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Talonn et al.

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[54] **BLOOD OXYGENATING DEVICE WITH HEAT EXCHANGER**

[75] Inventors: **Daniel A. Talonn**, University City, Mo.; **Denton A. Cooley**, Houston, Tex.

[73] Assignee: **Sherwood Medical Industries, Inc.**, St. Louis, Mo.

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[52] **U.S. Cl.** **23/258.5**, 128/DIG. 3, 165/46, 261/DIG. 28

[51] **Int. Cl.** **A61m 1/03**

[58] **Field of Search** 23/258.5; 128/DIG. 3; 261/DIG. 28; 165/46; 195/1.8

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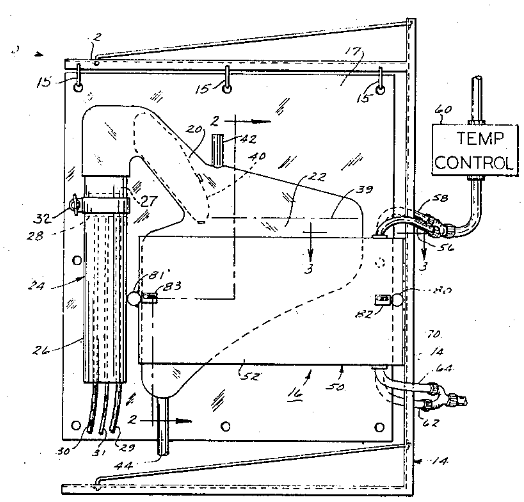
Primary Examiner—Barry S. Richman
Attorney, Agent, or Firm—Stanley N. Garber; William R. O'Meara

[57] **ABSTRACT**

A blood oxygenation device with a heat exchanger that includes a pair of plates disposed against the opposite sides of a flexible blood containing chamber of the device. The plates are relatively movable to selectively vary the volume of the chamber and the blood priming volume of the device. One or both of the plates are used as a heat exchange member to raise or lower the temperature of the blood flowing in the oxygenation device.

9 Claims, 5 Drawing Figures



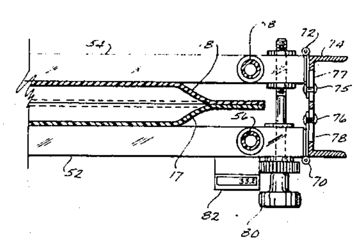


FIG. 1

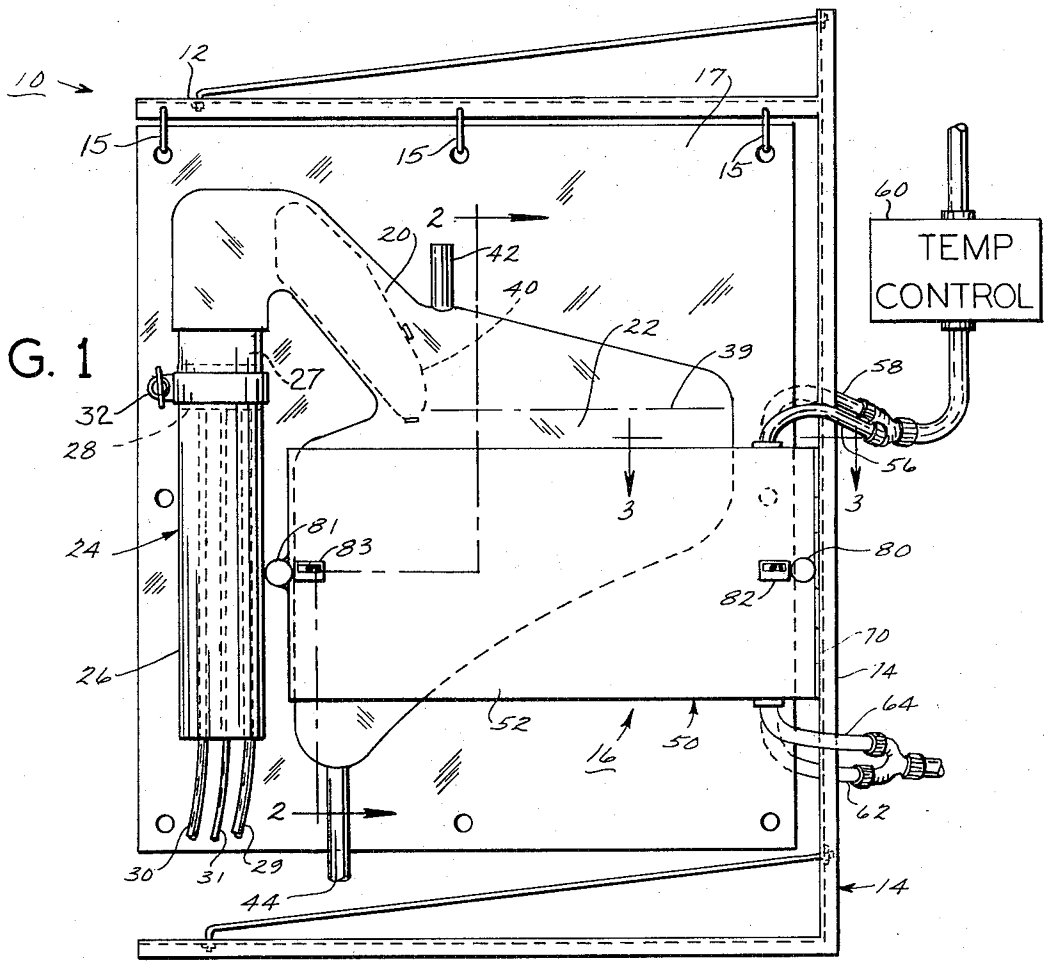


FIG. 3

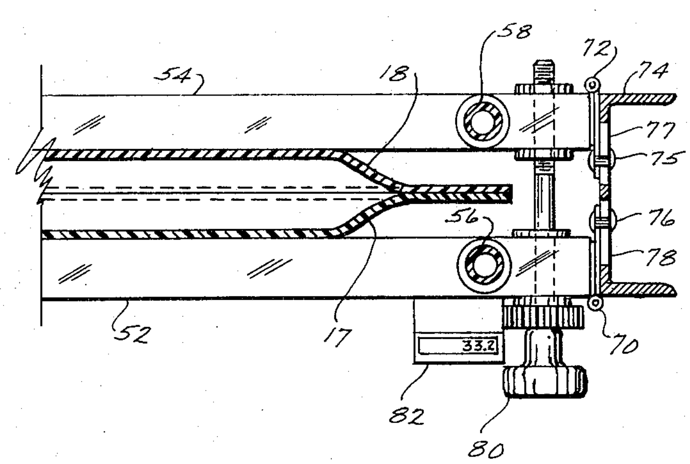


FIG. 2

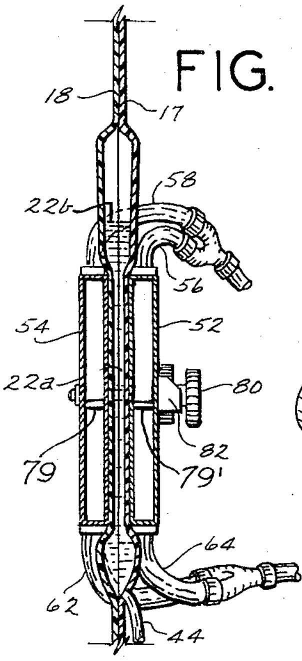


FIG. 5

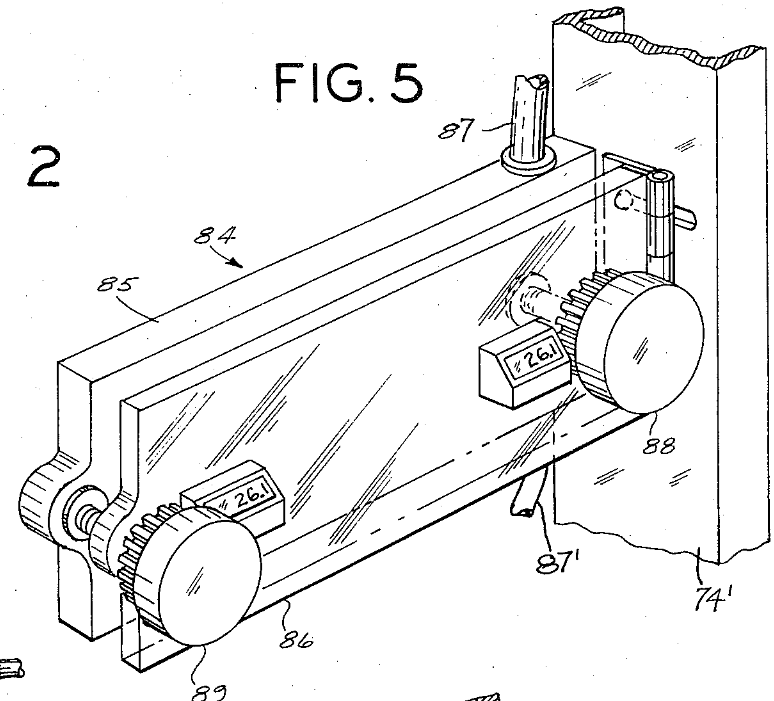
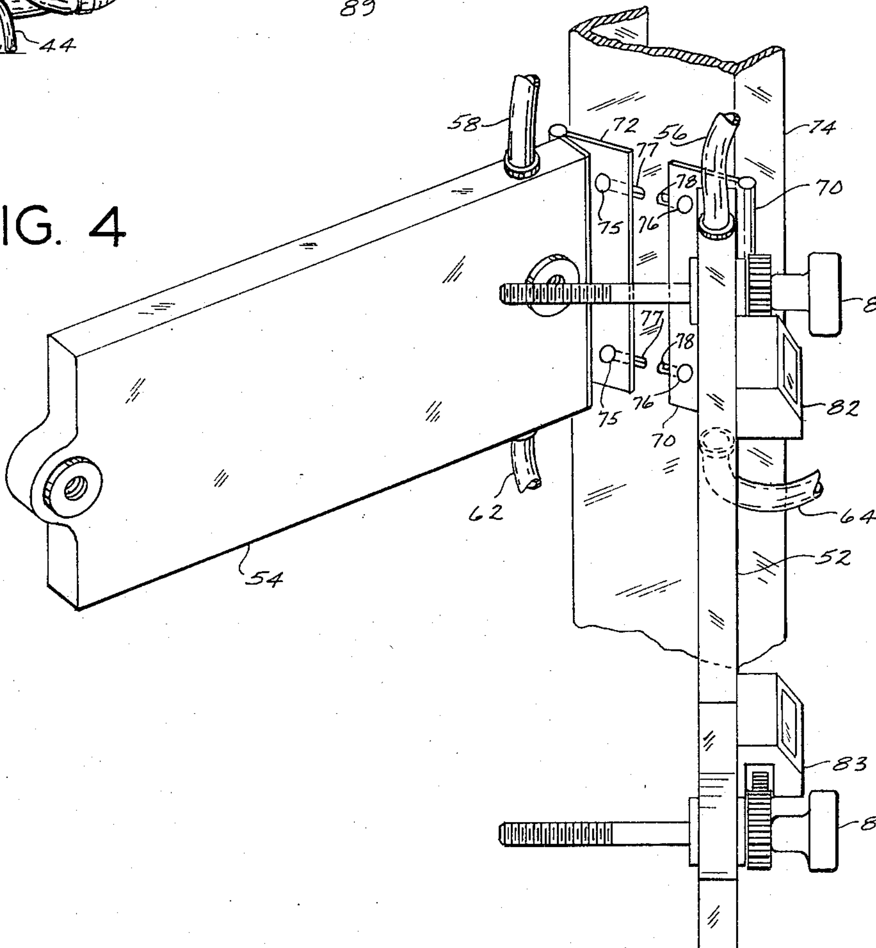


FIG. 4



BLOOD OXYGENATING DEVICE WITH HEAT EXCHANGER

BACKGROUND OF THE INVENTION

This invention relates to blood oxygenation apparatus and more particularly to an improved temperature control device for an oxygenation device.

Blood oxygenation devices are generally provided with blood temperature control devices which may include heat exchangers interposed in series in the extracorporeal circulating system. Various types of heat exchange devices have been proposed, however, they have not been entirely satisfactory for one reason or another. Some heat exchangers, for example, result in an increase in extracorporeal blood volume due to the blood priming requirement of the exchanger, and an increase in the length of the blood flow path thereby increasing the danger of damage to the bood. With some devices there exists the danger that, should any heat exchange fluid leak from the exchanger, the blood would be subjected to contamination by such fluid. Some proposed devices are lacking in other aspects such as heat transfer efficiency, and high cost.

In some cases, it is desired to change the blood volume or capacity of the oxygenation device in order to alter the priming volume of blood, for example, to minimize the priming volume for given patients. It is also desirable or necessary to maintain the blood in the reservoir chamber of an oxygenation device at its designed normal operating level so that the device functions in a manner consistent with its designed characteristics. While the blood capacity or level in the reservoir chamber can be varied by pinching off a portion of the chamber, such a method is not satisfactory because it affects the normal blood flow path through the device which may damage the blood, and it is an inaccurate way to vary the capacity.

SUMMARY OF THE PRESENT INVENTION

It is therefore an object of the present invention to provide an improved blood oxygenation device with a blood temperature control wherein the above-mentioned disadvantages are substantially obviated.

Another object is to provide an improved blood oxygenation device and blood temperature control in which the priming volume of blood may be readily and accurately varied and the temperature of the blooc efficiently controlled.

Another object is to provide a novel heat exchanger in combination with a blood oxygenation device which is highly efficient in operation to either heat or cool the blood, and which is capable of varying the bood capacity of the oxygenation device.

Another object is to provide a novel blood oxygenation device having a blood reservoir compartment of plastic material, and a heat exchange device which provides efficient heat transfer characteristics, is capable of adjusting the blood level, and wherein the danger of blood contamination from the heat exchanger device is eliminated.

Still another object is to provide improved blood oxygenation apparatus having a disposable blood oxygenation device with a reusable heat exchanger wherein blood does not come in contact with the heat exchanger and the danger of cross-infection is eliminated.

In accordance with one form of the present invention, blood oxygenation apparatus is provided which includes a compartment for containing blood, and a heat exchanger disposed in contact with the exterior of the blood compartment. In accordance with another aspect, the heat exchanger includes a pair of plates positioned respectively on opposite sides of a flexible blood compartment and are relatively movable to vary the volume of the compartment and effect heat transfer therewith.

These and other objects and advantages of the present invention will be apparent from the following detailed description and accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is an elevational view of an oxygenation device and a blood temperature control in accordance with a preferred embodiment of the present invention;

FIG. **2** is a cross-sectional view taken along the line **2—2** of FIG. **1**;

FIG. **3** is a cross-sectional view taken along the line **3—3** of FIG. **1**;

FIG. **4** is a perspective view of the heat exchanger of FIG. **1**; and

FIG. **5** is a perspective view of a modified form of heat exchanger.

DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring now to the drawings, and particularly to FIG. **1**, there is shown blood oxygenation apparatus including an oxygenation device **10** supported by a frame **12** connected to a standard **14**, and a temperature control device, indicated generally at **16**, which is also supported by the standard **14**. The device **10** is shown connected to frame **12** by a plurality of supporting rings **15**.

Oxygenation device **10** is of the plastic bag type which is generally formed by uniting a pair of supple plastic sheets **17** and **18**, such as by predeterminately located heat seals, to form a number of chambers or compartments such as a defoaming compartment **20**, and a settling reservoir compartment or chamber **22**. An oxygenator **24** is connected at the upper end thereof to the defoaming chamber **20**. Oxygenator **24** is similar to the oxygenator shown and described in copending application Ser. No. 263,049, filed June 15, 1972, by N. W. Burlis and assigned to the same assignee as this application and now, U.S. Pat. No. 3,827,860, issued Aug. 8, 1974.

Oxygenator **24** includes a hollow member **26** having interior walls forming an oxygenator column or chamber **27** which receives a movable oxygenating gas disperser and venous blood delivery member **28** shown in phantom in FIG. **1** and described in detail in the above copending application. The member **28** is provided with three tubes **29**, **30** and **31**, two of which, such as tubes **29** and **30**, may be connected to a source of venous blood while the tube **31** is connected to a source of oxygenating gas. The member **26** is cylindrical and may be of plastic material and formed by cutting it to size from plastic tubing. Member **26** is connected, such as by heat sealing, to the interior of the defoaming chamber **20**. The disperser member **28** is provided with an upper plate and a plurality of small holes for dispersing gas into the blood in the chamber **27**. It also has connections for connecting the tubes **29** and **30** through the member **28** to pass blood into chamber **27**, the blood flowing over the plate with the holes and being subjected to the gas bubbles, as described in the above mentioned copending application. A releasable clamp **32** is shown clamping the movable member **28** in a desired location in member **26** in sealing engagement with the walls of the chamber **27**. The member **28** is movable after releasing clamp **32**, by pulling on the tubes **29, 30** and **31** or by working the member externally through the tube **26** where the tube **26** is sufficiently supple, or a plunger rod (not shown) may be used to engage and connect with the member **28** to move it in one or both directions within the chamber **27** as desired. In this way the oxygenator **24** can be selectively adjusted to subject the venous blood to oxygenating gas for different lengths of time so that the same oxygenation device can be used to efficiently oxygenate venous blood for different flow rates and for patients of various sizes.

When the oxygenation device **10** is connected for operation and provided with a suitable amount of priming blood, venous blood flows in tubes **29** and/or **30** into the oxygenator chamber **27**, and oxygenating gas bubbles through the blood generating a blood foam which moves upwardly into defoaming chamber **20**. An antifoam member **40**, such as formed of plastic or metal fibers, is shown in phantom disposed in the defoaming chamber **20** and extending into the settling reservoir chamber **22** below the designed blood level, indicated at **39** in **FIG. 1**. The defoaming member **40** may be enclosed in a filter (not shown) such as a nylon woven stocking-like member. Blood flows into the settling chamber **22** with the excess oxygen gas and carbon dioxide leaving the defoaming chamber and settling chamber and passing to atmosphere by way of a vent indicated at **42**. The oxygenated blood flows through an outlet **44** at the bottom of chamber **22**, and, by means of a pump, into the arterial system of the patient to which it is connected.

The blood temperature control device **16** includes a heat exchanger **50** including front and rear heat exchange members **52** and **54** that engage the external sides of settling reservoir chamber **22** of device **10**. The members **52** and **54**, as also seen in FIG. **2**, are shown as hollow plates, for example, of stainless steel, having heat transfer fluid inlet conduits **56** and **58** connected to a suitable fluid temperature control device **60**, and a pair of outlet conduits **62** and **64** for discharging fluid from within the members **52** and **54** for returning it to the heat exchange system. The heat exchange members **52** and **54** are hinged together for pivotal movement relative to each other such as by hinges **70** and **72** connected to a vertical supporting member **74** of the standard **14**. The heat exchange members may be opened or moved away from each other, such as shown in FIG. **4**, to allow insertion of the oxygenation device **10**.

As seen more fully in FIGS. **3** and **4**, heat exchange members **52** and **54** are shown mounted for adjusting movement relative to each other by connecting the hinges **70** and **72** for movement relative to the supporting member **74** by rivets **75** and **76** slidable in slots **77** and **78** in member **74**. The space between the members **52** and **54** is accurately adjusted by a pair of threaded adjusting screws **80** and **81** provided with handles. The screws **80** and **81** are shown connected for rotation on member **52** and threadedly coupled to the member **54**.

The heat exchange members **52** and **54** are shown in FIG. **2** engaging the external, opposed sides of the blood reservoir compartment **22** for effecting a relatively narrow reservoir chamber main portion **22***a* therebetween which connects at its upper end with a relatively wide, shallow reservoir chamber portion **22***b* at the top. It will be apparent that by varying the distance between the heat exchange members **52** and **54** by means of screws **80** and **81**, the shape and volume of the reservoir chamber portion **22***a* can be varied and the total capacity of the chamber **22** changed. Also, the heat exchange members **52** and **54** intimately engage opposed sides of chamber **22** and, since chamber **22** is resilient or supple, compress and cause the chamber walls to conform in shape to the shape of the facing sides of the heat exchange members to maximize the areas of contact between the chamber of blood and heat exchange members for efficient heat transfer. The facing surfaces of the heat exchange members in the illustrated embodiment are planar and parallel to each other and contact the entire surface area of chamber portion **22***a* which constitutes the major surface area of the chamber **22**.

While the temperature of the plates **52** and **54** may be varied by various means other than fluids, for example, electronically, the temperature control device **16** may employ a liquid, such as water, flowing into the inlet tubes **56** and **58** and out the outlet tubes **62** and **64** to control the temperature of the heat exchange members. The temperature of the water is controlled by any suitable temperature monitoring and control means well known in the art to either heat or cool the water. Each of the heat exchange members **52** and **54** may be provided with internal baffling such as indicated at **79** and **79'** in FIG. **2**. The cooling or heating liquid flowing in the heat exchanger system may be used to cool or heat the blood as desired or required, and with the blood containing chamber **22** and heat exchanger disposed in the atmosphere of the operating room where they may be continuously viewed.

Because of the relatively shallow, relatively wide upper chamber portion **22***b* as a result of the clamping forces applied by the heat exchanger **50**, bubbles entering this portion readily rise and pass upwardly and out vent **42** to atmosphere, the relatively large surface of blood in portion **22***b* providing an efficient pool for the escape of such bubbles.

A pair of turn counters **82** and **83** are shown connected to heat exchange member **52** respectively adjacent the screws **80** and **81**. The counters may be of the well known tumbler type and geared to the screws to provide an indication of the number of turns that the screws have been rotated and the relative positions or spacing of the members **52** and **54**. By correlating the turns with the spacing between the members and the volume of the portions of reservoir chamber **22**, the counters give an accurate indication of the volume or blood capacity of the chamber **22** for any given setting of the screws **80** and **81**. Thus, the volume of the chamber **22** is readily adjusted to a desired value and can be readjusted or reset accurately by use of counters **82** and **83** which serve as volume indicating devices.

In FIG. **5**, there is shown a modification of the heat exchanger at **84**. Heat exchanger **84** includes a rear hollow heat exchange plate member **85** connected, such as by screws (not shown), to a vertical support **74'**. Member **85** has fluid inlet and outlet tubes **87** and **87'** for controlling the temperature of member **85.** A front plate member or panel **86** is hinged to support **74'** or to member **85** if desired. The members **85** and **86** are relatively movable toward and away from each other by means such as the sliding hinge shown and a pair of threaded adjustment screws **88** and **89.** In this case, the panel or front plate member **86** is formed of a transparent material such as glass or plastic, for the purpose of permitting the technician or surgeon to visually observe substantially the total blood flow in the oxygenation device, such as device **10,** that is to be inserted between members **84** and **85** during use. For example, it may be desirable to continuously observe the blood in the reservoir chamber, such as reservoir chamber **22** of device **10,** during surgery to ensure against the flow of a bubble into the outlet **44.** The heat exchanger **84** is capable of varying the blood carrying capacity of a supple or resilient plastic compartment, such as a settling reservoir chamber **22,** in the same manner as described herein in connection with the heat exchanger **50** of FIG. **1.** The chamber to be disposed between members **85** and **86,** such as the supple chamber **22** of oxygenation device **10,** has its facing sides conform to the surfaces of these members. In this illustrated arrangement, only member **85** is connected to a source of heat transfer fluid.

It will now be apparent that all of the objects and advantages of the present invention hereinbefore mentioned, as well as others, are provided by the present invention. It should be understood that although this invention has been described with reference to the illustrated preferred embodiments, modifications thereto may be made without departing from the true spirit and scope of the invention.

What is claimed is:

1. In combination, a blood oxygenation device including an oxygenator chamber, means for introducing venous blood and oxygenation gas to said oxygenator chamber for producing gas bubbles in the blood to oxygenate the blood, a defoaming chamber connected to receive blood from said oxygenator chamber and having anti-foam means therein for assisting in the removal of excess gas and vent means for venting excess gas to atmosphere, and a supple plastic blood settling reservoir chamber connected to receive blood from said defoaming chamber, said reservoir chamber having an outlet for discharging oxygenated blood, and blood temperature control means including a heat exchanger having a pair of relatively movable plates disposed respectively on opposite sides of said reservoir chamber, adjustment means for adjustably effecting relative movement between said plates to clamp at least a portion of said reservoir chamber therebetween to selectively vary the volume of said reservoir chamber, and means for varying the temperature of at least one of said plates to control the temperature of the blood.

2. The combination according to claim **1** wherein said adjustment means includes indicia to indicate the relative positions of said plates.

3. The combination according to claim **1** wherein said reservoir chamber and the other of said plates are transparent.

4. The combination according to claim **1** wherein said reservoir chamber portion comprises the major surface area of said reservoir chamber.

5. The combination according to claim **1** wherein said plates are adjustable to compress a main portion of said reservoir chamber and effect an upper reservoir chamber portion having a greater width than the portion of the reservoir chamber between said plates when blood is disposed in said reservoir chamber.

6. The combination according to claim **1** wherein at least one of said plates has a chamber therein, and said temperature varying means includes means for circulating heat exchange fluid through said chamber.

7. The combination according to claim **6** wherein said fluid is water.

8. The combination according to claim **1** further including upstanding frame means, and means hingedly connecting one of said plates to said frame means for pivotal movement toward and away from the other of said plates.

9. The combination according to claim **8** including means for connecting said oxygenation device to said frame means to support said oxygenation device between said plates.

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