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(54) **PASSIVE, PORTABLE BLOOD STORAGE SYSTEM**

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(57) **ABSTRACT**

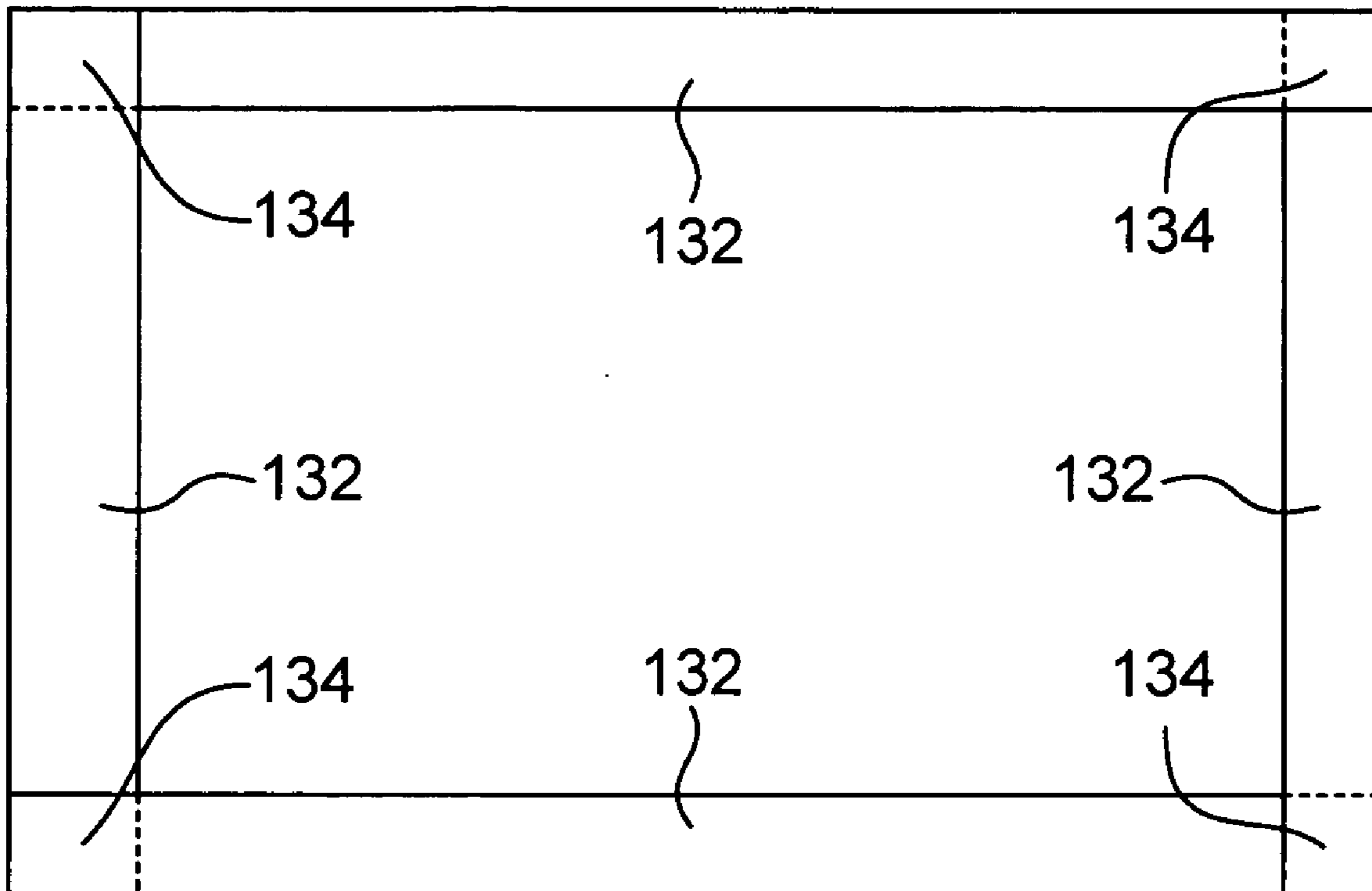
A passive, portable system and a method for storing blood are disclosed. The system comprises a sealable thermal isolation chamber which is preconditioned at a certain temperature for a predefined period of time. The thermal isolation chamber includes cavities of a phase change material which help to maintain the temperature of bags of human blood that are placed into the thermal isolation chamber for storage during transit. The thermal isolation chamber is surrounded by vacuum insulation panels and the vacuum insulation panels, encompassing the thermal isolation chamber, is placed into a durable carrying bag. The thermal isolation chamber is reusable along with the vacuum insulation panels and bag.

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Related U.S. Application Data

(60) Provisional application No. 60/535,844, filed on Jan. 12, 2004.



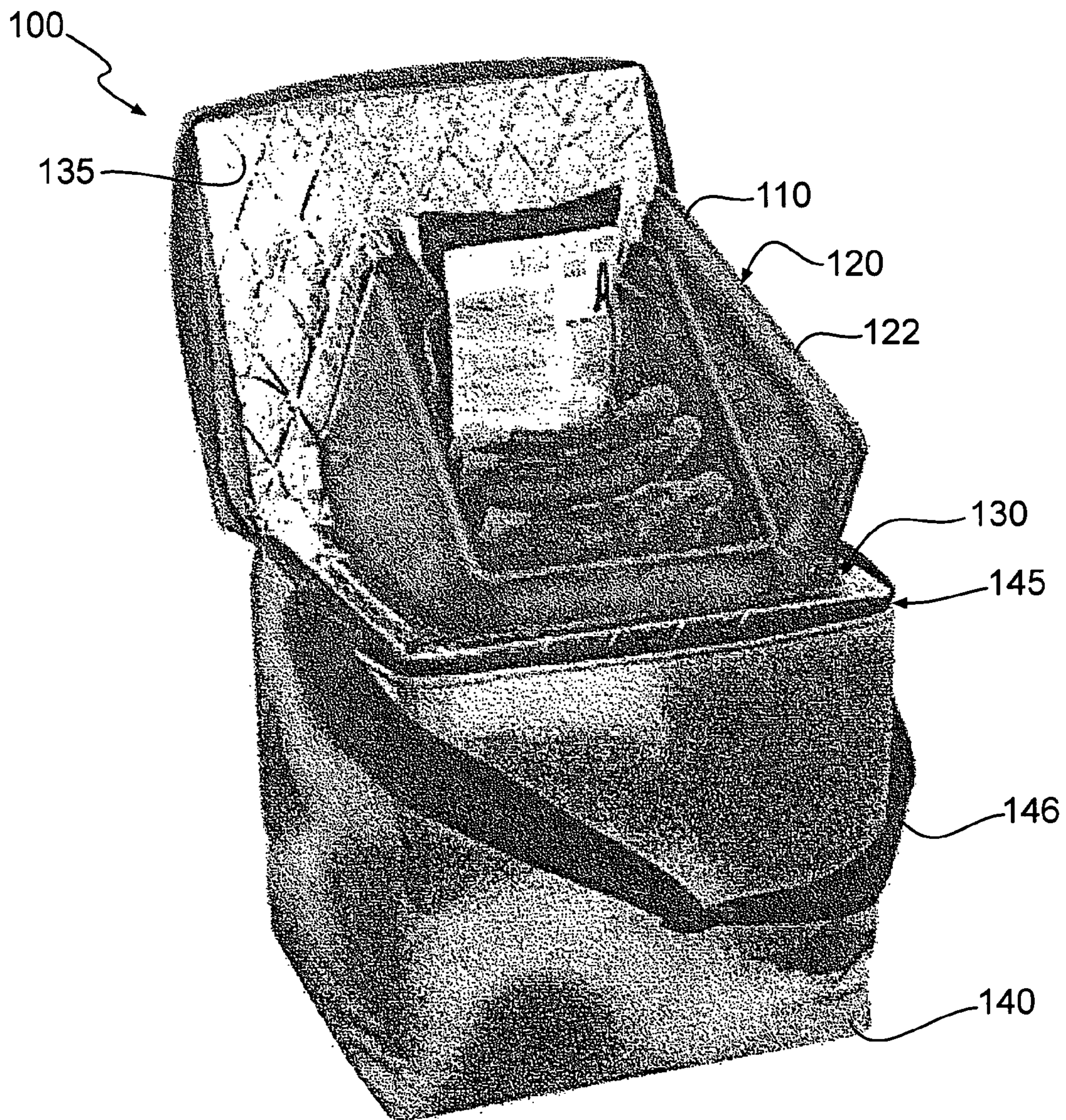


FIG. 1

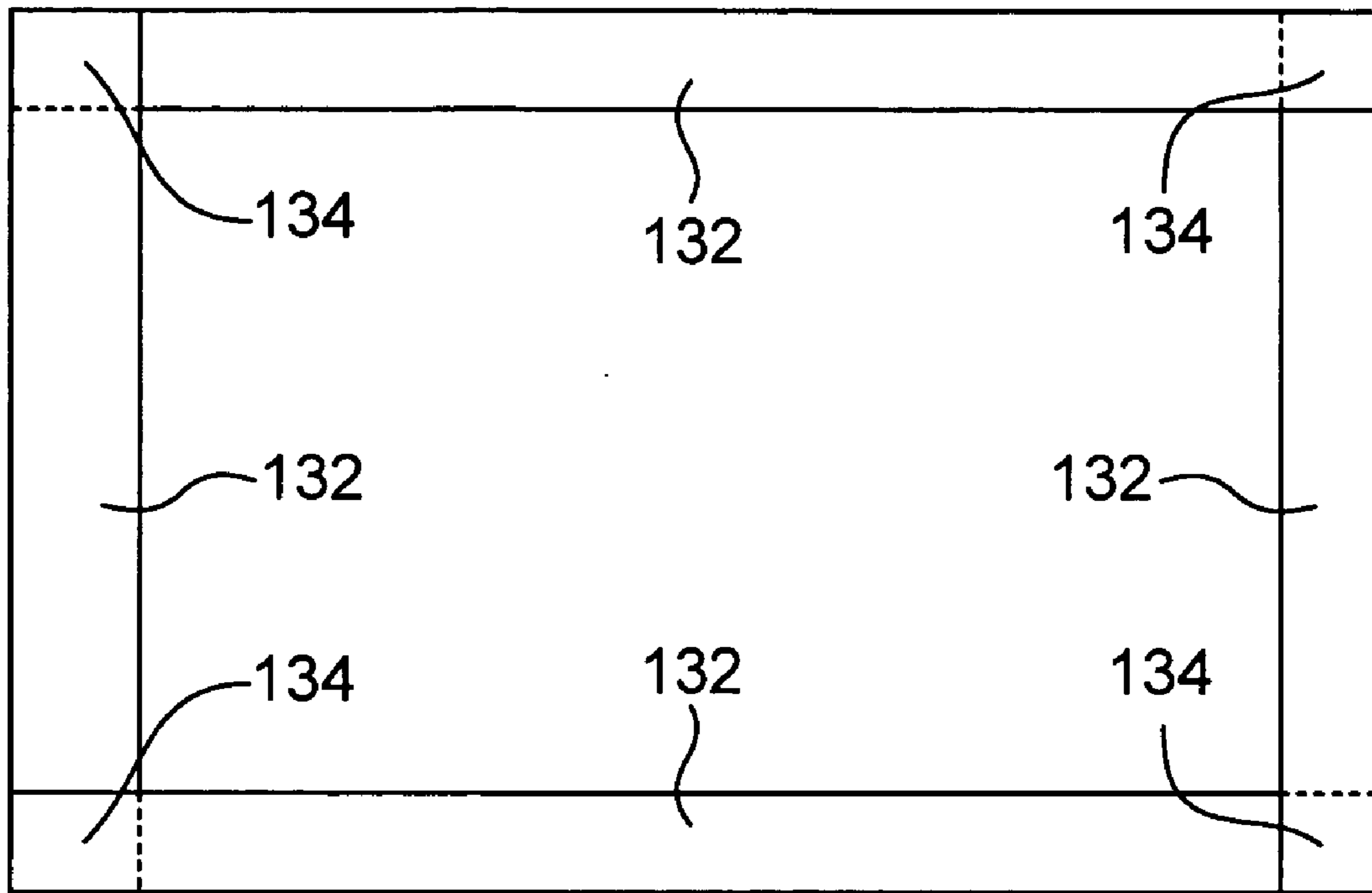


FIG. 2

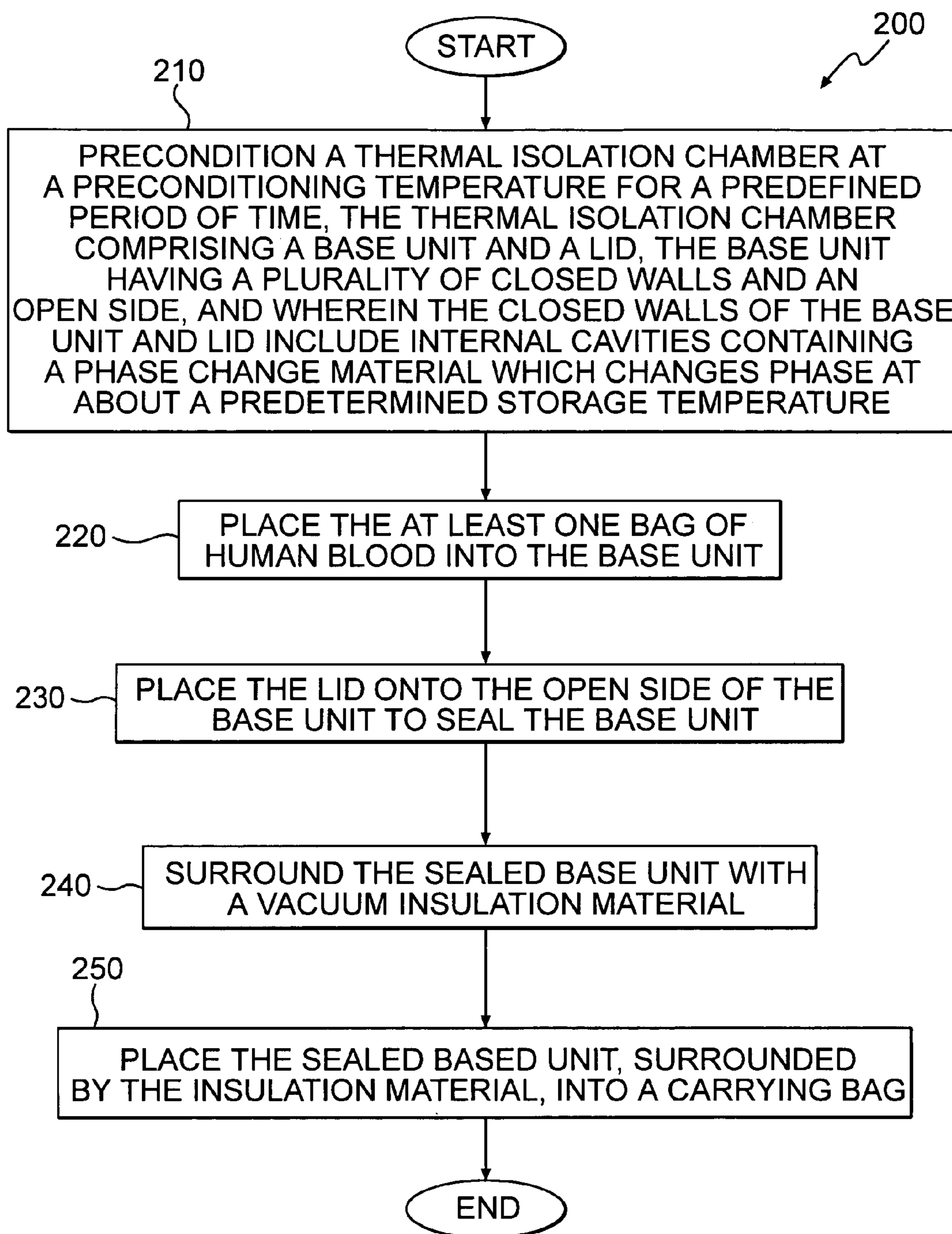


FIG. 3

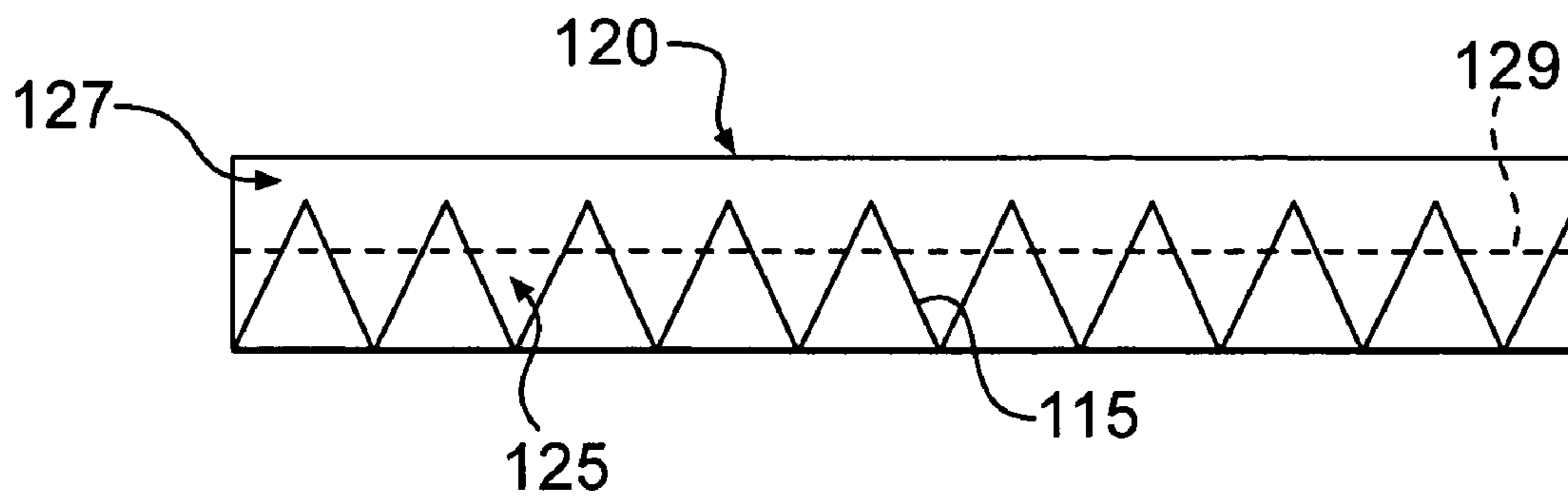


FIG. 3A

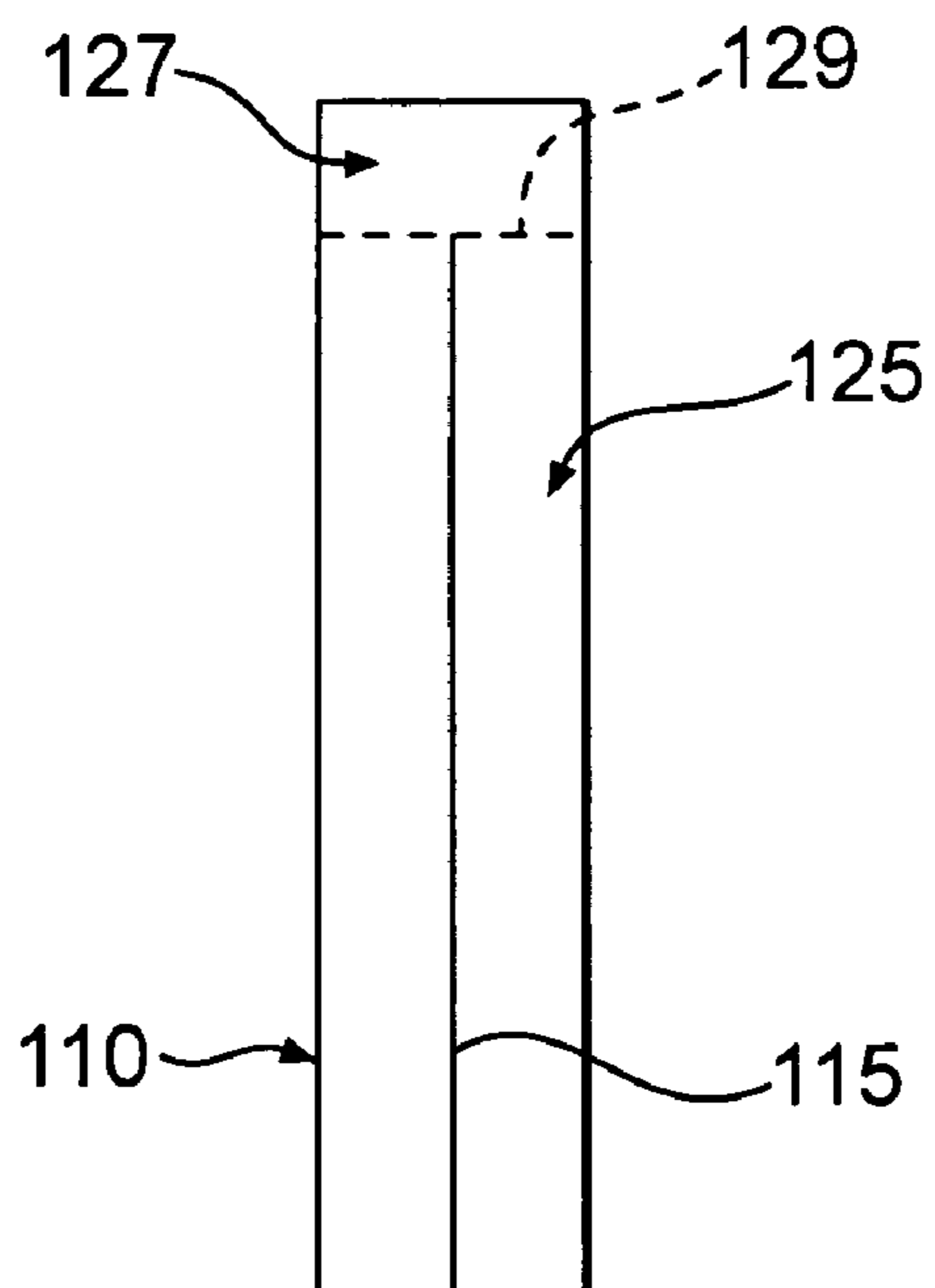


FIG. 3B

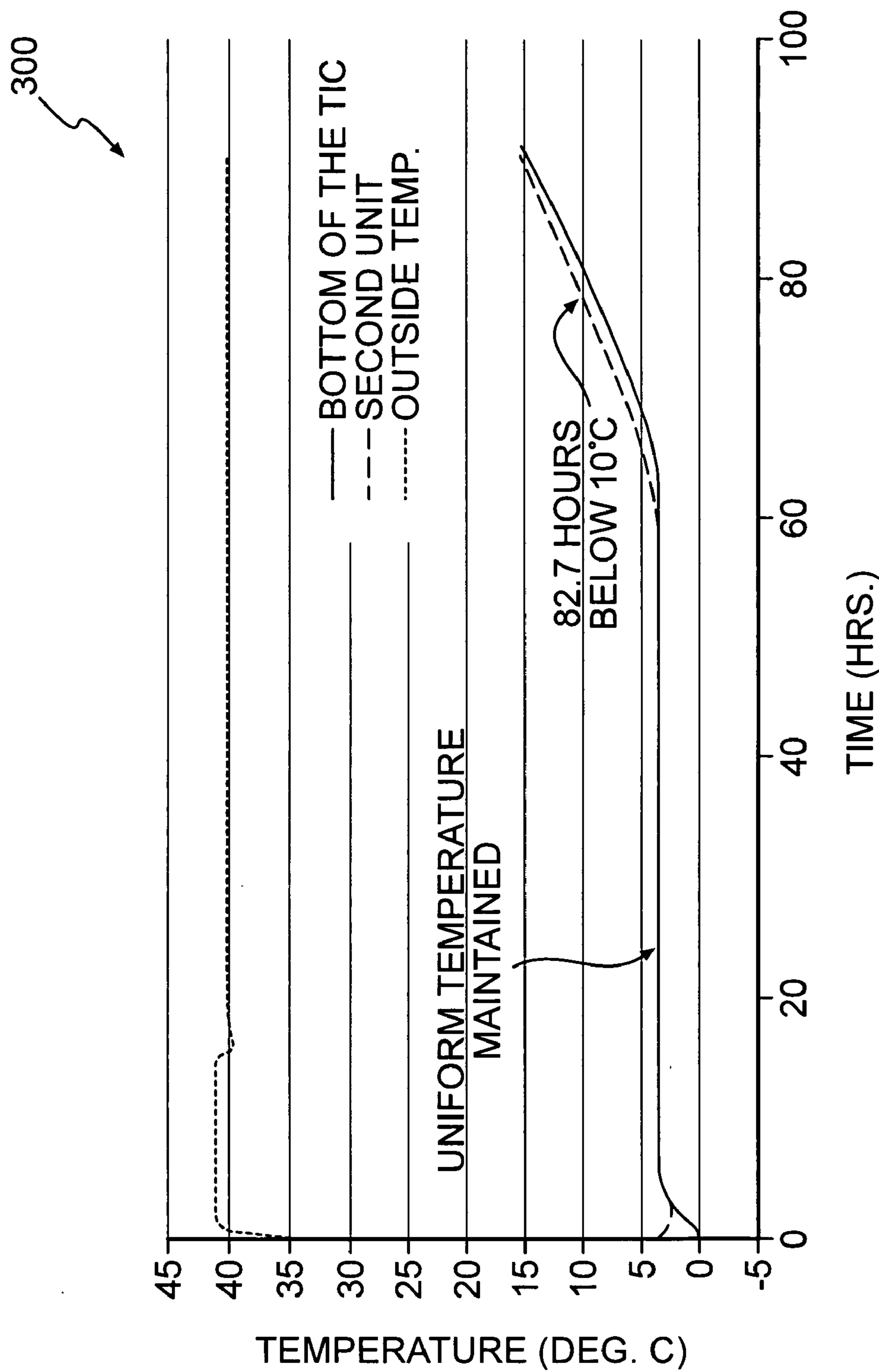


FIG. 4

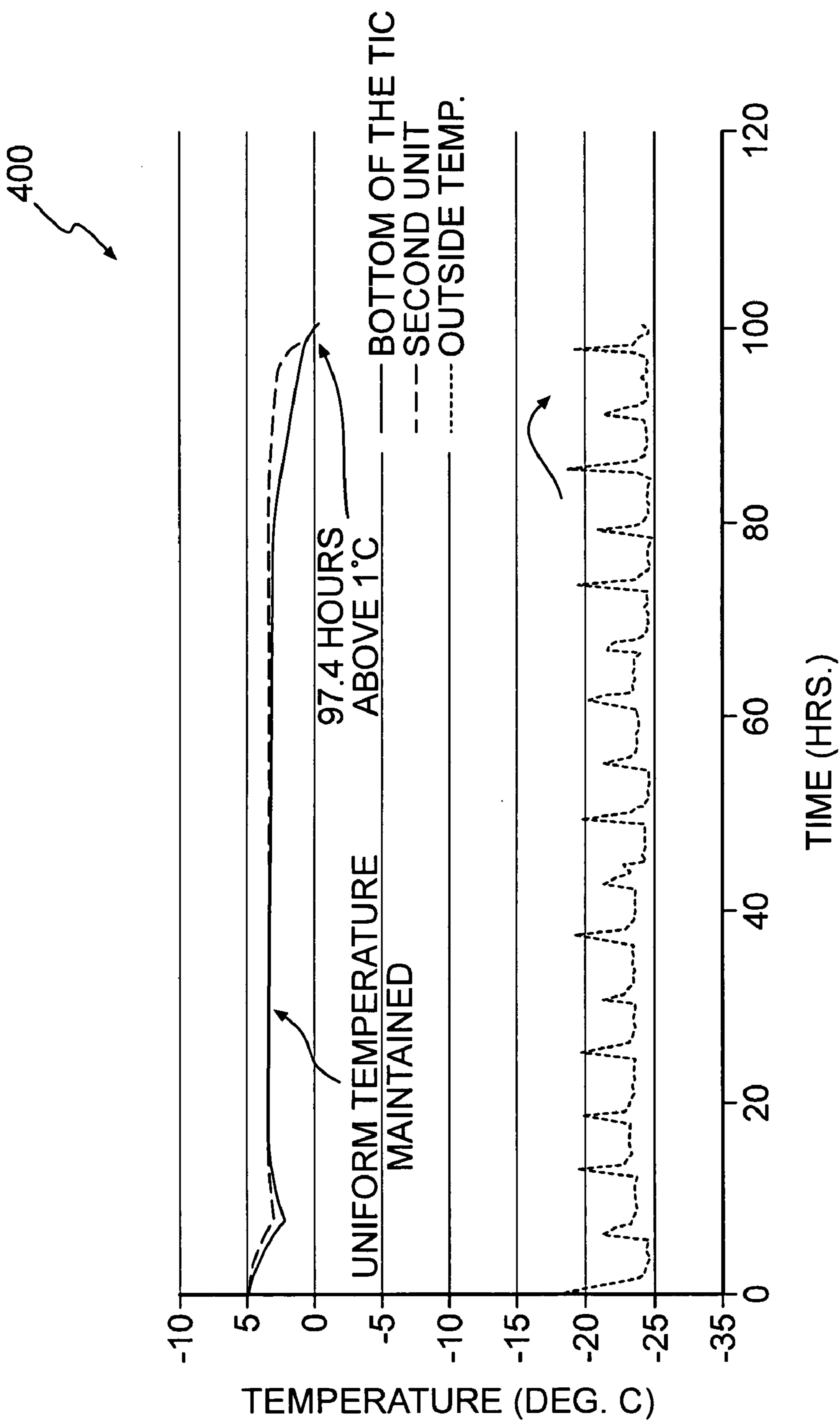


FIG. 5

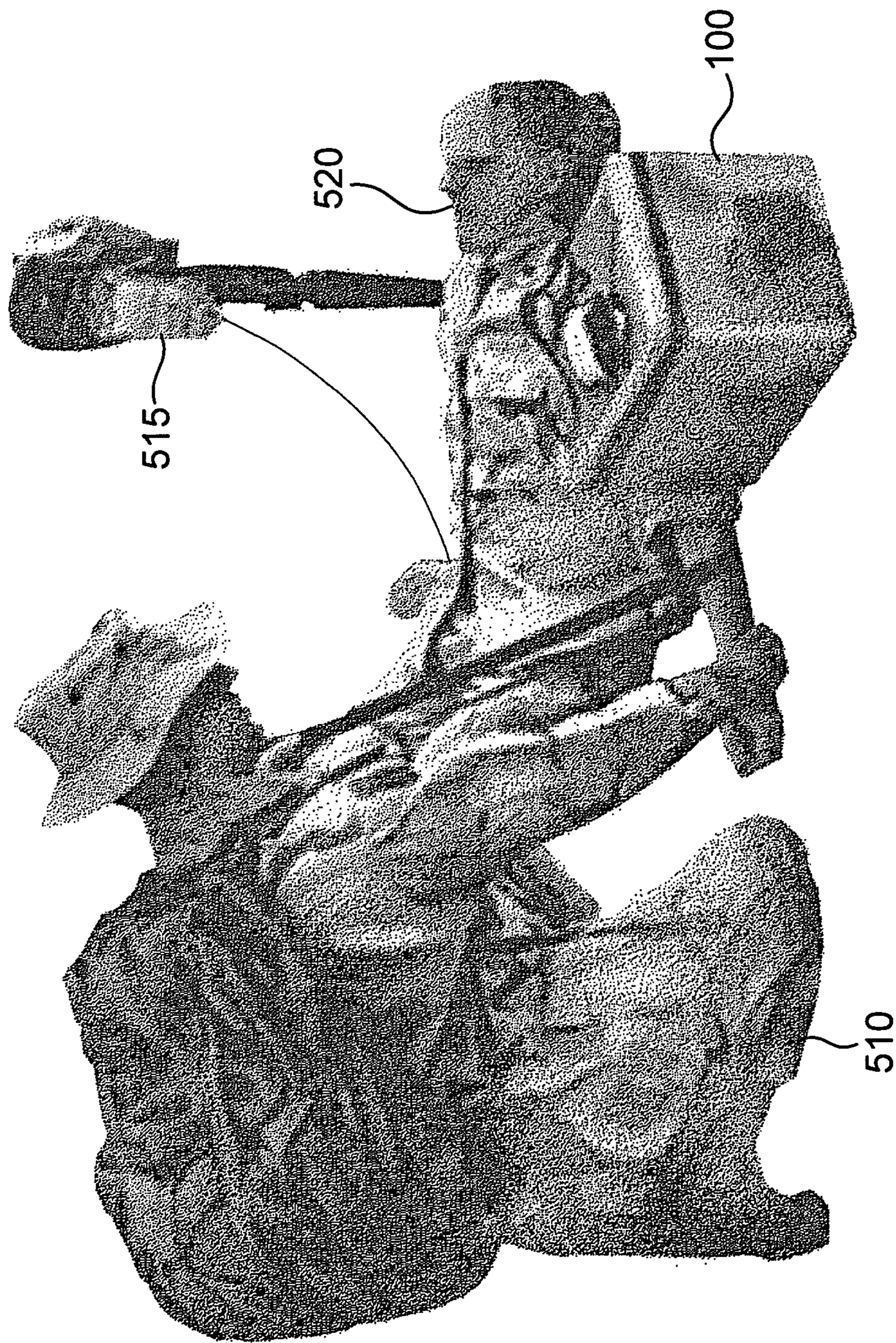


FIG. 6

PASSIVE, PORTABLE BLOOD STORAGE SYSTEM**CROSS-REFERENCE TO RELATED APPLICATIONS/INCORPORATION BY REFERENCE**

[0001] This application claims priority to provisional U.S. patent application Ser. No. 60/535,844 filed on Jan. 12, 2004, which is incorporated herein by reference in its entirety.

TECHNICAL FIELD

[0002] Certain embodiments of the present invention relate to the portable storage of materials within a temperature range, such as for the storage of human blood in the field. More particularly, certain embodiments of the present invention relate to a portable system that maintains a predetermined temperature range for materials kept therein, such as bags filled with human blood, over a long period of time and without requiring a source of power.

BACKGROUND OF THE INVENTION

[0003] A variety of materials are desirably maintained in a predetermined temperature for various purposes. For example, sensitive materials such as human blood are often stored in non-portable, powered refrigeration units to keep the blood at a temperature that will keep the blood from going degrading and becoming unusable. When the blood needs to be removed from a refrigeration unit and transported for use in the field (e.g., military combat situations, car accident victims, etc.) it is often transported in an insulated container which may or may not contain, for example, ice (i.e., frozen H₂O). However, such portable methods of transportation often allow the temperature of the blood to fluctuate more than desired and do not typically keep the temperature of the blood within the desired range for a long enough period of time. Other materials are also desirably maintained at a predetermined temperature in environments which do not allow refrigeration or the like.

[0004] As an alternative, a portable or semi-portable container with an internal active power and temperature regulation system to regulate the temperature within the container can be used. The active power system may include a battery or a fuel cell and a refrigerant system which adds to the complexity and weight of the container and may not have a desired level of reliability (e.g., the battery may discharge at a faster rate than desired). Another alternative is to use an external power source, such as a gasoline powered generator or external battery, which plugs into a temperature regulation system of the container in order to regulate the temperature within the container. This requires transporting the external power source along with the container.

[0005] It is desired to have a lightweight, highly reliable, portable container which maintains the temperature of bags of human blood over a relatively long period of time such that the blood can be administered to patients many hours after it was first placed into the container.

[0006] Further limitations and disadvantages of conventional, traditional, and proposed approaches will become apparent to one of skill in the art, through comparison of such systems with the present invention as set forth in the remainder of the present application with reference to the drawings.

BRIEF SUMMARY OF THE INVENTION

[0007] An embodiment of the present invention comprises a portable system for storing materials at a predetermined temperature range, such as human blood. The system comprises a base unit, having a plurality of closed walls and an open side, into which bags of human blood or other materials are placed. The closed walls of the base unit include internal cavities containing a phase change material. The system also includes a lid having an internal cavity containing the phase change material. The lid fits onto the open side of the base unit to seal the base unit when storing the bags of human blood. The system further comprises a vacuum insulation material surrounding the base unit and lid and an outer carrying bag surrounding the vacuum insulation material.

[0008] Another embodiment of the present invention comprises a method for storing materials, such as human blood. The method comprises preconditioning a thermal isolation chamber at a preconditioning temperature for a predefined period of time. The thermal isolation chamber comprises a base unit and a lid. The base unit has a plurality of walls and an open side. The closed walls of the base unit and the lid include internal cavities containing a phase change material which changes phase at about a predetermined storage temperature. The method also includes placing at least one bag of human blood into the base unit. The method further comprises placing a lid onto the open side of the base unit to seal the base unit. The method also includes surrounding the sealed base unit with a vacuum insulation material and placing the sealed base unit, surrounded by the insulation material, into a carrying bag.

[0009] These and other advantages and novel features of the present invention, as well as details of an illustrated embodiment thereof, will be more fully understood from the following description and drawings.

BRIEF DESCRIPTION OF SEVERAL VIEWS OF THE DRAWINGS

[0010] FIG. 1 is an exemplary illustration of an embodiment of a portable system for storing human blood, in accordance with various aspects of the present invention.

[0011] FIG. 2 is a schematic top view of the interior wall layer for the system as shown in FIG. 1.

[0012] FIGS. 3A and 3B show schematic representations of the side and bottom/top walls of the system as shown in FIG. 1.

[0013] FIG. 4 is a flow chart of an embodiment of a method of storing blood using the system of FIG. 1, in accordance with various aspects of the present invention.

[0014] FIG. 5 is an exemplary graph illustrating the temperature regulating capability of the system of FIG. 1 using the method of FIG. 2 in a hot environment, in accordance with an embodiment of the present invention.

[0015] FIG. 6 is an exemplary graph illustrating the temperature regulating capability of the system of FIG. 1 using the method of FIG. 2 in a cold environment, in accordance with an embodiment of the present invention.

[0016] FIG. 6 is an illustration of the system of FIG. 1 being used in the field in a combat situation, in accordance with an embodiment of the present invention.

DETAILED DESCRIPTION OF THE
INVENTION

[0017] FIG. 1 is an exemplary illustration of an embodiment of a portable system 100 for storing materials at a given temperature range over a period of time, such as human blood or other temperature sensitive materials. The embodiment of FIG. 1 shows various aspects of the present invention, and the system 100 generally comprises a base unit 110, having four side walls and a bottom wall. The base unit 110 also includes a removable or semi-removable lid 120 for sealing the base unit 110. The lid 120 may be hingedly attached to the base unit for example. The system 100 may further comprise vacuum insulation panels (or material) 130 to surround and help insulate the base unit 110 and lid 120, although depending on the environment in which the system 100 is to be used, panels 130 may not be needed. The vacuum insulation panels 130 have an R-value of 30 or other suitable value, and are configured such that a top panel 135 opens up providing access to the sealed base unit 110, in accordance with an embodiment of the present invention. In an embodiment, the temperature stability of the system is significantly enhanced by a pinwheel type attachment of the insulation panels 130 to one another at the locations of the intersection between panels 130, such as at the corners of the enclosure formed by the panels 130. As seen in FIG. 2, the sidewalls may have insulation panels 130 with a barrier material forming the interior surfaces 132, or the barrier material may be provided separate from panels 130. The barrier material forming surface 132 is configured with pinwheel type overlapping adjacent walls, such as by providing overlapping sections 134 arranged in a pinwheel type configuration, with each successive overlapping portion 134 corresponding to the corner regions of the enclosure. The overlapping portions 134 provide more effective sealing of the interior volume of system 100, to significantly reduce any thermal losses or gains at these locations, to facilitate providing a substantially uniform temperature atmosphere within system 100. Pinwheel attachment or overlapping attachment of panels 130 or of barrier material 132 at these intersections can reduce any edge loss, to thereby maintain temperature stability uniformly throughout the system 100.

[0018] In accordance with an embodiment of the present invention, the base unit 110 and lid 120 have internal cavities containing a phase change material. The walls and top/bottom of the system 100 may define a continuous cavity or discrete cavities may be provided if desired. As shown in FIGS. 3A and 3B, examples of the walls and top/bottom of the system 100 have a phase change material 125 in the cavity 126. The phase change material is preferably a gel-based material which melts and solidifies at a certain temperature and, in doing so, is capable of storing or releasing energy. As a result, the phase change material can be used to help maintain or regulate the temperature of other materials (e.g., blood). In accordance with an embodiment of the present invention, the phase change material is designed to change phase (i.e., melt or solidify) at approximately 1 to 10° C., or more preferably at approximately 4° C. As an example, a phase change such as deuterium oxide may be used in the base unit 110 and lid 120, but other phase change materials could be utilized which change phase at the desired temperatures. Using a phase change material which changes phase at approximately 1-10 C., provides a temperature for storing bags of human blood as an example. The base unit 110 and lid 120 constitute a removable thermal

isolation chamber (TIC). In accordance with an embodiment of the present invention, the base unit 110 can hold at least 4 standard units (i.e., bags) of blood. In an embodiment, the TIC may be usable in environments in which varying pressure could be encountered, such as in military operations wherein the system 100 could be deployed in higher altitudes or underwater. In such circumstances, it may be desirable to equalize pressure relative to the contents of the TIC. In such an embodiment, one or more equilibration ports 122 may be provided in the TIC, to allow equilibration with the outside atmosphere. The port(s) 122 may be a small air port having a Tyvek (or other suitable material) cover there over, which will allow gaseous exchange with the outside atmosphere, but prevent liquid exchange therethrough. Any suitable port system to allow equilibration between the TIC and outer atmosphere is contemplated. As merely an example, an equilibration port 122 may be provided in the top and bottom portions of the TIC.

[0019] The system 100 also includes a durable carrying bag 140 to hold the sealed base unit, which may be surrounded by the vacuum insulation panels 130. The carrying bag 140 may be made of durable nylon and include a zipper 145 and an adjustable strap 146, in accordance with an embodiment of the present invention. Other perishable medical supplies may be stored in the system 100 as well, in accordance with various embodiments of the present invention.

[0020] FIG. 4 is a flow chart of an embodiment of a method 200 of storing blood using the system 100 of FIG. 1, in accordance with various aspects of the present invention. In step 210, a thermal isolation chamber is preconditioned at a preconditioning temperature for a predefined period of time. The thermal isolation chamber comprises a base unit and a lid where the base unit has a plurality of closed walls and an open side. The closed walls of the base unit and the lid include a phase change material incorporated therewith which changes phase at about a predetermined storage temperature or temperature range. In step 220, at least one bag of blood is placed into the base unit. In step 230, the lid is placed onto the open side of the base unit to seal the base unit. In step 240, the sealed base unit is surrounded with a vacuum insulation material. In step 250, the sealed base unit, surrounded by the insulation material, is placed into a carrying bag.

[0021] In accordance with an embodiment of the present invention, the base unit 110 and lid 120 is preconditioned to a temperature of -20° C. for 6 hours for hot weather applications or to +4° C. for 2 hours for cold weather applications, before being integrated with the vacuum insulation panels 130 and the bag 140. As shown in FIGS. 3A and 3B, the internal cavities 127 of the base unit 110 and the lid 120 may also include thermal isolation members or fences 115, which may be provided so as to be exposed to the phase change material within the cavities of the base unit 110 and top 120. The members or fences 115 may be continuous layers of material, such as a thermally conductive material, which may also have a trigger material therewith. For example, the members 115 may be a light gauge aluminum material, which is coated with an aluminum oxide or other suitable material. The layers 115 are desirably dimensioned to be larger than the adjacent cavity and associated phase change material, so as to be exposed adjacent all of the phase change material. The phase change

material **125** is therefore filled to a point such as at **129**, such that the members **115** are in contact with the phase change material over their extent. As shown in these embodiments, the members **115** in the sidewalls as shown in **FIG. 3A** may be flat, and disposed approximately in the center of the cavity **127**. For the bottom and top members of the system **100**, the member **115** may have a corrugated, triangulated configuration. The coating with aluminum oxide or other suitable trigger material used in combination with the phase change material, may then be exposed to the phase change material throughout the cavities, to facilitate causing phase changes at a desired temperature or temperature range. This tends to maintain desired phase change characteristics throughout the side, bottom and top walls of the system **100**. The thermal isolation fences thus help to dispense conductivity over the face of the walls of the base unit **110** and lid **120**, in accordance with an embodiment of the present invention. Also, a trigger agent, such as an amount of aluminum oxide for use with a deuterium oxide phase change material, may be used within the phase change material to stimulate the phase change material to change phase at the desired temperature or temperature range.

[0022] The system **100** is a passive system in that it does not require an internal or external power source such as a battery, fuel cell, or generator. Also, the system **100** does not require any kind of active refrigeration system once it is preconditioned.

[0023] **FIG. 4** is an exemplary graph **300** illustrating the temperature regulating capability of the system **100** of **FIG. 1** using the method **200** of **FIG. 2**. In this example for use in a hot environment, as the graph **300** shows, in a sustained +105° F. (+40° C.) environment, bags of human blood are held at a constant temperature (about 4° C.) for over 60 hours and remain adequately chilled after 80 hours.

[0024] **FIG. 5** is an exemplary graph **400** illustrating the temperature regulating capability of the system **100** of **FIG. 1** using the method **200** of **FIG. 2** in a cold environment. In accordance with an embodiment of the present invention, as the graph **400** shows, in a sustained subzero -9° F. (-23° C.) environment, bags of human blood are held at a constant temperature (about 4° C.) for over 60 hours, remaining above +1° C. after 96 hours.

[0025] In accordance with an embodiment of the present invention, the system **100** carries at least 4 units (i.e., bags) of red blood cells for a period of at least 48 hours in an ambient temperature range of -20° C. to +40.5° C., keeping the blood contents between +1° C. and +10° C.

[0026] **FIG. 6** is an illustration of the system **100** of **FIG. 1** being used in the field in a combat situation, in accordance with an embodiment of the present invention. In **FIG. 5**, an army medical person **510** is administering a pint of blood **515** to a wounded soldier **520**. The portable system **100** is seen sitting on the ground next to the wounded soldier **520**.

[0027] In accordance with an embodiment of the present invention, the physical dimensions of the exterior of the system **100** are approximately 10" length, 9" width, and 10" depth. The dimensions of the interior (i.e., the inside of the TIC base unit **110**) are approximately 6" length, 5" width, and 6" depth. Other dimensions may be suitable for other particular applications and are contemplated herein.

[0028] In summary, a combat-portable, passive system safely stores blood and other perishable medical supplies

over a long period of time in climates ranging from very cold temperatures to very hot temperatures. The layered design (i.e., TIC, vacuum insulation, bag), and the equilibrium mechanism achieved by the layered design, reduce the risk of total product failure.

[0029] While the invention has been described with reference to certain embodiments, it will be understood by those skilled in the art that various changes may be made and equivalents may be substituted without departing from the scope of the invention. In addition, many modifications may be made to adapt a particular situation or material to the teachings of the invention without departing from its scope. Therefore, it is intended that the invention not be limited to the particular embodiment disclosed, but that the invention will include all embodiments falling within the scope of the appended claims.

What is claimed is:

1. A portable system for storing human blood, said system comprising:

a base unit, having a plurality of closed walls and an open side, into which containers of human blood are placed, and wherein said closed walls of said base unit include a phase change material positioned therein, the phase change material having phase change characteristics to substantially maintain a temperature of between 2-6° C.;

a lid including a phase change material, and wherein said lid fits onto said open side of said base unit to seal said base unit when storing said containers of human blood; and

an outer carrying bag surrounding said base unit and lid.

2. The system of claim 1 wherein said base unit and said lid constitute a thermal isolation chamber.

3. The system of claim 1, further comprising at least one equilibrium port for equalizing pressure of the interior of the system relative to the exterior atmosphere.

4. The system of claim 1, wherein the walls of said base unit and said lid include cavities of said base unit and said lid include cavities in which said phase change material is provided.

5. The system of claim 4, further comprising a thermal isolation member associated with each of said cavities positioned adjacent said phase change material therein.

6. The system of claim 5, wherein said thermal isolation members comprise a sheet member having a trigger material provided therein, the trigger material facilitating control of the phase change characteristics of said phase change material.

7. The system of claim 1, further comprising a trigger material to which said phase change material is exposed to facilitate control of the phase change characteristics of said phase change material.

8. The system of claim 1, wherein the interior of the walls of said base unit are covered with an insulating material wherein the insulating material is overlapped at the intersection of the walls.

9. The system of claim 7, wherein the overlapped portions are provided in a pinwheel-type configuration.

10. The system of claim 1, further comprising insulating panels surrounding the base unit and lid.

11. The system of claim 1, wherein the temperature is maintained within the range of 2-6° C. for at least forty-eight hours.

12. The system of claim 1, further comprising at least one cavity in which the phase change material is positioned.

13. The system of claim 12, further comprising at least one thermal isolation member within the cavity.

14. The system of claim 13, wherein the at least one thermal isolation member is provided with a trigger material thereon, which is in contact with the phase change material.

15. The system of claim 13, wherein the thermal isolation member is configured to be flat or corrugated.

16. A method for storing human blood, said method comprising:

preconditioning a thermal isolation chamber at a preconditioning temperature for a predefined period of time, said thermal isolation chamber comprising a base unit and a lid, said base unit having a plurality of closed

walls and an open side, and wherein said closed walls of said base unit and said lid include internal cavities containing a phase change material which changes phase within a predetermined storage temperature range;

placing at least one container of human blood into said base unit;

placing said lid onto said open side of said base unit to seal said base unit;

surrounding said sealed base unit with a vacuum insulation material; and

placing said sealed base unit surrounded by said insulation material into a carrying bag.

* * * * *