(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
19 June 2014 (19.06.2014)

WIPO | PCT

(10) International Publication Number
WO 2014/092802 A1

(51) International Patent Classification:
A61M 37/00 (2006.01)

(21) International Application Number:
PCT/US2013/048801

(22) International Filing Date:
29 June 2013 (29.06.2013)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
13/709,340 10 December 2012 (10.12.2012) US

(71) Applicant: **CURE CARE, INC.** [US/US]; 1195 Linda Vista Drive, Suite C, San Marcos, CA 92078 (US).

(72) Inventor: **PELKUS, Adrian**; 3011 Highpoint Avenue, Escondido, CA 92027 (US).

(74) Agent: **MILLER, Kimberly, J.**; Knobbe, Martens, Olson & Bear, LLP, 2040 Main Street, Fourteenth Floor, Irvine, CA 92614 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

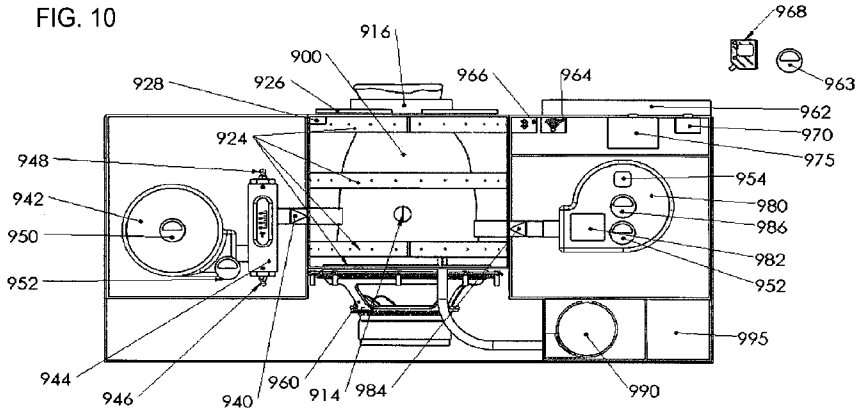
Published:

— *with international search report (Art. 21(3))*

WO 2014/092802 A1

(54) Title: MEDICAL TREATMENT SYSTEM AND METHOD OF USE

FIG. 10



(57) Abstract: A medical treatment system including a treatment chamber, a source of an aqueous mist containing a medication, a source of an oxygen-enriched gas, and a control system adapted to alternately surround a human body part with a mist containing a medication and the oxygen enriched gas, which can be used to treat various skin disorders including infected lesions, bacterial infections such as acne (i.e. *Propionibacterium acnes*), fungal infections such as Athelete's foot (i.e. fungal genus *Trichophyton*), conditions associated with hair loss including alopecia as well as ulcerations and frostbite resulting from poor circulation.. A method of treating skin disorders is also disclosed, that includes providing a mist containing a medication and enriched oxygen gas to the site being treated as well as providing oxygen to the patient during treatment.

MEDICAL TREATMENT SYSTEM AND METHOD OF USE

RELATED APPLICATION

None

TECHNICAL FIELD

The present disclosure relates in general to medical treatment systems. More particularly, the present disclosure relates to a medical treatment apparatus, methods of using the medical treatment apparatus and a system for treatment of medical conditions including bacterial and fungal infections, hair loss and surface wounds.

BACKGROUND

Medical professionals and healthcare providers such as nurses and doctors routinely treat patients having various skin disorders including infected lesions, bacterial infections such as acne (*i.e. Propionibacterium acnes*), fungal infections such as Athelete's foot (*i.e.* fungal genus *Trichophyton*), conditions associated with hair loss including alopecia areata (patch baldness), alopecia totalis (complete baldness of the scalp) and alopecia universalis (body baldness) as well as ulcerations and frostbite resulting from poor circulation. Variations in skin disorders and other patient indications dictate variations in desired medications for treatment, such as antibiotics, growth factors, enzymes, hormones, protocols, such as delivery rates for medication and temperature control.

A vast majority of bacteria are harmless or beneficial. However, there are a few that are pathogenic. One such bacteria, *Propionibacterium acnes* causes acne vulgaris that is painful, causing seborrhea (scaly red skin), comedone (blackheads and whiteheads) and pimples often resulting in scarring and in extreme cases disfigurement. It is estimated that nearly 85% of people between the ages of 12 to 24 develop acne. Young men are more likely to suffer the effects of acne for longer periods of time then Young women because testosterone tends to make acne worse. In 2013, it was estimated that there were over 316 million people in the United States and approximately one third of those individuals were between the ages of 10 and 24. With close to 100 million suffering from acne in the US alone the skin care industry for the past fifty or so years has been developing treatments with limited success. Currently, most medications include one or more of the following chemicals: benzoyl peroxide, salicylic acid, glycolic acid, sulfur and azelaic acid. However, because most individuals skin is unique it is difficult to find the appropriate formulation

that will relieve or eliminate acne. Consequently, many individuals do not obtain proper treatment and are left to suffer with acne and often have scaring as a result. The need for a proper treatment is evidenced by individuals spending over 78 billion dollars on skin care worldwide in 2010 with facial care capturing 64% of this market.

Athelete's foot also known as Tinea pedis is an inflammatory condition and represents the most common of all superficial fungal skin infections. Over 1 million individuals in the United States contract Athlete's foot each year. It is predominantly caused by a group of fungi called dermatophytes which includes *Trichophyton rubrum, Trichophyton mentogrophytes* var. *interdigitale* and *Epidermophyton floccosum*. For most patients, recurrent or chronic foot fungal infections are more of an inconvenience than a problem. Rarely is treatment sought. This may explain the high prevalence of the disease. Cellulitis is a more serious consequence of an untreated fungal foot infection. Although treatable, it can be a limb-threatening disease for patients with comorbidities. Individuals with diabetes have an increased risk of developing this complication. The frequent outcome for this group is hospitalization and an increased length of stay when compared to their non-diabetic counterparts.

There are three main groups of topical agents for treating fungal skin infections, allylamines (i.e. terbinafine), imidazoles (i.e. clotrimazole, ketoconazole, sulconazole and miconazole) and morpholine derivatives (i.e. amorolfine). All have been demonstrated to be more effective than placebo. However, their speed of action varies making compliance difficult and often resulting in ineffective treatment.

Alopecia, or hair loss, effects approximately 35 million men and 21 million women in the United States. Alopecia areata is a disorder that causes sudden hair loss on the scalp and other regions of the body. It affects more than 5 million Americans, 60% of them under the age of 20. It is not a health threat, but can be psychologically damaging, especially for children, to cope with baldness. Of men being treated for Alopecia approximately 85 % are being treated with Minoxidil and approximately 15% are being treated with Finasteride. Minoxidil, more commonly known as Rogaine is a nonprescription medication approved for androgenetic alopecia and alopecia areata. In a liquid or foam, it is rubbed into the scalp twice a day. This is the most effective method to treat male-pattern and female-pattern hair loss. However, only 30–40% of patients experience hair growth and it is not effective for other causes of hair loss. Hair regrowth can take 8 to 12 months and treatment must be continued indefinitely because hair loss resumes if treatment is stopped. Finasteride (Propecia) is used in male-pattern hair loss in a pill form taken on a daily

basis. It is not indicated for women and is not recommended in pregnant women. Treatment is effective within six to eight months of treatment. Side effects include decreased libido, erectile dysfunction, ejaculatory dysfunction, gynecomastia, and myopathy. Treatment should be continued as long as positive results occur. Once treatment is stopped, hair loss resumes again. In 2013, it is anticipated that men will spend over $225 million on medicinal therapies like Rogaine. Unfortunately, the low percentage of success, potential side effects and lifetime treatment regimen make this option difficult for many individuals.

Another particular area of concern involves foot or limb wounds in diabetic patients. It is known that foot wounds in diabetic patients represent a significant public health problem throughout the world. Diabetes is a large and growing problem in the United States and worldwide, costing an estimated $45 billion dollars to the U.S. health care system. Patients afflicted with diabetes often have elevated glucose and lipid levels due to inconsistent use of insulin, which can result in a damaged circulatory system and high cholesterol levels. Often, these conditions are accompanied by deteriorating sensation in the nerves of the foot. As a result, diabetics experience a high number of non-healing foot ulcers.

It is estimated that each year up to three million leg ulcers occur in patients in the U.S., including venous stasis ulcers, diabetic ulcers, ischemic leg ulcers, and pressure ulcers. The national cost of chronic wounds is estimated at $6 billion. Diabetic ulcers often progress to infections, osteomyelitis and gangrene, subsequently resulting in toe amputations, leg amputations, and death. In 1995, approximately 70,000 such amputations were performed at a cost of $23,000 per toe and $40,000 per limb. Many of these patients progress to multiple toe amputations and contralateral limb amputations. In addition, the patients are also at a greatly increased risk of heart disease and kidney failure from arteriosclerosis which attacks the entire circulatory system.

The conventional methods of treatment for non-healing diabetic ulcers include wound dressings of various types, antibiotics, wound healing growth factors, skin grafting including tissue engineered grafts, use of wheelchairs and crutches to remove mechanical pressure, and finally amputation. In the case of ischemic ulcers, surgical revascularization procedures via autografts and allografts and surgical laser revascularization have been applied with short term success, but with disappointing long term success due to reclogging of the grafts. In the treatment of patients with venous stasis ulcers and severe venous disease, antibiotics and thrombolytic anticoagulant and anti-aggregation drugs are often indicated. The

failure to heal and the frequent recurrence of these ulcers points to the lack of success of these conventional methods. Accordingly, the medical community has a critical need for a low cost, portable, non-invasive method of treating diabetic, venous, ischemic and pressure ulcers to reduce mortality and morbidity and reduce the excessive costs to the health care system.

Most problematic of all is that treatment of diabetic foot ulcers has been focused on amputation and not on limb salvage, as many of the wounds have not been properly treated. Improper treatment can be attributed to lack of an easy and inexpensive treatment system and method and severe inconvenience to the patient in using current methods. There is a need to prevent amputation by healing such wounds, particularly at an early stage.

Furthermore, amputation for conditions such as foot ulcers and frostbite becomes less avoidable the longer the condition is either left untreated or is unsuccessfully treated. Therefore, it is crucial to apply an effective treatment regimen as soon as possible. Unfortunately, foot wounds in patients with, for example, diabetes develop because of a process called neuropathy. Diabetes causes loss of sensation such that skin injury and complete breakdown (ulcer) can develop with no or minimal pain. These wounds tend not to heal because of ongoing mechanical trauma not felt at all by the patient as painful. Therefore, by the time the patient discovers the wound, the wound has often progressed so that the patient's treatment options have become severely limited.

In many cases, such wounds can only be healed by protecting them from mechanical trauma. Small plantar ulcers in diabetic patients area usually seen by primary care practitioners and endocrinologists. The present method for healing plantar ulcers is a total contact cast for the foot, which provides complete mechanical protection. This method is not ideally suited for either of these practice settings, because it requires skilled and specialized care in application, along with frequent follow up. Most patients perceive the cast to be an inconvenience at the early stages of such a wound, while perceiving that such a wound is not a serious matter. The alternative to the cast is to ask the patient to be non-weight bearing through the use of a wheelchair, crutches, or a walker, which provide complete mechanical protection only with complete patient compliance. This alternative rarely proves to be effective in healing wounds within a reasonable time period.

What is needed is a treatment that primary care physicians and their staff can employ to treat bacterial and fungal skin infections, hair loss, skin ulcers and other wounds that do not require extended physician time and that is effective even at later stages of the medical condition. Also, what is needed is a treatment that allows patients to be able to continue their active lives without the need to wear casts, or be confined to wheelchairs and crutches.

SUMMARY

In one embodiment, a wound treatment apparatus includes a treatment vessel having a treatment chamber and an opening to the treatment chamber that are sized to receive a human limb. A removable and substantially gas impermeable liner lines the chamber of the vessel and forms a treatment zone around the patient's limb. A cuff is removably coupled to the opening of the vessel and is sized to sealingly engage a human limb when the limb is inserted through the opening. A mixture tank holds a humidifying agent and is in fluid communication with the chamber of the vessel. A first array of light emitting diodes is coupled to the chamber and emits ultraviolet light into the chamber. A speaker is attached to the vessel and delivers low frequency sound waves to the chamber. A second array of light emitting diodes is coupled to the chamber and emits pulsed light into the chamber.

A wound treatment system includes a vessel that is sized to receive a human limb. The vessel includes a chamber with an opening leading into the chamber. A removable liner lines the chamber of the vessel and forms a treatment zone. A humidifier in fluid communication with the treatment zone humidifies a solution of water and antibacterial agent. An oxygen source is in fluid communication with the treatment zone. A speaker is coupled to the vessel and emits low frequency sound waves to the chamber. A first array of light emitting diodes that emits ultraviolet light is coupled to the vessel near the opening of the treatment chamber. A second array of light emitting diodes that emits pulsed light into the chamber is coupled to the chamber. The system also includes a control panel.

A wound treatment method for treating a wounded limb is also described. The method includes cleaning the wound. The method also includes disinfecting the limb by passing the limb through a ring of ultraviolet light emitting diodes that emit ultraviolet light on the limb as the limb passes through the ring. The limb is placed into a vessel having a chamber that is lined, with a substantially gas impermeable liner by passing the limb through a cuff that sealingly surrounds a portion of the limb, thus forming a substantially gas impermeable treatment zone around a portion of the limb distal the cuff. The limb is

heated by introducing warm water into the chamber, which causes the inner liner to collapse around the patient's limb. The warm water is emptied out of the chamber, and a temperature controlled mist of topical hyperbaric oxygen, water and an antibacterial solution is introduced into the treatment zone. The limb is massaged by activating a speaker coupled to the vessel that transmits low frequency sound waves to the treatment zone. The limb is heated and kept warm by activating an array of light emitting diodes coupled to the vessel that emits pulsed light onto the limb.

In another aspect, a method for treating an individual having a medical condition or an infection is provided. The method comprises the steps of (a) introducing a body part of an individual having a medical condition or infection into a treatment chamber; (b) surrounding the body part in the treatment chamber with a mist containing water and a medication; and (c) surrounding the body part in the treatment chamber with an O_2-enriched gas without increasing the pressure around the body part to 22 mm Hg.

The medical condition may be acne vulgaris resulting from infection by *Propionibacterium acnes* or Athlete's foot caused by a group of fungi of the genus *Trichophyton.* The body part may be the face or an appendage. More specifically, a hand, a forearm, a hand and forearm, a hand, forearm and upper arm, a foot, a calf, a foot and calf or a foot, calf and thigh.

The medications may be general such as betadine, isopropyl alcohol, bacitracin, hydrogen peroxide, and combinations thereof. Alternatively, they may be specific for the infection, such as benzoyl peroxide, salicylic acid, glycolic acid, sulfur, azelaic acid or combinations thereof for the treatment of acne or 6-piperidin-1-ylpyrimidine-2,4-diamine 3-oxide (Minoxidil), N-(1,1-dimethylethyl)-3-oxo-(5α,17β)-4-azaandrost-1-ene-17-carboxamide (Finasteride), (11β,16α)-9-fluoro-11,16,17,21-tetrahydroxypregna-1,4-diene-3,20-dione (Triamcinolone), 17-hydroxy-7α-mercapto-3-oxo-17α-pregn-4-ene-21-carboxylic acid, γ-lactone acetate (Spironolactone) or combinations thereof for the treatment of Athlete's foot.

The treatment zone may receive an adiabatic mist comprised of water or water mixed with medication. This treatment may be followed by displacing the mist with oxygen-enriched gas. Alternatively, the gas may be pure oxygen. This process may be performed multiple times in a single treatment. Under one treatment method steps b and c are repeated four times in one treatment lasting 80 minutes.

The one or more chambers may also be flooded with either one or both ultraviolet light and/or infrared light during treatment.

In yet another aspect, a variable hyperoxia treatment apparatus is provided that includes one or more treatment chambers being sized to receive a human body part. A removable and substantially gas impermeable liner that lines each of said chambers and forms a treatment zone around the human body part. A mixture tank holds a humidifying agent and has a medicinal filling port for receiving medications to be mixed with the humidifying agent. The mixture tank is in fluid communication with the gas impermeable liners. The oxygen concentrator concentrates O_2 from the environment and is provided with an O_2 dispensing port in gas tight communication with the gas impermeable liners. The one or more treatment chambers having an inlet port for receiving fluid and an outlet port for dispensing the fluid.

In one configuration of the variable hyperoxia treatment apparatus, the electric components and mixture tank are separated from the oxygen concentrator and oxygen receiving port by the one or more treatment chambers. Alternatively, the oxygen components are housed in a container separated from the electric components. In addition, the variable hyperoxia treatment apparatus may further comprise a variety of other functional components. For example, the variable hyperoxia treatment apparatus may include a fluid connection between the humidifier and the mixture tank; an oxygen control valve; a pump that pumps water into and/or out of the one or more chambers; a cuff removably coupled to the opening of the one or more treatment chambers and sized to sealingly engage a human body part; a nasal cannula and/or facemask in communication with said oxygen concentrator for administering oxygen to an individual during treatment; a speaker that delivers low frequency sound waves to the one or more chambers when they contain water; ultraviolet and/or infrared light emitting diodes to illuminate the surface of the human body part; or a variety of sensors in fluid communication with the treatment zone such as a temperature sensor; a humidity sensor and/or a pressure sensor.

The liner is made of a sterile or sterilizable plastic material and may further comprise a pressure release valve fluidly connecting the treatment zone with the one or more chambers; or one-way valves in fluid connection with the mixture tank and/or oxygen concentrator.

In other embodiments of this aspect of the invention, the cuff may be made of an open cell material configured to naturally leak fluid forming a baffle for the treatment zone.

In still another aspect of the invention, a variable hyperoxia therapy treatment system is provided with a control panel for operating the system. One or more treatment chambers are provided, each having at least one opening and sized to receive a human body part. A removable and substantially gas impermeable liner lines each of the chambers and forms a treatment zone around the human body part. A humidifier creates a mist from a solution of water that may include one or more medications and an oxygen source are both in fluid communication with the treatment zone. The oxygen received by the treatment zone may be provided by an outside oxygen source such as an oxygen tank or may be provided through the oxygen concentrator.

The control panel comprises a master power switch and may be operated manually or automatically according to a predetermined regimen. If operated automatically, a plurality of automatic settings corresponding to a plurality of predetermined regimens may be utilized.

In one embodiment of this aspect of the invention, one or more treatment chambers may be affixed securely to a human body part. Alternatively, a human body part may be inserted into one or more chambers for treatment. In addition, the system may further comprise a fluid source for filling the one or more chambers with fluid.

In another embodiment of this aspect of the invention, the variable hyperoxia therapy treatment system may further comprise an adiabatic humidifier; an ultrasonic energy source to form a mist from a solution of water that may include one or more medications; an oximeter; an O_2 concentrator; a wireless transmitter adapted to transmit data; a barcode data reader and/or a sensor in communication with a foam cuff that determines the position of the cuff when fitted about the human body part. The position establishes a volume range of humidified solution containing one or more medications to be dispensed into the liner for treatment of the body part.

Other aspects of the invention are found throughout the specification.

DESCRIPTION OF DRAWINGS

These and other features and advantages will be apparent from the following more particular description thereof, presented in conjunction with the following drawings, wherein:

FIG. 1 is a three-dimensional view of a wound treatment system.

FIG. 2 is a is an illustration of a control panel of a wound treatment system.

FIG. 3A is another three-dimensional view of the wound treatment system depicted in FIG. 1.

FIG. 3B is a three dimensional view of the wound treatment system depicted in FIG. 1 with patient being treated.

FIG. 4A is a three dimensional view of a lid assembly of a wound treatment system.

FIG. 4B is a three dimensional view of a treatment vessel of a wound treatment system.

FIG. 5 is a side exploded view of a treatment vessel of a wound treatment system.

FIG. 6A is a front transparency view of the treatment vessel depicted in FIG. 5.

FIG. 6B is a top view of the wound treatment tank depicted in FIG. 5.

FIG. 7A is a front transparency view of a wound treatment chamber.

FIG. 7B is a bottom view of the wound treatment chamber depicted in FIG. 7B.

FIG. 8A is a rear view of a wound treatment system with a rear panel removed.

FIG. 8B is another rear view of the wound treatment system depicted in FIG. 8B further depicting a humidifier.

FIG. 9A is a front transparency view of a water reservoir used in a wound treatment system.

FIG. 9B is a side transparency view of the water reservoir depicted in FIG. 9A.

FIG. 10 is a side transparency view of one aspect of the variable hyperoxia therapy treatment system showing separation of the electrical components from the components that receive and dispense oxygen, an oxygen concentrator for collecting and administering oxygen to the liner and/or patient during treatment and the liner with separate openings and one-way valves for receiving mist from the humidifier and oxygen from the oxygen concentrator.

FIG. 11 shows optional adapters that may be connected to the variable hyperoxia therapy treatment system in FIG 10 to treat areas of the body that cannot be inserted into the central chamber of the device such as the back and scalp.

DETAILED DESCRIPTION

The apparatus, systems, and methods described herein provide hyperbaric oxygen to open, chronic wounds as an adjunct therapy in wound management and treatment. In addition, per determination by the healthcare providers that use the described apparatus, systems, and methods, they can also provide mild heat, gentle massage, infrared and ultraviolet light therapy, moisture therapy, and application of antibacterial agents. These features are intended to promote the rate of healing and suppression of bacterial growth.

Turning to FIG. 1, a wound treatment system 10 is shown, which generally includes a topical oxygen chamber for limbs and is intended to surround a patient's limb and apply humidified water, antibacterial agent, and oxygen topically at a pressure slightly greater than atmospheric pressure. The wound treatment system 10 includes a rectangular, rigid plastic carriage 15 having a treatment vessel 800 forming a chamber 810 (shown in FIG. 5) that is sized to accommodate a patient's limb, particularly a patient's foot and a portion of the leg up to the knee. A padded leg rest 18 supports the patient's leg during treatment sessions. The system also includes a control panel 30, a cart 40 housing a first reservoir 600 for water, an adiabatic humidifier 400 that holds a solution of water and antibacterial agent, a water pump 500 (all shown in FIGS. 8A and 8B), and a control box (beneath the control panel) that houses the circuit boards that control the system 10. A mist control valve unit 50 is attached to a back panel of the cart 40. A hose 70 connects the mist control valve unit 50 to the vessel 20, and one or more hoses 71 connect the humidifier 400 to the mist control valve unit 50.

Covering the vessel 800 is a lid assembly 60 (shown in FIGS. 1 and 4A) that includes a first lower lid 61 that is hinged to the vessel 800 at the proximal end 64 of the vessel 800 opposite the end abutting the back panel of the cart 40. The lower lid 61 includes a circular opening 161 that provides access to a chamber 810 formed inside the vessel.

The lid assembly 60, as shown in FIGS. 1 and 4A, also includes a second upper lid that is formed by two opposing covers 62 and 63. Cover 62 covers the distal side 64 of the vessel 800 and cover 63 covers the proximal side 65 of the vessel 800. The covers 62 and 63 are completely removable from the top of the vessel 800. The distal side of cover 63 forms a half circular indentation that is matched by a half circular indentation in the proximal side of cover 62 so that when the distal side of cover 63 and the proximal side of cover 62 join, a round opening 169 is formed when the covers 62 and 63 are secured over lid 61. Each cover 62 and 63 has a raised half circular wall 67 and 68 projecting vertically from its top surface around its corresponding half circular indentation. When the covers are joined as shown in FIG. 1, the walls 67 and 68 join to form a cylinder 69. The round opening 169 formed when the half circular indentations are joined is concentric with the circular opening 161 of the lower lid 61 so that a patient's limb can project down through the cylinder 69, through opening 169 formed by the covers 62 and 63, through opening 161 of the lower lid 61, and into the chamber 830 of the vessel 20.

An oxygen inlet port 77 on the cover 62 (or alternatively cover 63) receives a hose 78 connected to an oxygen source, such as an oxygen tank or a central oxygen source in a hospital. The inlet port 77 can include a fitting (not shown) to sealingly secure the hose 78 to the cover 62. The cover 62 includes a vapor inlet port 72 that receives the hose 70. The vapor inlet port 72 can include a fitting 73 to sealingly secure the hose 70 to the vapor inlet port 72. Either of the covers 62 or 63 can also include a temperature sensor 92, a humidity sensor 94, and a pressure sensor 96, each of which are in fluid communication with a treatment zone formed by a treatment bag 100 sealed to the lid 61 of the vessel (FIG. 4B). The cart 40 includes wheels 41 at each corner to mobilize the system 10.

As shown in FIG. 2, the control panel 30 includes a display with various knobs and switches that controls the operation of the wound treatment system 10. The panel includes controls 130 that control the humidifier, controls 140 that control an array of ultraviolet light emitting diodes (LEDs) 310 (see FIGS. 4A and 4B) controls 150 that control an array or board of infrared light 880 (see FIGS. 4B, 6A, and 7A)

and an audio transducer or speaker 870 (see FIGS. 5, 6A, 7A, and 7B), controls 160 that control a water pump 500 (see FIG. 8A), and controls 170 that control the master power for the system 10.

The humidifier functions of the system are controlled by controls 130, which include at least some of the following: an on/off switch 131 that turns on the humidifier function; a button 132 that can be used to manually activate or open the mist control valve unit 50 and that illuminates when the mist control valve unit 50 is open and allowing the flow of therapeutic mist into the chamber 830; a button 133 that opens an electronic oxygen flow valve in the tubing 78 connected to the oxygen source and illuminates when the oxygen flow valve is open and allowing oxygen flow into the chamber 810; an auto/manual switch 134 that sets the humidifier function to either manual operation or auto operation; a mist timer knob 135 that is used to set the amount of time for mist flow into the chamber 810; and an oxygen timer knob 136 that sets the amount of time for oxygen flow into the chamber 810.

The UV functions of the system is controlled by controls 140, which include at least some of the following: an on/off switch 141 that turns on the UV function; a foot in button 142 that illuminates when the patient inserts his foot through the opening 169--the collar 300 can have a sensor 360 that senses the foot and sends a signal back to the control box to activate the UV LEDS; a UV on button 143 that can be depressed to manually activate the UV LEDS 310 and that illuminates when the UV LEDS 310 are activated; an auto/manual switch 144 that sets the UV function to either manual operation or auto operation; and an UV timer knob 145 that sets the amount of time that the UV LEDS will remain on once they are activated.

The IR/Audio functions of the system is controlled by controls 150, which include at least some of the following: an on/off switch 151 that turns on the IR/Audio function; an IR button 152 that can be used to manually activate the IR LEDS and that illuminates when the IR LEDS and speaker are operating; an Audio, button 153 that can be used to manually activate the speaker or audio transducer and that illuminates when the speaker is operating; an auto/manual switch 154 that sets the IR/Audio function to either manual operation or auto operation; and a timer knob 155 that sets the amount of time that the IR LEDS and speaker will remain on once they are activated.

The pump control functions of the system is controlled by controls 160, which include at least some of the following: an an/off switch 161 that turns on the pump control function; a drain button 162 that can be

used to manually operate the timing of drainage of the chamber 810 and that illuminates when the chamber 810 is draining; a fill button 163 that can be used to manually operate the timing of filling the chamber 810 with warm water and that illuminates when the chamber is filling with water; and an auto/manual switch 164 that sets the pump control function to either manual operation or auto operation.

The master control buttons 170 include at least some of the following: a master control switch 171 that turns the system on and off; a start button 171 that is used to start the operation of the system and that illuminates when the system is operating; and a stop button 172 that can be depressed to prematurely stop the operation of the system.

In one embodiment, the control panel 30 also includes a thermostat (not shown) that is electrically coupled to a submergible water heater 680 (see FIG. 9A) that is located in the water reservoir tank 600. The thermostat can be used to control the temperature of the water that is pumped from the water reservoir tank 600 into the chamber 810.

In operation, the system 10 works by switching the master power switch 170 to the on position, which turns the system on and puts the system in ready mode. The healthcare provider then decides which of the functions will be used in the specific regimen for the particular patient. Depending on the patient and the ailment, the regimen may provide for operation of all of the functions, or just some of the functions. For example, a regimen may call for warming the limb with injection of warm water into the chamber and then treating the wound with the antibiotic mist, but may not require infrared treatment and low frequency sound vibrations. Thus, all of the on/off switches would be switched to the one position except for the IR/Audio control switch 151, which would remain in the off position. When operating under normal conditions, all of the functions can be turned on by switching all of the on/off switches to the on position. This sets all of the functions to ready mode. The mist timer knob 135 and oxygen timer knob 136 can then be set to operate for the appropriate amount of time. According to one embodiment, the mist can be set at about fifteen minutes, while the oxygen is set at about five minutes. The UV timer knob 145 is set to operate for an appropriate amount of time. According to one embodiment, the UV timer is set to operate for less than 5 seconds, less than 4 seconds, less than 3 seconds, less than 2 seconds, or less than 1 second. The IR/Audio timer can be set to operate for a period of time coinciding with the warm water bath of the limb, which is when the chamber is filled with warm water, which warms the limb. This period can last from about one minute to about ten minutes or more. All of the auto/manual switches can

be set to auto for a predetermined and default regimen. Next the healthcare provider depresses the start button 171, which begins the regimen.

According to one embodiment, when all of the functions are in operation and auto modes, and the start button 171 is depressed, the system operates as follows. First the system waits for the sensor 360 to detect the insertion of a limb of a patient P, as shown in FIG. 3B) into the chamber 810. After the wound in the limb is cleaned, the limb is inserted through the opening 169 of the covers 62 and 63 and the opening 161 of the lid 61. The sensor 360 detects the limb as it passes through the opening 161 and activates the UV function, which activates the ring of UV LEDs 310 located concentrically around the opening 161. The UV LEDS 310 briefly stimulate the limb (about one to five seconds) as it passes through the opening of the chamber 810 and then the UV LEDs 310 deactivate. The UV on button 143 illuminates while the UV LEDs are on.

Next, a cuff 90 is placed around the limb and the lids 62 and 63 closed around the cuff 90 so that the half circular walls 67 and 68 form a substantial seal around the cuff. The cuff will be discussed in more detail later. The limb is placed in a bag or liner 100 that is substantially impermeable to gas. The top opening of the bag 100 is sealed to the bottom surface of the lid 61 and forms an airtight seal with the bottom surface of the lid 61. Thus, when the limb is surrounded by the cuff 90, which is surrounded by the half circular walls 67 and 68, the portion of the limb distal the cuff is inside the bag in a substantially sealed treatment zone.

Once the limb is secured as described, the pump 500 is activated and pumps warm water from the water reservoir 600 to the chamber 810 of the vessel 800 through a hose 510 that is connected to an outlet port 660 in the reservoir 600 on one end and the pump 500 on the other end. Another hose 520 carries the water from the pump 500 to a water pipe protruding from the vessel 20 that is connected to an opening in the chamber 810. The water pump 500 shuts off automatically after a predetermined amount of water is drained from the reservoir 600. The warm water entering the chamber 810 causes the bag 100 to collapse around the limb and creates a warm southing sensation on the limb. The warm water bath remains in the chamber 810 for a predetermined amount of time, generally between about one minute and ten minutes or more. The array of IR LEDs 880 in the chamber 810 is activated and transmits a pulsed (or steady) IR light during the warm water bath. The IR LEDS further warm the limb increasing circulation.

Also contemporaneous with the activation with the IR LEDs 880, the audio transducer or speaker 870 is activated and generates a low frequency sound wave that surrounds the limb. This creates a massaging effect, stimulates the skin and further enhances circulation. The water pump 500 is then activated in reverse and the warm water is pumped out of the chamber 810 and back into the reservoir 600. The IR LEDs 880 and the audio transducer 870 are turned off.

An adiabatically-humidified, temperature-controlled vapor of water and a topical antibacterial, antiseptic or antibiotic agent is released from the humidifier 400 by mist control valve unit 50. The vapor travels through the tube 70 and, enters the treatment zone through a port 72 in the lid 62, which is substantially sealed to the tube 70. The vapor hydrates the wound and provides antibacterial effects. This vapor treatment can last between about two minutes and about thirty minutes, depending on the timer 135 set by the healthcare provider. In one embodiment, vapor treatment lasts about fifteen minutes. Then the mist control valve unit 50 is activated to close the valve between the humidifier 400 and the tube 70.

At this time, the oxygen release valve is opened and oxygen flows from the oxygen source, which can either be an oxygen tank as shown or a wall mounted oxygen unit connected to a central oxygen source, such as in a hospital setting (not shown). The oxygen flows through the tube 78 into an oxygen inlet port 77 on the surface of the lid 62. The oxygen displaces the vapor and oxygenates the wound. Oxygenation can last between about one minute and about fifteen minutes. In one embodiment, oxygenation lasts about five minutes. The process between vapor treatment and oxygenation can be repeated several times. In one embodiment, vapor treatment and oxygenation are repeated three times for a total of four rounds of treatment lasting approximately eighty minutes. The patient's oxygen level can be monitored during treatment using an oximeter connected to the patients finger or other body part. The oximeter can be electrically connected to the control circuits in the control box of the system 10, and a display can warn the user to stop treatment or introduction of oxygen if the patient's blood oxygen level is too low or too high according to a predetermined level, such as below 80% saturation for an extended period of time. An extended period of time can be two or more minutes.

FIG. 3A shows the wound treatment system 10 with the control panel 30 lid removed and the lid 61 opened. Underneath the lid of the control panel reside the various electronics and circuitry of the system 10. A 12V power supply 220 can be used to power the system. A sweep function generator 210 is used to generate a low frequency waveform for the audio function. The sweep function generator 210 can

generate an adjustable frequency of between about 1 Hz and about 1000 Hz. It can generate various types of waveforms, such as sweeping waveforms and ramping waveforms within that range of frequencies. The sweep function generator 210 produces a sin wave signal that is transmitted to the audio amplifier 230, which can be a 12V amplifier. The amplifier 230 amplifies, the signal to about 50 W and transmits the amplified signal to the speaker or audio transducer 870 connected to the vessel 800. The sweep function generator 220 can be preset to a default frequency and waveform. In one embodiment, it can be preset to generate a 60 Hz signal, which can be manually altered to produce a signal at other frequencies between the range of about 1 Hz and about 1000 Hz. An assembly control cable 240 connects the control box (not shown) with the electronic components of the system. The control box (not shown), which is housed underneath the control panel lid 30, houses all of the circuit boards required to operate the system 10.

In one embodiment, as shown in FIGS. 3A and 4B, on the bottom surface 61B of the lid 61 is a circular collar 300 that forms a perimeter around the opening 161 on the bottom surface 61B of the lid 61. An array of UV LEDs 310 is mounted on the inner surface of the collar forming a ring. The UV LEDs 310 each point toward the center of the opening 161. There can be as few as four LEDS and as many as one hundred twenty or more LEDs in the array of UV LEDs 310. The array of UV LEDs 310 can deliver 330 W of UVA at about 320 nm to about 400 nm. Alternatively, or in addition to, the array of UV LEDs 310 can deliver 330 W of UVB at about 290 nm to about 320 nm. Alternatively, or in addition to, the array of UV LEDs 310 can deliver 330 W of UVC at about 100 nm to about 200 nm. In one embodiment, there are ninety UV LEDs delivering 330 W of UVA at about 374 nm to about 392 nm, delivering a total of about 324 mW or 324 W. The collar 300 also includes a motion sensor 360 to detect when a limb has been inserted through the collar and the ring of UV LEDs 310. The motion sensor is connected to the control box through a wire 312 that is threaded through a hole in the collar and then a hole in the bottom of the carriage 15 and up through the bottom of the cart 40. The wire 312 is eventually bundled in the cable 240 and carries an electrical signal to the circuitry in the control box. The array of UV LEDs 310 receives its electrical signals from the control box through a wire 311 that is also threaded through the hole in the collar and then a hole in the bottom of the carriage 15 and up through the bottom of the cart 40 and eventually bundled in the cable 240.

The lid 61 is raised by lifting the distal side of the lid while the proximal side pivots along its hinges. Chains or wires 85 are connected at one of their ends to the bottom surface 61B of the lid 61 and at their

other ends to the back panel of the cart with hooks or other securement means. The lid 61 falls back and is supported by the chains 85. The bottom surface 61B of the lid 61 includes a gasket 184 around its square or rectangular perimeter that seals the bottom surface 61B of the lid 61 to the vessel 800 when the lid 61 is closed.

As shown in FIG. 4A, the lid 61 can have a substantially circular crown 350 projecting vertically from its upper surface 340. This crown is in lieu of the collar 300 shown in FIGS. 3A and 4B. The array of UV LEDs 310 is coupled to the inside surface of the crown 350, as is the motion detector 360. The upper lid is formed by covers 62 and 63. Each of the covers 62 and 63 can form a corresponding half washer shaped raised portion 62 and 63. Projecting vertically from the center of each raised portion 62 and 63 is a half circular wall 67 and 68. When the covers 62 and 63 are placed over the lid, the washer shaped raised portions 62 and 63 join to form a raised washer shaped portion that fits over the circular crown 350 to form a substantial seal between the outer wall of the crown 350 and the inner wall of the washer shaped raised portion. The outer wall of the crown 350 can include a gasket (not shown) to reinforce the seal. The half circular walls 67 and 68 also join to form a cylinder with an opening 169 in the center that is concentric with and open to the opening 161 of the lid 61.

An oxygen inlet port 77 on the washer shaped raised portion 62 (or alternatively on washer shaped raised portion 63) receives a hose (not shown) connected to an oxygen source, such as an oxygen tank or a central oxygen source in a hospital. The oxygen inlet port 77 can include a fitting (not shown) to sealingly secure the hose to the cover raised portion 62. The raised portion 62 includes a vapor inlet port 72 that receives the hose 70 (shown in FIG. 1). The vapor inlet port 72 can include a fitting 73 (shown in FIG. 1) to sealingly secure the hose 70 to the vapor inlet port 72.

There are only two components of the wound treatment system 10 that make physical contact with the patient's skin: a liner or bag 100 (as shown in FIGS. 3A and 4B) into which the patient's limb is placed; and a foam cuff 90 (as shown in FIGS. 3B and 4A), which is placed around the patient's limb.

The liner 100 forms a treatment zone around the wound and makes contact with the open wound. Therefore, it is preferable that the liner 100 be biocompatible and sterile. The liner 100 can be discarded or sterilized after each use and/or replaced with a new or sterilized liner 100.

The material from which the liner 100 is made can be any strong substantially gas impermeable material. Extruded flexible plastic film material, such as polyethylene (hdpe, ldpe, lldpe, polyprolene, etc,), polyurethane ether or ester open cell foam (e.g., United States Plastics Corp. Stock No. 47154), polyethylene terephthalate, polyvinyl chloride, or ethylene/polyvinyl copolymer sheet stock, and vapor proof treated fabric, such as nylon, are suitable. The material can be puncture resistant and transparent. The flexible sheet material can have a variety of shapes. It can be a single layer, such as a bag to surround a limb, or have multiple layers. The bag or liner 100 may also be co or tri axially oriented.

The term "substantially gas impermeable", as used herein with respect to the sheet material, means gas impermeable to the extent needed to prevent excessive gas escape from the treatment zone through the sheet material. Total gas impermeability seldom is needed, particularly for continuous flow treatment devices. However, generally high impermeability is desirable for static treatment devices.

The perimeter of the opening of the liner 100 can have an adhesive strip with a removable backing. The backing can be removed and the perimeter of the lining can be substantially sealed against the crown 350 (or the collar 300), thus forming a sealed connection between the perimeter of the opening of the liner 100 and the lid 61. Alternatively, the liner 100 can be taped to the crown 350 (or the collar 300) to form a substantial seal between the lid 61 and the liner 100.

In one embodiment, the liner 100 includes a pressure release valve 105 built into it. The design of the pressure release valve 105 is not critical. Many different types are suitable. For example, the valve 105 can be a ball valve or a baffle valve such as a flap or butterfly baffle valve. Other valves are equally suitable, so long as they are capable of accurately setting the maximum release pressure and are inexpensive and so discardable. If desired the adjustable valve 105 can be calibrated to show the pressure setting. In one embodiment, the maximum release pressure can be set at 22 mm of mercury so that the pressure inside the liner 100 never surpasses that amount of pressure. The valve body can be made of any rigid plastic, although metals such as stainless steel can be used also. The spring can be steel or plastic. Very inexpensive completely plastic valves can be used as well.

The pressure release valves 105 integrated with the liner 100 are inexpensive yet reliably accurate, within the preferred accuracy ranges. If desired, they can be removed from a used liner 100 and reused on new liners. Using a valve that is in communication with the treatment zone and not with the gas supply

eliminates the need for a separate pressure control mechanism between the chamber 810 and the oxygen source. The chamber 810 can be connected directly to a gas or oxygen tank or a hospital gas supply line.

With any of the embodiments described herein, a foam cuff 90, as shown in FIG. 3B, is placed around the patient's limb and inserted concentrically with the cylinder formed by the half circular walls 67 and 68. The foam cuff 90 can be disjoined so that it can be opened and placed around a limb. The foam cuff 90 can be made of a biocompatible open cell material that is compressible and resilient and forms a substantial seal or baffle between the patient's limb and the cylinder formed by the walls 67 and 68. The open cell configuration prevents rapid fluid leakage through the cuff, but does allow for some fluid leakage at pressures approaching 22 mm of mercury, thus acting as a baffle. The pressure inside the treatment zone should not reach 22 mm of mercury, and the fluid leakage through the foam cuff 90 as the pressure inside the treatment zone increases will prevent pressures from building up beyond that level. Thus, with the use of an open cell material in the foam cuff 90, a pressure release valve 105 in the liner 100 may not be necessary. The foam cuff 90 can also include a backing on its outer non-skin contacting surface that can be peeled away, exposing a sticky surface that sticks to the cylinder. The foam cuff 90 can be made of a polyurethane ester or a natural material.

FIGS. 5-7B show the vessel 800 in which the patient's wound is treated. The vessel 800 sits inside of the rigid plastic carriage 15 shown in FIG. 1. As shown in FIGS. 5 and 6A, the vessel 800 is formed by inserting chamber 810 into tank 830. The outer dimensions of the chamber 810 are slightly smaller than the inner dimensions of the tank 830 so that the chamber 810 is nested securely within the tank 830. The only dimension of the tank 830 that is substantially different from the chamber 810 is that the tank 830 is several inches deeper than the chamber 810. This provides for extra room at the bottom of the tank 830 for the audio transducer or speaker 870 connected to the bottom of the chamber 810, so that when the chamber 810 is placed in the tank 830, the top edges 812 and 832 of the chamber 810 and tank 830 are substantially coplanar as shown in FIG. 6A.

The tank 830 is made of a molded plastic or metal that is rigid and durable. As shown in FIGS. 6A and 6B, the tank 830 has a foam platform 835 forming an inner bottom surface of the tank 830. The foam platform 835 has a circular pipe hole 836 cut into it that receives the audio transducer or speaker 870. The foam platform 835 has a second pipe hole 837 cut into it that is matched up with a hole 838 cut in the bottom of the tank 830 to form an outlet port for the water pipe 818 projecting vertically downward from

the bottom surface of the chamber 810. Bolts 833 projecting vertically downward from the bottom of the tank 830 are used to guide and connect the tank 830 to the carriage 15.

Turning to FIGS. 7A and 7B, chamber 810 is shown in more detail. The chamber 810 includes a sealing member 813 that surrounds the chamber just beneath its edge 812. The sealing member 813 forms a substantially fluid-tight seal between the chamber 810 and the tank 830. Inside the chamber 810 is an IR board 880 with an array of IR LEDs. The board 880 has bolts 881 on its corners that are used to bolt the board 880 to the bottom of the chamber 810. PCB wiring 881 is coupled to the IR board 880 and exits from the chamber 810 through hole 882 drilled into the bottom of the chamber 810. The hole 882 can be drilled at a location beneath the IR board 880 and can be about 1/4 inch. Silicone, hot glue, and/or other sealing materials can be used to form a fluid tight seal between the wiring 881 and the hole 882 to seal the chamber 810, hardware, and wires from leaks. The wiring 881 is lead through the pipe hole 837 in the tank 830 and connects with a connection to the control box.

The IR board 880 includes IR LEDs arranged in a pattern on a square or rectangular board. The IR LEDs can emit energy at infrared frequencies of between about 700 nm and 50,000 nm. The IR board 880 can be controlled by the control panel to adjust the frequency. In one embodiment, the IR LEDs deliver about 2000 mW of infrared light at about 810 nm. In one embodiment, the IR board 880 can also generate about 1.2 W of Red light at about 660 nm for a combined total light output of 1911 mW. For example, the IR board 880 can be a Thor DDII IR Lamp System.

Turning to FIG. 7A, a hole is drilled through the bottom of the chamber 810, and the water pipe 818 is inserted through the hole, projecting vertically downward through the hole and out the bottom of the chamber 810. A tub seal pipe coupling 819 is used to form a fluid tight seal between the pipe 818 and the hole through which it is inserted through the chamber 810. The water pipe 818 is open at both ends to allow water to flow in and out of the chamber 810 when the chamber 810 is connected to the reservoir 600 through a water hose.

As shown in FIGS. 7A and 7B, coupled to the outside of the chamber at the bottom of the chamber 810 is an audio transducer or speaker 870. The speaker 870 is bolted to the bottom of the chamber 810. Transducer wires 876 are connected to the speaker 870 and, like the IR wiring, are threaded through the pipe hole 837 in the tank 830 to form a connection with the control box. As shown in FIGS. 5 and 6A, a

rigid plastic or metal collar 890 with a hole 892 is placed around the speaker 870 to protect the speaker 870. The speaker 870 emits energy at a low frequency sound wave, of between about 1 Hz and about 1000 Hz. In one embodiment, the speaker emits energy at about 60 Hz. This causes a therapeutic vibration on the chamber 830 and a massaging effect on the patient's limb.

In one embodiment the foam platform 835 is a premolded piece that is inserted into the bottom of the tank 810, and the chamber 810 is placed on top of the foam 835. In another embodiment, a hardening foam gel is poured into the bottom of the tank 810 to a predetermined depth, and the chamber 810 with speaker 870 and collar 890 are quickly placed into the tank 810. The foam gel hardens around the pipe 838 and wires 881 and 876, the collar 890, and the bottom of the chamber 810. The tank 830 is ultimately bolted to the rigid plastic carriage 15.

Now turning to FIGS. 8A and 8B, the components of the wound treatment system 10 that are housed in the cart 40 are shown. Both FIGS. 8A and 8B are front views of the cart 40 looking at the cart 40 from the direction of viewing the control panel 30. FIG. 8A shows the components with the humidifier 400 removed so that the water pump 500 is visible. FIG. 8B shows the components with the humidifier 400 in its normal position blocking a view of the pump 500, which sits behind the humidifier 400.

As shown in FIG. 8A, a warm water reservoir 600 rests on a shelf 43 at the bottom of the cart 40. A first hose 510 is connected to the water pump 500 through fitting 512. The other end of the hose 510 is secured to a hose fitting 630 (shown in FIG. 9B) laterally projecting from the reservoir 600 so that the hose is in fluid communication with the inside of the reservoir 600. A second hose 520 is connected to the water pump 500 through fitting 522. The other end of hose 520 is connected to the water pipe 818 projecting vertically from the bottom of the vessel 800 so that the hose 520 is in fluid communication with the inside of the chamber 810. Cables 510 electrically couple the water pump to the control box. The reservoir 600 has a rigid lid 610 that can, be removed to expose the inside of the reservoir and fill it with water.

Turning to FIGS. 9A and 9B, the reservoir 600 is shown in more detail. The reservoir 600 includes two float switches 640 and 650. An upper float switch 640 is used to determine when the reservoir 600 is full and a lower float switch 650 is used to determine when the reservoir 600 is empty. Switch 640 has a lead 642 that is electrically connected to terminal block 660 with wire 645. Switch 650 has a lead 652 that is electrically connected to terminal block 660 with wire 655. Terminal block 660 is electrically connected

to the pump with wires 670. The spacing between the switches 640 and 650 determines the amount of water that will be pumped into the chamber 830 when the system 10 is activated and the pump function is operating. The switches 640 and 650 are arranged so that the optimal amount of water is pumped into the chamber 830. If too much water is pumped into the chamber, the lid 61 can dislodge causing the chamber 830 to leak. If there isn't enough water, the patient's limb will not be warmed enough. In one embodiment, about five gallons of water is pumped from the reservoir 600 to the chamber 830. When the pump function is activated, the pump begins to pump water 500 out of the reservoir 600 through fitting 660. When the water level reaches the lower switch 650 and the floating arm 653 of the switch 650 begins to dip fall, an electrical signal is transmitted to the pump 500 through wires 670, and the pump 500 automatically shuts off. When the drain function is activated, the pump 500 begins to pump in reverse, draining the water from the chamber 830 and back into the reservoir 600. When the water in the reservoir reaches the upper switch 650 and the floating arm 643 of the switch 640 begins to rise, an electrical signal is transmitted to the pump 500 through wires 670, and the pump automatically turns off.

In one embodiment, the water is kept at an optimal temperature with a portable heating unit 680 that is adjustable between a range of about 70.degree. F. and about 90.degree. F. In another embodiment, a more sophisticated heating unit is used (not shown) that is electrically coupled to the control box and can be controlled with a thermostat in the control panel 30.

Turning back to FIG. 8B, the humidifier unit 400 sits atop the lid 610 of the reservoir 600. The humidifier has a removable lid 410 that can be removed to fill the reservoir of the humidifier 400 with water and an antibacterial agent, such as ionic silver, hydrogen peroxide, bacitracin, betadine, or isopropyl alcohol. In one embodiment, adiabatically humidified 1% hydrogen peroxide/silver solution is used, but other FDA approved topical antibacterial, antibiotic, antiseptics and antimicrobial solutions and agents, such as those described above, may also be used.

The humidifier 400 has a misting unit that constantly produces mist as long as the humidifier function on the control panel 30 is activated. The misting unit can be an adiabatic temperature controlled humidifier or ultrasonic nebulizer. The humidifier 400 can generate room temperature mist or heated mist. It can include a built-in heater (not shown) with an on/off switch and an indicator light that shows that the heater is on and at operating temperature. Warm mist temperature in the bag 100 can reach between about 77.degree. F. and about 82.degree. F. as measured with a temperature gauge in the lid assembly. The

humidity in the bag 100 can reach about 89% to about 91% as measured by a humidity gauge. The humidifier has a transducer that generates ultrasonic energy at about 40 kHz to create an adiabatic/humid mist that creates a cloud. Ultrasonic energy from the misting unit is not transmitted to the limb, which is about two feet away from the misting unit. When the valve control unit 50 is opened, the mist travels from the humidifier 400 into the exit tube 410 and out through the exit port 420 where it enters the valve control unit 50. From there the mist travels through the tube 70 and into the treatment zone formed by the bag 100 surrounding the patient's limb.

In another aspect of the present invention, the variable hyperoxia treatment apparatus as shown in FIG. 10, provides at least one treatment chamber for receiving a body part that separates the electronic components of the apparatus from the oxygen supply and concentrator. Many of the component parts of this apparatus are similar or identical to those discussed in previous embodiments and aspects. A majority of the electrical components of the apparatus are isolated from the oxygen source and the components that deliver oxygen to the treatment chamber and the patient. In particular, the water fill port 975, the medicine fill port 970, the adiabatic humidifier 980, the ultrasound device 982, the humidifier control valve 984, the control panel 962, the temperature sensor 952, the pressure sensor 950, the humidity sensor 986, the lid sensor 928, the electrical connections to the UV/IR LED arrays 924 are preferably on one side of the treatment chamber while the oxygen intake port 946, oxygen control valve 940, oxygen concentrator 942 and oxygen delivery ports 948 are on the other side of the treatment chamber. Alternatively, the oxygen intake port 946, oxygen control valve 940, oxygen concentrator 942 and oxygen delivery ports 948 may be securely housed in a separate chamber isolated from electronic components of the apparatus but not separated by the treatment chamber.

Multiple arrays of UV and IR LEDs 942 that irradiate the surface of the body part are mounted to the chamber. There may be as few as five LEDS one mounted to illuminate the front, one for the back, one for the left side, one for the right side and one for the base of the body part. Alternatively, there may be arrays 942 of ten to several hundred positioned similarly to irradiate the entire body part in the treatment chamber. The array of UV LEDs 942 can deliver 330 W of UVA at about 320 nm to about 400 nm. Alternatively, or in addition to, the array of UV LEDs 942 can deliver 330 W of UVB at about 290 nm to about 320 nm. Alternatively, or in addition to, the array of UV LEDs 942 can deliver 330 W of UVC at about 100 nm to about 200 nm. In one embodiment, there are ninety UV LEDs delivering 330 W of UVA at about 374 nm to about 392 nm, delivering a total of about 324 mW or 324 W.

The IR board includes IR LEDs 942 arranged in a pattern about the chamber. The IR LEDs 942 can emit energy at infrared frequencies of between about 700 nm and 50,000 nm. The IR LEDs 942 can be controlled by the control panel 962 to adjust the frequency. In one embodiment, the IR LEDs 942 delivers about 2000 mW of infrared light at about 810 nm. In one embodiment, the IR LEDs 942 can also generate about 1.2 W of red light at about 660 nm for a combined total light output of 1911 mW. For example, the IR LEDs 942 can be a Thor DDII IR Lamp System. The programmed treatment also sends electrical signals from the control box to the arrays of UV/IR LEDs 942 through a wire that is also threaded through the device and eventually bundled in the cable leading to the control panel 962.

The lid is provided as a two-piece circular collar 926 that forms a perimeter around the opening of the treatment chamber. Sliding apart the two pieces of the circular collar 926 opens the lid. The lid also includes a sensor 928 to detect the diameter of the body part that has been inserted through the collar 926. The sensor 928 wire is threaded through the device and eventually bundled in the cable leading to the control panel 962. The diameter of the body part is relayed to a processor in the control panel 962 that establishes the amount of humidified mist and oxygen that will be applied to the body part for each step of the programmed treatment.

An oxygen inlet port 946 receives a hose (not shown) connected to an oxygen source, such as an oxygen tank or a central oxygen source in a hospital. The oxygen inlet port 946 allows oxygen to flow from the source to an oxygen flow meter 944 in communication with the oxygen concentrator 942. The oxygen concentrator 942 and/or oxygen flow meter 944 is in communication with the liner 900 through a one-way valve 940 allowing control of oxygen to the treatment zone. The oxygen concentrator 942 and/or oxygen flow meter is also in communication with a cannula or facemask that may be worn by the patient during treatment. The oxygen supply line hose may be sealingly affixed to an inlet port 946 on the side of the apparatus (not shown) which is directly connected to the oxygen flow meter 944 and/or oxygen concentrator 942.

The liner 900 forms a treatment zone around the wound and makes contact with the open wound. Therefore, it is preferable that the liner 900 be biocompatible and sterile. The liner 900 can be discarded or sterilized after each use and/or replaced with a new or sterilized liner 900. The material from which the liner 900 is made can be any strong substantially gas impermeable material. Extruded flexible plastic film

material, such as polyethylene (hdpe, ldpe, lldpe, polyprolene, etc,), polyurethane ether or ester open cell foam (e.g., United States Plastics Corp. Stock No. 47154), polyethylene terephthalate, polyvinyl chloride, or ethylene/polyvinyl copolymer sheet stock, and vapor proof treated fabric, such as nylon, are suitable. The material can be puncture resistant and transparent. The liner 900 also has at least two one-way inlet valves 940 at or about its base for receiving mist/medicated mist from the humidifier 980 and oxygen from the oxygen flow meter 944 and/or oxygen concentrator 942. The design of the one-way valves 940 is not critical. A variety of different types may be utilized. The liner 900 may also have an outlet port (not shown) that may be utilized for allowing replacement of agents in the treatment zone with fresh or other agents during the programmed treatment.

The perimeter of the opening of the liner 900 can have an adhesive strip with a removable backing. The backing is removed and the perimeter of the lining substantially is sealed against the two-pieces of the collar 926 thus forming a sealed connection between the perimeter of the opening of the liner 900 and the lid. Alternatively, the liner 900 may have a foam rim or cuff 916 about the opening with a drawstring. The foam rim 916 provides a comfortable seal around the body part being treated when the drawstring is tightened.

The liner 900 may also have a pressure release valve 914. The design of the pressure release valve 914 is not critical. Many different types are suitable. For example, the valve 914 can be a ball valve or a baffle valve such as a flap or butterfly baffle valve. Other valves are equally suitable, so long as they are capable of accurately setting the maximum release pressure. If desired the adjustable valve can be calibrated to show the pressure setting. In one embodiment, the maximum release pressure can be set at 22 mm Hg so that the pressure inside the liner 900 never surpasses that amount of pressure. The valve body is preferably made of any in expensive rigid plastic.

Coupled to the bottom of the chamber on its outside surface is an audio transducer or speaker 960. Transducer wires are connected to the speaker and threaded through the apparatus to form a connection with the control panel 962. A rigid plastic or metal collar with a hole is placed around the speaker 960 to protect the speaker 960 during use. The speaker 960 emits energy at a low frequency sound wave, of between about 1 Hz and about 1000 Hz. In one embodiment, the speaker 960 emits energy at about 60 Hz. This causes a therapeutic vibration on the chamber and a massaging effect on the patient's body part.

The components of the variable hyperoxia treatment apparatus are housed in a cart. A warm water reservoir 995 is contained at the bottom of the cart. A first hose is connected to the water pump 990 and the other end of the hose is secured and in fluid communication with the inside of the one or more chambers. A second hose (not shown) is connected to the water pump 990 and the other end of hose can be connected to a waste container or drain. Cables electrically couple the water pump to the control box. The reservoir 995 provides an opening that allows the reservoir to be filled with water.

The water may be kept at an optimal temperature with a portable heating unit (not shown) that is adjustable between a range of about 70°F to about 90°F. Alternatively a heating unit within the apparatus may be used (not shown) that is electrically coupled to the control panel 962 and can be controlled with a thermostat in the control panel 962.

The humidifier 980 is positioned above the warm water reservoir 995. The humidifier 980 is in fluid communication with a water reservoir 975 that has a removable lid to enable filling with fluid and/or medication. A medication reservoir 970 for receiving medications and/or medication dosage is in fluid communication with the humidifier 980 so that it may be mixed with fluid to create an adiabatic vapor or mist for treatment.

The humidifier 980 produces mist when the humidifier function on the control panel 962 is activated. The misting unit can be an adiabatic temperature controlled humidifier 980 or ultrasonic nebulizer 982. The humidifier 980 can generate room temperature mist or heated mist. The humidifier may further comprise a temperature controller 954 with an on/off switch and an indicator light that shows when the temperature controller 954 is on and at operating temperature. When the humidifier control valve 984 to the humidifier 980 is opened, the mist travels from the humidifier 980 into the treatment zone through a one-way valve in the liner 900. Warm mist temperature in the liner 900 can reach between about 77°F to about 82°F as measured by a temperature sensor. The humidity in the liner 900 can reach about 89% to about 91% as measured by a humidity sensor 986. The humidifier 980 has a transducer that generates ultrasonic energy in the ultrasonic nebulizer 982 at about 40 kHz to create an adiabatic/humid mist. Ultrasonic energy from the misting unit is not transmitted to the limb.

In another embodiment, the oxygen flow meter 944 and concentrator 942 and humidifier 980 are also in fluid communication with an outlet port that is in fluid communication 916 with a treatment chamber

remote to the cart. The treatment chamber 910/914 (Figure 11) comprises a pre-molded form adapted to encompass a non-limb body part such as a scalp, a thigh or the back. The chamber 910/914 is composed of a semi-rigid polymer having a cushioned perimeter edge for sealingly engaging the body part. Its configuration will depend on the area being treated. For example, a half domed shape may be desired for treating a particular location on the back while a helmet shaped chamber would be desirable for treating the scalp. The chamber may have at least two inlet ports, one for the humidified mist from the humidifier 980 and one for oxygen from the oxygen flow meter 944 and/or oxygen concentrator 942. There may be an additional outlet port (not shown) to allow for replacing the existing agents in the chamber with new or other agents. The treatment chamber 910/914 may further comprise UV/IR LEDs for illuminating the treatment area. The UV/IR LEDs are in electrical communication with the control panel 962. This electrical communication line may be affixed to or integrated within tubing 912 and has a connector near adapters 916 for connecting to the control panel 962. A disposable or autoclavable liner 900 having at least two one-way ports at 940 and 984 for receiving humidified mist and oxygen lines the chamber. The liner 900 may also have a pressure release valve 914. The perimeter edge of the liner 900 may have adhesive for affixing the liner 900 to the rim of the chamber before use.

The disclosure set forth above is provided to give those of ordinary skill in the art a complete disclosure and description of how to make and use embodiments of the compositions and methods of the present invention, and are not intended to limit the scope of what the inventors regard as their invention. Modifications of the above-described modes (for carrying out the invention that are obvious to persons of skill in the art) are intended to be within the scope of the following claims. All publications, patents, and patent applications cited in this specification are incorporated herein by reference in their entirety as if each such publication, patent or patent application were specifically and individually indicated to be incorporated herein by reference.

CLAIMS

Other embodiments are within the scope of the following claims:

1. A method for treating a wound, comprising: (a) introducing a human limb having a wound into a treatment chamber; (b) surrounding the limb in the treatment chamber with a mist containing water and an antibiotic; and (c) surrounding the limb in the treatment chamber with an O.sub.2-enriched gas without increasing the pressure around the foot to 22 mm Hg.

2. The method of claim 1, wherein the wound is a chronic lesion.

3. The method of claim 1, wherein the wound is a post-surgical infection, a gangrenous lesion, a decubitus ulcer, or a venous stasis.

4. The method of claim 1, wherein the wound is a skin ulceration due to amputation, skin graft, burn, or frostbite.

5. The method of claim 1, wherein the limb is a foot.

6. The method of claim 1, wherein the limb is a leg.

7. The method of claim 1, wherein the antibiotic is a topical antibiotic.

8. The method of claim 1, wherein the antibiotic is selected from betadine, isopropyl alcohol, bacitracin, and hydrogen peroxide, and combinations thereof.

9. The method of claim 1, wherein the antibiotic is ionic silver.

10. The method of claim 1, wherein the O_2-enriched gas displaces the mist.

11. The method of claim 1, wherein the O_2-enriched gas is substantially pure O.sub.2.

12. The method of claim 1 further comprising repeating the treatment periodically until the foot ulcer is healed.

13. The method of claim 1, wherein step (b) is performed for about 2 to about 30 minutes.

14. The method of claim 12, wherein step (b) is performed for approximately 15 minutes.

15. The method of claim 1, wherein step (c) is performed for about one minute to about 15 minutes.

16. The method of claim 14, wherein step (c) is performed for approximately 5 minutes.

17. The method of claim 1, wherein the mist is an adiabatic mist.

18. The method of claim 1, wherein steps (b) and (c) are performed sequentially multiple times in a single treatment.

19. The method of claim 17, wherein steps (b) and (c) are performed 4 times, the single treatment lasting approximately 80 minutes.

20. The method of claim 1 further comprising massaging the foot with low frequency sound waves or heating the limb with pulsed light.

21. A method for treating an individual having an infection, comprising: (a) introducing a body part of said individual having an infection into a treatment chamber; (b) surrounding said body part in said treatment chamber with a mist containing water and a medication; and (c) surrounding said body part in said treatment chamber with an O_2-enriched gas without increasing the pressure around the body part to 22 mm Hg.

22. The method according to claim 21, wherein said infection is a bacterial or fungal infection.

23. The method according to claim 21, wherein said bacterial infection causes acne vulgaris (Others).

24. The method according to claim 23, wherein the bacteria that causes acne vulgaris is *Propionibacterium acnes.*

25. The method according to claim 21, wherein said fungal infection causes Athlete's foot (Others).

26. The method according to claim 21, wherein the fungus that causes Athlete's foot is of the genus *Trichophyton.*

27. The method according to claim 21, wherein said body part is an appendage.

28. The method according to claim 21, wherein said appendage is a hand, a fore arm, a hand and fore arm, a hand, forearm and upper arm, a foot, a calf, a foot and calf, or a foot, calf and thigh.

29. The method according to claim 21, wherein said body part is the face.

30. The method according to claim 21, wherein said medication is benzoyl peroxide, salicylic acid, glycolic acid, sulfur or azelaic acid (Incorporate list of medications for acne).

31. The method according to claim 21, wherein said medication is (RS)-1-(2-(2,4-Dichlorobenzyloxy)-2-(2,4-dichlorophenyl)ethyl)-1H-imidazole (Miconazole), 1-[(2-chlorophenyl)(diphenyl)methyl]-1H-imidazole (Clotrimazole), [(2E)-6,6-dimethylhept-2-en-4-yn-1-yl](methyl)(naphthalen-1-ylmethyl)amine (Terbinafine), O-2-naphthyl methyl(3-methylphenyl)thiocarbamate (Tolnaftate) or [(4-tert-butylphenyl)methyl](methyl)(naphthalen-1-ylmethyl)amine (Butenafine) (Incorporate list of medications for Athlete's foot).

32. The method according to claim 21, wherein said medication is betadine, isopropyl alcohol, bacitracin, and hydrogen peroxide, and combinations thereof (Any others that may be specific to an injury?).

33. The method according to claim 21, wherein said O_2-enriched gas displaces said mist.

34. The method according to claim 21, wherein said O_2-enriched gas is substantially pure O_2.

35. The methods according to claim 21, further comprising administering oxygen to said individual during treatment.

36. The method according to claim 21, further comprising repeating said treatment periodically until said infection is eliminated.

37. The method according to claim 21, wherein the mist is an adiabatic mist.

38. The method according to claim 21, further comprising illuminating said human body part within said treatment zone with ultraviolet light.

39. The method according to claim 21, further comprising illuminating said human body part within said treatment zone with infrared light.

40. The method according to claim 21, wherein steps (b) and (c) are performed sequentially multiple times in a single treatment.

41. The method according to claim 21, wherein steps (b) and (c) are performed 4 times, the single treatment lasting approximately 80 minutes.

42. A method for treating a medical condition, comprising: (a) introducing a human body part having a medical condition into a treatment chamber; (b) surrounding said body part in said treatment chamber with a mist containing water and a medication; and (c) surrounding said body part in said treatment chamber with an O_2-enriched gas without increasing the pressure around the body part to 22 mm Hg.

43. The method according to claim 42, wherein said body part is the scalp.

44. The method according to claim 42, wherein said medical condition is alopecia.

45. The method according to claim 42, wherein said alopecia is alopecia areata or alopecia totalis.

46. The method according to claim 42, wherein said medication is 6-piperidin-1-ylpyrimidine-2,4-diamine 3-oxide (Minoxidil), N-(1,1-dimethylethyl)-3-oxo-(5α,17β)-4-azaandrost-1-ene-17-carboxamide (Finasteride), (11β,16α)-9-fluoro-11,16,17,21-tetrahydroxypregna-1,4-diene-3,20-dione (Triamcinolone), 17-hydroxy-7α-mercapto-3-oxo-17α-pregn-4-ene-21-carboxylic acid, γ-lactone acetate (Spironolactone) or combinations thereof.

47. The method according to claim 42, wherein said O_2-enriched gas displaces said mist.

48. The method according to claim 42, wherein said O_2-enriched gas is substantially pure O_2.

49. The methods according to claim 42, further comprising administering oxygen to said individual during treatment.

50. The method according to claim 42, further comprising repeating said treatment periodically until said medical condition is improved.

51. The method according to claim 42, wherein steps (b) and (c) are performed sequentially multiple times in a single treatment.

52. The method according to claim 42, wherein steps (b) and (c) are performed 4 times, the single treatment lasting approximately 80 minutes.

53. The method of claim 42, wherein the mist is an adiabatic mist.

54. A variable hyperoxia treatment apparatus, comprising: one or more treatment chambers being sized to receive a human body part; a removable and substantially gas impermeable liner that lines each of said chambers and is adapted to form a treatment zone around said human body part; a mixture tank that holds a humidifying agent and has a medicinal filling port for receiving medications to be mixed with said humidifying agent, an oxygen concentrator has a O_2 receiving port for receiving oxygen from an oxygen source and an O_2 dispensing port, said mixture tank and oxygen concentrator are in communication with said gas impermeable liner within said treatment chambers

wherein said one or more treatment chambers have an inlet port for receiving fluid and an outlet port for dispensing said fluid.

55. The variable hyperoxia treatment apparatus according to claim 54, wherein the electric components and said mixture tank are separated from said oxygen concentrator and oxygen receiving port by said one or more treatment chambers.

56. The variable hyperoxia treatment apparatus according to claim 54, wherein said gas impermeable liner comprises a sterile plastic material.

57. The variable hyperoxia treatment apparatus according to claim 54, further comprising a speaker; wherein said speaker configured to deliver low frequency sound waves to said one or more chambers when water is introduced into said one or more chambers.

58. The variable hyperoxia treatment apparatus according to claim 54, further comprising a pump configured to pump water into and/or out of said one or more chambers.

59. The variable hyperoxia treatment apparatus according to claim 54, further comprising a humidifier in fluid communication with said mixture tank.

60. The variable hyperoxia treatment apparatus according to claim 54, wherein said liner further comprises a pressure release valve fluidly connecting said treatment zone to said one or more chambers.

61. The variable hyperoxia treatment apparatus according to claim 54, wherein said liner further comprises a one-way valve in fluid connection with said mixture tank and/or a one-way valve in gas tight connection with said oxygen concentrator.

62. The variable hyperoxia treatment apparatus according to claim 54, further comprising a cuff, wherein said cuff is removably coupled to said opening of said one or more treatment chambers and sized to sealingly engage a human body part when said human body part is engaged by said one or more treatment chambers.

63. The variable hyperoxia treatment apparatus according to claim 62, wherein said cuff comprises an open cell material configured to naturally leak fluid, thereby forming a baffle for said treatment zone.

64. The variable hyperoxia treatment apparatus according to claim 54, further comprising a temperature sensor in fluid communication with said treatment zone.

65. The variable hyperoxia treatment apparatus according to claim 54, further comprising a humidity sensor in fluid communication with said treatment zone.

66. The variable hyperoxia treatment apparatus according to claim 54, further comprising a pressure sensor in fluid communication with said treatment zone.

67. The variable hyperoxia treatment apparatus according to claim 54, further comprising a nasal cannula and/or facemask in communication with said oxygen concentrator for administering oxygen to an individual during treatment.

68. The variable hyperoxia treatment apparatus according to claim 54, further comprising an oxygen regulator valve.

69. The variable hyperoxia treatment apparatus according to claim 54, further comprising ultraviolet light emitting diodes to provide illumination to the surface of said human body part within said treatment zone.

70. The variable hyperoxia treatment apparatus according to claim 54, further comprising infrared light emitting diodes to provide illumination to the surface of said human body part within said treatment zone.

71. A variable hyperoxia therapy treatment system, comprising: one or more treatment chambers being sized to receive a human body part, said one or more treatment chambers each having at least one opening; a removable and substantially gas impermeable liner that lines each of said chambers and

forms a treatment zone around said human body part; a humidifier configured to humidify a solution of water that may include one or more medications, said humidifier in fluid communication with said treatment zone; an O_2 source in fluid communication with the treatment zone; and a control panel.

72. The variable hyperoxia therapy treatment system according to claim 71, wherein the electric components and said humidifier are separated from said oxygen source by said one or more treatment chambers.

73. The variable hyperoxia therapy treatment system according to claim 71, wherein at least one of said one or more treatment chambers may be affixed securely to a human body part or wherein a human body part may be inserted into said one or more chambers for treatment.

74. The variable hyperoxia therapy treatment system according to claim 71, wherein said humidifier is an adiabatic humidifier.

75. The variable hyperoxia therapy treatment system according to claim 71, wherein said adiabatic humidifier is configured to use ultrasonic energy to form a mist from said solution of water that may include one or more medications.

76. The variable hyperoxia therapy treatment system according to claim 71, wherein said control panel comprises: a humidifier control configured to control the operation of said humidifier; and a master power switch.

77. The variable hyperoxia therapy treatment system according to claim 71, wherein said liner further comprises a one-way valve in fluid connection with said humidifier and/or a one-way valve in gas tight connection with said oxygen source.

78. The variable hyperoxia therapy treatment system according to claim 71, further comprising a source of fluid, said source in fluid communication with said one or more chambers.

79. The variable hyperoxia therapy treatment system according to claim 71, further comprising a pump configured to pump fluid out of said one or more chambers.

80. The variable hyperoxia therapy treatment system according to claim 71, wherein said control panel comprises a manual control switch configured to permit manual operation of said system.

81. The variable hyperoxia therapy treatment system according to claim 71, wherein the control panel comprises an auto control switch configured to permit automatic operation of said system according to a predetermined regimen.

82. The variable hyperoxia therapy treatment system according to claim 81, wherein said auto control switch comprises a plurality of automatic settings corresponding to a plurality of predetermined regimens.

83. The variable hyperoxia therapy treatment system according to claim 71, further comprising a foam cuff adapted to form a seal about said human body part and said opening of said one or more chambers.

84. The variable hyperoxia therapy treatment system according to claim 83, wherein said foam cuff comprises an open cell material configured to slowly leak fluid.

85. The variable hyperoxia therapy treatment system according to claim 83, further comprising a sensor in communication with said foam cuff wherein the position of said foam cuff when fitted about said human body part establishes a volume range of humidified solution containing one or more medications to be dispensed into said liner for treatment of said body part.

86. The variable hyperoxia therapy treatment system according to claim 71, further comprising an oximeter in electrical communication with control circuitry integrated with said control panel.

87. The variable hyperoxia therapy treatment system according to claim 71, further comprising a pressure sensor in communication with said treatment zone.

88. The variable hyperoxia therapy treatment system according to claim 71, further comprising a humidity sensor in communication with said treatment zone.

89. The variable hyperoxia therapy treatment system according to claim 71, further comprising a temperature sensor in communication with said treatment zone.

90. The variable hyperoxia therapy treatment system according to claim 71, further comprising ultraviolet light emitting diodes to provide illumination to the surface of said human body part within said treatment zone.

91. The variable hyperoxia therapy treatment system according to claim 71, further comprising infrared light emitting diodes to provide illumination to the surface of said human body part within said treatment zone.

92. The variable hyperoxia treatment apparatus according to claim 71, further comprising a nasal cannula or facemask in communication with said oxygen source for administering oxygen to an individual during treatment.

93. The variable hyperoxia therapy treatment system according to claim 71, further comprising an O_2 concentrator.

94. The variable hyperoxia therapy treatment system according to claim 71, further comprising a wireless transmitter adapted to transmit data.

95. The variable hyperoxia therapy treatment system according to claim 71, further comprising a barcode data reader.

Figure 1

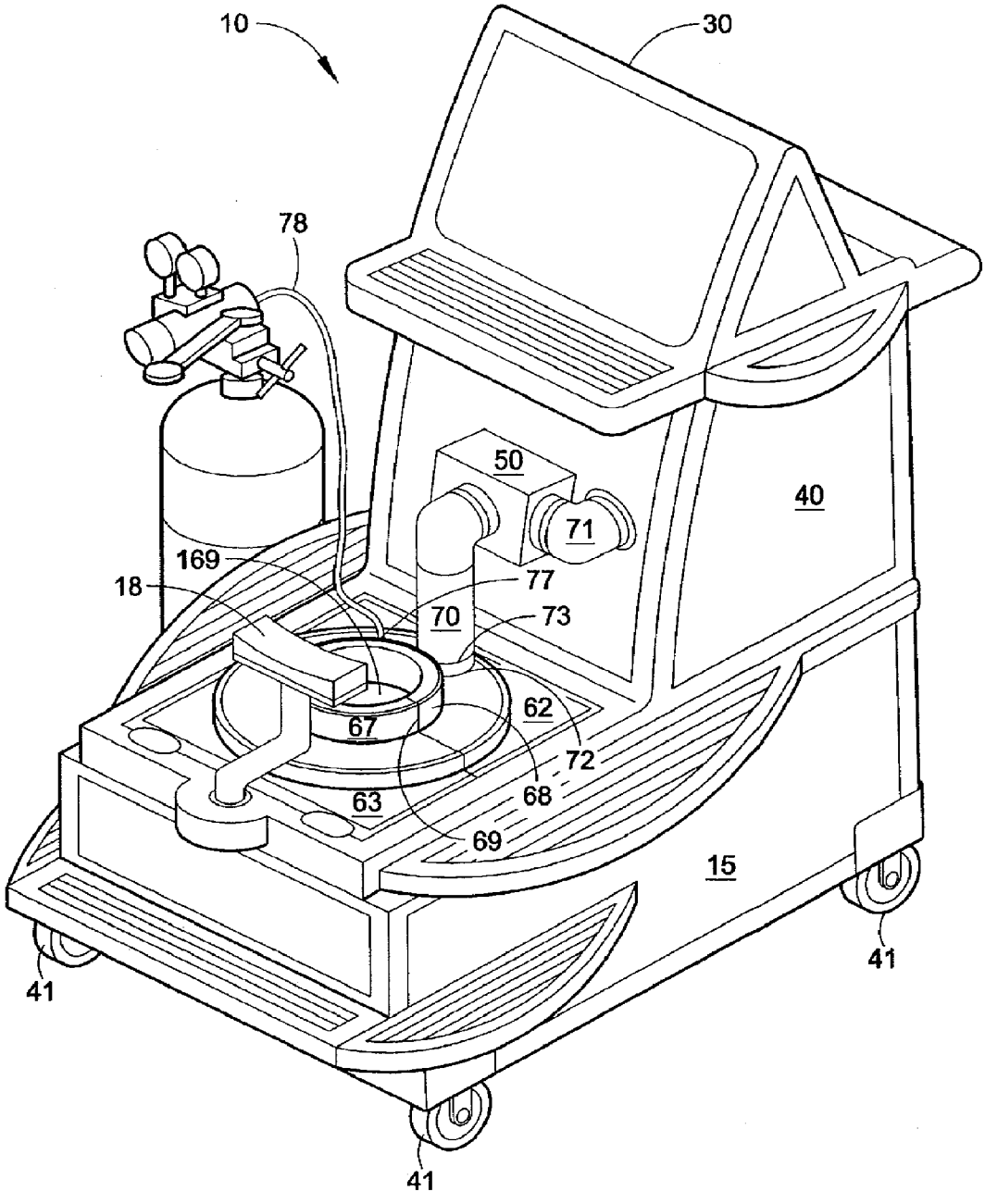
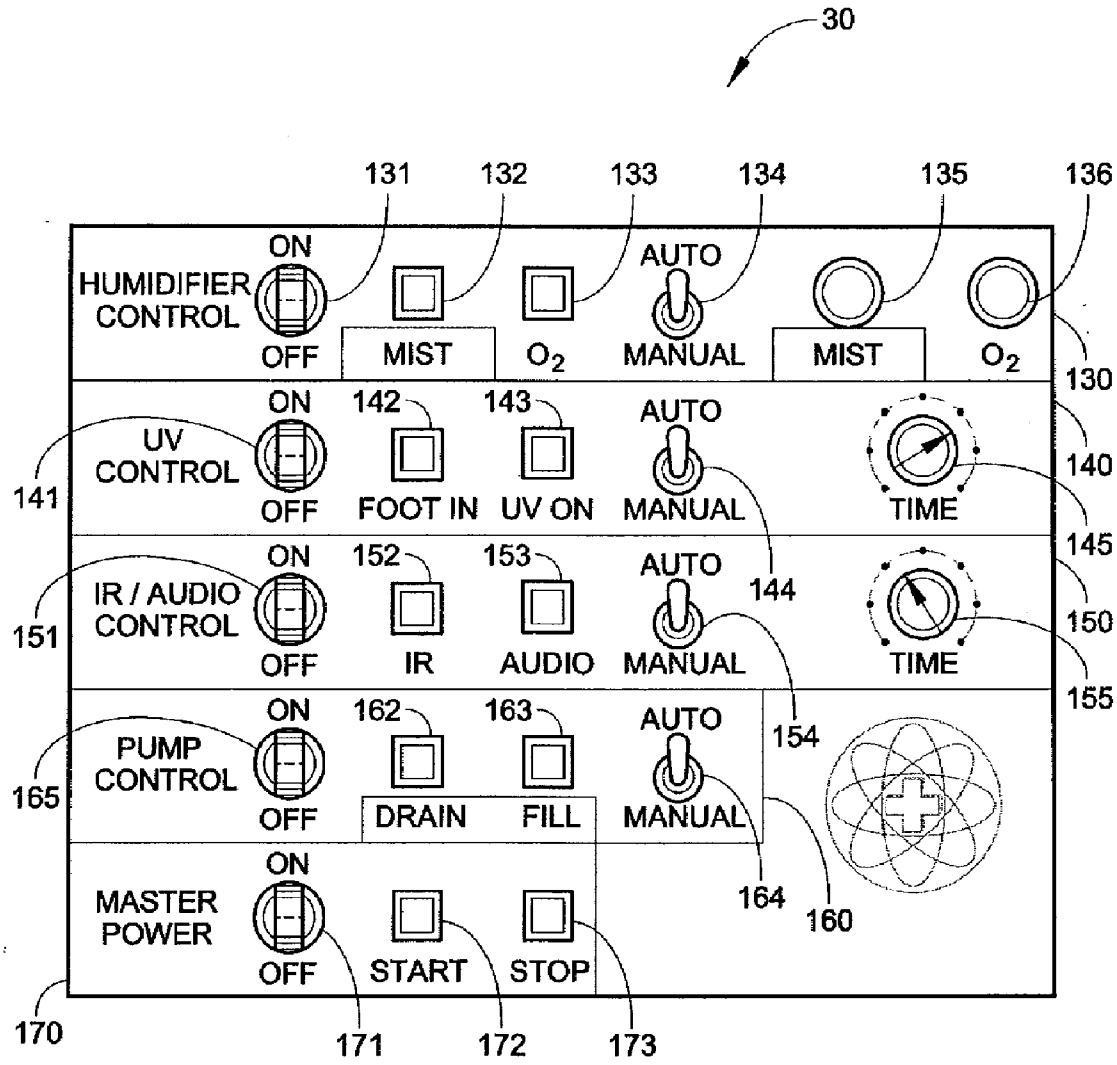


Figure 2


30
131
132
133
134
135
136
ON
HUMIDIFIER CONTROL
OFF
MIST
O_2
AUTO
MANUAL
MIST
O_2
130
ON
UV CONTROL
OFF
142
143
FOOT IN
UV ON
AUTO
MANUAL
TIME
140
141
145
ON
IR / AUDIO CONTROL
OFF
152
153
IR
AUDIO
AUTO
MANUAL
144
TIME
150
151
155
ON
PUMP CONTROL
OFF
162
163
DRAIN
FILL
AUTO
MANUAL
154
165
164
160
ON
MASTER POWER
OFF
START
STOP
170
171
172
173

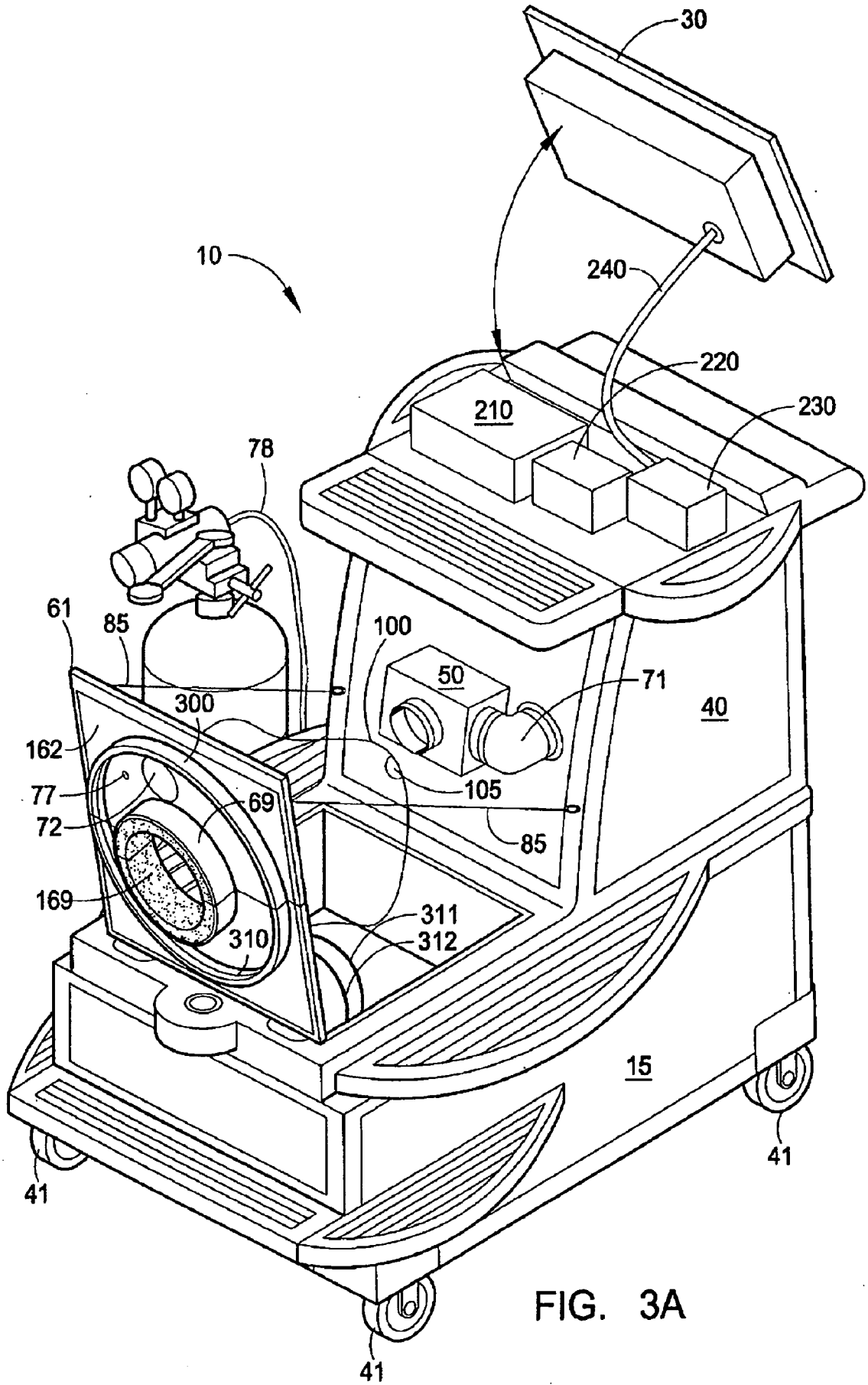

30
10
240
220
210
230
78
61
85
100
50
71
40
300
162
77
69
105
72
85
169
311
312
310
15
41
41
41

FIG. 3A

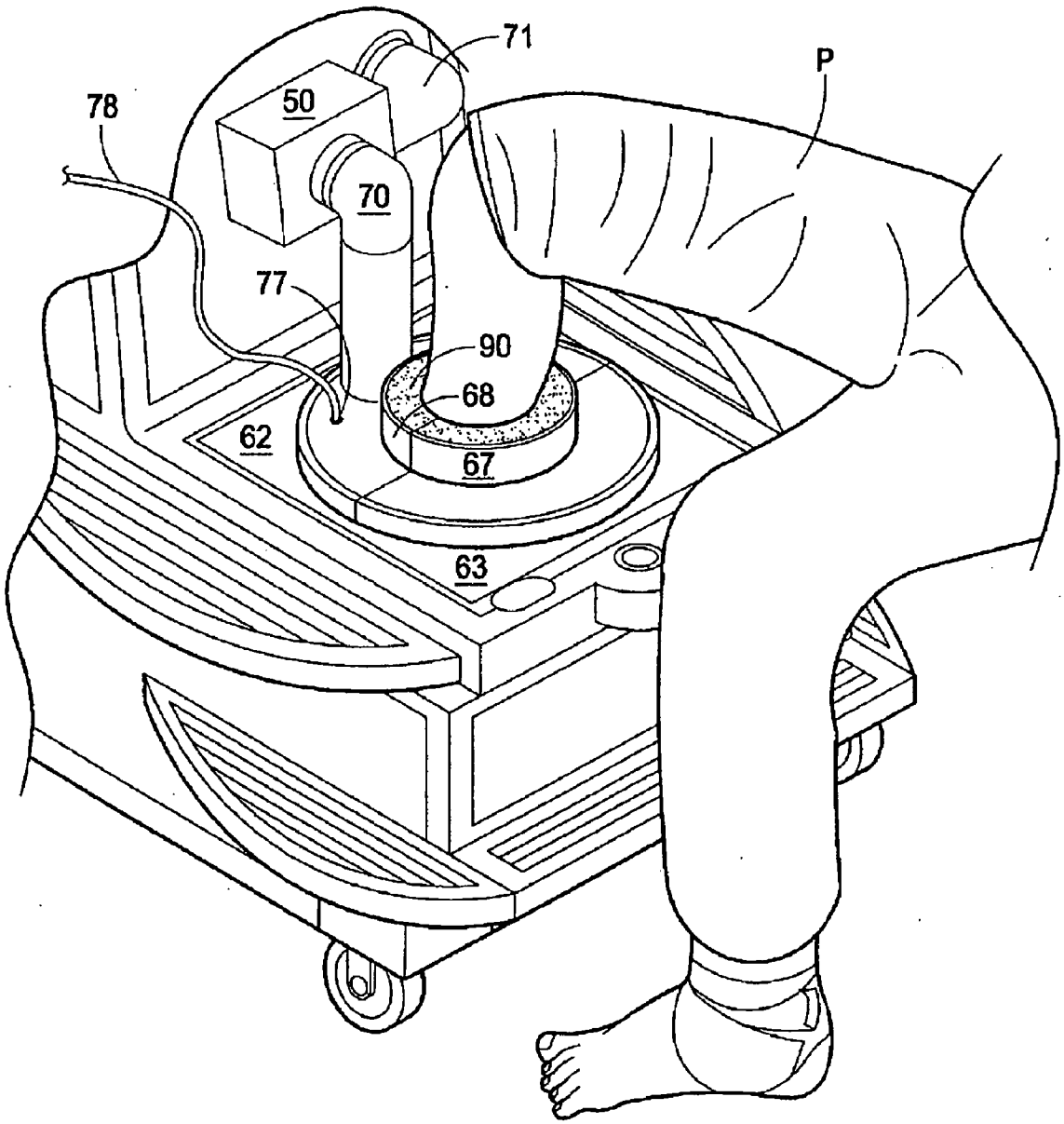


FIG. 3B

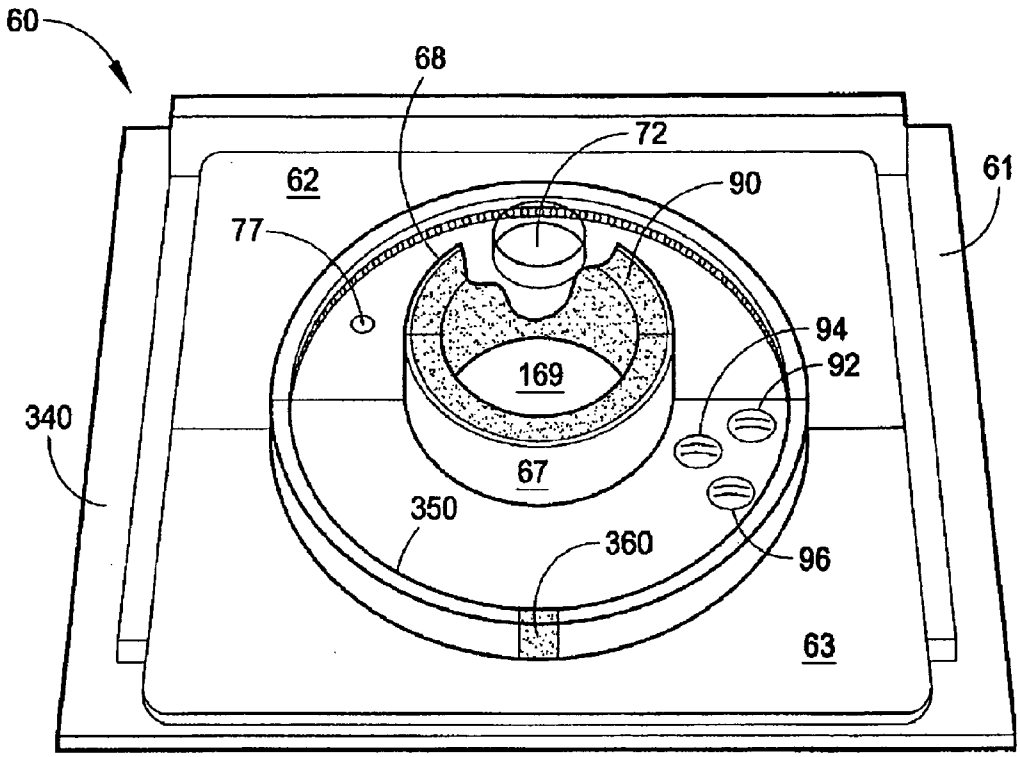

60
68
72
62
90
61
77
94
92
169
340
67
350
360
96
63

FIG. 4A

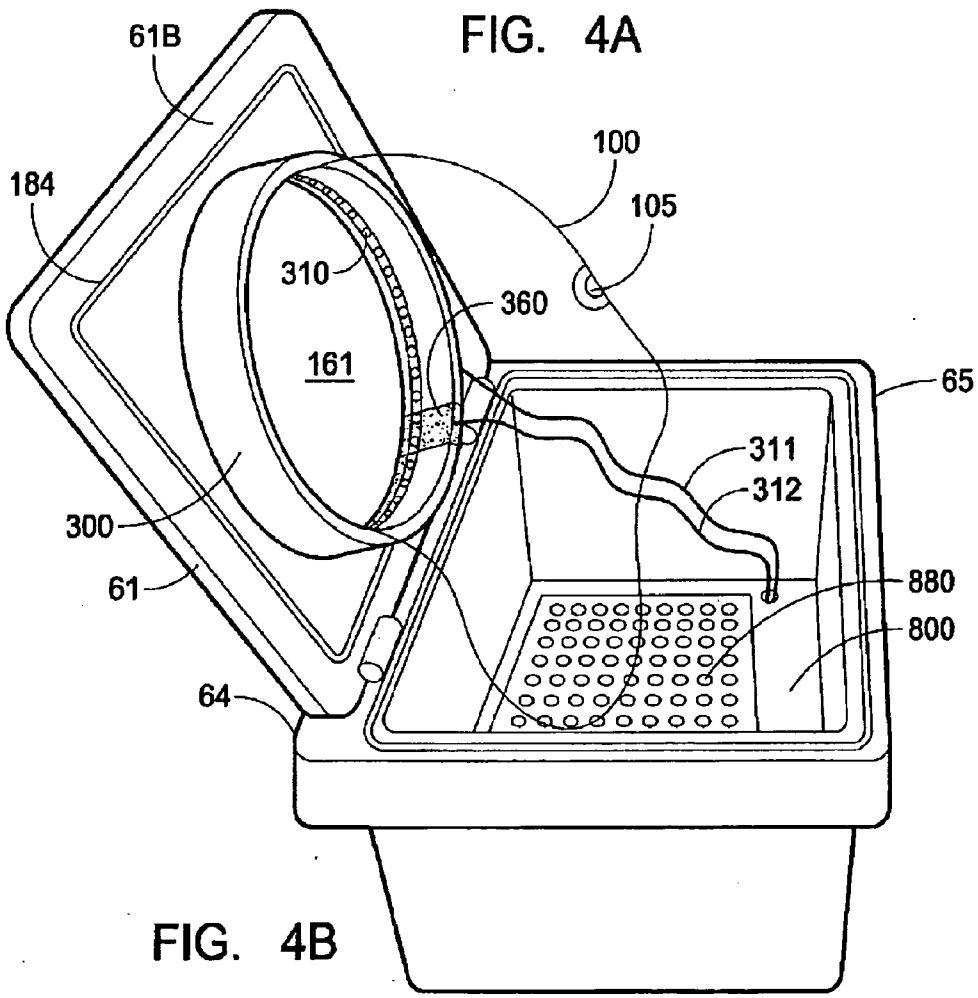

61B
100
184
105
310
360
161
65
311
312
300
880
61
800
64

FIG. 4B

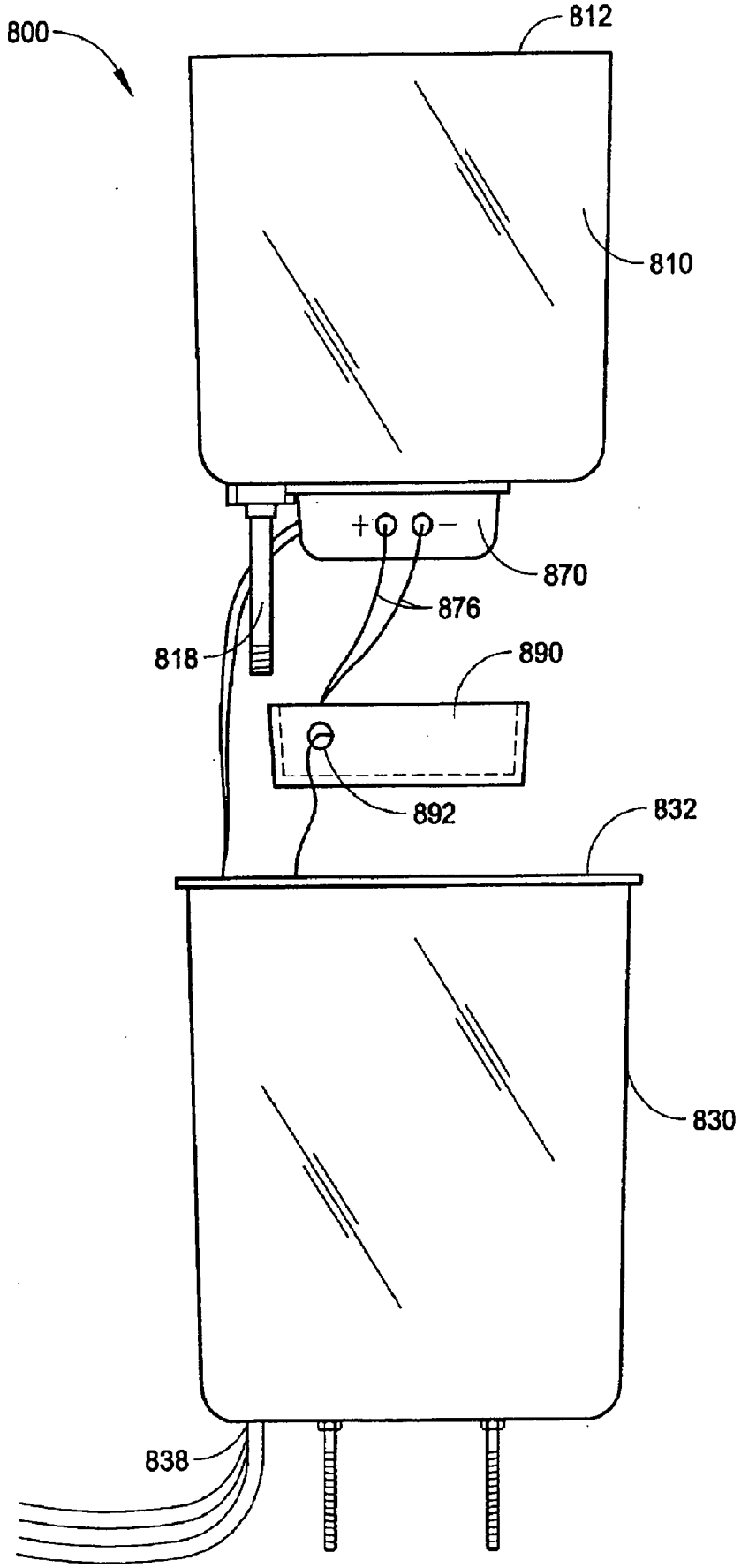


FIG. 5

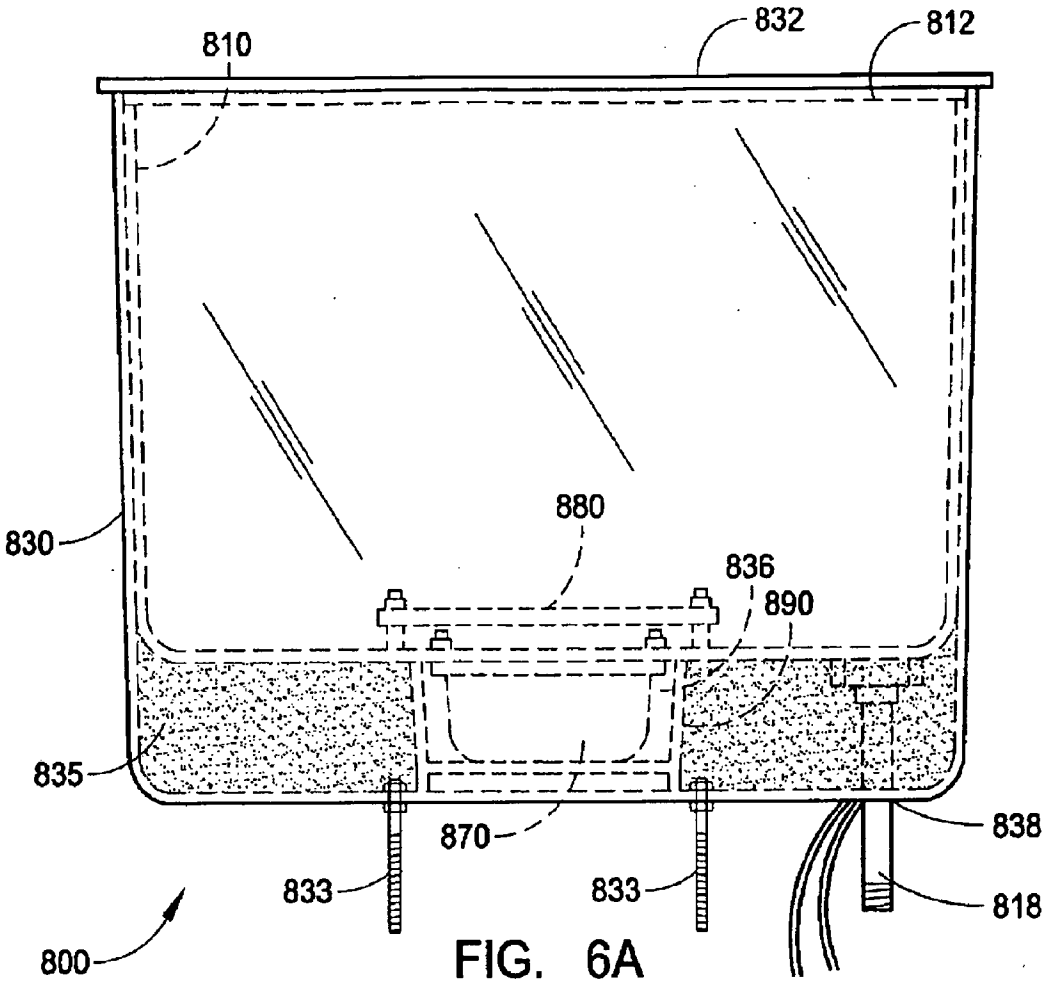

832
812
810
880
830
836
890
835
870
838
833
833
818
800

FIG. 6A

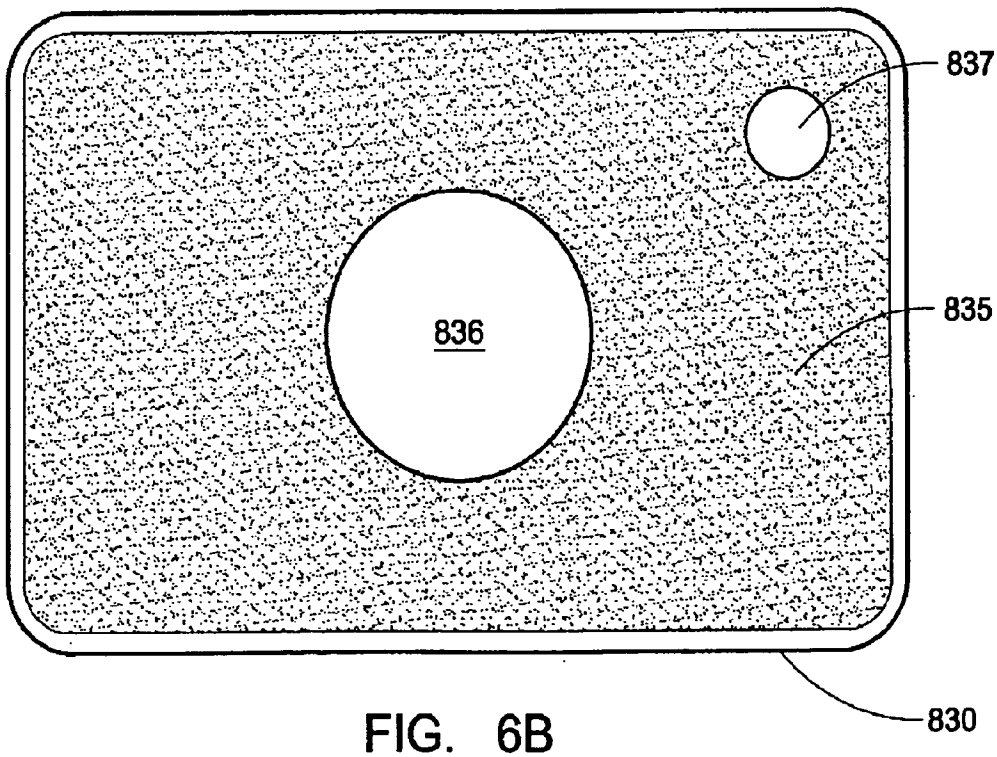

837
836
835
830

FIG. 6B

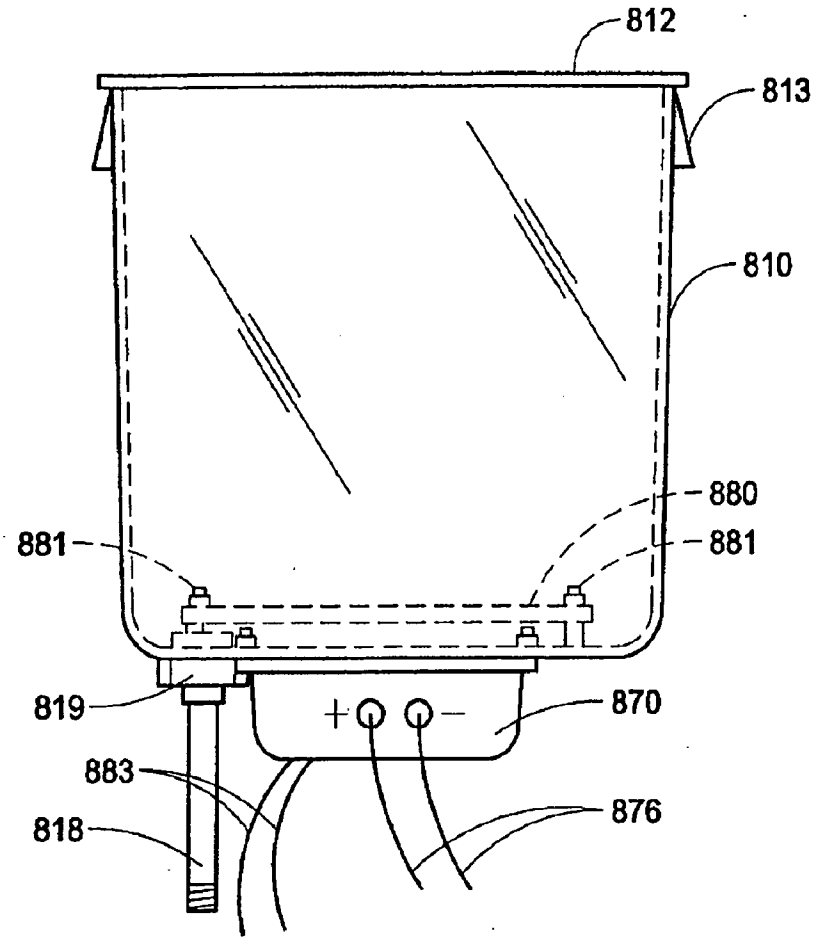

812
813
810
880
881
881
819
870
883
876
818

FIG. 7A

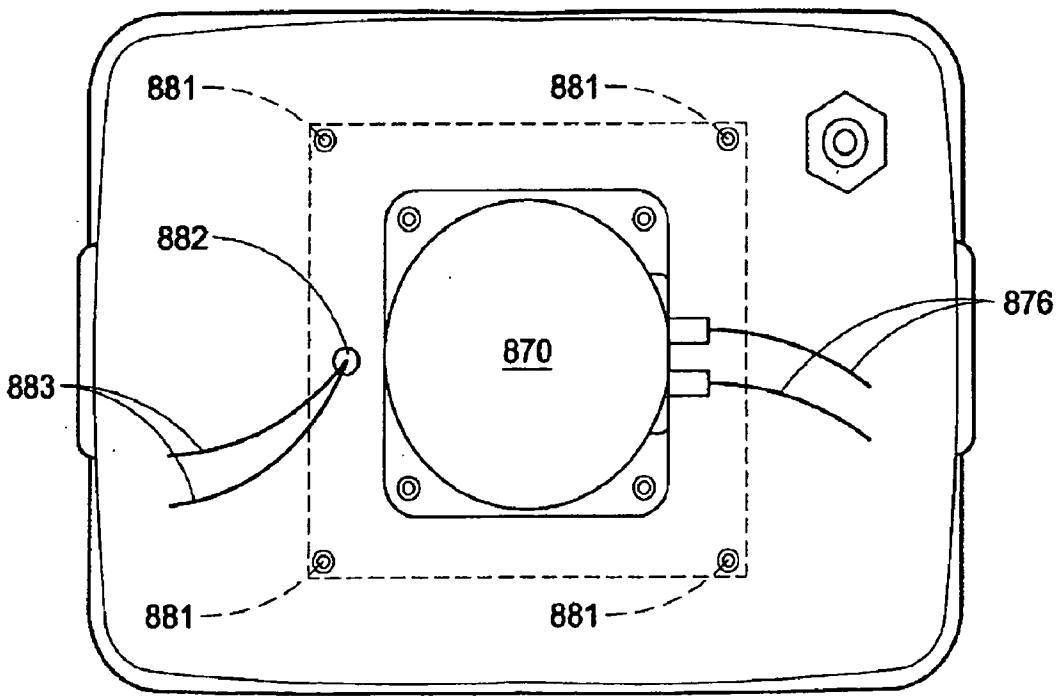

881
881
882
870
876
883
881
881

FIG. 7B

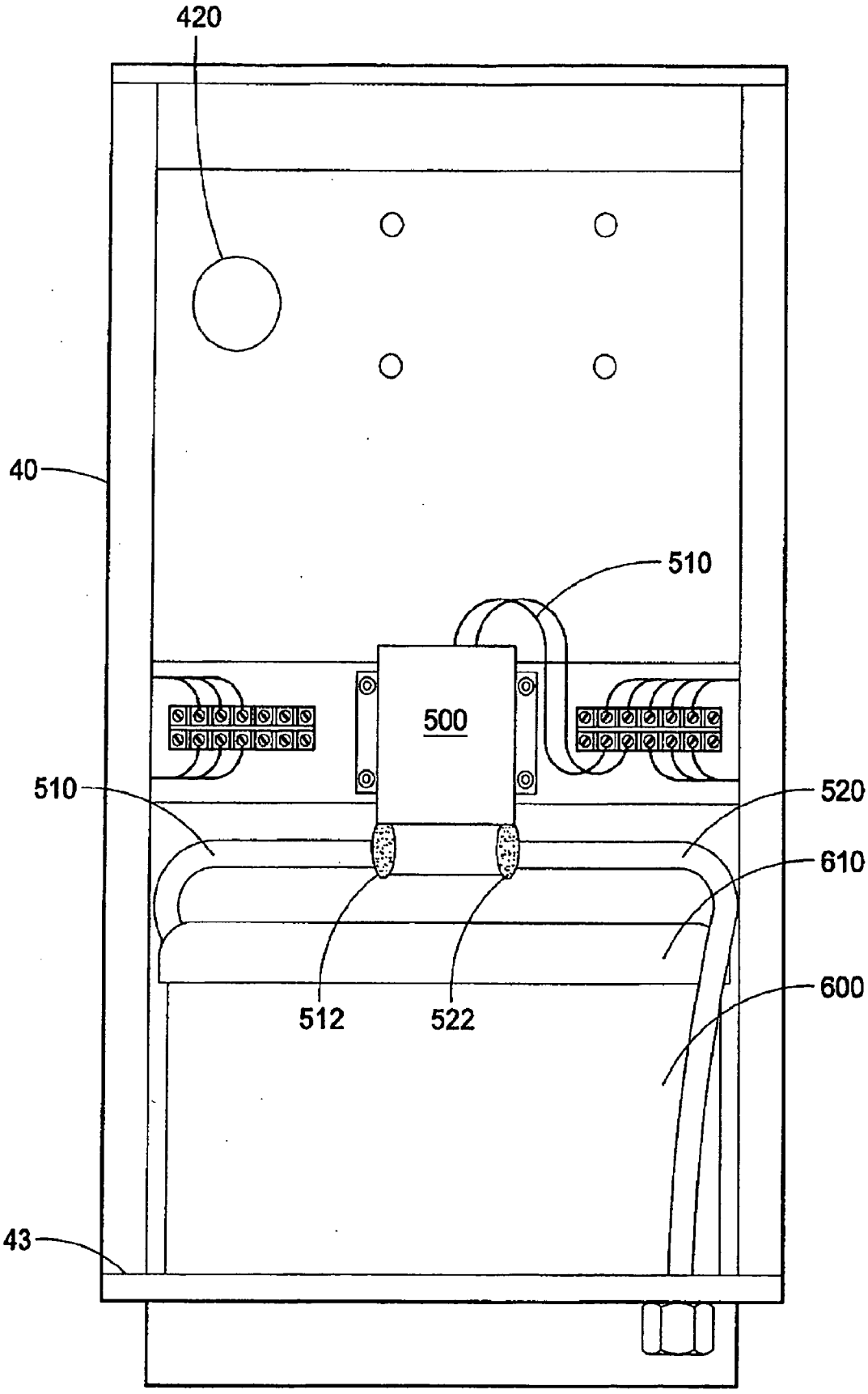


FIG. 8A

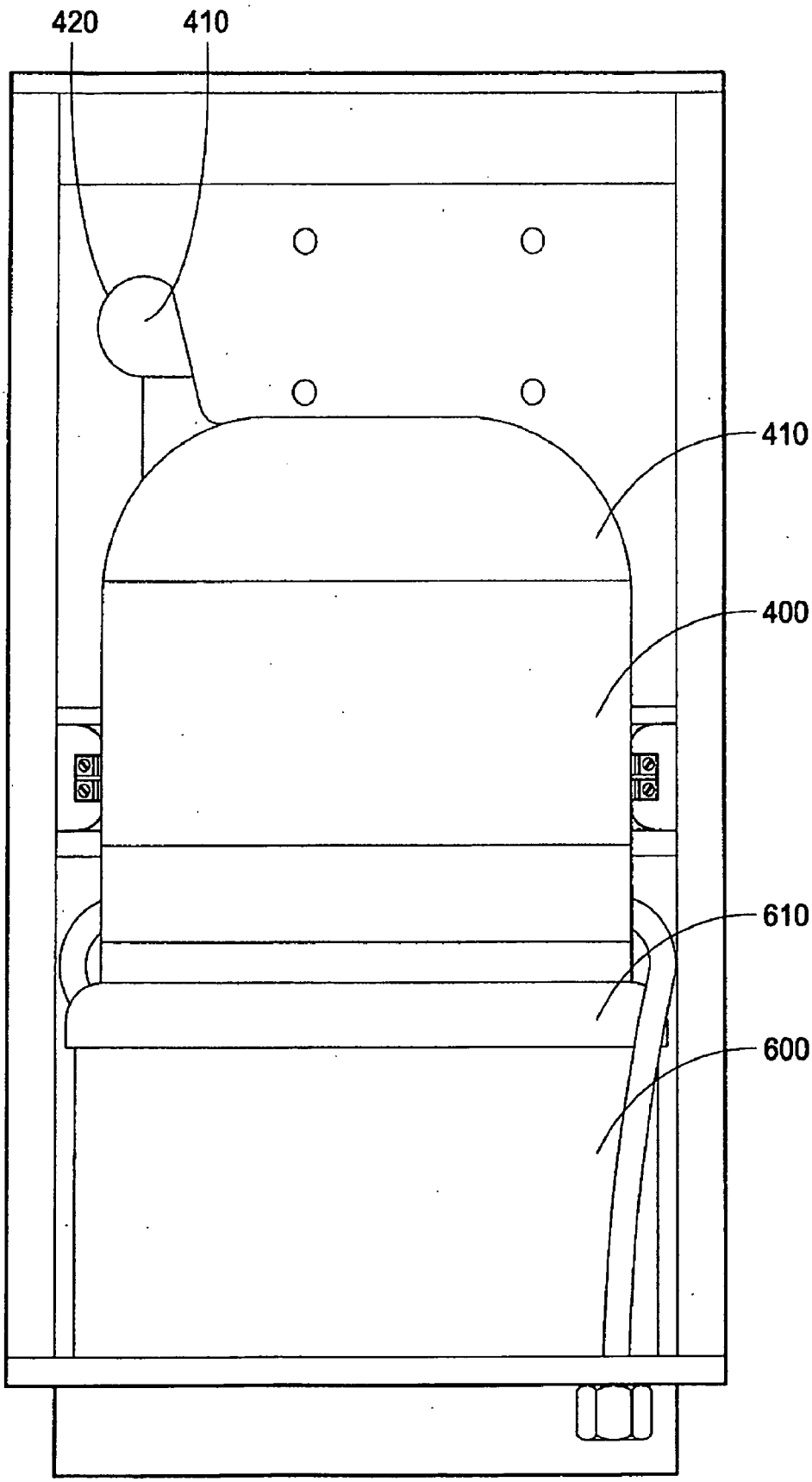


FIG. 8B

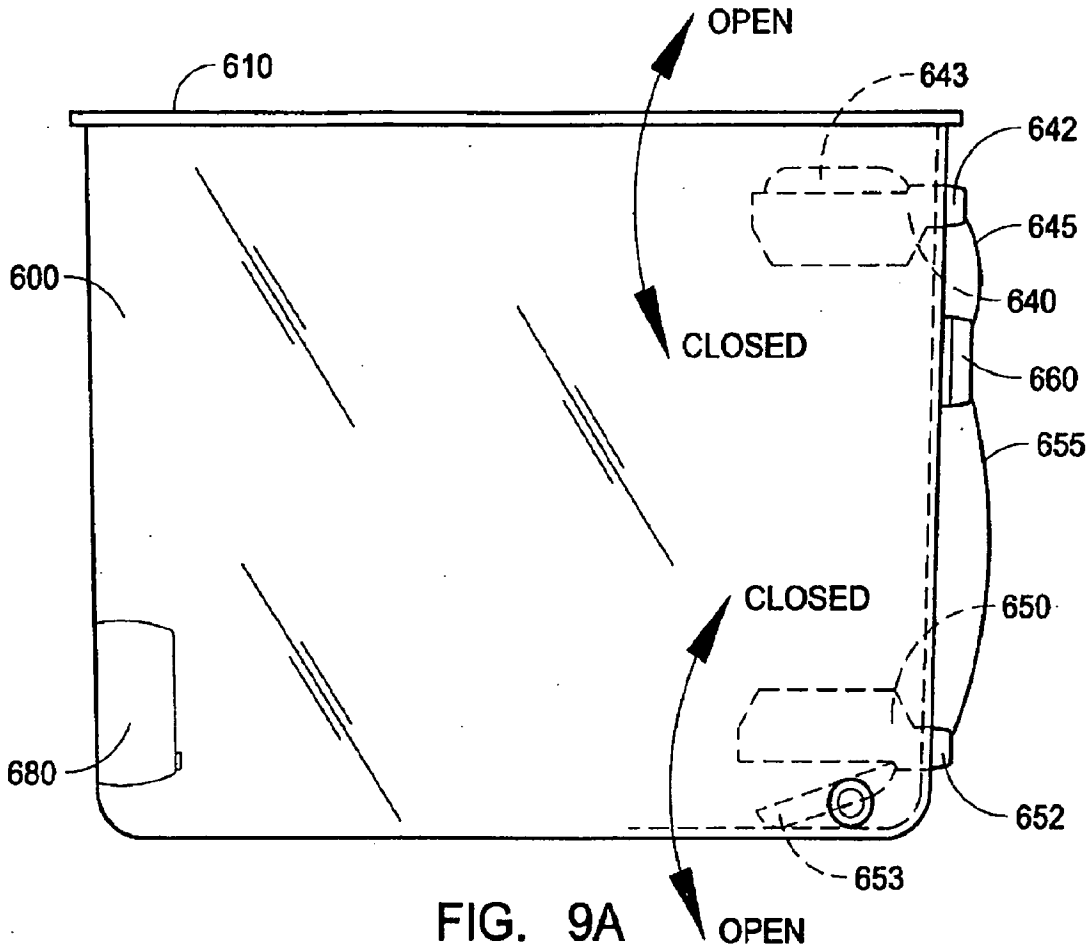

OPEN
610
643
642
645
600
640
CLOSED
660
655
CLOSED
650
680
652
653
OPEN

FIG. 9A

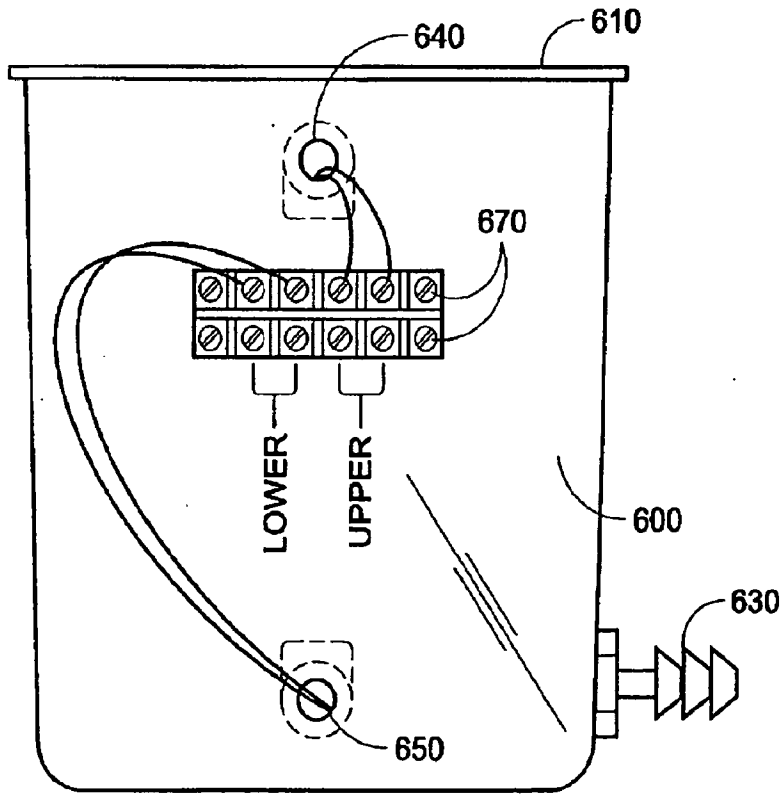

640
610
670
LOWER
UPPER
600
630
650

FIG. 9B

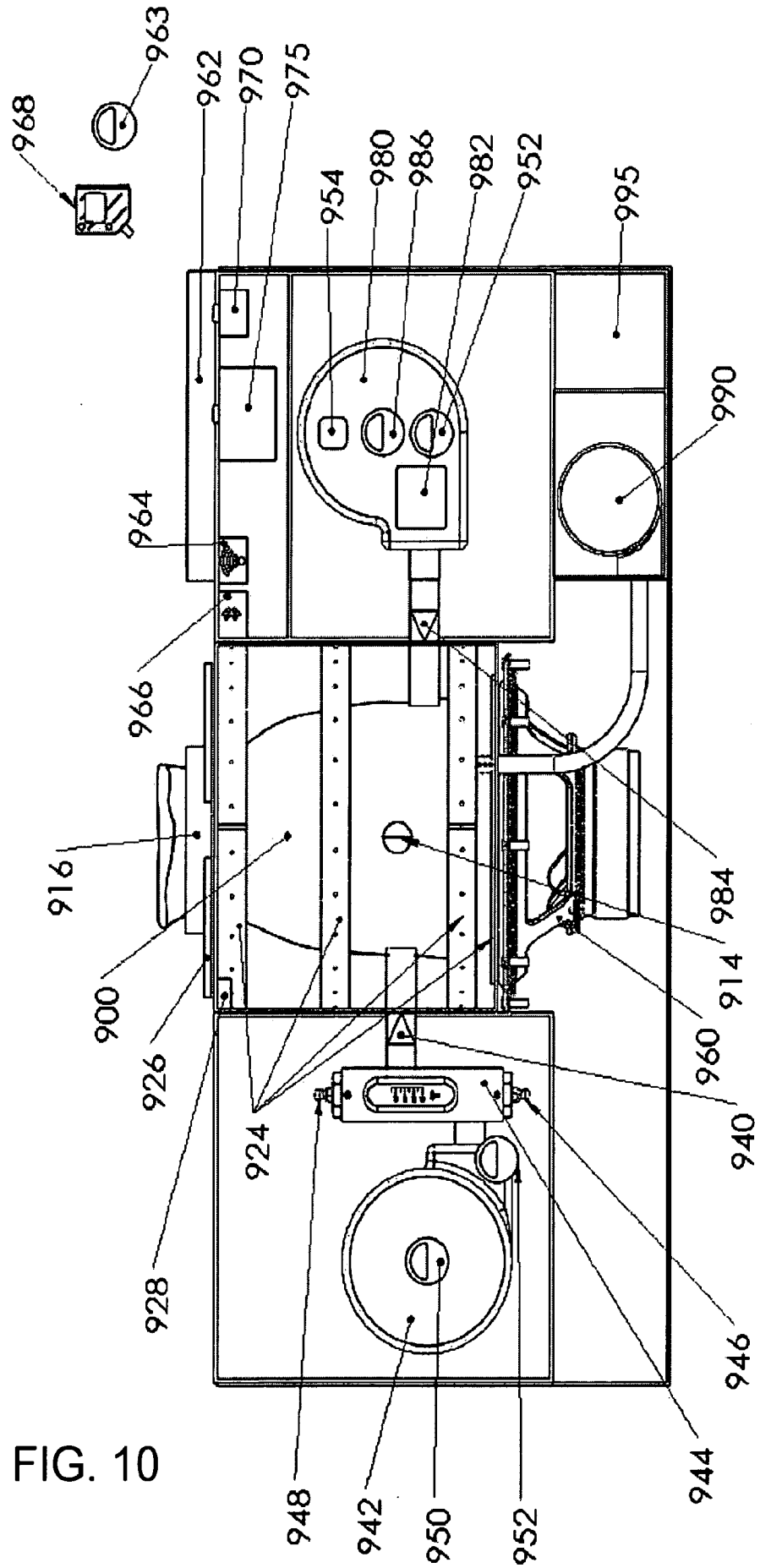

963
962
970
975
968
980
986
982
952
954
995
990
964
966
916
984
914
900
926
960
940
924
928
946
944
948
942
950
952

FIG. 10

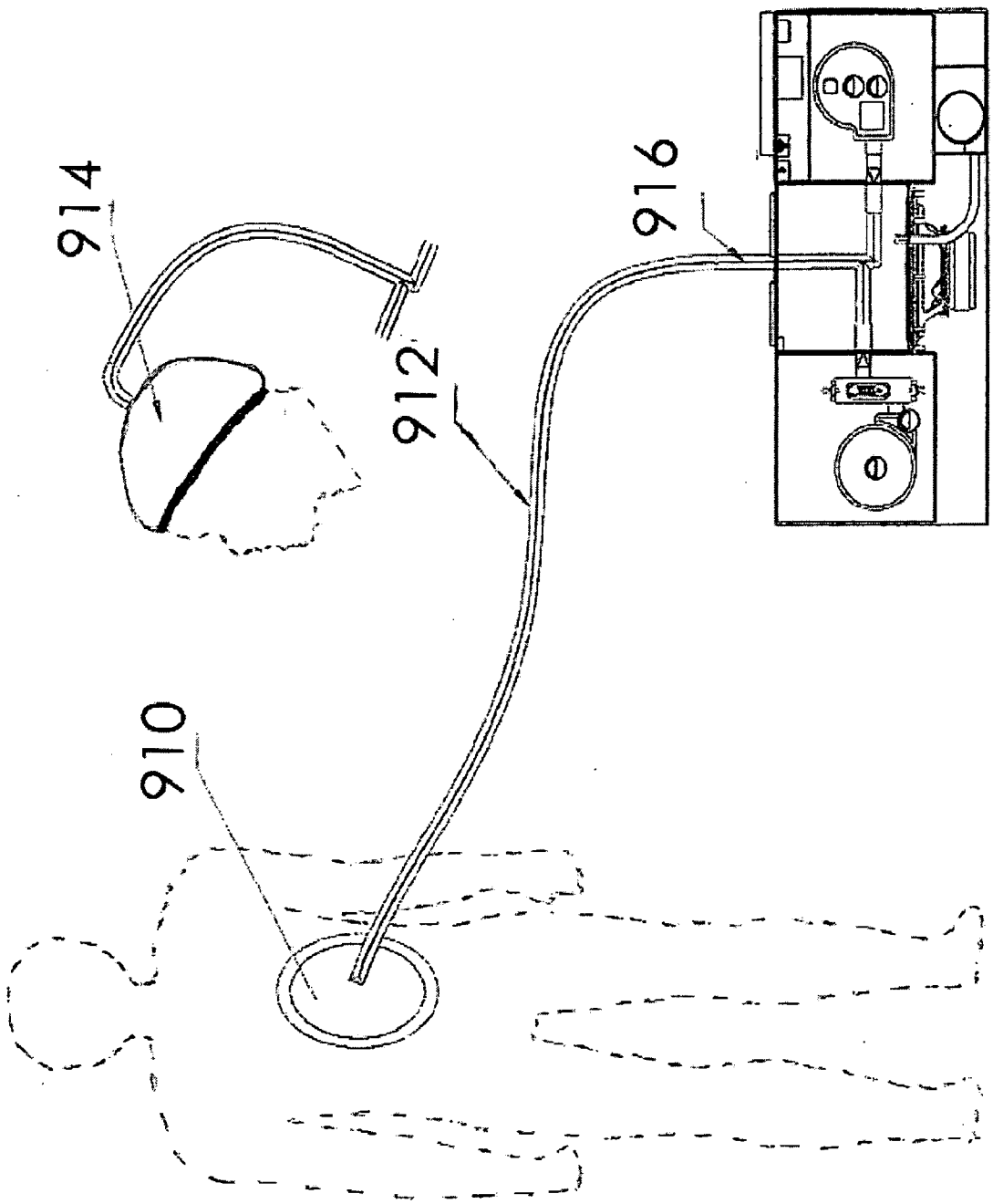


FIG. 11

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2013/048801

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61M 37/00 (2014.01)
USPC - 604/20
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)
IPC(8) - A61M 35/00, 37/00; A61N 5/06; G06K 7/10 (2014.01)
USPC - 128/200.14; 601/9,11,12; 604/20, 23, 24, 289, 290, 500; 606/9

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
CPC - A61M 35/00, 37/00; A61N 5/06; G06K 7/10 (2014.01)

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2010/0022941 A1 (PELKUS) 28 January 2010 (28.01.2010) entire document	1-22, 27, 28, 32-34, 36-42, 47, 48, 50-66, 68-84, 86-91, 93-95
Y		23-26, 29-31, 35, 43-46, 49, 67, 85, 92
Y	US 2008/0091179 A1 (DURKIN et al) 17 April 2008 (17.04.2008) entire document	23, 24, 29
Y	US 2009/0234270 A1 (LOEBEL et al) 17 September 2009 (17.09.2009) entire document	25, 26
Y	WO 2011/061479 A1 (BURT et al) 26 May 2011 (26.05.2011) entire document	30
Y	US 2005/0107766 A1 (OTT et al) 19 May 2005 (19.05.2005) entire document	31
Y	US 2007/0286809 A1 (WILLIAMS et al) 13 December 2007 (13.12.2007) entire document	35, 49, 67, 92
Y	US 5,228,431 A (GIARRETTO) 20 July 1993 (20.07.1993) entire document	43, 44, 46
Y	US 2003/0023283 A1 (MCDANIEL) 30 January 2003 (30.01.2003) entire document	45
Y	US 2012/0302976 A1 (LOCKE et al) 29 November 2012 (29.11.2012) entire document	85

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

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
16 January 2014	31 JAN 2014
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2013/048801

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

See Extra Sheet

1. ☒ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2013/048801

Continuation of Box III

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I, claims 1-53 are drawn to a method for treating a wound.

Group II, claims 54-95 are drawn to a variable hyperoxia treatment apparatus.

The inventions listed as Groups I - II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the special technical features of Group I, surrounding the limb in the treatment chamber with a mist containing water and an antibiotic; and surrounding the limb in the treatment chamber with an O.sub.2-enriched gas without increasing the pressure around the foot to 22 mm Hg., are not present in Group II; and the special technical features of Group II, a removable and substantially gas impermeable liner that lines each of said chambers; said mixture tank and oxygen concentrator are in communication with said gas impermeable liner within said treatment chambers wherein said one or more treatment chambers have an inlet port for receiving fluid and an outlet port for dispensing said fluid, are not present in Group I.

Groups I and II share the technical features of a treatment chamber containing a mist mixed with antibiotic/medication and O2. However, these shared technical features do not represent a contribution over the prior art. Specifically, US 8,241,258 B2 to Pelkus teaches a wound treatment system (10) and method (Abstract) comprising a treatment chamber (810; Fig. 5) containing a mist control unit (50) with humidifier (400); the humidifier releases a vapor mixed with antibiotic/medication (col. 8, lines 14-26). A separate O2 inlet port (77) fed from an O2 tank (col. 5, lines 24-26) supplys enriched gas to treatment zone of the treatment chamber (col. 5, lines 24-37).

Since none of the special technical features of the Groups I - II inventions is found in more than one of the inventions, unity is lacking.