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(54) **APPARATUS FOR TREATMENT OF WOUNDS AND SKIN MEDICAL CONDITIONS AT A PREDETERMINED SKIN AREA OF A HUMAN BODY**

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(58) **Field of Classification Search**
None
See application file for complete search history.

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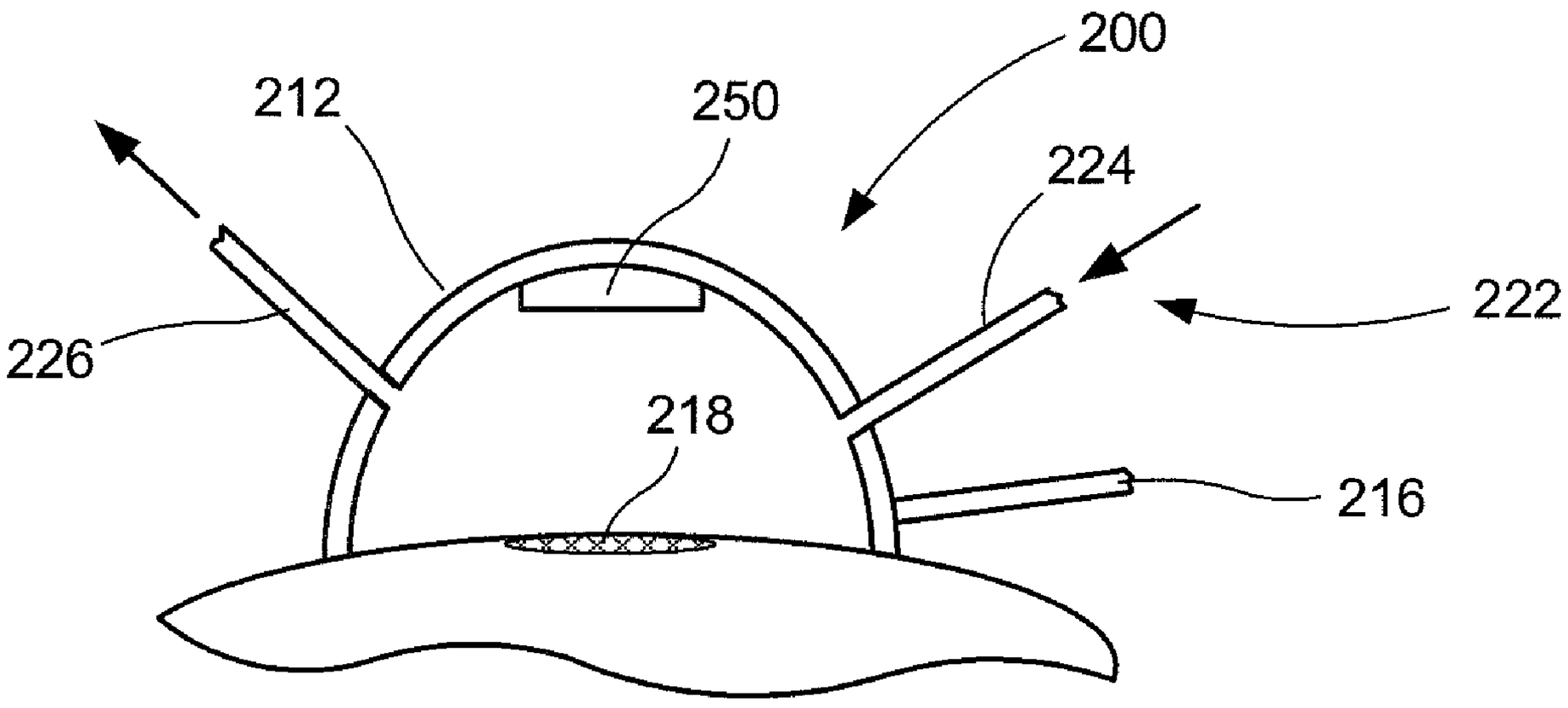
(57) **ABSTRACT**

An apparatus for treatment of fungal infections and/or other foot skin disorders, comprises a shoe-type housing having a substantially hollow interior forming a treatment chamber, a supporting platform disposed within the hollow chamber; so that a foot of a patient positioned within the treatment chamber is supported by the platform, so that nails are disposed at the lower level of the front part of the chamber, whereas the heel of the foot is being elevated a rear part thereof. A delivery and control assembly for the aqueous solution is provided. At least one light delivery arrangement is disposed within or in the vicinity of the treatment chamber.

15 Claims, 6 Drawing Sheets



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of application No. 14/216,995, filed on Mar. 17, 2014, now Pat. No. 9,375,586.

(60) Provisional application No. 61/799,896, filed on Mar. 15, 2013.

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A61M 37/00	(2006.01)
A61B 18/00	(2006.01)

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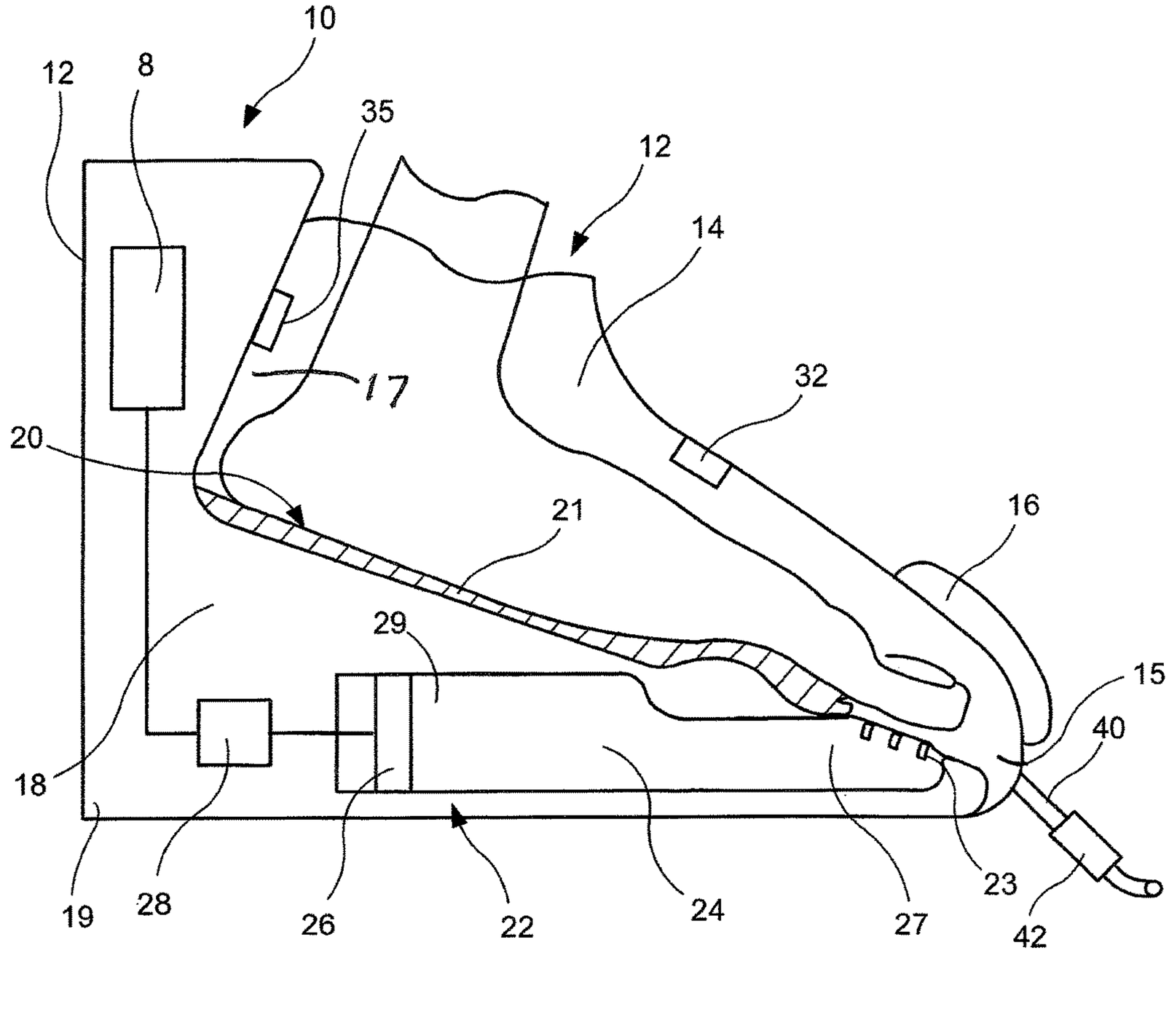

FIG. 1

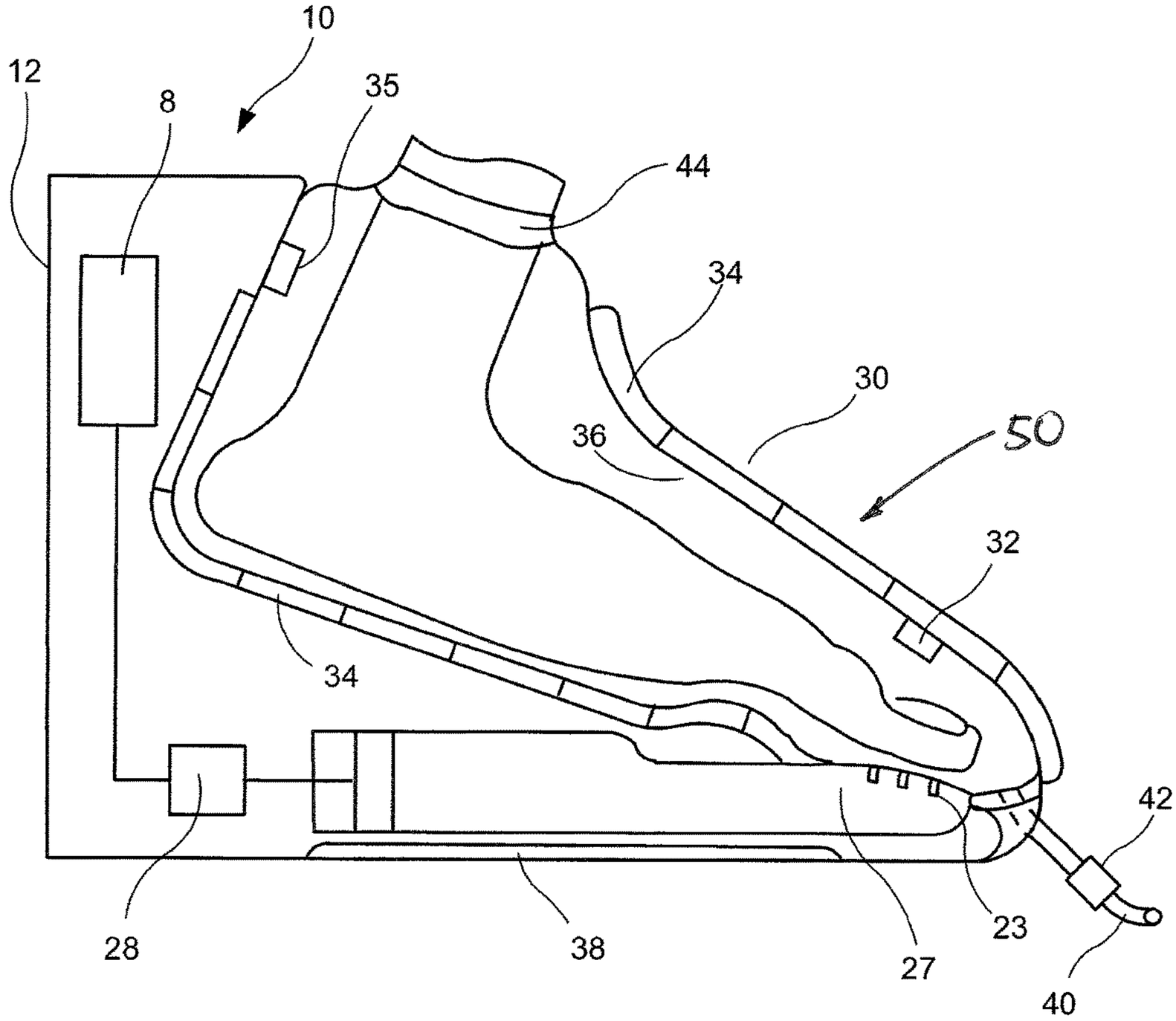

FIG. 2

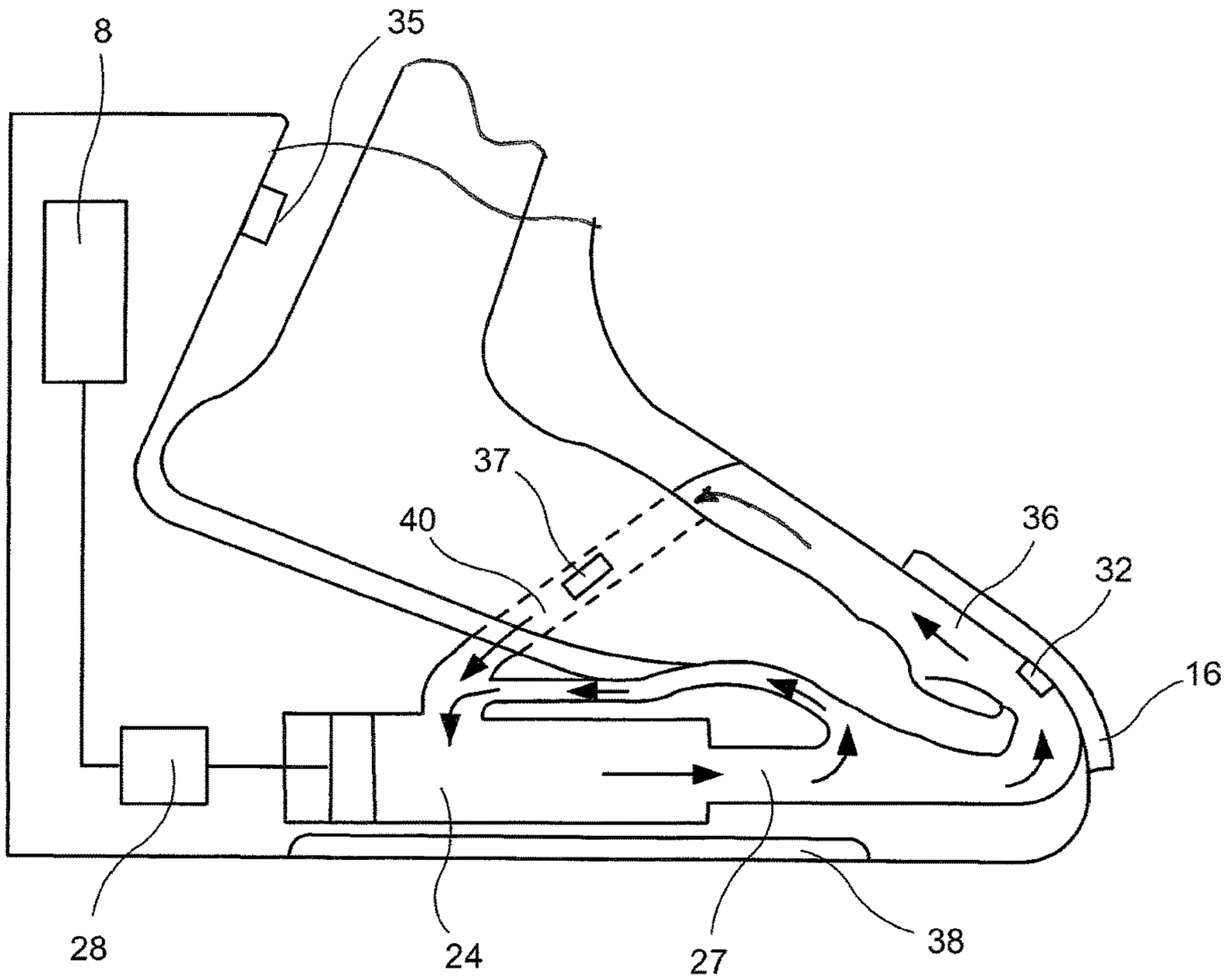

FIG. 3

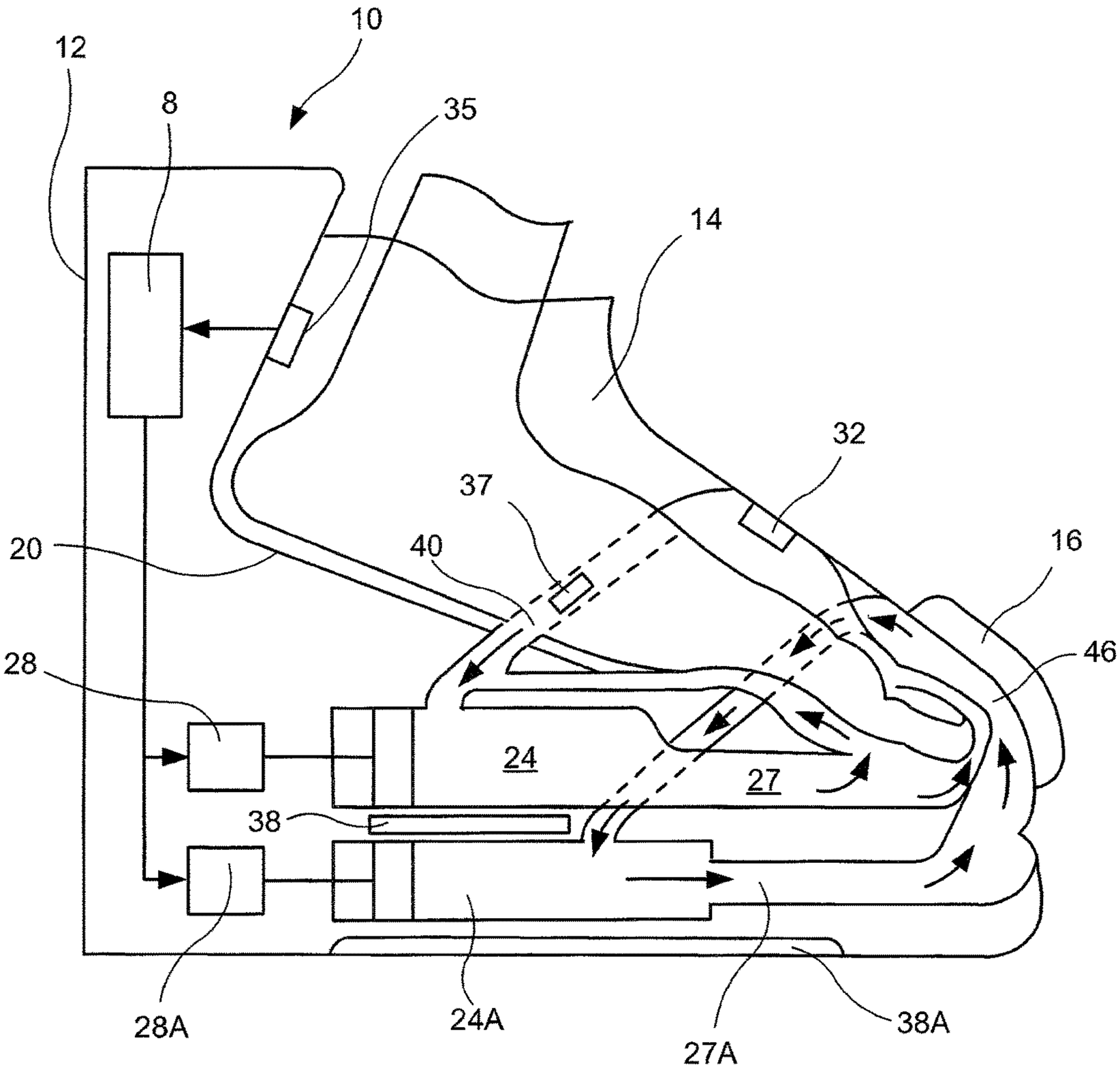

FIG. 4

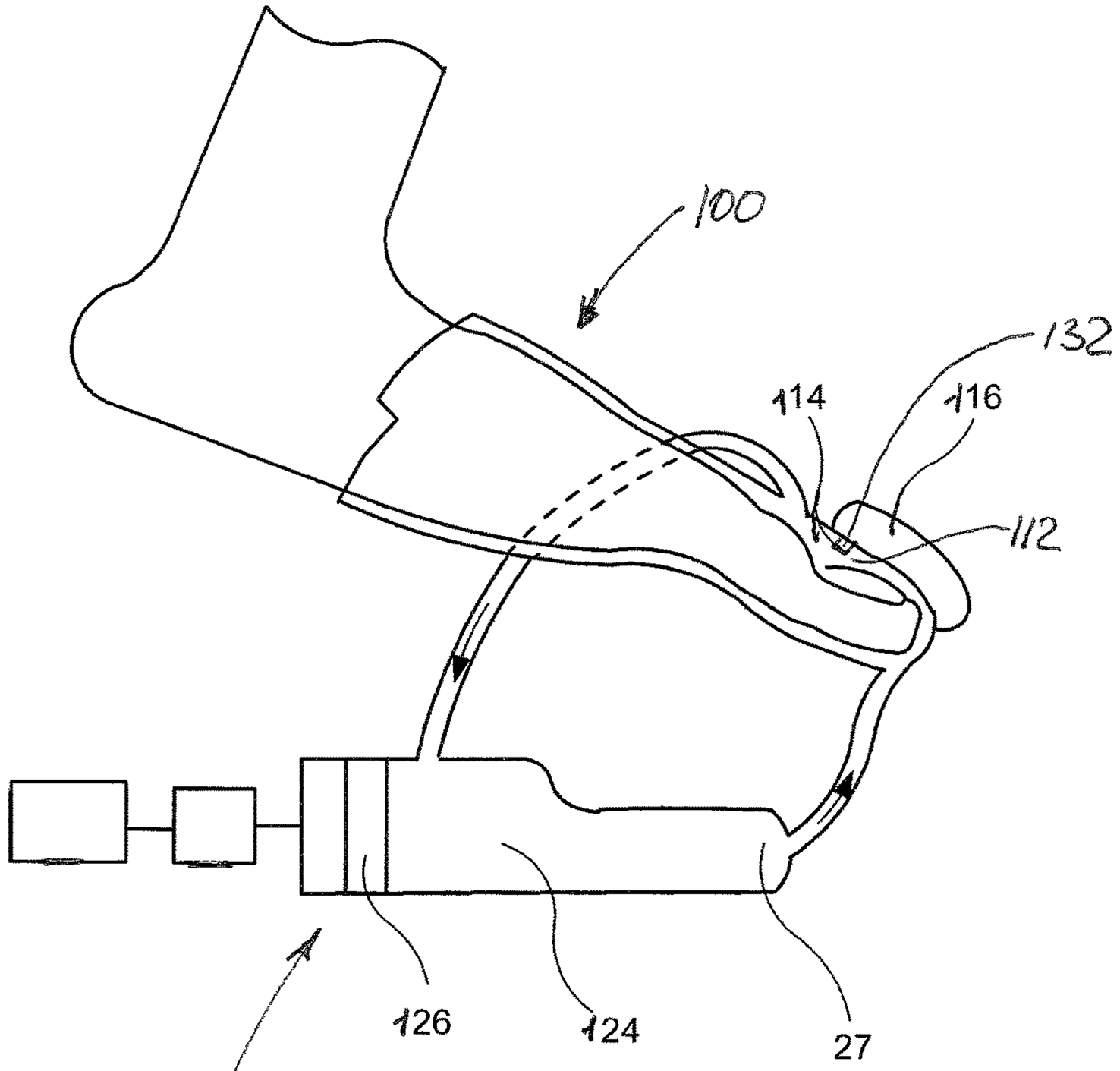

FIG. 5

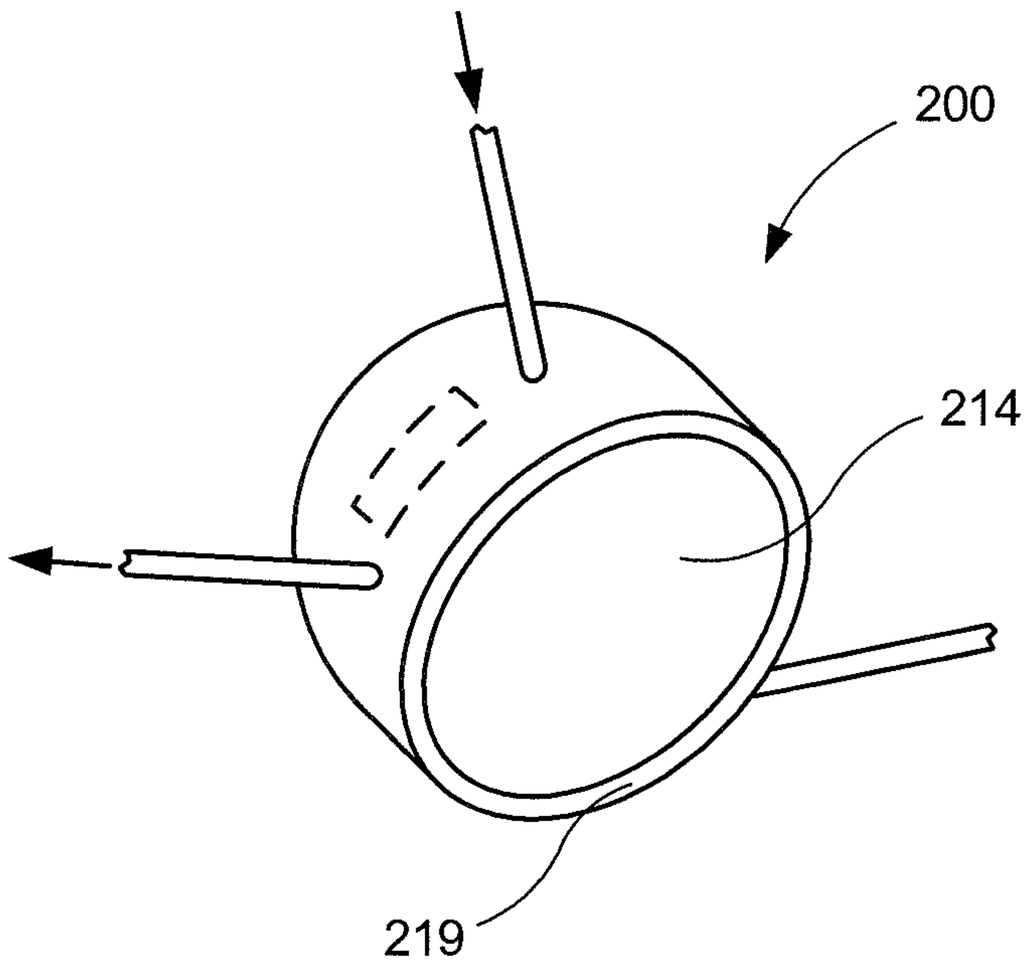

FIG. 6A

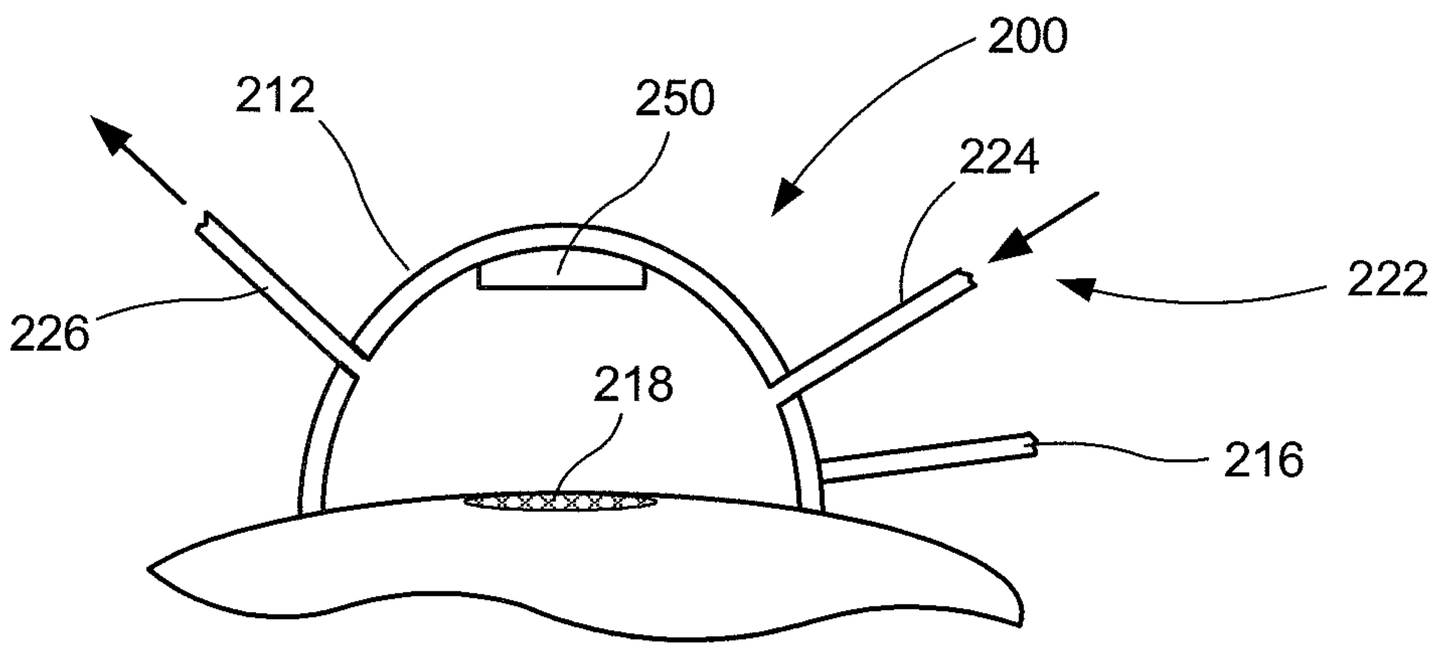

FIG. 6B

APPARATUS FOR TREATMENT OF WOUNDS AND SKIN MEDICAL CONDITIONS AT A PREDETERMINED SKIN AREA OF A HUMAN BODY

REFERENCE TO RELATED APPLICATION

This Application is a Divisional of currently pending U.S. application Ser. No. 15/168,896 filed: May 31, 2016, issued as U.S. Pat. No. 9,694,200, which claims priority of U.S. application Ser. No. 14/216,995 Filed: Mar. 17, 2014, issued as U.S. Pat. No. 9,375,586, which claims priority of Provisional Application Ser. No. 61/799,896 filed Mar. 15, 2013. All above applications are incorporated herein by reference in their entirety.

BACKGROUND OF THE INVENTION

Skin and nail disorders affect all population at different stages of our life with increased level of incidence in the aging population. Many of such skin disorders are caused by a wide variety of different pathogens that reside on the skin and nails as well as in the deeper skin tissue. Such skin pathogens may include fungi, mold, parasites, bacteria, viruses and other microorganisms. There are different treatments, methods and techniques used to destroy or suppress such pathogens however mostly such treatments would affect one or few of such pathogens without affecting others or the treatment is only applied to a certain part of the foot for example like nails affected by onychomycosis leaving other foot skin untreated. However pathogens residing in other areas of foot skin often cause decease in other foot areas like mold or fungus on the foot skin can easy migrate to the nails. Therefore there is a strong need for a method and device that could integrate multiple treatments of foot skin and nails into a one complex treatment which will result in increased clinical efficacy and outcome for patients as well as it will provide for cost saving for the healthcare system overall.

It is estimated that up to 35 million Americans have onychomycosis, a condition relating to fungal infections of the toenails or fingernails. Onychomycosis is often caused by yeast, dermatophytes, or other molds, and represents approximately 50% of all nail disorders. Toenail infection accounts for approximately 80% of onychomycosis incidence, while fingernails are affected in about 20% of the cases. Dermatophytes are the most frequent cause of nail plate invasion, particularly in toenail onychomycosis. Discoloration, onycholysis, and accumulation of subungual debris and nail plate dystrophy characterize the disease. The disease adversely affects the quality of life of its victims, with subject complaints ranging from unsightly nails and discomfort with footwear, to more serious complications including secondary bacterial infections.

Many methods are known for the treatment of fungal infections, including use of oral and topical drugs. However, onychomycosis has proven to be resistant to most treatments. Nail fungal infections reside in an area difficult to access by conventional topical treatment and anti-fungal drugs cannot readily penetrate the nail plate to reach the infection sites under the nail as well into the nail matrix where infection is often resided therefore clinical efficacy of topical medications is low (20-25% estimated). Also onychomycosis has traditionally been treated by oral administration of anti-fungal drugs. However, the clinical efficacy of the treatment is still not complete (50-60% estimated) and there is a high rate of fungal infection recurrence and with

multiple treatment courses patients developed resistant to the oral medication which further reduce the clinical efficacy. There is also known potential for serious side effects of such drugs. Recently significant interest has developed in the use of light irradiation by laser to destroy fungal material through superheating (coagulation) of soft tissue affected with fungus. Exposure of fungi to high temperatures inhibits their growth as well as cause their cell damage and death. This type of therapy using proper light parameters such as wavelength and pulse duration and high level of energy has shown a high clinical efficacy in fungal infection destruction. Light sources capable of emitting high energy in the infrared spectrum proved to be most efficient in eradicating of onychomycosys because high energy infrared radiation with optimum parameters can penetrate deep into skin tissue through the nail plate and into the nail bed as well as deep into the nail matrix coagulating fungal material often residing in these deep skin area. It also has the added benefit of avoiding side effects of oral drugs mentioned above and other systemic concerns for the patient. However delivering of high energy levels to the pathogen affected skin tissue may require efficient cooling mechanisms to remove heat build up in the skin tissue to prevent unwanted collateral damage and provide for a more comfortable treatment for a patient.

Thus, it has been a long felt and unsolved need for an apparatus and method for treatment of fungal infection disease of the lower and upper limbs, including, but not limited to toenails and fingernails that could integrate multiple treatments available now into a one complex treatment and which can be efficiently provided without threat of side effects.

In addition to nails fungal east and bacterial infection, including athlete's foot, mold, viruses, parasites, or other organisms or microorganisms can reside on the skin surface of lower and upper limbs causing chronic infections, which may result in development of wounds including chronic wounds. Some other serious skin disorders like psoriasis and others are common for the skin surface of lower and upper limbs as well. Therefore it is preferable that such method and apparatus will allow to treat in one treatment all or most of foot and hand skin deceases including but not limited to the nails fungal and bacterial infection not only on and under the nails but also on all areas of skin of the lower and upper limbs as well is that it can be used for treatment of wounds, psoriasis and other skin disorders.

SUMMARY OF THE INVENTION

The invention provides a method, means and apparatus to simultaneously or in one procedure treat multiple foot and hand skin and nail deceases. Further in the text skin should be understood as both skin and nail of the lower and upper limbs and other body areas if applicable. The method includes simultaneous or alternate application of some or all of the following steps:

Step One relates to application of energy radiation to selectively destroy, coagulate, or damage pathogen elements causing disorders of skin and nail with such energy radiation to include thermal radiation, electromagnetic radiation including but not limited to light, laser irradiation, electrical current, RF (radio frequency), microwave etc, ultrasonic, mechanical and other; with proper parameters such energy application may also stimulate a wound healing response including enhancing of colagenesis.

Step Two relates to washing of treated skin with aqueous solution which to include any type of aqueous solution

containing substances capable of destroying skin pathogens and/or is used for treatment of wounds, psoriasis and other skin disorders. It should be noted however that in an alternate embodiment the step of washing can be conducted after the step of applying energy irradiation.

Step Three relates to the use of the aqueous solution as per above or special separate aqueous or gas substance as a cooling agent to remove heat build up in the skin tissue and nails caused by the application of energy radiation.

Step Four, which can be optional, relates to drying the aqueous solution applied in the Step Two and/or Three from the treated skin to prepare the skin for the application of energy radiation described in Step One to avoid absorption of such radiation in the aqueous solution which may reduce effect of energy irradiation or result in superficial overheating of the skin;

In one of the embodiments of the invention apparatus comprises a shoe-type housing having a substantially hollow interior forming a treatment chamber adapted to place a patient foot. At least one energy radiation/light delivery arrangement is disposed within or in the vicinity of the treatment chamber. A delivery and control assembly for the aqueous solution is provided allowing for full or partial washing of patient foot. A power and control unit providing operation of the apparatus in accordance with the steps described above is provided.

A supporting platform is disposed within the hollow chamber; so that a foot of a patient is conveniently positioned within the treatment chamber and supported by the platform. In the main embodiment of the chamber the support platform is positioned in such a way so that nails are disposed at the lower level of the front part of the chamber, whereas the heel of the foot is being elevated a rear part thereof. Such foot position allows for an option when only nails area is washed by the aqueous solution. An alternative platform positioning whereas the nails are being elevated and a rear part of the foot is put at the lower level thereof can be considered as well. In a situation when the apparatus may be used by multiple patients, for sanitary reasons and to prevent any cross contamination by pathogens the single use internal liner for the treatment chamber can be used. Alternatively the complete treatment chamber part of the apparatus can be designed as a single use disposable.

The energy radiation/light delivery outlets can be located in all areas of the treatment chamber to provide optimum irradiation of all skin areas. Different types of energy/light parameters can be used for irradiating different skin areas. For example for irradiation of nails for onychomycosis treatment the deep penetrating energy is preferred in order to coagulate fungal structures that may reside in nail bed or matrix. For other parts of the skin where pathogens are resided superficially a more superficially absorbed energy can be used to protect internal skin structures.

The aqueous solution in this invention delivers serves the following main objectives. First it may contain active ingredients that adversely effect skin pathogens and facilitate treatment and healing of different skin diseases. The aqueous solution delivery and control system allows for full or partial washing of patient foot depending on clinical objectives. It also provides for optimum time exposure of the skin to aqueous solution. Second, aqueous solution provides cooling of the nails and skin area treated with energy irradiation. This may be necessary to prevent unnecessary collateral overheating of the skin tissue and for patient comfort. Cooling elements are integrated into the apparatus design to control the aqueous solution temperature. In another embodiment there are two separate aqueous circulation loops, which may contain different types of aqueous solutions. In such case, first solution and first circulation loop will be used to circulate aqueous solution for washing foot skin. And the second circulation loop will fill the optically (energy) transparent pocket located near the nails area which is designed to provide contact cooling to the nails while being maximum transparent to the energy irradiation being delivered to the nail to treat onychomycosis. In another embodiment such optically (energy) transparent pocket can alternatively be filled with cooled gas or cryogen.

Because some energy irradiation may be absorbed in water or other aqueous solution used it is preferable that skin is dried before such energy irradiation is applied. For such purposes the apparatus may incorporate an air dryer subsystem designed to dry the skin by blowing air to it or by vacuuming an air stream from and through the treatment chamber.

Multiple sensors are installed within the treatment chamber to monitor different skin parameters including but not limited to temperature, melanin, hemoglobin, oxygen and water concentration in the skin, blood pressure and other heart related characteristic may be measured as well for better patient control. Using data collected by the monitoring sensors a power and control unit of the apparatus directs and controls operation of the apparatus in accordance with the treatment protocols.

Multiple embodiments of the treatment chamber can be used and adapted for different clinical applications. Some examples may include:

- a treatment chamber designed to accept just toes for onychomycosis treatment;
- a treatment chamber designed to accept hands or fingers;
- a treatment chamber designed to treat other parts of patient body skin where shape of such chamber design will be adapted to conveniently accept and locate such treatment site within such chamber. In such cases the energy radiation production arrangement, a delivery and control assembly for the aqueous solution and a power and control unit providing operation of the apparatus may be located separately from the treatment chamber and connected to it through a variety of connecting tubes, electrodes or optical fibers that will feed and control the corresponding outlets within the treatment chamber. It is possible that such treatment chambers can be adapted for single use, so as to be disposable for the purposes of patient's hygiene and safety. Multiple electronic and mechanical safety features are incorporated in the apparatus design including but not limited to preventing reuse of the disposable treatment chambers.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a schematic diagram illustrating one embodiment of an apparatus for treatment of foot and nail disease according to the invention;

FIG. **2** is a schematic diagram of another embodiment of the apparatus of the invention;

FIG. **3** is a schematic diagram of a further embodiment of the apparatus of the invention;

FIG. **4** is a schematic diagram of a still another embodiment of the apparatus of the invention;

FIG. **5** is a schematic diagram of a further embodiment of the apparatus of the invention; and

FIGS. **6**A and **6**B are schematic diagrams of an alternate embodiment of the apparatus of the invention.

DETAILED DESCRIPTION OF THE INVENTION

The following terms are intended to have the following general meanings as they are used in the application.

Aqueous solution: any type of aqueous solution containing substances capable of eliminating skin pathogens including but not limited to fungus organisms, east and bacterial infection, including athlete's foot etc., treat psoriasis, acceleration of wound healing or treating any other skin disorders. Such substances are capable of either completely eliminating/destroying skin pathogens or substantially delaying reducing the rate of its growth. The treatment solutions include but not limited to the salt solution like sea water and etc., solutions containing Ethanol Alcohol, Isopropyl alcohol, p-Chloro-o-benzylphenol, o-Phenylphenol, Potassium hydroxide, dimethylbenzylammonium chloride, Lactic acid, Hydrogen Peroxide, fluconazole, itraconazole, terbinafine amorolfine, methylphenols, creosols, and any other solutions that inhibits pathogens. Treatment solution may also include substances that promote healthy skin, wound healing and/or psoriasis treatment.

Light at any wavelengths can be absorbed by a skin or nails of the patient. Such wavelengths include wavelengths selected from the continuous electromagnetic spectrum such as ultraviolet ("UV"), visible, the infrared (near, mid and far) i.e. from approximately 300 nm to 12,000 nm, etc. The light may be produced by any suitable art-disclosed light emitting devices such as lasers, light emitting diodes ("LEDs"), incandescent sources, fluorescent sources, flash lamps or the like. The light can be pulsed or having a continuous mode. Under Light in this invention one can understand any energy radiation that can penetrate and affect the skin tissue including electromagnetic fields, radio frequency, and acoustic including ultra sound.

The light applied during the irradiating step of the method of the invention can be supplied by a single light emitting device or a plurality of light emitting devices. Any suitable art-disclosed light emitting device(s) such as lasers, light emitting diodes ("LEDs"), flash lamps, incandescent sources, fluorescent sources, germicidal light or the like may be used to provide the required wavelength(s). Lasers include any art-disclosed lasers such as solid state lasers, diode lasers, pulsed lasers, gas lasers, gas or vapor lasers, dye lasers, fibers lasers or diode pumped solid state lasers or the like. LEDs include any art-disclosed LEDs such as semiconductor LEDs, organic LEDS or a combination thereof. Fluorescent sources include any art-disclosed fluorescent sources such as fluorescent tubes, LED pumped fluorescent devices, cold cathode fluorescent panels or the like.

The light applied during the irradiating step of the method of the invention provides the required wavelength(s). Such wavelength(s) include wavelengths selected from the continuous electromagnetic spectrum such as ultra violet ("UV"), visible, the infrared (near, mid and far), etc. The wavelength, pulse duration/continuous mode, energy density to the skin or number and repetition rate of energy pulses is optimized to achieve optimal and selective absorption in the skin pathogens or skin components like melanin, oxyhemoglobin or water as well as optimum depth of skin penetration for the best clinical efficacy outcome.

The time required for the step of exposing the infected area to an aqueous solution and the irradiating step of the method may vary depending on the existing conditions (e.g., type of the disease, the skin pathogens, the light source, the aqueous solution, the skin type, melanin concentration in the skin, hemoglobin concentration in the skin, moisture of the skin, temperature of the skin etc.). As to the irradiating step, a suitable duration will generally be from about 1 nanosecond to about 60 minutes. It is also possible and within the scope of the present invention for the light applied during the irradiating step of the therapy to be applied by a lower energy power for much longer durations (e.g., more than about 30 minutes to hours).

Referring now to the drawings, and more particularly to FIG. **1** illustrating therapeutic apparatus **10** of one embodiment of the invention which is adapted to treat toenail fungus and other medical conditions. In this embodiment the apparatus **10** is in the form of a shoe-type appliance **12** having a substantially hollow interior adapted to accommodate a treatment chamber **14**. The chamber **14** extends between front **15** and rear **17** area is designed as a bath adapted to allow either one or both feet of a patient to fit comfortably and be immersed in the solution. The treatment chamber or the bath **14** is capable of holding amount of an aqueous solution required for a complete treatment of a patient. At least one energy or light source **16** is provided to allow irradiation of the foot over and around the toes and the nails. The energy source **16** is typically disposed in the vicinity of the front area **15** of the treatment chamber **14**.

It should be obvious to a person skilled in the present art that the therapeutic apparatus of the invention can be also adapted for treatment of other parts of a body, which can be easily immersed into the solution contained within the chamber **14**, for example, hands.

An inclined supporting platform **18** is disposed within the lower part of the interior of the apparatus. As illustrated in FIG. **1**, a top surface **20** of the supporting platform is disposed at an acute angle to the bottom **19** of the apparatus. Other angles of inclination of the supporting platform to the bottom of the apparatus are within the scope of the invention. A foot of a patient is positioned within the treatment chamber **14**, and supported by the platform **18** in such a manner that toenails of toes are disposed at a low level at the front area **15** of the chamber, whereas a heel of the foot is elevated at the rear area **17**. In the illustrated embodiment of the invention a delivery and control system **22** for the aqueous solution is provided within the platform **18** at the vicinity of the bottom **19** of the apparatus. It should be noted however, that any alternate location of the system **22** inside or outside of the apparatus is within the scope of the invention. In the illustrated embodiment, the control system **22** consists of at least one cylinder **24** with a piston **26** slideably movable between proximal **27** and distal **29** ends thereof, and a control means or arrangement **28**. The proximal end **27** of the cylinder is in fluid communication with the front area **15** of the treatment chamber **14**. Control valve **23** is provided at the front area **15**, so as to direct movement of the solution from the cylinder **24** into the treatment chamber **14**. The control valve **23** is adapted to close communication with the treatment chamber **14** and the hollow interior of the apparatus when aqueous solution is reseeded. After being used during the treatment, the aqueous solution is discharged from the treatment chamber **14** through the discharged unit **40** which can be in the form of a pipeline initiated at the front area **15** of the treatment chamber. A filter **42** is provided at the discharge unit **40** to filter the discharged aqueous solution before it is being be re-circulated to the cylinder **24** or sent to an accumulator (not shown) for further use and/or storage.

As the piston **26** is activated, the aqueous solution through the front end **27** of the cylinder and the uni-directional valve arrangement **23** is delivered into the treatment chamber **14**. During the treatment, a front of the foot with the toes and toenails, disposed at a low elevation of the front area **15**, are submerged into the aqueous solution. The fungus infected toenails are washed, bathed within the aqueous solution, so that the aqueous solution flows around the infected areas. In this manner, the infected toenails are exposed to a greater degree to the medicated aqueous solution than the rest of the foot. Upon completion of this phase of the treatment, the aqueous solution is discharged from the treatment chamber **14** through the discharge unit **40** and the filter **42**. As shown in FIG. **2**, a resilient cuff **44** can be provided at a top portion of the treatment chamber **14** to surround an upper portion of an ankle and to prevent spillage of the aqueous solution.

In one embodiment of the invention, the top surface **20** of the platform supporting the foot is made from a resilient material. To enhance performance of the device, this resilient material is capable of adapting to a specific shape of the foot of the each individual patient. As illustrated in FIG. **1**, a layer of gel **21** can be disposed below the resilient upper surface of the platform. In this manner, the top surface **20** of the supporting platform closely follows the shape of the foot facilitating substantial engagement therebetween. This feature is also important in the step of irradiation, which will be discussed with reference to the embodiment of FIG. **2**, where energy sources or light elements are provided near the top surface of the platform.

As illustrated in FIGS. **2-4**, a cooling arrangement in the form of at least one cooling plate **38**, for example, is situated in the vicinity of the control system **22**. One of the main functions of the cooling arrangement is to reduce the temperature in the treatment chamber including a temperature of the aqueous solution. Use of the cooling arrangement is especially beneficial in the embodiments where the aqueous solution is circulated within the apparatus between the treatment chamber having elevated temperature and the cylinder **24** (see FIGS. **3** and **4**). As illustrated in FIGS. **3** and **4**, in such systems, the cylinder or reservoir **24**, the cooling plate **38** and the treatment chamber **14** are arranged as parts of the aqueous solution circulation loop **36**. This arrangement allows the aqueous solution to circulate between the cylinder/reservoir **24**, cooled by the cooling plate **38**, to the interior of the treatment chamber **14**, wherein a foot of a patient is positioned for treatment. As shown in FIG. **3**, upon activation of the piston **26**, the aqueous solution is being discharged from the cylinder **24** at the proximal end thereof **27** into the treatment chamber **14**. After flowing around the infected areas of the foot, the aqueous solution through the circulation loop **36** is being recycled back to the cylinder **24**. To facilitate efficient circulation of the solution, a circulation pump or any other similar conventional means **37** can be provided within the circulation loop **36**.

Although, the cooling arrangement is in the form of the cooling plate **38** has been discussed hereinabove, it should be understood that any type of cooling arrangement provided to reduce a temperature of the aqueous solution within the treatment chamber is within the scope of the invention. For example, in an alternate embodiment of the invention, the entire supporting platform **18** is made from a resilient material, whereas an inner part of the platform is substantially hollow and filled with a cooling substance/liquid. The cooling substance cools the foot in general and the toes and toenails thereof in particular with the infected areas are treated by the apparatus and method of the invention.

In the embodiment of the apparatus shown in FIG. **4**, a resilient light transparent pocket **46** filled with a cooling substance or cooling gel is provided at the front area of the chamber **14**. In use the pocket **46** can adapt to the shape of the toes and toenails for a better cooling and better transmission of the light energy. The system of this embodiment is formed with at least two sets of cylinders or reservoirs **24** and **24**A. The purpose of the cylinder **24** is similar to the analogous cylinders of the above-discussed embodiments, so as to provide delivery and/or circulation of the aqueous solution within the treatment chamber **14**. The main objective of the reservoir **24**A is to provide delivery and circulation of the cooling fluid within the auxiliary circulation loop **46**. After being discharge from the reservoir **24**A, the cooling fluid circulates within the light transparent pocket **46** and cools the nails area, so as to make application of irradiation energy to the nails area safer and more comfortable. The embodiment of FIG. **4** is formed with two cooling arrangements **38** and **38**A. The cooling arrangement or cooling plate **38** is located in the vicinity of the cylinder **24** and provided to reduce the temperature of the solution delivered the treatment chamber **14**. On the other hand the purpose of the cooling plate **38**A positioned near the cylinder **24**A is to reduce the temperature of the cooling solution circulating within an auxiliary circulation loop **46** adapted to cool the toe nail treatment area.

FIG. **5** illustrates a further embodiment of the apparatus **100** of the invention. In this embodiment, the body of the apparatus extends from the toes to about the middle of the foot with a limited treatment chamber **114** adapted to accommodate the foot front area including toes and toenails. The treatment chamber **114** includes a toe region **112** that surrounds the toes of a foot of a patient inserted thereinside. In some embodiments, toe region tapers from the inner area of the chamber to the outer area of the chamber such that it generally follows the contour of a human foot where larger toes exist at the inside of the foot, and the foot tapers to smaller toes on the outside. This can be functionally advantageous as the treatment chamber more closely conforms to the shape of the human foot. However, of ordinary skill in the art should appreciate that various shapes for toe region are within the scope of the invention.

Although, the apparatus **100** is formed with the treatment chamber **114** adapted to accommodate various sizes of human foot, an apparatus with a custom-formed treatment chamber designed to accommodate a custom foot configurations of a specific patient is within the scope of the invention. Such custom configured chambers are especially useful for patients with substantial foot deformities, as well as invalids having a part of a foot being removed, etc.

The apparatus of the embodiment illustrated in FIG. **5** is typically made from a resilient material such as rubber, for example. At least one energy light source **116** is provided at the proximal end of the chamber for irradiation of the foot in general and the toes and nails specifically. A tightening arrangement, such as a cuff **44** for example (see FIG. **2**), can be formed at the distal end of the chamber to facilitate tight connection between the apparatus and the foot of the patient and to prevent leakage of the aqueous solution from the treatment chamber.

In the embodiment of FIG. **5**, the delivery and control system **122** for the aqueous solution is situated outside of the apparatus. Similar to the above-discussed embodiments, the liquid control system **122** may include a cylinder **124** with a piston **126** movable thereinside. During the treatment, the front of the foot, including the toenails is submerged within the aqueous solution provided within the treatment chamber.

A sensor **132** can be provided within the treatment chamber to further control the treatment process.

The resilient material used for manufacturing of the apparatus **100** is impermeable to the aqueous solution. In view of the relatively low cost of production, the apparatus is disposable in nature. The apparatus is convenient for specific treatment sessions arranged for particular patients. The control system **122** positioned outside of the apparatus is reusable and can disconnected from the treatment chamber **114** upon completion of the prescribed treatment. If needed, the control system **122** can be re-connected to another unit. Such arrangement provides substantial cost saving to an operator.

As indicated above, multiple embodiments of the apparatus of the invention including various treatment chambers can be used and adapted for different clinical applications. FIGS. **6**A and **6**B show the embodiment of the apparatus **200** of the invention provided for treatment of wounds and skin conditions 218 practically at any part of human body. The body **212** of the apparatus has a semi-spherical configuration with a hollow treatment chamber **214** formed thereinside. A vacuum arrangement **216** is provided to create a vacuum within a hollow space **219** formed between the walls of the treatment chamber **214**, which are in contact with the skin. This arrangement facilitates better engagement between outer periphery of the body and the skin area to be treated. A delivery and control system **222** for the aqueous solution consisting of inlet **224** and outlet ports **226** is provided. A radiation energy source **250** is disposed within the chamber **214**.

The light delivery arrangement **50** of the present invention includes a light source, an energy source in power communication to the light source; and a controller that controls amount and/or duration of light to be applied to the patient by the light source and sensors **32**, **35** to measure skin/nails characteristics.

As discussed above, the light source can be any suitable art-disclosed light emitting device(s) such as lasers, LEDs, incandescent sources, fluorescent sources, or the like may be used to provide the required wavelength(s). A light source can be a visible infrared light generated by any conventional sources, including light bulbs, impulseable laser as well as the devices capable of absorbing and concentrating the sunlight.

In the embodiment of the invention illustrated in FIG. **2**, the light source **34** is an array of LEDs or other energy sourses. In another exemplary embodiment, the light source is an array of optical fibers powered by a laser. The apparatus of the invention also includes an energy source in power communication with the light source and is adapted to provide power to the light source. The energy source can be DC and/or AC. The housing of the apparatus can optionally be adapted to contain an autonomous energy source (e.g., batteries or the like). Alternatively, the energy source can be located outside of the housing, but is in power communication with the light source via any conventional means, including cable(s). The apparatus further includes a controller that controls the amount (including duration) of the light that is applied to the treated area.

One embodiment of the device and method of the invention involve use of arrays of light emitting diodes (LEDs), comprising at least one set of LEDs which emit light at the required wavelength. The set of LEDs is configured within the array in predetermined patterns, and is activated at the required frequency in sequence for predetermined durations of time. In certain aspects of the invention, treatments are provided involving inserting the limb into the device, adjusting for comfort, and activating the device for a pre-programmed treatment of approximately 5-45 minutes.

When a laser is utilized as a light source, the generated beam is controllably absorbed in the target tissue at the required depths.

Utilization of a laser in the present invention as a light source is accompanied by automatic target thermal feedback to precisely control the dosimetry of the laser, intense light or intense pulsed light irradiation. This is needed to prevent damage to surrounding tissue and reduces pain. For this purpose, a non-contact thermal detector can be provided. The output of the non-contact thermal detector is used to adjust the power output of the laser to maintain a selected treatment temperature at the treatment site.

In the invention, absorption of laser energy by the nail bed of the infected toe or finger results in a controlled elevation in temperature, to a temperature effective of disinfection at the infected regions or areas. In the invention, this occurs without causing irreversible thermal damage to the infected nails. The laser control system of the invention adjusts the energy to maintain a pre-selected target temperature at the spot. In one embodiment of the invention, to maximize patient comfort and safety, an optional continuous or pulsed cooling device can be provided to deliver a stream of coolant to the target treatment spot during or after each laser treatment session.

As best illustrated in FIGS. **1**, **2**, **3** and **4**, energy or light source(s) **16** is disposed within front part of the apparatus in the vicinity of the treatment chamber **14**, which is adapted to accommodate toes and toenails of a patient and additional energy or light sources to provide energy irradiation to all other skin areas.

To further control the treatment process, a sensor **32** is provided within the treatment chamber **14**. The sensor **32** is capable of detecting the level of melanin, hemoglobin or water/moisture content, etc., within the skin of a patient positioned within the chamber. Thus, optimal levels of radiation can be achieved for each zone of treatment. For example, a higher level of radiation can be provided at the front area **15** of the treatment chamber **14** which accommodates toes and toenails infected with a fungus. On the other hand, lower levels of radiation will be generated and directed to the areas of the treatment chamber accommodating a heel and the surrounding regions of the foot. To further control the treatment a condition of the surrounding tissue is monitored by a detecting arrangement or detector **35** adopted to detect irradiation reflected from such tissue. One of the main functions of the detector **35** is to control the effect of the energy or light source on the surrounding tissue of a patient. In every individual case a doctor sets specific characteristics of the irradiation to produce the required effect. If situation in the treatment chamber become unfavorable, for example the temperature exceeds predetermined limits, the detector **35** generates a signal directed to the control unit **8** which in turn produces a correcting signal to the power unit or to the control arrangement **28** of the cooling system **22**. This in turn energizes circulation pumps **37** and/or cooling plates **38**, so as to directly and indirectly lower temperature in the treatment chamber **14**. Similar signals can be also produced when the prearranged levels of the energy density, power density or other characteristics of the operating laser are attained. This is necessary to exclude possibility of damaging an adjacent healthy skin tissue. The detecting arrangement **35** can be made utilizing a wide variety of photoelements, photoresistors, photodiodes and similar devices.

In the embodiment of the invention illustrated in FIG. **2** a plurality of energy sources **34**, such as an array of LEDs for example, are disposed within the walls of the treatment chamber formed within the hollow interior of the apparatus. Although the multiple energy sources can be randomly provided, in the illustrated embodiment such energy sources **34** are uniformly distributed through the inner surface of the treatment chamber.

In a further embodiment of the invention, the inner surface of the treatment chamber **14** is covered by a light reflective material. In this manner, the energy of the light sources disposed at the reflected layer are fully reflected and directed to the foot positioned within the treatment chamber **14**.

According to still yet another embodiment of the invention, the inner area of the treatment chamber is covered by a plastic material impermeable to the aqueous solution, and transparent to light radiation generated by the energy/light sources. Thus, the plastic material forms a disposable envelope adapted to accommodate a foot of a patient and usable only during a specific treatment session arranged for a particular individual/patient. The envelope is removed from the apparatus upon completion of the treatment and properly disposed. Use of such disposable envelopes prevents transmission of fungus and other diseases from one patient to another.

According to an essential aspect of the invention, the refractive index of the aqueous solution and/or any other material or substance which is in contact with the skin surface of a patient, should match or to be substantially identical to the refractive index of the skin of the patient itself. The same principal is applicable to light sources used in the apparatus and the method of the invention. This means that the refractive index of a transparent light window surface (through which the light is irradiated by the light source) should match or be substantially identical to the refractive index of the material in contact with it and eventually with the skin surface of a patient.

In a still further embodiment of the invention, a pressure source can be provided within the treatment chamber **14**. This embodiment is especially beneficial with the treatment chamber being formed with resilient walls or when the flexible plastic envelope **44** is used in the chamber. Thus, upon pressure being elevated, the resilient walls or the flexible envelope disposed within the treatment chamber closely surrounds the foot and the toes subjected to a treatment within the chamber. This arrangement makes the steps of applying the aqueous solution or irradiating the step of irradiation even more efficient.

According to the method of the invention, initially the foot partially submerged into an aqueous solution can be also subjected to a light radiation treatment. The level of the solution within the treatment chamber is periodically raised, so as to cover the entire surface of the foot. After completion of the treatment, the solution is removed into a reservoir or recycled; and the foot is dried by an air stream formed by a vacuuming air-pump which can be connected to the treatment chamber **14** through the exit tube **40**.

The method of the present invention also includes the steps of irradiating the infected area with the light or energy sources **16**, **34** at a wavelength absorbed by skin chloroforms including but not limited to melanin, hemoglobin, oxyhemoglobin, or water in the skin or nails of a patient, so as to destroy fungal and/or bacterial infection, and/or microbes, and/or coagulate contaminated or diseased tissue in the nail, under the nail, in the nail matrix or at any other affected are of the skin. Since light can penetrate through the skin and through the nail, the irradiating step is achieved by irradiating either directly or indirectly through the nail with a light source at the required wavelength, so as to destroy infected material on the nail bed as well as in the matrix below and around the nail bed.

In the method of the invention, the steps of treating the infected area by an aqueous solution and the step of irradiating the infective area with a light source can be conducted separately/independently of each other or in combination.

What is claimed is:

1. An apparatus for treatment of wounds and skin medical conditions at a predetermined skin area of a human body, comprising:

a housing having a semi-spherical configuration formed by spaced from each other inner and outer semi-spherical walls, a circular outer periphery defined by said spaced from each other inner and outer semi-spherical walls at a bottom portion of the housing facing said predetermined skin area, a hollow space between said inner and outer semi-spherical walls, a hollow treatment chamber formed within an interior of the housing, a vacuum arrangement provided to create a vacuum within the hollow space between said inner and outer walls and to facilitate engagement between the outer periphery of the housing and the predetermined skin area to be treated, at least one energy delivery arrangement configured to deliver skin treatment energy to said hollow treatment chamber and to said predetermined skin area positioned within the treatment chamber; a delivery and control system for circulating an aqueous solution within the treatment chamber including inlet and outlet ports passing through said inner and outer semi-spherical walls, said delivery system configured to provide a level of the aqueous solution in the treatment chamber to partially or fully submerge said predetermined skin area within the treatment chamber in the aqueous solution; one or more sensors within the treatment chamber configured to detect one or more skin parameters from the group consisting of skin melanin concentration, skin hemoglobin concentration, and skin water content; a power and control unit configured to control the circulation assembly and the at least one energy delivery arrangement, wherein the power and control unit is configured to control a duration of exposure of said predetermined skin area to the aqueous solution and an amount of the skin treatment energy to be delivered based on the one or more skin parameters of said predetermined skin area detected by the one or more sensors and to control the level of the aqueous solution to allow for full or partial washing of said predetermined skin area within the treatment chamber.

2. The apparatus of claim **1**, wherein an inner area of the treatment chamber is covered by a flexible material transparent to light radiation.

3. The apparatus of claim **1**, further comprising: a cooling arrangement provided for reducing a temperature of the aqueous solution within the treatment chamber, wherein the cooling arrangement and the interior of the treatment chamber form part of the circulation assembly allowing the aqueous solution to circulate within the apparatus.

4. The apparatus of claim **1**, wherein said at least one energy delivery arrangement comprises a light source selected from a group consisting of lasers, light emitting diodes, incandescent sources, fluorescent sources, and a combination thereof.

5. The apparatus of claim 4, wherein the at least one energy delivery arrangement further comprises: an energy source is in power communication with the light source, and energy delivery controller for controlling the amount of light delivered from the light source to the treatment chamber.

6. The apparatus of claim 4, wherein the energy delivery is a light source in the form of a laser including a target thermal feedback arrangement to control intensity of the laser.

7. The apparatus of claim 1, wherein a blood pressure sensor is provided within the treatment chamber.

8. The apparatus of claim 1, wherein said at least one energy delivery arrangement is configured to provide different levels of radiation for different zones of treatment based on the one or more skin parameters.

9. The apparatus of claim 1, further comprising a detecting arrangement for detecting irradiation reflected from said part of the skin to be treated.

10. The apparatus of claim 9, wherein: the detecting arrangement is functionally associated with the power and control unit, and is configured to detect a predetermined condition within the treatment chamber and to generate a signal directed to the power and control unit; upon receipt of said signal from said detecting arrangement, said power and control unit produces a correcting signal directed to the circulation loop containing the cooling fluid for activation thereof to adjust the condition in the treatment chamber.

11. The apparatus of claim 9, wherein the detecting arrangement is selected from the group consisting of photoelements, photoresistors and photodiodes.

12. The apparatus of claim 1, wherein said housing is custom formed to accommodate specific skin configurations of a specific patient.

13. The apparatus of claim 1, further comprising: a blood pressure sensor within the treatment chamber.

14. The apparatus of claim 1, further comprising a detector provided to detect irradiation in the treatment chamber, upon reaching a predetermined condition in the treatment chamber the detector generates a signal directed to the power and control unit to energize the circulation assembly.

15. The apparatus of claim 1, wherein said housing is disposable.

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