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(54) Title: DEVICE AND METHOD FOR ENHANCED WOUND TREATMENT

(57) Abstract: An apparatus and method for facilitating the healing of a wound on a limb of a body of a subject, the apparatus including: (a) a wound treatment assembly having: (i) a sealing arrangement adapted to cover an area above the wound, and to contact and at least partially seal a volume from an ambient environment, and (ii) a vacuum mechanism fluidly communicating with the volume, and adapted to produce a sub-atmospheric pressure therein; (b) a muscle contraction device having at least first and second electrodes, each adapted to operatively contact the limb; (c) a control unit, adapted to connect to a power supply and operatively connected to each electrode, and further adapted to provide, via the electrodes, a sequence of electrical impulses to points associated with the limb, whereby muscle tissue associated with the points contracts to effect a localized increase in a flow of blood through a blood vessel in the limb, the control unit being operatively connected to the assembly and further adapted to control an operation thereof.

Device and Method for Enhanced Wound Treatment

This application draws priority from U.S. Provisional Patent Application Serial No. 61/027,464, filed February 10, 2008.

The present invention relates to a method and device for treating a wound by means of a sub-atmospheric pressure applied in the vicinity of the wound, and more particularly, to a treatment method and device in which sub-atmospheric pressure therapy is effected in conjunction with a method and device for contracting muscles to locally increase the flow of blood in that vicinity.

It is generally accepted that such sub-atmospheric-based treatments are indicated only for patients who have a reasonably healthy local flow of blood in the vicinity of the wound to be treated. One parameter correlated with peripheral blood flow is the ankle-brachial index (ABI) test. This test measures blood pressure at the ankle and in the arm while a person is at rest. Measurements are then repeated at both sites after 5 minutes of walking on a treadmill. The ankle-brachial index (ABI) result may be used to predict the severity of peripheral arterial disease (PAD). A decrease in the ABI result with exercise is a sensitive indicator that significant PAD may be present.

A resting ankle-brachial index of 1 or 1.1, or at least 0.95, may be considered to be normal. These values indicate that the blood pressure measured at the ankle is the same or greater than the pressure measured at the arm, and there is no significant narrowing or blockage of blood flow.

A resting ankle-brachial index of less than 0.95 to 1 may be abnormal. By way of example, if the ABI is less than 0.90, significant narrowing of one or more blood vessels in the legs may be indicated. If the ABI is less than 0.8, pain in the foot, leg, or buttock may occur during exercise (intermittent claudication). The poor circulation and blockage of blood in the leg arteries may produce an aching, tired, and sometimes burning pain in the legs. If the ABI is less than 0.4, various symptoms may occur even when the patient is at rest. If the ABI is less than 0.25 or below, severe limb-threatening PAD may very well be present.

Calcification of the arteries may be particularly pronounced in patients suffering from diabetes or renal insufficiency.

To date, a low ABI index (e.g., below about 0.7) may be a clear contra-indication for using sub-atmospheric pressure therapy. For a vast number of patients having a low ABI index, such sub-atmospheric pressure therapy may be largely ineffective, and may also cause infection, or promote the spreading of such infection.

It is believed that there is room and need for further improvements in methods and devices for treating a wound using sub-atmospheric pressure, and the subject matter of the present disclosure and claims is aimed at fulfilling this need.

SUMMARY OF THE INVENTION

According to the teachings of the present invention there is provided an apparatus for facilitating the healing of a wound on a limb of a body of a subject, the apparatus including: (a) a wound treatment assembly including: (i) a wound cover adapted to cover an area above the wound; (ii) a sealing arrangement, associated with the cover, adapted to contact and at least partially seal a volume beneath the cover from an ambient environment; (iii) a vacuum mechanism fluidly communicating with the volume, and adapted to produce a sub-atmospheric pressure between about 0.01 and 0.99 bar (absolute) within the volume; (b) a muscle contraction device having at least a first electrode and a second electrode, each electrode adapted to operatively contact the limb; (c) a control unit, adapted to connect to a power supply and operatively connected to each electrode, the control unit further adapted to provide, via the electrodes, a sequence of electrical impulses to neural points associated with the limb, whereby muscle tissue associated with the neural points contracts to effect a localized increase in a flow of blood through a blood vessel in the limb, the control unit operatively connected to the wound treatment assembly and further adapted to control an operation of the treatment assembly.

According to another aspect of the present invention there is provided an apparatus for facilitating the healing of a wound on a limb of a body of a subject, including: (a) a wound treatment assembly including: (i) a sealing arrangement

adapted to cover an area above the wound, and to contact and at least partially seal a volume from an ambient environment, and (ii) a vacuum mechanism fluidly communicating with the volume, and adapted to produce a sub-atmospheric pressure within the volume; (b) a muscle contraction device having at least a first electrode and a second electrode, each electrode adapted to operatively contact the limb; (c) a control unit, adapted to connect to a power supply and operatively connected to each electrode, the control unit further adapted to provide, via the electrodes, a sequence of electrical impulses to points associated with the limb, whereby muscle tissue associated with the points contracts to effect a localized increase in a flow of blood through a blood vessel in the limb, the control unit operatively connected to the wound treatment assembly and further adapted to control an operation of the treatment assembly.

According to yet another aspect of the present invention there is provided a method of facilitating the healing of a wound on a limb, including the steps of: disposing a wound cover over the wound; contacting a sealing arrangement with skin surrounding the wound; activating a vacuum mechanism to produce a sub-atmospheric pressure within the volume, and (e) delivering a sequence of electrical impulses, via the electrodes, to effect a localized change in a flow of blood through a blood vessel in the limb.

According to further features in the described preferred embodiments, the control unit has at least a first operating mode enabling a combined treatment protocol including both operation of the wound treatment assembly and operation of the muscle contraction device.

According to still further features in the described preferred embodiments, the control unit is configured to implement a combined treatment protocol including simultaneous operation of the wound treatment assembly and the muscle contraction device.

According to still further features in the described preferred embodiments, the control unit is configured to implement a combined treatment protocol including at least intermittent operation of both the wound treatment assembly and the muscle contraction device.

According to still further features in the described preferred embodiments, the control unit is configured to implement the combined treatment protocol responsive to a pre-determined sequencing.

According to still further features in the described preferred embodiments, the control unit is configured to receive the pre-determined sequencing via an input unit associated with the control unit.

According to still further features in the described preferred embodiments, the control unit has at least a second operating mode enabling a treatment protocol including solely operation of the wound treatment assembly.

According to still further features in the described preferred embodiments, the control unit has at least a second operating mode enabling a treatment protocol including solely operation of the muscle contraction device.

According to still further features in the described preferred embodiments, the apparatus further includes a mode selection switch, associated with the control unit, adapted to select between the first and second operating modes.

According to still further features in the described preferred embodiments, the control unit is configured to prompt a user for an ankle-brachial index (ABI) of the subject.

According to still further features in the described preferred embodiments, the control unit is disposed in a single housing.

According to still further features in the described preferred embodiments, the control unit is configured to perform at least one safety operation responsive to an ABI below a pre-determined value.

According to still further features in the described preferred embodiments, the safety operation includes producing a warning signal.

According to still further features in the described preferred embodiments, the safety operation includes displaying a recommended treatment protocol.

According to still further features in the described preferred embodiments, the safety operation includes disabling an option of operating solely the wound treatment assembly.

According to still further features in the described preferred embodiments, the operation of the treatment assembly includes a depth of vacuum produced by the vacuum mechanism.

According to still further features in the described preferred embodiments, the apparatus further includes a measurement unit adapted to produce at least one measurement of a parameter associated with blood flow in the subject, the control unit being configured to perform at least one safety operation responsive to the measurement.

According to still further features in the described preferred embodiments, the wound cover includes a screen, disposed within the volume, the screen being adapted to prevent overgrowth of tissue in the wound.

According to still further features in the described preferred embodiments, the screen includes an open-cell polymer foam.

According to still further features in the described preferred embodiments, the sealing arrangement includes a flexible sealing rim adapted to sealably contact skin surrounding the wound.

According to still further features in the described preferred embodiments, the sealing arrangement includes a flexible polymer sheet, the polymer sheet having an adhesive on at least one surface to attach and seal the polymer sheet to skin surrounding the wound.

According to still further features in the described preferred embodiments, the sealing arrangement includes a flexible polymer sheet overlying the screen, the polymer sheet having an adhesive on at least one surface to attach and seal the polymer sheet to skin surrounding the wound.

According to still further features in the described preferred embodiments, the sealing arrangement includes a sealing cuff in contact with skin surrounding the wound.

According to still further features in the described preferred embodiments, the control unit is adapted to produce the electrical impulses of a magnitude and frequency to effect a series of individual, substantially continuous muscle contractions.

According to still further features in the described preferred embodiments, the control unit includes a signal generator adapted to produce the electrical impulses to effect a series of muscle contractions.

According to still further features in the described preferred embodiments, the muscle tissue is activated to effect venous milking within the limb.

According to still further features in the described preferred embodiments, the muscle tissue is activated to promote a local arterial flow within the limb.

According to still further features in the described preferred embodiments, the muscle tissue is activated to promote a draining of fluid in the muscle tissue, thereby producing the localized increase in the flow of blood.

According to still further features in the described preferred embodiments, the method further includes the steps of: (f) providing an ankle-brachial index (ABI) of the subject, and (g) responsive to the ABI, controlling the apparatus to treat the subject.

According to still further features in the described preferred embodiments, the method further includes the steps of: (f) providing the control unit with an ankle-brachial index (ABI) of the subject, and (g) responsive to the ABI, controlling the apparatus, using the control unit, to treat the subject.

According to still further features in the described preferred embodiments, when the ABI is below a pre-determined value, the control unit is configured to perform at least one safety operation.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention is herein described, by way of example only, with reference to the accompanying drawings. With specific reference now to the drawings in detail, it is stressed that the particulars shown are by way of example and for purposes of illustrative discussion of the preferred embodiments of the present invention only, and are presented in the cause of providing what is believed to be the most useful and readily understood description of the principles and conceptual aspects of the invention. In this regard, no attempt is made to show structural details of the invention in more detail than is necessary for a fundamental understanding of the invention, the description taken with the drawings making apparent to those skilled in the art how the several forms of the invention may be embodied in practice. Throughout the drawings, like-referenced characters are used to designate like elements.

In the drawings:

Figure 1 provides a cross-sectional view of a sub-atmospheric pressure device of the prior art, the device including an open-cell polymer screen, a flexible hose connecting the foam section to a suction pump, and a flexible polymer sheet overlying the foam-hose assembly to provide the necessary seal;

Figure 2A provides a cross-sectional view of a sub-atmospheric pressure device of the prior art, the device including a porous screen, an inflatable cuff attached to a semi-rigid cup, and a flexible hose extending from a suction pump to a point within the sealed volume of the cup-cuff assembly;

Figure 2B provides a side view of a vacuum arrangement of a sub-atmospheric pressure device of the prior art;

Figure 3 is a block diagram showing the components of a muscle pump stimulation device according to U.S. Patent Application Serial No. 11/438070;

Figure 4A provides a schematic representation of one aspect of an integrated device or apparatus of the present invention, including both a sub-atmospheric therapy apparatus and a muscle pump device, and

Figure 4B provides a schematic representation of the integrated device of Figure 4A, disposed on a limb of a subject.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

The principles and operation of the treatment method and device of the present invention may be better understood with reference to the drawings and the accompanying description.

Before explaining at least one embodiment of the invention in detail, it is to be understood that the invention is not limited in its application to the details of construction and the arrangement of the components set forth in the following description or illustrated in the drawings. The invention is capable of other embodiments or of being practiced or carried out in various ways. Also, it is to be understood that the phraseology and terminology employed herein is for the purpose of description and should not be regarded as limiting.

One aspect of the present invention is a method and device for treating a wound by means of a sub-atmospheric pressure applied in the vicinity thereof, and more particularly, to a treatment method and device utilizing sub-atmospheric pressure therapy in conjunction with a method and device for locally increasing the flow of blood in that vicinity.

It is known to treat skin tissue damage by applying a sub-atmospheric pressure to a wound over an area sufficient to promote migration of epithelial and subcutaneous tissue toward the wound, with the sub-atmospheric pressure being maintained for a time sufficient to facilitate closure of the wound. It has been postulated that wound closure requires that epithelial and subcutaneous tissue migrate from the wound border toward the wound. Other understandings of the healing mechanism have been postulated.

Without wishing to be bound by theory, it is believed that tension on this border tissue, provided by the use of sub-atmospheric pressure, accelerates tissue migration. It has been observed that the use of sub-atmospheric pressure also causes, within the wound, increased formation of granulation tissue, a matrix of collagen, fibronectin, and hyaluronic acid carrying macrophages, fibroblasts, and neovasculature that aids in healing.

Referring now to the drawings, Figure 1 is an exemplary embodiment of a sub-atmospheric pressure therapy device **100** as provided by United States Patent No. 5,645,081 to Argenta, et al., which is incorporated by reference for all purposes as if fully set forth herein. Device **100** has a flat open cell polyester foam section **10** sufficiently large to cover a wound **5** and thus prevent wound

overgrowth, a flexible hollow tube **11** inserted into foam section **10** and joined thereto with an adhesive, and extending to attach at its opposite end to a suction device such as a vacuum pump **15**. Device **100** further includes a covering and sealing arrangement such as an adhesive sheet **12** overlying foam section **10** and tube **11**. Adhesive sheet **12** may be adapted to completely surround foam section **10**, and may adhere to the skin surrounding wound **5**, forming a seal that allows the generation of a sub-atmospheric pressure when vacuum pump **15** operates.

Figure 2A provides a cross-sectional view of a sub-atmospheric pressure device **200** of the prior art, the device including a porous screen, a cuff such as inflatable cuff **22** attached to a semi-rigid cup **21**, and a flexible hose or tubing **23** extending from a suction pump (shown in Figure 2B) to a point within a sealed volume **26** of the cup-cuff assembly.

Cuff **22** and semi-rigid cup **21** may at least partially define a housing such as an adult cardiopulmonary resuscitation (CPR) mask **20**. Inflatable cuff **22** is adapted to contact a skin surface **28**. Device **200** further includes an open cell polyester screen **24** overlying wound **5**, and a flexible suction hose **23** connected by a tubing connector (not shown) to a vacuum arrangement **25** and extending through a sealed hole **27** in cup **21**. Device **200** may be configured such that hose **23** enables fluid communication between cup **21** and a liquid trap bottle **32** (shown in Figure 2B), to collect any liquid exudate, and between cup **21** and a vacuum pump **34**. Device **200** is adapted to be attached over wound **5**. After device **200** is attached, suction (e.g., 2-6 pounds vacuum) may be applied. The treatment may significantly accelerate healing and closure of wounds of various

types.

As will be apparent to one of ordinary skill in the art, vacuum arrangement **25** may include liquid trap bottle **32**, vacuum pump **34**, and a vacuum filter **36** coupled between trap bottle **32** and pump **34**. Liquid trap bottle **32** may fluidly communicate with a dedicated drainage tube (not shown) to collect liquid in and above wound **5**. The sub-atmospheric pressure produced by vacuum arrangement **25** may facilitate drainage, and may facilitate closure of wound **5**.

It will be appreciated that there exist many types and variations of sub-atmospheric pressure devices for wound treatment, and that additional types and variations may be conceived by those skilled in the art.

It is generally accepted that the use of such sub-atmospheric pressure devices may be indicated solely for patients having a reasonably healthy local flow of blood in the vicinity of the wound to be treated. As described in greater detail hereinabove, a low ABI index, and more particularly, an ABI index below about 0.7, may be a clear contra-indication for using sub-atmospheric pressure therapy. For a vast number of patients having a low ABI index, such sub-atmospheric pressure therapy may be largely ineffective, and may also cause infection, or promote the spreading of such infection.

The inventive treatment device and method utilize a sub-atmospheric pressure device for treating a wound or skin surface, in conjunction with a method and/or device for locally increasing the flow of blood in the immediate vicinity of the wound or skin surface. By activating the local muscle tissue using

electrical stimulation via the neural motor points (as in functional electrical stimulation devices), an appreciable increase in the local flow of blood (i.e., in the vicinity of the wound) may be safely achieved, enabling many patients having a low ABI index to enjoy the benefits of sub-atmospheric pressure therapy.

One presently-preferred device and method for effecting the localized increase in blood flow is taught by U.S. Patent Application Serial No. 11/438,070, which is incorporated by reference for all purposes as if fully set forth herein.

Figure 3 is a block diagram showing the components of a stimulation device **300** according to U.S. Patent Application Serial No. 11/438070. Signal generator **310** may be operatively connected to a power supply **312**. Also connected to power supply **312**, may be control unit or microprocessor **314** and display **316**. Signal generator **310** may also be integral with microprocessor **314**. Signal generator **310** may also operatively connected to a plurality of electrodes **320** via switching mechanism **318**. Control unit **314** controls signal generator **310** so as to produce a series of electrical stimulation impulses. These impulses are delivered to electrodes **340**, which are adapted to be positioned on a limb or limb segment of the patient. Switching mechanism **318** determines to which pair of electrodes the stimulation impulses will be delivered. Switching mechanism **318** may also be configured as a distributing mechanism that simultaneously distributes a positive or negative signal to two or more electrodes.

Various embodiments of switching mechanism **318** may include a mechanical switching system, an electromechanical relay mechanism, or preferably, an electrical/electronic switching system controlled by control unit **314**. A solid state relay having a photo-sensitive metal oxide semiconductor effect transistor (MOSFET) device with an LED to actuate the device is one presently preferred embodiment for switching mechanism **318**.

The device and method of the present invention may be better understood with reference to Figures 4A and 4B. Figure 4A provides a schematic representation of one aspect of an integrated device or apparatus **400** of the present invention, including both a sub-atmospheric therapy system or apparatus **450**, and a muscle pump or stimulation device **470** that may be similar to stimulation device **300** described hereinabove. Figure 4B provides a schematic representation of device **400**, disposed on a limb of a subject, by way of example, a lower leg. A power supply **412** may provide power to a high-voltage generator **415**, a control unit **414**, a signal generator **410**, a display **416**, an input or inputting device **426**, an alarm or alarm device **428**, a switching mechanism such as an isolation switch matrix **418**, and to sub-atmospheric therapy apparatus **450**. Control unit **414** may be connected to, or may communicate with, both sub-atmospheric therapy apparatus **450** and various components of stimulation device **470**, such as high-voltage generator **415**, signal generator **410**, display **416**, input **426**, alarm **428**, and switch matrix **418**. Electrodes **440** may be connected to control unit **414** via switch matrix **418**, or via high-voltage generator **415**.

Although signal generator **410**, as shown, is disposed within control unit **414**, it will be appreciated that signal generator **410** may be disposed outside control unit **414**. It will be further appreciated that display **416** and input **426** may serve both sub-atmospheric therapy apparatus **450** and muscle pump or stimulation device **470**.

Control unit **414** may be connected to the various controlled components using analog, discrete, and/or serial I/O signals, according to the requirements of the interfaces of the respective components. It will be appreciated that the communication mechanism may include an electronic network of various designs, including serial bus or parallel bus architectures.

Control unit **414** may effect automated control of sub-atmospheric therapy apparatus **450** and stimulation device **470** for a variety of treatment protocols.

With specific reference now to Figure 4B, a lower leg **490** of a subject has a surface wound, such as a surface wound disposed on the calf, and/or a surface wound disposed on the instep. Each of these surface wounds may be covered by a wound covering and sealing arrangement that includes wound cover and sealing arrangements **420a** and **420b**, respectively. As described, vacuum arrangement **425** provides suction to the volume defined by a wound cover and sealing arrangement (such as arrangement **420a**) and the surface of the limb thereunder, responsive to control unit **414**, so as to achieve a sub-atmospheric pressure within that volume.

The efficacy of the sub-atmospheric pressure therapy may be limited by the rate at which blood -- containing oxygen, nutrients, white blood cells, and

other constituents -- is delivered to the area around the wound. For patients having a low ABI index, such therapy may be of extremely limited value, or may even cause or spread infection, or be of otherwise negative influence.

We have found, however, that various mechanical compression methods for locally increasing the flow of blood to be unsuitable, and possibly deleterious, for use in conjunction with sub-atmospheric pressure therapy, particularly in the case of patients having a low ABI index. Compression techniques may be extremely painful when applied in the vicinity of a wound, even when applied against unbroken skin.

By sharp contrast, we have found that by activating the local muscle tissue using electrical stimulation via the neural motor points, a significant increase in the flow of blood in the vicinity of the wound may be safely achieved. Without wishing to be bound by theory, we believe that electrically stimulated muscle movement gently and rhythmically pressures the local blood vessels to increase the local flow of blood. The muscle movement is effected from within the limb, such that sensitive skin and surface wounds associated with the skin may be completely or substantially unharmed. In various external compression techniques, however, the driving force -- compression -- is delivered from outside the surface of the body, such that the skin and wound area lie between the driving force and blood vessels such as deep veins within the limb, and must therefore disadvantageously absorb and transfer the compressive forces.

In one preferred embodiment, the electrical stimulation of the local muscle tissue is performed to effect venous milking.

In another preferred embodiment, the electrical stimulation of the local muscle tissue is performed to promote at least the local arterial flow.

In another preferred embodiment, the electrical stimulation of the local muscle tissue is performed to promote draining of the blood in the local muscle tissue, thereby producing a local increase in the blood flow.

Stimulation device **470** includes at least two electrodes **440a**, **440b** adapted to be disposed on the skin surface of the patient. Electrodes **440a**, **440b** may be fabricated from a conventional conducting foil and a conducting hydrogel adhesive, or from various other conducting medium that will be readily apparent to one of ordinary skill in the art. Various electrodes used in transcutaneous electrical nerve stimulation (TENS) pain reduction devices may be particularly suitable.

While switch matrix **418** may enable the use of at least three, and typically, at least four electrodes, the present invention is capable of operating without such a switch matrix, and with a minimum of two electrodes.

Electrodes **440a**, **440b** are placed on the skin surface of the subject. The general size, shape, and placement of electrodes **440a**, **440b** are advantageously determined to achieve superior stimulation of the particular underlying muscles. In the case of lower leg **490** shown in Figure 4B, the most important underlying muscles include the soleus and gastrocnemius muscles.

Typically, electrodes **440a**, **440b** may be disposed on either side (e.g. on an upstream side and a downstream side, with respect to the venous return) of the wound, such as on either side of a surface wound covered by cover arrangement **420a**. However, an appreciable increase in the flow of blood to the wound area may be achieved even when the wound area is not between the electrodes, and is upstream, with respect to the venous return, from the electrodes. By way of example, electrodes **440a**, **440b** are both disposed downstream of the wound on the instep, covered by cover arrangement **420b**. Upon activating muscle pump **470**, venous return may be enhanced, and fluid pressure, and associated pain within the foot may be at least partially alleviated. Furthermore, the stimulated muscles are in the calf, far removed from the instep, such that vigorous contraction of the muscles may be effected without causing discomfort to the instep area.

Thus, according to one aspect of the present invention there is provided an apparatus for facilitating the healing of a wound on a limb of a body of a subject, the apparatus including: (a) a wound treatment assembly having: (i) a wound cover adapted to cover an area above the wound; (ii) a sealing arrangement, associated with the cover, adapted to contact and at least partially seal a volume beneath the cover from an ambient environment; (iii) a vacuum mechanism fluidly communicating with the volume, and adapted to produce a sub-atmospheric pressure within the volume; (b) a muscle contraction device having at least a first electrode and a second electrode, adapted to operatively contact the limb; (c) a control unit, adapted to connect to a power supply and operatively

connected to each the electrode, the control unit further adapted to provide, via the electrodes, a sequence of electrical impulses to neural motor points associated with the limb, whereby muscle tissue associated with the neural motor points contracts to effect a localized increase in a flow of blood through a blood vessel in the limb, the control unit being operatively connected to the wound treatment assembly and further adapted to control an operation of the treatment assembly.

The control unit may have a first operating mode enabling a combined treatment protocol including both operation of the wound treatment assembly and operation of the muscle contraction device. The combined treatment protocol may include simultaneous operation of the wound treatment assembly and the muscle contraction device, or including at least intermittent operation of both the wound treatment assembly and the muscle contraction device.

We have found that in many patients, particularly those having a low ABI index, are largely insusceptible to muscle fatigue due to lengthy muscle contraction treatments. This may, in turn, enable lengthy sub-atmospheric treatments of at least 2 to 3 hours, in some cases, at least 6 hours, or even substantially continuously. We have further found that in some cases, the length of the treatment may be extended by intermittently operating the muscle contraction device at a lower than optimal intensity. By doing so, increased blood flow may be sustained over continuous operation (at least 6-24 hours, possibly more), while benefitting from concurrent operation of the sub-atmospheric pressure therapy.

The control unit may advantageously be disposed in a single housing.

The control unit may be configured to implement the combined treatment protocol responsive to a pre-determined sequencing. The control unit may be configured to receive the pre-determined sequencing via an input unit such as input unit **426**.

The control unit may have an additional operating mode enabling a treatment protocol including solely operation of the wound treatment assembly, and/or an additional operating mode enabling a treatment protocol including solely operation of the muscle contraction device. The control unit may also have a mode selection switch such as mode selection switch **460**, for selecting between the various operating modes.

The control unit may be configured to prompt a user for an ankle-brachial index (ABI) of the subject. For example, responsive to an ABI below a pre-determined value, the control unit may be configured to perform at least one safety operation, including but not limited to producing a warning signal, displaying a recommended treatment protocol, and/or disabling an option of operating the wound treatment assembly without the muscle contraction device. In various circumstances, the control unit may activate alarm **428**.

The control unit may be configured to control various parameters pertaining to the vacuum arrangement, including a depth of vacuum produced by the vacuum mechanism. Various other control functions pertaining to the vacuum arrangement will be recognized by one of ordinary skill in the art.

The inventive apparatus may further include a measurement unit **436** adapted to produce at least one measurement of a parameter associated with blood flow in the subject. The control unit may be configured to perform at least one safety operation or other operation responsive to this measurement. Examples of such measurement units include:

- blood velocity measurement, e.g., using a Doppler instrument;
- on-line ABI measurement (can be input or directly transferred to the control unit);
- RTS (Refill Time Sensor) - measures cyclic changes in the leg (limb) volume due to blood flow (inflow and reflux) using body impedance plethysmography measurements;
- MCS (Muscle Contraction Sensor) - measures the magnitude of muscle contraction to provide, inter alia, direct feedback on the physical placement of the electrodes, and effective treatment with reduced user discomfort through the modification of the electrical signal characteristic (e.g. current intensity, pulse train modulation etc.);
- LTS (Limb Temperature Sensor) - measures the limb border temperature to provide a clinical treatment indication (e. g., for PAD);
- UAS (Ultrasound Artery Sensor) - measures arterial blood flow, e.g., by means of a miniature ultrasonic transducer, to provide quick, direct feedback regarding therapy efficacy.

Using the apparatus and method of the present invention, patients having a characteristically low ABI, below 0.7, below 0.6, below 0.5, and in some cases, as low as about 0.3, may be efficaciously treated with the sub-atmospheric pressure therapy, and substantially without risk, or with significantly reduced risk of infection. In some cases, however, the ABI is not an accurate measurement, and a toe brachial index (TBI) may be used. TBI is a calculation

based on the systolic blood pressures of the arm and the systolic blood pressures of the toes. The examination is similar to the ABI except that it is performed with a photoplethysmograph (PPG) infrared light sensor and a small blood pressure cuff placed around the toe. A TBI of 0.8 or greater is considered normal.

As used herein in the specification and in the claims section that follows, the term "limb" is specifically meant to include an arm or a leg. The hand, forearm, upper arm, and shoulder are considered to be parts of a single limb. Similarly, the foot, lower leg, and upper leg are considered to be parts of a single limb.

Although the invention has been described in conjunction with specific embodiments thereof, it is evident that many alternatives, modifications and variations will be apparent to those skilled in the art. Accordingly, it is intended to embrace all such alternatives, modifications and variations that fall within the spirit and broad scope of the appended claims. All publications, patents and patent applications mentioned in this specification, including U.S. Patent Nos. 5,645,081, 6,458,109, and U.S. Patent Publication No. 20070270917, are herein incorporated in their entirety by reference into the specification, to the same extent as if each individual publication, patent or patent application was specifically and individually indicated to be incorporated herein by reference. In addition, citation or identification of any reference in this application shall not be construed as an admission that such reference is available as prior art to the present invention.

WHAT IS CLAIMED IS:

1. An apparatus for facilitating the healing of a wound on a limb of a body of a subject, the apparatus comprising:

(a) a wound treatment assembly including:

(i) a wound cover adapted to cover an area above the wound;

(ii) a sealing arrangement, associated with said cover, adapted to contact and at least partially seal a volume beneath said cover from an ambient environment;

(iii) a vacuum mechanism fluidly communicating with said volume, and adapted to produce a sub-atmospheric pressure between about 0.01 and 0.99 bar (absolute) within said volume;

(b) a muscle contraction device having at least a first electrode and a second electrode, each said electrode adapted to operatively contact the limb;

(c) a control unit, adapted to connect to a power supply and operatively connected to each said electrode, said control unit further adapted to provide, via said electrodes, a sequence of electrical impulses to neural points associated with the limb, whereby muscle tissue associated with said neural points contracts to effect a localized increase in a flow of blood through a blood vessel in the limb,

said control unit operatively connected to said wound treatment assembly and further adapted to control an operation of said treatment assembly.

2. The apparatus of claim 1, wherein said control unit has at least a first operating mode enabling a combined treatment protocol including both operation of said wound treatment assembly and operation of said muscle contraction device.

3. The apparatus of claim 1, wherein said control unit is configured to implement a combined treatment protocol including simultaneous operation of said wound treatment assembly and said muscle contraction device.

4. The apparatus of claim 1, wherein said control unit is configured to implement a combined treatment protocol including at least intermittent operation of both said wound treatment assembly and said muscle contraction device.

5. The apparatus of claim 4, wherein said control unit is configured to implement said combined treatment protocol responsive to a pre-determined sequencing.

6. The apparatus of claim 5, wherein said control unit is configured to receive said pre-determined sequencing via an input unit associated with said control unit.

7. The apparatus of claim 2, wherein said control unit has at least a second operating mode enabling a treatment protocol including solely operation of said wound treatment assembly.

8. The apparatus of claim 2, wherein said control unit has at least a second operating mode enabling a treatment protocol including solely operation of said muscle contraction device.

9. The apparatus of claim 7 or claim 8, further comprising a mode selection switch, associated with said control unit, adapted to select between said first and said second operating modes.

10. The apparatus of any of claims 1-9, wherein said control unit is configured to prompt a user for an ankle-brachial index (ABI) of the subject.

11. The apparatus of any of claims 1-9, wherein said control unit is disposed in a single housing.

12. The apparatus of claim 10, wherein, responsive to an ABI below a pre-determined value, said control unit is configured to perform at least one safety operation.

13. The apparatus of claim 12, wherein said safety operation includes producing a warning signal.

14. The apparatus of claim 12, wherein said safety operation includes displaying a recommended treatment protocol.

15. The apparatus of claim 12, wherein said safety operation includes disabling an option of operating solely said wound treatment assembly.

16. The apparatus of any of claims 1-9, wherein said operation of said treatment assembly includes a depth of vacuum produced by said vacuum mechanism.

17. The apparatus of any of claims 1-9, further comprising a measurement unit adapted to produce at least one measurement of a parameter associated with blood flow in the subject, said control unit configured to perform at least one safety operation responsive to said measurement.

18. The apparatus of any of claims 1-9, said wound cover including a screen, disposed within said volume, said screen adapted to prevent overgrowth of tissue in the wound.

19. The apparatus of claim 18, said screen including an open-cell polymer foam.

20. The apparatus of any of claims 1-9, said sealing arrangement including a flexible sealing rim adapted to sealably contact skin surrounding the wound.

21. The apparatus of any of claims 1-9, said sealing arrangement including a flexible polymer sheet, said polymer sheet having an adhesive on at least one surface to attach and seal said polymer sheet to skin surrounding the wound.

22. The apparatus of any of claims 1-9, said sealing arrangement including a sealing cuff in contact with skin surrounding the wound.

23. The apparatus of any of claims 1-9, wherein said control unit is adapted to produce said electrical impulses of a magnitude and frequency to effect a series of individual, substantially continuous muscle contractions.

24. The apparatus of any of claims 1-9, wherein said control unit includes a signal generator adapted to produce said electrical impulses to effect a series of muscle contractions.

25. A method of facilitating the healing of the wound, comprising the steps of:

(a) providing the apparatus of any of claims 1-9;

(b) disposing said wound cover over the wound;

(c) contacting said sealing arrangement with skin surrounding the wound;

(d) activating said vacuum mechanism to produce said sub-atmospheric pressure within said volume, and

(e) delivering said sequence of electrical impulses, via said electrodes, to effect said localized change in said flow of blood.

26. The method of claim 25, wherein said muscle tissue is activated to effect venous milking within the limb.

27. The method of claim 25, wherein said muscle tissue is activated to promote a local arterial flow within the limb.

28. The method of claim 25, wherein said muscle tissue is activated to promote a draining of fluid in said muscle tissue, thereby producing said localized increase in said flow of blood.

29. The method of claim 25, further comprising the steps of:
(f) providing an ankle-brachial index (ABI) of the subject, and
(g) responsive to said ABI, controlling the apparatus to treat the subject.

30. The method of claim 25, further comprising the steps of:
(f) providing said control unit with an ankle-brachial index (ABI) of the subject, and
(g) responsive to said ABI, controlling the apparatus, using said control unit, to treat the subject.

31. The method of claim 25, wherein, when said ABI is below a pre-determined value, said control unit is configured to perform at least one safety operation.

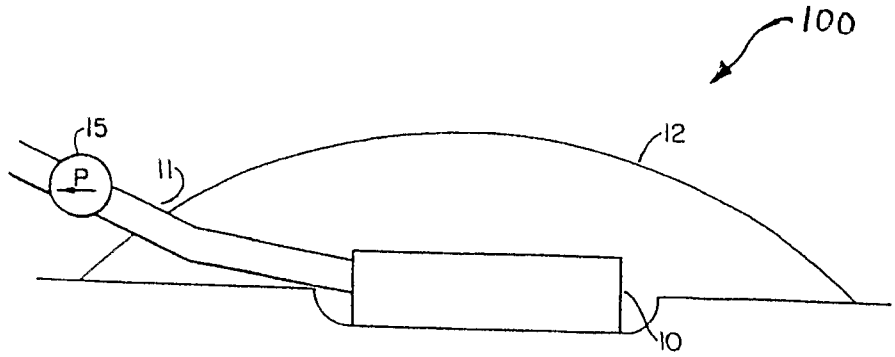


FIG. 1.

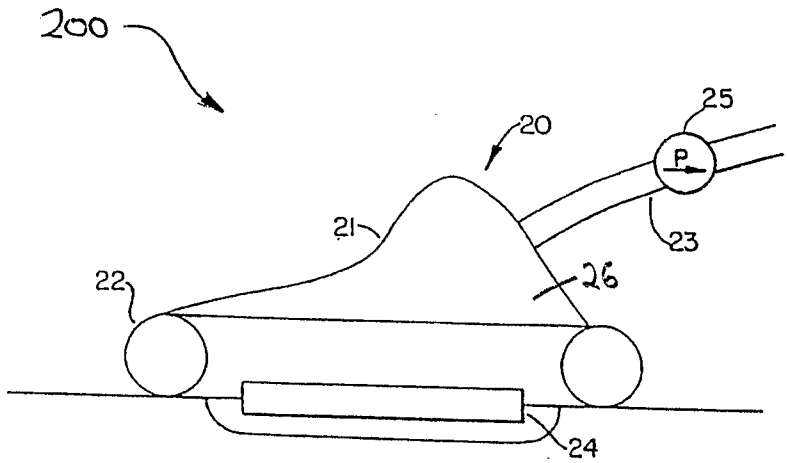


FIG. 2A

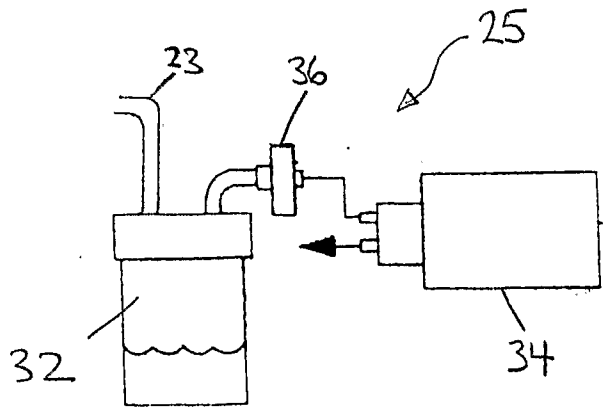
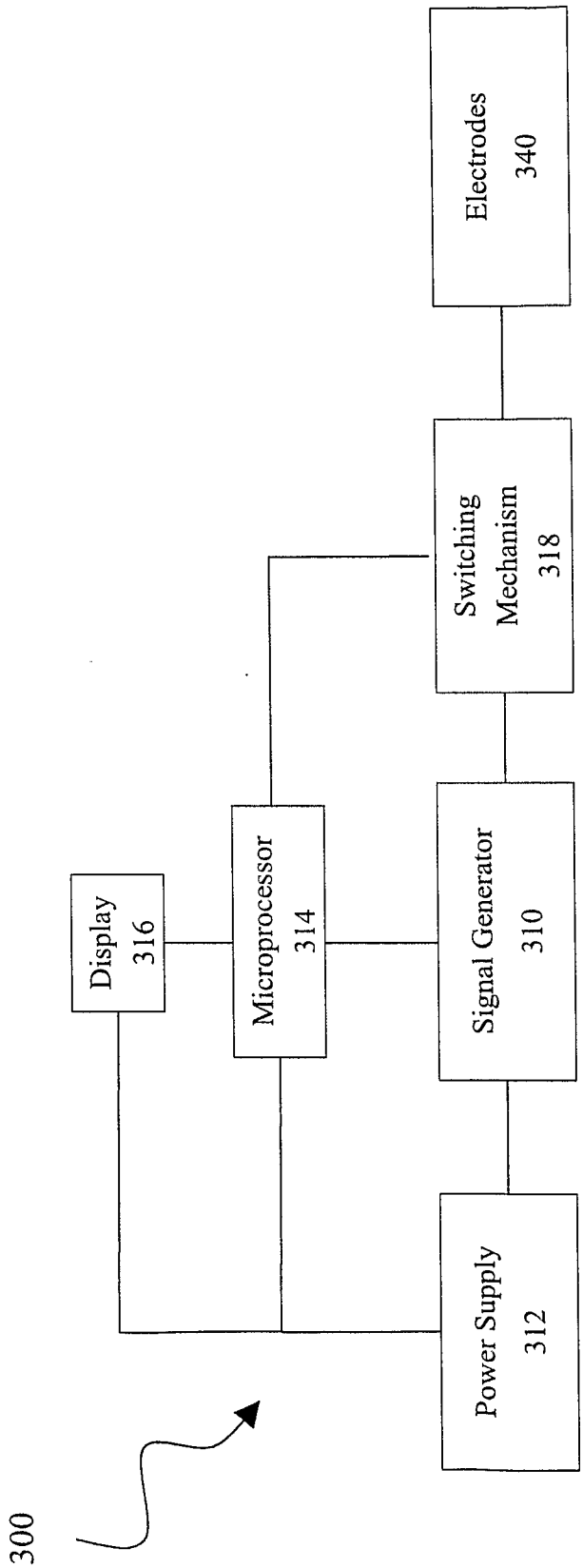


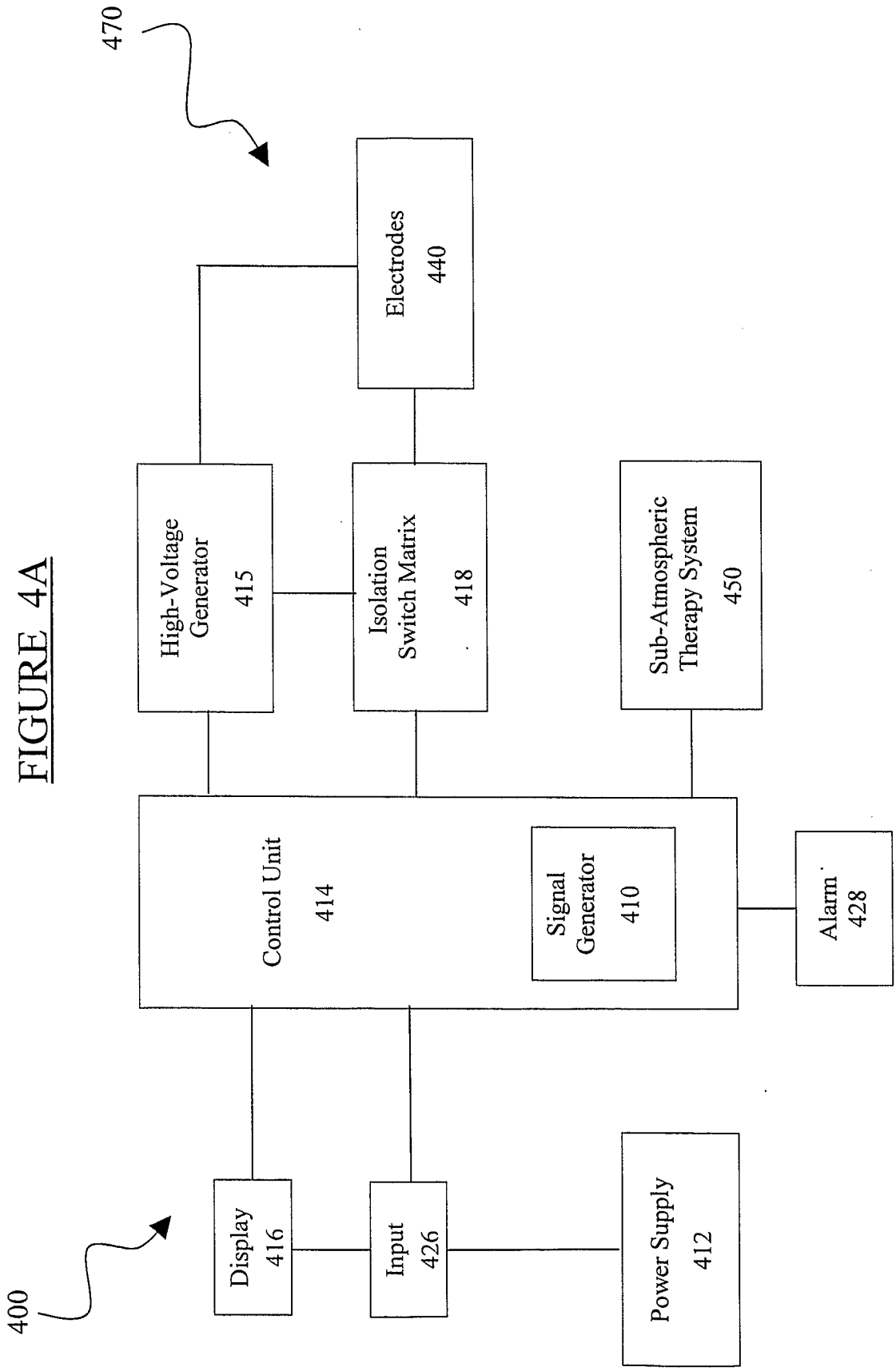
FIG. 2B

FIGURE 3



Based on US patent application No. 11/438,070

FIGURE 4A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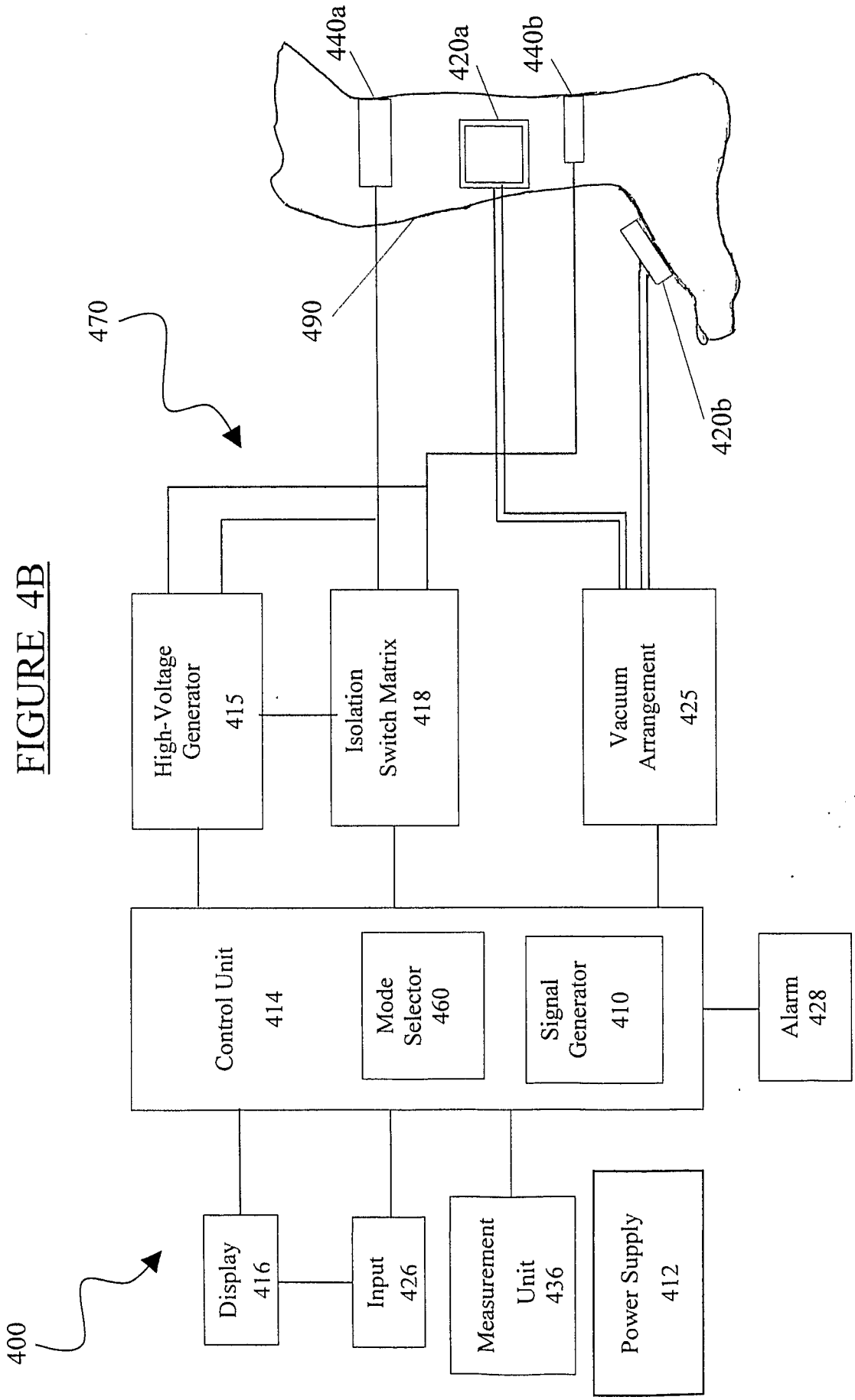
Electrodes
440
High-Voltage
Generator
415
Isolation
Switch Matrix
418
Sub-Atmospheric
Therapy System
450
Control Unit
414
Signal
Generator
410
Alarm
428
400
Display
416
Input
426
Power Supply
412

FIGURE 4B


400
Display 416
Input 426
Measurement Unit 436
Power Supply 412
Control Unit 414
Mode Selector 460
Signal Generator 410
Alarm 428
High-Voltage Generator 415
Isolation Switch Matrix 418
Vacuum Arrangement 425
470
490
440a
420a
440b
420b