United States Patent

Birtwell

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[54] PROCESS AND APPARATUS FOR SYNCHRONOUS ASSISTING OF BLOOD CIRCULATION

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[21] Appl. No.: **92,606**

[52] **U.S. Cl.** **128/64**

[51] **Int. Cl.** **A61h 7/00**

[58] **Field of Search** ..... 128/24 R, 24.1, 40, 64, 30, 128/30.2

[56] **References Cited**

UNITED STATES PATENTS

3,303,841 2/1967 Dennis ..... 128/24 R

3,403,673 10/1968 MacLeod 128/40

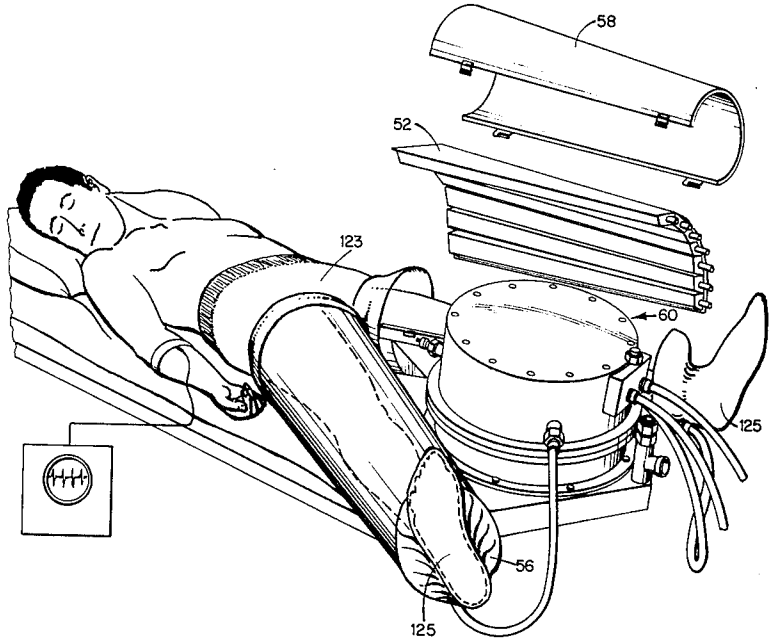
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[57] **ABSTRACT**

Apparatus useful in enhancing or assisting the circulation of blood, reducing the work of the heart and increasing the coronary blood flow, said apparatus comprising a rigid, incompressible system which provides an external pulsatile pressure environment on a portion of the body which is synchronous and phased with cardiac action. A rigid chamber or chambers with a liquid filled system of non-distensible, yet expandable, seals houses a portion of the body (e.g., the limbs) in such a way that the pressure exerted on the body can be varied above and below atmospheric pressure by adding or removing liquid from the system.

13 Claims, 7 Drawing Figures



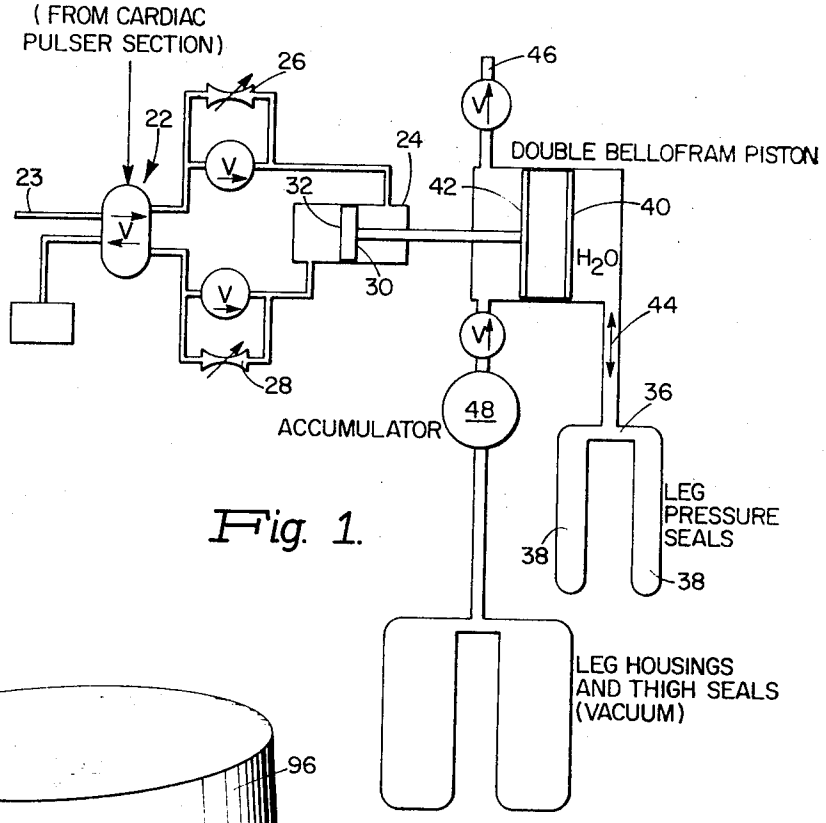


Fig. 1.

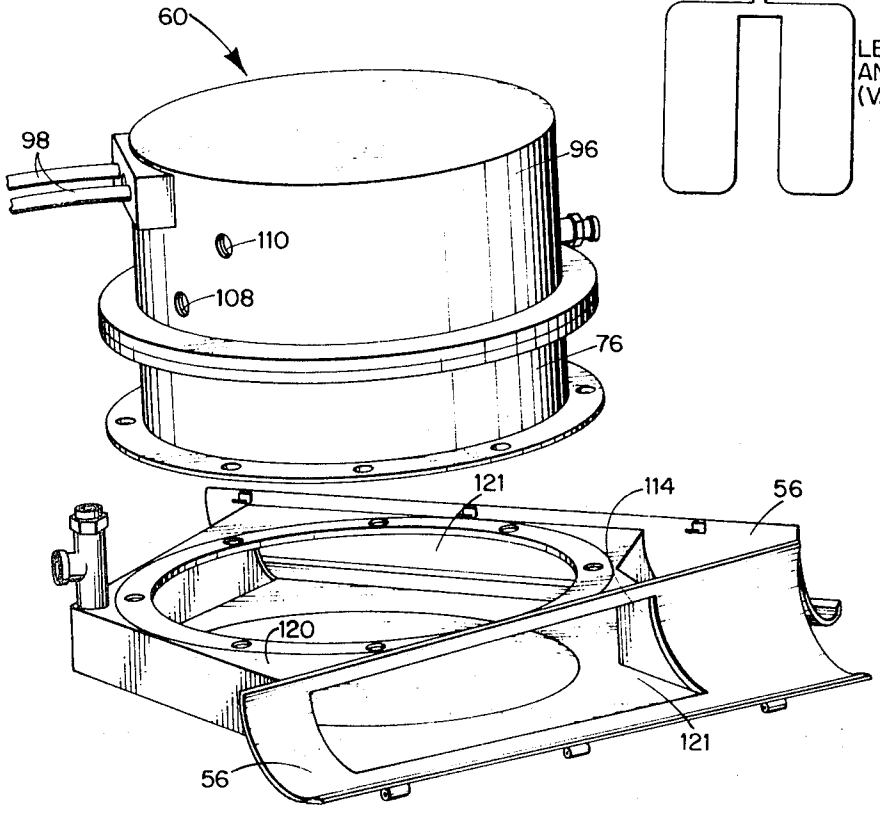


Fig. 7.

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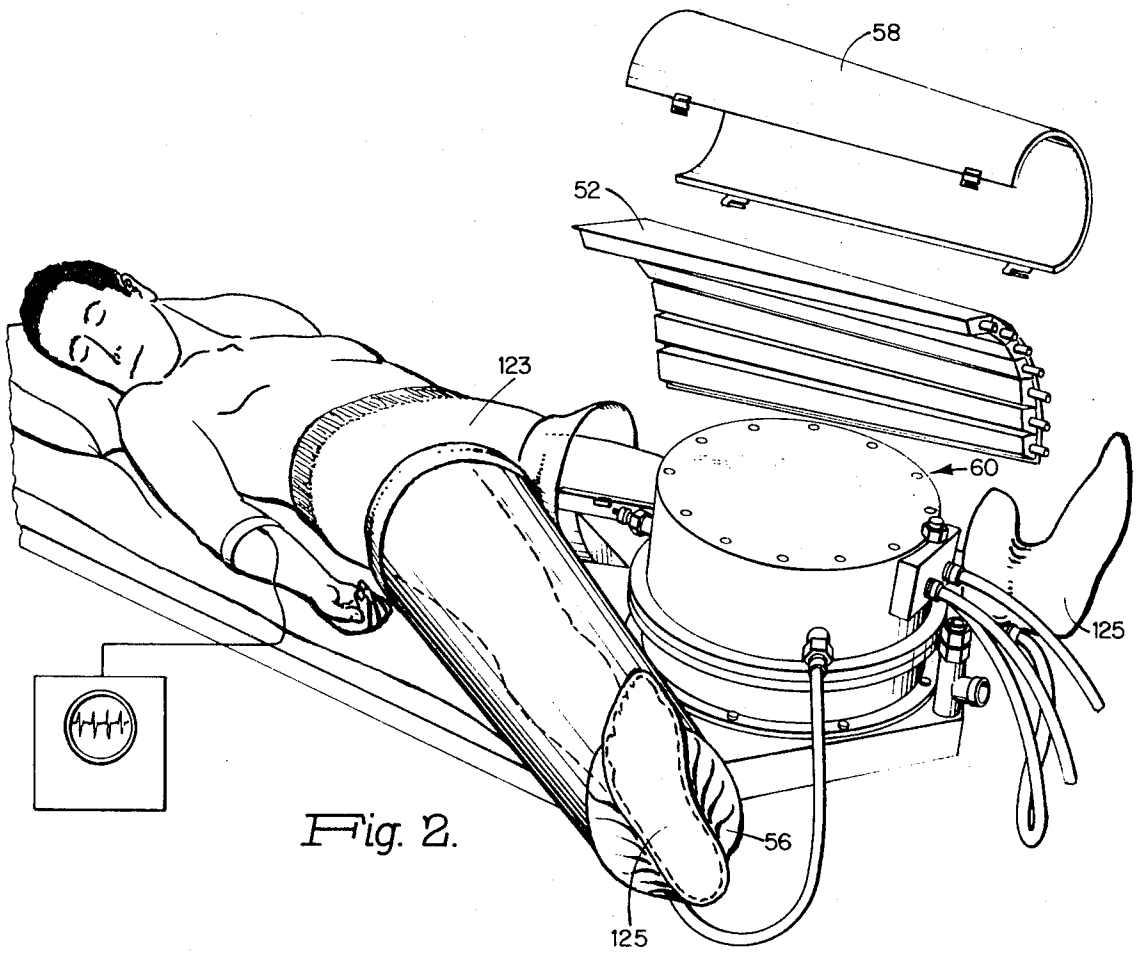


Fig. 2.

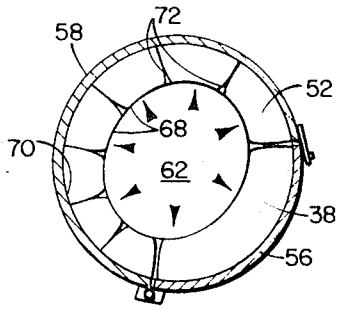


Fig. 3.

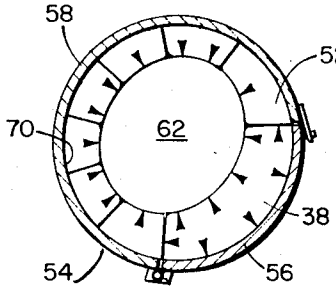


Fig. 4.

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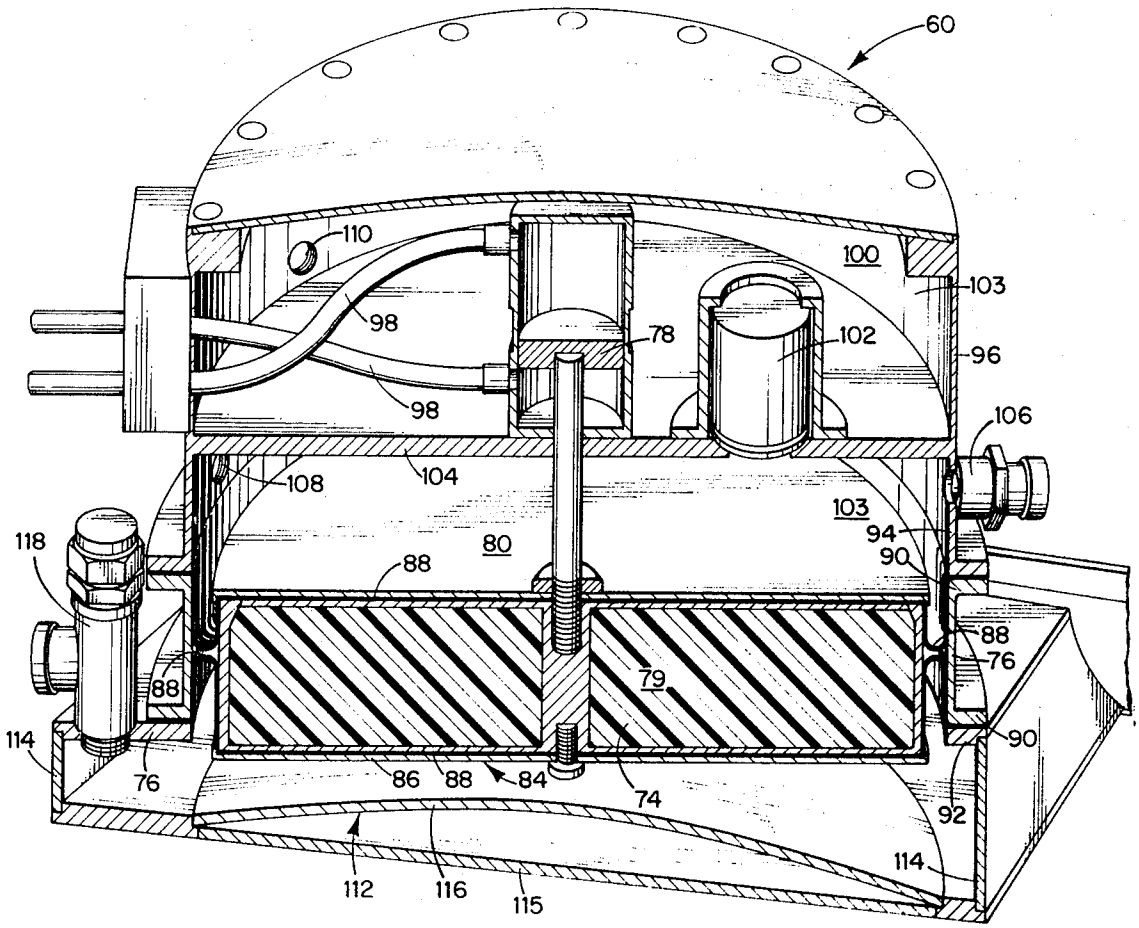


Fig. 6.

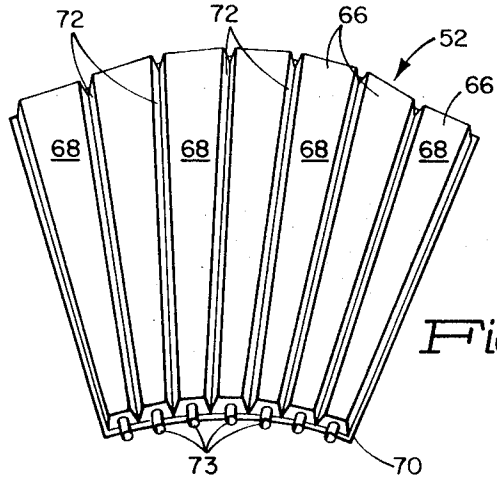


Fig. 5.

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PROCESS AND APPARATUS FOR SYNCHRONOUS ASSISTING OF BLOOD CIRCULATION

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates to a novel apparatus for assisting blood flow through the circulatory system by synchronizing the pulsing of an external assist means with the heartbeat. The invention also relates to a novel process achieved by use of the apparatus.

2. Background of the Invention

Methods for atraumatically assisting blood circulation of patients have been described in the art. In U.S. Pat. No. 3,303,841 to Dennis, a process is described whereby an external compressing of the lower part of the body expresses a volume of blood larger than the volume of blood pumped in a single stroke of the heart. The blood so expressed is forced back into the aorta and greater arterial vessels and thereby allows a reduction in ventricular workload while maintaining a satisfactory perfusion of blood during ventricular diastole. This general type of process has been elaborated upon in an article entitled "Synchronous Assisted Circulation" by Birtwell et al. appearing in the *The Canadian Medical Association Journal* (Vol. 95, pages 652–664) on Sept. 24, 1966. In general, synchronous external pressure assist processes are distinguishable and advantageous over pre-existing counterpulsation processes because the latter kind of procedure involves the cannulation of a major artery, use of an extra-corporeal blood handling device, the use of stringently sterile techniques and the necessity of administering anti-coagulants to the patient. Moreover, the blood trauma or hemolysis produced by extracorporeal pumping devices limits permissible duration of the assist procedure and compromises the condition of the patient. These procedures are not only time-consuming but can present a real hazard to many patients and increase the risk factor in treating all patients.

Specific apparatus usable in a synchronous assist process is disclosed in U.S. Pat. No. 3,403,673 to MacLeod. In general, the apparatus consists of a leg-encasing arrangement with means for cycling the pressure on the legs within the casing. The invention described in U.S. Pat. No. 3,403,673 has a number of problems associated with its use. For example, the constrictive type seals thereof are believed to interfere with optimum blood circulation. Moreover, the inertia of the pressurizing system which includes elastic type expansible linings is believed to interfere with obtaining an optimum pressure-time profile on the legs.

The apparatus suggested in the prior art has a number of drawbacks in that it is cumbersome to use, i.e., the patient is inserted into and removed from the device with excessive effort; and it is excessively difficult to achieve the proper pressure-pulsation profile and impossible to achieve what the inventors believe is the more advantageous mode of operation, i.e. at an ambient pressure at or below atmospheric pressure.

It is important that such problems be solved economically but without using means which expose the patient to undue physical strain.

SUMMARY OF THE INVENTION

Therefore, it is an object of the invention to provide a novel process for synchronously assisting blood circulation by external pressure variation on the limbs of a patient.

It is a further object of the invention to provide an improved apparatus useful in synchronously assisting blood circulation.

Another object of the invention is to provide improved apparatus capable of being controlled to maintain a lower mean or reference pressure than has heretofore been obtainable on that part of a patient's body being subjected to external pressure variation.

Another object of the invention is to provide apparatus capable of maintaining a pulsed pressure at more nearly the pressure profile desired for a particular patient.

Still another object of the invention is to provide an apparatus into which the patient can be placed or from which the patient can be removed with relative ease and comfort.

A further object of the invention is to provide an apparatus which does not allow the external pressure variation to impart an undesirable movement to the patient being treated therewith.

Another object of the invention is to increase the output of the coronary vasculature.

Another object of the invention is to achieve the foregoing objects with a relatively compact apparatus.

Other objects of the invention will be obvious to those skilled in the art on reading this application.

The present invention is partly based on the discovery that the coronary vasculature can be made to produce a higher volume of blood flow when the pressure of blood flowing thereto is artifically modified. Ordinarily during the heartbeat, there is a "muscular squeeze" on the vasculature during cardiac systole which reduces its output somewhat. By use of the apparatus of the invention, it has been found that the capacity of a portion of the arterial system can be increased during systole and the vascular resistance and pressure exerted by the left ventricle can be lowered. During cardiac diastole, the capacity of the aforesaid portion of arterial system can be decreased, thus returning blood to the aorta and thereby increasing diastolic pressure and perfusion flow.

It is also believed that the "collateral circulation" system (i.e. "spare vessels" which normally do not provide very significant blood flow but which ordinarily come into important operation when a damaged vascular system is attempting to repair itself) is caused to function during the diastole phase of the external pressure assist process of the invention.

The above objects have been substantially achieved by the construction of apparatus for assisting circulation by synchronous pulsation which apparatus is constructed of a receiving compartment for a portion of a patient's body which compartment comprises therein active inflatable seal bags and passive seal bags through which pressure can be exerted, e.g. most conveniently on the patient's limbs. The active seal bags contain a non-compressible liquid such as water and are in direct hydraulic communication with a piston means for increasing the water content and consequently the volume of the expansible bags. The liquid in the passive seal bags, which are pressurized by the pressure exerted by the expansion of the active bags, is fully enclosed. Means are provided for keeping air out of the limb-receiving compartment during operation of the device. In operation, negative pressure may be achieved immediately adjacent the limbs and then be overridden during that part of an operating cycle when expansion of the active seal bags causes them to bear against the passive seal bags and thereby transmit pressure completely around the legs.

As used above, "inflatable" is meant to define seal bags as being expandable when fluid is injected thereinto. It is not meant to suggest that the bags are constructed of elastic, i.e. rubber-like material. In fact, such distendable materials are not preferred because their distension would add to the inertia of the system and reduce the capability of the system to conform to desired cycle patterns.

It has been discovered that the ability to achieve a low-pressure condition in the limb-receiving compartment contributes to improved pressure cycle control and also to an improved mode of operation whereby the mean pressure on the leg may be maintained at a low level, preferably at or below atmospheric pressure. This mode of operation is highly desirable because it reduces the undesirable restriction of blood flow which can be experienced at the higher operating pressures required when previously known synchronous assist devices are utilized.

A particular advantage of the apparatus of the invention is the construction whereby leg-holding compartments are formed into a stationary compartment formed of a smaller casing segment and a larger casing segment. The smaller cas-

ing segment, advantageously not more than about 150 angular degrees and preferably not more than 120 angular degrees, carries the active inflatable hydraulic seal bags; the larger passive seal bags are attached to the larger casing segments which are pivotally mounted for quick and convenient enclosing of a patient's legs once they have been rested on the expansible seal bags.

Another particularly advantageous feature of the invention is the fact that the continuous availability of vacuum to the system allows excellent control of the pressure cycle on the leg of the patient. The inertial problems with use of apparatus comprising a single pneumatic or hydraulic pressure control system are largely avoided.

It has been discovered that, to avoid excessive movement of the patient by the pressure-pulsing operation, the passive seal bags should have the opposing internal sides thereof tethered together. Such tethering substantially alleviates the tendency of the apparatus to propel the patient out of the device with each pressure pulse.

ILLUSTRATIVE EMBODIMENT OF THE INVENTION

In this application and accompanying drawings, there is shown and described a preferred embodiment of the invention and there are suggested various alternatives and modifications thereof, but it is to be understood that these are not intended to be exhaustive and that other changes and modifications can be made within the scope of the invention. These suggestions herein are selected and included for purposes of illustration in order that others skilled in the art will more fully understand the invention and the principles thereof and will be able to modify it and embody it in a variety of forms, each as may be best suited in the condition of a particular case.

In the drawings

FIG. **1** is a schematic diagram explanatory of the operation of the apparatus of the invention.

FIG. **2** is a view showing the placement of a patient in relationship to the apparatus of the invention.

FIG. **3** is a section of the liquid-containing seal bags and rigid enclosure therefor, the bags being in non-expanded position.

FIG. **4** is a view similar to that shown in FIG. **3** with the bags being in expanded position.

FIG. **5** is a perspective view of the passive seal bags used in the invention.

FIG. **6** is a section, in perspective, of the pressure-pulsing system of the apparatus of the invention.

FIG. **7** is a partly exploded view showing how the device of the invention fits onto and hydraulically communicates with the leg encasing members of the apparatus.

Referring to FIG. **1**, it is seen that a pulsed signal input is received along conduit **18** from a cardiac pulser section **20**. This pulser section forms means to receive, screen and transmit signals from an electrocardiogram apparatus so that the apparatus of the invention will be properly synchronized with the heartbeat of a patient being treated.

The signal input is received by a solenoid valve control system **22** which controls the flow of hydraulic fluid through conduit **23** to either side of master control piston **24** through hydraulic sub-circuits **26** and **28** each of which comprises control valves **29** to adjust the rate at which fluid is applied to piston **24**.

Hydraulic fluid flowing through sub-circuit **26** is applied to face **30** of piston **24** causing the piston to move to the left. Conversely, hydraulic fluid flowing through sub-circuit **26** is applied to face **32** of piston **24** causing the piston to move to the right. A rightward movement of the piston causes a double bellofram-type piston **34** to move rightward also. This movement of piston **34** causes liquid contained in liquid seal system **36** to be driven into the active, i.e. expandable, seal bags **38** by face **40** of piston **34**. At the same time, the other face **42** of piston **34** moves to the right and tends to increase the availability of vacuum to the rigid legs housings which hold the seal bags **58**.

When hydraulic fluid is applied to face **30** of piston **24** causing the piston **24** to move to the left, the liquid pressure in liquid seal bags **38** is quickly reduced and, simultaneously, the movement of face **42** of the piston **34** to the left tends to expel some air in vacuum system **44**. A vacuum accumulator **48** maintained at sub-atmospheric pressure is used to dampen out fluctuations in vacuum magnitude. The reduction in liquid pressure in seal bags **38** results in a sub-atmospheric pressure being exerted on the leg, assuming, of course, that the vacuum system does not permit any substantial quantity of gas to be present therein.

In practice, it will be understood, the immediate environment of the leg will be at a sub-atmospheric pressure only until the repressurization of the legs is caused by the movement of piston face **40** to the right, the resultant movement of fluid into active leg seal bags **38** and the consequent expansion of these bags.

FIGS. **2**,**3**,**4** and **5** are illustrative of the arrangement whereby a pressure-expansible, i.e. active, seal bag **38** is held, together with a passive seal bag **52**, within a rigid casing **54** consisting of a fixed smaller casing segment **56** and a pivotally mounted larger casing segment **58**. As shown in FIGS. **2** and **7**, smaller casing segments **56** are integrally mounted with the pressure control module **60**.

Referring to FIG. **3**, it is seen that active seal bags **38** are attached on smaller casing segments **56**. After the leg **62** to be treated is rested on seal bag **38**, the passive seal bag **52** is placed over the leg **62**, larger casing segment **58** is pivoted inwardly to close over passive seal bag **52** and complete formation of the rigid casing **54**.

At this point, as best seen in FIG. **3**, there is no compression of the leg; indeed, the leg ordinarily expands somewhat.

In FIG. **4**, it is seen that, when the pressure is increased by the injection of liquid into inflatable active seal bag **38**, there is a sufficient distension of the inflatable bag to transmit hydraulic pressure through passive seal bag **62**, and thereby effectively apply compression to substantially all surfaces of leg **62**. When the liquid is withdrawn from seal bag **38**, the environmental pressure of the leg again tends to drop below the ambient pressure.

Illustrated in FIG. **5** is a passive seal bag **52** filled with a non-compressible liquid. The bag is formed of a plurality of elongated channels **66** adapted to run roughly parallel with one another and the leg of the patient being treated. Each channel **66** has a small conduit **73** therein for use in filling the channel with a fluid, for example, water. The walls **68** and **70** of the channels **66** are tapered outwardly from the "ankle end" to the "thigh end" thereof in order to accomodate the normally larger diameter of the upper leg.

It has been found that, although the face seal bags **52** are fastened to larger casing segments **58**, there is still an excessive force exerted on the legs of the patient tending to force him towards the head of the bed or table on which he is positioned. This force is a consequence of the generally wedge-shaped configuration of legs from ankle to thigh and the resultant force vector bearing upwardly against the legs. In FIG. **5** is illustrated a seal bag comprising a plurality of longitudinal liquid-containing compartments **66**.

Thus the walls **68** of sealing bags **58**, which walls bear against the leg, tend to be restrained from movement relative to walls **70** which are attached to casing **54**. This restraint is achieved by the tethering effect of sidewalls **72** between walls **68** and walls **70**. The tethering action markedly reduces the pushing effect on the legs of the patient being treated.

Each compartment **66** has an independent liquid fill port **74** which is clamped off after the compartment is filled.

FIGS. **6** and **7** illustrate a compact control module **60** which is normally mounted integrally with the above-described leg-enclosing members. In FIG. **6** it is seen that pressure control module **60** comprises a piston **74** which is analogous to the piston indicated at **34** in FIG. **1**. Piston **74** is contained in a piston housing **76** and is operated by means of a hydraulically activated piston **78**. Piston **78** is analogous to piston **24** of FIG. **1**.

Piston 74 is formed of a plastic foam core 79 which is protected on the vacuum system side 80 with a face plate 82 and protected on the pressure system side 84 with a face plate 86. Between each of face plates 82 and 86 and the foam core is an elastomeric seal member 88. These seal members 88 are generally circular in shape and extend between and are sealed by flanges 90 formed by piston housing member 76 and lower chassis member 92 (for the lower of the two seals) and formed by piston housing member 76 and the lower extension 94 of accumulator housing 96 (for the upper of the two seals).

Hydraulically activated piston 28 is supplied by drive fluid to each face thereof through hoses 98. Piston 28 is mounted within a vacuum accumulator tank 100 that is analogous to the accumulator 48 of FIG. 1. A check valve 102 is fastened in plate 104 which plate forms the bottom of tank 100 and also forms the top boundary of the cylinder 103 in which piston 74 reciprocates.

Check valve 102 provides means to avoid a backflow of gas into the accumulator tank 100 during the upward stroke of piston 74. A relief valve 106 is mounted in extension 94 of housing 96 to avoid an excessive vacuum build-up in accumulator tank 100.

Moreover, an exhaust port 108 is provided in this housing extension and provided with an exhaust valve, which valve is not shown in the drawings but is analogous to valve 46 of FIG. 1. The vacuum line to the leg seals is attached at port 110 in accumulator housing 96.

The pressure side 84 of piston 74 is bounded by face plate 86 and bottom plate assembly 112. Bottom plate assembly 112 consists of a bottom plate 115 and a dish-shaped plate 116 which effectively avoids flexing of assembly 112 during the reciprocating action of piston 74. A bleed valve 118 is provided for facilitating the removal of air from the liquid in the compression zone bounded by face plate 86 and bottom plate assembly 112.

In a particularly advantageous mode of the invention, low housing member 114 of bottom plate assembly 112 comprises an enclosed extension 120 which (as illustrated in FIG. 7 forms non-restricting conduit means 121 connecting active seal bags 38 to the pressure side 84 of piston 74. This arrangement provides excellent mechanical bracing of the various members of the apparatus and also minimizes any friction loss effects which would be caused by piping the pressurizing liquid through conventional conduits.

As is best seen in FIG. 2, the compact pressure control module 60 is advantageously placed in the V-section formed by the patient's legs. The resultant unit is compact and easily handled by hospital personnel. Also seen in FIG. 2 are waist seal belt 123 and foot-covering seal members 125. Belt 123 and members 125 form means to seal the extremities of the leg casings but do so without constricting the portion of the body at which the seal is effected. The sealing pressure is not achieved by a tight or snug mechanical fit but is achieved by use of the above-described vacuum system and therefore is readily adaptable to fit most patients while limiting the sealing pressure to less than atmospheric pressure.

It is also to be understood that the following claims are intended to cover all of the generic and specific features of the invention herein described and all statements of the scope of the invention which might be said to fall therebetween.

What is claimed is:

1. Apparatus for use in external synchronous assisting of the circulation of blood in a patient, said apparatus comprising

A. a rigid housing forming means to house a portion of a patient's body;

B. hydraulic compression and decompression means to cycle the pressure on said portion of a patient's body;

C. suction-producing means to provide a substantially gas-free environment for said compression and decompression means and

D. means to synchronize the overriding of said sub-atmospheric pressure with the patient's heartbeat.

2. Apparatus as defined in claim 1 wherein the hydraulic compression means comprises (A) expansible seal bags containing a volume of substantially non-compressible fluid which is in hydraulic communication with hydraulic means for increasing and decreasing the volume thereof and thereby expanding and contracting said expansible seal bags and (B) passive seal bags also containing a substantially non-compressible liquid and wherein the expansible seal bags are so arranged with respect to the passive seal bags that expansion of the former results in hydraulic pressure being exerted on the latter; said seal bags being enclosed in said rigid housing.

3. Apparatus as defined in claim 2 wherein the rigid housing is shaped for receiving a patient's limb and is divided into a larger circumferential segment, the expansible seal bags being supported on the smaller segment and the passive seal bags being affixed to the larger segment.

4. Apparatus as defined in claim 3 wherein said smaller circumferential segments of said leg housings are integrally attached to a suction-producing and hydraulic compression means mounted in a V-section formed by said leg housings.

5. Apparatus as defined in claim 2 wherein said housing is shaped for receiving a patient's limb and said passive seal bag comprises a plurality of tethering means running longitudinally therealong and connecting the walls of said passive seal which is affixed to said larger circumferential segments of said rigid casing.

6. Apparatus as defined in claim 3 wherein said smaller circumferential casing segments form an arc of up to about 120° and said larger circumferential casing segments form an arc of more than about 240° and wherein the larger segments are pivotally mounted on said smaller segments.

7. Apparatus useful in providing a continuous suction and a fluctuating hydraulic pressure to a treating zone, said apparatus characterized by its compactness and freedom from excess mechanical action and comprising, in integral relation with one another

A. a reciprocating piston mounted for movement in a housing between a suction zone and a hydraulic zone, said piston bearing seal means to maintain separation of one said zone from the other;

B. a vacuum accumulator chamber mounted adjacent to said housing and separated therefrom by a plate;

C. a check valve mounted in said plate for diminishing leakage of air from said suction zone to said accumulator chamber;

D. means for actuating said piston mounted in said vacuum accumulator chamber and

E. said hydraulic zone being bounded by said piston on one side thereof and by a bottom plate assembly comprising a convex plate facing said hydraulic zone and a flat plate proximate the circumference thereof.

8. Apparatus as defined in claim 1 wherein said means for providing gas-free environment comprises a non-constrictive suction-activated seal means.

9. Apparatus as defined in claim 1 wherein said expansible seal bags are constructed of substantially inelastic material.

10. Apparatus as defined in claim 2 wherein said means for providing a gas-free environment comprise a non-constrictive, suction-activated seal means and wherein said expansible seal bags are constituted of a substantially inelastic material.

11. In a process for externally assisting the circulation of blood by a synchronously actuated assist to the pumping action of the heart, by application of pulsatile pressure to a portion of a patient's body, the improvement consisting of applying said pulsatile pressure through a non-compressible liquid pre-positioned in inflatible but substantially non-elastic containers, while said containers envelope substantially all said patient's legs, and continuously applying a vacuum to remove any compressible gases from the environment of said body portion and thereby providing that the internal pressure of the patient's body and said pulsatile pressure are the only forces substantially effecting the blood circulation in said portion of said body.

12. A process as defined in claim **11** wherein said mean pressure on said legs is maintained at or below atmospheric pressure.

13. A process as defined in claim **11** wherein said compressive forces are transmitted through a compressing liquid medium and wherein a major portion of said compressing liquid is pre-positioned in passive sealing bags mounted proximate said legs and a minor portion of said compressing liquid is in direct hydraulic contact with a piston means, thereby minimizing the quantity of liquid which must be moved by the piston means.

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