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- (54) **Title:** METHOD AND DEVICE FOR TREATING LYMPHEDEMA

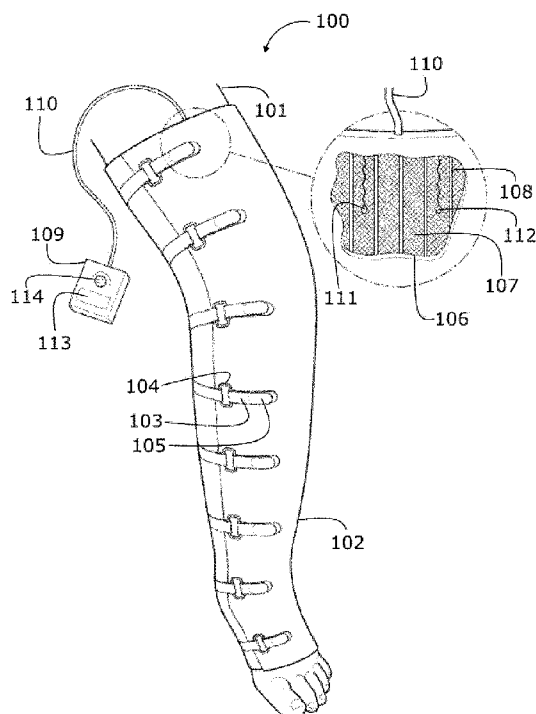


Figure 1

(57) **Abstract:** The current invention concerns a method for treating lymphedema and a device to perform the method. The method for treating lymphedema, for cosmetic and/or therapeutic purposes, comprises the application of heat and compressive pressure to a body portion of the anatomy of a living being to be treated. The body portion is heated to obtain a temperature at the skin surface of the body portion exceeding normal skin temperature, the temperature not exceeding 40 °C, preferably not exceeding 39.5 °C. Simultaneously and/or sequentially, a compressive pressure is applied to the skin surface of the body portion. The compressive pressure is the result of an externally applied circumferential pressure, and an internal pressure, the internal pressure being exerted at the skin surface by arterial pulsations and/or muscle action of the body portion.



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**METHOD AND DEVICE FOR TREATING LYMPHEDEMA****Technical field**

**[0001]** The invention relates to a method for treating lymphedema for cosmetic and/or therapeutic purposes and to a device for performing the method.

**5 Background**

**[0002]** The lymphatic system collects and filters the interstitial fluid of the body. Lymphedema, also known as “lymphoedema” or “lymphatic obstruction”, is an accumulation of interstitial colloid in the extracellular space that causes swelling, most often in the arms and/or legs and occasionally in other portions of the body due to a  
10 compromised lymphatic system. Lymphedema carries the constant risk of developing an uncontrolled infection in the affected body portions of the living being. Considering the swelling of body portions and the health risks related to lymphedema, treatment of lymphedema may be desired for cosmetic and/or therapeutic purposes.

**[0003]** There remains a need in the art for an improved treatment method of  
15 lymphedema. Treating lymphedema by applying compressive pressure to an affected body portion is commonly performed. The application of heat next to compressive pressure can improve the results of lymphedema treatment. The application of heat to a body portion has been mentioned in prior art documents related to pressure treatments for improving the circulation of interstitial colloid. WO Patent Application Publication No.  
20 98/25568 discloses a method and device for massaging a body portion, in which, by means of a sleeve, a pressure wave is being applied to the body portion while the same body portion is simultaneously heated to a temperature of 37 °C to 40 °C. Although the pressure wave applied by this treatment is described as an effective means to boost the circulation of interstitial colloid in a body portion, and thus being a possible treatment  
25 method for lymphedema, the treatment has been described in WO Patent Application Publication No. 98/25568 as a treatment for cellulite. The heating of the body portion is also directed to cellulite treatment and is described to result in dilation of the blood vessels and, as a consequence, in a boost of blood circulation. U.S. Patent Application Publication No. 2013/0253383 describes an apparatus, method and system for providing sequential  
30 gradient pressure and/or compression therapy with combined heating or cooling for use, for example, in reducing edema, pain, preventing deep vein thrombosis and/or lymphedema. This patent application does not relate both heating and a compression therapy to the treatment of lymphedema. In particular, heating is described to provide

temperature therapy while the application of pressure/compression is described as a lymphedema treatment. WO Patent Application Publication No. 02/19954 describes a method and device of use for lymphatic drainage. The device, an elastic brace, is able to produce discrete areas of varied high and low pressure points on the skin and underlying tissue of a body portion when the brace is in place. Using heated liquid, the treated body portion can be heated. A link between heating and lymphatic drainage is not mentioned in this patent application. Specifically, the heating is described to be desirable if a heated therapeutic effect is wanted. The nature of this heated therapeutic effect is however not explained. The mentioned prior art documents do not specifically combine heating with a compressive treatment for the treatment of lymphedema. Furthermore, pressure variations being exerted by the body portion itself when being pressurized by an external pressure, and the use thereof, are neglected in lymphedema treatment methods.

**[0004]** The present invention aims to resolve at least some of the problems mentioned above.

## 15 Summary of the invention

**[0005]** An aspect of the present invention provides a method for treating lymphedema for cosmetic and/or therapeutic purposes, comprising the steps of:

- (i) heating a body portion of the anatomy of a living being to be treated to obtain a temperature at the skin surface of said body portion exceeding normal skin temperature, the temperature not exceeding 40 °C, preferably not exceeding 39.5 °C;
- (ii) and simultaneously and/or sequentially applying a compressive pressure to the skin surface of said body portion, wherein said compressive pressure is the result of an externally applied circumferential pressure, and an internal pressure, the internal pressure being exerted at the skin surface by arterial pulsations and/or muscle action of said body portion.

**[0006]** Applying both heat and compressive pressure to a body portion provides an effective treatment of lymphedema. The combination of higher temperature and pressure has a synergistic effect leading to an increased absorption of edema matter. The internal pressure, being exerted at the skin surface by arterial pulsations and/or muscle action, assists in pressurizing the treated body portion.

**[0007]** In an aspect of the method, the compressive pressure and heat are applied to a body portion using a garment which is configured to fit around the body portion, by positioning the garment on the body portion and adjusting the circumference of the garment while being positioned on the body portion to apply a desired compression profile

to the body portion, and applying heat to the body portion by heating means comprised in the garment.

**[0008]** The use of a garment enables the application of both heat and compressive pressure to a body portion for lymphedema treatment while the body portion maintains a  
5 sufficient range of motion.

**[0009]** Another aspect of the invention provides a device for performing the lymphedema treatment method. The device corresponds to a garment comprising a multi-component sheet configured for being applied to a body portion. The multi-component sheet comprises at least one rigid outer layer and at least one softer inner layer, the rigid layer  
10 being extended throughout the sheet for maintaining a substantially constant cross-sectional perimeter of the multi-component sheet and said softer layer arranged at an inner side of the multi-component sheet such that, in use, the softer layer is interposed between the body portion and the rigid layer, wherein the softer layer is configured to enable close contact between the rigid layer and said body portion. Next to the multi-  
15 component sheet, the garment comprises a temperature control means including heating means for setting a temperature at the inner side of the multi-component sheet between 32.5 and 40 °C, preferably at least 36 °C, more preferably at least 36.5 °C, preferably at most 40 °C, more preferably at most 39.5 °C, wherein the heating means is configured to be interposed between the rigid layer and the body portion. The rigid layer of the multi-  
20 component sheet possesses a rigidity or stiffness higher than the rigidity or stiffness of a body portion, which enables the capturing of an internal pressure exerted at the skin surface by arterial pulsations and/or muscle action of a body portion while performing an externally applied circumferential pressure by the multi-component sheet. The multi-component sheet is configured to exert an externally applied circumferential pressure at  
25 pressure levels of at least 0.5 mm Hg, preferably at least 15 mm Hg, more preferably at least 28 mm Hg, and at most 200 mm Hg, preferably at most 100 mm Hg and more preferably at most 80 mm Hg and for the capturing of said internal pressure for pressure levels of at least 0.5 mm Hg, preferably at least 10 mm Hg, more preferably at least 20 mm Hg, and at most 260 mm Hg and preferably at most 90 mm Hg.

30 **[0010]** The presence of heating means and a multi-component sheet enables the garment to apply heat as well as compressive pressure to a body portion for performing the lymphedema treatment method. Furthermore, the configuration of the garment enables the application of the heat and pressure levels desired for performing the lymphedema treatment method.

**Description of figures**

**[0011]** For a better understanding of the present invention, reference is made to the detailed description of the invention, by way of example, which is to be read in conjunction with the following drawings, wherein:

- 5 **Figure 1** shows a possible design of a garment for the treatment of lymphedema being applied to a leg of a patient, according to embodiments of the present invention;

**Figure 2** shows a possible design of a garment for the treatment of lymphedema being applied to an arm of a patient, according to embodiments of the present invention.

**Detailed description of the invention**

- 10 **[0012]** The present invention concerns a method and device for treating lymphedema for cosmetic and/or therapeutic purposes.

- [0013]** Unless otherwise defined, all terms used in disclosing the invention, including technical and scientific terms, have the meaning as commonly understood by one of  
15 ordinary skill in the art to which this invention belongs. By means of further guidance, term definitions are included to better appreciate the teaching of the present invention.

**[0014]** “A”, “an”, and “the” as used herein refers to both singular and plural referents unless the context clearly dictates otherwise. By way of example, “a compartment” refers to one or more than one compartment.

- 20 **[0015]** “About” as used herein referring to a measurable value such as a parameter, an amount, a temporal duration, and the like, is meant to encompass variations of +/-20% or less, preferably +/-10% or less, more preferably +/-5% or less, even more preferably +/-1% or less, and still more preferably +/-0.1% or less of and from the specified value, in so far such variations are appropriate to perform in the disclosed invention. However, it is to  
25 be understood that the value to which the modifier “about” refers is itself also specifically disclosed.

- [0016]** “Comprise”, “comprising”, and “comprises” and “comprised of” as used herein are synonymous with “include”, “including”, “includes” or “contain”, “containing”, “contains” and are inclusive or open-ended terms that specifies the presence of what follows e.g.  
30 component and do not exclude or preclude the presence of additional, non-recited components, features, element, members, steps, known in the art or disclosed therein.

**[0017]** The recitation of numerical ranges by endpoints includes all numbers and fractions subsumed within that range, as well as the recited endpoints.

**[0018]** In a first aspect, the invention provides a method for treating lymphedema for  
5 cosmetic and/or therapeutic purposes, comprising the steps of:

- (i) heating a body portion of the anatomy of a living being to be treated to obtain a temperature at the skin surface of said body portion exceeding normal skin temperature the temperature not exceeding 40 °C, preferably not exceeding 39.5 °C;
- (ii) and simultaneously and/or sequentially applying a compressive pressure to the  
10 skin surface of said body portion, wherein said compressive pressure is the result of an externally applied circumferential pressure, and an internal pressure, the internal pressure being exerted at the skin surface by arterial pulsations and/or muscle action of said body portion.

**[0019]** Considering the swelling of body portions and the health risks related to  
15 lymphedema, treatment of lymphedema may be desired for as well cosmetic as therapeutic purposes. Throughout the text, "body portion" is used as a general term to designate a portion of the body of a living being. The combination of applying heat and compressive pressure to a body portion provides an effective treatment of lymphedema, as revealed by thorough studies carried out by the present inventors. Regarding the use  
20 of heat for lymphedema treatment, the present inventors found that increased temperature liquefies the edema made up of proteins and water, which at the normal skin temperature of about 32.5°C is in a gel state. Additionally, the skin temperature increase causes vasodilation of the cutaneous arteriovenous capillaries, which is accompanied by an increased capillary permeability. Even though vasodilation is an a priori aggravating  
25 condition for edemas, it has surprisingly been found to nevertheless become beneficial when a suitable compressive pressure is exerted in order to increase the tissue pressure and inverse the net driving force in the Starling equation of fluid movement across capillary membranes to favor absorption processes by the capillaries. Hence, according to the invention, the temperature increase is provided preferably in combination with the  
30 application of a compressive pressure at the skin surface. The combination of higher temperature and pressure has a synergistic effect leading to an increased absorption of edema matter, and particularly of proteins in addition to water. According to the present method, temperature and compressive pressure can also be applied sequentially next to simultaneously. For example, it may prove beneficial for lymphedema treatment to first  
35 apply heat to the skin surface of a body portion, liquefying the edema matter, after which a

compressive pressure is combined with the heat to evacuate the (solubilized) local interstitial colloid. The applied compressive pressure at the skin surface of the body portion is the result of a circumferential pressure, externally applied to a body portion of a patient, and an internal pressure, the internal pressure being exerted at the skin surface  
5 by arterial pulsations and/or muscle action of the body portion.

**[0020]** In a preferred embodiment of the method of the present invention, the applied temperature for heating the skin surface ranges from 32.5 to 40 °C, preferably from 36 to 39.5 °C, more preferably from 36 to 38 °C, and most preferably corresponds to a temperature slightly above 37 °C.

10 **[0021]** Increasing the temperature at the skin surface above the normal skin temperature of about 32.5 °C will result in the liquefaction of the edema (proteins), as discussed above. At temperatures above 40°C, a patient being treated for lymphedema will feel a discomfort.

**[0022]** In another preferred embodiment of the method, the externally applied  
15 circumferential pressure is at least 10 mm Hg, preferably at least 28 mm Hg, more preferably at least 40 mm Hg, most preferably at least 45 mm Hg, and at most 90 mm Hg, preferably at most 80 mm Hg and more preferably at most 70 mm Hg.

**[0023]** These pressure levels are in the range of the compression classes which are used for compression garments for the treatment of lymphedema. The effectivity of these  
20 pressure levels for lymphedema treatment is thus known. Besides, these pressure levels do not squeeze the microcirculation of a treated body part, the pressure in the microcirculation itself being approximately 30 mm Hg.

**[0024]** In another preferred embodiment of the method, the internal pressure is at least 20 mm Hg, preferably at least 35 mm Hg, at most 260 mm Hg, preferably at most 100 mm  
25 Hg, more preferably at most 90 mm Hg.

**[0025]** The concept of internal pressure can be explained as follows. The internal pressure is the pressure being exerted at the skin surface by arterial pulsations and/or muscle action of a patient. Arterial pulsations are rhythmic expansions of arteries. The pressure of circulating blood on the arteries results in an arterial pressure. With each  
30 arterial pulsation a pressure wave is generated, resulting in an arterial pressure waveform. The arterial pressure waveform results in pressure changes at the skin surface. When an external pressure is applied to a body portion of a patient, the surface veins, arteries, muscles, and other soft tissue is compressed, causing the circulating blood being forced

through narrower circulatory channels, increasing the arterial pressure. Movement of the body of a patient involves muscle action. Muscle action will result in pressure changes at the skin surface. When an external pressure is applied to a body portion, the muscles in that body portion have less freedom of movement compared to a situation where no external pressure is applied. Thus, when an external pressure is applied to a body portion, larger spikes in pressure will occur at the skin surface when a muscle activates compared to the situation without the application of an external pressure.

**[0026]** The internal pressure is in fact a time- and spatially-varying pressure, due to the arterial pulsations and the activity of muscles linked to body movement. The total compressive pressure being applied at the skin surface of a body portion, being the result of an externally applied pressure and internal pressure, is thus also a time- and spatially-varying pressure, the pressure fluctuating due to arterial pulsations and muscle action. For the method of the present invention, the time- and spatially-varying total compressive pressure at the skin surface preferably varies between amplitudes falling in the range between 5 mm Hg and 350 mm Hg, with amplitudes of preferably at least 10 mm Hg, more preferably at least 15 mm Hg, most preferably at least 35 mm Hg, utmost preferably at least 40 mm Hg, and with amplitudes of preferably at most 250 mm Hg, more preferably at most 100 mm Hg, most preferably at most 90 mm Hg. It should be emphasized that the high pressure peaks at the skin surface, which can reach values of 250 to 350 mm Hg, only occur for very short instances, due to the rhythmic nature of arterial pulsations and the intermittent nature of muscle action. Therefore, the high pressure peaks cannot create damage on microcirculation in a treated body portion. Instead, the time- and spatially-varying pressure will realize a massage effect on the treated body portion, effectively evacuating local interstitial colloid.

**[0027]** In another preferred embodiment of the method, the compressive pressure and heat are applied to a body portion using a garment which is configured to fit around the body portion, by positioning the garment on the body portion and adjusting the circumference of the garment while being positioned on the body portion to apply a desired compression profile to the body portion, and applying heat to the body portion by heating means comprised in the garment.

**[0028]** The use of a garment enables the application of both heat and compressive pressure to a body portion for lymphedema treatment while the body portion maintains a sufficient range of motion. Non-excluding examples of suitable garments are sleeves and braces. Garments may be provided with fastening means, such as a fastening strap combined with a ring, the ring having an aperture capable of receiving a free end of the

fastening strap through it, when the garment is wrapped. Such fastening means can aid in the configuration of a garment to fit a body portion. Resistors may be used as heating means.

**[0029]** In a more preferred embodiment, the operation of adjusting the circumference of the garment comprises setting the circumference of the garment to defined values at sections of the body portion.

**[0030]** The desired circumference of the garment, which may vary at different portions of the garment, depends on the compression profile desired by the method of the present invention, on material properties of the garment and on the dimensions of the treated body portion. Along the distance of a treated body portion, sections of the body portion having a smaller diameter will require a smaller circumference of the garment to obtain a defined tension or pressure value compared to sections of the same body portion having a larger diameter. As long as the elasticity or the tension of the garment is uniform, the application of a compressive pressure by the garment results in a pressure gradient due to Laplace law. The circumference of a body portion, such as a leg or an arm, increases from the distal to the proximal side, resembling a truncated cone. Due to this increase in circumference from the distal to the proximal side, it follows from Laplace law that the pressure decreases from the distal to the proximal side. The pressure gradient will push the edema matter in the desired direction (i.e., towards the proximal side of a treated body portion of a patient). Besides, a pressure gradient may be achieved by tightening the straps of a garment harder, thus achieving a higher tension, at the distal part compared to the proximal part of a treated body portion. The latter option is particularly of importance for swollen body portions which have lost their cone-like form due to an advanced level of lymphedema, the body portions rather resembling a cylinder shape, and thus the pressure gradient according to Laplace law being diminished or absent. The application of an elastic band at level of the proximal side of a treated body portion, to maintain a garment at the right position, should be avoided. The use of such an elastic band would compress the skin inducing a major change of pressure level, which may block the edema matter flowing to the desired direction (i.e., towards the proximal side of a treated body portion of a patient). In the course of time, an effective treatment of lymphedema will cause the treated body portions to reduce in volume. To maintain desired compression levels according to the method of the present invention, the circumference of the applied garment has thus to be varied in the course of time, in line with the changing volume of the treated body portions.

- [0031]** In a second aspect, the invention provides a device for performing the lymphedema treatment method. The device corresponds to a garment comprising a multi-component sheet configured for being applied to a body portion. The multi-component sheet comprises at least one rigid outer layer and at least one softer inner layer, the rigid layer being extended throughout the sheet for maintaining a substantially constant cross-sectional perimeter of the multi-component sheet and said softer layer arranged at an inner side of the multi-component sheet such that, in use, the softer layer is interposed between the body portion and the rigid layer, wherein the softer layer is configured to enable close contact between the rigid layer and said body portion. Next to the multi-component sheet, the garment comprises a temperature control means including heating means for setting a temperature at the inner side of the multi-component sheet between 32.5 and 40 °C, preferably at least 36 °C, more preferably at least 36.5 °C, preferably at most 40 °C, more preferably at most 39.5 °C, wherein the heating means is configured to be interposed between the rigid layer and the body portion. The rigid layer of the multi-component sheet possesses a rigidity or stiffness higher than the rigidity or stiffness of a body portion, which enables the capturing of an internal pressure exerted at the skin surface by arterial pulsations and/or muscle action of a body portion while performing an externally applied circumferential pressure by the multi-component sheet. The multi-component sheet is configured to exert an externally applied circumferential pressure at pressure levels of at least 0.5 mm Hg, preferably at least 15 mm Hg, more preferably at least 28 mm Hg, and at most 200 mm Hg, preferably at most 100 mm Hg and more preferably at most 80 mm Hg and for the capturing of said internal pressure for pressure levels of at least 0.5 mm Hg, preferably at least 10 mm Hg, more preferably at least 20 mm Hg, and at most 260 mm Hg and preferably at most 90 mm Hg.
- [0032]** The presence of heating means and a multi-component sheet enables the garment to apply heat as well as compressive pressure to a body portion for performing the lymphedema treatment method. Furthermore, the configuration of the garment enables the application of the heat and pressure levels desired for performing the lymphedema treatment method. The rigid layer provides a non-stretch or low-stretch layer when the sheet is wrapped around a body portion, such that the cross-sectional perimeter of the wrapped sheet remains substantially unaltered once tightened by fastening means. This is important for obtaining a compressive pressure at the skin surface. The rigid layer further acts as support for the other layers of a multi-component sheet. Besides, fastening means, such as fastening straps combined with rings, are advantageously attached to the inelastic layer situated at the outer side of the multi-component sheet. The positioning of a softer layer between a rigid layer and a body portion enables close contact of the rigid

layer with the surface of a body portion. Since the skin surface of a living being is irregular, the rigid layer alone, being a non-stretch or low-stretch layer, would have difficulties with making close contact to the whole skin area of a body portion. Preferably, the heating means is interposed between the rigid layer and the treated body portion. For example, the heating means may be situated between the rigid outer layer and the softer inner layer of a multi-component sheet being composed of those two layers. Heating means form part of a temperature control system, preferably including a controller and possibly a preferably portable (electrical) energy source, such as a battery. The temperature control system is arranged to control and set the temperature at the inner side of the sheet to temperatures between 32.5 and 40 °C. As mentioned above, increasing the temperature at the skin surface above the normal skin temperature of 32.5 °C will result in the liquefaction of the edema (proteins) while at temperatures above 40 °C, a patient being treated for lymphedema will feel a discomfort. The concept of internal pressure at the skin surface due to arterial pulsations and/or muscle action has been explained above. To effectively add the internal pressure to the externally circumferential pressure applied by the multi-component sheet, or, in other words, to capture the internal pressure, the rigidity or stiffness of the rigid layer has to be higher than the rigidity or stiffness of a body portion being treated.

**[0033]** By configuration, the garment is able to provide the required pressure levels at the skin surface of the treated body portion, which is meaning both the required externally applied pressure levels and the required internal pressure levels, for performing the lymphedema treatment method of the present invention. The desired pressure levels can be patient-specific as well as body-portion-specific. In first instance, the configuration of the multi-component sheet involves controlling the circumference of the garment. However, the configuration of the garment may also involve choosing the number of rigid and outer layers for the multi-component sheet and selecting materials with specific characteristics for the rigid and softer layers. Besides, garments according to the present invention are preferably portable, since a patient's movement causes muscular pressure increase, which increases the internal pressure and makes lymphedema treatment more effective. Therefore, the rigid layer is preferably formed such as to allow a movement of a body portion, such as knee or elbow bending. In this regard, the garment may comprise a successive disposition of a plurality of multi-component sheets flexibly attached to one another to provide for body portion movement, with each multi-component sheet capable of being wrapped around the body portion. As discussed above, due to the cone-like shape of body portions of a living being, it follows from Laplace law that, as long as the tension applied by the multi-component sheet is constant along the entire area of the

treated body portion, a natural pressure gradient is present, the pressure decreasing from the distal to the proximal side of a body portion. The pressure gradient will push the edema matter in the desired direction (i.e., towards the proximal side of a treated body portion of a patient). If the cone-like shape of a body portion of a living being disappears due to swelling caused by the lymphedema, the pressure gradient due to Laplace law is diminished or absent. In the latter case, the pressure gradient can be achieved by applying a higher tension at the distal side of a body portion compared to the proximal side, by tightening the multi-component sheet in a greater extent on the distal side compared to the proximal side of the body portion. Alternatively, a pressure gradient can be created by choosing different materials for the softer layer along the length of the multi-component sheet. Materials with a higher visco-elasticity will allow for a better capturing of internal pressure at the skin surface by arterial pulsations than materials with a lower visco-elasticity. In particular, the softer layer will be composed out of different sections from its distal to its proximal end, each section having different material properties. Since the material properties of such a multi-component sheet will differ from the proximal to the distal side, a pressure gradient can be applied on the treated body portion, even when the tension applied by the multi-component sheet is constant along the treated body portion. Therefore, the softer layer sections of such a multi-component sheet being closer to the distal part of the treated body portion should have a higher visco-elasticity than the softer layer sections being closer to the proximal part of the treated body portion.

**[0034]** Due to the massage effect caused by the time- and spatially-varying pressure at the skin surface of a treated body portion, obtained by performing the method of the present invention, the evacuation of local interstitial colloid will cause the treated body portion to deswell. Because of the semi-rigidity of the multi-component sheet, the distance between the skin surface and the sheet will increase when the body portion deswells, resulting in a loss of fitting and a reduced massage effect. In this situation, only the externally applied circumferential pressure will still be in place, which will impede the drained interstitial colloid to return to the edema, yet will not continue to reduce the edema. Therefore, when the body portion is deswelled to a certain extent, the multi-component sheet is preferably re-fitted to the new dimensions of the treated body part by tightening the sheet. For example, the sheet should be re-fitted approximately each half hour.

**[0035]** To allow for the externally applied circumferential pressure to be constant at a cross-sectional area of a treated body part, the applied garment should overlap as little as possible at that cross-sectional area. An overlapping part of the garment will increase

locally (longitudinally) the radius of curvature, leading in a reduction in pressure and thus resulting in a lower pressure compared to the pressure at the skin surface at level of the non-overlapping part of the garment. Therefore, the garment of the present invention is preferably tailored to the dimensions of the treated body part, avoiding substantial overlapping of the garment while the garment is tightened to achieve the compressive pressure levels desired in the method of the present invention.

**[0036]** In a preferred embodiment of the garment, the rigid layer is made of a non-stretch or short-stretch material that can be stretched by maximum 100%, preferably by maximum 75%, more preferably by maximum 50%, most preferably by maximum 25% along the direction of the circumference of the body portion when using the tension required to secure the garment.

**[0037]** In a more preferred embodiment of the garment, the rigid layer requires a force of at least 1 N, preferably at least 2 N, more preferably at least 5 N to stretch the rigid layer by 1% per meter width along the direction of the circumference of the body portion.

**[0038]** For example, a rigid layer with a width of 10 cm can be stretched by 1% with a force of at least 0.1 N, preferably at least 0.2 N, more preferably at least 0.5 N while a rigid layer with a width of 5 cm can be stretched by 1% with a force of at least 0.05 N, preferably at least 0.1 N, more preferably at least 0.25 N.

**[0039]** The high forces required to stretch the rigid layer implies that the rigid layer cannot be easily significantly stretched in the plane of the multi-component sheet. As mentioned above, this low stretch or considerable stiffness of the rigid layer is necessary to maintain a substantially unaltered cross-sectional perimeter of the multi-component sheet once tightened around a body portion, which is of importance for obtaining a compressive pressure at the skin surface. By way of example, the rigid layer may be made of a nonwoven fabric made of synthetic or natural fibers. It will be convenient to note that a variety of other materials may be used as rigid layer.

**[0040]** In other preferred embodiments of the garment, the softer layer is preferably made out of an elastic or visco-elastic material, for which the material properties are the following: the compressive modulus, as determined in a direction perpendicular to the plane of the softer layer, is at most 500 MPa, preferably at most 100 MPa, more preferably at most 10 MPa and most preferably at most 1 MPa; the relaxation constant is at most 20 s, preferably at most 10 s, and at least 1 ms, preferably at least 2 ms, and most preferably at least 20 ms; and the density is at least 10 kg/m<sup>3</sup>, preferably at least 15 kg/m<sup>3</sup> and at most 150 kg/m<sup>3</sup>, preferably at most 100 kg/m<sup>3</sup>.

**[0041]** The material properties of the softer layer, including compressive modulus, relaxation constant and density, are chosen in function of the softer layer's ability to assist in obtaining pressure variations at the skin surface by exploiting the arterial blood pressure variation. Particularly advantageous are softer layers having such visco-elastic properties that cause a phase shift in skin pressure variations relative to the arterial blood pressure. The relaxation constant of at least 1 ms endows the softer layer with a considerable viscous component. Softer layers can be made of one or a combination of known padding materials, such as, but not limited to: a high-density foam, such as a polyurethane foam, a polyethylene foam, an appropriate cellular material, a silicone gel, and a spacer fabric. They can as well be formed of different, stacked layers. Since lymphedemas may differ in their respective water content, it will be convenient to note that resilient layers having different mechanical properties may be selected to treat the different edemas.

**[0042]** In another preferred embodiment of the garment, the temperature control means comprises one or more temperature gauges arranged at the inner side of the multi-component sheet.

**[0043]** As mentioned above, the heating means of the garment form part of a temperature control system, which also contains a controller. The controller is connected to the heating means through a cable. The controller is arranged to control the temperature at the inner side of the multi-component sheet by controlling the actuation of the heating means. Temperature control can be effected by providing one or more temperature gauges, such as thermocouples, in or at the resilient layers, and electrically connected to the controller. The controller can have a user interface, such as a control knob, for adjusting the temperature as desired. The one or more temperature gauges can be provided inside the multi-component sheet, for example between softer layers, in a composition of the multi-component sheet containing multiple softer layers. Alternatively, the temperature gauges can be provided at the skin facing the external surface of the multilayer sheet (i.e. the external surface of innermost softer layer).

**[0044]** In another preferred embodiment of the garment, the heating means are electrical resistance heating wires and/or infrared heating means.

**[0045]** For heating purposes, the garment may be equipped with electrical heating wires or infrared heating means or a combination of both. The infrared heating means may be tubular infrared heating elements. The heating means are preferably distributed throughout the multi-component sheet. As an alternative or in addition thereto, other

suitable heating means, such as chemical heating elements, or channels in which a heating liquid circulates, may be provided.

**[0046]** In another preferred embodiment of the garment, the garment comprises one or more pressure gauges for measuring a pressure level at the inner side of the multi-  
5 component sheet and a controller to which the one or more pressure gauges are connected.

**[0047]** The garment is preferably equipped with one or several pressure gauges, possibly electrically connected to a controller, for measuring the static (or mean) compression when the sheet is wrapped around a body portion. A pressure gauge is preferably  
10 provided at the inner side of the multi-component sheet, and certainly internally relative to the rigid layer. The pressure gauge can be provided at the skin facing the external surface of the multilayer sheet (i.e. the external surface of the innermost layer, being a softer layer). Alternatively, the pressure gauge can be provided within the softer layers, in a composition of the multi-component sheet containing multiple softer layers. The controller  
15 may be equipped with a pressure level indicator, such as a readout screen, an indicator lamp or an acoustic signaling means and be configured to determine and indicate when a desired pressure level is attained. The desired pressure level can be expressed either as a minimal value, or as a range within which the static (or mean) pressure should fall. When pressure falls out of the range, i.e. is either too low or too high, controller may  
20 provide an indication. The static (or mean) pressure exerted by the garment on the body portion (skin surface) preferably falls in the range between 10 and 60 mm Hg. The desired pressure can be patient-specific as well as body-portion-specific. Alternatively to the pressure gauges, an indication of the applied pressure can be achieved by applying markings, e.g. squares, on the garment. When the garment is tightened to achieve a  
25 desired pressure or tension at the skin surface of the treated body portion, the dimensions of these markings will elongate in the direction in which the garment is tightened. The extent of elongation of the markings is an indication of the applied pressure.

**[0048]** In another preferred embodiment of the garment, the garment comprises a pressure control means for setting a compressive pressure at the inner side of said multi-  
30 component sheet.

**[0049]** The garment can comprise a pressure control means for maintaining a suitable static (or mean) compressive pressure at the skin surface during lymphedema resorption. The pressure control means may comprise one or more bladders arranged at the inner side of the rigid layer, and preferably interposed between the outer rigid layer and the

inner softer layer. One bladder may be provided which extends throughout the sheet. Alternatively, a plurality of smaller, possibly interconnected bladders arranged adjacent to one another may be provided. The pressure control means may further comprise a preferably portable fluid reservoir and a preferably portable pump in fluid connection with  
5 the bladder. By filling the bladder or bladders to certain extents with fluid, a suitable static (or mean) compressive pressure at the skin surface during lymphedema treatment can be maintained.

**[0050]** The invention is further described by the following non-limiting figures which further  
10 illustrate the invention, and are not intended to, nor should they be interpreted to, limit the scope of the invention.

**[0051]** Figure 1 shows a possible design of a garment (100) according to embodiments of the present invention, applied to a leg (101) of a patient. Figure 2 depicts a possible design of a garment (200) according to embodiments of the present invention, applied to  
15 an arm (201) of a patient. In the following, Figures 1 and 2 will be discussed simultaneously and both leg and arm of the patient will be referred to as body portion. Around the body portion (101, 201) affected with lymphedema, a multi-component sheet (102, 202) is wrapped. For keeping the multi-component sheet (102, 202) wrapped, the garment (100, 200) comprises fastening means, comprising a fastening strap (103, 203)  
20 attached at one edge of the sheet (102, 202) and a ring (104, 204) attached to the opposite edge of the sheet (102, 202). The ring (104, 204) has an aperture capable of receiving a free end of a fastening strap (103, 203) through it, when the sheet (102, 202) is wrapped. Suitable pads (105, 205) made of a hook and loop material may be attached on the fastening strap (103, 203) and possibly on the sheet (102, 202) for securing the  
25 free end of the fastening strap (103, 203) to the sheet (102, 202) upon tightening the fastening strap (103, 203) through the ring (104, 204). It will be convenient to note that the fastening straps (103, 203) and the hook and loop pads (105, 205) may be replaced by any other suitable fastening means, such as clasps. An advantage of fastening straps (103, 203) is that they allow for wrapping body portions which are sized within a  
30 considerable size range. This is advantageous, since the patient will not need to use or buy a large number of differently sized garments (100, 200) as the lymphedema will reduce in volume. Other fastening means which account for same effects will be advantageous as well. In both figures, the multi-component sheet (102, 202) is composed out of two layers, being a rigid layer (106, 206) situated on the outer side of the multi-  
35 component sheet (102, 202) and a softer layer (107, 207) situated on the inner side of the

multi-component sheet (102, 202) (i.e. the side facing the skin of the treated body portion (101, 201)). The rigid layer (106, 206) is the layer on which the fastening means are attached. For the specific function of both rigid (106, 206) and softer layer (107, 207) as well as for suitable materials for these layers, reference is made to the above discussion.

5 Heating means, such as electrical resistance heating wires (108, 208) are interposed between the outer rigid layer (106, 206) and inner softer layer (107, 207). Advantageously, the heating means (108, 208) are distributed throughout the multi-component sheet (102, 202). The heating means (108, 208) are connected to a controller (109, 209) by an electrical cable (110, 210). Heating means (108, 208) and controller (109, 209) are part of

10 a temperature control system, comprising a, possibly portable, (electrical) energy source, such as a battery (not shown on Figures 1 and 2). A temperature gauge, such as a thermocouple (111, 211) and a pressure gauge (112, 212) are electrically connected to the controller (109, 209). Both temperature gauge (111, 211) and pressure gauge (112, 212) are situated between the outer rigid layer (106, 206) and the inner softer layer (107,

15 207) of the multi-component sheet (102, 202). The temperature and pressure levels measured by the temperature gauge (111, 211) and pressure gauge (112, 212) are displayed on a readout screen (113, 213) of the controller (109, 209). The controller (109, 209) also possesses a control knob (114, 214) for setting the temperature level the heating means (108, 208) have to provide. The set temperature is displayed on the

20 readout screen (113, 213) of the controller (109, 209). The controller can be configured to monitor if the measured static (or mean) pressure exceeds a desired minimal pressure value and/or if the measured static (or mean) pressure is situated between an indicated pressure range. When the pressure is either too low or too high, the controller may provide an indication, e.g., an indicator lamp (not shown on Figures 1 and 2) may light up.

25 This indication warns the wearer of the garment (100, 200) that the pressure should be increased or decreased, which can be achieved by tightening or loosening the fastening straps (103, 203), respectively. Alternatively, a suitable compressive pressure at the skin surface during lymphedema resorption may be attained by a pressure control means (not shown on Figures 1 and 2), which can comprise one or more bladders, preferably

30 interposed between the outer rigid layer and the inner softer layer, which may be filled by certain extents with fluid using a preferably portable fluid reservoir and a preferably portable pump in fluid connection with the bladder. The garments (100, 200), as shown in Figures 1 and 2, are designed to be portable by a patient, maintaining the range of motion of a patient wearing such a garment (100, 200) on a body portion (101, 201). For the sake

35 of the patient's range of motion, the controller (109, 209) can be placed in a housing (not

shown on Figures 1 and 2) which is attached, either permanently or removably, to the multi-component sheet (102, 202).

**Claims**

1. Method for treating lymphedema for cosmetic and/or therapeutic purposes, comprising the steps of:
  - 5 (i) heating a body portion of the anatomy of a living being to be treated to obtain a temperature at the skin surface of said body portion exceeding normal skin temperature, the temperature not exceeding 40 °C, preferably not exceeding 39.5 °C;
  - 10 (ii) and simultaneously and/or sequentially applying a compressive pressure to the skin surface of said body portion, **characterized in that** said compressive pressure is the result of an externally applied circumferential pressure, and an internal pressure, said internal pressure being exerted at the skin surface by arterial pulsations and/or muscle action of said body portion.
- 15 2. The method of claim 1, **characterized in that** the applied temperature for heating the skin surface ranges from 32.5 to 40 °C, preferably from 36 to 39.5 °C, more preferably from 36 to 38 °C, and most preferably corresponds to a temperature slightly above 37 °C.
- 20 3. The method of claims 1-2, **characterized in that** said externally applied circumferential pressure is at least 10 mm Hg, preferably at least 28 mm Hg, more preferably at least 40 mm Hg, most preferably at least 45 mm Hg, and at most 90 mm Hg, preferably at most 80 mm Hg and more preferably at most 70 mm Hg.
- 25 4. The method of claims 1-3, **characterized in that** said internal pressure is at least 20 mm Hg, preferably at least 35 mm Hg, at most 260 mm Hg, preferably at most 100 mm Hg, more preferably at most 90 mm Hg.
- 30 5. The method of claims 1-4, **characterized in that** said compressive pressure and heat are applied to said body portion using a garment which is configured to fit around said body portion, by positioning said garment on said body portion and adjusting the circumference of said garment while being positioned on said body portion to apply a desired compression profile to said body portion, and applying heat to said body portion by heating means comprised in said garment.

6. The method of claim 5, **characterized in that** the operation of adjusting the circumference of said garment comprises setting the circumference of said garment to defined values at sections of said body portion.
7. Garment for performing the method of claims 1-6, comprising a multi-component sheet configured for being applied to said body portion, said multi-component sheet comprising at least one rigid outer layer and at least one softer inner layer, said rigid layer being extended throughout the sheet for maintaining a substantially constant cross-sectional perimeter of the multi-component sheet and said softer layer arranged at an inner side of the multi-component sheet such that, in use, the softer layer is interposed between the body portion and the rigid layer, wherein the softer layer is configured to enable close contact between the rigid layer and said body portion, and comprising a temperature control means including heating means for setting a temperature at the inner side of the multi-component sheet between 32.5 and 40 °C, preferably at least 36 °C, more preferably at least 36.5 °C, preferably at most 40 °C, more preferably at most 39.5 °C, wherein the heating means is configured to be interposed between the rigid layer and the body portion, **characterized in that** the rigid layer possesses a rigidity or stiffness higher than the rigidity or stiffness of said body portion, which enables the capturing of an internal pressure exerted at the skin surface by arterial pulsations and/or muscle action of said body portion while performing an externally applied circumferential pressure by said multi-component sheet, and in that the multi-component sheet is configured to exert said externally applied circumferential pressure at pressure levels of at least 0.5 mm Hg, preferably at least 15 mm Hg, more preferably at least 28 mm Hg, and at most 200 mm Hg, preferably at most 100 mm Hg and more preferably at most 80 mm Hg and for the capturing of said internal pressure for pressure levels of at least 0.5 mm Hg, preferably at least 10 mm Hg, more preferably at least 20 mm Hg, and at most 260 mm Hg and preferably at most 90 mm Hg.
8. Garment of claim 7, **characterized in that** said rigid layer is made of a non-stretch or short-stretch material that can be stretched by maximum 100%, preferably by maximum 75%, more preferably by maximum 50%, most preferably by maximum 25% along the direction of the circumference of the body portion when using the tension required to secure the garment.
9. Garment of claim 8, **characterized in that** said rigid layer requires a force of at least 1 N, preferably at least 2 N, more preferably at least 5 N to stretch said rigid

layer by 1% per meter width along the direction of the circumference of said body portion.

- 5 10. Garment of claims 7-9, **characterized in that** said softer layer is made out of an elastic or visco-elastic material and has a compressive modulus, as determined in a direction perpendicular to the plane of said softer layer, of at most 500 MPa, preferably at most 100 MPa, more preferably at most 10 MPa and most preferably at most 1 MPa.
- 10 11. Garment of claims 7-10, **characterized in that** said softer layer possesses a relaxation constant of at most 20 s, preferably at most 10 s, and at least 1 ms, preferably at least 2 ms, and most preferably at least 20 ms.
12. Garment of claims 7-11, **characterized in that** said softer layer possesses a density of at least 10 kg/m<sup>3</sup>, preferably at least 15 kg/m<sup>3</sup> and at most 150 kg/m<sup>3</sup>, preferably at most 100 kg/m<sup>3</sup>.
- 15 13. Garment of claims 7-12, **characterized in that** the temperature control means comprises one or more temperature gauges arranged at the inner side of said multi-component sheet.
14. Garment of claims 7-13, **characterized in that** the heating means are electrical resistance heating wires and/or infrared heating means.
- 20 15. Garment of claims 7-14, **characterized in that** said garment comprises one or more pressure gauges for measuring a pressure level at the inner side of said multi-component sheet and a controller to which the one or more pressure gauges are connected.
- 25 16. Garment of claims 7-15, **characterized in that** said garment comprises a pressure control means for setting a compressive pressure at the inner side of said multi-component sheet.

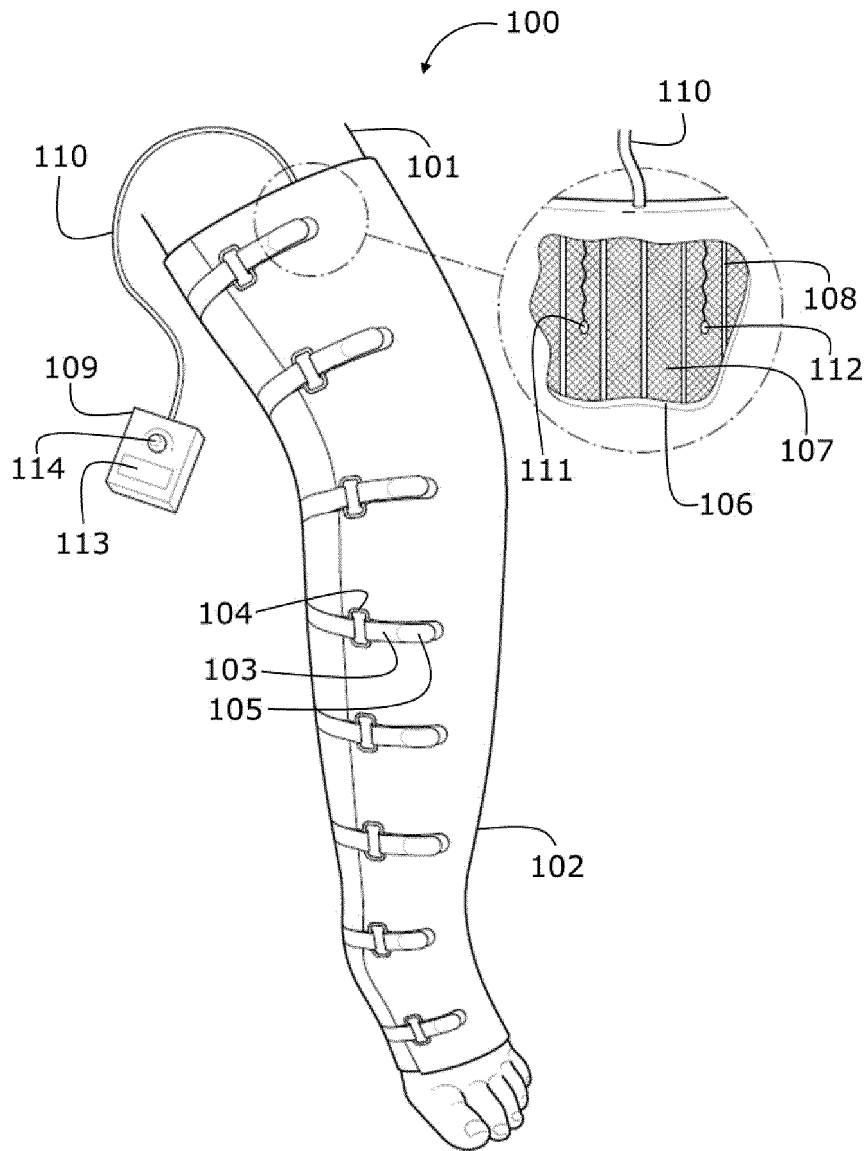


Figure 1

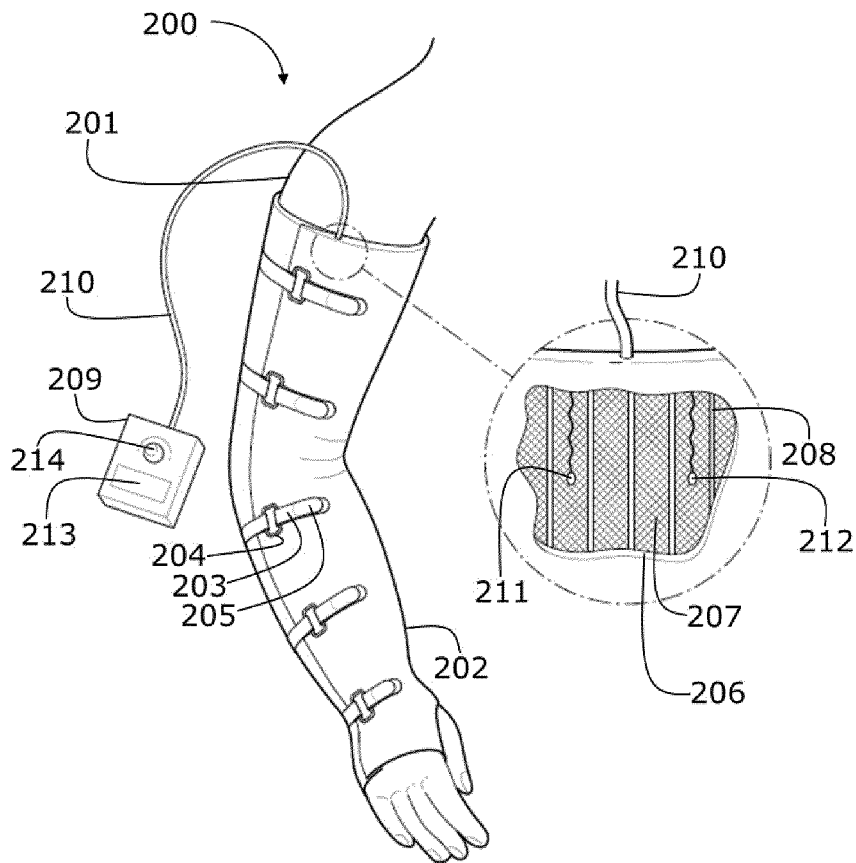


Figure 2

# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/EP2014/074593

## Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 1-6  
because they relate to subject matter not required to be searched by this Authority, namely:  
Claims 1-6 relate to a method for treatment of the human or animal body by therapy, which the International Searching Authority is not required to search in accordance with Rule 39.1(iv) PCT.
2. ☐ Claims Nos.:  
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

### Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

## INTERNATIONAL SEARCH REPORT

International application No

PCT/EP2014/074593

## A. CLASSIFICATION OF SUBJECT MATTER

INV. A61F7/00 A61F7/02  
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-Internal, WPI Data

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages                                                                                            | Relevant to claim No. |
|-----------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| X         | US 2014/276253 A1 (VARGA CHRISTOPHER M [US] ET AL) 18 September 2014 (2014-09-18)                                                                                             | 7-11, 13, 15, 16      |
| Y         | paragraphs [0007], [0008], [0042], [0078] - [0083], [0090], [0091]; figures 1-16                                                                                              | 12, 14                |
| Y         | -----<br>US 6 375 674 B1 (CARSON GARY ALLEN [US]) 23 April 2002 (2002-04-23)<br>column 3, line 60                                                                             | 12                    |
| Y         | -----<br>US 2013/030331 A1 (QUISENBERRY TONY [US] ET AL) 31 January 2013 (2013-01-31)<br>paragraph [0043]; figure 5A                                                          | 14                    |
| A         | -----<br>US 4 335 726 A (KOLSTEDT MARK W) 22 June 1982 (1982-06-22)<br>column 3, line 1 - column 4, line 25;<br>figures 1-6<br>column 5, line 28 - column 6, line 38<br>----- | 7-16                  |



Further documents are listed in the continuation of Box C.



See patent family annex.

## \* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

15 July 2015

Date of mailing of the international search report

22/07/2015

Name and mailing address of the ISA/

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Authorized officer

Viidebaum, Mikk

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/EP2014/074593

| Patent document<br>cited in search report |            |    | Publication<br>date |      | Patent family<br>member(s) |    |            | Publication<br>date |  |
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