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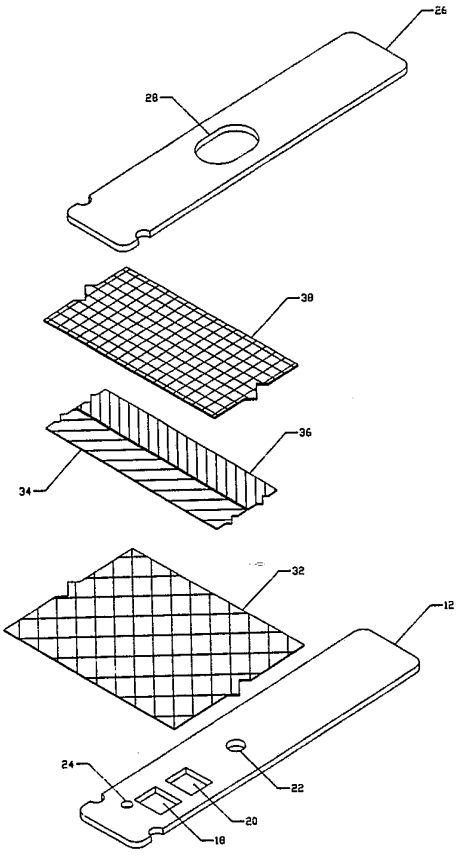
(54) Title: DISPOSABLE REAGENT UNIT WITH BLOOD OR FLUID GUARD

(57) Abstract

A disposable reagent unit including a base strip (12) with a plurality of spaced holes (24, 18, 20, 22), a double face tape (32), a reagent and a lot identification paper in side-by-side adjacent relationship, a wick (38), and a cover strip with a hole for engagement with a diagnostic instrument quantitative of an analyte in a liquid such as glucose in blood. Blood is deposited in the blood bowl (28) and is wicked to the reagent (36) for subsequent color change or other detectable change to be measured by a diagnostic instrument. The color intensify of the reagent is proportional to the analyte such as glucose in the blood. A blood or fluid guard of a predetermined geometrical shape can be secured to the reagent unit to protect the diagnostic instrument from transmission of fluid, such as blood. Any particular portion of the surface of the diagnostic reagent unit can be covered by the blood or fluid guard so as to protect, shield and cover the predetermined surfaces of the diagnostic instrument.



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DISPOSABLE REAGENT UNIT WITH BLOOD OR FLUID GUARD

CROSS REFERENCES TO CO-PENDING APPLICATIONS

The disposable reagent unit is for use with a diagnostic instrument of co-pending patent application of Anderson et al., U.S. Patent Application Serial No. 07/499,085, filed March 26, 1990, entitled "Medical Diagnostic System", and is a continuation-in-part of Anderson et al. U.S. Patent Application Serial No. 07/499,187, filed on March 26, 1990, entitled "Reagent Unit".

BACKGROUND OF THE INVENTION

1. **Field of the Invention** - The field of the present invention is the medical field, and more particularly, pertains to a disposable reagent unit with a blood or fluid guard for a diagnostic instrument for measuring the quantity of a certain analyte in a liquid, such as glucose in the blood.

2. **Description of the Prior Art** - One representative Patent is U.S. Patent No. 4,935,346, issued on June 19, 1990, to Phillips et al., for "Minimum Procedure System for the Determination of Analytes", which discloses a disposable reagent unit.

Present blood glucose monitors use a very low cost disposable reagent strip where blood is applied on the strip. The blood can then sometimes flow onto the instrumentation that reads the reagent strip. Some blood

glucose instruments have removable strip guides that must be manually cleaned or sterilized when blood gets on the instrument, such as on or in the strip guides.

The disposable reagent strips of some blood glucose systems do not have good blood containment. Great care must be taken in cleaning these blood glucose systems when being used on different patients, especially because of infection control reasons.

The present invention provides a disposable reagent unit without a lancet and with a blood or fluid guard for use in a diagnostic instrument, such as a medical diagnostic instrument, such as for measuring glucose in the blood.

SUMMARY OF THE INVENTION

The general purpose of the present invention is a multi-laminate disposable reagent test device with a blood or fluid guard for quantitative measurement of analyte in fluid with the use of a hand-held instrument. The test device contains an analytical component, a fluid transport component and an optional electronic detectable lot correction component. The blood or fluid guard is a member for engaging over and about the diagnostic instrument.

The general phrase "fluid" is intended to include blood, plasma, urine, feces, tears or any other body fluids or body components, such as skin.

Another general purpose of the present invention is a blood or fluid guard layer that is wide enough to cover the reagent strip engagement mechanism of a blood glucose or other monitoring instrument and prevent blood or fluid from contaminating the diagnostic instrument. The blood or fluid guard layer is a thin, flexible fluid impermeable material that is attached by tape, glue, ultrasonic welding or other attachment process to a disposable reagent strip.

One problem solved of the prior art is elimination of blood contamination of the reagent viewing instrumentation. This is particularly important because of AIDS, Hepatitis and other blood diseases of infection control considerations. The blood or fluid guard is part of the disposable reagent unit so no manual cleaning or other cleaning is required which greatly enhances user safety and convenience.

According to one embodiment of the present invention, there is provided a disposable reagent test device including a base strip with a plurality of ports, lot identification paper and adjacent reagent material, a wick, and a cover strip with at least one port, where the base strip and the cover strip are suitably secured together, such as by mechanical riveting, glue or adhesive. There is also provided a blood or fluid guard layer that is a thin, flexible, fluid impermeable

material attached by tape, glue, ultrasonic welding, or other attachment process to the disposable reagent strip. This blood or fluid guard prevents blood or fluid from contaminating the electronic instrument system that reads the disposable reagent strip.

Significant aspects and features of the present invention include a disposable reagent unit with a blood or fluid guard which is readily manufactured and packaged in a sterile foil package, and is leak proof when utilized with a liquid.

Another significant aspect and feature is a disposable reagent unit with a blood or fluid guard which can include one or more reagent windows, and an optional reagent specific calibration window.

Other significant aspects and features of the present invention is a disposable reagent unit with a blood or fluid guard which prevents blood from getting on the diagnostic instrumentation so that the system can be used on different patients; the blood or fluid guard is part of the disposable reagent unit so no cleaning of the instrument is required which enhances user safety and convenience; and the blood or fluid guard is a simple, low cost idea that provides significant user benefits which is compatible with high volume production processes.

Having thus described the embodiments of the present invention, it is a principal object hereof to provide a disposable reagent unit with a blood or fluid guard which is used to measure a quantity of at least one analyte in a liquid.

One object of the present invention is a disposable reagent unit with a blood or fluid guard to measure glucose and cholesterol in blood with the reagent strip, which engages in a diagnostic instrument which reads resultant color change of the reagent indicating the quantity of at least one component such as glucose in a liquid such as blood.

Another object of the present invention is a disposable reagent unit with a blood or fluid guard to measure a predetermined analyte in a liquid.

A further object of the present invention is a multi-laminate disposable reagent unit with a blood or fluid guard which is leak proof for purposes of infection control and for purposes of disposal.

BRIEF DESCRIPTION OF THE DRAWINGS

Other objects of the present invention and many of the attendant advantages of the present invention will be readily appreciated as the same becomes better understood by reference to the following detailed description when considered in connection with the accompanying drawings,

in which like reference numerals designate like parts throughout the figures thereof and wherein:

FIG. 1 illustrates a bottom view of a reagent strip;

FIG. 2 illustrates a side view of the reagent strip;

FIG. 3 illustrates a top view of a reagent strip;

FIG. 4 illustrates an exploded side view of the reagent strip;

FIG. 5 illustrates an exploded isometric view of the reagent strip;

FIG. 6 illustrates use of the reagent strip with a diagnostic instrument;

FIGS. 7A and 7B illustrate a first alternative embodiment of a bottom view and a top view of a reagent strip;

FIGS. 8A and 8B illustrate a second alternative embodiment of a bottom view and a top view of a reagent strip;

FIGS. 9A and 9B illustrate a third alternative embodiment of a bottom view and top view of a reagent strip;

FIG. 10 illustrates a perspective view of a disposable reagent unit with a blood or fluid guard;

FIG. 11 illustrates an exploded view of a disposable reagent unit with a double sided tape and a blood or fluid guard;

FIG. 12 illustrates a top view of the disposable reagent unit with a blood or fluid guard;

FIG. 13 illustrates a side view of the disposable reagent unit with a blood or fluid guard;

FIG. 14 illustrates a bottom view of the disposable reagent unit with a blood or fluid guard;

FIG. 15 illustrates a perspective view of the disposable reagent unit with a blood or fluid guard in a diagnostic instrument;

FIG. 16 illustrates a side view of the disposable reagent unit with a blood or fluid guard in a diagnostic instrument; and,

FIG. 17 illustrates a perspective view of a disposable reagent unit with a blood or fluid guard in a diagnostic unit which overlaps a significant area of the diagnostic instrument.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

FIG. 1 illustrates a bottom view of a multi-laminate reagent strip 10 including base strip 12 with a plurality of holes 14 and 16 for air holes and gripping grooves, a reagent specific calibration window on a lot-to-lot identification window 18, a reagent window 20, a lancet port hole 22, and a vent hole 24. Any geometrical aperture can be utilized in lieu of the holes, ports, openings or windows. The multi-laminate structure forms a housing for the reagent unit.

FIG. 2 illustrates a side view of the reagent strip 10 including a base strip 12 and a cover strip 26. An optional recess 13 is for accommodation of materials such as any reagent materials and lot-to-lot or calibration materials.

FIG. 3 illustrates a bottom view of the reagent strip 10 including a blood bowl 28 and a wick 30. The sample application port bowl 28, can be directly above the reagent or remove from the reagent. The transport of fluid is by capillary action, either by the wicking material which can be symmetric or asymmetric or by an air gap. The wicking material can also act as a filter. The vent hole can be adjacent to or spaced with respect to the transporting structure for the liquid. The reagent material can be a switchable membrane such as preformed material, such as polymer material; or a film or a fiber, such as paper or cloth material. The lot-to-lot identification window 18 can be optical detection, such as a gray scale or a color scale, a bar code or other optical code, magnetic detection, resistively detection, an EPROM with software, or any mechanical detection schemes such as with notches, etc., electrical detection schemes or electromechanical detection schemes. The lot-to-lot identification window is also optically used to detect a sufficient fluid sample and for reagent material lot programming. The strip housing can include

extruded plastic, molded plastic, or milled plastic. The disposal reagent unit is multi-laminate. At least one port is provided for detecting analyte, and two or more ports can be provided for detecting analyte. More than one reagent can be provided for detecting more than one analyte, such as for a blood panel of tests. The reagent unit can be utilized with diagnostic units configured to analyze multi-reagents such as for glucose, cholesterol, alcohol, or any other analytes in blood, liquid or fluids.

FIG. 4 illustrates an exploded side view of the reagent strip 10 including a base strip 12, a double face adhesive tape 32, a lot-to-lot paper 34, a reagent 36, a wick 38 and the cover strip 26.

FIG. 5 illustrates an exploded isometric view of the reagent strip 10 where all numerals correspond to those elements previously described.

FIG. 6 illustrates use of the reagent strip 10 in use with a diagnostic instrument 100.

MODE OF OPERATION

The blood glucose reagent strips are designed to be used with a reflectance meter for quantitative determination of glucose in whole blood. The glucose reagent employs a glucose oxidase/peroxidase chemistry in a dry reagent membrane enclosed in a black plastic

housing. The disposable reagent unit features and functions includes:

a. Blood Bowl - Blood application site that houses wick and lancet hole.

b. Wick - Transports blood sample from the blood bowl to the chemistry.

c. Lancet Hole - Opening through which lancet tip emerges when triggered by the instrument.

d. Reagent Window - Site of chemical reaction with glucose.

e. Lot-to-Lot Programming Window - Used for automatic programming of the appropriate instrument calibration and includes a calibration material. Other terms of definition include reagent specific calibration window and can also be used for sensing sufficient analyte as a secondary function.

f. Vent Hole - Opening to facilitate blood flow through the disposable reagent unit.

A drop of blood from a finger stick is applied to the white wick material located in the oval opening in the center of the disposable reagent unit. The wick transports the sample to the chemistry to initiate the reaction and helps compartmentalize the blood sample for safe and easy disposal.

The disposable reagent unit provides a simple and convenient means to measure blood glucose. With the

reagent strip, no washing, wiping, blotting, timing or calibration steps are required.

The chemistry of the disposable reagent unit includes a containment plastic housing that contains a nylon reagent membrane with a glucose oxidase/peroxidase chemistry, and the indicator O-Tolidine.

When a blood sample contacts the reagent membrane, the glucose, in the presence of oxygen, is converted to -Gluconolactone and hydrogen peroxide by the enzyme glucose oxidase (GOD) (Reaction 1).

The enzyme peroxidase (POD) catalyzes the reaction between the indicator (beige) and hydrogen peroxide to produce water and an oxidized indicator (blue) (Reaction 2).

$$\text{Glucose} + O_2 \xrightarrow{\underline{GOD}} \text{-Gluconolactone} + H_2O_2 \quad (1)$$

$$\text{O-Tolidine}_{(red)} + H_2O_2 \xrightarrow{\underline{POD}} \text{O-Tolidine}_{(ox)} + 2H_2O \quad (2)$$

The intensity of the color produced is proportional to the sample glucose concentration.

The reagents are in Table 1 as followed by way of example:

Table 1

O-tolidine	.23ug
Glucose Oxidase	2.8 I.U.
Peroxidase	.2.4 I.U.
Buffer (Stabilizers)	.13.7 ug
Inert Ingredients	.2630 ug

To perform a blood glucose test, a drop of blood can be obtained from a finger puncture using the lancing system built into the blood glucose monitor. Alternatively, fresh venous blood collected in EDTA or heparin containing tubes may also be used. To minimize glycolysis, test blood samples as close as possible (10 minutes or less) to the time the samples were collected.

Glucose concentration of venous and capillary bloods may differ as much as 10 percent depending on the time of sample collection after a meal.

The system results are displayed as milligrams of glucose per deciliter of whole blood (mg/dL). Blood glucose levels associated with well-controlled diabetes are:

Fasting: 60-130 mg/dL blood glucose

After meals (1 hour): less than 180 mg/dL

Blood glucose monitoring and interpretation of results should be done with the guidance of a diabetes health care professional. A physician would be consulted to establish target blood glucose values that are suitable, insulin dose or other medication resulting from interpretation of glucose readings.

DESCRIPTION OF THE FIRST ALTERNATIVE EMBODIMENTS

FIG. 7A illustrates a first alternative embodiment of a bottom view of a reagent strip 200, where the elements have been located at positions differing from

the reagent strip 10, and along and about the base strip 212 and the cover strip 226, as illustrated. The reagent strip 200 includes elements similar in structure, name and function to the reagent strip 10 of Fig. 1. The base strip 212 includes a plurality of holes 214 and 216 for gripping grooves, a lot-to-lot identification window 218, a reagent window 220, a lancet port 222 and a vent hole 224.

FIG. 7B illustrates a top view of the reagent strip 200 where all numerals correspond to those elements previously described. The cover strip 226 includes the blood bowl 228 and the wick 230. The blood bowl 228 is aligned substantially opposite the reagent window 220 on the opposing side of the base strip 212.

DESCRIPTION OF THE SECOND ALTERNATIVE EMBODIMENT

FIG. 8A illustrates a second alternative embodiment of a bottom view of a reagent strip 300 where the elements have been located at positions differing from the reagent strip 10, and along and about the base strip 312 and the cover strip 326, as illustrated. The reagent strip 300 includes elements similar in structure and function to the reagent strip 10 of Fig. 1. The base strip 312 includes a plurality of holes 314 and 316 for gripping grooves, a lot-to-lot identification window 318, a reagent window 320, a lancet port 322 and a vent hole 324. The lot-to-lot identification window 318, reagent

window 320, the lancet hole 322 and the vent hole 324, are located in close proximity to the end of the reagent strip 300, which is opposite the end with the plurality of holes and grooves 314 and 316.

FIG. 8B illustrates a top view of the reagent strip 300 where all numerals correspond to those elements previously described. The cover strip 326 includes the blood bowl 328 and the wick 330. The blood bowl 328, is aligned opposite the reagent window 320 on the opposite side of the base strip 312 and adjacent to the edge of the reagent strip 300.

DESCRIPTION OF THE THIRD ALTERNATIVE EMBODIMENT

FIG. 9A illustrates a third alternative embodiment of a bottom view of a reagent strip 400 where the elements have been located at positions differing from the reagent strip 10, and along and about the base strip 412 and the cove strip 426, as illustrated. The reagent strip 400 includes elements similar in structure and function to the reagent strip 10 of Fig. 1. The base strip 412 includes a plurality of holes 414 and 416 for gripping grooves, a lot-to-lot identification window 418, a reagent window 420, a spaced lancet port 422, and a vent hole 424. The lot-to-lot identification window 418, reagent window 420, and the vent hole 424, are located in close proximity to the end of the reagent strip 400,

which is opposite the end with the plurality of holes and grooves 414 and 416.

FIG. 9B illustrates a top view of the reagent strip 400 where all numerals correspond to those elements previously described. The cover strip 426 includes the blood bowl 428 and the wick 430. The blood bowl 428 is aligned opposite the reagent window 420 on the opposite side of the base strip 412 and adjacent to the edge of the reagent strip 400.

DESCRIPTION OF THE FOURTH ALTERNATIVE EMBODIMENT

FIG. 10 illustrates a perspective view of a fourth alternative embodiment of a disposable reagent unit with a blood or fluid guard 500, the present invention as now described in detail.

FIG. 11 illustrates an exploded view of the disposable reagent unit with a blood or fluid guard 500 including a geometrically shaped, thin, liquid-impermeable and flexible member 502 with a hole 503, double-sided tape 504, including a hole 505 and the disposable reagent strip 10, as described in FIGS. 1-5, all as an integral unit. The blood or fluid guard member 502 is floppy and flexible so as to allow for insertion of the disposable reagent strip 10 into the rail-like structure as illustrated in FIGS. 15 and 16, and overlap the rails and the surrounding edges of the diagnostic instrument 100 so as to prevent blood or fluid flow on or

about the diagnostic instrument, and particularly between the disposable reagent strip 10 and the rail slots or grooves which the disposable reagent strip engages into the diagnostic instrument. The blood or fluid guard member 502 includes the hole 503, a first width 506 substantially equal to the width of the disposable reagent strip 10, a second width 508 larger than the width of the disposable reagent strip 10, and an extending overlapping length 510. The holes 503 and 505 align with the hole in the disposable reagent strip 10. The overlapping second width 508 and length 510 serve to shield, cover and protect the edges of slots of the diagnostic instrument as later discussed in FIGS. 15 and 16. The blood or fluid guard member 502 can also be sold as an after-market accessory for existing disposable reagent units. The teachings of the present invention are also extendable to other similar types of disposable reagent units. Other securing processes can be used in lieu of the double-sided tape, such as preapplied adhesive to members 502 or 10, or after-market strips of tape or adhesive.

FIG. 12 illustrates a top view of the disposable reagent unit with the blood or fluid guard 500 where all numerals correspond to those elements previously described.

FIG. 13 illustrates a side view of the disposable reagent unit with the blood or fluid guard 500 where all numerals correspond to those elements previously described.

FIG. 14 illustrates a bottom view of the disposable reagent unit with the blood or fluid guard 500 where all numerals correspond to those elements previously described.

FIG. 15 illustrates a perspective view of the disposable reagent strip 10 engaged into the rails of a diagnostic unit, and with the blood or fluid guard member 502 which overlaps the edges of a diagnostic unit 550, and which particularly covers the intersection of the disposable reagent strip and the diagnostic instrument.

FIG. 16 illustrates a side view showing the opposing slots 552 and 554 on each side of the diagnostic instrument 550 which the disposable reagent strip 10 engages into, while the blood or fluid guard member 502 conforms to and covers the configured geometry of the housing of the diagnostic instrument, including the opposing slots.

FIG. 17 illustrates a perspective view of a disposable reagent unit with a large floppy blood or fluid guard 600 which covers a significant portion of a flip top 556 of the diagnostic instrument. The large floppy portion 602 extends forward of the disposable

reagent strip 10. An extension of the teachings of the present invention can include a rear large floppy portion 604 as illustrated in dashed lines which extends rearward of the disposable reagent strip 10, and is also applicable to FIGS. 1-16 as desired to further protect the diagnostic instrument or the user's body members, such as the user's fingers, hands or other body members.

Various modifications can be made to the present invention without departing from the apparent scope hereof. More than one reagent window or one calibration window can be provided on the strip housing or multi-laminate structure. The size, arrangement and spacing of the windows, holes, and components is determined by the diagnostic system which utilizes the reagent strip. The reagent strip is intended for any system for measuring an analyte, and is not limited strictly to a medical system, as other uses of the reagent strip are encompassing the teachings of a blood or fluid guard is applicable to other reagent units, as well as the related instrumentation. Any suitable material can be utilized for blood guard. The teachings of the present invention are also applicable for the process for covering a diagnostic reagent unit.

WE CLAIM:

1. A multi-laminate test device for a diagnostic instrument comprising:

a. a housing means for transportation and containment for a fluid;

b. at least one sample application port in said housing means;

c. a fluid transport means in said housing means;

d. a reagent means in said housing means for indication by a change of said reagent the presence of an analyte in said fluid; and,

e. a guard means affixed to at least a portion of said housing means, whereby said blood or fluid guard means prohibits transmission of body fluids to the diagnostic instrument.

2. Disposable reagent unit for a diagnostic instrument comprising in order:

a. a first strip including a first hole and at least one sample application port;

b. a reagent material over said application port;

c. a transport means communicating between said sample port and said reagent material;

d. a second strip including a corresponding second hole over said first hole; and,

e. a conforming member of a predetermined shape extending over and about at least a portion of said second strip whereby said conforming member acts as a guard to prevent fluid contamination.

3. Disposable reagent unit comprising in order:

a. a base strip including a first sample hole, a hole for lot-to-lot material and a hole for reagent material;

b. a lot-to-calibration material over said lot-to-calibration hole;
c. a reagent material over said reagent hole;
d. a wicking material from said blood hole to said reagent material and lot-to-calibration hole;
e. a cover strip including a corresponding second sample hole over said first sample hole, including means securing said strips together; and,
f. a conforming member of a predetermined shape extending over and about at least a portion of said second strip whereby said conforming member acts as a guard to prevent fluid contamination.

4. A disposable diagnostic reagent unit for operative engagement with a medical monitoring diagnostic system, said disposable unit comprising:

a. a housing;
b. means for operatively connecting said housing to said system;
c. blood reagent chemistry means supported within said housing;
d. fluid transporting means including a first opening in said housing for transporting a liquid substance flowing from a liquid substance to said reagent means;
e. aperture means through said housing adjacent the system positioned to pass a reflected light from at least a portion of said reagent means in said diagnostic unit to a sensing means in the system for a determination of change of said reagent means by the system whereby said change indicates a diagnostic condition; and,

f. a conforming member of a predetermined shape extending over and about at least a portion of said second strip whereby said conforming member acts as a guard to prevent fluid contamination.

5. The disposable unit of claim 4 wherein said housing includes opposed, substantially parallel first and second upper and lower portions.

6. The disposable diagnostic unit of claim 5 including at least two reagent means.

7. The disposable diagnostic unit of claim 6 wherein said opening for providing a liquid substance to said reagent means includes said opening.

8. The disposable unit of claim 4 wherein said fluid transporting means includes filter means for filtering at least one component from said liquid substance.

9. The disposable diagnostic unit of claim 4 including calibration means supported in an aperture in said housing next to said reagent means.

10. The disposable diagnostic unit of claim 4 wherein said fluid transporting means comprises a wicking means.

11. The disposable diagnostic unit of claim 4 wherein fluid transporting means comprises an air gap means for capillary action.

12. A disposable diagnostic disposable reagent unit for operating in engagement and use with a medical diagnostic system of a type having a puncturing means, connection means for operatively receiving said unit on said system and means in said system for reading a detectable change on the reagent means, said disposable diagnostic disposable reagent unit comprising:

a. a housing;

b. means on said housing for operatively connecting said housing to said system;

c. reagent means including a front side facing said system and a back side away from said system, supported within said housing;

d. liquid conveying means including a first opening in said housing for conveying a liquid substance from the punctured surface to said reagent means;

e. aperture means through said housing at a point adjacent said system unit for conveying light from a back side portion of said reagent means to said system for determination of change thereby indicating a diagnostic condition; and,

f. a conforming member of a predetermined shape extending over and about at least a portion of said second strip whereby said conforming member acts as a guard to prevent fluid contamination.

13. The disposable diagnostic unit of claim 12 wherein said liquid conveying means includes means for filtering at least one component of said liquid substance.

14. The disposable diagnostic unit of claim 12 wherein said liquid conveying means is an air gap.

15. The disposable diagnostic unit of claim 12 wherein said liquid conveying means is wicking material.

16. The disposable diagnostic unit of claim 12 wherein said surface is skin and said liquid substance is blood.

17. The disposable diagnostic unit of claim 12 wherein the color change of said reagent is caused by glucose in said liquid substance and said diagnostic condition is glucose level.

18. The disposable diagnostic unit of claim 12 wherein said fluid conveying means comprises a wicking means between said first opening and said reagent means.

19. A disposable diagnostic reagent unit for operating in engagement and use with a medical diagnostic system of a type having actuation means for driving of a puncturing means, connection means for operatively receiving said disposable reagent unit on said system and means in said system for reading a color change on the reagent means, said disposable diagnostic disposable reagent unit comprising:

a. a housing including opposing finger gripping tabs and a bottom plate;

b. at least one reagent means having a variable color responsive to the concentration of an

analyte in a liquid supported within said housing;

c. liquid conveying means including said first opening in said housing for conveying said liquid from said punctured surface to said reagent means;

d. aperture means through said housing for providing access for reading said reagent means for change of color by said system thereby indicating a diagnostic condition; and,

e. a conforming member of a predetermined shape extending over and about at least a portion of said second strip whereby said conforming member acts as a guard to prevent fluid contamination.

20. The unit of claim 19 wherein said liquid conveying means includes wicking means between said first opening and said aperture.

21. The unit of claim 19 wherein said liquid conveying means includes filter means between said reagent and said wicking means.

22. The unit of claim 19 including a second opening in said housing and a lot/lot calibration positioned about said second opening.

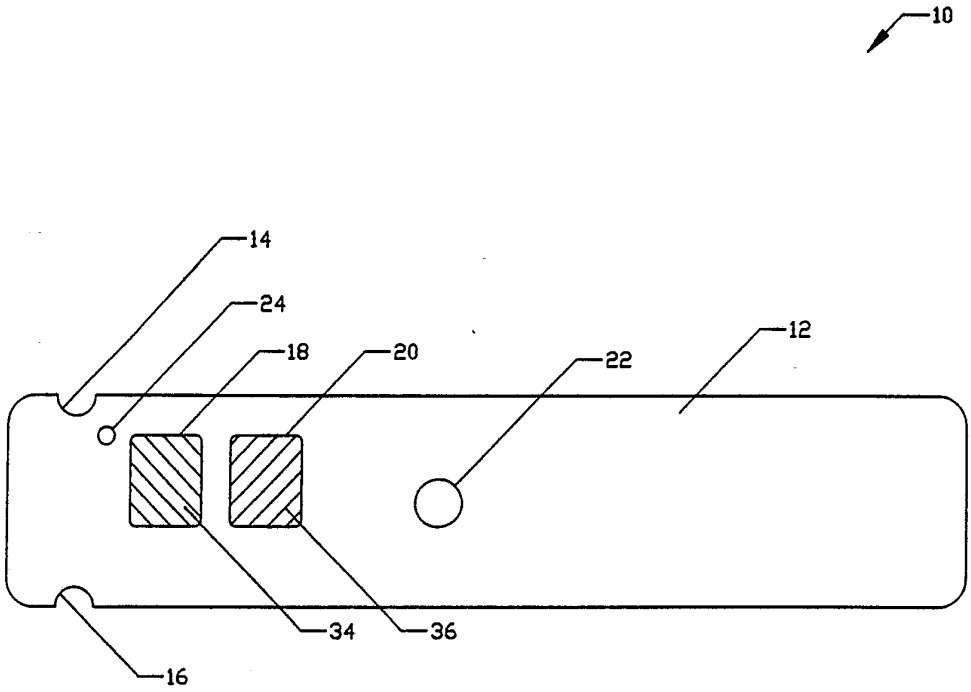

FIG. 1

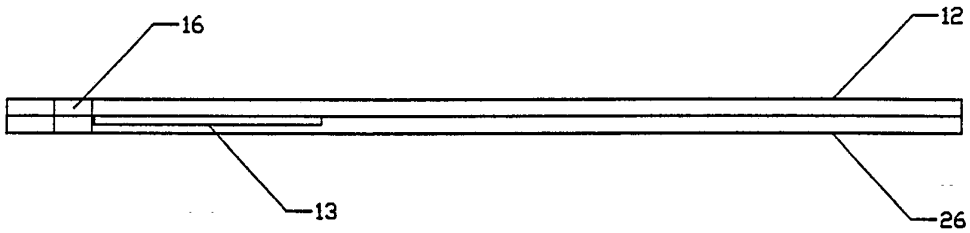

FIG. 2

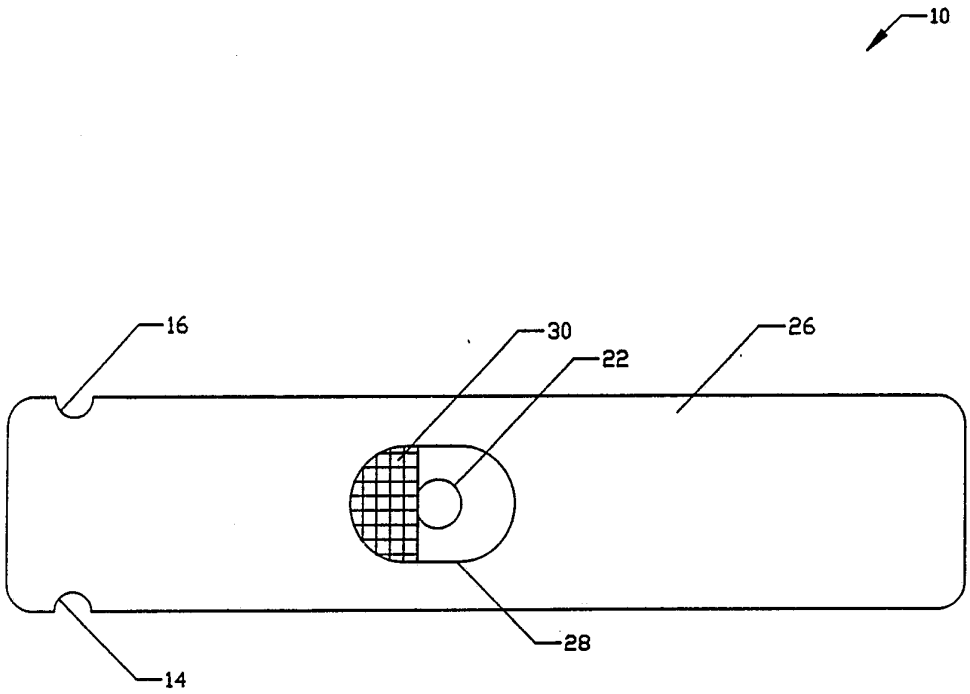

FIG. 3

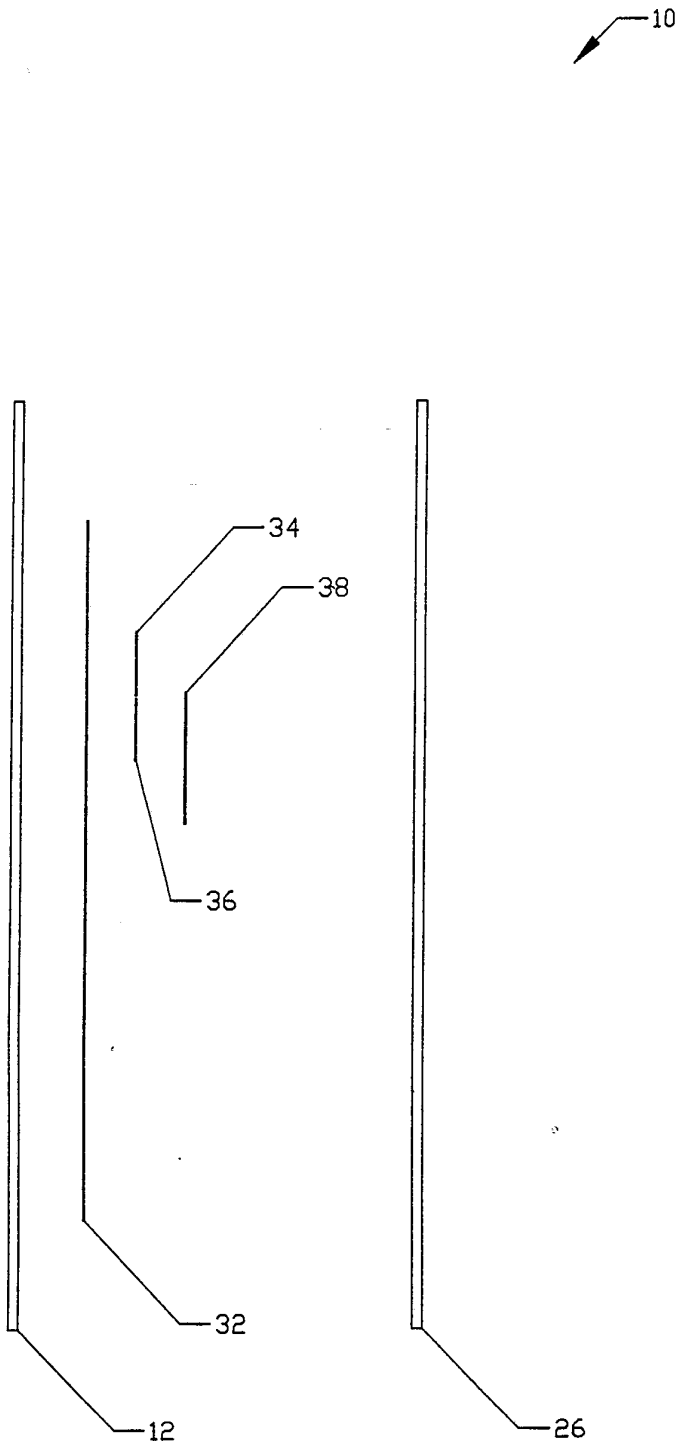

FIG. 4

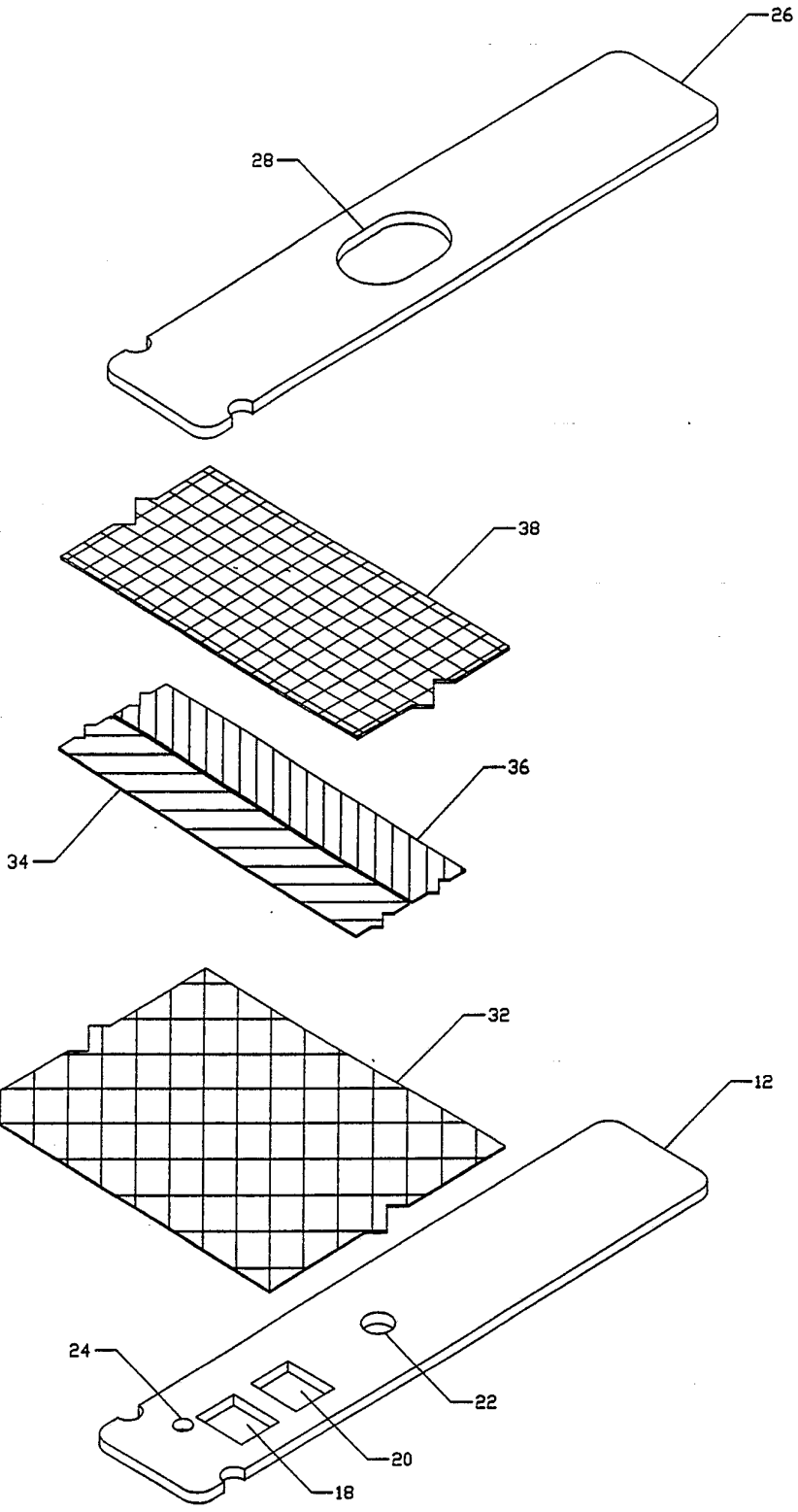

FIG. 5

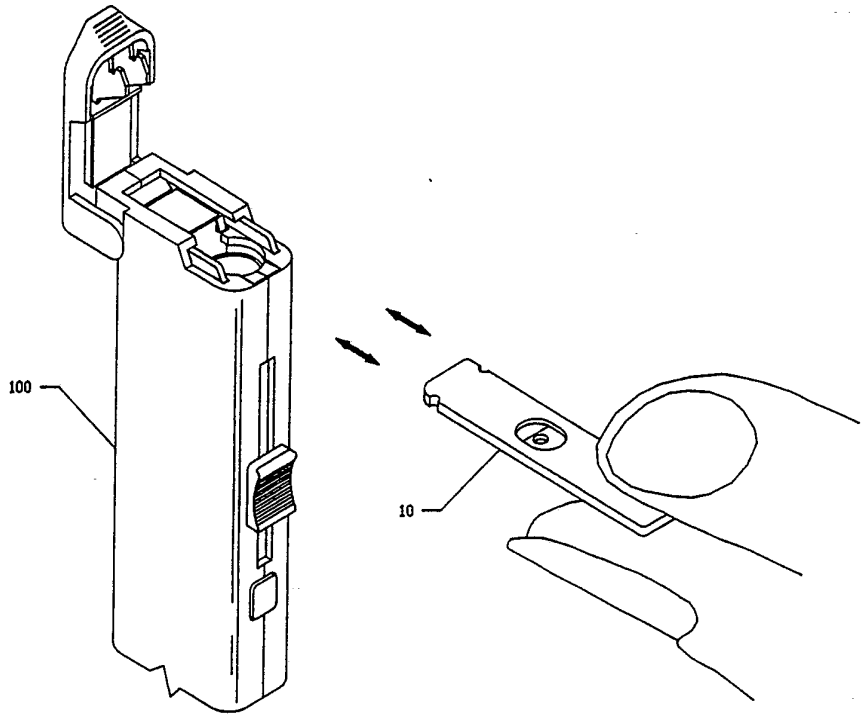

FIG. 6

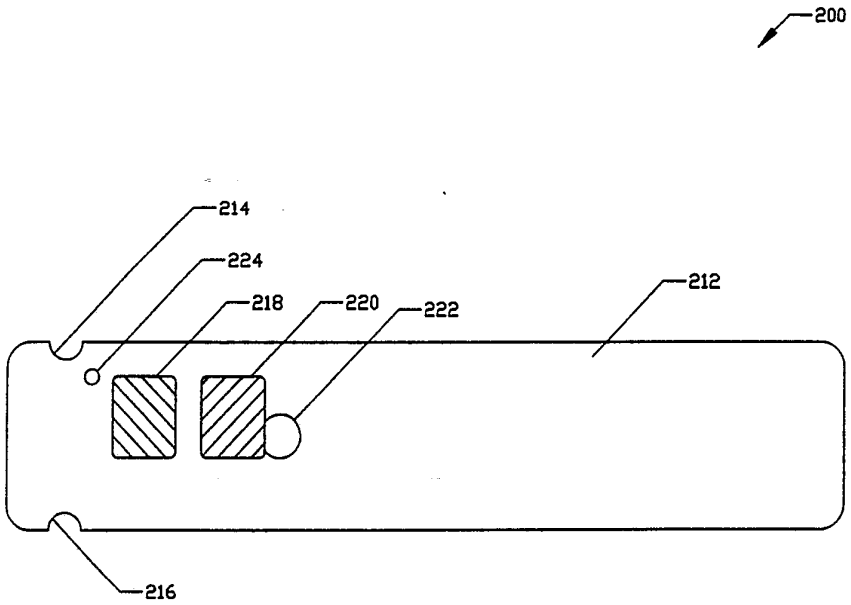

FIG. 7a

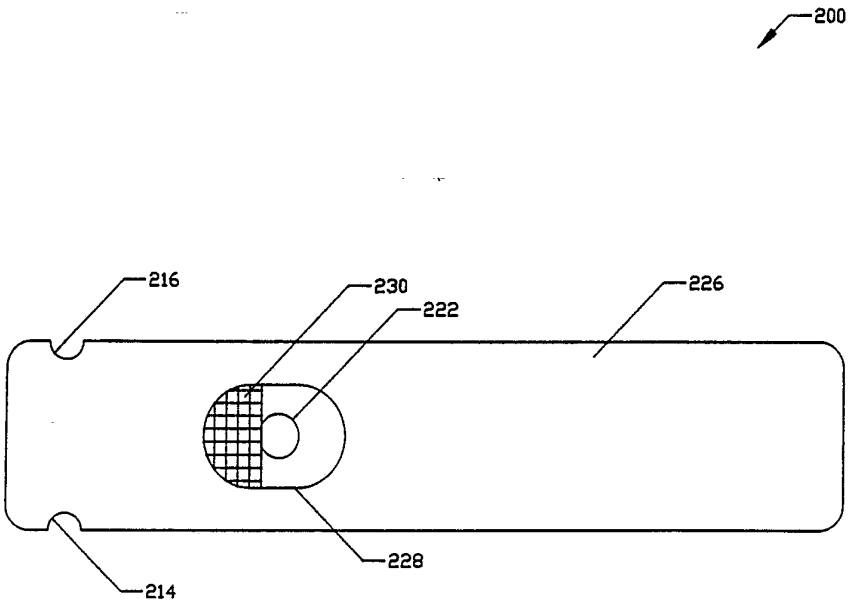

FIG. 7b

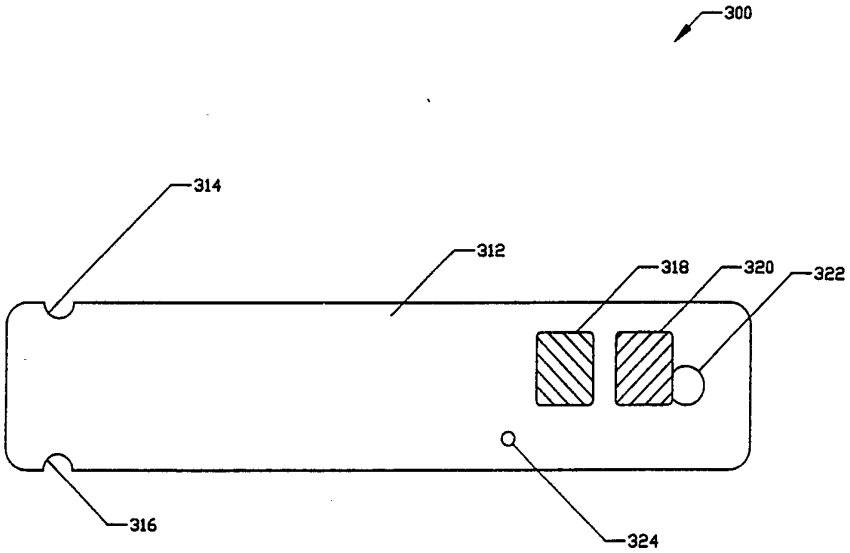

FIG. 8a

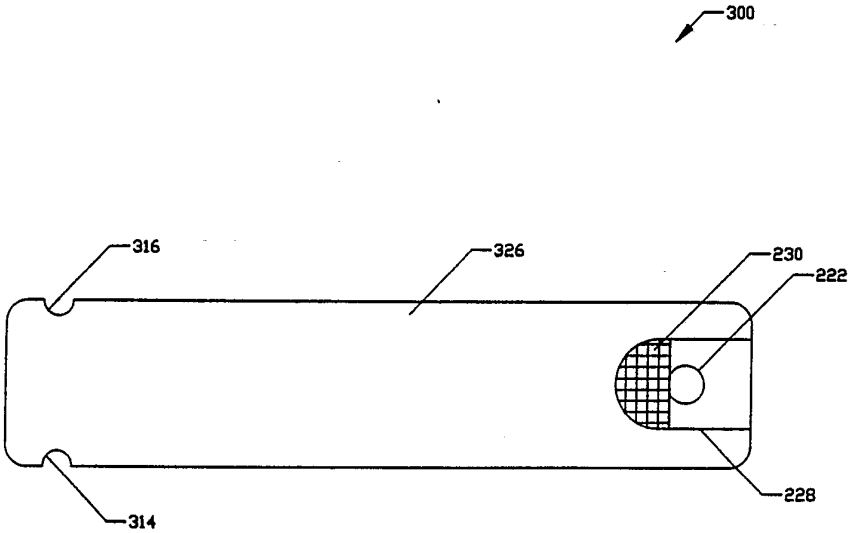

FIG. 8b

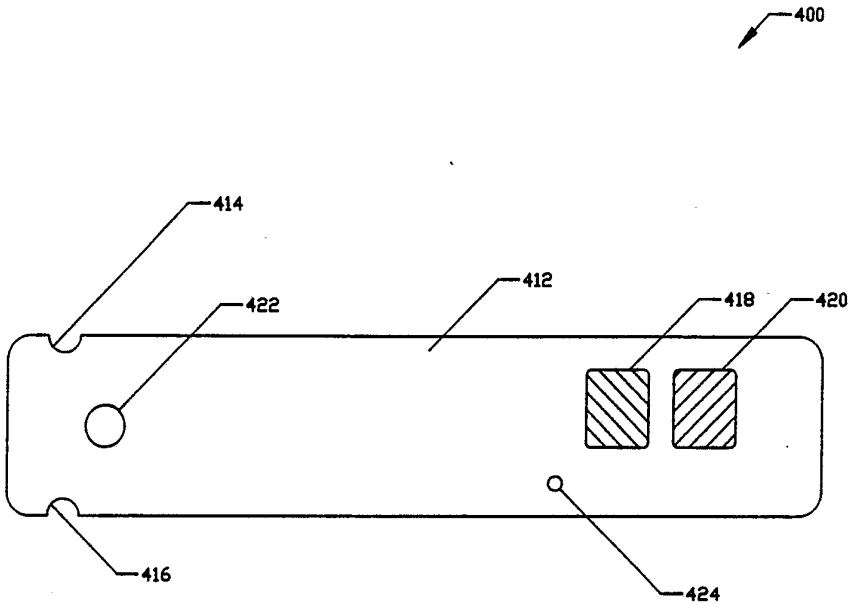

FIG. 9a

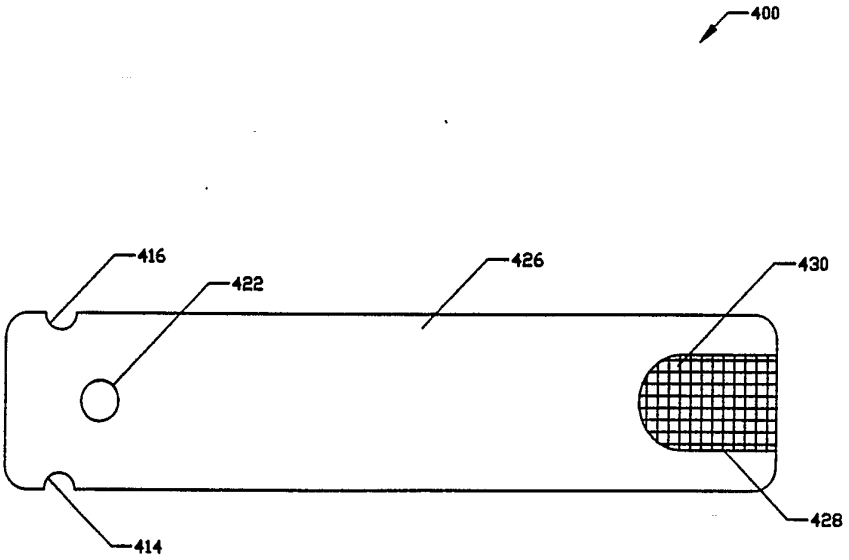

FIG. 9b

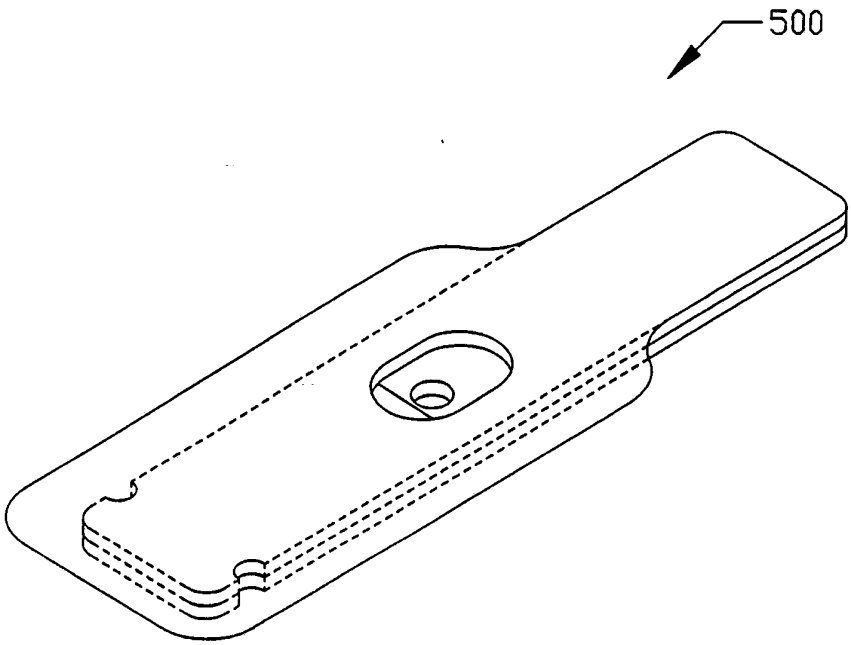

FIG. 10

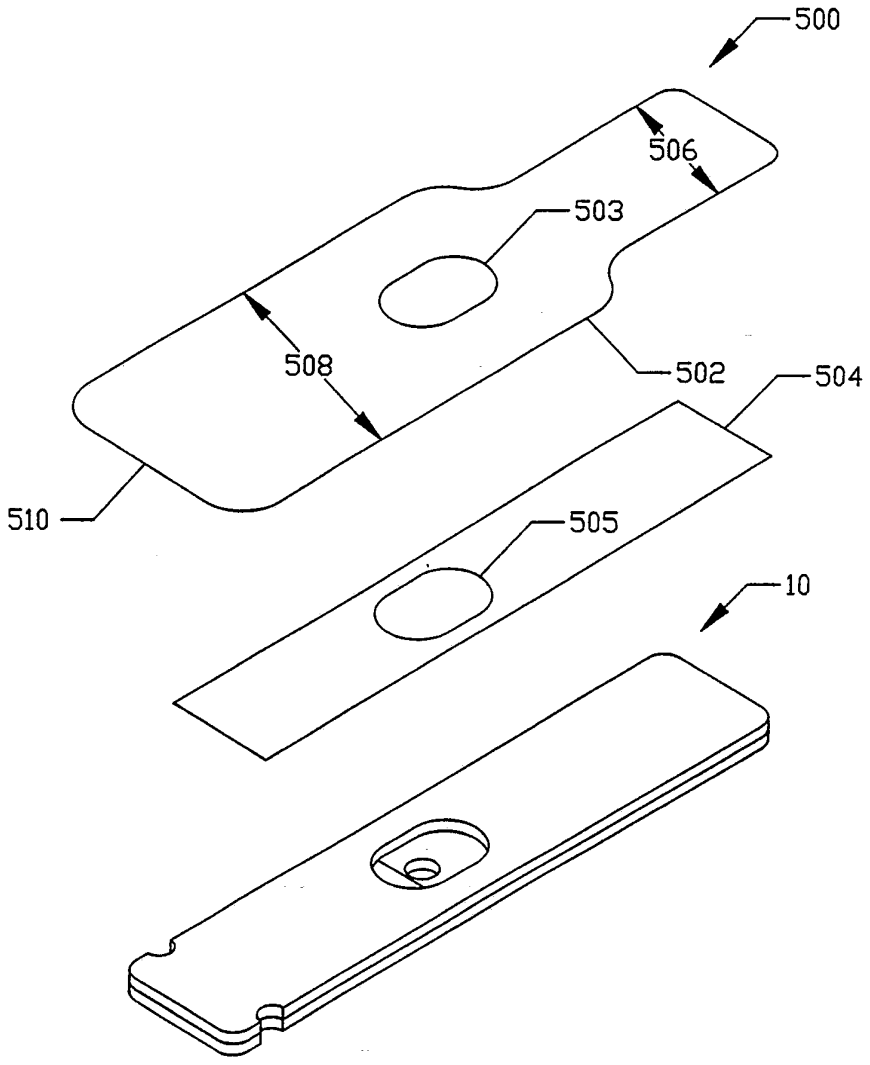

FIG. 11

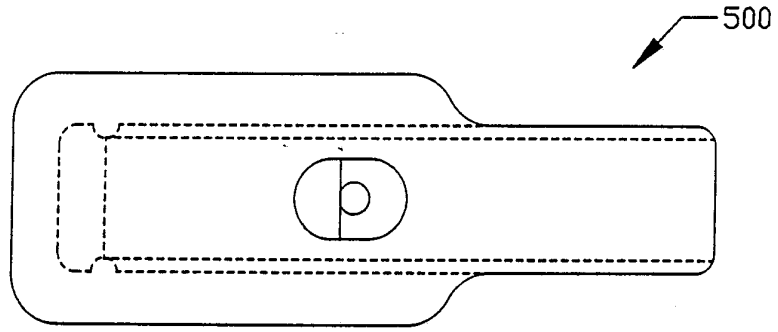

FIG. 12

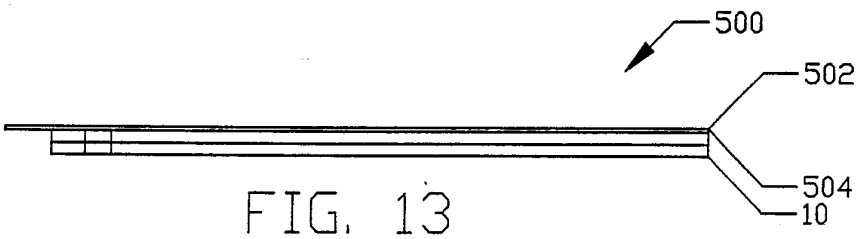

FIG. 13

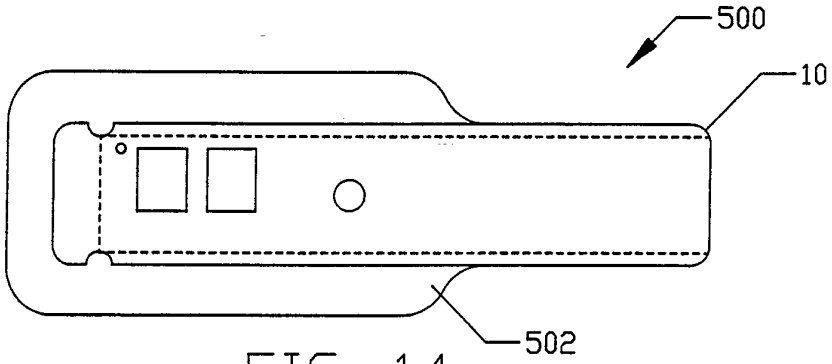

FIG. 14

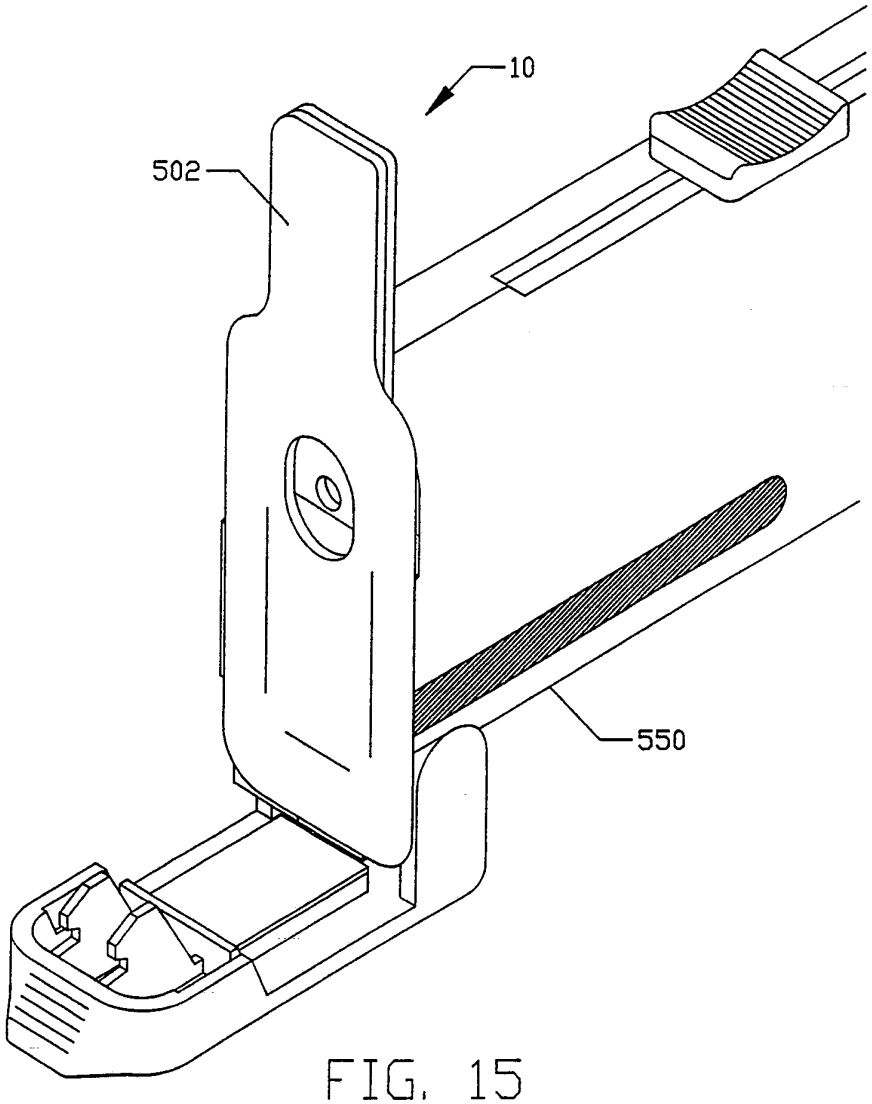

FIG. 15

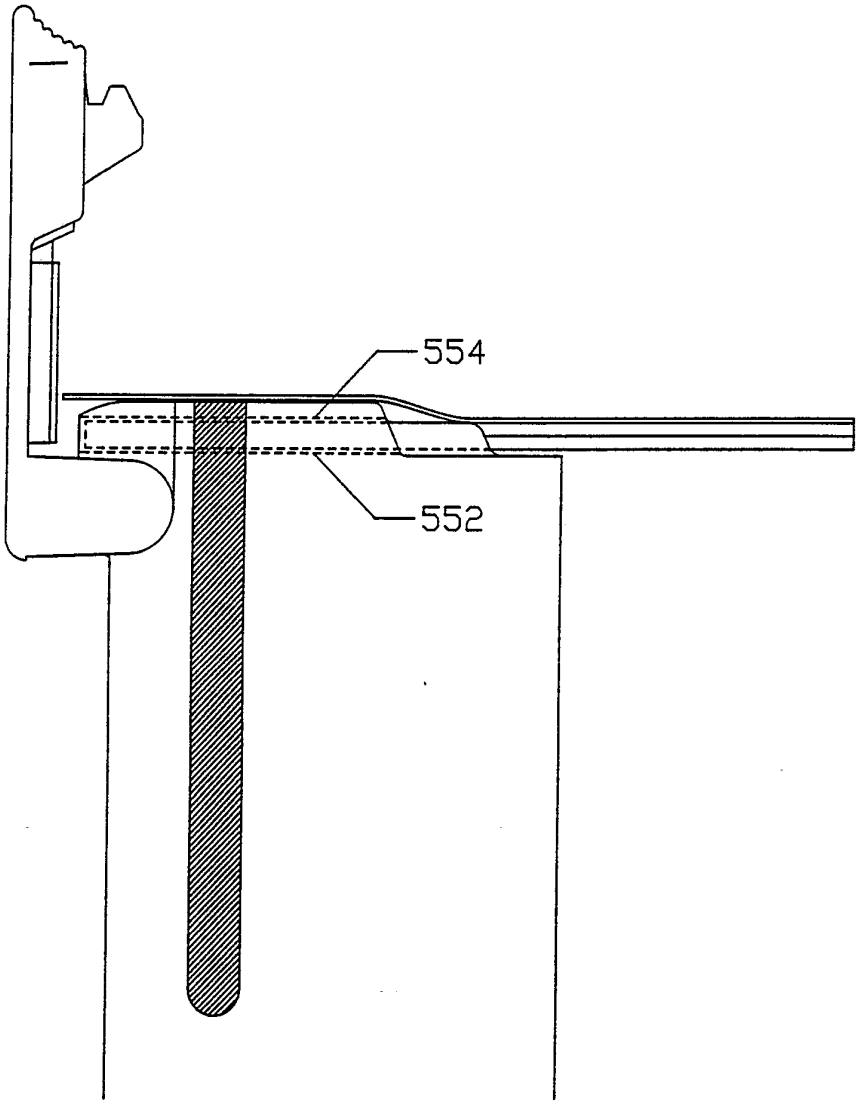

FIG. 16

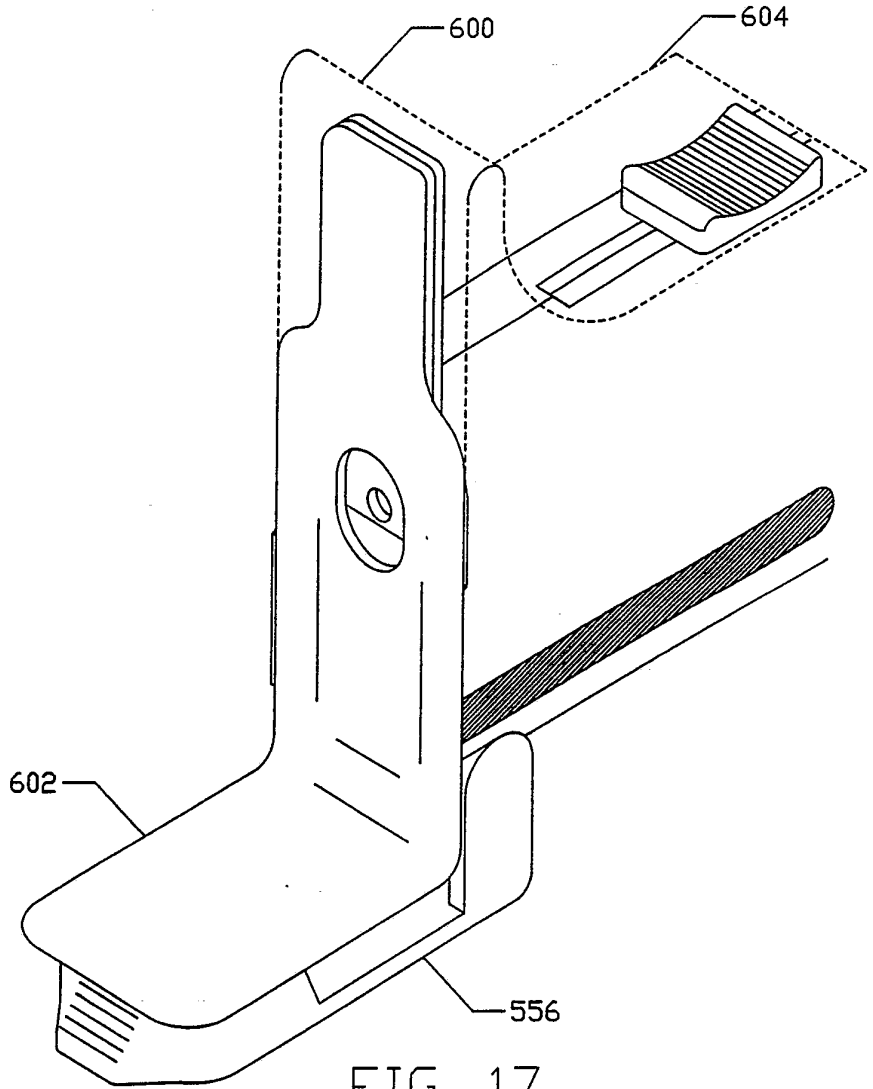

FIG. 17

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US92/07186

A. CLASSIFICATION OF SUBJECT MATTER

IPC(5) :A61B 5/14
US CL :128/632

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/633, 634, 670, 672

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US, A, 4,774,192 (Terminiello et al) 27 September 1988, See the entire reference.	1-22
X	US, A, 4,790,979 (Terminiello et al) 13 December 1988, See the entire reference.	1-22

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be part of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 23 DECEMBER 1992	Date of mailing of the international search report 05 JAN 1993
Name and mailing address of the ISA/ Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. NOT APPLICABLE	Authorized officer DAVID SHAY Telephone No. (703) 308-0858

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