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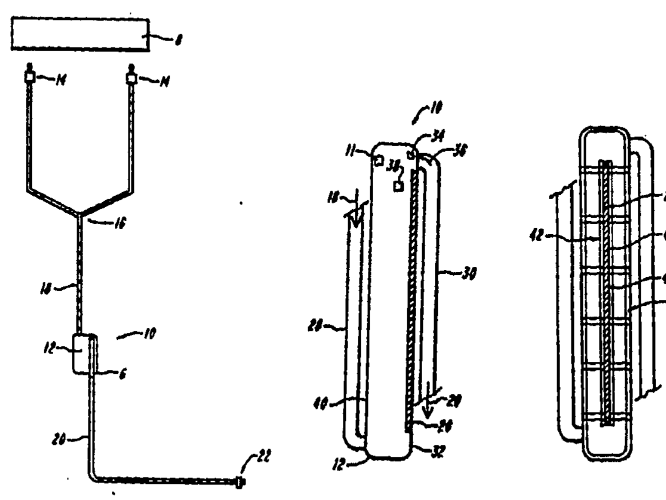

(57) Abstract

Devices and methods for heating a fluid to normothermic temperature prior to delivery of the fluid to a patient are disclosed. In one embodiment, a fluid to be warmed prior to delivery to a patient can be passed through a polymeric, flow-through structure disposed in the fluid delivery line. An electrically resistive heating element for heating the fluid can be molded into the flow-through structure to heat the fluid from room or ambient storage temperatures to a normothermic or body temperature of the patient. A probe of a temperature monitoring element can be used to monitor the temperature of the fluid exiting the flow-through structure. In another embodiment, this information can be relayed back to a controller for controlling the power to the resistance element and hence, the temperature of the fluid. In still another embodiment, an infrared temperature sensor can be used for monitoring the temperature on the fluid exiting the structure by scanning through a window in the outlet port of the flow-through structure or elsewhere in the fluid line.

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FLUID WARMING SYSTEM FOR HEATING A FLUID PRIOR TO DELIVERY OF THE FLUID TO A PATIENT

Background of the Invention

The field of this invention concerns heating fluids and, in particular, heating fluids for delivery to a patient.

One of the problems typically encountered in heating transfusion, infusion or irrigation fluids for delivery to a patient is that such fluids are typically stored at room temperature, which is much lower than a patient's body temperature. Introduction of cold fluids into a patient may well cause discomfort, shock, or another type of trauma. Storage of quantities of warmed fluids, however, is potentially unnecessarily expensive in terms of the energy costs. In addition, the temperature control involved in the storage of warmed fluids is problematic, because the temperature of such fluids still must be maintained while the fluids are transported from the storage area and delivered to the patients.

Various techniques have been used for heating a fluid in-line prior to delivery to a patient. Electrical resistive heating has been used to heat transfusion fluids, in particular. See, for example, U.S. Patent No. 4,906,816 by Van Leerdam; U.S. Patent No. 4,847,470 by Bakke; and U.S. Patent No. 4,532,414 by Shah *et al.*. Typically, a bag or a conduit containing a fluid to be warmed may be placed inside an enclosure. Heating plates contained inside the enclosure may be pressed or clamped against the fluid container. Electrical current is supplied to the heating plates, such that the plates warm the fluid container. When the desired heating is accomplished, the fluid container may be released or removed from the enclosure, and the warmed fluid may be delivered to the body.

Such devices can be cumbersome and awkward, however, because they require that an operator place the fluid container inside the enclosure, clamp or press the heating plates against the fluid container, and subsequently remove the fluid container before the fluid may be delivered to the body. In addition, the temperature monitoring of such devices may be limited, because they typically only measure the temperature of the fluid containers and/or heating elements.

Other various techniques have been used for heating a fluid in-line prior to delivery to a patient. See for example, U.S. Patent No. 5,362,310 by Semm, U.S. Patent No. 4,038,519 by Foucras, and U.S. Patent No. 1,995,302 by Goldstein issued in 1935. Typically, heating wires may be wrapped around or inside the walls of tubes or hoses. Such techniques may require lengthy warm-up times and/or lengthy heating tubes to achieve desired changes in fluid temperature, however, because wrapped heating wires may not provide efficient heat transfer. In addition, the temperature monitoring of such devices may be limited because they typically measure the temperature of the heating hose.

Accordingly, there exists a need for devices and methods for heating fluids, particularly for transfusion and/or irrigation purposes.

Summary of the Invention

Devices and methods are disclosed for heating a fluid to normothermic temperatures prior to the delivery of the fluid to a patient. The present invention is based on the recognition that an electrically resistive heating element can be molded into a flow-through structure, and this structure can be inserted in a flow-line for warming fluids to normothermic temperatures prior to the delivery of such fluids to a body. The term "normothermic temperatures", as used herein, encompasses equilibrium body temperatures in the range of about 34 °C to 45 °C.

In one embodiment of the invention, a fluid to be warmed prior to delivery to a patient can be passed through a polymeric flow-through structure disposed in the delivery fluid flow line. An electrically resistive heating element for heating the fluid is molded into the flow-through structure. In another embodiment, a temperature monitoring element, such as a thermistor, can be used to monitor the temperature of the fluid. In still another embodiment, the thermistor probe can be inserted directly into the fluid stream exiting the flow-through structure to measure the outlet fluid temperature.

In other embodiments of the present invention, the flow-through structure can consist of a chamber. The chamber can further consist of a disposable shell. The heating element can be inserted into a center wall in the chamber such that fluid can flow on both sides of the heating element for maximum heating efficiency. Alternatively, the heating element can be inserted into one or both of the chamber side walls. The chamber can contain baffles for providing a restricted labyrinth flow path for optimizing heating uniformity (e.g., by creating a turbulent flow stream). Alternatively, the chamber can provide a completely unrestricted flow path or can contain baffles for providing an unrestricted labyrinth flow path.

In still other embodiments of the invention, the flow-through structure can consist of flow-through tubing. The tubing can further be disposable. The heating element can be disposed along the outer side of the wall of the tube; in the center of the tubular wall; or along the inner fluid-side of the wall of the tube.

In further embodiments of the invention, the flow-through structure can have a capacity for a fluid flow ranging from about 10 ml/min to about 1000 ml/min. The fluid can flow by gravity or mechanical means into the flow-through structure. A biocompatible protective layer can be disposed between the heating element and the fluid. A flexible insulating material can also be disposed to surround a portion of the heating element or the flow-through structure to reduce heat losses. Flexible tubing can be used to deliver the fluid to and from the flow-through structure for increased ease and flexibility.

In still further embodiments of the invention, the electrically resistive heating element can include, but is not limited to, an etched metal foil, a carbon dispersion resistor or a dye-cut resistor. The heating element can have a capacity of at least about 50 Watts. In one embodiment of the invention, the heating element can heat the fluid a maximum of about 50 ° C above the fluid's storage temperature.

In another aspect of the invention, a system including a polymeric flow-through structure and an electrically resistive heating element, and further including an external controller can be used to warm a fluid prior to delivery to a patient. The controller can control the power supplied to the heating element through an electrical connection element having pads or other electrical connections disposed on the flow-through structure. The system can also include an attachment mechanism for attaching the controller to the flow-through structure to receive this electrical connection element. In addition, the system can include a mounting mechanism for mounting the controller to a support pole. The flow-through structure can consist of a chamber or a tube.

In yet another aspect of the invention, the temperature of the fluid can be monitored during operation of the system. In one embodiment, a temperature sensor can be deployed in the fluid flow path. Alternatively, the temperature of the heating element can be monitored. For example, the electrical resistance of the heating circuit can be monitored and used to calculate indirectly the temperature of the heating element and, hence, the fluid.

The temperature monitoring element and/or the resistance sensor can be integrated into the flow-through structure, but physically separate from the heating element. Alternatively, the temperature monitoring element and/or the resistance sensor can be integrated onto the controller.

The system can be equipped with a number of operational safety and control features to provide for safe and easy operation of the invention. The system can have a power shut-off circuit loop for automatically shutting off power and/or an alarm for sounding when a fault condition occurs. Fault conditions can include the outlet temperature of the fluid, the resistance of the heating element and/or the fluid resistance exceeding a pre-determined limit. Further, additional temperature monitoring and control can be accomplished with an infrared temperature sensor disposed on the controller which senses outlet fluid temperature through a window on the structure outlet or elsewhere in the fluid line. The system can also be equipped with a LED two-digital display of the outlet fluid temperature for easy visual temperature monitoring. In addition, the system can be equipped with one or more lights for indicating whether the desired pre-determined outlet fluid temperature has been reached.

Because of the simplicity and safety of the present invention's operation and its precise measurement of fluid temperature, the present invention represents a valuable addition to the art of biological fluid warming, and in particular, the art of irrigation fluid warming.

Brief Description of the Drawings

FIG. 1A is a schematic illustration of the flow-through structure of the present invention wherein the flow-through structure includes a chamber disposed in a gravity-fed fluid delivery line;

FIG. 1B is a schematic illustration of the chamber flow-through structure of the present invention disposed in a mechanically-fed fluid delivery line;

FIG. 2A is a cross-sectional, top view of a disk-shaped chamber flow-through structure;

FIG. 2B is a cross-sectional, side view of a chamber flow-through structure showing the heating element disposed on a side wall of the structure;

FIG. 3 is a cross-sectional side, view of a chamber flow-through structure with a heating element disposed on the center wall of the structure;

FIG. 4 is a cross-sectional, top view of a disk-shaped chamber flow-through structure with horizontal baffles for an unrestricted labyrinth flow path;

FIG. 5 is a cross-sectional, top view of a rectangular chamber flow-through structure with slanted baffles for a restricted labyrinth flow path;

FIG. 6 shows an etched metal foil resistor for use as a heating element in accordance with the invention;

FIG. 7 shows a carbon dispersion resistor for use as a heating element in accordance with the invention;

FIG. 8 shows a dye-cut resistor for use as a heating element in accordance with the invention;

FIG. 9A is a perspective view of the system of the present invention including a chamber flow-through structure mounted on a vertical support pole;

FIG. 9B is a front view of a controller capable of attachment to a chamber flow-through structure of the system of the present invention;

FIG. 9C is a back view of the controller of FIG. 9B;

FIG. 10 is a schematic diagram showing the internal circuit loop for the system of the present invention including a chamber flow-through structure for monitoring and controlling temperature and power equipped with an infrared temperature sensor;

FIG. 11 is a schematic illustration of another flow-through structure of the present invention wherein the structure includes a tube disposed in a gravity-fed fluid delivery line;

FIG. 12A is a more detailed view of the tubular flow-through structure of FIG. 11;

FIG. 12B is a cross-sectional view of yet another tubular flow-through of FIG. 11;

FIG. 13 is a cross-sectional view of yet another tubular flow-through structure of the present invention showing a heating element disposed in the center of the wall of the tubular flow-through structure;

FIG. 14A is a perspective view of a system of the present invention including a tubular flow-through structure mounted on a vertical support pole;

FIG. 14B is a front view of the controller of the system with the tubular flow-through structure shown in FIG. 14A;

FIG. 14C is a back view of the controller of FIG. 14A; and

FIG. 15 is a schematic diagram showing the internal circuit loop for the system of the present invention including a tubular flow-through structure for monitoring and controlling temperature and power equipped with an infrared temperature sensor.

Detailed Description of the Invention

The present invention provides an electrically resistive heating element molded into a polymeric flow-through structure for warming fluids in-line to normothermic temperatures prior to delivery to a patient. FIG. 1A illustrates a perspective view of the device 10 of the present invention having a flow-through structure 6 consisting of a chamber 12 disposed in association with a source of fluid 8 and a fluid delivery line consisting of two IV bag spikes 14, a Y connector 16, a gravity-fed fluid line 18 entering the chamber 12, a fluid line 20 exiting the chamber, and a luer connector 22 for connecting the fluid line 20 to a device such as irrigator or IV line for delivering the fluid 8 into a patient. Alternatively, the fluid entering the device of the present invention can be delivered by mechanical means 24, as shown in FIG. 1B.

FIG. 2A illustrates an inside frontal view of a chamber flow-through structure 12 having an electrically resistive heating element 26, an inlet port 28 and an outlet port 30. The fluid inlet port 28 directs the fluid to the bottom of the chamber flow-through structure 12 and the fluid outlet port 30 allows the fluid to exit from the top of the flow-through structure to facilitate air escape during priming of the chamber. FIG. 2B, which is an inside side view of the chamber flow-through structure 12, shows the electrically resistive heating element 26 disposed on a side wall 32 of the chamber flow-through structure 12 such that the fluid flows along one side of this element 26. A temperature monitoring element 34, such as a thermistor or a thermocouple, can be used to monitor the temperature of the fluid 20 exiting outlet port 30. A probe 36 of the temperature monitoring element 34 can be inserted directly into the fluid line 20 exiting the chamber flow-through structure 12 to measure the outlet fluid temperature. A resistance sensor 38 can be integrated into the chamber flow-through structure 12 but physically separate from the heating element to measure the fluid temperature. A liquid detection sensor 11 can also be employed to measure the resistance of the fluid in the chamber flow-through structure.

The chamber flow-through structure 12 can consist of a disposable shell with a capacity for a fluid flow ranging from about 10 ml/min to about 1000 ml/min. The chamber flow-through structure 12 can be manufactured through any number of known , such as injection molding with any FDA approved medical grade thermoplastic (e.g. polypropylene, polyethylene, nylon or PVC). The chamber flow-through structure can also be made of different shapes, and the rectangular and disk shapes shown in Figs. 1A and 2A, respectively, are illustrated for exemplary purposes only.

Although FIG. 2A shows the heating element 26 inserted into a chamber sidewall 32, the heating element 26 can also be inserted into either (or both) of the chamber side walls 32 and 40. Alternatively, FIG. 3 shows that the heating element 26 can be inserted into a center wall 42 of the chamber flow-through structure 12 such that fluid can flow on both sides of the heating element 26 for maximum heating efficiency. The heating element 26 can be contained between two layers 48 of a laminate material, such as polyimides or polyesters, that will have thermal properties such that they will not melt or otherwise degrade at the temperature of heater operation. In addition, FIG. 3 illustrates that a biocompatible protective layer 44, which does not further hinder the heat transfer to the fluid, can be disposed between at least one portion of the heating element and the fluid. Again, this layer can be made of any biocompatible material with high thermal conductivity (e.g. polypropylene, polyethylene, nylon or PVC). This layer can be applied to the heating element by a plasma coating process. FIG. 3 also illustrates that an insulating material 46 can be disposed to surround at least a portion of the outer surface of the heating element 26 or the chamber flow-through structure to reduce heat losses.

FIG. 4 shows that horizontal baffles 50 may be inserted into the chamber flow-through structure 12 to form an unrestricted labyrinth flow path 52. The unrestricted labyrinth flow path 52 does not allow the fluid to flow straight through the chamber flow-through structure 12, but at the same time, does not restrict the flow to a single defined flow path. Gaps 54 between the baffles and the chamber walls eliminate fluid dead spots or eddies that would normally occur when the flowing fluid is forced around a corner. FIG. 5 shows the chamber flow-through structure 12 with slanted baffles 56 forming a restricted labyrinth flow path 58. In a restricted labyrinth flow path 58, slanted baffles 56 force the fluid to flow in a defined labyrinth path. As in the unrestricted labyrinth flow path, the gaps 60 between the slanted baffles 56 and the walls of the chamber flow-through structure eliminate the fluid dead spots or eddies that normally occur when flowing fluid is forced around a corner. In addition, the slanted baffles 56 facilitate the escape of air during the priming process.

The electrically resistive heating element 26 is made up of a conductor which heats up in response to an applied electric current. This heating element 26 can include, but is not limited, to an etched metal foil 62, as shown in FIG. 6, a carbon dispersion resistor 64, as shown in FIG. 7, or a dye-cut resistor 66, as shown in FIG. 8. Different heating element shapes also can be used depending upon the shape and/or form of the flow-through structure. The heating element can have a capacity of at least about 50 Watts. This power requirement can be accomplished with a variety of resistance/voltage/current configurations. The area of the heating element can be about 15 cm^2 to about 600 cm^2. In one embodiment of the invention, the heating element can heat the fluid a maximum of about 50 °C above the storage temperature of the fluid.

The present invention also provides a system including a polymeric flow-through structure, an electrically resistive heating element, and an external controller for heating fluids prior to delivery to a patient. FIG. 9A shows an outside view of this system 70 wherein the system 70 includes a chamber flow-through structure 12 attached to the controller 72, which, in turn, is mounted to a vertical support pole with a mounting mechanism 74. The controller 72 can monitor the temperature of the outlet fluid and control the power supply to the heating element through an electrical connection element 76 having pads 78A, 78B, & 78C disposed on the front of the controller, shown in FIG. 9B, and pads 80A, 80B, & 80C disposed on the back of the chamber flow-through structure, as shown in FIG. 9C. Alternatively, other electrical connections such as prongs, jacks, plugs or the like can be used. All electrical connections can be safety interlocked to the proper installation of the disposable. The attachment mechanism 82 for attaching the front of the controller 72 to back of the chamber flow-through structure 12 to receive this electrical connection element is also shown in Figs. 9B and 9C.

FIG. 9B further illustrates that the front of the controller 72 can be equipped with a LED two-digital display 84 of the outlet fluid temperature for easy visual temperature monitoring. In addition, the front of the controller 72 can be equipped with one or more lights 86 for indicating a fault condition and/or whether the desired pre-determined outlet fluid temperature has been reached, a power ON/OFF switch 88 and a RESET switch 89 for easy operator access. The controller 72 can be AC line powered and switchable to operate at either 110 Vac or 220 Vac line voltage. The AC input power can be overload protected by dual (two line) fuses.

An internal circuit loop 90 for controlling temperature of and power to a chamber flow-through structure is shown in FIG. 10. The controller 72 supplies power from the power module 92 via electrical line 94 through electrical connection pads 80B and 78B to the heating element 26. The resistance of heating element 26 can be monitored via line 96 through electrical connection pads 80A and 78A by a resistance sensor 38 which can be disposed on the controller 72. Alternatively, a resistance sensor 38A (shown in dotted lines in FIG. 10) can be located on the chamber flow-through structure 12. In addition, if the alloy which makes up the conductor of the heating element 26 has a large temperature coefficient of resistance, the electrical resistance of the heating element 26 itself can be used to measure the temperature of the heating element and correlated to fluid temperature. Using this method, an upper limit on the resistance of the heating element 26 can be used as an over temperature sensor for the fluid.

The probe 36 of the temperature monitoring element 34 can be disposed in the outlet port 30 to monitor the temperature of the fluid 20 exiting the chamber flow-through structure 12. This information is transmitted back to the power module 92 via line 98 through electrical connection pads 80C and 78C. Alternatively, the temperature monitoring element 34A (shown in dotted lines in FIG. 10) can be disposed on the controller and its probe 36A can be inserted into a sleeve 37 or other portion of the outlet port 30 of the chamber flow-through structure 12. This information can be transmitted back to the power module 92 via line 98A. The actual temperature of the fluid can then be relayed via line 100 to the temperature display panel 102 and/or relayed via line 104 to at least one light 86A indicating whether the temperature has reached the desired level. Additional temperature monitoring and control can be accomplished with an infrared temperature sensor 108 disposed on the controller 72 which senses outlet fluid temperature through a window 110 on the chamber flow-through structure outlet port 30 or elsewhere in the fluid line. This information can be relayed to the power module 92 via line 112 and also used for the temperature monitoring. A liquid detection sensor 11 can be employed to measure the resistance of the fluid in the tube. If sensor 11 detects a lack of fluid (e.g., a high resistance) a shut-off signal can be relayed via line 136 and electrical connection pads 132 D and 134 D to the power module 92. The power ON/OFF switch 88 can be relayed to the power module 92 via line 114. The RESET switch 89 can be relayed to the power module 92 via line 116.

If the resistance or temperature exceeds a pre-determined level, the power module 92 can automatically shut off power to the heating element 26. In addition, the power module can sound an alarm 118 via line 120 and/or illuminate a warning light 86B via line 122 to warn the user of a fault condition.

FIG. 11 illustrates a perspective view of another embodiment of the invention including a device 140 of the present invention having a flow-through structure 138 consisting of a tube 142 disposed in association with a source of fluid 8 and a fluid delivery line consisting of two IV bag spikes 14, a Y connector 16, a gravity-fed fluid line 18 entering the tube 142, a fluid line 20 exiting the tube, and a luer connector 22 for connecting the fluid line 20 to a device such as irrigator or IV line for delivering the fluid 8 into a patient. Alternatively, the fluid entering the device 140 can be delivered by mechanical means. The tube 142 can consist of a disposable tubing with a capacity for a fluid flow ranging from about 10 ml/min to about 1000 ml/min. The tube 142 can be manufactured through any number of known continuous or batch methodologies, such as extrusion processes with any FDA approved medical grade thermoplastic (e.g., silicone, polyurethane or PVC). The tube 142 can be various lengths (e.g., from about 6 inches to several feet).

FIG. 12A illustrates an inside view of a tubular flow-through structure 142 having an electrically resistive heating element 144, an inlet port 146 and an outlet port 148. A temperature monitoring element 150, such as a thermistor or a thermocouple, can be used to monitor the temperature of the fluid 20 exiting outlet port 148. A probe 152 of the temperature monitoring element 150 can be inserted directly into the fluid line 20 at outlet port 148 to measure the outlet fluid temperature. A sensor 158 can be integrated into the tubular flow-through structure 142 but physically separate from the heating element to measure the resistance of the heating element which can then be correlated to the fluid temperature. A liquid detection sensor 160 can also be employed to measure the resistance of the fluid in the tube.

FIG. 12B, which is an inside side view of the tubular flow-through structure 142, shows the electrically resistive heating element 144 disposed on an inner side 162 of the wall of the tubular flow-through structure 142. Alternatively, the heating element 144 can also be inserted into the outer side 164 of the wall of the tubular flow-through structure 142. In addition, FIG. 13 shows that the heating element 144 can be inserted into the center 166 of the wall of the tubular flow-through structure 142. The heating element 144 can be contained between two layers 168 of a laminate material, such as polyimides or polyesters, that will have thermal properties such that they will not melt or otherwise degrade at the temperature of heater operation. In addition, FIG. 13 illustrates that a biocompatible protective layer 170, which does not further hinder the heat transfer to the fluid, can be disposed between at least one portion of the heating element and the fluid. Again, this layer can be made of any of a variety of known biocompatible materials (e.g., polypropylene, polyethylene, nylon or PVC). This layer can be applied to the heating element by a plasma coating process. FIG. 13 also illustrates that an insulating material 172 can be disposed to surround at least a portion of the outer surface of the heating element 144 or the tubular flow-through structure 142 to reduce heat losses.

The present invention also provides a system including a polymeric flow-through structure consisting of a tube, an electrically resistive heating element coupled to the tube, and an external controller for heating fluids prior to delivery to a patient. FIG. 14A shows an outside view of this system 180 with the tubular flow-through structure 142 attached to the controller 182, which, in turn, is mounted to a vertical support pole with a mounting mechanism 184. The controller 182 can monitor the temperature of the outlet fluid and can control the power supply to the heating element through an electrical connection element 186 having pads 188 A, 188 B, & 188 C disposed on the front of the controller, shown in FIG. 14B, and pads 190 A, 190 B, & 190 C disposed on the back of the tubular flow-through structure, as shown in FIG. 14C. Alternatively, other electrical connections such as prongs, jacks, plugs or the like can be used. All electrical connections can be safety interlocked to the proper installation of the disposable tubular flow-through structure 142. The attachment mechanism 192 for attaching the front of the controller 182 to back of the tubular flow-through structure 142 to receive this electrical connection element is also shown in Figs. 14B and 14C.

FIG. 14B further illustrates that the front of the controller 182 can be equipped with a LED two-digital display 191 of the outlet fluid temperature for easy visual temperature monitoring. In addition, the front of the controller 182 can be equipped with one or more lights 194 for indicating a fault condition and/or whether the desired predetermined outlet fluid temperature has been reached, a power ON/OFF switch 196 and a RESET switch 199 for easy operator access. The controller 182 can be AC line powered and switchable to operate at either 110 Vac or 220 Vac line voltage. The AC input power can be overload protected by dual (two line) fuses.

An internal circuit loop 200 for controlling temperature of and power to a tubular flow-through structure 142 is shown in FIG. 15. The controller 182 supplies power from the power module 202 via electrical line 204 through electrical connection pads 188B and 190B to the heating element 144. The resistance of heating element 144 can be monitored via line 206 through electrical connection pads 190A and 188A by a resistance sensor 158 which can be disposed on the controller 182. Alternatively, a resistance sensor 158A (shown in dotted lines in FIG. 16) can be located on the tube 142. In addition, if the alloy which makes up the conductor of the heating element 144 has a large temperature coefficient of resistance, the electrical resistance of the heating element 144 can be used to measure the temperature of the heating element 144, and hence, the temperature of the fluid. Using this method, an upper limit on the resistance of the heating element 144 can be used as an over temperature sensor.

The probe 152 of the temperature monitoring element 150 can be disposed in the outlet port 148 to monitor the temperature of the fluid 20 exiting the tubular flow-through structure 142. This information is transmitted back to the power module 202 via line 208 through electrical connection pads 190C and 188C. Alternatively, the temperature monitoring element 150A (shown in dotted lines in FIG. 15) can be disposed on the controller and its probe 152A can be inserted into a sleeve 154 or other portion of the outlet port 148 of the tubular flow-through structure 142. This information can be transmitted back to the power module 202 via line 208A. The actual temperature of the fluid can then be relayed via line 210 to the temperature display panel 191 and/or relayed via line 214 to at least one light 194A indicating whether the temperature has reached the desired level. Additional temperature monitoring and control can be accomplished with an infrared temperature sensor 218 disposed on the controller 182 which senses outlet fluid temperature through a window 220 on the tube outlet port 148 or elsewhere in the fluid line. This information can be relayed to the power module 202 via line 212 and also used for the temperature monitoring. A liquid detection sensor 160 can be employed to measure the resistance of the fluid in the tube. If sensor 160 detects a lack of fluid (e.g., a high resistance) a shut-off signal can be relayed via line 236 and electrical connection pads 232 D and 234 D to the power module 202. The power ON/OFF switch 196 can be relayed to the power module 202 via line 244. The RESET switch 199 can be relayed to the power module 202 via line 216.

If the resistance or temperature exceeds a pre-determined level, the power module 202 can automatically shut off power to the heating element 144. In addition, the power module can sound an alarm 240 via line 242 and/or illuminate a warning light 194B via line 222 to warn the user of a fault condition.

In sum, the present invention benefits from the recognition that an electrically resistive heating element can be molded into a flow-through structure, and this structure can be inserted in a flow-line for warming fluids to normothermic temperatures prior to the delivery of such fluids to a body. Further, the devices and methods of the present invention have several advantages over the traditional devices and techniques for heating such fluids. For example, the incorporation of the heating element inside the polymeric, flow-through structure provides that device can be inserted in one simple step directly in the fluid delivery line. In contrast, the traditional techniques may require multiple steps such as placing a bag or conduit of fluid inside an enclosure, pressing or clamping heating plates against the fluid container, and subsequently, removing the heating plates prior to fluid delivery.

Further, the coupling of an electrically resistive heating element, which is highly efficient in terms of heat transfer, to a polymeric, flow-through structure, such as a chamber or a tube, provides that the desired fluid heating can be accomplished quickly with a relatively compact device. In contrast, the traditional techniques involving wrapping heating wires around hoses may not be efficient in terms of heat transfer, and thus may require long warm-up times and lengthy hoses to accomplish the desired fluid heating.

In addition, in comparison with the traditional techniques for warming delivery fluids, the devices and methods of the present invention provide unique and accurate temperature monitoring and control. For example, the device can employ a probe of a temperature monitoring element inserted directly in the flow line of the fluid exiting the flow-through structure. Alternatively or additionally, the device can employ an infrared sensor for sensing the outlet fluid temperature through window molded in the exit port of the flow-through structure. In contrast, the traditional techniques typically only monitor the temperature of the heating plate and/or fluid container.

It will be understood that the above description is provided by way of illustration and not by way of limitation. For example, other structure shapes, flow paths, resistance and temperature monitoring and control configurations can be selected consistent with the present invention. The invention is further characterized according to the following claims.

What is claimed is:

1. A fluid heating apparatus for heating a fluid prior to delivery of the fluid to a patient, the apparatus comprising:

a polymeric flow-through structure through which the fluid flows; and

at least one electrically resistive heating element molded into the flow-through structure for heating the fluid.

2. The apparatus of claim 1 wherein the flow-through structure further comprises a chamber.

3. The apparatus of claim 2 wherein the chamber has a center wall and the heating element is molded into the center wall.

4. The apparatus of claim 2 wherein the chamber further comprises baffles for forming a restricted labyrinth flow path.

5. The apparatus of claim 1 wherein the flow-through structure further comprises a tube.

6. The apparatus of claim 5 wherein the heating element is disposed along an inner fluid-side wall of the tube.

7. The apparatus of claim 1, further comprising:

a temperature monitoring element for measuring an outlet temperature of the fluid exiting the flow-through structure.

8. The apparatus of claim 7 wherein the temperature monitoring element further comprises a probe disposed in an outlet flow path of the fluid exiting the flow-through structure.

9. The apparatus of claim 8 wherein the temperature monitoring element further comprises a thermistor.

10. The apparatus of claim 1 wherein the apparatus further comprises an electrical connection element for power and temperature control.

11. The apparatus of claim 1 wherein the apparatus further comprises a sensor for detecting the absence of fluid in the flow-through structure.

12. The apparatus of claim 1 wherein the apparatus is disposable.

13. The apparatus of claim 1 wherein the apparatus further comprises a biocompatible protective material disposed between the heating element surface and the inside of the flow-through structure.

14. The apparatus of claim 1 wherein the apparatus further comprises an insulating material to reduce heat losses.

15. The apparatus of claim 1 wherein the apparatus further comprises a mechanical means which drives the fluid flow.

16. The apparatus of claim 1 wherein the heating element has a capacity for emitting at least about 50 Watts.

17. The apparatus of claim 1 wherein the apparatus has a capacity for a fluid flow ranging from about 10 ml/min to about 1000 ml/min.

18. The apparatus of claim 1 wherein the apparatus further comprises the heating element selected from the group consisting of:

an etched metal foil,
a carbon dispersion resistive material, and
a dye-cut resistive material.

19. A fluid heating system for heating a fluid prior to delivery of the fluid to a patient, the system comprising:

a polymeric flow-through structure through which the fluid flows;

at least one electrically resistive heating element molded into the flow-through structure for heating the fluid; and

an external controller capable of attachment to the flow-through structure for controlling the power to the heating element.

20. The system of claim 19, further comprising:

an attachment mechanism for attaching the controller to the flow-through structure to receive an electrical connection element disposed on the flow-structure.

21. The system of claim 19, further comprising:

a resistance sensor for sensing an electrical resistance of the heating element.

22. The system of claim 19 wherein the system further comprises a power shut-off circuit loop for automatically shutting off power to the heating element when a fault condition occurs.

23. The system of claim 19 wherein the system further comprises an alarm for sounding when a fault condition occurs.

24. The system of claim 19 wherein the system further comprises a mounting mechanism for mounting the controller to a support pole.

25. The system of claim 19 wherein the system further comprises an infrared temperature sensor for sensing the outlet fluid temperature.

26. The system of claim 19 wherein the system further comprises a LED display for indicating a two-digit temperature display of an outlet fluid temperature and at least one light for indicating when the outlet fluid temperature is within a pre-determined temperature range.

27. The system of claim 19 wherein the flow-through structure is a chamber.

28. The system of claim 19 wherein the flow-through structure is a tube.

29. A method for heating a fluid entering a biological body, the method comprising the steps of:

providing a polymeric flow-through structure through which the fluid may pass;

providing at least one electrically resistive heating element that is molded into the flow-through structure;

flowing the fluid though the flow-through structure; and

heating the fluid with the heating element while the fluid passes through the flow-through structure.

30. The method of claim 29 wherein the heating step further comprises heating the fluid to a desired pre-determined temperature range of about 34 °C to about 45 ° C.

31. The method of claim 29 wherein the heating step further comprises heating the fluid to a maximum of about 50 °C above a storage temperature of the fluid.

32. The method of claim 29, further comprising the step of:

monitoring the temperature of the heating element by measuring the resistance across the heating element and correlating the resistance to the temperature of the heating element.

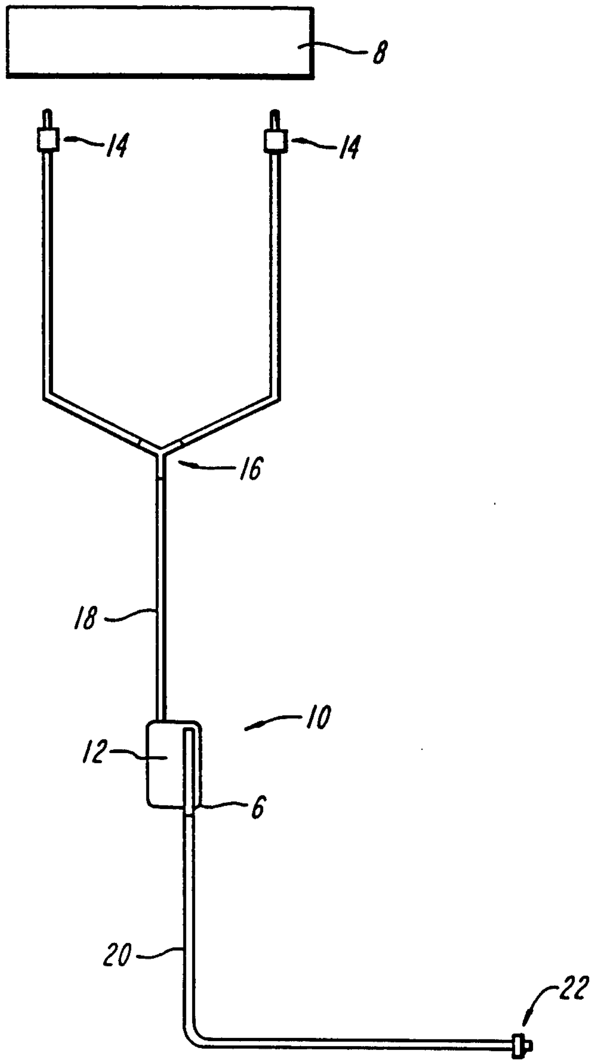


FIG. 1A

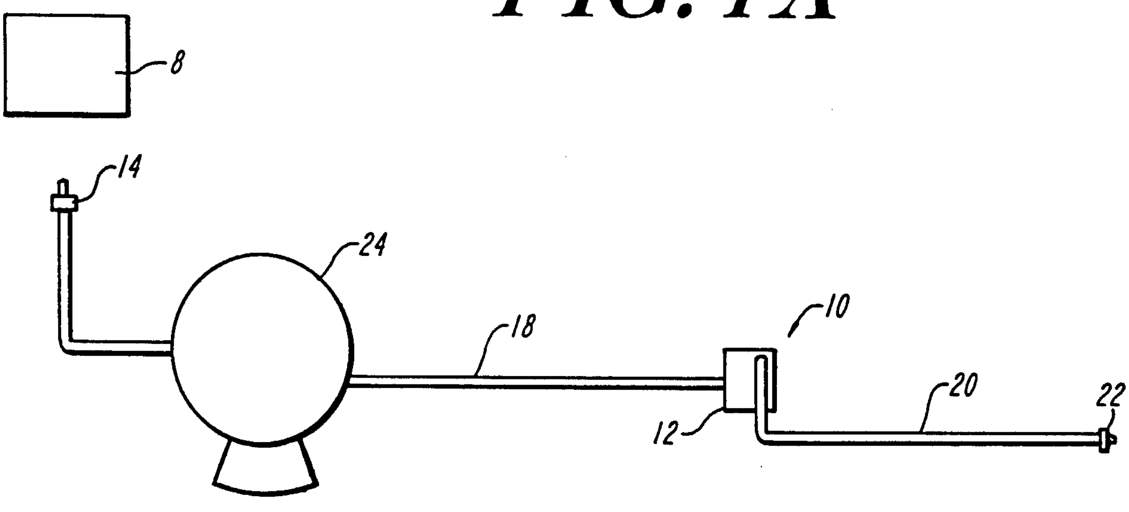


FIG. 1B

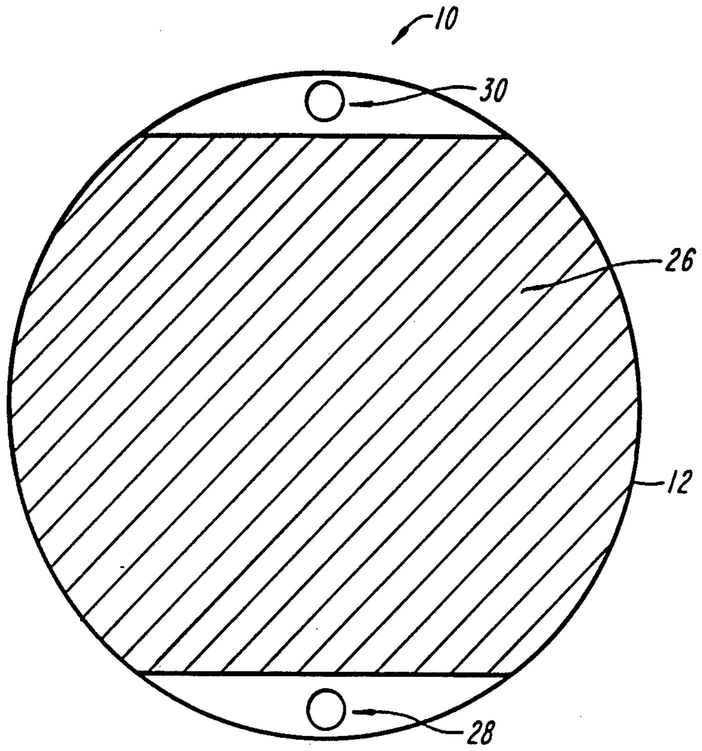


FIG. 2A

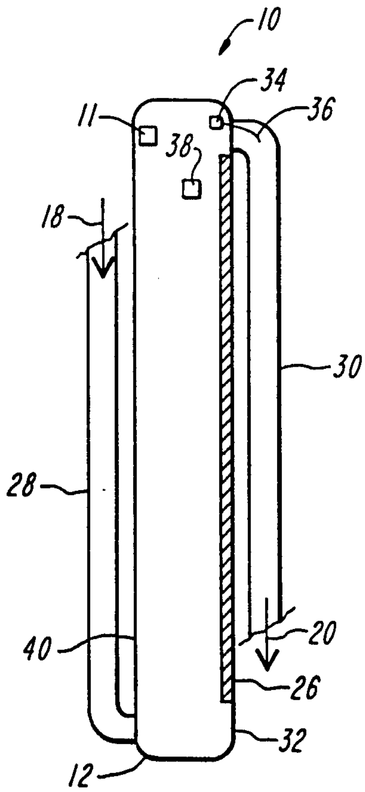


FIG. 2B

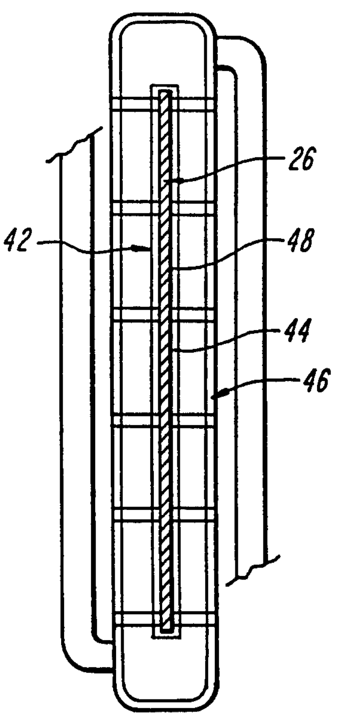
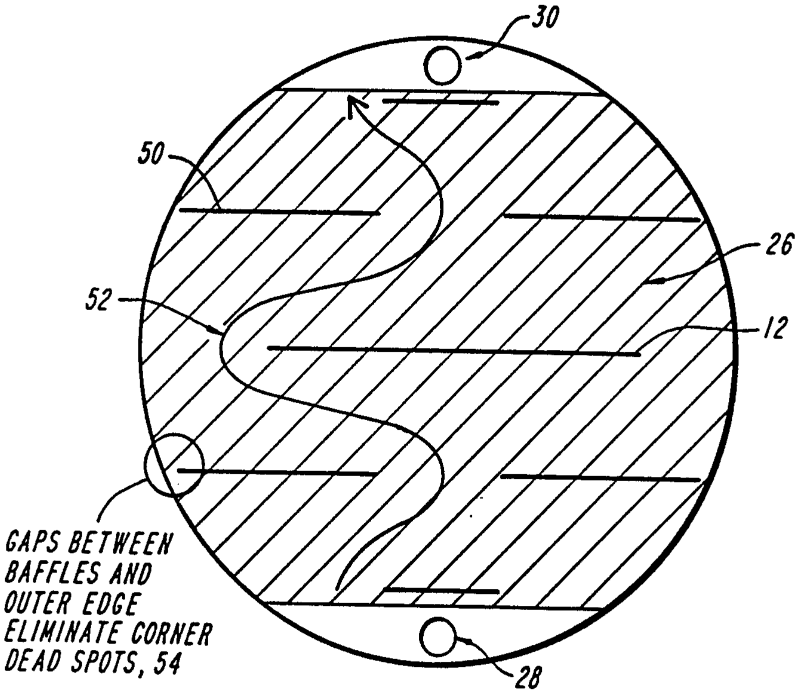


FIG. 3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GAPS BETWEEN BAFFLES AND OUTER EDGE ELIMINATE CORNER DEAD SPOTS, 54
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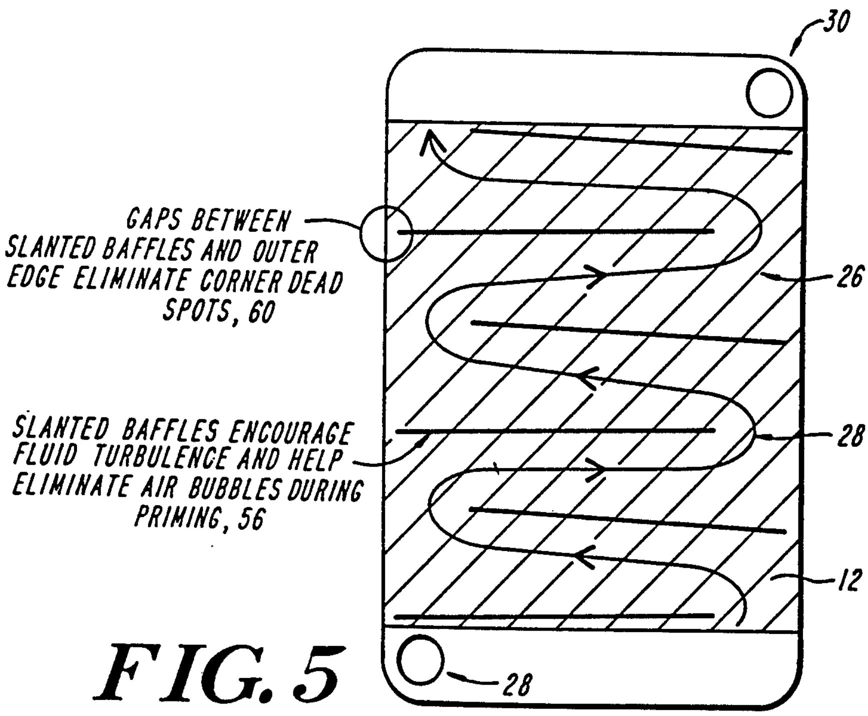
FIG. 4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GAPS BETWEEN SLANTED BAFFLES AND OUTER EDGE ELIMINATE CORNER DEAD SPOTS, 60
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SLANTED BAFFLES ENCOURAGE FLUID TURBULENCE AND HELP ELIMINATE AIR BUBBLES DURING PRIMING, 56
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FIG. 5

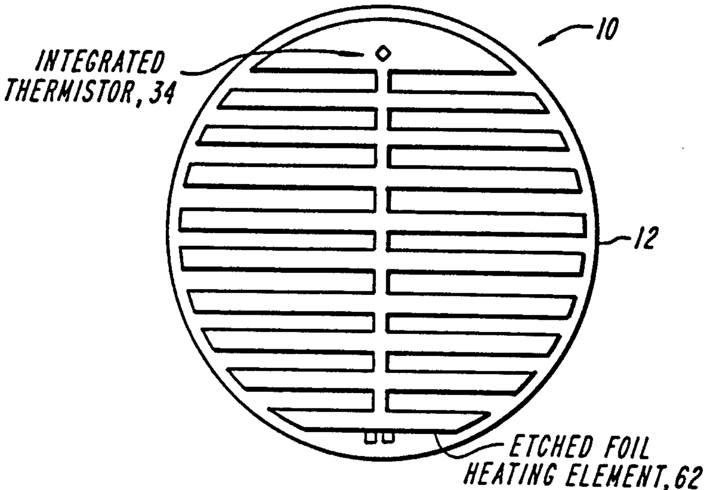

FIG. 6

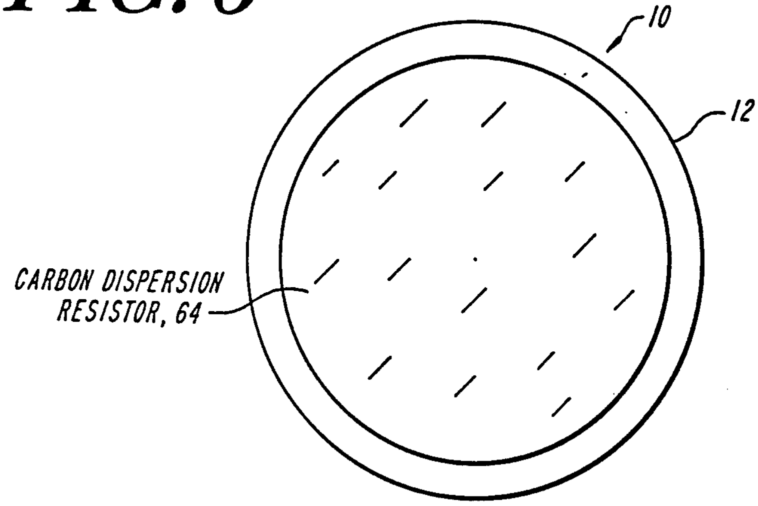

FIG. 7

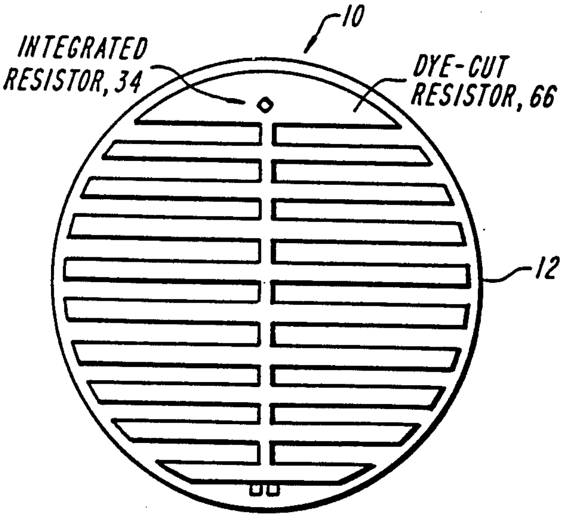

FIG. 8

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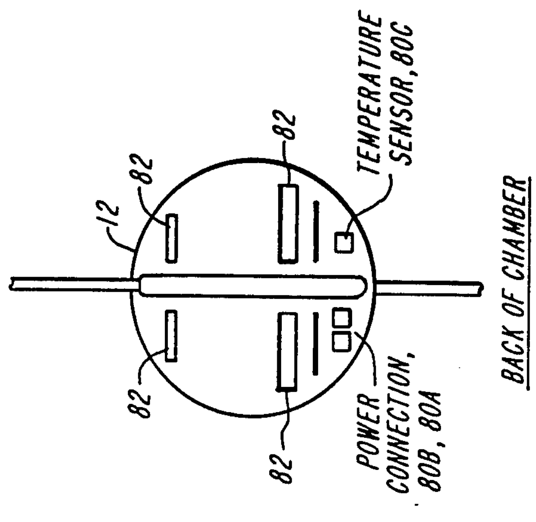


FIG. 9C

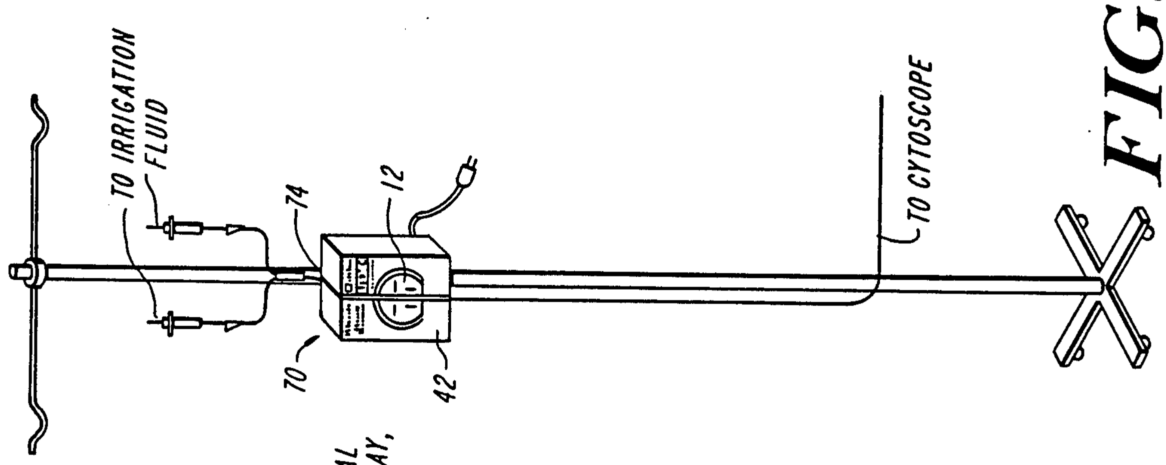


FIG. 9A

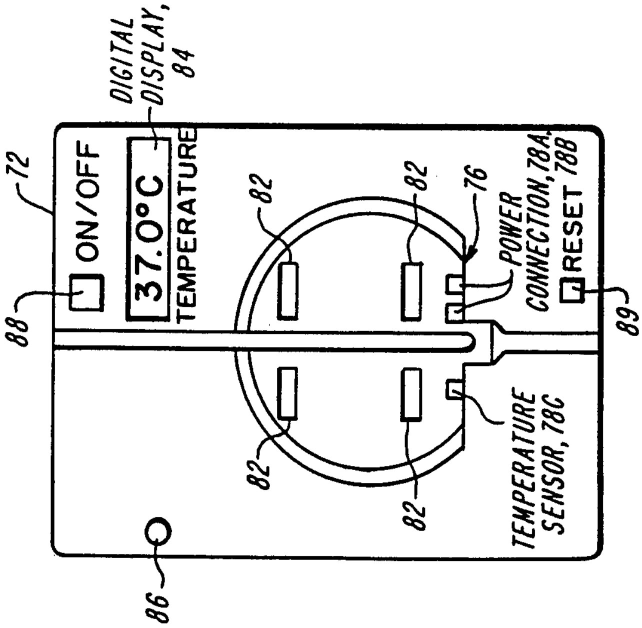
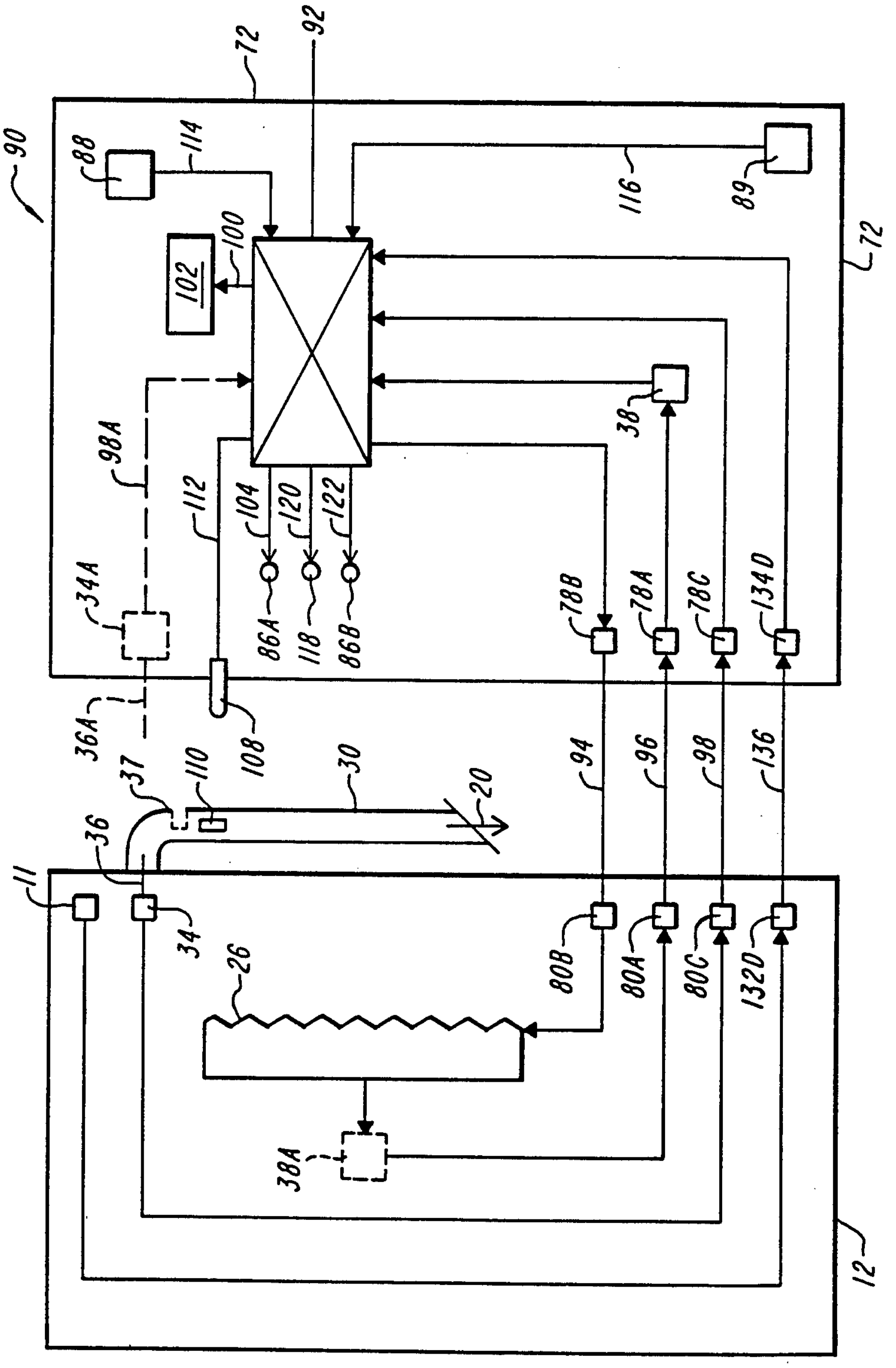


FIG. 9B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38A
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FIG. 10

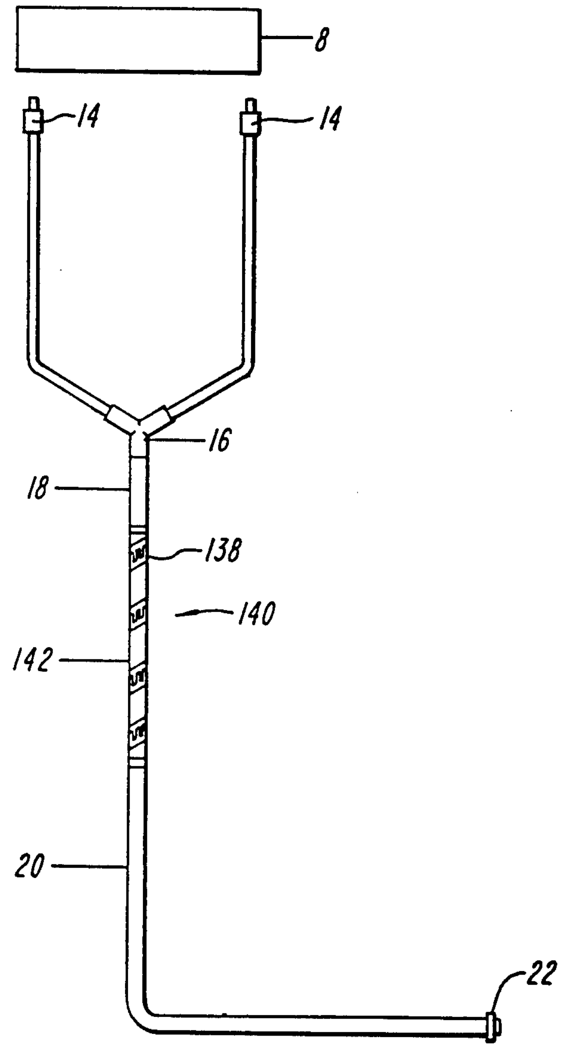


FIG. 11

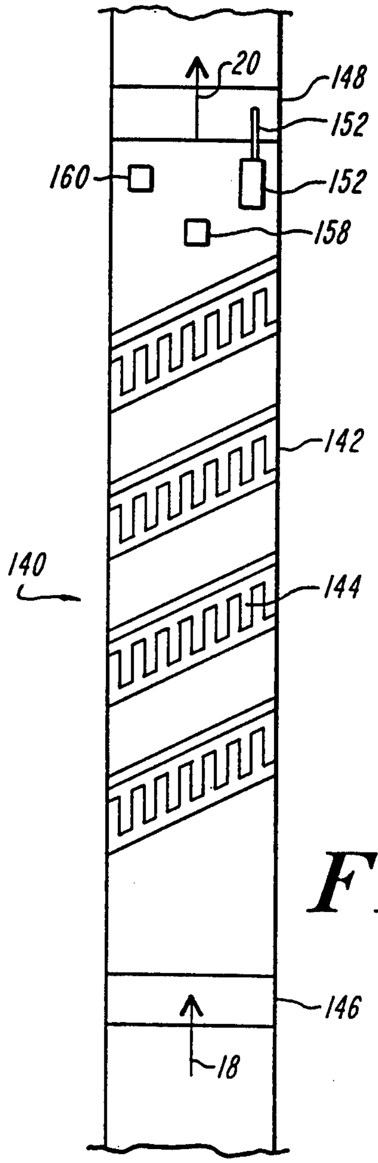


FIG. 12A

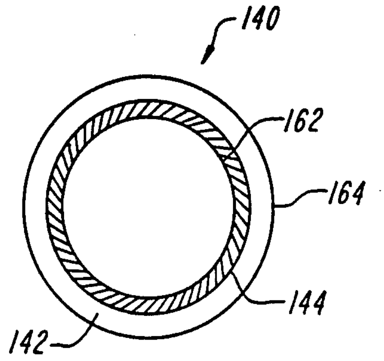


FIG. 12B

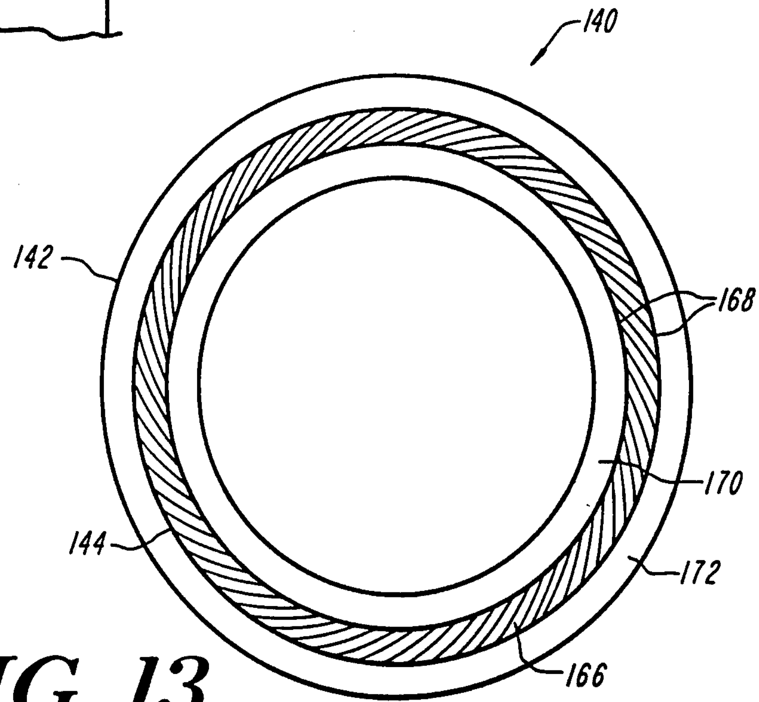
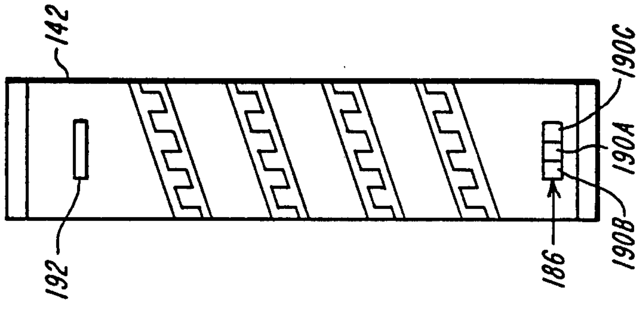


FIG. 13



BACK OF TUBE

FIG. 14C

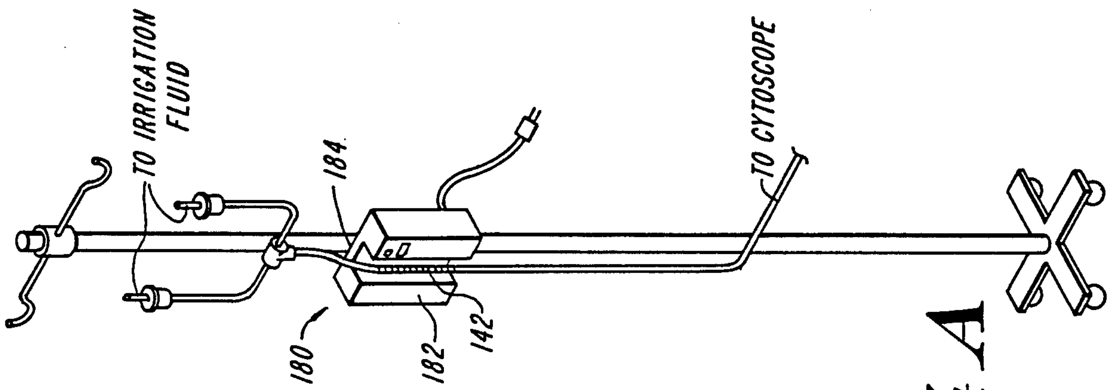
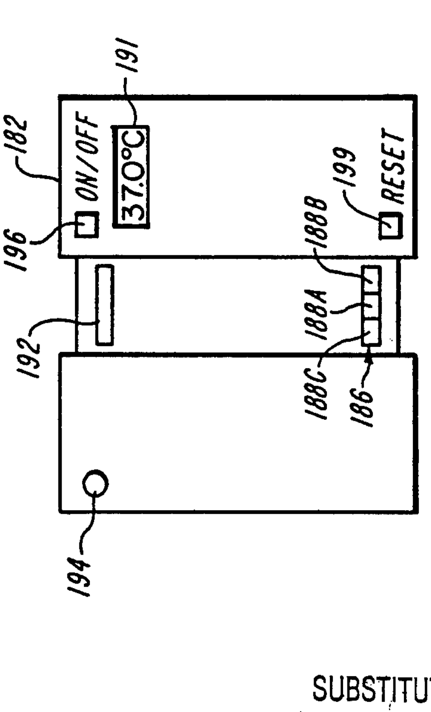


FIG. 14A



FRONT OF CONTROLLER

FIG. 14B

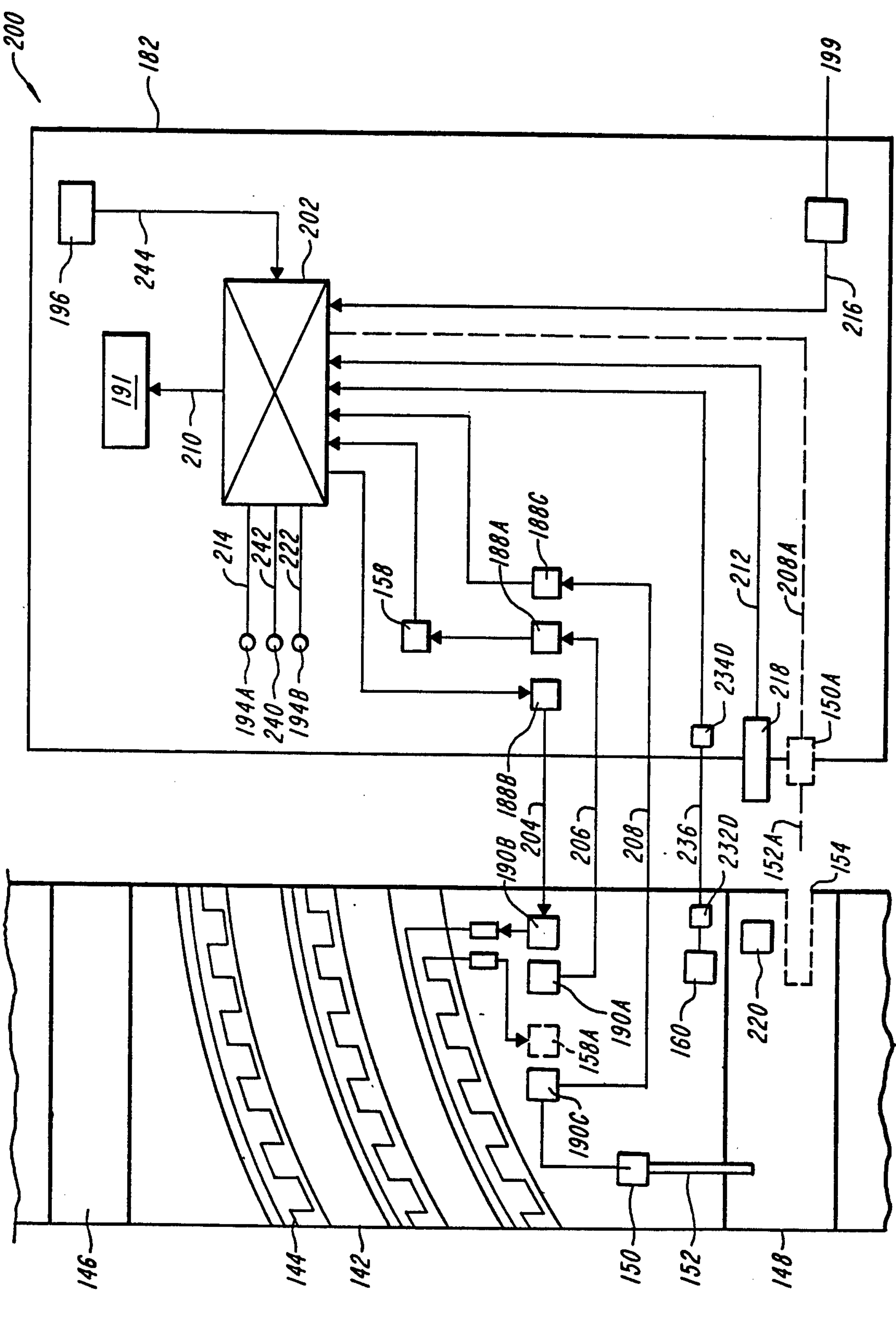

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FIG. 15

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 96/09681

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61M5/44

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 A61M

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	US,A,4 038 519 (RHONE-POULENC S.A., PARIS) 26 July 1977 cited in the application see column 6, line 52 - line 55 see claims 1,7; figures 1,2	1,2,5,6,12,13,19,29
A		17
X	CH,A,198 839 (SCHULER) 1 October 1938 see page 2, line 14 - line 23 see figure 1	1,2,5,6,12,13,29
A		27,28
A	GB,A,1 161 366 (POPPENDIEK) 13 August 1969 see page 3, line 127 - page 4, line 3 see figures 4,5	3

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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"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

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Date of the actual completion of the international search	Date of mailing of the international search report
15 October 1996	22.10.96

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Sedy, R

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 96/09681

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US,A,5 108 372 (SWENSON) 28 April 1992 see column 1, line 12 - line 13 see column 7, line 30 - line 37 see column 8, line 28 - line 30 see column 9, line 39 - line 63 see column 12, line 35 - line 46 see figures 5,7 ---	7,8,11, 16,17,25
A	WO,A,92 17040 (IN-TOUCH PRODUCTS CO.) 1 October 1992 see page 13, line 30 - line 36 see page 15, line 22 - line 24 see page 21, line 29 - line 33 see page 22, line 12 - line 14 see page 23, line 15 - line 32 see figures 1,2,11,14 ---	4,7-9, 21-23, 26,32
A	FR,A,2 505 294 (EXTRACORPOREAL MEDICAL SPECIALTIES, INC.) 12 November 1982 see claim 9; figure 2 ---	4
A	DE,C,40 30 368 (B. BRAUN MELSUNGEN AG.) 14 November 1991 see column 3, line 47 - line 55 see column 4, line 3 - line 22 see figure 2 ---	10,15, 19,20,24
A	DE,U,92 01 792 (BURGERT) 21 May 1992 see page 5, line 6 - line 9 ---	14
A	US,A,4 847 470 (BAKKE) 11 July 1989 cited in the application see column 3, line 42 - line 47 see figures 2,3 ---	18
A	US,A,5 211 631 (SHEAFF) 18 May 1993 see column 4, line 39 - line 45 -----	30,31

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INTERNATIONAL SEARCH REPORT

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Inte: ɔnal Application No
PCT/US 96/09681

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INTERNATIONAL SEARCH REPORT

Information on patent family members

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