

(12) **United States Patent**  
**Buchanan et al.**

(10) **Patent No.:** **US 8,052,624 B2**  
(45) **Date of Patent:** **Nov. 8, 2011**

(54) **NEGATIVE PRESSURE, THERMAL ENERGY TRANSFER DEVICE THAT ALSO PROVIDES POSITIVE PRESSURE TO THE PATIENT**

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(\* ) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 615 days.

(21) Appl. No.: **12/260,293**

(22) Filed: **Oct. 29, 2008**

(65) **Prior Publication Data**

US 2010/0106230 A1 Apr. 29, 2010

(51) **Int. Cl.**

**A61H 7/00** (2006.01)  
**A61F 7/00** (2006.01)

(52) **U.S. Cl.** ..... **601/11; 607/104; 607/111**

(58) **Field of Classification Search** ..... **601/6, 11; 607/96, 104, 107, 108, 111, 112**  
See application file for complete search history.

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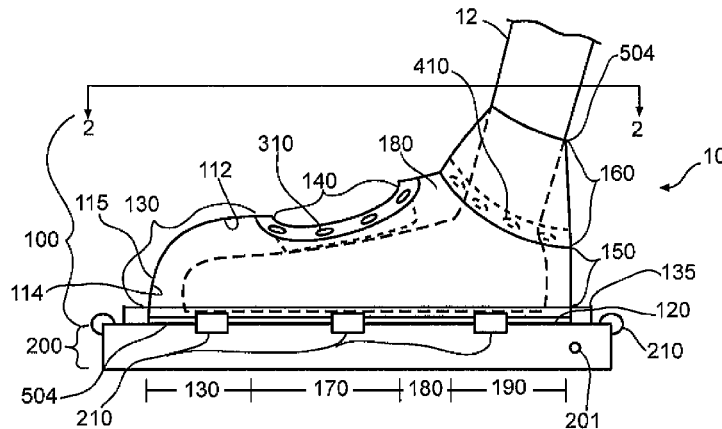
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(57) **ABSTRACT**

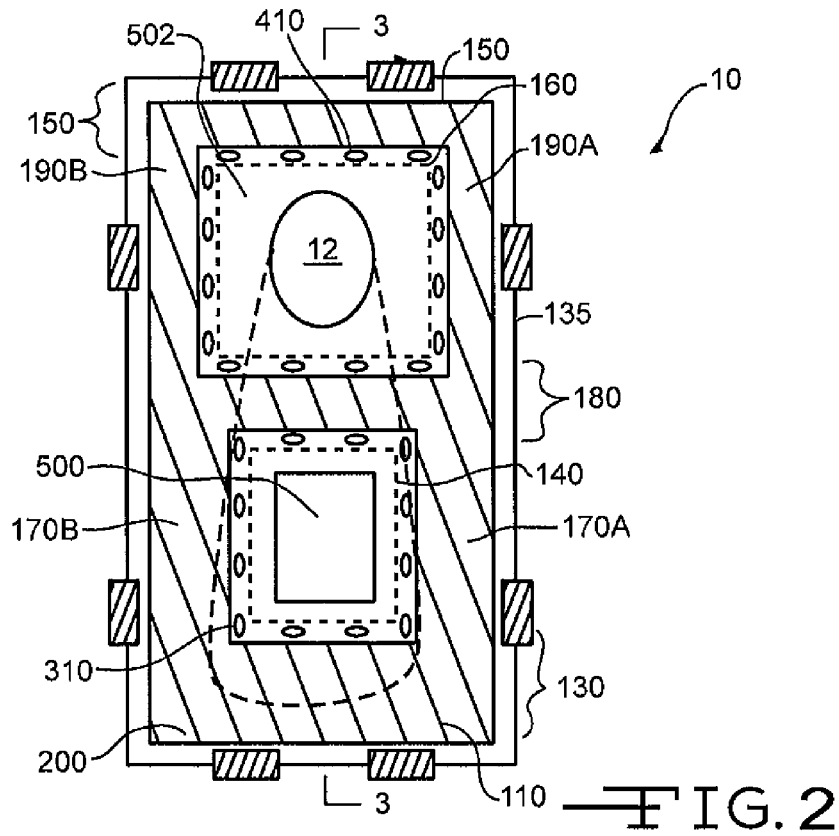
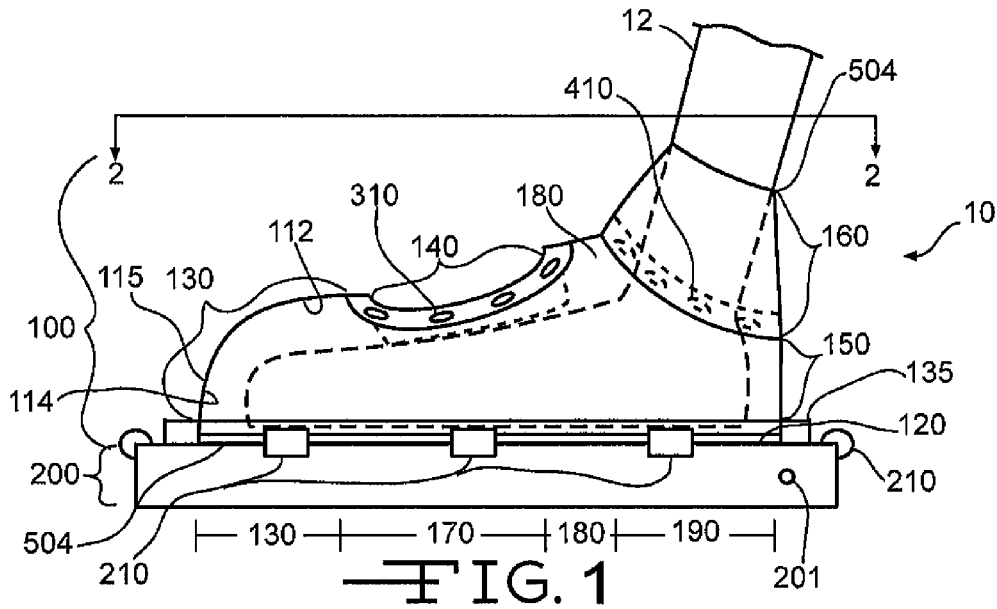
A negative pressure, thermal energy device has an enclosure that receives a patient's body part. The body part is positioned in the enclosure and contacts a thermal energy contacting surface. The thermal energy contacting surface transfers its thermal energy to the body part. While in the enclosure, the body part is also exposed to a negative pressure to cause vasodilation. The combination of the vasodilation and the thermal energy transfer alter the patient's body core temperature. To ensure the body part remains in contact with the thermal contacting surface, the enclosure has a portion thereof that moves when negative pressure is in the enclosure. When the negative pressure is applied, the deforming enclosure material is pulled toward the body part to provide a positive pressure on the body part that ensures the body part effectively contacts the thermal energy contacting surface.

**20 Claims, 5 Drawing Sheets**



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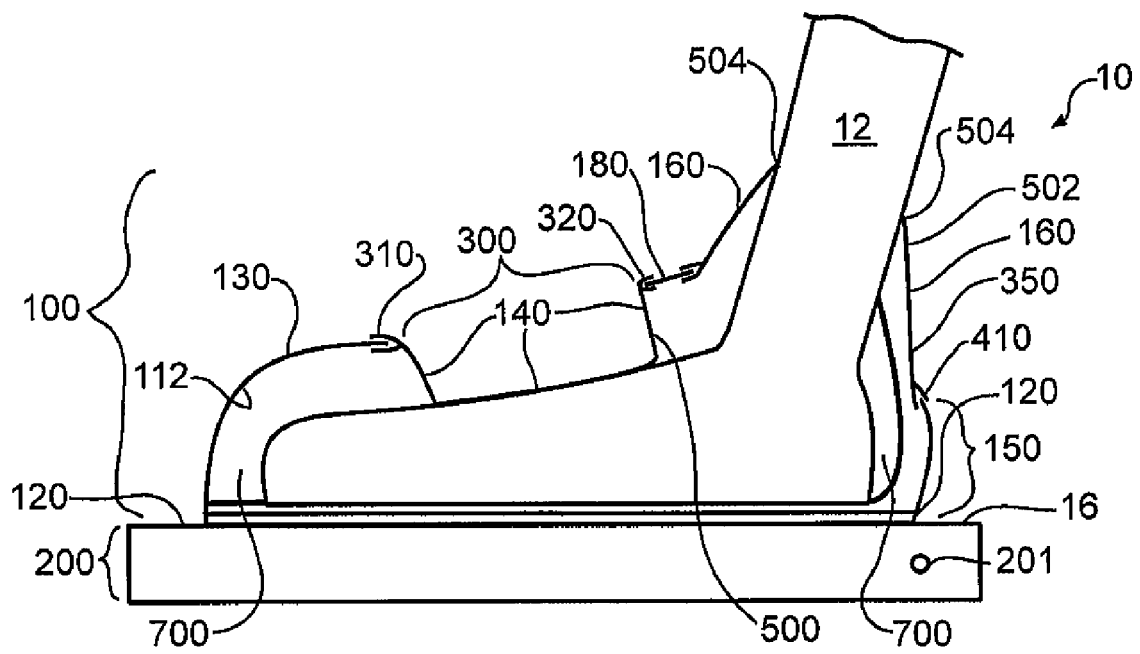


FIG. 3

FIG. 4

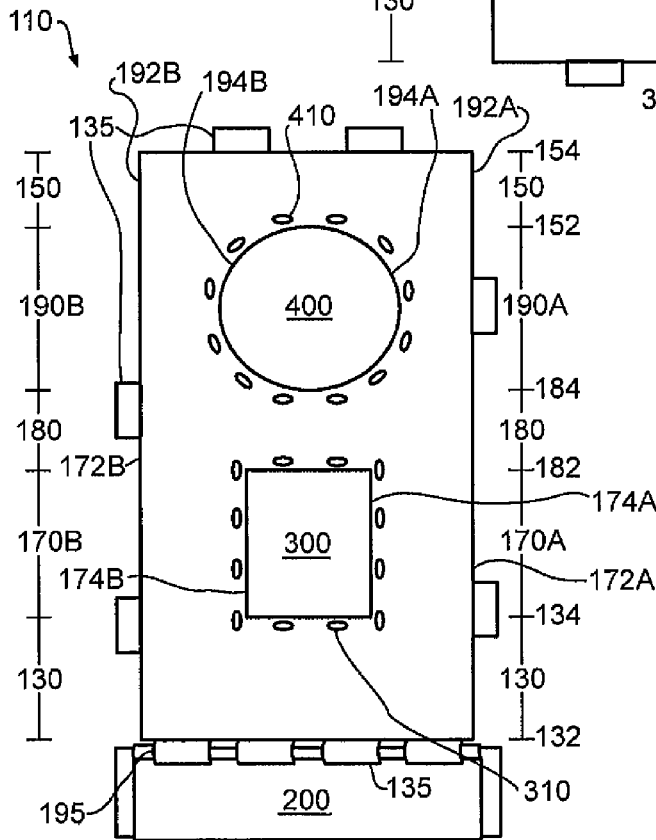
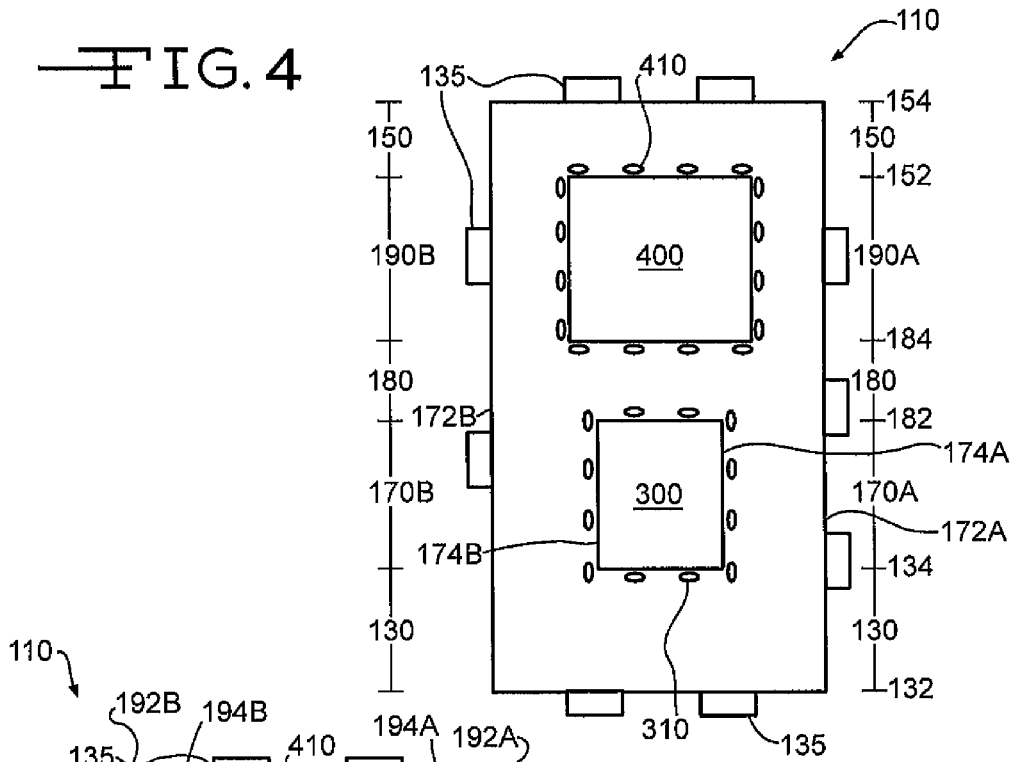


FIG. 5

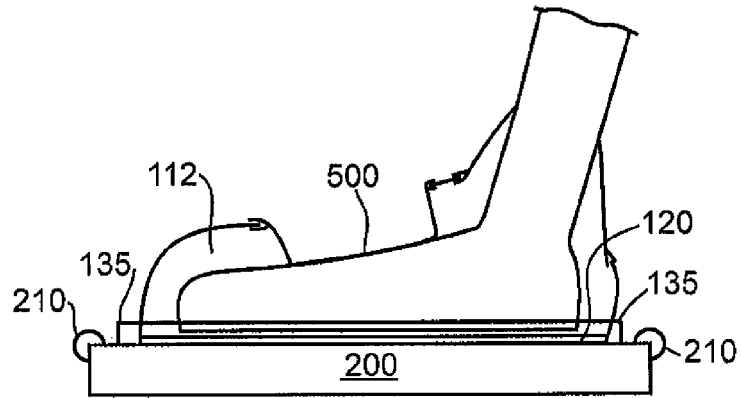


FIG. 6A

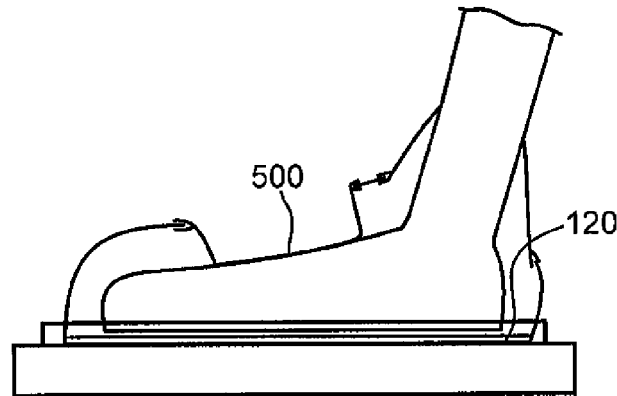


FIG. 6B

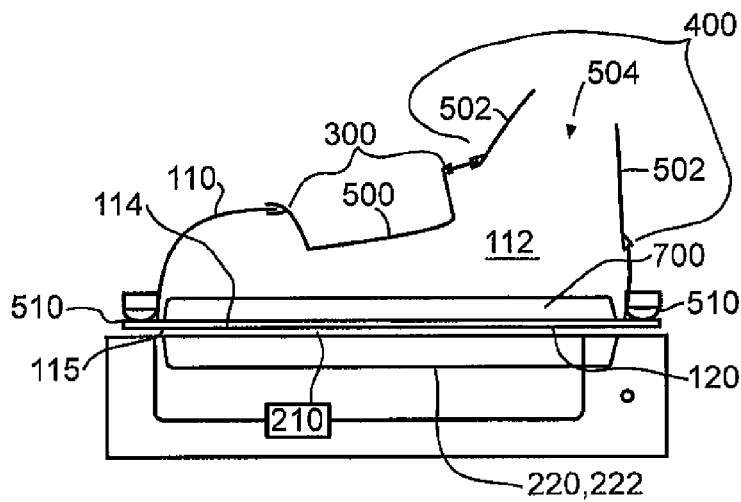


FIG. 7

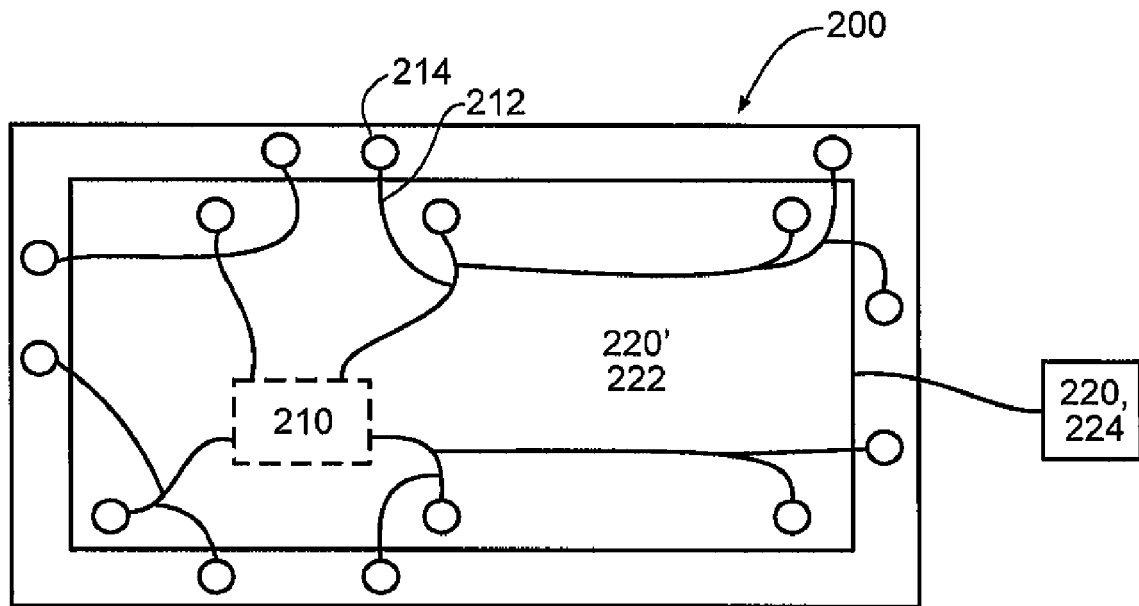


FIG. 8

**NEGATIVE PRESSURE, THERMAL ENERGY  
TRANSFER DEVICE THAT ALSO PROVIDES  
POSITIVE PRESSURE TO THE PATIENT**

FIELD OF THE INVENTION

The present invention relates to negative pressure, thermal energy transfer units for controlling, maintaining and/or adjusting the body core temperature of a mammal, in particular a human.

BACKGROUND OF THE INVENTION

Stanford University is the assignee of U.S. Pat. Nos. 5,683,438; 6,602,277; 6,673,099; 6,656,208; 6,966,922; 7,122,047; and 6,974,442. These patents disclose a negative pressure, thermal energy device that can be applied to a patient. The negative pressure device has the following elements: (1) a hard, non-shape altering enclosure having an opening to receive a portion of a patient's body that contains a venous plexus area, (2) a vacuum system that creates a negative pressure in the enclosure, (3) a seal positioned at the enclosure's opening to maintain the negative pressure in the enclosure, and (4) a thermal energy system having a thermal energy contacting element wherein the venous plexus area is exposed to the thermal energy from the thermal energy contacting element.

Enclosure

The enclosure surrounds a portion of a patient's body. In a preferred embodiment, the portion of the patient's body has a venous plexus area. The venous plexus area is a vascular network formed by numerous anastomoses between arteries and veins. A venous plexus area is, along with other locations, normally located at the patient's foot area and/or hand area.

The enclosure can be shaped like a glove, a mitten, a boot, a clam-shell, or equivalents thereof so long as there is an opening that receives the patient's body part. In many embodiments, the enclosure is a polymeric material that can withstand the formation of predetermined negative pressure values within its interior that receives the patient's body part.

Seal

The seal is mounted at the enclosure's opening that receives the patient's body part having a venous plexus area. The seal establishes (1) a vacuum-tight fit between the body portion and the enclosure or (2) a soft seal fit between the body portion and the enclosure.

The term "vacuum-tight", as interpreted by Dr. Grahn in some of the above-identified Stanford patents and he is one of the inventors of all of the Stanford patents, means a hard seal. In U.S. Pat. No. 7,182,776; Dr. Grahn wrote, "A "hard" seal is characterized as one designed to altogether avoid air leakage past the boundary it provides. In theory, a "hard" seal will allow a single evacuation of the negative pressure chamber for use in the methods. In practice, however, a "hard" seal can produce a tourniquet effect. Also, any inability to maintain a complete seal will be problematic in a system requiring as much."

A "soft" seal as described herein is characterized as providing an approximate or imperfect seal at a user/seal interface. Such a seal may be more compliant in its interface with a user. Indeed, in response to user movement, such a seal may leak or pass some air at the user/seal interface. In a negative-pressure system designed for use with a soft seal, a regulator or another feedback mechanism/routine will cause a vacuum pump, generator, fan or any such other mechanism capable of drawing a vacuum to respond and evacuate such air as necessary to stabilize the pressure within the chamber, returning

it to the desired level. Active control of vacuum pressure in real-time or at predetermined intervals in conjunction with a "soft" seal provides a significant advantage over a "hard" seal system that relies on simply pulling a vacuum with the hopes of maintaining the same.

Some of the Stanford patents disclose the seal is long to "Provide greater seal surface contact with a user." Greater seal surface contact to the patient increases tissue interface pressure. Increased tissue interface pressure is undesirable.

Vacuum System

The vacuum system connects to the enclosure for generating and, in some embodiments, maintaining a predetermined negative pressure inside the enclosure to cause vasodilation in the body portion surrounded in the enclosure. Negative pressure conditions are a pressure lower than ambient pressure under the particular conditions in which the method is performed. The magnitude of the decrease in pressure from the ambient pressure under the negative pressure conditions is generally at least about 20 mmHg, usually at least about 30 mmHg and more usually at least about 35 mmHg, where the magnitude of the decrease may be as great as 85 mmHg or greater, but typically does not exceed about 60 mmHg and usually does not exceed about 50 mmHg. The negative pressure applied to a portion of the body in the enclosure (a) decreases the temperature when vasoconstriction occurs and/or (b) increases the vasodilation in the body portion that is in the enclosure.

The negative pressure inducing element may be actuated in a number of different ways, including through motor driven aspiration, through a system of valves and pumps which are moved through movement of the mammal in a manner sufficient to create negative pressure in the sealed environment, etc.

Thermal Energy Contacting Element

The thermal energy contacting element transfers thermal energy to, or extracts thermal energy from the body portion in the vacuum enclosure. Whether the thermal energy transfers to or extracts from the body portion depends on the relative temperatures of the thermal energy contacting element and the body portion. The vasodilation in the body portion enhances the exchange of thermal energy between a patient's body core, surface of the body portion, and the thermal energy contacting element.

The thermal energy contacting element has been previously disclosed as (a) a conventional thermal warming plate or blanket, or a conventional thermal cooling plate or blanket, (b) a warm or cool water immersion element, (c) a warming or cooling gas element, and (d) a curved metal plate or a metal tube positioned in the interior of the enclosure.

The three latter embodiments deal with a fluid. In the conduit embodiments, the fluid (i) circulates within it and (ii) does not contact the body portion in the desired area—the venous plexus area. The fluid can be provided by a hypo/hyper/normothermia fluid temperature control device. An example of such a device, and not limited to, is Gaymar's Medi-Therm II hypo/hyper/normothermia fluid temperature control device. That device is disclosed and incorporated by reference in commonly assigned U.S. Pat. No. 6,517,510.

There are problems with the thermal energy contacting surfaces, a patient could elect (a) not to grip the thermal energy contacting element, (b) to re-position the body part, so the body part is not affected by the thermal energy contacting element or (c) to loosen (for example blanket embodiments) the thermal energy contacting element so it does not effectively contact the body part. The patient's election may be unintentional especially if the patient is sedated or under general anesthesia. It is therefore at least one object of the



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present invention to solve this potential contact problem by making the device invariant to a patient's desire to "grip" or contact the thermal energy contacting element.

Of these thermal energy contacting element embodiments, the metal plate and tube are considered by many to be an effective thermal energy contacting elements because (a) those components are easy to manufacture, (b) the thermal energy transfer efficiency to the patient is relatively acceptable and (c) using the product in actual use is easy.

#### BRIEF DESCRIPTION OF THE FIGURES

FIG. 1 illustrates a side view of the present invention.

FIG. 2 is a top view of FIG. 1 taken along the lines 2-2.

FIG. 3 is a cross-sectional view of FIG. 2 taken along the lines 3-3.

FIG. 4 is a top view of FIG. 1 without the body part and the shape altering, air impermeable materials.

FIG. 5 is an alternative embodiment of FIG. 4 wherein a hinge connects a portion of the contact section to the operation section.

FIG. 6A is a cross-section of FIG. 1 with positive pressure being applied in the negative pressured cavity.

FIG. 6B is a cross-section of FIG. 6A with no negative pressured cavity.

FIG. 7 is a slightly exploded view of FIG. 6A without a foot therein and illustrating a cross-sectional view of the operating section.

FIG. 8 is a top view of the operating section of FIG. 7.

#### SUMMARY OF THE INVENTION

A negative pressure, thermal energy device has an enclosure that receives a patient's hand or foot. The hand or foot is positioned in the enclosure and contacts a thermal energy contacting surface. The thermal energy contacting surface transfers its thermal energy to the patient. While in the enclosure, the hand and foot is also exposed to a negative pressure to cause vasodilation. The combination of the vasodilation and the thermal energy transfer, alters the patient's body core temperature. When the enclosure is just a non-shape altering material, the above-description is clearly disclosed in the prior art. A problem with the prior art is that if the patient moves its hand or foot from the thermal contacting surface, the patient does not receive the desired transfer of thermal energy. To ensure the patient's hand or foot remains in contact with the thermal contacting surface, the enclosure has portion thereof that is a shape altering material. When the negative pressure is applied to the shape altering material, the shape altering material is pulled toward the hand or foot to (a) provide a positive pressure on the hand or foot and (b) ensure the hand or foot effectively contacts the thermal energy contacting surface.

#### DETAILED DESCRIPTION OF THE INVENTION

Turning to FIGS. 1, 2 and 3, the present invention is directed to a thermal-energy, negative pressure device 10. For ease of reference, we have incorporated a patient's foot, not claimed, in the thermal-energy, negative pressure device illustrated in FIGS. 1, 2 and 3. Obviously a patient's hand could have been illustrated as well. This thermal-energy, negative pressure device 10 can be divided into sections.

The sections include and are not limited to a contact section 100 and an operation section 200. As illustrated at FIG. 1, the contact section 100 has components that enclose the patient's foot. The operation section 200 has the components that (a)

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create the negative-pressure in the contact section 100, (b) generate or provide the desired thermal energy that the patient's foot experiences in the contact section 100, and (c) in one embodiment, contact the patient's foot.

5 Contact Section

The contact section 100 is further divided into a hard shell (a.k.a., a non-shape altering, air impermeable enclosure) 110, a sole material (a.k.a., an air permeable, thermal transfer pad) 120, a pressure contact area 140, and a sealing area 160. Collectively and in one embodiment, the hard shell 110, the sole material 120, the pressure contact area 140, and the sealing area 160 have an interior surface 114 and an exterior surface 115. The interior surface 114 defines a cavity 112. The cavity 112 receives the patient's foot.

15 The hard shell area 110, as illustrated in FIGS. 2, 4, and 5, includes a toe area 130, a ledge 135, a first middle area 170A, a second middle area 170B, a transition support area 180, a first ankle area 190A, a second ankle area 190B, a heel area 150, a positive pressure opening 300, an appendage opening 400, and a negative pressure opening 700. See FIG. 3. The ledge 135 and the negative pressure opening 700 define a base area 116. From the base area 116, the hard shell area 110 extends upwards and sometimes toward the middle of the hard shell area 110.

25 The ledge 135 (a) circumvents the base area 116 of the hard shell area 110 as illustrated at FIG. 2, (b) is interspaced about the base area 116 of the hard shell area 110 as illustrated at FIG. 4, or (c) interspaced about portions of the base of the hard shell area 110 and having one base edge releasably interconnected, for example and not limited to a hinge embodiment 195, to the operation section 200 as illustrated at FIG. 5. The ledge 135 provides a surface for the sole material 120 to be removably positioned at the base area 116 of the hard shell 110 and between the hard shell 110 and the operation section 200. The ledge 135 also provides a surface for clips 210 (see FIG. 1) or equivalents thereof to removably secure the operation section 200 to the hard shell 110. The clips 210 could be an integral part of the operation section 200, the ledge 135, or removably connected to the operation section 200 and the ledge 135.

30 The hard shell area 110 is made of durable, hard thermoplastic material that is preferably air impermeable and non-shape altering. Non-shape altering means the hard shell 110 does not alter its shape when it is subjected to a negative pressure used in the normal operation of this device 10. An example of that durable, hard thermoplastic material is a polycarbonate material, a polypropylene material, a polyethylene material or combinations thereof. A specific example includes and is not limited to Bayer Material Science AG's Makrolon® 2658 polycarbonate. Whatever durable, hard thermoplastic material is used, the material should be injection moldable to form the ledge 135, the toe area 130, the first and second middle areas 170a,b, the transition support area 180, the first and second ankle areas 190a,b, and the heel area 150. In addition, the durable, hard thermoplastic material should not be an irritant to the patient's skin.

35 As illustrated in FIGS. 4 and 5, the toe area 130 has a distal end 132 and a proximal end 134; the transition support area 180 has a distal end 182 and a proximal end 184. The heel area 150 has a base end 152 and a top end 154. The base end 152 and the top end 154 can be in relation to the ledge perpendicular to each other as illustrated in FIG. 1, or angled in relation to each other.

40 The first middle area 170a has a base end 172a at the hard shell's base 116 and a top end 174a; and the second middle area 170b has a base end 172b at the hard shell's base 116 and a top end 174b. The top ends 174a,b do not meet each other,

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are spaced away from the respective base ends **172a,b**; and are equal to or, preferably, closer to the distance between the base ends **172a,b**.

The first ankle area **190a** has a base end **192a** at the hard shell's base **116** and a top end **194a**; and the second ankle area **190b** has a base end **192b** at the hard shell's base **116** and a top end **194b**. The top ends **194a,b** do not meet each other, are spaced away from the respective base ends **192a,b**; and are equal to or, preferably, closer to than the distance between the base ends **192a,b**.

The positive pressure opening **300** is defined in the hard shell **110** by a portion of the toe area's proximal end **134**, a portion of the transition support area's distal end **184**, and the top ends **174a,b** of the respective first and second middle areas **170a,b**. The positive pressure opening **300** is a first predetermined distance from the base **116**. The first predetermined distance is sufficient to allow the patient's foot in the cavity which means the top of the patient's foot, for the average patient, should not contact the interior surface **114** that defines the positive pressure opening **300**.

A first set of secure openings **310** in the hard shell **110** are spaced a pre-set distance from the positive pressure opening **300**. The first set of secure openings **310** also surrounds the positive pressure opening **300**. The first set of secure openings **310** are designed to secure a first air impermeable, shape altering thermoplastic material **500** (a) to the hard shell **110** and (b) over the positive pressure opening to form the pressure contact area **140**.

The first air impermeable, shape altering thermoplastic material **500** is overmolded to the hard shell **110** and by default over and/or at the positive pressure opening **300**. The term "shape altering" means the thermoplastic material will (a) alter its shape when it is subjected to a negative pressure used in the normal operation of this device **10**, and (b) essentially revert to its original shape or close to its original shape when it is not subjected to negative pressure. For example, when negative pressure is present in the cavity **112**, the first air impermeable, shape altering material **500** is drawn or pulled to the patient's foot. The negative pressured embodiment has the material **500** apply a positive pressure force against the patient's foot to ensure the patient's foot contacts the sole material **120** as illustrated in FIG. 6A. FIG 6B illustrates a non-negative pressure embodiment wherein the material **500** reverts to its original or close to original position that does not, should not, exert a positive pressure force against the patient's foot.

When the first air impermeable, shape altering thermoplastic material **500** is overmolded to the hard shell **110**, a portion of the first air impermeable, shape altering thermoplastic material **500** is positioned on (a) the exterior surface **115** possibly between the first set of secure openings **310** and the positive pressure opening **300** and possibly just beyond the first set of secure openings **310** away from the positive pressure opening **300** (see FIGS. 1, 2, 6A and 6B) and (b) the interior surface **114** possibly between the first set of secure openings **310** and the positive pressure opening **300** and possibly just beyond the first set of secure openings **310** away from the positive pressure opening **300** of the hard shell **110** (see FIGS. 6A and 6B). That way the first air impermeable, shape altering thermoplastic material **500** is securely attached to the hard shell **110**.

The appendage opening **400** is also defined in the hard shell **110** by a portion of the heel area top end **154**, a portion of the transition support area's proximal end **184**, and the top ends **194a,b** of the respective first and second ankle areas **190a,b**. The appendage opening **400** is sufficient to allow the patient's foot in the cavity **112** which means the top of the patient's

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foot, for the average patient, should not contact the interior surface **114** of the hard shell **110** that defines the appendage opening **300**.

A second set of secure openings **410** in the hard shell **110** are spaced a pre-set distance from the appendage opening **400**. The second set of secure openings **410** also surrounds the appendage opening **400**. The second set of secure openings **410** are designed to secure a second air impermeable, shape altering thermoplastic material **502** (a) to the hard shell **110** and (b) over the appendage opening **400** with an aperture **504** to receive the patient's foot and part of the patient's leg to form the sealing area **160**.

The second air impermeable, shape altering thermoplastic material **502** is overmolded to the hard shell **110** and by default over the appendage opening **400**. When the second air impermeable, shape altering thermoplastic material **502** is overmolded to the hard shell **110**, a portion of the second air impermeable, shape altering thermoplastic material **502** is positioned on (a) the exterior surface **115** possibly between the second set of secure openings **410** and the appendage opening **400** and possibly just beyond the second set of secure openings **410** away from the appendage opening **400** and (b) the interior surface **114** possibly between the second set of secure openings **410** and the appendage opening **400** and possibly just beyond the second set of secure openings **410** away from the appendage opening **400** of the hard shell **110**. That way the second air impermeable, shape altering thermoplastic material **502** is securely attached to the hard shell **110**.

The first and second air impermeable, shape altering thermoplastic materials **500**, **502** can be the same material or different materials. In many cases the two thermoplastic materials **500**, **502** are the same. In any case, the first and second air impermeable, shape altering thermoplastic materials **500**, **502** are non-rigid, pliable polymeric material that can move in response to negative pressure. A preferred, but not limited to, first and second air impermeable, pliable thermoplastic material **500**, **502**, is GLS corporation's Versaflex® CL2000X TPE alloy or variations thereof. A common characteristic of the first and second air impermeable, shape altering thermoplastic materials **500**, **502** is that each material creates a soft touch to the patient's body part when the material contacts the body part. Another common characteristic is that the materials **500**, **502** move toward the patient's foot in response to a negative pressure being applied within the cavity **112**. That movement is the basis for the first and second thermoplastic materials **500**, **502** being defined as air impermeable and shape altering. That movement in the second air impermeable, shape altering thermoplastic material **502** secures the material around the aperture **504** to the patient to create an air impermeable seal around the patient's leg. That movement in the first air impermeable, shape altering thermoplastic material **500** applies a positive pressure upon the patient's foot so it forces the patient's foot toward the sole material **120** to ensure the patient's foot remains in contact with the sole material **120** to obtain the maximize the transfer of thermal energy to the patient.

#### Sole Material

The hard shell **110**, the first air impermeable, pliable thermoplastic material **500**, the second air impermeable, pliable thermoplastic material **502**, and the operation section **200** (to be discussed later) are permanent components of the device **10**. In contrast, the sole material **120** is a replaceable material positioned over and/or at the negative pressure opening **700**. In particular the sole material **120** can be replaced after every use by a patient or between patients. For hygiene purposes, the applicant recommends replacing the sole material **120** after each use.

The sole material **120** is a barrier material that could provide bacteria penetration resistance, tear strength, and puncture resistance. The barrier material does not inhibit the transfer of thermal energy from the operation system **200** or inhibit the formation and maintaining of a negative pressure environment in the cavity **112** through the operation system **200**. An example of that material, and not limited to that material, is DuPont Corporation's Tyvek® material.

The sole material **120** can have a perimeter that corresponds with the hard shell's base area **116** perimeter. The sole material's perimeter can also have an adhesive that contacts to the base area **116**, which can also have a third air impermeable, shape altering thermoplastic material **510** (same material as the first and/or second air impermeable, pliable thermoplastic material **500**, **502**) overmolded on the base area **116**. Once the sole material **120** (a) is removably attached to the base area **116** or the third air impermeable, shape altering thermoplastic material **504** and (b) covers negative pressure opening **700**, the sole material **120** forms the contact section **100** with the interior surfaces **114** of the hard shell **110**, the first air impermeable, shape altering thermoplastic material **500**, the second air impermeable, shape altering thermoplastic material **502**; and the interior surface **114** of the sole material **120** defines the cavity **112** with the interior surfaces **114** of the hard shell **110**, the first air impermeable, shape altering thermoplastic material **500**, the second air impermeable, shape altering thermoplastic material **502**. (See FIG. 7)

The exterior surface **115** of the sole material **120** contacts the operation system **200**.

#### Operation System

The operation system **200** is a container having a perimeter that corresponds to the perimeter of the hard shell's base area **112**. The operation system **200** has a top surface, which contacts the sole material's exterior surface **120**, **115** or alternatively is a surface that helps defines the cavity **112** if the sole material **120** is not used. The operation system **200** also has sufficient space, preferably compact, to contain a conventional vacuum source **210** and a conventional thermal energy source **220**.

#### Thermal Energy Contacting Element

The thermal energy source **220** (see FIG. 8) has a thermal energy contacting element **222** that transfers thermal energy to, or extracts thermal energy from the body **5** portion in the negative pressured enclosure and a source **224** that provides the energy to run the contacting element **222** or provide fluid at a desired temperature to the element **222**. Whether the thermal energy transfers to or extracts from the foot depends on the relative temperatures of the thermal energy contacting element and the foot. The vasodilation in the foot enhances the exchange of thermal energy between a patient's body core, surface of the foot, and the thermal energy contacting element.

The thermal energy contacting element has been previously disclosed as (a) a conventional thermal warming plate or blanket, or a conventional thermal cooling plate or blanket, (b) a warm or cool water immersion element, (c) a warming or cooling gas element, and (d) a curved metal plate or a metal tube positioned in the interior of the enclosure.

The three latter embodiments can have a fluid (i) circulate within it and (ii) not contact the body portion in the desired area—the venous plexus area. The fluid can be provided by a hypo/hyper/normothermia fluid temperature control device. An example of such a device, and not limited to, is Gaymar's Medi-Therm II hypo/hyper/normothermia fluid temperature control device. That device is disclosed and incorporated by reference in commonly assigned U.S. Pat. No. 6,517,510.

Obviously, the electrical energy is supplied through an electrical conduit interconnected to an electrical source, and the hypo/hyper/normothermia fluid temperature control device is interconnected to the operation system **200** through a fluid conduit.

#### Vacuum System

The vacuum system **210** has conduits that draw the air from the cavity **112** through vacuum apertures **214** and the pad **120**, if used, to create the desired negative pressure in the cavity **112**. The system **210** connects to the enclosure for generating and, in some embodiments, maintaining a predetermined negative pressure inside the enclosure to cause vasodilation in the body portion surrounded in the enclosure. Negative pressure conditions are a pressure lower than ambient pressure under the particular conditions in which the method is performed. The magnitude of the decrease in pressure from the ambient pressure under the negative pressure conditions is generally at least about 20 mm Hg, usually at least about 30 mm Hg and more usually at least about 35 mm Hg, where the magnitude of the decrease may be as great as 85 mm Hg or greater, but typically does not exceed about 60 mm Hg and usually does not exceed about 50 mm Hg. The negative pressure applied to a portion of the body in the enclosure (a) decreases the temperature when vasoconstriction occurs and/or (b) increases the vasodilation in the body portion that is in the enclosure.

The negative pressure inducing element may be actuated in a number of different ways, including through motor driven aspiration, through a system of valves and pumps which are moved through movement of the mammal in a manner sufficient to create negative pressure in the sealed environment, etc.

In this invention, it is preferred the vacuum system **210** modulates its negative pressure in the cavity **112** from  $-60$  mm Hg to  $-10$  mm Hg, and preferably  $-40$  mm Hg to  $-25$  mm Hg. That modulation ensures the patient is not under a constant negative pressure. Constant negative pressure is undesired because the patient's body can become acclimated to the pressure and not cause vasodilation. Accordingly, it is desired that the negative pressure is modulated to retain and maintain the desired vasodilation effect.

The operation system **200** also has a leak aperture **201** that allows ambient air at a controlled rate to enter the cavity **112**. That leaked ambient air decreases the chances of the first and/or second shape altering, air impermeable material **500**, **502** from essentially becoming a tourniquet to the patient.

It is appreciated that various modifications to the inventive concepts described herein may be apparent to those of ordinary skill in the art without departing from the spirit and scope of the present invention as defined by the appended claims. Furthermore, while the present invention has been described with respect to a negative pressure, thermal energy device applied to a person's foot that should not be viewed as limiting its scope. Those skilled in the art after having read the present description will readily understand that the various enclosure structures are equally applicable for use with a patient's hand.

#### We claim:

1. A negative pressure, thermal energy device comprising: a non-shape altering, air impermeable enclosure having an appendage opening, a positive pressure opening, and a negative pressure opening; a first shape altering, air impermeable material positioned at the appendage opening, securely attached to the non-shape altering enclosure, and having an aperture to receive a portion of a patient's appendage;

- a second shape altering, air impermeable material positioned at the positive pressure opening and securely attached to the non-shape altering, air impermeable enclosure;
- an air permeable, thermal transfer pad (a) removably attached to the non-shape altering, air impermeable enclosure, (b) positioned at the negative pressure opening, and (c) having a top surface and a bottom surface;
- (a) the non-shape altering, air impermeable enclosure, (b) the first shape altering, air impermeable material, (c) the second shape altering, air impermeable material, and (d) the air permeable, thermal transfer pad define a cavity; an operating container
  - (a) that releasably attaches to the non-shape altering enclosure,
  - (b) has a thermal energy contacting surface that
    - (i) contacts at least a portion of the air permeable, thermal transfer pad's bottom surface,
    - (ii) transfers thermal energy through the air permeable, thermal transfer pad to the patient's body surface that contacts the air permeable, thermal transfer pad and
    - (iii) interconnects to or is a component of a thermal energy generating device; and
  - (c) has a vacuum source that generates a negative pressure in the cavity, the negative pressure in the cavity is sufficient to cause
    - (i) the patient's veins in the cavity to vasodilate, and
    - (ii) the second shape altering, air impermeable material to be pulled toward the patient to provide a positive pressure on the patient that ensures the patient's body part contacts the air permeable, thermal transfer pad.
- 2. The device of claim 1 wherein the negative pressure modulates.
- 3. The device of claim 2 wherein the negative pressure modulates between -25 and -40 mmHg.
- 4. The device of claim 1 wherein the operating container has a leak aperture that allows ambient air to enter the cavity.
- 5. The device of claim 4 wherein the leak aperture diminishes the chances that the first shape altering, air impermeable material will create a tourniquet effect on the patient.
- 6. The device of claim 1 wherein the thermal energy contacting surface defines a portion of a conduit, the conduit interconnects to the thermal energy generating device, the thermal energy generating device is a hyper/hypo/normothermia fluid temperature control device, the hyper/hypo/normothermia fluid temperature control device controls the temperature of the fluid, and the fluid at the predetermined temperature circulates in the conduit.
- 7. The device of claim 1 wherein the thermal energy contacting surface and the thermal energy generating device is a thermal heating plate or blanket.
- 8. The device of claim 1 wherein the thermal energy contacting surface and the thermal energy generating device is a thermoelectric cooler plate or blanket.
- 9. The device of claim 1 further comprising a third shape altering, air impermeable material positioned between the non-shape altering, air impermeable enclosure and the air permeable, thermal transfer pad.
- 10. The device of claim 1 wherein the first shape altering, air impermeable material is a sealed aperture.

- 11. A negative pressure, thermal energy device comprising: a non-shape altering, air impermeable enclosure having an appendage opening, a positive pressure opening, and a negative pressure opening; a sealed aperture to receive a portion of a patient's appendage; a first shape altering, air impermeable material positioned at the positive pressure opening and securely attached to the non-shape altering, air impermeable enclosure; an operating container that releasably attaches to the non-shape altering, air impermeable enclosure, and positioned at the negative pressure opening,
  - (a) the non-shape altering, air impermeable enclosure, (b) the sealed aperture, (c) the first shape altering, air impermeable material, and (d) the operating container define a cavity; furthermore, the operating container
    - (a) has a thermal energy contacting surface that transfers thermal energy to the patient's body surface and interconnects to or is a component of a thermal energy generating device; and
    - (b) has a vacuum source that generates a negative pressure in the cavity, the negative pressure in the cavity is sufficient to cause
      - (i) the patient's veins in the cavity to vasodilate, and
      - (ii) the first shape altering, air impermeable material to be pulled toward the patient to provide a positive pressure on the patient that ensures the patient's body part is positioned at the negative pressure opening to maximize the transfer of thermal energy from the thermal energy contacting surface to the patient's surface.
- 12. The device of claim 11 wherein the negative pressure modulates.
- 13. The device of claim 12 wherein the negative pressure modulates between -25 and -40 mmHg.
- 14. The device of claim 11 wherein the operating container has a leak aperture that allows ambient air to enter the cavity.
- 15. The device of claim 11 wherein the thermal energy contacting surface defines a portion of a conduit, the conduit interconnects to the thermal energy generating device, the thermal energy generating device is a hyper/hypo/normothermia fluid temperature control device, the hyper/hypo/normothermia fluid temperature control device controls the temperature of the fluid, and the fluid at the predetermined temperature circulates in the conduit.
- 16. The device of claim 11 wherein the thermal energy contacting surface and the thermal energy generating device is a thermal heating plate or blanket.
- 17. The device of claim 11 wherein the thermal energy contacting surface and the thermal energy generating device is a thermoelectric cooler plate or blanket.
- 18. The device of claim 11 further comprising an air permeable, thermal transfer pad removably attached to the negative pressure opening, and positioned between the non-shape altering, air impermeable enclosure and the operating container.
- 19. The device of claim 11 wherein the sealed aperture is a second shape altering, air impermeable material.
- 20. The device of claim 11 further comprising a third shape altering, air impermeable material positioned between the non-shape altering, air impermeable enclosure and the operating container.