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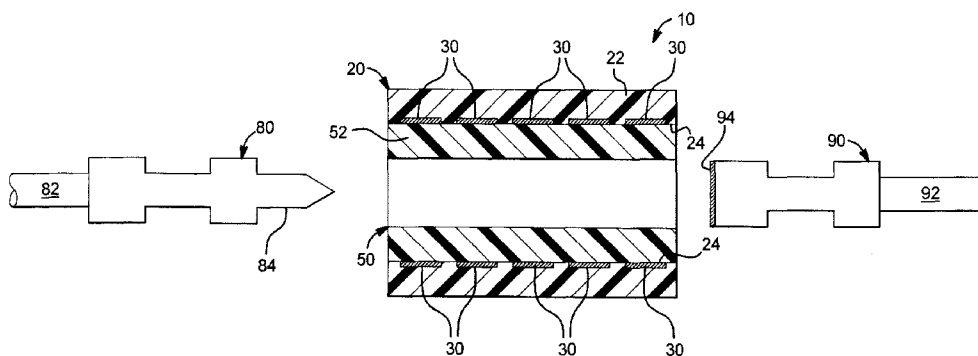
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(54) Title: PERITONEAL DIALYSIS PATIENT CONNECTION SYSTEMS USING ULTRAVIOLET LIGHT EMITTING DIODES FOR STERILISATION

FIG. 1



(57) Abstract: A light applicator (20) for a peritoneal dialysis conduit connection (80, 90) includes a housing having an inner surface; a plurality of ultraviolet ("UV") light-emitting diodes (30) ("LED's") positioned on the inner surface of the housing; and circuitry connected to the UV-LED's such that power can be supplied to energize the UV-LED's simultaneously.

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PERITONEAL DIALYSIS PATIENT CONNECTION SYSTEMS USING ULTRAVIOLET LIGHT
EMITTING DIODES FOR STERILISATION

BACKGROUND

[0001] The present disclosure relates generally to medical device connectors and more specifically to sterilized patient connection systems for peritoneal dialysis.

[0002] Due to various causes, a person's renal system can fail. Renal failure produces several physiological derangements. The balance of water, minerals and the excretion of daily metabolic load is no longer possible and toxic end products of nitrogen metabolism (urea, creatinine, uric acid, and others) can accumulate in blood and tissue.

[0003] Kidney failure and reduced kidney function have been treated with dialysis. Dialysis removes waste, toxins and excess water from the body that would otherwise have been removed by normal functioning kidneys. Dialysis treatment for replacement of kidney functions is critical to many people because the treatment is life saving.

[0004] One type of kidney failure therapy is peritoneal dialysis, which uses a dialysis solution, also called dialysate, which is infused into a patient's peritoneal cavity via a catheter. The dialysate contacts the peritoneal membrane of the peritoneal cavity. Waste, toxins and excess water pass from the patient's bloodstream, through the peritoneal membrane and into the dialysate due to diffusion and osmosis, i.e., an osmotic gradient occurs across the membrane. The spent dialysate is drained from the patient, removing waste, toxins and excess water from the patient. This cycle is repeated.

[0005] There are various types of peritoneal dialysis therapies, including continuous ambulatory peritoneal dialysis ("CAPD"), automated peritoneal dialysis ("APD"), tidal flow dialysate and continuous flow peritoneal dialysis ("CFPD").

[0006] The technique of CAPD to remove impurities from the blood of a patient whose kidneys have failed permits the patient being dialyzed to carry a surgically implanted catheter, which is generally connected (intermittently) to a peritoneal dialysis transfer set. For CAPD treatment, the transfer set, in turn, is connected to a bag of peritoneal dialysis solution, which is emptied through the

transfer set into the peritoneal cavity (CAPD infusion phase). For CAPD, the patient is not “tied” to a machine and can be ambulatory while the dialysis across the peritoneal membrane (CAPD dwell phase) occurs. After the dwell phase, the peritoneal dialysis solution is drained (CAPD drain phase) from the peritoneal cavity. This can be done by allowing the solution to flow back into the supply bag; there is preferably no disconnection of the bag during the dwell phase. After the drain phase, the bag with spent peritoneal dialysis solution may be disconnected from the transfer set and discarded.

[0007] Automated peritoneal dialysis (“APD”) is similar to CAPD in that the dialysis treatment includes drain, fill, and dwell cycles. APD machines or “cyclers”, however, perform the cycles automatically, typically while the patient sleeps. APD machines free patients from having to manually perform the treatment cycles and from having to transport supplies during the day. APD machines connect fluidly to an implanted catheter, to a source or bag of fresh dialysate and to a fluid drain. APD machines pump fresh dialysate from a dialysate source, through the catheter, into the patient’s peritoneal cavity, and allow the dialysate to dwell within the cavity, and allow the transfer of waste, toxins and excess water to take place. The source can be multiple sterile dialysate solution bags.

[0008] APD machines pump spent dialysate from the peritoneal cavity, through the catheter, to the drain. As with the manual process, several drain, fill and dwell cycles occur during dialysate. A “last fill” occurs at the end of CAPD and APD, which remains in the peritoneal cavity of the patient until the next treatment.

[0009] Both CAPD and APD are batch type systems that send spent dialysis fluid to a drain. Tidal flow systems are modified batch systems. With tidal flow, instead of removing all of the fluid from the patient over a longer period of time, a portion of the fluid is removed and replaced after smaller increments of time.

[0010] Continuous flow, or CFPD, systems clean or regenerate spent dialysate instead of discarding it. The systems pump fluid into and out of the patient, through a loop. Dialysate flows into the peritoneal cavity through one catheter lumen and out another catheter lumen. The fluid exiting the patient passes through a reconstitution device that removes waste from the dialysate, e.g., via a urea removal column that employs urease to enzymatically convert urea into ammonia. The ammonia is then

removed from the dialysate by adsorption prior to reintroduction of the dialysate into the peritoneal cavity. Additional sensors are employed to monitor the removal of ammonia. CFPD systems are typically more complicated than batch systems.

[0011] All of the above systems require the patient to connect the patient's indwelling catheter to a PD supply apparatus via a transfer set. The patient connection must be kept sterile or the patient can suffer from a condition called peritonitis. The patient connection should also be easy for the patient to make and unmake because the patient is usually performing these tasks at home and/or alone. Accordingly, a need exists for improved peritoneal dialysis patient connection systems.

SUMMARY

[0012] The present disclosure includes a system and method for connecting supply connectors to a patient for medical systems making such connections. Such connections need to be made in a sterilized environment in many cases so that contaminants from the supply connectors or from the connection process do not reach the patient. In peritoneal dialysis for example, a catheter is implanted into the patient's peritoneal cavity. The catheter terminates outside the body with a port. The port is connected to what is termed a patient transfer set. The patient transfer set, in turn, is connected to a supply line, extending for example from a supply bag (typical with manual peritoneal dialysis ("CAPD")) or from a disposable cassette.

[0013] The present disclosure provides a light-emitting applicator that surrounds the above-described connection, so that it can be made in a sterilizing environment. The applicator includes a housing, which is hinged to permit placement of a connection mechanism holding the connectors within the light applicator. The inner surface of the housing can have an ultraviolet ("UV") light-reflecting material, for example, an etched aluminum coating, to maximize the exposure of ultraviolet light applied to the contents of within the applicator. The connection mechanism is light-transmissive to allow light from the applicator to reach the connectors held by the connection mechanism.

[0014] Traditional UV light elements have used Xenon lamps. The Xenon lamps however require a relatively high operating voltage, e.g., on the order of hundreds of volts, to generate enough light energy. In the present disclosure, the light applicator includes a series of ultraviolet light emitting diodes ("LED's") that replace

the Xenon lamp. The UV-LED's do not require the same high voltage, allowing the light applicator to be made lighter and smaller.

[0015] The UV-LED's are spaced in an array about an inner surface of the light applicator, which can be at least substantially cylindrical. As mentioned, the cylindrical housing of the light applicator is hinged in one embodiment to allow a patient assist connection device to be loaded into the applicator. The light applicator also includes circuitry that connects to a power source, the circuitry operable to apply power to each of the UV-LED's simultaneously, so that the UV-LED's collectively supply a proper amount of power over a period of time to effectively disinfect the connectors of the patient set being connected or disconnected. The power source can be a battery source allowing for cordless operation, or an AC source, such as from a wall unit or from the PD cycler.

[0016] In an alternative embodiment, the power source is shifted to power the UV-LED's sequentially, e.g., full power to half of the UV-LED's for a period of time, then full power to the other half of the UV-LED's for the time period, and so on over the full period of irradiation. Power can be divided into sequential thirds or quarters and is not limited to being divided into halves. Further alternatively, the power source is manipulated to switch back and forth between simultaneous and sequential powering over the total time as many times as desired.

[0017] In one implementation each UV-LED radiates one milli-Watt of UV energy at a peak wavelength of 280 nanometers. If 0.2 Joules/cm^2 of total energy is needed, fifty UV-LED's can be placed in an array on the inner surface of the housing of the light applicator to provide the needed total energy over a workable time as described in more detail below. The UV-LED's are capable of irradiating the transversely disposed interior surfaces of the system, for example, the outer surface of a diaphragm initially covering a female (e.g., supply) connector, prior to its rupturing. The UV-LED's also irradiate the complex surfaces of the spike of the spike connector.

[0018] The light applicator in one embodiment includes a photocell that measures the total energy of ultraviolet light applied in each sterilization procedure. When the total energy reaches a predetermined overall desired exposure level, for example, about two-hundred millijoules (mJ)/ cm^2 , the photocell activates a transducer connected to the photocell to shut off the ultraviolet light element. The

overall exposure time depends on the microbiological load to be disinfected. Alternatively, the amount of energy required to produce an appropriate germicidal level is determined by microbiological evaluation before connection, yielding a total time of exposure needed. The light applicator is then energized for the predetermined time of exposure. Either way, the energy exposure level assures maximum antimicrobial effect on the spike and female connector.

BRIEF DESCRIPTION OF THE FIGURES

[0019] Fig. 1 illustrates an embodiment of a patient assist system of the present disclosure.

[0020] Fig. 2 is an end view of the ultraviolet (“UV”) light-emitting diode (“LED”) applicator of the system of Fig. 1, showing the connectors for reference, and illustrating that the applicator in one embodiment is hinged.

[0021] Fig. 3 is the end view of Fig. 2 showing the applicator closed about the connectors, such that the UV-LED’s of the applicator are positioned to emit light onto the connectors from many different angles.

[0022] Fig. 4 is a side elevation view of a section taken along line IV-IV of Fig. 3.

DETAILED DESCRIPTION

[0023] The apparatus and method discussed herein are illustrated in use with a peritoneal dialysis system, such as continuous ambulatory peritoneal dialysis (“CAPD”) or an automated peritoneal dialysis (“APD”). It should be appreciated however that the teachings associated with the appended drawings are applicable to many types of medical fluid systems. In CAPD and APD, the patient connects a supply line running to either a supply bag directly (CAPD) or to a disposable cassette (APD) operable with a pumping cyclor. It is important that such connection be made in a sterile manner. It is also desirable to have a convenient system for the patient, who may be ill or elderly, to operate.

[0024] The patient connects the supply line to a patient line, which can be part of a PD transfer set, which is in turn connected to a catheter dwelling within the patient’s peritoneum. The patient then has to connect the patient line to a drain bag to enable spent dialysate to be removed from the patient’s peritoneum. The patient may have to connect multiple supply lines, each running from a separate supply bag, to the

patient line. Between each supply bag, the patient has to connect to a drain bag. Here, it is important that the patient be able to disconnect an old supply line, correct a drain line and then connect a new supply line readily and in a sterilizing environment.

[0025] Referring now to the drawings and in particular to Fig. 1, system 10 illustrates one embodiment of a patient assist system of the present disclosure. Fig. 1 shows system 10 schematically and generally, highlighting the general physical and operable relationship between the components. System 10 includes an ultraviolet (“UV”) light applicator 20. Light applicator 20 includes a housing 22, which can be formed of a plastic or other suitable medical grade material. As shown in more detail below, housing 22 in one embodiment is hinged so that it can fit around a connection/disconnection device 50. A plurality of ultraviolet (“UV”) light emitting-diodes (“LED’s”) 30 are placed on an inner surface 24 of housing 22 of light applicator 20. UV-LED’s 30 are positioned to direct energy inwardly through a body 52 of connection/disconnection device 50 so as to direct disinfecting light onto a connection and disconnection of a patient connector 80 to and from, respectively, a supply or port connector 90. Body 52 of connection/disconnection device 50 is accordingly made of a UV transmissive material.

[0026] Disconnection/reconnection device 50 can have different configurations and still operate within system 10 with UV-LED applicator 20. One suitable disconnection/reconnection device however is disclosed in copending U.S. Patent Application Serial Number 11/773,623 (“The ’623 application”), filed July 5, 2007, entitled “Peritoneal Dialysis Patient Connection System”, assigned to the eventual assignee of the present application, the entire contents of which are incorporated herein by reference.

[0027] Patient connector 80 is connected sealingly to a patient tube 82, which can be part of the patient’s transfer set and connect fluidly to the patient’s indwelling catheter. Supply or port connector 90 in turn is connected to a supply line 92, which can run to either a supply bag directly or to a disposable cassette as described above. Port connector 90 includes a pierceable diaphragm 94. Patient or spike connector 80 includes or defines a spike 84, which pierces or ruptures diaphragm 94 of port connector 90 when the connectors are mated. While patient connector 80 is shown being male in nature and port connector 90 is shown being female in nature, the

reverse can alternatively be true. Connectors 80 and 90 are at least partially opaque to UV light in one embodiment.

[0028] Connection/disconnection device 50 enables connectors 80 and 90 to be connected and disconnected without physically touching such connectors and potentially contaminating same. Disinfecting light from UV LED's 30 is radiated onto connectors 80 and 90 generally just before the connectors are mated and just after the connectors are disconnected as shown and described in detail in the application.

[0029] Referring now to Figs. 2 to 4, UV applicator 20 is illustrated in more detail. Fig. 2 shows that housing 22 of UV applicator 20 is at least substantially cylindrical in shape in one embodiment and includes halves 26 and 28, separated by a hinge 32. Hinge 32 allows halves 26 and 28 to be fitted about connection/disconnect device 50, which holds connectors 80 and 90 shown for reference in Figs. 2 and 3.

[0030] Fig. 3 shows halves 26 and 28 closed about connectors 80 and 90. UV-LED's 30 are positioned to radiate energy onto the connection or disconnection of connectors 80 and 90. The at least substantially cylindrical shape of housing 22 focuses the light from each of UV-LED's 30 towards a centerline running through applicator 20, and thus towards the connectors. Fig. 4 is a view of the inner surface 24 of half 28 of housing 22 of light applicator 20, taken along line IV-IV shown in Fig. 3

[0031] Fig. 4 shows that each half 26 and 28 includes a five-by-five array of UV-LED's 30. Trace wires 34 are formed on inner surface 24 of halves 26 and 28 in one embodiment to power each UV-LED 30 simultaneously, so that the UV-LED's 30 supply a collective amount of energy to disinfect the connection and disconnection of connectors 80 and 90. As seen in Fig. 4, trace wires 34 terminate at power supply terminals V+ and V-. In an embodiment, a single pair of power supply terminals V+ and V- is provided for the UV-LED's 30 of both halves 26 and 28. UV-LED's 30 can be powered from a direct current ("DC") source, such as a onboard replaceable or rechargeable battery, or by a alternating current source, for example, via a wall outlet or from a cyclor or base instrument.

[0032] In an alternative embodiment, software and circuitry are configured to shift the power source to power the UV-LED's 30 sequentially, e.g., full power to half 26 of the UV-LED's 30 for a period of time, then full power to the other half 28 of the UV-LED's 30 for the time period, and so on over the full period of irradiation. Full

power can alternatively be shifted sequentially between halves, thirds, quarters or otherwise as desired. Further alternatively, the software and circuitry is configured to manipulate the power source to switch back and forth between simultaneous and sequential powering of UV-LED's 30 over the total time as many times as desired.

[0033] In an embodiment, each LED 30 operates on 0.6 Volts at 20mA, leading to a power requirement of 120 milliWatt/per LED 30. Fifty total LED's 30 would then require an overall power requirement of six Watts. This is significantly less than the approximately forty-three Watts required by the Xenon lamp applicator.

[0034] Inner surfaces 24 of halves 26 and 28 in one embodiment include a UV light reflective material, for example, an etched aluminum coating, which maximizes the exposure of UV light that UV-LED's 30 impart onto connectors 80 and 90. The material of housing 22 is otherwise made of a suitable medical grade material, which is relatively inexpensive, such as plastic, e.g., methacrylic resin yellow.

[0035] One suitable UV-LED 30 is provided from Seoul Semiconductor Co., Ltd, 148-29 Gasan-dong Geumcheon-gu Seoul, Korea, model number S8D28D. In one embodiment, each UV-LED 30 has a peak wavelength of about 280 nanometers. Each UV-LED 30 has a power output of about one milliWatt. If a predetermined proper disinfection of connectors 80 and 90 requires about .2 Joules in total energy, for example, fifty UV-LED's 30 are sufficient at the above rating to supply the needed energy over a suitable time period.

[0036] The five-by-five array of UV-LED's 30 in Fig. 4 is repeated on hinged half 26 to provide the fifty total UV-LED's 30. In one embodiment, the fifty UV-LED's 30 are spread out evenly over halves 26 and 28 of housing 22, which in one implementation has a ten mm inner diameter and forty mm length, e.g., roughly the size of the spike 84 of connector 80. Housing 22 can alternatively be larger, e.g., be large enough to encompass the connection/disconnection device of the '623 application. The '623 application discloses a hinged system in which half of the connection/disconnection device is connected to a lid, which is hinged to a housing holding motors and other apparatuses for automatic connection and disconnection of the connectors. In use with the connection/disconnection device of the '623 application, halves 26 and 28 would likely not be hinged to each other but instead place in the above-mentioned lid and housing, which are in turn hinged to each other.

Applicator 20 accordingly does not have to be hinged to itself. Each separate half could have its own power supply V+ and V-, which could be powered simultaneously to provide the needed total power. It should also be appreciated that in any configuration (hinged or separate), inner surfaces 24 of halves 26 and 28 can be removed for cleaning.

[0037] The combined radiation from fifty UV-LED's 30 provides a light intensity or luminance (L^{ux}) equal to $(1 \text{ milliWatt} \times 50 \text{ UV-LED's}) / (10 \text{ mm} \times \pi \times 40 \text{ mm}) = 4 \text{ milliWatts/cm}^2$.

[0038] The UV effectiveness energy $L^{ux\text{eff}}$, knowing that the Xenon wavelength is 254 nanometers ("nm") and that a 280 nm LED has a 90% sterilization efficiency to 254 nm light (Xeron or LED), then $L^{ux\text{eff}} = 4 \text{ milliWatts/cm}^2 \times 0.9 = 3.6 \text{ milliWatts/cm}^2$. Given a UV effectiveness for the fifty UV-LEDs of 3.6 milliJoules, the time required for a total energy output of .2 Joules/cm² is as follows: time of radiation = $200 \text{ milliJoules/cm}^2 / 3.6 \text{ milliWatts/cm}^2 = 56 \text{ seconds}$.

[0039] Another way of evaluating time of exposure, Xenon wavelength of 254 nm is used as a benchmark. That is, 200 mJ/cm² of Xenon light is sufficient for proper disinfection. It is therefore taken that 200 mJ/cm² of 254 nm UV-LED light is also sufficient sterilization. Sterilization efficiency of 280 nm UV-LED is $0.9 \times 254 \text{ nm}$, whether UV-LED or Xenon light is used. So if 280 nm UV-LED light is used, $200 \text{ mJ/cm}^2 / 0.9 = 222 \text{ mJ/cm}^2$ needs to be applied to the connector, e.g., spike connector 80. The spike 84 of connector 80 as discussed can be ten mm x four mm, yielding surface area $S = 10 \text{ mm} \times \pi \times 40 \text{ mm} = (4 \times \pi) \text{ cm}^2$. Fifty 280 nm LED's yield an output of $50 \text{ mW} = 50 \text{ mJ/second}$. Applicator 20 can accordingly deliver $50 \text{ mW} / S = 50 / (4 \times \pi) \text{ mJ} / \text{cm}^2 / \text{second}$. Knowing that 222 mJ is needed, fifty 280 UV-LED's will illuminate $222 \times (4 \times \pi) / 50$ in 55.8 seconds.

[0040] Fifty-six seconds of irradiation is an acceptable amount of time for the patient when connecting or disconnecting connectors 80 and 90. The relatively small size of UV-LED's 30 and their associated relatively small power requirement enables applicator 20 to be made in a small, lightweight package. Further, time for irradiation should decrease as LED power output increases. For example LED output has increased five to ten times over the last five years.

[0041] It should be understood that various changes and modifications to the presently preferred embodiments described herein will be apparent to those skilled in the art. Such changes and modifications can be made without departing from the spirit and scope of the present subject matter and without diminishing its intended advantages. It is therefore intended that such changes and modifications be covered by the appended claims.

CLAIMS

The invention is claimed as follows:

1. A light applicator for a peritoneal dialysis conduit connection comprising:
 - a housing having a inner surface;
 - a plurality of ultraviolet ("UV") light-emitting diodes ("LED's") positioned on the inner surface of the housing; and
 - circuitry connected to the UV-LED's such that power can be supplied to energize the UV-LED's simultaneously.
2. The light applicator of Claim 1, wherein the inner surface of the housing includes a UV reflective surface.
3. The light applicator of Claim 1, wherein the housing is operable and closeable to accept a peritoneal dialysis tubing connector.
4. The light applicator of Claim 1, wherein the inner surface of the housing is at least substantially cylindrical, the UV-LED's spaced circumferentially about the inner surface.
5. The light applicator of Claim 1, wherein the UV-LED's are spaced apart in a array about the inner surface of the housing.
6. The light applicator of Claim 1, wherein the UV-LED's in combination provide at least 0.2 Joules/cm^2 of radiant energy in less than one minute.
7. The light applicator of Claim 1, wherein at least one of the UV-LED's has at least one characteristic selected from the group consisting of: (i) having a peak wavelength of about 280 nanometers; and (ii) a power output of about one milliWatt.

8. The light applicator of Claim 1, wherein the housing is at least one of:
(i) less than or equal to 15 mm in inner diameter; and (ii) less than or equal to 50 mm in length.

9. The light applicator of claim 1, wherein the UV-LED's in combination supply enough energy to provide sufficient genocidal effectiveness to a peritoneal dialysis conduit connection in less than one minute.

10. A peritoneal dialysis patient assist device comprising:
a body configured to accept a first connector in fluid communication with a patient's indwelling catheter and a second connector in fluid communication with a supply of dialysate, the body further configured to mate the first and second connectors; and
a plurality of ultraviolet ("UV") light-emitting diode ("LED's") positioned with respect to the body so as to direct radiant energy towards the mating of the first and second connectors.

11. The peritoneal dialysis patient assist device of Claim 10, which includes a housing enclosing the body, the housing having an inner surface, the UV-LED's positioned on the inner surface.

12. The peritoneal dialysis patient assist device of Claim 11, wherein the housing includes at least one of: (i) an apparatus enabling the housing to open and close to receive the body; and (ii) a UV light reflecting inner surface.

13. The peritoneal dialysis patient assist device of Claim 10, which includes circuitry connected to the UV-LED's such that power can be supplied to energize the UV-LED's (i) simultaneously, (ii) sequentially or (iii) simultaneously and sequentially.

14. The peritoneal dialysis patient assist device of Claim 10, wherein the body is made of a UV light-transmissive material.

15. The peritoneal dialysis patient assist device of Claim 10, wherein the body is configured to translate the first and second connectors to mate and disconnecting the connectors.

16. A peritoneal dialysis system comprising:
a cyclor;
a disposable cassette operable with the cyclor;
a supply bag connected to the disposable cassette;
a supply line extending from the disposable cassette, the supply line terminating at a supply connector;
a body configured to connect the supply connector to a patient connector in fluid communication with a patient's indwelling catheter; and
a housing placeable around the body and including a plurality of ultraviolet ("UV") light-emitting diodes ("LED's") positioned to direct energy towards at least one of the supply and patient connectors.

17. The peritoneal dialysis system of claim 16, wherein the supply connector has at least one characteristic selected from the group consisting of: (i) being a female connector; (ii) having a pierceable diaphragm; and (iii) being at least partially opaque to UV light.

18. The peritoneal dialysis system of Claim 16, wherein the at least one UV-LED is powered (i) via a battery or (ii) via alternating current power.

19. The peritoneal dialysis system of Claim 16, which includes a transfer set, the transfer set connecting the patient connector to the indwelling catheter.

20. The peritoneal dialysis system of Claim 16, wherein the housing is hinged or halved to fit around the connecting body.

FIG. 1

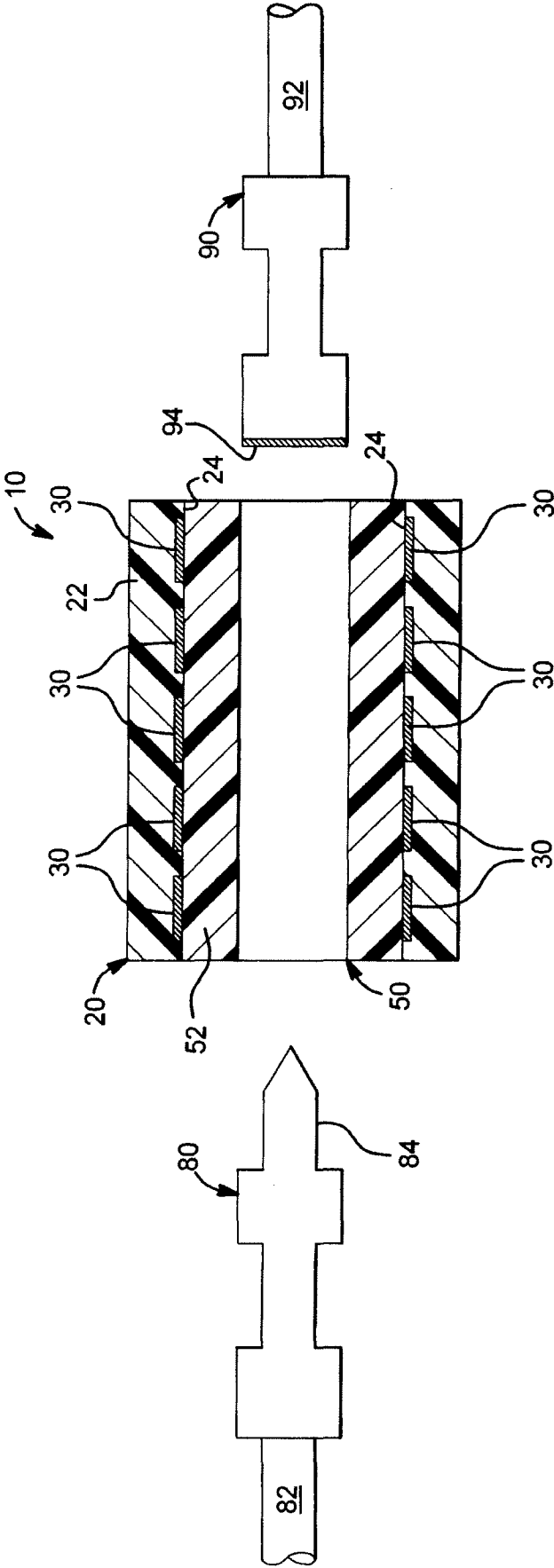


FIG. 2

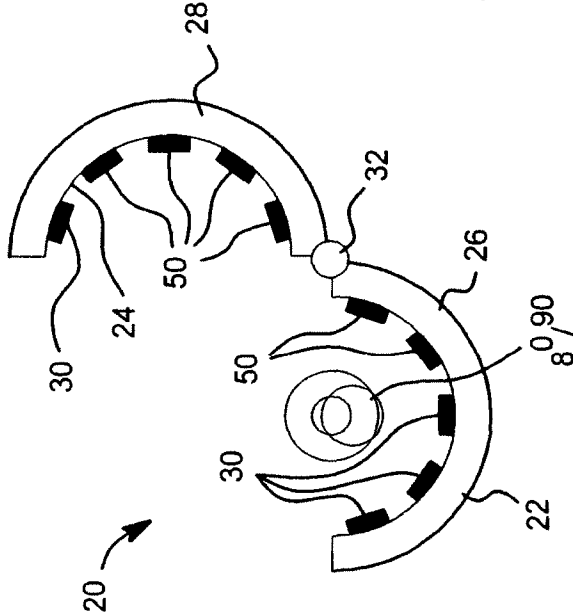


FIG. 3

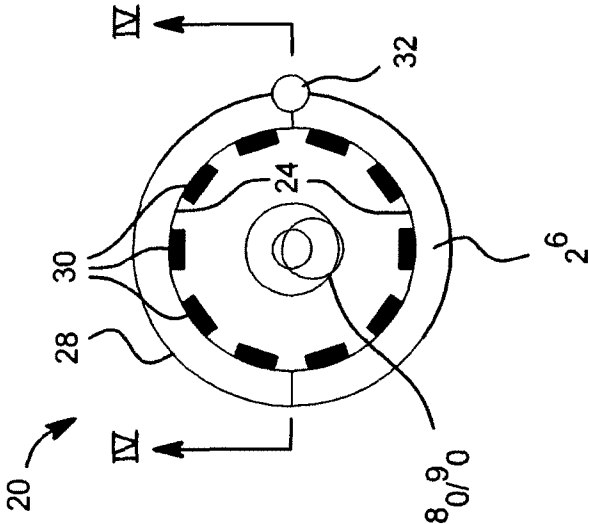
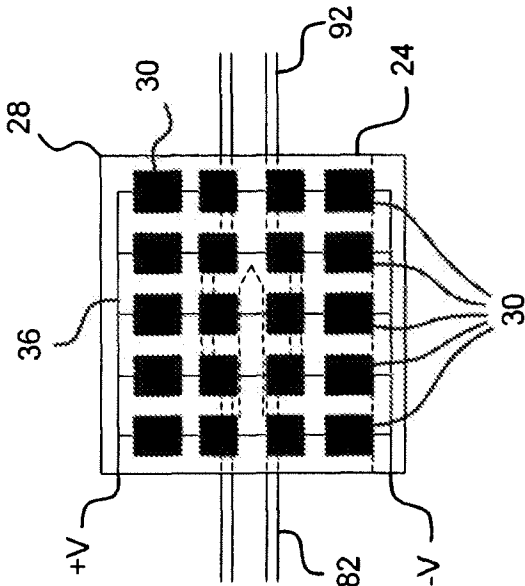


FIG. 4



INTERNATIONAL SEARCH REPORT

International application No
PCT/US2008/068976

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M39/18 A61L2/10
ADD. A61M39/16

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61M A61L

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

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

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2003/017073 A1 (ECKHARDT RICHARD [US] ET AL) 23 January 2003 (2003-01-23) paragraphs [0036] - [0039], [0060] - [0065]; figures 1, 8A-8C -----	1-20
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☐ Further documents are listed in the continuation of Box C.

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