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(54) **PRESSURE APPLICATION GARMENT**

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Description

FIELD OF INVENTION

[0001] The invention relates to a pressure application garment for applying pressure to the body of a subject, intended to apply pressure to the abdomen of the subject as well as to the lower limbs of the subject. In particular, the invention relates to a pressure application garment for applying pressure to the body of a subject in line with the "Lower Body Positive Pressure" (LBPP) principle, in order to enable revascularisation of the brain by mobilisation of the blood contained in the lower body of the subject. The present specification further describes a method, not being part of the invention, for placing such a pressure application garment on a subject, and also a method, not being part of the invention, for applying pressure to the body of a subject.

BACKGROUND OF INVENTION

[0002] The "Lower Body Positive Pressure" (LBPP) principle involves applying constant low pressure levels, that in particular lie in the range 10 to 40 mmHg, to the abdomen of a subject as well as to the lower limbs of the subject, whereby the pressure applied to the abdomen is strictly less than the pressure applied to the lower limbs. This concept was initially developed to ensure an adequate volume distribution in the infra- and supra-aortic areas, in particular for microgravity flight. LBPP has been documented to displace blood from the lower body to the upper body, thus increasing the central cardiopulmonary blood volume.

[0003] WO2008104861A1 discloses the use of LBPP for treating individuals suffering from a vascular deficiency affecting the upper part of the body, in particular a cerebral vascular deficiency or ocular disorder. This document describes the application of LBPP using anti-gravitational trousers or Medical Anti-Shock Trousers (MAST), such as those marketed by the company LIFE SUPPORT PRODUCTS INC, Saint Louis, Missouri, United States. Such medical anti-shock trousers comprise three independent air chambers allowing a positive pressure to be respectively applied to the abdomen and to the two lower limbs of a subject. The air chambers are each connected to a pneumatic extremity and manually inflated using a pump, whereby a pressure gauge is provided at each air chamber in order to provide instantaneous pressure values.

[0004] US9554964 B1 discloses a differential pressure body suit with external support against body suit migration. Such body suit may comprise a close-fitting, multi-layered suit sealed against a mammal's skin to contain the differential pressure, or a looser-fitting suit that bends at the mammal's joints with minimal force. External support means include either fixed or movable mechanical supports attached to the body suit, extraordinary air pressure levels for making the body suit rigid. A cyclic control system can turn the differential pressure condition within the body suit on and off on a selective basis to accommodate the movement of the legs of the mammal.

[0005] A pair of medical anti-shock trousers has a rigid structure, which complicates the placement thereof for bedridden subjects or for subjects suffering from limb paralysis, such as subjects that have suffered a stroke or cerebrovascular accident (CVA). Moreover, medical anti-shock trousers are generally available in one size, which does not fit all morphologies. Yet, if the morphology of a subject is not compatible with the size of the medical anti-shock trousers, there is a risk that the pressure values indicated by the pressure gauges do not correspond to the pressures effectively applied to the body parts of the subject. This makes the application of pressure to the body of a subject unreliable. The implementation of LBPP with medical anti-shock trousers further requires manual adjustment and monitoring of the pressures over time in order to guarantee that the pressures applied to the subject remain constant at each part of the body, which is time-consuming.

[0006] The invention more particularly aims to overcome these drawbacks by proposing a pressure application garment allowing homogeneous and constant pressure levels to be applied in an automatic, reliable and precise manner, to body parts of a subject.

SUMMARY

[0007] For this purpose, the invention relates to a pressure application garment for applying pressure to the body of a subject, comprising three active parts which are one abdominal active part intended to surround the subject's abdomen and two lower active parts each intended to surround one of the subject's lower limbs, each of the active parts comprising at least one bladder fillable with a fluid so as to obtain a homogeneous positive pressure applied by the active part to the whole of the corresponding body part of the subject among the abdomen and the lower limbs, wherein the pressure application garment comprises:

- for each active part, at least one interface pressure sensor configured to measure a surface pressure at the interface between the active part and the corresponding body part of the subject while being positioned between the active part and the corresponding body part of the subject,
- a control unit comprising a receiving module configured to receive the interface pressure measurements from the one or more interface pressure sensors of each active part, and a driving module configured to drive, based on the interface pressure measurements received by the receiving module for each active part, at least one injection device for injecting fluid into the one or more fillable bladders of the active part, so as to maintain a predefined interface pressure value for each active part, the prede-

fined interface pressure value for the abdominal active part being strictly less than the predefined interface pressure value for each lower active part.

[0008] A contribution of the invention is that the interface pressure taken into account by the control unit for each active part, which is measured by means of at least one interface pressure sensor positioned between the active part and the corresponding body part of the subject, is representative of the pressure actually applied by the active part to the corresponding body part of the subject, which allows an automatic, reliable and accurate application of pressure by means of the pressure application garment according to the invention. On the contrary, if the pressure taken into account by the control unit for each active part is only the filling pressure of each bladder of an active part, in particular measured using a pressure gauge installed in a connection pipe between the bladder and an injection device for injecting fluid into the bladder, the control of the applied pressure is not reliable because the filling pressure of a bladder is not systematically representative of the pressure actually applied by the bladder on the corresponding body part of the subject, which depends on the degree of adjustment of the garment around the body of the subject.

[0009] According to one feature, the control unit is configured to maintain:

- for the abdominal active part, a first predefined interface pressure value that lies in the range 10 to 20 mmHg, preferably equal to about 10 mmHg,
- for each of the two lower active parts, a second predefined interface pressure value that lies in the range 20 to 40 mmHg, preferably equal to about 20 mmHg,

the first predefined interface pressure value for the abdominal active part being strictly less than the second predefined interface pressure value for each lower active part.

[0010] The pressure application garment according to the invention is thus configured to automatically apply pressure to the body of a subject in line with the "Lower Body Positive Pressure" (LBPP) principle, creating a pressure gradient between the abdomen on the one hand and the lower limbs on the other hand, in order to enable revascularisation of the brain by mobilisation of the blood contained in the lower body of the subject. More specifically, the pressure application garment according to the invention allows the brain to be revascularized in a passive manner by increasing the circulating plasma volume. The control unit allows the interface pressure to be automatically controlled and the injection of fluid into the one or more bladders of each active part to be servo-controlled as a function of the interface pressure measurements and the interface pressure setpoint, which guarantees the application of a constant pressure throughout the duration of a session, without manual intervention.

[0011] It should be noted that the therapeutic passband for application of the LBPP regime must lie in the range 20 to 40 mmHg on the lower limbs, without exceeding 40 mmHg. More specifically, it has been seen that above 40 mmHg, the increase in cardiac preload (or filling pressure of the heart) is so great that it stimulates the sympathetic nervous system, which has a reflex action on the vascular tone of the large-sized arterial highways, which results in vasodilation as well as reduced arterial blood pressure. This in particular results, for subjects having suffered a stroke, in reduced cerebral perfusion since cerebral autoregulation has ceased as a result of the stroke. The application of a pressure value in excess of 40 mmHg to the lower limbs is thus harmful. Under these conditions, the pressure application garment according to the invention is configured to maintain a second predefined interface pressure value of less than or equal to 40 mmHg for each of the two lower active parts.

[0012] According to one feature, the control unit is configured to receive measurements representative of the subject's blood pressure, in particular taken continuously during the treatment session, and to control the or each injection device for injecting fluid into the one or more fillable bladders of the lower active parts so as to keep the subject's blood pressure values below predefined thresholds, in particular so as to keep the systolic blood pressure (SBP) strictly below 220 and the diastolic blood pressure (DBP) strictly below 120.

[0013] According to one feature, the control unit is configured to receive measurements representative of the intracerebral blood flow of the subject, in particular obtained by transcranial Doppler, and to correlate the change in the measurements representative of the intracerebral blood flow with the pressure gradient applied to the body parts of the subject by means of the pressure application garment. This configuration advantageously allows a practitioner to select a therapeutic goal, for example to aim for an average increase of 30% in intracerebral blood flow compared to that at the start of the treatment session. An alert can thus be created when said therapeutic goal has been reached, whereby the practitioner decides whether or not to continue the session as a function of the functional results obtained.

[0014] The provision of interface pressure sensors for each of the three active parts allows the pressure values effectively applied to the abdomen and lower limbs of the subject to be controlled, whereby each interface pressure sensor is directly positioned between the active part and the corresponding body part of the subject. In particular, in the case of LBPP, the pressure applied to the abdomen advantageously has a value that lies in the range 10 to 20 mmHg, preferably equal to about 10 mmHg, and the pressure applied to each lower limb advantageously has a value that lies in the range 20 to 40 mmHg, preferably equal to about 20 mmHg. Control using the interface pressure sensors further guarantees that the pressures applied remain constant on each body part of the subject

throughout the duration of a pressure application session, which in particular lasts about 90 minutes in the case of LBPP.

[0015] Preferably, each active part of the pressure application garment comprises a single fillable bladder in order to simplify the design of the garment. For each active part, the number and arrangement of the interface pressure sensors are suitable for providing pressure measurements representative of the pressure effectively applied to the body part of the subject, while in particular avoiding the positioning of sensors on bony parts.

[0016] By way of example, in one specific embodiment:

- the abdominal active part of the pressure application garment comprises three interface pressure sensors, comprising an anterior central sensor intended to be positioned in front of the centre of the abdomen, and two lateral sensors intended to be positioned on the sides of the abdomen;
- each lower active part of the pressure application garment comprises three to five interface pressure sensors, comprising one or two lower sensors intended to be positioned on the calf, in particular a posterior lower sensor on the posterior face of the calf and possibly a medial lower sensor on the medial face of the calf, and two or three upper sensors intended to be positioned on the thigh, in particular a posterior upper sensor on the posterior face of the thigh, a medial upper sensor on the medial face of the thigh and possibly an anteromedial upper sensor on the anteromedial face of the thigh.

[0017] The size, and more particularly the measurement surface area, of each interface pressure sensor can differ from one sensor to another, in particular as a function of the location thereof. Thus, by way of example, for the abdominal active part, the anterior central sensor can be chosen to have a measurement surface area that is greater than the measurement surface area of the lateral sensors.

[0018] According to one aspect of the invention, for each fillable bladder, the volume for receiving fluid is delimited by a flexible layer that is impervious to said fluid, in particular having a textile and/or plastic material base. Preferably, the material of the impervious layer has elasticity properties that can be obtained, for example, by incorporating elastane into the material of the layer or, in the case of a layer comprising a woven textile, by way of weaving the textile. Advantageously, the material of the impervious layer is selected such that it can be washed, on the outer surface thereof, i.e. the outwards-facing surface of the bladder.

[0019] In one embodiment, the fluid filling each bladder is air, whereby the flexible layer delimiting the volume of each bladder is thus airtight in a given pressure range, compatible with the air pressures that will be imposed in the bladder in order to exert the positive pressure required on the body of the subject. Such an airtight layer can in particular be a layer of plastic material, either self-supporting or deposited on a substrate. In particular, the airtight layer can comprise the superimposition of a woven or nonwoven textile layer, in particular having a nylon, polypropylene, polyester, polyamide or cotton base, and a coating layer, in particular having a polyurethane, silicone, polyvinyl chloride (PVC) or other plastic material base. Preferably, the weight per unit area of the textile layer lies in the range 150 to 250 g/m^2. One example of a material that can be used to form the airtight layer within the scope of the invention comprises a knitted nylon layer, one side whereof is coated with a polyurethane coating layer. Thanks to the airtightness of the flexible layer forming each of the bladders, no air chamber is necessary, since the bladder itself acts as an air chamber. This results in a flexible structure of each fillable bladder, which improves the wearing comfort of the pressure application garment and facilitates the placement thereof on a subject, including on a bedridden or paralysed subject.

[0020] Advantageously, each active part is a flexible part that can pass between a deployed configuration, allowing the placement thereof around the corresponding body part of the subject, and an adjusted configuration wherein it is adjusted around the corresponding body part of the subject. In the adjusted configuration, the active part has a tubular shape and the inwards-facing wall is capable of applying a positive pressure to the body part of the subject.

[0021] According to one embodiment, each active part is a part having a textile and/or plastic material base comprising a first portion and a second portion superimposed on one another and impervious to said fluid, which define therebetween the volume for receiving the fluid of each fillable bladder. In the adjusted configuration of the active part on the corresponding body part of the subject, the first portion is directed inwards, whereas the second portion is directed outwards. The first and second portions are advantageously connected to one another by a peripheral seam that is impervious to said fluid, or by any other peripheral connection means that is impervious to said fluid.

[0022] According to one advantageous feature, each interface pressure sensor is rigidly secured to the inner wall of the active part, i.e. the wall that is intended to be directed towards the corresponding body part of the subject. In particular, the interface pressure sensor can be housed in a compartment provided for this purpose on the inner wall of the active part. Alternatively, the interface pressure sensor can be rigidly secured to the inner wall of the active part by any other appropriate means, in particular by sewing or bonding, etc.

[0023] Advantageously, each fillable bladder of the pressure application garment comprises at least one filling end piece designed to be connected to a fluid injection device. For each fillable bladder, the pressure application garment is further provided with at least one filling pressure sensor for sensing the pressure to which the bladder is filled with fluid, such as a pressure gauge. In particular,

for each fillable bladder, said filling pressure sensor can be installed in a connection pipe between a filling end piece of the bladder and the corresponding fluid injection device. Advantageously, the pressure application garment comprises automatic servo-control means between the one or more filling pressure sensors and the one or more interface pressure sensors of each active part. In particular, the one or more filling pressure sensors of each active part can be connected to the control unit such that an automatic servo-control system can be set up between the filling pressure sensors and the interface pressure sensors of each active part in order to obtain a constant, controlled pressure applied to each body part of the subject throughout the duration of a pressure application session. In the case of LBPP, the principle involves the mobilisation of blood in the lower body, which must be constant, controlled and autoregulated in order to compensate for losses while not being too high in order to prevent deleterious effects. Such constant and controlled mobilisation of the blood requires the application of constant, controlled and autoregulated pressure to each body part of the subject throughout the duration of a session.

[0024] Within the scope of the invention, the injection device for injecting fluid into the one or more fillable bladders of each active part of the pressure application garment can be a pump, or a compressed air supply system such as those available in hospitals. In one advantageous embodiment, the injection device for injecting fluid into the one or more fillable bladders of each active part of the pressure application garment is a portable device, which allows the pressure application garment to be used during the transport of a subject. In one embodiment, the injection device for injecting fluid into the one or more fillable bladders of each active part of the pressure application garment is a portable pump incorporated into the garment.

[0025] According to one advantageous embodiment, each interface pressure sensor is a pneumatic sensor connected in a sealed manner to a measurement module, in particular by means of a flexible tube. The use of such a pneumatic sensor has the advantage of limiting the electronics that must be directly embedded in the active parts of the pressure application garment. In particular, the pneumatic sensor can be a sensor as disclosed in patent document WO2009072011A1, comprising a cushion having a flexible polymer casing, for example made of silicone, capable of receiving, in the inner volume thereof, a predetermined volume of injected air corresponding to a known positive pressure. The measurement module comprises a pressure gauge and an air injection piston, which are in fluid communication with one another and with the pneumatic sensor. The measurement module of each sensor is configured to transmit the interface pressure measurements to the receiving module of the control unit. This transmission of data can be carried out by any means, in particular by wired connection means or by wireless means such as Bluetooth or WiFi. Advantageously, the measurement module of each pressure sensor is integrated into a housing of the control unit.

[0026] Alternatively, each interface pressure sensor can be an electronic sensor, in particular a sensor that measures a force applied to a surface at the interface between the active part and the corresponding body part of the subject, from which an interface pressure is calculated. Each electronic sensor is configured to transmit the interface pressure values to the receiving module of the control unit. This transmission of data is preferably carried out by wireless connection means such as Bluetooth or WiFi.

[0027] According to one aspect of the invention, each active part comprises adjustment means for adjusting the active part around the corresponding body part of the subject, so as to take on, as best as possible, the shape of the corresponding body part of the subject and obtain the most effective and most homogeneous application of pressure possible to the corresponding body part of the subject.

[0028] According to one feature, for each active part, the adjustment means comprise patterning elements of the active part, capable of applying the active part against the corresponding body part of the subject when filling the or each fillable bladder of the active part.

[0029] The patterning elements of each active part allow the active part to be patterned in the filled state such that it is pressed against the corresponding body part of the subject and applies thereto a controlled and predictable surface pressure. This thus prevents any "buoy" effect when filling each active part, whereby the active part inflates without applying a controlled and uniform pressure to the body part of the subject.

[0030] In the particular example of LBPP, the specific patterning of the pressure application garment according to the invention allows the required pressure values to be applied in a reliable and controlled manner, i.e. a pressure applied to the abdomen having a value advantageously lying in the range 10 to 20 mmHg, preferably equal to about 10 mmHg, and a pressure applied to each lower limb having a value advantageously lying in the range 20 to 40 mmHg, preferably equal to about 20 mmHg.

[0031] In the case where each active part of the pressure application garment comprises a single fillable bladder, the presence of the patterning elements of each active part is even more important, in order to take on the shape of the corresponding body part of the subject upon filling of the fillable bladder of the active part, and to obtain a homogeneous application of pressure, in particular for the lower active parts which have a large filling volume.

[0032] According to one feature, for each active part of the pressure application garment, the patterning elements comprise at least one sculptural line of the layer delimiting the fluid-receiving volume of each fillable bladder of the active part, in particular a seam, which requires the shaping of the active part in the filled state in order

to take on the shape of the corresponding body part of the subject. As a whole, the patterning elements comprise raised patterns of the active part, capable of applying, or pressing, the active part against the corresponding body part of the subject when filling the or each fillable bladder of the active part. The raised patterns can be sculptural seams or thermofusing of the textile-based and/or plastic material-based flexible layer forming the one or more bladders of the active part.

[0033] The adjustment means are designed for adjusting each active part of the pressure application garment around the corresponding body part of the subject, in order to take on, as best as possible, the shape of the corresponding body part of the subject and obtain the most effective and most homogeneous application of pressure possible. In the adjusted configuration, the active part generally has a tubular shape.

[0034] According to one feature, the adjustment means comprise closing elements of the active part, allowing for the adjustment of the circumference of the active part around the corresponding body part of the subject, preferably in an adapted manner throughout the length of the tubular active part. According to one specific embodiment, the closing elements comprise at least one pair of gripping strips, comprising a first strip provided with hooks and a second strip provided with loops, which extend over the length of the active part. Alternatively, or in conjunction therewith, the closing elements can comprise a plurality of tightening strap and clip systems distributed over the length of the active part.

[0035] According to one feature, the lower active parts of the pressure application garment are connected to the abdominal active part so as to facilitate the placement of the garment on the body of the subject. According to one feature of the invention, each lower active part comprises, at the end thereof opposite the abdominal active part, a plurality of segments capable of being folded back on top of one another in order to adapt the length of the lower active part to the length of the corresponding lower limb of the subject. Similarly, the abdominal active part can comprise, at one end, a plurality of segments capable of being folded back on top of one another in order to adapt the length of the abdominal active part to the length of the abdomen of the subject. Preferably, for each active part, in the state wherein the segments are folded back on top of one another, the portion of the fillable bladder corresponding to the folded segments is not filled with fluid. In order to further increase the adaptability of the pressure application garment to the morphology of each subject, the presence of segments that can be folded or rolled up, can be combined with the provision of different garment sizes, for example S, M, L, XL.

[0036] According to one aspect of the invention, at least one of the lower active parts of the pressure application garment comprises an inner tightening element which, when the lower active part is in place around the lower limb of the subject, is capable of surrounding the thigh of the subject and of applying a tightening force thereto. The inner tightening element can thus act as a tourniquet, procuring vein occlusion at the thigh of the subject. Preferably, the inner tightening element is a cuff intended to be inflated to a standardised pressure (50 mmHg). The application of a vein occlusion at the thigh of the subject using the inner tightening element is advantageously combined with a measurement of the variations in the volume of the lower limb as a result of this occlusion and the release thereof, in order to assess the mobilisable blood volume (or "venous bed").

[0037] In the case where the estimation of the mobilisable blood volume is zero or less than a predefined value, an injection of liquid into the venous network, in particular of 500 mL normal saline, can be carried out before the pressure application session using the pressure application garment according to the invention.

[0038] Different plethysmography techniques can be used to measure the variations in the volume of the lower limb, in particular air plethysmography, for example by measuring the variations in air pressure in the lower active part of the pressure application garment forming an air-filled sleeve around the lower limb of the subject. More specifically, the implementation principle is as follows: the inner tightening element surrounding the thigh of the subject is inflated so as to procure vein occlusion at the thigh of the subject; the lower limb of the subject thus distends as a result of the blockage of the venous return; the thigh tourniquet is then released, and the lower limb of the subject recovers its initial volume since the venous return resumes normal flow. The variation in the volume of the lower limb provides an estimation of the mobilisable liquid volume, including the lymph and the venous blood. Advantageously, the pressure application garment according to the invention not only allows vein occlusion to be obtained by way of the inner tightening element of the lower active part, but also the measurement, by air plethysmography, of the difference between the volume of the lower limb when at rest and the volume of the lower limb a few minutes after application of the vein occlusion, by directly using the lower active part of the pressure application garment, which forms a sleeve around the lower limb of the subject, and by measuring the volume of air in this sleeve before and after application of the vein occlusion.

[0039] According to one advantageous feature, the pressure application garment comprises a protective textile, capable of being replaced upon each use of the garment, which is secured in a removable manner to the inner wall of one or of each active part of the garment, i. e. the wall of the active part that is facing inwards in the configuration in which the active part is adjusted around the corresponding body part of the subject. The protective textile acts as a "second skin", preventing irritation of the subject's skin as a result of contact with the active part. The protective textile also prevents fouling of the active part. Preferably, the protective textile is arranged on the inner wall of each active part, while being tensioned, and is held tensioned by any appropriate means,

such as gripping strips or other means. More specifically, it is important to avoid any folds in the protective textile within the scope of a pressure application session, in particular LBPP. Examples of textiles suitable for use as the protective textile are microfibre textiles having a weight per unit area that lies in the range 40 to 170 g/m^2.

[0040] The pressure application garment as described here above enables the implementation of a method, not being part of the invention, for placing it on a subject, said method comprising steps in which:

- each active part of the pressure application garment in the deployed configuration is positioned facing the corresponding body part of the subject;
- each active part of the pressure application garment in the deployed configuration is placed into an adjusted configuration in which it is adjusted around the corresponding body part of the subject;
- each fillable bladder of the pressure application garment is filled with fluid until a measurement is obtained, for each active part, from each interface pressure sensor of the active part that is substantially equal to a predefined interface pressure value for said active part.

[0041] In the case of a subject for whom placement of the pressure application garment can only take place with the subject in the laid-back position, the method for placing the pressure application garment, as described above, comprises steps in which:

- the pressure application garment is placed on a bed with each of the active parts in the deployed configuration;
- the subject is laid on their back on top of the pressure application garment, while positioning each body part of the subject on the corresponding active part of the garment;
- each active part of the pressure application garment in the deployed configuration is placed into an adjusted configuration in which it is adjusted around the corresponding body part of the subject;
- each fillable bladder of the pressure application garment is filled with fluid until a measurement is obtained, for each active part, from each interface pressure sensor of the active part that is substantially equal to a predefined interface pressure value for said active part.

[0042] The pressure application garment further enables the implementation of a method, not being part of the invention, for applying pressure to the body of a subject according to a predetermined protocol, including a first predefined pressure value to be applied to the subject's abdomen and a second predefined pressure value to be applied to each of the subject's lower limbs for a predefined duration, using a pressure application garment comprising three active parts, which are one abdominal active part intended to surround the subject's abdomen and two lower active parts each intended to surround one of the subject's lower limbs, each of the active parts comprising at least one bladder fillable with a fluid so as to obtain a homogeneous positive pressure applied by the active part to the whole of the corresponding body part of the subject among the abdomen and the lower limbs, the pressure application garment comprising, for each active part, at least one interface pressure sensor configured to measure a pressure at the interface between the active part and the corresponding body part of the subject, while being positioned between the active part and the corresponding body part of the subject, said method comprising steps in which:

- each active part of the pressure application garment in the deployed configuration is positioned facing the corresponding body part of the subject;
- each active part of the pressure application garment in the deployed configuration is placed into an adjusted configuration in which it is adjusted around the corresponding body part of the subject;
- each fillable bladder of the pressure application garment is filled with fluid until a measurement is obtained, for each active part, from each interface pressure sensor of the active part that is substantially equal to the predefined pressure value to be applied to the body part of the subject that corresponds to said active part;
- during the predefined duration, for each active part, the interface pressure measurements received for each active part are used as a basis to drive at least one injection device for injecting fluid into the one or more fillable bladders of the active part, so as to maintain a measurement from each interface pressure sensor of the active part that is substantially equal to the predefined pressure value to be applied to the body part of the subject that corresponds to said active part.

[0043] According to one version of the method described here-above for applying pressure, the or each fluid injection device is driven automatically using a control unit.

[0044] According to another version of the method for applying pressure described here-above, the predetermined protocol is a LBPP treatment, wherein:

- the first predefined pressure value to be applied to the subject's abdomen lies in the range 10 to 20 mmHg and is preferably equal to about 10 mmHg,
- the second predefined pressure value to be applied to each of the subject's lower limbs lies in the range 20 to 40 mmHg and is preferably equal to about 20 mmHg,
- the first predefined pressure value for the abdominal active part is strictly less than the second predefined pressure value for each lower active part,

- the predefined duration is equal to about 90 minutes.

[0045] According to a further version, the method for applying pressure described here-above comprises, prior to the step of filling each fillable bladder of the pressure application garment with fluid so as to apply the predefined pressure values to the body parts of the subject, a step of measuring the mobilisable blood volume, comprising the application of a vein occlusion on one of the subject's lower limbs and measuring, by plethysmography, variations in the volume of said lower limb as a result of said occlusion and the release thereof.

[0046] According to one feature, the vein occlusion is applied on the subject's lower limb by means of an inner tightening element of one of the lower active parts of the pressure application garment, said inner tightening element being, when the lower active part is in place around the corresponding lower limb of the subject, capable of surrounding the thigh of the subject and of applying a tightening force thereto.

[0047] According to one feature, the measurement of the variations in the volume of the lower limb as a result of the occlusion and the release thereof is carried out by air plethysmography, by measuring the variations in air pressure in the lower active part of the pressure application garment forming an air-filled sleeve around the lower limb of the subject.

[0048] According to one feature, when the mobilisable blood volume measured is less than a predefined threshold, an injection of normal saline into the venous network of the subject is carried out, prior to applying the predefined pressure values to the body parts of the subject by means of the pressure application garment, in order to increase the mobilisable blood volume.

DESCRIPTION OF THE DRAWINGS

[0049] Features and advantages of the invention will become apparent from the following description of embodiments of a pressure application garment, provided merely by way of example and with reference to the appended drawings in which:

- **Figure 1** is a front view of a pressure application garment according to a first embodiment of the invention;
- **Figure 2** is a rear view of the pressure application garment of Figure 1;
- **Figure 3** is a front view of the pressure application garment of Figure 1 with the active parts thereof in a deployed configuration;
- **Figure 4** is a sectional view at a larger scale along the plane IV-IV of Figure 3;
- **Figure 5** is a front view of the pressure application garment of Figure 1 placed on a subject and connected to air injection devices;
- **Figure 6** is a view similar to that of Figure 1 for a pressure application garment according to a second embodiment of the invention;
- **Figure 7** is a view similar to that of Figure 5 for a pressure application garment according to a third embodiment of the invention, from which the air injection devices have been omitted for better visibility; and
- **Figure 8** is a rear view of the pressure application garment of Figure 7.

ILLUSTRATIVE EMBODIMENTS OF THE INVENTION

[0050] As shown in Figures 1 to 5, the pressure application garment 1 of the first embodiment comprises three active parts, i.e. one abdominal active part 3, intended to surround the abdomen A of a subject, and two lower active parts 4, 5, each of which is intended to surround one leg, or lower limb L_1, L_2, of the subject. Each of the active parts 3, 4, 5 of the pressure application garment 1 is a flexible textile part made of an airtight material. In particular, in this example, the airtight material of each active part 3, 4, 5 comprises a knitted nylon textile layer coated, on one side, with a polyurethane coating layer. In order to ease the placement of the pressure application garment 1 on the body of the subject, the two lower active parts 4, 5 are connected to the abdominal active part 3 by joining elements 9, which are in particular elastic textile strips. Each active part 3, 4, 5 can be deformed between a substantially planar deployed configuration, shown in Figure 3, allowing for the placement thereof around the corresponding body part of the subject, and a tubular configuration, shown in Figures 1, 2 or 5, wherein it is capable of surrounding the corresponding body part of the subject and of being adjusted around same.

[0051] As shown for the active part 5 in the sectional view of Figure 4 (it being understood that the active parts 3 and 4 have similar sections to those of the active part 5), each active part 3, 4, 5 of the pressure application garment 1 comprises the superimposition of an inner textile portion 33, 43, 53, intended to be facing the body of the subject, and an outer textile portion 34, 44, 54, intended to be facing outwards, both of which being made of an airtight material as described above. For each active part 3, 4, 5, the inner textile portion 33, 43, 53 and the outer textile portion 34, 44, 54 made of an airtight material are connected together by a peripheral seam 32, 42, 52, which is also airtight. Thus, for each active part 3, 4, 5 of the pressure application garment 1, an airtight bladder 31, 41, 51 is delimited between the inner textile portion 33, 43, 53 and the outer textile portion 34, 44, 54, whereby the inner volume V of the bladder 31, 41, 51 is capable of being filled with air.

[0052] In this example, each active part 3, 4, 5 comprises a single fillable bladder 31, 41, 51, which has the advantage of simplifying the design of the pressure application garment 1. However, alternatively, each active part 3, 4, 5 can comprise a plurality of fillable bladders. Each fillable bladder 31, 41, 51 of the pressure application garment 1 is intended to be filled with air such that,

in the adjusted configuration of the active part 3, 4, 5 on the corresponding body part of the subject, the inner textile portion 33, 43, 53 applies a positive pressure thereto.

[0053] Each fillable bladder 31, 41, 51 of the pressure application garment 1 comprises a plurality of filling end pieces 36, 46, 56 distributed over the surface of the bladder in order to optimise the filling thereof. As diagrammatically shown in Figure 5, the filling end pieces 36, 46, 56 of the active parts 3, 4, 5 are suitable for being connected to air injection devices 63, 64, 65. Different types of air injection devices can be used within the scope of the invention. In particular, each air injection device 63, 64, 65 can be a portable pump integrated into the garment 1, or a compressed air infeed in a hospital. Each fillable bladder 31, 41, 51 is equipped with at least one pressure gauge 60 for measuring the pressure to which the bladder is filled with air. Preferably, in order to measure the filling pressure in the different areas of each fillable bladder 31, 41, 51, a pressure gauge 60 is installed in each connection pipe between a filling end piece 36, 46, 56 of the bladder and the corresponding air injection device 63, 64, 65.

[0054] In order to control the pressure effectively applied to the abdomen A of the subject by the abdominal active part 3 and to the lower limbs L_1, L_2 of the subject by the lower active parts 4, 5, the garment 1 comprises interface pressure sensors 2 mounted on the inner textile portion 33, 43, 53 of each active part 3, 4, 5. Each sensor 2 is intended to measure a pressure at the interface between the active part 3, 4, 5 onto which it is attached and the corresponding body part of the subject. Each sensor 2 can, for example, be sewn into a compartment provided for this purpose in the corresponding inner textile portion 33, 43, 53. Alternatively, each sensor 2 can be rigidly secured to the corresponding inner textile portion 33, 43, 53 by any other appropriate means, in particular by sewing or bonding, etc.

[0055] In one example embodiment, each interface pressure sensor 2 can be a pneumatic sensor as disclosed in patent document WO2009072011A1, comprising a flexible polymer cushion capable of receiving, in the inner volume thereof, a predetermined volume of injected air corresponding to a known positive pressure, the cushion being connected in a sealed manner by means of a flexible tube (not shown) to a measurement module 72. The measurement module 72 of each sensor 2 in particular comprises a pressure gauge and an air injection piston, which are in fluid communication with one another and with the pneumatic sensor 2. The use of such pneumatic sensors avoids the need for electronic components on the active parts 3, 4, 5 of the pressure application garment 1, whereby the electronics are offset in the measurement module 72 external to the textile parts. These pneumatic sensors also have the advantage of being compatible with the relatively low interface pressure levels sought after in the case of LBPP, which in particular lie in the range 10 to 40 mmHg. It goes without saying that, alternatively, the pressure application garment 1 can comprise electronic interface pressure sensors, provided that the sensitivity of these electronic sensors is compatible with the interface pressure levels sought after.

[0056] For each active part 3, 4, 5, the number and arrangement of the interface pressure sensors 2 are suitable for providing pressure measurements representative of the pressure effectively applied to the body part of the subject. By way of a non-limiting example, in this embodiment, the abdominal active part 3 of the pressure application garment 1 comprises three interface pressure sensors 2, i.e. an anterior central sensor 2 intended to be positioned in front of the centre of the subject's abdomen, and two lateral sensors 2 intended to be positioned on the sides of the abdomen. Each lower active part 4, 5 of the pressure application garment 1 comprises five interface pressure sensors 2, i.e. one posterior lower sensor 2 intended to be positioned to the rear of the subject's calf, one medial lower sensor 2 intended to be positioned on the medial face of the calf, one posterior upper sensor 2 intended to be positioned on the posterior face of the subject's thigh, one medial upper sensor 2 intended to be positioned on the medial face of the thigh, and one anteromedial upper sensor 2 intended to be positioned on the anteromedial face of the thigh.

[0057] The pressure application garment 1 comprises a control unit 7, shown in Figure 5, which can take on the form of a housing capable of being attached to the surface of a textile part of the pressure application garment 1, or to an element of furniture, such as a bed on which the pressure application session is carried out using the garment 1. In the case of interface pressure sensors 2 of the pneumatic type, the measurement module 72 associated with each pneumatic interface pressure sensor of the pressure application garment 1 is advantageously integrated into the housing of the control unit 7, which further comprises a receiving module 70 configured to receive the interface pressure measurements from the measurement module 72 of each pneumatic interface pressure sensor. The connection between each measurement module 72 and the receiving module 70 can thus be wired or wireless. In the case of interface pressure sensors 2 of the electronic type, each electronic interface pressure sensor is configured to transmit the interface pressure measurements directly to the receiving module 70 of the control unit 7, in particular by wireless connection means. The one or more filling pressure gauges 60 of each fillable bladder 31, 41, 51 are also connected to the receiving module 70 of the control unit 7. Thus, an automatic servo system can be produced between the filling pressure sensors 60 and the interface pressure sensors 2 of each active part 3, 4, 5.

[0058] As shown in Figure 5, the receiving module 70 of the control unit 7 is also configured to receive:

- measurements representative of the subject's blood pressure during the treatment session obtained, in particular continuously, using a tensiometer 67 com-

prising a cuff positioned on an arm of the subject; in particular, measurements representative of the subject's blood pressure include the systolic blood pressure (SBP), the diastolic blood pressure (DBP), the mean arterial blood pressure;

- measurements representative of the intracerebral blood flow of the subject during the treatment session obtained, in particular continuously, by transcranial Doppler using a device 68 comprising a probe positioned on the subject's head, typically a 2 MHz Doppler probe, associated with a computing unit; in particular, measurements representative of the intracerebral blood flow of the subject include the peak systolic velocity (PSV), the end-diastolic velocity (EDV), the resistive index, the area under the curve.

[0059] The control unit 7 further comprises a driving module 71, which is configured to drive the one or more air injection devices 63, 64, 65 as a function of:

- the interface pressure measurements received by the receiving module 70 for each active part 3, 4, 5, so as to maintain a predefined interface pressure setpoint for said active part;
- the measurements representative of the subject's blood pressure received by the receiving module 70, so as to keep the subject's blood pressure values below predefined thresholds, in particular so as to keep the systolic blood pressure (SBP) strictly below 220 and the diastolic blood pressure (DBP) strictly below 120:
- the measurements representative of the intracerebral blood flow of the subject received by the receiving module 70, so as to correlate the change in the measurements representative of the intracerebral blood flow of the subject with the pressure gradient applied to the body parts of the subject by means of the pressure application garment and/or to associate the measurements representative of the intracerebral blood flow of the subject with a therapeutic goal, for example an average increase of 30% in intracerebral blood flow compared to that at the start of the treatment session, with the possibility of creating an alert when said therapeutic goal has been reached, whereby the practitioner decides whether or not to continue the session as a function of the functional results obtained.

[0060] The control unit 7 provides automatic control of the interface pressure, and servo-control of the air injection in the bladder 31, 41, 51 of each active part 3, 4, 5 as a function of the interface pressure measurements from the sensors 2 and of the predefined interface pressure setpoint for each active part. It is thus possible to apply, in an automated manner, a constant and controlled pressure to each body part of the subject throughout the duration of a pressure application session using the pressure application garment 1, without manual intervention.

[0061] In particular, according to one example, for the application of LBPP using the pressure application garment 1, the predefined interface pressure setpoint for the abdominal active part 3 is 10 mmHg, and the predefined interface pressure setpoint for each lower active part 4, 5 is 20 mmHg, whereby the garment 1 is advantageously configured so as to maintain the predefined interface pressure setpoint for each active part 3, 4, 5 for a duration of about 90 minutes.

[0062] In order to better take on the shape of each body part of the subject and to obtain the most effective and homogeneous application of pressure possible to each part of the body, each active part 3, 4, 5 of the pressure application garment 1 comprises adjustment means for adjusting the active part 3, 4, 5 around the corresponding body part of the subject. In the example shown in Figures 1 to 5, these adjustment means comprise a pair of gripping strips on each active part 3, 4, 5, allowing the active part to be closed in the adjusted configuration around the corresponding body part A, L_1, L_2 of the subject.

[0063] More specifically, in the example shown, each active part 3, 4, 5 comprises, over the entire length thereof in the axial direction in the tubular configuration, a first gripping strip 37, 47, 57 provided with hooks, which is situated on a first longitudinal end of the active part, on the side of the outer textile portion 34, 44, 54, and a second gripping strip 38, 48, 58 provided with loops, which is situated on the second longitudinal end of the active part, this time on the side of the inner textile portion 33, 43, 53. The gripping strips 37, 38, 47, 48, 57, 58 allow the circumference of the active part 3, 4, 5 to be adjusted around the corresponding body part A, L_1, L_2 of the subject in an adapted manner over the entire length of the active part.

[0064] Each of the two lower active parts 4, 5 further comprise, opposite the abdominal active part 3, a portion 45, 55 that can be rolled up, intended to adapt the length of the lower active part 4, 5 to the length of the lower limbs L_1, L_2 of the subject and thus to apply a positive pressure to the lower limbs L_1, L_2 in the most targeted manner possible. As shown in Figures 1 and 5, each roll-up portion 45, 55 is formed by a plurality of segments S configured to be folded back on top of one another. Preferably, in the state wherein the segments S are folded back on top of one another, the portion of the fillable bladder 41, 51 corresponding to the folded segments S cannot be filled with air.

[0065] As shown in Figure 3, the lower active part 4 of the pressure application garment 1, which is intended to cover the right leg or the right lower limb L_1 of the subject, comprises an inner cuff 40 which, when the lower active part 4 is in place around the right lower limb L_1 of the subject, is capable of surrounding the subject's right thigh and of applying a tightening force thereto. The tightening cuff 40 can in particular be an inflatable cuff, comprising gripping strips in order to allow the cuff to be held in place around the subject's thigh, and intended to be filled with air at a standardised pressure of about 50 mmHg. The

tightening cuff 40 is intended to allow the subject's mobilisable blood volume (or "venous bed") to be assessed before carrying out a pressure application session, in particular LBPP, using the pressure application garment 1.

[0066] The procedure for assessing the mobilisable blood volume can advantageously comprise the application of a vein occlusion on the subject's right thigh using the tightening cuff 40, and the measurement of the variations in the volume of the right lower limb as a result of this occlusion and the release thereof, in particular by air plethysmography, by measuring the variations in air pressure in the lower active part 4 forming an air-filled sleeve around the right lower limb L_1 of the subject.

[0067] In the case of LBPP, the assessment of the mobilisable blood volume prior to a LBPP differential pressure application session using the pressure application garment 1 is important, since this volume determines the effectiveness of the LBPP treatment for the subject. In particular, when the mobilisable blood volume in the lower body of the subject is low, there is a risk that the transfer of blood to the upper body of the subject as a result of the application of LBPP does not allow for the effective revascularisation of the brain. In such a case, it is advantageous to "fill" the subject's venous network with a liquid, in particular with normal saline prior to the application of LBPP using the pressure application garment 1, in order to increase the mobilisable blood volume. It is considered that, when the mobilisable blood volume of the subject, assessed as stipulated above, is zero or less than a predefined value, an injection of 500 mL normal saline into the subject's venous network can advantageously be carried out prior to a LBPP session using the pressure application garment 1.

[0068] Preferably, as shown in Figure 5, when placed on a subject, the pressure application garment 1 comprises a disposable protective textile 8 between the body of the subject and each of the active parts 3, 4, 5. The protective textile 8, which is for example a microfibre textile having a weight per unit area that lies in the range 40 to 170 g/m^2, acts as a "second skin", preventing irritation of the subject's skin as a result of contact with the active parts 3, 4, 5. Advantageously, the protective textile 8 is applied in a removable manner on the inner textile portion 33, 43, 53 of each active part 3, 4, 5, while being held tensioned by any appropriate means, for example using gripping strips, so as to prevent the presence of folds that are likely to irritate the subject's skin. The protective textile further prevents fouling of the active parts 3, 4, 5 such that the pressure application garment 1 can be reused for different pressure application sessions without hygiene issues insofar as the protective textile 8 used during a session is removed at the end of the session and replaced with a new protective textile 8 for a later session.

[0069] One example of a method for applying pressure according to the "Lower Body Positive Pressure" (LBPP) principle, to the abdomen A and the lower limbs L_1, L_2 of a subject, using the pressure application garment 1 as described above, comprises steps as described below.

[0070] Firstly, the pressure application garment 1 is placed on the subject, preferably in a non-inflated state of the pressure application garment, i.e. a state in which each of the fillable bladders 31, 41, 51 of the garment is not filled with air or filled with very little air.

[0071] For this purpose, each active part 3, 4, 5 of the pressure application garment 1 is positioned in the deployed configuration thereof, as shown in Figure 3, and the protective textile 8 is applied on the inner textile portion 33, 43, 53 of each active part 3, 4, 5. The abdominal active part 3 of the pressure application garment 1 is then placed at the level of the subject's abdomen A, and the two lower active parts 4, 5 are each placed at the level of one lower limb L_1, L_2 of the subject. Each active part 3, 4, 5 is then closed, moving from the deployed configuration thereof into a tubular configuration around the corresponding body part of the subject, and is adjusted around the corresponding body part of the subject using gripping strips 37, 38, 47, 48, 57, 58.

[0072] In the case of a bedridden subject or a subject suffering from limb paralysis, the design of the pressure application garment 1 allows it to be placed on the subject in the laid-back position. In such a case, the pressure application garment 1 is positioned on a bed, with each of the active parts 3, 4 ,5 thereof in the deployed configuration and provided with the protective textile 8, then the subject is laid on his/her back on top of the pressure application garment 1, while positioning the subject's abdomen A at the level of the abdominal active part 3 and each of the subject's lower limbs Li, L_2 at the level of the corresponding lower active part 4, 5 of the pressure application garment. Each active part 3, 4, 5 is then closed by moving from the deployed configuration thereof into a tubular configuration around the corresponding body part of the subject lying down, and is adjusted around the corresponding body part of the subject using the gripping strips 37, 38, 47, 48, 57, 58, which have been provided at the front of the pressure application garment for this purpose.

[0073] The measurement of the mobilisable blood volume can then be carried out for the subject equipped with the pressure application garment 1. For this purpose, a vein occlusion is applied at the root of the subject's right thigh using the tightening cuff 40, and the variations in the volume of the right lower limb L_1 as a result of this occlusion and the release thereof are measured by plethysmography. This can, for example, be air plethysmography, measuring the variations in air pressure in the lower active part 4 forming an air-filled sleeve around the right lower limb L_1 of the subject. As a function of the value of the mobilisable blood volume thus assessed, an injection of normal saline can be carried out into the subject's venous network in order to increase the mobilisable blood volume and improve the effect of the LBPP in the event of a hypovolaemic venous bed.

[0074] Each bladder 31, 41, 51 of the pressure application garment 1 is then filled using air injection devices 63, 64, 65 connected to the filling end pieces 36, 46, 56

until a measurement is obtained for each active part 3, 4, 5 by each interface pressure sensor 2 of the active part that is substantially equal to the predefined interface pressure setpoint for said active part. In particular, according to one advantageous example of the application of LBPP using the pressure application garment 1, the predefined interface pressure setpoint for the abdominal active part 3 is 10 mmHg, and the predefined interface pressure setpoint for each lower active part 4, 5 is 20 mmHg. The control unit 7 of the pressure application garment 1 can be configured to fill the bladders 31, 41, 51 of the garment in an automatic manner.

[0075] The application of a constant and homogeneous pressure of 10 mmHg to the subject's abdomen A and of 20 mmHg to each of the subject's lower limbs L_1, L_2 for a determined duration, for example for a duration of 90 minutes, is then carried out automatically by the pressure application garment 1 thanks to the control unit 7 of the garment, which is configured to selectively actuate the air injection devices 63, 64, 65 as a function of the interface pressure measurements from the sensors 2 so as to maintain, for the determined duration, an interface pressure value measured by each sensor 2 that is equal to the predefined interface pressure setpoint for the active part 3, 4, 5 to which said sensor 2 is attached.

[0076] In the second embodiment shown in Figure 6, similar elements to those of the first embodiment are denoted by the same references. The pressure application garment 1 of this second embodiment differs from that of the first embodiment in that the adjustment means of the active parts 3, 4, 5 on the body of a subject are formed by a plurality of closing systems using tightening straps 37', 47', 57' and corresponding clips 38', 48', 58', in place of the gripping strips 37, 38, 47, 48, 57, 58. As shown in Figure 6, for each active part 3, 4, 5, the closing systems using tightening straps 37', 47', 57' and clips 38', 48', 58' are distributed over the entire length of the active part in the axial direction in the tubular configuration, so as to allow for the adjustment of the circumference of the active part 3, 4, 5 around the corresponding body part A, L_1, L_2 of the subject in an adapted manner over the entire length of the active part.

[0077] In the third embodiment shown in Figures 7 and 8, similar elements to those of the first embodiment are denoted by the same references. The pressure application garment 1 of this third embodiment differs from that of the first embodiment in that the adjustment means of the active parts 3, 4, 5 on the body of a subject are not restricted to gripping strips 37, 38, 47, 48, 57, 58 that close longitudinally. In this third embodiment, the adjustment means further comprise sculptural seams 39, 49, 59 of the textile of each active part 3, 4, 5. The seams 39, 49, 59 of each active part 3, 4, 5 are configured to impose a shape of the active part 3, 4, 5 which applies the active part against the corresponding body part A, L_1, L_2 of the subject during the filling of the fillable bladder 31, 41, 51 of the active part with air. The seams 39, 49, 59 of each active part 3, 4, 5 allow the active part to better take on the shape of the corresponding body part of the subject. Moreover, as shown in Figure 8, the pressure application garment 1 of this third embodiment encompasses the subject's buttocks. The part covering the subject's buttocks can be a fillable part, capable of being filled with air, and in particular can correspond to a fillable bladder, insofar as it can be useful to also apply a constant and controlled pressure to the subject's buttocks in order to expel blood from this area. Alternatively, the part covering the subject's buttocks can be non-fillable.

[0078] As shown in the previous examples, a pressure application garment according to the invention, comprising interface pressure sensors on the inner wall of each of the active parts thereof, allows homogeneous and constant pressures to be automatically applied to the abdomen and the lower limbs of a subject. In particular, the pressure application garment according to the invention is well-suited for the application of pressures according to the "Lower Body Positive Pressure" (LBPP) principle, involving differential pressures applied to the abdomen and lower limbs of a subject. Thanks to the airtightness and flexibility of the textile forming each of the active parts of the pressure application garment, each active part can act as an air chamber, while retaining a flexible structure, which procures high wearing comfort and eases the placement thereof on a subject, including a bedridden or paralysed subject. The possibility of providing the pressure application garment of the invention in different sizes, for example S, M, L, XL and the presence of adjustment means for adjusting the pressure application garment on each part of the body further allow the garment to adapt to the morphology of each subject, which contributes to the effectiveness of the garment for treatments by application of pressure, in particular according to the LBPP principle.

[0079] The invention is not limited to the examples described and illustrated. In particular, in the previous examples, each active part 3, 4, 5 of the pressure application garment comprises a single fillable bladder 31, 41, 51. Alternatively, the active parts of a garment according to the invention can each comprise any number of fillable bladders. Preferably, each fillable bladder of each active part is thus equipped with at least one interface pressure sensor. Moreover, the number and arrangement of the interface pressure sensors on each active part of a pressure application garment according to the invention can be different to those described in the previous examples. The interface pressure sensors used can also be of different sizes, adapted to suit the location thereof, and of different types, in particular pneumatic sensors, electronic sensors, or combinations of pneumatic and electronic sensors, etc. Finally, the pressure application garment according to the invention has been described above for the application of pressure corresponding to the "Lower Body Positive Pressure" (LBPP) principle. Alternatively, it can be used for the automatic application of all types of pressures to the abdomen and/or the lower limbs of a subject, for example pressures that vary over time, which

can thus be automatically controlled by the control unit of the pressure application garment.

[0080] The application of the "Lower Body Positive Pressure" (LBPP) by means of a pressure application garment according to the invention comprises the following treatments, without limitation:

Improvement of cerebral vascular recruitment in different clinical situations

[0081]

1- Acute phase of cerebral ischemia due to impairment of cerebral perfusion whatever the mechanism(s):

- Ischemic stroke
- Vasospasm.

2- Sub-acute phase of cerebral ischemia due to a persistent impairment of cerebral perfusion to improve functional recovery

- Ischemic stroke.

3- Chronic cerebral ischemia due to a chronic impairment of cerebral perfusion

- In vascular dementia.

4- Improvement of ocular vascular recruitment in different clinical situations

- Acute phase of carotid occlusion
- Anterior ischemic optic neuropathy (AION)
- Retinal artery occlusion
- Chronic impairment of choroidal perfusion
- Age related macular degeneration (AMD).

5- Use of LBPP to help or increase the delivery of a therapeutic agent for cerebral vascular deficiency selected from a group comprising anticoagulant agents, fibrinolytics, free radical-trapping agents, NO donors, in hypoperfused body zones.

6- Use of LBPP to help or increase the delivery of a therapeutic agent for ocular disorders selected from a group comprising antioxidants, anti-inflammatory agents, trophic factors, apoptosis inhibitors and statins, in hypoperfused body zones.

Claims

1. Pressure application garment (1) for applying pressure to the body of a subject, comprising three active parts (3, 4, 5) which are one abdominal active part (3) intended to surround the subject's abdomen (A) and two lower active parts (4, 5) each intended to surround one of the subject's lower limbs (L_1, L_2), each of the active parts (3, 4, 5) comprising at least one bladder (31, 41, 51) fillable with a fluid so as to obtain a homogeneous positive pressure applied by the active part to the whole of the corresponding body part of the subject among the abdomen (A) and the lower limbs (L_1, L_2), the pressure application garment (1) comprising:

- for each active part (3, 4, 5), at least one interface pressure sensor (2) configured to measure a pressure at the interface between the active part (3, 4, 5) and the corresponding body part of the subject while being positioned between the active part (3, 4, 5) and the corresponding body part of the subject,
- a control unit (7) comprising a receiving module (70) configured to receive the interface pressure measurements from the one or more interface pressure sensors (2) of each active part (3, 4, 5), and a driving module (71) configured to drive, based on the interface pressure measurements received by the receiving module for each active part, at least one injection device (63, 64, 65) for injecting fluid into the one or more fillable bladders (31, 41, 51) of the active part, so as to maintain a predefined interface pressure value for each active part, the predefined interface pressure value for the abdominal active part (3) being strictly less than the predefined interface pressure value for each lower active part (4, 5).

2. Pressure application garment according to claim **1,** wherein the control unit (7) is configured to maintain:

- for the abdominal active part (3), a first predefined interface pressure value that lies in the range 10 to 20 mmHg; and
- for each of the two lower active parts (4, 5), a second predefined interface pressure value that lies in the range 20 to 40 mmHg.

3. Pressure application garment according to either claim **1** or claim **2,** wherein the control unit (7) is configured to receive measurements representative of the subject's blood pressure, and to control the or each injection device (64, 65) for injecting fluid into the one or more fillable bladders of the lower active parts (4, 5), so as to keep the subject's blood pressure values (SBP, DBP) below predefined thresholds.

4. Pressure application garment according to any one of the preceding claims, wherein the control unit (7) is configured to receive measurements representative of the intracerebral blood flow of the subject, in

particular obtained by transcranial Doppler, and to correlate the change in the measurements representative of the intracerebral blood flow with the pressure gradient applied to the body parts of the subject (A, L_1, L_2) by means of the pressure application garment (1).

5. Pressure application garment according to any one of the preceding claims, wherein, for each fillable bladder (31, 41, 51), the volume (V) for receiving fluid is delimited by a flexible layer (32-34, 42-44, 52-54) that is impervious to said fluid, in particular having a textile and/or plastic material base.

6. Pressure application garment according to any one of the preceding claims, wherein each interface pressure sensor (2) is rigidly secured to the wall (33, 43, 53) of the active part (3, 4, 5) that is intended to be directed towards the body part of the subject.

7. Pressure application garment according to any one of the preceding claims comprising, for each fillable bladder (31, 41, 51), at least one filling pressure sensor (60) for sensing the pressure to which the bladder is filled with fluid, and automatic servo-control means between the one or more filling pressure sensors (60) and the one or more interface pressure sensors (2) of each active part (3, 4, 5).

8. Pressure application garment according to any one of the preceding claims, wherein each interface pressure sensor (2) is a pneumatic sensor connected in a sealed manner, in particular by means of a flexible tube, to a measurement module (72).

9. Pressure application garment according to any one of the preceding claims, wherein each active part (3, 4, 5) comprises adjustment means (37, 38, 39, 47, 48, 49, 57, 58, 59) for adjusting the active part around the corresponding body part of the subject, the adjustment means comprising patterning elements (39, 49, 59) of the active part, capable of applying the active part against the corresponding body part of the subject when filling the or each fillable bladder (31, 41, 51) of the active part.

10. Pressure application garment according to any one of the preceding claims, wherein each active part (3, 4, 5) comprises adjustment means (37, 38, 39, 47, 48, 49, 57, 58, 59) for adjusting the active part around the corresponding body part of the subject, the adjustment means comprising closing elements (37('), 38('), 47('), 48('), 57('), 58(')) of the active part (3, 4, 5), allowing for the adjustment of the circumference of the active part around the corresponding body part of the subject.

11. Pressure application garment according to any one of the preceding claims, wherein at least one of the lower active parts (4) comprises an inner tightening element (40) which, when the active part (4) is in place around the lower limb (L_1) of the subject, is capable of surrounding the thigh of the subject and of applying a tightening force thereto.

12. Pressure application garment according to any one of the preceding claims, comprising a protective textile (8), capable of being replaced upon each use of the pressure application garment, which is secured in a removable manner to the wall (33, 43, 53) of one or of each active part (3, 4, 5) intended to be facing the body part of the subject.

Patentansprüche

1. Druckanlegebekleidung (1) zum Anlegen von Druck an den Körper eines Patienten, die drei Wirkteile (3, 4, 5) umfasst, bei denen es sich um einen abdominalen Wirkteil (3), der dazu bestimmt ist, das Abdomen (A) des Patienten zu umgeben, und zwei untere Wirkteile (4, 5) handelt, die jeweils dazu bestimmt sind, eine der unteren Gliedmaße (L_1, L_2) des Patienten zu umgeben, wobei jeder der Wirkteile (3, 4, 5) mindestens eine Blase (31, 41, 51) umfasst, die so mit einem Fluid gefüllt werden kann, dass ein homogener positiver Druck erhalten wird, der vom Wirkteil an den gesamten entsprechenden Körperteil des Patienten aus dem Abdomen (A) und den unteren Gliedmaßen (L_1, L_2) angelegt wird, wobei die Druckanlegebekleidung (1) umfasst:

- für jeden Wirkteil (3, 4, 5) mindestens einen Grenzflächendrucksensor (2), der so ausgelegt ist, dass er einen Druck an der Grenzfläche zwischen dem Wirkteil (3, 4, 5) und dem entsprechenden Körperteil des Patienten misst, während er zwischen dem Wirkteil (3, 4, 5) und dem entsprechenden Körperteil des Patienten positioniert ist,
- eine Steuereinheit (7), die ein Empfangsmodul (70), das so ausgelegt ist, dass es die Grenzflächendruckmessungen von dem einen oder den mehreren Grenzflächendrucksensoren (2) jedes Wirkteils (3, 4, 5) empfängt, und ein Ansteuermodul (71) umfasst, das so ausgelegt ist, dass es auf Basis der vom Empfangsmodul für jeden Wirkteil empfangenen Grenzflächendruckmessungen mindestens eine Injektionsvorrichtung (63, 64, 65) zum Injizieren von Fluid in die eine oder die mehreren füllbaren Blasen (31, 41, 51) des Wirkteils so ansteuert, dass ein vordefinierter Grenzflächendruckwert für jeden Wirkteil aufrecht erhalten wird, wobei der vordefinierte Grenzflächendruckwert für den abdominalen Wirkteil (3) streng kleiner ist als der vordefinierte

Grenzflächendruckwert für jeden unteren Wirkteil (4, 5).

2. Druckanlegebekleidung nach Anspruch **1,** wobei die Steuereinheit (7) so ausgelegt ist, dass sie Folgendes aufrechterhält:

- für den abdominalen Wirkteil (3) einen ersten vordefinierten Grenzflächendruckwert, der im Bereich von 10 bis 20 mmHg liegt; und
- für jeden der zwei unteren Wirkteile (4, 5) einen zweiten vordefinierten Grenzflächendruckwert, der im Bereich von 20 bis 40 mmHg liegt.

3. Druckanlegebekleidung nach entweder Anspruch **1** oder Anspruch **2,** wobei die Steuereinheit (7) so ausgelegt ist, dass sie Messungen empfängt, die für den Blutdruck des Patienten repräsentativ sind, und die oder jede Injektionsvorrichtung (64, 65) zum Injizieren von Fluid in die eine oder die mehreren füllbaren Blasen der unteren Wirkteile (4, 5) so steuert, dass die Blutdruckwerte (SBD, DBD) des Patienten unter vordefinierten Schwellen gehalten werden.

4. Druckanlegebekleidung nach einem der vorstehenden Ansprüche, wobei die Steuereinheit (7) so ausgelegt ist, dass sie Messungen empfängt, die für den intrazerebralen Blutfluss des Patienten repräsentativ sind, welche insbesondere durch transkraniellen Doppler erhalten werden, und die Veränderung in den für den intrazerebralen Blutfluss repräsentativen Messungen mit dem mittels der Druckanlegebekleidung (1) an die Körperteile des Patienten (A, L_1, L_2) angelegten Druckgradienten korreliert.

5. Druckanlegebekleidung nach einem der vorstehenden Ansprüche, wobei bei jeder füllbaren Blase (31, 41, 51) das Volumen (V) zum Aufnehmen von Fluid durch eine flexible Schicht (32-34, 42-44, 52-54), die für das Fluid undurchlässig ist und die insbesondere eine Textil- und/oder Kunststoffmaterialbasis aufweist, begrenzt wird.

6. Druckanlegebekleidung nach einem der vorstehenden Ansprüche, wobei jeder Grenzflächendrucksensor (2) starr an der Wand (33, 43, 53) des Wirkteils (3, 4, 5), welche dazu bestimmt ist, in Richtung des Körperteils des Patienten gerichtet zu sein, gesichert ist.

7. Druckanlegebekleidung nach einem der vorstehenden Ansprüche, die für jede füllbare Blase (31, 41, 51) mindestens einen Fülldrucksensor (60) zum Abfühlen des Drucks, auf den die Blase mit Fluid gefüllt ist, und automatische Servosteuermittel zwischen dem einen oder den mehreren Fülldrucksensoren (60) und dem einen oder den mehreren Grenzflächendrucksensoren (2) jedes Wirkteils (3, 4, 5) umfasst.

8. Druckanlegebekleidung nach einem der vorstehenden Ansprüche, wobei es sich bei jedem Grenzflächendrucksensor (2) um einen pneumatischen Sensor handelt, der in einer dichten Art und Weise, insbesondere mittels eines flexiblen Schlauchs, mit einem Messmodul (72) verbunden ist.

9. Druckanlegebekleidung nach einem der vorstehenden Ansprüche, wobei jeder Wirkteil (3, 4, 5) Anpassmittel (37, 38, 39, 47, 48, 49, 57, 58, 59) zum Anpassen des Wirkteils um den entsprechenden Körperteil des Patienten herum umfasst, wobei die Anpassmittel strukturierende Elemente (39, 49, 59) des Wirkteils umfassen, die den Wirkteil beim Füllen der oder jeder füllbaren Blase (31, 41, 51) des Wirkteils an den entsprechenden Körperteil des Patienten anlegen können.

10. Druckanlegebekleidung nach einem der vorstehenden Ansprüche, wobei jeder Wirkteil (3, 4, 5) Anpassmittel (37, 38, 39, 47, 48, 49, 57, 58, 59) zum Anpassen des Wirkteils um den entsprechenden Körperteil des Patienten herum umfasst, wobei die Anpassmittel Verschlusselemente (37('), 38('), 47('), 48('), 57('), 58(')) des Wirkteils (3, 4, 5) umfassen, die das Anpassen des Umfangs des Wirkteils um den entsprechenden Körperteil des Patienten herum ermöglichen.

11. Druckanlegebekleidung nach einem der vorstehenden Ansprüche, wobei mindestens einer der unteren Wirkteile (4) ein inneres Spannelement (40) umfasst, das, wenn der Wirkteil (4) um die untere Gliedmaße (L_1) des Patienten herum angebracht ist, den Oberschenkel des Patienten umgeben und eine Spannkraft an diesen anlegen kann.

12. Druckanlegebekleidung nach einem der vorstehenden Ansprüche, die ein Schutztextil (8) umfasst, das bei jedem Gebrauch der Druckanlegebekleidung gewechselt werden kann und das in einer herausnehmbaren Art und Weise an der Wand (33, 43, 53) eines oder jedes Wirkteils (3, 4, 5), welche dazu bestimmt ist, dem Körperteil des Patienten zugewandt zu sein, gesichert ist.

Revendications

1. Vêtement d'application de pression (1) pour appliquer une pression sur le corps d'un sujet, comprenant trois parties actives (3, 4, 5) dont une partie active abdominale (3) destinée à entourer l'abdomen (A) du sujet et deux parties actives inférieures (4, 5) chacune destinée à entourer l'un des membres inférieurs (Li, L_2) du sujet, chacune des parties actives

(3, 4, 5) comprenant au moins une vessie (31, 41, 51) remplissable d'un fluide de manière à obtenir une pression positive homogène appliquée, par la partie active, sur l'ensemble de la partie du corps correspondante du sujet parmi l'abdomen (A) et les membres inférieurs (L_1, L_2), le vêtement d'application de pression (1) comprenant :

- pour chaque partie active (3, 4, 5), au moins un capteur de pression d'interface (2) configuré pour mesurer une pression à l'interface entre la partie active (3, 4, 5) et la partie du corps correspondante du sujet tout en étant positionné entre la partie active (3, 4, 5) et la partie du corps correspondante du sujet,
- une unité de commande (7) comprenant un module de réception (70) configuré pour recevoir les mesures de pression d'interface provenant d'un ou de plusieurs capteurs de pression d'interface (2) de chaque partie active (3, 4, 5), et un module de pilotage (71) configuré pour piloter, sur la base des mesures de pression d'interface reçues par le module de réception pour chaque partie active, au moins un dispositif d'injection (63, 64, 65) pour injecter du fluide dans une ou plusieurs vessies remplissables (31, 41, 51) de la partie active, de manière à maintenir une valeur de pression d'interface prédéfinie pour chaque partie active, la valeur de pression d'interface prédéfinie pour la partie active abdominale (3) étant strictement inférieure à la valeur de pression d'interface prédéfinie pour chaque partie active inférieure (4, 5).

2. Vêtement d'application de pression selon la revendication **1,** dans lequel l'unité de commande (7) est configurée pour maintenir :

- dans la partie active abdominale (3), une première valeur de pression d'interface prédéfinie comprise entre 10 et 20 mm Hg ; et
- dans chacune des deux parties actives inférieures (4, 5), une deuxième valeur de pression d'interface prédéfinie comprise entre 20 et 40 mm Hg.

3. Vêtement d'application de pression selon la revendication **1** ou la revendication **2,** dans lequel l'unité de commande (7) est configurée pour recevoir des mesures représentatives de la pression artérielle du sujet et pour commander le ou chaque dispositif d'injection (64, 65) afin d'injecter du fluide dans une ou plusieurs vessies remplissables des parties actives inférieures (4, 5), de manière à maintenir les valeurs de pression artérielle du sujet (SBP, DBP) en dessous de seuils prédéfinis.

4. Vêtement d'application de pression selon l'une quelconque des revendications précédentes, dans lequel l'unité de commande (7) est configurée pour recevoir des mesures représentatives du débit sanguin intracérébral du sujet, notamment obtenues par Doppler transcrânien, et pour corréler l'évolution des mesures représentatives du débit sanguin intracérébral avec le gradient de pression appliqué aux parties du corps du sujet (A, L_1, L_2) au moyen du vêtement d'application de pression (1).

5. Vêtement d'application de pression selon l'une quelconque des revendications précédentes, dans lequel, pour chaque vessie remplissable (31, 41, 51), le volume (V) destiné à recevoir le fluide est délimité par une couche souple (32-34, 42-44, 52-54) imperméable audit fluide, notamment à base de textile et/ou de matière plastique.

6. Vêtement d'application de pression selon l'une quelconque des revendications précédentes, dans lequel chaque capteur de pression d'interface (2) est fixé de manière rigide à la paroi (33, 43, 53) de la partie active (3, 4, 5) destinée à être orientée vers la partie du corps du sujet.

7. Vêtement d'application de pression selon l'une quelconque des revendications précédentes comprenant, pour chaque vessie remplissable (31, 41, 51), au moins un capteur de pression de remplissage (60) pour détecter la pression à laquelle la vessie est remplie de fluide, et des moyens d'asservissement automatique entre le ou les capteurs de pression de remplissage (60) et le ou les capteurs de pression d'interface (2) de chaque partie active (3, 4, 5).

8. Vêtement d'application de pression selon l'une quelconque des revendications précédentes, dans lequel chaque capteur de pression d'interface (2) est un capteur pneumatique relié de manière étanche, notamment au moyen d'un tube flexible, à un module de mesure (72).

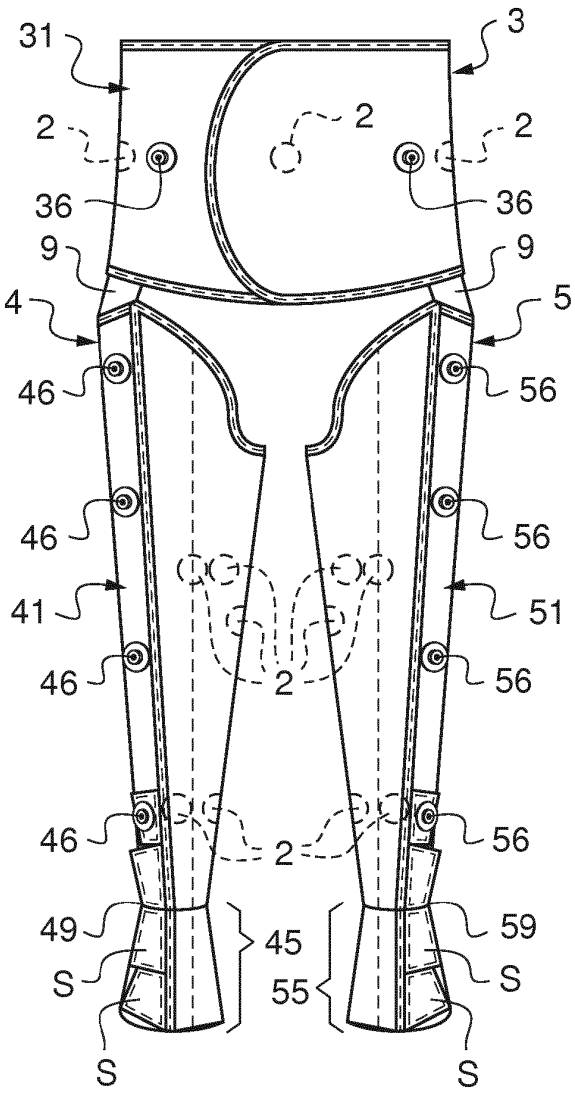
9. Vêtement d'application de pression selon l'une quelconque des revendications précédentes, dans lequel chaque partie active (3, 4, 5) comprend des moyens de réglage (37, 38, 39, 47, 48, 49, 57, 58, 59) pour ajuster la partie active autour de la partie du corps correspondante du sujet, les moyens de réglage comprenant des éléments de modelage (39, 49, 59) de la partie active, capables d'appliquer la partie active contre la partie du corps correspondante du sujet lors du remplissage de la ou de chaque vessie remplissable (31, 41, 51) de la partie active.

10. Vêtement d'application de pression selon l'une quelconque des revendications précédentes, dans lequel chaque partie active (3, 4, 5) comprend des moyens de réglage (37, 38, 39, 47, 48, 49, 57, 58,

59) pour ajuster la partie active autour de la partie du corps correspondante du sujet, les moyens de réglage comprenant des éléments de fermeture (37('), 38('), 47('), 48('), 57('), 58(')) de la partie active (3, 4, 5), permettant le réglage de la circonférence de la partie active autour de la partie du corps correspondante du sujet.

11. Vêtement d'application de pression selon l'une quelconque des revendications précédentes, dans lequel au moins une des parties actives inférieures (4) comprend un élément de serrage intérieur (40) qui, lorsque la partie active (4) est placée autour du membre inférieur (L_1) du sujet, est configurée pour entourer la cuisse du sujet et d'y appliquer une force de serrage.

12. Vêtement d'application de pression selon l'une quelconque des revendications précédentes, comprenant un textile de protection (8), susceptible d'être remplacé à chaque utilisation du vêtement d'application de pression, fixé de manière amovible à la paroi (33, 43, 53) d'une ou de chaque partie active (3, 4, 5) destinée à faire face à la partie du corps du sujet.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59
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S

Fig.1

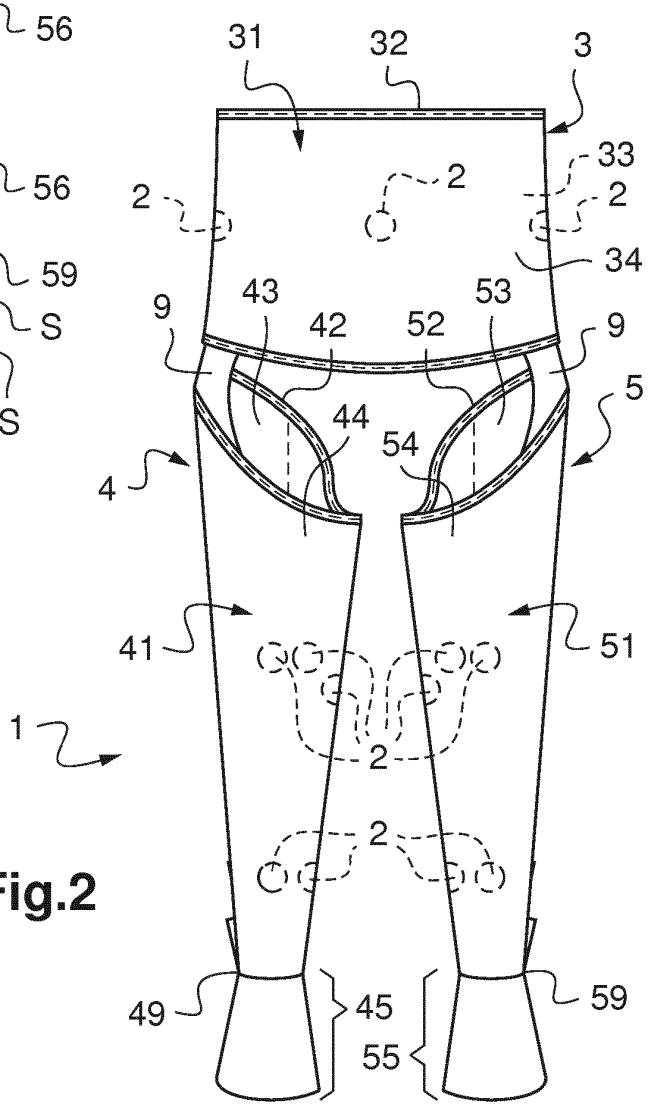
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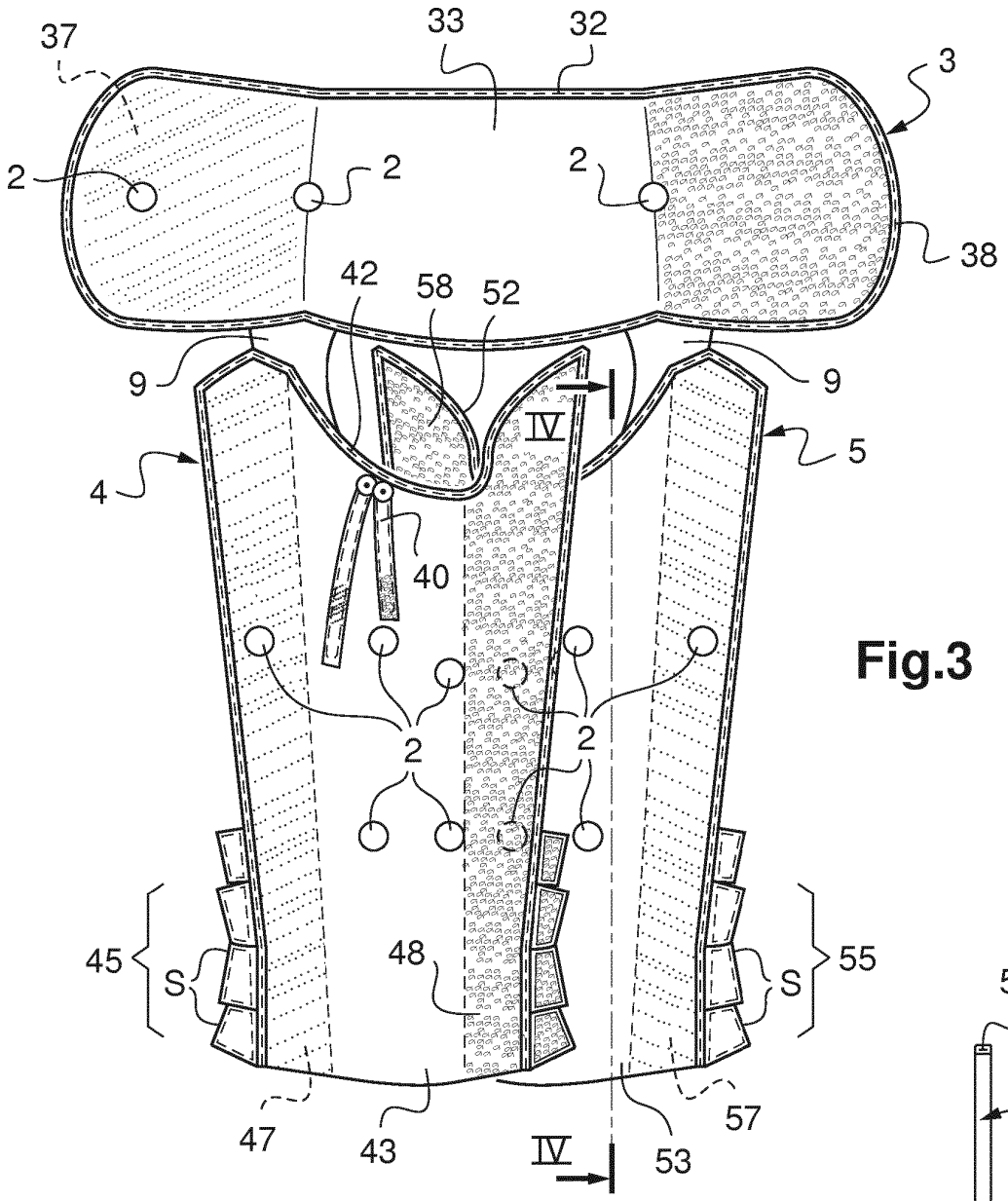
Fig.2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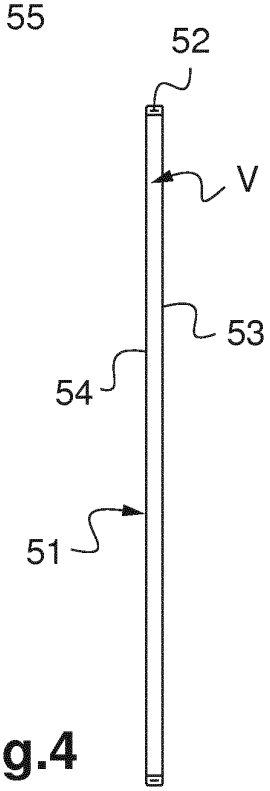
IV
53
57

Fig.3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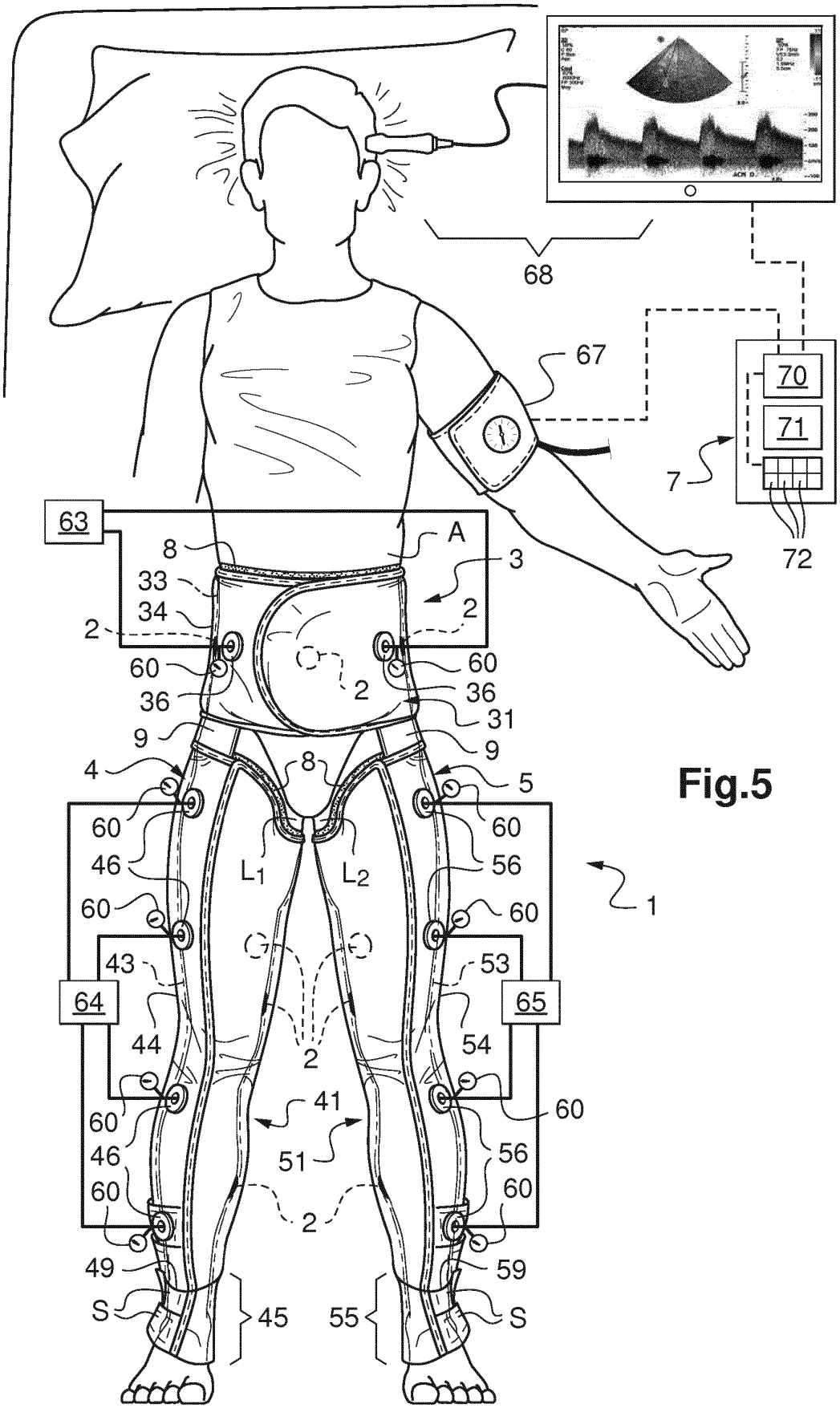
51

Fig.4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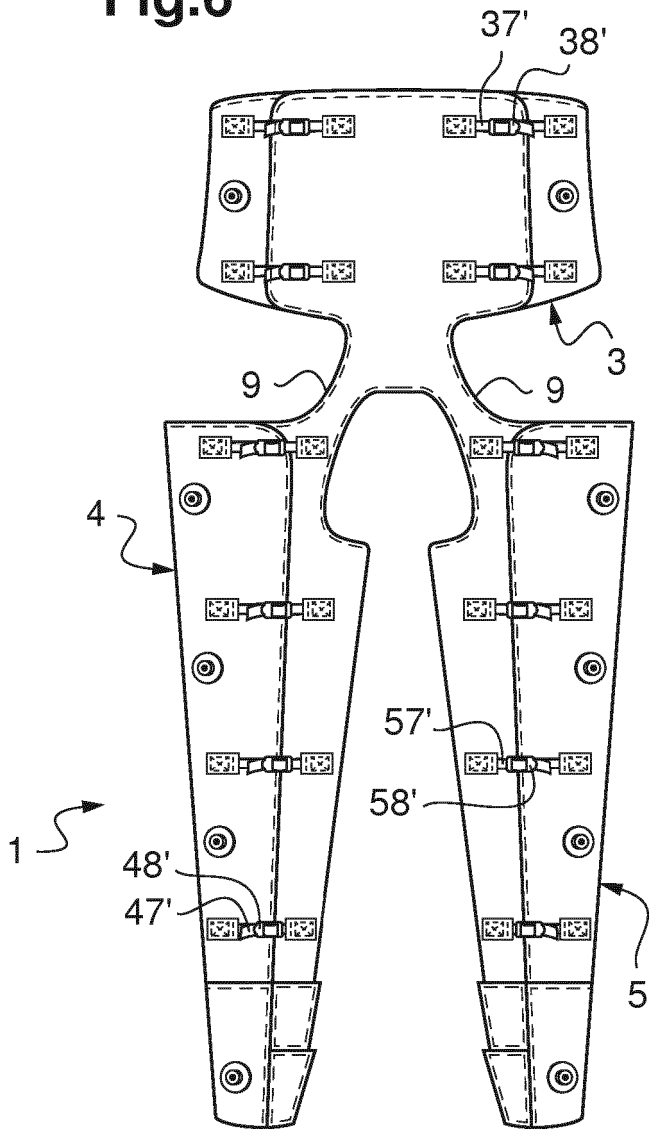
L1
L2

Fig.5

Fig.6



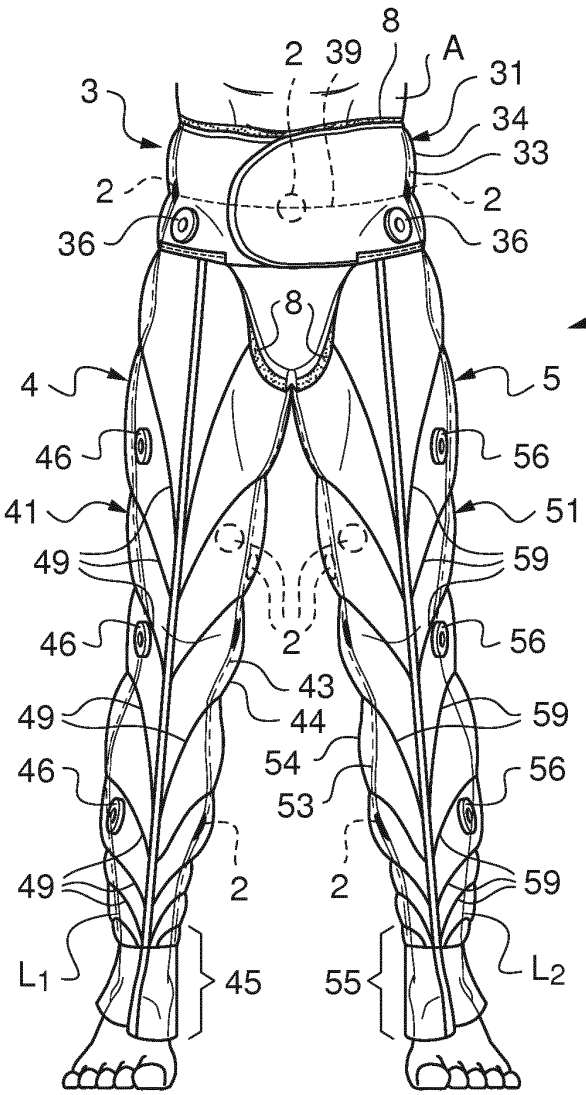

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Fig.7

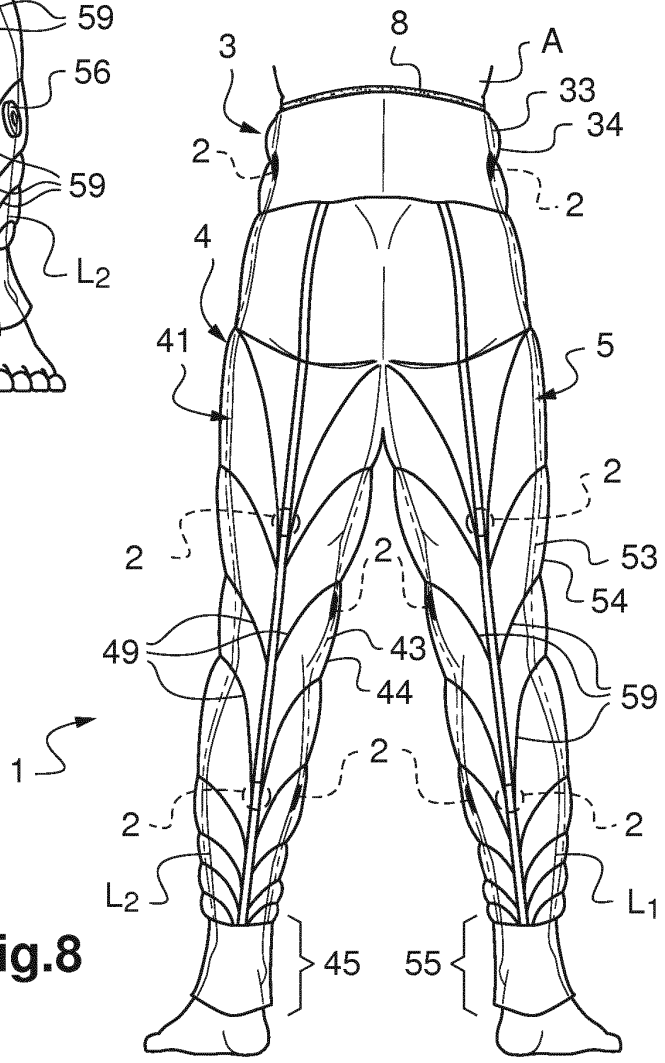
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Fig.8

REFERENCES CITED IN THE DESCRIPTION

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