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(54) **MONITORING SYSTEM AND PROBE**

ÜBERWACHUNGSSYSTEM UND SONDE

SYSTEME ET SONDE DE SURVEILLANCE

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Description

Background of the Invention

[0001] The present invention relates to a method and apparatus for use in analysing impedance measurements performed on a subject, and in particular to a probe that can be used in determining a limb impedance profile, which can in turn be used in determining the presence, absence or degree of oedema in a subject's limb.

Description of the Prior Art

[0002] The reference in this specification to any prior publication (or information derived from it), or to any matter which is known, is not, and should not be taken as an acknowledgment or admission or any form of suggestion that the prior publication (or information derived from it) or known matter forms part of the common general knowledge in the field of endeavour to which this specification relates.

[0003] Lymphoedema is a condition characterised by excess protein and oedema in the tissues as a result of reduced lymphatic transport capacity and/or reduced tissue proteolytic capacity in the presence of a normal lymphatic load. Acquired, or secondary lymphoedema, is caused by damaged or blocked lymphatic vessels. The commonest inciting events are surgery and/or radiotherapy.

[0004] For example, upper limb lymphoedema is a common sequela of treatment for breast cancer. Estimates of the incidence of breast cancer lymphedoema vary in the medical literature from low values in the range of 9%-10% to those that exceed 50%. Lymphoedema is associated with a reduced quality of life, particularly emotional, social and physical function, as well as body image and lifestyle.

[0005] The condition is incurable and has been found difficult to treat with drugs or surgery but symptomatic treatment by complex physical therapy has been shown to benefit patients. Critical to patient management is that the extent of lymphoedema be measured regularly to assess patient's progress. A decrease in limb size not only indicates that treatment is beneficial but also helps encourage patient compliance with a demanding treatment programme. Additionally, onset of lymphoedema is unpredictable and may develop within days of its cause or at any time during a period of many years after that cause.

[0006] Accordingly, there is a need to be able to easily monitor for and diagnose the presence or degree of lymphodema. A variety of methods have been used ranging in complexity from sophisticated imaging techniques such as MRI to simple geometrical volume calculations from limb circumference measurements. However, these techniques are either too costly, in the case of MRI, or insufficiently accurate in the case of limb circumference.

[0007] One existing technique for determining biological parameters relating to a subject, such as fluid levels, involves the use of bioelectrical impedance. This involves measuring the electrical impedance of a subject's body using a series of electrodes placed on the skin surface. Changes in electrical impedance at the body's surface are used to determine parameters, such as changes in fluid levels, associated with the cardiac cycle or oedema.

[0008] WO00/79255 describes a method of detection of oedema, such as lymphoedema by measuring bioelectrical impedance at two different anatomical regions in the same subject at a single low frequency alternating current. The two measurements are analysed to obtain an indication of the presence of tissue oedema by comparing with data obtained from a normal population.

[0009] However, whilst such techniques can be used to determine the presence of oedema over an entire limb, lymphoedema can be highly localised, and as the resolution of such techniques can be limited, this makes the detection of such localised oedema difficult.

[0010] US 2007/106342 describes an electronic pain treatment device delivering electrical energy to the tissue of a patient in pain, which includes a variable wave generator, an impedance measurement circuit, and at least one electrode probe. Associated methods for treating pain are also disclosed.

[0011] GB 2,426,824 describes a probe for measuring the electrical impedance of human or animal body tissue comprising a housing and at least two electrodes mounted on the surface of the housing. Contained within the housing are a current source coupled to the electrodes, a controller to control the current source to drive a current between the electrodes, a voltmeter to measure potential difference between the electrodes, and a communication circuit for wirelessly transmitting the measured potential difference to a remote device. The probe may also include a processor to calculate tissue impedance from the measured potential difference, in which case the communication circuit transmits the calculated impedance. Wireless telemetry may be via an optical or radio frequency (RF) connection, for example using an infra red transmitter. The transmission of data without the use of a wired connection improves measurement accuracy due to the removal of the parasitic capacitances arising from cable connections. The probe may be used for cancer screening. A method of measuring impedance is also disclosed.

[0012] US 6,714,814 describes an impedance measuring apparatus which is easy to use, and which is guaranteed to be free of incorrect measurement caused by some joints appearing in the current flowing passage intervening between

two selected body parts and by the indefinite length between two selected body parts. The measuring apparatus of the present invention limits the place of the body under measurement to "one body region", i.e. a selected joint-to-joint body portion or joint-free body portion such as the forearm extending from the wrist to the elbow or the portion extending from the ankle to the knee, and comprises a housing having a contact surface to be applied to one selected body region; a first pair of measurement current supplying electrodes so placed on the contact surface that the one selected body region may be put in contact with the current electrodes; and a first pair of voltage measuring electrodes so placed on the contact surface between the pair of current electrodes that the one selected body region may be put in contact with the voltage electrodes.

[0013] DE 2912349 describes a probe for measuring water content of the human skin. The system operates by measuring the resistance of the skin between two electrodes provided a set distance apart on the probe.

Summary of the Present Invention

[0014] In a first broad form the present invention provides apparatus as defined by claim 1 for use in performing impedance measurements on a subject.

[0015] Typically the housing is an elongate housing, the contact surface is provided at a first end of the housing and the connector is provided at a second opposing end of the housing.

[0016] Typically the housing is formed from an insulating material.

[0017] Typically the housing is formed from a perspex tube.

[0018] Typically the contact surface has a convex shape.

[0019] The contact surface includes a moving member for moving relative to the subject.

[0020] Typically the moving member is a roller ball, and wherein the housing includes a shaped mounting for receiving the roller ball.

[0021] Typically the moving member is a cylindrical roller mounted on an axle.

[0022] Typically the probe includes a contact for electrically connecting the moving member to the connecter.

[0023] Typically the contact is a spring.

[0024] The probe includes a sensor for sensing movement of the moving member.

[0025] Typically the sensor includes at least one of:

a) an optical sensor; and,
b) moving elements in contact with the moving member.

[0026] Typically the connector is for connecting to a lead of the measuring device.

[0027] Typically, in use, the probe is moved along a segment of the subject to thereby allow an impedance profile representing variations in impedance along the segment to be determined.

[0028] Typically, the measuring device includes a processing system for:

a) causing at least one electrical signal to be applied to the subject via first electrodes provided on the subject; and,
b) determining an indication indicative of at least one second electrical signal measured via a second electrode positioned on the subject, and via the probe.

[0029] In a second broad form the present invention provides a method of performing impedance measurements on a subject using a probe as defined by claim 9.

[0030] Typically the method includes, in the measuring device, displaying a representation of the impedance profile to thereby allow the impedance profile to be used in determining a presence, absence, degree or location of oedema in the subject.

[0031] Typically the method includes, in the measuring device:

a) causing a sequence of first electrical signals to be applied to the subject via first electrodes provided on the subject; and,
b) determining an indication of a sequence of second electrical signals measured via a second electrode positioned on the subject, and via the probe.

[0032] Typically the method includes, in the measuring device: using an indication of the first and second signals to determine an impedance profile, the impedance profile representing variations in measured impedance along the segment.

[0033] It will be appreciated that the broad forms of the invention may be used individually or in combination, and may be used for diagnosis of the presence, absence or degree of a range of conditions and illnesses, including, but not limited

to oedema, lymphoedema, body composition and the like.

Brief Description of the Drawings

[0034] An example of the present invention will now be described with reference to the accompanying drawings, in which: -

Figure 1 is a schematic diagram of an example of impedance determination apparatus;
Figure 2 is a flowchart of an example of a process for determining an impedance profile;
Figures 3A to 3C are schematic diagrams of examples of impedance measuring probes;
Figure 4 is a flowchart of an example of a process for determining an impedance profile for uni-lateral limb oedema;
Figures 5A and 5B are diagrams of examples of electrode positions for use in measuring limb impedances;
Figures 5C and 5D are schematic diagrams of examples of electrode positions for use in measuring limb impedances;
Figure 6A is a graphical representation of an example of a profile of typical arm volume and impedance;
Figure 6B is a graphical representation of an example of a correlation of arm segment volume measured using a perometer with that predicted by impedance;
Figure 6C is a graphical representation of an example of limits of agreement between measured and predicted segment volumes;
Figure 6D is a graphical representation of an example of impedance profiles of an arm with lymphoedema and a contralateral unaffected arm; and,
Figure 6E is a graphical representation of an example of cumulative limb volumes measured by perometry from wrist to shoulder.
Figures 7A to 7F are schematic diagrams of an example of the construction of a band electrode not forming part of the invention;
Figure 7G is a schematic diagram of the use of a band electrode not forming part of the invention;

Detailed Description of the Preferred Embodiments

[0035] An example of apparatus suitable for performing an analysis of a subject's bioelectric impedance will now be described with reference to Figure 1.

[0036] As shown the apparatus includes a measuring device 100 including a processing system 102 coupled to a signal generator 111 and a sensor 112. In use the signal generator 111 and the sensor 112 are coupled to first electrodes 113, 114, and second electrodes 115, 116, provided on a subject S, via respective first leads 123, 124, and second leads 125, 126. The second electrode 116 is in the form of a probe electrode 116 that can be moved over the subject S, during the impedance measurement procedure, as will be described in more detail below.

[0037] The connection may be via a switching device 118, such as a multiplexer, allowing the leads 123, 124, 125, 126 to be selectively interconnected to signal generator 111 and the sensor 112, although this is not essential, and connections may be made directly between the signal generator 111 and the first electrodes 113, 114, and the sensor 112 and the second electrodes 115, 116.

[0038] An optional external interface 103 can be used to couple the measuring device 100, via wired, wireless or network connections, to one or more peripheral devices 104, such as an external database or computer system, barcode scanner, or the like. The processing system 102 will also typically include an I/O device 105, which may be of any suitable form such as a touch screen, a keypad and display, or the like.

[0039] In use, the processing system 102 is adapted to generate control signals, which causes the signal generator 111 to generate one or more alternating signals, such as voltage or current signals, which can be applied to a subject S, via the first electrodes 113,114. The sensor 112 then determines the voltage across or current through the subject S, using the second electrodes 115, 116 and transfers appropriate signals to the processing system 102.

[0040] Accordingly, it will be appreciated that the processing system 102 may be any form of processing system which is suitable for generating appropriate control signals and interpreting an indication of the measured signals to thereby determine the subject's bioelectrical impedance, and optionally determine other information such as the presence, absence or degree of oedema, or the like.

[0041] The processing system 102 may therefore be a suitably programmed computer system, such as a laptop, desktop, PDA, smart phone or the like. Alternatively the processing system 102 may be formed from specialised hardware, such as an FPGA (field programmable gate array), or a combination of a programmed computer system and specialised hardware, or the like.

[0042] It will be appreciated that the processing system 102, the signal generator 111 and the sensor 112 may be integrated into a common housing and therefore form an integrated device. Alternatively, the processing system 102 may be connected to the signal generator 111 and the sensor 112 via wired or wireless connections. This allows the

processing system 102 to be provided remotely to the signal generator 111 and the sensor 112. Thus, the signal generator 111 and the sensor 112 may be provided in a unit near, or worn by the subject S, whilst the processing system 102 is situated remotely to the subject S.

[0043] In use, the first electrodes 113, 114 are positioned on the subject to act as drive electrodes allowing one or more signals to be injected into the subject S. The location of the first electrodes 113, 114 will depend on the segment of the subject S under study, and can include for example, positioning electrodes on the wrist and ankles of a subject, to allow the impedance of limbs to be determined.

[0044] Once the second electrodes 115, 116 are also positioned as will be described below, one or more alternating signals are applied to the subject S, via the first leads 123, 124 and the first electrodes 113, 114. The nature of the alternating signal will vary depending on the nature of the measuring device and the subsequent analysis being performed.

[0045] For example, the system can use Bioimpedance Analysis (BIA) in which a single low frequency current is injected into the subject S, with the measured impedance being used directly in the assessment of oedema. In contrast Bioimpedance Spectroscopy (BIS) devices utilise frequencies ranging from very low frequencies (4 kHz) to higher frequencies (1000 kHz), and can use 256 or more different frequencies within this range, to allow multiple impedance measurements to be made within this range.

[0046] Thus, the measuring device 100 may either apply an alternating signal at a single frequency, at a plurality of frequencies simultaneously, or by apply a number of alternating signals at different frequencies sequentially, depending on the preferred implementation. The frequency or frequency range of the applied signals may also depend on the analysis being performed.

[0047] In one example, the applied signal is a frequency rich current from a current source clamped, or otherwise limited, so it does not exceed a maximum allowable subject auxiliary current. However, alternatively, voltage signals may be applied, with a current induced in the subject being measured. The signal can either be constant current, impulse function or a constant voltage signal where the current is measured so it does not exceed the maximum allowable subject auxiliary current.

[0048] A potential difference and/or current are measured between the second electrodes 115, 116. The acquired signal and the measured signal will be a superposition of potentials generated by the human body, such as the ECG, and potentials generated by the applied current.

[0049] The distance between the second electrodes is measured and recorded. Similarly, other parameters relating to the subject may be recorded, such as the height, weight, age, sex, health status, any interventions and the date and time on which they occurred. Other information, such as current medication, may also be recorded.

[0050] To assist accurate measurement of the impedance, buffer circuits may be placed in connectors that are used to connect the second electrodes 115, 116 to the second leads 125, 126, as will be described in more detail below. This ensures accurate sensing of the voltage response of the subject S, and in particular helps eliminate contributions to the measured voltage due to the response of the second leads 125, 126, and reduce signal loss.

[0051] This in turn greatly reduces artefacts caused by movement of the second leads 125, 126, which is particularly important in some applications such as monitoring fluid levels during dialysis, in which sessions usually last for several hours and the subject will move around and change positions during this time, as well as being important during movement of the probe 116.

[0052] A further option is for the voltage to be measured differentially, meaning that the sensor used to measure the potential at each second electrode 115, 116 only needs to measure half of the potential as compared to a single ended system.

[0053] The measurement system may also have buffers placed in the connectors between the first electrodes 113, 114 and the first leads 123, 124. In one example, current can also be driven or sourced through the subject S differentially, which again greatly reduced the parasitic capacitances by halving the common-mode current. Another particular advantage of using a differential system is that the micro-electronics built into the connectors for each first electrode 113, 114 also removes parasitic capacitances that arise when the subject S, and hence the leads first 123, 124, move.

[0054] The acquired signal is demodulated to obtain the impedance of the system at the applied frequencies. One suitable method for demodulation of superposed frequencies is to use a Fast Fourier Transform (FFT) algorithm to transform the time domain data to the frequency domain. This is typically used when the applied current signal is a superposition of applied frequencies. Another technique not requiring windowing of the measured signal is a sliding window FFT.

[0055] In the event that the applied current signals are formed from a sweep of different frequencies, then it is more typical to use a processing technique such as multiplying the measured signal with a reference sine wave and cosine wave derived from the signal generator, or with measured sine and cosine waves, and integrating over a whole number of cycles. This process rejects any harmonic responses and significantly reduces random noise.

[0056] Other suitable digital and analog demodulation techniques will be known to persons skilled in the field.

[0057] In the case of BIS, impedance or admittance measurements are determined from the signals at each frequency by comparing the recorded voltage and current signal. The demodulation algorithm will produce an amplitude and phase

signal at each frequency.

[0058] An example of the operation of the apparatus to generate an impedance profile will now be described with reference to Figure 2.

[0059] In this example, at step 200 the processing system 102 causes a current signal to be applied to the subject S, with the induced voltage across the subject S being measured at step 210, with signals representing the measured voltage and the applied current being returned to the processing system 102 for analysis.

[0060] This is typically performed for at least a segment of the subject S that is suspected of being susceptible to oedema, and may also be repeated for a separate healthy segment of the subject. Thus, for example, in the case of limb oedema, this is typically performed on the affected or "at risk" limb (hereinafter generally referred to as the "affected" limb), and may also be performed on the contra-lateral limb.

[0061] During this process, the probe electrode 116 will be moved along the length of the respective limb or limb segment, so that a number of measurements are taken over the entire limb or segment length. In one example, the measurements for a single limb or segment are taken over a time period such as 20 seconds, with measurements being made at a sampling rate of 1ms, thereby providing a total of 20,000 readings for the limb, with the readings being distributed along the limb length. However, any suitable number of readings may be used, although it will be appreciated that the greater the number of measurements made, the higher the resolution of the impedance profile.

[0062] It will be appreciated that the application of the current and voltage signals may be controlled by a separate processing system to that used in performing the analysis to derive an impedance profile, and that the use of a single processing system is for the purpose of example only.

[0063] At step 220, measured voltage and current signals are used by the processing system 102 to determine a sequence of measured impedance values. In one example, this includes first impedance values representing the impedance profile of the unaffected limb or limb segment and second impedance values representing the impedance profile of the affected limb or limb segment, although this is not essential, and in one example, impedance measurements are only made for the affected limb or limb segment.

[0064] Once the impedance values are determined, these are used by the processing system 102, to derive an impedance profile. This may be achieved in any one of a number of ways depending on the preferred implementation.

[0065] In one example, the impedance profile is in the form of a graphical representation showing the variation in the measured impedance values along the length of the limb or limb segment. It will be appreciated that in one example, this involves measuring the position of the probe along the limb or limb segment, allowing the impedance value to be plotted against position. However, a number of variations on this are possible.

[0066] For example, it can be assumed that movement of the probe along the limb is performed at a relatively constant rate, in which case subsequently sampled measurements will be evenly spaced with respect to each other, on the resulting profile. Alternatively, the position can be derived from the impedance values themselves, as some portions of limbs, such as elbow or knee joints, have different impedance values to other portions of the limb, allowing the elbow or knee to be easily identified.

[0067] Additionally, or alternatively, the impedance profile can be based on parameters derived from measured impedance values, such as the impedance at zero, characteristic or infinite frequencies (R_0, Z_c, R_∞).

[0068] The impedance profile can be based solely on the impedance measured for the "affected" limb or limb segment. However, alternatively, the impedance profile can also include an indication of the impedances measured for the unaffected limb or limb segment, thereby allowing comparison between the limbs or segments. It will be appreciated that in a healthy person, the impedance of both limbs or corresponding limb segments will be similar, and consequently, differences in the impedance profiles can be used to help identify the presence, absence, degree and/or location of any oedema.

[0069] Additionally, and/or alternatively, the impedance profile can include a baseline or other reference. The baseline is typically a previous impedance profile measured for the same limb, or limb segment of the subject S, whereas the reference is typically determined from a reference population of healthy individuals, as will be described in more detail below.

[0070] Once the impedance profile is determined, a representation of the impedance profile can be displayed to an operator at step 230, as will be described in more detail below.

[0071] A first example of a probe electrode not forming part of the invention for use in determining an impedance profile will now be described with reference to Figure 3A.

[0072] In this example, the probe electrode 116 is formed from a housing 300 and a contact surface 301. The contact surface 301 is connected via an electrical connection 302 to a connector 303 which allows onward connection to the lead 126 shown in Figure 1.

[0073] In use the contact surface 301 is designed to be placed against the subject S, in contact with the subject's skin surface. To ensure accurate measurements are obtained, it is important to ensure good electrical contact between the contact surface 301 and the subject S, and accordingly, the contact surface 301 is typically formed from an electrically conductive material, such as stainless steel or the like, and may also be coated with an electro-conductive gel. In this

example, the contact surface 301 is formed from a convex curved smooth surface, to assist with smooth transit across the subject's skin, as the probe 116 is moved along the length of the subject's limb, as well as to maximise contact between the contact surface and the subject's skin, thereby ensuring good electrical connection.

[0074] The housing is configured to allow an operator to hold the probe electrode whilst it is placed in contact with the subject. To ensure that this does not interfere with measurements, the housing is typically formed from an electrically insulating material such as a Perspex tube, or the like, although a wide variety of probe arrangements may be used.

[0075] Alternative probe arrangements are shown in Figures 3B and 3C.

[0076] In the embodiment of the invention of Figure 3B the contact surface 301 is provided by a moving member, such as a roller ball arrangement. Accordingly in this instance the probe 116 is formed from a housing 310, such as a Perspex tube or the like. The housing 310 includes a shaped end portion, shown generally at 311, which forms a mounting adapted to receive a roller ball 312.

[0077] The roller ball 312 is positioned in the shaped portion 311 to allow rotational movement of the roller ball in any direction, whilst constraining translational movement. The roller ball 312 is generally formed from an electrically conducted substance such as stainless steel or the like, and may again be coated with an electrically conductive gel.

[0078] A compression spring 313 is mounted in the housing using a mounting (not shown), so that the spring is urged into contact with the roller ball 312 thereby ensuring good electrical contact between the roller ball 312 and the spring 313. The spring 313 is then connected via an electrical connection 314 to a connector 315 which in turn allows the probe to be connected to the lead 126. However, any suitable method of electrically connecting the roller ball 312 and the lead 126 may be used, such as brushes, or the like.

[0079] In addition to the provision of the roller ball 312, in this embodiment the probe 116 also includes a motion sensing system 316 configured to sense motion of the roller ball 312 and return an indication of the motion via an electrical connection 317. This would typically involve transferring signals indicative of movement of the roller ball 312, via the lead 126, or an appropriate other connection, to the measuring device 100.

[0080] It will be appreciated by persons skilled in the art that the mechanism for sensing motion of the roller ball 312 may be any appropriate mechanism. Thus, for example, the sensor 316 can include optical sensors adapted to optically detect movement of the roller ball. Alternatively, one or more moving elements, such as wheels, can be placed in contact with the roller ball 312 such that movement of the moving element can be detected. It will be appreciated that the ability to detect motion of a roller ball 312 is technology known from computer mouse or trackball peripheral devices, or the like, and accordingly this will not be described in any further detail.

[0081] A second probe arrangement forming part of the invention is shown at Figure 3C. In this embodiment the probe 116 includes two supports 320 which operate to support an axle 321. An electrically conductive roller 322, such as a stainless steel roller, is mounted to the axle with the roller 322 being positioned against the subject in use. The axle 321, which is also conductive, is connected via an electrical connection 323 to a connector 324 to allow onward connectivity to the lead 126.

[0082] In this embodiment, motion of the roller 322, for example to detect the distance moved by the probe 116 along a limb, can be detected in any one of a number of ways. In this embodiment, the roller 322 includes an aperture 325 extending therethrough. The aperture 325 is positioned so that once per revolution of the roller 322 the aperture 325 aligns with a radiation source 326, such as an LED (light emitting diode) and a corresponding detector 327. Accordingly, when the aperture 325 aligns with the radiation source 326 and detector 327, the detector 327 will detect radiation emitted by the source by allowing revolutions of the roller 322 to be counted. Again information regarding this can be transferred back to the measuring device utilising appropriate connections (not shown).

[0083] Operation of the probe 116 for use in determining the impedance profile of the subject's limb will now be described with reference to Figure 4. For the purpose of this example, measurements to determine a profile are performed along the entire length of the limb, but it will be appreciated that this can also be applied to limb segment or other body segments.

[0084] In this example, at step 400 subject details are optionally determined and provided to the processing system 102. The subject details will typically include information such as limb dominance, details of any medical interventions, as well as information regarding the subject as the subject's age, weight, height, sex, ethnicity or the like. The subject details can be used in referencing previous measurements made for the subject, for selecting other baselines or reference normal population values, as well as for generating reports, or the like.

[0085] It will be appreciated that the subject details may be supplied to the processing system 102 via appropriate input means, such as the I/O device 105. Thus, each time a subject measurement is performed this information can be input into the measuring device 100.

[0086] However, more typically the information is input a single time and stored in an appropriate database, or the like, which may be connected as a peripheral device 104 via the external interface 103. The database can include subject data representing the subject details, together with information regarding previous impedance profiles, baseline measurements or impedance measurements recorded for the subject.

[0087] In this instance, when the operator is required to provide subject details, the operator can use the processing

system 102 to select a search database option allowing the subject details to be retrieved. This is typically performed on the basis of a subject identifier, such as a unique number assigned to the individual upon admission to a medical institution, or may alternatively be performed on the basis of name or the like. Such a database is generally in the form of an HL7 compliant remote database, although any suitable database may be used.

[0088] In one example, the subject can be provided with a wristband or other device, which includes coded data indicative of the subject identifier. In this case, the measuring device 100 can be coupled to a peripheral device 104, such as a barcode or RFID (Radio Frequency Identification) reader allowing the subject identifier to be detected and provided to the processing system 102, which in turn allows the subject details to be retrieved from the database. The processing system 102 can then display an indication of the subject details retrieved from the database, allowing the operator to review these and confirm their accuracy before proceeding further.

[0089] As part of this process, an affected limb, or "at risk" limb, may be determined. This may be achieved in any one of a number of ways depending on the preferred implementation. Thus, for example, the affected limb can be indicated through the use of appropriate input means, such as the I/O device 105. Alternatively this information can be derived directly from the subject details, which may include an indication of the affected limb, or details of any medical interventions performed, which are in turn indicative of the affected limb.

[0090] At step 410 an operator positions the first electrodes 113, 114, and the second electrode 115 on the subject S, and connects these electrodes to the corresponding leads 123, 124, 125. The probe is also connected to the lead 126, if required.

[0091] The general arrangement is to provide electrodes on the hand at the base of the knuckles and between the bony protuberances of the wrist, as shown in Figure 5A, and on the feet at the base of the toes and at the front of the ankle, as shown in Figure 5B. The configurations shown in Figures 5C and 5D allow impedance profiles of the right arm 631 and the right leg 633 to be measured respectively, and it will be appreciated that equivalent arrangements can be used to derive impedance profiles for the left leg and left arm.

[0092] As a result of the electrode positioning, as the probe 116 is moved from the wrist towards the shoulder along the right arm 631, the value of the measured impedance will tend to drop, as the theory of equal potentials, indicates that the potential measured at the electrode 115 will be similar to the potential at the shoulder of the right arm 631.

[0093] It will be appreciated that using an electrode arrangement in this manner allows the electrode positions to provide reproducible results for impedance measurements. For example when current is injected between electrodes 113 and 114 in Figure 5C, the electrode 115 could be placed anywhere along the left arm 632, since the whole arm is at an equal potential, equivalent to if the electrode were positioned at the shoulder.

[0094] This is advantageous as it greatly reduces the variations in measurements caused by poor placement of the electrodes by the operator. It also greatly reduces the number of electrodes required to perform segmental body measurements, as well as allowing the limited connections shown to be used to measure each of limbs separately.

[0095] However, it will be appreciated that any suitable electrode and lead arrangement may be used.

[0096] At step 420 the impedance probe is positioned at a start measuring point. The start measuring point may vary depending on the particular measurements being made. Thus for example, in determining an arm limb impedance profile the probe 116 is initially located at the ulnar styloid process. Once the impedance probe is appropriately positioned the monitoring process is activated at step 430, typically using an appropriate input command provided to the measuring device 100, for example, via the I/O device 105.

[0097] At step 440 the measuring device 100 applies a current signal to the subject via the first electrodes 113, 114 and concurrently measures the voltage induced across the subject using the second electrode 115 and the probe 116. It will be appreciated that in practice the signal generator 111, and the sensor 112, return signals to the processing system 102 indicative of the applied current and the measured voltage, allowing impedances to be determined.

[0098] At step 450 the measuring device 100 will determine positional information from the probe. This may be achieved for example by having either the position sensor 316, or signals from the detector 327 transferred to the measuring device 100 and interpreted appropriately.

[0099] At step 460 the measuring device 100 determines if the process is complete and if not returns to step 440 to allow further measurements to be performed.

[0100] It will be appreciated by persons skilled in the art that whilst this is being performed the operator will slide or roll the probe 116 along the dorsal skin surface towards the acromion, allowing an impedance profile of the entire limb to be determined. In one example, the probe is held stationery at the beginning and end points for 5 seconds to allow stable end point readings to be determined. In this example, the measurement of an impedance profile typically takes approximately 20 seconds, although this of course depends on the preferred implementation.

[0101] Once the probe has been positioned at the acromion, the user can select an appropriate input command utilising the I/O device 105, allowing the measuring device 100 to determine the process is complete at step 460.

[0102] At step 470 the measuring device 100 will determine appropriate impedance parameter values, using these to generate impedance profiles at step 480. The manner in which this is achieved will depend on the nature of the impedance measurements performed.

[0103] In the case of BIS analysis, the impedance profile can be based on impedance parameter values, such as values of the impedance at zero, characteristic or infinite frequencies (R_0, Z_c, R_∞). These values can be derived based on the impedance response of the subject, which at a first level can be modelled using equation (1), commonly referred to as the Cole model:

$$Z = R_\infty + \frac{R_0 - R_\infty}{1 + (j\omega\tau)} \quad (1)$$

where:

R_∞= impedance at infinite applied frequency,
R_0= impedance at zero applied frequency,
ω = angular frequency,
τ is the time constant of a capacitive circuit modelling the subject response.

[0104] However, the above represents an idealised situation which does not take into account the fact that the cell membrane is an imperfect capacitor. Taking this into account leads to a modified model in which:

$$Z = R_\infty + \frac{R_0 - R_\infty}{1 + (j\omega\tau)^{(1-\alpha)}} \quad (2)$$

where:

α has a value between 0 and 1 and can be thought of as an indicator of the deviation of a real system from the ideal model.

[0105] The value of the impedance parameters R_0 and R_∞ may be determined in any one of a number of manners such as by:

- solving simultaneous equations based on the impedance values determined at different frequencies;
- using iterative mathematical techniques;
- extrapolation from a "Wessel plot";
- performing a function fitting technique, such as the use of a polynomial function.

[0106] Alternatively, in the case of a BIA analysis, the impedance profile is based on the actual measured impedance values, or parameters derived therefrom using suitable techniques.

[0107] It will be appreciated that whilst BIS analysis generally leads to an improved range of information, time constraints may limit its usage. For example, some examples measuring devices can take up to 800 msec to complete a frequency scan, in which case the probe may have to be moved at a rate that is too slow for practical purposes to prevent the probe moving a significant distance along the limb during a frequency scan. This in turn effects the usability of the process. Accordingly, in many cases it is preferred to perform measurements at a single selected frequency in the range 5 kHz to 1 MHz at a sampling rate of 1 reading per msec. Using this arrangement, with a twenty second measurement protocol allows 20,000 readings to be established along the length of the arm, thereby allowing a suitable profile to be established. It will be appreciated however that a greater or lesser number of measurements made be used depending for example on the intended use of the measurements.

[0108] Examples of derived profiles will now be described. For the purpose of this example, the profiles are compared to limb volumes, which are currently a preferred mechanism for determining the presence, absence or degree of oedema.

[0109] In this regard, the volume of a cylindrical body can be determined from measurements of its length and impedance according to the relationship:

$$Vol = \rho \frac{L^2}{Z} \qquad (3)$$

where:

L is length (cm),
Z is impedance (ohm); and,
ρ is the resistivity constant (ohm.cm).

[0110] Since a short segment of a limb approximates a cylinder, if the impedance (Z) of the segment is measured then the volume of the limb segment can be estimated. The value of ρ may be obtained from regression of the impedance quotient, L^2/Z, against limb volume, measured by a reference technique, such as DEXA (Dual Energy X-ray Absortiometry), MRI (Magnetic Resonance Imaging), perometry, or the like, in an independent group of subjects.

[0111] Example profiles are shown in Figure 6A. This shows example impedance profiles, along both the left and right arms, of a number of test subjects. The figure presents the impedances at zero and infinite frequency calculated from BIS measurements for sequential 2.5 cm segments, as well as perometer volume measurements for equivalent segment volumes. In this example, in which measurements are collected for segments only, a limited number of readings can be collected using the probe, or alternatively, the probe could be replaced by a number of second electrodes positioned along the limb.

[0112] The impedance profile along the arm is the inverse of that seen for segment volume as expected from Equation (3), with a high correlation between the impedance and volume measurements being demonstrated. The position of the elbow, indicated by a change in volume and impedance is clearly discernable.

[0113] Figure 6B shows the correlation of arm segment volume measured by perometer with that predicted by impedance according to Equation (3). As shown, in Figure 6C, limits of agreement between the two methods are variable depending upon the limb region being measured. For example, agreement was closest for the predominantly cylindrical regions of the forearm and biceps/triceps region and worse for the joint regions of the elbow and shoulder.

[0114] An example of the impedance profile of the arms of a subject with unilateral lymphoedema is shown in Figure 6D. As shown in this example, the impedance decreases as the electrode is moved from the wrist towards the shoulder reflecting the shortening inter-electrode distance between the second electrode 115 and the probe 116. Furthermore, the impedance is higher in the unaffected limb compared to that of the affected limb, highlighting the presence and magnitude of oedema.

[0115] It will be appreciated from this that when the measuring device 100 presents a measured impedance profile, it can include a reference or baseline measurement.

[0116] For example, a baseline is typically a previous impedance profile created from an impedance profile measurement that has significance in the treatment history of the subject. A common baseline in use might be an impedance profile measurement made on a patient suffering from lymphoedema before they start a course of management therapy. This measurement allows the practitioner to gauge accurately how much the patient has improved from the start of their treatment to the present measurement.

[0117] Baseline measurements may also be made pre-surgery and hence pre-lymphoedema, in which case the baseline impedance profile establishes the "normal" healthy impedance profile for the individual patient and can be used thereafter as a benchmark from which to monitor progress of the patient. Baselines can also be set using a single measurement or be created from the average of a number of measurements specified by the user.

[0118] The reference is typically formed from an impedance profile derived from a normal population (subject's not suffering from oedema) that is relevant to the subject under study. Thus, the normal population is typically selected taking into account factors such as medical interventions performed, ethnicity, sex, height, weight, limb dominance, the affected limb, or the like.

[0119] Therefore if the test subject has unilateral lymphoedema of the dominant arm and is female then the normalised data drawn from the normal population database will be calculated from the dominant arm measurements from female subjects that are present in the in the normal population database.

[0120] Accordingly, at this stage the processing system 102 typically accesses reference populations stored in the database, or the like. This may be performed automatically by the processing system 102 using the subject details. Thus for example, the database may include a look-up table that specifies the normal population that should be used given a particular set of subject details. Alternatively selection may be achieved in accordance with predetermined rules that can be derived using heuristic algorithms based on selections made by medically qualified operators during previous procedures. Alternatively, this may achieved under control of the operator, depending on the preferred implementation.

[0121] Operators may also have their own reference normal populations stored locally. However, in the event that

suitable populations are not available, the processing system 102 can be used to retrieve a reference from a central repository, for example via an appropriate server arrangement. In one example, this may be performed on a pay per use basis.

[0122] The reference may also need to be scaled to take into account differing limb lengths of subjects measured, which can be determined from probe positional information if this is present.

[0123] In this instance, the measured impedance profile can be displayed concurrently with reference impedance profiles representing healthy limbs and representing subjects with oedema, to thereby highlight to the operator whether oedema is likely, and if so, where on the limb this has occurred, or is most severe.

[0124] Additionally, and/or alternatively, in the case of unilateral oedema, impedance profiles can be displayed for each limb, thereby allowing comparison between contra-lateral limbs. Thus, in this example, the impedance profile of a healthy limb acts as a baseline or reference against which the profile of the affected limb can be compared.

[0125] Display of the representation may be achieved in a number of ways, such as by presenting the representation on a suitable display, for example, using the I/O device 105, or alternatively by providing the representation in a hard copy form using an appropriate printer, although any suitable technique may be used.

[0126] An example of comparable cumulative volume measurements are shown in Figure 6E, highlighting that the magnitude difference obtained between arms is greater for the impedance measurements (Figure 6D) than the equivalent volume measurements (Figure 6E).

[0127] Furthermore, as impedance analysis in the above described manner can be used to focus on the levels of extracellular fluid in the limb, this tends to provide a more accurate assessment of fluid distributions within the limb than volume measurements alone.

[0128] In particular, it can be seen that whilst the volumetric measurements in Figure 6E present a smooth curve, implying there is a relatively equal distribution of fluid along the limb, the impedance profiles of Figure 6D include a number of bumps and troughs, particularly in the lymphoedematous limb. Thus, the impedance profile of Figure 6D indicates not only that there is a difference in fluid levels between the limbs, and hence that there is the presence of lymphoedema, but also can be used to determine in which area of the arm fluid concentrations are highest and/or lowest, thereby allowing highly localised oedema to be diagnosed.

[0129] In the example of Figure 6D, it can be seen that there is a significant peak shown at 600 which was obtained near the start of the reading cycle. This suggests that a segment in the arm near the wrist has a high fluid level thereby indicative of lymphoedema. It is also noticeable that towards the end of the profile the readings are similar to the readings for the control arm and hence that the lymphoedema is prevalent primarily in the lower limb.

[0130] Accordingly, by correlating the impedance measurements with the distance travelled along the arm or other limb it is possible not only to detect that the limb is lymphoedematous but also the particular location of lymphoedema within the limb thereby rendering it easier to detect the presence, absence, degree or location of oedema using impedance profiling than volumetric measurements.

[0131] In the above described examples, impedance measurements along the limb or other body segment are achieved by moving a probe along the respective body segment. However, this is not essential, and as an alternative, a sequence of second electrodes not forming part of the invention may be placed along the subject's limb, to allow impedance measurements to be recorded at a number of different locations along the limb.

[0132] Whilst the electrodes can be standard electrodes, positioned as required by the operator, an alternative electrode configuration suitable for performing this will now be described with reference to Figures 7A to 7F.

[0133] In this particular example not forming part of the invention the electrode is a band electrode 700, which includes a number of separate electrodes. In this example the electrode is formed from an elongate substrate 710 such as a plastic polymer coated with shielding material and an overlaying insulating material.

[0134] A number of electrically conductive tracks 720 are provided on the substrate extending from an end of the substrate 711 to respective conductive contact pads 730, spaced apart along the length of the substrate in sequence. This allows a connector to be electrically coupled to the tracks 720 and provide onward connectivity to leads, such as leads 126.

[0135] The tracks 720 and the contact pads 730 may be provided on the substrate 710 in any one of a number of manners, including for example, screen printing, inkjet printing, vapour deposition, or the like, and are typically formed from silver or another similar material. It will be appreciated however that the tracks and contact pads should be formed from similar materials to prevent signal drift. Furthermore, whilst circular contact pads 730 are shown, in practice these could be of any suitable shape.

[0136] Following the application of the contact pads 730 and the tracks 720, an insulating layer 740 is provided having a number of apertures 750 aligned with the electrode contact pads 730. The insulating layer is typically formed from a plastic polymer coated with shielding material and an overlaying insulating material.

[0137] To ensure adequate conduction between the contact pads 730, and the subject S, it is typical to apply a conductive gel 760 to the contact pads 730. It will be appreciated that in this instance gel can be provided into each of the apertures 750 as shown.

[0138] A removable covering 770 is then applied to the electrode, to maintain the electrode's sterility and/or moisture level in the gel. This may be in the form of a peel off strip or the like which when removed exposes the conductive gel 760, allowing the electrode to be attached to the subject S.

[0139] In order to ensure signal quality, it is typical for each of the tracks 720 to comprise a shield track 721, and a signal track 722, as shown. This allows a shield on the leads 126 to be connected to the shield track 721, with the lead core being coupled to the signal track 722. This allows shielding to be provided on the electrode, to help reduce interference between applied and measured signals.

[0140] In use, the band electrode may be attached to a limb segment of the subject, such as the subject's arm, as shown in Figure 7G. The electrode will typically include an adhesive surface, allowing it to stick to the subject. This provides an electrode that is easy to attach and position on the subject, and yet can be worn for an extended period if necessary. The band electrode 700 may also be positioned on the subject at other locations, such as on the side of the subject's torso, or laterally above the naval, on the leg, or the like.

[0141] Once positioned, the band electrode can be connected to the switching device 118 via respective leads 126, with a separate lead being provided for each contact pad 730. In this instance, it will be appreciated that in this instance, the measuring device 100 can control the switching device 118 so that readings are taken from each of the contact pads 730 in turn. This allows readings along the entire body segment to be taken automatically by the measuring device 100, without requiring operator intervention, for example, by requiring the operator move the probe 116 along the subject's body segment.

[0142] In one example, the band electrode 700 provides sufficient electrodes to allow an impedance profile to be measured. In the above example, the band electrode includes six electrodes, however any suitable number may be used depending on the preferred implementation.

[0143] It will be appreciated that the use of a band electrode will generally not allow as great a resolution to be achieved as compared to the use of the probe described above, simply as readings can only be sampled at each of the contact pad locations, as opposed to continuous sampling along the length of the limb. However, the use of a band electrode does have some advantages.

[0144] Firstly, the contact pads are provided at definite positions on the band electrode, thereby allowing for easy and accurate determination of the position at which each impedance measurement is made.

[0145] Secondly, as the contact pads can be held in position for a longer period of time, this makes the band electrode particularly suited for performing BIS analysis over a large number of frequencies, in which readings at each position may take some time.

[0146] It will also be appreciated that as an alternative to using a band electrode, separate discrete electrodes may be positioned along the length of the limb.

[0147] Thus, for example, it will be appreciated that features from different examples above may be used interchangeably where appropriate. Furthermore, whilst the above examples have focussed on a subject such as a human, it will be appreciated that the measuring device and techniques described above can be used with any animal, including but not limited to, primates, livestock, performance animals, such race horses, or the like.

Claims

1. Apparatus for use in performing impedance measurements on a subject, the apparatus including a measuring device (100) and a probe, the probe including:

   a) a housing (300) configured to be held by an operator in use;
   b) a contact surface (301) for contacting the subject, wherein the contact surface (301) includes a moving member (312) for moving relative to the subject; and,
   c) a connector (303) for connecting the contact surface to the measuring device, wherein the probe is arranged to be moved along a segment of the subject and the measuring device is arranged to perform a sequence of impedance measurements as the probe (116) is moved along the segment by the operator, so that the measuring device (100) determines impedance measurements along the segment, **characterised in that** the probe includes a sensor (316) for sensing movement of the moving member (312) and for determining positional information along different positions on the segment, and the measuring device being further arranged to use the impedance measurements and the positional information to determine an impedance profile.

2. Apparatus according to claim 1, wherein the housing (300) is an elongate housing, the contact surface (301) is provided at a first end of the housing (300) and the connector (303) is provided at a second opposing end of the housing.

3. Apparatus according to claim 1 or claim 2, wherein the housing (300) is formed from an insulating material.

4. Apparatus according to any one of the claims 1 to 3, wherein the housing (300) is formed from a perspex tube.

5. Apparatus according to any one of the claims 1 to 4, wherein the contact surface (301) has a convex shape.

6. Apparatus according to any one of claims 1 to 5, wherein the probe includes a contact (313) for electrically connecting the moving member to the connecter (303).

7. Apparatus according to any one of the claims 1 to 6, wherein the connector (303) is for connecting to a lead of a measuring device.

8. Apparatus according to any one of the claims 1 to 7, wherein, the measuring device includes, a processing system (102) for

a) causing at least one electrical signal to be applied to the subject via first electrodes (113, 114) provided on the subject; and,
b) determining an indication indicative of at least one second electrical signal measured via a second electrode (115) positioned on the subject, and via the probe (116).

9. A method of performing impedance measurements on a subject using a probe (116), the probe including a housing (300) configured to be held by an operator in use, a contact surface (301) for contacting the subject wherein the contact surface (301) includes a moving member (312) for moving relative to the subject, a connector (303) for connecting the contact surface (301) to a measuring device (100), and a sensor (316) for sensing movement of the moving member, the method including:

a) positioning the probe (116) in contact with a segment of the subject; and
b) causing the measuring device (100) to perform a sequence of impedance measurements **characterised in that** the method further comprises;
c) the operator moving the probe (116) along the segment during the sequence of impedance measurements so that the measuring device (100):

i. determines positional information along different positions on the segment using the sensor (316); and,
ii. determines impedance measurements along the segment;

d) the measuring device using the impedance measurements and the positional information to determine an impedance profile.

10. A method according to claim 9, wherein the method includes, in the measuring device displaying a representation of the impedance profile.

11. A method according to claim 9 or claim 10, wherein the method includes, in the measuring device (100):

a) causing a sequence of first electrical signals to be applied to the subject via first electrodes (113, 114) provided on the subject; and,
b) determining an indication of a sequence of second electrical signals measured via a second electrode (115) positioned on the subject, and via the probe (116).

12. A method according to claim 11, wherein the method includes, in the measuring device:

using an indication of the first and second signals to determine an impedance profile, the impedance profile representing variations in measured impedance along the segment.

Patentansprüche

1. Vorrichtung zum Ausführen von Impedanzmessungen an einem Patienten, wobei die Vorrichtung ein Messgerät (100) und eine Sonde beinhaltet, wobei die Sonde Folgendes beinhaltet:

a) ein Gehäuse (300), das dafür gestaltet ist, während des Gebrauchs von einem Bediener gehalten zu werden,
b) eine Kontaktfläche (301) für den Kontakt mit dem Patienten, wobei die Kontaktfläche (301) ein bewegliches Element (312) für die Bewegung im Verhältnis zum Patienten beinhaltet, und
c) einen Anschluss (303), um die Kontaktfläche an das Messgerät anzuschließen, wobei die Sonde dafür angeordnet ist, entlang eines Körperteils des Patienten bewegt zu werden, und das Messgerät dafür angeordnet ist, eine Folge von Impedanzmessungen auszuführen, wenn die Sonde (116) vom Bediener entlang des Körperteils bewegt wird, so dass das Messgerät (100) entlang des Körperteils Impedanzmesswerte bestimmt,

dadurch gekennzeichnet, dass die Sonde einen Sensor (316) zum Abtasten der Bewegung des beweglichen Elements (312) und zum Bestimmen von Positionsinformationen an verschiedenen Positionen des Körperteils beinhaltet und das Messgerät ferner dafür angeordnet ist, die Impedanzmesswerte und die Positionsinformationen zu verwenden, um ein Impedanzprofil zu bestimmen.

2. Vorrichtung nach Anspruch 1, wobei das Gehäuse (300) ein längliches Gehäuse ist, die Kontaktfläche (301) an einem ersten Ende des Gehäuses (300) bereitgestellt ist und der Anschluss (303) an einem zweiten, gegenüberliegenden Ende des Gehäuses bereitgestellt ist.

3. Vorrichtung nach Anspruch 1 oder 2, wobei das Gehäuse (300) aus einem Isolationsmaterial gebildet ist.

4. Vorrichtung nach einem der Ansprüche 1 bis 3, wobei das Gehäuse (300) aus einem Acrylglasrohr gebildet ist.

5. Vorrichtung nach einem der Ansprüche 1 bis 4, wobei die Kontaktfläche (301) eine konvexe Form aufweist.

6. Vorrichtung nach einem der Ansprüche 1 bis 5, wobei die Sonde einen Kontakt (313) für das elektrische Anschließen des beweglichen Elements an den Anschluss (303) beinhaltet.

7. Vorrichtung nach einem der Ansprüche 1 bis 6, wobei der Anschluss (303) für das Anschließen an ein Kabel eines Messgerätes vorhanden ist.

8. Vorrichtung nach einem der Ansprüche 1 bis 7, wobei das Messgerät ein Verarbeitungssystem (102) beinhaltet, für das

a) Bewirken, dass mindestens ein elektrisches Signal über erste Elektroden (113, 114), die am Patienten bereitgestellt sind, am Patienten angelegt wird, und
b) Bestimmen einer Angabe, die mindestens ein zweites elektrisches Signal angibt, das über eine zweite Elektrode (115), die am Patienten angeordnet ist, und über die Sonde (116) gemessen wird.

9. Verfahren zum Ausführen von Impedanzmessungen an einem Patienten mit Hilfe einer Sonde (116), wobei die Sonde eine Gehäuse (300) beinhaltet, das dafür gestaltet ist, während des Gebrauchs von einem Bediener gehalten zu werden, eine Kontaktfläche (301) für den Kontakt mit dem Patienten, wobei die Kontaktfläche (301) ein bewegliches Element (312) für die Bewegung im Verhältnis zum Patienten beinhaltet, einen Anschluss (303), um die Kontaktfläche an ein Messgerät (100) anzuschließen, und einen Sensor (316) zum Abtasten der Bewegung des beweglichen Elements, wobei das Verfahren Folgendes beinhaltet:

a) Anordnen der Sonde (116) in Kontakt mit einem Körperteil des Patienten und
b) Bewirken, dass das Messgerät (100) eine Folge von Impedanzmessungen ausführt, **dadurch gekennzeichnet, dass** das Verfahren ferner Folgendes umfasst:
c) Bewegen der Sonde (116) durch den Bediener entlang des Körperteils während der Folge von Impedanzmessungen, so dass das Messgerät (100) Folgendes ausführt:

i) Bestimmen von Positionsinformationen an verschiedenen Positionen am Körperteil mit Hilfe des Sensors (316) und
ii) Bestimmen von Impedanzmesswerten entlang des Körperteils,
wobei

d) das Messgerät die Impedanzmesswerte und die Positionsinformationen verwendet, um ein Impedanzprofil zu bestimmen.

10. Verfahren nach Anspruch 9, wobei das Verfahren beinhaltet, dass im Messgerät eine Darstellung des Impedanzprofils angezeigt wird.

11. Verfahren nach Anspruch 9 oder 10, wobei das Verfahren im Messgerät (100) Folgendes beinhaltet:

a) Bewirken, dass eine Folge erster elektrischer Signale über erste Elektroden (113, 114), die am Patienten bereitgestellt sind, an den Patienten angelegt werden, und
b) Bestimmen einer Angabe einer Folge zweiter elektrischer Signale, die über eine zweite Elektrode (115), die am Patienten angeordnet ist, und über die Sonde (116) gemessen werden.

12. Verfahren nach Anspruch 11, wobei das Verfahren im Messgerät Folgendes beinhaltet:

Verwenden einer Angabe der ersten und zweiten Signale, um ein Impedanzprofil zu bestimmen, wobei das Impedanzprofil Schwankungen der gemessenen Impedanz entlang des Körperteils darstellt.

Revendications

1. Appareil à utiliser dans la réalisation de mesures d'impédance sur un sujet, l'appareil comprenant un dispositif de mesure (100) et une sonde, la sonde comprenant :

a) un logement (300) configuré pour être tenu par un opérateur en utilisation ;
b) une surface de contact (301) destinée à être en contact avec le sujet, dans lequel la surface de contact (301) comprend un organe mobile (312) destiné à se déplacer par rapport au sujet ; et
c) un connecteur (303) destiné à connecter la surface de contact au dispositif de mesure, dans lequel la sonde est agencée pour être déplacée le long d'un segment du sujet et le dispositif de mesure est agencé pour réaliser une séquence de mesures d'impédance lorsque la sonde (116) est déplacée le long du segment par l'opérateur, de sorte que le dispositif de mesure (100) détermine des mesures d'impédance le long du segment, **caractérisé en ce que** la sonde comprend un capteur (316) destiné à détecter le déplacement de l'organe mobile (312) et à déterminer des informations de position le long de différentes positions sur le segment, et le dispositif de mesure étant en outre agencé pour utiliser les mesures d'impédance et les informations de position pour déterminer un profil d'impédance.

2. Appareil selon la revendication 1, dans lequel le logement (300) est un logement allongé, la surface de contact (301) est agencée au niveau d'une première extrémité du logement (300) et le connecteur (303) est agencé au niveau d'une seconde extrémité opposée du logement.

3. Appareil selon la revendication 1 ou la revendication 2, dans lequel le logement (300) est formé d'un matériau isolant.

4. Appareil selon l'une quelconque des revendications 1 à 3, dans lequel le logement (300) est formé d'un tube en perspex.

5. Appareil selon l'une quelconque des revendications 1 à 4, dans lequel la surface de contact (301) a une forme convexe.

6. Appareil selon l'une quelconque des revendications 1 à 5, dans lequel la sonde comprend un contact (313) destiné à connecter électriquement l'organe mobile au connecteur (303).

7. Appareil selon l'une quelconque des revendications 1 à 6, dans lequel le connecteur (303) est destiné à assurer la connexion avec un fil conducteur d'un dispositif de mesure.

8. Appareil selon l'une quelconque des revendications 1 à 7, dans lequel le dispositif de mesure comprend un système de traitement (102) destiné à

a) provoquer l'application d'au moins un signal électrique au sujet via des premières électrodes (113, 114) agencées sur le sujet ; et
b) déterminer une indication indiquant au moins un second signal électrique mesuré via une seconde électrode (115) positionnée sur le sujet, et via la sonde (116).

9. Procédé de réalisation de mesures d'impédance sur un sujet en utilisant une sonde (116), la sonde comprenant un logement (300) configuré pour être tenu par un opérateur en utilisation, une surface de contact (301) destinée à être en contact avec le sujet, dans lequel la surface de contact (301) comprend un organe mobile (312) destiné à se déplacer par rapport au sujet, un connecteur (303) destiné à connecter la surface de contact (301) à un dispositif de mesure (100), et un capteur (316) destiné à détecter un déplacement de l'organe mobile, le procédé comprenant les étapes consistant à :

a) positionner la sonde (116) en contact avec un segment du sujet ; et
b) provoquer la réalisation par le dispositif de mesure (100) d'une séquence de mesures d'impédance **caractérisée en ce que** le procédé comprend en outre :
c) le déplacement par l'opérateur de la sonde (116) le long du segment pendant la séquence de mesures d'impédance de sorte que le dispositif de mesure (100) :

i. détermine des informations de position le long de différentes positions sur le segment en utilisant le capteur (316) ; et,
ii. détermine des mesures d'impédance le long du segment ;

d) l'utilisation par le dispositif de mesure des mesures d'impédance et des informations de position pour déterminer un profil d'impédance.

10. Procédé selon la revendication 9, dans lequel le procédé comprend, dans le dispositif de mesure, l'affichage d'une représentation du profil d'impédance.

11. Procédé selon la revendication 9 ou la revendication 10, dans lequel le procédé comprend les étapes consistant à, dans le dispositif de mesure (100) :

a) provoquer l'application d'une séquence de premiers signaux électriques au sujet via des premières électrodes (113, 114) agencées sur le sujet ; et
b) déterminer une indication d'une séquence de seconds signaux électriques mesurés via une seconde électrode (115) positionnée sur le sujet, et via la sonde (116).

12. Procédé selon la revendication 11, dans lequel le procédé comprend, dans le dispositif de mesure :

l'utilisation d'une indication des premier et second signaux pour déterminer un profil d'impédance, le profil d'impédance représentant des variations dans l'impédance mesurée le long du segment.

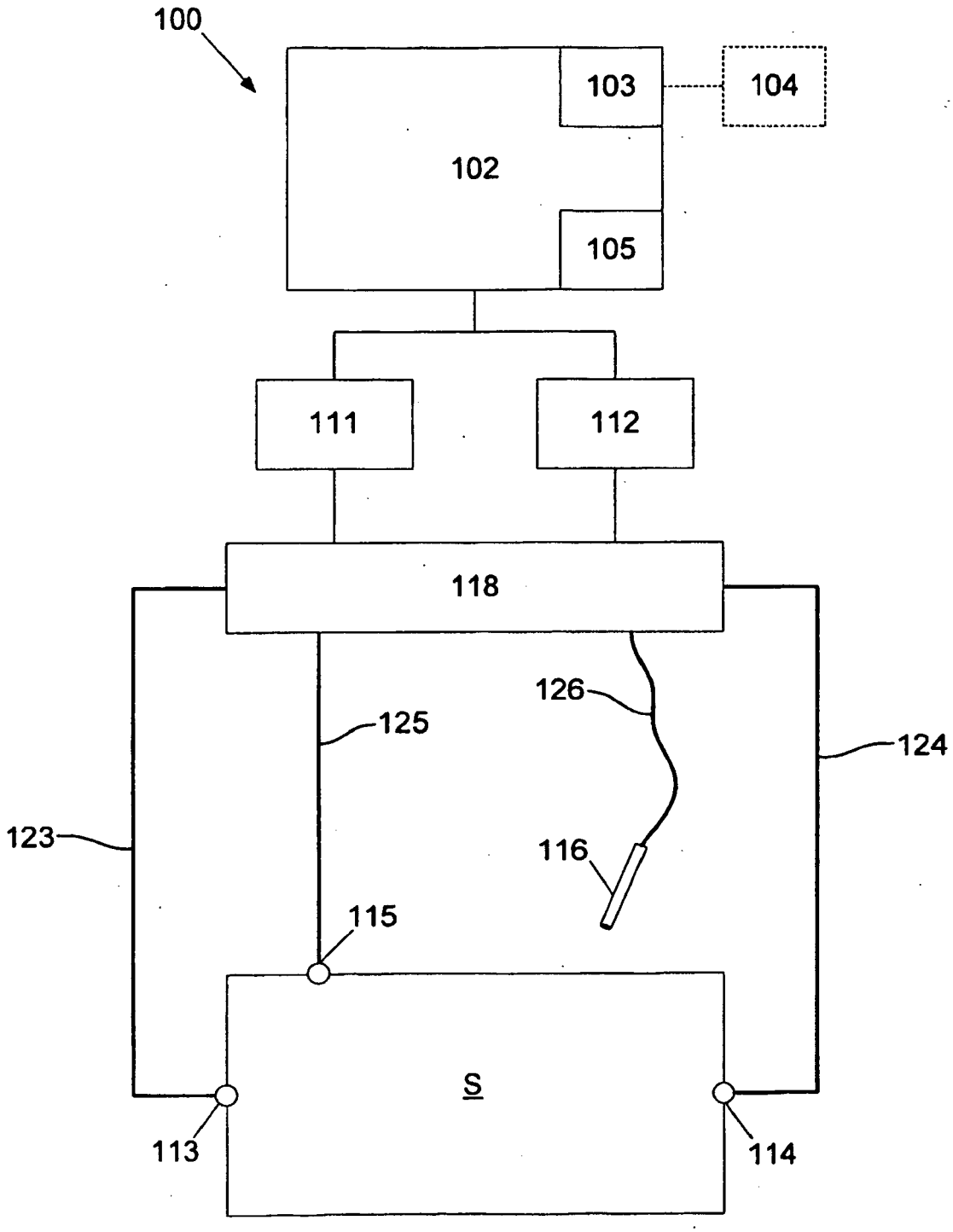


Fig. 1

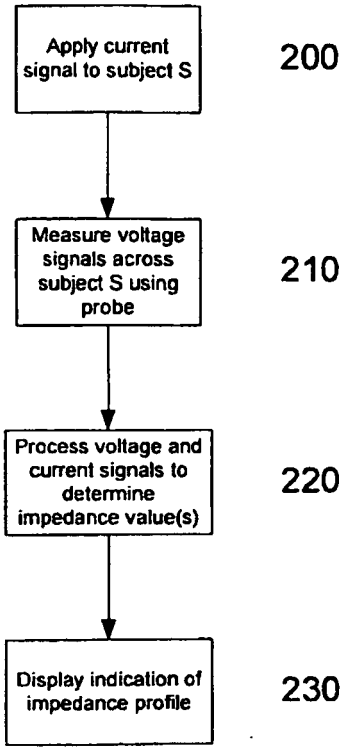

Apply current signal to subject S
200
Measure voltage signals across subject S using probe
210
Process voltage and current signals to determine impedance value(s)
220
Display indication of impedance profile
230

Fig. 2

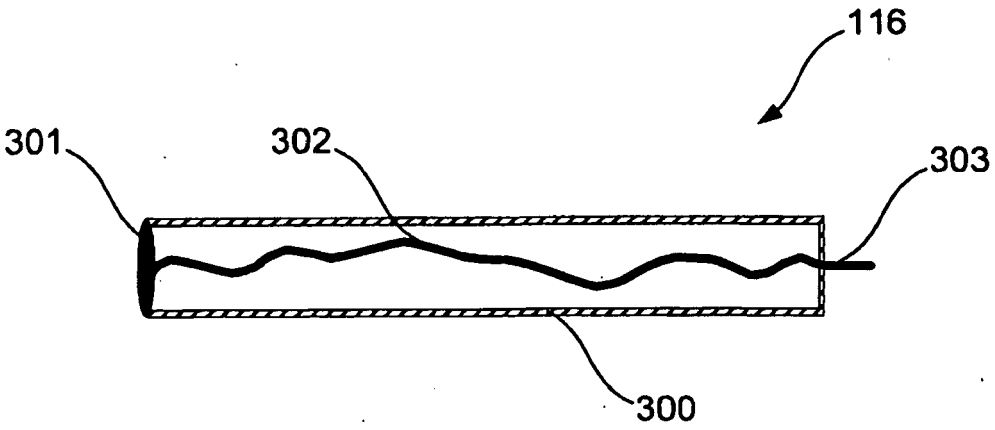


Fig. 3A

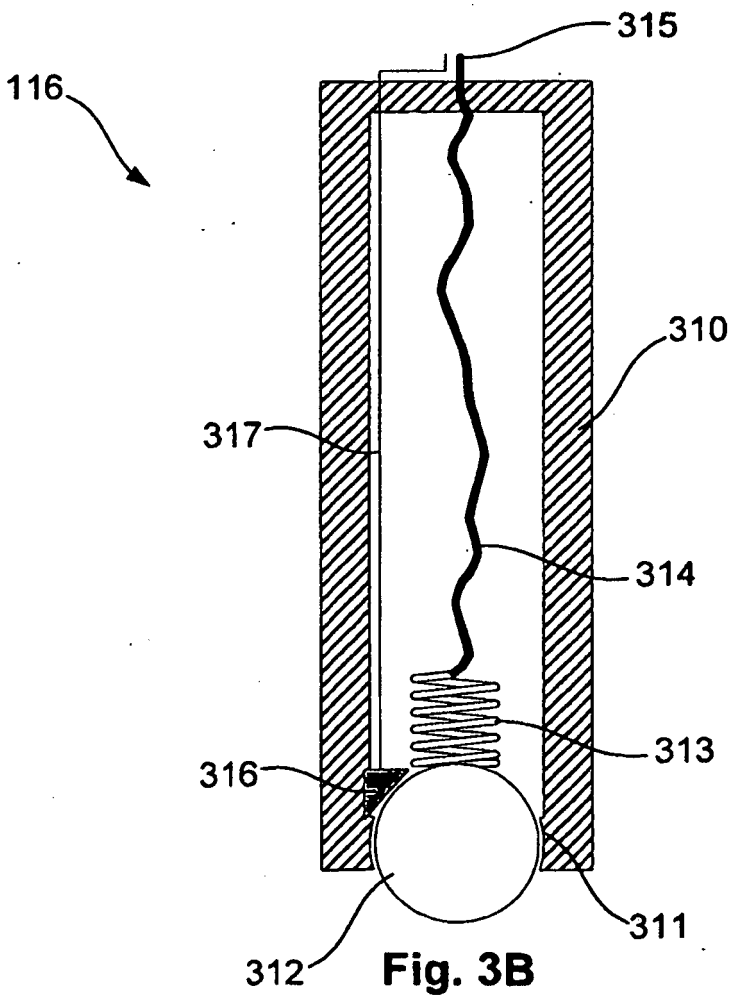


Fig. 3B

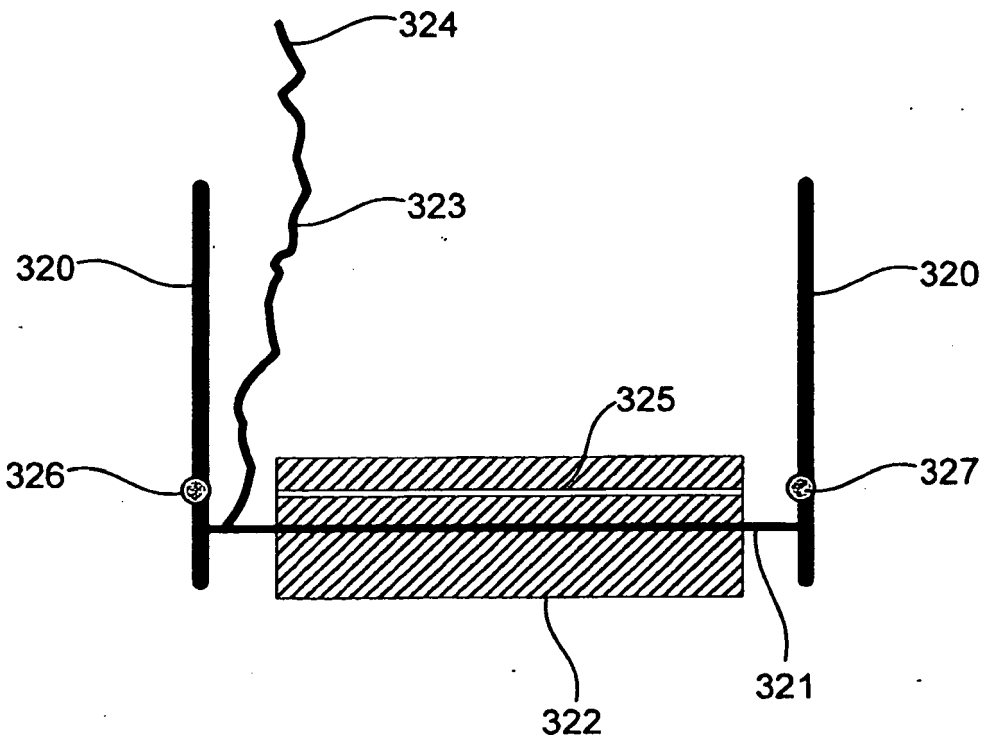


Fig. 3C

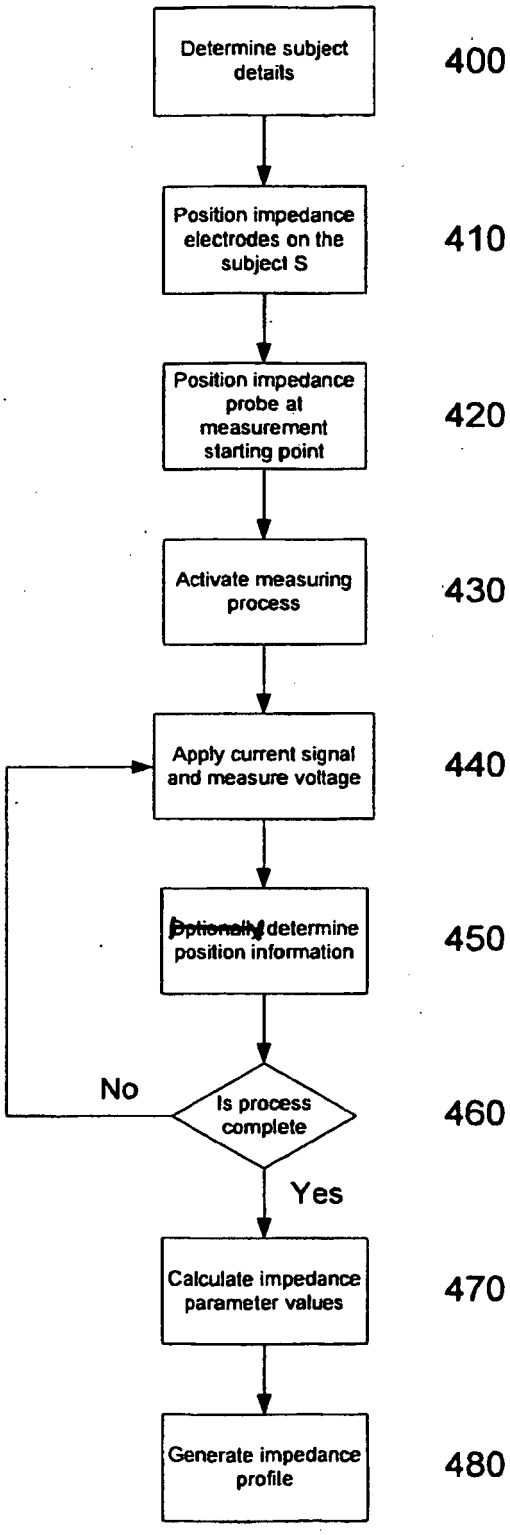

Determine subject details
400
Position impedance electrodes on the subject S
410
Position impedance probe at measurement starting point
420
Activate measuring process
430
Apply current signal and measure voltage
440
~~Optionally~~ determine position information
450
No
Is process complete
460
Yes
Calculate impedance parameter values
470
Generate impedance profile
480

Fig. 4

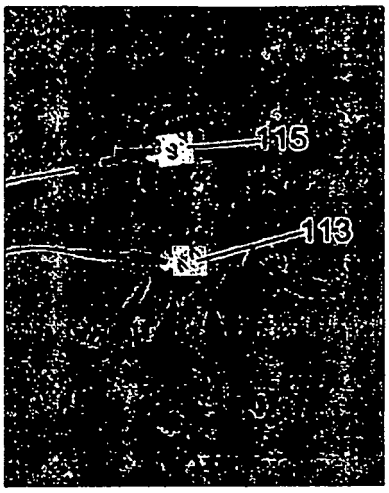


Fig. 5A

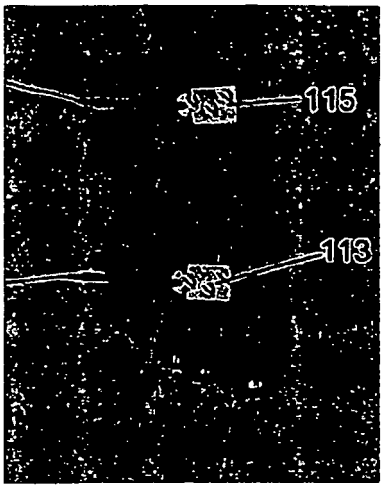


Fig. 5B

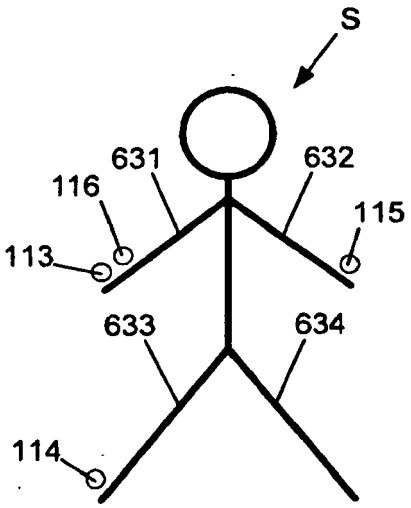


Fig. 5C

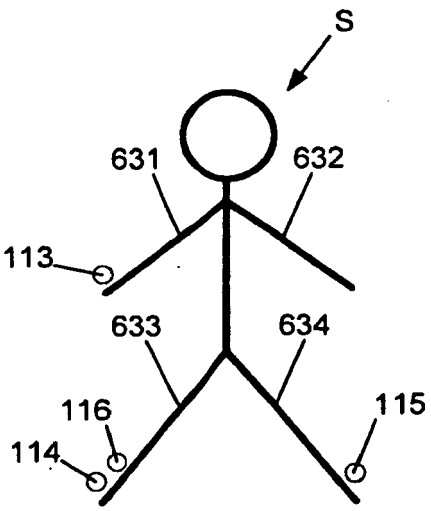


Fig. 5D

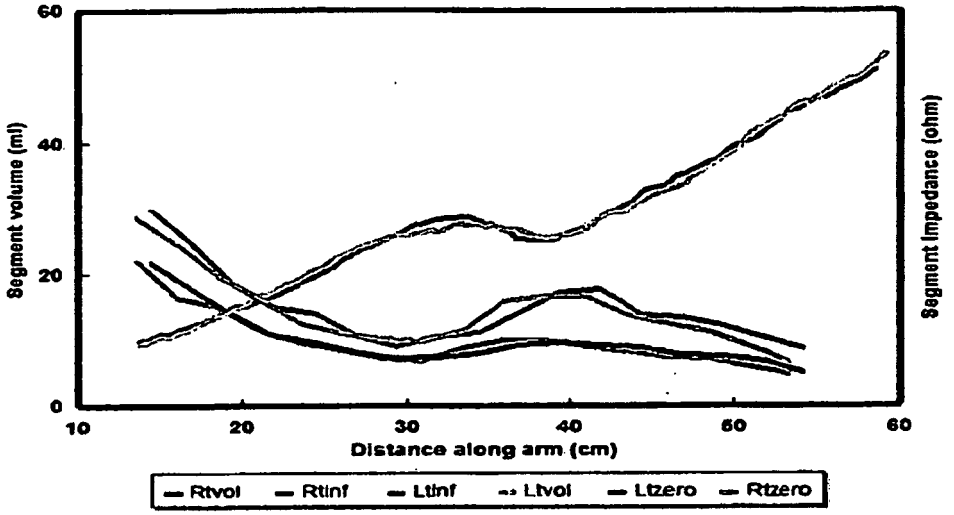


Fig. 6A

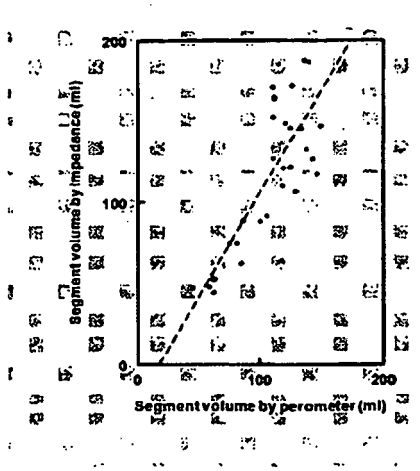


Fig. 6B

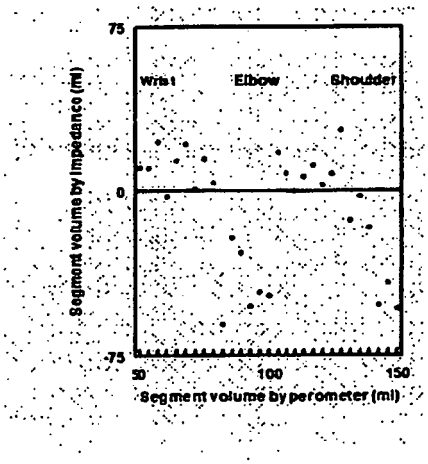


Fig. 6C

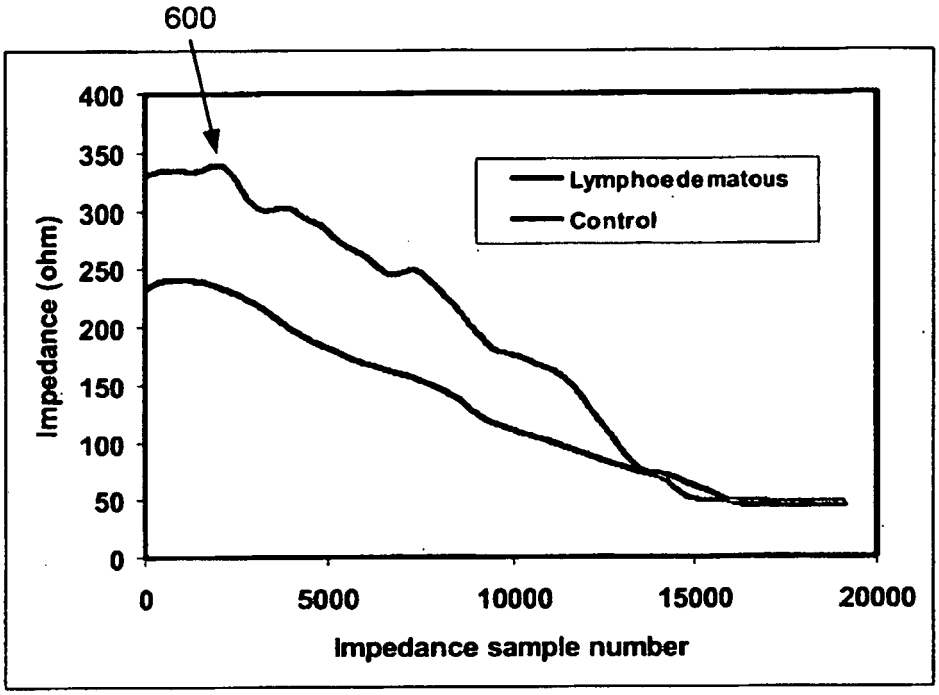

600
400
350
300
250
200
150
100
50
0
Impedance (ohm)
0
5000
10000
15000
20000
Impedance sample number
Lymphoedematous
Control

Fig. 6D

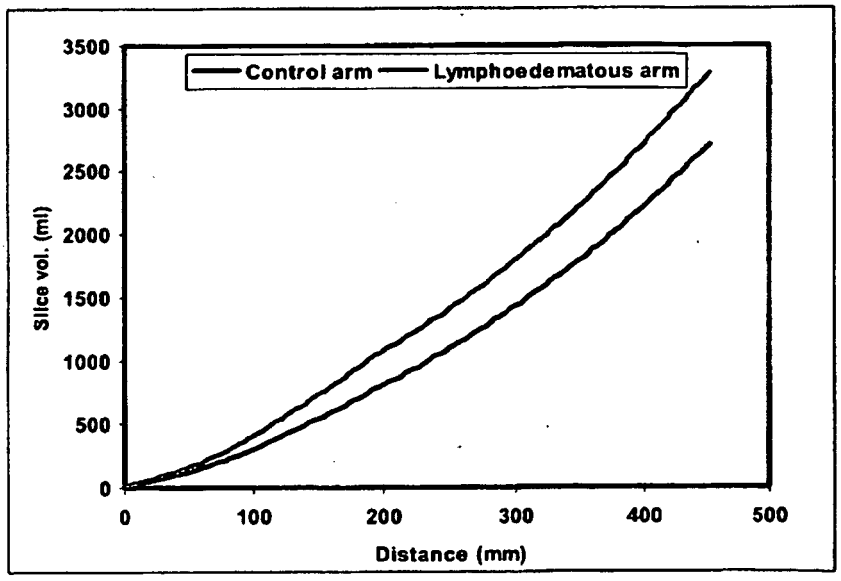

3500
3000
2500
2000
1500
1000
500
0
Slice vol. (ml)
0
100
200
300
400
500
Distance (mm)
Control arm
Lymphoedematous arm

Fig. 6E

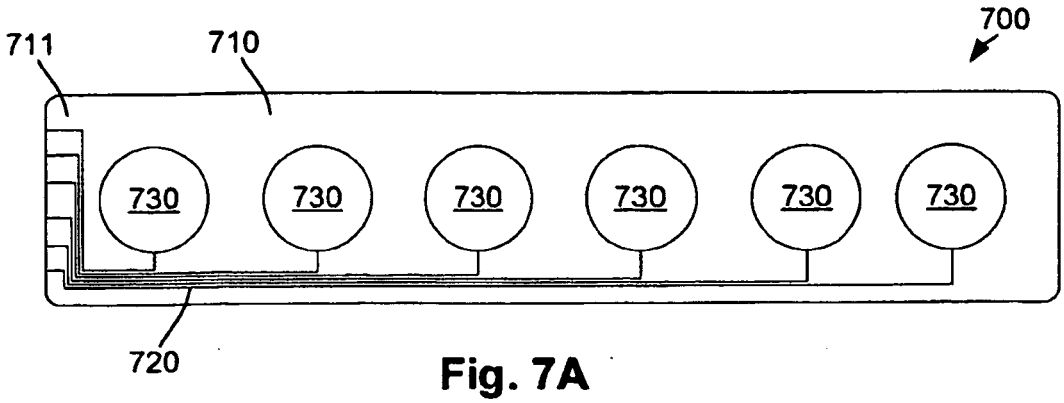


Fig. 7A

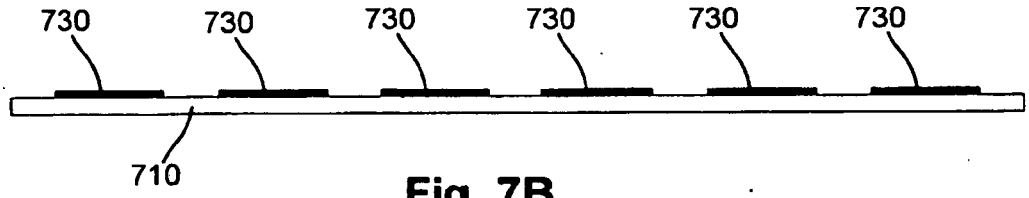


Fig. 7B

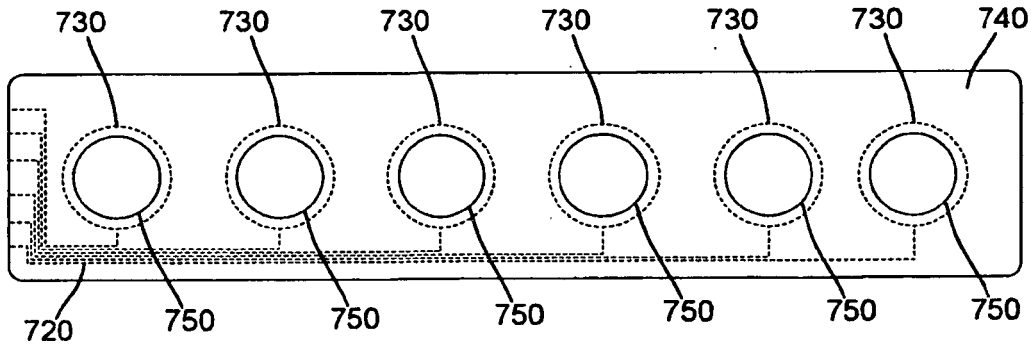


Fig. 7C

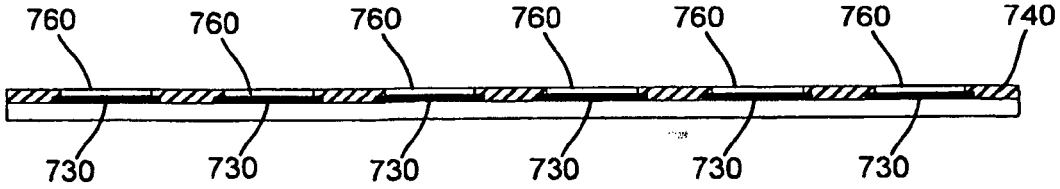


Fig. 7D

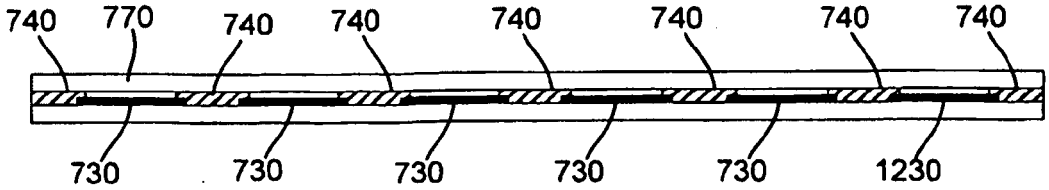


Fig. 7E

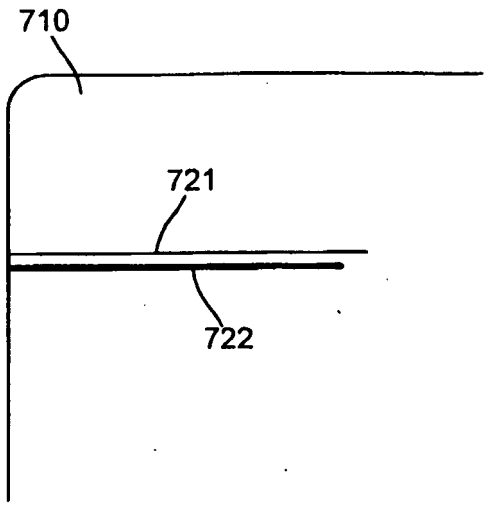


Fig. 7F

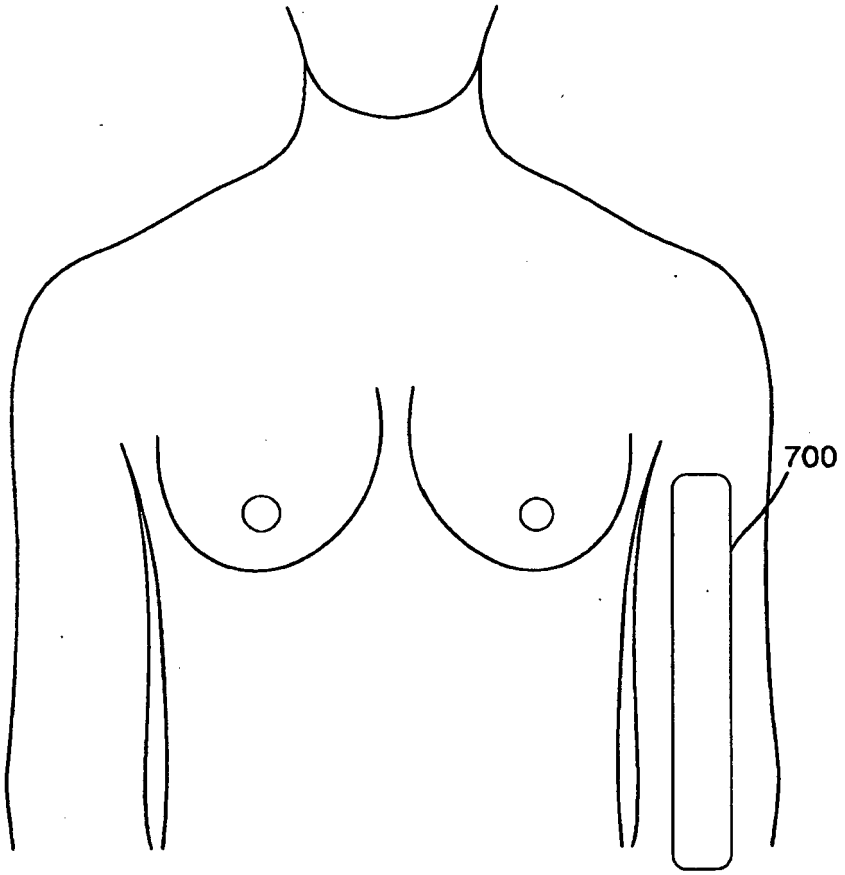


Fig. 7G

REFERENCES CITED IN THE DESCRIPTION

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- DE 2912349 **[0013]**