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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
3 September 2009 (03.09.2009)

PCT

(10) International Publication Number
WO 2009/108676 A2

(51) International Patent Classification:
A61B 5/00 (2006.01)

(21) International Application Number:
PCT/US2009/035101

(22) International Filing Date:
25 February 2009 (25.02.2009)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
12/036,787 25 February 2008 (25.02.2008) US
12/252,041 15 October 2008 (15.10.2008) US

(71) Applicant *(for all designated States except US)*: **GLUCOR SYSTEMS, LLC** [US/US]; 1470 South 360 West, Orem, UT 84058 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **DALEBOUT, Corey** [US/US]; 1947 Letterkenny Dr., Lincoln, CA 95648 (US). **SYBROWSKY, Josh** [US/US]; 2642 Briarton Dr., Lincoln, CA 95648 (US). **JOLLEY, Lincoln** [US/US]; 134 Country Club, Stansbury Park, UT 84074 (US).

(74) Agents: **BALLARD, Michael, M.** et al.; Workman Nydegger, 1000 Eagle Gate Tower, 60 East South Temple, Salt Lake City, UT 84111 (US).

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

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

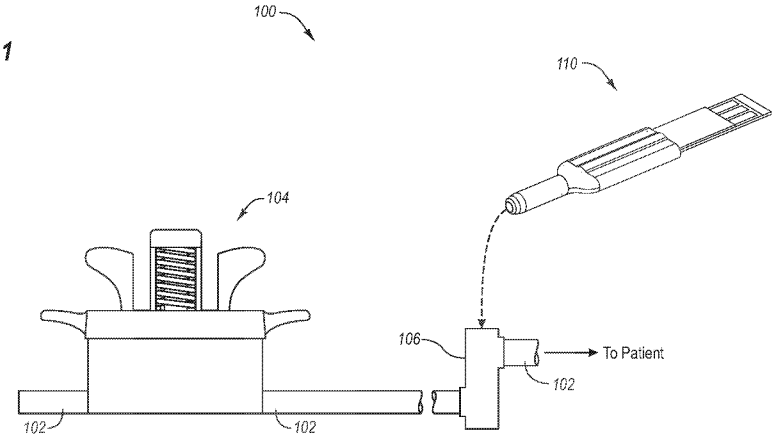
Published:

— *without international search report and to be republished upon receipt of that report (Rule 48.2(g))*

WO 2009/108676 A2

(54) **Title**: SYSTEMS, DEVICES, AND DEVICES FOR SAMPLING BODILY FLUID

Fig. 1



(57) **Abstract**: A fluid sampling system is disclosed comprising a fluid drawing device, a fluid sampling device, and an analysis device. The fluid drawing device can be used to draw bodily fluid into a sample port of an IV tube. The fluid sampling device can be used to access the sample port to obtain a fluid sample. The fluid sampling device can include a test strip housing for receiving a test strip therein. Extending from an end of the test strip housing is a blunt canula that can be inserted into the sample port to obtain the fluid sample and communicate the fluid sample to the test strip. The test strip housing is configured to allow the second end of the test strip to be received within an analysis device to facilitate analysis of the fluid sample.

SYSTEMS, METHODS, AND DEVICES FOR SAMPLING BODILY FLUID

BACKGROUND OF THE INVENTION

1. The Field of the Invention

The invention relates to medical systems, methods, and devices. More specifically, the invention relates to systems, methods, and devices for sampling bodily fluid.

2. Relevant Technology

In some medical procedures, the condition of a patient can require that an intravenous/intra-arterial tube or catheter be inserted into a blood vessel. The patient's blood vessel can be connected by the tube to a source of fluid, such as a medicament. The tube can also be connected to a pressure transducer that senses the pressure within the patient's blood vessel.

In critical care situations, it can be necessary to periodically obtain samples of the patient's bodily fluids, such as blood. For procedures carried out using a needle stick, the likelihood of a healthcare worker being inadvertently stuck can increase, thereby increasing the risk of infection from a contaminated needle. Rather than stick a patient with a needle each time blood must be drawn, blood can be drawn through the tube already connected to the patient's blood vessel. Since the tube connected to the patient's blood vessel can contain fluid other than blood, such as saline solution and medication, it is useful to draw the patient's blood up into the tube to a sample site so that a blood sample can be obtained which is substantially unadulterated by the fluid that is being supplied to patient through the tube. After the substantially unadulterated blood has been drawn up the tube to the sampling site, the blood sample can be accessed through the sampling site and collected into a sample container.

In 2001, a study of 1548 patients was performed to demonstrate the effects of "intensive insulin therapy" on mortality and morbidity. *See* Greet Van den Bergh, et. al., *Intensive Insulin Therapy in Critically Ill Patients*, The New England Journal of Medicine, Vol. 345:1359-1367, No. 19, Nov. 8, 2001. The study showed that patients with tightly controlled blood glucose levels (between 80-110mg/dl) had remarkably

improved outcomes. Overall mortality was decreased by 34%, blood stream infections decreased by 46%, acute renal failure requiring dialysis or hemofiltration decreased by 41%, and the median number of red cell transfusions decreased by 50% as well as requiring less time on the ventilator and fewer days in the ICU.

The medical community has been striving for successful implementation of intensive insulin therapy because of its documented benefits. In order to implement this therapy, patients may have their fingers stuck for glucose readings every hour for days, weeks, and even months. This can cause a significant amount of pain and torment to be inflicted on the patients. Additionally, the costs associated with repeated glucose level monitoring, in both dollars and nursing time, can be considerable.

For example, in a 2006 study of a level 1 trauma center, the time required to measure blood glucose levels and adjust insulin doses accordingly ranged from three to eight minutes, with an average time nearing five minutes. *See* Aragon, *Evaluation of Nursing Work Effort and Perceptions About Blood Glucose Testing in Tight Glycemic Control*, American Journal of Critical Care, Vol. 15:370-377, No. 4, July 2006. Based upon this average time as well as the average compensation for nurses, the study determined that a hospital's annual nursing cost for intensive insulin therapy is about $182,488. The study also found that about 75% of nurses use an arterial catheter to obtain the blood samples while about 25% of nurses used finger sticks to obtain the needed blood samples. Using these proportions and the supply costs for each method, including lancets, syringes, and test strips, the study found that a hospital's annual supply cost for intensive insulin therapy is about $50,670.

In addition to the time and financial costs associated with intensive insulin therapy, the study also found that nurses feel that the current testing methods are difficult and require too much work. As a result some nurses try to keep their patients off intravenous insulin if at all possible, despite the documented benefits. A large majority (86%) of the nurses surveyed indicated that an easier or more automated form of measurement was needed, while 76% indicated that they would be willing to devote an intravenous access for that purpose.

The subject matter claimed herein is not limited to embodiments that solve any disadvantages or that operate only in environments such as those described above.

Rather, this background is only provided to illustrate one exemplary technology area where some embodiments described herein may be practiced.

BRIEF SUMMARY OF THE INVENTION

Example embodiments of the medical system described herein can enable the user more freedom to deal with positional lines, obtain glucose readings and can save time by initiating the testing process. This system can accomplish various significant improvements over the current testing methods while still garnering the significant benefits of intensive insulin therapy and being adaptable for use in nearly all hospitals. One benefit of the present invention is that it can reduce pain and discomfort of patients by reducing repeated finger pricking and venous sticks to obtain lab samples. Further, the present invention can decrease the time necessary for practitioners to ascertain a patient's glucose levels and obtain blood samples for lab use. Another benefit of the present invention is that it can decrease the risk to practitioners and patients by reducing the need for needles used in the transfer of blood from sample ports to test strips, and those used with phlebotomy. Additionally, the present invention can decrease cross contamination risk by utilizing a contained blood sample within the sampling device.

Embodiments of the present invention described herein relate to a fluid sampling system. The fluid sampling system can include a fluid drawing device, a fluid sampling device, and a glucometer to analyze the fluid sample. The fluid drawing device of the fluid sampling system can be used to draw bodily fluid, such as blood, from a patient injection site into an IV tube or catheter. After the fluid has been drawn into the IV tube, the fluid sampling device can be introduced into a sample port of the IV tube to retrieve a sample of the bodily fluid. After a fluid sample has been retrieved, the fluid sample can be analyzed with an analysis device, such as a glucometer, that can be configured to accommodate the test strip and/or the fluid sampling device.

The fluid sampling system of the present invention can provide a safe method of obtaining a sample of bodily fluid from a patient. For instance, the fluid sampling system can reduce the need to use needles each time a blood sample is required, which in turn can reduce the pain and discomfort a patient experiences each time he

or she is pricked. Further, the possibility that a healthcare worker will be pricked with a contaminated needle can be reduced with use of the fluid sampling system. Additionally, the fluid sampling system can be simple to use, thus allowing healthcare workers to focus on other aspect of the patient's treatment.

The fluid sampling device of the fluid sampling system can comprise a first portion having a blunt canula, a platform in fluid communication with the blunt canula, and a first ridge and a second ridge operatively associated with the platform. The first ridge can extend further away from the blunt canula than the second ridge. The fluid sampling device can also include a second portion having a plurality of flanges adapted to engage at least one of the first ridge or the second ridge to couple the second portion to the first portion. Each of the plurality of flanges can include an inwardly projecting ridge adapted to engage at least one of the first ridge or the second ridge. The first portion and the second portion can be adapted to be coupled together with a test strip therebetween. The second portion can be adapted to couple to the first portion in a first position and in a second position relative to the first portion, wherein the second portion is biased toward the second position. The second portion can be in the first position when a test strip is placed between the second portion and the first portion. The second portion can automatically move from the first position to the second position when the test strip is removed from between the first portion and the second portion. The second portion and the first portion can be adapted to remove and retain excess fluid from the test strip when the test strip is removed from between the first portion and the second portion.

The fluid sampling device can further comprise a housing that is adapted to protect the first and second portions from damage and prevent contamination of the blunt canula. The housing can include a substrate that lies adjacent the second portion, a railing extending from the substrate, and a cover coupled to the railing and which extends around at least a portion of the first portion.

In another embodiment, the fluid sampling medical device includes a blunt canula adapted to be inserted into a sample port of an intravenous tube, the blunt canula comprising a lumen extending from a distal end of the blunt canula. The fluid sampling medical device further includes a base portion in fluid communication with the blunt canula, the base portion having an aperture in fluid communication with the

lumen of the blunt canula. The base portion includes a first wall and an opposing wall spaced apart from the first wall. The first wall includes a first ridge and a second ridge spaced apart from the first ridge, wherein the second ridge is positioned closer to the distal end of the blunt canula than the first ridge. The fluid sampling medical device also includes a top portion adapted to be coupled to the base portion, the top portion comprising a first flange and a second opposing flange spaced apart from the first flange. The first flange comprises an inwardly projecting ridge extending from an interior surface of the first flange, wherein the inwardly projecting ridge is adapted to engage at least one of the first ridge or the second ridge of the base portion to couple the top portion to the base portion.

The top portion and the base portion can be adapted to receive a test strip therebetween in an open position, wherein the inwardly projecting ridge engages the second ridge of the base portion. The top portion can be adapted to allow a user to see a portion of the test strip through an aperture of the top portion to determine when a predetermined amount of fluid has been absorbed by the test strip. The top portion can have a recess in a bottom surface thereof and a top surface of the base portion can have at least one groove therein, wherein the recess in the top portion and the at least one groove in the base portion are adapted to remove and retain excess fluid from the test strip when the test strip is removed from between the top portion and the base portion. Furthermore, the top portion can be biased toward a closed position, wherein the inwardly projecting ridge engages the first ridge of the base portion. The base portion can have at least one handle portion.

In another embodiment of the invention, a fluid sampling device adapted to be in fluid communication with a sample port of an intravenous tube comprises a base portion having a blunt canula extending therefrom. The base portion further having a first ridge and a second ridge spaced apart from the first ridge, wherein the second ridge is positioned closer to a distal end of the blunt canula than the first ridge. The fluid sampling device also comprises a top portion adapted to be coupled to the base portion, wherein the top portion comprises a flange having and inwardly projecting ridge extending from an interior surface of the flange. A test strip can be movably placed between the base portion and the top portion, wherein the fluid sampling device is adapted to transfer fluid from the intravenous tube to the test strip through

the blunt canula, wherein the inwardly projecting ridge of the top portion engages the first ridge of the base portion when the test strip is positioned between the base portion and the top portion, and wherein the inwardly projecting ridge of the top portion engages the second ridge of the base portion when the test strip is not positioned between the base portion and the top portion.

The top portion can have at least one recess in a bottom surface thereof and the base portion can have at least one recess in a top surface thereof. The at least one recess of each of the top portion and the base portion cooperate to remove and retain excess fluid from the test strip when the test strip is removed from the fluid sampling device. The base portion of the fluid sampling device can also have an aperture therein that is in fluid communication with the blunt canula and the test strip. The top portion of the fluid sampling device can have an aperture therein adapted to allow a user to determine when a predetermined amount of fluid has been collected on the test strip. The fluid sampling device can be in a first position when the inwardly projecting ridge of the top portion engages the first ridge of the base portion and the fluid sampling device can be in a second position when the inwardly projecting ridge of the top portion engages the second ridge of the base portion, and wherein the fluid sampling device is biased toward the second position.

In yet another embodiment of the present invention, a fluid sampling device comprises a blunt canula with a lumen extending therethrough, a platform in fluid communication with the lumen of the blunt canula, the platform comprising a mounting portion having opposing retaining walls, and a fluid monitoring device coupled to the mounting portion of the platform, the fluid monitoring device being in fluid communication with the lumen of the blunt canula. The platform further comprises an aperture and a groove adjacent the aperture, the aperture being in fluid communication with the lumen of the blunt canula. The fluid monitoring device comprises a test strip having electrical connections to facilitate analysis of a fluid sample received by the fluid sampling device. The fluid monitoring device can be coupled to the mounting portion of the platform with at least one of an adhesive and a mechanical fastener. The fluid monitoring device can be integrally formed with the platform.

A fluid sampling device according to the present invention can comprise a blunt canula having a lumen extending therethrough, the blunt canula being adapted for insertion into a sample port of a central line, a base portion in fluid communication with the blunt canula, the base portion comprising a mounting portion and an aperture, each of the mounting portion and the aperture being in fluid communication with the lumen of the blunt canula, and means for detecting properties of a fluid sample coupled to the base portion at least partly within the mounting portion, the means for detecting being in fluid communication with the lumen of the blunt canula. The base portion can comprise a handle portion having an alignment member to facilitate alignment of the blunt canula with the sample port of the central line. The means for detecting properties of a fluid sample can comprise a test strip. The mounting portion can comprise opposing side walls and an end wall, the opposing side walls and the end wall being arranged to correspond to the shape of the test strip. The fluid sampling device can further comprise a top portion adapted to be coupled to the base portion with the test strip disposed therebetween, the base portion having a retention wall to assist in maintaining the test strip in a desired position. The test strip can comprise a vent and the mounting portion can comprise a groove, wherein the vent and the groove cooperate to remove excess air from the test strip. Additionally, the blunt canula can comprise a valve.

In still a further embodiment of the present invention, a medical device comprises a fluid sampling device adapted to be in fluid communication with a sample port of an intravenous tube. The fluid sampling device comprises a test strip adapted to receive a fluid sample, a test strip receptacle having an interior portion adapted to receive at least a portion of the test strip therein, and a blunt canula extending from an end of the test strip receptacle, the blunt canula having a lumen extending therethrough, the lumen being in fluid communication with the interior portion of the test strip receptacle and the test strip. The test strip receptacle further comprises a groove adapted to assist in venting air from the test strip to enable the test strip to ready absorb a fluid sample. A longitudinal axis of the blunt canula can be generally parallel to a longitudinal axis of the test strip receptacle. The test strip can be coupled within the interior portion of the test strip receptacle with an adhesive.

In a further embodiment of the present invention, a test strip adapter is configured to convey a fluid sample from a sample port associated with a patient's blood stream directly to a test strip associated with the test strip adapter. The test strip adapter comprises a test strip housing adapted to receive a portion of the test strip therein, the size and shape of the test strip housing generally corresponding to the size and shape of the test strip portion received within the test strip housing. A blunt canula extends from the test strip housing, the blunt canula having a lumen extending therethrough, the lumen and the test strip housing being in fluid communication with one another to enable a fluid to flow therethrough to communicate a fluid to the test strip. The test strip adapter can further comprise means for venting air from the test strip housing. The means for venting air can comprise a groove disposed within an interior wall of the test strip housing. The groove can comprise an abutment portion that facilitates proper positioning of a test strip within the test strip housing. The means for venting air can also comprise a plurality of grooves disposed within one or more interior walls of the test strip housing. The blunt canula can be adapted to be received within a sample port to retrieve a fluid sample therefrom.

In an alternative embodiment of a test strip adapter configured to convey a fluid sample from a sample port associated with a patient's blood stream directly to a test strip associated with the test strip adapter, the test strip adapter comprises means for holding a test strip, wherein the means for holding substantially encloses a first end of the test strip therein while allowing a second end of the test strip to extend out of the means for holding a test strip, thereby exposing the second end, wherein the second end of said test strip is adapted to be inserted into an analysis device. The adapter can also include means for accessing an interior of a sample port, and means for communicating a fluid to the test strip, wherein the means for communicating extends from the means for holding.

The means for holding a test strip can comprise a plurality of grooves. The means for holding can comprise a test strip housing having an interior portion configured to receive a portion of the test strip therein, wherein the interior portion is sized and shaped to generally corresponding to the size and shape of the test strip portion received within the interior portion of the test strip housing. The means for accessing an interior of a sample port comprises a blunt canula. The means for

communicating a fluid comprises a lumen extending through the means for accessing. The lumen is in fluid communication with the means for holding a test strip.

In another embodiment, a fluid sampling device configured to obtain a fluid sample from a sample port associated with a patient and directly convey information about the fluid sample to an analysis device associated with the fluid sampling device comprises a test strip adapted to receive a fluid sample and convey at least one property of the fluid sample to the analysis device, and a test strip adapter configured to receive a first portion of the test strip therein while allowing a second portion of the test strip to extend out of the test strip adapter for association with the analysis device, the test strip adapter being configured to transfer a fluid sample directly from the sample port to the test strip, the test strip adapter comprising means for venting air from the test strip adapter.

The test strip comprises electrical leads, an absorbent material, a reagent, or a combination thereof. The test strip adapter comprises means for conveying a fluid from a sample port to the test strip. The means for conveying comprises a blunt canula. The blunt canula comprises a lumen extending therethrough. The means for conveying further comprises a tapered portion extending from the blunt canula, the tapered portion having an interior through which a fluid can pass. The test strip adapter comprises a test strip housing having a test strip receptacle for receiving the first portion of the test strip therein. The test strip is secured within the test strip receptacle. The test strip is selectively removable from within the test strip receptacle. The test strip adapter is configured to be inserted into the sample port to access a fluid supply, and wherein the test strip adapter is configured to convey a fluid from the sample port to the test strip while the test strip adapter is inserted in the sample port.

In an alternative embodiment, a fluid sampling device configured to obtain a fluid sample from a sample port associated with a patient and directly convey information about the fluid sample to an analysis device associated with the fluid sampling device comprises means for detecting at least one property of the fluid sample, means for conveying the at least one property to the analysis device, and means for communicating a fluid sample directly from the sample port to the means

for detecting while the means for communicating is simultaneously associated with the sample port and the means for detecting.

The means for detecting comprises electrical leads, an absorbent material, a reagent, or a combination thereof. The electrical leads are adapted to detect a resistance, impedance, or capacitance of the fluid sample. The means for conveying comprises electrical leads adapted to communicate the at least one property of the fluid sample to the analysis device. The means for detecting are at least partially disposed within a housing. The means for detecting and means for conveying comprise the same means. The means for communicating comprises a lumen extending through a blunt canula. The means for detecting can be selectively associated with the means for communicating.

In one embodiment of a fluid sampling system configured to receive a fluid sample from a patient and directly convey information about the fluid sample to an analysis device, the fluid sampling system comprises an intravenous tube in fluid communication with a patient's blood stream, the intravenous tube comprising a sample port; a test strip adapted to i) detect at least one property of a fluid sample received by the test strip, and ii) convey the at least one property of the fluid sample to the analysis device; and a test strip adapter associated with the test strip, the test strip adapter being configured to transfer the fluid sample from the sample port directly to the test strip while the test strip is associated with the test strip adapter and the test strip adapter is associated with the sample port. The test strip adapter can comprise a test strip housing having a first end and a second end, the first end of the test strip housing being adapted to receive a first end of the test strip therein, wherein the size and shape of the first end of the test strip housing generally corresponds to the size and shape of the first end of the test strip; and a blunt canula extending from the second end of the test strip housing, the blunt canula having a lumen extending therethrough for communicating fluid from the sample port to the first end of the test strip. The test strip housing further comprises a groove adapted to assist in venting air from the test strip to enable the test strip to ready receive the fluid sample. A longitudinal axis of the blunt canula is generally parallel to a longitudinal axis of the test strip housing.

The fluid sampling system can further comprise a fluid drawing device associated with the intravenous tube, the fluid drawing device being adapted to draw a fluid from a patient to the sample port. The fluid drawing device is adapted to create a negative pressure within the intravenous tube to draw the fluid from the patient.

The fluid sampling system can further comprise an analysis device for analyzing the at least one property of the fluid sample, wherein the analysis device is adapted to receive the second end of the test strip while the first end of the test strip is positioned within the test strip housing. The analysis device comprises a glucometer. The analysis device is adapted to analyze at least one of a resistance, an impedance, a capacitance, a luminescence, or a color change of the fluid sample.

In another embodiment, a fluid sampling system configured to receive a fluid sample from a patient and directly convey information about the fluid sample to an analysis device comprises an intravenous tube in fluid communication with a patient's blood stream, the intravenous tube comprising a sample port; a test strip adapted to detect at least one property of a fluid sample obtained through the sample port and convey the at least one property to the analysis device; and a test strip adapter having a first end and a second end, the first end being configured to receive a first portion of the test strip therein while allowing a second portion of the test strip to extend out of the test strip adapter, the second end of the test strip adapter being configured to be inserted into the sample port, the test strip adapter being configured to communicate a fluid sample from the sample port directly to the test strip while the first portion of the test strip is within the first end of the test strip adapter and the second end of the test strip adapter is inserted with the sample port, and an analysis device configured to receive the second portion of the test therein while the first portion of the test strip is within the first end of the test strip adapter, wherein the analysis device is adapted to analyze the at least one detected property of the fluid sample.

The test strip adapter of the fluid sampling system can comprise a test strip housing being adapted to receive the first portion of the test strip therein; and a blunt canula extending from the second end of the test strip housing, the blunt canula having a lumen extending therethrough for communicating fluid from the sample port to the test strip. The test strip is adapted to be simultaneously inserted within the analysis device and the test strip adapter, and wherein the second end of the test strip

adapter is adapted to be inserted within the sample port while the test strip is simultaneously inserted within the analysis device and the test strip adapter.

This Summary is provided to introduce a selection of concepts in a simplified form that are further described below in the Detailed Description. This Summary is not intended to identify key features or essential features of the claimed subject matter, nor is it intended to be used as an aid in determining the scope of the claimed subject matter.

Additional features and advantages will be set forth in the description which follows, and in part will be obvious from the description, or may be learned by the practice of the teachings herein. Features and advantages of the invention may be realized and obtained by means of the instruments and combinations particularly pointed out in the appended claims. Features of the present invention will become more fully apparent from the following description and appended claims, or may be learned by the practice of the invention as set forth hereinafter.

BRIEF DESCRIPTION OF THE DRAWINGS

To further clarify the above and other advantages and features of the present invention, a more particular description of the invention will be rendered by reference to specific embodiments thereof which are illustrated in the appended drawings. It is appreciated that these drawings depict only typical embodiments of the invention and are therefore not to be considered limiting of its scope. The invention will be described and explained with additional specificity and detail through the use of the accompanying drawings in which:

Figure 1 illustrates a fluid sampling system according to one embodiment of the present invention;

Figure 2 illustrates a perspective view of a fluid sampling device according to an exemplary embodiment of the present invention;

Figure 3 illustrates an end perspective view of a test strip housing portion of the fluid sampling device of Figure 2;

Figure 4 illustrates an exemplary fluid sampling device according to the present invention associated with a glucometer for analyzing a fluid sample obtained with the fluid sampling device;

Figure 5A illustrates a perspective view of another embodiment of the fluid sampling device of the present invention, the fluid sampling device being associated with a glucometer;

Figure 5B illustrates a perspective view of yet another embodiment of the fluid sampling device of the present invention, the fluid sampling device being associated with a glucometer;

Figure 6A illustrates a perspective view of the fluid sampling device of Figure 2 associated with a glucometer having a receptacle for receiving the fluid sampling device and an ejector for removing the fluid sampling device;

Figure 6B illustrates an end view of the glucometer of Figure 6A;

Figure 6C illustrates a perspective view of the glucometer of Figure 6A ejecting a fluid sampling device therefrom;

Figure 7A illustrates a top view of another fluid sampling device according to one embodiment of the present invention;

Figure 7B illustrates a side view of the fluid sampling device of Figure 7A;

Figure 8A illustrates a top view of an alternative embodiment of a fluid sampling device according to the present invention;

Figure 8B illustrates a bottom view of the alternative embodiment of the fluid sampling device of Figure 8A;

Figure 8C illustrates a cross-sectional view of the alternative embodiment of the fluid sampling device of Figure 8A;

Figure 8D illustrates a cross-sectional side view of the alternative embodiment of the fluid sampling device of Figure 8A;

Figure 9 illustrates a modified glucometer according to one embodiment of the present invention with the fluid sampling device of Figure 7A being associated therewith;

Figure 10 illustrates a cross-sectional side view of another alternative embodiment of a fluid sampling device according to the present invention;

Figure 11 illustrates a perspective view of a fluid sampling device according to yet another embodiment of the present invention;

Figure 12A illustrates an end view of the top portion of the fluid sampling device of Figure 11;

Figure 12B illustrates a side view of the top portion of the fluid sampling device of Figure 11;

Figure 12C illustrates a bottom view of the top portion of the fluid sampling device of Figure 11;

Figure 13A illustrates an end view of the base portion of the fluid sampling device of Figure 11;

Figure 13B illustrates a side view of the base portion of the fluid sampling device of Figure 11;

Figure 13C illustrates a top view of the base portion of the fluid sampling device of Figure 11;

Figure 14 illustrates a cross-sectional end view of the fluid sampling device of Figure 11;

Figure 15 illustrates a perspective view of a fluid sampling device according to a further embodiment of the present invention;

Figure 16A illustrates a side view of the base portion of the fluid sampling device of Figure 15;

Figure 16B illustrates a top view of the base portion of the fluid sampling device of Figure 15;

Figure 17 illustrates a perspective view of a fluid sampling device according to still yet another embodiment of the present invention;

Figure 18 illustrates a perspective view of the base portion of the fluid sampling device of Figure 17;

Figure 19 illustrates a perspective view of a fluid sampling device according to another alternative embodiment of the present invention;

Figure 20A illustrates a top perspective view of the base portion of the fluid sampling device of Figure 19;

Figure 20B illustrates a bottom perspective view of the base portion of the fluid sampling device of Figure 19;

Figure 21A illustrates a top perspective view of the test strip of the fluid sampling device of Figure 19;

Figure 21B illustrates a bottom perspective view of the test strip of the fluid sampling device of Figure 19;

Figure 22 illustrates exemplary fluid sampling devices according to the present invention associated with a glucometer;

Figure 23A illustrates a perspective view of a fluid sampling device according to one embodiment of the present invention disposed within a protective packaging; and

Figure 23B illustrates a partial cross-sectional view of the protective packaging of Figure 23A.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Embodiments of the present invention described herein relate to a fluid sampling system. The fluid sampling system can include a fluid drawing device, a fluid sampling device, and a glucometer to analyze the fluid sample. Other standard medical equipment used in conjunction with these elements can include a pressure transducer, an IV stand, a pressure bag, saline solution, IV tubing, and a vascular access, such as an IV, Arterial Line, or a Central Venous Line, for example.

The fluid drawing device of the fluid sampling system can be used to draw bodily fluid, such as blood, from a patient injection site into an IV tube or catheter. After the fluid has been drawn into the IV tube, the fluid sampling device can be introduced into a sample port of the IV tube to retrieve a sample of the bodily fluid. After a fluid sample has been retrieved, the fluid sample can be analyzed with an analysis device, such as a glucometer, that can be configured to accommodate the test strip and/or the fluid sampling device.

The fluid sampling system of the present invention can provide a safe method of obtaining a sample of bodily fluid from a patient. For instance, the fluid sampling system can reduce the need to use needles each time a blood sample is required, which in turn can reduce the pain and discomfort a patient experiences each time he or she is pricked. Further, the possibility that a healthcare worker will be pricked with a contaminated needle can be reduced with the use of the fluid sampling system. Additionally, the fluid sampling system can be simple to use, thus allowing healthcare workers to focus on other aspect of the patient's treatment.

In the disclosure, reference is made to the use of a test strip with a fluid sampling device. As used in the disclosure and the claims, a test strip can be any

device capable of detecting attributes of a fluid sample. By way of non-limiting example, a test strip can comprise a substrate with an absorbent material and a reagent disposed thereon. Alternatively, a test strip can comprise electrical leads or connections which can communicate various properties of a fluid sample to an analysis device, such as a glucometer. It will be appreciated that a test strip can also comprise a combination of any one or more of a reagent, an absorbent material, and electrical connections. While reference to specific types of test strips is made herein, it will be appreciated that the specific test strips referred to are provided merely as examples and it is contemplated that the present invention can be utilized or adapted for use with other types of test strips not specifically referred to herein. For example, a test strip having an absorbent material and/or a reagent can be replaced with a test strip having electrical connections.

In the disclosure, reference is also made to IV tubes used with the fluid sampling system. As used in the disclosure and claims, an IV tube can include, but is not limited to, a central line, a PICC line, a feeding tube, a drain tube, or nearly any type of fluid pathway or catheter, including urinary, pulmonary artery, or cardiac catheters.

In one example embodiment, an IV tube is connected to a pressure bag (or a pressure transducer) at one end thereof, while the other end of the IV tube is in fluid communication with a patient injection site. A fluid drawing device can be connected to the IV tube between the pressure bag and the patient such that fluid flowing through the IV tube also flows through the fluid drawing device or is otherwise in fluid communication with the fluid drawing device. In addition, the IV tube also includes a sample port between the fluid drawing device and the patient. The fluid sampling device can be inserted into the sample port in order to take a sample of the fluid in the IV tube.

When the fluid sampling system is configured as described above, a user, such as a doctor or nurse, can take a sample of a patient's bodily fluid, such as blood, by activating the fluid drawing device, which draws the bodily fluid into the IV tube past the sample port. The user can then insert the fluid sampling device into the sample port to retrieve a sample of the bodily fluid. When a sufficient fluid sample has been retrieved, the fluid sampling device can be removed from the sample port. The fluid

sampling device can be configured to have a test strip disposed therein. When the bodily fluid enters the fluid sampling device from the sample port, the bodily fluid can be absorbed by or come into contact with the test strip. The sample of bodily fluid can then be analyzed by an analysis device, such as a glucometer.

As seen in Figure 1, an exemplary embodiment of the fluid sampling system 100 can include an IV tube 102, a fluid drawing device 104, a sample port 106, and a fluid sampling device 110. Fluid drawing device 104 is in fluid communication with IV tube 102 so that fluid drawing device 104 can draw fluid from a patient through IV tube 102 past sample port 106. After fluid drawing device 104 has drawn fluid past sample port 106, fluid sampling device 110 can be introduced into sample port 106 to obtain a fluid sample, as illustrated by the dotted lines shown in Figure 1.

Figure 1 illustrates an exemplary embodiment of a fluid drawing device 104, details of which are disclosed in U.S. Patent Publication No. 2008/0255473, entitled SYSTEMS, METHODS, AND DEVICES FOR SAMPLING BODILY FLUID, which is incorporated herein by reference. It will be appreciated, however, that any device capable of drawing fluid through IV tube 102 past sample port 106 may be used in place of the illustrated fluid drawing device 104. For example, a syringe connected to IV tube 102 can be used to draw fluid from a patient into IV tube 102. Similarly, a VAMP® system made by Edwards Lifesciences Corporation can be used to draw fluid from a patient into IV tube 102.

In use, fluid drawing device 104 is connected to IV tube 102 such that fluid drawing device 104, when activated, is able to draw a patient's bodily fluid through IV tube 102 past sample port 106. The drawing of fluid through IV tube 102 can be accomplished in a variety of ways. In one implementation, activation of fluid drawing device 104 creates a negative pressure within IV tube 102. The negative pressure is sufficient to draw the fluid, such as blood, from a patient into IV tube 102 and past sample port 106. After the bodily fluid has been drawn past sample port 106, the user can then insert fluid sampling device 110 into sample port 106 to retrieve the desired fluid sample.

Figures 2 and 3 illustrate perspective views of an embodiment of fluid sampling device 110. Fluid sampling device 110 comprises a test strip 112 and a test strip adapter 114. Test strip adapter 114 includes a blunt canula 116 and a test strip

housing 118. As illustrated in Figures 2 and 3, test strip housing 118 has a generally flat, rectangular shape with a test strip receptacle 120. Test strip receptacle 120 is adapted to receive an end of test strip 112 therein. In the illustrated embodiment, test strip receptacle 120 is sized and configured to generally correspond to the size and shape of test strip 112 such that an end of test strip 112 can be inserted and maintained within test strip receptacle 120. Test strip 112 can be held within test strip receptacle 120 of test strip housing 118 by a variety of means, including frictional coupling, mechanical fasteners such as clamps or pins, and adhesives such as glue. Test strip housing 120, test strip receptacle 118, friction couplings, mechanical fasteners, and adhesives are each examples of means for holding a test strip. In addition, test strip housing 118 can function as a handle to facilitate simple and convenient use of fluid sampling device 110.

As can be seen in Figure 3, the walls of test strip receptacle 120 include grooves 122 which are adapted to assist in venting air from test strip 112 and/or test strip receptacle 120. Venting of air from test strip 112 and/or test strip receptacle 120 enables fluid to readily flow into test strip receptacle 120 and/or be absorbed by test strip 112. Grooves 122 are one example of means for venting air from test strip housing 118 and/or test strip receptacle 120. Additionally, grooves 122 can be adapted to assist in properly aligning test strip 112 when it is being inserted into test strip receptacle 120. Furthermore, grooves 122 can also assist in holding test strip 112 within test strip receptacle 120. Thus, grooves 122 are one example of means for holding test strip 112.

In the exemplary embodiment, grooves 122 extend from the opening of test strip receptacle 130 to about the opposing end of test strip receptacle 120. As illustrated, the opposing end of grooves 122 can include an abutment 132. Abutment 132 can be a means for ensuring proper positioning of test strip 112 within test strip receptacle 120. For example, as test strip 112 is inserted into test strip receptacle 120, abutment 132 can prevent over insertion as well as provide a tactile indication that test strip 112 has been fully inserted. It will be appreciated that grooves 122 can be configured in ways other than those illustrated. For example, grooves 122 can comprise a single groove or multiple grooves, and the size, shape, orientation and

positioning of grooves 122 can be altered based, for example, on the type of test strip used with test strip adapter 114.

Test strip 112 can be any one of a variety of test strips having electrical connections 120 or other means for detecting, analyzing and/or conveying properties of a fluid sample received by fluid sampling device 110. For example, test strip 112 could be a ONE TOUCH ULTRA® test strip made by LifeScan (a Johnson & Johnson subsidiary) or a COMFORT CURVE® test strip made by Accu-Chek (a Roche subsidiary). It will be appreciated that test strip 112 is not limited to the above-identified test strips. For example, test strip 112 can comprise an absorbent material, a reagent, and/or electrical leads that are not mounted on a substrate, but which can detect, convey, and/or analyze properties of a fluid sample. Thus, means for detecting, conveying, or analyzing a property of a fluid sample can include any one or more of electrical leads, an absorbent material, and a reagent.

Extending from an end of test strip housing 118 is a tapered portion 124. Tapered portion 124 is generally funnel shaped and connects test strip housing 118 to blunt canula 116. Blunt canula 116 has a lumen 126 extending from a distal end of blunt canula 116 to the interior 128 of tapered portion 124 in order to communicate a fluid sample through test strip adapter 114. Blunt canula 116, lumen 126, tapered portion 124, and interior 128 are each examples of means for communicating a fluid. The distal end of blunt canula 116 is adapted to be inserted into sample port 106 (Figure 1) to obtain a fluid sample, such as a blood sample. Blunt canula 116 is one example of means for accessing an interior portion of a sample port to obtain a fluid sample.

Fluid sampling device 110 can be made from medical device industry standard plastics including, but not limited to, thermoplastics, such as Polyethylene (PE), High Density Polyethylene (HDPE), Polypropylene (PP), Polystyrene (PF), Polyethylene Terephthalate (PET), and acrylic (for transparent properties), because of their low cost production, ability to be easily molded, sterility, and strength.

Fluid sampling device 110 can be formed of multiple discrete parts that are coupled together. For example, test strip housing 118, tapered portion 124, and blunt canula 116 can be made from discrete parts and joined together, such as with an adhesive. Alternatively, fluid sample device 110 can be formed as a single integral

piece through a molding process, for example. Additionally, a fluid monitoring device, such as an absorbent material or electrical connections, can be at least partially disposed within or in fluid communication with the test strip receptacle 120 such that various attributes of the fluid sample can be detected without the use of a conventional test strip.

In use, test strip 112 is positioned within test strip receptacle 120 of fluid sampling device 110. After fluid drawing device 104 has been activated and a fluid has been drawn into IV tube 102 past sample port 106, a user can insert the distal end of blunt canula 116 into sample port 106 to obtain a fluid sample. Pressure, such as hydrostatic, hemodynamic, or mechanically induced pressure, causes fluid from sample port 106 to enter lumen 126, move up through blunt canula 116 and tapered portion 124, and onto test strip 112. As noted, grooves 122 are disposed adjacent test strip 112 to facilitate the escape of air from test strip 112 and/or test strip receptacle 120, thus enabling the fluid sample to readily flow into test strip receptacle 120 and onto test strip 112.

When a sufficient fluid sample has been obtained, fluid sampling device 110 can be removed from sample port 106. Electrical connections 130 of test strip 112 can then be inserted into a glucometer, such as glucometer 200 illustrated in Figure 4, for analysis. The electrical connections 130 of test strip 112 can be inserted in glucometer 200 after the fluid sample has been obtained. Alternatively, test strip 112 can be inserted into glucometer 200 prior to inserting blunt canula 116 into sample port 106. In this manner, the fluid sample can be obtained and glucometer 200 can begin to analyze the sample immediately, without the intervening steps of removing fluid sampling device 110 from sample port 106 or inserting the test strip 112 into glucometer 200 after obtaining the fluid sample.

Glucometers, such as the one illustrated in Figure 4, are well known in the art. A typical glucometer 200 comprises a housing 202, keys 204, a display 206, internal analysis apparatus (not shown), and a receptacle 208 for receiving a test strip having a fluid sample, such as a blood sample, disposed thereon. Glucometer 200 shown in Figure 4 has a receptacle 208 that is designed to receive an end of test strip 112 therein. Disposed within receptacle 208 are electrical connections (not shown) which are adapted for electrical communication with electrical connections 130 of test strip

112 when the end of test strip 112 is inserted within receptacle 208. The internal analysis apparatus of glucometer 200 is adapted to analyze various electrical properties of the fluid sample received on test strip 112 and provide the results on display 206. Such electrical properties can include the resistance, impedance, capacitance, and the like of the fluid sample. Glucometer 200 is adapted to determine various attributes of the fluid sample, such as the glucose level of a blood sample, based on the electrical properties of the fluid sample. As noted above, fluid sampling system 100 can employ a glucometer that is adapted to analyze a fluid sample based on non-electrical properties of the fluid sample, including color changes, luminescence, and the like. In such a case, the internal analysis apparatus of the glucometer may have optical sensors, light sensors, or the like that are adapted to detect the non-electrical properties of the fluid sample.

Figures 5A and 5B illustrate alternative embodiments of the fluid sampling device of the present invention. The fluid sampling device 150 of Figure 5A is similar to fluid sampling device 110. In particular, fluid sampling device 150 includes a test strip adapter 114 that receives a test strip 112 therein. The test strip adapter 114 includes a blunt canula 116, a test strip housing 118, and a connecting or tapered portion 124 similar to those of fluid sampling device 110. In addition, fluid sampling device 150 also includes a stabilizing tab 134 that extends from the end of test strip housing 118 opposite blunt canula 116. Tab 134 is shaped and sized to extend around at least a portion of glucometer 200 when fluid sampling device 150 is associated with glucometer 200, as illustrated in Figure 5A.

Tab 134 is adapted to provide greater stability to fluid sampling device 150 when fluid sampling device 150 is used to obtain a fluid sample from sample port 106. When obtaining a fluid sample with fluid sampling device 150 when it is associated with glucometer 200 as illustrated, glucometer 200 acts as an enlarged handle for fluid sampling device 150. A user holding glucometer 200 can also hold tab 134 with the same hand, thereby providing greater rigidity and stability between glucometer 200 and fluid sampling device 150. Additionally, after the fluid sample has been obtained, tab 134 can be used to remove fluid sampling device 150 from glucometer 200. Specifically, a user can simply push on tab 134 in the direction of blunt canula 116 to disengage fluid sampling device 150 from glucometer 200.

Figure 5B illustrates an alternative embodiment of a stabilizing tab. In particular, tab 136 of Figure 5B extends from fluid sampling device 160 and is larger than tab 134 of Figure 5A. Tab 136 extends further around the end of glucometer 200. Tab 136 can provide even greater rigidity and stability between fluid sampling device 160 and glucometer 200.

Figure 5B also illustrates blunt canula 116 having a one-way valve 138 to prevent or limit the reflux of air into IV tube 102. In the illustrated embodiment, the valve 138 is coupled to the distal end of lumen 126. The valve 138 can also be disposed in other positions within lumen 126. One-way valves suitable for such medical devices are well known in the art. Valve 138 can be made of a medical grade plastic and/or rubber.

Attention is now directed to Figures 6A-6C, in which is illustrated a modified glucometer 210 for use with test strip adapter 110. Similar to glucometer 200, glucometer 210 includes a housing 202, keys 204, a display 206, internal analysis apparatus (not shown), and a receptacle 208 for receiving a test strip therein. Disposed within receptacle 208 are electrical connections (not shown) which are adapted for electrical communication with electrical connections 130 of test strip 112 when the end of test strip 112 is inserted within receptacle 208. The internal analysis apparatus of glucometer 210 is adapted to analyze various electrical properties of the fluid sample received on test strip 112 and provide the results on display 206. Such electrical properties can include the resistance, impedance, capacitance, and the like of the fluid sample. Glucometer 210 is adapted to determine various attributes of the fluid sample, such as the glucose level of a blood sample, based on the electrical properties of the fluid sample. As noted above, fluid sampling system 100 can employ a glucometer that is adapted to analyze a fluid sample based on non-electrical properties of the fluid sample, including color changes, luminescence, and the like.

In addition to the above-identified features, glucometer also includes a mechanism for securely coupling together and selectively releasing test strip adapter 110 and glucometer 210. More specifically, glucometer 210 includes a test strip adapter receptacle 212 for receiving an end of test strip adapter 110 therein. Test strip adapter receptacle 212 is formed adjacent test strip receptacle 208 such that when test strip adapter 110 is positioned within test strip adapter receptacle 212, test strip 112

can be positioned within both test strip receptacle 208 of glucometer 210 and test strip receptacle 120 of test strip adapter 110.

As illustrated in Figure 6B, the interior surface of test strip adapter receptacle 212 is configured to generally conform to the exterior surface shape of test strip adapter 110. The complimentary shapes of test strip adapter 110 and test strip adapter receptacle 212 facilitate the secure engagement of test strip adapter 110 within test strip adapter receptacle 212 during use. More specifically, the shape of test strip adapter receptacle 212 prevents test strip adapter 110 from moving relative to glucometer 210 when glucometer 210 and test strip adapter 110 are used to obtain a fluid sample. Thus, the configuration of test strip adapter receptacle 212 is adapted to maintain a desired orientation of test strip adapter 110 relative to glucometer 210.

Test strip adapter receptacle 212 is formed by housing 202 and an ejector 214. In the illustrated embodiment, housing 202 forms the lower half of test strip adapter receptacle 212, while ejector 214 forms the upper half of test strip adapter receptacle 212. Housing 202 and ejector 214 also cooperate to form channels 216 on opposing sides of test strip adapter receptacle 212. Channels 216, similar to grooves 122 described above, assist in venting air from test strip 112, test strip receptacle 120, and/or test strip adapter receptacle 212 to enable fluid to readily flow into test strip receptacle 120 and/or test strip 112. Channels 216 are, therefore, one example of means for venting air from test strip housing 118 and/or test strip receptacle 120.

In addition to assisting in maintaining the position and orientation of test strip adapter 110 within test strip adapter receptacle 212, ejector 214 also facilitates removal of test strip adapter 110 and/or test strip 112 from glucometer 210. Ejector 214 is movably coupled to housing 202 of glucometer 210. As illustrated in Figure 6C, ejector 214 can be slidably or otherwise coupled to housing 202 such that ejector 214 can move relative to housing 202 in a direction generally parallel to a longitudinal axis of housing 202.

When ejector 214 is in a receiving position as illustrated in Figure 6A, test strip adapter 110 can be inserted and maintained within test strip adapter receptacle 212 as described herein. As noted, ejector 214 can be moved relative to housing 202 as illustrated in Figure 6C. By moving ejector 214 as shown in Figure 6C, test strip adapter 110 is made readily removable from test strip adapter receptacle 212. In

particular, ejector 214 includes a ridge 218 that engages a rear surface of test strip adapter 110. As ejector 214 is moved to the position shown in Figure 6C, ridge 218 pushes against the rear surface of test strip adapter 110, thereby pushing test strip adapter 110 in the same direction that ejector 214 is moving.

Ejector 214 can be configured to completely remove test strip adapter 110 from test strip adapter receptacle 212 without requiring a user to touch test strip adapter 110. In particular, a user can simply move ejector 214 to the position shown in Figure 6C, at which point test strip adapter 110 would no longer be within test strip adapter receptacle 212 and test strip adapter 110 would disengage from glucometer 210. Alternatively, ejector 214 can be adapted to partially remove test strip adapter 110 from test strip adapter receptacle 212. For example, a user could move ejector 214 to the position shown in Figure 6C, which would slide test strip adapter 110 out of test strip adapter receptacle 212 far enough that a user could easily remove test strip adapter 110 from glucometer 210.

Ejector 214 can be biased towards the receiving position illustrated in Figure 6A. In particular, ejector 214 can be biased such that prior to inserting test strip adapter 110 into test strip adapter receptacle 212, ejector 214 is held in the receiving position illustrated in Figure 6A so that test strip adapter 110 can be inserted into test strip adapter receptacle 212 as described above. Similarly, after obtaining a fluid sample and removing test strip adapter 110 using ejector 214, ejector 214 can be biased back toward the receiving position shown in Figure 6A. Ejector 214 can be biased with any suitable biasing means, including springs, such as coil springs, leaf springs, and the like.

With reference to Figures 7A-23B, various alternative embodiments of fluid sampling devices according to the present invention will now be described.

Figures 7A and 7B illustrate an exemplary embodiment of a fluid sampling device 250 according to the present invention. Fluid sampling device 250 comprises a handle 252, a blunt canula 254, and a main body 256 having an interior portion and windows 256a and 256b. Blunt canula 254 is sized and shaped to fit within sample port 106 (see Figure 1). Blunt canula 254 has an opening in an end thereof that is in fluid communication with the interior portion of main body 256. The interior portion of main body 256 is adapted to hold a fluid sample, such as a blood sample.

Windows 256a and 256b are disposed on opposing sides of main body 256 and allow a user to view the interior portion of main body 256. Windows 256a and 256b also facilitate analysis of the fluid sample when analyzed by a modified glucometer, as discussed below. Handle 252 is ergonomically shaped to allow a user to easily and comfortably hold fluid sampling device 250 with a thumb and forefinger, for example.

In use, after fluid drawing device 104 has been activated and a fluid has been drawn past sample port 106 as discussed above, blunt canula 254 can be inserted into sample port 106. A small volume of fluid can be drawn through the blunt canula into the interior portion of main body 256 by pressure, such as hydrostatic, hemodynamic, and/or mechanically induced pressure. Windows 256a and 256b enable a user to view the fluid sample and determine when a sufficient sample has been obtained. Fluid sampling device 250 can then be removed from sample port 106 and the fluid sample can be analyzed by a modified glucometer, as discussed below.

Figures 8A-8D illustrate another alternative exemplary embodiment of a fluid sampling device 260. Similar to the previous embodiment, fluid sampling device 260 comprises a handle 262, a main body 266, and windows 266a and 266b. In addition, fluid sampling device 260 of the present embodiment comprises a diaphragm 268, a vacuum chamber 270 disposed within main body 266, a first channel 272, a second channel 274, a lure lock tip 276, and a testing compartment 278 disposed within main body 266.

As seen in the Figures, adjacent handle 262, and disposed within main body 266, is vacuum chamber 270. Vacuum chamber 270 is defined by main body 266 and diaphragm 268. Diaphragm 268 is generally arch shaped and is made from a resilient, pliable material, such as rubber or plastic, so that a user can depress diaphragm 268 to decrease the volume of vacuum chamber 270. Vacuum chamber 270 is in fluid communication with first channel 272 such that when diaphragm 268 is depressed, air from vacuum chamber 270 is expelled through first channel 272. First channel 272 extends from vacuum chamber 270 to testing compartment 278.

Testing compartment 278 is disposed within main body 266 and is partially defined by windows 266a and 266b which are on opposing sides of main body 266. Windows 266a and 266b allow a user to view the interior of testing compartment 278 and determine when a sufficient sample of fluid has been obtained. Within testing

compartment 278 is an absorbent material 280, such as foam, and a testing reagent 282. Absorbent material 280 absorbs and retains a fluid sample that is retrieved from sample port 106 as described below. Testing reagent 282 is disposed adjacent absorbent material 280 such that absorbed fluid will contact testing reagent 282. Testing reagent 282 will react to various attributes of the fluid sample, such as glucose levels of a blood sample.

Testing compartment 278 is in fluid communication with second channel 274. Second channel 274 extends through lure lock tip 276 and opens at the end of lure lock tip 276. Lure lock tip 276 can be retrofitted with a blunt canula in order to access various applicable systems, such as sample port 106.

Fluid sampling device 260 of the present embodiment is used in a manner similar to fluid sampling devices 110 and 250 of the previous embodiments. When fluid drawing device 104 has been activated and a fluid has been draw into IV tube 102 past sample port 106, fluid sampling device 260 can be used to retrieve a fluid sample from sample port 106. The present example embodiment of fluid sampling device 260, however, does not rely on hydrostatic or hemodynamic pressure to draw fluid from sample port 106 into fluid sampling device 260. Rather, the present embodiment of fluid sampling device 260 utilizes a negative pressure within vacuum chamber 270 to draw fluid from sample port 106 into fluid sampling device 260. Specifically, prior to inserting lure lock tip 276 into sample port 106, a user will depress diaphragm 268 to expel air out of vacuum chamber 270 through first channel 272, testing compartment 278, and second channel 274, thus creating a potential vacuum within vacuum chamber 270. Once the potential vacuum has been created in vacuum chamber 270, lure lock tip 276, either as shown in the Figures 8A-8D or retrofitted with a blunt canula, is inserted into sample port 106 (see Figure 1). The user then releases diaphragm 268 to return to its original shape and position. As diaphragm 268 returns to its original position, a negative pressure or vacuum is created within vacuum chamber 270. Vacuum chamber 270 and diaphragm 268 are sized adapted to create a negative pressure within fluid sampling device 260 sufficient to draw a desired quantity of fluid from sample port 106, through second channel 274, and into testing compartment 278.

As the fluid enters testing compartment 278, absorbent material 280 will absorb the fluid and distribute it across testing reagent 282. Absorbent material 280 also functions to retain fluid within fluid sampling device 260. Windows 266a and 266b allow a user to view absorbent material 280 in testing compartment 278 to determine when an adequate fluid sample has been achieved. When a sufficient quantity of fluid has been drawn into testing compartment 278, the user removes fluid sampling device 260 from sample port 106.

Having obtained a fluid sample within fluid sampling device 260, the fluid sample can then be analyzed using a modified glucometer 290 as seen in Figure 9. As noted above, glucometers are well known in the art and typically include a housing 292, a keypad 294, internal analysis apparatus (not shown), and a receptacle 296 for receiving a test strip having a fluid sample, such as a blood sample, disposed thereon. The modified glucometer 290 shown in Figure 9 has a reconfigured receptacle 296 that is designed to receive a fluid sampling device therein, such as fluid sampling device 250 or 260. Receptacle 296 is adapted such that when fluid sampling device 260 is inserted therein, windows 266a and 266b are in alignment with an analyzer light (not shown) of modified glucometer 290. The analyzer light of modified glucometer 290 is directed through one or both of windows 266a and 266b to analyze various attributes of the fluid sample, such as glucose levels of a blood sample. While glucometer 290 is illustrated and described in association with fluid sampling device 260, it will be appreciated that glucometer 290 can also be configured for use in association with other fluid sampling devices, such as fluid sampling device 250 illustrated in Figures 7A-7B.

Figure 10 illustrate yet another exemplary embodiment of a fluid sampling device 300. Fluid sampling device 300 of the present embodiment comprises handle 302, a vacuum chamber 304, a diaphragm 306, a testing compartment 308, a lure lock tip 310, a channel 312, a test strip 314, a reagent 316, and valve 318. Vacuum chamber 304 is in fluid communication with channel 312 to allow air to be expelled from vacuum chamber 304 through channel 312 when diaphragm 306 is depressed. Expulsion of air from vacuum chamber 304 creates a potential vacuum therein.

Fluid sampling device 300 is adapted to receive a standard test strip 314 disposed at least partially therein. In the illustrated embodiment, test strip 314 is

received within testing compartment 308, vacuum chamber 304, and handle 302. Fluid sampling device 300 can be adapted to receive standard supply test strips such as the SureStep Pro test strip made by LifeScan (a J&J subsidiary).

Fluid sampling device 300 of the present embodiment is used in a manner similar to fluid sampling device 260. Specifically, a user depresses diaphragm 306 to expel air out of vacuum chamber 304 and create a potential vacuum therein. Lure lock tip 310, either as illustrated or retrofitted with a blunt canula, is inserted into sample port 106 and diaphragm 306 is released to create a negative pressure within vacuum chamber 304. The negative pressure within vacuum chamber 304 draws fluid from sample port 106 through channel 312 into testing compartment 308. Fluid entering testing compartment 308 is absorbed by test strip 314. Having received a sufficient fluid sample, fluid sampling device 300 can be removed from sample port 106.

As seen in Figure 10, unlike fluid sampling devices 250 and 260, handle 302 of the present embodiment can be removed to expose an end of test strip 314. Handle 302 can be coupled to fluid sampling device 300 with the use of clamps, clips, or the like. With handle 302 detached from fluid sampling device 300, test strip 314 can be removed from fluid sampling device 300 for analysis of the fluid sample. By adapting fluid sampling device 300 with a removable handle 302, the fluid sample disposed on test strip 314 can be analyzed using conventional means, such as a typical glucometer that is adapted to receive standard test strips. To prevent potential air leaks through handle 302 that would reduce the drawing force of vacuum chamber 304 and diaphragm 306, fluid sampling device 300 has a one-way valve 318 disposed across the opening through which test strip 314 is inserted.

Figure 11 illustrates a perspective view of yet another embodiment of a fluid sampling device 350. Fluid sampling device 350 of the present embodiment comprises a top portion 352 and a base portion 354 that are adapted to be coupled together. Top portion 352 and base portion 354 can be couple together in a first position and a second position. In the first position, fluid sampling device 350 can have a test strip 226 disposed between base portion 354 and top portion 352 (as seen in Figures 11 and 14). It is contemplated that standard test strips, such as the SureStep Pro test strip made by LifeScan (a J&J subsidiary) can be used in combination with

fluid sampling device 350. Top portion 352 is biased toward base portion 354 such that when test strip 226 is removed, top portion 352 moves toward base portion 354. Fluid sampling device 350 can be configured for insertion within sample port 106 to obtain a fluid sample. In an alternative embodiment, top portion 352 can comprise test strip 226. In this embodiment, base portion 354 and test strip 226 can be coupled together with a flange, an adhesive such as glue, or a mechanical fastener.

Figures 12A-12C illustrate end, side, and bottom views of top portion 3522. As seen in the Figures, top portion 352 comprises a top surface 356, a bottom surface 358, flanges 360, and recess 362. Top surface 356 defines an aperture 364 that can allow a user to view the interior of fluid sampling device 350 to determine when a sufficient fluid sample had been obtained. Flanges 360 are disposed on opposing sides of top portion 352 and extend from bottom surface 358. The ends of flanges 360 are rounded in toward the center of top portion 352. Recess 362 is a cavity in bottom surface 358. The various elements of top portion 352 can be integrally formed as a unitary piece, or the elements can be individually formed and then coupled together. As noted above, top portion 352 can comprise test strip 226.

Figures 13A-13C illustrate end, side, and bottom views of base portion 354. Base portion 354 comprises a platform 364, walls 366, and a blunt canula 368. Platform 364 has a bottom surface 370 and a top surface 372 with grooves 374 therein as seen in Figure 13C. The opposing ends 376 of platform 364 can function as handles to facilitate simple and convenient use of fluid sampling device 350. Walls 366 are disposed on opposing sides of platform 364. The ends of wall 366 are rounded in toward the center of base portion 354. Walls 366 have first ridges 378 and second ridges 380 extending along its outer surface. As seen best in Figure 13A, first ridges 378 are vertically above second ridges 380 and extend further out than second ridges 380. Extending from bottom surface 370 is blunt canula 368. Blunt canula 368 has a lumen 382 extending from a distal end of blunt canula 368 through an aperture 384 in platform 364. The distal end of blunt canula 368 is adapted to be inserted into sample port 106 to obtain a fluid sample, such as a blood sample.

Figure 14 is a cross-sectional end view of fluid sampling device 350 illustrating how top portion 352 and base portion 354 couple together. As noted above, the ends of wall 366 and flanges 360 are rounded. The rounded ends of walls

366 and flanges 360 facilitate alignment of top portion 352 and base portion 354 and prevent horizontal movement of top portion 352 relative to base portion 354. The interior surfaces of flanges 360 each has an inwardly projecting ridge 384 that is adapted to engage ridges 378 and 380. Specifically, top portion 352 is aligned with base portion 354 and flanges 360 extend over walls 366 and ridges 384 engage ridges 378 when test strip 226 is disposed between top portion 352 and base portion 354. Top portion 352 is sized such that when test strip 226 is in place and ridges 384 are engaged with ridges 378, flanges 360 are deflected slightly away from base portion 354. When test strip 226 is removed, the deflection in flanges 360 causes top portion 352 to be biased toward base portion 354. Therefore, when test strip 226 is removed, top portion 352 moves toward base portion 354 until bottom surface 358 of top portion 352 comes into contact with top surface 372 of platform 364. At this point, ridges 384 of flanges 360 engage ridges 380 of walls 366. The engagement between ridges 384 and either ridges 378 or ridges 380 prevents top portion 352 from becoming undesirably separated from base portion 354. In embodiments in which top portion 352 comprises test strip 226, test strip 226 can be couple to base portion 354 with a flange similar to flanges 360, or test strip 226 can be bonded to base portion with a glue or plastic.

In use, fluid sampling device 350 will have test strip 226 inserted between top portion 352 and base portion 354. After fluid drawing device 104 (Figure 1) has been activated and a fluid has been drawn into IV tube 102 past sample port 106, a user can insert the distal end of blunt canula 368 into sample port 106. Pressure, such as hydrostatic, hemodynamic, or mechanically induced pressure, causes fluid from sample port 106 to enter lumen 382 and move up through base portion 354 and onto test strip 226. When a sufficient fluid sample has been obtained, fluid sampling device 350 can be removed from sample port 106. Test strip 226 can then be withdrawn from between top portion 352 and base portion 354 and analyzed in a glucometer as described above. In embodiments in which test strip 226 comprises top portion 352, fluid sampling device 350 can be removed from sample port 106 after a fluid sample has been obtained and a glucometer modified to receive fluid sampling device 350 can be used to analyze the fluid sample. In some embodiments in which

test strip 226 comprises top portion 352, test strip 226 can be removed from base portion 354 and the fluid sample can be analyzed with a standard glucometer.

When fluid, such as blood, is drawn from sample port 106 into fluid sampling device 350, excess fluid may be received within fluid sampling device 350 and on test strip 226. To prevent excess fluid from leaking out of fluid sampling device 350 or remaining on test strip 226 when it is removed from fluid sampling device 350, top portion 352 has recess 362 and base portion 354 has grooves 374 in top surface 372 that cooperate to eliminate these problems. Specifically, grooves 374 act like a squeegee to remove excess fluid from test strip 226 as test strip 226 is withdrawn from fluid sampling device 350. When test strip 226 is removed from fluid sampling device 350, top portion 352 and base portion 354 come together as described above, and grooves 374 and recess 362 cooperate to retain the excess fluid within fluid sampling device 350.

Grooves 374 also facilitate the entry of a fluid sample within fluid sampling device 350 and the absorption of the fluid sample by test strip 226. Prior to receiving a fluid sample, test strip 226 and fluid sampling device 350 may have air therein. In order for fluid to flow up through lumen 382 and into test strip 226, the air within test strip 226 must be removed. Grooves 374 provide an area to which the air within test strip 226 can escape. Thus, as a fluid sample begins to flow into fluid sampling device 350 and onto test strip 226, the air within test strip 226 is able to escape or be vented into grooves 374. Grooves 374 are one example of means for venting air from test strip fluid sampling device 350 and/or test strip 226.

Figure 15 illustrates a perspective view of yet another embodiment of a fluid sampling device, generally denoted at 400. Fluid sampling device 400 of the present embodiment comprises a top portion 402 and a base portion 404 that are adapted to be coupled together in the same manner as top portion 352 and base portion 354, as illustrated in Figure 14. Top portion 402 is identical to top portion 352 illustrated in Figures 12A-12C. Likewise, base portion 404 is similar to base portion 354 illustrated in Figures 13A-13C. Also like fluid sampling device 350, top portion 402 and base portion 404 are adapted to receive test strip 226 therebetween. It is contemplated that standard test strips having electrical connections 236, such as the One Touch Ultra test strip made by LifeScan (a J&J subsidiary) or the Comfort Curve test strip made

by Accu-Chek (a Roche subsidiary) can be used in combination with fluid sampling device 400. Fluid sampling device 400 can also be configured for insertion within sample port 106 to obtain a fluid sample in the same manner as fluid sampling device 350.

Figures 16A and 16B illustrate side and top views of base portion 404. Base portion 404 comprises a platform 414, walls 422, and a blunt canula 426. Platform 414 has a bottom surface 420 and a top surface 416 with groove 418 therein as seen in Figure 16B. The opposing ends 438 of platform 414 can function as handles to facilitate simple and convenient use of fluid sampling device 400. Opposing ends 438 of platform 414 also have retention walls 440 and 442 extending upwardly from top surface 416. Retention walls 440 and 442 are adapted to abut edges 232 and 234 of test strip 226 (Figure 15) to prevent test strip 226 from being removed from between top portion 402 and base portion 404. In addition to retention walls 440 and 442, test strip 226 can be coupled to top portion 402 and/or base portion 404 with an adhesive such as glue, or a mechanical fastener.

Walls 422 of base portion 404 are disposed on opposing sides of platform 414. The ends of wall 422 are rounded in toward the center of base portion 404. Walls 422 have first ridges 424 and second ridges 428 extending along their outer surfaces. First ridges 424 are vertically above second ridges 428 and extend further out than second ridges 428 in the same manner as first ridges 378 and second ridges 380 as illustrated in Figure 13A. Walls 422 and first and second ridges 424 and 428 facilitate coupling of base portion 404 to top portion 402 in a manner similar to that of top portion 352 and base portion 354 as illustrated in Figure 14.

Extending from bottom surface 420 of base portion 404 is blunt canula 426. Blunt canula 426 has a lumen 430 extending from a distal end of blunt canula 426 through an aperture 436 in platform 414. The distal end of blunt canula 426 is adapted to be inserted into sample port 106 (Figure 1) to obtain a fluid sample, such as a blood sample. Blunt canula 426 can also include a one-way valve 444 (not shown) to prevent or limit the reflux of air into the IV tube 102. In one embodiment, valve 444 is coupled to the distal end of lumen 430. Valve 444 can also be disposed in other positions within lumen 430. Valve 444 can be made of a medical grade plastic and/or rubber.

In use, fluid sampling device 400 will have test strip 226 inserted between top portion 402 and base portion 404. After fluid drawing device 104 has been activated and a fluid has been drawn into IV tube 102 past sample port 106, a user can insert the distal end of blunt canula 426 into sample port 106. Pressure, such as hydrostatic, hemodynamic, or mechanically induced pressure, causes fluid from sample port 106 to enter lumen 430 and move up through base portion 404 and onto test strip 226. Groove 418 is disposed adjacent aperture 436 and test strip 226 to facilitate the escape of air from test strip 226, thus enabling the fluid sample to readily flow into test strip 226. When a sufficient fluid sample has been obtained, fluid sampling device 400 can be removed from sample port 106. Electrical connections 236 can then be inserted into a glucometer, such as glucometer 600 illustrated in Figure 22, for analysis. Glucometers, such as glucometer 600, are adapted to analyze various properties of the fluid sample absorbed by test strip 226 by determining the electrical properties, such as the resistance, of the fluid sample.

When fluid, such as blood, is drawn from sample port 106 into fluid sampling device 400, excess fluid may be received within fluid sampling device 400 and on test strip 226. In some embodiments it may be desirable to remove excess fluid from test strip 226. Groove 418 of base portion 404 can also be adapted to receive excess fluid received within fluid sampling device 400. In the illustrated embodiment, groove 418 extends around aperture 436 to receive excess fluid that flows into fluid sampling device 400 through lumen 430. It will be appreciated that groove 418 can comprise multiple concentric grooves, or any other configuration of one or more grooves that are adapted to receive excess fluid in fluid sampling device 400.

Figure 17 illustrates a perspective view of still yet another embodiment of a fluid sampling device, generally denoted at 450. Fluid sampling device 450 of the present embodiment comprises a test strip 226 and a base portion 452 that are adapted to be coupled together. Test strip 226 can be any one of a variety of test strips having electrical connections 236 or other means for analyzing properties of the fluid sample received by fluid sampling device 450. For example, test strip 226 could be a One Touch Ultra test strip made by LifeScan (a J&J subsidiary) or a Comfort Curve test strip made by Accu-Chek (a Roche subsidiary). Base portion 452 has a configuration similar to base portions 354 and 404 of the previous embodiments. Fluid sampling

device 450 can also be configured for insertion within sample port 106 to obtain a fluid sample in the same manner as the previously discussed fluid sampling devices.

Figure 18 illustrates a top perspective view of base portion 452. Base portion 452 comprises a platform 454, mounting portion 456, and a blunt canula 458. Platform 454 has a bottom surface 460 and a top surface 462. Mounting portion 456 extends from a first end of base portion 452 to about the middle of base portion 452, and is generally defined by opposing side walls 464, end wall 466, and support surface 468. Support surface 468 has grooves 470 therein for receiving excess fluid in that same manner as groove 374 and 418 of fluid sampling devices 350 and 400. Opposing side walls 464, end wall 466, and support surface 468 are adapted to abut edges of test strip 226 such that the shape of mounting portion 456 corresponds to the shape of test strip 226 so as to assist in maintaining test strip 226 in a desired position. In addition, test strip 226 can be coupled to base portion 452 with an adhesive such as glue, or a mechanical fastener. The opposing ends 464 of platform 454 can function as handles to facilitate simple and convenient use of fluid sampling device 450.

Extending from bottom surface 460 of base portion 452 is blunt canula 458. Blunt canula 458 has a lumen 472 extending from a distal end of blunt canula 458 through aperture 474 in support surface 468. In the illustrated embodiment, blunt canula 458 is offset toward one end of platform 454. However, it will be appreciated that base portion 452 can be configured with blunt canula 458 extending from platform 454 in other locations to accommodate various test strips 226. The distal end of blunt canula 458 is adapted to be inserted into sample port 106 (Figure 1) to obtain a fluid sample, such as a blood sample. Blunt canula 458 can also include a one-way valve (not shown) to prevent or limit the reflux of air into IV tube 102. In one embodiment, the one-way valve is coupled to the distal end of lumen 472. The one-way valve can also be disposed in other positions within lumen 472. The one-way valve can be made of a medical grade plastic and/or rubber.

In use, fluid sampling device 450 will have test strip 226 coupled to base portion 452 within mounting portion 456. After fluid drawing device 104 has been activated and a fluid has been drawn into IV tube 102 past sample port 106, a user can insert the distal end of blunt canula 458 into sample port 106. Pressure, such as hydrostatic, hemodynamic, or mechanically induced pressure, causes fluid from

sample port 106 to enter lumen 472 and move up through base portion 454 and onto test strip 226. Grooves 470 are disposed adjacent aperture 474 and test strip 226 to facilitate the escape of air from test strip 226, thus enabling the fluid sample to readily flow into test strip 226. When a sufficient fluid sample has been obtained, fluid sampling device 450 can be removed from sample port 106. Electrical connections 236 can then be inserted into a glucometer, such as glucometer 600 illustrated in Figure 22, for analysis. Glucometers, such as glucometer 600, are adapted to analyze various properties of the fluid sample absorbed by test strip 226 by determining the electrical properties, such as the resistance, of the fluid sample.

When fluid, such as blood, is drawn from sample port 106 into fluid sampling device 450, excess fluid may be received within fluid sampling device 450. In some embodiments it may be desirable to remove excess fluid received within fluid sampling device 450 from test strip 226. Grooves 470 of base portion 454 can also be adapted to receive excess fluid received within fluid sampling device 450. In the illustrated embodiment, grooves 470 extend parallel to each other on two opposing sides of aperture 474 to receive excess fluid that flows into fluid sampling device 450 through lumen 472. It will be appreciated that grooves 470 can comprise one or more grooves that extend around at least a part of aperture 474.

Figure 19 illustrates a perspective view of still yet another embodiment of a fluid sampling device, generally denoted at 500. Fluid sampling device 500 of the present embodiment comprises a test strip 226 and a base portion 502 that are adapted to be coupled together. Base portion 502 has a configuration similar to base portion 452. Fluid sampling device 500 can also be configured for insertion within sample port 106 to obtain a fluid sample in the same manner as the previously discussed fluid sampling devices.

Figures 20A and 20B illustrate top and bottom perspective views of base portion 502. Base portion 502 comprises a platform 504, mounting portion 506, and a blunt canula 508. Platform 504 has a bottom surface 510 and a top surface 512. Mounting portion 506 is generally defined by opposing side walls 514, end wall 516, and support surface 518. Support surface 518 has grooves 520 therein for venting air from test strip 226 as described below. Opposing side walls 514, end wall 516, and support surface 518 are adapted to abut edges of test strip 226 to assist in maintaining

test strip 226 in a desired position. One or both of side walls 514 can include a projecting portion 522 that extends toward the middle of mounting portion 506. In this manner, mounting portion 506 can be configured to fit around specific shaped test strips 226, as illustrated in Figure 19. In addition, test strip 226 can be coupled to base portion 502 with an adhesive such as glue, or a mechanical fastener. The opposing ends 524 of platform 504 can function as handles to facilitate simple and convenient use of fluid sampling device 500.

Extending from bottom surface 510 of base portion 502 is blunt canula 508. Blunt canula 508 has a lumen 526 extending from a distal end of blunt canula 508 through aperture 528 in support surface 518. In the illustrated embodiment, blunt canula 508 is offset toward one side of platform 504 to accommodate test strip 226 as described below. However, it will be appreciated that base portion 502 can be configured with blunt canula 508 extending from platform 504 in other locations. The distal end of blunt canula 508 is adapted to be inserted into sample port 106 (Figure 1) to obtain a fluid sample, such as a blood sample. Blunt canula 508 can also include a one-way valve 530 to prevent or limit the reflux of air into IV tube 102. In the illustrated embodiment, valve 530 is coupled to the distal end of lumen 526. It will be appreciated that valve 530 can also be disposed in other positions within lumen 526. Valve 530 can be made of a medical grade plastic and/or rubber. Also disposed on bottom surface 510 are alignment members 532 which extend from blunt canula 508 toward opposing ends 524 of platform 504. Alignment members 532 provide a reference point to enable a user to center the blunt canula 508 in their fingers and to determine the center position of the offset blunt canula 508. Alignment members 532 also add additional mass, and thus strength, to fluid sampling device 500.

Figures 21A and 21B illustrate one example embodiment of test strip 226 that can be used with fluid sampling device 500. The illustrated embodiment of test strip 226 is a Comfort Curve test strip made by Accu-Chek (a Roche subsidiary). However, test strip 226 can be any one of a variety of test strips having electrical connections 236 or other means for analyzing properties of the fluid sample received by fluid sampling device 500, such as the One Touch Ultra test strip made by LifeScan (a J&J subsidiary).

Test strip 226 includes electrical connections 236, fluid intake 238, and vent 240. As discussed herein, electrical connections 236 can be used in conjunction with a glucometer to analyze the fluid sample retrieved with fluid sampling device 500. Fluid intake 238 can be an opening in the side, or other surface, of test strip 226. Fluid intake 238 is adapted to receive a fluid sample, such as blood, therein. To enable a fluid to readily flow into fluid intake 238, the air disposed within fluid intake 238 must be removed. Vent 240 is in fluid communication with fluid intake 238 and allows the air in fluid intake 238 to escape therefrom as a fluid sample enters fluid into 238.

In use, fluid sampling device 500 will have test strip 226 coupled to base portion 502 within mounting portion 506. After fluid drawing device 104 has been activated and a fluid has been drawn into IV tube 102 past sample port 106, a user can insert the distal end of blunt canula 508 into sample port 106. Pressure, such as hydrostatic, hemodynamic, or mechanically induced pressure, causes fluid from sample port 106 to enter lumen 526 and move up through aperture 528 of base portion 502. The fluid sample then enters fluid intake 238 of test strip 226. Air within fluid intake 238 can escape test strip 226 through vent 240. Grooves 520 are disposed adjacent vent 240 to facilitate the escape of air from test strip 226 through vent 240, thus enabling the fluid sample to readily flow into test strip 226. When a sufficient fluid sample has been obtained, fluid sampling device 500 can be removed from sample port 106. Electrical connections 236 can then be inserted into a glucometer, such as glucometer 600 illustrated in Figure 22, for analysis. Glucometers, such as glucometer 600 are adapted to analyze various properties of the fluid sample absorbed by test strip 226 by determining the electrical properties, such as the resistance, of the fluid sample.

When fluid, such as blood, is drawn from sample port 106 into fluid sampling device 500, excess fluid may be received within grooves 520. In some embodiments it may be desirable to remove excess fluid received within fluid sampling device 500 from test strip 226. In the illustrated embodiment, grooves 520 extend in multiple directions adjacent vent 240. It will be appreciated that grooves 520 can comprise one or more grooves that that are shaped in any many.

Each of the fluid drawing devices described herein can be made from medical device industry standard plastics including, but not limited to thermoplastics, such as Polyethylene (PE), High Density Polyethylene (HDPE), Polypropylene (PP), Polystyrene (PF), Polyethylene Terephthalate (PET), and acrylic (for transparent properties), because of their low cost production, ability to be easily molded, sterility, and strength.

Having obtained a fluid sample within one of the fluid sampling devices described herein, the fluid sample can then be analyzed using a glucometer 600 as seen in Figure 22. Glucometers are well known in the art. A typical glucometer 600 comprises a housing 602, keys 604, internal analysis apparatus (not shown), a display 606, and a receptacle 608 for receiving a test strip having a fluid sample, such as a blood sample, disposed thereon. The glucometer shown in Figure 22 has a receptacle 608 that is designed to receive an end of test strip 226 therein. Disposed within receptacle 608 are electrical connections (not shown) which are adapted for electrical communication with electrical connections 236 of test strip 226 when the end of test strip 226 is inserted within receptacle 608. The internal analysis apparatus of glucometer 600 is adapted to analyze various electrical properties of the fluid sample received on test strip 226. Such electrical properties can include the resistance, impedance, capacitance and the like of the fluid sample. Glucometer 600 is adapted to determine various attributes of the fluid sample, such as the glucose level of a blood sample, based on the electrical properties of the fluid sample.

Figures 23A-23B illustrate an example embodiment of a protective housing 650 that is adapted to receive one of fluid sampling devices 350, 400, 450, and 500 therein. The example embodiment of protective housing 650 is shown and described with specific reference to fluid sampling device 350. However, it will be appreciated that protective housing 650 can also be employed with any one of fluid sampling devices 350, 400, 450, and 500, either as described herein or with minor modifications that will be readily apparent to one of ordinary skill in the art.

In the illustrated embodiment, protective housing 650 comprises substrate 652, a railing 654, and a cover portion 656. Substrate 652 has a top surface 658 and a bottom surface 660 that lays adjacent top surface 356 of top portion 352. Extending from bottom surface 660 is railing 654. Railing 654 extends around fluid sampling

device 350 and down to about top surface 372 of platform 364. Substrate 652 and railing 654 can be formed as a unitary piece, or can be individually formed and coupled together.

Attached to the lower edge of railing 654 is cover portion 656. Cover portion 656 extends over blunt canula 368. Cover portion 656 can comprise two layers of plastic 656a and 656b with air disposed therebetween. Layers of plastic 656a and 656b can be bonded together at various points to create pockets of air therein. As shown in Figure 23B, layers of plastic 656a and 656b are bonded together near railing 654 and the distal end of blunt canula 368, thus creating air pockets 662 and 664. In some embodiments, cover portion 656 comprises a single layer of plastic 656a that extends from railing 654 around base portion 354.

Protective housing 650 is adapted to protect fluid sampling device from physical damages prior to use, such as during shipment. Protective housing 650 also maintains the sterility of a fluid sampling device by preventing undesirable contamination through exposure to a non-sterile surface, such as a user's hands.

Fluid sampling device 350 packaged in protective housing 650 is used in a manner similar to that described above with respect to fluid sampling device 350. However, when fluid sampling device 350 is packaged in protective housing 650, cover portion 656 must be ruptured prior to inserting blunt canula 368 into sample port 106. Typically, a user will hold fluid sampling device 350, disposed within protective packaging 650, with their thumb or palm on top surface 658 of substrate 652, and their index and middle fingers extending around opposing sides of cover portion 656. Holding fluid sampling device 350 and protective housing 650 in this manner, a user can squeeze protective housing 650 with enough force to rupture air pockets 662 and 664. Once air pockets 662 and 664 have been ruptured, the distal end of blunt canula 368 can be forced through layers of plastic 656a and 656b to expose blunt canula 368. With blunt canula 368 exposed, a user can then insert blunt canula into sample port 106 to obtain a fluid sample in the same manner as previously described.

In some embodiments, one or both of layers of plastic 656a and 656b of cover portion 656 can be formed of a resilient material, such as a semi-rigid plastic, a shape memory material, a foam, or a rubber material. When employing a resilient cover

portion 656, a user can obtain a fluid sample in a manner similar to that described above (i.e., compress cover portion 656 until blunt canula 368 extends through cover portion 656 and insert blunt canula 368 into sample port 106). However, unlike the previously described embodiments, a resilient cover portion 656 can regain its shape after the user removes pressure from cover portion 656. As cover portion 656 regains its original shape, blunt canula 368 is once again enclosed within cover portion 656. Thus, protective housing 650 can be configured so as to expose blunt canula 368 when being inserted into sample port 106. Reducing the time that blunt canula 368 is exposed, both before and after use, provides numerous benefits. As discussed above, protective housing 650 can prevent contamination of blunt canula 368 prior to use. Additionally, use of a resilient cover portion 656 can also reduce the risk of exposure to a user, such as a nurse, by enclosing blunt canula 368, and any excess fluid thereon, within protective housing 650.

As noted above, each of fluid sampling devices 350, 400, 450, and 500 can be disposed within protective housing 650. As is readily apparent to one of ordinary skill in the art, various modifications can be made to protective housing 650 to accommodate various embodiments of fluid sampling devices. For example, when protective housing 650 is utilized with fluid sampling devices 450 or 500, bottom surface 660 of substrate 652 lays adjacent test strip 226 and top surface 462 or 512 rather than top portion 352 or 402. Similarly, substrate 652 can also function to enclose the opening between aperture 528 and fluid intake 238 to assist in directing fluid received through blunt canula 508 into fluid intake 238 of test strip 226. Substrate 652 can also assist in preventing fluid received within fluid sampling device 500 from leaking out of fluid sampling device 650.

The present invention may be embodied in other specific forms without departing from its spirit or essential characteristics. The described embodiments are to be considered in all respects only as illustrative and not restrictive. The scope of the invention is, therefore, indicated by the appended claims rather than by the foregoing description. All changes which come within the meaning and range of equivalency of the claims are to be embraced within their scope.

CLAIMS

What is claimed is:

1. A test strip adapter configured to convey a fluid sample from a sample port associated with a patient's blood stream directly to a test strip associated with said test strip adapter, the test strip adapter comprising:

a test strip housing adapted to receive a portion of the test strip therein, the size and shape of said test strip housing generally corresponding to the size and shape of the test strip portion received within said test strip housing;

a blunt canula extending from said test strip housing, said blunt canula having a lumen extending therethrough, said lumen and said test strip housing being in fluid communication with one another to enable a fluid to flow therethrough to communicate a fluid to the test strip.

2. The test strip adapter of claim 1, further comprising means for venting air from said test strip housing.

3. The test strip adapter of claim 2, wherein said means for venting air comprises a groove disposed within an interior wall of said test strip housing.

4. The test strip adapter of claim 3, wherein said groove comprises an abutment portion that facilitates proper positioning of a test strip within said test strip housing.

5. The test strip adapter of claim 2, wherein said means for venting air comprises a plurality of grooves disposed within one or more interior walls of said test strip housing.

6. The test strip adapter of claim 1, wherein said blunt canula is adapted to be received within a sample port.

7. A test strip adapter configured to convey a fluid sample from a sample port associated with a patient's blood stream directly to a test strip associated with the test strip adapter, the test strip adapter comprising:

means for holding a test strip, wherein said means for holding substantially encloses a first end of the test strip therein while allowing a second end of the test strip to extend out of said means for holding a test strip, thereby exposing said second end, wherein said second end of said test strip is adapted to be inserted into an analysis device;

means for accessing an interior of a sample port; and

means for communicating a fluid to the test strip, wherein said means for communicating extends from said means for holding.

8. The test strip adapter of claim 7, wherein said means for holding a test strip comprises a plurality of grooves.

9. The test strip adapter of claim 7, where said means for holding comprises a test strip housing having an interior portion configured to receive a portion of the test strip therein, wherein said interior portion is sized and shaped to generally corresponding to the size and shape of the test strip portion received within said interior portion of said test strip housing.

10. The test strip adapter of claim 7, wherein said means for accessing an interior of a sample port comprises a blunt canula.

11. The test strip adapter of claim 7, wherein said means for communicating a fluid comprises a lumen extending through said means for accessing.

12. The test strip adapter of claim 11, wherein said lumen is in fluid communication with said means for holding a test strip.

13. A fluid sampling device configured to obtain a fluid sample from a sample port associated with a patient and directly convey information about the fluid sample to an analysis device associated with the fluid sampling device, the fluid sampling device comprising:

a test strip adapted to receive a fluid sample and convey at least one property of the fluid sample to the analysis device; and

a test strip adapter configured to receive a first portion of said test strip therein while allowing a second portion of said test strip to extend out of said test strip adapter for association with the analysis device, said test strip adapter being configured to transfer a fluid sample directly from the sample port to said test strip, said test strip adapter comprising means for venting air from said test strip adapter.

14. The fluid sampling device of claim 13, wherein said test strip comprises electrical leads, an absorbent material, a reagent, or a combination thereof.

15. The fluid sampling device of claim 13, where said test strip adapter comprises means for conveying a fluid from a sample port to said test strip.

16. The fluid sampling device of claim 15, wherein said means for conveying comprises a blunt canula.

17. The fluid sampling device of claim 16, wherein said blunt canula comprises a lumen extending therethrough.

18. The fluid sampling device of claim 16, wherein said means for conveying further comprises a tapered portion extending from said blunt canula, said tapered portion having an interior through which a fluid can pass.

19. The fluid sampling device of claim 13, wherein said test strip adapter comprises a test strip housing having a test strip receptacle for receiving said first portion of said test strip therein.

20. The fluid sampling device of claim 19, wherein said test strip is secured within said test strip receptacle.

21. The fluid sampling device of claim 19, wherein said test strip is selectively removable from within said test strip receptacle.

22. The fluid sampling device of claim 13, wherein said test strip adapter is configured to be inserted into the sample port to access a fluid supply, and wherein said test strip adapter is configured to convey a fluid from the sample port to said test strip while said test strip adapter is inserted in said sample port.

23. A fluid sampling device configured to obtain a fluid sample from a sample port associated with a patient and directly convey information about the fluid sample to an analysis device associated with the fluid sampling device, the fluid sampling device comprising:

means for detecting at least one property of the fluid sample;

means for conveying the at least one property to the analysis device; and

means for communicating a fluid sample directly from the sample port to said means for detecting while said means for communicating is simultaneously associated with the sample port and said means for detecting.

24. The fluid sampling device of claim 23, wherein said means for detecting comprises electrical leads, an absorbent material, a reagent, or a combination thereof.

25. The fluid sampling device of claim 24, wherein said electrical leads are adapted to detect a resistance, impedance, or capacitance of the fluid sample.

26. The fluid sampling device of claim 23, wherein said means for conveying comprises electrical leads adapted to communicate the at least one property of the fluid sample to the analysis device.

27. The fluid sampling device of claim 23, wherein said means for detecting are at least partially disposed within a housing.

28. The fluid sampling device of claim 23, wherein said means for detecting and means for conveying comprise the same means.

29. The fluid sampling device of claim 23, wherein said means for communicating comprises a lumen extending through a blunt canula.

30. The fluid sampling device of claim 23, wherein said means for detecting can be selectively associated with said means for communicating.

31. A fluid sampling system configured to receive a fluid sample from a patient and directly convey information about the fluid sample to an analysis device, the fluid sampling system comprising:

an intravenous tube in fluid communication with a patient's blood stream, the intravenous tube comprising a sample port;

a test strip adapted to i) detect at least one property of a fluid sample received by said test strip, and ii) convey the at least one property of the fluid sample to the analysis device; and

a test strip adapter associated with said test strip, said test strip adapter being configured to transfer the fluid sample from said sample port directly to said test strip while said test strip is associated with said test strip adapter and said test strip adapter is associated with said sample port, said test strip adapter comprising:

a test strip housing having a first end and a second end, said first end of said test strip housing being adapted to receive a first end of said test strip therein, wherein the size and shape of said first end of said test strip housing generally corresponds to the size and shape of said first end of said test strip; and

a blunt canula extending from said second end of said test strip housing, said blunt canula having a lumen extending therethrough for communicating fluid from said sample port to said first end of said test strip.

32. The fluid sampling system of claim 31, wherein said test strip housing further comprises a groove adapted to assist in venting air from said test strip to enable said test strip to ready receive the fluid sample.

33. The fluid sampling system of claim 31, wherein a longitudinal axis of said blunt canula is generally parallel to a longitudinal axis of said test strip housing.

34. The fluid sampling system of claim 31, further comprising a fluid drawing device associated with said intravenous tube, said fluid drawing device being adapted to draw a fluid from a patient to said sample port.

35. The fluid sampling system of claim 34, wherein the fluid drawing device is adapted to create a negative pressure within said intravenous tube to draw the fluid from the patient.

36. The fluid sampling system of claim 31, further comprising an analysis device for analyzing the at least one property of the fluid sample, wherein said analysis device is adapted to receive said second end of said test strip while said first end of said test strip is positioned within said test strip housing.

37. The fluid sampling system of claim 36, wherein said analysis device comprises a glucometer.

38. The fluid sampling system of claim 36, wherein said analysis device is adapted to analyze at least one of a resistance, an impedance, a capacitance, a luminescence, or a color change of the fluid sample.

39. A fluid sampling system configured to receive a fluid sample from a patient and directly convey information about the fluid sample to an analysis device, the fluid sampling system comprising:

an intravenous tube in fluid communication with a patient's blood stream, the intravenous tube comprising a sample port;

a test strip adapted to detect at least one property of a fluid sample obtained through said sample port and convey the at least one property to the analysis device; and

a test strip adapter having a first end and a second end, said first end being configured to receive a first portion of said test strip therein while allowing a second portion of said test strip to extend out of said test strip adapter, said second end of said test strip adapter being configured to be inserted into said sample port, said test strip

adapter being configured to communicate a fluid sample from said sample port directly to said test strip while said first portion of said test strip is within said first end of said test strip adapter and said second end of said test strip adapter is inserted with said sample port, and

an analysis device configured to receive said second portion of said test therein while said first portion of said test strip is within said first end of said test strip adapter, wherein said analysis device is adapted to analyze the at least one detected property of the fluid sample.

40. The fluid sampling system of claim 39, wherein said test strip adapter comprises:

a test strip housing being adapted to receive said first portion of said test strip therein; and

a blunt canula extending from said second end of said test strip housing, said blunt canula having a lumen extending therethrough for communicating fluid from said sample port to said test strip.

41. The fluid sampling system of claim 39, wherein said test strip is adapted to be simultaneously inserted within said analysis device and said test strip adapter, and wherein said second end of said test strip adapter is adapted to be inserted within said sample port while said test strip is simultaneously inserted within said analysis device and said test strip adapter.

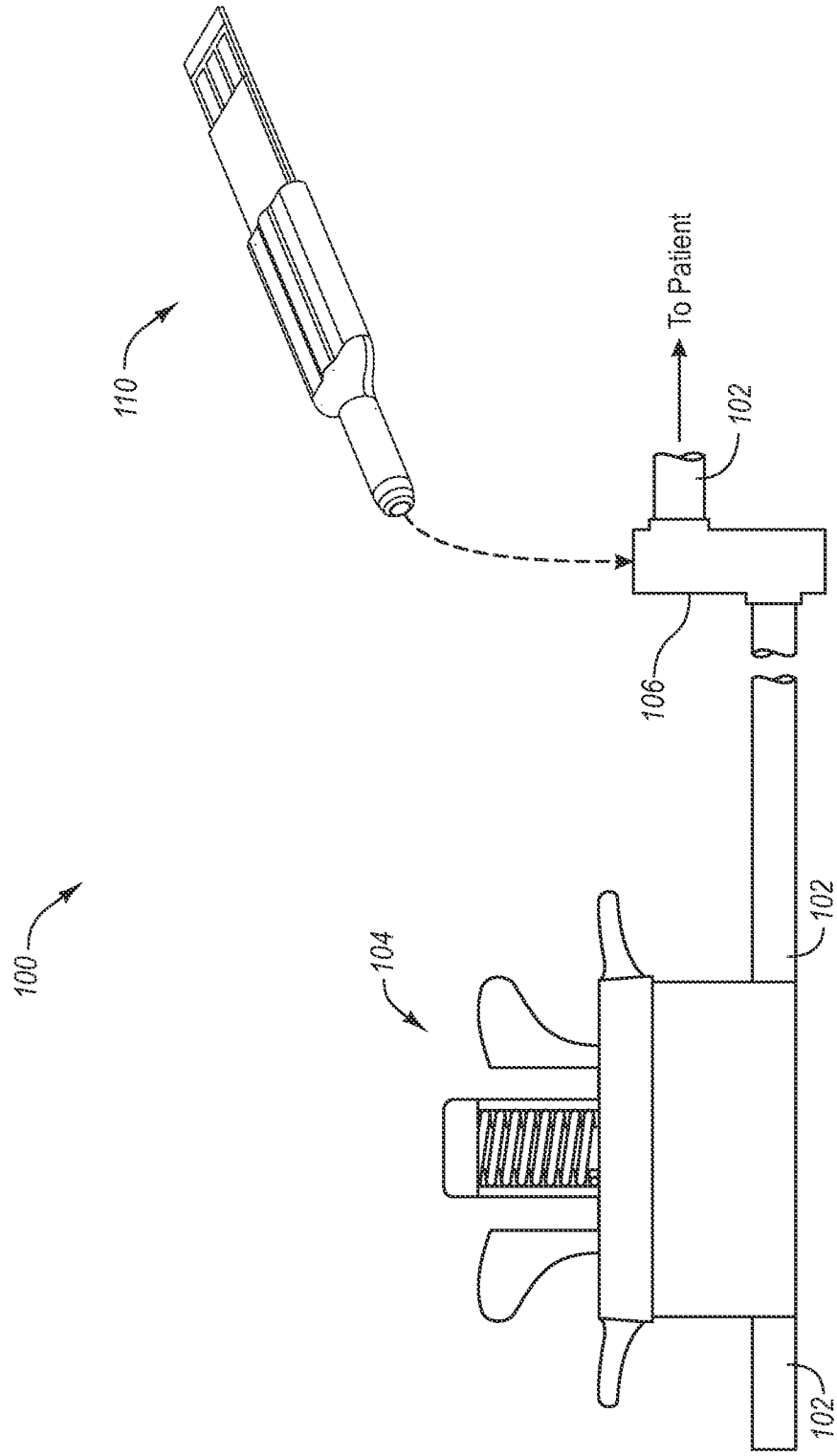


Fig. 1

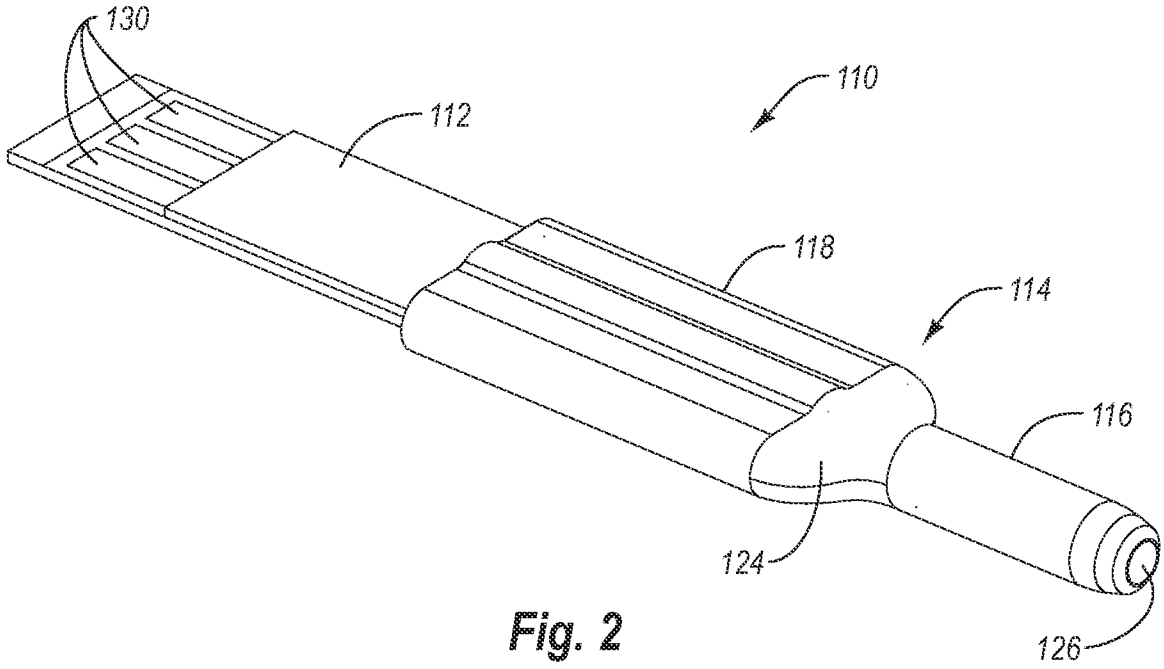

130
110
112
118
114
116
124
126

Fig. 2

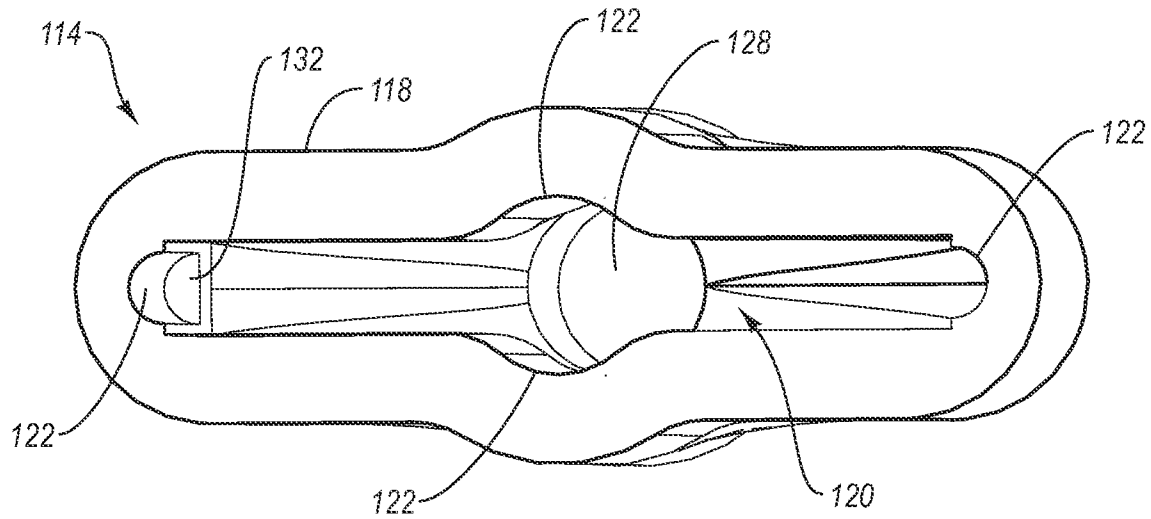

114
132
118
122
128
122
122
122
120

Fig. 3

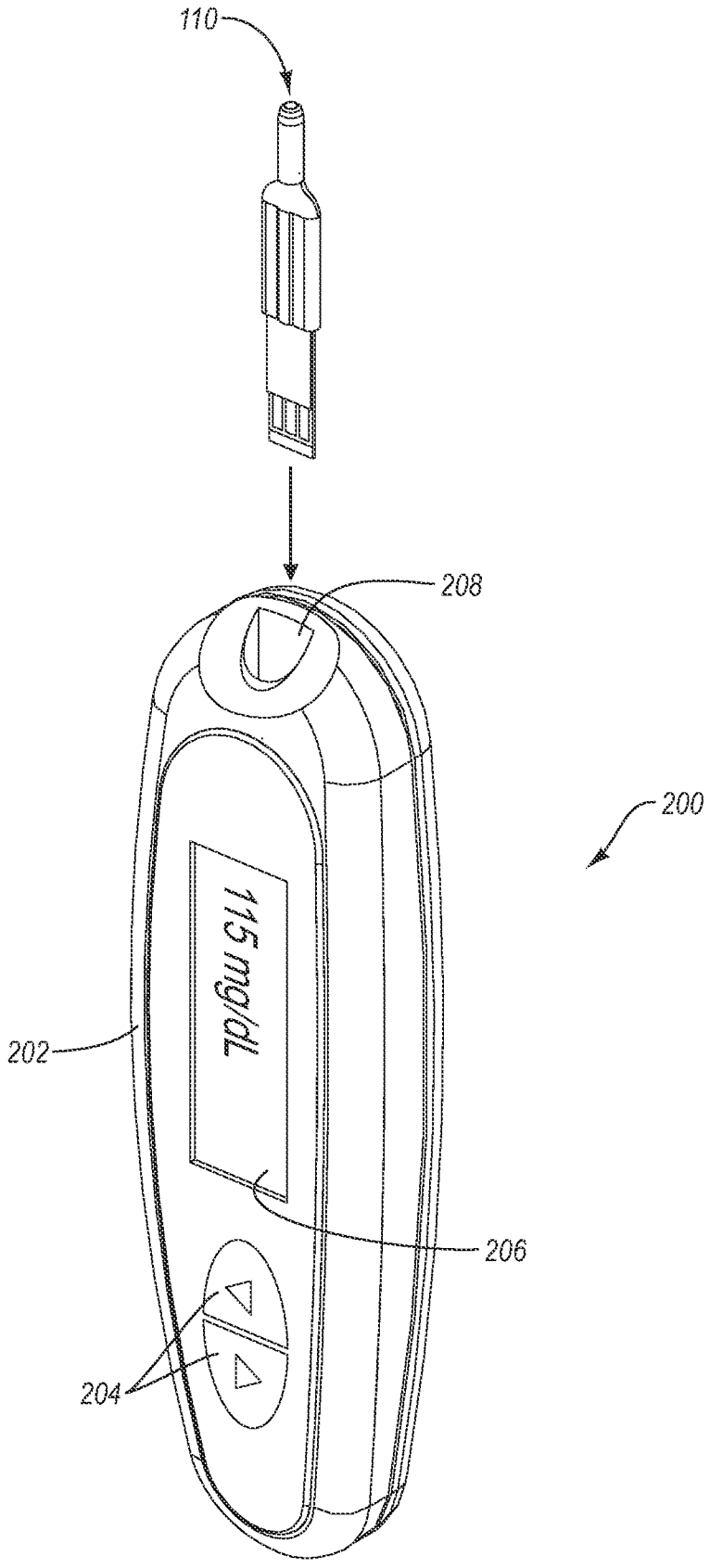


Fig. 4

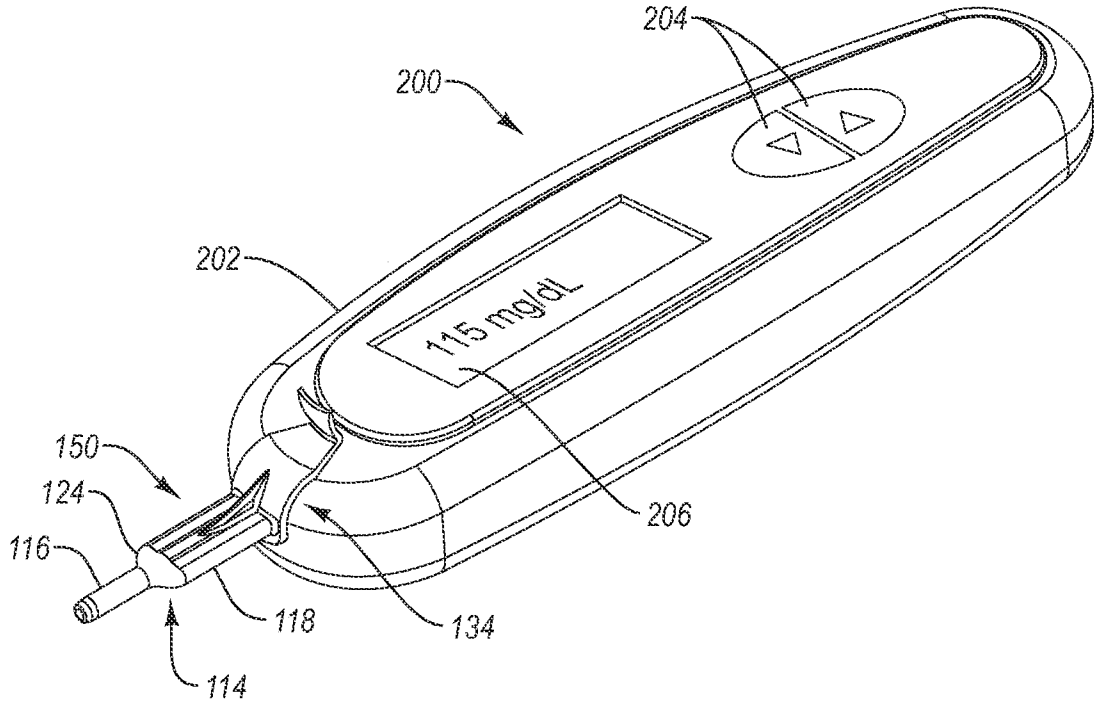

204
200
202
115 mg/dL
150
124
116
206
118
134
114

Fig. 5A

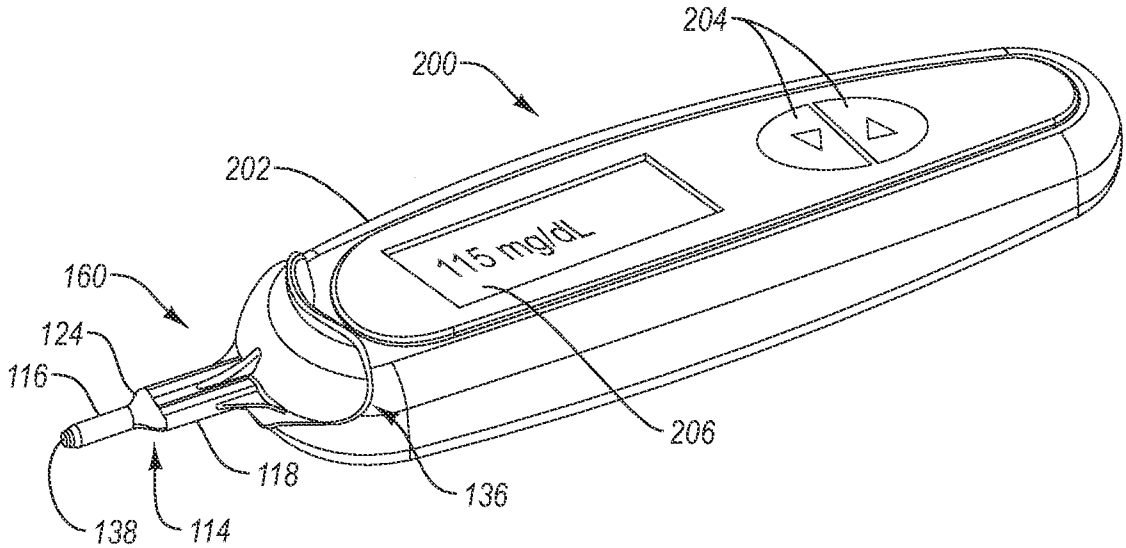

204
200
202
115 mg/dL
160
124
116
206
118
136
138
114

Fig. 5B

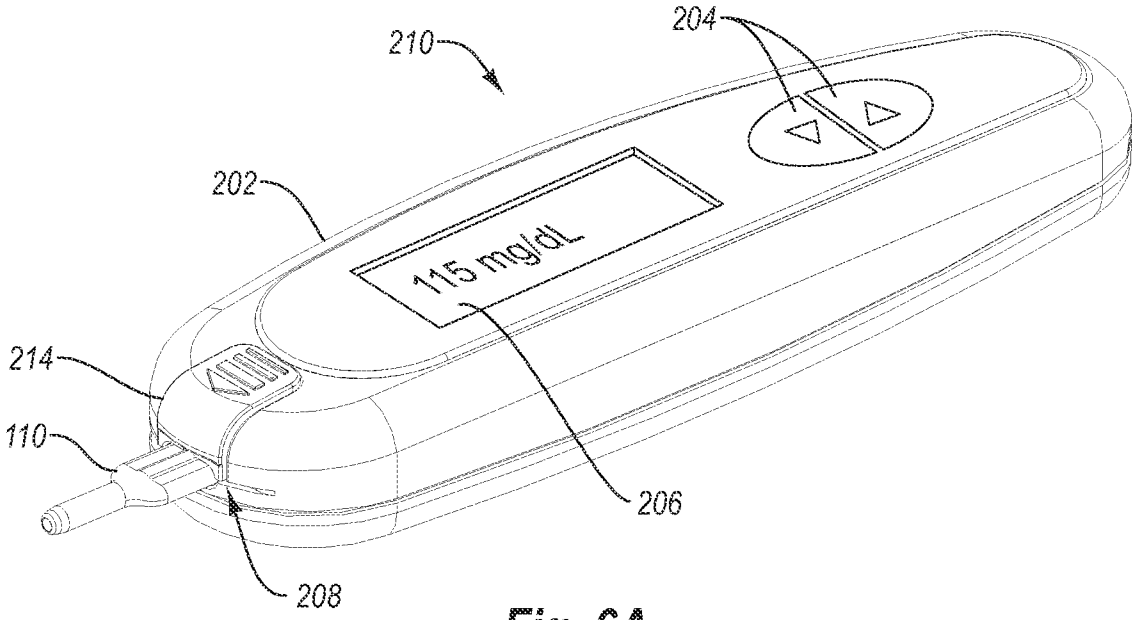

210
204
202
115 mg/dL
214
110
206
208

Fig. 6A

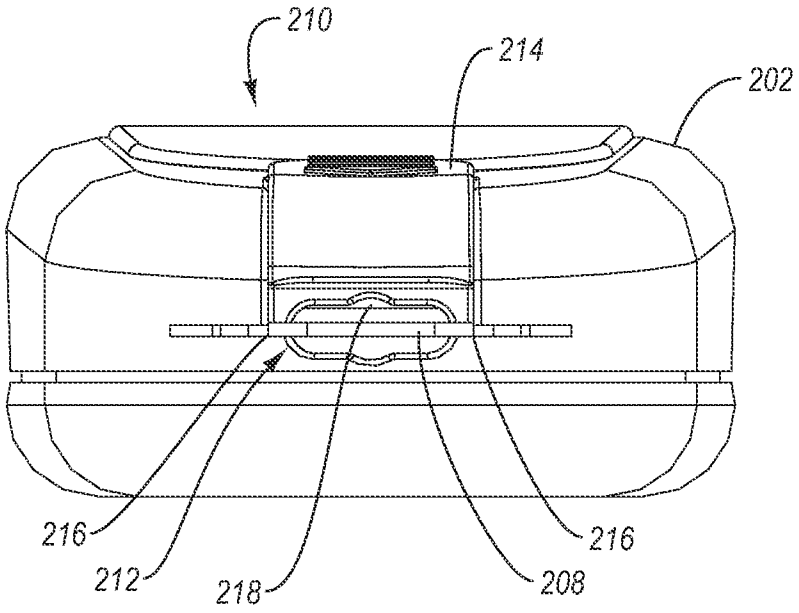

210
214
202
216
212
218
208
216

Fig. 6B

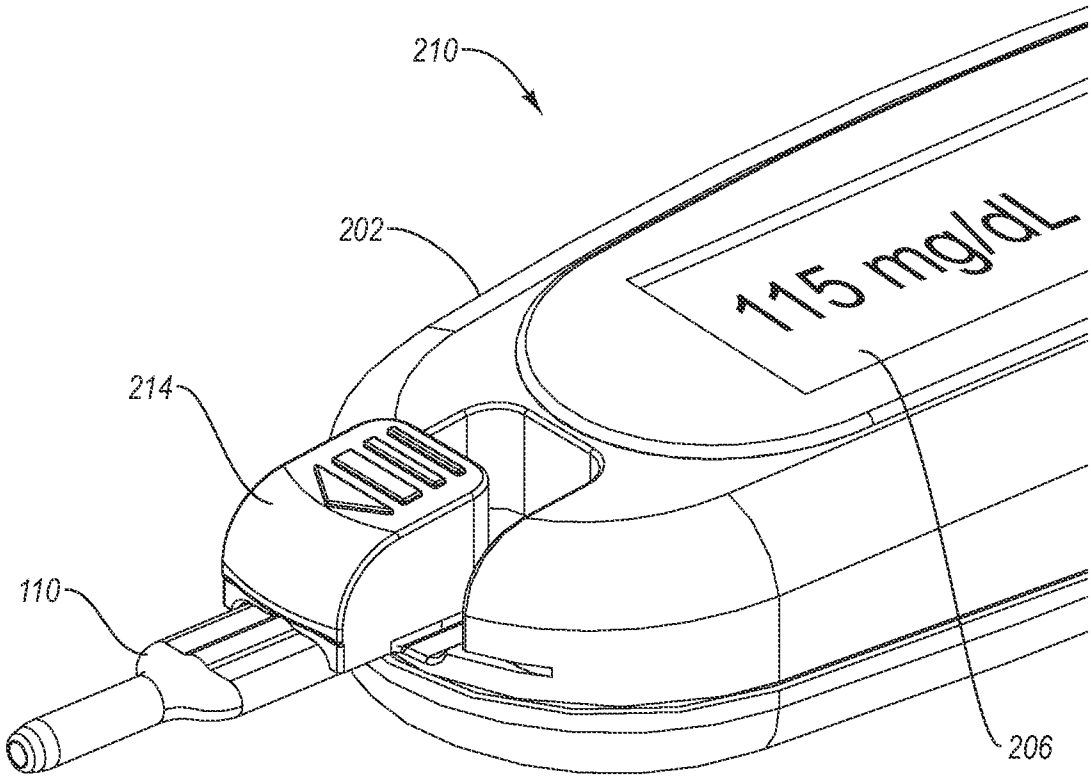


Fig. 6C

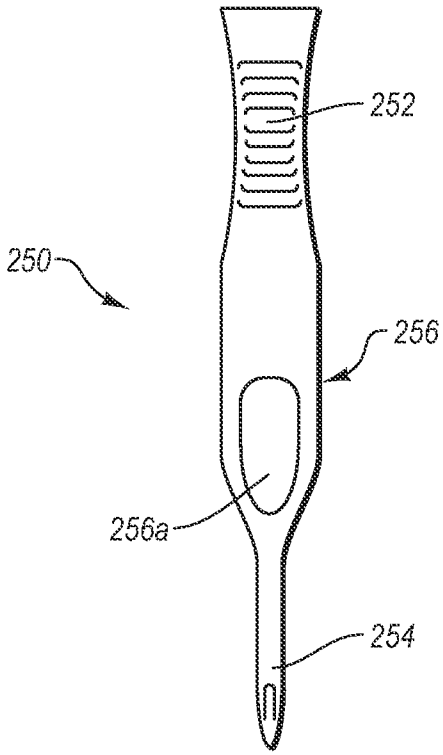


Fig. 7A

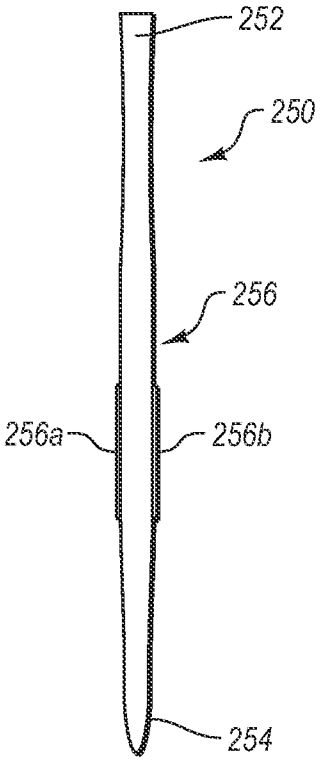


Fig. 7B

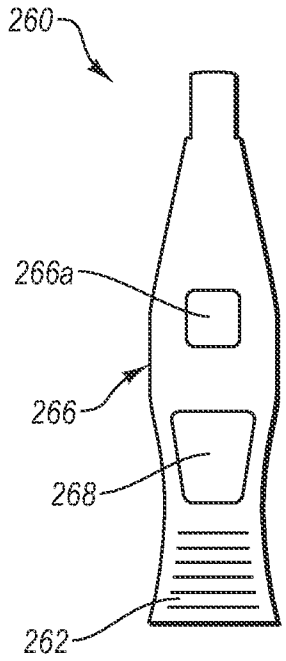


Fig. 8A

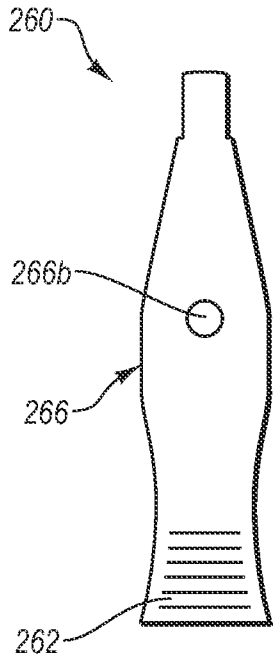


Fig. 8B

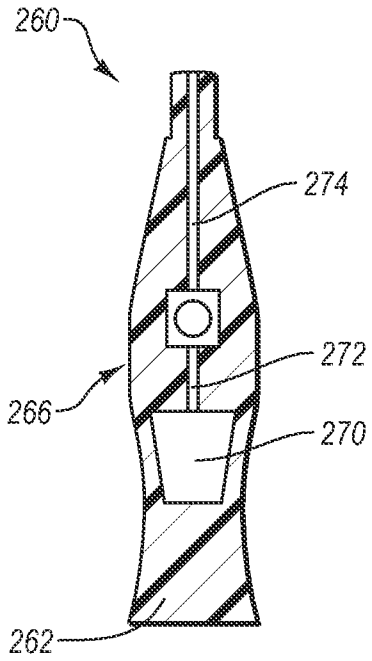


Fig. 8C

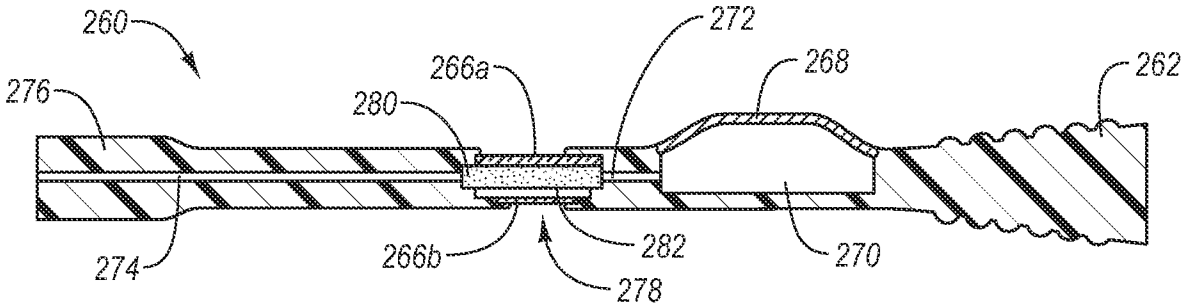


Fig. 8D

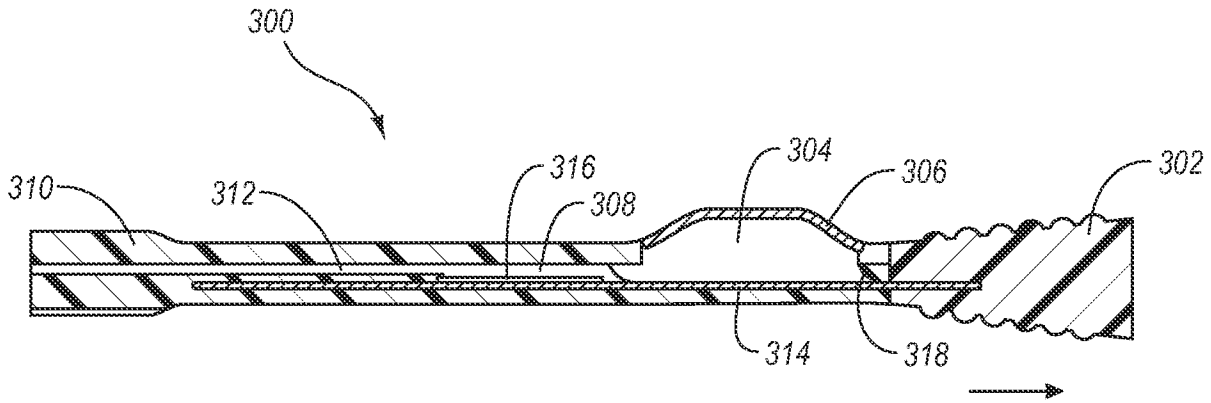


Fig. 10

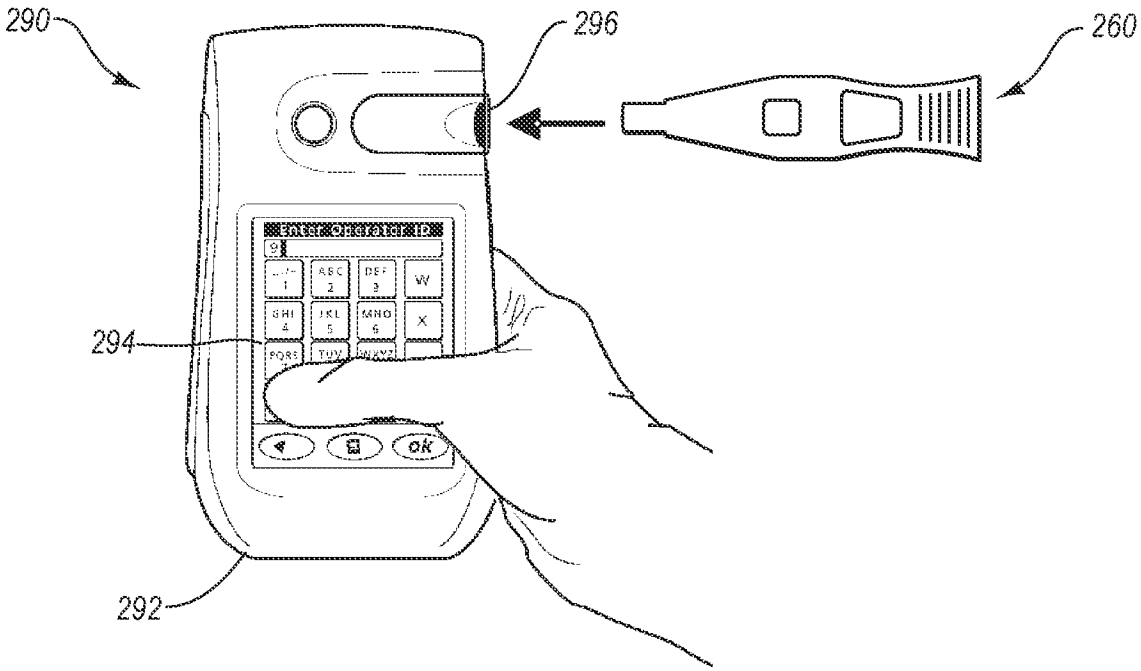


Fig. 9

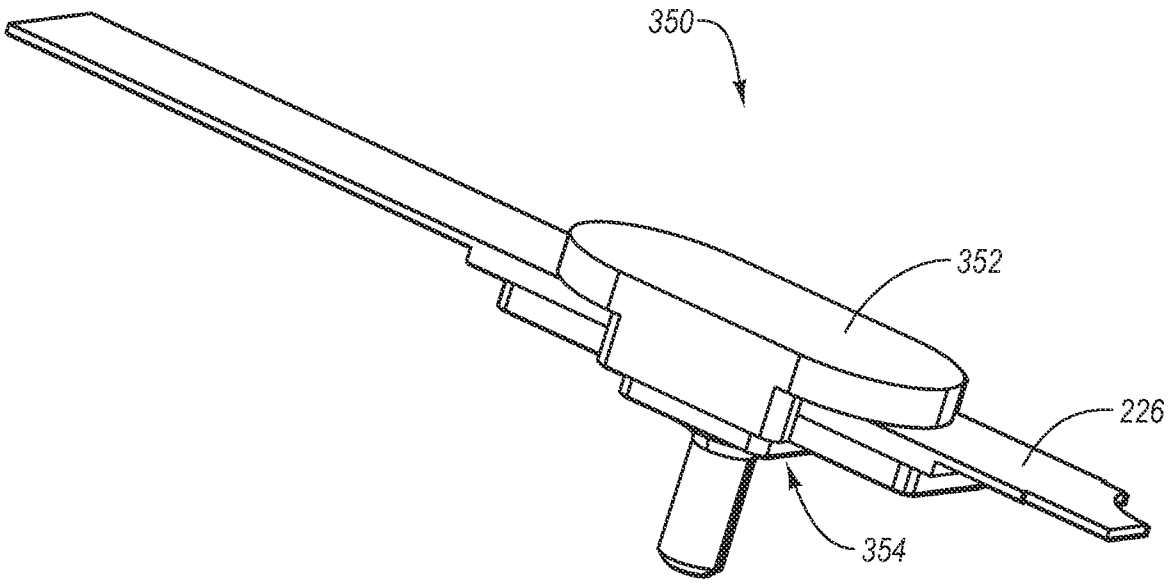


Fig. 11

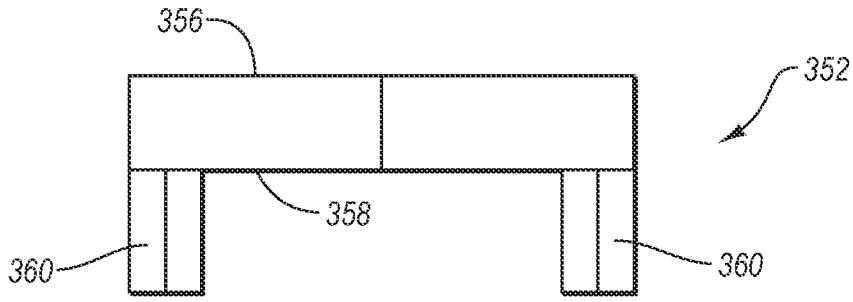


Fig. 12A

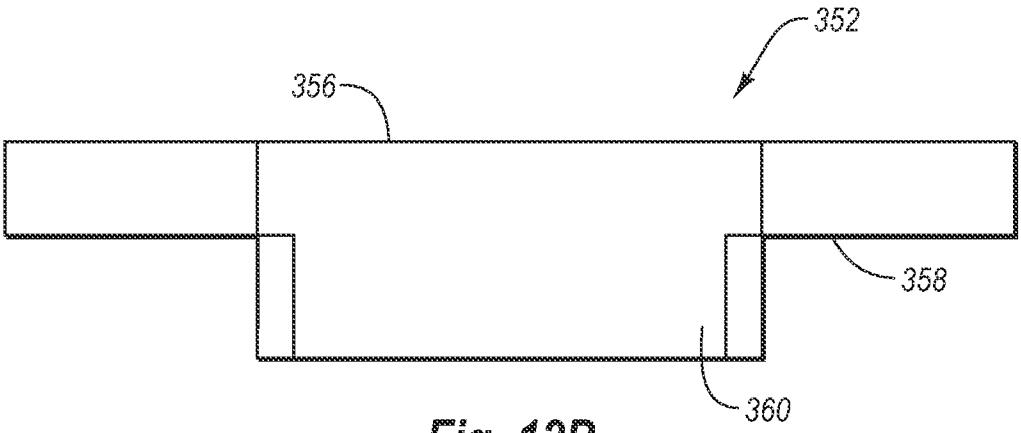


Fig. 12B

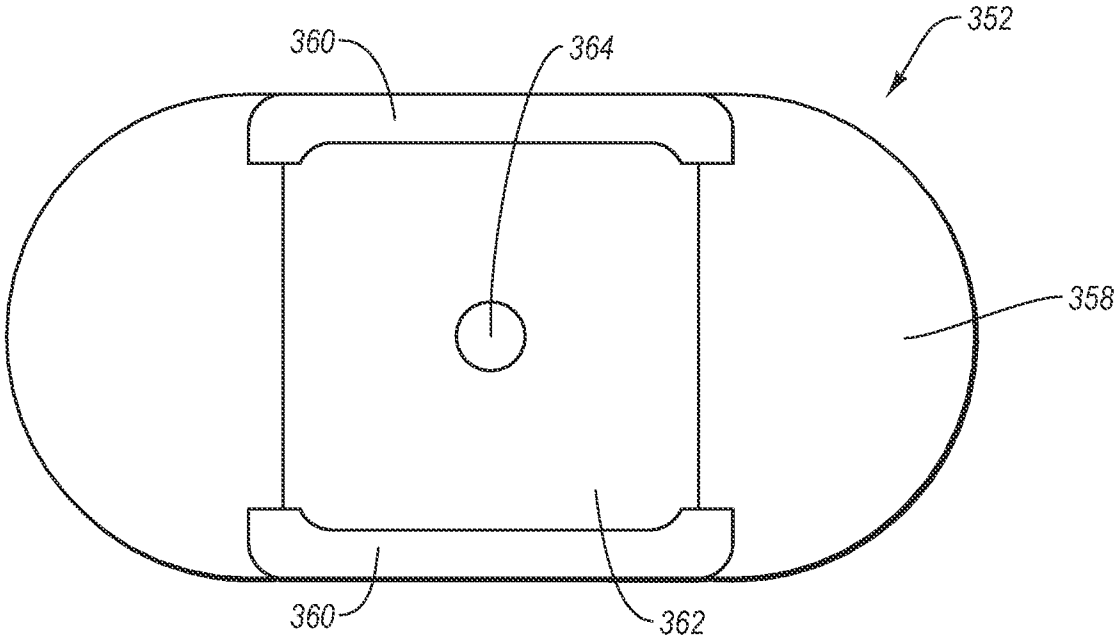


Fig. 12C

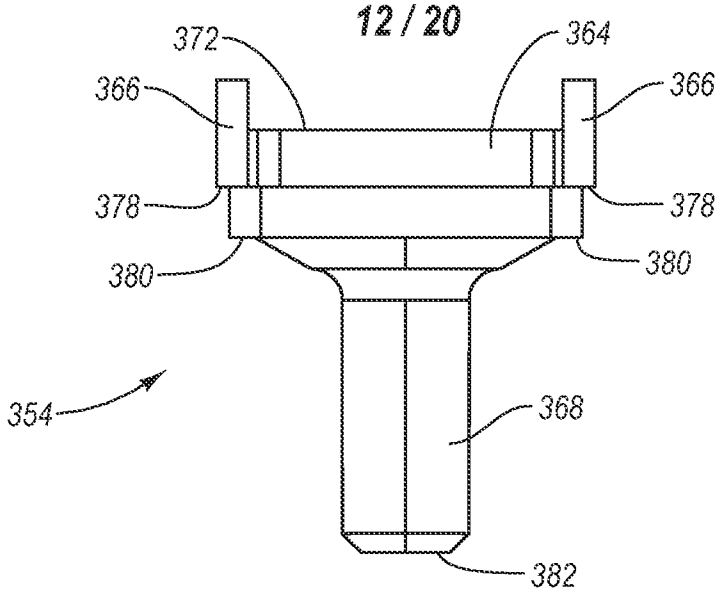


Fig. 13A

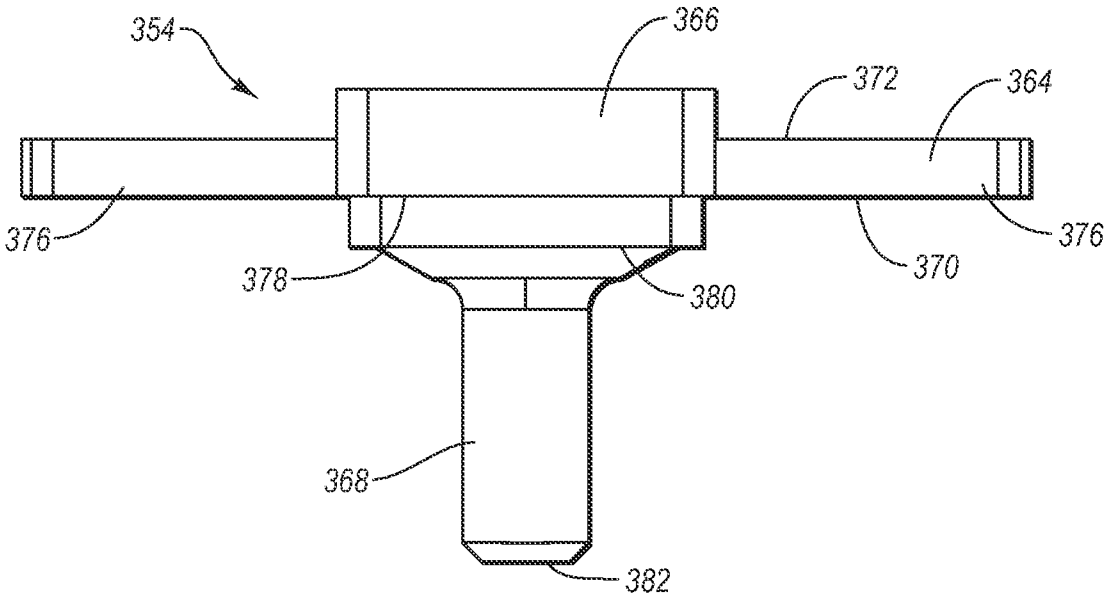


Fig. 13B

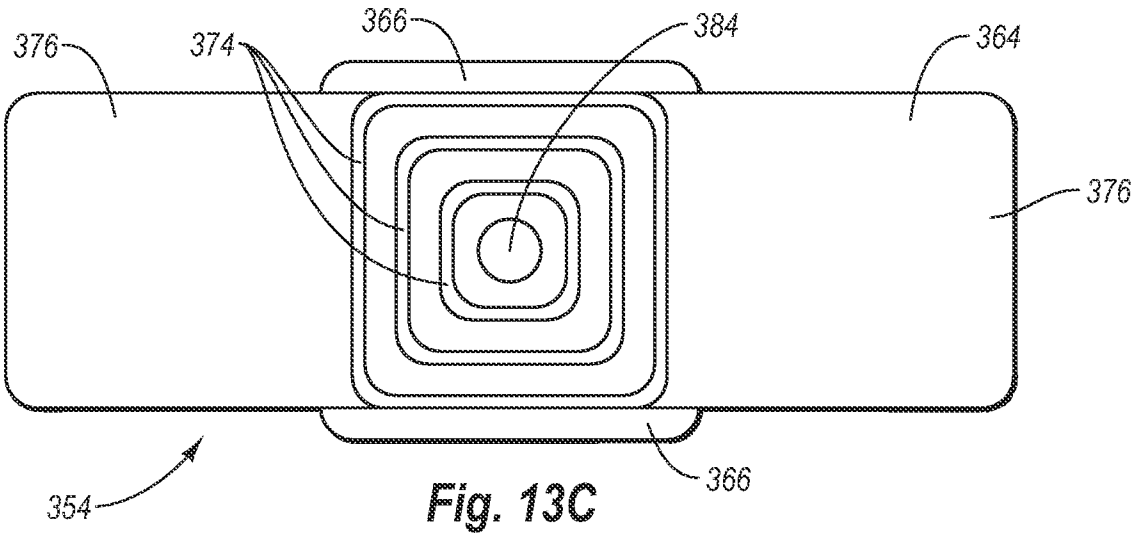


Fig. 13C

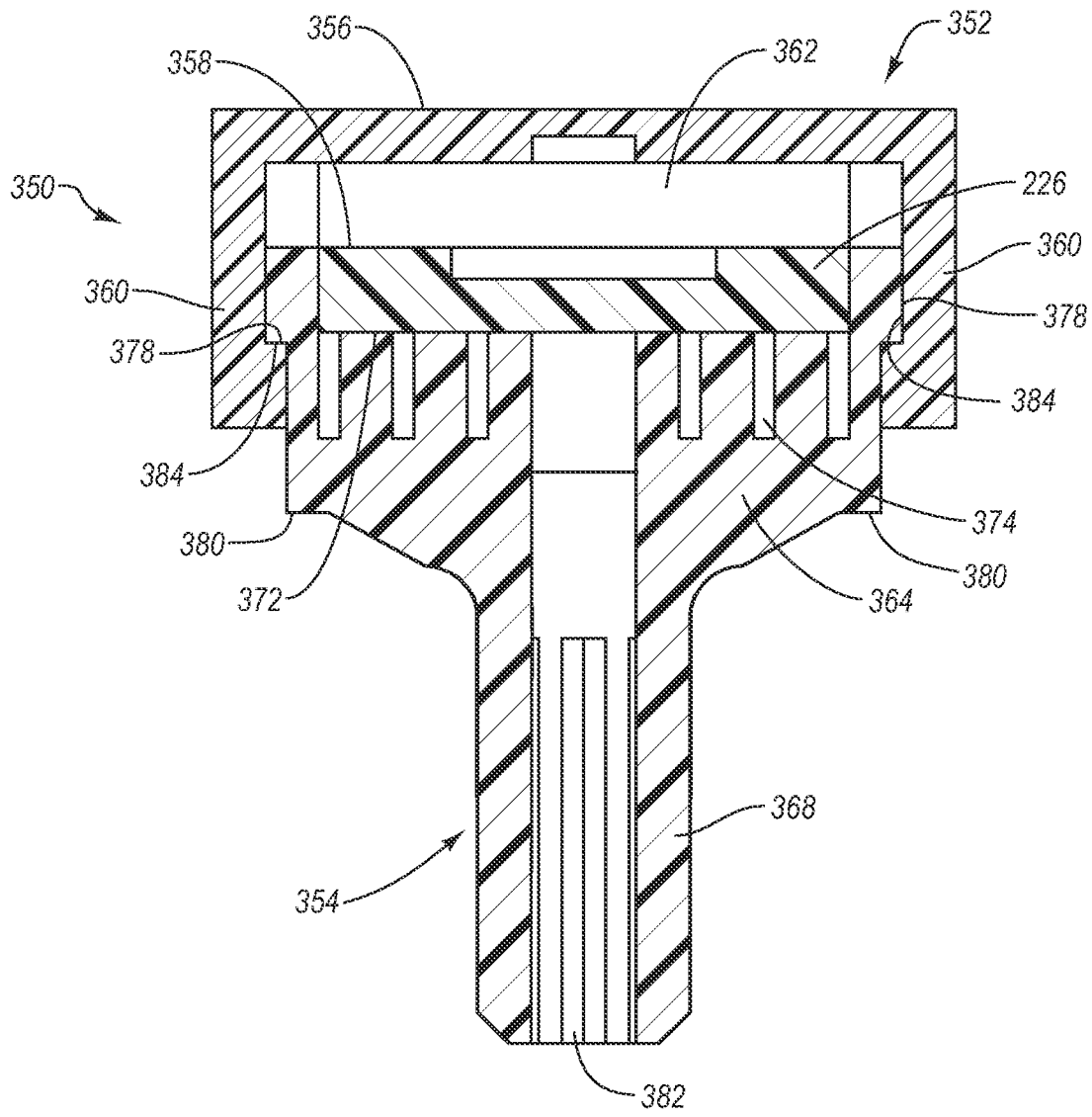

356
358
362
352
350
226
360
360
378
378
384
384
374
380
380
372
364
368
354
382

Fig. 14

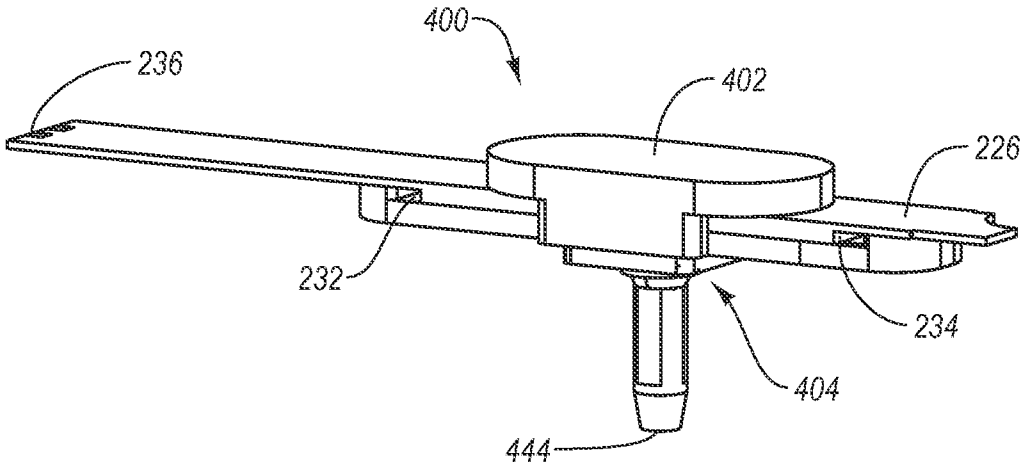


Fig. 15

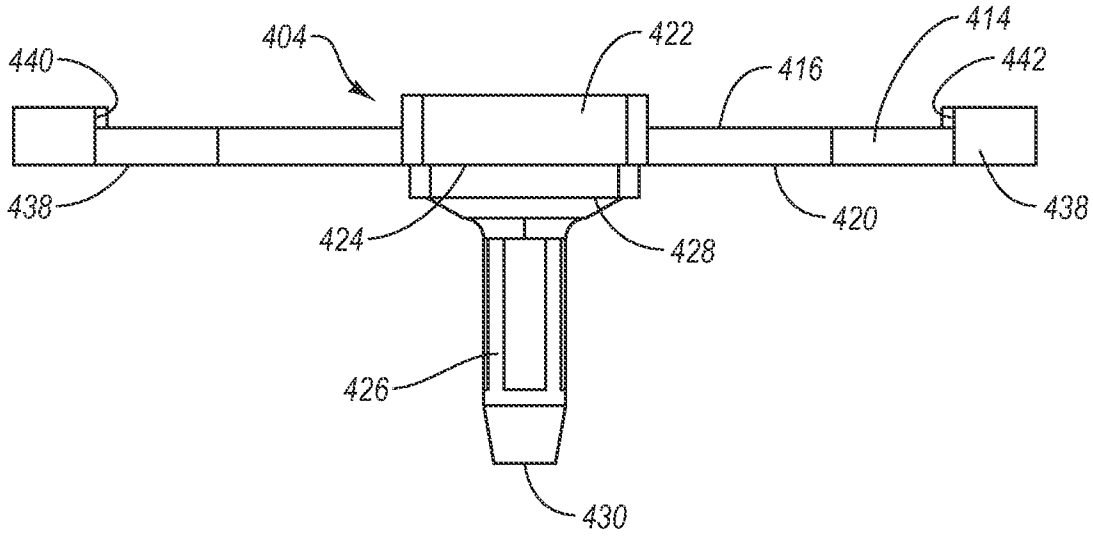


Fig. 16A

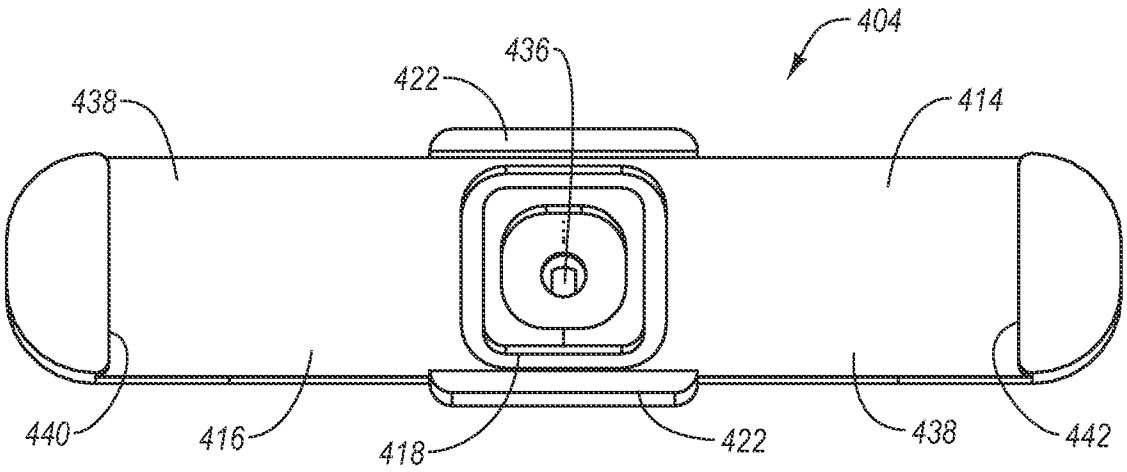


Fig. 16B

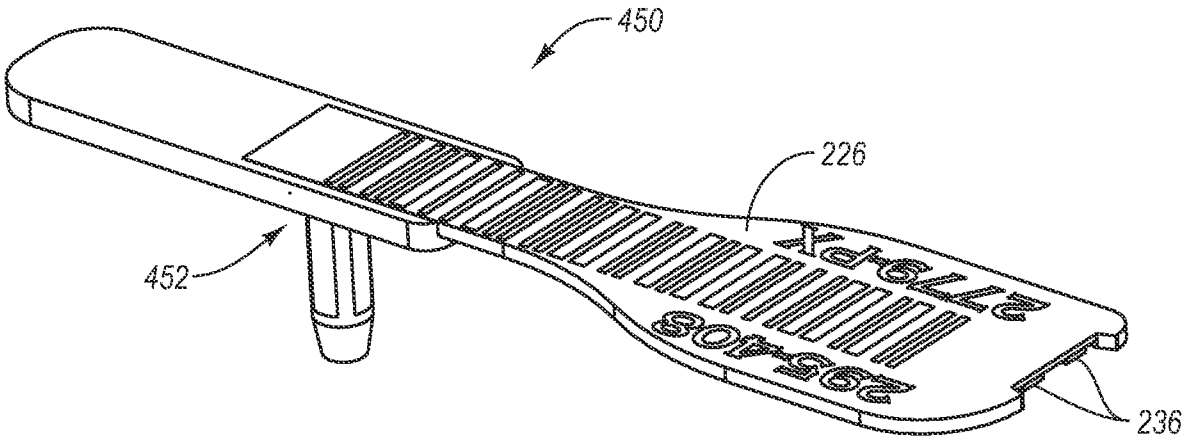


Fig. 17

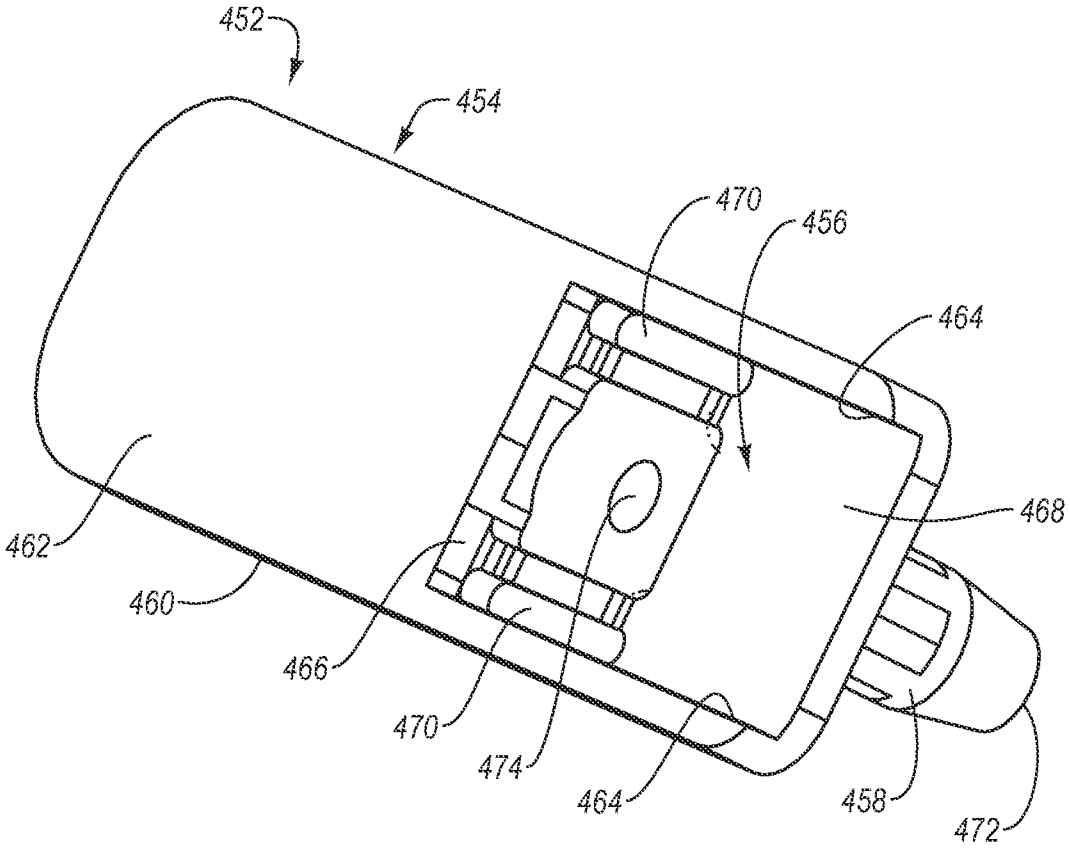

452
454
470
456
464
468
462
460
466
470
474
464
458
472

Fig. 18

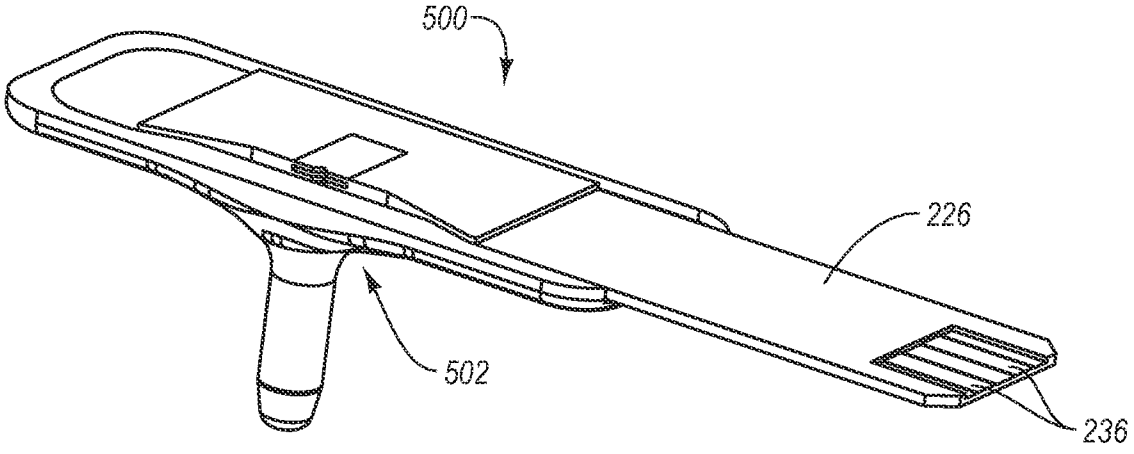

500
226
502
236

Fig. 19

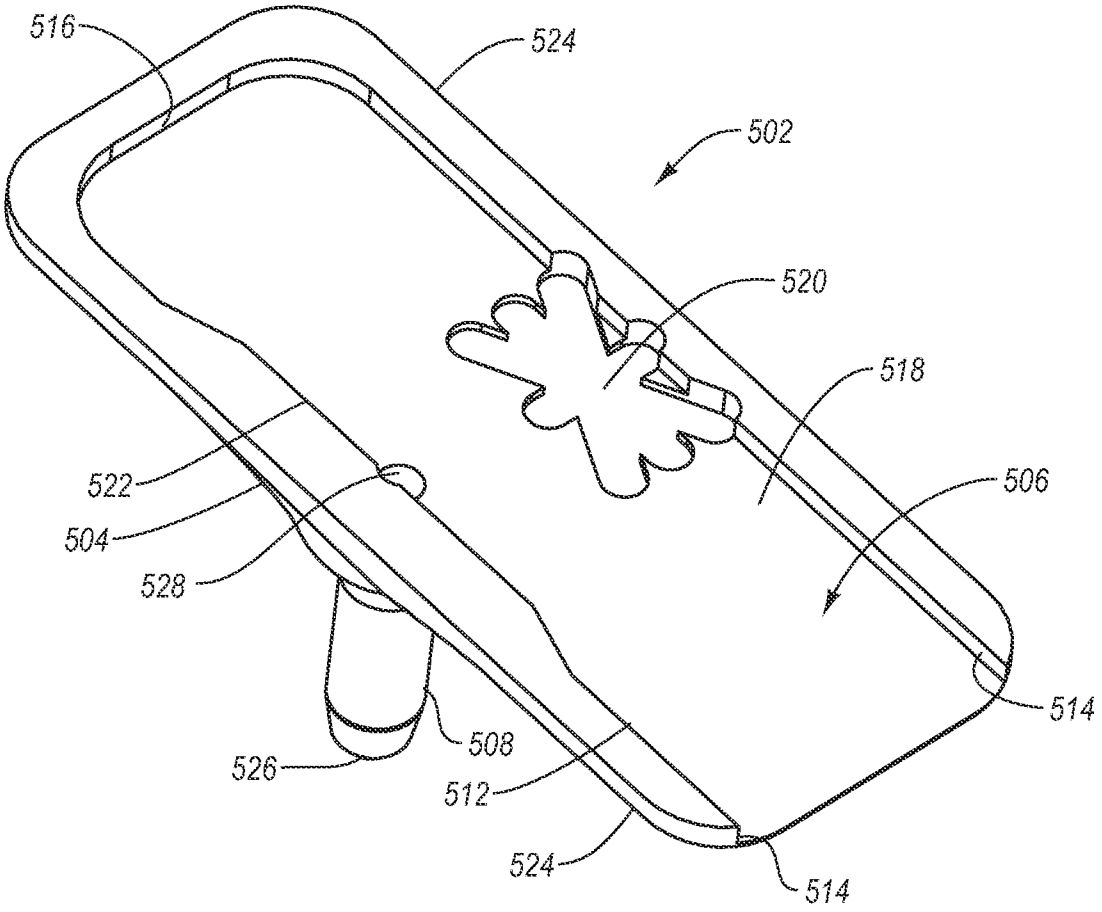


Fig. 20A

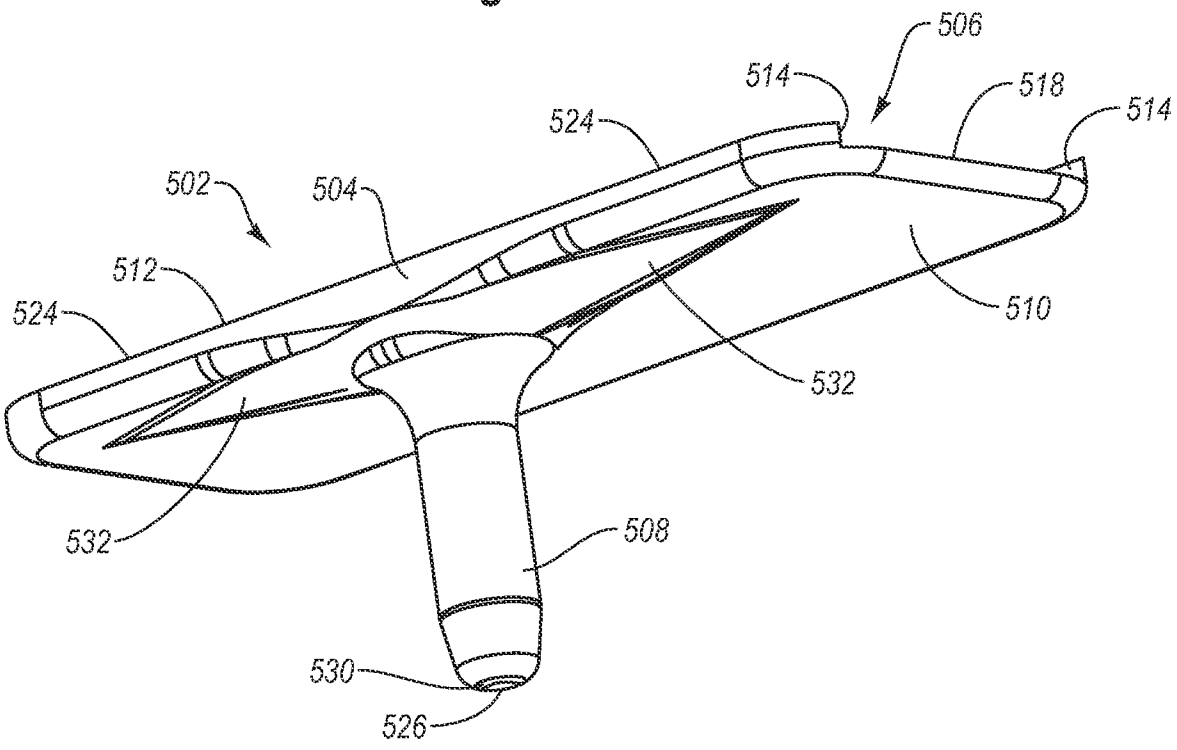


Fig. 20B

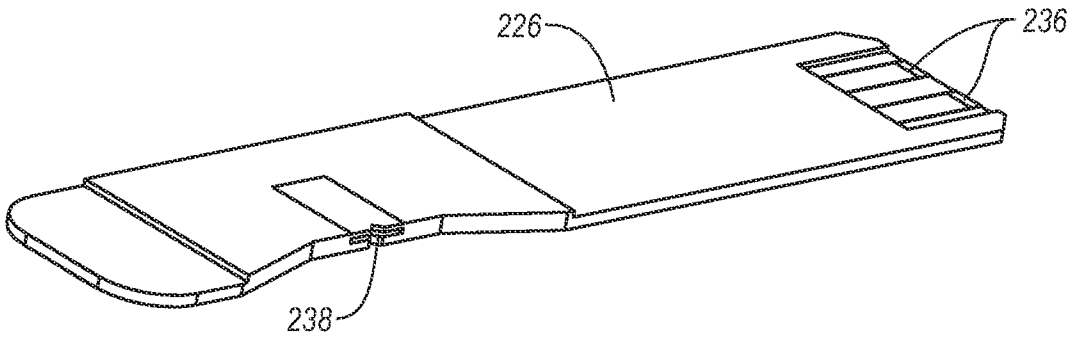


Fig. 21A

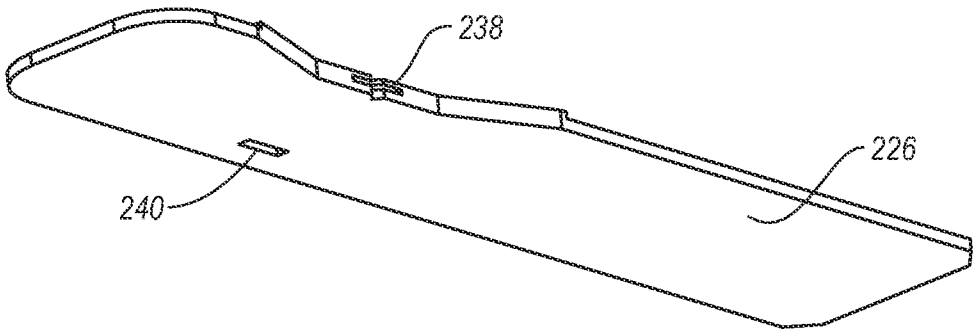


Fig. 21B

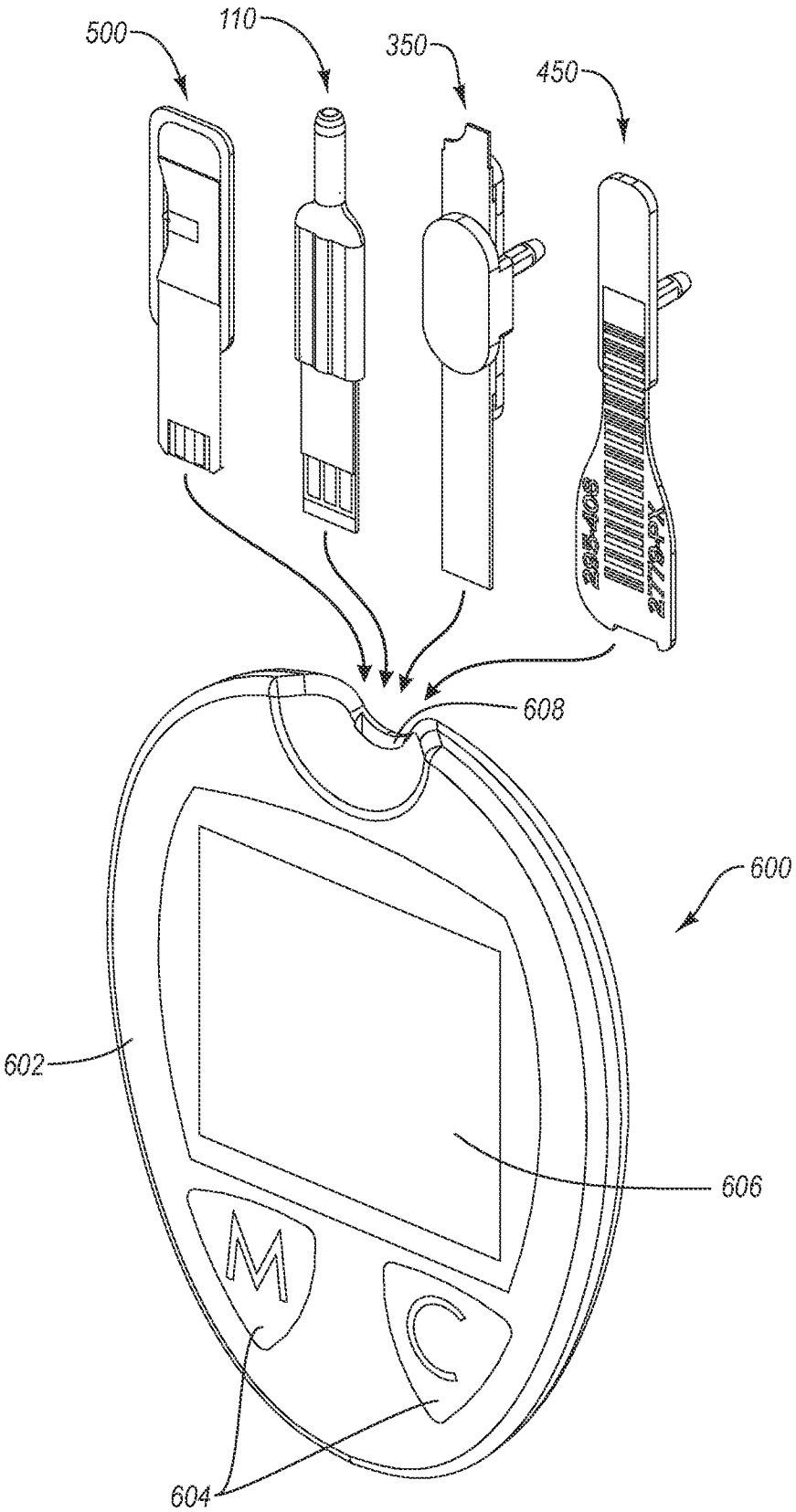


Fig. 22

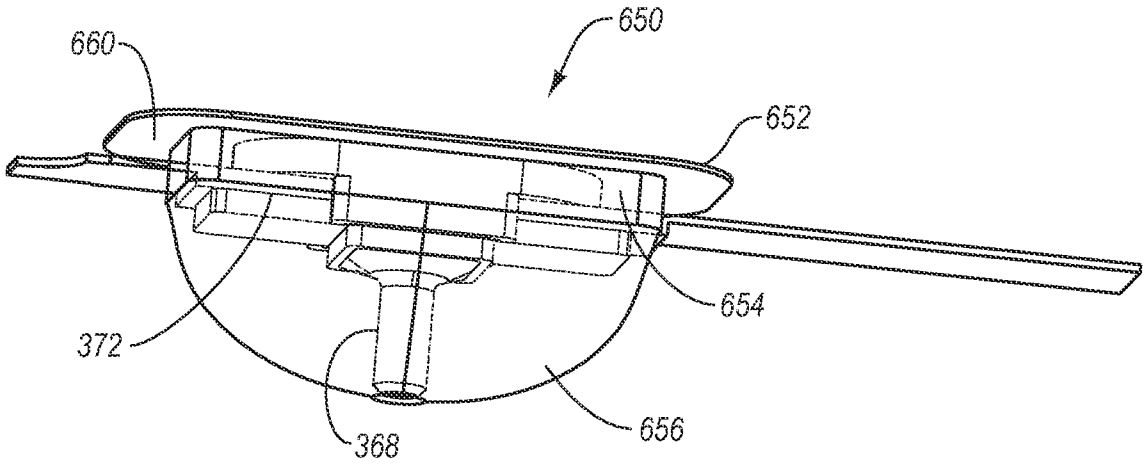


Fig. 23A

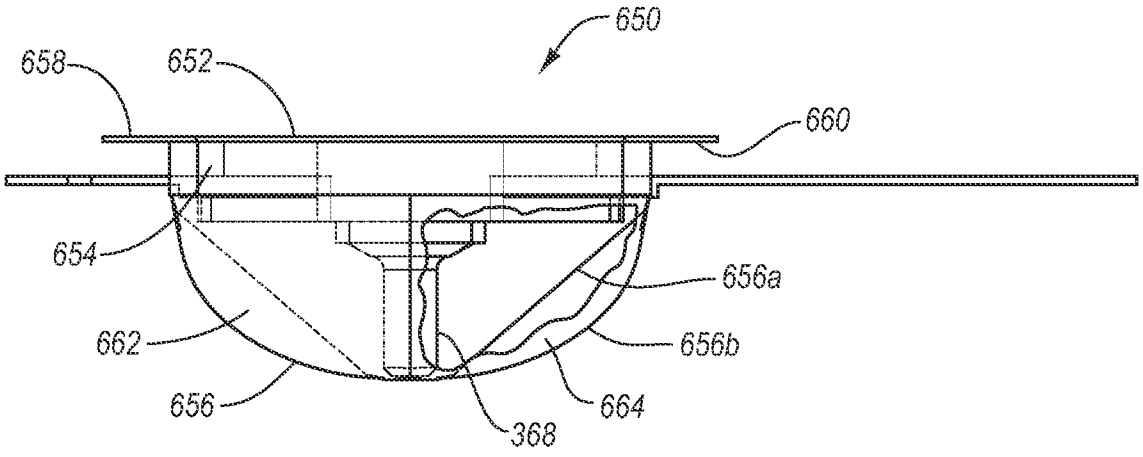


Fig. 23B