

1 576 026

- (21) Application No. 13250/77 (22) Filed 29 March 1977 (19)
- (31) Convention Application No. 671 029 (32) Filed 29 March 1976 in
- (33) United States of America (US)
- (44) Complete Specification published 1 Oct. 1980
- (51) INT. CL.<sup>3</sup> A61H 9/00
- (52) Index at acceptance  
 A5R BP  
 A3V 1A2C 5J 6E1 6E2 7B3.



(54) APPARATUS FOR APPLYING PULSATING PRESSURE TO THE BODY

(71) We, ALBA-WALDENSIAN, INC., a corporation organised under the laws of the State of Delaware, United States of America, of Post Office Box 100, Valdese, North Carolina 28690, United States of America, do hereby declare the invention, for which we pray that a patent may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement:—

This invention relates generally to apparatus for applying pulsating pressure to the human body and includes stockings for intermittently applying pressure to the legs in order to stimulate fluid flow within the legs of the wearer and thereby to induce the likelihood of venous thrombosis. More specifically, the stocking includes a seamless knitted leg portion which is fashioned generally to conform to the configuration of the leg of the wearer and is of relatively lightweight construction so that the stocking is comfortable for wear by a bed patient or an ambulant patient.

It has been recognized that surgery and other types of bed patients are particularly susceptible to venous thrombosis. Various types of pneumatic leggings, boots, pressure chambers and the like have been proposed for periodically compressing and releasing the legs of the wearer to accelerate blood flow. However, such prior devices have disadvantages which have prevented their widespread use. In many instances, these prior devices have been heavy and cumbersome, thereby preventing or at least limiting ambulation and other movement of the bed patient. The pressure applying means extends completely around the legs of the wearer in many of these prior devices and this could actually operate to limit blood circulation in the patient.

In an apparent attempt to overcome these disadvantages, it has been proposed in U.S. Patent No. 2,747,570 to provide an envelope surrounding the leg of the patient with an inflatable tube, or a pair of tubes, extending up one side of the envelope. When the tube is expanded, direct inward

pressure is applied against the area of the leg covered by the tube. However, the inflatable tube is of a relatively small diameter so that it engages only a small area of the circumference of the leg of the wearer and may apply so much pressure in such a small area as to be uncomfortable and may restrict blood circulation or may cause localized tissue damage.

With the foregoing in mind, it is an object of the present invention to provide apparatus for applying pulsating pressure to a leg of a human for stimulating fluid within the body and thereby to reduce the likelihood of venous thrombosis.

From one aspect, the invention consists in apparatus for applying pulsating pressure to a leg of a human, comprising a stocking comprising a seamless knitted leg portion generally conforming to the configuration of the leg on which said stocking is to be worn, said seamless knitted leg portion being sufficiently stretchable to permit easy placement and removal, a pocket extending longitudinally of the leg portion, said pocket being arranged to extend from at least adjacent the ankle of the wearer to a position immediately below the knee, and an expandable bladder positioned in said pocket and extending longitudinally of said leg portion, and pumping and controlling means for periodically expanding said bladder to exert direct pressure against the portion of the leg covered thereby and circumferentially to contact said leg portion and apply pressure to the corresponding portion of the leg encompassed by said leg portion.

The stocking is easy to apply and remove and may be formed so as to be of lightweight and comfortable for wear by bed patients or ambulant patients in the hospital or in the home.

The pocket and bladder may be centred on the front of the leg portion of the stocking and encompass a substantial portion of the circumference of the leg portion so that the front portion of the wearer's leg is subjected to direct pressure when the bladder is expanded while the rear portion of the

50

100

leg is subjected to a contracting pressure as the stocking tightens around the leg. For example, the pocket may extend widthwise substantially for half the circumference of the leg portion of the stocking.

The expandable bladder may be easily connected and disconnected to the pumping and controlling unit for periodically expanding the bladder to exert pressure against the leg of the wearer. The pocket may include an outer layer formed by the seamless knitted leg portion of the stocking and an inner layer formed of a substantially rectangular piece of fabric positioned inside of the leg and being sewn on three sides to the leg of the stocking with one end being open to permit easy placement and removal of the expandable bladder in the pocket. The substantially rectangular piece of fabric forming the inner layer of the pocket prevents the bladder from direct engagement with the leg and is provided with inwardly extending terry loops to provide a soft cushion against the leg of the wearer.

From another aspect, the invention consists in stocking for use with apparatus for applying pulsating pressure to a leg of the wearer, said stocking comprising a seamless knitted leg portion fashioned generally to conform to the configuration of the leg on which said stocking is to be worn, said seamless knitted leg portion being sufficiently stretchable to permit easy placement and removal, a seamless knitted foot portion adapted to cover the foot and toes of the wearer, and a longitudinally extending pocket in said leg portion of said stocking, said pocket being arranged to extend from at least adjacent the ankle of the wearer to a position immediately below the knee.

In order that the invention may be more readily understood, reference will be made to the accompanying drawings, in which:—

Figure 1 is an isometric view of the pressure applying apparatus, illustrated in the form of a pair of stockings positioned on the legs of a patient and illustrating the manner in which the stockings are connected to the pumping and controlling unit for periodic expansion to apply pulsating pressure against the legs;

Figure 2 is an enlarged isometric view, with parts broken away, of one of the stockings as it would appear on the leg;

Figure 3 is an enlarged fragmentary vertical sectional view through the upper end portion of the stocking, being taken substantially along the line 3-3 in Figure 2;

Figure 4 is a transverse vertical sectional view taken substantially along the line 4-4 in Figure 1 and illustrating the bladder in partially relaxed or contracted condition;

Figure 5 is a view similar to Figure 4 but showing the bladder in expanded position and with the stocking applying pressure to the leg of the wearer; and

Figure 6 is a greatly enlarged view of a small fragmentary portion of the knit fabric forming the leg and foot of the stocking, being taken in the dotted line area 6 in Figure 2.

The pressure-applying apparatus illustrated and described includes an appliance in the form of a pair of stockings with seamless knitted leg and foot portions adapted to fit the legs of the wearer. Each stocking includes a seamless knitted leg portion 10 formed on a circular hosiery knitting machine with fashioning gradually to reduce the size of the stitch loops so that the leg portion 10 generally conforms to the configuration of the leg.

The leg portion 10 is preferably knitted from the top downwardly in Figure 2 and includes an upper cuff portion 11, illustrated in the form of a turned welt with elastomeric yarn incorporated therein, to aid in supporting the upper end of the stocking. The leg portion 10 is sufficiently stretchable to permit easy placement and removal of the stocking on the leg but is otherwise substantially unstretchable and is preferably knitted of a non-stretchable yarn in a knit and float stitch construction, such as illustrated in Figure 6. This stitch construction provides an open mesh appearance to provide ventilation and limits the stretchability of the leg portion. The stocking is relatively sheer and is knitted of non-stretchable yarn, such as nylon, within the range of about 50 to 300 denier. It has been found that a satisfactory stocking can be produced by utilizing 100 denier nylon in the leg portion 10. As will be recognized, the alternate courses C-1 and C-3 have stitch loops formed in every wale while the intervening courses C-2 and C-4 have stitch loops formed in every other wale with the yarn being floated across the remaining wales. The floats in the course C-2 are offset relative to the floats in the course C-4.

A longitudinally extending pocket is provided in the leg portion 10 of the stocking and extends from at least adjacent the ankle of the wearer to a position immediately below the knee. However, it is to be understood that the pocket could extend down into any portion of the foot of the stocking and the stocking and pocket may extend upwardly above the knee and cover the thigh area, if desired. The stocking is provided with a foot portion 12 including a heel pocket 13 and a toe pocket 14. A toe inspection opening 15 is provided adjacent the toe pocket 14 and normally extends across and beneath the toes of the

wearer so that the toes of the patient may be exposed through the toe opening 15 for inspection by the doctor. The heel and toe portions 13, 14 are preferably knitted in the usual manner by reciprocation of the needle cylinder while fashioned widened and narrowed gussets are formed. The heel and toe portions 13, 14 are preferably knitted with plain stitch loops and may be formed of stretchable yarn.

The longitudinally extending pocket in the seamless knit leg portion 10 of the stocking should have a width which is greater than one-fourth the circumference of the leg portion 10 of the stocking but the width should be less than the entire circumference of the leg portion in both the extended and unextended conditions. The pocket is centered along the front of the leg portion 10 and is illustrated as encompassing substantially one-half the circumference of the leg. The pocket includes an outer layer formed by the seamless knitted leg portion 10 of the stocking and an inner layer 16 formed by a substantially rectangular piece of material, such as fabric positioned inside of the leg.

The rectangular piece of fabric forming the inner layer 16 is longer in the longitudinal direction than in the widthwise direction and seams 17, 18 connect opposite longitudinal sides of the inner layer 16 to the leg 10 while a seam 19 connects the lower end of the inner layer 16 to the leg portion 10 to form a pocket which is open at its upper end. The upper end of the inner layer 16 is preferably turned to form a welt 20 and the piece of fabric forming the inner layer 16 is knitted with terry loops provided on the inner surface, as illustrated in Figure 3, to provide a cushion against the leg of the wearer and also absorb moisture.

The apparatus also includes an expandable bladder, broadly indicated at *B*, which generally conforms to the size of the pocket and is positioned within the pocket. The expandable bladder *B* includes respective inner and outer sheets of flexible plastic material 21, 22 which are heat sealed together around the outer peripheral edges thereof. An inlet nozzle, in the form of an elbow 23 is provided at the lower end of the bladder *B* and passes through a small opening in the leg portion 10. The elbow 23 is communicatively connected with the space between the inner and outer layers 21, 22 of the bladder.

Of course, the bladder *B* may also be formed with other types of material and although it is illustrated as being substantially rectangular, the bladder may be formed in other configurations. While the bladder *B* is illustrated as being supported in a pocket in the stocking, which includes

an inner layer 16 formed from a simple piece of material, it is to be understood that the inner layer of the pocket may be formed of any other suitable construction which will support the bladder in the leg portion 10.

The apparatus also includes a pumping and controlling unit, indicated at 26, for periodically expanding the bladders *B*. Lines 24, 25 are connected at one end to the pumping and controlling unit 26 and their other ends are connected to the bladders *B* in the stockings on the legs of the patient (Figure 1). The lines 24, 25 can be disconnected from the elbows 23 so that the bladders *B* may be easily removed through the open upper ends of the pockets in the leg portions 10 of the stockings. The ease of removal and replacement of the bladders *B* permits use of the bladders in other stockings and permits laundering of the stockings without harm to the bladders.

The pumping and controlling unit 26 is preferably provided with suitable gauges to indicate the amount of pressure applied through the lines 24, 25 and a timing device for alternately applying pressure to each of the legs of the wearer of the stockings. The amount of pressure applied and the time cycle may be varied, depending upon the condition of the patient. Generally, it has been found that a pressure of 50 millimeters of mercury applied to one leg for a period of approximately 90 seconds and then the same pressure applied to the other leg for the next 90 second period will stimulate venous blood flow sufficiently to reduce the likelihood of venous thrombosis. While the pressure is being applied to one leg, the pressure on the other leg is released to permit the blood to be resupplied to this leg. The means for periodically expanding the bladders *B* in an alternating manner to exert pressure against the legs of the wearer may include a pump for pumping any type of fluid, such as air, into the bladders *B*.

As illustrated in Figure 5, when the proper amount of pressure is built up in the bladder *B*, direct pressure is applied against the front portion of the leg and the remaining portion of the leg portion 10 of the stocking is circumferentially contracted and maintained in a contracted condition for the desired period of time, approximately 90 seconds. When the pressure in the bladder is released, the pressure against the leg of the wearer is also released and the pressure is not again applied until the leg has had an opportunity to be resupplied with blood. This repeated cycle of expanding and contracting stimulates the venous blood flow in the legs of the

wearer and thereby reduces the likelihood of venous thrombosis in the patient.

Although the apparatus of the present invention has been described as being of particular value in stimulating fluid flow to reduce the likelihood of venous thrombosis, it is to be understood that the apparatus also provides other benefits. For example, the application of pulsating pressure provides a massaging effect which simulates normal muscle and tissue activity which, in turn, promotes reduction of edema (the presence of large amounts of fluid) and release of clot dissolving substances and produces other desirable chemical changes.

The pulsating pressure applying apparatus of the present invention is thus economically formed and is lightweight and comfortable for wear by either bed or ambulant patients. The open mesh nature of the stocking permits ventilation of the leg. The stockings may be easily connected to the pumping and controlling unit for applying the required amount of pulsating pressure to the legs of the wearer. Because of the economical cost of the stockings, they may be discarded after use or the bladders may be removed from the pocket and the stockings may be laundered for reuse.

#### WHAT WE CLAIM IS:—

Apparatus for applying pulsating pressure to a leg of a human, comprising a stocking comprising a seamless knitted leg portion generally conforming to the configuration of the leg on which said stocking is to be worn, said seamless knitted leg portion being sufficiently stretchable to permit easy placement and removal, a pocket extending longitudinally of the leg portion, said pocket being arranged to extend from at least adjacent the ankle of the wearer to a position immediately below the knee,

and an expandable bladder positioned in said pocket and extending longitudinally of said leg portion, and pumping and controlling means for periodically expanding said bladder to exert direct pressure against the portion of the leg covered thereby and circumferentially to contract said leg portion and apply pressure to the corresponding portion of the leg encompassed by said leg portion.

2. A stocking for use with apparatus for applying pulsating pressure to a leg of the wearer, said stocking comprising a seamless knitted leg portion fashioned generally to conform to the configuration of the leg on which said stocking is to be worn, said seamless knitted leg portion being sufficiently stretchable to permit easy placement and removal, a seamless knitted foot portion adapted to cover the foot and toes of the wearer, and a longitudinally extending pocket in said leg portion of said stocking, said pocket being arranged to extend from at least adjacent the ankle of the wearer to a position immediately below the knee.

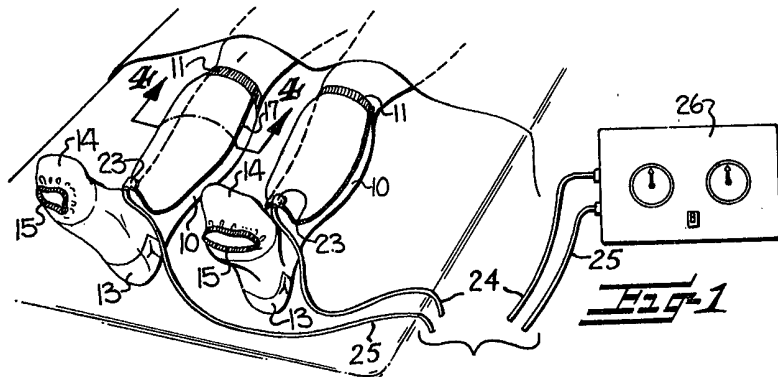
3. Apparatus or a stocking as claimed in Claim 1 or 2, wherein the width of the pocket is greater than one-fourth the circumference of the knitted leg portion.

4. Apparatus or a stocking as claimed in Claim 1, 2 or 3, wherein the pocket extends up the front of the seamless knitted leg portion with said pocket being centered on the front of the leg portion.

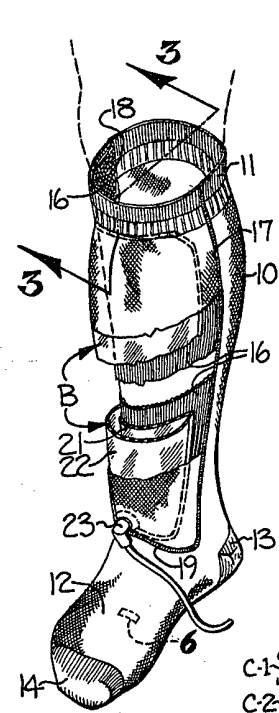
5. Apparatus or a stocking for applying pulsating pressure to a leg of a human, substantially as hereinbefore described with reference to the accompanying drawings.

BARON & WARREN,  
Chartered Patent Agents,  
16 Kensington Square,  
London W8 5HL.

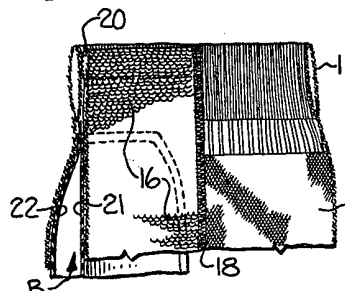
This drawing is a reproduction of the Original on a reduced scale



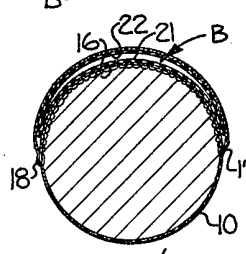
**Fig-1**



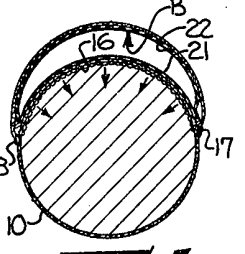
**Fig-2**



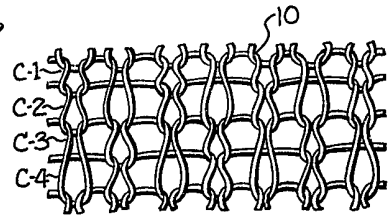
**Fig-3**



**Fig-4**



**Fig-5**



**Fig-6**