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(71) Applicant: **SIEMENS HEALTHCARE DIAGNOSTICS INC.** [US/US]; 511 Benedict Avenue, Tarrytown, New York 10591 (US).

(72) Inventor: **BENCO, John**; 139 Rolling Meadow Drive, Holliston, Massachusetts 01746 (US).

(74) Agents: **PETAJA, Kyle D.** et al.; Siemens Corporation, Intellectual Property Dept., 3501 Quadrangle Blvd Ste 230, Orlando, Florida 32817 (US).

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(54) Title: FOLDABLE OPPOSING SENSOR ARRAY

Fig. 6

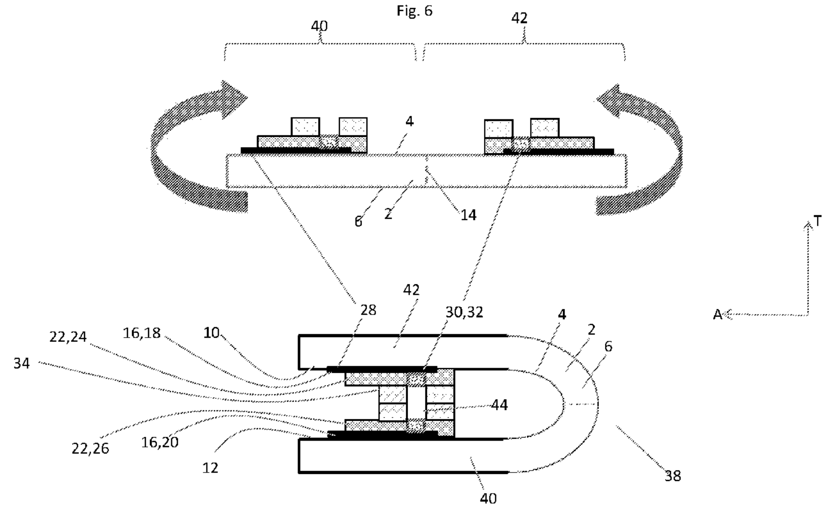

Fig. 7

(57) **Abstract**: A test device comprising a single substrate having a first surface with a first area that opposes a second area, a conductor layer disposed on the single substrate comprising a first group of electrodes printed in the first area and a second group of electrodes printed in the second area; a dielectric layer disposed on the conductor layer comprising a first area of dielectric material disposed on the first group of electrodes and a second area of dielectric material disposed on the second group of electrodes; and a spacer layer adjacent to the first area of dielectric material and the second area of dielectric material, the spacer layer forming a flow path between a first group and a second group of reaction wells.

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FOLDABLE OPPOSING SENSOR ARRAY

[0001] The subject application claims benefit under 35 USC § 119(e) of US Provisional Application No. 62/095,420, filed December 22, 2014. The entire contents of the above-referenced patent application are hereby expressly incorporated herein by reference.

BACKGROUND

1. Field of the Disclosure

[0002] This disclosure relates to sensor arrays that require a reduced sample size of sample liquid in order to perform a plurality of diagnostic tests.

2. Brief Description of the Related Art

[0003] Patients that are hospitalized undergo a wide range of diagnostic tests. When these tests involve whole blood they have been shown to consume large amounts of blood inducing anemia which is correlated to poor outcomes. Neonates are particularly susceptible to blood loss and obtaining samples large enough to analyze is especially difficult. Therefore there is a great need to reduce the size of whole blood samples required to perform diagnostic tests. Due to these factors the diagnostic instrumentation industry has been miniaturizing their products over the past 20 years. The focus has been on reducing the size of the sensors that detect the analytes of interest and the accompanying sample pathway.

[0004] For example, U.S. Pat. No. 5,916,425 discloses a single sensor substrate with a sensor array and subminiature thru-holes enabling electrical connection. This single substrate limits the number of analytes which can be measured and still achieve a small sample volume. U.S. Pat. No. 6123,820 discloses a cartridge that has two separate sensor arrays facing each other with an intermediate spacer having a complicated zig-zag flow path. U.S. Pat. App. 2009/0060789 A1 discloses a design of a first and second opposing sensor array and a spacer with two openings. Although these concepts can reduce the size of the sample needed for a diagnostic test they are complicated designs requiring multiple pieces for construction and limit the number of analytes that can be measured with a single whole blood sample. Therefore new designs are required to solve the unmet need of reduce sample volume.

BRIEF DESCRIPTIONS OF THE DRAWINGS

[0005] Figs. 1 through 7 depict illustrative embodiments and an illustrative method of making a test device.

[0006] Fig. 8 depicts another embodiment of the test device.

DETAILED DESCRIPTION OF THE INVENTIVE CONCEPT(S)

[0007] Before explaining at least one embodiment of the inventive concepts disclosed herein in detail, it is to be understood that the inventive concepts are not limited in their application to the details of construction and the arrangement of the components or steps or methodologies set forth in the following description or illustrated in the drawings. The inventive concepts disclosed herein are capable of other embodiments or of being practiced or carried out in various ways. Also, it is to be understood that the phraseology and terminology employed herein is for the purpose of description and should not be regarded as limiting the inventive concepts disclosed and claimed herein in any way.

[0008] In the following detailed description of embodiments of the inventive concepts, numerous specific details are set forth in order to provide a more thorough understanding of the inventive concepts. However, it will be apparent to one of ordinary skill in the art that the inventive concepts within the instant disclosure may be practiced without these specific details. In other instances, well-known features have not been described in detail to avoid unnecessarily complicating the instant disclosure.

[0009] As used herein, the terms "comprises," "comprising," "includes," "including," "has," "having" or any other variation thereof, are intended to cover a non-exclusive inclusion. For example, a composition, a process, method, article, or apparatus that comprises a list of elements is not necessarily limited to only those elements but may include other elements not expressly listed or inherently present therein.

[0010] As used herein the terms “approximately,” “about,” “substantially” and variations thereof are intended to include not only the exact value qualified by the term, but to also include some slight deviations therefrom, such as deviations caused by measuring error, manufacturing tolerances, wear and tear on components or structures, settling or precipitation of cells or particles out of suspension or solution, chemical or biological degradation of solutions over time, stress exerted on structures, and combinations thereof, for example.

[0011] As used herein, the term “sample” and variations thereof is intended to include biological tissues, biological fluids, chemical fluids, chemical substances, suspensions, solutions, slurries, mixtures, agglomerations, tinctures, slides, powders, or other preparations of biological tissues or fluids, synthetic analogs to biological tissues or fluids, bacterial cells (prokaryotic or eukaryotic), viruses, single-celled organisms, lysed biological cells, fixed biological cells, fixed biological tissues, cell cultures, tissue cultures, genetically engineered cells and tissues, genetically engineered organisms, and combinations thereof, for example.

[0012] Unless expressly stated to the contrary, "or" refers to an inclusive or and not to an exclusive or. For example, a condition A or B is satisfied by anyone of the following: A is true (or present) and B is false (or not present), A is false (or not present) and B is true (or present), and both A and B are true (or present). An inclusive or may be understood as being the equivalent to: at least one of condition A or B.

[0013] In addition, use of the "a" or "an" are employed to describe elements and components of the embodiments herein. This is done merely for convenience and to give a general sense of the inventive concepts. This description should be read to include one or at least one and the singular also includes the plural unless it is obvious that it is meant otherwise.

[0014] Finally, as used herein any reference to "one embodiment" or "an embodiment" means that a particular element, feature, structure, or characteristic described in connection with the embodiment is included in at least one embodiment. The appearances of the phrase "in one embodiment" in various places in the specification are not necessarily all referring to the same embodiment.

[0015] Finally, the embodiments of the low-volume sensing device disclosed herein may be understood with reference to a first, second, and third direction such as, for example, lateral direction ‘A’, a longitudinal direction ‘L’ which is perpendicular to lateral direction ‘A’, and a transverse direction ‘T’ which is perpendicular to longitudinal direction ‘L.’ The longitudinal direction L and the lateral direction A extend horizontally as illustrated, and the transverse direction T extends vertically, though it should be appreciated that these directions may change depending, for instance, on the orientation of the low-volume sensing device. It should also be understood that first direction may be referred to as the lateral direction. It should also be understood that second direction may be referred to as the longitudinal direction. It should also be understood that third direction may be referred to as the transverse direction.

[0016] The inventive concepts disclosed herein are generally directed to a diagnostic test device, and method of making the same, in which two opposing sensor arrays are supported by a single substrate folded into a “U” shape. As best illustrated in Figs. 6 and 7, the invention is based on the concept of constructing coplanar layers on two separate areas of a single substrate and then folding the substrate in half thereby forming an integrated sample pathway between two opposed sensor arrays. This sensor comprises a single substrate, a conductor layer comprising electrodes printed onto the single substrate, a dielectric layer printed on the conductor layer, and a spacer layer placed on the dielectric layer.

[0017] Figs. 1 through 7 depict illustrative embodiments and an illustrative method of making test device 100. Test device 100 can perform a diagnostic test on a sample—such as, but not limited to, whole blood.

[0018] Fig. 1 shows a first substrate 2 of test device 100 in a flat, or “unfolded” configuration. When in the flat or “unfolded” configuration (as also shown in Figs. 2 through 5), substrate 2 is substantially planar with a first substantially planar upper surface 4 and a second substantially planar lower surface 6—both of which extend in the lateral direction A and the longitudinal direction L and are separated by a thickness extending along the transverse direction T (as shown in Fig. 6). Test device 100 can further include two openings 8—one of which functions as a sample inlet and the other as a sample outlet. As will be explained further below, these openings 8 form part of an integrate sample pathway. Substrate 2 further has a first area 10 and a second area 12 disposed on the upper surface 4 and separated by an folding line 14.

[0019] In Fig. 2, a conductive layer is shown. The conductive layer 16 can be formed using any number of techniques such as, for example, deposition, screen printing, adhesion, etching, and/or laser ablation. The conductor layer 16 is disposed on the upper surface 4 of the substrate 2 and has at least a first group of one or more electrodes 18 printed on the first area 10 of substrate 2 and a second group of one or more electrodes 20 printed on the second area 12 of substrate 2. The first group of electrodes 18 and the second group of electrodes 20 may be formed using any of a variety of methods and materials known to a person of ordinary skill in the art. For example, the electrodes may be formed using a thick film approach (e.g., screen printing, rotogravure, pad printing, stenciling, ink jetting or aerosol jetting conductive material such as carbon, Cu, Pt, Pd, Au, and/or Nanotubes (such as carbon nanotubes), etc…) or a thin film approach (e.g., by sputtering, thermal spraying, and/or cold spraying conductive material). The electrodes may be partitioned using, for example, etching or laser ablation. It should be understood that the configurations of the first group of electrodes 18 and the second group of electrodes 20 depicted herein are merely for illustrative purposes only and a person of ordinary skill in the art will appreciate that the electrodes may be distributed on substrate 2 in a variety of ways. In at least one embodiment of the present invention first group of electrodes 18 and the second group of electrodes 20 may be each be coplanar. As will be appreciated by those skilled in the art, the term “coplanar,” as used herein to describe electrodes should be understood as encompassing those electrodes which are substantially coplanar (as well as those which are fully co planar. Thus, individual electrodes can be slightly raised, recessed, and/or angled as compared other coplanar electrodes on substrates 2 and still be considered coplanar.

[0020] In Fig. 3, one or more intermediate layer(s) 22 are formed over both the upper surface 4 of the substrate 2 and the conductive layer 16. Similar to substrates 2, in the flat or “unfolded” configuration of Figs. 1-4 intermediate layers 22 may be substantially planar with a substantially planar upper surface and substantially planar lower surface—both of which extend in the lateral direction A and the longitudinal direction L (as shown in Fig. 3) and are separated by a thickness extending along the transverse direction T. The intermediate layer(s) 22 may be formed using a variety of methods and materials known to a person of ordinary skill in the art. For example, intermediate layer(s) 22 may be made out of an inert substrate such as a dielectric, pressure sensitive adhesive, laminate, etc… Alternatively, intermediate layer(s) 22 can be integrated onto substrate 2 and conductive layer 16 by forming intermediate layer(s) 22 directly on the upper surface of conductive layer 16 or the lower surface of substrate 8. One or more of intermediate layer(s) 22 can be an isolating layer(s) made from a dielectric or insulating material which isolates one or more, up to all, of first group of electrode 18 and the second group of electrodes 20. At least a portion of each electrode in the first group of electrodes 18 and the second group of electrodes 20 is left uncovered by intermediate layer(s) 22. These uncovered portions serve as electrical contacts 28—allowing external medical devices to interface with the respective electrodes of conductive layer 16. The intermediate layer(s) 22 may be partitioned using, for example, etching or laser ablation.

[0021] As shown in Fig. 3, intermediate layer(s) 22 contains a first section of intermediate layer(s) 24 and a second section of intermediate layer(s) 26—leaving the area above the folding line 14 devoid of intermediate layer(s) 22. The first section of intermediate layer(s) 24 is disposed above the first area 10 and first group of electrodes 18. The second section of intermediate layer(s) 26 is disposed above the second area 12 and the second group of electrodes 20. In yet another embodiment of the invention (which is described in more detail with respect to Fig. 8), the first section of intermediate layer(s) 24 and the second section of intermediate layers 26 are part of a single section of intermediate layers 22 formed over all of first area 10, the second area 12, the first group of electrodes 18, the second group of electrodes 20, and the folding line 14.

[0022] Intermediate layers 22 may define one or more sensing areas 30. For example, the sensing areas 30 are depicted in the Figures as circular apertures (which can also be referred to as reaction wells) formed in intermediate layers 22 which extend through the respective intermediate layers 22 and are devoid of the material used to construct the intermediate layers 22. Sensing areas 30 may also be fully or partially filled with a chemical/reagent 32 which may react with the sample and produce an electrochemical signal indicative of the amount of an analyte in the sample. The electrochemical signal being detectable by the electrodes of the conductive layer 16. The sensing areas 30 are formed above or are otherwise electrically coupled to one or more, up to all, of electrodes in the first and second group of electrodes 18, 20. Thus sensing areas 30 should be understood as being electrically coupled to the electrodes in the first and second group of electrodes 18, 20. Alternatively, individual sensing areas 30 may also be defined without the need for intermediate layer(s) 22 by applying chemicals and/or reagents directly on one or both first or second group of electrodes 18, 20.

[0023] Fig. 4 and 6—Fig. 6 showing the test device 100 along line A-A'—depict one or more spacer layer(s) 34 placed over one or both of the first and the second section of intermediate layer(s) 24, 26. Similar to substrate 2, in the flat or "unfolded" configuration of Figs. 1-4 spacer layer(s) 34 may be substantially planar with a substantially planar upper surface and substantially planar lower surface—both of which extend in the lateral direction A and the longitudinal direction L (as shown in Fig. 3) and are separated by a thickness extending along the transverse direction T. The spacer layer(s) 34 may be formed using a variety of methods and materials known to a person of ordinary skill in the art. For example, spacer layer(s) 34 may be made out of an inert substrate such as a dielectric, pressure sensitive adhesive, laminate, gasket, etc… Alternatively, spacer layer(s) 34 can be integrated onto intermediate layer(s) 22 by forming spacer layer(s) 34 directly on intermediate layer(s) 22. As will be appreciated by those skilled in the art, while Figs. 4 and 6 show a spacer layer 34 on both of the first and the second section of intermediate layers 24, 26 an alternative configuration of the test device has only one section of intermediate layer(s) 22 formed on one, but not both, of the first or the second section of intermediate layer(s) 24, 26. In yet another alternative configuration (which is described in more detail with respect to Fig. 8), where the first section of intermediate layer(s) 24 and the second section of intermediate layer(s) 26 are part of a combined section of intermediate layer(s) 22 formed over the combination of the first area 10, the second area 12, the first group of electrodes 18, the second group of electrodes 20, and the folding line 14, the spacer layer(s) 34 may extend over the entire combined section of intermediate layer(s) 22. Furthermore, the dimensions of the spacer layer 34 may vary along one, two or all three of the lateral direction A, the longitudinal direction L, and the transverse direction T.

[0024] As best shown in Fig. 6, the one or more spacer layer(s) 34 leave the area above the sensing areas 30 and the openings 8 free from spacer layer(s) 34. This area is later used to form a flow path. Stated differently, spacer layer(s) 34 are formed such that an area proximate to the intermediate layer 22 located above the sensing areas 30 and the openings 8 is left devoid of spacer layer(s) 34. This area will form part of the flow channel 44 through which sample can flow. It should also be understood that reagents 32 can also be placed in sensing areas 30 after the spacer layer 34 has been formed.

[0025] Figs. 5 and 7—Fig. 7 shows the test device 100 along line B-B'—depicts the substrate 2 in a folded configuration 38. In the folded configuration 38, the substrate 2 is folded along the folding line 14 such that a first half 40 of the test device 100 is aligned with a second half 42 of the test device 100. As best shown in Figs. 4 and 6, the respective first half 40 and second half 42 of the test device 100 is the respective first area 10 and second area 12 of the substrate 2 as well as the respective conductive layer(s) 16, intermediate layer(s) 22, and spacer layer(s) 34 disposed thereon. For example, according to the illustrative embodiment depicted in Figs. 1-7, the first half 40 of the test device 100 includes the first group of electrodes 18, the first section of intermediate layer(s) 24, and spacer layer(s) 34. The second half 42 of the illustrated test device 100 includes the second group of electrodes 20, the second section of intermediate layer(s) 26, and spacer layer(s) 34.

[0026] As best shown in Figs. 6 and 7, during folding along folding line 14 (which is denoted by the two arrows in Fig. 6) the two halves of the test device 100 are positioned such that the respective sensing areas 30 of the respective intermediate layer(s) 26 are aligned with one another along the lateral direction A with the region 44 devoid of spacer layer(s) 34 positioned in between. By aligning the respective sensing areas 30 above one another along lateral direction A the first half 40 and the second half 42 of the sensing device 100 form an enclosed flow path 44. Sample enters and exists the flow path 44 through openings 8—coming into contact with sensing areas 30 along the way. Individual sensing areas 30 allow fluid traveling through the fluid flow path 44 to come into contact with the reagents 32 and electrodes contained therein or coupled thereto. An external device can then connect to electrical contacts 28 to interpret the electrochemical signal generated by sensing areas 30. In should be appreciated that the configuration of the first and second group of electrodes 18, 20 in Figs. 1 to 7 is one example among many. Alternative configurations include (1) backside contacts (i.e., where one or both of the configuration of the first and second group of electrodes 18, 20 extends along the lower surface 6 of the substrate 2; and (2) re-routing one or both of the first and second group of electrodes 18, 20 such their respective electrical contacts 28 are coplanar and can all be accessed by an external device from the same area on upper surface 4 of the substrate 2.

[0027] To arrive at the folded configuration 38, the substrate 2 is folded along the folding line 14. If the substrate 2 is made of suitable flexible material, the substrate 2 will remain in tact (e.g., it will not break) and will take on the "U" shaped configuration depicted in Fig. 7. Alternatively, the substrate 2 may be constructed out of a brittle material that will partially or completely breaks along folding line 14 during or after the folding step. The substrate 2 may also be scored, perforated, or otherwise weakened along imagery line 14 to encourage the substrate 2 to break (either completely or partially) along folding line 14 during the folding step. It should be appreciated that while folding line 14 in Figs. 1-7 is positioned such that the first area 10 is substantially equal in size to the second area 12, this does not have to be the case. Furthermore, the first area 10 and the second area 12 need not be rectangular as shown.

[0028] Fig. 8 illustrates an embodiment in which one continuous intermediate layer(s) 22 includes both the first and the second sections of intermediate layer(s) 24, 26. In this embodiment, the intermediate layer(s) 22 are bent at the folding line 14. As with the substrate 2, the intermediate layer(s) 22 may be constructed out of a brittle materials that partially or completely breaks along folding line 14 during or after the folding step. The the intermediate layer(s) 22 may also be scored, perforated, or otherwise weakened along imagery line 14 to encourage the intermediate layer(s) to 22 break (either completely or partially) along folding line 14 during the folding step. Spacer layer(s) 34 may also be formed in this manner.

[0029] In further embodiment of the inventive concepts disclosed herein, a method of teaching the construction of an opposing sensor array includes: (1) providing the opposing sensor array described herein to an individual; and (2) teaching the individual to folded the single flexible substrate along the folding line 14.

[0030] The construction described above is simpler than the designs disclosed in the prior art, it allows for a large array of sensing elements in a compact size requiring minimal sample volume. In one embodiment of the sensor, a spacer of 3.0 cm length, 0.2 cm width and 0.05 cm thickness allows for a sample volume to be as low as 30 μL. With these dimensions a senor array of capable of measuring at least Hct, pO2, glucose, lactate, creatinine, BUN, Na, K, Ca, Mg, Cl, pH and pCO2 is possible.

[0031] The following is a non-limiting list of illustrative embodiments of the inventive concepts disclosed herein:

[0032] 1. A test device comprising: a single substrate, the substrate having a first surface, the first surface having a first area and a second area separated by a line, the first area opposing the second area of the first surface of the single substrate; a conductor layer disposed on the single substrate, the conductor layer comprising a first group of electrodes printed in the first area and a second group of electrodes printed in the second area; a dielectric layer disposed on the conductor layer, the dielectric layer comprising a first area of dielectric material disposed on the first group of electrodes and a second area of dielectric material disposed on the second group of electrodes, the first area of dielectric material and the second area of dielectric material each comprising a respective first group and a second group of reaction wells formed in the dielectric layer, at least one reaction well being electrically coupled to a respective electrode and containing chemistries; and a spacer layer adjacent to the first area of dielectric material and the second area of dielectric material, the spacer layer forming a flow path between the first group and the second group of reaction wells.

[0033] 2. The test device of illustrative embodiment 1, wherein along the transverse direction T the conductive layer, dielectric layer, and spacer layer are disposed between the opposing first area and second area. The opposing first and second areas being parallel to one another and extending in at least the lateral direction A.

[0034] 3. The test device of illustrative embodiment 2, wherein along the transverse direction T the first area of the dielectric layer and the second area of the dielectric layer oppose one another with the spacer layer disposed in between.

[0035] 4. The test device of illustrative embodiment 3, wherein along the transverse direction T the first group of electrodes and the second group of electrodes oppose one another with the dielectric layer and spacer layer disposed in between.

[0036] 5. The test device of illustrative embodiment 4, wherein along the transverse direction T the first area of the first surface opposes the second area of the first surface with the conductive layer, dielectric layer, and spacer layer disposed in between along the transverse direction T.

[0037] 6. The test device of illustrative embodiment 1, wherein the single substrate forms a U shape.

[0038] 7. The test device of illustrative embodiment 1, wherein the single substrate stays intact in the U shape.

[0039] 8. The test device of illustrative embodiment 1, wherein the single substrate at least partially breaks along the line.

[0040] 9. The test device of illustrative embodiment 8, wherein the single substrate is weakened along the line such that the single substrate at least partially breaks along the line in the U shape.

[0041] 10. An opposing sensor array comprising: a single substrate, having a first area and a second area; a conductor layer disposed on the single substrate, the conductor layer comprising a first group of electrodes printed in the first area and a second group of electrodes printed in the second area; a dielectric layer printed on the conductor layer, the dielectric layer comprising a first area of dielectric material disposed on the first group of electrodes and a second area of dielectric material disposed on the second group of electrodes, the first area of dielectric material and the second area of dielectric material each comprising a respective first group and a second group of reaction wells, each reaction well being aligned with a respective electrode and containing chemistries; and a spacer layer disposed on the first area of dielectric material, wherein when the single substrate is folded along a line, the spacer layer comes into contact with the first area of dielectric material and the second area of dielectric material forming a flow path between the first group and a second group of reaction wells.

[0042] 11. A method of making the test device as in any of illustrative embodiments 1 to 10.

What is claimed is:

1. A test device comprising:

a single substrate, the substrate having a first surface, the first surface having a first area and a second area separated by a line, the first area opposing the second area of the first surface of the single substrate;

a conductor layer disposed on the single substrate, the conductor layer comprising a first group of electrodes printed in the first area and a second group of electrodes printed in the second area;

a dielectric layer disposed on the conductor layer, the dielectric layer comprising a first area of dielectric material disposed on the first group of electrodes and a second area of dielectric material disposed on the second group of electrodes, the first area of dielectric material and the second area of dielectric material each comprising a respective first group and a second group of reaction wells formed in the dielectric layer, at least one reaction well being electrically coupled to a respective electrode and containing chemistries; and

a spacer layer adjacent to the first area of dielectric material and the second area of dielectric material, the spacer layer forming a flow path between the first group and the second group of reaction wells.

2. The test device of claim 1, wherein the conductive layer, dielectric layer, and spacer layer are disposed between the opposing first area and second area.

3. The test device of claim 2, wherein the first area of the dielectric layer and the second area of the dielectric layer oppose one another with the spacer layer disposed in between.

4. The test device of claim 3, wherein the first group of electrodes and the second group of electrodes oppose one another with the dielectric layer and spacer layer disposed in between.

5. The test device of claim 4, wherein the first area of the first surface opposes the second area of the first surface with the conductive layer, dielectric layer, and spacer layer disposed in between.

6. The test device of claim 1, wherein the single substrate forms a U shape.

7. The test device of claim 1, wherein the single substrate stays intact in the U shape.

8. The test device of claim 1, wherein the single substrate at least partially breaks along the line.

9. The test device of claim 8, wherein the single substrate is weakened along the line such that the single substrate at least partially breaks along the line in the U shape.

10. An opposing sensor array comprising:

a single substrate, having a first area and a second area;

a conductor layer disposed on the single substrate, the conductor layer comprising a first group of electrodes printed in the first area and a second group of electrodes printed in the second area;

a dielectric layer printed on the conductor layer, the dielectric layer comprising a first area of dielectric material disposed on the first group of electrodes and a second area of dielectric material disposed on the second group of electrodes, the first area of dielectric material and the second area of dielectric material each comprising a respective first group and a second group of reaction wells, each reaction well being aligned with a respective electrode and containing chemistries; and

a spacer layer disposed on the first area of dielectric material,

wherein when the single substrate is folded along a line, the spacer layer comes into contact with the first area of dielectric material and the second area of dielectric material forming a flow path between the first group and a second group of reaction wells.

11. A method of making the test device as in an of claims 1 to 10.

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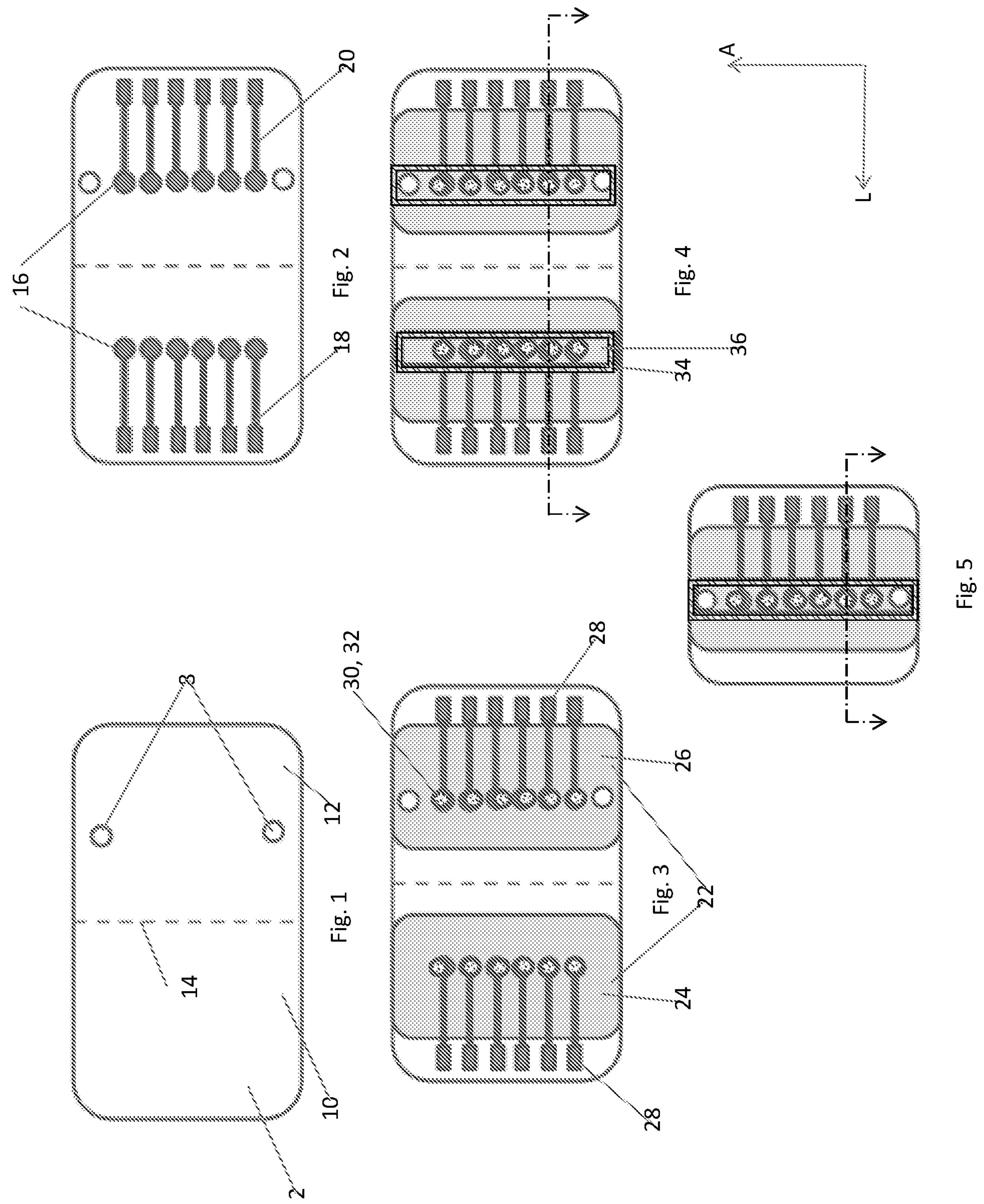
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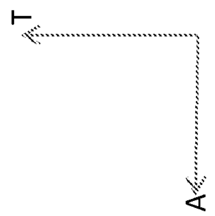
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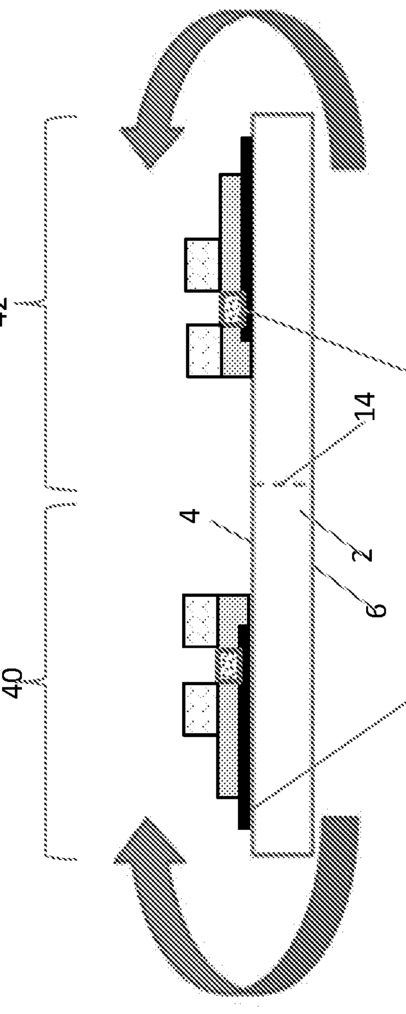
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Fig. 6

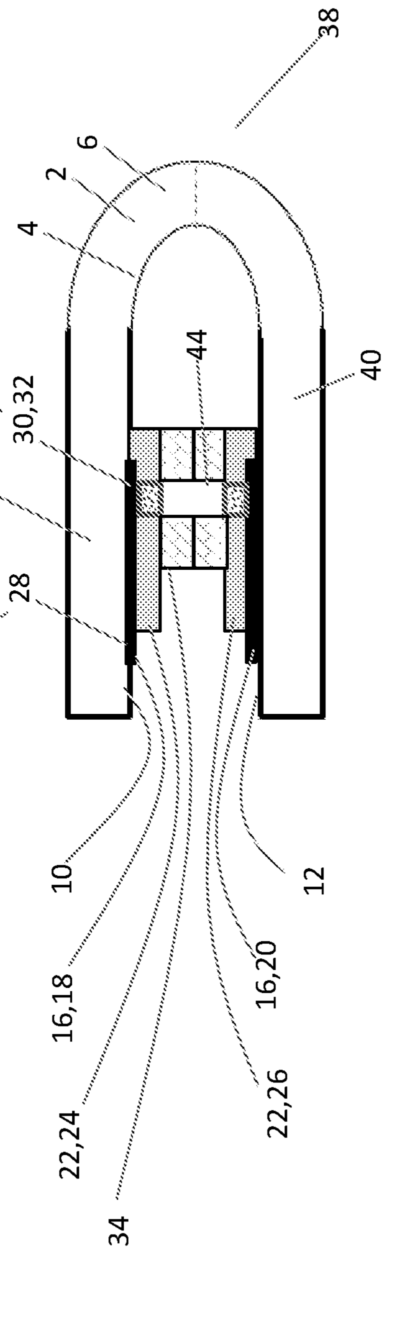
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Fig. 7

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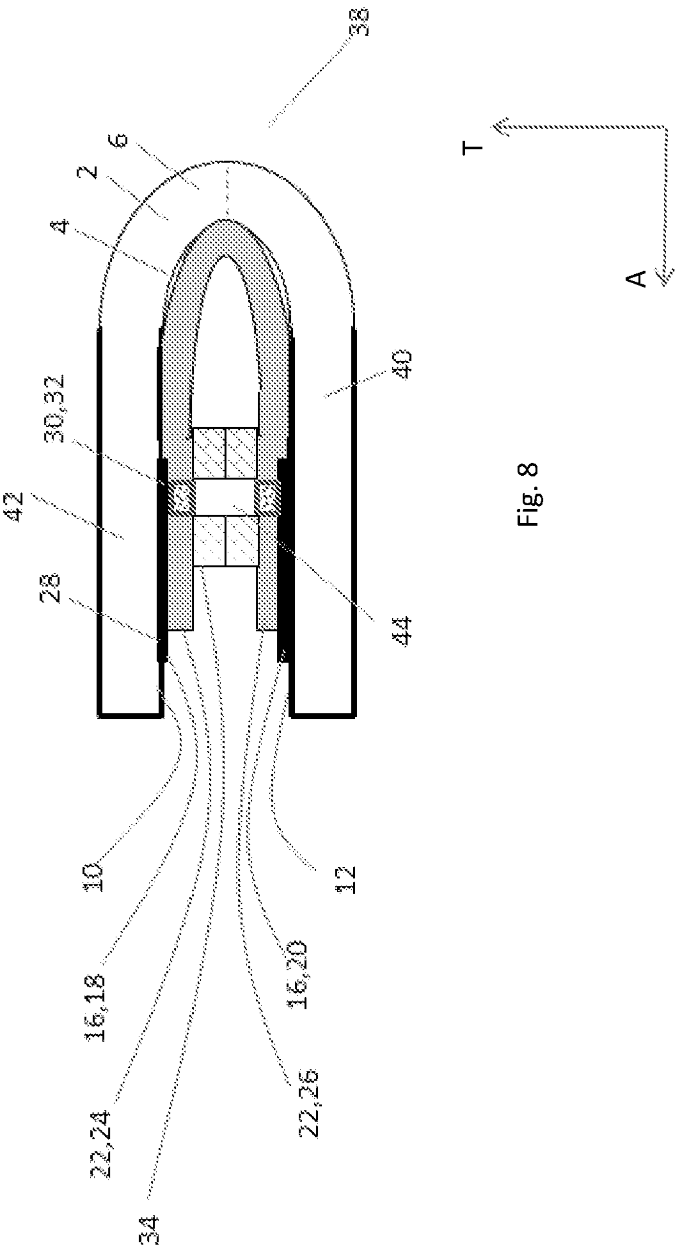

Fig. 8