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(54) **METHOD AND APPARATUS FOR PRESSURE INFUSION AND TEMPERATURE CONTROL OF INFUSED LIQUIDS**

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CPC ***A61M 5/148*** (2013.01); ***A61M 5/1483*** (2013.01); ***A61M 5/44*** (2013.01); ***A61M 5/445*** (2013.01); *A61M 5/1424* (2013.01); *A61M 5/1689* (2013.01); *A61M 5/172* (2013.01); *A61M 2205/3368* (2013.01); *A61M 2205/3653* (2013.01); *A61M 2209/04* (2013.01)
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(58) **Field of Classification Search**
USPC 604/65–67, 113, 251–255
See application file for complete search history.

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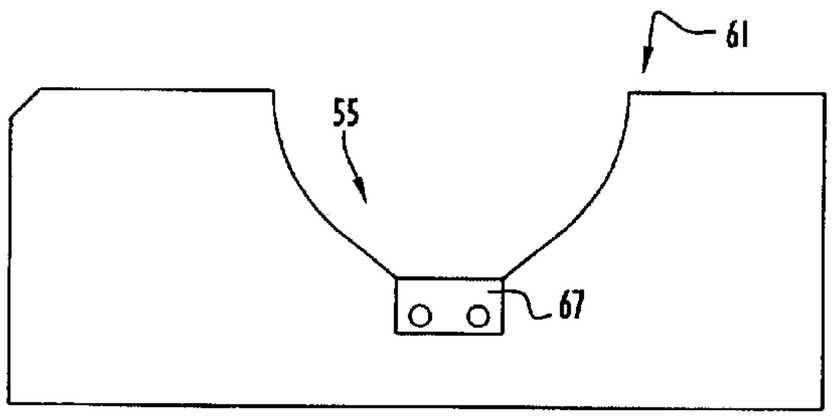
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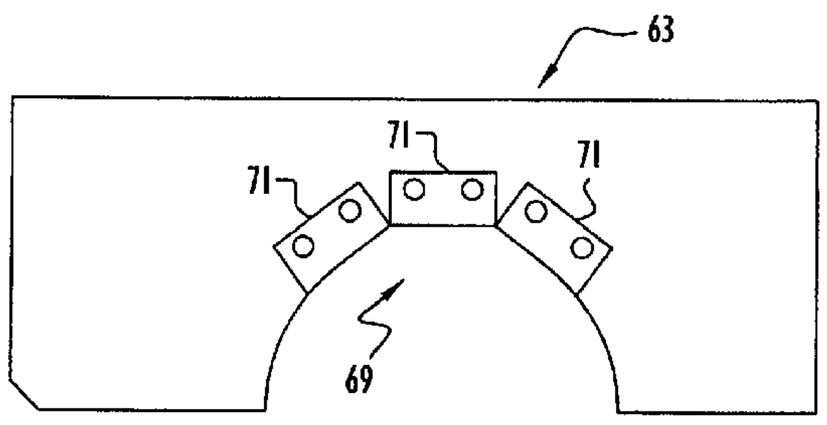
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(57) **ABSTRACT**

A method and apparatus for pressure infusion and temperature control of infused liquids including an infrared sensing device mounted proximate a drip chamber to ascertain drip count. The infrared sensing device having particular features such as emission and detection window shapes, arrangement of emission and detection windows and different numbers of emitters and detectors.

16 Claims, 15 Drawing Sheets





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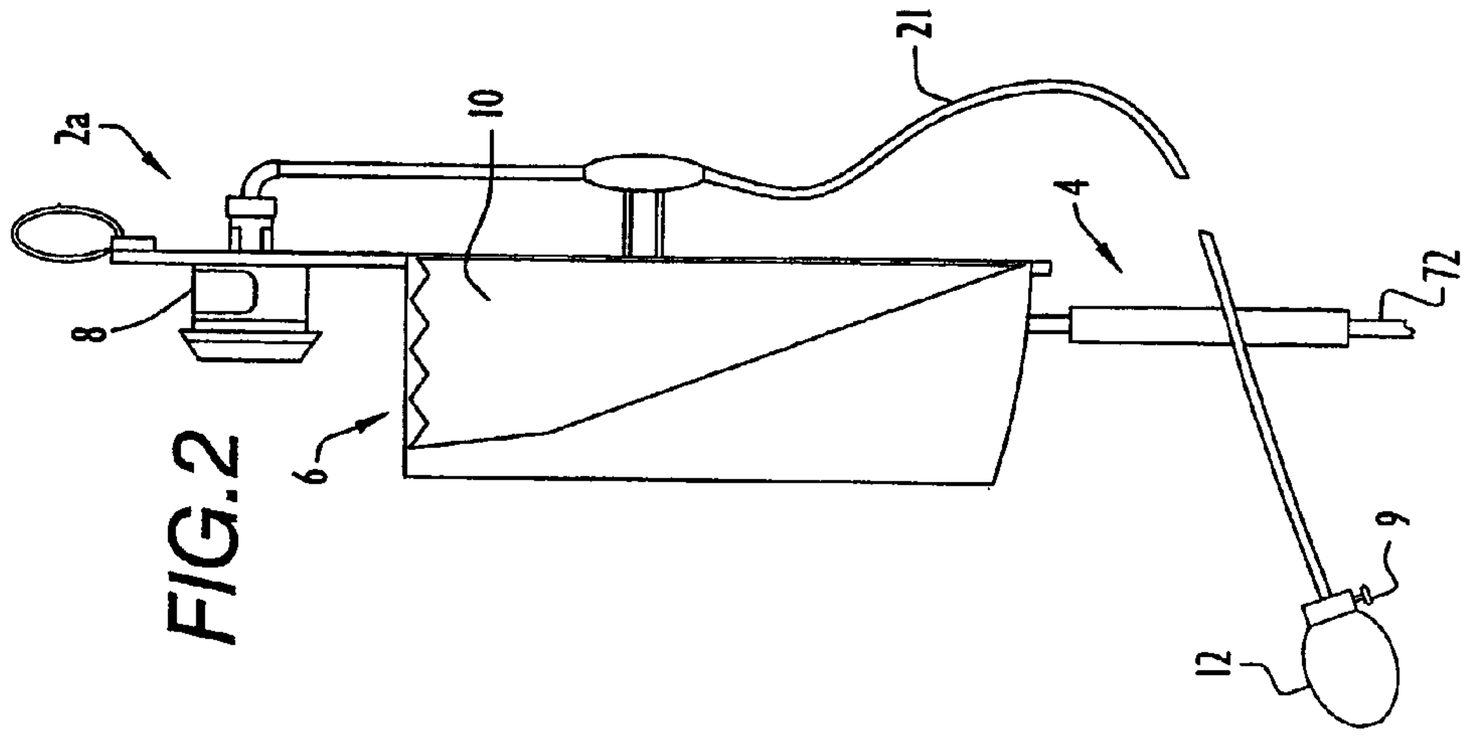


FIG.2

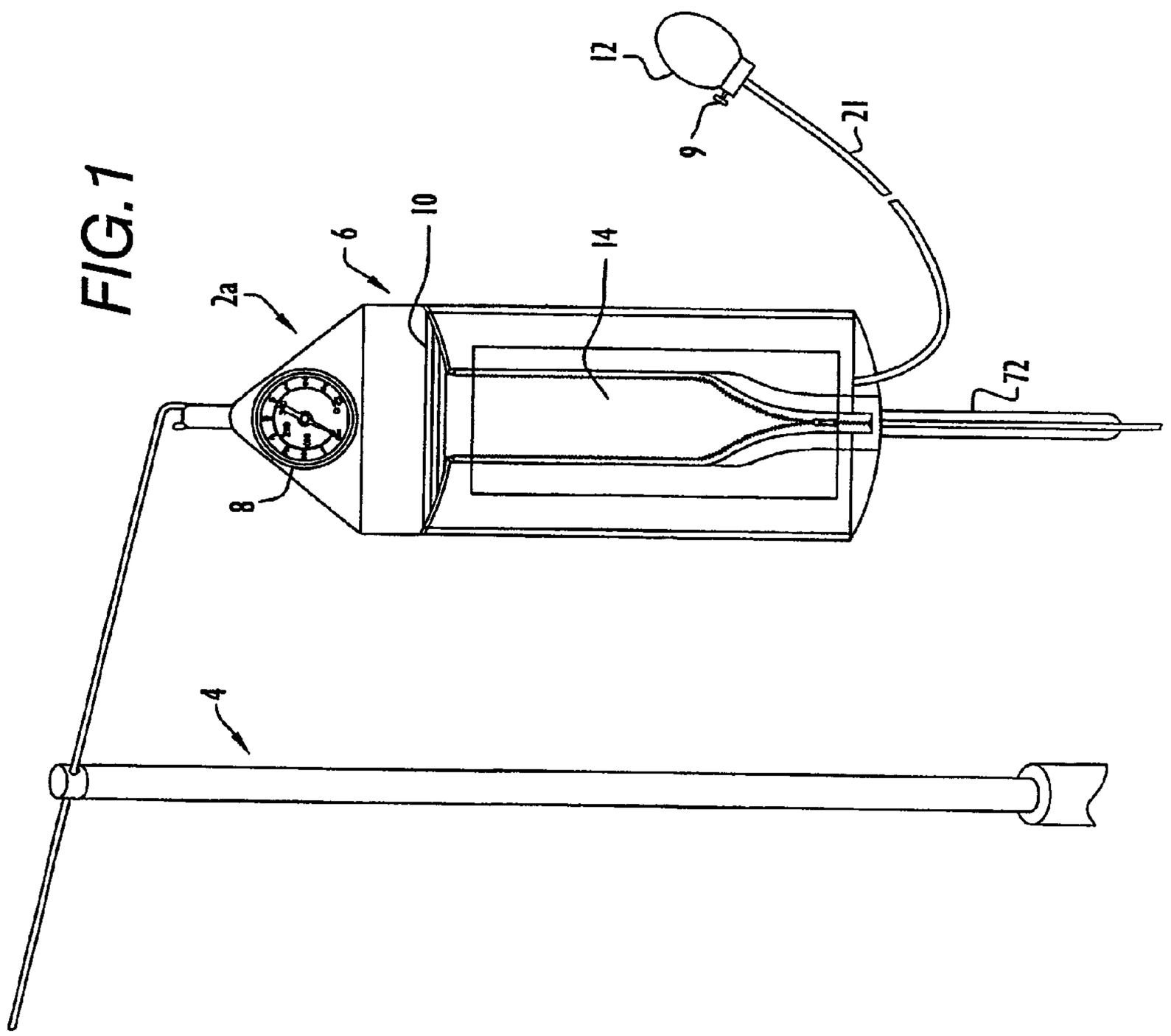


FIG.1

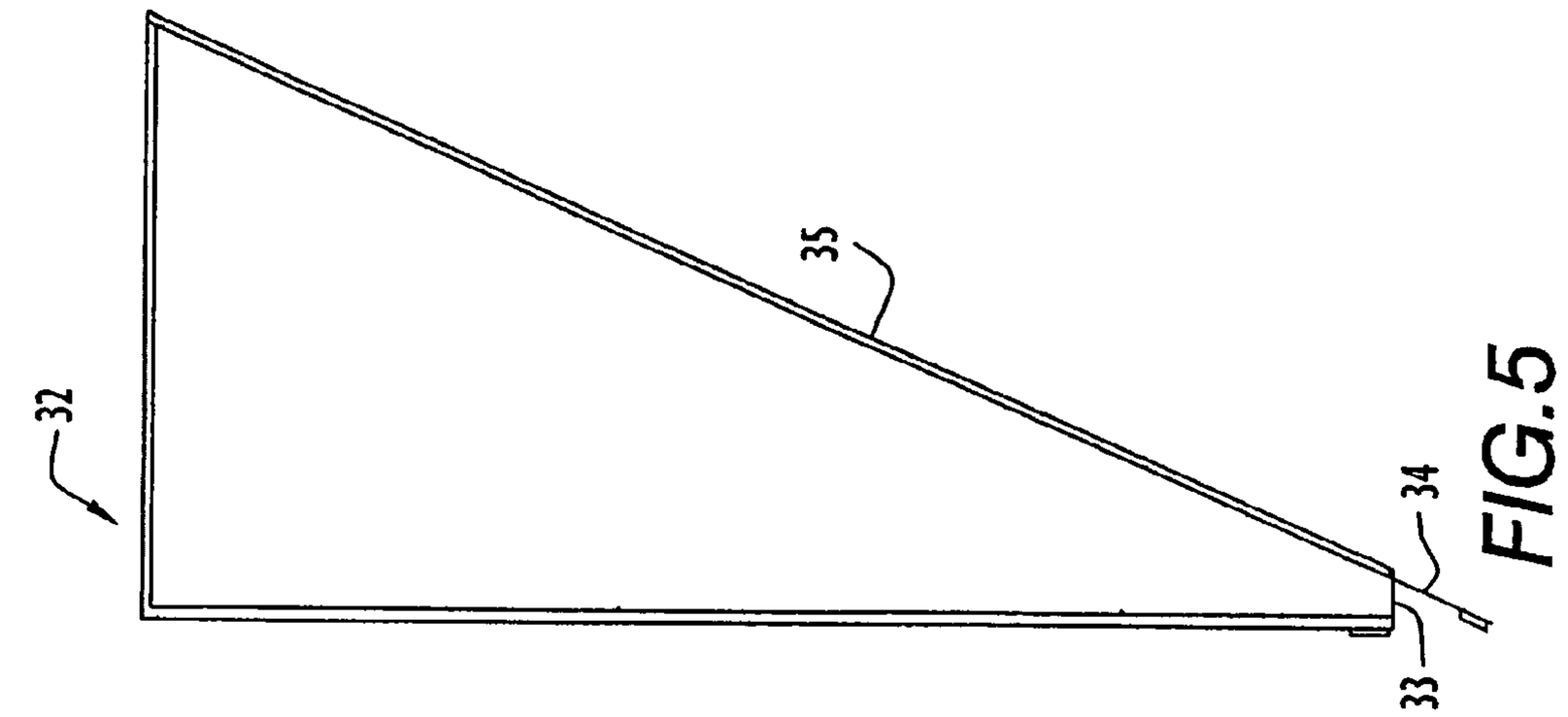


FIG.5

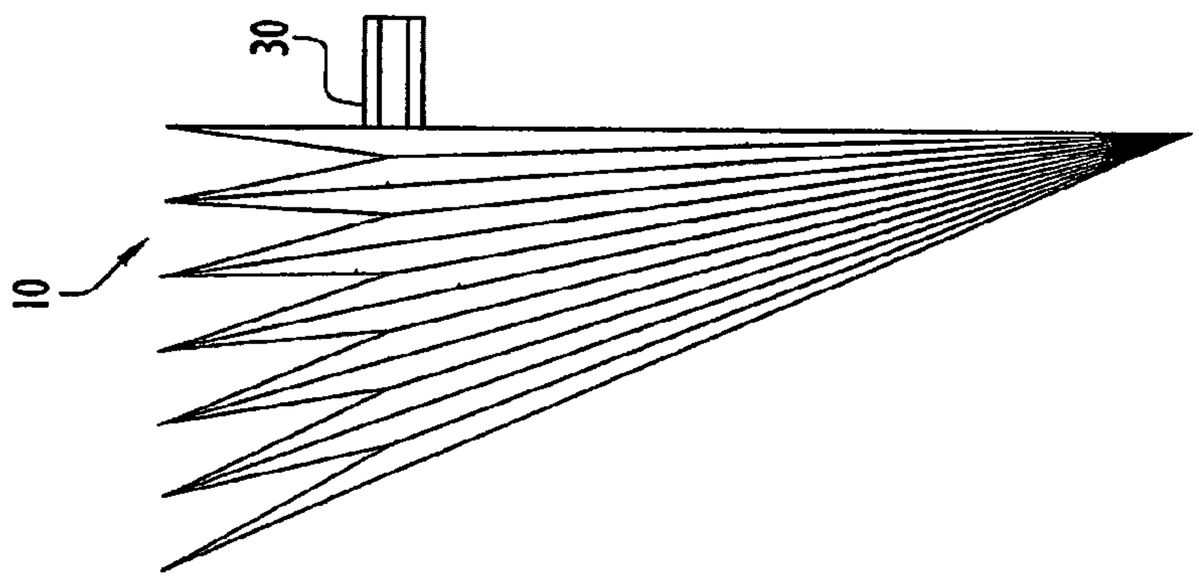


FIG.4

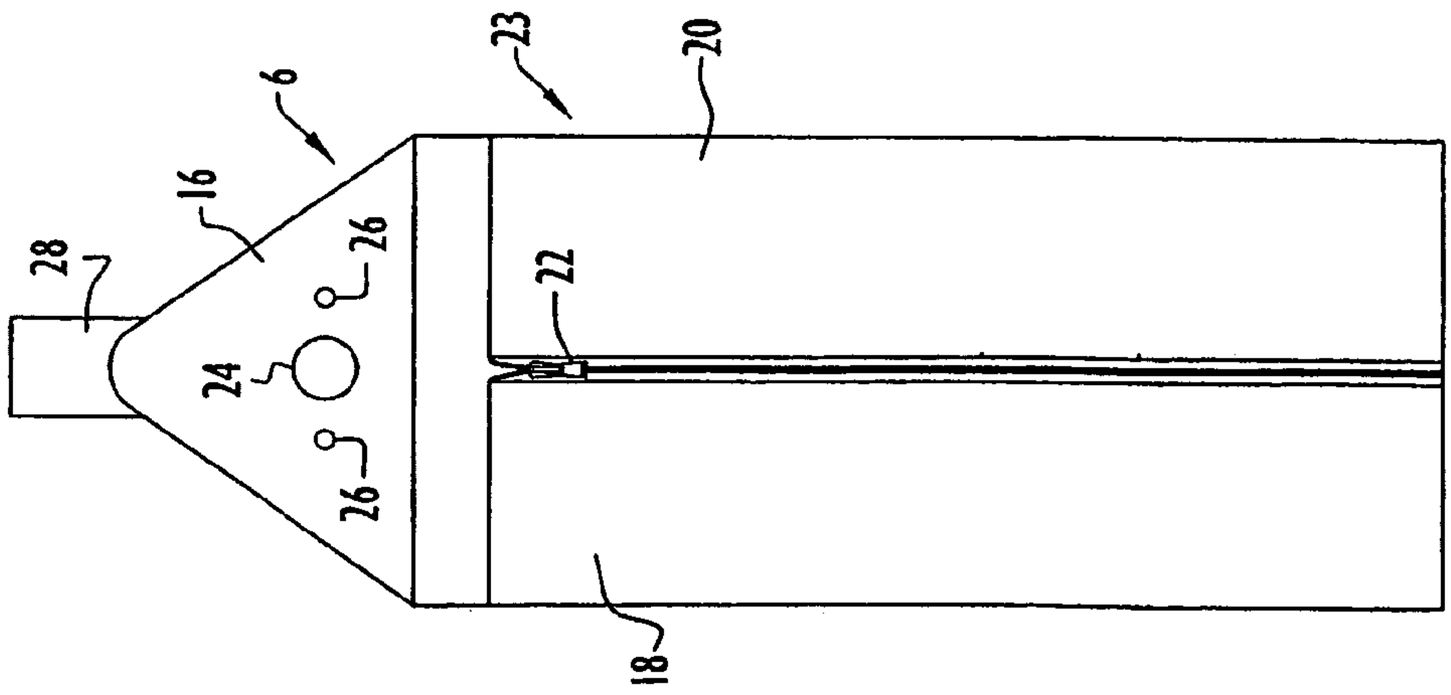


FIG.3

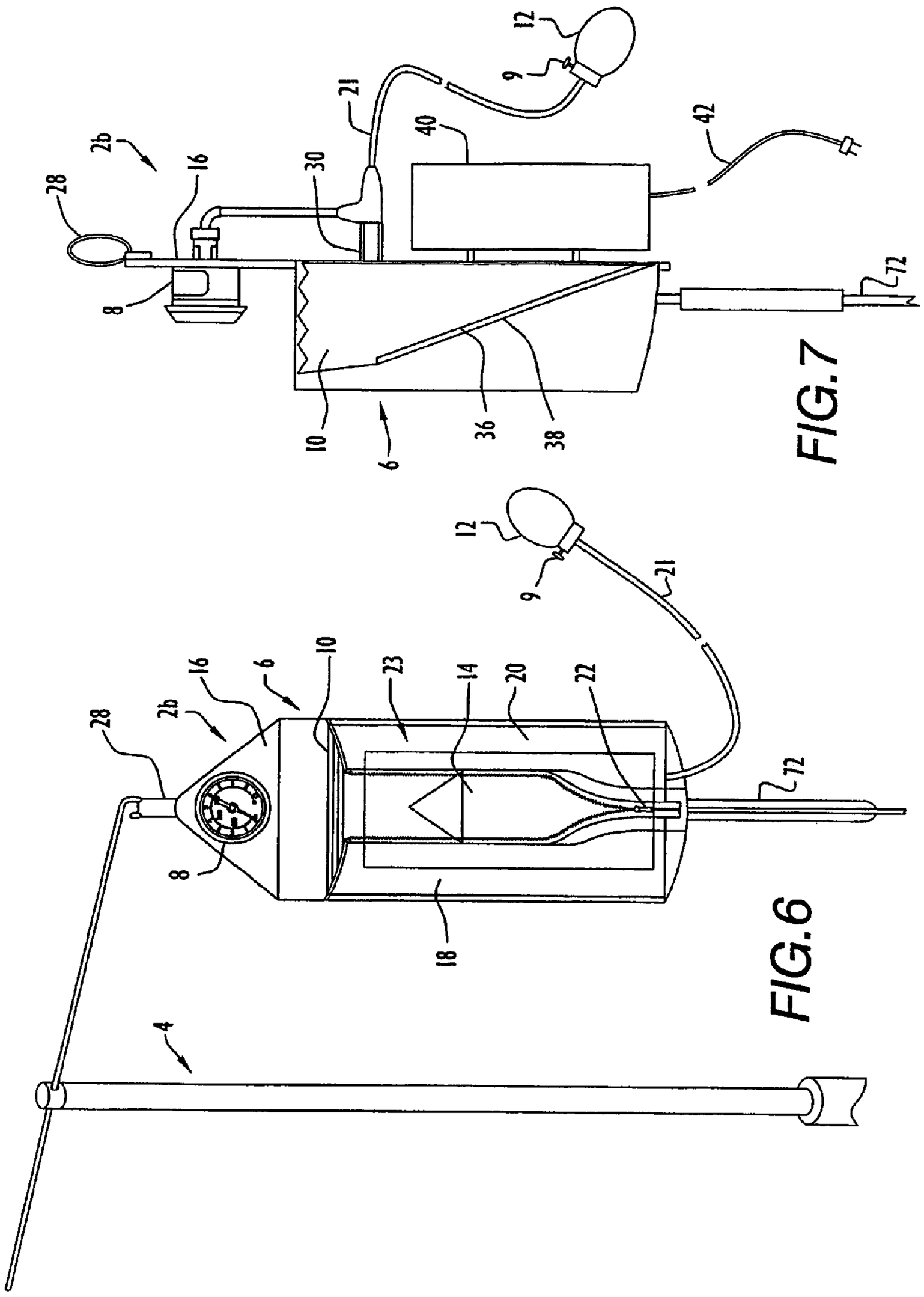

12
9
21
42
40
2b
16
30
28
8
72
10
6
36
38

FIG.7

12
9
21
16
6
10
23
14
20
22
2b
28
72
8
18
4

FIG.6

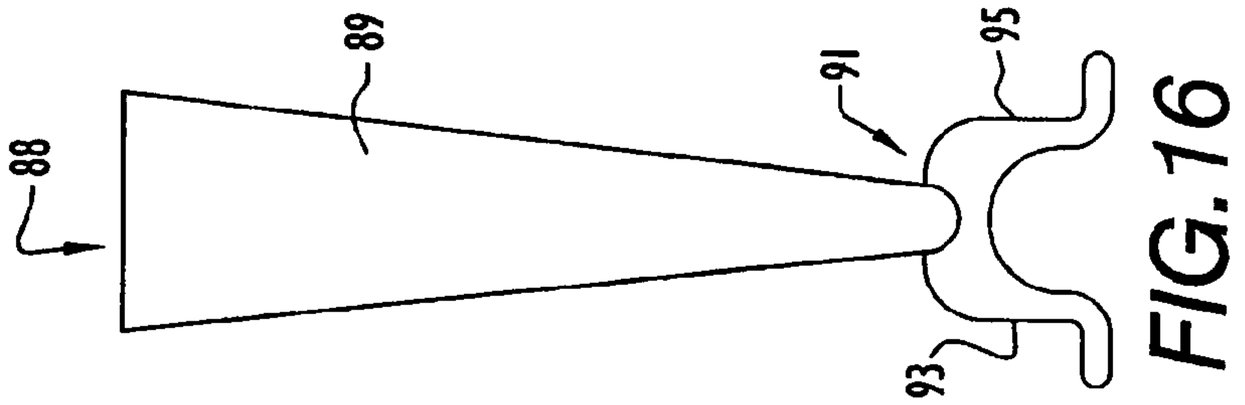


FIG.16

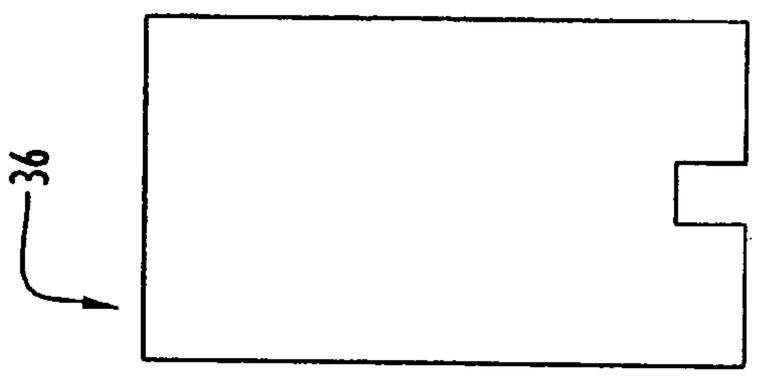


FIG.9

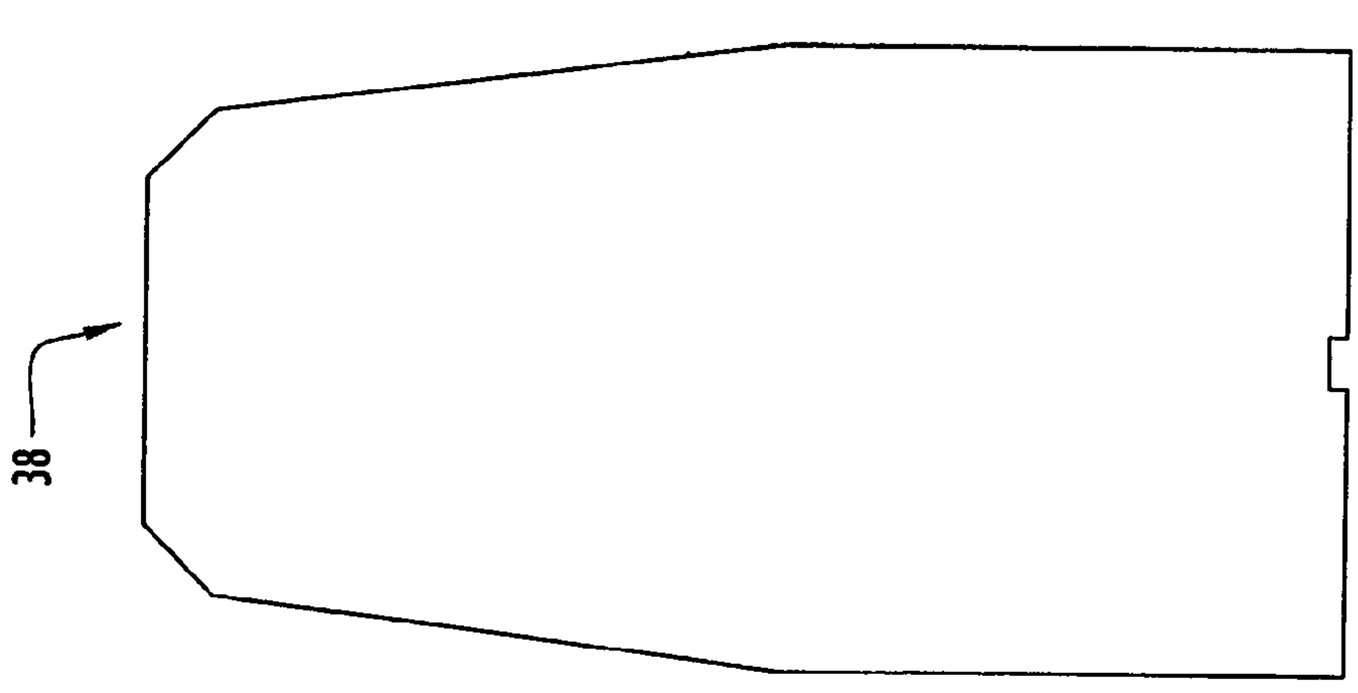


FIG.8

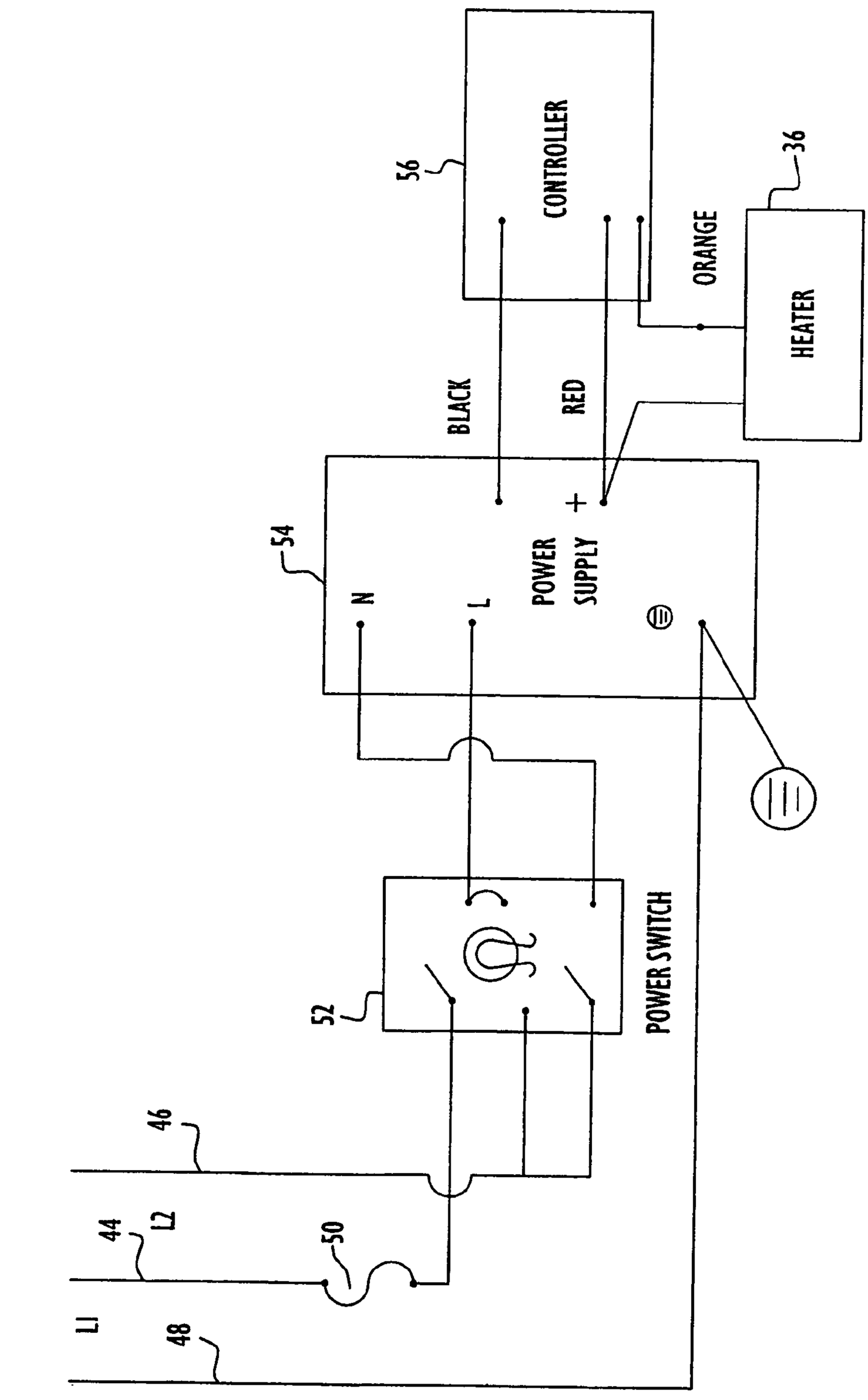

56
CONTROLLER
36
ORANGE
HEATER
BLACK
RED
54
POWER SUPPLY
+
N
L
52
POWER SWITCH
46
44
L2
50
L1
48

FIG. 10

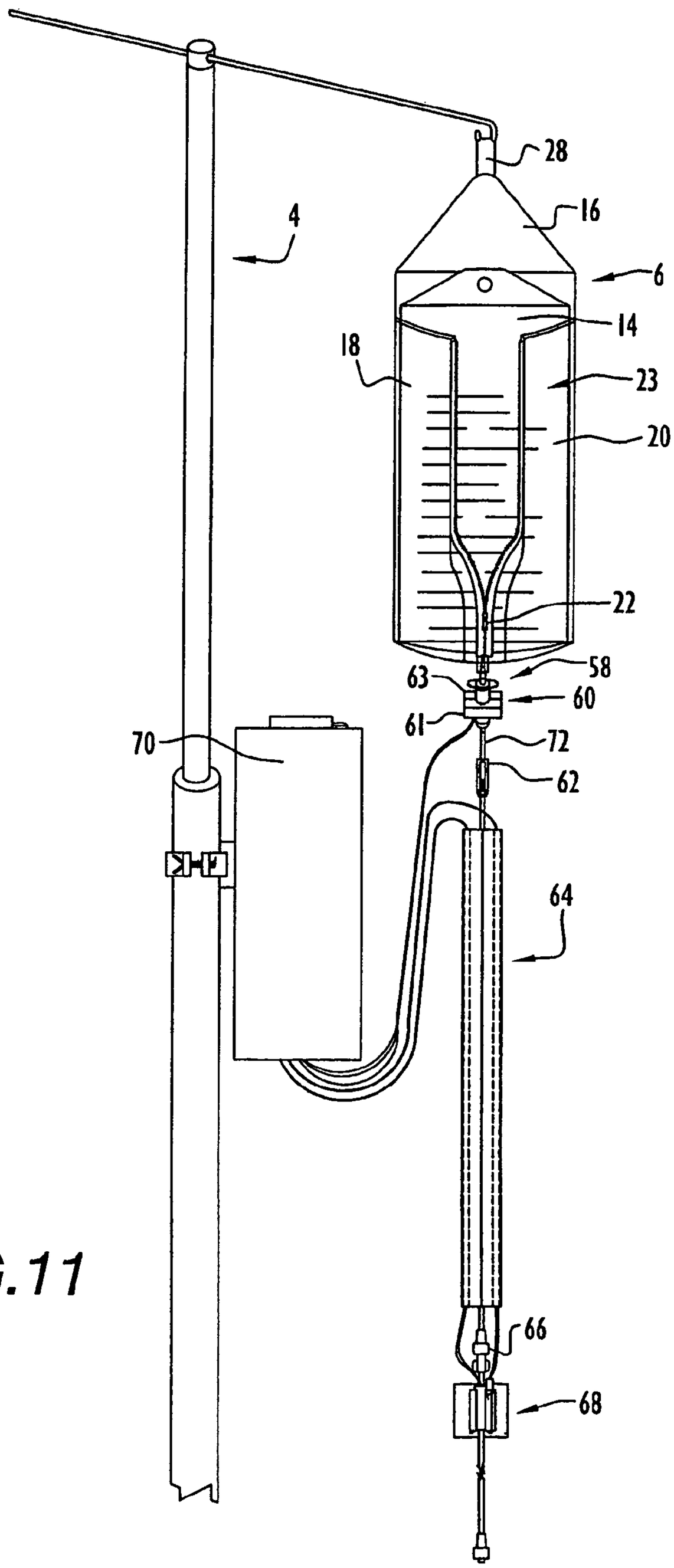


FIG.11

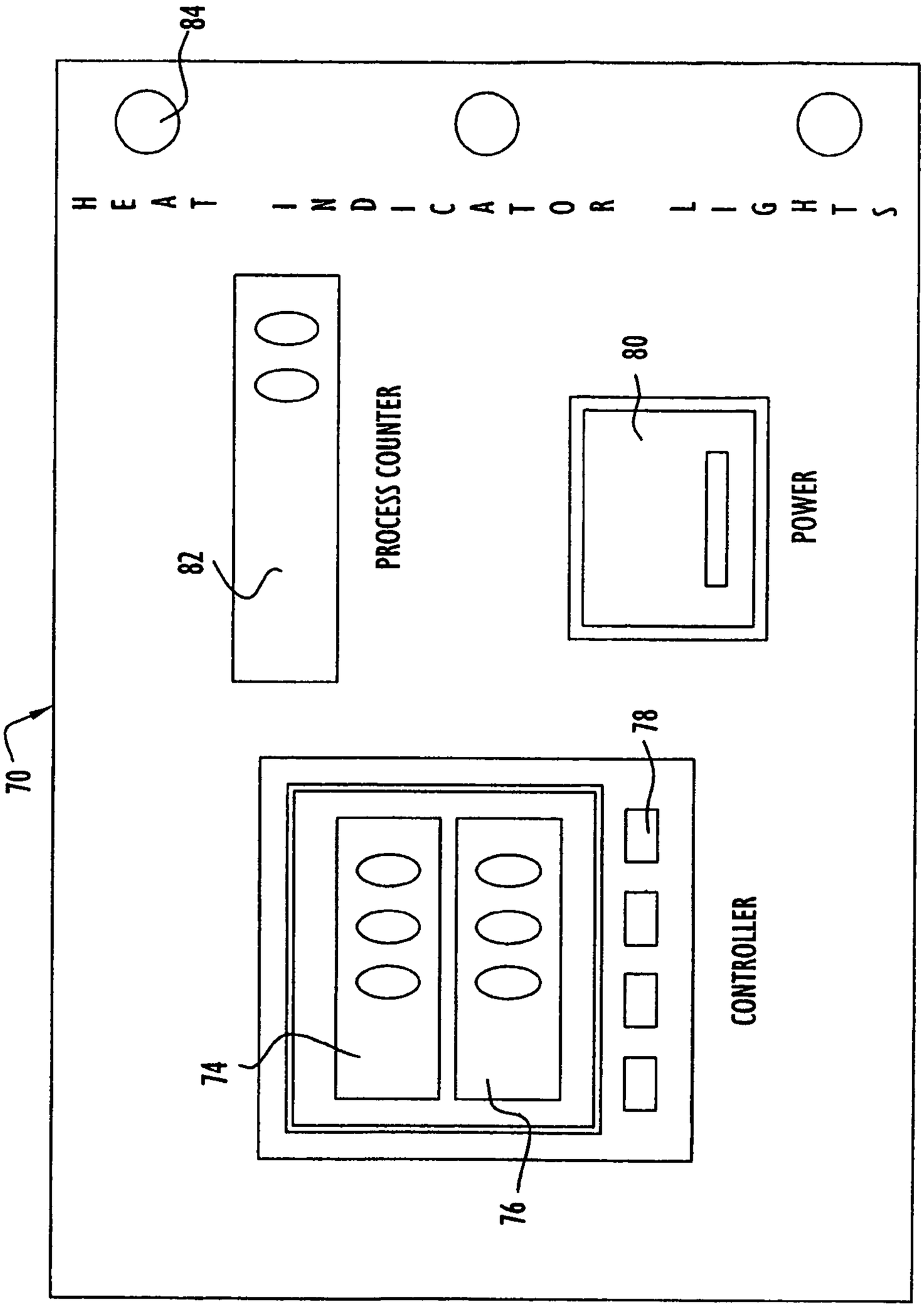

84
HEAT INDICATOR LIGHTS
82
PROCESS COUNTER
80
POWER
70
78
74
76
CONTROLLER

FIG. 12

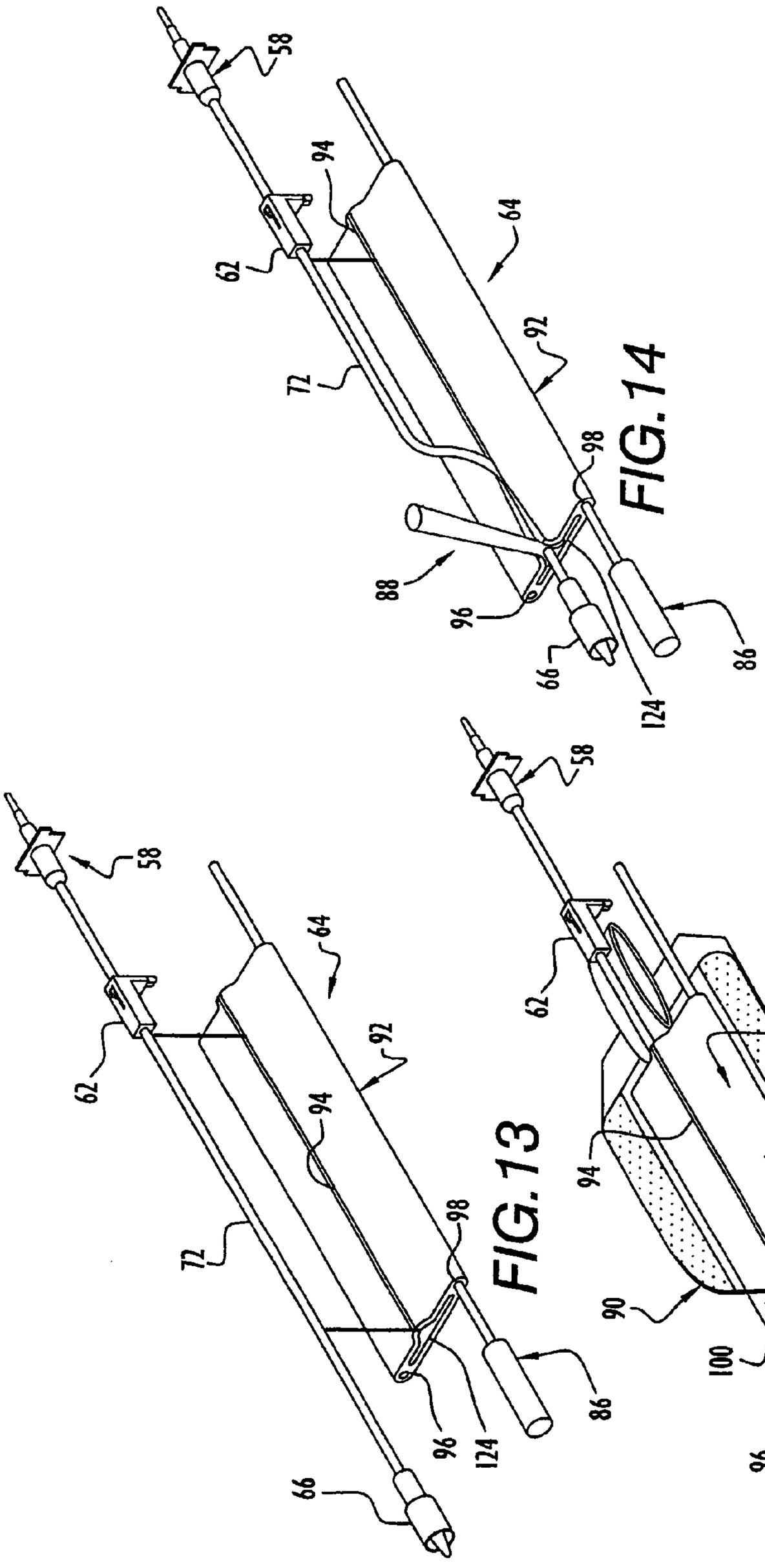


FIG. 14

FIG. 13

FIG. 15

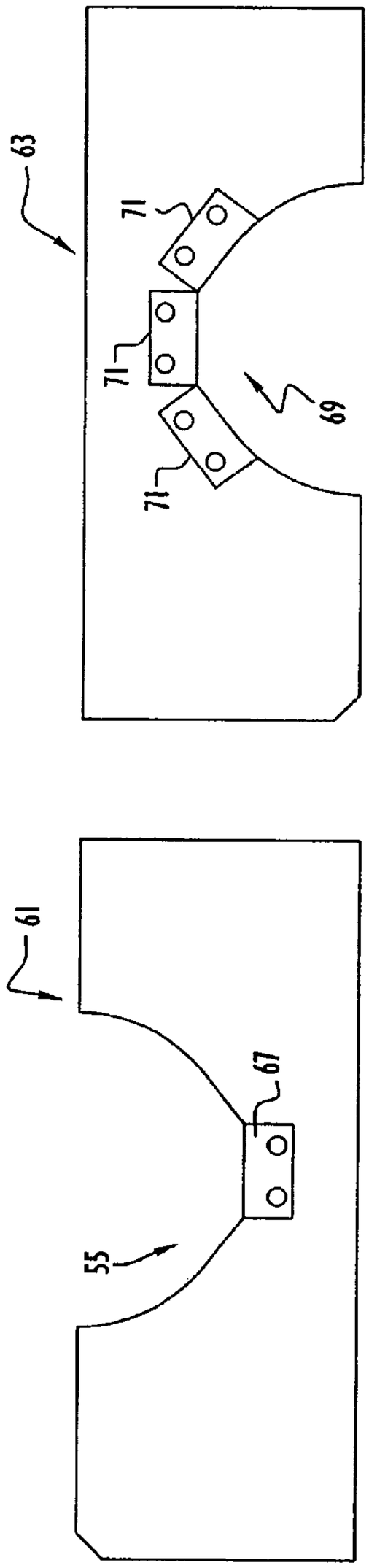


FIG. 18

FIG. 17

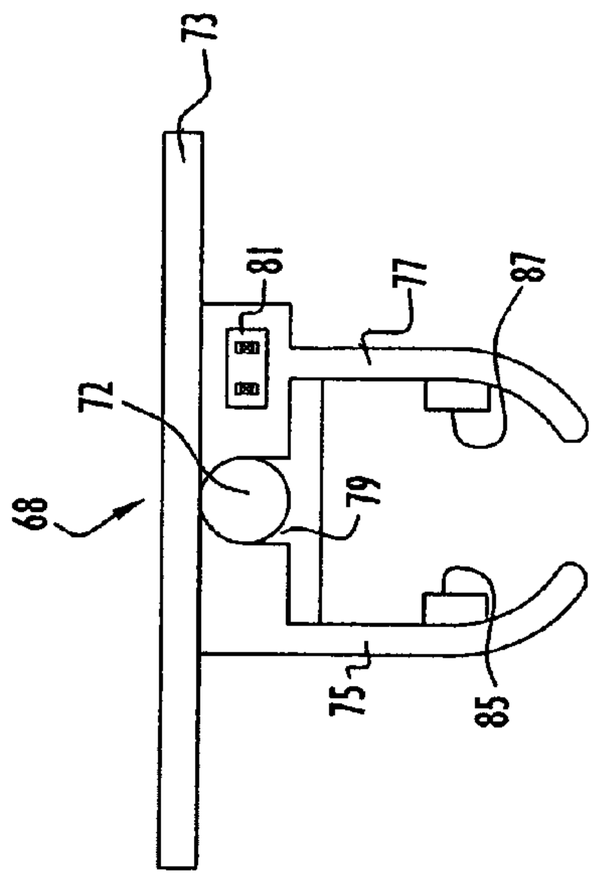


FIG. 19

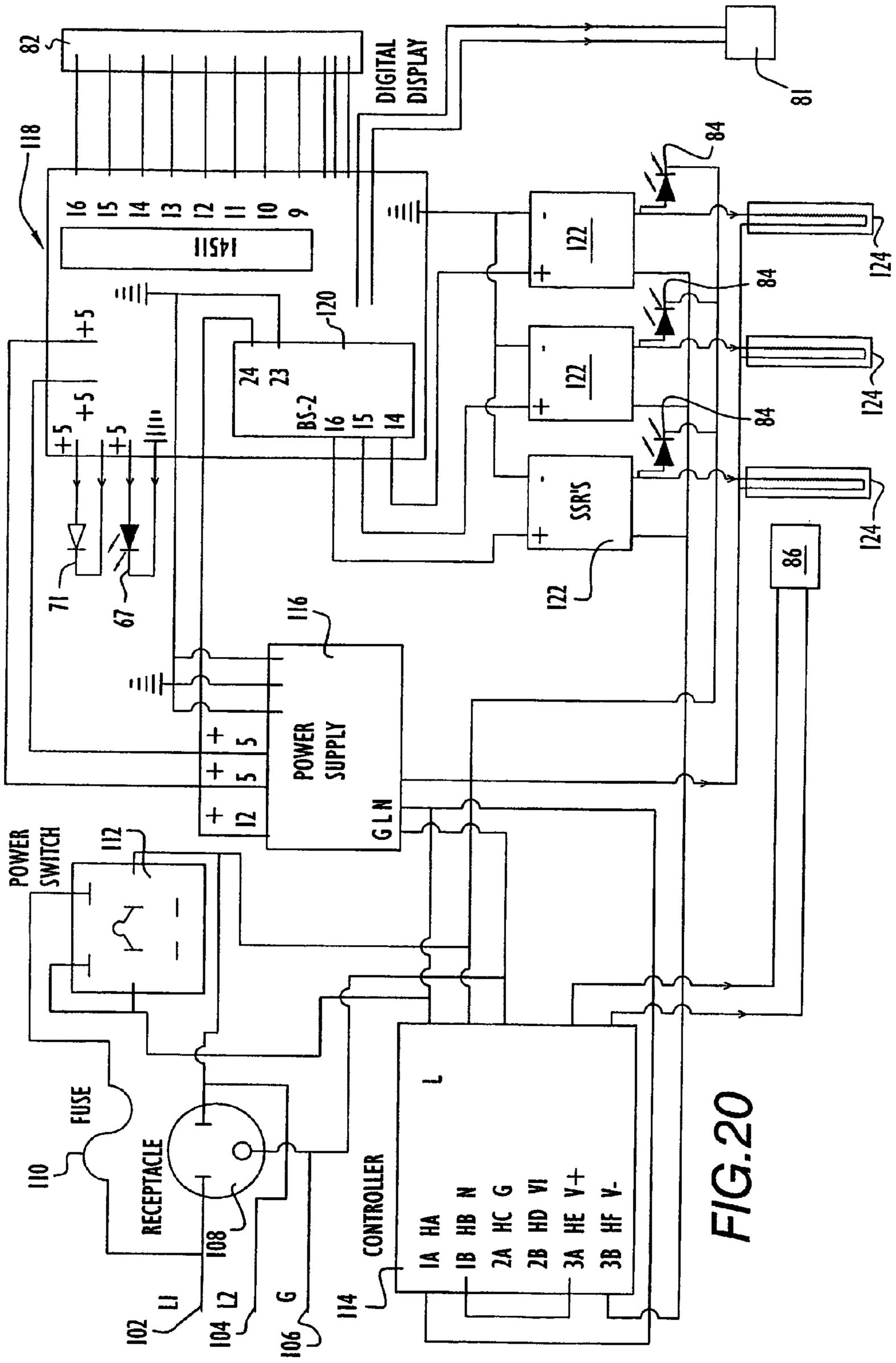

82
118
DIGITAL DISPLAY
81
84
16 15 14 13 12 11 10 9
1451I
+5
120
24 23
BS-2
16 15 14
122
124
71
67
116
POWER SUPPLY
+ 5
+ 5
+ 12
G L N
SSR'S
86
POWER SWITCH
112
FUSE
110
RECEPTACLE
108
102 L1
104 L2
106 G
114 CONTROLLER
1A HA
1B HB N
2A HC G
2B HD VI
3A HE V+
3B HF V-

FIG.20

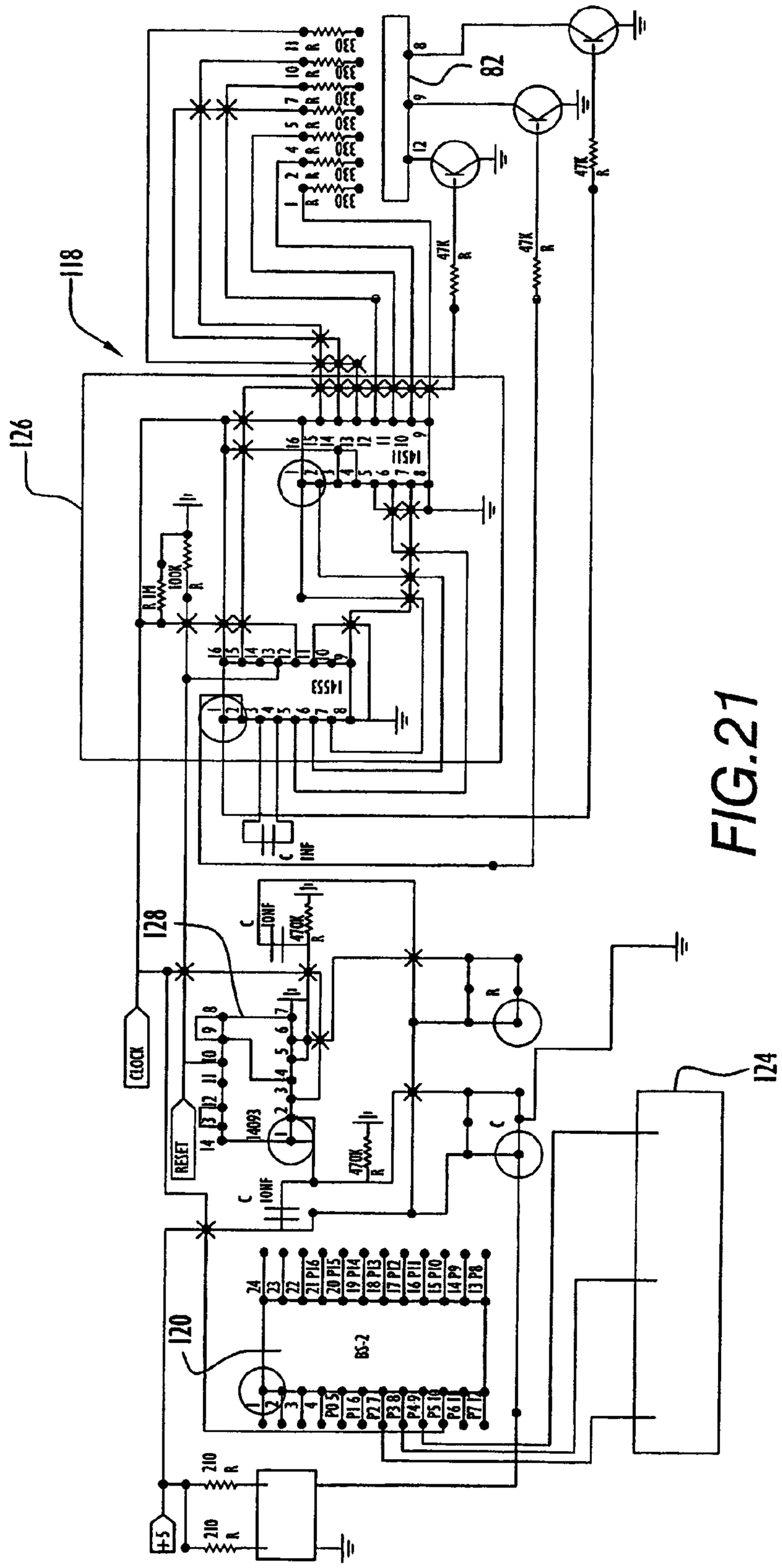

118
126
82
330 R
47K R
14511
14553
100K R
1M R
10NF C
470K R
128
CLOCK
RESET
14093
210 R
+5
120
BS-2
124

FIG.21

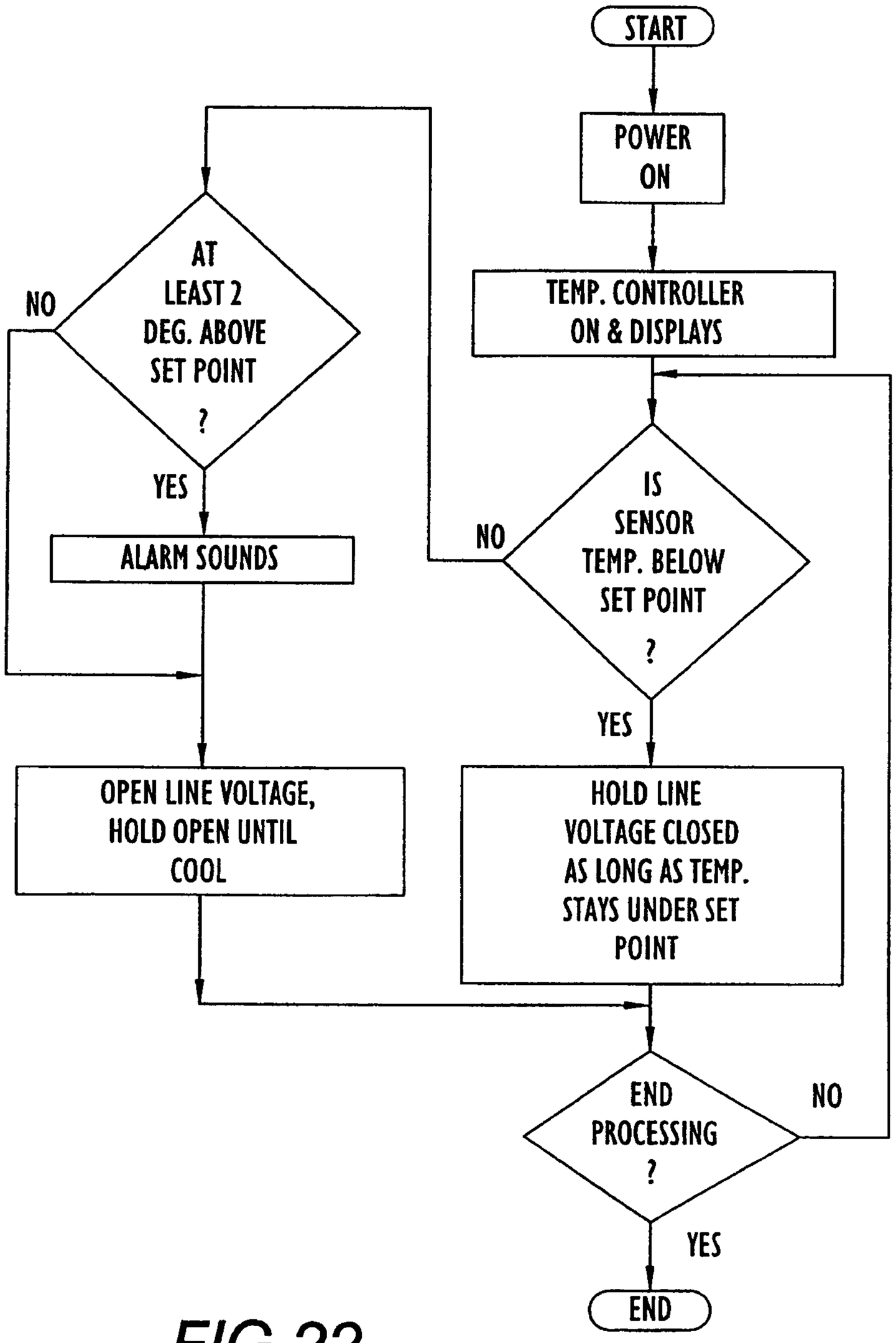

START
POWER ON
TEMP. CONTROLLER ON & DISPLAYS
IS SENSOR TEMP. BELOW SET POINT ?
NO
YES
HOLD LINE VOLTAGE CLOSED AS LONG AS TEMP. STAYS UNDER SET POINT
AT LEAST 2 DEG. ABOVE SET POINT ?
NO
YES
ALARM SOUNDS
OPEN LINE VOLTAGE, HOLD OPEN UNTIL COOL
END PROCESSING ?
NO
YES
END

FIG.22

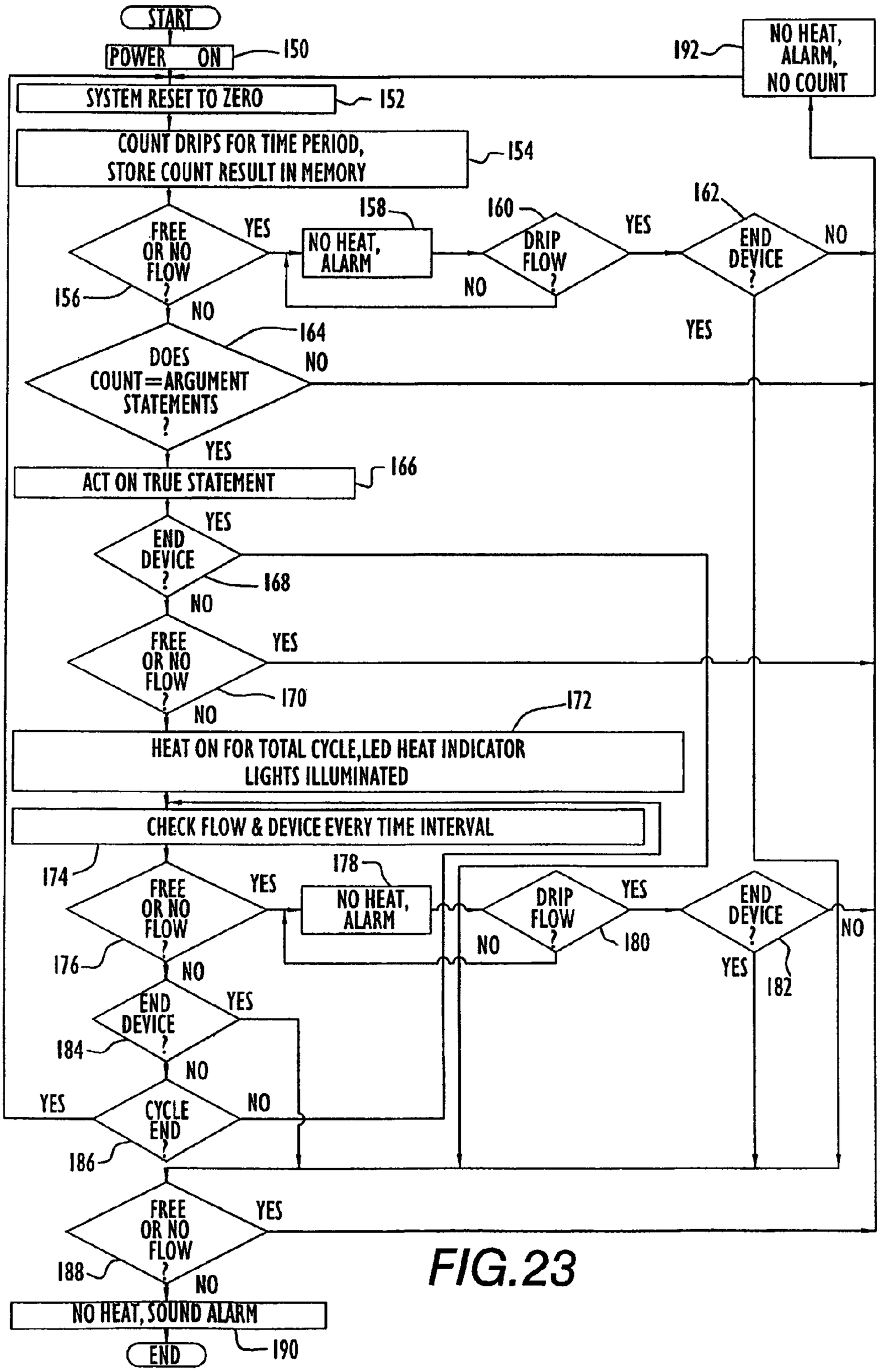

START
POWER ON
150
192
NO HEAT, ALARM, NO COUNT
SYSTEM RESET TO ZERO
152
COUNT DRIPS FOR TIME PERIOD, STORE COUNT RESULT IN MEMORY
154
158
160
162
FREE OR NO FLOW ?
YES
NO HEAT, ALARM
DRIP FLOW ?
YES
END DEVICE ?
NO
156
NO
NO
YES
164
DOES COUNT=ARGUMENT STATEMENTS ?
NO
YES
ACT ON TRUE STATEMENT
166
YES
END DEVICE ?
168
NO
FREE OR NO FLOW ?
YES
170
NO
172
HEAT ON FOR TOTAL CYCLE,LED HEAT INDICATOR LIGHTS ILLUMINATED
CHECK FLOW & DEVICE EVERY TIME INTERVAL
174
178
FREE OR NO FLOW ?
YES
NO HEAT, ALARM
DRIP FLOW ?
YES
END DEVICE ?
NO
176
NO
NO
180
YES
182
END DEVICE ?
YES
184
NO
CYCLE END ?
YES
NO
186
FREE OR NO FLOW ?
YES
188
NO
NO HEAT, SOUND ALARM
190
END

FIG.23

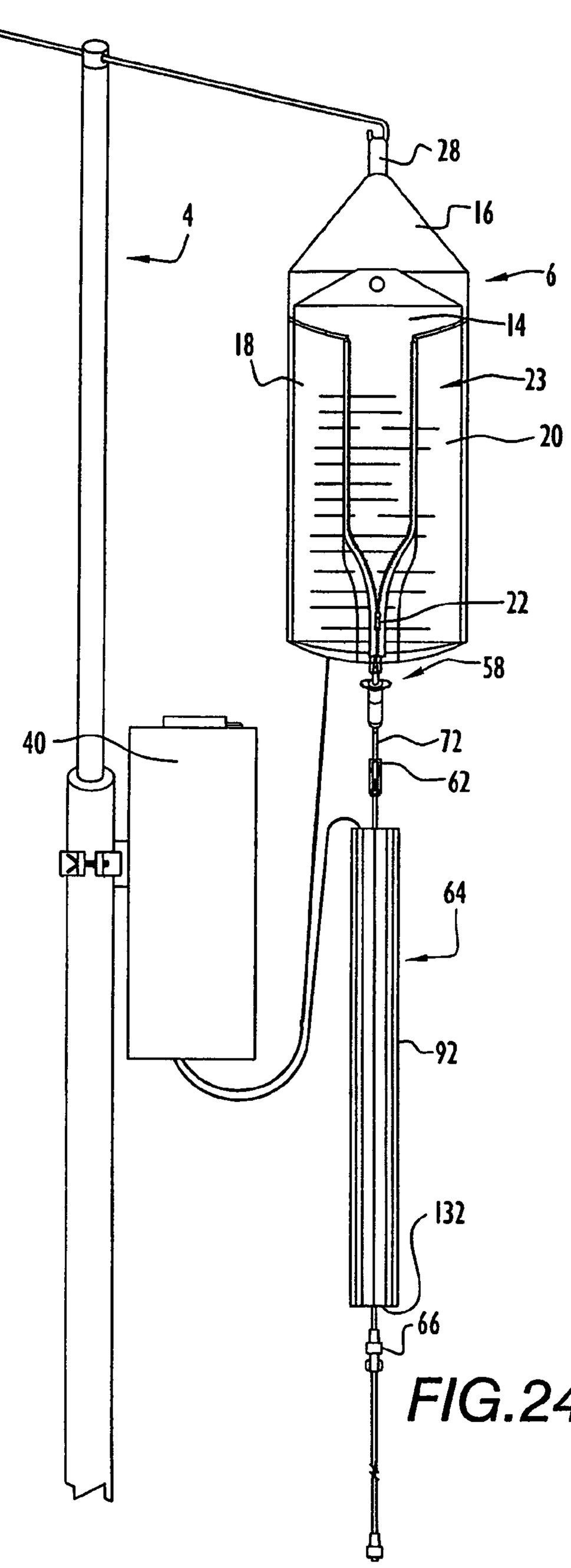


FIG.24

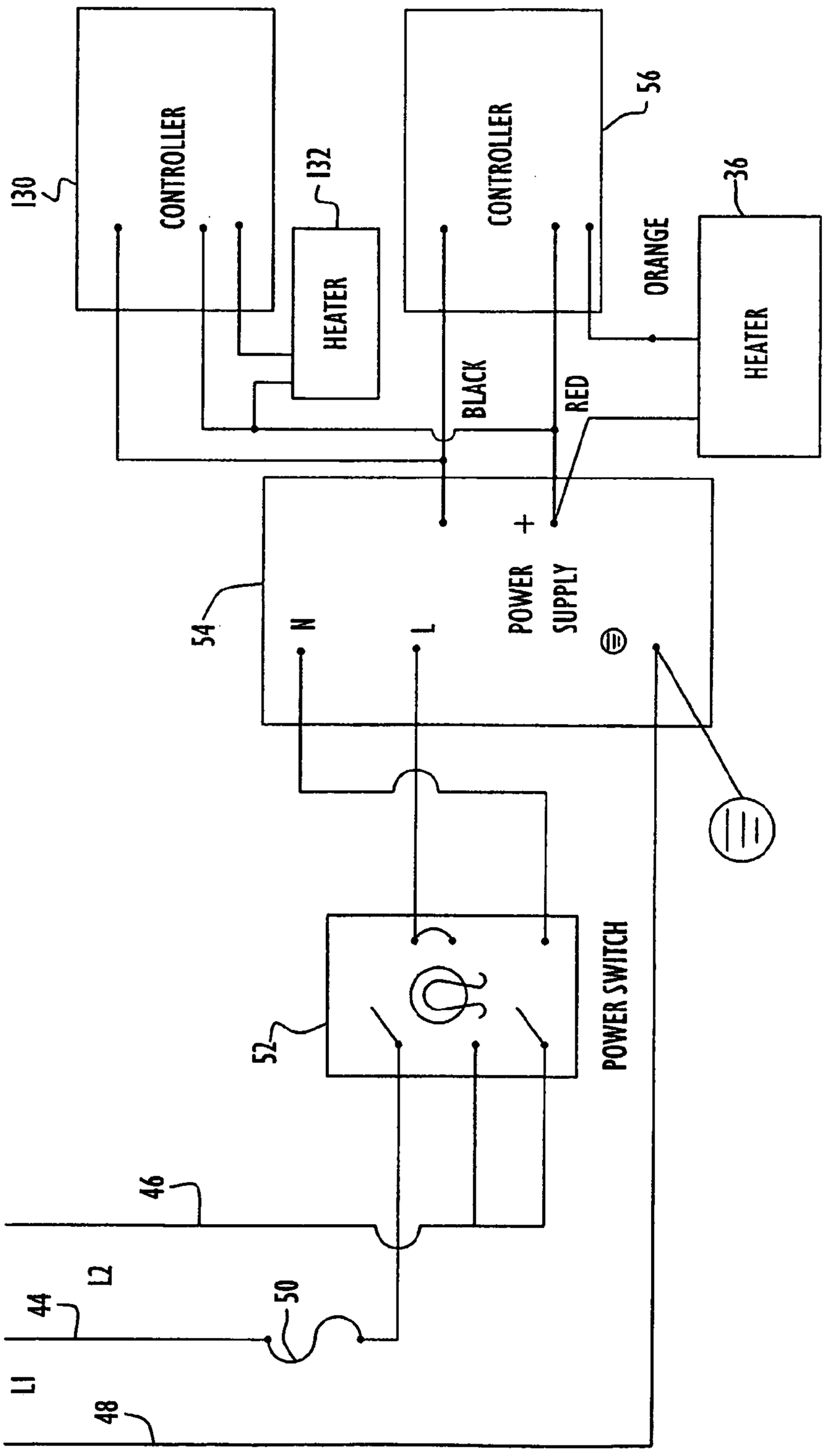

130
CONTROLLER
132
HEATER
CONTROLLER
56
ORANGE
36
HEATER
BLACK
RED
+
POWER SUPPLY
54
N
L
POWER SWITCH
52
46
L2
44
50
L1
48

FIG.25

METHOD AND APPARATUS FOR PRESSURE INFUSION AND TEMPERATURE CONTROL OF INFUSED LIQUIDS

CROSS REFERENCE TO RELATED APPLICATIONS

This application is a divisional of U.S. patent application Ser. No. 10/913,512, now U.S. Pat. No. 7,942,851, entitled "Method and Apparatus for Pressure Infusion and Temperature Control of Infused Liquids" and filed Aug. 9, 2004, which is a continuation of U.S. patent application Ser. No. 09/380,507, filed Apr. 24, 2000, entitled "Method and Apparatus for Pressure Infusion and Temperature Control of Infused Liquids", now U.S. Pat. No. 6,824,528, which is a National Stage Application of PCT International Application No. PCT/US98/04199, filed Mar. 3, 1998, entitled "Method and Apparatus for Pressure Infusion and Temperature Control of Infused Liquids", which claims priority from U.S. Provisional Patent Application Ser. No. 60/040,885, filed Mar. 3, 1997, entitled "Method and Apparatus for Measurement and Control of Temperature for Infused Liquids", and U.S. Provisional Patent Application Ser. No. 60/062,315, filed Oct. 17, 1997, entitled "Method and Apparatus for Pressure Infusion and Temperature Control of Infused Liquids". The disclosures of the above-identified patent and patent applications are incorporated herein by reference in their entireties.

BACKGROUND OF THE INVENTION

1. Technical Field

The present invention pertains to pressurized infusion and temperature control apparatus or systems for infused liquids. In particular, the present invention is directed toward pressurized infusion of liquids into a patient and/or temperature control of that liquid during infusion into a patient.

2. Discussion of Prior Art

Generally, intravenous (I.V.) solution or other liquids are infused into a patient by disposing a liquid-filled bag containing intravenous solution or other liquid on a pole structure to permit gravitational forces to direct liquid from the liquid-filled bag through an intravenous or other tube into the patient. However, gravitational forces may be insufficient to drive certain viscous liquids, such as refrigerated blood, into the patient, or drive liquids into the patient at a sufficient rate. The prior art has attempted to overcome the aforementioned inadequacies of gravitational forces by applying pressure to the liquid-filled bag to enhance liquid flow from the liquid-filled bag to the patient. For example, U.S. Pat. No. 4,090,514 (Hinck et al) discloses a pressure infusion device including a bladder wherein the device encases a liquid-filled bag with the bladder surrounding at least eighty percent of that bag. Upon inflation of the bladder, liquid within the liquid-filled bag is infused under pressure to a patient. Further, U.S. Pat. No. 4,551,136 (Mandl) discloses a pressure infuser including an inflatable bladder that wraps about a liquid-filled bag. The bladder includes a vertical strip at each end and a strap that wraps about the bladder and liquid-filled bag. The vertical strips overlap to provide a complete wrap about the liquid-filled bag, while the strap maintains the overlapping strip portions in contact. The bladder is inflated to a desired pressure whereby pressure is applied by the bladder to the liquid-filled bag to infuse liquid into a patient.

The Hinck et al and Mandl devices suffer from several disadvantages. In particular, the Hinck et al device includes a bladder that substantially surrounds a liquid-filled bag, however, the bladder may not expand sufficiently to apply

adequate pressure to the liquid-filled bag when small volumes of liquid are present within the liquid-filled bag, thereby operating less efficiently when smaller volumes of liquid reside within the liquid-filled bag and requiring premature replacement of the liquid-filled bag prior to utilization of liquid within that bag. Similarly, the Mandl infuser utilizes a strap to maintain a bladder about a liquid-filled bag wherein pressure exerted by the bladder on the liquid-filled bag is focused substantially coincident the strap, thereby operating less efficiently, especially when smaller volumes of liquid reside within the liquid-filled bag, since various pressures are applied to different portions of the liquid-filled bag (e.g., the bladder portions disposed near the strap apply the greatest amounts of pressure, while the bladder portions disposed furthest from the strap apply the least amounts of pressure), and requiring premature replacement of the liquid-filled bag prior to utilization of liquid within that bag. In other words, when the liquid-filled bags become partially depleted and thin, the bladders of the Hinck et al and Mandl devices may not maintain adequate pressure on the thinner bags for infusion of liquid into a patient. Further, the bladders of these devices generally include certain dimensions, thereby only being compatible or satisfactorily operable with liquid-filled bags of a particular size. Moreover, the Hinck et al and Mandl devices do not thermally treat the liquid-filled bags in any manner during infusion.

In addition to providing pressurized infusion as described above, it is desirable during surgical procedures to maintain a patient's body temperature at approximately 98.6° F. or 37° C. (i.e., normal body temperature) to avoid hypothermia and complications that may arise with minute decreases in body temperature (e.g., decreases of approximately 2-3° C.). Further, infusion into a patient of liquids having temperatures below the normal body temperature may produce further complications, such as shock, cardiac dysfunction, increased coagulation time, and in certain patients, clumping of blood cells.

In order to avoid hypothermia and other complications described above, warmers are typically employed during surgical or other medical procedures to maintain the temperature of infused liquids at or near body temperature. Generally, prior art warmer systems employ various techniques to heat infused liquids. In particular, infused liquid may be directed within tubing or a bag through a solution bath (e.g., warmed liquid); infused liquid may be directed about a tube through which warmer liquid flows in an opposing direction; infused liquid may traverse tubing or be stored in a bag placed proximate heating plates; infused liquid may be disposed in a bag placed about a heating element; infused liquid may be warmed by a heat exchanger in the form of a cassette placed between heating plates; or infused liquid may be warmed via heated air or microwave energy. For example, U.S. Pat. No. 1,390,500 (Christian) discloses a flexible water heater and dripper wherein water and other liquid flow from a container and are heated while traversing a flexible heating element having a conduit. The heating element includes resistance coils and is connected to a rheostat having a sliding member to control current to the heating device to provide a desired degree of heat.

U.S. Pat. No. 1,726,212 (Bucky) discloses an irrigator including a container filled with liquid having a heater for heating the liquid to a desired temperature. A bulb pumps air into the container to produce a pressure that drives the liquid through tubing to an irrigation site.

U.S. Pat. No. 1,995,302 (Goldstein) discloses an adjustable heating infusion apparatus wherein a flexible tube conveying fluid is heated via an electric resistance wire spirally wound

about the tube outer surface. The wire spirals are more concentrated at a tube proximal end to raise liquid temperature toward a desired level, while the remaining windings maintain the liquid temperature at substantially that desired level. A thermostatic current control regulates current to the resistance wire to maintain a predetermined temperature.

U.S. Pat. No. 3,247,851 (Seibert) discloses an apparatus for applying liquids to the body wherein a heating unit extends along a length of a tube to heat liquid as the liquid flows from a receptacle. The heating unit includes heating wires and a thermostat to heat the liquid in the tube.

U.S. Pat. No. 5,250,032 (Carter, Jr. et al) discloses a heater for in vivo blood infusion including a housing having a channel for receiving a portion of an intravenous tube. A heating element is mounted proximate a slot disposed within the channel to heat the tube wherein the heating element is controlled by a control circuit and powered by batteries. The control circuit controls the heating element in response to sensed temperatures.

U.S. Pat. No. 5,254,094 (Starkey et al) discloses a physiological fluid warmer including two chambers having coils for fluid to flow, while a warming liquid flows through the chambers along the coils in a direction opposite to the fluid flow. The fluid warmer may be controlled by a microprocessor to operate in response to either fluid or warming liquid temperature.

The prior art warmer systems described above suffer from several disadvantages. In particular, the prior art warmer systems heating liquid within an intravenous or other tube tend to employ and control a single heating element disposed along the tube, thereby limiting control accuracy of the liquid temperature and typically producing hot spots (e.g., certain sections of the tube may become warmer than other sections of the tube) along the tube. Some of the prior art warmer systems require pre-heating of a liquid-filled bag prior to use in and external of those systems, thereby requiring additional time to heat the liquid. Further, the prior art warmer systems heating liquid within an intravenous or other tube typically rely on gravitational forces to direct the liquid to the patient. These gravitational forces may be inadequate to produce desired flow rates or enable flow of viscous solutions as described above. Moreover, certain prior art warmer systems heat liquid flowing within an intravenous or other tube at a site located a substantial distance from the patient entry point, thereby permitting heated liquid to cool by the time the heated liquid reaches the patient. In addition, the prior art warmer systems typically control liquid heating based solely on temperature measurements of the liquid, thereby limiting control options and providing for less accurate control. The prior art warmer systems typically maintain activation of heating elements in cases of excessive liquid or heating element temperatures or interruptions in liquid flow, thereby enabling the heating elements to heat the liquid to temperatures beyond the liquid utilization temperature range and possibly injure a patient and/or damage an intravenous or other tube. A further disadvantage of the prior art warmer systems heating liquid within an intravenous or other tube is that the temperature of liquid contained within a liquid-filled bag or receptacle is typically substantially below a desired temperature, thereby requiring significant heating of the liquid during infusion as the liquid traverses the tube.

OBJECTS AND SUMMARY OF THE INVENTION

Accordingly, it is an object of the present invention to infuse liquid under pressure into a patient by exerting pressure in a downward fashion on a liquid-filled bag until virtually all of the liquid is spent.

It is another object of the present invention to infuse heated liquid under pressure into a patient.

Yet another object of the present invention is to control temperature of infused liquid via multiple individually controlled heaters disposed along an intravenous or other tube.

Still another object of the present invention is to control temperature of infused liquid flowing in an intravenous or other tube based on temperature and flow rate of the infused liquid.

A further object of the present invention is to control temperature of infused liquid by heating a liquid-filled bag or receptacle to a desired temperature and maintaining liquid from the liquid-filled bag at that temperature during infusion into a patient via a heater disposed along an intravenous or other tube.

The aforesaid objects are achieved individually and in combination, and it is not intended that the present invention be construed as requiring two or more of the objects to be combined unless expressly required by the claims attached hereto.

According to the present invention, a method and apparatus for pressure infusion and temperature control of infused liquids includes a receptacle for receiving a liquid-filled bag containing intravenous solution or other liquid and an inflatable pressure device or bellows. The bellows is disposed within a bellows bag and is positioned proximate the liquid-filled bag in the receptacle. The receptacle is typically suspended from an intravenous pole or other structure. A conventional bulb is manipulated to inflate the bellows wherein the bellows expands within the bellows bag upon inflation and exerts pressure on the liquid-filled bag to direct liquid from the liquid-filled bag through an intravenous or other tube to a patient. Further, the bellows bag includes a pocket that may receive a heating element and conductive plate to enable pressurized infusion of heated liquid into a patient. The heating element heats the liquid-filled bag to a desired temperature through the conductive plate, while the bellows exerts pressure on the liquid-filled bag to direct heated liquid from the liquid-filled bag to the patient in substantially the same manner described above.

Intravenous solution or other liquid may be maintained at a desired temperature during infusion via a heating assembly disposed along an intravenous or other tube. The tube extends to a patient entry site from a drip chamber that is coupled to a liquid-filled bag containing intravenous solution or other liquid. The liquid-filled bag is typically suspended from an intravenous pole or other structure. The heating assembly includes a sleeve having a substantially centrally disposed slot for receiving a portion of the tube and a plurality of individually controlled heaters located proximate the slot. The tube portion is typically inserted into the slot via a special tool, while the sleeve is disposed within a jacket. An infrared sensing device is mounted proximate the drip chamber to ascertain a drip count rate or, in other words, a liquid flow rate wherein a heat controller controls the heaters based on the drip count rate. In addition, a temperature sensor is disposed within a thermocouple holder that is positioned toward the entry site on the patient. The thermocouple holder positions the temperature sensor proximate the tube to obtain an accurate temperature measurement of the liquid near the entry site. A temperature signal is sent from the temperature sensor to an additional safety controller that displays the liquid temperature and disables the heaters in response to the liquid temperature being equal to or exceeding the desired temperature. Thus, the safety controller and heat controller, in combination, control the heating assembly heaters to maintain the liquid temperature substantially at the desired temperature

based on liquid temperature and flow rate, respectively, wherein disablement of the heating assembly heaters by the safety controller overrides any heater controls given by the heat controller. Alternatively, the liquid-filled bag may be heated to a desired temperature and the heating assembly sleeve may contain a single heater controlled by a controller to maintain the liquid at the desired temperature during infusion of the liquid into a patient.

The above and still further objects, features and advantages of the present invention will become apparent upon consideration of the following detailed description of specific embodiments thereof, particularly when taken in conjunction with the accompanying drawings wherein like reference numerals in the various figures are utilized to designate like components.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a view in perspective of a pressurized infusion system according to the present invention.

FIG. **2** is a side view in elevation of the pressurized infusion system of FIG. **1**.

FIG. **3** is a front view in elevation of a receptacle of the pressurized infusion system of FIG. **1** for containing a liquid-filled bag and a bellows disposed within a bellows bag.

FIG. **4** is a side view in elevation of a bellows of the pressurized infusion system of FIG. **1**.

FIG. **5** is a side view in elevation of a bellows bag for containing the bellows of FIG. **4**.

FIG. **6** is a view in perspective of a pressurized infusion system that heats infused liquids according to another embodiment of the present invention.

FIG. **7** is a side view in elevation of the pressurized infusion system of FIG. **6**.

FIG. **8** is a view in elevation of a conductive plate of the pressurized infusion system of FIG. **6**.

FIG. **9** is a view in elevation of a heating element of the pressurized infusion system of FIG. **6** for heating infused liquids.

FIG. **10** is an electrical schematic diagram of an exemplary heater control circuit for the pressurized infusion system of FIG. **6**.

FIG. **11** is a view in perspective of a temperature control system for infused liquids according to yet another embodiment of the present invention.

FIG. **12** is a front view in elevation of a control panel box of the temperature control system of FIG. **11**.

FIG. **13** is an exploded view in perspective of a heating assembly of the temperature control system of FIG. **11** receiving a portion of an intravenous or other tube.

FIG. **14** is an exploded view in perspective of a portion of an intravenous or other tube inserted within the heating assembly of FIG. **13** via a tool.

FIG. **15** is a view in perspective of the heating assembly of FIG. **13** encased within a jacket.

FIG. **16** is a view in elevation of the tool of FIG. **14** for inserting a portion of an intravenous or other tube within the heating assembly of FIG. **13**.

FIG. **17** is a view in elevation of a portion of a drip detector of the temperature control system of FIG. **11** having an infrared emitter to detect drips of infused liquid.

FIG. **18** is a view in elevation of a portion of a drip detector of the temperature control system of FIG. **11** having infrared detectors to detect drips of infused liquid.

FIG. **19** is a view in elevation of a thermocouple holder of the temperature control system of FIG. **11** for maintaining a temperature sensor in the proper position to provide an accurate temperature measurement of liquid within an intravenous or other tube.

FIG. **20** is an electrical schematic diagram of an exemplary control circuit of the temperature control system of FIG. **11** for controlling system operation.

FIG. **21** is an electrical schematic diagram of an exemplary circuit board of the control circuit of FIG. **20**.

FIG. **22** is a procedural flow chart illustrating the manner in which temperature control system heaters are disabled in response to a liquid temperature measurement being equal to or in excess of a desired liquid temperature within the temperature control system of FIG. **11**.

FIG. **23** is a procedural flowchart illustrating the manner in which temperature control system heaters are controlled based on flow rate within the temperature control system of FIG. **11**.

FIG. **24** is a view in perspective of a temperature control system for infused liquids heating both a liquid-filled bag and liquid within an intravenous or other tube according to still another embodiment of the present invention.

FIG. **25** is an electrical schematic diagram of an exemplary control circuit for the temperature control system of FIG. **24**.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

A pressurized infusion apparatus or system for irrigating a patient or directing infused liquids into a patient is illustrated in FIGS. **1-2**. Specifically, system **2***a* is typically mounted on a conventional intravenous (I.V.) pole **4** and includes a receptacle **6** for containing intravenous solution or other liquid and engaging pole **4**, a pressure gauge **8**, an inflatable pressure device or bellows **10**, a bulb **12** for regulating fluid pressure within the bellows via a hose **21**, and an intravenous or other tube **72** for directing liquid from the receptacle to a patient. Receptacle **6** typically receives a liquid-filled bag **14** (e.g., a bag containing intravenous solution or other liquid) and bellows **10** wherein the bellows is disposed within a bellows bag **32** (FIG. **5**) and positioned adjacent the liquid-filled bag. Hose **21** extends between bellows **10** and bulb **12** wherein manipulation of the bulb drives fluid into or from the bellows through hose **21**. Hose **21** is typically implemented by a conventional or other type of hose, may be of any size or shape and may be constructed of any suitable materials. Inflation of bellows **10** via bulb **12** enables the bellows to expand within bellows bag **32** and apply pressure to liquid-filled bag **14**, thereby driving liquid from the liquid-filled bag through tube **72** to a patient. Bulb **12** includes a valve **9** to release fluid from bellows **10** such that the bulb may add or reduce pressure applied by the bellows to liquid-filled bag **14** based on pressure levels within the bellows indicated by pressure gauge **8**. For example, increased fluid pressure within the bellows increases pressure exerted by the bellows onto the liquid-filled bag, while decreased fluid pressure within the bellows reduces pressure exerted by the bellows onto the liquid-filled bag. Pressure gauge **8** may be implemented by any conventional or other type of pressure gauge or device, and provides a measurement and indication of fluid pressure within the bellows produced by manipulation of bulb **12**. The bellows and bellows bag each include a substantially triangular or wedge shape and are typically disposed in receptacle **6** with their respective portions having the greatest thickness positioned toward the upper portion of liquid-filled bag **14**. However, the bellows and bellows bag may be of any shape or size, while the bellows may be implemented by any device capable of applying pressure to the liquid-filled bag. Pressure is

applied by bellows **10** to liquid-filled bag **14** in a downward manner to drive the liquid downward, to control the flow rate of the liquid and to produce an even flow. It is to be understood that the terms "upper", "lower", "up", "down", "front", "back", "rear", "top", "bottom", "side", "left", "right", "far", "near", "height", "width", "thickness" and "length" are used herein merely to describe points of reference and do not limit the present invention to any particular configuration or orientation.

Referring to FIG. **3**, receptacle **6** includes a compartment or storage area **23** and a generally triangular projection **16** extending from the upper portion of the compartment to engage pole **4** (FIGS. **1-2**). The compartment is in the form of a substantially rectangular bag having an open top portion and includes dimensions greater than the combined dimensions of liquid-filled bag **14** and bellows bag **32** (i.e., containing bellows **10**) in order to receive these items. The front portion of compartment **23** includes strips **18**, **20** that are fastened together via a zipper **22** or any other fastening device. Zipper **22** is typically implemented by a conventional zipper and generally extends along a substantially central longitudinal axis of the compartment front portion to fasten an edge of strip **18** to an adjacent or facing edge of strip **20**. The zipper enables the compartment front portion to be substantially closed to maintain bellows bag **32** (i.e., containing bellows **10**) and liquid-filled bag **14** within the compartment. In other words, zipper **22** essentially enables placement and removal of the bellows bag (i.e., containing the bellows) and liquid-filled bag within the compartment. The zipper or other fastening device may be disposed anywhere on the compartment in any fashion to facilitate placement and removal of items within the compartment. The compartment rear portion typically includes an opening (not shown) to permit fluid transfer between bulb **12** and bellows **10** via hose **21** (FIG. **2**). The opening may be of any size or shape capable of permitting the hose to extend to the bellows.

Generally triangular projection **16** extends from the upper back portion of compartment **23** and includes openings **24**, **26** and a loop **28**. Openings **24**, **26** are defined toward the projection center with opening **24** disposed between openings **26**. These openings enable pressure gauge **8** (FIGS. **1-2**) to be mounted on the receptacle. Loop **28** is disposed toward the upper portion of a rear exterior surface of the projection to engage pole **4** and to enable receptacle **6** to be attached to the pole. The receptacle houses the liquid-filled bag and bellows bag (i.e. containing the bellows) to produce pressurized infusion of liquids as described above. The compartment, projection and loop may be of any size or shape, and may be constructed of plastic, rubber or any other suitable materials. By way of example only, the compartment has a height of approximately ten inches and a width of approximately nine inches, while the projection extends approximately three inches from the compartment with the loop extending approximately one inch from the projection.

Bellows **10** for driving liquid from liquid-filled bag **14** to a patient is illustrated in FIG. **4**. Specifically, bellows **10** is generally right triangular and in the form of a wedge. The bellows may be of any size or shape, may be constructed of plastic, rubber, fabric or any other suitable materials, and may be implemented by any conventional or other type of expandable device. By way of example only, the bellows has a height of approximately nine inches, a width of approximately four and one-half inches and an uninflated thickness of approximately four inches (i.e., the thickness varies depending on the amount of inflation). The upper portion and sides of the bellows typically include a series of peaks and recesses in a sawtooth configuration extending between front and rear surfaces of the bellows similar in structure to an accordion. An inlet or port **30** is disposed on a rear exterior surface of the bellows to permit fluid to flow into and from the bellows. The port is typically connected to bulb **12** via hose **21** (FIGS. **1-2**), and may be of any size or shape and disposed anywhere on the bellows. When bulb **12** is manipulated to drive fluid into bellows **10**, the bellows expands laterally and downward within bellows bag **32** (FIG. **5**) and applies pressure to liquid-filled bag **14** to drive liquid to a patient as described above.

Bellows **10** is disposed within bellows bag **32** and is positioned in receptacle **6** adjacent liquid-filled bag **14** as described above wherein bellows bag **32** for housing the bellows is illustrated in FIG. **5**. Specifically, bellows bag **32** is generally right triangular in the form of a wedge with a front tilted surface and includes dimensions greater than the dimensions of bellows **10** to accommodate the bellows in an expanded or compressed state. The bellows bag is typically constructed of cordura nylon, however, the bellows bag may be constructed of any fabric or suitable materials. Bellows bag **32** includes an opening **33** disposed at the bellows bottom for insertion of the bellows into the bellows bag. A flap **34** is disposed proximate opening **33** and extends from the bottom portion of the bellows bag to cover opening **33** and to maintain the bellows within the bellows bag. Further, a port opening (not shown) may be defined in the bellows bag rear surface to enable fluid transfer between bellows **10** and bulb **12** (FIG. **2**) via port **30** (FIG. **4**) and hose **21** as described above. In addition, a pocket **35** may be disposed on the bellows bag front tilted surface for receiving a conductive plate and heating element to heat liquid-filled bag **14** (FIG. **6**) as described below. The bellows bag may be of any size or shape and, by way of example only, includes a height of slightly greater than approximately nine inches, a width of slightly greater than approximately four and one-half inches and a depth of approximately three inches.

Operation of the pressurized infusion system is described with reference to FIGS. **1-5**. Specifically, bellows **10** is disposed within bellows bag **32** and is placed along with liquid-filled bag **14** in receptacle **6**. The receptacle is typically mounted on pole **4** via loop **28** as described above. Bellows bag **32** (i.e., containing bellows **10**) is disposed proximate liquid-filled bag **14** such that liquid-filled bag **14** compresses the bellows within bellows bag **32**. Bulb **12** is manipulated to direct fluid into bellows **10** through hose **21** to enable the bellows to expand within bellows bag **32** and exert pressure in a downward manner on liquid-filled bag **14** to drive liquid to a patient. Valve **9** may be manipulated to release pressure from the bellows as described above such that the pressure and flow rate of the liquid may be controlled. Pressure gauge **8** measures and displays the fluid pressure within bellows **10** produced by manipulation of the bulb, and upon reaching the desired pressure, liquid is driven from liquid-filled bag **14** to a patient at a certain flow rate.

Alternatively, system **2***a* may further include a heater or heating element to heat liquid-filled bag **14** for pressurized infusion of heated liquid into a patient as illustrated in FIGS. **6-7**. Specifically, system **2***b* is substantially similar to system **2***a* described above except that system **2***b* heats liquid-filled bag **14** or maintains the temperature of a pre-heated liquid-filled bag for infusion of heated liquid into the patient. Bellows **10** is disposed within bellows bag **32** and is placed along with liquid-filled bag **14** in receptacle **6** as described above. Bellows bag **32** (i.e., containing bellows **10**) is disposed adjacent liquid-filled bag **14** such that the bellows expands within the bellows bag via inflation by bulb **12** to exert pressure on liquid-filled bag **14** and drive liquid to a patient in substantially the same manner described above. A heater or heating

element **36** and conductive plate **38** are disposed within pocket **35** of bellows bag **32** (FIG. **5**) such that the heating element and conductive plate are located adjacent liquid-filled bag **14**. Pocket **35** is typically formed on bellows bag **32** via additional material extending for a substantial portion of the bellows bag height and having a substantially central opening for permitting the conductive plate to apply heat from the heating element to liquid-filled bag **14**. As bellows **10** is inflated, the bellows presses conductive plate **38** against liquid-filled bag **14** to heat the liquid contained within that bag. A substantially rectangular control box **40** is mounted on pole **4** and includes circuitry to control power supplied to heating element **36**. Control box **40** typically receives power from a common wall outlet jack via power cord **42**, and may be of any shape or size and may be constructed of any suitable materials.

Referring to FIG. **8**, conductive plate **38** is generally rectangular having a notch disposed at the approximate center of its bottom edge. The plate tapers slightly along its shorter dimension towards the upper portion of the plate and includes truncated or cut-off upper portion corners. By way of example only, the plate is constructed of copper and has a height of approximately eight and one-half inches and a width of approximately four and one-half inches, however, the plate may be constructed of any suitable conductor materials and may be of any size or shape. The conductive plate applies heat from heating element **36** (FIG. **7**) to a substantial portion of liquid-filled bag **14**.

Heating element **36** for applying heat to the liquid-filled bag through conductive plate **38** is illustrated in FIG. **9**. In particular, the heating element is substantially rectangular and includes a notch disposed at the approximate center of its bottom edge. The heating element is disposed between the conductive plate and bellows bag to convey heat through the conductive plate to a substantial portion of the liquid-filled bag. By way of example only, heating element **36** is constructed of copper and includes a height of approximately four and one-quarter inches and a width of approximately two and one-half inches, however, the heating element may be constructed of any suitable conductor materials and may be of any size or shape.

A control circuit for controlling heating element **36** is illustrated in FIG. **10**. Specifically, lines **44**, **46** and **48** represent the power received from power cord **42** (FIG. **7**) with line **48** connected to ground. Line **44** is connected in series with a fuse **50** to protect the circuit from power surges and spikes. Lines **44**, **46** are connected to a power switch **52** that controls power to the circuit. The power switch enables a power supply **54** to provide power, typically up to a maximum of 24V, to heating element **36** via a controller **56**. Controller **56** is connected to power supply **54** and heating element **36** to control power to the heating element based on a temperature measurement. Controller **56**, in essence, includes both control circuitry and a sensor to control heating element **36** based on a predetermined temperature. The controller measures resistance through heating element **36**, thereby providing a temperature indication. A predetermined resistance is programmed into controller **56** to provide a preset temperature wherein the controller compares the measured heating element resistance to the predetermined resistance to control the heating element. If the measured resistance is below the predetermined resistance (i.e., measured temperature is below the preset temperature), then controller **56** increases power to the heating element to increase heat and resistance. Conversely, if the measured resistance is above the predetermined resistance (i.e., measured temperature is above the preset temperature), controller **56** decreases power to the heating element to decrease heat and resistance. Thus, the controller maintains heating element **36** substantially at the predetermined resistance (i.e., temperature) by passing appropriate amounts of power to the heating element. The lines, power supply, heating element and controller may be implemented by any conventional components, however, by way of example only, controller **56** is implemented by a Minco CT-198 controller. The control circuitry is typically disposed within controller box **40** (FIG. **7**) mounted on pole **4** described above.

Operation of the heating and pressurized infusion system is described with reference to FIGS. **6-10**. Specifically, a temperature or resistance is preset into controller **56** as described above, while bellows **10** is disposed within bellows bag **32** and is placed along with liquid-filled bag **14** in receptacle **6**. The receptacle is typically mounted on pole **4** as described above. Bulb **12** is manipulated to drive fluid into bellows **10** as described above wherein the bellows expands within the bellows bag and presses conductive plate **38**, heated via heating element **36**, against the liquid-filled bag, thereby heating the liquid-filled bag, controlling flow rate and driving liquid to a patient. The control circuit measures the resistance of heating element **36** and varies power to the heating element to maintain temperature of the heating element, and hence, the liquid-filled bag at the predetermined temperature. Alternatively, a pre-heated liquid-filled bag (e.g., heated to 100° F.) may be inserted within receptacle **6** adjacent bellows bag **32** (i.e., containing bellows **10**). Heating element **36** may be controlled via controller **56** to maintain the pre-heated liquid-filled bag at the predetermined temperature, while the bulb and bellows may be used to control flow rate and drive liquid from the pre-heated liquid-filled bag to a patient in substantially the same manner described above.

A temperature control or warming system for heating liquid traversing an intravenous or other tube during irrigation or infusion is illustrated in FIG. **11**. The temperature control system may be utilized in combination with the pressure infusion systems described above. An exemplary configuration includes receptacle **6**, a drip chamber **58**, a drip detector **60**, an intravenous or other tube **72**, a roller lock **62**, a heating assembly **64**, a connector **66** and a thermocouple holder **68**. Receptacle **6** typically contains a liquid-filled bag **14**, while being mounted on an intravenous (I.V.) pole **4**. The receptacle may further include bellows **10** and bellows bag **32** (FIG. **5**) with or without heating element **36** and conductive plate **38** as described above (FIGS. **2** and **7**). Liquid flows from liquid-filled bag **14** to drip chamber **58** having drip detector **60** surrounding the drip chamber to detect each drip. Drip detector **60** typically employs an infrared emitter and several infrared detectors as described below to ensure accurate detection of drips. Tube **72** extends from drip chamber **58** wherein roller lock **62** is disposed on tube **72** subsequent the drip chamber to control fluid flow in the tube. After the roller lock, tube **72** traverses heating assembly **64**, in the form of a sleeve having heaters disposed therein, to maintain the liquid at a predetermined temperature. Subsequent heating assembly **64**, tube **72** traverses connector **66** (e.g., a Luer connector) and interfaces thermocouple holder **68**. Thermocouple holder **68** maintains a temperature sensor, preferably an infrared sensor, in the proper position adjacent tube **72** to obtain an accurate temperature measurement of the liquid near an entry point on a patient. The thermocouple holder is typically attached to a patient's limb or body near the entry point via an approved medical biocompatible adhesive or any other techniques (e.g., tape). Following thermocouple holder **68**, tube **72** extends to the entry point to infuse liquid into the patient via a needle or other medical device. A substantially rectangular

control panel box **70** is mounted on pole **4** and controls system operation, while displaying the temperature and drip count to a user. The control panel box may be of any shape or size and may be constructed of any suitable materials.

Control panel box **70** displays various items and controls system operation as illustrated in FIG. **12**. Specifically, control panel box **70** includes temperature display **74**, set point (i.e., predetermined or desired temperature) display **76**, controller program buttons **78**, power switch **80**, counter display **82** and heater indicator lights **84**. Power switch **80** enables power to the system and is disposed at the approximate center of the lower portion of the control panel box front surface. Heater indicator lights **84** are substantially vertically aligned toward a far edge (e.g., rightmost edge as viewed in FIG. **12**) of the control panel box front surface and are illuminated to indicate activation of the heaters, which heaters are activated, and the length of time a heater is activated in a cycle according to the drip rate. Temperature and set point displays **74**, **76** are disposed toward the central portion of an edge (e.g., leftmost edge as viewed in FIG. **12**) of the control panel box front surface opposing heater indicator lights **84** with temperature display **74** disposed above set point display **76**. Temperature display **74** displays the liquid temperature as detected by a temperature sensor described below, while set point display **76** displays the predetermined or desired liquid temperature. Controller program buttons **78** are disposed below set point display **76** and enable the set point and other information to be programmed into a safety controller described below. The buttons typically include functions, such as up, down, scroll and page, to program and enter data into the controller. Counter display **82** is disposed above power switch **80** between temperature display **74** and indicator lights **84**, and displays a count of the drips detected by drip detector **60** (FIG. **11**) during a predetermined time interval. The counter display further indicates proper operation of drip detector **60** and may be utilized for system diagnostics. Additional displays may be included on the control panel box front surface to display total drip counts and total volume of liquid dispensed. The displays may be implemented by any conventional LED or LCD or other displays, while the lights and power switch may be implemented by any conventional components, such as diodes and switches, respectively. The control panel displays, lights and switches may be arranged in any fashion and disposed anywhere on the control panel box or on a separate panel.

Referring to FIGS. **13-15**, heating assembly **64** typically includes an elongated sleeve **92** having a plurality of heaters **124** disposed therein to heat liquid in tube **72**. Any quantity of sleeves or heating assemblies may be utilized by the system. Sleeve **92** includes a slot **94** extending longitudinally along an upper sleeve surface for receiving a portion of tube **72**, and has a generally elliptical cross-section with channels **96**, **98** defined through the sleeve for accommodating wiring. Typically, channels **96**, **98** accommodate voltage wires extending from the heaters to prevent the heaters from heating or burning the wires. The plurality of heaters are disposed coincident the slot between channels **96**, **98** such that the tube portion is disposed against the heaters to enable temperature control of liquid within the tube. Sleeve **92** is designed to secure the tube portion against the heaters and to provide insulation to protect the patient from burns. The heaters are typically manufactured by Watlow, but may be implemented by any conventional or other type of heater, for example, Kapton heaters. The tube portion is typically inserted within slot **94** via a tool **88** described below. A temperature sensor **86** is initially positioned external of heating assembly **64** with wires extending from the sensor to the control panel box. Channel **96** (e.g., the leftmost channel in FIGS. **13-15**) typically accommodates wires extending between control panel box **70** and the heaters, while channel **98** (e.g., the rightmost channel in FIGS. **13-15**) typically accommodates wires for temperature sensor **86**. The tube portion is typically disposed in the heating assembly with temperature sensor **86** subsequently disposed within thermocouple holder **68** (FIG. **11**) as described below. A jacket **90**, typically constructed of canvas, encases heating assembly **64** and is closed via a zipper **100** that extends along substantially the entire length of sleeve **92** to protect users, patients and equipment from burns and to secure the heating sections of the assembly. Jacket **90** is typically placed over the heating assembly after placement of the tube portion and temperature sensor as described above. The sleeve may be constructed of plastic, silicon, rubber or any suitable materials and may be of any size or shape to accommodate various heaters and any sized tube portion from any type of tube.

Typically, heating assembly **64** includes three twenty watt, 120V heaters **124** individually controlled by a heat controller described below. However, any quantity or combination of heaters having various power characteristics may be utilized. For example, three forty watt heaters, or a forty watt and a twenty watt heater may be utilized in the heating assembly. Heaters **124** are each controlled, in part, by a heat controller or processor based on a count of drips detected, during a predetermined time interval, within drip chamber **58** (FIG. **11**) via an infrared emitter and infrared detectors described below. In other words, the processor activates individual heaters based on liquid flow rate or the drip count. Heaters **124** each directly supply heat to tube **72** via heating assembly **64** as described above, and may be activated by the processor in any combination (e.g., a first heater may be activated, while a second heater is activated intermittently, all heaters may be activated or only a single heater may be activated) as described below. The processor controls each heater **124** based on a drip count by controlling line voltage to a solid state switching relay associated with that heater to activate that heater for a specified time interval and then deactivate the heater (i.e., the drip count determines which heaters to activate and the time interval for activation).

The utilization of multiple heaters **124** provides enhanced control, as compared to utilization of a single heater, for various flow ranges without burning tube **72**. Further, the multiple heater arrangement avoids hot spots by selectively heating different portions of the tube. The temperature control system further includes a separate safety controller that disables heaters **124** in response to detecting temperatures equal to or above the predetermined or desired temperature. This avoids residual heat (e.g., heat applied to the tube after a malfunction or an interruption in the liquid flow) and prevents temperature change from reaching a patient. The disablement of heaters **124** by the safety controller overrides any heater controls issued by the heat controller. Thus, operation of heaters **124** is controlled by criteria empirically obtained based on measured drip count and temperature.

The system further includes various safety features to disable heaters **124** based on detection of certain events. For example, when the drip counter malfunctions, the temperature sensor becomes loose at the user end, the liquid-filled bag is tipped or relatively empty, the liquid temperature is equal to or exceeds a threshold temperature range (e.g., approximately 104-107° F.), or the liquid flow is interrupted, the system may disable the heaters.

Since the system heats the tube as needed at less than full power and intermittently (e.g., the safety controller disables the heaters in response to liquid temperature), the desired set point (i.e., temperature) is attained rapidly, while the liquid

temperature drops rapidly at shut down (e.g., approximately 13° F. or more in a minute with reset occurring within one second). The safety controller may include an audible alarm for high and low temperatures that typically sounds prior to a patient feeling a temperature change. Further, an alarm may warn when a liquid-filled bag is at a low level. A change in drip size and/or density may affect the waveshape of the infrared detectors, thereby activating heaters less within a cycle, while the temperature decreases. The safety controller can sense this occurrence and provide an alarm giving advanced warning. Alternatively, two alarms may be utilized wherein a first alarm sounds in advance (e.g., during depletion of the liquid-filled bag) and a second alarm sounds when liquid is substantially spent from the liquid-filled bag. The phase down prevents heat residual within the tube.

Tool **88** for inserting a portion of tube **72** within slot **94** of sleeve **92** is illustrated in FIGS. **14** and **16**. Specifically, tool **88** includes a handle **89** and tube interface **91**. Handle **89** is disposed at the tool proximal end and is generally rectangular having a rounded distal end toward tube interface **91**. Tube interface **91** is disposed at the handle distal end and includes legs **93**, **95** each having a curved portion to form a generally semi-circular opening between the legs for receiving tube **72**. However, the opening may be of any shape or size capable of receiving the tube. Legs **93**, **95** each transversely extend in opposing directions from the distal end of their respective curved portion to engage slot **94** and facilitate placement of the tube portion within the heating assembly. The tool receives tube **72** in the opening between legs **93**, **95**, while the transverse portions of the legs penetrate slot **94** to place the tube portion snugly within the slot adjacent heaters **124** in order to enable the heaters to heat liquid within the tube. The tool may be constructed of aluminum or any other suitable materials and may be of any size or shape, however, by way of example only, the tool includes a height of approximately three inches.

Drip detector **60** utilizes infrared emitters and detectors, typically manufactured by Honeywell, to sense the presence of a drip within the drip chamber as illustrated in FIGS. **17-18**. Specifically, drip detector **60** (FIG. **11**) includes a substantially rectangular housing having an opening defined through the approximate center of the housing to enable drip chamber **58** to be disposed through the opening. However, the housing may be of any shape or size and may be constructed of any suitable materials. The housing includes a pair of substantially symmetrical housing blocks **61**, **63** housing an infrared emitter and infrared detectors, respectively. Housing block **61** is substantially rectangular having a truncated or cut-off upper side corner (e.g., left side upper corner as viewed in FIG. **17**) and a substantially semi-circular recess **55** extending from an upper block edge toward the approximate center of the block. An infrared emitter **67** is disposed toward the apex of the recess for emitting infrared energy through the drip chamber. Block **63** is substantially similar to block **61** and includes a truncated or cut-off lower side corner (e.g., left side lower corner as viewed in FIG. **18**) and a substantially semi-circular recess **69** extending from a lower block edge toward the approximate center of the block. A plurality of infrared detectors **71**, preferably three, are positioned toward the recess apex to detect infrared energy emitted from emitter **67**. The detectors detect the infrared energy emitted from emitter **67**, while substantially rejecting ambient light. Blocks **61**, **63** are connected to form the drip detector housing such that the drip chamber is disposed through the generally circular opening formed by block recesses **55**, **69** to enable the emitter and detectors to sense drips within the drip chamber.

Emitter **67** emits a broad signal, typically a 50° conical emission, wherein a drip within the drip chamber focuses the signal on any of infrared detectors **71**, each generally having a 50° conical window. The infrared detector windows overlap each other to provide a wide drip view and higher count accuracy. The detectors are connected in parallel to each other within system control circuitry (FIG. **20**) to allow more current to flow in the detectors, however, this arrangement slightly degrades detector current to opticouplers associated with drip counting circuitry described below. The reduction in current is alleviated by reducing resistance within the circuit. The detectors typically include a high resistance such that when a drip focuses infrared energy on the detectors, the detectors pass a greater amount of current/voltage to the opticouplers. The passage of varying amounts of current and voltage form a sinusoid wave that the drip counting circuitry may detect and count as pulses. Detectors **71** typically generate analog wave pulses that are counted by the drip counting circuitry during a specified time interval. One pulse typically includes three-hundred sixty degrees of the analog wave. A continuous or free-flow (e.g., no drips, but rather, a continuous stream) of liquid virtually always focuses infrared energy onto a detector, thereby enabling the detectors to pass a relatively high constant amount of current/voltage to the opticouplers. Similarly, an interruption in liquid flow enables the detectors to pass a relatively low constant amount of current/voltage to the opticouplers since the infrared energy is not focused on any detector. Since a continuous or free-flow of liquid and an interruption in liquid flow each pass a relatively constant amount of current/voltage to the opticouplers, the drip counting circuitry does not detect pulses and typically produces a zero count in response to these occurrences.

Alternatively, the detectors may generate a high output and transition to a low output when infrared energy is not detected (i.e., when drips pass through the infrared emission pattern). A high to low transition within the detector output indicates the presence of a drip since the drip prevents the detectors from sensing the infrared energy. A continuous or free-flow of liquid enables the detectors to generate a relatively constant high output, while an interruption in liquid flow enables the detectors to generate a relatively constant low output. Since a continuous or free-flow of liquid and an interruption in liquid flow do not produce any transitions, a zero count is typically produced in response to these occurrences. It is to be understood that the detectors may be implemented to generate low to high transitions in response to detecting a drip wherein the detectors sense drips in substantially the same manner described above. Since the size of a drip varies with tubing size and typically changes shape between the top and bottom of a drip tube (e.g., forming the drip chamber), the detectors are typically positioned such that their overlapping windows cover all areas of the drip tube to ensure that a drip is not missed. Thus, a drip is detected even if the drip tube is slanted and the drip does not pass through the center of the drip chamber. The detectors are generally spaced by approximately 24.4°, however, the detectors may be spaced by any amount (e.g., 37°) based on the area needed to be covered and the angle of the conical window. Generally, the angular spacing of detectors **71** may be varied by approximately five degrees (e.g., plus or minus five degrees) for the arrangement described above. Any quantity of emitters and detectors having dispersion and detection patterns of various angles with the emitters having the same or different angles as the detectors may be utilized, depending upon the strength of signals and areas covered. The emitters and detectors may be positioned in any fashion and may be implemented by any con-

ventional or other types of emitters and detectors that accommodate various forms of energy (e.g., light, specific signal frequencies, etc.)

Referring to FIG. **19**, thermocouple holder **68** includes a substantially flat rectangular base or platform **73**, having curved prongs **75**, **77** extending down from the platform and curving toward each other. Prongs **75**, **77** each include transversely extending projections **85**, **87** that extend from their respective prongs toward each other. A channel **79** is disposed below platform **73** to receive tube **72** (FIG. **11**), while temperature sensor **86** (FIGS. **13-15**) is disposed between projections **85**, **87** of prongs **75**, **77** proximate tube **72** to obtain an accurate temperature measurement of the liquid in the tube. The thermocouple holder is typically attached to a patient with platform **73** interfacing a patient body part, such as an arm. The thermocouple holder ensures proper mounting of temperature sensor **86** and enables accurate temperature control via a precise temperature measurement of liquid within tube **72** (i.e., not skin or ambient temperature) wherein the temperature sensor provides a true liquid temperature measurement. The temperature sensor is typically matched to the safety controller described above to provide accuracy and increased sensitivity and precision. A safety circuit **81** is disposed adjacent channel **79** between platform **73** and prong **77**. The safety circuit must be complete or closed to enable operation of the system. The heat controller described above monitors the circuit and disables operation when the circuit is broken or open. The safety circuit may include a resistor across wires that creates a specific resistance detected by the heat controller. Alternatively, the safety circuit may be implemented by a Hall effect transistor that switches based on magnetic fields. Magnetic beads may be disposed within the thermocouple holder wherein the beads are matched to the transistor (e.g., as to strength of the field). The transistor senses the beads to enable system operation. Thermocouple holder **68** and tube **72**, typically with Luer locks (e.g., male and female), are generally disposable wherein thermocouple holder **68** is typically attached (e.g., via an approved medical biocompatible adhesive) to a patient near the entry site for infused liquids. The thermocouple holder may be implemented with a butterfly base, may be attached to a patient in any fashion at any location, may be of any size or shape and may be constructed of plastic or any other suitable materials, however, by way of example only, the holder has a height slightly less than approximately one inch and a width (e.g., between prongs) of slightly less than approximately one-half inch.

A circuit for controlling system operation is illustrated in FIG. **20**. Specifically, the control circuit includes lines **102**, **104** and **106** extending from a common wall outlet jack receptacle **108**. A fuse **110** is connected in series with line **102** from receptacle **108** between the receptacle and a power switch **112**. Power switch **112** enables power to the circuit from lines **102**, **104** (e.g., line voltage (e.g., 120V AC) is typically provided to a power supply **116**, the load side of solid state relays **122** and a safety controller **114** each described below). Power supply **116**, typically 120V AC having +/−12V DC, +/−5V DC, +5V and −5V DC outputs (e.g., fused at the power supply and generally on the device (e.g., control circuit and/or circuit board **118**)), is connected to power switch **112** and provides power to safety controller **114**, a circuit board **118**, and heaters **124**. All control and processor functions are performed at low voltage. Safety controller **114**, typically implemented by a Love or Eurotherm controller, receives power from power supply **116** and a temperature signal from temperature sensor **86** (e.g., an RTD sensor is typically utilized with a Love controller, while an infrared sensor is typically utilized with a Eurotherm controller) indicating the temperature of the liquid. Safety controller **114** may alternatively be implemented by any conventional or other processor, controller or circuitry. The true temperature is received by safety controller **114** from the infrared sensor such that no additional calculations are required. The safety controller, typically implemented as a safety override, respectively displays the liquid and set point temperatures on displays **74**, **76** (FIG. **12**), and is connected in series to a plurality of solid state heat relays **122** that control power to heaters **124**, or an alarm relay (not shown). Each solid state relay is further connected to an indicator light **84** of control panel box **70** to indicate the status (i.e., on/off) of a corresponding heater. When the temperature signal from temperature sensor **86** indicates that the liquid temperature equals or exceeds a predetermined or desired liquid temperature, safety controller **114** disables power (e.g., cuts line voltage or opens relays **122**) to heaters **124**. If temperature sensor **86** fails, safety controller **114** defaults to open circuit (e.g., opens relays **122** to disable heaters **124**) and the display flashes alarm. The Eurotherm controller includes a sensor brake alarm loop, temperature response alarm loop and a high temperature alarm, while the Love controller includes a high temperature alarm and sensor brake alarm loop.

Circuit board **118** houses the circuitry that maintains a drip count and controls heaters **124** in response to liquid flow rate. The circuit board includes a heat controller or processor **120** that, via software, manipulates solid state relays **122** to control individual heaters **124** in response to drip counts. The processor, preferably a Parallax BS2 (i.e., Basic Stamp configuration), typically utilizes binary, hexadecimal and Basic programming and includes defaults of no outputs and inputs on (e.g., the processor defaults to having no outputs). Each software instruction is typically executed within one microsecond and the processor includes 5V, 25 ma (i.e., milliamp) outputs for control of the temperature control system. The circuit board further receives signals from safety circuit **81** to disable the system when a complete circuit is not detected, and displays the drip count for a predetermined time interval on display **82**. Infrared emitter **67** and detectors **71** are connected to the circuit board wherein detectors **71** transmit signals indicating the presence of a drip as described above to enable the circuit board to count drips. Any quantity of detectors detecting a drip may enable incrementation of the drip count, however, by way of example only, drip detection by any of the detectors increments the drip count. The drip count is sent to processor **120** to manipulate individual heaters as described above.

Referring to FIG. **21**, circuit board **118** includes processor **120**, opticoupler circuit **128** for infrared emitter and detectors, a counting circuit **126** and display **82**. The processor and opticoupler are implemented by conventional integrated circuits, while the counting circuit preferably includes two conventional integrated circuits. The processor, opticoupler and counting circuits may be implemented by any conventional or other circuitry capable of receiving signals from detectors **71** and producing a drip count. Counting circuit **126** increments a count for each drip detected within the drip chamber, and may be reset by processor **120**. Infrared detectors **71** are coupled to the counting circuit via opticoupler circuit **128** such that the counting circuit increments the count for each drip detected by the detectors. The opticoupler circuit essentially receives signals from detectors **71** and determines from those signals whether or not a drip is present. The opticoupler subsequently sends a signal to counting circuit **126** to increment the count in response to detection of a drip wherein the count is displayed on display **82**. Processor **120** receives the drip count and, in combination with safety controller **114**

(FIG. **20**), controls heaters **124**, via software, to maintain liquid within tube **72** (FIG. **11**) at a desired temperature.

A procedural flow chart for safety controller **114** to display measured liquid and set point temperatures and control heaters **124** in response to liquid temperature is illustrated in FIG. **22**. Specifically, safety controller **114** (FIG. **20**) is enabled and displays the liquid temperature detected by temperature sensor **86** and the set point temperature (i.e., predetermined or desired liquid temperature) entered via buttons **78** (FIG. **12**) on displays **74**, **76**, respectively. The sensed temperature is compared to the set point temperature by the safety controller to determine if the sensed temperature is below the set point temperature. The safety controller sounds an alarm when the sensed temperature exceeds the set point temperature by at least two degrees (e.g., Fahrenheit or Celsius depending upon the scale utilized), while disabling power to heaters **124** (e.g., cutting line voltage or opening solid state relays **122**) in response to the sensed temperature being equal to or exceeding the set point temperature by any margin. However, the safety controller may be programmed to sound the alarm when the sensed temperature exceeds the set point temperature by any desired amount. If the sensed temperature is below the set point temperature, the safety controller maintains power to heaters **124** (e.g., maintains line voltage or closes solid state relays **122**) to enable heat controller or processor **120** to control temperature of the liquid based on measured drip counts as described below. Safety controller **114** repeatedly compares sensed liquid temperatures to the set point temperature to control heaters **124** as described above until processing is complete (e.g., power down of the system). Disablement of heaters **124** by the safety controller overrides any controls issued by the heat controller, however, the heat controller continues to generate heater controls as described below whether or not the heater controls are overridden by the safety controller.

A procedural flowchart for heat controller or processor **120** (FIG. **20**) to control heaters **124** based on liquid flow rate is illustrated in FIG. **23**. The processor software is implemented such that only one command or step may be performed at any one time in sequential order. Generally, processor **120** requests the drip counting circuitry (e.g., the infrared detectors, opticoupler circuit and counting circuit (FIG. **21**)) to generate drip counts for predetermined time intervals wherein the processor utilizes the drip counts to control heaters **124**. Processor **120** further monitors liquid flow and disables heaters **124** in response to detecting a free-flow of liquid or an interruption of liquid flow to prevent residual heat from reaching a patient. In addition, processor **120** disables system operation in response to safety circuit **81** being open during liquid flow (e.g., the safety circuit is open when a free-flow of liquid or an interruption of liquid flow has each not occurred). Specifically, power is enabled to processor **120** at step **150** and the processor resets the system at step **152** by initializing variables and system parameters to particular values (e.g., zero). The processor requests that a drip count be generated by the drip counting circuitry for a predetermined time interval at step **154** wherein the drip count result is stored in memory, while changes in the drip count are also stored in memory during software execution. The drip count is inspected by the processor at step **156** to determine whether or not a free-flow of liquid or an interruption of liquid flow has occurred (e.g., a drip count of zero for a predetermined time interval indicates a free-flow of liquid or an interruption of liquid flow as described above). If a free-flow of liquid or an interruption of liquid flow has occurred (e.g., the drip count for a predetermined time interval equals zero), processor **120**, at step **158**, disables heaters **124** and sounds an alarm until the processor determines at step **160** that the liquid flows at a drip flow rate (e.g., until the drip detector senses drips within the drip chamber or, in other words, the drip count for a predetermined time interval is greater than zero).

When the processor determines at step **160** that the liquid flows at a drip flow rate, the processor inspects safety circuit **81** at step **162**. This is typically accomplished by examining a circuit variable stored within the processor memory and having a value generated from a poll of the safety circuit wherein the circuit variable value corresponds to the safety circuit status. By way of example only, a circuit variable value equal to or greater than one indicates proper operation or a complete safety circuit, however, the circuit variable may have any values to indicate the safety circuit status. If processor **120** determines that safety circuit **81** is complete at step **162** (e.g., the circuit variable has a value equal to or greater than one), the processor disables heaters **124** and sounds an alarm at step **192**, and subsequently resets the system for a new cycle at step **152**. Otherwise, in response to determining that the safety circuit is open at step **162** (e.g., the circuit variable has a value less than one), processor **120** inspects the drip count at step **188** to detect a free-flow of liquid or an interruption in liquid flow. When a free-flow of liquid and an interruption of liquid flow has each not occurred (e.g., the drip count for a predetermined time interval is greater than zero), processor **120** disables heaters **124** and sounds an alarm at step **190**, and subsequently terminates system operation. However, in response to detecting a free-flow of liquid or an interruption of liquid flow at step **188** (e.g., the drip count for a predetermined time interval equals zero), processor **120** disables heaters **124** and sounds an alarm at step **192**, and subsequently resets the system for a new cycle at step **152**.

In response to determining at step **156** that a free-flow of liquid and an interruption of liquid flow has each not occurred (e.g., the drip count for a predetermined time interval is greater than zero), processor **120** utilizes the drip count to determine, at step **164**, an appropriate control scheme for heaters **124** (e.g., the specific heaters to activate and the length of time of their activation). Specifically, the drip count is compared to values within a series of logical expressions formed in a priority hierarchy with instructions (e.g., heater control schemes) associated with higher priority expressions executed first. The instructions associated with a first true logical expression are executed even if other lower expressions are true. If the drip count does not correspond with a heater control scheme (e.g., the drip count does not correspond to a particular count or range associated with a control scheme), processor **120** disables heaters **124** and sounds an alarm at step **192**, and subsequently resets the system for a new cycle at step **152**. When a drip count corresponds to a heater control scheme (e.g., the drip count corresponds to a particular count or range associated with a control scheme), that heater control scheme is executed at step **166**.

Processor **120**, at initial execution of a control scheme, inspects safety circuit **81** at step **168**. If processor **120** determines at step **168** that safety circuit **81** is not complete (e.g., the circuit variable has a value less than one), the processor inspects the drip count at step **188** to detect a free-flow of liquid or an interruption of liquid flow. When a free-flow of liquid and an interruption of liquid flow has each not occurred (e.g., the drip count for a predetermined time interval is greater than zero), processor **120** disables heaters **124** and sounds an alarm at step **190**, and subsequently terminates system operation. However, in response to detecting a free-flow of liquid or an interruption of liquid flow at step **188** (e.g., the drip count for a predetermined time interval equals zero), processor **120** disables heaters **124** and sounds an alarm at

step **192**, and subsequently resets the system for a new cycle at step **152**. When processor **120** determines at step **168** that safety circuit **81** is complete (e.g., the circuit variable has a value equal to or greater than one), the processor determines at step **170** whether or not a free-flow of liquid or an interruption of liquid flow has occurred. If a free-flow of liquid or an interruption of liquid flow has occurred (e.g., the drip count for a predetermined time interval equals zero), processor **120** disables heaters **124** and sounds an alarm at step **192**, and subsequently resets the system for a new cycle at step **152**.

When processor **120** respectively determines at steps **168** and **170** that safety circuit **81** is complete (e.g., the circuit variable has a value equal to or greater than one) and a free-flow of liquid and an interruption of liquid flow has each not occurred (e.g., the drip count for a predetermined time interval is greater than zero), processor **120** performs the control scheme associated with the drip count at step **172** wherein specific heaters **124** are activated for a particular time interval, while the appropriate heater indicator lights are illuminated. During a heating cycle, processor **120**, at step **174**, conducts an inspection approximately every ten seconds or any other time interval to ensure that safety circuit **81** remains complete and that the liquid flow has not been changed (e.g., user intervention to enable free-flow of liquid or an interruption of liquid flow). If processor **120** determines at step **176** that liquid flow has been altered (e.g., the drip count for a predetermined time interval equals zero indicating a free-flow of liquid or an interruption of liquid flow), processor **120**, at step **178**, disables heaters **124** and sounds an alarm until the processor determines at step **180** that the liquid flows at a drip flow rate (e.g., the drip count for a predetermined time interval is greater than zero) as described above.

When processor **120** determines at step **180** that the liquid flows at a drip flow rate, the processor inspects safety circuit **81** at step **182**. If processor **120** determines that safety circuit **81** is complete at step **182** (e.g., the circuit variable has a value equal to or greater than one), the processor disables heaters **124** and sounds an alarm at step **192**, and subsequently resets the system for a new cycle at step **152**. Otherwise, in response to determining that safety circuit **81** is open at step **182** (e.g., the circuit variable has a value less than one), processor **120** inspects the drip count at step **188** to detect a free-flow of liquid or an interruption in liquid flow. When a free-flow of liquid and an interruption of liquid flow has each not occurred (e.g., the drip count for a predetermined time interval is greater than zero), processor **120** disables heaters **124** and sounds an alarm at step **190**, and subsequently terminates system operation. However, in response to detecting a free-flow of liquid or an interruption of liquid flow at step **188** (e.g., the drip count for a predetermined time interval equals zero), processor **120** disables heaters **124** and sounds an alarm at step **192**, and subsequently resets the system for a new cycle at step **152**.

Referring back to step **176**, when a free-flow of liquid and an interruption of liquid flow has each not occurred (e.g., the drip count for a predetermined time interval is greater than zero), processor **120** inspects safety circuit **81** at step **184**. If processor **120** determines at step **184** that safety circuit **81** is not complete (e.g., the circuit variable has a value less than one), the processor inspects the drip count at step **188** to detect a free-flow of liquid or an interruption of liquid flow. When a free-flow of liquid and an interruption of liquid flow has each not occurred (e.g., the drip count for a predetermined time interval is greater than zero), processor **120** disables heaters **124** and sounds an alarm at step **190**, and subsequently terminates system operation. However, in response to detecting a free-flow of liquid or an interruption of liquid flow at step **188** (e.g., the drip count for a predetermined time interval equals zero), processor **120** disables heaters **124** and sounds an alarm at step **192**, and subsequently resets the system for a new cycle at step **152**.

When processor **120** respectively determines at steps **176** and **184** that a free-flow of liquid and an interruption of liquid flow has each not occurred (e.g., the drip count for a predetermined time interval is greater than zero) and that safety circuit **81** is complete (e.g., the circuit variable has a value equal to or greater than one), the processor determines at step **186** whether or not a control scheme or cycle is complete. In response to completion of a cycle, processor **120** resets the system for a new cycle at step **152**; otherwise, the processor continues inspecting liquid flow and the safety circuit at predetermined time intervals as described above (i.e., steps **174**, **176**, and **184**) until the cycle is complete. Heaters **124** are controlled by processor **120** in the manner described above wherein the heaters function in accordance with controls received from processor **120** unless safety controller **114** disables the heaters as described above. However, processor **120** continues to generate controls for heaters **124** as described above whether or not the controls from the processor have been overridden by the safety controller. In other words, processor **120** continues to generate heater controls even if the heaters are prevented from functioning in response to those controls.

The temperature control system may further include multiple chips (e.g., controllers) to permit greater simultaneous functionality (e.g., temperature control of multiple bags having different uses, such as intravenous and irrigation). Further, the temperature control system may be controlled via a personal or other type of computer from a remote location, such as a lab. The remote system may control temperature and flow rate wherein troubleshooting may further be accomplished via modem from a remote location.

Alternatively, heating assembly **64** may contain a single heater and be used in combination with a heated liquid-filled bag as illustrated in FIG. **24**. Specifically, the configuration illustrated in FIG. **24** is similar to the configuration illustrated in FIG. **11** and includes receptacle **6**, drip chamber **58**, tube **72**, roller lock **62** and connector **66**, each as described above for FIG. **11**. The configuration further includes control box **40**, as described above for FIG. **11**, housing a heater control circuit (FIG. **25**) and a heating assembly **64** that is substantially similar to the heating assembly described above for FIGS. **13-15** except that a single elongated heater or heating element **132** is utilized within heating assembly sleeve **92**. Heater **132** is similar to heating element **36** (FIG. **9**) described above, and is controlled by a controller based on sensed resistance in heater **132** in substantially the same manner described above for the heated pressurized infusion system. Receptacle **6** typically contains liquid-filled bag **14**, conductive plate **38** (FIG. **8**) and heating element **36** (FIG. **9**) as described above for the heated pressurized infusion system. The heating element and conductive plate may be disposed on a bellows bag **32** (FIG. **5**), containing a bellows and positioned adjacent the liquid-filled bag within receptacle **6**, to heat the liquid-filled bag as described above. However, the heating element and conductive plate may be utilized without the bellows and bellows bag and may be disposed within the receptacle in any fashion. Drip chamber **58** is coupled to liquid-filled bag **14** wherein tube **72** extends from the drip chamber and traverses roller lock **62**, heating assembly **64** and connector **66** as described above for FIG. **11** to direct heated liquid from the liquid-filled bag to an entry site on a patient. A portion of tube **72** is disposed within heating assembly sleeve **92** as described above to enable heating assembly **64** to main-

tain the heated liquid at a desired temperature and prevent liquid cooling as the heated liquid flows within the tube from liquid-filled bag **14** to a patient.

A control circuit for controlling heating element **36** and heater **132** is illustrated in FIG. **25**. The control circuit is substantially similar to the circuit described above for FIG. **10** except that the control circuit includes an additional controller **130** to control heater **132** of heating assembly **64**. Controller **130** is substantially similar to controller **56** and controls power to heater **132**. Specifically, power switch **52** enables power to power supply **54** as described above wherein the power supply directs power to controllers **56**, **130** and corresponding heating element **36** and heater **132**, respectively. Controller **56** senses resistance within heating element **36** and controls power to the heating element to maintain the heating element and liquid-filled bag at a desired temperature as described above. Controller **130** senses resistance within heater **132** and controls power to that heater in substantially the same manner described above for controller **56** to maintain the heater and heated liquid within tube **72** at a desired temperature as the heated liquid flows within the tube from the liquid-filled bag to a patient.

It will be appreciated that the embodiments described above and illustrated in the drawings represent only a few of the many ways of implementing a method and apparatus for pressure infusion and temperature control of infused liquids.

The various embodiments of the present invention, namely the pressurized infusion systems and the temperature control systems may be utilized either individually or in any combination to warm liquid. For example, the non-heated pressurized infusion system may be utilized individually or in combination with the multiple heater temperature control system, while the heated pressure infusion system may be utilized individually or in combination with the single heater temperature control system. Further, the systems may be utilized for any applications requiring heated fluids, or fluids heated during fluid flow.

The receptacle may be of any shape or size, and may be constructed of any suitable materials. Further, the receptacle may be attached to intravenous poles or other structures via any type of hook, opening or by any other fastening techniques. The receptacle may include any type of zipper or other fastening devices disposed anywhere on the receptacle in any fashion to close the compartment. The pressure gauge may be implemented by any conventional or other type of device for measuring and indicating pressure levels, and may be disposed on the receptacle, intravenous pole or at any other location capable of conveying pressure readings to a user.

The bellows may be implemented by any inflatable device capable of expanding upon inflation, and may be inflated via any type of fluid, such as a gas (e.g., air) or liquid. The bellows may be of any shape or size capable of applying pressure to the liquid-filled bag, may be constructed of any suitable materials, and may be oriented in any fashion within the bellows bag or receptacle. Further, any quantity (e.g., at least one) of bellows may be utilized to apply pressure to the liquid-filled bag in substantially the same manner described above. The bellows port may be disposed anywhere on the bellows. The bellows may be utilized without being disposed within the bellows bag. The bellows bag may be of any shape or size capable of receiving the bellows or covering any portion of the bellows, and may be constructed of any suitable materials. The bellows bag opening may be of any shape or size and may be disposed anywhere on the bellows bag capable of enabling insertion of the bellows into the bellows bag. The bellows bag opening may be covered by any flap or other object to maintain the bellows within the bellows bag. The port opening in the bellows bag may be of any shape or size and may be disposed at any location capable of enabling fluid transfer between the bellows and an inflation/deflation device. The hose for directing fluid to and from the bellows may be implemented by any conventional or other type of hose or tube, may be of any size or shape, and may be constructed of any suitable materials. The bellows bag opening may alternatively be utilized for receiving hoses or tubes for facilitating fluid transfer between the bellows and an inflation/deflation device. The bellows bag pocket may be of any shape or size, and may be disposed anywhere on the bag to enable the heating element and conductive plate to be applied to the liquid-filled bag. The bellows may be inflated by any type of inflating device or pump including any type of valve or other device for controlling inflation and deflation of the bellows.

The heating element and conductive plate may be of any shape or size, and may be constructed of any materials capable of conducting heat. The heating element may be utilized without the conductive plate, may be disposed adjacent the liquid-filled bag, and may be implemented by any type of heater or heating element. The heating element and conductive plate may alternatively be disposed anywhere proximate the liquid-filled bag to heat that bag, and not necessarily within the receptacle. The pressurized and heated pressurized infusion systems are not limited to application with intravenous poles, but may be utilized with various structures.

The heating element temperature may be measured by any conventional or other type of temperature measuring devices to control heating element temperature. The heating element control circuitry may include any conventional or other type of power switch (e.g., lighted), power supply and controller. The heating element controller is typically implemented by a commercially available controller pre-programmed and loaded with its own software, but may be implemented by any conventional or other type of controller, microprocessor, or circuitry capable of controlling the heating element to attain a desired temperature. The control box may be of any shape or size, and may be constructed of any suitable materials. The control box may be disposed on an intravenous pole or at any location capable of enabling the heating element control circuit to control the heating element.

The control panel box may be of any shape or size, and may disposed anywhere on an intravenous pole or at any other location capable of controlling the heating assembly. The control panel front surface may include any types of displays, lights or other indicators, or switches (e.g., lighted) arranged in any fashion. The displays may be implemented by any conventional or other types of displays, such as LED or LCD displays. The indicator lights may be implemented by any type of light or other indicator, such as audio, voice or display, to indicate heater activation. The power switch may be implemented by any type of conventional or other type of switch or button that may include a light for illuminating the switch or button. The displays may display any quantity of digits to reflect the actual and set point temperatures.

The heating assembly sleeve may be of any shape or size, and may be constructed of any suitable materials. The slot may be of any length and be defined anywhere in the sleeve to engage the tube. Alternatively, the sleeve may include any type of fastener to engage the tube. The sleeve may include channels or other openings disposed anywhere on the sleeve to accommodate wiring. The heaters may be disposed anywhere within or adjacent the sleeve capable of heating the tube. The sleeve may include any quantity of heaters (e.g., at least one) to heat the tube. The sleeve may be encased by a jacket of any shape or size and constructed of any suitable

materials. The jacket may include any type of zipper or other fastener to maintain the sleeve within the jacket. The temperature sensor may be implemented by any conventional or other type of infrared, resistive temperature (RTD) or other temperature sensing devices. The heating assembly may be disposed anywhere along the tube and accommodate any sized portion of the tube to heat the liquid, while the tube may be implemented by any conventional intravenous or other type of tube. The drip chamber may be implemented by any conventional drip chamber or other device that enables the fluid to drip. The drip detector may include any type of mechanical or other type of detector to detect drips. The emitter may be implemented by any conventional infrared or other type of emitter to detect the drip, such as emitters for transmitting signals at infrared or any other frequency or light band. The detectors may be implemented by any conventional infrared or other type of detector capable of detecting the signal emitted by the emitter. The drip detector may include any quantity of emitters and detectors (e.g., at least one emitter and one detector). The drip detector housing may be of any shape, and may be constructed of any suitable materials. The drip detector may be disposed at any location near the drip chamber capable of detecting a drip. The emitter may have any type of emission spread (e.g., conical) with any angle, while each detector may include any detection window (e.g., having any angle) to detect the emitter signal. The emitter and detectors may be arranged in any fashion within the drip detector housing to detect a drip.

The control circuitry for the temperature control system may include any conventional or other types of fuses, receptacles, controllers, switches (e.g., lighted), power supplies, and relays. The safety controller is typically implemented by a commercially available pre-programmed controller loaded with its own software, but may be implemented by any type of controller, microprocessor or other circuitry capable of disabling the heaters in response to a temperature measurement. The power supply may be implemented by any conventional or other type of power supply, while the solid state relays may be implemented by any type of solid state or other relays or switches. The power switch may be implemented by any conventional or other type of switch (e.g., lighted) or button. The heat controller may be implemented by any type of controller, microprocessor or other circuitry capable of controlling the heaters in response to flow rate. The heat controller or processor and safety and heating element controllers, if the safety and heating element controllers are implemented by a programmable controller requiring software, may be programmed in any suitable computer language wherein the program and algorithm may be modified in any fashion to control heaters for maintaining liquid temperature. For example, the time intervals for maintaining heater activation may be adjusted to control heating of the liquid within the tube based on a desired drip or flow rate. It is to be understood that one of ordinary skill in the computer and/or programming arts can develop the software for the heat controller or processor and heating element and safety controllers, if the heating element and safety controllers are implemented by programmable controllers requiring software, based on the functional description of controller operation in the specification and flow charts illustrated in the drawings.

The circuit board may include any type of circuitry to interpret detector signals and increment a counter. The counter may be implemented by any conventional or other type of counting circuitry, such as integrated circuits, a microprocessor, registers, memory, etc. The opticouplers may be implemented by any conventional or other type of opticoupler or other circuitry capable of receiving detector signals and determining whether or not to increment a counter.

The thermocouple holder may be of any size or shape, and may be constructed of any suitable materials. The thermocouple holder may receive the tube and sensor in any fashion to enable the sensor to obtain temperature measurement of the liquid within the tube. The holder may be disposed at any location near the entry site, and may be attached to a patient via any suitable fastening technique. The safety circuit may be implemented by any type of circuit enabling operation of the system wherein any values may be utilized within the heat controller to indicate safety circuit status (e.g., complete or open).

The single heater temperature control system may include any type of heating element or heater disposed within the heating assembly. The heating element may be of any size or shape, and may be disposed at any location within the sleeve capable of heating the liquid within the tube. The control circuit of the single heater temperature control system may include any conventional or other type of fuse, power switch (e.g., lighted) or controllers as described above for the control circuit of the heated pressurized infusion system. The controllers of the single heater temperature control system may be implemented by any controllers, microprocessors or other circuitry capable of controlling the heating element and heater in response to a temperature measurement as described above.

It is to be understood that the heating assembly heaters may be controlled by the heat controller based on the relationship between flow rate, liquid viscosity and temperature. The relationship between the viscosity and temperature of any liquid is known. Since the viscosity of the infused liquid is known, and the flow rate is measured, the temperature of the liquid, and hence, heater operation may be controlled based on the known viscosity and measured flow rate. That is, the heat controller may control the heating assembly heaters based on flow rate (e.g., and known viscosity) to maintain liquid temperature at substantially a desired temperature. From the foregoing description, it will be appreciated that the invention makes available a novel method and apparatus for pressure infusion and temperature control of infused liquids wherein an inflatable device is disposed adjacent a liquid-filled bag to apply pressure to the liquid-filled bag to drive liquid from the liquid-filled bag to a patient, while the inflatable device may further include a conductive plate and heating element to apply heat to the liquid-filled bag. Further, a heating assembly including at least one heater may be disposed along an intravenous or other tube to heat liquid flowing within the tube from a liquid-filled bag to a patient.

Having described preferred embodiments of a new and improved method and apparatus for pressure infusion and temperature control of infused liquids, it is believed that other modifications, variations and changes will be suggested to those skilled in the art in view of the teachings set forth herein. It is therefore to be understood that all such variations, modifications and changes are believed to fall within the scope of the present invention as defined by the appended claims.

What is claimed is:

1. In an apparatus for controlling temperature of infused liquids as liquid flows from a liquid-filled container through a drip chamber and tube to an entry site on a patient, wherein said drip chamber includes a transparent tube portion and is disposed along said tube subsequent said liquid-filled container, an apparatus for detecting drips within said drip chamber comprising:

a housing including:

an opening for receiving said drip chamber;

a first housing member including an emitter disposed therein for emitting signals through said transparent tube portion in the form of non-visible light to minimize the effect of ambient visible light in the vicinity of said transparent tube portion; and

a second housing member coupled to said first housing member to form said opening and including a plurality of detectors disposed therein each for detecting said non-visible light signals emitted by said emitter of said first housing member and modified by drips within said transparent tube portion to sense the presence of drips within said drip chamber, wherein each said detector includes an angular detection window providing view of an area within said transparent tube portion and detects said non-visible light signals within said view, and wherein said plurality of detectors are angularly displaced from each other about said transparent tube and are arranged to include overlapping detection windows for detecting said non-visible light signals emitted through said transparent tube portion by said emitter of said first housing member, wherein at least one angular detection window comprises a conical window.

2. The apparatus of claim **1** wherein said housing includes an exterior surface disposed along a periphery of said opening, and said detectors are disposed within said housing at said exterior surface.

3. The apparatus of claim **2** wherein said emitter is disposed at said exterior surface of said housing.

4. The apparatus of claim **1** wherein said detectors are positioned within said housing to receive said ambient visible light through said transparent tube portion without permitting said received ambient visible light to affect said drip detection.

5. The apparatus of claim **1**, wherein:

the emitter generates a broad signal; and

the broad signal is detectable by multiple detectors of the plurality of detectors.

6. The apparatus of claim **1**, wherein the emitter generates a broad signal toward multiple detectors of the plurality of detectors.

7. In an apparatus for controlling temperature of infused liquids as liquid flows from a liquid-filled container through a drip chamber and tube to an entry site on a patient, wherein said drip chamber includes a transparent tube portion and is disposed along said tube subsequent said liquid-filled container, an apparatus for detecting drips within said drip chamber comprising:

a housing including:

an opening for receiving said drip chamber;

a first housing member including an emitter disposed therein for emitting signals through said transparent tube portion in the form of non-visible light to minimize the effect of ambient visible light in the vicinity of said transparent tube portion; and

a second housing member coupled to said first housing member to form said opening and including a plurality of detectors disposed therein each for detecting said non-visible light signals emitted by said emitter of said first housing member and modified by drips within said transparent tube portion to sense the presence of drips within said drip chamber, wherein each said detector includes an angular detection window providing view of an area within said transparent tube portion and detects said non-visible light signals within said view, and wherein said plurality of detectors are angularly displaced from each other about said transparent tube and are arranged to include overlapping detection windows for detecting said non-visible light signals emitted through said transparent tube portion by said emitter of said first housing member, wherein the emitter generates a conical signal.

8. The apparatus of claim **7**, wherein the signal is a 50° conical signal.

9. In an apparatus for controlling temperature of infused liquids as liquid flows from a liquid-filled container through a drip chamber and tube to an entry site on a patient, wherein said drip chamber includes a transparent tube portion and is disposed along said tube subsequent said liquid-filled container, and said apparatus includes a drip detector having a housing including an opening, a method for detecting drips within said drip chamber comprising:

(a) receiving said drip chamber through said opening of said housing, wherein said housing includes first and second housing members coupled together to form said opening;

(b) emitting signals through said transparent tube portion in the form of non-visible light, via an emitter disposed within said first housing member, to minimize the effect of ambient visible light in the vicinity of said transparent tube portion; and

(c) detecting said non-visible light signals emitted by said emitter of said first housing member and modified by drips within said transparent tube portion, via a plurality of detectors disposed within said second housing member, to sense the presence of drips within said drip chamber, wherein each said detector includes an angular detection window providing view of an area within said transparent tube portion and detects said non-visible light signals within said view, and wherein said plurality of detectors are angularly displaced from each other about said transparent tube and arranged to include overlapping detection windows for detecting said non-visible light signals emitted through said transparent tube portion by said emitter of said first housing member, wherein at least one angular detection window comprises a conical window.

10. The method of claim **9** wherein:

said housing includes an exterior surface disposed along a periphery of said opening, and

step (c) further includes: (c.1) positioning said detectors within said housing at said exterior surface.

11. The method of claim **10** wherein step (c) further includes: (c.2) disposing said emitter at said exterior surface of said housing.

12. The method of claim **9** wherein step (c) further includes: (c.1) positioning said detectors within said housing to receive said ambient visible light through said transparent tube portion without permitting said received ambient visible light to affect said drip detection.

13. The method of claim **9**, wherein (b) further comprises (b.1) emitting a broad signal detectable by multiple detectors.

14. The method of claim **9**, wherein (b) further comprises (b.1.) emitting a signal toward multiple detectors of the plurality of detectors.

15. In an apparatus for controlling temperature of infused liquids as liquid flows from a liquid-filled container through a drip chamber and tube to an entry site on a patient, wherein said drip chamber includes a transparent tube portion and is disposed along said tube subsequent said liquid-filled container, and said apparatus includes a drip detector having a housing including an opening, a method for detecting drips within said drip chamber comprising:

(a) receiving said drip chamber through said opening of said housing, wherein said housing includes first and second housing members coupled together to form said opening;

(b) emitting signals through said transparent tube portion in the form of non-visible light, via an emitter disposed

within said first housing member, to minimize the effect of ambient visible light in the vicinity of said transparent tube portion; and

(c) detecting said non-visible light signals emitted by said emitter of said first housing member and modified by drips within said transparent tube portion, via a plurality of detectors disposed within said second housing member, to sense the presence of drips within said drip chamber, wherein each said detector includes an angular detection window providing view of an area within said transparent tube portion and detects said non-visible light signals within said view, and wherein said plurality of detectors are angularly displaced from each other about said transparent tube and arranged to include overlapping detection windows for detecting said non-visible light signals emitted through said transparent tube portion by said emitter of said first housing member, wherein: the signal is conical; and (b) comprises (b.1) emitting a conical signal toward the plurality of detectors.

16. The method of claim **15**, wherein the signal is a 50° conical signal.

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