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(54) ELECTROCHEMICAL CELL DEVICE FOR ELECTROCHEMICAL MEASUREMENT

(57) The device is a multi-cell test device, comprising:
a plurality of coplanar electrochemical cells, comprising, in sequence:
(a) a common first substrate (1101) having a layer of conductive material applied to a first surface thereof;
(b) a common electrically-resistive middle layer (1104); and
(c) a common second substrate (1102) having a layer of conductive material applied to a first surface thereof, the first surface of the first substrate and the first surface of the second substrate being adhered to the electrically resistive middle layer. Each electrochemical cell comprises:

a sample-receiving end,
a connector end having a plurality of connectors, and
a sample space passing through the electrically resistive middle layer, bounded on opposing sides by a portion of the conductive material of the first and second substrates forming an unpatterned first electrode, and being connected with the sample-receiving end of the device.

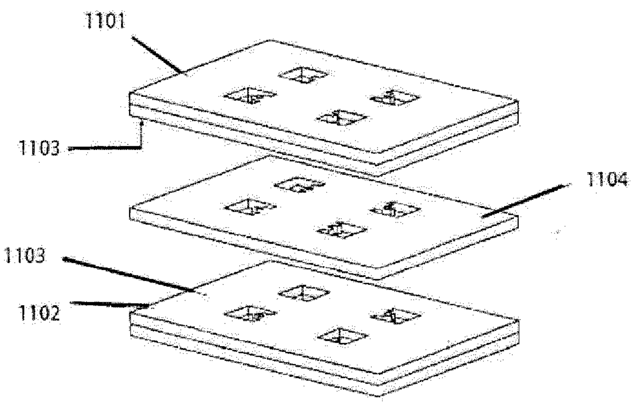

Fig. 1

EP 3 059 580 A1

Description

[0001] This application is a divisional application of our EP05739481.9 dated 20 May 2005, which claims priority from US Provisional Application Serial No. 60/521,555, filed May 21, 2004. EP05739481.9 is derived from PCT application IB2005/051657 (published as WO2005/114159 A1). Because this application is a divisional application, the entire disclosure of EP05739481.9 is incorporated herein, and parts of that disclosure may be used to illustrate preferred features of the present invention (as will now be described in more detail in the following specification and claims).

[0002] The present invention relates to an electrochemical cell device used to perform electrochemical measurement by evaluating an electrochemical parameter (that is, potential, current, resistance, etc) between two or more electrodes which are in contact with a sample. Electrode sensors typically include a working electrode and either a counter or a reference/counter ("reference") electrode.

[0003] The abovementioned EP05739481.9 describes and claims a method of manufacturing an electrochemical cell having opposing first and second electrodes separated by an electrically resistive sheet, which method comprises the steps of:

(a) forming a first bound opening in an electrically resistive sheet thereby forming a punched electrically resistive sheet;

(b) adhering the punched electrically resistive sheet to a first electrically conductive sheet thereby forming a combined sheet, wherein a first portion of a conductive surface of the first electrically conductive sheet is exposed through the first bound opening, and a second portion of the conductive surface of the electrically conductive sheet is exposed either through a second bound opening in the electrically resistive sheet or as an extension beyond an edge of the electrically resistive sheet;

(c) punching a notching opening through the electrically resistive sheet and the first electrically conductive sheet of the combined sheet, wherein the notching opening intersects the first bound opening in the electrically resistive sheet thereby transforming the first bound opening into a notch in the electrically resistive sheet, and punching a first contact area opening through the second exposed portion of the electrically conductive sheet visible to form a first electrical contact, thereby forming a punched combined sheet;

(d) punching a second electrically conductive sheet with a punch or punches to form an electrically conductive sheet having a notching opening corresponding to that of the punched combined sheet and a second contact area in the second electrically conductive sheet, thereby forming an opposite electrode sheet;

(e) adhering the opposite electrode sheet to the electrically resistive sheet portion of the punched combined sheet with an electrically conductive surface facing the electrically resistive sheet, said opposite electrode sheet being adhered such that the notching opening corresponding to the notching opening in the combined sheet is aligned with the notching opening in the combined sheet, and the second contact area is aligned with the second bound opening, thereby forming an electrochemical sheet, and

(f) cleaving the electrochemical sheet thereby forming a spent electrochemical sheet and a free electrochemical cell having a sample space for receiving a sample defined by the first and second conductive sheets and the notch in the electrically resistive sheet, and first and second contact areas in electrically conductive contact with electrode portions of the first and second conductive sheets exposed in the sample space for connection of said first and second electrode portions with a meter.

[0004] The term "bound opening" refers to an opening which is surrounded by the material of the electrically resistive sheet, where there is no direct connection between the opening and the periphery of the resistive sheet. As described in greater detail in WO2005/114159 A1, a bound opening may have a single major open area, for example an opening having a rectilinear cross-section, or it may have more than one major open area connected by a generally narrower connecting portion.

[0005] The term "an opening having a rectilinear cross-section" is an opening having four straight sides. The reference to straight sides refers merely to sides that are not obviously curved when viewed, and does not imply a criticality of perfect linearity from the punching process. Non-limiting examples of rectilinear cross-section openings are trapezoids, parallelograms, squares and rectangles. The corners of the rectilinear openings are desirably rounded. Openings of this shape are preferred because the straight edges have less error in cutting, and the rounded corners are less prone to tearing.

[0006] The term "major open area" refers to a portion of a bound opening in which either the sample space or the connectors of an electrochemical cell will be formed.

[0007] The term "opposing electrodes" refers to electrodes disposed on different substrates used in the formation of the sample cell, such that they are disposed in different planes on the top and bottom (or on the two sides) of a cell, such that movement of charge carriers occurs in a direction generally perpendicular to the plane of the electrodes. "Opposing electrodes" are thus different from side-by-side electrodes in which an electrode pair is disposed on a common surface in a common plane, and the movement of charge carriers is generally parallel to the plane of both electrodes.

[0008] The term "punching" refers to the act of cutting through a sheet of material in a direction substantially perpendicular to the major surface. The term "substantially" in this case recognizes that there may be slight manufacturing deviations from absolutely perpendicular, but that these should be minimized to avoid top to bottom inconsistency in the dimensions of the openings created. Punching can be performed using a die cutting apparatus or other apparatus that physically cuts the layers into the desired shape. Laser cutting can also be employed where heat generation and/or evolution of volatiles is not a concern. Chemical etching through the materials might also be used.

[0009] The abovementioned WO2005/114159 A1 further describes an electrochemical cell device having a sample-receiving end and a connector end comprising, in sequence:

(a) a first substrate, having an unpatterned layer of conductive material applied to a first surface thereof;
(b) an electrically-resistive middle layer, and
(c) a second substrate, having an unpatterned layer of conductive material applied to a first surface thereof;

wherein the first surface of the first substrate and the first surface of the second substrate are adhered to the electrically resistive middle layer; wherein the cell has a hole disposed near the sample receiving end, but spaced away from the free edge of the cell, the hole passing through the first substrate, the electrically resistive middle layer, and the second substrate, wherein the cell has a sample space, the sample space passing through electrically resistive middle layer and being bounded on opposing sides by the unpatterned conductive materials of the first substrate and the unpatterned conductive material of the second substrate; and the sample space extending from the free edge of the cell to the hole and being open at both ends.

[0010] WO2005/114159 A1 further discloses that, where appropriate to the cell being made, the electrochemical cell may also include a reagent in the sample space. The document further discloses that multiple cells can be formed from each sheet of material by formation of multiple sets of punches adjacent to one another. Such multiple cells can be formed immediately adjacent to each other, so that no excess material is left between them when they are cleaved. Multiple strips can also be formed from a single sheet in a "nose to tail" or "nose to nose and tail to tail" arrangement such that punching of a single bound opening forms the nose of one strip and the tail of the next strip at once, or nose and nose, or tail and tail.

[0011] The present invention (as defined in claim 1) provides a multi-cell test device of the sequence set out above, wherein the first substrate, the middle layer and the second substrate are all common to the multi-cells, such that each test device comprises a sample receiving end, a connector end having a plurality of connectors, and a sample space passing through the electrically resistive middle layer and being bounded on opposing sides by a portion of the conductive material of the first and second substrates forming the unpatterned first electrode and being connected with the sample-receiving end of the device.

[0012] Preferred features of the invention are defined in the subsidiary claims.

[0013] The term "unpatterned layer of conductive material" as used herein refers to a deposition of conductive material, for example by painting, sputtering, evaporation, screen printing, chemical vapour deposition, or electroless deposition onto the surface of a material without any defined patterning to define the electrode area. Patterning may be used for contact pads or connector tracks, however, a wholly unpatterned layer is employed for the conductive layers on the first and second substrates. This is advantageous since fewer manufacturing steps are involved.

[0014] The unpatterned layer is desirably a uniform coating, although random scratches, pits or other defects that may occur as a result of handling or manufacturing processes do not render a conductive material patterned.

[0015] Depending on the analyte to be detected, the electrochemical cell may include a reagent composition disposed within the space for receiving a sample. The term "analyte" means a component of a sample to be measured. Non-limiting examples of specific analytes include glucose, hemoglobin, cholesterol, and vitamin C.

[0016] In the case of an electrochemical cell device for the detection of glucose, this reagent composition suitably comprises an enzyme effective to oxidize glucose, for example glucose oxidase, and a redox mediator, for example ferricyanide. Reagent compositions for this purpose are known in the art, for example from US Patents 4711245 and 5437999.

[0017] A particular embodiment of the reagent comprises glucose oxidase and ferricyanide. The term "redox mediator" means a chemical species, other than the analyte, that is oxidized and/or reduced in the course of a multi-step process transferring electrons to or from the analyte to an electrode of the electrochemical cell. Examples of such mediators are disclosed in the abovementioned WO2005/114159 A1.

[0018] Embodiments of the invention will now be described, by way of example, with reference to the accompanying drawings, in which:

Fig. 1 illustrates the formation of an exemplary multicell test device according to the invention.
Figs. 2A and B show cross sections through a multicell test device of Fig. 1.
Fig. 3 illustrates the formation of another embodiment of a multi-cell test device according to the invention.
Fig. 4 shows another embodiment of multi-cell test device according to the invention.
Fig. 5 shows another embodiment of multi-cell test device according to the invention.

[0019] Fig. 1 illustrates a first embodiment of multi-cell test device, in which two test cells are stacked one on top of the other. In this embodiment, two punched combined sheets 1101 and 1102 are formed, as described and claimed in the abovementioned EP05739481.9.

[0020] Reagent is added to each punched combined sheet 1101, 1102 consistent with the analyte to be tested. The reagents added to sheets 1101 and 1102 may be the same, or they may be different to provide for simultaneous testing of two analytes. Punched combined sheets 1101 and 1102 each have an adhesive inner surface 1103, 1103' and are adhered via this surface to an intermediate punched sheet 1104 formed from an electrically insulating material coated on both sides with a conductive layer. After cleaving the cell from the sheet, the result is a test device that has two stacked test cells.

[0021] Fig 2A shows a cross section through the resulting multi-cell test device at a point remote from the sample space and vent hole.

[0022] Fig. 2B shows a cross section through the resulting multi-cell test device at a point intersecting the sample spaces 1222, 1222' and vent hole 1224.

[0023] In each figure, the conductive surfaces are illustrated by a wavy line. Because of the small size of the test cells, and the proximity of the openings, sample can be easily introduced into both cells concurrently.

[0024] Fig. 3 illustrates an alternative embodiment of the formation of a multi-cell test device. In this embodiment, two or more adjacent sample spaces are formed. As depicted in Fig. 3, two openings are formed in place of the single first bound opening used to define the sample space in the embodiments described above. In the specific embodiment shown in Fig. 3, two co-linear openings 1301, 1302 perpendicular to the long axis of the device are formed in the electrically resistive sheet. When the combined strip is punched along the dashed lines to form the device nose 1304 and vent hole 1305, the ends of both openings are cleaved, creating two sample spaces. In this configuration, the sample spaces are suitably filled from the vent hole.

[0025] A cut or scribe along the dotted line 1306 is made in the electrically conductive sheet prior to assembly to provide electrical isolation for the two sample spaces. It will be appreciated that the same result could be achieved with one elongated opening that combined openings 1301 and 1302, and extended across the vent hole area between. Further, it will be appreciated that the relative specific positions of the openings formed in this embodiment are not critical, and that they need not be co-linear provided that isolated electrical connections can be made to each sample space.

[0026] In a further embodiment of the invention, multi-cell test devices can be made using a combination of the embodiments shown in Figs. 1 and 2 with the embodiment illustrated in Fig. 3. In this embodiment, the resulting device may have one or more cells in each stacked level.

[0027] In yet a further modification of the device of Fig. 3, by displacing the openings 1301, 1302, and providing separate vent holes, two sample spaces can be formed in such a way that only one space is fillable from the outside edge, and the other only from the inside edge. In the absence of a cut along line 1306, it does not matter which of the sample spaces is filled. This creates greater user convenience, since the sample collection point (the manner in which the strip is used) does not impact the result.

[0028] Filling of both spaces can be distinguished from filling of only one based on determinations of effective electrode area, for example as described in US Patent Publication 2005-0069892 A1 and US Patent Application No. 10/907,813 filed April 15, 2005 (US Patent Publication 2006-0231418).

[0029] Figs. 4 and 5 show two other embodiments of multi-cell test devices according to the invention. In Fig. 4, four sample spaces 1401 are formed, all of which are accessed via a common surface. Since filling (or partial filling) of any or all of these is sufficient to obtain a measurement, this configuration reduces the need to align a particular portion of the device tip with a blood/fluid droplet 1402.

[0030] In Fig. 5, six sample spaces 1501 are aligned in a ring around a hexagonal multi-strip and extend from the outside of the ring to vent spaces 1502. The devices are separated by scribe lines 1503 and have connector tabs 1504 directed to the centre axis. In Fig. 5, only one conductive layer and the spacer layer are shown. A top layer with a conductive surface would complete the device with the other electrode and its associated connector tab(s).

[0031] Thus, it can be seen that the invention provides flexibility in the formation of electrochemical test cell devices that include multiple sample spaces. These sample spaces may be coplanar, in which case they can be arranged in parallel, in a nose-to-tail arrangement, like the spokes of a wheel, in a wheel or in any other desired configuration. The sample spaces may also occupy multiple planes.

Claims

1. A multi-cell test device, comprising:

   a plurality of coplanar electrochemical devices, comprising, in sequence:

   (a) a common first substrate (1101) having a layer of conductive material applied to a first surface thereof;
   (b) a common electrically-resistive middle layer (1104); and
   (c) a common second substrate (1102) having a layer of conductive material applied to a first surface thereof, the first surface of the first substrate and the first surface of the second substrate being adhered to the elec-

trically resistive middle layer,

wherein each electrochemical device comprises:

a sample receiving end,
a connector end having a plurality of connectors, and
a sample space (1222, 1222') passing through the electrically resistive middle layer and being bounded on opposing sides by a portion of the conductive material of the first and second substrates forming an unpatterned first electrode and being connected with the sample-receiving end of the device.

2. A multi-cell test device according to claim 1, which includes a plurality of sample spaces (1301,1302) that are coplanar and arranged in a linear fashion.

3. A multi-cell test device according to claim 1, which includes a plurality of sample spaces that are coplanar and arranged in parallel, in a nose-to-tail arrangement, in a nose-to-nose arrangement, arranged radially, or in a hexagonal ring arrangement (1501).

4. A multi-cell test device according to any of claims 1 to 3, wherein the plurality of electrochemical devices are separated by scribe lines (1306, 1503).

5. A multi-cell test device according to any of claims 1 to 4, further comprising a reagent disposed within each sample space.

6. A multi-cell test device according to claim 5, wherein the reagent comprises an enzyme (such as glucose oxidase) and a redox mediator.

7. A multi-cell test device according to any one of claims 1 to 5, wherein the first connector and the second connector have space therebetween.

8. A multi-cell test device according to any one of claims 1 to 7, wherein the first connector has two contact pads, the second connector has at least one contact pad, and the at least one contact pad of the second connector is between the two contact pads of the first connector when viewed in the plane of the strip.

9. A multi-cell test device according to any one of claims 1 to 8, wherein when a conductive portion of the first connector faces a conductive portion of the second connector within the connector end of the device, they are separated by the common electrically resistive middle layer.

10. A multi-cell test device according to any one of claims 1 to 9, wherein, except for the sample space, the facing conductive portions of the common first substrate and the common second substrate are separated by the common electrically resistive middle layer.

11. A multi-cell test device according to any one of claims 1 to 10, wherein the plurality of connectors extend from a common edge of each of the electrochemical test devices, or from a common edge of the multi-cell test device.

12. A multi-cell test device according to any one of claims 1 to 11, wherein there is electrical continuity between the plurality of electrochemical test devices, or wherein each electrochemical test device is electrically separated from the plurality of electrochemical test devices.

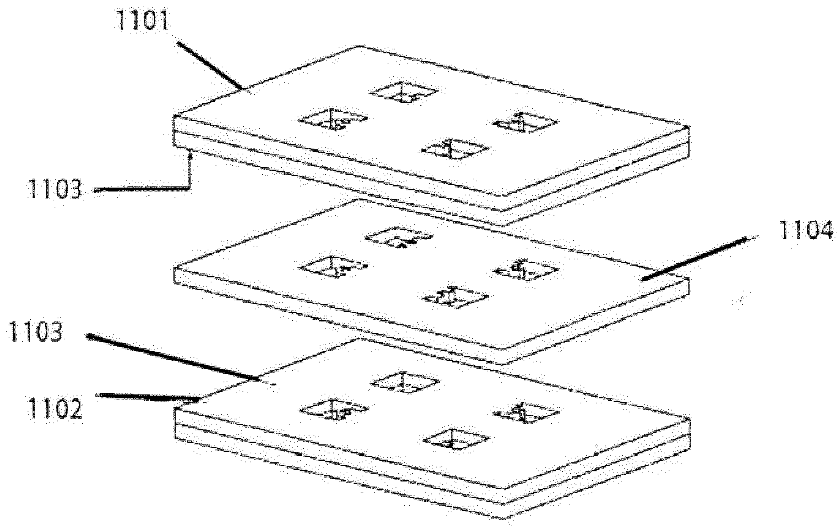

Fig. 1

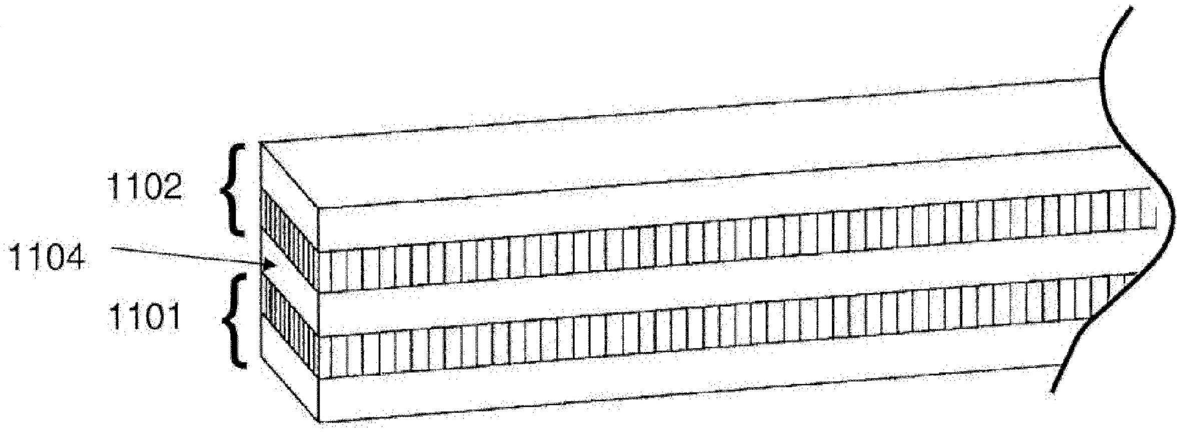

Fig 2A

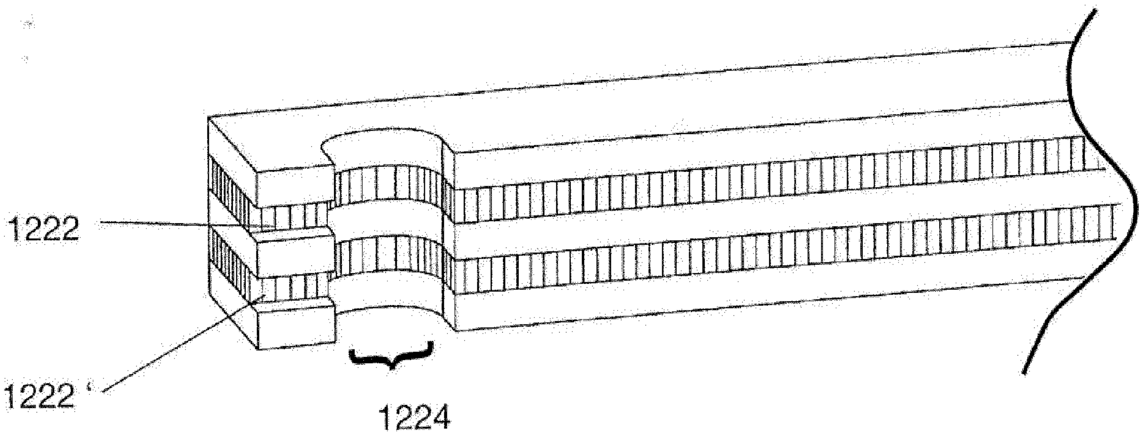

Fig 2B

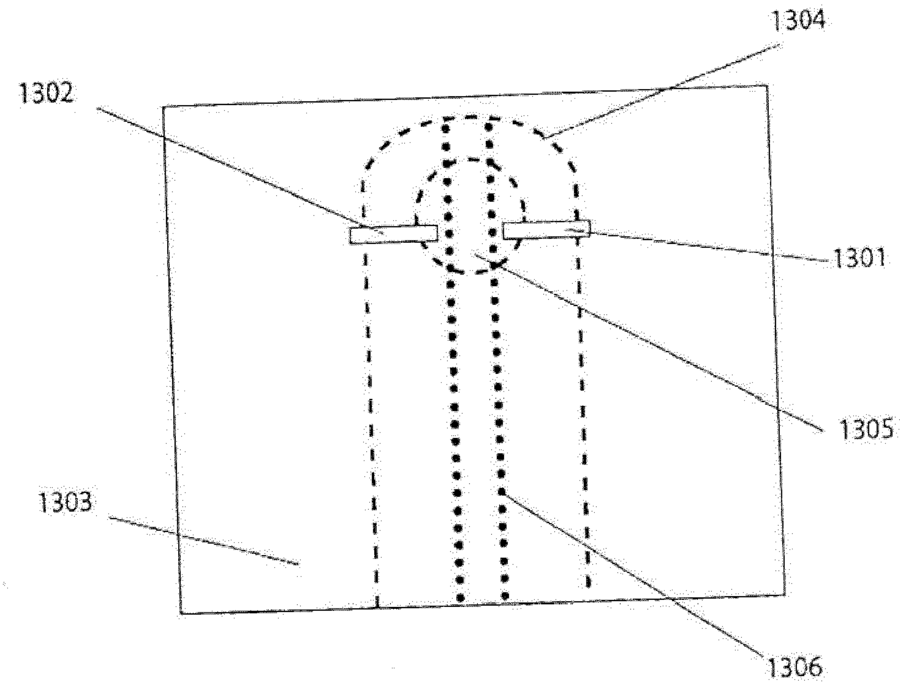

Fig. 3

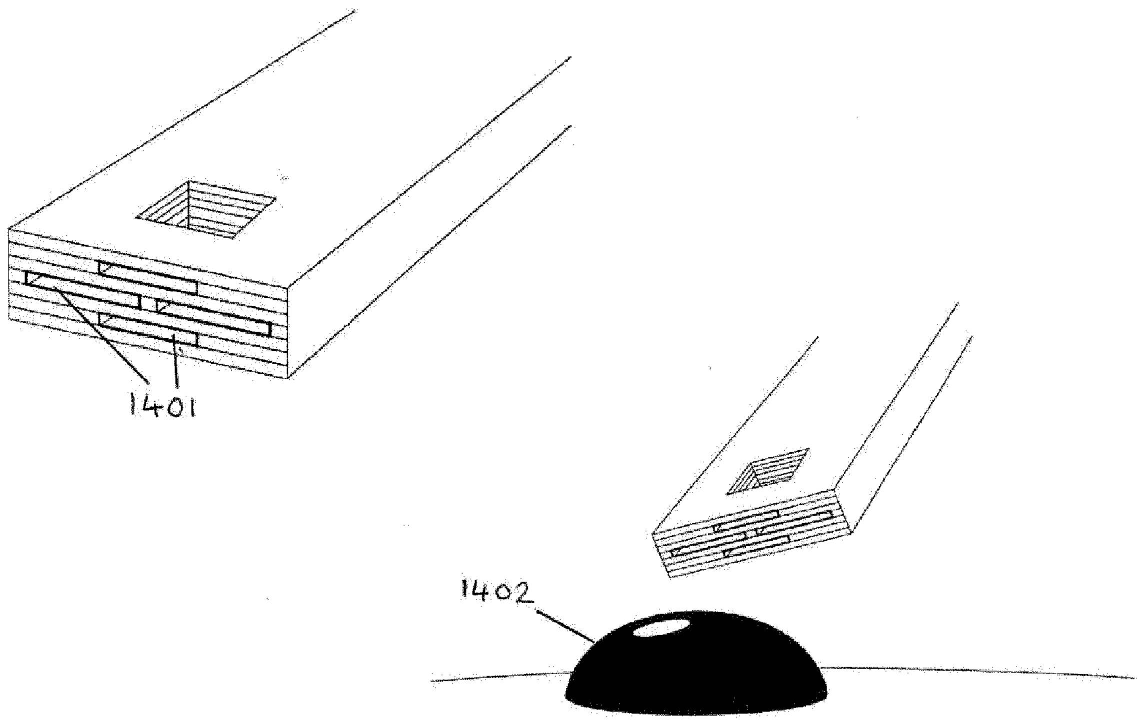

Fig 4

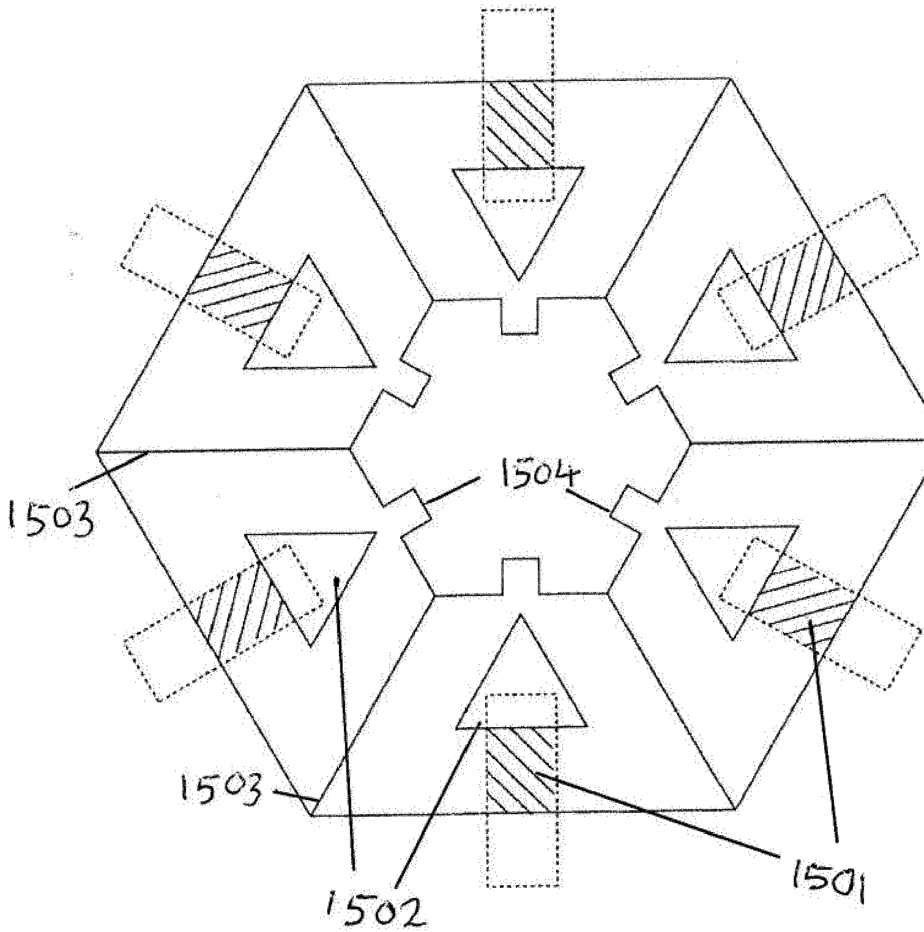

Fig 5

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Application Number
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The present search report has been drawn up for all claims

1

Place of search	Date of completion of the search	Examiner
Munich	21 June 2016	Komenda, Peter

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