(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
12 February 2015 (12.02.2015)

WIPO | PCT

(10) International Publication Number
WO 2015/019257 A1

(51) International Patent Classification:
*A61M 19/00* (2006.01) *A61F 7/00* (2006.01)

(21) International Application Number:
PCT/IB2014/063606

(22) International Filing Date:
1 August 2014 (01.08.2014)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/862,131 5 August 2013 (05.08.2013) US
61/862,139 5 August 2013 (05.08.2013) US

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(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

**Published**:

— *with international search report (Art. 21(3))*

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*

(54) Title: METHOD AND SYSTEM FOR PRODUCING AND DELIVERING AIRLESS MEDICAL ICE SLURRY TO INDUCE HYPOTHERMIA

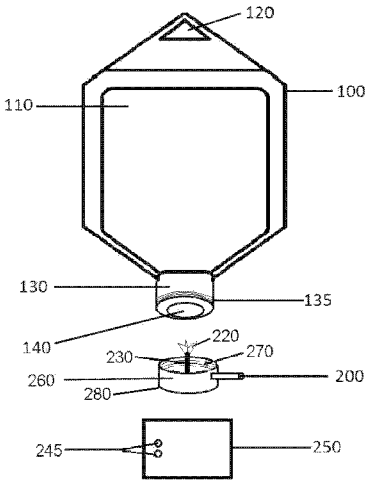


Fig. 1

(57) Abstract: The present invention relates to a method and system for producing and delivering sterile, airless, and highly loaded ice slurry for inducing therapeutic hypothermia. The method is capable of producing and delivering ice slurry in a patient to induce hypothermia through internal and external cooling methods such as subcutaneous, intravascular, intraperitoneal, gastrointestinal, and lung methods. The method is capable of producing and delivering saline ice slurry or other phase-change slurries compatible with human tissues. Ice slurry is made by crushing, smoothing, and mixing ice slush in an airtight and self-collapsible liquid container, followed by being pumped out through flexible tubing and injection port into a patient body without air. The novel method and system are simple, and easy to use, which facilitate long term storage, immediately ready to use, and airless delivery.

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# Description

# Title of Invention: METHOD AND SYSTEM FOR PRODUCING AND DELIVERING AIRLESS MEDICAL ICE SLURRY TO INDUCE HYPOTHERMIA

## Technical Field

[1] The present invention relates to a method for the preparation of sterile and airless medical ice slurry and using it for inducing hypothermia in a patient. Still more specifically this invention relates to an improved method and apparatus for the preparation, storage, and delivery of sterile medical ice slurry that is deliverable through a variety of small diameter catheters inserted into patient's blood vessel or body for inducing therapeutic hypothermia without introducing air bubbles into the blood stream.

## Background Art

[2] Control of a patient's body temperature down to therapeutic hypothermia while undergoing medical treatments such as surgical procedures in the operating room, emergency room, or intensive care unit is beneficial. Despite various types of cooling apparatus and methods have been utilized in the past for inducing therapeutic hypothermia, it lacks a rapid and efficient cooling technology to meet the time window for optimal efficacy.

[3] Recently, ice slurry was introduced to as a method to achieve hypothermia. It allows rapid and highly controlled cooling of a specific organ or group of organs and in most cases allows multiple targets or whole body to be protectively cooled to optimum individually protective temperatures.

[4] The use of medical ice slurry to induce hypothermia is known in the art. A slurry of frozen saline is administered through injection means to rapidly cool organs to reduce metabolic demand and increase the likelihood of cell survival during periods of oxygen deprivation. A different number of apparatuses are utilized to create and produce the medical ice slurry utilized in this process.

[5] For example, U.S. Pat. No. 6,547,811 by Lance B. Becker, Terry Vanden Hoek, and Kenneth E. Kasza issued Jul. 2, 2002, and entitled "Method for Inducing Hypothermia" discloses systems for phase-change particulate slurry cooling equipment and methods to induce hypothermia in a patient through internal and external cooling. Subcutaneous, intravascular, intraperitoneal, gastrointestinal, and lung methods of cooling are carried out using saline ice slurries or other phase-change slurries compatible with human tissue. Perfluorocarbon slurries or other slurry types compatible with human tissue are used for pulmonary cooling. Traditional external cooling methods are

improved by utilizing phase-change slurry materials in cooling caps and torso blankets. U.S. Patent No. 7389653 B2 by Kenneth E. Kasza et al., discloses an apparatus for producing sterile ice slurries for medical cooling applications. The apparatus includes a slurry production reservoir adapted to contain a volume of a saline solution, or other solution containing a freezing point depressant. A flexible membrane crystallization surface is provided within the slurry production reservoir. The membrane is chilled to a temperature below a freezing point of the saline solution within the reservoir such that ice particles form on the membrane. A deflector in the form of a reciprocating member is provided for periodically distorting the membrane and dislodging the ice particles, which form on the membrane.

[6] U.S. Patent number 8,505,315 published Aug. 13, 2013, filed Feb. 6, 2009, by Kenneth E. Kasza et al., discloses an apparatus for producing sterile ice slurries for medical cooling applications. The ice slurry production apparatus includes a blender container receiving sterile saline carrier liquid and sterile chunk ice, a cutter blade, a slurry conditioning-agitator mechanical mechanism coupled to blender cover, a slurry delivery tube and a tubing pump, and an electric power transformer for controlling blender speed.

## Disclosure of Invention

### Technical Problem

[7] Principal aspects of the present invention are to provide an enhanced method and device for the preparation, storage, and delivery of sterile medical ice slush and slurry. Important aspects of the present invention are to provide such method and device for the producing and delivering of sterile medical ice slurry substantially without negative effect and that overcome some of the disadvantages of prior art arrangements.

[8] For instance, U.S. Patent No. 8,505,315 teaches the use of a blender device. This patent teaches the creation of sterile slurry modules which are placing the saline solution and ice in the form of cubes or crushed ice, which are then emptied into a blender, which chops the ingredients of the slurry modules to create ice particles of the desired size. One of the main problems with this blender method of making ice slurry is that start-up of the motor under peak load conditions--i.e., with the blender filled with ice and saline solution--often require large power to operate blender motor. Additionally, the use of ice cubes or chopped ice causes the blender blades to make a great deal of heat while melting the ice particles and reducing the ice loading rapidly. Moreover, its mechanism is limited because the open use of the blender is likely to create an unnecessary and dangerous level of air in the medical slurry. As the blender chops up the chunks of ice and sends the medical slurry to a delivery tube, air surrounding the slurry can be incorporated to the medical slurry. The air incorporated into

the medical slurry has the capability to form unwanted gas bubbles in the delivery system of the medical slurry. These gas bubbles may be delivered intravenously to the patient receiving the medical slurry. As such, these gas bubbles may cause the patient to experience an arterial gas embolism. Additionally, the blender device needs a conditioning-agitator mechanical mechanism to enhance mixing, further complicated the system. Therefore, what is needed is a simple method and device which may create and deliver sterile medical slurry efficiently without incorporating gas into the slurry.

## Advantageous Effects of Invention

### Advantageous Effects

[9] The following presents a simplified summary in order to provide a basic understanding of some aspects of the disclosed innovation. This summary is not an extensive overview, and it is not intended to identify key/critical elements or to delineate the scope thereof. Its sole purpose is to present some concepts in a simplified form as a prelude to the more detailed description that is presented later.

[10] In summary, the state of the art related to the preparation of fine sterile medical ice slurry comprises: methods and devices for efficient and rapid production and delivery of medical ice slurry through small diameter medical catheters without blending gas bubbles into.

[11] In accordance with features of the invention, a method and a system utilize: an airtight deformable container containing sterile pre-conditioned ice slurry ingredients, an agitator used to crush, smooth, and mix the slurry ingredients into ice slurry, An outlet port coupled by a slurry delivery tube, a slurry delivery tubing pump, and an associated specially designed slurry injector tip connected to the discharge end of a pump tube is used to pump slurry out of the deformable container. A variable electric power transformer is used to control agitator speed and cycle during the crushing, smoothing and mixing, and delivering processes. The tubing pump through calibration allows the setting of slurry delivery rate and also tracts amount delivered both of which facilitate reaching a targeted protective cooling temperature.

[12] In accordance with features of the invention, the use of the partially frozen slush with weak molecular bonding for the production of medical ice slurry rather than solid or chunk ice in prior art generates less heat to melt the ice in crushing process and require less power assumption. Therefore a light duty power supply and electric motor is sufficient, which is favor to miniaturize the system.

[13] In accordance with features of the invention, a less rigid container can be used in the system rather than a rigid blender container. An airtight deformable container prevents air being blended in the ice slurry, which is essential for deliver ice slurry via blood stream. The container collapses while the ice slurry is pumped out. The collapsed

container wall pushes ice slurry toward the mixing device and the outlet port, and reduces the need of an additional conditioning-agitator mechanical mechanism.

[14] Moreover, the option of using pre-conditioned ice slush in an airtight deformable container eliminates transferring ingredients into additional blender container for pumping. The preparation, storage, and delivery of ice slurry can be processed in the same container without additional transfer process, which maintains the sterility. Blender ingredients preparation procedures provide improved capability for making medical sterile slurry from sterile slush and enable quick and reliable delivery of sterile slurry.

[15] In accordance with features of the invention, the ice slush can be formed in the airtight deformable container, and be stored in the same container at right condition for long period of time such as a week, before being converted to ice slurry and being used in patient. The long term storage warrants a massive production in practice.

[16] In accordance with features of the invention, the components which have direct contact with ice slush or slurry can be disposables, reducing the re-sterilization challenge.

[17] Still other objects of the present invention will become readily apparent to those skilled in this art from the following description wherein there is shown and described the embodiments of this invention, simply by way of illustration of one of modes suited to carry out the invention. As it will be realized, the invention is capable of other different embodiments and its several details are capable of modifications in various obvious aspects all without departing from the scope of the invention. Accordingly, the drawing and descriptions will be regarded as illustrative in nature and not as restrictive.

## Brief Description of Drawings

### Description of Drawings

[18] Various exemplary embodiments of this invention will be described in detail, wherein like reference numerals refer to identical or similar components, with reference to the following figures, wherein:

[19] FIG. 1 is a side view of the self-collapsible container, mixing device, and driver.

[20] FIG. 2 is a side view of the self-collapsible container with a storage lid.

[21] FIG. 3 is a side view of the self-collapsible container attached to the mixing device and the mixing device connected to a pump device.

[22] FIG. 4A is a side view of another embodiment of the mixing device.

[23] FIG. 4B is a side view of another embodiment of the mixing device.

[24] FIG. 5 is a schematic view of integrated producing and delivering system.

[25] FIG. 6 is a perspective view of an embodiment of the slurry ingredients formation device.

[26] FIG. 7 is a perspective view of another embodiment of the slurry ingredients formation device.

## Best Mode for Carrying out the Invention

### Best Mode

[27] The claimed subject matter is now described with reference to the drawings. In the following description, for purposes of explanation, numerous specific details are set forth in order to provide a thorough understanding of the claimed subject matter. It may be evident, however, that the claimed subject matter may be practiced with or without any combination of these specific details, without departing from the spirit and scope of this invention and the claims.

[28] In literature, ice slush and ice slurry are both defined as a mixture of small ice crystals and liquid water. The ice slush and ice slurry are used interchangeably without commonly agreed distinction. In this application, the ice slush is different from ice slurry with the main advantage of the latter being able to pump through small sized tubing, e.g. a catheter which has 7-French (~2.33mm) diameter. At present invention, 'slurry ingredients' is used to referring both, when they are added in invented device as ingredients and before being pumped out.

[29] The medical ice slurry production and delivery is made by two general steps, each has multiple variations. Step 1: Fill an airtight and self-collapsible container, which has a mouth opening, with slurry ingredients. The self-collapsible container and its content of slurry ingredients may be stored at the storing temperature (such as -1.0°C) for several days before being used. During the storage, a lid is used to seal the mouth opening. Step 2: Before being on a patient body, the lid for storage is removed. A mixing device, with an agitator and an outlet port, is attached to the airtight and self-collapsible container via the mouth opening. If air entered into the container during the attaching, the air will be removed by pointing the outlet port upwards and squeezing the air bubble out through the outlet port. The outlet port is connected to a flexible tubing. The other end of the flexible tubing connects to a medical port / catheter directly or via an adaptor for delivering the ice slurry into patient. The agitator mixes and agitates the slurry ingredients in the container to breaks the weak bonds between ice particles into fine and smooth particles during operation. Thus the slurry ingredients are converted into ice slurry which is pumpable through small sized tubing. Then the ice slurry is pumped out through the outlet port by a pump via the flexible tubing, and through the medical port / catheter into the patient without air bubble.

[30] To make sterile ice slurry, the following components should be sterile: the slurry ingredients, and the inner surfaces of the container, flexible tubing, catheter, and the mixing device. If a peristaltic pump is used, the pump element need not be sterile.

[31] The process of preparing the slurry ingredients for step 1 can be done through many number of methods. One of methods involves filling liquid solutions in an airtight and self-collapsible container, slowly rotating the container in a cooling unit, and stopping the freezing process after a set fraction of water (such as <70%) is frozen. The mouth opening of the container is covered by a removable lid after the container is filled. The liquid solutions are mixture of water, at least one type of freezing point depressing chemical(s), and zero or more other types of chemical(s) and / or component(s) (e.g. blood plasma). The rotation of the container provides top and bottom circulation so the mixture is well mixed with the same temperature. When the temperature of the mixture is below freezing temperature, the initial phase change (water freezing into micro ice nuclei) happens in the container homogenously. The circulation keeps the solution mixed and tends to promote an even temperature distribution. The freezing of ice continues into forming a soft dendritic form, whose bond between the ice particles is easy to break. After additional mixing and smoothing, there is no big particles or sharp edge inside the slush ingredients. During the operation the self-collapsible container may be partially filled under its maximum filling capacity. No air is allowed in the container through the collapse of the container wall. A mixing device may be used to replace the lid to seal the air tight container during freezing and storing to reduce operation procedure.

[32] The partially filling of the container and the absence of air further promote the deforming of the flexible container wall when the liquid flows inside the flexible container during the rotation. The deforming of the container wall acts as an extra mixing feature to: 1) evenly mix the ice and liquid mixture across the container, 2) scrape off the thin dendritic ice layer frozen on the inner surface of the container wall, 3) prevent the forming of big ice crystals, and 3) break up larger crystal matrices and promote the creation and maintenance of a small slush mixture (as opposed to coarse).

[33] Alternative method of preparing the slurry ingredients may use the method disclosed in United States Patent 7,874,167 by filling the airtight and self-collapsible container with saline or other chemical solution and seal the mouth opening with a lid.

[34] Another method is to transfer the ice slurry made by the method disclosed in United States Patent 5,402,644 or the method disclosed in United States Patent No. 8,505,315 into the airtight and self-collapsible container as slurry ingredients for airless delivery.

[35] Referring to FIG. 1, one of the embodiments of the invention is displayed. The system utilizes a container 100 and a mixing device 280. The container 100 has a collapsible pouch 110 which holds the slurry ingredients. The container 100 has a hanging point 120 which allows a user to hang the container 100 from a supporting hook. One end of the container 100 has a container neck 130. The container neck 130 has a mouth opening 140. The container neck 130 has an external neck thread 135 which allows the

container 100 to be attached and secured to the mixing device 280. The container neck 130 could be formed from a rigid material.

[36] The mixing device 280 has a container attachment 260 for attaching the container 100 to the mixing device 280. The container attachment 260 has an internal attachment thread 270 which is complementary to the external neck thread 135. It may have a rubberized or silicone gasket or o-ring (not shown) to further ensure an airtight fit between the container 100 and container attachment 260. The outlet port 200 is located on the side wall of container attachment 260. The mixing device has an agitator 230. The agitator 230 has a long rotational axel which terminates in a plurality of agitating protrusions 220. The agitator 230 is driven by a driver 250, which is controlled by a control means 245. A user can operate the driver 250 via the control means 245. When the driver 250 is turned on the agitator 230 rotates about its longitudinal axis. The user can also control the speed at which the agitator 230 rotates via the control means 245. The agitator 230 rotates around the rotational axis, causing the agitating protrusions 220 to spin around. The agitator 230 serves multiple purposes: crushing and smoothing big ice particles into fine particles and mixing the ice and liquid mixture during the delivery with constant or variable speed. The control means 245 may be any type of structure or means which permits a user to turn on the driver 250 and control the speed of use. For instance the control means 245 could be one or more knobs, one or more switches, one or more buttons, a touchscreen, any combination of these elements, or merely an on/off in power supply. Those of skill in the art may find that the ice slurry may be used directly by removing it from container 100 through mouth opening 140.

[37] Referring to FIG. 2, the container 100 may be stored prior to being attached to the mixing device 280. To ensure that the slurry ingredients do not leak from the container 100, a container lid 150 may be placed on the container neck 130. The container lid 150 is also placed on the container neck 130 during the formation process of forming the slurry ingredients. The container lid 150 may have a rubberized or silicone gasket or o-ring (not shown) to further ensure an airtight fit between the container 100 and container lid 150. In the embodiment shown the container lid 150 has a lid internal thread 155 which is complementary to the external neck thread 135.

[38] The means of securing the container 100 to the mixing device 280 or container lid 150 may be made through any known means or other embodiments. The referenced figures display a means of securing by screwing the container 100 onto the mixing device 280 or container lid 150. The container 100 may be attached to the mixing device 280 or container lid 150 by snapping the components together or using another attachment means that creates an airtight seal between the container 100 and the mixing device 280 or the container lid 150.

[39] Referring to FIG. 3, the conjunction between the container 100 and the mixing

device 280 and the utilization of the system is displayed. The container 100 is attached by to the mixing device by securing the container neck 130 to the container attachment 260 on the mixing device 280. In the embodiment displayed the external neck thread 135 (shown in FIG. 1) is threaded to the internal attachment thread 270 (shown in FIG. 1) to removably secure the container 100 to the mixing device 280. The container neck 130 and container attachment 260 form an airtight connection to prevent any leakage of medical ice slurry from the container 100 and prevent the intrusion of any air into the container. A rubberized or silicone gasket or o-ring (not shown) may be placed within the container attachment 260 to further ensure an airtight fit between the container 100 and mixing device 280. When the container 100 is secured to the mixing device 280, the agitator 230 protrudes through the mouth opening 140 of the container and contacts the slurry ingredients in the container 100.

[40] The container 100, containing slurry ingredients, is secured to the mixing device 280. Initially, the agitator 230 stirs to crush big ice particles and break the conglomeration of ice particles for short period of time, such as 20 seconds, then a pump 400 starts to pump the ice slurry out of the outlet port 200 and continues through a flexible tubing 300. The medical ice slurry is pumped out of the container 100 by the pump 400. The medical ice slurry is delivered to the patient through the flexible tubing 300 and an injection port 600. The flexible tubing 300 and the injection port 600 may be interfaced with an adapter 500.

[41] The mixing device 280 is installed to the container 100 after removing the container lid 150 which is used during freezing and storing. The outlet port 200 is plugged into the flexible tubing 300. The flexible tubing 300 is routed through a pump 400, which is used to pump medical ice slurry through the injection port 600 for a particular medical cooling application. The pump 400 may be any pump known to those with skill in the art, such as a peristaltic pump. The injection port 600, such as various catheters or medical ports, known for different medical applications are connected to the other end of flexible tubing 300 directly or via a tubing adaptor 500. The slurry ingredients, the inside of the container 100, the mixing device 280, the flexible tubing 300, tubing adaptor 500, and the injection port 600 have direct contact with ice slurry have to be sterile for making a sterile ice slurry. A driver 250 will drive the agitator 230 (shown in FIG.1) to crush, smooth, and mix slurry ingredients.

[42] A wire guard 210 may be used to protect the cutting or scratching of the collapsible pouch 110 from the agitator 230 as referred by FIG. 4A. In this embodiment the mixing device 280 has a wire guard 210 which is placed around the agitator 230. The wire guard 210 prevents the agitating protrusions 220 from coming in contact with the collapsible pouch 110 in the container 100. If a wire guard 210 is not used, the container neck 130 and the lower portion of the container which connects to the neck

130 may be made of rigid material to protect the pouch being cut when it collapse due to air pressure.

[43] Referring to FIG. 4B, other embodiments of the mixing device 280 could be used. In these embodiments the agitator 230 is elongated and contains multiple sets of agitating protrusions 220. The agitating protrusions 220 may be flat blades (as shown) or spherical balls (not shown) which cut, smooth, and agitate the slurry ingredients in the collapsible pouch 110. The agitator 230 may be in any length or shape sufficient to rotate about a longitudinal axis to stir the medical ice slurry. The agitator 230 may have any number of agitating protrusions 220 placed in any location on the agitator 230. The agitating protrusions 220 may be any shape sufficient to break the medical ice slurry and mix the slurry. Each blade may have different shape and design associated with different functions such as cutting, mixing and circulating. The agitator 230 and agitating protrusions 220 may be made of any material, including but not limited to metal or plastic, such as stainless steel or polyethylene or polystyrene. Protective means, such as a wire guard, may be used to prevent the pouch being cut by the protrusions.

[44] FIG. 5 is a scheme of one embodiment with the driver 250 and the pump 400 being integrated. The mixing device 280 is connected to the driver 250, which gets power from a power source 254. The power source 254 may be an external power source or an internal power source. The driver 250 and the pump 400 are controlled by a microcontroller (MCU) 252, which may be any type of central processing unit. The MCU 252 receives commands from the control means 245 for the settings of driver 250 and pump 400. A user can control the producing and delivering of medical ice slurry through the control means 245. The MCU 252 may display information at a display screen 256. The display screen 256 displays information such as status of ice slurry, the amount of ice slurry pumped through the mixing device 280 and the pump rate setting.

[45] The display screen 256 may also display rotation speed or setting of the driver 250. The MCU 252 controls the driver 250. The driver 250 provides the rotation to the agitator 230. In some embodiments the driver 250 may cause the agitator 230 to rotate both clockwise and counterclockwise. The driver 250 may also cause the agitator 230 to move in a longitudinal direction. In this manner the agitator 230 may move further into the container 100 and back out in and in and out motion. This motion may be made while the agitator 230 rotates. The agitator 230 is connected to the driver 250 by a motor shaft attachment 235. The agitator 230 may be permanently or removeably attached to the mixing device 280. In one embodiment, the agitator 230 may be removed and replaced with another agitator 230. The exterior of the mixing device 280 and the driver 250 may have features such as a pair of matching groove and bulge re-

spectively to prevent the relative rotation between the two.

[46] The utilization of the system will now be described. First a known amount of slurry ingredients are produced elsewhere and transferred to the flexible and self-collapsible container 100 via the mouth opening 140. In other option, ice slush can be directly made by putting the container 100, which is filled with saline solution and closed with a container lid 150, in a cooling unit. The container lid 150 is replaced by the mixing device 280 before pump and delivery. The mixing device 280, which has the same matching threads as container lid 150, is screwed onto mouth opening 140 to seal the container to prevent air entering and liquid leaking. If there is air in the container, it can be removed via the outlet port 200 by orienting the outlet port 200 upward and squeezing air out through outlet port 200. Once air is removed, a flexible tubing 300 is connected to the outlet port. The flexible tubing 300 may be clamped by any known means such as the roller of a peristaltic pump to prevent air getting into the container 100.

[47] The mixing device 280 with an agitator 230, driven by a driver 250, is used to mix / agitate the liquid and ice mixture. The agitator 230 also breaks the weak bonds between ice particles to form fine particles during operation and smooth the sharp edges and rough surfaces of the ice particles. A selected mixing speed or energy level is selected together with a selected mixing duration to further cause ice particles suspending in the ice slurry mixture. The slurry fluidity depends on ice fraction, the size and shape of the ice particles, and the evenly mixing of the mixture. A flexible tubing 300, such as a silicone delivery tubing, connects the outlet port 200, the adaptor 500 (optional), and the injection port 600, which is inserted into the patient. The pump 400 transports the ice slurry through the above components from container 100 to patient while the agitator 230 is mixing and agitating the ice slurry mixture.

[48] The container 100 is flexible and self-collapsible due to the collapsible pouch 110. While the ice slurry is pumped out, the collapsible pouch wall collapses (by air pressure) and pushes slurry particles and liquid toward the outlet port 200 and pushes the ice slurry into the vortex caused by the agitator 230. The airtight feature of the container 100 prevents air from getting into ice slurry from outside of the container 100, eliminating air embolism for intravascular applications, and forces the container 100 to collapse and push the ice slurry to the vortex. Preventing air from entering the container 100 also forces the space between ice particles to be occupied by liquid, facilitating the flowing of the mixture.

[49] One of ordinary skill in the art will recognize that other choices and arrangements of components could be made in order to deliver ice slurry without air embolism. The following are examples only and are not intended to limit the scope of the invention. The agitator 230 may be tilted at various angles from the axis of the container 100 to

ensure thorough mixing of the ice particles and liquid, and preventing the creation of undesirable stagnant pools of unmixed slurry within the container 100. The axis of the container 100 may be in directions other than up and down. The outlet port 200 can be integrated on the container 100 instead of being incorporated on the container attachment 260.

[50] One of ordinary skill in the art will recognize that the mixing device 280 can be at places other than bottom of the container, such as located at the top of the container 100. The top or bottom location is referring to the direction of gravity force. In this embodiment the mixing device 280 may be mounted on a wall or on a medical cart with the container attachment 260 positioned downwards. The container 100 is then attached onto the container attachment 260 from below. The ice slurry is pumped out from the outlet port 200 at top. Since ice particles in ice slurry have a lower density than water, the ice particles flow to the top of the slurry mixture. Pumping from the top may increases the ice fraction of delivered ice slurry while a squeezing device may be required to push the contents of the container upwards.

[51] A squeezing device may be applied on the wall of container 100. The squeezing device could be a pair of rollers, a pair of squeezing pads or inflatable cuff connected to an air pump. The squeezing device may provide additional agitation and mixing effect on the collapsible pouch 110 to the ice slurry. The squeezing device could be coupled to move towards or opposite to each other to squeeze and mix the ice slurry.

[52] One of ordinary skill in the art will recognize that the mixing device 280 may also be at side of the container 100. The location is referring to the direction of gravity force.

[53] One of skill in the art will recognize that some of the alternative implementations set forth above are not universally mutually exclusive and that in some cases additional implementations can be created that employ aspects of two or more of the variations described above. Likewise, the present disclosure is not limited to the specific examples or particular embodiments provided to promote understanding of the various teachings of the present disclosure. Moreover, the scope of the claims which follow covers the range of variations, modifications, and substitutes for the components described herein as would be known to those of skill in the art.

[54] The slurry ingredients are formed in the container 100 prior to connecting the container 100 to the mixing device 280. The slurry ingredients may be formed in any manner and any known process. Referring to FIG. 6, a novel slurry ingredients formation device is displayed. The formation device has a rotating member 710 for holding the container 100 (the container neck is omitted for simplification of the figures). The rotating member 710 may hold one or more containers 100 during the formation process. In the embodiment displayed the rotating member 710 is a cylindrical wire frame. The rotating member 710 has an opening 715 to permit a user

to add and remove containers 100. The rotating member 710 is attached at either end of the cylinder to an axel 720. One axel 720 is connected to a motor 730 which provides rotational power and movement to the rotating member 710. On one side the axel 720 is connected to a support frame 740. On the opposite side the motor 730 is connected to another support frame 740.

[55] The container 100 is placed directly in the rotating member 710 via an opening 715. The opening 715 is opened for receiving or removing the container 100, and remains close during the slurry ingredients formation and storage. When the rotating member 710 rotates, the container 100 rotates / tumbles freely in the rotating member 710. Those of skill in the art will appreciate that the rotating member 710 may be a wired frame or mesh, or a container with plenty of wholes.

[56] To form pre-conditioned slurry ingredients, the novel device is placed within a cooling unit (not shown). The cooling unit has a door (not shown) to open to receive or remove rotating member 710 and to shut to maintain the air temperature to cool the container 100. The container 100 is filled with mixture of water, at least one type of freezing point depressing chemical(s) such as sodium chloride, and zero or more other types of chemical(s) and / or component(s) (e.g. blood plasma or blood substitute). The rotating member 710 rotates while thecontainers 100 are cooled to turn the enclosed fluid solution into ice liquid mixture. The rotating member 710 rotates relative to its axle 720, which is mainly horizontal, installed through holes on the sidewall of cooling unit. A motor 730 placed outside or inside the cooling unit is used to rotate the rotating member 710 by providing rotation energy to the axle 720. Those of skill in the art will appreciate that for cooling unit (not shown) , a range of cooling systems could be used including but not limited to a standard compressor type system or a solid state Peltier cooling system.

[57] The purpose of the cooling unit (not shown) is to chill the air surrounding the container 100 below the freezing point of the mixture within the container 100. The cooling unit may be adapted to include one or more device(s) such as fans (not shown) to circulate the cooled air to promote the cooling speed of the container 100, and the even distribution of air temperature in cooling unit.

[58] The rotation of the container 100 provides top and bottom circulation so the mixture is well mixed and has no temperature gradient. When the temperature of the mixture is below freezing temperature, and the initial phase change (water freezing into micro ice nuclei) happens in the container 100 homogenously. The circulation keeps the solution mixed and tends to promote an even temperature distribution. Thus the ice nuclei distributes randomly across the whole body. The freezing of ice continues into soft dendritic form, which is easy to break, without big particles or sharp edges.

[59] During operation, if a flexible and deformable container 100 is used, the container

100 can be partially filled under its maximum capacity. The intended partially filling capacity and the absence of air promotes the deforming of the collapsible pouch 110 when liquid flows inside the collapsible pouch 110 during the rotation. The deforming of the collapsible pouch 110 acts as an external mixing mechanism so the mixture is evenly mixed. This deforming also provides a periodical distorting to scrape off the thin dendritic ice layer frozen on the inner surface of the wall of the collapsible pouch 110 and breaks up larger crystal matrices to promote the creation and maintenance of a fine slush mixture.

[60] The deforming of the collapsible pouch 110 acts as an external mixing device to: 1) evenly mix the mixture across the container 100, 2) scrape off the thin dendritic ice layer frozen on the inner surface of the collapsible pouch 110, 3) prevent the forming of big ice crystals, and 4) break up larger crystal matrices and promote the creation and maintenance of a fine slush mixture (as opposed to coarse).

[61] The container 100 may have exterior bagging to protect the sterility of the inner container's exterior surface during the operation. It is not necessary to maintain sterility for the cooling unit and rotating member 710.

[62] The cooling unit regulates its internal air temperature to within a specified range to allow slush / slurry of ice and liquid mixture to be produced and maintained. A temperature control system of the cooling unit can have an initial target temperature that is well below the freezing point to expedite the initial freezing of slush / slurry but then have a separate maintenance temperature intended for storage when the mixture reaches a set ice fraction. This maintenance temperature is set at or above the temperature of the mixture. The air temperature in cooling unit is allowed to fluctuate above and below the target temperature (as with a normal two temperature control scheme that results in a saw tooth temperature profile).

[63] Referring to FIG. 7, another embodiment of the slurry ingredients formation device is displayed. In this embodiment the rotating member 710 is adapted to accept support frame(s) 750. In this embodiment an axel 720 is connected at each end of the rotating member 710. One axel 720 is connected to a motor 730 which provides rotational power and movement to the rotating member 710. In this embodiment the motor 730 may be within the cooling unit (not shown) or placed outside of the cooling unit (not shown).

[64] The rotating member 710 is designed to hold one or more support frame(s) 750 that a container 100 is fastened onto. The support frame 750 can receive one container, or may be adapted to receive more containers.

[65] Each container 100 is attached to the support frame 750 by one or more attachment points 760. Each support frame 750 is then secured to the rotating member 710. The support frame 750 can be secured to the rotating member 710 by any means. In the

displayed embodiment each support frame 750 slides into one of a number of slots located in the rotating member 710 which hold the support frames 750. The container 100 is fastened on a support frame 750 via fastening techniques known to those with skill in the art, such as via a clamp, clip or Velcro. The container 100 attaches to the support frame 750 via attachment points 760 on the edges of the container 100. One with ordinary skill in the art will recognize that other choices and arrangements of components could be made in order to fasten the container 100 to the support frame 750. The following are examples of alternatives. The support frame may 750 receive more than one container. The container 100 may have exterior bagging to protect the inner container's outer surface sterility, thus the attachment points 760 are on the external bagging. The attachment points 760 could be located on the container's peripheral edges / corners or on the body of external bagging. Attachment points 760 which are located on the peripheral edges or corners are attached to support frame 750 via attachment mechanisms known to those of skill in the art, such as a clamp, clip or Velcro. The support frame 750, along with the container 100, is fastened on the rotating member 710 via mechanism known to those of skill in the art.

[66] The suspension of the containers 100 in the rotating member 710 prevents the shock and big deformation of the container 100 at low temperature. This feature facilitates a long term storage to prevent the leakage of the container 100 from the fatigue the material.

[67] The rest of the device structure and operating steps are similar for both embodiments such as the temperature control, the container, and its contents. During the freezing and storing the ice slush, the motor 730 drives the rotating member 710 to rotate about the rotating axle 720, and causes support frame 750 to rotate. This in-turn causes the container 100 to rotate. The container 100 may be rotated at a relatively slow speed (~60rpm). However, a broad range of speeds may be used. The rotation speed is determined by the balance between evenly mixing / agitating the mixture and the fatigue of the collapsible pouch 110 due to continuously deforming in long period of storage.

[68] One of ordinary skill in the art will recognize that other choices and arrangement of components could be made in order to effect the rotation of the containers 100. The following are examples only and are not intended to limit the scope of the invention. The motor 730 could be located inside of the cooling unit (not shown). The motor 730 may drive the rotating member 710 directly or via roller chains, belt, or gear(s). The support frame 750 may be arranged other than parallel. The support frame 750 may be arranged so that it orbits around the rotating axle 720, instead of spinning around. The rotating member 710 and support frame 750 could be coupled together as one piece to receive the container 100.

[69] One with skill in the art will recognize that some of the alternative implementations

set forth above are not universally mutually exclusive and that in some cases additional implementations can be created that employ aspects of two or more of the variations described above. Likewise, the present disclosure is not limited to the specific examples or particular embodiments provided to promote understanding of the various teachings of the present disclosure. Moreover, the scope of the claims which follow covers the range of variations, modifications, and substitutes for the components described herein as would be known to those of skill in the art.

[70] What has been described above includes examples of the claimed subject matter. It is, of course, not possible to describe every conceivable combination of components or methodologies for purposes of describing the claimed subject matter, but one of ordinary skill in the art can recognize that many further combinations and permutations of such matter are possible. Accordingly, the claimed subject matter is intended to embrace all such alterations, modifications and variations that fall within the spirit and scope of the appended claims. Furthermore, to the extent that the term "includes" is used in either the detailed description or the claims, such term is intended to be inclusive in a manner similar to the term "comprising" as "comprising" is interpreted when employed as a transitional word in a claim.

## Priority

[71] This application claims the benefit of U.S. Provisional Patent Application No. 61/862,131 filed August 5, 2013 and U.S. Provisional Patent Application No. 61/862,139 filed August 5, 2013, both of which are fully incorporated herein.

# Claims

[Claim 1] A system for producing and delivering medical ice slurry comprising

a. A container, said container comprising

i. a collapsible pouch;

ii. a container neck;

iii. Wherein said container neck has a mouth opening through which material can be passed into the internal cavity of said collapsible pouch.

b. A mixing device, said mixing device comprising

i. A container attachment;

ii. An agitator;

c. A driver;

d. Wherein said container neck can be removably secured to said container attachment;

e. Wherein said container neck and said container attachment form an airtight seal when secured together;

f. Wherein said agitator passes through said mouth opening when said container is secured to said mixing device;

g. Wherein said driver drives said agitator to fracture, smooth, and mixes said slurry ingredients at constant or variable speed;

h. Wherein said collapsible pouch contains slurry ingredients for use in a patient;

i. Wherein said agitator fractures, smooth, and mixes said slurry ingredients to ice slurry;

j. Wherein the wall of said collapsible pouch collapses and forces the space between ice particles of said slurry ingredients being occupied by liquid to provide fluidity for said ice slurry being well crushed and smoothed.

[Claim 2] The slurry ingredients as in claim 1 are ice slush or ice slurry.

[Claim 3] The container as in claim 1 is flexible, semi-flexible, or partially rigid and partially flexible.

[Claim 4] The agitator as in claim 1 further comprising

A plurality of agitating protrusions;

[Claim 5] The agitator as in claim 1 rotates around the rotational axis which inclines relative to vertical direction in any angle.

[Claim 6] The system as in claim 1 further comprising

a. A wire guard;

b. Wherein said wire guard is connected to said mixing device;
c. Wherein said agitator is surrounded by said wire guard;
d. Wherein said wire guard prevents said collapsible pouch from contacting said agitator when said collapsible pouch collapses down.

[Claim 7] The system as in claim 1 further comprising
a. An outlet port;
i. Wherein said outlet port protrudes from said container or from said container attachment of said mixing device;
b. A flexible tubing;
c. A pump;
d. An injection port;
e. Wherein said ice slurry is pumped from said container through said outlet port;
f. Wherein the first end of said flexible tubing is connected to said outlet port and the second end of said flexible tubing terminates in said injection port in a patient body;
g. Wherein said pump applies a mechanical force to move said ice slurry from said container into said injection port to a patient body.

[Claim 8] The pump as in claim 7 is a peristaltic pump.

[Claim 9] The system as in claim 7 further comprising
a. An adapter;
b. Wherein said flexible tubing and injection port are connected via said adaptor.

[Claim 10] The system as in claim 1 said container further comprising
a. An external mechanical device;
b. Wherein said external mechanical device applies mechanical force to said container to facilitate the smoothing and moving of said ice slurry;

[Claim 11] The external mechanical device as in claim 10 is a pair of roller, a pair of squeezing pad or inflatable cuff connected to an air pump, or an ultrasonic device.

[Claim 12] The system as in claim 1 further comprising a microcontroller.

[Claim 13] The system as in claim 1 further comprising a display.

[Claim 14] The system as in claim 1 further comprising a power source.

[Claim 15] The container as in claim 1 has one or more external bagging to protect the sterility of the exterior surface of said container before said ice slurry is used.

[Claim 16] An integrated producing and delivering device utilized to fracture, smooth, and deliver medical ice slurry to a patient comprising:

a. A container comprising
    i. a collapsible pouch contains slurry ingredients for use in a patient;
    ii. a container neck;
    iii. Wherein said container neck has a mouth opening through which said slurry ingredients can be passed into the internal cavity of said collapsible pouch.
b. A mixing device comprising
    i. A container attachment;
    ii. An agitator;
    iii. Wherein said container attachment is attached to said container neck to form an air tight seal when securing said container and mixing device together.
    iv. Wherein said agitator further comprises a plurality of agitating protrusions;
c. A driver which drives said agitator to fracture and smooth said slurry ingredients into ice slurry and mixes said ice slurry in delivery process at constant or variable speed;
d. A wire guard which is connected to said mixing device and surround said agitator to protect said collapsible pouch from contacting said agitator;
e. A control means;
f. A display;
g. A microcontroller;
h. A pump;
i. An outlet port locates either on said container or said mixing device;
j. An injection port connects to a patient body;
k. A flexible tubing
    i. Wherein the first end of said flexible tubing is connected to said outlet port and the second end of said flexible tubing is connected to said injection port;
l. Wherein said ice slurry is pumped from said container through said flexible tubing and injection port into patient body;
m. Wherein said control means, display, and microcontroller provide information to and accept control from the operator.

[Claim 17] A slurry ingredients formation device comprising:
a. A cooling unit;
b. A rotating member in said cooling unit which accepts a plurality of

collapsible containers and rotates said collapsible containers;

c. Wherein said collapsible container is filled with mixture of chemical constituents of said slurry ingredients.

[Claim 18] The cooling unit as in claim 17 is a standard compressor type freezer or a solid state Peltier cooling system.

[Claim 19] The formation device as in claim 17 further comprising a temperature controller to change the internal air temperature to a target temperature.

[Claim 20] The target temperature as in claim 19 is lower than the freezing temperature of said mixture for freezing water into ice.

[Claim 21] The target temperature of claim 19 is equal to or above the storing temperature of said slurry ingredients with desired ice fraction by volume.

[Claim 22] The formation device of claim 17 further comprising a timer and / or a temperature sensor(s) for shifting said target temperature from said freezing temperature to said storing temperature when said desired ice fraction by volume is reached.

[Claim 23] The desired ice fraction by volume as in claim 21 is between 5% and 75%.

[Claim 24] The rotating member as in claim 17 is a wired frame or mesh, or a hollow object with plenty of holes on the face.

[Claim 25] The formation device as in claim 17 further comprising a rotating mechanism and means for said rotating member to rotate at continuously variable speed.

[Claim 26] The collapsible containers as in claim 17 are fastened to said rotating member.

[Claim 27] The collapsible containers as in claim 17 freely tumble in said rotating member.

[Claim 28] A method for producing and delivering airless medical ice slurry to a patient comprising

a. Preparing a collapsible container, said collapsible container comprising

i. a collapsible pouch contains slurry ingredients;

ii. a container neck;

iii. Wherein said collapsible container neck has a mouth opening through which said slurry ingredients can be passed into the internal cavity of said collapsible pouch.

b. Securing said collapsible container to a mixing device, said mixing device comprising

i. A container attachment;

ii. An agitator;

iii. Wherein said collapsible container and said mixing device form an airtight seal when secured together ;

iv. Wherein said agitator passes through said mouth opening when said collapsible container is secured to said mixing device;

c. Removing any air from said container through an outlet port on said container or said mixing device if there is air in said container;

d. Causing said agitator to agitate, smooth, and mix said slurry ingredients in said collapsible pouch to ice slurry;

e. Pumping said ice slurry out of said collapsible container through said outlet port using a pump and a flexible tubing;

f. Delivering said ice slurry to a patient via an injection port;

g. Whereby the wall of said collapsible pouch collapses and forces the space between ice particles being occupied by liquid ingredients to provide fluidity for said ice slurry;

h. Whereby air tight feature of said collapsible container and steps of removing air from said collapsible container enables airless delivery of said ice slurry by said pump to said injection port.

[Claim 29] The collapsible container as in claim 28 is flexible, semi-flexible, or partially rigid and partially flexible.

[Claim 30] The slurry ingredients as in claim 28 are sterile or aseptic.

[Claim 31] The chemical constituents of said slurry ingredients as in claim 28 are water, one or more types of freezing point depressing chemical(s), and zero or more types of other chemicals and components.

[Claim 32] The chemical constituents as in claim 31 are sodium-chloride and water.

[Claim 33] The chemical constituents as in claim 32 are equivalent to isotonic saline solution.

[Claim 34] The chemical constituents as in claim 31 are water and blood substitute liquid.

[Claim 35] The other chemicals and components as in claim 31 are blood plasma.

[Claim 36] The method as in claim 28 further comprising

a. Adding said other chemicals and components to said slurry ingredients in said collapsible container before securing said collapsible container to said mixing device.

[Claim 37] The slurry ingredients as in claim 28 are ice slush or ice slurry.

[Claim 38] The slurry ingredients as in claim 28 are produced elsewhere then transferred into said collapsible container.

[Claim 39] A method to produce said slurry ingredients as in claim 28 comprising
a. Mixing a known amount of chemical constituents of said slurry ingredients into a mixture;
b. Filling said mixture into said collapsible container through said mouth opening of said collapsible container.
c. Sealing said mouth opening of said collapsible container with a lid or said mixing device to restrain said mixture inside said collapsible container;
d. Placing said collapsible container in a formation device, said formation device comprising
i. A cooling unit;
ii. A rotating member in said cooling unit which accepts a plurality of collapsible containers and rotates said collapsible containers;
iii. Wherein said collapsible container rotates in said formation device to prevent the formatting of big ice blocks;
iv. Wherein said mixture partially freeze into said slurry ingredients;
e. Removing said collapsible container from said formation device.

[Claim 40] The method as in claim 39 further comprising
a. Monitoring temperature inside cooling unit using temperature sensor(s);
b. Controlling internal air temperature of said cooling unit to constant or variable target temperature;

[Claim 41] The target temperature as in claim 40 is lower than the freezing temperature of said mixture for freezing water into ice.

[Claim 42] The target temperature of claim 40 is equal to or above the storing temperature of said slurry ingredients with desired ice fraction.

[Claim 43] The slurry ingredients at said storing temperature as in claim 42 are ready to be crushed and smoothed to said ice slurry.

[Claim 44] The method as in claim 39 further comprising
a. Scooping or pouring said ice slurry ingredients out of said collapsible container through said mouth opening for use.

[Claim 45] The method as in claim 39 further comprising
a. Crushing said slurry ingredients to said ice slurry using said mixing device;
b. Scooping or pouring said ice slurry out of said collapsible container through said mouth opening for use.

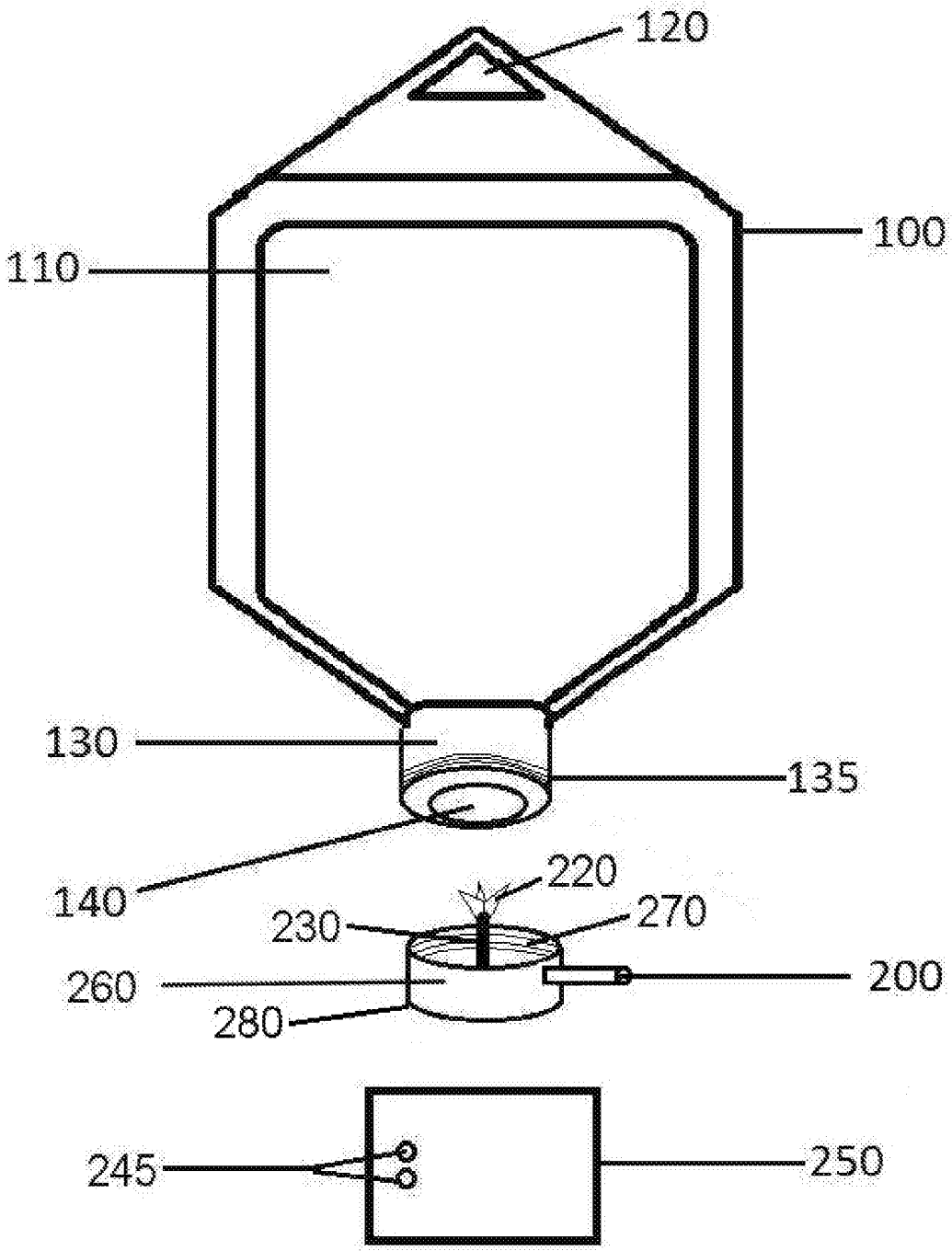



Fig. 1

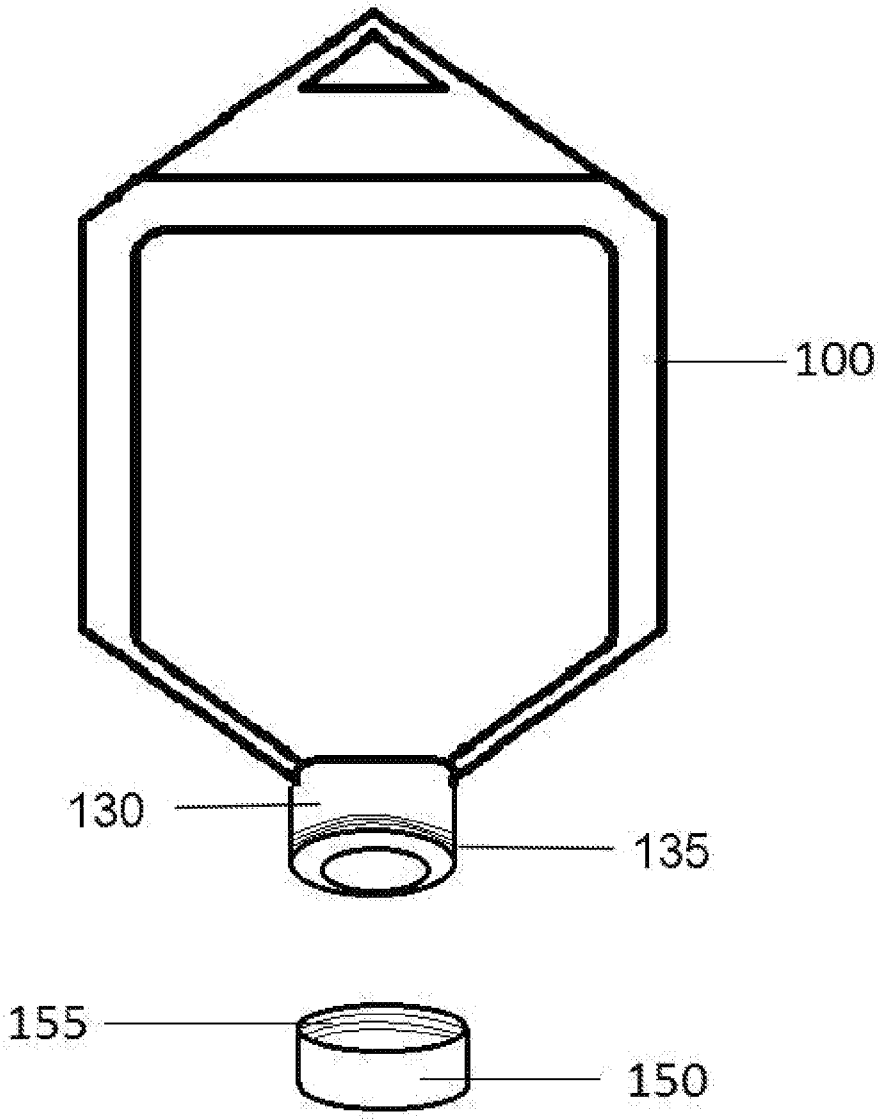



Fig. 2

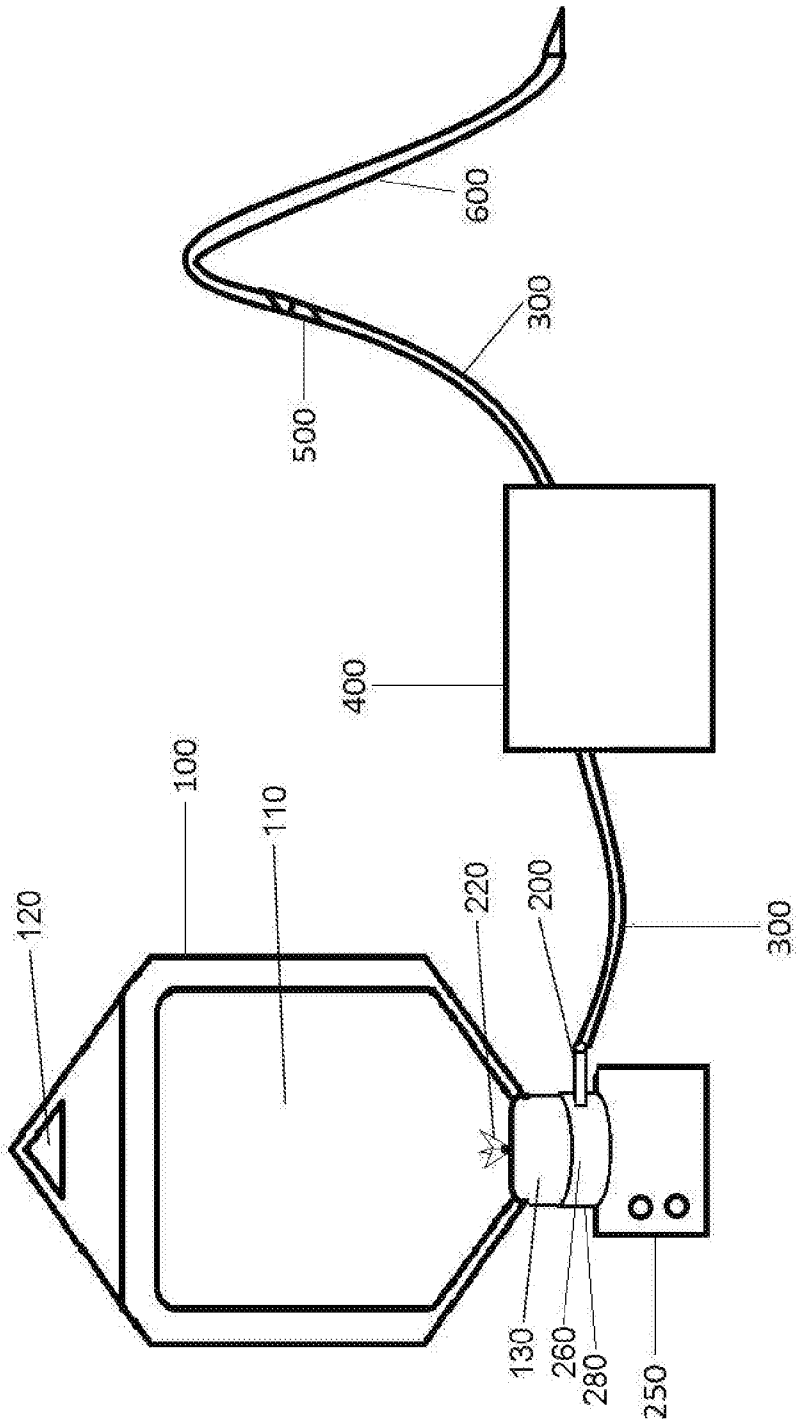



Fig. 3

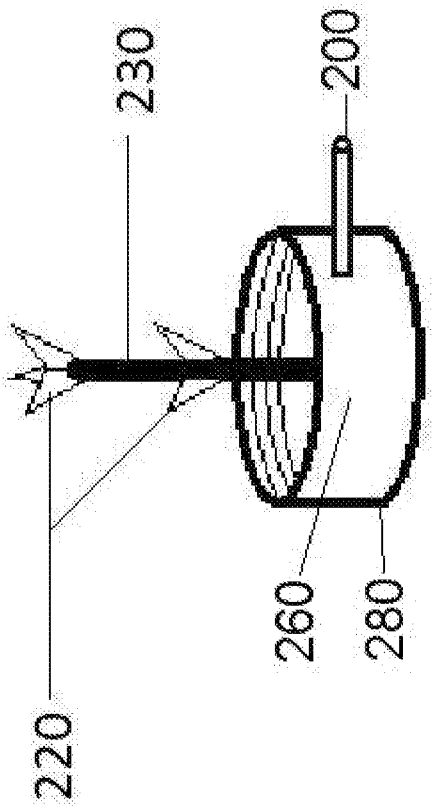



Fig. 4B

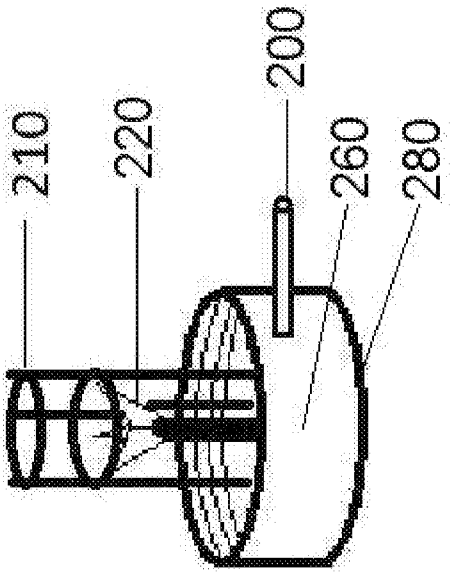
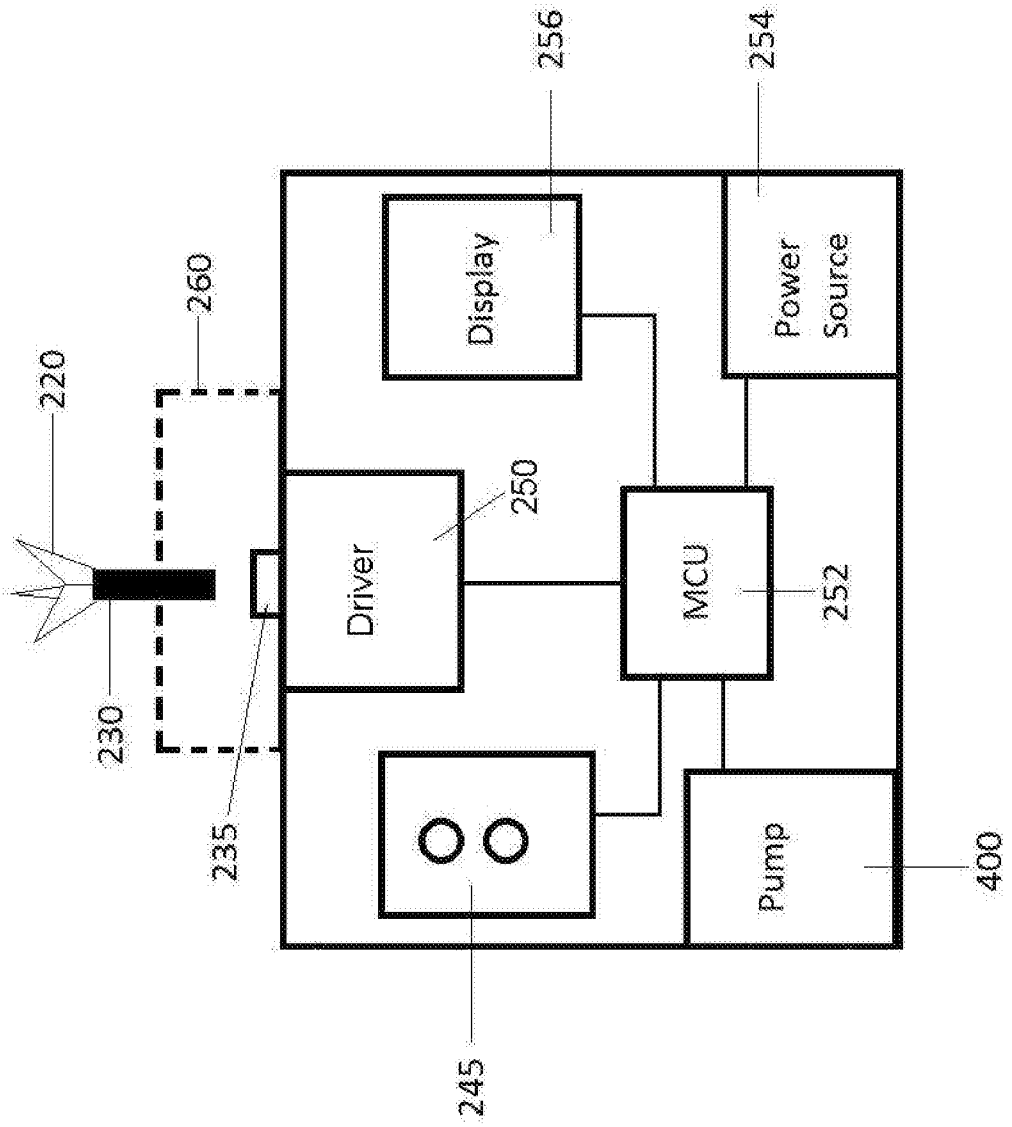



Fig. 4A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254
260
Display
Power Source
220
250
Driver
MCU
252
230
235
Pump
400
245

Fig. 5

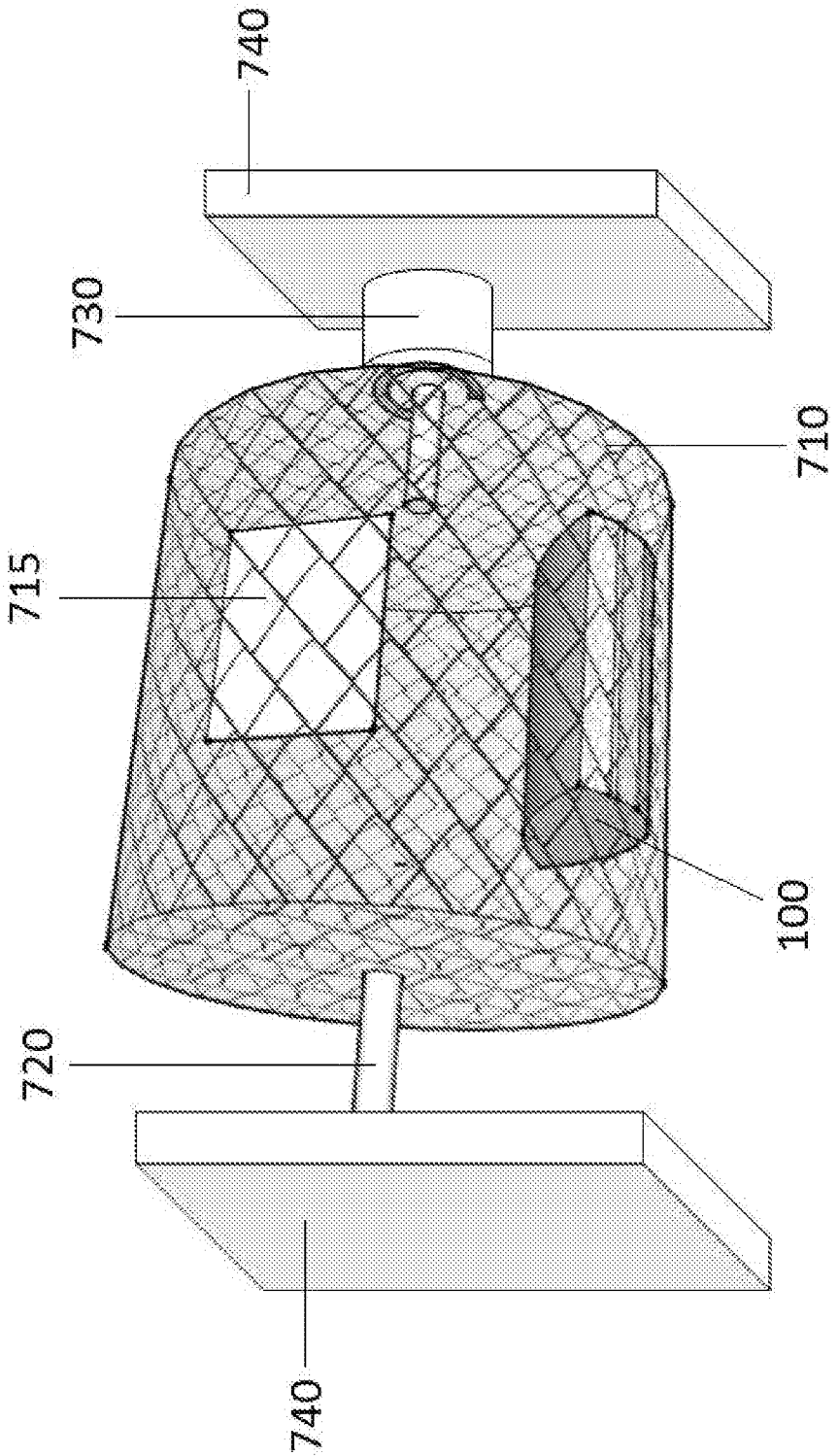


Fig. 6

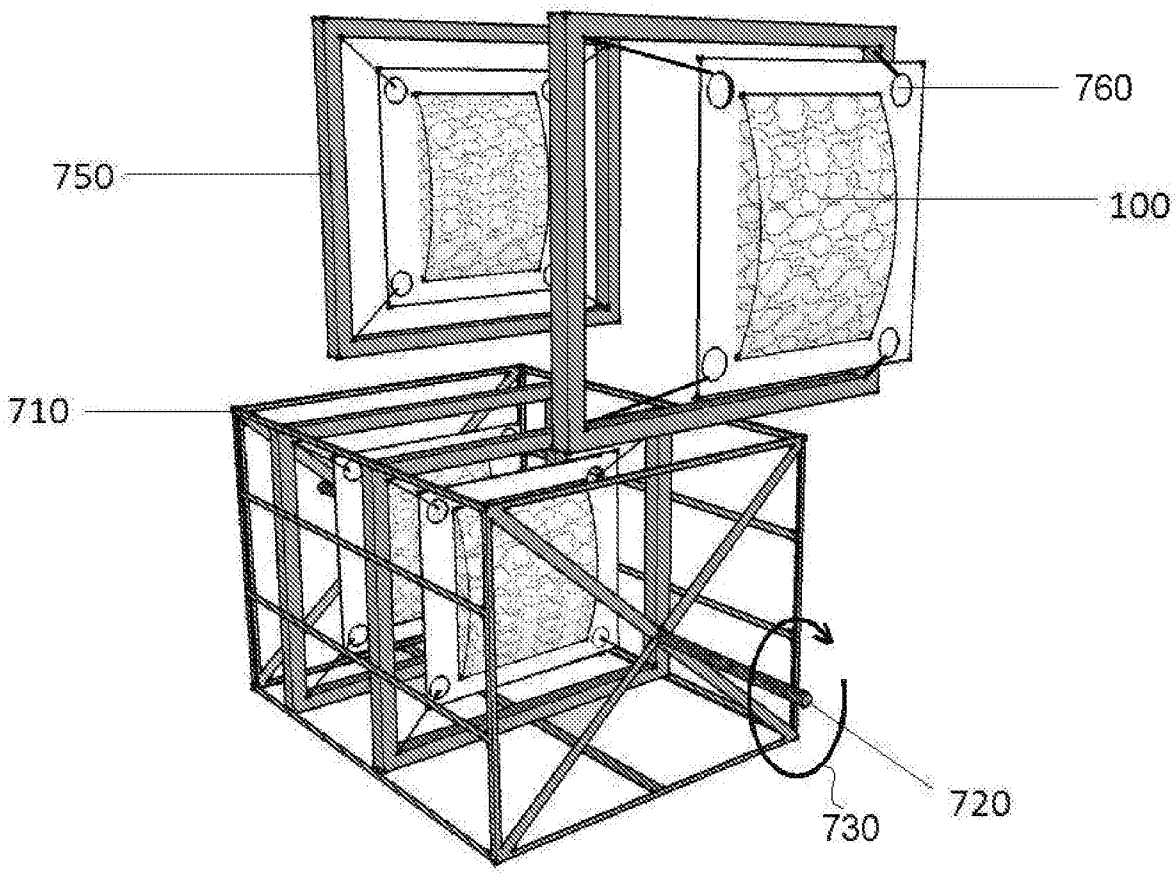


Fig. 7

**INTERNATIONAL SEARCH REPORT**

International application No.
**PCT/IB2014/063606**

**A. CLASSIFICATION OF SUBJECT MATTER**

**A61M 19/00(2006.01)i, A61F 7/00(2006.01)i**

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)
A61M 19/00; C09K 5/00; F25C 1/00; A23G 9/00; A61F 7/00

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
Korean utility models and applications for utility models
Japanese utility models and applications for utility models

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
eKOMPASS(KIPO internal) & keywords: hypothermia, medical ice slurry, slush, collapsible, container, pouch, air tight, seal, rotate

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| X | US 7874167 B2 (KAMMER, P. et al.) 25 January 2011<br>See claims 1, 22, column 6, lines 2-5, column 6, lines 23-25, and figures 8, 11. | 17-27 |
| A | | 1-16 |
| A | US 2009-0255276 A1 (KASZA, K. E. et al.) 15 October 2009<br>See entire document. | 1-27 |
| A | US 2010-0308257 A1 (LAMPE, J. W. et al.) 9 December 2010<br>See entire document. | 1-27 |
| A | US 2007-0056313 A1 (KASZA, K. E. et al.) 15 March 2007<br>See entire document. | 1-27 |
| A | US 6547811 B1 (BECKER, L. B. et al.) 15 April 2003<br>See entire document. | 1-27 |

☐ 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 | Date of mailing of the international search report |
|---|---|
| 24 December 2014 (24.12.2014) | **24 December 2014 (24.12.2014)** |


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# INTERNATIONAL SEARCH REPORT

International application No.
**PCT/IB2014/063606**

**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.: 28, 36, 39, 40, 44, 45
because they relate to subject matter not required to be searched by this Authority, namely:
Claims 28, 36, 39, 40, 44, 45 pertain to methods for treatment of the human body and thus relate to a subject-matter which this International Searching Authority is not required to search under PCT Article 17(2)(a)(i) and PCT Rule 39.1(iv).

2. ☒ Claims Nos.: 29-35, 37-38, 41-43
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:
Claim 28 relates to a method for producing and delivering airless medical ice slurry to a patient, but claims 29-35, 37-38, 41-43 substantially dependant on claim 28, relate to the components of the method. As claims 29-35, 37-38, 41-43 do not clearly define the matter for which protection is sought, these claims do not meet the requirement of PCT Article 6.

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:

1. ☐ As all required addtional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of any 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.:

**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.

**INTERNATIONAL SEARCH REPORT**

Information on patent family members

International application No.
**PCT/IB2014/063606**

| Patent document cited in search report | Publication date | Patent family member(s) | Publication date |
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| | | EP 2299808 A4 | 01/01/2014 |
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| | | WO 2009-149230 A2 | 10/12/2009 |
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| | | EP 1207807 A4 | 28/12/2005 |
| | | EP 1208338 A1 | 29/05/2002 |
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