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UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

'09 CV 2872 W NLS

DJO, LLC, a Delaware corporation, Plaintiff, v. VITALWEAR, Inc., a California corporation, Defendant.	CASE NO. COMPLAINT FOR PATENT INFRINGEMENT DEMAND FOR JURY TRIAL

Plaintiff DJO, LLC ("DJO"), for its Complaint against defendant VitalWear, Inc. ("VitalWear"), hereby alleges as follows:

JURISDICTION AND VENUE

1. This is an action for patent infringement arising under the Patent Act of the United States, 35 U.S.C. §§ 271 and 281. This Court has subject matter jurisdiction over the matters complained of under 28 U.S.C. §§ 1331 and 1338.

2. Venue is proper in this judicial district pursuant to 28 U.S.C.

§§ 1391(b) and (c), and 1400(b), in that DJO and VitalWear reside in this district and VitalWear committed acts in this District that are alleged herein to constitute patent infringement.

THE PARTIES

3. DJO is a Delaware corporation having its principal place of business at 1430 Decision Street, Vista, California.

4. VitalWear is a California corporation having its principal place of business at 384 Oyster Point Blvd., Suite 16, South San Francisco, California.

GENERAL BACKGROUND ALLEGATIONS

5. DJO is a leading global developer, manufacturer, and distributor of high-quality medical devices that provide solutions for musculoskeletal health, vascular health, and pain management, including "cold therapy" products, such as the Iceman® Cold Therapy System.

6. On February 2, 1999, United States Patent No. 5,865,841 (the "'841 patent"), entitled "Cold Therapy Apparatus," was duly and legally issued to Paul T. Kolen and Thomas D. Ford. DJO is the assignee and owner of the '841 patent. A true and correct copy of the '841 patent is attached hereto as Exhibit A.

7. On November 9, 1999, United States Patent No. 5,980,561 (the "'561 patent"), entitled "Applying Thermal Therapy To Living Tissue," was duly and legally issued to Paul T. Kolen and Thomas D. Ford. DJO is the assignee and owner of the '561 patent. A true and correct copy of the '561 patent is attached hereto as Exhibit B.

FIRST CLAIM FOR RELIEF AGAINST VITALWEAR

(Patent Infringement — '841 patent)

8. DJO incorporates by reference the allegations contained within paragraphs 1 through 7 of this Complaint as if fully set forth herein.

9. On information and belief, after the '841 patent was issued, VitalWear infringed, and continues to infringe, the '841 patent, both literally and

under the doctrine of equivalents, by making, using, marketing, and selling its cold therapy products, including, but not limited to, products marketed under the names "VitalWrap System," and "RecoveryWrap System."

10. DJO has suffered and, unless this Court issues an injunction, will continue to suffer, irreparable harm for which there is no adequate remedy at law as a result of VitalWear's infringement of the '841 patent. Accordingly, DJO is entitled to a preliminary and permanent injunction enjoining VitalWear from its infringing activities.

11. VitalWear's infringement of the '841 patent has proximately damaged DJO in an amount to be proven at the time of trial.

12. On information and belief, VitalWear's past and continuing infringement of the '841 patent has been, and is, deliberate and willful. VitalWear had prior knowledge of the '841 patent, as evidenced by the fact that VitalWear cited the '841 patent in one of its own patent applications. Thus, this is an exceptional case entitling DJO to an award of treble damages and attorneys' fees pursuant to 35 U.S.C. §§ 284 and 285.

SECOND CLAIM FOR RELIEF AGAINST VITALWEAR

(Patent Infringement — '561 patent)

13. DJO incorporates by reference the allegations contained within paragraphs 1 through 12 of this Complaint as if fully set forth herein.

14. On information and belief, after the '561 patent was issued, VitalWear infringed, and continues to infringe, the '561 patent, both literally and under the doctrine of equivalents, by making, using, marketing, and selling its cold therapy products, including, but not limited to, products marketed under the names "VitalWrap System," and "RecoveryWrap System."

15. DJO has suffered and, unless this Court issues an injunction, will continue to suffer, irreparable harm for which there is no adequate remedy at law as a result of VitalWear's infringement of the '561 patent. Accordingly, DJO

is entitled to a preliminary and permanent injunction enjoining VitalWear from its infringing activities.

16. VitalWear's infringement of the '561 patent has proximately damaged DJO in an amount to be proven at the time of trial.

17. On information and belief, VitalWear's past and continuing infringement of the '561 patent has been, and is, deliberate and willful. On information and belief, VitalWear had prior knowledge of the '561 patent, as evidenced by the fact that VitalWear cited the '841 patent in one of its own patent applications, and the '561 patent is in the same family as the '841 patent. Thus, this is an exceptional case entitling DJO to an award of treble damages and attorneys' fees pursuant to 35 U.S.C. §§ 284 and 285.

PRAYER FOR RELIEF

WHEREFORE, DJO prays for Judgment as follows:

1. For a preliminary and permanent injunction restraining and enjoining VitalWear, and its officers, agents, servants, employees, and attorneys, and any persons who are in active concert or participation with them, from directly or indirectly infringing the '841 and '561 patents;

2. For an order requiring VitalWear, and its officers, agents, servants, employees, and attorneys, and any persons who are in active concert or participation with them, to surrender to DJO all products that infringe the '841 and '561 patents;

3. That DJO be awarded, under 35 U.S.C. § 284, damages adequate to compensate it for VitalWear's infringement of the '841 and '561 patents;

4. That all of DJO's damages be trebled in light of VitalWear's willful and deliberate infringement;

5. That this case be deemed exceptional under 35 U.S.C. § 285, thereby entitling DJO to its reasonable attorneys' fees;

6. For costs of suit incurred herein;

7. For prejudgment interest; and

8. For such other and further relief as this Court deems just and proper.

Dated: December 22, 2009

LATHAM & WATKINS LLP

By _____
Mark A. Finkelstein
Attorneys for Plaintiff
DJO LLC

JURY DEMAND

A trial by jury is hereby demanded on all issues triable to a jury.

Dated: December 22, 2009

LATHAM & WATKINS LLP

By _____
Mark A. Finkelstein
Attorneys for Plaintiff
DJO, LLC

EXHIBIT A

US 5865841A

United States Patent [19]

Kolen et al.

[11] **Patent Number: 5,865,841**

[45] **Date of Patent: Feb. 2, 1999**

[54] **COLD THERAPY APPARATUS**

[76] Inventors: **Paul T. Kolen**, 139 Fourth St., Encinitas, Calif. 92024; **Thomas D. Ford**, 10405 Orozco St., San Diego, Calif. 92124

[21] Appl. No.: **450,641**

[22] Filed: **May 25, 1995**

[30] **Foreign Application Priority Data**

Mar. 1, 1995 [IE] Ireland S950163

[51] **Int. Cl.**[6] **A61F 7/00**

[52] **U.S. Cl.** **607/104**; 607/114; 126/204

[58] **Field of Search** 607/104, 108–112, 607/114; 601/15, 148–152

[56] **References Cited**

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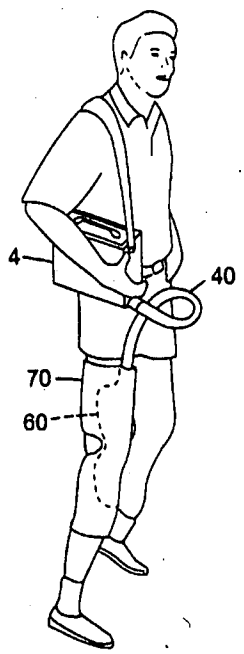
Primary Examiner—Robert L. Nasser

Attorney, Agent, or Firm—Fish & Richardson P.C.

[57] **ABSTRACT**

A thermal therapy apparatus for applying temperature controlled therapy to a therapy site on a mammalian body includes a therapy pad for applying a selected therapy temperature to the therapy site; a recirculating fluid loop, including a fluid channel defined by the therapy pad; a thermal reservoir; a heat exchanger coupling the thermal reservoir with the recirculating fluid loop, the heat exchanger including a pump for circulating fluid through the recirculating fluid loop; and a control mechanism coupled to the heat exchanger for enabling adjustable control of therapy temperature. The heat exchanger selectively mixes fluid recirculating in the fluid loop with fluid from the thermal reservoir in an adjustable mixing ratio to achieve the selected therapy temperature at the therapy site.

11 Claims, 4 Drawing Sheets



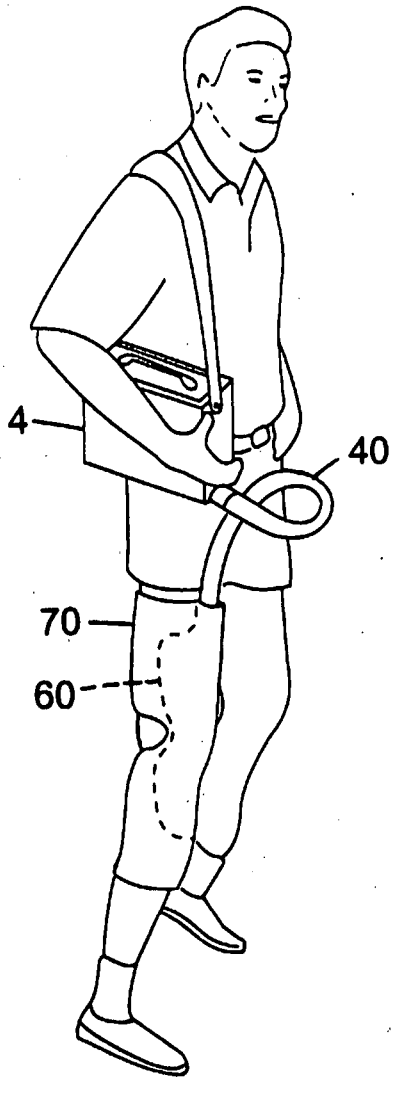


FIG. 1

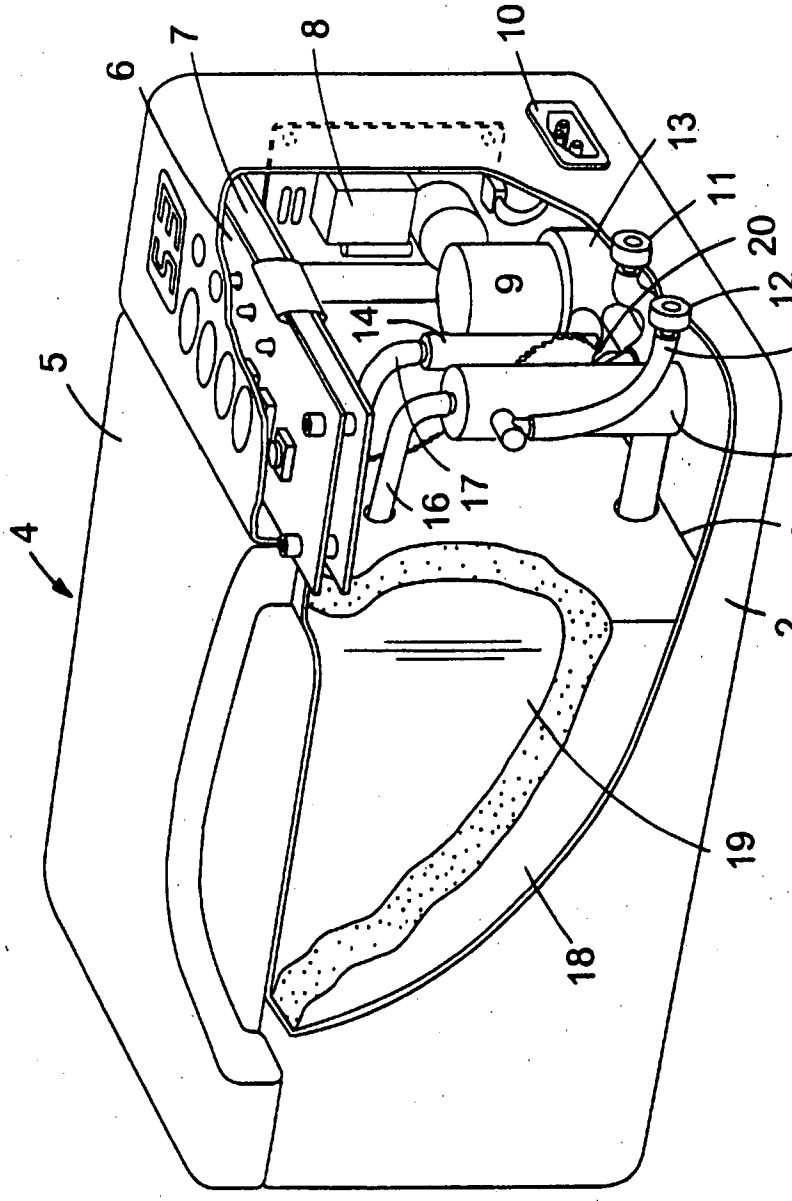


FIG. 2

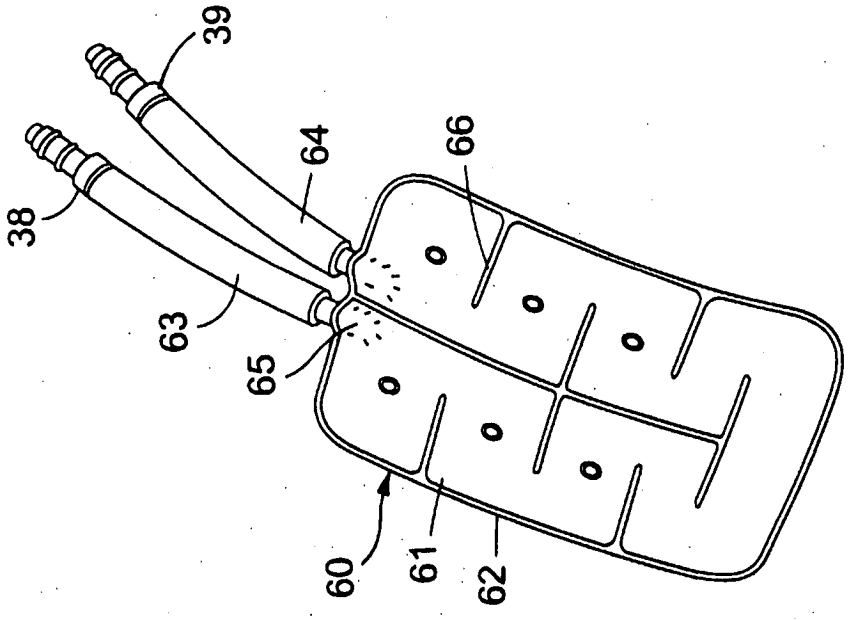
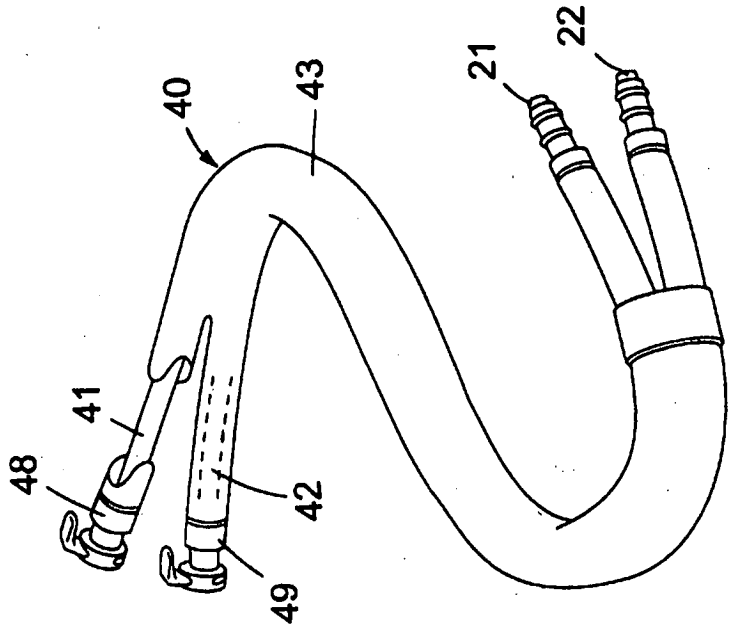


FIG. 3



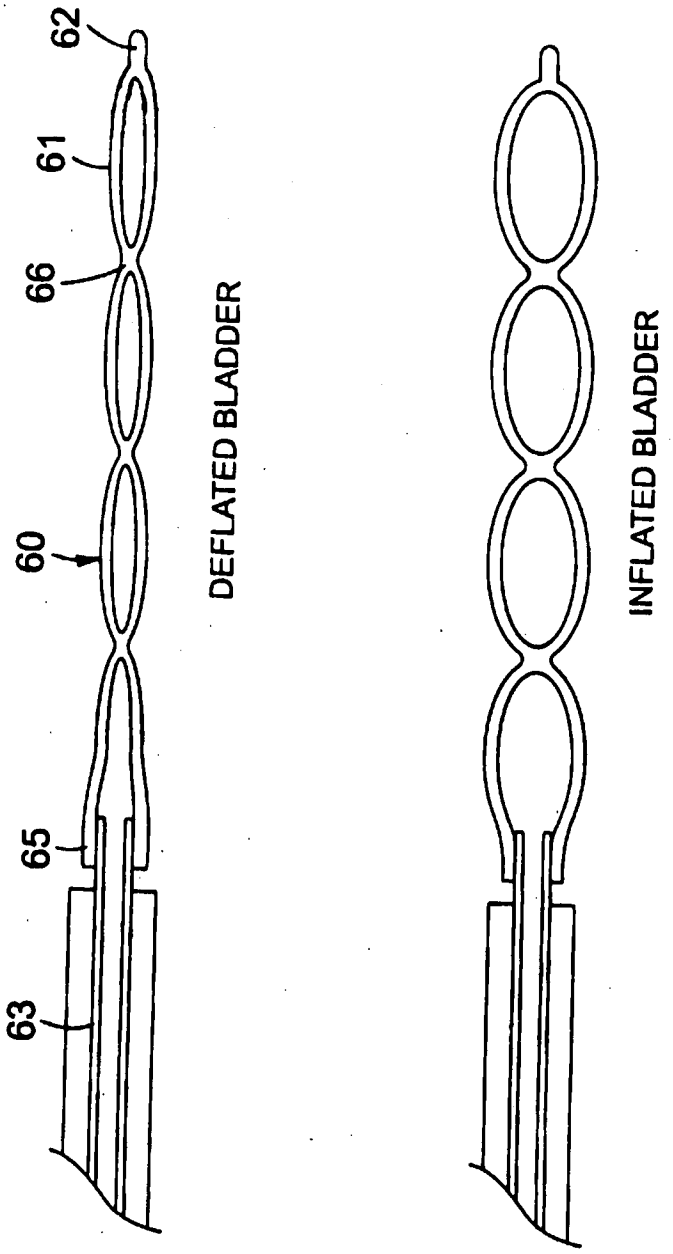


FIG. 4

COLD THERAPY APPARATUS

BACKGROUND OF THE INVENTION

This invention relates to the application of cold or heat to affect heat transfer to or from the human or mammalian body. The necessity for such an application may arise in a wide range of circumstances. Most common are injuries, bruises, sprains, or other trauma to bone, muscle, ligaments, tendons, skin and other forms of mammalian tissue. The application of cold or cooling to reduce swelling, reduce pain and promote healing at the traumatized area of the human or mammalian body is often recommended. Similarly, the application of heat or heating to the human or mammalian body is used to warm up or "loosen-up" joint tissue such as ligaments or tendons prior to use to facilitate an increased range of motion prior to normal or strenuous physical activities.

Other circumstances in which the need for application of cold or heat therapy to the human or mammalian body may arise include post-surgical therapy to reduce pain and swelling and promote healing, as well as in orthopedic therapy, sports medicine therapy and rehabilitation programs and applications. Of particular importance are the areas of athletic injury and subsequent therapy, healing and rehabilitation in humans, and injury and subsequent therapy, healing and rehabilitation in thoroughbred race horses.

The most common method of achieving the desired cooling effect has been application of an ice bag to the desired therapy site. This method has several limitations. Ice bags can be cumbersome to apply, and in the case of animals, for example thoroughbred race horses, may be difficult to maintain on the therapy site. Ice bags can apply uneven cooling to the therapy site, are often difficult to contour to the area of the mammalian body to be treated, and the intensity of cooling is difficult to control. Often the application is either too cold, or not cold enough. A common ice bag has further limitations as well. As the ice melts, an ice bag may leak, causing inconvenience or more serious consequences. Finally, the static application of cold or cooling can become uncomfortable and unpleasant, usually resulting in the subject prematurely terminating the application before the full beneficial affect can be achieved.

A number of variations have been proposed to improve upon the ice bag or pack, but none fully addressed all of its shortcomings. For example, some have been known to use a bag of frozen peas (or other vegetables) as a substitute for an ice bag. The frozen peas allow more uniform cooling of the site, generally contour to the site better than a bag of ice cubes, and apply less severe cooling. Of course, this alternative has a number of drawbacks as well. A bag of frozen peas has limited available cooling capacity, and as with any bag, contouring to a part of the mammalian body such as the human knee can be difficult or impossible, resulting in uneven cold application.

Other variations on the basic ice bag or ice pack include a wrap or strap-on device which holds the source of cooling on the therapy site. These devices generally are designed for use on specific locations on the human body, and generally contour better to the therapy site and are held in place by means of belts or straps. These devices also have several shortcomings, however. Certain types have built-in reservoirs to provide a source of cooling, such as containers of frozen water. These devices must be kept frozen until ready to use, and once their cooling capacity is expired, they must be re-frozen before they can be used again. The intensity of cooling with these wrap or strap-on devices is also difficult to control, and they are capable of applying only static cooling to the site. There are also generally cumbersome, as the source of thermal cooling must be located entirely within the device and held at or on the therapy site.

Also available are chemical cold-packs comprised of two or more chemical substances stored separately in a flexible packet. When needed, the packet is manipulated, causing an internal seal to break and the chemical substances to mix. The substances, when mixed, have an endothermic reaction which causes the packet to cool. While these devices are useful in remote sites and in certain emergency situations, they afford little advantage over the ordinary ice bag. Furthermore, they can generally be used only one time, are of limited cooling capacity or duration, operate at one non adjustable temperature, and are prohibitively expensive for use in a regular cold therapy program.

More recently, a commercially available apparatus for accomplishing the desired cooling of the human knee has been developed which incorporates a cold reservoir consisting of a large cooler. The water within the cooler is circulated by means of a pump which circulates the cooled water from the cooler through a tube to a bladder and back trough a tube to the cooler. The bladder is applied to the therapy site and held in place by means of a wrap or strap device. This apparatus has many advantages over an ice pack or ice wrap. The cooler and source of cooling, generally ice, is held in a container separate from the therapy site. In this type of device, the rate of cooling is adjusted by increasing or decreasing the flow resistance by using a manually operated flow restriction valve or electrically setting the pump speed to a predetermined fixed value.

This apparatus also has several shortcomings. The device is incapable of supplying a measured and controlled cooling temperature to the therapy site, and is incapable of providing tactile stimulation to the therapy site. The device is also cumbersome in that the pump used to circulate the cooling fluid must be manually submerged in the cooler, and there is an ever-present danger of electrical shock due to the proximity of the electrical power cord and the circulating water.

The most common method for achieving the desired heating effect has been through the application of a hot water bottle or steamed towels to an injury site. As with similar cold therapy modalities, this form of heat therapy suffers from the same shortcomings in terms of ease of application and temperature regulation due to a lack of any temperature control mechanism at the injury site.

DESCRIPTION OF THE PRIOR ART

Heretofore, a number of devices and systems have been employed to impose cold with or without pressure on parts of the human or mammalian body. Miller (U.S. Pat. No. 2,531,074 of Nov. 21, 1950) discloses an appliance for a dry massage of a therapy site by water of controlled temperature in a sequence at alternatively high and low pressures applied to a multitude of adjacent chambers of flexible wall material and suggests that the water can be either heated or cooled.

Chessey (U.S. Pat. No. 2,726,658 of Dec. 13, 1955) discloses a system, including a coolant control and supply unit, and a liquid-impervious appliance receiving the coolant and applied as a pad to a body portion of an animal, including a mechanical refrigeration system thermostatically controlled by the temperature of the coolant which is pumped through the appliance.

Grossan (U.S. Pat. No. 3,993,053 of Aug. 5, 1975) discloses a massaging system including a flexible pad having fixed to one face a set of elastic tubing coils forming part

of a recirculating hydraulic system, including a pump for creating pulsating fluid flow, and suggests that the pressure and temperature of the circulating liquid may be controlled by the operator.

Copeland, et al. (U.S. Pat. No. 4,149,529 of Sep. 16, 1977) discloses a portable apparatus for controllably cooling and variably applying pressure to a portion of a mammalian body including a liquid supply, control unit, means to circulate the liquid and heat exchanger in the fluid reservoir mounted in a supply unit of sufficient size to support the weight of a human and receive a human limb such that the reservoir may be employed as a whirlpool bath.

Although all the devices described above may be functional and presumably operable, there is a need for an improved apparatus for applying cold or heat to a human or mammalian body which is small enough to be easily transported and used in a wide variety of locations, adaptable to many different mammalian body forms and potential therapy sites, capable of providing controlled temperature therapy at a preset temperature or by a preprogrammed temperature profile, capable of monitoring the therapy temperature directly at the therapy site, and capable of providing tactile stimulation to the therapy site to alleviate the problems of static cooling and enhance the beneficial effects of the cooling therapy. The present invention fulfills these needs, and further provides related advantages.

SUMMARY OF THE INVENTION

The present invention provides an easily transportable apparatus for applying closed-loop temperature controlled cold or heat to a portion of the human or mammalian body. The apparatus comprises an insulated water reservoir within a sturdy housing, covered by a splash-proof lid, and is small enough is be easily situated in any convenient location for cold/heat therapy by the user. Within the reservoir housing but external to the reservoir is contained a self-priming fluid pump with a means of exchanging a measured portion of the re-circulation water with water from the reservoir to maintain the circulation water at a desired temperature. The pump is powered by a small mechanically integrated electric motor. Also contain in this area are the microprocessor-based temperature and pump/heat exchanger control electronics, and internal fluid tubing connections between the pump and the water reservoir, and between the pump and supply line connectors mounted on the housing. User controls and a temperature read-out display are also located on the reservoir housing.

The reservoir in the reservoir housing can accommodate crushed ice, ice cubes or a pre-formed freezable cold source, such as commonly used in portable coolers, and contains enough cooling capacity for generally all therapy applications. The reservoir may be easily recharged with additional ice if needed while therapy is continuing, and without the need for the subject to remove the bladder from the therapy site. For heat therapy, hot water can be introduced into the reservoir or the reservoir fluid can be actively heated by an immersible heater to maintain a constant temperature for controlled heating applications.

The apparatus monitors the therapy temperature and produces an audible signal when the cold or heat source is exhausted and the apparatus is no longer able to maintain the desired therapy temperature within certain preset tolerances.

The fluid supply lines from the pumps are connected to self-sealing, "quick disconnect" connectors, allowing the user to quickly and conveniently attach and detach various bladder types for various therapy applications. The apparatus can also be adapted to support simultaneous use of multiple bladders fluidly connected in series for therapy at multiple sites, as in bilateral surgery applications. Connecting the bladder to the reservoir housing is a pair of fluid supply lines which are terminated at one end by the mating half of the "quick disconnect" connectors mounted in the reservoir housing.

The supply line pair is held together and encapsulated by a layer of insulating material, such as closed-cell polyurethane foam, making the entire tubing assembly water-tight, durable, flexible, and fully insulated to reduce the ambient heat load on the unit and enhance the comfort and ease of use of the therapy apparatus. The supply line assembly may be of various lengths to suit the particular therapy subject and application. The supply line assembly may be permanently affixed to the bladder or attached by means of "quick-disconnect" connectors at its terminal end. Affixed within the supply line assembly is a pair of thermistors or other suitable temperature-sensing devices, one located in each of the pair of fluid supply lines at or near the quick disconnect mounted in the reservoir housing, the output of which is monitored by the control electronics to implement the closed-loop temperature control of the cold or heat therapy.

Various shapes and sizes of bladder are contemplated to accommodate the various therapy subjects, whether human or animal, and the various therapy sites of the mammalian body. All bladders will generally consist of two layers of flexible plastic or other material, completely sealed or welded at the edge or seam, and constructed to allow generous expansion and contraction in response to the varying pressure imposed by the pumps when applying tactile stimulation, and to ensure even distribution of circulation water or other fluid and the subsequent cooling/heating effect on the therapy site.

The bladder is generally held within a mating strap or wrap, depending upon the therapy subject and site. The strap or wrap may be a fabric or rubber type material, such as neoprene rubber, which is secured to the therapy site by means of belts, straps, "Velcro" fasteners. The strap or wrap, when fastened properly, holds the bladder firmly and evenly against the therapy site, while allowing expansion and contraction in response to the pressure fluctuations created by the pump when applying tactile stimulation.

The apparatus maintains temperature control at the therapy site by a controlled dynamic mixing of cold/hot water from the reservoir with the re-circulation water returning from the bladder within the heat exchanger. By using the real-time temperature information generated by the temperature sensing devices, the microprocessor controls the rate of reservoir/recirculation fluid mixing within the heat exchanger. This maintains the circulation water temperature, and thus the injury site bladder temperature. To ensure even temperature distribution at the therapy site or sites, particularly when multiple bladders are used in series, maximum flow rates and delivery pressure is maintained to minimize the difference between outgoing and returning water temperatures regardless of the heat load. To achieve tactile stimulation at the desired therapy temperature, the pump is periodically turned off for a brief interval to allow the pressure within the bladder to return to zero before turning the pump back on. This action causes the bladder to undergo a deflation/inflation cycle which in turn causes a tactile stimulation in the tissue directly in contact with the bladder. The microprocessor-based control electronics and associated operating program operate the pump accordingly to provide maximum flow of circulation fluid and impose periodic pressure variations on the bladder such that the

desired temperature control and tactile stimulation are provided at the therapy site.

The present invention provides an important advance in cold/heat therapy of human and other mammalian subjects that improves ease of use and enhances therapy effectiveness. Other features and advantages of the present invention will be apparent from the following more detailed description of the preferred embodiment, taken in conjunction with the accompanying drawings, which illustrates, by way of example, the principles of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a schematic view of the apparatus as typically used by a human subject when applying cold therapy to the knee joint.

FIG. **2** is a perspective view of the reservoir housing with portions removed or broken away to reveal internal structure.

FIG. **3** is a schematic view of the insulated supply lines and bladder showing the internal structure of the bladder.

FIG. **4** is a cross-sectional view of a bladder.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring initially to FIG. **2**, there is shown the reservoir housing **4** which includes a protective outer case **2**, and inner ice reservoir **19** which is formed within the outer case **2** and open at the top, but otherwise leak-proof. The walls of the reservoir **19** are spaced within and apart from the walls of the outer case **2**, the internal space thus formed around the inner reservoir **19** is filled with a thermal insulation **18**. The bottom wall **3** of the reservoir **19** is also covered with thermal insulation **18**, thus insulating the reservoir **19**. The reservoir **19** is covered during operation of the apparatus using a lid **5** which is also thermally insulated and incorporates a seal which fits snugly in the opening of the reservoir **19** to prevent leakage caused by splashing during movement of the apparatus.

The device has pump/heat exchanger **13** that includes an electric-powered fluid pump and a heat exchanger. The fluid pump is connected to micro-processor-based control electronics and an associated operating program. The fluid pump has its fluid input connected to the heat exchanger containing controlled temperature fluid and its fluid output connected by a fluid supply tube to a bladder device. The pump has the capability of pumping fluid from the heat exchanger to the bladder device when operated.

Within the space adjacent to the reservoir **19** and within the outer case **2** are mounted the pump/heat exchanger **13**, electric motor **9**, microprocessor-based control electronics **7**. Pressurized water from the pump/heat exchanger **13** is supplied to the outlet quick disconnect **11** with the return water routed to the air/water separator **15** via the return quick disconnect **12** through return tube **1**. To maintain a closed system, air from the priming valve **14** is vented back to the reservoir **19** via vent tube **17**, with air vented from the air/water separator **15** via vent tube **16**. Closed loop control is affected by two thermistors **20** placed in the supply tube to the outlet quick disconnect **11**.

The fluid pump/heat exchanger has its fluid input connected to the reservoir containing cooled/heated fluid and the returning circulation water. The mixing of the reservoir and returning water is controlled by the control electronics to provide output water at a constant selected temperature to the bladder device via the supply tubes.

Electrical power is supplied from a conventional AC wall outlet through power connector **10** and power leads connecting to the switching power supply electronics **8**.

Mounted on the reservoir housing **4** are user-operated display/control electronics **6** with push-button controls for user input and a digital display for setting and monitoring therapy temperature and time.

Referring to FIG. **3**, the bladder supply line assembly **40** is attached to the reservoir housing **4** by the mating halves of the "quick-disconnect" supply line connectors **21** and **22**, connecting a pair of flexible supply tubes **41** and **42** to the internal fluid supply tubes via quick disconnects **11** and **12**. The flexible supply tubes **41** and **42** are encased in thermal insulation **43** which reduces ambient heat loads and provides a comfortable means of managing the supply line assembly **40** on the therapy subject. Various lengths for the supply line assembly **40** are contemplated depending upon the particular therapy subject and application.

The supply line assembly **40** may be permanently affixed to the bladder **60** or attached by means of additional "quick-disconnect" supply line connectors **48** and **49**.

Referring to FIG. **3**, the bladder **60** may be permanently affixed to the supply line assembly **40** or attached by means of the mating halves of additional "quick-disconnect" supply line connectors **38** and **39**. Various bladder shapes and sizes are contemplated for application on specific therapy sites, such as the human knee, ankle, or elbow, to sufficiently surround the therapy site to achieve optimal cold therapy results. The general structure of the bladder **60** is preferably two layers of flexible, weldable polymer or other suitable material **61**, which are heat-welded or otherwise sealed completely around the outer seam of the bladder **62**. Bladder supply tubes **63** and **64** are attached to the bladder **60** by means of a leak-proof seal **65**. The bladder **60** may incorporate one or more internal seams **66** or internal walls (not shown), the function of which is to direct the flow of cooling fluid from the bladder supply tubes **63** and **64** uniformly through the bladder **60**, and provide control over expansion of the bladder **60** in response to the higher periodic pressure imposed during tactile stimulation of the therapy site as illustrated in FIG. **4**.

Referring to FIG. **1**, the bladder **60** is held on the therapy site preferably by means of a wrap **70** made of neoprene rubber or other suitable insulating, flexible material, which is shaped to hold the bladder **60** snugly on the therapy site but allow flexibility for expansion and contraction of the bladder **60** during tactile stimulation of the therapy site. The wrap is held in place preferably by means of "Velcro" fasteners which are attached or sewn onto the wrap **70** such that the wrap **70** can be adjusted by the particular user to fit snugly and comfortably.

The apparatus maintains therapy temperature control at the therapy site by pumping circulation water at a precisely determined temperature from the pump/heat exchanger **13** through the bladder **60** to achieve the desired preset therapy temperature or preprogrammed therapy temperature-time profile, as monitored by the thermistors **20**. The reservoir **19**, pump/heat exchanger **13**, supply tubes **41** and **42**, and bladder **60** form a fluid circuit in which fluid may flow in either direction. Net flow through the bladder **60** is achieved by creating a pressurized output flow via the pump/heat exchanger **13** with the spent water returning from the bladder **60** to the air/water separator and ultimately to the inlet side of the pump/heat exchanger **13**. The pump/heat exchanger **13**, under microprocessor control, continuously displaces a precise amount of re-circulation water with water

from the constant temperature reservoir to precisely maintain the temperature of the circulation water exiting the pump/heat exchanger **13**. The displaced re-circulation water is returned to the reservoir via the air/water separator **15** to maintain a constant volume in the circulation system. To ensure a uniform temperature distribution at the therapy site or sites, particularly when multiple bladders are used in series in post-bilateral surgery therapy, maximum flow rate and pressure through the circulation system is maintained.

To achieve tactile stimulation when this mode of operation is selected by the user, while maintaining the preset or preprogrammed therapy temperature, the pump/heat exchanger **13** is periodically turned off for preprogrammed intervals to periodically allow the pressure in the bladder **60** to be cycled between zero and maximum. This imposed periodic pressure variation on the bladder **60** will provide tactile stimulation at the therapy site while maintaining the desired therapy temperature through the resulting deflation/inflation cycles in response to the pressure variations.

The control electronics **7** incorporate sufficient non-volatile electronic memory to allow storage, recall and implementation of a plurality of preprogrammed or user-programmed therapy temperature-time profiles, in addition to the operating program of the apparatus. In addition to the plurality of preprogrammed therapy temperature-time profiles contemplated to be provided with the apparatus, user-programming may be accomplished through the keys incorporated into the control/display electronics **6**.

The control electronics and associated operating program have the capability of comparing the therapy temperature applied at the therapy site or sites to a constant therapy temperature, or to a time-varying therapy temperature-time profile in real time for purposes of implementing closed-loop therapy temperature control. The control electronics and associated operating program monitor the output of the thermistors and produce an audible signal from a sound emitting device when the temperature detected by the thermistors indicates that the cooling/heating capacity in the reservoir is insufficient to maintain the closed-loop therapy temperature control within a preset temperature tolerance value.

The present invention provides an easily transportable cold therapy apparatus providing closed-loop therapy temperature control and tactile stimulation of the therapy site which may be used by human and mammalian subjects and employed on various therapy sites. Other embodiments within the scope of the invention are feasible. For example, a device with dual pumps capable of bi-directional flow closed-loop temperature control and increased tactile stimulation is feasible. A dual pump device could implement closed-loop temperature control using analog control electronics in the form of a solid state thermostat with the therapy site temperature selected with a mechanically operated device, such as a potentiometer in conjunction with a temperature read-out device. Increased tactile stimulation for a dual pump device could be achieved by engaging both pumps simultaneously, imposing momentary higher pressure on the bladder with no net fluid flow momentarily. Since many changes could be made in the above construction and many apparently widely different embodiments of this invention could be made without departure from the scope thereof, it is intended that all matter contained in the above description or shown in the accompanying drawings shall be interpreted as being illustrative only and not limiting.

We claim:

1. A thermal therapy apparatus for applying temperature-controlled therapy to a therapy site on a mammalian body, comprising:

a therapy pad for applying temperature-controlled therapy to the therapy site;

a recirculation fluid loop comprising a fluid channel defined by said therapy pad;

a pump for circulating fluid through said recirculation fluid loop;

a thermal reservoir for containing fluid;

a fluid exchanger coupling said thermal reservoir with said recirculation fluid loop, said fluid exchanger being constructed to mix a controllable amount of thermal reservoir fluid into said recirculation fluid loop; and

a control mechanism coupled to said fluid exchanger for enabling adjustable control of the mixing of thermal reservoir fluid into said recirculation fluid loop to thereby control the temperature of the fluid circulating in said recirculation fluid loop.

2. The therapy apparatus of claim **1**, wherein said heat exchanger comprises means for delivering a predetermined volume of fluid from said thermal reservoir into said recirculating fluid loop.

3. The therapy apparatus of claim **1**, wherein said therapy pad includes a flexible surface and wherein said control mechanism is coupled to said pump for enabling adjustable control of fluid pressure in said therapy pad.

4. The therapy apparatus of claim **3**, wherein said control mechanism is adapted to vary pressure of recirculating fluid within said therapy pad in a manner to apply tactile stimulation to a therapy site by increasing and decreasing fluid pressure in said therapy pad.

5. The therapy apparatus of claim **1**, wherein said control mechanism comprises an alarm adapted to actuate whenever said thermal reservoir lacks thermal capacity to maintain a predetermined therapy temperature.

6. The therapy apparatus of claim **1**, wherein said recirculating fluid loop comprises a first temperature sensor for monitoring therapy temperature.

7. The therapy apparatus of claim **6**, wherein said control mechanism comprises control electronics for said heat exchanger, said control electronics being coupled to said first temperature sensor, user-operated controls and a display for manual selection and visual confirmation of therapy temperature, said control electronics comprising an associated operating program and means for programming, storing and retrieving a therapy temperature-time profile for implementing therapy temperature control.

8. The apparatus of claim **7**, wherein said control electronics further comprises means for determining a time-varying therapy temperature specified in said therapy temperature-time profile in real time for implementing therapy temperature control.

9. The apparatus of claim **8**, wherein said control electronics further comprises means for comparing time-varying therapy temperature applied at said therapy site to a temperature specified in said therapy temperature-time profile in real time for implementing closed-loop therapy temperature control.

10. The therapy apparatus of claim **7**, wherein said control electronics further comprises an alarm for warning a user when said thermal reservoir lacks thermal capacity to maintain therapy temperature.

11. The therapy apparatus of claim **10**, wherein said alarm comprises a second temperature sensor connected to said control electronics for monitoring temperature in said recirculating fluid loop of fluid exiting said therapy pad, said first temperature sensor monitoring temperature in said recirculating fluid loop of fluid entering said therapy pad, said

control electronics monitoring said first temperature sensor and said second temperature sensor and producing a signal when temperatures detected by said first temperature sensor and said second temperature sensor indicate that said thermal reservoir has insufficient thermal capacity to maintain a selected therapy temperature within a preset tolerance value.

* * * * *

US005980561A

United States Patent [19]

Kolen et al.

[11] Patent Number: 5,980,561

[45] Date of Patent: *Nov. 9, 1999

[54] **APPLYING THERMAL THERAPY TO LIVING TISSUE**

[76] Inventors: **Paul T. Kolen**, 139 Fourth St., Encinitas, Calif. 92024; **Thomas D. Ford**, 10405 Orozco St., San Diego, Calif. 94124

[*] Notice: This patent is subject to a terminal disclaimer.

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[22] PCT Filed: **Mar. 1, 1995**

[86] PCT No.: **PCT/US96/02824**

§ 371 Date: **Dec. 31, 1997**

§ 102(e) Date: **Dec. 31, 1997**

[87] PCT Pub. No.: **WO96/26693**

PCT Pub. Date: **Sep. 6, 1996**

Related U.S. Application Data

[63] Continuation-in-part of application No. 08/450,641, May 25, 1995, Pat. No. 5,865,841.

[30] **Foreign Application Priority Data**

Mar. 1, 1995 [IE] Ireland S950163

[51] **Int. Cl.**[6] **A61F 7/00**

[52] **U.S. Cl.** **607/104**; 607/114

[58] **Field of Search** 607/104, 107, 607/108–112, 114; 236/12.12, 12.1, 12.11

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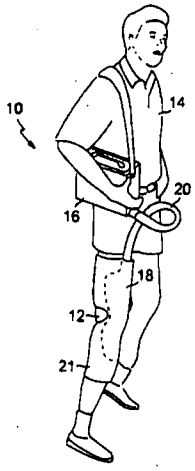
Primary Examiner—Robert L. Nasser
Attorney, Agent, or Firm—Fish & Richardson P.C.

[57] **ABSTRACT**

A thermal therapy device for applying temperature controlled therapy to a therapy site on a mammalian body, comprising: a therapy pad for applying a selected therapy temperature to the therapy site; a recirculating fluid loop comprising a fluid channel defined by the therapy pad; a pump for circulating fluid through the recirculating fluid loop; a thermal reservoir; a heat exchanger coupling the thermal reservoir with the recirculating fluid loop; and a control mechanism coupled to the heat exchanger for enabling adjustable control of therapy temperature. The heat exchanger selectively mixes fluid recirculating in the fluid loop with fluid from the thermal reservoir in an adjustable mixing ratio to achieve the selected therapy temperature at the therapy site.

38 Claims, 8 Drawing Sheets



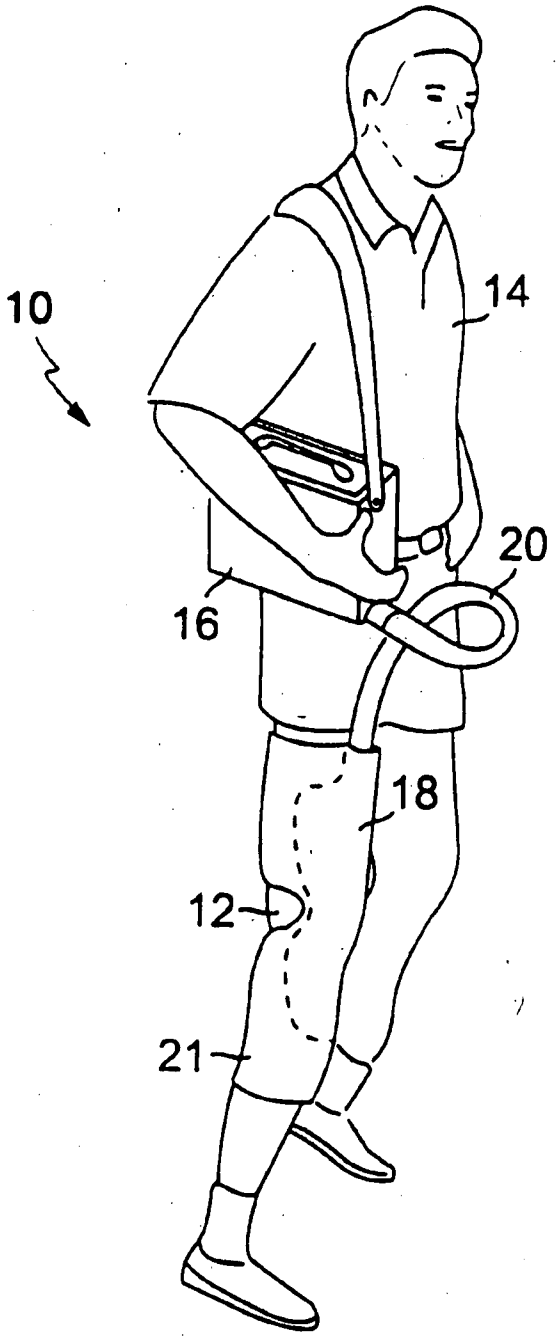


FIG. 1

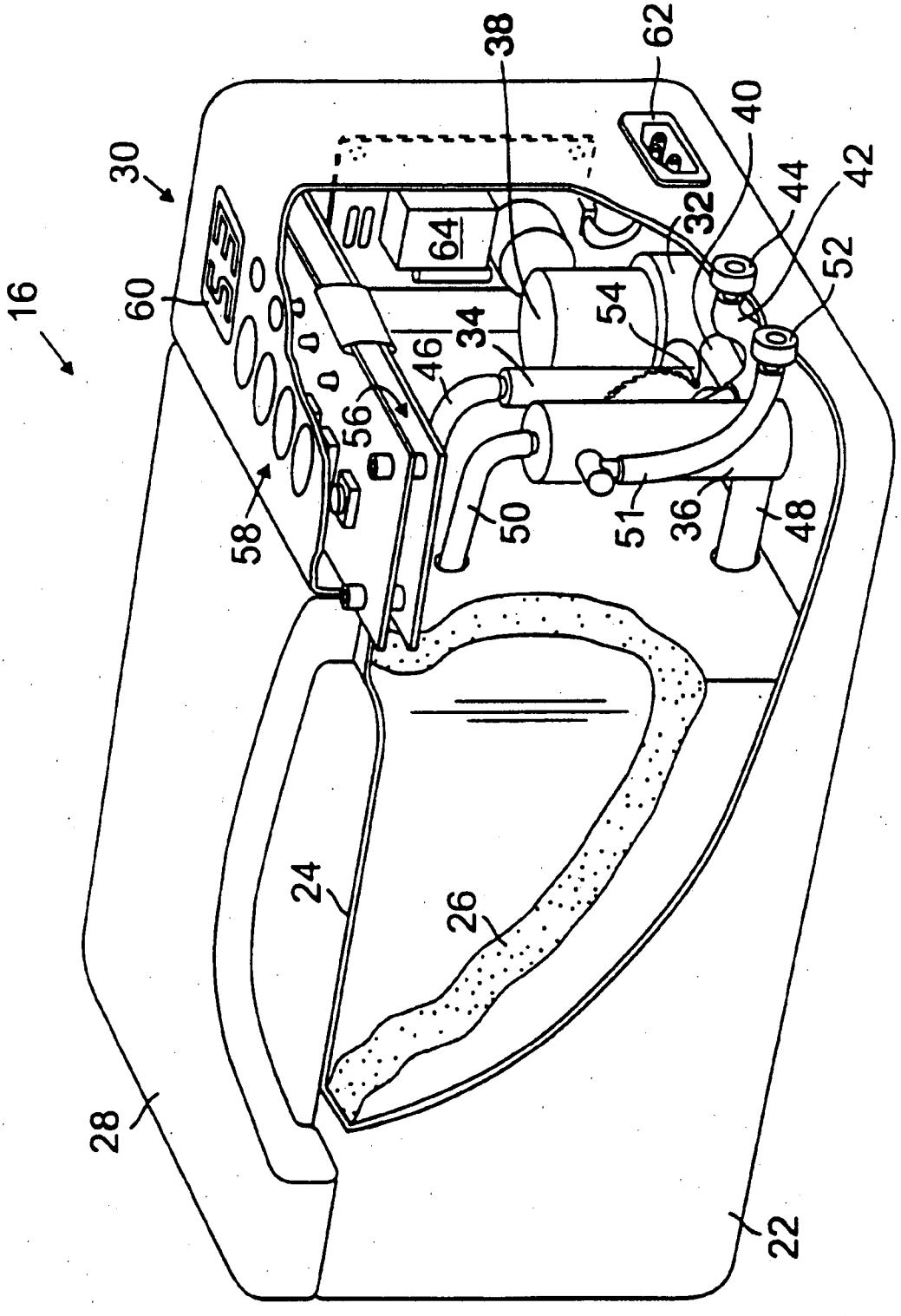


FIG. 2

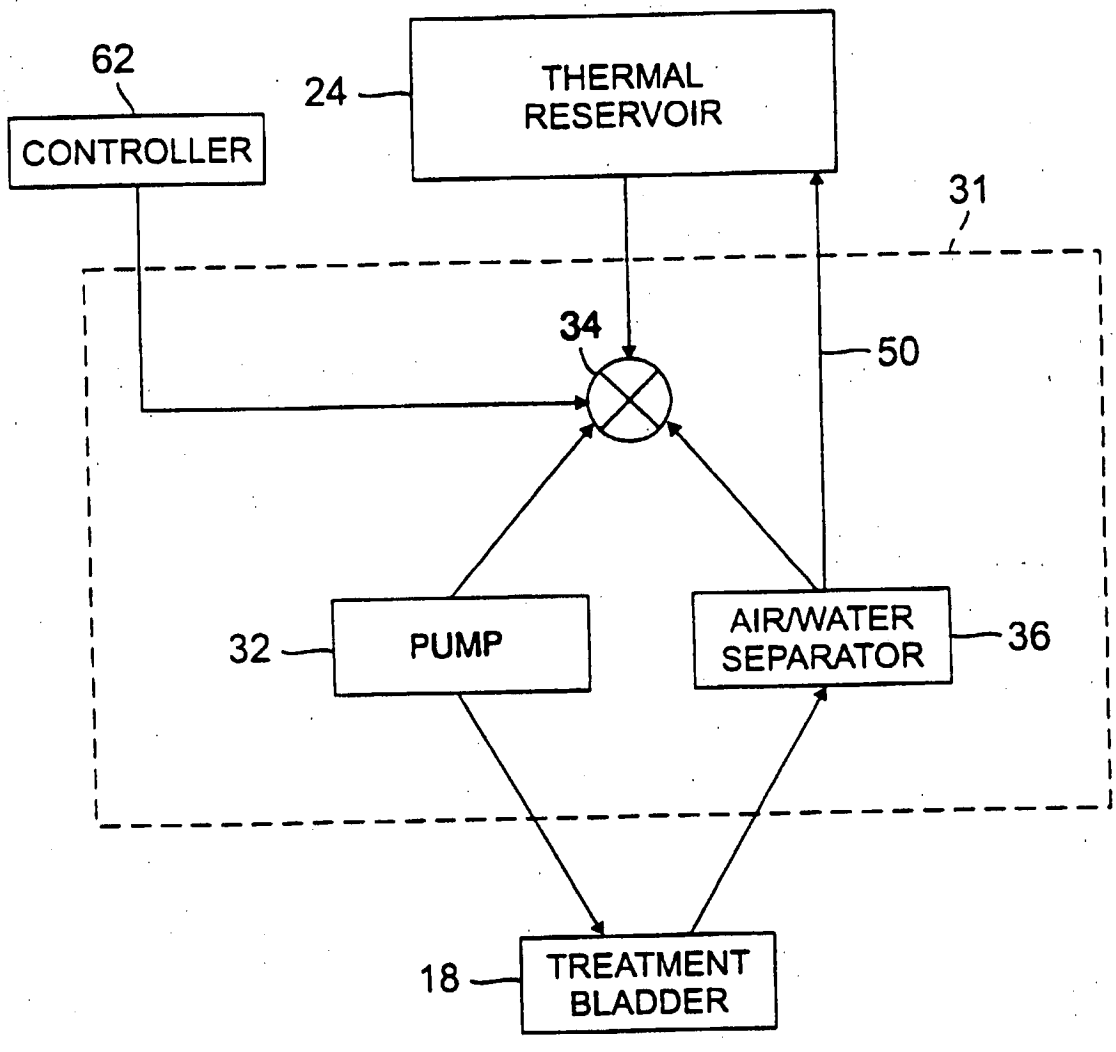

62
CONTROLLER
24
THERMAL RESERVOIR
31
34
50
32
PUMP
AIR/WATER SEPARATOR
36
18
TREATMENT BLADDER

FIG. 2A

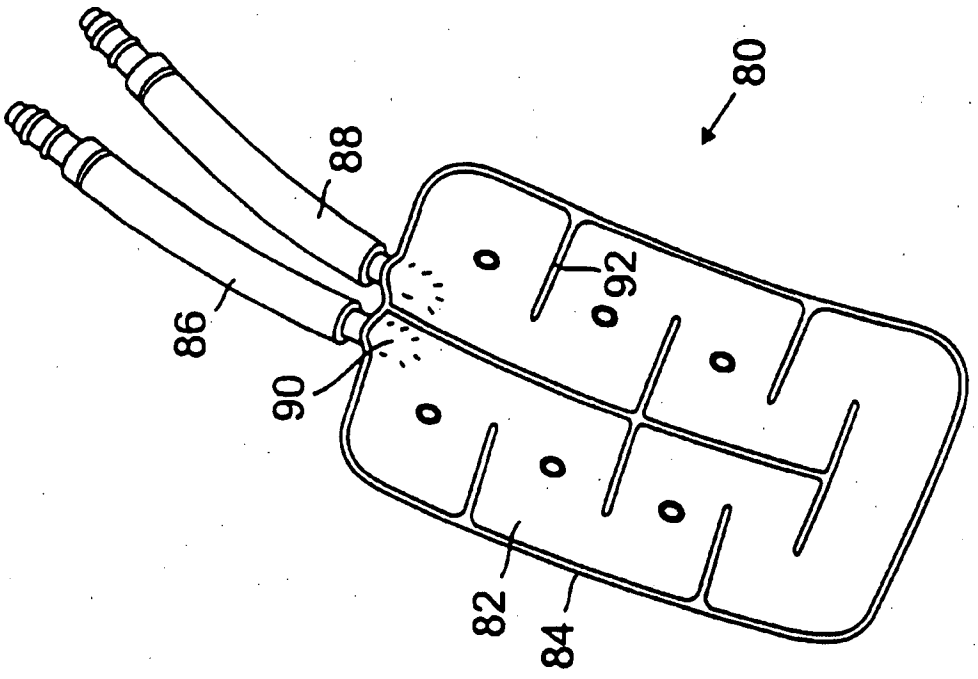


FIG. 4

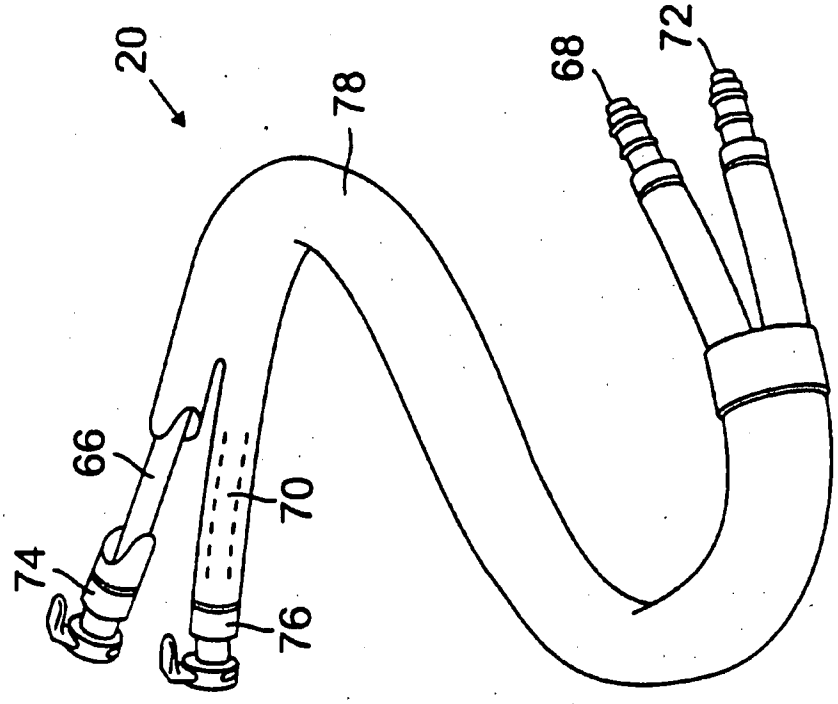


FIG. 3

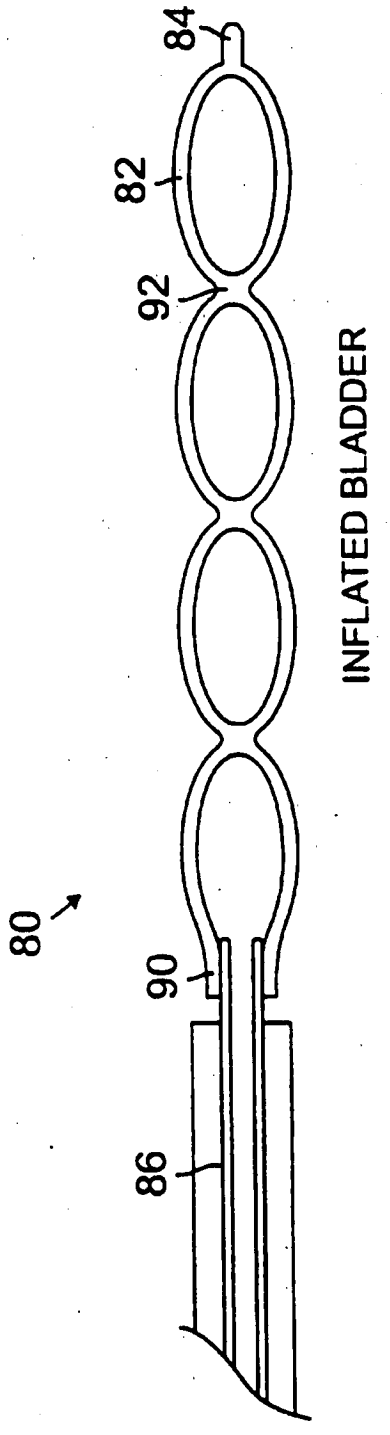

84
82
92
INFLATED BLADDER
80
90
86

FIG. 5

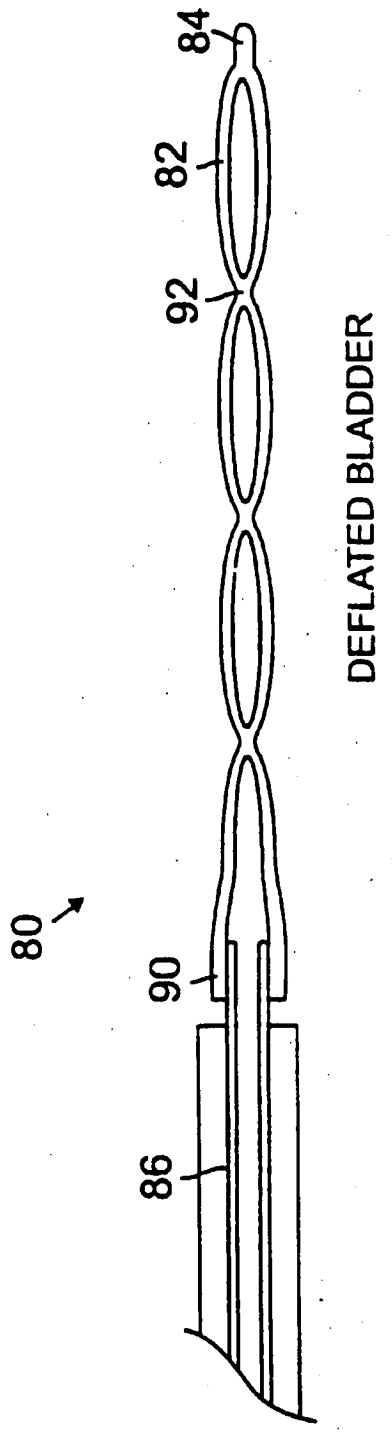

84
82
92
DEFLATED BLADDER
80
90
86

FIG. 5A

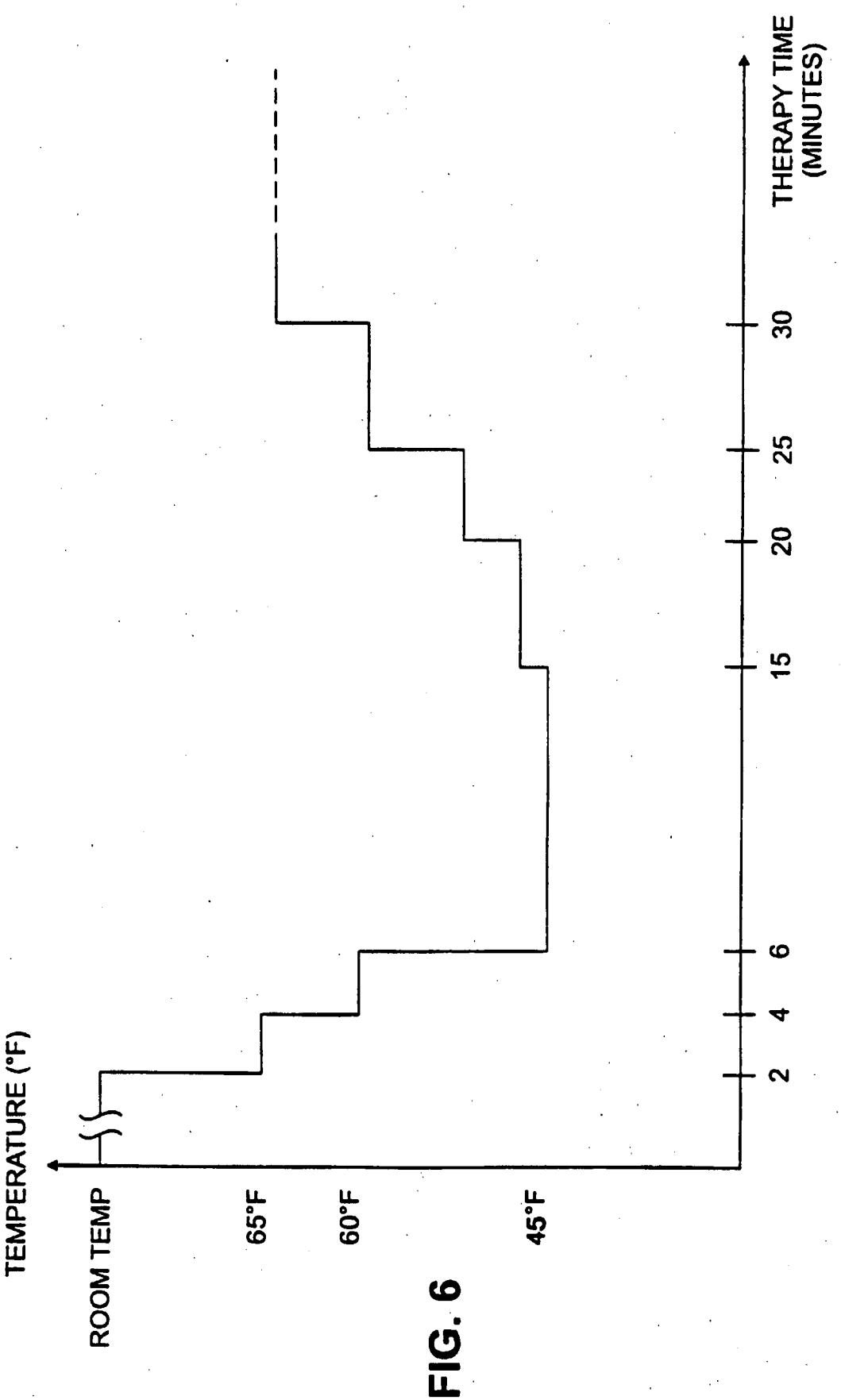

THERAPY TIME (MINUTES)
2
4
6
15
20
25
30
TEMPERATURE (°F)
ROOM TEMP
65°F
60°F
45°F

FIG. 6

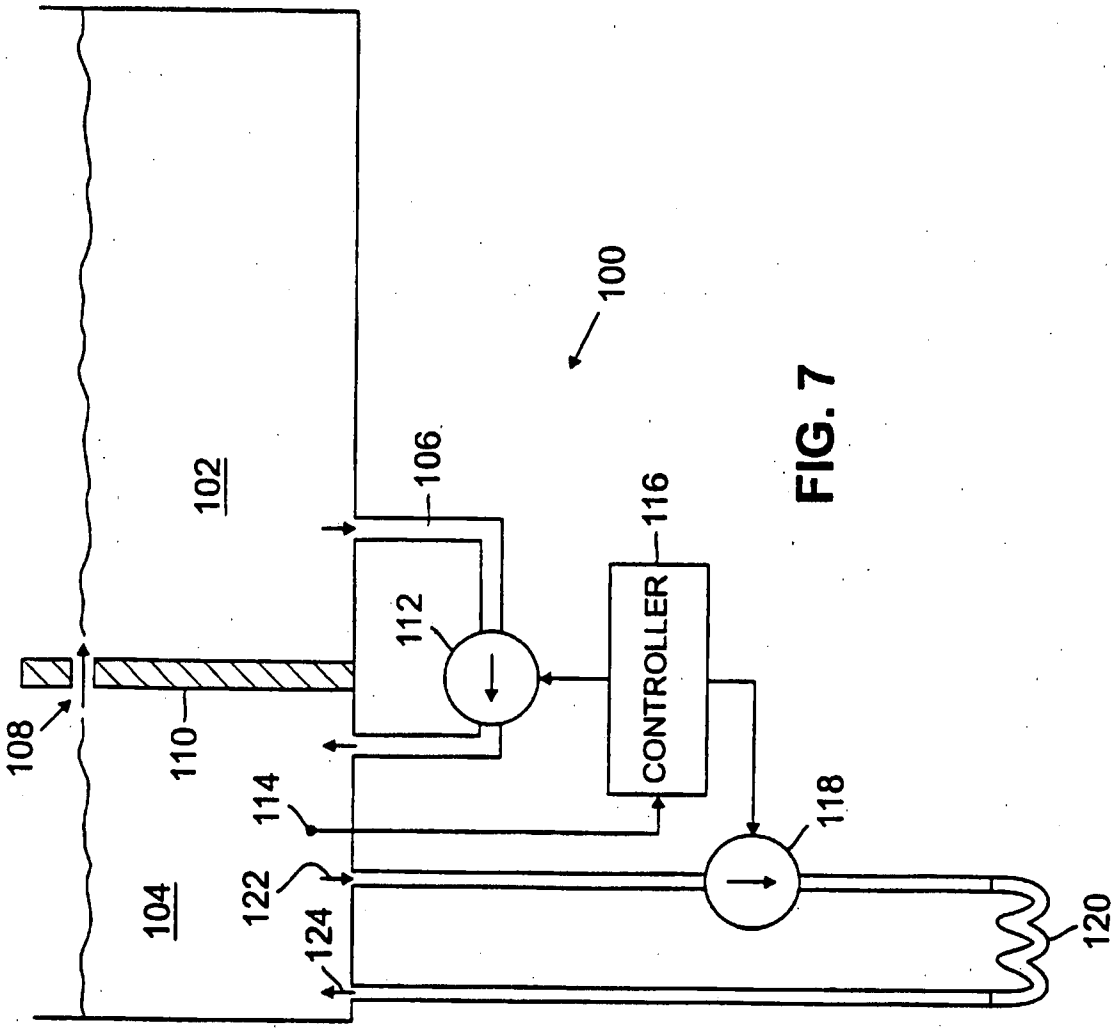


FIG. 7

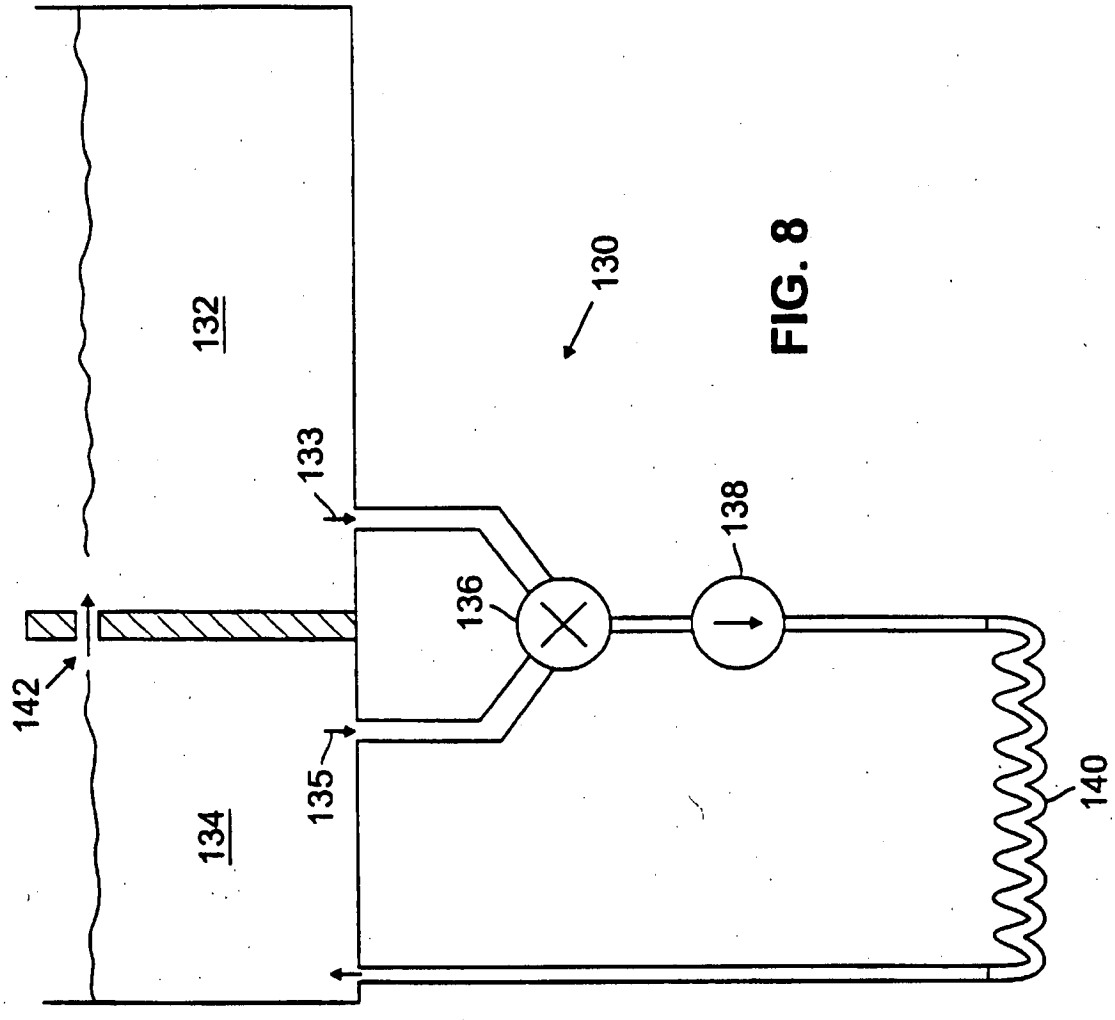


FIG. 8

APPLYING THERMAL THERAPY TO LIVING TISSUE

This is a continuation-in-part of U.S. application Ser. No. 08/450,641, filed May 25, 1995, now U.S. Pat. No. 5,865,841.

BACKGROUND OF THE INVENTION

This invention relates to devices and methods for applying thermal therapy to living tissue.

Thermal therapy involves the application of heat or cold to tissue to heal and rehabilitate injuries, such as, bruises, sprains, or other trauma to bone, muscle, ligaments, tendons, and skin. Cold therapy can be used to reduce swelling, reduce pain and promote healing of injured tissue. Heat therapy can be used to loosen joint tissue, such as, ligaments and tendons, to increase range of motion, e.g., before strenuous activity. Thermal therapy can be used after surgery to reduce pain and swelling and promote healing. Thermal therapy can also be used as part of an orthopedic therapy program, a sports medicine program, and to heal and rehabilitate animals, such as, thoroughbred race horses.

Common thermal therapy methods, e.g., application of an ice bag or a hot water bottle, are difficult to hold in place, are statically applied, cause uneven cooling or heating across the treatment site, and do not allow the cooling or heating temperature to be readily controlled.

A number of devices have been proposed for applying cold therapy to living tissue, with or without pressure. One device that has been developed for cooling a human knee includes a large cooler that contains chilled water which is circulated through a tube and into a cooling pad. The cooling pad is applied to a desired therapy site and held in place by a strap. The cooling rate is adjusted by increasing or decreasing the flow resistance through the tube leading to the cooling pad. Miller U.S. Pat. No. 2,531,074 describes a device which includes a flexible, multi-chamber thermal pad into which heated or cooled water is alternately injected at high and low pressures to provide temperature-controlled message therapy. Chessey U.S. Pat. No. 2,726,658 describes a system in which a coolant is pumped directly from a thermostatically-controlled refrigeration system into a cooling pad. Grossan U.S. Pat. No. 3,993,053 describes a massaging pad that includes a set of elastic tubing coils through which temperature controlled fluid is pulsed at high and low pressures to achieve a massaging effect. Copeland U.S. Pat. No. 4,149,529 describes a system that delivers heated or cooled liquid into a dry appliance for performing temperature and intermittent compression treatment; the system also provides a thermal therapy bath treatment.

SUMMARY OF THE INVENTION

In one aspect, the invention features a thermal therapy device for applying temperature controlled therapy to a therapy site on a mammalian body, comprising: a therapy pad for applying a selected therapy temperature to the therapy site; a recirculating fluid loop comprising a fluid channel defined by the therapy pad; a pump for circulating fluid through the recirculating fluid loop; a thermal reservoir; a heat exchanger coupling the thermal reservoir with the recirculating fluid loop; and a control mechanism coupled to the heat exchanger for enabling adjustable control of therapy temperature.

In another aspect, the invention features a thermal therapy device for applying temperature-controlled therapy to a therapy site on a mammalian body, comprising: a therapy pad for applying a selected therapy temperature to the therapy site; a recirculating fluid loop comprising a fluid channel defined by the therapy pad; a thermal reservoir; and a heat exchanger coupling the thermal reservoir with the recirculating fluid loop, the heat exchanger being constructed and arranged to selectively mix fluid recirculating in the fluid loop with fluid from the thermal reservoir in an adjustable mixing ratio to achieve the selected therapy temperature at the therapy site.

Embodiments of the invention may include one or more of the following features. The heat exchanger preferably comprises means for delivering a predetermined volume of fluid from the thermal reservoir into the recirculating fluid loop. The therapy pad preferably includes a flexible surface, and the control mechanism is preferably coupled to the pump for enabling adjustable control of fluid pressure in the therapy pad. The control mechanism is preferably adapted to vary pressure of recirculating fluid within the therapy pad in a manner to apply tactile stimulation to a therapy site by increasing and decreasing fluid pressure in the therapy pad. The control mechanism preferably comprises an alarm adapted to actuate whenever the thermal reservoir lacks thermal capacity to maintain a predetermined therapy temperature.

In some embodiments, the recirculating fluid loop comprises a first temperature sensor for monitoring therapy temperature. In these embodiments, the control mechanism preferably comprises control electronics for the heat exchanger. The control electronics are preferably coupled to the first temperature sensor, user-operated controls and a display for manual selection and visual confirmation of therapy temperature. The control electronics also preferably comprise an associated operating program and means for programming, storing and retrieving a therapy temperature-time profile for implementing therapy temperature control. The control electronics further preferably comprise means for determining a time-varying therapy temperature specified in the therapy temperature-time profile in real time for implementing therapy temperature control. The electronics may comprise means for comparing time-varying therapy temperature applied at the therapy site to a temperature specified in the therapy temperature-time profile in real time for implementing closed-loop therapy temperature control. The control electronics may also comprise an alarm for warning a user when the thermal reservoir lacks thermal capacity to maintain therapy temperature. The alarm preferably comprises a second temperature sensor connected to the control electronics for monitoring temperature in the recirculating fluid loop of fluid exiting the therapy pad, the first temperature sensor monitoring temperature in the recirculating fluid loop of fluid entering the therapy pad, the control electronics monitoring the first temperature sensor and the second temperature sensor and producing a signal when temperatures detected by the first temperature sensor and the second temperature sensor indicate that the thermal reservoir has insufficient thermal capacity to maintain a selected therapy temperature within a preset tolerance value.

The heat exchanger preferably comprises a second thermal reservoir. The heat exchanger also preferably comprises a valve for selectively mixing fluid from the first thermal reservoir with fluid from the second thermal reservoir according to a prescribed mixing ratio and for introducing mixed fluid to the pump for circulation in the recirculating fluid loop. In some embodiments, the control mechanism comprises a knob for manually adjusting the valve to achieve the prescribed mixing ratio.

In some embodiments, the second thermal reservoir comprises an air/water separator. In other embodiments, the heat

exchanger comprises a second pump for delivering fluid from the first thermal reservoir to the second reservoir, and further comprises an overflow fluid path for returning excess fluid in the second thermal reservoir to the first thermal reservoir. The control mechanism preferably selectively adjusts the second pump to achieve a prescribed fluid temperature in the second thermal reservoir.

There is a need for a cost-effective thermal therapy device for applying cold or heat therapy to a human or mammalian body that is small enough to be easily transported and used in a wide variety of locations, adaptable to many different mammalian body forms and potential therapy sites, capable of providing controlled temperature therapy at a preset temperature or by a preprogrammed temperature profile, capable of monitoring the therapy temperature directly at the therapy site, and capable of providing tactile stimulation to the therapy site to alleviate the problems of static thermal therapy and enhance the beneficial effects of thermal therapy. The present invention fulfills these needs, and further provides related advantages.

Other features and advantages of the invention will become apparent from the following description of presently preferred embodiments, and from the claims.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a diagrammatic view of a thermal therapy device of the invention for applying thermal therapy to the knee of a person.

FIG. **2** is a perspective view, partially broken away, of a reservoir housing for a thermal therapy device of the invention.

FIG. **2A** is a schematic diagram of the thermal therapy device of FIG. **1**, including a thermal reservoir, a heat exchanger, and a treatment pad.

FIG. **3** is a diagrammatic view of insulated fluid supply and return lines a thermal therapy device of the invention.

FIG. **4** is a diagrammatic view of a thermal therapy treatment pad for a device of the invention.

FIGS. **5** and **5A** are cross-sectional views of the treatment pad of FIG. **4** shown in inflated condition and deflated condition, respectively.

FIG. **6** is a therapy temperature time profile programmed into a therapy device controller.

FIG. **7** is a schematic diagram of an alternative thermal therapy device.

FIG. **8** is a schematic diagram of another alternative thermal therapy device.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring to FIG. **1**, a thermal therapy device **10** applies temperature-controlled thermal therapy to the knee **12** of a person **14**. Thermal therapy device **10** includes a portable reservoir **16** that is connected to a thermal therapy treatment pad **18** by a thermally insulated supply and return assembly **20**. As described in detail below, thermal therapy device **10** uniformly heats or cools the person's knee according to a predetermined temperature schedule, and can be programmed to stimulate the patient's knee by controllably varying the inflation pressure inside treatment pad **18**. A wrap **21**, which is made of, e.g., neoprene rubber, is shaped to snugly hold treatment pad **18** in place at the therapy site, while allowing the treatment pad to expand and contract during tactile stimulation of the person's knee. Wrap **21** is held in place by VELCRO®, i.e. hook-and-loop type, fasteners that allow the wrap to be selectively adjusted to fit firmly, evenly and comfortably in place at the therapy site.

Referring to FIG. **2**, in one embodiment, portable reservoir **16** includes a protective outer case **22** and an inner, leak-proof thermal reservoir **24**. Reservoir **24** is thermally insulated by a thermal lining **26**, which fills the space between the outer walls of reservoir **24** and the inner wall of outer case **22**. A thermally insulated lid **28** opens to provide access to reservoir **24**. Lid **28** includes a seal (not shown) sized and constructed to form a fluid-tight seal between lid **28** and the top opening of reservoir **24** when the lid is closed, to prevent fluid from leaking during use.

A fluid control system **30** is contained within the housing, in a compartment space provided between the thermal reservoir and the outer casing. A heat exchanger **31**, within the fluid control system, includes a pump **32**, a single pole, double-throw priming valve **34**, and an air/water separator **36**. (In some embodiments, a solenoid valve may replace the single pole, double-throw priming valve.) Pump **32** includes an input **40** and an output **42**, and is powered by a motor **38**. Pump input **40** is connected to the output of priming valve **34**, and pump output **42** is connected to a quick-disconnect outlet **44**, through which fluid flows from the pump to the treatment pad. An input **46** of priming valve **34** is connected to thermal reservoir **24**, and an input **48** of the priming valve is connected to an output of air/water separator **36**. An overflow tube **50** provides a fluid path between the air/water separator and thermal reservoir **24**. Air/water separator **36** receives fluid from the treatment pad through tubing **51** from a quick-disconnect inlet **52**. The temperature of the fluid that is supplied to the treatment pad is monitored by thermistors **54** placed in the fluid paths of the supply and return lines of supply and return assembly **20**.

Reservoir **24** accommodates crushed ice, ice cubes and pre-formed freezable cold sources, such as, those commonly used in portable coolers. The reservoir is easily recharged with additional ice if needed during use, without requiring the person to remove the pad from the therapy site. For heat therapy, hot water can be introduced into the reservoir, or the reservoir fluid can be controllably heated using an immersion heater.

The temperature of the fluid supplied to the treatment pad is controlled by a microprocessor-based controller **56** (control electronics). Based on the therapy temperature measured by thermistors **54**, controller **56** produces an audible alarm signal when the cold or heat source in the reservoir is exhausted and the desired therapy temperature cannot be maintained within preset tolerances; an alarm also sounds if the unit detects a restricted flow in the circulation system. Controller **56** incorporates a non-volatile electronic memory for storing, recalling and implementing one or more preprogrammed or user-defined therapy temperature time profiles. Input keys **58** are used to program the desired temperature profile into controller memory. The monitored temperature is shown on a digital display **60**. Display **60** may also indicate the amount of therapy time remaining. Electrical power is supplied to fluid control system **30** from a conventional wall outlet, through power connector **62**, to switching power electronics **64**.

As shown in FIG. **2A**, heat exchanger **31** controls the temperature of treatment pad **18** by mixing a controlled amount of fluid from thermal reservoir **24** with recirculated fluid returning from the treatment pad through air/water separator **36**. By using the real-time temperature information generated by thermistors **54**, controller **56** adjusts valve **34**

to control the proportion of reservoir fluid that mixes with the recirculation fluid received from the pad to achieve the prescribed treatment pad temperature. For example, if the fluid injected to the treatment pad through quick-disconnect outlet **44** is at the prescribed temperature, controller **56** will adjust valve **34** so that no fluid is received from reservoir **24**; in other words, pump **32**, treatment pad **18**, and air/water separator **36** form a closed-loop system (the fluid may flow in either direction). If the output fluid temperature drops, however, controller **56** will adjust valve **34** so that fluid from reservoir **24** mixes with recirculated water from air/water separator **36** in the proportion selected to achieve the desired output fluid temperature. Because the fluid volume in the fluid flow path defined by the pump, the treatment pad, and the air/water separator is substantially fixed, some recirculated fluid will be displaced and flow into reservoir **24** via overflow tube **50** to complete the heat exchange process.

To ensure uniform temperature distribution at the therapy site (or sites), a high flow rate is used to reduce the temperature gradient that develops across the treatment pad as a result of heat transfer at the treatment site. In some embodiments, the thermal therapy device includes multiple treatment pads coupled in series, which can be used, e.g., in the treatment of post bilateral surgery therapy. High flow rates are generally needed in these multi-pad embodiments to reduce the temperature differential between the upstream and downstream treatment pads. The flow rate can also be selected based on the anticipated heat load at the treatment site.

Referring to FIG. **3**, insulated supply and return assembly **20** includes a flexible fluid supply line **66** that connects to quick-disconnect outlet **44** via a mating quick-disconnect connector **68**, and a flexible fluid return line **70** that connects to quick-disconnect return inlet **52**. In the embodiment shown in FIG. **3**, the supply and return line assembly **20** is attached to the treatment pad via quick-disconnect connectors **74**, **76**. The flexible supply and return lines **66**, **70** are encased in thermal insulation **78** (e.g., polyurethane foam) that reduces ambient heat loads, makes the entire line assembly fluid tight, durable and flexible, and is more comfortable for the user to handle. The length of the supply and return line assembly is selected based at least in part on the size of the user and on the anticipated thermal therapy treatment.

Various treatment pad shapes and sizes are contemplated depending on the selected treatment site (e.g., ankle, knee, elbow), with the object being to sufficiently cover the treatment site to achieve optimal therapy results. In the embodiment shown in FIG. **4**, a treatment pad **80** is formed of two layers of flexible polymeric material **82** that are heat-welded or otherwise sealed together at the outer edge **84** of the pad. In this embodiment, supply and return lines **86**, **88** are permanently attached to treatment pad **80** by a leak proof seal **90**. Pad **80** also includes one or more internal seams **92** (or internal walls), which uniformly direct the flow of cooling fluid through the pad; the internal seams also control the expansion and contraction of the pad.

Referring to FIGS. **5** and **5A**, treatment pad **80** is constructed to allow the pad to expand (FIG. **5**) and to contract (FIG. **5A**) in response to varying fluid pressures applied by the heat exchanger, and to ensure a uniform distribution of circulating fluid within the pad. To achieve tactile stimulation, pump **32** is turned off and on at preprogrammed intervals to periodically allow the pressure in the treatment pad to be cycled between low and high values. Such a periodic pressure variation in the treatment pad provides tactile stimulation at the therapy site while achieving the desired therapy temperature. Controller **56** (FIG. **2**) can be programmed to simultaneously provide the desired temperature profile and the desired tactile stimulation.

Although a constant therapy temperature time profile may be programmed into controller **56**, it is preferable to vary the temperature during treatment to avoid discomfort and permit long term thermal therapy without causing tissue damage. As shown in FIG. **6**, a preferred cold therapy temperature time profile calls for a reduction in the applied therapy temperature from room temperature to a predetermined minimum temperature (e.g., 45° F.) during an initial treatment stage; during an intermediate stage the minimum therapy temperature is maintained for a fixed period (e.g., nine minutes); and during a final treatment stage the temperature is increased at regular intervals (e.g., every five minutes) until the treatment temperature is at about 65° F. The applied therapy temperature is maintained at 65° F. for the duration of the prescribed treatment period.

Other embodiments are within the scope of the claims.

For example, in one embodiment, the thermal therapy device uses two pumps, instead of the combination of a single pump and a single pole, double-throw valve, to achieve bi-directional flow, closed-loop temperature control and increased tactile stimulation. Such a dual-pump device implements closed-loop temperature control using analog control electronics in the form of a solid state thermostat with the therapy site temperature selected with a mechanically operated device, such as a potentiometer in conjunction with a temperature read-out device. Increased tactile stimulation for a dual-pump device could be achieved by engaging both pumps simultaneously, imposing momentary higher pressure on the pad with no net fluid flow.

Automatic Closed-Loop Heat Exchanger

Referring to FIG. **7**, a thermal therapy device **100** includes a primary reservoir **102** that is coupled to a secondary reservoir **104** by an active flow path **106** and by an overflow path **108**; the primary and secondary reservoirs are separated by a thermal barrier **110**. Active flow path **106** includes a dedicated constant pressure circulation pump **112**. The temperature of the fluid in the secondary reservoir is monitored using a thermal sensor **114**. A controller **116** adjusts the pump rate to maintain the temperature in the secondary reservoir at a desired temperature by controlling the fluid flow from the primary reservoir. Any excess fluid in the secondary reservoir is returned to the primary reservoir through overflow fluid path **108**, completing the heat exchange circuit. A high speed circulation pump **118** controllably injects fluid from secondary reservoir **104** into a thermal therapy treatment pad **120**.

The closed-loop electronic control allows the temperature of the secondary reservoir fluid to be maintained at a desired set-point value within about ±0.3° F. in a desired temperature range (e.g., 45° F. to 65° F., with the temperature of the primary reservoir fluid at about 35° F.) for practical thermal loads. When the secondary reservoir fluid temperature corresponds to the programmed temperature, the controller adjusts the pump speed so that the thermal transfer from the primary reservoir makes up for the thermal transfer at the treatment site through the treatment pad, which is represented by the difference in temperature between fluid **122** injected into the pad and fluid **124** returning from the pad. When the temperature profile programmed into controller **116** indicates that the therapy temperature is to be changed, the controller increases or decreases the speed of pump **112**, depending on whether the applied temperature is to be

increased or decreased. Because the fluid from the secondary reservoir is injected into the treatment pad at a high rate, the thermal load at the treatment site does not substantially affect the temperature of the fluid through the treatment pad and, consequently, the temperature differential across the treatment pad is maintained within about 2–3° F. of the programmed set-point value.

Reservoir **102** accommodates crushed ice, ice cubes and pre-formed freezable cold sources, such as, those commonly used in portable coolers. The reservoir is easily recharged with additional ice if needed during use, without requiring the person to remove the pad from the therapy site. For heat therapy, hot water can be introduced into the reservoir, or the reservoir fluid can be controllably heated using an immersion heater. Because ice water is used for the primary thermal reservoir, the thermal therapy device is highly cost-effective.

Manual Open-Loop Heat Exchanger

Referring to FIG. **8**, a thermal therapy device **130** includes a primary thermal reservoir **132** and a secondary thermal reservoir **134**. As in the embodiments described above, primary thermal reservoir **132** can accommodate a mixture of water and crushed ice or other cold source, or heated fluid. The mixing ratio of primary reservoir fluid **133** and recirculation fluid **135** from the secondary reservoir is adjusted by a manually-controlled valve **136**. A high speed circulation pump **138** controls the flow of fluid into a thermal therapy treatment pad **140**. Any excess fluid in the secondary reservoir is returned to the primary reservoir through overflow path **142**, which completes the heat exchange circuit.

By adjusting valve **136** a user can empirically control the temperature of the secondary in an open-loop fashion. The water is mixed within the pump creating a near constant temperature within the circulation loop and the secondary reservoir. Preferably, valve **136** includes markings that indicate the correspondence between valve position and treatment temperature. For example, in one embodiment, valve **136** includes a marking that corresponds to a mixing ratio needed to provide a temperature of 45° F., which the user may apply to the treatment site for the initial period of treatment (e.g., ten to fifteen minutes). Valve **136** also includes a second marking that corresponds to a mixing ratio needed to provide a temperature of 65° F., which the user may apply to the treatment site indefinitely.

Still other embodiments are within the scope of the claims.

We claim:

1. A thermal therapy device for applying temperature-controlled therapy to a therapy site on a mammalian body, comprising:

a therapy pad for applying temperature-controlled therapy to the therapy site;

a recirculation fluid loop comprising a fluid channel defined by said therapy pad;

a thermal reservoir for containing fluid;

a fluid exchanger coupling said thermal reservoir with said recirculation fluid loop, said fluid exchanger being constructed to exchange an adjustable amount of fluid in said recirculation fluid loop with thermal reservoir fluid.

2. The therapy device of claim **1**, further comprising a control mechanism coupled to said fluid exchanger for enabling adjustable control of the exchange of fluid in said recirculation fluid loop with thermal reservoir fluid to thereby control the temperature of the fluid circulating in said recirculation fluid loop.

3. The therapy device of claim **2**, further comprising a pump for circulating fluid through said recirculation fluid loop, wherein said therapy pad includes a flexible surface and wherein said control mechanism is coupled to said pump for enabling adjustable control of fluid pressure in said therapy pad.

4. The therapy device of claim **3**, wherein said control mechanism is adapted to vary pressure of recirculating fluid within said therapy pad in a manner to apply tactile stimulation to a therapy site by increasing and decreasing fluid pressure in said therapy pad.

5. The therapy device of claim **2**, wherein said control mechanism comprises an alarm adapted to actuate whenever said thermal reservoir lacks thermal capacity to maintain a predetermined therapy temperature.

6. The therapy device of claim **1**, wherein said recirculating fluid loop comprises a first temperature sensor for monitoring therapy temperature.

7. The therapy device of claim **6**, further comprising control electronics coupled to said first temperature sensor, user-operated controls and a display for manual selection and visual confirmation of therapy temperature, said control electronics comprising an associated operating program and means for programming, storing and retrieving a therapy temperature-time profile for implementing therapy temperature control.

8. The device of claim **7**, wherein said control electronics further comprises means for determining a time-varying therapy temperature specified in said therapy temperature-time profile in real time for implementing therapy temperature control.

9. The device of claim **8**, wherein said control electronics further comprises means for comparing time-varying therapy temperature applied at said therapy site to a temperature specified in said therapy temperature-time profile in real time for implementing closed-loop therapy temperature control.

10. The therapy device of claim **7**, wherein said control electronics further comprises an alarm for warning a user when said thermal reservoir lacks thermal capacity to maintain therapy temperature.

11. The therapy device of claim **10**, wherein said alarm comprises a second temperature sensor connected to said control electronics for monitoring temperature in said recirculating fluid loop of fluid exiting said therapy pad, said first temperature sensor monitoring temperature in said recirculating fluid loop of fluid entering said therapy pad, said control electronics monitoring said first temperature sensor and said second temperature sensor and producing a signal when temperatures detected by said first temperature sensor and said second temperature sensor indicate that said thermal reservoir has insufficient thermal capacity to maintain a selected therapy temperature within a preset tolerance value.

12. The therapy device of claim **1** further comprising a second thermal reservoir.

13. The therapy device of claim **12**, wherein said second thermal reservoir is constructed and arranged to function as an air/water separator.

14. The therapy device of claim **12** wherein said heat exchanger comprises a valve for selectively mixing fluid from said first thermal reservoir with fluid from said second thermal reservoir according to a prescribed mixing ratio and for introducing mixed fluid to said pump for circulation in said recirculating fluid loop.

15. The therapy device of claim **14** wherein said control mechanism comprises a knob for manually adjusting said valve to achieve the prescribed mixing ratio.

16. The therapy device of claim 12, wherein said fluid exchanger is adapted to inject a controllable amount of fluid from said first thermal reservoir into said second thermal reservoir.

17. The therapy device of claim 12, wherein said recirculation fluid loop is adapted to deliver fluid into, and to draw fluid from, said second thermal reservoir.

18. The therapy device of claim 12, wherein said fluid exchanger is adapted to supply fluid into said recirculation fluid loop from said first and second thermal reservoirs in an adjustable mixing ratio.

19. The therapy device of claim 18, wherein the fluid channel of said recirculation fluid loop is coupled between said second thermal reservoir and said fluid exchanger.

20. A thermal therapy device for applying temperature controlled therapy to a therapy site on a mammalian body, comprising:

a therapy pad for applying a selected therapy temperature to the therapy site;

a recirculation fluid loop comprising a fluid channel defined by said therapy pad;

a first pump for circulating fluid through said recirculating fluid loop;

a first thermal reservoir;

a heat exchanger coupling said thermal reservoir with said recirculating fluid loop, said heat exchanger comprising a second thermal reservoir and a second pump for delivering fluid from said first thermal reservoir to said second thermal reservoir, and further comprising an overflow fluid path for returning excess fluid in said second thermal reservoir to said first thermal reservoir; and

a control mechanism coupled to said heat exchanger for enabling adjustable control of therapy temperature.

21. The therapy device of claim 20 wherein said control mechanism selectively adjusts said second pump to achieve a prescribed fluid temperature in said second thermal reservoir.

22. A thermal therapy device for applying temperature controlled therapy to a therapy site on a mammalian body, comprising:

a therapy pad for applying a selected therapy temperature to the therapy site;

a recirculating fluid loop comprising a fluid channel defined by said therapy pad;

a thermal reservoir; and

a fluid exchanger coupling said thermal reservoir with said recirculating fluid loop, said heat exchanger being constructed and arranged to selectively mix fluid recirculating in said fluid loop with fluid from said thermal reservoir in an adjustable mixing ratio to achieve the selected therapy temperature at the therapy site.

23. The therapy device of claim 22 further comprising a pump for circulating fluid through said recirculating fluid loop.

24. The therapy device of claim 23 further comprising a control mechanism coupled to said fluid exchanger for enabling adjustable control of the mixing ratio to achieve the selected therapy temperature at the therapy site.

25. A thermal therapy device comprising:

a reservoir for containing a fluid;

a fluid line having an input for delivering fluid to a therapy pad and an output for receiving fluid from the therapy pad;

a pump coupled to the fluid line for circulating fluid through the fluid line; and

a fluid exchanger for exchanging a controlled amount of fluid in said fluid line with fluid from the reservoir to achieve a desired fluid temperature in the fluid line.

26. The thermal therapy device of claim 25 wherein the fluid exchanger comprises a diverter valve.

27. The therapy device of claim 26 wherein the diverter valve is manually-controllable.

28. The thermal therapy device of claim 25 wherein the fluid line comprises a second reservoir.

29. The thermal therapy device of claim 25 further comprising a therapy pad coupled to the input and the output of the fluid line.

30. The thermal therapy device of claim 25 wherein the fluid exchanger is adapted to displace a controlled amount of fluid out of the fluid line.

31. The thermal therapy device of claim 30 wherein the amount of fluid mixed into the fluid line from the reservoir is substantially equal to the amount of fluid displaced out of the fluid line.

32. The thermal therapy device of claim 21 wherein the fluid exchanger comprises a second pump.

33. A thermal therapy device comprising:

a reservoir for containing a fluid;

a fluid line having an input for delivering fluid to a therapy pad and an output for receiving fluid from the therapy pad;

a pump coupled to the fluid line for circulating fluid through the fluid line; and a fluid exchanger for mixing a controlled amount of fluid from the reservoir into the fluid line to achieve a desired fluid temperature in the fluid line, the fluid exchanger comprising a second pump.

34. A thermal therapy device for applying temperature-controlled therapy to a therapy site on a mammalian body, comprising:

a therapy pad for applying temperature-controlled therapy to the therapy site;

a recirculation fluid loop comprising a fluid channel defined by the therapy pad and containing recirculation fluid;

a thermal reservoir constructed to contain fluid;

a fluid exchanger coupling the thermal reservoir with the recirculation fluid loop, the fluid exchanger being constructed to exchange an adjustable amount of recirculation fluid returning from the therapy pad with a substantially equal amount of thermal reservoir fluid and to mix the unexchanged recirculation fluid returning from the therapy pad with the substantially equal amount of thermal reservoir fluid, wherein the unexchanged recirculation fluid and the substantially equal amount of thermal reservoir fluid are delivered to the therapy pad.

35. The therapy device of claim 34, further comprising a control mechanism coupled to the fluid exchanger for enabling adjustable control of the exchange of recirculation fluid with thermal reservoir fluid to thereby control the temperature of the fluid circulating in the recirculation fluid loop.

36. The therapy device of claim 35, further comprising a pump for circulating fluid through the recirculation fluid loop.

37. A thermal therapy device for applying temperature-controlled therapy to a therapy site on a mammalian body, comprising:

a therapy pad including recirculation fluid for applying temperature-controlled therapy to the therapy site;

a pump;

a diverter valve; and

a thermal reservoir constructed to contain fluid coupled to the pump;

wherein fluid flows through a recirculation loop comprising the pump, the therapy pad, and the diverter valve and containing recirculation fluid, the diverter valve diverting from the recirculation loop an adjustable amount of recirculation fluid returning from the therapy pad, and the pump draws from the thermal reservoir and injects into the recirculation loop an amount of thermal reservoir fluid substantially equal to the amount of recirculation fluid diverted by the diverter valve, wherein non-diverted recirculation fluid returning from the therapy pad mixes with fluid drawn from the thermal reservoir and is delivered to the therapy pad.

38. The therapy device of claim **37**, wherein the diverter valve is further coupled to the thermal reservoir for delivering recirculation fluid diverted from the recirculation loop into the thermal reservoir.

* * * * *

JS 44 (Rev. 12/07)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

I. (a) PLAINTIFFS
DJO, LLC

DEFENDANTS
VITALWEAR, INC.

FILED
09 DEC 22 PM 3:19
CLERK, U.S. DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA
BY DEPUTY

(b) County of Residence of First Listed Plaintiff San Diego
(EXCEPT IN U.S. PLAINTIFF CASES)

County of Residence of First Listed Defendant San Francisco
(IN U.S. PLAINTIFF CASES ONLY)
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE LAND INVOLVED.

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Attorneys (If Known)

'09 CV 2872 W NLS

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- ☐ 1 U.S. Government Plaintiff
- ☒ 3 Federal Question (U.S. Government Not a Party)
- ☐ 2 U.S. Government Defendant
- ☐ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT (Place an "X" in One Box Only)

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excl. Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury

PERSONAL INJURY
- ☐ 362 Personal Injury - Med. Malpractice
- ☐ 365 Personal Injury - Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 444 Welfare
- ☐ 445 Amer. w/Disabilities-Employment
- ☐ 446 Amer. w/Disabilities-Other
- ☐ 440 Other Civil Rights

PRISONER PETITIONS
- ☐ 510 Motion to Vacate Sentence
- Habeas Corpus:
- ☐ 530 General
- ☐ 535 Death Penalty
- ☐ 540 Mandamus & other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition

FORFEITURE/PENALTY
- ☐ 610 Agriculture
- ☐ 620 Other Food & Drug
- ☐ 625 Drug Related Seizure of Property 2 1 USC 88 1
- ☐ 630 Liquor Laws
- ☐ 640 R.R. & Truck
- ☐ 650 Airline Regs.
- ☐ 660 Occupational Safety/Health
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Mgmt. Relations
- ☐ 730 Labor/Mgmt. Reporting & Disclosure Act
- ☐ 740 Railway Labor Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Empl. Ret. Inc. Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 463 Habeas Corpus - Alien Detainee
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☒ 830 Patent
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS - Third Party 26 USC 7609

OTHER STATUTES
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 810 Selective Service
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 875 Customer Challenge 12 USC 3410
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 892 Economic Stabilization Act
- ☐ 893 Environmental Matters
- ☐ 894 Energy Allocation Act
- ☐ 895 Freedom of Information Act
- ☐ 900 Appeal of Fee Determination Under Equal Access to Justice
- ☐ 950 Constitutionality of State Statutes

V. ORIGIN (Place an "X" in One Box Only)
☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from another district (specify) ☐ 6 Multidistrict Litigation ☐ 7 Appeal to District Judge from Magistrate Judgment

VI. CAUSE OF ACTION
Cite the U.S. Civil Statute under which you are filing **(Do not cite jurisdictional statutes unless diversity)**:
35 U.S.C. § 271 and 281
Brief description of cause:
Patent Infringement Action

VII. REQUESTED IN COMPLAINT: ☐ CHECK IF THIS IS A **CLASS ACTION** UNDER F.R.C.P. 23 **DEMAND $**
☐ CHECK YES only if demanded in complaint: **JURY DEMAND:** ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY (See instructions): JUDGE Dana M. Sabraw DOCKET NUMBER 08 CV 1721 DMS WMc

DATE
December 22, 2009

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