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- (54) Title: CLOSED BLOOD SAMPLING SYSTEM WITH ACCESS PORT FOR ANALYTE MEASUREMENT

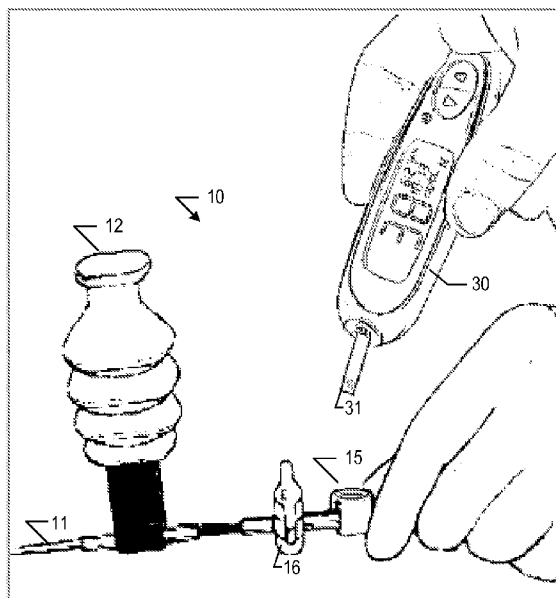


FIG. 4

(57) Abstract: Systems and methods are provided for allowing access to blood samples from a subject to facilitate analyte concentration measurements. The system includes a sampling line having an end configured for location in a subject's vasculature. The system also includes an access port located in fluid communication with the sampling line. The access port is configured for receiving at least a portion of the blood sample receiving end of an analyte test strip. Using the test strip, a user may determine an analyte concentration of the subject's blood.



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CLOSED BLOOD SAMPLING SYSTEM WITH ACCESS PORT FOR ANALYTE MEASUREMENT

TECHNICAL FIELD

[0001] A closed blood sampling system for sampling blood from a subject, wherein such system comprises an access port in fluid communication with the vasculature of a subject for insertion of an analyte test strip to perform an analyte measurement of the blood.

BACKGROUND

[0002] Various medical procedures and protocols require frequent blood analyte measurement of a patient. For example, some protocols may require measurement of an analyte, such as glucose concentration, every hour or so from a patient over an extended time. Frequent blood draws can be disruptive to the patient's care and can also unnecessarily waste patient blood.

[0003] For this reason, closed systems have been developed that allow for frequent blood draws and conservation of patient blood. These systems include needle or catheter access to a patient's vasculature and a sampling line comprising a vacuum device and an access port. The access port is configured to receive a syringe needle. The care giver draws blood from the patient using the vacuum device. The blood is drawn to the access port. The user can then draw blood using a syringe inserted into the access port. The remaining blood is then returned to the patient. The blood sample may either be provided to a laboratory for analysis or the blood from the syringe may be dropped on a conventional analyte strip (*e.g.*, a glucose strip) for analysis by a conventional analyte meter (*e.g.*, a conventional glucose meter).

[0004] Present methods for measuring the concentration of an analyte in a subject's blood, however, have a number of drawbacks. First, sending a blood sample for a laboratory for analysis is time consuming and not suitable for real-time or near-real-time analyte concentration monitoring. In addition, using a syringe for regularly drawing blood samples is inconvenient and requires the disposal of each syringe used. This method also

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does not efficiently conserve the patient's blood, due to the excess blood drawn by the syringe.

SUMMARY

[0005] Systems and methods are provided for allowing access to blood samples from a subject via a closed blood sampling system, such that an analyte concentration measure of the blood may be made with an analyte test strip. Using the test strip, a user may determine an analyte concentration of the subject's blood.

[0006] In one aspect, the present invention embraces a closed blood sampling system that includes (i) a sampling line having a first end configured for location in the vasculature of a subject, (ii) a vacuum device positioned in fluid communication with the sampling line, and (iii) a first access port in fluid communication with the sampling line. The first access port is located between the first end of the sampling line and the vacuum device. The first access portion is configured for (i) receiving at least a portion of a sample receiving end of an analyte test strip and (ii) introducing a blood sample from the subject to the at least a portion of the sample receiving end of the analyte test strip for analyte measurement.

[0007] In another aspect, the present invention embraces a closed blood sampling system that includes (i) a sampling line having a first end configured for location in the vasculature of a subject and a second end, (ii) a first access port in fluid communication with the sampling line, and (iii) a second access port in fluid communication with the sampling line. The first access portion is configured for (i) receiving at least a portion of a sample receiving end of an analyte test strip and (ii) introducing a blood sample from the subject to the at least a portion of the sample receiving end of the analyte test strip for analyte measurement. The second access port is located between the first access port and the second end of the sampling line. The second access port is configured for receiving a vacuum device.

[0008] In a further aspect, the present invention embraces a method for measuring an analyte in a subject's blood. First, a closed blood sampling system is provided. The closed blood sampling system includes (i) a sampling line having a first end configured for location in the vasculature of the subject, (ii) a vacuum device positioned in fluid

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communication with the sampling line, and (iii) a first access port in fluid communication with the sampling line. The first access port is located between the first end of the sampling line and the vacuum device. The first access portion is configured for (i) receiving at least a portion of a sample receiving end of an analyte test strip and (ii) introducing a blood sample from the subject to the at least a portion of the sample receiving end of the analyte test strip for analyte measurement. Next, the first end of the sampling line is inserted into the vasculature of the subject. Then a vacuum pressure is applied with the vacuum device to thereby draw blood from the subject to the location of the first access port. At least a portion of a sample receiving end of an analyte test strip is inserted into the first access port to expose at least a portion of the sample receiving end of the analyte test strip to the subject's blood. Finally, a blood analyte concentration of the subject's blood is determined using the analyte test strip.

BRIEF DESCRIPTION OF THE DRAWINGS

[0009] Having thus described embodiments of the system in general terms, reference will now be made to the accompanying drawings, where:

[0010] FIG. 1 is a perspective view of an exemplary closed blood sampling system in accordance with the present invention;

[0011] FIGs. 2A and 2B are cross-sectional views of an exemplary access port in accordance with the present invention;

[0012] FIG. 3 is a perspective view of another exemplary closed blood sampling system in accordance with the present invention; and

[0013] FIG. 4 is perspective view of an analyte measurement device being used in conjunction with a closed blood sampling system in accordance with the present invention.

[0014] FIG. 5 is a flow chart for an exemplary method for measuring an analyte in a subject's blood in accordance with the present invention.

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DETAILED DESCRIPTION

[0015] Embodiments of the present system and methods now may be described more fully hereinafter with reference to the accompanying drawings, in which some, but not all, embodiments of the system are shown. Indeed, the system and methods may be embodied in many different forms and should not be construed as limited to the embodiments set forth herein; rather, these embodiments are provided so that this disclosure may satisfy applicable legal requirements. Like numbers refer to like elements throughout.

[0016] As used in the specification, and in the appended claims, the singular forms “a”, “an”, “the”, include plural referents unless the context clearly dictates otherwise. The term “comprising” and variations thereof as used herein is used synonymously with the term “including” and variations thereof and are open, non-limiting terms.

[0017] Blood, as used herein, should be construed broadly to include any body fluid with a tendency to occlude lumens of various body-access devices during sampling. The body access devices include blood access devices such as catheters, tubes, and stents.

[0018] Systems and methods are provided herein for allowing access to blood samples from a subject via a closed blood sampling system, such that an analyte concentration measure of the blood may be made. Generally, the system of the present invention includes an access port in fluid communication with a sampling line of the closed blood sampling system. The access port is configured to receive a test sampling end of an analyte test strip and place the analyte test strip in contact with subject blood in the sampling line. In this manner, a measurement of an analyte concentration in the blood can be determined via analysis of the analyte test strip. The analyte concentration determined from analysis of the analyte test strip may be used as an independent determination of the analyte concentration of the subject's blood.

[0019] Accordingly, in one aspect, the present invention embraces a closed blood sampling system for facilitating analyte measurements of a subject's blood. An exemplary closed blood sampling system 10 in accordance with the present invention is depicted in FIG. 1. The blood sampling system 10 typically includes a sampling line 11, a vacuum device 12, and an access port 15. The sampling line 11 includes a first end (*e.g.*, a proximal end) that is configured for location in the vasculature of a subject.

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[0020] The vacuum device 12 is in fluid communication with the sampling line 11. The vacuum device 12 is configured for drawing a blood sample from the subject and directing the blood sample to the access port 15. The vacuum device 12 is thus considered upstream of the first end of the sampling line 11. In this regard, the vacuum device 12 typically includes a pump 12a (*e.g.*, a hand pump or a rotating valve structure) for creating a suction force for drawing a blood sample from the subject. That said, the vacuum device 12 may be any device capable of drawing a blood sample from the subject and directing the blood sample to the access port 15. As depicted in FIG. 1, the vacuum device 12 may include a reservoir 13 for retaining a portion of a blood sample drawn from the patient. As depicted in FIG. 1, the vacuum device 12 is typically integrated with the closed blood sampling system 10.

[0021] The access port 15 is in fluid communication with the sampling line 11 and with the vacuum device 12. The access port 15 is positioned between the first end of the sampling line 11 and the vacuum device 12. In terms of blood sample flow, the access port 15 is positioned so that the vacuum device 12 can draw a blood sample from the subject and direct the blood sample to the access port 15. Accordingly, the access port 15 may be upstream of the first end of the sampling line 11 and downstream of the vacuum device 12.

[0022] The access port 15 is configured to provide access to fluid within the access port 15. As depicted in FIGs. 2A and 2B, the access port 15 typically includes a hollow bore 20 in fluid communication with the sampling line 11 and a sealing septum 21. The sealing septum 21 typically includes a resealable aperture 22 through which fluid within the access port 15 can be accessed. In this regard, the sealing septum 21 may have a first portion 21a and a second portion 21b with an aperture (*e.g.*, slit) therebetween. The first portion 21a and the second portion 21b typically join to form a mechanical seal to prevent leakage through the aperture 22. The septum 21 can be formed of a latex, silicone, urethane, or synthetic rubber material. Alternately, the septum 21 can be formed of a thermoplastic elastomer. The material used for the septum typically is non-toxic and sterilizable such as by means of radiation, steam, or Ethylene Oxide.

[0023] The access port 15 is typically configured to receive at least a portion of a sample receiving end of an analyte test strip (*e.g.*, a test strip used to measure glucose,

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cholesterol, proteins, uric acid, phenylalanine, ketones, or enzymes). The dimensions of the hollow bore, septum, and aperture are sized to receive the test strip. In this regard, the aperture typically has at least one dimension (*e.g.*, a length) of between about 5 millimeters and 10 millimeters for receiving the sample receiving end of an analyte test strip (*e.g.*, a glucose test strip). In some embodiments, this dimension may be at least about 6 millimeters. When a portion of a test strip is inserted into the access port 15, the outer surface of the sealing septum 21 (*e.g.*, the first portion 21a and the second portion 21b) mates with the test strip to form a mechanical seal to prevent leakage through the aperture 22.

[0024] In some alternative embodiments, the septum may not include an aperture but may be merely puncturable by a portion of a test strip, for example, a wicking portion of the strip. In this instance, the septum would have at least one dimension (*e.g.*, a length or a radius) of between about 5 millimeters and 10 millimeters for receiving sample receiving end of an analyte test strip. In some embodiments, this dimension may be at least about 6 millimeters.

[0025] Any commercially available strip can be adapted to the present device and methods. In one aspect, a low volume (*e.g.*, a few microliters, sub-microliters, or nanoliters), wicking-type analyte strip is used in conjunction with a low-volume access port to minimize the amount and duration of the blood need for the analyte strip. In other aspects, a custom strip, or portions of a commercial strip are customized, for the instant device and method. Thus, the depth of penetration of the portion of the strip can be very shallow (*e.g.*, a few microns or millimeters).

[0026] The access port 15 allows a user or caregiver to obtain a sample of a subject's blood for analyte concentration measurement. For example, the vacuum device 12 can be operated to draw a blood sample from the subject via the sampling line 11 such that blood is present at the access port 15. A sample receiving end of an analyte strip may then be introduced through the access port 15 to contact the subject's blood. The analyte test strip may then be used to determine a concentration of an analyte in the blood (*e.g.*, a blood glucose concentration).

[0027] As depicted in FIG. 1, the closed blood sampling system may include a shut off valve 16 located between the access port 15 and the vacuum device 12. The shut off valve

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16 may be used to maintain a blood sample at the access port 15 after a blood draw to facilitate blood sampling. In particular, the shut off valve 16 may be closed after the blood draw to maintain a vacuum and thereby the blood at the access port 15 for sampling. Closing the shut off valve 16 to maintain a vacuum may be particularly helpful if the vacuum device 12 is manually operated.

[0028] In an alternative embodiment, at least a portion of the vacuum device 12 may be removable from the closed blood sampling system 10. By way of an exemplary alternative embodiment depicted in FIG. 3, the closed blood sampling system 10 may include a vacuum-device access port 14 that is in fluid communication with the sampling line 11 and is configured for receiving a removable vacuum device 12. In a particular exemplary embodiment, the removable vacuum device 12 could be a syringe. The vacuum-device access port 14 typically includes a hollow bore and a sealing septum having a resealable aperture through which access to fluid within the second access port can be accessed. The aperture typically has at least one dimension of between about 0.1 millimeter and 5 millimeters for receiving a portion of the removable vacuum device (*e.g.*, for receiving a syringe needle or syringe tip). The septum may not include an aperture and instead may be puncturable, in which case the septum may have a dimension of between about 0.1 millimeter and 5 millimeters for receiving a syringe needle. The septum can be formed of a latex, silicone, urethane, or synthetic rubber material. Alternately, the septum can be formed of a thermoplastic elastomer. The material used for the septum typically is non-toxic and sterilizable such as by means of alcohol swabbing, peroxide vapor, radiation, steam, UV, or Ethylene Oxide. The vacuum-device access port may include a luer for connecting the second access port to a syringe or other form of vacuum device.

[0029] In another aspect, the present invention embraces a method for measuring an analyte in a subject's blood. In this regard, FIG. 5 depicts an exemplary method 50 for measuring an analyte in a subject's blood. First, as shown in step 51, a closed blood sampling system 10 as described herein is provided. Next, as shown in step 52, the first end of the sampling line 11 is inserted into the vasculature of a subject. As shown in step 53, a vacuum pressure is then applied with the vacuum device 12 to thereby draw blood from the subject to the location of the access port 15. If the closed blood sampling

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system 10 includes a shut off valve 16, the shut off valve 16 may then be closed to maintain a vacuum and, thus, ensure that blood is at the access port 15 for sampling. As shown in step 54 and as depicted in FIG. 4, at least a portion of a sample receiving end of an analyte test strip 31 is then inserted into the access port 15 to expose at least a portion of the sample receiving end of the analyte test strip 31 to the subject's blood. Finally, as shown in step 55, a blood analyte concentration of the subject's blood is determined using the analyte test strip 31. For example, the opposite end of the test strip 31 may be inserted into an analyte measurement device 30 for determining a concentration of an analyte (*e.g.*, blood glucose).

[0030] The results of the analyte measurement from the test strip can be used in various ways. In some embodiments, the results can be used as an independent verification of current analyte concentration. In other embodiments, the results may be used in conjunction with data from an alternative analyte monitoring system, such as a continuous analyte monitoring, for purposes of calibration, trend analysis, etc. of the alternative analyte monitoring system. As an example, embodiments of the invention may be used in conjunction with an interstitial fluid (IF) analyte sensor or an intravenous analyte sensor. By way of a particular example, in one embodiment, a method of the present invention may further comprise determining a blood analyte concentration of the subject's blood using an IF or intravenous analyte sensor. An offset value representing a difference between an analyte concentration determined from the analyte test strip and an analyte concentration determined from the analyte sensor could then be generated.

[0031] Where the analyte measurement device 30 and test strip 31 are considered of sufficient accuracy, the results from the test strip may be used as a data point for calibrating an analyte sensor based on the offset value. Alternatively, the test results and offset value may be used to compensate subsequent analyte concentration values determined from samples of the subject's blood using analyte test strips.

[0032] As an example of the latter scenario, one or more readings from an analyte measurement device 30 could be taken over time and compared with corresponding readings from an analyte monitoring system. This can be used to determine an accurate offset between the readings of the two devices, such that once the analyte monitoring system is removed from the subject, subsequent readings from the analyte measurement

device 30 can be applied to this offset to provide a more accurate analyte reading. In other words, in one stage of patient care an IF or intravenous analyte sensor may provide continuous analyte monitoring, whereas a closed blood sampling system as described herein may be used in conjunction with the analyte monitoring device 30 to provide analyte monitoring during another stage of patient care.

[0033] As another example, one or more readings from an analyte measurement device 30 could be taken over time and compared with corresponding readings from an analyte monitoring system. Trending information may be established indicating a drift by either the measurement device 30 or the analyte monitoring system.

[0034] Although many embodiments of the present system have just been described above, the present system may be embodied in many different forms and should not be construed as limited to the embodiments set forth herein; rather, these embodiments are provided so that this disclosure will satisfy applicable legal requirements. Also, it will be understood that, where possible, any of the advantages, features, functions, devices, and/or operational aspects of any of the embodiments of the present system described and/or contemplated herein may be included in any of the other embodiments of the present system described and/or contemplated herein, and/or vice versa.

[0035] While certain exemplary embodiments have been described and shown in the accompanying drawings, it is to be understood that such embodiments are merely illustrative of and not restrictive on the broad system, and that this system not be limited to the specific constructions and arrangements shown and described, since various other changes, combinations, omissions, modifications and substitutions, in addition to those set forth in the above paragraphs, are possible. Those skilled in the art will appreciate that various adaptations, modifications, and combinations of the just described embodiments can be configured without departing from the scope and spirit of the system. Therefore, it is to be understood that, within the scope of the appended claims, the system may be practiced other than as specifically described herein.

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WHAT IS CLAIMED IS:

1. A closed blood sampling system, comprising:
a sampling line comprising a first end configured for location in the vasculature of a subject;
a vacuum device positioned in fluid communication with said sampling line; and
a first access port located between the first end of said sampling line and said vacuum device, said first access port being in fluid communication with said sampling line, said first access port being configured for (i) receiving at least a portion of a sample receiving end of an analyte test strip and (ii) introducing a blood sample from the subject to the at least a portion of the sample receiving end of the analyte test strip for analyte measurement.
2. The system of claim 1, comprising a shut off valve positioned between said vacuum device and said first access port.
3. The system of claim 1, wherein said first access port comprises a septum comprising an aperture having at least one dimension of between about 5 millimeters and 10 millimeters for receiving the sample receiving end of an analyte test strip.
4. The system of claim 1, wherein said first access port comprises a septum comprising an aperture having at least one dimension of at least about 6 millimeters for receiving the sample receiving end of an analyte test strip.
5. The system of claim 1, wherein said first access port comprises a septum comprising a resealable aperture for receiving the sample receiving end of an analyte test strip.
6. The system of claim 1, wherein said first access port has a volume of between about one nanoliter and one milliliter.

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7. A closed blood sampling system, comprising:

a sampling line comprising a first end configured for location in the vasculature of a subject and a second end;

a first access port being in fluid communication with said sampling line, said first access port being configured for (i) receiving at least a portion of a sample receiving end of an analyte test strip and (ii) introducing a blood sample from the subject to the at least a portion of the sample receiving end of the analyte test strip for analyte measurement; and

a second access port located between said first access port and the second end of said sampling line, said second access port being in fluid communication with said sampling line, said second access port being configured for receiving a vacuum device.

8. The system of claim 7, wherein said second access port comprises a septum comprising an aperture having at least one dimension in the range of 0.1 to 5 millimeters for receiving a syringe.

9. The system of claim 7, wherein said second access port comprises a luer for connecting said second access port to a syringe.

10. The system of claim 7, comprising a shut off valve positioned between said first access port and said second access port.

11. The system of claim 7, wherein said first access port comprises a septum comprising an aperture having at least one dimension of between about 5 millimeters and 10 millimeters for receiving the sample receiving end of an analyte test strip.

12. The system of claim 7, wherein said first access port comprises a septum comprising an aperture having at least one dimension of at least about 6 millimeters for receiving the sample receiving end of an analyte test strip.

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13. The system of claim 7, wherein said first access port comprises a septum comprising a resealable aperture for receiving the sample receiving end of an analyte test strip.

14. The system of claim 7, wherein said first access port has a volume of between about one nanoliter and one milliliter.

15. A method for measuring an analyte in a subject's blood, comprising:
providing a closed blood sampling system comprising:

a sampling line comprising a first end configured for location in the vasculature of the subject;

a vacuum device positioned in fluid communication with the sampling line;
and

a first access port located between the first end of the sampling line and the vacuum device, the first access port being in fluid communication with the sampling line, the first access port being configured for (i) receiving at least a portion of a sample receiving end of an analyte test strip and (ii) introducing a blood sample from the subject to the at least a portion of the sample receiving end of the analyte test strip for analyte measurement;

inserting the first end of the sampling line into the vasculature of the subject;

applying a vacuum pressure with the vacuum device to thereby draw blood from the subject to the location of the first access port;

inserting at least a portion of a sample receiving end of an analyte test strip into the first access port to expose at least a portion of the sample receiving end of the analyte test strip to the subject's blood; and

determining a blood analyte concentration of the subject's blood using the analyte test strip.

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16. The method of claim 15, wherein:

the closed blood sampling system comprises a shut off valve positioned between the vacuum device and the first access port; and

the method further comprises closing the shut off valve after applying a vacuum pressure with the vacuum device to thereby draw blood from the subject to the location of the first access port.

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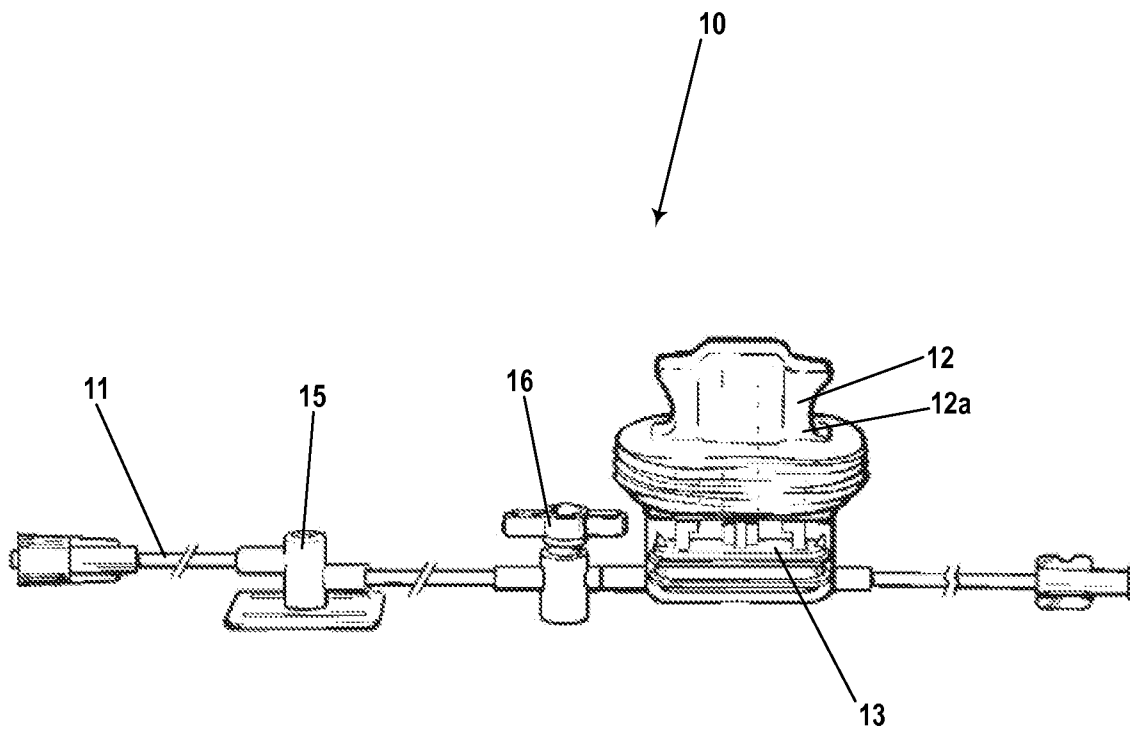


FIG. 1

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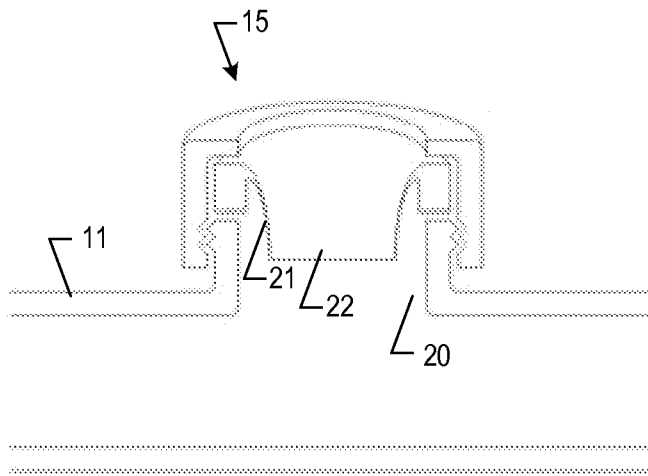


FIG. 2A

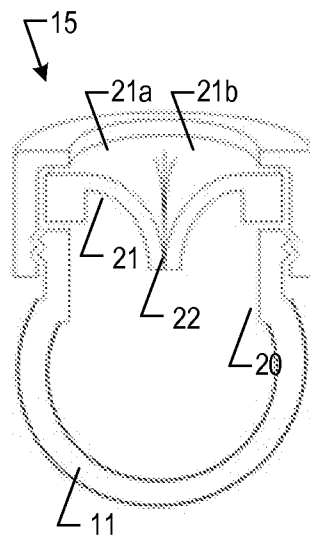


FIG. 2B

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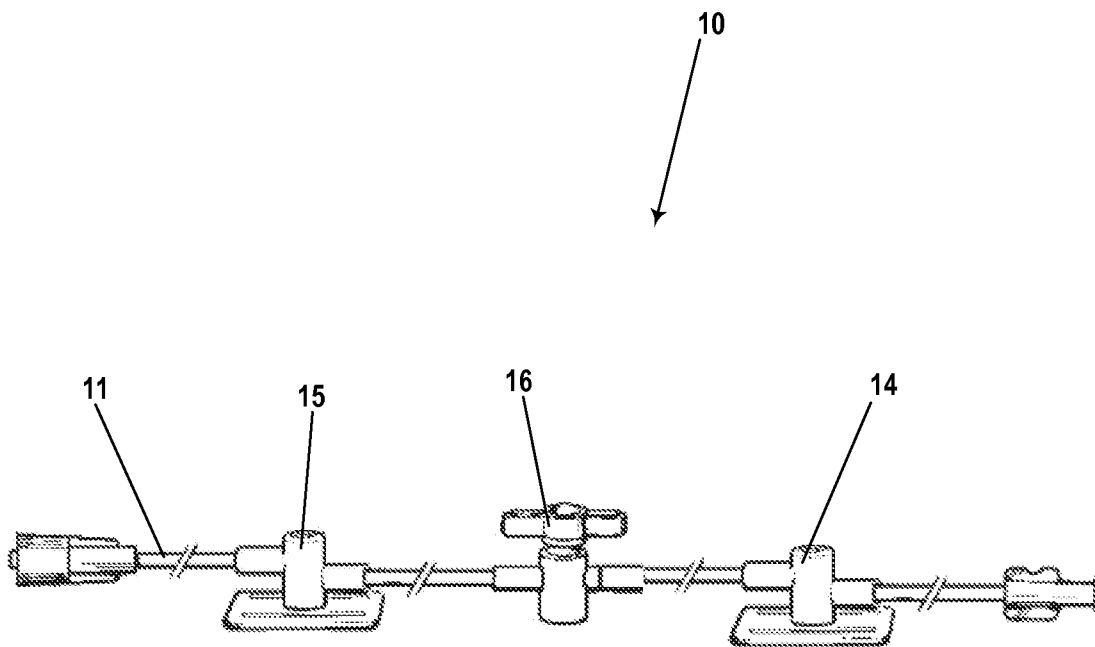
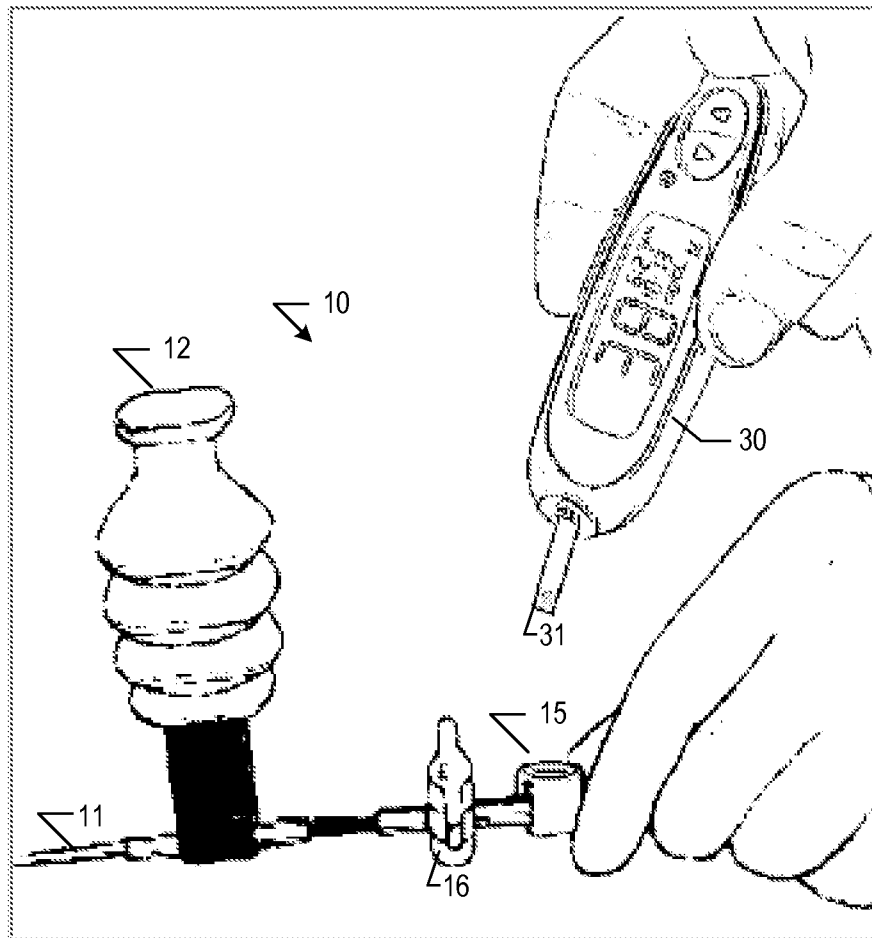
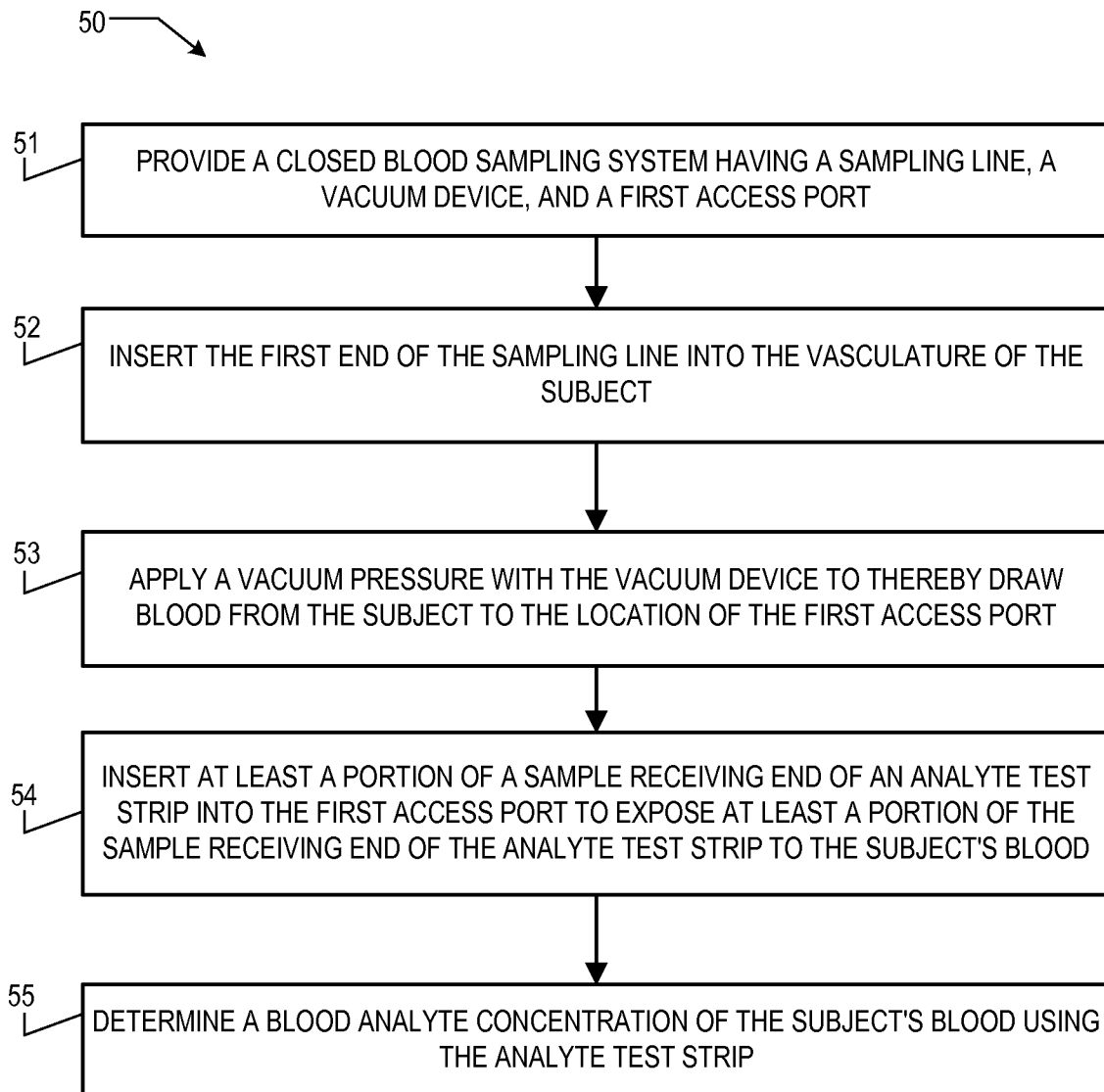


FIG. 3

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**FIG. 4**

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**FIG. 5**

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2014/017036**A. CLASSIFICATION OF SUBJECT MATTER****A61B 5/145(2006.01)i, A61B 5/157(2006.01)i**

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61B 5/145; A61B 10/00; B61B 5/00; A61B 19/00; A61B 5/157; A61K 35/16; A61B 5/15

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

Korean utility models and applications for utility models

Japanese utility models and applications for utility models

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

eKOMPASS(KIPO internal) & Keywords: sampling, vasculature, vacuum, fluid, analyte, septum, port, valve

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 6224561 B1 (DAVID L. SWENDSON et al.) 01 May 2001 See abstract, column 1, lines 31-35, column 3, lines 56-65, column 6, lines 16-29, column 13, lines 48-50, claim 1 and figures 1, 3, 8a.	1-16
Y	US 6506168 B1 (MARWAN A. FATHALLAH et al.) 14 January 2003 See abstract, column 18, lines 62-64, claim 31 and figure 10.	1-16
A	US 2002-0019621 A1 (JEAN-MARIE MATHIAS et al.) 14 February 2002 See abstract, paragraphs [0035]-[0039], claim 1 and figure 1.	1-16
A	JP 2012-532683 A (BECTON DICKINSON & CO.) 20 December 2012 See paragraphs [0017]-[0019], claim 1 and figure 1.	1-16
A	KR 10-2012-0027340 A (BIOTECHNOLOGY INSTITUTE, I MAS D, S. L.) 21 March 2012 See abstract, paragraphs [0063]-[0066], claim 1 and figures 1-2.	1-16



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents:

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Date of the actual completion of the international search

23 May 2014 (23.05.2014)

Date of mailing of the international search report

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Name and mailing address of the ISA/KR

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INTERNATIONAL SEARCH REPORT

Information on patent family members

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PCT/US2014/017036

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