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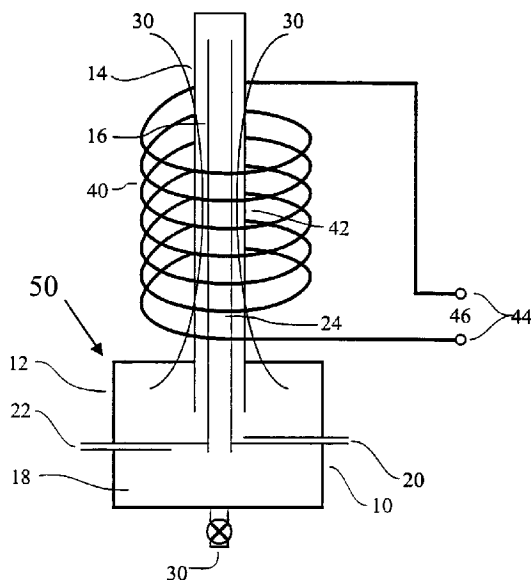
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(54) **DISPOSITIF D'OXYGENATION POUR PRODUIRE DES
CHANGEMENTS DANS LES EFFETS DE L'INTENSITE
CONTROLEE DU CHAMP MAGNETIQUE STATIQUE SUR
DES REACTIONS CONCERNANT DES RADICAUX LIBRES
SYNTHETISES DANS DES SUBSTRATS BIOLOGIQUES**

(54) **AN OXYGENATION DEVICE TO PRODUCE CHANGES IN THE
EFFECTS BY CONTROLLED STATIC MAGNETIC FIELD
STRENGTH ON SYNTHESIZED FREE RADICAL REACTIONS
IN BIOLOGICAL SUBSTRATES**



(57) Divulcation d'un dispositif pour traiter les produits biologiques et contrôler les réactions dans ces produits. Le dispositif, qui peut transférer efficacement un gaz comme l'ozone, est entouré par une source de champ magnétique.

(57) A device for processing biologics and controlling reactions in biologics by surrounding a device that can effectively transfer a gas, such as ozone, to the biologics with a magnetic field source.

Abstract of the Disclosure

A device for processing biologics and controlling reactions in biologics by surrounding a device that can effectively transfer a gas, such as ozone, to the biologics with a magnetic field source.

Field of Invention

This invention relates generally to a gas diffusion device and more particularly to a gas diffusion device that processes biological fluids utilizing a precision vacuum control means to control the flow rate, and mixing process of gas and biological fluids.

Background of Invention

Biological fluids, such as blood and blood products, can be treated with a gas, such as oxygen or ozone, to effectively inactivate various bacteria and other contaminants. In other application such gas may be used to activate blood components such as leucocytes, natural killer (NK) cells and the like. However the treatment of biological fluids which utilizes a gas mass transfer device, often results in mechanical damage to the cellular components of the biological fluid. Prior art gas transfer devices or blood oxygenators have encountered difficulties with the bubbling or frothing of the blood which can lead to the destruction of the blood cells, and consequently an ineffective transfer of the gas to the biological fluid.

Specifically, the gas transfer or oxygenation of the biological fluid requires a careful balance between the gas flow and the formation of gas bubbles within the biological fluid. The formation of the fluid gas bubbles, allows for the transfer of the gas to the biological fluid.

An improved gas diffusion device that processes biological fluids utilizing a precision vacuum control means to control the flow rate, and mixing process of gas and biological fluids is desirable.

Summary of Invention

In the first aspect of the present invention there is provided a bubble forming device for mixing a gas with a fluid comprising of a means for producing a fluid film,

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a means for developing a pressure differential across the film so as to produce bubbles and a passage means for receiving the bubbles.

5 In another aspect of the present invention the means for developing a pressure differential across the film to produce bubbles is achieved by a vacuum controlled means.

10 In a second aspect of the invention there is provided a bubble forming device having a means for producing a fluid film, a pressure equalizing orifice associated with the means for producing a film, a passage means for receiving the bubbles and a means for developing a pressure differential across the film so as to produce bubbles.

15 In another aspect of the present invention there is provided a method for forming bubbles by mixing a gas and a fluid using a means for producing a fluid film, a means for developing a pressure differential across the film so as to produce the bubbles and a passage means for receiving the bubbles.

20 An object of one aspect of the invention is to provide an improved gas diffusion device that processes biological fluids utilizing a precision vacuum control means to control the flow rate, and mixing process of gas and biological fluids.

25 In accordance with another aspect of the invention, there is provided a vacuum controlled fluid/gas bubble diffuser device comprising a fluid containment chamber, a vacuum controlled exhaust gas outlet, a fluid inlet port, a jet nozzle, a gas/fluid diffusion chamber or mixing chamber, a gas inlet port, fluid outlet and bubble sizing tubes, a stopping means, and a fluid draining means.

30 In accordance with still another aspect of the invention, there is provided a vacuum controlled fluid/gas bubble diffuser device further comprising a series of check valves so as to control the flow rate of the vacuum, gas and fluid.

Brief Description of Drawings

A detailed description of the preferred embodiments are provided herein below by way of example only, with reference to the following drawings, in which:

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Fig. 1 is a cross-sectional view of the vacuum controlled fluid/gas bubble diffuser device in accordance with a preferred embodiment of the invention.

10 Fig. 2 is a cross-sectional view of the vacuum controlled fluid/gas bubble diffuser device in accordance with a preferred embodiment of the invention.

Fig. 3 is a cross-sectional view of the vacuum controlled fluid/gas bubble diffuser device in accordance with a preferred embodiment of the invention.

15 Fig. 4 is a cross-sectional view of the vacuum controlled fluid/gas bubble diffuser device in accordance with a preferred embodiment of the invention.

Fig. 5 is a cross-sectional view of the fluid/gas diffuser device in accordance with a preferred embodiment of the invention.

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Fig. 6 is a cross-sectional view of the vacuum controlled fluid/gas bubble diffuser device in accordance with a preferred embodiment of the invention.

25 Fig. 7 is a cross-sectional view of the jet nozzle of the gas bubble diffuser device in accordance with a preferred embodiment of the invention.

Fig. 8 is a cross-sectional view of the dual mixing jet nozzle of the gas bubble diffuser device in accordance with a preferred embodiment of the invention.

30 Fig. 9 is a cross-sectional view of the vacuum controlled fluid/gas bubble diffuser device in accordance with a preferred embodiment of the invention.

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Fig. 10 shows the use of a bubble reduction screen mesh means.

Fig. 11 is a cross-sectional view of the vacuum controlled fluid/gas bubble device in accordance with the preferred embodiment of the invention.

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Fig. 12 is a cross-sectional view of the device containing a diaphragm and a pressure equalizing orifice.

Fig. 13 is a cross-sectional view of the vacuum controlled fluid/gas bubbling device having a second controlled gas flow inlet port and hypodermic needle.

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Fig. 14 is a cross-sectional view of the vacuum controlled fluid/gas bubbling device in accordance with Figure 6.

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Fig. 15 is a cross-sectional view of the vacuum controlled fluid/gas bubbling device wherein the fluid pre-treatment containment chamber is surrounded by the fluid post-treatment containment chamber.

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Fig. 16 is a cross-sectional view of a vacuum controlled fluid/gas bubbling device having two pre-treatment chambers with the pressure differential tubes located externally and a second controlled gas pressure port.

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Fig. 17 is a cross-sectional view of the preferred embodiment shown in Figure 16 having only one gas inlet port.

Fig. 18 is a cross-sectional view of the device wherein the pressure differential tubes are located internally in each pre-treatment chamber.

Fig. 19 shows a cross-sectional view of the vacuum controlled fluid/gas bubbling device with the pre-treatment chambers located in a different orientation.

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Fig. **20** is a cross-sectional view of the vacuum controlled fluid/gas bubbling device in the shape of cylindrical post treatment fluid containment chamber.

Fig. **21** is a cross-sectional view of the device as shown in Figure 20 having a syringe luer lock fluid inlet port and draw port.

Fig. **22** is a cross-sectional view of the vacuum controlled fluid/gas bubbling device in a bag format.

Fig. **23** is a cross-sectional view of the bag format wherein the blood post-treatment outlet tube is contained internally.

Fig. **24** is a cross-sectional view of the vacuum controlled fluid/gas bubbling device treating blood and treated PBS.

Fig. **25** is a cross-sectional view of the device as shown in Figure 24 and including a pressure control valve.

Fig. **26** is a cross-sectional view of the device as shown in Figures 24 and 25 including gas flow interrupt valves.

Fig. **27** shows a cross-sectional view of the vacuum controlled fluid/gas bubbling device wherein a static mixer is included to mix fluids from two containers.

Fig. **28** is a cross-sectional view of the device as shown in Figure 27 wherein there is only one fluid pre-treatment container.

Fig. **29** is a cross-sectional view of the vacuum controlled fluid/gas bubbling device showing a diffusion nozzle.

Fig. **30** is a cross-sectional view of the vacuum controlled fluid/gas bubbling device wherein the chambers have a different orientation.

Best Mode for Carrying Out the Invention

In the description which follows, like parts are marked throughout the specification and the drawings with the same respective reference numerals. The drawings are not necessarily to scale and in some instances proportions may have been exaggerated in order to more clearly depict certain features of the invention.

Referring to Fig. 1 there is illustrated a vacuum controlled fluid/gas bubble diffuser device 10 in accordance with preferred embodiments of the invention. The vacuum diffuser device 10 includes a fluid containment chamber 12, a vacuum controlled exhaust gas outlet port 14 having a check valve 15, a fluid inlet port 16 having a check valve 17, a gas nozzle 18, a gas/fluid diffusion chamber 20, a gas inlet port 22 having a check valve 23, fluid outlet and bubble sizing tubes or bubble control tubes 24 having a fluid outlet nozzle 25, a stopcock 26 and a fluid drain 28. The gas nozzle 18 is attached to the gas inlet port 22 and directs the gas into the gas/fluid diffusion chamber 20.

Fluid inlet port 16 allows the biological fluid, such as blood, to flow into the gas/fluid diffusion chamber 20 where the biological fluid comes in contact with the gas in the form of a thin layer or film. The chamber 20 has a gap thickness to produce a thin film of biological fluid which will form into a bubble. This gap thickness is generally in the order 5 to 10 thousandths of an inch. Such dimension is not limiting but included as an example. The device 10 may be constructed from biocompatible polymers such as polycarbonate.

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The device 10 utilizes vacuum control via the vacuum controlled exhaust outlet port 14 to control the mixing process and therefore controls the transfer of a selected concentration and volume of ozone/oxygen gas into a biological fluid such as whole blood or blood products. This is accomplished in the form of uniform singlet bubbles derived from the gas passing into a thin layer of the biological fluid (but not through gas bubbles rising through a column of biological fluid) and expelling the bubbles from the fluid exit nozzle along the bubble sizing column 40 into a contained gaseous ozone and or

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ozone/oxygen atmosphere in a single pass. The bubble sizing tubes consist of a bubble sizing column 40 which has inside of it a coaxially disposed tube 42 which communicates with the mixing chamber 20. In particular, the bubbles of fluid travel through the tube 42 and then out between the space between the column 40 and tube 42 to pool into the
5 bottom of the fluid containment chamber.

In operation, a vacuum of 1" to 20" of water column is applied to the exhaust gas outlet port 14 via check valve 15, while at the same time gas at a flow rate of between 5ml/min to 500ml/min is fed to the gas inlet port 22 via check valve 23, stopcock 26 is
10 in the closed position. The fluid inlet port 16 and check valve 17 are connected to the biofluid to be treated.

As the vacuum is increased at the exhaust gas outlet port 14, the biofluid is drawn into the gas/fluid diffusion chamber 20 where it is contacted and diffused with the
15 incoming gas from the gas nozzle 18, the fluid then proceeds to the fluid outlet nozzle 25 and exits from the fluid outlet nozzle 25 into the fluid containment chamber 12 in the form of uniform gas filled bubbles, the thin film of fluid that constitutes the make up of the bubble allows for excellent gas mass transfer.

20 When the fluid bubbles reform into their fluid state the fluid is released from the fluid containment chamber 12 by the stopcock 26 and exits at the fluid drain outlet 28.

Referring to Figs. 2, 3 and 4 there is described the vacuum controlled fluid/gas bubble diffuser device 10 as generally described in Fig. 1 wherein the position of the
25 gas/fluid diffusion chamber 20 to the fluid outlet and bubble sizing tubes 24 is variable.

In Fig. 1 the bubble sizing tubes 24 are in line with the gas nozzle 18. In Fig. 2 the bubble sizing tubes 24 communicate with the mixing chamber 20 but are not in line with the gas nozzle 18.

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Fig. 3 illustrates that the fluid containment chamber 12 communicates with the bubble control tubes 24 but is separated from the bubble sizing tubes 24.

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Fig. 4 shows a fluid outlet bubble tube 48 in place of the bubble control tubes 24.

Referring to Figs. 5 and 6, there is described the vacuum controlled fluid/gas bubble diffuser device 10 as generally described in Fig. 1, wherein the fluid containment chamber 12 has a different orientation to the gas/fluid diffusion chamber 20.

In Fig. 6 the bubble size tubes 24 extend beyond the fluid containment chamber 12 sometimes herein referred to as a post-treatment containment chamber.

Fig. 7 shows the cross-section of the bubble jet nozzle 18.

Fig. 8 illustrates that the invention can be used for mixing two fluids. The first fluid is introduced into first fluid inlet port 50 into first mixing chamber 52, while the second fluid is introduced into the second fluid inlet port 60 into second mixing chamber 62. Bubbles of fluid from mixing chambers 52 and 62 exit from the fluid bubble exit nozzle 64 into tube 42.

Referring to Figs. 7 and 8, there is described the bubble jet nozzle 18 of the vacuum controlled fluid/gas bubble diffuser device 10 as generally described in Fig. 1, wherein the bubble jet nozzle in combination with the vacuum controls the flow of the gas into a single gas/fluid diffusion chamber 20 or mixing chamber or a dual gas/fluid diffusion chamber 20.

Referring to Fig. 9, there is described the vacuum controlled fluid/gas bubble diffuser device 10 as generally described in Fig. 1, wherein the fluid containment chamber 12 has a different orientation to the gas/fluid diffusion chamber 20. The device 10 has a vacuum that draws blood from the fluid inlet port 16 which mixes with the gas in the gas/fluid diffusion chamber 20 and is drawn through fluid outlet sizing tubes 24. A large surface area for the bubbles is therefore available to be exposed to ultra violet light and/or a static magnetic field. The size of the bubble can be precisely controlled by the applied vacuum and the jet nozzle diameter. Break down of the bubbles is caused

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by closing the vacuum check valve 15 and allowing the incoming gas to pressurize the chamber.

Fig. 10 shows the use of a screen mesh bubble reduction filter 70 such as a number 40 mesh biocompatible polymer for example.

Operating Parameters

The invention as described in Figures 1 through 10 can be operated under a variety of gas pressures, gas flow rates and vacuums. In particular, without restricting the generality of the foregoing, good results have been observed by using a gas pressure of between 0.25 to 5 psi in the gas inlet port 22 at a gas flow rate of between 5ml/min to 500ml/min and a vacuum of between 0" and 20" of water column.

Further Embodiments

Figure 11 is a further embodiment of the device 10 described above. In particular, the device 10 shown in Figure 11 includes a blood pre-treatment chamber 100 which is adapted to receive biological fluids such as blood. The blood communicates with the mixing chamber or mixing jet assembly 102 by means of communicating through fluid inlet ports 104. The device 10 also includes a vacuum controlled off gas port 106 having a check valve 108. A jet nozzle 110 communicates with the gas inlet port 112 which has check valve 114. Bubble control tubes 116 are also included and operate as described in relation to the bubble sizing tubes.

The blood is inserted into the blood pre-treatment chamber 100 by means of syringe injection port 118 and a thin layer of blood is produced in the mixing jet assembly 110 as previously described. At the same time, gas such as ozone is introduced into the gas inlet port 112 at a gas pressure of, for example, between 0.25 to 5 psi and a gas flow rate of between 5ml/min to 500ml/min. Moreover, a vacuum is also produced at the same time of between 0" to 200" of water.

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The bubbles of blood are produced as described hereinbefore and travel up through the bubble control tubes 116 as previously described and collect in the blood post-treatment chamber 120. The blood may be removed by means of the syringe injection port blood retrieval 122.

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The embodiment shown in Figure 11 includes a pressure equalizing orifice 124 which is connected to an external oxygen or ozone source at pressure. The pressure equalizing orifice 124 assists fluid flow and enhances the fluid flow rate and formation of uniform bubbles through the bubble control tubes 116.

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The Gas Pressure inside the fluid pre-treatment chamber 100 drives the fluid into the fluid inlet ports 104 up and into the mixing jet nozzle assembly 102 that produces the bubbles from the fluid film.

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Changing the gas pressure jet nozzle diameter size of the pressure equalizing orifice 124 will effect the pressure inside the fluid pre-treatment chamber above the liquid level 126.

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Depending on the pressure equalizing jet nozzle diameter selected, the fluid flow rate to the mixing jet nozzle assembly can be changed i.e. a small diameter pressure jet nozzle will produce a low fluid flow rate, a large diameter pressure jet nozzle will produce a high fluid flow rate, thus differing ratios of gas/fluid mixtures can be achieved.

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The diameter of the pressure jet nozzle of pressure must always be greater than that of the mixing jet diameter object nozzle 110 (mixing jet assembly) for the device to function correctly.

Figure 11 also shows the liquid level 126 of the blood.

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Figure 12 illustrates the device 10 generally described in Figure 11 with the addition of a diaphragm 128 and that the pressure equalizing orifice is located in the jet nozzle housing so as to assist in equalizing the pressure. In particular, the pressure

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equalizing orifice or passage 124 communicates above the diaphragm 128 and the gas which is flowing into the jet nozzle 110. The space above the diaphragm 128 and the separation between pre-treatment chamber 100 and the post-treatment chamber 120 is filled with the same gas which is being introduced into the device 10. Accordingly, the pressure equalizing orifice or passageway 124 assists in maintaining the fluid flow and the uniform sizing and passage of bubbles through the bubble control tubes 116. A diaphragm 128 is used so that the diaphragm can move so as to increase the pressure at the fluid surface to enhance fluid flow automatically as required.

Figure 13 is similar in operation to Figure 11 except the device 10 includes a second control gas flow inlet port 130 which introduces gas such as ozone by means of a hypodermic needle 132 which passes through the appropriate membrane 134. Figure 13 does not include a diaphragm and the pressure equalizing orifice passageway 124 vents to the space above the liquid level 126 to enhance fluid flow.

Figure 14 includes a jet nozzle 110 arrangement similar to that shown in Figure 6. The pressure equalizing nozzle 124 communicates with the conduit that connects with the gas inlet 112 and vents into the pre-treatment chamber 100.

Figure 15 illustrates another embodiment which operates similarly to the embodiments referred to above. Figure 15 shows a fluid post-treatment containment chamber 120 which surrounds the pre-treatment chamber 100. As the bubbles exit from the bubble transport and control tubes 116, the bubbles migrate downwards as shown by the arrows into the fluid post-treatment containment chamber 120. The pressure equalizing orifice 124 vents in a manner similar to that shown in Figures 12, 13 and 14.

Figure 16 shows the invention having two fluids, namely blood and PBS. Accordingly, Figure 16 illustrates a first blood pre-treatment chamber 140 and a second PBS pre-treatment chamber 142. Blood inlet 144 and PBS inlet 146 are provided. Gas is introduced through gas inlet port 112 and the blood and PBS is drawn through the tubes 148 and 150 respectively. The blood and PBS mix in mixing jet nozzle unit 102 as previously described so as to form bubbles travelling through the bubble control tubes

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116 which then fall down into the post-treatment chamber 120. Figure 16 also shows the use of the external pressure tubes that enhance fluid flow 152. Moreover, a second control gas pressure inlet port 154 is also provided. The external pressure differential tubes 152 communicate simultaneously with the chambers 140 and 142.

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Figure 17 is similar to that of Figure 16 except the external pressure differential tube 152 communicates with the gas inlet port 112.

10 Figure 18 is similar in operation to that shown in Figure 17 and 16, but the pressure equalizing orifice 124 vents internally of the unit as shown.

Figure 19 is similar to that of the device 10 in Figure 18 except that the blood pre-treatment chamber 140 is stacked side-by-side with PBS pre-treatment chamber 142. The pressure equalizing orifices 124 vent internally to the respective chambers.

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Figure 20 shows a further embodiment whereby the device 10 is constructed in the shape of a cylinder. Figure 20 also shows the pressure equalizing orifice 124.

20 Figure 21 is similar to the construction shown in Figure 20 and also includes syringe luer lock 156 and syringe luer lock fluid draw off port 158. The differential gas pressure outlet port 124 is also shown.

Figure 22 illustrates another embodiment of the invention applied to a bag. In particular, Figure 22 illustrates a blood pre-treatment containment bag 160 having a blood inlet tube 162 whereby the blood is driven up into the mixing chamber assembly 102 by the gas pressure venting from the equalize port 124 (and communicates with the gas inlet port) and bubbles are formed as previously described and exit into the blood post-treatment outlet tube 164 into the bag. The gas equalizing pressure port 124 vents into the pre-treatment containment bag 160. The device 10 shown in Figure 22 includes a separator 166 which separates the blood pre-treatment containment bag 160 from the post-treatment containment bag 168.

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Figure 23 illustrates the invention in relation to a bag whereby the post-treatment outlet tube 164 is located internally of the bag.

5 Figure 24 is similar to operation as shown in Figure 16 whereby the blood and treated PBS is located in separate containers and the pressure equalizing ports communicate with the blood and treated PBS containers.

Figure 25 is similar to Figure 24 and includes a pressure control valve 170 so as to control the pressure in the treated PBS container as well as in the blood container.
10 The pressure equalizing ports 124 also communicate with the gas inlet port 112.

Figure 26 is similar to that shown in Figure 24 and includes gas flow interrupt valves 172-1, 172-2, and 172-3.

15 For example, in one operation of the invention, the valve 172-1 can be closed on ozonation of PBS. Moreover, valve 172-2 could be open on ozonation of PBS. Valve 172-3 can be closed on ozonation of PBS while valve 172-1 can be open when treated biological fluids. Furthermore, valve 172-2 could be closed when treating biological fluids and valve 172-3 can be open when treating biological fluids.

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Figure 27 is similar to the previous embodiments but includes a static mixer 174 which communicates with the fluid injection jets 176. The fluid injection jets 176 inject PBS fluid into the static mixer 174. A gas flow and pressure regulator 178 is shown. Figure 27 also illustrates the use of one-way check valve luer lock fluid inlet ports 180.
25 The static mixer 174 also communicates with the biological fluid as well as the mixed biological fluid and PBS.

Figure 28 is similar to that shown in Figure 27 except that the pressure equalizing conduit 124 communicates with the gas inlet port 112 as well as the fluid pre-treatment
30 containment chamber 100.

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Figure 29 is similar to the embodiment shown in Figure 24 except only fluid mixing is achieved. No gas is applied at the diffusion nozzle assembly.

Figure 30 illustrates another arrangement of the invention described herein.

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The device 10 described in all of the embodiments illustrates the precision gas flow and pressure differential control of a mixing process which control the transfer of a pre-selected concentration and volume of ozone/oxygen gas mixture into a biological fluid such as whole blood or blood products in the form of uniform thin film singlet
10 bubbles, derived from the gas passing into a thin layer of the biological fluid (but not through gas bubbles rising through a column of biological fluid), and expelling the bubbles from a fluid exit jet nozzle along a bubble sizing column into a contained gaseous ozone and/or ozone/oxygen atmosphere in a single pass. In other words, the formed bubbles are not broken by the gas.

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As the gas flow/pressure is increased at the gas inlet port and within the fluid containment chamber through the pressure equalizing port 124, and the vacuum increased proportionately at the exhaust gas ports 106, the biofluid is caused to flow by pressure differential to the mixing jet assembly chamber 102 where it is contacted and diffused
20 into the incoming gas from the jet nozzle 110. The fluid then proceeds to and exits in the form of bubbles into the bubble control tubes 116 to the fluid post-treatment containment chamber 120 in the form of uniform gas-filled bubbles. Any excess gas is vented from the post-treatment containment chamber 120 via the vacuum-assisted exhaust gas port 106.

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When the bubbles return to their fluid state, the treated fluid is drawn from the post-treatment chamber 120 via the syringe injection retrieval port 118

The thin film of fluid that constitutes the makeup of the bubble allows for
30 excellent gas mass transfer between the ozone and blood or other biological fluids. Moreover, gas or ozone can be introduced into the post-treatment chamber 120 so that the mass transfer occurs externally of the bubble as well as internally of the bubble.

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The embodiment shown in Figures 11 to 30 include an improvement over the embodiment shown in Figures 1 to 10. The embodiment shown in Figures 1 to 10 work and function extremely well without a pressure differential orifice. By utilizing the pressure differential orifice, this further improves the invention shown in Figures 1 to 10.

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Moreover, the embodiments which illustrate the use of a diaphragm can consist of a polymer diaphragm. Pressure applied to the fluid surface can be accomplished by utilizing an internally incorporated thin expandable polymer diaphragm where the incoming gas pressure would expand the diaphragm, thus applying pressure to the fluid surface to create mode of force. Using this configuration allows for substantially the complete isolation of gas from the fluid inside the fluid pre-treatment chamber.

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Moreover, Figure 13 which showed the use of a hypodermic needle 132 shows that as the bubbles move up the bubble column, they impinge on the hypodermic needle and are reinfused with the ozone/oxygen gas mixture before being transported to the post-treatment chamber. This reinfusion of ozone/oxygen gas replaces spent gas used during the reactive phase of ozone within the cellular components of the biological fluid being treated.

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By utilizing the controlled pressure differential structure shown in Figures 11 to 30 rather than a venturi effect to control fluid flow to the gas fluid mixing nozzle and diffusing a gas such as ozone or oxygen or a mixture of ozone and oxygen gas, into the fluid within the mixing nozzle and to expel and produce from the jet nozzle a fine spray of ozonated or oxygenated fluid droplets rather than gas-filled fluid bubbles is an alternative method of treating biological fluids.

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Moreover, the various embodiments illustrated herein exhibit the following advantages:

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1. Ozonation of PBS completed automatically in a self contained chamber directly before mixing.

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2. Virtually no degradation in ozone concentration transferred to PBS before initialization of the mixing process.
3. The unique fluid/fluid mixing gas jet nozzle assembly allows for further ozonation of the mixed fluids during processing if and when required.
4. Ability to change the mixing ratios of the two fluids.
5. Ability to change the gas to fluid mixing ratios.
6. Processing after introduction of PBS and the selected biological fluid, is confined to a sterile closed system, consisting of a biological fluid containment chamber, a PBS containment chamber, the fluid mixing nozzle assembly, and the processed and mixed fluid containment chamber.
7. No need for electromechanically driven fluid pumps.
8. May be designed as a reusable or disposable system.
9. Versatile and user friendly.
10. Cost effective.

Moreover, the device 10 described herein can be dimensioned so as to utilize the gas flow rate in combination with the biological fluid exit nozzle diameter and tube sizing means to determine bubble size. Furthermore, the embodiments show an integrated gas jet exit nozzle and fluid exit nozzle that have identical dimensions so as to minimize or substantially prevent venturi action to occur within the device.

The invention also shows an integrated diffusion device 10 that is adapted to mix two fluid types fed from separate fluid containment chambers simultaneously to a single mixing chamber and jet nozzle and controlling the differential pressure internally or

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externally with an ozone or oxygen gas or a mixture of ozone and oxygen gas within at least one fluid containment chamber so as to control fluid flow rate and the mixing and mixing ratios of two fluid types arriving at the jet nozzle orifice.

5 Various embodiments of the invention have now been described in detail. Since changes in and/or additions to the above-described best mode may be made without departing from the nature, spirit or scope of the invention, the invention is not to be limited to said details. For example, as described above one obtains a pressure differential between the vacuum used and gas that is introduced into the unit. It is
10 possible that one may introduce the gas at a pressure without utilizing a vacuum so as to produce the results described herein provided one does not produce a spray but either uniform bubbles as described.

Claims

The embodiments of the invention in which an exclusive property or privilege is claimed are defined as follows:

1. A device for processing biologics with a gas comprising:
 - (a) means to transfer said gas to said biologics; and
 - (b) static magnetic field surrounding said means to transfer said gas to said biologics.
2. A device as claimed in claim 1 including at least one helix coil to produce said static magnetic field.
3. A device as claimed in claim 1 including a selectively controllable direct current source for selecting the strength of said static magnetic field surrounding said biologics.
4. A device as claimed in claim 3 wherein said biologics comprise a biological fluid which is external to a body and said gas comprises ozone.
5. A device as claimed in claim 4 wherein said means to transfer said gas to said biological fluid comprises:
 - (a) a first pre-treatment chamber for containing said biological fluid;
 - (b) a second post-treatment chamber for collecting treated biological fluid; and
 - (c) a passage means communicating between the first pre-treatment chamber and said post-treatment chamber for receiving said treated biological fluid by said gas mixing with said biological fluid and travelling through said passage means to collect in said second post-treatment chamber as said treated biological fluid.

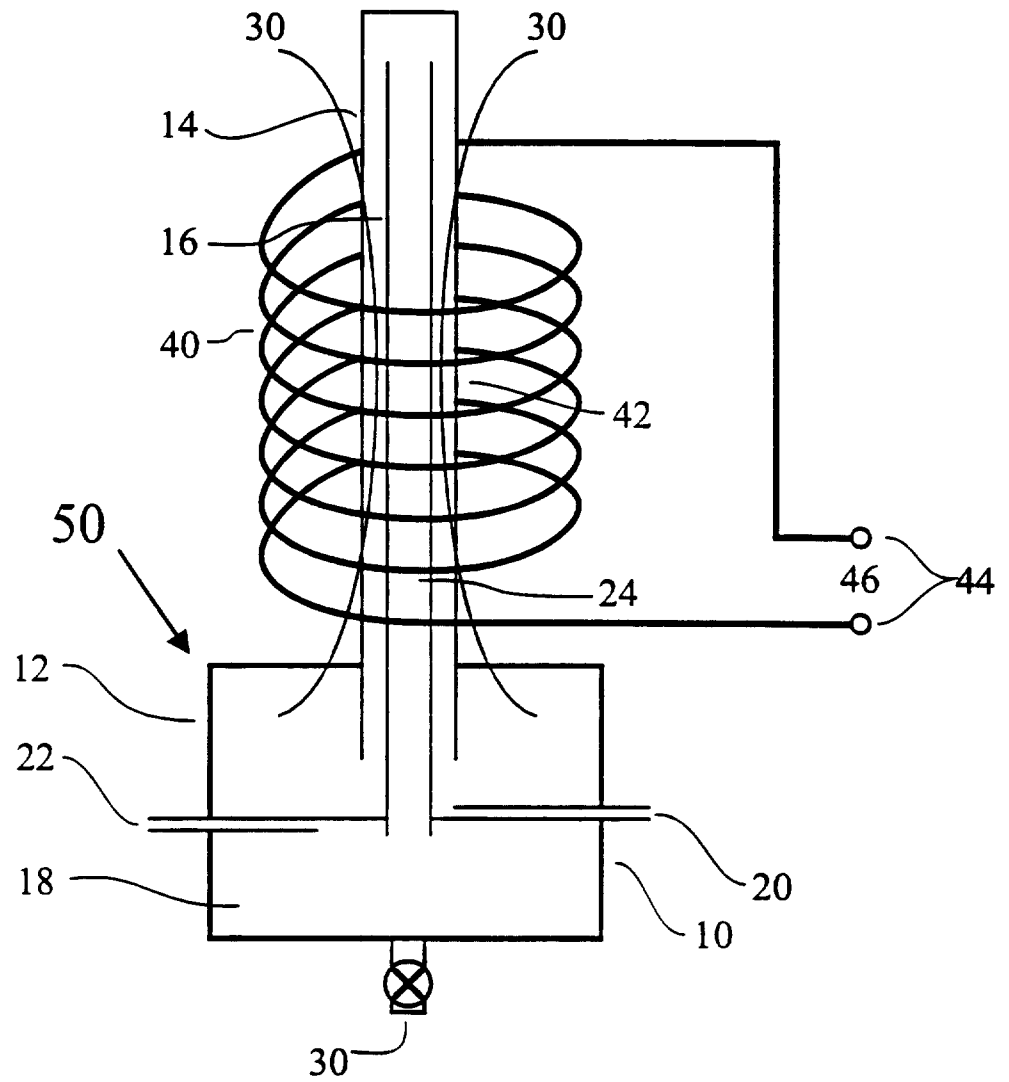
6. A device as claimed in claim 5 wherein said passage means comprises coaxial tubes.
7. A device as claimed in claim 3 wherein said coaxial tubes present a gap for controlling the size of bubbles produced by said gas mixing with said biological fluid.
8. A device for processing biological fluid with a gas as claimed in claim 7 wherein said helix coil includes a hollow coil for receiving said coaxial tubes.
9. A device for processing biological fluid with a gas as claimed in claim 8 wherein said helix coil contacts said coaxial tubes.
10. A device as claimed in claim 3 wherein said helix coil includes a hollow core for receiving a body, limb, or part of a body and applying said static magnetic field thereto.
11. A method for processing biologics with a gas using a static magnetic field to surround a means to transfer a gas to said biologics and delivering a specified concentration of said gas to said biologics while said static magnetic field is energized.
12. A method as claimed in claim 11 wherein said static magnetic field is produced by a helix coil energized by a controllable DC current source.
13. A method as claimed in claim 12 wherein said static magnetic field affects changes in the kinetics of free radical reactions and dipole movements within said biologics wherein said gas is transferred to said biologics.
14. A method as claimed in claim 12 for treating humans or animals.
15. A method as claimed in claim 14 wherein said treatment is a conventional process selected from the group comprising treatment with ozone, ozone oxygen gas mixture, vaccine or drug.

16. A method as claimed in claim 15 wherein said biologics is selected from the group comprising blood, blood products, and seminal fluid.

17. A method as claimed in claim 15 wherein said biologics is selected from the group of bone or cartilage.

18. A method as claimed in claim 16 wherein said treatment is conducted outside of said body.

19. A method as claimed in claim 16 wherein said treatment is conducted in vivo.

**Figure 1**

