HEAT-EXCHANGE DEVICE WITH IMPROVED SEAL

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ABSTRACT

A module for thermal exchange with a portion of a mammal is provided. The module is used with advanced methods related to body temperature control and management. A portion of a mammal is placed in a sealed enclosure that is in thermal communication with a heat exchange fluid. The enclosure is also adapted to provide a negative pressure environment and includes an improved interface with the external environment.
HEAT-EXCHANGE DEVICE WITH IMPROVED SEAL

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] The present application is related to and claims priority from the U.S. Provisional Patent Application Serial No. 60/285,060 filed on Apr. 19, 2001 entitled “Negative pressure heat-exchange device with improved seal”, the disclosure of which is herein incorporated by reference in its entirety.

FIELD OF INVENTION

[0002] This application relates to body temperature control and management, and more particularly to, a system for applying or removing thermal energy to or from a mammalian body, the system having an improved interface with the external environment.

BACKGROUND

[0003] Regulating human or mammalian body temperature is desirable in many instances. For example, it may be desirable to raise the core body temperature to treat hypothermia arising, for example, from prolonged exposure to cold environments, trauma or post-operative conditions. Raising body temperature to induce hyperthermia is desirable as well. For example, various treatments for viral diseases and cancers call for elevated body temperatures. Another avenue for body temperature regulation is the lowering of body temperature to treat hyperthermia that may arise, for example, from fever, heat stroke, extreme environments, multiple sclerosis, exercise or exertion induced conditions. Lowering body temperature to induce hypothermia is also desirable to minimize damage to the brain when a patient has suffered a stroke, for example, or to minimize damage to heart or brain tissue when a patient has undergone cardiac arrest. It may sometimes also be desirable to induce hypothermia during surgery to minimize tissue damage. Generally, there are numerous therapeutic reasons for thermal regulation that is aimed at raising, maintaining or lowering body temperature. Whether to induce certain therapies or to normalize body temperature, core body temperature control and management is valuable and potentially life-saving.

[0004] Advanced temperature control and management involves not only adding or removing heat, but also, includes an understanding of the complex autonomic thermoregulatory system within the body. Examples of thermoregulatory responses that maintain the body at a near constant normothermic temperature include sweating and vasodilation to enhance heat loss, arterio venous shunting and vasoconstriction to enhance heat retention, and shivering to enhance increased production of body heat. One important effector of the regulatory system is blood flow to specialized skin areas where heat from the deep body core can be dissipated to the environment. Normally, when body and/or environmental temperatures are high, the dilation of certain blood vessels favors high blood flow to these surfaces, and as environmental and/or body temperatures fall, vasoconstriction reduces blood flow to these surfaces and minimizes heat loss to the environment. Generally, thermoregulatory mechanisms provide a formidable defense when attempts are made to change the body temperature and there is a great interest in the development of methods in which the thermoregulatory system is manipulated so that energy can be transferred into or out of the core body without triggering an opposing thermoregulatory response.

[0005] Core body temperature control and management methods may involve various drugs and methods that are employed to control the thermoregulatory response so that energy may be added or removed as efficiently and safely as possible. One temperature control and management method involves the application of a negative pressure to a portion of the body in order to induce vasodilatation for regulated heat transfer. Devices for practicing temperature control and management methods that involve the application of a negative pressure include means for providing the negative pressure environment for a portion of the body as well as a heat exchange medium. In many embodiments, this means for providing a negative pressure environment includes a means for sealing a portion of the mammal's body in an enclosed environment in which negative pressure conditions can be produced. Representative enclosing means include sleeves, boots/shoes, gloves, etc. which are in operational relationship with a negative pressure inducing means, e.g., a vacuum, that is capable of producing a negative pressure environment in a sealed enclosure. The devices also include a means for thermal communication with a heat exchange medium. The interface of the negative pressure environment with the environment outside of the sealed enclosure must permit a portion of the mammal to be received and be substantially sealed within the enclosure while maintaining an adequate negative pressure within the environment.

[0006] Aquarius, Inc. (Scottsdale, Ariz.) produces a system that utilizes a “hard” seal interface with a user. 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. Hence, it is desirable that the chamber interface substantially prevents escape of vacuum air without unduly constricting the portion of the body that is sealed within the negative pressure environment. The “soft” seal as described in the present invention provides a unique solution to this problem while accommodating movement of the portion of the normal. However, the “soft” seal of the present invention that accommodates movement is susceptible to leaks across the seal. These leaks are variable in terms of degree of leak flow rate and, hence, a unique vacuum regulation control method is additionally set forth in this invention.

[0007] Another challenge is providing a seal configuration that permits ease of entry and exit from the device. Entry and exit from the Aquarius seal is difficult. Whether “hard” or “soft” in function, the system of this invention provides an advantageous solution.

SUMMARY OF INVENTION

[0008] In accordance with one aspect of the invention, there is provided a module for thermal exchange with a portion of a mammal. The module includes a chamber that defines a chamber opening and is adapted to receive the portion of the mammal. The module includes an exchange surface in thermal communication with the first chamber.
seal is connected to the first chamber at the chamber opening. The seal includes a seal opening and a waist opening. The chamber opening and the seal opening are greater than the waist opening such that a ramped entry and exit is provided for the portion of the mammal.

[0009] In accordance with another aspect of the invention, there is provided a module for thermal exchange with a portion of a mammal. The module includes a housing including a first chamber and an exchange surface. The first chamber includes a chamber opening and is adapted to receive a portion of a mammal. The exchange surface is in thermal communication with the first chamber. A seal is connected to the first chamber at the chamber opening. The seal forms a variable opening adapted to substantially conform against the mammal to seal the portion of the mammal inside the first chamber.

[0010] In accordance with yet another aspect of the invention, there is provided a module for thermal exchange with a portion of a mammal. The module includes a housing including a first chamber and an exchange surface. The first chamber is adapted to receive a portion of a mammal and is adapted to provide a negative pressure environment. The first chamber includes a chamber opening. The exchange surface is in thermal communication with the first chamber. A seal is connected to the first chamber at the chamber opening. The seal has a longitudinal axis and comprises a flexible wall member that provides substantial contact sealing against at least a portion of the external surface of the mammal while accommodating motion of the portion of the mammal that is lateral to the longitudinal axis.

[0011] In accordance with another aspect of the invention, there is provided a module for thermal exchange with a portion of a mammal. The module includes a housing including a first chamber and an exchange surface. The first chamber includes a chamber opening. The first chamber is adapted to receive a portion of a mammal and is adapted to provide a negative pressure environment. The exchange surface is in thermal communication with the first chamber. A seal is connected to the first chamber at the chamber opening. The seal comprises a flexible sleeve including a waist portion. The waist portion is adapted to engage at least a portion of the external surface of a portion of the mammal. The sleeve is deflectable with movement of the portion of the mammal.

[0012] In accordance with another aspect of the invention, there is provided a module for thermal exchange with a portion of a mammal. The module includes a housing including a first chamber and an exchange surface. The first chamber is adapted to receive a portion of a mammal and is adapted to provide a negative pressure environment. The first chamber includes a chamber opening. The exchange surface is in thermal communication with the first chamber. A seal is connected to the first chamber at the chamber opening. The seal includes an elastic element to bias the seal against the portion of the mammal.

[0013] In accordance with yet another aspect of the invention, there is provided a module for thermal exchange with a portion of a mammal. The module includes a first chamber and an exchange surface. The first chamber defines a chamber opening and a port. The first chamber is adapted to receive a portion of a mammal via the chamber opening. The first chamber being adapted to receive a negative pressure via the port. The exchange surface is in thermal communication with the first chamber. A seal is connected to the first chamber at the chamber opening to seal the portion of the mammal inside the first chamber.

[0014] In accordance with another aspect of the invention, there is provided a module for thermal exchange with a portion of a mammal. The module includes a housing having a first end and a second end. The housing includes a chamber that is adapted to receive a portion of the mammal and a heat exchange cavity in thermal communication with the chamber. A seal is connected to the housing at the second end. The seal defines a chamber opening, a waist opening, and a seal opening. The waist opening is located between the chamber opening and the seal opening. The chamber opening is located proximate to the plate relative to the seal opening. A seal frame is connected to the housing at the second end and supports the seal.

[0015] In accordance with another aspect of the invention, there is provided a module for thermal exchange with a portion of a mammal that includes a base having an exchange surface and a base perimeter. The module further includes a cover connected to the base to form a chamber for receiving the portion of a mammal such that the portion of the mammal is in thermal communication with the exchange surface. The chamber is adapted to receive a negative pressure environment relative to atmospheric pressure. The cover has a cover perimeter. The module includes a seal for contacting the portion of the mammal to substantially prevent leakage of air across the seal.

[0016] In accordance with another aspect of the invention, there is provided a method for thermal exchange with a portion of a mammal. The method comprises the steps of providing a module having a chamber for receiving a portion of the mammal. The module includes a seal that allows a variable leakage of air across the seal. A vacuum pump that is coupled to the chamber to draw air from the chamber is also provided. A control system that is coupled to the vacuum pump for regulating the air pressure within the chamber is also provided. The method further includes the steps of selecting a pressure set-point and establishing an air pressure inside the chamber that is substantially equal to the pressure set-point. Furthermore, the method includes the step of maintaining the pressure set-point within the chamber.

BRIEF DESCRIPTION OF THE DRAWINGS

[0017] The foregoing and other advantages of the invention will become apparent upon reading the following detailed description and upon reference to the drawings in which:

[0018] FIG. 1 is a fore perspective view of the thermal exchange module of the present invention;

[0019] FIG. 2 is an aft perspective view of the thermal exchange module of the present invention;

[0020] FIG. 3 is an exploded view of the thermal exchange module of the present invention;

[0021] FIG. 4 is a rear elevational view of the thermal exchange module of the present invention;

[0022] FIG. 5 is a cross-sectional view along line A-A of FIG. 4 of the thermal exchange module of the present invention;
FIG. 6 is a cross-sectional view along line B-B of FIG. 4 of the thermal exchange module of the present invention;

FIG. 7 is a perspective view of the thermal exchange module of the present invention;

FIG. 8 is a perspective view of the thermal exchange module with a detached seal cartridge of the present invention;

FIG. 9 is an exploded view of the thermal exchange module of the present invention;

FIG. 10 is a perspective view of the thermal exchange module of the present invention;

FIG. 11 is a perspective view of the thermal exchange module of the present invention;

FIG. 12 is a perspective view of the thermal exchange module and heat exchange element of the present invention; and

FIG. 13 is a perspective view of the thermal exchange module of the present invention with a human hand inserted therein.

While the invention is susceptible to various modifications and alternative forms, specific variations have been shown by way of example in the drawings and will be described herein. However, it should be understood that the invention is not limited to the particular forms disclosed. Rather, the invention is to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the invention as defined by the appended claims.

DETAILED DESCRIPTION

This invention relates generally to hardware configured for carrying out the methodologies in particular, those described in Provisional Patent Application entitled METHODS AND DEVICES FOR EXTRACTING THERMAL ENERGY FROM THE BODY CORE OF A MAMMAL filed on Apr. 20,2000, Provisional Patent Application entitled METHODS AND DEVICES FOR ENHANCING THE PHYSICAL ABILITY OF A MAMMAL filed on Apr. 20,2000, Provisional Patent Application entitled METHODS AND DEVICES FOR MANIPULATING THE THERMOREGULATORY STATUS OF A MAMMAL filed on Jun. 9,2000 and Provisional Patent Application entitled METHODS AND DEVICES FOR PREVENTION OF HYPOTHERMIA IN A MAMMAL DURING PROLONGED EXPOSURE TO EXTREME COLD, each to Dr. H. Craig Heller and Dr. Dennis Grahn, each incorporated by reference herein in its entirety.

FIGS. 1 and 2 provide aforesaid and perspective views of a negative pressure thermal exchange module (100). FIG. 3 provides an exploded view of the same. The system components not shown in the figures include a thermal control or perfusion unit. Such a unit may be adapted to provide a stream of heat exchange media such as fluid at elevated temperatures, lowered temperatures or both. Various methods of thermal exchange known to those skilled in the art fall within the scope of this invention. Examples of thermal exchange methods include employing a temperature-controlled fluid, thermoelectric elements, desiccants, micro-refrigeration, and chemical reactions. Examples of temperature-controlled fluids include water, alcohol, and chlorofluorocarbons (CFCs). Further, a vacuum source and regulator optionally used with module (100) are not shown. Any sort of vacuum source or regulator/control mechanism may be used with module (100) as would be apparent to one with skill in the art. At least one unique vacuum control mechanism is described below. Together, these components work to maintain a desired pressure and temperature within module (100) during use.

As shown, module (100) includes a housing (102) defining a negative pressure chamber (104), a heat-exchange element (106) and a soft, two-sided seal (108) supported by seal frame elements (110).

Housing (102) may be made from a cover (112) and a base (114). Negative pressure chamber (104) is preferably provided between heat exchange element (106) and cover (112). Chamber (104) is adapted to receive a portion of a mammal and to provide a negative pressure environment. The chamber (104) is in thermal communication with the heat exchange element (106) that is in thermal communication with a working medium located in a heat exchange cavity (126). In one embodiment, the heat exchange cavity (126) is external to the module (100). The embodiment shown is adapted to fit the hand of a human user. Chamber (104) is preferably configured to fit a human hand of any size, however the invention is not so limited and any functional portion of a mammal may be employed. In order to provide a more space-efficient package, however, it may be more preferably sized to fit 95% of human hand sizes. Alternately, it may be sized for more particularized groups, such as children. It is also contemplated that the housing (102) may be configured to fit a human foot since the under surface of a foot may also be used effectively as a heat exchange surface.

Housing (102) may be constructed from multiple pieces, including an end cap (116) as shown, or it may be provided as a unitary structure. Cap (116) is shown including a ports (118). A first port may be utilized for connection to a vacuum source, while the second may be utilized for a vacuum gauge. Of course, alternate port placement is also possible.

Preferably, housing (102) is made of plastic. Most preferably, the material and design of at least a portion of module (100) are such that housing (102) may be produced by vacuum forming or molding techniques.

Where discrete cover (112) and base (114) portions are used, they may be mechanically secured to one another via fastening means such as through bolt holes (120), adhesive, or retention bands that help form a substantially airtight seal. In such an instance, a gasket or caulking may be employed to seal the periphery of housing (102).

Providing a separable cover (112) and base (114) or heat exchange element (106) provide advantageous access to clean module (100) after use. However, it is contemplated that the top and bottom portions of the module may be fused together, for instance, by ultrasonic welding, chemical bonding or otherwise. Also, as noted above, it is contemplated that housing (102) may be provided in a single piece.

Regardless of the construction, sizing or overall appearance of housing (102), it defines a portion of chamber (104). A heat exchange surface (122) for delivering or
accepting a thermal load from a user also defines a portion of chamber (104). A user may directly contact heat exchange surface (122). Alternatively, a user may wear a glove or sock or take other prophylactic measures. Heat exchange surface (122) may be provided by a member separate from heat exchange member (106) such as by an intermediate layer of foil, metalized Mylar or another material.

[0041] Heat exchange element (106) is preferably made of aluminum, stainless steel or another high thermally conductive and non-corrosive material. It may be in communication with a thermal electric heating element such as a Peltier device, a desiccant cooling device or an endothermic or exothermic chemical reaction to provide a temperature variance. More preferably, however, heat exchange member (106) is in communication with an inlet and an outlet (124) to accommodate a flow of perfusion liquid behind heat exchange surface (122). Chillied or heated water may be used to maintain the contact surface of the element at a desired temperature. Optimally, perfusion fluid is run through a series of switchboxes in cavity (126) between element (106) and base (114) to ensure adequate thermal contact with the heat exchange surface (122) and to maintain even heating or cooling by avoiding hot or cold spots.

[0042] A rear portion of housing (102) and heat exchange member (106) may be provided by plate (128). As depicted, this portion may include provision for inlet and outlet (124) to heat exchange cavity (126) and a chamber opening (130) to chamber (104). A preferred manner of constructing seal (108) is disclosed in connection with plate (128).

[0043] Views detailing preferred geometric aspects of seal (108) are shown in FIGS. 4, 5 and 6. FIG. 4 shows an end-on view of seal (108). The seal (108) having a longitudinal axis (L) includes a chamber portion (129), a waist portion (135), and a seal portion (137) each defining a chamber opening (131), a waist opening (136), and a seal opening (138) respectively. The chamber portion (129) of the seal (108) is connected to the housing (102) at the chamber opening (130). Preferably, at least portions of seal (108) are ovalized in form. An elliptical shape may be preferred. A circular shape may also be used. Still, a shape having a major axis (132) and a minor axis (134) will be preferred, at least for the waist opening (136) of seal (108). An ovalized shape approximately corresponds to the shape of the wrist or forearm of a user. A shape having a major axis (132) and a minor axis (134) will also be preferred at chamber opening (131) and seal opening (138). This will assist in providing clearance for hand entry and exit of module (100). It will also simplify the construction of the seal.

[0044] Whether or not ovalized features are utilized for seal (108), it will be shaped roughly like an hourglass. Seal (108) will most closely resemble an hourglass if openings (131), (136) and (138) are circular. When ovalization is applied, different projected views of seal (108)—such as viewed in FIG. 5, for the section taken along line A-A and in FIG. 6 for the section taken along line B-B—display an hourglass shape.

[0045] Of course, the shapes depicted may be characterized as other than “hourglass” forms. For instance, profiles of seal (108) may be viewed as hyperbolic or parabolic. Further, simple raduised or semi-circular cross-sections may be utilized in producing seal (108). Further straightened sections may be used, especially, between the openings (131) and (138) and waist (136).

[0046] Whatever the case, a seal with outside openings of a greater size than that of the inside opening is to be used in module (100). For example, the opening 131 and the seal opening 138 are greater relative to the waist opening 136. This geometry provides for ramps or transition sections for appendage entry and exit. These features assist in stretching the seal interface or waist (136) sufficiently wide to pass a hand or foot both for insertion into and removal from module (100).

[0047] Material selection is important in providing such a seal. Clearly, the material must be able to stretch. Further, it should provide a substantial barrier to air flow. To meet each of these criteria, a urethane-backed lyca visible from Malden Mills (Malden, Mass.) has proven effective. Still, it is contemplated that other materials may be used. The material (or materials) selected for webbing (140) preferably has a finish that does not grip onto a user so as to complicate entry and exit from module (100). The urethane skin of the referenced material has a satin finish. This decreases friction with the skin and hair of a user.

[0048] In addition to providing sufficient stretch, the seal webbing material should also have sufficient strength to avoid being drawn too far into cavity (104) upon the application of vacuum. When in use, the open construction of seal (108) will result in cavity-side webbing material exposed to partial vacuum within chamber (104) to be forced by ambient pressure inward. This self-inflation phenomenon observed for the chamber-side of the seal is of assistance in providing seal patency with a user. However, if too much material bows inward, it will result in an uncomfortable or disconcerting displacement of the user’s hand or foot into the device. Therefore, an elasticity of the seal material is selected such that too much material does not bow inwardly when negative pressure is applied in the chamber. A less elastic seal will not bow inwardly as much when compared to a seal that is more elastic. In operation, when the user inserts an appendage into the device and the vacuum is applied, the seal will bow inwardly to reduce at least the waist opening by an amount sufficient to contact the appendage without uncomfortably cinching the wrist. Therefore, the elastic seal permits sealing upon the application of a vacuum without the use of a “hard” seal such as an inflatable bladder cuff. Accordingly, with proper material choice, the side of seal (108) opposite chamber (104) provides not only a transition section for entry and exit, but also a stabilizing feature for seal position.

[0049] Seal (108) is preferably formed by a sleeve made by stitching two pieces of webbing material (140) together where they are shown broken apart in the exploded view of FIG. 3, although the invention is not so limited. By constructing the sleeve from two or more pieces, complex shapes can be easily produced. To secure the sleeve webbing (140) in place to form seal (108), it is folded over rings (142) at each end as variously depicted. Then the cavity-side ring and webbing is captured in opening (130) of plate (128). The opposite side of seal webbing (140) is captured between outer ring (142) and retainer member (144). Standoffs (146) or equivalent structure space plate (128) and ring retainer (144) apt to define the overall length of seal (108). Of course, the length of the standoffs or seal may be varied as well as the other parameters of seal (108) that effect fit.
In this respect, it is noted that it may be desirable to provide a longer overall seal in some instances. Increasing overall length provides further design flexibility with seal shape. This may be best taken advantage of by increasing the length of waist (134) to provide greater seal surface contact with a user. This may beneficially reduce any undesirable constricting effects. Furthermore, it is to be appreciated that the nature of the material used for the seal webbing (140) may be advantageously varied. While the noted lyera-based material is isotropically in nature, an anisotropic material or effect may be preferred for the webbing. This is to say that greater radial expansion of the sleeve may be desirable, whereas longitudinal compliance may not be. By reducing compliance along the axis of the sleeve relative to a radial or lateral component, it will tend to be drawn into chamber (104) to a lesser degree upon the application of vacuum. For a very high-stretch material, this will allow for smaller seal openings to fit the same population (since they can still stretch webbing (140) laterally and have it return sufficiently to form a desired seal), without forfeiting the full set of advantages that the two-sided seal described offers.

Such an anisotropic effect may be achieved in a number of ways. It may be accomplished by providing longitudinal reinforcement member(s) associated with the webbing. They may be incorporated through braiding techniques, by bonding/affixing stiffener(s) to the sleeve surface or by other means as would be apparent to one with skill in the art.

The seal (108) includes a relaxed position defined by the fact that no portion of the mammal is contact with the seal (108). When the portion of the mammal is inserted through the seal (108), at least the waist opening (136) will expand under force of the moving portion of the mammal as it is being inserted. Hence, the elastic material of the seal provides a waist opening (136) that varies in size with the insertion of the portion of the mammal and substantially conforms to seal against the portion of the mammal. The waist opening (136), when in a relaxed position, may be sized smaller than the expected size of the portion of the mammal to pass therethrough, or alternatively, the waist opening (136) may be miniscule. The invention is not limited to a variable waist opening (136). The seal opening (138) may likewise be variable as are portions between the waist opening (136) and the chamber opening (131) and the seal opening (138). Overall, at least a portion of the seal (108) includes an elastic element to bias the seal (108) against the portion of the mammal. Hence, the seal (108) forms a variable opening adapted to substantially conform against the mammal to contact or seal a portion of the mammal inside the chamber (104).

The seal (108) includes a flexible wall member that provides substantial contact sealing at least a portion of the external surface of the mammal while accommodating motion of the portion of the mammal wherein the motion of the mammal is in a direction lateral to the longitudinal axis (L) of the seal (108). For example, when a hand is inserted into the seal (108), and if the middle finger first breaches the seal opening (138), it may do so with or without forcing expansion of the seal opening (138). Next, the middle finger, for example, may breach the waist opening (136) and it may do so with or without forcing expansion of the waist opening (136). However, once the widest portion of the hand contacts the seal (108), the seal (108) will surely expand and circumferentially conform to seal against the hand. Any one portion or at least the waist portion (135) will engage at least a portion of the external boundary of the portion of the mammal. When the hand is positioned within the chamber, another portion of the mammal, for example, the wrist will rest within the seal (108). Of course, with the wrist substantially aligned with the longitudinal axis (L) of the seal (108), the seal (108) will preferably engage the entire boundary of the external surface of that portion of the wrist. The seal (108) is no longer in a relaxed position, but in what may be called an active engaged position.

The seal (108) is designed to substantially accommodate movement of the portion of the mammal yet substantially prevent leakage of vacuum fluid from the chamber (104). To use the same example of a hand, the seal (108) accommodates motion of the hand that is eccentric or lateral to the longitudinal axis (L). Hence, the seal (108) is said to be laterally deflectable with motion of the portion of the mammal relative to the rest of the module (100). When, for example, motion of the portion of the mammal, the wrist, for example, is substantially lateral relative to the longitudinal axis (L), a portion of the seal will be overly compressed on one side whereas the opposing side will tend to approach the relaxed position, thereby, providing an avenue for air leak thereafter. This feature is advantageous with respect to providing a seal design that is comfortable for the user.

A “soft” seal as described herein is characterized as providing an approximate or imperfect seal at a user/ seal interface while accommodating substantial eccentricities of the portion of the mammal received. 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 as described above. 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.

Vacuum regulation in the application of body temperature regulation is very important. A negative pressure environment is generated within the module to distend the blood vessels of the appendage located inside the module. This distension dilates the blood vessels, which allows higher bloodflow rates, which is advantageous for delivery of energy from the appendage to the rest of the body or from the body to the appendage for dissipation into the module. Furthermore, the distension of blood vessels pools more blood volume in the region that is in thermal communication with the module.

First, a set-point for the desired level of negative pressure within the chamber is selected. This set-point level of negative pressure within the negative pressure chamber is then established and maintained by a control system. The control system is in communication with a vacuum pump that is in communication with the negative pressure chamber for withdrawing air therefrom. The control system monitors...
the pressure within the chamber and adjusts a valve to throttle it accordingly until the pressure within the chamber is re-established at the selected set-point.

[0058] As described above, the “soft” seal is designed such that leakage of air at the seal is possible in order to avoid a tourniquet effect at the wrist. The negative pressure control system is adapted to maintain a negative pressure environment at the set-point pressure despite a great variability in leaks. The variability of leaks arises, for example, when an appendage is displaced by varying distances from the longitudinal axis and by the time period of such displacements. Also, varying appendage geometries of different or same users may create a variability of leaks. Simply repositioning the appendage can create a very large, small, or no leak at all. Uniquely, the allowability of leaks is inherent in the seal design of the present invention. This allowability of leaks is intended to comfortably accommodate a user. The negative pressure control system is adapted to maintain a functional negative pressure for optimum heat exchange with the appendage that involves the maintaining a constant level of vacuum throughout a wide range of leaks having varying leak flow rates. For example, if there is a large leak, the vacuum regulator must draw air from the chamber at a very high flow rate in a short amount of time to re-establish the set-point pressure without over-drawing. The control system monitors the leak flow rate and responds to the leak flow rate with an equivalent vacuum draw rate by throttling the valve accordingly.

[0059] Regardless of the particulars of seal construction and whether it is utilized to provide a “hard” or “soft” user interface, the dual-sided seal disclosed provides a superior manner of carrying out the methodology noted above. Though a “soft” two-sided seal as shown in the figures is preferred for its elegance in approach and proven effectiveness, a “hard” or more complex “soft” seal approach might sometimes be desired.

[0060] In order to utilize the dual-sided seal in a “hard” approach, supplemental forcing means may be provided to apply pressure around seal waist (134). Mechanical means such as at least one of a strap, Velcro™, belt or chin may be used. Alternately an inflatable cuff or bladder portions around the periphery of the seal may be employed. In one variation, the “soft” seal (108) is designed to have a waist opening (136) that is smaller than the seal opening (138) and chamber opening (131). Expansion means to expand or pull the seal open for insertion of the appendage is connected to the seal. The expansion means, for example, include cordage, mechanical linkage and any other expansion means known to a person skilled in the art. In one variation, the expansion means includes stop means to keep the opening constant for tailored sealing with a particular user. For example, a user expands the seal using the expansion means until insertion of the hand is easy and comfortable and a seal is properly established without undue constriction. Then, the user can engage the stop means to prevent the seal from contracting back to its initial opening and creating an uncomfortable tourniquet effect. Examples of stop means include any device or mechanical linkage that limits the travel of the expansion and contraction of the seal and those known to one skilled in the art.

[0061] While the system complexity will increase due to provision for providing the supplemental pressure and controlling it by either automated or manual means, certain potential advantages arise. It may enable a single-evacuation procedure for chamber (104) rather than relying on constant or periodic vacuum replenishment. It may also provide greater design flexibility for seal (108). Particularly, by providing another variable to utilize in design decisions, a lesser emphasis may be placed on webbing material choice or opening sizing since the supplemental forcing capacity may be used to shape the seal as desired in use. Further, it may enable fitting the seal (108) to a wider range of a populace for a given configuration of hard elements, such as those that make-up seal frame (110).

[0062] Supplemental forcing or seal shaping means may also be used to produce a more complex “soft” seal than that described above. As with a “hard” seal approach, this would open design and fit possibilities. Forcing or seal shaping parameters may, again, be controlled manually or automatically. Except, in a complex “soft” seal, the control of pressure applied to waist (134) is gauged to provide a compliant feel or fit. Since the application of pressure on the seal interface with the user may be the only difference between a complex “soft” seal approach and a “hard” seal approach utilizing the dual-sided configuration, the same apparatus may be configured to function in either manner, for instance, by providing variable pressure control.

[0063] In one variation, the seal (108) is adapted such that one end of the seal (108) is rotatable relative to the other end of the seal (108) to reduce the opening of the seal. For example, ring (142) carrying the chamber portion (129) is adapted to rotate relative (128) to ring (144). Ring (144) may remain stationary or rotate by a lesser degree such that there is relative movement of the chamber portion (129) of the seal (108) with respect to the seal portion (137) of the seal (108). Of course ring (142) may remain stationary or rotate by a lesser degree such that there is relative movement of the chamber portion (129) with respect to the seal portion (137). Rotation of one end of the seal (108) relative to the other end of the seal (108) constrains the seal (108) inwardly to reduce at least one of the openings (131), (136) and (138). Twisting the seal can finely control the degree to which the openings in the seal are reduced or expanded.

[0064] When twisted, folds in the seal (108) may be created. In one variation, to avoid creating folds, the seal (108) is inserted into a cylindrical sheath or sock (not shown). The sheath encompasses the seal (108) and is substantially coaxial with respect to the seal (108). The sheath is made of similar material as the seal (108) or it can be made of any suitable material. The sheath is supported by the seal frame or by a sheath frame. In this variation, the seal (108) is not rotatable. The sheath is adapted such that one end of the sheath is rotatable relative to the other end of the sheath. When one end of the sheath rotates relative to the other end of the sheath, the sheath opening is reduced. Reduction of the sheath opening will gently push against the seal (108) to reduce the opening of the seal without generating folds in the seal (108). Folds are created in the twisted sheath and not in the seal (108). The sheath is easily adapted into the frame elements of the device to provide a complex “soft” seal variation.

[0065] Referring now to FIGS. 7-9, there is depicted another variation of a negative pressure thermal exchange module (200). The module (200) includes a housing (202)
and a seal cartridge (204). The seal cartridge (204) is removably connected to the housing (202).

[0066] The housing (202) includes a cover (206), a base (208), a plate (212), and a heat exchange element (210) having a heat exchange surface (222). The cover (206) is connected to the base (208) and plate (212) to define a chamber (214) for receiving a portion of a mammal via a chamber opening (216) defined in the plate (212). The chamber (214) is defined between the heat exchange surface (222) and the cover (206). As depicted, the cover (206) is made of transparent plastic material; however, the invention is not so limited and any suitable material, transparent or not, is within the scope of the present invention.

[0067] The base (208) includes a heat exchange cavity (218). Thermal exchange media (not shown) is received within the heat exchange cavity (218) via inlet and outlet ports (not shown) such that the media is communication with an element (not shown) that is external to the module (200) such as a thermal electric heating element such as a Peltier device, a desiccant cooling device or an endothermic or exothermic chemical reaction to provide a temperature variance. As shown, the base (208) includes pathways (220) in the form of switchbacks for the media to ensure adequate thermal contact with the heat exchange element (210) and to maintain even heating and cooling.

[0068] The heat exchange element (210) is in thermal communication with the heat exchange surface (222) and in thermal communication with the media received in the pathways (220). The heat exchange element (210) is in thermal communication with the heating and/or cooling element that is preferably external to the device. The heat exchange element (210) is preferably made of aluminum or another highly conductive, non-corrosive material. The heat exchange element (210) includes a surface (222) with which the mammalian appendage comes into contact. The contact surface (222), in one variation, is separable from the heat exchange element (210). One advantage of the separability of the heat exchange surface (222) from the heat exchange element (210) is to dispose of a used or soiled surface for the replacement of a new one. Another advantage of a separable heat exchange surface (222) is to have the heat exchange element external to the module (200). Furthermore, the heat exchange element (210) is shown to be convex with respect to inside the chamber (214). Of course, the contact surface (222) substantially conforms to the curvature of the heat exchange element (210). Aside from its aesthetic appeal and ornamental quality, the curvature of the heat exchange element (214) provides for a naturally curved surface for an appendage such as a human hand to comfortably rest in a relaxed position on top of the surface (222).

[0069] The plate (212) is connected to the rear portion of the housing (202) such that its chamber opening (216) provides passage to the chamber (214). The chamber opening (216) is suitably sized to receive a wide range of appendage sizes. The plate (212) also includes additional ports. For example, in one variation, a pressure port (224) is formed in the plate (212) for the attachment of a pressure gauge (226). Also, ports (228) for vacuum induction are also be formed in the plate (212) in one variation. Of course, ports for receiving various fasteners (230) are also provided for fastening the seal cartridge (204).

[0070] The seal cartridge (204) will now be described. The seal cartridge (204) forms an element that is separable from the housing (202). The seal cartridge (204) includes a seal (232) and seal frame elements (234) supporting the seal (232) on both sides. The seal (232) is the same seal as that described above with respect to FIGS. 1 through 6. The frame elements (234) include a first frame element (236) that is adapted for connecting with the plate (212). The first frame element (236) is spaced apart with standoff (238) from a second frame element (240). The first frame element (236) includes a ring (242), a first retaining member (244) and a second retaining member (246). The second frame element (240) includes a ring (248), a first retaining member (250) and a second retaining member (252). To secure the seal (232), one side of the seal (232) is folded over ring (242) and captured between the first and second retaining members (244), (246) of the first frame element (236). The other end of the seal (232) is folded over ring (248) and likewise captured between the first and second retaining members (250), (252) of the second frame element (240). Standoffs (238) or equivalent structure space the first and second frame elements (236), (240) apart to define the overall length of the seal (232). Of course, the length of the standoffs (238) or seal (232) are varied as well as other parameters of the seal (232) that affect fit.

[0071] The seal cartridge (204) is removably connected to the housing (202) with fasteners (254). Alternative fastening means are within the scope of the invention and are known to one skilled in the art. For example, the seal cartridge (204) can be rotateably connected or attached in a snap-fit engagement. One advantage associated with the seal cartridge (204) is that different users can have personal seal cartridges (204) that are customized for differently sized appendages, yet operably attachable with one or more housings (202). Personal seal cartridges (204) are also adjustable with respect to the individual requirements relating tolerance, ease, or speed of insertion. For example, an unconscious patient whose temperature is being regulated is not available to actively participate in positioning and insertion into the device. Nonetheless, use of a personal seal-cartridge that is appropriately selected would allow efficient use of the device in such a scenario. Another example, an athlete may be more concerned with speed of insertion, or be encumbered with layers of clothing and therefore would require a personalized seal cartridge that is more accommodating with respect to those factors.

[0072] As mentioned above, the device is adapted for the insertion of a mammalian appendage such as a hand; however, the invention is not so limited and the device may be designed to accommodate an appropriate appendage. For example, as shown in FIG. 10, there is depicted a negative pressure thermal exchange module (300) that is shaped to accommodate a human foot. The module (300) includes a housing (302) and a seal cartridge (304). The seal cartridge (304) is configured as described above with respect to FIGS. 7-9 or FIGS. 1-6 and may be removably attached via fasteners (305) or other means.

[0073] Similar to the variations described above, the housing (302) includes a cover (306), a base (308), a heat exchange element (310) and a plate (312). The cover (306) is connected to the base (308) and plate (312) to define a chamber (314) for receiving the foot. Entry into the chamber (314) is provided in the top of the module instead of through an opening in the plate (312). The heat exchange element (310) includes a convex heat exchange surface (316) when viewed from inside the chamber (314) to comfortably accommodate the natural curvature of the foot received therein. All components are similar to the corresponding components of the module described above as is readily apparent to one skilled in the art.
Referring now to FIGS. 11-13, there is depicted another variation of a negative pressure thermal exchange module (400). The module (400) includes a cover (402) pivotally connected to a base (404). The cover (402) includes a first end (406) and a second end (408). A perimeter (409) encompasses a surface (410). The surface (410) is shaped to accommodate an appendage. As shown, the surface (410) is curved or concave. The cover (402) includes an opening portion (412). As shown in FIG. 11, the opening portion (412) is formed in the perimeter (409). The opening portion (412) is a curved portion that is adapted to receive at least a portion of a seal (413) and a portion of an appendage such as a wrist of a human hand (407) as shown in FIG. 13. In one variation, the seal (413) is a “hard” seal. Alternatively, the seal (413) is a soft seal of the type described above.

The base (404) includes a first end (414) and a second end (416). A perimeter (420) encompasses a chamber surface (418) that includes a heat exchange surface (422). The base perimeter (420) includes an opening portion (424). The opening portion (424) is a curved portion that is adapted to receive at least a portion or second half of a seal (426). In one variation, the seal (426) is a “hard” seal. Alternatively, the seal (426) is a soft seal of the type described above. The module (400) is preferably formed of molded plastic poly-carbonate. The heat exchange surface (422) is made of thermally conductive material such as metallic foil or a thin film of thermally conductive plastic.

In one variation, the first end (406) of the cover (402) is connected to the first end (414) of the base (404) such that the cover (402) is hinged and is rotatable between at least a substantially open first position and at least a substantially closed second position. A substantially open position is depicted in FIG. 11 and a substantially closed position is depicted in FIGS. 12 and 13. When in the open position, an appendage, such as the wrist of a human hand (407) hand is rested on the seal (426) that is securely disposed within the opening portion (424) of the base (404). The hand (407) comfortably rests and is in thermal communication with the heat exchange surface (422). The cover (402) is then rotated about its first end (406) to a substantially closed position. When in the closed position, the perimeter (409) of the cover (402) substantially aligns with the perimeter (420) of the base (404) and is attached thereto. The perimeter (409) of the cover (402) is connected to the perimeter (420) of the base (404) with an adhesive layer (430), for example, located on either perimeter (409), (420). A protective release layer (not shown) is removed to expose the adhesive layer (430) therebeneath so that the adhesive layer (430) can seal the cover (402) to the base (404) in order to maintain a substantially leak-proof negative pressure environment. Alternatively or in conjunction with the adhesive layer (430), the cover (402) is attached to the base (404) in a snap-fit engagement or by employing a variety of fasteners (432).

When in the closed position, the seal-receiving portion (412) of the cover (402) substantially aligns with the seal-receiving portion (424) of the base (404) to contact an appendage located therebetween and to substantially prevent the leakage of air across the seal. Surfaces (410) and (418) also substantially align to form a chamber (428) for receiving the appendage. Ports (not shown) for supplying a negative pressure environment are formed in either the cover (402) or base (404) and in communication with the chamber (428).

The module (400) is designed to be separable from a heat exchange element (434). For example, with the hand (407) positioned inside the chamber (428), the module (400) is placed over a heat exchange element (434) such that the heat exchange element (434) is in thermal communication with the heat exchange surface (422) and in thermal communication with the appendage (407) inside the chamber (428). The heat exchange element (434) is made from aluminum, stainless steel, or other highly thermally conductive and non-corrosive material. It may be in communication with a thermal electric heating element such as a Pelletier device, a desiccant cooling device or an endothermic or exothermic chemical reaction to provide a temperature variance.

The heat exchange surface (422) is shaped to conform to the general aspects of the appendage inserted within the chamber (428). Furthermore, the heat exchange element (434) is shaped to substantially conform to the heat exchange surface (422). In one variation, the heat exchange surface (422) is flexible and made from a material that is easily conformable to the appendage (407) such as metallic foil. As a vacuum is generated inside the chamber (428), a flexible heat exchange surface (422) is drawn in contact with the appendage (407). The module (400) is placed over the heat exchange element (434) such that the heat exchange element (434) is received outside of the heat exchange surface (422). In one variation, the heat exchange surface (422) is substantially convex with respect to the outside of the module (400) and the outer surface of the heat exchange element (434) is substantially convex such that when the module (400) is placed over the heat exchange element (434) it is substantially conformingly received within the outer concavity of the heat exchange surface (422). The invention is not so limited and irrespective of the concavity of either the heat exchange surface (422) or the heat exchange element (434), the surface (422) and the element (434) have generally complementary shapes so as to place the surface (422) in closer thermal communication with the element (434). The module (400) is adapted such that the heat exchange element (434) can be secured to the module (400). For example, the module (400) can be secured to the heat exchange element (434) in a snap-fit engagement or with fasteners. The module (400) is easily separated from the thermal exchange element (434) making the module (400) easily portable with the patient as the patient is moved from bed to bed, for example, with separate heat exchange elements (434) awaiting the patient in different locations. The variation of FIGS. 11-13, is a disposable version most suitable for the hospital environment where individual modules are desired for sanitary purposes.

While the present invention has been described with references to one or more particular variations, those skilled in the art will recognize that many changes may be made therein without departing from the spirit and scope of the present invention. Each of these embodiments and obvious variations therefrom are contemplated as falling within the spirit and scope of the claimed invention, which is set forth in the following claims.

1. A module for thermal exchange with a portion of a mammal, comprising:
a first chamber defining a chamber opening and adapted to receive a portion of the mammal;
an exchange surface in thermal communication with the first chamber; and
a seal connected to the first chamber at the chamber opening; the seal including a seal opening and a waist opening; the chamber opening and the seal opening being greater than the waist opening such that a ramped entry and exit is provided for the portion of the mammal.

2. The module of claim 1 wherein the seal is substantially hourglass shaped.

3. The module of claim 1 wherein the seal is made from an elastic material such that the waist opening varies with the insertion of the portion of the mammal and substantially conforms to seal against the portion of mammal.

4. The module of claim 1 wherein the waist opening is regulated by an inflatable bladder, expansion means, belt, cinch, or strap.

5. The module of claim 1 wherein the waist opening is substantially elliptical in shape.

6. The module of claim 1 wherein the seal is made from an elastic material such that the seal opening varies with the insertion of the portion of the mammal and substantially conforms to seal against the portion of mammal.

7. The module of claim 1 further including a second chamber adapted to receive a thermal exchange medium; the second chamber being in thermal communication with the exchange surface.

8. The module of claim 1 wherein the seal is part of a seal cartridge that is removably coupled to the first chamber.

9. A module for thermal exchange with a portion of a mammal, comprising:

   a housing including:
   a first chamber including a chamber opening and adapted to receive a portion of a mammal; and
   an exchange surface in thermal communication with the first chamber; and
   a seal connected to the first chamber at the chamber opening; the seal forming a variable opening adapted to substantially conform against the mammal to contact the portion of the mammal inside the first chamber.

10. The module of claim 9 further including a vacuum source coupled to the first chamber such that the vacuum source is capable of drawing a negative pressure in the first chamber.

11. The module of claim 9 wherein the seal includes two pieces.

12. The module of claim 9 further including a second chamber adapted to receive a thermal exchange medium; the second chamber being in thermal communication with the exchange surface.

13. A module for thermal exchange with a portion of a mammal, comprising:

   a housing including:
   a first chamber adapted to receive a portion of a mammal and adapted to provide a negative pressure environment, the first chamber including a chamber opening; and
   an exchange surface in thermal communication with the first chamber; and
   a seal connected to the first chamber at the chamber opening and having a longitudinal axis; the seal comprising a flexible wall member that provides substantial contact sealing against at least a portion of the external surface of the mammal while accommodating motion of the portion of the mammal that is lateral to the longitudinal axis.

14. The module of claim 13 further including a second chamber adapted to receive a thermal exchange medium; the second chamber being in thermal communication with the first chamber.

15. The module of claim 13 wherein the seal leaks air with motion of the portion of the mammal that is substantially lateral to the longitudinal axis.

16. A module for thermal exchange with a portion of a mammal, comprising:

   a housing including:
   a first chamber including a chamber opening; the first chamber being adapted to receive a portion of a mammal and being adapted to provide a negative pressure environment; and
   an exchange surface in thermal communication with the first chamber; and
   a seal connected to the first chamber at the chamber opening; the seal comprising a flexible sleeve including a waist portion; at least the waist portion being adapted to engage at least a portion of the external surface of a portion of the mammal; the sleeve being deflectable with movement of the portion of the mammal.

17. The module of claim 16 wherein the waist portion defines a waist opening; the waist opening including a relaxed position; the waist opening being expandable relative to the relaxed position with insertion of the portion of the mammal.

18. The module of claim 17 wherein the waist opening substantially conforms to circumferentially contact the portion of the mammal.

19. The module of claim 16 further including a second chamber adapted to receive a thermal exchange medium; the second chamber being in thermal communication with the first chamber.

20. The module of claim 16 wherein the waist portion defines a waist opening; the waist opening including a relaxed position; the waist opening being expandable relative to the relaxed position via expansion means.

21. The module of claim 16 further including stop means for maintaining the seal in a non-relaxed expanded position.

22. The module of claim 20 wherein the expansion means is selected from the group consisting of cordage, mechanical linkage and other expansion means known to one skilled in the art.

23. A module for thermal exchange with a portion of a mammal, comprising:

   a housing including:
   a first chamber being adapted to receive a portion of a mammal and adapted to provide a negative pressure environment; the first chamber including a chamber opening; and
   an exchange surface in thermal communication with the first chamber; and
a seal connected to the first chamber at the chamber opening; the seal including an elastic element to bias the seal against the portion of the mammal.

24. The module of claim 23 wherein the seal includes a longitudinal axis, the seal being laterally deflectable relative to the longitudinal axis with motion of the portion of the mammal.

25. The module of claim 23 wherein the seal defines a waist portion having a variable waist opening, the waist portion having at least a relaxed position and an engaged position; the waist opening being smaller when in a relaxed position relative to the portion of the mammal against which the seal engages.

26. The module of claim 23 wherein the seal includes a longitudinal axis, and wherein the seal is adapted to leak air from the first chamber with substantial lateral displacement of the portion of the mammal relative to the longitudinal axis.

27. The module of claim 23 further including a second chamber adapted to receive a thermal exchange medium; the second chamber being in thermal communication with the exchange surface.

28. The module of claim 23 wherein the seal includes an elastic element such that when the negative pressure environment is established in the first chamber, the seal will bow inwardly to bias the seal against the portion of the mammal.

29. A module for thermal exchange with a portion of a mammal, comprising:

- a first chamber defining a chamber opening and a port; the first chamber being adapted to receive a portion of a mammal via the chamber opening; the first chamber being adapted to receive a negative pressure via the port;
- an exchange surface in thermal communication with the first chamber; and
- a seal connected to the first chamber at the chamber opening to seal the portion of the mammal inside the first chamber.

30. The module of claim 29 wherein the seal substantially corresponds to the shape of the portion of the mammal.

31. The module of claim 29 wherein the seal includes a seal opening and a waist opening; the seal opening being larger than the waist opening to provide ramped entry and exit for the portion of the mammal.

32. The module of claim 29 and 31 wherein the seal includes a chamber opening and a waist opening; the chamber opening being larger than the waist opening to provide a ramped entry and exit for the portion of the mammal.

33. The module of claim 29 wherein the seal includes a waist opening that is smaller than the chamber opening of the first chamber; the waist opening being variable.

34. The module of claim 29 wherein the seal includes a variable seal opening.

35. The module of claim 34 wherein the seal includes a waist opening; the seal opening being larger than the waist opening; the waist opening being variable.

36. The module of claim 29 wherein the seal includes a chamber opening and a waist opening; the chamber opening of the seal is larger than the waist opening; the chamber opening and the waist opening being variable.

37. The module of claim 29 wherein the seal is made of a material that is capable of stretching isotropically.

38. The module of claim 29 wherein the seal is made of a material that is capable of stretching anisotropically such that the seal stretches in a direction lateral to a longitudinal axis of the seal.

39. The module of claim 29 wherein the seal includes reinforcement members.

40. The module of claim 29 wherein the first chamber substantially corresponds to the shape of the portion of the mammal.

41. The module of claim 29 wherein the seal includes a longitudinal axis and is flexible such that lateral movement relative to the longitudinal axis of the portion of the mammal is substantially afforded while maintaining a contact seal against the portion of the mammal.

42. The module of claim 29 and 41 wherein the seal includes a longitudinal axis and is flexible such that lateral movement relative to the longitudinal axis of the portion of the mammal is substantially afforded while allowing air to leak across the seal.

43. The module of claim 29 further including:

- a vacuum pump coupled to the first chamber to draw air from the first chamber;
- a control system coupled to the vacuum pump; the control system being adapted to maintain the pressure of the first chamber at a set-point.

44. The module of claim 43 wherein the control system is adapted to extract air from the first chamber at a vacuum flow rate that is substantially equal to the air leak rate into the first chamber.

45. The module of claim 29 further including a second chamber adapted to receive a thermal exchange medium; the second chamber being in thermal communication with the first chamber.

46. A module for thermal exchange with a portion of a mammal, comprising:

- a housing having a first end and a second end comprising:
  - a chamber adapted to receive a portion of the mammal;
  - a heat exchange cavity in thermal communication with the chamber;
  - a seal connected to the housing at the second end; the seal defining a chamber opening, a waist opening, and a seal opening; the waist opening being located between the chamber opening and the seal opening; the chamber opening being located proximate to the plate relative to the seal opening; and
  - a seal frame connected to the housing at the second end and supporting the seal.

47. The module of claim 46 wherein the housing includes:

- a heat exchange element located between the chamber and the heat exchange cavity.

48. The module of claim 47 wherein the housing includes:

- a cover; and
- a base connected to the cover.

49. The module of claim 48 wherein the heat exchange element is located between the cover and the base.

50. The module of claim 49 wherein the heat exchange cavity is defined between the heat exchange element and the base.
51. The module of claim 46 wherein the housing further includes an end cap connected to the first end.

52. The module of claim 51 wherein the end cap includes at least one port in fluid communication with the chamber.

53. The module of claim 46 wherein the housing further includes a plate connected to the second end; the plate including an opening to the chamber.

54. The module of claim 53 wherein the plate includes an inlet port and an outlet port in fluid communication with the heat exchange cavity.

55. The module of claim 46 wherein the chamber opening and the seal opening are greater than the waist opening providing a ramped entry.

56. The module of claim 46 wherein the seal frame includes:
   a first ring connected to the seal at the chamber opening; the first ring being connected to the plate;
   a retainer member;
   a second ring; the seal being captured between the retainer member and the second ring; and
   at least one standoff interconnecting the retainer member and the plate.

57. The module of claim 46 wherein the seal frame includes:
   a first frame element supporting a first end of the seal; and
   a second frame element supporting a second end of the seal.

58. The module of claim 57 wherein the seal frame forms a seal cartridge that is removably attached to the housing.

59. The module of claim 57 wherein the first frame element includes a ring and a first and second retaining member; the first end of the seal being coupled to the ring and captured between the first and second retaining members.

60. The module of claim 57 or 59 wherein the second frame element includes a ring and a first and second retaining member; the second end of the seal being coupled to the ring and captured between the first and second retaining members.

61. The module of claim 46 wherein the seal includes a first end and a second; the first end of the seal being rotatable relative to the second end of the seal to reduce at least the waist opening.

62. The module of claim 46 further including:
   a sheath that encompasses the seal such that the sheath is substantially coaxial with respect to the seal; the sheath having a first end and a second end and a sheath opening; the first end of the sheath being rotatable relative to the second end of the seal to reduce the sheath opening and at least the waist opening of the seal.

63. The module of claim 62 further including a sheath frame connected to the housing and supporting the sheath.

64. A module for thermal exchange with a portion of a mammal, comprising:
   a base having an exchange surface and a base perimeter;
   a cover connected to the base to form a chamber for receiving the portion of a mammal such that the portion of the mammal is in thermal communication with the exchange surface; the chamber being adapted to receive a negative pressure environment relative to atmospheric pressure; the cover having a cover perimeter and
   a seal for contacting the portion of the mammal to substantially prevent leakage of air across the seal.

65. The module of claim 64 wherein the exchange surface has an outer surface adapted to receive a heat exchange element.

66. The module of claim 64 wherein the exchange surface is made from thermally conductive material.

67. The module of claim 66 wherein the exchange surface is made of flexible material.

68. The module of claim 67 wherein the exchange surface bows inwardly into the chamber upon the application of a negative pressure to contact the portion of the mammal.

69. The module of claim 64 wherein the cover is rotatably coupled to the base such that the module includes at least an open position and at least a closed position such that when in the closed position at least a portion of the base perimeter is aligned with at least a portion of the cover perimeter.

70. The module of claim 69 wherein at least one of the base perimeter or cover perimeter includes an adhesive.

71. The module of claim 64 wherein a portion of the base perimeter includes a base opening portion.

72. The module of claim 71 wherein the seal is located in the base opening portion.

73. The module of claim 64 wherein a portion of the cover perimeter includes a cover opening portion.

74. The module of claim 73 wherein the seal is located in the cover opening portion.

75. The module of claim 64 wherein a portion of the cover perimeter includes a cover opening portion; a portion of the base perimeter includes a base opening portion; the module having at least an open position and at least a closed position such that when in the closed position the cover opening are aligned to form an opening.

76. The module of claim 75 wherein the seal is a split seal such that a portion of the seal is disposed in the cover opening portion and a portion of the seal is disposed within the base opening portion.

77. A method for thermal exchange with a portion of a mammal comprising the steps of:
   providing a module having a chamber for receiving a portion of the mammal; the module including a seal that allows a variable leakage of air across the seal;
   providing a vacuum pump coupled to the chamber to draw air from the chamber;
   providing a control system coupled to the vacuum pump for regulating the air pressure within the chamber;
   selecting a pressure set-point;
   establishing an air pressure inside the chamber that is substantially equal to the pressure set-point;
   maintaining the pressure set-point within the chamber.

78. The method of claim 77 wherein the step of maintaining the pressure set-point includes extracting air from the chamber at a vacuum flow rate that is substantially equal to the air leak rate into the first chamber.

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