface 30, and through inlet line 28. As may be appreciated, the described operation may advantageously establish a negative pressure in medical pad(s) 10 to draw the circulated fluid therethrough. By way of example, a negative pressure of between about -.5 psi and -10 psi may be provided.

Heat exchanger 23 may include a circulation tank 210 to receive the circulated fluid from fluid pump 21. In order to provide for an adequate amount of fluid, heat exchanger 23 may also optionally include a supply tank 214 for containing fluid that may flow into circulation tank 210 as

needed in order to maintain a predetermined minimum amount of fluid in circulation tank 210 for flow in the described arrangement.

Heat exchanger 23 may further include a chiller tank 212 and a mixing pump 230 for pumping fluid from within circulation tank 210 into chiller tank 212. Additionally, heat exchanger 23 may include a chiller pump 232 and an evaporator/chiller 234, wherein upon operation of chiller pump 233 fluid may be pumped from chiller tank 212 through evaporator/chiller 234 and back into chiller tank 212 to yield cooling of fluid within chiller tank 212. In turn, fluid contained within chiller tank 212 may flow back into circulation tank 210 (e.g., by flowing over a barrier), wherein the fluid contained in circulation tank 210 may be cooled to a desired temperature via operation of mixing pump 230, chiller pump 232, and evaporator/chiller 234.

In that regard, operation of mixing pump 230, chiller pump 232, and evaporator/chiller 234 may be controlled by the output signals 52 of controller 50. As described above, the output signals 52 may be generated by controller 50 utilizing the first temperature signal 25 provided by first temperature sensor 24. As shown in Fig. 6 the first temperature sensor 24 may be located to sense the temperature of the fluid in circulation tank 210.

As further shown in Fig. 6, a second fluid temperature sensor 26 may be provided downstream of inlet port 33 to sense the temperature of the circulated fluid that is returned from the pad(s) 10. The second fluid temperature sensor 26 may provide a second temperature signal to controller 50 indicative of the sensed temperature for use in generation of output signals 52. Further, a third fluid temperature sensor 227 may be provided to sense the temperature of fluid within chiller tank 212 and provide a third temperature signal indicative of the sensed temperature. In turn, the third temperature signal may be utilized by controller 50 to generate output signals 52. To provide redundancy in relation to the first fluid temperature sensor 24, a fourth fluid

temperature sensor 228 may also be provided within circulation tank 210 to provide a fourth temperature signal indicative of the sensed temperature for redundant potential usage by controller 50 in generating output signals 52.

In the arrangement illustrated in Fig. 6, a fluid pressure sensor 28 may also be provided to sense the pressure of the circulated fluid returning from medical pad(s) 10. In turn, the pressure sensor 28 may provide a pressure signal to controller 50 indicative of the sensed pressure. In turn, controller 50 may utilize the pressure signal to generate output signals 52 provided to fluid pump 21, e.g., to control the speed of fluid pump 21 to provide for a desired negative pressure within the medical pad(s) 10.

With further reference to Fig. 6, heat exchanger 23 may include a heater 229 for selective heating of the fluid contained in circulation tank 210. In that regard, heater 229 may be provided to receive output signals 52 from controller 50 to provide a desired degree of heating to the fluid in circulation tank 210. As may be appreciated, operation of heater 229 may be utilized to heat the circulated fluid so as to effect patient rewarming in various embodiments.

Fig. 7 illustrates one embodiment of a controller 50. The controller 50 may be computer-based (e.g., a microprocessor) and may include a programmable control module 120 and a user interface 110 for receiving user control input and for providing corresponding signals 112 to the programmable control module 120. User interface 110 may be further adapted to receive signals 114 from the programmable control module 120 for use in the display of control and measured data and for operative, interactive interface with a user at user interface 110.

The programmable control module 120 may be provided to store control data (e.g., via a computer readable medium) and generate signals in corresponding relation to a plurality of

different temperature control phases. In that regard, the programmable control module may comprise control logic for utilizing the control data to provide output signals to the heat exchanger 23 and/or the fluid pump 21, wherein the temperature of the circulated fluid is controlled in a predetermined manner for each of the plurality of different temperature control phases. Additionally or alternatively, the programmable control module 120 may be provided to facilitate the establishment of one or more programmed protocols that each comprise control data for use in the control of each of the plurality of temperature control phases. By way of example, a given protocol may comprise control data that includes target patient temperature data for each of a plurality of treatment phases. Further, for one or more of the phases, the protocol may comprise control data comprising a set duration for thermal treatment. As may be appreciated, the user interface 110 may be adapted for use in receiving user input to establish the control data corresponding with each of the plurality of different patient temperature control phases on a protocol-specific basis.

For each given protocol the programmable control module 120 may provide output signals 52 to at least the heat exchanger 23, and optionally to fluid pump 21, on a phase-specific basis. In turn, thermal exchanger 23 may be provided to responsively change the temperature of the circulated fluid to affect a desired thermal exchange with a patient, e.g., to cool, maintain the temperature of, or warm a patient via contact thermal exchange via contact pad(s) 90. For example, and as noted above, heat exchanger 23 may comprise various componentry which operate to change the temperature of the circulated fluid in corresponding relation to control signals 52 output from the programmable control module 120.

As discussed above, system 1 may comprise a first fluid temperature sensor 24 for sensing the temperature of the circulated fluid on an ongoing basis and providing a corresponding first fluid temperature signal 25 to the controller 50. Further, patient temperature sensor 80 may

be provided to sense the temperature of the patient P on an ongoing basis and provide corresponding signal 82 to the controller 50. In turn, the signals may be employed by the programmable control module 120, together with control data and preset algorithms, to generate (e.g., via the processor logic) the control signals 52 provided to heat exchanger 23, so as to yield the desired temperature of the circulated fluid (e.g., on a single phase or phase specific basis).

In one approach, the control data for a first phase of the plurality of different control phases may be established so that, during the first phase, the circulated fluid may be cooled to so that the patient reaches an established target patient temperature (e.g., corresponding with induced hypothermia). For such purposes, the controller 50 may utilize a patient temperature signal 82 as referenced above to determine whether or not and when a patient has reached the established target patient temperature (e.g., by comparison of the corresponding patient temperature to the established target patient temperature) and to provide output signals 52 to the heat exchanger 23 and/or fluid pump 21 responsive thereto. In one implementation, the circulated fluid may be cooled at a predetermined rate (e.g., a predetermined maximum rate) to cool a patient to the established target patient temperature as rapidly as possible (e.g., within predetermined system limits).

Optionally, the control data for the first phase of the plurality of different control phases may further comprise an established duration measure, wherein once the established target patient temperature is reached the patient is maintained at the established target patient temperature for any remaining portion of the established duration measure. Alternatively, the control data for a second phase of the plurality of different control phases may be established so that, during the second phase, the circulated fluid may be maintained at a temperature so that, via thermal exchange at medical pad(s), the patient is maintained at the established target patient temperature for an established duration of the second phase. Again, for such purposes, the

controller 10 may utilize a patient temperature signal 82, as referenced above (e.g., to compare the corresponding patient temperature to the established target patient temperature) and to provide output signals 52 to the heat exchanger 23 and/or fluid pump 21 responsive thereto.

In further conjunction with the described approach, the control data for an additional phase after the first phase (e.g., a second phase or a third phase of the plurality of different control phases) may be established so that, during such phase, the circulated fluid may be warmed (e.g., at a predetermined rate) so that the patient reaches another established target patient temperature (e.g., corresponding with normothermia), and optionally, so that once such another established target patient temperature is reached, the patient is maintained at the another established target patient temperature for any remaining balance of an established duration of the additional phase or until the thermotherapy procedure is manually terminated by a user. For such purposes, the controller 50 may again utilize a patient temperature signal 82, as referenced above (e.g., to compare the corresponding patient temperature to the another established target patient temperature), and to provide output signals 52 to the heat exchanger 23 and/or fluid pump 21 responsive thereto.

As noted, the controller may comprise a user interface 110 for receiving user input and providing user control signals, wherein the control logic of the programmable processor control module 110 utilizes the user control signals together with the control data to provide the output signals 52. The user interface 110 may be further provided to establish and modify the control data stored by the programmable control module.

In some arrangements, the programmable control module may be operable to store at least two protocols comprising corresponding, different control data. In turn, the user interface

110 may be employable by user to select either of the two protocols for use by the programmable control module in generating the output signals.

Optionally, the user interface 110 may be provided to include a graphic display to visually present a plot of a target patient temperature adjustment rate that is based on the stored control data for a plurality of different temperature control phases. Further, the graphic display may be operable to display a plot of a sensed patient temperature (e.g., as sensed by the patient temperature sensor) in corresponding time relation to the plot of the target patient temperature adjustment rate. Further, the graphic display may be operable to display a plot of a sensed temperature of the circulated fluid (as sensed by the first fluid temperature sensor) in corresponding time relation to the plot of the target patient temperature adjustment rate.

In relation to one example of system 1, the fluid conditioning assembly 20 may utilize the Arctic Sun 5000 Temperature Management System product of Medivance, Inc., located in Louisville, Colorado, USA.

Fig. 8 illustrates one embodiment of a method 400 for controlling the temperature of a patient via control of the temperature of the circulated fluid in a multi-phase temperature control system. As illustrated, the method 400 may include an initial step 402 of establishing a protocol that includes target patient temperatures for a plurality of different temperature control phases (e.g., two or more non-overlapping phases having different patient temperature exchange objectives). Such phases may be successive in time and/or spaced in time. The establishment of a protocol may be achieved via use of the programmable control module 120 and operatively interconnected user interface 110 of Fig. 3.

By way of example, the protocol may be established to include target patient temperatures for at least three phases. Such an approach facilitates a procedure in which a patient is cooled to a first target patient temperature in a first phase of therapy, maintained at or within a predetermined range of a second target patient temperature during a second phase (e.g., equal or different than the first target temperature), and warmed to a third target patient temperature during a third phase. In other embodiments, following a third phase of therapy it may be desirable to establish a fourth target patient temperature for use in temperature control during a fourth phase of therapy.

The method may further include a step 404 of controlling the temperature of the circulated fluid based on the protocol for each of the plurality of phases, e.g., via control of the heat exchanger 23 via output signals 52 to control the temperature of the circulated fluid of Figs. 5 – 7. In that regard, the protocol may be further established at step 406 so as to include a set duration for one or more of the phases, e.g., via use of a programmable control module 120 and user interface 110 of Fig. 3. In turn, the controlling step 404 may be carried out during such phase(s) for a duration(s) that corresponds with the set duration.

In one approach, the controlling step 404 may be carried out in step 408 for each phase by controlling the temperature of the circulated fluid based upon a sensed patient temperature and the target patient temperature for such phase, e.g., via use of a patient temperature signal 82 from patient temperature sensor 80 by the programmable control module 120 of Fig. 1. By way of example, the patient temperature may be sensed on an ongoing basis during a given phase and compared to the corresponding target patient temperature for such phase. Based upon such comparison, system 1 may provide for cooling and/or heating of the circulated fluid according to any of a plurality of pre-established algorithms, e.g., via control of the heat exchanger 23 by the programmable multi-phase control module 120 of controller 50 of Fig. 5.

In one approach, a control algorithm may provide for simply turning on/off the cooling/heating componentry of the heat exchanger 23 of system 1 (e.g., evaporator/chiller 234, chiller pump 232, and mixing pump for fluid cooling, and heater 229 for fluid heating) in intervals that depend upon a degree of difference reflected by comparison of the sensed patient temperature and target patient temperature. In another approach, a control algorithm may provide for controlling an output magnitude of the cooling/heating componentry of the heat exchanger 23 of system 1 (e.g., evaporator/chiller 234, chiller pump 232, and mixing pump for fluid cooling, and heater 229 for fluid heating) based upon a degree of difference reflected by comparison of the measured patient temperature and target patient temperature.

In another approach, the controlling step 404 may be completed as step 410 for a given phase by controlling the temperature of a thermal exchange medium based upon a sensed patient temperature, an established target patient temperature for such phase, and an established set duration for such phase. For example, utilization of the noted parameters accommodates the determination and control use of a target patient temperature adjustment rate for the phase, wherein gradual patient cooling/warming over a desired time period may be facilitated.

In yet another approach, one or more sensed circulated fluid temperature(s) (e.g., as sensed by first temperature sensor 23 and optionally second temperature sensor 26) may be employed together with a sensed patient temperature (e.g., as sensed by patient temperature sensor 80) and established target patient temperature (e.g., comprising control data stored at programmable control module 110) to control the heating/cooling of the circulated fluid. Such an approach may yield enhanced system response.

The illustrated method 400 may further provide for modification of a given protocol based on user input at step 412, e.g., via user input at the user interface 110 of Fig. 7. In this regard, a modified protocol may be employed for the remaining duration of a modified phase(s) and for any phase(s) that have not yet been initiated.

In the illustrated method, a given phase may be automatically terminated at step 414 by expiration of a corresponding set duration included within the programmed protocol for such phase. In that regard, the termination of a given phase may generally correspond with a change in the mode (e.g., cooling or heating) or a change in the magnitude of thermal exchange between the circulated fluid and a patient.

Method 400 may also provide for the termination and initiation of successive phases at step 416 in response to a comparison of a sensed patient temperature and a target patient temperature. That is, upon determining that a target patient temperature has been reached during a given phase (e.g., via comparison of a sensed patient temperature and a target patient temperature for an initial phase of treatment), such phase may be automatically terminated and a successive phase automatically initiated. Alternatively and/or additionally, the method 400 may also provide for the termination and initiation of successive phases in response to the expiration of a set duration for a first one of the two successive phases. The automatic phase termination/initiation features may be selectively established by a user for a given protocol on a phase-specific basis.

The foregoing description of the present invention has been presented for purposes of illustration and description. Furthermore, the description is not intended to limit the invention to the form disclosed herein. Consequently, variations and modifications commensurate with the above teachings, and skill and knowledge of the relevant art, are within the scope of the present

invention. The embodiments described hereinabove are further intended to explain known modes of practicing the invention and to enable others skilled in the art to utilize the invention in such or other embodiments and with various modifications required by the particular application(s) or use(s) of the present invention. It is intended that the appended claims be construed to include alternative embodiments to the extent permitted by the prior art.

CLAIMS

What Is Claimed Is:

1. A medical pad for contact and thermal exchange with a patient, comprising:

a fluid circulation layer for containing a thermal exchange fluid circulatable therethrough;

a first port fluidly interconnected to the fluid circulation layer for circulating the thermal exchange fluid into the fluid circulation layer;

a second port fluidly interconnected to the fluid circulation layer for circulating the thermal exchange fluid out of the fluid circulation layer; and,

a hydrogel layer interconnected to and extending across one side of the fluid circulation layer to define an adhesive surface for adherence to a patient's skin, wherein said hydrogel layer comprises an ultra violet light-cured composition that includes:

a cross-linking copolymer in an amount of between about 15% to 30% by weight of said composition;

water in an amount of between about 15% to 40% by weight of said composition; and,

glycerol in an amount of between about 25% to 35% by weight of the composition.

2. The medical pad recited in Claim 1, wherein the ultra violet light-cured composition includes the cross-linking copolymer in an amount of between about 25% to 30% by weight of said composition; the water in an amount of between about 25% to 35% by weight of said composition; and the glycerol in an amount of between about 27.5% to 32.5% by weight of the composition.

3. The medical pad recited in Claim 1, wherein said hydrogel layer has a thermal conductivity of at least about 1.9 cal/hr-cm-°C.

4. The medical pad recited in Claim 3, wherein said hydrogel layer has a thermal conductivity of between about 1.9 cal/hr-cm-°C and 2.37 cal/hr-cm-°C.

5. The medical pad recited in Claim 1, wherein said adhesive surface has a tack strength of between about 20g and 65g, as determined according to ISO 9665:1998(E).

6. The medical pad recited in Claim 5, wherein said hydrogel layer has a thermal conductivity of between about 1.9 cal/hr-cm-°C and 2.37 cal/hr-cm-°C.

7. The medical pad recited in Claim 1, wherein the hydrogel layer has a thickness of between about .018" and .04".

8. The medical pad recited in Claim 7, wherein the hydrogel layer has a thickness of between about .022" and .032".

9. The medical pad recited in Claim 1, wherein said fluid circulation layer is defined by:

a flexible film layer; and,

a flexible base member interconnected to said film layer for containing the circulatable thermal exchange fluid in an internal volume defined therebetween, wherein said hydrogel layer has a thermal conductivity of at least about 1.9 cal/hr-cm-°C.

10. The medical pad as recited in Claim 1, wherein said fluid circulation layer defines an internal volume having a geometric height across the fluid circulation layer of at least about .06".

11. The medical pad as recited in Claim 10, wherein said fluid circulation layer comprises:

a flexible film layer; and,

a flexible base member interconnected to said film layer for containing the circulatable thermal exchange fluid in an internal volume defined therebetween, wherein the flexible base member includes a plurality of rib members interconnected to the flexible film layer.

12. The medical pad as recited in Claim 11, wherein the plurality of rib members define a plurality of fluid flow channels through the fluid circulation layer.

13. The medical pad as recited in Claim 12, wherein the flow channels direct flow of the circulatable fluid flow between the inlet port and the outlet port.

14. The medical pad as recited in Claim 11, wherein said rib members project from a base portion of the base member by a distance that defines said geometric height of the circulation layer.

15. The medical pad as recited in Claim 14, wherein said projection distance is between about .06" and .1".

16. The medical pad as recited in Claim 15, wherein said base member further includes a plurality of offset projections that project from the base portion of the base member by a distance substantially equal to said projection distance.

17. The medical pad as recited in Claim 16, wherein said hydrogel layer has a thermal conductivity of between about 1.9 cal/hr-cm-°C and 2.37 cal/hr-cm-°C.

18. The medical pad recited in Claim 17, wherein said adhesive surface has a tack strength of between about 20g and 65g, as determined according to ISO 9665:1998(E).

19. The medical pad as recited in Claim 18, wherein the ultra violet light-cured composition includes the cross-linking copolymer in an amount of between about 25% to 30% by weight of said composition; the water in an amount of between about 25% to 35% by weight of said composition; and the glycerol in an amount of between about 27.5% to 32.5% by weight of the composition.

20. The medical pad as recited in Claim 19, wherein the hydrogel layer has a thickness of between about .022" and .032".

21. A system for contact thermal exchange with a patient, comprising:

a medical pad including:

a fluid circulation layer for containing a thermal exchange fluid circulatable therethrough;

a first port fluidly interconnected to the fluid circulation layer for circulating the thermal exchange fluid into the fluid circulation layer;

a second port fluidly interconnected to the fluid circulation layer for circulating the thermal exchange fluid out of the fluid circulation layer; and,

a hydrogel layer interconnected to and extending across one side of the fluid circulation layer to define an adhesive surface for adherence to a patient's skin, wherein said hydrogel layer comprises an ultra violet light-cured composition that includes:

a cross-linking copolymer in an amount of between about 15% to 30% by weight of said composition;

water in an amount of between about 15% to 40% by weight of said composition; and,

glycerol in an amount of between about 25% to 35% by weight of the composition;

a fluid conditioning assembly including:

a fluid pump for circulating the thermal exchange fluid through the heat exchanger and medical pad; and,

a heat exchanger for use in controlling a temperature of the circulated fluid;

a controller for providing output signals for controlling operation of the heat exchanger to provide for temperature control of the circulated fluid in a predetermined manner.

22. The system as recited in Claim 21, wherein the fluid pump is operable to circulate the fluid through the pad at a negative pressure.

23. The system as recited in Claim 21, further comprising:

a patient temperature sensor for sensing a patient temperature and providing a patient temperature signal indicative thereof, wherein the controller is operable to utilize the patient temperature signal in providing the output signals to the heat exchanger.

24. The system as recited in Claim 21, wherein the fluid conditioning assembly includes:

a fluid temperature sensor for sensing a temperature of the circulated fluid and for providing a fluid temperature signal indicative thereof, wherein the controller is operable to utilize the fluid temperature signal in providing the output signals to the heat exchanger.

25. The system as recited in Claim 21, wherein the hydrogel layer of the medical pad has a thermal conductivity of between about 1.9 cal/hr-cm-°C and 2.37 cal/hr-cm-°C.

26. The system as recited in Claim 25, wherein said fluid circulation layer of the medical pad defines an internal volume having a geometric height across the fluid circulation layer of at least about .06".

27. The system as recited in Claim 26, wherein the ultra violet light-cured composition of the hydrogel layer of the medical pad includes the cross-linking copolymer in an amount of between about 25% to 30% by weight of said composition; the water in an amount of between about 25% to 35% by weight of said composition; and the glycerol in an amount of between about 27.5% to 32.5% by weight of the composition.

28. The system as recited in Claim 27, wherein the hydrogel layer of the medical pad has a thickness of between about .022" and .032".

29. The system as recited in Claim 28, wherein said fluid circulation layer of the medical pad defines an internal volume having a geometric height across the fluid circulation layer of at least about .06".

30. The system as recited in Claim 29, wherein said fluid circulation layer of the medical pad comprises:

a flexible film layer; and,

a flexible base member interconnected to said film layer for containing the circulatable thermal exchange fluid in an internal volume defined therebetween, wherein the flexible base member includes a plurality of rib members interconnected to the flexible film layer; and,

wherein said rib members project from a base portion of the base member by a distance that defines said geometric height of the circulation layer.

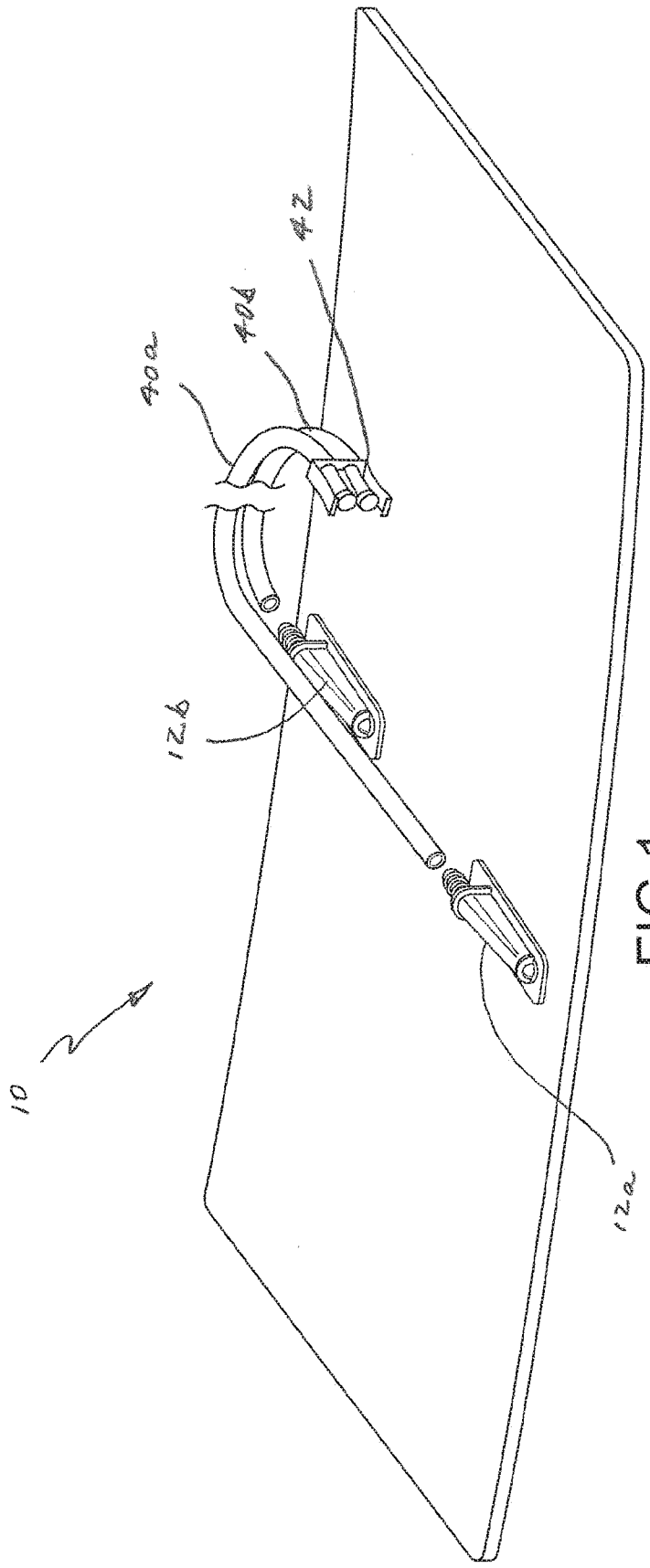


FIG.1

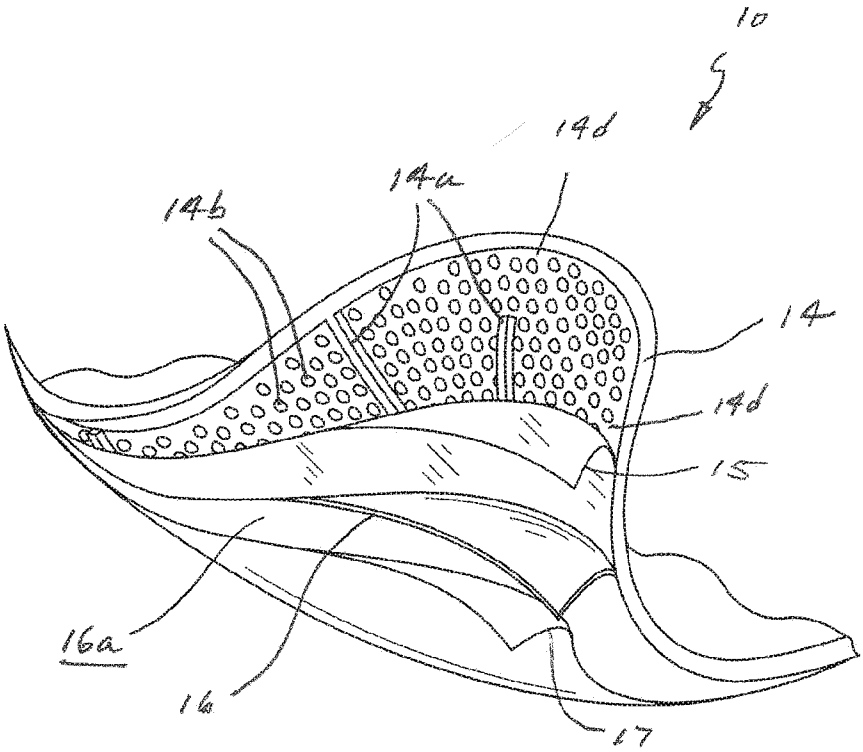


FIG.2

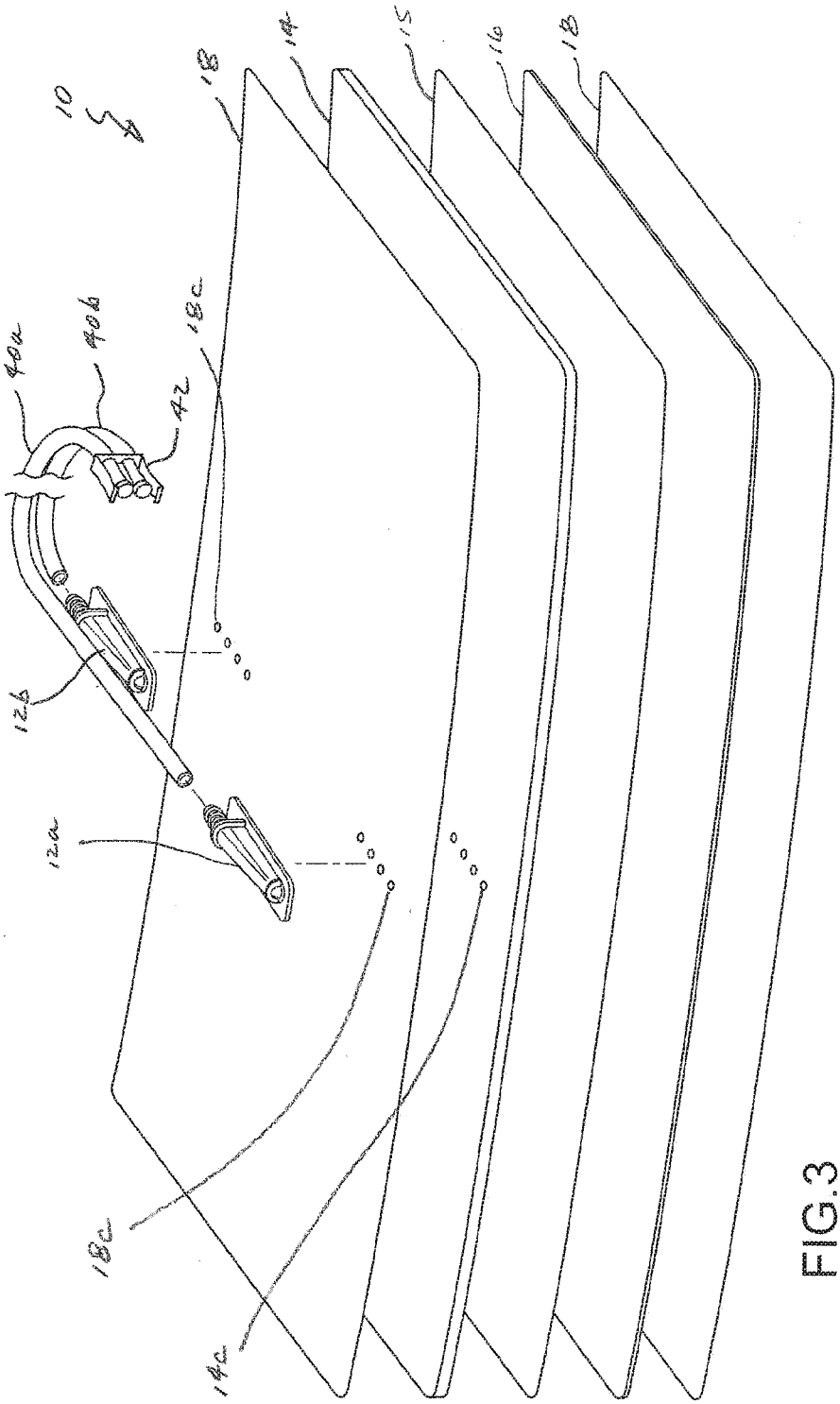


FIG.3

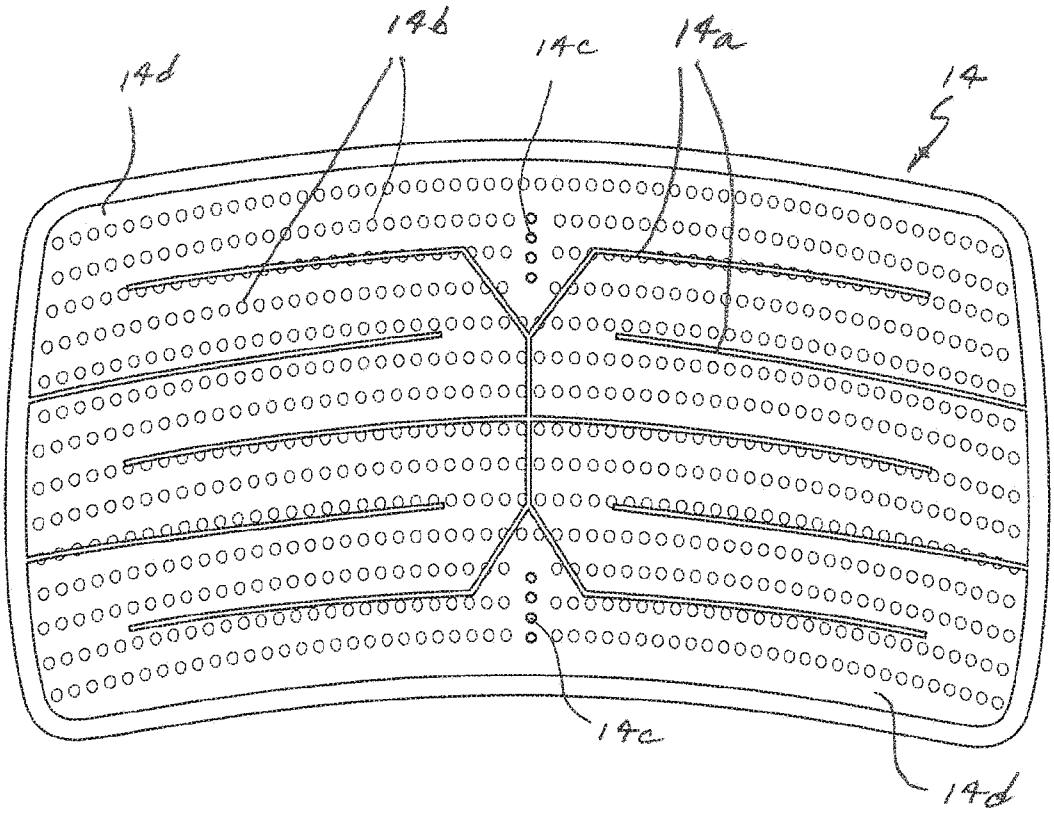
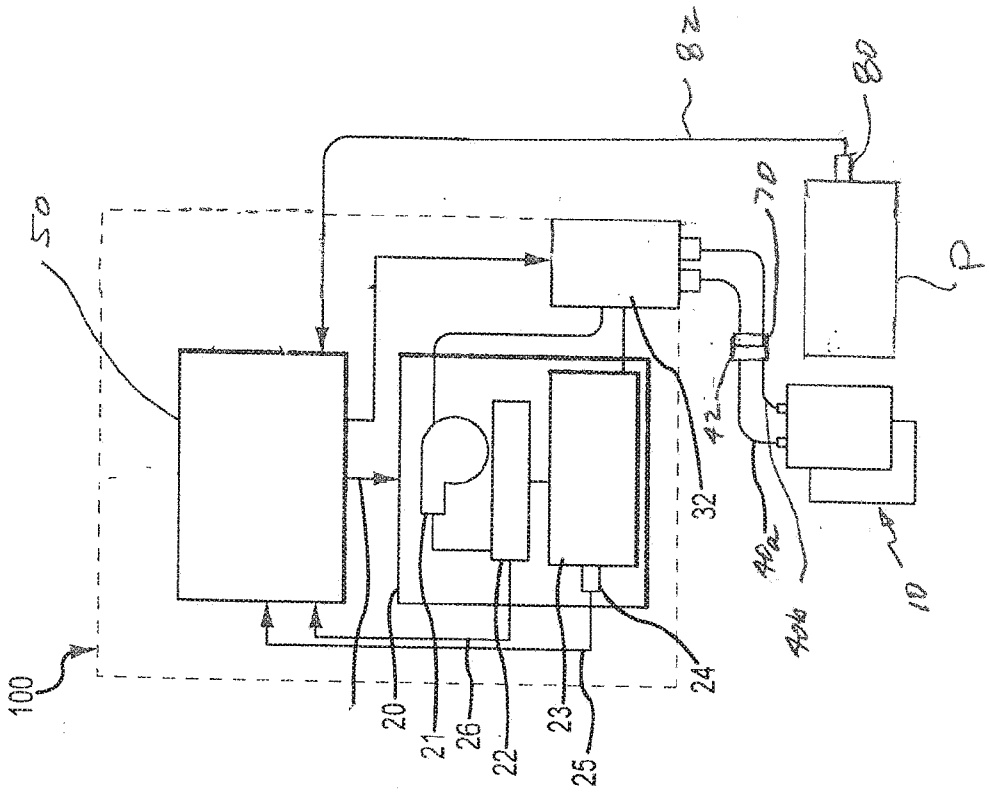


FIG.4

FIG. 5



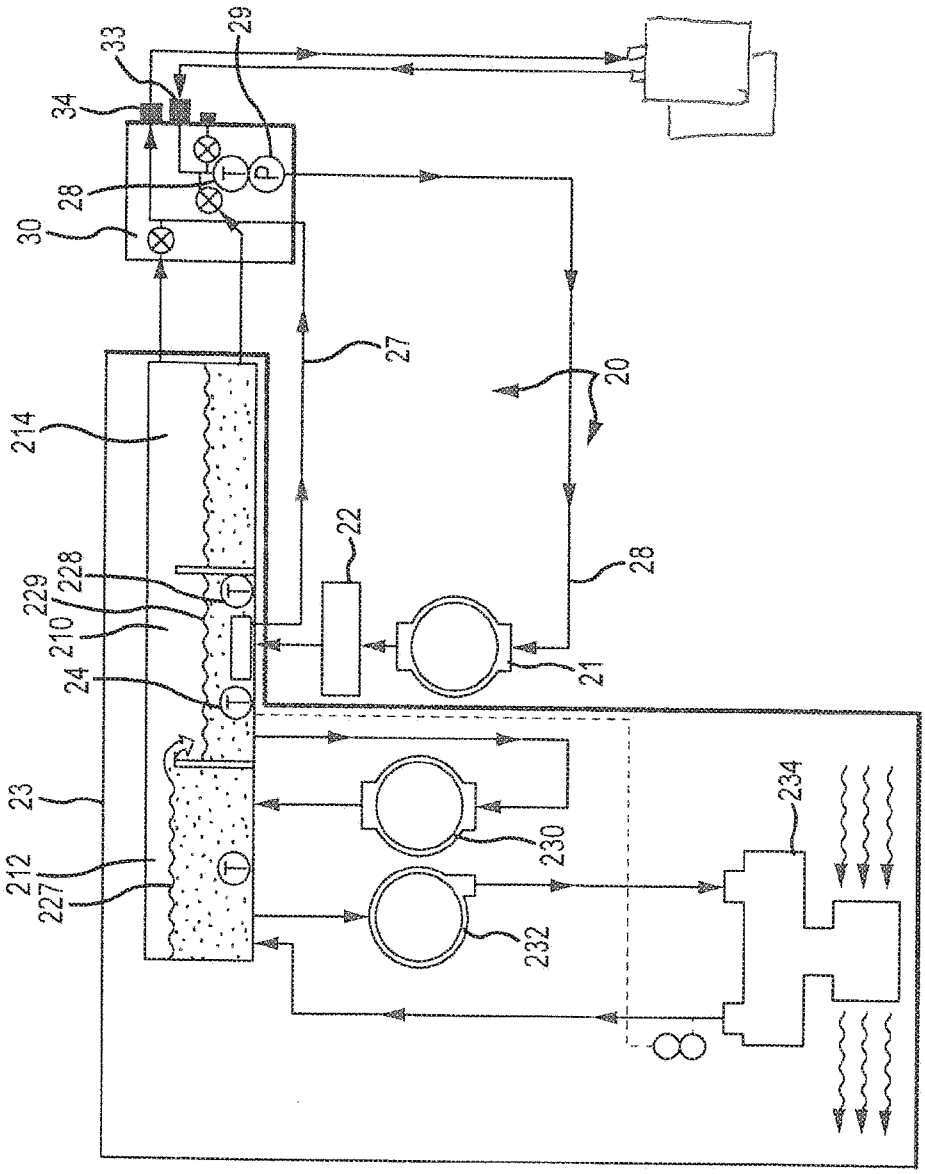

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FIG. 6

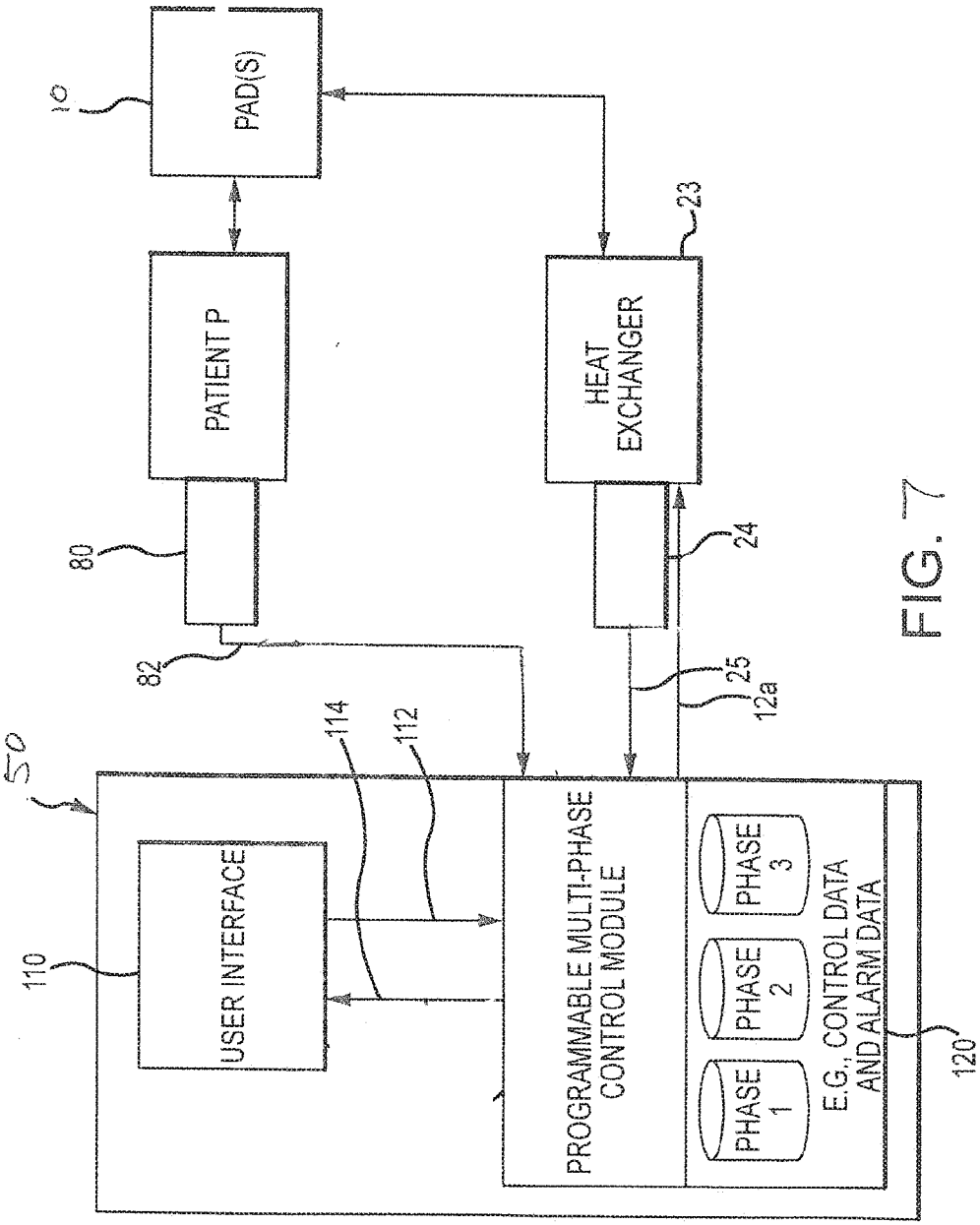
10
PAD(S)
23
PATIENT P
HEAT EXCHANGER
80
24
82
25
12a
114
112
50
110
USER INTERFACE
PROGRAMMABLE MULTI-PHASE CONTROL MODULE
PHASE 1
PHASE 2
PHASE 3
E.G., CONTROL DATA AND ALARM DATA
120

FIG. 7

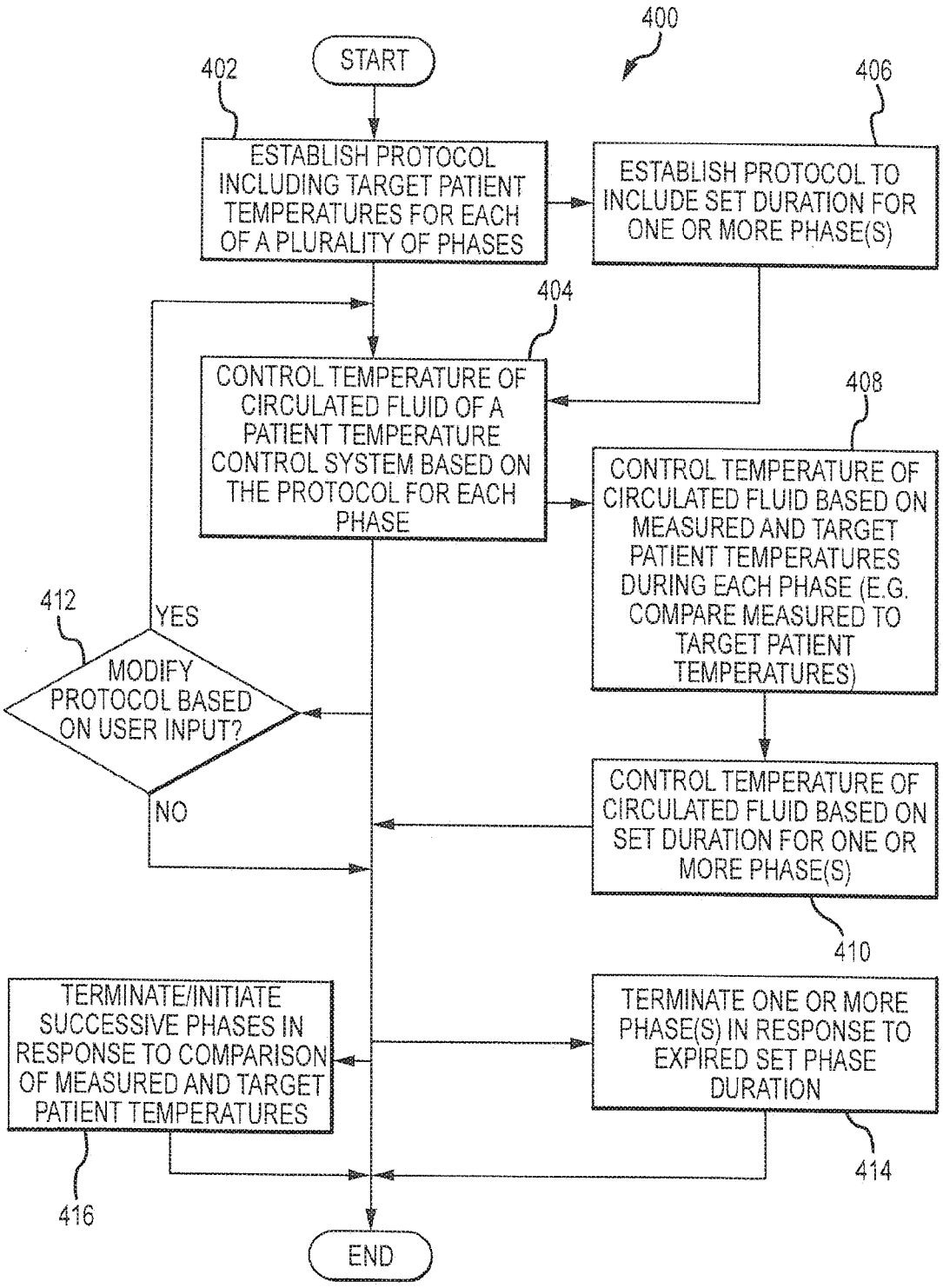
400
START
402
406
ESTABLISH PROTOCOL INCLUDING TARGET PATIENT TEMPERATURES FOR EACH OF A PLURALITY OF PHASES
ESTABLISH PROTOCOL TO INCLUDE SET DURATION FOR ONE OR MORE PHASE(S)
404
CONTROL TEMPERATURE OF CIRCULATED FLUID OF A PATIENT TEMPERATURE CONTROL SYSTEM BASED ON THE PROTOCOL FOR EACH PHASE
408
CONTROL TEMPERATURE OF CIRCULATED FLUID BASED ON MEASURED AND TARGET PATIENT TEMPERATURES DURING EACH PHASE (E.G. COMPARE MEASURED TO TARGET PATIENT TEMPERATURES)
412
YES
MODIFY PROTOCOL BASED ON USER INPUT?
NO
CONTROL TEMPERATURE OF CIRCULATED FLUID BASED ON SET DURATION FOR ONE OR MORE PHASE(S)
410
TERMINATE/INITIATE SUCCESSIVE PHASES IN RESPONSE TO COMPARISON OF MEASURED AND TARGET PATIENT TEMPERATURES
TERMINATE ONE OR MORE PHASE(S) IN RESPONSE TO EXPIRED SET PHASE DURATION
414
416
END

FIG. 8

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2016/015688

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61F 7/10 (2016.01)
CPC - A61F 7/10 (2016.01)
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)
IPC(8) - A61B 17/00; A61F 7/00, 7/02, 7/08, 7/10, 13/00, 13/02; B23B 27/00, 27/04 (2016.01)
CPC - A61F 7/00, 2007/0054, 2007/0056, 7/0085, 7/02, 2007/0219, 2007/0226, 7/10, 7/12 (2016.01)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
USPC - 442/63, 118; 602/43; 607/104, 108, 111, 112, 114, 19
(keyword delimited)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
Orbit, Google Patents, Google, Google Scholar
Search terms used: medical pad, heat exchange, thermal, pump, inlet, outlet, controller, temperature, adhesive, cross-link polymer, fluid circulation, hydrogel, water amount, glycerol, ultra violet, thermal conductivity, flexible film, rib, base, projection, ISO 9665, heating pad, cooling pad.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 7,678,716 B2 (YAHIAOUI et al) 16 March 2010 (16.03.2010) entire document	1-30
Y	US 2013/0116760 A1 (MEDIVANCE INCORPORATED) 09 May 2013 (09.05.2013) entire document	1-20
Y	US 6,461,379 B1 (CARSON et al) 08 October 2002 (08.10.2002) entire document	21-30
Y	US 7,892,269 B2 (COLLINS et al) 22 February 2011 (22.02.2011) entire document	23
A	US 2012/0185021 A1 (JOHNSON et al) 19 July 2012 (19.07.2012) entire document	1-30
A	US 2007/0100404 A1 (KO et al) 03 May 2007 (03.05.2007) entire document	1-30

☐ 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
11 March 2016	01 APR 2016
Name and mailing address of the ISA/ Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, VA 22313-1450 Facsimile No. 571-273-8300	Authorized officer Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774