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(54) **COMPRESSION TREATMENT SYSTEM**

Kompressionsbehandlungssystem

Système de traitement par compression

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(56) References cited:
EP-A2- 1 226 804 GB-A- 2 295 235
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Description**BACKGROUND****1. Technical Field**

[0001] The present disclosure generally relates to the field of vascular therapy for application to a limb of a body, and more particularly, to a compression treatment system having a controller that regulates fluid flow.

2. Description of the Related Art

[0002] A major concern for immobile patients and persons alike are medical conditions that form clots in the blood, such as, deep vein thrombosis (DVT) and peripheral edema. Such patients and persons include those undergoing surgery, anesthesia, extended periods of bed rest, etc. These blood clotting conditions generally occur in the deep veins of the lower extremities and/or pelvis. These veins, such as the iliac, femoral, popliteal and tibial return deoxygenated blood to the heart. For example, when blood circulation in these veins is retarded due to illness, injury or inactivity, there is a tendency for blood to accumulate or pool. A static pool of blood is ideal for clot formations. A major risk associated with this condition is interference with cardiovascular circulation. Most seriously, a fragment of the blood clot can break loose and migrate. A pulmonary emboli can form blocking a main pulmonary artery, which may be life threatening.

[0003] The conditions and resulting risks associated with patient immobility may be controlled or alleviated by applying intermittent pressure to a patient's limb, such as, for example, a leg including the thigh, calf and foot to assist in blood circulation. Known devices have been employed to assist in blood circulation, such as, one piece pads and compression boots. See, for example, U.S. Patent Nos. 6,290,662 and 6,494,852.

[0004] For example, sequential compression devices have been used, which consist of an air pump connected to a disposable wraparound pad by a series of air tubes. The wraparound pad is configured for placement about a portion of a patient's leg, such as the thigh, calf or foot. Multiple pads may be mounted to the leg to cover the various portions of the leg. Air is then forced into different parts of the wraparound pad(s) in sequence, creating pressure around the thigh, calf or foot, thereby improving venous return.

[0005] US 5575762 discloses a compression treatment system according to the preamble of claim 1. It discloses a gradient sequential compression system for preventing deep vein thrombosis including a pressure-based system controller for controlling transfers of air from a source of pressurized air to inflatable chambers of a limb sleeve, so that prophylactic modality is provided to the limb. The system controller includes means for detecting low and high pressure fault conditions which can be caused by disconnected or occluded conduits, and sleeves that are wrapped too loosely or too tightly about a limb."

[0006] GB 2295235 discloses an inflatable garment for applying compression to the limb of a patient which has two inflatable chambers for each limb. Both the lower and upper chambers are directly connected sequentially to a common source of inflation. A non-return valve prevents any deflation of the first chamber when beginning to inflate the second chamber. Pressure in the chambers is monitored by pressure transducers. A microprocessor is programmed to activate an alarm if the rate of increase in pressure falls outside a predetermined limit rate.

[0007] EP 1226804 (D3) discloses a pressure applying apparatus comprising a compression sleeve with a plurality of inflatable annular cells, a control block with pneumatic valves connected to said annular cells and a pressurized fluid source connected to said control block, which is adapted to perform with said sleeve a regular compression procedure. EP 1226804 discloses a scanning of cells by applying low pressure to each cell. The scanning detects the number of cells in the sleeve and adjusts the device operation accordingly. The scanning procedure is also used to detect malfunctioning cells.

[0008] These known devices may suffer from various drawbacks due to their bulk and cumbersome nature of use. These drawbacks reduce comfort, compliance and may disadvantageously prevent mobility of the patient as recovery progresses after surgery.

[0009] Further, such known sequential compression devices typically include a controller assembly that regulates air flow and pressure in the wraparound pad(s). The controller assembly can be mounted to a bed and plugged into a wall outlet for power during use. This arrangement, however, can present challenges for example, when the patient needs to perform certain tasks, e.g., bathroom, physical therapy, etc. In these situations, the pads are usually removed, thus disadvantageously discontinuing vascular therapy. Thus, these controller assemblies suffer from various drawbacks because they do not accommodate patient transport or mobility and are not typically adaptable for inflation of thigh, calf and foot pads.

[0010] Therefore, it would be desirable to overcome the disadvantages and drawbacks of the prior art with a compression treatment system having a controller that is adaptable for inflating thigh, calf and foot sleeves and accommodates patient transport and mobility to provide continuous vascular therapy. It would be desirable if the system automatically

detects the types of sleeves connected thereto. It would be highly desirable if the system included a pneumatic circuit that facilitates pressure monitoring with a single pressure transducer to achieve the advantages of the present disclosure. It is contemplated that the compression treatment system is easily and efficiently manufactured.

Summary

[0011] According to the invention, a compression treatment system as claimed in claim 1 is provided.

[0012] Preferred embodiments of the present invention are defined in the dependent claims.

Brief description of the drawings

[0013] The present disclosure, both as to its organization and manner of operation, together with further objectives and advantages, may be best understood by reference to the following description, taken in connection with the accompanying drawings, which are described below.

FIG. 1 is a front view of one particular embodiment of a compression treatment system in accordance with the principles of the present disclosure;

FIG. 2 is a side view of the compression treatment system shown in FIG. 1;

FIG. 3 is a top view of the compression treatment system shown in FIG. 1;

FIG. 4 is a rear view of the compression treatment system shown in FIG. 1;

FIG. 5 is a schematic representation of a pneumatic circuit of the compression treatment system shown in FIG. 1;

FIG. 6 is a plan view of a sleeve of the compression treatment system shown in FIG. 1 being disposed about a limb;

FIG. 7 is an alternate embodiment of the sleeve shown in FIG. 6; and

FIG. 8 is an alternate example of the sleeve shown in FIG. 6 not covered by the claims.

Detailed description of exemplary embodiments

[0014] The exemplary embodiments of the compression treatment system and methods of operation disclosed are discussed in terms of vascular therapy including a prophylaxis compression apparatus for application to a limb of a body and more particularly in terms of a compression treatment system having a controller that is adaptable for inflating thigh, calf, ankle and foot sleeves and accommodates patient transport and mobility. It is contemplated that the compression treatment system may be employed for preventing and overcoming the risks associated with patient immobility. It is further contemplated that the compression treatment system alleviates the conditions arising from patient immobility to prevent for example, DVT, peripheral edema, etc. It is contemplated that the compression treatment system according to the present disclosure may be attributable to all types of venous compression systems, including, but not limited to a prophylaxis sequential compression apparatus. The term "prophylaxis sequential" shall not be construed as limiting the general venous compression treatment system described herein. It is envisioned that the present disclosure, however, finds application with a wide variety of immobile conditions of persons and patients alike, such as, for example, those undergoing surgery, anesthesia, extended periods of bed rest, obesity, advanced age, malignancy, prior thromboembolism, etc.

[0015] In the discussion that follows, the term "proximal" refers to a portion of a structure that is closer to a torso of a subject and the term "distal" refers to a portion that is further from the torso. As used herein the term "subject" refers to a patient undergoing vascular therapy using the compression treatment system. According to the present disclosure, the term "practitioner" refers to an individual administering the compression treatment system and may include support personnel.

[0016] The following discussion includes a description of the compression treatment system, followed by a description of an exemplary method of operating the compression treatment system in accordance with the principles of the present disclosure. Reference will now be made in detail to the exemplary embodiments and disclosure, which are illustrated with the accompanying figures.

[0017] Turning now to the figures, wherein like components are designated by like reference numerals throughout the several views. Referring initially to FIGS. 1-5, there is illustrated a compression treatment system 10, constructed in accordance with the principles of the present disclosure. Compression treatment system 10 includes a housing 12. Housing 12 encloses the components of a controller 14 (shown schematically in FIG. 5) disposed therein.

[0018] Housing 12 has a semi-circular configuration and has a handle cutout 16 along its apex 18 to facilitate transport and subject mobility. It is envisioned that housing 12 may be variously configured and dimensioned such as, for example, rectangular, spherical, etc. It is further envisioned that housing 12 may be assembled by any appropriate process such as, for example, snap fit, adhesive, solvent weld, thermal weld, ultrasonic weld, screw, rivet, etc. Alternatively, housing 12 may be monolithically formed or integrally assembled of multiple housing sections and may be substantially trans-

parent, opaque, etc. Housing 12 may include ribs, ridges, etc. to facilitate manipulation of compression treatment system 10.

[0019] The components of housing 12 can be fabricated from a material suitable for medical applications, such as, for example, polymeric or metals, such as stainless steel, depending on the particular medical application and/or preference of a clinician. Semi-rigid and rigid polymeric are contemplated for fabrication, as well as resilient materials, such as molded medical grade polypropylene. However, one skilled in the art will realize that other materials and fabrication methods suitable for assembly and manufacture, in accordance with the present disclosure, also would be appropriate.

[0020] Housing 12 is portable to facilitate continuous vascular therapy to a subject (not shown). Housing 12 includes a bracket 20 that facilitates releasable mounting of housing 12 with for example, a hospital bed, table, etc. Bracket 20 extends from a rear portion 22 of housing 12 and provides a hook configuration for suspending housing 12 from a subject's bed, etc. It is contemplated that bracket 20 may be suspended from various structure for releasable mounting of housing 12, or alternatively, that housing 12 does not include a bracket and may be placed on a floor or other supporting surface. Alternatively, housing 12 includes a shoulder strap 24, as shown in FIG. 2, that allows housing 12 to be worn on the subject or practitioner during transport. Shoulder strap 24 may be employed with or without bracket 20 and may, for example, be secured to any portion of the housing 12 including handle 16.

[0021] Compression treatment system 10 employs an electrical AC/DC switching power supply for operation of its components. A power cord 26 is connected to housing 12 for conducting power to the components of controller 14. Power cord 26 accesses an AC power supply via a wall outlet, etc. Controller 14 may include a transformer or other electronics for connecting to the power supply. It is envisioned that power cord 26 may be wrapped around bracket 20 for storage and during transport and subject mobility. It is further envisioned that compression treatment system 10 may include a storage capture mechanism that retains power cord 26 with housing 12. The storage capture mechanism may include an elastic cord, pulley, etc.

[0022] Compression treatment system 10 also employs a battery 28 for powering the components of controller 14 to facilitate transport and subject mobility. Battery 28 is disposed within a battery compartment 30 of housing 12. It is contemplated that battery 28 may include one or a plurality of cells. The battery cells may be lithium-ion type, etc. It is further contemplated that battery 28 is rechargeable and may be employed for various ranges of operation time, such as, for example, 6 hours, 8 hours, 10 hours, etc. For example, power cord 26 may be unplugged and captured by the storage capture mechanism of housing 12. Compression treatment system 10 then runs on battery 28 power and the subject is ambulatory.

[0023] It is envisioned that battery 28 may be mounted to an exterior surface of housing 12 or separate therefrom. It is further envisioned that compression treatment system 10 may include alternate sources of power supply, such as, for example, solar, non-electrical, etc., or alternatively may not include battery power.

[0024] Housing 12 has a control panel 32 disposed on a front surface 34 thereof. Control panel 32 includes controls and indicators for operation of compression treatment system 10. Control panel 32 has an LED display 36 that provides status indicia, messages, etc. of the various components of system 10, such as, for example, power, battery, sleeve identification and connection, inflation, venting, venous refill, errors, etc. Control panel 32 also includes manually activated switches for powering system 10, etc. It is contemplated that such switches are membrane type actuated by finger pressure, etc.

[0025] Rear portion 22 of housing 12 defines ports 38, 40 (FIG. 4). Ports 38, 40 include output ports 38a, 38b, 38c, and output ports 40a, 40b, 40c, respectively. Output ports 38a, 38b, 38c, and output ports 40a, 40b, 40c are in fluid communication with inflatable chambers 46a, 46b, 46c of a compression sleeve 46 and inflatable chambers 48a, 48b, 48c of a compression sleeve 48, respectively, which are configured to fit around the legs of a subject, via a mating connector 42 and tubing set 44, as will be discussed. Output ports 38a, 38b, 38c, 40a, 40b, 40c are configured for connection to tubing set 44. Each of ports 38, 40 are connectable to a particular compression sleeve, for example, leg sleeve, foot sleeve, etc.

[0026] Ports 38, 40 are also connected with the components of controller 14 disposed within housing 12 to facilitate inflation of selected compression sleeves, as illustrated in the pneumatic circuit shown in FIG. 5. Controller 14 includes a pressurized fluid source, such as, for example, a pump 50 that fluidly communicates with a valve manifold 52 for connection with ports 38, 40, as will be discussed. Pump 50 includes a motor that compresses air to valve manifold 52 via tubing or the like. The speed of the pump motor is electronically controlled to provide a corresponding compressor speed for respective output pressures as desired. It is contemplated that a power supply board, including the necessary electronics, circuitry, software, etc. known to one skilled in the art, is connected to the pump motor and other components of controller 14 to regulate power thereto. It is envisioned that pump 50 may be a diaphragm pump.

[0027] Controller 14 also includes a check valve 54 that prevents air leakage back through pump 50 when monitoring bladder pressure during venous refill detection, as will be discussed. A pressure relief valve 56 is disposed with the pneumatic circuit to protect against over pressure in the compression sleeves. Pressure relief valve 56 is configured to bleed excess air pressure if necessary. It is contemplated that various types of valves may be employed such as, for

example, spring loaded plunger valves, etc.

[0028] Valve manifold 52 includes solenoid valves 58a, 58b, 58c, 60a, 60b, 60c that are coupled to output ports 38a, 38b, 38c, 40a, 40b, 40c, respectively. Solenoid valves 58a, 58b, 58c, 60a, 60b, 60c each have an associated solenoid that is electrically driven via a control processor of controller 14. The solenoid is coupled to a valve seat of each particular solenoid valve 58a, 58b, 58c, 60a, 60b, 60c such that the seat is operative to open and close the respective solenoid valve upon actuation of the solenoid. See, for example, the solenoid valves described in U.S. Patent No. 5,876,359 to Bock et al. It is contemplated that the control processor of controller 14 includes the necessary electronics, circuitry, software, etc. known to one skilled in the art to actuate solenoid valves 58a, 58b, 58c, 60a, 60b, 60c in response to varying conditions of compression treatment system 10 and other indications and measurements sensed by the components of controller 14. It is envisioned that one or a plurality of solenoid valves may be employed, or alternatively, that other types of valves may be used.

[0029] Solenoid valves 58a, 58b, 58c, 60a, 60b, 60c and their associated valve components are mounted to ports 38, 40 on the interior of housing 12. Solenoid valves 58a, 58b, 58c, 60a, 60b, 60c are two position, three-way normally closed valves, which have openings 62a, 62b, 62c, 64a, 64b, 64c, respectively. In the open position, air flows through openings 62a, 62b, 62c, 64a, 64b, 64c to the associated output port 38a, 38b, 38c, 40a, 40b, 40c and into inflatable chambers 46a, 46b, 46c of compression sleeve 46 and inflatable chambers 48a, 48b, 48c of compression sleeve 48. In the closed position, openings 62a, 62b, 62c, 64a, 64b, 64c are blocked and air from compression sleeves 46, 48 flows back through output port 38a, 38b, 38c, 40a, 40b, 40c and through vent ports 66a, 66b, 66c, 68a, 68b, 68c of the associated valve to deflate inflatable chambers 46a, 46b, 46c, 48a, 48b, 48c.

[0030] Solenoid valves 58a, 58b, 58c, 60a, 60b, 60c are operated in sequence to pressurize inflatable chambers 46a, 46b, 46c, 48a, 48b, 48c and provide sequential pressurization thereof and venting of the chambers under the control processor of controller 14. It is contemplated that solenoid valves 58a, 58b, 58c, 60a, 60b, 60c may be selectively actuated when cooling operation of the sleeves is desired, see for example, U.S. Patent No. 5,876,359 to Bock et al.

[0031] Solenoid valves 58a, 58b, 58c, 60a, 60b, 60c are driven by pulse width modulated signals provided by the control processor of controller 14. The solenoid drive signals are initially at a higher power level for rapid and positive actuation of the solenoid valves. After initial actuation, the drive signals can be decreased, for example, by approximately 70% to maintain valve activation, thereby reducing power consumption. It is envisioned that solenoid valves 58a, 58b, 58c, 60a, 60b, 60c may be deactivated as desired. It is further envisioned that the control processor of controller 14 includes the ability to verify the status of solenoid valves 58a, 58b, 58c, 60a, 60b, 60c. As the condition of solenoid valves 58a, 58b, 58c, 60a, 60b, 60c changes, the control processor verifies their status. For example, if a particular valve is detected to be shorted or open, compression treatment system 10 will go into a particular error mode, as will be discussed.

[0032] Controller 14 also includes a pressure transducer 66 disposed within housing 12. Pressure transducer 66 is coupled to the pneumatic circuit and disposed between pump 50 and solenoid valves 58a, 58b, 58c, 60a, 60b, 60c via tubing or the like. Pressure transducer 66 is in fluid communication with inflatable chambers 46a, 46b, 46c, 48a, 48b, 48c for monitoring pressure in each of inflatable chambers 46a, 46b, 46c, 48a, 48b, 48c. The control processor of controller 14 directs pressure transducer 66 to measure any of inflatable chambers 46a, 46b, 46c, 48a, 48b, 48c that are connected to their respective solenoid valve and thus in fluid communication therewith. Disposing pressure transducer 66 before the solenoid valves, on the manifold side of the pneumatic circuit, advantageously facilitates use of only a single pressure transducer for measuring the pressure in the inflatable chambers. This configuration facilitates inflation of one or a plurality of inflatable chambers. This configuration also advantageously reduces bulk of controller 14 to contribute to the compact and lightweight design of compression treatment system 10, facilitates transport, patient mobility and reduces manufacturing costs.

[0033] For example, during a selected compression cycle, solenoid valves 58a, 58b, 58c, 60a, 60b, 60c are sequentially energized to the open position for pressurizing, in sequence, inflatable chambers 46a, 46b, 46c, 48a, 48b, 48c. In the open position, solenoid valves 58a, 58b, 58c, 60a, 60b, 60c allow passage of air from pump 50 through the respective output ports 38a, 38b, 38c, 40a, 40b, 40c to the inflatable chambers. Pressure transducer 66 monitors the pressure of each of inflatable chambers 46a, 46b, 46c, 48a, 48b, 48c of the pneumatic circuit and provides an electrical signal input to the control processor of controller 14 for feedback control.

[0034] At the end of the selected compression cycle, solenoid valves 58a, 58b, 58c, 60a, 60b, 60c are simultaneously de-energized to the closed position for disconnecting pump 50 from sleeves 46, 48. In the closed position, pump 50 air is blocked and solenoid valves 58a, 58b, 58c, 60a, 60b, 60c vent sleeve pressure to the atmosphere via vent ports 66a, 66b, 66c, 68a, 68b, 68c on valve manifold 52. It is contemplated that compression treatment system 10 can alternate inflation of the chambers between a first limb and a second limb. It is further contemplated that compression treatment system 10 can individually inflate each bladder.

[0035] Referring to FIG. 6, compression treatment system 10, similar to that described above, is assembled and packaged for use. In operation, compression treatment system 10 includes controller 14 disposed with housing 12, described above, and a sleeve 112. Sleeve 112 includes a thigh bladder 114, a calf bladder 116 and an ankle bladder

118. Sleeve 112 includes a connector 120 that mates with mating connector 42, which is connected to port 38 via tubing 44. Connector 120 fluidly communicates with the chambers of sleeve 112 via tubing set 122. Thus, this configuration facilitates fluid communication between bladders 114, 116, 118 and pump 50. It is contemplated herein that connector 120 may further include a valve mechanism to control fluid flow.

[0036] Sleeve 112 is provided and manipulated for disposal about leg L of the subject (not shown). Connector 120 is mated with mating connector 42 to establish fluid communication between sleeve 112 and the pneumatic circuit. Sleeve 112 is wrapped about leg L and secured thereto via hook and loop pads 124, 126. It is contemplated that compression treatment system 10 may treat a second leg of a subject with a compression sleeve, similar to sleeve 112, via connection to port 40. The second leg is treated in compression cycles alternate to the compression cycles described below for treatment of leg L, as described below in the alternative.

[0037] The portable features of housing 12 and controller 14, described above, provide a compression treatment system 10 that facilitates transport and subject mobility. This advantageous configuration provides uninterrupted DVT prophylaxis as the system is used throughout a treatment facility, and can be worn and used continuously by the subject during the entire period of risk. Compression treatment system 10 advantageously facilitates continuous vascular therapy during subject activity and tasks such as, for example, transport for testing, bathroom, physical therapy, etc. Compression treatment system 10 prevents interruptions in therapy by providing controller 14 that will run on battery 28 when power cord 26 is not plugged in, and will also be comfortable, compact, and light enough to move with the subject as needed.

[0038] The manually activated switches of control panel 32 of controller 14 switch compression treatment system 10 on for powering thereof. As compression treatment system 10 is initially switched on, a series of self-tests are conducted by the control processor of controller 14. The LED indicators of display 36 are illuminated and audible indicia are sounded to verify the operability of the visual and audible indicators. Display 36 is illuminated to verify display operability. Controller 14 also verifies operability of the software of the control processor. If any of the verification fails, error codes provide a representative audible and/or visual indicia.

[0039] It is contemplated that if the control processor of controller 14 cannot continue normal software execution, an error code will be triggered. This causes compression treatment system 10 to reset and restart normal operation. Sleeve 112 would vent during a restart procedure. Audible and visual indicia may also engage to represent the condition.

[0040] Upon completion of the self-test sequence compression for treatment system 10, controller 14 begins a sleeve detection procedure to determine the type(s) of sleeves attached to ports 38, 40. Sleeve detection is performed during a first inflation (detection) cycle after controller 14 is initially powered on. During the detection cycle, air is delivered alternately through ports 38, 40 with pump 50 operating for two seconds, or until the pressure reaches a default threshold. One second later, pressure transducer 66 takes a pressure measurement to determine whether or not a bladder is connected to a particular output port, 38a, 38b, 38c, 40a, 40b or 40c under sleeve detection.

[0041] For example, the detection procedure is conducted for bladders 114, 116, 118 for each of sleeve ports 38, 40. If there is no backpressure at a particular outlet port for connection with a bladder, then the control processor of controller 14 determines that a bladder is not being used with a particular outlet port. The control processor adjusts the compression therapy for the detected sleeve configuration accordingly. For the 3-bladder sleeve, back pressure is detected at bladders 114, 116, 118 when connected to controller 14. It is contemplated that if no sleeves are detected by this procedure at either port 38 or 40, or if the detected configuration is not recognized, then a low pressure error is triggered with corresponding audible indicia. It is further contemplated that various timing periods may be employed for detection inflation and pressure measurement, according to the requirements of a particular application.

[0042] Alternatively, thigh bladder 114 is removable from calf bladder 116. For example, calf bladder 116 is removably connected to thigh bladder 114 via a perforated attachment, see, for example, the sleeve described in U.S. Patent Application Serial No. 10/784,607, filed on February 23, 2004 and entitled Compression Apparatus.

For the removable thigh bladder 114, the

control processor of controller 14 performs a similar sleeve detection procedure, as described above. The control processor will detect a 3-bladder sleeve due to a flow-restricting valve (not shown) fitted with connector 120. See, for example, the flow-restricting valve described in U.S. Patent Application Serial No. 10/784,639, filed on February 23, 2004 and entitled Fluid Conduit Connector Apparatus.

The flow restricting valve simulates the

backpressure created by thigh bladder 114 when there is actually no bladder connected. Thus, the conversion from a 3-bladder thigh length sleeve to a 2-bladder knee length sleeve does not significantly impact the compression parameters, and controller 14 continues vascular therapy as if thigh bladder 114 was still intact.

[0043] In an alternate embodiment, as shown in FIG. 7, sleeve 112 includes thigh bladder 114 and a unitary second bladder 218. Second bladder 218 has a calf portion 220 and an ankle portion 222. Pump 50 fluidly communicates with sleeve 112 via valve connector 224 and separate tubing 226, 228, for employment similar to that described above, including the optional removal of thigh bladder 114 via perforations or the like.

[0044] In one particular compression cycle for compression treatment system 10, the compression parameters include an 11-second inflation period for inflating bladders 114, 116, 118 followed by 60 seconds of venting for deflating bladders

114, 116, 118. The 11-second inflation period is sequential:

- 1) initially ankle bladder 118 is inflated for a first time period starting at 0 seconds;
- 2) thereafter and during the first time period, inflation of calf bladder 116 is initiated for a second time period, the initiation of the second time period coinciding with approximately 2.67 seconds duration of the first time period;
- 3) thereafter and during the second time period, inflation of thigh bladder 114 is initiated for a third time period, the initiation of the third time period at approximately 3.0 seconds duration of the second time period and approximately 5.67 seconds of the first time period; and
- 4) after 11 seconds of the first time period, bladders 114, 116, 118 vent for a minimum of 20 seconds and a maximum of 60 seconds. An example is illustrated in Table 1 below.

Table 1

	Start of Sequence	End of Sequence
Ankle Compression:	0 seconds	2 2/3 seconds
Ankle/Calf Compression:	End of Ankle	5 2/3 seconds
Ankle/Calf/Thigh Compression:	End of Ankle/Calf	11.0 seconds
Decompression/Vent:	Minimum 20 seconds, maximum 60 seconds	

[0045] It is contemplated that the vent period is measured from the end of one inflation cycle to the beginning of the next inflation cycle on leg L. It is further contemplated that both limbs of the subject may be treated and compression treatment system 10 alternates vascular therapy from leg L to the second leg. It is envisioned that the time period from the end of the inflation cycle for leg L to the initiation of the inflation cycle for the second leg can range, for example, from 4.5-24.5 seconds.

[0046] During the initial inflation cycle for treating leg L, as described above, pump 50 initiates a low default voltage so as to not over-inflate bladders 114, 116, 118 on the initial cycle. Solenoid valves 58a, 58b, 58c are energized to the open position, as described, such that the valves open to deliver air to ankle bladders 118, then calf bladder 116, then thigh bladder 114 of sleeve 112 using a desired cycle timing sequence. Pressure transducer 66 monitors the pressure in each of bladders 114, 116, 118 throughout the 11-second compression cycle. At the conclusion of the inflation cycle, pump 50 stops and solenoid valves 58a, 58b, 58c de-energize to the closed position to allow bladders 114, 116, 118 to deflate through vent ports 66a, 66b, 66c.

[0047] It is envisioned that if a second leg of the subject is treated for vascular therapy, solenoid valves 60a, 60b, 60c are energized to the open position, as described, such that the valves open to deliver air to corresponding bladders of a sleeve disposed about the second leg, similar to sleeve 112, using a desired cycle timing sequence. Pressure transducer 66 monitors the pressure in each of the corresponding bladders throughout the 11-second compression cycle. At the conclusion of the inflation cycle, pump 50 stops and solenoid valves 60a, 60b, 60c de-energize to the closed position to allow the corresponding bladders to deflate through vent ports 68a, 68b, 68c. It is further envisioned that the inflation cycle for treatment of the second leg may be initiated approximately 24.5 seconds after completion of the inflation cycle for treating leg L. This process may be reiterated for cycles pertaining to both legs. Other cycle times are contemplated.

[0048] In this embodiment, the pressures, as measured by pressure transducer 66 and the corresponding signal relayed to the control processor of controller 14, of bladders 114, 116, 118 during the inflation cycle remain gradient with the pressure of ankle bladder 118 being greater than the pressure of calf bladder 116, and the pressure of calf bladder 116 being greater than the pressure of thigh bladder 114. The end of cycle pressures, for example, include 45 mm Hg in ankle bladder 118, 40 mm Hg in calf bladder 116, and 30 mm Hg in thigh bladder 114. An example is illustrated in Table 2 below. It is contemplated that compression continues in this cyclical pattern until either compression treatment system 10 is turned off or controller 14 indicates and error code via audible or visual indicia. Other cycles pressures are contemplated.

Table 2

	Thigh-Length Sleeve	Knee-Length Sleeve	Pressure (mmHg)
Ankle bladder 118	Ankle	Ankle	45 mmHg
Calf	Calf	Lower Calf	40 mmHg

(continued)

	Thigh-Length Sleeve	Knee-Length Sleeve	Pressure (mmHg)
bladder 116			
Thigh bladder 114	Thigh	Upper Calf	30 mmHg

[0049] For inflation cycles subsequent to the initial inflation cycle for leg L, as described, a pressure feedback adjustment can be made pursuant to the pressure measurement taken by pressure transducer 66. At the completion of the initial inflation cycle for leg L, the end of cycle pressure in ankle bladder 118 is measured by pressure transducer 66 and compared by the control processor of controller 14 with the set pressure of 45 mm Hg. If the pressure of ankle bladder 118 is higher or lower than the set pressure, then a corresponding decrease or increase in the speed of pump 50 is required to decrease or increase pressure delivery. The pump speed adjustment is based on the following calculation: Adjustment = $|45 - P|$, where P = pressure at the ankle

[0050] If the pressure is less than the set pressure, then the pump speed for the next cycle is increased by the adjustment amount. If the pressure is greater than the set pressure, then the pump speed for the next cycle is decreased by the adjustment amount. It is contemplated that the adjustment process continues even after the set pressure range is reached. It is further contemplated compression treatment system 10 may adjust for separate pump speeds for each sleeve connected to controller 14. Other sequential compression cycles are also contemplated.

[0051] In an alternate example, compression treatment system 10 performs venous refill time measurement. Venous refill time (VRT) measurement is an air plethysmographic technique that determines when the veins of a limb have completely refilled with blood following a compression cycle. See, for example, the venous refill time measurement described in U.S. Patent No. 6,231,532 to Watson et al.

The VRT minimizes the amount of time that the blood remains stagnant inside the veins. The VRT will be substituted for the default rest time (60 seconds) as long as the VRT is between 20 and 60 seconds. If the VRT is less than 20 seconds then the default of 20 seconds is used. If the VRT is greater than 60 seconds then the maximum of 60 seconds is used. The VRT measurement is made when the system first reaches set pressure and once every 30 minutes thereafter. It is contemplated that the VRT technique and algorithm can be used for both sleeve and foot compression.

[0052] The VRT measurement uses an air plethysmographic technique where a low pressure is applied to the calf bladders. As the veins fill with blood, the pressures in the calf bladders increase until a plateau is reached. The time that it takes for the pressure to plateau is the VRT. If two sleeves are connected to controller 14, then the VRT is determined separately for each limb being compressed and the greater of the two measurements is used as the new vent time of the compression cycle. The VRT measurement for each sleeve is made as each particular sleeve reaches set pressure independently. However, the vent time is not updated until VRT measurements have been calculated for both sleeves.

[0053] For example, compression treatment system 10 may employ the VRT measurement after the system initiates vascular therapy. Subsequently, after 30 minutes have elapsed, a VRT measurement will be taken on the next full inflation cycle. After any of the sleeves described above inflates, the bladder(s) of the particular sleeve are vented down to zero as in the default inflation cycle.

[0054] It is contemplated that a selected bladder pressure is monitored and the vent to the bladder is closed when the pressure falls to 5-7 mm Hg. If the pressure in the bladder is 5-7 mm Hg on a current cycle then a VRT measurement is taken. If the pressure in the bladder does not vent down to 5-7 mm Hg then the vent time will remain at its current value and another measurement will be made in 30 minutes. If an error occurs, a corresponding alarm provides audible and/or visual indicia.

[0055] The VRT measurement algorithm determines when the pressures in the selected bladders plateau after compression. The VRT will be determined separately for both legs. The longer of the two refill times will be used as the new vent time. If compression is applied to only one leg, the VRT for that leg is used as the new vent time. The VRT measurement algorithm initiates with a time counter started from the end of the inflation cycle, which occurs after the selected bladder reaches 5-7 mm Hg (enough pressure to cause the bladder to remain in contact with the surface of the leg) and the venting is stopped. The VRT measurement initiates with the time counter started from the end of the inflation cycle.

[0056] The pressure in the selected bladder is then monitored. By way of example, the pressure is monitored with a 10-second, moving sample window. The window moves in 1-second intervals. When the difference between the first and last values in the window is less than approximately 0.3 mm Hg the curve has reached its plateau. The VRT measurement is considered done, and the time interval is determined. The end of the window is considered to be the point at which the venous system in the limbs has refilled.

[0057] Independent of the VRT measurement, the selected bladder is allowed to vent for at least 15 seconds before the next compression cycle on that same limb is started. As a safety factor, 5 seconds are added to the measured refill

time so the limb is not compressed too early. It is contemplated that the vent time may be equivalent to the measured refill time plus 5 seconds. For example, as a result of patient movement, the standard deviation in the sample window may be too high making the measurement erroneous. At this point, the calculation is discarded and the old value of the VRT is used. The VRT measurement is considered erroneous if at any time during the measurement, the pressure in the selected bladder is below 2 mmHg, the calculation is discarded, and the old value of VRT is used. This may occur if there is a leak in the system. It is contemplated that if the pressure is greater than 20 mmHg at any time during the VRT measurement the old value of the VRT is used. It is further contemplated that if the VRT calculation is done for both legs, the longer VRT of both legs is used. It is envisioned that if the VRT is calculated to be greater than 60 seconds, a value of 60 seconds is used. If the VRT is calculated to be less than 20 seconds, a value of 20 seconds is used.

[0058] Alternatively, compression treatment system 10 may employ one, a plurality or all of the following error codes to provide audible and/or visual indicia of system error or failure. These features advantageously enhance safety to the subject during vascular therapy. Several error conditions may cause compression treatment system 10 to provide alarm and stop a particular compression cycle. It is contemplated that compression treatment system 10 may flash error indicators, sound continuous signals, etc., causing a user to reset compression treatment system 10. Controller 14 may provide an error alarm for one, a plurality or all of the following error conditions: high pressure error, including those pressures detected in excess of set pressure; low pressure error, including those pressures detected below set pressure and if no sleeves are detected; system pressure error, including pressure determined within an inflation cycle outside of desired parameters; valve error; software error; pump error; vent and deflation error; battery error; and temperature error, including temperatures detected outside of specified environmental conditions.

[0059] In an alternate example not covered by the claims, as shown in FIG. 8, compression treatment system 10, similar to that described above, includes a foot sleeve 312 configured to provide vascular therapy to the foot of the subject. Foot sleeve 312 includes a bladder 314 that is inflated with air to provide application of pressure to the foot and then deflated. See, for example, the sleeve described in U.S. Patent Application Serial No. 10/784,604, filed on February 23, 2004 and entitled Compression Apparatus.

[0060] Pump 50 fluidly communicates with foot sleeve 312. Sleeve 312 includes a connector 316 that mates with mating connector 42, which is connected to port 40 via tubing 44. Valve connector 316 fluidly communicates with bladder 314 of sleeve 312 via tubing 318. Thus, this configuration facilitates fluid communication between bladder 314 and pump 50. Foot sleeve 312 wraps about the side portions of the foot via a hook and loop type connector flap 320 that transverses the instep of the foot and a hook and loop type connector ankle strap 322.

[0061] Upon completion of the self-test sequence compression for treatment system 10, similar to that described, controller 14 begins the sleeve detection procedure to determine the type(s) of sleeves attached to ports 38, 40. With regard to foot sleeve 312, back pressure is detected by the control processor of controller 14 corresponding to bladder 314, which is connected to outlet port 40b. It is contemplated that compression treatment system 10 may treat the foot of a second leg of a subject with foot sleeve 312 and also treat leg L, as described above, in alternate inflation cycles.

[0062] In one particular exemplary compression cycle for foot sleeve 312, the compression parameters include a 5-second inflation period followed by 60 seconds of venting. An example is illustrated in Table 3 below.

Table 3

	Start of Sequence	End of Sequence
Foot Compression:	0 Seconds	5.0 seconds
Decompression/Vent:	Minimum 20 seconds,maximum 60 seconds	

[0063] It is contemplated that the vent period is measured from the end of one inflation cycle to the beginning of the next inflation cycle on the foot of the subject. It is further contemplated that both limbs of the subject may be treated and compression treatment system 10 alternates vascular therapy from leg L to the second leg. It is envisioned that the time period from the end of the inflation cycle for leg L to the initiation of the inflation cycle for the second leg can range from 7.5-27.5 seconds.

[0064] During the initial inflation cycle for treating the foot of the subject, as described above, pump 50 initiates a low default voltage so as to not over-inflate bladder 314 on the initial cycle. Solenoid valve 60b is energized to the open position, as described, such that the valve opens to deliver air to bladder 314 using a desired cycle timing sequence. Pressure transducer 66 monitors the pressure in bladder 314 throughout the 5-second compression cycle. At the conclusion of the inflation cycle, pump 50 stops and solenoid valve 60b de-energizes to the closed position to allow bladder 314 to deflate through vent port 68b.

[0065] It is envisioned that if a second foot of the subject is treated for vascular therapy, solenoid valve 58b is energized to the open position, as described, such that the valve opens to deliver air to a corresponding bladder of a foot sleeve disposed about the other leg, similar to foot sleeve 312, using a desired cycle timing sequence. For example, pressure

transducer 66 monitors the pressure in the corresponding bladder throughout the 5-second compression cycle. At the conclusion of the inflation cycle, pump 50 stops and solenoid valve 58b de-energizes to the closed position to allow the corresponding bladder to deflate through vent port 66b. It is further envisioned that the inflation cycle for treatment of the second foot may be initiated approximately 27.5 seconds after completion of the inflation cycle for treating the foot treated by foot sleeve 312. This process may be reiterated for cycles pertaining to both feet, or in the alternative, for foot sleeve of a first leg and a leg sleeve of a second leg. It is contemplated that compression treatment system 10 may provide alternating compression to any combination of a sleeve and a foot garment and that if such a combination is employed, then, for example, a 6-second buffer of additional vent timing is added to all vent periods after the foot inflation cycle so that the overall timing is consistent with the default sleeve compression parameters. Other cycle times are contemplated.

[0066] In this embodiment, the target pressure, as measured by pressure transducer 66 and the corresponding signal relayed to the control processor of controller 14, of bladder 314 is, for example, 130 mm Hg. It is contemplated that compression continues in this cyclical pattern until either compression treatment system 10 is turned off or controller 14 indicates an error code via audible or visual indicia.

[0067] For inflation cycles subsequent to the initial inflation cycle for foot sleeve 312 described, a pressure feedback adjustment can be made pursuant to the pressure measurement taken by pressure transducer 66. At the completion of the initial inflation cycle for foot sleeve 312, the end of cycle pressure in bladder 314 is measured by pressure transducer 66 and compared by the control processor of controller 14 with the set pressure of 130 mm Hg. If the pressure of bladder 314 is higher or lower than the set pressure, then a corresponding decrease or increase in the speed of pump 50 is required to decrease or increase pressure delivery. The pump speed adjustment is based on the following calculation:

$$\text{Adjustment} = |130 - P|,$$

where P = pressure at the foot

[0068] If the pressure is less than the set pressure, then the pump speed for the next cycle is increased by the adjustment amount. If the pressure is greater than the set pressure, then the pump speed for the next cycle is decreased by the adjustment amount. It is contemplated that the adjustment process continues even after the set pressure range is reached. It is further contemplated that compression treatment system 10 may adjust for separate pump speeds for each sleeve connected to controller 14. Other sequential compression cycles are also contemplated.

[0069] It will be understood that various modifications may be made to the embodiments disclosed herein. Therefore, the above description should not be construed as limiting, but merely as exemplification of the various embodiments. Those skilled in the art will envision other modifications within the scope of the claims appended hereto.

Claims

1. A compression treatment system (10) comprising:

a pump (50) as a fluid source;
 a sleeve (46,48) including multiple bladders (46a,46b,46c,48a,48b,48c) adapted to be supported about a limb and in fluid communication with the fluid source;
 a housing (12) including a control panel (32), ports (38, 40) and said pump, solenoid valves (58, 60) in fluid communication with the pump (50) for selectively passing or blocking a flow of fluid from the pump (50) to the bladders;
 a pressure transducer (66);
 a pneumatic circuit to allow the inflation of the bladders (46a,46b,46c,48a,48b,48c) and a pressure monitoring using the pressure transducer (66), wherein;
 the pressure transducer (66) is coupled to the pneumatic circuit and disposed between the pump (50) and the solenoid valves (58a,58b,58c,60a,60b,60c) via tubing ; **characterized by**
 a control processor in the housing (12) in communication with the control panel (32), the pump (50) and the solenoid valves (58, 60) for controlling operation of the pump (50) and the solenoid valves (58, 60), the control processor being programmed to execute a sleeve detection procedure during a first inflation cycle after the control processor (14) is initially powered on and upon completion of a self-test sequence, the sleeve detection procedure including the following steps:

- (a) delivering air through the ports (38, 40) with pump (50) until the pressure reaches a default threshold;
- (b) taking a pressure measurement with the pressure transducer (66) to determine whether or not a bladder

(46, 48) is connected to a particular port (38a,38b,38c,40a,40b,40c) under sleeve detection;
 (c) determining that a bladder (46a,46b,46c,48a,48b,48c) is not being connected with a particular port (38a,38b,38c,40a,40b,40c) if there is no backpressure ;
 (d) detecting which ports are connected and determining what type of sleeve (46,48) is connected, and
 (e) adjusting the appropriate compression therapy accordingly.

2. The compression treatment system according to claim 1,

characterized in that

the type of sleeve (46,48) is a leg sleeve or a foot garment.

3. The compression treatment system according to claim 1 or 2,

characterized in that

the control processor executes a further step of triggering a low pressure error with corresponding audible indicia if no sleeves (46,48) are detected at the ports (38, 40) or if the detected type is not recognized.

Patentansprüche

1. Kompressionsbehandlungssystem (10), umfassend:

eine Pumpe (50) als eine Fluidquelle;

eine Hülse (46, 48), welche mehrere Balgen (46a, 46b, 46c, 48a, 48b, 48c) umfasst, welche ausgebildet sind, um um ein Körperlged gehalten zu sein und welche mit der Fluidquelle fluidisch kommunizieren;

ein Gehäuse (12), welches ein Bedienpult (32), Anschlüsse (38, 40) und die Pumpe umfasst,

Magnetventile (58, 60), welche mit der Pumpe (50) zum selektiven Durchlassen oder Sperren einer Fluidströmung von der Pumpe (50) zu den Balgen fluidisch kommunizieren;

einen Druckgeber (66);

einen Pneumatikkreis, um das Aufblasen der Balgen (46a, 46b, 46c, 48a, 48b, 48c) zu ermöglichen und eine Drucküberwachung, welche den Druckgeber (66) verwendet, wobei

der Druckgeber (66) mit dem Pneumatikkreis gekoppelt ist und zwischen der Pumpe (50) und den Magnetventilen (58a, 58b, 58c, 60a, 60b, 60c) mittels Leitungen angeordnet ist;

gekennzeichnet durch

einen Steuerprozessor im Gehäuse (12), welcher mit dem Bedienpult (32), mit der Pumpe (50) und mit den Magnetventilen (58, 60) zur Steuerung des Betriebs der Pumpe (50) und der Magnetventile (58, 60) kommuniziert, wobei der Steuerprozessor programmiert ist, um eine Hülsendetektionsprozedur während eines ersten Aufblaszyklus auszuführen, nachdem der Steuerprozessor (14) anfänglich eingeschaltet wird und beim Abschließen einer Selbsttest-Sequenz, wobei die Hülsendetektionsprozedur die folgenden Schritte umfasst:

(a) Zuführen von Luft durch die Anschlüsse (38, 40), mit der Pumpe (50), bis der Druck eine Standard-schwelle erreicht;

(b) Ausführen einer Druckmessung mit dem Druckgeber (66), um zu bestimmen, ob ein Balg (46, 48) mit einem besonderen Anschluss (38a, 38b, 38c, 40a, 40b, 40c) während der Hülsendetektion verbunden ist;

(c) Bestimmen, dass ein Balg (46a, 46b, 46c, 48a, 48b, 48c) nicht mit einem besonderen Anschluss (38a, 38b, 38c, 40a, 40b, 40c) verbunden ist, wenn kein Gegendruck vorhanden ist;

(d) Detektieren der Anschlüsse, welche verbunden sind, und Bestimmen des Typs der verbundenen Hülse (46, 48), und

(e) Einstellen der entsprechenden geeigneten Kompressionsbehandlung.

2. Kompressionsbehandlungssystem nach Anspruch 1,

dadurch gekennzeichnet, dass der Typ der Hülse (46, 48) eine Beinhülse oder eine Fußmanschette ist.

3. Kompressionsbehandlungssystem nach Anspruch 1 oder 2,

dadurch gekennzeichnet, dass

der Steuerprozessor einen weiteren Schritt des Aktivierens eines Niedrigdruckfehlers mit entsprechenden hörbaren Zeichen ausführt, falls keine Hülsen (46, 48) an den Anschlüssen (38, 40) detektiert werden oder falls der detektierte Typ nicht erkannt wird.

Revendications

1. Système de traitement par compression (10) comprenant :

une pompe (50) en tant que source de fluide ;
 un manchon (46, 48) qui inclut de multiples vessies (46a, 46b, 46c, 48a, 48b, 48c) qui sont adaptées de manière à ce qu'elles soient supportées autour d'un membre et en communication en termes de fluide avec la source de fluide ;
 un boîtier (12) qui inclut un panneau de commande (32), des orifices (38, 40) et ladite pompe ;
 des électrovannes (58, 60) en communication en termes de fluide avec la pompe (50) pour, de façon sélective, laisser passer ou bloquer un écoulement de fluide depuis la pompe (50) jusqu'aux vessies ;
 un transducteur de pression (66) ;
 un circuit pneumatique pour permettre le gonflage des vessies (46a, 46b, 46c, 48a, 48b, 48c) et une surveillance de la pression en utilisant le transducteur de pression (66) ; dans lequel
 le transducteur de pression (66) est couplé au circuit pneumatique et est disposé entre la pompe (50) et les électrovannes (58a, 58b, 58c, 60a, 60b, 60c) via un tubage ;
caractérisé par
 un processeur de commande à l'intérieur du boîtier (12) en communication avec le panneau de commande (32), la pompe (50) et les électrovannes (58, 60) pour commander le fonctionnement de la pompe (50) et des électrovannes (58, 60), le processeur de commande étant programmé de manière à ce qu'il exécute une procédure de détection de manchon pendant un premier cycle de gonflage après que le processeur de commande (14) est initialement alimenté et suite à l'achèvement d'une séquence d'autotest, la procédure de détection de manchon incluant les étapes qui suivent :

- (a) la délivrance d'air au travers des orifices (38, 40) à l'aide de la pompe (50) jusqu'à ce que la pression atteigne un seuil par défaut ;
- (b) la prise d'une mesure de pression à l'aide du transducteur de pression (66) de manière à déterminer si oui ou non une vessie (46, 48) est connectée à un orifice particulier (38a, 38b, 38c, 40a, 40b, 40c) en cours de détection de manchon ;
- (c) la détermination qu'une vessie (46a, 46b, 46c, 48a, 48b, 48c) n'est pas connectée à un orifice particulier (38a, 38b, 38c, 40a, 40b, 40c) s'il n'y a pas de contre-pression ;
- (d) la détection de quels orifices sont connectés et la détermination de quel type de manchon (46, 48) est connecté ; et
- (e) le réglage de la thérapie par compression appropriée en conséquence.

2. Système de traitement par compression selon la revendication 1, **caractérisé en ce que** le type de manchon (46, 48) est un manchon pour la jambe ou un vêtement pour le pied.

3. Système de traitement par compression selon la revendication 1 ou 2, **caractérisé en ce que** le processeur de commande exécute une étape supplémentaire consistant à déclencher une erreur de pression faible avec des indications audibles correspondantes si aucun manchon (46, 48) n'est détecté au niveau des orifices (38, 40) ou si le type détecté n'est pas reconnu.

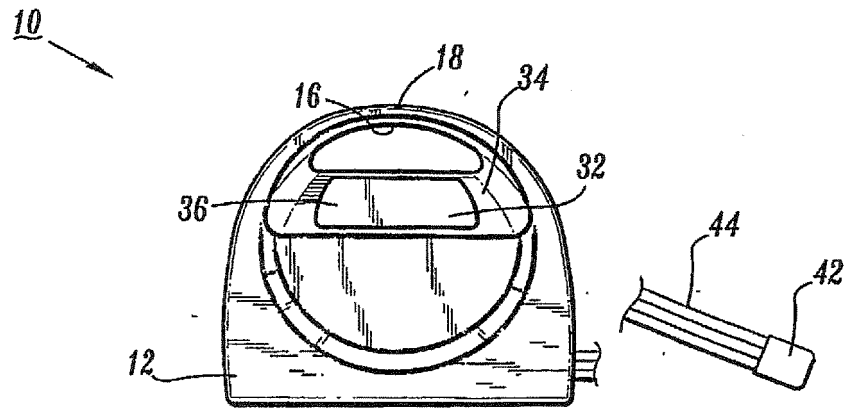


FIG. 1

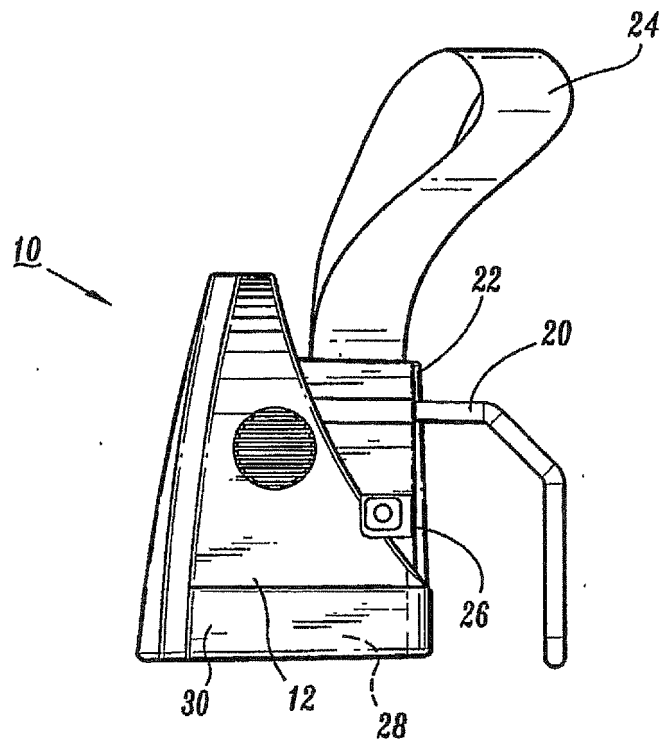


FIG. 2

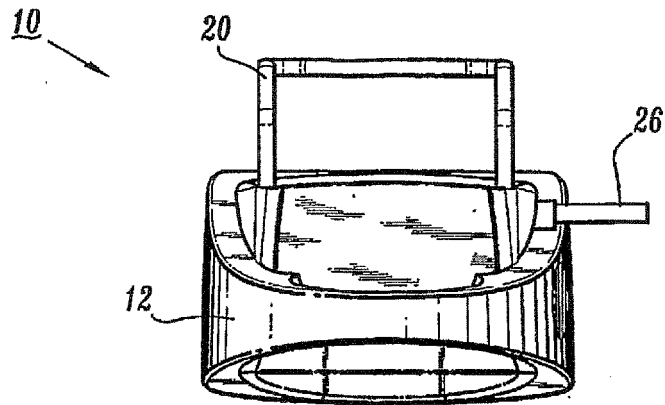


FIG. 3

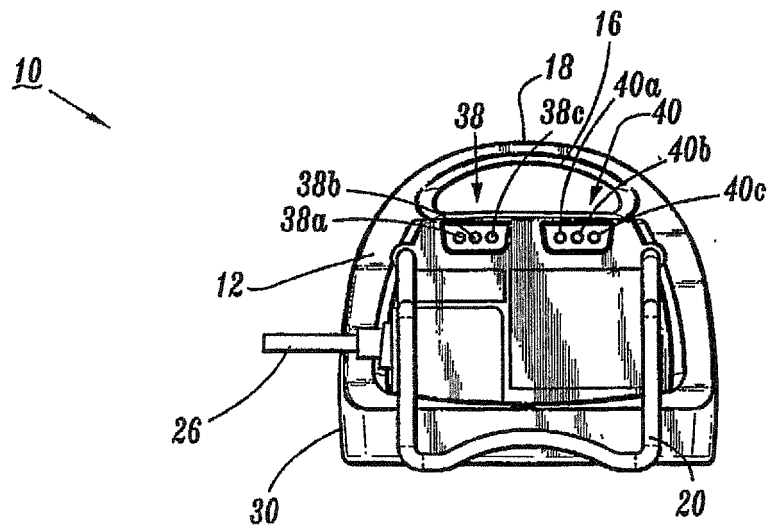


FIG. 4

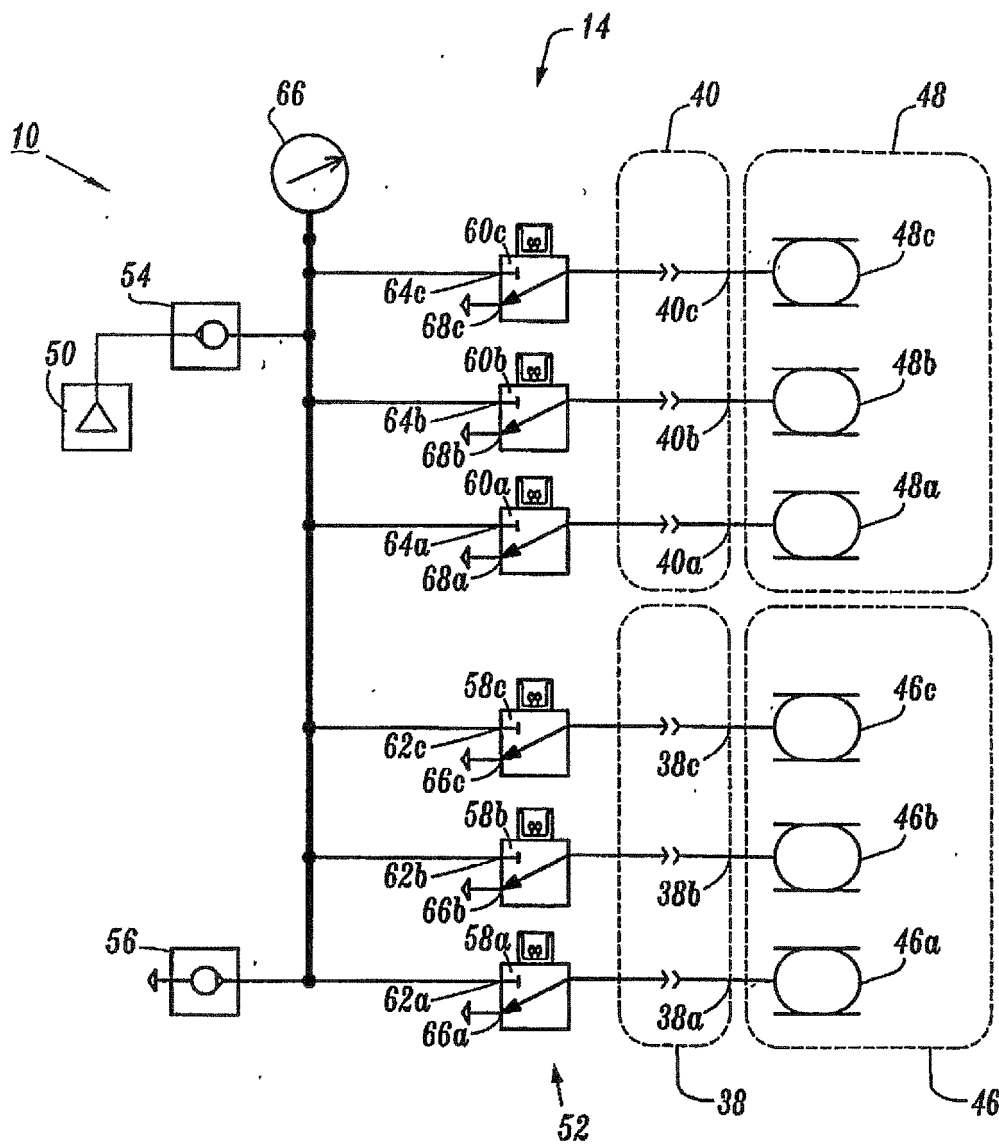


FIG. 5

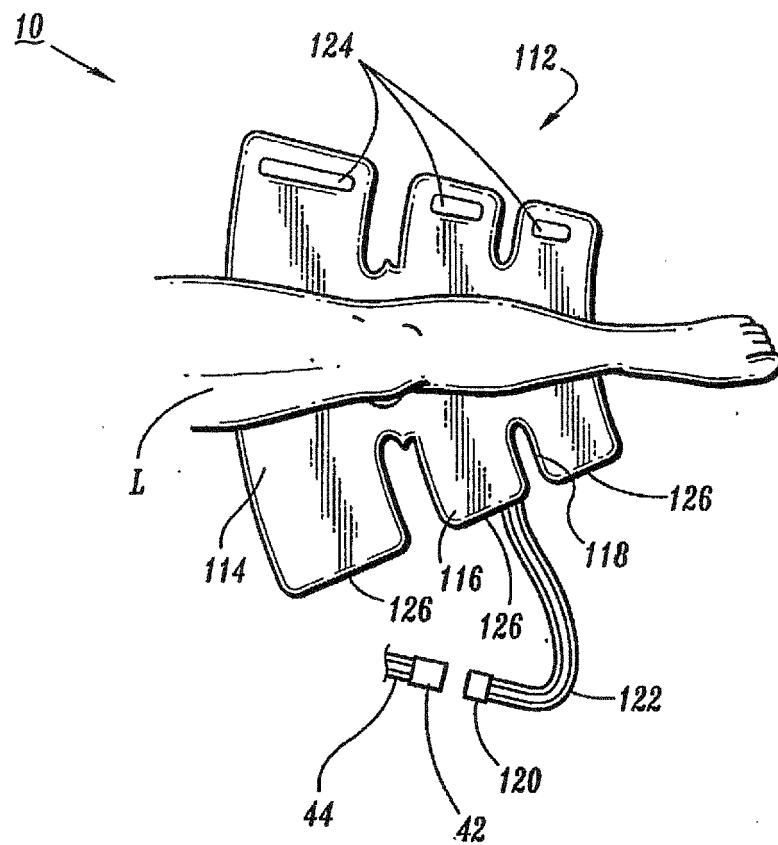


FIG. 6

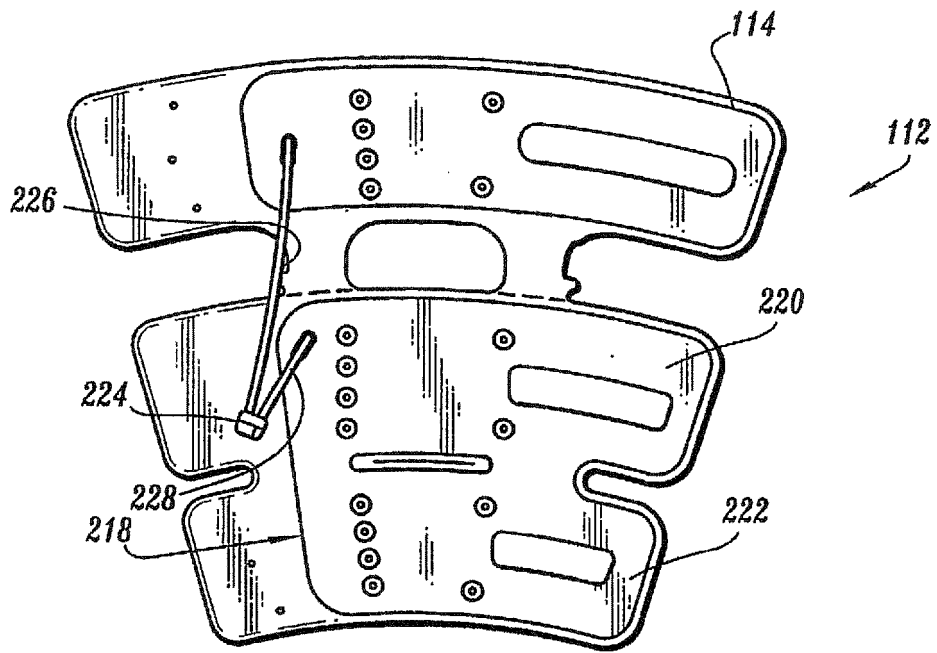


FIG. 7

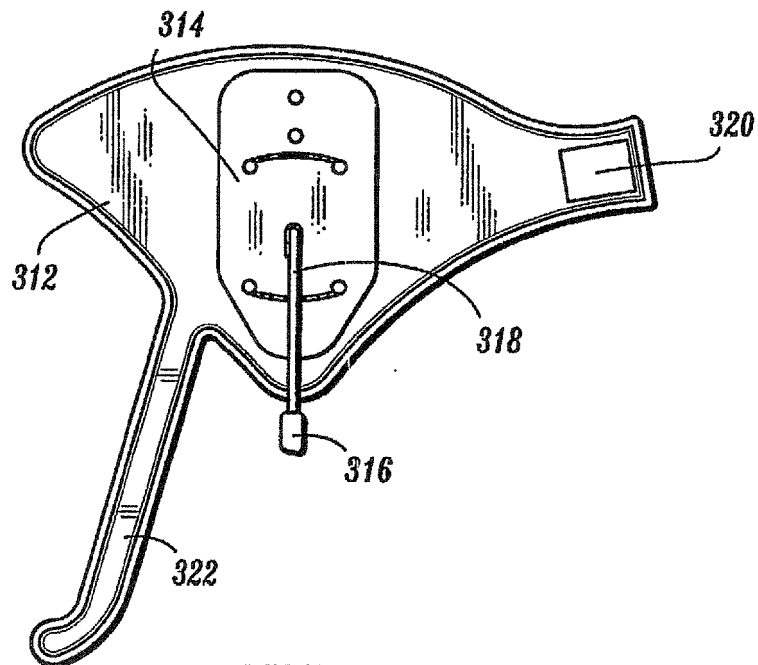


FIG. 8

REFERENCES CITED IN THE DESCRIPTION

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Patent documents cited in the description

- US 6290662 B [0003]
- US 6494852 B [0003]
- US 5575762 A [0005]
- GB 2295235 A [0006]
- EP 1226804 A [0007]
- US 5876359 A, Bock [0028] [0030]
- US 78460704 [0042]
- US 78463904 [0042]
- US 6231532 B, Watson [0051]
- US 78460404 [0059]