



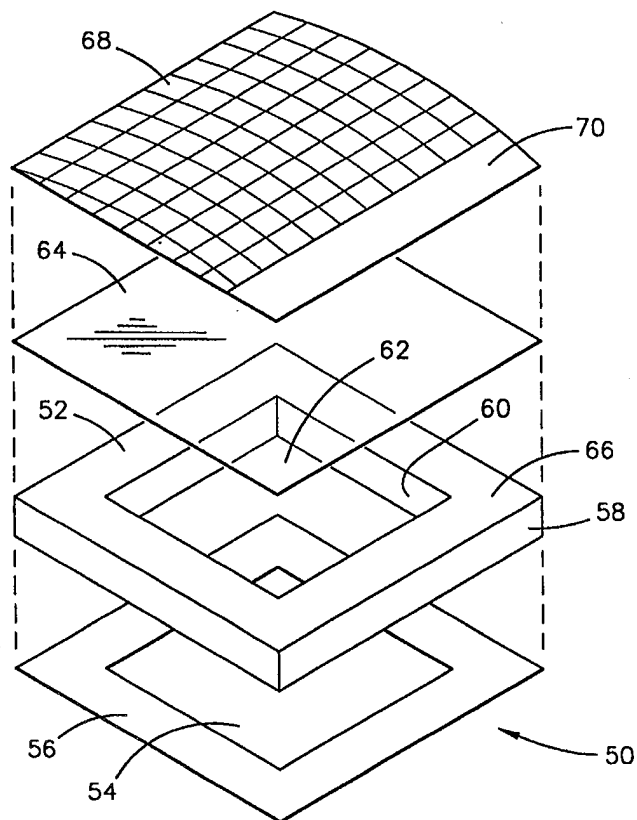
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<p>(21) International Application Number: PCT/US97/21013 (22) International Filing Date: 12 November 1997 (12.11.97) (30) Priority Data: 08/786,714 21 January 1997 (21.01.97) US (63) Related by Continuation (CON) or Continuation-in-Part (CIP) to Earlier Application US 08/786,714 (CON) Filed on 21 January 1997 (21.01.97) (71) Applicant (for all designated States except US): AUGUSTINE MEDICAL, INC. [US/US]; Suite 100, 10393 West 70th Street, Eden Prairie, MN 55344 (US). (72) Inventor; and (75) Inventor/Applicant (for US only): AUGUSTINE, Scott, D. [US/US]; 9017 Cavell Circle, Bloomington, MN 55438 (US). (74) Agent: MEADOR, Terrance, A.; Baker, Maxham, Jester & Meador, Suite 3100, 750 B Street, San Diego, CA 92101 (US).</p>	<p>(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).</p> <p>Published <i>With international search report.</i></p>	

(54) Title: NEAR HYPERTHERMIC HEATER WOUND COVERING

(57) Abstract

A non-contact controllable heater wound covering having a peripheral sealing ring covered by a layer to which is attached a heater and this assembly is attached to the skin with an adhesive so that the heater is held proximate the wound area in a non-contact position. The layer and peripheral sealing ring together define a treatment volume proximate the wound. The wound covering includes a programmable active heater control and the sealing ring may dispense water to control the humidity of the treatment volume. One form of active heat is an electrical resistive filament in variable geometric shapes providing versatility in application of heat to different types of wounds and wound area geometries. Another form of active heat is the transfer of a heated gas to the wound covering.



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NEAR HYPERTHERMIC HEATER WOUND COVERINGTECHNICAL FIELD

This invention relates to a wound covering for wound treatment and, in particular, wound covers having a substantial portion of the wound cover in non-contact with the wound and capable of delivering heat to the wound. The wound covering preferably
5 controls the temperature, humidity and other aspects of the environment at the wound site.

BACKGROUND ART

Wounds in general, as used in this context, are breaks in the integrity of the skin of a patient. Wounds may occur by several different mechanisms. One such mechanism is through mechanical traumatic means such as cuts, tears, and abrasions. There are many
10 instruments of causality for mechanical wounds, including a kitchen bread knife, broken glass, gravel on the street, or a surgeon's scalpel. A different mechanism cause for mechanical wounds is the variable combination of heat and pressure, when the heat alone is insufficient to cause an outright burn. Such wounds that result are collectively referred to as pressure sores, decubitus ulcers, or bed sores, and reflect a mechanical injury that is
15 more chronic in nature.

Another type of mechanism causing a wound is vascular in origin, either arterial or venous. The blood flow through the affected region is altered sufficiently to cause secondary weakening of the tissues which eventually disrupt, forming a wound. In the case of arterial causes, the primary difficulty is getting oxygenated blood to the affected area.
20 For venous causes, the primary difficulty is fluid congestion to the affected area which backs up, decreasing the flow of oxygenated blood. Because these wounds represent the skin manifestation of other underlying chronic disease processes, for example, atherosclerotic vascular disease, congestive heart failure, and diabetes, these vascular injuries also are chronic in nature, forming wounds with ulcerated bases.

25 Traditional wound coverings, such as bandages, are used to mechanically cover and assist in closing wounds. Such bandages typically cover the wound in direct contact with the wound. This may be acceptable for acute, non-infected traumatic wounds, but it must

be kept in mind that direct bandage contact with a wound can interfere with the healing process. This interference is particularly prevalent for chronic ulcerated wounds because of the repeated mechanical impact and interaction of the bandage with the fragile, pressure sensitive tissues within the wound.

5 The benefits of application of heat to a wound are known, and documented benefits include: increased cutaneous and subcutaneous blood flow; increased oxygen partial pressure at the wound site; and increased immune system functions, both humoral and cell mediated, including increased migration of white blood cells and fibroblasts to the site.

10 However, heat therapy for the treatment of wounds, either infected or clean, has been difficult to achieve in practice. For instance, heating lamps have been used, but these resulted in drying of wounds, and in some cases, even burning tissue from the high heat.

15 Due to these and other difficulties, and since most acute wounds usually heal over time, physicians no longer consider the application of heat to the wound as part of the treatment process. The thinking among medical personnel is that any interference in a natural process should be minimized until it is probable that the natural process is going to fail. Additionally, the availability of antibiotics for use in association with infected wounds has taken precedence over other therapies for the treatment of chronic wounds and topical infections.

20 In French patent number 1,527,887 issued April 29, 1968 to Veilhan there is disclosed a covering with a rigid oval dome, its edge resting directly on the patient's skin. One aspect of the Veilhan wound protector is a single oval heating element resting on the outer surface of the rigid dome, positioned at the periphery of the rigid dome. Veilhan does not discuss the heating aspect other than to state that it is a component.

25 The benefits of controlling other environmental parameters around the wound site are not as well known. Controlling the humidity at the wound site and the benefits of isolating the wound have not been extensively studied and documented.

30 While the benefit of applying heat to wounds is generally known, the manner of how that heat should be used or applied is not known. Historically, heat was applied at higher temperatures with the goal of making the wound hyperthermic. These higher temperatures often resulted in increasing tissue damage rather than their intended purpose of wound therapy and healing. There is a need for appropriate wound care management

incorporating a heating regimen that is conducive to wound healing, yet safe and cost effective.

DISCLOSURE OF INVENTION

5 The present invention disclosed herein approaches the treatment of wounds with heat based on an understanding of physiology. The normal core temperature of the human body, defined herein for purposes of this disclosure, is $37^{\circ}\text{C} \pm 1^{\circ}\text{C}$ ($36^{\circ} - 38^{\circ}\text{C}$), which represents the normal range of core temperatures for the human population. For purposes of discussion and this disclosure, normal core temperature is the same as normothermia. Depending on the environmental ambient temperature, insulative clothing and location on
10 the body, skin temperature typically ranges between about 32°C and about 37°C . From a physiologic point of view, a 32°C skin temperature of the healthy distal leg is moderate hypothermia. The skin of the distal leg of a patient with vascular insufficiency may be as low as 25°C under normal conditions, which is severe hypothermia.

A fundamental physiologic premise is that all cellular physiologic functions,
15 biochemical and enzymatic reactions in the human body are optimal at normal body core temperature. The importance of this premise is seen in how tightly core temperature is regulated. Normal thermoregulatory responses occur when the core temperature changes as little as $\pm 0.1^{\circ}\text{C}$. However, the skin, as noted above, is usually hypothermic to varying degrees. For example, the skin of the torso is usually only slightly hypothermic, whereas
20 the skin of the lower legs is always hypothermic. Consequently, wounds and ulcers of the skin, regardless of location, are usually hypothermic. This skin hypothermia slows cellular functions and biochemical reactions, inhibiting wound healing.

The effects of hypothermia on healing are well known. A number of regulatory systems within a human are affected, such as the immune system and coagulation, with
25 both platelet function as well as the clotting cascade affected. Patients with hypothermic wounds experience more infections which are more difficult to treat, have increased bleeding times and have been shown to require more transfusions of blood. All of these complications increase morbidity and the cost of patient care and, to a lesser extent, increase the likelihood of mortality.

One purpose of the present invention is to raise the wound tissue and/or periwound tissue temperatures toward normothermia to promote a more optimal healing environment. The present invention is not a "heating therapy", per se, where it is the intent of "heating therapy" to heat the tissue above normothermia to hyperthermia levels. Rather, the present invention is intended to bring the wound and periwound tissues toward normothermia without exceeding normothermia.

The medical community has not historically considered normothermic heating to be therapeutic. Many physicians feel that hypothermia is protective and, therefore, desirable. Studies with the present invention would indicate that this widely held belief that hypothermia is at least benign or possibly beneficial is incorrect with regard to wound healing.

The present invention is a wound covering for application to a selected treatment area of a patient's body that includes, at least as a portion of the selected treatment area, a selected wound area. The selected treatment area may also include a portion of the area immediately proximate to the wound area referred to as the periwound area. The wound covering comprises a heater suitable for providing heat to the selected treatment area, an attachment for attaching the heater in a non-contact position proximate the selected treatment area, and a heater controller, connected to the heater and including a power source for the heater, for controlling the temperature of the heater in a temperature range from 38° C temperature to about 46° C. Ambient temperature is that temperature of the environment immediately around the selected treatment area not a part of the patient's body, i.e., the bed, the air in the room, the patient's clothing.

The heater is selectable from among several types of heat sources such as warmed gases directed over the selected treatment area and electrical heater arrays placed proximate the selected treatment area. Electrical heater arrays are adaptable for construction into a layer of variable proportion and geometry or as a point source. The present invention anticipates the ability to provide several different sizes and geometric configurations for the heater. The present invention is flexible in being able to provide uniform heating over the entire selected treatment area or provide a non-uniform heating distribution over selected portions of the selected treatment area. Alternate heat source embodiments could include

warm water pads, exothermic chemical heating pads, phase-change salt pads, or other heat source materials.

The present invention anticipates that the controller is able to control both the temperature and the duration of the application of heat. This control may extend from manual to fully automatic. Manual control anticipates the controller maintaining the heater temperature at an operator-selected temperature for as long as the operator leaves the heater on. More automatic modes provide the operator an ability to enter duty cycles, to set operating temperatures, as well as to define therapy cycles and therapeutic sequences. As used herein, a duty cycle is a single on cycle when heating of the heater is occurring, measured from the beginning of the on cycle to the end of that on cycle. A heater cycle is a single complete on/off cycle measured from the beginning of a duty cycle to the beginning of the next duty cycle. Consequently, a duty cycle may also be represented in a percentage of, or as a ratio of the time on over the time off. A plurality of heater cycles are used to maintain heater temperature around a selectable temperature set point during a therapy cycle which is defined as an "on" period, composed of a plurality of heater cycles, and an "off" period equivalent to remaining off for an extended period of time. A therapeutic sequence, as used herein, is a longer period of time usually involving a plurality of therapy cycles spread out over an extended period of time, the most obvious being a day in length. The present invention anticipates the use of any period of time as a therapeutic sequence and involving one, or more than one therapy cycles.

The present invention also anticipates programmability for a number of modalities including peak heater temperature for a duty cycle and/or therapy cycle, average heater temperature for a duty cycle and/or therapy cycle, minimum heater temperature for a heater cycle and/or therapy cycle, ratio of duty cycle, length of therapy cycle, number of duty cycles within a therapy cycle, and number of therapy cycles in a therapeutic sequence. Different duty cycles within a therapy cycle may be programmed to have different peak heater temperatures and/or heater cycles may have average heater temperatures over that therapy cycle. Different therapy cycles within a therapeutic sequence may be programmed to have different peak heater temperatures and/or average heater temperatures over each therapy cycle. The wound covering control is operator-programmable or may have

preprogrammed duty cycles, therapy cycles, and therapeutic sequences selectable by the operator.

5 A preferred form of the wound covering includes an attachment as a peripheral sealing ring which, in use, completely surrounds the area of the wound and periwound, i.e., the selected treatment area. The upper surface of the peripheral sealing ring is spanned by a continuous layer which is preferably transparent and substantially impermeable, although the present invention also anticipates the use of a gas permeable layer suitable for some applications. Once in position, the sealing ring and the layer define a wound treatment volume which surrounds the wound. Additionally, the layer spanning the peripheral sealing
10 ring may be sealed about the periphery of the sealing ring and act as a barrier layer over the wound treatment volume. Optionally, the heater may be incorporated into the barrier layer or the barrier layer may be incorporated into the heater. An adhesive and a suitable release liner is applied to the lower surface of the peripheral sealing ring to facilitate the application of the wound covering to the patient's skin.

15 The barrier layer may include a pocket adapted to receive an active heater. An alternate form of the invention provides for the transport of heated air from a remote heat source to the wound treatment volume. In the active heater embodiments a thermostat and/or a pressure-activated switch may be used to control the heating effects of the heater. Each of these heated embodiments promote wound healing by maintaining the wound site
20 at a generally elevated, but controlled, temperature.

In general, the peripheral sealing ring is made from an absorbent material which may act as a reservoir to retain and/or dispense moisture into the treatment volume increasing the humidity at the wound site. The reservoir may also contain and deliver medicaments and the like to promote healing.

25 The present invention is designed to directly elevate the temperature of the hypothermic skin and subcutaneous tissue of the selected wound area to a temperature which is close to or at normothermia. The purpose of this device is to create within the wound and periwound tissues of the selected treatment area a more normal physiologic condition, specifically a more normothermic condition, which is conducive to better wound
30 healing. The present invention anticipates the use of an active heater that creates small heat gradient from heater to wound and periwound tissues. The usual temperature gradient for

tissues goes from about 37° C deep in the body core down to about 32° C at the skin surface of the leg. The heater of the present invention operates in the range above 38° C to about 46° C which is slightly above the body core temperature. Since heat must flow down a temperature gradient, heat will flow directly from the near hyperthermic heater to the wound and periwound tissues. The thermal mass of the body, the blood flow and the inefficiencies of heat transfer will result in tissue temperatures that are less than 38° C.

In contrast, typical local heating therapy (e.g. hot water bottles, hot water pads, chemical warmers, infrared lamps) deliver temperatures greater than 46° C to the skin. The goal of traditional heating therapy is to heat the tissue above normal, to hyperthermic temperatures.

The present invention differs from infrared lamps in two ways. First, the present invention includes a dome over the wound that is relatively impermeable to water vapor transmission. After application of the bandage, moisture from the intact skin or wound evaporates, and air within the dome quickly reaches 100% relative humidity. The interior of the present invention is now warm and humid. For example, a 2.5 square inch bandage at 28° C requires only 0.0014 g of water to reach saturation. When the air is thus saturated, no further evaporation can occur and, therefore, no drying of the wound can occur. This equilibrium will be maintained as long as the bandage is attached to the patient.

When heat is provided by the preferred embodiment of the present invention, the absolute amount of water needed to reach 100% relative humidity is slightly increased since warm air has a greater capacity for holding moisture. However, the air within the dome of the bandage still reaches water vapor saturation very quickly, and no further evaporation occurs. For example, a 2.5 square inch bandage of the present invention at 38° C requires only 0.0024 g of water to reach saturation. Excess moisture is absorbed by the foam ring, but still is retained within the bandage. The enclosed dome design maintains 100% humidity over the wound which also prevents evaporation due to the heat. As long as the humidity is retained within the bandage, heating therapy could theoretically be continued indefinitely without causing the wound to dry. In contrast, when using infrared lamps, the wounds are open and exposed to the environment. The result is excessive drying of the wound, increasing tissue damage.

Secondly, the present invention operates at low temperatures, from 38° C to about 46° C. This causes only minimal heating of the skin. In contrast, infrared lamps operate at temperatures in excess of 200° C. These lamps heat the wound to hyperthermic temperatures which can cause thermal damage to the tissue of the wound.

5 At the low (normothermic) operating temperatures of the present invention, the heat transfer to the skin is minimal. The low wattage heater, the inefficiencies of the heat transfer into the tissue, the thermal mass of the tissue and the blood flow (even if markedly reduced), all prevent the wound temperature from reaching the heater temperature. Hypothermic wound tissue is warmed as a result of "migration" of the body's core
10 temperature zone toward the local wound area.

The following data document the tissue temperatures resulting from a 38° C heater of the present invention on:

	<u>Average</u>	<u>Maximum</u>
Normally perfused human skin	36° C	36° C
Arterial/diabetic foot ulcers	32° C	35° C
15 Venous/arterial leg/foot ulcers	33° C	35° C
Non-perfused human model	35° C	35° C

When warmed with a 38° C heater, wounds on poorly perfused legs reach stable average temperatures of 32-33° C. In contrast, normally perfused skin reaches 36° C. It is important to note that these data are contradictory to the assumption that poorly perfused
20 tissue would reach a higher temperature than normally perfused tissue. This result substantiates the physiologic finding that the "migration" of the core temperature zone toward the local wound zone, decreasing the gradient difference between the core and surface temperatures, is the cause for the observed increased wound temperatures. Core temperature regulation is heavily dependent on perfusion, and migration of the core
25 temperature zone is also heavily dependent on perfusion. At no point in time did the poorly perfused tissue reach normothermia. Consequently, poorly perfused legs are much colder than normally perfused legs, and, thus, poorly perfused legs constitute a substantially deeper heat-sink.

A wound-healing pilot study is under way, studying patients with chronic arterial
30 and/or venous ulcers of the lower leg. These patients have suffered from these ulcers for

many months and, in some cases, even years, despite aggressive medical and surgical therapy. Of 29 patients enrolled, 24 have completed the study protocol or are still being treated. Of these 24 patients, 29% are completely healed, and 38% show a significant reduction of the wound size within 2-5 weeks of receiving therapy with the present invention.

A known consequence of restoring normothermia to tissues is to induce some degree of vasodilatation which increases local blood flow. Preliminary data collected during trials of the present invention, studying the effects of the present invention on normal subjects and on wound healing, has borne this out. An added effect has been to increase the partial pressure of oxygen in the subcutaneous tissues ($P_{sq}O_2$), which is an indirect indicator of the status of the tissue. The higher the $P_{sq}O_2$, the greater the likelihood the tissue will benefit and improve the healing process. The results of some of these studies are presented in Tables 1-4.

In conducting the studies presented in Tables 1-4, a wound covering according to the present invention is placed over the skin. The temperature of the subcutaneous tissue is then measured over time. From -60 minutes to the 0 minute mark, the heater is off in order to obtain a baseline temperature. At the 0 minute mark the heater is activated and its temperature kept constant over the next 120 minutes when it is turned off. Temperature measurements were taken during this 120 minute period and for an additional 180 minutes after turning the heater off. As shown in Table 1, with activation of the heater to 38° C, the subcutaneous tissue temperature rapidly rose from about 34.3° C to about 36° C over the first 30 minutes. The temperature of the subcutaneous tissue continued to slowly raise over the next 90 minutes to a temperature of about 36.7° C. After turning the heater off, the temperature of the subcutaneous tissue fell to about 35.9° C and held this temperature fairly uniformly for at least the next 120 minutes.

Table 2 presents the skin temperature data collected from within the wound cover of the present invention for the same periods as those in Table 1. The general curve shape is similar to the subcutaneous tissue temperature curve. The baseline temperature at the 0 minute mark was about 33.5° C. After turning the heater on to 38° C, the skin temperature rose rapidly to about 35.8° C in the first 30 minutes, then slowly rose to about 36.2° C by

the end of the 120 minute heating period. After turning the heater off, the skin temperature fell to about 35° C and held there for at least the next two hours.

Table 3 represents laser Doppler data collected from the tissue during the experiments and correlates to blood flow through the local area being treated with heat. The baseline flow is approximately 80 ml/100g/min and rises to about 200 ml/100g/min at its peak, half way through the heating period. The flow "normalizes" back to baseline during the last half of the heating period and remains at about baseline for the remainder of the measuring period.

The change in $P_{sq}O_2$ is followed in Table 4. The baseline $P_{sq}O_2$ is about 75 when heating begins and rises steadily to about 130 by the end of the heating period. The $P_{sq}O_2$ remains at this level for the remainder of the measuring period despite the lack of heating for the last 180 minutes. The added benefit of increased $P_{sq}O_2$ by heating continues well into the period of time after active heating has ceased. Wounds will continue to benefit from the effects of heating for substantial periods of time after the heating is turned off. The consequences of this study with the present invention is that the heating need not be constant, but deliverable over a heater therapy cycle or cycles that may or may not be part of a larger therapeutic sequence.

Similar trials were conducted using a heater temperature of 46° C. This data is presented in tables 5-8. Only slight additional benefits were found in any of the four measured parameters when studied at this higher temperature. The benefits imparted by active heating according to the present invention seem to peak at about 46° C. In many instances, 43° C appears to be the optimal temperature for maximal efficiency in terms of least energy required for the greatest therapeutic gain.

Our initial human clinical data shows that the beneficial effects of heating on blood flow and $P_{sq}O_2$ last at least one hour longer than the actual duration of heat application. Further, we have noted that cycled heating seems to be more effective for wound healing than continuous heating. Therefore, the data recommends cycling the heater in a therapy cycle (e.g. 1 hour "on" and 1 hour "off") for a total heating time of 2-8 hours per day as a therapeutic sequence.

None of the 29 patients with compromised circulation treated to date have shown any indication of skin damage due to 38° C heat. Furthermore, none of these wounds have

exceeded 35° C tissue temperature, with an average wound temperature of 32-33° C. The present invention raises the wound temperature toward normothermia, but even on a poorly perfused leg, the tissue does not reach normothermia.

BRIEF DESCRIPTION OF DRAWING

5 The objects, advantages and features of this invention will be more readily appreciated from the following detailed description, when read in conjunction with the accompanying drawing, in which:

 Figure 1A is an exploded view of a wound covering according to the present invention;

10 Figure 1B illustrates an assembled view of the wound covering of Figure 1A;

 Figure 2A is a view of an alternate wound covering;

 Figure 2B is a view of an alternate wound covering of Figure 2A with passive heating card inserted in the wound covering;

 Figure 3A is an exploded view of an additional alternate wound covering;

15 Figure 3B is an assembled view of the wound covering of Figure 3A;

 Figure 4 is a side elevation view of a wound covering;

 Figure 5 is an enlarged top plan view of a wound covering;

 Figure 6 is an enlarged sectional view taken along line 6-6 of Figure 5;

 Figure 7 is a bottom view of the wound covering of Figure 4;

20 Figure 8A is an exploded view of an alternate wound covering;

 Figure 8B is an assembly view showing the air flow through the wound covering;

 Figure 9A is a perspective view of an alternate wound covering;

 Figure 9B is a side view of the wound covering of Figure 9A;

 Figure 10 is a perspective view of an alternate wound covering;

25 Figure 11A is a perspective view of an alternate wound covering;

 Figure 11B is a side elevational view of the wound covering of Figure 11A;

 Figure 11C is a view of the wound covering of Figure 11A;

 Figure 12 is a perspective view of an alternate connector apparatus for the wound covering;

30 Figure 13A is an alternate connector arrangement for the wound covering;

- Figure 13B is a side sectional view of the wound covering of Figure 13A;
Figure 14 is a view of a rigid connector for engagement with a wound covering;
Figure 15 is an alternate fluid inlet line for the wound covering;
Figure 16A is a view of a two ply barrier layer wound covering;
5 Figure 16B is a side elevational view of the wound covering of Figure 16A;
Figure 17 is an alternate wound covering;
Figure 18A is an alternate wound covering;
Figure 18B is a side sectional view of the wound covering of Figure 18A;
Figure 19 is a side elevational view of an alternate wound covering
10 Figure 20 is a schematic diagram of an embodiment of the present invention; and
Figure 21A is a schematic representation of an alternate embodiment of the heater
array distribution shown in Figure 20;
Figure 21B is a schematic representation of an alternate embodiment of the heater
array distribution shown in Figures 20 and 21 A;
15 Figure 21C is a schematic representation of an alternate embodiment of the heater
array distribution shown in Figures 20, 21A, and 21B;
Figure 21D is a schematic representation of an alternate embodiment of the heater
array distribution shown in Figures 20, 21A, 21B, and 21C;
Figure 22 is a graphical representative sample of an operational scheme for an
20 embodiment of the present invention, such as the embodiment shown in Figure 20;
Figure 23 is a graphical representative sample of an additional operational scheme
for an embodiment of the present invention, such as the embodiment shown in Figure 20
using the scheme depicted in Figure 22; and
Figure 24 is a graphical representative sample of another additional operational
25 scheme for an embodiment of the present invention, such as the embodiment shown in
Figure 20 using the schemes depicted in Figures 22 and 23.

BEST MODE FOR CARRYING OUT THE INVENTION

The present invention is directed to a non-contact wound covering for controlling
the local environment at a wound site on a patient. A wound site includes those portions
30 of the patient's skin obviously definable as the wound area and the immediately adjacent

periwound area as the selected treatment area of the wound site. The wound covering protects the wound from contamination by materials from the outside environment and also prevents the wound site from shedding contaminants into the local environment of the patient, i.e. the hospital room. The treatment volume formed over the wound site can be controlled to create an optimal healing environment. The word "wound" as used herein refers generically to surgical incisions, ulcers, or other lesions or breaks in the skin.

First, a substantially vertical wall is provided to encircle the selected treatment area on the surface of the patient's skin. This vertical wall provides an upper surface to support a layer spanning this structure above the level of the wound and a lower surface suitable for attachment to the patient's skin. This structure is referred to throughout as an attachment or a peripheral sealing ring. Together these elements form a wound treatment volume between the layer and the surface of the selected treatment area. The fact that the layer does not contact the wound itself promotes healing by minimizing mechanical stresses on the tissues. The lower surface suitable for attaching to the skin may include an adhesive and a complimentary release liner assembly to facilitate the attachment of the wound covering to the skin of the patient. The present invention anticipates using a heater such that the layer may comprise the heater formed as the layer or as a layer which includes a heater within some portion of the layer. The layer may also include functioning as a barrier layer completely enclosing the wound treatment volume.

In accordance with the present invention, the climate within the wound treatment volume may be controlled. Typically the temperature, humidity, and gas composition, for example adding oxygen, nitric oxide or ozone, are controlled. Also, aerosolized medications or compounds may be released into this volume as well. The above list is exemplary of the climate controls which may promote healing of the wound, and is not intended to limit the scope of the present invention. It will be understood by those skilled in the art that numerous other climate factors can be controlled within the treatment volume of the present wound covering system without departing from the scope of the invention.

Figure 1A illustrates an exploded view of a wound covering 50. In this embodiment, a peripheral sealing ring 52 is substantially square in outline. Peripheral sealing ring 52 is intended to be attached to uninjured skin surrounding a selected treatment area 54 using an adhesive 56. In this embodiment, a layer of adhesive hydrogel is shown

as the adhesive 56. Additionally, peripheral sealing ring 52 is preferably constructed of an open cell hydrophilic foam plastic having a sealed outer surface 58 which isolates the wound from the environment. The peripheral sealing ring is fabricated from a material which may conform to the curved surface of the patient's body. An inner surface 60 of
5 sealing ring 52 is preferably porous or absorbent so that it can form a reservoir to contain and release moisture or water vapor into the air within a treatment volume 62 to create a high humidity environment if desired. Additionally, the hydrophilic absorbent nature of peripheral sealing ring 52 absorbs fluids and blood weeping from the wound.

A layer 64 is preferably attached to an upper surface 66 of peripheral sealing ring 52
10 as a barrier layer to seal treatment volume 62. Layer 64 is preferably constructed of a flexible synthetic polymeric film, such as polyethylene, polyvinyl chloride, polyurethane, or polypropylene. Additionally, other polymeric films, natural and semi-synthetic, that are suitable for use in medical applications such as cellulose and cellulose acetate, may be used. A wound tracing grid 68, also constructed of a substantially clear flexible material, may
15 optionally be used as, or attached to, layer 64 to facilitate wound care management so that the physician can draw an outline of the wound as an aid to tracking the healing process of the wound. The wound tracing grid preferably contains a labeling area 70 for identifying the patient, date when the wound was traced, and other patient medical data.

It will be understood by those skilled in the art that the volume of peripheral sealing
20 ring 52 will depend on the structural strength of the support material and the amount of fluid absorption desired. Additionally, the total area of peripheral sealing ring 52 is dependent on the size of the wound. For example, larger wounds and more flexible covers will require a thicker sealing ring so that the center of the cover does not touch the wound.

Upper surface 66 of peripheral sealing ring 52 is preferably sealed by extending
25 barrier layer 64 over the entire area of upper surface 66 as shown in Figures 1A and 1B. Adhesive 56 for attaching peripheral sealing ring 52 to uninjured skin surrounding selected treatment area 54 may take any form, however, the preferred adhesive is preferably a two-faced hydrogel which attaches to a lower surface 72 of peripheral sealing ring 52. This adhesive 56 permits the attachment of peripheral sealing ring 52 to the patient's skin.
30 Finally, peripheral sealing ring 52 may serve as a reservoir for retaining water or

medicaments in treatment volume 62 in order to maintain a high humidity in the air within the volume. Water may be added to peripheral sealing ring 52 at any time during treatment.

It will be understood by those skilled in the art that peripheral sealing ring 52 can be supplied in a variety of shapes and sizes to accommodate various wounds. The shapes
5 may include circles, squares, or rectangles. Although it is preferred to dispense the wound covering as a unitary assembly it should be apparent that individual segments of peripheral ring material could be assembled into any shape necessary to form a perimeter around the wound area. Likewise, barrier layer 64 and wound tracing grid 68 could be provided in large sheets which may be cut to size and then attached to the peripheral sealing ring.

10 Figure 1B is an assembled view of wound covering 50 of Figure 1A. To dispense the assembled product, a release liner 74 of Figure 1B is applied to adhesive 56 in Figure 1A. Release liner 74 may span the entire lower surface of the covering to maintain the sterility of treatment volume 62. Release liner 74 preferably has a grip tab 76 to facilitate removal of release liner 74 from wound covering 50 immediately prior to
15 application of wound covering 50 to the skin of a patient.

Figures 2A and 2B illustrate an alternate embodiment of the present invention as a wound covering 80 utilizing passive heating of the treatment volume 62. Because heat is constantly being radiated from the patient's skin surface, the insulation properties of the trapped air within treatment volume 62 will reduce this heat loss. By adding an infrared
20 reflector 82 over treatment volume 62, the infrared heat from the body can be reflected back to the skin for added passive heating.

An edge 84 of wound tracing grid 86 is preferably not attached to the barrier layer to form an envelope or a pocket 94 between the wound tracing grid 86 and the barrier layer. A piece of reflective foil material 88 may be inserted into pocket 94. A thin layer of
25 insulating material 90 may be optionally attached to foil layer 88 to enhance heat retention and to provide foil layer 88 with additional resiliency. A tab 92 is preferably attached to infrared reflector 82 to allow easy insertion and removal from pocket 94 and wound covering 80.

Figures 3A and 3B illustrate a preferred alternate embodiment of a non-contact
30 wound covering 108 utilizing active heating of a treatment volume 112. Wounds may be

safely and easily heated utilizing a heater assembly 100. Heater assembly 100 alternatively comprises a pressure-sensitive switch 102, an insulating layer 104, and a foil heater 106.

Pressure-sensitive switch 102 is optionally laminated to the upper surface of heater assembly 100. The purpose of switch 102 is to shut off power to foil heater 106 in the event that external pressure is applied to wound covering 108 with sufficient force to cause foil heater 106 to contact the skin or wound below. This feature prevents the possibility of applying heat and pressure to the skin at the same time. The combination of heat and pressure is known to cause burns even at low temperatures (40° C) because the pressure prevents blood flow in the skin making it susceptible to thermal injury. Pressure-sensitive switch 102 preferably covers the entire area of heater assembly 100 so that pressure applied anywhere to the surface of heater assembly 100 will deactivate foil heater 106.

It will be understood by those skilled in the art that a variety of devices are suitable for use as pressure-sensitive switch 102. Force sensing resistors, resembling a membrane switch, which change resistance inversely with applied force are one such example of a pressure sensitive switch. Devices of this type offer the substantial advantage of being low cost, flexible, and durable. A variety of other force sensing switch devices may be utilized as well.

An alternative safety feature anticipated by the present invention is a monitoring function for detecting dramatic increases in power utilization by the heater trying to maintain an operating temperature. Under normal operation, the heater is in a non-contact position proximate the selected treatment area and the heater will have been programmed to operate at a temperature that may be either a straight temperature value or an averaged value for either a duty cycle, therapy cycle or therapeutic sequence. If physical pressure is placed on the heater and it comes into contact with the patient's body, there will be a considerable increase in the rate of heat loss from the heater because of the body's greater heat sink capacity. The heater controller would sense this drop in temperature and initially adjust either the duty cycle ratio or power output, or both, in an attempt to compensate for the increase rate of loss. The safety aspect of this monitoring function would be to override this increase and turn off the device, thus preventing heating the tissue while in direct contact with, and under pressure from, the heater.

Heater element 106 is preferably a thin film type resistance heater which is commercially available. Such thin film resistance heaters utilize low voltage, minimizing the electrical risk to the patient and allowing for battery-powered mobility. Foil heater 106 is preferably sized for each wound covering 108. In actual use, foil heater 106 is preferably provided in sheets with a pair of electrical leads 110 along one edge. While an electrical resistance heater is the preferred embodiment of the invention, other heating devices are anticipated such as warm water pads, exothermic chemical heating pads, and phase-change salt pads.

Heater assembly 100 is preferably insertable into a pocket 114 formed between wound tracing grid 86 and the barrier layer as discussed above. Finally, a temperature monitoring device, such as a liquid crystal temperature monitor, may be applied to an upper surface of heater assembly 100 or within treatment volume 112 to monitor the temperature within treatment volume 112.

Figures 4-7 illustrate an alternate embodiment of wound covering 10. In this embodiment, wound covering 10 includes a generally circular head, designated generally at 12, which transitions to an elongated non-kinking, collapsible air supply or hose 14.

The apparatus, as illustrated in Figure 4, is connected by suitable supply line or tube 16 to a source 18 of thermally controlled air which is schematically illustrated. The term air as used herein is intended to encompass mixtures of gases of controlled composition. The apparatus is constructed to apply a continuous stream of thermally controlled air to a wound treatment volume.

The specific form of the apparatus and details of construction can best be understood by reference to the various figures. The overall appearance of the wound covering is best seen in Figure 4 and Figure 5. It is preferred to construct the apparatus from top and bottom sheets of thin heat-sealable polymer film which overlay one another. A top sheet or membrane 20 overlies a bottom sheet or membrane 22 which are heat sealed together along a plurality of seal lines, including a continuous outer seam 24, which extends in a circle around head 12 and continues in a sinusoidal or convoluted fashion along and forming hose 14. An inner continuous circular seam 26 is provided as best seen in Figures 6 and 7. This inner-seam 26 secures the sheets together along a continuous circle to form the inner wall of a torus defining a supply volume 28.

The inner circular portion of the two sheets 20, 22 lying in the plane within the center of the supply volume 28 forms a wall 30 separating a lower wound treatment volume 32 from an upper insulation chamber 34. Wall 30 includes a plurality of apertures 36 formed by making small circular seals 38 and cutting and removing circular portions within the circular seals 38. Thus, wall 30, with a plurality of apertures 36, is formed between the wound treatment volume 32 and insulation chamber 34. A plurality of apertures 40 are formed in the common circular wall surrounding treatment volume 32 for distributing and conveying heated air or gases from supply volume 28 into wound treatment volume 32.

The heated air flowing into treatment volume 32 bathes the wound surface of a patient's body 42. The air circulates throughout wound treatment volume 32, and then passes through apertures 36 into the upper or insulating chamber 34, where it then passes through a filter 44 forming an outer wall of insulation chamber 34. Filter 44 filters the air leaving wound treatment volume 32, trapping contaminants shed from the wound. Filter 44 may be constructed of a filter paper bonded along its periphery to the outer tangential walls of head 12 forming the torus. The filter paper also provides an insulating layer which suppresses loss of heat by radiation through upper wall 30.

The lower surface of the head 12 as shown in Figures 6 and 7 is provided with a peripheral sealing ring 46 made of an absorbent material such as foam and bonded by a suitable adhesive to the walls of head 12 and skin 42 of the patient around the wound. Preferably, foam or cotton peripheral sealing ring 46 is provided with a peel-off tape so that it adheres to the wall of the housing and on the other side to the skin of the patient. The adhesive or tape holds the apparatus in place and prevents airflow escape between the device and the skin of the patient. The absorbent material of the ring absorbs weeping blood and fluids and insulates the skin from direct conduction of heat from head 12.

Hose 14 is designed to be non-kinking by forming it of symmetrically convoluted flexible material. The hose and housing are integrally formed essentially of a unitary structure, such as a thin film membrane. Hose 14 is inflatable upon the application of heated air through supply line 16. The indentations in hose 14 permit it to bend without kinking and, thus, differentiate from a straight tubular hose which may kink when bent.

Since the thermal body treatment apparatus of the invention and the supply hose section are formed from two, thin, sealed-together membranes, the hose, and in fact the entire apparatus, is collapsible. This prevents the possibility of applying heat and pressure to the skin as might happen if a patient rolled over on the device. Instead, the weight of the patient's body collapses the device, obstructing the flow of air, and preventing the application of heat.

The film membrane may preferably be transparent to enable viewing the wound without removal. However for cosmetic reasons the layer may be opaque. Filter paper 44 is attached across the tangential surfaces of the toroidal housing, thus providing a large area of filter for the escaping air. Head 12 of the apparatus may be about one foot in diameter for most applications. However, it may be made smaller for certain other applications.

Figure 8A illustrates an exploded view of an alternate embodiment of a non-contact wound covering 120 with climate control within a treatment volume 122 as shown in Figure 8B. An inflatable structure 124 is preferably attached to a fluid inlet line 126 at a fluid inlet port 129 on the perimeter of inflatable structure 124. Inflatable structure 124 is preferably attached to an absorbent peripheral sealing ring 128, which is in turn attached to a wound area 54 by a suitable adhesive 56. Peripheral sealing ring 128 preferably has a sealed outer surface and a porous inner surface which performs the same function as peripheral sealing ring 52 discussed above. A barrier layer 130 having an exhaust filter 132 is attached to a top surface 134 on inflatable structure 124.

Turning now to the assembly illustrated in Figure 8B, a gas, illustrated by direction arrows "A", is introduced into inflatable structure 124 from an external source (not shown) through inlet line 126. The gas pressurizes inflatable structure 124 in order to maintain barrier layer 130 and exhaust filter 132 in an elevated position relative to wound area 54. An inner surface 136 of inflatable structure 124 preferably has a plurality of apertures 138 through which the fluid is introduced into wound treatment volume 122. As pressure within the treatment chamber increases, excess pressure is relieved through exhaust filter 132. In this fashion, various fluids or gases can be introduced into wound treatment volume 122.

The use of the term "fluid" in the context of this application refers to both liquid and gaseous materials, and combinations thereof. In one embodiment, oxygen may be

introduced into treatment volume 122 through apertures 138 of inflatable structure 124. The presence of oxygen within wound treatment volume 122 may increase the oxygen available to the superficial layer of growing cells in wound area 54. Nitric oxide alternatively may be infused into treatment volume 122. Nitric oxide (NO) is a potent vasodilator which in theory may be absorbed across the wound surface and increase localized blood flow. A very small concentration of NO (parts per million) may provide this effect. NO may also be pre-absorbed into absorbent peripheral sealing ring 128 and then allowed to passively diffuse into the volume once it is applied to the wound. Finally, gaseous or aerosolized medications or compounds may be introduced into the gas flow entering treatment volume 122.

Figures 9A and 9B illustrate an alternate embodiment of the climate control system discussed above wherein a fluid inlet line 140 may form part of a barrier layer 142. Barrier layer 142 is unitary with fluid inlet line 140 and is preferably attached to an exhaust filter media 144 to allow excess pressure to be released from a wound treatment volume 146. In this embodiment, filter media 144 forms part of barrier layer 142. The arrows "A" in Figure 9B illustrate the movement of the fluid through fluid inlet line 140, treatment volume 146, and exhaust filter 144.

Figure 10 illustrates an alternate embodiment wherein an exhaust filter 154 is retained in a recess 150 formed in one side of a peripheral sealing ring 152. This structure allows excess fluid to be exhausted through the side of peripheral sealing ring 152, rather than through the top, as illustrated in Figures 9A and 9B.

Figure 11A is a perspective view of the embodiment illustrated in Figure 9A, wherein a connector 160 on the end of a fluid supply line 162 engages with an opening 164 on fluid inlet line 140. Figure 11B illustrates a side view of fluid supply line 162 as it engages with fluid inlet line 140. Figure 11C illustrates the embodiment in Figures 11A and 11B where fluid inlet line 140 is folded over the top of peripheral sealing ring 152 to seal treatment volume 146 when supply line 162 is uncoupled.

Figure 12 illustrates an alternate embodiment in which a fluid inlet slot 170 engages with a rigid connector 172 on a fluid inlet line 174. Fluid inlet slot 170 forms an opening in one portion of a peripheral sealing ring 176. The opening is in fluid communication with

a treatment volume 178. This configuration allows for quick disconnection of fluid inlet line 174 from wound covering 180 providing the patient with additional mobility.

Figure 13A is a perspective view of an alternate non-contact wound covering 190 having a fluid inlet connector 192 attached to a top surface 194 of a peripheral sealing ring 196. Fluid inlet connector 192 preferably contains an inlet filter media 198. A rigid connector 200 on a fluid inlet line 202 mates with fluid inlet connector 192. As illustrated in Figure 13B, a cover 204 extends from the top of fluid inlet connector 192 across the top of peripheral sealing ring 196 where it engages with an exhaust filter media 206. Figure 14 illustrates the embodiment of Figures 13A and 13B utilizing a non-disposable fluid supply line 210.

Figure 15 illustrates an alternate embodiment which utilizes a manifold structure 220 as part of a fluid inlet line 222 to provide even distribution of the fluid being introduced into a treatment volume 224. Fluid inlet line 222 preferably has a series of seals 226 along its edge which are interrupted by a plurality of side openings 228 from which the fluid can be transmitted into treatment volume 224. The embodiment disclosed in Figure 15 illustrates an exhaust filter 230 recessed into the side of peripheral sealing ring 232. However, it will be understood that a variety of exhaust filter configurations are possible with the disclosed manifold structure 220.

Figures 16A and 16B illustrate an alternate wound covering 240 with a top barrier layer 242 and a lower layer 244 having a plurality of holes 246. As is illustrated in Figure 16B, a top cover 243 forms the barrier layer 242 and it extends substantially across the area of the peripheral sealing ring 248. Lower layer 244 likewise extends across the peripheral sealing ring 248. Thus, an upper insulating layer 250 is formed between lower layer 244 and the top of barrier layer 242. Fluid in a fluid inlet line 252 is directed into upper insulating layer 250. The pressurized fluid in upper insulating layer 250 passes through holes 246 into a treatment volume 254. Holes 246 in lower layer 244 provide a generally even distribution of the fluid within wound treatment volume 254. An optional seal 258 may be formed in the center portion of barrier layer 242 and lower layer 244 to provide these layers with additional structural support. An exhaust filter medium 256 is provided in a recess along one side of peripheral sealing ring 248 to relieve pressure in treatment volume 254.

Figure 17 illustrates an alternate embodiment of a non-contact wound covering 260 utilizing semi-rigid supports 262 to retain a barrier layer 264 above a wound area. It will be understood by those skilled in the art that a variety of semi-rigid supports 262 may be utilized for this application. For example, plastic or resilient rubber materials may provide
5 sufficient support to barrier layer 264 with a minimum risk of injuring the patient.

Figures 18A and 18B illustrate an alternate exhaust filter medium 270 with an enlarged surface area to accommodate larger volumes of air flow through a non-contact wound covering 280. Exhaust filter 270 is incorporated into a fluid inlet line 272. Fluid inlet line 272 also forms a portion of a barrier layer 274, which is in turn attached to a
10 peripheral sealing ring 276. As is best shown in Figure 18B, fluid illustrated as the arrows "A" is introduced into a fluid inlet line 272, where it is directed into a wound treatment volume 278, past the wound area and out through exhaust filter medium 270.

Figure 19 illustrates a bi-directional line 290 with a center divider 292. Fluid is introduced into a fluid inlet line 294 where it proceeds through a fluid inlet port 296 into
15 a treatment volume 298. The fluid then is forced through a fluid outlet port 300 where it is driven away from treatment volume 298 in a fluid outlet line 302. It will be understood by those skilled in the art that it would be possible to utilize separate fluid inlet and outlet lines to achieve the same result.

A schematic diagram of an embodiment of the present invention using active heating and control is depicted in Figure 20 as an active heater assembly 310 including a
20 heater 312, a heater filament 314 within heater 312, a controller 316, electrically coupled between heater filament 314 and a power source 318 by electrical connectors 315, and using a heater temperature sensor 320, and an operator interface 322 suitable for an operator to input programming parameters into controller 316. Heater assembly 310 is useful in
25 several different configurations, for example, as providing a heater layer for use directly in a pocket such as that depicted by heater 100 inserted into pocket 114 shown in Figures 3A and 3B or as a heat source for warming air that is circulated proximate the wound as is depicted in the several embodiments of Figures 4 through 19.

In addition to the various suggested fluid delivered heater "geometries" depicted in
30 Figures 4-19, the present invention anticipates numerous possible heater electrical resistive filament 314 geometries. Examples of four such geometries are shown in Figures 21A, B,

C, and D wherein there is depicted additional alternate heater array geometries for heating filament 314 within heater 312. In Figure 21A, there is depicted a linear geometry for heater filament 314. This geometry is suitable for non-uniform heating where maximum heating is desired over a linear area, such as a linear surgical wound without direct heating over adjacent periwound areas. Figure 21B depicts a geometry for heater filament 314 consistent more as a point source. Figure 21C depicts an ovoid geometry for filament 314 suitable for non-uniform heating of selected periwound area. Alternatively, this non-uniform heating may be achievable with circular, square, rectangular, triangular or other such geometries depending on the type and shape of wound encountered.

10 In operation, heater assembly 310 is programmable, controlling several parameters, such as heater temperature, duty cycle, therapy cycle, number of duty cycles per therapy cycle, average heater temperature per duty cycle, average heater temperature per therapy cycle, peak and minimum heater temperatures per heater cycle, and peak and minimum heater temperatures for a therapy cycle. The programming may be preset at time of manufacture and may provide a menu of several treatment scenarios. Additionally, the parameter programmability may be entirely under the control of an operator and suitable for inputting any number of custom treatment regimens.

By way of example, and not limiting in scope of treatment versatility, Figure 22 is a graphic representation of one such therapy cycle represented by several heater and duty cycles. In Figure 22, several duty cycles have been defined within a therapy cycle where time (t) is represented along the abscissa and heater temperature (T) along the ordinate. At t_0 330, the heater is at ambient temperature T_{amb} 332 and the first of several duty cycles begins at t_0 330 by turning on the heater to heat up to a temperature at about T_{peak} 334. Upon reaching T_{peak} 334 by t_1 336, the heater power is turned off and the heater cools to T_{min} 338. The first duty cycle is completed at t_1 336 when the heater is turned off. The first heater cycle is completed at t_2 340 when the heater is turned back on to begin the next duty and heater cycle. This first heater cycle and subsequent heater cycles maintain an average heater temperature T_{set} 342. The duty cycle is given by the ratio of the duration of t_0-t_1 over t_0-t_2 . Those familiar with the art of heater activity control will appreciate there are a variety of methods for manipulating heater activity, including proportional action controllers using processor logic to maximize heater action and control. A therapy cycle for this example

is the time duration from t_0 330 to t_1 344 during which time the heater temperature has been allowed to fall to T_{amb} 332, where at t_1 344 the heating regimen begins again starting the next therapy cycle.

For the above example, a peak temperature, T_{peak} 334 may be the parameter inputted into the program. For the present invention anticipating a guard heater function, this range is preferably from above 38° C to about 46° C. The present invention anticipates alternative selections of temperatures inputted for the operating temperature. A first alternative is to establish an average heater cycle temperature. In Figure 22, this concept is represented by T_{set} 342. For the present invention this average heater cycle temperature would have the same range, from above 38° C to about 46° C. Alternatively, the temperature selection may be inputted as a T_{peak} 334 and a T_{min} 338, both temperatures selected from the same range.

By way of another example, and not limiting in scope of treatment versatility, a plurality of therapy cycles are depicted in Figure 23, wherein individual heater cycles within each therapy cycle have been averaged out for purposes of clarification and for purposes herein are treated as the heater being "on". A first therapy cycle begins at t_0 350 as depicted by the heater turning "on", i.e., a series of heater cycles is begun, and the heater heats to T_{set} 352. This "on" segment goes until t_1 354 at which time the heater is turned "off" and allowed to cool to T_{amb} 356. This first therapy cycle ends at t_2 358 when a second therapy begins by turning "on" the heater again. As in the first therapy cycle, this second therapy cycle heats to T_{set} 352 and has a duration from t_2 358 to t_3 360. A third therapy cycle begins at t_3 360 turning "on" the heater. For purposes of example to depict anticipated versatility of the present invention, this third therapy cycle is given a different T_{set} 362. The heater is turned "off" at t_4 364. This entire period of multiple therapy cycles may also be part of a therapeutic sequence, depicted in Figure 23 as that period of time from t_0 350 to t_4 366 encompassing three therapy cycles. The present invention anticipates the use of any number of therapy cycles having any length or duration per cycle and different set temperatures.

Another aspect of heater therapy control, averaging therapy cycle and therapeutic sequence temperatures, is depicted in Figure 24 as an additional example, the example not intended to be limiting in scope of treatment versatility. In Figure 24, a therapy cycle starts

at t_0 370 and ends at t_1 372. The overall heater temperature average T_{ave} 374 for this therapy cycle may be pre-selected or programmed. The heater, beginning at an ambient temperature T_{amb} 376, heats to an appropriate temperature for the "on" phase and then is "off" for an additional appropriate time such that the total period of time is equivalent to
5 the period t_0 370 to t_1 372 and the average temperature for this period is equivalent to T_{ave} 374.

An alternative approach, depicted in Figure 24, anticipates the programming of a number of therapy cycles as elements of a therapeutic sequence, in this example there being three therapy cycles of varying time and heater temperature. The present invention
10 versatility provides for the inputting of an average temperature T_{ave} 378 for the therapeutic sequence. The therapeutic sequence begins at time t_0 370 and ends at time t_1 380. The heater temperatures and durations of the therapy cycles within the therapeutic sequence are averaged by the controller over the entire period of time from t_0 370 to t_1 380 so as to achieve the therapeutic average temperature T_{ave} 378. Each of these average temperatures,
15 whether an average over a therapy cycle or over a therapeutic sequence, is intended to have the same temperature range from above 38° C to about 46° C. A secondary consequence of this controller regimen is that if average temperatures are used, either over the therapy cycle and/or therapeutic sequence, then the resultant peak temperatures achieved by the heater may be substantially higher than the 38° C to about 46° C range. These peak
20 temperatures are short lived by comparison and do not represent a safety concern.

The present invention is the development of a safe, efficacious non-contact heater wound covering providing heat to a patient's wound from the heater that is in a temperature range from above 38° C to about 46° C or controlled to an average temperature range from above 38° C to about 46° C. While the invention has been illustrated by means of specific
25 embodiments and examples of use, it will be evident to those skilled in the art that many variations and modifications may be made therein without deviating from the scope and spirit of the invention. However, it is to be understood that the scope of the present invention is to be limited only by the appended claims.

Table 1:

	Time (in minutes)	Subcutaneous Temperature (°C mean ± S.D.)
5	-60	33.9 ± 1.1
	0	34.7 ± 1.2
	30	36.9 ± 0.6
	60	37.1 ± 0.4
	90	37.4 ± 0.5
10	120	37.6 ± 0.5
	180	36.0 ± 0.4
	240	36.1 ± 0.2
	300	35.8 ± 0.6

Table 2:

	Time (in minutes)	Skin Temperature Inside Covering (°C mean ± S.D.)
15	-60	33.2 ± 1.1
	0	33.9 ± 1.1
	30	36.7 ± 0.5
	60	37.0 ± 0.4
	90	37.1 ± 0.4
	120	37.2 ± 0.4
	180	35.2 ± 0.5
	240	35.2 ± 0.4
20	300	35.1 ± 0.5

Table 3:

	Time (in minutes)	Laser Doppler Flow (ml/100g/min mean \pm S.D.)
	-60	64 \pm 42
5	0	110 \pm 100
	30	199 \pm 191
	60	178 \pm 131
	90	222 \pm 143
	120	271 \pm 235
10	180	158 \pm 146
	240	146 \pm 125
	300	173 \pm 158

Table 4:

	Time (in minutes)	Subcutaneous Oxygen Tension ($P_{sq}O_2$) (mm Hg mean \pm S.D.)
	-60	54 \pm 10
	0	110 \pm 60
	30	109 \pm 58
	60	122 \pm 59
20	90	136 \pm 57
	120	159 \pm 55
	180	153 \pm 60
	240	156 \pm 61
	300	148 \pm 52

Table 5:

	Time (in minutes)	Subcutaneous Temperature (°C)
5	-60	33.8 ± 1.5
	0	35.2 ± 1.5
	30	37.1 ± 1.1
	60	37.3 ± 0.8
	90	37.4 ± 0.7
10	120	37.3 ± 0.8
	180	35.8 ± 1.2
	240	35.8 ± 1.0
	300	36.1 ± 0.9

Table 6:

	Time (in minutes)	Skin Temperature Inside Covering (°C)
15	-60	32.9 ± 1.5
	0	34.5 ± 1.0
	30	37.1 ± 0.6
	60	37.5 ± 0.5
	90	37.6 ± 0.5
20	120	37.6 ± 0.5
	180	34.9 ± 0.8
	240	35.0 ± 0.7
	300	35.2 ± 0.6

Table 7:

	Time (in minutes)	Laser Doppler Flow (ml/100g/min)
	-60	44 ± 22
5	0	95 ± 132
	30	142 ± 155
	60	191 ± 150
	90	207 ± 209
	120	161 ± 91
10	180	73 ± 29
	240	70 ± 30
	300	71.5 ± 25

Table 8:

	Time (in minutes)	Subcutaneous Oxygen Tension ($P_{sq}O_2$) (mm Hg)
15	-60	58 ± 11
	0	123 ± 73
	30	128 ± 67
	60	145 ± 69
20	90	157 ± 73
	120	153 ± 55
	180	148 ± 73
	240	142 ± 73
	300	143 ± 76

CLAIMS

1. A wound covering for application to a selected treatment area of a patient's body, said wound covering comprising:
 - a heater suitable for providing heat to the selected treatment area;
 - 5 flexible attachment means for attaching the heater in a non-contact position proximate the selected treatment area; and
 - means, operably connected to the heater, for controlling the temperature of the heater in a temperature range from above 38° C to about 46° C.
- 10 2. The wound covering of claim 1 in which the heater includes an electrically resistive filament.
3. The wound covering of claim 1 in which the heater comprises a source of heat selected from the group consisting of: warm water pads, exothermic chemical heating pads, and phase-change salt pads.
- 15 4. The wound covering of claim 1 in which the heater is suitable for uniformly heating the selected treatment area.
5. The wound covering of claim 1 in which the heater is suitable for non-uniform heating of the selected treatment area.
- 20 6. The wound covering of claim 1 in which the flexible attachment means comprises a sealing ring having an upper surface and lower surface, and defining an open cavity and sealing around the selected treatment area.
7. The wound covering of claim 6 in which the sealing ring comprises a conformal polymeric ring.

8. The wound covering of claim 7 in which the conformal polymeric ring includes a polymeric foam.
9. The wound covering of claim 1 further comprising a layer spanning the flexible attachment means suitable for maintaining a treatment volume proximate the selected wound area.
10. The wound covering of claim 9 in which the layer comprises a flexible sheet material.
11. The wound covering of claim 10 in which the flexible sheet material comprises a polymeric film.
10. 12. The wound covering of claim 11 in which the polymeric film is selected from a group of polymers consisting of: cellulose, cellulose acetate, polyethylene, polyvinyl-chloride, polyurethane, and polypropylene.
13. The wound covering of claim 9 in which the layer comprises a gas permeable material.
15. 14. The wound covering of claim 1 in which the flexible attachment means includes a pocket for releasable attachment of the heater.
15. The wound covering of claim 1 further comprising a pressure response switch to turn off the heater when pressure is applied to the wound covering.
20. 16. The wound covering of claim 9 in which the layer is sealed to the flexible attachment means as a barrier layer.
17. A wound covering for application to a selected treatment area of a patient's body, said wound covering comprising:

a heater layer suitable for providing heat to the selected treatment area;
means for attaching the heater layer in a non-contact position proximate the selected
treatment area; and
means, operably connected to the heater layer, for controlling the temperature of the
5 heater layer in a temperature range from above 38° C to about 46° C.

18. The wound covering of claim 17 in which the heater layer is suitable for
uniformly heating the selected wound area.

19. The wound covering of claim 17 in which the heater layer is suitable for
non-uniform heating of the selected wound area.

10 20. The wound covering of claim 17 in which the attachment means comprises
a sealing ring having an upper surface and lower surface, and defining an open cavity and
sealing around the selected treatment area.

21. The wound covering of claim 20 in which the sealing ring comprises a
conformal polymeric ring.

15 22. The wound covering of claim 21 in which the conformal polymeric ring
includes a polymeric foam.

23. The wound covering of claim 17 in which the heater layer includes spanning
the attachment means suitable for maintaining a treatment volume proximate the selected
wound area.

20 24. The wound covering of claim 17 in which the heater layer comprises a
flexible sheet material.

25. The wound covering of claim 24 in which the flexible sheet material
comprises a polymeric film.

26. The wound covering of claim 25 in which the polymeric film is selected from a group of polymers consisting of: cellulose, cellulose acetate, polyethylene, polyvinyl-chloride, polyurethane, and polypropylene.

5 27. The wound covering of claim 24 in which the heater layer includes a gas permeable material.

28. The wound covering of claim 17 in which the attachment means includes a pocket for releasable attachment of the heater layer.

29. The wound covering of claim 23 in which the heater layer includes sealing to the attachment means as a barrier.

10 30. A wound covering for application to a selected treatment area of a patient's body, said wound covering comprising:

a heater suitable for providing heat to the selected treatment area;

flexible attachment means for attaching the heater in a non-contact position proximate the selected treatment area; and

15 means, operably connected to the heater, for controlling the average temperature of the heater in a temperature range from above 38° C to about 46° C.

31. The wound covering of claim 30 in which the heater is suitable for uniformly heating the selected treatment area.

20 32. The wound covering of claim 30 in which the heater is suitable for non-uniform heating of the selected treatment area.

33. The wound covering of claim 30 in which the control means includes selectable pre-set average temperature settings.

34. The wound covering of claim 30 in which the control means is programmable to provide heat at the average temperature over a therapy cycle.

35. The wound covering of claim 30 in which the control means is programmable to provide heat at the average temperature over a therapeutic sequence.

5 36. The wound covering of claim 30 in which the control means is pre-programmed to provide heat at the average temperature over a therapy cycle.

37. The wound covering of claim 30 in which the control means is pre-programmed to provide heat at the average temperature over a therapeutic sequence.

10 38. A wound covering for application to a selected wound area of a patient's body, said wound covering comprising:

a heater layer suitable for providing heat to the selected wound area;

means for attaching the heater layer in a non-contact position proximate the selected wound area; and

15 means, operably connected to the heater layer, for controlling the average temperature of the heater layer in a temperature range from above 38° C to about 46° C.

39. A method for treating a skin wound of a patient, the method comprising the steps of:

selecting a wound treatment area of the patient's skin including the wound;

providing a heater;

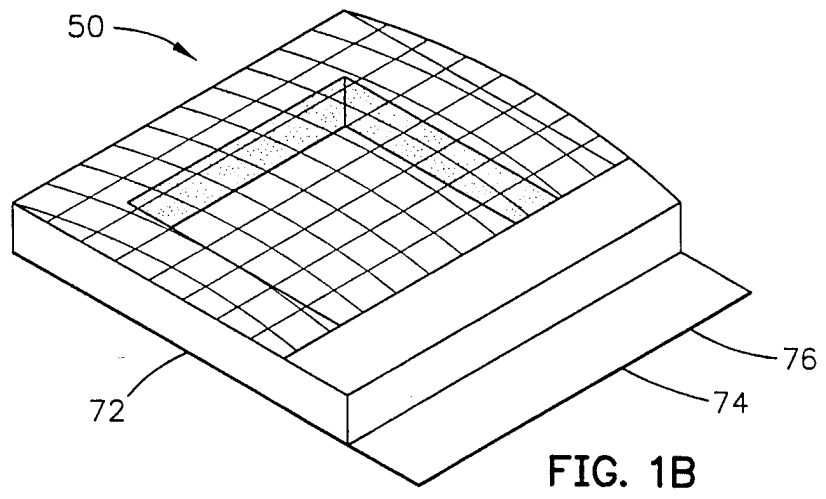
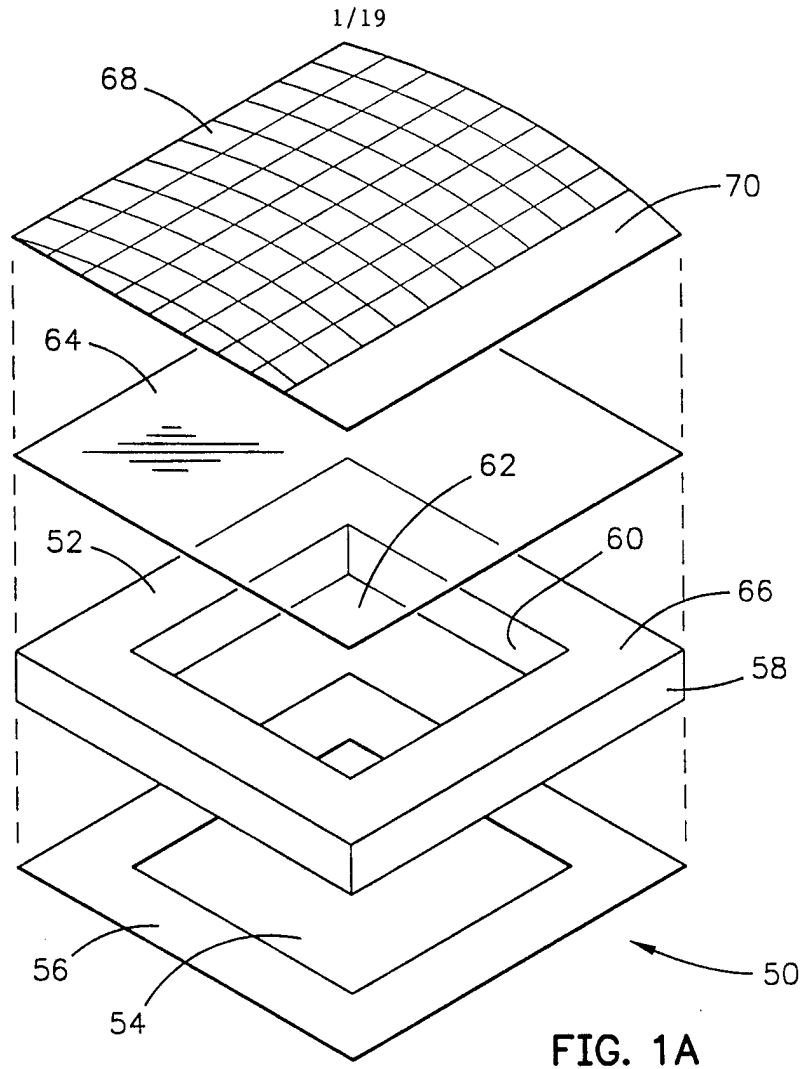
20 providing a controller operably connected to the heater;

attaching the heater proximate the selected wound treatment area in a non-contact position;

heating the heater over at least a portion of selected treatment area; and

25 controlling the heater so as to have a temperature in a range from above 38° C to about 46° C.

40. The method of claim 39 further comprising the step of programming the controller to control the temperature of the heater over a duty cycle.
41. The method of claim 39 further comprising the step of programming the controller to control the temperature of the heater over a therapy cycle.
- 5 42. The method of claim 39 further comprising the step of programming the heater to control the temperature over a therapeutic sequence.
43. The method of claim 39 in which controlling the heater includes controlling the heater temperature at an average heater temperature.
44. The method of claim 43 further comprising the step of programming the
10 controller to control the average temperature of the heater over a therapy cycle.
45. The method of claim 43 further comprising the step of programming the controller to control the average temperature of the heater over a therapeutic sequence.
46. The method of claim 39 further comprising the step of inputting a temperature to the controller in a temperature range above 38° C to about 46° C.
- 15 47. The method of claim 39 further comprising the step of inputting an average temperature to the controller in an temperature range from above 38° C to about 46° C.



SUBSTITUTE SHEET (rule 26)

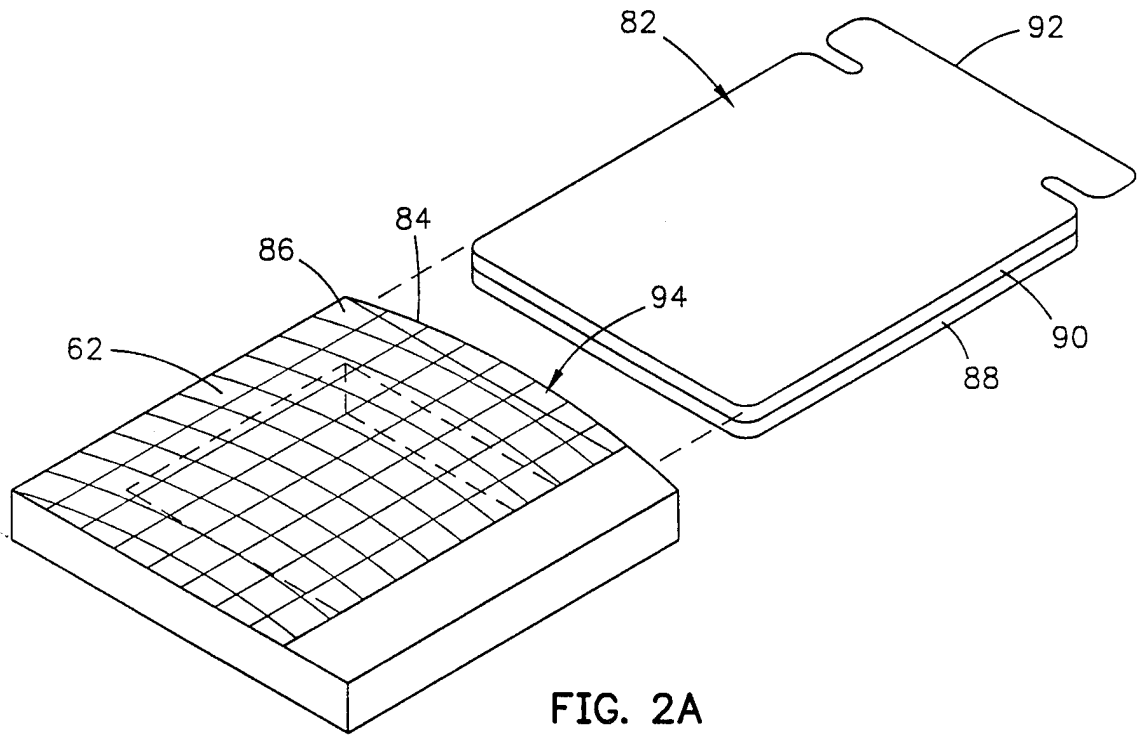


FIG. 2A

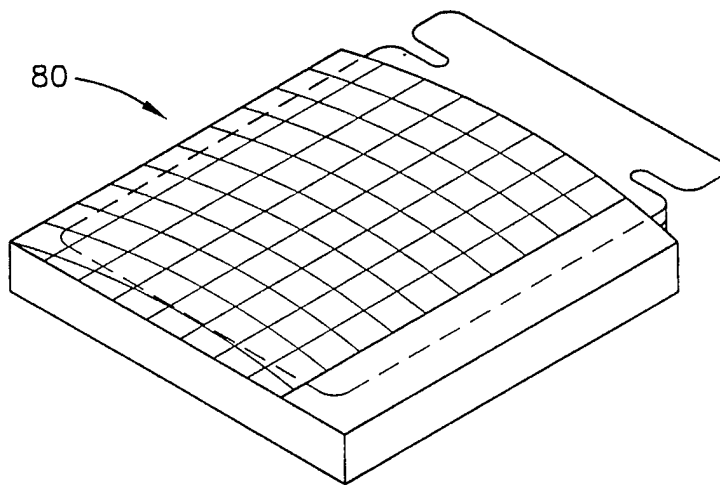


FIG. 2B

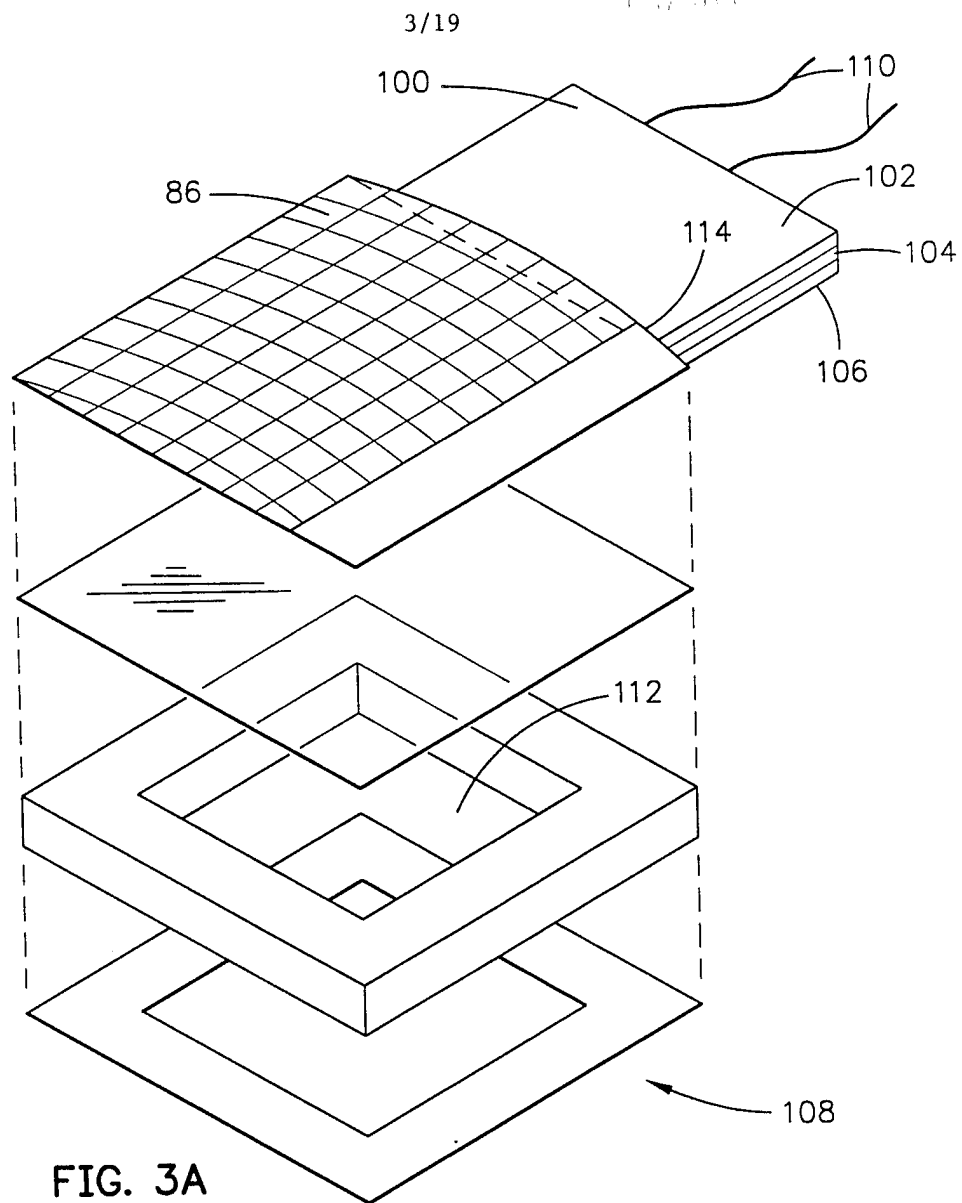


FIG. 3A

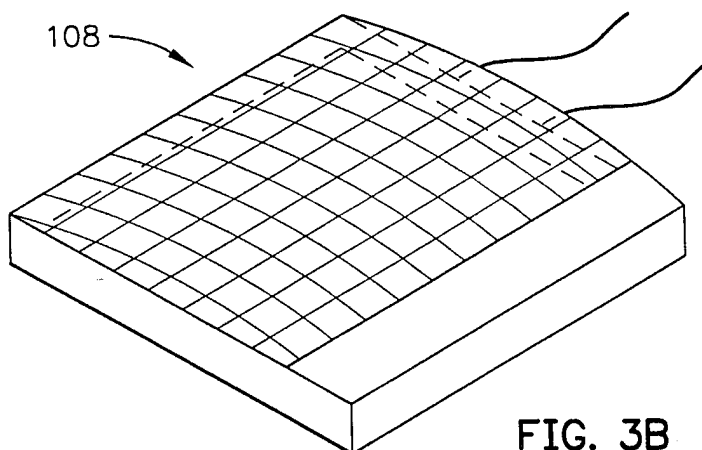


FIG. 3B

SUBSTITUTE SHEET (rule 26)

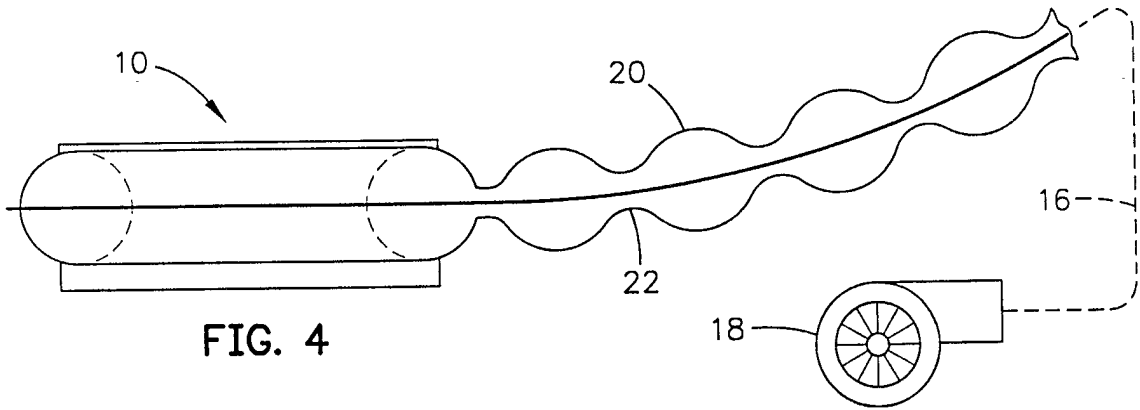


FIG. 4

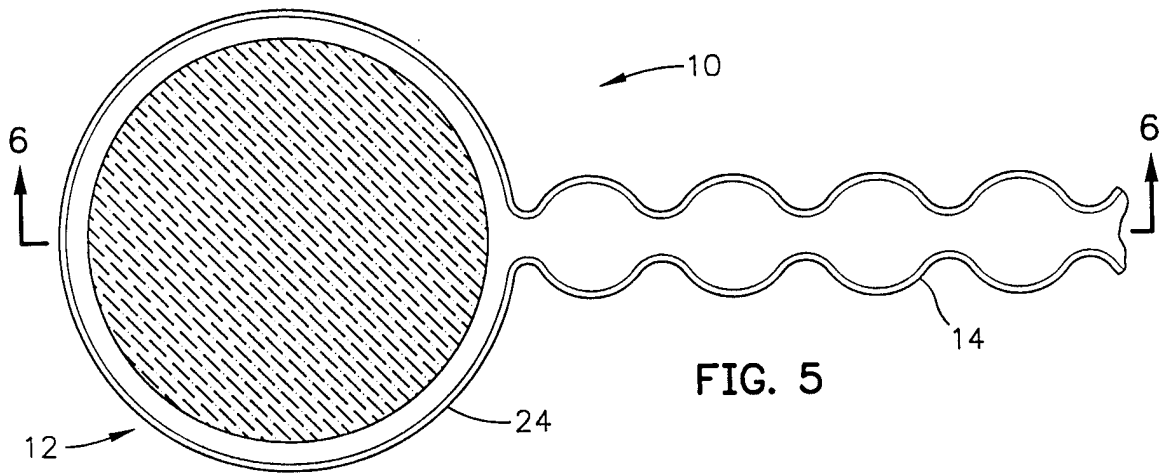


FIG. 5

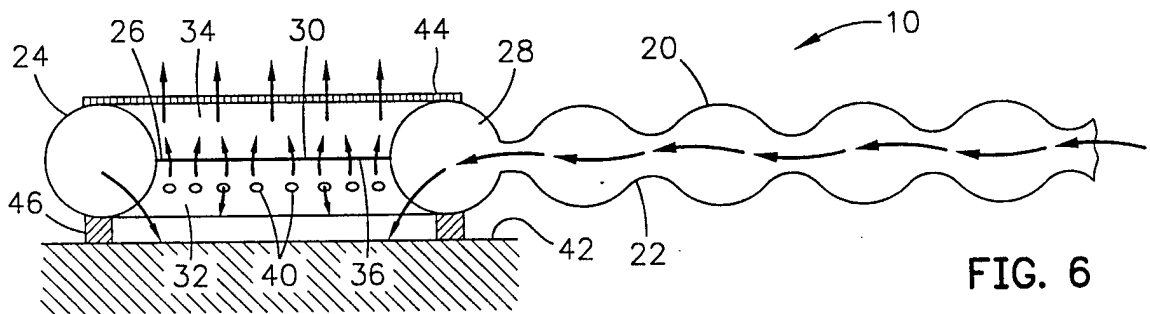


FIG. 6

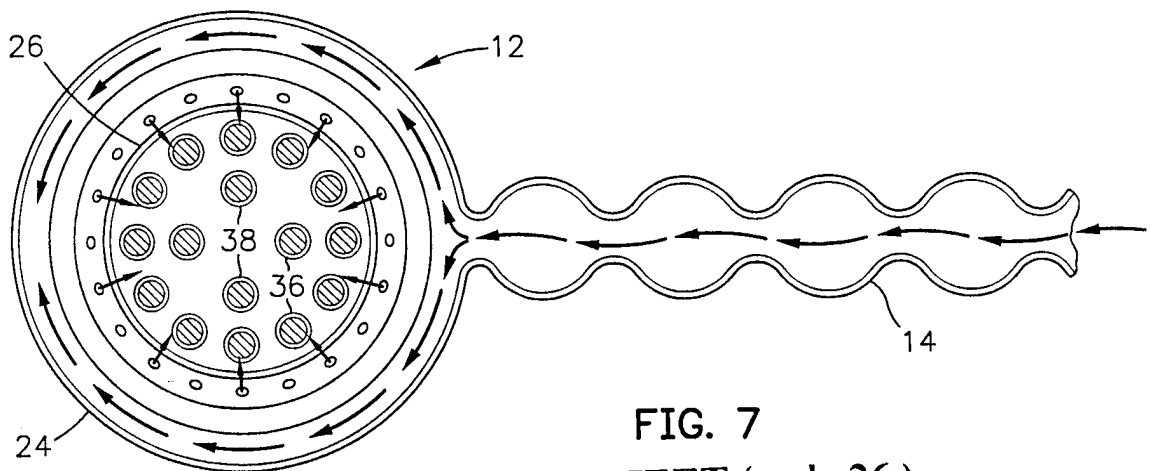
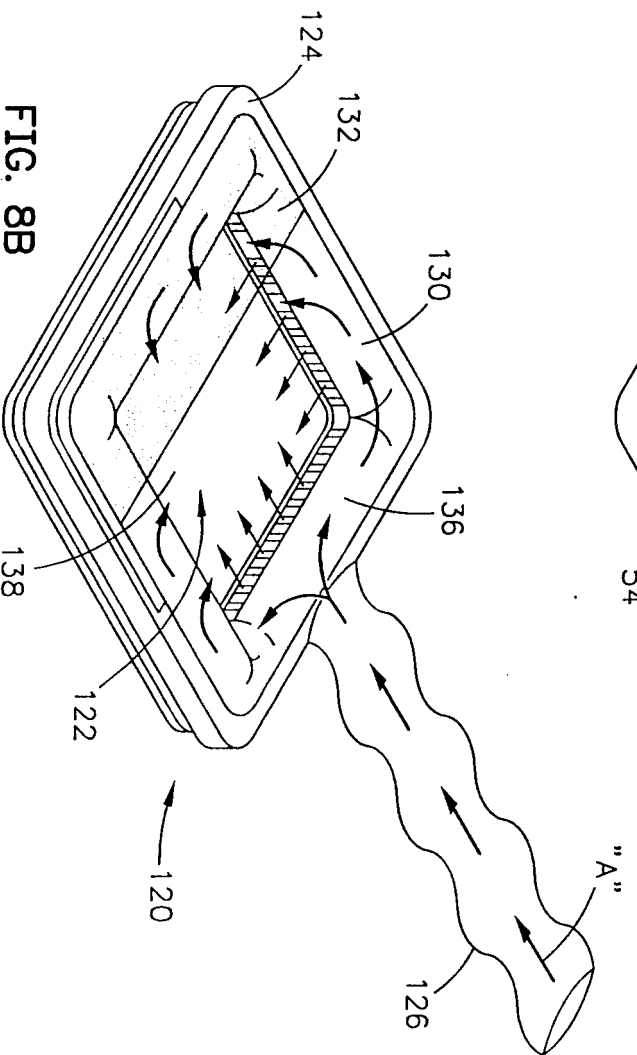
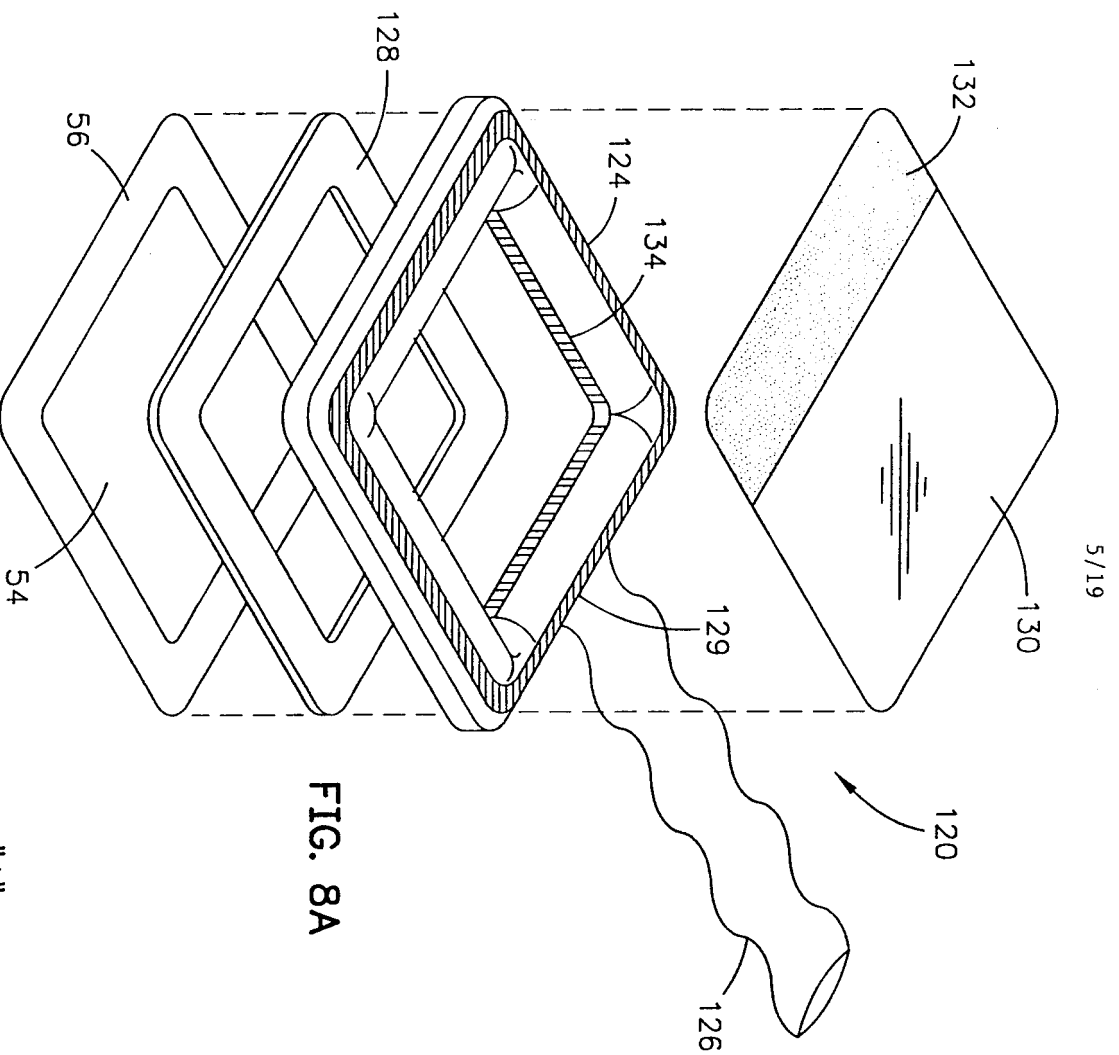


FIG. 7

SUBSTITUTE SHEET (rule 26)



SUBSTITUTE SHEET (rule 26)

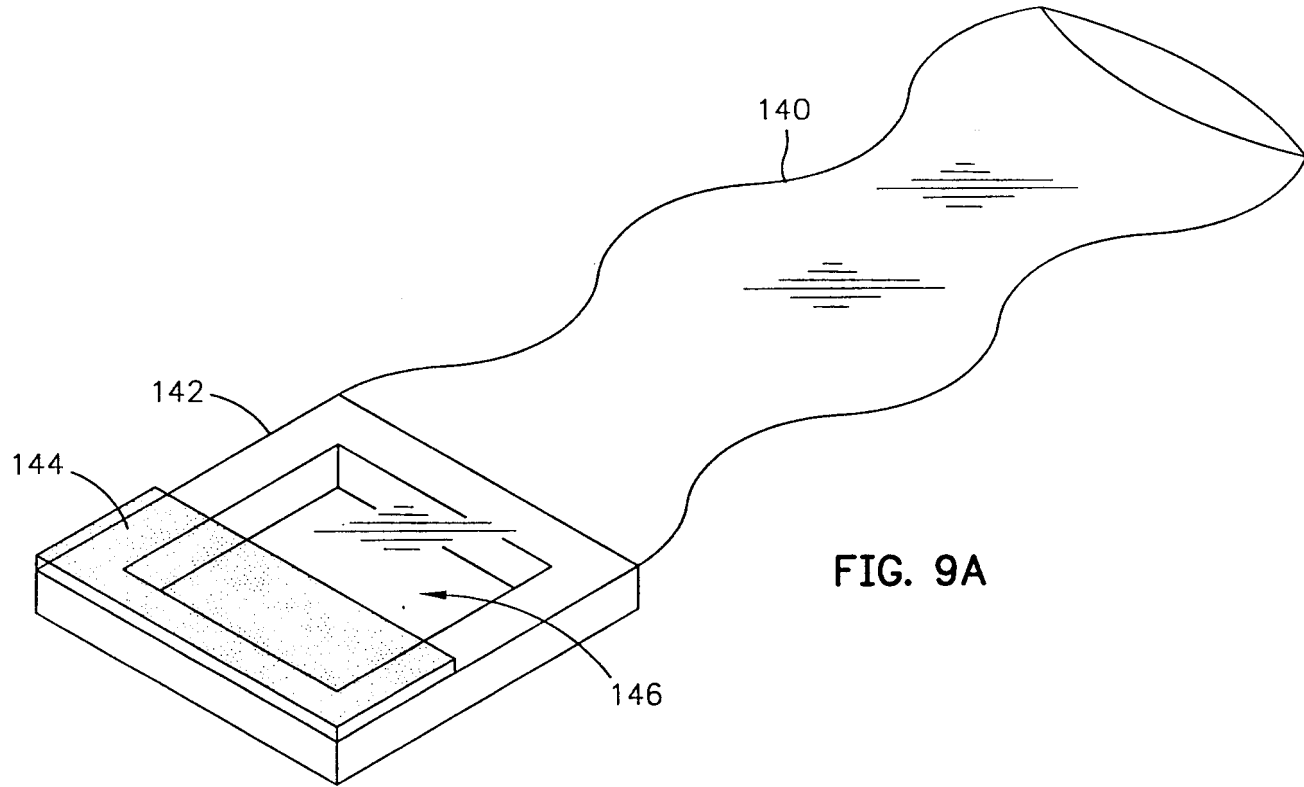


FIG. 9A

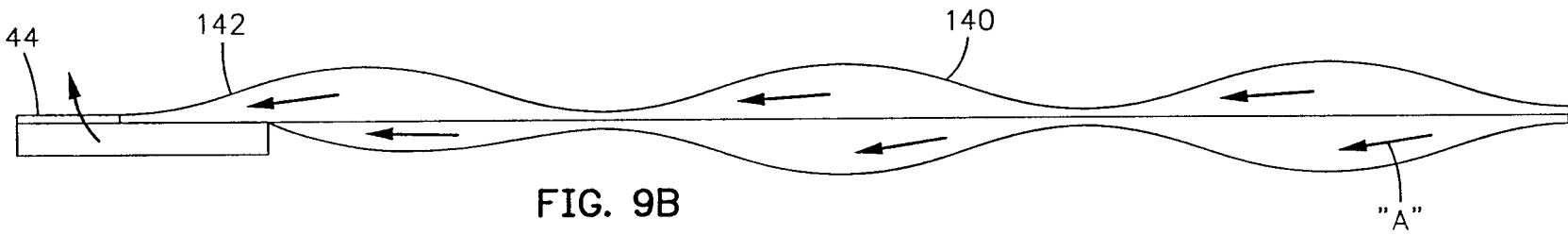
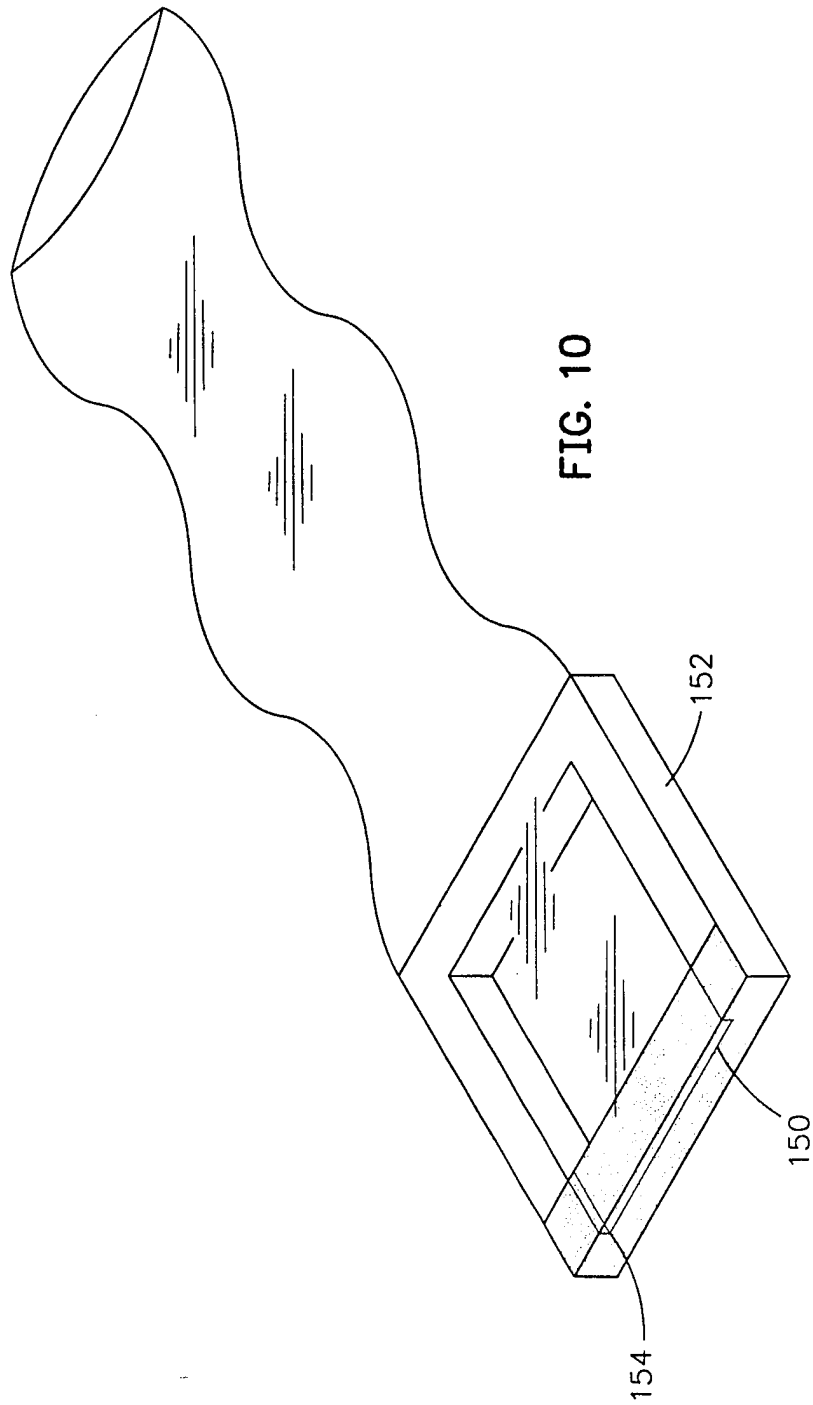


FIG. 9B



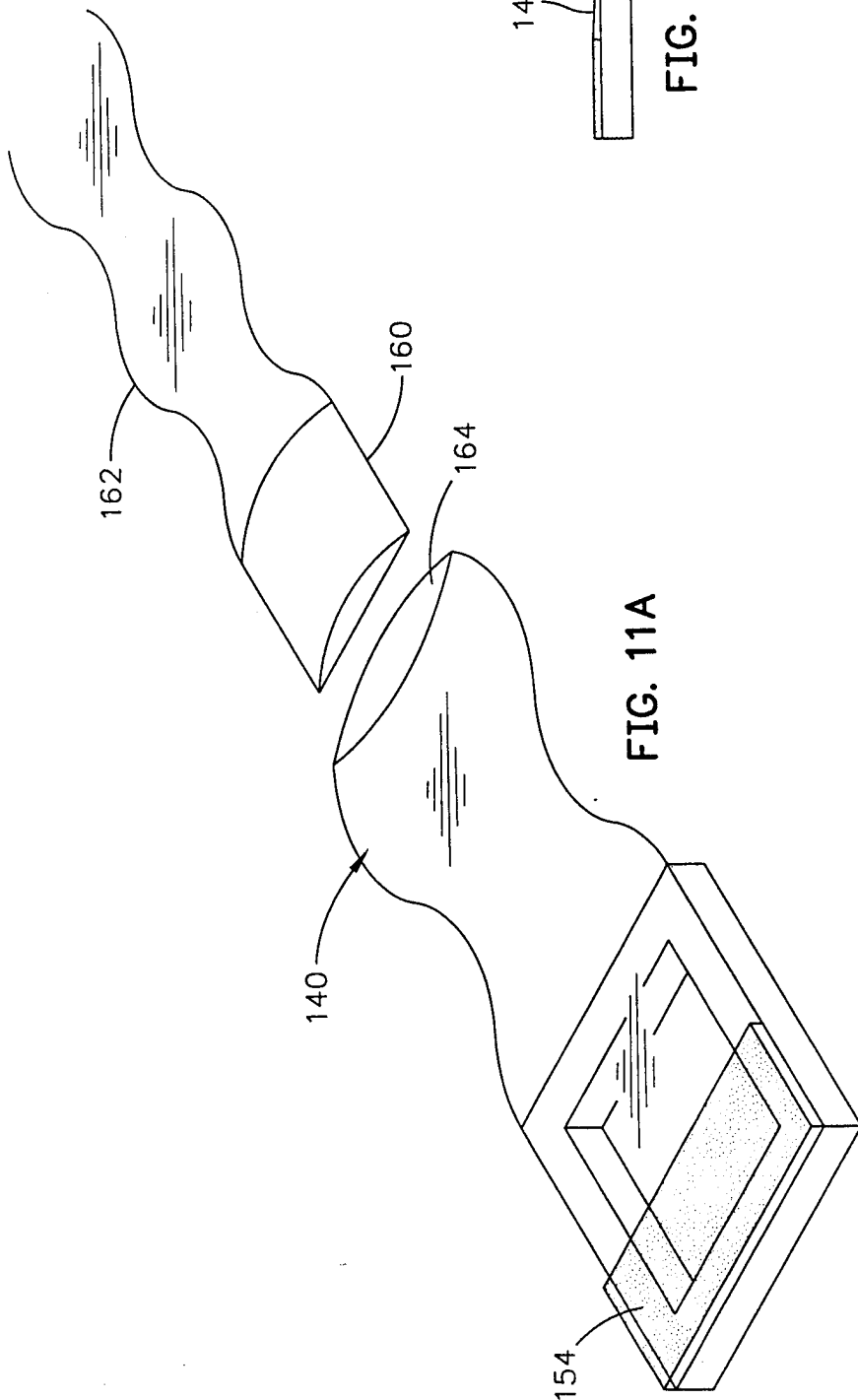


FIG. 11A

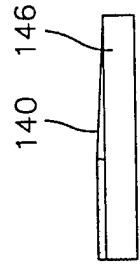


FIG. 11C

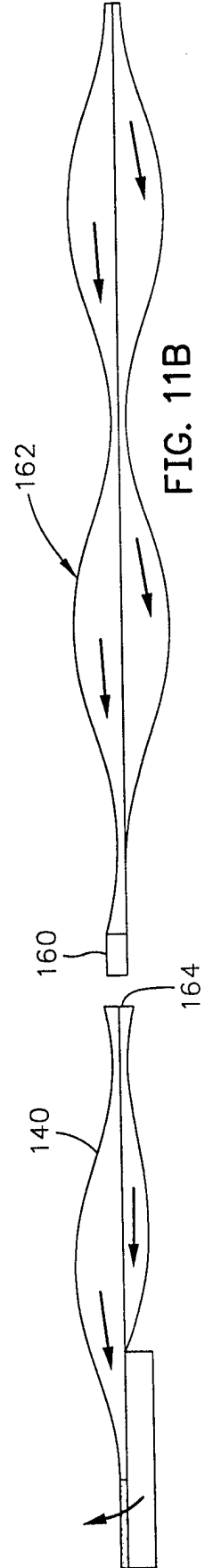


FIG. 11B

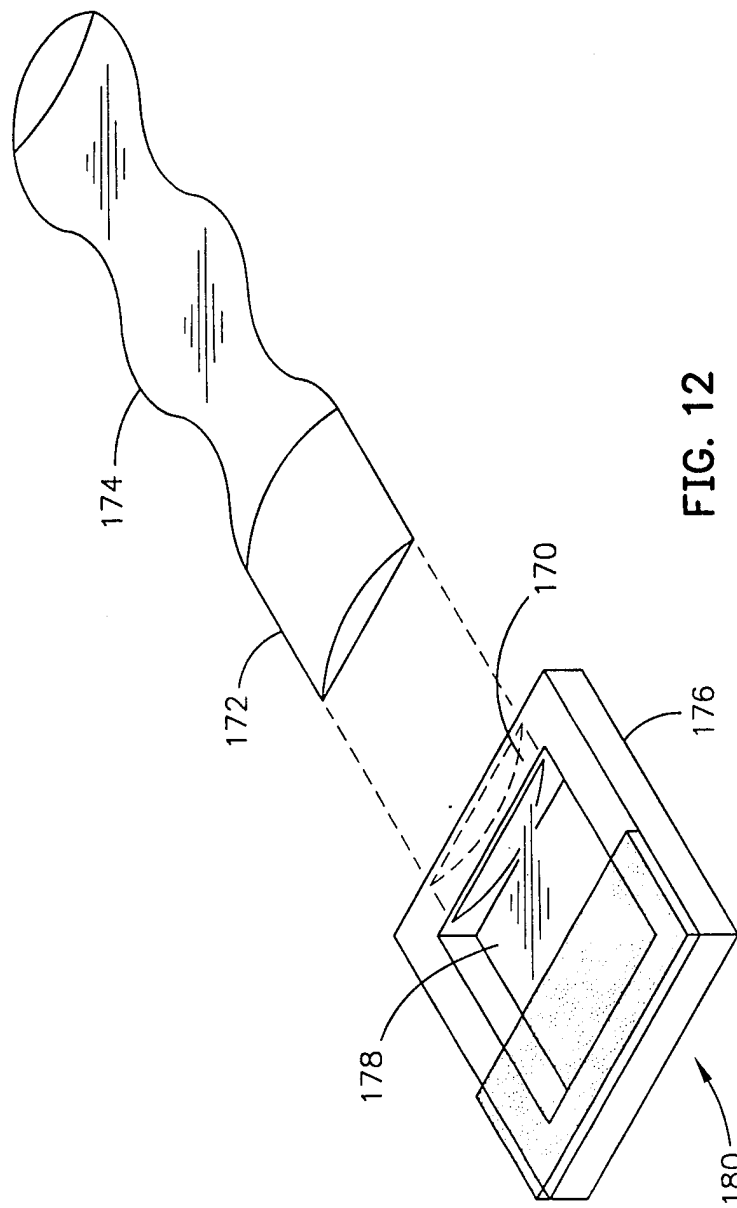


FIG. 12

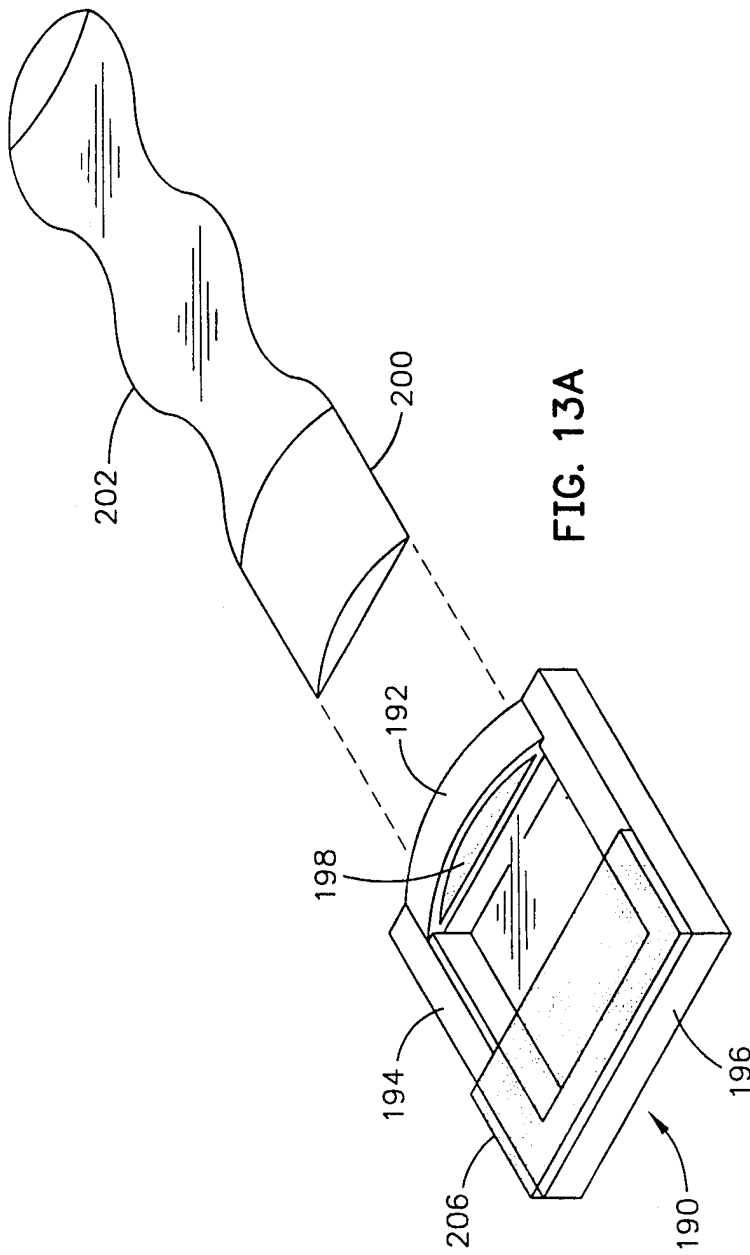


FIG. 13A

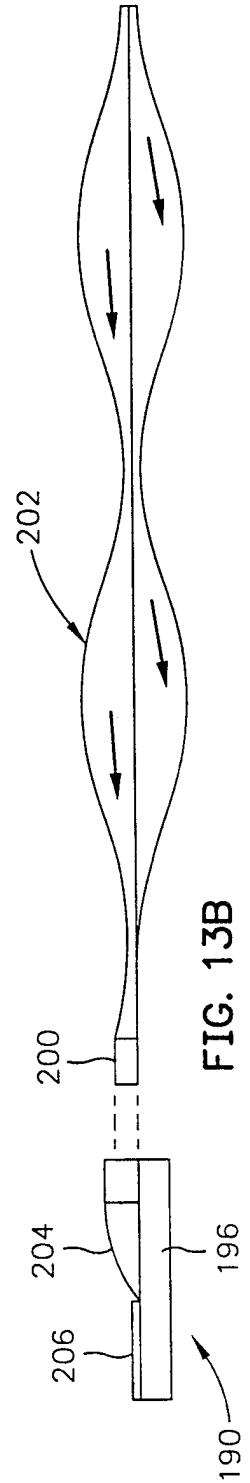


FIG. 13B

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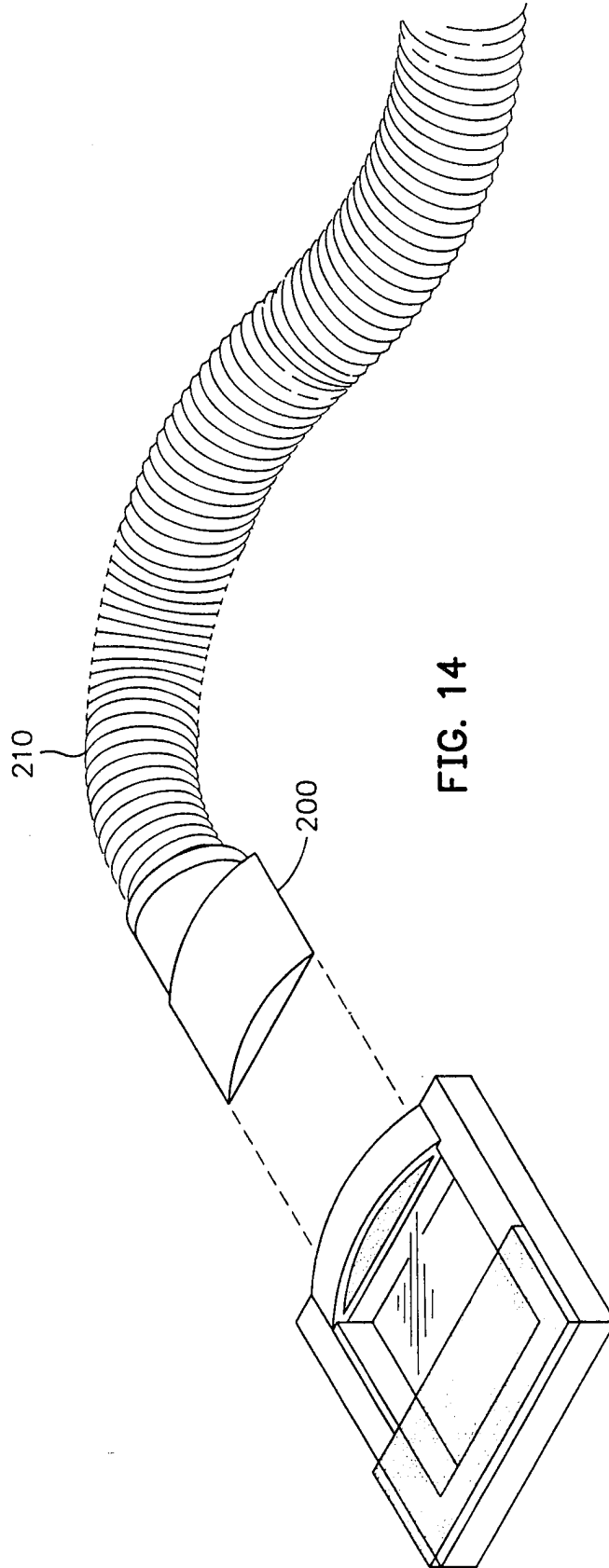


FIG. 14

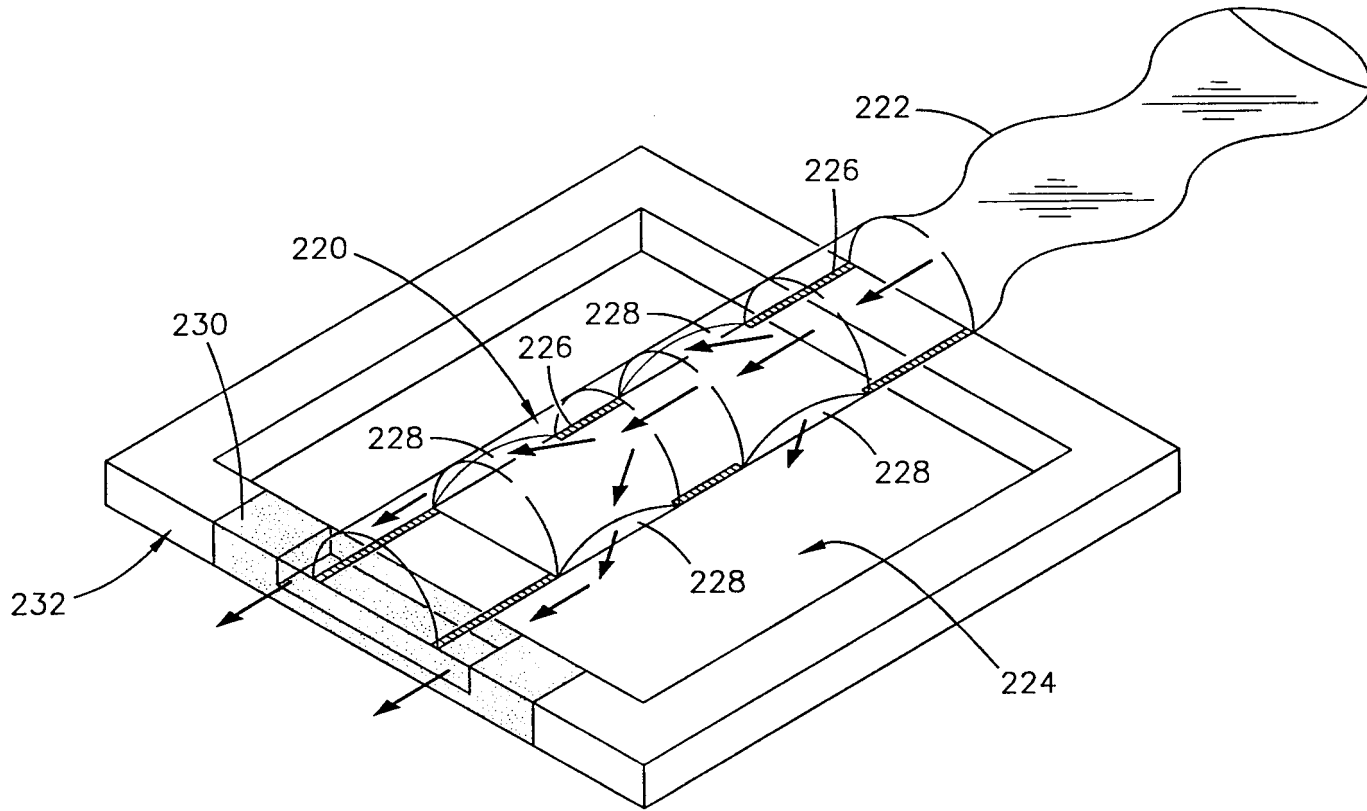


FIG. 15

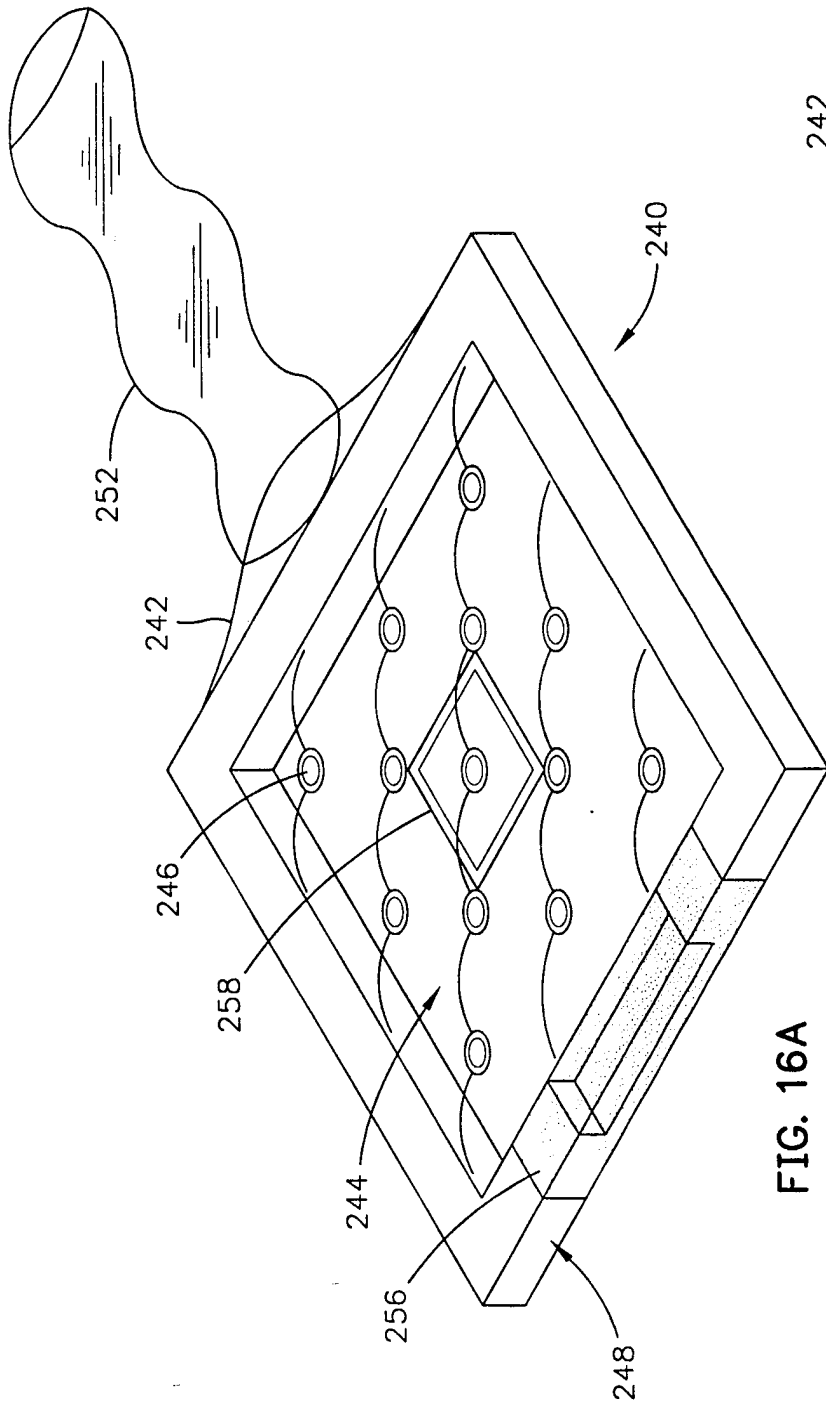


FIG. 16A

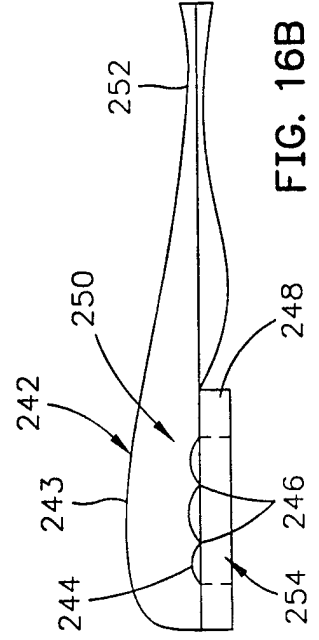


FIG. 16B

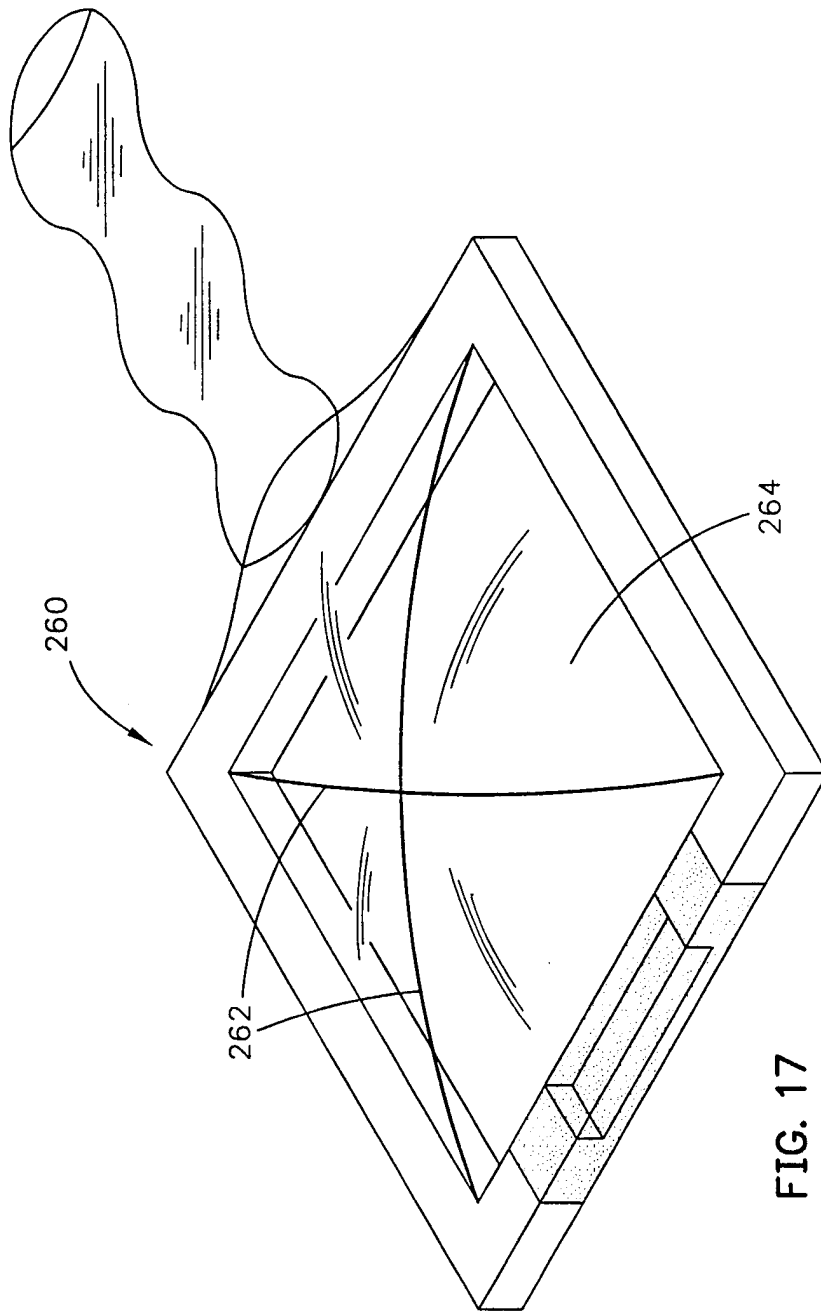
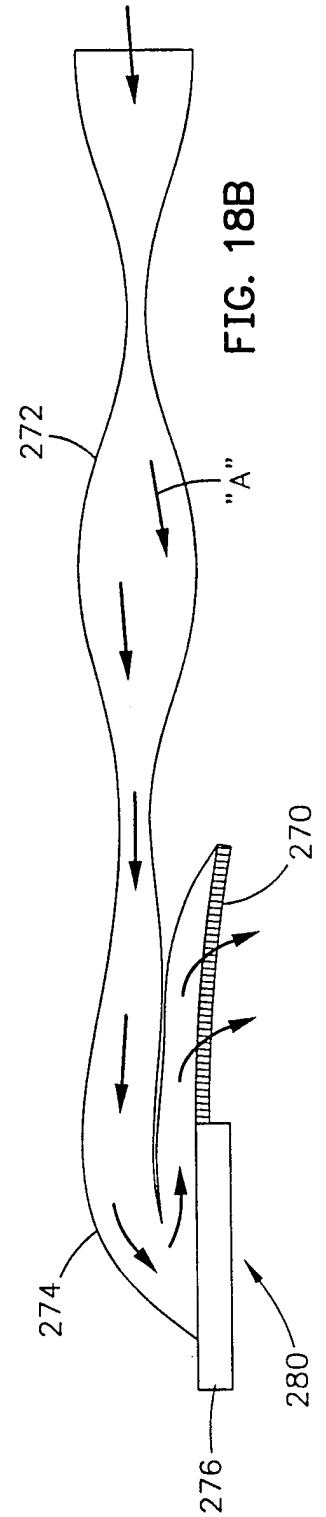
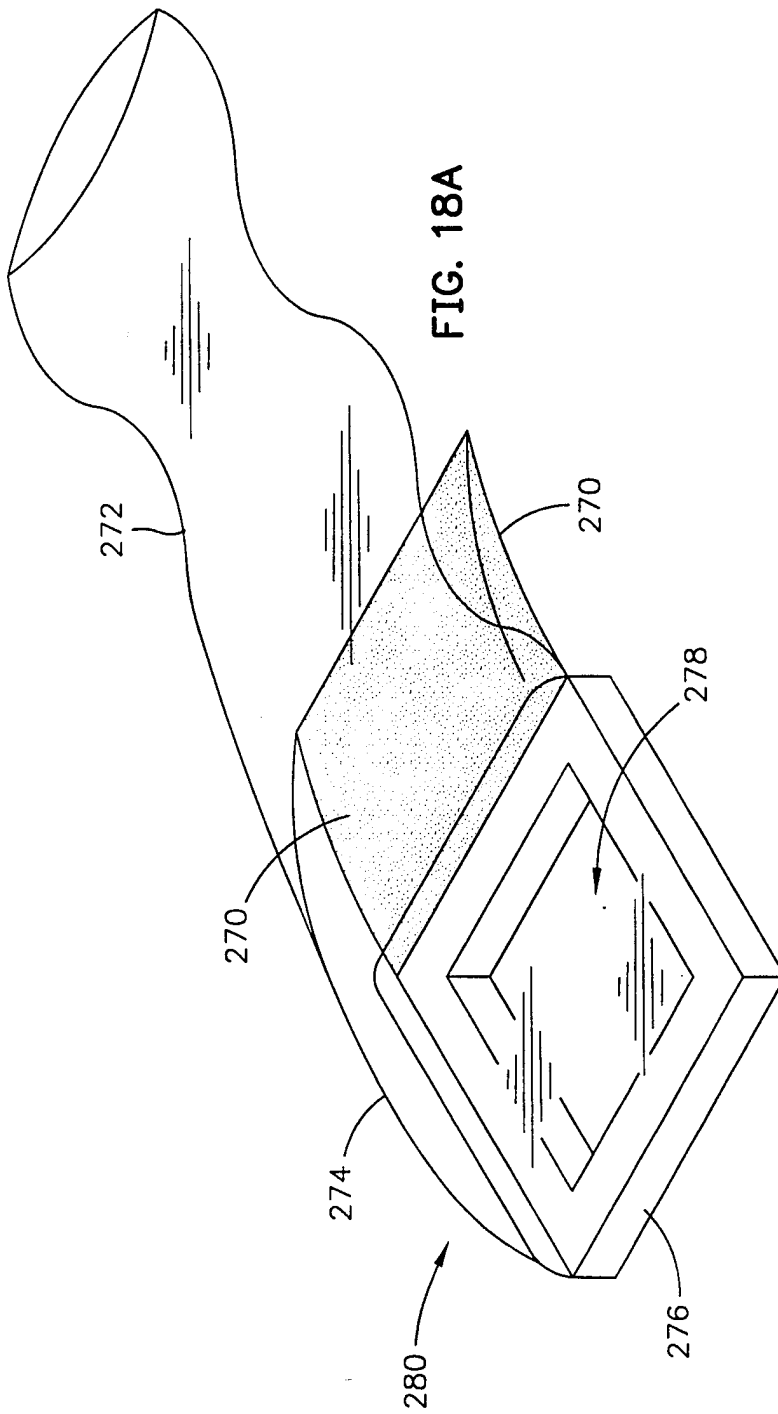


FIG. 17



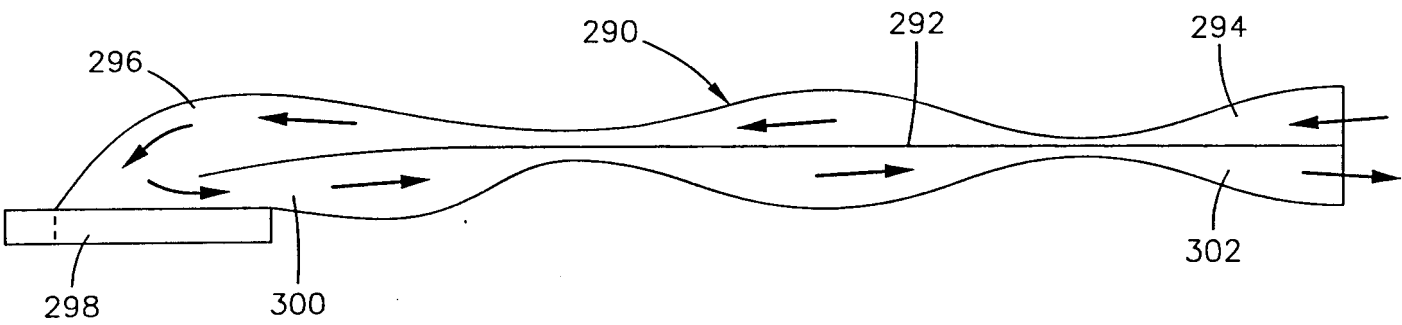


FIG. 19

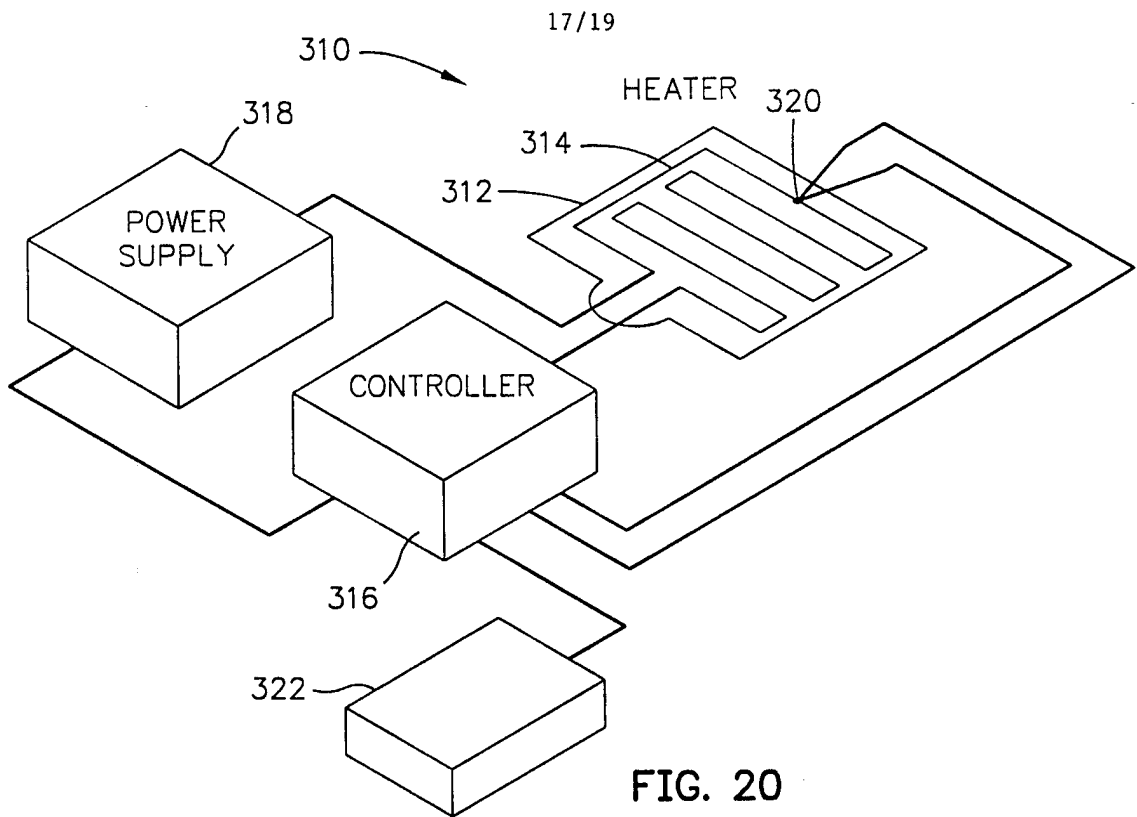


FIG. 20

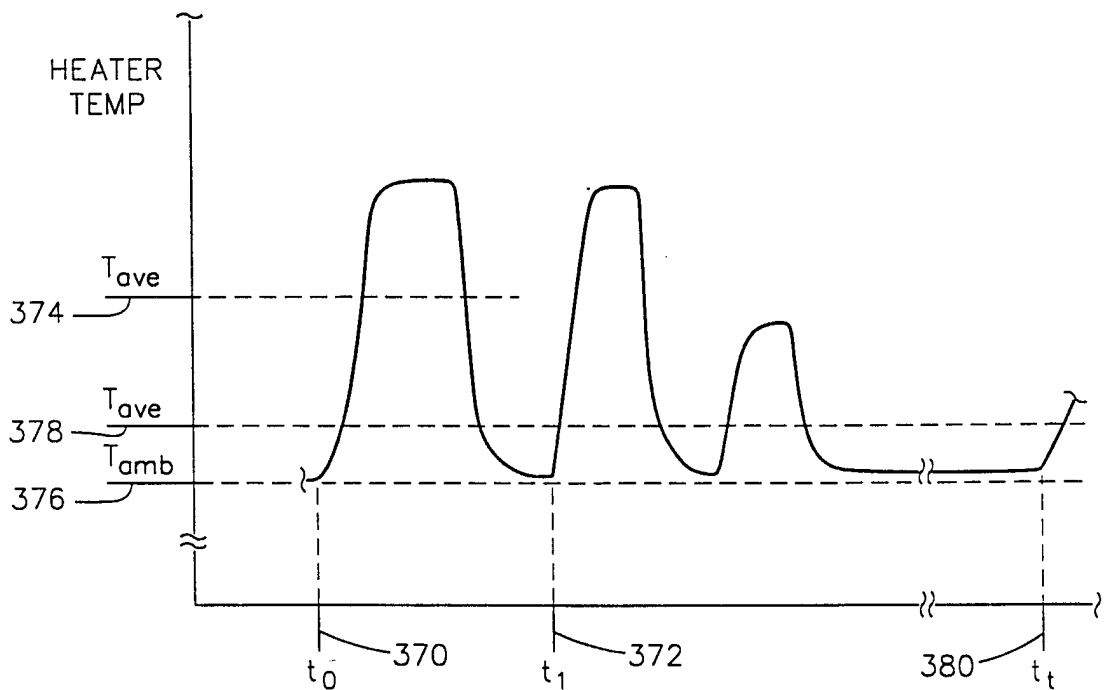
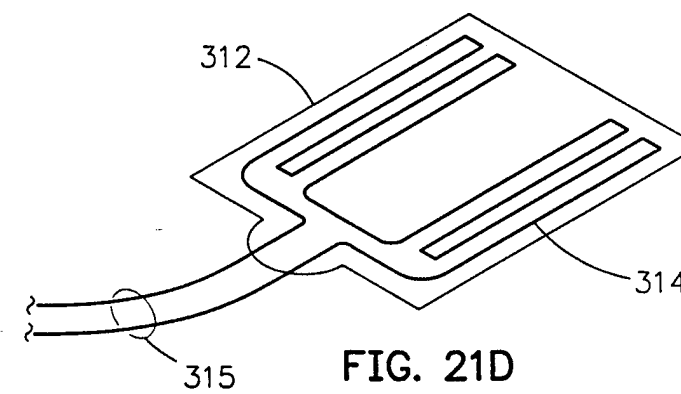
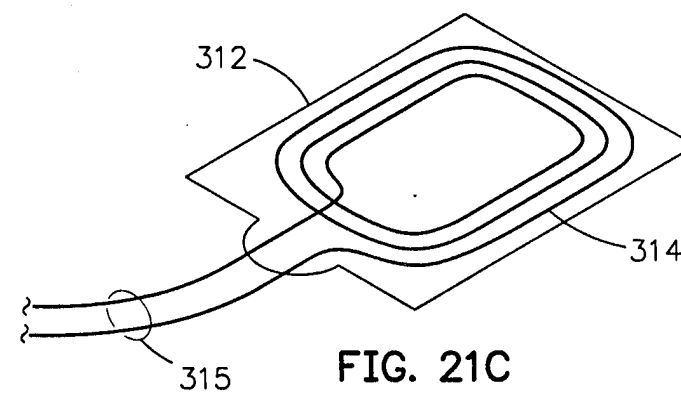
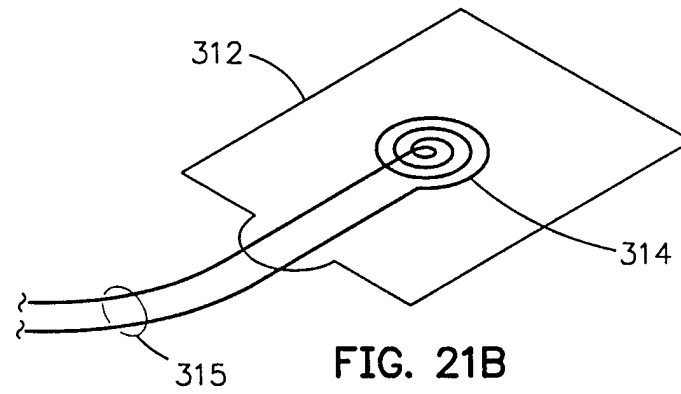
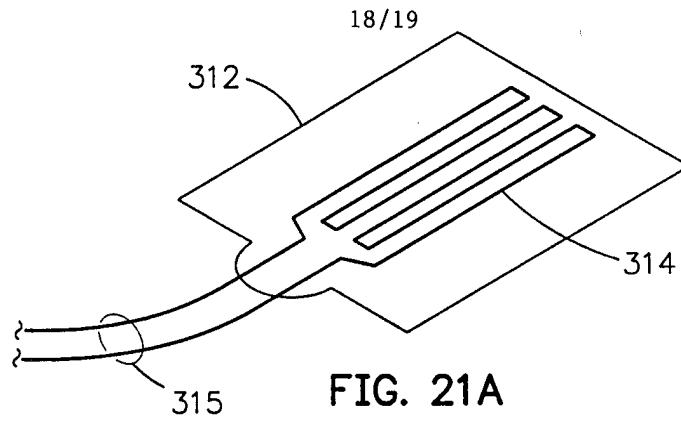


FIG. 24



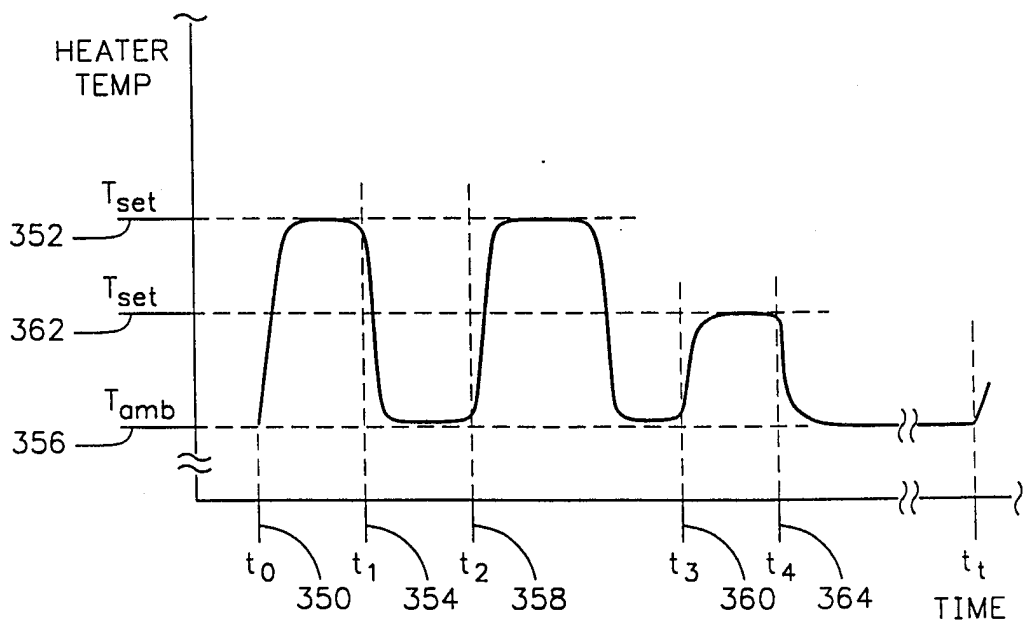
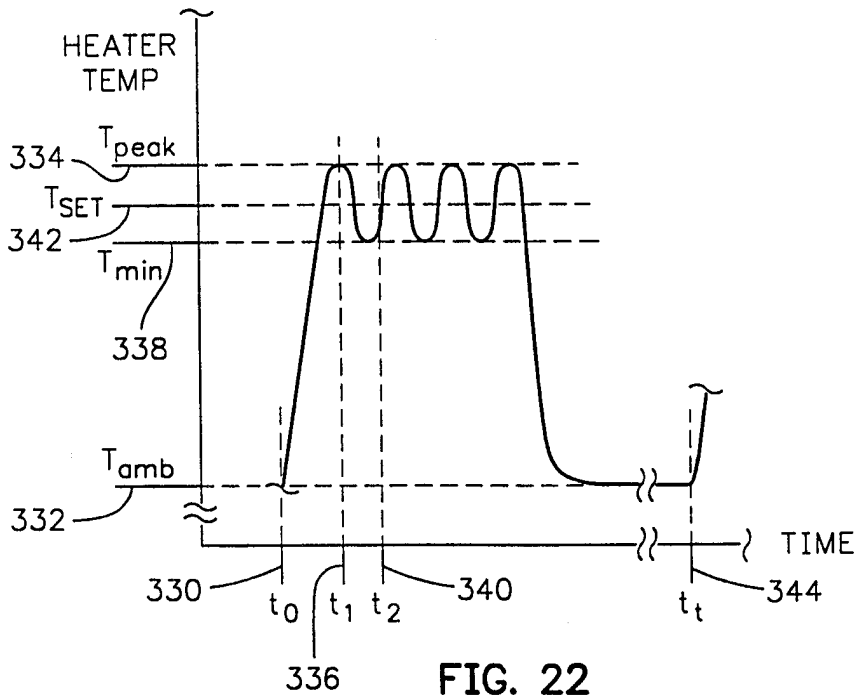


FIG. 23

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 97/21013

A. CLASSIFICATION OF SUBJECT MATTER
 IPC 6 A61F7/02 A61F7/03

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)
 IPC 6 A61F

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 practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 93 19706 A (COLOPLAST) 14 October 1993	1-4, 17, 18, 30, 31, 33-38
A	see page 1, paragraph 4 see page 3, paragraph 4 - page 4, paragraph 1 see page 9, paragraph 1 see page 13, paragraph 2 see page 15, paragraph 2 - page 16, paragraph 5 see page 17, paragraph 4 see claims; figures ---	5-16, 20-27, 29
X	EP 0 638 300 A (KIRIBAI CHEMICAL INDUSTRY) 15 February 1995 see the whole document ---	1-4, 17, 18, 30, 31, 38
	-/--	

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"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)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"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

"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

"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.

"&" document member of the same patent family

Date of the actual completion of the international search

17 March 1998

Date of mailing of the international search report

23.03.98

Name and mailing address of the ISA

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 Fax: (+31-70) 340-3016

Authorized officer

Raybould, B

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 97/21013

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category ³	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 053 024 A (DVORETZKI) 1 October 1991 see column 3, line 50 - line 52 -----	1,17,30, 38
A	WO 96 10379 A (SARINGER RESEARCH) 11 April 1996 see claims 5-8 -----	1,2,17, 30,38

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 97/21013

Box I Observations where certain claims were found unsearchable (Continuation of item 1 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.: 39-47
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 II Observations where unity of invention is lacking (Continuation of item 2 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 fee, this Authority did not invite payment of any additional fee.
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.
- No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 97/21013

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9319706 A	14-10-93	DK 40992 A AU 3948993 A EP 0632712 A US 5662624 A	28-09-93 08-11-93 11-01-95 02-09-97
EP 638300 A	15-02-95	US 5366492 A	22-11-94
US 5053024 A	01-10-91	NONE	
WO 9610379 A	11-04-96	US 5628769 A AU 3516095 A	13-05-97 26-04-96