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Swing Lance with Integrated Sensor

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SWING LANCE WITH INTEGRATED SENSOR

Abstract

An apparatus (10) for lancing skin and collecting a liquid sample. The apparatus (10) having a housing (8) with an outer periphery (23) and a rotatable arm (11) having a lance (12) to puncture the skin. A sample collection area (13) is attached to the arm (11). The arm (11) of the apparatus (10) rotates from a first position to a second position. As the arm (11) rotates, the lance (12) extends beyond the housing (8) allowing the lance (12) to contact the user's skin and create a lance site. As the arm (11) continues to move to the second position, the lance (12) is brought out of contact with the user's skin and back within the housing (8) while the collection area (13) is brought into position. When the arm (11) is located in the second position, the collection area (13) is in substantially the same location as the lance site on the user's skin.

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COMPLETE SPECIFICATION

FOR A STANDARD PATENT

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Invention Title:	Swing Lance with Integrated Sensor

The following statement is a full description of this invention, including the best method of performing it known to me/us:-

SWING LANCE WITH INTEGRATED SENSOR

FIELD OF THE INVENTION

The present invention relates generally to body fluid monitoring devices, and more particularly to a lancing mechanism and body fluid collection system.

BACKGROUND OF THE INVENTION

It is often necessary to obtain a sample of a body fluid and perform an analysis of an analyte in that body fluid. Preferably, the obtaining of body fluid is as painless as possible, and the collection of the sample is as simple as possible. One example of a need to obtain a sample of a body fluid is in connection with a blood glucose monitoring system where a user must frequently use the system to monitor the user's blood glucose level.

Those who have irregular blood glucose concentration levels are medically required to regularly self-monitor their blood glucose concentration level. An irregular blood glucose level can be brought on by a variety of reasons including illness such as diabetes. The purpose of monitoring the blood glucose concentration level is to determine the blood glucose concentration level and then to take corrective action, based upon whether the level is too high or too low, to bring the level back within a normal range. The failure to take corrective action can have serious implications. When blood glucose levels drop too low – a condition known as hypoglycemia – a person can become nervous, shaky, and confused. That person's judgment may become impaired and that person may eventually pass out. A person can also become very ill if his blood glucose level becomes too high – a condition known as hyperglycemia. Both conditions, hypoglycemia and hyperglycemia, are both potentially life-threatening emergencies.

One method of monitoring a person's blood glucose level is with a portable, hand-held blood glucose testing device. The portable nature of these devices enables the users to conveniently test their blood glucose levels wherever they may be. To check the blood glucose level, a drop of blood is obtained from the fingertip using a separate lancing device. The lancing device contains a needle lance to puncture the skin. Once the requisite amount of blood is produced on the fingertip, the blood is harvested using the blood glucose testing device. The blood is drawn inside the testing device, which

then determines the concentration of glucose in the blood. The results of the test are communicated to the user via a display on the testing device.

One problem related with the prior art devices containing a separate lance and sample collection mechanism is that the user must carry both devices with him. The need to carry multiple devices opens the possibility of forgetting or losing one of the devices. If the user forgets to bring both the lance and the testing device with him, he will not be able to test his blood; adverse consequences may result.

Another problem with a monitoring a system comprising a lancing device to lance the skin and a separate collection unit to collect the blood is that there is a greater chance of contaminating the sample. The user must be careful that he does not contaminate the blood drop that forms on the lance site or contaminate the collection device used. If any contamination occurs, the test result may not accurately reflect the level of the glucose present in the tested blood.

A third problem with having a device for lancing and a separate device for collection is the size of the sample needed. Users prefer to make smaller cuts, also referred to as lance sites, on their skin to produce a blood sample. A smaller lance site is usually less painful to make than a larger lance site, and should heal more quickly than a larger lance site. Generally, a smaller lance site will produce a smaller blood sample. The smaller the sample, the more important proper collection of the sample becomes. And a smaller sample requires greater precision in placing the collection device relative to the lance site. If the collection device is not properly positioned relative to the lance site on the user's skin, the requisite amount of sample may not be collected. If the requisite amount of sample is not collected an underfill condition occurs. The results of analyzing an underfill will not accurately reflect the amount of glucose present in the sample, or in the user.

Another problem with current lancing devices is that accidental lancing may occur from the exposed lance. If the lance is exposed it may come into contact with the user's skin in a location that the user did not intend to serve as a lance site. This cut may be painful and limit the available locations for a lance site.

Accordingly, there exists the need of a device that combines lancing capability and collection capability into one instrument. The combination device should be suitable

for lancing skin and aligning the collection device at the lance site, collecting a small sample of blood from a small lance site on the skin, and reducing risk of accidental lance sites being formed from an exposed lance.

SUMMARY OF THE INVENTION

An apparatus for lancing skin and collecting a liquid sample, having a housing with an outer periphery. The apparatus contains a rotatable arm having a lance to puncture the skin and a sample collection chamber attached to the arm. The arm of the apparatus rotates from a first position to a second position. As the arm rotates, the lance extends beyond the housing allowing the lance to contact the user's skin and create a lance site. As the arm continues to move to the second position, the lance is brought out of contact with the user's skin and back within the housing. When the arm is located in the second position, the collection area is in substantially the same location as the lance site on the user's skin.

BRIEF DESCRIPTION OF THE DRAWINGS

Other objects and advantages of the invention will become apparent upon reading the following detailed description in conjunction with the drawings in which:

FIG. 1 is a side view of an apparatus for sampling fluid and showing a housing and a rotatable arm.

FIG. 2 is a side view of the apparatus shown in FIG. 1 with the arm in a first position with the lance in the housing.

FIG. 3 is a side view of the apparatus shown in FIG. 2 as the arm rotates from the first position to a second position with the lance extended and lancing a site.

FIG. 4 is a side view of the apparatus of FIG. 3 with the arm in the second position with the lance in the housing and a collection area positioned at the lance site.

FIG. 5A shows a top view of an alternate embodiment of the present invention in which a sample collection area can be removed from the apparatus.

FIG. 5B illustrates the embodiment of FIG. 5A as a new sample collection area is being loaded into the apparatus.

FIG. 5C illustrates the embodiment of FIG. 5A as the lance is extended beyond the outer periphery of the housing of the apparatus.

FIG. 5D illustrates the embodiment of FIG. 5A with the sample collection area positioned in substantially the same position as the lance site that was made as shown in FIG. 5C.

DETAILED DESCRIPTION OF THE DRAWINGS

As discussed in the background section, the need to obtain a sample of blood and perform an analysis of that sample occurs frequently for persons with various medical conditions. Many people who suffer from conditions such as diabetes must regularly test the level of glucose contained in their blood. One way to perform this test would be with a device that combines the operation of lancing the skin and collecting the sample.

Referring now to FIG. 1, an apparatus 10 for lancing skin and collecting a liquid sample is illustrated. The apparatus 10 has a housing 8 with an outer periphery 23. A movable arm 11 is connected in the housing 8 to swing in a predefined path. Connected to movable arm 11 is a lance 12 and a sample collection area 13. As the arm 11 swings, the lance 12 is sequentially extended beyond the outer periphery 23 and retracted into housing 8.

Referring now to FIG. 2, the arm 11, which comprises the lance 12, and the collection area 13, pivots about point 22 as the arm 11 swings from a first position to a second position. The lance 12 has a sharp penetration end 14 that is capable of lancing a user, thereby creating a lance site on the skin to obtain a liquid sample for analysis. In a preferred embodiment, the lance 12 is a flat surface laying the plane of rotation of the arm 11. The flat surface is useful to stabilize the lance 12 relatively to the arm 11. The collection area 13 is used to collect a liquid sample that forms at the lance site created by the lance 12. The second position of the arm 11 is predetermined to position the collection area 13 at the lance site created as the arm 11 rotates tot he second rotation.

In one embodiment of the current invention, the collection area 13 includes a capillary channel 15 through which the sample moves as it is collected. As the sample moves up the capillary channel 15, displaced air exits from the capillary channel 15 via a

vent hole 17. In the illustrated embodiment, the collection area 13 includes a biosensor 16.

When an electrochemical biosensor is used, the biosensor 16 contains a reagent designed to react with the analyte in the sample and produce a change in current. The change in current is measured across electrodes 18 and 19. Additional detail concerning electrochemical biosensors is found in commonly owned U.S. Patent No. 5,759,364, which is incorporated herein by reference in its entirety. The change in current is measured by a meter coupled to terminals 20 and 21 of traces 18 and 19 coupled to electrodes (not shown) in the capillary.

The collection area 13 may be provided with the biosensor 16 having a reaction area that includes a reagent for producing a reaction with an analyte within the liquid sample 25. The reaction is indicative of the concentration of the analyte within that sample. In the case of a glucose tester, the reagent could be a mixture containing glucose oxidase and potassium ferricyanide. In one embodiment of the current invention, the biosensor is an electrochemical sensor. An optical sensor may also be used to analyze the liquid sample.

Another suitable biosensor is a colorimetric sensor; details of which is described in U.S. Patent No. 5,723,284, which is incorporated herein by reference in its entirety.

To obtain a sample of blood, the user places the apparatus 10 on his skin 24 at a site to lance. In FIG. 2, the apparatus 10 is applied to the skin 24 of the user. The rotatable arm 11 is shown in a first position. Next, the user activates the device by for example, pressing the trigger mechanism on the apparatus 10 (not shown). Pressing the trigger releases a torsion spring (not shown) that forces the arm 11 to rotate from the first position to a second position. The arm 11 is, in the illustrated embodiment, a pendulum that swings through a predefined arc about pivot point 22.

Referring now to FIG. 3, the arm 11 is between the first position and the second position. The penetration end 14 of the lance 12 extends beyond the outer periphery 23 of the housing 8 to cut the skin 24 to a predetermined depth and create a lance site. The lance site on the skin 24 allows a liquid sample 25 (see FIG. 4) to form near the lance site.

Referring now to FIG. 4, the arm 11 rotated to the second position. The second position is a predefined stopping point for the pendulum 11 that positions the collection area 13 over the lance site to collect the sample 25. At the second position, the penetration end 14 of lance 12 is within the housing 8. The collection area 13 is in substantially the same location of the skin 24 at which the penetration end 14 of the lance 12 created the lance site. When the sample collection area 13 is over the lance site in the skin 24, the liquid sample 25 is able to move into the sample collection area 13 via capillary channel 15, or be contacted by other sample structure used instead of the collection area. Figures 1-4 illustrate the collection area 13 spaced apart from the lance 12. In some embodiments, the lance penetration end 14 and collection area 13 are colocated.

A rotating lance, such as for example illustrated in FIGS. 1-4, can be combined with structure for storing a plurality of disposable sensors, in for example a cartridge. Referring now to FIG. 5A a top view of such an apparatus 40 for lancing skin and positioning a disposable sensor to collect a liquid sample. The apparatus 40 has a housing 42 with an outer periphery 44. The apparatus 40 comprises a rotatable arm 46 (or disc 46) having a lance 48 and a nest 50 for receiving a disposable sensor. The housing 42 contains cartridge 52 comprising a stack of disposable sensors. The disc 46 is adapted to rotate three hundred and sixty degrees within the housing 42. In FIG. 5A, the cartridge 52 is sealed against the disc 46 and the lance 48 is stored.

Referring now to FIG. 5B, arm 46 is rotated ninety degrees clockwise from the position shown in FIG. 5A. The nest 50 is located under the cartridge 52 so that a new sensor can be loaded. The sensor is pushed into the nest 50 by spring pressure from within the cartridge 52. The lance 48 is still located within the housing 42 and the lance drive, e.g., a spring, is cocked.

Referring now to FIG. 5C, the disc 46 is rotated ninety degrees clockwise from the position shown in FIG. 5B. The lance 48 is extended beyond the outer periphery 44 of the housing 42 to puncture the skin. A sensor 53 ejected from cartridge 52 is shown on nest 50. The cartridge 52 comprising the stack of disposable sensors has not been moved and is again sealed against the disc 46.

Referring now to FIG. 5D, the movable disc 46 is rotated ninety degrees clockwise from the position shown in FIG. 5C. The lance 48 is stored within the housing 42. The sensor 53 positioned on nest 50 is positioned so that it is in substantially the same location as the lance site created by the lance 48. In this position of the disc 46, sensor 53 collects the liquid sample.

The disc 46 is rotated ninety more degrees clockwise to eject the now used sensor 53 and store the nest 50. The disc 46 is then in the position shown in FIG. 5A.

Further details concerning disposable sensors and device for dispensing sensors is found in U.S. Patent Nos. D456,514; 6,316,264; 5,854,074; 5,810,199; and 5,632,410, all of which are incorporated herein by reference in their entirety.

While the invention is susceptible to various modifications and alternative forms, specific embodiments thereof have been shown by way of example in the drawings herein described in detail. It should be understood, however, that it is not intended to limit the invention to the particular forms disclosed, but on the contrary, the intention is to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the invention as defined by the appended claims.

The claims defining the invention are as follows:

1. An apparatus for lancing skin and collecting a liquid sample comprising:

a housing sized to be handheld and having an outer periphery;

a rotatable arm rotatably positioned in the housing and having an end movable from a from a first predefined position to a second predefined position;

a lance for lancing skin, the lance being movable with the end of the rotatable arm, wherein the lance is fully within the outer periphery of the housing when the end of the rotatable arm is in the first position and the lance extends beyond the outer periphery of the housing as the arm is rotating from the first position to the second position to create a lance site in skin of a user; and

a sample collection area movable with the end of and in general fixed relation to the lance as the arm moves from the first position to the second position, wherein the sample collection area is positioned within an effective range of the lance site to collect liquid from the lance site when the arm is at the second predefined position.

2. The apparatus of Claim 1, wherein the sample collection area overlaps at least a portion of the lance site when the arm is at the second predefined position.

3. The apparatus of Claim 1, wherein the end of the arm moves in an arc from the first position to the second position.

4. The apparatus of Claim 3, wherein the end of the arm moves in a continuous motion from the first position to the second position after being released.

5. The apparatus of Claim 1, wherein the sample collection area comprises a biosensor.

6. The apparatus of Claim 5, wherein the biosensor is an electrochemical biosensor.

7. The apparatus of Claim 5, wherein the biosensor is an optical biosensor.

8. The apparatus of Claim 1, wherein the sample collection area includes a capillary channel for collecting the sample and moving the sample to a reaction area within the collection area, the reaction area having a reagent for producing a reaction with an analyte in the sample indicative of the concentration of the analyte in the sample.

9. The apparatus of Claim 1, wherein the lance comprises a generally flat blade end.

10. The apparatus of Claim 1, wherein the lance lies along the arm and the generally flat blade end extends beyond the end of the arm.

11. The apparatus of Claim 1, wherein the arm comprises a nest at the end of the arm in fixed relation to the lance and a disposable sensor comprising the collection area is positioned in the nest.

12. An apparatus for lancing skin and collecting a liquid sample from a lance site created by the apparatus, wherein the apparatus comprises:

a housing sized to be handheld;

rotatable structure connected to the housing and rotatable from a first stationary position to a second stationary position, wherein the structure comprises:

a lance positioned to be within the housing when the rotatable structure is at the first and second stationary positions and to extend beyond the housing and lance skin as the rotatable structure rotates between the first stationary position and the second stationary position and thereby produce the liquid sample at the lance site, and

collection structure positioned to collect the liquid sample from the lance site when the rotatable structure is positioned at the second stationary position.

13. The apparatus of Claim 12, wherein the collection structure comprises a collection area fixed relative to the lance.

14. The apparatus of Claim 13, wherein the lance comprises a generally flat penetration end extending beyond the rotatable structure, wherein the penetration end extends beyond the housing only as the rotatable structure rotates between the first position and the second position.

15. The apparatus of Claim 12, wherein the collection structure comprises a nest for sensor, the nest being fixed relative to the lance.

16. The apparatus of Claim 15, comprising a cartridge in the housing containing a plurality of disposable sensors, wherein the rotatable structure is rotatable to a third stationary position that positions the nest to receive one of the plurality of disposable sensors when the one disposable sensor is ejected from the cartridge.

17. An apparatus for lancing skin and collecting a liquid sample from a lance site, the apparatus comprising:

a housing sized to be handheld;

a lance supported on a rotatable member and comprising penetration end movable to extend beyond the housing to create the lance site and to withdraw into the housing to avoid inadvertent punctures; and

a collection area supported on the rotatable member to be positioned to collect liquid from the lance site after the lances the skin without moving the housing relative to the lance site.

18. The apparatus of Claim 17, wherein the lance penetration end and the collection area move in an arc that positions the penetration end in the housing when the collection area is positioned to collect liquid from the lance site.

19. The apparatus of Claim 18, wherein the penetration end and the collection area are both within the housing when the lance is cocked.

20. The apparatus of Claim 18, wherein the lance comprises a flat surface in the plane comprising the arc in which the penetration end moves.

21. The apparatus of Claim 20, wherein the rotatable member is adapted to rotate 360° in the plane comprising the arc.

22. A method of collecting a liquid sample with a hand held apparatus, the method comprising:

positioning the handheld apparatus at a site to be lanced;

releasing a lance in the handheld apparatus;

allowing the lance to rotate through an arc that extends the lance from the housing and moves the lance into the housing;

maintaining the handheld apparatus in a generally fixed position relative to the site as a collection area is rotated into a position sufficient close to the site to collect liquid from the site.

23. A method of collecting a blood sample, the method comprising:

rotating a lance through a predefined path relative to a housing supporting the lance;

extending the lance beyond the housing to create a lance site withdrawing the lance into the housing as the lance is rotated through the predefined path;

stopping rotation of the lance at a predetermined point along the predefined path;

positioning the lance within the housing when the lance is stopped at the predetermined point along the path;

coupling movement of a collection area to movement of the lance;

rotating the collection area relative to the housing; and

positioning the collection area sufficiently close to collect blood from the lance site when the lance is positioned at the predetermined along the predefined path, wherein the collection area is rotated to the sufficiently close position to collect blood from the lance site.

24. An apparatus for lancing skin and collecting a liquid sample, said apparatus being substantially as hereinbefore described with reference to Figs. 1 to 4; or Figs. 5A to 5D of the accompanying drawings.

25. A method of collecting a liquid sample with a handheld apparatus, said method being substantially as hereinbefore described with reference to Figs. 1 to 4; or Figs. 5A to 5D of the accompanying drawings.

Dated 14 July, 2004
Bayer Healthcare LLC
Patent Attorneys for the Applicant/Nominated Person
SPRUSON & FERGUSON

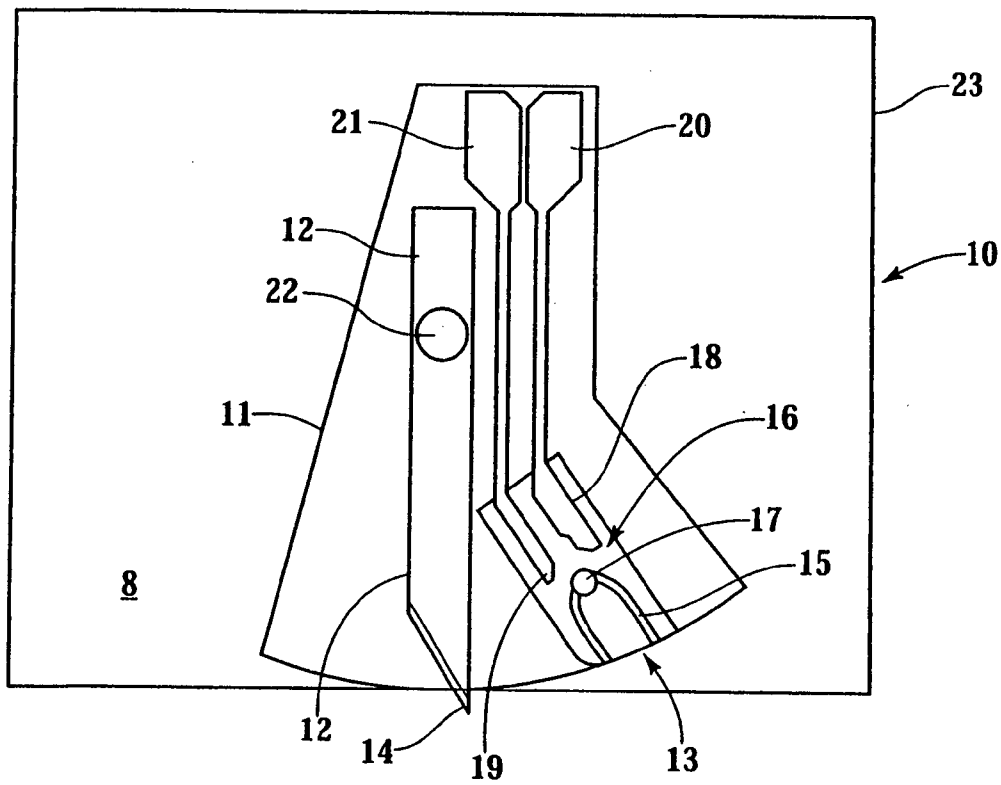
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Fig.1

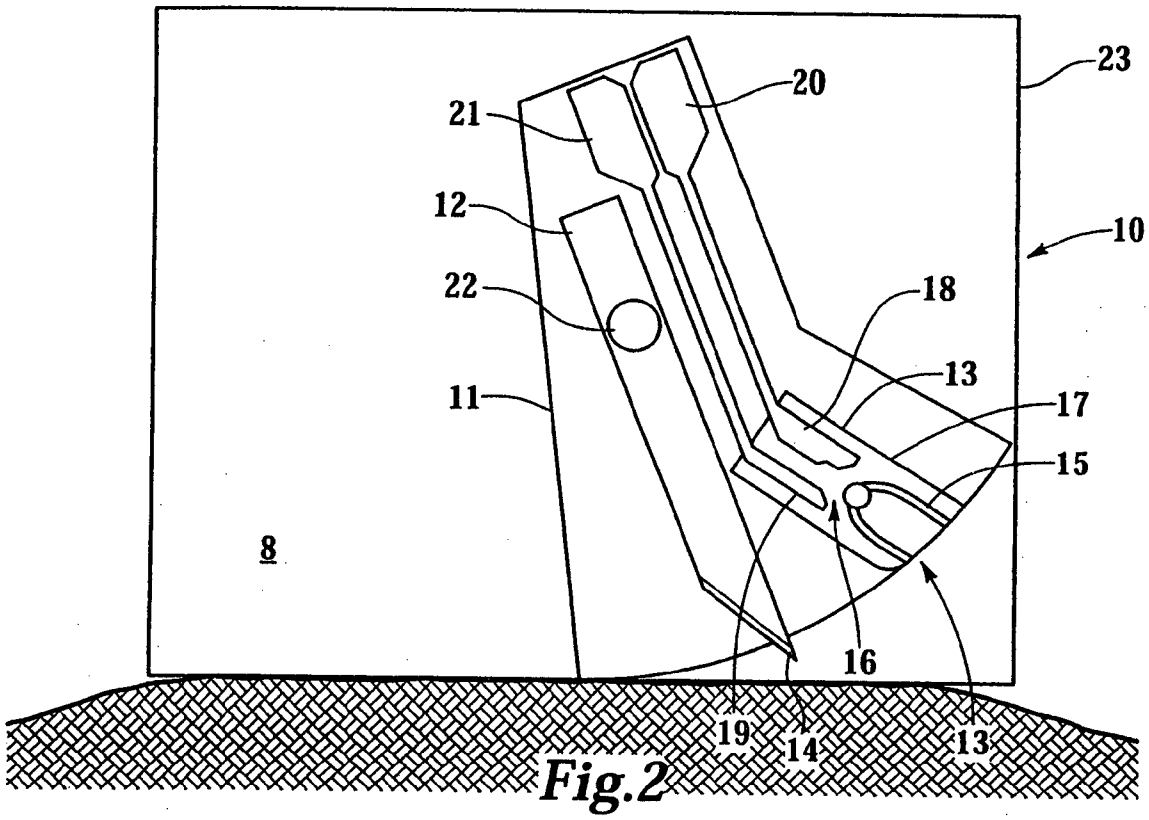
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Fig.2

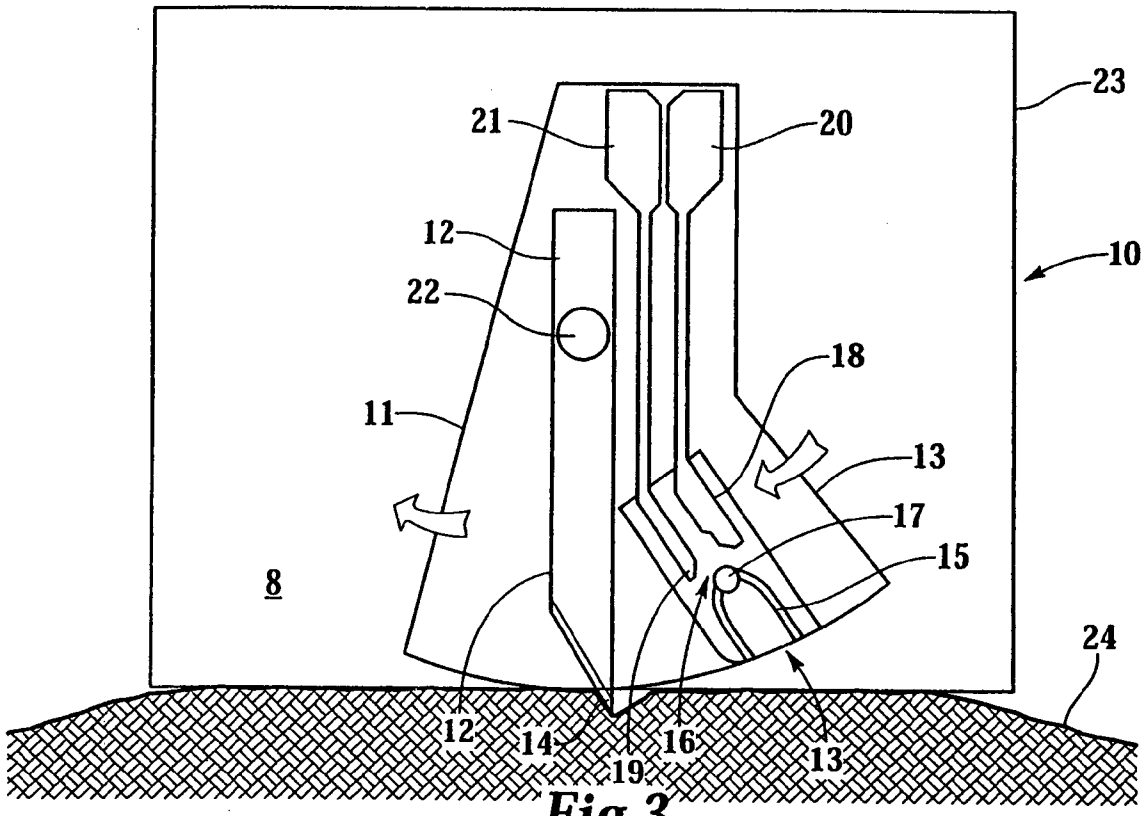
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Fig.3

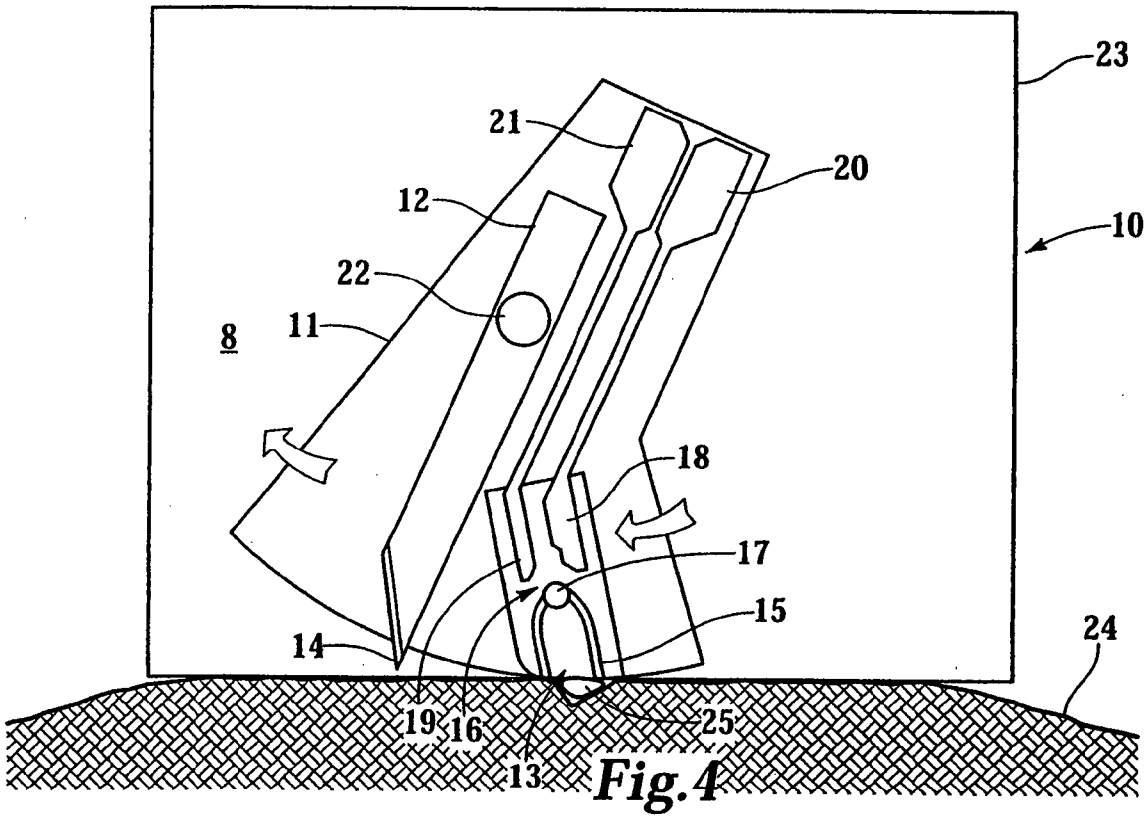
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Fig.4

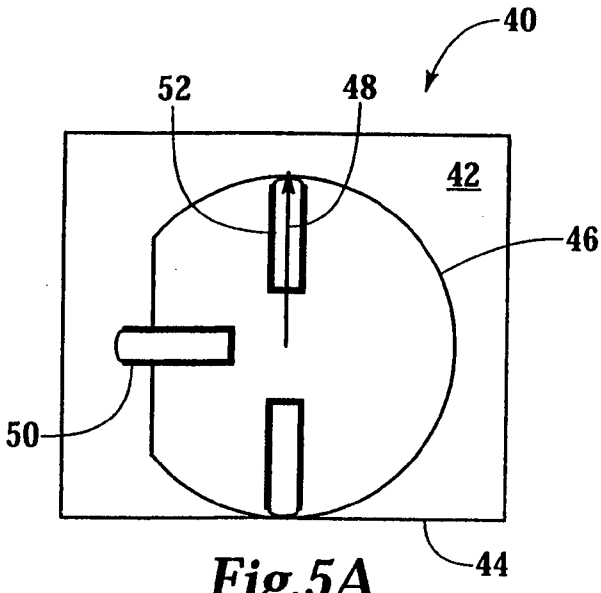

Fig.5A

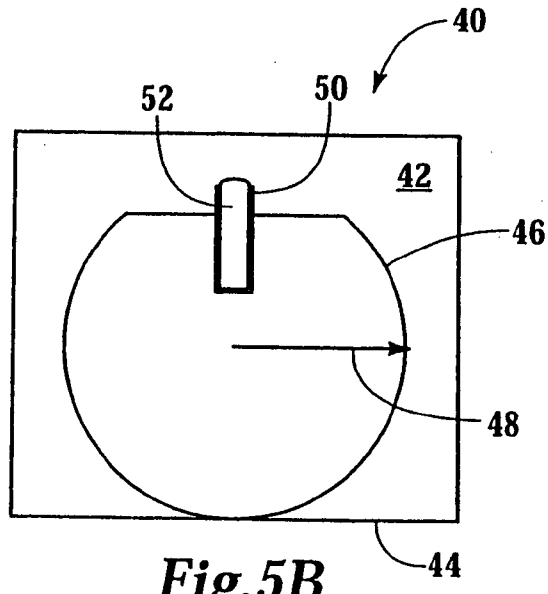

Fig.5B

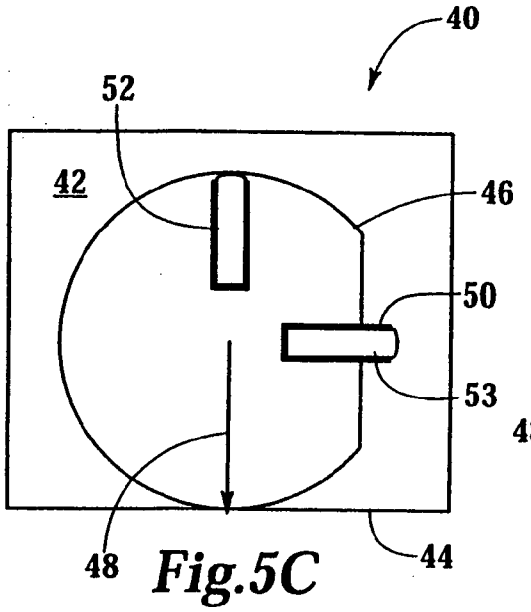

Fig.5C

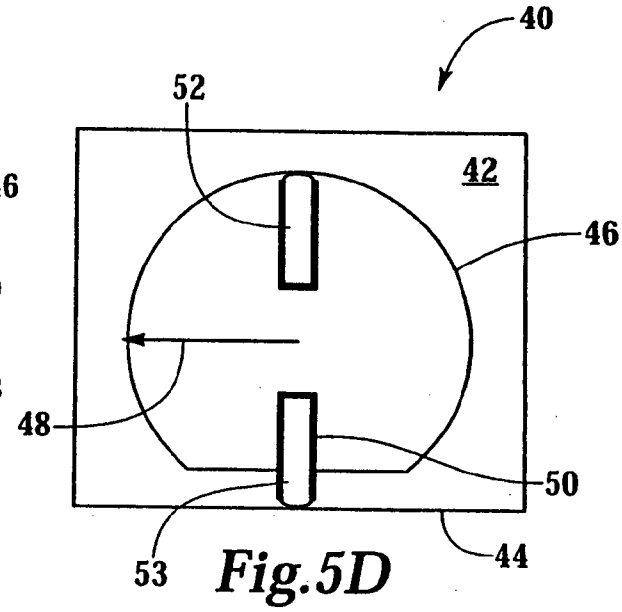

Fig.5D