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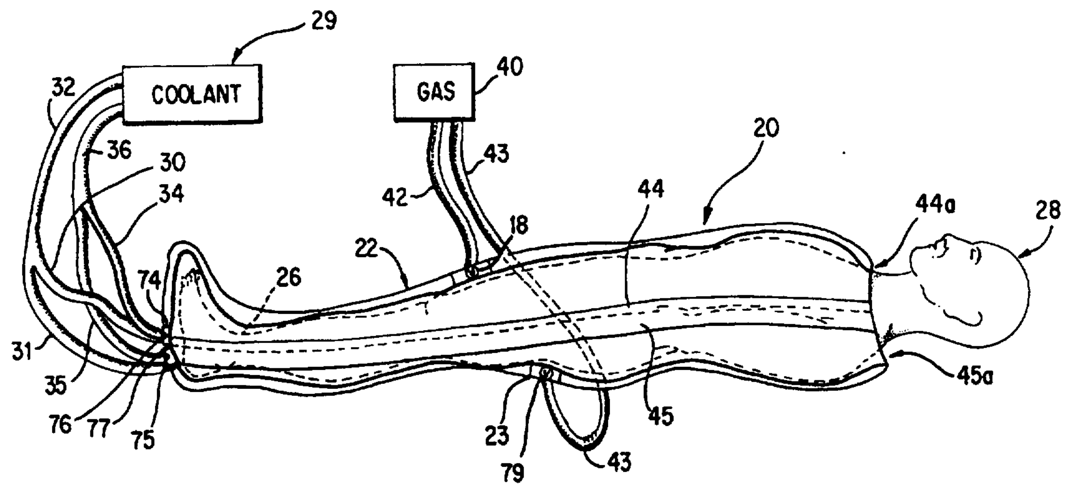

(57) Abstract

This invention is a device and a method for keeping the organs of a live or dead patient functioning at a reduced metabolic rate while within the body, such as to extend the viability of the organs. The invention includes an apparatus having at least one flexible sheet (22) for wrapping around the body. The flexible sheet (22) is brought into contact with the body by means of inflatable bladders or vacuum suction, and includes a system for distributing (29) coolant fluid (liquid or gas) (40) for rapid cooling. As a result of this rapid cooling of the body, the metabolic rates of the organs therein are slowed and remain viable such that a live person survives metabolic insults, and the organs in a brain-dead body or freshly dead body (cadaver) are suitable for harvesting and subsequent transplant.

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TOTAL BODY COOLING SYSTEM

Field of the Invention

The present invention relates to cooling devices for cooling the body and internal organs therein and, in particular, a cooling blanket with air bladders either alone or in combination with auxiliary structures for cooling portions of the body and the organs contained therein.

Background of the Invention

During ischemic or anoxic trauma, either blood or oxygen, or both, are not flowing to the brain. These conditions typically occur when a person is undergoing a heart attack or a stroke. Previous inventions, such as those described in U.S. Patent Nos. 5,149,321 to Klatz et al. ('321), 5,234,405 to Klatz et al. ('405) and 5,261,399 to Klatz et al. ('399), address the need to direct resuscitation efforts toward the brain, such that the victim can survive ischemic or anoxic trauma neurologically intact. Specifically, the '321 and '405 patents discuss devices and methods for resuscitating the brain such that its metabolism is slowed in order that the victim survive these metabolic insults neurologically intact. The '399 patent discloses a device and method for externally cooling the brain and associated tissues.

Along with brain cooling, it is advantageous to cool internal organs in the body such that their metabolism is slowed in order that they survive these metabolic insults fully intact. Typical current methods for cooling organs include ice packs or large scale machinery, such as that disclosed in U.S.S.R. Patent No. 1138152A ('152). However, these methods and devices both have drawbacks.

Ice packs are typically small in area, and when applied to a person, do not provide the rapid cooling necessary to slow the metabolism of internal organs. The device disclosed in the U.S.S.R. '152 patent exhibits the drawback of providing cryogenic cooling that is too extreme for organ resuscitation during metabolic insults or organ preservation in brain-dead persons. This device is not suited for field use, as it is a large structure restricted to clinical facilities capable of handling dangerous gases such as liquid nitrogen. Moreover, it must be used by a skilled surgical team and maintained by skilled technicians.

Additionally, despite the dramatic success and increase in the number of organ transplants, there remains a massive shortfall of organs suitable for donation and subsequent transplant. The demand for organs remains greater than the supply. As a result, thousands of people unnecessarily die for lack of viable donor organs.

This situation is particularly ironic because of the potential abundance of suitable organs. Specifically, each year more than 1.5 million Americans die from trauma, accidents or cardiac arrest with organs suitable for transplant, and could easily have their organs salvaged.

Present salvaging techniques include putting the organ in ice after having been perfused with a Collins solution. This Collins solution mimics the internal environment of the cells which form the organ tissue, and keeps the organ viable for approximately 24 hours. In most cases, these present methods do not permit sufficient time to transfer a suitable, viable organ to the needy recipient. This lack of viability occurs because organs which are deprived of oxygenated, nutrient-rich blood in a body at normal body temperatures suffer irreversible damage and injury in just a few hours or less. For example, the heart must be salvaged almost immediately after loss of blood flow, while kidneys must be salvaged within only one to three hours.

Summary of the Invention

The present invention focuses on a device and a method which uses submetabolic cooling for keeping the organs of a live or dead patient, while within the body, functioning at a lower metabolic rate, such that the live person can recover from the metabolic insult with their organs fully intact; or in the case of a dead person, the organs function at a low metabolism, such that they remain viable for subsequent harvesting and transplant. The invention is an apparatus that envelopes the body with adjoining sheets or a single wrap-around sheet, preferably in an air-tight manner. These sheets or sheet provide for circulation of a coolant fluid (liquid or gas), from a coolant fluid source, within their interiors. The coolant fluid is at a temperature substantially below body temperature so as to provide rapid cooling to the body when the cooled portions of the sheets, the inner layer(s) of the sheet(s) are pressed into contact with the body. The sheets or sheet include inflatable structures, supplied with inflation gas from a gas source, to press the cooled inner layer(s) into contact with the body. As a result of this rapid cooling from contact with the cooled sheets, the body is rapidly cooled in such a manner that the metabolic rates of the organs therein are slowed and remain viable, such that the live person survives metabolic insults, and the organs in a brain dead body or freshly dead body (cadaver) are suitable for harvesting and subsequent transplant.

Brief Description of the Drawings

The present invention will be described with reference to the accompanying drawings, wherein like reference numerals identify corresponding or like components.

In the drawings:

FIG. 1 is a perspective view of a first apparatus of the invention;

FIG. 2A is a cross-sectional view of the top sheet of the apparatus of FIG. 1 taken along line A-A of FIG. 4;

FIG. 2B is a cross-sectional view of the top sheet of the apparatus of FIG. 1 taken along line B-B of FIG. 4;

FIG. 3A is a cross-sectional view of the bottom sheet of the apparatus of FIG. 1 taken along line B-D of FIG. 4;

FIG. 3B is a cross-sectional view of the bottom sheet of the apparatus of FIG. 1 taken along line B-B of FIG. 4;

FIG. 4 is a bottom view of the inner layer of the top sheet (and also the bottom sheet) of the apparatus of FIG. 1;

FIG. 5A is a bottom view of the inner layer of a second arrangement for the top sheet (and also the bottom sheet) of the apparatus of FIG. 1;

FIG. 5B is a bottom view of the inner layer of a third arrangement for the top sheet (and also the bottom sheet) of the apparatus of FIG. 1;

FIG. 6 is a perspective view of an embodiment of the apparatus of FIG. 1 prior to activation;

FIG. 7 is a perspective view of the apparatus of FIG. 6 once activated;

FIG. 8 is a perspective view of an embodiment of the apparatus of FIG. 1 prior to activation;

FIG. 9 is a perspective view of the apparatus of FIG. 8 once activated;

FIG. 10 is a perspective view of a head section cooling apparatus of the present invention;

FIG. 11 is a side cross-sectional view of the chambers in the head section cooling apparatus of FIG. 10;

FIG. 12 is a top cross-sectional view of the chambers in the head section cooling apparatus of FIG. 10;

FIG. 13 is a perspective view of a cooling wrap of the present invention;

FIG. 14 is a cross-sectional view of another embodiment of the present invention;

FIG. 15A is a bottom view of the top sheet of the apparatus of FIG. 14;

FIG. 15B is a top view of the bottom sheet of the apparatus of FIG. 14;

FIG. 16A is a top view of the top sheet of the top sheet of the apparatus of FIG. 14; and

FIG. 16B is a bottom view of the bottom sheet of the top sheet of the apparatus of FIG. 14.

Detailed Description of the Invention

FIG. 1 shows the apparatus 20 of the present invention. The apparatus 20 includes a top sheet 22 connected to a bottom sheet 23 that when attached form a cavity 26 therebetween. The cavity 26 is preferably sized for an adult human body 28, brain dead body, freshly dead body (cadaver) (collectively "body"), but can be easily modified for pediatric or veterinary use. The apparatus 20 is designed to move coolant fluid (liquid or gas) from a coolant source 29 and circulate it through the top sheet 22 and bottom sheet 23 respectively, to cool the organs of the body 28 in the cavity 26. Inflow lines 30, 31 (typically formed as branched lines from a main line 32) for delivering coolant fluid from the coolant source 29 and outflow lines 34, 35 (typically formed as branched lines terminating in a main line 36) for returning coolant fluid to the coolant source 29 are attached to the top 22 and bottom 23 sheets. Inflatable bladders 38, 39 are positioned along the exterior face of the sheets 22 and 23. These bladders 38, 39, upon inflation and subsequent filling with gas (e.g. air) from a gas source 40, the gas supplied through lines 42, 43, press the sheets 22, 23 (now cooled) against the body 28 (patient or cadaver) in the cavity 26. This contact permits a greater heat transfer between the top and bottom sheets 22, 23 and the body 28 and therefore more rapid body cooling.

The top 22 and bottom 23 sheets are connected together along their peripheries 44, 45, to form a substantially air-tight attachment and air-tight seal around the body. The attachment is preferably formed of quick release VELCRO®, or other suitable fastening materials. Mechanisms such as zippers, combinations of VELCRO® and zippers, or other equivalent fasteners can also be used to make this connection. These fastening materials and/or mechanisms allow rapid closure of the top 22 and bottom 23 sheets as well as rapid access to the cavity 26. At the upper peripheral portions of the top and bottom sheets 44a, 45a, through which the neck of the body 28 extends, there may be an area free of the fastening material (e.g., VELCRO®), that includes sealing material, such as commercially available non-toxic skin sensitive adhesives, or any commercially available EKG electrode gel or ultrasound gel, to maintain the air-tight cavity 26. The adhesive or gel would be retained under paper, wax-based or TYVEK® sheets, that are peeled off and disposed of when use is desired. Alternately, these peripheral portions 44a, 45a may also be covered with double sided adhesive tape, such as Scotch Brand double coated tape, No. 665, available from 3M Corp., St. Paul, MN.

Turning also to Figs. 2A, 2B, 3A, 3B, 4, 5A and 5B, the top sheet 22 and bottom sheet 23 are formed of an outer layer 52, 53, for contacting the ambient environment, an inner layer 54, 55, that contacts the body 28 in the cavity 26, and an intermediary layer 56, 57, between the respective outer 52, 53 and inner 54, 55 layers. These layers are joined at their peripheral edges 58, 59 to form an airtight seal by any one of several conventional bonding constructions such as ultrasonic welding, vibration welding, radio frequency welding, heat welding, electromagnetic welding, and induction welding, as well as thermal sealing and adhesive bonding techniques. The preferred method of joining the outer 52, 53, inner 54, 55, and intermediary 56, 57 layers is heat sealing. In particular, the layers 52, 53, 54, 55, 56, 57 are joined together at their peripheral edges (except for port openings to receive coolant lines, preferably between the inner and intermediary layers, or valve openings for vacuum lines, that may be between the outer and the intermediary layers).

The spaces between the outer 52, 53 and inner 54, 55 layers, respectively, and the intermediary layers 56, 57, define lumens 60, 61 and 64, 65 for coolant circulation systems and inflatable bladders 38, 39. The top and bottom sheets 22, 23 are of similar construction (as will be referred to throughout), although the bottom sheet 23 may include padding 67, or other soft material to cushion the body 28 from the ground or other hard surface.

Each of the top sheet 22 and the bottom sheet 23 includes a coolant circulation or distribution system within lumens 60, 61, respectively, formed by the inner layers 54, 55 and intermediary layers 56, 57, respectively. The coolant distribution system provides for circulation of coolant within the sheet without letting the coolant touch the body 28. This coolant circulation system has intermittent (non-continuous) linear joints 70, 71 (having a length in a range of approximately 0.2 cm to 10.0 cm), formed by heat sealing portions of the inner 54, 55 and intermediary 56, 57 layers to form these intermittent linear joints 70, 71 that create a pathway for coolant fluid to circulate through the respective upper and lower sheets. These intermittent linear joints 70, 71 are preferably uniform in size (length and width) and are intended as such in the drawings (FIGS. 4, 5A and 5B are not drawn exactly to scale).

These intermittent linear joints 70, 71 may be created in a number of formats, including a series of side-by-side, parallel rows, as is shown in FIG. 4, staggered rows, as is shown in FIG. 5A, or in a "lightning bolt" pattern, as is shown in FIG. 5B. The inner layers 54, 55 and intermediary layers 56, 57 may also be joined in other suitable linear or non-linear formations to create channels for laminar or non-laminar flow of coolant fluid through the top 22 and bottom 23 sheets. The advantage of these intermittent linear joints 70, 71 is that they permit high fluid flow rates while preventing ballooning of the layers. Ballooning is disfavored, since it reduces the extent of contact between the skin and membrane, and thus reduces the rate of body cooling. As a result of these arrangements, the maximum amount of cooled surface area can be contacted with the body 28 (patient or cadaver) in the cavity 26, for maximum cooling in a short amount of time. Alternately, continuous linear (and also bent or non-linear) joints may be formed by the methods above, that extend substantially the entire length of the sheets (bonded inner and intermediary layers), but provide space between the sheet ends and the beginnings of the joints to allow for coolant from the coolant source to enter all of the channels between the joints, to provide cooling to the maximum amount of sheet surface area contacting the body, as well as exit from the channels for return to the coolant source.

While joining of portions of the inner layer and the intermediary layer (by heat sealing) for coolant circulation through the top 22 and bottom 23 sheets is preferred, alternate embodiments may involve the use of a tube or tubes, in a serpentine or similar pattern to maximize cooled surface area, located between the inner layers 54, 55 and the intermediary layers 56, 57. The tubes may have cross sectional shapes that are circular, rectangular, square, oval, triangular, diamond, or any other shape suitable to accommodate coolant flow through the tube. The tube or tubes may be attached to either the inner layers 54, 55, the intermediary layers 56, 57, both layers, or not attached to either the inner layer or the intermediary layer. If a tube or tubes are not attached to the upper and lower sheets, the intermediary layer may be eliminated altogether, and construction of the sheets 22, 23 would be similar to that disclosed above, except for the intermediary layer.

The coolant fluid is delivered from the coolant source 29 to the top 22 and bottom 23 sheets by means of inflow lines 30, 31 and returned from the sheets 22, 23 to the coolant source 29 through outflow lines 34, 35. Multiple coolant inflow and outflow lines are also permissible with this apparatus. Both the coolant inflow lines 30, 31 and outflow lines 34, 35 are preferably formed of main lines 32, 36 that branch or divide into sub-lines or alternately through connection joints, adapters, coupling points, or the like, for attaching with additional sub-lines. These coolant inflow lines 30, 31 and outflow lines 34, 35 connect to the respective top 22 and bottom 23 sheets at ports 74, 75 and 76, 77, preferably located at or proximate to the lower periphery (peripheral edges) of the top 22 and bottom 23 sheets. These ports 74, 75 and 76, 77 are preferably formed in the top 22 and bottom 23 sheets at openings between the inner 54, 55 and intermediary layers 56, 57, but could also be at openings in the intermediary layers 56, 57 or the inner layers 54, 55, or at other locations, and could be located anywhere along the top 22 and bottom 23 sheets respectively. It is preferred to have a coolant circuit formed by the coolant source 29, coolant inflow 30, 31 and outflow 34, 35 lines, and a coolant circulation system within the sheets 22, 23, formed by the linear joints 70, 71. However, in cases of emergency and the like involving short set up times, the coolant circuit need not be completely established by leaving the coolant outflow lines 30, 31 unattached to the sheets 22, 23 and the outflow port(s) on the sheets 76, 77 open to the ambient environment.

These ports 74, 75 and 76, 77 are designed to receive the coolant inflow 30, 31 and outflow 34, 35 lines in a friction fit to form airtight connections therewith. The ports 74, 75 and 76, 77 are affixed to the top 22 and bottom 23 sheets (between the inner 54, 55 and intermediary 56, 57 layers or directly into the inner layers 54, 55) in an airtight manner by thermal seals, welds, adhesives or the like. These ports 74, 75 and 76, 77 may also include valves (not shown) subject to electronic control from a logic control unit (not shown), preferably microprocessor based. Thermistor temperature sensors and microprocessors may be used to control the cooling device and allow zone cooling or sequential cooling of specific parts of the body, or to enhance coolant control. Alternatively, the valves may be manually controlled in order to optimize coolant conditions in the apparatus 20.

The preferred coolant source 29 is a refrigeration unit capable of generating cooled fluid (liquid and/or gas) at temperatures as low as -60 degrees Fahrenheit and at pressures as great as 60 psig, and preferably at temperatures approximately -10 degrees Fahrenheit and pressures approximately 10 psig. Multiple coolant sources are also permissible. Coolant fluid may be any fluid, liquid or gaseous, including chilled water, slushed ice, capable of imparting the desired cooling effect.

Additives may be included to lower the freezing point of the coolant fluid, such as propylene glycol, alcohol, saline and ethylene glycol. Both ethylene glycol and propylene glycol exhibit low corrosiveness and low volatility. A bacteriostatic agent may also be added to prevent the growth of bacteria and other organisms.

Additional coolant fluids include R-134A (Forane, Tetrafluoroethane), which is considered to be one of the most environmentally safe refrigerants available. R-134A is nonflammable, does not contain known reproductive toxins, is insoluble in water, has a freezing point below (-)1010C, and is generally stable at low temperatures. Furthermore, R-134A is non-irritating upon contact with the skin, other than potential excessive cooling. R-134A does not contain components listed by NTP, IARC, or OSKA as being carcinogens. R-134A has a low acute inhalation toxicity (4 hour CCSO in the rat > 500,000 ppm).

As previously described, the lumens 64, 65 between the outer layers 52, 53 and the intermediary layers 56, 57 define inflatable bladders 38, 39, or alternatively multiple bladders (if partitioned accordingly) that are designed to be inflated with liquid, or gases, to press the inner layers into contact with the body 28 (person or cadaver) in the cavity 26. The bladders 38, 39 may be inflated with gas from a source 40, the source 40 including pressurized air tanks, portable or solid state air compressors, manually or automatically driven air pumps, or vapor generating chemical reactions. The gas used to inflate the bladder(s) may include any suitable non-toxic gas, including air, nitrogen, helium, oxygen, and carbon dioxide.

Alternately, the gas source may include several valves for attaching to multiple gas lines, each valve may be under microprocessor control or each valve may be part of a series of automatically cycling valves. This allows each valve to control the supply of inflation gas to a single bladder (in multiple bladder devices) to create wave-like inflation of the bladders.

Another alternative gas supply may provide gas in repeating inflation and deflation modes, in response to preset or regulated pressures, or time, or flow. The gas source would include a supply of any of the inflation gases disclosed above, and would also include specialized pumps, pressure sensors and valves, electronically connected, and preferably under microprocessor control (with a manual override) that serve to inflate the bladder(s) and then deflate them when a preset pressure is reached. once deflation reaches a preset pressure, the bladder(s) is/are inflated. This can continue for as long as desired, as is controlled by the user.

Each of the bladders 38, 39 are connected and supplied inflation gas thereto, from the gas source 40 by one line 42, 43 (to each sheet) or multiple lines from the gas source 40. Multiple gas sources are also permissible. These lines 42, 43 may be permanently attached to either or both the respective sheets 22, 23, or the gas source 40, but are preferably removably connected to both. The lines 42, 43 connect to the sheets 22, 23 and the bladders 38, 39 therein, at ports 78, 79. These ports 78, 79 are constructed similarly to those discussed above for receiving the coolant inflow 31, 32 and outflow lines 34, 35 (to receive the lines 42, 43 in an airtight friction fit) but also preferably include valves (V), such as a check valve or stop cock to prevent escape of gas from the bladders 38, 39, once the lines 42, 43 are disconnected, or to permit the input or discharge of gas as desired. The ports 78, 79 may be located anywhere along the top 22 and/or bottom 23 sheets, and may be imbedded in the outer layers 52, 53 or may be attached between the outer layers 52, 53 and the intermediary layers 56, 57, by conventional fastening techniques that maintain air tight seals.

Alternately, the bladders 38, 39 may be formed of individual compartments, each compartment independent of each other compartment and separated by walls, and each compartment provided with inflation gas by its own line or lines from the gas source 40. The bladders 38, 39 may also be an inflatable unit or units placed into the lumens 64, 65, each inflatable unit or units provided inflation gas by its own line or lines from the gas source 40. Moreover, an inflatable bladder or inflatable bladders may be separate from the bonded inner and intermediary layers, as the bladder or bladders may be attached to the intermediary layers of the sheets 22, 23. Similar to the bladders disclosed above, the bladder or bladders for each sheet 22, 23 would be provided with inflation gas by its own line or lines from the gas source 40.

The outer 52, 53, inner 54, 55 and intermediary 56, 57 layers of the top 22 and bottom 23 sheets are preferably made of a material impervious to liquid and gas. Thermoplastic elastomers (TPEs) which can be made into film or sheeting by extrusion casting, calendaring, or other manufacturing process as are appropriate. Included among these TPEs are polyurethane, copolyesters, styrene copolymers, olefins, and elastomeric alloys. Preferred TPEs will have good elongation and tear strength, good resistance to flex fatigue at both low and high temperatures, good dynamic properties, resist water, alcohols, and dilute bases and acids, and exhibit good thermal conduction properties to permit the rapid transfer of heat from the person or cadaver. The materials for the inner layer and intermediate layer may also be TEFLON® TYVEK® or Gore-tex®.

The material of the inner layer may also include microscopic pores. These microscopic pores permit small quantities of coolant to enter the cavity (on the side of the inner layer contacting the body) and moisten the skin. This skin moistening destroys the insulative air layer that exists on the skin and allows direct contact with the cooled inner layer for maximum heat transfer to the body.

The inner layer may also be gelled, with gels such as any commercially available EKG electrode gel or ultrasound gel. The gel would be retained under paper, wax-based or TYVEK® sheets, that peel off when use of the apparatus is desired.

The material for the outer layer may also be TEFLON® TYVEC® Gore-tex® nylon, rubber or any non-porous flexible material.

FIGS 6 and 7 show another cooling sheet type apparatus 80 of the present invention, that employs an inflatable bladder or bladders to press cooled layers against the body of a patient or cadaver. The apparatus 80 is a single wrap-around sheet 81 (as opposed to the top 22 and bottom sheets of the first apparatus 20) constructed similarly to the apparatus 20 disclosed above, but with only a single series of edges. The sheet 81 includes a coolant circulation system therein arranged in accordance with those systems shown in FIGS. 4, 5A and 5B, above and described above. The coolant fluid (liquid or gas) is supplied to the sheet 81 from a coolant source 82 (similar to the coolant source 29 described above) through a coolant inflow line 86 or lines, and returned to the coolant source 82 from the sheet 81 through a coolant outflow line 86 or lines. Multiple independent circulating systems for coolant fluid in the sheet 81, with constructions in accordance with FIGS. 4, 5A and 52, are also permissible, with each individual system are being serviced by single or multiple coolant inflow line(s) and coolant outflow line(s). It is preferred that all coolant inflow and outflow line connections to the sheet 81 be made with ports (not shown in FIGS. 6 and 7), the ports being similar to those described above, and located anywhere along the sheet 81.

Similar to the bladders disclosed above, single or multiple bladders may be used, with multiple bladders being preferred, in order to compress the cavity enveloping the body 28 (FIG. 7), so that it is as small as possible for maximum cooling. These bladders are supplied with inflation from a gas source 40a connected to a gas line 87 that in turn connects to the sheet 81, preferably at a port or ports, similar to those described above (including valves or the like), for receiving gas lines 42, 43 in the top 22 and bottom 23 sheets. These gas ports may be positioned anywhere along the sheet 81.

In this configuration, the body 28 (person or cadaver) to be cooled is preferably placed supine in the center of the sheet 81, the sheet 81 in turn is wrapped around the body 28. The sheet edges side 88, 89 and bottom edges 90, 91 may include a means for attaching to one another. Such means may include velcro, zippers, snaps, buttons, or other appropriate fastening devices.

FIGS 8 and 9 show another cooling apparatus 100 of the present invention. This apparatus 100 is also a wrap-around cooling sheet 101, similar to that disclosed above in FIGS. 6 and 7, but further modified such that it is segmented, for selective cooling to various areas of the body. The segments are preferably designed to correspond to the torso 102, arms 104, 105, legs 106, 107, the neck 108 and the head 110. These segments can individually envelope the specified body portion and cool independently of each other, to allow portions of the body to be accessible while also permitting the other (remaining) portions of the body to be cooled. Such a design is particularly useful when medical procedures are being performed on a portion of the body.

Each segment includes its own coolant circulation system (that could include several independent systems) constructed in accordance with those detailed in FIGS. 4, 5A and 5B above (and described above), serviced by its own coolant inflow line 112, 114, 115, 116, 117, 118, 120 (C_{in}) and outflow line 132, 134, 135, 136, 137, 138, 140 (C_{out}), each an independent line from or to the coolant source (not shown, but similar to that disclosed above) or part of branched lines (as described above). It is preferred that all coolant inflow and outflow line connections to the sheet 101 be made with ports (not shown in FIGS. 8 and 9), the ports being similar to those described above, and located anywhere along the sheet 101. Multiple coolant inflow and outflow lines may also be used for coolant inflow and outflow to each segment and/or coolant circulation system.

Also, each segment includes its own bladder or bladders, configured in accordance with the description above, each bladder or bladders being supplied by a single line 152, 154, 155, 156, 157, 158, 160 (G) or multiple lines (preferably removably connected line or lines) from a gas source, similar to that disclosed above. It is preferred that gas lines 152, 154, 155, 156, 157, 1S8, 160 (G) connect to the segments 102, 104, 105, 106, 107, 108, 110 of the sheet 101, preferably at a port or ports (if multiple gas lines are used), similar to those described above (including valves or the like), for receiving gas lines 42, 43 in the top 22 and bottom 23 sheets. These gas ports may be positioned anywhere along the segments 102, 104, 105, 106, 108, 110 of the sheet 101.

Separate coolant circulation systems along with separate bladders for each segment are preferred, such that each segment may be maintained at an optimum pressure which may vary from segment to segment, or there may be sequential cooling and individualized temperatures for each segment. Furthermore, individual bladders for each segment permit one segment to be discharged and opened without affecting the pressure and cooling in the other segments.

Further alternate embodiments may include the top and bottom sheets being integral on as many as three sides that form the periphery. one side would remain open and preferably closed by VELCRO® or other suitable fastening material along the upper (top) and lower (bottom) sides of the opening. The sheet could have elasticized portions, to facilitate enhanced patient/cadaver ingress and egress.

Turning now to FIGS. 10-13, there are shown two types of individual section coolers for providing additional cooling to areas such as the chest, groin, axilla, neck and/or head. Additional cooling may be desired in these areas, as these areas are responsible for significant heat transfer in the human body.

Specifically turning to FIG. 10, there is shown a head section cooler 161. This head section cooler 161 provides supplemental cooling to the head, and preferably also to the forehead and cheeks. The head section cooler 161 includes a sheet 162 that is designed to envelope the head, as well as cover the forehead and cheeks. The flow may be conducted through channels 164, a laminar structure, similar to that described above in FIGS. 4, 5A and 5B having been scaled accordingly, or rectangular, tubular or serpentine conduits. These coolant flow systems in the sheet 162 are supplied coolant from an inflow tube 166 (or multiple inflow tubes), with spent coolant exiting the sheet 162 through a coolant outflow tube 168 (or multiple coolant outflow tubes). This sectional cooler 161 can be made from the same materials as the above disclosed layers forming the top 22 and bottom 23 sheets and by the same techniques. The coolant sheet 162 with its channels 164 and inflow 166 and outflow 168 tubes may be designed to withstand very cold fluids (liquids and/or gases) at high pressures and low rates (ranging between 0 and 100 psi, and 0 to 20 liters/sec).

FIGS. 11 and 12 detail coolant channels 164, each channel 165 being preferably pentagonal in shape, although other shapes (e.g. hexagonal, triangular, circular, elliptical) are also permissible. The channels 165 include openings 170 in their walls 172, and protrusions 174 at their center. These structures provide turbulent flow for the coolant for effective sectional cooling. Alternately, the coolant channels 164 may include the protrusions alone absent the walls.

These coolant inflow tubes 166 and outflow tubes 168 return the coolant fluid to the coolant source as part of a coolant circuit. These coolant inflow 166 and outflow 168 tubes for the head section cooler 161 are preferably directly connected to the coolant source, by attaching to lines from the coolant source (not shown, but similar to coolant source 29 of FIG. 1 above), but could also be branched or connected to the main coolant inflow line or lines and outflow line or lines. Alternately, the coolant outflow tubes 168 need not be connected back to the coolant source if a coolant circuit is not desired.

The coolant inflow 166 and outflow 168 tubes, supplying the head section cooler 161 could include valves anywhere along their length. These valves may be controlled manually, pneumatically, hydraulically, magnetically, or electronically (microprocessor based subject to a logic control unit), as disclosed above. The head section cooler 161 is retained on the head by a formfitting stretchable cap 169 that fits snugly to the head to press the cooling sheet 162 against the head, neck, and face. Additional securement, especially in areas of the forehead and cheeks, could be achieved by the addition of adhesive to the skin contacting side of the head section cooler 161. This adhesive would preferably be applied to the forehead and cheek areas of the head section cooler. The sheet 162 may also be extended around the eyes, with adhesive placed on areas surrounding the eyes, so as to provide cooling to the eyes.

FIG. 13 details a cooling wrap 180, for extending around various areas of the body, such as the torso, arms, legs, neck and the like, with the cooling wrap 180 being proportionally sized for these areas. The wrap 180 includes a cooling sheet 182 with laterally disposed fastening areas 184, 185. The fastening areas 184, 185 are preferably elasticized for providing a snug fit for the cooling wrap, and preferably includes hook 184a and loop 185a, or VELCRO® type fasteners.

The cooling wrap 180, may include a series of channels 186 (detailed in FIGS. 11 and 12), identical to those disclosed above, that the coolant circulates through. Alternatively, laminar or serpentine flow patterns may be used. The cooling wrap 180 is supplied with coolant from an inflow tube 188, with spent coolant exiting the sheet through a coolant outflow tube 190. As stated above, the coolant outflow tube 190 may be attached to lines for returning the coolant fluid to the coolant source (not shown, but similar to coolant source 29 of FIG. 1, above). These coolant inflow 188 and outflow 190 lines for the cooling wrap 180 are preferably directly connected to the coolant source as they attach to carrier tubes or other similar conduits, but could also be branched or connected to the main coolant inflow and outflow lines. Alternately, the coolant outflow tubes 188, 190 need not be connected back to the coolant source if a coolant circuit is not desired.

The coolant inflow 188 and outflow 190 tubes, supplying the cooling wrap 180 could include valves anywhere along their length. These valves may be controlled manually, pneumatically, hydraulically, magnetically, or electronically (microprocessor based subject to a logic control unit), as disclosed above.

In operation, the body (person or cadaver) is placed on the bottom sheet, preferably in a supine orientation. The top sheet is then placed over the body 28 up to the neck to cover them, except for the head. The top sheet is then joined to the bottom sheet such that the sheets envelope the body in an air-tight engagement.

Coolant inflow and outflow lines are then connected to their respective ports on the top and bottom sheets, as well as lines into ports on the sheets, the gas lines from a gas source. The coolant source is then activated and circulation of coolant begins and continues for as long as desired. Simultaneously, the gas supply to the bladder(s) is activated, inflating the bladder(s) and bringing the sheets tight against the body to enhance the cooling process. The gas source may also be one, as described above, that inflates and deflates the bladder in accordance with the regulated modes, as described above, in order to compress or create blood flow in peripheral vessels and/or to enhance cooling. This process can continue for as long as desired.

An alternative embodiment, detailed in FIGS. 14, 15A, 15B, 16A and 16B, is similar to those embodiments disclosed above, except that the apparatus 220 employs vacuum suction to bring the top sheet 222 and the bottom sheet 223 (both sheets preferably chilled to the requisite temperatures for submetabolic cooling) into contact with the body 28 (patient or cadaver) in the cavity 226 to maximize cooling. The vacuum suction is attained by a vacuum system, employed as an alternative to the inflatable bladders of the previous embodiments disclosed above.

The vacuum system (shown schematically) of this apparatus 220 includes a vacuum source 227 and lines 230, 231, (either single or multiple) either alone or as part or other line arrangements (branched or attached, similar to the coolant line arrangements disclosed above) extending therefrom, that preferably connect with ports 234, 235, having valves or the like (similar to those disclosed above). These ports 234, 235 provide access to the interior of the apparatus 220, and in particular to vacuum tubes 238, 239, 240, 241, 242, 243 at locations along the ends of each of the inner layers 254, 255 of the top 222 and bottom 223 sheets. These vacuum tubes 238, 239, 240, 241 include openings 256, 257 for vacuum suction to reach the cavity 226 and are attached to the respective inner layers 254, 255 by being embedded directly in the inner layers 254, 255, such as with thermal sealing or welding, but could also be fastened to the inner layers 254, 255 by mechanical fasteners, adhesives or the like. Additional securement of the vacuum tubes 238, 239, 240, 241, 242, 243, may be achieved by fastening the tubes to the outer layers 260 by adhesives, welds or the like.

While this branched vacuum tube arrangement within the cavity 226 is preferred, additional vacuum tubes branching from the ports 234, 235, or any of the vacuum tubes 238, 239, 240, 241, 242, 243 are also permissible. Also, individual vacuum tubes, supplied with suction from lines directly from the vacuum source 227, attached to the top 222 and bottom 223 sheets, in accordance with the disclosure above, are also permissible.

With additional respect to the vacuum line(s), an additional vacuum line or lines may be connected directly into the cavity 226 between the top 222 and bottom 223 sheets. This additional vacuum line or lines may be branched from the main vacuum line (as disclosed above) or may be a direct line(s) from the vacuum source 227. In other embodiments, the vacuum line(s) may be placed so as to extend directly into the cavity 226, and may be the only vacuum line(s) for the apparatus 220.

The apparatus 220 and variations thereof, employ coolant systems similar to those disclosed above, involving a coolant source 270 and coolant inflow lines 272, 273, (single or multiple) for transporting coolant to the sheets 222, 223 of the apparatus 220, and coolant outflow lines 274, 275 (single or multiple), for transporting coolant from the sheets 222, 223 to the coolant source 270 (these coolant inflow and outflow lines are shown schematically). The inner 254, 255 and outer layers 260, 261, that form the top 222 and bottom 223 sheets, respectively, are joined together in accordance with that shown above in FIGS. 4, 5A and 5B, to form a coolant circulation system within the top 222 and bottom 223 sheets. Multiple independent circulating systems for coolant fluid in the sheets 222, 223, with constructions in accordance with FIGS. 4, 5A and 5B, are also permissible, with each individual system are being serviced by single or multiple coolant inflow line(s) and coolant outflow line(s). It is preferred that all coolant inflow and outflow line connections to the sheets 222, 223 be made with ports (not shown), the ports being similar to those described above, and located anywhere along the sheets 222, 223. While a coolant circuit is preferred, the coolant outflow lines need not be employed.

These embodiments and variations thereof, employing vacuum suction, may be designed to be segmented, similar to that shown in FIGS. 8 and 9 (above), for sectional cooling. Each segment would have an independent cooling and vacuum system, in accordance with those described above, with coolant and vacuum supplied by single or multiple coolant and vacuum sources.

Another similar embodiment employing vacuum suction is configured similarly to that shown in FIGS. 1-5B above, except that single or multiple vacuum tubes with openings along their length are arranged in the lumen between the intermediary layer and the outer layer instead of a bladder or bladders. It is preferred that these openings be of sufficient size to allow the vacuum suction to reach the cavity in order to draw the top and bottom sheets together, around and into contact with the body (patient or cadaver) to maximize rapid cooling. These vacuum tubes terminate in ports (similar to those described above) in either the outer layer or the junction between the outer layer and the intermediary layer, that attach to vacuum lines (connected to the vacuum source), the vacuum lines arranged similar to those disclosed above.

These embodiments and variations thereof, employing vacuum suction, may be designed to be segmented, similar to that shown in FIGS. 8 and 9 (above), for sectional cooling. Each segment would have cooling and vacuum systems, in accordance with those described above, with coolant and vacuum supplied by single or multiple coolant and vacuum sources.

While several alternate arrangements of coolant inflow and outflow and vacuum conduits have been disclosed above in connection to the top and bottom sheets of the apparatus, any combination of these arrangements is also permissible for the apparatus of the invention. Moreover, it is possible to have only one sheet, preferably the top sheet, with a cooling and/or vacuum system, while the bottom sheet would be inactive and only padded.

In operation, the body (person or cadaver) is placed on the bottom sheet, preferably supine on the bottom sheet. The top sheet is then placed over the person up to the neck to cover them, except for the head. The top sheet is then joined to the bottom sheet such that the sheets envelope the body in an air-tight engagement.

Coolant inflow and outflow lines are then connected to their respective ports on the top and bottom sheets, as well as lines from the vacuum source to their respective single or multiple ports on the top and bottom sheets. The coolant source is then activated and circulation of coolant begins and continues for as long as desired. Simultaneously, the vacuum source is activated, bringing the sheets tight against the body to enhance the cooling process. Pressure may be regulated to be peristaltic to compress or create blood flow in peripheral vessels and/or to enhance cooling. This process can continue for as long as desired.

These embodiments of the apparatus are portable and suitable for field use, such as in ambulances, battlefields, athletic fields, aircraft, marine vehicles, spacecraft, emergency treatment facilities, and the like. They are lightweight and can be carried directly to the patient. These embodiments can also be modified for clinical (hospital type) settings. While the apparatus of the present invention is preferably designed for the treatment of humans, it can also be used in treating other mammals such as dogs, horses or the like, and sized accordingly.

While particular embodiments of the invention have been shown, it will be understood, of course, that the invention is not limited thereto, since modifications may be made by those skilled in the art, particularly in light of the foregoing teachings. It is therefore, contemplated by the appended claims to cover any such modifications as incorporate those features which constitute the essential features within the true spirit and scope of the invention.

WHAT IS CLAIMED IS:

1. An apparatus for cooling a mammalian body comprising:

a. means for enveloping a mammalian body, the enveloping means including at least a first sheet and a second sheet, at least one of the first and second sheets including means for distributing coolant within the at least one of the first and second sheets at temperatures substantially below body temperature;

b. means, which is separate from the coolant distributing means, for pressing the coolant distributing means of the at least one of the first and second sheets against a mammalian body; and

c. a coolant source in communication with the coolant distributing means for supplying a coolant to the coolant distributing means;

whereby a mammalian body is rapidly cooled to slow metabolic rates of organs therein such that the organs remain viable.

2. The apparatus of claim 1, wherein the first and second sheets are removably connectable to each other.

3. The apparatus of claim 17, further comprising a conduit and an inflation device in communication with the pressing means and comprising a pressurized gas source, the conduit being removably attachable to both the pressurized gas source and the at least one of said first and second sheets.

4. The apparatus of claim 1, wherein the coolant source communicates with the coolant distributing means by way of a first conduit, the first conduit being removably attachable to both the coolant source and the at least one of said first and second sheets.

5. The apparatus of claim 4, wherein the coolant source further communicates with the coolant distributing means by way of at least a second conduit removably attachable to both the coolant source and the at least one of said first and second sheets, and providing a path for spent coolant from the coolant distributing means to said coolant source.

6. An apparatus for cooling a mammalian body comprising:

a sheet, said sheet including at least one inflatable bladder and at least one coolant distribution system within the sheet,

an inflation device in communication with the at least one inflatable bladder; and

a coolant source in communication with the at least one coolant distribution system;

wherein the at least one inflatable bladder is inflated by the inflation device to press the at least one coolant distribution system against a mammalian body to effectuate cooling of the mammalian body.

7. The apparatus of claim 6, wherein said sheet includes more than one inflatable bladder and more than one coolant distribution system.

8. The apparatus of claim 6, wherein the at least one coolant distribution system comprises:

a first layer and a second layer; and

intermittent joints connecting the first layer to the second layer, the intermittent joints defining a coolant flow pathway.

9. The apparatus of claim 8, wherein the intermittent joints are arranged in parallel rows.

10. The apparatus of claim 8, wherein the intermittent joints are arranged in staggered rows.

11. The apparatus of claim 1, wherein the coolant source contains a coolant and the coolant is at least one member selected from the group consisting of R-134, water, propylene glycol, alcohol, saline and ethylene glycol.

12. The apparatus of claim 1, wherein the inflation device contains an inflation gas and the inflation gas is at least one member selected from the group consisting of air, nitrogen, helium, oxygen and carbon dioxide.

13. The apparatus of claim 6, wherein the sheet is divided into segments adapted for predetermined portions of a mammalian body, each of the segments including at least one inflatable bladder and at least one

coolant distribution system, such that different parts of a mammalian body may be selectively cooled.

14. An apparatus for cooling a mammalian body comprising:

a sheet foldable onto itself for enveloping a mammalian body within a cavity formed thereby, said sheet including at least one coolant distribution system;

a vacuum system for drawing the at least one coolant distribution system against a mammalian body to effectuate cooling of the mammalian body;

wherein the vacuum system is at least partially attached to the sheet, the vacuum system including a series of vacuum conduits for providing suction to the cavity and a vacuum source in communication with the series of vacuum conduits.

15. The apparatus of claim 14, wherein the series of vacuum conduits comprises tubes embedded into the sheet and connected to the vacuum source.

16. The apparatus of claim 14, wherein the series of vacuum conduits is positioned between the mammalian body and an inner surface of the sheet, and is connected to the vacuum source.

17. The apparatus of claim 1, further comprising an inflation device in communication with the pressing means.

18. An apparatus for cooling a mammalian body comprising:

a sheet, said sheet including at least first and second layers and at least one coolant distribution system within said sheet,

at least one inflatable bladder disposed on the first layer of said sheet, said at least one inflatable bladder being in communication with an inflation device; and

a coolant source in communication with the at least one coolant distribution system;

wherein the at least one inflatable bladder is inflated by the inflation device to press the at least one coolant distribution system against a mammalian body to effectuate cooling of the mammalian body.

19. The apparatus of claim 18, wherein the sheet further comprises a third layer and the at least one inflatable bladder is formed by the third and first layers of the sheet.

20. An apparatus for cooling a mammalian body comprising:

a. means for enveloping a mammalian body, the enveloping means including at least a first sheet and a second sheet, at least one of the first and second sheets including means for distributing coolant within the at least one of the first and second sheets without letting the coolant touch the mammalian body at temperatures substantially below body temperature;

b. means for pressing the coolant distributing means of the at least one of the first and second sheets against a mammalian body; and

c. a coolant source in communication with the coolant distributing means for supplying a coolant to the coolant distributing means;

whereby a mammalian body is rapidly cooled to slow metabolic rates of organs therein such that the organs remain viable.

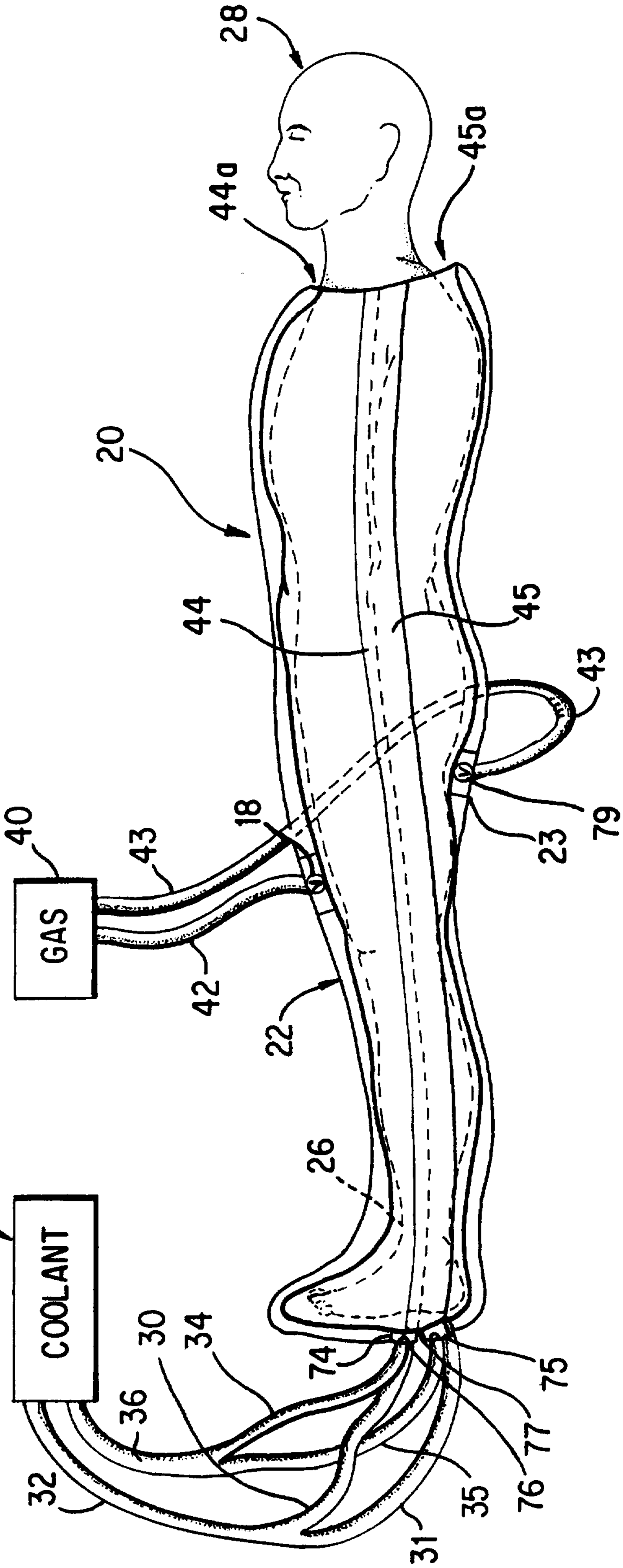
GAS
COOLANT
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FIG.1

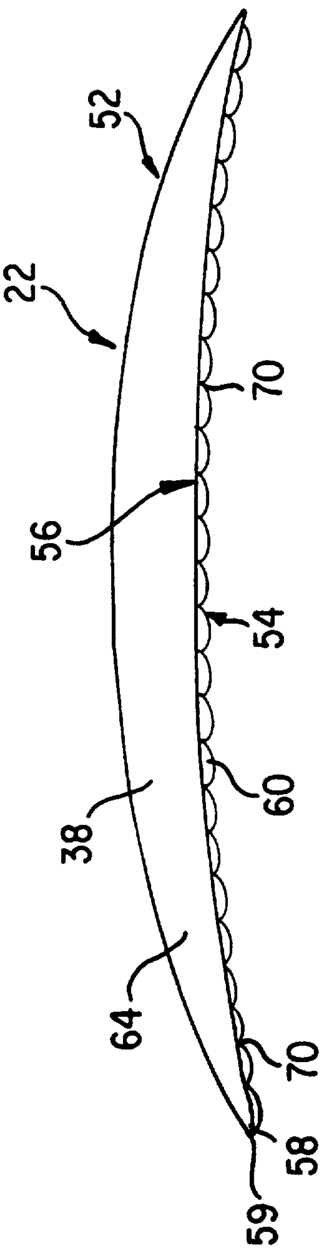


FIG. 2A

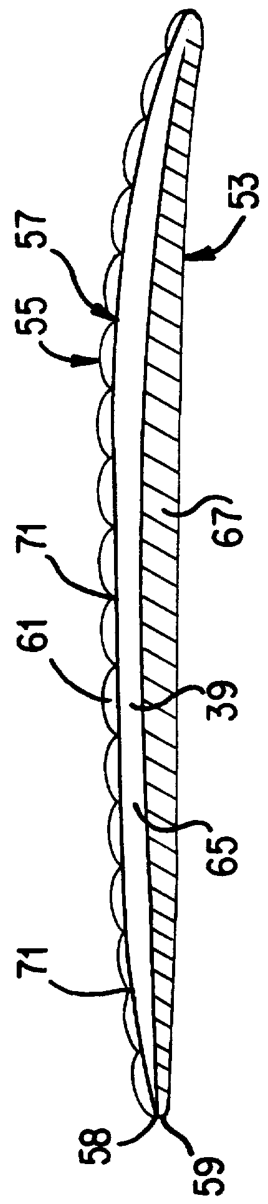


FIG. 3A

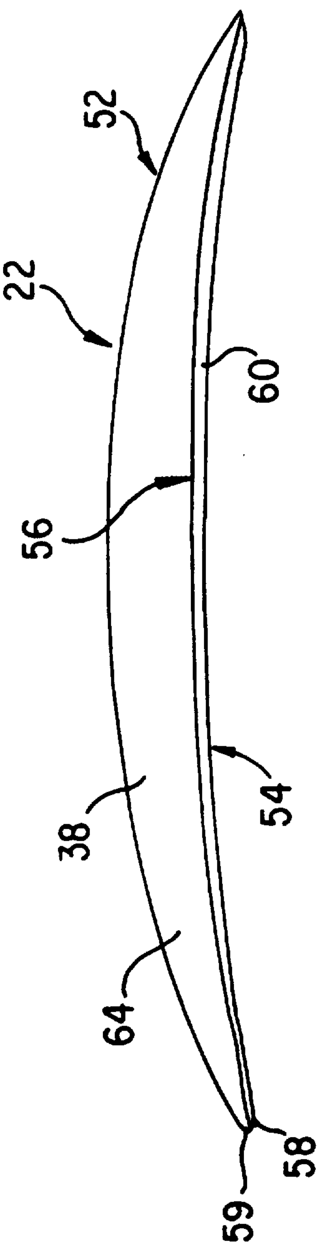


FIG.2B

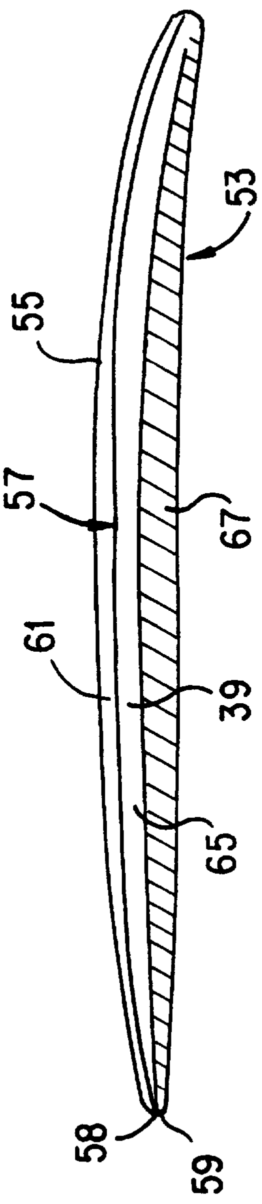


FIG.3B

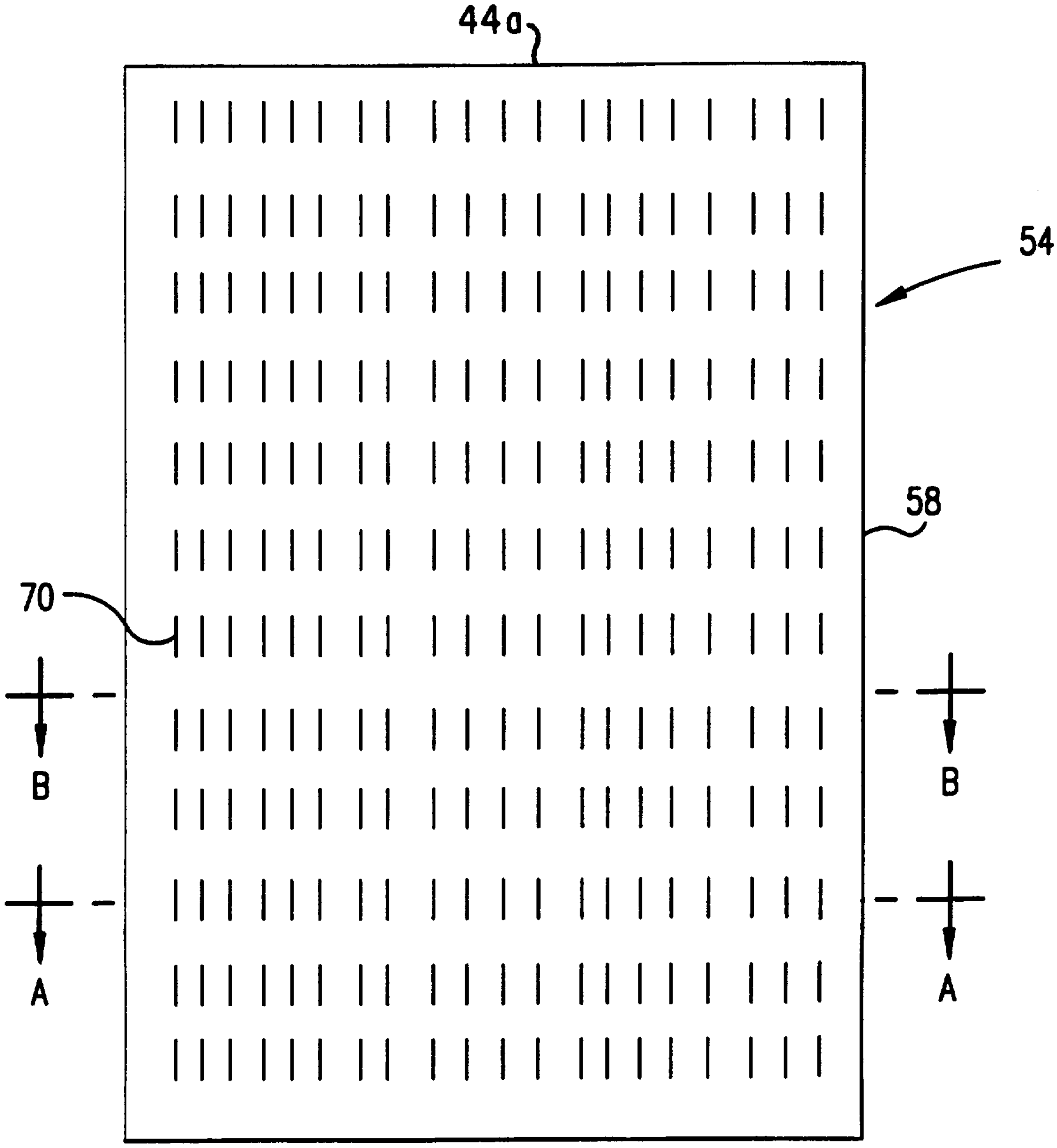


FIG.4

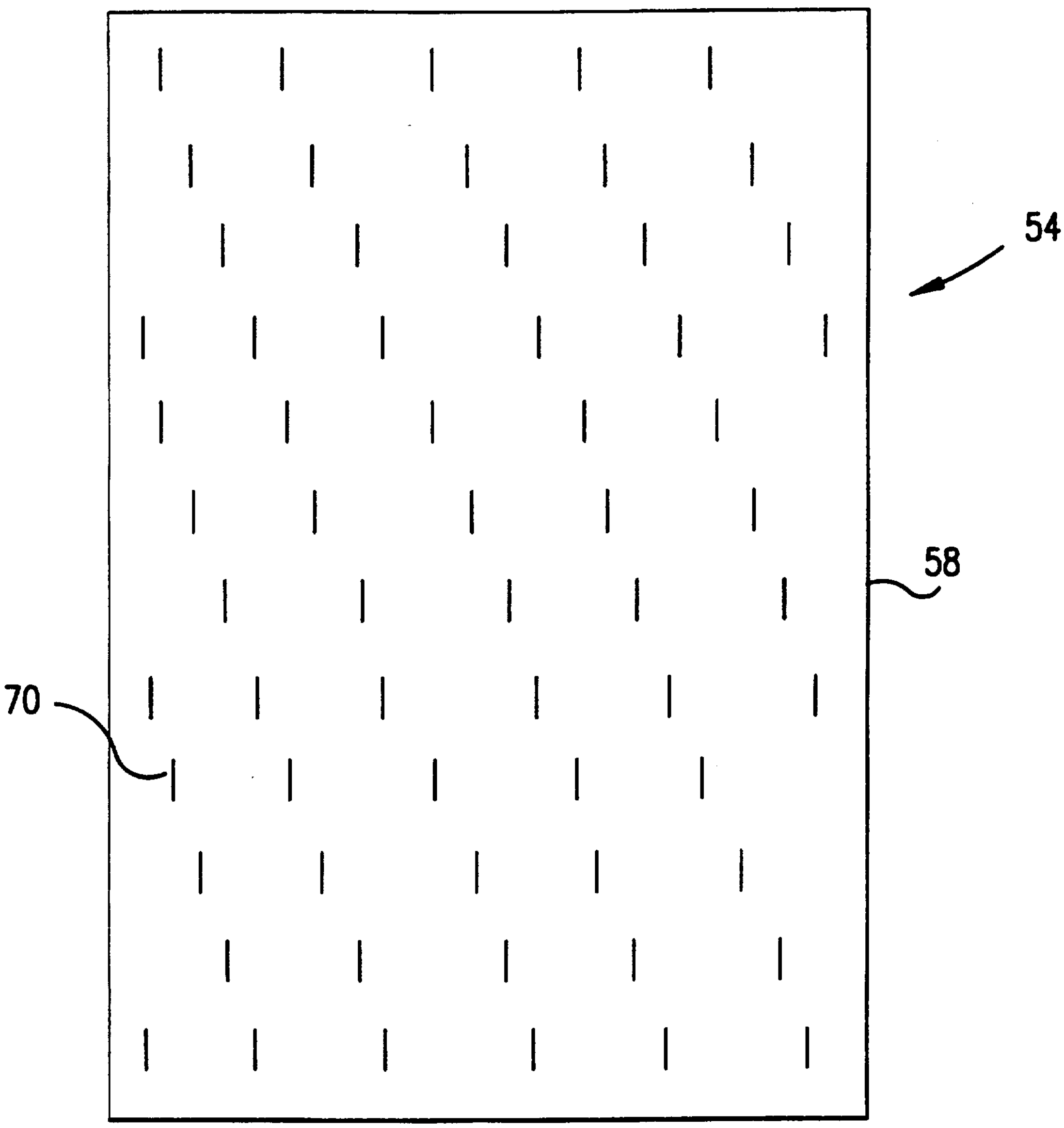


FIG.5A

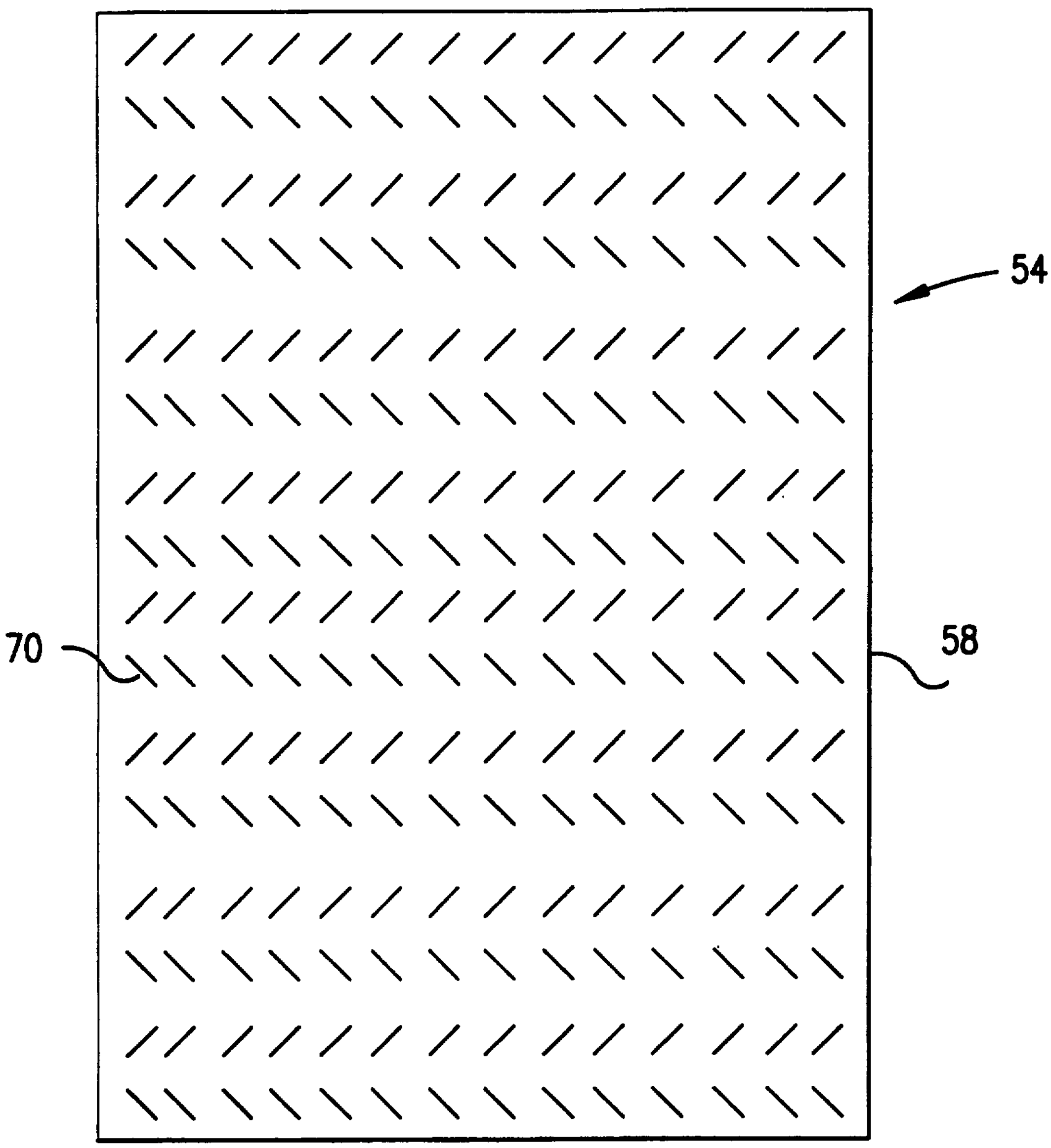


FIG.5B

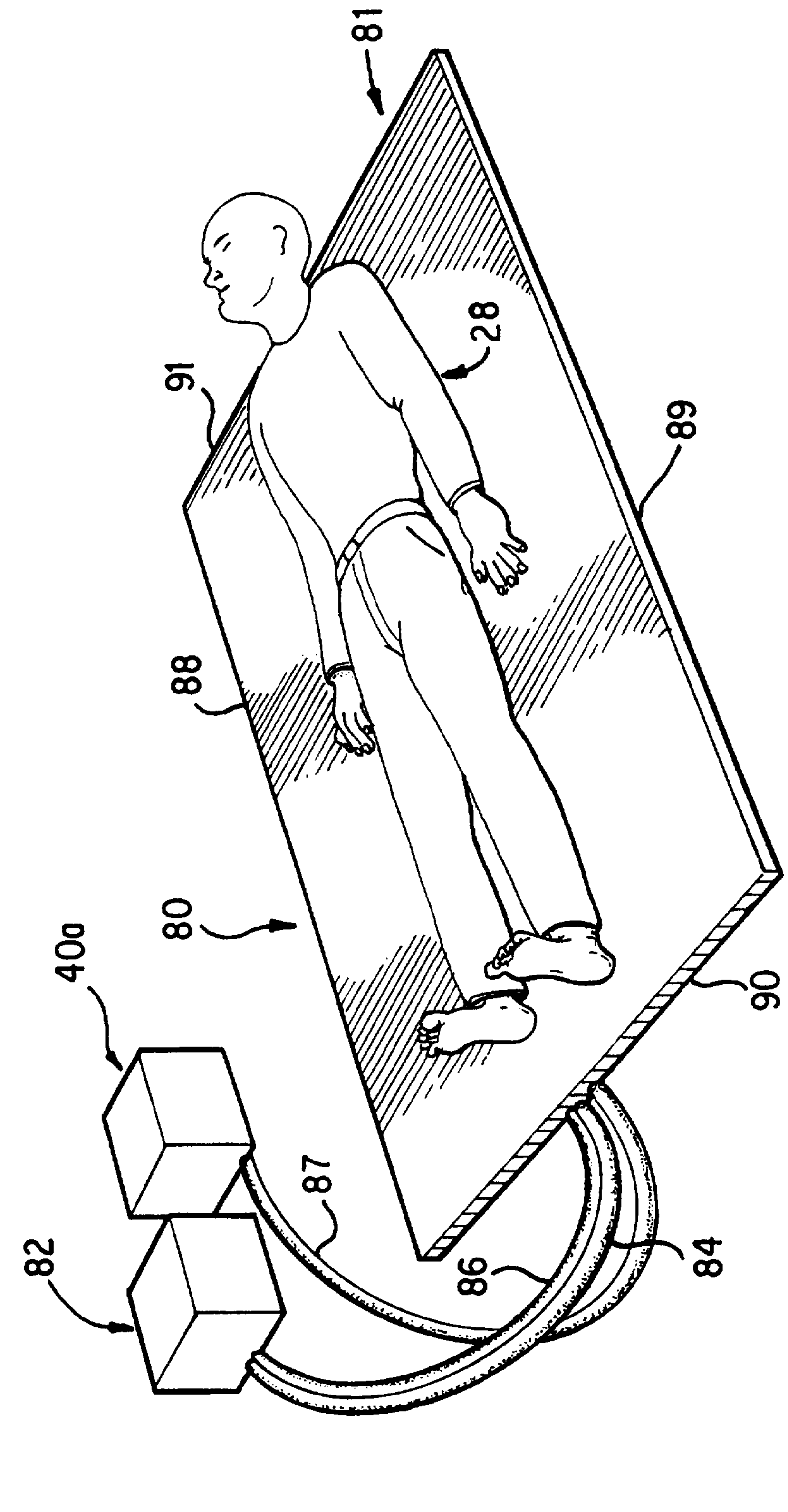


FIG. 6

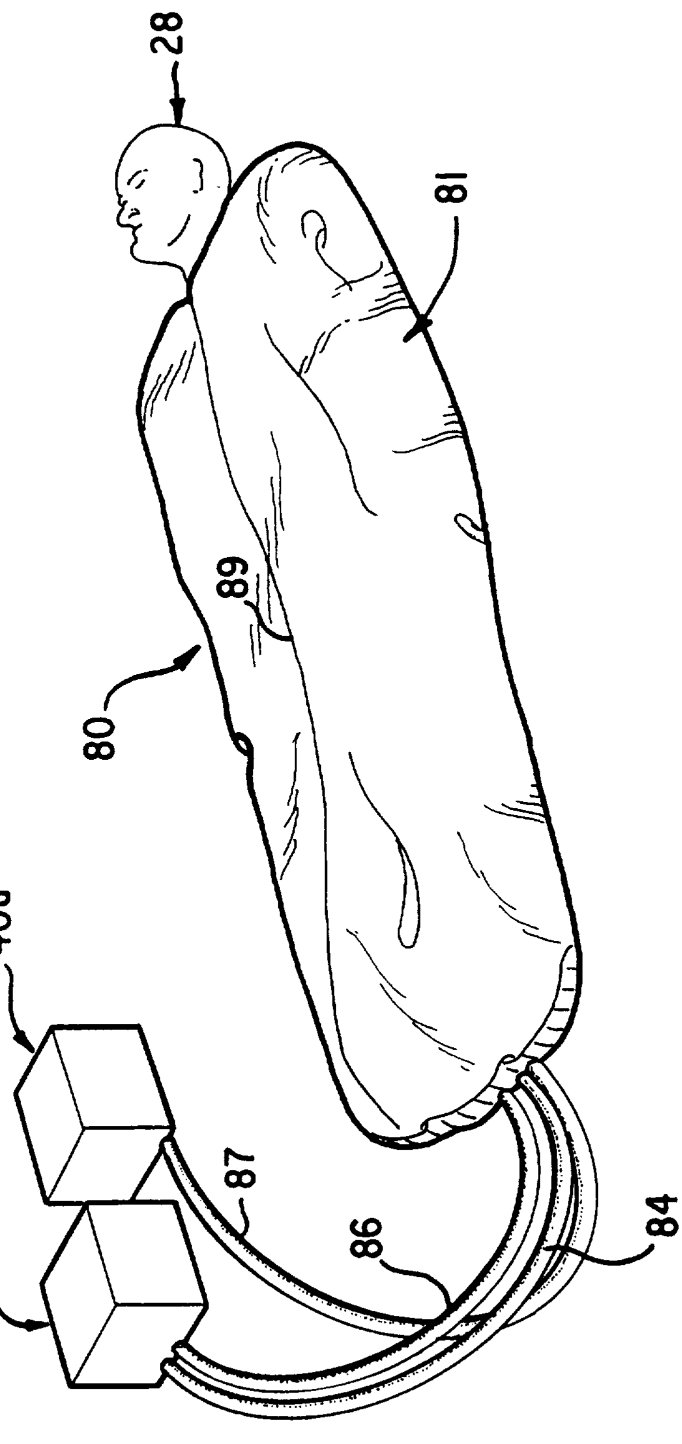
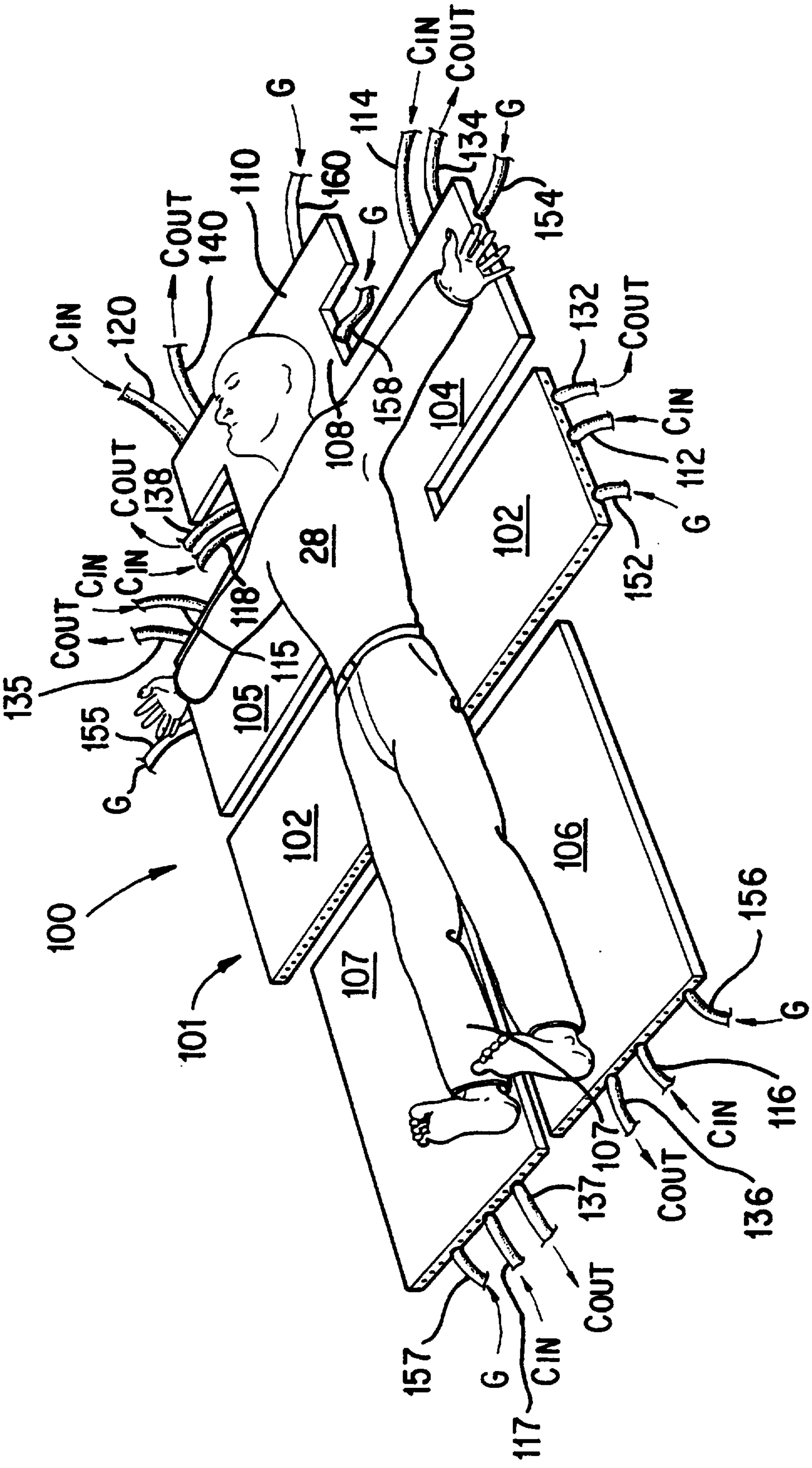


FIG. 7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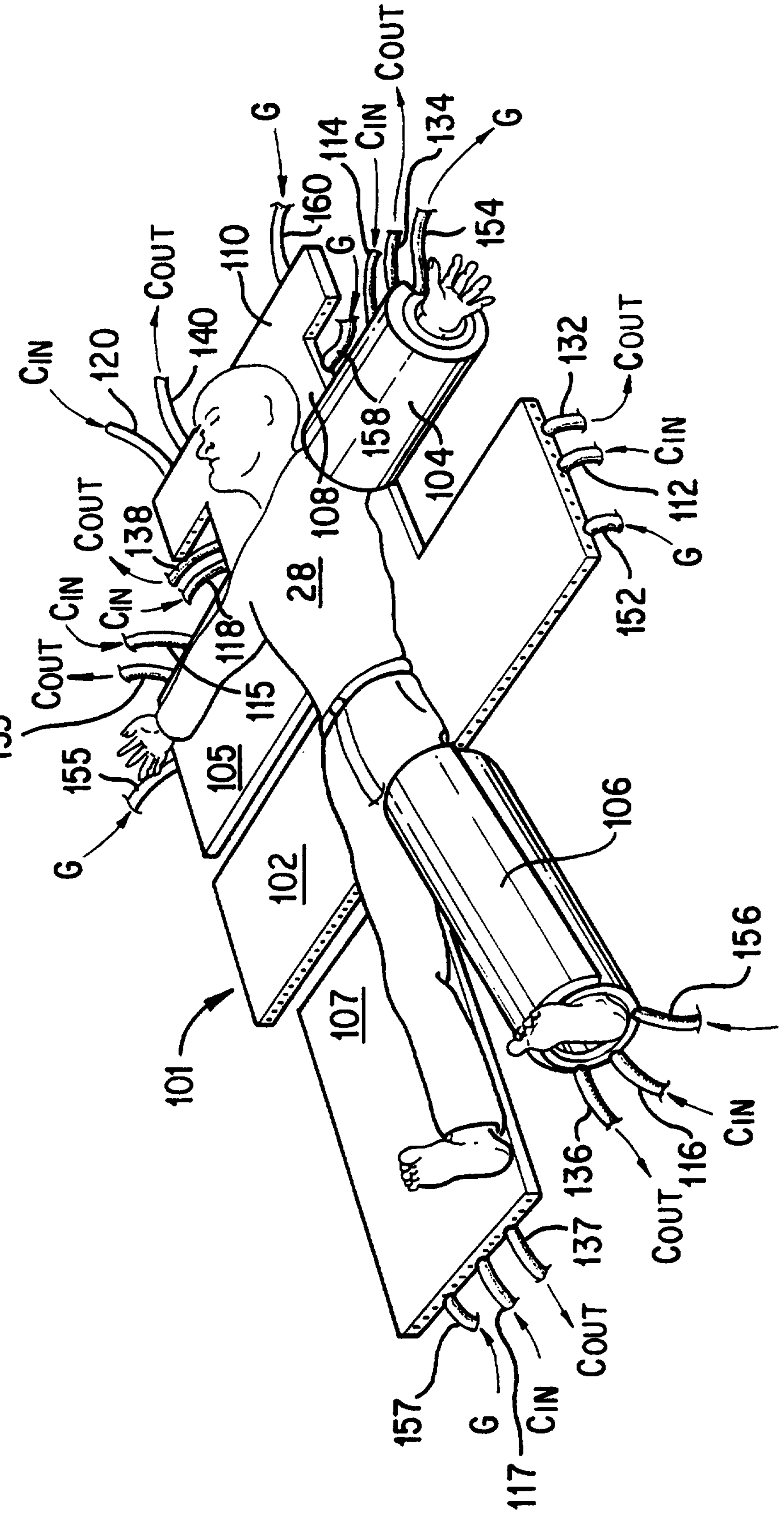
156
157
158
160
28
CIN
COUT
G

FIG. 8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118
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152
154
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157
158
160
28
G
CIN
COUT

FIG.9

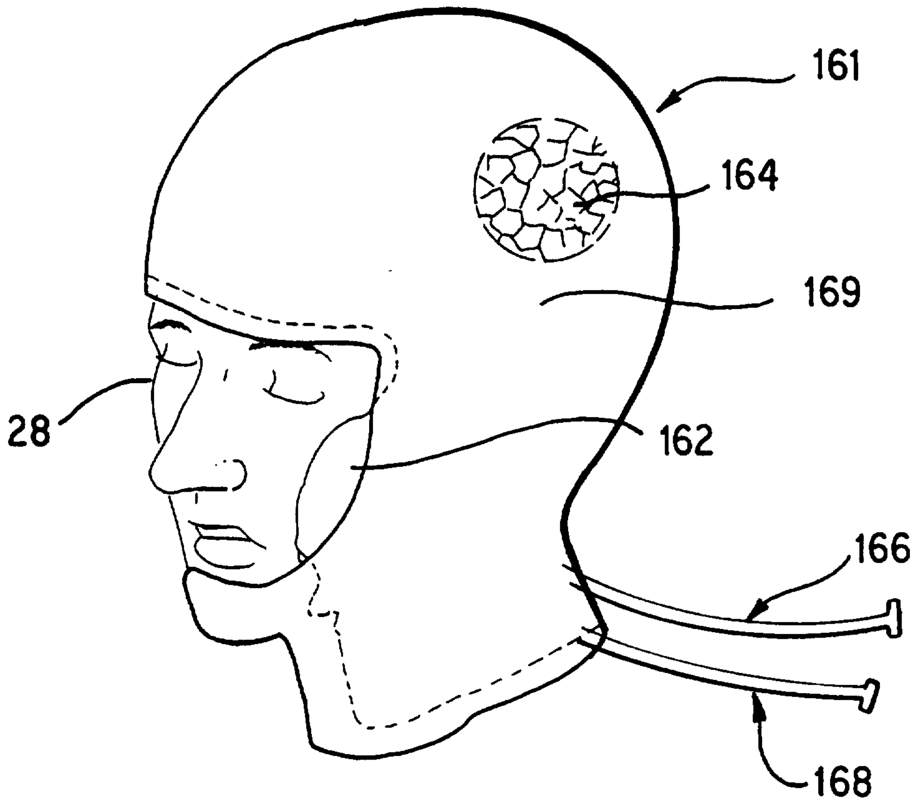

FIG.10

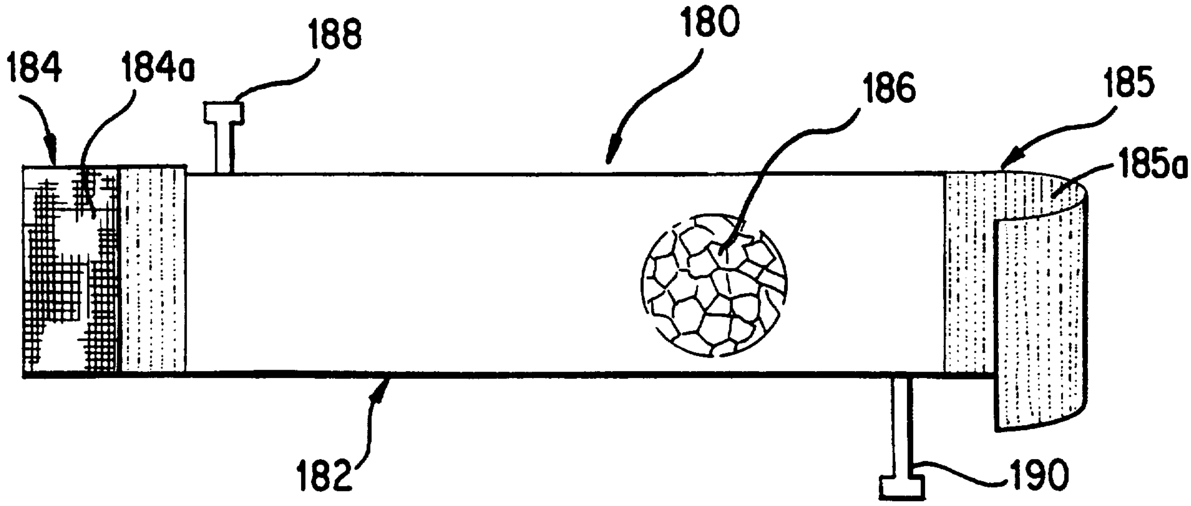

FIG.13

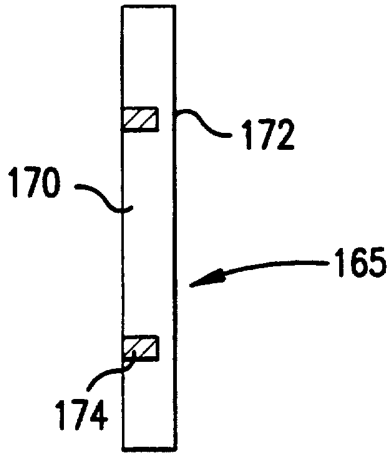

FIG.11

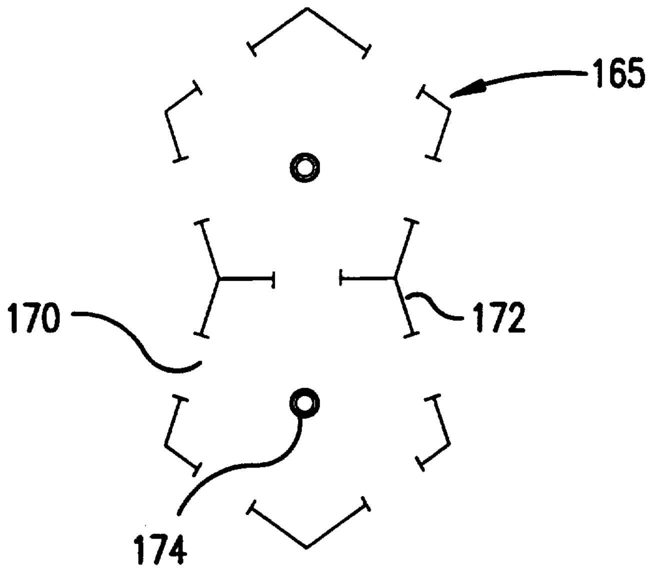

FIG.12

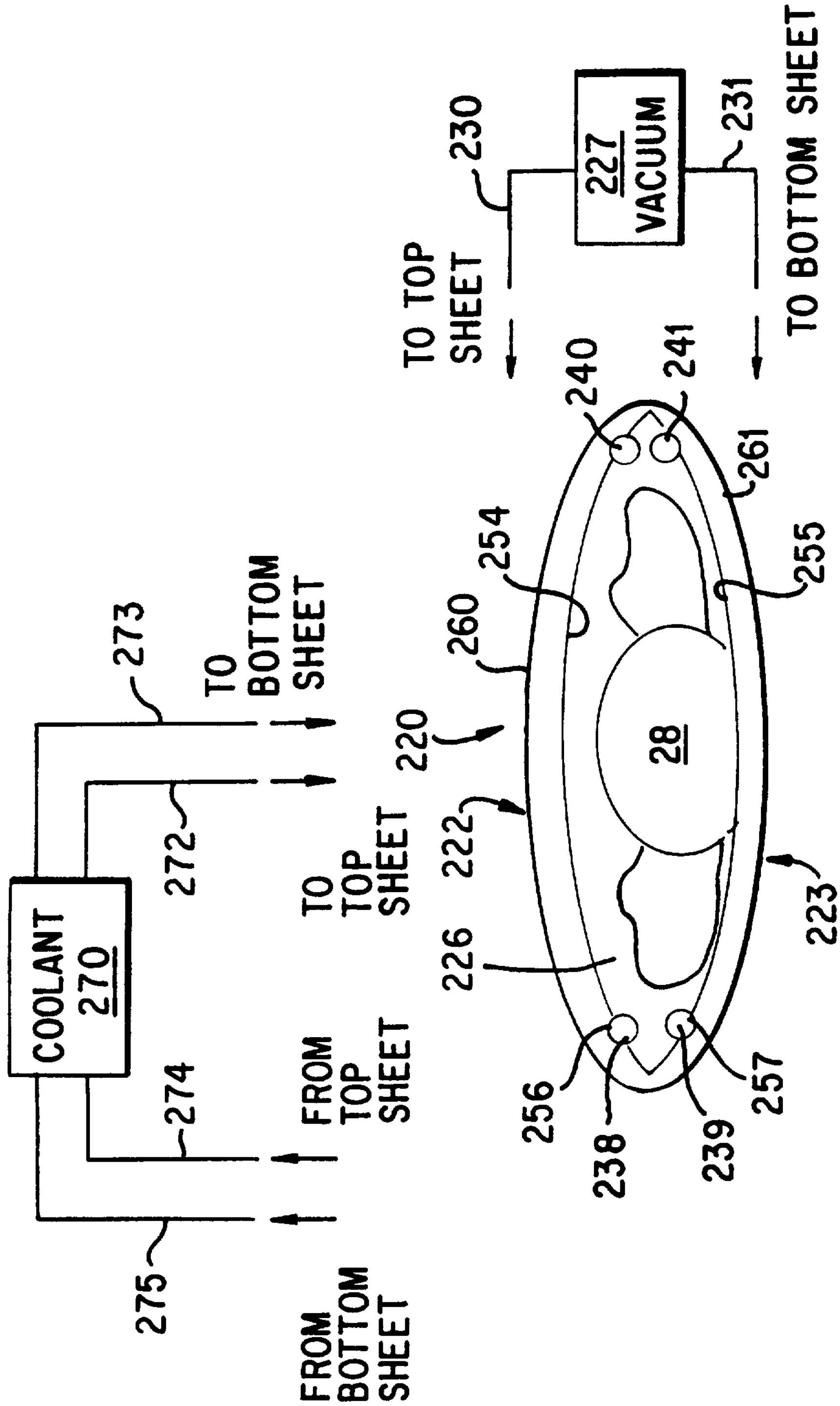
TO TOP SHEET
230
227
VACUUM
231
TO BOTTOM SHEET
240
241
261
254
255
260
28
220
222
223
226
256
238
239
257
COOLANT
270
273
TO BOTTOM SHEET
272
TO TOP SHEET
274
FROM TOP SHEET
275
FROM BOTTOM SHEET

FIG.14

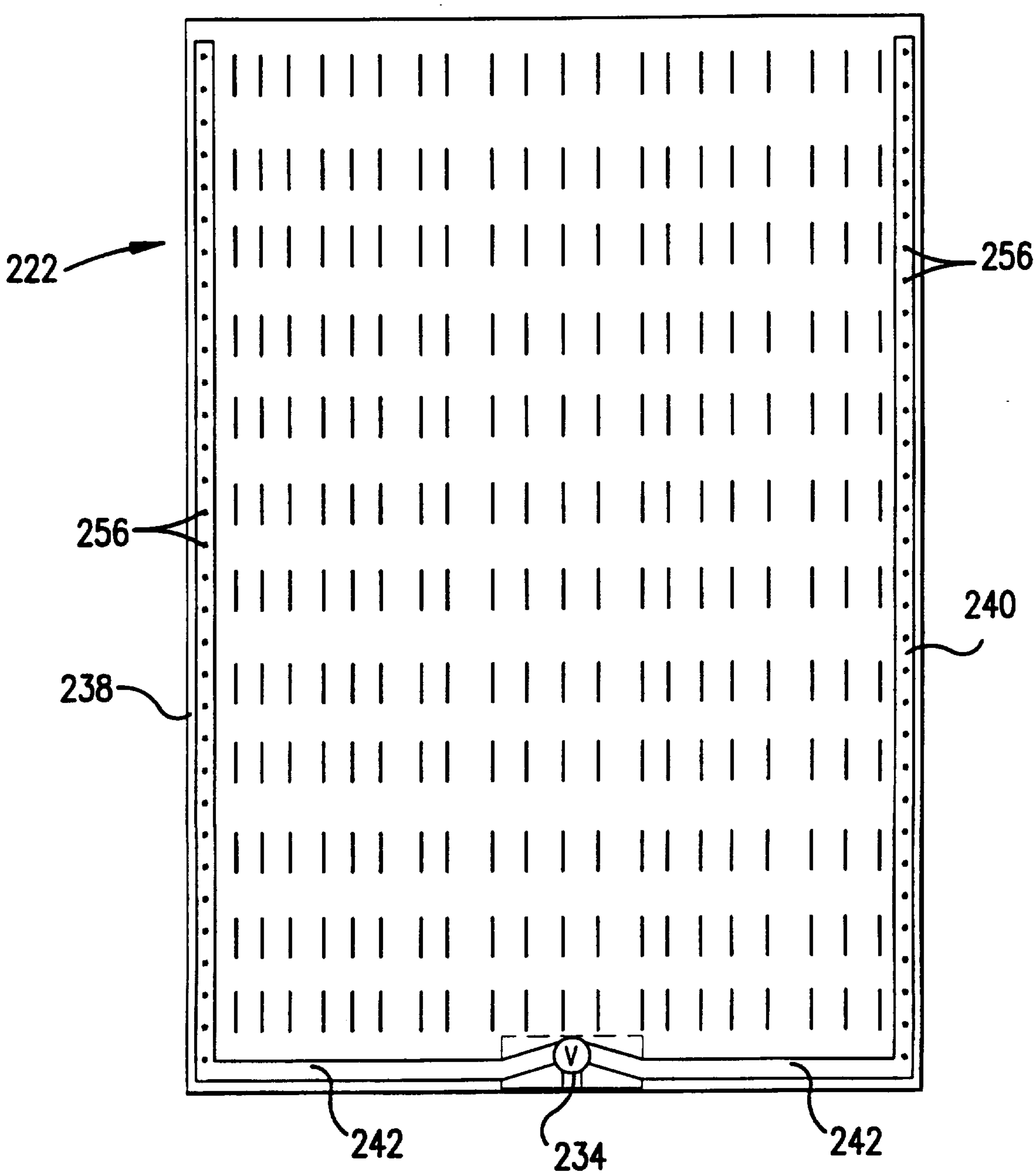

FIG.15A

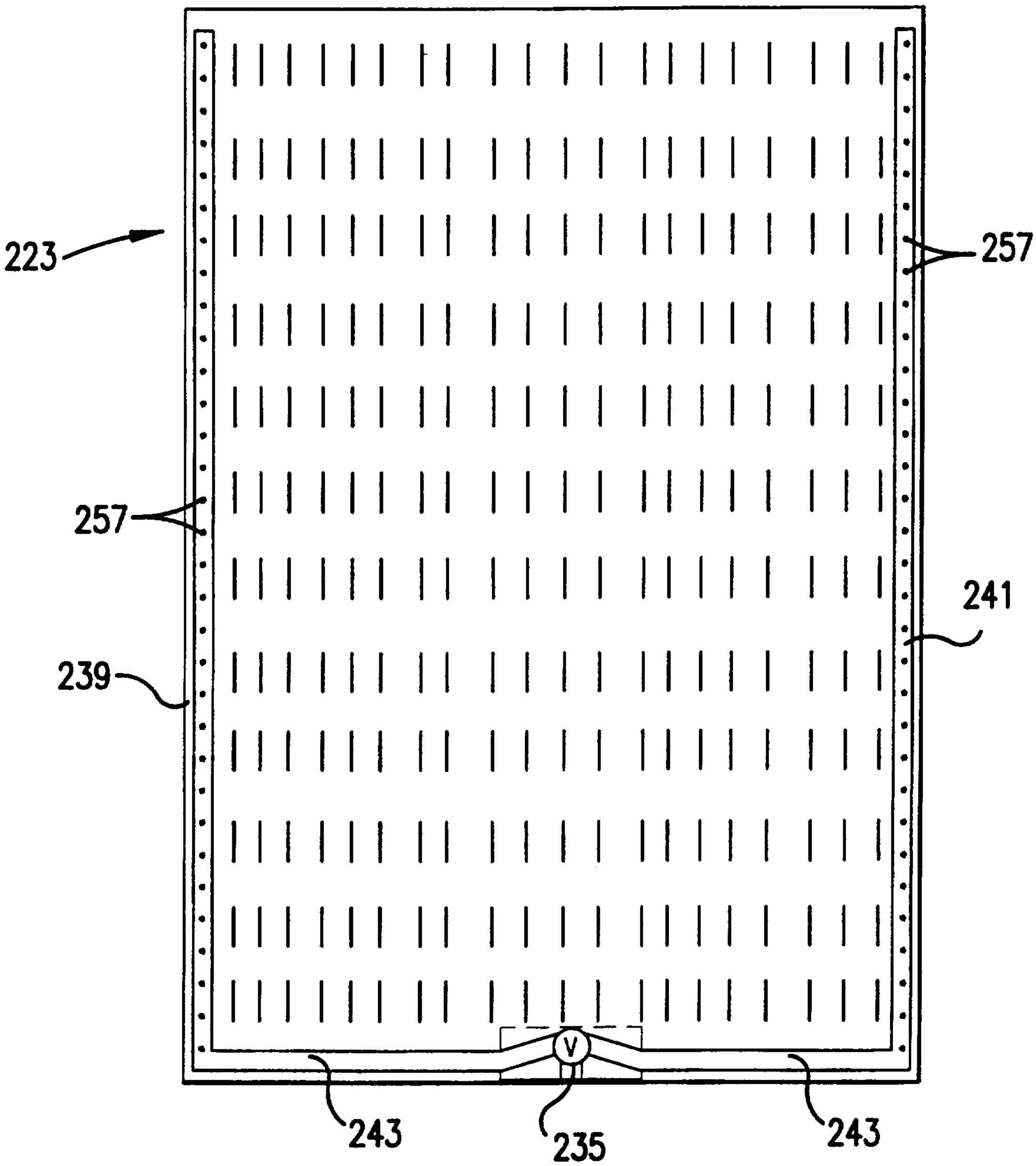

FIG.15B

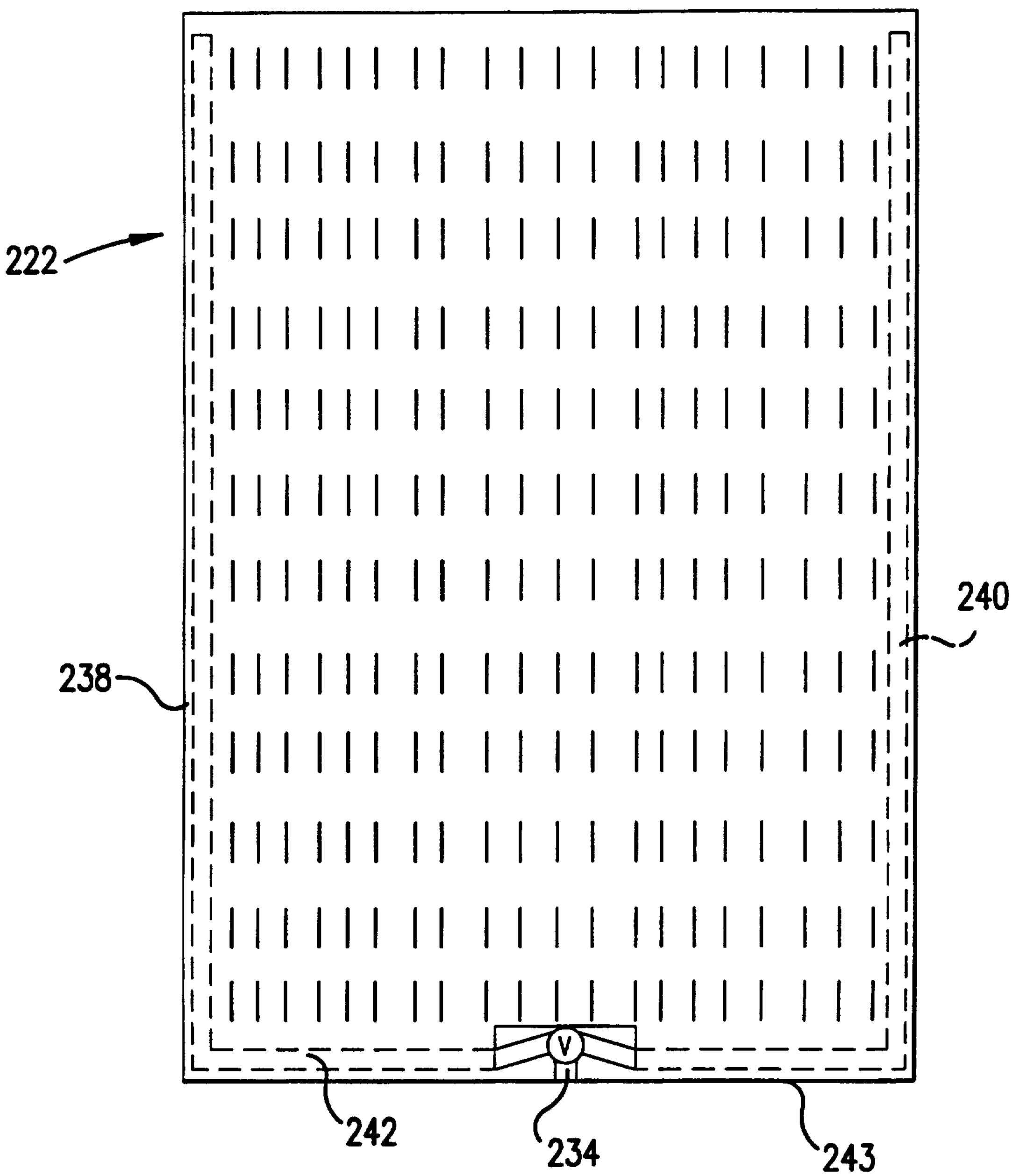

FIG.16A

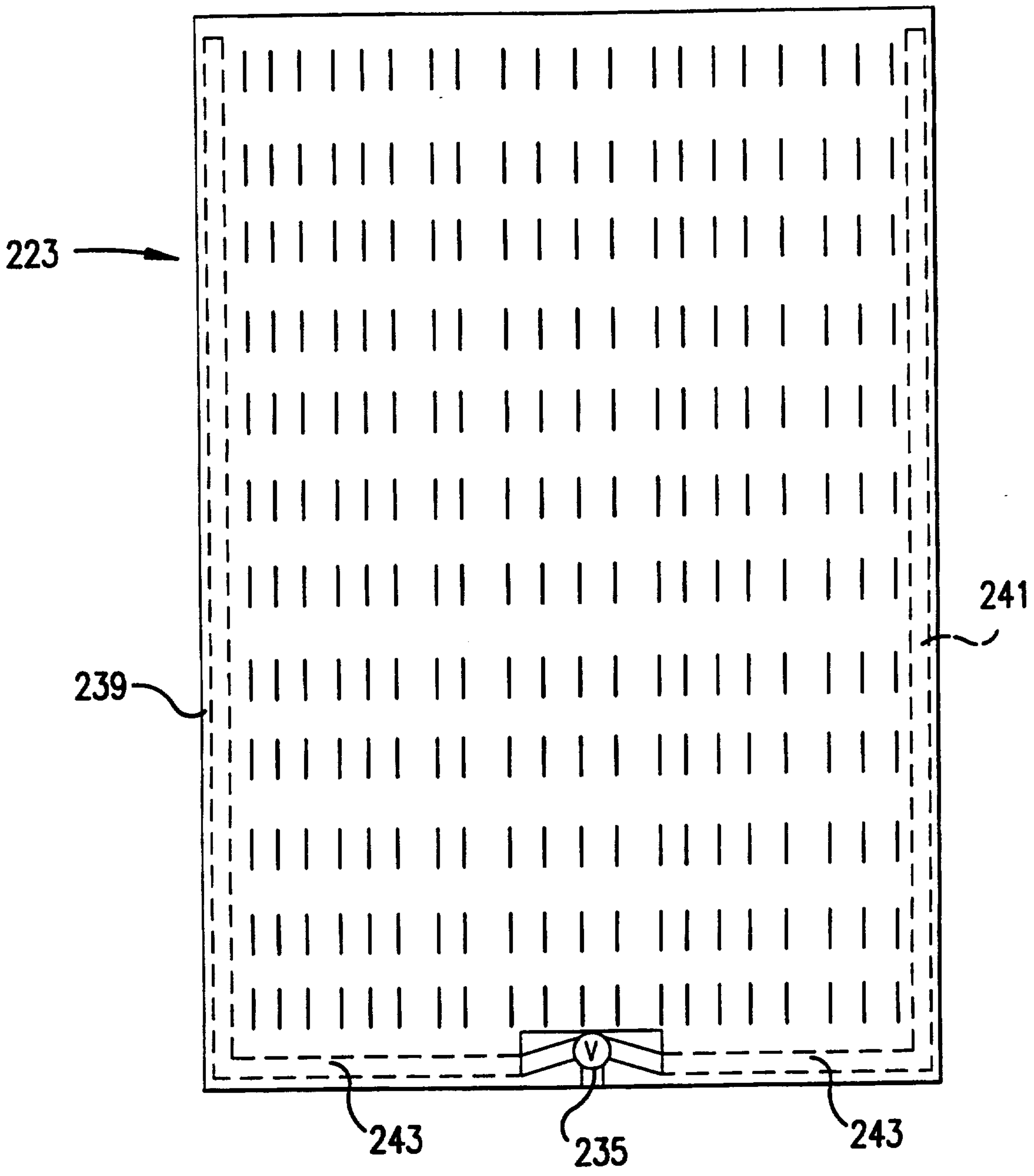

FIG.16B

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US96/20639

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61F 7/00
US CL :607/104,107,108
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 607/96, 104, 107, 108, 114

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

APS
search terms: vacuum, 607/clas

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5,350,417 A (AUGUSTINE) 27 September 1994, col.4, lines 16-68; and col. 5, lines 1-68.	6-10,13,18,19
Y, P	US 5,486,207 A (MAHAWILI) 23 January 1996, col. 3, lines 20-29.	6-10,13
A	US 5,383,918 A (PANETTA) 24 January 1995.	1-5,11,12

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be of particular relevance	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E" earlier document published on or after the international filing date	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&" document member of the same patent family
"O" document referring to an oral disclosure, use, exhibition or other means	
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search	Date of mailing of the international search report
14 FEBRUARY 1997	17 MAR 1997
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	Authorized officer FOR ROSILAND S. KEARNEY
Facsimile No. (703) 305-3590	Telephone No. (703) 308-2711

Form PCT/ISA/210 (second sheet)(July 1992)★