

PCTWORLD INTELLECTUAL PROPERTY
ORGANIZATION
International I

INTERNATIONAL APPLICATION PUBLISHED UNDER

WO 9606647A1

(51) International Patent Classification⁵ :

A61M 1/36, F21V 29/00

A1

(11) International Publication Number:

WO 96/06647

(43) International Publication Date:

7 March 1996 (07.03.96)

(21) International Application Number: PCT/US95/10700

(22) International Filing Date: 22 August 1995 (22.08.95)

(30) Priority Data:

08/299,398

1 September 1994 (01.09.94)

US

(71) Applicant: BAXTER INTERNATIONAL INC. [US/US]; One Baxter Parkway, Deerfield, IL 60015 (US).

(72) Inventor: D'SILVA, Edmund, D.; 15 Timber Lane, #12, Vernon Hills, IL 60061 (US).

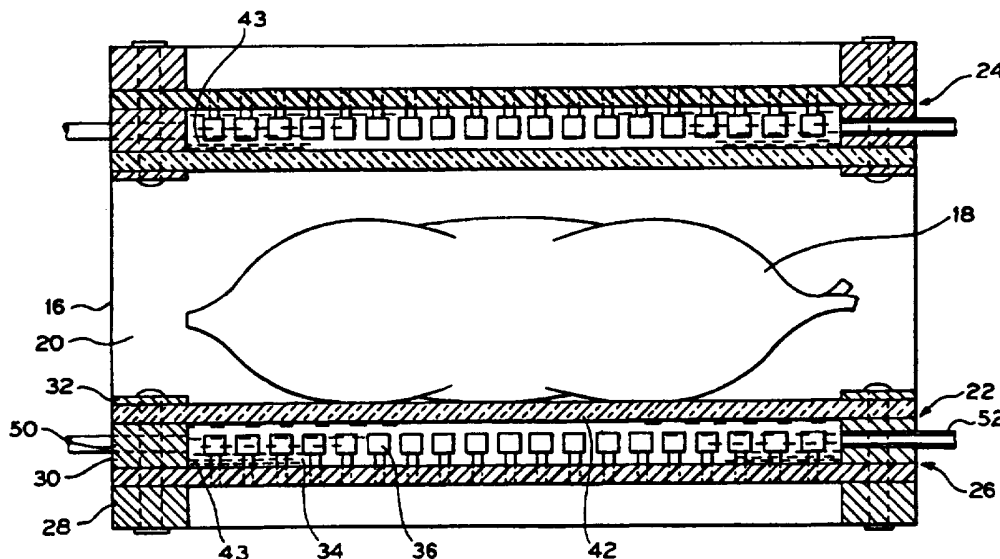
(74) Agents: BARRETT, Joseph, B. et al.; Baxter International Inc., One Baxter Parkway, Deerfield, IL 60015 (US).

(81) Designated States: CA, JP, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published

With international search report.

(54) Title: APPARATUS AND METHOD FOR ACTIVATING PHOTOACTIVE AGENTS



(57) Abstract

The present invention provides improved methods and apparatus for irradiating a product with light of specific wavelength to activate the photoactive agent that is contained in the product. To this end, in an embodiment, a device (22, 24) is provided that comprises a source of radiation including a plurality of light emitting diodes (36). Each light emitting diode includes a body portion through which radiation is transmitted. The body of the diode (36) is surrounded by a fluid (43). In this regard, a first housing (26) is provided that includes an interior (34) that contains the light emitting diodes (36) and a fluid (43). The housing (26) includes a transparent window (42) for allowing radiation generated by the light emitting diodes (36) to flow through the window (42) and irradiate a product (18) that is in juxtaposition to the window (42).

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	GB	United Kingdom	MR	Mauritania
AU	Australia	GE	Georgia	MW	Malawi
BB	Barbados	GN	Guinea	NE	Niger
BE	Belgium	GR	Greece	NL	Netherlands
BF	Burkina Faso	HU	Hungary	NO	Norway
BG	Bulgaria	IE	Ireland	NZ	New Zealand
BJ	Benin	IT	Italy	PL	Poland
BR	Brazil	JP	Japan	PT	Portugal
BY	Belarus	KE	Kenya	RO	Romania
CA	Canada	KG	Kyrgyzstan	RU	Russian Federation
CF	Central African Republic	KP	Democratic People's Republic of Korea	SD	Sudan
CG	Congo	KR	Republic of Korea	SE	Sweden
CH	Switzerland	KZ	Kazakhstan	SI	Slovenia
CI	Côte d'Ivoire	LI	Liechtenstein	SK	Slovakia
CM	Cameroon	LK	Sri Lanka	SN	Senegal
CN	China	LU	Luxembourg	TD	Chad
CS	Czechoslovakia	LV	Latvia	TG	Togo
CZ	Czech Republic	MC	Monaco	TJ	Tajikistan
DE	Germany	MD	Republic of Moldova	TT	Trinidad and Tobago
DK	Denmark	MG	Madagascar	UA	Ukraine
ES	Spain	ML	Mali	US	United States of America
FI	Finland	MN	Mongolia	UZ	Uzbekistan
FR	France			VN	Viet Nam
GA	Gabon				

- 1 -

S P E C I F I C A T I O NTITLE**APPARATUS AND METHOD FOR ACTIVATING
PHOTOACTIVE AGENTS**

5

BACKGROUND OF THE INVENTION

The present invention relates generally to medical devices and methods and apparatuses for treating individuals. More specifically, the present invention relates to apparatuses and methods for utilizing photoactive compounds to inactivate contaminants in body fluids.

In a wide variety of therapies, such as transfusions and transplants, body fluids, especially blood components such as red blood cells, platelets, plasma, and bone marrow, are infused from one or more individuals into a patient. Although such therapies provide treatments, many of which are life saving and cannot otherwise be provided, due to the transmission of infectious diseases, there may a potential risk to such therapies.

For example, it is known that blood can carry infectious agents such as hepatitis virus, human immune deficiency virus (HIV), cytomegalovirus, Epstein Barr virus, and herpes virus. Although screening methods exist to identify blood that may include such viruses, current screening methods do not insure that every blood unit that contains such a virus is identified.

For example, in this regard, one of the difficulties in testing blood components for viral contamination, such as HIV, is that many current diagnostic tests are based on an identification of antibodies. Therefore, a contaminated blood component will only exhibit a positive test if it includes antibodies for the virus, e.g., anti-HIV.

- 2 -

With respect to intracellular viral infections, an individual may not generate the antibodies immediately upon infection. Rather, there is a window period that extends from the initial infection of the patient with
5 the virus to the generation of antibodies. When an individual is in this window period, diagnostics tests that are based on antibodies will not identify the individual, or the blood unit, as being infected. But, even though antibodies are not present, the blood unit
10 can still transmit an infection.

With respect to HIV infection, it is believed that this window period can extend from approximately six weeks up to many months. During this time period, the individual who has been infected with HIV and
15 accordingly, whose blood will transmit same, will register a negative antibody response. Typically used blood screening methods will not identify a contaminated blood unit from an individual who is infected with HIV but who has not generated anti-HIV.

In order to address the limitations of typical diagnostic techniques and also deal with the concern of transmission of viral contaminants and other pathogens to a patient receiving a transfusion, recent attention has focussed on the development of viral inactivating
20 agents. It is envisioned that these viral inactivation agents would be added to the body fluid prior to the body fluid being administered to the patient.
25

For example, a number of photoactive agents that have antiviral action have been explored. These
30 photoactive agents are generally agents that upon activation with light will inactivate or destroy pathogens, e.g., a virus that may be present. Such photoactive agents include: psoralens; porphyrins;

- 3 -

phthalocyanines; and dyes such as methylene blue. See, for example, U.S. Patent Nos.: 4,748,120; 4,878,891; 5,120,649; and German Patent Application No. DE 39 30 510 A1 (Mohr).

5 Although much effort has been focussed on commercializing such methods using photoactive agents, the inventors believe that such methods are currently not commercially viable. It is believed that such a system for utilizing a photoactive agent to treat blood to
10 irradiate or remove viral and other contaminants would entail combining the blood with a photoactive agent in a container and irradiating the resultant mixture with light of the appropriate wavelength.

15 A number of devices and methods have been postulated for use in adding and activating photoactive agents in a body fluid.

20 U.S. patent application Serial No. 08/090,381 entitled: "APPARATUS AND METHOD FOR INACTIVATING VIRAL CONTAMINANTS" filed on July 12, 1993 discloses an apparatus and method for inactivating viral contaminants in body fluids. In an embodiment of the invention, a method for inactivating viruses is provided comprising the steps of forming a mixture including a
25 therapeutically effective amount of methylene blue and an amount of a body fluid in a container under sterile conditions. The mixture is irradiated with a light field of a suitable intensity and wavelength for activating the methylene blue for a time sufficient to inactivate viruses in the mixture. During the process, the mixture
30 is maintained in a substantially static state within the container. The apparatus includes a light source that is disposed along a path of travel and configured to generate a light field over the path of travel with a

- 4 -

frequency suitable for activating the photoactive agent. In an embodiment, light emitting diodes are mounted on a printed circuit board. Two arrays are mounted facing each other in a spaced apart relationship so that a gap is presented within which the container containing the body fluid can pass.

U.S. patent application Serial No. 08/174,211 entitled: "SYSTEMS AND METHODS FOR IRRADIATING CONTAMINANTS USING PHOTOACTIVE MATERIALS AND FLUID LIKE BLOOD USING DISCRETE SOURCES OF RADIATION," filed December 28, 1993, discloses, in an embodiment, a system for treating a fluid carrying a contaminant to which a photoactive material has been bound. The system directs fluid through a treatment chamber in a predetermined flow path. The system establishes at least two discrete sources of radiation in a flow path at spaced apart locations along the direction of fluid flow.

Other systems and apparatuses for treating a fluid with a photoactive material are disclosed in U.S. Patent Nos. 5,300,019 and 5,290,221, as well as U.S. patent application Serial No. 08/289,175 filed August 11, 1994 entitled: "SYSTEMS AND METHODS FOR SIMULTANEOUSLY REMOVING FREE AND ENTRAINED CONTAMINANTS IN FLUID LIKE BLOOD USING PHOTOACTIVE THERAPY AND CELLULAR SEPARATION TECHNIQUES," which is a continuation of U.S. Serial No. 07/630,864. Additionally, U.S. Patent No. 5,278,432 discloses an apparatus for providing radiant energy.

One of the difficulties, however, in using light emitting diodes for activating a photoactive compound is that the light emitting diodes will burn out if they overheat. In this regard, most light emitting diodes (LEDs) have a junction temperature rated around 100°C. If the junction temperature exceeds 100°C, the light

- 5 -

emitting diode will burn out. A problem arises because the greater the intensity of light that is generated the greater the temperature of the LEDs. Thus, heretofore, one had to sacrifice efficiency and cycle time in proposed light activating systems to prevent LED burnout.

There therefore is a need for an improved system and method for activating photoactive agents.

SUMMARY OF THE INVENTION

The present invention provides improved methods and apparatus for irradiating a product with light of a specific wavelength to activate the photoactive agent that is contained therein.

To this end, in an embodiment, a device is provided that comprises a source of radiation including a plurality of light emitting diodes. Each light emitting diode includes a body portion through which radiation is transmitted. The body of the diode is surrounded by a fluid. In this regard, a first housing is provided that includes an interior that contains the light emitting diodes and a fluid. The housing includes a transparent window for allowing radiation generated by the light emitting diodes to flow through the window and irradiate a product that is in juxtaposition to the window.

In an embodiment, the device includes a body for supporting the housing and an opening for allowing the product to be placed in juxtaposition to the window and removed from same.

In another embodiment, the device includes a second housing for enclosing a second plurality of light emitting diodes, the second housing including a transparent window. In an embodiment, the first housing

- 6 -

and second housing are located in planes that are substantially parallel to each other.

5 In an embodiment, the housing includes an inlet for allowing fluid to flow into the interior and an outlet for allowing fluid to flow out of the interior. Preferably, the inlet and outlet are connected to fluid conduits and a pump is provided to pump fluid through a first fluid conduit into the inlet. Preferably, the device includes means for cooling fluid before it enters
10 the fluid inlet.

In an embodiment, the fluid is chosen from the group consisting of: distilled water; propylene glycol containing fluids; and oil based fluids.

15 In an embodiment, the refractive index of the fluid is greater than the refractive index of the body of the LED.

In an embodiment, the refractive index of the fluid is less than the refractive index of the body of the LED.

20 In another embodiment, the present invention provides a system for irradiating a container including a fluid that includes a photoactive agent. The system comprises a housing including an interior for receiving a container and a first and second photodiode device. Each photodiode device includes a body defining a chamber
25 that includes a plurality of photodiodes for generating radiation of a specific wavelength. Each chamber includes a fluid therein for cooling the photodiodes. The first and second photodiode devices are located in planes that are substantially parallel to each other and define a space therebetween in the interior for receiving
30 the container. The housing includes an opening for allowing the container to be placed within the space and removed therefrom.

- 7 -

In a further embodiment, the present invention provides a system for irradiating a container including a fluid that includes a photoactive agent. The system comprises a housing including an interior for receiving
5 a container, and a photodiode device including a body that includes a plurality of photodiodes for generating radiation of a specific wavelength. The chamber includes an inlet for receiving a fluid therein for cooling the photodiodes. The body includes a transparent window that
10 supports the container when it is placed in the interior. The system includes means for cooling fluid prior to the fluid entering the inlet.

In another embodiment of the present invention, a method for irradiating a product with light of a specific
15 wavelength is provided. The method comprises the steps of: providing a device including an interior for receiving a product, the device including a chamber including a plurality of photodiodes and a fluid; placing the container in the device; and irradiating the product
20 with light of a specific wavelength.

In a further embodiment, pursuant to the present invention, a method for inactivating viral contaminants in blood comprising the steps of: adding a photoactive agent to a blood component; providing a device including
25 an interior for receiving a product, the device including a chamber including a plurality of photodiodes; cooling the photodiodes using a fluid; placing the container in the device; and irradiating the product with light of a specific wavelength.

30 In an embodiment of the method, the intensity of the light is varied by choosing a fluid having a desired refractive index.

- 8 -

An advantage of the present invention is to provide an improved apparatus for activating photoactive agents that may be contained in a fluid.

5 A further advantage of the present invention is that it provides an improved method for activating a photoactive agent that may be contained in a fluid.

Moreover, an advantage of the present invention is to provide an improved method for treating a body fluid to at least substantially inactivate viral contaminants that may be contained therein.

10 Furthermore, an advantage of the present invention is that it provides a method for inactivating or eliminating pathogens from blood or its components before they are infused into a patient.

15 Still further, an advantage of the present invention is that it provides an apparatus and method that allows light emitting diodes to be operated at a higher intensity than theretofore possible without burning out.

Another advantage of the present invention is that it provides a method for varying the intensity of light that is provided by an array of light emitting diodes.

20 Further, an advantage of the present invention is that it provides an economical method for cooling light emitting diodes.

25 Additional features and advantages of the present invention are described in, and will be apparent from, the detailed description of the presently preferred embodiments and from the drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

30 Figure 1 illustrates a schematic view of an apparatus of the present invention.

- 9 -

Figure 2 illustrates an exploded view of a light emitting diode (LED) unit of the apparatus for irradiating a container of Figure 1.

5 Figure 3 illustrates a cross-sectional view of the apparatus for irradiating a container of Figure 1.

DETAILED DESCRIPTION

OF THE PRESENTLY PREFERRED EMBODIMENTS

10 The present invention provides an apparatus, as well as method, for activating photoactive agents that are contained in a product. In the preferred embodiment discussed herein, the present invention is directed to activating photoactive agents that are added to a body fluid, such as blood or a blood component. Such blood
15 components include red blood cells, platelets, plasma, leukocytes, and bone marrow. These products are typically housed in flexible plastic containers constructed from, for example, polyvinyl chloride. Such containers are available from Baxter International Inc.
20 as well as other companies.

Although in the preferred embodiment, the present invention is directed to activating photoactive agents that are added to a body fluid such as blood or its components, it should be appreciated that the present
25 invention can be used in a variety of other applications. In this regard, the present invention provides an improved method and apparatus for generating light of a specific wavelength.

30 Currently much research is being conducted in utilizing photoactive agents to inactive viral contaminants that may be present in a body fluid. A variety of photoactive agents have been proposed and can be used pursuant to the present invention. For example,

- 10 -

the photoactive agents can be chosen from the group including, but not limited to: porphyrins; porphyrin derivatives; merocyanines, such as MC540; phthalocyanines, such as aluminum phthalocyanine; other
5 pyrrolic macrocycles; psoralens; and other photoactive dye stuffs, such as methylene blue. It is believed the present invention can be used with any photoactive agent. What is required is that the LEDs, or other light source
10 of the present invention, must be modified so that it generates light of an appropriate wavelength. As stated above, photoactive agents are activated by light of a specific wavelength.

Likewise, the present invention can be utilized with any method for adding the photoactive agent to the body
15 fluid. For example, the photoactive agent can be added to the body fluid contained in the source container after the blood is collected from a donor. An example of a method and apparatus that can be used for adding photoactive agents to a body fluid is set forth in U.S.
20 patent application Serial No. 07/952,427 entitled: "STEAM STERILIZABLE SYSTEM FOR INACTIVATING VIRAL CONTAMINANTS IN BODY FLUIDS", filed October 5, 1992, the disclosure of which is incorporated herein by reference. In that application, in an embodiment, methylene blue is
25 added to a body fluid. However, other methods can be utilized pursuant to the present invention for adding photoactive agents to a body fluid.

Referring now to Figure 1, generally a system 10 including an apparatus 12 is illustrated for activating
30 a photoactive agent present in a body fluid that is housed in a container. The apparatus 12 includes a housing 14 that has an opening 16 for allowing a product 18, e.g., a bag containing blood and a photoactive agent,

- 11 -

to be received within a chamber 20. In an embodiment, the housing 14 includes a drawer (not illustrated) having a handle that allows one to access the opening 16 to place the product 18 within the chamber 20 and close same. However, a variety of other means can be utilized to access the chamber 20 of the housing 14.

Located within the housing 14 are, in the preferred embodiment illustrated, two light emitting diodes (LED) devices 22 and 24. Figure 2 illustrates an exploded view of one of the LED devices 22. The LED devices 22 and 24 are constructed and arranged so as to generate light of an appropriate wavelength to activate the photoactive agent contained within the container 18. Because the container (bag) 18 is transparent, the light will be transmitted through the bag into the body fluid activating the photoactive agent contained therein.

As illustrated in Figures 2 and 3, each of the LED devices 22 and 24 includes a housing 26. In the embodiment illustrated, the housing 26 includes three structures that define the housing. In this regard, there is a lower frame 28, a middle frame 30, and an upper frame 32. The frames 28, 30, and 32 define the housing 26 that contains the LEDs therein. The frames can be constructed from a variety of materials. In a preferred embodiment, the upper and lower frames 28 and 32 are constructed from stainless steel and the middle frame 30 from plastic.

The housing 26 defines an interior 34 for containing the LEDs 36. Preferably, the LEDs 36 are located on an LED board 38. This board 38 is connected to a cable (not shown) to power the LEDs 36. Such a connection is known in the art. Preferably, the LEDs 36 are mounted so that they are not flush with the board 38. To this end, each

- 12 -

LED 36 has two electrodes coming out of the bottom which are mounted the board 38. The LEDs 36 are arranged on a board 38 in rows or arrays. Depending on space and the size of the product, a variety of different LED arrays
5 can be used.

By way of example, the LEDs 36 can comprise any of a variety of LEDs including those available from: Hewlett Packard; Marktech; and Gilway. For example, for treating red blood cells, it may be desirable to use
10 photodiodes available from Hewlett Packard under the designation HLMP-8150 15 candela. These photodiodes use transparent substrate aluminum gallium arsenide material (TsAlGaAs). These photodiodes emit a band of radiation at a relatively narrow viewing angle of about 4 degrees.
15 The prescribed band of radiation has a relatively precise wavelength displaying a red color having a peak wavelength of about 660 nm. Red blood cells are essentially transparent to radiation at this wavelength. However, the photoactive agent benzoporphyrin is not and
20 if contained in a container with red blood cells will be activated. Of course, depending on the photoactive agent and type of fluid, different LEDs 36 will be used.

As illustrated, each of the LED devices 22 and 24 include a transparent window 42. The transparent window
25 42 allows radiation from the LEDs to enter the chamber of the apparatus. In the preferred embodiment illustrated, the transparent window 42 supports the container 18 within the apparatus. A number of materials can be used to construct the window 42. In a preferred
30 embodiment, the window 42 is constructed from polycarbonate plastic.

Pursuant to the present invention, the LEDs 36 are cooled by a fluid 43. The fluid 43 removes the heat from

- 13 -

the LEDs 36. In the preferred embodiment illustrated, the fluid 43 is trapped in the interior 34 between the LED board 38 and the middle frame 30 and a clear window 42 which is located between the upper 32 and middle frame 30.

Although the fluid is passed over the top of the LED board 38, if desired, however, the entire board, top and bottom, can be located within the fluid.

To allow fluid flow through the interior 34 defined by the middle frame 30, LED board 38, and clear window 42, an inlet port 50 and outlet port 52 is provided. This allows the fluid to be circulated and cooled. The cooling of the fluid will be discussed hereinafter.

A number of different fluids can be used in the present invention. Preferably, the fluid is chosen from the group consisting of: distilled water; propylene glycol based fluids; and oil based fluids. Examples of such fluid are Dow Frost from Dow Chemical, Calflow LT from Petro Canada, and Paratherm NF from Paratherm Corporation.

Any fluid that does not conduct electricity can be used in the present invention. In choosing the fluid, one needs to insure that the fluid is not and does not become contaminated. Contaminated fluid will then conduct electricity.

Pursuant to the present invention, the LEDs 36 are cooled so that they do not experience a temperature change of greater than 10°. For example, if the room temperature is 25°C, the fluid should insure that the LEDs 36 will not be heated to a temperature of greater than 35°C. This will provide a junction temperature for the LEDs of 50°C or less. Because LEDs are rated at a

- 14 -

junction temperature of around 100°C, at such a temperature, the LEDs will not fail.

Preferably, the fluid flows into the inlet port 50 and, therefore, into the interior 34 of the LED device 22, at ambient temperature. However, if desired, the temperature of the fluid can be lower or higher than ambient temperature.

Preferably, the fluid fills the entire interior 34 of the LED device 22. This is desirable so that no air bubbles are present that would affect the refractive index of the fluid.

Referring now to Figure 1, preferably, the system 10 of the present invention includes a pump 56 for pumping fluid into the inlet ports 50 of the LED devices 22 and 24 and thereby out of the outlet ports of the devices. In the illustrated embodiment of the system 10, a heat exchanger/thermal electric cooler 58 is also provided to cool the fluid after it has left the LED device. A variety of heat exchanger/thermal electric coolers 58 can be used. It is believed it is only necessary to cool the fluid down to ambient conditions.

Due to the use of the fluid, heat can be removed from the LEDs 36 allowing the LEDs to run at a higher intensity. For example, manufacturers recommend that typical LEDs 36 run at a maximum of 50 milliamps. However, utilizing the fluid of the present invention, the LEDs 26 can be run at 90 milliamps for extended periods of time. This is due to the fact that so much heat is removed by the fluid.

A further advantage of the present invention is that in addition to cooling the LEDs 36 with fluid, the intensity of the light generated by the LED can be varied by the fluid. The angle of light generated by LED and

- 15 -

its brightness is originally dependent on the type of LEDs. By choosing a liquid that has a refractive index higher or lower than the material from which the LED is created, one can change the intensity of light.

5 For example, the refractive index of plastic that is used for the body of some LEDs 36 is approximately 1.6. If one chooses a refractive index that is less than 1.6, the angle of the light will be less and therefore, the light will be more intense. If one picks a fluid
10 with a refractive index that is higher than 1.6, this will increase the angle of the light and make the light less intense.

 Therefore, if one wants brighter light in certain areas during the photoactivation process, by selecting
15 the appropriate fluid, one can increase the intensity of light in certain areas. In a similar vein, if one wants a broad illumination, this can be accomplished by choosing a fluid that has a refractive index that is greater than the material from which the LED is
20 manufactured.

 It is believed that one will probably want to increase the power (brightness) of the light generated by the LEDs so that the radiation of the fluid can be accomplished much cheaper and reduce the cycle time.
25 Therefore, it is envisioned that one will choose a fluid having a refractive index that is less than 1.6 if LEDs having a plastic body are used.

 By way of example, and not limitation, example of the present invention will now be given:

30 EXAMPLE NO. 1

 The purpose of the experiment was to determine if LEDs could be run at a high intensity without burning out. 8103 LEDs available from Hewlett Packard were used

- 16 -

in a device similar to the apparatus 10 discussed above. The LEDs were cooled with distilled water.

The temperature of the fluid was measured while running the LEDs @ 90 mA (milliamps). A thermometer was placed in the fluid flow conduits directly before and directly after the LED array.

<u>Time</u>	<u>Inlet Temperature</u>	<u>Outlet Temperature</u>
9:30	26°C	26°C
11:00	26°C	26°C
11:30	26°C	26°C
12:15	26°C	26°C

Note: Water (deionized) was flowing freely into the interior housing of the LEDs. Therefore, no major rise in temperature occurred.

Conclusion: The LEDs held up to large current very well. No ill affects are noticeable. The water did not adversely affect the LEDs, which makes the application feasible.

EXAMPLE NO. 2

Affects of Paratherm NF from Paratherm Corp. on 8103 Array.

The 8103 array was run @ 50 mA which is equal to the 4.1 volts, measured across the 82 Ω resistor, using the Simpson meter.

Current	Liquid - for cooling LEDs	Peak Wavelength	Intensity mW/cm ²
50 mA	None	660 nm	14.23
50 mA	Paratherm NF	660 nm	15.32
50 mA	Calflo	660 nm	14.78

- 17 -

As indicated above, the fluid increased the intensity of the light generated by the LEDs.

5 It should be understood that various changes and modifications to the presently preferred embodiments described herein will be apparent to those skilled in the art. Such changes and modifications can be made without departing from the spirit and scope of the present invention and without diminishing its attendant advantages. It is therefore intended that such changes
10 and modifications be covered by the appended claims.

- 18 -

I CLAIM:

1. A device for irradiating a product with light of a specific wavelength comprising:

5 a source of radiation including a plurality of light emitting diodes, the light emitting diodes including a body portion through which radiation is transmitted, the body portion being surrounded by a fluid; and

10 a first housing for enclosing the light emitting diodes and fluid in an interior thereof, the housing including a transparent window for allowing radiation to flow through the window and irradiate a product that is in juxtaposition to the window.

15 2. The device of Claim 1 including a body for supporting the housing and providing an opening for allowing the product to be placed in juxtaposition to the window and removed from same.

20 3. The device of Claim 1 including a second housing for enclosing a second plurality of light emitting diodes, the second housing including a transparent window.

4. The device of Claim 3 wherein the first housing and second housing are located in planes that are substantially parallel to each other.

25 5. The device of Claim 1 wherein the housing includes an inlet for allowing fluid to flow into the interior and an outlet for allowing fluid to flow out of the interior.

30 6. The device of Claim 5 wherein the inlet and outlet are connected to fluid conduits and a pump is provided to pump fluid through a first fluid conduit into the inlet.

7. The device of Claim 5 including means for cooling fluid before it enters a fluid inlet.

- 19 -

8. The device of Claim 1 wherein the fluid is chosen from the group consisting of: distilled water; propylene glycol containing fluids; and oil based fluids.

5 9. A system for irradiating a container including a fluid that includes a photoactive agent comprising:

a housing including an interior for receiving a container;

10 a first and second photodiode device, each photodiode device including a body defining a chamber that includes a plurality of photodiodes for generating radiation of a specific wavelength, the chamber including a fluid therein for cooling the photodiodes, the first and second photodiode devices being located in planes that are substantially parallel to each other and
15 defining a space therebetween in the interior for receiving the container; and

the housing including an opening for allowing the container to be placed within the space and removed therefrom.

20 10. The system of Claim 9 wherein the first photodiode device defines a surface for supporting the container.

11. The system of Claim 9 including means for cooling the fluid.

25 12. The system of Claim 9 wherein each photodiode device includes a fluid inlet and a fluid outlet.

13. The device of Claim 9 wherein the fluid is chosen from the group consisting of: distilled water; propylene glycol containing fluids; and oil based fluids.

30 14. A system for irradiating a container including a fluid that includes a photoactive agent comprising:

a housing including an interior for receiving a container; and

- 20 -

5 a photodiode device including a body that has a chamber that includes a plurality of photodiodes for generating radiation of a specific wavelength, the chamber including a fluid therein for cooling the photodiodes, the body including a transparent window that supports the container when it is placed in the interior.

10 15. The system of Claim 14 including a second housing for enclosing a second plurality of light emitting diodes, the second housing including a transparent window.

16. The system of Claim 15 wherein the first housing and second housing are located in places that are substantially parallel to each other.

15 17. The system of Claim 14 wherein the housing includes an inlet for allowing fluid to flow into the interior and an outlet for allowing fluid to flow out of the interior.

20 18. The system of Claim 17 wherein the inlet and outlet are connected to fluid conduits and a pump is provided to pump fluid through a first fluid conduit into the inlet.

19. The system of Claim 17 including means for cooling fluid before it enters a fluid inlet.

25 20. The system of Claim 17 wherein the fluid is chosen from the group consisting of: distilled water; propylene glycol containing fluids; and oil based fluids.

21. A method for irradiating a product with light of a specific wavelength comprising the steps of:

30 providing a device including a plurality of photodiodes;

placing the container in the device;

irradiating the product with light of a specific wavelength; and

- 21 -

cooling the photodiodes with a fluid.

22. The method of Claim 21 including the step of choosing the fluid so as to achieve a desired light intensity.

5 23. The method of Claim 21 including the step of cooling the fluid.

24. A method for inactivating viral contaminants in blood comprising the steps of:

adding a photoactive agent to a blood component;

10 providing a device including an interior for receiving a product, the device including a chamber including a plurality of photodiodes and a fluid;

placing the container in the device; and

15 irradiating the product with light of a specific wavelength.

25. The method of Claim 24 wherein the photoactive agent is chosen from the group consisting of: psoralens; porphyrins; phthalocyanines; and photoactive dyes.

20 26. The method of Claim 24 including the step of choosing the fluid so as to achieve a desired light intensity.

27. The method of Claim 24 including the step of cooling the fluid.

FIG. 1

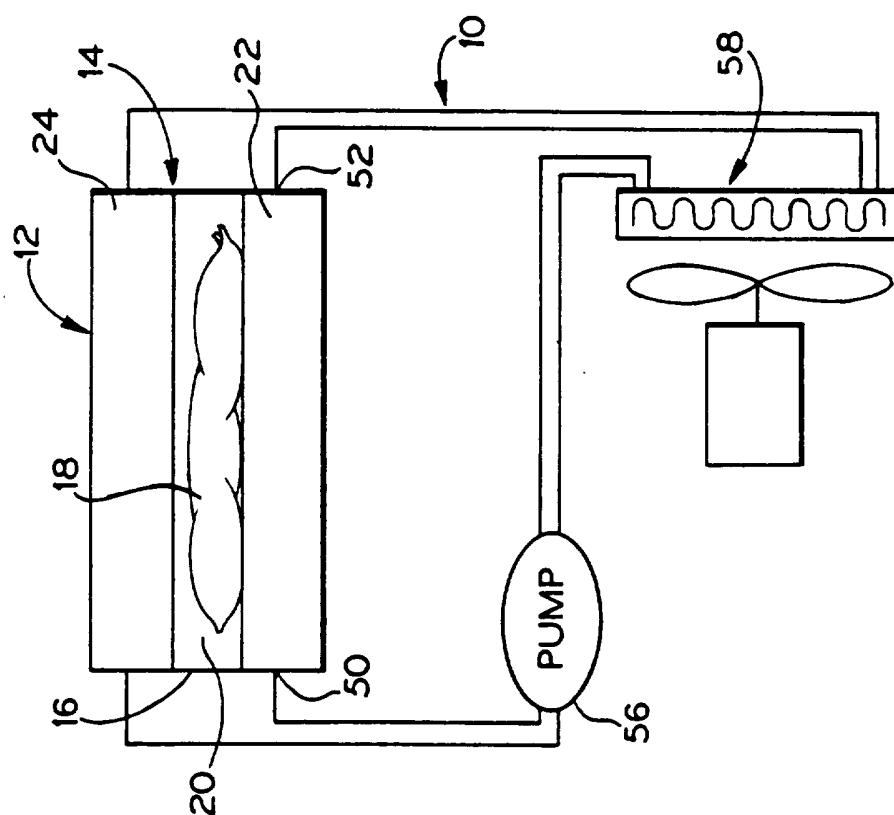


FIG. 2

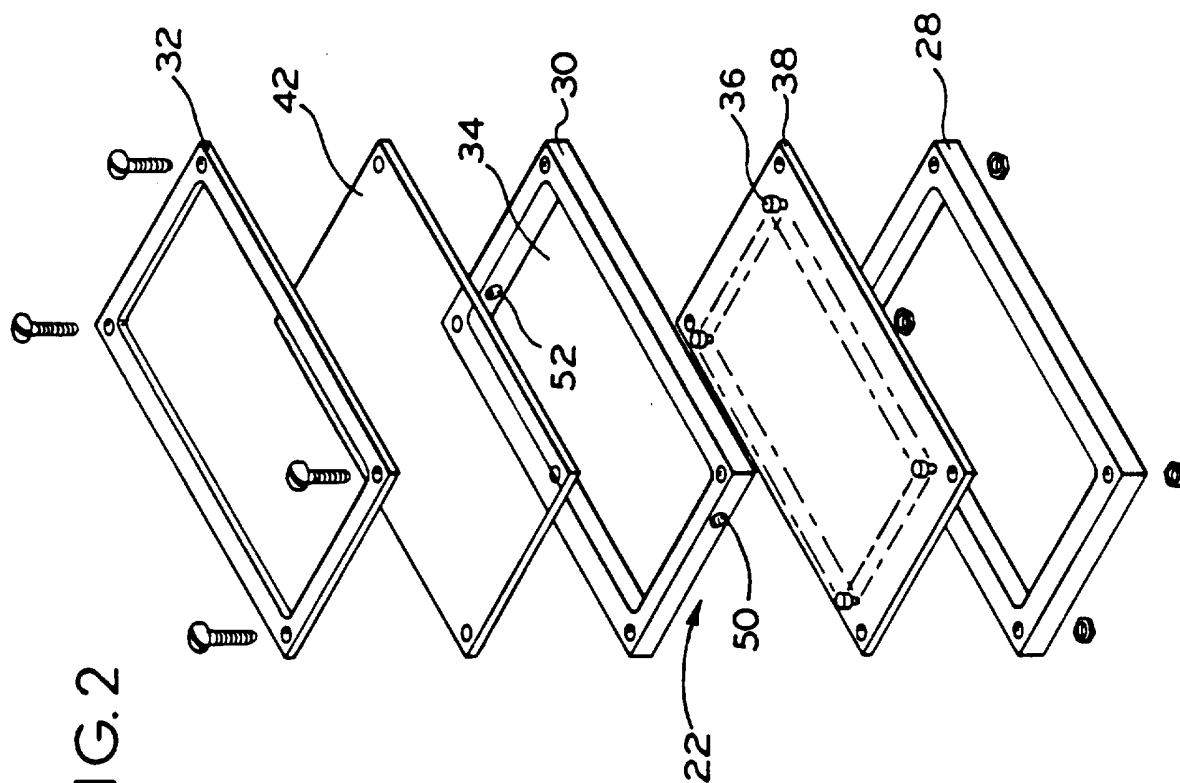
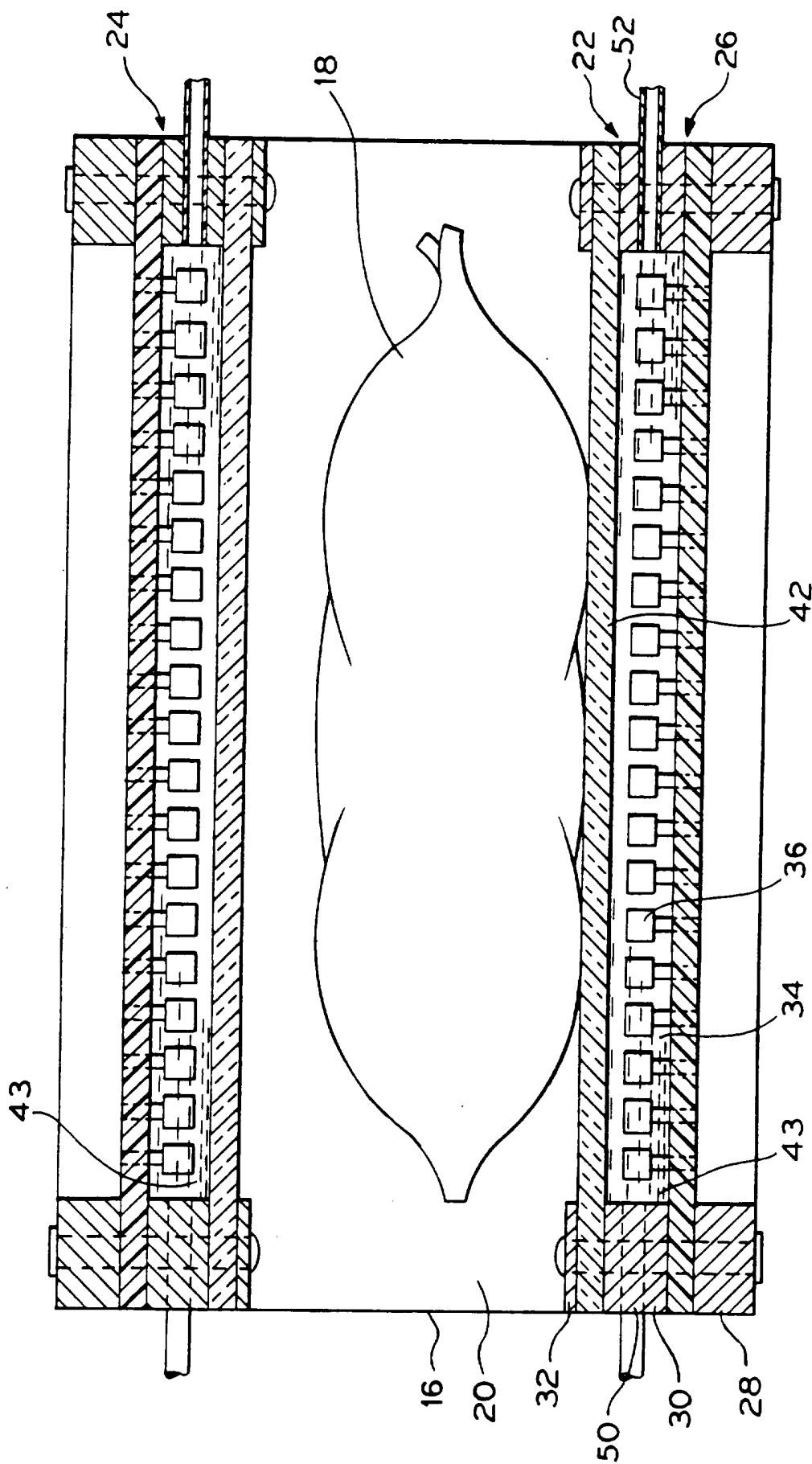


FIG. 3



INTERNATIONAL SEARCH REPORT

International application No.

PCT/US95/10700

A. CLASSIFICATION OF SUBJECT MATTER

IPC(5) : A61M 1/36; F21V 29/00

US CL : 422/23, 44; 362/294; 250/455.11; 604/4

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)

U.S. : 422/23, 44, 186; 362/294, 373, 800; 250/455.11; 604/4, 20; 435/2; 313/12, 23, 28, 32, 35, 36, 40

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

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

APS, search terms: photodiode, LEDs, cooling fluids, photactive, blood

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US, A, 4,866,282 (MIRIPOL ET AL) 12 September 1989, see Figure 1 and abstract.	1-27
Y	US, A, 4,878,891 (JUDY ET AL) 7 November 1989, see entire document.	1-27
Y	US, A, 5,290,221 (WOLF, JR. ET AL) 01 March 1994, see column 7, lines 15-21 and column 6, lines 44-55.	1-27
X	US, A, 5,301,090 (HED) 05 April 1994, see entire document.	1, 5-7
---		-----
Y		1-27

☐ Further documents are listed in the continuation of Box C.

☐ See patent family annex.

* Special categories of cited documents:	*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
A document defining the general state of the art which is not considered to be of particular relevance	*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
E earlier document published on or after the international filing date	*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
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)	*&*	document member of the same patent family
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		

Date of the actual completion of the international search

27 SEPTEMBER 1995

Date of mailing of the international search report

19 OCT 1995

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized officer

LEIGH DAWSON

Telephone No. (703) 305-0196