

[54] **EXTERNAL CARDIAC ASSIST APPARATUS**

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

[58] Field of Search..... **128/24 R, 64, 297, 299, 128/DIG. 20**

[56] **References Cited**

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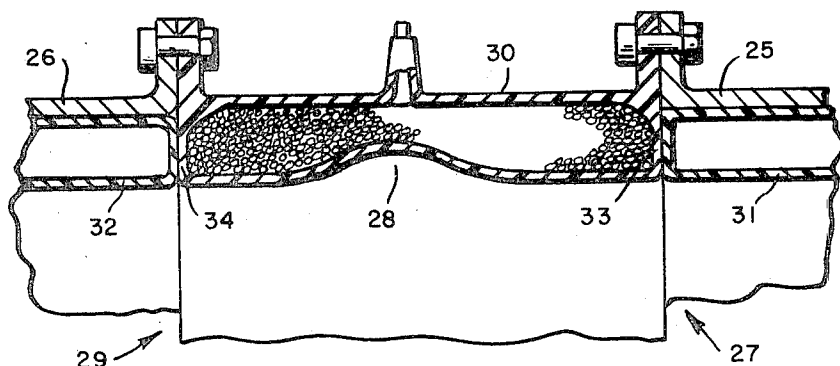
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Primary Examiner—Lawrence W. Trapp
Attorney, Agent, or Firm—Dike, Bronstein, Roberts, Cushman & Pfund

[57] **ABSTRACT**

An apparatus for providing external assistance for the circulation of blood in a patient in which a pressure medium forming one or more active regions is enclosed in at least a portion of a housing which in turn encloses a part of the patient's body, such as the legs and/or other parts thereof generally below the waist. At least a portion of the housing is in the form of a rigidizable means, such means being in a non-rigid state when it is applied to or placed on the patient's body and being capable of assuming a rigid state when the apparatus is in operation. A pressure actuation system cyclically applies pressure to the active regions of the patient's body via the pressure medium in synchronism and in correct phase with the patient's heart-beat.

29 Claims, 7 Drawing Figures



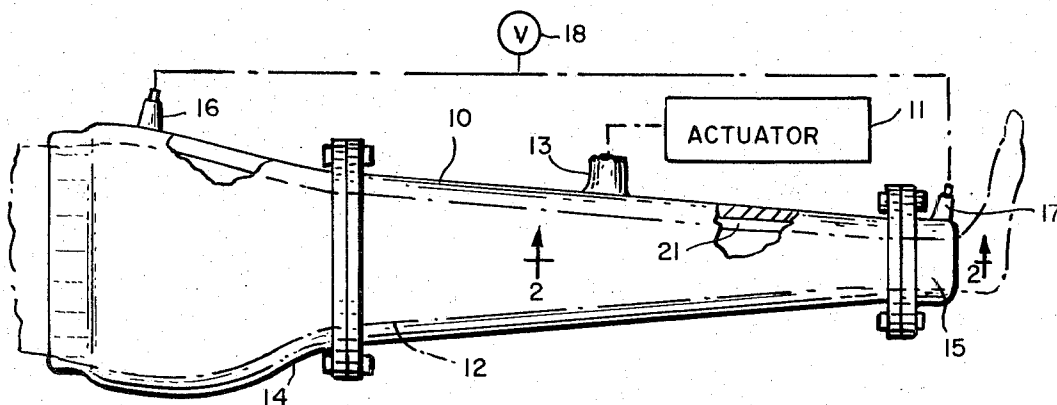


FIG. 1

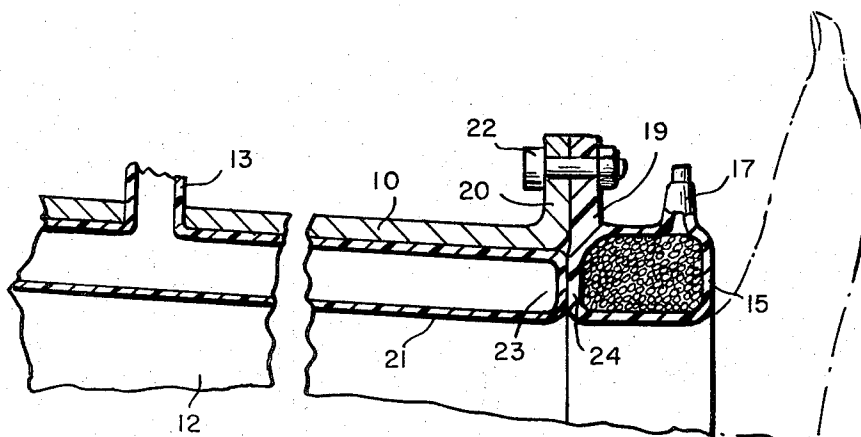


FIG. 2

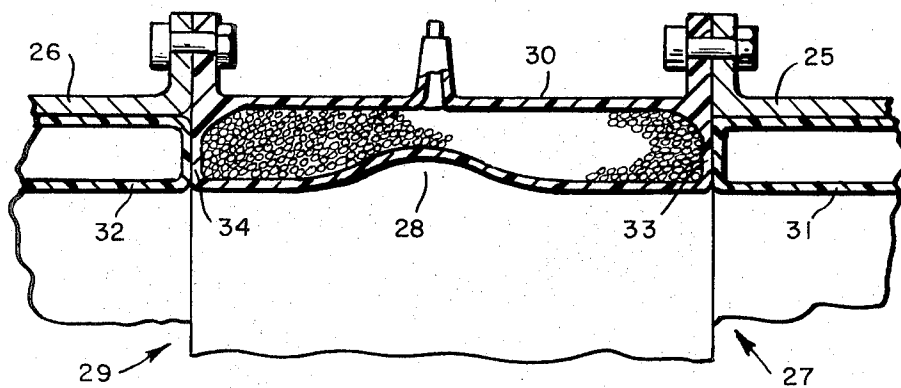


FIG. 3

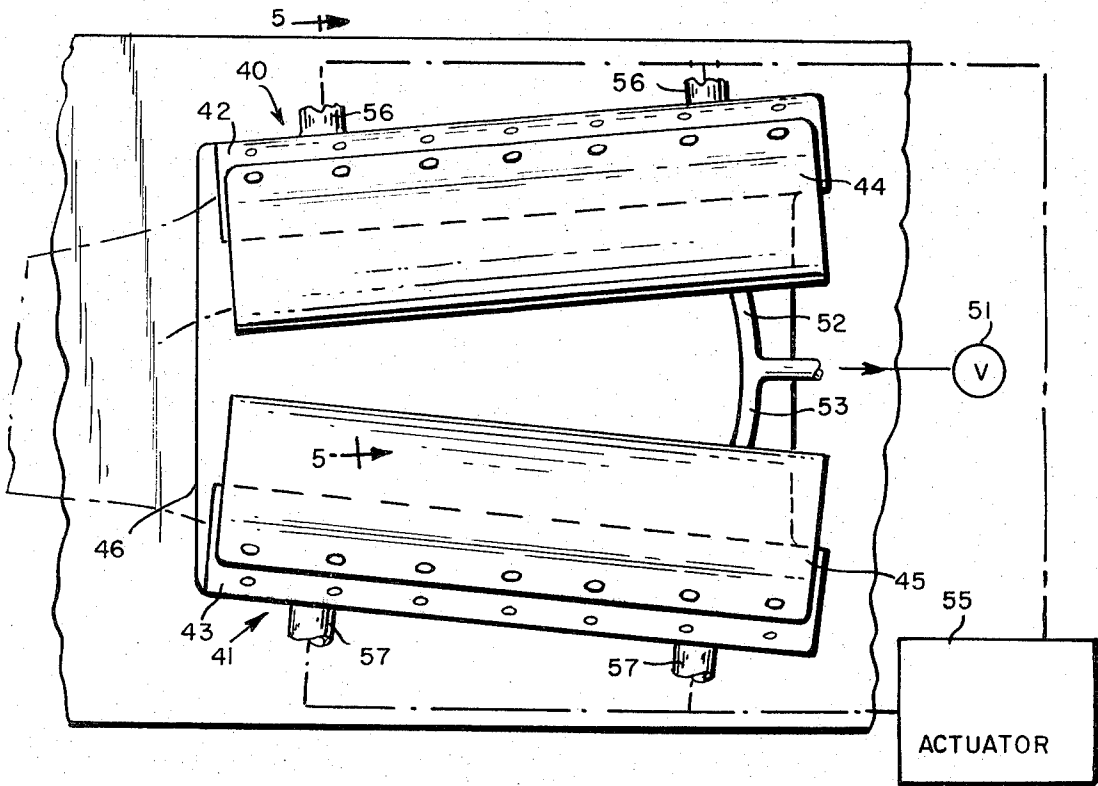


FIG. 4

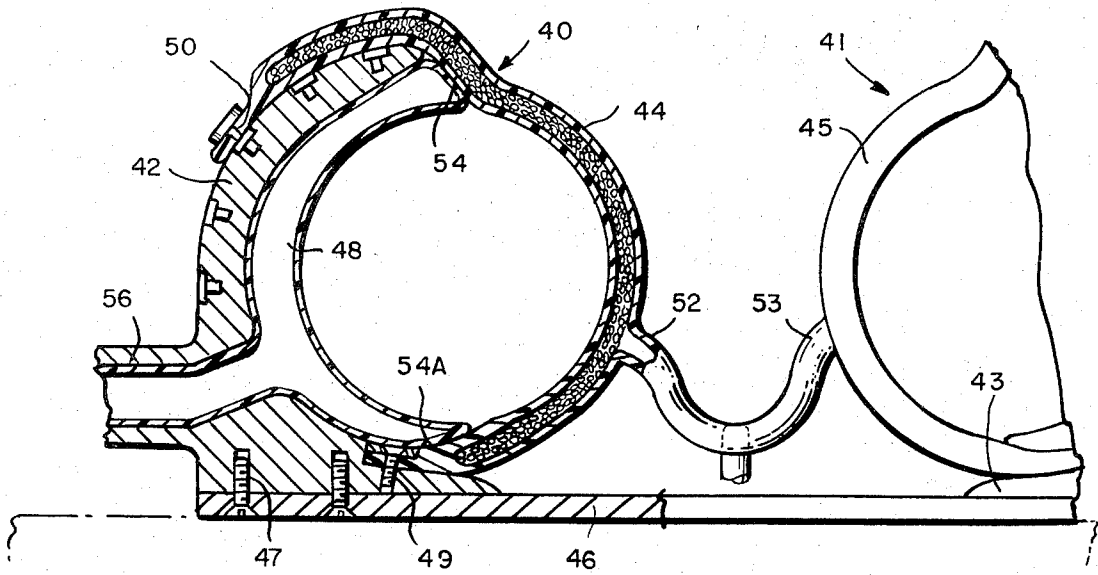


FIG. 5

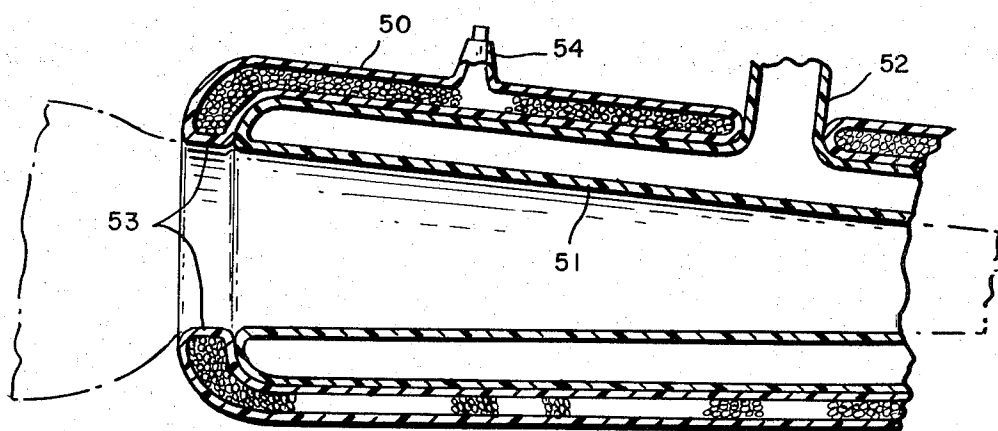


FIG. 6

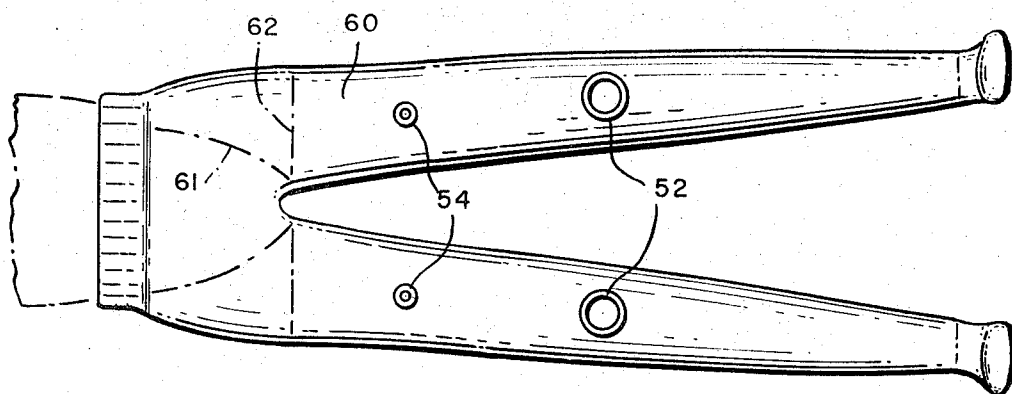


FIG. 7

EXTERNAL CARDIAC ASSIST APPARATUS

INTRODUCTION

This invention relates generally to apparatus for assisting the circulation of blood in a human being and more particularly to an apparatus for doing so externally by the utilization of counter-pulsation techniques.

BACKGROUND OF THE INVENTION

Apparatus for providing external assistance in the circulation of blood in patients has been described in previously issued articles and patents, particularly U.S. Pat. No. 3,654,919 issued to W. C. Birtwell, wherein a rigid housing encloses a portion of the patient's body, such as the legs, and a non-compressible hydraulic fluid is present within such housing. A suitable hydraulically actuated compression and decompression means is then utilized to cycle the pressure on said body portions via the non-compressible hydraulic fluid. Means are provided therein specifically to assure that the environment within the rigid housing is gas free so that no effective dead space is present and the efficiency of the compression and decompression energy transfer is maximized. Further, in the decompression portion of the cycle, a negative pressure is achieved immediately adjacent the body portion and means are provided for synchronously overriding the subatmospheric pressure which is so obtained, such overriding being in appropriate synchronism with the patient's heartbeat.

A number of problems arise in the use of the device described in the above Birtwell patent. First of all, it is a relatively cumbersome structure to handle, the use of a non-compressible hydraulic fluid, such as water, making the overall apparatus quite heavy. Moreover, the hydraulic actuation equipment which is required to cause the compression and decompression flow of fluid within the housing must be placed relatively near the patient so as to avoid excessive hydraulic pressure drops along the fluid lines thereof, usually such actuator being placed on the table on which the patient himself lies, often substantially centrally located between the patient's legs, as shown in the patent.

Not only is such apparatus therein difficult to use because of the large size and weight of the rigid housing and the hydraulic fluid, together with the hydraulic actuation equipment therefor, but the presence of such elaborate equipment in the direct view of the patient may tend to produce an adverse psychological reaction on the part of the patient when the apparatus is being applied to the patient's limbs.

Moreover, the use of such rigid, fixed volume housing requires that they be made sufficiently large to fit the limbs of the largest patient to which the apparatus is expected to be applied. Thus, for patients with relatively small limbs, substantially more hydraulic liquid is required to fill the enclosure, a factor which only adds to the weight of the overall device and its difficulty in use.

Alternative structures for providing effective external assistance for the circulation of blood have been devised as shown in our copending U.S. patent application Ser. No. 332,629, filed on Feb. 15, 1973, by the same inventors of the invention described herein, the design thereof providing for a reduction in the disadvantages of the device in the abovementioned Birtwell patent while still maintaining an effective energy transfer.

In accordance therewith, the copending application discloses apparatus which utilizes a compressible fluid, such as air, either alone or in combination with a non-compressible fluid, such as water, for energy transfer at the body interface. The structure shown therein has the advantage of being lighter in weight and less cumbersome to use than the previous Birtwell apparatus, and further, can be designed to reduce considerably the possibility of producing a traumatic experience for the patient. The effect of increased interface damping which may result from the use of at least a partially compressible fluid medium therein is taken into account by utilizing a more efficient actuation system designed as a "closed" system wherein energy expended in transfer to the patient's body is effectively stored and returned to the system for reuse with a minimization of overall energy loss during operation. Further, the effects of such increased damping can be overcome in other embodiments of the structure shown in our copending application by utilizing housing units having adjustable volumes, the adjustment thereof being arranged to reduce the volume and, hence, the dead space which may give rise to damping at the interface of the medium with the patient's body.

While the proposed alternatives in our copending application offset much of the disadvantages of the previously patented Birtwell apparatus, such alternatives do not fully provide for improvements which can be made by reducing the many damping effects which arise in various ways when the apparatus is in use. As discussed therein, such damping effects can be broadly identified as arising from two major sources. A first source is herein referred to as "system" damping and lies in the apparatus itself which comprises the system for producing the cyclic compression and decompression energy transfer to the patient's body. Thus, system damping can arise because of the distensibility of the housing which is used as well as the distensibility of the unsupported areas of the sealed portion of the system which contains the actuating fluid at the interface between the system and the portion of the patient's body to which the pulsating pressure is applied. Further, the instability of the shape of such sealed portion (i.e., the fact that such sealed portion does not retain its shape during the pulsating cycle) also contributes to the overall system damping. The compressibility of the actuating medium which gives rise to the presence of dead space within the housing also contributes to the system damping. Finally, both the presence of trapped air at various points within the system as well as the failure to provide an adequate contact between the sealed interface portion of the system and the patient's body can introduce additional damping into the system.

A second source of damping is herein referred to as "physiologic" damping and relates to the physical nature of the patient's body itself. Such damping arises, for example, from the overall motion of the patient's body which can occur during the application of the pressure actuation system thereto. Additional factors which contribute to such physiologic damping include the displacement of body tissue, both in the areas to which the pressure is directly applied and in the areas adjacent thereto, and the compressibility of the body in those areas thereof which can contain gas, such as the abdomen and/or the thoracic cavity.

A primary consideration in the design of the embodiments of our copending application is the desire to re-

duce the weight and awkwardness of the apparatus which hampers the handling thereof in use as well as to lessen the traumatic effect of the appearance of the apparatus to the patient. The use of a compressible gas permitted such advantages to be obtained at the expense of increasing to some extent the damping due to such gas compressibility, thereby requiring increased energy capacity of the energy source. Such increased damping was compensated for by the use of a "closed" energy actuation system, as described therein, and by the use of variable volume housings which could be adjusted to reduce the dead space which arises because of the use of a wholly or partially compressible gas as the energy coupling interface medium.

Despite the advantages which accrue as a result of the apparatus design disclosed in our prior copending application, it has been found that further improvements in the structure and efficiency of operation of an overall system of this type can be achieved if other damping factors, present therein, can be reduced or effectively eliminated.

SUMMARY OF THE INVENTION

This invention provides for a more effective transfer of actuation energy via the coupling medium from the actuation source to the body portion through the reduction in damping effects both from a system and from a physiologic viewpoint. The invention makes use of flexible closed members having a plurality of particles, such as plastic beads, such members being capable in their flexible state of conforming to a surface external thereto with which they are in contact. Further, the air within such members can be evacuated so that the members are changed from a flexible state to a rigid state upon such evacuation. Such rigidizable members can be utilized in the invention in a variety of ways either as "active" housing elements or as "passive" housing elements, as discussed in more detail below, in order to improve the efficiency of energy transfer from the actuator through the coupling medium to the patient's body.

The use of such rigidizable members permits a reduction in both system damping and in physiologic damping so as to improve the overall efficiency of operation thereof. Moreover, the flexible nature of such members prior to evacuation permits them to be applied more easily to the patient's body with a minimum of effort and a lessening of any traumatic experience to the patient due to their use. Further, the patient's comfort is improved immeasurably by their use and the portability and general handling of the overall system becomes greatly improved.

The use of such rigidizable members, either alone or in conjunction with rigid housing elements of the type discussed in our previous application, permits a reduction in system damping which arises because of the distensibility of the housing itself as well as because of the distensibility of the unsupported areas of the sealed portions of the system which contain the actuating interface fluid medium, as explained in detail below. The fact that such rigidizable members can be made to better conform to the configuration of the patient's body permits an even greater reduction in the dead space which may be present in the sealed portions of the system containing the active fluid medium than is possible with the use of the variable volume rigid housings of our copending application, so that the use of a fully or

partially gaseous, or compressible, medium will not adversely affect the overall efficiency of energy coupling. Further, such conformability reduces the possibility of the presence of trapped air and permits a better contact between the sealed interface portion of the system and the patient's body.

Further, the placement of the rigidizable members can be such as to reduce the overall motion of the patient's body during the application of the pressure actuation system thereto. Longitudinal tissue displacement can be minimized both in the areas to which the pressure is directly applied and in the areas adjacent thereto so that not only is the damping reduction due to such factors reduced sufficiently to create improvements in the energy transfer efficiency but also undesirable motion of the patient during the application of the apparatus and consequent discomfort of the patient is greatly lessened. Further, the rigidizable elements permit the apparatus to be more easily adjusted to patients of different sizes during use, particularly in emergency or semi-emergency situations.

Particular embodiments of the invention are discussed in more detail below with the help of the accompanying drawings wherein

FIG. 1 shows a side elevation view of a portion of one embodiment of the apparatus of the invention;

FIG. 2 shows an enlarged view in cross-section of a portion of the embodiment shown in FIG. 1;

FIG. 3 shows a view in cross-section of a portion of another embodiment of the invention;

FIG. 4 shows a plan view of a portion of another embodiment of the apparatus of the invention;

FIG. 5 shows a view in cross-section of a portion of the embodiment shown in FIG. 4;

FIG. 6 shows a view in cross-section of still another embodiment of the apparatus of the invention; and

FIG. 7 shows a plan view of still another embodiment of the apparatus of the invention.

FIG. 1 shows a portion of one embodiment of the invention in which a pair of rigid housing units encloses the legs of a patient from approximately a point above the ankles thereof to a point near the top of the thighs thereof. For convenience only one of such housing units is illustrated in the figure and a similar unit is utilized on the other leg of the patient. Each such rigid housing unit can be substantially of the form shown and discussed with reference to FIG. 1 of our above-referred to copending application and may be made of suitable rigid material, such as plastic or aluminum. As can be seen in FIG. 1 of this application, a rigid housing member 10 encloses a sealed flexible member 21 which contains a pressurizable fluid medium for coupling energy from an energy actuation system, or actuator, 11 to the patient's leg 12. The rigid housing means 10 extends from a region near the upper portion of the patient's thigh to the ankle region. Although not necessarily limited thereto, the sealed flexible member within the housing can be formed separately from the rigid housing member itself and, as discussed and shown with reference to FIG. 3 of our copending application, can be in the shape of a tubular sealed container made of suitable flexible material, such as a nylon-neoprene cloth, for example. As described in our copending application, the container has an appropriate integrally formed fitting 13 which is inserted through a suitable opening in the rigid housing and which is adapted to be connected to the pressure actuation source 11. The

major portion of the patient's leg is encased in the sealed flexible member within housing 10 so that pressure applied to the pressurizable medium therein via fitting 13 is then coupled to the patient's leg so as to produce a compression/decompression cycle in a manner in appropriate synchronism and in correct phase with the patient's heartbeat, as described in our previous application and in the references to the literature cited therein.

The coupling medium therein can be, for example, a compressible gas or a combination of a compressible gas with a non-compressible liquid and appropriate manifold means may be used within the interior of the flexible container to prevent collapse of the outer surface thereof against the inner surface adjacent the wall of the housing, as discussed in our previous application. At the region above that end of the housing 10 which encloses the patient's thighs, a rigidizable member 14 is placed so as to encircle such region and so as to have one end thereof suitably buttressed against the upper end of rigid housing 10, as discussed in more detail below. A similar rigidizable member 15 is placed around the ankle region of the patient's leg just below and in an abutting relationship to the lower end of the rigid housing 10 which encloses the patient's calf region.

The rigidizable members 14 and 15 are effectively formed as tubular members, ankle member 15 being shown in more detail in FIG. 2 as enclosing primarily the ankle region. Waist member 14 is of substantially the same configuration and is made large enough to enclose the region of the patient's body from the thigh to the waist. Ankle member 15, alternatively, may be formed so as to completely enclose the entire foot and ankle in the form of a "boot-like" structure, if desired.

Both rigidizable members 14 and 15 are appropriately connected through fittings 16 and 17, respectively, to a vacuum pump 18 which is used to evacuate the air within the rigidizable members during use. Both rigidizable members contain a large number of plastic beads and their structure is a modification of a structure for similar members used for a different purpose and sold under the trademark "VAC-PAC," for example, as made and sold by Olympic Surgical Company, Seattle, Wash. As seen in FIG. 2 the members are modified so as to form a rigid flange 19 which can be suitably connected to a flange 20 on rigid housing member 10 by means of one or more bolt elements 22 as shown.

Members 14 and 15 are normally in a flexible state and can be manipulated manually to cause them to conform generally to the shape of the body region over which they are placed. When the apparatus is put into operation, the interior of the flexible members 14 and 15 are evacuated by vacuum pump 18 via a one-way valve in each of fittings 16 and 17 and, when evacuated, the members then assume an extremely rigid shape so that the interior surface thereof conforms to the body portions which they enclose.

When the pressure actuation cycle for causing compression and decompression of the sealed member within the rigid housing 10 is actuated, the then rigidized members 14 and 15 serve at least two important functions in the operation of the overall apparatus. First of all, the ends of the sealed member 21 abut the inner ends of the rigidized members 14 and 15. Thus, as shown in FIG. 2, end 23 of sealed member 21 abuts inner end 24 of rigidized member 15. A similar abut-

ment occurs at the opposite end of sealed member 21 and the inner end of rigidized member 14. Accordingly, the rigidized members act as barriers to the longitudinal movement of the sealed member so as to prevent the latter from moving outwardly from the rigid housing 10 due to its longitudinal distensibility. Thus, the coupling fluid medium within sealed member 21 is better confined to the region of the leg to which pressure must be applied and the transfer of energy through the coupling medium to the body becomes more efficient than if the thigh and ankle rigid members 14 and 15 were absent.

Another advantageous effect of utilizing such rigidized ankle and thigh members is that by preventing longitudinal movement of the sealed member 21 containing the coupling fluid medium, the overall motion of the patient's body is effectively minimized and the discomfort and potential fear engendered in the patient by such undesirable movement is greatly lessened.

In discussing the arrangement shown in FIGS. 1 and 2 it is convenient to refer to the rigid housing member 10 within which the coupling medium is contained in sealed member 21 of the apparatus as an "active" member and, further, to refer to the rigidizable ankle and thigh members which do not enclose the coupling medium as "passive" members. In such discussions the term "active" member shall mean a member in which working or coupling fluid is displaced by the actuation system in a compression/decompression cycle so as to provide the appropriate change in pressure at the body member as required. The term "passive" member will mean a member which does not contain coupling fluid so that changes in pressure occur therein not because of the displacement of working or coupling fluid, per se, but because of the displacement of tissue in the patient's body.

In connection with the apparatus of FIGS. 1 and 2, therefore, one can see that the rigid housing enclosing the sealed member which contains coupling fluid represents the "active" element present in the "active" region from the patient's ankles to the upper portion of the patient's thighs. Further, the rigidizable members at either ends thereof represent the "passive" elements in the "passive" regions which are enclosed thereby. Thus, while a change in pressure occurs in the active region because of the direct displacement of coupling fluid by the actuator, additional changes in pressure also occur in the passive regions to further assist the required pressure changes within the bloodstream because of the presence of the rigidizable members.

Accordingly, the overall efficiency of the system is further increased over that available with previously known apparatus of this general type and physiologic damping which is due to displacement of body tissue is reduced since such displacement, particularly in the active region, is confined solely to that region and the active tissue is not displaced longitudinally outward therefrom to so great an extent as in prior devices.

FIG. 3 shows a modification of the structure shown in FIGS. 1 and 2 wherein the rigid housing 10 of FIG. 1 is now formed as two separate rigid housing members, each partially shown as members 25 and 26, the former extending from a region 27 just below the patient's knee 28 to the ankle region (not shown in FIG. 3) and the latter extending from a region 29 just above the knee to the upper region of the thigh (not shown in FIG. 3). In accordance with such structure the active

pressure changes required are more effectively confined to those regions of the leg where the majority of the fat and muscle tissues are present and little or no active pressure changes are provided in those regions where primarily bony structure exists. Accordingly, in the embodiment of FIG. 3, the rigid housing being formed as two separate housings encloses the calf and thigh regions where the primary movable fat and muscle tissue is present and does not enclose the bony region of the knee. In the embodiment shown, the knee region is enclosed by a rigidizable member 30 which, in the same manner as discussed above with reference to the rigidizable end members 14 and 15, acts as a passive member only. Thus, during operation, actuating fluid is supplied to sealed members 31 and 32 within each of the rigid housing members 25 and 26, respectively, in substantially the same manner as shown in FIGS. 1 and 2. The ends 33 and 34 of rigidizable member 30 about the knee ends of sealed members 31 and 32, respectively, and assist in confining the active pressure changes to the thigh and calf regions and, hence, reduce the system damping due to the distensibility of the sealed members 31 and 32.

The embodiment of FIG. 3 has an additional advantage in that, when the apparatus is first placed on the patient, the rigidizable member 30 at the knee region is in a flexible form. The patient is then permitted to assume a more comfortable position than he is able to assume in the apparatus of FIG. 1, for example, by being able to flex his knees as desired prior to the rigidizing of the knee member 30. Moreover, if the leg is bent at the knee the forces which tend to move the patient longitudinally (and, hence, tend to eject the patient from the apparatus) have a greater tendency to balance out so the tendency for longitudinal patient motion is reduced.

In the embodiment shown in FIG. 3 the passive members at the regions above the thighs and below the ankles may or may not be used, as desired, in the particular application in which the apparatus is used.

In the embodiments discussed with reference to FIGS. 1-3, the active portions thereof are shown as comprising rigid housing members completely enclosing the active regions of the patient's body. FIGS. 4 and 5 show an alternative embodiment of the invention wherein the active housing member is shown as being formed of a rigid portion and a rigidizable portion. Thus, the active members 40 and 41 include rigid portions 42 and 43 and flexible members 44 and 45, respectively. As can be seen best in FIG. 5, with reference to active member 40, rigid portion 42 is fixedly attached along one longitudinal side to a base member 46 as by a plurality of appropriate screws, two of which are shown as screws 47, or other suitable attaching means. Rigid portion 42 has an essentially semi-circular cross-section and thereby forms approximately one-half of the active member along the patient's leg from approximately the upper region of the thigh to the ankle region. Rigid portion 42 encloses a sealed flexible member 48 which contains the coupling fluid and which is appropriately connected to an actuator system 55 of the type discussed above, via appropriate connectors 56 and 57.

The remaining portion of the active member comprises flexible member 44 containing plastic beads of the general type shown above for the passive waist, ankle and knee members discussed with reference to

FIGS. 1-3. Flexible member 44 is fixedly attached along one longitudinal side parallel to the fixedly attached side of rigid portion 42. Member 44 can be attached prior to the placement of fluid sealed member 48 via a plurality of screws one of which is shown as screw 49, or other suitable attaching means. Flexible member 44 can be shaped to the inner part of the patient's leg and can be adjusted in accordance with the leg diameter to provide for the closest conformity thereto by affixing its non-attached side to the rigid portion along one of a plurality of parallel spaced longitudinal regions via appropriate attaching means 50, as shown. Both flexible members 44 and 45 are connected to a vacuum pump 51 via connectors 52 and 53.

Flexible member 44 can be suitably shaped while in its flexible state not only to conform to the shape of the patient's leg but also to abut against the ends 54 and 54A of sealed member 48 so that upon evacuation member 44 assumes a rigid shape so as to confine the sealed member 48 to the position shown and, thereby, to reduce the damping which arises because of the distensibility of the member 44. Because of the presence of rigid portion 42 and the ability of rigidizable member 44 to conform closely to the leg, sufficient pressure changes can be achieved with the construction shown to produce the desired pulsation effect without the need to completely enclose the leg with sealed member 48. Alternatively, however, a sealed member 48 completely enclosing the leg between the leg and both the rigid and rigidizable portions may be used. Although the embodiment shown in FIGS. 4 and 5 utilizes rigid and rigidizable portions of the active units, each of which encloses approximately one-half of the leg, in some applications it may be found desirable to alter the shape of such portions to enlarge or decrease the portion of the leg enclosed by either one. Moreover, the construction shown in FIGS. 4 and 5 can be used with or without the passive ankle and waist members discussed above with reference to the embodiments of FIGS. 1-3. Further the embodiments of FIGS. 4 and 5 can be alternatively constructed so as to comprise two separate active units at the thigh and calf regions while simultaneously using a passive knee member as shown in FIG. 3, either with or without the waist and ankle passive members discussed above.

FIG. 6 shows a portion of an active housing configuration which can be substituted for the rigid housing member of FIG. 1. As shown in FIG. 6, the active housing member can be formed of a rigidizable member 50 which can extend from the ankle to the upper thigh region. A sealed member 51 is placed around the patient's leg between the rigidizable member 50 and the leg, member 51 containing the coupling fluid and being connected to an actuating system via a suitable connector 52 drawn through an opening in rigidizable member 50. In its flexible state member 50 can be appropriately shaped around the leg and sealed member 51 to reduce the tendency to form dead space during operation. Member 50 can be further shaped at its end points to conform closely to the leg, as shown, for example, at region 53. When member 50 is evacuated via a vacuum pump (not shown) connected to connector 54, sealed member 51 is appropriately confined within the then rigidized member 50 so as to further reduce the system damping.

The rigidizable active housing unit of FIG. 6 can be utilized with rigidizable passive members at the waist

and ankle ends thereof in substantially the same manner discussed with reference to FIG. 1, or such passive end units may be omitted as desired. Further, rigidizable active housing members of the type shown in FIG. 6 can be substituted for the two separate rigid thigh and calf active housing members of FIG. 3 which configuration is then usable with the passive rigidizable member at the knee region and with or without the passive members at the ankle and waist ends of the active housing units.

FIG. 7 shows still another alternative embodiment of the invention wherein a single rigidizable member 60 is formed in a pant-like configuration which extends substantially from the patient's waist to the patient's feet. In such a configuration, a sealed member which contains the coupling medium may be formed as a single member (not shown) which also is in a pant-like configuration and extends from the ankle region to the waist and is enclosed by rigidizable member 60. In such a case the active cycle pressure transfer via the coupling fluid is substantially the same at all points contacted by the inner sealed member. Accordingly, the effectiveness of the energy transfer is enhanced because active pressure transfer occurs not only at the muscle and fat tissue on the leg but also at such tissues on the patient's abdomen and buttock regions.

In some applications where sufficiently high pressures may be utilized in the structure of FIG. 7 to produce discomfort or even potential damage to the patient's organs within the abdomen and at the genitalia, the rigidizable structure and interior activated sealed member containing the active coupling medium may be shaped so as to extend only from the ankle region to the region enclosing the patient's buttocks, there being no structure, rigidizable or otherwise, placed at or across the abdomen and genital region shown by the dashed line 61 in FIG. 6, so that no pressure at all is applied thereto. Alternatively, the rigidizable member 60 may be arranged in its flexible state to form a bridging structure at the region 61 to act as a non-pressurized region in that manner.

As a further alternative the entire region above the thighs from about line 62 to the patient's waist may be made passive. In one form thereof, an interior sealed member containing coupling fluid may be used within rigidizable member 60 but such interior coupling member is separate from the active coupling members at the legs and the coupling fluid therein is not directly connected to the pressure actuation system. Alternatively, the passive interior coupling member above line 62 may be omitted so that the upper portion of rigidizable member 60 can be arranged in its flexible state to be positioned in direct conformable contact with the entire region from waist to thigh so that in its rigid state it confines the interior active sealed member to the region below line 62 from thighs to ankles.

The use of the configuration of FIG. 7 wherein there is passive pressurization of the region from waist to thighs at least at the buttock region, reduces the physiologic energy loss which is due to damping arising from patient motion. Additionally, such passive pressurization of the buttocks increases the potential quantity of blood which can be caused to flow to the heart over that which is caused to flow when such passive pressurization is not used. Such operation will tend to permit a reduction in the stroke volume of the actuator and, hence, a corresponding reduction in the power require-

ments at the actuator source, so that equivalent overall system efficiency at lower power inputs is obtained as compared to systems using active housing members applied only to the patient's legs. Such efficiency can be maintained even with the lower power requirements because of the recapture of some of the energy which is normally lost in moving the patient out of the leg units. In the embodiment described any such motion causes pressurization of buttock region against the rigidized passive container positioned between the waist and thighs. The tissue pressure created by this patient motion is effective in increasing retrograde blood flow in the arterial system. The phasing of this passive tissue pressurization is inherently correct with respect to the phase of the external pressure on the legs.

Alternatively, a separate passive rigidizable member can be used from waist to thighs in combination with any appropriate active or active/passive units on the legs, such latter units being of any convenient configuration shown in the previously described embodiments of FIGS. 1-6 or the embodiments of the leg units shown in our previously filed application mentioned above.

Further, while a rigidizable member in the form of the vacuum operated containers discussed above is presently believed to be preferable in the embodiments disclosed, other rigidizable members may be substituted therefor. For example, a rigidizable foam which is relatively flexible, or fluidic, in nature may be used, which material is then allowed to harden into a rigid state upon the addition of a catalyst. Other similar rigidizable means may occur to those in the art.

Accordingly, the invention is not to be construed as limited only to the specific embodiments shown and described herein except as defined by the appended claims.

What is claimed is:

1. Apparatus for providing external assistance for the circulation of blood in a patient comprising
 - housing means for enclosing a portion of said patient's body;
 - means for cyclically applying pressure to said body portion within at least a portion of said housing means, said pressure applying means including
 - pressure actuation means;
 - a pressure medium positioned in said portion of said housing means between said pressure actuation means and said portion of the patient's body, said pressure medium being responsive to said pressure actuation means to apply pressure to said body portion;
 - means for synchronizing the operation of said pressure actuation means to apply said pressure cyclically to produce alternating compression and decompression of said body portion in synchronism and in correct phase with said patient's heartbeat;
 - at least a portion of said housing means comprising rigidizable means which is in a non-rigid state when applied to or placed on said patient and which is capable of substantially conforming to any of a plurality of different shapes of the portion of said patient's body to which it is applied when in said non-rigid state, said rigidizable means being further capable of assuming a rigid state and retaining said conformity when in said rigid state; and
 - means for rigidizing said rigidizable means for operation of said apparatus.

2. Apparatus in accordance with claim 1 wherein said housing includes

a substantially rigid means;
means for enclosing said pressure medium within said rigid means to form an active region of said housing; and

at least one rigidizable means positioned adjacent at least one end of said rigid means for forming a passive region of said housing.

3. Apparatus in accordance with claim 2 wherein said active rigid means encloses a substantial portion of each of the legs of said patient extending from at least the ankle region to at least the upper thigh region of each said leg; and

said passive rigidizable means are positioned on each of said legs adjacent the ankle ends and the thigh ends of said rigid means.

4. Apparatus in accordance with claim 1 wherein said housing includes

at least two substantially rigid means enclosing at least two portions of said patient's body;

means for enclosing said pressure medium within each of said substantially rigid means to form at least two active housing regions; and

a rigidizable means forming a passive region of said housing positioned between and adjacent each of said rigid means.

5. Apparatus in accordance with claim 4 wherein said rigid means extend respectively from a region above the ankles to a region below the knees and from a region above the knees to a region at the upper portion of the thighs on each leg of said patient; and

said rigidizable means extend from a region below the knees to a region above the knees on each leg of said patient.

6. Apparatus in accordance with claim 5 and further including

at least one additional rigidizable means positioned on each of said legs adjacent at least one end of one of said rigid means for forming a passive region of said housing.

7. Apparatus in accordance with claim 6 wherein said additional rigidizable means are positioned adjacent both the ankle ends and the thigh ends of rigid means on each leg of said patient.

8. Apparatus in accordance with claim 1 wherein at least a part of said housing means includes

an active housing section formed of a substantially rigid portion and a rigidizable portion; and
means for enclosing said pressure medium within said active housing section to form an active housing region at said patient's body.

9. Apparatus in accordance with claim 8 and further including

at least one rigidizable means positioned adjacent at least one end of said active housing region for forming a passive housing region at said patient's body.

10. Apparatus in accordance with claim 9 wherein said active housing section extends from at least the ankles to at least the upper portion of the thighs on each of the legs of said patient; and

said rigidizable means are positioned adjacent both the ankle ends and the thigh ends of the active housing section on each said leg.

11. Apparatus in accordance with claim 8 wherein said active housing section includes means for adjusting the rigidizable portion thereof so as to conform said active housing section generally to the configuration of the portion of said patient's body which is enclosed thereby.

12. Apparatus in accordance with claim 8 wherein said active housing section includes

a pair of active housing sections on each leg of said patient extending respectively from a region above the ankle to a region below the knee and from a region above the knee to a region at the upper thigh; means for enclosing said pressure medium within said active housing sections; and

rigidizable means positioned on each leg of said patient between and adjacent said pair of active housing sections to form a passive region at the knee of each said leg.

13. Apparatus in accordance with claim 12 wherein said active housing sections on each said leg include means for adjusting the rigidizable portions thereof so as to conform said housing sections generally to the portions of said patient's leg which are enclosed thereby.

14. Apparatus in accordance with claim 1 wherein said rigidizable means substantially completely forms said housing means.

15. Apparatus in accordance with claim 14 wherein said rigidizable housing means forms an active housing on each leg of said patient extending from at least the upper thigh region to the ankle region on each said leg; and

further including means for enclosing said pressure medium within said rigidizable housing means on each said leg.

16. Apparatus in accordance with claim 15 and further including

additional rigidizable means for forming a passive region on each said leg positioned adjacent at least one end of said active rigidizable housing means on each said leg.

17. Apparatus in accordance with claim 16 wherein said additional passive rigidizable means are positioned at each end of said active rigidizable means on each said leg.

18. Apparatus in accordance with claim 14 wherein said rigidizable housing means forms a pair of active housings on each leg of said patient extending from at least the upper thigh region to at least the ankle region on each said leg, said apparatus further including means for enclosing said pressure medium within each of said rigidizable active housings on each said leg; and

additional rigidizable means for forming a passive region on each said leg positioned intermediate said active housings at the knee region thereof.

19. Apparatus in accordance with claim 18 and further including

further rigidizable means for forming at least one further passive region on each said leg adjacent an end of at least one of said rigidizable active housings on each said leg.

20. Apparatus in accordance with claim 19 wherein said further rigidizable passive means includes passive rigidizable means positioned adjacent both the ankle end and the upper thigh end of said rigidizable active housings on each said leg.

21. Apparatus in accordance with claim 14 wherein said rigidizable housing means is in the form of a pant-like configuration which extends from the waist region of said patient's body to at least the ankle regions of both legs thereof; and further including

means for enclosing said pressure medium within said rigidizable housing means to form an active housing from the waist region of said patient to at least said ankle regions.

22. Apparatus in accordance with claim 14 wherein said rigidizable housing means is in the form of a pant-like configuration which extends from the waist region of said patient's body to at least the ankle region of both legs thereof; and further including

means for enclosing said pressure medium within said rigidizable housing means to form one or more active regions within a portion of said rigidizable housing means at the parts of the patient's body enclosed thereby, the remaining portion of said rigidizable housing means forming one or more passive regions at the remaining parts of the patient's body enclosed thereby.

23. Apparatus in accordance with claim 22 and further including

means for enclosing said pressure medium within said remaining portion of said rigidizable housing means, said pressure medium therewithin not being directly connected to said pressure actuation means.

24. Apparatus in accordance with claim 22 wherein said active regions are formed at least at a portion of each leg of said patient extending from the thigh region to the ankle region thereof.

25. Apparatus in accordance with claim 22 wherein said active regions are formed at a portion of said patient's body extending from the patient's waist to the thigh regions of each leg and further at portions of said patient's body extending from said thigh regions to the ankle regions of each said leg.

26. Apparatus in accordance with claim 22 wherein an active region is formed at least at a region of said patient's body substantially enclosing the buttocks of said patient.

27. Apparatus in accordance with claim 26 wherein said active regions are further formed at least at a portion of the patient's body extending from the thigh regions to the ankle regions on each leg thereof.

28. Apparatus in accordance with claim 1 wherein said rigidizable means extends from the waist to the thigh regions of said patient's body.

29. Apparatus in accordance with claim 1 wherein said rigidizable means is in a non-rigid state when the interior thereof is not evacuated and is capable of assuming a rigid state when said interior is evacuated; and

said rigidizing means is a means for evacuating the interior of said rigidizable means.

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