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(54) **BLOOD FLOW STIMULATOR**

VORRICHTUNG ZUR FÖRDERUNG DER DURCHBLUTUNG

APPAREIL DE STIMULATION DE LA CIRCULATION SANGUINE

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Description

[0001] The invention, as originally conceived, pertains to a method and means for therapeutically and/or prophylactically dealing with a thrombotic or with a potentially thrombotic condition in a human limb, particularly in a leg. Such thrombotic conditions generally occur in the deep veins, hence, the term deep-vein thrombosis, herein abbreviated to DVT.

[0002] The literature[1] is beginning to accumulate important evidence of the successful use of a so-called foot pump in reducing the chances of thrombo-embolism, following surgery wherein a blood clot in the venous system may otherwise have proven fatal. By foot-pump use is meant methods and means as disclosed and discussed in United States patents, numbered Re. 32,939, Re. 32,940, 4,696,289, and 4,721,101.

[0003] It suffices for present purposes to state that a foot-pump appliance of the character indicated makes use of a Gardner/Fox discovery reported in 1983 ("The Venous Pump of the Human Foot-Preliminary Report", Bristol Medico-Chirurgical Journal; Gardner and Fox; pp. 109-112; July 1983), namely that plantar veins of the foot provide a pool of blood for return via the venous system, and that in unafflicted persons, the transfer of weight-bearing from one to the other foot in the course of walking entails a transient stretching of plantar veins and thus a transient shrinking of plantar-vein capacity, such as to drive venous flow back to the heart via the check-valve action of the veins. Significantly, no muscular action is involved in this venous-return flow. The foot-pump disclosures of said patents provide the patient who is bed-ridden or otherwise unable to walk with a mechanical substitute for the intermittent weight-bearing action available to ambulatory individuals. The mechanical substitute involves periodic application of a relatively short pulse of compression against the underside of the foot, between the ball and the heel of the foot, to a degree sufficient to transiently reduce the volume of the plantar veins, thus driving an increment of venous return flow back to the heart, primarily via the deep veins of the leg.

[0004] In the circumstance of using the mechanical foot pump to deal with a thrombotic condition in the leg, the deep veins will have been partially or wholly blocked by a developing or a developed clot accumulation, so that deep-vein resistance to stimulated flow compels superficial veins to assume an abnormal flow, for each foot-pump stimulation. This can be the source of increased pain and may result in a long-term abnormal reliance upon the superficial veins. Moreover, in the event that a thrombolitic agent, such as streptokinase, has been introduced into the circulatory system for purposes of dissolving the clotted condition, any diversion of venous-return flow to superficial veins in a by-passing of the deep-vein target of therapy; this can be interpreted to mean that an unnecessarily great proportion of thrombolitic agent must be introduced or that the time of therapeutic treatment may be longer than necessary, were it possible to more effectively focus delivery of the thrombolitic agent at the deep-vein situs of thrombosis.

[0005] It is an overall object of the invention to provide improved means for dealing with a blood-circulatory abnormality in a human leg.

[0006] It is a specific object of the invention to provide an improved means for therapeutically and/or prophylactically dealing with a deep-vein thrombosis (DVT) condition in a leg.

[0007] Another specific object is to provide an improved means for directing foot-pump stimulated venous-return flow, with emphasis on deep-vein conduct of such flow.

[0008] Still another specific object is to provide means to achieve the foregoing objects, with selectively available further applicability to improvement of venous and arterial flow for a patient who is confined to bed with a leg elevated above his body.

[0009] A further object is to achieve the above objects while also achieving an enhancement of arterial flow in the same leg.

[0010] It is also an object to achieve the foregoing objects without impairing arterial flow.

[0011] A general object is to achieve the above-stated objects with apparatus of relative simplicity and offering a range of options to operating medical personnel, both for accommodation to the differing symptoms and tolerances of successive patients, and for accommodation to the changing symptoms and tolerances of a given patient in the course of administering a therapeutic treatment to the patient.

[0012] According to one aspect of the invention there is provided medical apparatus for therapeutically and/or prophylactically treating a blood-circulation abnormality in a patients leg, comprising a single inflatable cuff adapted for application to the calf, first means for transiently inflating said cuff to a first pressure level sufficient to induce local tourniquet-pressure action on the calf, an inflatable foot-pump adapted for application of inflation pressure primarily at the plantar region between the ball and heel of the foot, second means for transiently inflating said foot-pump to a peak pressure in excess of said first pressure level, and cyclically operable control means for coordinated inflation / deflection

[1] See, for example, Stranks/MacKenzie/Grover/Fail, "The A-V Impulse System Reduces Deep-Vein Thrombosis and Swelling after Hemiarthroplasty for Hip Fracture"; Journal of Bone Joint Surgery (British), Vol. 74-B, No. 5, September 1992, pp. 775-778, including references cited therein; and see also Bradley/Krugener/Jager, "The Effectiveness of Intermittent Plantar Venous Compression in Prevention of Depth Venous Thrombosis after Total Hip Arthroplasty", The Journal of Arthroplasty, Vol. 8, No. 1, 1993.

cyclical operation of said first and second means, said control means including separate means of pressure-fluid supply only to said single inflatable cuff and said inflatable foot-pump, and said control means being sequential operation of only said single inflatable cuff and said inflatable foot-pump in each cyclical operation such that:

(a) initially, via said first means, said cuff is supplied with pressure fluid to transiently retain tourniquet-pressure action on the calf;
(b) via said second means, said foot-pump is transiently inflated to said peak pressure in the circumstances of said tourniquet-pressure action on the calf, and said foot-pump is relieved of inflation pressure after achievement of said peak pressure; and
(c) via said first means, cuff pressure is relieved from tourniquet action in selectively timed relation to inflation and at least commencement of relief of foot-pump pressure;
said control means providing a cycle-completing interval of time between said control operations via said first and second means prior to control-means re-initiation of the next-succeeding cyclical operation, wherein successive cycles recur at a periodic interval which is in the range of 15 to 60 seconds.

[0013] The invention will be described in detail in conjunction with the accompanying drawings, in which:

Fig. 1 is a simplified side view of an appliance of the invention, partly broken away and in installed position on a human leg, with a schematic diagram of interrelated components for operation pursuant to a presently preferred mode;
Fig. 2A is a graphical illustration of pressure as a function of time, for operation of a foot-pump portion of the appliance of Fig. 1;
Fig. 2B is a graphical illustration of pressure as a function of time, for operation of a tourniquet-cuff portion of the appliance of Fig. 1, the illustrations of Figs. 2A and 2B being exaggerated and juxtaposed for better illustration of time-coordinated functions of the appliance;
Fig. 3A is a simplified graphical illustration of foot-pump pressure as a function of time for a modified mode of operation of the invention;
Fig. 3B is a simplified graphical illustration of tourniquet-cuff pressure as a function of time, the illustrations of Figs. 3A and 3B being juxtaposed for better illustration of coordination functions of the modified mode;
Fig. 4 is a schematic diagram of interrelated components for operation pursuant to the modified mode of Figs 3A and 3B;
Fig. 5 is another schematic diagram of interrelated components for selective control as to mode of operation;
Fig. 6A is a graphical illustration of pressure as a function of time, for foot-pump operation of Fig. 5, as in Fig. 2A;
Fig. 6B is a graphical illustration of pressure as a function of the time scale of Fig. 6A, for tourniquet-cuff operation of Fig. 5, as in Fig. 2B;
Fig. 6C is a graphical illustration of pressure as a function of time scale of Fig. 6A, for a first-modified tourniquet-cuff operation of Fig. 5; and
Fig. 6D is a graphical illustration of pressure as a function of the time scale of Fig. 6A, for a second-modified tourniquet-cuff operation of Fig. 5.

[0014] With initial reference to Fig. 1, the invention is shown in application to the foot and distal calf of a human leg, wherein a foot-pump element 10 is applied to the foot, a tourniquet-calf element 11 is applied to the distal calf, and pneumatic actuating and control means 12 is connected to elements 10 and 11 for coordinated operation of the same, pursuant to a repetitive cycle, within the range 15 to 60 seconds.

[0015] The foot-pump element 10 is suitably as described in said patents, so that simplified identification of parts will suffice for present purposes. As shown, the foot-pump element 10 comprises an inflatable bag or bladder 14 shaped for engagement with the sole of the foot and in the plantar arch, namely between the ball and the heel of the foot. A flexible pipe 15 connects bag 14 to the pneumatic supply and control means 12. The foot-pump element 10 further comprises a suitably padded wrap 16, embracing the bag 14 and over the instep 17 of the foot, and secured as by hook and loop fastening elements 18, to complete a circumferential tie at and round the mid-tarsal joint. The wrap 16 is shown covered by a cloth slipper 19 which covers the majority of the foot, leaving the toes exposed for the physician's inspection and reaction-testing of the involved foot. In use, apparatus to be described at 12 operates rapidly to inflate the bag 14, which reacts against the circumferentially tied wrap 16 to apply pumping pressure to the sole of the foot while also urging the ball and heel of the foot away from each other, thus applying upward and spreading force and transiently flattening the plantar arch, as would occur if the foot were placed on the ground (i.e., body-weight bearing) during normal ambulation, thereby stimulating venous blood flow.

[0016] The tourniquet-cuff element 11 may be a commercially available inflatable item, providing a circumferential tie around an inflatable bladder (not shown) which is preferably applied to the distal-calf region; the only exposed part of the inflatable cuff element 11 is its flexible supply pipe 20, which receives its inflation/deflation air supply from the control means 12.

[0017] The pneumatic actuating and control means 12 of Fig. 1 operates from an accumulator 21 of pressurized air, which in the case of certain hospitals may be provided by a central source of suitably pressure-regulated supply. However, as shown, self-contained means

12 comprises an air pump 22, motor-driven at 23, with a relief valve 24 to determine a suitable upper limit of air pressure at accumulator 21. Pressurized air from the accumulator is connected for inflation-air delivery to the foot-pump supply pipe 15, via a first solenoid-operated valve 25 of the normally closed (NC) variety, and for inflation-air delivery to the tourniquet-cuff supply pipe 20, via a second normally closed solenoid-operated valve 26. Third and fourth normally closed solenoid-operated valves 27, 28 are respectively connected to the foot-pump and cuff pipes 15, 20 for controlled discharge to ambient air of the respective inflatable elements 10, 11. Programmable control means 30 will be understood to be presettable for the sequentially and suitably timed operation of the respective solenoid-operated valves, thus determining particular valve-opening events, suggested by time legends T_1, T_3, T_4, T_6 which will be discussed in connection with the adjacent graphs of Figs. 2A and 2B to the same time scale.

[0018] The graph of Fig. 2A displays, with some exaggeration for clarity, a representative inflation/deflation pressure pulse for the foot-pump element 10, and the graph of Fig. 2B is a similar display for a representative inflation/deflation pressure pulse for the tourniquet-cuff element 11. Separately identified times T_1, T_2, ... T_6 within each cycle of appliance operation serve to mark various coordinating events, as between foot-pump and tourniquet operation in the cycle, and the use of time designations T_1 to T_6 will be understood to indicate initiation of solenoid-valve actuations by means 30 in Fig. 1. Also, separately adjustable variable orifices 31, 32 in the respective inflation lines to the foot-pump and cuff elements 10 and 11 will be understood to provide selective control of inflation rates for these elements.

[0019] As seen in Fig. 2B, a representative cycle of appliance operation will commence with an actuating signal from control means 30 at time T_1, thus opening valve 26 and initiating inflation of cuff 11. The flow of inflation air from accumulator 21 will preferably have been adjusted at 32 to provide a relatively slow rate of cuff inflation, so that, based on operational experience with the presssure of air from accumulator 21, an event T_2 determined by the program of means 30 will terminate the supply of accumulator air to cuff 11, by terminating the excitation of valve 26, thereby allowing valve 26 to return to its normally closed condition, with cuff 11 temporarily locked in inflated condition, at a level 33 of cuff pressure P_c which will have been selected for the desired degree of local primary flow-restriction action on superficial veins, with relatively little flow-restricting action on deep veins. Suitably and illustratively, this level of cuff-inflation pressure is in the range of 30 to 100-mm Hg, being preferably in the range of 40 to 60-mm Hg; and the rate of cuff inflation is relatively slow, with cuff inflation accomplished within no less than one second.

[0020] At a time T_3 which may be determined by control means 30 to be at or soon after time T_2, the solenoid valve 25 is actuated to open condition, thus admitting inflation air from accumulator 21 to the foot-pump bag, pursuant to the rate of air supply selected by prior adjustment of orifice 31. The rising slope 34 of inflation air to a peak foot-pump pressure in excess of the transiently locked-inflation pressure 33 of cuff 11 is desirably relatively rapid and in the range up to one second, being preferably in the range of 0.5 second or less. Achievement of peak foot-pump inflation pressure may be signalled by a pre-set pressure sensitive switch for terminating the actuating signal to solenoid valve 25, but in the circuitry shown in Fig. 1, a peak-timing event at T_4 is operative (a) to terminate the actuating signal to valve 25 and (b) to initiate actuation of solenoid valve 27, for discharge of inflation air from foot-pump element 10, thus deflating the foot-pump bag 14 as rapidly as possible and substantially immediately upon achievement of peak foot-pump pressure. In Fig. 2A, the curve 35 of resulting relief of foot-pump pressure has been exaggerated to enable better identification of subsequent events in the illustrative cycle of appliance operation. Experience in appliance operation will establish awareness that, at a particular time T_5 (related to a selected peak of foot-pump pressure), the curve 35 of deflating pressure will cross and reduce below the locked cuff-inflation level 33, and therefore, based on this experience, the control means 30 will have been set to issue a valve-opening signal T_6 to the cuff-deflating solenoid valve 28.

[0021] Figs. 3A, 3B and 4 illustrate a modification wherein sensed pressure thresholds determine key events in the operative sequence of cuff and foot-pump actuation in each cycle. Pneumatic circuitry remains substantially as already described for Figs. 1, 2A and 2B, and therefore the same reference numbers are used, where applicable. Threshold sensing of a predetermined limit of cuff-inflation pressure is provided by pressure-sensitive switch means 40 in the air-supply line from solenoid valve 26 to cuff 11, and threshold sensing of a predetermined peaking limit of foot-pump pressure is provided by pressure-sensitive switch means 41 in the air-supply line from solenoid valve 25 to foot-pump 10. And a differential-pressure switch 42 is connected for differential response to instantaneous cuff and foot-pump pressures, such that switch 42 may produce an electrical output signal in line 43 to solenoid valve 28 when foot-pump pressure has been sensed to drop to or below cuff-inflation pressure.

[0022] Each pulsing cycle of Figs. 3A, 3B and 4 commences with an electrical actuating signal from control means 30 to solenoid valve 26, thus opening valve 26 and admitting inflation air to cuff 11 at a relatively slow rate determined by pre-set adjustment of orifice 32. Achievement of cuff inflation to the limit 33, predetermined at 40, will activate switch 40 (a) to terminate the actuated open condition of solenoid valve 26, and (b) to actuate solenoid valve 25 to open condition.

Valve 25 then admits inflation air to foot-pump 10, at a relatively fast rate determined by pre-set adjustment of orifice 31. Achievement of peak foot-pump inflation pressure to a limit 44 pre-set at 41 (above cuff limit 33) will activate switch 41 (a) to terminate the actuated open condition of solenoid valve 25, and (b) to actuate solenoid valve 27 (via line 46) to open condition, thus initiating deflation of the foot-pump. Then, when the differential-pressure switch 42 has sensed foot-pump deflation to the level of inflated-cuff pressure, switch 42 is operative to deflate cuff 11. A predominant fraction 45 of the cycle period remains inactive, with both elements 10, 11 deflated, or substantially deflated, until control means 30 calls for recycled operation of inflation events, by again actuating solenoid valve 26 to open condition.

[0023] The described operation of Fig. 4 will be seen to involve foot-pump deflation as soon as possible, once the peak-inflation level has been sensed by switch means 41. That being the case, the circuit of Fig. 4 can produce substantially the same coordination of cuff inflation and foot-pump inflation as was the case described in connection with Fig. 1. In certain situations, however, it may be desired to provide a selected relatively short period of holding the peak of foot-pump inflation pressure, before initiating the deflation process. It should be clear that such retention of foot-pump inflation in the case of Fig. 1 is achievable, merely by preselecting, at control means 30, a suitable interval between times T_3 and T_4, for example, a selected interval of 1 to 5 seconds. In the case of Fig. 4, a preselected peak-holding period of similar nature is selectively available by placing preselected timer terminals 47 (of control means 30) in series with a break in line 46, wherein such a break for series connection to terminals 47 is suggested by an "x" mark 48.

[0024] Use of the described appliance, whether by way of pre-set timing as in Fig. 1 or by way of sensed pressure levels as in Fig. 4, will be seen to achieve stated objects and to be pursuant to the following criteria for each cycle:

(a) A first level (33) of transient tourniquet pressure is applied to the leg; in the case of a diagnosed or suspected possible DVT condition or development, it is preferred that cuff 11 be applied at the distal-calf region, which for most cases will be distal to the DVT condition. And even if the DVT condition extends to the distal calf, the preferred distal-cuff application of cuff 11 is recommended.

(b) Transient venous-pumping pressure is then applied to the plantar region of the foot, at a relatively rapid rate and to a peaking level which exceeds that of the tourniquet action at the cuff; the cuff will thus have reduced the availability of superficial veins to accommodate pumped venous flow, so that deep veins may be targeted with enhanced effect. If a thrombolitic agent is introduced at the dorsum of the foot, as at location A in Fig. 1 (e.g., through a local opening in slipper 19), then direct plantar-vein acceptance of the thrombolitic agent can occur, and the existence of tourniquet-cuff action will necessarily mean delivery of the thrombolitic agent to the deep veins with enhanced efficiency and DVT-dissolving effect.

(c) The venous-pumping pressure may be relieved immediately or following a short peak-holding period, at the option of the physician who may have preferred to provide a measure of concurrent enhanced arterial flow to the leg, pursuant to the teaching of Patent No. 4,721,101. Whatever the selected time for retention of peak venous-pump pressure, the holding time is short compared to the cycle time, so that in no case is arterial flow impaired.

(d) The tourniquet pressure is relieved once the venous pressure has reduced to or below the level of transiently applied tourniquet pressure. Even with a preferred relatively slow rate of tourniquet-pressure development, the period of tourniquet-pressure application is short relative to the indicated range of cycle duration, so that arterial flow remains unimpaired if not enhanced.

[0025] Quite aside from the described DVT-treating uses and features, the invention is also seen to have further application for the bed-ridden patient for whom the orthopedic surgeon may have ordered a foot to be suspended in elevated relation with respect to the heart. In that situation, the plantar veins will necessarily be above heart elevation, thus inviting slow gravitational drainage of plantar veins and preventing such plantar-vein accumulation of blood as could be the subject of artificial foot-pump actuation. To avoid such drainage and at the same time to provide a means of plantar-vein accumulation of blood for foot-pumped venous-return flow, the cuff 11, particularly when located at the distal calf and inflated to the already indicated pressure range, and for the relatively long period up to 10 seconds, or for a period of at least 10 seconds prior to foot-pump actuation, will permit a desirable volume of plantar-vein accumulation by the time the foot-pump is activated at the rate and to the peak-pressure range already discussed. Of course, on discharge of foot-pump inflation, the cuff 11 should also be deflated, until need for renewed cuff inflation for the next cycle of coordinated cuff and foot-pump actuation.

[0026] Fig. 5 provides further schematic illustration of appliance components capable of various selected operations of cuff 11 in timed relation to foot-pump (14) operation, wherein programmable control means 130 is seen to determine the sequencing and/or interlacing of events governed by four solenoid valves, 125, 126, 127, 128, which may be of normally closed variety, as suggested by the symbol NC, it being understood that in Fig. 5 such flow-control devices as suitably adjusted variable orifices in the respective lines for these sole-

noid valves have been omitted, for simplification of the drawing. As shown in Fig. 5, separate regulator valves 124, 124' operate from a single pressure-fluid source and are selectively adjustable to determine, respectively, a first and relatively low regulated pressure available for cuff inflation from a first accumulator 121, and a second and relatively elevated regulated pressure available for foot-pump inflation from a second accumulator 121'.

[0027] With additional reference to Fig. 6A, the programmed timing of valve (125) opening will be understood to effect relatively rapid inflation of foot-pump 14 via a relatively fast rise 134 to a peak of pressure (P_p), followed by a relatively gentle relaxation (135) from peak inflation pressure upon actuation of a venting solenoid 127 (with valve 125 in its NC condition); alternatively, with delayed actuation of the venting solenoid 127 (to the delayed extent Δ), peak inflation pressure can be retained, and the gentle relaxation profile 135' will be correspondingly delayed. The arterial-flow enhancement properties of delayed retention of peak foot-pump inflation pressure are discussed in greater detail in U.S. Patent Re. 32,940.

[0028] A concurrent program of cuff-11 inflation and relaxation is controlled by means 130 to supply cuff-inflation pressure fluid from accumulator 121 upon actuation of valve 126, the cuff inflation being shown in Fig. 6B to be retained until relaxation of foot-pump pressure reduces at least to the level of cuff-inflation pressure. The designation PC1 is adopted in Fig. 6B, for consideration alongside the foot-pump pressure profile of Fig. 6A, to illustrate use of the control apparatus of Fig. 5 to determine the DVT-reducing mode described in connection with Figs. 1, 2A and 2B.

[0029] Further uses of the control apparatus of Fig. 5 are illustrated by the respective cuff-pressure profiles PC2 and PC3 of Figs. 6C and 6D, which are particularly helpful in aid of a patient whose leg must be supported in an elevated state that necessarily places his foot, the foot-pump 14 and the cuff 11 above the elevation of his heart, as he lies in bed.

[0030] More particularly, in Fig. 6C, which presents the cuff-inflation pressure profile (PC2) to the same time scale as the foot-pump inflation profile (P_p) of Fig. 6A, the inflation of cuff 11 occurs for a substantial fraction (e.g., one half) of the full cycle, as an event serving to "prime" the plantar veins immediately prior to foot-pump inflation, so that foot-pump action may have a fuller accumulation of blood in readiness for pumped venous return. In Fig. 6C, the priming is fully completed at the instant of commencing foot-pump inflation, and in Fig. 6D, the profile (PC3) of cuff pressure inflation is seen to lap the foot-pump inflation profile (P_p) at least during the rise time of foot-pump inflation. The result of pumped venous-return effectiveness is substantially the same for Fig. 6C and for Fig. 6D, but the venting of cuff pressure is preferred to be substantially complete, as of the initiation of foot-pump inflation.

[0031] In the "priming" situations illustrated by Figs. 6C and 6D, the criteria expressed in the above-noted patents for foot-pump operation are desirable, i.e., with inflation up to 225-mm Hg in less than one second, but the cuff-inflation pressure for "priming" should be in the order of 40 to 50-mm Hg, to allow the patient's heart action to supply the uphill flow for plantar-vein priming purposes. For patient comfort, there is no need for rapid inflation of the cuff, and the reduced slope shown for all cuff inflations in Figs. 6B, 6C and 6D (compared to the steep slope of Fig. 6A for foot-pump inflation) is a schematic indication of this fact.

[0032] In general, it can be said that the peak of foot-pump pressure needed for the DVT treatment situation does not call for such elevated magnitudes as for a situation where DVT is not a problem. In other words, the DVT treatment wherein a thrombolizing agent is injected at the dorsum of the foot is relying upon the cuff to apply tourniquet action on the superficial veins so that deep veins can be more efficiently treated with the thrombolizing agent, in which case a cuff pressure in the order of 50-mm Hg and a peak foot-pump pressure in the range 100 to 200-mm Hg may be sufficient, and with a more gentle rising slope (e.g., to peak foot-pump pressure within 2 seconds or less). On the other hand, for an otherwise healthy leg that must remain elevated above the patient's body, the priming cuff pressure (except for timing) may be substantially the same as for DVT treatment, but with preferably a pressure peak of foot-pump inflation of at least 200-mm Hg.

Claims

1. Medical apparatus for therapeutically and /or prophylactically treating a blood-circulation abnormality in a patient's leg, comprising a single inflatable cuff (11) adapted for application to the calf of the leg, first means (21,26,28,32,40,121,126) for transiently inflating said cuff (11) to a first pressure level sufficient to induce local tourniquet-pressure action on the calf, and permitting deflation thereafter, an inflatable foot-pump (10,14,16,17,18 and 19) adapted for application of inflation pressure primarily at the plantar region between the ball and heel of the foot, second means (21,25,27,31,41,121,125) for transiently inflating said foot-pump to a peak pressure in excess of said first pressure level, and permitting deflation thereafter, and cyclically operable control means (30,130) for coordinated inflation / deflation cyclical operation of said first and second means, and including separate means of pressure-fluid supply only to said single inflatable cuff (11) and said inflatable foot-pump (10,14,16,17,18 and 19) and characterised in that said control means (30,130) is provided with a timing device, preset to determine the sequential operations of said cuff (11) and of said foot-pump (10,14,16,17,18 and 19), as well as

the periodic interval of recurrent cycling such that

(a) initially, via said first means (21,26,28,32,40,121,126), said cuff (11) is supplied with pressure fluid to transiently retain tourniquet-pressure action on the calf;
(b) via said second means (21,25,27,31,41,121,125), said foot-pump (10,14,16,17, 18 and 19), is transiently inflated to said peak pressure in the circumstances of said tourniquet-pressure action on the calf, and is relieved of inflation pressure after achievement of said peak pressure; and
(c) via said first means (21,25,27,31,41,121,125), cuff pressure is relieved from tourniquet action in selectively timed relation to inflation and at least commencement of relief of foot-pump pressure;
the timing device of said control means (30,130) providing a cycle-completing interval of time between said control operations via said first means (21,26,28,32,40,121,126), and said second means (21,25,27,31,41,121,125) prior to re-initiation of the next-succeeding cyclical operation, wherein successive cycles recur at a periodic interval which is in the range of 15 to 60 seconds.

2. Medical apparatus according to claim 1, in which said control means (30,130) includes selectively operable means (21,26,28,32,40,121,126) for relief of foot-pump pressure in the range of substantially zero to five seconds following achievement of said peak pressure.

3. Medical apparatus according to claim 1, in which said control means (30,130) includes selectively operable means (21,25,27,31,40,121,125) for inflating and holding the inflation of said cuff (11) over a period of time that exceeds the period of time of foot-pump inflation and relief from said peak pressure.

4. Medical apparatus according to claim 1, for treating a leg which is supported in a raised position above the level of bed support to the patient's body, said control means (30,130) including selectively operable means (21,25,27,31,40,121,125) for inflating and retaining tourniquet pressure on the calf for a period of time immediately prior to foot-pump inflation.

5. Medical apparatus according to claim 1, for treating a DVT condition in the leg at a location that is proximal with respect to cuff application to the calf, said control means (30,130) including selectively operable means (21,25,27,31,40,121,125) for retaining said cuff pressure substantially only during a period of also inflating said foot-pump peak pressure and substantially relieving said foot-pump from peak pressure.

6. Medical apparatus according to claim 1, in which said control means (30,130) includes selectively operable means (21,25,27,31,40,121,125) for retaining inflated-cuff pressure in at least some timed concurrence with inflation of said foot-pump to peak pressure and relief of said foot pump from peak pressure.

7. Medical apparatus according to claim 1, in which said control means (30,130) includes selectively operable means (21,25,27,31,41,121,125) for initiating the inflation of said cuff prior to initiating the inflation of said foot-pump and for initiating the relief of foot-pump pressure prior to initiating the relief of cuff-pressure.

8. Medical apparatus according to claim 2, in which said selectively operable means 21,26,28,32,40,121,126) includes means for selecting at least one selling from the group consisting of zero second, one second, two seconds, three seconds, four seconds, and five seconds.

9. Medical apparatus according to claim 2, in which the periodic interval of recurrent cycling is substantially 20 seconds.

10. Medical apparatus according to claim 1, in which the transient inflation of said cuff (11) is at a rate slower than the transient inflation of said foot-pump (10,14,16,17,18 and 19).

11. Medical apparatus according to claim 1, in which the transient inflation of said foot-pump (10,14,16,17,18 and 19) is effected within one second.

12. Medical apparatus according to claim 1, in which the transient inflation of said foot-pump (10,14,16,17,18 and 19) is effected within 0.5 second or less.

13. Medical apparatus according to claim 11, in which the transient inflation of said cuff (11) is effected within no less than one second.

14. Medical apparatus according to claim 1, in which the level of tourniquet-pressure action is in the range of 30 to 100mm Hg.

15. Medical apparatus according to claim 1, in which the level if tourniquet-pressure action is in the range of 40 to 60mm Hg.

16. Medical apparatus according to claim 1, in which the peak-pressure level of foot-pump inflation is in the range up to substantially 225mm Hg.

17. Medical apparatus according to claim 1, in which the peak-pressure level of foot-pump inflation is at least substantially 200mm Hg.

18. Medical apparatus according to claim 1, in which said control means (30,130) includes pressure-responsive means (10,42) connected for response to instantaneous cuff pressure for initiating inflation of said foot-pump (10,14,16,17,18,19) upon detected achievement of said first-pressure level of cuff inflation.

19. Medical apparatus according to claim 1, in which said control means (30,130) includes pressure-responsive means (10,42) connected for response to the difference between cuff pressure and instantaneous foot-pump pressure for initiating deflation of said cuff (11) upon detected reduction of instantaneous foot-pump pressure to the instantaneous level of cuff pressure.

Patentansprüche

1. Medizinische Vorrichtung für therapeutische und/oder prophylaktische Behandlung einer Blutzirkulation-Abnormalität in einem Bein eines Patienten, bestehend aus einer einzigen, aufblasbaren Manschette (11), die für eine Anwendung an der Wade des Beines angepaßt ist, aus ersten Mitteln (21, 26, 28, 32, 40, 121, 126) zum vorübergehenden Aufblasen der Manschette auf ein erstes Druckniveau, welches ausreicht, um auf die Wade eine lokale Staubandagen- oder Staubindenwirkung auszuüben, sowie zur Entlüftung der Manschette im Anschluß daran, aus einer aufblasbaren Fußpumpe (10, 14, 16, 17, 18 und 19) geeignet für die Anwendung eines Aufblasdrucks primär im Plantarbereich zwischen dem Ballen und der Ferse des Fußes, aus zweiten Mitteln (21, 25, 27, 31, 41, 121, 125) zum vorübergehenden Aufblasen der Fußpumpe auf eine Druckspitze oberhalb des ersten Druckniveaus und für eine anschließende Entlüftung, aus zyklisch betätigbaren Steuermitteln (30, 130) für einen koordinierten Aufblaus/Entlüftungszyklus der ersten und zweiten Mittel, sowie aus separaten Mittel für eine Druckfluidversorgung nur an die einzige aufblasbare Manschette (11) und an die aufblasbare Fußpumpe (10, 14, 16, 17, 18 und 19), **dadurch gekennzeichnet**, daß die Steuermittel (30, 130) mit einer Timereinrichtung versehen ist, die eingestellt ist, um die sequentielle Betätigung der erwähnten Manschette (11) und der erwähnten Fußpumpe (10, 14, 16, 17, 18 und 19) sowie auch das periodische Intervall des wiederkehrenden Zyklus zu bestimmen, und zwar in der Weise:

(a) daß zunächst über die ersten Mittel (21, 26, 28, 32, 40, 121, 126) die Manschette (11) mit dem Druckfluid versorgt ist, um an der Wade die Staubindendruckwirkung zu erreichen;
(b) daß über die erwähnten zweiten Mittel (21, 25, 27 31, 41, 121, 125) die Fußpumpe (10, 14, 16, 17, 18 und 19) vorübergehend auf den erwähnten Spitzendruck aufgeblasen wird, und zwar immer dann, wenn der erwähnte Staubindendruck an der Manschette anliegt, und nach Erreichen der Druckspitze von dem Aufblasdruck entlastet wird, und
(c) daß über die ersten Mittel (21, 25, 27, 31, 41, 121, 125) der Manschettendruck von der Staubandagen- oder Staubindenwirkung entlastet wird, und zwar in einer selektiv getimten Beziehung zum Aufblasen und wenigstens zum Anfang der Entlastung des Fußpumpendruckes;
wobei die Timereinrichtung der erwähnten Kontroll- oder Steuermittel (30, 130) ein den Zyklus vervollständigendes Zeitintervall zwischen den Steueroperationen über die ersten Mittel (21, 26, 28, 32, 40, 121, 126) und den erwähnten zweiten Mitteln (21, 25, 27, 31, 41, 121, 125) vorsehen, und zwar vor dem Wiederaufblasen der nächsten, nachfolgenden Zyklusoperation, wodurch aufeinanderfolgende Zyklen in einem periodischen Intervall in der Größenordnung von 15 - 60 Sekunden wiederkehren.

2. Medizinische Vorrichtung nach Anspruch 1, dadurch gekennzeichnet, daß die erwähnten Kontroll- oder Steuermittel (30, 130) selektiv betätigbare Mittel (21, 26, 28, 32, 40 121, 126) aufweisen, für das Entlasten des Fußpumpendruckes im Bereich von im wesentlichen 0 und 5 Sekunden, und zwar nach Erreichen des Spitzendruckes.

3. Medizinische Vorrichtung nach Anspruch 1, dadurch gekennzeichnet, daß die Steuermittel (30, 130) selektiv betätigbare Mittel (21, 25, 27, 31,40 121, 125) zum Aufblasen der Manschette (11) und Halten des aufgeblasenen Zustandes über eine Zeitperiode aufweisen, die die Zeitperiode des Aufblasens der Fußpumpe und des Entlastens von dem Spitzendruck übersteigt.

4. Medizinische Vorrichtung nach Anspruch 1, dadurch gekennzeichnet, daß für die Behandlung eines Beines, welches in einer angehobenen Position abgestützt ist, und zwar oberhalb des Niveaus der Bettlagerung des Patientenkörpers, die Steuermittel (30, 130) selektiv betätigbare Mittel (21, 25,

27, 31, 40, 121, 125) aufweisen, und zwar zum Aufblasen und zum Halten des Staubindendrucks an der Manschette über eine Zeitperiode unmittelbar vor dem Aufblasen der Fußpumpe.

5. Medizinische Vorrichtung nach Anspruch 1, dadurch gekennzeichnet, daß für die Behandlung eines DVT-Zustandes in einem Bein an einem in bezug auf die Manschettenanwendung an der Wade proximalen Bereich die Steuermittel (30, 130) selektiv betätigbare Mittel (21, 25, 27, 31, 40, 121, 125) zur Aufrechterhaltung des erwähnten Wadendruckes im wesentlichen nur während einer Periode des gleichzeitigen Aufblasens der Fußpumpendruckspitze und des Entlastens der Fußpumpendruckspitze aufweisen.

6. Medizinische Vorrichtung nach Anspruch 1, dadurch gekennzeichnet, daß die erwähnten Steuermittel (30, 130) selektiv betätigbare Mittel (21, 25, 27, 31, 40, 121, 125) zum Aufrechterhalten des aufgeblasenen Manschettendruckes in wenigstens einer teilweisen zeitlichen Übereinstimmung mit dem Aufblasen der erwähnten Fußpumpe auf den Spitzendruck und der Entlastung der erwähnten Fußpumpe von dem Spitzendruck aufweisen.

7. Medizinische Vorrichtung nach Anspruch 1, dadurch gekennzeichnet, daß die erwähnten Steuermittel (30, 130) selektiv betätigbare Mittel (21, 25, 27, 31, 41, 121, 125) für das Einleiten des Aufblasens der Manschette vor dem Einleiten des Aufblasens der erwähnten Fußpumpe sowie für das Einleiten der Entlastung des Fußpumpendruckes vor dem Einleiten der Entlastung des Manschettendruckes aufweisen.

8. Medizinische Vorrichtung nach Anspruch 2, dadurch gekennzeichnet, daß die selektiv betätigbaren Mittel (21, 26, 28, 32, 40, 121, 126) Mittel zur Auswahl wenigstens einer Einstellung aus der Gruppe bestehend aus null Sekunden, eine Sekunde, zwei Sekunden, drei Sekunden, vier Sekunden und fünf Sekunden aufweisen.

9. Medizinische Vorrichtung nach Anspruch 2, dadurch gekennzeichnet, daß das periodische Intervall des wiederkehrenden Zyklus im wesentlichen 20 Sekunden beträgt.

10. Medizinische Vorrichtung nach Anspruch 1, dadurch gekennzeichnet, daß das Aufblasen der erwähnten Manschette (11) mit einer Geschwindigkeit erfolgt, die kleiner ist als beim Aufblasen der Fußpumpe (10, 14, 16, 17, 18 und 19).

11. Medizinische Vorrichtung nach Anspruch 1, dadurch gekennzeichnet, daß das zunehmende Aufblasen der Fußpumpe (10 14, 16, 17, 18 und 19) innerhalb einer Sekunde erfolgt.

12. Medizinische Vorrichtung nach Anspruch 1, dadurch gekennzeichnet, daß das zunehmende Aufblasen der Fußpumpe (10, 14, 16, 17, 18 und 19) innerhalb von 0,5 Sekunden oder kürzer erfolgt.

13. Medizinische Vorrichtung nach Anspruch 11, dadurch gekennzeichnet, daß das zunehmende Aufblasen der Manschette (11) in nicht weniger als einer Sekunde erfolgt.

14. Medizinische Vorrichtung nach Anspruch 1, dadurch gekennzeichnet, daß der Pegel der zunehmende in dem Bereich von 30 - 100 mm Hg liegt.

15. Medizinische Vorrichtung nach Anspruch 1, dadurch gekennzeichnet, daß der Pegel der Staubindendruckanwendung in der Größenordnung von 40- 60 mm Hg liegt.

16. Medizinische Vorrichtung nach Anspruch 1, dadurch gekennzeichnet, daß der Pegel der Druckspitze des Aufblasens der Fußpumpe in einem Bereich bis etwa 225 mm Hg liegt.

17. Medizinische Vorrichtung nach Anspruch 1, dadurch gekennzeichnet, daß der Pegel der Druckspitze beim Aufblasen der Fußpumpe wenigstens etwa 200mm Hg beträgt.

18. Medizinische Vorrichtung nach Anspruch 1, dadurch gekennzeichnet, daß die Steuermittel (30, 130) auf Druck ansprechende Mittel (10, 42) aufweisen, die so vorgesehen sind, um auf den momentanen Bandagendruck anzusprechen, und zwar für das Einleiten des Aufblasens der Fußpumpe (10, 14, 16, 17, 18, 19) beim Detektieren des Erreichens des erwähnten ersten Druckpegels beim Aufblasen der Manschette.

19. Medizinische Vorrichtung nach Anspruch 1, dadurch gekennzeichnet, daß die erwähnten Steuermittel (30, 130) auf Druck ansprechende Mittel (10, 42) aufweisen, die für ein Ansprechen auf die Differenz zwischen dem Maschettendruck und dem momentanen Fußpumpendruck vorgesehen sind, um das Entlasten der Manschette (11) dann einzuleiten, wenn ein Abfalls des anstehenden Fußpumpendruckes auf den momentanen Pegel des Manscheuendruckes festgestellt wird.

Revendications

1. Appareil médical destiné à traiter de manière thérapeutique et/ou prophylactique une anomalie de la circulation sanguine dans une jambe d'un patient,

comprenant un manchon gonflable (11) unique destiné à être appliqué au mollet de la jambe, des premiers moyens (21, 26, 28, 32, 40, 121, 126) pour gonfler de manière transitoire ledit manchon (11) à un premier niveau de pression suffisant pour produire une action de pression de garrot locale sur le mollet, et pour permettre le dégonflage par la suite, une pompe à pied gonflable (10, 14, 16, 17, 18 et 19) destinée à appliquer une pression de gonflage principalement à la région plantaire entre la boule et le talon du pied, des seconds moyens (21, 25, 27, 31, 41, 121, 125) pour gonfler de manière transitoire ladite pompe à pied à une pression crête dépassant ledit premier niveau de pression, et pour permettre le dégonflage par la suite, et des moyens de commande actionnables de manière cyclique (30, 130) pour l'opération cyclique coordonnée de gonflage/dégonflage desdits premier et second moyens, et comprenant des moyens séparés d'alimentation en fluide sous pression uniquement dudit manchon gonflable (11) unique et de ladite pompe a pied gonflable (10, 14, 16, 17, 18 et 19) et caractérisé en ce que lesdits moyens de commande (30, 130) sont pourvus d'un dispositif de synchronisation préréglé pour déterminer les opérations séquentielles dudit manchon (11) et de ladite pompe à pied (10, 14, 16, 17, 18 et 19), ainsi que l'intervalle périodique du cycle récurrent, de sorte que :

(a) initialement, via lesdits premiers moyens (21, 26, 28, 32, 40, 121, 126), ledit manchon (11) est alimenté en fluide sous pression pour maintenir de manière transitoire l'action de pression de garrot sur le mollet ;
(b) via lesdits seconds moyens (21, 25, 27, 31, 41, 121, 125), ladite pompe à pied (10, 14, 16, 17, 18 et 19) est gonflée de manière transitoire à ladite pression crête dans la situation de ladite action de pression de garrot sur le mollet, et la pression de gonflage est relâchée une fois que ladite pression crête a été atteinte ; et
(c) via lesdits premiers moyens (21, 25, 27, 31, 41, 121, 125), la pression du manchon de l'action de garrot est relâchée dans une relation synchronisée de manière sélective avec le gonflage et au moins avec le commencement du relâchement de la pression de la pompe à pied ;
le dispositif de synchronisation desdits moyens de commande (30, 130) fournissant un intervalle de temps d'achèvement de cycle entre lesdites opérations de commande via lesdits premiers moyens (21, 26, 28, 32, 40, 121, 126), et lesdits seconds moyens (21, 25, 27, 31, 41, 121, 125) avant le nouveau lancement de l'opération cyclique immédiatement suivante, dans lequel les cycles successifs se reproduisent à un intervalle périodique qui se situe dans la plage de 15 à 60 secondes.

2. Appareil médical selon la revendication 1, dans lequel lesdits moyens de commande (30, 130) comprennent des moyens susceptibles d'être commandés de manière sélective (21, 26, 28, 32, 40, 121, 126) pour le relâchement de la pression de la pompe à pied dans la plage sensiblement de zéro à cinq secondes qui suit l'obtention de ladite pression crête.

3. Appareil médical selon la revendication 1, dans lequel lesdits moyens de commande (30, 130) comprennent des moyens susceptibles d'être commandés de manière sélective (21, 25, 27, 31, 40, 121, 125) pour gonfler et maintenir le gonflage dudit manchon (11) pendant un intervalle de temps qui dépasse l'intervalle de temps de gonflage de la pompe à pied et de relâchement de ladite pression crête.

4. Appareil médical selon la revendication 1, pour traiter une jambe qui est supportée dans une position surélevée au dessus du niveau du support de lit par rapport au corps du patient, lesdits moyens de commande (30, 130) comprenant des moyens susceptibles d'être commandés de manière sélective (21, 25, 27, 31, 40, 121, 125) pour le gonflage et le maintien de la pression de garrot sur le mollet pendant un intervalle de temps immédiatement avant le gonflage de la pompe à pied.

5. Appareil médical selon la revendication 1, pour traiter une condition de thrombose veineuse profonde dans la jambe à un emplacement qui est proximal par rapport à l'application du manchon au mollet, lesdits moyens de commande (30, 130) comprenant des moyens susceptibles d'être commandés de manière sélective (21, 25, 27, 31, 40, 121, 125) pour maintenir ladite pression de manchon sensiblement uniquement pendant une période de gonflage également de ladite pompe à pied à la pression crête et sensiblement de relâchement de la pression crête de ladite pompe à pied.

6. Appareil médical selon la revendication 1, dans lequel lesdits moyens de commande (30, 130) comprennent des moyens susceptibles d'être commandés de manière sélective (21, 25, 27, 31, 40, 121, 125) pour maintenir la pression du manchon gonflé au moins dans une certaine concurrence synchronisée avec le gonflage de ladite pompe à pied à la pression crête et le relâchement de la pression crête de ladite pompe à pied.

7. Appareil médical selon la revendication 1, dans lequel lesdits moyens de commande (30, 130) com-

prennent des moyens susceptibles d'être commandés de manière sélective (21, 25, 27, 31, 41, 121, 125) pour lancer le gonflage dudit manchon avant de lancer le gonflage de ladite pompe à pied et pour lancer le relâchement de la pression de la pompe à pied avant de lancer le relâchement de la pression du manchon.

8. Appareil médical selon la revendication 2, dans lequel lesdits moyens susceptibles d'être commandés de manière sélective (21, 26, 28, 32, 40, 121, 126) comprennent des moyens pour sélectionner au moins un réglage parmi le groupe consistant en zéro seconde, une seconde, deux secondes, trois secondes, quatre secondes, et cinq secondes.

9. Appareil médical selon la revendication 2, dans lequel l'intervalle périodique du cycle récurrent est sensiblement de 20 secondes.

10. Appareil médical selon la revendication 1, dans lequel le gonflage transitoire dudit manchon (11) se fait à une vitesse plus lente que le gonflage transitoire de ladite pompe à pied (10, 14, 16, 12, 18 et 19).

11. Appareil médical selon la revendication 1, dans lequel le gonflage transitoire de ladite pompe à pied (10, 14, 16, 17, 18 et 19) est effectué en moins d'une seconde.

12. Appareil médical selon la revendication 1, dans lequel le gonflage transitoire de ladite pompe à pied (10, 14, 16, 17, 18 et 19) est effectué en moins de 0,5 seconde.

13. Appareil médical selon la revendication 11, dans lequel le gonflage transitoire dudit manchon (11) n'est pas effectué en moins d'une seconde.

14. Appareil médical selon la revendication 1, dans lequel le niveau de l'action de pression de garrot se situe dans la plage de 30 à 100 mm de Hg.

15. Appareil médical selon la revendication 1, dans lequel le niveau de l'action de pression de garrot se situe dans la plage de 40 à 60 mm de Hg.

16. Appareil médical selon la revendication 1, dans lequel le niveau de pression crête du gonflage de la pompe à pied se situe dans la plage qui va jusqu'à sensiblement 225 mm de Hg.

17. Appareil médical selon la revendication 1, dans lequel le niveau de pression crête du gonflage de la pompe à pied est au moins sensiblement de 200 mm de Hg.

18. Appareil médical selon la revendication 1, dans lequel lesdits moyens de commande (30, 130) comprennent des moyens sensibles à la pression (10, 42) connectés pour répondre à la pression instantanée du manchon pour lancer le gonflage de ladite pompe à pied (10, 14, 16, 17, 18, 19) lors de l'obtention détectée dudit premier niveau de pression du gonflage du manchon.

19. Appareil médical selon la revendication 1, dans lequel lesdits moyens de commande (30, 130) comprennent des moyens sensibles à la pression (10, 42) connectés pour répondre à la différence entre la pression du manchon et la pression instantanée de la pompe à pied pour lancer le dégonflage dudit manchon (11) lors de la réduction détectée de la pression instantanée de la pompe à pied au niveau instantané de la pression du manchon.

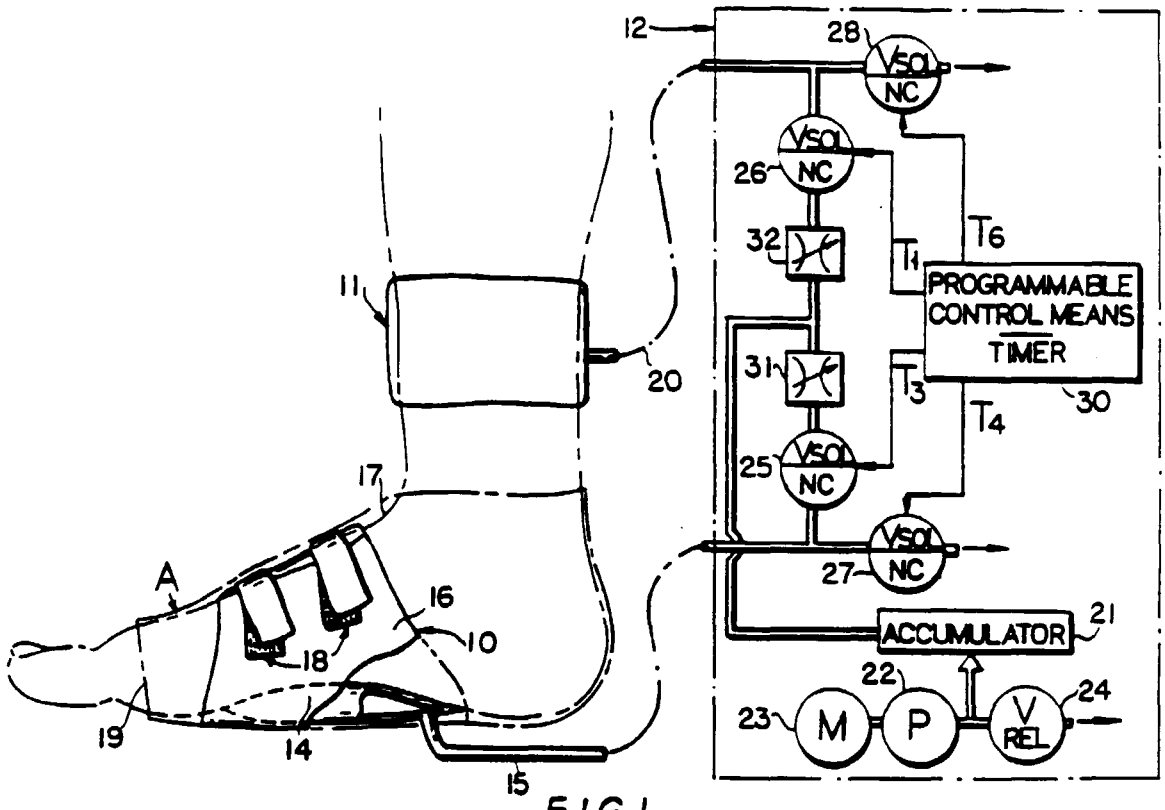

FIG. 1

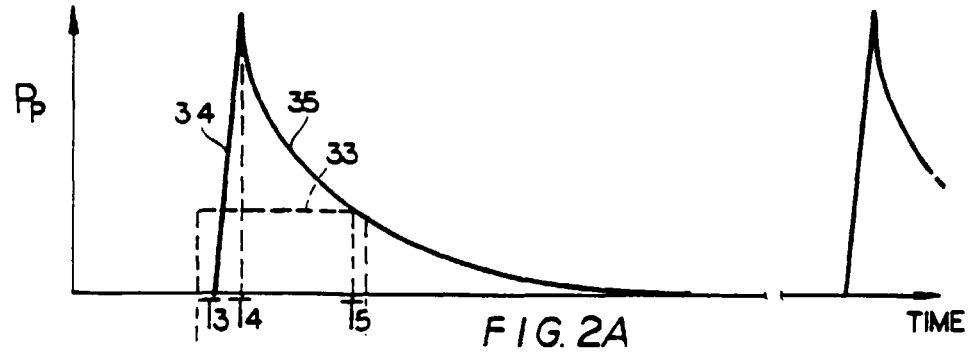

FIG. 2A

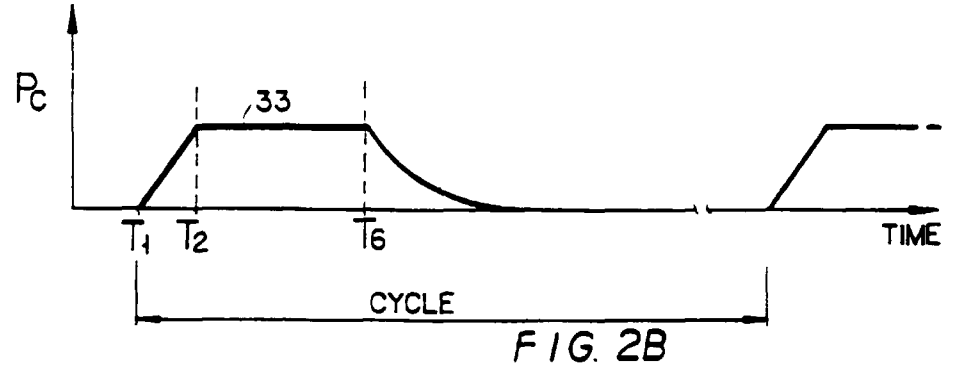

FIG. 2B

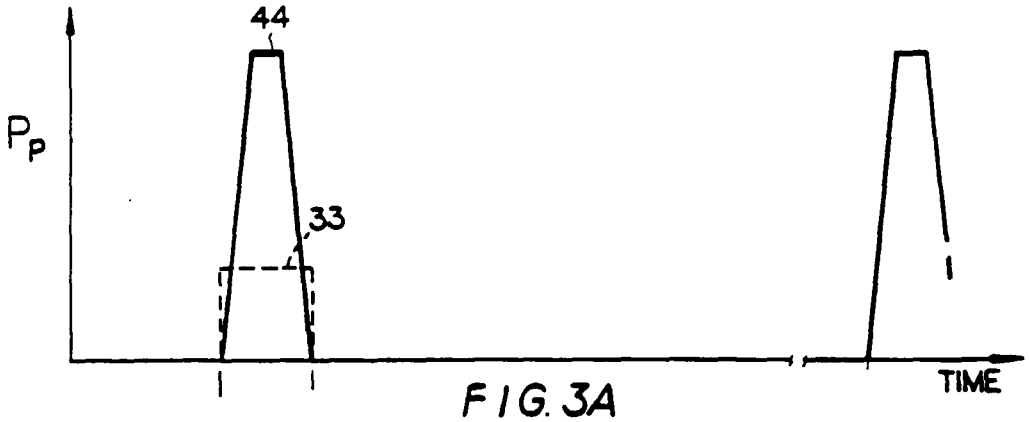

FIG. 3A

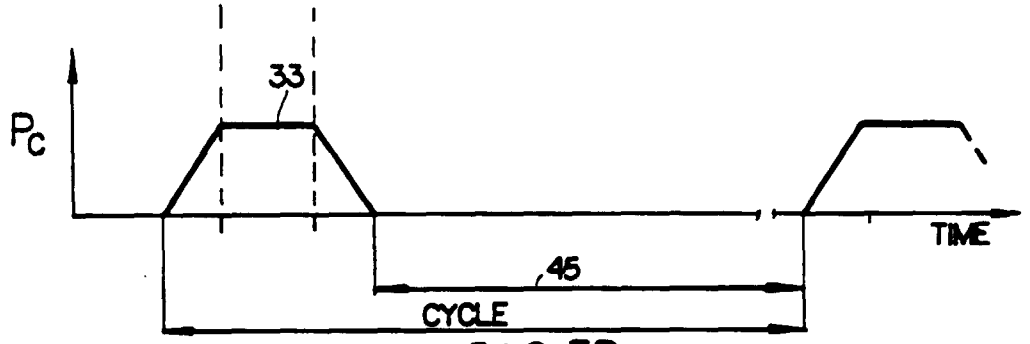

FIG. 3B

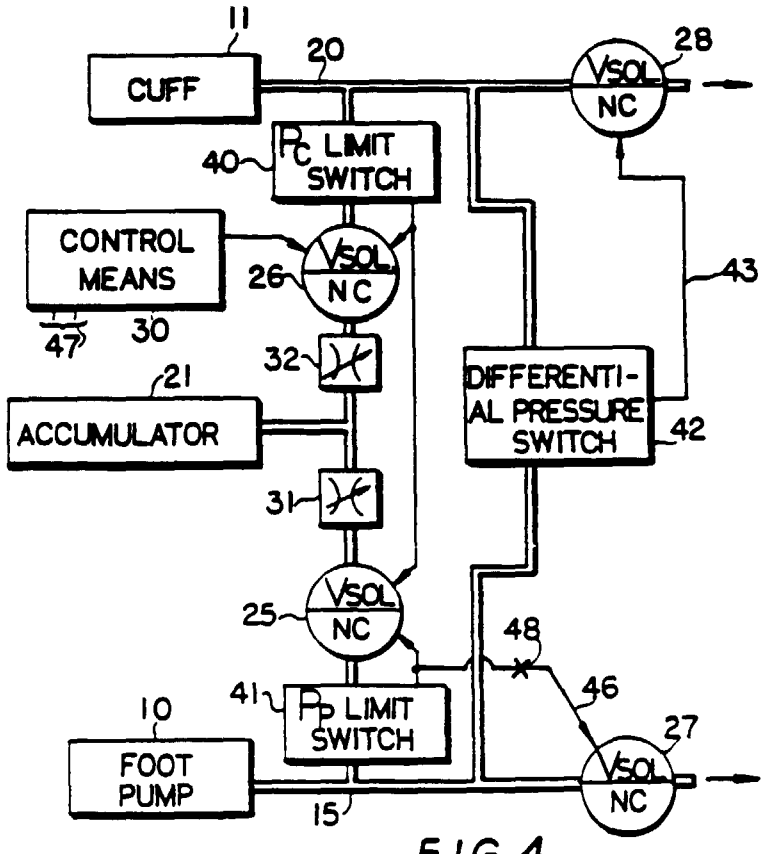

FIG. 4

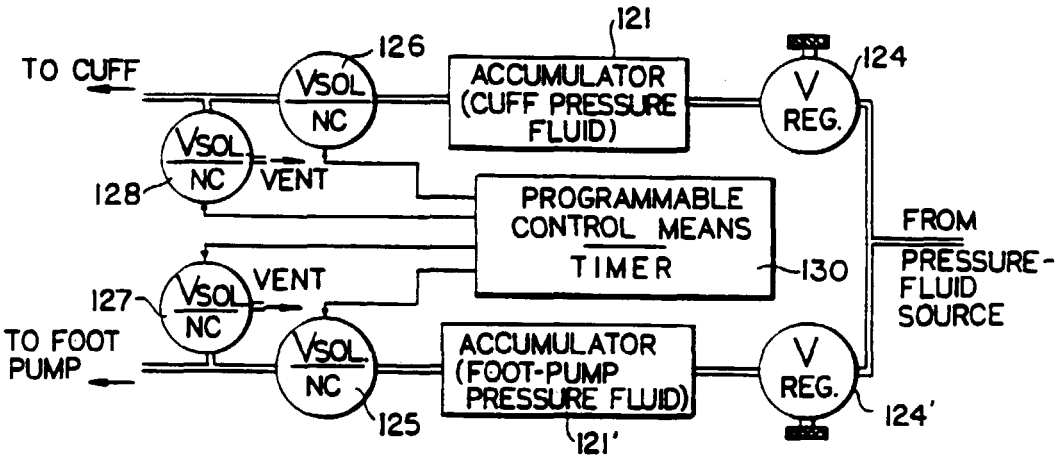

FIG. 5

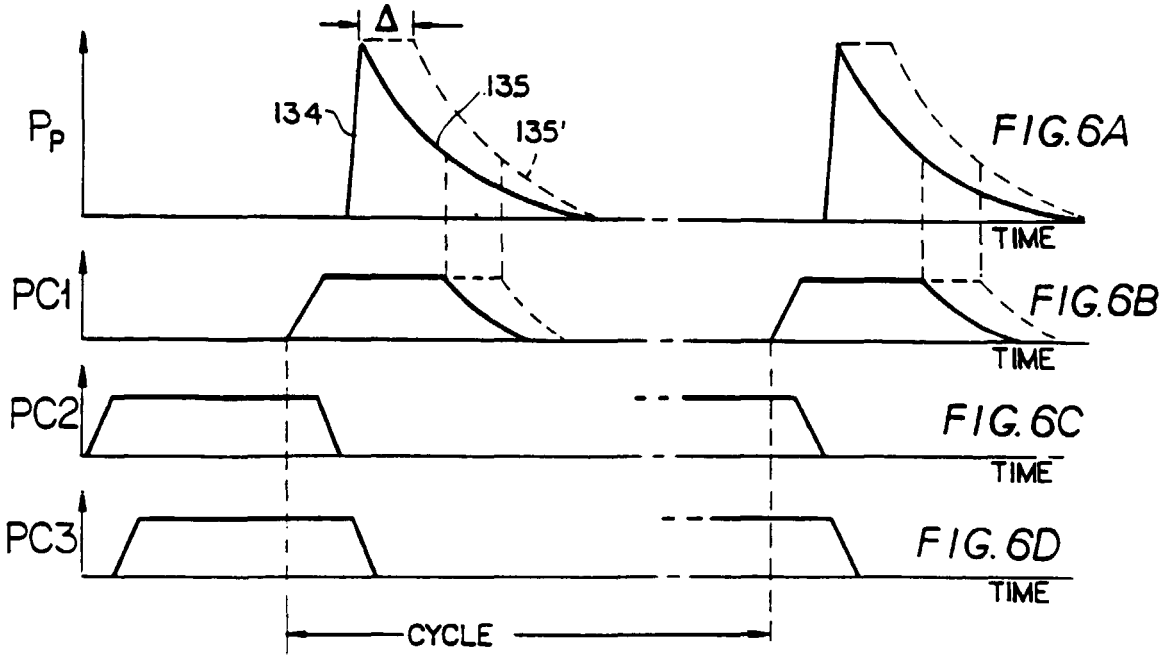

FIG. 6A

FIG. 6B

FIG. 6C

FIG. 6D