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(71) Applicant: HEALTH CRAFT INTERNATIONAL, INC. [US/US]; 85 North El Molino Avenue, Pasadena, CA 91101 (US).

(72) Inventor: PARSONS, Stuart, J.; 23875 Longspur Court, Laguna Niguel, CA 92677 (US).

(74) Agent: RAHN, LeRoy, T.; Christie, Parker & Hale, P.O. Box 7068, Pasadena, CA 91109-7068 (US).

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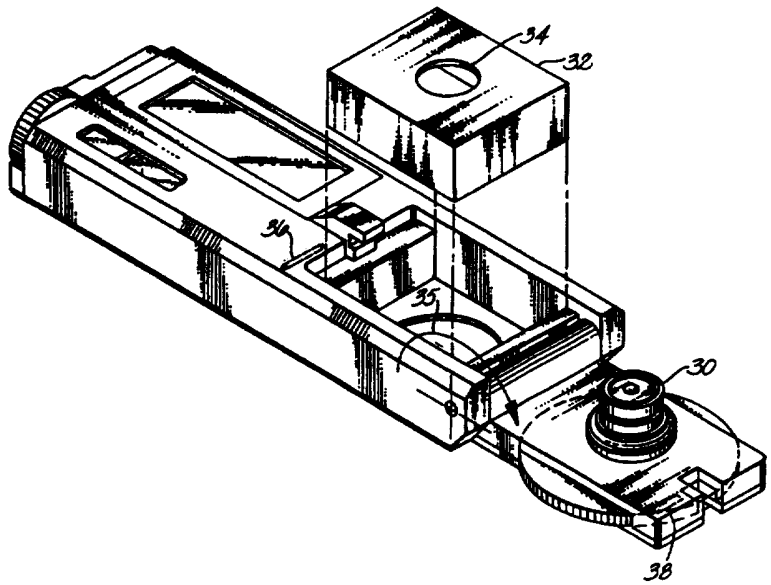

(57) Abstract

An apparatus for monitoring glucose level has a case (10). A lid (22) is adapted to cover and uncover the base of case (10). A recplaceable membrane hat (30) is mounted on a glucose level sensor (31). A sheet of membrane material (44) is stretched across and mounted on the top of the hat so as to conform to the surface or the sensor. The reservoir has an access opening (34) into which the membrane hat and sensor fit when the lid covers the base. A freely moveable buffer fluid is disposed in the reservoir to wet the membrane when the lid covers the base. The membrane hat has a round base that abuts the reservoir and an O-ring (40) that seals the reservoir when the lid is closed. The face of the case has a display (12) from which the sensor can be read.

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APPARATUS FOR MONITORING GLUCOSE LEVEL

Background of the Invention

This invention relates to the field of medical testing and, more particularly, to a method and apparatus for measuring human glucose levels.

For a number of years, polarographic systems with an enzyme electrode have been used to measure glucose level in blood samples.

For example, Clark Patent No. 3,539,455 teaches the use of a platinum anode and silver cathode to measure the hydrogen peroxide produced by the reaction of glucose and oxygen in the presence of a glucose oxidase enzyme. Newman Patent 3,979,274 discloses a laminated membrane for an enzyme electrode in which the enzyme is coupled with an adhesive between the lamina. The lamina of the multiple membrane comprises an outer support layer that serves as a barrier to high molecular weight substances and an inner homogeneous layer that serves as a barrier to interfering low molecular weight materials, but permits hydrogen peroxide to pass through, and an intermediate enzyme layer that reacts with glucose and bonds the outer and inner layers together. Glucose passes through the outer layer and reacts with a surplus of oxygen in the presence of the contained enzyme.

Hydrogen peroxide, which is one of the reaction products, passes through the inner layer to the electrode. The resulting electric current is a measure of the level of glucose in the sample fluid under test.

Reinhart Patent No. 4,750,496 teaches the use of the described polarographic cell system to measure the glucose level (concentration) on a mucosal surface in the oral cavity of a living being.

Specifically, the enzyme electrode membrane of a glucose monitoring instrument is positioned on the buccal mucosa, and a surplus of oxygen from the atmosphere is conveyed to the membrane through a passageway in the instrument. The oxygen reacts with the glucose that migrates through the outer layer of the membrane in the presence of the enzyme, and the resulting hydrogen peroxide migrates through the inner layer of the membrane to the electrodes while the membrane remains in contact with the mucosal surface. This, a non-invasive glucose measurement is made on a sample of mucosal fluid of patient in situ, rather than carrying a blood fluid sample to a free standing instrument.

Parsons Patent Application Serial No. 07/374,535; filed June 29, 1989, shows the use of a hand-held monitor embodying a fluid flushing system, electronics, and a multi-layer glucose membrane and electrode, used for self-glucose testing. Between tests, the membrane, mounted on a lid flap, is maintained in a wet state by closing the lid and immersing the membrane in the fluid system reservoir which is housed in the monitor case. The membrane is flushed after each test.

Flushing action is activated by the user in two ways: a control valve is released to

permit free fluid flow in the system and a valve is depressed which causes a stroke which moves new fluid into the membrane chamber and forces the resident fluid to leave the chamber, thus flushing the membrane.

Shults, et al Patent Application Serial No. 4,757,022, filed July 12, 1988, shows the use of a multi-layer membrane that restricts glucose transport thereby better balancing glucose and oxygen resulting in accurate glucose readings over a broader range of values. The sensor and membrane system are described and the membrane is contained in a plastic cartridge which snap fits over the sensor. The cartridge is so designed that a small well is formed to receive the blood sample and the cartridge cover can be shut to protect the membrane. The sensor, embodied in the monitor case, has two electrodes and works much as the Clark electrode mentioned earlier.

The blood sample does not have to be diluted for a glucose reading.

Summary of the Invention

According to one aspect of the invention, a hand-held monitor box is designed with a hinged, top flap which can be rotated 180 degrees to expose a sensor tip covered by a membrane, positioned for a glucose test. This simplifies the usual glucose monitoring process where disposable test strips are removed from capped vials and placed beside the glucose monitors to receive the test sample.

According to another feature of the invention, a buffer based fluid is maintained in a chamber in the body of the hand-held monitor box in such a position that the membrane/sensor resides in this chamber when the monitor lid is closed. This feature satisfies the requirement that the membrane be continually moist between tests. The lid is opened by rotating a knurled disk built into the lid top which engages a latch post, which positions the membrane for a test with a blood sample. Excess buffer solution is wiped away with a small tissue before the glucose test.

According to another aspect of the invention, the monitor ON and OFF controls are activated by small switches imbedded in the hand-held monitor box just under the lid and at the hinge of the lid. This permits the monitor to be automatically activated when the lid is opened and to be shut off when the lid is closed.

According to another aspect of the invention, the monitor test start point is automatically determined when the monitor is activated and when the sensor detects an increase in glucose signal strength equal to 20 mg/dl or more from a starting point which is + or - 7 mg/dl. This permits a test subject to begin a glucose test by placing a drop of blood on the membrane which is independent of a timing sequence imposed by the hand-held monitor and for a highly accurate start point for the test which is terminated by the monitor in exactly 20 seconds. A shorter test cycle occurs if the peak signal reading is achieved prior to 20 seconds. In this case, the electronics circuits hold and display the peak reading.

According to another aspect of the invention, a plastic sleeve shaped like a top hat

containing the membrane is placed over the sensor tip and screwed in to keep it securely in place.

This plastic hat is in two parts - the body base cylinder and threaded flange which screw onto the sensor base and a top cap which contains a small 4 mm diameter hole. The membrane material is placed between the base body and cap, which snap fit. A conforming mask is placed over the membrane and adhesive joins the cap, body, membrane, and conforming mask. When the plastic hat is placed down onto the sensor, the membrane is stretched against the domed sensor head and the membrane is forced underneath the small hole in the conforming mask, forming, on the top side, a shallow well for the glucose test sample with sides formed by the conforming mask and the bottom by the membrane material. The round opening in the top cap forms a larger test surface area for the inner circle well. The well is not covered but is exposed as the monitor lid is rotated open.

The membrane plastic hat assembly, and therefore the test well, is maintained in the buffer fluid bath between uses.

According to another aspect of the invention, the plastic buffer reservoir chamber is removable by opening the lid and pushing the reservoir through an opening in the bottom of the monitor body. The reservoir is replaced, the cap removed and placed on the old reservoir, the lid closed, and the old reservoir is discarded. The fresh buffer stimulates the electrochemical reaction among the blood, membrane glucose oxidase, and sensor during glucose testing.

According to another aspect of the invention, calibration is accomplished by adjusting the signal amplification through a thumb wheel which drives a potentiometer in the signal circuit. The thumb wheel is available for adjustment by rotating a wheel guard plate which releases the thumb wheel and activates the calibration phase in the electronics. The user places a known glucose standard onto the membrane and moves the thumb wheel to change the display to the known standard value. The signal amplification is adjusted to the new calibration setting, the wheel guard is replaced, the thumb wheel is locked, and the monitor electronics reenter the test mode.

According to another aspect of the invention, as calibration occurs, a small indicator on a horizontal gauge underneath the display is moved to indicate the remaining life of the membrane.

The indicator in the left portion of the gauge shows a new membrane condition and the indicator in the right position of the gauge alerts the user that the membrane needs replacement.

Brief Description of the Drawings

The features of specific embodiments of the best mode contemplated of carrying out the invention are illustrated in the drawings, in which:

FIG. 1 is a top view of the face of a monitor case 10 showing a display 12, a narrow gauge 14 with an index marker 16, a lid 22 and hinge 24 which occupy approximately forty percent of the monitor face area, and a latch post 18 and disk dial 20 which hold the lid closed. A reed switch 26 in the monitor case and a magnet 28 in the base of the lid are shown which control the ON and OFF monitor status;

FIG. 2 is a top view of the monitor case, as in FIG. 1, with the lid open revealing a replaceable membrane hat 30 mounted on a sensor which is contained on the inside of the lid, disk dial mechanism, lid hinge, lid latch post, and a removable buffer reservoir 32 (shown exploded from the monitor case). The reservoir has a sensor access opening 34. The sensor and attached membrane hat pivot up and out of the buffer reservoir as the lid is rotated open. A finger hole 35 is formed in the bottom of the case to permit the reservoir to be pushed out of the case when replacement is needed. Another reed switch 36 and magnet 38, placed in the monitor box Just under the latch post and at the inside and end of the lid, work with the set in FIG. 1 to control the monitor ON and OFF status;

FIG. 3 shows the top view of the replaceable membrane hat with the lid opened, as in FIG. 2, which exposes the removable buffer reservoir opening. When the lid is opened, the monitor is activated by switches as shown in FIGS. 1 and 2. Next, the membrane is dabbed with a tissue to clear excess buffer fluid prior to testing a blood sample. The lid disk dial is shown in the closed or latched position;

FIG. 4 is similar to FIG. 3 and diagrams the opened lid, the sensor mounted on the lid, and the membrane hat which is attached to the sensor with a drop of blood placed on the membrane. The lid disk dial is shown in the open or unlatched position;

FIG. 5 is a diagram of the side view of the opened monitor which shows the replaceable membrane hat assembly 30 that encloses a sensor 31 exploded from the lid and sensor. The sensor contains electrodes to sense a small electric current that is generated, depending on the glucose concentration in the blood sample. The sensor and the membrane are preferably constructed in the manner described in U.S. Patent 3,979,274, the disclosure of which is incorporated fully herein by reference. The base of the membrane hat screws into external threads 33 on the base of the sensor, and an O-ring 40 on the brim of the membrane hat acts as a seal for the buffer reservoir when the monitor lid is closed. With the lid closed, the membrane hat extends through opening 34 into the buffer reservoir chamber to keep the membrane wet. When the lid is opened, the sensor and attached membrane hat are withdrawn from the buffer reservoir and opening 34 is clear;

FIG. 6 is a side view of the membrane hat assembly removed from the electrode. This shows a membrane hat bezel 42, a sheet of membrane material 44, a conformal mask

46, and a membrane hat body 48 with internal mounting screw threads 50, which engage threads on the underside of the lid, and the O-ring seal; When the sensor hat assembly is mounted on the sensor inside of the monitor lid, tightening the screw fitting to the stops forces the preferably plastic bezel with mask and membrane downward against the slightly domed, rigid sensor head. The result forces sensor head up against the membrane material and the mask, which is a thin, bendable preferably plastic annular disk. The membrane is held in place to the mask by an adhesive, which also joins the mask to the bezel. The result is a shallow well 52 defined by the mask, the membrane, and the sloping interior wall of the bezel. The membrane material is the bottom of the well. Supporting the well bottom is the top of the sensor dome;

FIG. 7 is an end view of the monitor case showing the calibration gauge and index marker, calibration wheel guard 52, a reed switch 54 and magnet 56, and a thumb wheel 58, which is locked by a cam action exerted by the guard. To calibrate the monitor, the guard is lifted and swings upwards away from the thumb wheel, as shown in FIG. 5 and in phantom in FIG. 7. The open reed switch places the monitor in a calibration mode. After a known glucose standard is placed onto the test area (as in a blood test), the user advances the thumb wheel until the display reaches 200 (the glucose standard value). When this is done, the guard is replaced to close the reed switch and place the monitor back into the test mode, and calibration is complete. The index marker on the narrow gauge on the monitor face also indicates the remaining life of the membrane. At each calibration, as more amplification is required to display an accurate reading, the index marker is repositioned along the gauge. When the index marker reaches the left side, much as a fuel gauge, the membrane must be replaced; and

FIG. 8 is a view of the removable buffer reservoir installed in the monitor case with the lid closed showing the membrane hat assembly and sensor immersed in the buffer fluid 60. The buffer fluid maintains the membrane between uses, furnishes oxygen to the electrochemical reaction, and cleanses the membrane after each test.

Detailed Description of the Specific Embodiment

In FIGS. 1 and 2, the large LCD display is used to show glucose level readings. An index marker on the narrow gauge below the LCD display indicates when to change the membrane. The sensor, mounted on the monitor lid flap, in FIG. 5 is surrounded by a plastic sleeve. As shown in FIG. 6, this sleeve, referred to as a membrane hat assembly, is screwed onto the base of the sensor which positions the membrane material contained near the top of the hat in place against the sensor tip. In use, the buffer reservoir is filled with a buffer fluid which bathes the membrane and sensor when the monitor lid is closed. It is important that all the buffer fluid in the reservoir be substantially free to flow around the membrane surface under the influence of convection, agitation, and natural fluid motion. As a result, the buffer fluid brings sufficient oxygen to the membrane to carry out the current generating chemical reaction and dilutes the effect of contaminants such as cellular byproducts and particulate matter on the membrane and the chemical reaction. In other words, substantially all the buffer fluid in the reservoir is freely available to the membrane to carry out the above-described functions. The term "freely movable buffer fluid" is used in this sense in the claims as distinguished from the buffer fluid in U.S. Patent No. 4,933,066, which is immobilized by a sponge. The sponge is in contact with the membrane in this patent, and therefore impedes the availability of buffer fluid to the membrane, traps contaminants at the surface of the membrane, and occupies part of the space that would otherwise be occupied by the buffer fluid. Reservoir 34 is preferably located in the base of case 10, rather than in lid 22 so the freely moveable buffer fluid does not spill out when the monitor is in use, i.e., when lid 22 is opened. Alternatively, reservoir 34 could be located in the lid of special measures are taken to prevent spillage. The pivot pin in FIGS. 1 and 2 acts as a hinge for the monitor lid assembly which carries the sensor.

In FIGS. 3 and 4, the open monitor lid shows the sensor and membrane hat positioned for a glucose test. It should be noted that the sensor and membrane hat form a pedestal on the lid which presents a prominent blood drop target to facilitate the deposit of the users blood at the proper location. The micro switches which are under the closed lid and below the lid hinge are activated as the lid is opened and activate the monitor display which turns on and displays the reading from the neutral buffer. The system is ready to test when the reading displayed is under 10. The electronic circuitry for driving the display responsive to the electrode current is described in application Serial No. 07/374,535, filed on June 29, 1989, the disclosure of which is incorporated fully herein by reference. In operation, after opening the lid of the monitor to turn the monitor on, the user removes excess buffer fluid from the membrane test area with a tissue, as in FIG.3, before placing a sample of fluid (blood) onto the membrane test surface or well area, as in FIG. 4. The monitor electronics automatically sense a surge in signal when the fluid sample touches the membrane during testing and this surge marks the start of the test timing interval. Twenty (20) seconds later,

the monitor electronics end the test and the final glucose level reading is displayed and held. To complete the test sequence, excess fluid sample (blood) is wiped from the membrane with a tissue and the lid is closed which turns the monitor off. In FIG. 8, the sensor and membrane are immersed in the buffer reservoir where they remain, wet and energized with a small electric charge, until the next test. The membrane receives a replenishment of oxygen from the reservoir fluid in preparation for further testing.

In FIG. 5, the three sets of reed switch and magnet pairs are shown which control the ON and OFF status of the monitor and the test or calibrate mode of the monitor box.

Here also, the replaceable membrane hat assembly is shown lifted from the sensor. The O-ring on the membrane hat assembly brim or base seals the removable buffer reservoir when the monitor lid is closed.

In FIG. 6, the membrane hat assembly is diagrammed which shows the top bezel and conformal mask with a small diameter opening which, with the membrane material as a base, forms a shallow well where the fluid sample is placed for testing. The membrane material is laid across the top of the membrane hat cylinder base, a conformal mask is placed over the membrane material, and the top disk or cap is snapped onto the body or sleeve base. Forcing the cap of the plastic membrane hat assembly down against the domed sensor slightly stretches the membrane upward and positions it firmly against the openings in the conformal mask and the top disk. As the cylinder base is screwed down onto the sensor base, the membrane is stretched, i.e., tensioned uniformly

by the slightly domed sensor tip. When installed on the sensor, the membrane hat assembly positions the membrane material flush against the bottom of the 4 mm diameter hole in the conformal mask and top disc forming a shallow 1 mm well or depression with the membrane as a base and sides formed by the thickness of the conformal mask. As a result, there is uniform contact between the electrode and the membrane.

In FIG. 7, the calibration guard and thumb wheel control are shown. Calibration is performed daily and when the neutral buffer reading is over 10. To calibrate, the guard cover is opened which signals the system to enter the calibration mode. A know glucose standard sample is placed onto the membrane test area as in a regular test. The reading is displayed and the thumb wheel is turned to advance (or reduce) the displayed figure to the known standard value. When the standard value is displayed, calibration is complete and the guard cover is replaced which locks the thumb wheel, and the switch is reset which places the monitor into the test mode.

In FIG. 8, the membrane hat assembly and sensor are shown projecting into the removable buffer reservoir, when the lid is closed. This is the usual position between tests where the buffer fluid cleanses the membrane and introduces fresh oxygen into the membrane.

WHAT IS CLAIMED IS:

1. Apparatus for monitoring glucose level comprising:

a case having a base member and a lid member adapted to cover and uncover the base member;

a reservoir disposed in one of the members;

a polarographic membrane cell and a glucose level sensor mounted in the other member such that the membrane lies in the reservoir when the lid member covers the base member;

a freely movable buffer fluid disposed in the reservoir to wet the membrane when the lid member covers the base member; and means for displaying the sensor reading.

2. The apparatus of claim 1, additionally comprising a hinge for connecting the lid member to the base member to permit the base member to swing open to expose the membrane and the swing closed to cover the reservoir.

3. The apparatus of claim 2, in which the reservoir is removable form the case.

4. The apparatus of claim 3, in which the sensor is disposed in a removable hat having a round base and the reservoir has a round opening into which the hat is adapted to fit such that the round base abuts the reservoir.

5. The apparatus of claim 4, additionally comprising an O-ring seal surrounding the base of the hat to seal the reservoir when the lid member is closed.

6. The apparatus of claim 5, in which the membrane is mounted in the hat and the sensor is mounted on the lid member so the hat fits over the sensor and the sensor supports the membrane.

7. The apparatus of claim 6, in which the hat has a threaded connection to the lid member.

8. The apparatus of claim 7, additionally comprising means for turning off the sensor and the displaying means when the lid member covers the reservoir.

9. The apparatus of claim 1, in which the reservoir is removable from the case.

10. The apparatus of claim 1, in which the sensor is disposed in a removable hat having a round base and the reservoir has a round opening into which the hat is adapted to fit such that the base abuts the reservoir.

11. The apparatus of claim 10, additionally comprising an O-ring seal surrounding the base of the hat to seal the reservoir when the lid member is closed.

12. The apparatus of claim 10, in which the membrane is mounted in the hat and the sensor is mounted on the lid member so the hat fits over the sensor and the sensor supports the membrane.

13. The apparatus of claim 12, in which the hat forms a well around the membrane to hold a test sample of blood.

14. The apparatus of claim 10, in which the hat has a threaded connection to the

lid member.

15. The apparatus of claim 1, additionally comprising means for turning off the sensor and the displaying means when the lid member covers the reservoir.

16. The apparatus of claim 1, in which the displaying means is mounted in the case member.

17. The apparatus of claim 1 in which the reservoir is disposed in the base and the cell and the sensor are mounted in the lid.

18. The apparatus of claim 1, in which the buffer fluid is disposed in the reservoir in the absence of a sponge.

19. The apparatus of claim 1, in which the buffer fluid is in direct exclusive contact with the membrane.

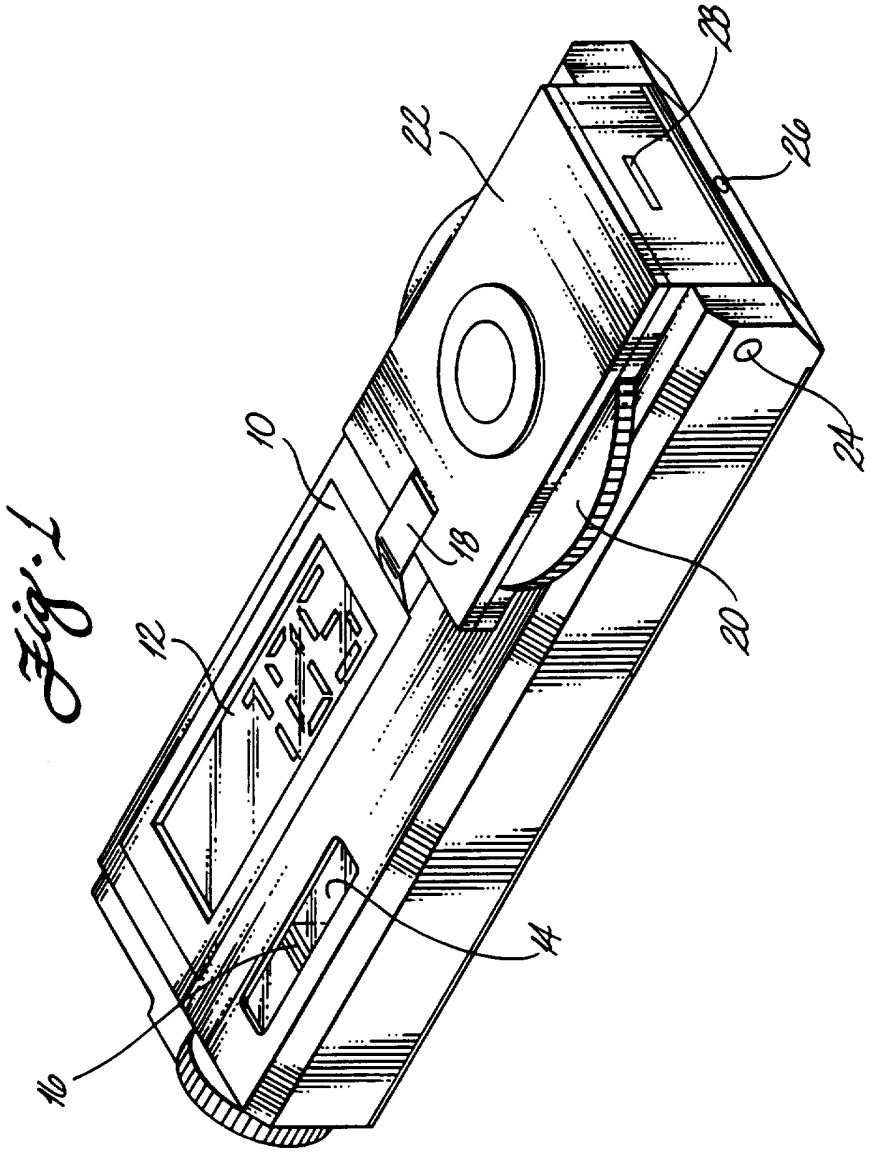


Fig. 1

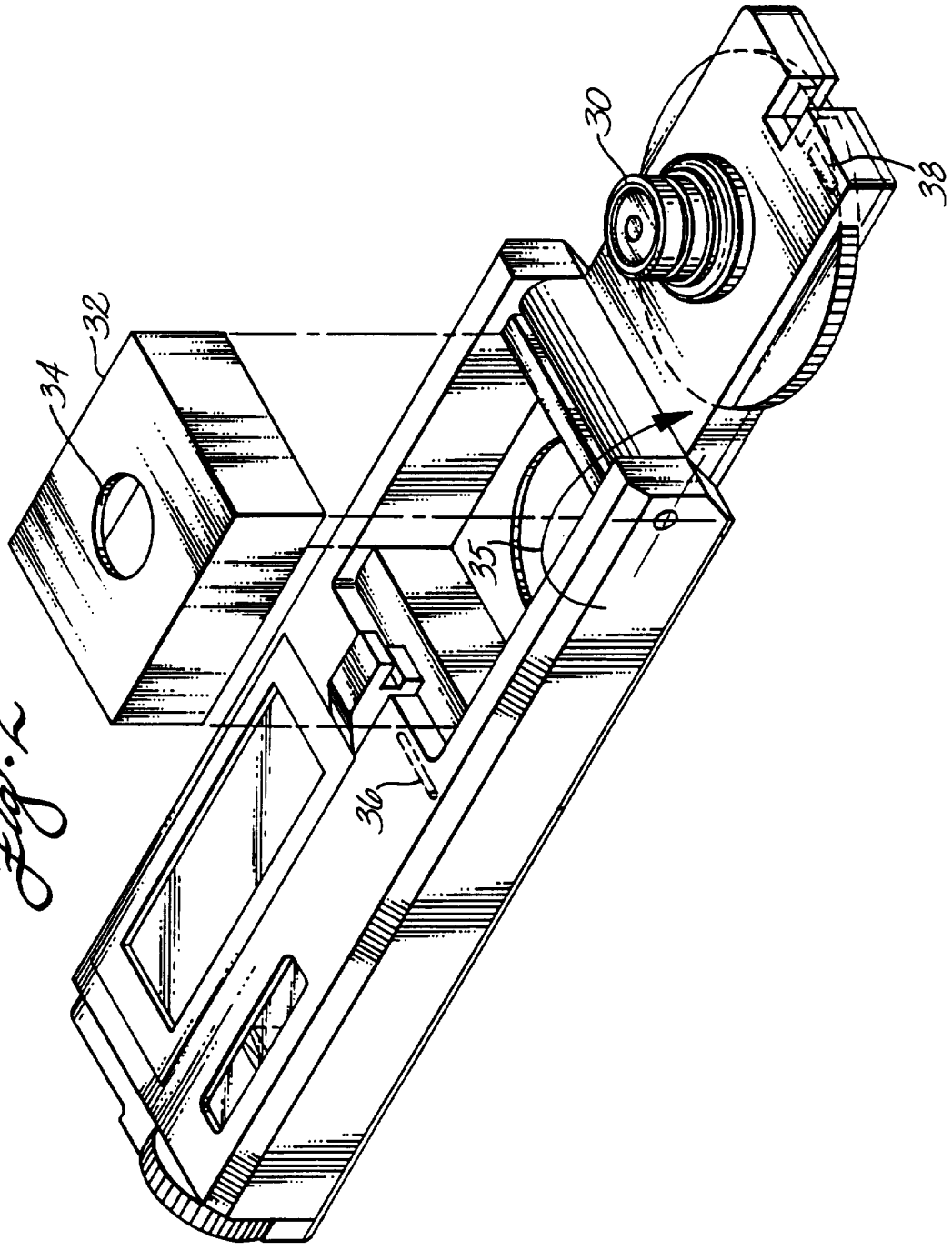


Fig. 2

Fig. 3

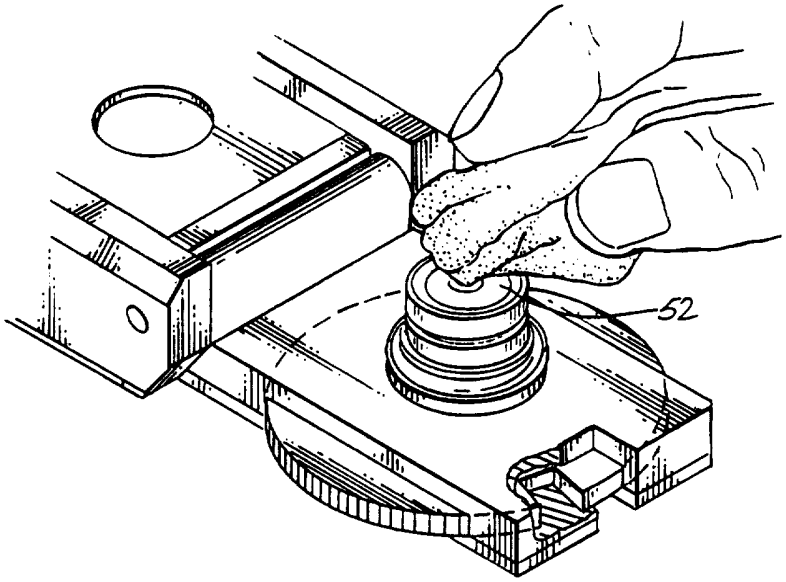
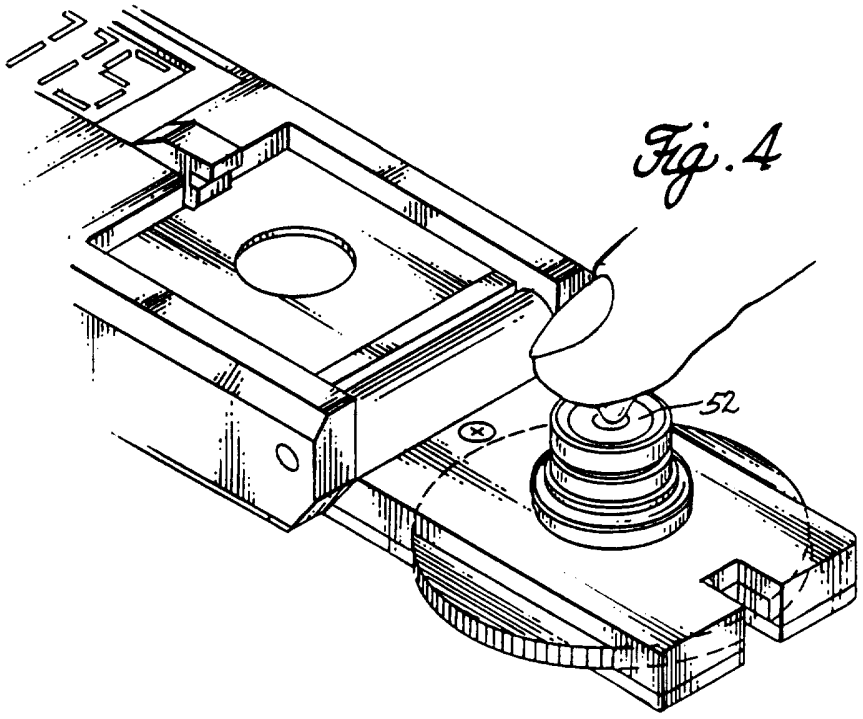


Fig. 4



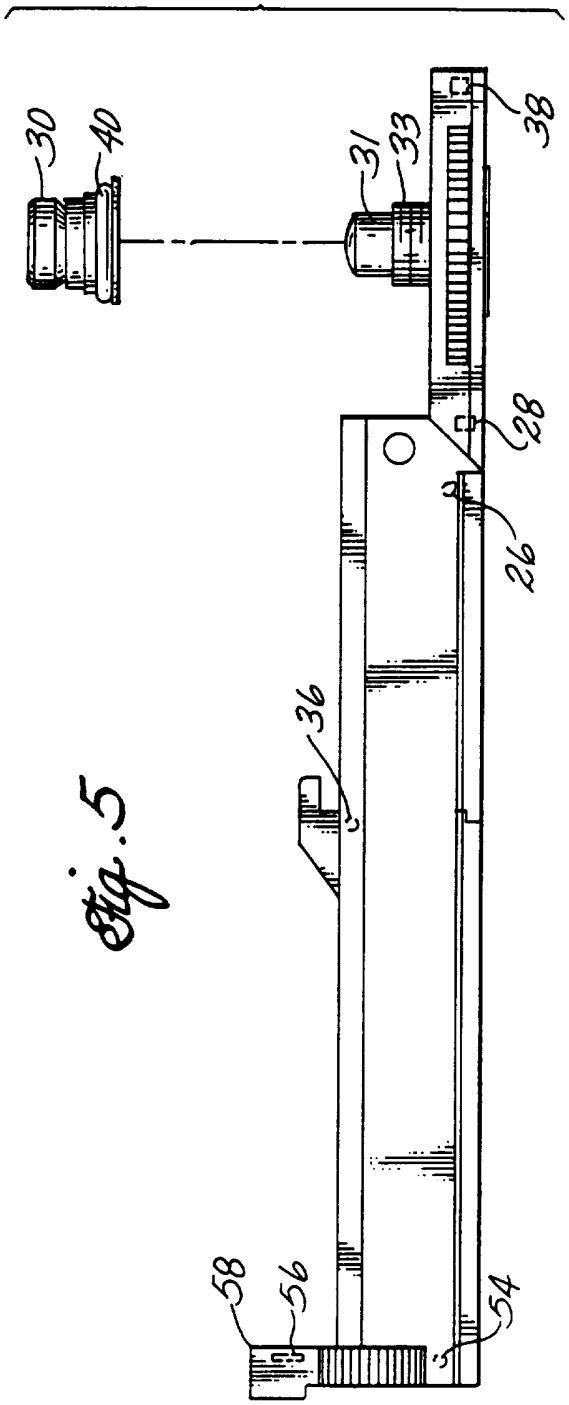
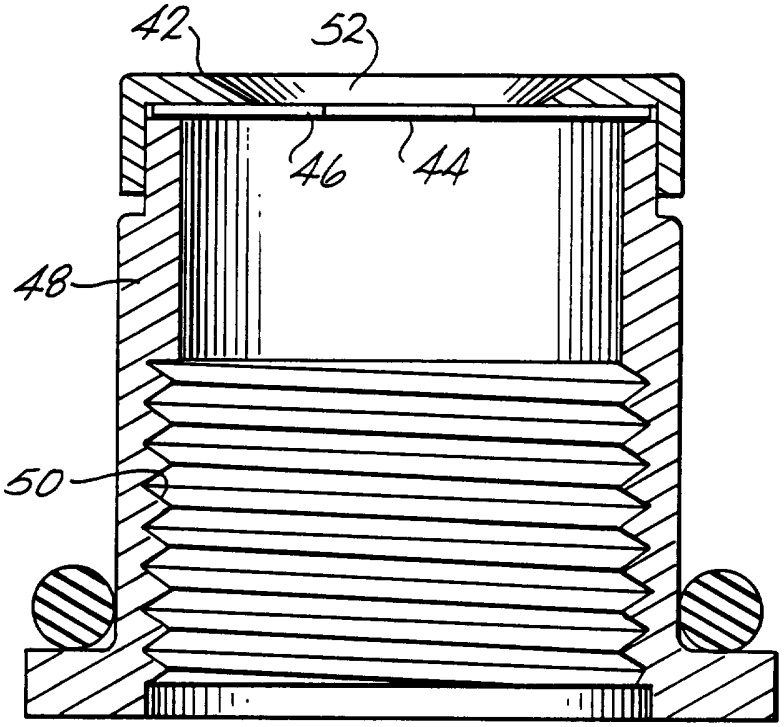


Fig. 5

Fig. 6



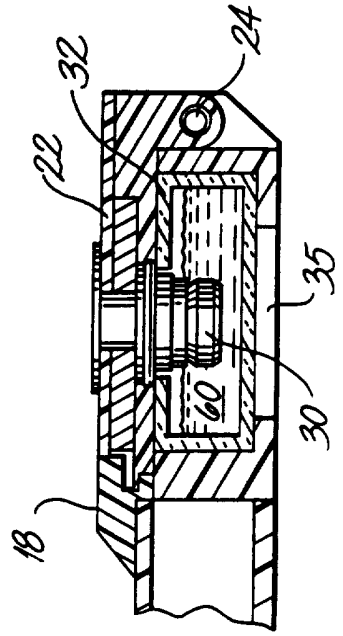


Fig. 8

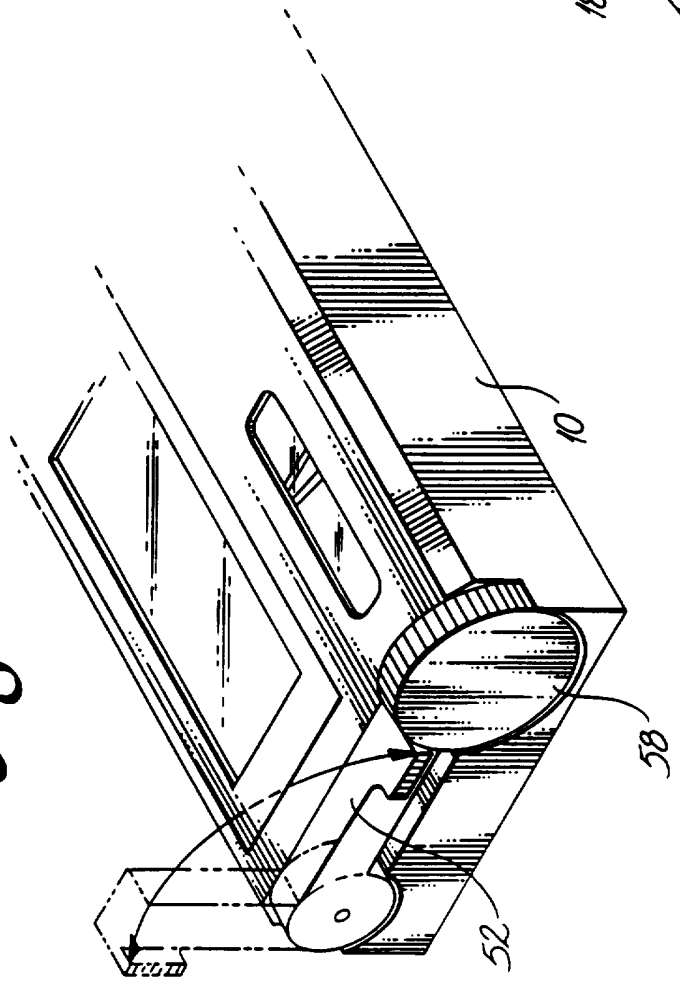


Fig. 7

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US95/03390

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :G01N 27/30; A61B 5/05
US CL :128/635
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. : 128/635, 639, 760, 771; 436/95

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

NONE

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

APS
Search Terms: polarographic, glucose, electrode, remov?, cover, lid

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO, A, 90/00738, (MARKWELL MEDICAL INSTITUTE, INC.), 25 January 1990. See entire document.	1-19
A	US, A, 4,303,076, (DANEK), 01 December 1981. See entire document.	1-19
A	US, A, 4,290,431, (HERBERT ET AL.), 22 September 1981. See entire document.	1-19

☐ 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
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Date of the actual completion of the international search 22 JUNE 1995	Date of mailing of the international search report 05 JUL 1995
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