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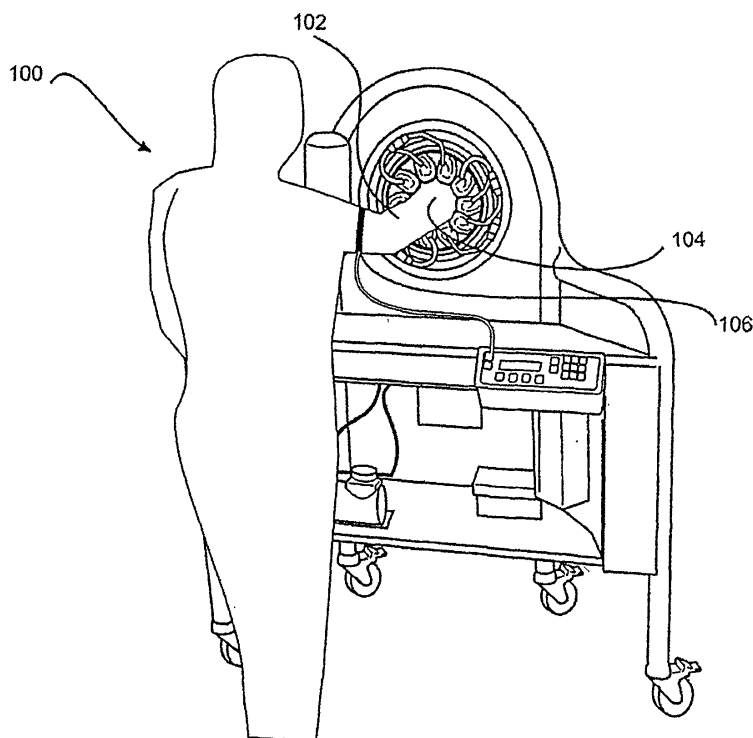
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71665 Vaihingen/Enz (DE)****(54) Method and apparatus for the treatment of lymphoedema**

(57) A vibratory transducer for medical application is disclosed. The vibratory transducer has an armature suspended in a magnetic field. The armature has a plurality of electrical conductive paths to provide electrical current flow in said armature to react with said magnetic field and cause movement in the armature controlled by variation in the electrical current flow. A contact surface is secured to the armature, with a surface area for frictionally coupling to a corresponding surface area of a patient for ex-

ample. Movement of the vibratory transducer induces movement in the patient, and the transducer can produce movement in the contact surface in at least two dimensions simultaneously. A plurality of compartments, that are adapted to surround and closely conform to a limb of the patient, are able to apply a pressure stimulus at particular locations around the limb. Medical application can include treatment of bone fractures, oedema, and in elastography, amongst other applications.

**Figure 2****EP 1 721 594 A1**

## Description

### Field of the Invention

**[0001]** The present invention relates to the treatment of lymphoedema and, more generally, to the treatment of conditions involving the accumulation of fluid in dependant tissue

### Background

**[0002]** If left untreated the accumulation of fluid in dependant tissue can lead to significant inflammatory problems. In some circumstances the inflammation can have a significant adverse effect on the quality of a person's life and the enjoyment he or she derives from activities associated with everyday living. Ulcers, wounds and lymphoedemas are a few examples.

**[0003]** In the case of lymphoedema the accumulation of lymphatic fluid occurs in the first 2 cm of tissue below the skin and may even be much deeper on oedema affected body parts. In more severe cases the lymphatic fluid may inflame the tissue to a thickness of 10 cm or more.

**[0004]** Typically lymphoedema occurs when the lymphatic vessels of the lymphatic system are missing, impaired or damaged, or when the lymph nodes are removed.

**[0005]** Filariasis lymphoedema is a condition where the lymph nodes are impaired by parasitic filarial worms that lodge themselves in the lymphatic system. In 2000 the World Health Organisation estimated that over 120 million people had been affected by the condition with over 40 million of those people being seriously incapacitated and disfigured. The condition is said to exert a heavy social burden including both further complications and social stigmatization.

**[0006]** It is commonly accepted that some forms of radiotherapy and/or surgery of the breast, prostate, bladder, and colon place the patient at risk of developing lymphoedema. With cancer patients the most common situations in which lymphoedema results are related to women who have had mastectomy surgery, because of breast cancer, and patients who have had surgery or radiotherapy for cancers of the reproductive system, bowel or prostate. It is estimated that 20-30% of people who have undergone these types of surgery will develop lymphoedema.

**[0007]** Left untreated lymphoedema results in swelling which may in turn lead to serious complications including immobility, painful joints, taut dry skin and subcutaneous tissue becoming fibrotic. Bacteria and fungi may also infect the lymphatic fluid which provides a rich protein food source. This complication is commonly known as lymphangitis and can be life threatening.

**[0008]** US patent application US2003/0171795 to Walmsley and Angel notes some of the more common symptoms of lymphoedema as being limb heaviness,

weakness, pain, restricted mobility, burning pains, elevated skin temperature, obvious deformity, social isolation and psychological morbidity. The current management and treatment of lymphoedema requires continual health professional intervention and patient care.

**[0009]** Treatment methods including breathing exercises, bandaging, massage, small movement and rapid exercise have produced limited results. It would be a great advantage to community, and patients, if the treatment of lymphoedema could be performed more effectively.

**[0010]** The most common of all treatments available is known as "Manual Lymphatic Drainage" (MLD) massage with pressure bandaging. MLD massage is the current world gold standard method and is taught to physiotherapists and occupational therapists throughout the world. With MLD the therapist manipulates the patient with specially learned techniques to draw fluid out of the affected area and into areas where it can be better absorbed by a non-retarded lymphatic network.

**[0011]** In a two-week period of intensive treatment, a patient would typically receive a one hour massage session each morning and afternoon. Each massage session would be followed by wrapping the affected limb in special bandages and keeping it wrapped until the start of the next massage session. At the end of the course of treatment, patients are typically advised to wear a compression garment covering the limb at all times during the day and, also, to bandage the limb or wear a special overnight type of compression garment every night. This is very cumbersome and inconvenient for the patient.

**[0012]** Other treatment techniques include compression pumps with inflatable sleeves and low level laser therapy.

**[0013]** Practitioners typically prescribe a regime of patient care comprising: (i) washing and moisturising the skin to avoid infection; (ii) protecting the skin from cuts, scratches, insect bites, knocks and sunburn; (iii) using an electric razor; (iv) applying a disinfectant and contacting a doctor if injury occurs; (v) avoiding wearing watches, rings and bracelets, which in some circumstances could damage the skin; (vi) avoiding standing still for long periods of time; (vii) ensuring that the limb is exercised normally; and (viii) avoiding any pushing or lifting of heavy objects. Even when adhering to such a regime of patient care, recurrent inflammatory episodes are a common complication.

**[0014]** A method of vibration for the treatment of lymphoedema is disclosed in US2004/0077978 to Nelson et al. This method and methods of vibration that have been available to date are not particularly effective.

### Summary of the Invention

**[0015]** According to one aspect of the invention there is provided a method of treating a patient having affected tissue, the method comprising applying to a limb or body portion of the patient a pressure stimulus operating in

multiple directions in a plane substantially perpendicular to the limb or body portion, the stimulus stimulating the epidermis, dermis and subcutaneous layers of the affected tissue such that there is a relatively rapid movement of interstitial fluid in the affected tissue into the lymphatic system.

**[0016]** In preferred arrangements the pressure stimulus is applied cyclically.

**[0017]** In another particular aspect of the invention the pressure stimulus includes pressure variations directed substantially along a path that is arranged within an area and which substantially avoids travelling back and forth over a central region of the area.

**[0018]** The path may consist of twenty path elements arranged end to end, with each end positioned to lie substantially on a circle such that the twenty path elements form a continuous and substantially symmetrical twenty-pointed star. With this arrangement the method may achieve a movement of 80 millilitres of interstitial fluid into the lymphatic system in less than a 30 minute treatment session. In one particularly preferred arrangement about 80 millilitres of interstitial fluid is moved into the lymphatic system in less than a 10 minute treatment session.

**[0019]** Preferably the pressure stimulus includes pressure variations directed substantially along a continuous path and the total absolute angular displacement over the path is more than 360 degrees. In one arrangement the total absolute angular displacement over the path is about 540 degrees. In another arrangement the total absolute angular displacement over the path is about 720 degrees.

**[0020]** Preferably there are at least two distinct changes in direction over a cycle of oscillation of the pressure stimulus.

**[0021]** The epidermis, dermis and subcutaneous layers of the affected tissue may be stimulated to the extent that a ripple effect is induced along the surface of the patient's skin away from the stimulus. Without being limited to a particular theory it is thought that the method operates to stimulate the anchoring filaments of the initial lymphatics in a concerted manner so as to influence the opening of the endothelial cell gates of the initial lymphatics and thereby cause the relatively rapid movement of interstitial fluid.

**[0022]** With the advantages of the system, preferred arrangements may limit the pressure stimulus to ensure that the movement of interstitial fluid into the lymphatic system is controlled and is not so rapid as to adversely affect the patient. To assist with rapidly and controllably moving interstitial fluid into the lymphatic system the method may include receiving response information from the epidermis and adjusting the pressure stimulus according to the response information and predetermined criteria.

**[0023]** The pressure stimulus may be applied to a relatively thin band around a limb of the patient and the ripple effect may extend at least to where the limb is con-

nected to the body of the patient.

**[0024]** In some arrangements the method includes selecting a resonant frequency of the layers of tissue and subjecting the patient to a stimulus at that frequency. To improve the patient response the anchoring filaments of the initial lymphatics may be stimulated in a concerted manner over a range of sweeping frequencies so as to influence the opening of the endothelial cell gates of the initial lymphatics and thereby cause the relatively rapid movement of interstitial fluid in the affected tissue into the lymphatic system.

**[0025]** In one arrangement the layers of tissue are stimulated at amplitude of between about 0.1mm and about 5 mm, peak to peak, and at a frequency of between about 10 and 100 Hz. The pressure stimulus may be applied from a base point moving at a velocity of about 100 mm per second. In another arrangement the layers of tissue are stimulated an amplitude of between about 0.5 mm and about 5 mm, peak to peak, and at a frequency of between about 1 and 50 Hz.

**[0026]** The pressure variations may be two dimensional by virtue of the area comprising a surface arranged substantially perpendicular to the length of a body part or limb of the patient which is being treated. Furthermore, the pressure stimulus path may consists of five path elements arranged end to end, with each end positioned to lie substantially on a circle, such that the five path elements form a continuous and substantially symmetrical five pointed star. Each path element may comprise a line that is slightly curved so as to have rounded points.

**[0027]** Alternatively the pressure stimulus path may consists of three lines arranged end to end, with each end positioned to lie substantially on a circle, such that three path elements form a continuous and substantially symmetrical triangle.

**[0028]** In one particularly preferred arrangement the pressure stimulus path consists of twenty path elements arranged end to end, with each end positioned to lie substantially on a circle such that the twenty path elements form a continuous and substantially symmetrical twenty-pointed star. As would be apparent in this arrangement there many more than at least two distinct changes in direction over a cycle of oscillation of the pressure stimulus.

**[0029]** The method may including translating a member that surrounds the limb of the patient, the member being translated in a two dimensional path in a plane to create the pressure variations. Preferably the member is substantially rigid.

**[0030]** According to another aspect of the invention there is provided a method of treating a patient having affected tissue, the method comprising subjecting the patient to a complex pressure stimulus operating in multiple directions, the stimulus stimulating the epidermis, dermis and subcutaneous layers of the affected tissue such that the anchoring filaments of the initial lymphatics vibrate in a relatively rapid manner that is conducive to stimulating a resetting of their elastic properties.

**[0031]** A ripple effect along the surface of the skin away from the stimulus may be evident. Thus, according to yet another aspect of the invention there is provided a method of treating a patient having affected tissue, the method comprising: subjecting the patient to a pressure stimulus operating in multiple directions such that a ripple effect along the surface of the skin away from the stimulus is evident, which method includes, and the ripple effect being indicative of, the epidermis, dermis and subcutaneous layers of the affected tissue being stimulated by the stimulus in multiple directions so that the anchoring filaments of the initial lymphatics vibrate in a relatively rapid manner that is conducive to stimulating a resetting of their elastic properties.

**[0032]** According to a further aspect of the invention there is provided apparatus for treating a patient having affected tissue, the apparatus including a plurality of compartments that are adapted to surround and closely conform to a limb of the patient, the compartments being substantially isolated from each other so that each compartment is able to apply a relatively independent pressure stimulus at particular locations around the limb. Preferably particular compartments can be rendered inoperable so as to avoid stimulating a sensitive area of the limb, and the compartments may be adapted to dynamically adjust to the limb during treatment so as to maintain a contact that is appropriate for the size and condition of the limb.

**[0033]** The apparatus may include a receiver for receiving response information from the patient and control means for adjusting the pressure stimulus according to the response information and predetermined criteria. The predetermined criteria may be formulated for ensuring that the movement of interstitial fluid into the lymphatic system is controlled so as to gain a relatively maximum patient response and meter the rate of transfer not to be adverse to the patient.

**[0034]** According to yet another aspect of the invention there is provided a method of preventing secondary lymphoedema comprising applying to the patient a pressure stimulus operating in multiple directions such that the epidermis, dermis and subcutaneous layers of the affected tissue are stimulated to the extent that there is a flexure in the tissue at a magnitude between about 0.5 mm and 3 mm, peak to peak, at a frequency of between about 1 and 50 Hz. Preferably, if the method were to be applied to a case of primary lymphoedema there would be a relatively rapid movement of interstitial fluid in the affected tissue into the lymphatic system.

**[0035]** Insight into the advantages and characteristics of the present invention can be gained from the following description of preferred embodiments and the accompanying drawings. Further aspects and preferred features may be apparent.

#### Brief Description of the Drawings

**[0036]** Several preferred embodiments of the invention

will now be described in the following description made with reference to the drawings, in which:

Figure 1 is a perspective view, partly cut away, of an apparatus treating a patient according to a first embodiment of the invention.

Figure 2 is a front view of the apparatus shown in Figure 1, the apparatus being coupled to a sensor whereby the arrangement, in combination, is in accordance with a second embodiment of the invention;

Figure 3 is an enlarged view of a cuff structure incorporated in the apparatus shown in Figures 1 and 2;

Figure 4 is a perspective view of an armature used in the apparatus shown in Figure 1, 2 and 3;

Figure 5 is a line drawing of a photograph showing a woman having lymphoedema in her left arm;

Figure 6 is a schematic perspective view, in section, of a layer of skin;

Figure 7 is a schematic view of a lymphatic in the skin shown in Figure 6, the lymphatic being stimulated according to an embodiment of the invention;

Figure 8 is a schematic representation of the application of an embodiment of the present invention;

Figure 9 is a schematic representation of a pressure stimulus being applied to a human body in accordance an embodiment of the invention;

Figure 10 is a view of a path followed in the application of a pressure stimulus according to an embodiment of the invention;

Figure 11 is a schematic view of a further embodiment of the invention;

Figure 12 is a schematic view of various paths that may be used in embodiments of the invention; and

Figures 13 and 14 are more detailed views of two of the paths shown in Figure 12.

#### Best Mode(s) for Carrying Out the Invention

**[0037]** Referring now to Figure 1 there is shown a patient 100 being treated with an apparatus 101 according to a first preferred embodiment of the invention. The patient 100 has lymphoedema in his left arm 102. The arm 102 and the tissue affected by the lymphoedema is stimulated with a pressure stimulus applied in a plane substantially perpendicular to the arm and varies around the arm 102 in accordance with a particular pressure variation pattern. Various pressure stimulus patterns are applied in the plane substantially perpendicularly to the length of the arm 102.

**[0038]** As a result of the varying pressures a relatively rapid movement of interstitial fluid moves from the affected arm 102 into the lymphatic system of the patient 100.

**[0039]** Whilst various forms of pressure stimulus patterns such as a symmetrical five pointed star (described below) are encompassed by embodiments of the present invention, to provide the advantages thereof, the stimulus

in each embodiment stimulates the epidermis, dermis and subcutaneous layers of the affected tissue such that there is a relatively rapid movement of interstitial fluid in the affected tissue into the lymphatic system. When an embodiment of the present invention employs a symmetrical 20 point star pattern, a movement of 80 millilitres over a seven minute treatment session is able to be achieved in the circumstances of a patient having relatively mild case of lymphoedema in their arm. This is a significant improvement over prior methods of moving lymphatic fluid out of interstitial tissue back into what is otherwise a depressed lymphatic system.

**[0040]** In the lymphatic system lymphatics can be categorized as initial and collecting lymphatics. Collecting lymphatics are provided with smooth muscle intima and contain lymphangions. The lymphangions are formed in series and are separated from each other by a valve.

**[0041]** Whilst in no way being limited to any particular theory, and noting that the operation of the lymphatic system has not been conclusively determined, it is thought that present embodiment is able to achieve the above results by setting up a special induced vibration of the contractile lymphangions of the lymphatic system.

**[0042]** Gerli, Ibba and Frishecilli in their article entitled "Morphometric analysis of elastic fibres in human skin lymphatic capillaries, *Lymphoglogy*, 1989 Dec; 22(4), 167-72 explained that the elastic fibre network commonly seen adjacent to collecting lymphatics is orientated substantially longitudinally to the lymphatic vessel wall.

**[0043]** The anchoring structure of microbrils of lymphatics capillaries is discussed by the same authors in their article entitled "Ultrastructural cytochemistry of anchoring filaments of human lymphatic capillaries and their relation to elastic fibres, *Lymphoglogy*, 1991 Sep; 24(3), 105-12.

**[0044]** Very basically the initial lymphatics provide the first point of entry and collection for the lymphatic fluid. They provide a pliable structure of endothelial cell gates or intercellular clefts which are driven by pressure gradients across the walls of the structure.

**[0045]** It is considered that if the interstitial fluid can gain entry into the initial lymphatics through the cell gates it will fill and stimulate the flow of interstitial fluid on a one way journey past the first valve set into the start of the collecting lymphatics. Expansion and contraction of the initial lymphatics will commence once the peristaltic pumping process of the lymphatic system has started.

**[0046]** It is thought that embodiments of the present method stimulate the anchoring filaments of the initial lymphatics in a concerted manner so as to influence the opening of the endothelial cell gates of the initial lymphatics, thereby causing the relatively rapid movement of interstitial fluid in the affected tissue into the lymphatic system. This method of stimulating the lymphatic system has not been previously performed.

**[0047]** The process of dilatation of the initial lymphatics aids the absorption of the interstitial fluid in through the endothelial cell gates to fill the lymphatic lumen and signal

the start of the pumping procedure. The dilation of the initial lymphatics causes the lymphatic pressure to gradually decrease in the lymphatic lumen below the interstitial fluid in the tissue, causing the unattached endothelial cells to open inward allowing for fluid entry into the initial lymphatics. As the lumen fills the fluid pressure inside increases, effectively closing off the endothelial cell gates to stop reflux flow back into the tissue spaces. This is the same effect of the hydrostatic or osmotic pressure gradient for fluid lymphatic transfer.

**[0048]** The anchoring filaments can be generally viewed as semi-elastic fibres that hold the initial lymphatics in place and attach to the many individual endothelial cell walls of the initial lymphatics. The anchoring filaments cause flexing on the endothelial cells and aid the opening and closing of the intercellular junctions so that proteins, fluids and small molecules can move into the initial lymphatics and be taken away.

**[0049]** Once the interstitial fluid has entered and filled the initial lymphatics it triggers the next pulsatile muscle chamber to contract, moving what is now called the lymph fluid along a network of one-way pulsatile collectors to the lymph node junctions throughout the body.

**[0050]** In terms of what can be physically observed, the embodiment induces a ripple effect along the arm of the patient 100. The ripple effect is induced along the surface of the patient's skin away from the stimulus and extends at least all the way up to the shoulder of the patient 100. Whilst the stimulus is applied to a relatively thin band around the forearm 104 of arm 102, the method as evidenced by the ripple effect operates over the length of the arm 102.

**[0051]** While some prior art methods such as that described in US2004/0077978 entitled "Leg Ulcer, Lymphoedema and DVT Vibratory Treatment and Device", to Nelson et al, do exist, the pressure variations applied in these methods comprise simple varying sinusoids applied in orthogonal x, y and z directions through a central origin. With the prior art the path followed by the vibration in the x and y plane is circular due to the centrifugal motion of the rotating counterweight. There is no complex pressure stimulus nor a directional stimulation change.

**[0052]** The pressure stimulus may depart from just a simple circular sinusoidal motion and in this sense disturbs ordinary motion and is perturbed. In various embodiments the pressure stimulus may be applied in different 2 dimensional patterns such as clover leaves, five pointed stars, figures of eight and so on. Pointed stars patterns have directional stimulation change at the point of the star that is particularly advantageous for inducing a relatively rapid movement of interstitial fluid in affected tissue into the lymphatic system.

**[0053]** The embodiment shown in Figure 2 includes a receiver 106 for receiving response information from the patient 100 and control means for adjusting the rate and intensity of the stimulus according to the response information and predetermined criteria. The predetermined criteria is formulated for ensuring that the movement of

interstitial fluid into the lymphatic system is controlled so as not to be adverse to the patient. In some circumstances the movement of fluid may need to be regulated for the general health of the patient.

**[0054]** The receiver 106 is also used to detect the extent of the ripple along the arm 102 of the patient. By detecting the extent of the ripple, including possibly both its magnitude and direction, the apparatus 100 is able to determine and select a resonant frequency of the layers of tissue of the arm 102 and alter the pressure stimulus so as to increase or decrease the pressure variations at that frequency to assist with maximizing the fluid transfer for that patient.

**[0055]** With reference to Figure 3 in particular, it can be seen that the apparatus 100 includes a cuff structure in the form ten compartments 108 that are adapted to surround and closely conform to the arm 102 of the patient 100. The compartments 108 are connected together by a porting system to ensure that the compartments 108 are substantially, in the sense of at least partially, isolated from each other when pressurized with working fluid. In this embodiment water provides a suitable working fluid. The water is held in a reservoir that is advantageously pressurized by air from a provided pressure source. By virtue of the working fluid being water there is provided a good transfer medium for vibration. In alternate arrangements varying density foams could also be used as could any conforming gas or material.

**[0056]** When pressurized, the compartments provide a contact surface with a surface area for frictionally coupling to a corresponding surface area of the patient 100, namely the forearm 104. The corresponding surface area extends about the arm 102 of the patient 100. The compartments 108 may be viewed as a particular and advantageous form of a bellows arrangement.

**[0057]** With reference to figure 4, each of the compartments 108 is connected to a rigid circular boss (or member) attached to an armature 110 of an electric motor having a plurality of electrical coils 112. The compartments 108 are filled with the working fluid. While not shown in the drawings in particularly preferred arrangements the boss is provided in the form of a collapsible iris having segmented parts that allow for variable size adjustment. The electrical coils are placed in a transverse magnetic field and the current is applied to the coils such that thrust forces are applied to the armature 110 in the plane of the armature. By controlling the phase, frequency and amplitude of the currents in the coils 112, the armature is driven to move in two dimensions in its plane in an orbital/cycloidal manner. The motion can follow an essentially limitless number of different path configurations or patterns. This motion is imparted to the compartments 108 and in turn applied to the arm 102. By having individual substantially isolated compartments 108, each compartment 108 is able to apply a relatively independent pressure at particular locations around the arm 102. A full description of the operation and features an electric motor comprising the armature 110 is provided in Appli-

cant's US patent no. 6,703,724 the contents of which are incorporated herein by way of reference. Further an additional description of an apparatus 100 is provided in Applicant's International publication no. WO 2004/103179, the contents of which are incorporated herein by way of reference.

**[0058]** As a consequence of basic geometry, diametrically opposite compartments 108 move in similar directions thereby applying a consequential pressure variation around the axial direction of the arm. This has advantageous benefits for providing ripple effect and stimulation of the anchoring filaments in multiple directions without potentially damaging compression of the tissue from opposing sides.

**[0059]** The armature 110 has two degrees of translational freedom in the x, and y directions. However in alternate embodiments armatures may be used that may have six degrees of freedom (pitch, yaw, roll and three translational degrees of freedom). An armature that is able to stimulate the arm in multiple modes of operation, that is dimensions of movement is readily constructed. The above mentioned US 6,703,724 entitled "Electric Machine" provides guidance as to how the electrical coils 112 are employed to form a complete motor that can provide the required motion.

**[0060]** Figure 5 is a line drawing taken from a photograph of a woman having lymphoedema in her left arm. The difference in the sizes of her arms is real.

**[0061]** A course of treatment using embodiments of the present method is envisaged to be applied at home or in a specialised clinic and may require, depending on the particular situation, at least two treatments over a two week period, each treatment taking about 15 minutes each without the subsequent requirement of pressure bandaging.

**[0062]** A layer of skin is shown in Figure 6 for completeness. The first layer is known as the epidermis 114. The epidermis 114 is translucent. The second layer is known as the dermis 116. The dermis 116 contains blood vessels, nerves, hair roots, lymphatics and sweat glands. The third layer is known as the subcutaneous layer 118. The subcutaneous layer 118 contains larger blood vessels and nerves and is primarily made up of fat-filled cells called adipose cells. The third layer has large lymphatic supplies. There are abundant publications on the make up of the skin and the reader is referred thereto for a complete analysis.

**[0063]** A number of anchoring filaments 120 in the subcutaneous layer 118 are shown in Figure 7. The anchoring filaments 120 are connected to endothelial cell gates 122 as previously described. The anchoring filaments 120 are stimulated by the complex pressure variations to cause the relatively rapid movement of interstitial fluid in the affected tissue, into the lymphatic system.

**[0064]** Figure 8 illustrates an embodiment of the invention in schematic form that operates on a number of lymphatics as shown in Figure 7. A patient 100 is subject to a complex pressure stimulus 124 operating in multiple

directions. The stimulus 124 stimulates the affected tissue 125 of the patient 100 such that there is a relatively rapid movement of interstitial fluid 126 in the affected tissue into the lymphatic system 127. Depending on the circumstances and on the particular method of pressure stimulus applied, about 80 millilitres of fluid may be moved in seven minutes.

**[0065]** The particular pressure pattern used is shown in detail in Figure 9. A member 110 surrounds the arm 102 and is translated in accordance with a two dimensional pattern of movement 128.

**[0066]** By virtue of the compartments 108 being connected to the member 110 the translation of the member 110 creates variations in the pressure applied to the arm 102 of the patient. The pressure variations are generally designated 130. As is apparent the pressure variations 130 are directed substantially along a path 132 that is arranged within a circular area 134 and form the pressure stimulus.

**[0067]** Furthermore the path 132 substantially avoids travelling back and forth over a central region 136 of the area 134. The central region 136 is bounded by a pentagon formed by the path 134. This is thought to set up particularly beneficial pressure fluctuations operating to have the effect of causing relatively high fluid movement in the lymphatic system.

**[0068]** The pressure variations are applied by the compartments 108 in multiple directions substantially normal to the axial length of the arm 102 by virtue of the circular area 134 being arranged substantially perpendicular to the length of the arm 102.

**[0069]** As can be seen from Figure 9 the path 132 comprises five path elements 140 arranged end to end, with each end positioned to lie substantially on the circular area 134, so that the five path elements 140 form a continuous and substantially symmetrical five-pointed star.

**[0070]** The pressure in the compartments 108 is maintained so that the layers of tissue are stimulated an amplitude of about 2 mm, peak to peak, at a frequency of about 35 Hz. The frequency and amplitude are dynamically varied according to the condition of the patient 100, and as the effects of resonance are observed. The frequency of 35 Hz is measured in terms of the time taken to complete a full cycle of the pattern of the pressure stimulus along path 132, being 35 full cycles per second. The velocity of any one path element of the whole path is at a rate of one fifth of the full pattern rate, that is the whole pressure variation is one fifth of this amount.

**[0071]** A linear oscillator travelling a distance of 0.5 meters each stroke at 1 Hz will have a velocity of 1000 mm per second. Comparatively a five pointed star travel path of the embodiment operating at 1 Hz within a confining circle of 0.5m in diameter will have a velocity of approximately 2380 mm per second with a cord length of about 475mm. So to maintain the same frequency an embodiment would have to travel 2.4 times faster than the linear oscillator. To apply the same velocity to a persons arm, in comparison to a 1 Hz liner oscillator, the

embodiment would have to operate at a frequency of 0.42 Hz.

**[0072]** An alternate six leafed clover path 142 is shown in Figure 10. The use of variable leafed clover paths together with various paths 152 as shown in Figure 12 represent a small selection of many different paths that may be incorporated in embodiments of the present invention. The paths 152 are complex and are not spherical, cycloidal or linear. They may be further characterised as having at least three non-colinear points for each cycle of stimulation. Various other paths fall within the scope of the invention.

**[0073]** In a particular embodiment producing notable benefits, the path 132 comprises twenty path elements arranged end to end, with each end positioned to lie substantially on a circle such that the twenty path elements form a continuous and substantially symmetrical twenty-pointed star. Each path element of the pointed star is slightly curved at its ends so that the star is formed with rounded points. As would be apparent the invention comprehends any star pattern, or any other pattern, that is non-symmetrical in its displaced path.

**[0074]** Particular paths according to some the embodiments of the invention have paths that are most notably characterised by the total of the absolute of the angular displacement over a cycle of the path being more than 360 degrees. As is evident from Figure 21 a figure of eight has a 540 degree total and a five pointed star has a 720 degree total. These paths are perturbed in the sense that they transverse over more than 360 degrees as compared with 360 degrees as would be the case with elliptical motion. Alternate embodiments also comprehend triangular paths which would have a 360 degree total.

**[0075]** With triangular paths there are at least two distinct changes in direction over a cycle of oscillation of the pressure stimulus.

**[0076]** In related embodiments it has been realised that the anchoring filaments may develop a relaxed memory effectively releasing their hold on the open gates of the initial lymphatics when in a stagnant state. In this embodiment and for the purpose of advantageously working towards the workings of a healthy lymphatic system, the anchoring filaments are strained or flexed in a reciprocating or pulsating manner so that they retain their elastic integrity and functionality. Figure 11 illustrates the further embodiment wherein a stimulus 144 having variations as described above is applied to a patient 146 having affected tissue 145 whereby anchoring filaments 150 of that affected tissue are exercised.

**[0077]** Thus in this embodiment the patient is subjected to similar pressure variations that are configured to vibrate the anchoring filaments of the initial lymphatics at a rate that is conducive to stimulating a resetting of their elastic properties. By configuring the pressure variations to a particular magnitude and frequency the anchoring filaments can be exercised in a concerted manner. In contradistinction to prior art methods there is a

reconditioning of anchoring filaments that have been subjected to a continual strain for extended periods of time due to the increased fluid pressure acting on the body of the initial lymphatics.

**[0078]** It is known that the rate of lymphatic drainage depends on a number of factors including both Myogenic factors and Neurogenic factors. Myogenic factors generally are determined by the presence of the material sought to be removed and Neurogenic factors relate primarily to information coming down the nerves. The respiratory rate and muscular movement of the patient are known to also have an effect. Embodiments of the present invention show that it is possible to externally generate relatively high interstitial fluid movements through the lymphatic system when then lymphatic system is depressed and that the lymphatic system can, in some circumstances, be reset. Embodiments of the present invention relate to the lymphatic system and affected tissue and not merely lymphoedema.

**[0079]** Vibrational massage of the form disclosed herein could just as well be ideally suited for conditions involving poor tissue and cellular health associated with the accumulation of materials in the tissue spaces. Such disorder and disease areas may include but are not limited to myxoedema, lipoedema, poor wound healing, venous oedemas, inflammatory conditions, pressure soars and ulcerations of all causes but specifically those related to diabetes. Embodiments of the present invention is not to be taken as limited to lymphoedema.

**[0080]** It should be appreciated that the scope of the invention is not limited to the particular embodiment disclosed herein.

## Claims

1. A method of treating a patient having affected tissue, the method comprising applying to a limb or body portion of the patient a pressure stimulus operating in multiple directions in a plane substantially perpendicular to the limb or body portion, the stimulus stimulating the epidermis, dermis and subcutaneous layers of the affected tissue such that there is a relatively rapid movement of interstitial fluid in the affected tissue into the lymphatic system.
2. A method as claimed in claim 1 wherein the pressure stimulus is applied cyclically.
3. A method as claimed in claim 1 or 2 wherein the pressure stimulus comprises pressure variations directed substantially along a path which is continuous and has a total absolute angular displacement over more than 360 degrees.
4. A method as claimed in claim 3 wherein the total absolute angular displacement over the path is about 540 degrees.
5. A method as claimed in claim 3 wherein the total absolute angular displacement over the path is about 720 degrees.
6. A method as claimed in any one of claims 1 to 5 wherein there is at least two changes in direction over a cycle of oscillation of the pressure stimulus.
7. A method as claimed in any one of claims 1 to 6 wherein about 80 millilitres of interstitial fluid is moved into the lymphatic system in less than a 30 minute treatment session.
8. A method as claimed in any one of claims 1 to 7 wherein about 80 millilitres of interstitial fluid is moved into the lymphatic system in less than a 10 minute treatment session.
9. A method as claimed in anyone of claims 1 to 8 wherein the epidermis, dermis and subcutaneous layers of the affected tissue are stimulated to the extent that a ripple effect is induced along the surface of the patient's skin away from the stimulus.
10. A method as claimed in anyone of claims 1 to 9 wherein said pressure stimulus stimulates movement of the anchoring filaments of initial lymphatics in a concerted manner so as to influence the opening of the endothelial cell gates of the initial lymphatics and thereby cause the relatively rapid movement of interstitial fluid in the affected tissue into the lymphatic system.
11. A method as claimed in anyone of claims 1 to 10 wherein the method includes receiving response information from the epidermis and adjusting the frequency and/or amplitude of the pressure stimulus according to the response information and predetermined criteria.
12. A method as claimed in anyone of claims 9 to 11 wherein the pressure stimulus is applied to a relatively thin band around a limb of the patient and the ripple effect extends at least to where the limb is connected to the body of the patient.
13. A method as claimed in anyone of claims 1 to 12 wherein said applying the pressure stimulus comprise applying the pressure stimulus at a resonant frequency of the tissue.
14. A method as claimed in anyone of claims 1 to 13 wherein applying the pressure stimulus comprises stimulating the layers of tissue to stimulate movement of the anchoring filaments of the initial lymphatics in a concerted manner over a range of sweeping frequencies so as to influence the opening of the endothelial cell gates of the initial lymphatics and

thereby cause the relatively rapid movement of interstitial fluid in the affected tissue into the lymphatic system.

15. A method as claimed in anyone of claims 1 to 14 wherein the layers of tissue are stimulated at an amplitude of between about 0.1mm and about 5mm, peak to peak, and at a frequency of between about 10 and 100 hertz.
16. A method as claimed in anyone of claims 1 to 15 wherein the pressure stimulus is applied from a base point moving at a velocity of about 100 mm per second.
17. A method as claimed in anyone of claims 1 to 14 wherein the layers of tissue are stimulated at an amplitude of between about 0.5mm and about 5mm, peak to peak, and at a frequency of between about 0.1 and 50 hertz.
18. A method according to anyone of claims 3 to 17 wherein the pressure stimulus is directed substantially along a path that is arranged within an area and which substantially avoids travelling back and forth over a central region of the area, the pressure stimulus stimulating the epidermis, dermis and subcutaneous layers of the affected tissue such that there is a relatively rapid movement of interstitial fluid in the affected tissue into the lymphatic system.
19. A method as claimed in claim 18 wherein the path consists of five path elements arranged end to end, with each end positioned to lie substantially on a circle, such that the five path elements form a continuous five-pointed star.
20. A method as claimed in claim 18 wherein the path consists of three path elements arranged end to end, with each end positioned to lie substantially on a circle, such that the three path elements form a continuous triangle.
21. A method as claimed in claim 18 wherein the path consists of twenty path elements arranged end to end, with each end positioned to lie substantially on a circle such that the twenty path elements form a continuous twenty-pointed star.
22. A method as claimed in claim 18 wherein the path resembles the shape of a six leafed clover.
23. A method as claimed in anyone of claims 1 to 22 wherein there is at least two distinct changes in direction over a cycle of oscillation of the pressure stimulus.
24. A method as claimed in anyone of claims 1 to 23

wherein applying the pressure stimulus comprises translating a member that surrounds the limb of the patient.

25. A method as claimed in claim 24 wherein the member is substantially rigid.
26. A method according to anyone of claims 1 to 25 wherein the pressure stimulus is applied such that the anchoring filaments of the initial lymphatics vibrate in a relatively rapid manner that is conducive to stimulating a resetting of their elastic properties.
27. An apparatus for treating a patient having affected tissue, the apparatus including a plurality of compartments that are adapted to surround and closely conform to a limb of the patient, the compartments being substantially isolated from each other so that each compartment is able to apply a relatively independent pressure stimulus at particular locations around the limb.
28. An apparatus as claimed in claim 27 wherein particular compartments can be rendered inoperable so as to avoid stimulating a sensitive area of the limb.
29. An apparatus as claimed in claim 27 or 28 wherein the compartments are adapted to dynamically adjust to the limb during treatment so as to maintain contact that is appropriate for the size and condition of the limb.
30. An apparatus as claimed in anyone of claims 27 to 29 further comprising a receiver for receiving response information from the patient and control means for adjusting the pressure stimulus according to the response information and predetermined criteria.
31. An apparatus as claimed in anyone of claims 27 to 30 wherein the predetermined criteria is formulated for ensuring that the movement of interstitial fluid into the lymphatic system is controlled so as to gain an appropriate patient response and meter the rate of transfer not to be adverse to the patient.

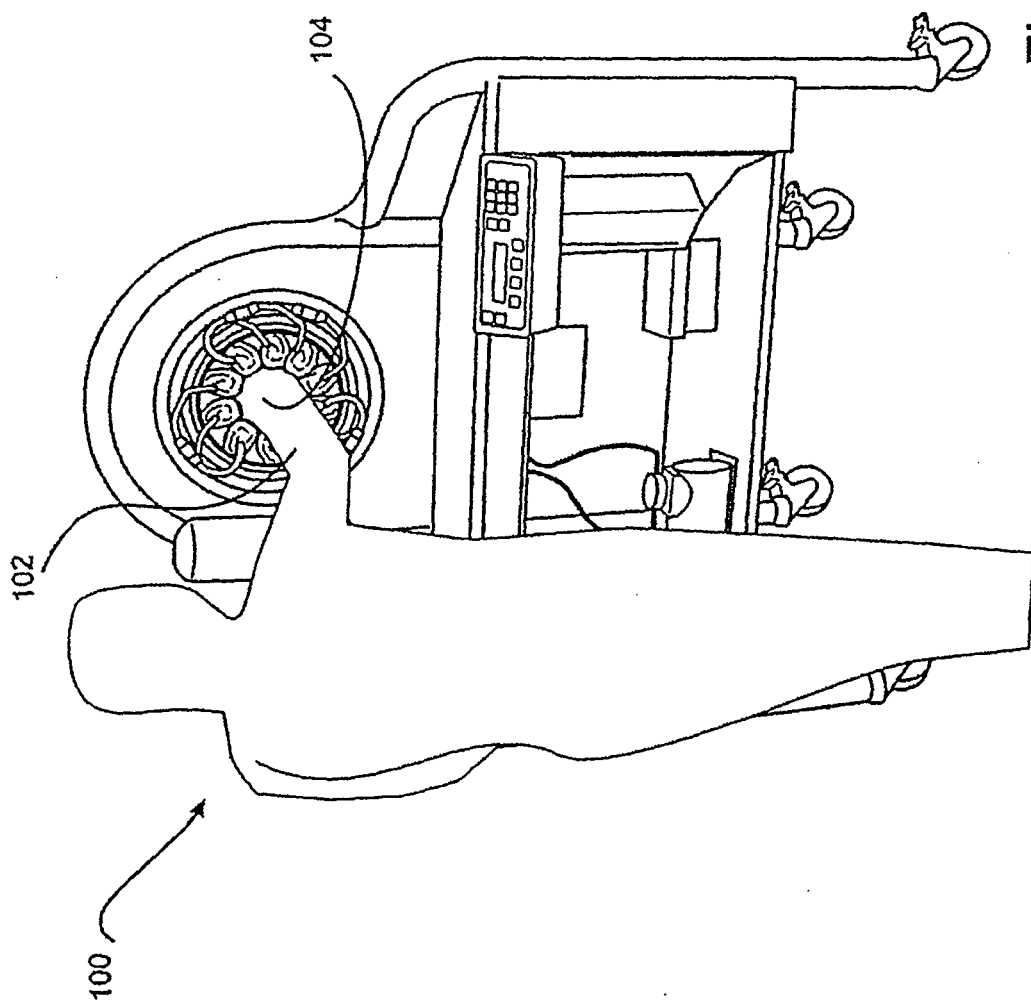


Figure 1

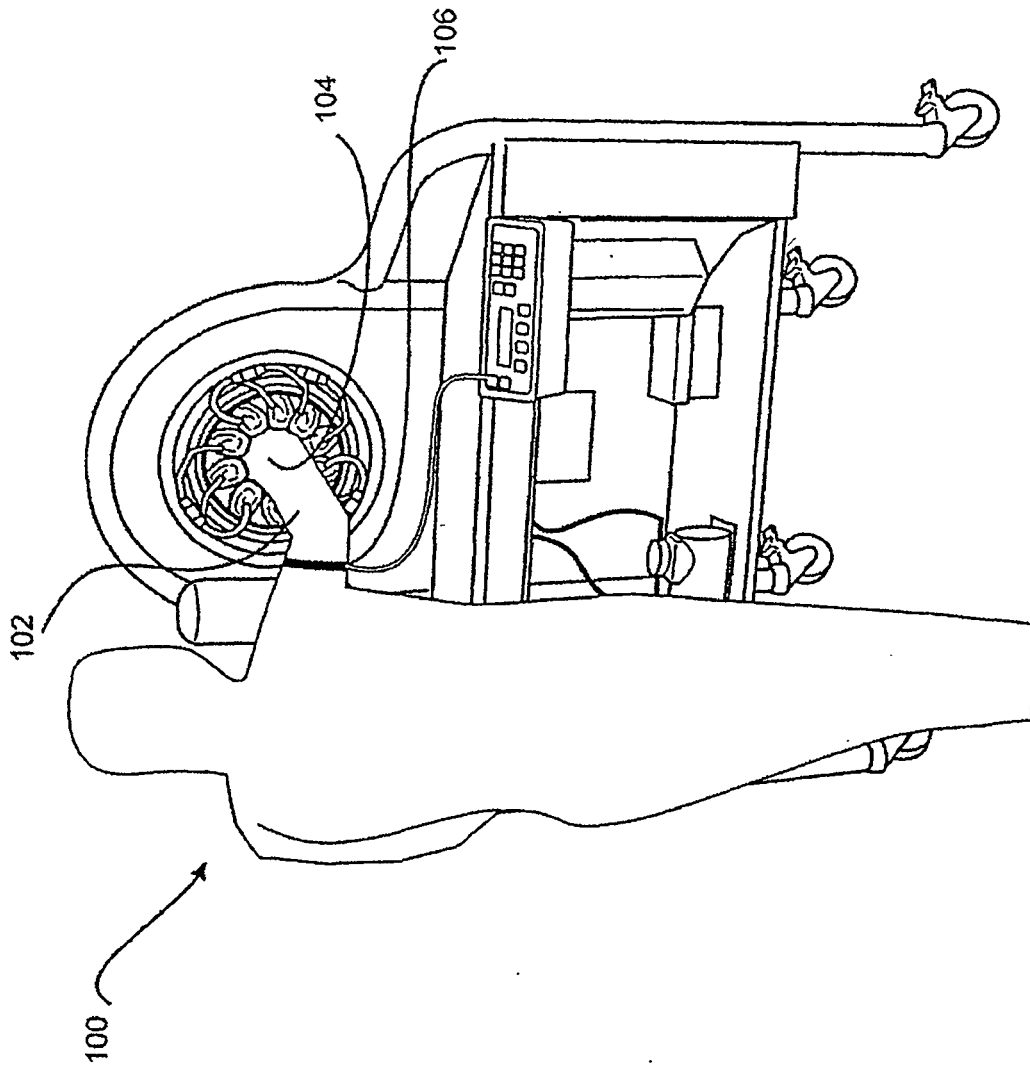


Figure 2

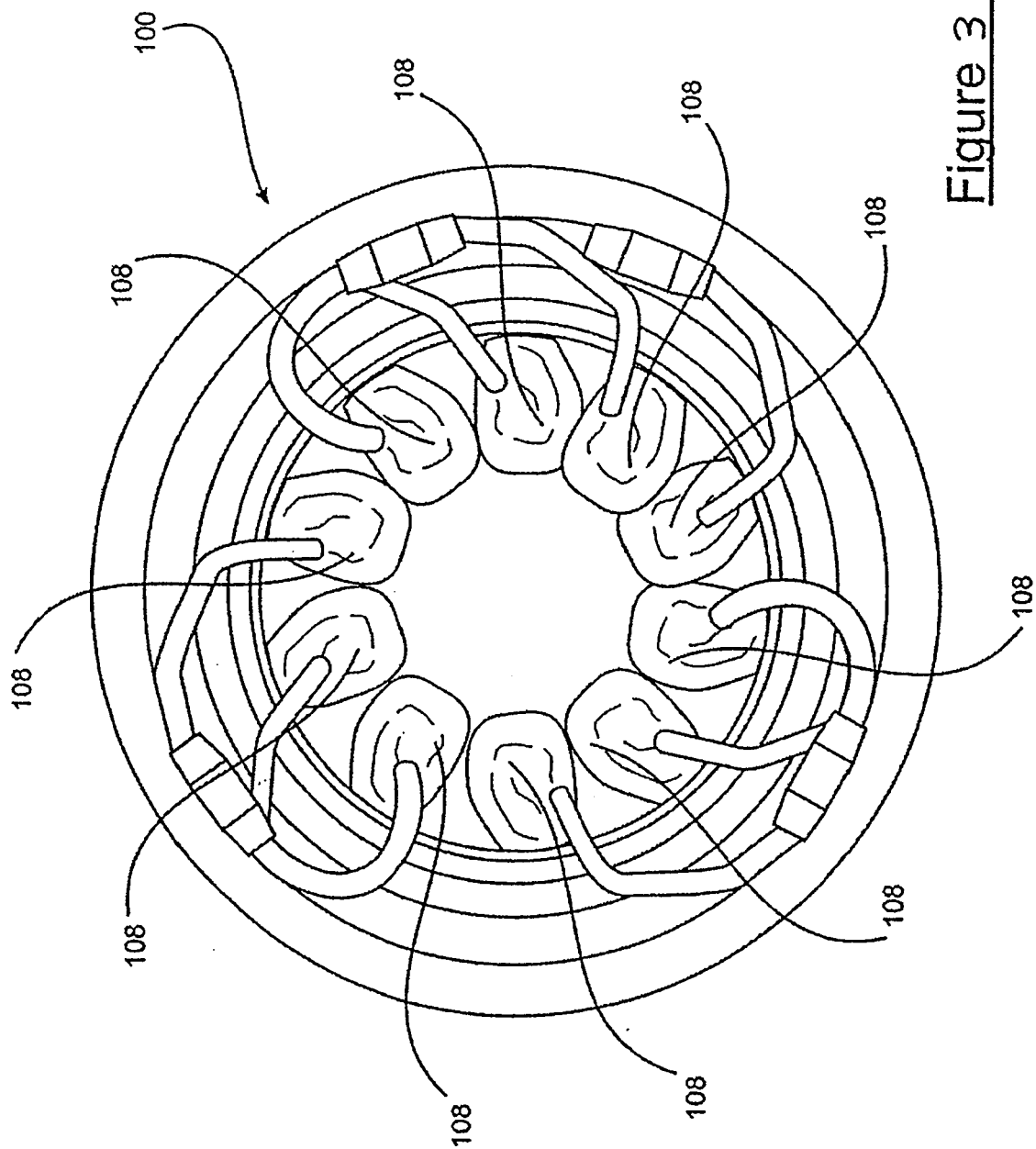


Figure 3

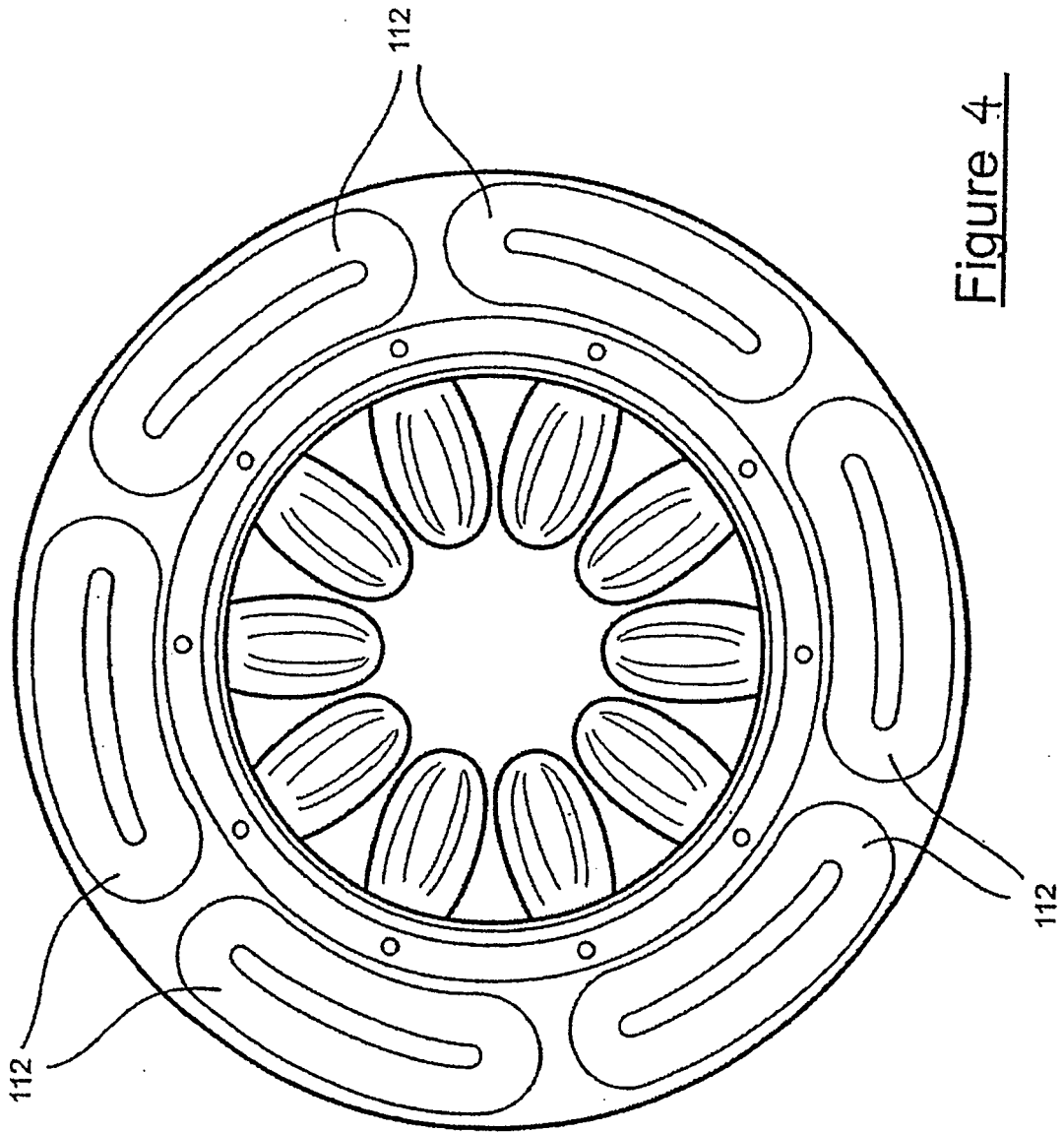


Figure 4

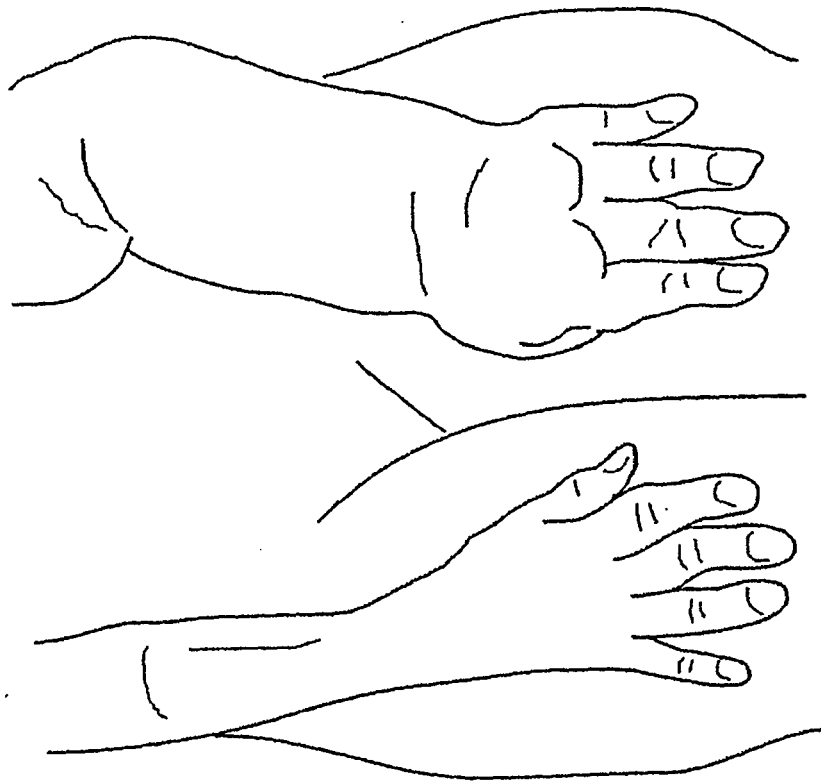


Figure 5

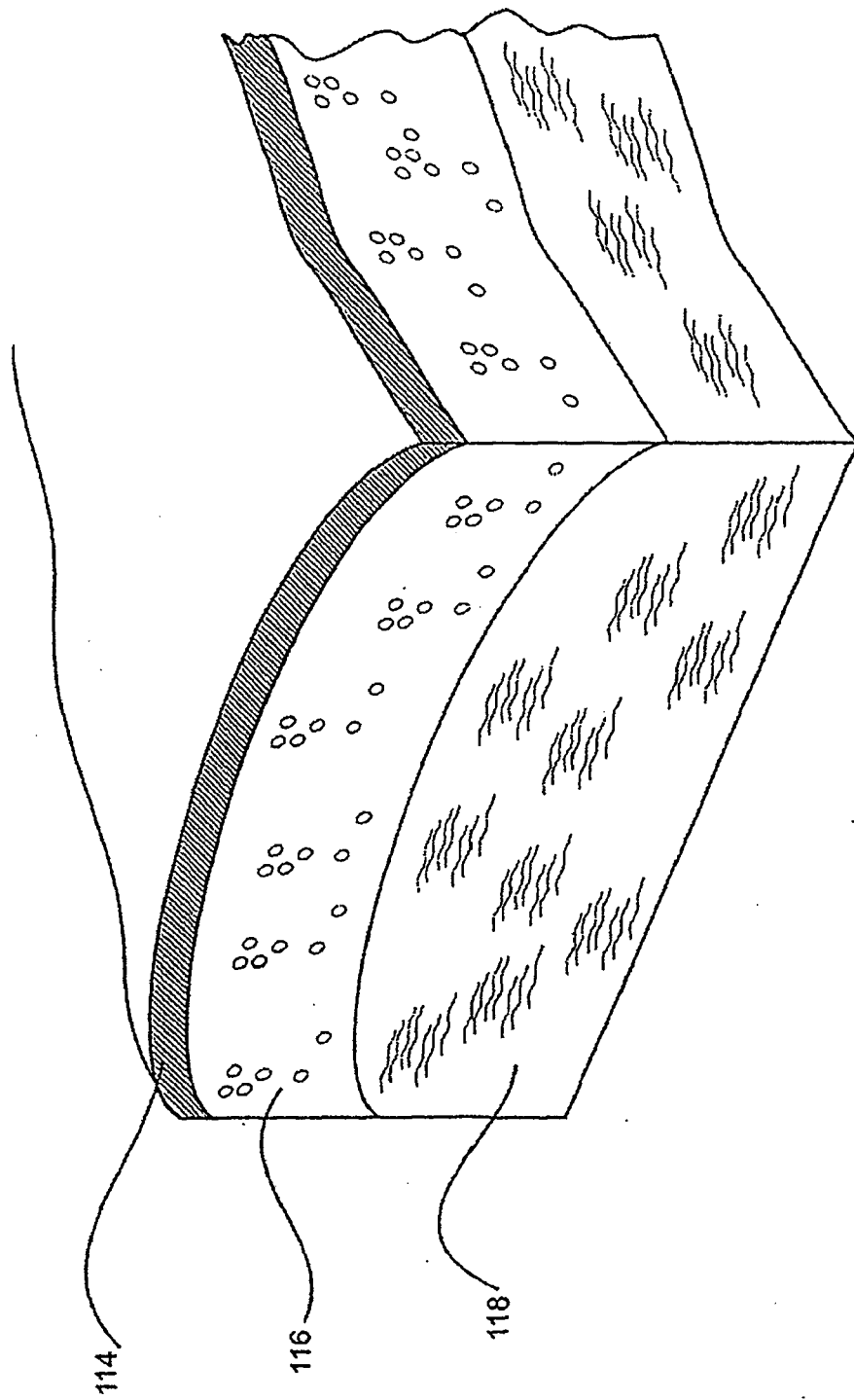


Figure 6

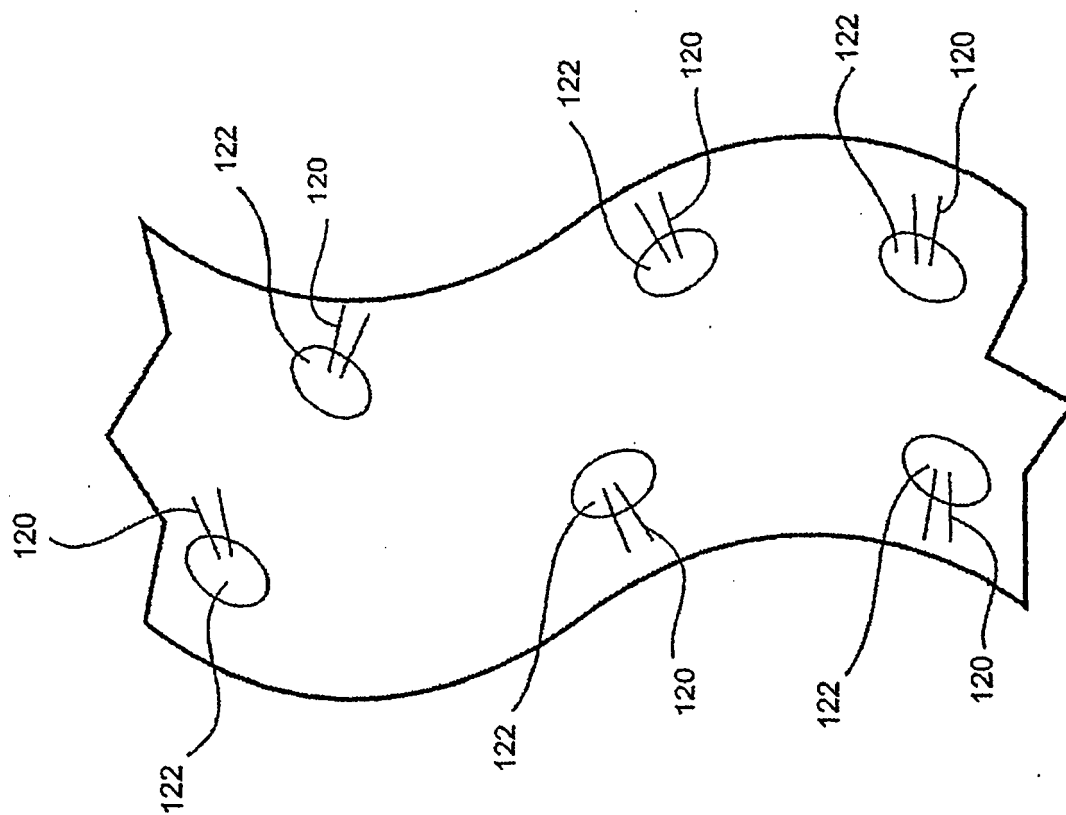


Figure 7

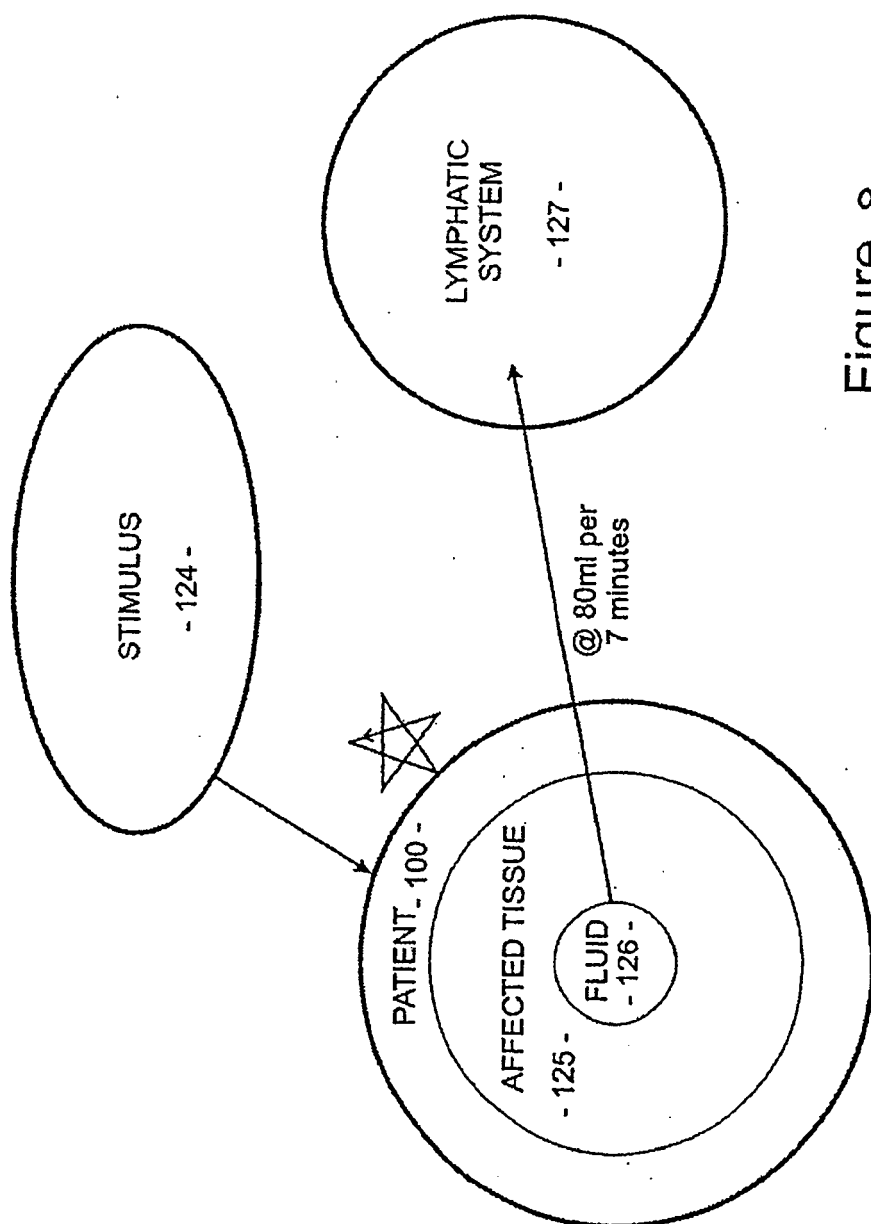


Figure 8

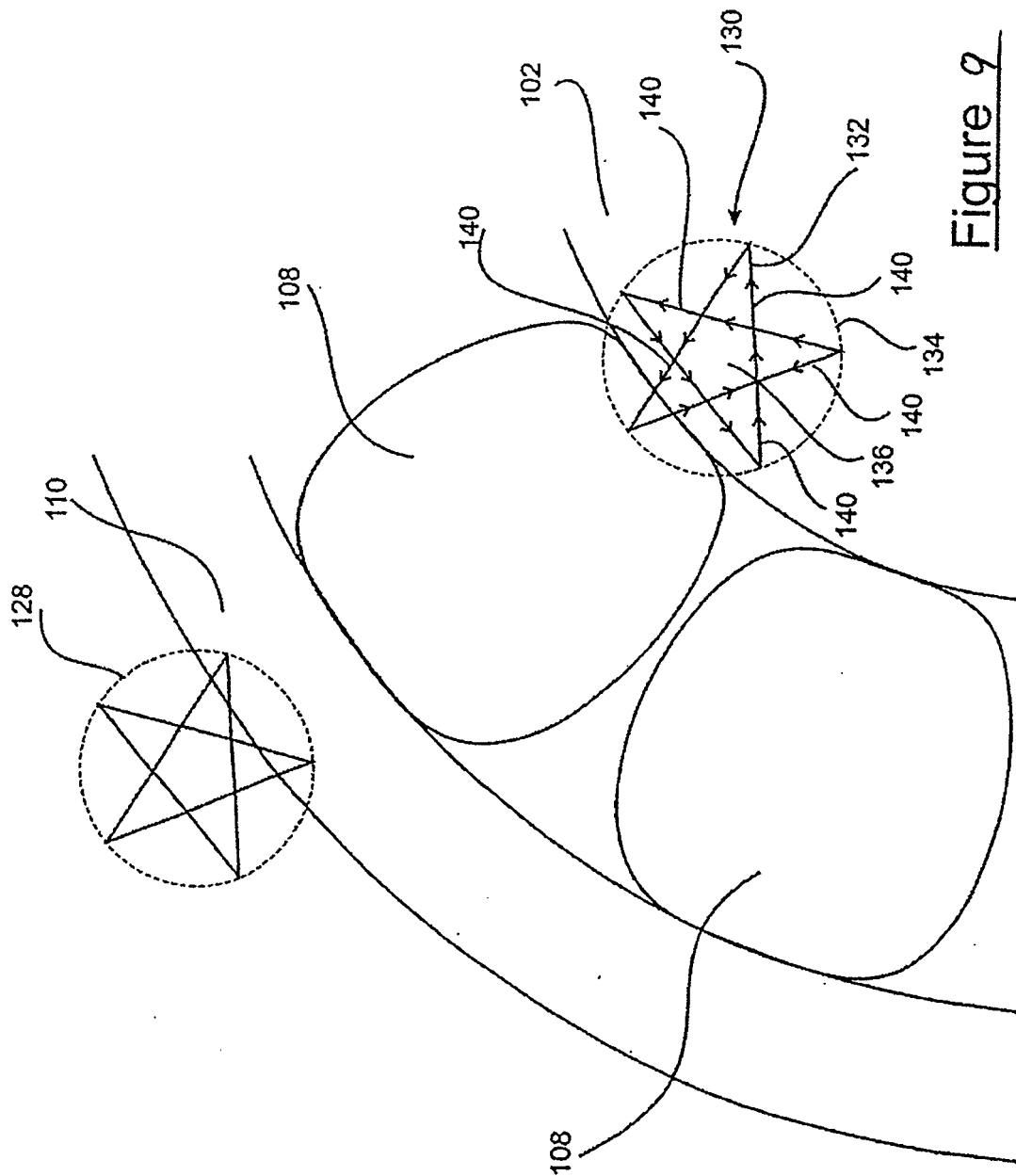


Figure 9

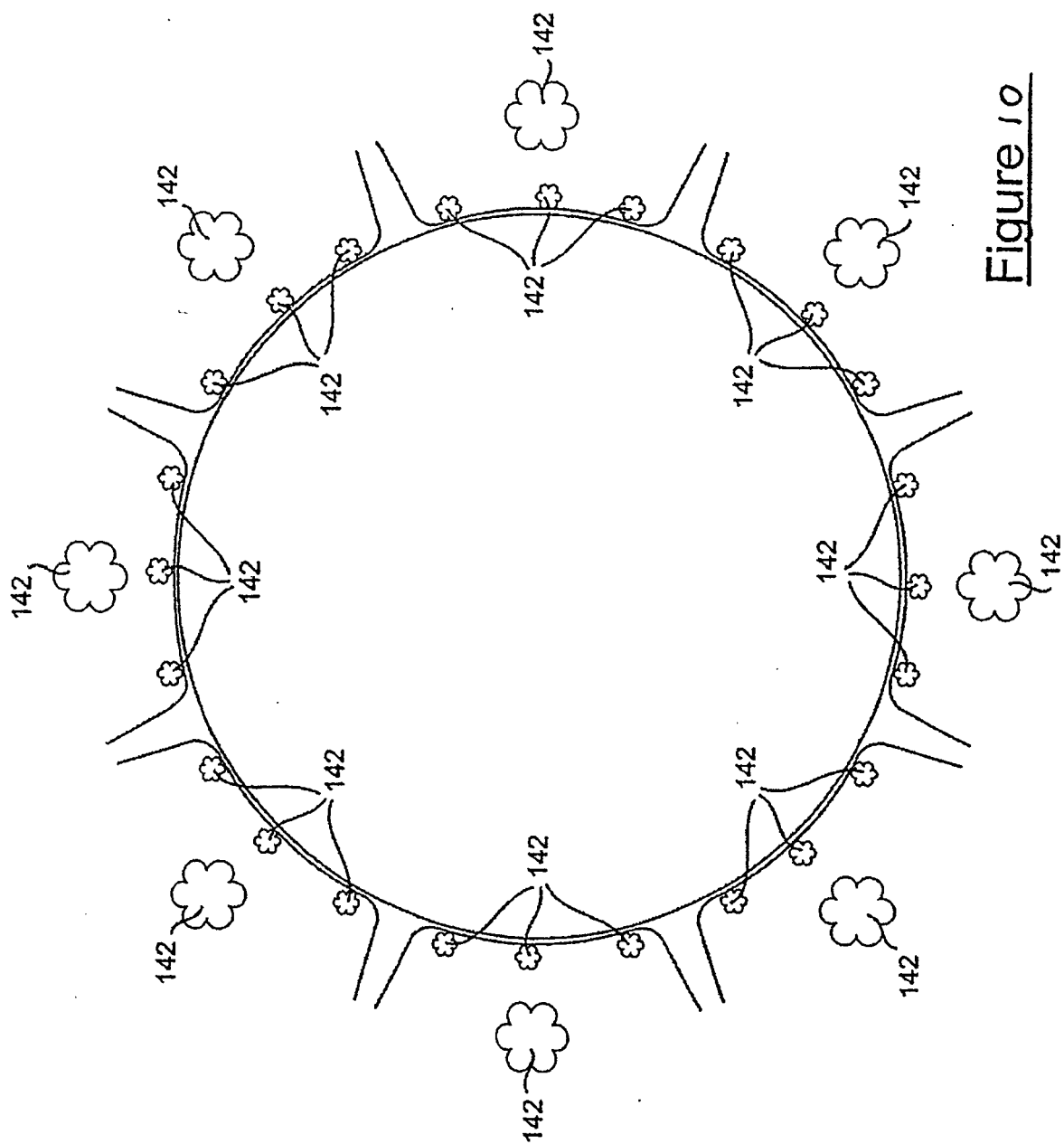


Figure 10

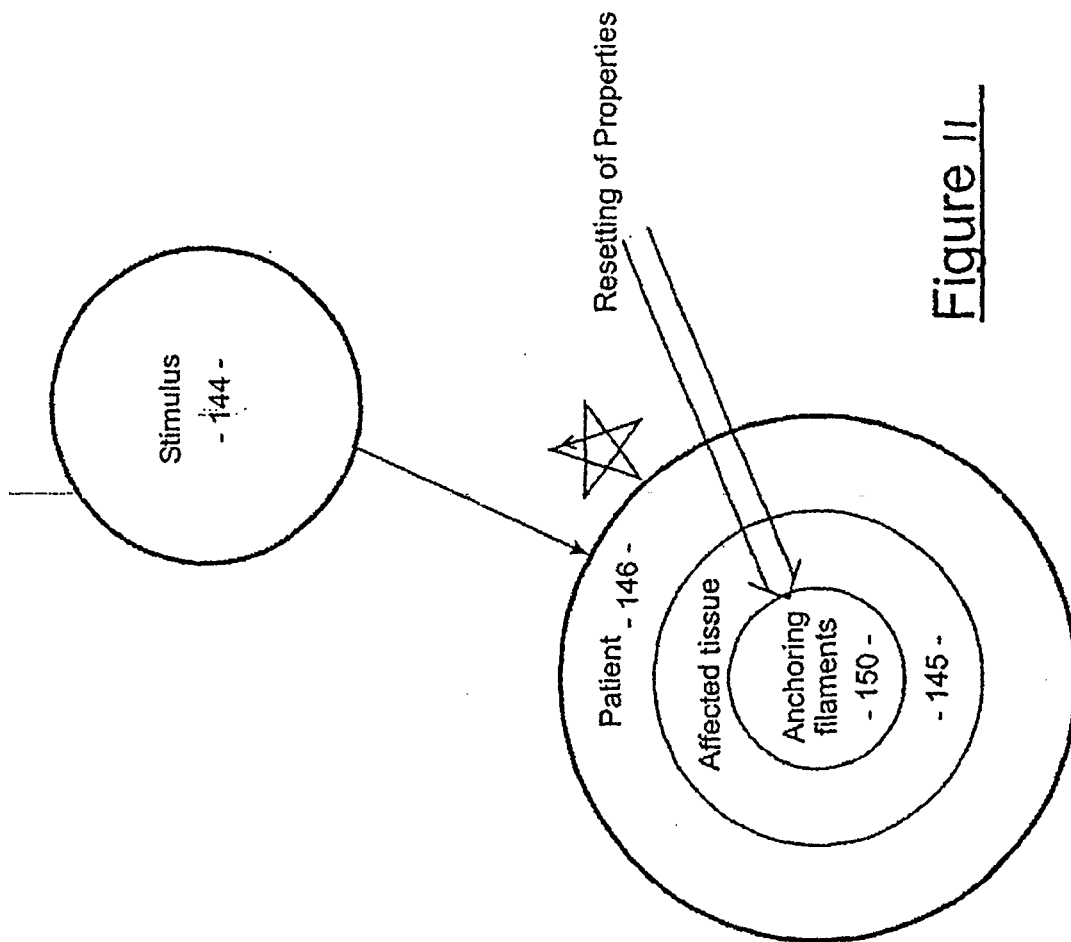
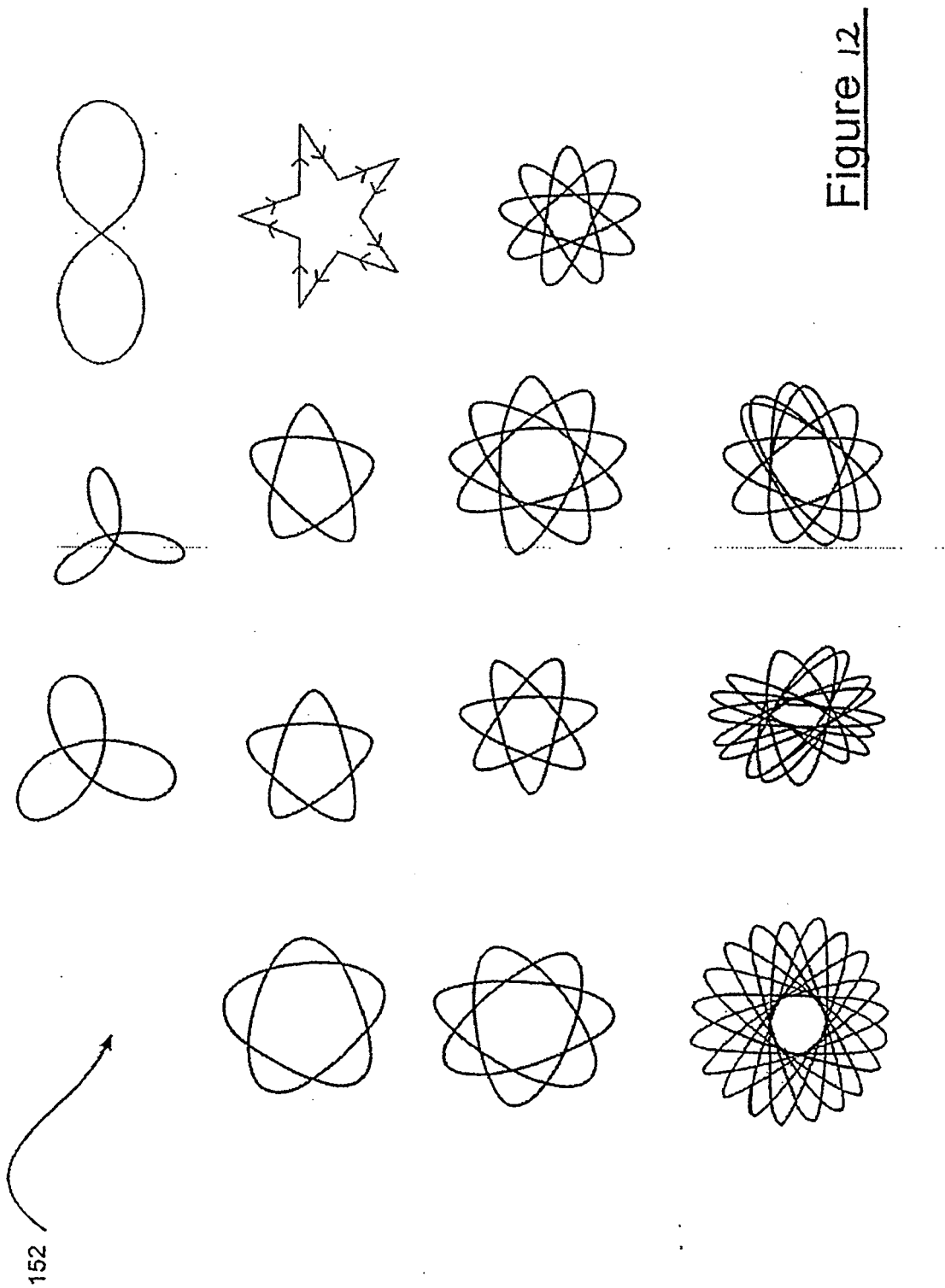


Figure 11



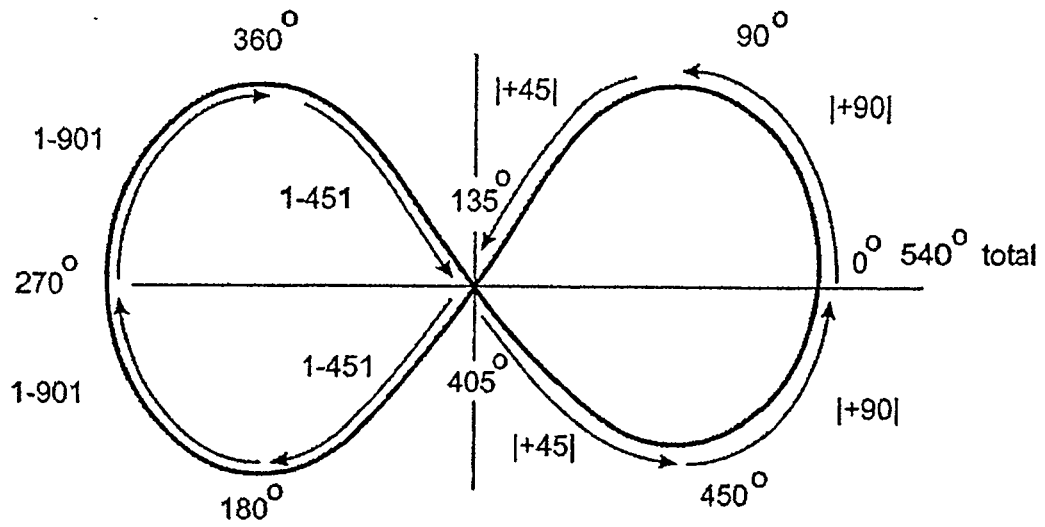


Figure 13

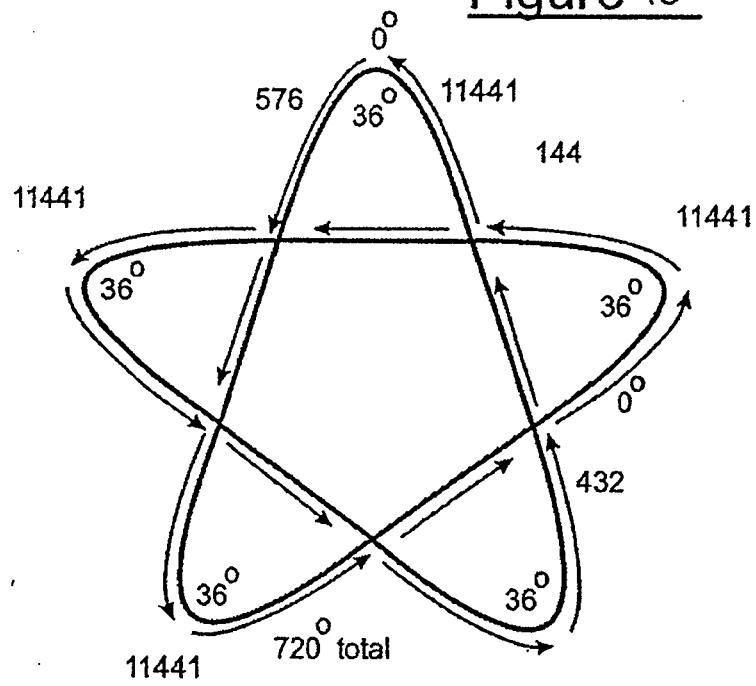


Figure 14



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# PARTIAL EUROPEAN SEARCH REPORT

Application Number

which under Rule 45 of the European Patent Convention EP 06 00 5971 shall be considered, for the purposes of subsequent proceedings, as the European search report

| DOCUMENTS CONSIDERED TO BE RELEVANT                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                        |                                                                                                                                                                                                                                                                                                         |                                         |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------|
| Category                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Citation of document with indication, where appropriate, of relevant passages                          | Relevant to claim                                                                                                                                                                                                                                                                                       | CLASSIFICATION OF THE APPLICATION (IPC) |
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|                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                        |                                                                                                                                                                                                                                                                                                         | A61H                                    |
| <b>INCOMPLETE SEARCH</b>                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                        |                                                                                                                                                                                                                                                                                                         |                                         |
| <p>The Search Division considers that the present application, or one or more of its claims, does/do not comply with the EPC to such an extent that a meaningful search into the state of the art cannot be carried out, or can only be carried out partially, for these claims.</p> <p>Claims searched completely :</p> <p>Claims searched incompletely :</p> <p>Claims not searched :</p> <p>Reason for the limitation of the search:</p> <p>see sheet C</p> |                                                                                                        |                                                                                                                                                                                                                                                                                                         |                                         |
| Place of search                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                        | Date of completion of the search                                                                                                                                                                                                                                                                        | Examiner                                |
| Munich                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                                                        | 26 May 2006                                                                                                                                                                                                                                                                                             | Sopelana Martínez, J                    |
| CATEGORY OF CITED DOCUMENTS                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                                                        | <p>T : theory or principle underlying the invention</p> <p>E : earlier patent document, but published on, or after the filing date</p> <p>D : document cited in the application</p> <p>L : document cited for other reasons</p> <p>&amp; : member of the same patent family, corresponding document</p> |                                         |
| <p>X : particularly relevant if taken alone</p> <p>Y : particularly relevant if combined with another document of the same category</p> <p>A : technological background</p> <p>O : non-written disclosure</p> <p>P : intermediate document</p>                                                                                                                                                                                                                 |                                                                                                        |                                                                                                                                                                                                                                                                                                         |                                         |

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EPO FORM 1503 03.82 (P04C07)



European Patent  
Office

**INCOMPLETE SEARCH  
SHEET C**

Application Number  
EP 06 00 5971

Claim(s) not searched:  
1-26

Reason for the limitation of the search (non-patentable invention(s)):

Article 52 (4) EPC - Method for treatment of the human or animal body by therapy

**ANNEX TO THE EUROPEAN SEARCH REPORT  
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EP 06 00 5971

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report. The members are as contained in the European Patent Office EDP file on  
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26-05-2006

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