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[54] **THERAPEUTIC METHOD FOR TREATING ULCERS**

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[73] Assignee: **KCI Licensing, Inc.**, San Antonio, Tex.

[21] Appl. No.: **08/903,026**

[22] Filed: **Jul. 30, 1997**

Related U.S. Application Data

[60] Provisional application No. 60/053,902, Jul. 28, 1997, abandoned.

[51] **Int. Cl.**[7] **A61B 19/00**

[52] **U.S. Cl.** **128/898**; 601/152

[58] **Field of Search** ..... 128/898, DIG. 20; 601/152; 604/307, 290, 305, 180, 30

[56] **References Cited**

U.S. PATENT DOCUMENTS

3,026,874	3/1962	Stevens .
4,382,441	5/1983	Svedman .
4,614,179	9/1986	Gardner et al. .
4,969,880	11/1990	Zamierowski .
5,149,331	9/1992	Ferdman et al. .

FOREIGN PATENT DOCUMENTS

WO 93/09727 5/1993 WIPO .

OTHER PUBLICATIONS

U.S. Patent Application No. 08/517,901 filed Aug. 22, 1995.

Kinetic Concepts, Inc., The VAC, Assisting in Wound Healing, Date Unknown.

U.S. Patent Application No 08/039,574 filed Mar. 25, 1993.

Kinetic Concepts, Inc., The Plexipulse All in 1 System, Date Unknown.

Dillon, Richard S., Treatment of Resistant Venous Stasis Ulcers and Dermatitis with the End–Diastolic Pneumatic Compression Boot, Angiology–The J. of Vascular Diseases 37: 47–56, 1986.

Herrmann, Louis G. et al., The Conservative Treatment of Arteriosclerotic Peripheral Vascular Disease Ann. Surg. 100; 750–760, 1934.

Landis, Eugene M. et al., The Clinical Value of Alternate Suction and Pressure in the Treatment of Advanced Peripheral Vascular Disease, Am. J. Med. Sci. 189: 305–325, 1935.

Landis, Eugene M. et al., The Effects of Alternate Suction and Pressure on Blood Flow to the Lower Extremeties, J. Clin. Investigation 12: 925–961, 1933.

Murray, James, On the Local and General Influence on the Body of Increased and Diminished Atmospheric Pressure, Lancet 1:909–917, 1835.

Selahaddin Rastgeldi, Pressure Treatment of peripheral Vascular Disease, 1956, 1972.

Selahaddin Rastgeldi, Intermittent Pressure Treatment of Peripheral Vascular Disease, 1959, 1972.

P. Gaskell & J. Parrott, The Effect of a Mechanical Venous Pump on the Circulation, Apr. 1978.

J.C.W. Parrot, The Effect of a Mechanical Venous Pump on the Circulation in the Feet, Oct. 1972.

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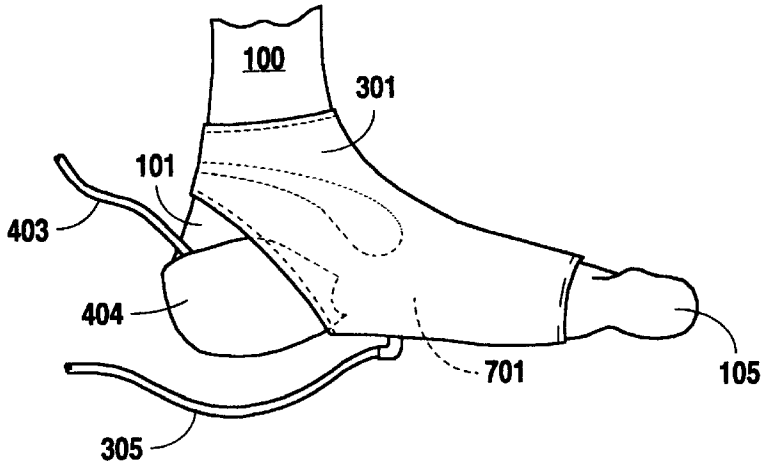
Attorney, Agent, or Firm—Wayne J. Colton, Inc.

[57] **ABSTRACT**

A method and apparatus for providing concurrent applications of intermittent pneumatic compression therapy and vacuum assisted closure therapy generally comprises a wound dressing for introduction of a negative pressure into a wound on a patient's foot and a foot wrap for application of positive, compressive forces to substantially all of the patients foot. A suction pump, having an associated vacuum sensor and first feedback mechanism, supplies negative pressure to the wound dressing. A ventable source of pressurized gas, having an associated pressure transducer and second feedback mechanism, supplies positive force to the foot wrap. At least one control system is operably associated with the suction pump and ventable source of pressurized gas for controlling the negative and positive applications of pressure to the patient's foot. Controlled modes for operation include continuous or intermittent application of one or both therapies and simultaneous or cycled application of the therapies.

13 Claims, 7 Drawing Sheets



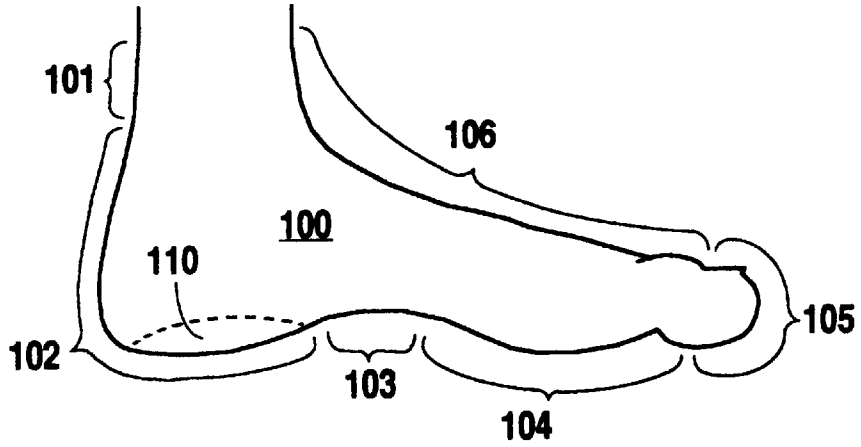


Fig. 1

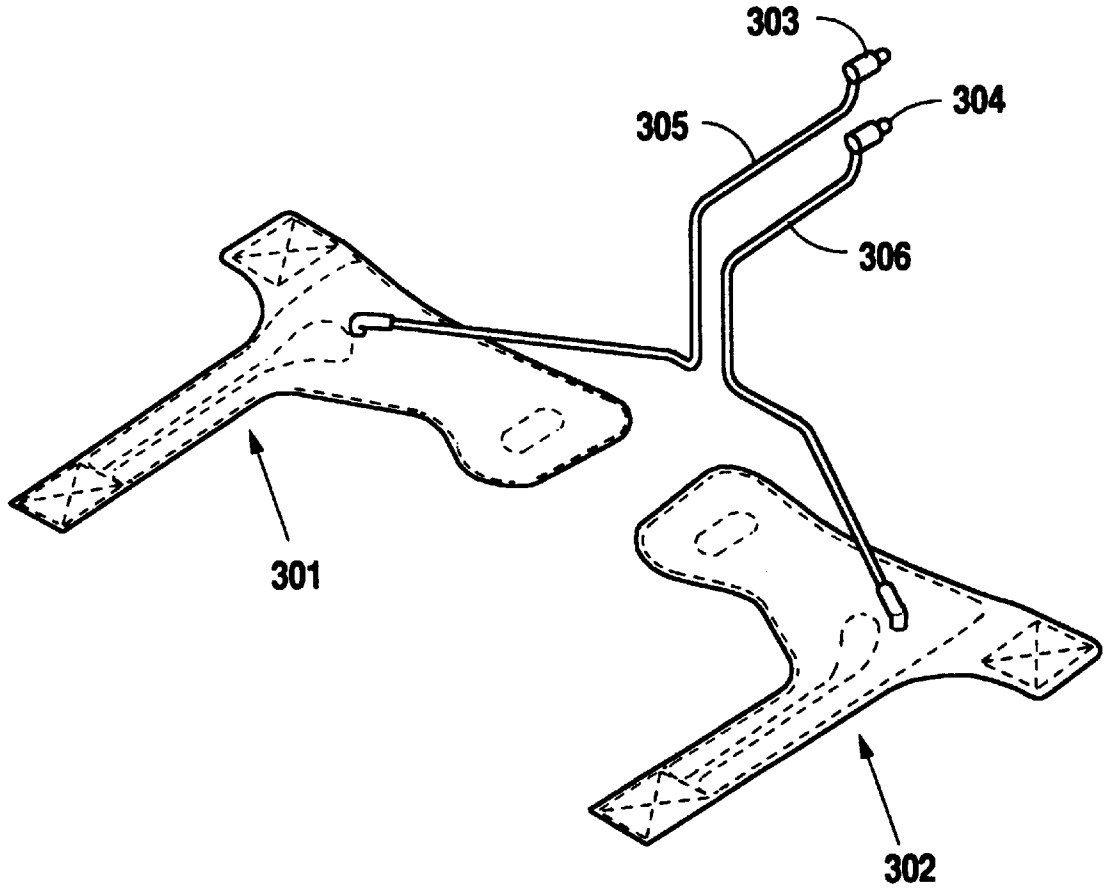


Fig. 3

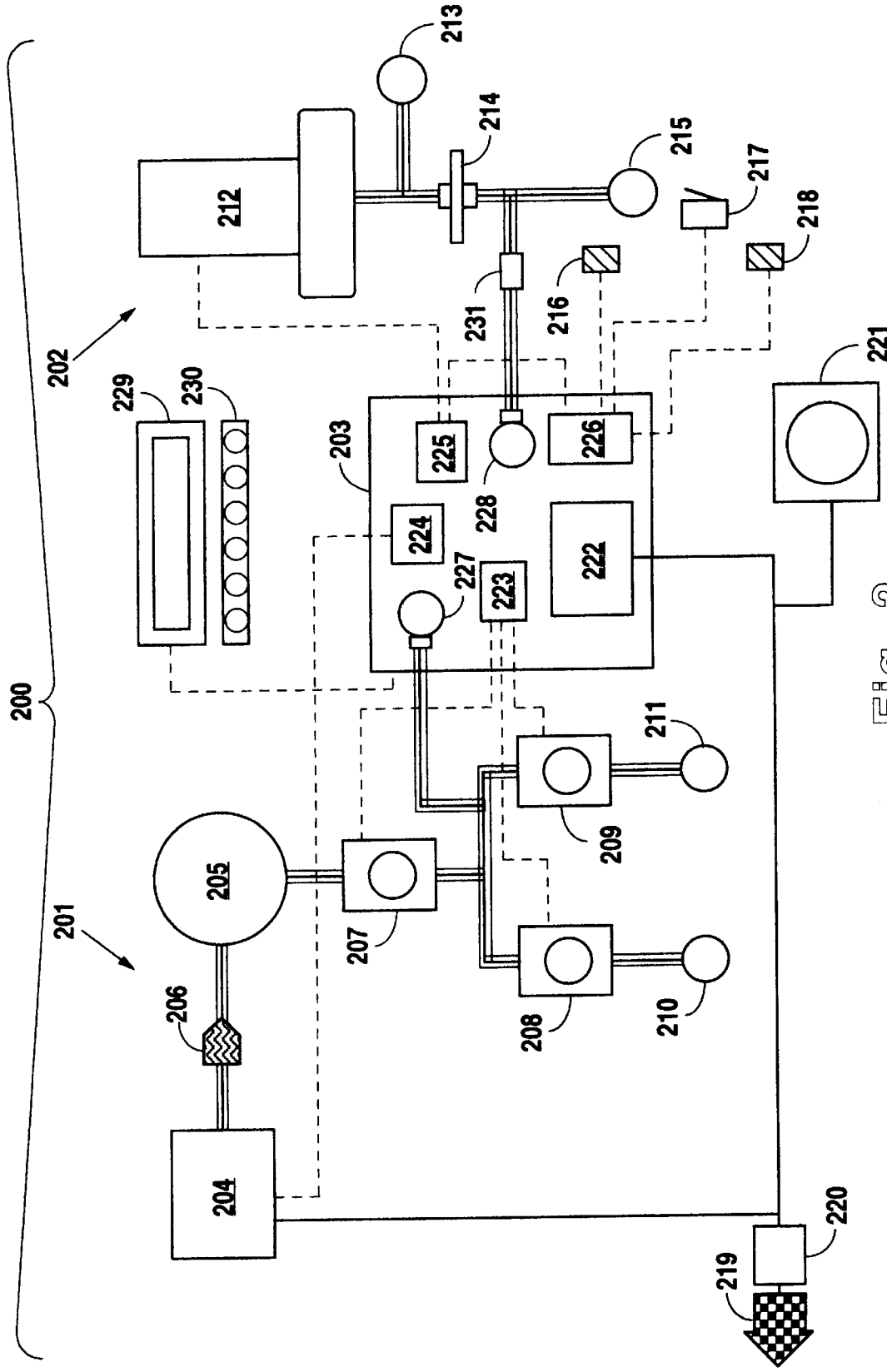

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Fig. 2

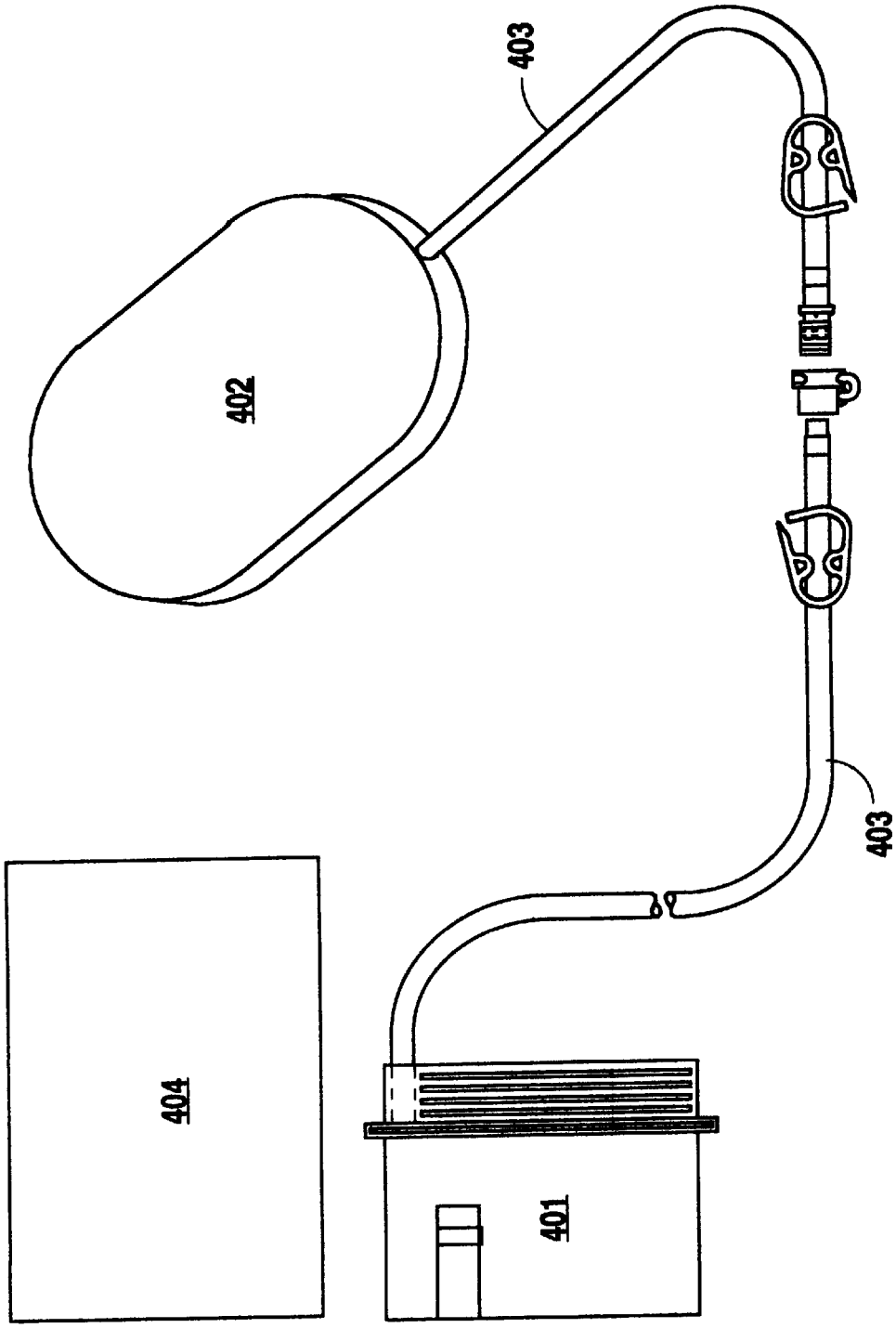

Fig. 4

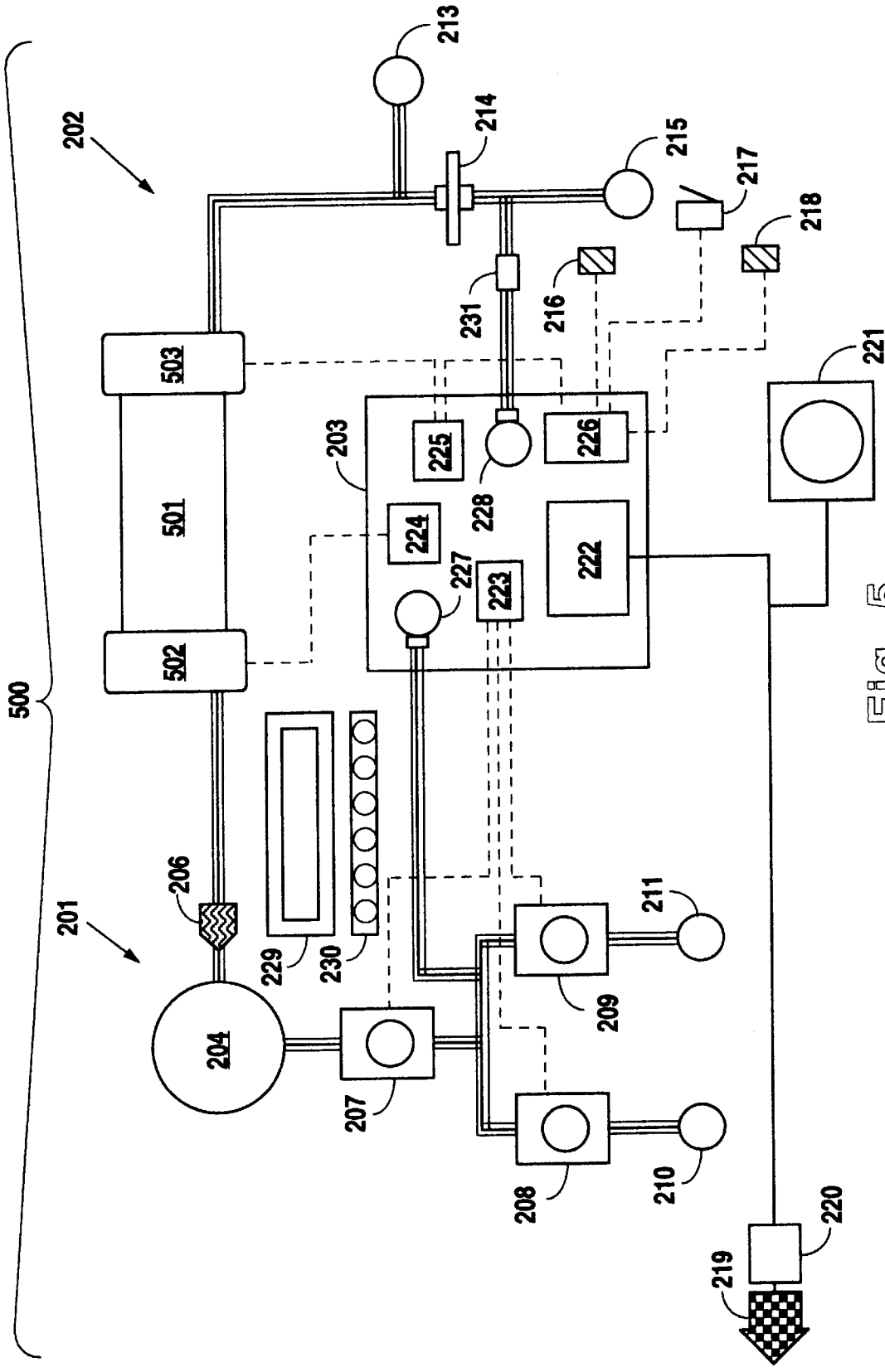
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Fig. 5

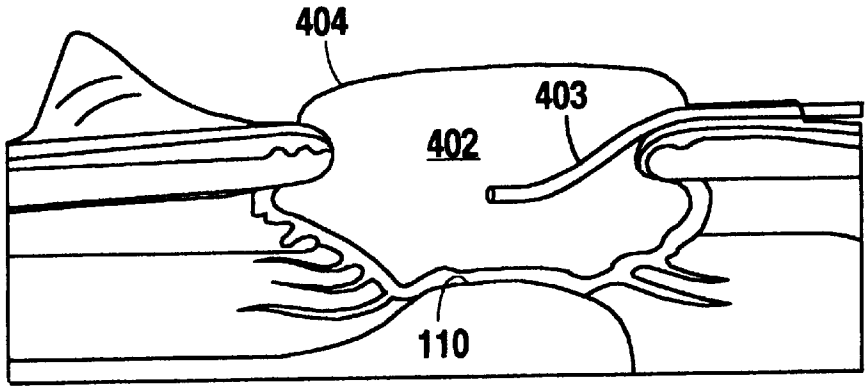

Fig. 6A

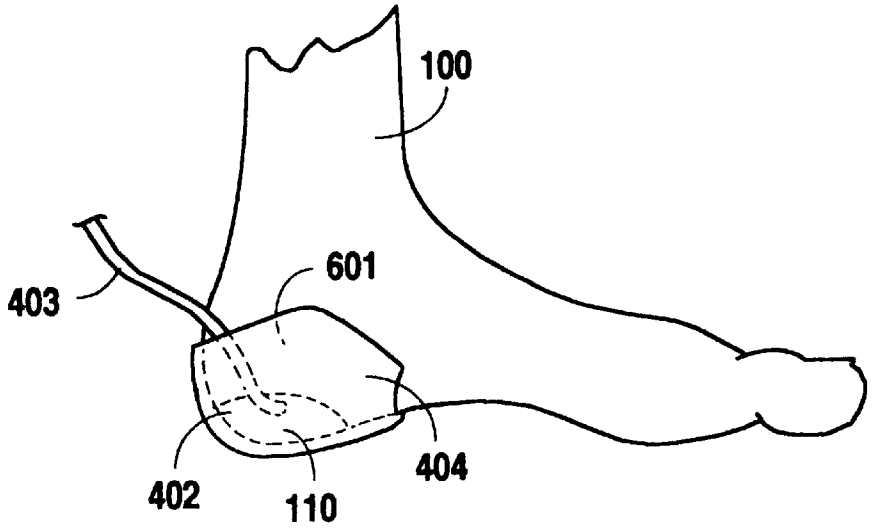

Fig. 6B

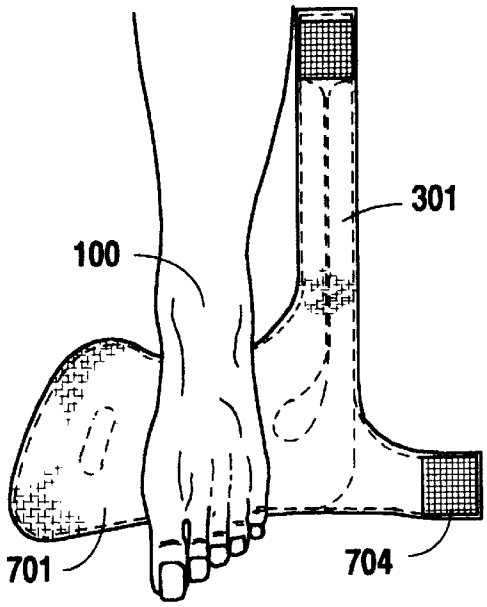

Fig. 7A

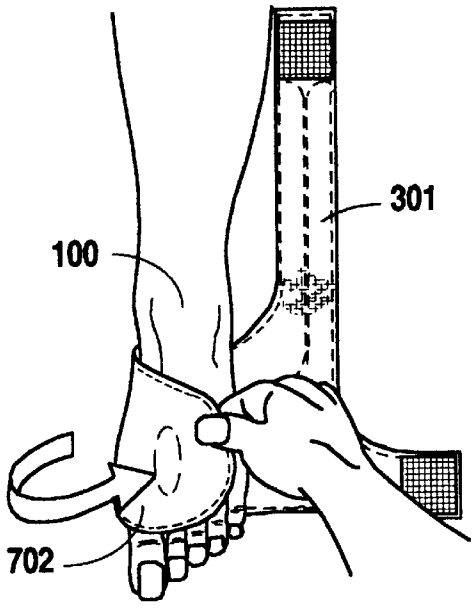

Fig. 7B

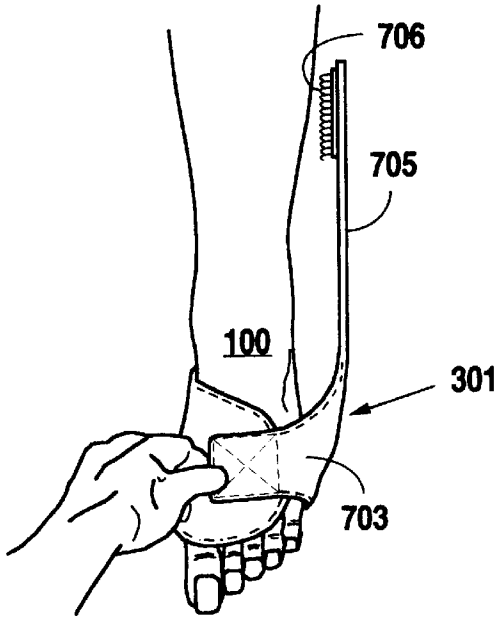

Fig. 7C

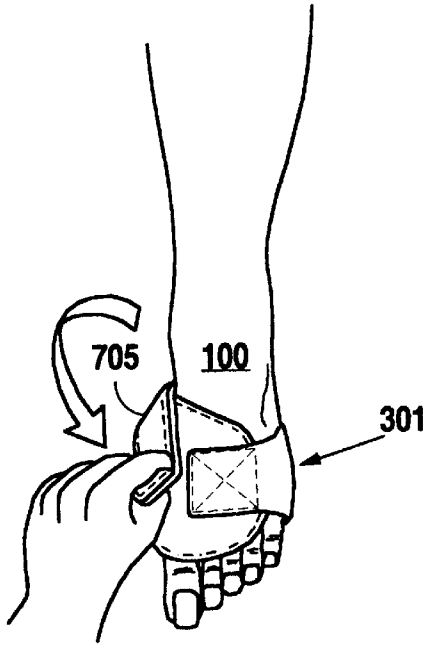

Fig. 7D

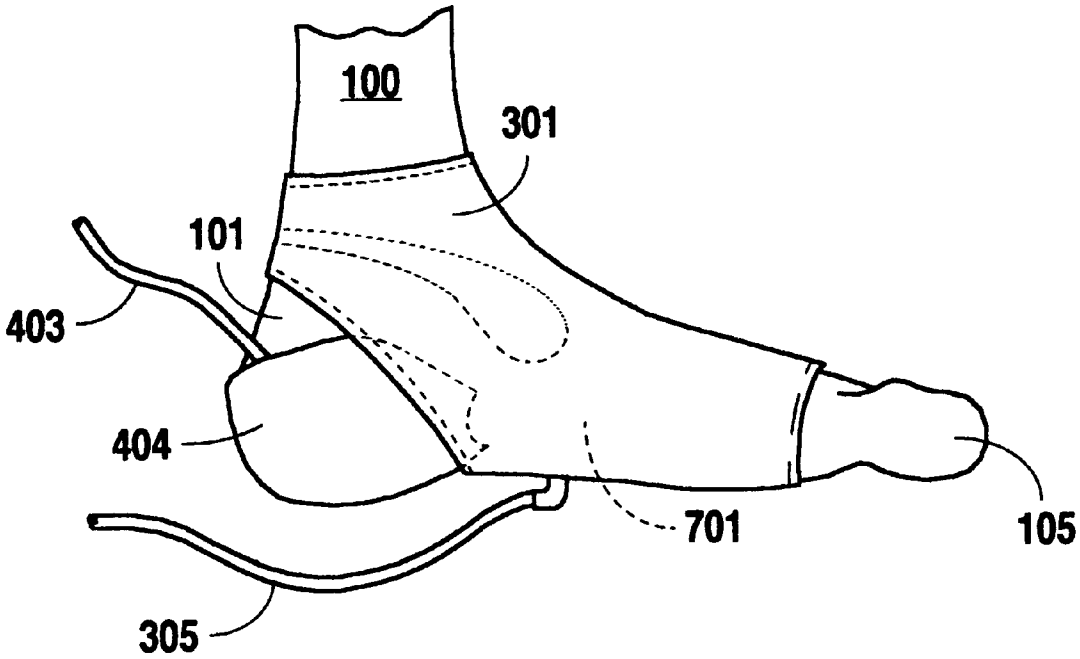

Fig. 8

THERAPEUTIC METHOD FOR TREATING ULCERS

RELATED APPLICATION

The present application claims, under 35 USC § 119(e), all available benefit of the filing of U.S. provisional patent application Ser. No. 60/053,902 filed Jul. 28, 1997 now abandoned.

FIELD OF THE INVENTION

The present invention relates to methods and apparatus for treating foot ulcers. More particularly, the invention relates to methods and apparatus for applying positive and/or negative pressures to treat foot ulcers such as diabetic ulcers, arterial ulcers, venous stasis ulcers, pressure ulcers, and the like.

BACKGROUND OF THE INVENTION

Foot ulcers can be devastating—they are difficult to heal and are potentially limb-threatening. One of the difficulties is that a patient will often lose sensation in the area of an ulcer and, as a result, the patient tends to abuse the ulcer without notice. Foot ulcers, in particular, are troublesome because they are out of the patient's sight, especially when located on or near the patient's heel. Unseen and unfelt, the patient does not realize that the foot ulcer is colliding into a wheelchair, bed post or the like. Consequently, the onset of a foot ulcer may place the foot at a significant risk for progression toward sepsis, gangrene and, ultimately, amputation.

Current treatment options for foot ulcers are varied, but all tend to be costly and traumatic; greater efficacy is thus desired. One of the most common treatment options is debridement of necrotic tissue followed by an attempt to physically close the ulcer, typically with sutures, skin grafts or the like. Unfortunately, many patients do not respond quickly, or at all, to such traditional treatment and the patient's condition often worsens. The resulting economic and emotional costs to the patient, and the patient's family, are staggering.

On the positive side, there have long been techniques available for promoting healthy circulation of body fluids. The concept of applying positive and/or negative pressure to help affect circulation is ancient, and many have sought to apply this concept to the foot in the form of inflatable boots that squeeze the foot and/or leg. Some have applied alternating positive and negative pressures, in a cyclic fashion, to first force blood out of the foot with positive pressure and then draw blood back into the foot with negative pressure. Recent products offered by Applicant under the trade designation "PLEXIPULSE" have provided intermittent compression, for a variety of indications, through pneumatic force externally applied to the foot. Such products are used, for example, to help prevent venous stasis and to promote circulation or to help treat and assist healing of cutaneous ulceration.

Another approach, for treatment of wounds, is represented by Applicant's products recently made commercially available under the trade designations "V.A.C." or "VACUUM ASSISTED CLOSURE." The "V.A.C." products generally comprise the application of negative pressure directly to a wound site, either on a continuous or intermittent basis. Such therapy units direct negative pressure to the wound site through a disposable pad, which includes a wound dressing and associated tubing, filters and drainage receptacles. The dressing itself includes a porous foam dressing sized to fit within the wound, the tubing directs the negative pressure into the foam, and the combination is sealed into the wound with the use of an adhesive drape that overlaps the entire wound site as well as a margin of surrounding intact skin. This therapy is promising for treatment of pressure ulcers and chronic open wounds, including decubitus ulcers and diabetic ulcers.

Both of the above-described therapies are currently available as of the filing date of this present application; despite the availability of such progressive therapies, however, foot ulcers continue to present serious concerns for patients and caregivers. It is therefore a fundamental object of the present invention to advance upon the prior art by providing an improved method and apparatus for effecting intermittent pneumatic compression concurrently with vacuum assisted closure. Many additional problems, obstacles and challenges present in existing modalities for the treatment of foot ulcers will be evident to caregivers and others of experience and ordinary skill in the art.

SUMMARY OF THE INVENTION

In accordance with the foregoing objects, the present invention—an improved method and apparatus for providing concurrent applications of intermittent pneumatic compression and vacuum assisted closure—generally comprises a wound dressing for introduction of a negative pressure into a wound on a patient's foot and a foot wrap for application of positive, compressive forces to substantially all of the patients foot. A suction pump, having an associated vacuum sensor and first feedback mechanism, supplies negative pressure to the wound dressing. A ventable source of pressurized gas, having an associated pressure transducer and second feedback mechanism, supplies positive force to the foot wrap. At least one control system is operably associated with the suction pump and ventable source of pressurized gas for controlling the negative and positive applications of pressure to the patient's foot.

In preparation for operation, the wound dressing is preferably first applied to the patient's foot followed by application of the foot wrap. Each is then in turn operably connected to its respective pressure source. Specifically, for application of the wound dressing, a porous pad, having plastic tubing inserted therein for connection to the suction pump, is inserted at least partially into the wound on a patient's foot. The wound dressing, and margin of impact surrounding the wound, is then preferably covered with a wound drape. The foot wrap, having fluid connection hardware associated therewith, is then placed in operable position over the wound dressing. Finally, the pad's plastic tubing is placed in fluid communication with the suction pump and the foot wrap's connection hardware is placed in fluid communication with the ventable source of pressurized gas.

In operation, negative pressure to the wound dressing is monitored and adjusted as necessary, by an integrated control system, to achieve desired therapy. Similarly, the positive, compressive force delivered to substantially the entire foot through the foot wrap is monitored and adjusted as necessary, also by an integrated control system, to achieve the desired therapy. Also effected by the integrated control system, the application timing of each component therapy is adjustable to allow concurrent application of pneumatic compression therapy and vacuum assisted closure therapy. It is to be understood that such concurrent therapy may entail continuous or intermittent application of one or both therapies and may or may not involve simultaneous application of the therapies.

Finally, many other features, objects and advantages of the present invention will be apparent to those of ordinary skill in the relevant arts, especially in light of the foregoing discussions and the following drawings, exemplary detailed description and appended claims.

BRIEF DESCRIPTION OF THE DRAWINGS

Although the scope of the present invention is much broader than any particular embodiment, a detailed description of the preferred embodiments follows together with illustrative figures, wherein like reference numerals refer to like components, and wherein:

FIG. **1** illustrates, for reference purposes, regions **101–106** of a typical foot **100**;

FIG. **2** shows, in a schematic block diagram, a first configuration **200** of the preferred embodiment of the present invention;

FIG. **3** shows, in perspective view, exemplary foot compression wraps **301**, **302** as are utilized in the implementation of the preferred embodiment of the present invention;

FIG. **4** shows, in semi-perspective view, an exemplary wound closure dressing **402** and fluid reservoir **401** as are utilized in the implementation of the preferred embodiment of the present invention;

FIG. **5** shows, in a schematic block diagram, a second configuration **500** of the preferred embodiment of the present invention;

FIGS. **6**A and **6**B illustrate, in plan view, application, as taught for implementation of the preferred embodiment of the present invention, of a wound closure dressing **402**, **404** to a human foot **100**;

FIGS. **7**A–**7**D illustrate, in perspective view, application, as taught for implementation of the preferred embodiment of the present invention, of a foot compression wrap **301**, **302** to a human foot **100**; and

FIG. **8** shows a wound closure dressing **404** and foot compression wrap **301** as simultaneously applied to a human foot **100** in implementation of the preferred embodiment of the present invention.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENT

By this reference, the full disclosures of Applicant's U.S. patent application Ser. No. 08/039,574 filed Mar. 23, 1993 and U.S. patent application Ser. No. 08/517,901 filed Aug. 22, 1995, are each incorporated herein as though set forth in their respective entireties. Copies of each of these applications are submitted herewith, through an accompanying Information Disclosure Statement, for entry into this application's file wrapper.

Although those of ordinary skill in the art will readily recognize many alternative embodiments, especially in light of the illustrations provided herein, this detailed description is exemplary of the preferred embodiments of the present invention, the scope of which is limited only by the claims appended hereto.

For reference purposes, various regions **101–106** of a typical foot **100** are shown in FIG. **1**. Region **101** is referred to as the ankle region. Region **102** is referred to as the heel region. Region **103** is referred to as the plantar arch region. Region **104** is referred to as the metatarsal head, or ball, region. Region **105** is referred to as the toe region. Region **106** is referred to as part of the dorsal aspect region. Although these regions are shown as being mutually exclusive, this representation is for purposes of illustration only. It should be understood that one region may overlap another. For example, reference to the heel region **102** is not necessarily confined to that region illustrated in the drawings; the reference may actually include the heel region **102** and overlapping portions of adjacent regions such as the ankle region **101** or plantar arch region **103**. The same may be true of references to the metatarsal head **104**, or other, regions. Ulcers may occur either centrally or on either side of the foot **100** in any of the regions **101–106** shown; however, clinical evidence has shown that ulcers are most prevalent in the heel region **102** and the forefoot beneath the metatarsal head region **104**. A representative location **110** of an ulcer is designated with a dashed margin in FIG. **1**, at the bottom of the heel region **102**.

FIG. **8** illustrates a typical preferred application of the present invention for treating and ulcer, or other wound, at ulcer location **110**. Using the various apparatus and methods described further herein, localized negative pressure is induced on a foot **100** at the ulcer location **110** while positive, compressive force is applied to the foot **100**. The resulting combination actively stimulates healing at the ulcer site **110** while also promoting healthy circulation of blood and nutrients.

Referring to FIGS. **2–4**, there is shown a first configuration **200** of a system for therapeutic treatment of foot ulcers such as that shown at the ulcer location **110**. This first configuration generally comprises an efficient combination of previously available vacuum assisted closure and intermittent pneumatic compression technologies for concurrent application of positive and negative pressures to an affected foot. According to the first configuration **200** of the preferred embodiment, there is generally provided an intermittent pneumatic compression unit **201** and a vacuum assisted closure unit **202** in operable communication with a single embedded microcontroller unit **203**. The micro-controller unit **203** may be implemented in any of a variety of hardware and/or software designs as will be apparent to those of ordinary skill in the relevant arts. As will be apparent herein, the micro-controller unit **203** provides a single point of feedback driven control for both the intermittent pneumatic compression unit **201** and the vacuum assisted closure unit **202**.

The intermittent pneumatic compression unit **201** of the first configuration **200** generally comprises an oscillating air compressor **204** in fluid communication with an air reservoir **205** through a one-way check valve **206**. As will be understood further herein, the check valve **206** serves to prevent pneumatic back flow from the air reservoir **205** to the oscillating air compressor **204** during periods in which the air compressor **204** is not in operation. The air reservoir **205** of the preferred embodiment is in fluid and operable communication with one or more foot compression wraps **301**, **302** through a series of three-way solenoid valves **207–209**, ports **210**, **211**, connectors **303**, **304** and plastic, or other suitable material, tubing **305**, **306**.

Each of the solenoid valves **207–209** of the pneumatic compression unit **201** is chosen to be normally closed (when the coils are not energized) to the air reservoir **205** and normally open (when the coils arc not energized) between the foot compression wraps **301**, **302** and the atmosphere. When the coils are energized, atmosphere is closed off and a two-way pneumatic flow path is established between the air reservoir **205** and the foot compression wraps **301**, **302**. Two of the solenoid valves **208**, **209** are designated as the left foot solenoid valve **208** and the right foot solenoid valve **209**. Through this designation, independent control is main-

tained for inflation of either the left foot compression wrap **301**, the right foot compression wrap **302**, or both **301**, **302**. As will be further understood herein, the third solenoid valve **207** is necessary only in an alternate embodiment of the present invention and, even then, may be dispensed with in implementations utilizing solenoid valves **208**, **209** having a "no-flow" capability.

The vacuum assisted closure unit **202** of the first configuration **200** of the preferred embodiment generally comprises a vacuum pump **212** in fluid communication with a fluid reservoir **401** through a dryer filter **214**. An intake vent **213** is provided for connection, through appropriate tubing **403**, of a porous foam dressing **402** to be inserted into a patient's wound **110**, as will be understood further herein. The dryer filter **214** serves to protect the vacuum pump **212**, which is not readily decontaminated, from the potentially hazardous or infectious wastes drawn from the wound site **110**. A port **215** is provided for releasable connection to the fluid reservoir **401** in order that the reservoir **401** may be removed and discarded when full.

Various sensors are provided to promote safety in the operation of the system **200**. For example, a mercury activated tilt sensor **216** indicates attitudes in which there is a danger of spilling fluids from the reservoir **401**, a push-button interlock switch **217** in the back of the reservoir port indicates improper or incomplete placement of the reservoir **401**, and a capacitively-activated level sensor **218** indicates a full condition of the reservoir **401**. Feedback from any of these sensors **217–219** will cause termination of vacuum pump **212** operation, as will be understood herein. Those of ordinary skill in the art will quickly recognize that many other safety features may be integrated into the system **200** as desired.

Further details as to the construction and operation of the intermittent pneumatic compression unit **201**, including the foot compression wraps **301**, **302**, may be gleaned from Applicant's U.S. patent application Ser. No. 08/039,574 filed Mar. 23, 1993 which has been incorporated herein by reference. Details as to the construction and operation of the vacuum assisted closure unit **202** may be gleaned from Applicant's U.S. patent application Ser. No. 08/517,901 filed Aug. 22, 1995 which also has been incorporated herein by reference. Those products embodying the foregoing applications, commercially available from Kinetic Concepts, Inc. of San Antonio, Tex. under the trade designations "PLEXIPULSE" and "V.A.C." are presently preferred by Applicant for implementation of this present invention. It is to be understood, however, that many other intermittent pneumatic compression and vacuum assisted closure products, as well as products for sequential therapy, wound drainage and other related therapies, are also presently available. Most all of these products should be considered functional equivalents for implementation of this present invention.

According to the preferred embodiment of the present invention, there is provided a single embedded micro-controller unit **203** for operation of both the intermittent pneumatic compression unit **201** and the vacuum assisted closure unit **202**. The micro-controller unit **203**, intermittent pneumatic compression unit **201** and vacuum assisted closure unit **202** all receive electrical power through a conventional wall plug **219** fitted with a hospital grade EMI/RFI filter, fuse and switch unit **220**. A power supply **222** is provided with the micro-controller unit **203** for conversion of alternating current to direct current at an appropriate voltage level for the integrated circuitry and displays **229**, **230** present on the unit **203**. The micro-controller unit **203** is fitted with a conventional variable speed cooling fan **221**, as is known in the art.

Additionally, the micro-controller unit **203** is provided with a solenoid valve control circuit **223**, a compressor control circuit **224**, a vacuum pump speed control circuit **225**, a vacuum pump control circuit **226**, a pressure sensor **227** and a vacuum sensor **228**. Each circuit **223–226** of the unit **203** is operatively connected, directly or indirectly, to the system components being controlled and to the various sensors **227**, **228** upon which operation of the system components is based. In operation, the solenoid valve control circuit **223** opens or closes the left and/or right solenoid valves **208**, **209** according to a predetermined timing cycle in order to intermittently apply positive forces to substantially all, but in particular the plantar region **103**, of the patient's foot **100**.

In a preferred mode referred to as the "equilibrium mode," the oscillating air compressor **204** fills the air reservoir **205** to an automatically determinable target pressure, typically in the range of 350 mm Hg as measured by the pressure sensor **227**. Once the pressure within the air reservoir **205** reaches the target pressure, the compressor **204** is shut off under the control of the compressor control circuit **224**. Upon release of the compressed air into the left and/or right foot compression wraps **301**, **302**, an equilibrium pressure is reached between the air reservoir **205** and the wraps **301**, **302**. This equilibrium pressure, typically in the range of 160 mm Hg, is then measured by the pressure sensor **227** whereby an accurate indication of the actual pressure delivered to the plantar region arch **103** is obtained. The compressor control circuit **224** of the micro-controller unit **203** is then able to make use of this measurement to adjust, for subsequent compression cycles, the pressure of the air initially delivered to the air reservoir **205**. Through this compression cycle-by-compression cycle adjustment scheme, the actual force applied to the patient's plantar region **103** may be robustly and accurately controlled, largely independent of wrap placement, changes in swelling or edema, or patient movements. Finally, at the end of the compression cycle and under the control of the solenoid valve control circuit **223**, air is exhausted from the left and/or right foot compression wraps **301**, **302**, to the atmosphere, through the left and/or right solenoid valves **208**, **209**.

Alternatively, a third solenoid valve **207** may be incorporated to implement a timed-mode embodiment of the present invention. In this alternate embodiment, the oscillating air compressor **204** may operate continuously, the pressure ultimately delivered to the plantar regions **103** being controlled by the timed opening and closing of the third solenoid valve **207**. According to the timed-mode embodiment, the air reservoir **205** is filled to the extent of the air compressor's capability, typically in the range of 800–900 mm Hg. Measurement of the initial pressure within the air reservoir is not necessary, so long as a relatively high pressure may be obtained within the capability of the air compressor **204**. In operation, the solenoid valve control circuit **223** opens or closes the left and/or right solenoid valves **208**, **209** in order to pre-select either the left or right foot, or both feet, for application of positive forces to the corresponding plantar regions **103**. Substantially concurrent with the left and/or right foot selection, the solenoid valve control circuit **223** opens, for a short period of time, and then closes the third solenoid valve **207**, causing a substantially impulsive burst of air to be released from the air reservoir **205** into the left and/or right foot compression wraps **301**, **302**. Following closure of the third solenoid valve **207**, the pressure sensor **223** measures the pressure of the air released

into the left and/or right foot compression wraps **301**, **302**. If necessary in order to achieve the desired compression wrap pressure, the open time of the third solenoid valve **207** may then be increased or decreased for subsequent compression cycles. Alternatively, the solenoid valve control circuit **223** may be implemented to produce only very short bursts of air from the air reservoir **205** into the foot compression wraps **301**, **302**. In this implementation, the number of bursts per compression cycle, and/or the time there between, may be increased or decreased during the present compression cycle, or in subsequent compression cycles, in response to the measured pressure in the foot compression wraps **301**, **302**. Like the equilibrium mode embodiment, the timed-mode embodiment provides a compression cycle-by-compression cycle adjustment scheme by which the actual force applied to the patient's plantar region **103** may be robustly and accurately controlled, largely independent of wrap placement, changes in swelling or edema, or patient movements. Finally, at the end of the compression cycle and under the control of the solenoid valve control circuit **223**, air is exhausted from the left and/or right foot compression wraps **301**, **302**, to the atmosphere, through the left and/or right solenoid valves **208**, **209**.

In a further modification of the timed-mode embodiment, it is possible to dispense with the third solenoid valve **207** in favor of utilizing left and right solenoid valves **208**, **209** having an intermediate "no-flow" capability. According to this modification, the left and right solenoid valves **208**, **209** are normally closed (when the coils are not energized) between the foot compression wraps **301**, **302** and both the air reservoir **205** and the atmosphere, i.e. are in a "no-flow" state. Short bursts of air are then delivered from the air reservoir **205** to the left and/or right foot compression wraps **301**, **302**, according to the foregoing timed-mode methods, by toggling the left and/or right solenoid valves **208**, **209** between their no-flow states and their states of open flow between the air reservoir **205** and respective wrap **301**, **302**. At the end of the compression cycle, air is exhausted from the wraps **301**, **302** by opening the flow paths to the atmosphere. Although technologically feasible, such solenoid valves are not as of this date readily available; therefore, the three-valve implementation of the timed-mode embodiment is presently preferred over the two-valve implementation of the timed-mode embodiment.

In further operation, the negative pressure induced by the vacuum pump **212** is measured by a vacuum sensor **228** in fluid communication with the fluid reservoir **401** through an interposed orifice restrictor **231**. The restrictor **231** serves to protect the vacuum sensor **228** from the relatively large negative pressures necessary in the treatment process as these pressures are typically too excessive for direct measurement under presently available sensor technologies. Vacuum feedback is monitored by the vacuum pump control circuits **226** to adjust the speed, through the vacuum pump speed control circuit **225**, of the vacuum pump's motor in order to increase or decrease delivered vacuum. Additionally, the vacuum pump control circuit **226** monitors the various safety features **216**–**218** of the vacuum assisted closure unit **202** in order to effect shut down of the system **200** in the event of a hazardous condition.

Finally, all operations may be monitored through a liquid crystal display (LCD) readout **229** and/or light emitting diode (LED) display bar **230**. Other feedback mechanisms, such as computer interfaces and others known to those of ordinary skill in the art, may be incorporated as desired. All such user interfaces are considered within the scope of the present invention.

In a second configuration **500** of the preferred embodiment, shown in FIG. **5**, the oscillating air compressor **204** and vacuum pump **212** are replaced by a single integrated compressor and vacuum pump unit **501** having internally thereto two separate plenums **502**, **203**. Operation is identical to that of the first configuration **200**, with the exception that instead of speed control of the motors of the compressor **204** and vacuum pump **212**, a clutch mechanism similar to that of automobile air conditioning units is utilized. Such mechanisms are readily understood by those of ordinary skill in the art. In essence, the appropriate control circuits **224**, **225** generate pulse streams by which the respective clutch mechanisms are activated in pulse width modulated fashion.

Referring to FIGS. **6**A and **6**B, there is shown the typical application of a wound closure dressing **402** to an example ulcer **110**. Following debridement of necrotic tissue in and around the wound site **110**, a porous foam dressing **402**, having inserted therein tubing **403** for establishing fluid communication with the vacuum assisted closure unit **202**, is inserted into the site **100**. The porous foam dressing **402** and tubing **403** are anchored, and substantially sealed, within the wound site **110** by a covering of adhesive drape **404**. The drape **404** physically covers the wound site **110** as well as the margin of impact **601** surrounding the wound site **110**. A typical application, therefore, has a diameter of approximately four to eight inches, as measured if the drape **404** was laid flat.

In operation, the vacuum assisted closure unit **202** applies negative pressure, through the tubing **403**, to the ulcer site **110**. The porous foam dressing **402** serves to promote distribution of this negative pressure throughout the ulcer site **110**. As a result, this distribution may be considered substantially uniform. The adhesive drape **404**, itself or in concert with such other provisions as may be implemented by caregivers, serves to provide a seal around the wound site **110**. This seal provides infection control for the wound while also minimizing leaks of the negative pressures applied thereto.

Referring now to FIGS. **7**A–**7**D, there is shown the application of a foot compression wrap **301** to a foot **100**. As shown particularly in FIG. **7**A, the wrap **301** is first laid flat, generally beneath the heel, plantar arch and metatarsal head regions **102**–**104** of the foot **100**. Then, as shown in FIG. **7**B, a first tab **702** is wrapped about the dorsal aspect region **106** of the foot **100**. A second tab **703**, as shown in FIG. **7**C, is next also wrapped about the dorsal aspect region **106** of the foot **100** and secured to the outside of the first tab **702** by conventional securing means such as, for example, releasably engageable hook and loop type material as is known by those of ordinary skill in the art and commercially available under the trademark "VELCRO." In the preferred embodiment of the present invention, a trademark "VELCRO" type patch **704** of hook-type material engages the outer surface of the wrap **301** which comprises hook compatible loop-type material. Finally, as shown in FIGS. **7**C and **7**D, a third tab **705** is wrapped about the ankle region **101** of the foot **100** and secured over the dorsal aspect region **106** by a tab **706** of hook-type material. As can be seen with reference to FIGS. **7**A–**7**D, it is a specific object of such a foot compression wrap to cover a substantial portion of the foot with the inflatable bladder **701** integral thereto. In accordance with this object, both the deep and peripheral veins in the foot are compressed by operation of the intermittent pneumatic compression unit **201**. This enables virtually complete emptying, on an intermittent basis, of the blood in the foot **100** to which the wrap **301**, **302** is applied.

As clearly shown in FIG. **8**, depicting the foot **100** with both the porous wound dressing **402**, with drape **404**, and the foot compression wrap **301** in operable position, portions of the heel region **102** and toe region **105** are not covered by the foot compression wrap **301** notwithstanding the object of compressing substantially the entire foot **100**. This serves to enable viewing, by caregivers, of the exposed portions of the toe region **105** and heel region **102** for purposes of assessing the health of the foot **100** while the foot compression therapy is ongoing. This also readies skin on the foot **100** to minimize accumulation of moisture and the attendant risks of maceration.

In implementing the present invention, the wound closure dressing **402**, **404** is applied first, in its entirety, and then the foot compression wrap **301** is applied. Due to the varying locations of ulcers on the foot **100**, application of the foot compression wrap **301** may overlap the wound dressing site **601**. Many applications within the scope of the present invention will also involve lapping the inflatable bladder **701** of the foot compression wrap **301** over the actual ulcer site **110**. In such applications, the foam dressing **402** also serves the added function of helping to cushion the actual ulcer site **110** from the compressive action of the foot compression wrap **301**. As shown in FIG. **8**, the foot compression wrap **301** may overlap a portion of the ulcer site **110** to an extent that the inflatable bladder of the foot compression wrap **301** applies a compressive force over and onto the ulcer site **110**.

Once the wound closure dressing **402** is operatively situated on an ulcer site **110** on the foot **100** of the patient and the foot compression wrap **301** or **302** is applied over the wound closure dressing **402** and its drape **404**, the foot compression wrap **301** is then operatively connected to the intermittent pneumatic compression unit **201** and the wound dressing **402** is operatively connected to the vacuum assisted closure unit **202**. Vacuum assisted closure therapy and intermittent pneumatic foot compression therapy can then be concurrently implemented, i.e., either simultaneously or in some indefinitely repeated cycle between positive and negative applications during which, it is to be understood, temporal overlap of positive and negative applications may or may not occur.

In the preferred embodiment of the present invention, the vacuum assisted closure unit **202** is provided with various settings for both intermittent and continuous application of negative pressure to the wound closure dressing **402**. The most preferred selection of therapy options, i.e., intermittent or continuous vacuum, has not been determined at this time, although it is contemplated that either setting may be applicable. In any case, typical implementation of the invention will involve some periods of time during which negative pressure is actually applied to the ulcer site **110** notwithstanding the substantially concurrent application of compressive forces via the foot compression wrap **301**, **302**.

In a second mode of application of the present invention, the applications of positive and negative pressures are timed such that negative pressure is applied to the ulcer site **110** over a first period of time and positive pressure is then applied to substantially the entire foot **100** over a second period of time. Such alternating applications of negative pressure and positive pressure over the corresponding regions of the foot are then repeated indefinitely for the duration of the therapy.

While the foregoing description is exemplary of the preferred embodiments of the present invention, those of ordinary skill in the relevant arts will recognize the many variations, alterations, modifications, substitutions and the like as are readily possible, especially in light of this description, the accompanying drawings and claims drawn thereto. For example, while the preferred embodiment of the present invention calls for implementation of the intermittent pneumatic compression unit **201** and the vacuum assisted closure unit **202** in a single integrated unit **200**, **500**, those of ordinary skill in the art will recognize that, in the alternative, the present invention may be practiced, with only some corresponding loss in efficiency, with separate units for provision of intermittent compression therapy and vacuum assisted closure therapy. Such individual units are readily available and exemplary ones are described in detail in U.S. patent application Ser. No. 08/039,574 filed Mar. 23, 1993 and U.S. patent application Ser. No. 08/517,901 filed Aug. 22, 1995, each of which has been incorporated herein by reference. Products embodying each of these applications are commercially available from Kinetic Concepts, Inc. of San Antonio, Tex. under the trade designations "PLEXIPULSE" and "V.A.C." In such an alternate embodiment, calling for separate therapy units, synchronization of the therapy timing may be provided by interface circuitry, manual adjustment of the individual units or any number of other techniques readily available to those of ordinary skill in the relevant arts. Further, other modifications, such as the provision of independent, switched control of the intermittent pneumatic compression unit **201** and vacuum assisted closure unit **202** within the single integrated unit **200**, **500**, should be considered design expedients, within the scope of the present invention, especially in light of the foregoing exemplary description and appended claims. In any case, because the scope of the present invention is much broader than any particular embodiment, the foregoing detailed description should not be construed as a limitation of the scope of the present invention, which is limited only by the claims appended hereto.

We claim:

1. A method for therapeutic treatment of a foot wound, said method comprising the steps of:

inducing a negative pressure within said wound on a portion of a patient's foot; and

applying a positive compressive force, concurrently with said inducing a negative pressure step, to said foot.

2. The method of claim **1**, wherein said inducing a negative pressure step and said applying a positive compressive force step are alternately repeated over a period of time.

3. The method of claim **2**, wherein said inducing a negative pressure step and said applying a positive compressive force step overlap, such that at least some part of one said applying a positive compressive force step occurs simultaneously with at least some part of one said inducing a negative pressure step.

4. The method of claim **1**, wherein said inducing a negative pressure step comprises:

inserting a porous pad at least partially into said wound;

connecting said porous pad, through a first hose, to a suction pump; and

applying negative pressure, generated by said suction pump, from said suction pump to said wound, through said first hose and said porous pad.

5. The method of claim **4**, wherein said applying negative pressure step comprises substantially continuous application of negative pressure.

6. The method of claim **4**, wherein said applying negative pressure step comprises intermittent application of negative pressure.

7. The method of claim 4, wherein said applying a positive compressive force step comprises:

applying a compressive wrap over a portion of a patient's foot;

connecting said compressive wrap, through a second hose, to a source of pressurized gas; and

applying positive pressure from said source of pressurized gas to said foot, through said second hose and said compressive wrap.

8. The method of claim 7, wherein said applying positive pressure step comprises compressing substantially all of said foot such that both the deep and peripheral veins of said foot are compressed, said deep and peripheral veins being thereby substantially emptied of the blood therein.

9. The method of claim 8, wherein said applying positive pressure step further comprises intermittently repeated applications of positive pressure.

10. The method of claim 9, wherein said applying positive pressure step further comprises:

establishing a target pressure within a gas reservoir;

venting said gas reservoir into said compressive wrap;

measuring, after said venting step, an equilibrium pressure between said gas reservoir and said compressive wrap; and

adjusting said target pressure in response to said equilibrium pressure to arrive, in a subsequent intermittent application of positive pressure, at a desired equilibrium pressure.

11. The method of claim 10, wherein said target pressure is between about 300 mm Hg and about 400 mm Hg and said desired equilibrium pressure is between about 140 mm Hg and about 180 mm Hg.

12. The method of claim 9, wherein said applying positive pressure step further comprises:

establishing a pressure within a gas reservoir;

venting, for a determinable period of time, said gas reservoir into said compressive wrap;

measuring, after said venting step, the internal pressure of said wrap; and

adjusting said determinable period of time to arrive at a desired internal pressure within said wrap.

13. The method of claim 1, wherein said positive compressive force is applied to a first region of said foot and said negative pressure is induced on a second region of said foot, and wherein said first region overlaps said second region.

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