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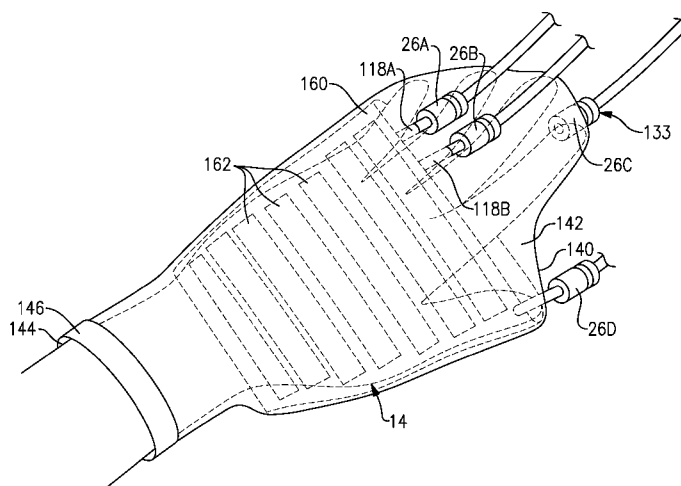


FIG. 43

(57) **Abstract:** An example core body temperature adjustment system includes an impermeable flexible membrane that defines a negative pressure chamber for an appendage, a thermal element that is situated against the impermeable flexible membrane, and a rigid layer that extends around the appendage and spaces the impermeable flexible membrane away from the appendage. Another example core body temperature adjustment system includes an impermeable flexible membrane that defines a negative pressure chamber for an appendage, a thermal element that is situated against the impermeable flexible membrane and includes opposing first and second faces and a plurality of passages that extend between the first and second faces, and a spacing layer that spaces the impermeable flexible membrane away from the appendage.



METHODS AND DEVICES FOR CORE BODY TEMPERATURE MANAGEMENT**STATEMENT REGARDING FEDERALLY SPONSORED
RESEARCH OR DEVELOPMENT**

[0001] This invention was made with government support under Contract No. N62645-15-C-4022 awarded by the United States Navy. The Government has certain rights in this invention.

CROSS-REFERENCE TO RELATED APPLICATION

[0001] This application claims priority to U.S. Provisional Application No. 62/253,736, filed 11/11/2015.

TECHNICAL FIELD

[0002] The present disclosure relates to thermophysiology, and more particularly to methods and devices for managing the core body temperature of patients based on applying targeted heating or cooling to glabrous skin areas.

BACKGROUND

[0003] Cooling of human or other mammalian skin can provide one or more benefits, particularly in situations or circumstances where a subject's skin and/or body temperature is elevated relative to normal, acceptable, comfortable and/or safe levels. For example, in some instances, a person's skin and/or body temperature may be dangerously high because of fever and/or another medical condition (e.g., infection, allergy or other adverse reaction, disease, etc.). In other cases, a subject's temperature may be elevated due to exposure to heat or sun and/or other source of heat (e.g., workspace). In other circumstances, it may be desirable to heat a person's skin or other anatomical location, either in lieu of or in addition to cooling, as desired or required. For example, heating can be used to treat hypothermia, chills and/or any other condition or ailment.

[0004] Another situation where it may be useful to alter the bodily temperature of individuals is during and/or after surgery. Anesthesia compromises patients' ability to thermoregulate their core bodily temperature. Because anesthesia can cause the bodily

temperature of patients to drop, medical practitioners may wish to control a patient's core temperature during and/or after a surgical procedure.

[0005] Yet another example where it may be desirable to adjust core body temperature is reducing muscle fatigue in athletes. Researchers have found that temperature can be a primary limiting factor for athletic performance. Reducing the core temperature of athletes during periods of physical exertion can enable athletes to partake in greater physical exertion without damaging muscles from overwork.

[0006] In the context of surgical procedures, one device that has been used to control core temperature is the BAIR HUGGER from 3M. The device, which works like a forced-air heater, carries warmed air through a hose to a special blanket that is draped over a patient. The BAIR HUGGER is often used to cover large bodily areas (e.g., a patient's entire torso or entire lower body), which can obstruct access to various bodily areas during a surgical procedure. Also, because of its size the BAIR HUGGER can be impractical to use in many environments.

[0007] Researchers have recently discovered that the major sites of heat exchange in the human body (and other mammals) are limited to the non-hairy (glabrous) skin areas. These areas include the palms of the hands, the soles of the feet, and non-hairy parts of the face. These areas of skin are underlain by unique sets of blood vessels that have the capacity to circulate a large portion of the total blood volume (up to 60% of the total cardiac output) directly beneath the skin surface. This thermoregulatory structure facilitates direct heat transfer between the body core and the external environment.

[0008] Underlying glabrous skin areas - the palms of hands, soles of the feet, and parts of the face and ears - are natural heat exchange portals with unique vascular network structures beneath the surface of the skin. These specialized networks of the thermoregulatory system, which allow blood flow from the arteries to the veins, are called arteriovenous anastomoses (AVAs). When the pathway is opened, the AVAs enable a significant increase in blood flow beneath the skin in glabrous regions. The function of these vascular structures has only recently been appreciated, and fine anatomy of unique vascular structures has only recently been characterized. Dilation and contraction of the AVAs are controlled by the body's thermoregulatory system. When the body perceives conditions which would cause its temperature to rise above normal, the AVAs dilate to increase blood flow near the skin

surface, thereby increasing heat loss to the environment. When the body perceives conditions leading to a decrease in core temperature, the AVAs constrict, decreasing blood flow, allowing the body to conserve more of its metabolic heat.

[0009] Special vascular structures enable these adjustments of blood flow to glabrous skin. As noted above, the unique vascular structures - only recently recognized and characterized - are composed of AVAs and a dense network of interwoven venous structures. The AVAs are direct shunts between arteries and veins that bypass capillaries, and provide a low-resistance pathway for the movement of blood through the glabrous skin regions. The receiving venous structures (retia venosa) are arranged in a plexus or large network of vessels that have a large surface-to-volume ratio and can contain a large volume of blood. Thus, the venous plexus acts as a radiator. The AVAs are gated by smooth muscle. When open, there is a very high blood flow, and therefore heat transport, into the low resistance venous radiators. When the AVAs are closed, a greatly reduced blood flow goes through the high-resistance nutritive capillaries of the skin. It is those capillaries that “nourish” cells with blood. In the normothermic individual, a person whose thermoregulation is within the normal range, proportional control of the AVAs balances internal heat production and heat loss. The relative blood flow through these radiator-like structures is referred to as vasomotor tone. Vasodilation defines the condition in which the AVAs are open and blood is flowing freely through the venous plexuses. Vasoconstriction defines the condition in which the AVAs are closed and blood is not flowing through the venous plexuses.

SUMMARY

[0010] One example embodiment of core body temperature adjustment system includes an impermeable flexible membrane that defines a negative pressure chamber for an appendage, and a thermal element that is situated against the impermeable flexible membrane. A rigid layer extends around the appendage and spaces the impermeable flexible membrane away from the appendage.

[0011] In another example embodiment of the above described core body temperature adjustment system, application of negative pressure within the negative pressure chamber draws the impermeable flexible membrane towards a glabrous skin area of the appendage.

[0012] In another example embodiment of any of the above described core body temperature adjustment systems, the impermeable flexible membrane is situated between the thermal element and a glabrous area of the appendage.

[0013] In another example embodiment of any of the above described core body temperature adjustment systems, the rigid layer comprises a first wall facing a first side of the appendage that includes the glabrous area, and a second wall facing an opposing, second side of the appendage. The first and second walls form an enclosure around the appendage.

[0014] In another example embodiment of any of the above described core body temperature adjustment systems, the rigid layer comprises a plurality of inflatable air struts that are aligned along and extend around a longitudinal axis of the enclosure.

[0015] In another example embodiment of any of the above described core body temperature adjustment systems, the second wall is situated within the negative pressure chamber, and the first wall is situated outside of the negative pressure chamber.

[0016] In another example embodiment of any of the above described core body temperature adjustment systems, the first wall is substantially flat and the second wall is arched.

[0017] In another example embodiment of any of the above described core body temperature adjustment systems, the second wall includes a plurality of discrete, spaced apart arches.

[0018] In another example embodiment of any of the above described core body temperature adjustment systems, the first and second walls are detachable from each other.

[0019] In another example embodiment of any of the above described core body temperature adjustment systems, the enclosure is entirely within the negative pressure chamber.

[0020] In another example embodiment of any of the above described core body temperature adjustment systems, the first wall includes a central opening, and the core body temperature adjustment system includes an adhesive that seals the impermeable flexible membrane to an outer surface of the first wall along a perimeter of the central opening.

[0021] In another example embodiment of any of the above described core body temperature adjustment systems, the first wall includes a central opening, and a portion of the

impermeable flexible membrane that extends across the central opening along an outer surface of the first wall separates the thermal element from the glabrous area.

[0022] In another example embodiment of any of the above described core body temperature adjustment systems, the first wall includes a first quantity of openings, and the second wall includes a greater, second quantity of openings.

[0023] In another example embodiment of any of the above described core body temperature adjustment systems, the second wall comprises a plurality of openings arranged in a honeycomb pattern.

[0024] In another example embodiment of any of the above described core body temperature adjustment system, the first and second walls extend along a longitudinal axis of the enclosure between opposing first and second ends of the enclosure, and the enclosure includes one or more flaps at the first end that extend inward in a direction generally perpendicular to the longitudinal axis. The one or more flaps retain the appendage within the enclosure after the appendage is inserted into the enclosure.

[0025] In another example embodiment of any of the above described core body temperature adjustment systems, the thermal element comprises a housing that contains a temperature distribution medium, and the core body temperature adjustment system comprises a pump operable to provide circulation within the temperature distribution medium.

[0026] In another example embodiment of any of the above described core body temperature adjustment systems, the impermeable flexible membrane is non-woven.

[0027] One example embodiment of a core body temperature adjustment system includes an impermeable flexible membrane that defines a negative pressure chamber for an appendage. A thermal element is situated against the impermeable flexible membrane and comprises opposing first and second faces. A plurality of passages extend between the first and second faces, and a spacing layer spaces the impermeable flexible membrane away from the appendage.

[0028] In another example embodiment of the above described core body temperature adjustment system, application of negative pressure within the negative pressure chamber compresses the thermal element against a glabrous skin area of the appendage.

[0029] In another example embodiment of any of the above described core body temperature adjustment systems, the impermeable flexible membrane defines the negative pressure chamber against a single, first side of the appendage, such that digits of the appendage, and an opposite second side of the appendage are outside of the negative pressure chamber.

[0030] In another example embodiment of any of the above described core body temperature adjustment systems, the impermeable flexible membrane encloses less than 50% of a surface area of a non-digital portion of the appendage within the negative pressure chamber.

[0031] In another example embodiment of any of the above described core body temperature adjustment systems, a pump is fluidly connected to an outlet of the impermeable flexible membrane and is operable to apply negative pressure within the plurality of openings.

[0032] In another example embodiment of any of the above described core body temperature adjustment systems, the spacing layer comprises a reticulated fabric or a reticulated foam.

[0033] In another example embodiment of any of the above described core body temperature adjustment systems, the first and second faces are radio frequency welded or thermally bonded to each other along a perimeter of each of the plurality of passages.

[0034] One example embodiment of a method of controlling the core body temperature of a patient includes inserting an appendage of the patient into an appendage enclosure, such that the appendage enclosure extends around the appendage, and spaces the appendage away from an impermeable flexible membrane. The method also includes applying negative pressure within a negative pressure chamber defined by the impermeable flexible membrane, wherein the appendage is situated in the negative pressure chamber, and the appendage enclosure is at least partially situated in the negative pressure chamber. The method also includes transferring heat between a thermal element and the glabrous area of the appendage during the applying.

[0035] In another example embodiment of the above described method, the method includes sealing the impermeable flexible membrane against a limb from which the appendage extends to maintain the negative pressure.

[0036] In another example embodiment of any of the above described methods, the method includes inflating the appendage enclosure to a rigid state, and the applying and transferring are performed while the appendage enclosure in the rigid state.

[0037] In another example embodiment of any of the above described methods, the method includes situating the thermal element against a glabrous area of the appendage and within the appendage enclosure, but outside of the negative pressure chamber.

[0001] The embodiments described herein may be taken independently or in any combination. Features described in connection with one embodiment are applicable to all embodiments, unless such features are incompatible.

BRIEF DESCRIPTION OF THE DRAWINGS

[0002] The disclosure can be further understood by reference to the following detailed description when considered in connection with the accompanying drawings wherein:

[0003] Fig. 1 depicts target areas for core body temperature management with interface electronics.

[0004] Fig. 2 schematically depicts an example glove that includes a thermal transfer element for heating and/or cooling a patient's hand.

[0005] Fig. 3 schematically depicts an example foot garment that includes a thermal transfer element for heating and/or cooling a patient's foot.

[0006] Figs. 4-6 schematically depict additional foot garment embodiments.

[0007] Fig. 7 schematically depicts an example mask that includes a thermal transfer element for heating and/or cooling a patient's face.

[0008] Figs. 8A-B, 9, and 10 schematically illustrate other example mask features.

[0009] Fig. 11 schematically depicts a core body temperature adjustment system with a related fluid pumping configuration.

[0010] Fig. 12 schematically depicts an enlarged view of the pumping configuration of Fig. 8.

[0011] Fig. 13 schematically illustrates an example pumping configuration.

[0012] Fig. 14 schematically illustrates an arrangement for pumping fluid to heat or cool a patient's hand.

[0013] Fig. 15 schematically illustrates an example peristaltic pump that may be used in the embodiment of Fig. 14.

[0014] Fig. 16 schematically illustrates another example arrangement for pumping fluid to heat or cool a patient's hand

[0015] Figs. 17-18 schematically illustrate example thermoelectric device configurations.

[0016] Figs. 19-21 schematically illustrate embodiments in which a glove includes a flap for securing a thermal transfer element to a patient's palm.

[0017] Figs. 22-25 schematically illustrate additional example features for heating or cooling a patient's palm.

[0018] Figs. 26-27 schematically illustrate embodiments in which a temperature distribution medium comprises a fluid, and a pump is configured to circulate the fluid.

[0019] Figs. 28-31 schematically illustrate embodiments in which negative pressure can be applied to a patient's palm.

[0020] Figs. 32-33 schematically illustrate embodiments in which a thermoelectric device is mounted to a palm area of a glove.

[0021] Fig. 34 is a flowchart of an example method of controlling the core body temperature of a patient.

[0022] Figs. 35-37 schematically illustrate another embodiment in which negative pressure can be applied to a bodily area.

[0023] Figs. 38-39 schematically illustrate another embodiment in which negative pressure can be applied to a bodily area.

[0024] Figs. 40-43 schematically illustrate examples of inflatable air struts that can be used on combination with the application of negative pressure.

[0025] Figs. 44A-E schematically illustrate examples of a non-collapsible exoskeletal appendage enclosure that can be used in combination with the application of negative pressure.

[0026] Fig. 45 schematically illustrates another example non-collapsible exoskeletal appendage enclosure.

[0027] Fig. 46 is a flowchart of another example method of controlling the core body temperature of a patient.

[0028] The embodiments described herein may be taken independently or in any combination. Features described in connection with one embodiment are applicable to all embodiments, unless such features are incompatible.

DETAILED DESCRIPTION

[0029] The present disclosure describes techniques for adjusting the core temperature of patients based on applying targeted heating or cooling to glabrous bodily areas at which arteriovenous anastomoses (AVAs) are located. Because these areas are natural heat exchange portals, applying heating and/or cooling to them can yield considerable efficiency improvements over the prior art. For example, some of the devices and techniques discussed herein can be implemented without limiting access to a patient's hands and/or fingers, as such access may be needed for common field medicine assessments, such as blood pressure monitoring.

[0030] The devices and techniques discussed herein are also effective if contact is only possible with only one limb or facial interface, as in the case of casualties with multiple traumas affecting one or more limbs. Still further, these devices and techniques can facilitate a greater variety of patient postures (e.g., upright, seated, or lying down) than was possible in the prior art. The devices and techniques discussed herein can be used to maintain patient warming at a level of performance seen in current standard of care systems, but with reduced package size, and reduced power consumption.

[0031] According to another aspect of the present disclosure, a heating and/or cooling loop is attached to a flexible fluid pack (containing, e.g., a gas, liquid, gel and/or conductive slurry) that can conform to the palm of the hand (or foot or face). Circulation within the loop facilitates heat transfer with a glabrous skin area. Power can be provided onboard via batteries or from an external power source (e.g., an electrical outlet). Similarly, pumps, a control unit, and other related components can be part of the onboard pack or accessed through a remote connection (i.e., tube, wire, etc.).

[0032] According to one aspect of the present disclosure, techniques are disclosed for controlling a patient's core body temperature without applying heating or cooling directly to the patient's core. This can be achieved by instead applying heat to one or more glabrous areas of the patient's body via thermal transfer elements. Such core body temperature control

can be useful for perioperative care (i.e., preoperative, intraoperative, and postoperative care). In some embodiments, heating and/or cooling is still provided to a patient's torso area (e.g., stomach or back) to provide comfort.

[0033] According to one aspect of the present disclosure, an impermeable flexible membrane defines a negative pressure chamber for an appendage, a thermal element is situated against the impermeable flexible membrane, and a rigid layer extends around the appendage and spaces the impermeable flexible membrane away from the appendage.

[0034] The various thermal elements may be centrally controlled by a shared control circuit, or may have individual localized control circuits. In some embodiments, the localized control circuits are configured to communicate with each other using wireless signaling.

[0035] A system for core body temperature adjustment system may comprise a disposable portion, and a reusable portion. For example, in some embodiments the thermal transfer element comprises a circulation loop that circulates fluid on glabrous areas. In some such embodiments, the circulation loop is detachable into first and second conduits, with one portion of the conduit being disposable, and the other portion being reusable.

[0036] Fig. 1 depicts target areas for core body temperature management with interface electronics for a core body temperature adjustment system 10. The target areas of patient 12 are glabrous areas, and they include portions of the patient's hands 14, feet 16, and head 18. In particular, the glabrous areas include a palm of the hands 14, a sole of the feet 16, and a cheek and/or forehead area of the head 18.

[0037] The system 10 includes a set of discrete, thermal transfer elements 24, each of which is mounted to a different glabrous area of a patient's body, and is configured to heat and/or cool its associated glabrous area (see Figs. 2-7). Electronic control circuitry (shown as electronic control unit "ECU" 20 in Fig. 1) is operatively connected to the thermal transfer elements 24, and is configured to control a temperature of the thermal transfer elements 24. In some embodiments, each thermal transfer element 24 is detachable from its operative connection to its associated control circuitry via one or more detachable connectors (e.g., electrical or fluid connectors).

[0038] Each thermal transfer element 24 is part of a respective garment, such that the set of thermal transfer elements corresponds to a set of thermal garments. In embodiments

in which more than one garment is used, the set of thermal garments may include at least two of the following:

- a right hand glove configured to situate its thermal transfer element on a palm of patient's right hand 14A;
- a left hand glove configured to situate its thermal transfer element on a palm of a patient's left hand 14B;
- a right foot covering configured to situate its thermal transfer element on a sole of a patient's right foot 16A;
- a left foot covering configured to situate its thermal transfer element on a sole of a patient's left foot 16B; and
- a mask configured to situate its thermal transfer element on a patient's forehead, cheek, or both.

[0039] Fig. 2 schematically depicts an example glove 22 sized to at least partially enclose a patient's hand 14. The glove 22 includes a thermal transfer element (TTE) 24 for heating and/or cooling the patient's hand 14. The TTE 24 is mounted to the glove 22, and includes detachable connectors 26. In some embodiments, the TTE 24 is embedded within the glove 22. In other embodiments, the TTE 24 is mounted to an interior or exterior of the glove 22. In Fig. 2, the TTE 24 follows a winding (e.g., serpentine) path along the palm of the hand 14, which is a glabrous area. The glove 22 also includes straps 25 for securing the glove to the hand 14 (e.g., using a snap, a hook and loop fastener, or some other fastener). Although a fingerless glove is shown in Fig. 2 and various other figures, it is understood that a glove including finger coverings, a mitten, or a pouch that encloses the entire hand could be used instead.

[0040] Throughout this disclosure, reference numeral 24 will be generically used to refer to a TTE. In some embodiments discussed herein, the TTE 24 is an electrical heat exchanger (e.g., for heating and/or cooling), and its associated connectors 26 are electrical connectors. In other embodiments, the TTE 24 includes a conduit through which a fluid can flow for heating and/or cooling the palm of a patient's hand, and its associated connectors 26 facilitate a flow of fluid through the conduit. For example, in some conduit embodiments, if disconnected, the connectors 26 prevent fluid from flowing into and out of the conduit (e.g.,

water, air, a gel, etc.). In such embodiments, connector 26A can serve as a fluid inlet, and connectors 26B can serve as a fluid outlet (or vice versa).

[0041] In embodiments in which the TTE 24 is an electrical heat exchanger, a variety of different electric heat sources could be used. One example electric heat source is a wire-based electric heating element (e.g., one that follows a winding path). Another example electric heat source is a positive temperature coefficient (PTC) heater that utilizes a conductive ink (e.g., a carbon based ink, often combined with bus bars that made from highly conductive silver ink) that is deposited onto a substrate. Yet another example electric heat source is a carbon fiber woven material in which certain threads of the conductive material are woven with other threads which may be non-conductive. Yet another example electric heat source is a thermoelectric device (TED). Other options for providing heating function may include metallic foils (aluminum, copper or others), silicone-based heaters, or non-woven sheets of materials with conductive properties. Although some of these electric heat sources may follow a winding path (e.g., as depicted in Fig. 2), it is understood that in other embodiments the electric heat source may not follow a winding path, or may not have a well-defined path at all since the resistive element is distributed over an area (for example, in a PTC heater).

[0042] Fig. 3 schematically depicts an example foot garment 28A that includes a TTE 24 for heating and/or cooling a patient's foot 16. In Fig. 3, the TTE 24 follows a winding path along a sole of the foot 16, which is a glabrous area. Here too, the TTE 24 could comprise an electrical heat exchanger or a conduit, and includes connectors 26. In Fig. 3, the foot garment comprises a sock that includes a heel opening 29A, and also includes a toe opening 29B that is sized for a plurality of the patient's toes to extend through. Although not shown, it would be possible for the foot garment to include a thong member that would be inserted between two toes to prevent the sock from sliding up the patient's leg. Although a toeless foot garment is shown in Fig. 3 and various other figures, it is understood that a foot garment including toe coverings could be used instead.

[0043] Figs. 4-6 schematically illustrate some alternative embodiments of the foot garment. In Figs. 4-5 the foot garments 28B-C include a slip-on shoe. In Fig. 5 the TTE 24 winds along a heel area at the rear of the garment 28C and an upper foot area on the top of the garment 28C. Although not shown in Fig. 5, it is understood that the TTE 24 would also

wind along a sole area of the garment 28C as shown in Fig. 4. Fig. 6 depicts a sock foot garment 28D in which the TTE 24 also winds along a top and heel of a patient's foot 16.

[0044] Fig. 7 schematically depicts an example mask 30A that includes a TTE 24 for heating and/or cooling a patient's face. In Fig. 7, the TTE 24 follows a winding path along a cheek of a patient, which is a glabrous area. In other embodiments, the TTE 24 may follow a path along the patient's forehead instead of, or in addition to, the cheek. The mask 30A may be used in conjunction with a breathing mask 31A. In Fig. 7, the mask 30A includes a chinstrap 32 for placement on the patient's head 18.

[0045] Figs. 8A-B and 9-10 illustrate other example mask features. In Figs. 8A-B, a mask 30B has a TTE 24 that follows a winding path along a patient's forehead. Also, the mask 30B omits the chinstrap 32 of Fig. 7. Fig. 9 illustrates a breathing mask 31B, and Fig. 10 illustrates how a seal portion 36 of the breathing mask 31B may abut a patient's nose 35 along cross-section A-A of Fig. 9.

[0046] Referring again to Fig. 1, the ECU 20 is connected to a thermal element 33 and a power supply 34. In some embodiments, the thermal element 33 includes an electrical connection to an electrical heat exchanger TTE 24. In some embodiments, the thermal element 33 includes a heating or cooling device for heating and/or cooling a fluid in a conduit TTE 24. In some embodiments, a combination of these may be used (e.g., use electrical heat exchanger TTE 24 for hands 14, but conduit TTE 24 for feet 16, or some other combination). The power supply 34 includes at least one of the following: a rechargeable or non-rechargeable battery (e.g. a 12 volt battery), a connection to an AC or a DC power source (e.g., 120 VAC), or the like.

[0047] The ECU may optionally also be connected to one or more of the following: a fluid pump 38, a fan or blower (generically referred to as 40 herein), a communication circuit 42, and one or more sensors 44.

[0048] In embodiments in which sensor(s) 44 are included, the ECU 20 is configured to control the temperature of the TTE 24 based on input received from the sensor(s). Some example sensors that may be used include a heat flux sensor, a temperature sensor, a blood flow sensor (e.g., a perfusion sensor), a blood pressure sensor, a heart rate sensor, a blood oxygenation sensor, a negative pressure sensor, or a combination thereof. In some embodiments, a remote sensor is used, such as esophageal temperature sensor 45,

which communicates wirelessly with ECU 20 via communication circuit 42 (the wireless communication is shown schematically as 46 in Fig. 1). Of course other temperature sensors could be used. In some embodiments, “local” temperature sensors are used that are either on, or in close proximity to a glabrous area (e.g., on a palm, or forearm, on a foot or lower leg, etc.). Such local temperature sensors could be an alternative to an esophageal temperature sensor 45, for example. If a pump 38 is included for circulating fluid within one or more of the TTEs 24, the pump may be a peristaltic pump, a centrifugal pump, a hand pump, or any other kind of pump.

[0049] An optional warming blanket 19 is also shown in Fig. 1 on a torso area of the patient 12. The blanket 19 is not intended to achieve core body temperature adjustment, but rather is intended (if it is used at all) to give a pleasant warm sensation to a patient while that patient’s body is being warmed (e.g., after a general anesthesia if the patient is cognitive). The blanket 19 is controlled and powered by circuitry 21 that is separate from the ECU 20 and its related components, but may be similarly controlled (e.g., using a TTE 24 as discussed in the other embodiments). Although illustrated on a patient’s chest (anterior torso area), the blanket 19 could be used in other locations, such as on the patient’s back (posterior torso area). In one or more embodiments, the blanket 19 is part of a larger body sleeve (e.g., a sleeping bag type enclosure that has built-in heating features).

[0050] Figs. 11-12 schematically depict a pumping configuration 46 for circulating fluid through the TTEs 24 in embodiments in which the TTEs 24 comprise conduits, with Fig. 11 depicting the configuration 46 in its system context, and Fig. 12 depicting the configuration 46 in an enlarged view. Referring to Fig. 12, the configuration includes a pump 38, supply manifold 50, a return manifold / reservoir 52, thermostat 54, bypass 56, and restriction 58. Optionally, these components may be situated within a housing 47. Although Fig. 11 shows the housing 47 situated on a torso area of the patient 12, it is understood that the housing 47 could be situated away from the patient 12, and that warming blanket 19 could instead be situated on the torso area of the patient 12 (e.g., as shown in Fig. 1).

[0051] In the configuration 46, fluid circulates through the pump 38 and through the bypass 56. ECU 20 is operatively connected to the pump 38 to control operation of the pump 38. In one or more embodiments, the thermostat 54 comprises a wax thermostatic

element configured to selectively shutoff a flow of fluid to the supply manifold 50 based on a temperature (e.g., a temperature of the fluid being pumped and/or a patient temperature). In this regard, the thermostat 54 can be configured to act as a valve. The bypass 56 may be utilized, in some embodiments, to ensure that the pump 38 does not deadhead or cavitate when the valve of thermostat 54 is shut.

[0052] Of course, a single pump 38 does not have to be used for multiple TTEs 24 as shown in Fig. 11. Instead, individual pumps 38 could be used, and those pumps could optionally be situated in closer proximity to the glabrous areas being heated and/or cooled (e.g., on a forearm and/or on a leg). As an example, Fig. 13 depicts a pumping configuration 46' that is the same as configuration 46, but includes less supply and return lines because pumping is only being performed for a single TTE 24.

[0053] Fig. 14 illustrates an arrangement for pumping fluid to heat and/or cool a patient's hand, in which TTE 24 is a first conduit having a fluid inlet at connector 26A, and a fluid outlet at connector 26B (of course these roles could be reversed, so connector 26A has a fluid outlet and connector 26B has a fluid inlet). A second conduit 60 connects to the fluid inlet and fluid outlet of the first conduit (TTE 24) to form a circulation loop 61. The second conduit 60 is secured to a forearm sleeve 68 (e.g., secured on or within the forearm sleeve 68). A pump 38 is configured to circulate fluid in the circulation loop 61. A thermal element 33 is configured to adjust a temperature of a fluid in the circulation loop 61, and ECU 20 is configured to control the pump 38 and is configured to control a temperature of the thermal element 33. In one or more embodiments, the thermal element 33 and ECU 20 are located within housing 64. ECU 20 may be situated within the housing 64 (as shown in Fig. 14), or may be situated outside of the housing 64.

[0054] As shown in Fig. 14, a majority of the circulation loop 61 has a generally uniform radius and circumference, but the circulation loop 61 also includes an enlarged portion 66 sized to be a fluid reservoir in the circulation loop 61. Use of a reservoir (e.g., a bladder) can be helpful in maintaining a consistent pressure in the circulation loop 61, for example. In one or more embodiments, the forearm sleeve 68 and glove 22 are detachable (e.g., along dotted line 70). In some such embodiments, the glove 22 may be a disposable piece, while the forearm sleeve 68 is reusable. Of course, it is also possible that the forearm sleeve 68 and glove 22 may be permanently secured to each other and be non-detachable.

Fig. 15 illustrates an example peristaltic fluid pump 38' that could be used in the embodiment of Fig. 14.

[0055] Fig. 16 illustrates another example arrangement for pumping fluid to heat or cool a patient's hand. Here too, TTE 24 is a first conduit having a fluid inlet at connector 26A, and a fluid outlet at connector 26B (of course these roles could be reversed, so connector 26A has a fluid outlet and connector 26B has a fluid inlet). Also, forearm sleeve 68 includes a second conduit 60 that connects to the first conduit to form circulation loop 61. A reservoir 66 and fluid pump 38 are also included.

[0056] In Fig. 16, a thermoelectric device (TED) 72 acts as the thermal element 33. The TED 72 is configured to heat or cool fluid in circulation loop 61. The TED 72 may be a Peltier device, for example. The TED 72 includes thermally conductive sleeves 74, each of which surrounds a portion of the second conduit 60, to provide a heating and/or cooling effect to the surrounded portions of the second conduit 60. In one or more embodiments, the TED 72 is a Peltier device having opposing first and second faces 73A-B (see Fig. 17), and is configured, when a voltage is applied to the Peltier device, to provide heating to the first face 73A and to provide cooling to the second face 73B (or vice versa). In one or more embodiments, the thermally conductive sleeves 74 are part of the first or second face of the Peltier device. The ECU 20 and power supply 34 may be situated within housing 75, for example.

[0057] Figs. 17-18 illustrate example TED configurations that utilize a fan or blower (generically referred to as 40 herein). In each of these figures, a heat exchanger 76 (e.g., a heat sink) is mounted to one of the first or second faces 73A-B, and comprises fins 80 that define a plurality of channels 81 in the heat exchanger 76. In Fig. 17, a fan 40 is situated on top of the heat exchanger 76 for either drawing air into the air channels 81 from opposing ends of the channels 81, or for forcing air from above the heat exchanger 76 out of the opposing ends of the channels 81. An axis of rotation A1 of the fan 40 extends through the TED 72 in Fig. 17. In Fig. 18, a blower 40 is used to blow air into the air channels formed by the fins 80. An axis of rotation A2 of the blower 40 is offset from the TED 72 and does not extend through the TED 72 in Fig. 18.

[0058] Figs. 19-31 schematically illustrate embodiments in which a glove 22 may be used that includes a flap 90 for securing a thermal housing 92 to a patient's palm (although

the flap 90 is not shown in every one of these figures). Reference numeral 92 is generically used herein to refer to a thermal housing that is situated against a glabrous area. Referring first to Fig. 19, the thermal housing 92 encloses TTE 24 within a temperature distribution medium 93. In one or more embodiments, the temperature distribution medium 93 comprises a fluid (e.g., gas, water, a gel, or a slurry). In one or more embodiments, a spacing material is situated within the thermal housing 92, and the temperature distribution medium 93 flows through the spacing material. Some example spacing materials may include a mesh with air pockets (e.g., a three-dimensional spacer fabric from Müller Textil) or any other reticulated fabric or foam, a hard or inflatable skeletal structure, air struts, and/or elliptical rings. The spacing material, which will be discussed in more detail below, provides spacing between an item (e.g., a face of thermal housing 92) and a glabrous skin area. In some embodiments, the temperature distribution medium 93 includes a solid plate (e.g., a foil or plate).

[0059] A second housing 94 encloses ECU 20 and a power supply 34. The ECU 20 is configured to control a temperature of the TTE 24 situated in a palm area of the glove 22. In the example of Fig. 19, the second housing 94 is mounted to a top face of the thermal housing 92. The glove 22 includes a strap 90 for securing the glove 22 (e.g., using a snap, or a hook and loop fastener, or some other fastener). The thermal housing 92 and second housing 94 form an assembly 96 that may be removably secured to a glabrous palm area through an opening 95 (see Fig. 20). This could be useful to facilitate sanitization or disposal of the glove 22 and/or to facilitate charging of the power supply 34 in the second housing 94. Flap 90 can be closed over the assembly 96 and fastened using its own straps 25, to place the assembly 96 directly against the glabrous palm area of the glove 22 through the opening 95. Alternatively, in place of the opening 95 a fabric membrane may be used that is situated between the thermal housing 92 and the glabrous palm area. An adhesive layer may be used on a bottom side of the thermal housing 92 that is opposite to the second housing 94 to further secure the assembly 96 to the glove 22 or patient's palm. Fig. 20 schematically illustrates the assembly 96 when separated from the glove 22.

[0060] Fig. 21 schematically illustrates how a sensor 44 may be utilized in conjunction with the embodiment of Fig. 19-20. In Fig. 21, the thermal housing 92 includes an opening 97 that the sensor 44 can reside within when the thermal housing 92 is situated in the glove 22. If the sensor 44 is not directly connected to ECU 20 within the second housing

94, then sensor circuitry 98 may be used to obtain readings from the sensor 44, and communicate them to the ECU 20 (e.g., through wireless signal transmissions to communication circuit 42).

[0061] Fig. 22 illustrates another embodiment that uses an alternate thermal housing 92 with its sensor opening 97 in a different location. Here, ECU 20 could be mounted to the thermal housing 92, or could be separately mounted to the glove 22. The sensor 44 in this embodiment could be a heat flux sensor, for example. Although not shown, a flap 90 could be used for securing the thermal housing 92 against the glove 22.

[0062] Fig. 23 schematically illustrates other example features for heating and/or cooling a patient's palm. In particular, Fig. 23 illustrates another example path that the TTE 24 can follow within the thermal housing 92 (e.g., a spiral). Also, Fig. 23 illustrates how the ECU 20 and power supply 34 can be located in a wrist area, while the thermal housing 92 is located in a patient's palm. In Fig. 23 a sensor 44 (e.g., a temperature sensor) is situated in the palm area to measure a patient temperature. The ECU 20 may control the TTE 24 based on sensor data from the sensor 44. An elongated flap 90' may be used to secure the housings 92, 94 to the glove 22. Figs. 24-25 provide alternate views of the thermal housing 92 and/or second housing 94. Of course, although Fig. 25 illustrates TTE 24 being on top of thermal housing 92, it is understood that the TTE 24 may alternatively be situated within the thermal housing 92.

[0063] Figs. 26-27 schematically illustrate embodiments in which the temperature distribution medium 93 comprises a fluid, and a fluid pump 38 is configured to circulate the fluid, which may favorably achieve a more uniform temperature within the temperature distribution medium 93.

[0064] Fig. 27 schematically illustrates an adhesive layer 100 that may be situated on a bottom of the housing 92, for securing the thermal housing 92 to the glove 22 or to the patient's palm or to a portion of the glove 22 that is situated on the palm. An adhesive backing 102 may be peeled away to expose the adhesive layer 100.

[0065] Figs. 28-31 schematically illustrate examples of how negative pressure can be applied to a patient's palm to facilitate greater heat transfer with the palm. In Figs. 28-29, a seal ring 110 surrounds a perimeter of an opening 95 in the glove 22. A pump 38 is configured to apply negative pressure to an area between the flap 90 and a palm of a patient's

hand, such that the seal ring 110 abuts the palm of the patient's hand, and the negative pressure is applied to the palm from a palm-facing side of the thermal housing 92 (e.g., through openings 115 in the thermal housing 92). A negative pressure sensor (e.g., sensor 44) may optionally be used to monitor an amount of negative pressure being applied the hand.

[0066] In the example of Fig. 30, a spacing material 114 (e.g., a mesh with air pockets such as a reticulated fabric or foam) is situated within thermal housing 92 to space a top of the thermal housing 92 away from the palm of the hand 14 when negative pressure is applied. In some examples, the opening 95 facilitates direct skin contact from a thermal housing (e.g., a TTE 24 or a housing within which the TTE resides 24). In the example of Fig. 31, instead of using seal ring 110, an adhesive 116 is used along a perimeter of the housing 92 to provide a seal.

[0067] Figs. 32-33 schematically illustrate example embodiments in which a TED 72 and heat exchanger 76 similar to the ones shown in Fig. 17 are utilized, but instead of exchanging heat with a conduit that is on a forearm and that carries a fluid to a patient's palm, in these embodiments the TED 72 is situated on a patient's palm (via glove 22) and exchanges heat with the patient's palm without requiring use of a fluid conduit. A fan 40 is situated on the TED 72 and facilitates heat transfer by the TED 72. In one example, airflow is drawn upwards away from the TED 72. Of course, the opposite configuration could be used instead, in which airflow is drawn downwards onto the TED 72.

[0068] Fig. 34 schematically illustrates a method 200 of controlling the core body temperature of a patient. A TTE 24 is situated on glabrous area of the patient 12 (block 202). An example of this is shown in Fig. 1. At least one sensor is mounted near the patient (block 204). Heat from the TTE 24 is applied to the glabrous area to effectuate core temperature heating of the patient (block 206). An amount of heat applied to the glabrous area is controlled based on data received from the at least one sensor (block 208). A warming blanket is separately applied to a non-glabrous torso area of the patient 12 to enable patient thermal comfort, wherein the warming blanket is not controlled based on the data received from the at least one sensor (block 210). Although the method 200 has been described with a single TTE 24, it is understood that the method could be performed using a plurality of TTEs 24 that are each on different glabrous areas of a patient and are controlled based on the same or different sensors.

[0069] Figs. 35-45 illustrate a plurality of embodiments that include an impermeable flexible membrane that at least partially defines a negative pressure chamber, and also include a component (e.g., a rigid structure or spacing material) situated at least partially within the negative pressure chamber that is operable to space the collapsible appendage enclosure away from a patient's appendage when negative pressure is applied within the negative pressure chamber. The impermeable flexible membrane may be non-woven and/or made of plastic, for example.

[0070] Figs. 35-37 schematically illustrate a thermal housing 92 that includes an appendage covering 120 that provides a first chamber 126 filled with a temperature distribution medium (e.g., a heated or cooled fluid, such as a liquid or gel) that is circulated within the first chamber 126 to heat or cool a bodily area that is in contact with the appendage covering 120. Using the example of a fluid, the fluid is circulated within the first chamber 126 using an inlet 118A and an outlet 118B. Although shown in a certain order in Fig. 35, it is understood that this arrangement could be altered (e.g., such that the outlet 118B was situated on a left side and the inlet 118A on a right side). The appendage covering 120 includes a plurality of openings 128 that form passages 129 through the appendage covering 120. In one or more embodiments, the openings 128 are formed by radio-frequency (RF) welding or thermally bonding a first face 122 and a second face 124 of the appendage covering 120 along a perimeter of the openings 128.

[0071] Fig. 36 illustrates a thermal housing 92 that includes the appendage covering 120 as well as a spacing material 114, and a top layer 132. The top layer 132 acts as an impermeable flexible membrane. The spacing material 114 is situated between the top layer 132 and the first face 122 of the covering 120. The spacing material 114 at least partially prevents the top layer 132 from collapsing into the passages 129. The second face 124 of the covering 120 is situated and adapted to contact and engage a bodily area, such as a palm, and form a seal between the thermal housing 92 and the bodily area. The spacing material 114 may include a reticulated fabric or foam, for example. The top layer 132 is attached to the first face 122 along the edges of the first face 122 to at least partially enclose the spacing material 114. A fluid port 133 is configured to apply negative pressure within a second chamber 134 that includes the spacing material 114 and that extends through the plurality of passages 129 formed by openings 128. The fluid port 133 connects to a suction

device (e.g., pump 38 shown in Fig. 26) that provides negative pressure within the chamber 134. The chamber 134 is in fluid communication with a bodily area (e.g., a palm) which facilitates formation of a seal between the second face 124 and glabrous skin areas 148 beneath the openings 128, and application of negative pressure to those glabrous skin areas. Additionally, the chambers 126, 134 are isolated from each other by the first and second faces 122, 124 of the appendage covering 120.

[0072] In one or more embodiments, creation of the thermal housing 92 of Figs. 35-36 includes the following. A first sheet (corresponding to face 122) and a second sheet (corresponding to face 124) are sealed together along their outer perimeter (e.g., using RF welding) to form the chamber 126. The sheets are also RF welded or thermally bonded together at various locations to form the openings 128 and their associated passages 129 through the appendage covering 120, while still maintaining the chamber 126. The spacing material 114 is then situated against the face 122, and a sheet corresponding to the top layer 132 is situated on top of the spacing material 114 and is sealed to the first face 122 (e.g., using RF welding) to form the thermal housing 92 and the chamber 134, such that the chambers 126, 134 are isolated. The first and second sheets may be polyurethane sheets, for example.

[0073] Referring now to Fig. 37, the thermal housing 92 is situated on the palm of a hand 14, and a flap 90' may be used to secure the thermal housing 92 to the palm of the hand 14. The flap 90' includes straps 25 for securing the thermal housing 92 to a bodily area. In the example of Fig. 37, that bodily area is the palm of hand 14. The straps 25 may use a snap, hook and loop fastener, or some other fastener to secure the thermal housing 92 to the hand 14 (e.g., by connecting to a fastening portion of the glove 22 on the back side of the hand 14). Connectors 26A-B provide connections for inlet 118A and outlet 118B (e.g., as shown in Fig. 14). Connector 26C connects fluid port 133 to a pump 38 for providing negative pressure in the chamber 134 (see Fig. 36), and forming a seal between face 124 of the thermal housing 92 and the various glabrous skin areas 148 of the palm of hand 14 that are situated beneath the openings 128.

[0074] In addition to providing passages 129 for applying negative pressure to a body area, the openings 128 may be arranged to also provide obstructions in the chamber 126 to facilitate circulation of the temperature distribution medium within the chamber 126. The

spacing material 114 permits airflow within the chamber 134, while also at least partially defining the chamber 134 to include a space between the first face 122 and top layer 132. The pump 38 connected to connector 26C may be electrically actuated, or may be a hand pump, for example. Optionally, a pressure sensor may be utilized to prevent the pump 38 from applying too much negative pressure within the chamber 134. The pumping from the pump 38 may be continuous or intermittent, for example. The embodiments of Figs. 35-37 can be used to strike a desired balance between applying sufficient negative pressure to a bodily area (e.g., a palm of a hand) while also applying thermal transfer to a desired portion of the bodily area (e.g., the majority of the bodily area).

[0075] Figs. 38-39 illustrates an embodiment that includes an impermeable flexible membrane 140 that is collapsible against an appendage when negative pressure is within an enclosure formed by the membrane. Figs. 38-39 also omit the top layer 132 of Fig. 36. The impermeable flexible membrane 140 forms a negative pressure chamber 142 that is sized to accommodate a patient's appendage, which in the example of Figs. 38-39 is a hand 14 that includes a glabrous area 148. The impermeable flexible membrane 140 includes an opening 144 that is sized to receive the hand 14 within the negative pressure chamber 142. A seal 146 (e.g., a strap or rolled closure) is situated along the opening 144 and is operable seal against a limb from which the appendage extends to provide an air seal for the negative pressure chamber 142. In some embodiments, the seal 146 comprises an adhesive strip that is situated within the opening 144. In the example of Figs. 38-39, the impermeable flexible membrane 140 includes first and second connectors 26A-B that facilitate connections for inlet 118A and 118B. A third connector 26C is configured for connection to a pump 38 to apply a negative pressure within the negative pressure chamber 142.

[0076] The embodiment of Figs. 38-39 include a spacing material 114, while omitting the top layer 132 of Fig. 36. Instead of using the top layer 132 to define a negative pressure chamber, the impermeable flexible membrane 140 defines the negative pressure chamber 142 against the appendage 14. Once negative pressure is applied via connector 26C, the impermeable flexible membrane 140 may constrict to the hand 14 and to covering 120, but the spacing material 114 spaces the impermeable flexible membrane 140 away from glabrous area 148 when the negative pressure is applied. The spacing material 114 may include a reticulated fabric or reticulated foam, for example.

[0077] Figs. 40-43 schematically illustrate examples of an exoskeletal appendage enclosure 160 that can be used as a rigid layer and spacing material to space a impermeable flexible membrane 140 away from a patient's appendage. The exoskeletal appendage enclosure 160 includes a plurality of inflatable air struts 162 that are aligned along a longitudinal axis L1 and extend around the longitudinal axis L1. The air struts 162 are inflatable through a shared connector 26D. As shown in Fig. 40, a plurality of RF welds 164 cause seams to form along edges of the enclosure 160 between walls 166, 168. In the example of Figs. 41-42, wall 166B of the enclosure 160B has a more arched profile than the wall 166A of Fig. 40. In Fig. 42, wall 168B is substantially flat.

[0078] In the example of Fig. 42, a pocket 170 is defined between wall 168B and sheet 172 for insertion of thermal housing 92. In the example of Fig. 42, the sheet 172 is part of the impermeable flexible membrane 140, such that the pocket 170 and wall 168B are outside of the negative pressure chamber 142, but the wall 166B is within the negative pressure chamber 142. Of course, it is understood that in some embodiments the entire exoskeletal appendage enclosure 160 could be situated within the negative pressure chamber 142. A glabrous area 148 of appendage 14 faces towards the pocket 170.

[0079] Fig. 43 illustrates an example embodiment in which the exoskeletal appendage enclosure 160 is entirely situated within impermeable flexible membrane 140. A thermal housing 92 (not shown) is in fluid communication with connectors 26A-B for providing circulation within the thermal housing. Fluid port 133 is used to provide negative pressure within the negative pressure chamber 142 via connector 26D, including against a glabrous skin area (e.g., a palm 148 of hand 14). Once negative pressure is applied, the impermeable flexible membrane 140 may constrict to the hand 14, but the air inflatable passages 162 space the impermeable flexible membrane 140 away from glabrous area when the negative pressure is applied. Inflation of the air struts 162 may be performed through connector 26D.

[0080] Figs. 44A-E illustrate examples of another exoskeletal appendage enclosure 180A that may be used as a rigid layer in conjunction with the impermeable flexible membrane 140. In these examples, the exoskeletal appendage enclosure 180A is non-collapsible, and is entirely situated within the impermeable flexible membrane 140. The exoskeletal appendage enclosure 180A extends along a central longitudinal axis L2, and

includes first and second longitudinal walls 182A, 184A, which may be separable from each other along edges 186. In these examples, non-collapsible refers to the enclosure 180A being non-collapsible when assembled. The “non-collapsible” feature does not preclude disassembly of the enclosure 180A along seams 186.

[0081] The first wall 182A includes a central opening 188A, and the second wall 184A includes a plurality of openings 190, which in some embodiments are arranged in a honeycomb pattern (see Fig. 44B). The first wall 182A faces a glabrous area of on a first side of an appendage, and the second wall 184A faces an opposite, second side of the appendage.

[0082] In some examples, an adhesive 192 is situated along a perimeter of the central opening 188A to substantially prevent the impermeable flexible membrane 140 from collapsing through the central opening 188A.

[0083] The exoskeletal appendage enclosure 180A extends from a first end 194A to a second end 196A along the longitudinal axis L2. In some examples, one or more flaps 198A-B are situated at first end 194A. The flaps 198 extend inward in a direction generally perpendicular to the longitudinal axis L2, and retain the appendage within the exoskeletal appendage enclosure 180A after it is inserted into the exoskeletal appendage enclosure 180A. The flaps 198 may be secured to each other (as shown in Fig. 44E) or they may be separate, discrete flaps.

[0084] Fig. 45 schematically illustrates another example exoskeletal appendage enclosure 180B. The enclosure 180B includes first and second walls 182B, 184B that extend along central longitudinal axis L3 between ends 194B, 196B. The wall 182B includes a central opening 188B for providing access to a glabrous skin area, and may also include an adhesive 192 (not shown) along a perimeter of the central opening 188B. In the example of Fig. 45, wall 184B is provided by a plurality of discrete, spaced apart arches 199. The arches may be metal, plastic, or inflatable, for example. Although shown as terminating at the wall 182B in Fig. 45, in some examples the arches may be elliptical rings that extend through and/or around the wall 182B.

[0085] Although the exoskeletal appendage enclosures 160, 180 have been illustrated in conjunction with hands, it is understood that they could be used with feet, and could be adapted if needed to better accommodate the profile of a foot.

[0086] Situating the thermal housing 92 outside of the impermeable flexible membrane 140 could avoid the need for sterilizing a reusable thermal housing 92 between uses, because the impermeable flexible membrane 140 would serve as a barrier between the thermal housing 92 and a glabrous skin area, such that the thermal housing 92 would not directly contact the glabrous area.

[0087] The embodiments of Figs. 35-45 provide a number of benefits over the prior art. For example, the arrangements described in these embodiments can be made to be lighter and more portable than prior art devices, which included larger, helmet-like devices for forming a negative pressure chamber, instead of the impermeable flexible membrane 140 disclosed above. Also, as discussed above, use of the impermeable flexible membrane 140 can facilitate use of thermal elements that do not require sterilization. Still further, the embodiment of Figs. 36-37 localizes the application of negative pressure to one portion of an appendage, so that negative pressure does not have to be applied to the entire appendage.

[0088] The embodiments discussed herein, not only those of Figs. 35-45 but the other figures as well, provide a number of additional benefits as well. Many of the embodiments discussed above can be manufactured at a low cost, in some instances by using some components that are reusable (e.g., thermal housing 92 in Fig. 19) and some others that are either washable or disposable (e.g., glove 22 in Fig. 19).

[0089] Various embodiments discussed above can also provide adjustability to accommodate varying appendage sizes. As an example, the impermeable flexible membrane 140, while potentially large when an appendage is inserted, can shrink upon application of internal negative pressure to compress against a wide variety of appendage sizes. Likewise, if the seal 146 of Fig. 38 could accommodate a wide variety of wrist and/or ankle sizes. For example, if the seal 146 includes an adhesive strip, the strip could be configured to adhere against either a limb (e.g., wrist or ankle) or itself. As another example, if the seal 146 of Fig. 38 is a strap then that strap could be tightened as needed to snugly fit against a variety of wrist and/or ankle sizes. Strap 25 of Fig. 2 is similarly adjustable to accommodate varying limb sizes.

[0090] Fig. 46 is a flowchart of another example method 300 of controlling the core body temperature of a patient. The method 300 can be performed using the devices of Figs. 40-45, for example. An appendage of a patient is inserted into an appendage enclosure

160, 180, such that the appendage enclosure extends around the appendage, and spaces the appendage away from an impermeable flexible membrane (block 302). Negative pressure is applied within a negative pressure chamber defined by the impermeable flexible membrane 140, wherein the appendage is situated in the negative pressure chamber, and the appendage enclosure 160, 180 is at least partially situated in the negative pressure chamber (block 304). Heat is transferred between a thermal element (e.g., TTE 24 or thermal housing 92) and the glabrous area of the appendage during the application of negative pressure in block 304 (block 306).

[0091] Although negative pressure has been discussed primarily in connection with the embodiments of Figs. 28-31 and Figs. 35-45, it is understood that the application of negative pressure to glabrous skin areas could be added to other embodiments as well (e.g., that of Fig. 16-27) using the features described in connection with Figs. 28-31 and 35-45.

[0092] Also, although Figs. 35-45 are described as being separate from Figs. 28-31, it is understood that the features of Figs. 35-45 could be combined with the features from Figs. 28-31, or any other embodiment, in any combination. For example, the seal ring 110 feature of Fig. 29 could be combined with the features of Figs. 35-41. Also, instead of pumping a fluid within the first chamber 126 to achieve a heating or cooling effect, an electric heat source could be situated within the appendage covering 120 of Figs. 35-39 (e.g., such that the appendage covering 120 forms a housing for the electric heat source but omits the chamber 126). Any of the electric heat sources discussed above could be used. If the chamber 126 of Figs. 36 and 39 is omitted, then inlet 118A and outlet 118B may include electrical connections instead of fluid connections. In one or more embodiments, the thermal transfer element 24 of any one of Figs. 2-4, 7, and 14 is used within the covering 120, in addition to or instead of including the first chamber 126 and pumping a fluid within the first chamber 126.

[0093] Also, although connectors 26 are shown as exiting a garment and/or enclosure near wrists or ankles in some embodiments (e.g., Figs. 2-3) and exiting near fingers or toes in other embodiments (e.g., Figs. 38 and 43), it is understood that either would be possible in the embodiments discussed above. It is further understood that any of the embodiments above depicting hands are equally applicable to feet, and vice versa.

[0094] Also, although human patients have been depicted and discussed above, it is understood that the techniques disclosed herein could also be used to control the core body temperature of non-human mammals.

[0095] Additionally, although some specific types of sensors and pumps have been disclosed, it is understood that these are non-limiting examples.

[0096] Although example embodiments have been disclosed, a worker of ordinary skill in this art would recognize that certain modifications would come within the scope of the claims. For that reason, the following claims should be studied to determine their true scope and content.

CLAIMS

What is claimed is:

1. A core body temperature adjustment system comprising:
 - an impermeable flexible membrane that defines a negative pressure chamber for an appendage;
 - a thermal element that is situated against the impermeable flexible membrane; and
 - a rigid layer that extends around the appendage, and spaces the impermeable flexible membrane away from the appendage.
2. The core body temperature adjustment system of claim 1, wherein application of negative pressure within the negative pressure chamber draws the impermeable flexible membrane towards a glabrous skin area of the appendage.
3. The core body temperature adjustment system of claim 1, wherein the impermeable flexible membrane is situated between the thermal element and a glabrous area of the appendage.
4. The core body temperature adjustment system of claim 1, wherein the rigid layer comprises a first wall facing a first side of the appendage that includes the glabrous area, and a second wall facing an opposing, second side of the appendage, the first and second walls forming an enclosure around the appendage.
5. The core body temperature adjustment system of claim 4, wherein the rigid layer comprises a plurality of inflatable air struts that are aligned along and extend around a longitudinal axis of the enclosure.
6. The core body temperature adjustment system of claim 4, wherein the second wall is situated within the negative pressure chamber, and wherein the first wall is situated outside of the negative pressure chamber.
7. The core body temperature adjustment system of claim 4, wherein the first wall is substantially flat and the second wall is arched.

8. The core body temperature adjustment system of claim 7, wherein the second wall comprises a plurality of discrete, spaced apart arches.
9. The core body temperature adjustment system of claim 4, wherein the first and second walls are detachable from each other.
10. The core body temperature adjustment system of claim 4, wherein the enclosure is entirely within the negative pressure chamber.
11. The core body temperature adjustment system of claim 4, wherein the first wall includes a central opening, the core body temperature adjustment system comprising an adhesive that seals the impermeable flexible membrane to an outer surface of the first wall along a perimeter of the central opening.
12. The core body temperature adjustment system of claim 4, wherein the first wall includes a central opening, and wherein a portion of the impermeable flexible membrane that extends across the central opening along an outer surface of the first wall separates the thermal element from the glabrous area.
13. The core body temperature adjustment system of claim 4, wherein the first wall includes a first quantity of openings, and the second wall includes a greater, second quantity of openings.
14. The core body temperature adjustment system of claim 13, wherein the second wall comprises a plurality of openings arranged in a honeycomb pattern.

15. The core body temperature adjustment system of claim 4:
wherein the first and second walls extend along a longitudinal axis of the enclosure between opposing first and second ends of the enclosure; and
wherein the enclosure comprises one or more flaps at the first end that extend inward in a direction generally perpendicular to the longitudinal axis, the one or more flaps retaining the appendage within the enclosure after the appendage is inserted into the enclosure.

16. The core body temperature adjustment system of claim 1, wherein the thermal element comprises a housing that contains a temperature distribution medium, and the core body temperature adjustment system comprises a pump operable to provide circulation within the temperature distribution medium.

17. The core body temperature adjustment system of claim 1, wherein the impermeable flexible membrane is non-woven.

18. A core body temperature adjustment system comprising:
 - an impermeable flexible membrane that defines a negative pressure chamber for an appendage;
 - a thermal element that is situated against the impermeable flexible membrane and comprises opposing first and second faces, and a plurality of passages that extend between the first and second faces; and
 - a spacing layer that spaces the impermeable flexible membrane away from the appendage.
19. The core body temperature adjustment system of claim 18, wherein application of negative pressure within the negative pressure chamber compresses the thermal element against a glabrous skin area of the appendage.
20. The core body temperature adjustment system of claim 18, wherein the impermeable flexible membrane defines the negative pressure chamber against a single, first side of the appendage, such that digits of the appendage, and an opposite second side of the appendage are outside of the negative pressure chamber.
21. The core body temperature adjustment system of claim 18, wherein the impermeable flexible membrane encloses less than 50% of a surface area of a non-digital portion of the appendage within the negative pressure chamber.
22. The core body temperature adjustment system of claim 18, comprising a pump fluidly connected to an outlet of the impermeable flexible membrane and operable to apply negative pressure within the plurality of openings.
23. The core body temperature adjustment system of claim 18, wherein the spacing layer comprises a reticulated fabric or a reticulated foam.
24. The core body temperature adjustment system of claim 18, wherein the first and second faces are radio frequency welded or thermally bonded to each other along a perimeter of each of the plurality of passages.

25. A method of controlling the core body temperature of a patient, comprising:
inserting an appendage of a patient into an appendage enclosure, such that the appendage enclosure extends around the appendage, and spaces the appendage away from an impermeable flexible membrane;
applying negative pressure within a negative pressure chamber defined by the impermeable flexible membrane, wherein the appendage is situated in the negative pressure chamber, and the appendage enclosure is at least partially situated in the negative pressure chamber; and
transferring heat between a thermal element and the glabrous area of the appendage during the applying.
26. The method of claim 25, comprising sealing the impermeable flexible membrane against a limb from which the appendage extends to maintain the negative pressure.
27. The method of claim 25, comprising inflating the appendage enclosure to a rigid state, and performing the applying and transferring while the appendage enclosure in the rigid state.
28. The method of claim 25, comprising situating the thermal element against a glabrous area of the appendage and within the appendage enclosure, but outside of the negative pressure chamber.

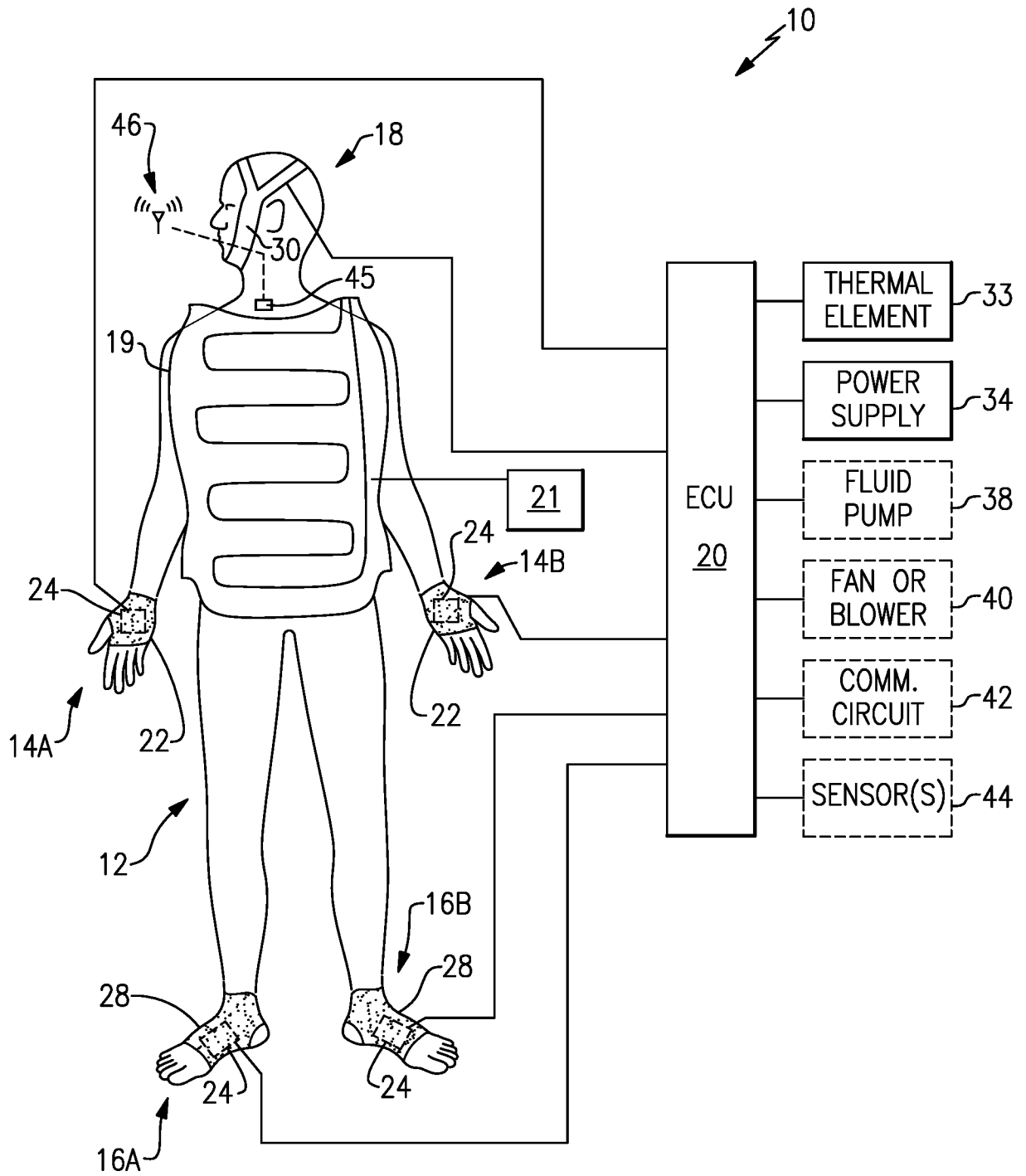
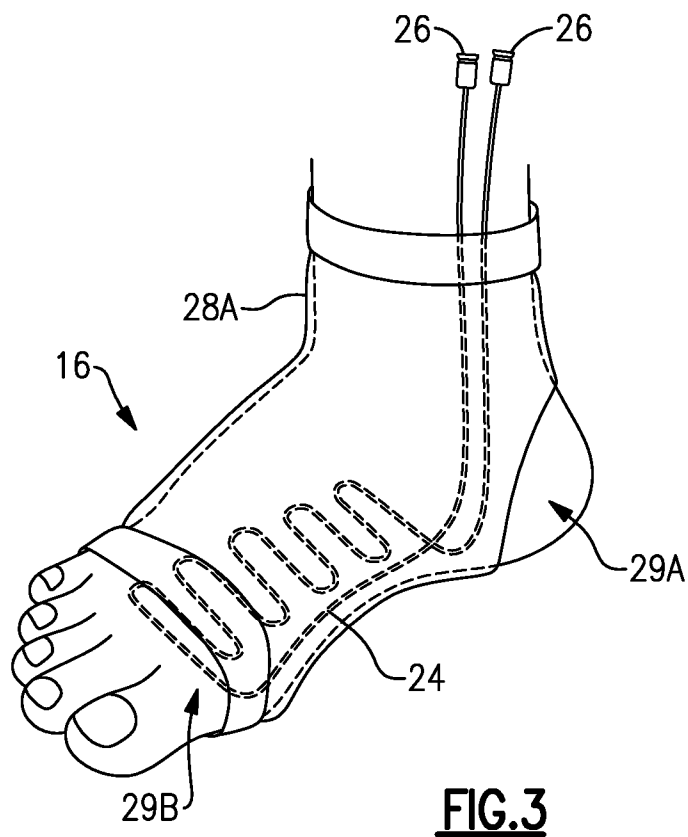
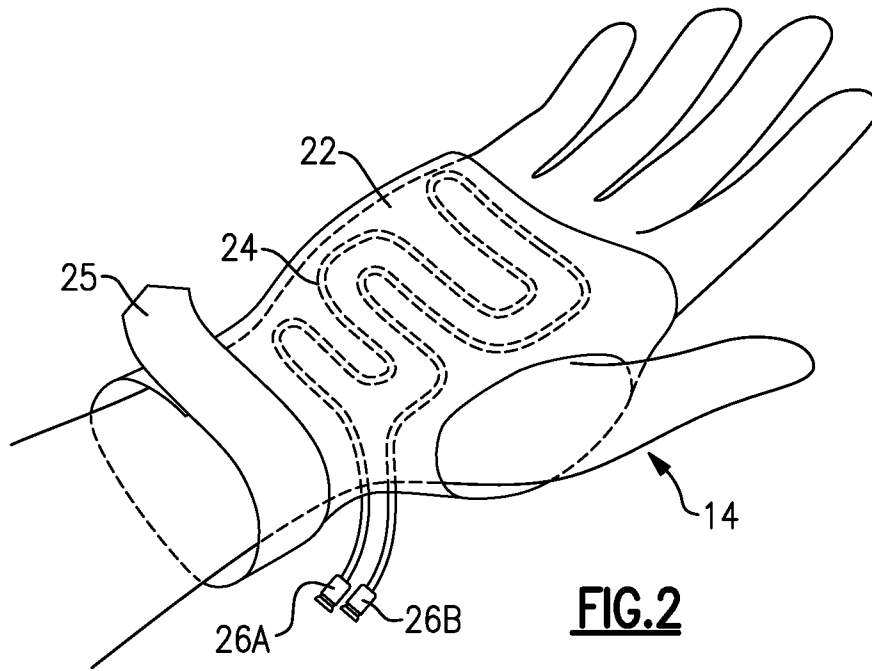


FIG.1



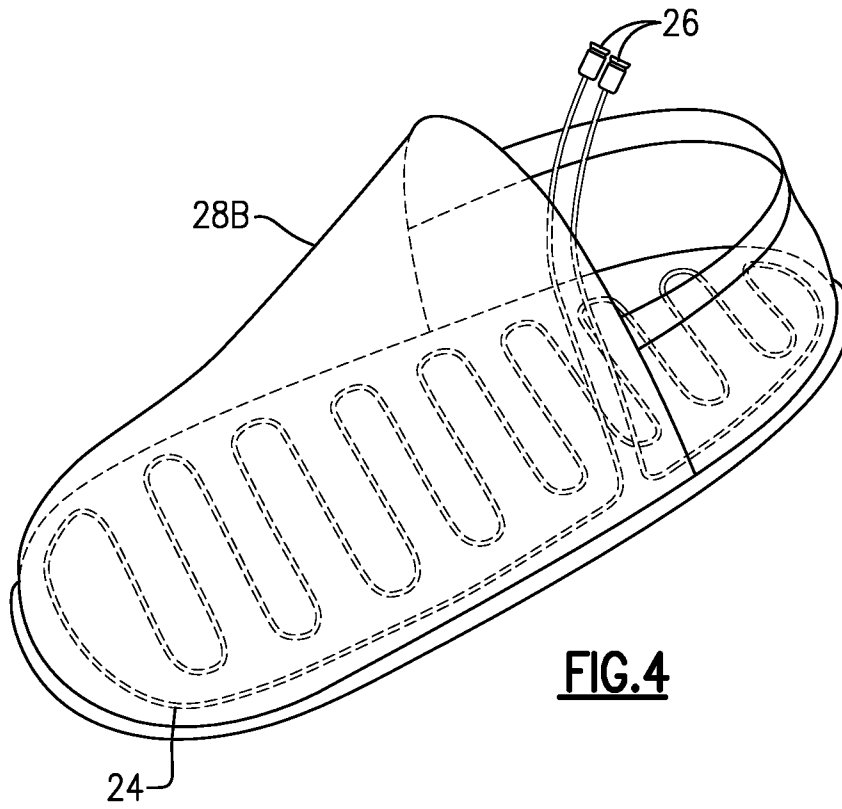


FIG. 4

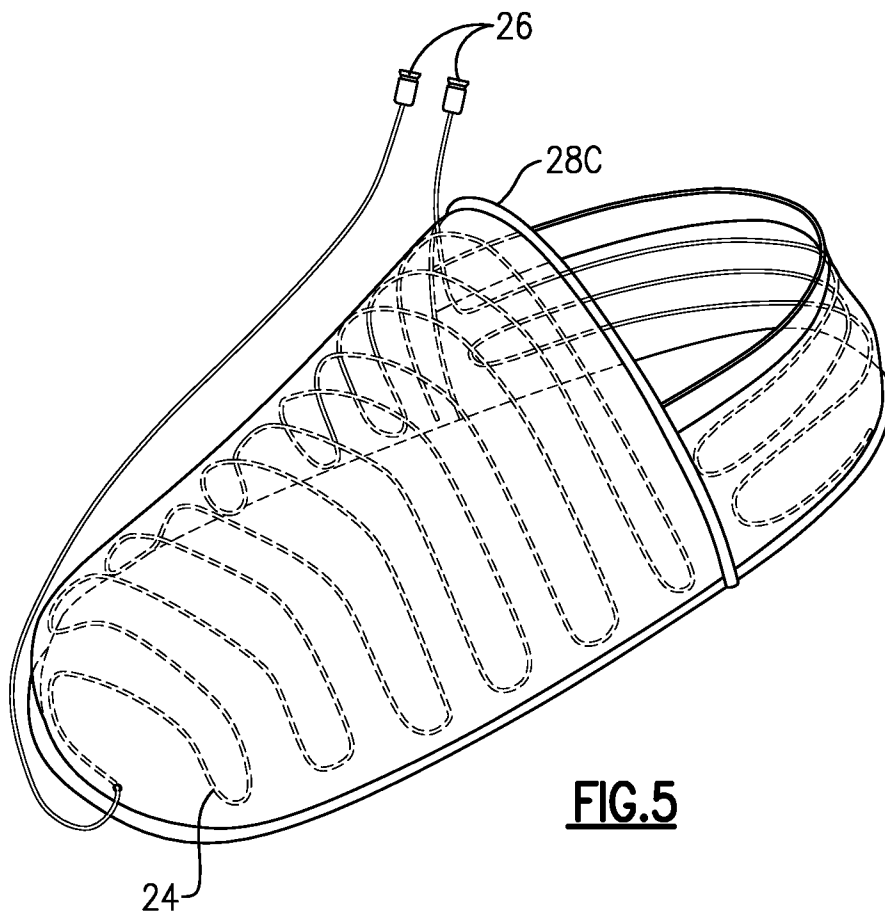


FIG. 5

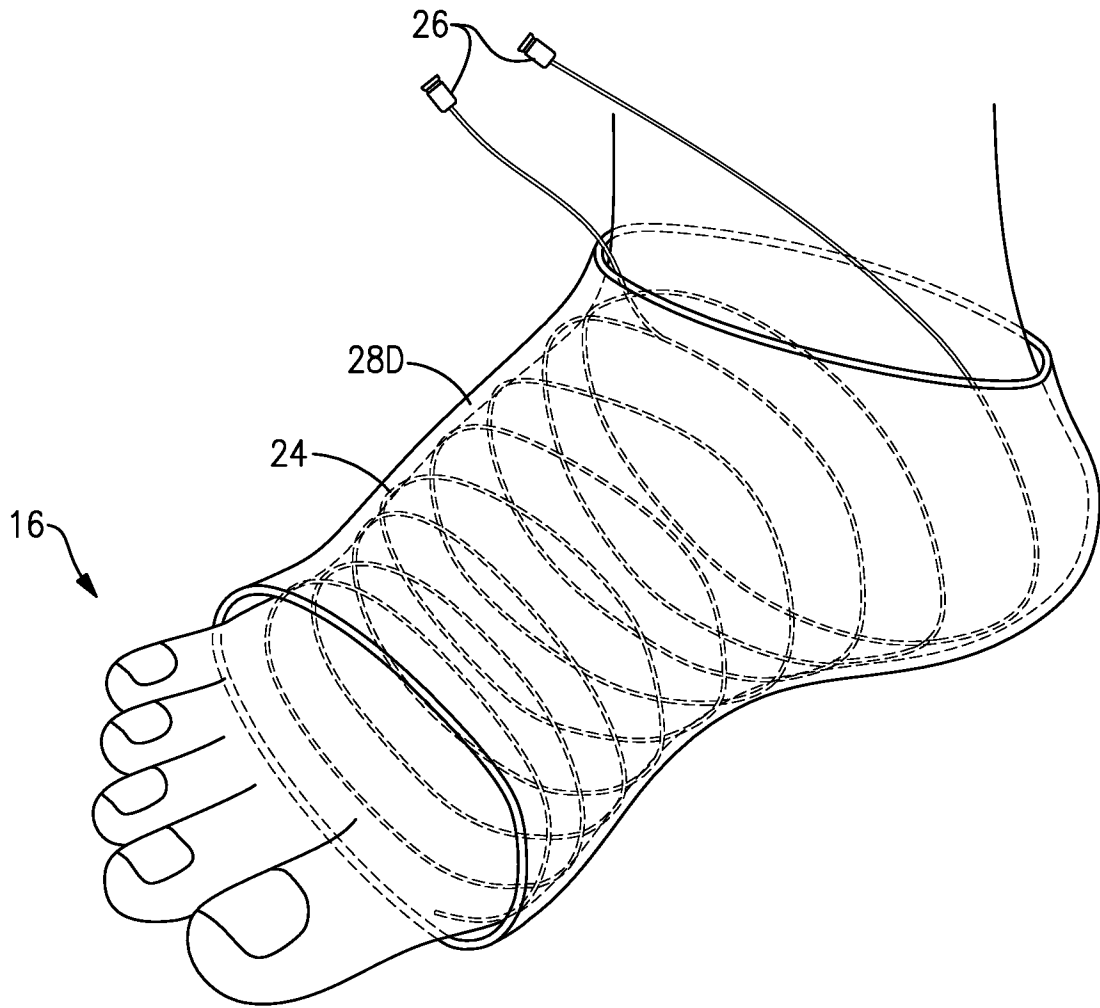


FIG.6

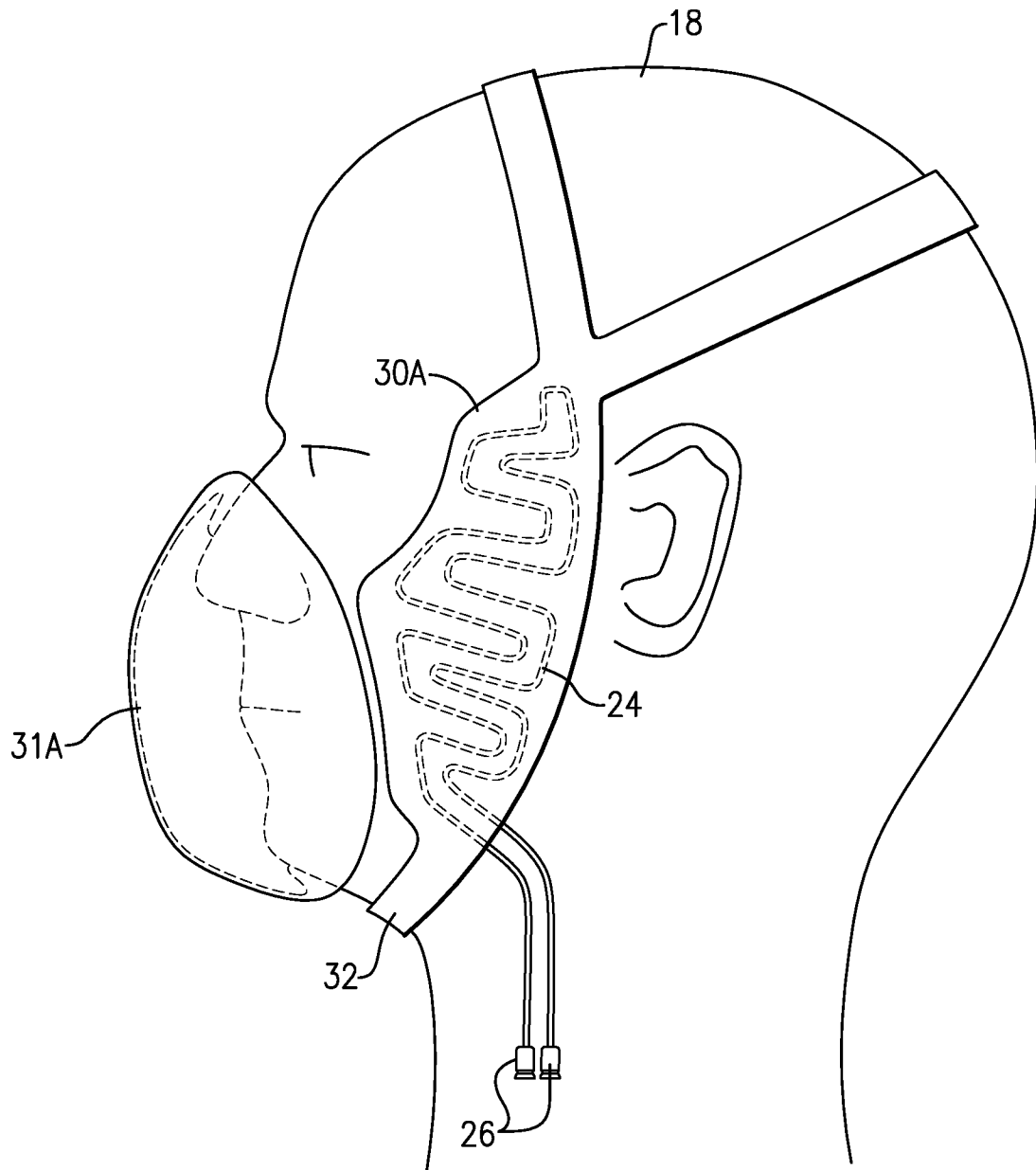


FIG.7

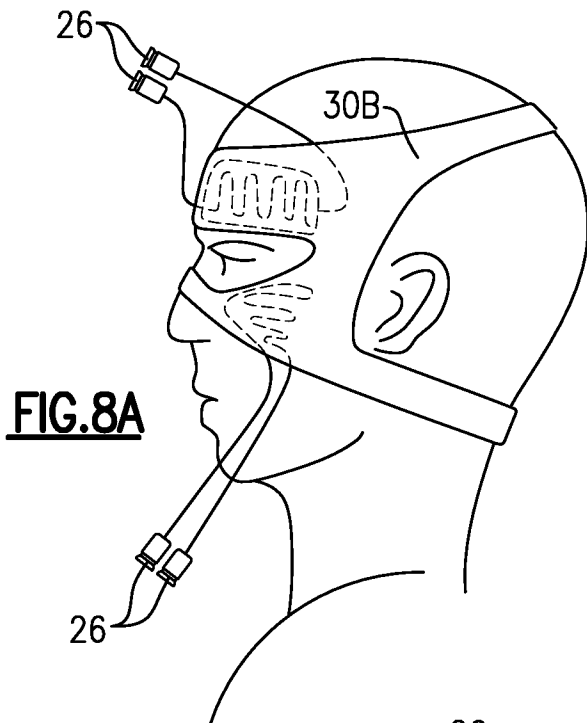


FIG. 8A

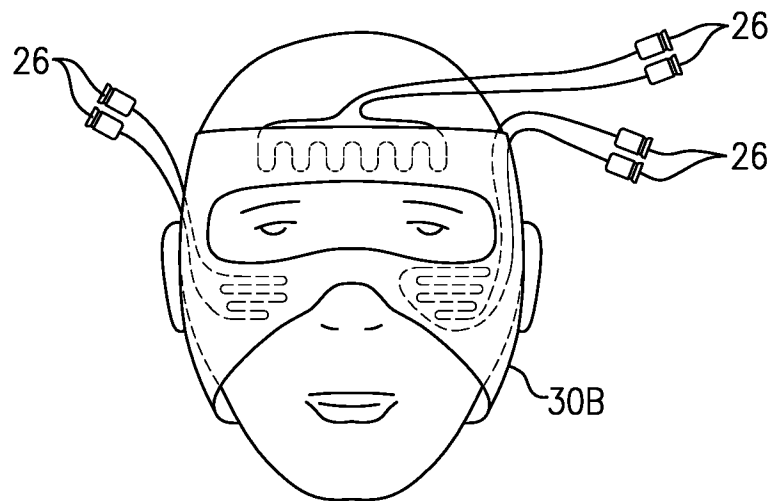


FIG. 8B

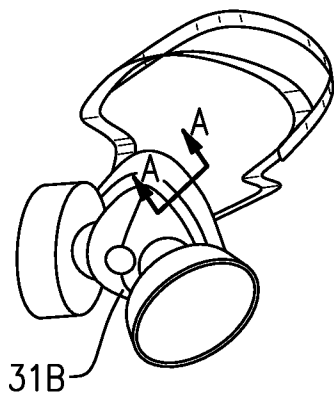


FIG. 9

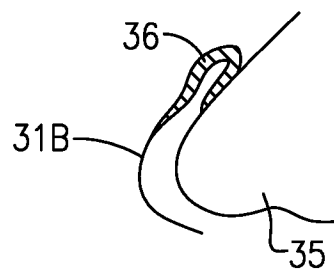


FIG. 10

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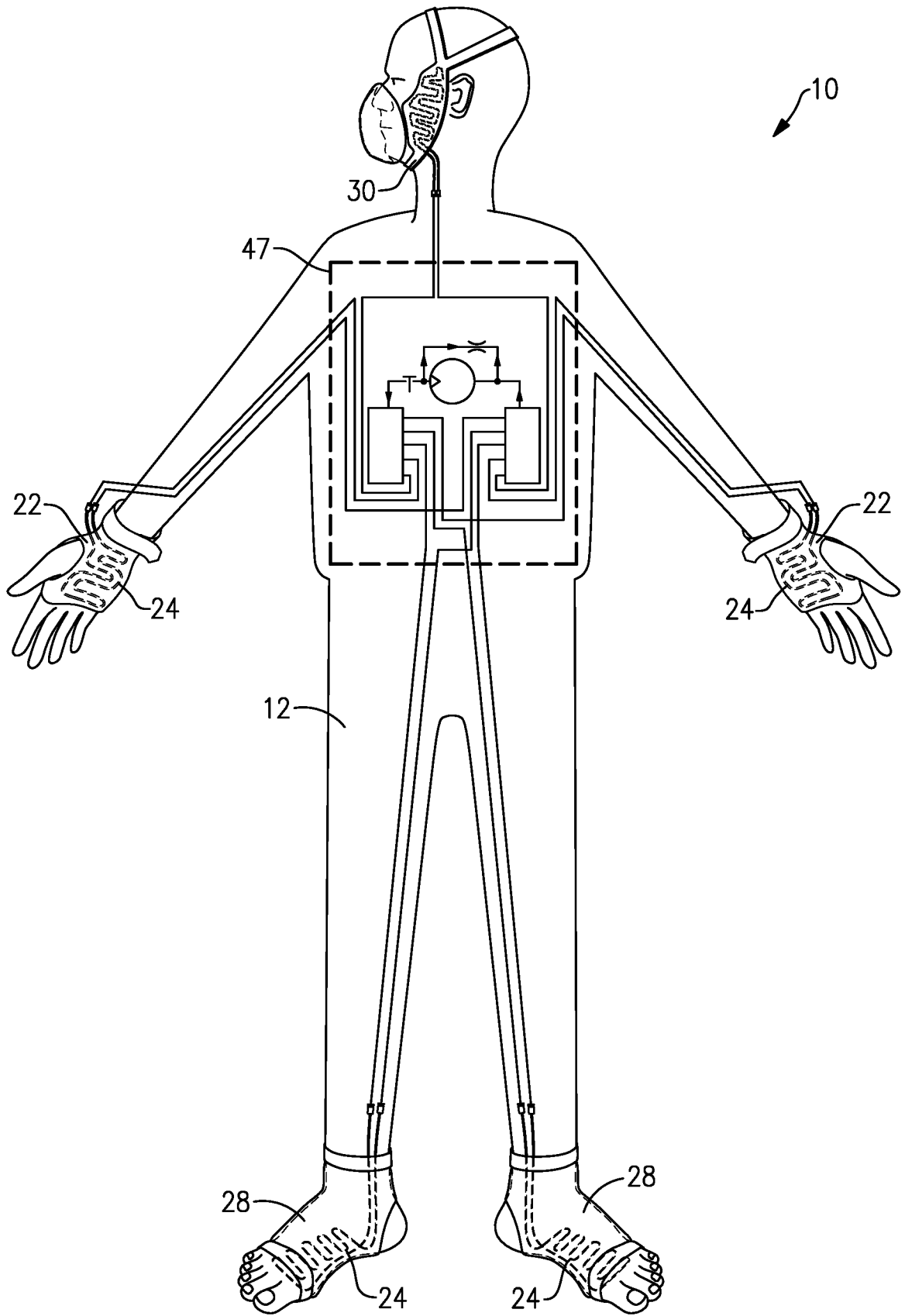


FIG.11

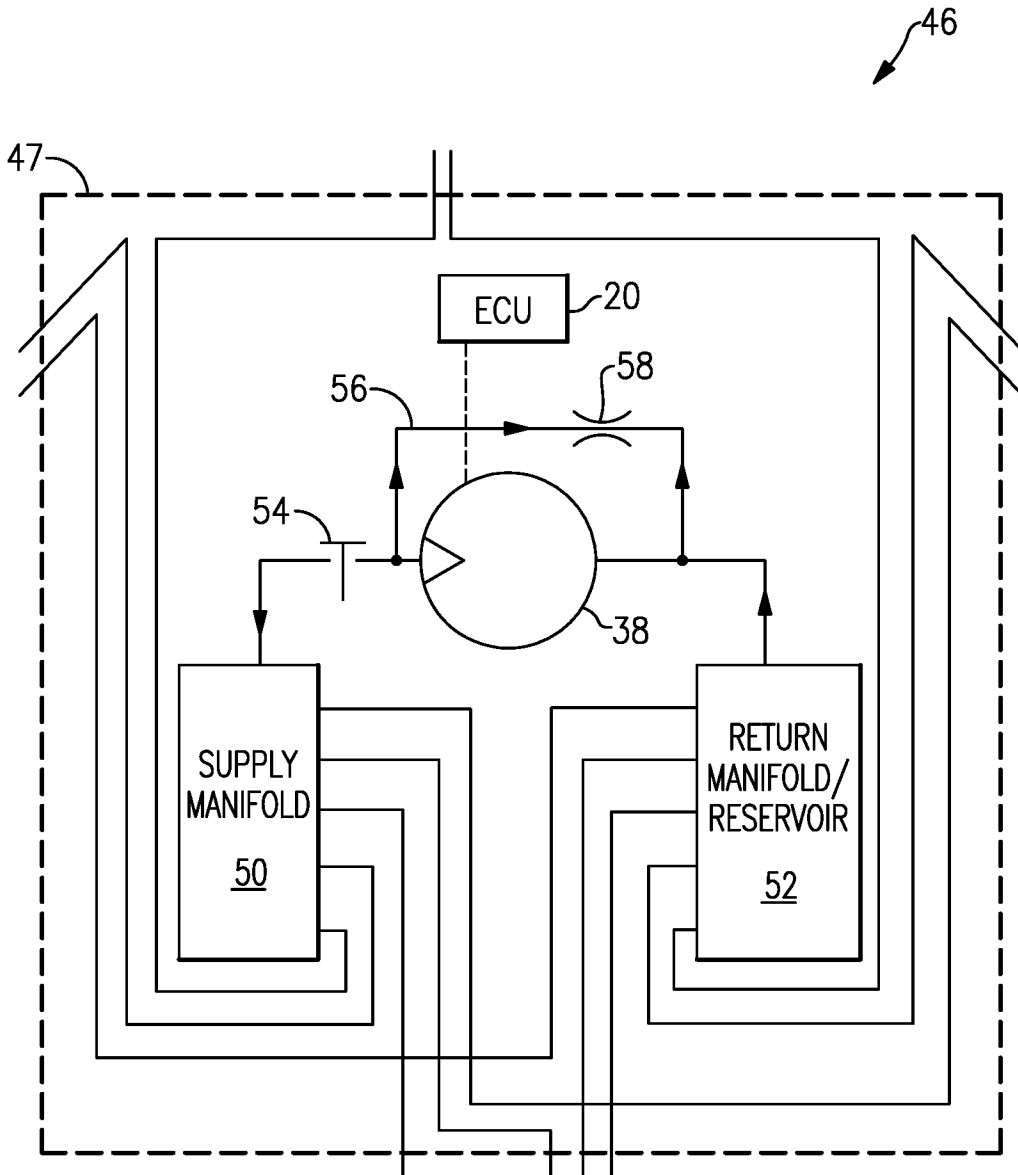


FIG.12

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46'

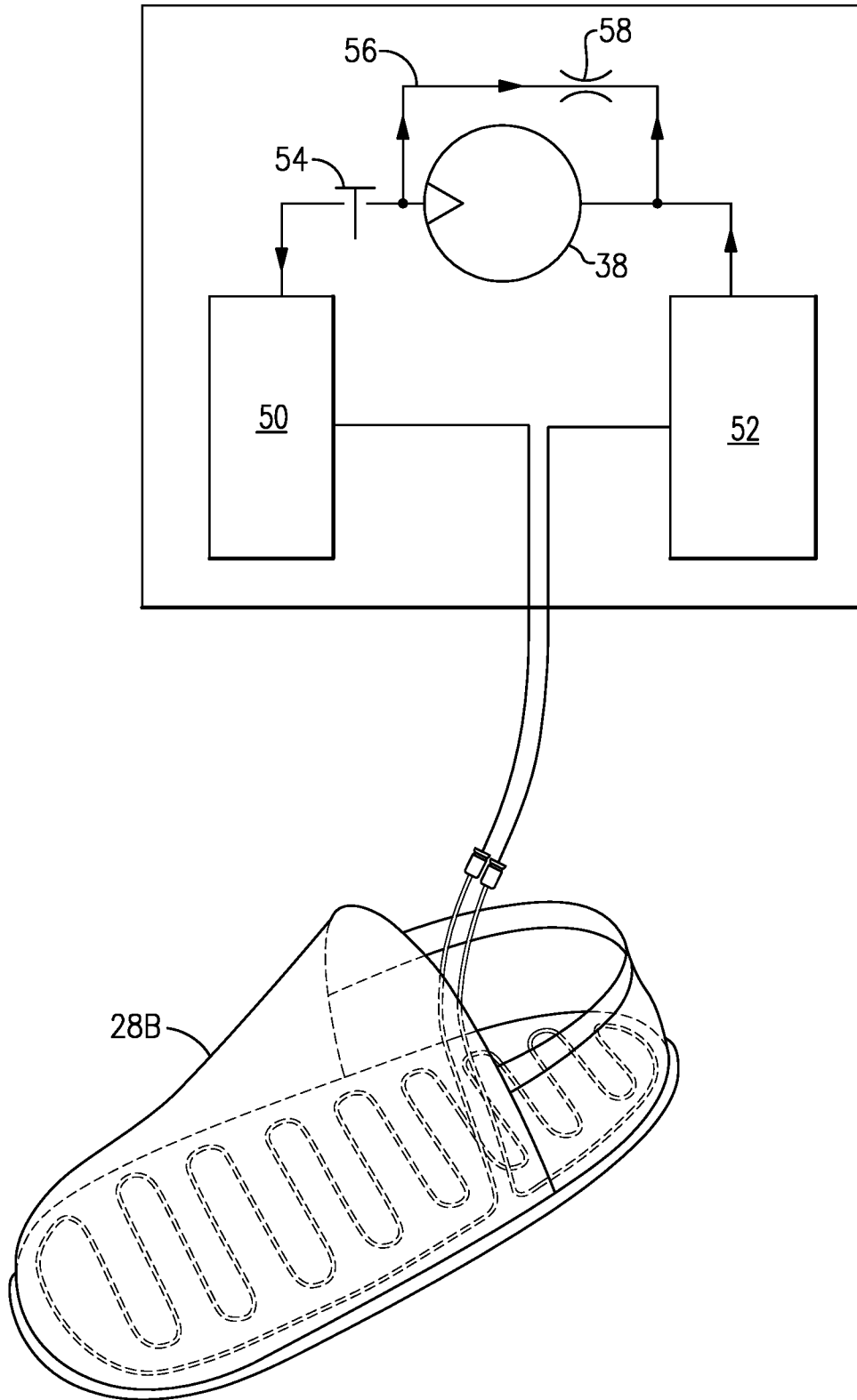
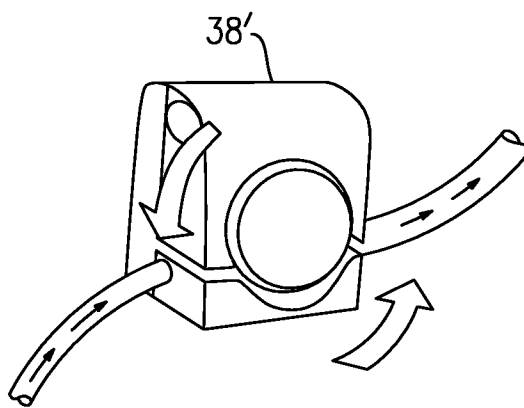
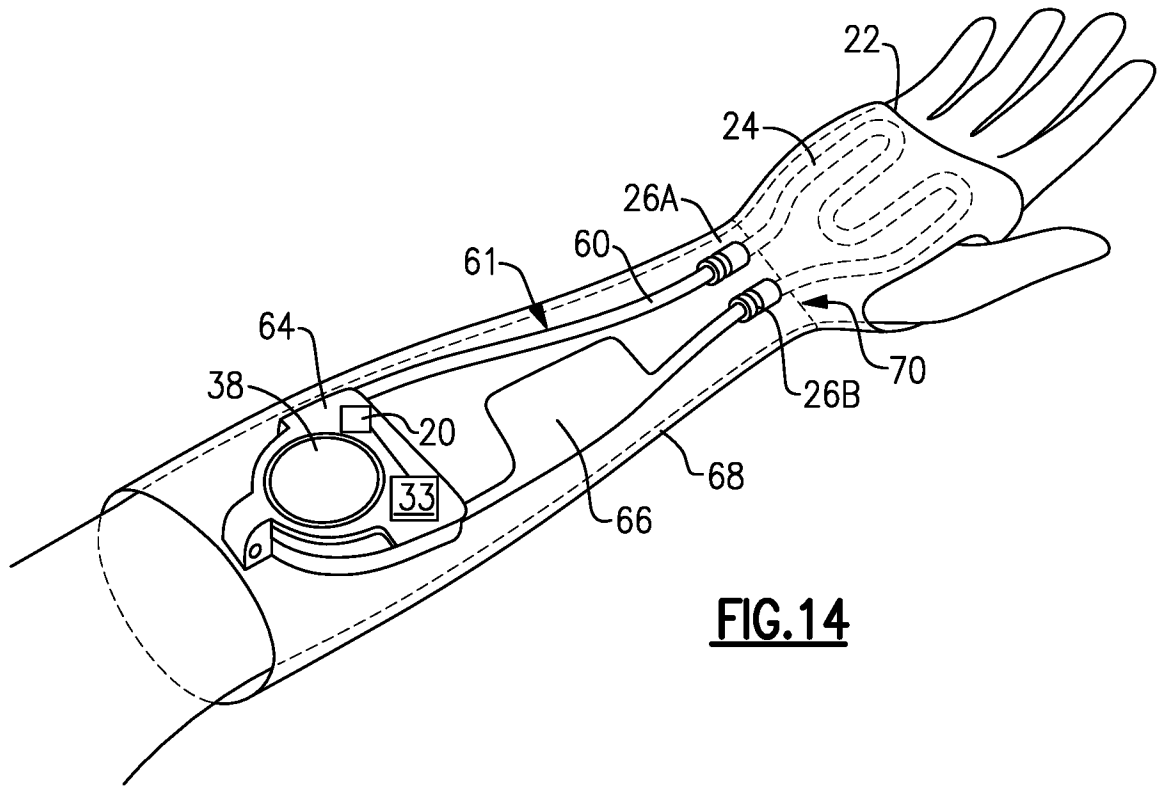


FIG. 13



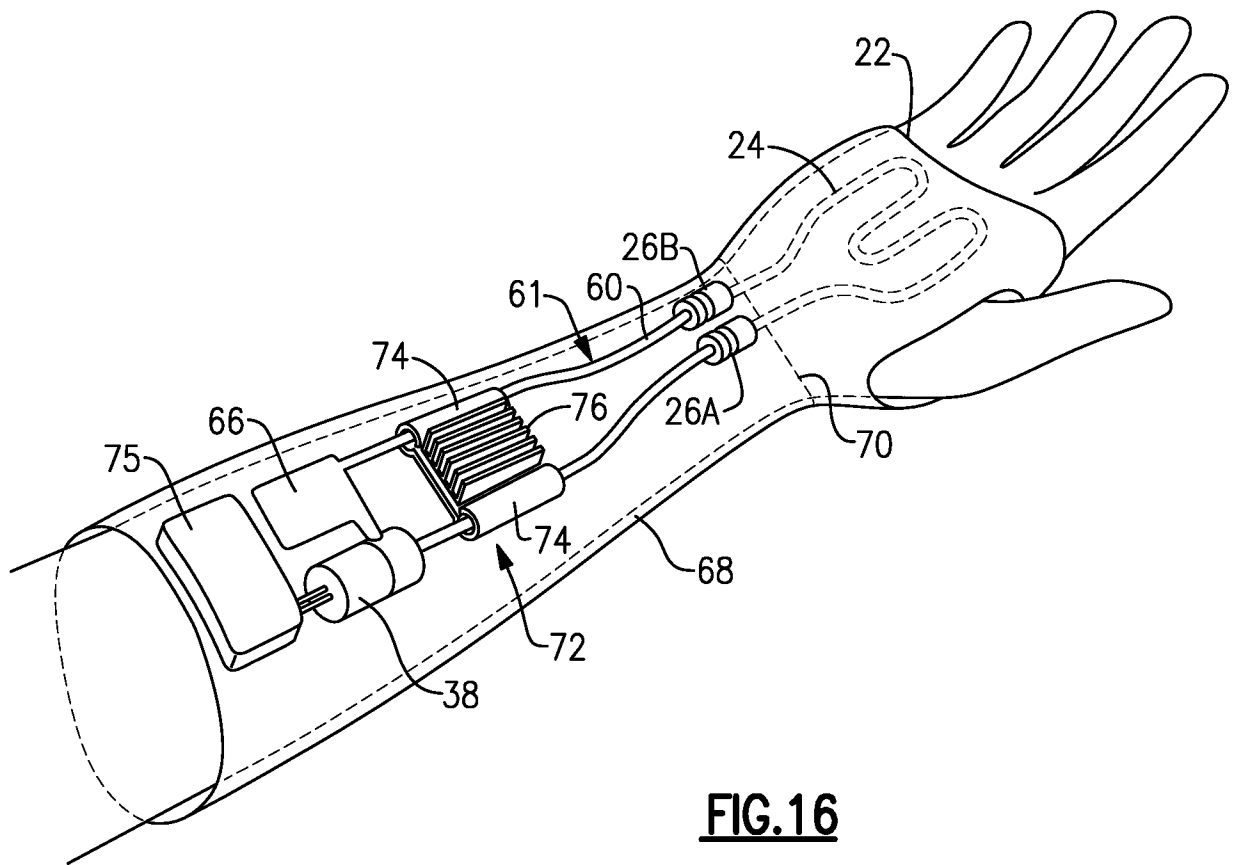


FIG. 16

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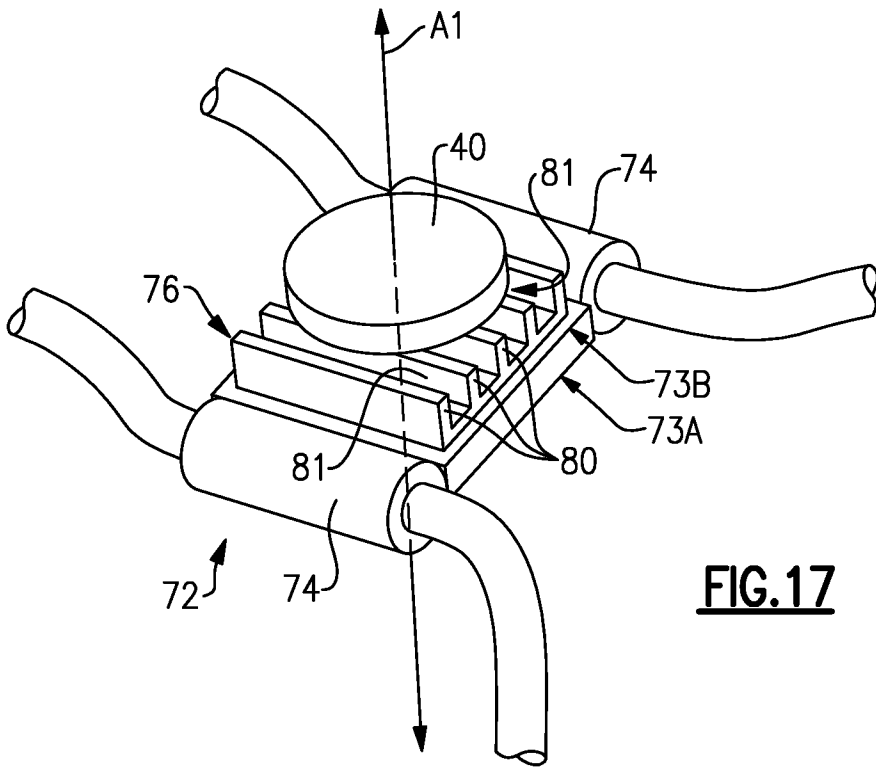


FIG.17

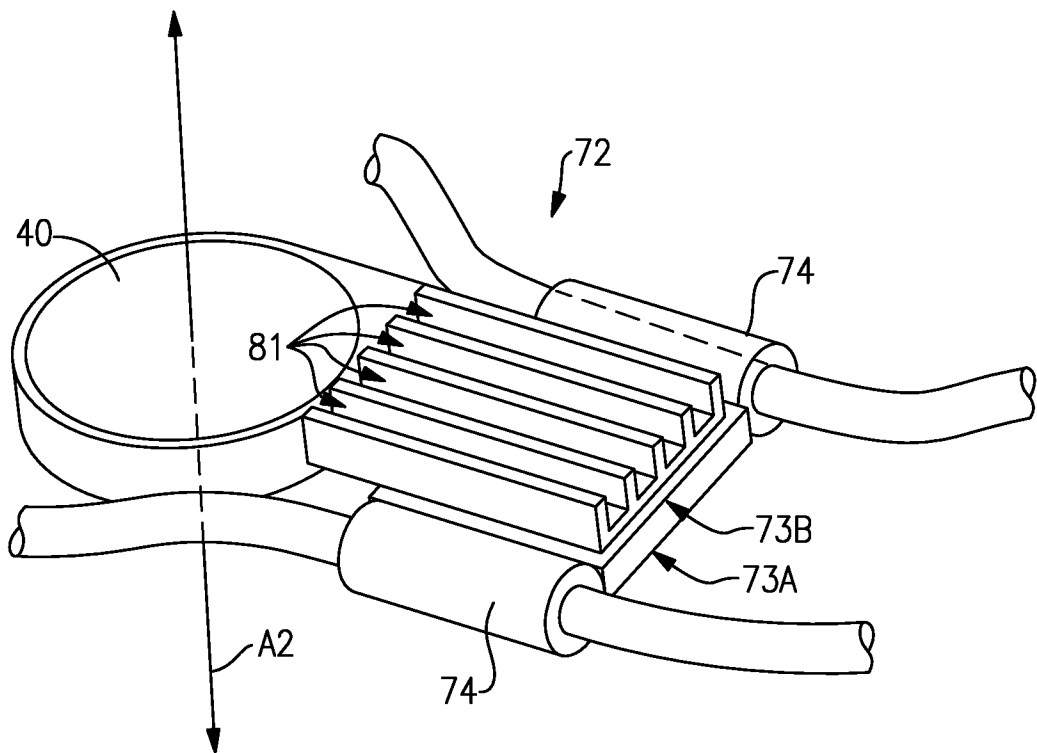
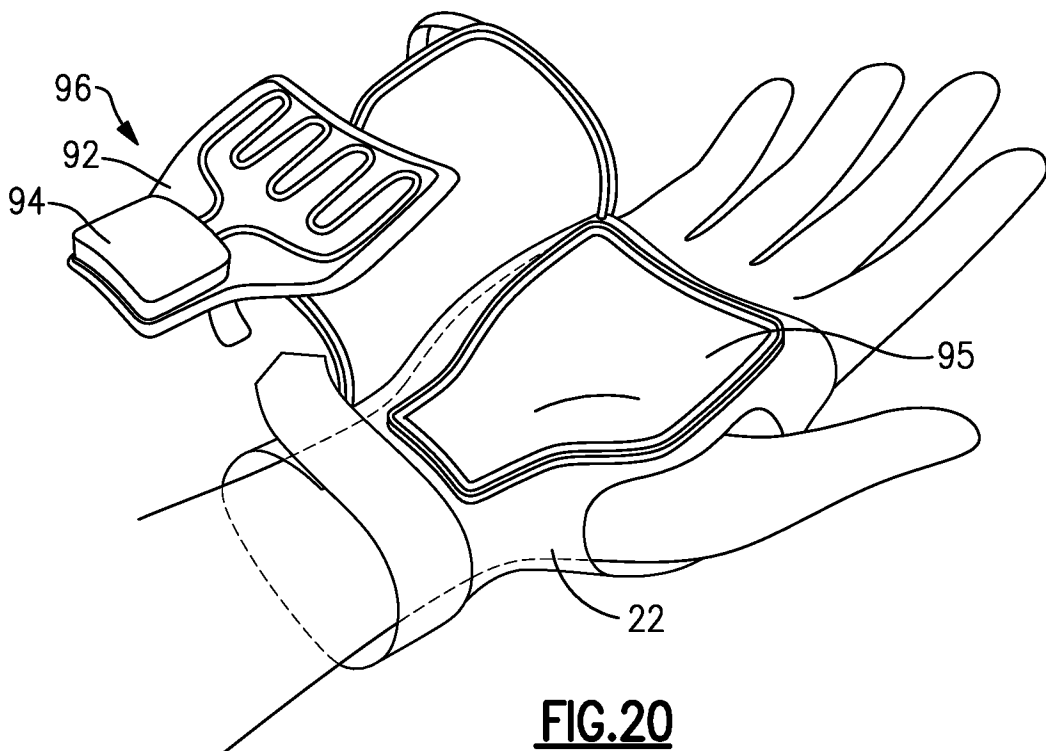
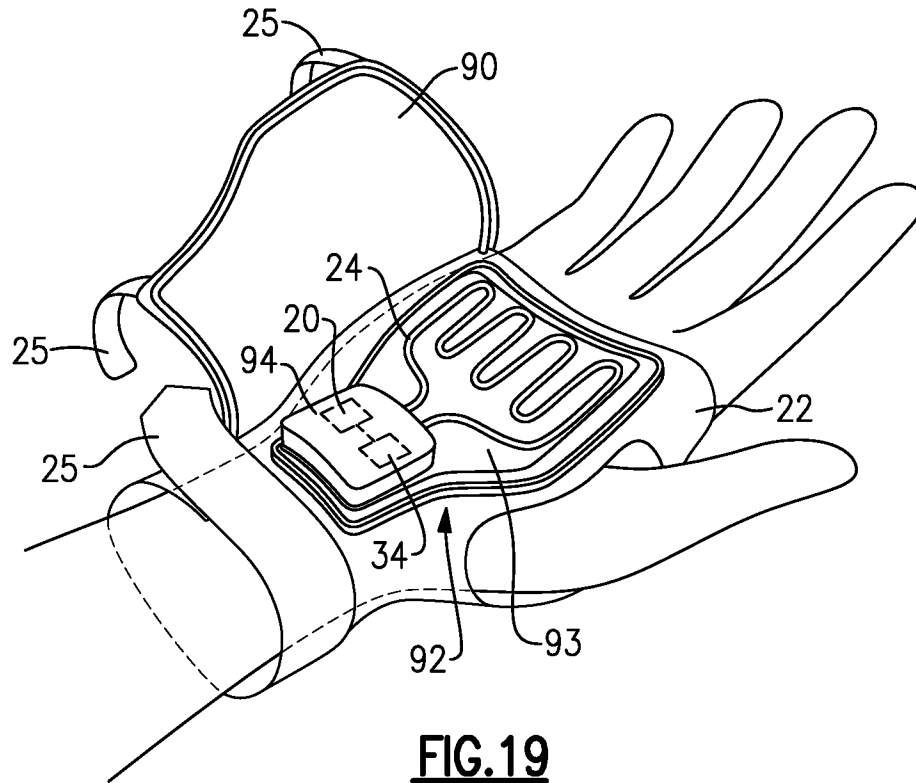
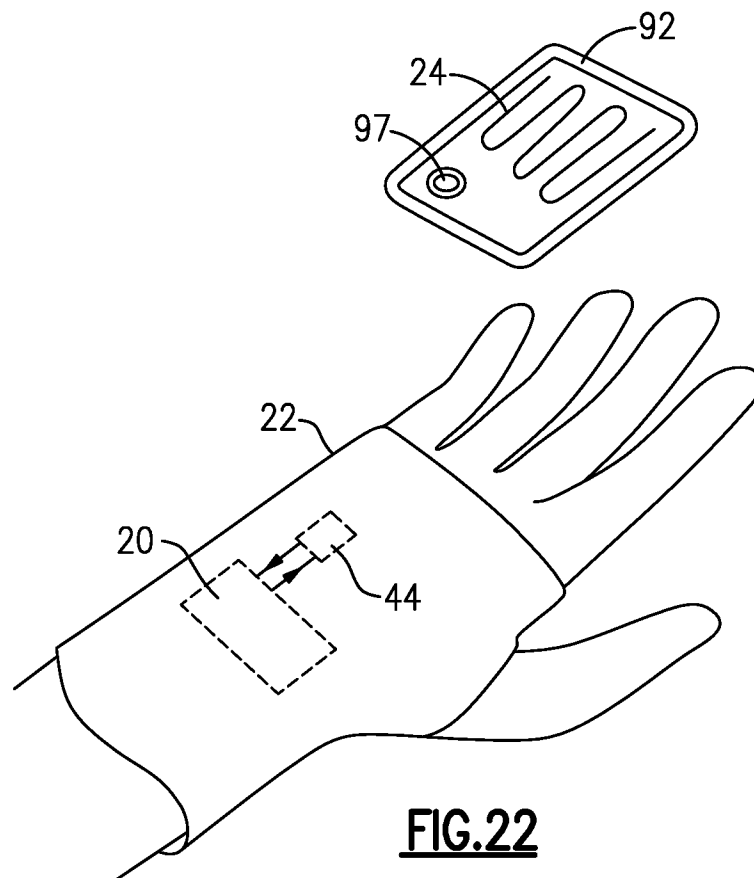
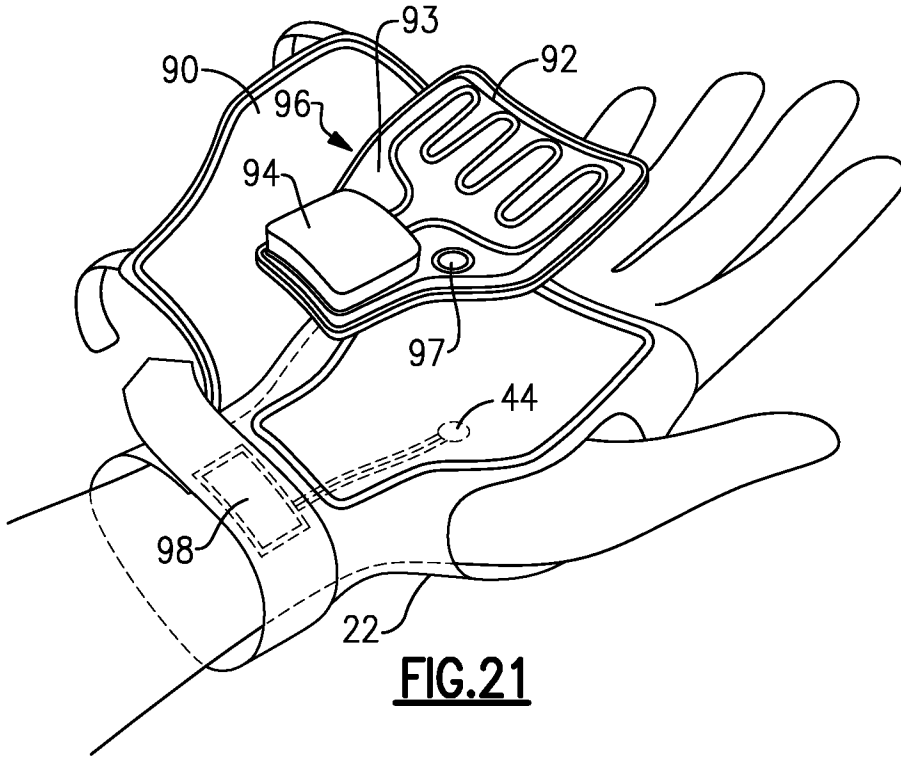
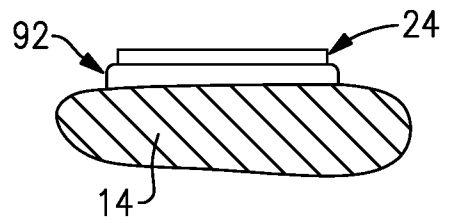
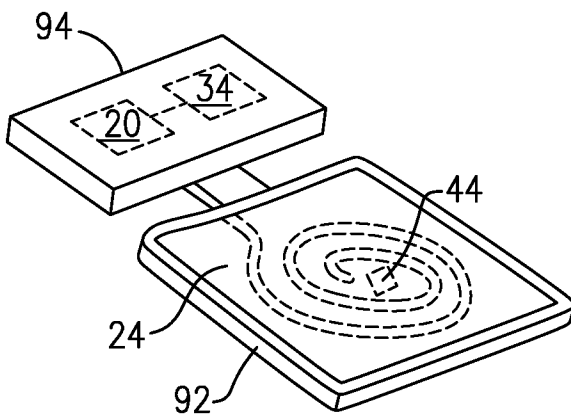
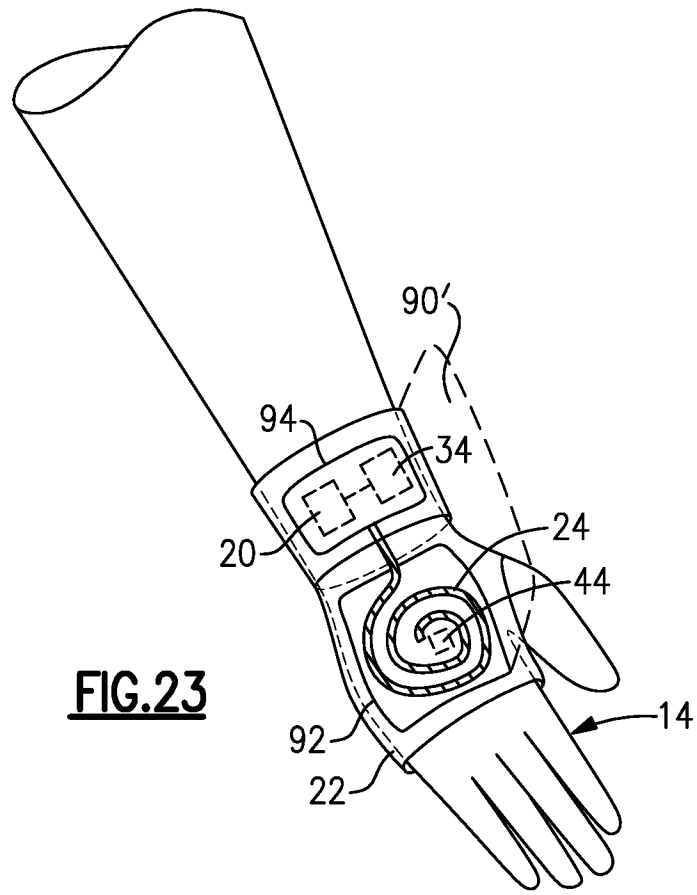


FIG.18







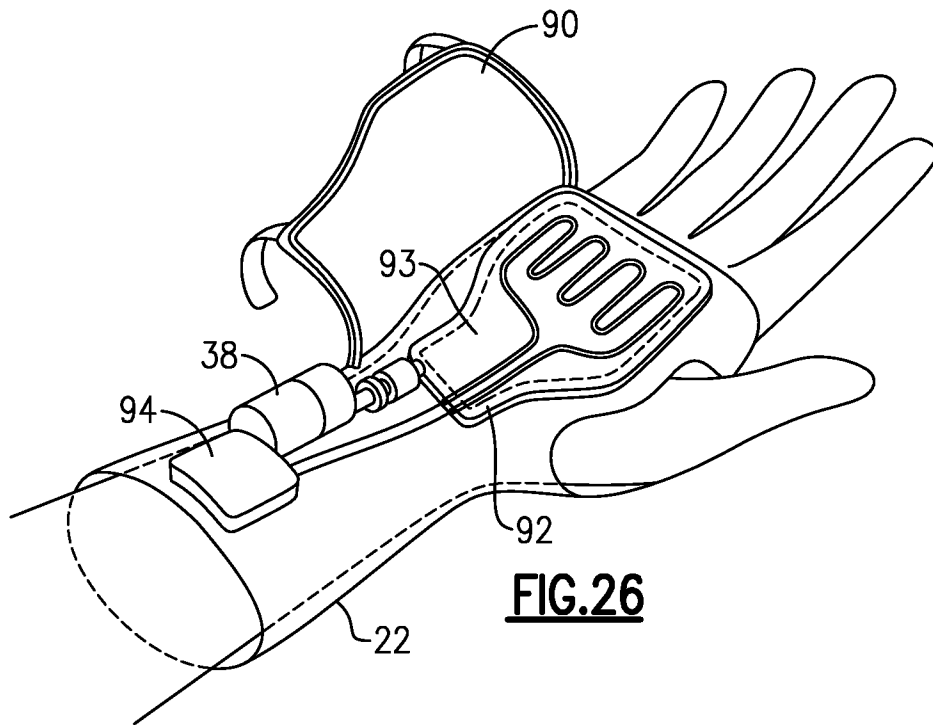


FIG.26

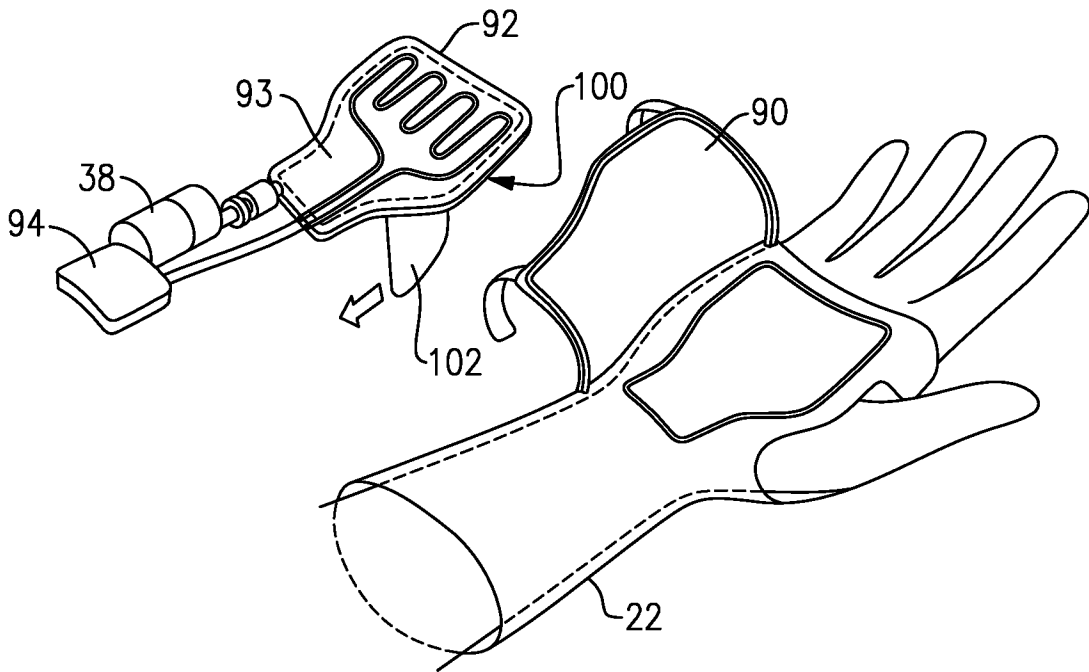
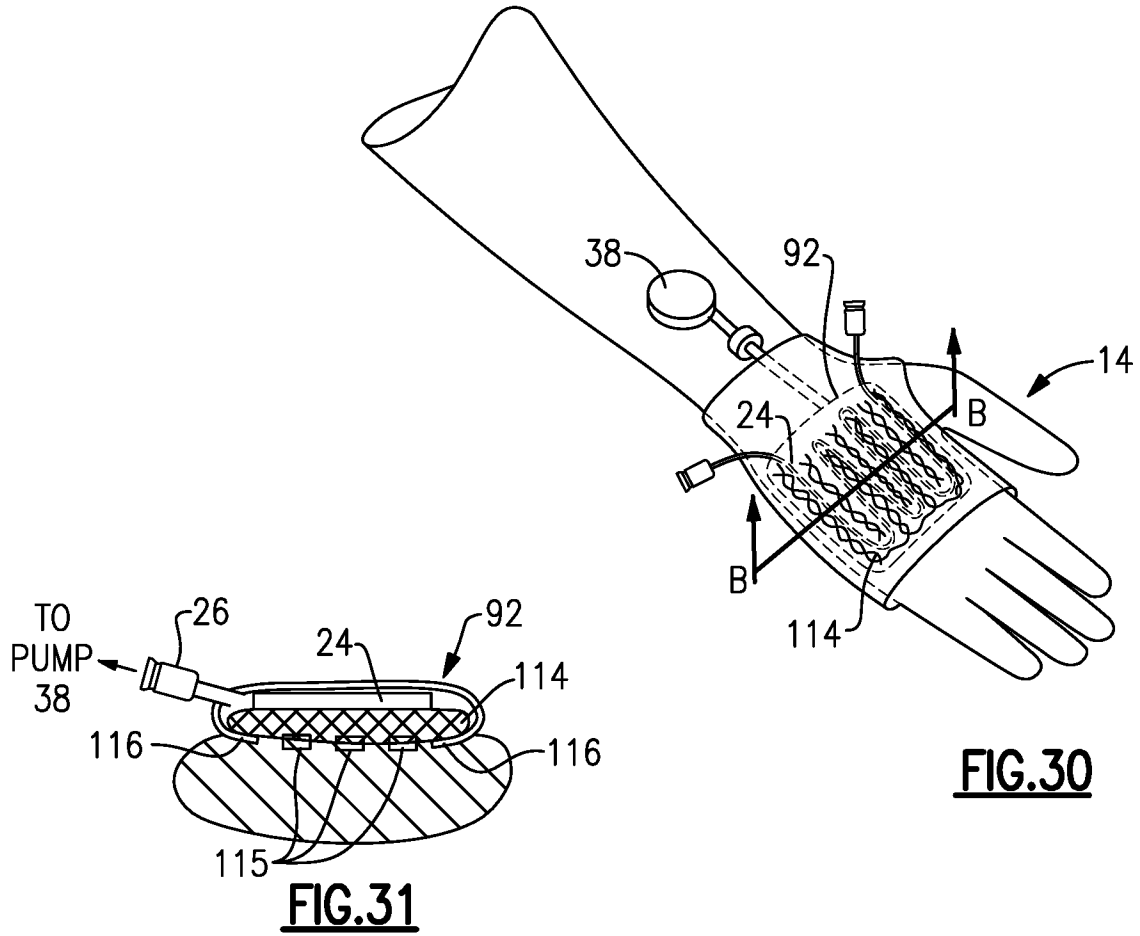
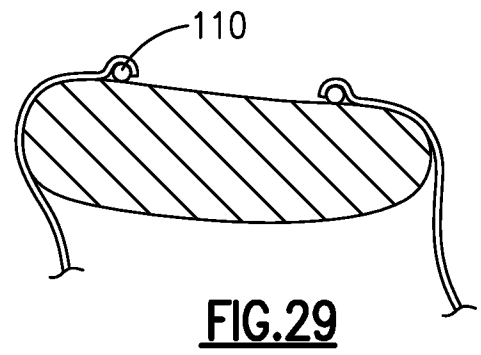
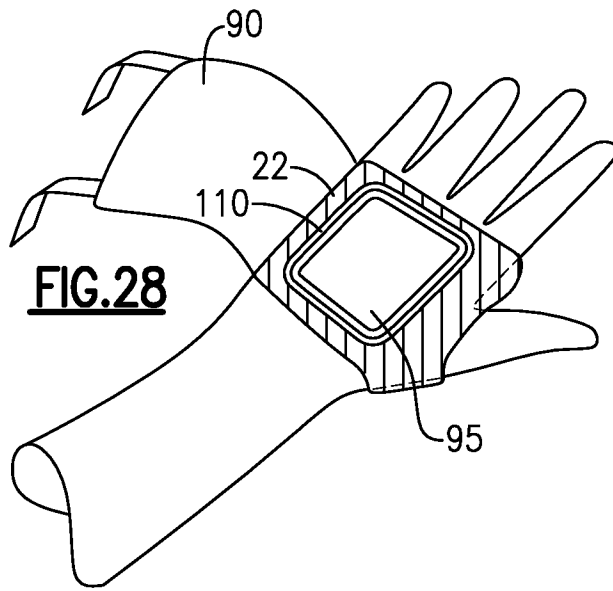


FIG.27



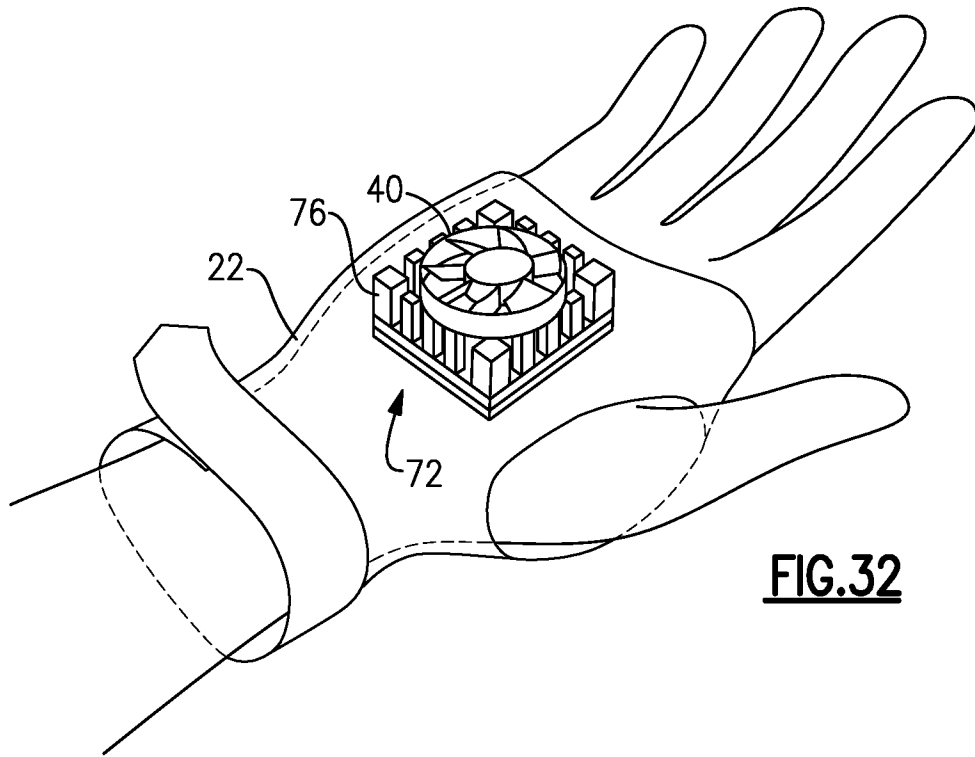


FIG.32

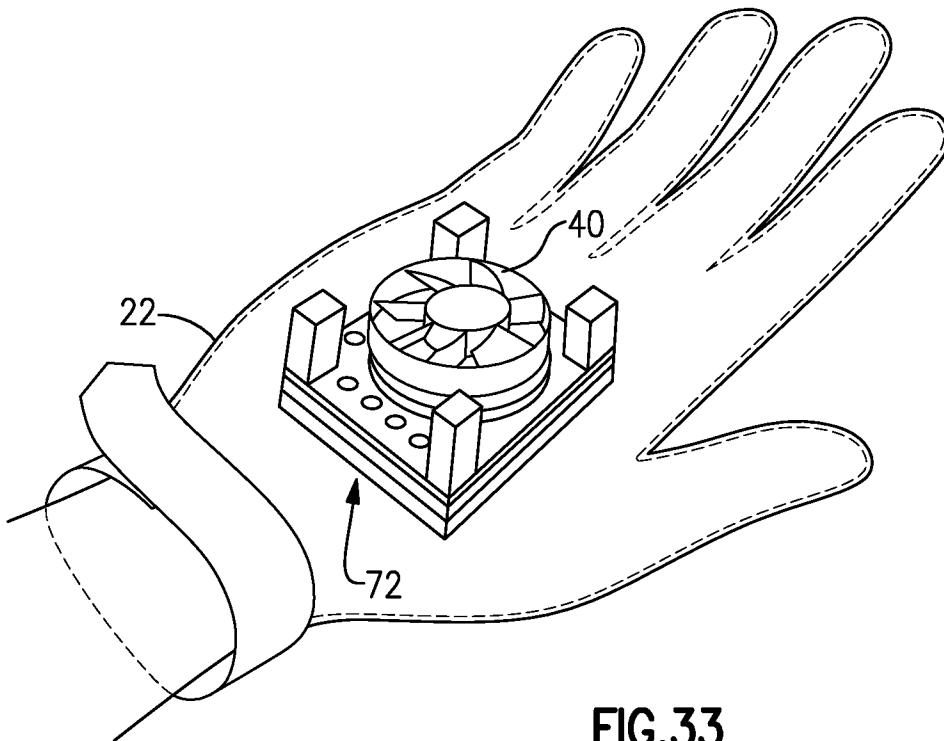
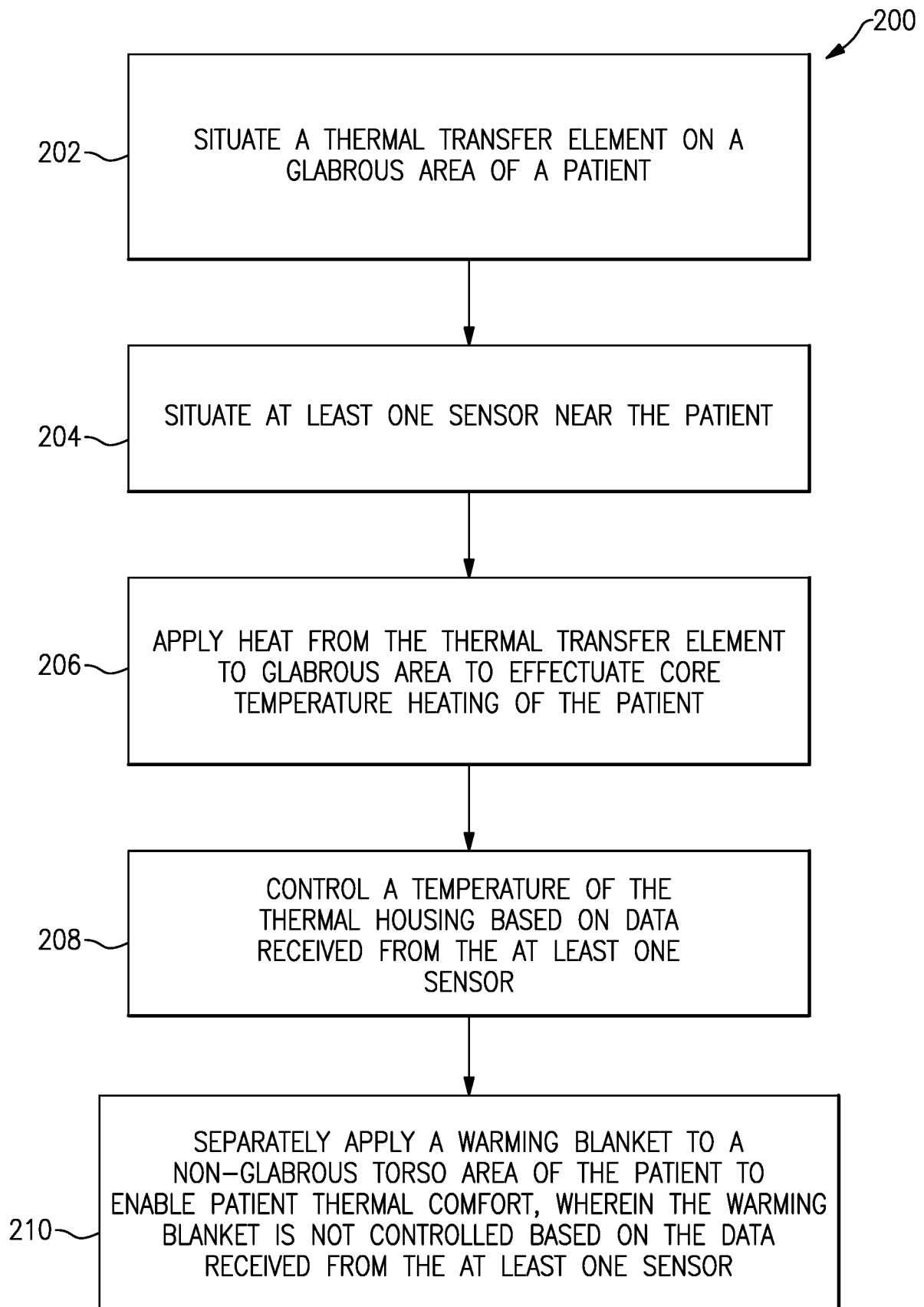


FIG.33

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**FIG.34**

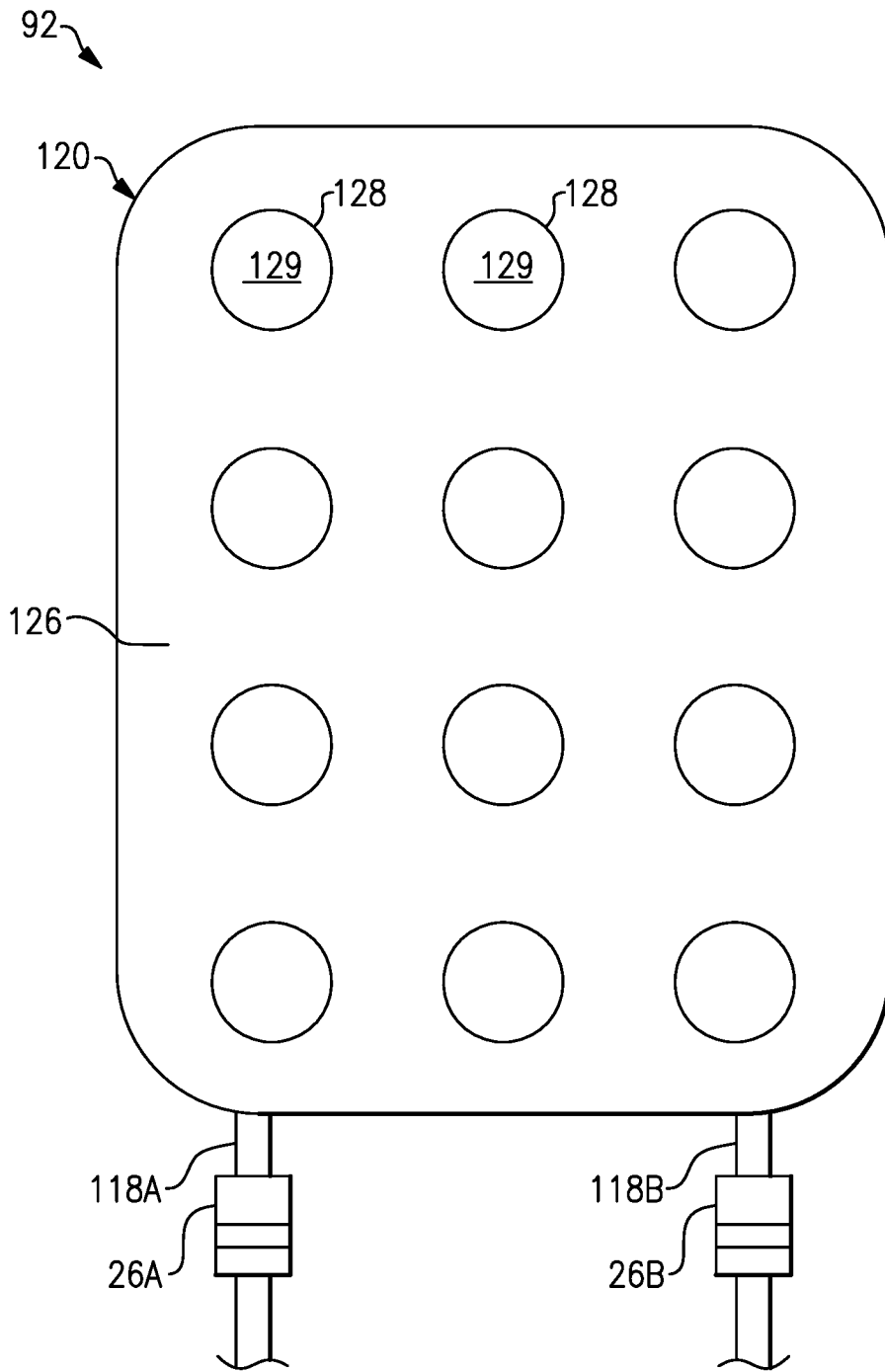


FIG.35

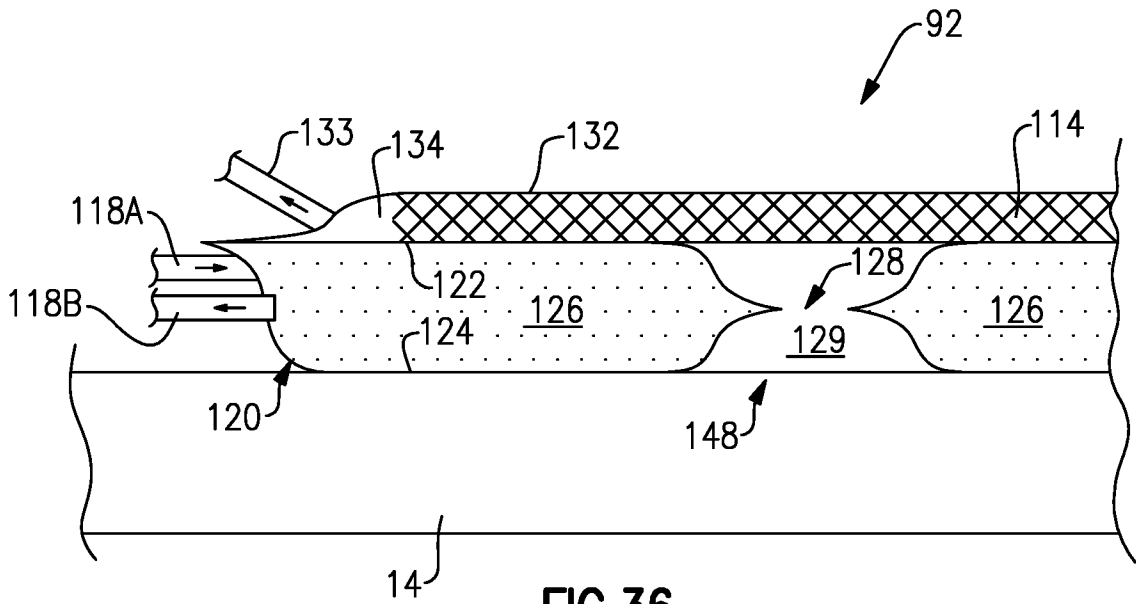


FIG.36

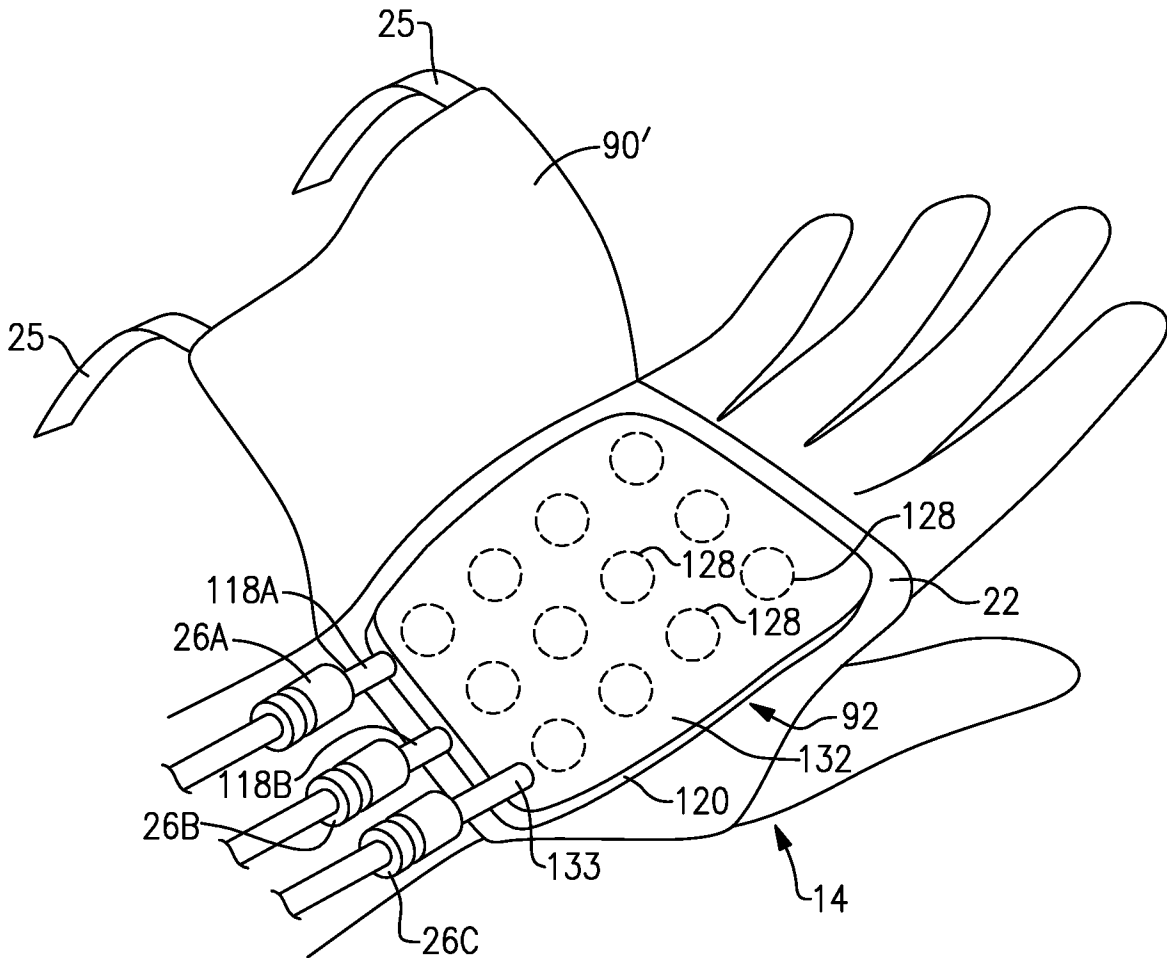


FIG.37

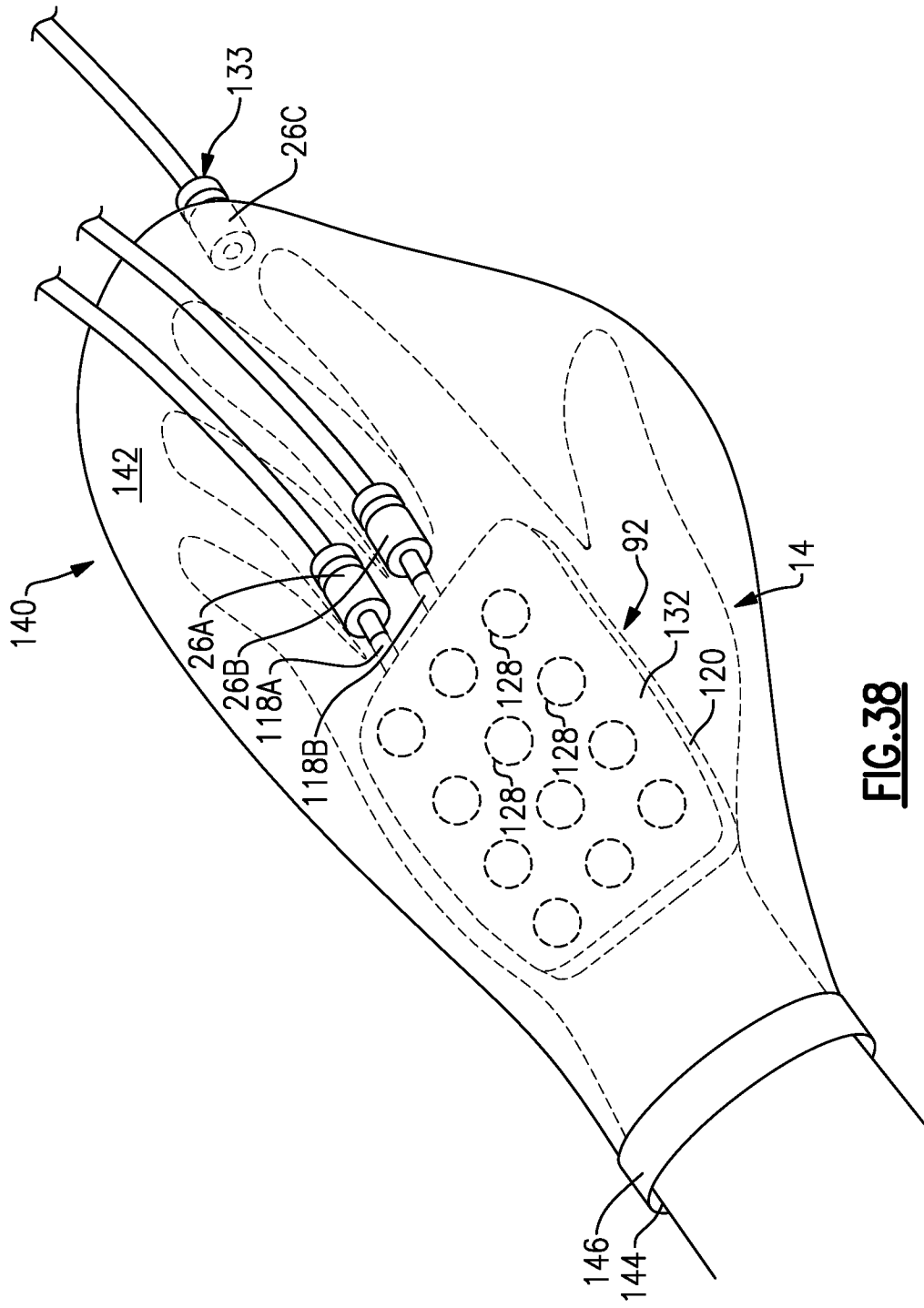


FIG. 38

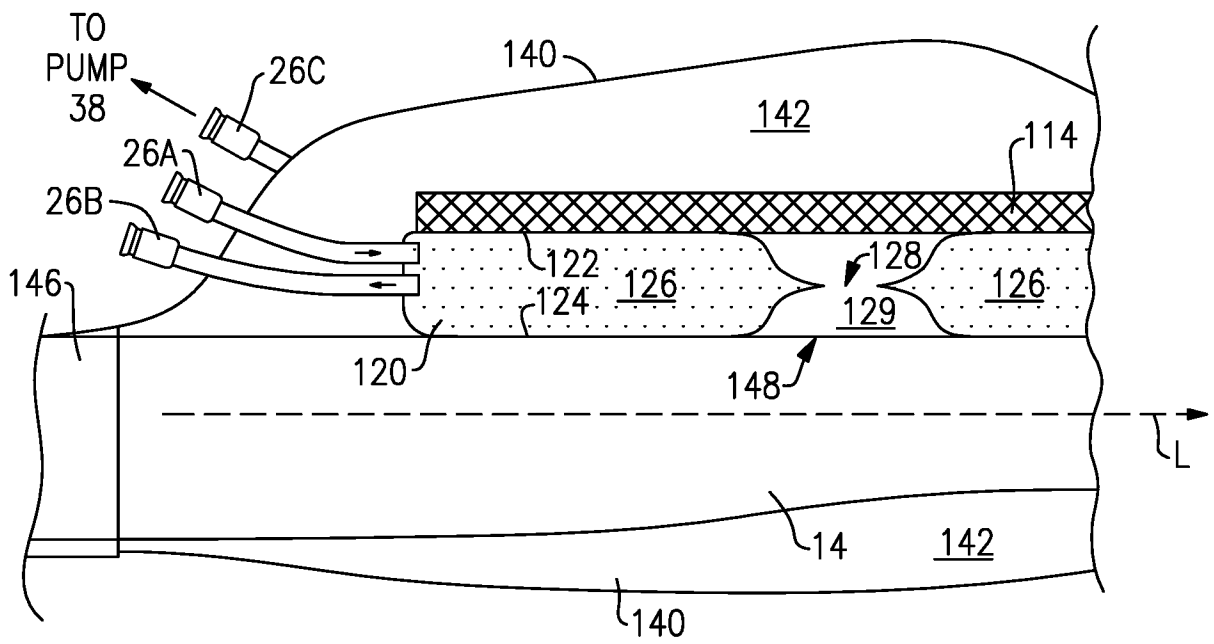


FIG.39

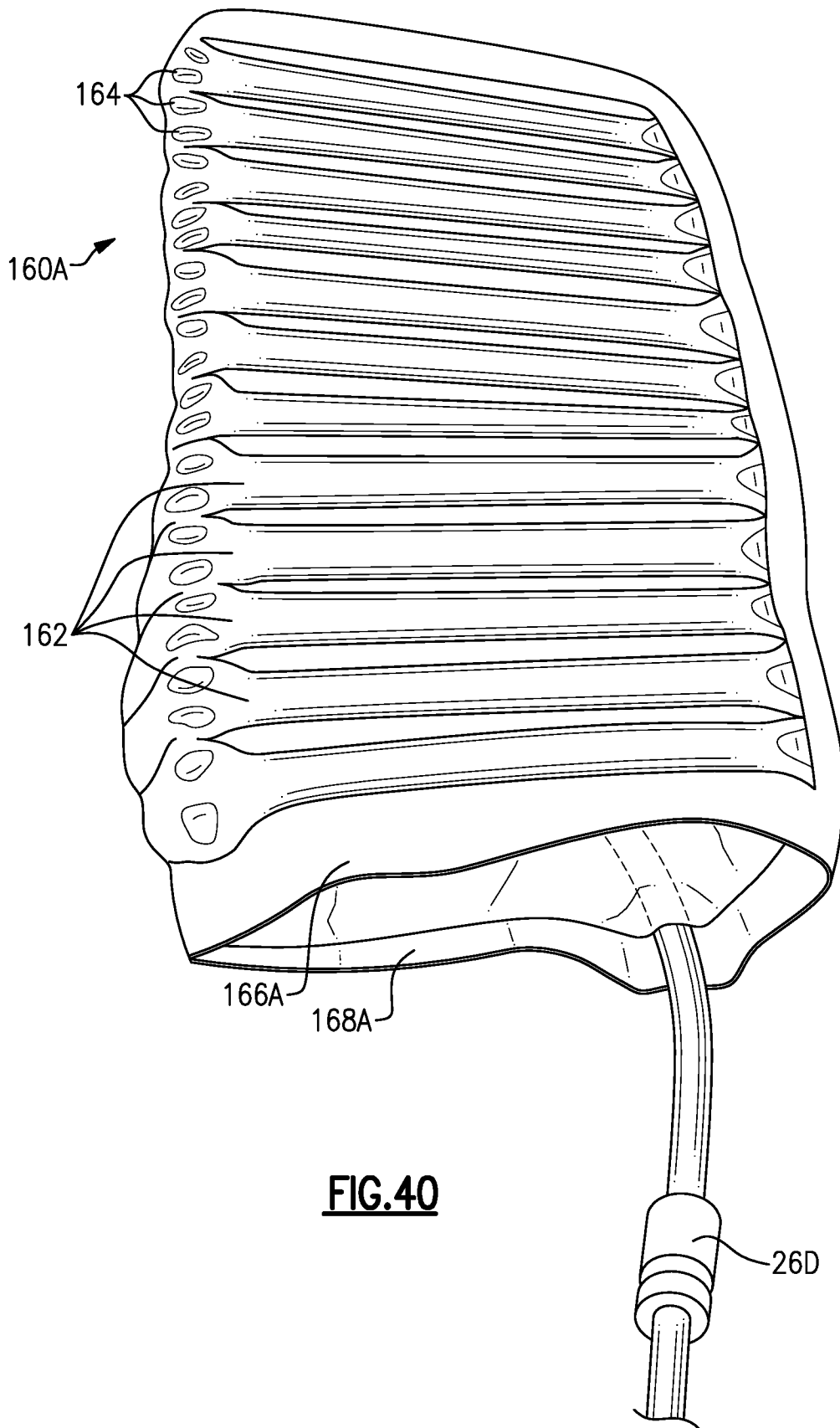
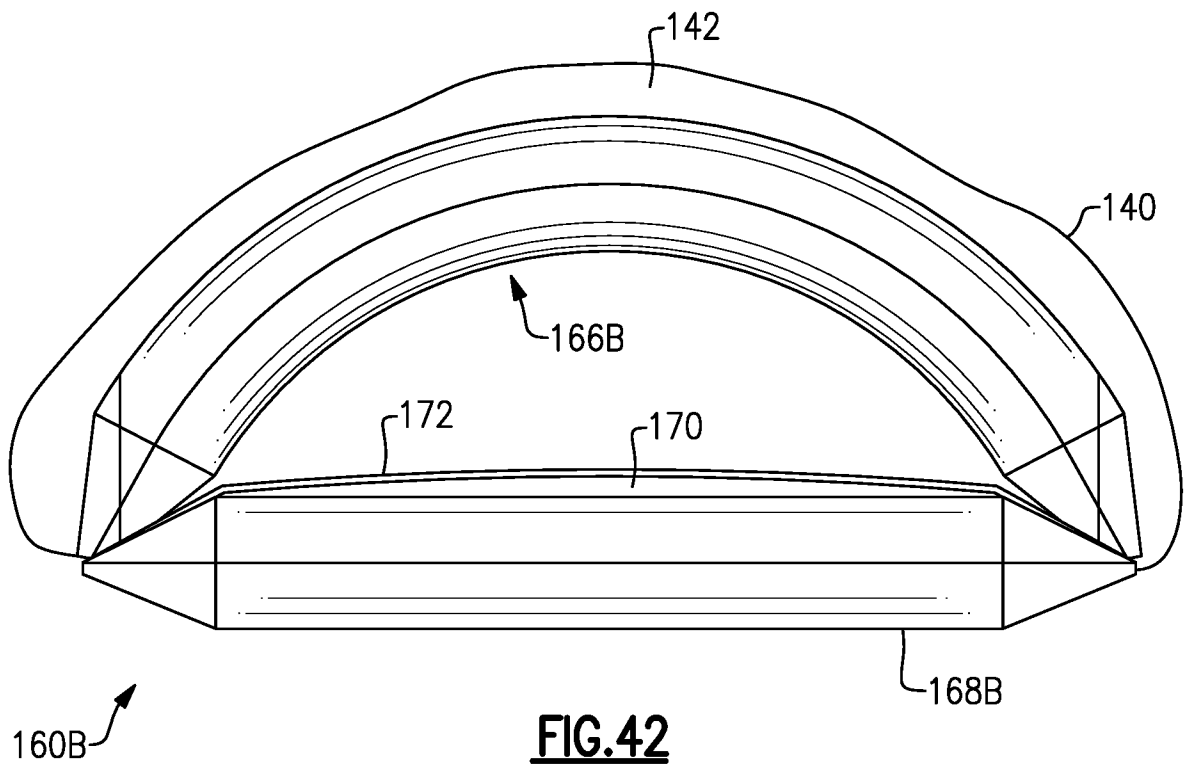
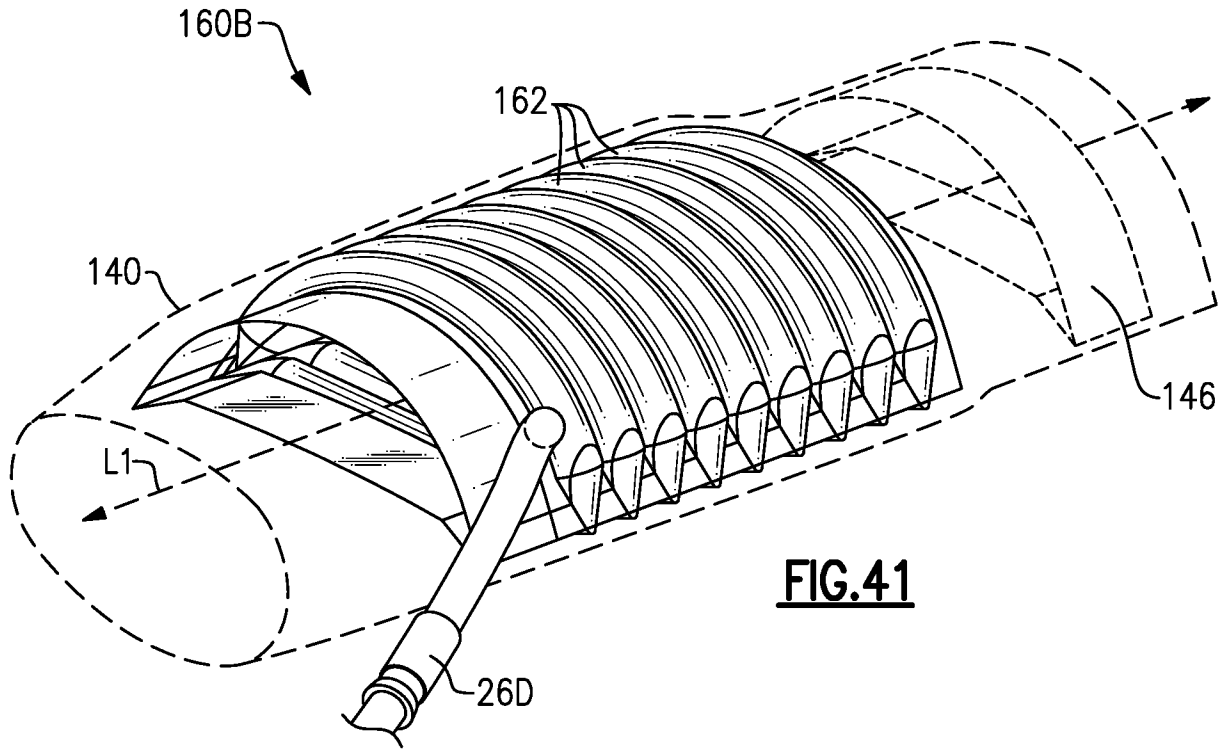


FIG.40



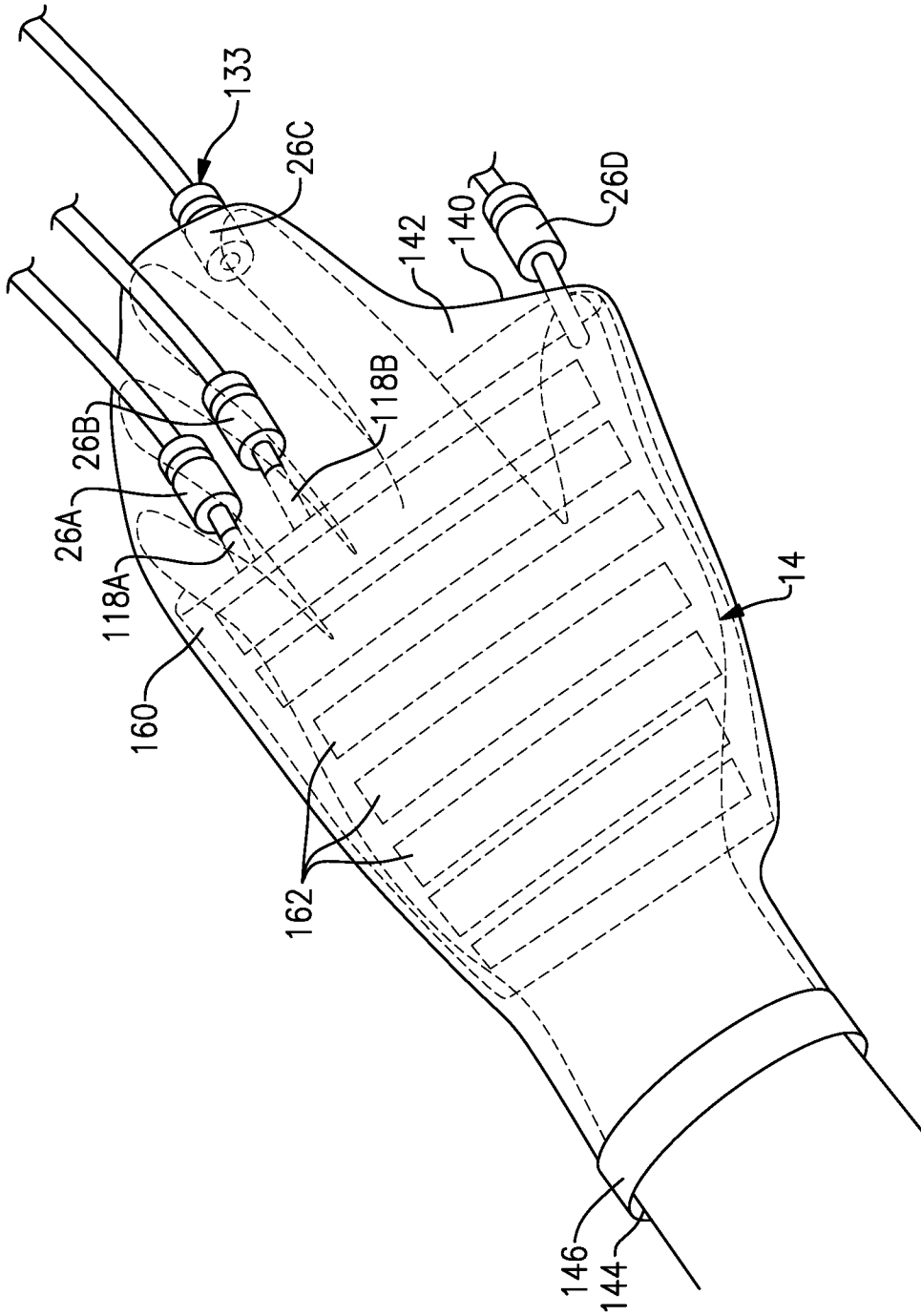
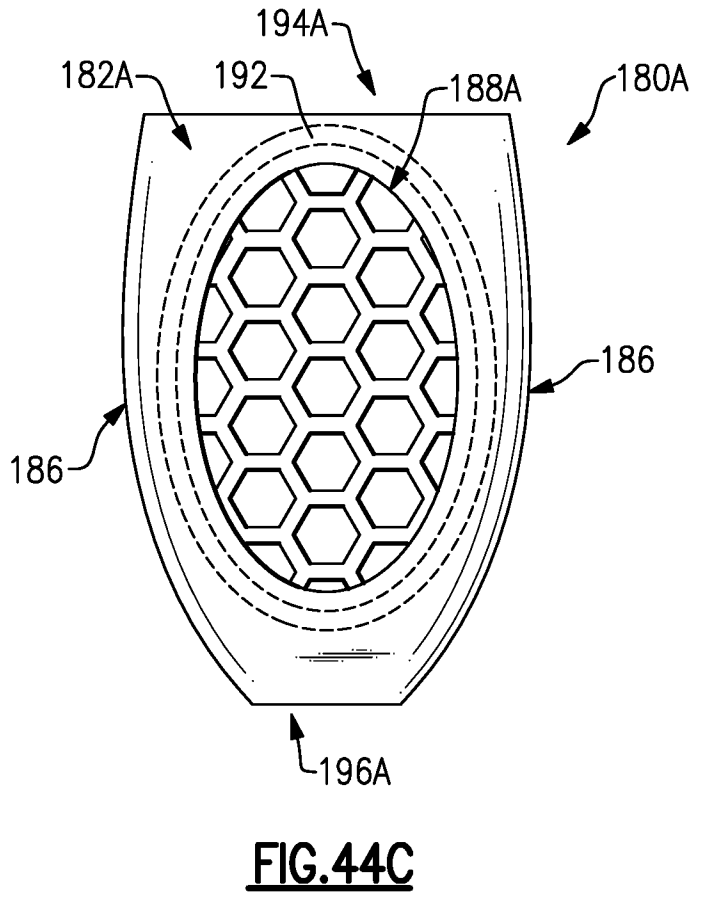
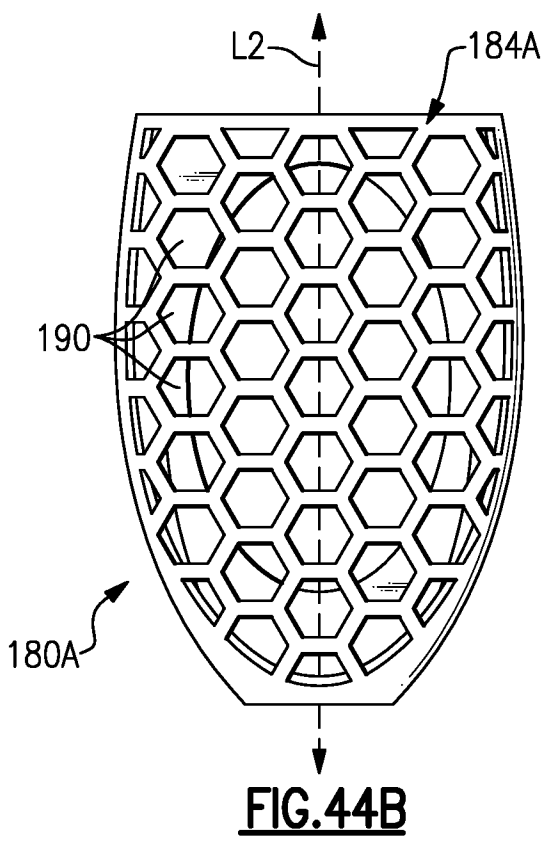
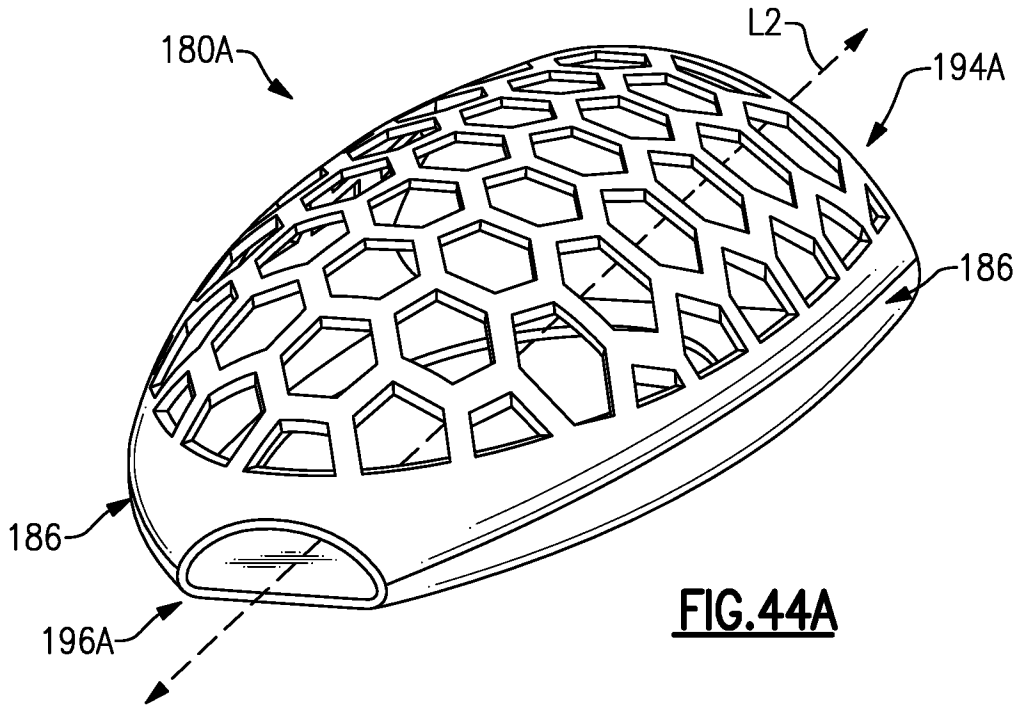


FIG. 43



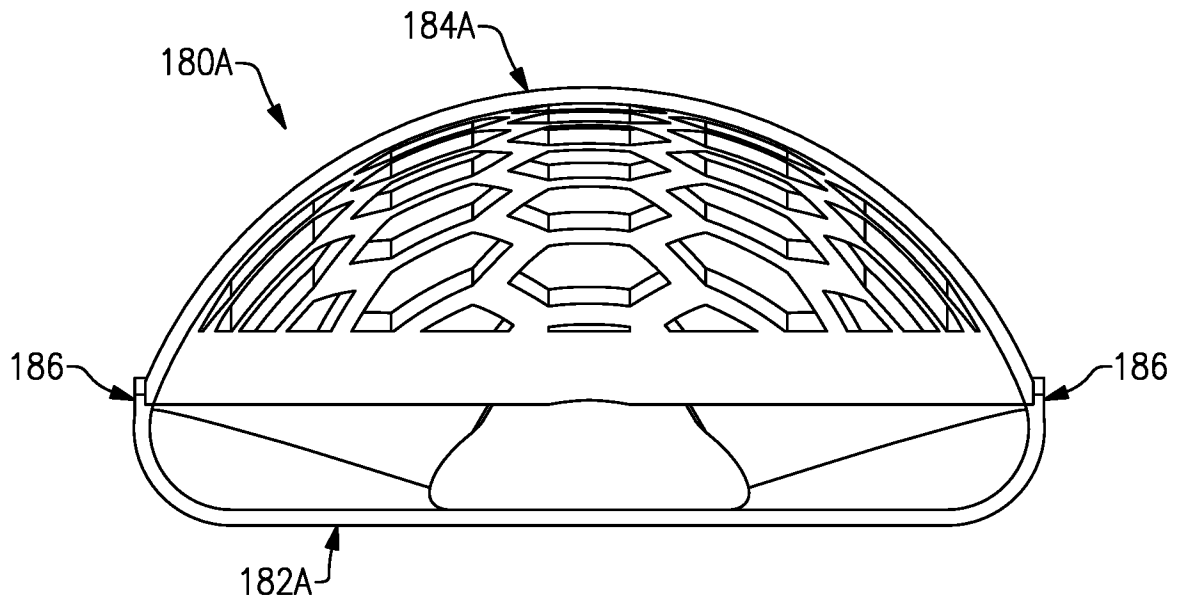


FIG.44D

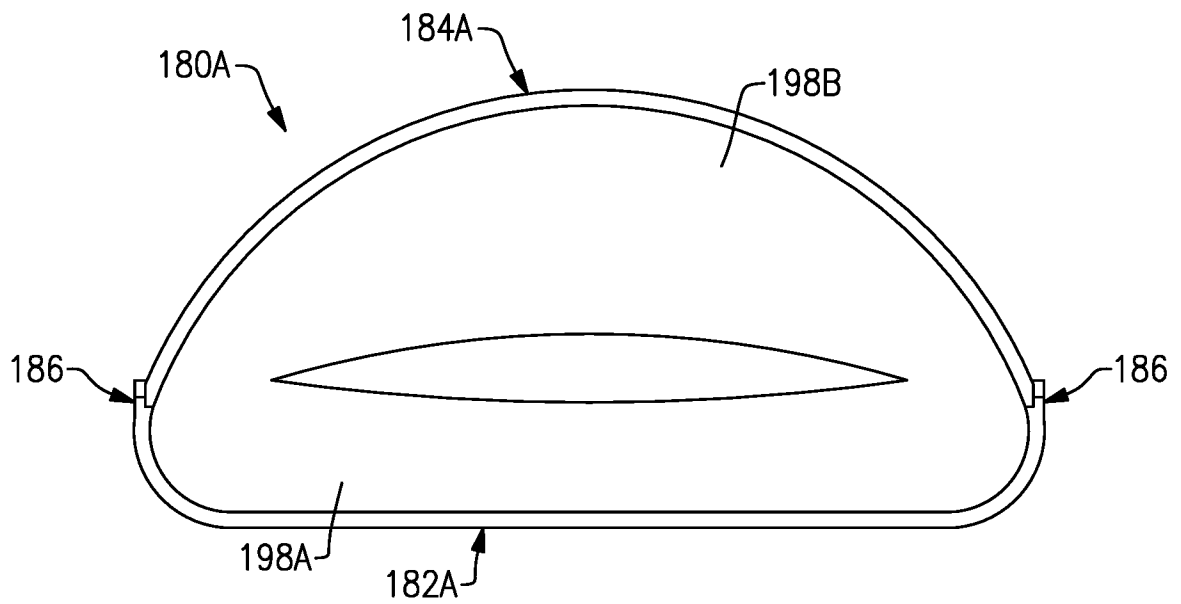


FIG.44E

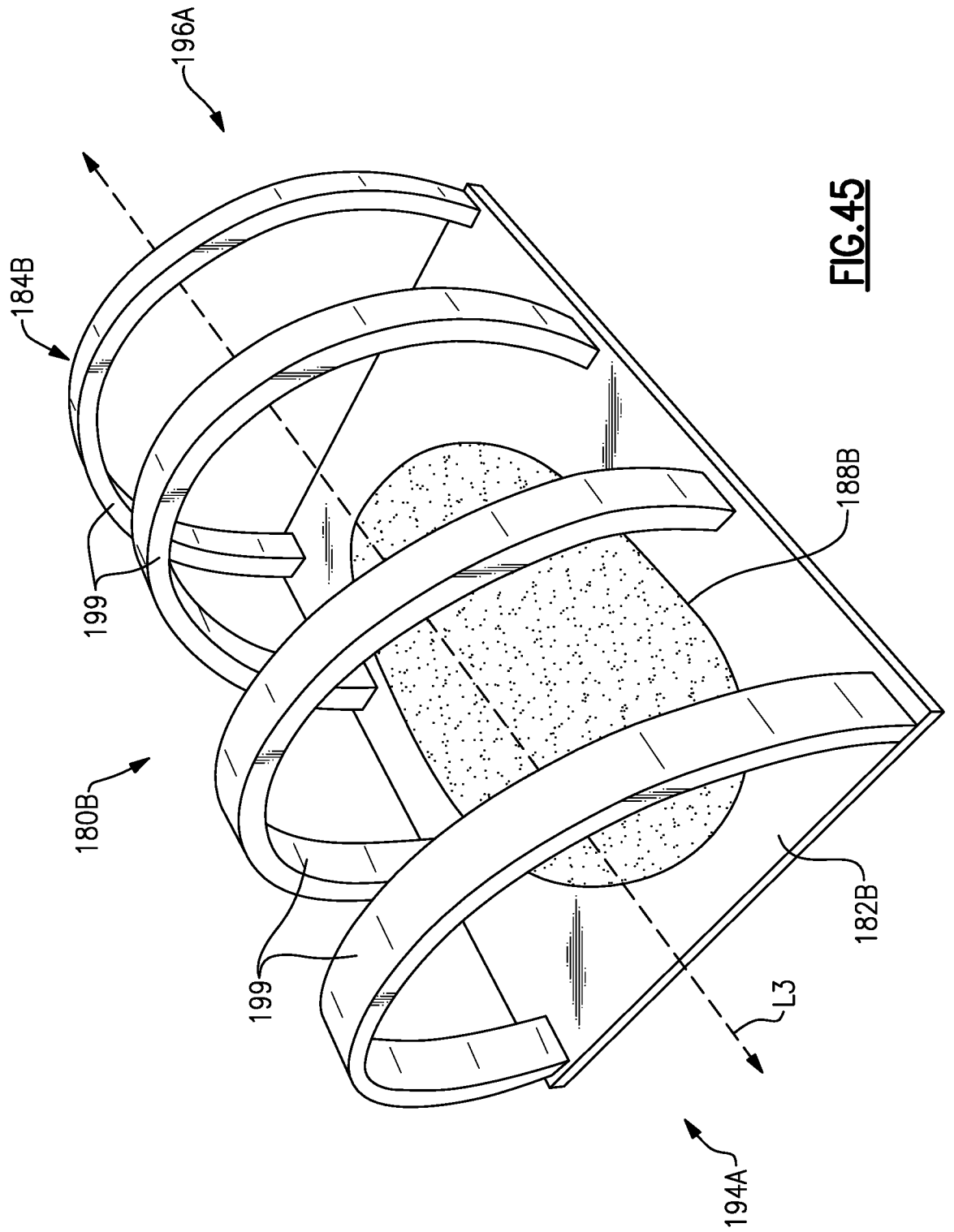
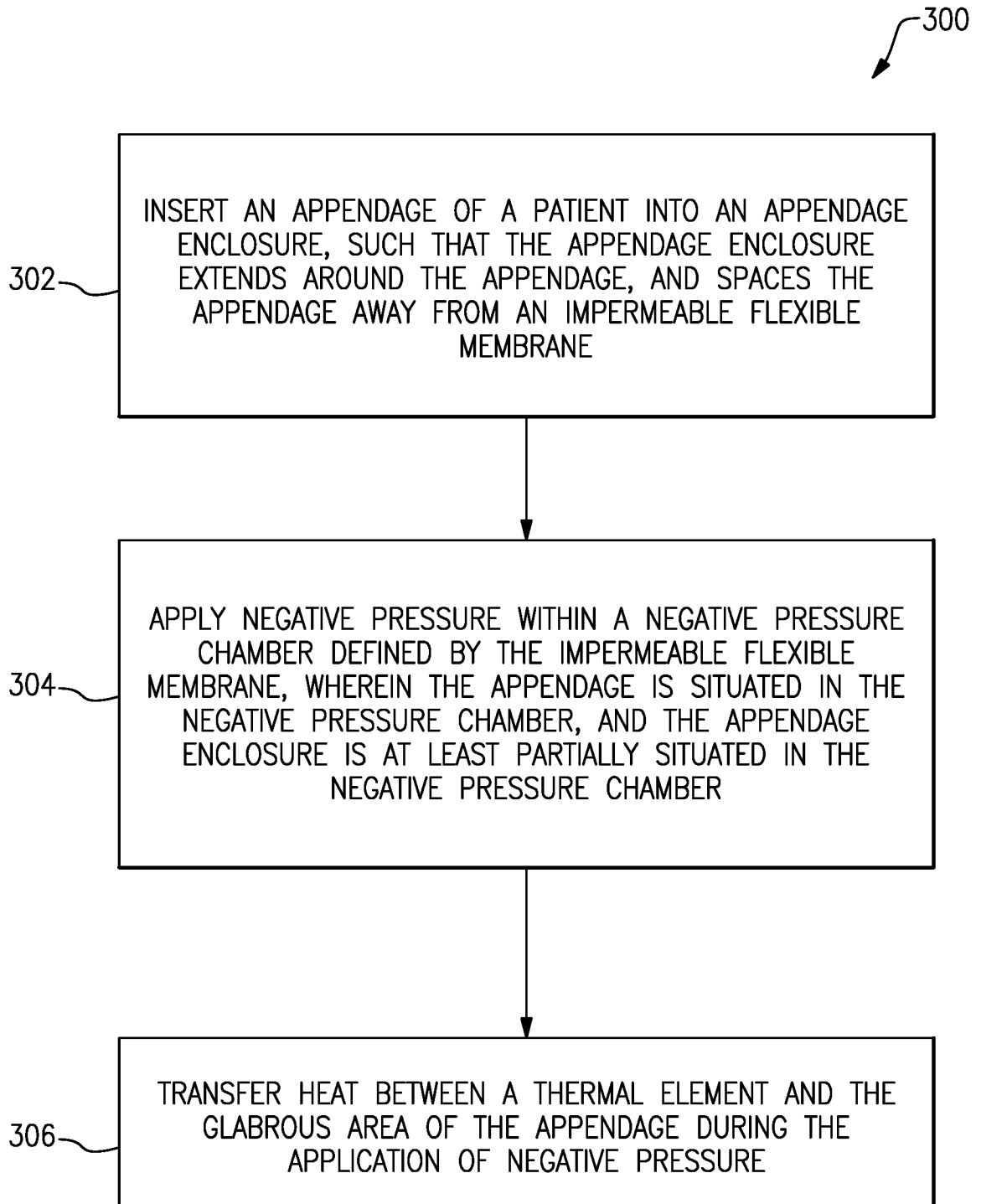


FIG. 45

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**FIG.46**

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2016/061573

A. CLASSIFICATION OF SUBJECT MATTER
 INV. A61F7/00 A61H9/00
 ADD.
 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)
 A61F A61H
 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)
 EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X A	EP 1 929 980 A1 (DYNATHERM MEDICAL INC [US]) 11 June 2008 (2008-06-11) paragraphs [0085] - [0092]; figures 4a-4D,5 -----	1,2,4, 10,16,17 3,5-9, 11-15
X	US 2008/033228 A1 (RASTEGAR JAHANGIR [US] ET AL) 7 February 2008 (2008-02-07) paragraphs [0069] - [0074], [0088]; figures 1,6 -----	1,2,4, 10,17
X Y A	US 2003/097163 A1 (KANE JOHN R [US] ET AL) 22 May 2003 (2003-05-22) paragraphs [0039], [0066]; figures 2a,3,10 -----	18,19, 21,22,24 23 1-17,20
Y	US 2009/048649 A1 (PERET JAMES [US] ET AL) 19 February 2009 (2009-02-19) paragraph [0059]; figure 6 -----	23

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

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance	"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
"E" earlier application or patent but published on or after the international filing date	"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
"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)	"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
"O" document referring to an oral disclosure, use, exhibition or other means	"&" document member of the same patent family
"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 31 January 2017	Date of mailing of the international search report 08/02/2017
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Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Authorized officer Mayer-Martenson, E
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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2016/061573

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.: 25-28
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy
2. Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
3. As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2016/061573

Patent document cited in search report	Publication date	Patent family member(s)	Publication date	
EP 1929980	A1	11-06-2008	EP 1929980 A1	11-06-2008
			EP 2394616 A2	14-12-2011
			JP 2008155007 A	10-07-2008
			US 2008132976 A1	05-06-2008
			US 2013190667 A1	25-07-2013
			US 2016374852 A1	29-12-2016

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US 2003097163	A1	22-05-2003	AT 521313 T	15-09-2011
			AU 2002343759 A1	10-06-2003
			EP 1446078 A1	18-08-2004
			US 2003097163 A1	22-05-2003
			WO 03045289 A1	05-06-2003

US 2009048649	A1	19-02-2009	NONE	
