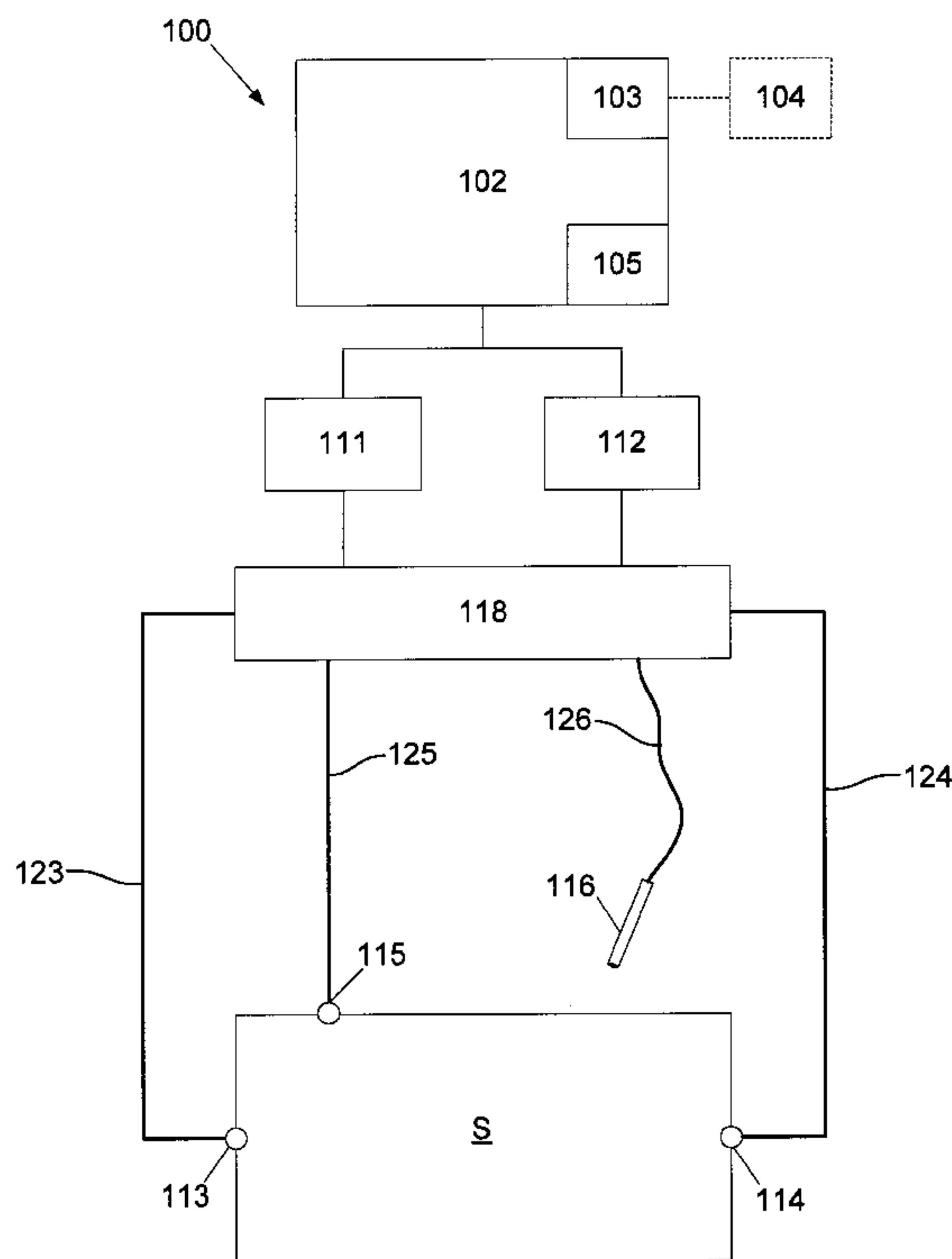




(86) Date de dépôt PCT/PCT Filing Date: 2008/04/17  
 (87) Date publication PCT/PCT Publication Date: 2008/10/30  
 (45) Date de délivrance/Issue Date: 2017/05/30  
 (85) Entrée phase nationale/National Entry: 2009/10/16  
 (86) N° demande PCT/PCT Application No.: AU 2008/000539  
 (87) N° publication PCT/PCT Publication No.: 2008/128281  
 (30) Priorité/Priority: 2007/04/20 (AU2007902109)

(51) Cl.Int./Int.Cl. *A61B 5/053* (2006.01)  
 (72) Inventeur/Inventor:  
 WARD, LEIGH CORDWIN, AU  
 (73) Propriétaire/Owner:  
 IMPEDIMED LIMITED, AU  
 (74) Agent: OYEN WIGGS GREEN & MUTALA LLP

(54) Titre : **SYSTEME ET SONDE DE SURVEILLANCE**  
 (54) Title: **MONITORING SYSTEM AND PROBE**



(57) **Abrégé/Abstract:**

A probe for use in performing impedance measurements on a subject. The probe includes a housing for being held by an operator in use, a contact surface for contacting the subject and a connector for connecting the contact surface to a measuring device.

## (12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization  
International Bureau



(43) International Publication Date  
30 October 2008 (30.10.2008)

PCT

(10) International Publication Number  
**WO 2008/128281 A1**

(51) International Patent Classification:  
*A61B 5/053* (2006.01)

(21) International Application Number:  
PCT/AU2008/000539

(22) International Filing Date: 17 April 2008 (17.04.2008)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:  
2007902109 20 April 2007 (20.04.2007) AU

(71) Applicant (for all designated States except US): **IMPED-  
IMED LIMITED** [AU/AU]; Unit 1, 50 Parker Court,  
Pinkenba, QLD 4008 (AU).

(72) Inventor; and

(75) Inventor/Applicant (for US only): **WARD, Leigh  
Cordwin** [AU/AU]; 90 Creekside Street, Kenmore Hills,  
Queensland 4069 (AU).

(74) Agents: **SMITH, Alistair James** et al.; Davies Collison  
Cave, Level 14, 255 Elizabeth Street, Sydney, New South  
Wales 2000 (AU).

(81) Designated States (unless otherwise indicated, for every  
kind of national protection available): AE, AG, AL, AM,  
AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA,  
CH, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE,  
EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID,  
IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC,  
LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN,  
MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH,  
PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, SV,  
SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN,  
ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every  
kind of regional protection available): ARIPO (BW, GH,  
GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM,  
ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM),  
European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI,  
FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MT, NL,  
NO, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG,  
CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— with international search report

(54) Title: MONITORING SYSTEM AND PROBE

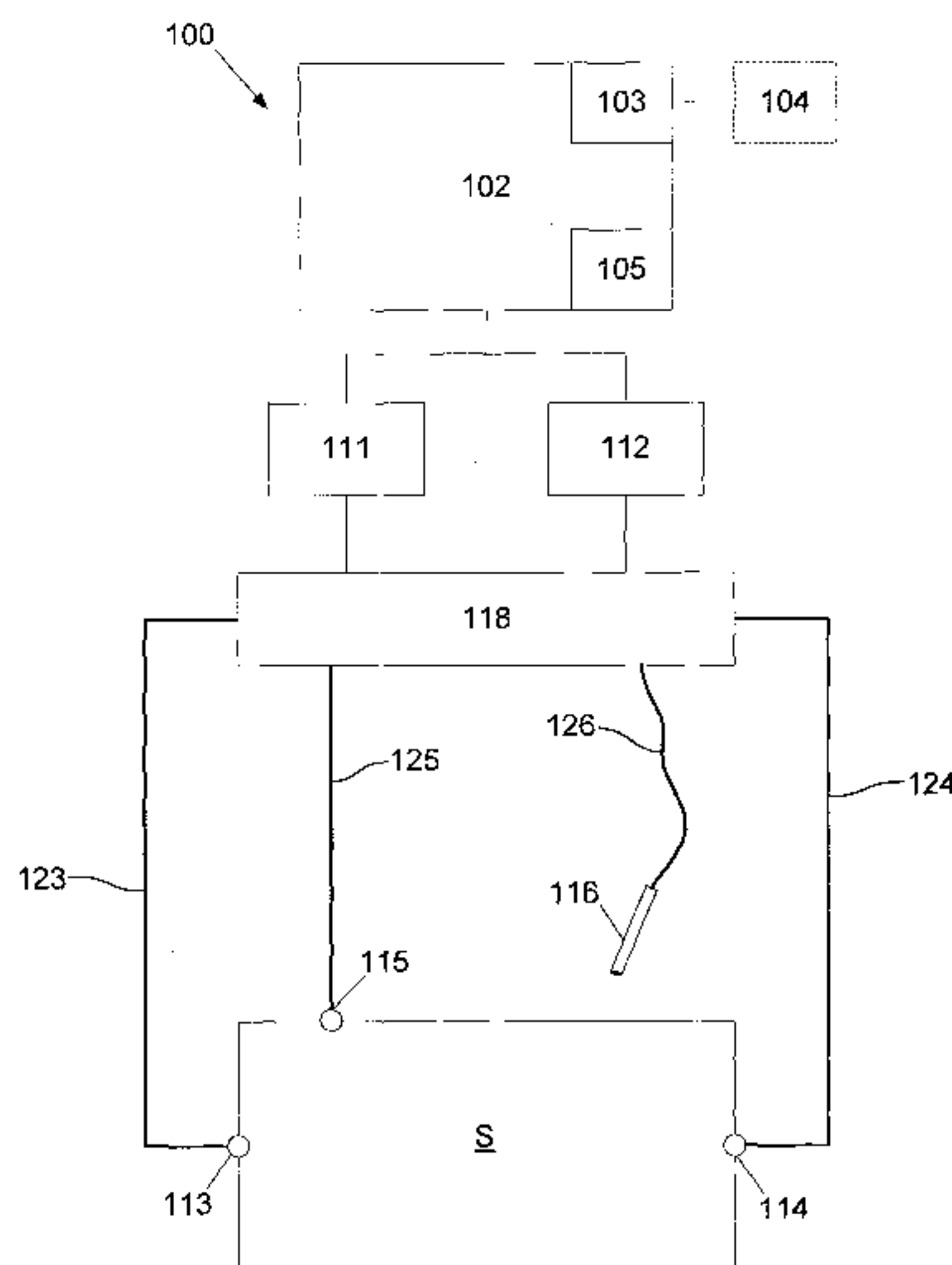


Fig. 1

(57) Abstract: A probe for use in performing impedance measurements on a subject. The probe includes a housing for being held by an operator in use, a contact surface for contacting the subject and a connector for connecting the contact surface to a measuring device.

WO 2008/128281 A1

## MONITORING SYSTEM AND PROBE

### **Background of the Invention**

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

### **Description of the Prior Art**

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

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

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

The condition is incurable and has been found difficult to treat with drugs or surgery but symptomatic treatment by complex physical therapy has been shown to benefit patients.  
25 Critical to patient management is that the extent of lymphoedema be measured regularly to assess patient's progress. A decrease in limb size not only indicates that treatment is beneficial but also helps encourage patient compliance with a demanding treatment

- 2 -

programme. Additionally, onset of lymphoedema is unpredictable and may develop within days of its cause or at any time during a period of many years after that cause.

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

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

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

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

### **Summary of the Present Invention**

In a first broad form the present invention provides a probe method for use in performing impedance measurements on a subject, the probe including:

- a) a housing configured to be held by an operator in use;
- b) a contact surface for contacting the subject; and,
- c) a connector for connecting the contact surface to a measuring device.

- 3 -

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

Typically the housing is formed from an insulating material.

Typically the housing is formed from a perspex tube.

5 Typically the contact surface has a convex shape.

Typically the contact surface includes a moving member for moving relative to the subject.

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

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

10 Typically the probe includes a contact for electrically connecting the moving member to the connector.

Typically the contact is a spring.

Typically the probe includes a sensor for sensing movement of the moving member.

Typically the sensor includes at least one of:

- 15
- a) an optical sensor; and,
  - b) moving elements in contact with the moving member.

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

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

20 Typically, in use, the probe is connected to a measuring device the measuring device including, a processing system for:

- a) causing at least one electrical signal to be applied to the subject via first electrodes provided on the subject; and,

- 4 -

- b) determining an indication indicative of at least one second electrical signal measured via a second electrode positioned on the subject, and via the probe.

In a second broad form the present invention provides a method of performing impedance measurements on a subject using a probe, the probe including a housing configured to be held  
5 by an operator in use, a contact surface for contacting the subject and a connector for connecting the contact surface to a measuring device, the method including:

- a) positioning the probe in contact with a segment of the subject;
- b) causing the measuring device to perform a sequence of impedance measurements;  
and,
- 10 c) moving the probe along the segment during the sequence of impedance measurements so that the measuring device determines impedance measurements along the segment.

Typically the method includes, in the measuring device:

- a) using the impedance measurements to determine an impedance profile; and,
- b) displaying a representation of the impedance profile to thereby allow the impedance  
15 profile to be used in determining a presence, absence, degree or location of oedema in the subject.

Typically the method includes, in the measuring device:

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

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

25 In a third broad form the present invention provides a method for use in analysing impedance measurements performed on a subject, the method including, in a processing system:

- a) determining a sequence of impedance values measured along a segment of the  
subject; and,

- 5 -

- b) determining an impedance profile using the sequence of impedance values.

Typically the method includes, in the processing system, displaying a representation of the impedance profile to thereby allow the impedance profile to be used in determining a presence, absence, degree or location of oedema in the subject.

5 Typically the method includes in the processing system:

- a) causing a sequence of first signals to be applied to the subject via first electrodes provided on the subject;
- b) determining an indication indicative of a sequence of second electrical signals measured via second electrodes provided on the subject; and,
- 10 c) determining the sequence of impedance values using indications of the sequences of first and second signals.

Typically one of the second electrodes is a probe, and wherein the method includes determining an indication of at least some of the second electrical signals as the probe is moved along the segment.

15 Typically the method includes:

- a) positioning the probe in contact with a segment of the subject;
- b) causing the processing system to perform a sequence of impedance measurements; and,
- c) moving the probe along the segment during the sequence of impedance measurements
- 20 so that the measuring device determines impedance measurements along the segment.

Typically the method includes, in the processing system:

- a) determining one or more impedance parameter values from measured impedance values; and,
- b) determining the impedance profile using the impedance parameter values.

25 Typically the impedance parameter values include at least one of:

- a) an impedance at infinite applied frequency ( $R_{\infty}$ );
- b) an impedance at zero applied frequency ( $R_0$ ); and,
- c) an impedance at a characteristic frequency ( $Z_c$ ).

- 6 -

Typically the method includes, in the processing system, determining the impedance parameter values at least in part using the equation:

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

where:  $R_{\infty}$  = impedance at infinite applied frequency;

5  $R_0$  = impedance at zero applied frequency;

$\omega$  = angular frequency;

$\tau$  is the time constant of a capacitive circuit modelling the subject response; and,

$\alpha$  has a value between 0 and 1.

10 Typically the representation includes at least one of:

- a) a baseline impedance profile for the segment;
- b) a reference impedance profile derived from a normal population; and,
- c) an impedance profile for a contra-lateral segment.

Typically the method includes, in the processing system:

- 15
- a) determining one or more subject details; and,
  - b) selecting a reference at least partially in accordance with the subject details.

Typically the subject details include at least one of:

- 20
- a) limb dominance;
  - b) ethnicity;
  - c) age;
  - d) sex;
  - e) weight; and,
  - f) height.

Typically one of the second electrodes is formed from a band electrode including:

- 25
- a) a substrate having provided thereon:
    - i) a number of electrically conductive contact pads; and,



- 7 -

- ii) a corresponding number of electrically conductive tracks, each track extending from an edge of the substrate to a respective contact pad;
- b) an insulating layer provided on the substrate, the insulating layer including a number of apertures, and being positioned to thereby overlay the tracks with at least a portion of each pad contact aligned with a respective aperture; and,
- 5 c) an electrically conductive medium provided in the apertures.

Typically the method includes measuring the sequence of second electrical signals via the contact pads.

In a fourth broad form the present invention provides apparatus for use in analysing impedance measurements performed on a subject, the apparatus including a processing system for:

- a) determining a sequence of impedance values measured along a segment of the subject; and,
- b) determining an impedance profile using the sequence of impedance values.

15 Typically the apparatus includes:

- a) a signal generator for applying one or more electrical signals to the subject using a first set of electrodes;
- b) a sensor for measuring electrical signals measured across a second set of electrodes; and,
- 20 c) a controller for:
  - i) controlling the signal generator; and,
  - ii) determining the indication of the measured electrical signals.

Typically at least one of the second electrodes is a probe, the probe including:

- a) a housing configured to be held by an operator in use;
- 25 b) a contact surface for contacting the subject; and,
- c) a connector for connecting the contact surface to the sensor.

In a fifth broad form the present invention provides a probe for use in diagnosing oedema in a body segment of a subject, the probe including:

- 8 -

- a) a housing configured to be held by an operator in use;
- b) a contact surface for contacting the segment of the subject; and,
- c) a connector for connecting the contact surface to a measuring device.

In a sixth broad form the present invention provides a method of diagnosing oedema in a  
5 body segment of a subject using a probe, the probe including a housing configured to be held  
by an operator in use, a contact surface for contacting the subject and a connector for  
connecting the contact surface to a measuring device, the method including:

- a) positioning the probe in contact with a segment of the subject;
- b) causing the measuring device to perform a sequence of impedance measurements;
- 10 c) moving the probe along the segment during the sequence of impedance measurements  
so that the measuring device determines impedance measurements along the segment;  
and,
- d) determining an impedance profile using the sequence of impedance values, the  
impedance profile being indicative of a presence, absence, degree or location of  
15 oedema in the subject.

In a seventh broad form the present invention provides a method for use in diagnosing  
oedema in a body segment of a subject, the method including, in a processing system:

- a) determining a sequence of impedance values measured along a segment of the  
subject; and,
- 20 b) determining an impedance profile using the sequence of impedance values, the  
impedance profile being indicative of a presence, absence, degree or location of  
oedema in the subject.

In an eighth broad form the present invention provides apparatus for use in diagnosing  
oedema in a body segment of a subject, the apparatus including a processing system for:

- 25 a) determining a sequence of impedance values measured along a segment of the  
subject; and,
- b) determining an impedance profile using the sequence of impedance values, the  
impedance profile being indicative of a presence, absence, degree or location of  
oedema in the subject.

It will be appreciated that the broad forms of the invention may be used individually or in combination, and may be used for diagnosis of the presence, absence or degree of a range of conditions and illnesses, including, but not limited to oedema, lymphoedema, body composition and the like.

## 5 **Brief Description of the Drawings**

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

Figure 1 is a schematic diagram of an example of impedance determination apparatus;

Figure 2 is a flowchart of an example of a process for determining an impedance profile;

10 Figures 3A to 3C are schematic diagrams of examples of impedance measuring probes;

Figure 4 is a flowchart of an example of a process for determining an impedance profile for uni-lateral limb oedema;

Figures 5A and 5B are diagrams of examples of electrode positions for use in measuring limb impedances;

15 Figures 5C and 5D are schematic diagrams of examples of electrode positions for use in measuring limb impedances;

Figure 6A is a graphical representation of an example of a profile of typical arm volume and impedance;

20 Figure 6B is a graphical representation of an example of a correlation of arm segment volume measured using a perometer with that predicted by impedance;

Figure 6C is a graphical representation of an example of limits of agreement between measured and predicted segment volumes;

Figure 6D is a graphical representation of an example of impedance profiles of an arm with lymphoedema and a contralateral unaffected arm; and,

25 Figure 6E is a graphical representation of an example of cumulative limb volumes measured by perometry from wrist to shoulder.

Figures 7A to 7F are schematic diagrams of an example of the construction of a band electrode;

Figure 7G is a schematic diagram of the use of a band electrode;

- 10 -

**Detailed Description of the Preferred Embodiments**

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

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

The connection may be via a switching device 118, such as a multiplexer, allowing the leads  
123, 124, 125, 126 to be selectively interconnected to signal generator 111 and the sensor  
112, although this is not essential, and connections may be made directly between the signal  
generator 111 and the first electrodes 113, 114, and the sensor 112 and the second electrodes  
15 115, 116.

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

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

Accordingly, it will be appreciated that the processing system 102 may be any form of  
processing system which is suitable for generating appropriate control signals and  
interpreting an indication of the measured signals to thereby determine the subject's

- 11 -

bioelectrical impedance, and optionally determine other information such as the presence, absence or degree of oedema, or the like.

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

It will be appreciated that the processing system 102, the signal generator 111 and the sensor 112 may be integrated into a common housing and therefore form an integrated device.  
10 Alternatively, the processing system 102 may be connected to the signal generator 111 and the sensor 112 via wired or wireless connections. This allows the processing system 102 to be provided remotely to the signal generator 111 and the sensor 112. Thus, the signal generator 111 and the sensor 112 may be provided in a unit near, or worn by the subject S, whilst the processing system 102 is situated remotely to the subject S.

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

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

For example, the system can use Bioimpedance Analysis (BIA) in which a single low  
25 frequency current is injected into the subject S, with the measured impedance being used directly in the assessment of oedema. In contrast Bioimpedance Spectroscopy (BIS) devices utilise frequencies ranging from very low frequencies (4 kHz) to higher frequencies (1000

- 12 -

kHz), and can use 256 or more different frequencies within this range, to allow multiple impedance measurements to be made within this range.

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

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

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

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

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

This in turn greatly reduces artefacts caused by movement of the second leads 125, 126, which is particularly important in some applications such as monitoring fluid levels during dialysis, in which sessions usually last for several hours and the subject will move around and

- 13 -

change positions during this time, as well as being important during movement of the probe 116.

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

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

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

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

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

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

- 14 -

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

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

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

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

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

At step 220, measured voltage and current signals are used by the processing system 102 to  
25 determine a sequence of measured impedance values. In one example, this includes first impedance values representing the impedance profile of the unaffected limb or limb segment and second impedance values representing the impedance profile of the affected limb or limb



- 15 -

segment, although this is not essential, and in one example, impedance measurements are only made for the affected limb or limb segment.

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

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

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

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

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

Additionally, and/or alternatively, the impedance profile can include a baseline or other reference. The baseline is typically a previous impedance profile measured for the same

- 16 -

limb, or limb segment of the subject S, whereas the reference is typically determined from a reference population of healthy individuals, as will be described in more detail below.

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

5 A first example of a probe electrode for use in determining an impedance profile will now be described with reference to Figure 3A.

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

10 In use the contact surface 301 is designed to be placed against the subject S, in contact with the subject's skin surface. To ensure accurate measurements are obtained, it is important to ensure good electrical contact between the contact surface 301 and the subject S, and accordingly, the contact surface 301 is typically formed from an electrically conductive material, such as stainless steel or the like, and may also be coated with an electro-conductive  
15 gel. In this example, the contact surface 301 is formed from a convex curved smooth surface, to assist with smooth transit across the subject's skin, as the probe 116 is moved along the length of the subject's limb, as well as to maximise contact between the contact surface and the subject's skin, thereby ensuring good electrical connection.

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

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

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

- 17 -

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

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

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

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

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

- 18 -

In this example, motion of the roller 322, for example to detect the distance moved by the probe 116 along a limb, can be detected in any one of a number of ways. In this example the roller 322 includes an aperture 325 extending therethrough. The aperture 325 is positioned so that once per revolution of the roller 322 the aperture 325 aligns with a radiation source  
5 326, such as an LED (light emitting diode) and a corresponding detector 327. Accordingly, when the aperture 325 aligns with the radiation source 326 and detector 327, the detector 327 will detect radiation emitted by the source by allowing revolutions of the roller 322 to be counted. Again information regarding this can be transferred back to the measuring device utilising appropriate connections (not shown).

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

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

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

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

- 19 -

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

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

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

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

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

- 20 -

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

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

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

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

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

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

At step 450 the measuring device 100 will optionally determine positional information from the probe. This may be achieved for example by having either the position sensor 316, or

- 21 -

signals from the detector 327 transferred to the measuring device 100 and interpreted appropriately.

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

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

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

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

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

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

where:  $R_\infty$  = impedance at infinite applied frequency,  
 $R_0$  = impedance at zero applied frequency,  
25  $\omega$  = angular frequency,

- 22 -

$\tau$  is the time constant of a capacitive circuit modelling the subject response.

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

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

where:  $\alpha$  has a value between 0 and 1 and can be thought of as an indicator of the deviation of a real system from the ideal model.

The value of the impedance parameters  $R_0$  and  $R_{\infty}$  may be determined in any one of a number of manners such as by:

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

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

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



- 23 -

measurements made be used depending for example on the intended use of the measurements.

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

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

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

where: L is length (cm),

10 Z is impedance (ohm); and,

$\rho$  is the resistivity constant (ohm.cm).

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

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

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

- 24 -

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

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

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

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

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

The reference is typically formed from an impedance profile derived from a normal population (subject's not suffering from oedema) that is relevant to the subject under study. Thus, the normal population is typically selected taking into account factors such as medical

- 25 -

interventions performed, ethnicity, sex, height, weight, limb dominance, the affected limb, or the like.

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

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

15 Operators may also have their own reference normal populations stored locally. However, in the event that suitable populations are not available, the processing system 102 can be used to retrieve a reference from a central repository, for example via an appropriate server arrangement. In one example, this may be performed on a pay per use basis.

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

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

Additionally, and/or alternatively, in the case of unilateral oedema, impedance profiles can be displayed for each limb, thereby allowing comparison between contra-lateral limbs. Thus, in

- 26 -

this example, the impedance profile of a healthy limb acts as a baseline or reference against which the profile of the affected limb can be compared.

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

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

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

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

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

Accordingly, by correlating the impedance measurements with the distance travelled along the arm or other limb it is possible not only to detect that the limb is lymphoedematous but also the particular location of lymphoedema within the limb thereby rendering it easier to

- 27 -

detect the presence, absence, degree or location of oedema using impedance profiling than volumetric measurements.

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

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

In this particular example the electrode is a band electrode 700, which includes a number of separate electrodes. In this example the electrode is formed from an elongate substrate 710 such as a plastic polymer coated with shielding material and an overlaying insulating material.

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

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

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

- 28 -

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

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

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

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

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

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

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

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

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

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

Persons skilled in the art will appreciate that numerous variations and modifications will  
15 become apparent. The scope of the claims should not be limited by the preferred embodiments set forth above, but should be given the broadest interpretation consistent with the description as a whole.

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

The above described processes can be used for determining the health status of an individual, including the body composition of the individual, or diagnosing the presence, absence or  
25 degree of a range of conditions and illnesses, including, but not limited to oedema, lymphoedema, or the like. It will be appreciated from this that whilst the above examples use the term impedance profile, this is for the purpose of example only and is not intended to be limiting. Accordingly, the impedance profile can be referred to more generally as an

- 30 -

indicator when used in analysing impedance measurements with respect to more general health status information such as body composition, or the like.



## CLAIMS:

- 1) An apparatus comprising:
- a signal generator;
  - 5 a sensor;
  - a pair of first electrodes coupled to the signal generator, the pair of first electrodes independently positionable on different limbs of a subject; and
  - a pair of second electrodes coupled to the sensor, the pair of second electrodes positionable on different limbs of the subject,
  - 10 wherein the pair of second electrodes includes a probe for use in performing impedance measurements on a subject, the probe comprising:
    - a) a housing configured to be held by an operator in use;
    - b) a contact surface for contacting the subject, wherein the contact surface includes a moving member for moving relative to the subject, and wherein the moving member is movably mounted to the housing and is configured to roll within the housing and along a tissue surface of the subject;
    - 15 c) a connector for connecting the contact surface to the apparatus; and,
    - d) a position sensor for sensing movement of the moving member, wherein the position sensor is configured to sense rolling motion of the moving member with respect to the housing.
    - 20
- 2) The apparatus according to claim 1, wherein the housing is an elongate housing, the contact surface is provided at a first end of the housing and the connector is provided at a second opposing end of the housing.
- 25
- 3) The apparatus according to claim 1 or claim 2, wherein the housing is formed from an insulating material.
- 4) The apparatus according to any one of the claims 1 to 3, wherein the housing is formed
- 30 from a poly(methyl) methacrylate tube.

- 5) The apparatus according to any one of the claims 1 to 4, wherein the contact surface has a convex shape.
- 6) The apparatus according to any one of the claims 1 to 5, wherein the moving member is a roller ball, and wherein the housing includes a shaped mounting for receiving the roller ball.
- 7) The apparatus according to any one of the claims 1 to 6, wherein the moving member is a cylindrical roller mounted on an axle.
- 8) The apparatus according to any one of the claims 1 to 7, wherein the probe includes a contact for electrically connecting the moving member to the connector.
- 9) The apparatus according to claim 8, wherein the contact is a spring.
- 10) The apparatus according to any one of the claims 1 to 9, wherein the position sensor for sensing movement of the moving member includes at least one of:
- a) an optical sensor; and,
  - b) moving elements in contact with the moving member.
- 11) The apparatus according to any one of the claims 1 to 10, wherein the connector is for connecting to a lead of the apparatus.
- 12) The apparatus according to any one of the claims 1 to 11, wherein, in use, the probe is moved along a segment of the subject to thereby allow an impedance profile representing variations in impedance along the segment to be determined.
- 13) The apparatus according to any one of the claims 1 to 12, wherein, in use, the probe is connected to a processing system for:
- a) causing at least one electrical signal to be applied to the subject via the pair of first electrodes provided on the subject; and,

- b) determining an indication indicative of at least one second electrical signal measured via the second pair of electrodes positioned on the subject, including via the probe.

14) A method of performing impedance measurements on a subject using an apparatus, the apparatus comprising:

a signal generator;

a sensor;

a pair of first electrodes coupled to the signal generator, the pair of first electrodes independently positionable on different limbs of a subject; and

a pair of second electrodes coupled to the sensor, the pair of second electrodes positionable on different limbs of the subject,

wherein the pair of second electrodes includes a probe comprising: a housing configured to be held by an operator in use, a contact surface for contacting the subject wherein the contact surface includes a moving member for moving relative to the subject and wherein the moving member is movably mounted to the housing and is configured to roll within the housing and along a tissue surface of the subject, a connector for connecting the contact surface to the apparatus, and a position sensor for sensing movement of the moving member wherein the position sensor is configured to sense rolling motion of the moving member with respect to the housing,

the method, comprising:

a) positioning the probe in contact with a segment of the subject, the segment being on a limb of the subject;

b) causing the apparatus to perform a sequence of impedance measurements; and,

c) moving the probe along the segment during the sequence of impedance measurements so that the apparatus:

i) determines positional information along different positions on the segment using the position sensor; and,

ii) determines impedance measurements along different positions on the segment.

15) The method according to claim 14, wherein the method includes:

a) using the impedance measurements to determine an impedance profile; and,

b) displaying a representation of the impedance profile to thereby allow the impedance profile to be used in determining a presence, absence, degree or location of oedema in the subject.

5 16) The method according to claim 14 or claim 15, wherein the method includes:

a) causing a sequence of first electrical signals to be applied to the subject via the pair of first electrodes provided on the subject connected to the signal generator; and,

b) determining an indication of a sequence of second electrical signals measured via the pair of second electrodes positioned on the subject including via the probe.

10

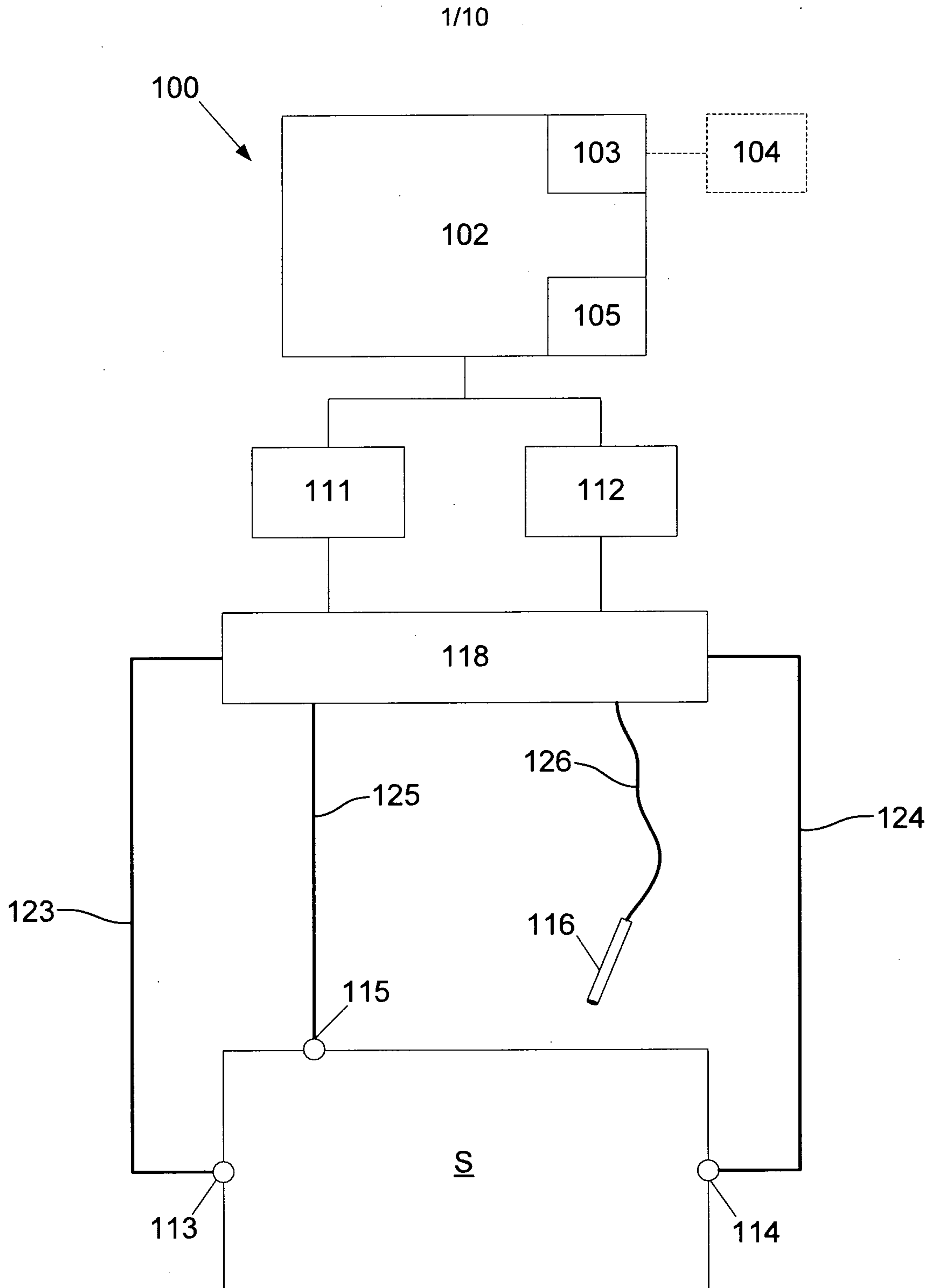
17) The method according to claim 16, wherein the method includes using an indication of the first and second signals to determine an impedance profile, the impedance profile representing variations in measured impedance along the segment.

15 18) The apparatus according to any one of the claims 1 to 13, wherein the probe is for use in diagnosing oedema in a body segment of the subject.

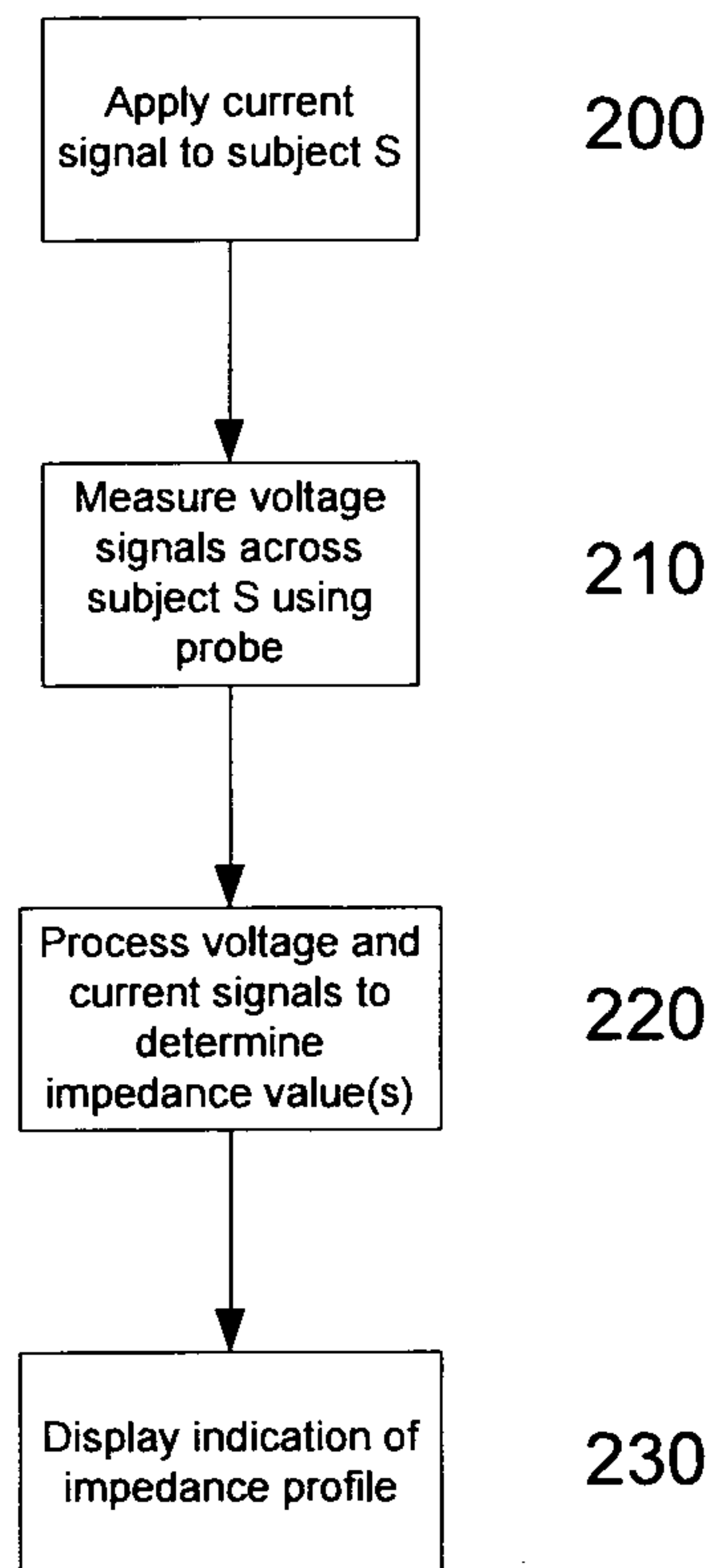
19) A method of diagnosing oedema in a body segment of a subject, the method comprising:

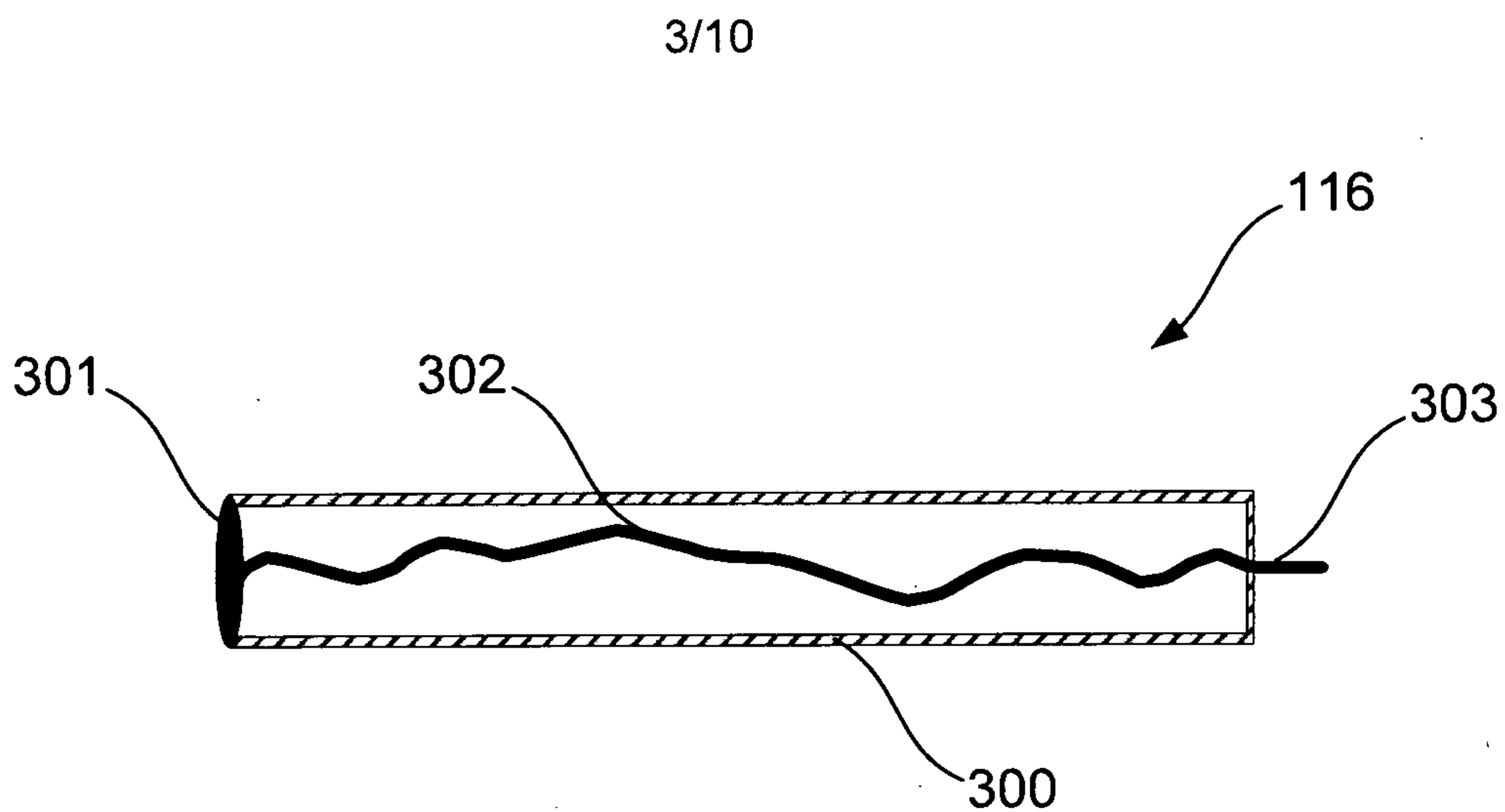
20 a) performing impedance measurements on the subject according to the method of any one of claims 14 to 17; and,

b) determining an impedance profile using the sequence of impedance values and the positional information, the impedance profile being indicative of a presence, absence, degree or location of oedema in the subject.

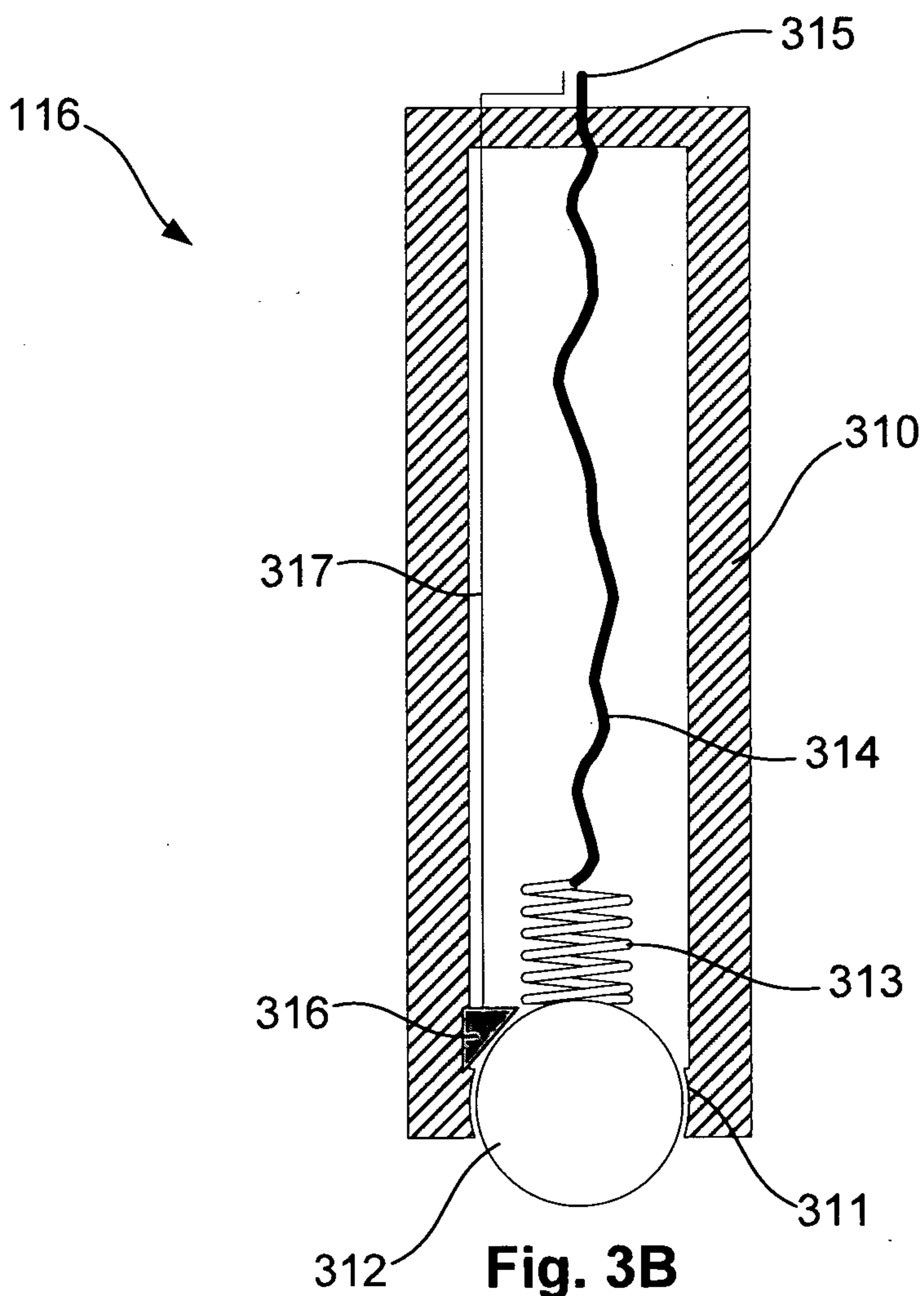
**Fig. 1**

2/10

**Fig. 2**



**Fig. 3A**



**Fig. 3B**

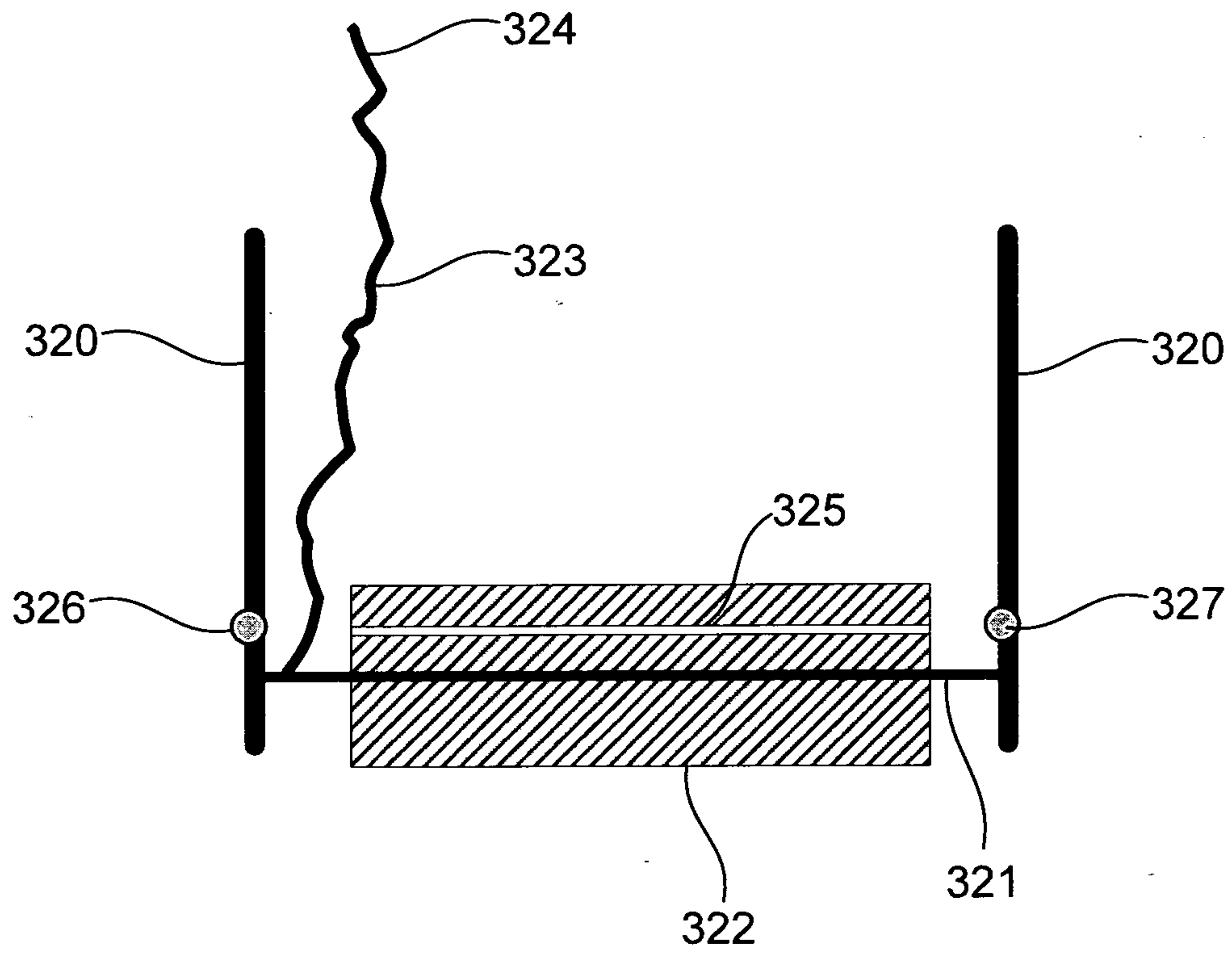


Fig. 3C



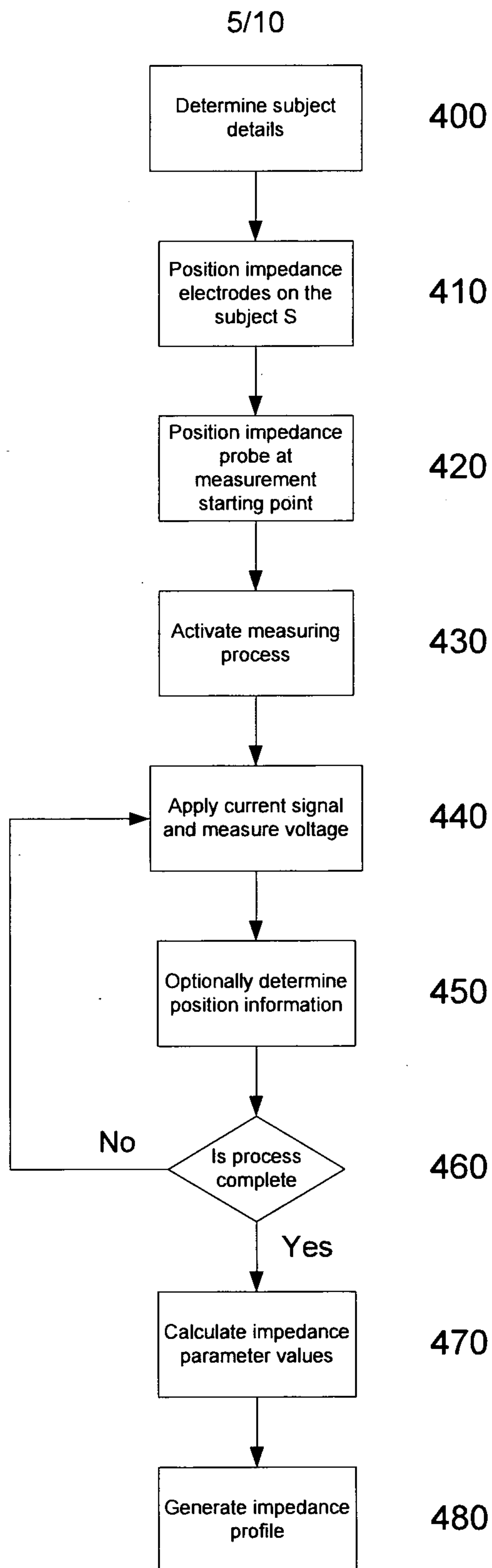


Fig. 4

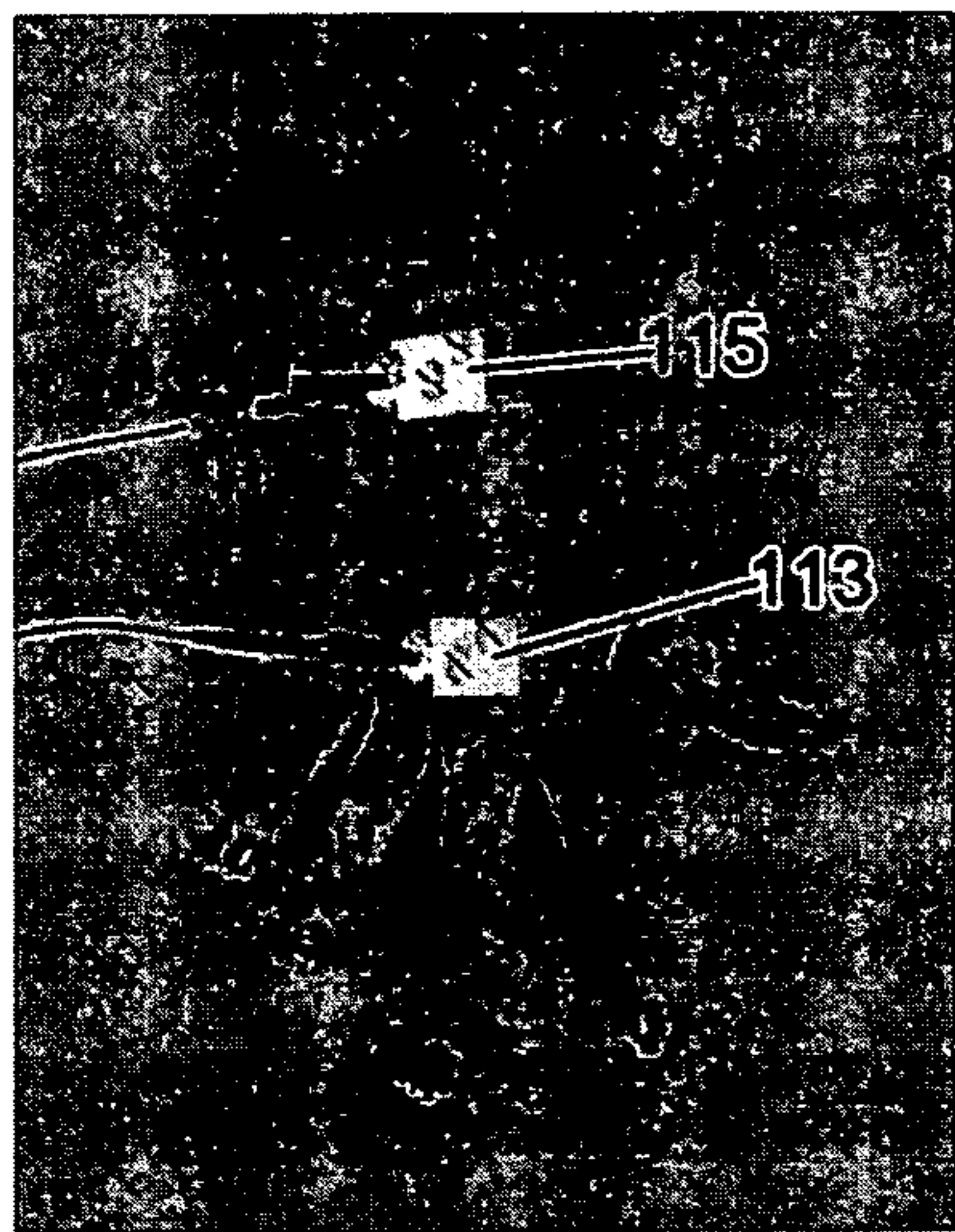


Fig. 5A

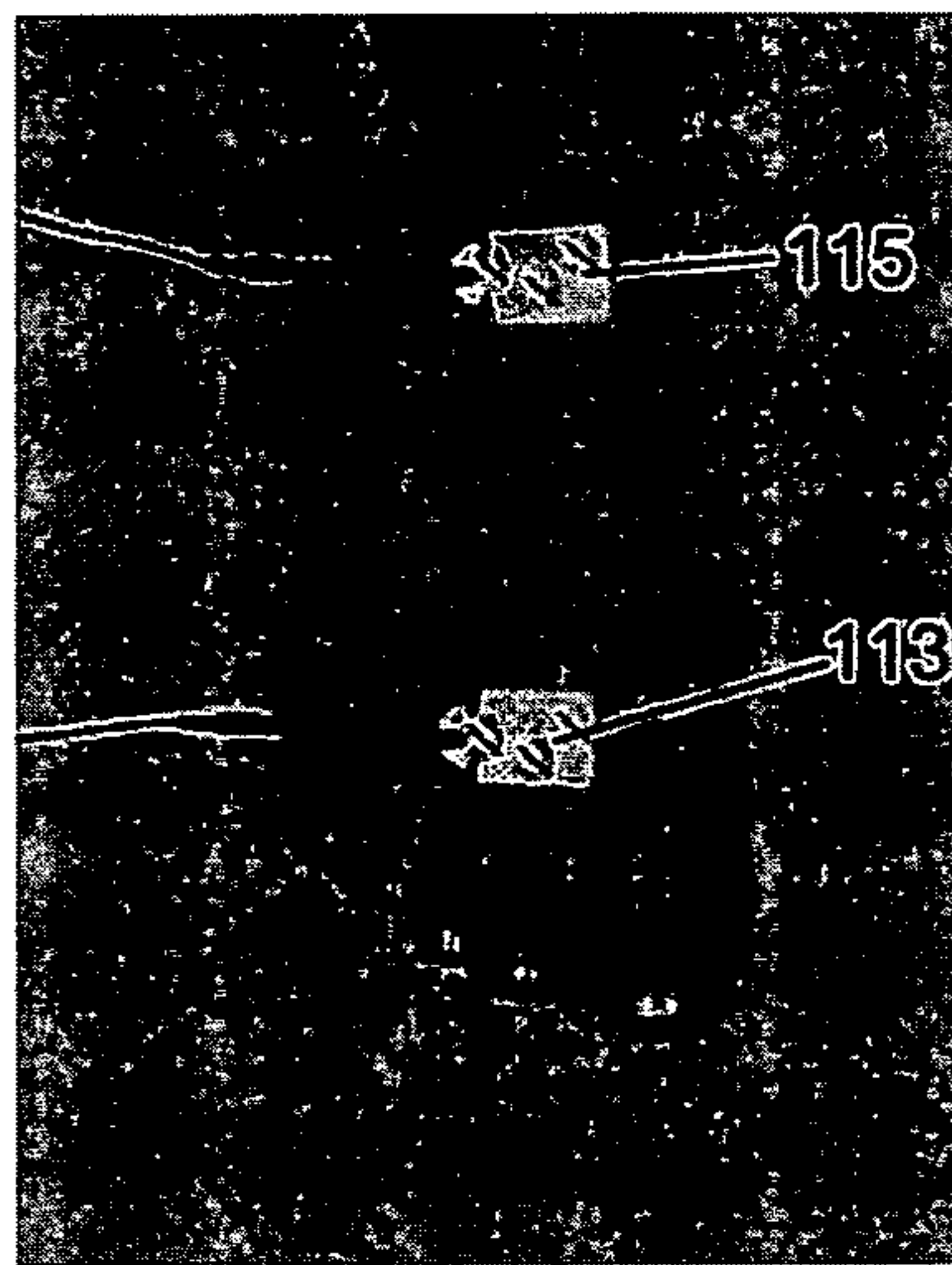


Fig. 5B

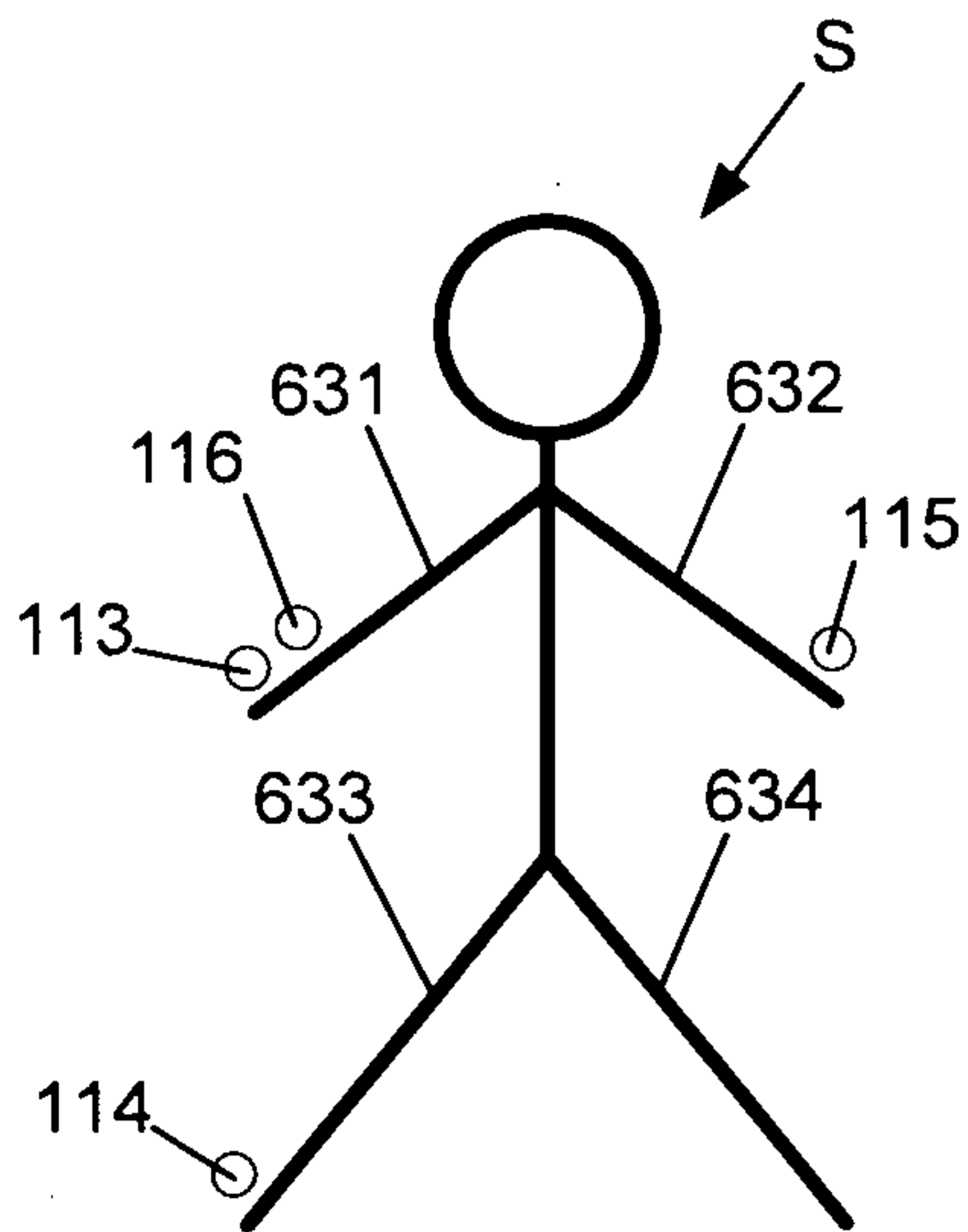


Fig. 5C

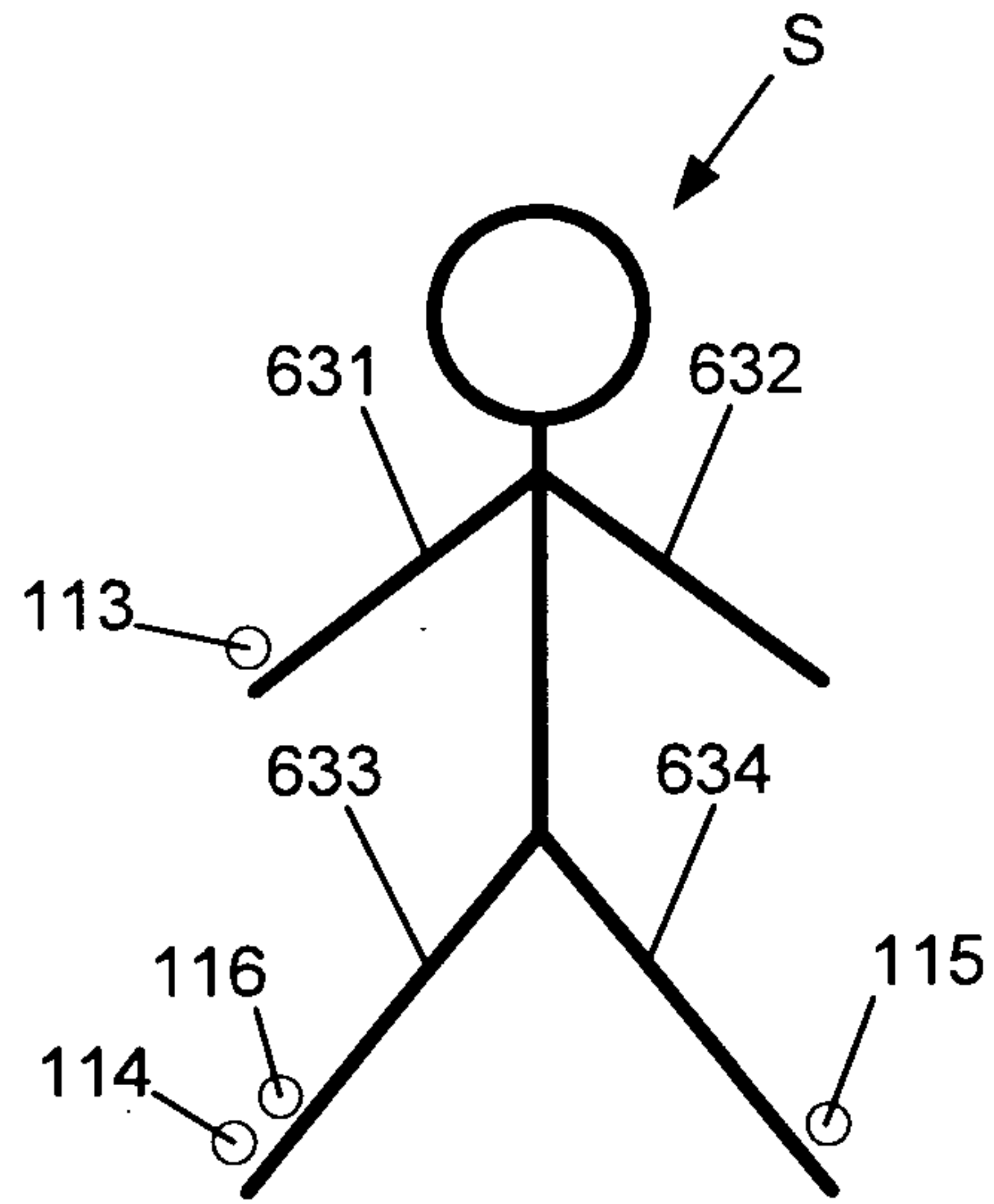


Fig. 5D

7/10

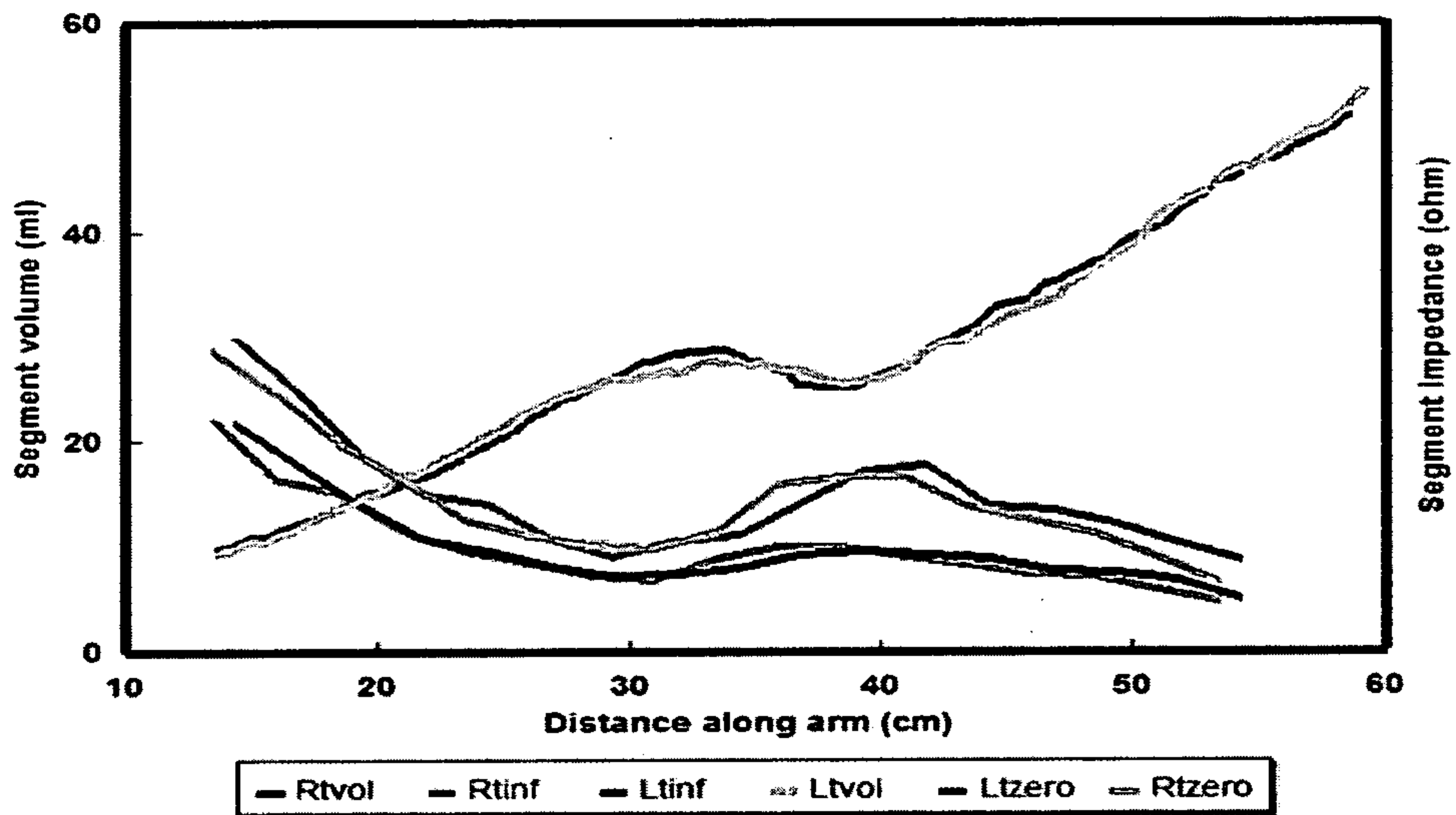


Fig. 6A

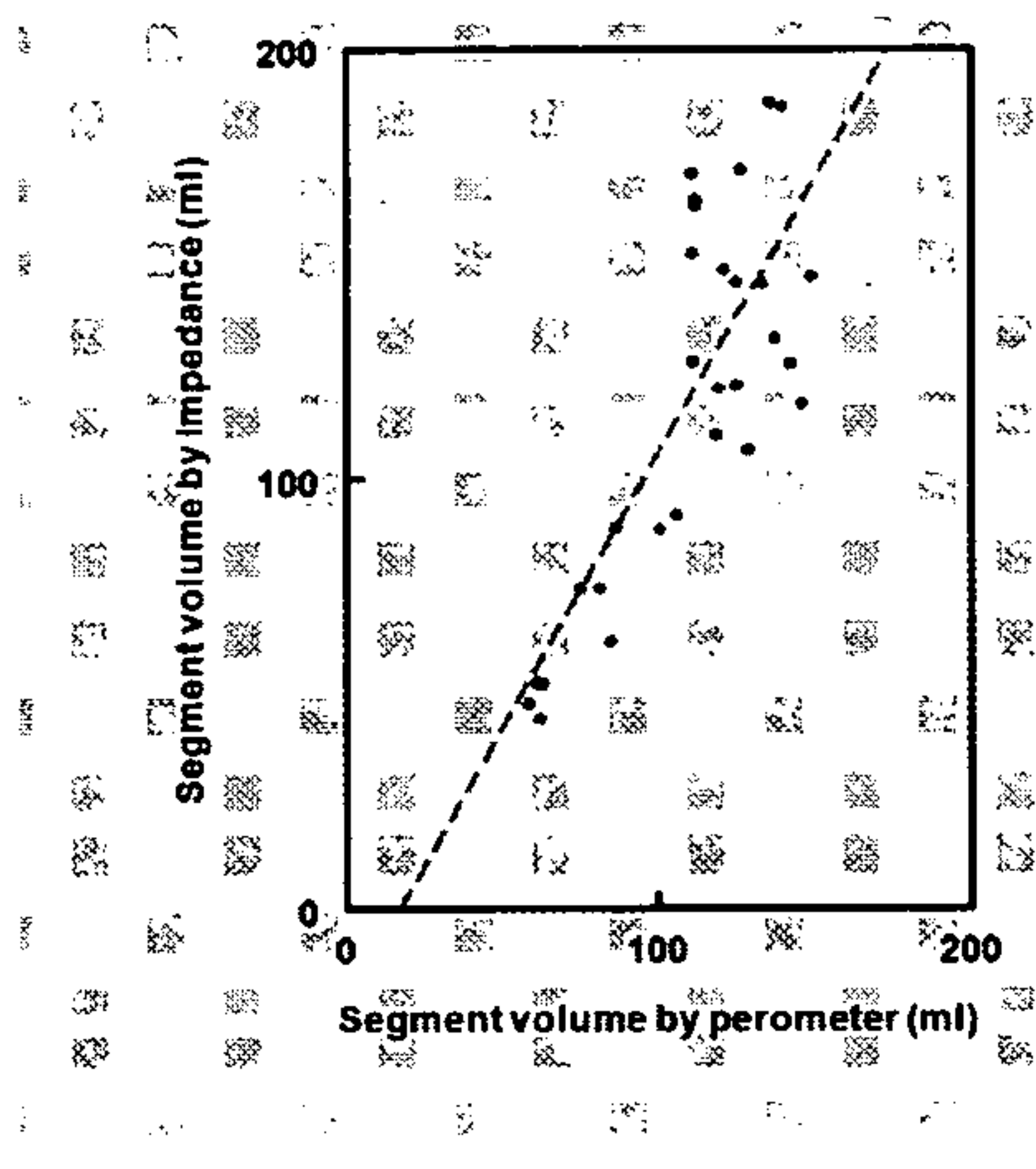


Fig. 6B

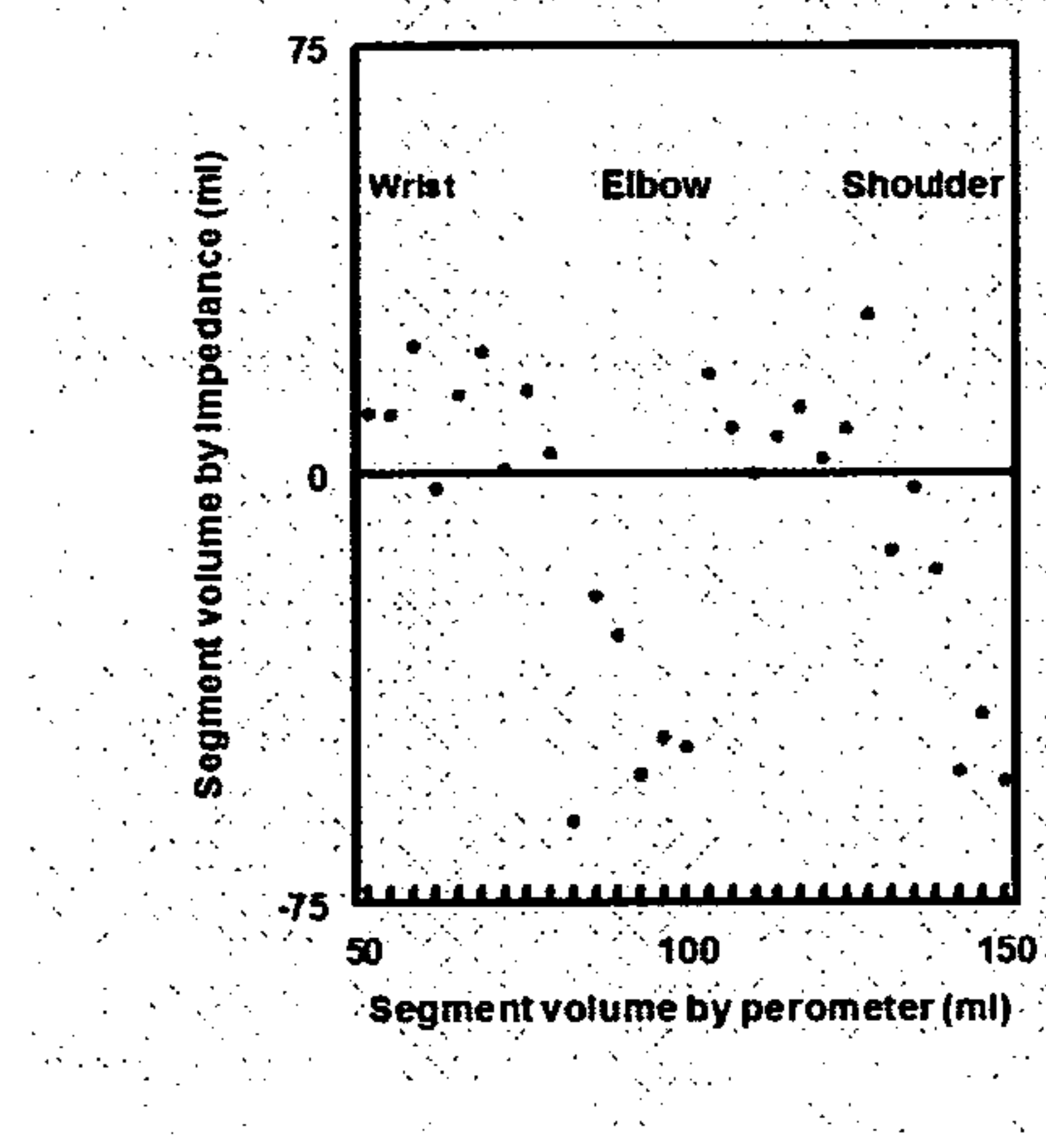


Fig. 6C

8/10

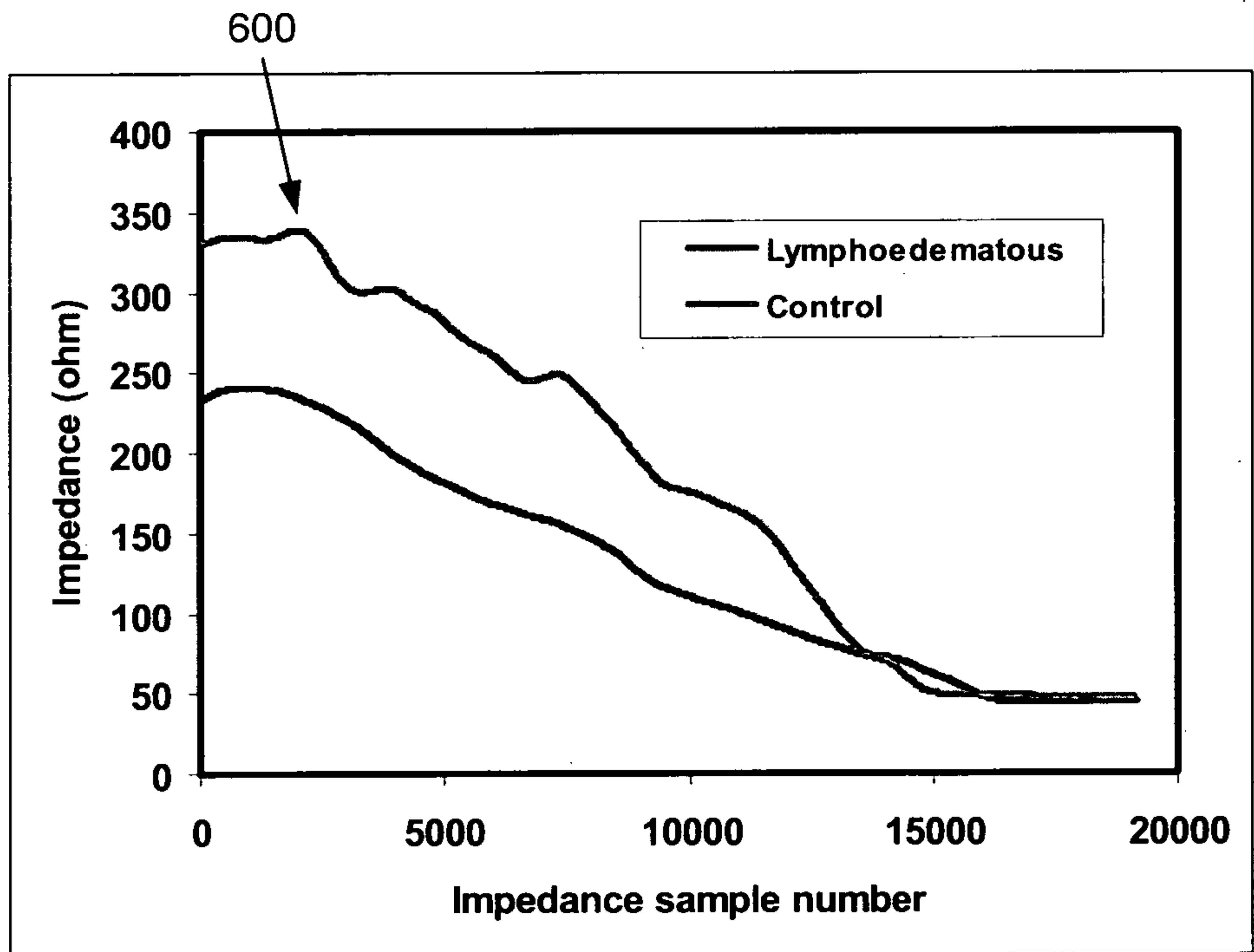


Fig. 6D

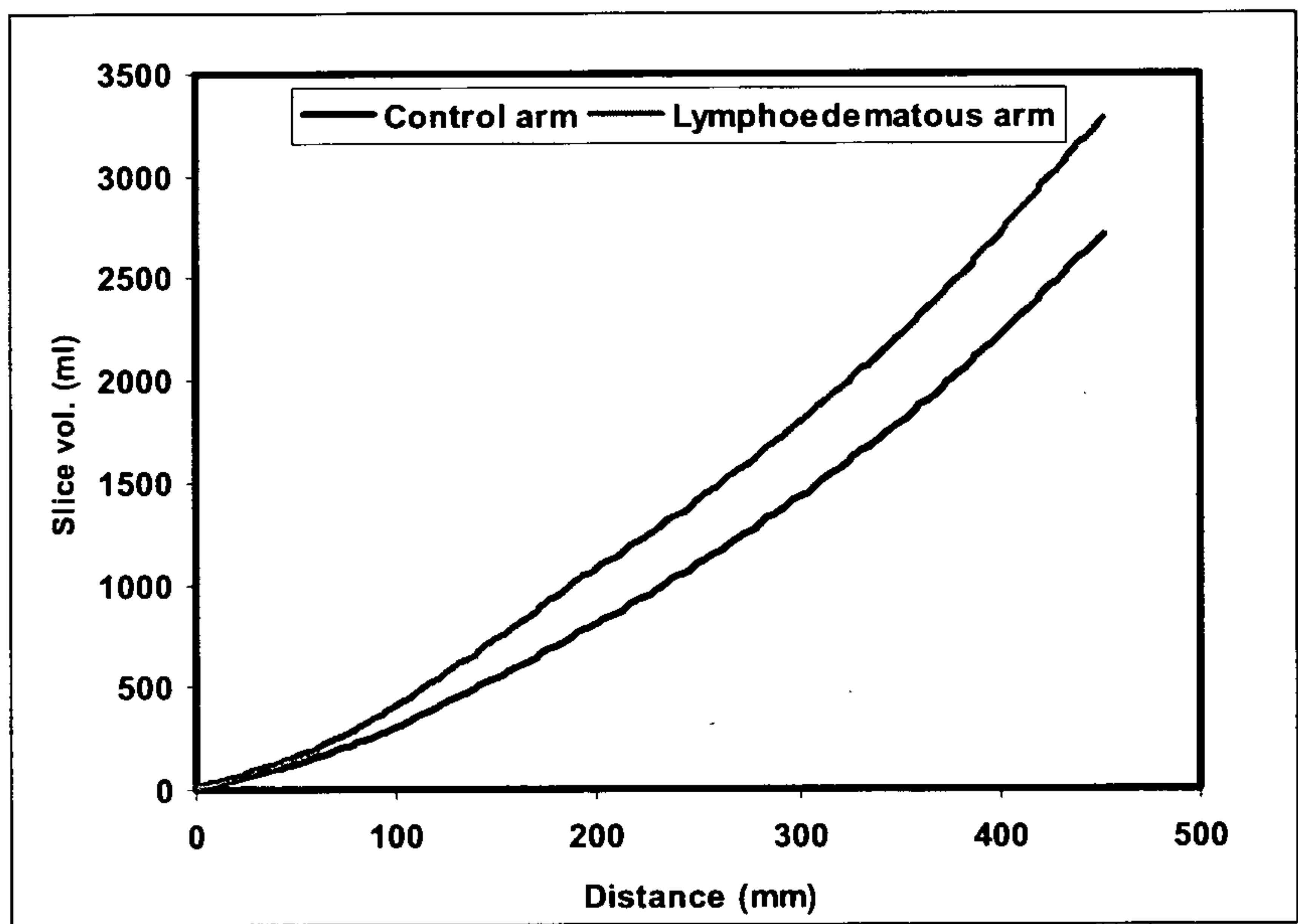
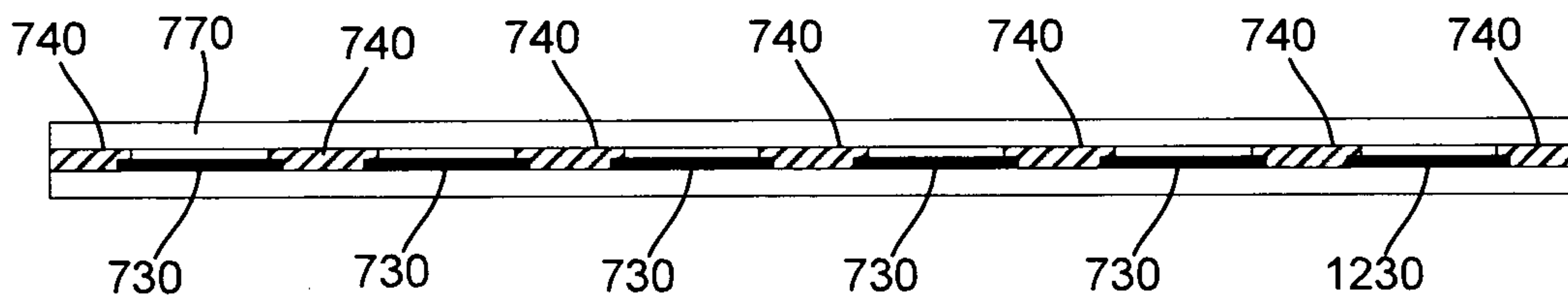
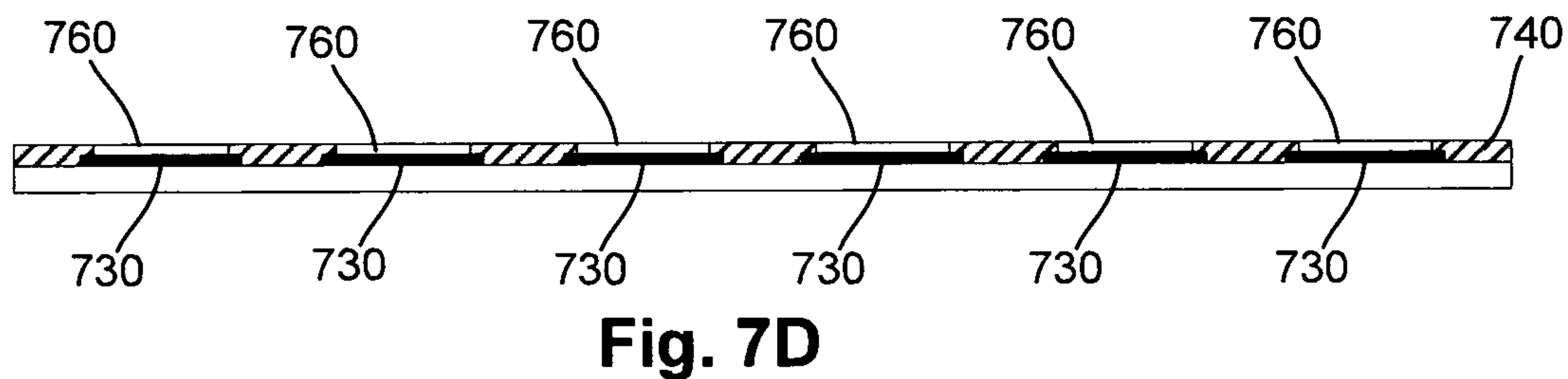
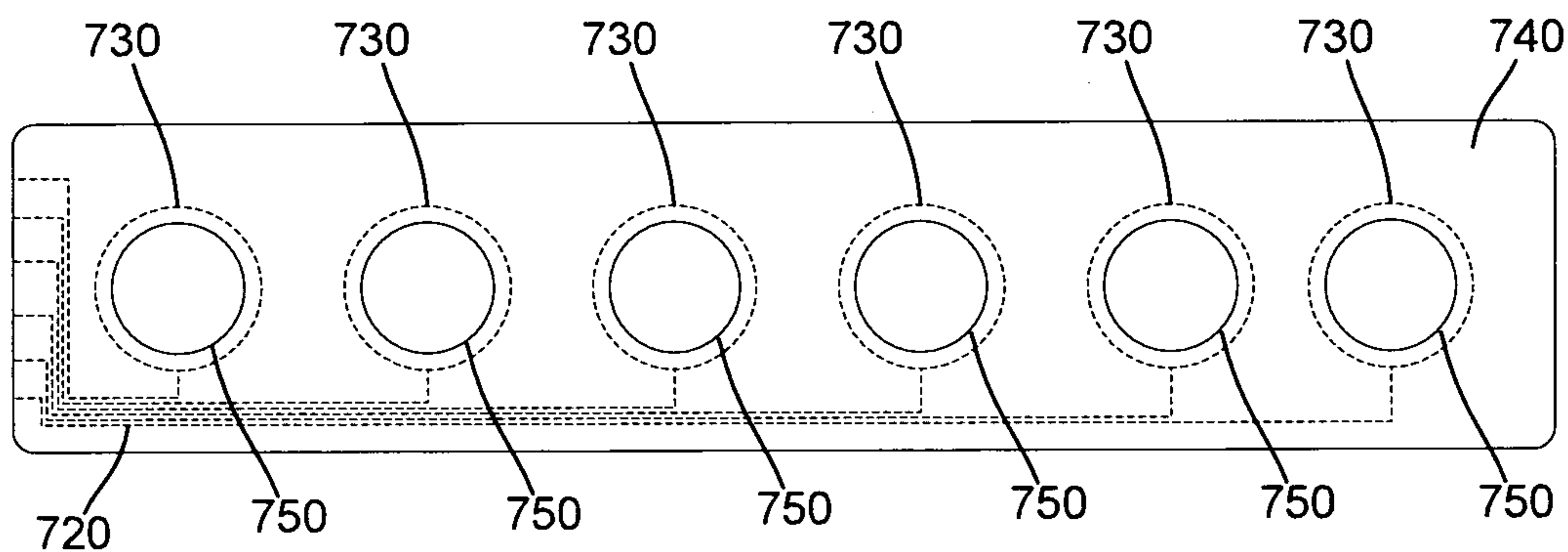
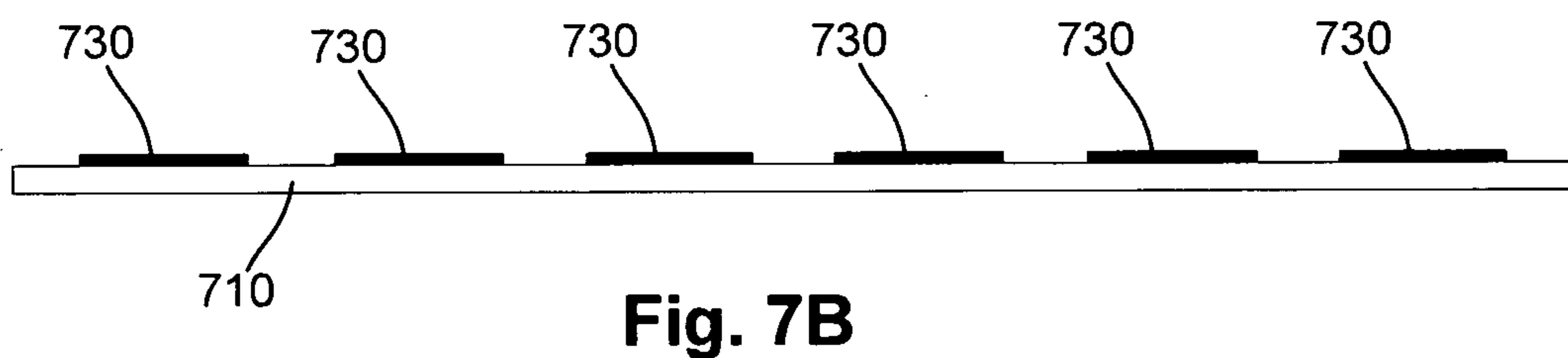
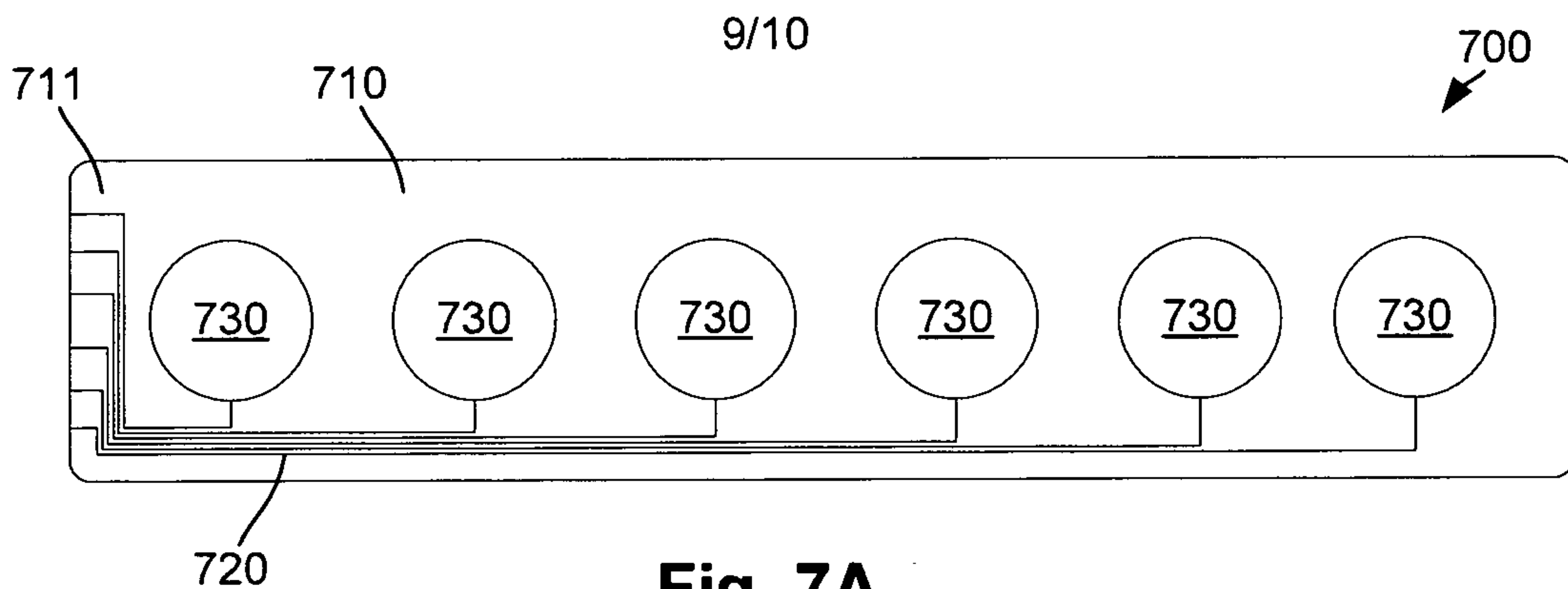
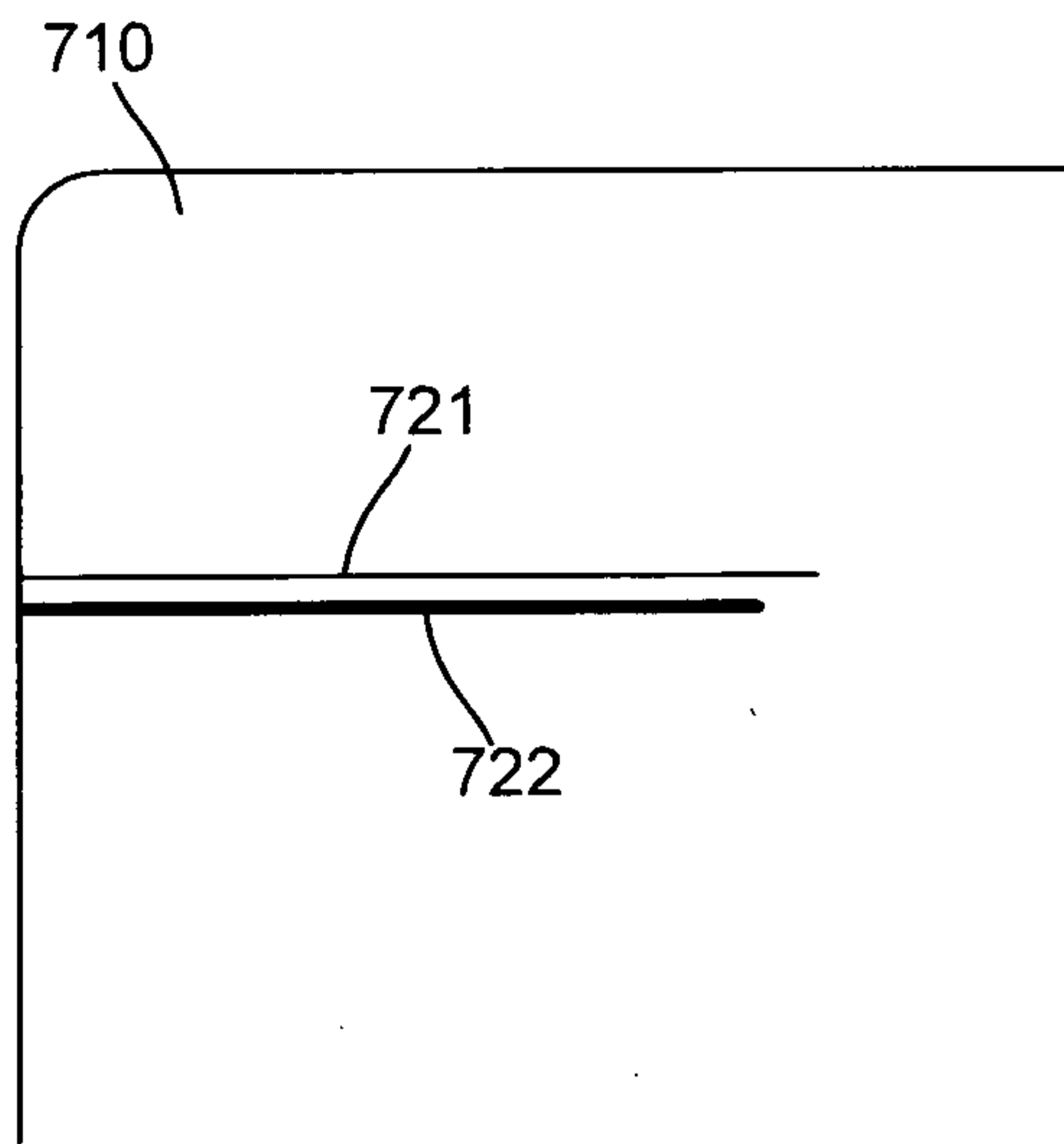


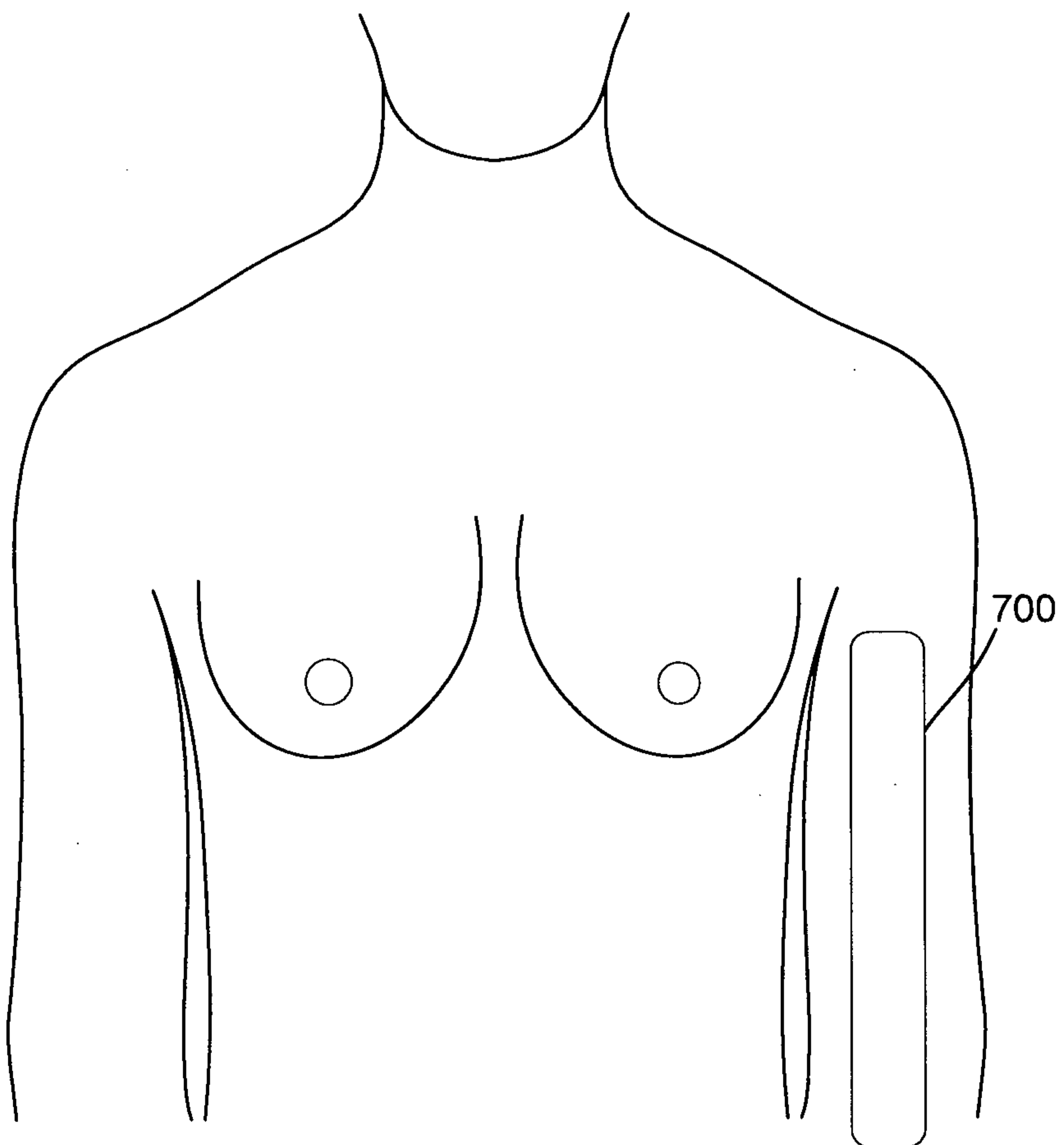
Fig. 6E



10/10



**Fig. 7F**



**Fig. 7G**

