

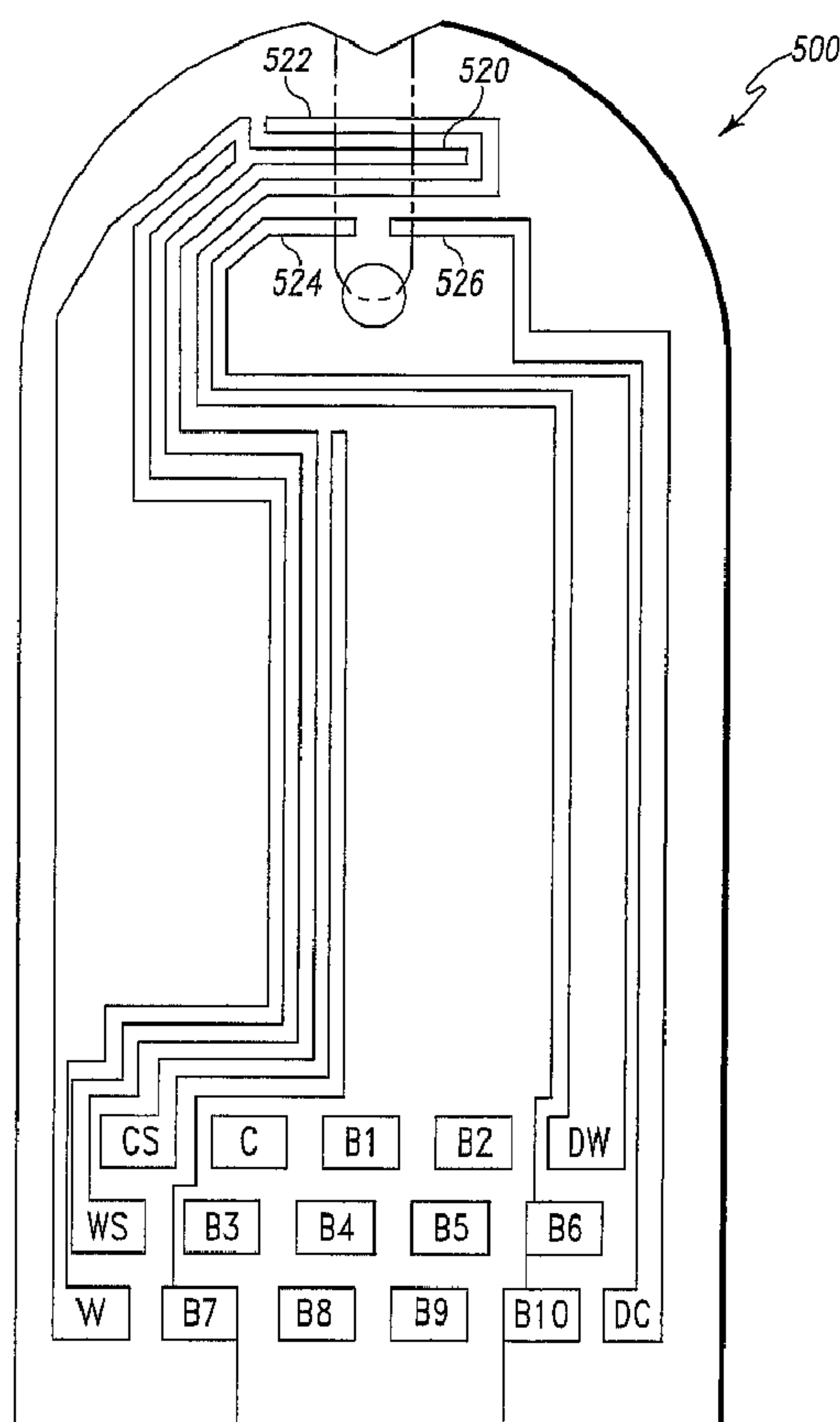


(86) Date de dépôt PCT/PCT Filing Date: 2004/06/18
(87) Date publication PCT/PCT Publication Date: 2004/12/29
(45) Date de délivrance/Issue Date: 2011/08/02
(85) Entrée phase nationale/National Entry: 2005/12/14
(86) N° demande PCT/PCT Application No.: US 2004/019653
(87) N° publication PCT/PCT Publication No.: 2004/113914
(30) Priorité/Priority: 2003/06/20 (US60/480,199)

(51) Cl.Int./Int.Cl. *G01N 33/487* (2006.01),
G01N 27/417 (2006.01)
(72) Inventeur/Inventor:
GROLL, HENNING, US
(73) Propriétaire/Owner:
F.HOFFMANN-LA ROCHE AG, CH
(74) Agent: NORTON ROSE OR S.E.N.C.R.L., S.R.L./LLP

(54) Titre : SYSTÈME ET PROCÉDE DE CODAGE D'INFORMATIONS SUR UNE BANDELETTE D'ESSAI DE TYPE BIOCAPTEUR

(54) Title: SYSTEM AND METHOD FOR CODING INFORMATION ON A BIOSENSOR TEST STRIP



(57) Abrégé/Abstract:

The present invention provides a test strip for measuring a concentration of an analyte of interest in a biological fluid, wherein the test strip may be encoded with information that can be read by a test meter into which the test strip is inserted.

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

(19) World Intellectual Property
Organization
International Bureau



(43) International Publication Date
29 December 2004 (29.12.2004)

PCT

(10) International Publication Number
WO 2004/113914 A1

(51) International Patent Classification⁷: **G01N 33/487**,
27/417

(72) Inventor; and

(75) Inventor/Applicant (for US only): **GROLL, Henning**
[DE/US]; 6050 Halfmoon Lane, Indianapolis, IN 46220
(US).

(21) International Application Number:
PCT/US2004/019653

(22) International Filing Date: 18 June 2004 (18.06.2004)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/480,199 20 June 2003 (20.06.2003) US

(71) Applicant (for all designated States except DE): **ROCHE
DIAGNOSTICS GMBH** [DE/DE]; Sandhofer Str. 116,
D-68298 Mannheim (DE).

(74) Agents: **COLE, Troy, J.** et al.; Woodard, Emhardt, Mori-
arty, McNett & Henry LLP, Bank One Center/Tower, Suite
3700, 111 Monument Circle, Indianapolis, IN 46204 (US).

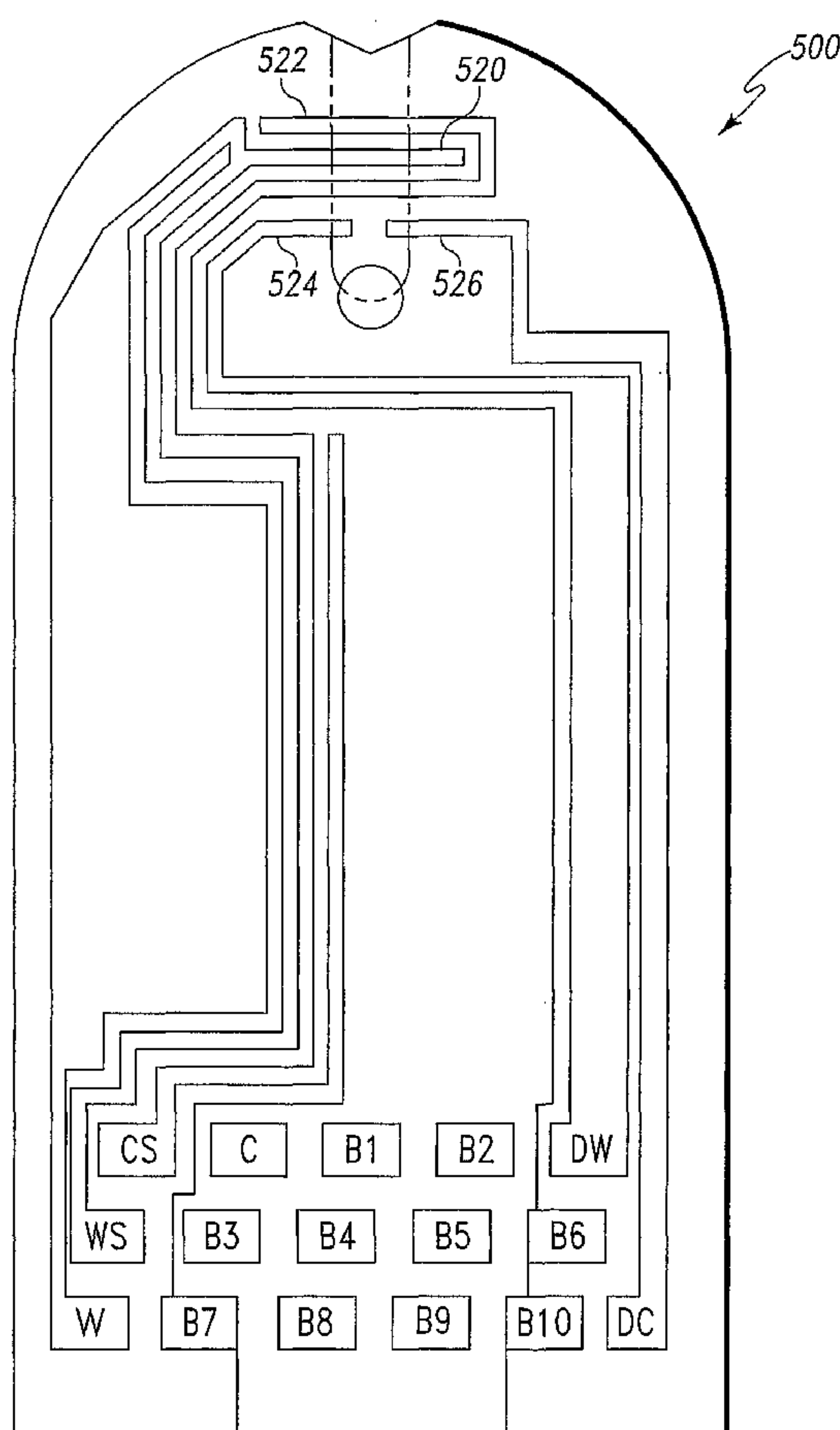
(81) Designated States (unless otherwise indicated, for every
kind of national protection available): AE, AG, AL, AM,
AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN,
CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI,
GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE,
KG, KP, KR, KZ, LC, LK, LR,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

(71) Applicant (for all designated States except DE, US): **F.
HOFFMANN-LA ROCHE AG** [CH/CH]; Grenzacher-
strasse 124, CH-4070 Basel (CH).

(84) Designated States (unless otherwise indicated, for every
kind of regional protection available): ARIPO (BW, GH,

[Continued on next page]

(54) Title: SYSTEM AND METHOD FOR CODING INFORMATION ON A BIOSENSOR TEST STRIP



(57) Abstract: The present invention provides a test strip for measuring a concentration of an analyte of interest in a biological fluid, wherein the test strip may be encoded with information that can be read by a test meter into which the test strip is inserted.

WO 2004/113914 A1

WO 2004/113914 A1



GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— with international search report

— before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

SYSTEM AND METHOD FOR CODING INFORMATION
ON A BIOSENSOR TEST STRIP

5

10

TECHNICAL FIELD OF THE INVENTION

15

The present invention relates to an apparatus for use in measuring concentrations of an analyte in a biological fluid. The invention relates more particularly to a system and method for coding information on a biosensor test strip.

BACKGROUND OF THE INVENTION

20

Measuring the concentration of substances in biological fluids is an important tool for the diagnosis and treatment of many medical conditions. For example, the measurement of glucose in body fluids, such as blood, is crucial to the effective treatment of diabetes.

25

Diabetic therapy typically involves two types of insulin treatment: basal, and meal-time. Basal insulin refers to continuous, e.g. time-released insulin, often taken before bed. Meal-time insulin treatment provides additional doses of faster acting insulin to regulate fluctuations in blood glucose caused by a variety of factors, including the metabolism of sugars and carbohydrates. Proper regulation of

30

blood glucose fluctuations requires accurate measurement of the concentration of glucose in the blood. Failure to do so can produce extreme complications, including blindness and loss of circulation in the extremities, which can ultimately deprive the diabetic of use of his or her fingers, hands, feet, etc.

5

Multiple methods are known for determining the concentration of analytes in a blood sample, such as, for example, glucose. Such methods typically fall into one of two categories: optical methods and electrochemical methods. Optical methods generally involve spectroscopy to observe the spectrum shift in the fluid caused by concentration of the analyte, typically in conjunction with a reagent that produces a known color when combined with the analyte. Electrochemical methods generally rely upon the correlation between a current (Amperometry), a potential (Potentiometry) or accumulated charge (Coulometry) and the concentration of the analyte, typically in conjunction with a reagent that produces charge-carriers when combined with the analyte. See, for example, U.S. Patent Nos. 4,233,029 to Columbus, 4,225,410 to Pace, 4,323,536 to Columbus, 4,008,448 to Muggli, 4,654,197 to Lilja et al., 5,108,564 to Szuminsky et al., 5,120,420 to Nankai et al., 5,128,015 to Szuminsky et al., 5,243,516 to White, 5,437,999 to Diebold et al., 5,288,636 to Pollmann et al., 5,628,890 to Carter et al., 5,682,884 to Hill et al., 5,727,548 to Hill et al., 5,997,817 to Crismore et al., 6,004,441 to Fujiwara et al., 4,919,770 to Friedel, et al., and 6,054,039 to Shieh.

The biosensor for conducting the tests is typically a disposable test strip having a reagent thereon that chemically reacts with the analyte of interest in the biological fluid. The test strip is mated to a nondisposable test meter such that the test meter can measure the reaction between the analyte and the reagent in order to determine and display the concentration of the analyte to the user.

It is common practice in such test meter/test strip systems to ensure proper identification of the test strip in order to ensure proper test results. For example, a single test meter may be able to analyze several different types of test strips, wherein each type of test strip is designed to test for the presence of a different analyte in the

biological fluid. In order to properly conduct the test, the test meter must know which type of test is to be performed for the test strip currently in use.

Also, lot-to-lot variations in the test strips normally require calibration
5 information to be loaded into the test meter in order to ensure accurate test results. A common practice for downloading such calibration information into the test meter is the use of an electronic read-only memory key (ROM key) that is inserted into a socket of the test meter. Because this calibration data may only be accurate for a particular production lot of test strips, the user is usually asked to confirm that the lot
10 number of the test strip currently in use matches the lot number for which the ROM key was programmed.

Many other instances in which it is desirable to have information relating to the test strip are known to those having skill in the art. Prior art attempts to code
15 information onto the test strip for reading by the test meter have suffered from many problems, including a severely limited amount of information that can be coded and the use of relatively large amounts of test strip surface area for the information coding function.

20 Thus, a system and method are needed that will allow information to be coded onto a biosensor for reading of the information by the test meter. The present invention is directed toward meeting this need.

SUMMARY OF THE INVENTION

The present invention provides a test strip for measuring a concentration of an analyte of interest in a biological fluid, wherein the test strip may be encoded with
5 information that can be read by a test meter into which the test strip is inserted.

In one form of the invention, a method for forming a test strip for measuring a concentration of an analyte of interest in a biological fluid is disclosed, the method comprising the steps of: providing a basic test strip design comprising: a substrate
10 having a surface and at least one measurement electrode formed thereon; a plurality of conductive contact pads formed upon the substrate surface, including at least one information contact pad and at least one measurement contact pad; and a plurality of potential conductive links conductively coupling various ones of the plurality of contact pads; wherein the at least one information contact pad is not coupled to any
15 of the at least one measurement electrodes except by one or more of the plurality of potential conductive links, and the at least one measurement contact pad is coupled to one of the at least one measurement electrodes by a path other than one or more of the plurality of potential conductive links; defining a set of valid test strip designs; wherein each one of the set of valid test strip designs incorporates none, one or more
20 than one of the plurality of potential conductive links; and wherein at least one of the plurality of potential conductive links couples a first one of the information contact pads to a first one of the measurement contact pads in a first valid test strip design, and at least one of the plurality of potential conductive links couples the first one of the information contact pads to a second one of the measurement contact pads in a
25 second valid test strip design; selecting one design from the set of valid test strip designs; and forming a test strip per said selected one design.

In another form of the invention, a plurality of test strips for measuring a concentration of an analyte of interest in a biological fluid is disclosed, each of the
30 plurality of test strips being substantially identical to one another except for a presence or absence of a plurality of potential conductive links, at least one of the test strips comprising: a substrate having a surface and at least one measurement

electrode formed thereon; a plurality of conductive contact pads formed upon the substrate surface, including at least one information contact pad and at least one measurement contact pad; and a plurality of conductive links selected from the plurality of potential conductive links, wherein the plurality of conductive links
5 conductively couple at least three contact pads together; wherein the at least one information contact pad is not coupled to any of the at least one measurement electrodes except by one or more of the plurality of potential conductive links, and the at least one measurement contact pad is coupled to one of the at least one measurement electrodes by a path other than one or more of the plurality of potential
10 conductive links.

In another form of the invention, a method for forming a test strip for measuring a concentration of an analyte of interest in a biological fluid is disclosed, the method comprising the steps of: providing a basic test strip design comprising: a
15 substrate having a surface and at least one measurement electrode formed thereon; a plurality of conductive contact pads formed upon the substrate surface, including at least one information contact pad and at least one measurement contact pad; and a plurality of potential conductive links conductively coupling various ones of the plurality of contact pads; wherein the at least one information contact pad is not
20 coupled to any of the at least one measurement electrodes except by one or more of the plurality of potential conductive links, and the at least one measurement contact pad is coupled to one of the at least one measurement electrodes by a path other than one or more of the plurality of potential conductive links; defining a set of valid test strip designs; wherein each one of the set of valid test strip designs incorporates
25 none, one or more than one of the plurality of potential conductive links; and wherein at least one of the set of valid test strip designs includes conductive links that conductively couple at least three contact pads together; selecting one design from the set of valid test strip designs; and forming a test strip per said selected one design.

30

In another form of the invention, a test strip for measuring a concentration of an analyte of interest in a biological fluid is disclosed, the test strip comprising: a

substrate having a surface and at least one measurement electrode formed thereon; a plurality of conductive contact pads formed upon the substrate surface, including at least one information contact pad and at least one measurement contact pad; and at least one conductive link conductively coupling at least three of the contact pads; wherein the at least one information contact pad is not coupled to any of the at least one measurement electrodes except by one or more of the at least one conductive links, and the at least one measurement contact pad is coupled to one of the at least one measurement electrodes by a path other than one or more of the at least one conductive links.

10

In another form of the invention, a test strip for measuring a concentration of an analyte of interest in a biological fluid is disclosed, the test strip comprising: a substrate having a surface and at least one measurement electrode formed thereon; a plurality of conductive contact pads formed upon the substrate surface, including at least one information contact pad and at least one measurement contact pad; and at least one conductive link conductively coupling at least three of the contact pads; wherein the at least one information contact pad is not coupled to any of the at least one measurement electrodes except by one or more of the at least one conductive links, and the at least one measurement contact pad is coupled to one of the at least one measurement electrodes by a path other than one or more of the at least one conductive links.

15

20

In another form of the invention, a test strip for measuring a concentration of an analyte of interest in a biological fluid is disclosed, the test strip adapted to be inserted into a test meter having at least one connector contact that touches the inserted test strip, the test strip comprising: a substrate having a top surface; a conductive layer formed on at least a portion of the substrate top surface; and at least one predetermined contact pad position defined upon the substrate top surface; wherein each of the at least one contact pad positions is touched by a respective one of the at least one connector contacts when the at least one connector contacts touch the test strip; wherein a presence of the conductive layer in a respective one of the contact pad positions is operative to indicate a first state of a binary bit to the test

25

30

meter; and wherein an absence of the conductive layer in a respective one of the contact pad positions is operative to indicate a second state of a binary bit to the test meter.

5 In another form of the invention, a method for measuring a concentration of an analyte of interest in a biological fluid, comprising the steps of: providing a test meter having at least one connector contact that touches an inserted test strip, providing a test strip adapted to be inserted into the test meter, the test strip comprising: a substrate having a top surface; a conductive layer formed on at least a
10 portion of the substrate top surface; and at least one predetermined contact pad position defined upon the substrate top surface; touching each of the at least one predetermined contact pad positions with a respective one of the at least one connector contacts; indicating a first state of a binary bit within the test meter in response to a presence of the conductive layer in a respective one of the contact pad
15 positions; and indicating a second state of a binary bit within the test meter in response to an absence of the conductive layer in a respective one of the contact pad positions.

In another form of the invention, a test strip for measuring a concentration of
20 an analyte of interest in a biological fluid is disclosed, the test strip comprising a substrate having a surface; a first measurement electrode formed on the surface; a second measurement electrode formed on the surface; a third potential electrode formed on the surface; a fourth potential electrode formed on the surface; a first contact pad formed on the surface and conductively coupled to the first measurement
25 electrode; a second contact pad formed on the surface and conductively coupled to the second measurement electrode; a third contact pad formed on the surface and conductively coupled to the third potential electrode; a fourth contact pad formed on the surface and conductively coupled to the fourth potential electrode; and a conductive link coupling one of the third and fourth potential electrodes to the first
30 measurement electrode, whereby another one of the third and fourth potential electrodes becomes an actual electrode.

In another form of the invention, a method of using a test meter and associated test strip for measuring a concentration of an analyte of interest in a biological fluid is disclosed, comprising the steps of a) providing a test strip comprising a substrate having at least a first, second and third contact pad formed thereon; b) providing a test meter comprising a connector configured to make
5 conductive contact with the first, second and third contact pads when the test strip is inserted into the test meter; c) operating the test meter to determine if conductivity exists between the first and second contact pads; d) operating the test meter to determine if conductivity exists between the first and third contact pads; e)
10 designating the second contact pad to have a first function and the third contact pad to have a second function if the test meter determines that conductivity exists between the first and second contact pads and that conductivity does not exist between the first and third contact pads; and f) designating the second contact pad to have the second function and the third contact pad to have the first function if the
15 test meter determines that conductivity does not exist between the first and second contact pads and that conductivity exists between the first and third contact pads.

In another form of the invention, a method of using a test meter and associated test strip for measuring a concentration of an analyte of interest in a
20 biological fluid is disclosed, comprising the steps of a) providing a test strip comprising a substrate having at least a first, second and third contact pad formed thereon; b) providing a test meter comprising a connector configured to make conductive contact with the first, second and third contact pads when the test strip is inserted into the test meter; c) operating the test meter to determine if conductivity
25 exists between the first and second contact pads; d) designating the second contact pad to have a first function and the third contact pad to have a second function if the test meter determines that conductivity exists between the first and second contact pads; and e) designating the second contact pad to have the second function and the third contact pad to have the first function if the test meter determines that
30 conductivity does not exist between the first and second contact pads.

In another form of the invention, a method of using a test meter adapted to measure a concentration of an analyte of interest in a biological fluid placed on a test strip is disclosed, the method comprising the steps of a) inserting the test strip into the test meter such that the test meter makes electrical contact with the test strip; b) operating the meter to read information encoded onto the test strip; and c) choosing a language in which the test meter displays user operating instructions based upon the information read from the test strip.

In another form of the invention, a method of using a test meter adapted to measure a concentration of an analyte of interest in a biological fluid placed on a test strip is disclosed, the method comprising the steps of a) inserting the test strip into the test meter such that the test meter makes electrical contact with the test strip; b) operating the meter to read information encoded onto the test strip; and c) determining if the test meter and the test strip were sold in the same geographic market based upon the information read from the test strip.

In another form of the invention, a method of using a test meter adapted to measure a concentration of an analyte of interest in a biological fluid placed on a test strip is disclosed, wherein the test meter is not intended for use with subscription test strips sold on a subscription basis, the method comprising the steps of a) inserting the test strip into the test meter such that the test meter makes electrical contact with the test strip; b) operating the meter to read information encoded onto the test strip; c) determining if the test strip is a subscription test strip based upon the information read from the test strip; and d) preventing use of the test strip by the meter if the test strip is a subscription test strip.

In another form of the invention, a method of using a test meter adapted to measure a concentration of an analyte of interest in a biological fluid placed on a test strip is disclosed, the method comprising the steps of a) inserting the test strip into the test meter such that the test meter makes electrical contact with the test strip; b) operating the meter to read information encoded onto the test strip; and c) activating a latent feature of the test meter based upon the information read from the test strip.

In another form of the invention, a method of using a test meter adapted to measure a concentration of an analyte of interest in a biological fluid placed on a test strip is disclosed, the method comprising the steps of a) inserting the test strip into the test meter such that the test meter makes electrical contact with the test strip; b) operating
5 the meter to read information encoded onto the test strip; and c) changing the user operating instructions displayed to the user based upon the information read from the test strip.

In another form of the invention, a test system for measuring a concentration of an analyte of interest in a biological fluid is disclosed, the test system comprising a
10 test meter comprising a connector having at least six, preferably at least ten contacts; and a test strip adapted to be inserted into the test meter connector, the test strip comprising: a substrate having a surface; at least six, and preferably at least ten contact pads formed on the surface; wherein the at least six, preferably at least ten contacts make contact with the respective at least six, and preferably at least ten
15 contact pads when the test strip is inserted into the test meter connector, and wherein the test meter is adapted to read information encoded on the test strip; and an electrode is formed on the surface.

In particular, at least two contact pads are information contact pads, and at least one information contact pad is conductively connected to the electrode.
20 In one particular embodiment of the invention there are at least ten contact pads formed on the surface, which make contact with the corresponding at least ten contact pads when the test strip is inserted into the test meter connector.

In another particular embodiment of the invention, all contact pads remain functional even when each of the contacts removes all conductive material from the
25 test strip under the respective contact as the test strip is inserted into the test meter. In particular the contact pads are in a spaced apart staggered relationship on the surface, transversely of a direction of insertion of the test strip into the test meter; and more especially the contact pads are spaced apart side by side in transverse rows, with the contact pads in each row being staggered relative to the contact pads in the
30 adjacent row.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will be further described, by way of example only, with reference to the accompanying drawings, in which:

5

FIG. 1 is an exploded perspective view of a first typical test strip for use in measuring the concentration of an analyte of interest in a biological fluid.

FIG. 2 is a schematic plan view of a first embodiment test strip electrode and contact pad arrangement according to the present invention.

10

FIG. 3 is a table showing a first embodiment coding sequence for the test strip of FIG. 2.

FIG. 4 is a perspective view of a second typical test strip for use in measuring the concentration of an analyte of interest in a biological fluid.

15

FIG. 5 illustrates a view of an ablation apparatus suitable for use with the present invention.

FIG. 6 is a view of the laser ablation apparatus of Figure 5 showing a second mask.

FIG. 7 is a view of an ablation apparatus suitable for use with the present invention.

20

FIG. 8 is a schematic process flow diagram of a prior art process for verifying the applicability of the calibration data in the test meter to the test strip currently inserted into the test meter.

25

FIG. 9 is a schematic process flow diagram of a first embodiment process of the present invention for verifying the applicability of the calibration data in the test meter to the test strip currently inserted into the test meter.

FIG. 10 is a schematic plan view of a second embodiment test strip electrode and contact pad arrangement according to the present invention.

FIG. 11 is a schematic plan view of a third embodiment test strip electrode and contact pad arrangement according to the present invention.

30

FIG. 12 is a schematic plan view of an electrical connector-to-test strip contact pad interface illustrating worst case left tolerance stack-ups.

FIG. 13 is a schematic plan view of the electrical connector-to-test strip contact pad interface of FIG. 12 illustrating normal case tolerance stack-ups.

FIG. 14 is a schematic plan view of the electrical connector-to-test strip contact pad interface of FIG. 12 illustrating worst case right tolerance stack-ups.

5 FIG. 15 is a schematic plan view of a fourth embodiment test strip electrode and contact pad arrangement according to the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

For the purposes of promoting an understanding of the principles of the invention, reference will now be made to the embodiment illustrated in the drawings, and specific language will be used to describe that embodiment. It will nevertheless
5 be understood that no limitation of the scope of the invention is intended. Alterations and modifications in the illustrated device, and further applications of the principles of the invention as illustrated therein, as would normally occur to one skilled in the art to which the invention relates are contemplated, are desired to be protected. In
10 particular, although the invention is discussed in terms of a blood glucose meter, it is contemplated that the invention can be used with devices for measuring other analytes and other sample types. Such alternative embodiments require certain adaptations to the embodiments discussed herein that would be obvious to those skilled in the art.

15

Although the system and method of the present invention may be used with test strips having a wide variety of designs and made with a wide variety of construction techniques and processes, a typical electrochemical test strip is illustrated in FIG. 1, and indicated generally at 10. Referring to FIG. 1, the test strip
20 10 comprises a bottom substrate 12 formed from an opaque piece of 350 μm thick polyester (such as MelinexTM 329 available from DuPont) coated on its top surface with a 50 nm conductive (gold) layer (by sputtering or vapor deposition, for example). Electrodes, connecting traces and contact pads therefor are then patterned in the conductive layer by a laser ablation process. The laser ablation process is
25 performed by means of an excimer laser which passes through a chrome-on-quartz mask. The mask pattern causes parts of the laser field to be reflected while allowing other parts of the field to pass through, creating a pattern on the gold which is ablated where contacted by the laser light. The laser ablation process is described in greater detail hereinbelow. For example, working 20, counter 22, dose sufficiency
30 working 24, and dose sufficiency counter 26 electrodes may be formed as shown and coupled, respectively, to measurement contact pads W, C, DW and DC. These contact pads provide a conductive area upon the test strip 10 to be contacted by a

connector contact of the test meter once the test strip 10 is inserted into the test meter.

The bottom substrate 12 is then coated in the area extending over the electrodes with a reagent layer 14 as a continuous, extremely thin reagent film. The reagent layer 14 is a stripe of approximately 6 millimeters width across the substrate 12 in the region labeled "Reagent Layer" on FIG. 1. For example, this region may be coated at a wet-coat weight of 50 grams per square meter of coated surface area. The reagent strip is dried conventionally with an in-line drying system where the nominal air temperature is at 110°C. The rate of processing is nominally 30-38 meters per minute and depends upon the rheology of the reagent.

The materials are processed in continuous reels such that the electrode pattern is orthogonal to the length of the reel, in the case of the substrate 12. Once the substrate 12 has been coated with reagent, the spacers 16 are slit and placed in a reel-to-reel process onto the substrate 12. Two spacers 16 formed from 100 μm polyester (for example, MelinexTM 329 available from DuPont) coated with 25 μm PSA (hydrophobic adhesive) on both the dorsal and ventral surfaces are applied to the bottom substrate 12, such that the spacers 16 are separated by 1.5 mm and the working, counter and dose sufficiency electrodes are centered in this gap. A top foil layer 18 formed from 100 μm polyester coated with a hydrophilic film on its ventral surface (using the process described in U.S. Patent No. 5, 997,817) is placed over the spacers 16. The hydrophilic film is coated with a mixture of VitelTM and RhodapexTM surfactant at a nominal thickness of 10 microns. The top foil layer 18 is laminated using a reel-to-reel process. The test strips can then be produced from the resulting reels of material by means of slitting and cutting.

Although the basic test strip 10 illustrated in FIG. 1 can provide accurate measurements of blood glucose in a whole blood sample, it does not provide any means for the test meter into which it is inserted to identify anything about the test strip. The present invention presents several systems by which information relating

to the test strip can be coded directly onto the test strip itself, such that this information can be conveyed to a test meter into which the test strip is inserted.

In a first embodiment of the present invention, information about the test strip can be coded directly onto the test strip by the addition of two or more contact pads dedicated to reading such coded information. As illustrated in FIG. 2, a pair of additional information contact pads B1 and B2 are added to the proximal end of the test strip. Additionally, potential conductive links between the information contact pads B1 and B2 and between them and measurement contact pads connected to test strip measurement electrodes are identified at 28, 30, 32, 34 and 36. These links are denominated as potential conductive links because they may either be present or absent in the finished test strip, depending upon the information that is to be coded onto the test strip. Therefore, a "potential conductive link" indicates a conductive link that is found on some, but not all, of a group of otherwise substantially identical test strips. As used herein, the phrase "information contact pad" is defined as a contact pad on the test strip that is either not conductively coupled to a measurement electrode of the test strip at all, or is so coupled only by a potential conductive link. As used herein, the phrase "measurement contact pad" is defined as a contact pad on the test strip that is always conductively coupled to a measurement electrode of the test strip, regardless of the presence or absence of the potential conductive links.

Specifically, potential conductive link 28 couples the DC contact pad and the B1 contact pad. Potential conductive link 30 couples the B1 contact pad and the B2 contact pad. Potential conductive link 32 couples the B2 contact pad and the C contact pad. Potential conductive link 34 couples the DC contact pad and the B2 contact pad. Potential conductive link 36 couples the B1 contact pad and the C contact pad. It should be noted that the first embodiment of the present invention illustrates potential conductive links between the information contact pads B1 and B2 and the measurement contact pads DC and C by way of example only, and that the information contact pads may be conductively linked to any desired measurement contact pad(s) on the test strip.

FIG. 3 illustrates a table showing the possible combinations for the potential conductive links 28-36 formed on any one test strip of the first embodiment. The first five columns of the table represent each of the potential conductive links 28-36, which are labeled C1-C5, respectively. Each of the nine rows of the table numbered 0-8 represent a different number that can be encoded using the potential conductive links 28-36. A "0" in a table position indicates that the potential conductive link is not formed when encoding the number of that row, while a "1" in a table position indicates that the potential conductive link is formed when encoding the number of that row. Note that there are some combinations of potential conductive links that are not allowed because the DC contact pad and the C contact pad cannot be conductively linked without harming the measurement functionality of the test strip measurement electrodes. For example, potential conductive links 34 and 36 may not be used at the same time, as they cross one another and therefore would conductively connect the DC contact pad to the C contact pad. Similarly, potential conductive links 28, 30 and 32 may not be used at the same time.

The last two columns of the table of FIG. 3 are labeled B1 and B2, respectively, and indicate to which of the other contact pads the labeled contact pad is coupled when the number of that row is encoded onto the test strip. For example, when the number six (6) is encoded onto the test strip (i.e. potential conductive links 28 and 32 are formed on the test strip) the B1 contact pad is conductively coupled to the DC contact pad, and the B2 contact pad is conductively coupled to the C contact pad, but B1 and B2 are not conductively coupled to any other contact pads (including to each other). Therefore, a measurement by the test meter of the resistance (either directly or indirectly) between each of the contact pads DC, B1, B2 and C will indicate which of the eight (8) possible numbers has been encoded onto the test strip. The present invention also comprehend other methods for determining the presence or absence of potential conductive links on the test strip other than by measurement of resistance or conductivity. By way of non-limiting example, the potential conductive links can also be sensed in a non-contact fashion by inducing and sensing eddy currents using an electromagnetic field, by capacitive means, by

optical scanning techniques, or by other methods that would be apparent to one having ordinary skill in the art.

Note that the absence of all of the potential conductive links 28-36 is preferably not considered to be a valid state as this could be caused by a localized defect obliterating the region of the test strip containing the potential conductive links 28-36, but this state could be considered a valid state in other, non-preferred, embodiments. It should also be noted that a reading of conduction between combinations of contact pads not indicated as a valid combination in the table of FIG. 3 will be interpreted by the test meter as a defective strip with an unintended short.

It will be appreciated that the use of measurement contact pads in combination with dedicated information contact pads in the present invention, and the opportunity to potentially couple each information contact pad to more than one measurement contact pad significantly increases the amount of numbers that may be encoded onto the test strip. By way of comparison, the two (2) information contact pads of the first embodiment of the present invention conservatively allow the coding of eight (8) numbers. The design disclosed in JP 2000352034 would only allow two (2) possible states with two information contact pads, while the design disclosed in EP 1152239A1 would only allow four (4) possible states with two information contact pads.

One method of preparing a test strip encoded with information as described herein is by the use of laser ablation techniques. Examples of the use of these techniques in preparing electrodes for biosensors are described in US 2002/0192115, "Biosensors with Laser Ablation Electrodes with a Continuous Coverlay Channel" filed May 25, 2001, and in US Patent No. 6,662,439 entitled "Laser Defined Features for Patterned Laminates and Electrode", filed October 4, 1999.

It is desirable in the present invention to provide for the accurate placement of the electrical components relative to one another and to the overall biosensor. In a preferred embodiment, the relative placement of components is achieved, at least in part, by the use of broad field laser ablation that is performed through a mask or
5 other device that has a precise pattern for the electrical components. This allows accurate positioning of adjacent edges, which is further enhanced by the close tolerances for the smoothness of the edges.

Figure 4 illustrates a simple biosensor 401 useful for illustrating the laser
10 ablation process of the present invention, including a substrate 402 having formed thereon conductive material 403 defining electrode systems comprising a first electrode set 404 and a second electrode set 405, and corresponding traces 406, 407 and contact pads 408, 409, respectively. The conductive material 403 may contain pure metals or alloys, or other materials, which are metallic conductors. Preferably,
15 the conductive material is absorptive at the wavelength of the laser used to form the electrodes and of a thickness amenable to rapid and precise processing. Non-limiting examples include aluminum, carbon, copper, chromium, gold, indium tin oxide (ITO), palladium, platinum, silver, tin oxide/gold, titanium, mixtures thereof, and alloys or metallic compounds of these elements. Preferably, the conductive
20 material includes noble metals or alloys or their oxides. Most preferably, the conductive material includes gold, palladium, aluminum, titanium, platinum, ITO and chromium. The conductive material ranges in thickness from about 10 nm to 80 nm, more preferably, 30 nm to 70 nm, and most preferably 50 nm. It is appreciated that the thickness of the conductive material depends upon the transmissive property
25 of the material and other factors relating to use of the biosensor.

While not illustrated, it is appreciated that the resulting patterned conductive material can be coated or plated with additional metal layers. For example, the conductive material may be copper, which is then ablated with a laser into an
30 electrode pattern; subsequently, the copper may be plated with a titanium/tungsten layer, and then a gold layer, to form the desired electrodes. Preferably, a single layer of conductive material is used, which lies on the base 402. Although not generally

necessary, it is possible to enhance adhesion of the conductive material to the base, as is well known in the art, by using seed or ancillary layers such as chromium nickel or titanium. In preferred embodiments, biosensor 401 has a single layer of gold, palladium, platinum or ITO.

5

Biosensor 401 is illustratively manufactured using two apparatuses 410, 410', shown in Figures 4,6 and 7, respectively. It is appreciated that unless otherwise described, the apparatuses 410, 410' operate in a similar manner. Referring first to Figure 5, biosensor 401 is manufactured by feeding a roll of ribbon 420 having an 80 nm gold laminate, which is about 40 mm in width, into a custom fit broad field laser ablation apparatus 410. The apparatus 410 comprises a laser source 411 producing a beam of laser light 412, a chromium-plated quartz mask 414, and optics 416. It is appreciated that while the illustrated optics 416 is a single lens, optics 416 is preferably a variety of lenses that cooperate to make the light 412 in a pre-determined shape.

15

A non-limiting example of a suitable ablation apparatus 410 (Figures 5-6) is a customized MicrolineLaser 200-4 laser system commercially available from LPKF Laser Electronic GmbH, of Garbsen, Germany, which incorporates an LPX-400, LPX-300 or LPX-200 laser system commercially available from Lambda Physik AG, Göttingen, Germany and a chromium-plated quartz mask commercially available from International Phototool Company, Colorado Springs, Co.

20

For the MicrolineLaser 200-4 laser system (Figures 5-6), the laser source 411 is a LPX-200 KrF-UV-laser. It is appreciated, however, that higher wavelength UV lasers can be used in accordance with this disclosure. The laser source 411 works at 248nm, with a pulse energy of 600mJ, and a pulse repeat frequency of 50 Hz. The intensity of the laser beam 412 can be infinitely adjusted between 3% and 92% by a dielectric beam attenuator (not shown). The beam profile is 27x15mm² (0.62 sq. inch) and the pulse duration 25ns. The layout on the mask 414 is homogeneously projected by an optical elements beam expander, homogenizer, and field lens (not shown). The performance of the homogenizer has been determined by measuring the

25

30

energy profile. The imaging optics 416 transfer the structures of the mask 414 onto the ribbon 420. The imaging ratio is 2:1 to allow a large area to be removed on the one hand, but to keep the energy density below the ablation point of the applied chromium mask on the other hand. While an imaging of 2:1 is illustrated, it is appreciated that the any number of alternative ratios are possible in accordance with this disclosure depending upon the desired design requirements. The ribbon 420 moves as shown by arrow 425 to allow a number of layout segments to be ablated in succession.

The positioning of the mask 414, movement of the ribbon 420, and laser energy are computer controlled. As shown in Figure 5, the laser beam 412 is projected onto the ribbon 420 to be ablated. Light 412 passing through the clear areas or windows 418 of the mask 414 ablates the metal from the ribbon 420. Chromium coated areas 424 of the mask 414 blocks the laser light 412 and prevent ablation in those areas, resulting in a metallized structure on the ribbon 420 surface. Referring now to Figure 6, a complete structure of electrical components may require additional ablation steps through a second mask 414'. It is appreciated that depending upon the optics and the size of the electrical component to be ablated, that only a single ablation step or greater than two ablation steps may be necessary in accordance with this disclosure. Further, it is appreciated that instead of multiple masks, that multiple fields may be formed on the same mask in accordance with this disclosure.

Specifically, a second non-limiting example of a suitable ablation apparatus 410' (Figure 7) is a customized laser system commercially available from LPKF Laser Electronic GmbH, of Garbsen, Germany, which incorporates a Lambda STEEL (Stable energy eximer laser) laser system commercially available from Lambda Physik AG, Göttingen, Germany and a chromium-plated quartz mask commercially available from International Phototool Company, Colorado Springs, Co. The laser system features up to 1000 mJ pulse energy at a wavelength of 308 nm. Further, the laser system has a frequency of 100 Hz. The apparatus 410' may be formed to produce biosensors with two passes as shown in Figures 5 and 6, but

preferably its optics permit the formation of a 10x40 mm pattern in a 25 ns single pass.

While not wishing to be bound to a specific theory, it is believed that the
5 laser pulse or beam 412 that passes through the mask 414, 414', 414'' is absorbed within less than 1 μm of the surface 402 on the ribbon 420. The photons of the beam 412 have an energy sufficient to cause photo-dissociation and the rapid breaking of chemical bonds at the metal/polymer interface. It is believed that this rapid chemical bond breaking causes a sudden pressure increase within the absorption region and
10 forces material (metal film 403) to be ejected from the polymer base surface. Since typical pulse durations are around 20-25 nanoseconds, the interaction with the material occurs very rapidly and thermal damage to edges of the conductive material 403 and surrounding structures is minimized. The resulting edges of the electrical components have high edge quality and accurate placement as contemplated by the
15 present invention.

Fluence energies used to remove or ablate metals from the ribbon 420 are dependent upon the material from which the ribbon 420 is formed, adhesion of the metal film to the base material, the thickness of the metal film, and possibly the
20 process used to place the film on the base material, i.e. supporting and vapor deposition. Fluence levels for gold on KALADEX[®] range from about 50 to about 90 mJ/cm^2 , on polyimide about 100 to about 120 mJ/cm^2 , and on MELINEX[®] about 60 to about 120 mJ/cm^2 . It is understood that fluence levels less than or greater than the above mentioned can be appropriate for other base materials in accordance with the
25 disclosure.

Patterning of areas of the ribbon 420 is achieved by using the masks 414, 414'. Each mask 414, 414' illustratively includes a mask field 422 containing a precise two-dimensional illustration of a pre-determined portion of the electrode
30 component patterns to be formed. Figure 5 illustrates the mask field 422 including contact pads and a portion of traces. As shown in Figure 6, the second mask 414'

contains a second corresponding portion of the traces and the electrode patterns containing fingers. As previously described, it is appreciated that depending upon the size of the area to be ablated, the mask 414 can contain a complete illustration of the electrode patterns (Figure 7), or portions of patterns different from those illustrated in Figures 5 and 6 in accordance with this disclosure. Preferably, it is contemplated that in one aspect of the present invention, the entire pattern of the electrical components on the test strip are laser ablated at one time, i.e., the broad field encompasses the entire size of the test strip (Figure 7). In the alternative, and as illustrated in Figures 5 and 6, portions of the entire biosensor are done successively.

While mask 414 will be discussed hereafter, it is appreciated that unless indicated otherwise, the discussion will apply to masks 414', 414'' as well. Referring to Figure 5, areas 424 of the mask field 422 protected by the chrome will block the projection of the laser beam 412 to the ribbon 420. Clear areas or windows 418 in the mask field 422 allow the laser beam 412 to pass through the mask 414 and to impact predetermined areas of the ribbon 420. As shown in Figure 5, the clear area 418 of the mask field 422 corresponds to the areas of the ribbon 420 from which the conductive material 403 is to be removed.

Further, the mask field 422 has a length shown by line 430 and a width as shown by line 432. Given the imaging ratio of 2:1 of the LPX-200, it is appreciated that the length 30 of the mask is two times the length of a length 434 of the resulting pattern and the width 432 of the mask is two times the width of a width 436 of the resulting pattern on ribbon 420. The optics 416 reduces the size of laser beam 412 that strikes the ribbon 420. It is appreciated that the relative dimensions of the mask field 422 and the resulting pattern can vary in accordance with this disclosure. Mask 414' (Figure 6) is used to complete the two-dimensional illustration of the electrical components.

Continuing to refer to Figure 5, in the laser ablation apparatus 410 the excimer laser source 411 emits beam 412, which passes through the chrome-on-

quartz mask 414. The mask field 422 causes parts of the laser beam 412 to be reflected while allowing other parts of the beam to pass through, creating a pattern on the gold film where impacted by the laser beam 412. It is appreciated that ribbon 420 can be stationary relative to apparatus 410 or move continuously on a roll through apparatus 410. Accordingly, non-limiting rates of movement of the ribbon 420 can be from about 0 m/min to about 100 m/min, more preferably about 30 m/min to about 60 m/min. It is appreciated that the rate of movement of the ribbon 420 is limited only by the apparatus 410 selected and may well exceed 100 m/min depending upon the pulse duration of the laser source 411 in accordance with the present disclosure.

Once the pattern of the mask 414 is created on the ribbon 420, the ribbon is rewound and fed through the apparatus 410 again, with mask 414' (Figure 6). It is appreciated, that alternatively, laser apparatus 410 could be positioned in series in accordance with this disclosure. Thus, by using masks 414, 414', large areas of the ribbon 420 can be patterned using step-and-repeat processes involving multiple mask fields 422 in the same mask area to enable the economical creation of intricate electrode patterns and other electrical components on a substrate of the base, the precise edges of the electrode components, and the removal of greater amounts of the metallic film from the base material.

The ability to code information directly onto the test strip can dramatically increase the capabilities of the test strip and enhance its interaction with the test meter. For example, it is well known in the art to supply the test meter with calibration data applicable to any given manufacturing lot of test strips. Typically, this is done by supplying a read-only memory key (ROM key) with each vial of test strips, where the ROM key has encoded thereon the calibration data applicable to the test strips in the vial. Before using the test strips from the vial, the user inserts the ROM key into a port in the test meter so that the test meter may have access to this data while performing tests using the test strip. The quality of the measurement result can be verified by allowing the meter to electronically assess the applicability of the ROM key data to the test strip currently inserted into the meter, without the

need for an optical reader to read bar code information on the test strip as has been taught in the prior art.

Current commercially-available products require the user to be involved in
5 verifying the correct ROM key has been inserted into the test meter for the test strip currently being used. For example, FIG. 8 illustrates a typical prior art process for verifying the match between the ROM key data and the test strip lot identification (ID) number. Prior to executing this process, the ROM key has been inserted into the test meter, the ROM data has been loaded into the test meter, and the test meter
10 is turned off. The process begins by inserting a test strip (step 100) into the test meter, which causes the test meter to automatically turn on (step 102). The test meter displays the lot ID of the currently loaded calibration data (step 104) in order to give the user the chance to verify that this lot ID matches the lot ID printed on the vial/package (for example) containing a plurality of test strips from the same
15 production lot as the test strip currently inserted into the test meter.

Because the process relies upon the user to perform this check, there is no way to guarantee that it is done or if it is, that it is done accurately. The process of FIG. 8 therefore indicates an optional step for the user to compare the lot ID on the
20 test meter display to the lot ID on the test strip vial (step 106) and to determine (step 108) if there is a match. If the two lot IDs do not match, then the user should remove the test strip (step 110) and insert the ROM key that matches the test strip vial into the test meter (step 112) so that the proper calibration code can be loaded into the test meter. The process would then start over at step 100 with the insertion
25 of the test strip. Once it has been determined that the test meter's calibration code lot ID matches the lot ID of the test strip (step 108), then the measurement sequence can continue by applying blood to the test strip (step 114) and beginning the blood glucose measurement cycle (step 116).

30 It will be appreciated that responsibility for verification of the accuracy of the measurement calibration data has been placed completely in the hands of the user in the prior art process of FIG. 8. It is sometimes encountered that users ignore stated

use instructions provided with the test strips. One such example is the removal of test strips from a first vial that were manufactured in lot X and consolidating these test strips into a second vial containing test strips manufactured in lot Y. Therefore, it is desirable to bring lot specific calibration information to the individual test strip level instead of to the vial level as is done in the prior art.

In order to remove the possibility of human error or neglect from the process, and to thereby improve the quality of the measurement, the information contact pads of the present invention allow the test meter itself to perform checks as to the applicability of the currently loaded calibration data to the currently inserted test strip. A first embodiment process of the present invention to allow the test meter to actively participate in such verification is illustrated in FIG. 9. The steps of the process of FIG. 9 that are identical to the corresponding steps in FIG. 8 are numbered with the same reference designators.

Prior to executing this process, the ROM key has been inserted into the test meter, the ROM data has been loaded into the test meter, and the test meter is turned off. The process begins by inserting a test strip (step 100) into the test meter, which causes the test meter to automatically turn on (step 102). The test meter then measures the conductivity between the various information and measurement contact pads on the test strip that have been designated for encoding information onto the test strip in order to ascertain the lot or family ID of the test strip (step 200). Depending upon the quantity of information that may be encoded onto the test strip, it may or may not be possible to code a unique production lot number onto the test strip. If there is not sufficient space for unique production lot IDs to be encoded, it is still possible to encoded calibration family information onto the test strip. For example, the test strips usable in the test meter may be of two or more families where significant differences exist between the family test strip designs. For example, two families may use a different reagent on the test strip. In such situations, the test meter can still verify that the loaded calibration data matches the test strip family encoded onto the test strip, even if it is not possible to verify the precise production lot of the test strip. Therefore, as used herein, the phrase "lot ID"

is intended to encompass any information that identifies a group to which the test strip or calibration data belongs, even if that group is not as small as a production lot of the test strip.

5 Returning to the process of FIG. 9, the test meter compares (step 202) the lot ID of the calibration data stored within the ROM key currently inserted into the meter (or calibration data previously-loaded into the test meter internal memory) to the lot ID read from the test strip. If they do not match, the test meter displays the lot ID of the currently loaded calibration data (step 204) and a warning in order to
10 give the user the chance to insert a correct test strip or to insert a different ROM key into the test meter. Alternatively, the test meter may simply display an error message to the user. The fact that the lot IDs do not match is flagged (step 206) in the test meter's result memory 208 so that there is a record in the memory 208 that the measurement result obtained is suspect in view of the discrepancy in the lot IDs.
15 Alternatively, the user may be prohibited from running a test and the process may be aborted.

Because in some embodiments it is desired that the test meter not be completely disabled if the lot IDs do not match, the process of FIG. 9 indicates an
20 optional step for the user to compare the lot ID on the test meter display to the lot ID on the test strip vial (step 106) and to determine (step 108) if there is a match. If the two lot IDs do not match, then the user should remove the test strip (step 110) and insert the ROM key that matches the test strip vial into the test meter (step 112) so that the proper calibration code can be loaded into the test meter. The process would
25 then start over at step 100 with the insertion of the test strip.

Also optionally, if the test meter has the capacity to store more than one calibration dataset within the meter's internal memory, then the meter may determine the multiple lot IDs of calibration data that may be stored within the test
30 meter and automatically choose the calibration dataset that matches the test strip currently inserted into the meter. The meter can then return to step 114.

Once it has been determined that the test meter's calibration code lot ID matches the lot ID of the test strip (step 108), then the measurement sequence can continue by applying blood to the test strip (step 114) and beginning the blood glucose measurement cycle (step 116). It will be appreciated that the process of
5 FIG. 9 represents an improvement over the prior art process of FIG. 8 in that the user is automatically warned when the lot ID of the test strip does not match the lot ID of the currently-selected calibration dataset. Furthermore, if a test is conducted with this mismatched combination, then the result memory within the test meter is
10 flagged to indicate that the result may not be as accurate as would be the case if the correct calibration dataset were used.

As a further example of the usefulness of encoding information directly onto the test strip, the present invention allows the test strip to activate or deactivate certain features programmed into the test meter. For example, a single test meter
15 may be designed to be used in several different geographic markets, where a different language is spoken in each market. By encoding the test strips with information indicating in which market the test strips were sold, the encoded information can cause the test meter to display user instructions and data in a language that is appropriate for that market. Also, a meter may be designed for sale
20 in a certain geographic market and it is desired that the meter not be used with test strips obtained in a different geographic market (for example when governmental regulations require the test strips sold in one geographic market to have different features than those sold in other geographic markets). In this situation, information coded onto the test strip may be used by the test meter to determine that the test strip
25 did not originate in the designated geographic market and therefore may not provide the features required by regulation, in which case the test may be aborted or flagged.

Further, a business model (subscription business model) may be applied for the distribution of test strips where proliferation of the test strips into other sales
30 channels is not desired. For example, users may enroll into a subscription program in which they are provided with a test meter designed for use by subscription participants, and the subscription participants may be provided with subscription test

strips on a regular basis (for example by mail or any other convenient form of delivery). Using the techniques of the present invention, the “subscription test strips” may be encoded to indicate that they were supplied to a subscription participant. For a variety of reasons, the manufacturer of the subscription test strips may not want the subscription test strips to be sold in other channels of trade. One way to prevent this is to design test meters provided to users who are not subscription participants that will not work with subscription test strips. Therefore, the present invention may be used to provide test meters to subscription participants in the subscription business model that are programmed to accept subscription test strips encoded to indicate that they are delivered to a user on the basis of a subscription, while other test meters are programmed not to accept subscription test strips so encoded.

As a further example, the test meter can have certain functionalities (software- and/or hardware-implemented) designed into the meter that are not active when the test meter is first sold. The performance of the test meter can then be upgraded at a later date by including information encoded on the test strips sold at that later time that will be recognized by the meter as an instruction to activate these latent features. As used herein, the phrase “activating a latent feature of the test meter” comprehends turning on a test meter functionality that previously was not active, such that the test meter functionality thereafter remains activated indefinitely (i.e. after the current test with the present test strip is finished).

Another example of information that can be encoded onto the test strip using the present invention is an indication of whether the test strip was sold to the hospital market or to the consumer market. Having this information may allow the test meter to take action accordingly, such as displaying user instructions in less detail for the hospital professional. It will be appreciated by those skilled in the art that a variety of types of communication between the test strip and the test meter may be facilitated by the information encoding provided by the present invention.

A second embodiment test strip configuration that allows information to be encoded directly onto the test strip is illustrated in FIG. 10 and indicated generally at 300. The test strip 300 may preferably be formed generally as described above with respect to the test strips 10 and 401, with working 320, counter 322, dose sufficiency
5 working 324, and dose sufficiency counter 326 electrodes may be formed as shown and coupled, respectively, to measurement contact pads W, C, DW and DC. These contact pads provide a conductive area upon the test strip 300 to be contacted by an electrical connector contact of the test meter once the test strip 300 is inserted into the test meter. The test strip may be formed with a sample inlet in the distal end of
10 the test strip (as shown in FIG. 10), or with a sample inlet on the side of the test strip as shown in FIG. 1. The functionality of the information encoding portion thereof is not affected by the positioning of the measurement electrodes in either position.

It will be noted from an examination of FIG. 10 that the area surrounding the
15 counter electrode contact pad C is formed to provide a relatively large expanse of conductive layer, which is divided into information contact pad positions B1 – B7. In the second embodiment of the present invention, the conductive layer may be formed during manufacture of the test strip such that the conductive layer is either present or absent within each of the contact pad positions B1 – B7, depending upon
20 what number is to be encoded onto the test strip 300. It should be noted that the counter electrode contact pad C is always formed with the conductive layer present in this area, as this contact pad is always necessary for the making of measurements.

Each of the contact pads C, W, DC and DW, as well as each of the contact
25 pad positions B1 – B7 are contacted by individual contacts of a multi-pin electrical connector located within the test meter when the test strip 300 is inserted into the test meter. The multi-pin electrical connector allows electrical signals to be applied from the test meter to the test strip and vice versa. The test meter is programmed (by means well-known in the art), to measure the conductivity between the counter
30 electrode contact pad C and each of the contact pad positions B1 – B7. The contact pad C can therefore be selectively conductively coupled to each of the contact pad positions B1 – B7 depending upon whether the conductive layer is formed,

respectively, in each of the contact pad positions B1 – B7. By measuring the conductivity between the contact pad C and each of the contact pad positions B1 – B7, the test meter is able to determine the presence or absence of the conductive layer in each of the contact pad positions B1 - B7. By assigning, for example, a digital value of “1” when the conductive layer is present in a particular contact pad position and a digital value of “0” when the conductive layer is absent in a particular contact pad position, a digital word may be encoded onto the test strip 300.

It will be appreciated that all of the desirable benefits discussed hereinabove with respect to the first embodiment of the present invention may also be achieved using the second embodiment of the present invention. The second embodiment has the added advantage that, because the contact pad positions B1 – B7 can never be conductively coupled to more than one measurement electrode, there are no “forbidden” states and each of the contact pad positions B1 – B7 may be coded as a “0” or “1” in any possible seven digit digital word to be encoded onto the test strip. This provides 2^7 or 128 possible unique words that can be encoded onto the test strip using the contact pad positions B1 – B7. The number of contact pad positions that can be designated for such information encoding is only limited by the available space on the test strip surface, the resolution of the process used to define the conductive features on the test strip, the electrical connector contact spacing, and the tolerance stack-ups relevant to placing the connector contact on the contact pad position once the test strip is inserted into the test meter.

Furthermore, the number of possible states in the second embodiment of the present invention can be further increased by severing the conductive path between individual pairs of the contact pad positions B1 – B7. Therefore, a connector contacting contact pad B1 (for example) can check for electrical continuity not only with contact pad C (as described hereinabove), but also for electrical continuity with any of the other contact pads B2 – B7.

30

The laser ablation process described hereinabove allows for resolution of test strip conductive features not previously achievable using prior art techniques such as

screen printing and photolithography. Because of this, relatively large quantities of data can be coded onto the test strip when the conductive features are formed using the laser ablation process. For example, a third embodiment of the present invention is illustrated in FIG. 11 and indicated generally at 500. The test strip 500 is similar to the test strip 300 of FIG. 10, except that the resolution of the laser ablation process allows for an even greater number of contact pads to be formed on the test strip.

Equivalent structures in FIG. 11 are given the same reference designators as used in FIG. 10. A total of sixteen contact pads are formed on the test strip 500, with B 1- B10 being designated as information contact pads in addition to the measurement contact pads W, WS, C, CS, DW and DC coupled to working 520, counter 522, dose sufficiency working 524, and dose sufficiency counter 526 electrodes. These contact pads provide a conductive area upon the test strip 500 to be contacted by an electrical connector contact of the test meter once the test strip 500 is inserted into the test meter. The test strip may be formed with a sample inlet in the distal end of the test strip (as shown in FIG. 11), or with a sample inlet on the side of the test strip as shown in FIG. 1. The functionality of the information encoding portion thereof is not affected by the positioning of the measurement electrodes in either position.

As with the second embodiment of FIG. 10, it will be noted from an examination of FIG. 11 that the area surrounding the counter electrode contact pad C is formed to provide a relatively large expanse of conductive layer, which is divided into information contact pad positions B 1-B 10. In the third embodiment of the present invention, the conductive layer may be formed during manufacture of the test strip such that the conductive layer is either present or absent within each of the contact pad positions B 1-B 10, depending upon what number is to be encoded onto the test strip 500. As noted hereinabove, the counter electrode contact pad C is always formed with the conductive layer present in this area, as this contact pad is always necessary for the making of measurements.

It can be seen in FIG. 11 (and also FIG.10) that the contact pads are in a staggered relationship, transversely of the direction of insertion of the test strip into a test meter (as illustrated in FIGS. 12-14). In particular the contact pads are spaced apart side by side in transverse rows with the contact pads in each row being staggered relative to the contact pads in the adjacent row. Each of the contact pads C, CS, W, WS, DC and DW, as well as each of the contact pad positions B 1-B 10 are contacted by individual contacts of a multi-pin electrical connector located within the test meter when the test strip 500 is inserted

into the test meter. The multi-pin electrical connector allows electrical signals to be applied from the test meter to the test strip and vice versa. The test meter is programmed to measure the conductivity between the counter electrode contact pad C and each of the contact pad positions B1 – B10. The contact pad C can therefore
5 be selectively conductively coupled to each of the contact pad positions B1 – B10 depending upon whether the conductive layer is formed, respectively, in each of the contact pad positions B1 – B10. By measuring the conductivity between the contact pad C and each of the contact pad positions B1 – B10, the test meter is able to determine the presence or absence of the conductive layer in each of the contact pad
10 positions B1 – B10. By assigning, for example, a digital value of “1” when the conductive layer is present in a particular contact pad position and a digital value of “0” when the conductive layer is absent in a particular contact pad position, a digital word may be encoded onto the test strip 500.

15 It will be appreciated that, as with the second embodiment, all of the desirable benefits discussed hereinabove with respect to the first embodiment of the present invention may also be achieved using the third embodiment of the present invention. Like the second embodiment, the third embodiment has the added advantage that, because the contact pad positions B1 – B10 can never be
20 conductively coupled to more than one measurement electrode, there are no “forbidden” states and each of the contact pad positions B1 – B10 may be coded as a “0” or “1” in any possible ten digit digital word to be encoded onto the test strip. This provides 2^{10} or 1,024 possible unique words that can be encoded onto the test strip using the contact pad positions B1 – B10.

25 Furthermore, as with the second embodiment test strip 300, the number of possible states in the third embodiment test strip 500 of the present invention can be further increased by severing the conductive path between individual pairs of the contact pad positions B1 – B10. Therefore, a connector contacting contact pad B1
30 (for example) can check for electrical continuity not only with contact pad C (as described hereinabove), but also for electrical continuity with any of the other

contact pads B2 – B10. This greatly increases the number of unique digital words that can be encoded onto the test strip 500.

It should be noted that the contact pad densities achieved in the present invention through the use of the laser ablation process represent a significant advancement over the prior art. For example, published European patent application EP 1 024 358 A1 discloses a system which uses up to 35 contact pads on a single test strip; however, the density of features is so low that the inventors are forced to contact only five of those contact pads at any one time. Not only does this require much more test strip surface area than the present invention to form the same number of contact pads, but it is impossible for the test meter to make conductivity checks between each of the contact pads because the test meter is never in contact with more than five of the contact pads at any one time. The tight control of feature dimensions enabled by the laser ablation process of the present invention allows for the use of contact pad density never before achieved in the art. For example, the embodiment of FIG. 10 allows eleven contact pads to be contacted simultaneously by the test meter connector. Even greater density is achieved in the embodiment of Figure 11, where sixteen contact pads may be contacted simultaneously by the test meter connector. Some embodiments of the present invention therefore preferably include at least ten test strip contact pads coupled to at least ten test meter connector contacts; more preferably include at least eleven test strip contact pads coupled to at least eleven test meter connector contacts; and most preferably includes at least fifteen test strip contact pads coupled to at least fifteen test meter connector contacts.

FIGs. 12-14 illustrate a preferred embodiment multiple-pin electrical connector mating with the third embodiment test strip 500 of FIG. 11. The electrical connector is housed in the test meter (not shown) and includes multiple contacts that produce contact traces 502 when mated with respective contact pads on the test strip 500 when the test strip 500 is inserted into the test meter electrical connector. FIG. 13 illustrates the nominal case in which each electrical connector contact is positioned approximately at the center of the respective test strip 500 contact pad when the test strip 500 is mated to the test meter. In the preferred embodiment, the

tolerances of the placement of the conductive features on the test strip 500, as well as the tolerances of the placement of the electrical connector contacts with respect to the test strip mating port of the test meter are controlled such that the worst case tolerance stack-ups will still result in reliable contact between each connector contact and the respective contact pad. As can be seen in FIG. 12, when all of the tolerances are at their maximum so as to move the connector contacts left with respect to their respective contact pads, the electrical contacts are still positioned to make reliable electrical contact with the respective contact pad, and all of the contact pads B1-B10 are still electrically connected to the contact pad C (if their respective metallization is present) even if the mechanical interaction of the connector contacts with the test strip during insertion completely removes the metallization in the areas of contact traces 502. Similarly, as can be seen in FIG. 14, when all of the tolerances are at their maximum so as to move the connector contacts right with respect to their respective contact pads, the electrical contacts are still positioned to make reliable electrical contact with the respective contact pad, and all of the contact pads B1-B10 are still electrically connected to the contact pad C (if their respective metallization is present) even if the mechanical interaction of the connector contacts with the test strip during insertion completely removes the metallization in the areas of contact traces 502.

20

A fourth embodiment test strip of the present invention is schematically illustrated in FIG. 15 and designated as 600. The test strip 600 is similar to the test strip 300 of FIG. 10, except that the fourth embodiment uses only six contact pads on the test strip. Embodiments using fewer or more contact pads are contemplated by the present invention. Equivalent structures in FIG. 15 are given the same reference designators as used in FIG. 10. The test strip includes a working electrode 320, a counter electrode 322, a dose sufficiency working electrode 324, and two potential dose sufficiency counter electrodes 326A and 326B. Each of the electrodes is coupled to at least one contact pad formed on the test strip 600.

30

The working electrode 320 is coupled to both a W and a WS contact pad. The counter electrode 322 is coupled to a C contact pad and a CS contact pad,

although which contact pad is designated as C is optional as explained hereinbelow. The dose sufficiency working electrode 324 is coupled to a DW contact pad. The dose sufficiency counter electrode 326A/326B is coupled to a DC contact pad, although which contact pad is designated as DC is optional as explained
5 hereinbelow.

The test strip 600 allows a single binary bit to be encoded onto the test strip 600, depending on which of the two potential conductive links 602 and 604 are formed on the test strip 600. At least one of the potential conductive links 602/604
10 is preferably formed on the test strip 600, and both potential conductive links 602/604 may not be formed at the same time without losing the second separate dose sufficiency electrode functionality.

If the potential conductive link 602 is formed on the test strip 600 and the
15 potential conductive link 604 is not formed, then the contact pad 606 becomes the C contact pad (since it is coupled to the counter electrode 322 by the potential conductive link 602). Without the presence of the potential conductive link 604, electrode 326B functions as the actual dose sufficiency counter electrode and contact pad 608 becomes the DC contact pad.

20 Similarly, if the potential conductive link 604 is formed on the test strip 600 and the potential conductive link 602 is not formed, then the contact pad 608 becomes the C contact pad (since it is coupled to the counter electrode 322 by the potential conductive link 604). Without the presence of the potential conductive link
25 602, electrode 326A functions as the actual dose sufficiency counter electrode and contact pad 606 becomes the DC contact pad.

Once the test strip 600 is inserted into the test meter, the test meter can easily determine if the potential conductive link 602 is present by checking the
30 conductivity between the CS contact pad and the contact pad 606. Conductivity between these two contact pads indicates the presence of the potential conductive link 602. Similarly, the test meter can determine if the potential conductive link 604

is present by checking the conductivity between the CS contact pad and the contact pad 608. Conductivity between these two contact pads indicates the presence of the potential conductive link 604. Once the test meter has determined which potential conductive link 602/604 is present, it thereafter knows which contact pad to treat as the C contact pad and which to treat as the DC contact pad. In one embodiment, the test meter only checks for the presence or absence of one of the potential conductive links 602/604 and assumes that the other potential conductive link 602/604 is absent or present, respectively. In another embodiment, the test meter confirms the presence or absence of both potential conductive links 602/604, which is a more robust methodology as it is more likely to detect a damaged test strip.

In another embodiment, the code key inserted into the test meter tells the test meter which of the two possible configurations to expect. The test meter then checks to see if the expected contact pad 606/608 is coupled to the CS contact pad. If the expected connection is not present, then the meter checks to see if the other contact pad 606/608 is coupled to the CS contact pad. If the wrong contact pad 606/608 is coupled to the CS contact pad, then the meter indicates a code key error (i.e. a code key has been inserted into the test meter that does not match the test strip inserted into the test meter). If neither contact pad 606/608 is coupled to the CS contact pad, then the test meter indicates a strip error (i.e. the test strip is defective and cannot be used).

More importantly than assigning contact pad functionalities, by determining which potential conductive link 602/604 is present, the test meter has been supplied with one bit of information from the test strip 600. This single bit of information can convey important information to the test meter, such as whether the test strip is designed to test for a first analyte or a second analyte, where the test meter should look for calibration information relating to the test strip, etc. Therefore, supplying a single bit of information by simply reassigning the functions of some of the contact pads on the test strip can easily provide important information to the test meter about the test strip that has been inserted therein.

5 While the invention has been illustrated and described in detail in the
drawings and foregoing description, the description is to be considered as illustrative
and not restrictive in character. Only the preferred embodiment, and certain other
embodiments deemed helpful in further explaining how to make or use the preferred
embodiment, have been shown. All changes and modifications that come within the
10 spirit of the invention are desired to be protected.

CLAIMS:

1. A test system for measuring a concentration of an analyte of interest in a biological fluid, the test system comprising:

5 a test meter comprising a connector having at least six contacts;

a test strip adapted to be inserted into the test meter connector, the test strip comprising a substrate having a surface, an electrode formed on the surface, and at least six contact pads formed on the surface of which at least two contact pads are information contact pads, at least one information contact
10 pad being conductively connected to the electrode;

said contact pads being in a spaced apart staggered relationship on said surface, transversely of a direction of insertion of the test strip into the test meter such that the at least six contacts make contact with the respective at least six contact pads when the test strip is inserted into the test meter
15 connector,

wherein all contact pads remain functional even when each of the contacts removes all conductive material from the test strip under the respective contact as the test strip is inserted into the test meter; and

wherein the test meter is adapted to read information encoded on the test
20 strip.

2. The test system of claim 1, wherein the test meter comprises at least ten contacts and the test strip comprises at least ten contact pads.

25 3. The test system of claim 2, wherein the test meter comprises at least sixteen contacts and the test strip comprises at least sixteen contact pads.

4. The test system of any one of claims 1 to 3, wherein said contact pads are spaced apart side by side in transverse rows, with the contact pads in each row being staggered relative to the contact pads in the adjacent row.
- 5 5. A test system for measuring a concentration of an analyte of interest in a biological fluid, the test system comprising:
- a test meter comprising a connector having at least six contacts;
 - a test strip adapted to be inserted into the test meter connector, the test strip comprising a substrate having a surface, an electrode formed on the
 - 10 surface, and at least ten contact pads formed on the surface of which at least two contact pads are information contact pads, at least one information contact pad being conductively connected to the electrode;
 - said contact pads being in a spaced apart staggered relationship on said surface, transversely of a direction of insertion of the test strip into the test
 - 15 meter, the at least ten contacts make contact with the respective at least ten contact pads when the test strip is inserted into the test meter connector, and
 - wherein the test meter is adapted to read information encoded on the test strip.
- 20 6. The test system of claim 5, wherein the test meter comprises at least sixteen contacts and the test strip comprises at least sixteen contact pads.
7. The test system of claim 5 or 6, wherein said contact pads are spaced apart side by side in transverse rows, with the contact pads in each row being
- 25 staggered relative to the contact pads in the adjacent row.

1/13

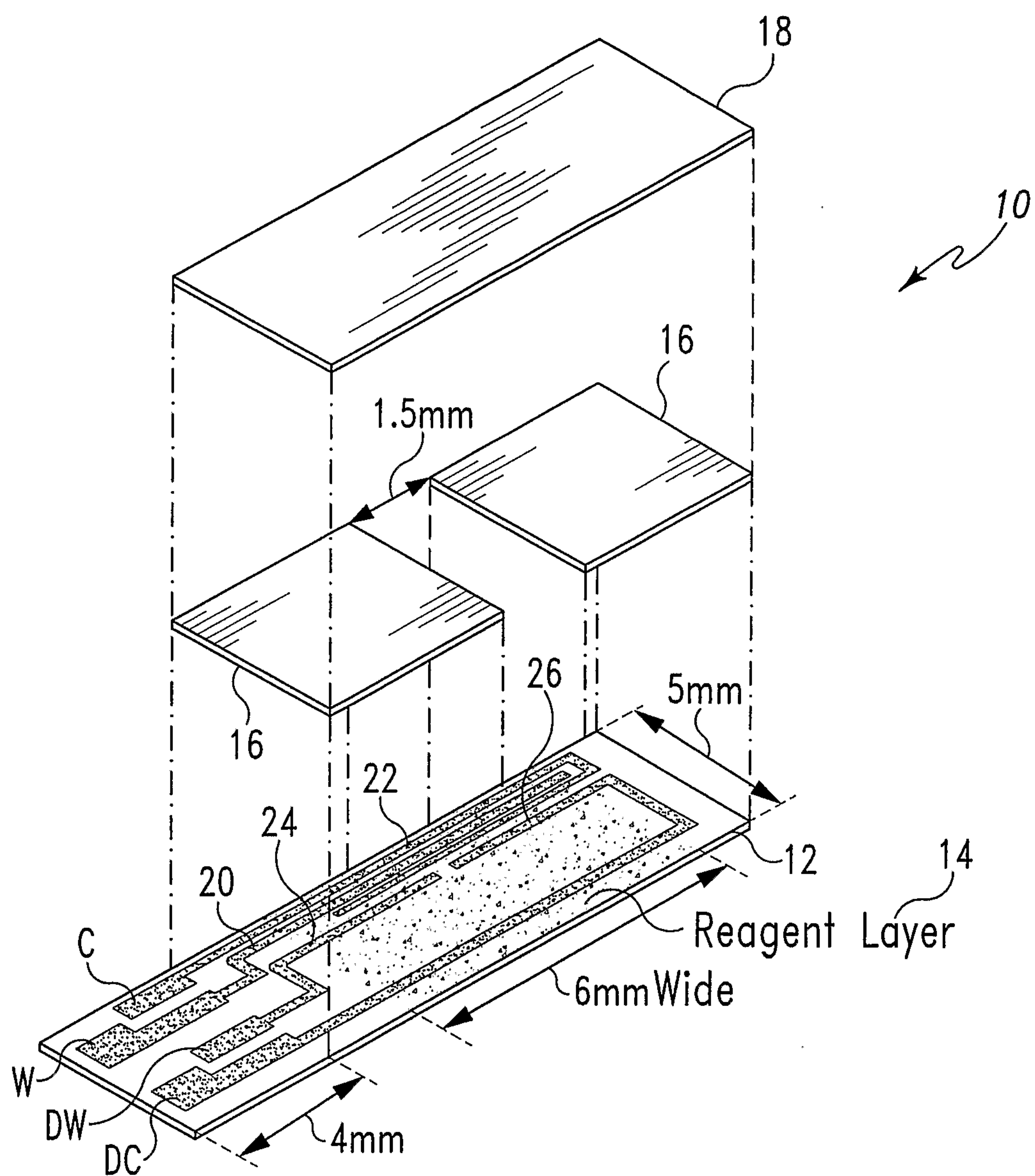


Fig. 1

2/13

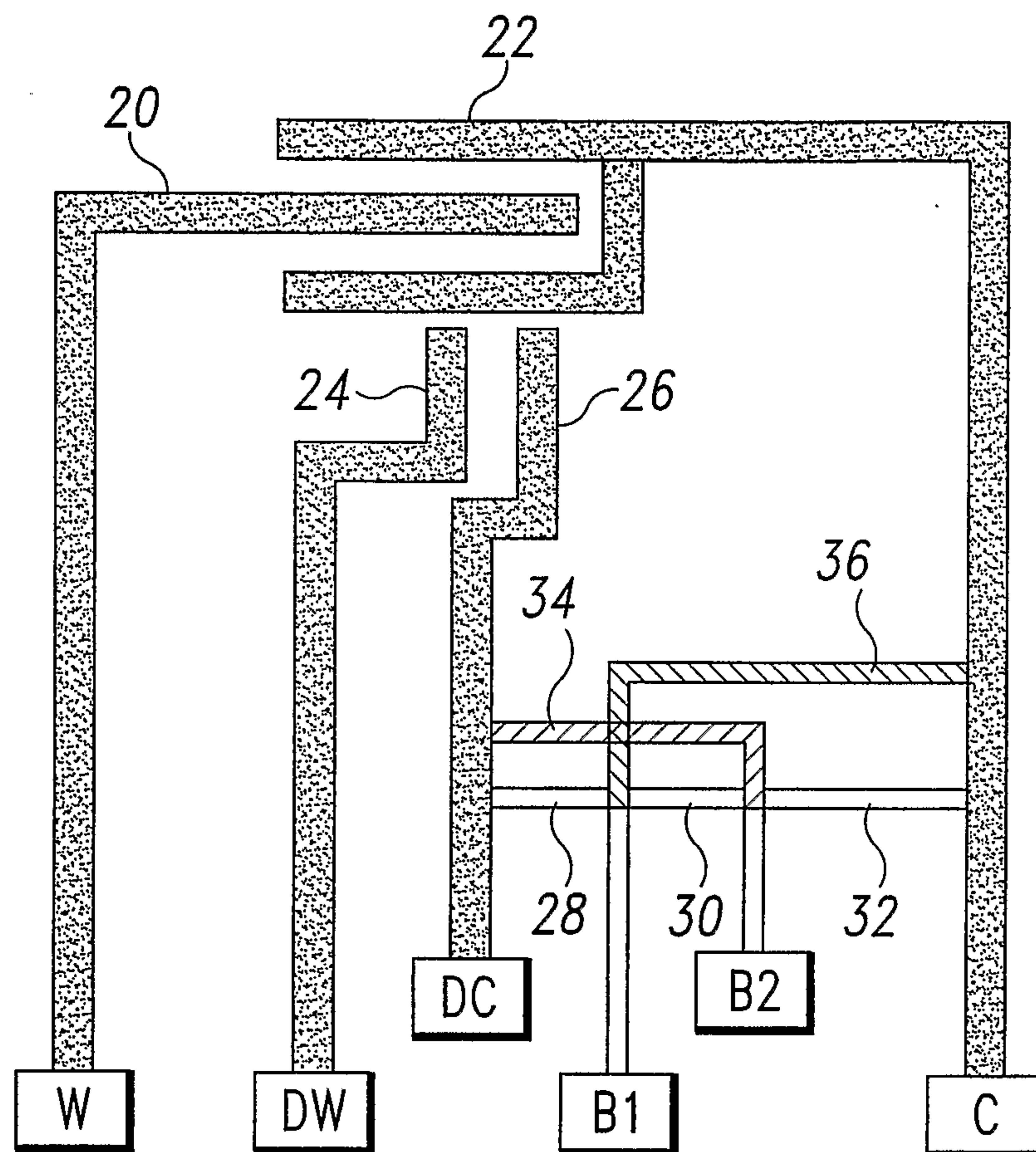


Fig. 2

3/13

#	C1	C2	C3	C4	C5	B1	B2
0	0	0	0	0	0	—	—
1	0	0	0	1	0	—	DC
2	0	0	1	0	0	—	C
3	0	1	0	1	0	DC/B2	DC/B1
4	0	1	1	0	0	C/B2	C/B1
5	1	0	0	0	0	DC	—
6	1	0	1	0	0	DC	C
7	0	0	0	0	1	C	—
8	0	1	0	0	0	B2	B1

Fig. 3

4/13

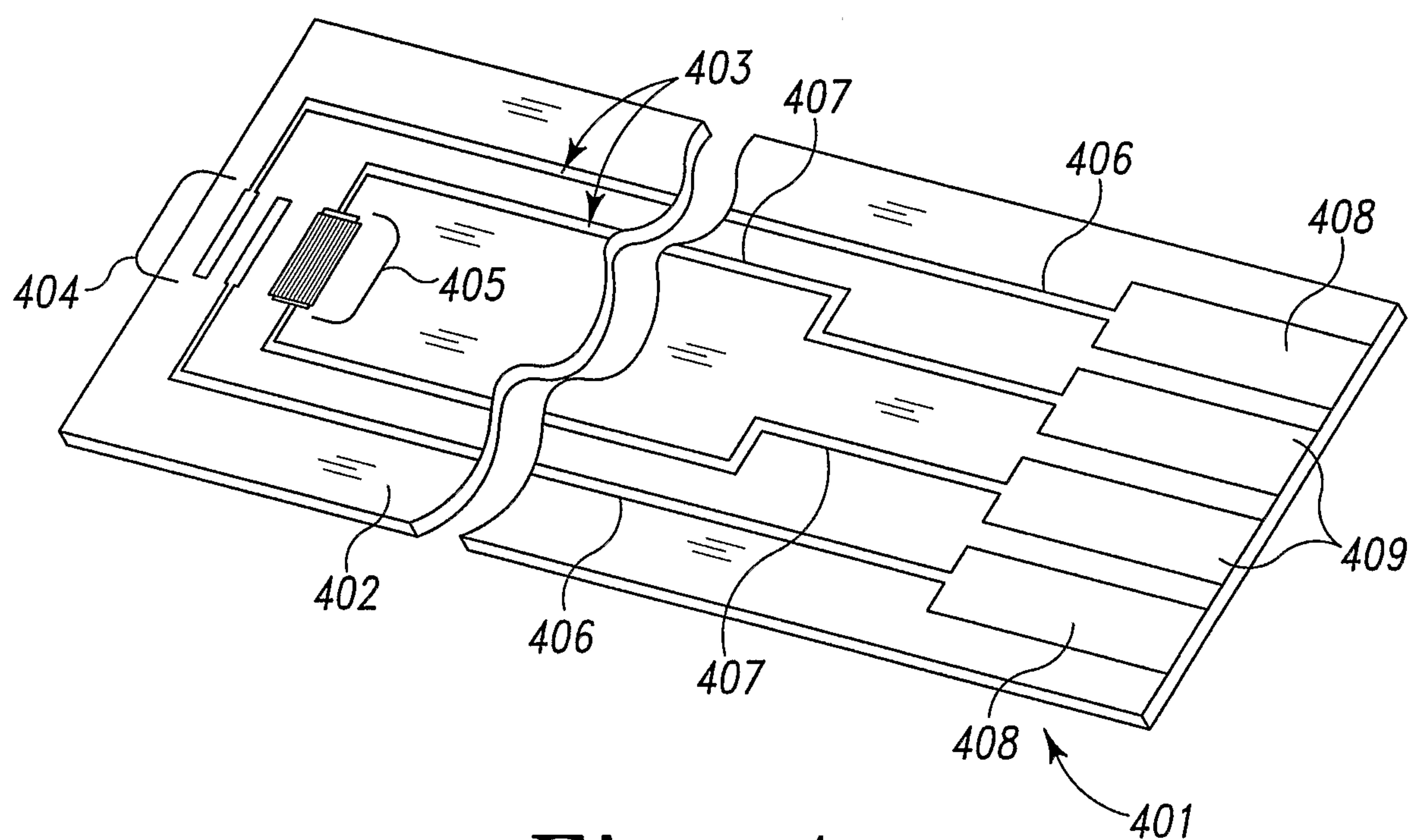


Fig. 4

5/13

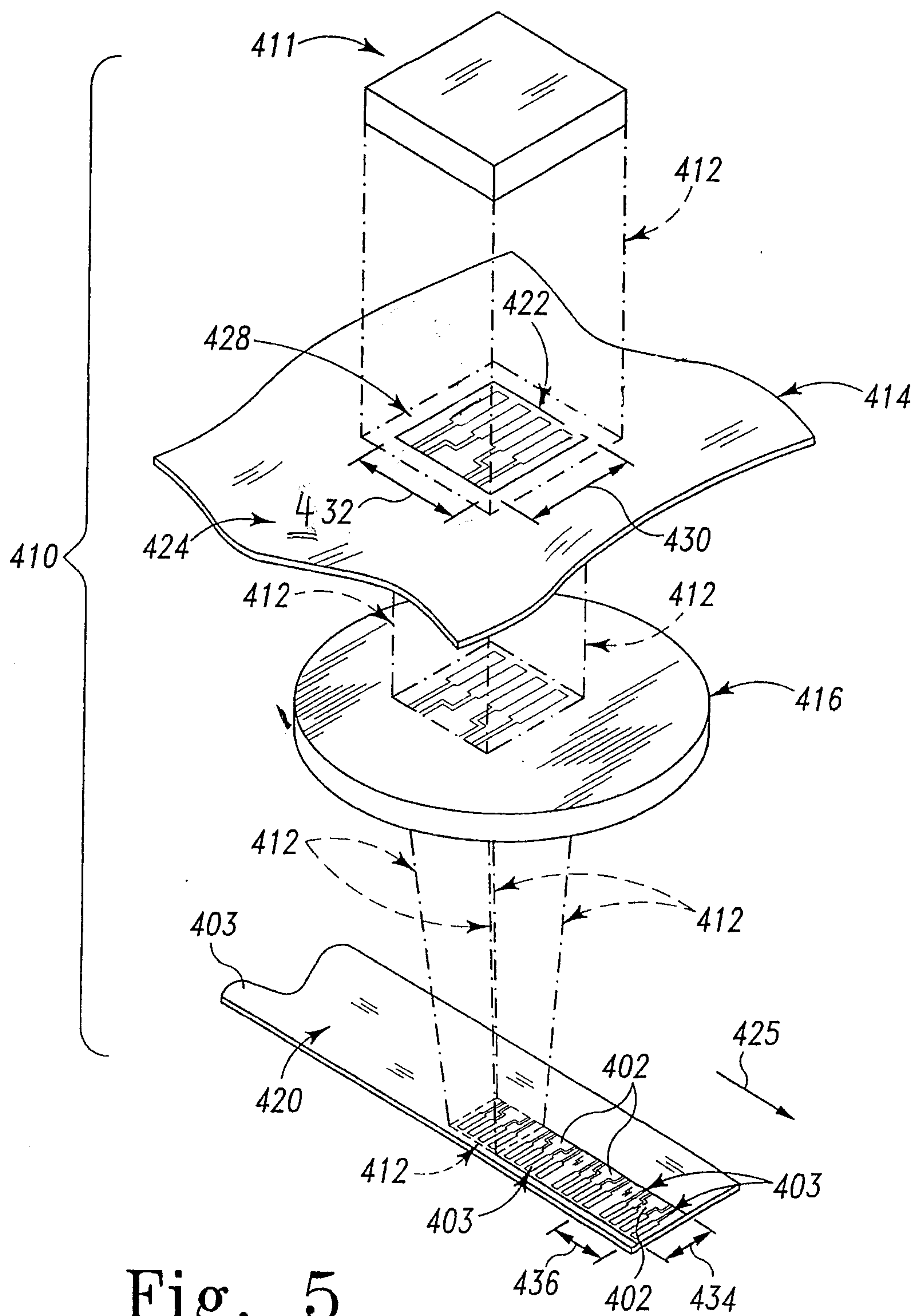


Fig. 5

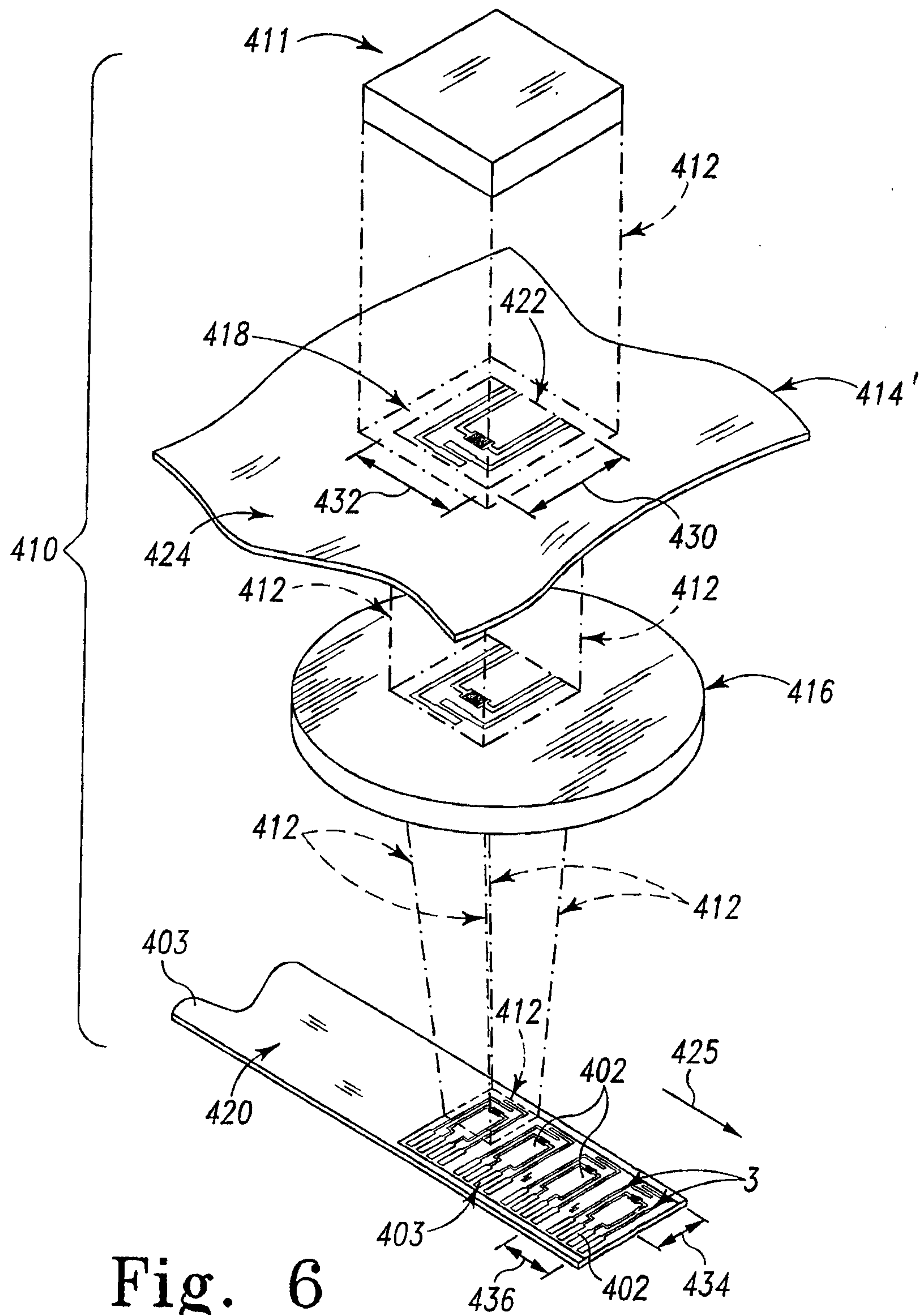


Fig. 6

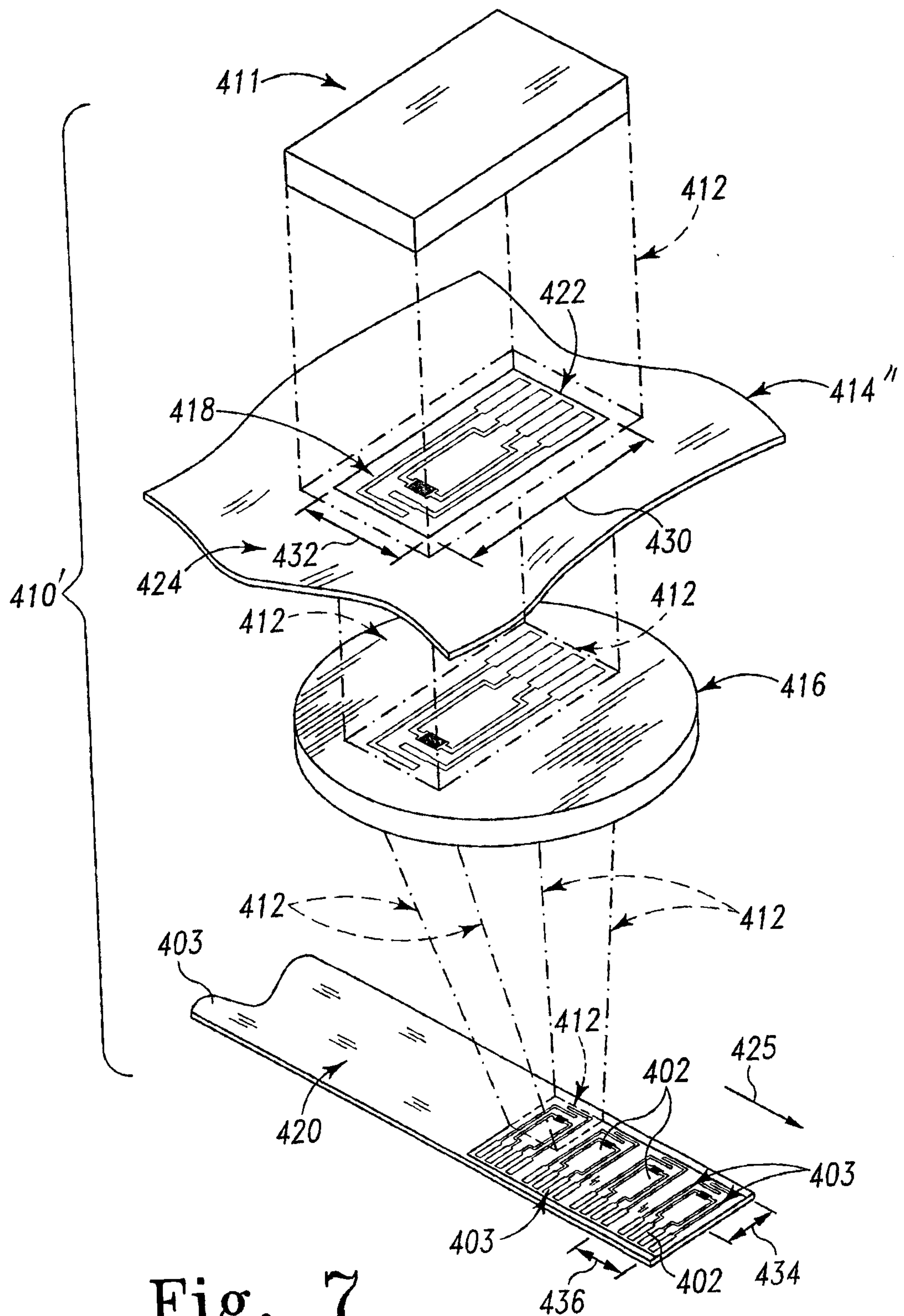


Fig. 7

8/13

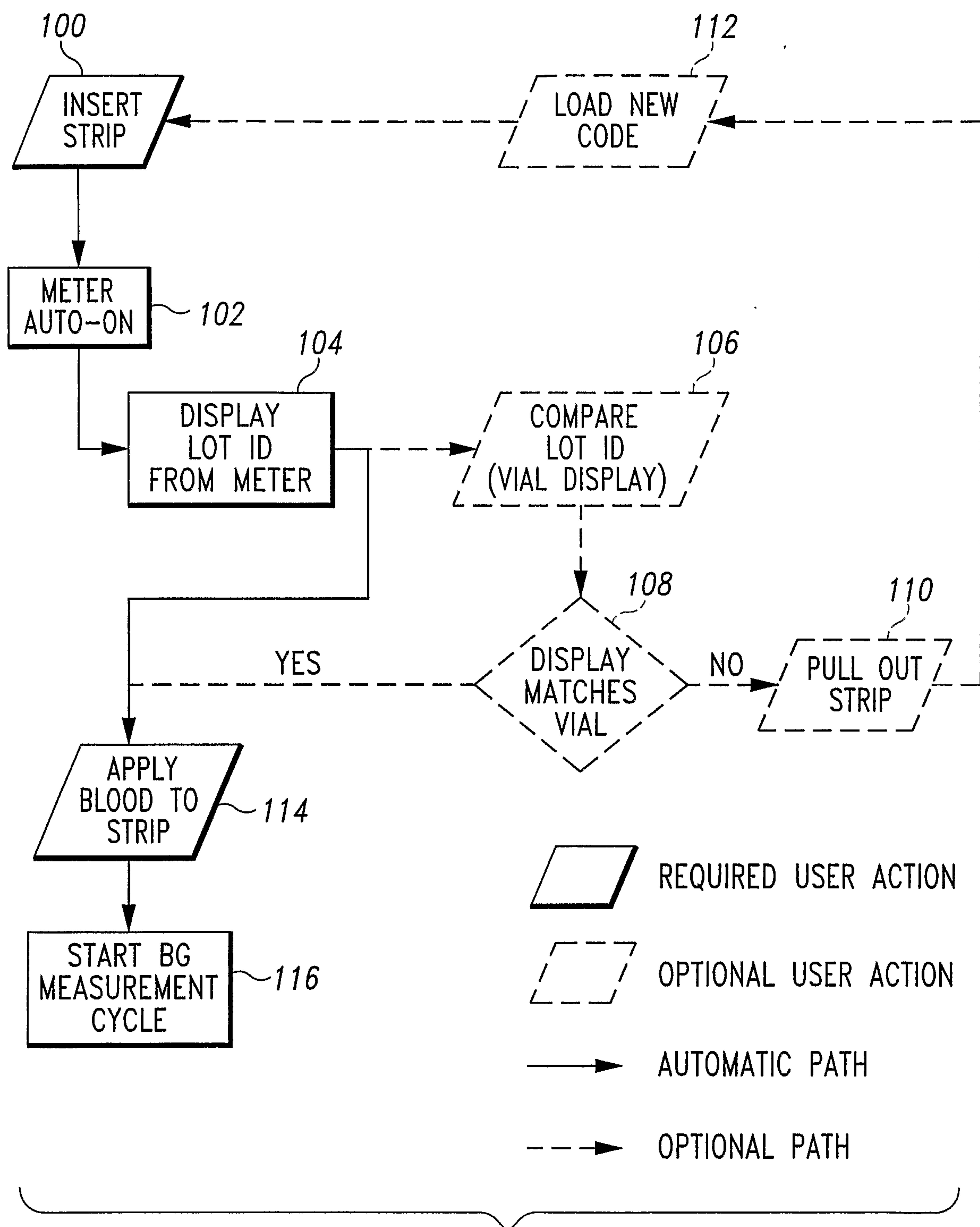


Fig. 8
(Prior Art)

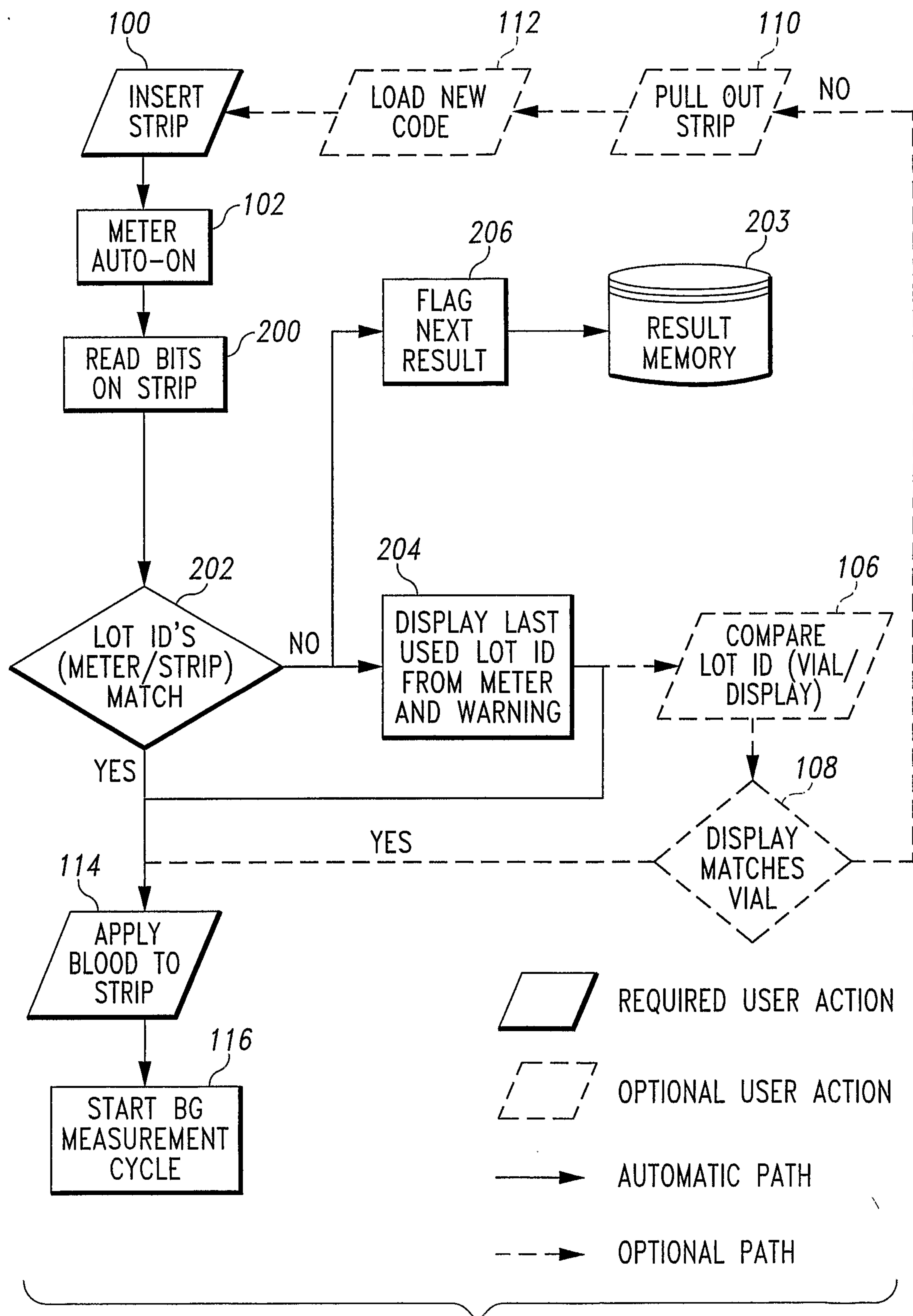


Fig. 9

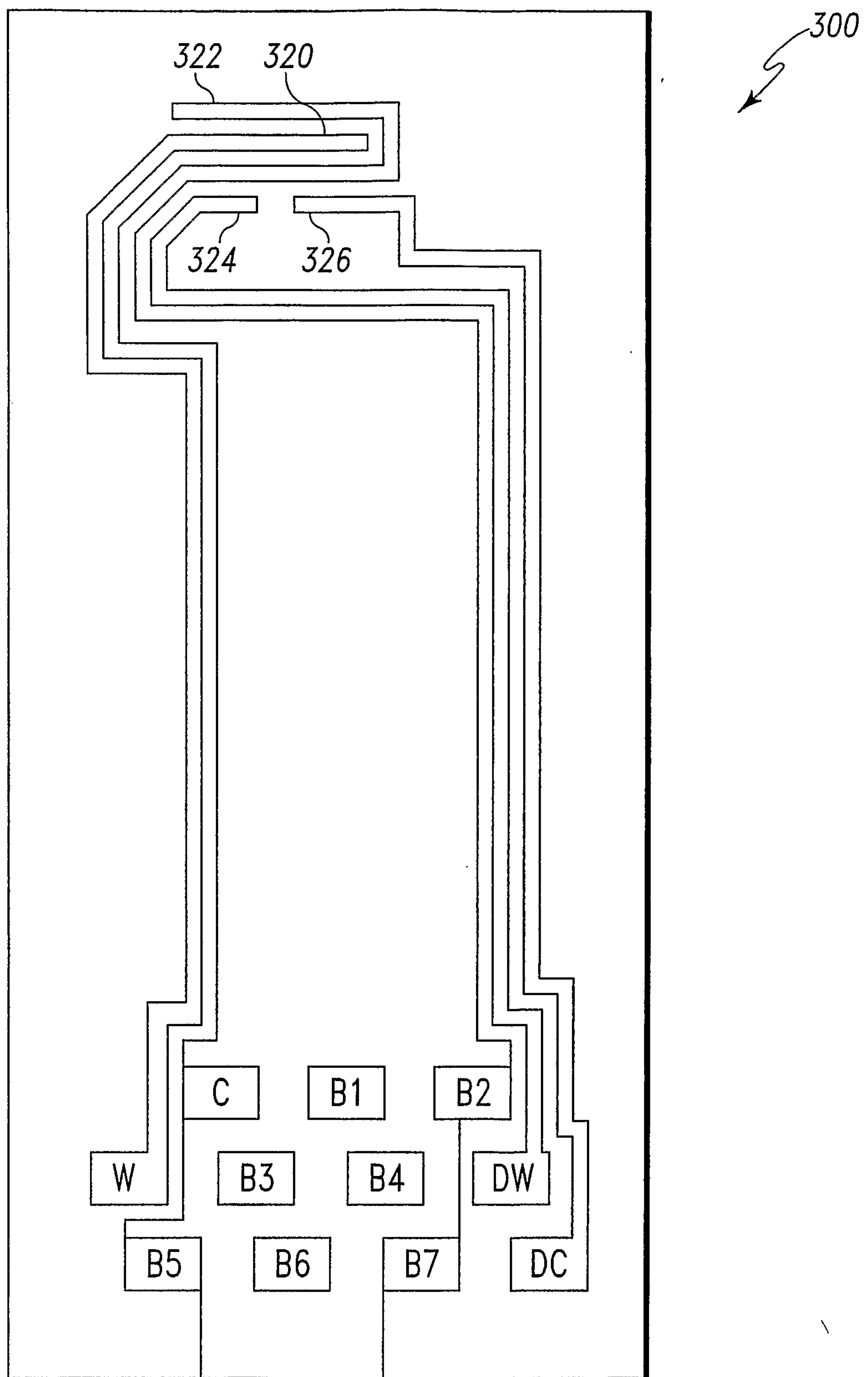


Fig. 10

11/13

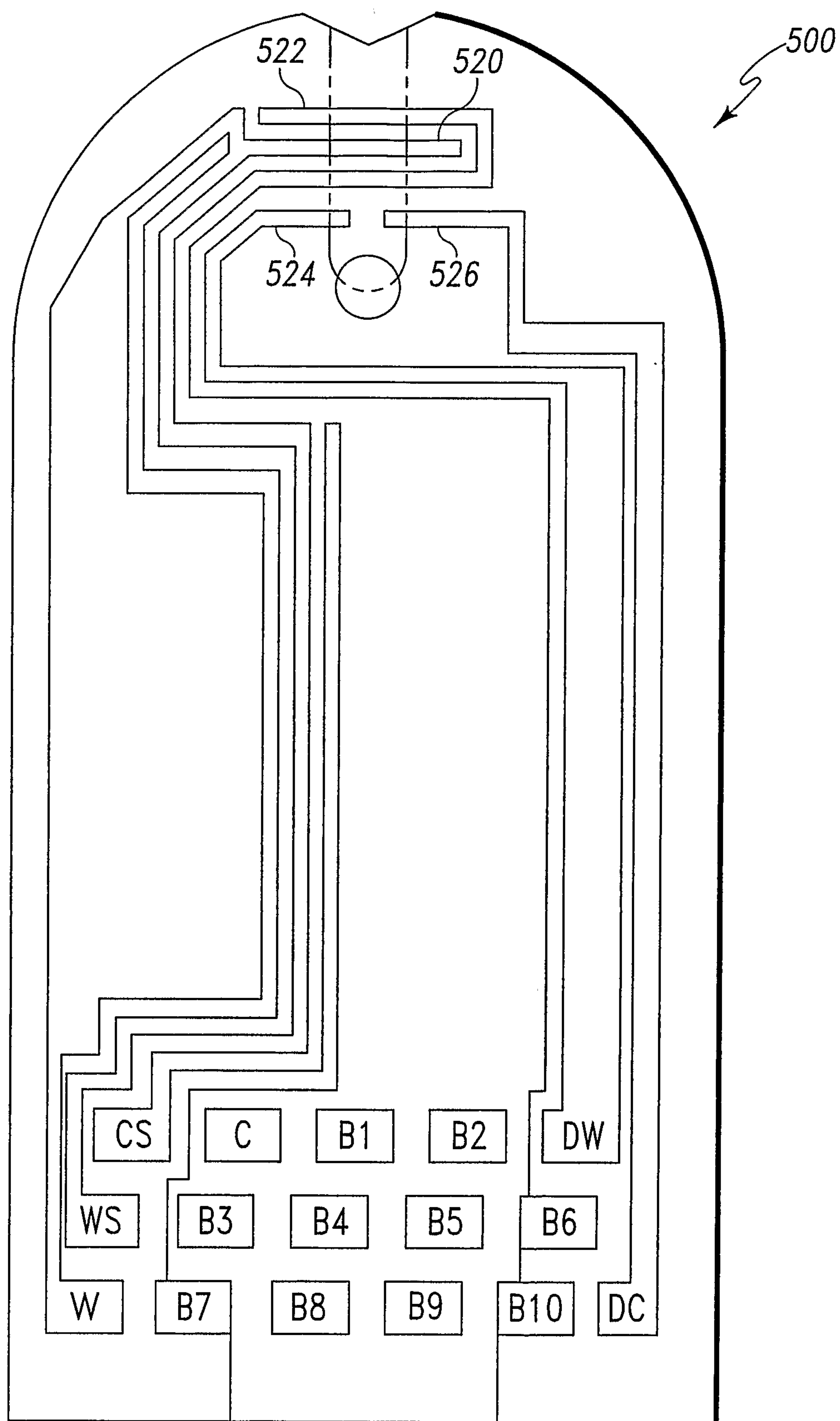


Fig. 11

12/13

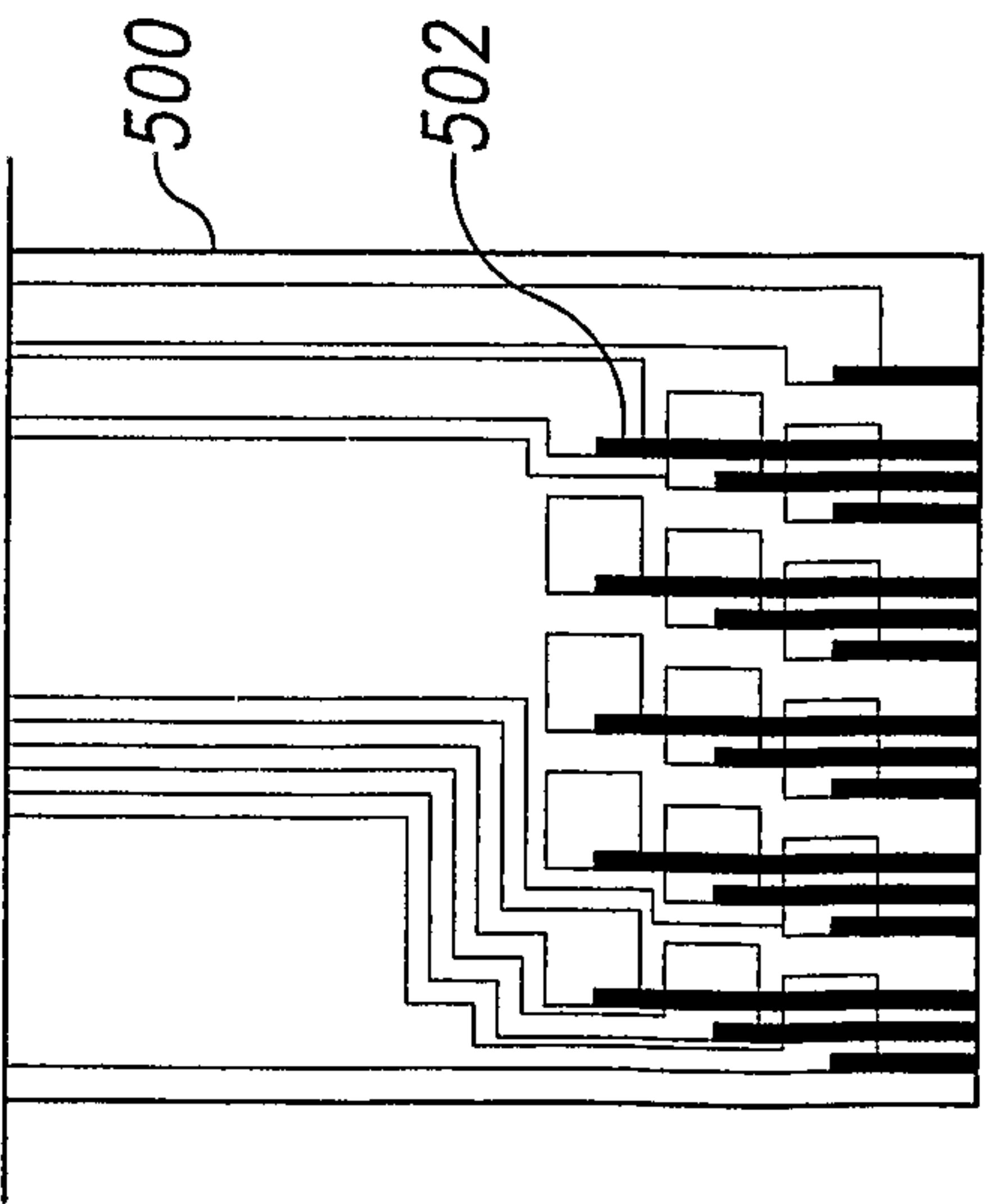
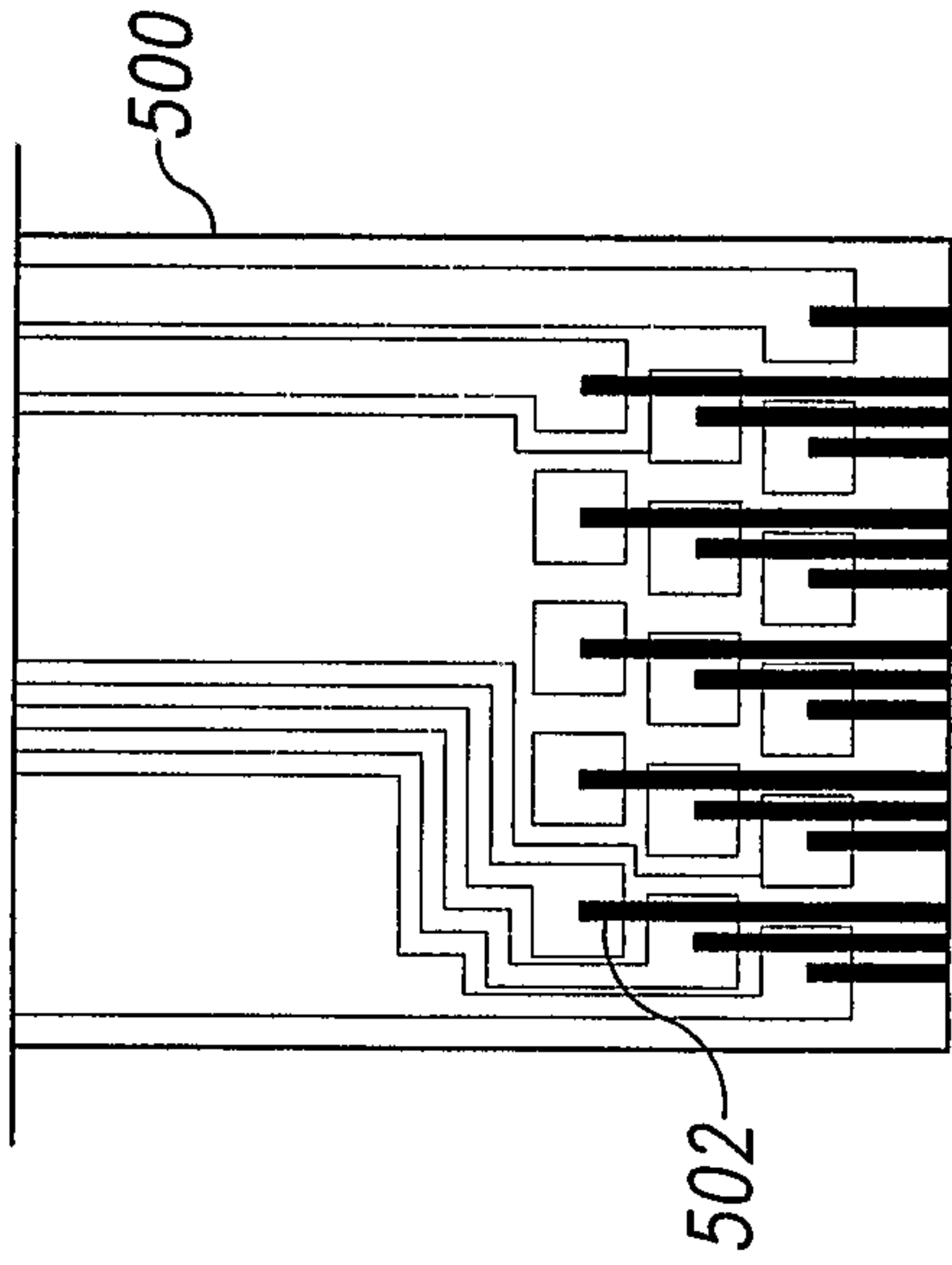
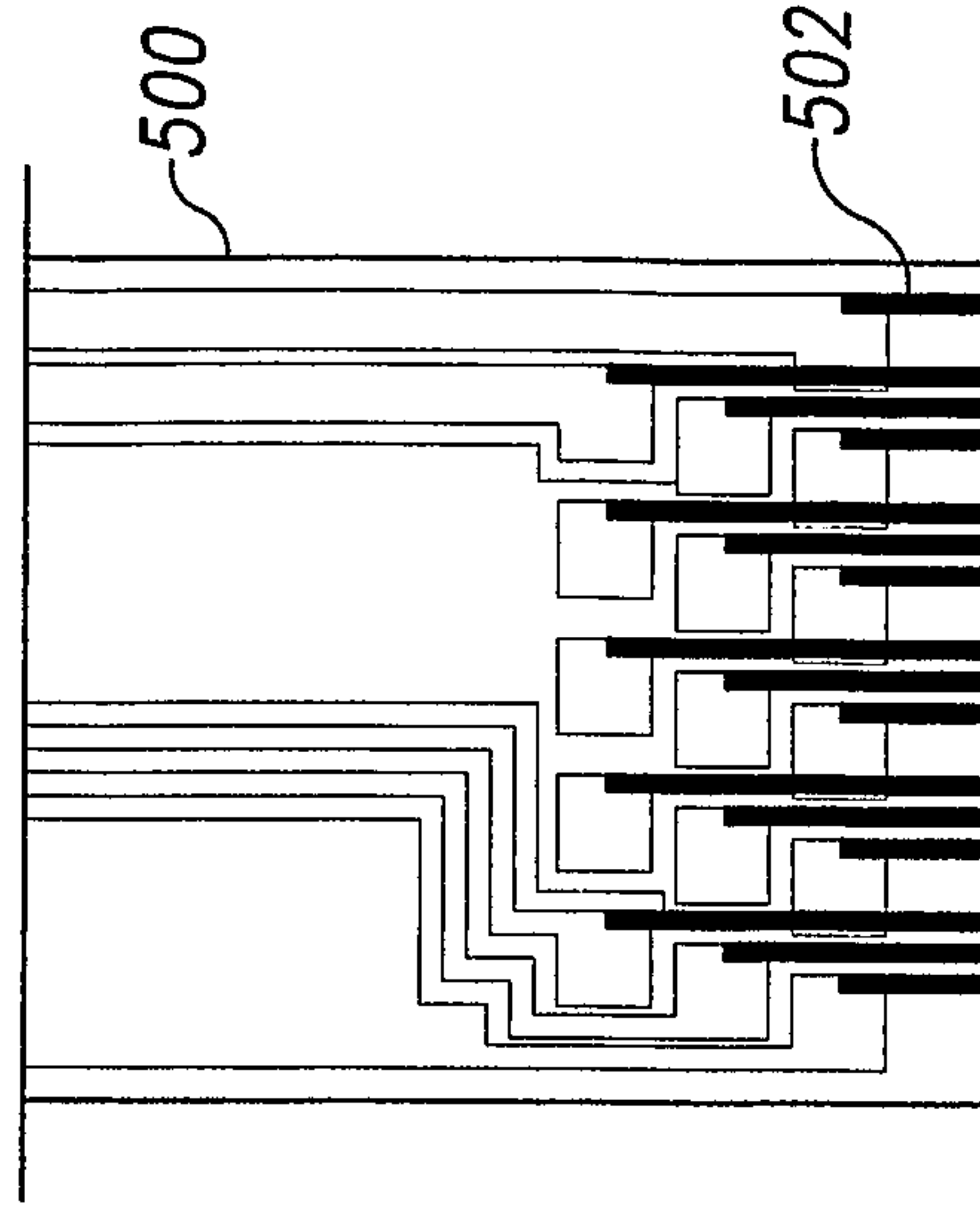
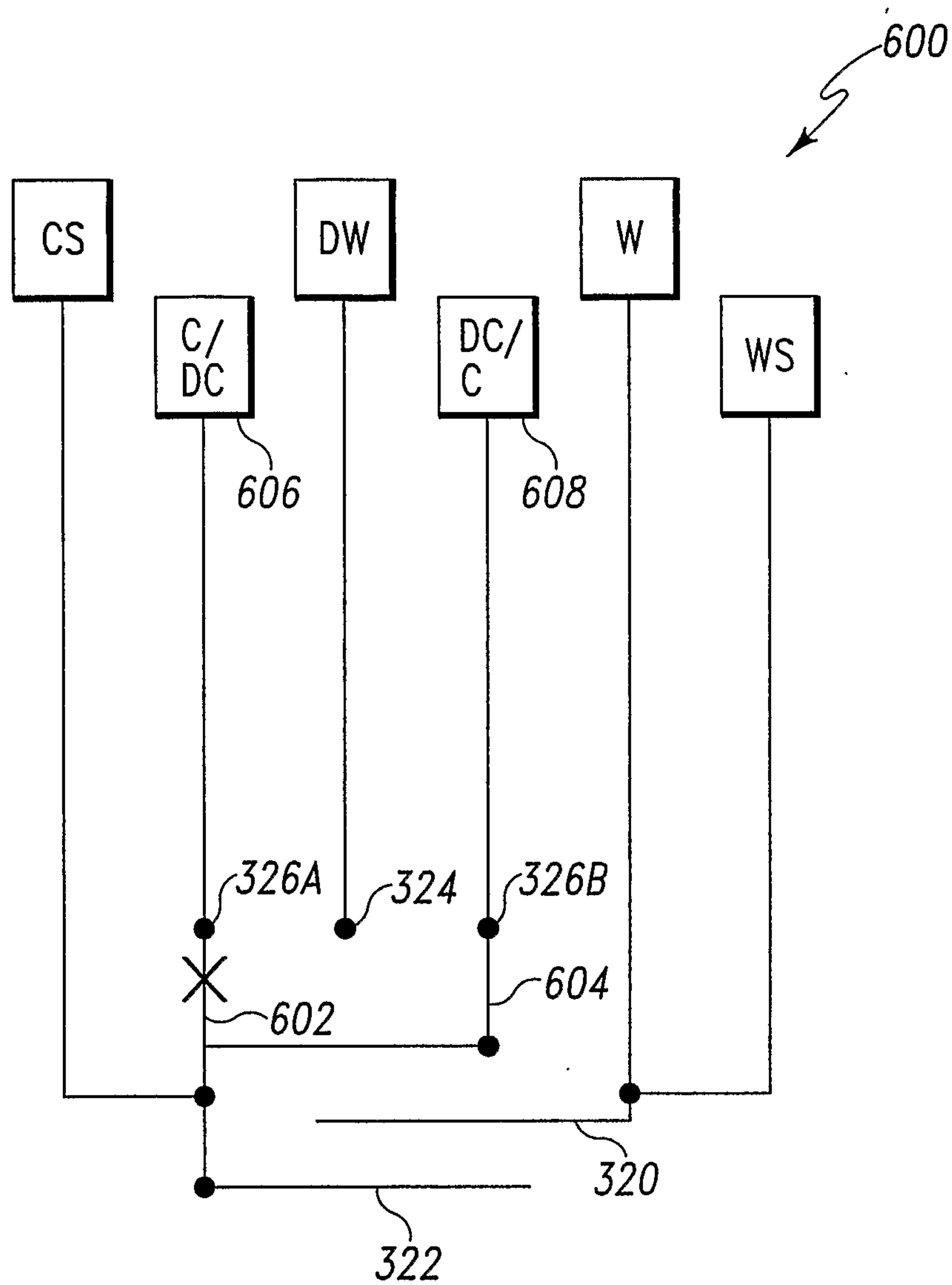


Fig. 12 Fig. 13 Fig. 14

**Fig. 15**

