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(54) **TEMPERATURE SENSOR ASSEMBLIES FOR ELECTRIC WARMING BLANKETS**

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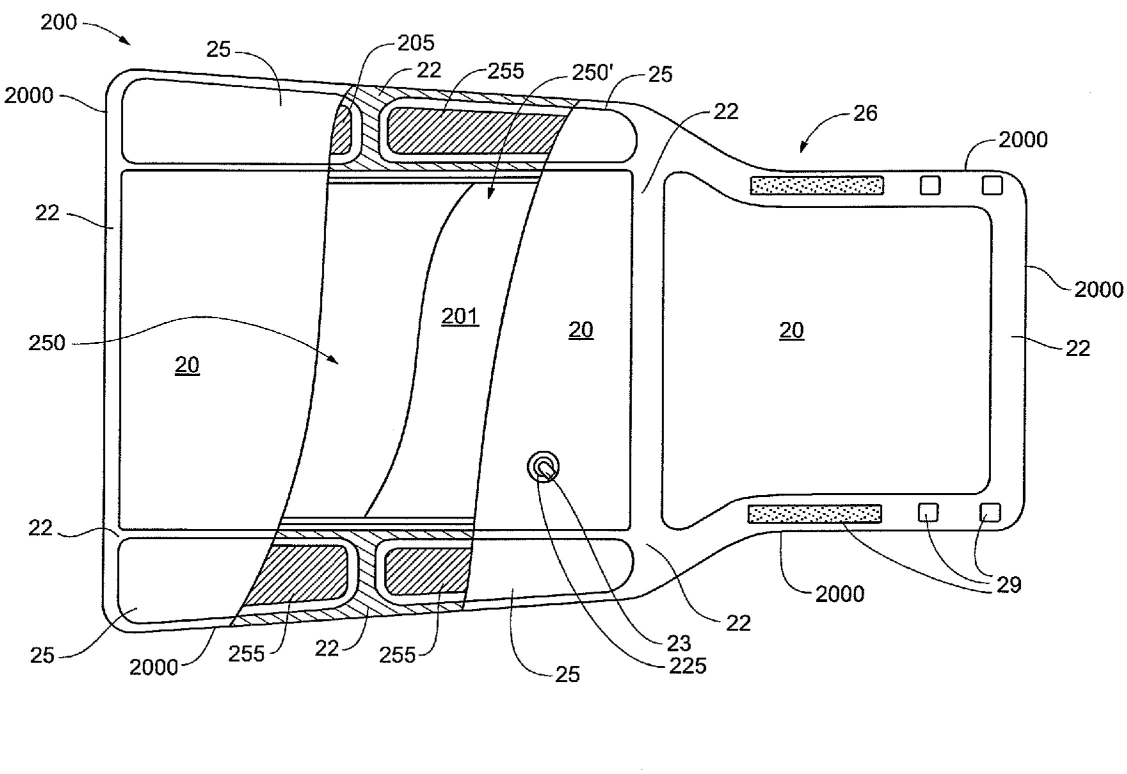
(57) **ABSTRACT**

An electric warming blanket for warming patients during surgery and other medical procedures includes a flexible heater and a temperature sensor assembly coupled thereto; a first layer of water resistant material coupled to a second layer of water resistant material, about a perimeter of the heater, forms a substantially hermetically sealed space for the heater and the temperature sensor assembly. The blanket may further include a thermal insulation layer disposed between the temperature sensor assembly and the first layer of water resistant material. The temperature sensor assembly may provide input of an average temperature over a portion of a surface area of the heater to a temperature controller, when the heater and sensor assembly are coupled to the controller.



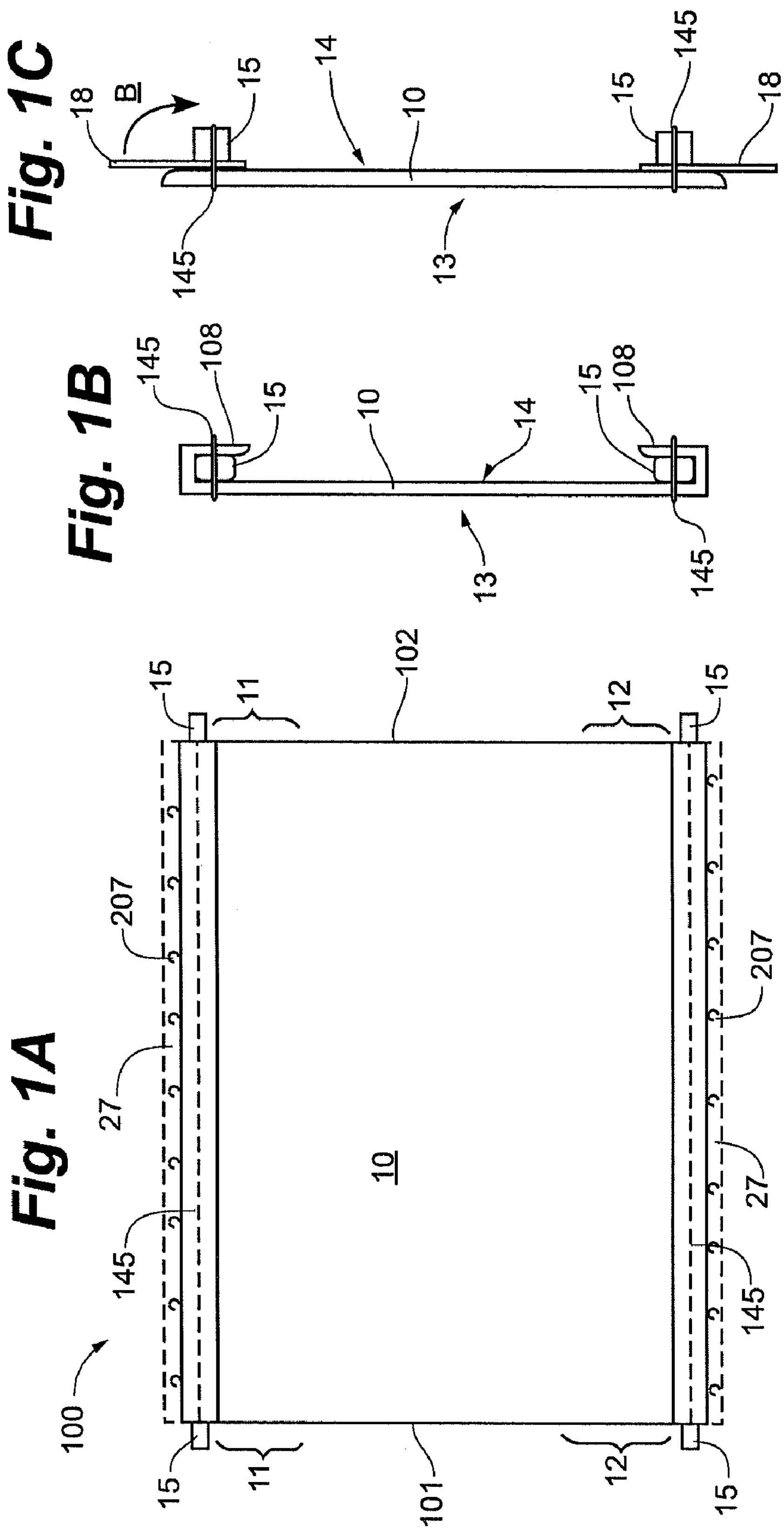


Fig. 1A
Fig. 1B
Fig. 1C
10
11
12
13
14
15
18
27
100
101
102
108
145
207
B

Fig. 1D

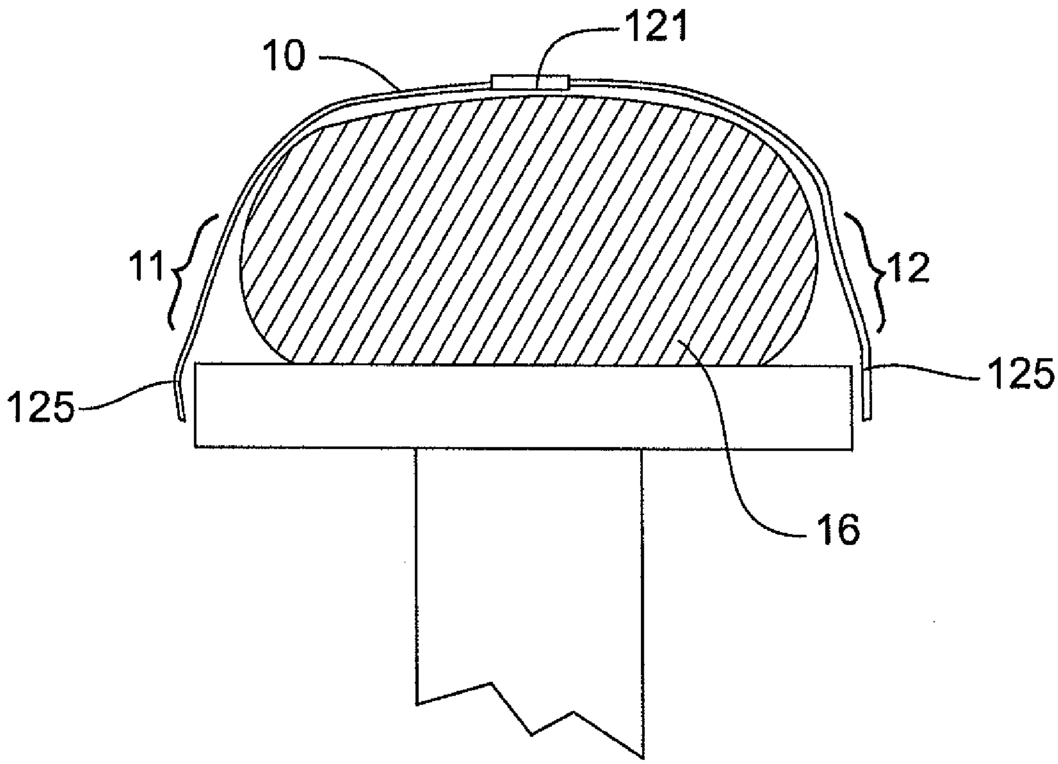


Fig. 2B

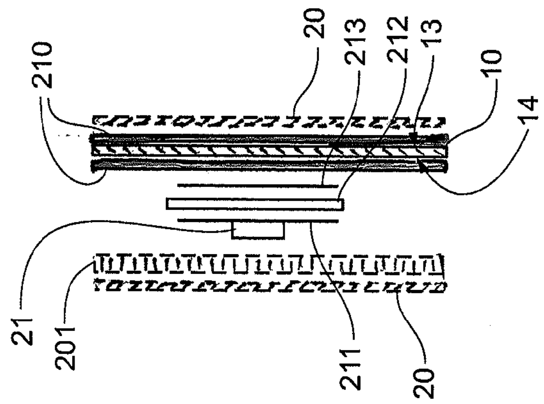

20
213
212
13
210
10
14
21
201
211
20

Fig. 2A

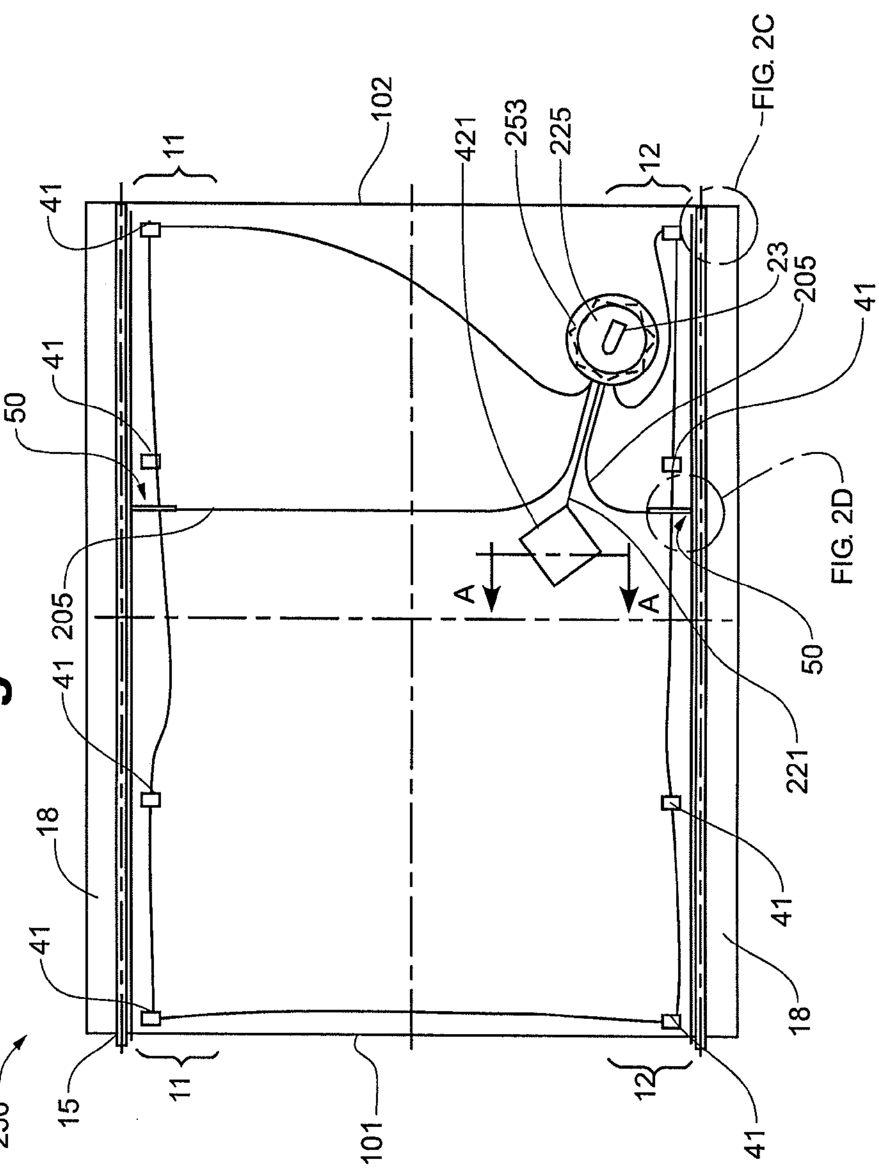

102
421
253
225
11
12
FIG. 2C
41
23
205
50
FIG. 2D
A
205
221
18
250
15
101
41

Fig. 2C

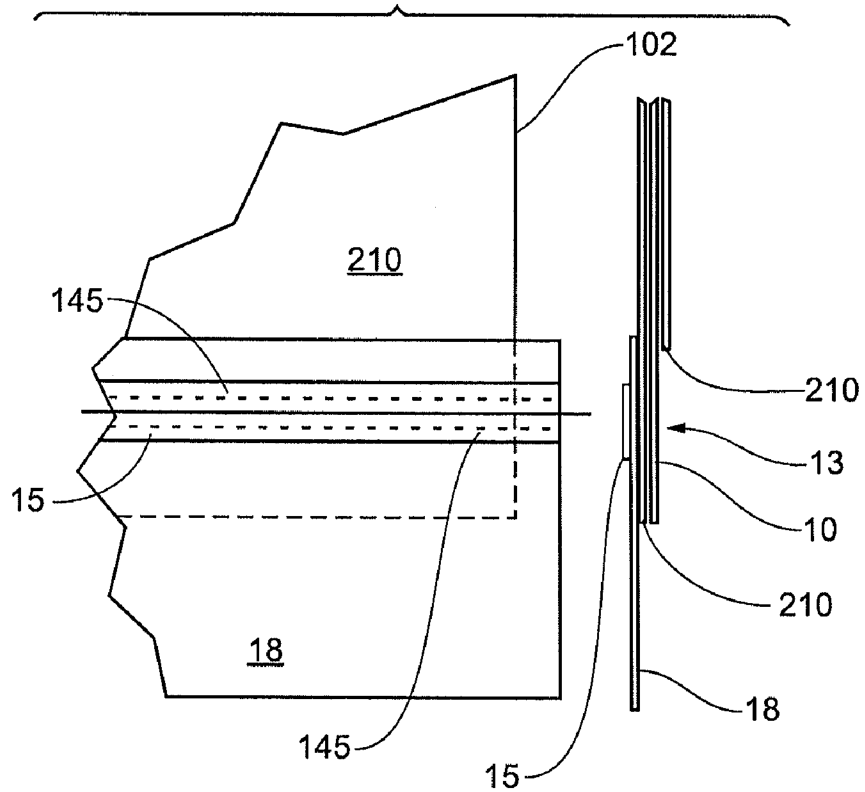
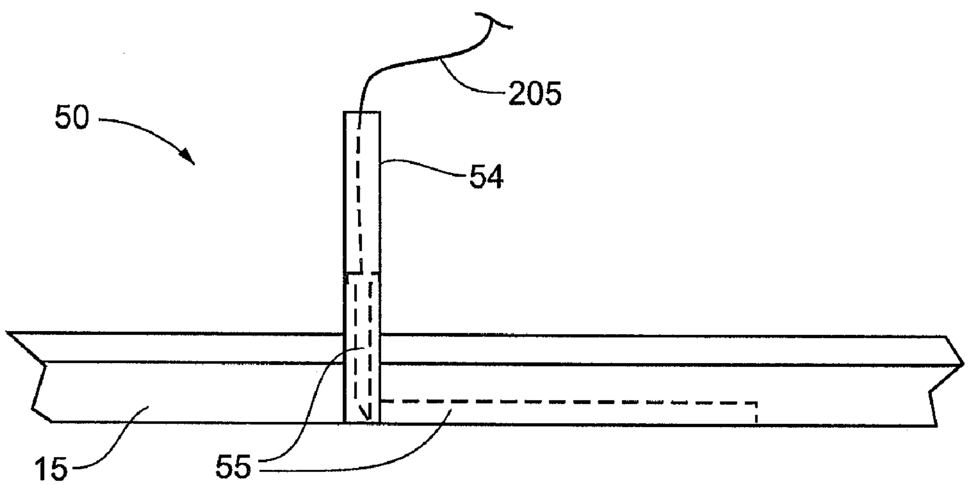


Fig. 2D



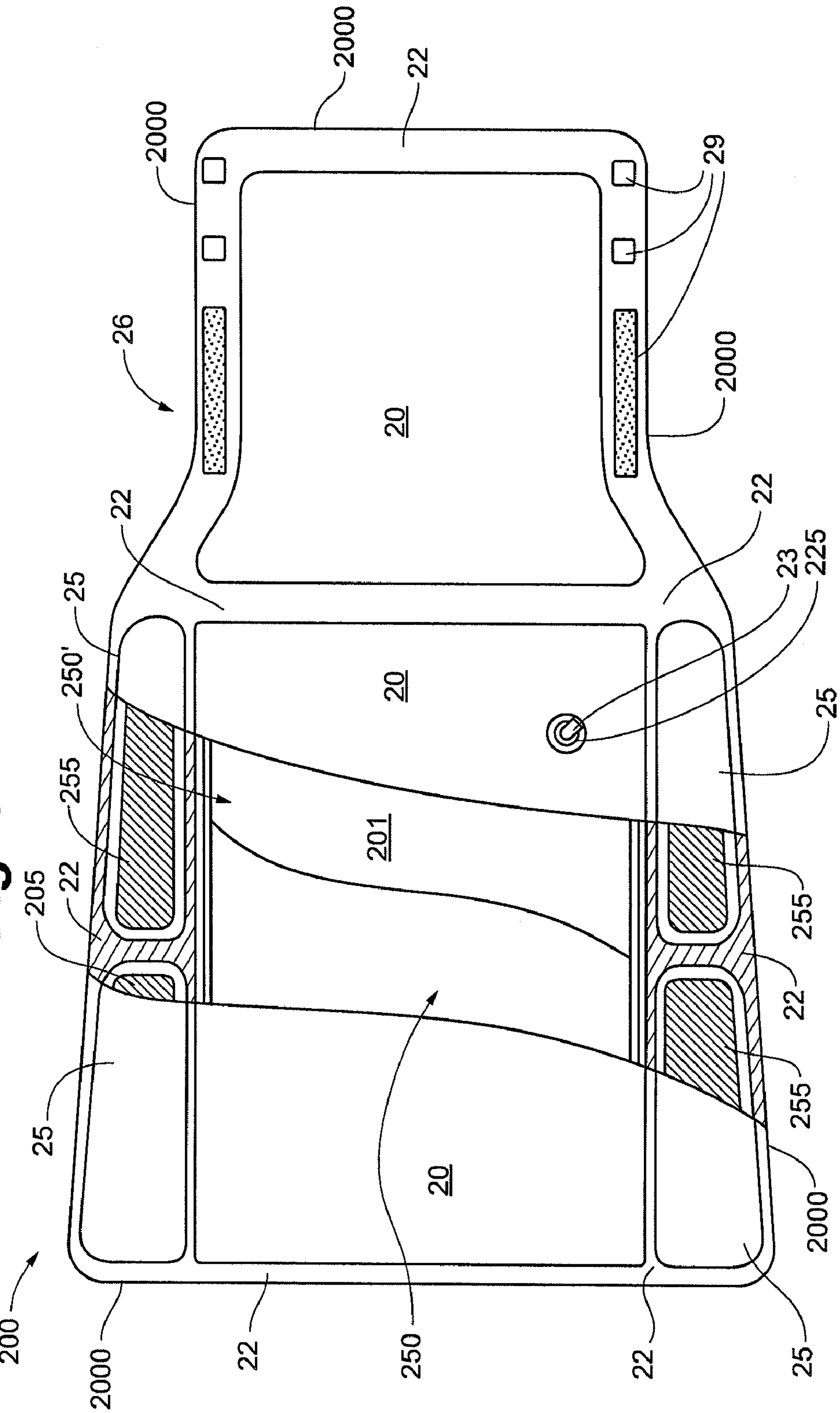
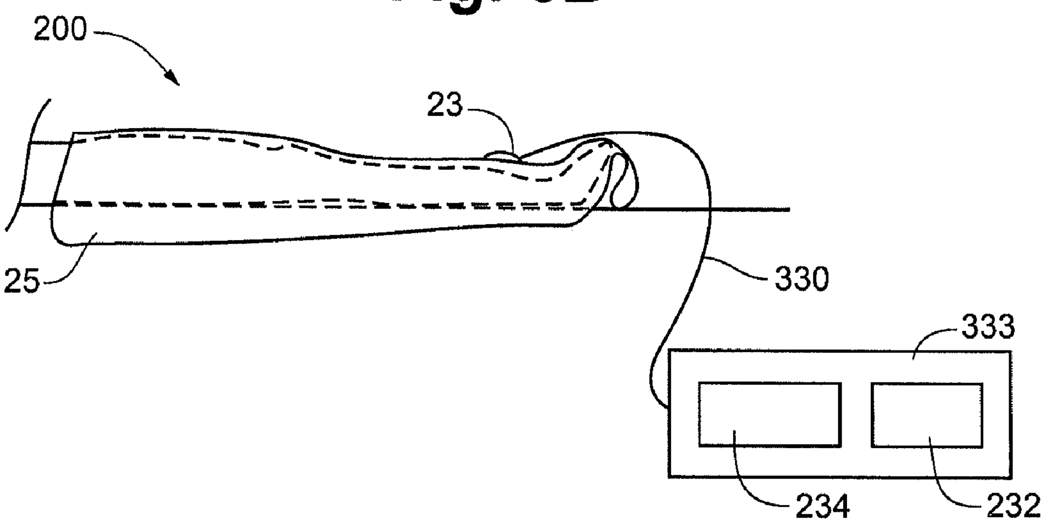

2000
22
2000
29
26
20
2000
22
22
25
23
225
250'
20
25
255
201
205
22
255
22
255
25
250
20
2000
200
2000
22
22
25

Fig. 3A

Fig. 3B



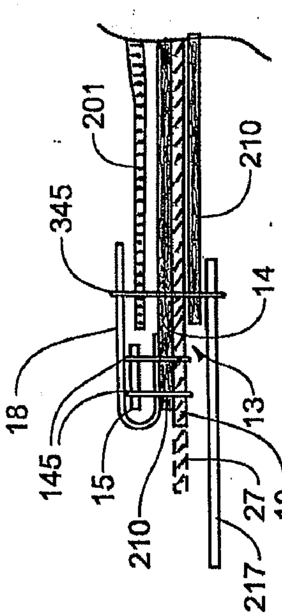

345
201
210
18
145
15
210
27
10
13
14
217

Fig. 3D

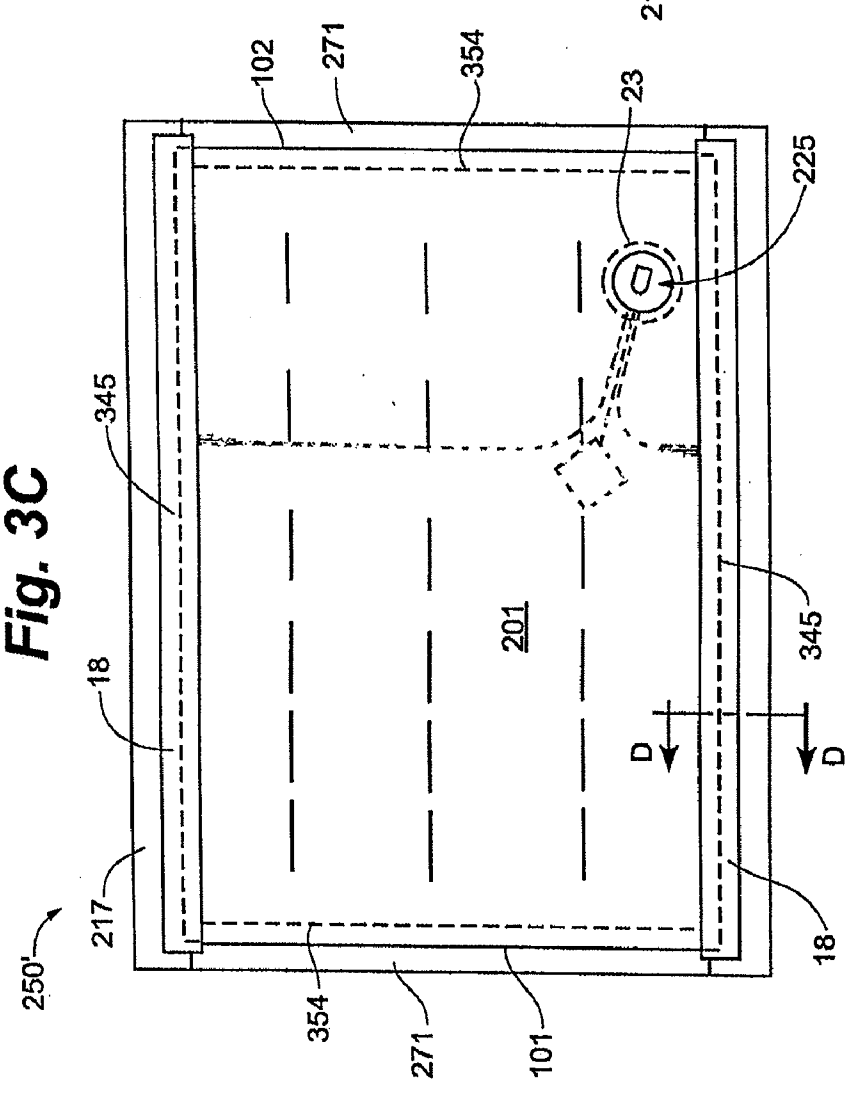

250'
217
18
345
201
23
225
102
271
354
D
D
345
18
354
271
101

Fig. 3C

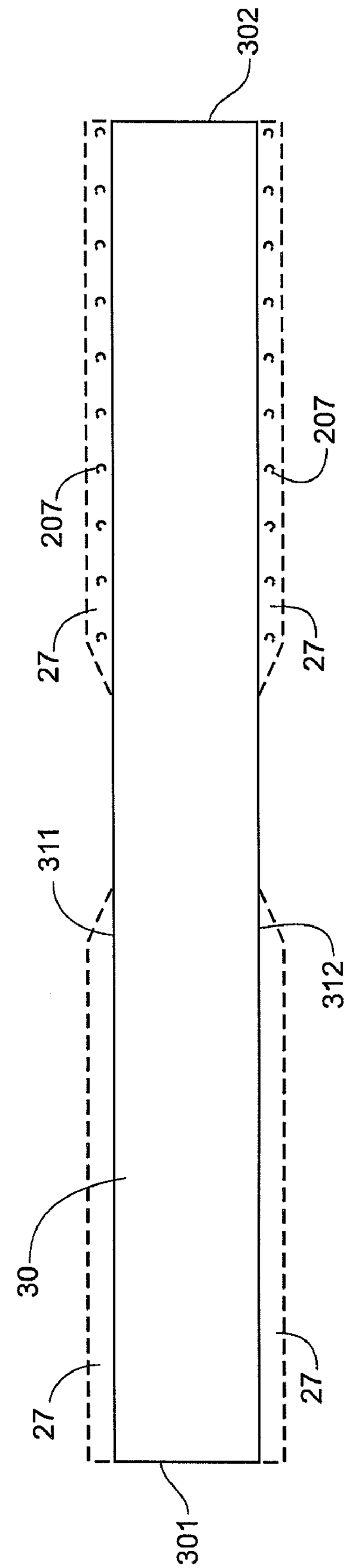


Fig. 4A

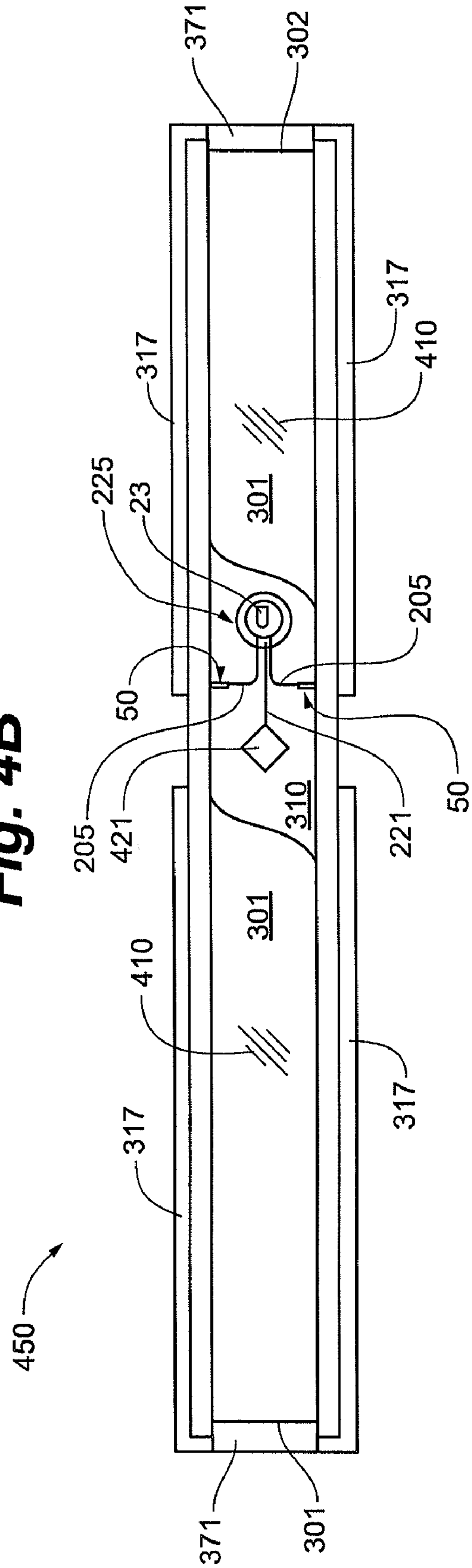

371
302
317
317
410
410
225
23
301
301
205
205
50
50
421
221
310
317
317
450
371
301

Fig. 4B

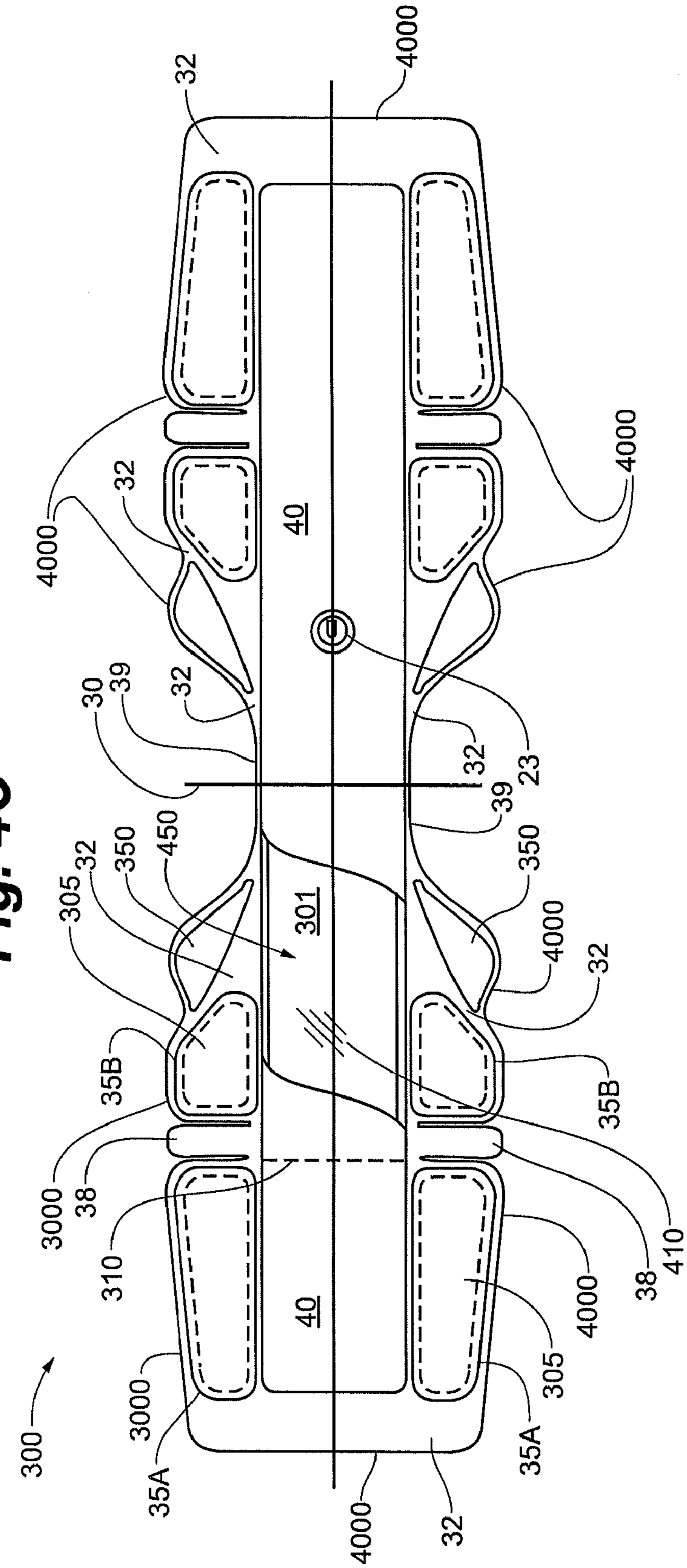


Fig. 4C

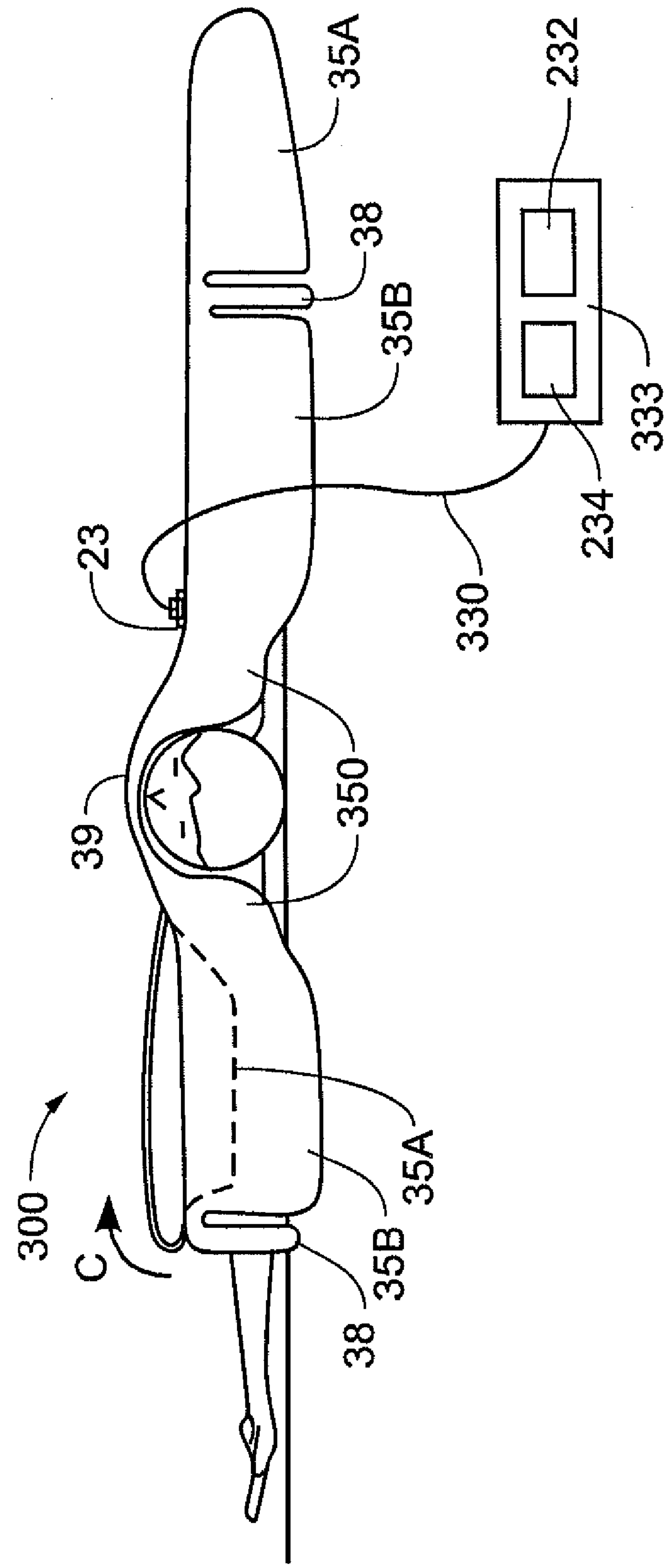


Fig. 4D

TEMPERATURE SENSOR ASSEMBLIES FOR ELECTRIC WARMING BLANKETS

PRIORITY CLAIM

[0001] The present application is a divisional of U.S. application Ser. No. 11/537,189, which was filed on Sep. 29, 2006 and claims priority to each of the following provisional applications: Ser. No. 60/825,573, entitled HEATING BLANKET SYSTEM filed on Sep. 13, 2006; Ser. No. 60/722,106, entitled ELECTRIC WARMING BLANKET INCLUDING TEMPERATURE ZONES AUTOMATICALLY OPTIMIZED, filed Sep. 29, 2005; and Ser. No. 60/722,246, entitled HEATING BLANKET, filed Sep. 29, 2005. Each of the above-referenced applications are hereby incorporated by reference, in their entireties, herein.

RELATED APPLICATIONS

[0002] The present application is related to the following co-pending and commonly assigned utility patent applications, all of which are hereby incorporated by reference in their entireties: A) ELECTRIC WARMING BLANKET HAVING OPTIMIZED TEMPERATURE ZONES, Ser. No. 11/537,173; B) NOVEL DESIGNS FOR HEATING BLANKETS AND PADS, Ser. No. 11/537,179; C) FLEXIBLE HEATING ELEMENT CONSTRUCTION, Ser. No. 11/537,199; D) BUS BAR ATTACHMENTS FOR FLEXIBLE HEATING ELEMENTS, Ser. No. 11/537,212; and E) BUS BAR INTERFACES FOR FLEXIBLE HEATING ELEMENTS, Ser. No. 11/537,222.

TECHNICAL FIELD

[0003] The present invention is related to heating or warming blankets or pads and more particularly to those including electrical heating elements.

BACKGROUND

[0004] It is well established that surgical patients under anesthesia become poikilothermic. This means that the patients lose their ability to control their body temperature and will take on or lose heat depending on the temperature of the environment. Since modern operating rooms are all air conditioned to a relatively low temperature for surgeon comfort, the majority of patients undergoing general anesthesia will lose heat and become clinically hypothermic if not warmed.

[0005] Over the past 15 years, forced-air warming (FAW) has become the "standard of care" for preventing and treating the hypothermia caused by anesthesia and surgery. FAW consists of a large heater/blower attached by a hose to an inflatable air blanket. The warm air is distributed over the patient within the chambers of the blanket and then is exhausted onto the patient through holes in the bottom surface of the blanket.

[0006] Although FAW is clinically effective, it suffers from several problems including: a relatively high price; air blowing in the operating room, which can be noisy and can potentially contaminate the surgical field; and bulkiness, which, at times, may obscure the view of the surgeon. Moreover, the low specific heat of air and the rapid loss of heat from air require that the temperature of the air, as it leaves the hose, be dangerously high—in some products as high as 45° C. This poses significant dangers for the patient. Second and third degree burns have occurred both because of contact between the hose and the patient's skin, and by blowing hot air directly from the hose onto the skin without connecting a blanket to the hose. This condition is common enough to have its own name—"hosing." The manufacturers of forced air warming equipment actively warn their users against hosing and the risks it poses to the patient.

[0007] To overcome the aforementioned problems with FAW, several companies have developed electric warming blankets. However, there is still a need for electrically heated blankets or pads that can be used safely and effectively warm patients undergoing surgery or other medical treatments. These blankets need to be flexible in order to effectively drape over the patient (making excellent contact for conductive heat transfer and maximizing the area of the patient's skin receiving conductive as well as radiant heat transfer), and should incorporate means for precise temperature control.

[0008] Precise temperature control is important because non-uniform heat distribution can occur within an electric warming blanket. Unfortunately, many temperature sensors used to provide feedback to a temperature controller do not dependably report an accurate average temperature of the blanket because they sense temperature from too small of an area. For example, if the temperature of a measured location is cooler than the average blanket temperature, the temperature sensor will cause the controller to deliver more power to the heater and the resulting average temperature of the heater will be higher than desired.

[0009] Further, an electric blanket can overheat if the temperature sensor is thermally grounded to a cool object. This condition can occur if a cool object such as a metal pan is placed on top of the heater in the area of the temperature sensor. The sensor "feels" cool and tells the temperature controller to deliver more power to the heater.

[0010] Accordingly, there is a need for a blanket that utilizes a temperature sensor that takes temperature measurements that are representative of the average temperature of the blanket. Further, there is a need for a blanket with a temperature sensor that will not cause the blanket to overheat if a cool object is placed in proximity to it. Various embodiments of the invention described herein solve one or more of the problems discussed above.

BRIEF DESCRIPTION OF THE DRAWINGS

[0011] The following drawings are illustrative of particular embodiments of the present invention and therefore do not limit the scope of the invention. The drawings are not to scale (unless so stated) and are intended for use in conjunction with the explanations in the following detailed description. Embodiments of the present invention will hereinafter be described in conjunction with the appended drawings, wherein like numerals denote like elements.

[0012] FIG. **1**A is a plan view of a flexible heating blanket subassembly for a heating blanket, according to some embodiments of the present invention.

[0013] FIGS. **1**B-C are end views of two embodiments of the subassembly shown in FIG. **1**A.

[0014] FIG. **1**D is a schematic showing a blanket including the subassembly of FIG. **1**A draped over a body.

[0015] FIG. **2**A is a top plan view of a heating element assembly, according to some embodiments of the present invention, which may be incorporated in the blanket shown in FIG. **3**A.

[0016] FIG. **2**B is a section view through section line A-A of FIG. **2**A.

[0017] FIG. **2**C is an enlarged plan view and corresponding end view schematic of a portion of the assembly shown in FIG. **2**A, according to some embodiments of the present invention.

[0018] FIG. **2**D is an enlarged view of a portion of the assembly shown in FIG. **2**A, according to some embodiments of the present invention.

[0019] FIG. **3**A is a top plan view, including partial cut-away views, of a lower body heating blanket, according to some embodiments of the present invention.

[0020] FIG. **3**B is a schematic side view of the blanket of FIG. **3**A draped over a lower body portion of a patient.

[0021] FIG. **3**C is a top plan view of a heating element assembly, which may be incorporated in the blanket shown in FIG. **3**A.

[0022] FIG. **3**D is a cross-section view through section line D-D of FIG. **3**C.

[0023] FIG. **4**A is a plan view of flexible heating element, according to some alternate embodiments of the present invention.

[0024] FIG. **4**B is a top plan view, including a partial cut-away view, of a heating element assembly, according to some embodiments of the present invention, which may be incorporated in the blanket shown in FIG. **4**C.

[0025] FIG. **4**C is a top plan view, including a partial cut-away view, of an upper body heating blanket, according to some embodiments of the present invention.

[0026] FIG. **4**D is a schematic end view of the blanket of FIG. **4**B draped over an upper body portion of a patient.

DETAILED DESCRIPTION

[0027] The following detailed description is exemplary in nature and is not intended to limit the scope, applicability, or configuration of the invention in any way. Rather, the following description provides practical illustrations for implementing exemplary embodiments of the present invention. Examples of constructions, materials, dimensions, and manufacturing processes are provided for selected elements, and all other elements employ that which is known to those of skill in the field of the invention. Those skilled in the art will recognize that many of the examples provided have suitable alternatives that can be utilized. The term 'blanket', used to describe embodiments of the present invention, may be considered to encompass heating blankets and pads.

[0028] FIG. **1**A is a plan view of a flexible heating blanket subassembly **100**, according to some embodiments of the present invention; and FIGS. **1**B-C are end views of two embodiments of the subassembly shown in FIG. **1**A. FIG. **1**A illustrates a flexible sheet-like heating element, or heater, **10** of subassembly **100** including a first end **101**, a second end **102**, a first lateral portion **11** extending between ends **101**, **102**, and a second lateral portion **12**, opposite first lateral portion **11**, also extending between ends **101**, **102**. According to preferred embodiments of the present invention, heater **10** comprises a conductive fabric or a fabric incorporating closely spaced conductive elements such that heater **10** has a substantially uniform watt density output, preferably less than approximately 0.5 watts/sq. inch, and more preferably between approximately 0.2 and approximately 0.4 watts/sq. inch, across a surface area, of one or both sides **13**, **14** (FIGS. **1**B-C), the surface area including and extending between lateral portions **11**, **12** of heater **10**. Some examples of conductive fabrics which may be employed by embodiments of the present invention include, without limitation, carbon fiber fabrics, fabrics made from carbonized fibers, woven or non-woven non-conductive substrates coated with a conductive material, for example, polypyrrole, carbonized ink, or metalized ink.

[0029] FIG. **1**A further illustrates subassembly **100** including two bus bars **15** coupled to heating element **10** for powering element **10**; each bar **15** is shown extending alongside opposing lateral portions **11**, **12**, between first and second ends **101**, **102**. With reference to FIG. **1**B, according to some embodiments, bus bars **15** are coupled to heating element **10** within folds of opposing wrapped perimeter edges **108** of heating element **10** by a stitched coupling **145**, for example, formed with conductive thread such as silver-coated polyester or nylon thread (Marktek Inc., Chesterfield, Mo.), extending through edges **108** of heating element **10**, bars **15**, and again through heating element **10** on opposite side of bars **15**. According to alternate embodiments heating element **10** is not folded over bus bars **15** as shown. Alternative threads or yarns employed by embodiments of the present invention may be made of other polymeric or natural fibers coated with other electrically conductive materials; in addition, nickel, gold, platinum and various conductive polymers can be used to make conductive threads. Metal threads such as stainless steel, copper or nickel could also be used for this application. According to an exemplary embodiment, bars **15** are comprised of flattened tubes of braided wires, such as are known to those skilled in the art, for example, a flat braided silver coated copper wire, and may thus accommodate the thread extending therethrough, passing through openings between the braided wires thereof. In addition such bars are flexible to enhance the flexibility of blanket subassembly **100**. According to alternate embodiments, bus bars **15** can be a conductive foil or wire, flattened braided wires not formed in tubes, an embroidery of conductive thread, or a printing of conductive ink. Preferably, bus bars **15** are each a flat braided silver-coated copper wire material, since a silver coating has shown superior durability with repeated flexion, as compared to tin-coated wire, for example, and may be less susceptible to oxidative interaction with a polypyrrole coating of heating element **10** according to an embodiment described below. Additionally, an oxidative potential, related to dissimilar metals in contact with one another is reduced if a silver-coated thread is used for stitched coupling **145** of a silver-coated bus bar **15**.

[0030] According to an exemplary embodiment, a conductive fabric comprising heating element **10** comprises a non-woven polyester having a basis weight of approximately 130 g/m^2 and being 100% coated with polypyrrole (available from Eeonyx Inc., Pinole, Calif.); the coated fabric has an average resistance, for example, determined with a four point probe measurement, of approximately 15-20 ohms per square inch at about 48 volts, which is suitable to produce the preferred watt density of 0.2 to 0.4 watts/sq. in. for surface areas of heating element **10** having a width, between bus bars **15**, in the neighborhood of about 20 inches. Such a width is suitable for a lower body heating blanket, some embodiments of which will be described below. A resistance of such a conductive fabric may be tailored for different widths between bus bars (wider requiring a lower resistance and narrower requiring a higher resistance) by increasing or decreasing a surface area of the fabric that can receive the conductive coating, for example by increasing or decreasing the basis weight of the fabric. Resistance over the surface area of the conductive fabrics is generally uniform in many embodiments of the present invention. However, the resistance over different portions of the surface area of conductive fabrics such as these may vary, for example, due to variation in a thickness of a conductive coating, variation within the conductive coating itself, variation in effective surface area of the substrate which is available to receive the conductive coating, or variation in the density of the substrate itself. Local surface resistance across a heating element, for example heater **10**, is directly related to heat generation according to the following relationship:

$$Q(\text{Joules})=I^2(\text{Amps})\times R(\text{Ohms})$$

Variability in resistance thus translates into variability in heat generation, which is measured as a temperature. According to preferred embodiments of the present invention, which are employed to warm patients undergoing surgery, precise temperature control is desirable. Means for determining heating element temperatures, which average out temperature variability caused by resistance variability across a surface of the heating element, are described below in conjunction with FIGS. **2**A-B.

[0031] A flexibility of blanket subassembly **100**, provided primarily by flexible heating element **10**, and optionally enhanced by the incorporation of flexible bus bars, allows blanket subassembly **100** to conform to the contours of a body, for example, all or a portion of a patient undergoing surgery, rather than simply bridging across high spots of the body; such conformance may optimize a conductive heat transfer from element **10** to a surface of the body. However, as illustrated in FIG. **1**D, heating element **10** may be draped over a body **16** such that lateral portions **11**, **12** do not contact side surfaces of body **16**; the mechanism of heat transfer between portions **11**, **12** and body **16**, as illustrated in FIG. **1**D, is primarily radiant with some convection.

[0032] The uniform watt-density output across the surface areas of preferred embodiments of heating element **10** translates into generally uniform heating of the surface areas, but not necessarily a uniform temperature. At locations of heating element **10** which are in conductive contact with a body acting as a heat sink, for example, body **16**, the heat is efficiently drawn away from heating element **10** and into the body, for example by blood flow, while at those locations where element **10** does not come into conductive contact with the body, for example lateral portions **11**, **12** as illustrated in FIG. **1**D, an insulating air gap exists between the body and those portions, so that the heat is not drawn off those portions as easily. Therefore, those portions of heating element **10** not in conductive contact with the body will gain in temperature, since heat is not transferred as efficiently from these portions as from those in conductive contact with the body. The 'non-contacting' portions will reach a higher equilibrium temperature than that of the 'contacting' portions, when the radiant and convective heat loss equal the constant heat production through heating element **10**. Although radiant and convective heat transfer are more efficient at higher heater temperatures, the laws of thermodynamics dictate that as long as there is a uniform watt-density of heat production, even at the higher temperature, the radiant and convective heat transfer from a blanket of this construction will result in a lower heat flux to the skin than the heat flux caused by the conductive heat transfer at the 'contacting' portions at the lower temperature. Even though the temperature is higher, the watt-density is uniform and, since the radiant and convective heat transfer are less efficient than conductive heat transfer, the 'non-contacting' portions must have a lower heat flux. Therefore, by controlling the 'contacting' portions to a safe temperature, for example, via a temperature sensor **121** coupled to heating element **10** in a location where element **10** will be in conductive contact with the body, as illustrated in FIG. **1**D, the 'non-contacting' portions, for example, lateral portions **11**, **12**, will also be operating at a safe temperature because of the less efficient radiant and convective heat transfer. According to preferred embodiments, heating element **10** comprises a conductive fabric having a relatively small thermal mass so that when a portion of the heater that is operating at the higher temperature is touched, suddenly converting a 'non-contacting' portion into a 'contacting' portion, that portion will cool almost instantly to the lower operating temperature.

[0033] According to embodiments of the present invention, zones of heating element **10** may be differentiated according to whether or not portions of element **10** are in conductive contact with a body, for example, a patient undergoing surgery. In the case of conductive heating, gentle external pressure may be applied to a heating blanket including heating element **10**, which pressure forces heating element **10** into better conductive contact with the patient to improve heat transfer. However, if excessive pressure is applied the blood flow to that skin may be reduced at the same time that the heat transfer is improved and this combination of heat and pressure to the skin can be dangerous. It is well known that patients with poor perfusion should not have prolonged contact with conductive heat in excess of approximately 42° C. 42° C. has been shown in several studies to be the highest skin temperature, which cannot cause thermal damage to normally perfused skin, even with prolonged exposure. (Stoll & Greene, Relationship between pain and tissue damage due to thermal radiation. J. Applied Physiology 14(3):373-382, 1959. and Moritz and Henriques, Studies of thermal injury: The relative importance of time and surface temperature in the causation of cutaneous burns. Am. J. Pathology 23:695-720, 1947) Thus, according to certain embodiments of the present invention, the portion of heating element **10** that is in conductive contact with the patient is controlled to approximately 43° C. in order to achieve a temperature of about 41-42° C. on a surface a heating blanket cover that surrounds element **10**, for example, a cover or shell **20**, **40** which will be described below in conjunction with FIGS. **3**A and **4**C. With further reference to FIG. **1**D, flaps **125** are shown extending laterally from either side of heating element **10** in order to enclose the sides of body **16** thereby preventing heat loss; according to preferred embodiments of the present invention, flaps **125** are not heated and thus provide no thermal injury risk to body if they were to be tucked beneath sides of body **16**.

[0034] Referring now to the end view of FIG. **1**C, an alternate embodiment to that shown in FIG. **1**B is presented. FIG. **1**C illustrates subassembly **100** wherein insulating members **18**, for example, fiberglass material strips having an optional PTFE coating and a thickness of approximately 0.003 inch, extend between bus bars **15** and heating element **10** at each stitched coupling **145**, so that electrical contact points between bars **15** and heating element **10** are solely defined by the conductive thread of stitched couplings **145**.

[0035] FIG. **2**A is a top plan view of a heating element assembly **250**, according to some embodiments of the present invention, which may be incorporated by blanket **200**, which is shown in FIG. **3**A and further described below. FIG. **2**B is a section view through section line A-A of FIG. **2**A. FIGS.

2A-B illustrate a temperature sensor assembly **421** assembled on side **14** of heater **10**, and heater **10** overlaid on both sides **13**, **14** with an electrically insulating layer **210**, preferably formed of a flexible non-woven high loft fibrous material, for example, 1.5 OSY (ounces per square yard) nylon, which is preferably laminated to sides **13**, **14** with a hotmelt laminating adhesive. In some embodiments, the adhesive is applied over the entire interfaces between layer **210** and heater **10**. Other examples of suitable materials for layer **210** include, without limitation, polymeric foam, a woven fabric, such as cotton or fiberglass, and a relatively thin plastic film. According to preferred embodiments, overlaid layers **210**, without compromising the flexibility of heating assembly **250**, prevent electrical shorting of one portion of heater **10** with another portion of heater **10** if heater **10** is folded over onto itself. Heating element assembly **250** may be enclosed within a relatively durable and waterproof shell, for example shell **20** shown with dashed lines in FIG. **2**B, and will be powered by a relatively low voltage (approximately 48V). Layers **210** may even be porous in nature to further maintain the desired flexibility of assembly **250**.

[0036] FIG. **2**C is an enlarged plan view and a corresponding end view schematic showing some details of the corner of assembly **250** that is circled in FIG. **2**A, according to some embodiments. FIG. **2**C is representative of each corner of assembly **250**. FIG. **2**C illustrates insulating layer **210** disposed over side **14** of heater **10** and extending beneath bus bar **15**, optional electrical insulating member **18**, and layer **210** disposed over side **13** of heater **10** and terminated adjacent bus bar **15** within lateral portion **12** so that threads of conductive stitching **145** securing bus bars **15** to heater **10** electrically contact heating element **10** along side **13** of heating element **10**. FIG. **2**C further illustrates two rows of conductive stitching **145** coupling bus bar **15** to heating element **10**, and bus bar **15** and insulating member **18** extending past end **102**.

[0037] FIG. **2**A further illustrates junctions **50** coupling leads **205** to each bus bar **15**, and another lead **221** coupled to and extending from temperature sensor assembly **421**; each of leads **205**, **221** extend over insulating layer **210** and into an electrical connector housing **225** containing a connector **23**, which will be described in greater detail below, in conjunction with FIGS. **3**A-C. FIG. **2**D is an enlarged view of junction **50**, which is circled in FIG. **2**A, according to some embodiments of the present invention. FIG. **2**D illustrates junction **50** including a conductive insert **55** which has been secured to bus bar **15**, for example, by inserting insert **55** through a side wall of bus bar **15** and into an inner diameter thereof. FIG. **2**D further illustrates lead **205** coupled to insert **55**, for example, via soldering, and an insulating tube and strain relief **54**, for example, a polymer shrink tube, surrounding the coupling between lead **205** and insert **55**.

[0038] Returning now to FIG. **2**B, temperature sensor assembly **421** will be described in greater detail. FIG. **2**B illustrates assembly **421** including a substrate **211**, for example, of polyimide (Kapton), on which a temperature sensor **21**, for example, a surface mount chip thermistor (such as a Panasonic ERT-J1VG103FA: 10K, 1% chip thermistor), is mounted; a heat spreader **212**, for example, a copper or aluminum foil, is mounted to an opposite side of substrate **211**, for example, being bonded with a pressure sensitive adhesive; substrate **211** is relatively thin, for example about 0.0005 inch thick, so that heat transfer between heat spreader **212** and sensor is not significantly impeded. Temperature sensor assembly **421** may be bonded to layer **210** with an adhesive layer **213**, for example, hotmelt EVA. Although not shown, it should be noted that sensor assembly **421** may be potted with a flexible electrically insulating material, such as silicon or polyurethane.

[0039] According to the illustrated embodiment, heat spreader **212** is sized to contact an enlarged surface area so that a temperature sensed by sensor **21** is more representative of an average temperature over a region of heater **10** surrounding sensor **21**, which is positioned such that, when a heating blanket including heater **10** is placed over a body, the regions surrounding sensor **21** will be in conductive contact with the body. As previously described, it is desirable that a temperature of approximately 43° C. be maintained over a surface of heater **10** which is in conductive contact with a body of a patient undergoing surgery. Other types of heat spreaders, in addition to metallic foils, include metallic meshes or screens, or an adhesive/epoxy filled with a thermally conductive material.

[0040] Heat spreader **212** is a desirable component of a temperature sensor assembly, according to some embodiments of the present invention, since conductive fabrics employed by heating element **10**, such as those previously described, may not exhibit uniform resistance across surface areas thereof. Heat spreader **212**, having a surface area that does not exceed approximately four square inches, according to a preferred embodiment, may be effective in averaging out relatively small scale spatial resistance variation, for example, about 3% to 10% variability over less than about one or two inches. Such a limitation on heat spreader **212** surface area may be necessary so that heat spreader **212** does not become too bulky, since the larger the surface area, the greater the thickness of spreader **212** needed in order to maintain effective heat transfer across spreader **212** and to sensor **21**. In addition, if spreader **212** is too thick, a thermal mass of spreader **212** will cause spreader **212** to respond too slowly to changes in heat loss or gain by heating element. According to an exemplary embodiment of the present invention, spreader **212** has a surface area of no greater than approximately four square inches and a thickness of no greater than approximately 0.001 inch. Some alternate embodiments of the present invention address a non-uniform resistance across a surface area of element **10** by employing a distributed temperature sensor, for example, a resistance temperature detector (RTD) laid out in flat plane across a surface of heater **10**, or by employing an infrared temperature measurement device positioned to receive thermal radiation from a given area of heater **10**. An additional alternate embodiment is contemplated in which an array of temperature sensors are positioned over the surface of heater **10**, being spaced apart so as to collect temperature readings which may be averaged to account for resistance variance.

[0041] According to a preferred embodiment, assembly **421** includes a second, redundant, temperature sensor mounted to substrate **211**, close enough to sensor **21** to detect approximately the same temperature; while sensor **21** may be coupled to a microprocessor temperature control, the second sensor, for example, a chip thermistor similar to sensor **21**, may be coupled to an analog over-temperature cutout that cuts power to element **10**, and/or sends a signal triggering an audible or visible alarm. The design of the second sensor may be the same as the first sensor and need not be described again. Another safety check may be provided by mounting an identification resistor to substrate **211** in order to detect an increase in resistance of element **10**, due, for example, to degradation of the material of element **10**, or a fractured bus bar; the optional identification resistor monitors a resistance of heating element **10** and compares the measured resistance to an original resistance of element **10**.

[0042] According to some embodiments of the present invention, for example as illustrated in FIG. **2**A, super over-temperature sensors **41** are incorporated to detect overheating of areas of assembly **250** susceptible to nicking, that is areas, for example, lateral portions **11**, **12**, where assembly **250** is most likely to be folded over on itself, either inadvertently or on purpose to gain access to a portion of a patient disposed beneath a blanket including assembly **250**. An area of assembly **250** which is beneath the folded-over portion of assembly **250**, and not in close proximity to sensor assembly **421**, can become significantly warmer due to the additional thermal insulation provided by the folded-over portion that goes undetected by sensor **21**. According to preferred embodiments, sensors **41** are wired in series, as illustrated in FIG. **2**A. Super over-temperature sensors **41** may be set to open, or significantly increase resistance in, a circuit, for example, the over-temperature circuit, thereby activating an alarm and/or cutting power to heating element **10**, at prescribed temperatures that are significantly above the normal operating range, for example, temperatures between approximately 45° C. and approximately 60° C. Alternately, sensors **41** may be part of the bus bar power circuit, in which case sensors **41** directly shut down power to heating element **10** when in an open condition or add sufficient resistance when in a high resistance condition to substantially reduce heating of element **10**.

[0043] FIG. **3**A is a top plan view, including partial cut-away views, of a lower body heating blanket **200**, according to some embodiments of the present invention, which may be used to keep a patient warm during surgery. FIG. **3**A illustrates blanket **200** including heating element assembly **250** covered by flexible shell **20**; shell **20** protects and isolates assembly **250** from an external environment of blanket **200** and may further protect a patient disposed beneath blanket **200** from electrical shock hazards. According to preferred embodiments of the present invention, shell **20** is waterproof to prevent fluids, for example, bodily fluids, IV fluids, or cleaning fluids, from contacting assembly **250**, and may further include an anti-microbial element, for example, being a SILVERion™ antimicrobial fabric available from Domestic Fabrics Corporation. According to the illustrated embodiment, blanket **200** further includes a layer of thermal insulation **201** extending over a top side (corresponding to side **14** of heating element **10**) of assembly **250**; layer **201** may or may not be bonded to a surface of assembly **250**. Layer **201** may serve to prevent heat loss away from a body disposed on the opposite side of blanket **200**, particularly if a heat sink comes into contact with the top side of blanket **200**. FIG. **3**C illustrates insulation **201** extending over an entire surface of side **14** of heating element **10** and over sensor assembly **421**. According to the illustrated embodiment, layer **201** is secured to heating element assembly **250** to form an assembly **250'**, as will be described in greater detail below. According to an exemplary embodiment of the present invention, insulating layer **201** comprises a polymer foam, for example, a 1 pound density 30 ILD urethane foam, which has a thickness between approximately $1/8^{th}$ inch and approximately $3/4^{th}$ inch. According to alternate embodiments layer **201** comprises any, or a combination of the following: high loft fibrous polymeric non-woven material, non-woven cellulose material, and air, for example, held within a polymeric film bubble.

[0044] FIG. **3**A further illustrates shell **20** forming flaps **25** extending laterally from either side of assembly **250** and a foot drape **26** extending longitudinally from assembly **250**. According to exemplary embodiments of the present invention, a length of assembly **250** is either approximately 28 inches or approximately 48 inches, the shorter length providing adequate coverage for smaller patients or a smaller portion of an average adult patient. FIG. **3**B is a schematic side view of blanket **200** draped over a lower body portion of a patient. With reference to FIG. **3**B it may be appreciated that flaps **25**, extending down on either side of the patient, and foot drape **26**, being folded under and secured by reversible fasteners **29** (FIG. **3**A) to form a pocket about the feet of the patient, together effectively enclose the lower body portion of the patient to prevent heat loss. With reference to FIG. **2**A, in conjunction with FIG. **3**B, it may be appreciated that temperature sensor assembly **421** is located on assembly **250** so that, when blanket **200** including assembly **250** is draped over the lower body of the patient, the area of heating element **10** surrounding sensor assembly **421** will be in conductive contact with one of the legs of the patient in order to maintain a safe temperature distribution across element **10**.

[0045] According to some embodiments of the present invention, shell **20** includes top and bottom sheets extending over either side of assembly **250**; the two sheets of shell **20** are coupled together along a seal zone **22** (shown with cross-hatching in the cut-away portion of FIG. **3**A) that extends about a perimeter edge **2000** of blanket **200**, and within perimeter edge **2000** to form zones, or pockets, where a gap exists between the two sheets.

[0046] FIG. **3**A further illustrates flaps **25** including zones where there are gaps between the sheets to enclose weighting members, which are shown as relatively flat plastic slabs **255**. Alternately flaps **25** can be weighted by attaching weighting members to exterior surfaces thereof.

[0047] FIG. **3**C is a top plan view, including partial cut-away views, of heating element assembly **250'**, which may be incorporated in blanket **200**; and FIG. **3**D is a cross-section view through section line D-D of FIG. **3**C. FIGS. **3**C-D illustrates heating element assembly **250'** including heating element **10** overlaid with electrical insulation **210** on both sides **13**, **14** and thermal insulation layer **201** extending over the top side **14** thereof (dashed lines show leads and sensor assembly beneath layer **201**). According to the illustrated embodiment, layer **201** is inserted beneath a portion of each insulating member **18**, each which has been folded over the respective bus bar **15**, for example as illustrated by arrow B in FIG. **1**C, and then held in place by a respective row of non-conductive stitching **345** that extends through member **18**, layer **201** and heating element **10**. Although layer **210** is shown extending beneath layer **201** on side **14** of heating element, according to alternate embodiments, layer **201** independently performs as a thermal and electrical insulation so that layer **210** is not required on side **14** of heating element **10**.

[0048] Returning now to FIG. **2**A, to be referenced in conjunction with FIGS. **3**A-C, connector housing **225** and connector **23** will be described in greater detail. According to certain embodiments, housing **225** is an injection molded thermoplastic, for example, PVC, and may be coupled to assembly **250** by being stitched into place, over insulating layer **210**. FIG. **2**A shows housing **225** including a flange **253** through which such stitching can extend. With reference to FIGS. **3**A-B, it can be seen that connector **23** protrudes from shell **20** of blanket **200** so that an extension cable **330** may couple bus bars **15** to a power source **234**, and temperature sensor assembly **421** to a temperature controller **232**, both shown incorporated into a console **333**. In certain embodiments, power source **234** supplies a pulse-width-modulated voltage to bus bars **15**. The controller **232** may function to interrupt such power supply (e.g., in an over-temperature condition) or to modify the duty cycle to control the heating element temperature. According to the illustrated embodiment, a surface **252** of flange **253** of housing **225** protrudes through a hole formed in thermal insulating layer **201** (FIG. 3C) so that a seal **202** (FIG. 3A) may be formed, for example, by adhesive bonding and/or heat sealing, between an inner surface of shell **20** and surface **252**.

[0049] FIGS. 3C-D further illustrate a pair of securing strips **217**, each extending laterally from and alongside respective lateral portions **11**, **12** of heating element **10** and each coupled to side **13** of heating element **10** by the respective row of stitching **345**. Another pair of securing strips **271** is shown in FIG. 3C, each strip **271** extending longitudinally from and alongside respective ends **101**, **102** of heating element **10** and being coupled thereto by a respective row of non-conductive stitching **354**. Strips **217** preferably extend over conductive stitching **145** on side **13** of heating element **10**, as shown, to provide a layer of insulation that can prevent shorting between portions of side **13** of heating element **10** if element **10** were to fold over on itself along rows of conductive stitching **145** that couple bus bars **15** to heating element **10**; however, strips **217** may alternately extend over insulating member **18** on the opposite side of heating element **10**. According to the illustrated embodiment, securing strips **217** and **271** are made of a polymer material, for example polyurethane, so that they may be heat sealed between the sheets of shell **20** in corresponding areas of heat seal zone **22** in order to secure heating element assembly **250'** within the corresponding gap between the two sheets of shell **20** (FIG. 3A).

[0050] FIG. 4A is a plan view of flexible heating element **30**, according to some alternate embodiments of the present invention. Heating element **30** is similar in nature to previously described embodiments of heating element **10**, being comprised of a conductive fabric, or a fabric incorporating closely spaced conductive elements, for a substantially uniform watt density output, preferably less than approximately 0.5 watts/sq. inch. While a shape of the surface area of heating element **10** is suited for a lower body blanket, such as blanket **200**, that would cover a lower abdomen and legs of a patient (FIG. 3B) undergoing upper body surgery, the shape of a surface area of heating element **30** is suited for an upper body heating blanket, for example, blanket **300** shown in FIG. 4C, that would cover outstretched arms and a chest area of a patient undergoing lower body surgery (FIG. 4D). With reference to FIG. 4B, which shows heating element **30** incorporated into a heating element assembly **450**, it can be seen that bus bars **15** are coupled to element **30** alongside respective lateral edges **311**, **312** (FIG. 4A).

[0051] FIG. 4B is a top plan view, including partial cutaway views, of heating element assembly **450**, according to some embodiments of the present invention, which may be incorporated in blanket **300** shown in FIG. 4C. FIG. 4B illustrates assembly **450** having a configuration similar to that of assembly **250'**, which is illustrated in FIGS. 3C-D. According to the embodiment illustrated in FIG. 4B, temperature sensor assembly **421** is coupled to heating element **30** at a location where element **30**, when incorporated in an upper body heating blanket, for example, blanket **300**, would come into conductive contact with the chest of a patient, for example as illustrated in FIG. 4D, in order to maintain a safe temperature distribution across element **30**; bus bar junctions **50** and connector housing **225** are located in proximity to sensor assembly **421** in order to keep a length of leads **205** and **221** to a minimum. With reference back to FIGS. 3C-D, in conjunction with FIG. 4B, an electrical insulating layer **310** of assembly **450** corresponds to insulating layers **210** of assembly **250'**, a thermal insulating layer **301** of assembly **450** corresponds to layer **201** of assembly **250'**, and securing strips **317** and **371** of assembly **450** generally correspond to strips **217** and **271**, respectively, of assembly **250'**.

[0052] FIG. 4C is a top plan view, including partial cutaway views, of upper body heating blanket **300**, according to some embodiments of the present invention. FIG. 4C illustrates blanket **300** including heating element assembly **450** covered by a flexible shell **40**; shell **40** protects and isolates assembly **450** from an external environment of blanket **300** and may further protect a patient disposed beneath blanket **300** from electrical shock hazards. According to the illustrated embodiment, shell **40**, like shell **20**, includes top and bottom sheets; the sheets extend over either side of assembly **450** and are coupled together along a seal zone **32** that extends around a perimeter edge **4000** and within edge **4000** to form various zones, or pockets, where gaps exist between the two sheets. The sheets of shell **40** may be heat sealed together along zone **32**, as previously described for the sheets of shell **20**. With reference to FIG. 4B, securing strips **317** may be heat sealed between the sheets of shell **40** in corresponding areas of seal zone **32**, on either side of a central narrowed portion **39** of blanket **300**, in order to secure heating element assembly **450** within the corresponding gap between the two sheets of shell **40**. According to an alternate embodiment, for example, as shown with dashed lines in FIG. 4A, lateral edges **311**, **312** of heating element **30** extend out to form securing edges **27** that each include slots or holes **207** extending therethrough so that inner surfaces of sheets of shell **40** can contact one another to be sealed together and thereby hold edges **27**. It should be noted that either of blankets **200**, **300**, according to alternate embodiments of the present invention, may include more than one heating element **10**, **30** and more than one assembly **250/250'**, **450**.

[0053] With reference to FIG. 4C, it may be appreciated that blanket **300** is symmetrical about a central axis **30** and about another central axis, which is orthogonal to axis **30**. FIG. 4C illustrates shell **40** forming flaps **35**A, **35**B and **350**, each of which having a mirrored counterpart across central axis **30** and across the central axis orthogonal to axis **30**. According to the illustrated embodiment, each of flaps **35**A, B include weighting members **305**, which are similar to members **255** of blanket **200**, and which may stiffen flaps **35**A,B (dashed lines indicate outlines of members **305** held between the sheets of cover **40** by surrounding areas of seal zone **32**).

[0054] FIG. 4C further illustrates straps **38**, each extending between respective flaps **35**A-B. With reference to FIG. 4D, which is a schematic end view of blanket **300** draped over an upper body portion of a patient, it may be appreciated that flaps **35**A-B and **350** extend downward to enclose the outstretched arms of the patient in order to prevent heat loss and that straps **38** secure blanket **300** about the patient.

[0055] With further reference to FIG. 4D, it may also be appreciated that, when blanket **300** is positioned over the patient, each strap **38** is positioned in proximity to an elbow of the patient so that either end portion of blanket **300**, corresponding to each pair of flaps **35**A, may be temporarily folded back, as illustrated, per arrow C, in order for a clinician to access the patient's arm, for example, to insert or adjust an IV. According to some embodiments of the present invention, super over-temperature sensors, for example, sensors **41**, previously described, are included in blanket **300** being located according to the anticipated folds, for example at general locations **410** illustrated in FIGS. **4**B-C, in order to detect over-heating, which may occur if blanket **300** is folded over on itself, as illustrated in FIG. **4**D, for too long a time, and, particularly, if flaps **35**A of folded-back portion of blanket are allowed to extend downward as illustrated with the dashed line in FIG. **4**D. FIG. **4**D further illustrates connector cord **330** plugged into connector **23** to couple heating element **30** and temperature sensor assembly **421** of blanket **300** to control console **333**.

[0056] In the foregoing detailed description, the invention has been described with reference to specific embodiments. However, it may be appreciated that various modifications and changes can be made without departing from the scope of the invention as set forth in the appended claims. Although embodiments of the invention are described in the context of a hospital operating room, it is contemplated that some embodiments of the invention may be used in other environments. Those embodiments of the present invention, which are not intended for use in an operating environment and need not meet stringent FDA requirements for repeated used in an operating environment, need not including particular features described herein, for example, related to precise temperature control. Thus, some of the features of preferred embodiments described herein are not necessarily included in preferred embodiments of the invention which are intended for alternative uses.

1.-**16**. (canceled)

17. An electric warming blanket for warming patients during surgery and other medical procedures, comprising:

a flexible heater including a first side, a second side, opposite the first side, and a first edge and a second edge, opposite the first edge, the heater having a substantially uniform watt density output across a surface area of the first and second sides, when the heater is electrically powered;

a pair of bus bars for powering the heater, a first of the pair of bus bars being coupled to the one of the first side and the second side of the heater, along the first edge thereof, and a second of the pair of bus bars being coupled to one of the first side and the second side of the heater, along the second edge thereof;

a temperature sensor assembly coupled to the first side of the heater at a first location on the first side between the first and second bus bars, the temperature sensor assembly including a first temperature sensor, a second temperature sensor and a heat spreader, the heat spreader extending over the first location between the first side of the heater and the first and second temperature sensors, and the first and second temperature sensors detecting approximately the same temperature; and

a first layer of water resistant material extending completely over the first side of the heater and the temperature sensor assembly, and a second layer of water resistant material extending completely over the second side of the heater, the first and second layers being coupled together along a seal zone that extends about a perimeter edge of the blanket to form a substantially hermetically sealed space for the heater and the temperature sensor assembly.

18. The blanket of claim **17**, wherein:

the temperature sensor assembly provides input of the detected temperature to a means for controlling a supply of power to the bus bars based on the detected temperature; and

the second temperature sensor of the assembly provides input to a means for cutting the supply of power based on the detected temperature.

19. The blanket of claim **17**, wherein:

the temperature sensor assembly provides input of the detected temperature to a means for controlling a supply of power to the bus bars based on the detected temperature; and

the second temperature sensor of the assembly provides input to trigger an alarm.

20. The blanket of claim **17**, wherein the heat spreader has a surface area that is no greater than approximately four square inches.

21. The blanket of claim of claim **17**, wherein the heat spreader comprises a metal foil.

22. The blanket of claim **21**, wherein the metal is copper.

23. The blanket of claim **17**, wherein the heat spreader has a thickness of approximately 0.001 inch.

24. The blanket of claim **17**, further comprising:

at least one super over-temperature sensor coupled to the heater between the first and second bus bars at another location spaced apart from the first location;

wherein the at least one super over-temperature sensor is adapted to interrupt a supply of power to the first and second bus bars and/or to activate an alarm at a prescribed temperature that exceeds a normal operating range.

25. The blanket of claim **24**, wherein the at least one super over-temperature sensor comprises a plurality of super over-temperature sensors wired in series with one another.

26. The blanket of claim **25**, wherein one of the plurality of super over-temperature sensors is located in proximity to one of the first and second bus bars.

27. The blanket of claim **24**, wherein the at least one super over-temperature sensor is adapted to activate an alarm at the prescribed temperature.

28. The blanket of claim **24**, wherein the prescribed temperature is between approximately 45° C. and approximately 60° C.

29. The blanket of claim **17**, further comprising a first layer of flexible electrically insulating material extending between the temperature sensor assembly and the first side of the heater.

30. The blanket of claim **29**, wherein:

the first layer of flexible electrically insulating material is laminated to the first side of the heater; and

the temperature sensor assembly is bonded to the first layer of flexible electrically insulating material.

31. The blanket of claim **29**, further comprising a layer of thermal insulation extending over the entire first side of heater, between the first and second bus bars, and over the temperature sensor assembly, the first layer of water resistant material also extending over the layer of thermal insulation.

32. The blanket of claim **17**, further comprising a layer of thermal insulation extending over the entire first side of heater and over the temperature sensor assembly, the first layer of water resistant material also extending over the layer of thermal insulation.

33. The blanket of claim **17**, wherein:

the first location on the first side of the heater is located within a first temperature zone of the surface area of the heater, the first temperature zone being defined by a contacting portion of the second side of the heater, the contacting portion being in conductive contact with a patient when the blanket is placed over the patient; and

the surface area of the heater further includes a second temperature zone, the second temperature zone being defined by a non-contacting portion of the second side of the heater, the non-contacting portion not being in conductive contact with the patient when the blanket is placed over the patient.

34. The blanket of claim **33**, further comprising a temperature controller, the temperature controller being adapted to control a supply of power to the first and second bus bars, according to the detected temperature, in order to maintain a temperature of first temperature zone lower than a higher temperature of the second temperature zone.

35. The blanket of claim **33**, further comprising:

at least one super over-temperature sensor coupled to the heater between the first and second bus bars at another location spaced apart from the first location;

wherein the at least one super over-temperature sensor is adapted to interrupt a supply of power to the first and second bus bars at a prescribed temperature that exceeds a normal operating range.

36. The blanket of claim **35**, wherein the prescribed temperature is between approximately 45° C. and approximately 60° C.

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