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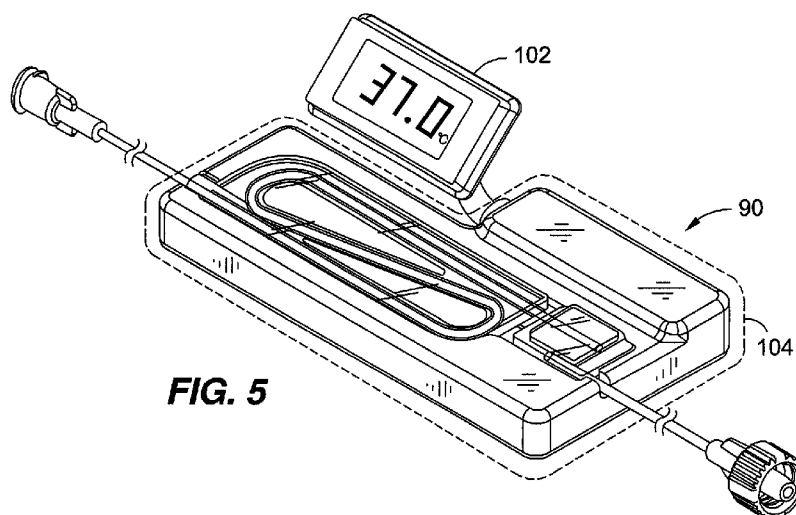


FIG. 5

(57) Abstract: A heating system for heating neonate nutritional liquid, including a heater and a control module. The heater includes a heating portion having a serpentine shaped groove for receiving a tube. The tube may be a serpentine feeding tube module, having a serpentine tube portion, or a serpentine feeding tube cassette, having a serpentine tube portion covered by a rigidly attached poly-
meric sheet. The serpentine feeding tube cassette may include an inline thermocouple to measure the temperature of the warmed nu-
tritional liquid as it exits the cassette.

NEONATAL FLUID TUBING HEATER

CROSS-REFERENCE TO RELATED APPLICATIONS

5 Not Applicable

STATEMENT RE: FEDERALLY SPONSORED RESEARCH/DEVELOPMENT

Not Applicable

10 BACKGROUND

The embodiments disclosed herein relate to a heater for warming nutritional liquid fed to a pre-term infant.

Nutritional delivery to a preterm infant or enteral feeding is an important part of caring for the preterm infant in neonate-natal intensive care units. Typically, the preterm infant is fed with a feeding tube that delivers breast milk or neonatal formula directly into the stomach of the preterm infant. The feeding tube is generally introduced either through the nose (i.e., nasally) or through the mouth (i.e., orally). Previously, the breast milk or neonatal formula was fed to the neonate while the breast milk or neonate formula was at room temperature (i.e., below body temperature). However, studies have shown that preterm infants respond favorably when the nutritional liquid (e.g., breast milk or neonatal formula) coincides with the body temperature of a person (i.e., 98.6°F). When the nutritional liquid is provided to the preterm infant at a temperature closer to the body temperature of a person, the preterm infant was found to digest more of the nutritional liquid. Moreover, other studies have found that the lower the body temperature of the preterm infant, the higher the likelihood of mortality of the preterm infant. As such, it is important to preserve the preterm infant's energy so that the preterm infant does not need to divert energy away from heating and growth to generate heat. If the nutritional liquid is fed to the preterm infant at room temperature, the preterm infant must divert energy that could be used for healing and growth to heat him or herself due to digestion of the cold nutritional liquid. Accordingly, it would be beneficial to feed preterm infants with nutritional liquid raised to the body temperature of a person to reduce the amount of energy diverted away from healing and growth to digestion and heat generation.

In response, prior art devices have been introduced for warming nutritional liquid (e.g., breast milk or neonate formula) provided to pre-term infants. Typically, the nutritional liquid is warmed in a neonate feeding syringe or warm nutritional liquid is poured into the syringe and then fed to the neonate. Unfortunately, even if the nutritional liquid is pre-warmed to body temperature, the temperature of the nutritional liquid in the feeding syringe decreases to room temperature during feeding due to the long feeding time. The average feeding time is about 30 minutes to 4 hours. Heat is lost through the neonate feeding syringe. Also, heat is lost through a tube routed to the stomach of the neonate. In particular, as the nutritional liquid flows from the feeding syringe to the neonate through the tube, significant heat loss is experienced through the tubing since the nutritional liquid travels through the tubing at a relatively slow rate. Accordingly, even if the nutritional liquid in the neonate feeding syringe is raised to the body temperature of the mother, such warming is rendered ineffective since there is a significant temperature drop as the nutritional liquid flows through the tube.

Additionally, medical professionals that care for preterm infants are typically very busy managing care for a number of preterm infants. However, feeding of the preterm infant is not as important as other life critical services in a neonatal intensive care unit (NICU). As such, feeding schedules may be compromised. For example, a pre-term infant that might have stopped breathing would receive care before feeding of another preterm infant. As such, it is important for the medical professional (i.e., nurse) to be capable of quickly setting up the feeding apparatus so that the medical professional may attend to more critical needs of other preterm infants.

Accordingly, there is a need in the art for an improved method and device for heating nutritional liquid fed to the pre-term infant.

BRIEF SUMMARY

The embodiments discussed herein address the needs discussed above, discussed below and those that are known in the art.

A system for heating nutritional liquid to be fed to a preterm infant which can be quickly and efficiently set up is disclosed. The system has a heater with an internal cavity for receiving a cartridge portion of a tube through which the nutritional liquid flows during the feeding process. The heater warms up the nutritional liquid flowing

through the tube, and more particularly, the cartridge portion of the tube so that the preterm infant is fed warm nutritional fluid. Preferably, the warm nutritional fluid is delivered to the preterm infant at about a standard body temperature of a person (i.e. between about 95°F and about 99° F). One end of the tube is connected to a container
5 which stores the nutritional liquid during the feeding process. The other end of the tube is disposed within the preterm infant's stomach or connected to a feeding tube which is disposed within the preterm infant's stomach. In this manner, the nutritional liquid flows through the tube and into the preterm infant's stomach. The heater warms up the nutritional fluid as it flows through the cartridge portion of the tube to about
10 standard body temperature for the preterm infant.

The cartridge portion of the tube may have a preformed bent configuration so that the nutritional liquid may remain within the heater for a longer period of time so that the nutritional liquid can be more slowly heated, compared to a straight configuration. Moreover, the cartridge portion of the tube may be generally rigid (i.e.,
15 retain its bent shape) so that a medical professional need not fumble with the cartridge portion, especially when the medical professional inserts the cartridge portion into the internal cavity of the heater. This problem is accentuated when the internal cavity is defined by a groove having a particular shape such as a serpentine shape. The cartridge portion of the tube may have a corresponding serpentine shape that is
20 preformed and generally rigid so that the medical professional can quickly drop the serpentine shaped cartridge portion of the tube into the serpentine shaped groove defining the internal cavity. The medical professional need not route or slowly push and hold the tube into the serpentine shaped groove. To further hold the bent shape of the cartridge portion, a sheet may be attached to one side of the cartridge portion of
25 the tube.

More particularly, a system for heating neonate nutritional liquid so that a temperature of the nutritional liquid approximates a standard body temperature of a neonate during feeding is disclosed. The system may comprise a container, a tube and a heater. The container is for the purposes of storing the neonate nutritional liquid
30 during feeding. The tube defines first and second ends. The first end of the tube may be connected to the container. The second end of the tube may be disposed within a stomach of the neonate or connected to a feeding tube for flowing the neonate nutritional liquid from the container to the neonate during feeding. A cartridge portion

of the tube may be preformed into a bent configuration. The heater may have a heating unit and a heat sink. The heat sink may define an internal cavity of the heater wherein the internal cavity is sized and configured to receive the bent cartridge portion of the tube for heating the neonate nutritional liquid as the neonate nutritional liquid flows from the container to the neonate during feeding through the heater.

The cartridge portion of the tube may have a zig zag configuration, Z shaped configuration, L shaped configuration, U shaped configuration or combinations thereof. The zig zag configuration of the cartridge portion of the tube may be a serpentine configuration.

The system may further comprise a backing member with a first side of the cartridge portion of the tube attached to the backing member for rigidly fixing the bent configuration of the cartridge portion to facilitate insertion of the cartridge portion of the tube into the internal cavity of the heater. The heater may further comprise a heat sink having a groove with a corresponding bent configuration compared to the bent cartridge portion of the tube so that the cartridge portion of the tube is easily insertable into the groove of the heat sink.

The cartridge portion of the tube may be disposed between the rigid backing and the heating unit so that the rigid backing aids in retaining heat within the cartridge portion. The rigid backing may be fabricated from a polymeric sheet or an insulation material.

The system may further comprise a temperature sensor connected to the heating unit for sensing a temperature of the heating unit and sending a signal to a control module to cut off power to the heating unit when the temperature of the heating unit exceeds a preset upper limit.

The heater may have a heater base and a cover. The cover may be traversed between a closed position and an opened position. The system may further comprise a switch disposed adjacent to the cover so that in the closed position, the switch is depressed and operative to turn on a heater active signal, and in the opened position, the switch is released and operative to turn off the heater active signal. The heater active signal may be a light.

In another aspect, a tube for use in a system for heating neonate nutritional liquid so that a temperature of the nutritional liquid approximates a standard body temperature of a person during feeding is disclosed. The tube may comprise an

elongate body having a central lumen. The elongate body may define first and second ends. The first end of the tube may be connected to a container with the neonate nutritional liquid therein. The second end may be disposed within a stomach of the neonate or connected to a feeding tube for routing the neonate nutritional liquid from the container to the neonate during feeding. A cartridge portion of the elongate body may be preformed into a bent configuration and disposed in an internal cavity of a heater.

A first side of a sheet may be attached to one side of the bent cartridge portion of the elongate body for rigidly fixing the bent configuration of the cartridge portion. The cartridge portion of the tube may be recessed within a groove formed on a side of the sheet.

The tube may further comprise a temperature sensor attached to the elongate body downstream of the cartridge portion for reading a temperature of the neonate nutritional fluid after exiting the heater.

More particularly, the elongate body may comprise first and second elongate bodies. Each of the first and second elongate bodies may have a central lumen. The tube may further comprise an inline temperature sensor. The inline temperature sensor may comprise a body defining a flow path. The first and second elongate bodies may be attached to the body in line with the flow path. A thermocouple may be attached to the body for directly measuring a temperature of the nutritional liquid after the nutritional liquid exits a heater of the system.

In another aspect, a heating system for heating neonate nutritional liquid is disclosed. The heating system includes a heater and a control module. The heater includes a heater base, a heating portion having a serpentine shaped groove for receiving a tube, and a heater cover rotatably connected to the heater base. The heating portion is located within the heater base. The control module includes a means for controlling the heater.

The heater may further include a microswitch positioned such that the microswitch is depressed when the heater cover is in a closed position abutting the heater base. In particular, the heater may only operate when the microswitch is depressed. The heater may further include an operating indicator that may illuminate when the microswitch is depressed. The heater may further include a thermocouple for monitoring the temperature of the heating portion. The heater may also further

include a thermal cutoff, to cease operation of the heater if it exceeds normal operating temperatures in case of a control module failure. For example, if the control module fails, the heater may continue to heat up, thereby potentially heating up the nutritional fluid excessively. The hot nutritional fluid may burn the preterm infant.

- 5 The thermal cutoff shuts off electrical power to the heater when the heater is too hot.

The control module may include a display capable of presenting information about the heater's operation. The control module may be in electrical communication with the heater through a control cable, or the control module may be integrated directly into the heater.

- 10 The tube may be configured as a serpentine shaped feeding tube module. In this embodiment, the serpentine shaped feeding tube module includes a serpentine configured tube portion complementarily shaped to the pattern of the serpentine groove formed in the heater, and further includes a proximal connector on one end and a distal connector on the opposite end. The proximal connector may be fluidly
15 connectable to a nutritional liquid source and the distal connector may be fluidly connectable to a feeding tube positioned in fluid communication with a stomach of the neonate.

- In another aspect, a heating system for heating neonate nutritional liquid is also disclosed, wherein the system includes a heater and a control module. In this
20 embodiment, the heater includes a heating portion having a serpentine shaped groove for receiving a feeding tube cassette. The control module may be directly integrated into the heater. In this embodiment, a feeding tube cassette has a serpentine tube portion configured to match the pattern of the serpentine groove formed in the heater, which is located between a proximal connector and a distal connector. A polymeric
25 sheet is rigidly attached to and covers the serpentine tube portion. The serpentine feeding tube cassette may further include a thermocouple located between the serpentine tube portion and the distal connector. The thermocouple may be configured to measure the temperature of the warmed nutritional liquid as it exits the cassette. The thermocouple may be in electric communication with the control module.

- 30 In another aspect, a system for providing warm nutritional liquid to a neonate is disclosed. The system includes a neonate nutritional liquid source, a feeding tube in fluid connection with the nutritional liquid source and a stomach of the neonate, and a heater mounted about the feeding tube. The feeding tube includes a serpentine

configured feeding tube portion positioned closer to the neonate than the nutritional liquid source, and the heater is mounted about this serpentine shaped feeding tube portion. The serpentine feeding tube portion may be formed as a feeding tube module and the heater may include a heating portion having serpentine shaped groove located within a base of the heater for receiving the feeding tube module, and a heater cover. Alternatively, the serpentine shaped feeding tube portion may be a serpentine feeding tube cassette having a thermocouple and a polymeric sheet rigidly attached to the serpentine shaped feeding tube portion. In this embodiment, the heater may include a heating portion having serpentine shaped groove for receiving the serpentine feeding tube cassette.

BRIEF DESCRIPTION OF THE DRAWINGS

These and other features and advantages of the various embodiments disclosed herein will be better understood with respect to the following description and drawings, in which like numbers refer to like parts throughout, and in which:

Figure 1 is an illustration of a first embodiment of the heating system;

Figure 2 is a perspective view of the first embodiment of the heating system showing the heater opened with a serpentine shaped feeding tube module in place;

Figure 3 is a perspective view of Figure 8 with the serpentine shaped feeding tube module removed;

Figure 4 is an exploded perspective view of the heater shown in Figures 1-3;

Figure 5 is an illustration of a second embodiment of the heating system showing a feeding tube cassette in place;

Figure 6 is a perspective view of Figure 11 with the feeding tube cassette removed;

Figure 7 is a top view of the heater shown in Figure 5;

Figure 8 is a side view of the feeding tube cassette;

Figure 9 is a cross-sectional view of the feeding tube cassette of Figure 8;

Figure 10 is a cross-sectional view of a thermocouple of the feeding tube cassette; and

Figure 11 is a bottom view of the feeding tube cassette.

DETAILED DESCRIPTION

Referring now to the drawings, an in line nutritional fluid heater 22, 104 is shown. A tube 30, 120 runs from a storage container 20 containing nutritional liquid for a preterm infant to a feeding tube that is disposed within a stomach of the preterm infant. The nutritional liquid is forced through the heater 22, 104 with a pump, gravity or other mechanism to warm-up the nutritional liquid flowing through the tube 30, 120 to a temperature above room temperature and preferably to about the body temperature of a person (i.e., between about 95°F and about 99°F). The other end of the tube 30, 120 is connected to a feeding tube which is disposed within the preterm infant's stomach to deliver the nutritional liquid to the preterm infant directly into his/her stomach. Feeding warm nutritional liquid to the neonate facilitates digestion of the nutritional liquid and preserves the neonate's energy for healing and growing instead of diverting such energy to warming up cold nutritional liquid.

In order to facilitate quick setup of the tube 30, 120 through the heater 22, 104, the tube 30, 120 may define a cartridge portion 28, 118 that is preformed to correspond to an internal cavity 74, 132 of the heater 22, 104. By way of example and not limitation, the cartridge portion 28, 118 of the tube 30, 120 may have a serpentine configuration. The internal cavity 74, 132 of the heater 22, 104 may also have a groove 34, 122 corresponding to the serpentine configuration of the cartridge portion 28, 118 of the tube 30, 120. To insert the cartridge portion 28, 118 of the tube 30, 120 into the heater 22, 104, the medical professional opens up the heater 22, 104 to expose the groove 34, 122. Since the preformed cartridge portion 28, 118 remains in the serpentine configuration, the user need only drop the serpentine configured cartridge portion 28, 118 of the tube 30, 120 into the serpentine configured groove 34, 122 of the heater 22, 104. To further retain the serpentine configuration or any other desired configuration of the cartridge portion 28, 118 of the tube 30, 120, a sheet may be attached to one side of the serpentine configured cartridge portion 28, 118 of the tube 30, 120.

Referring now to Figures 1-4, a heating system 20 is shown. The system 20 includes a heater 22 and a control module 24. As shown in Figures 2 and 3, the system 20 also includes a feeding tube module 26 having a serpentine shaped feeding tube capable of being inserted into the heater 22. In particular, a cartridge portion 28 of a tube 30 of the feeding tube module 26 may be disposed proximal to a heating

portion 28 of the heater 22. More particularly, the heating portion 32 may feature a corresponding serpentine shaped groove 30, into which the cartridge portion 28 of the feeding tube module 26 is inserted. While Figures 2 and 3 show the cartridge portion 28 of the tube 30 as having two curve portions, thus creating a path with three straight portions within the heating portion 28, it is contemplated that this is just one example and various shapes and flow paths may be envisioned for use. The benefit of using a serpentine shape for the cartridge portion 28 is that the nutritional liquid spends an extended period of time within the heating portion 32, in comparison to a straight path. By extending the period of time within the heating portion 32, the nutritional liquid may be heated using an overall lower temperature, thereby preventing heat degradation of the nutritional liquid from extreme temperatures, while also maintaining the ability of allowing the nutritional liquid to reach body temperature. As such, the use of the terms “serpentine” or “serpentine shaped” is intended to encompass configurations that extend the flow path of the feeding tube within the heating portion 32. For example, additional configurations that could be utilized are Z-shaped configurations, zigzag configurations, and other configurations (e.g., U shaped, L shaped) that extend the length of the flow path of the tube within the heating portion 32.

The cartridge portion 28 of the tube 30 of the feeding tube module 26 is formed to correspond in shape and design to the serpentine shaped groove 34 formed in the heating portion 32 of the heater 22, so that the cartridge portion 28 of the tube 30 of the feeding tube module 26 may be quickly and easily placed directly into, and registered within, the groove 34. The cartridge portion 28 is formed in that it retains its shape even though no external forces are imposed on the cartridge portion 28 of the tube 30. The cartridge portion 28 is preformed into a particular bent shape such as a serpentine shape, L shape, U shape, zig zag shape. Additionally, the feeding tube module 26 has a proximal connector 36 on one end and a distal connector 38 on the opposite end. The proximal connector 36 may be attachable to a source of nutritional liquid, while the distal connector 38 may be attachable to a feeding tube 40 placed within the patient (i.e., preterm infant). The feeding tube module 26 may be formed of any suitable material or polymer that is both medical grade and that will retain the serpentine shape during use and under heat.

As seen in Figure 1, the heater 22 is electrically connected with the control module 24 via a control cable 42. Additionally, the heater 22 may include an operating indicator 44 or heater active signal which may be a light that illuminates when the heater cover 46 is closed and the heater 22 is operational. The operating indicator 44 may be enabled by the closing of a microswitch 48. In particular, the microswitch 48 may be positioned within the heater 22 in such a fashion that it 48 is depressed by the closing of the heater cover 46, such that the operating indicator 44 will not illuminate and the heater heating portion 32 will not begin heating unless the heater cover 46 is in a fully closed position. When the cover 46 is in the opened position, the switch 48 is not depressed and the operating indicator is not illuminated. This prevents raising the temperature of the heating portion 32 while the cover 46 is in an open position, thereby reducing the possibility of burn injuries by users of the heater 22 and allows users to visually confirm the heater 22 is operating by viewing the illuminated operating indicator 44.

Referring now to Figure 4, an exploded view of the heater 22 is shown. As can be seen, the heater cover 46 may be rotatably attached to a heater case 50 by way of a cam mount 52. In particular, the heater case 50 may cover the majority of internal components of the heater 22, and also features the serpentine shaped groove 34 into which the cartridge portion 28 of the tube 30 of the feeding tube module 104 is inserted during use. The cam mount 52 may have a rotating portion so that the heater cover 46 may be lifted and lowered in relation to the heater case 50 during use. Furthermore, the microswitch 48 may be disposed within the cam mount 52, so that when the heater cover 46 is lifted, operation of the heater 22 ceases as the cover 46 is no longer in contact with the microswitch 48. Conversely, as the heater cover 46 is lowered into position for use, it may depress the microswitch 48 thereby activating the heater 22 and the operating indicator 44. Additionally, the heater 22 may include an illumination source 54, for example a light emitting diode (LED), positioned below the operating indicator 54, such that when the heater cover 46 is closed and the heater 22 is operational, the illumination source 54 is illuminated to visually indicate the operation of the device. The cam mount 52 may further include a cable connector 56, such that the control cable 42 connects to the control module 24 on one end and the heater 22 on the other end by way of the cam mount 52 and cable connector 56.

The heater 22 further includes a heater base 58 located in a lowermost position that contains the majority of the internal heater components. It is envisioned that the heater cover 46, heater case 50, and heater base 58 may be fabricated out of suitable polymer plastic material, but may be made of metal or other materials. Located within, and directly attached to, the heater base 58 may be a heater clamp 60 to which is attached a heating unit 62. The heater 22 may further include a thermocouple 64 located proximally to the heating unit 62. The heating unit 62 and thermocouple 64 may be in electrical communication with the control module 24, such that when the heater 22 is activated the heating unit 62 receives power and increases the temperature of the heating portion 32 and the thermocouple 64 monitors the temperature of the heating portion 32 and conveys that information to the control module 24. The heater 22 may further include a thermal cutoff 66 in electrical communication with the heating unit 62. When the thermal cutoff 66 reaches a set temperature or a preset upper limit above normal operating conditions of the heater 22, the thermal cutoff 66 will trip, thereby eliminating the flow of power to the heating unit 62 and preventing an unsafe temperature during operation. The thermal cutoff 66 blocks electricity to the heating unit when the measured temperature exceeds normal operating conditions. Alternatively, the thermal cutoff may send a signal to the control module to shut off the heating unit. This is important to prevent burn injury to a preterm infant if the system malfunctions. While not shown in Figure 4, it is contemplated that the electrical components described herein are connected in electronic communication with each other as would be readily understood and achieved by a person of ordinary skill in the art.

While the heating unit 62 may take a substantially flat configuration, there may be attached to it a heat sink 68 into which the feeding tube module 26 is actually inserted. As such, the heat sink 68 may be formed to include a complementary shaped serpentine groove pattern to readily accept and register the cartridge portion 28 of the tube 30 of the feeding tube module 26. The heat sink 68 may be attached to the heating unit 62 by a polyimide tape 70. To avoid excess heat escape, the heat sink 68 may be surrounded by a heat sink O-ring 72, or other type of gasket, that seals any gap between the heat sink 68 and the heater case 50. As can be seen, the serpentine shape of the groove 34 of the heat sink 68 fits and registers within an internal cavity 74 of the heater case 50 to allow for insertion of the cartridge portion 28 of the tube

30 of the feeding tube module 26. Additionally, to prevent heat loss between the serpentine portions of the heat sink 68, inserts 76 may be inserted into the open spaces of the heat sink 68. Further, a case O-ring 78, or other type of gasket, may be positioned between the heater base 58 and the heater case 50 to prevent heat escape
5 from the heater 22 and to prevent the entry of liquids from potential spills on the heater 22.

Referring now to Figures 5-7, a second embodiment of the heating system 100 is shown. As can be seen in Figure 5, the system 100 is substantially similar to that discussed above, with the exception that the control module 102 is integrated directly
10 into the heater 104. This eliminates the need for a standalone control module 24, and allows for the input and monitoring of information to occur directly at the heater 104 by way of an integrated display 106, rather than on a separate control module 24 connected by an electronic cable 42.

As is illustrated in Figures 8-11, it is contemplated that in place of the
15 serpentine feeding tube module 104, as discussed above, one may use a serpentine feeding tube cassette 108 that may include an inline thermocouple 110 (inline temperature sensor) to directly monitor the temperature of the nutritional fluid as it exits the heater 104 of the system 100. In particular, the inline thermocouple 110 may have a body 130 with a flow path 132 as show by the arrows and dash lines in Figure
20 11. The body 130 receives an end of an elongate tube 120a and an end of elongate body 120b on which a distal connector 114 is connected to. The elongate bodies 120a, b form the tube 120 which is connected to the feeding tube. Each of the tubes 120a and b has a central lumen to allow the nutritional liquid to flow therethrough. A thermocouple 134 directly senses the temperature of the nutritional fluid, and not the
25 temperature of the exterior surface of the tube 120. The cassette 108 may include a proximal connector 112 on the entry side of the cassette 108. As discussed, the distal connector 114 is connected at the opposite end of the cassette 108. The proximal connector 112 may be attachable to a source of nutritional liquid, while the distal connector 114 may be attachable to the feeding tube 116 placed within the patient.
30 Adjacent to the proximal connector 112 is a cartridge portion 118 having a serpentine configuration, while adjacent to the distal connector 114 is the thermocouple 110. As such, it can be seen that upon entry of the cassette 108, and more particularly, the cartridge portion 118 and the inline thermocouple 110 into the heater 90 of the system

100, the nutritional liquid is heated as it moves through the cartridge portion 118 of the tube 120. The tube 120 of the cassette 108 may have a serpentine configuration which may be placed within the serpentine shaped groove 122 of the heater 60, and then the temperature of the nutritional liquid is monitored by the thermocouple 110 as it exits the cartridge portion 118 of the tube 120 of the cassette 204. The thermocouple 110 may be in electrical communication with the control module 102 to monitor the temperature. The tube 120 of the cartridge portion 118 of the cassette 108 may have a serpentine configuration but other configurations are also contemplated as discussed above. By way of example and not limitation, the tube 120 of the cartridge portion 118 of the cassette 108 may more broadly have a bent configuration such as a zig zag configuration, L shaped configuration, U shaped configuration, Z shaped configuration and other configurations as well.

The tube 120 of the cartridge portion 118 may also be preformed into a particular shape such as a serpentine shape as discussed in relation to the serpentine configuration of the cartridge portion 28 of the tube 30. However, the cartridge portion 118 of the tube 120 of the cassette 204 differs from the cartridge portion 28 of the serpentine feeding tube module 26, described above, in that it 118 further includes a polymeric sheet 124 which may act as a backing member attached to the upper portion of the cartridge portion 118 of the tube 120 of the cassette 108. This sheet 124 operates to serve multiple functions. In particular, the sheet 124 maintains the serpentine configuration of the tube 120 at the cartridge portion 118 rigidly in place to aid in the insertion of the serpentine shaped tube 120 of the cartridge portion 118 of the cassette 108 into the heater serpentine groove 122. The sheet 124 may be bendable but preferably is not stretchable so that the shape of the cartridge portion 118 is retained. Additionally, the sheet 124 aids in retaining heat within the cartridge portion 118 of the tube 120 by creating a physical barrier to prevent heat loss. In this regard, the sheet 124 may be fabricated from a material classified as an insulator. It is envisioned that both the feeding tube module 26 and the cassette 108 may be manufactured as disposable pieces, such that they are used for one feeding and then disposed of, rather than cleaned between uses of the heater.

Referring now to Figure 9, the sheet 116 may be a molded sheet that fits the contours of the tube 118. The bottom surface of the sheet 116 may fit the contour of the upper surface of the tube 118.

The above mentioned features of the preferred embodiments and variants described herein and in the claims may be combined with each other thereby forming additional preferred embodiments.

The above description is given by way of example, and not limitation. Given
5 the above disclosure, one skilled in the art could devise variations that are within the scope and spirit of the invention disclosed herein, including various ways of flow nutritional fluid through the tube 30, 120. Further, the various features of the embodiments disclosed herein can be used alone, or in varying combinations with each other and are not intended to be limited to the specific combination described
10 herein. Thus, the scope of the claims is not to be limited by the illustrated embodiments.

WHAT IS CLAIMED IS:

1. A system for heating neonate nutritional liquid so that a temperature of the nutritional liquid approximates a standard body temperature of a person during feeding, the system comprising:

5 a container for storage of the neonate nutritional liquid during feeding;
a tube defining first and second ends and a cartridge portion between the first and second ends, the first end of the tube connectable to the container and the second end disposable within a stomach of the neonate or connectable to a feeding tube for routing the neonate nutritional liquid from the container to the neonate during feeding, the cartridge portion of the tube being preformed into a bent configuration;

10 a heater having a heating unit and a heat sink defining an internal cavity of the heater wherein the internal cavity is sized and configured to receive the bent cartridge portion of the tube for heating the neonate nutritional liquid as the neonate nutritional liquid flows from the container to the neonate during feeding.

2. The system of Claim 1 wherein the cartridge portion of the tube has a zig zag configuration, Z shaped configuration, L shaped configuration, U shaped configuration or combinations thereof.

3. The system of Claim 2 wherein the zig zag configuration of the cartridge portion of the tube has a serpentine configuration.

4. The system of Claim 1 further comprising a backing member with a first side of the cartridge portion of the tube attached to the backing member for rigidly fixing the bent configuration of the cartridge portion to facilitate insertion of the cartridge portion of the tube into the internal cavity of the heater, and the internal cavity of the heat sink having a groove with a corresponding bent configuration compared to the bent cartridge portion of the tube so that the cartridge portion of the tube is easily insertable into the groove of the heat sink.

5. The system of Claim 4 wherein the cartridge portion of the tube is disposable between the rigid backing and the heating unit so that the rigid backing aids in retaining heat within the cartridge portion.

6. The system of Claim 4 wherein the rigid backing is a polymeric sheet or an insulation material.

7. The system of Claim 1 further comprising a temperature sensor connected to the heating unit for sensing a temperature of the heating unit and sending
5 a signal to a control module to cut off power to the heating unit when the temperature of the heating unit exceeds a preset upper limit.

8. The system of Claim 1 wherein the heater has a heater base and a cover, the cover being traversable between a closed position and an opened position, the system further comprising a switch disposed adjacent to the cover so that in the
10 closed position, the switch is depressed and operative to turn on a heater active signal, and in the opened position, the switch is released and operative to turn off the heater active signal.

9. The system of Claim 8 wherein the heater active signal is a light.

10. A tube for use in a system for heating neonate nutritional liquid so that
15 a temperature of the nutritional liquid approximates a standard body temperature of a person during feeding, the tube comprising:

an elongate body having a central lumen, the elongate body defining first and second ends and a cartridge portion between the first and second ends, the first end of the elongate body connectable to a container with the
20 neonate nutritional liquid therein and the second end of the elongate body disposable within a stomach of the neonate or connectable to a feeding tube for routing the neonate nutritional liquid from the container to the neonate during feeding, the cartridge portion of the elongate body being preformed into a bent configuration and disposable in an internal cavity of a heater.

25 11. The tube of Claim 10 further comprising a sheet with a first side of the bent cartridge portion of the elongate body being attached to the sheet for rigidly fixing the bent configuration of the cartridge portion.

12. The tube of Claim 10 wherein the cartridge portion is recessed within a groove formed on a side of the sheet.

30 13. The tube of Claim 10 further comprises a temperature sensor attached to the elongate body downstream of the cartridge portion for reading a temperature of the neonate nutritional liquid after exiting the heater.

14. The tube of Claim 10 wherein the elongate body comprises first and second elongate bodies, each of the first and second elongate bodies having first and second central lumens, and the tube further comprises an inline temperature sensor, the inline temperature sensor comprising:

5 a body defining a flow path, the first and second elongate bodies attached to the body in line with the flow path, a thermocouple attached to the body for directly measuring a temperature of the nutritional liquid after the nutritional liquid exits a heater of the system.

15 15. A system for heating neonate nutritional liquid so that a temperature of the nutritional liquid approximates a standard body temperature of a person during feeding, the system comprising:

 a container for storage of the neonate nutritional liquid during feeding;

 a tube defining a first end, a second end and a cassette, the first end of the tube being connectable to the container and the second end disposed within
15 a stomach of the neonate or connectable to a feeding tube for routing the neonate nutritional liquid from the container to the neonate during feeding, the cassette comprising a portion of the tube between the first and second ends having a preformed bent configuration and a backing member to retain the preformed bent configuration during manipulation of the cassette by a medical
20 professional;

 a heater having a heating unit and a heat sink defining an internal cavity of the heater wherein the internal cavity is sized and configured to receive the cassette of the tube for heating the neonate nutritional liquid as the neonate nutritional liquid flows from the container to the neonate during
25 feeding.

16. The system of Claim 15 wherein the internal cavity is a groove having a corresponding configuration to the preformed bent configuration of the cassette of the tube.

17. The system of Claim 15 wherein the backing member is a polymeric
30 material.

18. A system for heating neonate nutritional liquid so that a temperature of the nutritional liquid approximates a standard body temperature of a person during feeding, the system comprising:

a container for storage of the neonate nutritional liquid during feeding;

a tube defining a first end, a second end and a cassette, the first end of the tube being connectable to the container and the second end disposed within a stomach of the neonate or connectable to a feeding tube for routing the neonate nutritional liquid from the container to the neonate during feeding, the cassette comprising a portion of the tube between the first and second ends having a preformed bent configuration and a backing member attached to one side of the portion of the tube;

a heater having a heating unit and a heat sink defining an internal cavity of the heater wherein the internal cavity is sized and configured to receive the portion of the tube having the pre bent configuration for heating the neonate nutritional liquid as the neonate nutritional liquid flows from the container to the neonate during feeding and the back member retains the heat from the heating unit in the portion of the tube having the pre bent configuration.

19. A system for heating neonate nutritional liquid so that a temperature of the nutritional liquid approximates a standard body temperature of a person during feeding, the system comprising:

a heater having a heating unit for generating heat and a heat sink disposed adjacent to the heating unit, the heat sink having an internal cavity for receiving a tube with the neonate nutritional liquid flowing therethrough during feeding for raising the temperature of the neonate nutritional liquid;

a control module connected to the heater with a control cable, the control module operative to regulate the heating unit;

a thermal cutoff switch electrically connected to the heating unit, the thermal cutoff switch monitors a temperature of the heating unit and shuts off power to the heating unit when the temperature of the heating unit exceeds a preset upper limit.

20. A system for heating neonate nutritional liquid so that a temperature of the nutritional liquid approximates a standard body temperature of a person during feeding, the system comprising:

a container for storage of the neonate nutritional liquid during feeding;

5 a tube defining first and second ends, the first end of the tube connectable to the container and the second end disposable within a stomach of the neonate or connectable to a feeding tube for routing the neonate nutritional liquid from the container to the neonate during feeding, the tube defining a cartridge portion;

10 a heater having a heating unit and a heat sink defining an internal cavity of the heater wherein the internal cavity is sized and configured to receive the cartridge portion of the tube for heating the neonate nutritional liquid as the neonate nutritional liquid flows from the container to the neonate during feeding;

an inline thermocouple carried by the tube downstream of the heating unit, the tube further having first and second elongate bodies, each of the first and second elongate bodies having first and second central lumens, the inline thermocouple comprising:

15 a temperature sensor:

a body defining a flow path, the first and second elongate bodies attached to the body in line with the flow path, the temperature sensor attached to the body for directly measuring a temperature of the nutritional liquid.

21. The system of Claim 19 wherein the heater has a second cavity for
20 receiving the inline thermocouple.

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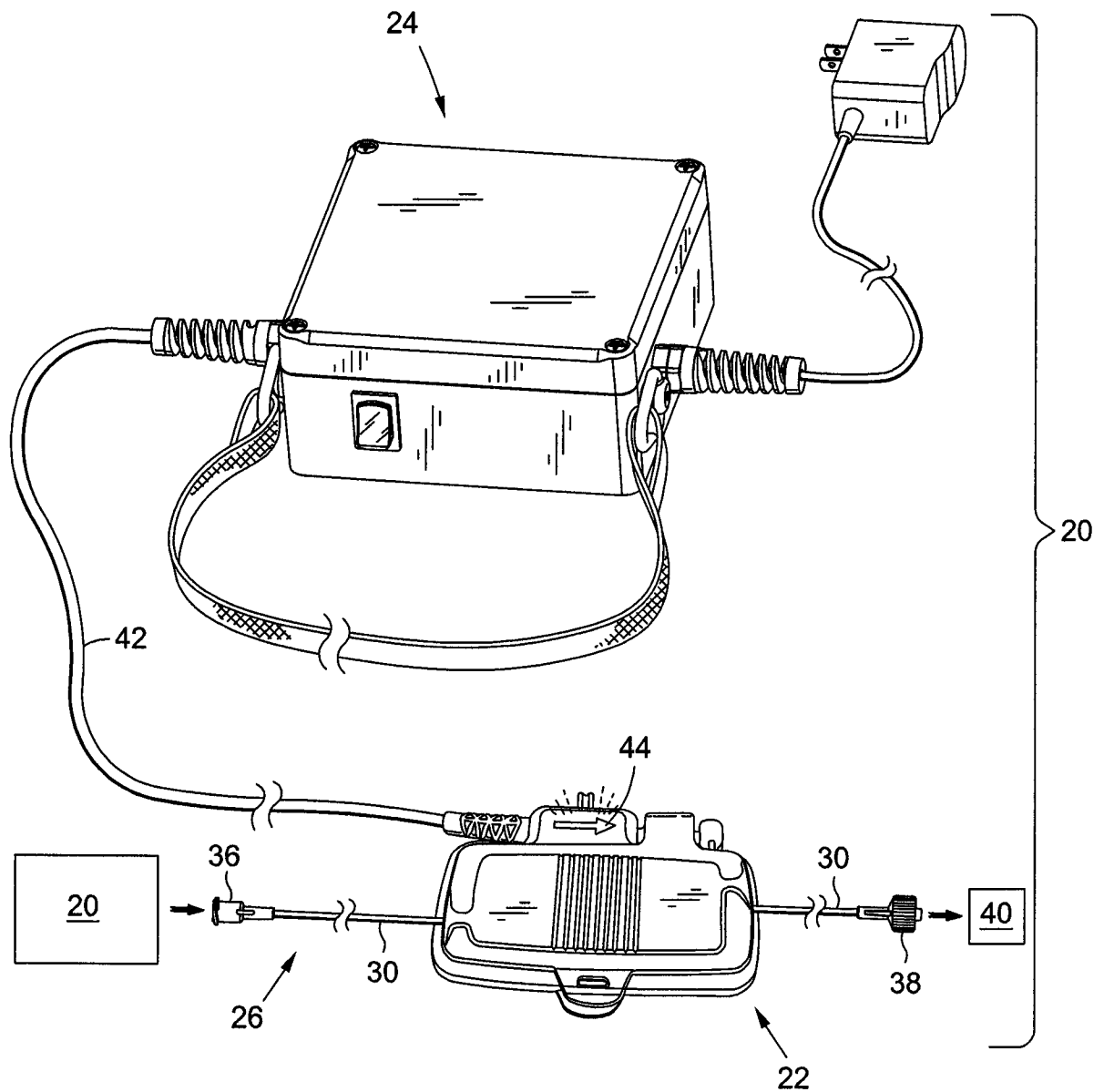


FIG. 1

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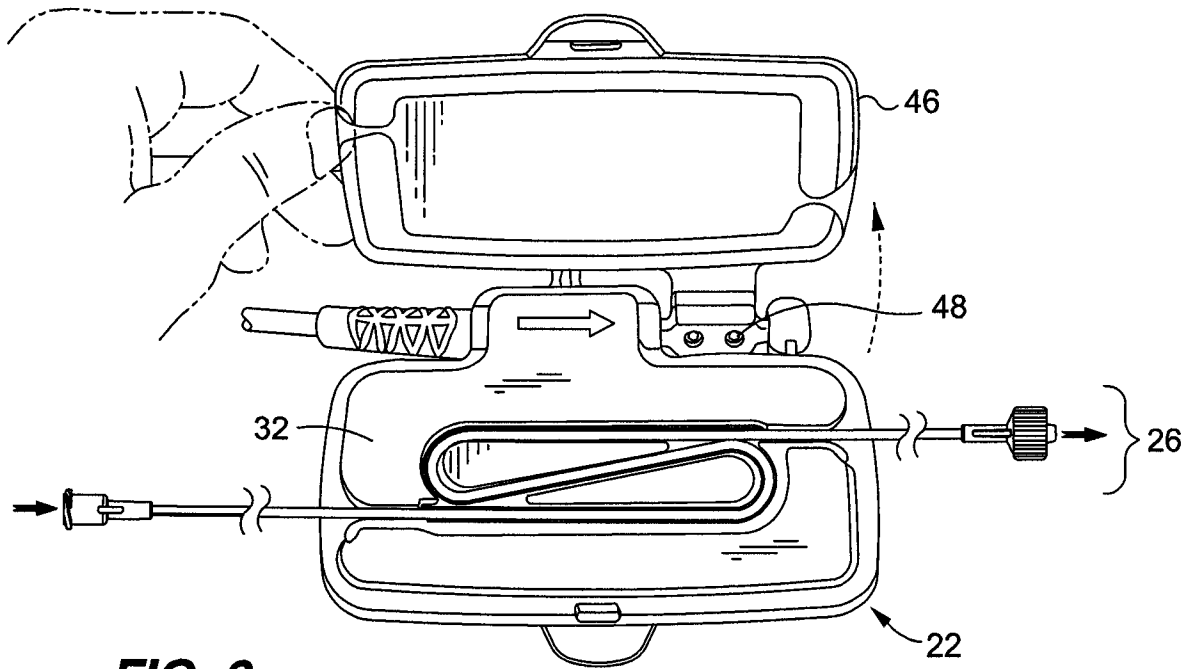


FIG. 2

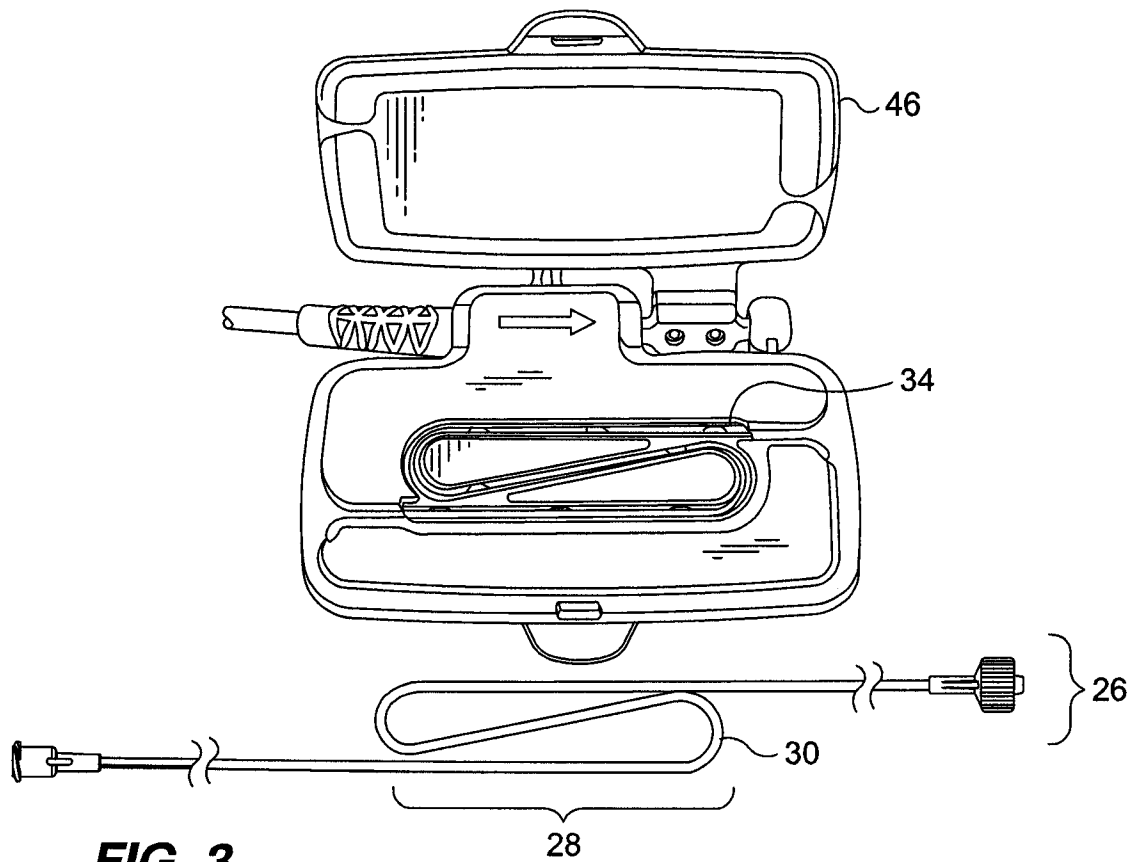


FIG. 3

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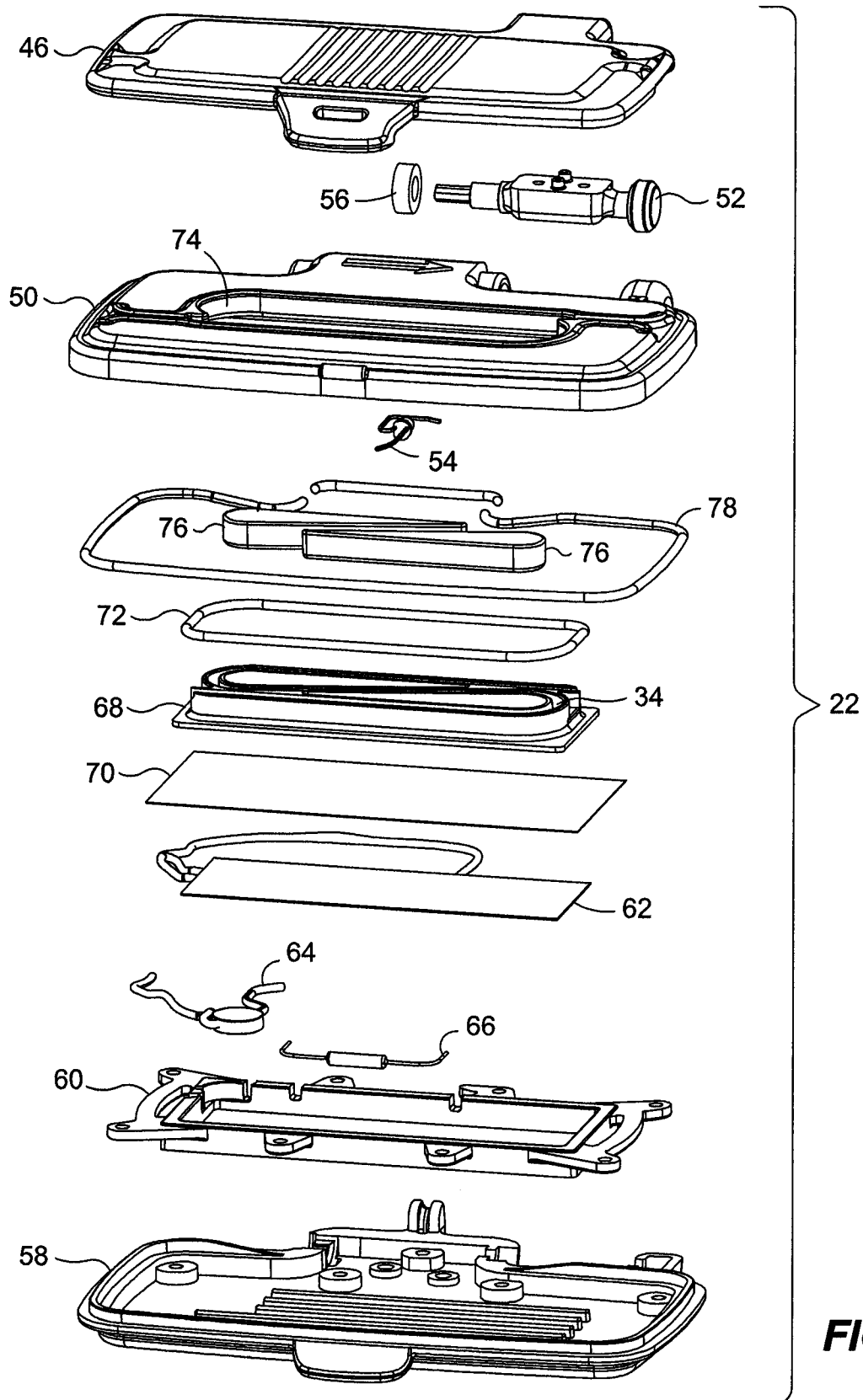
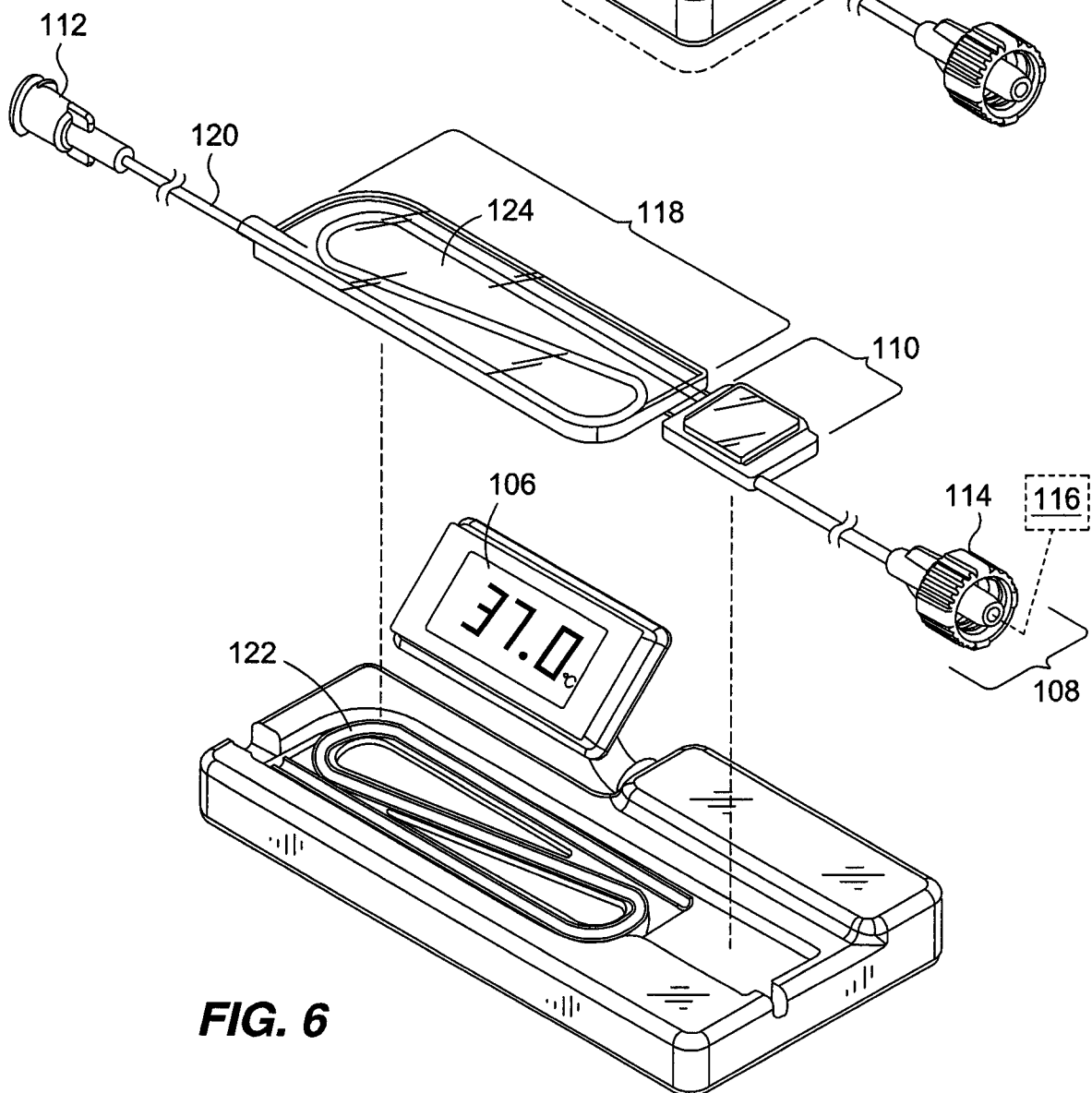
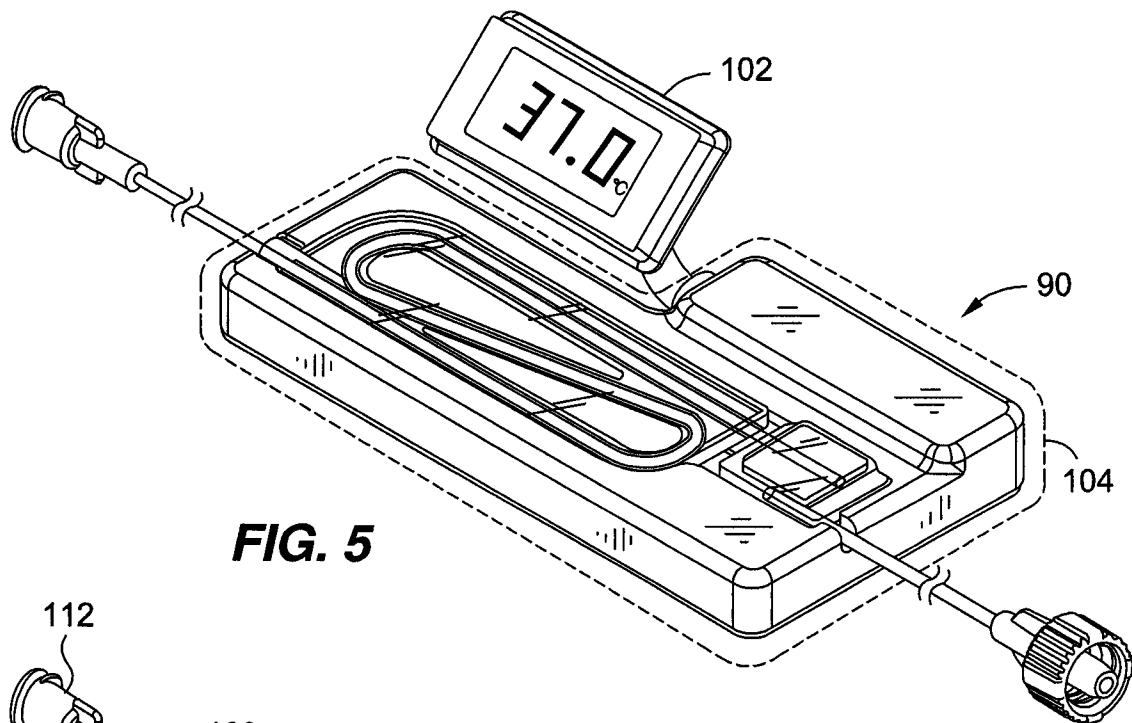


FIG. 4

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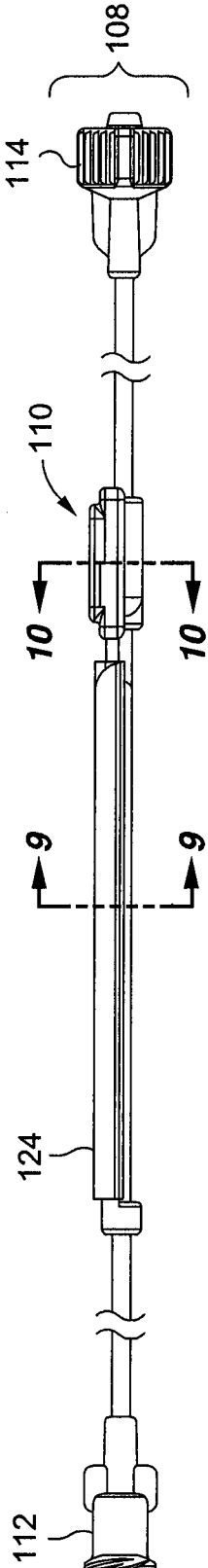
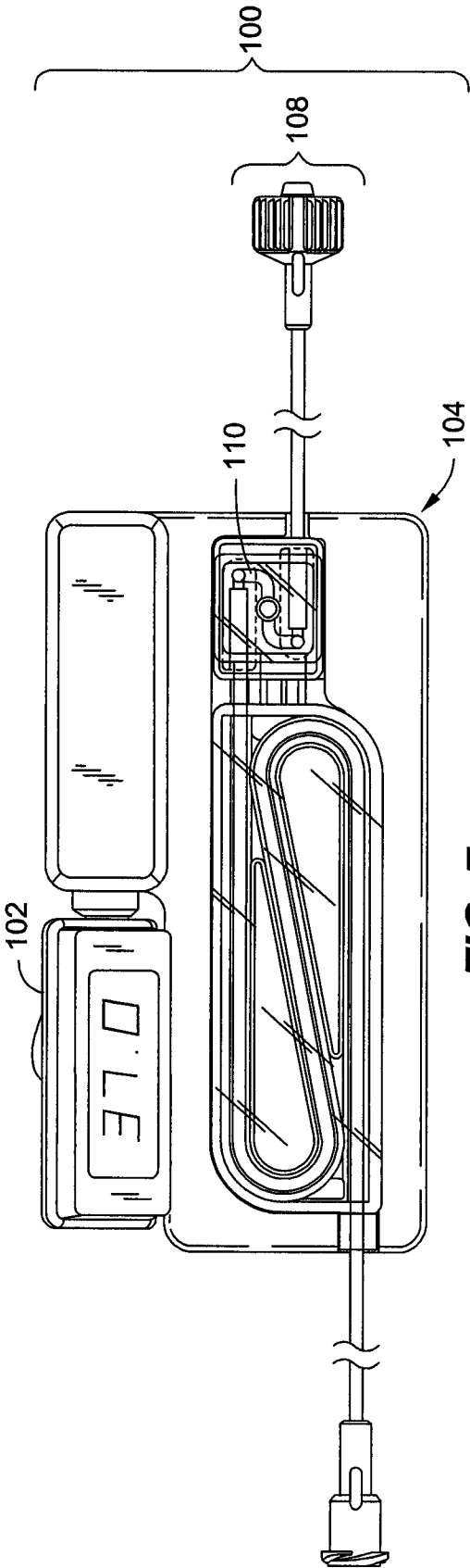


FIG. 10

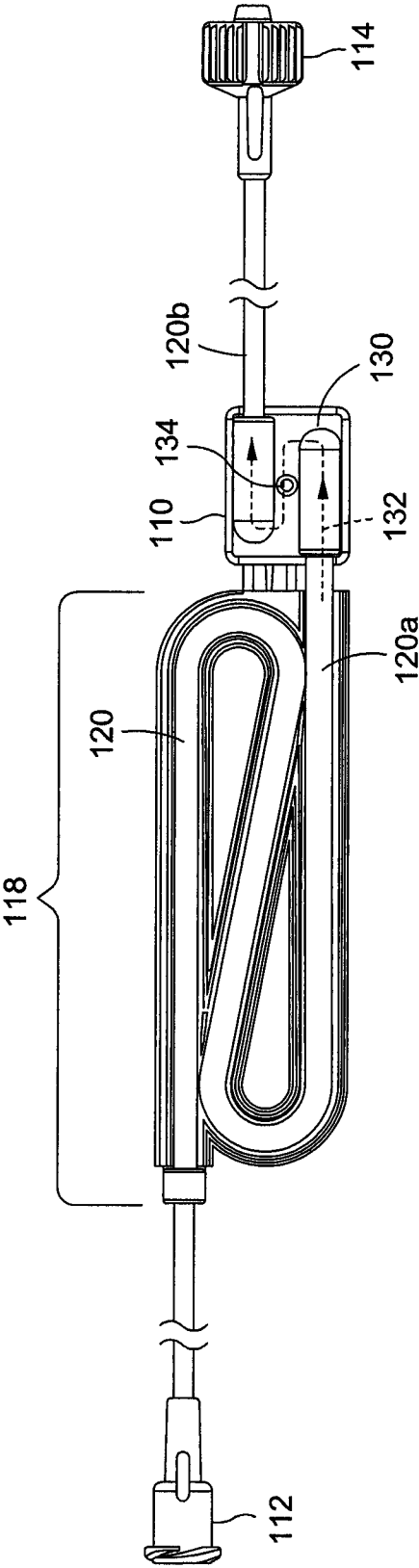


FIG. 11

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2014/048079

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61M 5/44 (2014.01)

CPC - A61M 5/445 (2014.10)

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC(8) - A61F 7/00, 7/12; A61J 15/00; A61M 5/00, 5/44 (2014.01)

CPC - A61J 15/00, 15/0026, 2015/0076, 2015/008, 2015/0084, 2015/008; A61M 5/00, 5/44, 5/445, 2240/00 (2014.10)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

USPC - 604/19, 48, 93.01, 113

(keyword limited)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

Orbit, Google Patents, Google, ProQuest Dialog, YouTube

Search terms used: heating, neonatal liquid, bent, tubing, backing

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2012/0271271 A1 (HYUN et al) 25 October 2012 (25.10.2012) entire document	19
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Y		1-3, 7-10
Y	CN 201139844 Y (JINGCHUN) 29 October 2008 (29.10.2008) see machine translation	1-3, 7-10
A	US 2005/0008354 A1 (CASSIDY) 13 January 2005 (13.01.2005) entire document	1-21
A	US 2008/0262409 A1 (DERRICO et al) 23 October 2008 (23.10.2008) entire document	1-21
A	CN 201814947 U (HONG et al) 04 May 2011 (04.05.2011) entire document	1-21

☐ Further documents are listed in the continuation of Box C.


* Special categories of cited documents:

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

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

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

31 October 2014

Date of mailing of the international search report

18 NOV 2014

Name and mailing address of the ISA/US

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