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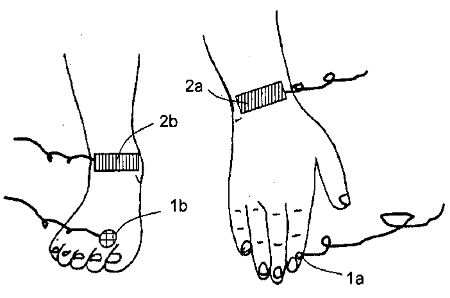
(54) **Title**: APPARATUS AND METHOD FOR BIOELECTRICAL IMPEDANCE ANALYSIS AND MONITORING

Fig. 2



(57) **Abstract**: A method and apparatus for determining bioimpedance in a body is described. One or more current injection electrodes (1a) are connected to a first hand or foot of the body; and a current return electrode (1b) is connected to a second hand or foot of the body, or to an arm or leg directly connected to a second hand or foot of the body. The one or more current injection electrodes and/or the current return electrode are connected to one or more acupuncture points of the body. First and second voltage sensing electrodes (2a, 2b) are connected at spaced apart positions of the body. Bioimpedance across meridian-defined whole body portions and meridian-defined segments of the body can be determined.

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"Apparatus and method for bioelectrical impedance analysis and monitoring"

Cross-Reference to Related Application

The present application claims priority from Australian Provisional Patent Application No 2009906285 filed on 24 December 2009, the content of which is incorporated herein by reference.

Field of the Invention

The present invention relates to non-invasive analysis, and/or monitoring, of bioimpedance properties of a patient's body.

Background

Bioimpedance analysis involves the measurement of the response of a living organism to externally applied electrical current. Bioimpedance parameters such as resistance, reactance and phase angle can be recorded, for example, for the purposes of determining blood flow and body composition (e.g., water and fat content). Nonetheless, there exists an accumulating body of evidence that at least the phase angle parameter of bioimpedance analysis has applications beyond its general use in body composition determination, as an indicator of general health status and as a promising prognostic tool. Phase angle is generally recognized to be an indicator of cell membrane integrity and the distribution of fluid in the intra- and extracellular spaces at the cellular level, for example. Ongoing research indicates that phase angle may also reflect other biologic properties.

Any discussion of documents, acts, materials, devices, articles or the like which has been included in the present specification should not to be taken as an admission that any or all of these matters form part of the prior art base or were common general knowledge in the field relevant to the present invention as it existed before the priority date of each claim of this application.

Throughout this specification the word "comprise", or variations such as "comprises" or "comprising", will be understood to imply the inclusion of a stated element, integer or step, or group of elements, integers or steps, but not the exclusion of any other element, integer or step, or group of elements, integers or steps.

Summary

According to a first aspect, the present invention provides a method of determining bioimpedance in a body, the method comprising:

connecting one or more current injection electrodes to a first hand or foot of the body; and

connecting a current return electrode to a second hand or foot of the body, or an arm or leg directly connected to a second hand or foot of the body;

wherein the one or more current injection electrodes and/or the current return electrode are connected to one or more acupuncture points;

connecting first and second voltage sensing electrodes at spaced apart positions of the body;

applying an electrical signal between at least one of the current injection electrodes and the current return electrode;

measuring with the voltage sensing electrodes, the voltage drop of the electrical signal across at least a portion of the body between the current injection electrodes and the current return electrode; and

using the voltage drop measurement to determine the bioimpedance of the at least a portion of the body.

According to a second aspect, the present invention provides apparatus for determining bioimpedance in a body, the apparatus comprising:

a drive circuit comprising:

one or more current injection electrodes configured to be connected to a first hand or foot of the body; and a current return electrode configured to be connected to a second hand or foot of the body, or to an arm or leg directly connected to a second hand or foot of the body, wherein the one or more current injection electrodes and/or the current return electrode are configured to be connected to one or more acupuncture points; and

a sensing circuit comprising:

a first voltage sensing electrode configured to be connected to the body and

a second voltage sensing electrode configured to be connected to the body at a position spaced apart from the first voltage sensing electrode;

the voltage sensing electrodes of the sensing circuit being configured to measure, upon application of an electrical signal between at least one of the current injection electrodes and the current return electrode, the voltage drop of the electrical signal across at least a portion of the body between the connection positions of the current injection electrodes and the current return electrode.

The apparatus of the second aspect may further comprise a processor, configured to use the voltage drop measurement to determine the bioimpedance of the at least a portion of the body.

In the first and second aspects, by connecting the one or more current injection electrodes and/or the current return electrode to one or more acupuncture points, it has been found that current may be transmitted across one or more preferential electrical pathways such as meridian-defined electrical pathways of the body. Accordingly, bioimpedance may be determined along at least a portion of a meridian-defined pathway of the body. In a simple approach, bioimpedance (Z) may be determined using Ohm's law, $Z = E/I$ where E is the voltage drop and I is the current applied across the electrodes.

In this specification, connecting an electrode to the body may involve releasably contacting a portion of the electrode with the body, e.g. the skin of the body. The electrode may contact the body directly, or it may contact a conductive element, e.g., a foil pad or disc, fixed to the body, for example. Whilst the electrode is in contact with the body or other conductive element, a force may be applied to maintain contact. The force may be a force applied by a clinician or a force applied by the patient, through the patient gripping or standing or resting on the electrode, for example. Additionally or alternatively, fastening means may be used, such as a strap, band, belt, adhesive or tape.

Further, in this specification, the terms current injection electrode and current return electrode are used to distinguish different drive electrodes that apply a current to the body at different parts of the body. In practice, however, through use of AC current, the current injection electrodes and current return electrodes may be substantially indistinguishable in terms of electrical function and/or other features.

The one or more of the current injection electrodes may be connected at respective biologically active points of the first hand or foot. Biologically active points include, at least as a subset, acupuncture points. For simplicity, throughout the subsequent description and the claims, the more widely-recognised term "acupuncture points", is used to refer to biologically active points and may include points defined by the WHO (1991) and include both classical and extra points. For example, the current injection electrodes may be connected at one or more "*Jing* points" or "*Yuan* points" of the first hand or foot.

If the return electrode is connected to an arm or leg, preferably it is connected at a position distal to the elbow or knee of the arm or leg respectively.

Preferably, at least the one or more current injection electrodes are connected to one or more acupuncture points.

The current return electrode may be connected to an acupuncture point, a nail, or other region (skin area, zone and/or point etc.) of the arm or leg. However, it may be preferable that the current return electrode is not connected to an acupuncture point. If the return electrode is connected to an acupuncture point (and not substantially the skin surrounding the acupuncture point) the skin-contact surface of the return electrode may need to be relatively small, e.g., less than 15 mm diameter or less than 10 mm diameter, or less than 200 mm^2 or less than 100 mm^2, meaning high current-return electrode impedances and errors in bioimpedance measurement associated with stray capacitance may result. It may therefore be preferable not to connect the return electrode to an acupuncture point so that it may instead have a relatively large skin contact area to reduce these undesirable effects. Nonetheless, it is conceived that active electrodes may be used to overcome high electrode impedance problems, which electrodes can have small or unit amplification close to the electrode.

As indicated above, the acupuncture points of the hands and feet at which the current-injection and/or return electrodes can be connected may be *Jing* points or *Yuan* points. The term "*Jing* point" is intended to refer to an anatomically well-defined acupuncture point (also known as *Tsing*, *Sei*, and Well point) listed in Table 1 below. Similarly, the term "*Yuan* point" is intended to refer to an anatomically well-defined acupuncture point (also known as source point) listed in Table 2 below. The *Jing* points and *Yuan* points, are points on the skin which have been reported to have higher conductivity than surrounding skin or nail, and are arranged in lines known as "meridians". The *Jing* points lie at the extremities of each of the 12 bilateral regular meridians.

LU 11	Lung 11 [*Shaoshang*] – about 2 mm superior to the radial base of the fingernail of the thumb
LI 1	Large Intestine 1 [*Shangyang*] - about 2 mm superior to the radial base of the fingernail on the
PC 9	Pericardium 9 [*Zhongchong*] – about 2 mm behind the radial base of the 3rd fingernail
TE 1	Triple Energizer 1 [*Guanchong*] - about 2 mm above the ulnar base of the 4th fingernail
HT 9	Heart 9 [*Shaochong*] – about 2 mm behind the radial base of the 5th fingernail
SI 1	Small Intestine 1 [*Shaoze*] – about 2 mm behind the ulnar base of the 5th fingernail
SP 1	Spleen 1 [*Yinbai*] – about 2 mm behind the medial base of the 1st toenail
LR 1	Liver 1 [*Dadun*] – about 2 mm behind the lateral base of the 1st toenail
ST 45	Stomach 45 [*Lidui*] – about 2 mm behind the lateral base of the 2nd toenail
GB 44	Gall Bladder 44 [*Zuqiaoyin*] – about 2 mm behind the lateral base of the 4th toenail
KI 1a*	Kidney 1a- about 2 mm behind the medial base of the 5th toenail
BL 67	Bladder 67 [*Zhiyin*] – about 2 mm behind the lateral base of the 5th toenail
KI 1	Kidney 1 [*Yongquan*] – between the 2nd & 3rd toes 1/3 of the way from the anterior plantar line to the posterior plantar line
* Although this point is not traditionally identified as a *Jing* point, it is nevertheless considered as being closely associated with KI1, the Kidney meridian *Jing* point, and for simplicity, it is referenced as a *Jing point* in the present description.	

Table 1 – Detailed Anatomical Location of the *Jing* points

Table 1 data from: A Proposed Standard International Acupuncture Nomenclature: Report of a WHO Scientific Group, WHO Headquarters in Geneva, 1991; "Illustration of Acupoints" by Haruto Kinoshita, Ido-No-Nippon-Sha, Tokyo, Japan, 1976; and "Essentials of Chinese Acupuncture" Foreign Languages Press, Beijing, China, 1980

LU 9	Lung 9 [*Taiyuan*] – at the radia artery on the skin fold of the palmar aspect of the wrist
LI 4	Large Intestine 4 [*Hegu*] - on the back of the hand between the bases of the 1st and 2nd
PC 7	Pericardium 7 [*Daling*] – on the skin fold on the palmar aspect of the wrist between the m.
TE 4	Triple Energizer 4 [*Yangchi*] - on the skin fold on the dorasl aspect of the wrist between the
HT 7	Heart 7 [*Shenmen*] – in the center of the palmar fold at the wrist on the radial aspect of the m.
SI 4	Small Intestine 1 [*Wangu*] – on the dorsal ulnar aspect of the hand between the base of the 5th
SP 3	Spleen 3 [*Taibai*] – on the medial posterior ridge of the head of the 1st metatarsal bone
LR 3	Liver 3 [*Taichong*] – between the anterior aspects of the bases of the 1st and 2nd metatarsals
ST 42	Stomach 42 [*Chongyang*] – at the highest point in the dorsum of the foot, in the depression
GB 40	*Gall Bladder 40 [Qiuxu] – on the anterior inferior surface of the lateral condyle*
BL 64	Bladder 64 [*Jinggu*] – on the lateral aspect of the posterior ridge of the base of the 5th proximal
KI 3	Kidney 3 [*Taixi*] – posterior to the vertex of the medial condyle in the area of the dorsal tibial

Table 2 – Detailed Anatomical Location of the *Yuan* points

Table 2 data from: A Proposed Standard International Acupuncture Nomenclature: Report of a WHO Scientific Group, WHO Headquaters in Geneva, 1991; "Illustration of Acupoints" by Haruto Kinoshita, Ido-No-Nippon-Sha, Tokyo, Japan, 1976; and "Essentials of Chinese Acupuncture" Foreign Languages Press, Beijing, China, 1980)

In any of the aspects of the invention, determining the bioimpedance of the body may include determining the phase angle. It has been have found unexpectedly that placement of current injection and return electrodes at certain positions of the hands and feet, particularly at *Jing*, *Yuan*, and/or nail sites, gives rise to position-dependent phase angle measurement, even when the sensing electrodes are located at a distance greater than 10 to 15 cm (even greater than 60 cm) from the current injection and return electrodes. This is considered indicative of the different electrical statuses of meridian-defined body segments, and recent findings that there may exist preferential pathways (including networks of pathways) in the body for current flow. By measuring along different meridian-defined body segments, a more detailed analysis and/or monitoring of the body composition and/or health status of a patient may be achieved by the present invention. Since phase angle is theoretically largely insensitive to differences in the shapes and cross-sectional areas of measured regions, it is a particularly useful parameter for comparing body composition and/or health status of left and right body segments. Thus, even if one segment of the body is larger than the other (one arm or leg may be more dominant, for example, and thus have a larger girth than the other) phase angle (given by the relationship $\theta = \text{atan}(X/R)$) will be largely unaffected by such geometrical differences.

In accordance with aspects of the present invention, by employing the four electrodes at the specified positions of the first and second hands or feet, bioimpedance data can be obtained across relatively large segments of a subject's body with little or no contribution from electrode impedance. For example, bioimpedance can be directly measured along meridian-defined whole body portions, or relatively large meridian-defined segments thereof. This contrasts with a two-electrode technique, for example, where bioimpedance data is dominated by local impedance contributions, including electrode impedance, especially at a small probe electrode, and thus even successive analysis at different positions along the meridian defined length of the body, and/or extrapolation of data, would not enable similar results to be obtained.

The methods and apparatuses may be employed as treatment monitoring or assessment aids in bioimpedance analysis applications of conventional medicine. Additionally or alternatively, particularly since electrical signals can be applied across one or more meridian-defined body segments, the methods and apparatuses may be employed in traditional Chinese and integrative medicine-based assessments and treatments. In essence, the methods and apparatuses may bridge the seemingly disparate technologies of conventional-medicine bioimpedance analysis and acupuncture based principles of health diagnosis, providing enhanced diagnostic tools in either area.

Reference is made to determination of the phase angle parameter of bioimpedance in the present description. It is intended, however, that reference to phase angle measurement may include not only measurement of phase angle *per se*, but additionally combined phase angle and impedance measurement, with the combined data being used to define a bioimpedance vector. From this, resistance and reactance values can be calculated if required. Alternatively, phase angle measurement may include measurement of resistance and reactance, with phase angle (and optionally impedance magnitude and associated bioimpedance vector) being calculated from these two parameters.

In general, phase angle has been considered as an indicator of general health status, and has shown promise as a prognostic tool, for an ever growing number of conditions. Examples of such prognostic applications have been reported for patients that have cirrhosis of the liver, bacteraemia, are undergoing haemodialysis, have chronic obstructive pulmonary disease, amyotrophic lateral sclerosis, trauma, sepsis and/or various cancers (colorectal, breast, lung and pancreatic). By providing for more detailed analysis of bioimpedance across a wide range of meridian-defined body segments, the apparatus and methods of the present invention may provide enhanced health assessment and/or prognostic tools in these areas.

As indicated, a plurality of current injection electrodes may be provided. Each current injection electrode may be connected at a different position of the first hand or foot (at or distal to the wrist or ankle), and current signals may be transmitted between each injection electrode and the return electrode in turn, permitting a number of meridian-based segments of the body to be analysed or monitored sequentially without requiring reconfiguration of the electrode arrangement. Additionally or alternatively, a plurality of return electrodes may be provided to increase total contact area, each connected at a different position on the second hand or foot (and/or other part of the associated arm or leg), and current signals may be transmitted in turn between each injection electrode and the return electrodes connected together in parallel.

Nonetheless, one injection electrode and/or one return electrode may be moveable (e.g. when there is only one injection and/or one return electrode), to permit various points to be probed successively, allowing a similar analysis to be made. For example, the injection electrode may be configured as a probe, moveable to connect at one *Jing* point of the hand or foot and, after analysis of a meridian-defined pathway related to that *Jing point,* it may movable to connect at another *Jing* point of the hand or foot, to permit analysis of another meridian-defined pathway, and so forth.

To avoid transmission of the electrical current through vital organs, particularly across the heart, and in accordance with the traditionally defined longitudinal orientations of the twelve bilateral regular meridians, the first and second hands or feet can be ipsilateral, i.e. on the same side of the body. For example, the injection electrodes may be connected to the right hand and the return electrodes to the right foot or leg, or the injection electrodes may be connected to the right foot and the return electrodes to the right hand or arm. Similarly, the injection electrodes may be connected to the left hand and the return electrodes to the left foot or leg, or the injection electrodes may be connected to the left foot and the return electrodes to the left hand or arm. However, it is conceived in some circumstances that the first and second hands or feet can be contralateral, i.e. on different sides of the body. This may be possible if low current levels are used, for example. With this in mind, the injection and return electrodes may be connected to any hand or foot, and any other hand or foot, respectively. For example, the injection electrodes may be connected to the left foot and the return electrodes to the right foot, or *vice-versa*. As another example, the injection electrodes may be connected to the left hand and the return electrodes to the right hand, or *vice-versa*. As another example, the injection electrodes may be connected to the left hand and the return electrodes to the right foot, or *vice-versa*

In one embodiment, the injection electrode(s) are connected to any one or more of the following *Jing* points of the right or left foot: SP1, LR1, ST45, GB44, KI1a, BL67 and KI1, and the return electrode(s) are connected to the hand on the ipsilateral side under test.

In another embodiment, the injection electrode(s) are connected to any one or more of the following *Jing* points of the right or left hand: LU11, LI1, PC9, TE1, HT9 and SI1, and the return electrode(s) are connected to the foot on the ipsilateral side under test.

Following from these embodiments, the methods and apparatuses may therefore be used to obtain information on the status of any one or more of the 12 regular acupuncture meridians on the left and right sides of the body: the six regular meridians of the legs (SP, LR, ST, GB, KI and BL); and the six regular meridians of the arms (LU, LI, PC, TE, HT and SI).

To measure bioimpedance along substantially the whole length of the body portion between the connection positions of the injection electrodes and the return electrodes, the first voltage sensing electrode can be connected at, or proximal to, the arm, wrist, leg or ankle directly connected to the first hand or foot of the body, and the second voltage sensing electrode can be connected at or proximal to the arm, wrist, leg or ankle directly connected to the second hand or foot of the body.

However, additionally or alternatively, specific regions of the body between the connection positions of the injection electrodes and the return electrodes may be measured. This may be achieved by connecting one or both of the aforementioned voltage sensing electrodes, or one or more additional voltage sensing electrodes, to the arm, wrist, leg or ankle, for example, directly connected to a hand or foot other than the first and second hand and foot.

For example, the one or more injection electrodes and the one or more return electrodes may be connected to the right hand and right foot respectively. Accordingly, electrical signals can be applied between the right hand and right foot, via the right leg, torso, and right arm, enabling bioimpedance to be determined all along that path. By connecting one of the voltage sensing electrodes to the right ankle, and another voltage sensing electrode to the left leg or ankle, the sensing electrodes can be used to measure the voltage drop of the electrical signal across each meridian-defined segment of the right leg only, and the corresponding bioimpedances to be determined. Accordingly, the apparatus allows bioimpedance of each meridian-defined segment of the right leg to be determined individually. Additionally or alternatively, by connecting one of the voltage sensing electrodes to the right wrist, and another of the voltage sensing electrodes to the left arm or wrist, the sensing electrodes can be used to measure the voltage drop of the electrical signal across each meridian-defined segment of the right arm only and the corresponding bioimpedances to be determined. Accordingly, the apparatus allows bioimpedance of each meridian-defined segment of the right arm to be determined separately. Additionally or alternatively, by connecting one of the voltage sensing electrodes to the left arm or wrist, and another of the voltage sensing electrodes to the left leg or ankle, the sensing electrodes can be used to measure the voltage drop of the electrical signal across each meridian-defined segment generated along the right side of the torso only and the corresponding bioimpedances to be determined. Accordingly, the apparatus allows bioimpedance of each meridian-defined segment of the right side of the torso to be determined separately. Various other connection points are conceivable to achieve similar separate region analysis. The arrangements may be translated to the left side of the body for analysis of the left leg, the left arm and the left side of the torso.

The analysis of the various different body regions may be performed in 'real-time', allowing continuous monitoring of the various meridian-defined body segments set out above. Optionally, analysis and monitoring can be performed on different body regions at the same time, through the use of multi-channel sensing arrangements.

Notably, despite the large distances between the injection electrodes and sensing electrodes when placing the sensing electrodes on the other side of the body from the injection electrodes, rather than bioimpedance data reaching a single plateau, independent of which injection electrode is selected, differences in the bioimpedance data for each pathway analysed is observable. Again this is indicative of the different electrical statuses of preferential electrical pathways, such as the meridian-defined pathways, and is consistent with recent findings that point to the existence of preferential pathways in the body for current flow.

As discussed above, the apparatus of the present invention may allow bioimpedance analysis along multiple preferential electrical pathways, e.g. meridian-defined pathways, of the separate body regions. The result of such detailed analysis is that the present invention may extend the application of body composition analysers beyond the realm of providing a very general health assessment of the individual through the generation of a single phase angle reading. Rather, a matrix of phase angles may be generated, one for each combination of body pathway and body region analysed. The data generated can be used, for example, to identify corresponding left and right meridian-defined segments of selected regions that have poor left-right balance and/or meridian-defined segments that are associated with excessively high or low phase angles. As a result, the method and apparatus may provide an assessment tool or aid for healthcare providers (acupuncturist, physical therapist etc.) to specify treatment protocols for that individual. Furthermore, the method and apparatus may be used during the treatment itself, as a means of achieving a detailed, non-invasive, monitoring of the response of the body to treatment, in real time if required, to allow objective assessment of the efficacy of the treatment.

As indicated, the apparatus may be applied particularly to the left or right side of the body. The electrodes may be moved between left and right sides. Alternatively, two sets of electrodes may be provided (i.e., at least 8 electrodes in total), allowing analysis and/or monitoring of the whole length of the left and right sides of the body, in addition to analysis on of each arm, leg and the torso on each side of the body individually. By employing two sets of electrodes, once the apparatus is set up, the analysis or monitoring may be performed without having to move the electrodes from one side of the body to the other.

When the injection and return electrodes are connected at or adjacent the distal ends of the digits of the hands and feet (e.g., at a nail or *Jing* point, etc.), the voltage sensing electrodes may be connected adjacent to the associated wrists or ankles, as discussed above. However, when the injection and return electrodes are connected at *Yuan* points, the most proximal of which are at or adjacent the wrist or ankle, the voltage sensing electrodes may be located further up the associated arm or leg, e.g. at or adjacent the knee or elbow.

In any of the aspects of the present invention, the drive circuit can be connected to drive apparatus for controlling the electrical signals, e.g. controlling the current or voltage level of the electrical signal, the pattern of electrical signals (e.g. pulsed signals (voltage or current pulsed)) and/or the sequence of electrical signals sent to different current-injection electrodes of the circuit. The drive apparatus may include a computer interface for automatic control of the drive circuit signals, and/or to permit a user (e.g. the patient, or a clinician, doctor, or other health worker) to control the drive circuit signals prior to and/or during analysis or monitoring. The drive apparatus may be powered by the batteries or the mains. A.C. electrical signals may be used.

The sensing circuit can be connected to sensing apparatus, for sensing the electrical signals across the sensing electrodes, for providing corresponding raw data, for processing the raw data, and for providing an output of the processed data in a suitable form for the end user. For example, the apparatus may include voltage detection circuitry, a multiplexer and a computer interface with appropriate software. The drive apparatus and sensing apparatus may be combined to allow feedback between the two systems.

In accordance with the fourth to fifth aspects of the invention described below, alternative methods and apparatuses to the previous aspects may be provided for determining bioimpedance in a body, particularly of core impedance of the body between two electrodes, based on a technique first documented by Horton and van Ravenswaay in 1935 ("the HvR technique"). In essence, the HvR technique is based on the model that total impedance between any two surface electrodes can in general be decoupled into two types of components: local impedances associated with each electrode and a core (or non-local) impedance between the two electrodes. The former is considered to include contributions from the electrode, from the electrode-to-skin contact impedance and from upper layers of the skin, while the latter is considered to relate to vaguely defined sub-dermal tissue. Details of the equations associated with the HvR technique are provided at the end of the present description.

According to a third aspect, the present invention provides a method of determining bioimpedance in a body, the method comprising:

connecting a first outer electrode to a first hand or foot of the body;

connecting a second outer electrode to a second hand or foot of the body, or an arm or leg directly connected to a second hand or foot of the body,

wherein the one or more current injection electrodes and/or the current return electrode are connected to one or more acupuncture points;

connecting first and second inner electrodes to spaced apart positions of the body, inwardly of the first and second outer electrodes;

applying an electrical signal in turn between all six combinations of first and second outer and inner electrodes;

measuring the voltages across each combination of electrodes in response to the respective applied electrical signals;

using the voltage data to determine the impedance between each electrode combination; and using this impedance data to calculate the bioimpedance of a core portion of the body between the connection positions of the inner electrodes.

According to a fourth aspect, the present invention provides apparatus for determining bioimpedance in a body, the apparatus comprising:

a first outer electrode configured to be connected to a first hand or foot of the body;

a second outer electrode configured to be connected to a second hand or foot of the body, or an arm or leg directly connected to a second hand or foot of the body, wherein the one or more current injection electrodes and/or the current return electrode are configured to be connected to one or more acupuncture points;

first and second inner electrodes configured to be connected to spaced apart positions of the body, inwardly of the first and second outer electrodes; and

bioimpedance measurement apparatus, configured to measure, in response to an electrical signal applied in turn across all six combinations of first and second outer and inner electrodes, the voltages across each combination of electrodes and configured to use the voltage data to determine the impedance between each electrode combination and calculate the bioimpedance of a core portion of the body between the connection positions of the inner electrodes.

The bioimpedance of the intermediate portion of the body between the connection positions of the inner electrodes may be calculated using the HvR technique. Equation A3-i, A3-ii or A3-iii of the HvR technique recited further below may be used.

In the third and fourth aspects, the outer electrodes may be connected to the body at positions as discussed with respect to the first and second aspects (regarding the current injection and return electrodes) discussed above. For example, the outer first electrode may be connected at a *Jing* points or *Yuan* points of the first hand or foot, and the outer second electrode may be connected to a nail of a digit of the second hand or foot or elsewhere. If an outer electrode is connected to an arm or leg, preferably it is connected at a position distal to the elbow or knee of the arm or leg respectively.

In the third and fourth aspects, the inner and outer electrodes may additionally be used to carry out bioimpedance measurement in accordance with a general 4-electrode technique method, as described below with respect to Fig. 1 for example. Two-electrode bioimpedance from one of the outer electrodes to the closest inner electrode may be determined, for example.

In further alternative aspects, methods and apparatuses for determining bioimpedance in a body may utilise two pairs of drive electrodes, wherein each pair is positioned in accordance with the positioning of the current injection and return electrodes of the first and second aspects of the present invention. The two pairs of electrodes may be located at left and right sides of the body respectively. Using the HvR technique, the degree of electrical interconnection between paired left and right meridian-defined segments may be estimated.

Brief Description of the Drawings

By way of example only, embodiments are now described with reference to the accompanying drawings, in which:

Fig. 1 shows connection positions on a foot and hand of electrodes of general bioimpedance analysis apparatus;

Fig. 2 shows connection positions on a foot and hand of electrodes of bioimpedance analysis apparatus according to one embodiment of the present invention;

Fig. 3 shows connection positions on a foot and hand of electrodes of bioimpedance analysis apparatus according to another embodiment of the present invention

Fig. 4 shows a mobile probe electrode for use in apparatus according to an embodiment of the present invention;

Fig. 5 shows connection positions on a foot and hand of electrodes of bioimpedance analysis apparatus according to another embodiment of the present invention;

Fig. 6 shows possible connection points on the hand and foot for electrodes of embodiments of the present invention;

Fig. 7 shows bioimpedance analysis apparatus according to another embodiment of the present invention;

Figs. 8a and 8b show the bioimpedance analysis apparatus of Fig. 7 applied to a foot, and similar bioimpedance analysis apparatus applied to a hand, respectively.

Fig. 9 shows a schematic of bioimpedance analysis apparatus according to an embodiment of the present invention;

Figs. 10a to 10d show possible electrode positions for bioimpedance analysis apparatus according to embodiments of the present invention, to achieve analysis of different body regions;

Fig. 11 shows an idealized representation of surface measured impedances decoupled into local and core (non-local) impedances, for use in an HvR measuring technique;

Fig. 12 shows an idealized representation of a non-linear arrangement of four electrodes as shown in Fig. 11;

Figs. 13a and 13b show graphs of exemplary impedance and phase angle profiles respectively; and

Figs. 14a and 14b show graphs of exemplary impedance profiles before and after an electrostimulation step for the left and right sides of the body respectively, and Figs. 14c and 14d show graphs of exemplary phase angle profiles before and after an electrostimulation step for the left and right sides of the body respectively; step.

Embodiments

It will be appreciated by persons skilled in the art that numerous variations and/or modifications may be made to the invention shown in the specific embodiments discussed below without departing from the scope of the invention as broadly described. The present embodiments are, therefore, to be considered in all respects as illustrative and not restrictive.

For simplicity, the following description and accompanying figures refer to the positioning of electrodes for analysis and monitoring generally of the right side of the body. However, it is intended, and the skilled person will understand, that the apparatus can be adapted for analysis and monitoring of the left side of the body.

With reference to Fig. 1, a general four-electrode bioelectrical impedance analysis measurement apparatus is described. A first pair of electrodes 1a', 1b' provides a drive circuit, and a second pair of electrodes 2a', 2b' provides a sensing circuit. The drive circuit electrodes 1a', 1b', are located on the dorsal surface of the right hand proximal to the metacarpal phalangeal joints and the dorsal surface of right foot proximal to the metacarpal phalangeal joints, respectively, for example. The sensing circuit electrodes 2a', 2b' are positioned inwardly of the drive electrodes 1a', 1b', and located on the right wrist midway between the ulna and radial styloid processes, and on the dorsum of the right ankle between the medial and lateral malleoli respectively, for example. Electrical current is applied between the drive electrodes, and the sensing electrodes are used to measure the bioimpedance of the 'whole-body' segment located therebetween. It is known to position sensing electrodes inwardly from the respective drive electrodes by at least 5 cm. This has been on the previous understanding that measurements of the bioimpedance parameters such as phase angle of the body is essentially unaffected by the positioning of the respective drive electrodes when positioned at distances greater than about 5 cm from the sensing electrodes.

With reference to Figs. 2 and 3, according to an embodiment of the present invention, bioimpedance measurement apparatus is provided that includes a first pair of electrodes 1a, 1b forming part of a drive circuit, and a second pair of electrodes 2a, 2b (voltage sensing electrodes) forming part of a sensing circuit. The first pair of electrodes includes a current injection electrode 1a and a current return electrode 1b. The injection electrode 1a is arranged for connection to a patient's hand or foot on the right side of the body. The return electrode 1b is arranged for connection to the other hand or foot on the same side of the body, or to an arm or leg directly connected to that other hand or foot.

Particularly, the injection electrode 1a is arranged for connection to positions such as the nail, region at the tip of a digit, and/or a *Jing* point of a hand or foot. The return electrode is arranged for connection to positions such as a nail, region at the tip of a digit and/or *Jing* point or other regions (skin area, zone and./or point, etc.) of a a hand or foot or arm or leg.

As shown in Fig 2, the injection electrode 1a can be connected to a specific *Jing* point on the right hand, such as LI1, near the radial base of the nail of the index finger of the right hand. Meanwhile, the return electrode 1b can be connected to an area proximal to the toes of the right foot. In an alternative embodiment, as shown in Fig 3, the injection electrode 1a can be connected to a specific *Jing* point of the right foot, such as ST45, near the lateral base of the nail of the second toe. Meanwhile, the return electrode can be connected to an area proximal to the fingers of the right hand.

By connecting one or both of the electrodes 1a, 1b at opposing extremities of the hand and foot, e.g., at *Jing* points, electrical signals may be transmitted across one or more different preferential electrical pathways of the body. Particularly, electrical signals may be transmitted along one or more meridian-defined preferential electrical pathways of the body. It has been have found unexpectedly that placement of current injection and return electrodes at certain positions of the hands and feet, particularly at *Jing*, *Yuan*, and/or nail sites, gives rise to position-dependent phase angle measurement, even when the sensing electrodes are located at a distance greater than 10 to 15 cm (even greater than 60 cm) from the current injection and return electrodes.

To monitor the bioimpedance of substantially a whole meridian-defined region of the body between the injection electrode 1a and return electrode 1b, the sensing circuit electrodes 2a, 2b in this embodiment are located on the right wrist midway between the ulna and radial styloid processes and right ankle between the medial and lateral malleoli.

Bioimpedance across a number of different preferential electrical pathways of the body may be determined, however, by moving the injection electrode 1a between different positions on the hand or foot. The injection electrode 1a may take the form of a mobile probe, which can be sequentially pressed against different points, e.g. *Jing* points, of the digits or otherwise, whilst bioimpedance data for each probe point/meridian is recorded. The probe may be configured as shown in Fig. 4, for example, the probe having a main section 10, which can be held by the user to allow manipulation of the probe, and a removable contact section 11. The main section 10 is connected to a wire 103 at its proximal end 101, for supplying electrical current. At the distal end 102 of the main section 10, a recess is provided (not shown) for receiving a conductive stud (e.g. of stainless steel material) located on one side of the contact section 11 in a snap-fit or click-fit manner. On the opposing side of the contact section 11, a hydrogel electrolyte coating or a suitable dry electrode material is provided to ensure good releasable electrical contact between the probe and the patient's skin or nail. Once the analysis has been carried out, the contact section 11 can be removed and cleaned or replaced. A number of variations of the probe are conceivable, including having the contact section integral with the main section and forming the contact section of material that is relatively easy to clean or disinfect *in situ*, e.g. gold plating. Another option is to fix one or more contact sections to the patient. For example, conductive discs, e.g. a plurality of aluminium foil discs may be connected to the patient, e.g., via conductive adhesive gel on one side of each disc. The discs may be about 8 mm in diameter, for example. The discs can be placed on all the current injection sites (e.g., *Jing* points near finger and toenails). Measurement may simply involve sequential contact of a probe against each of the discs. Thus, a probe similar to that shown in Fig. 4 may be used, but with a contacting tip of metal rather than a disposable gel stud electrode, for example. As an alternative to aluminium, other conductive materials may be used for the foil, including gold, tin or gold-coated aluminium. The thickness of the foil may range from 5 microns to 50 microns, for example.

Although only one injection electrode 1a is employed in the apparatus of Figs. 2 and 3, in other embodiments a plurality of injection electrodes can be provided. Thus, the injection electrodes can be connected at the same time to various positions, such as *Jing* points, of the hand or foot. An electrical signal may be applied to each injection electrode sequentially, whilst the bioimpedance data for the associated body meridian defined pathway can be recorded, optionally automatically. By using a plurality of injection electrodes, a plurality of pathways can be analysed or monitored without requiring reconfiguration of the electrode arrangement.

Following from this, in the embodiment shown in Fig. 5, six injection electrodes 1a are provided, each connected to a respective *Jing* point of the six regular meridians of the right foot (SP1, LR1, ST45, GB 44, KI1a, and BL67). These points, and other example *Jing* points to which the current injection electrodes may be connected are shown in Fig. 6.

An alternative apparatus in which a plurality of injection electrodes are provided is shown in Fig. 7, 8a and 8b. The apparatus includes an electrode arrangement that may be applied to either the hand or foot. The arrangement includes a plurality of current injection electrodes 1a and current return electrodes 1b and a voltage sensing electrode 2a/2b. The arrangement has similarities to the apparatus shown in Fig. 5, and the electrodes may be connected to the various acupuncture points as indicated in Fig. 6. However, the current injection electrodes 1a are mounted on a plurality of digit straps 121 configured to wrap around different digits of the hand or foot, the current return electrode 1b is mounted on a centre strap 122 configured to wrap around the palm of the hand or arch of the foot, and a voltage sensing electrode 2a/2b is mounted to a wrist/ankle strap 123 configured to wrap around the wrist of the hand or ankle of the foot. Each strap 121, 122, 123 includes a hook-loop fastening means 124 to connect ends of the strap together in order to securely tighten and fix the straps around the respective parts of the hand or foot. The voltage sensing electrode 2a/2b comprises electroconductive textile or a disposable adhesive gel piece on a permanent conductive base or a conducting contact that contacts a prefixed electrode with an outer conducting surface. The current injection and return electrodes 1a , 1b may also comprise electroconductive textile or a disposable adhesive gel piece on a permanent conductive base a conducting contact that contacts a prefixed electrode with an outer conducting surface. In similar embodiments to those shown in Figs. 7a, 8a and 8b, the electrode arrangements applied to the hand and foot may be comprised in a glove device or sock device, respectively. At least a portion of each electrode may be disposed on an inner surface of the glove or sock. Contact portions, e.g. metal foils, may be pre-attached at the desired acupuncture points of the hand or foot to ensure reliable electrical contact between the patient's hand or foot and the electrodes when the glove or sock is worn.

Electrical leads 125 extend between the straps 121, 122, 123 to supply electrical current to the current injection and return electrodes and to allow monitoring of the voltage sensing electrode. The leads 125 are semi-flexible and connect each of the electrodes to a ribbon cable 126, which in turn is connected via a connector tab 127 to a user interface/multiplexer connector 128. The connection arrangement allows each of the electrodes to be independently addressed via the single ribbon cable 126 and to enable automation of bioimpedance data collection.

Figs. 8a and 8b shows the apparatus in place on the hand and feet, with the locations of the electrodes 1a, 1b, 2a, 2b relative to the hand or foot indicated by dotted lines.

The injection electrodes 1a and return electrode 1b of Fig. 5 or Figs. 7, 8a and 8b can form part of the bioimpedance measurement apparatus shown schematically in Fig. 9. The apparatus comprises integrated drive and voltage sensing circuitry 71, the circuitry 71 being connected to the current return electrode 1b, and connectable, via a multiplexer 72, to any one of the plurality of the injection electrodes 1a, to deliver current, from a power supply, across the patient 74. The circuitry 71 and multiplexer 72 are controlled by a controller 75 and integral user interface and data processor 76. The user interface allows the patient or clinician to control, through a graphical interface 77 connected thereto, the order in which current is applied to the current injection electrodes 1a, for example. The circuitry 71 is further connected to the voltage sensing electrodes 2b, 2a, and arranged to receive voltage readings and deliver the voltage readings to the data processor 76 which is configured to generate corresponding bioimpedance data and present the data to the user via the graphical interface 77. The user interface and data processor 76, and graphical interface 77, may form part of a general purpose computer, or a custom-built device.

In addition to making measurements across substantially a 'whole body segment' (e.g. from ankle to wrist), additionally or alternatively, bioimpedance across individual regions of the body segment may be measured. This may be achieved by connecting one or both of the voltage sensing electrodes, or additional voltage sensing electrodes, to the arm, wrist, leg or ankle associated with the other hand and foot to that having the injection electrode(s) and return electrode connected thereto.

Considering again the 'whole body' analysis arrangement, with reference to Fig.10a, the one or more injection electrodes 1a, and the return electrode 1b, are connected to the right hand and right foot respectively. Accordingly, electrical signals can be transmitted between the right hand and right foot, via the right leg, torso, and right arm, and voltage drop across that path, indicated generally by an unbroken line 3, will take place. The measurement of the voltage drop is made using the voltage sensing electrodes 2a, 2b, located on the right wrist and right leg respectively, which monitor voltage drop across the path between them, indicated generally by a broken line 4. Thus, the section for which bioimpedance can be determined in this arrangement is substantially the whole body segment between the injection electrodes 1a and the return electrode 1b.

However, with reference to Fig. 10b, by connecting one voltage sensing electrode 2a to the right wrist, and another voltage sensing electrode 2c to the left wrist, voltage drop will be measured along a new path, indicated by broken line 41, extending across the right arm, upper torso and left arm. Since the region between the voltage sensing electrode 2c and the upper part of the right shoulder is at the same potential (because there is no current flow between these two sites), the voltage drop and therefore the calculated bioimpedance will only relate to that section of the right arm (along path 31) between the current injection and return electrodes 1a, 1b. Thus, the apparatus can be configured in this manner to determine bioimpedance of the right arm separately.

Similarly, with reference to Fig. 10c, by connecting one voltage sensing electrode 2b to the right ankle, and another voltage sensing electrode 2d to the left ankle, the voltage drop will be measured along another new path, indicated by broken line 42, extending across the right leg, lower torso and left leg. Since the region between the voltage sensing electrode 2d and the upper part of the right leg is at the same potential (because there is no current flow between these two sites), the voltage drop and therefore the calculated bioimpedance will only relate to that section of the right leg (along path 32) between the current injection and return electrodes 1a, 1b. Thus, the apparatus can be configured in this manner to determine bioimpedance of the right leg separately.

Similarly, with reference to Fig. 10d, by connecting one voltage sensing electrode 2c to the left wrist, and another voltage sensing electrode 2d to the left ankle, the voltage drop will be measured along yet another new path, indicated by broken line 43, extending across the left arm, torso and left leg. Since the region between the voltage sensing electrode 2c and the upper part of the right arm is at the same potential (because there is no current flow between these two sites), and the region between the voltage sensing electrode 2d and the upper part of the right leg is at the same potential (because there is no current flow between these two sites either) the voltage drop and therefore the calculated bioimpedance will only relate to that section of the right torso (along path 33) between the current injection and return electrodes 1a, 1b. Thus, the apparatus can be configured in this manner to determine bioimpedance of the right torso separately.

As indicated above, the apparatus may be adapted for analysis of the left side of the body in a similar manner.

According to one embodiment, a method of determining bioimpedance using the apparatus discussed above will now be described.

a. With a general four-electrode arrangement e.g. as shown in Fig. 1, the whole-body phase angle on the right side of the body is determined.

b. With the right foot current return electrode contacting the dorsal surface of the right foot proximal to the second metatarsal phalangeal joint as shown in Fig. 2, the phase angle associated with each of the six *Jing* points of the right hand is determined.

c. With the right hand current return electrode contacting the dorsal surface of the right hand proximal to the midpoint between the second and third metacarpal phalangeal joints as shown in Fig. 3, the phase angle associated with each of the six *Jing* points of the right foot, is determined.

d. With the general four-electrode arrangement e.g. as shown in Fig. 1, translated to the left side of the body, the whole-body phase angle on the left side of the body is determined.

e. With the left foot current return electrode contacting the dorsal surface of the left foot proximal to the second metatarsal phalangeal joint, the phase angle associated with each of the six *Jing* points of the left hand is determined.

f. With the left hand current return electrode contacting the dorsal surface of the left hand proximal to the midpoint between the second and third metatarsal phalangeal joints , the phase angle associated with each of the six *Jing* points of the left foot, is determined.

g. The ratio of the phase angle of each meridian-defined segment on the right side of the body to the whole-body phase angle on the right side of the body is calculated. Likewise, the ratio of the phase angle of each meridian-defined segment on the left side of the body to the whole-body phase angle on the left side of the body is calculated.

h. The left-side percentage difference in raw phase angle between left-right matched meridian-defined segments is determined.

i. The left-right percentage difference in ratios of meridian phase angle to whole-body phase angle between left-right matched meridian-defined segments is determined.

j. Results are output graphically and numerically.

To carry out this method or alternative methods of using the electrode apparatus of the present invention, in one embodiment the drive circuit and sensing circuit are connected to a power supply and control apparatus. The control apparatus comprises a controller, which controls the current or voltage level of the electrical signal, the pattern of electrical signals (e.g. pulsed signals) and the sequence of electrical signals sent to different current-injection electrodes of the circuit; a patient interface, which allows a user to set appropriate electrical signal control, e.g. so that a user can select a particular meridian-defined segment for analysis, or the electrical signal parameters prior to and/or during analysis; and data processor, which receives the raw data such as phase angle and impedance magnitude from the sensing circuit, and processes the raw data; and a graphical interface, which provides an output of the processed data in a suitable form for interpretation by the end user. The methods of the present invention may be implemented using computer software, e.g. arranged to execute the method steps a to j, or variations thereof, set out above.

In an alternative embodiment, the voltage sensing electrodes may be substituted with a second set of dual drive/sensing electrodes. Thus, with reference to Fig. 11, there may be an inner pair of drive electrodes B, C and an outer pair of drive electrodes A, D, connected to a patient's skin and/or nails 5, for example. In line with the "HvR" technique, an electrical signal can be applied in turn between all six combinations of outer and inner electrodes and the voltage drop, and therefore the bioimpedance, across each combination of electrodes may be determined. From this data, the bioimpedance (BC) of an intermediate portion between the inner pair of electrodes can be determined. This approach provides another method of determining bioimpedance across different portions of the body, and is based on the concept that impedance between any two surface electrodes can in general be decoupled into two types of components: local impedances associated with each electrode and a core (or non-local) impedance between the two electrodes. The bioimpedance Z_C (BC) of the core portion can be determined using the HvR equations provided at the end of the present description (see equation A3-i, for example).

With reference to Fig. 12, the degree of electrical interconnection between paired left and right meridian-defined segments can be estimated using Equation A4-ii of the HvR technique. For example, sets of four bioimpedance measurements may be made, e.g., (i) between a right foot *Jing* point and a site on the right hand; (ii) between a right foot *Jing* point and a site on the left hand; (iii) between a left foot *Jing* point and the site on the left hand; and (iv) between a left foot *Jing* point and the site on the right hand, and DZc , the degree of electrical interconnection (in impedance terms) between the left and right meridian-defined segments, calculated according to Equation A4-ii. Likewise, DRc, DXc and Dθc can also be determined from the DZc impedance data if required, where DRc, DXc and Dθc represent the degree of electrical interconnection in terms of resistance, reactance and phase angle, respectively.

Furthermore, equations A1-i (&-ii) and A2-i (& ii) can be used to estimate local impedance beneath the inner pair of electrodes in a linear or quasi-linear arrangement of four electrodes. This can not only be advantageous in assuring good electrode-to-skin contact of the inner electrodes but can in principle be used to estimate the transverse impedance of the skin (plus subcutaneous tissue) underlying the electrodes. Bilateral ratios of such transverse impedances can then be used to identify tissue changes such as is known to occur with unilateral lymphoedema, for example.

Various further non-limiting arrangements, configurations, parameters and techniques that may be used in embodiments of the apparatus and methods of the present invention are set out below.

Electrical Signals

The electrical signals delivered by the drive circuit electrodes may be AC (sinusoidal signals). The signals may have a frequency range of 1 kHz to 100 MHz, preferably 5 kHz to 300 kHz. Signals may be in the form of a single frequency, a set of frequencies (i.e. multi-frequency) or a continuous sweep (spectrum) of frequencies. For controlled current drive, applied current may be 0.2 μA to 2 mA, preferably 5 μA to 250 μA. For controlled voltage drive, the applied voltage may be 0.05V to 5.0 V, preferably 0.2 V to 2.0 V. A constant current drive may be preferable to counteract slight variations in the skin or nail surface profile / quality of electrode contact at the current-injection electrode connection points.

The electrical signals may be pulsed, e.g. a voltage pulse or a current pulse.

Principle Outcome Measures

Principle outcome measures may be in the form of impedance magnitude, resistance, reactance, or their reciprocals (admittance magnitude, conductance, susceptance), phase angle, reactance divided by resistance or as derived quantities such resistance divided by patient height, reactance divided by patient height etc. Furthermore, these quantities can be related to a single applied frequency, a range of applied frequencies, or a continuous sweep of applied frequencies.

Electrodes

Any one or more of the drive circuit (current-injection) electrodes or sensing circuit (voltage sensing) electrodes may use a wet-type contact (e.g. using a conductive paste or hydrogel etc.). The contact may be adhesive or non-adhesive.

Alternatively or additionally, any one or more of the electrodes may use a dry-type contact (e.g. using metal, conductive textile, microstructured carbon or ultrafine microneedle arrays etc.).

Any one of more of the electrodes can be active electrodes which have small or unit amplification close to the electrode. This may allow the electrodes to be used without electrode gel, for example.

Any one or more of the electrodes may rely on an adhesive contact with the patient, and/or may be held in position using straps, bands or belts or patient pressure (e.g. through a patient gripping or standing or resting on the electrodes).

The electrodes may be comprised in an automated probe system, where contact is made between the electrode and the patient through movement of, for example, a robotic arm carrying the electrode. An automated system such as this may be used for remote analysis or monitoring of a patient.

Any one more of the electrodes may be fixed to the patient or moveable.

Any one or more of the electrodes may take the form of metal plates, discs, strips, ellipses, heart-shapes, or other irregular shapes. The discs for the current injection and return electrodes may have a diameter of between 0.1 and 15 mm, preferably 2 mm to 10 mm. The strips for the current injection and return electrodes may have a width of 2 mm to 10 mm and/or a length of 2 mm to 25 mm. For example, the strip may be about 5 mm wide and 20 mm long. Nonetheless, the sizes may be adjusted, e.g., outside of the ranges provided, as appropriate for contacting different regions of the patient's skin or nail. The electrodes may also take the form of gloves or socks or spheres.

To make electrical contact with the patient's skin or nail, pressure may be applied to the skin or nail that is sufficient to ensure stable and reproducible electrode-skin or electrode-nail contact.

Physical contact is preferably avoided between the examiner and the patient during measurement to prevent the introduction of short-circuit contributions into the electrical measurement. The examiner may wear insulating gloves to prevent this possibility.

All or part of any one of the electrodes may be disposable, and discarded following testing to reduce the likelihood of cross-infection between patients.

Alternatively, any one or more of the electrodes may be disinfected after use, and suitably dried.

Standard medically-approved leads and cables may be used to connect the electrodes to the control apparatus, multiplexer and power supply etc. The leads may be directly connected into the multiplexer, or connected to a wireless transmission unit for wireless transfer of data and/or electrical signals.

Body Positioning

During analysis, the patient's body may be located in the supine position, or they may be standing, or seated with hands and feet resting on a suitable insulating surface. The patient may be resting or standing on a non-conducting surface with arms and legs not touching each other or the patient's torso. The position of the body may be modified, however, when the electrodes are to be held in contact with the patient through the patient gripping or standing or resting on electrodes, for example.

The patient's skin or nails may be wiped with disinfecting alcohol prior to electrode contact, with a sufficient, e.g. 5 minute, drying period subsequently. Body hair on the legs or arms is preferably not removed unless excessive.

The patient's palms may be facing down on an insulating surface with fingers gently extended and not touching each other.

If necessary, insulating material (e.g. cotton, foam etc.) may be inserted between the fingers or toes to act as spacers to prevent inter-digit contact.

HvR method

Assuming surface impedance contributions to be insignificant, with reference to Fig. 11, which shows a schematic diagram of electrodes A to D placed in contact with a surface of skin 5, and associated local impedances (B) and (C) and core impedance (BC), it can be shown that using simple combinations of two electrode measurements, two separate estimates for local impedance (B), $Z_S(B)$ & $Z'_S(B)$, can be obtained using electrode pairs A & C and A & D, respectively, as "reference" electrodes:

$$\mathbf{Z_S(B) = [Z_T(AB) + Z_T(BC) - Z_T(AC)]/2} \qquad \textbf{(A1-i)}$$

where $Z_T(AB)$, $Z_T(BC)$ & $Z_T(AC)$ represent total measured impedance between electrodes A & B, B & C, and A & C, respectively,

and

$$\mathbf{Z'_S(B) = [Z_T(AB) + Z_T(BD) - Z_T(AD)]/2} \qquad \textbf{(A1-ii)}$$

where $Z_T(AB)$, $Z_T(BD)$ & $Z_T(AD)$ represent total measured impedance between electrodes A & B, B & D, and A & D, respectively.

In the same way, two estimates can be obtained for local impedance (C), $Z_S(C)$ & $Z'_S(C)$:

$$Z_S(C) = [Z_T(BC) + Z_T(CD) - Z_T(BD)]/2 \qquad \text{(A2-i)}$$

where $Z_T(BC)$, $Z_T(CD)$ & $Z_T(BD)$ represent total measured impedance between electrodes B & C, C & D, and B & D, respectively.

and

$$Z'_S(C) = [Z_T(AC) + Z_T(CD) - Z_T(AD)]/2 \qquad \text{(A2-i)}$$

where $Z_T(AC)$, $Z_T(CD)$ & $Z_T(AD)$ represent total measured impedance between electrodes A & C, C & D, and A & D, respectively.

Next, from the possible four combinations of local impedances ($Z_S(B)$ & $Z_S(C)$, $Z'_S(B)$ & $Z_S(C)$ etc), it can be shown that there exist three estimates for core impedance (BC):

From equations (A1-i) from (A2-i) we get

$$Z_C(BC) = [Z_T(AC) + Z_T(BD) - Z_T(AB) - Z_T(CD)]/2 \qquad \text{(A3-i)}$$

And from equations (A1-i) & (A2-ii) and also (A1-ii) and (A2-i) we get

$$Z'_C(BC) = [Z_T(AD) + Z_T(BC) - Z_T(AB) - Z_T(CD)]/2 \qquad \text{(A3-ii)}$$

And from equations (A1-ii) & (A2-ii) we get

$$Z''_C(BC) = Z_T(AD) + Z_T(BC) - [Z_T(AB) + Z_T(AC) + Z_T(BD) + Z_T(CD)]/2 \qquad \text{(A3-iii)}$$

Extending the equations of Horton & van Ravenswaay, the following parameters can also be obtained as differences between these estimated body core impedances of segment BC:

$$dZ_C(BC\leftrightarrow AD) = Z_C(BC) - Z'_C(BC) = Z'_C(BC) - Z''_C(BC)$$

$$= [Z_T(AC) + Z_T(BD) - Z_T(AD) - Z_T(BC)]/2 \qquad \text{(A4-i)}$$

and

$$DZc(BC \leftrightarrow AD) = Z_C(BC) - Z''_C(BC)$$

$$= Z_T(AC) + Z_T(BD) - Z_T(AD) - Z_T(BC) \qquad \text{(A4-ii)}$$

where the symbol ↔ represents the degree of electrical interconnection between the two specified segments

Example 1 – Methods and Instrumentation

Testing was carried out on a healthy female human subject seated upright in chair, with arms extended and resting on a table with palms face downwards, and with digits of fingers and toes kept separated by insertion of insulated wadding material.

After allowing the subject to remain resting in the seated position for more than 5 minutes, various bioimpedance electrodes, and also electrodes for electrostimulation, were connected to the patient. In particular, a voltage sensing electrode with dimensions 55 mm x 23mm was connected to standard bioimpedance analysis sites on each of the left and right wrists and ankles of the subject; and a current return electrode, with dimensions 20 mm x 20 mm, was connected to standard bioimpedance analysis sites on the dorsal surface of each of the left and right feet of the subject. Furthermore, a current injection electrode, configured as an 8 mm diameter aluminium-foil adhesive gel electrode, was provided, to connect to (probe in this instance) various *Jing* points of the left and right hands of the subject. A pair of electrical stimulation electrodes in the form of conductive rubber silicone electrodes with 28 mm diameters, used in conjunction with conductive electrolyte gel, were taped onto the left leg of the subject at acupuncture point ST 36 (about 2 cm lateral to the inferior ridge of the tibial tuberosity), and at a site 80 mm directly inferior to that point.

Once the electrodes were in position, a pre-stimulation meridian bioimpedance measurement step was carried out in which right-side whole-body meridian bioimpedance measurements were made by sequentially probing the right *Jing* points of the hand in four measurement cycles according to the sequence: LU, LI PC, TE, HT & SI; followed by SI, HT, TE, PC, LI, LU; followed by LU, LI PC, TE, HT, SI; followed by SI, HT, TE, PC, LI, LU. Left-side whole-body meridian bioimpedance measurements were then made by probing the left *Jing* points of the hand following the analogous probing sequence to that used on the right side.

The bioimpedance measurements were made using an in-house fabricated bioimpedance instrument, configured to deliver electrical signals at a frequency of 100 kHz, with a constant current value of 100 μA. Four bioimpedance readings were made with respect to each probe site and the readings were averaged to provide results.

Following the pre-stimulation measurement step, an electrostimulation step was carried out in which electrostimulation having low intensity at 1.4 Hz was directed to the left ST 36 point for 10 minutes. After that time, the electrostimulation instrumentation was switched off and leads disconnected from the instrumentation.

Following completion of electrostimulation, a post-stimulation meridian bioimpedance measurement step was carried out in which whole-body hand meridian bioimpedance measurements were once again made, this time starting first on the left side of the body of the subject and then the right side. Four sets of measurement cycles were carried out in the same sequence as followed during the pre-stimulation bioimpedance measurement step (namely, LU, LI, PC, TE, HT, SI; followed by SI, HT, TE, etc).

Example 1 – Results and Discussion

Figs. 13a and 13b show the profiles of impedance and phase angle, respectively, for the whole-body regions associated with the meridian-defined segments of the left and right hands. Each point is the average of the four measurements at each point obtained during the four different measurement sequences. The dotted lines represent ± 1 statistical difference.

Table 3 sets forth the differences in the average impedance and phase angle measured for each point with respect to the left and right sides of the body, together with an estimate of the statistical significance of that difference based on the Student's unpaired t test.

Table 3

	LU	LI	PC	TE	HT	SI
Impedance Difference (L-R) (Ohms)	3	7***	7**	-3	12	7**
Phase Angle Difference (L-R) (Degrees)	0.13	0.15	-0.14	-0.28**	-0.11	-0.52***

* Significant difference ($0.01 < p \leq 0.05$)

** Very significant difference ($0.001 < p \leq 0.01$)

*** Extremely significant difference ($p \leq 0.001$)

Referring to the impedance profiles of Fig. 13a, it can be seen that the impedance of the left side of the body is on average about 5 Ohms higher than that of the right side. This is considered to reflect a slight geometrical asymmetry of the subject associated with her right-handedness.

Referring to the phase angle profiles of Fig.13b, it can be seen that the left/right differences associated with TE and SI are classified statistically as being very significant and extremely significant, respectively. It is also worth pointing out that very statistically significant differences exist in phase angle of meridian-defined segments on the same side of the body (e.g., between LI and SI on the right side, PC and SI on the left side). Such differences are indicative of the different electrical statuses of the respective meridian-defined body segments.

That the meridian type bioimpedance measurement at each *Jing* point reflects a particular electrical contribution from the respective meridian-defined segment can be demonstrated by the selective electrostimulation of a remote acupuncture point and the subsequent meridian bioimpedance measurement carried out in the electrostimulation and post-stimulation meridian bioimpedance measurement steps.

Figures 14a to 14d show a comparison of the pre-and post-stimulation profiles for the left and right meridians of the hand for meridian-based whole-body impedance and phase angle. With reference to Table 4, in the case of the left side of the body, statistically significant and very significant changes were observed in the phase angle of meridian defined segments LI and TE, respectively. No statistically different changes in phase angle in any of the meridian-defined segments however were observed on the right hand side of the body. Taken together, these results are consistent with electrostimulation at ST36 on the left leg causing selective or at least non-uniform changes in the electrical properties of meridian-defined segments.

Referring again to Figs. 14a and 14b, it can be seen that the average impedance across the meridians as a whole increased post-stimulation (compared to pre-stimulation) by 7 Ohms on the left side of the body but *decreased* on the right side by 11 Ohms.

Table 4

LEFT	LU	LI	PC	TE	HT	SI
Impedance Difference (Post - Pre) (Ohms)	10	6***	5*	8*	7*	5*
Phase Angle Difference (Post - Pre) (Degrees)	0.06	-0.29*	-0.22	-0.17**	-0.06	-0.06
RIGHT	**LU**	**LI**	**PC**	**TE**	**HT**	**SI**
Impedance Difference (Post - Pre) (Ohms)	-10***	-9**	-12**	-17*	-6	-13*
Phase Angle Difference (Post - Pre) (Degrees)	-0.21	0.24	-0.25	-0.20	-0.10	0.05

* Significant difference ($0.01 < p \leq 0.05$)

** Very significant difference ($0.001 < p \leq 0.01$)

*** Extremely significant difference ($p \leq 0.001$)

CLAIMS:

1. A method of determining bioimpedance in a body, the method comprising:

connecting one or more current injection electrodes to a first hand or foot of the body; and

connecting a current return electrode to a second hand or foot of the body, or to an arm or leg directly connected to a second hand or foot of the body,

wherein the one or more current injection electrodes and/or the current return electrode are connected to one or more acupuncture points;

connecting first and second voltage sensing electrodes at spaced apart positions of the body;

applying an electrical signal between at least one of the current injection electrodes and the current return electrode;

measuring with the voltage sensing electrodes, the voltage drop of the electrical signal across at least a portion of the body between the current injection electrodes and the current return electrode; and

using the voltage drop measurement to determine a bioimpedance of the at least a portion of the body.

2. The method of claim 1, wherein the one of more current injection electrodes are connected to one or more acupuncture points.

3. The method of claim 2, wherein the current return electrode is not connected to an acupuncture point.

4. The method of claim 3, wherein the current return electrode is connected at a position of the arm or leg distal to the elbow or knee respectively.

5. The method of any one of the preceding claims, wherein one or more of the acupuncture points are *Jing* points.

6. The method of any one of the preceding claims, wherein one or more of the acupuncture points are *Yuan* points.

7. The method of any one of the preceding claims, wherein the acupuncture points include any one or more of the following points: LU11; LI 1; PC 9; TE 1; HT 9; SI 1; SP 1; LR 1; ST 45; GB 44; KI 1a; BL67 and KI 1.

8. The method of any one of the preceding claims, wherein determining the bioimpedance includes determining phase angle.

9. The method of any one of the preceding claims, wherein the first hand or foot is ipsilateral with the second hand or foot.

10. The method of any one of the preceding claims, comprising connecting the first voltage sensing electrode to the first hand or foot, or to the arm or leg directly connected to the first hand or foot, and connecting the second voltage sensing electrode to the second hand or foot, or to the arm or leg directly connected to the second hand or foot.

11. The method of claim 9, comprising connecting the first voltage sensing electrode to a third hand or foot of the body, or to an arm or leg directly connected to a third hand or foot of the body, wherein the first hand or foot is contralateral with the first and second hand or foot.

12. The method of claim 11, comprising connecting the second voltage sensing electrode to a fourth hand or foot of the body, or to an arm or leg directly connected to the fourth hand or foot of the body, wherein the fourth hand or foot is ipsilateral with the third hand or foot and is contralateral with the first and second hand or foot.

13. The method of any one of the preceding claims, comprising connecting a first of said one or more current injection electrodes to a plurality of the acupuncture points in sequence, and, while the first current injection electrode is connected to each acupuncture point:

applying an electrical signal between the first current injection electrode and the current return electrode;

measuring with the voltage sensing electrodes, the voltage drop of the electrical signal across at least a portion of the body between the first current injection electrodes and the current return electrode; and

using the voltage drop measurement to determine a bioimpedance of the at least a portion of the body.

14. The method of claim 13, wherein the first current injection electrode is in the form of an electrical probe.

15. The method of any one of claims 1 to 12, comprising connecting a plurality of current injection electrodes to different acupuncture points of the first hand or foot of the body and, sequentially, for each current injection electrode:

applying an electrical signal between that current injection electrode and the current return electrode;

measuring with the voltage sensing electrodes, the voltage drop of the electrical signal across at least a portion of the body between the current injection electrodes and the current return electrode; and using the voltage drop measurement to determine a bioimpedance of the at least a portion of the body.

16. The method of any one of claims 13 to 15, comprising determining bioimpedance across a plurality of meridian-defined whole body portions.

17. The method of any one of the preceding claims comprising determining bioimpedance across a plurality of meridian-defined body segments.

18. The method of claim 17, wherein the plurality of meridian-defined segments include a leg, a torso and/or an arm. .

19. The method of any one of the preceding claims, wherein the one or more electrodes connected to one or more acupuncture points have a diameter or width of between 0.1 mm and 15 mm.

20. The method of any one of the preceding claims, wherein the one or more electrodes connected to one or more acupuncture points have a diameter or width of between 2 mm and 10 mm.

21. The method of any one of the preceding claims, wherein the electrical signal has a frequency of between 1kHz and 100 MHz.

22. The method of any one of the preceding claims, wherein the electrical signal has a frequency of between 20kHz and 300 kHz.

23. The method of claim 1, wherein

a plurality of the current injection electrodes are connected to acupuncture points of the first hand of the body;

the current return electrode is connected to the second foot of the body,

a plurality of further current injection electrodes are connected to acupuncture points of the second foot of the body,

a further current injection electrode is connected to the first hand of the body;

the first voltage sensing electrode is connected to the wrist of the first hand of the body; and

the second voltage sensing electrode is connected to the ankle of the second foot of the body.

24. A method of determining bioimpedance in a body, the method comprising:

connecting a first outer electrode to a first hand or foot of the body;

connecting a second outer electrode to a second hand or foot of the body, or an arm or leg directly connected to a second hand or foot of the body,

wherein the one or more current injection electrodes and/or the current return electrode are connected to one or more acupuncture points;

connecting first and second inner electrodes to spaced apart positions of the body, inwardly of the first and second outer electrodes;

applying an electrical signal in turn between all six combinations of first and second outer and inner electrodes;

measuring the voltages across each combination of electrodes in response to the respective applied electrical signals;

using the voltage data to determine the impedance between each electrode combination; and

using this impedance data to calculate the bioimpedance of a core portion of the body between the connection positions of the inner electrodes.

25. The method of claim 24, wherein the one of more current injection electrodes are connected to one or more acupuncture points.

26. The method of claim 25, wherein the current return electrode is not connected to an acupuncture point.

27. Apparatus for determining bioimpedance in a body, the apparatus comprising:

a drive circuit comprising:

one or more current injection electrodes configured to be connected to a first hand or foot of the body; and a current return electrode configured to be connected to a second hand or foot of the body, or to an arm or leg directly connected to a second hand or foot of the body, wherein the one or more current injection electrodes and/or the current return electrode are configured to be connected to one or more acupuncture points;

a sensing circuit comprising:

a first voltage sensing electrode configured to be connected to the body; and a second voltage sensing electrode configured to be connected to the body at a position spaced apart from the first voltage sensing electrode; and

a processor, the processor being connected to the voltage sensing electrodes and configured to measure, upon application of an electrical signal between at least one of the current injection electrodes and the current return electrode, the voltage drop of the electrical signal across at least a portion of the body between the connection positions of the current injection electrodes and the current return electrode, and to use the voltage drop to determine a bioimpedance of the at least a portion of the body.

28. The apparatus of claim 27, wherein the one of more current injection electrodes are configured to be connected to one or more acupuncture points.

29. The apparatus of claim 27 or 28, wherein the current return electrode is configured to be connected to a position of the arm or leg distal to the elbow or knee respectively.

30. The apparatus of any one of claims 27 to 29, wherein one or more of the acupuncture points are *Jing* points.

31. The apparatus of any one of claims 27 to 30, wherein one or more of the acupuncture points are *Yuan* points.

32. The apparatus of any one of claims 27 to 31, wherein the acupuncture points comprise are any one or more of the following points: LU11; LI 1; PC 9; TE 1; HT 9; SI 1; SP 1; LR 1; ST 45; GB 44; KI 1a; BL67 and KI 1.

33. The apparatus of any one of claims 27 to 32, wherein the first hand or foot is ipsilateral with the second hand or foot.

34. The apparatus of any one of claims 27 to 33, wherein

a first of said one or more current injection electrodes is configured to be connected to a plurality of the acupuncture points in sequence, and

the apparatus is configured such that, when the first current injection electrode is connected to each acupuncture point, an electrical signal is applied between the first current injection electrode and the current return electrode and the processor determines the voltage drop of the electrical signal across at least a portion of the body between the connection positions of the first current injection electrode and the current return electrode, and to use the voltage drop to determine a bioimpedance of the at least a portion of the body.

35. The apparatus of claim 34, wherein the first current injection electrode is an electrical probe.

36. The apparatus of any one of claims 27 to 33, comprising:

a plurality of current injection electrodes, each of said current injection electrodes being configured to be connected to different acupuncture points of the first hand or foot of the body,

wherein the apparatus is configured such that, when the current injection electrodes are connected to the different acupuncture points, an electrical signal is applied between each current injection electrode and the current return electrode in sequence, and in relation to each electrical signal, the processor is configured to determine the voltage drop of the electrical signal across at least a portion of the body between the connection position of the respective current injection electrode and the current return electrode, and to use the voltage drop to determine a bioimpedance of the at least a portion of the body.

37. The apparatus of any one of claims 35 to 37, wherein the processor is configured to determine bioimpedance across a plurality of meridian-defined whole body portions.

38. The apparatus of any one of claims 27 to 37, wherein the processor is configured to determine bioimpedance across a plurality of meridian-defined body segments.

39. The apparatus of claim 38, wherein the plurality of meridian-defined segments include a leg, a torso and/or an arm.

40. The apparatus of any one of claims 27 to 39, wherein the one or more electrodes configured to be connected to one or more acupuncture points have a diameter or width of between 0.1 mm and 15 mm.

41. The apparatus of any one of claims 27 to 40, wherein the one or more electrodes configured to be connected to one or more acupuncture points have a diameter or width of between 2 mm and 10 mm.

42. The apparatus of any one of claims 27 to 41, wherein the electrical signal has a frequency of between 1 kHz and 100 MHz.

43. The apparatus of any one of claims 27 to 42, wherein the electrical signal has a frequency of between 20 kHz and 300 kHz.

44. The apparatus of claim 1, comprising;

a plurality of the current injection electrodes configured to be connected to acupuncture points of the first hand of the body,

wherein the current return electrode is configured to be connected to the second foot of the body, the first voltage sensing electrode is configured to be connected to the wrist of the first hand of the body; and the second voltage sensing electrode is configured to be connected to the ankle of the second foot of the body, the apparatus further comprising:

a plurality of further current injection electrodes configured to be connected to acupuncture points of the second foot of the body, and

a further current injection electrode configured to be connected to the first hand of the body.

45. The apparatus of claim 44, wherein the electrodes configured to be connected to the first hand of the body are comprised in a glove device.

46. The apparatus of claim 44 or 45, wherein the electrodes configured to be connected to the second hand of the body are comprised in a sock device.

47. Apparatus for determining bioimpedance in a body, the apparatus comprising:

a first outer electrode configured to be connected to a first hand or foot of the body;

a second outer electrode configured to be connected to a second hand or foot of the body, or an arm or leg directly connected to a second hand or foot of the body, wherein the one or more current injection electrodes and/or the current return electrode are configured to be connected to one or more acupuncture points;

first and second inner electrodes configured to be connected to spaced apart positions of the body, inwardly of the first and second outer electrodes; and

bioimpedance measurement apparatus, configured to measure, in response to an electrical signal applied in turn across all six combinations of first and second outer and inner electrodes, the voltages across each combination of electrodes and configured to use the voltage data to determine the impedance between each electrode combination and calculate the bioimpedance of a core portion of the body between the connection positions of the inner electrodes.

48. The apparatus of claim 47, wherein the one of more current injection electrodes are configured to be connected to one or more acupuncture points.

AMENDED CLAIMS
received by the International Bureau on 13 April 2011 (13.04.2011)

1. A method of determining bioimpedance in a body, the method comprising:

connecting one or more current injection electrodes to a first hand or foot of the body; and

connecting a current return electrode to a second hand or foot of the body, or to an arm or leg directly connected to a second hand or foot of the body,

wherein the one or more current injection electrodes and/or the current return electrode are connected to one or more acupuncture points;

connecting first and second voltage sensing electrodes at spaced apart positions of the body, such that the first and second voltage sensing electrodes are each positioned at least 5 cm from the current injection electrodes and from the current return electrode;

applying an electrical signal between at least one of the current injection electrodes and the current return electrode;

measuring with the voltage sensing electrodes, the voltage drop of the electrical signal across at least a portion of the body between the current injection electrodes and the current return electrode; and

using the voltage drop measurement to determine a bioimpedance of the at least a portion of the body.

2. The method of claim 1, wherein the one of more current injection electrodes are connected to one or more acupuncture points.

3. The method of claim 2, wherein the current return electrode is not connected to an acupuncture point.

4. The method of claim 3, wherein the current return electrode is connected at a position of the arm or leg distal to the elbow or knee respectively.

5. The method of any one of the preceding claims, wherein one or more of the acupuncture points are *Jing* points.

6. The method of any one of the preceding claims, wherein one or more of the acupuncture points are *Yuan* points.

7. The method of any one of the preceding claims, wherein the acupuncture points include any one or more of the following points: LU11; LI 1; PC 9; TE 1; HT 9; SI 1; SP 1; LR 1; ST 45; GB 44; KI 1a; BL67 and KI 1.

8. The method of any one of the preceding claims, wherein determining the bioimpedance includes determining phase angle.

9. The method of any one of the preceding claims, wherein the first hand or foot is ipsilateral with the second hand or foot.

10. The method of any one of the preceding claims, comprising connecting the first voltage sensing electrode to the first hand or foot, or to the arm or leg directly connected to the first hand or foot, and connecting the second voltage sensing electrode to the second hand or foot, or to the arm or leg directly connected to the second hand or foot.

11. The method of claim 9, comprising connecting the first voltage sensing electrode to a third hand or foot of the body, or to an arm or leg directly connected to a third hand or foot of the body, wherein the first hand or foot is contralateral with the first and second hand or foot.

12. The method of claim 11, comprising connecting the second voltage sensing electrode to a fourth hand or foot of the body, or to an arm or leg directly connected to the fourth hand or foot of the body, wherein the fourth hand or foot is ipsilateral with the third hand or foot and is contralateral with the first and second hand or foot.

13. The method of any one of the preceding claims, comprising connecting a first of said one or more current injection electrodes to a plurality of the acupuncture points in sequence, and, while the first current injection electrode is connected to each acupuncture point:

applying an electrical signal between the first current injection electrode and the current return electrode;

measuring with the voltage sensing electrodes, the voltage drop of the electrical signal across at least a portion of the body between the first current injection electrodes and the current return electrode; and

using the voltage drop measurement to determine a bioimpedance of the at least a portion of the body.

14. The method of claim 13, wherein the first current injection electrode is in the form of an electrical probe.

15. The method of any one of claims 1 to 12, comprising connecting a plurality of current injection electrodes to different acupuncture points of the first hand or foot of the body and, sequentially, for each current injection electrode:

applying an electrical signal between that current injection electrode and the current return electrode;

measuring with the voltage sensing electrodes, the voltage drop of the electrical signal across at least a portion of the body between the current injection electrodes and the current return electrode; and

using the voltage drop measurement to determine a bioimpedance of the at least a portion of the body.

16. The method of any one of claims 13 to 15, comprising determining bioimpedance across a plurality of meridian-defined whole body portions.

17. The method of any one of the preceding claims comprising determining bioimpedance across a plurality of meridian-defined body segments.

18. The method of claim 17, wherein the plurality of meridian-defined segments include a leg, a torso and/or an arm.

19. The method of any one of the preceding claims, wherein the one or more electrodes connected to one or more acupuncture points have a diameter or width of between 0.1 mm and 15 mm.

20. The method of any one of the preceding claims, wherein the one or more electrodes connected to one or more acupuncture points have a diameter or width of between 2 mm and 10 mm.

21. The method of any one of the preceding claims, wherein the electrical signal has a frequency of between 1kHz and 100 MHz.

22. The method of any one of the preceding claims, wherein the electrical signal has a frequency of between 20kHz and 300 kHz.

23. The method of claim 1, wherein

a plurality of the current injection electrodes are connected to acupuncture points of the first hand of the body;

the current return electrode is connected to the second foot of the body,

a plurality of further current injection electrodes are connected to acupuncture points of the second foot of the body,

a further current injection electrode is connected to the first hand of the body;

the first voltage sensing electrode is connected to the wrist of the first hand of the body; and

the second voltage sensing electrode is connected to the ankle of the second foot of the body.

24. A method of determining bioimpedance in a body, the method comprising:

connecting a first outer electrode to a first hand or foot of the body;

connecting a second outer electrode to a second hand or foot of the body, or an arm or leg directly connected to a second hand or foot of the body, wherein the first outer electrode and/or the second outer electrode is connected to one or more acupuncture points;

connecting first and second inner electrodes to spaced apart positions of the body, inwardly of the first and second outer electrodes, such that the first and second inner electrodes are each positioned at least 5 cm from the first outer electrode and from the second outer electrode;

applying an electrical signal in turn between all six combinations of first and second outer and inner electrodes;

measuring the voltages across each combination of electrodes in response to the respective applied electrical signals;

using the voltage data to determine the impedance between each electrode combination; and

using this impedance data to calculate the bioimpedance of a core portion of the body between the connection positions of the inner electrodes.

25. The method of claim 24, wherein the first outer electrode is connected to an acupuncture point.

26. The method of claim 25, wherein the second outer electrode is not connected to an acupuncture point.

27. Apparatus for determining bioimpedance in a body, the apparatus comprising:

a drive circuit comprising:

one or more current injection electrodes configured to be connected to a first hand or foot of the body; and a current return electrode configured to be connected to a second hand or foot of the body, or to an arm or leg directly connected to a second hand or foot of the body, wherein the one or more current injection electrodes and/or the current return electrode are configured to be connected to one or more acupuncture points;

a sensing circuit comprising:

a first voltage sensing electrode configured to be connected to the body; and a second voltage sensing electrode configured to be connected to the body at a position spaced apart from the first voltage sensing electrode, such that the first and second voltage sensing electrodes are each positioned at least 5 cm from the current injection electrodes and from the current return electrode; and

a processor, the processor being connected to the voltage sensing electrodes and configured to measure, upon application of an electrical signal between at least one of the current injection electrodes and the current return electrode, the voltage drop of the electrical signal across at least a portion of the body between the connection positions of the current injection electrodes and the current return electrode, and to use the voltage drop to determine a bioimpedance of the at least a portion of the body.

28. The apparatus of claim 27, wherein the one of more current injection electrodes are configured to be connected to one or more acupuncture points.

29. The apparatus of claim 27 or 28, wherein the current return electrode is configured to be connected to a position of the arm or leg distal to the elbow or knee respectively.

30. The apparatus of any one of claims 27 to 29, wherein one or more of the acupuncture points are *Jing* points.

31. The apparatus of any one of claims 27 to 30, wherein one or more of the acupuncture points are *Yuan* points.

32. The apparatus of any one of claims 27 to 31, wherein the acupuncture points comprise are any one or more of the following points: LU11; LI 1; PC 9; TE 1; HT 9; SI 1; SP 1; LR 1; ST 45; GB 44; KI 1a; BL67 and KI 1.

33. The apparatus of any one of claims 27 to 32, wherein the first hand or foot is ipsilateral with the second hand or foot.

34. The apparatus of any one of claims 27 to 33, wherein

a first of said one or more current injection electrodes is configured to be connected to a plurality of the acupuncture points in sequence, and

the apparatus is configured such that, when the first current injection electrode is connected to each acupuncture point, an electrical signal is applied between the first current injection electrode and the current return electrode and the processor determines the voltage drop of the electrical signal across at least a portion of the body between the connection positions of the first current injection electrode and the current return electrode, and to use the voltage drop to determine a bioimpedance of the at least a portion of the body.

35. The apparatus of claim 34, wherein the first current injection electrode is an electrical probe.

36. The apparatus of any one of claims 27 to 33, comprising:

a plurality of current injection electrodes, each of said current injection electrodes being configured to be connected to different acupuncture points of the first hand or foot of the body,

wherein the apparatus is configured such that, when the current injection electrodes are connected to the different acupuncture points, an electrical signal is applied between each current injection electrode and the current return electrode in sequence, and in relation to each electrical signal, the processor is configured to determine the voltage drop of the electrical signal across at least a portion of the body between the connection position of the respective current injection electrode and the current return electrode, and to use the voltage drop to determine a bioimpedance of the at least a portion of the body.

37. The apparatus of any one of claims 35 to 37, wherein the processor is configured to determine bioimpedance across a plurality of meridian-defined whole body portions.

38. The apparatus of any one of claims 27 to 37, wherein the processor is configured to determine bioimpedance across a plurality of meridian-defined body segments.

39. The apparatus of claim 38, wherein the plurality of meridian-defined segments include a leg, a torso and/or an arm.

40. The apparatus of any one of claims 27 to 39, wherein the one or more electrodes configured to be connected to one or more acupuncture points have a diameter or width of between 0.1 mm and 15 mm.

41. The apparatus of any one of claims 27 to 40, wherein the one or more electrodes configured to be connected to one or more acupuncture points have a diameter or width of between 2 mm and 10 mm.

42. The apparatus of any one of claims 27 to 41, wherein the electrical signal has a frequency of between 1 kHz and 100 MHz.

43. The apparatus of any one of claims 27 to 42, wherein the electrical signal has a frequency of between 20 kHz and 300 kHz.

44. The apparatus of claim 27, comprising;

a plurality of the current injection electrodes configured to be connected to acupuncture points of the first hand of the body,

wherein the current return electrode is configured to be connected to the second foot of the body, the first voltage sensing electrode is configured to be connected to the wrist of the first hand of the body; and the second voltage sensing electrode is configured to be connected to the ankle of the second foot of the body, the apparatus further comprising:

a plurality of further current injection electrodes configured to be connected to acupuncture points of the second foot of the body, and

a further current injection electrode configured to be connected to the first hand of the body.

45. The apparatus of claim 44, wherein the electrodes configured to be connected to the first hand of the body are comprised in a glove device.

46. The apparatus of claim 44 or 45, wherein the electrodes configured to be connected to the second hand of the body are comprised in a sock device.

47. Apparatus for determining bioimpedance in a body, the apparatus comprising:

a first outer electrode configured to be connected to a first hand or foot of the body;

a second outer electrode configured to be connected to a second hand or foot of the body, or an arm or leg directly connected to a second hand or foot of the body, wherein the first outer electrode and/or the second outer electrode is configured to be connected to one or more acupuncture points;

first and second inner electrodes configured to be connected to spaced apart positions of the body, inwardly of the first and second outer electrodes, such that the first and second inner electrodes are each positioned at least 5 cm from the first outer electrode and from the second outer electrode; and

bioimpedance measurement apparatus, configured to measure, in response to an electrical signal applied in turn across all six combinations of first and second outer and inner electrodes, the voltages across each combination of electrodes and configured to use the voltage data to determine the impedance between each electrode combination and calculate the bioimpedance of a core portion of the body between the connection positions of the inner electrodes.

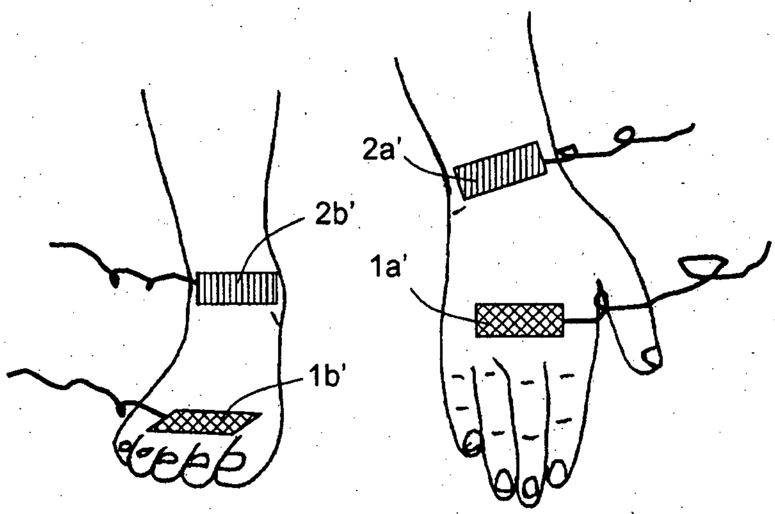


Fig. 1

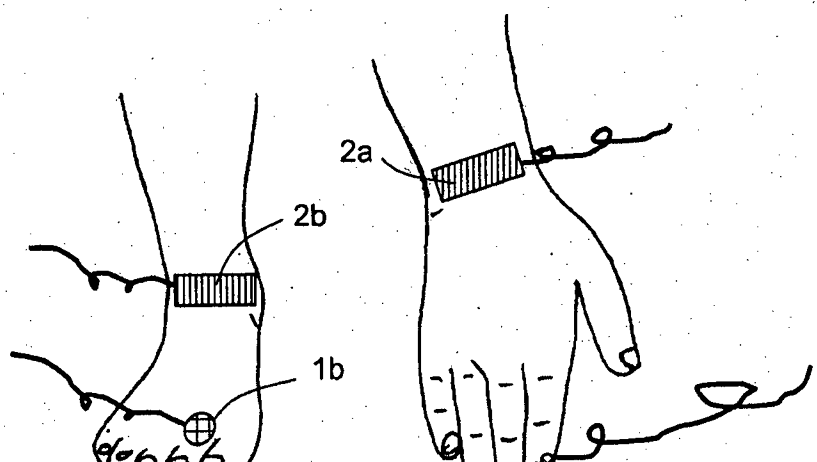


Fig. 2

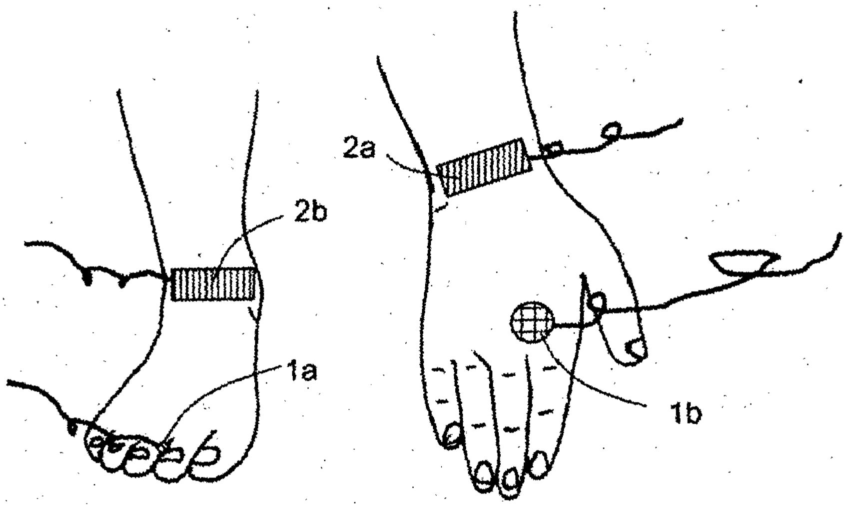


Fig. 3

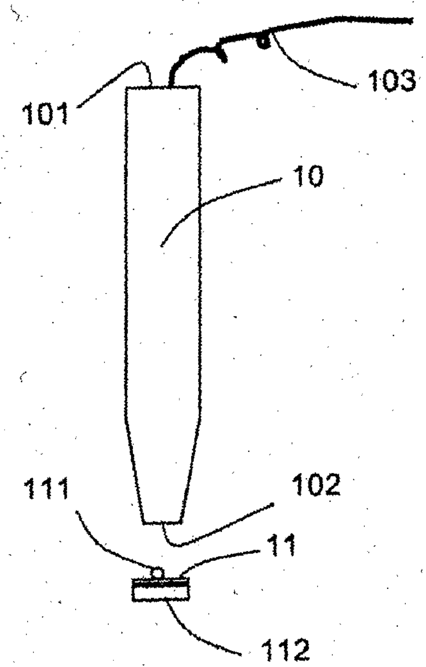


Fig. 4

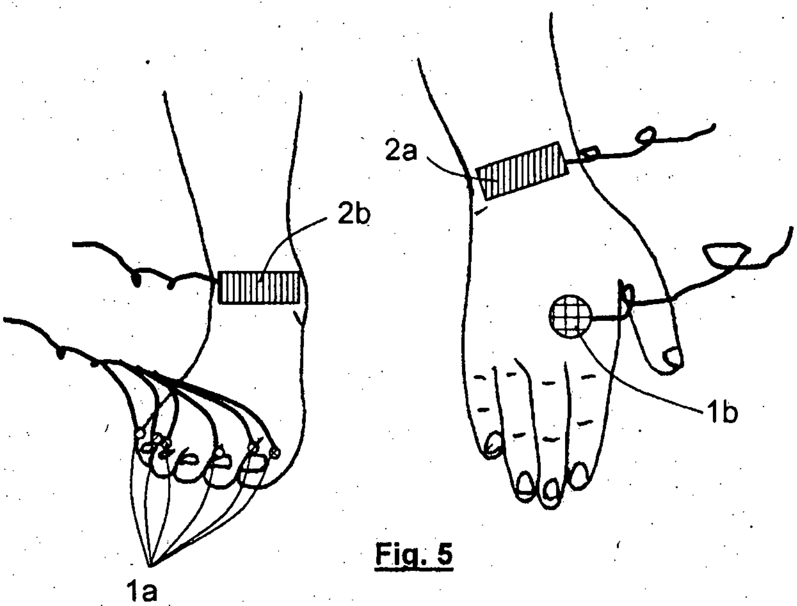
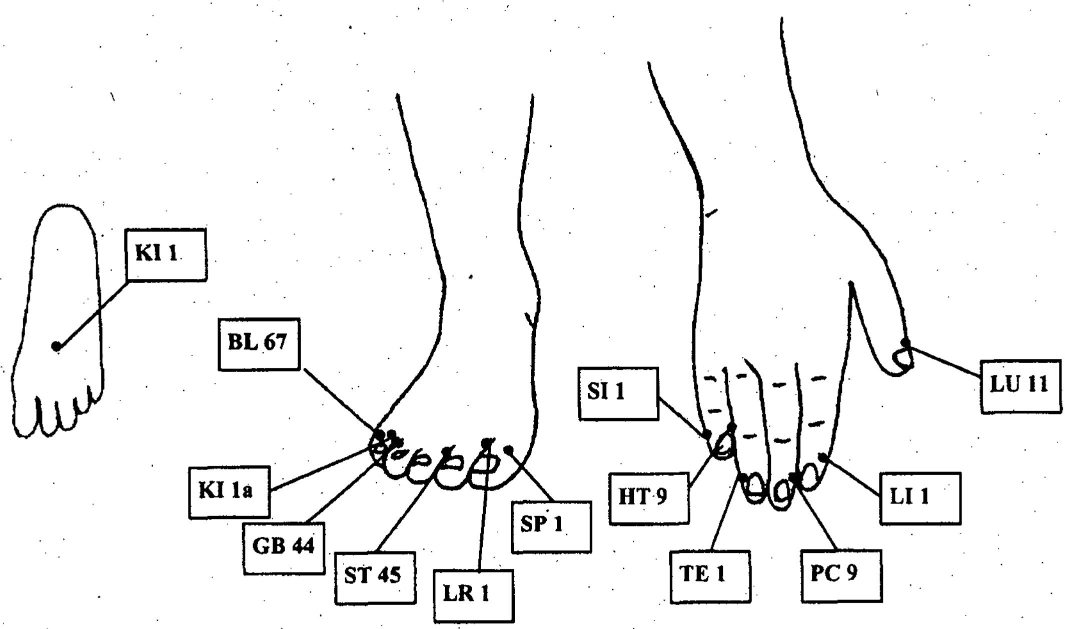

2a
2b
1b
1a

Fig. 5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ST 45
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Fig. 6

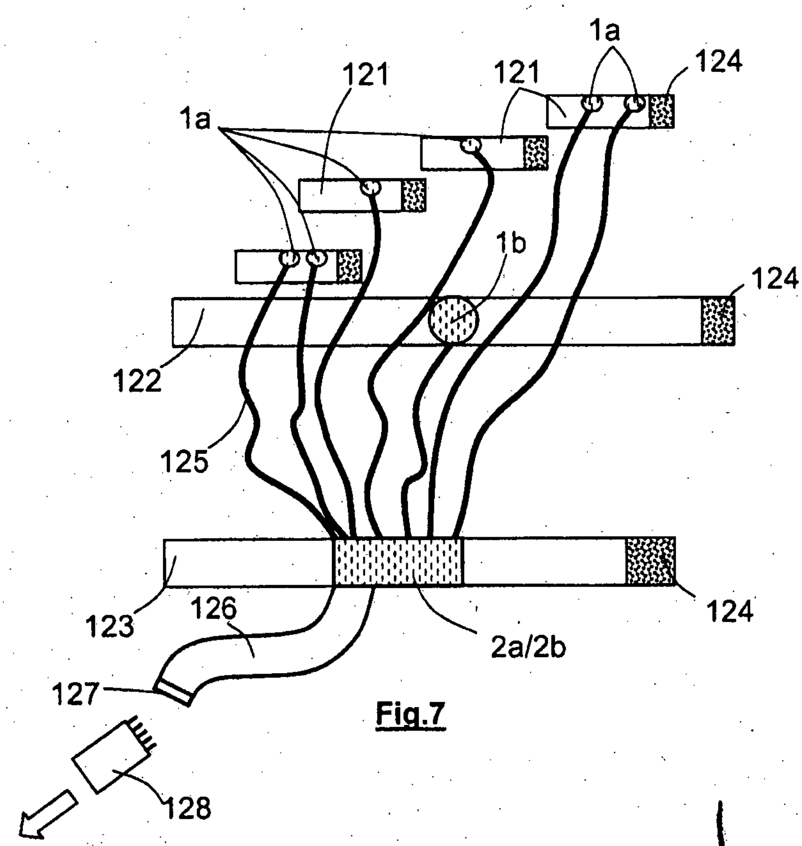

Fig.7

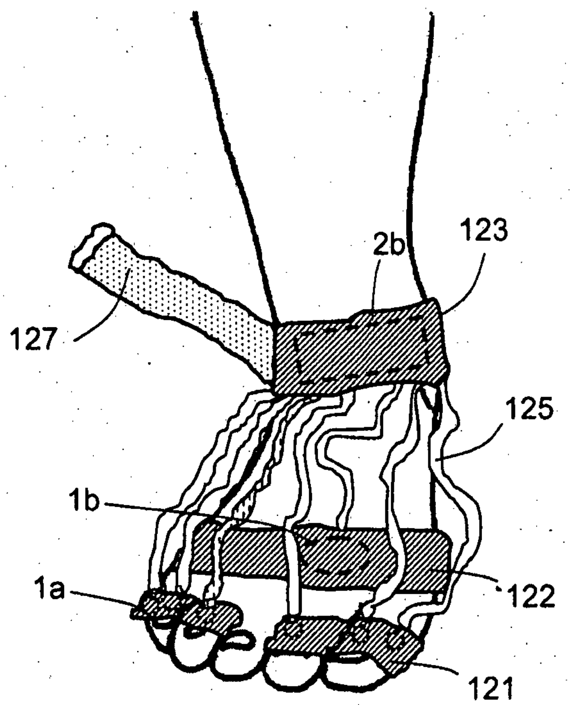

Fig. 8a

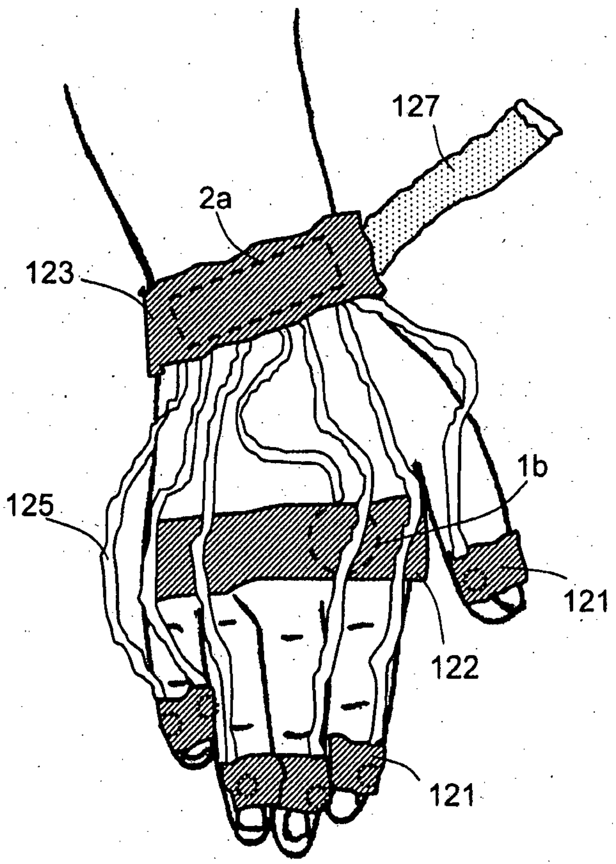

Fig. 8b

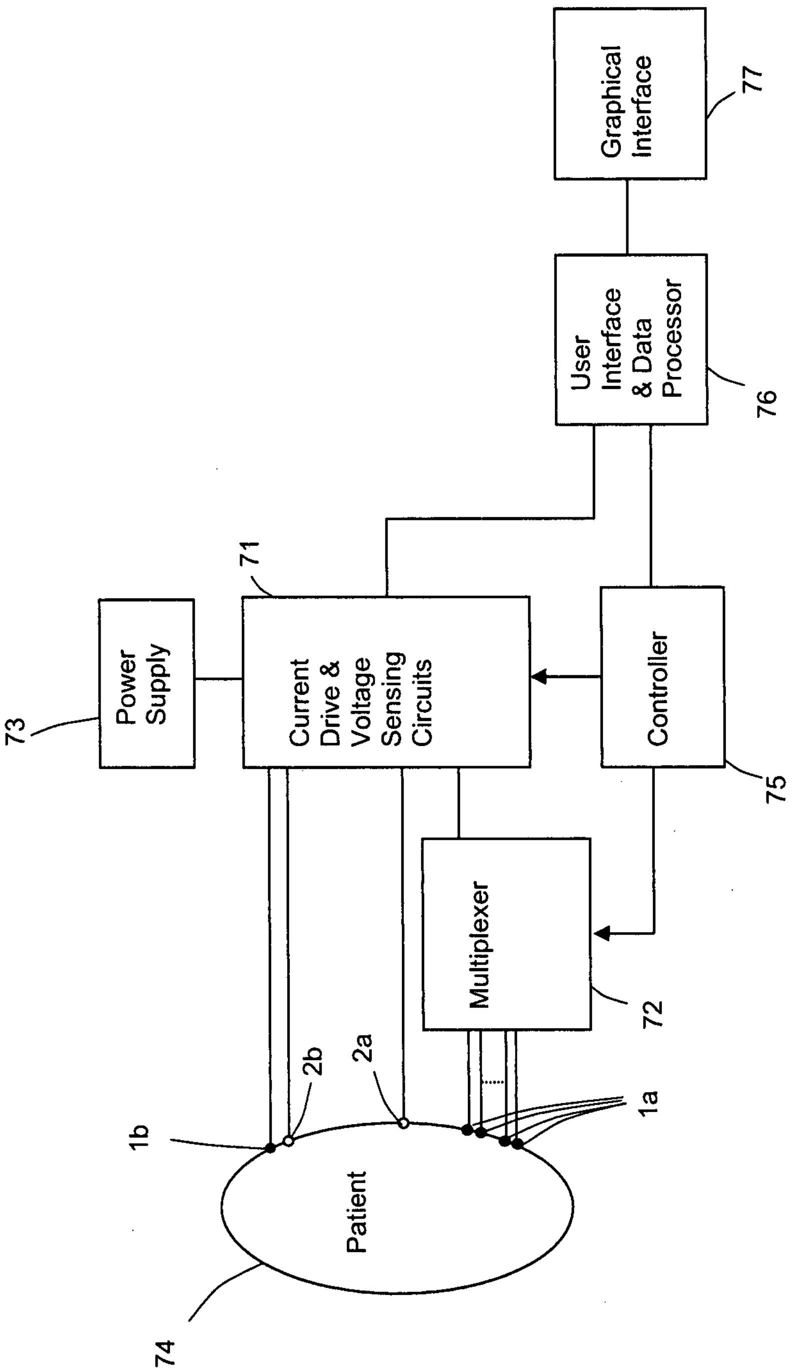
Graphical Interface
77
User Interface & Data Processor
76
71
Power Supply
73
Current Drive & Voltage Sensing Circuits
Controller
75
Multiplexer
72
2a
2b
1b
1a
Patient
74

Fig. 9

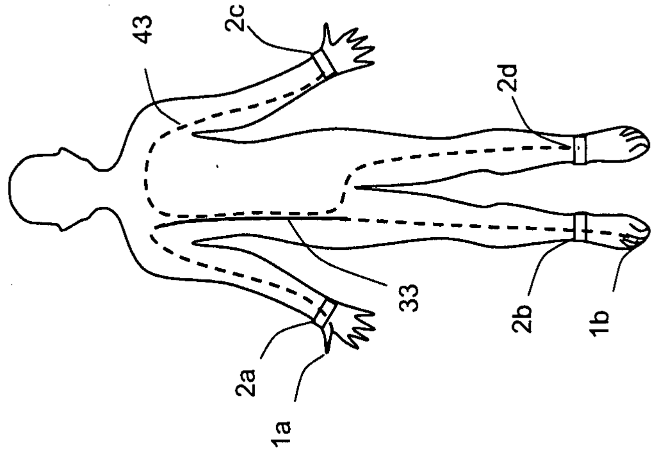

Fig. 10d

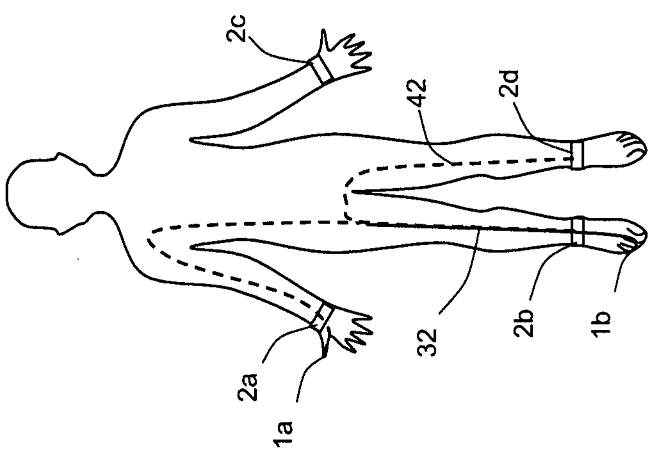

Fig. 10c

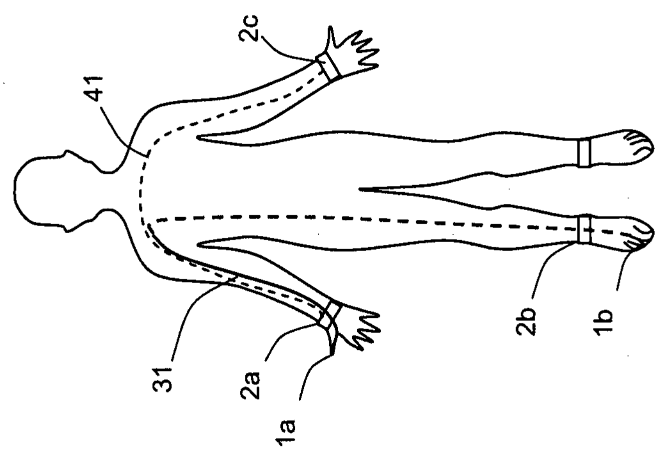

Fig. 10b

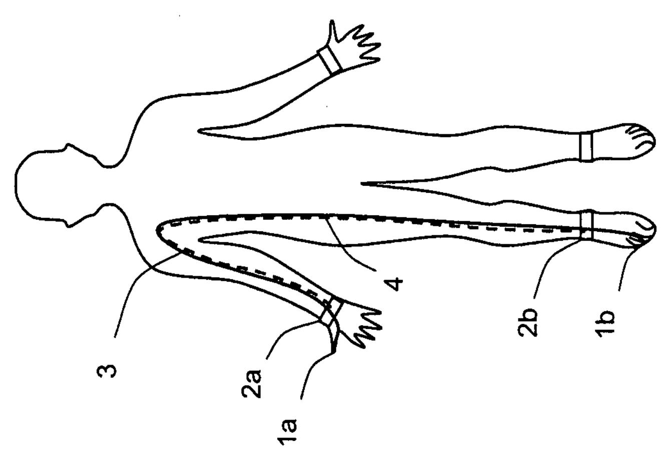

Fig. 10a

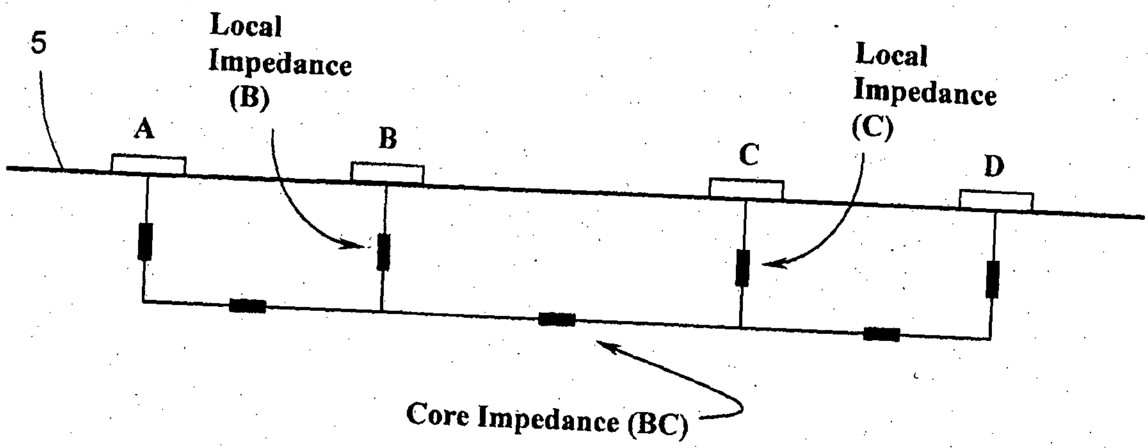
5
Local
Impedance
(B)
A
B
C
D
Local
Impedance
(C)
Core Impedance (BC)

Fig. 11

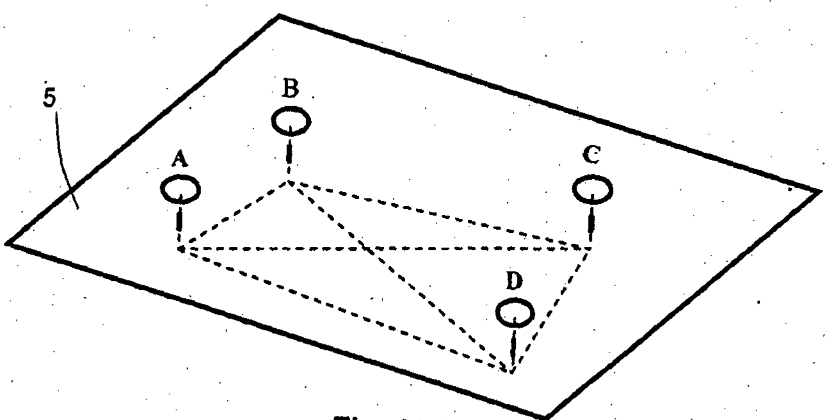
5
B
A
C
D

Fig. 12

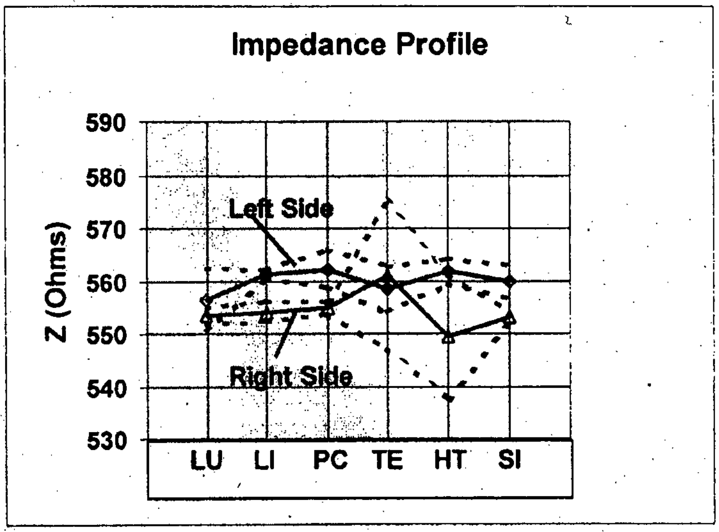

Fig. 13a

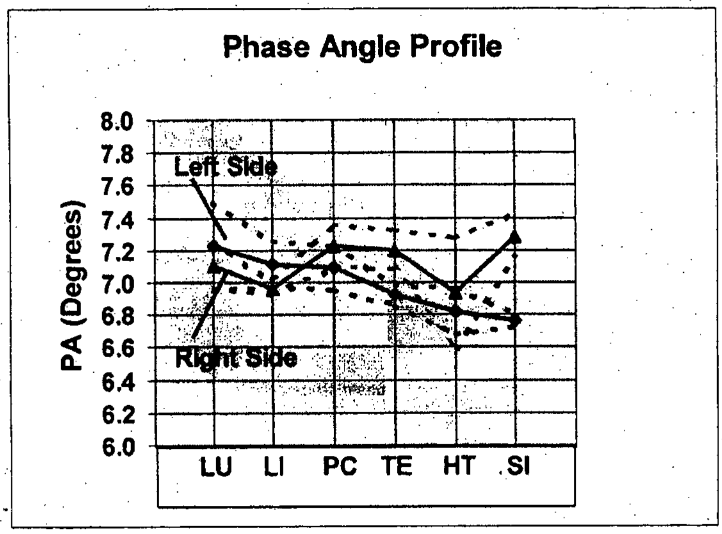

Fig. 13b

LEFT

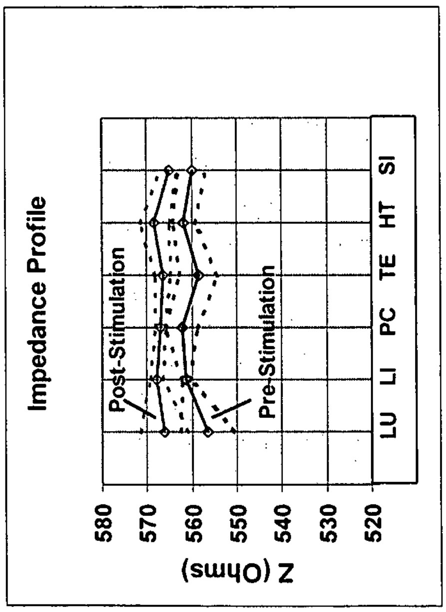

Fig. 14a

RIGHT

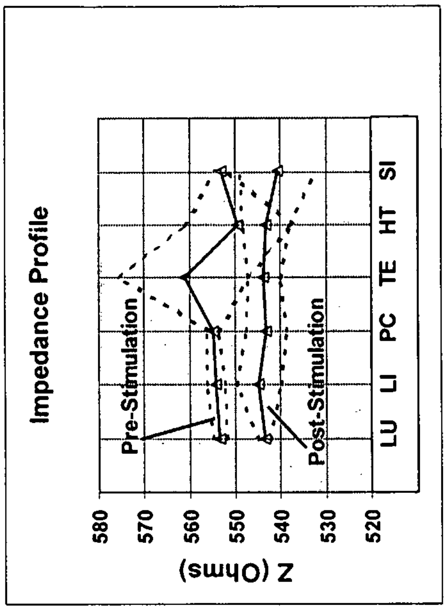

Fig. 14b

LEFT

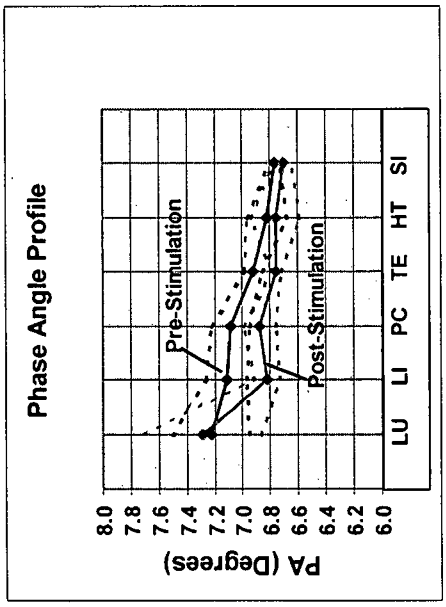

Fig. 14c

RIGHT

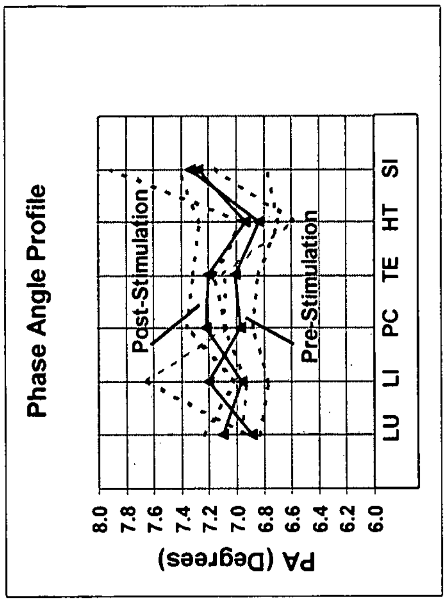

Fig. 14d

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2010/001710

A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl.

A61B 5/053 (2006.01) *A61B 5/0478* (2006.01) *A61N 1/08* (2006.01)

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPODOC, WPI: IPC, EC A61B 5/-, A61N 1/- and keywords: bioelectricity, bioimpedance, electrode, probe, acupuncture point, meridian, qi, impedance, resistance, phase angle, current, voltage, potential; and like terms
GOOGLE PATENTS keywords: bioimpedance, acupuncture, electrode, current, voltage; and like terms

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	JP 2003-126055 A (MUTEKI GOSUKE et al.) 07 May 2003 See abstract; paragraph [0014]; fig. 1 [machine translation of the document is available at *http://aipn1.ipdl.inpit.go.jp/aipn_call_transl.ipdl?N0000=7200&N0120=01&N2001=2&N3001=2001-087241*]	1-4, 10, 13, 14, 16-22, 27-29, 34, 35, 37-43
Y		5-9, 11, 12, 15, 23-26, 30-33, 36, 44-48
Y	CN 100342823 C (NI et al.) 17 October 2007 See page 9, table 1	5-7, 30-32
Y	EP 1384436 A2 (SAMSUNG ELECTRONICS CO., LTD.) 28 January 2004 See paragraphs [0054] and [0055]; figs. 6A and 6B	5-7, 30-32

[X] Further documents are listed in the continuation of Box C [X] See patent family annex

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search
14 February 2011

Date of mailing of the international search report
18 FEB 2011

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2010/001710

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2006/0085048 A1 (CORY et al.) 20 April 2006 See paragraphs [0140]-[0144]	8
Y	US 2004/0019292 A1 (DRINAN et al.) 29 January 2004 See paragraph [0035] and [0038]	8
Y	JP 2001-087241 A (TANITA SEISAKUSHO KK) 03 April 2001 See figs. 1-3	9, 11, 12, 24-26, 33, 47, 48
Y	US 3971366 A (MOTOYAMA) 27 July 1976 See column 5, lines 9-16 and lines 28-39; figs. 1a, 1b and 3	15, 23, 36, 44-46
Y	EP 1839574 A1 (SAKOWSKY et al.) 03 October 2007 See abstract and fig. 1	15, 23, 36, 44-46

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member					
JP	2003126055	NONE					
CN	100342823	CN	1522662				
EP	1384436	CN	1480097	EP	2002787	KR	20040010893
		US	2004122336	US	7474917		
US	20060085048	US	2006085049	US	7865236	WO	2006044868
		WO	2006045051				
US	20040019292	NONE					
JP	2001087241	NONE					
US	3971366	NONE					
EP	1839574	WO	2007113271				
WO	2006007665	AU	2005263203				

Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.

END OF ANNEX