(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) Publication number: **0 168 085**
A1

(12) EUROPEAN PATENT APPLICATION

(21) Application number: **85200934.9**

(51) Int. Cl.⁴: **A 61 H 23/04**

(22) Date of filing: **12.06.85**

(30) Priority: **13.06.84 NL 8401873**

(43) Date of publication of application:
15.01.86 Bulletin 86/3

(84) Designated Contracting States:
BE CH DE FR GB IT LI NL

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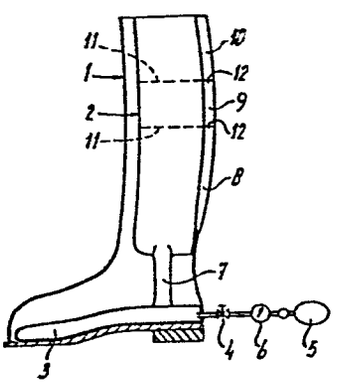
(54) Medical-therapeutic device.

(57) A device (1,2) for sustaining the operation of the blood vessels in a limb of the human body has different chambers (8,9,10) in contact with the limb and filled with a fluid, which is pulsatingly pressurized and decreased in pressure. The invention improves such known devices in order to avoid rapid backflow of venous blood towards the extremity of the limb during decrease of pressure in said chambers. This is obtained by applying only a small pressure drop in one or more proximal chambers (10 and possibly 9). The pulsations may be generated by a foot pump being a chamber (3) under the foot of the patient, or by external pressurizing and pulsating means. The device may be embodied as a boot (1) for a human leg or be mounted inside such a boot.

fig-1



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Medical-therapeutic device -1- 0168085

This invention relates to a device for sustaining the operation of the blood vessels in the human body, at least in part in one of the limbs thereof, with more than one chamber to be positioned in contact with different zones of the body, said chambers being adapted to take up a fluid such as air under pressure and having a flexible wall for transmitting said pressure to the body, with means to subject a fluid in said chambers to a pulsating pressure.

A device of this kind is known from U.S. patent 4,029,087 and from U.S. patent 4,030,488.

It is known that the blood supply to the human limbs, in particular to the legs, gives problems particularly by ageing by weakening of skin and muscles, so that the backflow of blood towards the heart is hampered, in particular by venous valve-insufficiency or decreased muscular pumping activity.

It has thus been proposed already to obtain improvement by supporting and exerting pressure on parts of such limbs. A good possibility to this end is the exertion of a pulsating pressure thereon, i.e. of a pressure which is increased and decreased alternately.

In U.S. patent specification 4,029,087 the said chambers are subjected to a pulsating pressure from an external source, subsequent chambers being filled from a chamber closest to the extremity of the concerning limb. During the decrease of pressure as second part of each pulsation, chambers positioned more remotely from the extremity of said limb (more proximal chambers) being emptied through chambers closer to said extremity (more distal chambers), or the reverse, it being also possible to connect the chambers each separately from the others to a relief discharge. Chambers, positioned more remotely from the extremity of said human limb are filled from more distal chambers through narrow throttling connections or by check valves opening against a relatively high pressure difference, so that proximal chambers in each pulsation cycle are subjected to a much lower pressure than distal chambers. The relief of the proximal chambers takes place through distal

chambers through check valves, opening against a much lower pressure difference (and of course in opposite direction) than the check valves used for filling the chambers with the fluid.

In U.S. patent specification 4,030,488 a device of this kind is given, in which the chambers are filled and emptied in a pulsating manner independently of each other through a common supply and discharge conduit to all the chambers, a throttling passage leading from this conduit to each chamber. For more distal chambers this passage is wider than for more proximal chambers. In this way a fluid pressure is built up in each chamber, which is lower for more proximal chambers. In the pressure relief phase of each pulsation a more proximal chamber is relieved more slowly than a more distal chamber, but by the lower pressure in said more proximal chamber it rapidly reaches a pressure as low as the pressure in such a more distal chamber before the next pressure rise begins.

The invention aims at improving such devices. In this respect it has appeared that in such known devices the operation is not optimal, and moreover that this is to be attributed to the fact that, during the pressure decreasing phase of the pulsations much venous blood flows back immediately to the distal part of the limb, in particular to the lower leg of standing or sitting patients.

In view thereof the invention proposes to embody such pulsating means in such a way that, during decrease of the pressure in said chambers, the pressure in one or more more proximal chambers is maintained at a much higher value than the pressure in one or more more distal chambers at least until the next pressure rise occurs.

Thereby, at least one more proximal chamber loses its pressure during the relief phase of the pulsations more slowly than at least one more distal chamber, which has a favourable influence as to avoiding such rapid back flow of venous blood.

It is possible to apply the invention with any desired number of chambers along different parts of a human leg and if desired also on an arm. The most proximal chamber may be present on part of the human torso, e.g. on breast, shoulder or hip.

For walking patients the pulsations may be generated by apply-

ing a flexible "pumping chamber" below the foot, which chamber is in fluid communication with one or more pressure chambers in contact with parts of the leg so that a fluid such as air is pumped to said pressure chambers by and from said pumping chamber when placing the foot during walking and that, when lifting the foot, this fluid flows back into said pumping chamber. This is e.g. known from British patent specification 817,521 and from European patent application 39,629.

For patients who cannot walk, e.g. are bedridden or in a wheeled chair, such pulsations may be generated with the aid of a pump or pressure vessel and a controlled pulsation device, e.g. as disclosed in the said U.S. patent specifications 4,030,488 and 4,029,087.

The invention moreover relates to preferred embodiments of said principle.

For further explanation of the invention it is good to note that, for avoiding said rapid backflow of venous blood during the pressure relief phase it is as such not at all necessary that the pressure in the most proximal chamber is decreased at all. It should, however, be avoided that, when the pulsations are stopped, e.g. if the patient stops walking, sits or lies down immediately after walking, or when stopping or inadvertent falling out of the external source for the pulsations proximal chambers remain at the same higher pressure and thus would tend to tie up the human limb during a longer period. It is thus necessary to relieve also the more and most proximal chamber(s), but so slowly that during operation of the pulsations the pressure in said chamber(s) remains high, as indicated, while nevertheless allowing slow but sufficiently rapid decrease of said pressure in the absence of pulsations.

Throttling openings for the pressure relief may be present between the different chambers, but they may also lead directly from each chamber to the outside.

The invention will now be explained in more detail with reference to the attached drawings. Therein:

Fig. 1 is a somewhat diagrammatic vertical section through a boot, embodied as or comprising a device according to the invention;

Fig. 2 is a detail of this device at a larger scale;

Fig. 3 shows, also on a larger scale, another embodiment of the detail of Fig. 2; and

Fig. 4 gives a graph of pressure against time for a device according to Fig. 1.

The device of Fig. 1 is embodied as a boot 1, provided with a number of chambers 3, 8, 9, 10 for pressure pulsations, being permanently or easily detachably mounted in said boot. The chambers have flexible fluid-tight walls, which preferably are not elastic or only very little, such as a fabric impregnated and/or covered by a suitable flexible plastics or rubber material. In this case they are mutually connected to a unit 2. The boot may have zippers or bootlaces not shown to be easily pulled on and taken off.

In the sole part this unit has a flexible chamber 3, extending under the entire surface of the human foot sole or under the greater part thereof. A closable connecting nipple 4 serves to keep said unit filled with a fluid such as air, e.g. by the use of a simple hand or foot pump 5 easily connectable thereto and detachable therefrom, e.g. as usual for inflating air beds or rubber boats, but it is also possible to fill this unit by blowing by mouth or connection to any source of pressurized air or other gas. A meter 6 shows the filling pressure.

The nippel 4 may be connected at any point to unit 2, e.g. to one side of the sole or higher.

The chamber 3 is in open fluid connection with a chamber 8 through a flexible duct 7 extending along foot and ankle. Above chamber 8 there are two further chambers 9 and 10. To avoid hindrance to the patient and/or closing of duct 7 by the patient's foot or ankle, this duct may be embedded in a suitable material such as elastic foam plastic.

Said chambers 8 to 10 extend along the back side and along part of the sides of the lower leg. There may also be one or more chambers in contact with the upper leg and it is even possible that e.g. a hose connects the upper chamber 10 to a chamber to be applied to the patient at the height of the hip. If desired the duct 7 may be very short and chamber 8 may extend downwardly along

the ankle, so that a pulsating pressure may also be exerted on the median or lateral ankle.

Within the unit 2 the chambers 8 to 10 are separated by substantially horizontal intermediary walls 11. Each wall 11 has a flow connection 12 between bordering chambers, indicated in Fig. 1 only diagrammatically by a dash. In Fig. 2 and 3 this connection 12 is shown in detail on a larger scale.

In the embodiment of Fig. 2 a valve casing 13 is mounted in an opening in each wall 11. This casing may be of metal, rather hard rubber or plastics material and it may be mounted by clamping, bonding or vulcanising or any other suitable connection method to wall 11. A valve body 14 is freely movable up and down in said casing and consists of metal, rubber or plastics material. At least one of the parts 13 and 14 is made of elastic material of such flexibility that body 14 is introduceable into casing 13. It is also possible to provide casing 13 with a separate part enclosing body 14 after introduction and mountable e.g. by screwing or screws, welding or glueing.

Valve body 14 has protrusions 15 such as battlements, which in the highest position of body 14 engage a shoulder 16 in casing 13 so as to allow fluid to pass through openings 17 in the battlements. Moreover this body 14 as a relatively narrow bore 18 and a conical outer surface 19 having the same cone angle as a seat 20 in casing 13. Said angle is chosen of such a high value that body 14 leaves said seat 20 upwardly easily and is not clamped thereby.

In Fig. 3 there is small tube 21 of rubber or the like elastic material, bonded, e.g. vulcanised, sealingly in a hole in wall 11. This tube 21 is open at its lower end and closed by end wall 22 at its top. Above wall 11 it has a longitudinal (vertical) cut 23, so narrow that it is closed (gas tight) if the air pressures to both sides thereof are equal and for all pressure differences with a higher pressure at the outside of this cut. Moreover, there is a small (throttling) hole 24 penetrating the wall of tube 21 above wall 11.

The operation of this device is as follows:
After the entire unit 2 is filled by air of a pressure somewhat higher than atmospheric, e.g. somewhat less than 40 mm Hg gauge

pressure, and a human being walks on this boot 1, the chamber 8 is compressed when putting down the foot, part of the air in this chamber is pushed by duct 7 to chamber 8 and raises the pressure therein. This causes opening (lifting to the position shown) of valve body 14 (Fig. 2) or of slot 23 (Fig. 3) between chambers 8 and 9 towards chamber 9. The pressure rise in chamber 9 causes valve body 14 or slot 23 between chambers 9 and 10 to open and chambers 8, 9 and 10 thus rapidly reach about the same pressure, upon which the valves 14 or slots 23 close.

When lifting the foot the air tends to flow in the opposite direction, chamber 8 is subjected to a decrease in pressure together with chamber 3 by the increase in volume of the latter. The throttling openings 18 (Fig. 2) or 24 (Fig. 3) now form the only flow connection between chambers 8, 9 and 10, so that the pressure in chamber 9 decreases more slowly than in chamber 8 and in chamber 10 the pressure drop is even more slow. By the relatively rapid sequence of steps during walking said pressure drop in chambers 9 and 10 is not only more slow but finally also, until the next pressure rise begins, less in amount, and, for chamber 10, even if desired negligible.

The pressure changes of course depend on the relatieve volumes of the chambers. The chambers 8, 9 and 10 may be relatively thin in a direction perpendicular to the leg, and chamber 3 is chosen at a relatively considerable volume.

The throttling opening 18 or 24 between chambers 8 and 9 is preferably wider than the same opening between chambers 9 and 10. Thereby, chamber 9 will, during the pressure relief phase, much more rapidly fall in pressure to a pressure, considerably lower than the pressure in chamber 10, for which it is important that the pressure remains high to avoid backflow of venous blood.

Fig. 4 shows possible pressure distributions and pressure pulsations in a device according to Fig. 1. In stable, stationary condition the pressure in the entire device is e.g. somewhat less than 40 mm Hg. When the patient walks and compresses chamber 3 below his foot sole, the pressure in chamber 8 near 4b rises quickly to about the same level. As this pressure rise quickly opens (lifts) check valve body 14 of Fig. 2 or slot 23 of Fig. 3 between

chambers 8 and 9, the pressure in chamber 9 also rises quickly to about the same value and the thereupon opening check valve body 14 of Fig. 2 or slot 23 of Fig. 3 between chambers 9 and 10 causes chamber 10 to follow almost the same pressure rise. With the weight of the patient fully resting on this foot and fully compressed chamber 3 the pressures in the chambers 8, 9 and 10 have risen to say about 70 mm Hg.

Upon lifting this foot the pressure in chambers 3 and 8 drops rapidly, e.g. to about 20 to 25 mm Hg. As check valve 14 of Fig. 2 drops (closes) as soon as the pressures in the adjacent chambers to both sides thereof are about equal, or as slot 23 closes in this situation, the chambers 8, 9 and 10 are now only in communication by the throttling openings 18 of Fig. 2 or 24 of Fig. 3. This causes the pressure in chamber 9 to decrease only gradually, e.g. to about 40 mm Hg, before the patient will again plant this foot (dashed line in Fig. 4). The pressure in chamber 10 will decrease even less (line of dots and dashes in Fig. 4), e.g. to 55 mm Hg when the next pressure rise begins. Without harm the pressure in chamber 9 may drop to lower values, e.g. by a wider throttling opening 18 or 24. The stationary pressure in the device of somewhat below 40 mm Hg is low enough to avoid undesired blood congestion.

The chambers 9 and 10 might also have a throttling relief opening to the outside for replacing or additional to openings 18 between chambers 8, 9 and 10.. During the pressure rise phase the pressure in more proximal chambers 9 and 10 will then remain lower than in chamber 8, but this may be acceptable, if only the unit 2 is not allowed to remain deflated, e.g. by making chamber 3 elastic in a sense to tend to increase in volume.

If a liquid is used instead of gas or air, it is preferable to apply elastic walls for at least part of the chambers.

It is possible to use the unit 2 without a surrounding boot, in which case it might be strapped onto the human leg.

Instead of any of the valves as shown in Figs. 2 and 3 there may be simple ball valves as check valves. Particularly in such a case the throttling opening between adjacent chambers may be provided in the separating wall 11 thereof itself, as shown by 18' in Fig. 2.

If an external source is used for the pulsations, e.g. for bedridden patients or patients in a wheeled chair, the chamber 3 may be omitted and said source may be connected to chamber 8. Particularly in that case but if desired also in all other cases, each chamber may have its own separate connection to such an external source in which case rises and falls in pressure are controlled, e.g. with the aid of a microprocessor in such a way that one or more more proximal chambers during the pressure fall are less relieved or less rapidly relieved than one or more distal chambers.

For the principle of the action of the pressure rise phases of the chambers for the blood circulation the use of more than three chambers may be deemed preferable, but this is known as such. For the principle of the present invention the number of subsequent chambers is of less importance, if only the most proximal chamber satisfies the requirement of the invention about a smaller value of its pressure drop during the relief phase.

CLAIMS

1. A device for sustaining the operation of the blood vessels in the human body, at least in part in one of the limbs thereof, with more than one chamber to be positioned in contact with different zones of the body, said chambers being adapted to take up a fluid such as air under pressure and having a flexible wall for transmitting said pressure to the body, with means to subject a fluid in said chambers to a pulsating pressure, characterized in that such pulsating means are embodied so that during decrease of the pressure in said chambers, the pressure in one or more more proximal chambers is maintained at a much higher value than the pressure in one or more more distal chambers at least until the next pressure rise occurs.

2. A device according to claim 1, in which a flow connection for the fluid is provided between two or more chambers, so that the pressure in one or more chambers is increased via said connection as a result of a pressure rise in another chamber, which is adapted to be positioned more distal with respect to the human limb, characterized in that said chamber(s), in which the pressure is raised through such a connection, has (have) a throttling relief opening giving more resistance to the flow of fluid therethrough than said flow connection, and that means are provided to close said flow connection during the periodic pressure relief phase of the pulsations.

3. A device according to claim 2, in which said throttling relief opening is provided between said chambers in order to allow relief of one chamber gradually towards a more distal chamber.

4. A device according to any of the preceding claims, in which a check valve is provided between adjacent chambers, embodied so as to close said flow connection between said chambers in the pressure relief phase of the pulsations.

5. A device according to claim 4 together with claim 2 or claim 3, in which the check valve has such a throttling opening in its valve body to allow passage of fluid therethrough in its closed position.

6. A device according to claim 4 in combination with claim 2 or claim 3, in which there is an elastic hose between adjacent chambers, closed at the end positioned in the more proximal chamber, having a throttling opening at or near said end in its wall and having a narrow slot in its part extending into said more proximal chamber, which slot is closed elastically by the elastic material of the hose along its sides and opening as soon as the fluid pressure inside the hose, being the pressure in the more distal one of said adjacent chambers, is higher than the fluid pressure in the more proximal chamber.

7. A device according to any of claims 2 to 6, in which a chamber is provided, adapted to be positioned below the human foot sole so that, in walking, this chamber is pressurized and substantially emptied when placing the foot and is decreased in pressure and filled by the fluid when the foot is lifted, there being a fluid flow connection between this chamber and an adjacent chamber adapted to be in contact with part of the human leg and from this latter to one or more further chambers adapted to be in contact with a more proximal part of the human body, at least the fluid connection between the two most proximal chambers having such a throttling relief opening and said closing means to close this connection during the periodic pressure relief phase of the pulsations.

8. A device according to claim 7, in which the flow connection between said chamber adapted to be positioned below the human foot and the most adjacent chamber is free from such closing and throttling means.

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Fig-1

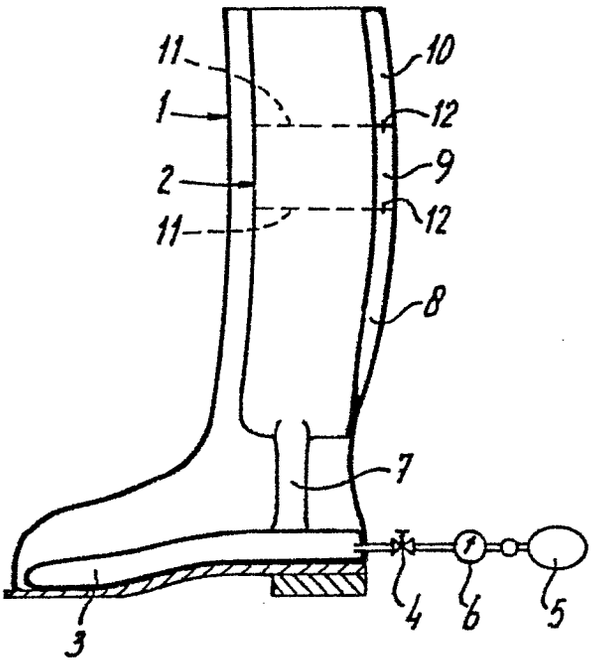

Fig-2

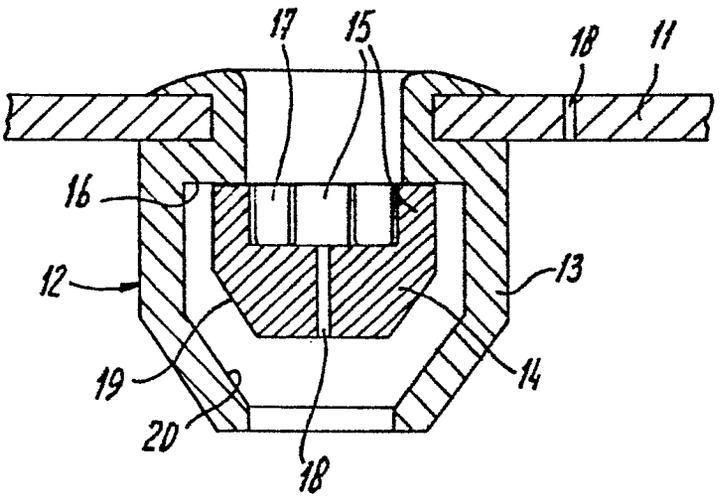

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Fig-3

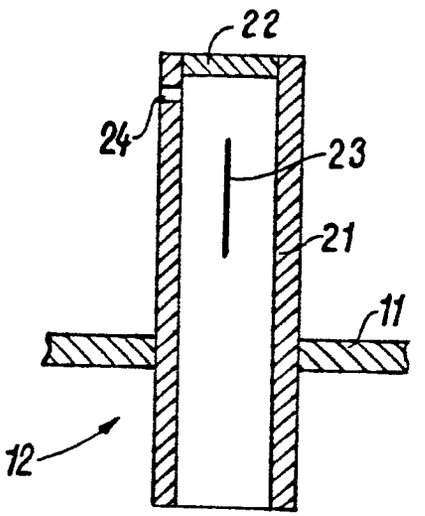
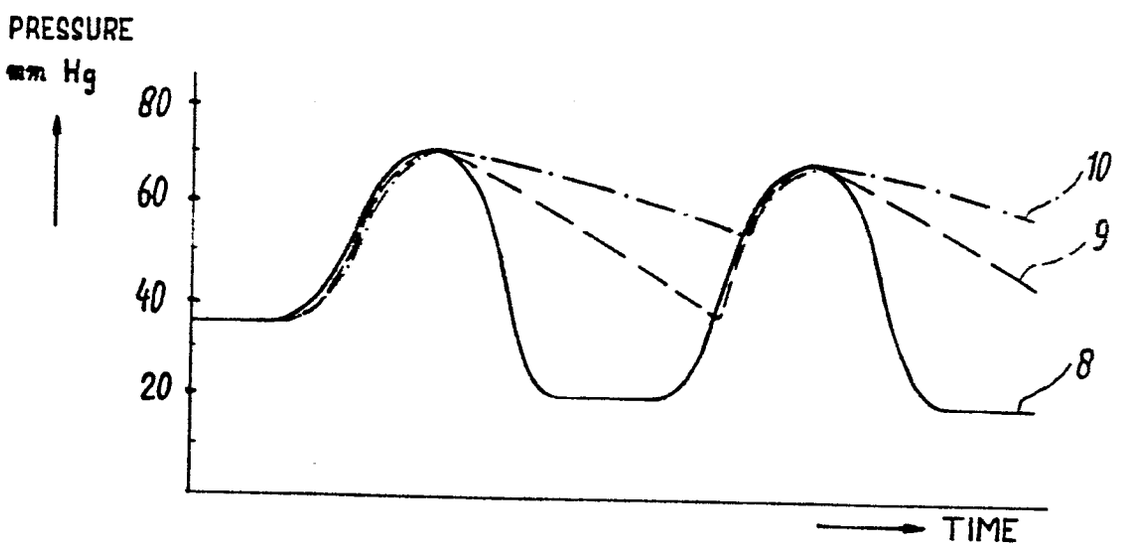


Fig-4



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EUROPEAN SEARCH REPORT

0168085
Application number

EP 85 20 0934

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl 4)
D,X	US-A-4 029 087 (J. DYE et al.) * Figures 1-4; column 4, line 36 - column 5, line 9; column 5, lines 41-52 *	1-4	A 61 H 23/04
Y		5-8	

X	NL-A-8 201 189 (J. HENNING) * Figures; page 6, line 6 - page 8, line 9 *	1	
Y		7,8	

Y	US-A-4 428 396 (G. WALL) * Figure 3; column 1, lines 8-14; column 4, lines 14-27 *	5,6	
	---		TECHNICAL FIELDS SEARCHED (Int. Cl 4)
Y	US-A-4 345 594 (J. BISERA et al.) * Figures 2,3; column 2, line 60 - column 3, line 14 *	6	A 61 H A 61 M F 16 K

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	20-09-1985	VEREECKE A.

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
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