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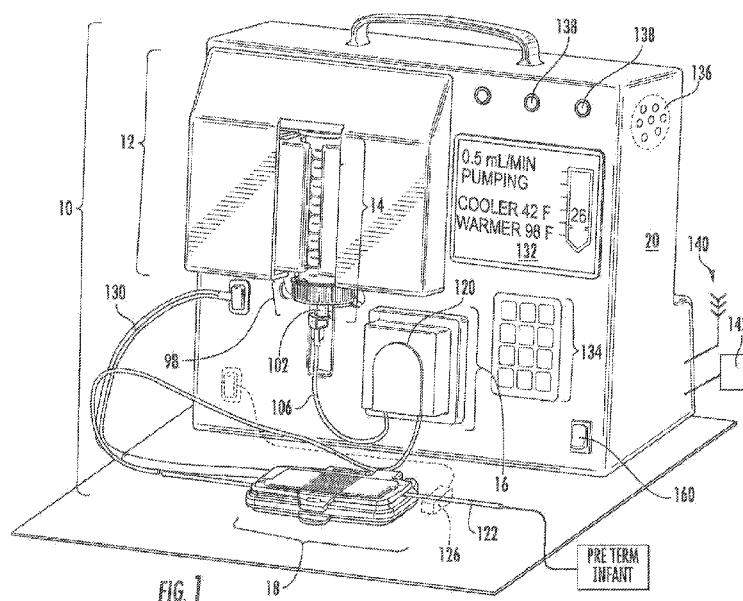
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(54) Title: NEONATAL ENTERAL FEEDING SYSTEM



(57) **Abstract:** A neonatal enteral feeding system for delivering neonate fluid is disclosed. The system includes a cooling unit for cooling the breast milk before, during and after a feeding cycle to mitigate unwanted bacterial growth and reduction of fat content in the breast milk. The system also includes a warming unit for heating the cold breast milk to a temperature above room temperature (preferably, standard body temperature) so that the neonate can focus his or her energy on healing, growth and digestion instead of heat generation. Additionally, the system has a peristaltic pump which draws the breast milk from a bottom side of the container and the container is vented so as to be capable of delivering all of the breast milk in the container to the neonate.

NEONATAL ENTERAL FEEDING SYSTEM

CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims the benefit of United States Provisional Patent
5 Application Serial No. 62/032,392, filed August 1, 2014, which is wholly
incorporated by reference in its entirety herein.

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BACKGROUND

The embodiments disclosed herein relate to systems and methods for feeding a
preterm infant or neonate. More particularly, the disclosed systems and methods relate
to improvements in maintaining the fat content and nutritional level of breast milk
15 used in feeding preterm infants. Also, the disclosed systems and methods relate to
delivery of all of the nutritional fluid (e.g., breast milk or formula) without delivery of
air to the preterm infant/neonate.

Nutritional delivery to a preterm infant or enteral feeding is an important part
of caring for the preterm infant in neonatal intensive care units. Typically, the preterm
20 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). When breast milk is
used as the nutritional fluid, it is typically obtained from the mother, or a donor, via a
conventional breast pump and stored within a container. The container is then
25 typically placed in a refrigerator or freezer for storage. Subsequently, when it is
desired to feed the neonate, the breast milk is typically transferred from the container
into a syringe for use in a conventional syringe pump, or alternatively, placed in a
gravity feeding container and subsequently delivered to the neonate via the feeding
tube. It has been reported, however, that the fat percentage of breast milk may be
30 reduced every time it is transferred from one container to another. Further, it has been
suggested that the fat content in milk may be higher in refrigerated milk than in non-
refrigerated milk. In addition, it is known that bacteria may grow more rapidly in non-
refrigerated milk compared to refrigerated milk. Additionally, studies have shown that

preterm infants respond favorably when the nutritional liquid (e.g., breast milk or neonatal formula) is closer to standard body temperature (i.e., 98.6°F) when digested by the preterm infant. When the nutritional liquid is provided to the preterm infant closer to standard body temperature, 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 healing and growth to generate heat.

Prior art devices for feeding preterm infants have been introduced into the marketplace. However, these devices typically do not address the refrigeration and/or heating aspects desirable for the storage of breast milk and its preferred use as a nutritional fluid at body temperature. Further, other prior art devices have been introduced for warming nutritional liquid (e.g., breast milk or neonate formula) provided to pre-term infants. For example, U.S. Patent No. 8,663,161 and U.S. Patent Application No. 14/222,832 (the entireties of which are herein incorporated by reference) disclose devices for heating nutritional fluids for use in feeding preterm infants.

Accordingly, there is a need in the art for improved methods and systems for feeding preterm infants in a manner that maximizes the fat content and nutritional aspect of breast milk, by keeping the breast milk refrigerated until administration to the infant, and by heating the breast milk to body temperature shortly before delivery to the infant.

BRIEF SUMMARY

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

A neonatal enteral feeding system is disclosed herein. The system uses a container with nutritional fluid (e.g., breast milk or neonatal formula) which is loaded into the system for dispensing the nutritional fluid to neonatal infant through oral or nasal feeding tubes. The container may be a standard breast milk container, or any other suitable container for retaining the breast milk during use. The system has a cooling unit for actively keeping the milk cold before, during and after a feeding

cycle. Additionally, the cooling unit of the system allows for a caregiver to insert the container with breast milk into the system at a time prior to beginning the feeding and programming the system to feed the preterm infant at a later time. This prevents feeding delays in the event that the medical professional cannot manually start a
5 feeding cycle at that particular time. During the interim period, the cooling unit keeps the breast milk refrigerated until feeding begins.

By way of example and not limitation, the system may include a delayed start timer, such that when the caregiver inserts the breast milk container into the system, the caregiver may select a desired start feed time. The cooling unit is turned on and
10 maintains the breast milk in the container in a refrigerated state at least until the feed time which is initiated without user intervention (i.e., automatically). Alternatively, the breast milk container may be kept cooled in the system with the cooling feature while waiting for the proper feeding time and feeding may be manually initiated at a later time by a medical professional (e.g., nurse). While it is envisioned that the milk
15 may be kept in the same container it is collected in, various other containers may be utilized in the system and are expressly contemplated herein. The system keeps the breast milk cold after removal from a refrigerator and throughout long-term feeding cycles, thereby reducing bacterial growth. The system then pumps the milk through tubing and preferably warms the milk to standard body temperature shortly before
20 being introduced into the neonate's stomach. It is envisioned that by reducing the loss of milk fat from transferring containers and uncooled milk, the present system allows for a more nutritious enteral feeding for distressed neonates and helps to focus the preterm infant's energy on growth and healing.

One embodiment of the present disclosure envisions a neonatal enteral feeding
25 system having a breast milk container, a cooling unit, a pump, a tube, and a warming unit. The cooling unit may be capable of receiving and cooling the breast milk container. However, it is also contemplated that the cooling unit may be alternatively configured. For example, the cooling unit may interface with or extend from a cap of the container to draw heat through the cap or provide cooling from the cap instead of
30 cooling the container. In this instance, the cap may receive the cooling unit such as a gel coolant. The tube may be in fluid connection with both the container and a stomach of the neonate. To deliver the breast milk to the neonate, the tube may be routed through the pump and the warming unit. The pump draws breast milk out of

the container. The warming unit provides warm milk to the preterm infant. The warming unit is preferably attached inline to the pump tubing proximal to the neonate and is capable of warming breast milk to a desired temperature before administration to the neonate.

5 As discussed, in one embodiment the container may optionally be a standard container capable of being used with a breast pump. It is envisioned that different container types may be utilized, for example, syringes, gravity feed bags or containers, and the like. Further, the container may utilize a removable cap with a venting mechanism to allow for the equalization of atmospheric pressure inside the
10 container so that a vacuum is not created within the container, and the entire volume of milk in the container may be fully dispensed. One embodiment of the venting mechanism includes a vent straw fitted with a hydrophobic filter. Various other venting mechanisms are contemplated herein including but not limited to the use of a valve in place of a hydrophobic filter, filter vents or valves located directly within the
15 cap, hydrophobic filters positioned between the container and the cap, filter vents or valves located directly within the container or between the container and the cap rather than the cap, and other venting mechanisms known within the art. The pump cap further may include a mating connector in fluid connection with the pump cap and the pump tubing to connect the pump tubing to the container.

20 The cooling unit can include one or more cooling modules, and may take various forms and be implemented in various configurations. For example, in one embodiment the cooling module may be made up of two separable cooling jackets (i.e., cold sinks) capable of surrounding the container. Other methods of cooling the breast milk container may be utilized, such as integrating a cooling element into the
25 container itself and/or the container cap. In an exemplary embodiment, each cooling jacket is part of a cooling module which may have a Peltier thermoelectric cooler disposed between the cold sink/cooling jacket and a heat sink. However, it is contemplated that various other conventional cooling systems may be utilized, for example, vapor-compression refrigeration, evaporative cooling, or cold gel packs.
30 Further, the cooling modules of the cooling unit may be traversable in relation to each other between opened and closed positions to allow for easy insertion, removal, and retention of the container within the cooling unit. In order to traverse the cooling modules, each cooling module may be attached to a common axle having two

different threads with different thread orientations. The common axle may be attached to an actuator, preferably a stepper motor. Alternatively, various method of adjusting the cooling jackets may be utilized, including manual methods (e.g., crank) and various manual slide and clamp mechanisms. At least one condensation air tube may
5 be used to blow air over the container and cooling jackets to prevent a buildup of condensation. Other moisture removal mechanisms are also contemplated such as a ring shaped sponge disposed around the container or cap.

The pump may take various forms, including a positive displacement pump such as a peristaltic pump. When a peristaltic pump is used, the pump tubing may
10 include a peristaltic section of tubing that is more compliant than the rest of the pump tubing, to allow for ease of use with the rollers of the pump. Furthermore, the pump may be physically attached to or contained within a body of the system. The system may further include an input device, such as a keypad, for example and a display. In certain embodiments, the input device and display may be combined as a unitary
15 touchscreen. Various aspects of the feeding cycle may be controlled by the input device, such as the rate of delivery, delayed start time of feeding, on and off cycles of feeding, and the like.

The system may further include a milk level monitoring device. For example, the milk level monitoring device may be a rotary encoder on the motor, a camera
20 vision system, an LED monitoring system, a laser monitoring system, or utilize other known liquid measuring techniques. The system may further include an agitation component, to mix or agitate the milk within the container to minimize fat loss. The agitation component may be, for example, a rotary-sealed propeller located in the lid of the breast milk container, a rotating magnetic device located in the pumping unit in
25 combination with embedded magnets placed within the container, an ultrasonic transducer, or utilize other known liquid agitating techniques.

Another embodiment of the present disclosure envisions methods of feeding a preterm infant/neonate. In one method, breast milk obtained from the mother of the neonate or from donor sources is cooled below body and/or room temperature in a
30 delivery container. The delivery container may be, but is not necessarily, a breast milk container. The cooled breast milk is pumped out of the delivery container and through a tube in fluid connection with the neonate's stomach. Within the tubing, the breast milk is heated prior to delivery of the breast milk to the neonate. The breast milk is

heated above room temperature, and in certain embodiments, is preferably heated to approximately the infant's body temperature.

In relation to the system described herein, the delivery container may be inserted into a cooling module capable of maintaining the breast milk at a temperature
5 below room temperature, wherein the container is fluidly connected to a feeding tube of the neonate via pump tubing. The pump tubing is routed through a pump and through a warming unit capable of warming the breast milk to a temperature above room temperature. The breast milk is then pumped into the feeding tube which is disposed in the neonate, thereby feeding the neonate.

10 The combination of components described herein allows for significantly improved feeding methods. For example, through the use of a peristaltic pump (or other positive displacement pumps) and the venting mechanism in the container and/or cap, it is possible to deliver the entirety of the breast milk in the system to the neonate without delivering excess air. In contrast to a syringe pump, the peristaltic
15 pump may continue to run after all of the breast milk has exited the container, thereby delivering the remaining breast milk contained within the tubing to the neonate. Also, a peristaltic pump provides a consistent flow rate of the nutritional liquid through the tubing. The venting mechanism allows for this continued feeding without the formation of a vacuum within the container. Additionally, by utilizing the milk level
20 monitoring device, it is possible to fully deliver the entirety of the breast milk to the neonate without delivering excessive amounts of air. In this respect, depending on the level monitoring device utilized, the system is capable of sensing when the container and/or tubing is empty, and in conjunction with the pumping unit's programming, the feeding cycle may be stopped at the appropriate time to prevent delivery of excess air
25 to the neonate. Further, the integrated cooling unit, or mechanism allows for breast milk to be stored directly in the system for prolonged periods of time with a reduced risk of bacterial growth or reduced nutritional content of the milk. For example, the cooling mechanism may allow for extended feeding times, which may be beneficial in certain cases. Additionally, the cooling mechanism allows for preset delayed feeding
30 times, wherein the milk container is inserted into the system prior to feeding at a later time by use of the delayed start timer. The various features discussed herein alone and in combination with each also facilitates the portability of the system.

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

5 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 a perspective view of a neonatal enteral feeding system;

10 Figure 2 is a front perspective view of internal components of the system shown in figure 1 with the case and other components removed for clarity;

Figure 3 is a rear perspective view of the internal components shown in Figure 2;

15 Figure 4 is a front perspective view of a cooling unit with first and second cooling modules in a closed position;

Figure 5 is a rear perspective view of the cooling unit shown in Figure 4 with the first and second cooling modules in an opened position;

Figure 6 is an exploded perspective view of a common breast milk collection container and a cap;

20 Figure 7 is an exploded perspective view of a common breast milk collection container and a cap with a venting mechanism and an output port for use with the system shown in Figure 1; and

Figure 8 is an exploded perspective view of one of the first and second cooling modules of the cooling unit.

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DETAILED DESCRIPTION

Referring now to the drawings, a system 10 for feeding a preterm infant breast milk is shown. The system 10 may comprise a cooling unit 12 for maintaining breast milk contained in a container 14 in a cold state before, during and after feeding of the preterm infant to mitigate bacteria growth and reduction of fat content in the breast milk. Additionally, the system 10 may include a peristaltic pump 16 which in conjunction with a venting mechanism of the container 14 allows the system 10 to dispense all of the breast milk contained in the container 14 without delivering

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excessive air to the preterm infant during feeding. Breast milk is the optimal food especially for preterm infants who may already be struggling for life. The system 10 helps to prevent waste of beneficial breast milk. The system 10 may also include a breast milk warming unit 18 for raising the temperature of the breast milk which is
5 kept in a cold state by the cooling unit 12 so that the preterm infant receives the breast milk at a standard body temperature to help focus the preterm infant's energy on healing and growth with the digestion of the warmed breast milk, not regulating his/her temperature due to consumption of cold breast milk.

Referring now to Figures 1, 2, 4, 5 and 8, the cooling unit 12 may be
10 incorporated into a body 20 of the system 10. The cooling unit 12 may have first and second modules 22, 24. The first and second modules 22, 24 may be traversed between a closed position as shown in Figure 4 and an opened position as shown in Figure 5. In the opened position, the container 14 may be inserted or removed from between cold sinks 26, 28 (or cooling jackets) of the first and second modules 22, 24.
15 In the closed position, the cold sinks 26, 28 may contact the exterior surface 56 of the container 14 to hold the container 14 in place between the first and second modules 22, 24 so as to serve as a holding mechanism. To remove the container 14 from the cooling unit 12, the first and second modules 22, 24 are traversed toward the opened position as shown in Figure 5 to release the container 14.

20 Referring to Figures 4 and 5, the first and second modules are traversable between the opened and closed positions with the use of a suitable device, such as, for example, a motor 30. Preferably, the motor 30 is a stepper motor so that the positions of the first and second modules 22, 24 may be determined by the amount of rotation of the output shaft 32 of the stepper motor 30. The stepper motor 30 may have a first
25 sprocket 34 which is connected to a second sprocket 36 with a timing belt 38. The second sprocket 36 is mounted to a common axle 40 having first and second threads 42, 44. The first and second threads 42, 44 may respectively be left-handed threads and right-handed threads or vice versa. Matching nuts 46, 48 may be threadably engaged to the first and second threads 42, 44. The matching nuts 46, 48 are fixedly
30 attached to the first and second modules 22, 24 of the cooling unit 12 with attachment fixtures 50, 52. When the stepper motor 30 rotates the output shaft 32 in a first direction about its longitudinal axis, the axle 40 is rotated which in turn traverses the first and second modules 22, 24 toward the closed position or the open position. To

traverse the first and second modules 22, 24 toward the open position or the closed position (i.e., opposite direction), the stepper motor reverses rotation of the output shaft 32.

In lieu of the motor 30, the common axle 40 may be rotated with a hand crank
5 that extends out of the body 20 of the system 10. In addition, other clamping/mounting devices are contemplated.

Referring now to Figure 8, one of the cooling modules 22, 24 of the cooling unit is shown. The other cooling module 22, 24 may be identical to the one shown in Figure 8 but oriented in the opposite direction, as shown in Figures 4 and 5. The
10 cooling module 22, 24 may have the cold sink 26. An interior surface 54 of the cold sink 26 may be sized and configured to match an exterior surface 56 of the container 14 (see Figure 7). In particular, when the first and second modules 22, 24 are traversed to the closed position, the entire interior surface 54 or a substantial portion of the interior surface of the cold sink 26 of the first and second modules 22, 24
15 preferably contacts the exterior surface 56 of the container 14 in order to allow maximum conduction of heat out of the breast milk contained in the container 14 through the container 14. For example, 50% or more of the interior surface 54 may contact the exterior surface 56. This allows for control of the temperature of the breast milk while waiting for the start of the feeding cycle, during the feeding cycle
20 and thereafter. The feeding cycle starts when the system 10 starts to flow nutritional liquid to the neonate and ends when the system 10 stops flowing nutritional liquid to the neonate.

It is also contemplated that a clear plastic door covering (not shown) may be disposed in front of the container 14. The door covering may be pivotable between an
25 opened and closed position and may be disposed in front of the container 14 when the first and second module 22, 24 are traversed to the closed position. Alternatively, the door covering may be fixed and cover the frontal area of the cooling unit 12 regardless of whether the first and second modules 22, 24 are at the closed or opened positions. In this alternative embodiment, the container 14 would be inserted and
30 removed from a cooled storage position between the first and second cooling modules 22, 24 from a bottom side of the system.

The cold sink 26 may preferably be fabricated from a material having a high heat transfer coefficient such as aluminum, copper or other material known in the art

or developed in the future. The cold sink 26 may be machined or die cast. The cold sink 26 may have recesses 58 for fixedly receiving threaded inserts 60. The threaded inserts 60 receive screws 62 that hold the various components of the first and second modules 22, 24 together. The cold sink 26 may have a flat surface 64 for receiving a thermoelectric cooler 66 (i.e., thermoelectric cooler) which transfers heat away from the cold sink 26 and into the heat sink 68. The flat surface 64 increases surface contact, and thus heat transfer, between the thermoelectric cooler 66 and the cold sink 26. Other equivalent devices in lieu of the thermoelectric cooler 66 are also contemplated such as vapor-compression refrigeration, evaporative cooling and cold gel packs or any other suitable device. Additionally, a lower surface 70 of the heat sink 68 may also have a corresponding flat surface that contacts the thermoelectric cooler 66 to also increase the surface contact and heat transfer coefficient therebetween 68, 66. An insulator 72 may be disposed between the cold sink 26 and the heat sink 68. The insulator 72 may be sized and configured to fit between the space defined by the cold sink 26 and the heat sink 68 and also provide an aperture 74 for allowing the thermoelectric cooler 66 to contact both the lower surface 70 of the heat sink 68 and the flat surface 64 of the cold sink 26. A heat transfer compound may be applied to opposed surfaces 76, 78 of the thermoelectric cooler 66 to increase efficiency of heat transfer between the cold sink 26 and the thermoelectric cooler 66 as well as the thermoelectric cooler 66 and the heat sink 68.

To further increase or maintain a high heat transfer coefficient from the cold sink 26 to the heat sink 68, pressure applied to the opposed surfaces 76, 78 of the thermoelectric cooler 66 by the lower surface 70 of the heat sink 68 and the flat surface 64 of the cold sink 26 may be evenly distributed about the opposed surfaces 76, 78. To aid in evenly distributing the forces, compressible spacers 80 which receive the screws 62 may be used to even the load applied to the opposed surfaces 76, 78 from the lower surface 70 of the heat sink 68 and the flat surface 64 of the cold sink 26. The compressible spacers 80 are preferably fabricated from a suitable polymer material such as rubber. Two fans 82 may be disposed over the heat sink 68 to blow air over the fins 84 of the heat sink 68. However, it is also contemplated that any other suitable arrangement for cooling, including material alterations or physical modifications can be incorporated into the system, as well as one or more fans 82 that may be used to blow air over the fins 84 of the heat sink. A body 86 of the module

22, 24 may encapsulate the thermoelectric cooler 66, insulation 72, spacers 80, heat sink 68 and the fans 82. The body 86 of the module 22, 24 may be fabricated from a strong polymer material. Moreover, the body 86 may have vent holes 87 to allow the fan to move the air across the fins 84 of the heat sink 68. The screws 62 are inserted
5 through apertures 88 of the body 86 and through one or more of the fans 82, heat sink 68, compressible spacers 80, insulation 72 are threaded onto the threaded inserts 60. Pressure on the opposed surfaces 76, 78 can be regulated by tightening and loosening one or more of the screws 62. The screws 62 can be held in place by wave springs 90 and washers 92.

10 Although the interior surface 54 of the cold sink 26 of the first and second modules 22, 24 are sized and configured to receive the exterior surface 56 of the container 14, it is also contemplated that a gap may exist therebetween. In this instance, the cold sink 26, 28 transfers heat out of the breast milk contained in the container 14 by cooling the air around the container 14 instead of through direct
15 conduction between the container 14 and the cold sink 26. Moreover, the cold sink 26 or a cap capture member may capture the replacement cap 98 or a flange 114 of the container 14 to hold the position of the container 14 in the cooling unit 12.

The thermoelectric cooler 66 may be controlled with a temperature controller 119. The temperature controller 119 may be in electrical communication with the
20 thermoelectric cooler and the power supply 146 through the leads of the thermoelectric cooler 66 in order to increase or decrease the Peltier effect.

A condensation reduction/blow-off apparatus 116 may have an air pump 117 which is in fluid communication with air tubes 118, as shown in Figures 2 and 3. The open or exhaust end of the air tubes 118 may be directed toward the cooling unit. The
25 open end of the air tubes 118 may be disposed below the cold sink 26 and be operative to blow air over the surface of the container 14 and/or through the vent holes 87 of the body 86 of the first and second modules 22, 24. By blowing air over these components, condensation is mitigated or does not form. Other means of containing and controlling condensation are also contemplated such as a disposable
30 ring shaped sponge placed around the container 14.

The above description of the cooling unit 12 revolved around first and second cooling modules 22, 24 that surround the container 14 about its exterior periphery. However, it is also contemplated that a cooling module may be configured and sized

to be disposed within a recess of the container 14 in lieu of or in addition to the first and second cooling modules 22, 24. The recess may be formed in a wall of the container 14 or in the cap 98. Beneficially, by doing so, the external size and configuration may be kept the same while changing the volume size of the container 14. In this way, the system 10 need not be changed to account for different volume containers 14. The container 14 may be a specially designed container 14 used for collecting breast milk with a breast pump and also have the recess for receiving the cooling module.

Referring now to Figures 6 and 7, the container 14 may be a common container used for collecting breast milk with a breast pump. The container 14 defines the exterior surface 56 which typically has a cylindrical configuration. However, it is also contemplated that other external configurations for the container 14 may be employed such as oval and square. The container 14 may also be provided with a cap 94 used to seal off the container 14. When the container 14 is filled with breast milk, threads of the cap 94 are threadably engageable to threads 96 disposed at the open end of the container 14. The cap 94 may be used to seal off the container 14 during storage.

The system 10 may provide a ventable cap 98. The container 14 and the cap 98 form a liquid holding system. The ventable cap 98 may also have threads formed in a cover component 100 that is threadably engageable to the threads 96 of the container 14. The cover component 100 may also have an output port 102 that can receive a connector 104 fitted onto a first end of an extension tube 106. The breast milk contained within the container 14 flows out of the output port 102 into the extension tube 106 during feeding. During feeding, the container 14 and the replacement cap 98 are inverted from the orientation shown in Figure 7. The inverted position of the container 14 and the replacement cap 98 is shown in Figure 1. In the inverted position, as breast milk flows out of the output port 102, air is introduced into the container 14 by way of vent 108 to prevent a vacuum from forming and allowing all of the nutritional fluid to be fed to the neonate. The vent 108 includes a hole 110 in the cover component 100 and a rigid elongate tube 112 that extends to a bottom of the container 14. The tube 112 is sufficiently rigid so long as the tube remains erect when the container 14 and the cap 98 are inverted. When the container 14 and the ventable cap 98 are inverted as shown in Figure 1, the breast milk flows toward the output port

102 and air is introduced into the upper portion of the inverted container 14. Moreover, optionally, the interior surface of the cover component 100 of the cap 98 may have a conical or concave configuration that leads to the hole 110 so as to drain all of the breast milk out of the container 14 during the feeding cycle. A hydrophobic
5 filter 114 may be fitted at a distal end of the elongate tube 112 to allow air to enter into the container 14 but to prevent breast milk from spilling out of the vent 108 of the container 14 during handling. The distal end of the elongate tube 112 is shown in Figure 7 as being located at the lower end of the elongate tube 112. The elongate tube 112 assists in introducing the air towards or above the top of the fluid level when the
10 container 14 is inverted during the feeding cycle.

The vent 108 may alternatively be a one-way valve or other structure known in the art or developed in the future for allowing air to enter into the container 14 but preventing the breast milk from spilling out of the vent 108, and more particularly, the hole 110. By way of example and not limitation, other venting systems known in the
15 art are those described in United States Patent Nos. 5,570,796 and 5,779,071. These and other venting systems incorporate the vent mechanism between the cap 98 and the container 14. Additionally, it is also contemplated that the hydrophobic filter 114 may be disposed at the hole 110. By doing so, air is still allowed to be introduced into the container 14 and breast milk is still prevented from spilling out of the container 14
20 through the hole 110 of the vent 108.

In the description of the system 10, a cylindrical container 14 is utilized. However, other container shapes and configurations are also contemplated. By way of example and not limitation, the container 14 may be a ventable nursing bottle or a collapsible bag without a vent. As a further alternative, a syringe body may be used
25 in lieu of the container 14 and cap 98. The needle side of the syringe is disposed toward the bottom side of the system. The plunger is removed and the top side of the syringe body is opened to the atmosphere to allow the breast milk or nutritional fluid in the syringe body to drain out the bottom of the container through the syringe needle. A permeable material or hydrophobic material may cover the open top side of
30 the syringe body to prevent particulate matter and contaminants from contaminating the breast milk.

The peristaltic pump 16 is operative to receive a section of the extension tube 106. In particular, the peristaltic pump has a groove 120 through which the extension

tube 106 may be inserted. The section of the extension tube 106 inserted into the groove 120 and interacting with rollers of the peristaltic pump 16 may be more compliant compared to the remaining portions of the extension tube 106. When the extension tube 106 is inserted into the groove 120, rollers (not shown) of the peristaltic pump 16 successively squeeze the extension tube 106 to flow the breast milk through the extension tube 106 and the feeding tube 122. In this regard, the peristaltic pump 16 causes the breast milk to flow through the tube 106, 122 at a highly controlled rate. In operation, when the container 14 is disposed within the cooling unit 12, the output port 102 is disposed on the bottom of the container so that gravity can force all of the breast milk through the output port 102. The breast milk flows through the output port 102 and into the extension tube 106. The peristaltic pump 16 creates a vacuum to pump out the breast milk from the container 14. Moreover, the peristaltic pump is capable of pumping out all of the breast milk contained within the container through the output port 102 and out of the extension tube 106 and the feeding tube 122 including the fat content that might line the lumen of the tube. The breast milk contained within the extension tube 106 and the feeding tube 122 may also be fed to the preterm infant by pumping air behind the breast milk contained in the tubes 106, 122. Beneficially, the air is not fed to the neonate because the pump 16 may be stopped when all of the breast milk is pumped out of the tube or when a small amount of nutritional liquid is left in the feeding tube. A vent 108 formed in the cap 98 allows air to continue to enter into the container 14 and be introduced into the tubes 106, 122 to prevent a vacuum from forming at the end of the feeding cycle and to allow the pump to continue pumping all of the breast milk out of the container 14 and the tubes 106, 122. The flow rate of the breast milk through the extension tube 106 and the feeding tube 122 may be calculated based on the size (e.g., length and inner diameter) of the tubes 106, 122 and the speed of the peristaltic pump 16. The volume of breast milk in the extension tube 106 and feeding tube 122 may be calculated with this information and be used to time stoppage of the pump 16. It is also contemplated that the extension tube 106 and the feeding tube 122 may be formed as a single tube that serves the two functions described in relation to the extension tube 106 and the feeding tube 122.

To feed all of the breast milk in the container 14 to the preterm infant, the peristaltic pump 16 may continue to operate (i.e., pump) for a period of time as soon

as a fluid level detector detects that the container 14 is empty. The fluid level detector may sense a level of the fluid in the container after start of the pump. When the container 14 is empty, the breast milk is located only in the tubes 106, 122. The continued operation of the pump 16 allows for feeding of the breast milk in the tubes 106, 122 to minimize waste of valuable breast milk. The pump 16 continues to operate for a period of time equal to the flow rate of breast milk through the tubes 106, 122 multiplied by the volume of the extension tube 106 and the feeding tube 122.

Referring now to Figure 3, to detect a level of the breast milk in the container 14, a suitable fluid level detection device, such as a camera 124 that makes up a cameral vision system may be disposed adjacent the container 14 when the container 14 is disposed between first and second modules 22, 24 in the closed position. The camera 124 may be operative to detect the level of the breast milk contained within the container 14 so as to detect when the breast milk is emptied out of the container 14 during the feeding process. Lights 125 which may also form a part of the camera vision system may be disposed behind the container 14 to illuminate the back of the container 14 to help gauge the level of the breast milk still contained within the container 14 with the camera 124. The camera 124 is operative to send a signal to a controller of the peristaltic pump 16 so that the peristaltic pump 16 stops pumping after the period of time described above so that all of the breast milk contained in the tubes 106, 122 is pumped out and administered to the preterm infant or neonate. A typical flow rate for the peristaltic pump 16 and tubes 106, 122 combination is typically about 0.5 to 20 ml per minute.

Other fluid level sensors are also contemplated in lieu of the camera 124 and lights 125. By way of example and not limitation, LED or laser fluid level measurement systems are also contemplated for detecting the level of breast milk in the container 14 or for detecting when fluid is emptied out of the container 14. Additionally or alternatively, a rotary encoder on the motor of the peristaltic pump 16 may be used to calculate when the breast milk is depleted from the container 14. In particular, the user may enter the fluid volume of breast milk initially in the container 14 when loading the container 14 in the cooling unit 12. This information is entered into a controller of the system 10 which calculates the appropriate period of time the peristaltic pump 16 should operate to administer all of the breast milk. The controller is operative to time shut off of the peristaltic pump 16 to deliver all of the breast milk

to the preterm infant and to prevent pumping air into the stomach of the preterm infant. In another embodiment, it is also contemplated that weight of the container 14 and the breast milk within the container 14 may be measured with a load cell to determine the remaining amount of breast milk in the container 14.

5 Other sensors are also contemplated that may be incorporated into the system 10 in order to assist in timing operation of the pump 16 in order to administer all of the breast milk in the container 14 yet not undesirably pump air into the preterm infant. By way of example and not limitation, a fluid sensor 126 may be disposed adjacent to the feeding tube 122 to detect when the last bit of breast milk is flowed
10 through the feeding tube 122. The pump 16 may be shut off shortly thereafter in order to allow the last remaining amount of breast milk still trapped in the feeding tube 122 to be fed to the preterm infant. The amount of time that the pump 16 is allowed to continue running after the fluid sensor 126 detects an absence of fluid may be calculated based on the flow rate of the breast milk through the feeding tube 122 and a
15 volume of breast milk still contained in the feeding tube 122 between the fluid sensor 126 and a proximal end of the tube 122. This information may be input into the controller of the system 10 with the keypad as discussed herein. The fluid sensor 126 may be placed at other locations on the feeding tube 122 and the extension tube 106. The fluid sensor 126 may be a laser or LED-based fluid sensor, camera imaging
20 system or other suitable fluid sensors

 The warming unit 18 may be operative to heat the breast milk being administered to the preterm infant above room temperature, and more preferably up to about standard body temperature which is 98.6 F. The system 10 may be used in a neonatal intensive care unit environment. These types of environments are regulated
25 to a room temperature between 72 °F to 76 °F with an air conditioning unit. The warming unit 18 may be identical to the structure described in United States Patent No.8,663,161 and Ser. No. 14/222,832, the entire contents of which are expressly incorporated herein by reference. The warming unit 18 may be controlled with a controller disposed within the body 20 of the system 10. The controller may be in
30 electrical communication with the warming unit 18 by way of cable 130. Additionally, power may be supplied to a heating element in the warming unit 18 through the cable 130. The warming unit 18 may be disposed closely adjacent to the preterm infant so that after the breast milk is heated, the heated breast milk does not

have to travel very far downstream of the warming unit 18 to the preterm infant. The reason is that oftentimes administration of breast milk to the preterm infant is a very slow process. The breast milk begins to cool down as soon as the breast milk exits the warming unit 18. By placing the warming unit 18 closely adjacent to the preterm
5 infant so that only a short portion of the feeding tube 122 is exposed to the environment, one may mitigate excessive cooling down of the heated breast milk so that the preterm infant receives the milk at or close ($\pm 2^{\circ}$ to 5°F) to the standard body temperature.

The system 10 may also have a display 132 and keypad 134. It is also
10 contemplated that the keypad 134 and display 132 may be incorporated into a touchpad. The keypad 134 and display 132 provide input and outputs for the user to communicate with the controller of the system 10. By utilizing the keyboard 134, the user may configure the controller and set various parameters such as total volume of breast milk to be administered to the preterm infant, time for infusion or feeding
15 cycle, infusion or flow rate of the breast milk to be administered to the preterm infant, target temperature of the breast milk being fed to the preterm infant, upper and lower acceptable temperature ranges of the breast milk to be fed to the preterm infant and other factors necessary or important to the operation of the system 10. The keypad 134 may also be used to configure various alarms which may be visual (i.e. LEDs,
20 informational text on the display 132) or auditory (i.e., bells, audible voices on a speaker of the system 10, warning sounds on the speaker of the system 10). The controller of the system 10 is operative to control the peristaltic pump 16, the warming unit 18, the cooling unit 12, the camera 124 or the fluid level indicator and other operational features of the system 10. The controller of the system 10 may also
25 incorporate a memory function to provide medical professionals with a fast setup of the system 10. In particular, the medication professional may recall a prior setting for a particular preterm infant in the NICU when setting up a feeding cycle for the preterm infant so that the medical professional need not reenter the same information for subsequent feedings. The controller may be programmable so as to receive various
30 inputs which control other parts of the system 10.

The system 10 may also have a speaker 136 for providing an audible response such as warnings, instructions and other useful information to the medical professional. Moreover, the system 10 may have one or more lights 138 that may also

serve to provide a warning signal to the medical professional of a malfunction or error in operation. Additionally, the display 132 may serve the same function in warning the medical professional and providing instruction as to operation as well as an error in operation of the system 10.

5 The system 10 may also be network enabled. The system 10 may have a wireless antenna 140 for transmitting and/or receiving information and/or command signals from a remote location such as a nurse's station. In this regard, the system 10 may have one or more sensors and data collection devices that measure a temperature of the breast milk contained in the container 14, the flow rate of the breast milk to the
10 neonate, entry and exit temperatures of the breast milk from the heater 18 and other important information of the system 10. This as well as other information may be transmitted to the remote location such as the nurse's station so that the nurse need not personally attend to the feeding of the neonate and may attend to other more critical tasks at hand unless a serious error occurs. In the event of a serious error, the
15 wireless antenna 140 may also be operative to receive commands from the remote location to increase or decrease flow rate of the breast milk, increase or decrease exit temperature of the breast milk and control other aspects of the system 10. The same may also be accomplished by providing for a hardwired connection to the system with a network port 142 which connects the system 10 to the network of a hospital so that
20 control of the system 10 at the remote location is possible.

 The system 10 requires energy to power the thermoelectric cooler 66, the display 132, the keyboard 134, the pump 16, the warming unit 18 and other components such as the lights 138, the speaker 136 and the sensor 126. Power may be provided to the system 10 by plugging the system 10 into an electrical outlet with
25 plug 144. Electricity is provided to power supply 146 which both provides power to the required components within the system 10 and also a backup rechargeable battery 148. The power supply 146 is operative to provide standard 110V AC power or DC electricity to the various components as needed. A battery receptacle 150 may hold the rechargeable battery 148 in place during use. However, in certain instances, it may
30 be desirable to replace the backup battery 148 with a fresh recharged battery. In this instance, the backup battery 148 may be selectively removed from the battery receptacle 150. During operation, the electrical plug provides electricity to the system 10 and also charges the backup battery 148. In the event of a power outage, the

backup battery 148 powers the system 10 until power is restored. In certain remote locations where electricity is not available, it may be desirable to carry multiple backup batteries which are switched out between feedings in order to utilize the system 10.

5 The system 10 may also include an agitation mechanism or system for stirring the breast milk contained in the container 14 during feeding. In particular, the agitation mechanism may include a stir bar which is disposable within the container 14. The stir bar may be inserted into the container 14 before sealing the container 14 with replaceable cap 98. The stir bar is rotatable with a rotating magnet device. The
10 rotating magnet device may be incorporated into the cap 98 and activated when the pump 16 is activated. In this instance, when the pump is activated, the rotating magnet device is operable to rotate the stir bar in order to stir the breast milk during the feeding process. The stir bar may be shaped in the form of a rotary propeller. Other mechanisms for stirring or agitating the breast milk are also contemplated. By way of
15 example and not limitation, it is also contemplated that a piezoelectric or ultrasonic vibration may be incorporated into the container 14 and/or cap 98.

As discussed above, the system 10 utilizes an extension tube 106 and a feeding tube 122. The extension tube 106 is fed through the peristaltic pump 16 and the warming unit 18. The feeding tube 122 is connected to the extension tube 106 so as to
20 be in fluid communication therewith. The feeding tube 122 is designed to be inserted into the stomach of the neonate. Although the above description of the system 10 is in conjunction with two separate tubes 106, 122, it is also contemplated that a single tube may be used to connect to the output port 102 of the cap 98, be fed through the peristaltic pump 16, routed through the warming unit 18 and inserted into the stomach
25 of the neonate.

The system 10 may also be configured to be mountable to an IV pole by way of clamp 152 where, for example the clamp is disposed about the IV pole and a knob 154 is tightened to clamp the system 10 to the IV pole. The system 10 may also be set on a tabletop.

30 In operation, the system 10 may be used to feed a preterm infant or neonate nutritional fluid such as a mother's breast milk, a donor mother's breast milk or a neonate nutritional formula. For breast milk whether it is the neonate's mothers or donor's breast milk, the breast milk is preferably pumped into the container 14 then

fed to the neonate immediately after pumping. In other cases, the breast milk is stored in a refrigerated state for later use. Refrigeration mitigates unwanted bacteria growth in the breast milk. The breast milk is typically stored at a temperature of about 39°F. The system 10 may incorporate commonly used containers 14 used in common breast pumps in the market. However, it is also contemplated that the system 10 may be designed to receive specially designed containers 14.

A preterm infant typically is unable to orally consume nutritional fluid (i.e., breast milk or neonate nutritional formula) through the mouth with a bottle. As such, preterm infants require assistance in receiving nutritional fluid by placing a feeding tube 122 through the infant's mouth or nose until a distal end of the feeding tube 122 reaches the infant's stomach. The system 10 may be utilized to feed preterm infants breast milk in a way that mitigates unwanted bacterial growth, retains the nutritional and fat content of breast milk, provides the nutritional fluid to the preterm infant at the optimal temperature (i.e., standard body temperature) and efficiently feeds the infant at a preselected time or interval, if desired, so that the medical professional may set up the system 10 for feeding at a later time and attend to more critical tasks at hand.

To utilize the system 10, the system 10 may be set up on a tabletop or attached to an IV pole with clamp 152 in close proximity to the preterm infant. A container 14 is removed from the refrigerator and prepared for feeding the breast milk in the container 14 to the preterm infant. The container 14 is preferably the same container that the neonate's mother or the donor mother used to pump her breast milk. Utilizing the same container 14 mitigates possible reduction of the fat content within the breast milk. Although it is preferable to use the same container 14, it is also sometimes necessary to transfer the breast milk from one container 14 to another such as when the feeding volume does not match stored volume or fortification in specific volume increments is necessary. To prepare the container 14 for feeding, the cap 94 is removed and the ventable cap 98 is placed on the container 14. The extension tube 106 is connected to the output port 102 and the feeding tube 122 is connected to the extension tube 106. Thereafter, the tubes 106, 122 are primed with the breast milk from the container 14 by inverting the container 14 in the orientation shown in Figure 1. Once the tubes 106, 122 are primed with the breast milk, the feeding tube 122 may be inserted through the preterm infant's mouth until a distal end is disposed or positioned within the infant's stomach.

The medical professional may power on the system 10 with power switch 160 which supplies power to the various components of the system 10. The medical professional operates a keyboard 134 to traverse the first and second modules 22, 24 to the opened position with the motor 30. Alternatively, the first and second modules 22, 24 may be traversed to the opened position with a hand crank. Once the first and second modules 22, 24 are in the opened position, the medical professional inverts the container 14 and inserts the container 14 between the first and second cooling modules 22, 24. While holding the container 14 between the first and second modules, the medical professional then operates the keyboard 134 in order to traverse the first and second modules 22, 24 to the closed position. In the closed position, the first and second cooling modules 22, 24 grip the container 14 to hold the container 14 in place.

The medical professional may then open the warming unit 18 in order to feed the extension tube 106 through the warming unit 18. At this point, the peristaltic pump 16 and the warming unit 18 are nonoperational. Moreover, fluid is not being flowed into the preterm infant's stomach.

Based on the preterm infant's condition and status, the medical professional may configure the controller of the system 10 in order to start the peristaltic pump 16 and the warming unit 18 at a later time. This is known as delayed start. For example, if the feeding time is at 1:00 PM, the medical professional may set up the system 10 at 12:30 and set the feeding cycle to start at 1:00 PM. The medical professional through the keyboard 134 also programs the system 10 with the total volume of breast milk to be fed to the preterm infant and the infusion rate or flow rate of the breast milk to be flowed to the preterm infant. By default, the warming unit 18 warms up the breast milk flowing through the extension tube 106 to a temperature of about 98.6°F (+/- 5°, and more preferably +/- 2°F) for the feeding cycle. It is also contemplated that the breast milk may be heated to a temperature above or below 98.6°F but the medical professional must alter such setting with the keyboard 134. Additionally, the medical professional may set an acceptable temperature range of the breast milk such as +/- 2°F from the target temperature (i.e., 98.6°F). A sensor may be used to track the temperature of the breast milk and send a signal to the controller to trigger an alarm when the temperature of the breast milk exceeds the range of the target temperature. It is also contemplated that the medical professional may immediately start the feeding cycle.

Additionally, the medical professional may set the target temperature of the breast milk in the container 14. In particular, as the system 10 waits for the start of the feeding cycle, it is beneficial to maintain the breast milk in the container 14 in a cooled state or a temperature below room temperature. The purpose is to mitigate unwanted bacterial growth and maintain fat content in the breast milk. To accomplish this, a suitable thermoelectric cooler, such as a Peltier module 66 of the first and second modules 22, 24 is activated. A noncontact temperature sensor may be utilized to gauge the temperature of the breast milk within the container 14 and provide feedback to the controller which in turn increases or decreases the Peltier effect of the thermally electric cooler 66 to maintain the breast milk at the target temperature. Additionally, if the temperature of the breast milk deviates from the target temperature, an alert, such as an alarm may be generated in order to alert a nurse at a remote location to attend to the situation.

When the feeding cycle starts, the system 10 powers the warming unit 18 and the peristaltic pump 16. Preferably, the system 10 powers the warming unit 18 prior to powering the peristaltic pump 16 in order to minimize the amount of cold breast milk being fed into the preterm infant. Once the warming unit 18 reaches the target temperature, the peristaltic pump 16 is powered up in order to begin flowing breast milk through the tubes 106, 122 and into the preterm infant. The breast milk is drawn through the bottom of the inverted container 14 and can draw all of the breast milk out of the container 14. Given that breast milk is the optimal type of nutritional fluid for the preterm infant, it is crucial to provide as much of the optimal type of nutritional fluid to the preterm infant who may already be struggling for life and may need all of the nutrients and immunological benefits of breast milk.

As the feeding cycle progresses, the level of breast milk in the container 14 decreases. The level of the breast milk in the container may be monitored with the camera 124 and if needed, the lights 125 may be turned on to illuminate the breast milk within the container 14 to assist the camera 124 in determining the level of the breast milk in the container 14. When the camera 124 detects that all of the breast milk is depleted from the container 14, a controller in the system may set a timer for stopping operation of the peristaltic pump 16 right before air is fed to the neonate. The peristaltic pump 16 delivers the breast milk in a highly controlled rate. As such, since the volume of the breast milk in the tubes 106, 122 and the flow rate through the tubes

106, 122 are known, the controller turns off the peristaltic pump 16 when the volume of breast milk in the tubes 106, 122 has been completely fed to the preterm infant right before air is introduced into the neonate. In this manner, all of the breast milk is fed to the preterm infant without pumping air into the preterm infant.

5 Other means of stopping the peristaltic pump 16 at the appropriate time to deliver all of the breast milk to the preterm infant while not introducing air to the preterm infant are also contemplated. By way of example and not limitation, a fluid sensor 126 may be located on various portions of the tube 106, 122. By way of example and not limitation, the fluid sensor 126 may be positioned near the preterm
10 infant's mouth on the feeding tube 122. Once the fluid sensor 126 detects an absence of breast milk or nutritional fluid in the feeding tube 122, the peristaltic pump 16 may be immediately stopped or stopped shortly thereafter.

 In certain instances, the preterm infant may not consume the entire fluid volume of breast milk contained in the container 14. By way of example and not
15 limitation, the preterm infant may consume one half of the volume of breast milk in the container 14. As such, the breast milk in the container 14 may be utilized for two feeding cycles. In this regard, after the first feeding cycle, the peristaltic pump 16 stops. The peristaltic pump 16 is stopped when the feeding volume set by the medical professional has been met. Additionally, the warming unit 18 is turned off to prevent
20 overheating of the breast milk contained in the tube 106 routed in the warming unit 18. The cooling unit 12 maintains the breast milk in the container 14 at the refrigerated temperature to mitigate bacterial growth so that the medical professional need not immediately attend to the preterm infant. When the next feeding cycle is desired, the tubes 116 and 122 can be replaced with sterile replacement tubes and the
25 warming unit 18 is powered back on until it reaches its target temperature. The peristaltic pump 16 begins to pump breast milk through the tubes 116, 122 and into the preterm infant. All of the fluid is then fed to the preterm infant by emptying out the breast milk from the container 14 and feeding all of the breast milk contained in the tube 106, 122 to the preterm infant as discussed above.

30 During operation, the warming unit 18, peristaltic pump 16 or the cooling unit 12 may fail. In this regard, the cooling unit 12 may fail to cool down the breast milk in the container 14. In this regard, the noncontact liquid temperature sensor may trigger one of the visual or audible alarms of the system 10 and also send a signal

through the wireless antenna 140 or the wired port 142 to a remote location (i.e., nurse's station) so that the medical professional at the remote location may quickly attend to the system 10.

Before, during and after the feeding cycle, the cooling unit 12 maintains the breast milk contained in the container 14 in a cold state. In this regard, condensation may form in or around the cooling unit 12 and the container 14. To mitigate condensation, a sponge may be disposed about the container 14 or air may be blown over such areas.

Additionally, during the feeding cycle, the agitation mechanism may be triggered to stir the breast milk within the container 14.

During the feeding cycle, the display 132 may show various parameters such as infusion rate, duration of the feeding cycle, remaining duration of the feeding cycle, temperature of the breast milk in the container 14, temperature of the warming unit 18 and any other relevant information.

The various aspects of the system 10 may be utilized to provide assisted feeding to neonates but may be especially beneficial to feed patients such as preterm infants that may already be struggling for life. For these patients, nutrition should be provided on time and regularly to provide the best chance of survival. However, the system 10 may also be used to provide assisted liquid feeding to children and adults that might not be able to orally intake food but must consume nutrition directly into the stomach.

The above description is given by way of example, and not limitation. Given 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 incorporating the warming unit into the system. 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 herein. Thus, the scope of the claims is not to be limited by the illustrated embodiments.

WHAT IS CLAIMED IS:

1. A system for feeding a neonate, the system comprising:
 - a cooling unit for cooling breast milk before and/or during and/or after
 - 5 a feeding cycle;
 - a pump for pumping the breast milk contained within a container to the neonate;
 - a warming unit for warming the cooled breast milk above room temperature as the breast milk is being administered to the neonate;
 - 10 a controller for controlling the cooling unit, the pump and the warming unit; and
 - wherein the controller initiates a signal that activates the cooling unit to cool the breast milk in the container to a temperature below room temperature before and/or during and/or after the feeding cycle to mitigate
 - 15 bacteria grown and reduction of fat content, and the controller initiates a signal that activates the pump and warming unit for the feeding cycle to facilitate digestion of the breast milk by the neonate.
2. The system of Claim 1 wherein the cooling unit remains activated for cooling the breast milk during feeding and the warming unit receives a tube with the
- 20 breast milk flowing therethrough delivering breast milk to the neonate, the warming unit thereby warming the breast milk pumped from the cooled container to the neonate
3. The system of Claim 1 wherein the cooling unit comprises:
 - first and second cooling modules traversable between opened and
 - 25 closed positions wherein the container having breast milk is disposable between the first and second cooling modules when the first and second cooling modules are in the opened position, and the first and second cooling modules grip the container when the first and second cooling modules are traversed to the closed position with the container disposed between the first
 - 30 and second cooling modules.
4. The system of Claim 3 wherein the first and second cooling modules are mounted to a common axle with first and second threads, the first module having a first threaded member threadably engaged to the first thread of the common axle, the

second module having a second threaded member threadably engaged to the second thread of the common axle wherein upon rotation of the common axle in a first rotational direction, the first and second cooling modules traverse toward either the opened or closed position and upon rotation of the common axle is a reversed second rotational direction, the first and second cooling modules traverse toward either the closed or opened position.

5 5. The system of Claim 3 further comprising a motor in rotational communication with the common axle, the motor capable of rotating the common axle in either the first rotational direction and the reversed second rotational direction for traversing the first and second modules between the opened and closed positions wherein the motor is activatable by the controller.

10 6. The system of Claim 3 wherein each of the first and second cooling modules each comprise a cold sink and a heat sink with a thermoelectric cooler and insulation disposed therebetween for drawing heat out of the breast milk in the container.

15 7. The system of Claim 1 further comprising a tube, a first end of the tube being connectable to the container and a second end of the tube being disposable within the neonate.

20 8. The system of Claim 7 wherein the tube is a single tube, or a plurality of tubes connected in fluid communication with each other.

 9. The system of Claim 1 wherein the pump is a peristaltic pump.

 10. The system of Claim 1 wherein the warming unit is positioned inline of a tube providing fluid communication between the container and the neonate so that the warming unit warms only the breast milk to be fed to the neonate.

25 11. The system of Claim 1 further comprising at least one air tube and an air pump for flowing air through the air tube, an exhaust end of the air tube being positioned to direct the pumped air toward the cooling unit for mitigating condensation on the container and the cooling unit.

 12. The system of Claim 1 further comprising a fluid indicator for detecting an amount of nutritional fluid to be fed to the neonate.

 13. The system of Claim 12 wherein the nutritional fluid indicator is a rotary encoder on the pump, a camera vision system disposable adjacent to the

container or tube, a light emitting diode fluid sensor disposable adjacent to the container or tube or a laser fluid sensor disposable adjacent to the container or tube.

14. The system of Claim 1 further comprising an agitation system for stirring the nutritional fluid contained within the container during feeding.

5 15. The system of Claim 14 wherein the agitation system includes a stir bar disposable within the container and rotatable with a rotating magnet device disposed outside of an interior volume of the container.

16. The system of Claim 15 wherein the rotating magnet device is incorporated into a cap for the container.

10 17. A system for feeding a neonate, the system comprising:
a holding mechanism for positioning a container in an inverted position so that breast milk contained within the container flows out downward from the container;

a pump for pumping the breast milk contained within the container;
15 a sensor for determining an amount of breast milk remaining in at least one of the container and a tube connectable to the container and disposable within the neonate; and

a controller for controlling the pump, the controller operative to regulate a speed of the pump to provide a consistent flow rate of the breast
20 milk to the neonate and to shut off the pump after determining the amount of breast milk remaining in the container and/or the tube so that all of the breast milk in the container is fed to the neonate and without delivering air into the neonate.

18. The system of Claim 17 further comprising a cooling unit for holding
25 the container and cool the breast milk contained in the container for mitigating bacterial growth before and during feeding.

19. The system of Claim 17 wherein the pump is a peristaltic pump for flushing all of the breast milk out of the tube.

20. The system of Claim 17 further comprising a cap for sealing the
30 container, the cap having an output port connectable in fluid communication with the tube.

21. The system of Claim 20 wherein the cap further comprises a venting mechanism for allow air to be introduced into the container as the breast milk is being drawn out of the output port.

22. The system of Claim 21 wherein the venting mechanism comprises a
5 hole in the cap and a hydrophobic filter disposed over the hole for allowing air into the container and prevent breast milk from spilling out of the hole.

23. The system of Claim 22 wherein the venting mechanism further comprises an elongate rigid tube connected in fluid communication with the hole in the cap and the hydrophobic filter is disposed at a distal end of the elongate rigid tube.

10 24. The system of Claim 17 wherein the sensor is a liquid level sensor for sensing a level of the breast milk in the container.

25. The system of Claim 17 wherein the sensor is liquid sensor disposed adjacent to the tube for sensing an absence of breast milk in the tube.

26. A system for feeding a neonate, the system comprising:
15 a holding mechanism for a container containing nutritional fluid for the neonate;

a pump for pumping the nutritional fluid contained within the container;

a controller operative to start and stop operation of the pump for
20 starting and stopping flow of nutritional fluid in a tube connected in fluid communication with the container and disposed within the neonate to deliver the nutritional fluid to the neonate; and

wherein the controller is operative to delay start of the pump after a period of time based on parameters set by a medical professional.

25 27. The system of Claim 26 further comprising a cooling unit for cooling the nutritional fluid to a temperature below room temperature for a neonatal intensive care unit in a hospital, the controller operative to start the cooling unit during the period of time while waiting for the delay start of the pump.

28. The system of Claim 26 further comprising a touchpad and/or a keypad
30 and display for configuring the controller for the delay start.

29. A method of operating a system for feeding a neonate, the system having a container with nutritional fluid for the neonate, the container having an output port on a first end of the container, a first end of a tube being connected to the

output port of the container and a second end of the tube being connected to a feeding tube or being disposed within the neonate, the container disposed within the system with the output port of the container positioned below the nutritional fluid contained within the container, the method comprising the steps of:

5 pumping the nutritional fluid out of the container with a pump at a flow rate;

 determining an amount of nutritional fluid to be fed to the neonate remaining in the container and/or the tube; and

 stopping operation of the pump based on the determined amount of
10 nutritional fluid to be fed to the neonate and the flow rate to administer substantially all of the nutritional fluid in the container to the neonate and prevent air from being administered to the neonate.

30. The method of Claim 29 wherein the determining step comprises the step of sensing a level of the nutritional fluid in the container after start of the
15 pumping step with a sensor.

31. The method of Claim 30 wherein operation of the pump ceases based on the flow rate of nutritional fluid to the neonate being pumped into the neonate and the determined amount of nutritional fluid to be fed to the neonate.

32. The method of Claim 29 wherein the determining step comprises the
20 step of sensing an absence of nutritional fluid in the tube.

33. The method of Claim 29 wherein the providing step includes the step of obtaining breast milk of a mother of the neonate, providing neonate formula, or obtaining breast milk from a breastmilk donor.

34. The method of Claim 29 further comprising the step of inputting into a
25 controller of the system a length of the tube and an inner diameter of the tube to calculate a total volume of an interior volume of the tube.

35. The method of Claim 29 wherein the determining step comprises the step of imaging a level of fluid in the container with a camera or detecting the level of fluid in the container with a light emitting diode fluid level sensor or a laser fluid level
30 sensor disposed adjacent to the container when the container is loaded into the system.

36. A method of operating a system for feeding a neonate, a tube being disposed into the neonate for feeding, a container having breast milk disposed in a

cooling unit of the system, the container being in fluid communication with the feeding tube, the method comprising the steps of:

receiving parameters into a controller of the system to start a feeding cycle after a period of time has elapsed;

5 cooling the breast milk in the cooling unit when the container is disposed in the cooling unit while waiting for a feeding cycle to start to mitigate bacteria growth and reduction of fat content; and

after the period of time has elapsed, initiating a pump to flow the breast milk out of the container into the tube and the neonate.

10 37. The method of Claim 36 wherein the period of time is at least 15 minutes.

38. The method of Claim 36 further comprising the steps of routing the tube in a warming unit and warming the breast milk up above room temperature to facilitate digestion of the breast milk by the neonate.

15 39. The method of Claim 38 wherein the warming step comprises the step of warming the breast milk up to standard body temperature.

40. The method of Claim 36 wherein the cooling step is performed before, during and after the feeding cycle.

20 41. The method of Claim 36 further comprising the step of cooling the breast milk between two subsequent feeding cycles.

42. The method of Claim 36 wherein the cooling step is performed after the container is placed in the cooling unit at least until the start of the feeding cycle.

43. The method of Claim 42 wherein the cooling step is performed at least until a latter half of the feeding cycle.

25 44. A cap for sealing a container wherein the cap and the container are disposable within a system for feeding a neonate, the cap comprising:

a body having a thread for threadable engagement to a mating thread of the container;

30 an output port in the body for providing fluid communication between an interior of the container when the cap is threaded onto the container and a tube connectable to the output port; and

a venting mechanism in the body for allowing air to be introduced into the container.

45. The cap of Claim 44 wherein the venting mechanism comprises a hole in the body and a hydrophobic filter disposed in the hole of the body for preventing spillage of nutritional fluid within the container through the hole in the body.

46. The cap of Claim 44 wherein the venting mechanism is a one way
5 valve.

47. The cap of Claim 44 further comprising:
a hole in the body;
an elongate rigid tube mounted to the body and aligned to the hole to
establish fluid communication between the hole and the tube; and
10 a filter disposed at a distal end of the elongate rigid tube.

48. The cap of Claim 47 wherein a length of the elongate rigid tube is at least $\frac{1}{2}$ of a length of an interior volume of the container.

49. A liquid holding system for holding nutritional liquid to be fed to a neonate, the liquid holding system being insertable into a neonate feeding system for
15 feeding the neonate, the liquid holding system comprising:

a container having a body, an interior and a thread formed adjacent to an opening of the container body;

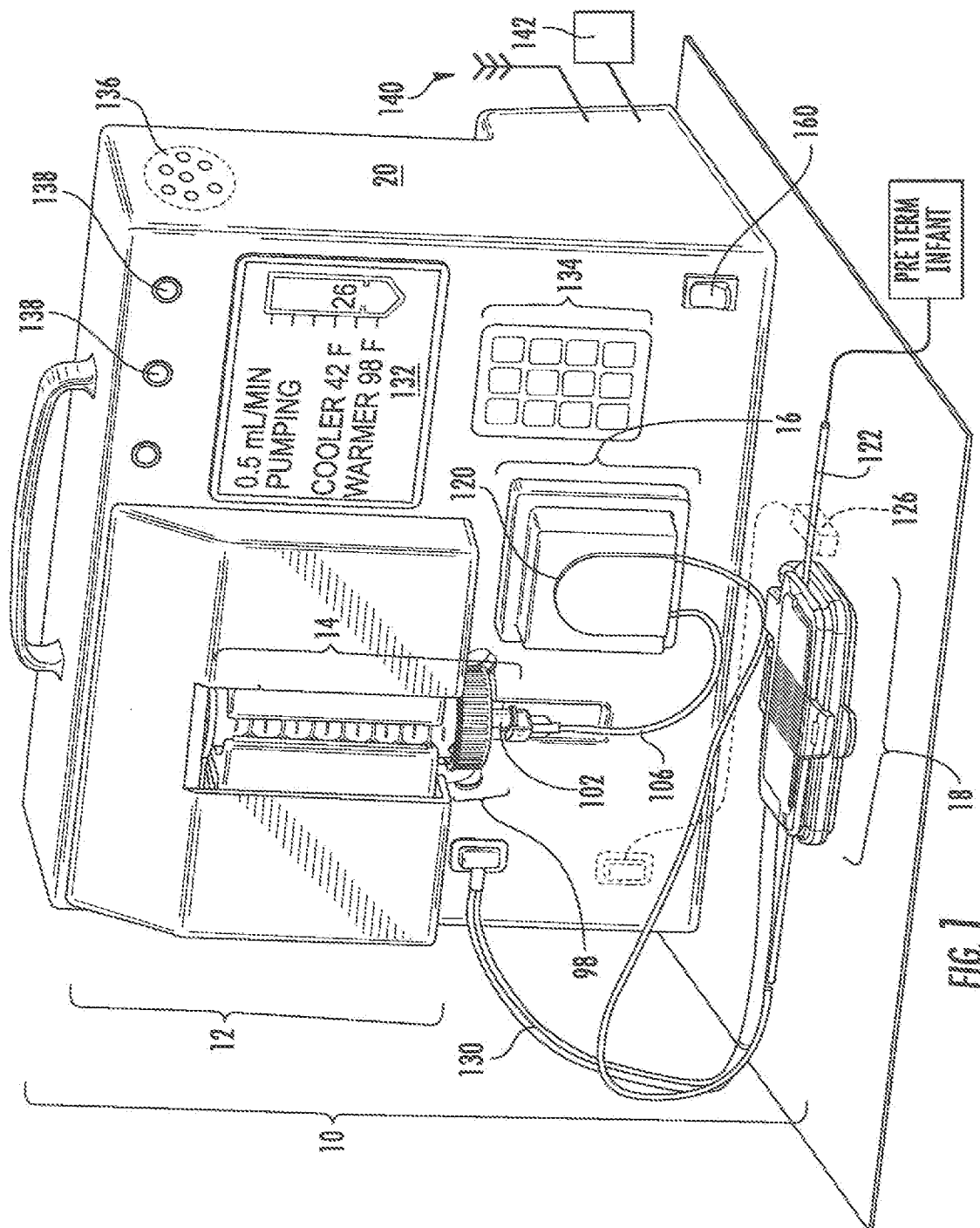
a cap comprising:

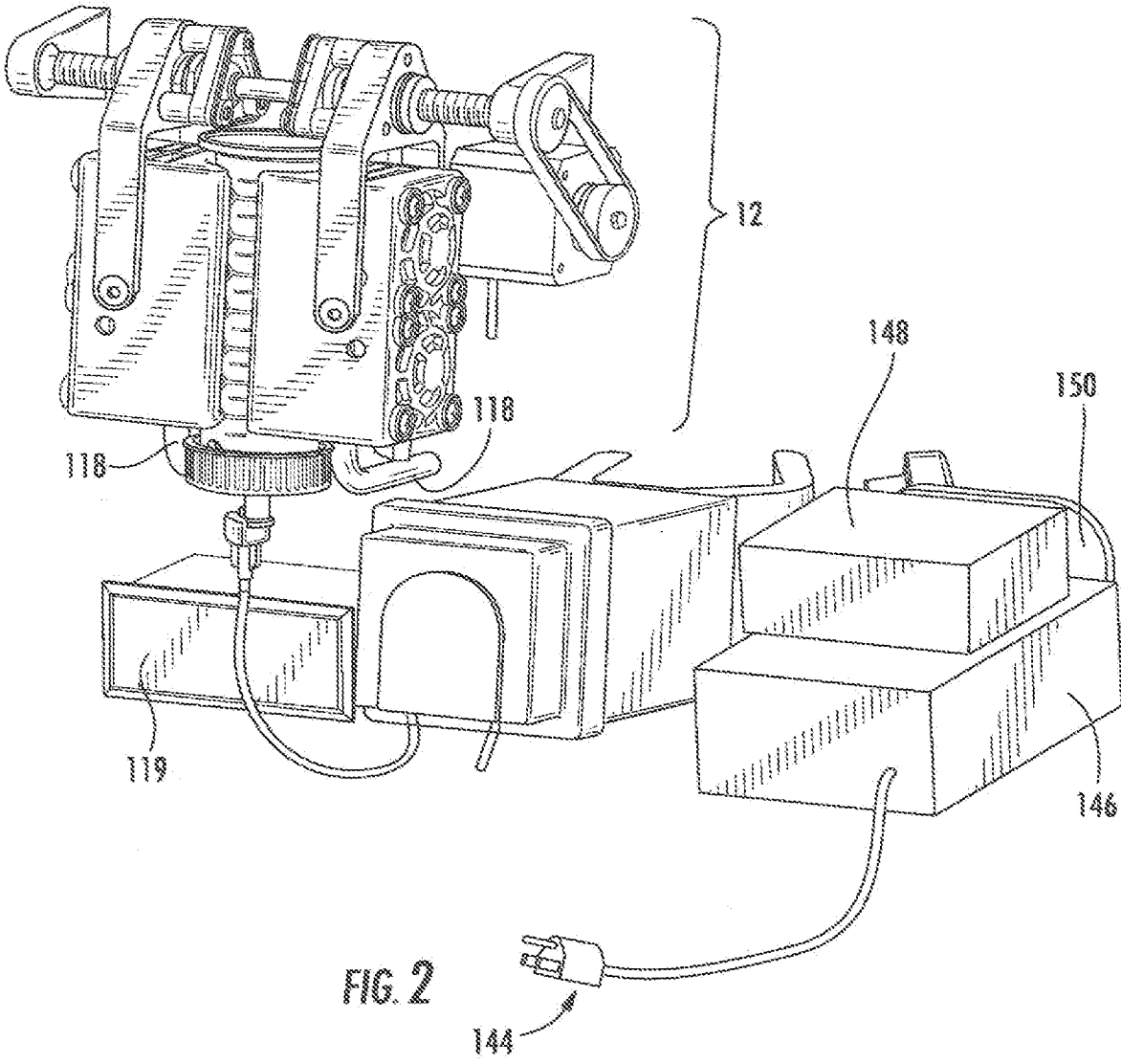
a cap body having a thread for threadable engagement to the
20 thread of the container;

an output port in the cap body for providing fluid communication between the interior of the container when the cap is threaded onto the container and a tube connectable to the output port; and

a venting mechanism in the cap body for allowing air to be
25 introduced into the interior of the container.

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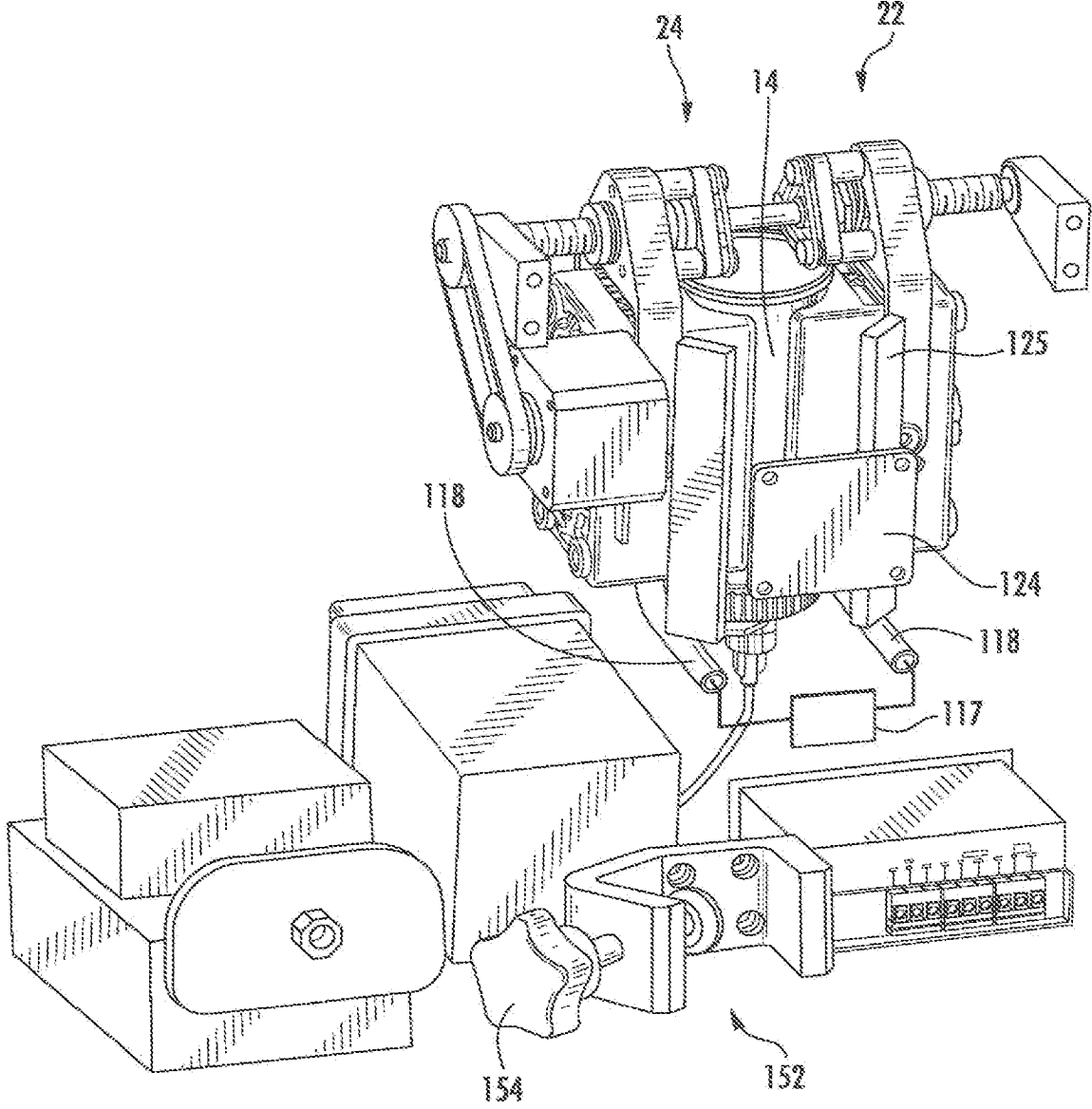
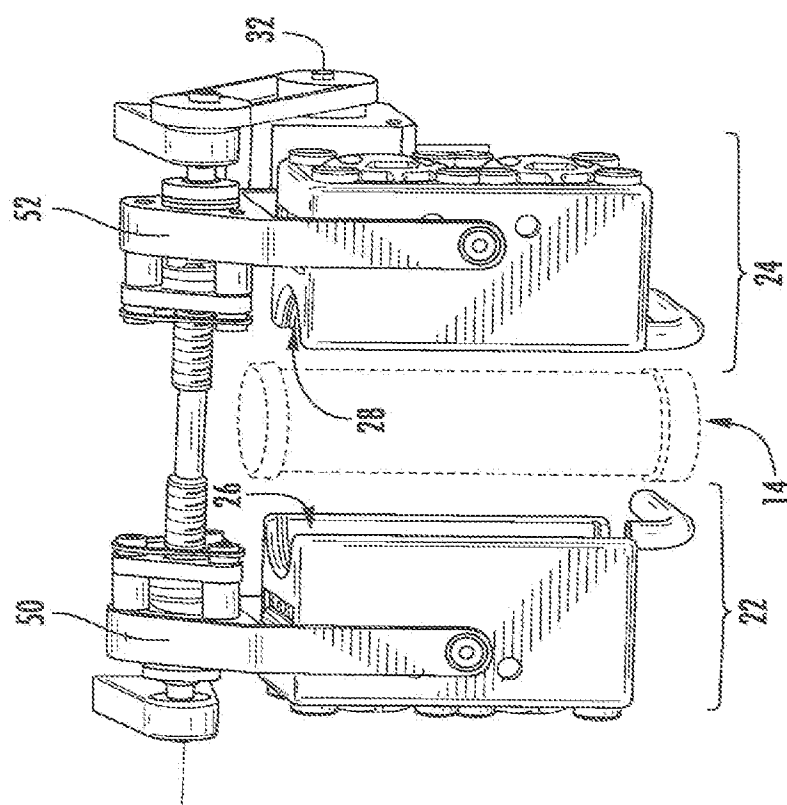
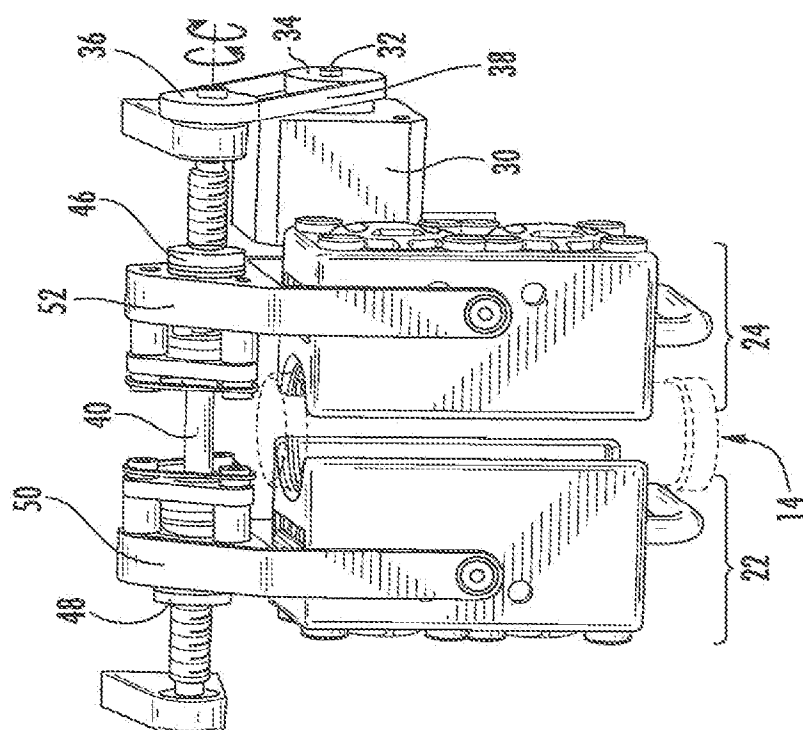


FIG. 3

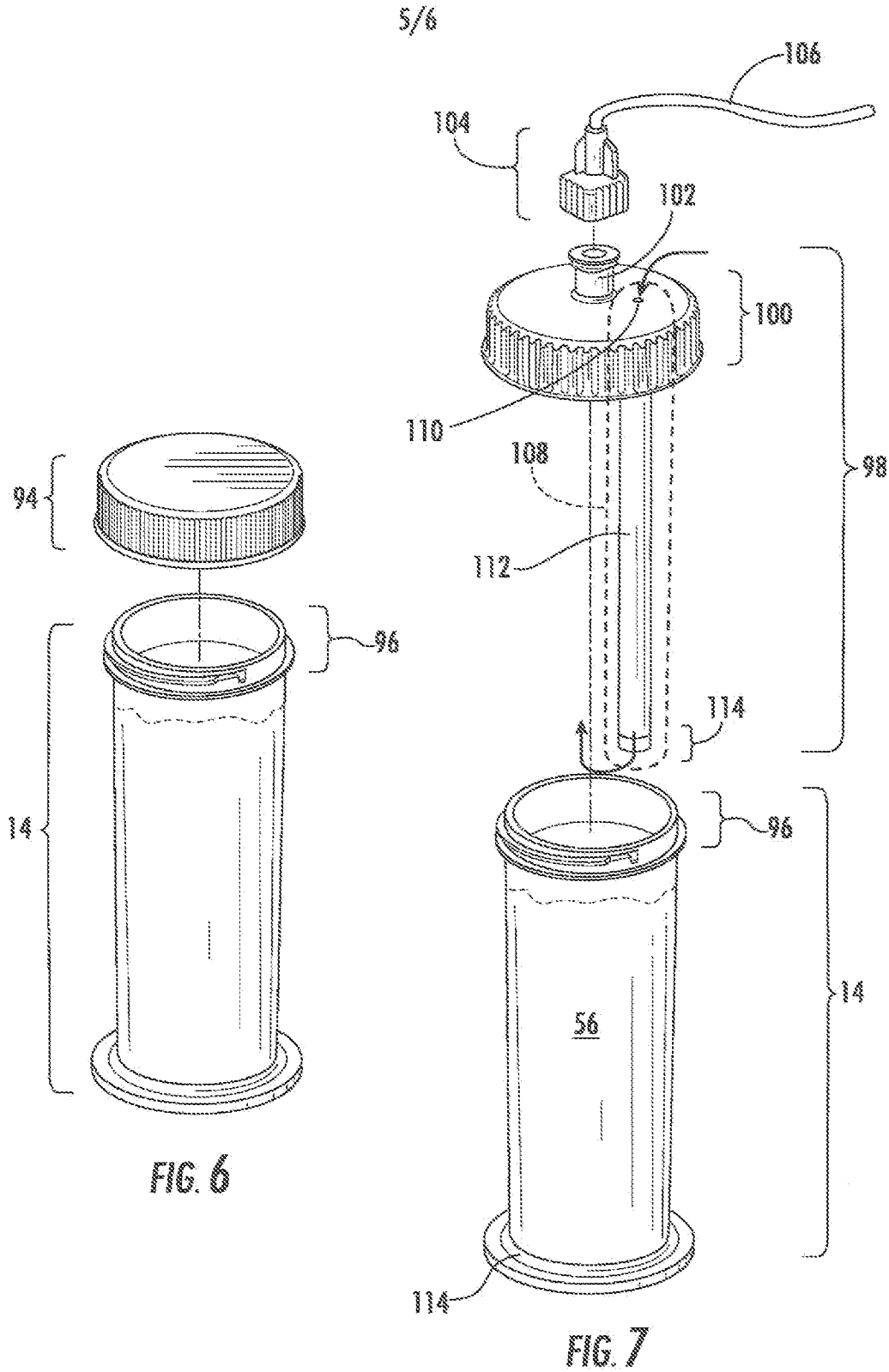
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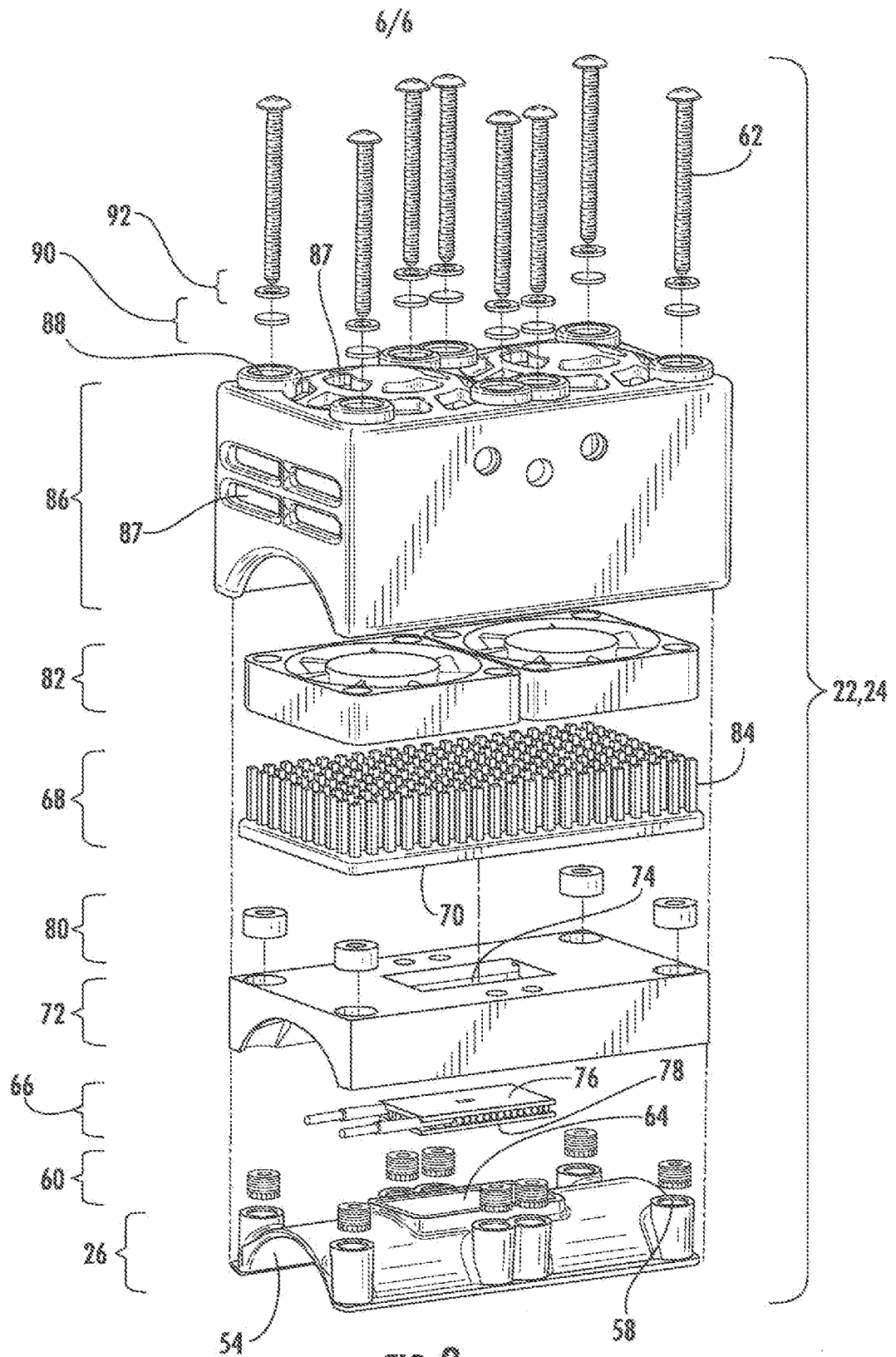


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2000





INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2015/042508

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A47J 36/24 (2015.01)

CPC - A47J 36/2433 (2015.11)

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) - A47J 36/24; A61J 9/00; A61M 1/00, 5/44; F25B 21/02 (2015.01)

CPC - A47J 36/2433, 36/2438; A61J 9/00; A61M 5/44; F25D 31/005, 31/007, 2331/803 (2015.11)

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

USPC - 62/3.6; 219/386, 387; 392/444; 604/93.01 (keyword delimited)

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

PatBase, Google Patents, Google Scholar

Search terms used: heating breast milk before giving to neonate cooling below room temperature controller sitr bar

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 2012/174315 A1 (SANDBOX MEDICAL LLC) 20 December 2012 (20.12.2012) entire document	1, 2, 7-10, 12-15, 36-43
Y	US 2004/0140304 A1 (LEYENDECKER) 22 July 2004 (22.07.2004) entire document	1, 2, 7-10, 12-15, 36-43
Y	US 4,162,855 A (BENDER) 31 July 1979 (31.07.1979) entire document	14, 15
A	US 2008/0075819 A1 (HARTMANN et al) 27 March 2008 (27.03.2008) entire document	1-16, 36-43
A	US 2010/0326285 A1 (KANG) 30 December 2010 (30.12.2010) entire document	1-16, 36-43
A	US 2007/0017229 A1 (SHIM) 25 January 2007 (25.01.2007) entire document	1-16, 36-43



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents:

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

“E” earlier application or patent but published on or after the international filing date

“L” document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

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

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

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

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

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

“&” document member of the same patent family

Date of the actual completion of the international search

19 November 2015

Date of mailing of the international search report

22 DEC 2015

Name and mailing address of the ISA/

Mail Stop PCT, Attn: ISA/US, Commissioner for Patents
P.O. Box 1450, Alexandria, Virginia 22313-1450

Facsimile No. 571-273-8300

Authorized officer

Blaine Copenheaver

PCT Helpdesk: 571-272-4300
PCT OSP: 571-272-7774

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2015/042508

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:
see extra sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-16, 36-43

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I, claims 1-16 and 36-43, are drawn to a system comprising a cooling unit.

Group II, claims 17-35, are drawn to a system comprising a controller for controlling a pump to provide a consistent flow rate.

Group III, claims 44-49, are drawn to a cap for sealing a container.

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical features of Group I, a system for feeding a neonate, the system comprising: a cooling unit for cooling breast milk before and/or during and/or after a feeding cycle; a pump for pumping the breast milk contained within a container to the neonate; a controller for controlling the cooling unit and the pump; and wherein the controller initiates a signal that activates the cooling unit to cool the breast milk in the container to a temperature below room temperature before and/or during and/or after the feeding cycle to mitigate bacteria growth and reduction of fat content, are not present in Groups II and III; the special technical features of Group II, a system for feeding a neonate, the system comprising: a holding mechanism for a container containing nutritional fluid for the neonate; a pump for pumping the nutritional fluid contained within the container; and a controller operative to start and stop operation of the pump for starting and stopping flow of nutritional fluid in a tube connected in fluid communication with the container and disposed within the neonate to deliver the nutritional fluid to the neonate, are not present in Groups I and III; and the special technical features of Group III, a cap for sealing a container wherein the cap and the container are disposable within a system for feeding a neonate, the cap comprising: a body having a thread for threadable engagement to a mating thread of the container; an output port in the body for providing fluid communication between an interior of the container when the cap is threaded onto the container and a tube connectable to the output port; and a venting mechanism in the body for allowing air to be introduced into the container, are not present in Groups I and II.

Groups I through III all share the technical feature of a system for feeding a neonate comprising a container. However this shared technical feature does not represent a contribution over the prior art. Specifically US 2008/0039778 A1 to Goldie et al. disclose a system for feeding a neonate comprising a container (FIG. 1; Abstract "computer controlled bottle system... for a preterm infant oral feeding... a method for delivering nutritional fluids orally to a preterm infant").

Groups I and II also share the technical feature of a pump for pumping the breast milk contained within a container to the neonate, and receiving parameters into a controller of the system to start a feeding cycle after a period of time has elapsed. However this shared technical feature does not represent a contribution over the prior art. Specifically US 2008/0039778 A1 to Goldie et al. disclose a pump for pumping the breast milk contained within a container to the neonate (pump assembly 430; FIG. 4; para. [0025] "peristaltic pump assembly 430... which in turn initiates fluid from the collapsible fluid bag 235"), and receiving parameters into a controller of the system to start a feeding cycle after a period of time has elapsed (para. [0021] "computer controlled bottle control software may be programmed to either terminate or delay the onset of milk delivery" and "nurse discretion may be counted upon to determine if infant milk delivery should be delayed or terminated").

Groups II and III also share the technical feature of an output port on a first end of the container, and a tube connectable to the output port. However this shared technical feature does not represent a contribution over the prior art. Specifically US 2008/0039778 A1 to Goldie et al. disclose an output port on a first end of the container (FIGS. 2-3 illustrate the nipple 210 being on a first end of the bottle container; para. [0023] "nipple 210 is shown with the distal end of two separate conduit ports, the milk delivery tube 220 and the intra-oral pressure tube 230"), and a tube connectable to the output port (milk delivery tube 220; FIGS. 2-3; para. [0023]).

Since none of the special technical features of the Group I-III inventions are found in more than one of the inventions, unity of invention is lacking.