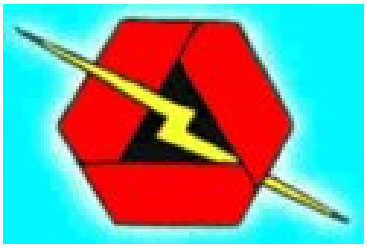

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Steven KAALI & Paul SCHWOLSKY

Blood Electrification vs AIDS (&c)

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http://educate-yourself.org/be/

The Story of Blood Electrification

by Ken Adachi

The Discovery

In the Fall of 1990, two medical researchers, Drs.William Lyman and Steven Kaali, working at Albert Einstein College of Medicine in New York City made an important discovery. They found that they could inactivate the HIV virus by applying a low voltage direct current electrical potential with an extremely small current flow to AIDS infected blood in a test tube. Initially, they discovered this in the lab by inserting two platinum electrodes into a glass tube filled with HIV-1 (type 1) infected blood. They applied a direct current to the electrodes and found that a current flow in the range of 50-100 microamperes (uA) produced the most effective results. Practically all of the HIV viral particles were adversely affected while normal blood cells remained unharmed. The viral particles were not directly destroyed by the electric current, but rather the outer protein coating of the virus was affected in such a way as to prevent the virus from producing reverse transcriptase, a necessary enzyme needed by the virus to invade human cells. Reverse transcriptase allows the virus to enter a human T cell line (called CEM-SS) and commandeer the DNA reproduction machinery. After using the host cell to reproduce itself into thousands of new virii, the swollen host cell (now called syncytia or giant cell) will burst and spew the contents into the bloodstream or lymph system. This is how the virus spreads, but lacking reverse transcriptase, the HIV virus can't invade the host cell and it becomes vulnerable to destruction by the body's immune system. (The details of this experiment can be read from Kaali's patent application.)

Getting the Word Out?

A brief announcement of this discovery appeared in The Houston Post (Mar 20, 1991), then in Science News (Mar. 30, 1991 pg. 207) and later in Longevitymagazine: (Dec.1992 pg. 14). Following their work in the Fall of 1990, Kaali and Lyman presented their findings at the First International Symposium on Combination Therapies (an AIDS conference) in Washington DC on March 14th, 1991. Kaali outlined two methods for treating an AIDS patient with this new therapy: One method involved removing a small amount of blood,

electrifying it and then returning it to the patient's body. The second method involved sewing a miniature electrifying power supply along with two tiny electrodes directly into the lumen of an artery. For long term treatment, the mini electrifying unit needed to be removed and relocated to a new artery site after 30-45 days since scar tissue and calcification forming around the implant unit would lead to artery blockage. Kaali (along with co-inventorPeter Schwolsky) filed for a patent on this implantable electrifying device on Nov 16, 1990 and nine months later was granted patent #5,139,684 on August 18, 1992. It's interesting to note two things here:

1. In order to obtain a patent from the United States Patent Office, Kaali and Schwolsky had to prove that the device works as claimed. Lacking solid proof, US patents are simply not granted.

2. Very often it takes years to obtain a patent, yet this patent was granted in only nine months; a further indication to me of the strength of their demonstrated claims

It's also interesting to note that other than the 3 publications mentioned above and the March '91 AIDS conference, nothing again appeared in print, radio, or TV about this important discovery as a potential treatment and cure for AIDS from Kaali and company. Most knowledgeable observers feel that Kaali and Lyman's discovery was intentionally suppressed following the March '91 AIDS conference presentation. If AIDS research was on the level and not the sham that it actually is, this should have made front page news around the world. (Around 1999, I was contacted by a woman with AIDS who had managed to reach Dr. William Lyman over the phone. She asked him about his experiments with Kaali regarding blood electrification and if she could obtain the treatment through them. Lyman denied any knowledge of any AIDS treatment or cure. He said he never heard of Dr. Kaali and he had no idea what she was talking about concerning blood electrification and then hung up on her. What does that tell about the power of the people behind the suppression of this discovery?)

Enter Dr Bob Beck

A man named Walter Schnitder drew Dr Robert C. Beck'sattention to the above-mentioned item in Science News. Beck looked up the patent and decided to try and duplicate the therapy, but he wanted to do it non-invasively; that is by applying the electric current from outside the body. Now if you apply a direct current (DC) potential to the skin, you're going to get an electrolysis effect and that can cause problems, so Beck designed a circuit that varied the voltage with an alternating current (AC) at a very low frequency and avoided the electrolysis problem. The waveform that Beck chose is not the typical sine wave seen in AC household outlets, but rather is a bi-phasic square wave, meaning that the waveform voltage has a positive half and a negative half, allowing the current to reverse direction each half cycle. Square waves generate a large number of harmonics. Harmonics are frequency multiples of the original frequency. Odd harmonics are mutibles of the original frequency multiplied by 3, 5, 7 etc. and even harmonics are multibles of 2. For example, the odd harmonics of a 4 Hertz (Hz) square wave would be 12 Hz , 20 Hz, 28 Hz, etc. right up into the radio frequency range.

Georges Lakhovsky, Nikola Tesla and many other scientists had discovered that everything in Nature has its own resonant frequency including every bacteria, virus, parasite, and fungus on the planet. Dr. Royal Rife was able to cure terminal, end stage cancers in the 1930's by applying the specific resonant frequencies of certain unique bacteria that are always assocaited wtih all types of cancers. The steady application of the bacteria's resonant

frequency by plasma wave radiation caused the bacteria to internally shatter and eviscerate, thus destroying it (and all the other bacteria within the body that possessed the same resonant frequency) .

While Kaali and Lyman used DC current to deactivate the AIDS virus, Beck found that he could get he same results using the 3.92HZ square wave. Kaali and Lyman found that the amount of the current applied was the critcal factor and if they kept the current within a range of 50-100 micro amperes- they were able to disable the HIV virus within a petri dish as mentioned above. Kaali then worked out a design of a small battery with two tiny electrodes that could be sewn directly into an artery in the arm or leg. By maintaining the current flow between the two electrodes within the 50-100 micro ampere range, the HIV particles were gradually disabled within the bloodstream and the AIDS victim would gradually recover his health. The procedure required surgery that costs about $5,000 (at that time). The implanted electrodes would cause scarring of the artery walls, so they had to be removed and implanted in a new section of an artery every month or so, costing another $5,000 each time the procedure was done. It took about 6 or 7 months to see a substantial improvement in the AIDS patient.

Beck studied Kaali's patent and tried applying the electrodes to the skin directly over those arteries that were close enough to the skin surface. The 50-100 micro ampere current could be created within the artery by electromagnetic induction allowing the entire therapy to be applied externally, without the need for implanting electrodes into the arteries. The device he put together to accomplish this is today called a blood electrifier.

Beck started by applying his blood electrifier to himself. He originally placed the electrodes over leg arteries near the ankles of either leg, then changed the location to two different spots on the arm, and finally found that it worked just as well if he placed the two electrodes near each other over the ulnar and radial arteries just behind the wrist. To find the correct location in order to center the electrodes exactly over the artieries, Bob recommends carefully feeling for the pulse of either artery and marking the path of the artery with a ball point pen. You can then memorize the correct location and align the electrodes over the artery path precisely and hold them in place with a stretchy wrist band that's held together with velcro.

Beck Breakfast Group

Bob Beck has been giving talks for many, many years on a variety of topics from Tesla to psychotronics. I first heard him in 1994 on an after-midnight radio show out of Los Angeles called "Something's Happening" with Roy of Hollywood (KPFK, 90.7 FM). Bob was getting ready to give a talk at the Pasadena Health Expo that upcoming weekend and proceeded to explain to Roy what he had discovered with blood electrification. I was amazed and blown away by what he told Roy. I had to learn more, so I made it my business to be at that convention and attend Bob's lecture...

US Patent # 5,185,086

Method and System for Treatment of Blood and/or Other Body Fluids and/or Synthetic Fluids using Combined Filter Elements and Electric Field Forces

US Cl. 210/748; 204/164; 204/543; 204/627; 205/701; 210/243; 210/251; 210/314; 210/335; 210/416.1; 210/472; 210/634; 422/101; 422/22; 422/44; 435/173.9; 435/2; 435/283.1; 55/487

Abstract ~ A method and system for the treatment of blood and/or other body fluids (such as amniotic fluids) as well as synthetic fluids such as tissue culture medium whereby a fluid to be treated is mechanically filtered for elimination of particles contained therein which exceed 0.2 microns in size (or some other minutely small size) and in addition subjecting the fluid being treated to electric field forces in the microwatt/milliwatt region induced by relatively low voltage of a few volts and low current density which does not exceed values which could impair the biological usefulness and characteristics of the blood or other fluid being treated.

References Cited:
U.S. Patent Documents: 2428328 ~ 3398082 ~ 3753886 ~ 3980541 ~ 4303530 ~ 4473449 ~ 4594138 ~ 4751003 ~ 4800011 ~ 5076933 ~ 5085773 ~ 5133352 ~ 5139684

Description

TECHNICAL FIELD

This invention relates to a novel combined filter and electrical field force method and system employing mechanical filtering in combination with the use of electric field forces to eliminate larger size particles entrained in fluids which are larger than 0.2 microns in size, and successively or simultaneously subject the fluid to electric field forces to attenuate virus, bacteria, parasites or fungus entrained in fluids such as blood or other body fluids and/or synthetic fluids such as tissue culture medium.

BACKGROUND OF THE INVENTION

U.S. patent applications Ser. No. 07/615,800, filed Nov. 16, 1990, now issued U.S. Pat. No. 5,139,684, entitled "Electrically Conductive Methods and Systems for Treatment of Blood and/or Other Body Fluids and/or Synthetic Fluids With Electric Forces"--Steven Kaali and Peter M. Schwolsky, Inventors, discloses novel electrically conductive methods and systems for transferring blood and/or other body fluids (such as amniotic fluids), and/or synthetic fluids such as tissue culture medium, from a donor to a transfusion recipient or storage receptacle, or vice versa, or for recirculating a single donor's blood or other body fluids through components of a treatment system external of the body or by implant devices for purging such contaminants. This treatment uses a novel low voltage, low current electrically operated vessel for direct electric treatment of blood and/or other body fluids, and/or synthetic fluids with electric field forces of appropriate field strength to attenuate contaminants such as bacteria, virus, fungus or parasites contained in the blood and/or other body fluid and/or synthetic fluids, and thereby render such contaminants and/or fluids ineffective to infect or affect normally healthy human cells. "Attenuate" means to reduce the infectivity of the blood, other body fluids, and/or synthetic fluids such as tissue culture medium being treated. The attenuation is believed to be achieved either by the direct and/or indirect physical effect of the electricity on the virus, bacteria, parasites and/or fungus, and/or the removal of such contaminants from the fluid being treated. The treatment, however, does not damage the fluid or render blood or other body fluid biologically unfit for use in humans or other mammals after the treatment. The treatment can be achieved with electric field forces during normally occurring transfer processing from a donor to a recipient or collection receptacle, or vice versa, or during recirculation of a single donor's blood or other body fluids, and/or synthetic fluids. A similar method and system using alternating current voltage and current is described in U.S. patent application Ser. No. 07/615,437 filed on Nov. 16, 1990 concurrently with the above-described U.S. patent application Ser. No. 07/615,800 now

issued U.S. Pat. No. 5,139,684. The disclosures of both these applications hereby are incorporated into the disclosure of this application in their entirety.

The above-described novel method and system originally disclosed in the above-noted pending U.S. patent applications did not, however, include within its disclosure appropriate and efficient means for screening out larger particles that might be entrained in the fluid being treated which are larger than 0.2 microns in size, prior to treatment. To overcome this deficiency, the present invention was devised.

SUMMARY OF THE INVENTION

It is therefore a principle object of this invention to provide an improved method and system for treating blood and/or other body fluids (such as amniotic fluids) of mammals as well as synthetic fluids. The improved method and system comprises subjecting a fluid to be treated to mechanical filtering for elimination of any particles contained therein which exceed 0.2 microns in size and additionally subjecting the fluid being treated to electric field forces in the microwatt/milliwatt region induced by a relatively low voltage of a few volts and low current densities of from about 1 microampere per square millimeter to about a few milliamperes per square millimeter which does not exceed a value that could impair the biological quality and characteristics of blood or other fluids being treated. The mechanical filtering preferably takes place serially in stages whereby increasingly smaller size particles are serially filtered out by mechanical filter means. The treatment with electric field forces preferably is done concurrently with the mechanical filtering, but alternatively may be done sequentially following and/or before the filtering.

BRIEF DESCRIPTION OF DRAWINGS

These and other objects, features and many of the attendant advantages of this invention will be appreciated more readily as the same becomes better understood from a reading of the following detailed description when considered in connection with the accompanying drawings, wherein like parts in each of the several figures are identified by the same reference characters, and wherein:

FIG. 1 is a partial schematic view of a new and improved combined mechanical filter and electric field force treatment system and apparatus according to the invention; and

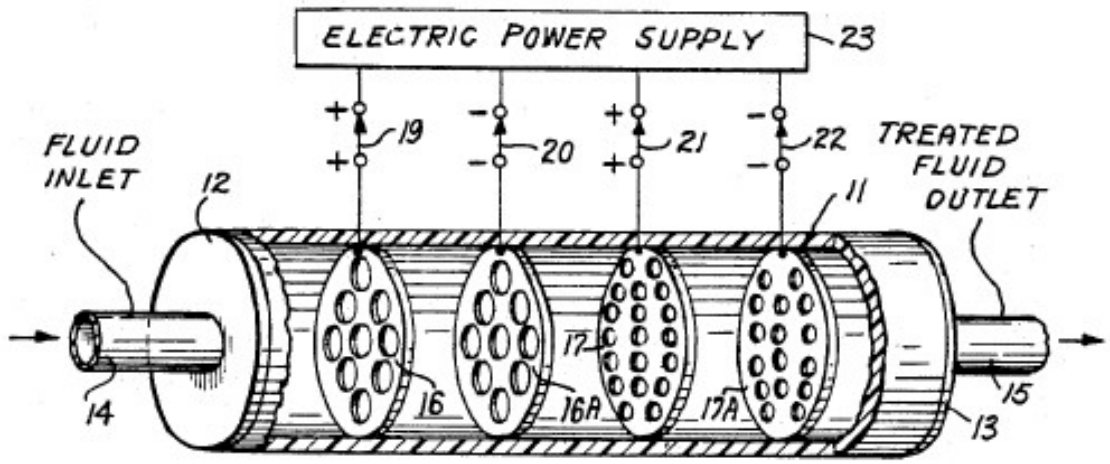
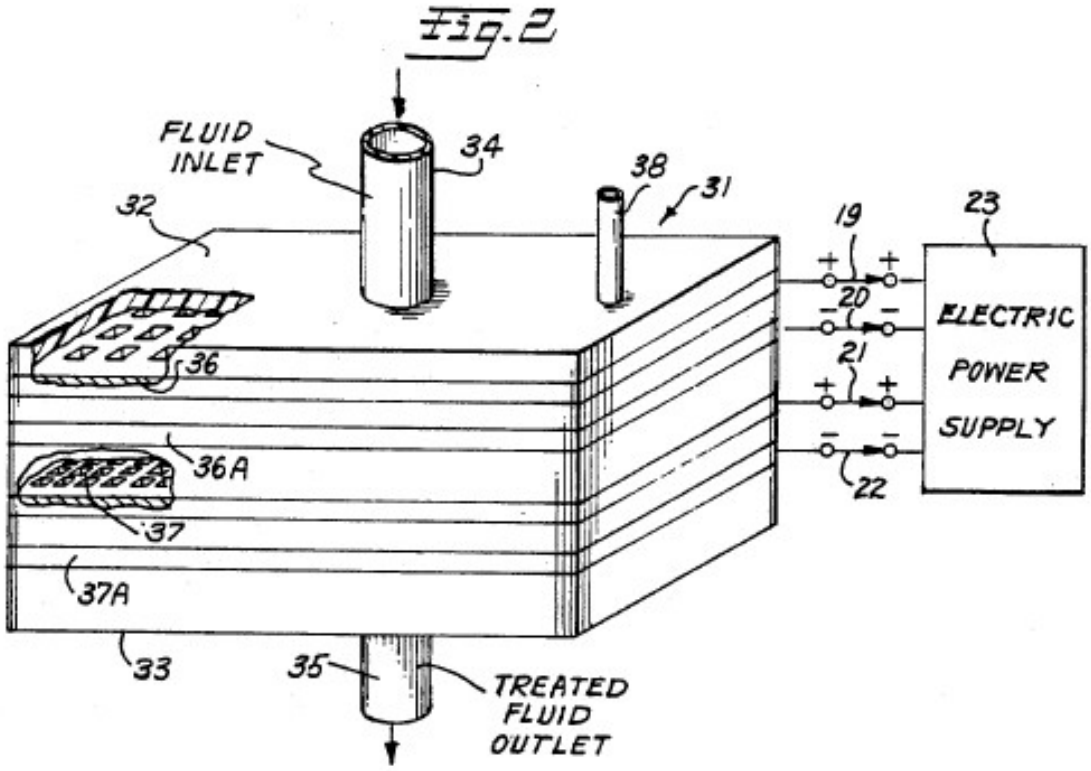


Fig. 1

FIG. 2 is a schematic view of an alternative form of system and apparatus according to the invention.



BEST MODE OF PRACTICING THE INVENTION

FIG. 1 is a partial schematic drawing of a novel filtration and electrical treatment method and system according to the invention. In FIG. 1 a plastic or other closed, electrically insulating, treatment vessel 11 is provided which has an elongated cylindrical shape with both ends closed as shown at 12 and 13. The ends 12 and 13 are provided with inlet and outlet openings through pipes 14 and 15, respectively. Secured within the hollow interior of cylindrical vessel 11 are a series of filter plate elements 16, 16A, 17 and 17A. The filter plate elements preferably are fabricated from an electrically conductive material such as platinum which is substantially chemically inert and does not chemically react with blood or other human body fluid or synthetic fluids such as tissue culture medium. Each of the filter plate elements 16 and 16A have a plurality of aperture openings formed therein, which may or may not be axially aligned with respect to each other, but are of a given size for screening out and blocking particles contained in fluids being filtered which are in excess of the given size. For example, filter plate elements 16 and 16A may serve to filter out particles having a cross sectional dimension which is equal to or greater than 4 microns in size.

Downstream in the liquid flow path through vessel 11, a second set of filter plate elements 17, 17A are supported. The filter plate elements 17, 17A likewise are fabricated from a suitable electrically conductive material such as platinum and have sets of aperture openings formed therethrough which may or may not be axially aligned with respect to each other. The aperture openings in the filter plate elements 17 and 17A however are smaller and more numerous than the openings in filter plates elements 16 and 16A. For example, the aperture openings in the filter plate elements 17, 17A may be sized to block or filter out particles having a size either equal to or in excess of 0.2 microns in size up to 4 microns in size. While

only two different size sets of filter plate elements have been illustrated, it is believed obvious to those skilled in the art that additional, differently sized filter plate elements may be included within the vessel 11 depending upon the nature of the particles which one desires to filter out from fluid being treated with the system. The filter plate elements 16, 16A and 17, 17A are mounted within the interior of hollow, cylindrical vessel 11 substantially at right angles to the flow path that extends longitudinally through vessel 11 from inlet end 12 to and through outlet end 13. The mounting of the filter plate elements is such that each filter element is electrically insulated from the other filter plate elements mounted within vessel 11.

In operation, fluid to be filtered is supplied to the inlet end 12 of insulated vessel 11 via inlet conduit 14 and traverses past the filter element plates 16, 16A, 17 and 17A then exits through the fluid outlet conduit 15. At the exit side all particles entrained in the fluid which are larger than 0.2 microns in size will have been filtered out.

Concurrently with the above-described filtering action, a low value electrical potential of the order from about 0.2 to about 12 volts is supplied to respective ones of the filter element plates 16, 16A, 17 and 17A from a direct current power source 23 via selector switches 19, 20, 21 and 22. Switches 19, 20, 21 and 22 serve to electrically connect respective ones of the filter plate elements to alternate polarity output electric potentials supplied from the direct current electric power supply 23. The electric potential supplied to respective ones of the filter plate elements 16, 16A and 17, 17A may vary in magnitude from about 0.2 to about 12 volts, for example, but are of opposite polarity relative to adjacent filter plate elements. For example, assume that a direct current electrical excitation voltage having positive (+) polarity and a value of 4 volts is supplied to the filter plate element 16. Then a negative (-) 4 volts or any other of the above-noted values is supplied to the neighboring filter plate element 16A. Consequently, there will be a potential difference of 8 volts between the adjacent filter plate elements 16 and 16A through which the fluid being treated must pass. If desired, the potential difference existing between the next adjacent pairs of plates 17, 17A may be adjusted either to higher or to lower values in order to adjust the strength of the electric field between the stages of filtration to a desired value.

In operation, the system functions in the same manner as was described more fully in the above-noted co-pending U.S. application Ser. No. 07/615,800 now issued U.S. Pat. No. 5,139,684, the disclosure of which has been incorporated into the disclosure of this application in its entirety. In effect, the electrical treatment attenuates any virus, bacteria, fungus and/or parasite so as to render them ineffective to infect normally healthy cells while maintaining the biological usefulness of blood, and/or other body fluids, and/or synthetic fluids being treated. During operation, the low voltage electric potentials applied to the respective filter plate elements should be of the order from about 0.2 to about 12 volts and should produce current flow through the fluid in current densities ranging from about 1 microampere per square millimeter of filter plate element area exposed to fluid being treated to about 1 milliampere per square millimeter with direct current excitation to about 2 milliamperes per square millimeter using alternating current excitation. Treatment time within this range of parameters may extend for a period of from about 1 minute to about 12 minutes during electrification. However, treatment time may be longer where, in certain cases, more complete attenuation of the contaminants in the fluid being treated is desired. Also, in certain circumstances where faster attenuation of contaminants is desired, the excitation voltage may exceed the 0.2 to about 12 volt range indicated for most treatments.

During operation of the method and system described with relation to the system described in the above-noted U.S. patent application Ser. No. 07/615,800 now issued U.S. Pat. No.

5,139,684, it has been observed that under certain conditions bubbling of gas around one or more of the plate elements such as 16, 16A, 17 or 17A can occur. To avoid any adverse effects on the fluids being treated, it is possible to reduce or even eliminate the production of bubbles at the plate elements during operation by a number of techniques. One is to fill the treatment vessel 11 so completely that a gas phase cannot develop above the liquid in the vessel.

Another technique that can be used to avoid bubbling at the plates is to provide a suitable vent pipe such as shown at 38 in the embodiment of the invention shown in FIG. 2 of the drawings. By introducing pressurized air or a suitable inert gas that does not chemically react with the fluids being treated, the liquid can be pressurized to the point that the liquid will not pass into the gas phase. Another alternative is to vent any gas produced by bubbling to the atmosphere via a vent tube such as 38 shown in FIG. 2. Other techniques for obviating the bubbling around the filter plate elements will be suggested to those skilled in the art.

During operation of the filter elements 16, 16A, 17, 17A it is possible that one or more of the filter elements can become clogged either partially or otherwise. In this eventuality the system can be shut down and the clogged element replaced with a new clean filter element. Alternatively, it is possible to design the system so as to provide two parallel treatment paths together with suitable valve means to selectively supply fluid being treated to one treatment path or the other. With such an arrangement it would not be necessary to shut the system down during operation to remove and replace a clogged filter plate element.

FIG. 2 is a partial perspective view of a second embodiment of the invention which employs a generally rectangular, box-like treatment vessel 31 fabricated from plastic or other electrical insulating material closed by an insulating top 32 and an insulating bottom 33. A fluid inlet conduit 34 is provided in top 32 and an outlet conduit 35 is provided in bottom 33. The near sides and top of vessel 31 have been broken away to show the construction of the mechanical filter elements 36, 36A and 37, 37A all of which are fabricated from platinum or other relatively inert electrically conductive material which is compatible with human blood, and/or body fluids, and/or synthetic fluids, and/or tissue. As shown in FIG. 2, the upper set of filter plate elements 36 and 36A are relatively coarse compared to the lower set of filter plate elements 37 and 37A. Again, for example, the upper filter plate pair 36, 36A may be designed to prevent particles which are 4 microns or larger in cross section from passing through the elements while the lower set of elements 37, 37A may be designed to prevent the passage of particles 0.2 microns or larger from passing through. Again, as a matter of design, the passages through the sets of filter plates elements 36, 36A and 37, 37A may be axially aligned or relatively displaced from each other so as to form a more tortuous path for fluid flowing downwardly from the fluid inlet 34 to the discharge outlet 35.

An electric power supply 23 is provided which may be either direct current or alternating current so long that measures are taken to assure that the electric potential supplied to the respective filter plate elements 36, 36A and 37, 37A are out of phase relative to each other to assure that a potential difference exists between adjacent pairs of the filter elements as described with relation to FIG. 1.

In operation, the embodiment of the invention shown in FIG. 2 functions in substantially the same manner as that shown in FIG. 1 to provide for mechanical filtering out of particles entrained in fluid to be treated by the system which are greater than 0.2 microns in size. Concurrently, electrification of the filter plate elements in the manner described with relation to FIG. 1 causes attenuation of virus, bacteria, fungus, and/or parasites which might be

entrained in the fluid being treated by the system thereby rendering them ineffective as described more fully in the above-referenced co-pending U.S. patent applications.

If necessary, anticoagulants may be used in the fluids being treated with either embodiment of the invention shown in FIG. 1 or FIG. 2.

INDUSTRIAL APPLICABILITY

The present invention provides a combined filtration-electrical treatment method and system which in operation serves to attenuate virus, bacteria, fungus and/or parasites found in blood, body fluids and/or synthetic fluids (such as tissue culture medium) used in the production and purification of biologicals. The system is designed such that no damage or impairment of the biological usefulness of the fluids being treated occurs as a result of the combined filtration and electrification treatments.

Having described two embodiments of a novel combined filtration and electrification treatment method and system according to the invention, other modifications and variations of the invention will be suggested to those skilled in the art in the light of the above teachings. It is therefor to be understood that changes may be made in the particular embodiments of the invention described which are within the full intended scope of the invention as defined by the appended claims.

US Patent # 5,188,738

Alternating Current Supplied Electrically Conductive Method and System for Treatment of Blood and/or Other Body Fluids and/or Synthetic Fluids with Electric Forces

Abstract

A new alternating current process and system for treatment of blood and/or other body fluids and/or synthetic fluids from a donor to a recipient or storage receptacle or in a recycling system using novel electrically conductive treatment vessels for treating blood and/or other body fluids and/or synthetic fluids with electric field forces of appropriate electric field strength to provide electric current flow through the blood or other body fluids at a magnitude that is biologically compatible but is sufficient to render the bacteria, virus, parasites and/or fungus ineffective to infect or affect normally healthy cells while maintaining the biological usefulness of the blood or other fluids. For this purpose low voltage alternating current electric potentials are applied to the treatment vessel which are of the order of from about 0.2 to 12 volts and produce current flow densities in the blood or other fluids of from one microampere per square millimeter of electrode area exposed to the fluid being treated to about two milliamperes per square millimeter.

U.S. Class: 210/748 ; 204/164; 205/701; 210/243; 422/22; 422/44; 604/21; 604/6.0

References Cited
U.S. Patent Documents: 592735 ~ 672231 ~ 2490730 ~ 3692648 ~ 3753886 ~ 3878564 ~ 3965008 ~
3994799 ~ 4473449 ~ 4616640 ~ 4770167 ~ 4932421 ~ 5049252 ~ 5058065 ~ 5133932

Foreign Patent Documents: 995848

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Journal of Clinical Microbiology, vol. 17, No. 2, Feb. 1983, pp. 374-376, "Photodynamic Inactivation of Pseudorabier Virus with Methylene Blue Dye, Light and Electricity"--Janine A. Badyisk et al..

Parent Case Text

FIELD OF INVENTION

Description

This invention relates to novel electrically conductive methods and systems employing electrically conductive vessels provided with electrically conductive surfaces for use in subjecting blood and/or other body fluids and/or synthetic fluids such as tissue culture medium to direct treatment by alternating current electric forces.

BACKGROUND PROBLEM

It is now well known in the medical profession and the general public that blood collected in a blood bank from a large number of donors may be contaminated by contaminants such as bacteria, virus, parasites and/or fungus obtained from even a single donor. While screening of donors has done much to alleviate this problem, the screening of donors can and does miss occasional donors whose blood is unfit for use. When this occurs and the unfit blood is mixed with otherwise usable blood, the entire batch must be discarded for transfusion purposes. Because of this problem, the present invention has been devised to attenuate any bacteria, virus (including the AIDS HIV virus) parasites and/or fungus contained in blood contributed by a donor to the point that any such contaminant is rendered ineffective for infecting a normally healthy human cell, but does not make the blood biologically unfit for use in humans. Similar problems exist with respect to treatment of other body fluids, such as amniotic fluids. The treatment method and system is also applicable to mammals other than humans.

In addition to the above, there is a need for methods and systems for the treatment of blood and other body fluids both in in-situ processing wherein the treated blood and/or other body fluids are withdrawn from the body, treated and then returned to the body in a closed loop, recirculating treatment process that is located near but outside the patient's body, or the treatment can be effected through implanted treatment system components.

In co-pending United States application serial No. 07/615,800 entitled "Electrically Conductive Methods and Systems for Treatment of Blood and Other Body Fluids with

Electric Forces"-Steven Kaali and Peter M. Schwolsky, inventors, filed concurrently and co-pending with this application, a similar treatment method and system employing direct current excitation potentials is described and claimed. The disclosure of co-pending application Ser. No. 07/615,800 hereby is incorporated into this application in its entirety.

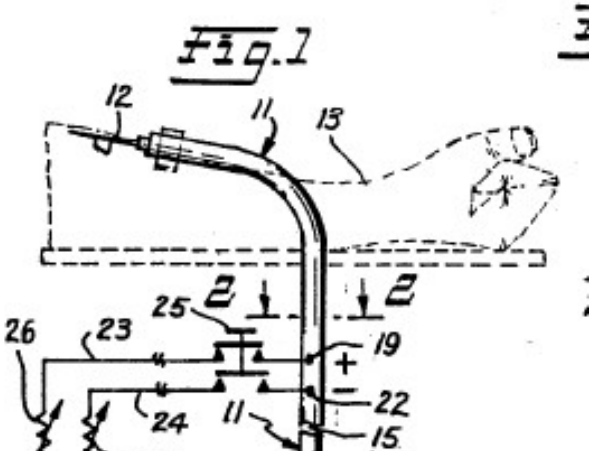
SUMMARY OF INVENTION

The present invention provides new electrically conductive methods and systems using alternating electric current excitation potentials for treating blood and/or other body fluids, such as amniotic fluids, and/or synthetic fluids such as tissue culture medium from a donor to a transfusion recipient or to a storage receptacle, or for recirculating a single donor's or patient's blood or other body fluids. The treatment can be accomplished in a treatment system external of the body or by implant devices for purging contaminants using a novel electrically conductive vessel for direct electric treatment of blood or other body fluids, such as amniotic fluids, with alternating current electric field forces of appropriate electric field strength to attenuate such contaminants to the extent that bacteria, virus, fungus, and/or parasites contained in the blood or other body fluids are rendered ineffective to infect and/or affect normally healthy human cells. The treatment, however, does not render the blood or other body fluids biologically unfit for use in humans or other mammals after the treatment. The new methods and systems according to the invention achieve these ends without requiring time consuming and expensive processing procedures and equipment in addition to those normally required in the handling of blood or other body fluids or synthetic fluids. The invention can be used to achieve the electric field force treatment during the normally occurring transfer processing from a donor to a recipient or to a collection receptacle, or recirculation of a single donor's or patient's blood or other body fluids, such as amniotic fluids.

BRIEF DESCRIPTION OF DRAWINGS

The above and many other objects, features and attendant advantages of this invention will be appreciated more readily as the invention becomes better understood from a reading of the following detailed description, when considered in connection with the accompanying drawings, wherein like parts in each of the several figures are identified by the same reference characters, and wherein:

FIG. 1 is a diagrammatic, fragmentary, elevational view of a new blood transfer system using a novel alternating current electrically conductive treatment vessel in the form of conductive tubing to directly treat blood being transferred to a storage receptacle with electric field forces according to the invention;



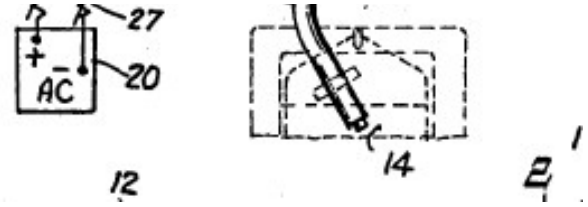


FIG. 2 is an enlarged, horizontal cross sectional view of the novel electrically conductive tubing treatment vessel taken across lines 2--2 of FIG. 1;

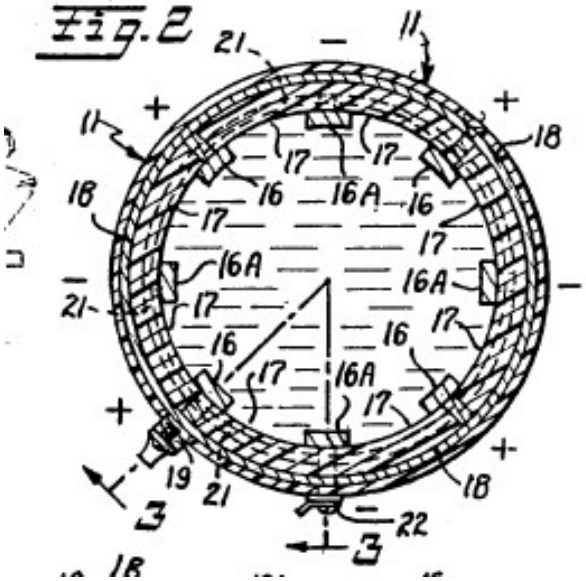


FIG. 3 is a longitudinal, vertical sectional view of the novel electrically conductive tubing treatment vessel taken along the staggered section lines 3--3 of FIG. 2;

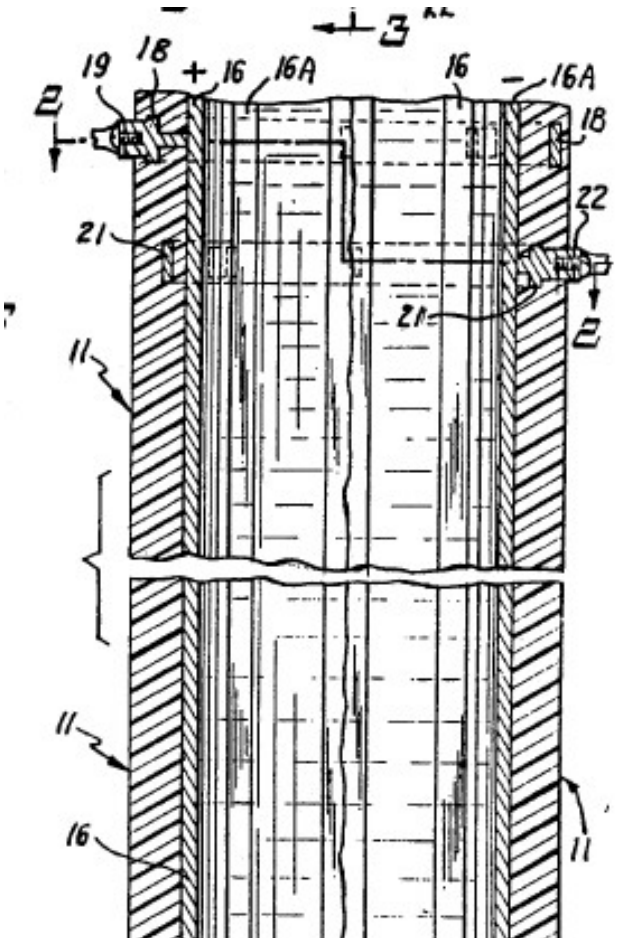


Fig. 3

FIG. 4 is a view similar to FIG. 2 showing a different construction of the novel electrically conductive tubing treatment vessel;

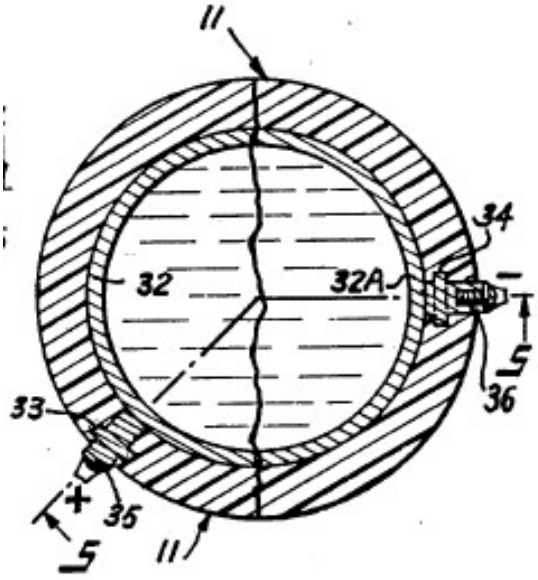
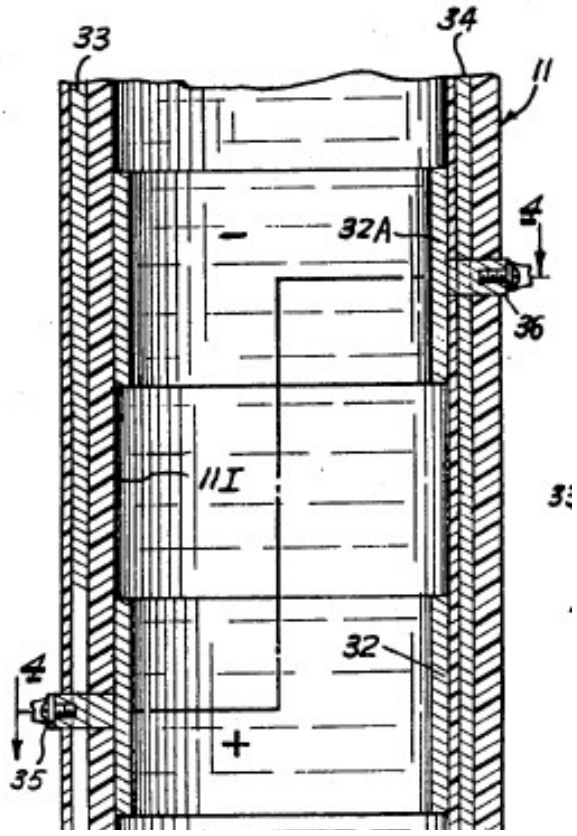


Fig. 4

FIG. 5 is a view similar to FIG. 3, taken along the staggered section lines 5--5 of FIG. 4;



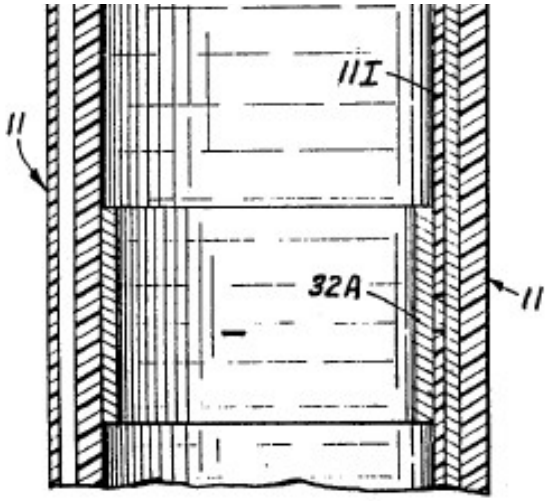


Fig. 5

FIG. 6 is a diagrammatic, fragmentary, elevational view showing a different modification of a novel blood transfer system using a novel electrically conductive tubing treatment vessel, and which employs a blood pump and a blood flow regulator;

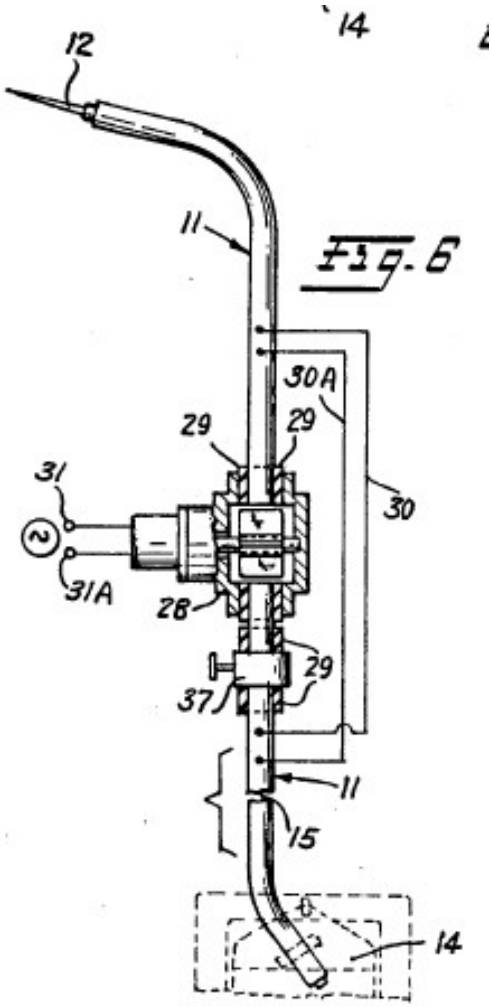


Fig. 6

FIG. 7 is an enlarged cross sectional view, similar to FIG. 2 that shows an electrically conductive tubing treatment vessel fabricated from longitudinally extending, integrally molded strips of alternate polarity, conductive polymer interconnected by integrally molded, insulating, longitudinally extending strips made of polymer or other insulating material;

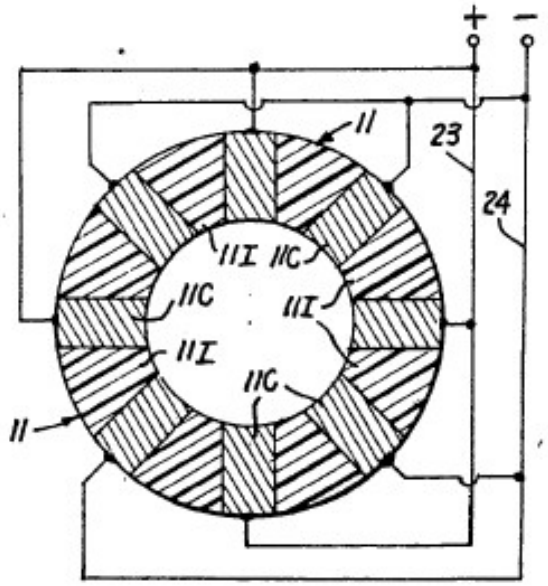


Fig. 7

FIG. 8 is a diagrammatic, fragmentary elevational view showing a different form of a blood transfer system according to the invention wherein a small electrically conductive vessel in the form of a short piece of tubing and a miniaturized battery power source are implanted in the arm of a human being to provide a novel electrically conductive blood and other body fluid treatment system which operates in a closed loop, recirculating manner;

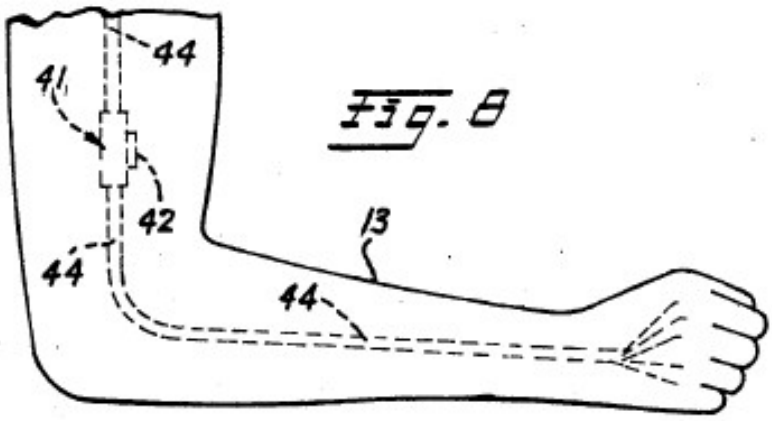


Fig. 8

FIG. 9 is a partial, diagrammatic sectional view of the upper arm portion of a human being and shows in greater detail the construction of a specially designed miniaturized, electrically conductive treatment vessel with associated miniaturized battery electric power source and DC to AC power converter for use in the implant treatment system shown in FIG. 8;

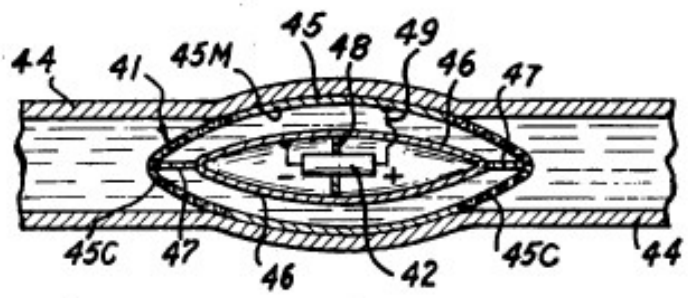
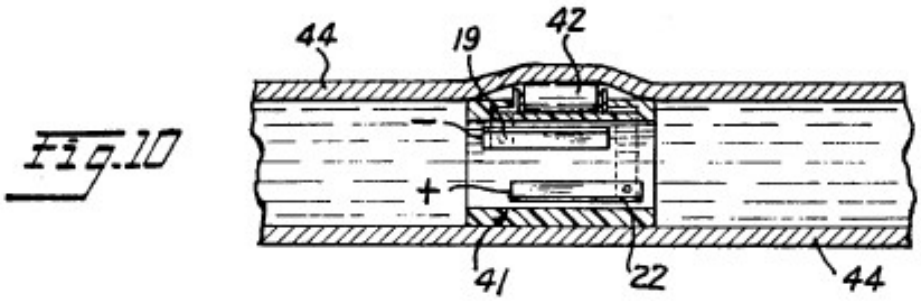
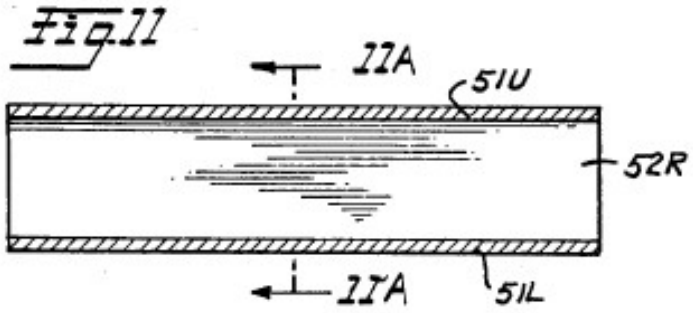


Fig. 9

FIG. 10 illustrates the details of construction of a somewhat different form of miniaturized electrified treatment tubing for use in an implanted treatment system of the type shown in FIG. 8 and built according to the invention;



FIGS. 11 and 11A illustrate still a different construction for the electrified treatment tubing for use in practicing the invention wherein the tubing has a square or rectangular cross section with upper and lower conductive sides and intervening right and left sides separating the two conductive sides made from plastic or other suitable electrical insulating material;



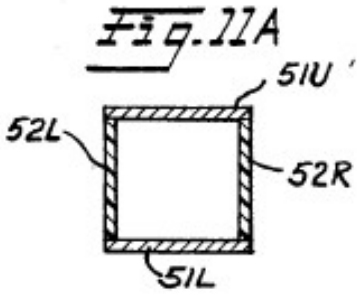
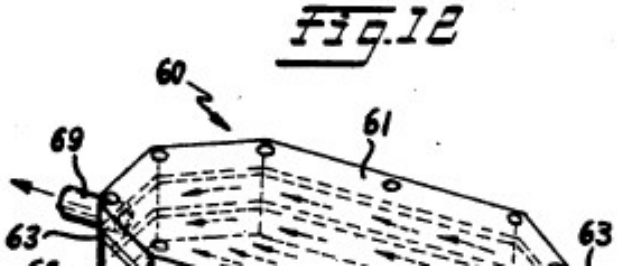


FIG. 12 is a perspective top and side view of a novel electrified, closed, octagonally-shaped, flat, box-like treatment vessel having an enlarged cross sectional area relative to the cross sectional diameter of the inlet and outlet tubes supplying the interior of the treatment vessel;



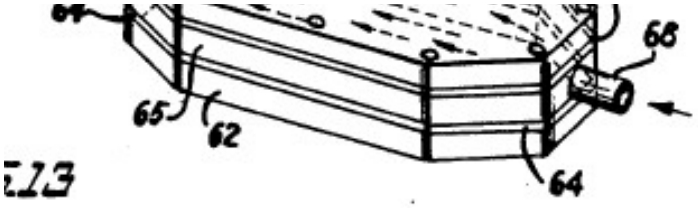


FIG. 12A is a partial, cross sectional view of the enlarged treatment vessel shown in FIG. 12;

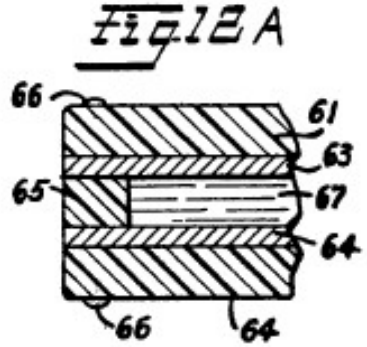


FIG. 13 is a perspective view of a second form of enlarged cross sectional area treatment vessel having an exterior shape similar to that of FIG. 12, but wherein the electrically conductive electrodes of the treatment vessel comprise interleaved conductive plates with one set of alternate ones of the plates being electrically insulated from the remaining set, and wherein different polarity electric potentials are applied to the respective sets. If desired, the electrode plates may be formed from an electrically conductive porous material;

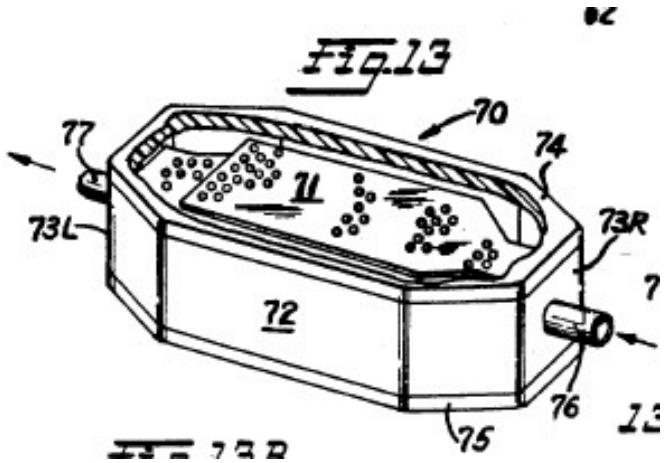


FIG. 13A is a partial, cross sectional view taken through the electrically conductive treatment vessel shown in FIG. 13;

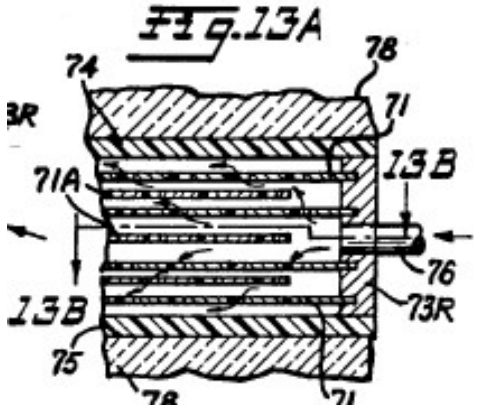


FIG. 13B is a sectional view taken through staggered line 13B--13B of FIG. 13A;

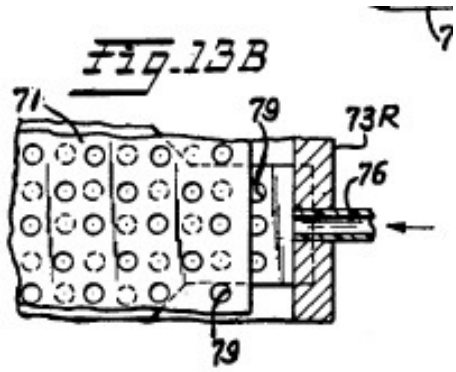


FIG. 14 is a longitudinal sectional view of still a different form of enlarged diameter electrified treatment vessel wherein the vessel is in the form of an elongated cylinder, and the sets of conductive electrodes mounted therein are concentrically arrayed within the interior of the treatment vessel and maintained at different electric potentials;

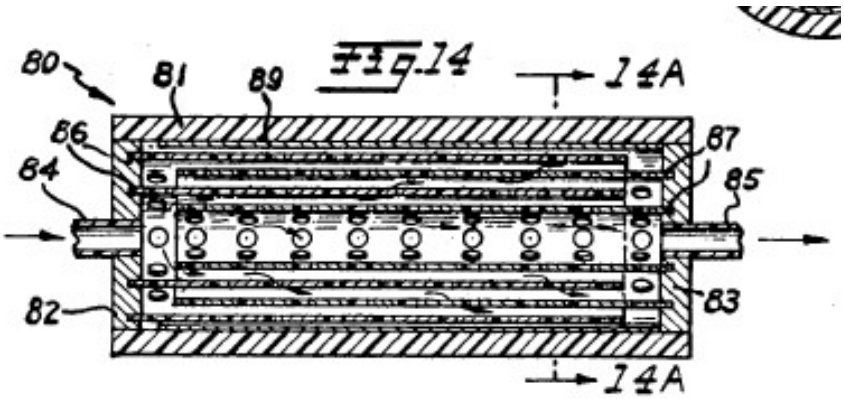


FIG. 14A is a cross sectional view of FIG. 14 taken through plane A--A;

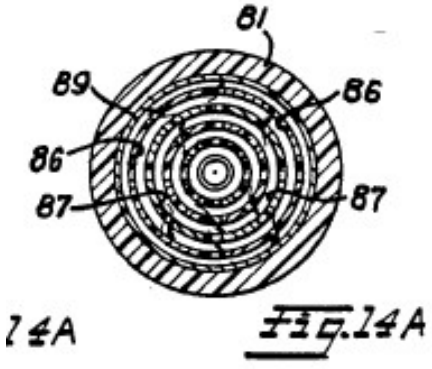
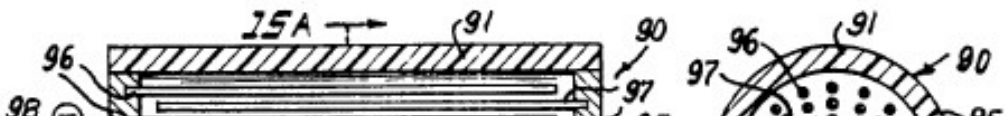


FIG. 15 is an enlarged longitudinal sectional view of still another form of an enlarged cross sectional area treatment vessel according to the invention wherein the electrically conductive electrodes of the treatment vessel are comprised by longitudinally extending needle-like electrodes with alternate ones of the needle-like electrodes being provided with opposite polarity electric potentials;



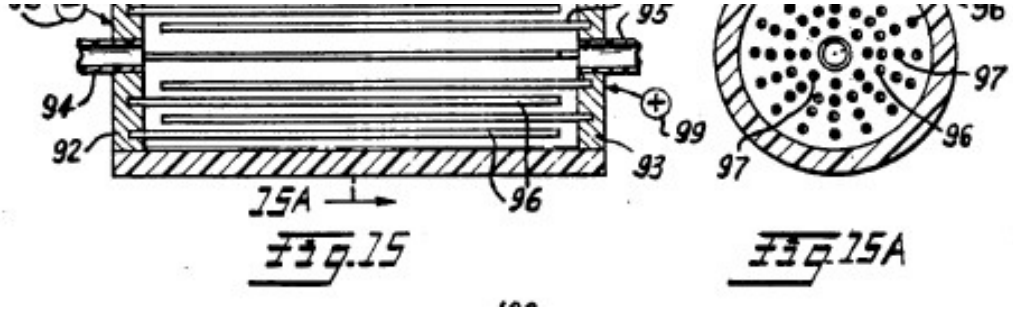


Fig. 15 Fig. 15A

FIG. 15A is a cross sectional view of the treatment vessel shown in FIG. 15 taken through plane A--A of FIG. 15;

FIG. 16 is a perspective view of still another form of enlarged cross sectional area treatment vessel according to the invention wherein the treatment vessel comprises a relatively large block of insulating material having parallel, longitudinally extending, open ended tubes formed through its length. The tubes are provided with electrically separated, opposed, parallel extending conductive plate electrodes which have opposite polarity electric potentials applied thereto. The ends of the tubes open into and are supplied from, or supply, respective reservoirs formed on the respective ends of the central block of insulating material containing the tubes, with inlet and outlet conduits for body fluids to be treated connected to the free ends of the respective reservoirs;

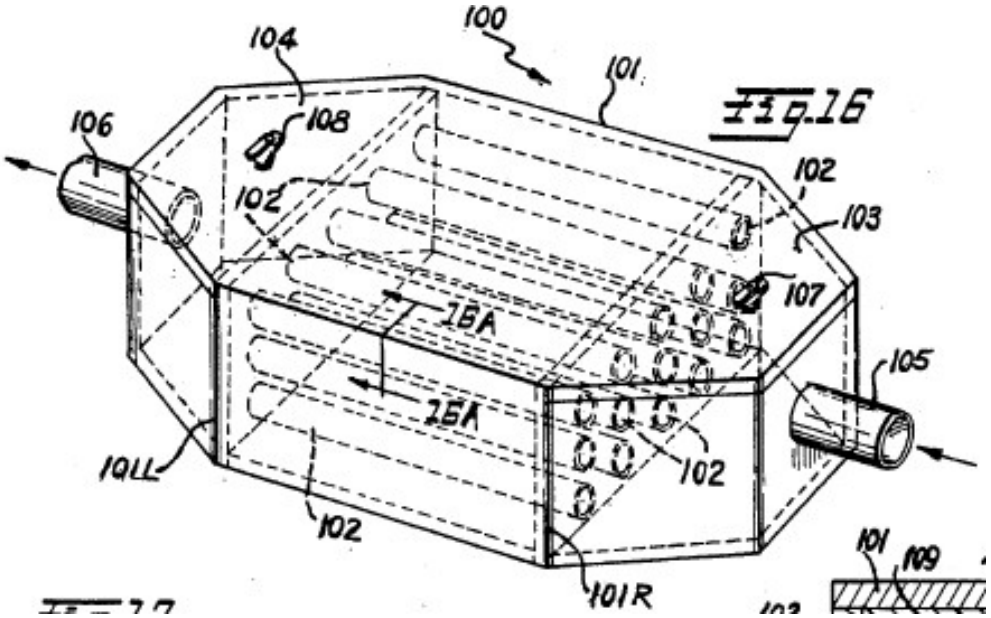


Fig. 16

FIG. 16A is a partial cross-sectional view taken through 16A--16A of FIG. 16;

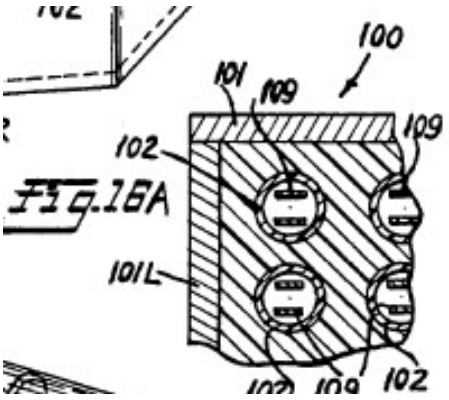


Fig. 16A

FIG. 17 is a perspective view of an enlarged cross sectional area treatment vessel similar to FIG. 16 wherein the body of the treatment vessel is cylindrical in nature;

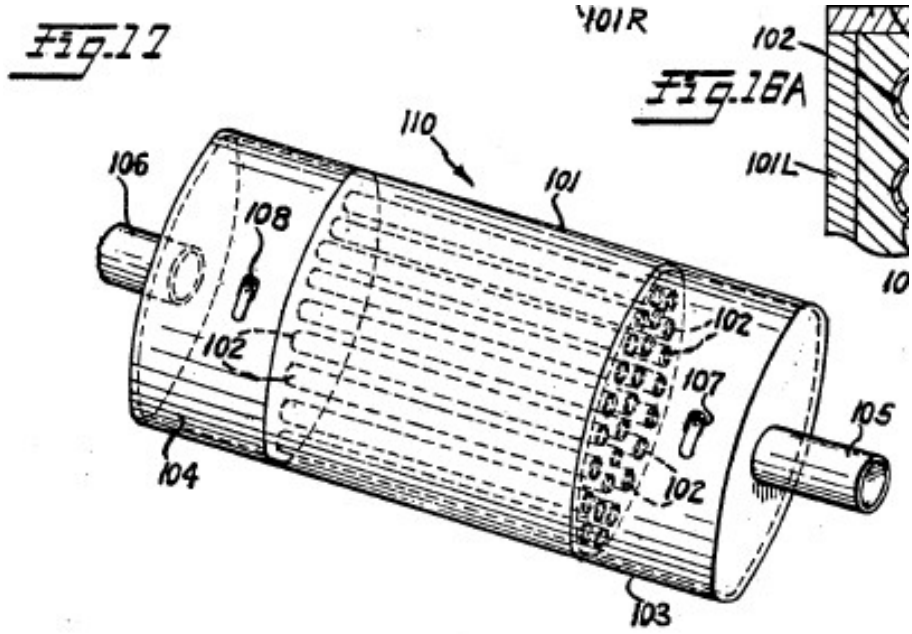


FIG. 18 is a diagrammatic, fragmentary elevational view of a human blood or other body fluid treatment system according to the invention employing one of the larger cross sectional dimension fluid treatment vessels shown in any one of FIGS. 12-16 of the drawings, and which is suitable for use in a continuous flow through recirculating body fluid treatment system; and

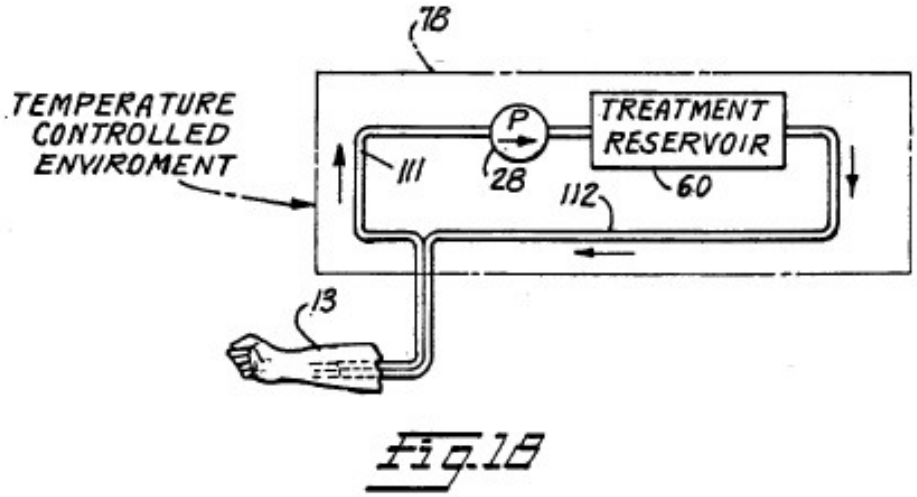


FIG. 19 is a diagrammatic, fragmentary elevational view of still another human blood or other body fluid, closed loop, recirculating treatment system according to the invention designed for use with the enlarged diameter fluid treatment vessels illustrated in FIGS. 12-16, and which employs both inlet and outlet fluid pumps on each side of the treatment vessel. With this arrangement the system can be operated in an intermittent manner to allow batch treatment of the body fluids to fully take place before passage of the body fluids being treated back to the patient.

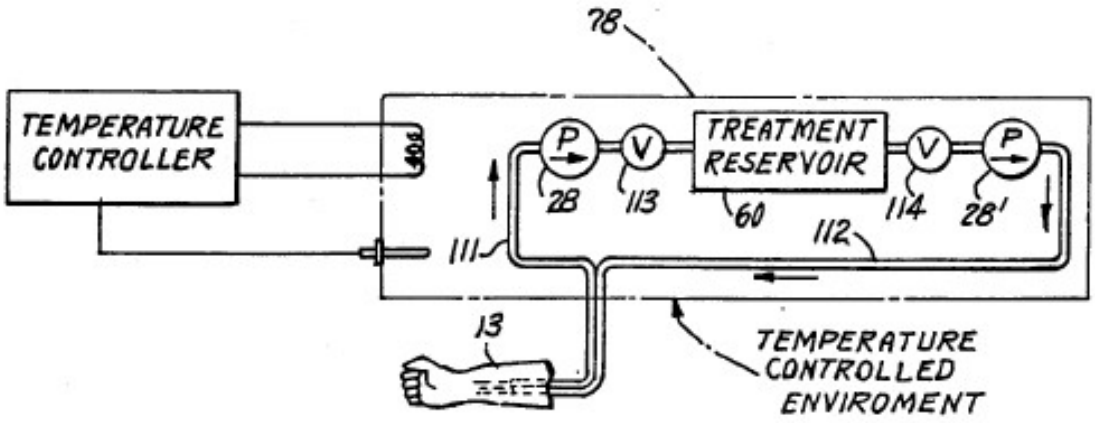


FIG. 19.

BEST MODE OF PRACTICING INVENTION

FIG. 1 is a schematic illustration of one form of a novel blood and other body fluid treatment system according to the invention. FIG. 1 shows an electrically conductive blood and/or other body fluid treatment vessel constructed according to the invention which is in the form of intravenous tubing 11 interconnected between a hypodermic needle 12 and a blood storage receptacle 14. The needle 12 is inserted in an artery or vein of the arm 13 of a blood donor and the tubing 11 leads from the arm 13 to the receptacle 14. Alternatively, the system could be set up to transfer blood from the storage receptacle 14 to the arm of a recipient or could be designed to recirculate the blood through electrified tubing 11 back to the donor. The electrically conductive tubing 11 may be of any desired length as indicated by the break at 15 so that it can be appropriately set up to lead from a comfortable position for the donor from whose arm 13 the blood is being taken to a proper storage location for the receptacle 14. The greater the length of the electrified portion of tubing 11, then the more extended is the exposure of the blood (or other body fluid) to the electric field force effects and low level, biologically compatible current flow through the body fluid being treated thereby assuring adequate electrification treatment of the fluid without impairing the biological usefulness of the blood or other body fluid being treated.

FIG. 2 is a cross sectional view of the electrically conductive tubing 11 taken through plane 2--2 of FIG. 1. The tubing 11 may be from 1 to about 20 millimeters in inside diameter, although it may be larger or smaller in diameter depending upon the intended application. For example, if the blood transfer system is for the purpose shown in FIG. 6, then the tubing may have a cross sectional dimension of about 5 millimeters. However, if the intended use is in an implanted blood treatment system, such as shown in FIG. 8, then the tubing diameter must be designed to result in a flow-through rate corresponding to the natural circulatory blood flow rate of the patient in which the system is implanted, and must be long enough to assure effective electrification treatment at the flow rate selected. The tubing 11 is formed from plastic, rubber, medical grade polymer, or other suitable material which is compatible with human fluids and/or tissue. A plurality of physically separated, electrically conductive surface segments form opposed, parallel electrodes shown at 16 and 16A on the inside of tubing 11 from electrically conductive materials such as platinum, platinum alloys, silver, silver or platinum covered alloys, or other similar conductive materials such as conductive polymers, or silver or platinum covered polymers which are compatible with human fluids and tissue. The spacing between opposed electrodes 16 and 16A is of the order of 1 to 19 millimeters and perhaps may be more or less dependent upon the application and the

conductivity of the body fluids being treated.

FIG. 3 is a longitudinally extending sectional view along the axis of tubing 11 taken through staggered section lines 3--3 of FIG. 2. From FIG. 3 of the drawings it will be seen that the electrically conductive surface segments 16 and 16A all comprise longitudinally extending, zebra-like stripe or strip electrodes which extend longitudinally in parallel with the longitudinal axis of the tubing 11. In between each longitudinally extending conductive stripe electrode 16 or 16A is a longitudinally extending electric insulating area 17 which electrically isolates the alternate electrically conductive, zebra-like stripe electrodes 16 and 16A one from the other.

As best shown in FIG. 3, a first set of alternate electrically conductive surface stripes 16 are electrically connected in common to a first annular terminal buss 18 which circumferentially surrounds the tubing 11 and is embedded within the sidewalls of the tubing 11 at a suitable point along its length. The design is such that the first annular terminal buss 18 is electrically isolated from the remaining second set of alternate, electrically conductive surface stripe electrodes 16A and is electrically connected through a conductor terminal 19 to an alternating current source of electric excitation potential. AC source 20 may comprise the output from an AC to AC voltage converter for converting 110 volt AC potential to the desired 0.2 volts to 12 volts for use in the invention. For those treatment systems which are to be implanted as described hereafter, the AC source may comprise a miniaturized DC to AC converter for converting the DC voltage from a miniaturized battery to low voltage (0.2 to 12 volts) AC. As best depicted in FIG. 2, all of the first set of positive electrically conductive stripes 16 are physically and electrically connected in common to the first annular terminal buss 18 so that all of the conductive stripes 16 are maintained at a constant, alternating current electric excitation potential.

A second annular terminal buss 21, which circumferentially surrounds the tubing 11, is embedded within the tubing 11 at a point along its length displaced from the position of the first annular terminal buss 18 and is spaced inwardly towards the inside diameter of the tubing relative to the first annular buss 18. By this arrangement it is possible to electrically connect the remaining second set of alternate electrically conductive surface stripes 16A in common to the second annular terminal buss 21 in a manner such that the second annular terminal buss is electrically isolated from the first annular terminal buss 18 as well as the first set of alternate electrically conductive surface stripes 16. As shown in FIG. 3, the second annular terminal buss 21 is provided with an outside terminal conductor connection 22 for connecting the annular buss 21 and annular buss 18 across AC source 20 as shown in the system drawing of FIG. 1. The second set of alternate electrically conductive surface stripes 16A are all provided with internal connector studs which physically and electrically connect all of the 16A stripes in common to the second annular terminal buss 21 so that all of these conductive stripes will be maintained at a potential opposite to that from the potential applied to the first set of electrically conductive stripes 16 by annular buss 18.

As described earlier, the AC source of electric potential 20 may constitute an AC to AC converter for converting 110 volt AC to 0.2 to 12 volt AC or a DC to AC converter for converting 12 volt DC to 0.2 to 12 volt AC. The AC source 20 is connected to the conductor terminals 19 and 22 through electric supply conductors 23 and 24 preferably by a double pole, double throw, on-off control switch 25. In preferred embodiments of the invention, voltage controlling variable resistors 26 and 27 also are included in the electric supply conductors 23 and 24 in order to control the value of the excitation voltage developed between the alternate sets of conductive surface stripes 16, 16A.

In operation, the donor whose blood is to be taken, or the recipient who is to be given blood, or is to have his or her blood recycled, is made comfortable on a cot with his or her arm 13 extended and the interconnecting electrically conductive tubing 11 having the hypodermic needle 12 for withdrawal, or supplying, or recycling of blood set up as shown in FIG. 1. When both the donor/recipient and the system is in readiness, the control switch 25 is closed so that an electric field is built up across the oppositely disposed electrically conductive zebra-like stripes 16, 16A, etc. Voltages of the order of from 0.2 to 12 volts are applied to the conductive surfaces 16, 16A For this purpose it is important to note that the hypodermic needle should be electrically isolated via conventional electrically insulating IV tubing from any of the zebra stripe electrodes 16, 16A so that the donor/recipient does not receive a shock. By this precaution, he or she will not even be aware of the existence of the electric field within the electrically conductive tubing 11. With the treatment system thus conditioned, the hypodermic needle is inserted into a vein in the donor's/recipient's arm and blood is withdrawn, given, or recycled through the tubing 11.

As the blood passes through the electric fields produced within the electric conductive tubing 11 it will be subjected to and treated by biologically compatible electric current flow through the blood or other body fluid with a current density of from one microampere per square millimeter (1 .mu.A/mm.sup.2) of electrode cross sectional area exposed to the fluid to about two milliamperes per square millimeter (2 mA/mm.sup.2) dependent upon field strength of the electric field gradient existing between electrodes 16 and 16A, the space between the electrodes 16, 16A and the conductivity (resistivity) of the body fluid being treated. Recent experiments have proven that exposure to electric fields induced by supply voltages in the range produces electric current flow through blood of the order of 1 to 100 microamperes. Effectiveness is dependent upon length of time of treatment in conjunction with the magnitude of the biologically compatible current flow. For example, treatment of virus in media at 100 microamperes for 3 minutes has been observed to substantially attenuate (render ineffective) the AIDS virus. Similar treatment at other field strength values and lengths of time will have a similar attenuating effect on bacteria, virus, parasites and/or fungus which are present in blood or other body fluids being treated. By controlling the length of time and field strength values that blood is subjected to the electric field forces, undesirable contaminants such as virus, bacteria, fungus and/or parasites will be adequately attenuated to the point that they are rendered ineffective by the sustained action of the electric current flow as the blood travels from the hypodermic needle 12 to the storage bag 14, or vice versa, or in a recycling mode. The length of travel of the blood through the sustained electric field induced current flow also can be adjusted so that the blood is subjected to the electric field force for time periods of the order of from one to six minutes at least. At the current values noted above this is believed adequate to attenuate (render ineffective) bacteria, virus (including the AIDS virus), parasites and/or fungus entrained in blood or other body fluids, but does not render the fluids unfit for human use or impair their biological usefulness.

The species of the invention shown in FIGS. 2 and 3 is advantageous since it is possible to fabricate the treatment tubing by preforming the conductive segments 16 and 16A on the tubing walls while it is in a flat planar condition, and then rolling the walls into tubular form using a suitable mandrel. The adjoining longitudinal edges of the planar member after rolling are thereafter heat sealed along a longitudinally extending seam located within one of the electrically insulating sections 17. Particular attention must be paid to the juncture of the ends of the annular terminal busses 18 and 21 during the rolling and heat sealing steps to assure that good electrical interconnection and continuity at these junctures of the annular terminal

busses is provided in the completed treatment tubing. The conductive electrode segments 16, 16A may be electro-deposited, chemically formed, separately formed conductive polymer surfaces, or conductive foil or wires adhesively secured to the side walls of the tubing 11 in advance of the rolling and sealing using techniques well known in the printed circuit and integrated circuit manufacturing technologies.

FIG. 6 is a diagrammatic, fragmentary, elevational view of a modified blood treatment system using the novel electrically conductive treatment tubing in accordance with the invention. In the FIG. 6 embodiment of the invention, a blood pump 28 of conventional, commercially available construction is inserted in the tubing 11 at some point along its length. The blood pump 28 is electrically isolated from the zebra striped conductive surfaces 16, 16A by suitable insulators 29 formed on the blood input-output connections of pump 28. Provision for electrically bypassing the blood pump 28 (if need be) is made through the shunt conductors 30, 30A which maintain electrical continuity of the alternating current excitation potential applied to the conductive stripes 16, 16A on each side of pump 28. For convenience, the alternating current excitation source 20 and its connection to the electrically conductive tubing 11 has not been shown in FIG. 6 but would have to be provided. A separate source of excitation current for running the blood pump 28 is provided from a conventional 110 volt alternating current source through the input terminals 31, 31A.

In systems employing a blood pump, it may be desirable in some applications to provide a blood flow regulating valve 37 inserted in the system at the output of blood pump 28 and within the by-pass loop 30, 30A for the conductive stripes 16, 16A. By thus controlling blood flow, the electrified transfer system safely can be employed in a closed loop recycling system for withdrawing blood from a patient, electrically treating the blood as described above and then returning the electrically treated blood to the patient. This procedure is referred to herein as recycling. The system of FIG. 6 also can be used in those situations where the blood flow of a donor's blood is not sufficient to assure supply of an adequate amount of blood to or from the collection receptacle 14 or other recipient. It may also be desirable to have a blood flow regulating valve such as 37 in non-pump systems.

FIGS. 4 and 5 of the drawings show another embodiment of the invention wherein the electrically conductive treatment tubing 11 includes electrically conductive electrode segments 32 and 32A which are in the form of zebra stripes that extend radially around the inside diameter of tubing 11 in spaced-apart, alternating polarity, conductive annular bands 32 and 32A separated by insulating surface bands 11I which serve to electrically isolate the respective first set of conductive zebra stripes 32 from the second set of conductive zebra stripes 32A. The first set of alternate ones of the electrically conductive annular stripes 32 are electrically connected in common to a first longitudinally extending terminal buss bar 33 that is embedded within tubing 11 in parallel with the longitudinal axis of the tubing and electrically isolated from the remaining second set of alternate electrically conductive annular stripes 32A. The first longitudinally extending terminal buss bar 33 is designed for connection to one output terminal of a source, such as 20, of alternating current electric excitation potential through a supply conductor connection 35 on the exterior surface of the tubing 11.

A second longitudinally extending terminal buss bar 34 is embedded within the body of tubing 11 and is electrically connected to the remaining second set of alternate electrically conductive annular stripes 32A. The second longitudinally extending terminal buss bar 34 is electrically isolated from the first longitudinally extending terminal buss 33 and the first set of alternate electrically annular stripes 32. Terminal buss bar 33 is designed for connection to

a second output terminal for the alternating current source of electric excitation potential. For this purpose an input supply conductor connection 36 is directly connected through the exterior surface of tubing 11 and to the second longitudinally treatment extending terminal buss bar 34.

In operation, the embodiment of the invention shown in FIGS. 4 and 5 is physically arranged in a blood treatment system in the manner illustrated in FIG. 1 of the drawings with the positive polarity and negative polarity zebra annular stripes being connected to the respective output terminals of AC source 20 via control switch 25. If required, a blood pump such as 28 and blood flow regulating valve 37 shown in FIG. 6 can be included in the blood transfer system employing electrified tubing as shown in FIGS. 4 and 5.

Similar to the system shown in FIG. 1, a blood transfer system employing the embodiment of the invention shown in FIGS. 4 and 5 would be electrically excited in advance of injection of the hypodermic needle 12 into the arm of a blood donor so that all blood passing through the tubing 11 will be subjected to electric forces produced between the alternate polarity annularly formed conductive bands 32 and 32A. Experience with the invention will establish what length is required for the electrification field. However, for initial installations the length of the electrified field as related to the flow of blood through electrified tubing 11 should correspond to at least the 1-6 minute treatment time mentioned earlier. This is achieved by using an extended array of the alternate annular zebra bands 32 and 32A of adequate length to assure thorough subjection of blood to electric current flow produced between the alternating polarity zebra stripes 32 and 32A. The electric field force intensity applied to the blood by means of the electrified tubing is anticipated to be of the order of from 0.2 to 12 volts similar to the embodiment of the invention shown in FIGS. 1-3.

In place of supplying continuous alternating current excitation to the conductive stripes 16, 16A of FIGS. 2 and 3 or 32, 32A of FIGS. 4 and 5, it also is possible to excite these electrically conductive segments of tubing 11 with pulsed waveform direct current excitation potentials. For use in this manner, the pulse rate of the pulsed waveform excitation potentials must be sufficiently high to maintain continuous current flow through blood being treated. In addition, it may be desirable to couple a bank of storage capacitors in parallel across respective pairs of opposite polarity electrically conductive segments 16, 16A and 32, 32A where operation in a pulsed DC mode is desired.

FIG. 7 of the drawings is a cross sectional view of another embodiment of the invention which is substantially different from those previously described. In FIG. 7, the material used for fabrication of the tubing 11 is one of the new space-age polymer materials which can be either highly electrically conductive, insulating, or semiconducting and may have values of conductivity ranging from essentially fully conductive to insulating. In the embodiment of the invention of FIG. 7, the conductive surface areas on the inside diameter of the tubing 11 are actually formed into segments, such as 11C, of the cross sectional area of the tubing 11 fabricated from the highly conductive polymer material. The intervening segments of the tubing 11I which separate the conductive segments 11C are integrally formed from the highly insulating polymer material. Suitable positive polarity and negative polarity potentials are applied to the exterior surface areas of alternate ones of the sets of conductive polymer segments 11C from a source of electric potential via the conductors 23 and 24 as illustrated schematically in FIG. 7.

It will be appreciated that the embodiment of the invention shown in FIG. 7 is much simpler and hence less expensive to make in that it requires fewer processing steps than the

embodiments of the invention shown in FIGS. 1-6. In other respects, the embodiment of the invention shown in FIG. 7 would be used in a blood transfer system similar to that shown in FIG. 1 or 6 with or without a blood pump 28 and blood flow regulating valve 37 to effect transfer of blood from a donor to a receptacle or recipient in the event of a transfusion or recycling. During the blood transfer process, again it would be necessary to provide alternating current excitation potentials across the spaced-apart, alternate sets of electrically conductive polymer segments 11C prior to passing blood through the tubing 11. This will assure that all of the blood being transferred is subjected to the electric field forces produced between the alternate conductive surfaces 11C. As a variation of the FIG. 7 embodiment, which visualizes that the segments 11C and 11I all extend longitudinally and parallel to the longitudinal axis of tubing 11, it would be possible, but more elaborate to design, to employ alternate radially surrounding annular conductive segments 11C and interlacing insulating segments 11I similar to FIG. 5, but such fabrication would require somewhat more complex terminal buss bar electric supply connections 23 and 24 than those shown in FIG. 7.

FIG. 8 is a fragmentary, diagrammatic, elevational view showing a form of blood treatment system according to the invention wherein a small electrically conductive vessel 41 in the form of a short piece of electrified tubing and a combined miniaturized DC to AC converter and battery power source 42 are implanted in the arm of a human being. The electrified tubing 41 may be in the form of any of the prior disclosed electrified tubing structures described with relation to FIGS. 1-7, but which are fabricated in miniaturized form so that the tubing 41 and power package 42 can be inserted in a section of or surrounding a vein 44 of the arm 13 of a patient whose blood is being treated. The implantation is such that the blood through the patient's vein 44 naturally is pumped through the short piece of electrified tubing 41 while circulating blood to the hand of the patient to thereby form a closed loop, recirculating, implanted treatment system that comprises an integral part of the circulatory system of the patient being treated. Because the parameters of such an implanted system are necessarily small, a single passage through the implanted electrified tube 14 may accomplish relatively little attenuation of contaminants in the blood. Therefore, it is the repeated passage of small portions of the patient's blood continuously twenty-four hours a day and for as many days as are needed which will gradually attenuate the contaminants to the point where they are rendered ineffective as described earlier.

FIG. 9 is a partial, fragmentary, sectional view of the upper arm portion 13 of a vein or artery of a patient in which a treatment system according to the invention has been implanted, and shows in greater detail the construction of a specialized, miniaturized, electrically conductive treatment vessel with associated miniaturized battery electric power source and DC to AC converter for use in an implanted treatment system as shown in FIG. 8. In FIG. 9, the electrified vessel 41 is in the form of an outer housing 45 that is in the shape of a football which is implanted within the interior walls 44 of an artery or a vein. The outer housing 45 is comprised by a central, cylindrically-shaped portion 45M of solid conductor such as platinum which is biocompatible with human blood and tissue and has integrally formed, conically-shaped porous ends 45C which are attached to and form an electrically conductive screen grid (at the same potential) as the mid portion 45M. The conical end portions 45C both are perforated and may be in the nature of a screen or mesh wire and of the same material composition as the mid portion 45M. Disposed within the outer housing 45 is a inner housing 46 which is tear-drop shaped and secured within the central portion 45M of the outer housing by suitable insulating support spider legs 47. The inner housing 46 likewise is formed from platinum or other suitable biocompatible conductive material and has supported within its interior a miniaturized AC source comprising a miniaturized battery and AC to DC converter

42 secured to the conductive walls of inner housing 46 by conductive support legs 48. The support legs 48 serve as terminal connectors from one terminal of AC power converter 42 to the inner housing 46 so that it is maintained at one polarity excitation potential. The remaining opposite polarity terminal of miniaturized AC source 42 is connected through an insulated conductor 49 to the central portion 45M of outer housing 45 whereby the entire outer housing including the meshed conical end portions 45C are maintained at an opposite polarity potential from the inner housing 46.

Prior to implantation in a patient, the electrified vessel shown in FIG. 9 is activated by connection to AC source 42 so that an electric field gradient is produced across the space between the inner and outer housings 45 and 46. Following implantation of the activated, electrified treatment vessel 41, its presence in a vein or artery will cause all blood flowing through the vein or artery to pass between the side walls of the inner and outer housings 45 and 46 so as to be subjected to the electric field force gradient existing in these spaces. The presence of the electric field forces will induce a current flow through the blood passing between the interior and outer housings as explained above which will result in attenuating bacteria, virus, parasites and/or fungus which are present in the blood as contaminants. Here again, because of the relatively small portion of the total blood flowing in a patient that will be treated by the device within a given time period, it is the repeated, recycling process treatment of the blood over a prolonged period of time that will result in attenuation of the contaminants in the blood to the point where such contaminants are rendered ineffective as described earlier.

In order to further assure adequate treatment of the blood of a patient receiving the implant device, it is recommended that the blood be treated in an external treatment processing facility such as described earlier in FIGS. 1 and 6 or to be described hereinafter with relation to FIGS. 18 and 19 in which the total capacity of the treatment system is greater whereby substantial attenuation effect can be achieved in a comparatively shorter time period yet to be determined, and then the in vitro implant treatment system such as shown in FIGS. 8, 9 and 10 can be used to maintain the attenuated condition and to prevent any subsequent build up of contaminants after the initial treatment, if determined to be desirable.

FIG. 10 is a fragmentary, diagrammatic view of a partial vein or artery 44 showing in greater detail the cylindrical or tubular electrified treatment vessel 41 originally described with relation to FIG. 8. This implant treatment vessel 41 is miniaturized so that it is in effect an open-ended cylinder in shape and has a diameter comparable to that of a large vein or artery and so that it can be grafted or implanted into the vein or artery as illustrated in FIG. 10. The tubular treatment vessel 41 may be designed pursuant to FIGS. 2 and 3 of the drawings, for example. For this application, the battery source of power and interconnected DC to AC converter 42 are annular in shape and are slipped over the tubular treatment vessel 41 in the manner shown. In FIG. 10 a longitudinal sectional view of the hollow annular-shaped treatment vessel 41 and AC power source 42 is illustrated. At the point where the battery driven AC power source 42 fits over the tubular treatment vessel 41, the respective terminals of the AC power source 42 are exposed to engage the corresponding positive and negative supply terminals 19 and 22 of the tube 41 so that the resulting structure has a minimum exterior profile to facilitate implantation. From a comparison of FIG. 10 to FIG. 9 of the drawings, it will be appreciated that the FIG. 9 treatment vessel introduces some flow restriction in the vein or artery in which it is implanted and for this reason the construction shown in FIG. 10 is preferred.

FIGS. 11 and 11A of the drawings illustrate a construction for the electrified treatment vessel

51 wherein the treatment vessel is in the form of square or rectangular cross sectionally-shaped open-ended tubing. The treatment tubing 51 provided with a square or rectangular shape so that provision of opposed, parallel conductive electrode surfaces 51U and 51L is greatly simplified as best seen in FIG. 11A of the drawings, which is a cross sectional view taken through plane 11A--11A of FIG. 11. By fabricating the upper and lower surfaces of the tubing 11 from electrically conductive material such as platinum, etc., and separating the upper and lower surfaces 51U and 51L by electrically insulating side walls 52R and 52L, provision of the electrically isolated, opposed, parallel electrode surfaces is simplified and the resulting treatment vessel introduces minimum restriction to flow of blood. By connecting the upper surface 51U to one terminal of the AC power source 42 and connecting the lower surface 51L to the opposite terminal, AC electrification of the interior area of the tubing wherein the fluids to be treated flow is readily achieved with a greatly simplified electrode structure. Variations of this structural feature wherein the side insulating surfaces 52R and 52L are curved with their concave surfaces facing each other and the cross sectional area of the upper and lower conductive surfaces 51U and 51L tailored to provide a desired current density, tubular treatment vessels such as shown in FIGS. 11 and 11A could be readily provided for use in implantation devices such as that illustrated in FIG. 8.

FIG. 12 is a perspective view of a novel, electrified, closed, octagonally-shaped, flat, box-like treatment vessel 60 according to the invention which provides an enlarged cross-sectional area relative to the cross sectional diameter of the inlet and outlet tubing supplying the interior of the treatment vessel whereby increased through-put of a fluid being treated can be achieved in a given time period. The treatment vessel 60 shown in FIG. 12 is comprised essentially of upper and lower, octagonally-shaped, flat insulating plates 61 and 62, respectively, of an insulating material which is compatible with human blood and/or other body fluids. Disposed immediately below and above the upper and lower plates 61 and 62 are octagonally-shaped, conductive electrode members 63 and 64, respectively, which are separated and electrically isolated one from the other by a surrounding electric insulating gasket member 65. The entire structure is sandwiched together and held in assembled relation by threaded thru-pins 66 as best seen in FIG. 12A of the drawings. The insulating gasket 65 which may be of teflon defines an open space 67 between the two conductive electrode members 63 and 64 into which the blood or other body fluid to be treated is introduced via inlet and outlet conduits 68 and 69. Alternating current electric potentials are applied across the respective conductive plates 63 and 64 to produce an electric field force across the intermediate space 67 through which the fluids being treated flow between electrode plates 63 and 64. By thus structuring the treatment vessel, increased treatment surface area is provided to the blood or other body fluid flowing through the space 67 whereby in a given time period an increased quantity of fluids can be treated.

FIG. 13 is a perspective view of another form of enlarged cross sectional area treatment vessel 70 having an exterior shape similar to that of the treatment vessel shown in FIG. 12. The electrified treatment vessel shown in FIG. 13 differs from that in FIG. 12, however, in the construction of its electrically conductive electrodes which comprise a plurality of interleaved, conductive, flat, electrode plates 71 and 71A. The electrode plates 71 are secured in and project inwardly from a right hand (RH) conductive end plate 73R as shown in FIG. 13A. The alternate set of flat electrode plates 71A are secured to and project inwardly from a corresponding conductive end plate 73L on the left hand end of the treatment vessel 70. The conductive end plates 73R and 73L and coacting insulating side plates 72 which insulate the conducting end plates from one another, form an octagonally-shaped box frame which is closed by upper and lower insulating top and bottom insulating plates 74 and 75. The

conductive end plates 73R and 73L have a central opening formed therein into which inlet and outlet tubes 76 and 77 are secured as best seen in FIG. 13 for providing inlet and outlet flow through connection to the treatment vessel 70.

The alternate sets of flat electrode plates 71 and 71A extend parallel to one another and are provided with alternating current electric potentials supplied across the respective sets of interleaved electrode plates via the respective conductive end members 73R and 73L. If desired, the respective flat conductive electrode plates 71 and 71A may be fabricated from a perforated material as shown in FIG. 13B of the drawings. Also, it may be desirable that some form of thermal insulation, or a thermally controlled chamber be provided around the exterior of the treatment vessel 70 as indicated by the thermal insulation 78 shown in FIG. 13A.

In operation, electrified treatment vessel 70 shown in FIGS. 13, 13A and 13B functions in essentially the same manner as was described earlier with respect to FIGS. 1-7 to effect attenuation of contaminants such as bacteria, virus and fungus contained in blood and/or other body fluids being treated in the flow through treatment vessel of FIG. 13.

FIG. 14 is a longitudinal sectional view of still another form of enlarged cross sectional area, electrified treatment vessel 80. The treatment vessel 80 shown in FIG. 14 is in the form of an open-ended, elongated cylinder 81 whose cylindrical walls are fabricated from an insulating material which is biocompatible with human blood and/or other body fluids and whose open ends are closed by circular-shaped conductive end pieces 82 and 83. Inlet and outlet tubular openings 84 and 85 are provided to the interior of cylindrical housing 81 through centrally formed apertures in the circular end plates 82 and 83. Within the interior of the cylindrical, insulating housing 81 at least two, separate, concentric, perforated, cylindrically-shaped electrode members 86 and 87 are provided which extend longitudinally through the interior of the outer cylindrical housing 81. The first set of concentric, perforated, electrically conductive electrodes 86 is embedded in and supported by the conductive end plate 82 which serves as an electrical terminal for applying electric potentials to all of the concentric electrode member 86. Similarly, the concentric, perforated, conductive electrode member 87 is physically supported by and electrically connected to the conductive end plate 83 for the supply of alternating current potentials thereacross. Additionally, if desired, one or more additional perforated concentric electrode members similar to 86 may be spaced apart from the inner concentric electrode member 86 outwardly along the diameter of the circular end member 82 with additional perforated concentric electrode members 87 being sandwiched between the two electrode members 86 and spaced apart therefrom so as to provide an electric field force between all the spaced apart, separated electrically conductive electrode members 86 and 87. Additionally, if desired, a conductive surface 89 may be formed around the interior walls of the outer, insulating cylindrical housing member 81 and electrically connected to the conductive end plate 82 or 83. This will assure that the entire interior of the treatment 80 vessel cross sectional area is crossed by the electric field force and all blood or other body fluid passing the cylindrical housing member 81 is subjected to biologically compatible low electric current flow as a consequence of the alternating current electric fields produced between the different concentric electrode members including the coated surface 89 within the interior insulating housing member 81.

In operation, the embodiment of the invention shown in FIG. 14 and 14A operates in substantially the same manner as described with relation to earlier embodiments of the invention to assure production of biologically compatible electric current flow through the blood or other body fluid being treated in the treatment vessel 80.

FIG. 15 is a longitudinal sectional view of still another embodiment of an enlarged cross-sectional area treatment vessel 90. The treatment vessel 90 again comprises an outer, hollow, open-ended cylindrically-shaped, insulating body member 91 whose open ends are closed by electrically conductive, circular end plates 92 and 93, respectively. Inlet and outlet tubular openings 94 and 95 are provided through the central axial opening in the conductive end plates 92 and 93 for passage of blood and/or other body fluids being treated into the interior of the treatment vessel 90. The conductive end plates 92 and 93 have respective sets of opposite polarity potential needle-like electrodes 96 and 97, respectively, projecting therefrom inwardly into the interior of the treatment vessel 90. Alternating current electric potentials are applied to the respective conductive end plates 92 and 93 through respective AC supply terminals indicated at 98 and 99. If desired, and in order to assure complete saturation of the entire volumetric area within treatment vessel 90 with electric fields, a conductive coating similar to that shown at 89 in FIG. 14 can be provided to the inner surface of the hollow, cylindrically-shaped outer body member 91 of treatment vessel 90.

FIG. 15A is a cross sectional view taken through plane A-A of FIG. 15 and shows how the array of needle-like electrodes appear within the interior of the treatment vessel 90. In operation, the treatment vessel 90 will function in substantially the same manner as has been described previously with relation to earlier described embodiments of the invention.

FIG. 16 is a perspective view of still another form of enlarged cross sectional area treatment vessel 100 according to the invention and FIG. 16A is a partial cross sectional view taken through plane 16A--16A of FIG. 16. The treatment vessel 100 comprises a relatively large rectangular-shaped block 101 of electrical insulating material which is biocompatible with blood and/or other human body fluids. The insulating block 101 has a plurality of parallel, longitudinally extending, open-ended, tubular-shaped openings 102 formed therein through the entire length of the block. The tubes 102 are provided with electrically isolated, opposed, parallel extending conductive plate electrodes 109 as best shown in FIG. 16A, which have alternating current electric potentials applied thereacross. One set of these electrodes, formed for example by the lower electrode 109 in each tube, extend out to and engage a conductive surface coating formed on one end of the insulating block, for example 101R, and the remaining upper electrodes 109 form a second set which extend out of the left hand end of the tubes and contact a conductive coating formed on the remaining end 101L of block 101. Alternating current electric potentials are connected across the respective conductive surfaces 101R and 101L so that a potential difference exists between the sets of electrodes 109 within each longitudinally extending tube in block 101. The ends of the tubes 102 open into and are supplied from, or supply, respective header reservoirs 103 and 104 formed on the respective opposite ends of the block of insulating material 101. Each of the reservoirs 103 and 104 has a centrally formed opening for receiving either an inlet tube 105 applied to header 103 or an outlet tube 106 secured to header 104 for supply of blood or other body fluids to be treated to and from the treatment vessel 100. If desired, a blood pump or other fluid pump can be inserted between the supply tube 105 and header 103, or between outlet tube 106 and the or outlet from the header reservoir 104, or both. Alternatively, both inlet and outlet pumps can be used. In operation, the electrified treatment vessel 100 shown in FIG. 16 functions in the same manner as those species of treatment vessels described previously.

For some treatment applications, it may be desirable to provide exhaust vents such as shown at 107 and 108 in FIG. 16 to the inlet reservoir 103 and/or the outlet reservoir 104 with the vents that can be selectively operated by valves that can be automatically or manually controlled for venting off gases that might be trapped in the tops of reservoirs and which

otherwise might interfere with the proper operation of the electrified treatment vessel. In a similar manner, suitable venting apparatus may be provided to other of the large cross sectional area electrified treatment vessels described previously.

FIG. 17 is a perspective view of still another enlarged cross-sectional area treatment vessel 110 which is similar in all respects to the treatment vessel shown in FIG. 16 with the exception that the body or block of insulating material 101 through which the elongate tubular openings are made, is cylindrically shaped as illustrated in FIG. 17. In other respects, the embodiment of the invention shown in FIG. 17 would be identical to FIG. 16 in the fabrication and operation of its component parts including the reservoir headers 103 and 104 and would operate in a similar manner.

FIG. 18 is a diagrammatic, sketch of a human blood or other body fluid treatment system employing one of the larger cross-sectional dimension fluid treatment vessels 60, such as any one of those shown in FIGS. 12-17 of the drawings. The particular fluid treatment system shown in FIG. 18 is for a continuous flow-through recirculating body fluid treatment wherein blood is withdrawn from the arm 13 of a patient and supplied through IV tubing 111 to a commercially available blood pump 28 and thence to an electrified treatment vessel 60. The treatment vessel 60 may be like any of the treatment vessels described with relation to FIGS. 12-17 of the drawings wherein the blood or other body fluid being treated is exposed to a low voltage, low current electric current flow for attenuating to the point of rendering them ineffective, any contaminants entrained in the blood, such as bacteria, virus and fungus. The treated blood appearing at the output of the treatment vessel 60 then is recirculated back through IV tubing 112 to the arm 13 of the patient whose blood or other body fluid is being treated. If desired, IV tubing 111 and 112 could also be treatment tubing such as described in FIGS. 1-7 and 11. This could provide double treatment for the fluid if that were desirable. In the event that the entire treatment does not take place in an air conditioned, temperature controlled room, then it may be desirable to provide a temperature controlled enclosure indicated by dotted lines 78 around at least the pump 28, electrified treatment vessel 60 and the interconnecting IV tubing sections 111 and 112 in order to assure maintaining a substantially constant viscosity of the blood or body fluid being treated.

Normally, the system of FIG. 18 would be used in a continuous flow-through recirculating treatment system wherein blood from the patient's arm 13 is supplied through pump 28 to the treatment vessel 60 where it is treated and then discharged back through tubing section 112 to the arm of the patient. The flow rate of the blood thus processed would be adjusted to correspond substantially to the natural flow rate of blood circulated through the patient's body to the extent possible.

In addition to operation in the above manner, it would also be possible to operate the system of FIG. 18 in a stopped-flow, batch treatment manner wherein the blood pump is intermittently stopped to allow for more extended electrical treatment of the blood or other body fluid contained in the treatment vessel 60 during the period of time (referred to as the dwell time) that the blood pump is stopped thereby assuring fuller electrification treatment and the greater attenuation of the bacteria, virus, parasites and/or fungus entrained in the blood.

FIG. 19 is a diagrammatic sketch of a form of closed loop, flow-through recirculating treatment system according to the invention that is somewhat similar to the system shown in FIG. 18. FIG. 19 differs from FIG. 18 in that an inlet pump 28 and an outlet pump 28' are connected to, respectively, the intake to and outlet from the electrified treatment vessel 60. If

desired, an inlet control valve 113 and an outlet control valve 114 also can be interconnected between the inlet pump 28 and the intake to the treatment vessel 60 and between the output from the treatment vessel 60 and the intake to the outlet blood pump 28'. These inlet and outlet control valves indicated at 113 and 114 preferably are automatically operated in a time sequence which allows the system of FIG. 19 to be operated as a two pump, start-stop flow through system. When operated in this manner, the first pump 28 is allowed to operate and discharge blood from the arm 13 of the patient to be pumped into the treatment vessel 60 and thereafter is closed off with both the inlet and outlet valves 113 and 114 in their closed condition. At this point electrification treatment of the blood or other body fluid takes place for a predetermined, scheduled time period to assure adequate attenuation to the point of rendering ineffective the contaminant bacteria, virus, parasites or fungus. Upon completion of the pre-scheduled treatment period, the outlet valve 114 is opened and outlet pump 28' actuated to return the treated blood to the arm of the patient 13. Operation in this semi-continuous, start-stop, batch fashion will assure that adequate electrified treatment of the blood has been accomplished while achieving this end in a somewhat continuous manner suitable for use in a closed loop, recycling blood treatment process.

PRACTICAL USES OF INVENTION

While the disclosure herein presented has been directed to principally the electrical treatment of blood, it is believed obvious to those skilled in the art that the invention can be applied with corresponding effect to other body fluids which are electrically conductive for the treatment of contaminants such as bacteria, virus, parasites and/or fungus contained therein. Further, while voltages of the order of from about 0.2 volts to 12 volts AC have been indicated as preferable, it is possible that certain virus may be attenuated (or attenuated at a faster rate) if they are subjected to greater electric current magnitudes of the order of 500 microamperes for shorter time periods. Acceptable current magnitudes normally would require an excitation voltage of from 0.2 to 12 volts. However, in certain cases where faster or more complete attenuation of the contaminants in body fluids may be desired under certain circumstances and conditions, the excitation voltage supplied to the conductive tubing may in fact exceed the 0.2 to 12 volt range indicated for most treatments.

Although it is uncertain what is specifically causing the attenuation of the contaminants (virus, bacteria, parasites and/or fungus), some possible explanations have been put forward. One is that the attenuation is caused simply by the direct affect of the electric current and voltage. Another entails the following. When a voltage is applied to the electrodes, a small current will flow through the electrically conductive medium. The applied voltage and ensuing current will induce changes in the complex biologically active fluid. Current can flow through the media if positive and/or negative charges are transported through said media. The transport might induce changes in the charge distribution of the biologically active molecules thus changing their biological activity. Furthermore, the voltage and current can induce the production or elimination of different ions, radicals, gases and/or PH levels which may affect, alone or in combination, the biologically active molecules and/or cells. The above products of the electrical processes may either be very short lived and stay in the close proximity of the electrodes or can diffuse or mix in the bulk of the media and react with the biologically active molecules or cells to result in their attenuation.

Having described several embodiments of new and improved electrically conductive treatment methods and vessels for use in practicing the novel method for the treatment of blood and/or other body fluids with electric field forces and treatment systems employing the same, it is believed obvious that other modifications and variations of the invention will be

suggested to those skilled in the art in the light of the above teachings. It is therefore to be understood that changes may be made in the particular embodiments of the invention described which are within the full intended scope of the invention as defined by the appended claims.

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http://groups.yahoo.com/group/microelectricitygermkiller/ <----how to make devices yourself.

http://www.bolenreport.com/articles/timbolen.html <---background to suppression

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http://www.papimi.gr/safe-hiv/AppendixE.htm

Positive Electricity Experiments on HIV-1 Virus.
Lab Test Results of HIV Inactivation by Electric Current from US Patent 5,139,684
(of
Kaali & Schwolsky 8-18-92)

by

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Running title: Electricity reduces HIV-1 infectivity

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SUMMARY

In this report, we present the results of double-blinded studies on the use of direct electric current to alter the infectivity o£ HIV-1 for susceptible cells in vitro. Two lymphoblastoid cell lines (H9 and CEM-SS) were exposed to aliquots of the RT strain of HIV-1 treated with direct current. Results of these studies show that virus treated with currents from 50 to 100 microamperes (ìA) has a significantly reduced infectivity for susceptible cells.

These experimental currents were equal to 3.85 and 7.7.ìÁ/mm2 current densities respectively. The reduction of infectivity was dependent upon, the total electric charge (ìA x min) passing through the chamber to which the virus was exposed. Viral infectivity was determined by two independent measures: a syncytium-formation assay which can be used to quantify the production of infectious particles; and. a reverse transcriptase assay which is an index of viral protein production. Additional experiments demonstrated that the currents employed were biocompatible. Uninfected H9 cells were exposed to the same conditions

used for the viral aliquots.

There was no significant change in the percentage of viable uninfected cells exposed to any of the currents tested. Therefore, because biocompatible direct electric current attenuates the infectivity of cell-free virus, this treatment may allow development of new strategies to prevent transmission of HIV-1 through either treating the general blood supply or developing alternative barrier contraceptive devices. Additionally, biocompatible electric. current may be applicable for the direct treatment of AIDS patients by utilizing either extracorporeal systems or self contained indwelling electrodes. Lastly, because the virus is being attenuated, electric current may also render treated HIV-1 suitable for vaccine development.

INTRODUCTION

The number of individuals infected by the human immunodeficiency virus type-1 (I-(HIV-1) continues to increase on a world-wide basis (1). A significant percentage, if not all, of these individuals will eventually develop the acquire d immunodeficiency syndrome (AIDS) (2)- While horizontal transmission in the homosexual. population may be contained or decreasing (3), heterosexual transmission and infection through contaminated blood supplies continues to increase (4). Additionally ver tical transmission from infected females to their fetuses is also on the rise with a resultant increase in the number of children with AIDS (5). New strategies, therefore, must be devised in order to limit more effectively the spread of this virus.

In this regard, three principal approaches are currently being investigated. In order to decrease susceptibility to the consequences of infection, vaccines are being sought which will induce the production of protective antibodies (6). As treatment modalities, the use of soluble antagonists to block the receptor for HIV-1 is being studied (7) as are pharmacologic agents such as nucleic acid analogs which can interfere with the transcription of viral genomic sequences (8). Each of these systems has---------- and limitations and to date none has proven completely effective.

Because heat or light in combination with drugs and dyes can inactivate viruses including HIV-2 in vitro (9), others have suggested the use of these forms of energy to treat .. AIDS patients. The results of studies using heat have not been peer- reviewed and are therefore impossible to evaluate. The use of light with drugs ["photopheresis"] (10) appears to be efficacious although this treatment may be limited by drug toxicity and the potential long-term effects of ultraviolet radiation on blood c ell nucleic acids. Also, by its nature, this last system may not be suitable for the treatment of tissue-associated virus.

As result of our interest in the use of electric current to alter biological systems , we focused our investigations on the ability of direct electrical current at biocompatible levels to alter the infectivity of HTV-1 for susceptible CD4 positive cell s in vitro.

MATERIALS AND METHODS

Electrical treatment of HIV 1:

The RF strain of HIV-I (AIDS Reagent Program) was cryopreserved prior to treatment at -70°C. Fur treatment, a sample of virus was thawed and maintained on ice at 4°C . Ten microliters (ìl) of HIV-1 at a concentration of 105 infectious particles per ml were placed into a chamber which included a pair of platinum electrodes 1mm apart permanently mounted into

a well 1.56mm in length an d 8.32mm in depth equal to 12.9 ìl volume capacity. The chamber was connected to a power supply capable of creating constant direct current. The viral aliquots were exposed to direct currents ranging from 0 microamperes (ìA) for up to 12 minutes to 100ìA for up to 6 minutes. Intermediate currents of 25, 50 and 75ìA were used to expose similar viral aliquots. Under these conditions, for example, 0, 50 and 100ìA represent 0, 3.85 and 7 .7ìA/mm2 current densities respectively. The current was monitored throughout the experiment. A matrix of current and time employed is shown in Table 1.

After the exposure of virus to electric current, the contents of the chamber were removed and placed into sterile microtubes. Five ìl of each sample were removed and diluted with 95ìl tissue culture medium supplemented with 10% fetal calf serum (FCS) for subsequent assays.

Syncytium-formation assays:

This assay was performed as previously described by Nara et al (11). Briefly, 105 CEM-SS cells were dispensed into poly-L-lysine coated microliter wells. Thereafter, tenfold dilutions o f H9 cells incubated with the treated HIV-1 samples were co-cultured in triplicate for up to 4 days with the CEM-SS cells. Identical wells were prepared with control uninfected and infected cells. The wells were examined for syncytium formation at 2 and 3 days and quantified using an inverted microscope.

Reverse trascriptase assay:

Uninfected H9 cells, were pelleted at 1,000 rpm for minutes at room temperature, the supernatant was decanted and the cells were resuspended in 100ìl treated viral sample. The cells were incubated for up to 6 hours with the viral samples. At the end of the incubation time, the viral/cell suspensions were centrifuged at 1,000 RPM for 5 minutes and the supernatant decanted. The cell pellet was then resuspended in 5ml of RPMI, 10% FCS and placed into a T25 tissue culture flask and maintained at 370C, 5% CO2 in a humidified chamber. At 2 day intervals (beginning at day 2}, 1ml of the cell suspensions was removed from each sample and centrifuged at 1,000 rpm for 5 minutes in order to pellet the cells. The supernatant was subsequently centrifuged at 14,000 RPM for I5 minutes. The pellet was resuspended in suspension buffer and assayed using standard methodology employing Mg+ + as the divalent cation poly (rA) oligo d(T) 12-18 as template primer, and tritiated thymidine (3H-TdR) which comprise the reaction mixture. Known HIV positive and negative control samples were included in each assay for reference. Thirty ìl of the reacti on mixture were added to each 10 ìl viral sample and incubated at 37 0C for 60 min. Samples were then incubated with 1ml of cold quench solution on ice for 15 minutes and filtered through a Millipore manifold. Chimneys were rinsed first with wash solution and followed by cold 95% ethanol. The filters were dried by vacuum and counted in scintillation fluid. Reverse transcriptase activity is expressed as counts per minute (cpm) and is considered positive only if cpm are at least five times greater than the cpm obtained with HIV negative control samples.

Biocompatibility of electric currents/time:

To determine if the electric currents used were in a biocompatibility range of energy, uninfected H9 cells were exposed to distinct currents for different amounts of time. The H9 cells were washed two times in Hanks Balance Salt Solution (HBSS). Thereafter, the cells were resuspended in RPMI, 10% FCS at a concentration of 106 cells per ml, Ten ìl of the cell samples were placed into the reaction c hamber. The cell samples were then exposed to 0, 50

or 100ìA for 0, 3 or 6 minutes. At the end of each test, the cell sample was removed from the chamber and approximately 10ìl of the sample was mixed with 90ìl of trypan blue. The number of viable cells w as determined by trypan blue exclusion using a hemocytometer and tight microscope. Results are expressed as percentage of viable cells from the total of all cells. At least 200 cells per field were counted.

Statistical analysis:

Results of the syncytium-formation and reverse transcriptase assays were tested for statistical significance by the Student's t test and analyses of variance.

RESULTS

Syncytium-formation assay:

Using this index of HIV-1 infectivity, it was determined that exposing virus to direct electric current suppressed its capacity to induce the formation of syncytia. Figure 1 shows a representative e xperiment and Table 2 shows the Croup data for 3 separate experiments. As can be noted in Figure l, a statistically significant ($p<0.001$) reduction in sycytium number was observed and this reduction was dependent upon the current applied to the viral i solate. At three different viral dilutions, there were analogous results in that a total charge of 200ìA x min (25ìA for 8 minutes) reduced the number of syncytia from 50 to 65% while a charge of 300ìA x min (50ìA for 6 minute s, 75ìA for 4 minutes or 100ìA for 3 minutes) resulted in 90% reduction.

Reverse transcriptase assays:

The direct electric currents to which HIV-1 was exposed also reduced reverse transcriptase activity. Five separate experiments were conducted and a representative experiment is shown in Figure 2 and the ;coup data are included in Table 3. As can be seen in Figure 2, there was a significant decrease in the amount of reverse transcriptase activity after exposure of the virus to either 50ìA for 3 or 6 minutes. An equivalent reduction in reverse transcriptase activity was also noted with exposure to, 100ìA for 3 minutes and almost ablation of reverse transcriptase activity was seen with exposure of the viral isolate to 100ìA for 6 minutes. The group data (Table 3} show that after exposure to 50ìA for 6 minutes, there was a 44% reduction in activity and treatment of virus with 100ìA for 6 minutes resulted in a 94% reduction. An analysis of variance indicates that t he decrease in reverse transcriptase activity was statistically significant ($p <0.0001$).

Biocompatibility of the electric currents/time:

The results of a viability analysis using trypan blue exclusion criteria applied to uninfected cells exposed to the different currents and times used far these studies are shown in Table 4. The viability of H9 cells, after exposure to 100ìA fur either 3 or b minutes, did not show a significant decrease when compared to the 0 Current control. After maximum treatment at 100ìA for 6 minutes, cell viability was 93%. Interestingly, in other preliminary experiments in which HIV-infected H9 cells were used, the results show that at 100 ìA there may have been a significant decrease in the number of viable cells. That is, while an insta ntaneous pulse of 100 ìA did not affect the viability of infected cells, at 3 and 6 minutes of exposure to 100 ìA, a decrease in viability was noted. This decrease was time dependent in that exposure to 100 ìA far 3 min utes resulted in a viability of 83% while 100 ìA for 6 minutes resulted in

a viability of 80%. Although these data are provocative, they only represent a preliminary experiment and require further investigation.

With respect to the possibility that the electric current was transduced into heat, the calculated rise in temperature within the chamber was determined to be less than 1°C. In order to verify this, a temperature microprobe was introduced into the cham ber containing tissue culture medium alone. Results of these studies are shown in Table S. Similar results were obtained when H9 cell-containing medium was placed in the reaction chamber. The data indicate that for the currents and times used for these ex periments, there was no alteration in the temperature of the chamber.

DISCUSSION

The results reported here demonstrate that HIV-1 treated with direct electric currents from 50 to 100ìA has a significantly reduced infectivity for susceptible cells in vitro. This reduction o f infectivity correlates with the total electric change passing through the chamber. Although extrapolation of these data predicts that ablation of HIV infectivity may be possible, and additional preliminary data support this prediction, the expectation t hat some virions may still escape the electrical effect cannot be discounted. Nevertheless, the .therapeutic potential of electric current may reside in its ability to lower the viral titer to subclinical significance or in its incorporation into a strate gy analogous to that of other therapies in which repeated cycles of treatment eventually achieve remission or cure.

The data presented in this report are based on both quantitative and quantal determinations of viral infectivity. Although the syncytium-formation assay can be used to quantify the number of infectious viral particles, this use with respect to HI V-1 may be abridged because of the ability of free fusigenic peptide (gp41) to induce syncytia by itself. Therefore, while syncytia were observed at some dilutions of electrically-treated virus, this may simply represent the presence of soluble gp41 in th e tissue culture medium. We believe that the correlation between total charge and reduction in syncytium number more adequately reflects the ability of direct electric current to reduce HIV-1 infectivity.

This belief is also supported by the results of the reverse transcriptase assays.

Although a decrease in HIV-1 reverse transcriptase does not assure reduced infectiousness of this virus for Susceptible cells; we feel that, taken together with the syncytium-formation data, the results indicate that significant attenua tion of HIV-I infectivity is achieved by treatment with direct electric currents.

With respect to the biocompatibility of the electric currents and total charges reported here, two separate sets of evidence are applicable. The first has to do with the results showing that, by trypan blue exclusion, no significant cyt otoxicity was induced in by any total charge tested. The other evidence is obtained from reports which clearly indicates that the amount of electricity used for these experiments is significantly below presently used therapeutic electric currents which ar e in the milliampere range (12-16).

Rather than negative effects, exposure of cells to electric current may actually have positive consequences for resistance to infection in that important cellular electrochemical changes correlate with enhancement of specific enzymatic activities. In particular, a facilitation of succinate dehydrogenase (SDH) and ATPase activity has been observed (12,15). Both of these enzymes are associated with the oxidative capacity of the cell. Specifically, it has been

suggested that an elec trochemical reaction occurs between mitochondrial membrane-bound H+ ATPase and ADP leading to the formation of ATP. Therefore, exposure of cells to direct electric current may directly or indirectly increase energy resources within a cell and facil itate cell metabolism. This, in turn, may actualIy render a cell less susceptible to the effects of viral infection.

In summary, the data presented here indicate that biocompatible direct electric current significantly reduces the infectivity of HIV-1. Continuing investigations are exploring the mechanisms through which this effect is mediated. The in itial focus of these experiments is centered on the potential role which ionic and molecular species generated by electrolysis may have on the virus. However, the complete mechanism by which direct electric current attenuates HIV-1 infectivity is undoubte dly far re complex than simple electrolysis. Nonetheless. and independent of a complete understanding of all of the mechanisms involved in the attenuation of HIV-1 infectivity, the present observations may serve as an initiaI step for the development of new strategies to treat infection or prevent transmission of HIV-1 through either treat ing the general blood supply or developing alternative barrier contraceptive devices. It may also be feasible to treat AIDS patients with direct electric current using either extracorporeal systems or self contained indwelling electrodes. Lastly, because viral infectivity is being attenuated, electric current may render treated HIV-1 suitable for vaccine development.

Figure 1. Results of a representative syncytium-formation assay. Five aliquots of the RF strain of HIV -1 were exposed to direct electric current for up to 8 minutes. Three of the samples were exposed to a total electric charge of 300.ìA x min (50/6, 75/4 and 100/3). At all the dilutions tested (shown here), electrical treatment of the virus aliquots resulted in a significant decrease in syncytium formation.

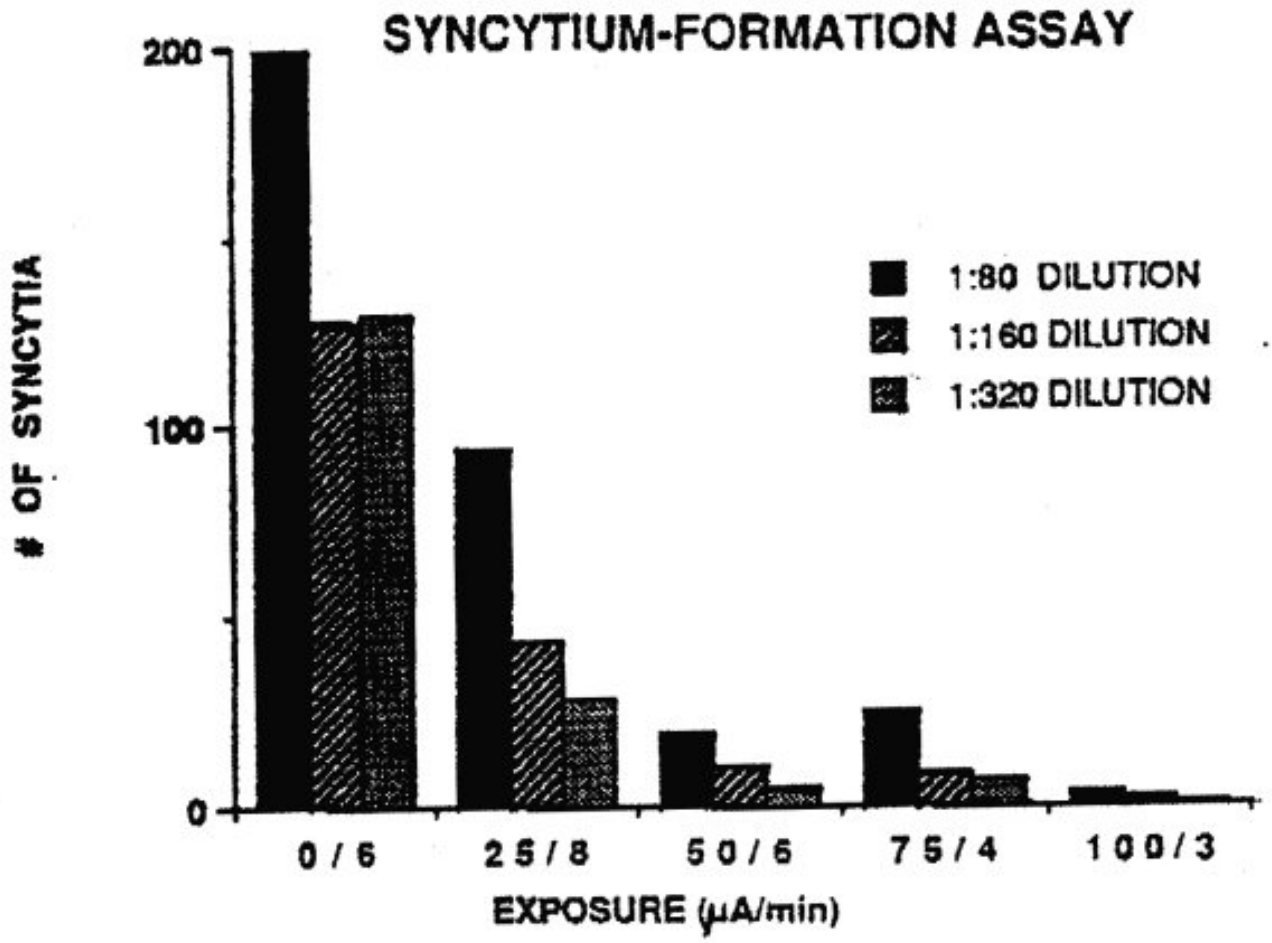

Figure 2. Results of a representative reverse transcriptase assay. Six aliquots o£ the RF strain of HIIV-1 were exposed to different amounts .of current for 3 or 6 minutes. A. significant decrease ($p < 0.005$)from 0 current levels (0/3 and 0/6) in reverse transcriptase activity is noted. However, the decrease is more significant ($p<0.0001$) when virus is exposed to 100iA for 6 minutes.

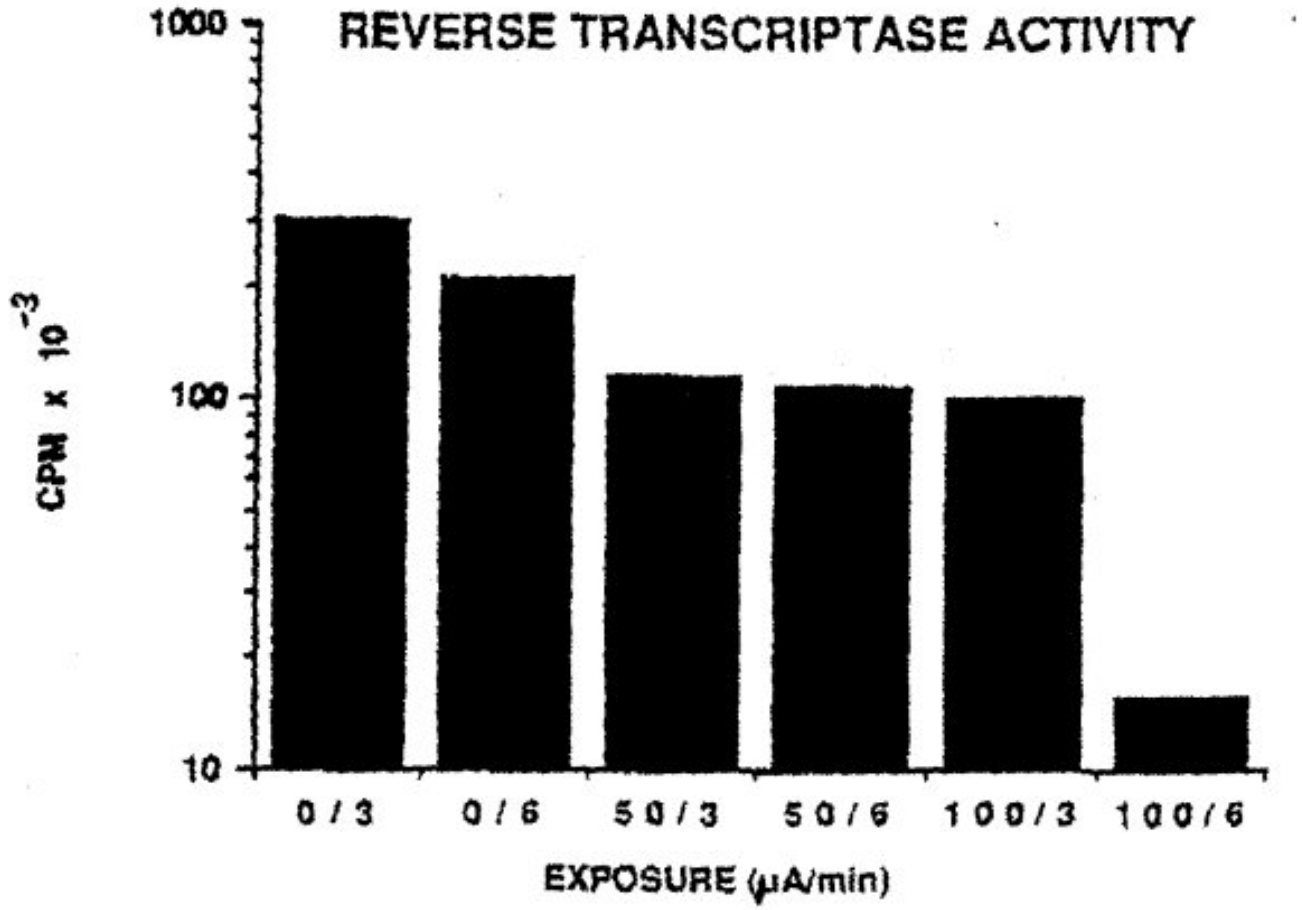

Table 1
Experimental Paradigm
Current (ì.A). Time (Minutes)
0 1 4 8 12
25 2 4 8 12
50 3 4 6 12
75 2 4 8 12
100 1 3 4 12

Table 2
Effect of ELECTRIC Current on Syncytium Formation
% of O Current Control (Ä%)b
Current (ìA) Six Minute Exposure
0 100 (0)
50 50 (-50)
100 35 (-65)

a = Value at I:160 dilution of virus.
b = Value equals the mean of 3 experiments.

Table 3
Effect of Electric Current on Reverse Transcriptase Activity
% of O Current Control (Ä%)
Current (ìa) Six Minute Exposure
0 100 (0)
50 56 (-44)
100 6 (-94)

a = Value equals the mean of 5 experiments.
The standard error of the mean in each case was less than10% of the mean value.

Table 4
Effect of Eclectic Current onViability of Uninfected H9 Cells
(% Viable CeIIsa)
Length of exposure (Minutes), Current (ìA) 0 3 6
0 96 94 6
50 98 95 98
100 96 97 93

a = At feast 200 cells counted in hemocytometer field

Table 5
Effect of Electric Current on Temperature of Tissue Culture Medium a (°C) Length of Exposure (Minutes)
Current (ìA) 0 3 6
0 19 19 19
50 19 19 19
100 19 19 19

a = The temperature was monitored before, during and after exposure.
Results shown are end-point determinations.

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ACKNOWLEDGMENTS

Thanks go to Mrs. Agnes Geoghan for her excellent secretarial assistance and to Dr.Gabor, Kemeny for important technical help. Additional thanks go to Drs. Frank Lilly and Philip Aisen for their constructive criticism of this manuscript.

EXPERIMENTAL RESULTS

Overview: A non-flow vessel or cell included a pair of platinum electrodes 1 mm apart

inserted into a well 1.56 mm in length and 8.32 mm in depth. The non-flow vessel was connected to a direct current source capable of creating an electric field at a constant voltage and constant amperage. Into this well was laced a suspension of the human immunodeficiency virus type 1 (HIV-1) at a concentration of 1,000,000 infectious particles per ml. An aliquot of approximately 10 ul of the virus suspension was placed into the well. Thereafter, the viral suspension was exposed to direct currents ranging from 0 microamps (uA) for up to 12 minutes, to 100 microamps for up to 6 minutes. Intermediate currents of 25, 50 and 75 microamps were used to expose similar viral aliquots. After exposure of the viral suspension to electric currents, the contents of the non-flow vessel were removed and placed into sterile microtubes. 5 ul of each sample were removed and diluted with 95 ul tissue culture medium supplemented with 10% fetal calf serum (FCS. unborn calf blood) In Experiment 1, the resuspended and treated viral stocks were incubated with a human T lymphoblastoid cell line named CEM-SS. This cell line, upon exposure to HIV-1, forms syncytia (giant cells). It is well documented that the viral titer (amount) used is directly correlated with the number of syncytia formed. Therefore, evaluation of infectivity of HIV-1 can be used with this assay. In contrast, Experiment No. 2 used a differnet human T lymphoblastoid cell line named H9. This cell line, in contrast to CEM-SS cells, produces, upon exposure to HIV-1, many viral particles. The amount of virus produced is proportional to the amount of virus to which the
cells are exposed. Therefore, quantitation of viral particles, or more commonly associated viral protein (in this case reverse transcriptase), can be used as an index of viral infection. In both assays, the CEM syncytia forming assay and the H9 viral protein assay, similar type results were obtained. That is, with the CEM cells, although syncytium formation and quantitation is preferrable, one can quantitate the HIV-1 associated protein (reverse transcriptase) activity and conversely with the H9 cells, although reverse transcriptase quantitation is preferred, one can quantitate giant cell (syncytia) formation. Both of these assays are widely used as reproducible measures of viral infection and can be used to determine if alterations in viral infectivity as a product of this electrical treatment can be detected.

Experiment #1

Approximately 100,000 CEM-SS cells per sample were incubated with a treated or untreated (control) viral aliquot for up to 4 days. The cells were placed into microtiter plate wells and monitored for formation of syncytia every 24 hours by microscopic observation. In a standardized fashion, as it has been reported in the literature and is currently being conducted in many laboratories, the number of syncytia at 3 and 4 days was determined. Table 2 summarizes the results from a representative experiment using this assay. As can be noted, the number of syncytia formed was inversely proportional to the amount of electric current. That is, additionally, with increased current (100 vs 50 uA) there was a reduction in the number of syncytia formed. These results and those of additional experiments using the CEM-SS cell line indicate a consistent finding that electrical treatment of the RF strain of HIV-1 attentuates the virus potential for inducing syncytium formation in this cell line.

Experiment #2

A separate and independent assay to determine the ability of electric current to alter HIV-1 infectivity using H9 cells was employed. The basic strategy was similar to that used for the CEM cells with the exception that the initial suspension of treated and controlled (non-treated) viral stock was incubated with 100,000 H9 cells for 2 hours at 37 degees Celsius. Thereafter, the cell virus suspensions were further diluted to 5 ml in standard tissue culture

medium. The cell-viral suspensions were then incubated for up to 14 days at 37 degrees Celsius with 5% carbon dioxide. At 3 day intervals (beginning at day 2), aliquots of cell suspension were removed from each sample. The aliquots were centrifuged at 1,000 rpm for 5 minutes in order to pellet the cells. After centrifugation, the supernatant and cell pellets were seperated. The supernatant was cyropreserved for subsequent reverse transcriptase assay and the cell pellets were resuspended in fixatives and maintained in a tissue bank for additional studies employing in situ hybridization and immunocytochemistry to detect qualitatively and semi-qualitatively viral infection by HIV-1. At the end of each experiment, the supernatant samples from each of the tests and time points were examined using standard reverse transcriptase assay. The results of the representative experiment are shown in Table 3. The results of this experiment indicate the ability of HIV-1 to infect H9 cells is attenuated by the magnitude of the electrical currents to which the virus is exposed. Additionally, at lower current magnitude, but with prolonged exposure time, attenuation of viral infectivity is achieved. That is, analogous to the results observed using syncytium formation and the CEM-SS cell line, either increased current or increased duration of exposure time was inversely proportional to the amount of reverse transcriptase produced by the cell line.

In conclusion, these experiments which have been repeated several times, and those using the CEM-SS cell line, indicate at a statistically significant level that direct electrical current at biocompatible amperages for discrete exposure time intervals can attenuate the ability of HIV-1 to infect normally healthy cells which are susceptible to the HIV-1 AIDS virus.

Electrified Intrauterine Device
GB 2,238,725

6-12-1991

EC: A61F6/14B2; A61N1/05V IPC: A61F6/14; A61N1/05; A61B17/42 (+4)

Electrical Generally Rounded Canopy-Like Contraceptiv e Devices
IN 171,695

1992-12-12-1992

EC: IPC: (IPC1-7): A61F5/46

Contraceptive Device Comprising Electrified Vaginal Ring
GB 2,213,385

8-16-1989

EC: A61F6/08 IPC: A61F6/08; A61F6/00; (IPC1-7): A61F5/46

Contraceptive Devices
GB 2,206,799

1-18-1989

EC: A61F6/08 IPC: A61F6/08; A61F6/00; (IPC1-7): A61F5/46 (+1)

Electrical, Generally Rounded Resilient, Canopy-like Contraceptive Devices
USP # 4,770,167

9-13-1988

EC: A61F6/08 IPC: A61F6/08; A61F6/00; (IPC1-7): A61F5/46

Contraceptive Method & Device Employing Electric Forces
IN 164,985

7-22-1989

EC: IPC: A61F5/00; A61F5/00; (IPC1-7): A61F5/00

Contraceptive Device
GB 2,195,253

4-07-1988

PORTER, Joseph; KAALI, Steven
EC: A61F6/14C; H01M2/10C2 IPC: A61F6/14; H01M2/10; H01M2/34 (+4)
