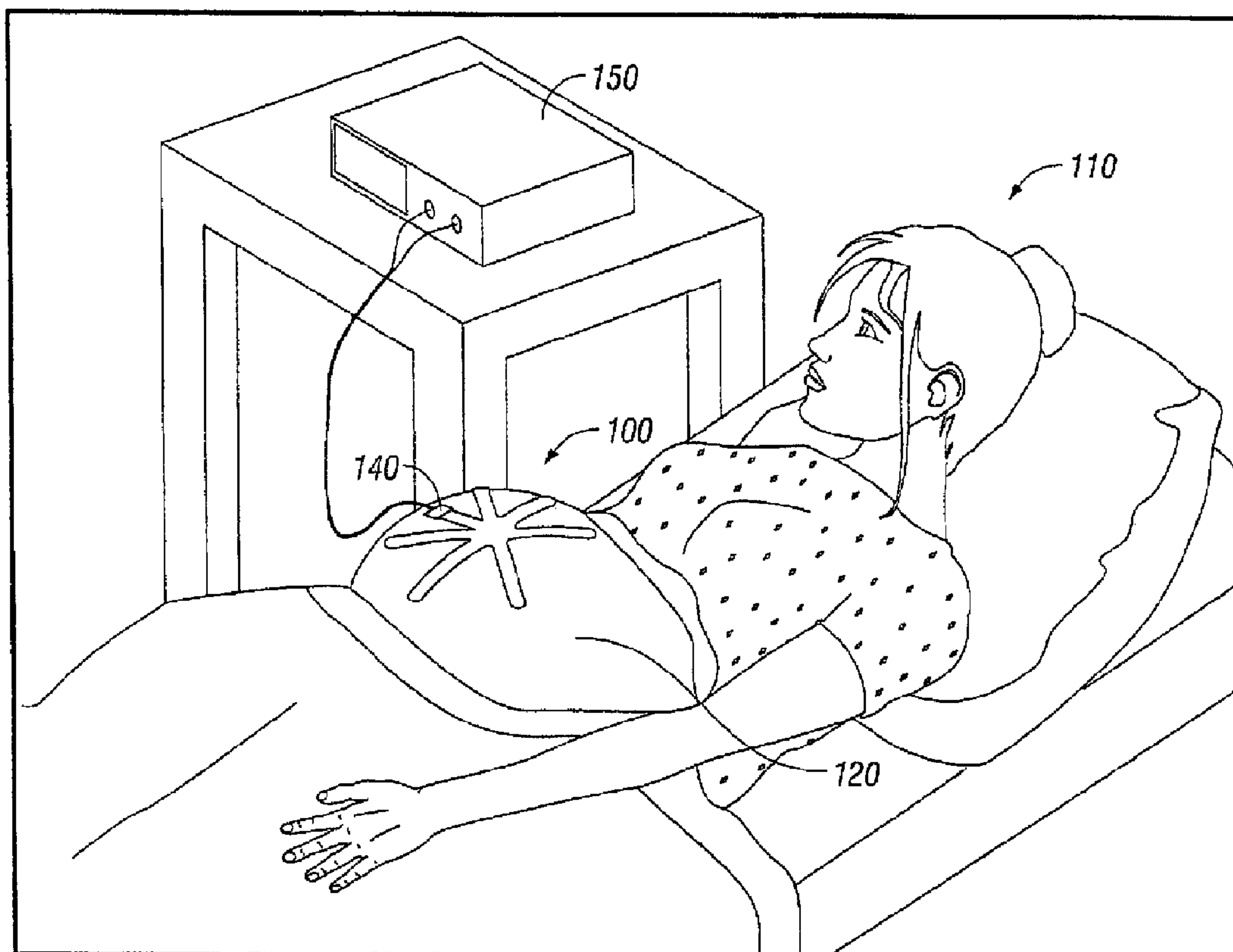




(22) Date de dépôt/Filing Date: 2007/04/23
 (41) Mise à la disp. pub./Open to Public Insp.: 2007/11/08
 (62) Demande originale/Original Application: 2 585 709
 (30) Priorités/Priorities: 2006/05/06 (US60/798,642);
 2006/09/28 (US11/529,651)

(51) Cl.Int./Int.Cl. *A61B 5/0448* (2006.01),
A61B 5/0408 (2006.01), *A61B 5/0492* (2006.01)
 (71) Demandeur/Applicant:
 TYCO HEALTHCARE GROUP LP, US
 (72) Inventeur/Inventor:
 MEYER, PETER, US
 (74) Agent: SMART & BIGGAR

(54) Titre : RANGEE RADIALE D'ELECTRODES
 (54) Title: RADIAL ELECTRODE ARRAY



(57) **Abrégé/Abstract:**

A sensor array apparatus for monitoring medical signals includes a flexible substrate adapted to generally conform to a topography of a skin surface. The flexible substrate includes a central portion arranged about a central focal point and a plurality of finger-like projections extending radially outwardly from the central portion. A medical electrode is disposed on at least one of the finger-like projections, preferably, each of the finger-like projections. Connector, in electrical communication with the medical electrode, is adapted to connect to an electronic system.

ABSTRACT

A sensor array apparatus for monitoring medical signals includes a flexible substrate adapted to generally conform to a topography of a skin surface. The flexible substrate includes a central portion arranged about a central focal point and a plurality of finger-like projections extending radially outwardly from the central portion. A medical electrode is disposed on at least one of the finger-like projections, preferably, each of the finger-like projections. Connector, in electrical communication with the medical electrode, is adapted to connect to an electronic system.

RADIAL ELECTRODE ARRAY

BACKGROUND

Technical Field

[0001] The present disclosure relates to a sensor array apparatus and, more particularly, relates to a sensor array apparatus for applying an array of electrodes to the body surface of a patient during, for example, maternal and fetal monitoring in connection with intrapartum monitoring and assessment of fetal and maternal well-being.

Description of Related Art

[0002] Medical electrodes are used to monitor bioelectric signals generated by the body. Electrodes are often covered or coated by a conductive gel, which serves as an electrochemical coupling agent and enhances the ability of the electrode to adhere to a patient's skin. Electrodes are connected to an electronic system, typically a signal monitoring system, and processed for use and analysis by medical personal.

[0003] The quality of the information obtained by each electrode is determined by the connection between the electrode and patient skin, the placement of the electrode on the patient relative to the signal source and consistent placement of electrodes relative to each other.

SUMMARY

[0004] Accordingly, the present disclosure is directed to an electrode sensor array apparatus useful in a diagnostic application, e.g., maternal and fetal monitoring, to collect

clinical data such as maternal electrocardiogram (ECG), maternal uterine electromyogram (EGH), fetal heart rate (FHR), fetal ECG, etc. The sensor array apparatus facilitates accurate and consistent electrode placement on the patient and ensures accurate and consistent placement of electrodes relative to each other during successive uses. The sensor array apparatus is adapted to conform to a non planar surface of the body.

[0005] In one preferred embodiment, a sensor array apparatus for monitoring medical signals includes a flexible substrate adapted to generally conform to a topography of a skin surface. The flexible substrate includes a central portion arranged about a central focal point and a plurality of finger-like projections extending radially outwardly from the central portion. A medical electrode is disposed on at least one of the finger-like projections, preferably, each of the finger-like projections. A connector is in electrical communication with the medical electrode and is adapted to connect to an electronic system.

[0006] At least one reference electrode may be disposed on the central portion of the substrate. The reference electrode may be generally aligned with respect to the central focal point of the central portion. The medical electrodes disposed on the finger-like projections are each a predetermined distance relative to the reference electrode when the flexible substrate is applied along the skin surface. Preferably, the predetermined distances for at least some of the electrodes are substantially the same.

[0007] The flexible substrate may be generally symmetrically arranged about an axis of symmetry whereby a finger like projection on one side of the axis of symmetry

has a corresponding finger-like projection on the opposite side of the axis of symmetry. With this arrangement, electrodes disposed on corresponding finger-like projections on each side of the axis of symmetry are spaced at substantially equal distances relative to the reference electrode when the flexible substrate is applied along the skin surface.

[0008] The flexible substrate may define at least one reference aperture for accommodating a body structure. The at least one reference aperture may be adapted to at least partially encapsulate umbilicus tissue. The flexible substrate also may define two reference apertures. With this arrangement, the orientation of the flexible substrate can be rotated to provide access to the electrical connector from either side of the patient tissue with one of the two reference apertures partially encapsulating umbilicus tissue.

[0009] The medical electrodes may be arranged as unipolar medical electrodes whereby bio-electric information is monitored between at least one of said unipolar electrodes and the reference electrode.

[00010] In an alternate embodiment, a sensor array apparatus for monitoring medical signals includes a flexible substrate defining a central focal point, a plurality of medical electrodes disposed on the periphery of the flexible substrate and at least one connector in electrical communication with the medical electrodes and adapted to connect to an electronic system. The flexible substrate may include an annular or enclosed member which generally defines a shape selected from a group consisting of a circle, triangle, square, rectangle, polygon, or oval. A plurality of tabs may extend outwardly from the annular member. Electrodes are preferably disposed on each tab and are arranged at substantially equal radial distances with respect to the central focal point.

A reference electrode is preferably mounted to the annular member of the substrate. The reference electrode may be annular in configuration and extend along the annular member of the flexible substrate. With this arrangement, the medical electrodes are each spaced at substantially equal distances with respect to the reference electrode.

[00011] In an alternative embodiment, a second flexible substrate may be provided and is adapted for positioning within the first mentioned substrate. The reference electrode is disposed on the second flexible substrate whereby bio-electric information is monitored between at least one of the medical electrodes and the reference electrode. The second flexible substrate defines at least one reference aperture adapted to at least partially encapsulate umbilicus tissue. The reference electrode extends around the inner perimeter of the reference aperture and each of the medical electrodes are a predetermined distance along the skin relative to the reference electrode, whereby the predetermined distance for each electrode is substantially the same.

[00012] In an embodiment, there is provided a sensor array apparatus for monitoring medical signals, which comprises: a flexible substrate defining a central focal point; a plurality of medical electrodes disposed on the periphery of the flexible substrate; and at least one connector in electrical communication with the medical electrodes and adapted to connect to an electronic system; wherein the flexible substrate defines at least two reference apertures for accommodating a body structure; and wherein the at least two reference apertures permit the connector to interface with the electronic system from either side of patient tissue.

BRIEF DESCRIPTION OF THE DRAWINGS

[00013] Various embodiments of the sensor array apparatus are described herein with reference to the drawings wherein:

[00014] **FIG. 1** is a perspective view of a sensor array apparatus for monitoring maternal and fetal bioelectrical signals applied to the abdomen of a full-term pregnant woman;

[00015] **FIG. 2A** is a view of the sensor array apparatus of **FIG. 1** illustrating the finger-like projections extending radial outwardly from the central portion;

[00016] **FIG. 2B** is a view of an alternating embodiment of a sensor array with asymmetrically arranged finger-like projections;

[00017] **FIG. 3** is a view of an alternate embodiment of a sensor array apparatus incorporating a reference electrode surrounding a single reference aperture;

[00018] **FIGS. 4A and 4B** are alternate embodiments of a sensor array apparatus incorporating two reference apertures;

[00019] **FIGS. 5A and 5B** are views of the sensor array apparatus of **FIG. 4A** applied to the abdomen of a full-term pregnant woman;

[00020] **FIG. 6A** is a view of another alternate embodiment of the sensor array apparatus incorporating a central focal point;

[00021] **FIGS. 6B, 6C, and 6D** are views of alternate embodiments of the sensor array apparatus of **FIG. 6A**;

[00022] **FIG. 7** is a view of another embodiment of the sensor array apparatus incorporating first and second flexible substrate associated with the central focus point;

[00023] **FIG. 8** is a view of another embodiment of sensor array apparatus with a second flexible substrate defining a slot aperture; and

[00024] **FIG. 9** is a view of another embodiment of sensor array apparatus with first and section first section of the flexible substrate associated with the central portion and a second portion of the flexible substrate associated with the periphery.

DETAILED DESCRIPTION

[00025] Embodiments of the presently disclosed sensor array apparatus will now be described in detail with reference to the drawing wherein like reference numerals identify similar or identical elements throughout the several views.

[00026] In general, the sensor array apparatus of the present disclosure includes medical electrodes to measure or collect data concerning electrical activity generated within the body. The type of electrode selected, and the placement of the electrode on the body, will determine the type of electrical activity measured. Any type of electrode known in the art may be used with the embodiments of the sensor array apparatuses described herein. The electronic system may be any system known in the art capable of receiving electronic signals. In one preferred embodiment, the sensor array apparatus is a component of an electronic system used in the non-invasive monitoring of maternal-fetal

health to extract various parameters including maternal ECG, fetal ECG, maternal and fetal heart rate etc . . . to ascertain the health and well being of the mother and fetus including such parameters of maternal and fetal distress, progress of labor, estimation of delivery time, etc. Other applications of the sensor array apparatus are also envisioned.

[00027] Referring now to **FIG. 1**, a first embodiment of a sensor array apparatus in accordance with the present disclosure will be discussed. In **FIG. 1**, sensor array apparatus **100** is illustrated applied to the abdomen **120** of a pregnant female **110** in connection with a maternal and fetal monitoring procedure. Medical electrodes of sensor array apparatus **100** are in contact with the abdomen **120** and in electrical communication with electronic system **150** through connector **140**. Electronic system **150** receives bio-electrical medical signals from the sensor array apparatus **100**. The bio-electrical medical signals contain information including maternal and fetal ECG and maternal EMG and/or any of the maternal and fetal parameters mentioned hereinabove.

[00028] With reference now to **FIG. 2A**, sensor array apparatus **100** includes flexible substrate **202**, medical electrodes **E1-E8**, reference electrode **R**, grounded reference electrode **G**, and connector **240**. Flexible substrate **202** is constructed of a flexible material capable of generally conforming to the topography of a skin surface. Preferably, flexible substrate **202** is formed from a material which is sufficiently flexible and sufficiently strong to maintain its position on the patient and the relative positioning of electrodes **E1 – E8**. Suitable materials include Mylar™ or any other biaxially-oriented polyethylene terephthalate polyester films, Teslin™ or any other polyolefin silica blend, natural woven fibers, synthetic non-woven material or paper.

[00029] Flexible substrate **202** includes central portion **204** and at least one finger-like projection **206A-206F**. Central portion **204** may define central focal point, represented as numeral **208**, on the flexible substrate **202**. Central focal point **208** corresponds to the central location of substrate **202**. Finger-like projections **206A- 206F** extend radially outwardly from central portion **204**. In one preferred embodiment, flexible substrate **202** contains six finger-like projections **206A- 206F**. However, it is envisioned that flexible substrate **202** may have more or less than six finger-like projections **206**.

[00030] The specific application determines the shape of the flexible substrate **202** and the number and arrangement of the finger-like projections **206**. In **FIG. 2A**, the flexible substrate **202** and finger-like projections **206A-206F** are generally arranged in a symmetrical arrangement with respect to the axis of symmetry **222** which divides the flexible substrate **202** into two sections. Finger-like projections **206A, 206C, 206E** are disposed on one side of the axis of symmetry **222** and opposing finger-like projection **206B, 206D, 206F** are disposed on the opposite side of the axis of symmetry **222**. Thus, sensor apparatus **100** including substrate **202**, and, more particularly, the electrode arrangement, is symmetrically arranged about the axis of symmetry **222**.

[00031] In an alternate embodiment, flexible substrate **202** may be scored or separated along the axis of symmetry **222** into two separate sensor arrays. Such arrangements may facilitate placement of sensor array apparatus on the abdomen. Each half of the sensor array may contain a central portion adjacent a central focal point, finger-like projections extending radially outward from the central portion, medical electrode and a connector adapted to connect to an electronic system.

[00032] Returning again to **FIG. 2A**, each finger-like projections **206A-206F** includes at least one electrode **E1-E8** in electrical communication with connector **240** which is adapted to connect to an electronic system. Any means for mounting electrodes **E1-E8** to substrate **202** are envisioned. One single electrode **E1, E2, E5, E4** is disposed on four of the six finger-like projections **206C-206F**. Two electrodes **E6, E7** and **E3, E8** are respectively disposed on finger-like projections **206A, 206B**. Electrodes **E1-E8** are each a predetermined distance relative to reference electrode **R**. In **FIG. 2A**, the respective distances between the reference electrode **R** and electrodes **E1, E2, E4** and **E5** are substantially equivalent. Similarly, the respective distances between the reference electrode **R** and the electrode pair **E7, E8** and the electrode pair **E3, E6** are substantially equivalent. Thus, when flexible substrate **202** is applied to a non-linear or curved skin surface such as the abdomen of a pregnant female subject, the relative distances of the corresponding electrodes **E1-E8** remain proportionally substantially equivalent with respect to reference electrode **R** and with respect to the remaining corresponding electrodes. Thus, this arrangement provides for accurate and consistent electrode placement on the curved skin surface, which thereby enhances the reliability and accuracy of the clinical data acquired during the monitoring process.

[00033] In a preferred system or application, electrodes **E1-E8** are unipolar or monopolar electrodes. In a unipolar system, electrodes **E1-E8** measure electrical activity relative to reference electrode **R**. Reference electrode **R** is generally disposed in central portion **204** of flexible substrate **202** or generally aligned with central focal point **208** of the flexible substrate **202**. Electrical activity at each electrode **E1-E8** is measured with

respect to the reference electrode **R**. A single reference electrode **R** is illustrated although it is envisioned that multiple reference electrodes may be utilized.

[00034] With continued reference to **FIG. 2**, conductive traces **231** place the electrodes **E1-E8**, **R**, **G** and the connector **240** in electrical communication. Conductive traces **231** can be printed directly onto flexible substrate **202** if the flexible substrate **202** is a dielectric. Alternatively, conductive traces **231** may be printed on a separate carrier sheet if flexible substrate **202** is not a dielectric material. Various methods of printing electrical traces **231** include silk screen printing, photoengraving, chemical etching, laser etching or mask electrode. Stretchable conductors, such as stretchable gold strip conductors, may be used with a flexible substrate that exhibits elongation properties as will be discussed.

[00035] Flexible substrate **202** may include one or more shielding layers to provide electrical shielding for at least a portion of the conductive traces **231** and/or one or more of the electrodes **E1-E8**, **R**.

[00036] In use of sensor array apparatus **100** as depicted in **FIG. 2A**, flexible substrate **202** is applied to, e.g., the abdomen of the female pregnant subject. In one preferred arrangement, the umbilicus is used as a reference point and flexible substrate **202** is positioned onto the abdomen such that central focal point **208** is substantially aligned with the umbilicus. Flexible substrate **202** is arranged about the midline of the patient's abdomen (i.e., the vertical line extending up the abdomen and intersecting the umbilicus) with corresponding finger-like projections **206A-F** and electrodes **E1-E8** symmetrically arranged about the patient's midline. The electronic system is activated

and data is collected by the electrodes **E1-E8**. This procedure may be repeated several times if desired. With each application, the umbilicus may be used as a reference point for application of flexible substrate **202** thereby ensuring accurate and consistent placement of the electrodes for successive data acquisition procedures.

[00037] In an alternative embodiment, flexible substrate **202** of sensor array apparatus **100** may exhibit properties of elongation. With this arrangement, placement on the abdomen may be accomplished by utilizing an electrode placement template. The electrode placement template details the desired arrangement of the electrode array. Thus, when placed on the abdomen, electrode placement locations may be marked on the patient's skin with the use of the template. Each marked location is a predetermined distance along the skin relative to the reference electrode. The marked locations for each unipolar electrode are a predetermined distance from the marked location for the reference electrode. The flexible substrate is elongated and placed on the abdomen such that each electrode is positioned on the marked locations. Multiple templates may ensure proper placement on various sized patients.

[00038] With a flexible substrate **202** incorporating elongation characteristics, means may be provided for preventing conductive traces **231** from breaking when flexible substrate **202** is elongated. Such means may include incorporating a zigzag pattern (e.g., accordion-structure or bellows) within conductive traces **231**, which straightens when flexible substrate **202** is elongated. Alternatively, portions of flexible substrate **202** and corresponding traces **231** may be folded over such that the folded section provides additional length when the substrate is elongated. As a further

alternative, conductive traces **231** may be formed of a material such as gold which exhibits a limited range of stretching or elongation.

[00039] Flexible substrate **202** also may be formed of material with an elastic memory. With an elastic memory material, flexible substrate **202** will remain under tension when elongated, but, is biased to return to its original shape. Placing flexible substrate **202** under constant tension would enable the measurement of tension changes due to physical movements of the abdomen by the placement of a strain gauge device on the flexible substrate **202**. Flexible substrate **202** may also be formed with materials without elastic memory. Materials without elastic memory exhibit elongation properties but once elongated, remain elongated and do not attempt to return to the original shape and length.

[00040] Furthermore, flexible substrate **202** may also be formed with multiple materials with or without elongation properties. Creation of elongation zones would enable some portions of the substrate to stretch, such as the finger-like projections, while sections without elongation properties would maintain in a fixed relationship to each other.

[00041] Referring now to **FIG. 2B**, finger-like projections **206** of the sensor array apparatus **200** need not be symmetrically arranged. Offset finger-like projections **206a**, **206b** are not symmetric about the axis of symmetry **222**. Offset finger-like projections **206a**, **206b** extend radially outward from the central portion **208**. Electrodes **E6**, **E7** and **E3**, **E8**, while disposed on the periphery of the flexible substrate **202**, are not symmetrically arranged.

[00042] Referring now to **FIG. 3**, another embodiment of sensor array apparatus **300** is disclosed. Sensor array apparatus **300** contains flexible substrate **302** which defines reference aperture **305**. Flexible substrate **302** is designed for placement on the abdomen of a pregnant patient and reference aperture **305** is configured to at least partially encapsulate a body structure such as umbilicus tissue. According to the present disclosure, partially encapsulating a body structure is the placement of a material adjacent to a body structure such that at least a portion of the material partially surrounds or partially encircles the body structure.

[00043] Placement of substrate **302** on the patient, with the umbilicus centered in the reference aperture **305**, ensures proper and ideal placement of the electrodes **E1-E8**, **R**, **G** on the patient. In general, the body structure is inserted through or positioned under reference aperture **305** to allow the flexible substrate **302** to be placed on the patient skin and accommodate the natural topography or curvature of the body. The body structure may serve as a reference for the medical personnel to ensure proper and consistent placement of the sensor array. The location of the aperture **305** ensures that all electrodes are properly placed relative to the body structure. The shape of aperture **305** may be adjusted to accommodate the specific shape of the body structure and may aid medical personnel by indicating the proper orientation.

[00044] In the embodiment of **FIG. 3**, electrodes **E1- E8** are also unipolar. The electronic system (not shown) connects to connector **340** and measures the signal at each electrode relative to a reference electrode **R**. Reference electrode **R** surrounds or encircles the reference aperture **305** and the portion of the umbilicus contained therewithin. The electronic system measures the average electrical activity generated

between each electrode **E1-E8** and reference electrode **R** at a particular moment in time. The sensor array apparatus **300** provides the electronic system with the average electrical activity at a plurality of locations on the abdomen.

[00045] Reference aperture **305** and reference electrode **R** permit sensor apparatus **300** to be oriented such that the connector **340** can be accessed from either side of the patient. Placement of electrodes **E6, E7** between the umbilicus and the pubic region will place the connector on one side of the patient while placement of electrodes **E8, E3** between the umbilicus and the pubic region will place the connector on the opposite side of the patient. In both orientations, the electrodes placement pattern on the abdomen is substantially identical.

[00046] **FIG. 4A** illustrates another embodiment of sensor array apparatus **400**. Flexible substrate **402** defines two reference apertures **405a 405b**, each aperture capable of at least partially encapsulating umbilicus tissue. Reference electrode **R** and grounded reference electrode **G** are disposed on the central portion between the two reference apertures **405a, 405b**. In this embodiment, the proper location of the reference electrode **R** and the grounded reference electrode **G** is above the umbilicus. The two reference apertures **405a, 405b** on opposing sides of the reference electrode **R** and grounded reference electrode **G** allow substantially identical electrode placement patterns on the abdomen, with the reference electrode **R** and the grounded reference electrode **G** above the umbilicus, regardless of which side the patient the electrical connector **440** is placed.

[00047] **FIG. 4B** illustrates finger-like projections **202** with elongated reference apertures **499a, 499b** in the sensor array apparatus **400**. The body structure may be

placed anywhere within the elongated reference apertures **499a, 499b**. The elongated reference aperture **499a, 499b** permits the placement of the reference electrode **R** to vary relative to the body structure.

[00048] **FIGS. 5A and 5B** illustrate placement of sensor array apparatus **400** of **FIG. 4A** on the abdomen **520** of the pregnant patient **510**. In **FIG. 5A**, reference aperture **505b** closest to pubis region **522** is positioned such that umbilicus **521**, or at least the portion of the umbilicus extending above abdomen **520**, protrudes through, or is positioned under, reference aperture **505b**. Connector **540** is accessible from the left side of the patient. In **FIG. 5B**, reference aperture **505a** located closest to the pubis region **522** is positioned such that umbilicus **521**, or at least the portion of the umbilicus extending above abdomen **520**, is protruding through reference aperture **505a**. The connector **540** is accessible from the right side of the patient. Reference electrode (not shown) and the grounded reference electrode (not shown), both located between the reference apertures **505a 505b**, are properly positioned above the umbilicus in both configurations.

[00049] **FIG. 6A** illustrates another embodiment of the present disclosure. Sensor array apparatus **600** includes flexible substrate **602** including annular member **604** and a plurality of radial tabs **606** extending radially outwardly from the annular member **604**. Annular member **604** defines enlarged central aperture **605** arranged about central focal point **608** which is the proximate center of the flexible substrate **602**. A plurality of medical electrodes **E1-E8, R** is peripherally disposed with respect to the annular member **604**. Eight electrodes **E1-E8** are disposed on radial tabs **606** adjacent the outer periphery of annular member **604** and an annular reference electrode **R** is disposed adjacent the

inner periphery of the annular member **604**. Reference electrode **R** encircles aperture **605** thereby placing each of the electrodes **E1-E8** disposed on radial tabs **606** at substantially equal distances with respect to reference electrode **R**.

[00050] Referring now to **FIGS. 6B, 6C** and **6D**, flexible substrate **602** may be various shapes and sizes. In **FIG. 6B**, flexible substrate **602** is generally rectangular shaped with outwardly depending tabs **606**. Electrical connector **640** may be disposed on the short side of the rectangle. Eight electrodes **E1-E8** are disposed on radial tabs **606** of the flexible substrate **602**. A reference electrode **R**, deposited on the inner periphery of enclosed member **604** of flexible substrate **602**, extends around the perimeter of the aperture **605**.

[00051] Flexible substrate **602** in **FIG. 6C** is generally square with the electrical connector **640** disposed on a side. Eight electrodes **E1-E8** are disposed on radial tabs **606** and reference electrode **R**, is disposed adjacent the inner periphery of enclosed member **604** of flexible substrate **602** encircling aperture **605**.

[00052] The flexible substrate **602** in **FIG. 6D** is generally hexagonal in shape with the electrical connector **640** located at one vertex. Six electrodes **E1-E4, E7-E8** are disposed on tabs **606** of flexible substrate **602**. Reference electrode **R**, disposed on the inner periphery of flexible substrate **602**, extends around the perimeter of the aperture **605**. Two electrodes **E5-E6** are disposed on the inner periphery of the apparatus on inwardly finger-like projections **606a, 606b** of the flexible substrate **602**.

[00053] In **FIGS. 6A, 6B, 6C** and **6D**, the general shape of the flexible substrate **602** define a central focal point **608**, with the central focal point **608** adjacent the

geometrical center of each shape. Proper positioning of the sensor array apparatus **600** on the abdomen of a pregnant female places the umbilicus adjacent the central focal point **608**. In use, the electrodes **E1-E8** disposed on tabs **606** of flexible substrate **602** are distributed on the abdomen in predetermined positions relative to each other and the reference electrode **R**. The average electrical activity between the reference electrode **R** and each unipolar medical electrode **E1-E8** is measured by the electronic system.

[00054] Flexible substrate **602** may define one or more apertures with the shape of the apertures being independent of the overall shape of the flexible substrate **602**. The apertures in **FIGS. 6A, 6B and 6C** may be circular, rectangular with rounded corners and square. In **FIG. 6D**, the shape of the aperture **606** is defined by tabs **606a,b** which extend into the aperture **607** and positions the electrodes **E5, E6** on the inner periphery of flexible substrate **602**.

[00055] Referring now again to **FIG. 6A**, the minimum size of the aperture **605** is determined by the curvature of the skin surface and the body structure the aperture **605** must accommodate. The abdomen of a first-trimester pregnant female is relatively flat compared to the abdomen of a full term pregnant female and may require no aperture or a small aperture for the umbilicus. On the other hand, the abdomen of a full term pregnant female, with an extended umbilicus, may require a large aperture and the flexible substrate may be narrow to accommodate the curvature of the abdomen.

[00056] The maximum size of the aperture is determined by the shape of the flexible substrate, the number of electrodes, the number and width of the traces printed on the flexible substrate, the location of the electrodes on the abdomen, and the

predetermined distance between the reference electrode **R** and each of the medical electrodes **E1-E8**.

[00057] With continued reference to **FIGS. 6A, 6B, 6C** and **6D**, electrodes **E1-E8** disposed on the flexible substrate **602** are arranged in various configurations. In this particular application, the placement of a sensor array apparatus **600** on the abdomen of a pregnant female, electrodes **E1-E8** are generally symmetrically arranged about an axis of symmetry **622** with the reference electrode a fixed distance along the skin from each electrode **E1-E8**. For other applications, the electrodes may not be symmetrically arranged.

[00058] With particular reference to **FIGS. 6A** and **6C**, electrodes **E1-E8** are positioned a substantially similar predetermined radial distance **D** with respect to the central focal point **608**.

[00059] With particular reference to **FIGS. 6B** and **6D**, electrodes are distributed into two groups with the electrodes in each group at a substantially similar predetermined radial distance with respect to the central focal point **608** although the distance for each electrode group is not the same. In **FIG. 6B** electrodes **E3, E4, E5** and **E6** are a fixed distance **D1** from the central focal point **608** and electrodes **E1, E2, E7** and **E8** are a fixed distance **D2** from the central focal point **608**, wherein **D1** does not equal **D2**. In **FIG. 6D**, electrodes **E1, E2, E3, E4, E7** and **E8** are a fixed distance **D3** from the central focal point **608** and the second group containing electrodes **E5, E6** are a distance **D4** from the central focal point **608**, wherein **D3** does not equal **D4**.

[00060] Referring still to **FIGS. 6A, 6B, 6C** and **6D**, electrodes **E1- E8** are unipolar electrodes. The electronic system measures the signal at each unipolar electrode **E1-E8** relative to a reference electrode **R**. In **FIGS. 6A, 6B, 6C** and **6D**, the reference electrode **R** surrounds or encircles the aperture **605** and places a portion of the reference electrode **R** a fixed distance from each of the unipolar electrodes **E1-E8**. In **FIGS. 6A, 6B** and **6C**, the distance from each electrode **E1-E8** and the reference electrode **R** on each sensor array **600** is substantially the same, with the respective distances equal to **D5, D6, D7**. In each sensor array apparatus, the distances **D5, D6, D7** between the electrodes **E1-E8** and the reference electrode **R** must be sufficiently large to obtain a signal which represents the average electrical activity generated between each electrode and the reference electrode **R** at a particular moment in time. The plurality of electrodes disposed on sensor array **600** provides the electronic system with the average electrical activity at a plurality of locations on the abdomen.

[00061] Referring now to **FIG. 6D**, the distance from each electrode **E1-E8** and the reference electrode **R** is not equal. The first group of electrodes **E1-E4, E7-E8** is a substantially similar distance **D8** from the reference electrode **R** while the second group of electrodes **E5, E6** are located a substantially similar distance **D9** from the reference electrode **R**, wherein the two distances **D8, D9** are not equal.

[00062] **FIG. 7** illustrates another embodiment of the present disclosure. Sensor array apparatus **700** includes a separate second flexible substrate **702A**, associated with the central focal point **708**. Reference electrode **R** and grounded reference electrode **G** are disposed on second flexible substrate **702A** and are in electrical communication with a second connector **741** adapted to connect with an electronic system (not shown). The

electronic system (not shown) monitors bio-electrical information between the reference electrode **R** and each of the medical electrodes **E1-E8**.

[00063] The second flexible substrate **702A** defines reference aperture **705** adapted to at least partially encapsulate umbilicus tissue. In **FIG. 7**, the reference aperture **705** fully encapsulates a portion of the umbilicus. The reference electrode **R**, disposed on the second flexible substrate **702A** extends around the perimeter of the reference aperture **705**. A reference electrode **R** and the grounded reference electrode **G** are disposed on the second flexible substrate **702A**, adjacent the reference aperture **705**.

[00064] The first and second flexible substrates **702**, **702A** are both placed on the abdomen relative to the umbilicus. The first flexible substrate **702** is positioned such that central focal point **708** is adjacent the umbilicus and second flexible substrate **702A** is positioned such that at least a portion of the umbilicus is positioned within the reference aperture **705**. Since the first and second flexible substrates **702**, **702A** are both positioned relative to the umbilicus, the reference electrode **R** is a predetermined distance from each of the medical electrodes **E1-E8**. In **FIG. 7**, the predetermined distance for each electrode **D10** is substantially the same. Referring now to **FIG. 7**, the shape of second flexible substrate **702A** assists medical personnel with the proper orientation of the second flexible substrate **702A**. In this embodiment, the proper placement of the grounded reference electrode **G** is below the umbilicus. Pointing the vertex of second flexible substrate **702A** toward the pubis region places the grounded reference electrode **G** in the proper position relative to the umbilicus.

[00065] FIG. 8 illustrates another alternate embodiment of the present disclosure. In FIG. 8, the distances **D11**, **D12**, **D13**, **D14** between the reference electrode **R** and electrodes in four sets of electrode are substantially the same, while the distance for each set of pairs are not equal (i.e. $D11 \neq D12 \neq D13 \neq D14$.)

[00066] FIG. 9 illustrates another embodiment. Sensor array apparatus **900** includes a flexible substrate **902**, a first section **902A** associated with the central focal point **908** and a second section **902B** associated with the outer periphery. The first and second sections **902A**, **902B** are mechanically connected and define at least one aperture between the first and second sections **902A**, **902B**. In the preferred embodiment, first and second sections **902A**, **902B** are connected through respective radial links **923**, **924**, **925** and define three apertures **907**, **908**, **909**.

[00067] First section **902A** also defines reference aperture **905**. As discussed in the prior embodiments, reference aperture **905** at least partially encapsulates a portion of the umbilicus when placed on the abdomen of a pregnant female. In use, the placement of the umbilicus within the reference aperture **905** ensures proper placement of the sensor array **900** on the abdomen.

[00068] Reference electrode **R** and grounded reference electrode **G** are disposed on the first section **902A** of the flexible substrate **902**. In this particular embodiment, reference electrode **R** surrounds reference aperture **905** insuring the distance between the reference electrode **R** and each of the medical electrodes, **E1-E8**, is a predetermined distance and the predetermined distance for each electrode **E1-E8** is substantially the

same. The reference electrode **R** and the grounded reference electrode **G** are in electrical communications by traces **231** printed on the flexible substrate **902**.

[00069] It is to be understood that the specific embodiments detailed in the foregoing description are not intended to be limiting. Other possible modifications will be apparent to those skilled in the art.

[00070] It is still further envisioned for several of the disclosed embodiments to be used in combination with each other.

What is claimed is:

1. A sensor array apparatus for monitoring medical signals, which comprises:
a flexible substrate defining a central focal point; a plurality of medical electrodes disposed on the periphery of said flexible substrate; and
at least one connector in electrical communication with said medical electrodes and adapted to connect to an electronic system;
wherein said flexible substrate defines at least two reference apertures for accommodating a body structure; and
wherein the at least two reference apertures permit said connector to interface with the electronic system from either side of patient tissue.
2. The sensor array apparatus according to claim 1 wherein said flexible substrate generally defines a shape selected from a group consisting of: circle, triangle, square, rectangle, polygon, and an oval.
3. The sensor array apparatus according to claim 1 wherein said electrodes are disposed at substantially equal predetermined radial distances with respect to said central focal point.
4. The sensor array apparatus according to claim 1 wherein said electrodes are generally symmetrically arranged on said flexible substrate about an axis of symmetry whereby a medical electrode on one side of said axis of symmetry has a corresponding medical electrode on the opposite side of said axis of symmetry.

5. The sensor array apparatus according to claim 1 further including a reference electrode.
6. The sensor array apparatus according to claim 5 wherein said reference electrode extends around the inner perimeter of said flexible substrate.
7. The sensor array apparatus according to claim 6 wherein said plurality of medical electrodes are each spaced at substantially equal distances with respect to said reference electrode.
8. The sensor array apparatus according to claim 1 further including:
a second flexible substrate associated with said central focal point; and
a reference electrode disposed on said second flexible substrate whereby bio-electric information is monitored between at least one of said medical electrodes and said reference electrode.
9. The sensor array apparatus according to claim 8 wherein said second flexible substrate associated with said central focal point and said flexible substrate associated with the periphery of said central focal point are in mechanical communication.
10. The sensor array apparatus according to claim 5 wherein said reference electrode extends around the inner perimeter of said reference aperture and each of said

medical electrodes are a predetermined distance along the skin relative to said reference electrode, whereby said predetermined distance for each electrode is substantially the same.

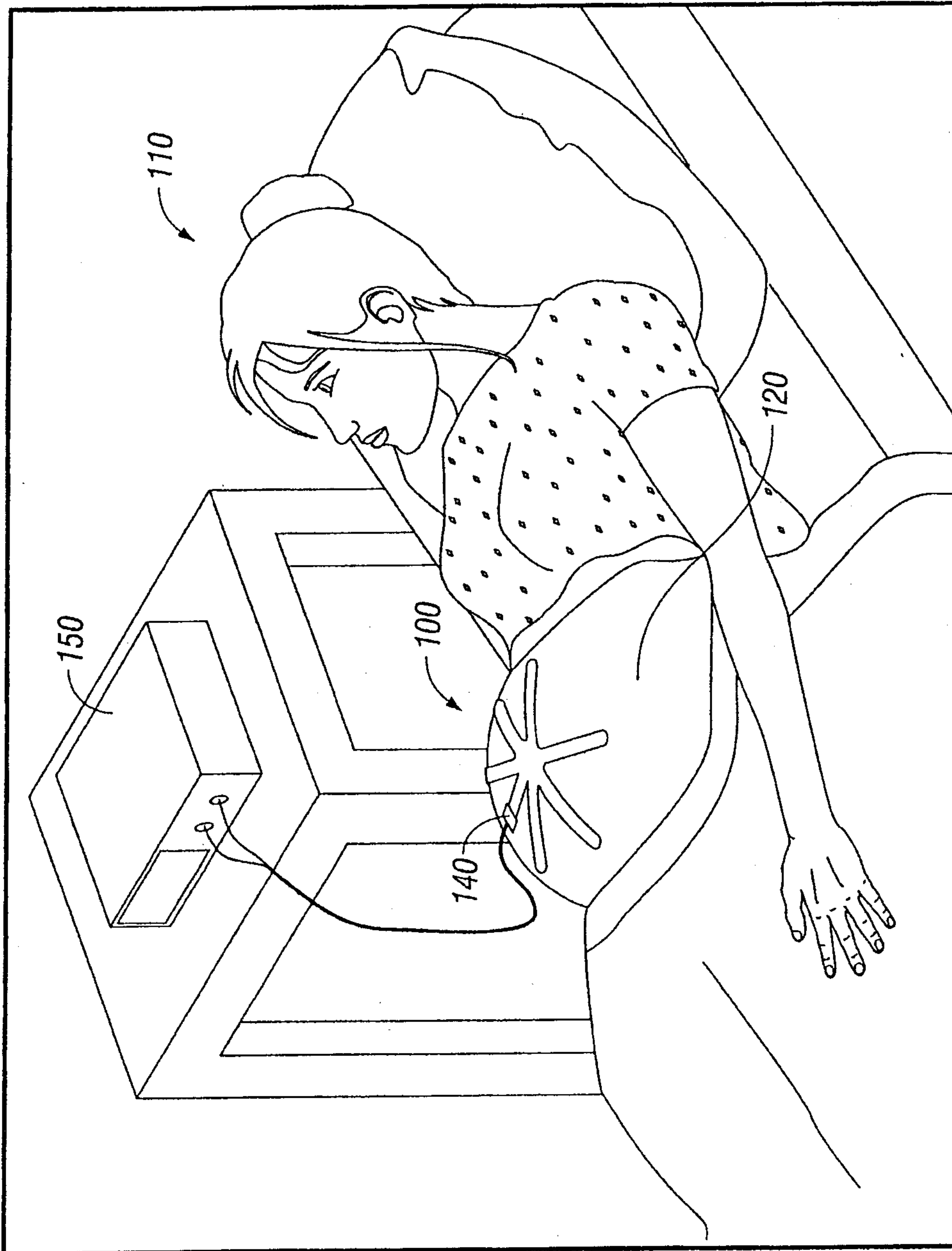


FIG. 1

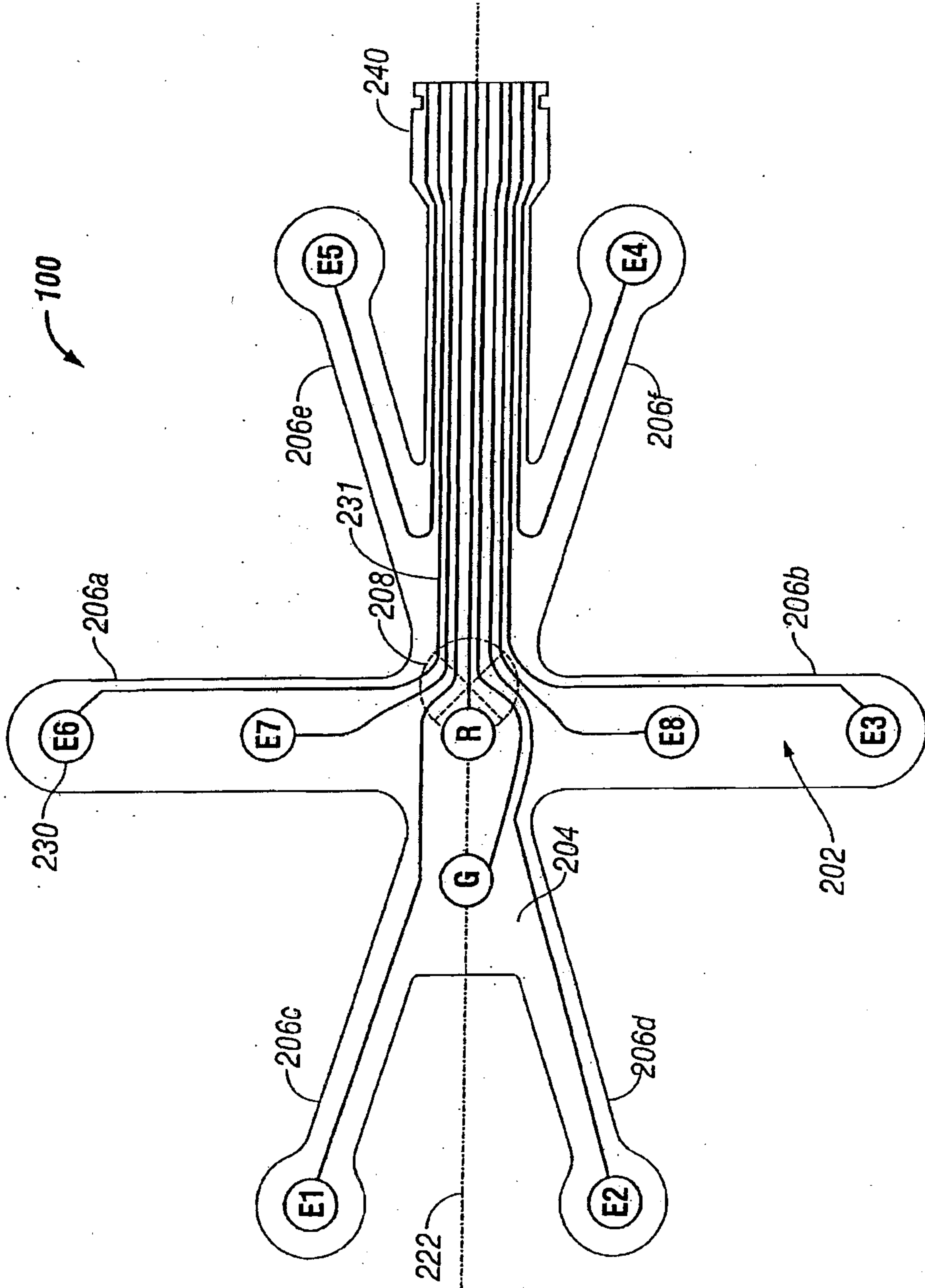


FIG. 2A

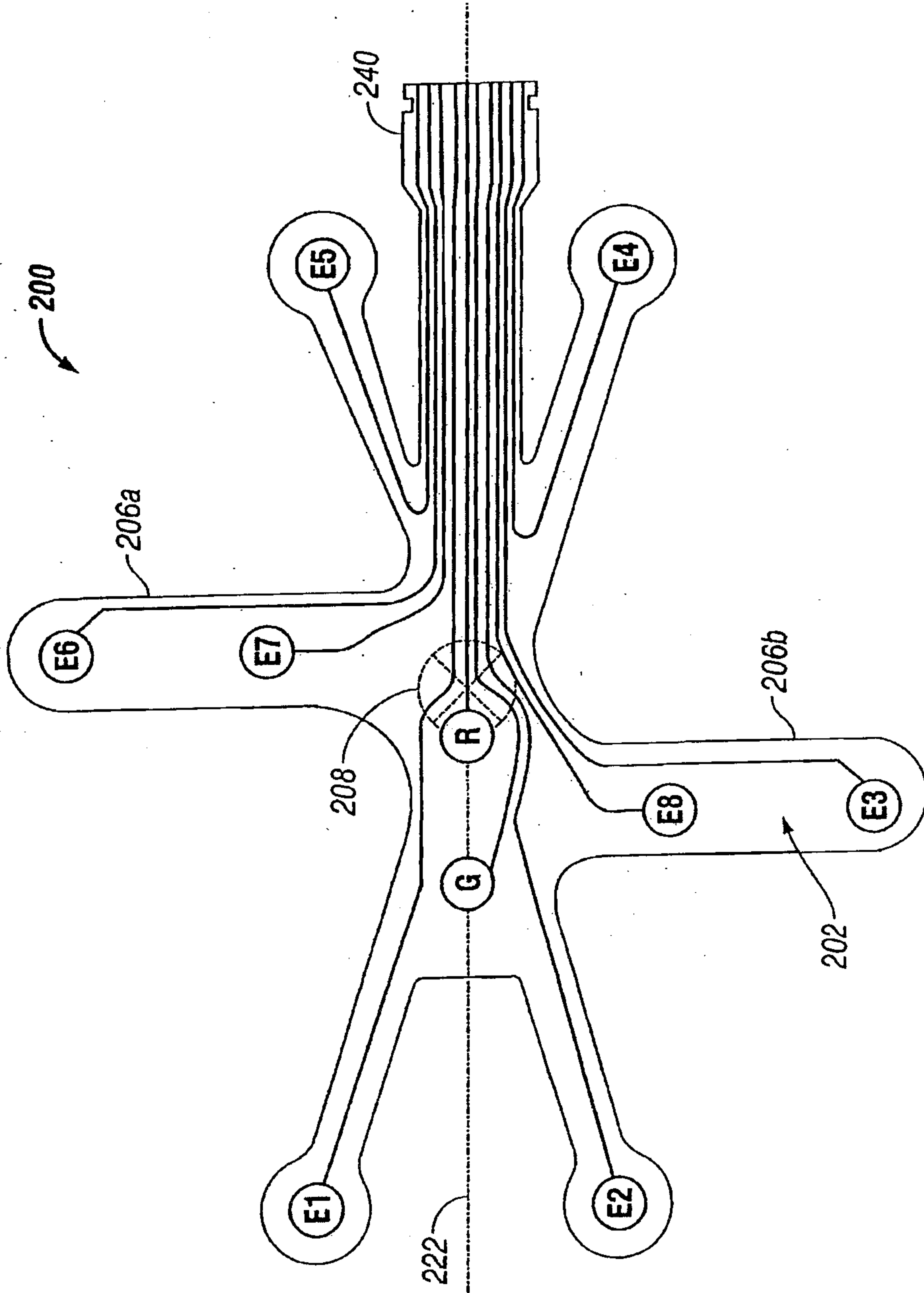


FIG. 2B

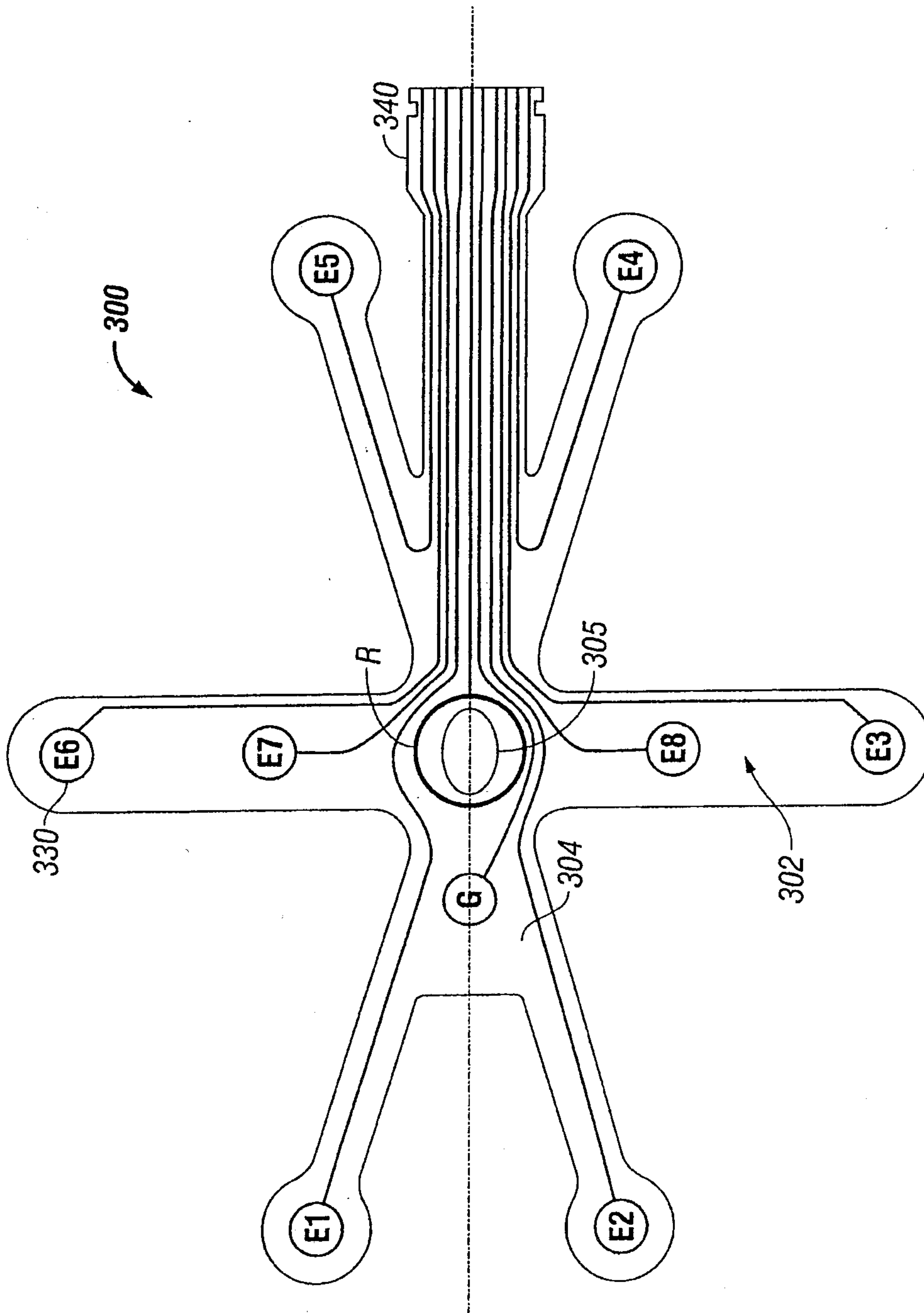


FIG. 3

5/14

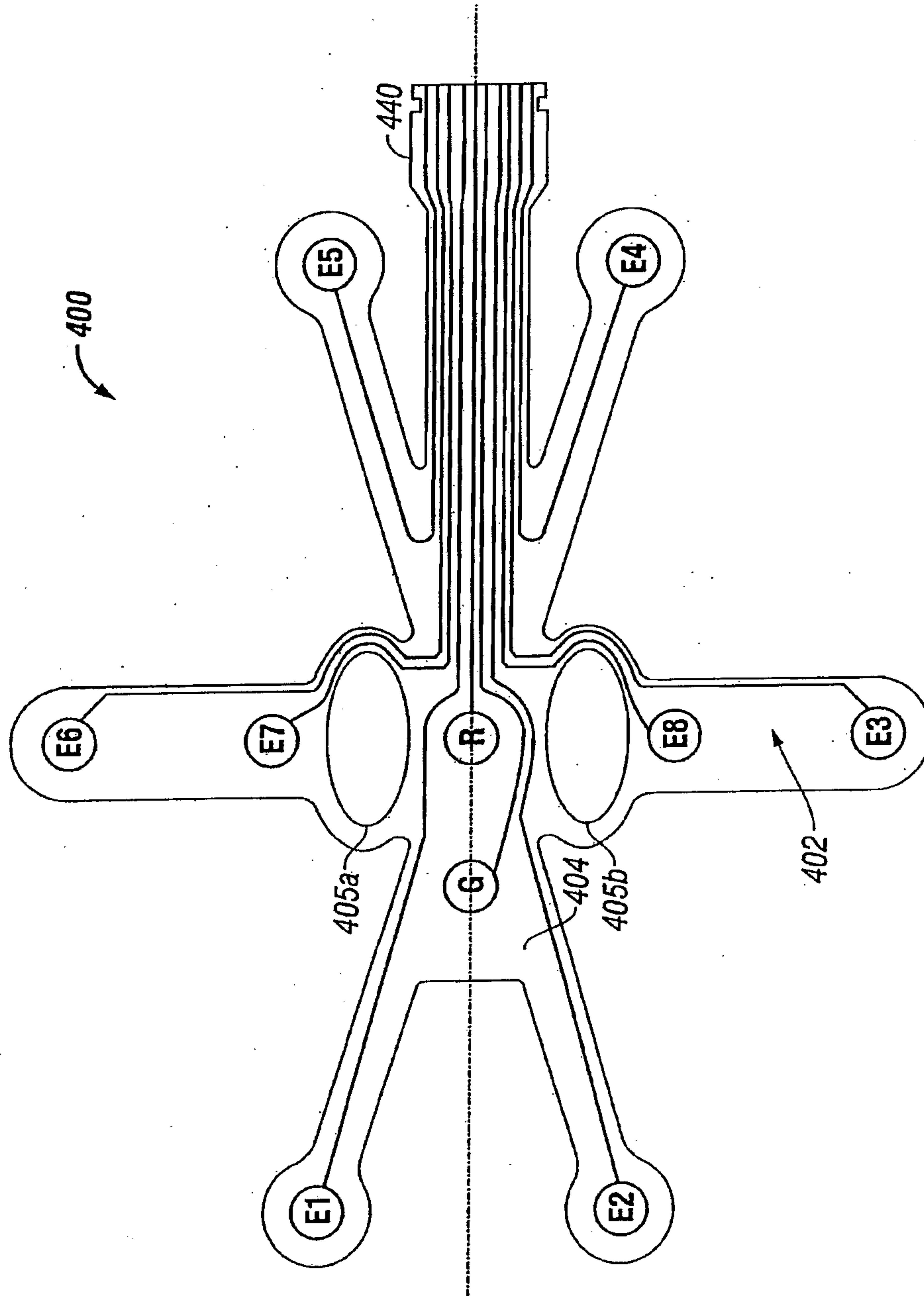


FIG. 4A

6/14

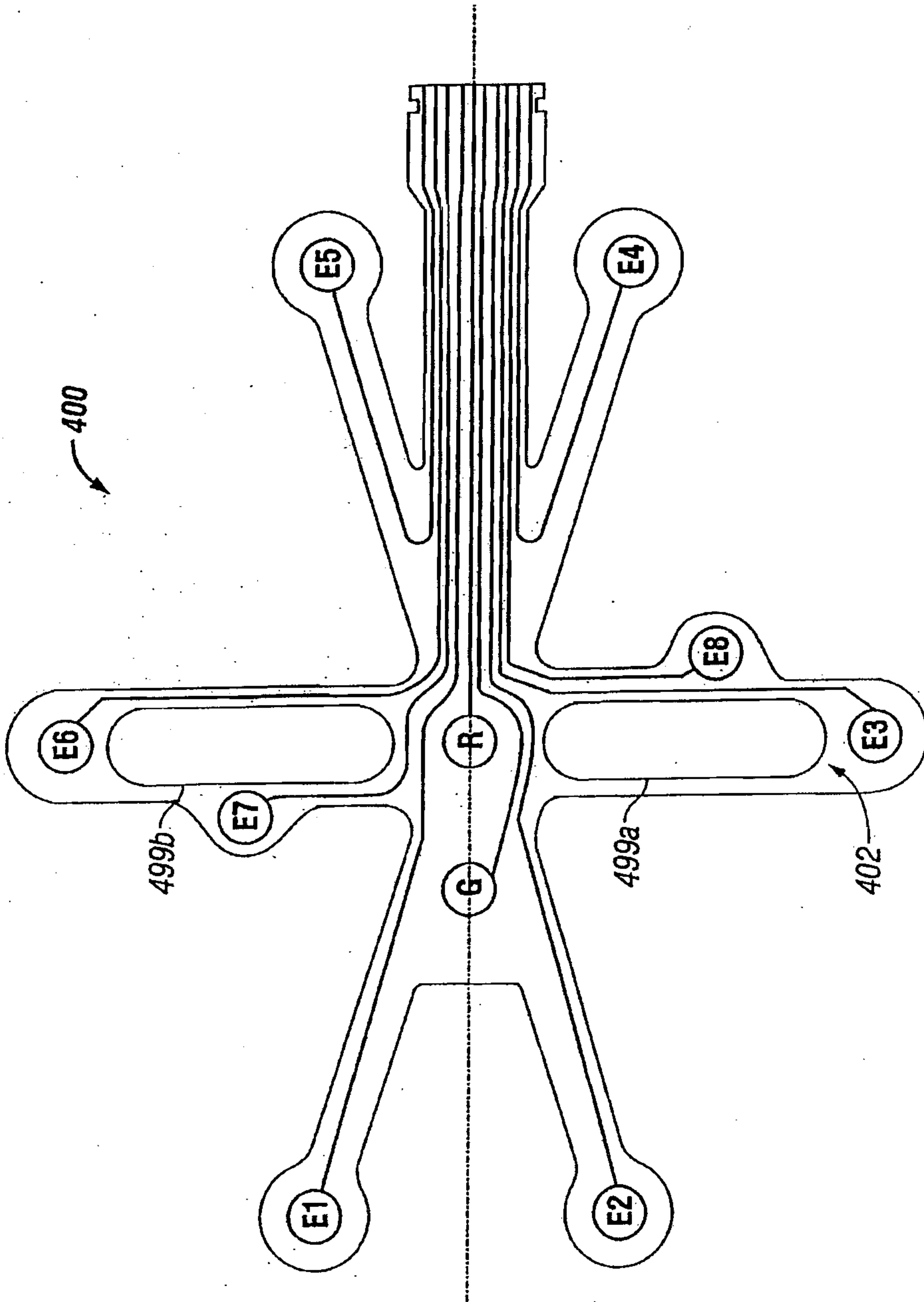


FIG. 4B

7/14

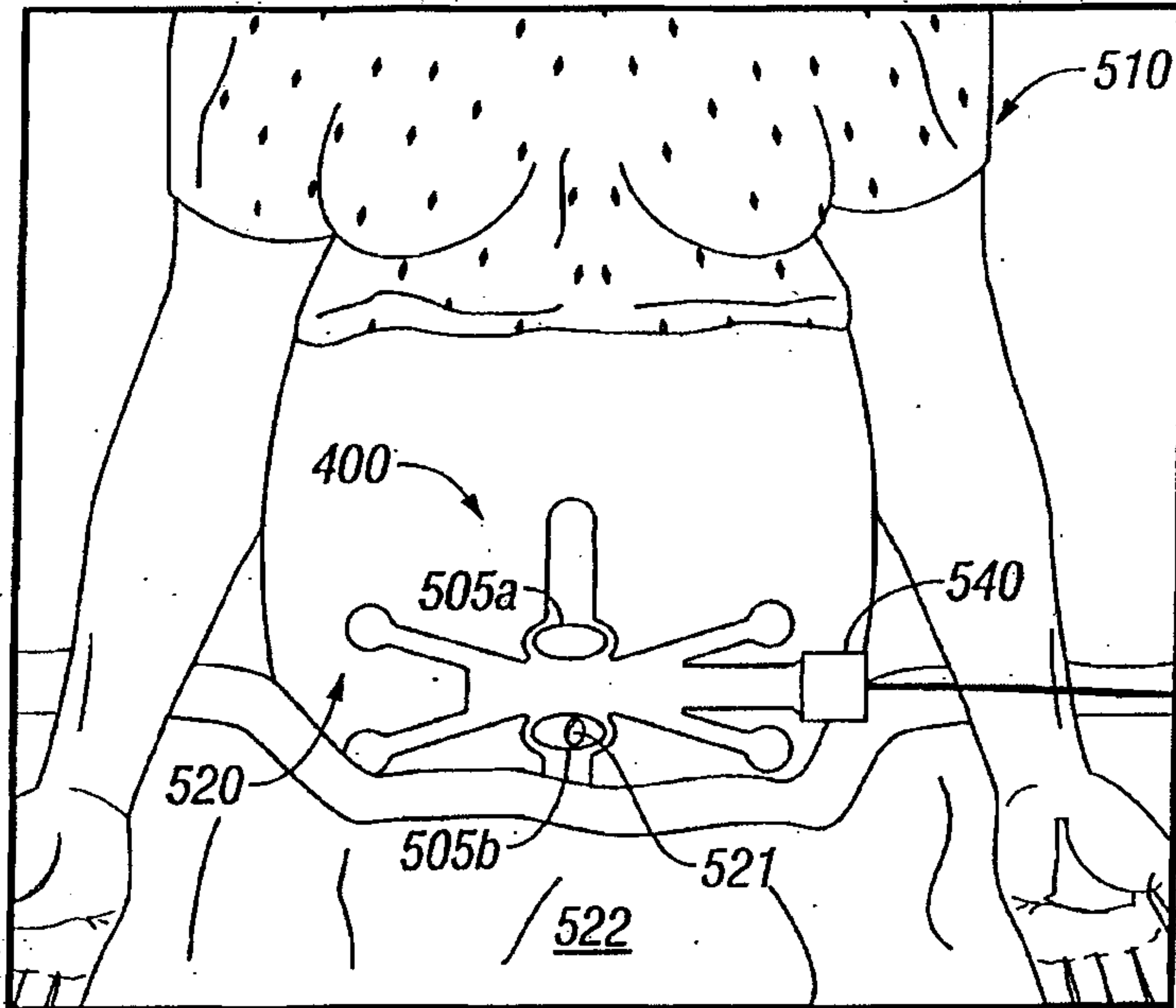


FIG. 5A

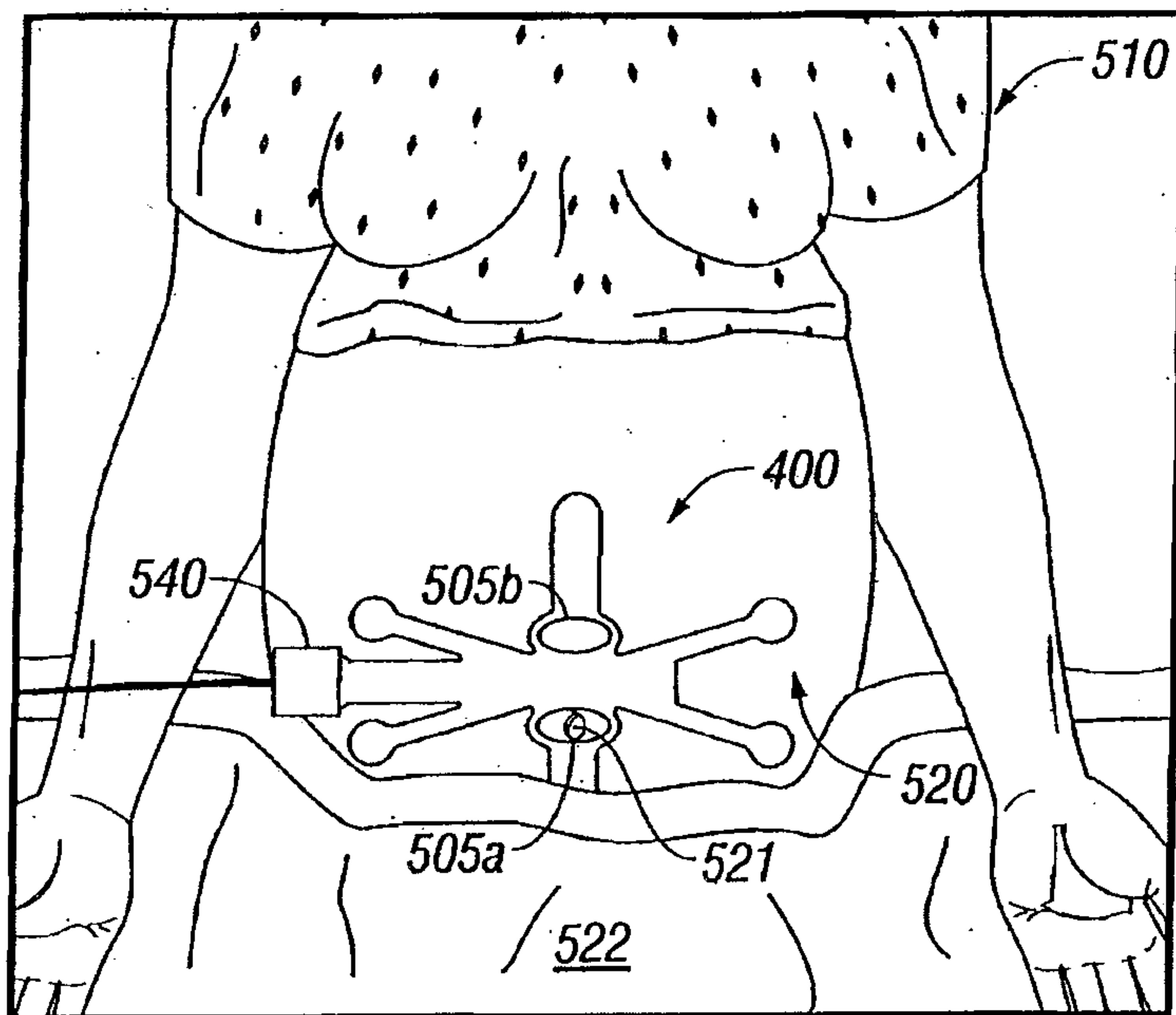


FIG. 5B

8/14

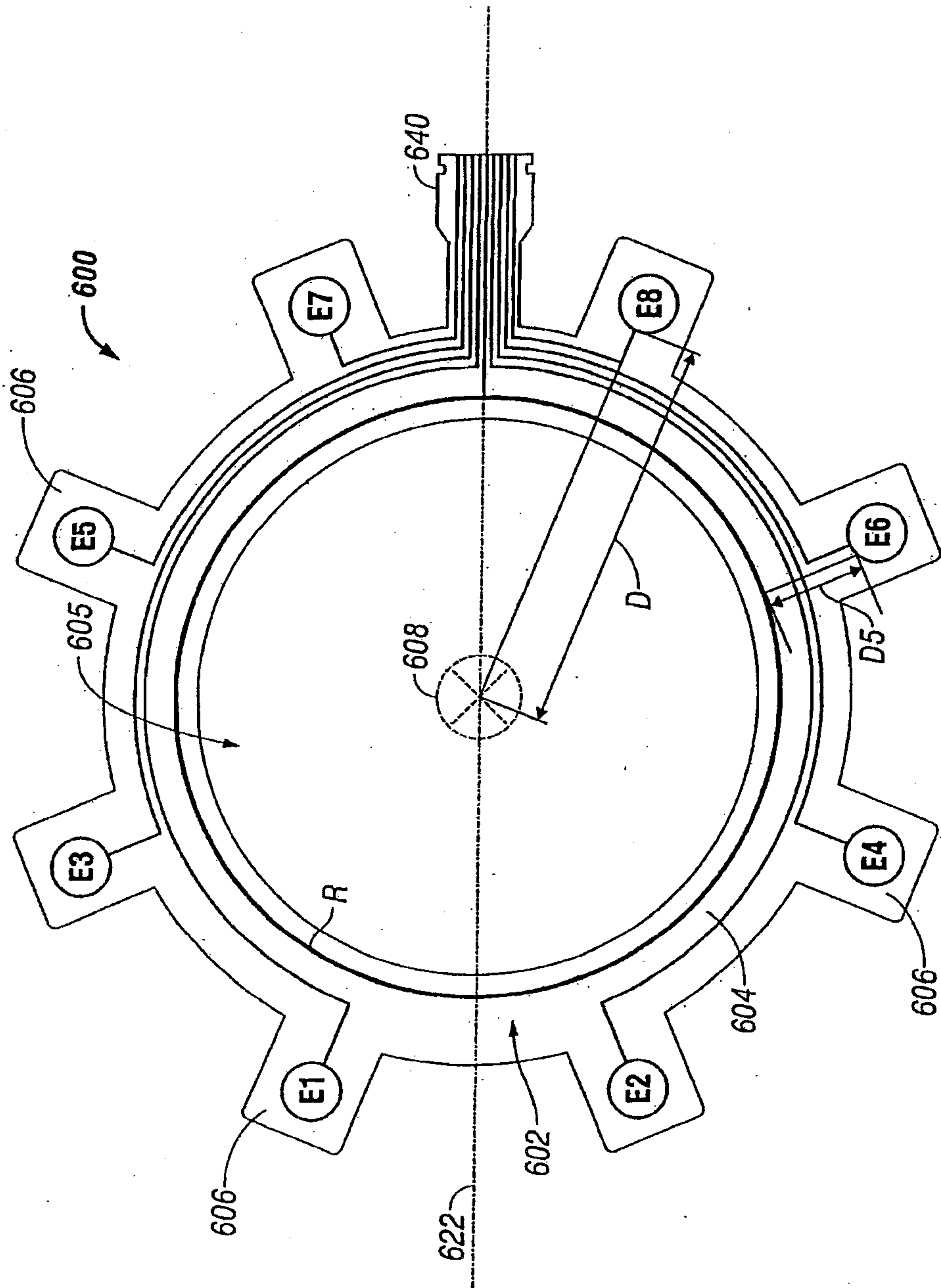


FIG. 6A

Patent Agents
Smart & Biggar

9/14

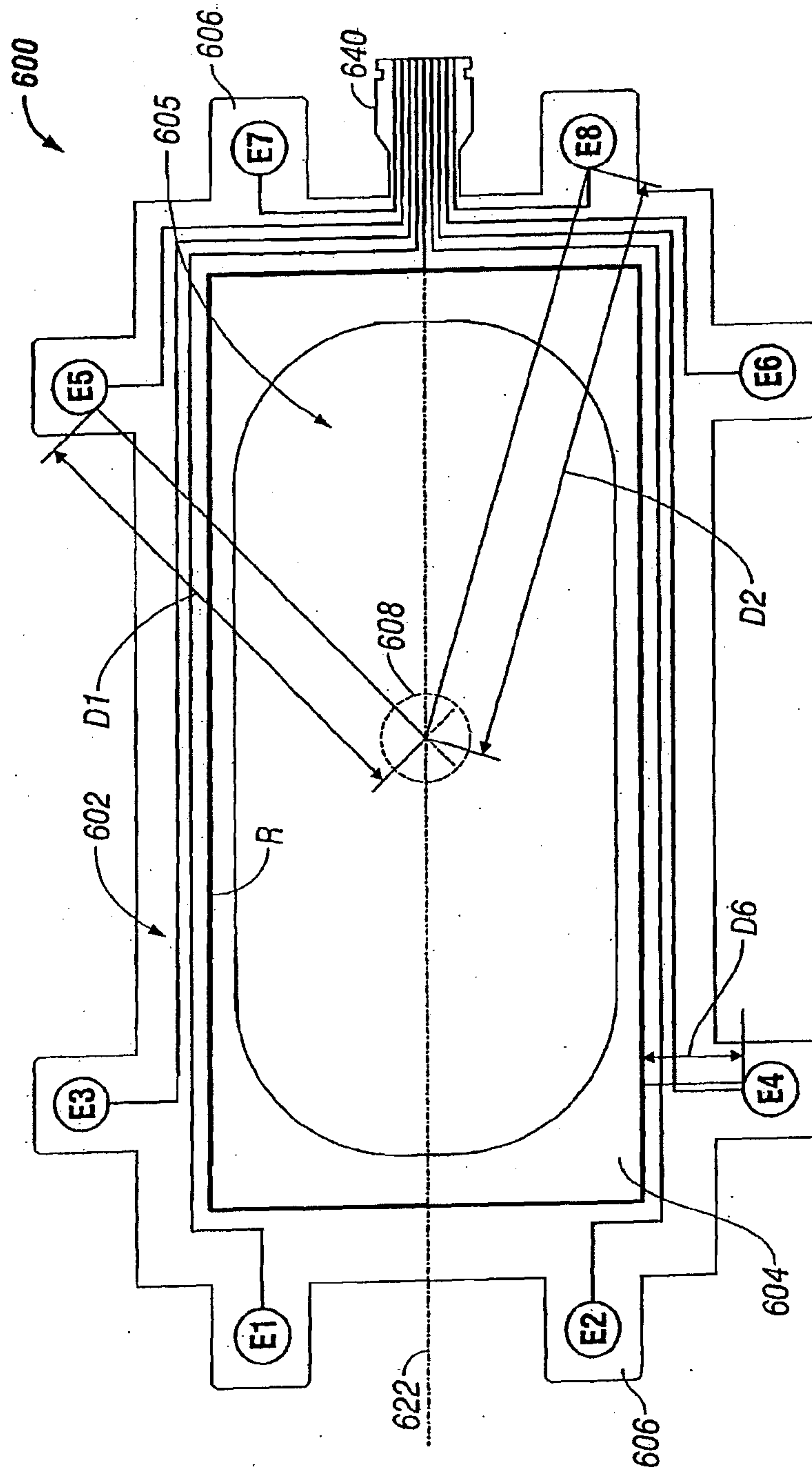


FIG. 6B

Patent Agents
Smart & Biggar

10/14

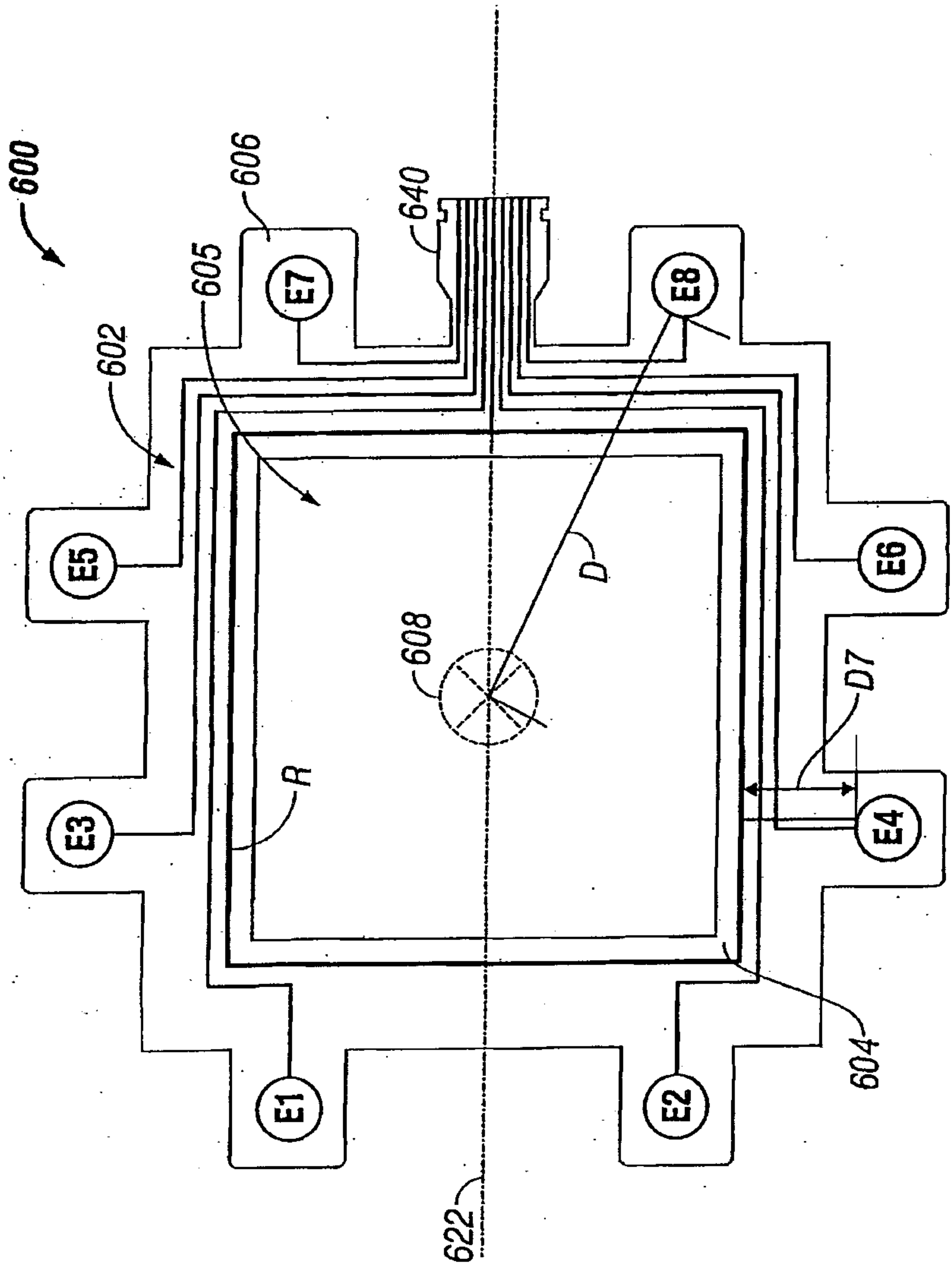


FIG. 6C

11/14

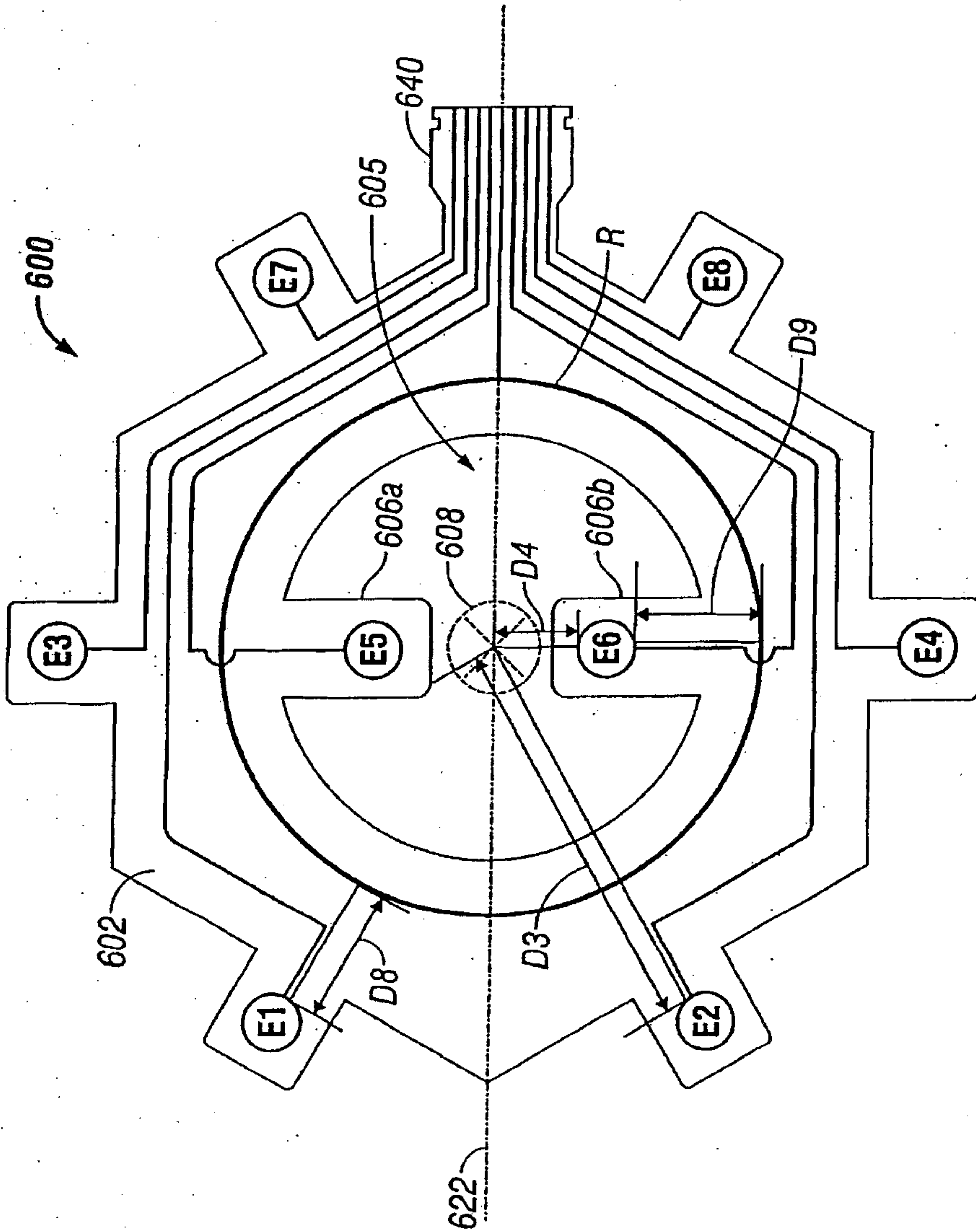


FIG. 6D

Patent Agents
Smart & Biggar

12/14

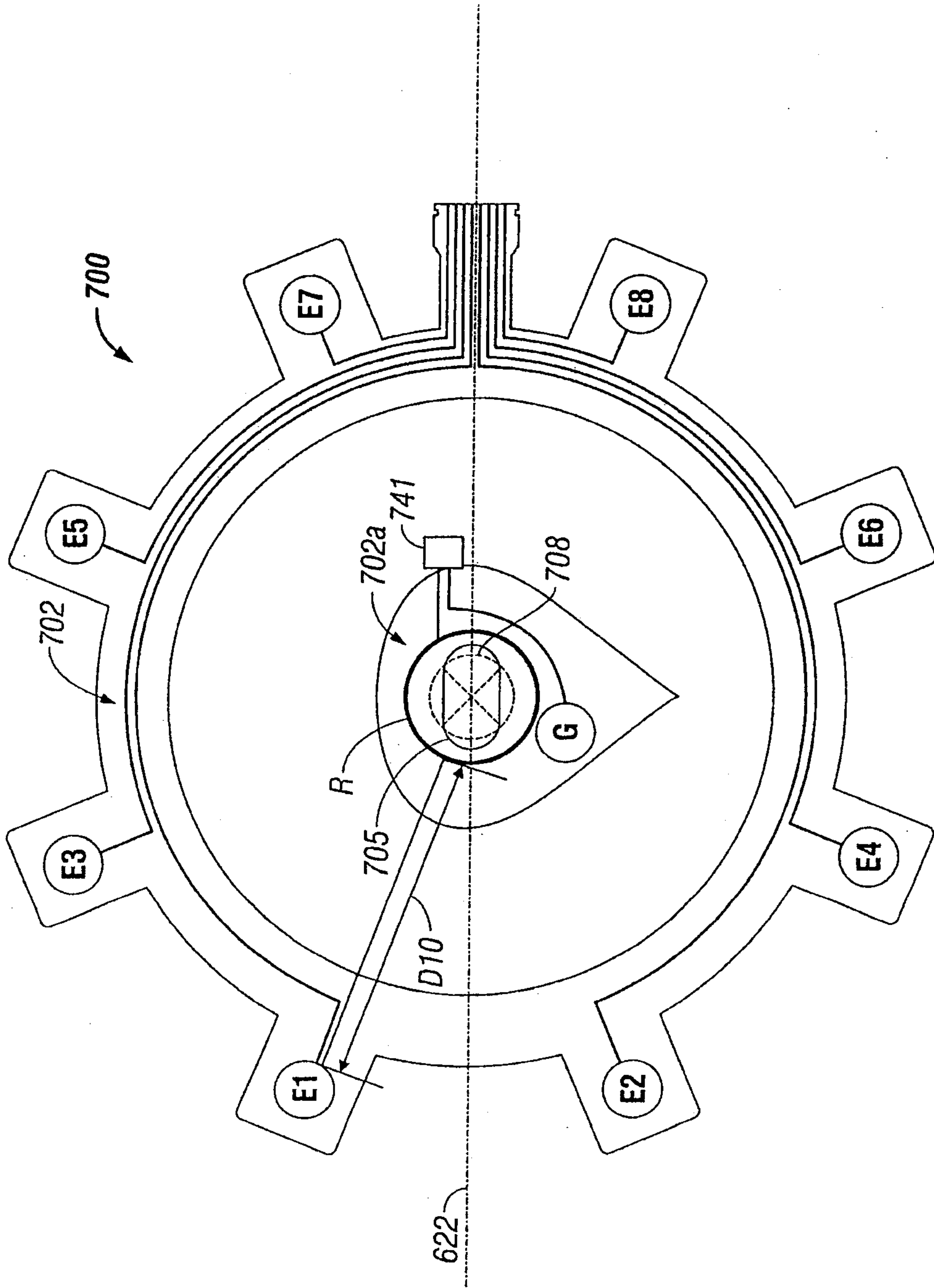


FIG. 7

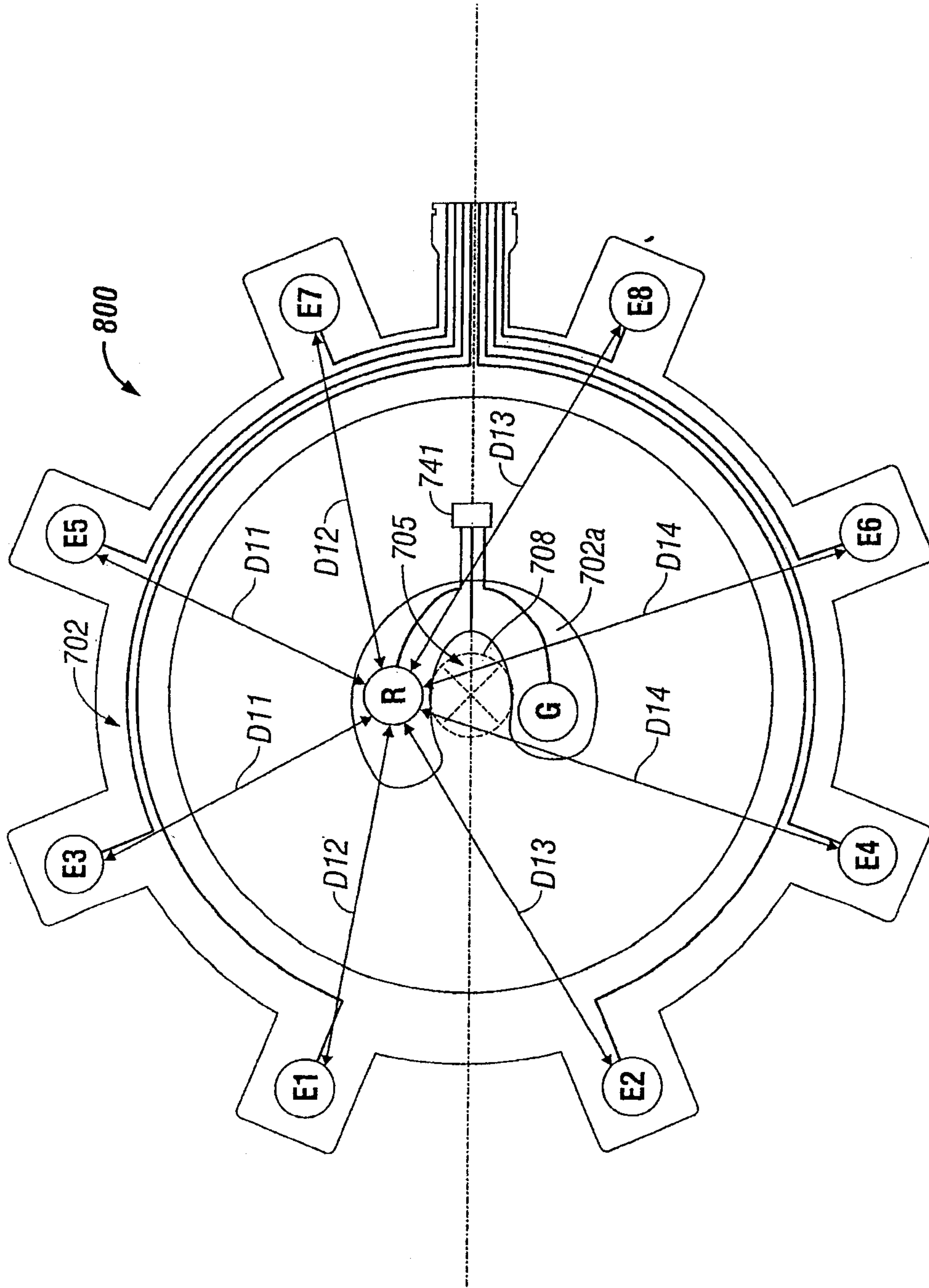


FIG. 8

