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(54) BIOLOGICAL FLUID SAMPLING TRANSFER DEVICE AND BIOLOGICAL FLUID SEPARATION AND TESTING SYSTEM

ÜBERTRAGUNGSVORRICHTUNG FÜR DIE ENTNAHME BIOLOGISCHER FLÜSSIGKEITSPROBEN SOWIE TRENNUNGS- UND TESTSYSTEM FÜR BIOLOGISCHE FLÜSSIGKEITEN

DISPOSITIF DE TRANSFERT D'UN PRÉLÈVEMENT DE LIQUIDE BIOLOGIQUE ET SYSTÈME DE SÉPARATION ET D'ANALYSE D'UN LIQUIDE BIOLOGIQUE

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Description

BACKGROUND OF THE INVENTION

1. Field of the Disclosure

[0001] The present disclosure relates generally to devices, assemblies, and systems adapted for use with capillary access devices. More particularly, the present disclosure relates to devices, assemblies, and systems adapted for collecting biological samples for use in point-of-care testing.

2. Description of the Related Art

[0002] Blood sampling is a common health care procedure involving the withdrawal of at least a drop of blood from a patient. Blood samples are commonly taken from hospitalized, homecare, and emergency room patients either by finger stick, heel stick, or venipuncture. Blood samples may also be taken from patients by venous or arterial lines. Once collected, blood samples may be analyzed to obtain medically useful information including chemical composition, hematology, or coagulation, for example.

[0003] Blood tests determine the physiological and biochemical states of the patient, such as disease, mineral content, drug effectiveness, and organ function. Blood tests may be performed in a clinical laboratory or at the point-of-care near the patient. One example of point-of-care blood testing is the routine testing of a patient's blood glucose levels which involves the extraction of blood via a finger stick and the mechanical collection of blood into a diagnostic cartridge. Thereafter, the diagnostic cartridge analyzes the blood sample and provides the clinician a reading of the patient's blood glucose level. Other devices are available which analyze blood gas electrolyte levels, lithium levels, and ionized calcium levels. Some other point-of-care devices identify markers for acute coronary syndrome (ACS) and deep vein thrombosis/pulmonary embolism (DVT/PE).

[0004] Despite the rapid advancement in point-of-care testing and diagnostics, blood sampling techniques have remained relatively unchanged. Blood samples are frequently drawn using hypodermic needles or vacuum tubes attached to a proximal end of a needle or a catheter assembly. In some instances, clinicians collect blood from a catheter assembly using a needle and syringe that is inserted into the catheter to withdraw blood from a patient through the inserted catheter. These procedures utilize needles and vacuum tubes as intermediate devices from which the collected blood sample is typically withdrawn prior to testing. These processes are thus device intensive, utilizing multiple devices in the process of obtaining, preparing, and testing blood samples. Each additional device increases the time and cost of the testing process.

[0005] Point-of-care testing devices allow for a blood sample to be tested without needing to send the blood sample to a lab for analysis. Thus, it is desirable to create a device that provides an easy, safe, reproducible, and accurate process with a point-of-care testing system.

[0006] US 5,636,640 describes an apparatus for sampling blood that includes a deformable housing and a puncturing element, which is disposed within the housing and adapted for movement between a pre-actuated position wherein the puncturing element is retained within the housing and a puncturing position wherein the puncturing element extends through an inlet port of the housing.

SUMMARY OF THE INVENTION

[0007] The present disclosure provides a biological fluid separation and testing system, such as a blood separation and testing system, for a blood sample. The biological fluid separation and testing system includes a biological fluid sampling transfer device, such as a blood sampling transfer device, adapted to receive a blood sample, a blood separation device, and a blood testing device. The blood separation device is adapted to receive a portion of the blood sampling transfer device such that with the blood sampling transfer device received within the blood separation device and a rotational force applied to the blood sampling transfer device, a plasma portion of the blood sample is separated from a cellular portion of the blood sample. The blood testing device is adapted to receive a portion of the blood sampling transfer device to analyze the plasma portion of the blood sample and obtain test results.

[0008] Some of the advantages of the blood sampling transfer device and the blood separation and testing system of the present disclosure over prior systems are that it is a closed system which reduces blood sample exposure, it provides passive and fast mixing of the blood sample with a sample stabilizer, and it is capable of transferring pure plasma to a point-of-care testing device. The clinician may collect and separate the blood sample and then immediately transfer the plasma portion to the point-of-care testing device without further manipulation. This enables collection and transfer of plasma to the point-of-care testing device without exposure to blood. Further, for tests which only require small amounts of blood, it eliminates the waste associated with blood collection and plasma separation with an evacuated tube. Also, the blood sampling transfer device of the present disclosure incorporates the concepts of lancing, blood collection, and blood separation.

[0009] In accordance with an embodiment of the present invention, a biological fluid sampling transfer device includes a housing having a resiliently deformable upper portion, a lower portion removably connectable to the upper portion, the lower portion having an inlet port, an outlet port, and a flow channel, with the inlet port and the outlet port in fluid communication via the flow channel. The upper portion is transitionable between an unde-

formed position and a deformed position. The device also includes a puncturing element, a portion of which is disposed within the housing and adapted for movement between a pre-actuated position wherein the puncturing element is retained within the housing and a puncturing position wherein the puncturing element extends through the inlet port of the lower portion of the housing.

[0010] In certain configurations, the blood sampling transfer device is adapted to receive a multi-component blood sample. The multi-component blood sample may include a first cellular component and a second plasma component. The flow channel may be adapted to receive the blood sample via the inlet port.

[0011] In other configurations, actuation of the upper portion from the undeformed position to the deformed position moves the puncturing element from a pre-actuated position to a puncturing position. After the puncturing element moves to the puncturing position, the upper portion returns to its undeformed position and returns the puncturing element to the pre-actuated position. With the blood sample received within the flow channel, the lower portion is removable from the upper portion. In certain configurations, the device also includes an adhesive disposed on an outside surface of the lower portion. The device may also include a check valve in the upper portion.

[0012] In accordance with yet another embodiment of the present invention, a biological fluid separation and testing system for a multi-component blood sample includes the blood sampling transfer device according to claim 1. The system also includes a blood testing device having a receiving port adapted to receive the outlet port of the lower portion of the housing of the blood sampling transfer device for closed transfer of a portion of the blood sample from the blood sampling transfer device to the blood testing device via the outlet port.

[0013] In certain configurations, the blood testing device may be a point-of-care testing device. When the blood sampling transfer device is received within the receiving port of the blood testing device, actuation of the upper portion from the undeformed position to the deformed position transfers the blood sample from the blood sampling transfer device to the blood testing device via the outlet port. When the blood sample is received within the flow channel, the lower portion is removable from the upper portion.

[0014] In other configurations, the system also includes a blood separation device, and when the lower portion is removed from the upper portion, the lower portion is receivable within the blood separation device. When the lower portion is received within the blood separation device, the blood sample contained within the lower portion is separated. Optionally, a portion of the housing includes a sample stabilizer.

BRIEF DESCRIPTION OF THE DRAWINGS

[0015] The above-mentioned and other features and advantages of this disclosure, and the manner of attaining them, will become more apparent and the disclosure itself will be better understood by reference to the following descriptions of embodiments of the disclosure taken in conjunction with the accompanying drawings, wherein:

Fig. 1 is an exploded, perspective view of a biological fluid sampling transfer device in accordance with an embodiment of the present invention.

Fig. 2 is an assembled, perspective view of a biological fluid sampling transfer device in accordance with an embodiment of the present invention.

Fig. 3 is a perspective view of a biological fluid sampling transfer device secured to a patient with a housing in an undeformed position in accordance with an embodiment of the present invention.

Fig. 4 is a perspective view of a biological fluid sampling transfer device secured to a patient with a housing in a deformed position in accordance with an embodiment of the present invention.

Fig. 5 is a cross-sectional view of the biological fluid sampling transfer device of **Fig. 4** in accordance with an embodiment of the present invention.

Fig. 6 is a cross-sectional view of the biological fluid sampling transfer device of **Fig. 3** with a blood sample received within the biological fluid sampling transfer device in accordance with an embodiment of the present invention.

Fig. 7 is a cross-sectional view of the biological fluid sampling transfer device of **Fig. 6** in accordance with an embodiment of the present invention, with an upper portion of the housing removed from a lower portion of the biological fluid sampling transfer device.

Fig. 8 is a perspective view of a biological fluid separation system in accordance with an embodiment of the present invention.

Fig. 9 is a cross-sectional view of a lower portion of the biological fluid sampling transfer device of **Fig. 8** in accordance with an embodiment of the present invention.

Fig. 10 is a perspective view of a lower portion of the biological fluid sampling transfer device and a point-of-care testing device in accordance with an embodiment of the present invention.

Fig. 11 is a cross-sectional view of a valve of a biological fluid sampling transfer device in accordance with an embodiment of the present invention, with the valve in a closed position.

Fig. 12 is a cross-sectional view of a valve of a biological fluid sampling transfer device in accordance with an embodiment of the present invention, with the valve in an open position.

[0016] Corresponding reference characters indicate corresponding parts throughout the several views. The exemplifications set out herein illustrate exemplary embodiments of the disclosure, and such exemplifications are not to be construed as limiting the scope of the dis-

closure in any manner.

DETAILED DESCRIPTION

[0017] The following description is provided to enable those skilled in the art to make and use the described embodiments contemplated for carrying out the invention. Various modifications, equivalents, variations, and alternatives, however, will remain readily apparent to those skilled in the art. Any and all such modifications, variations, equivalents, and alternatives are intended to fall within the scope of the present invention.

[0018] For purposes of the description hereinafter, the terms "upper", "lower", "right", "left", "vertical", "horizontal", "top", "bottom", "lateral", "longitudinal", and derivatives thereof shall relate to the invention as it is oriented in the drawing figures. However, it is to be understood that the invention may assume alternative variations and step sequences, except where expressly specified to the contrary. It is also to be understood that the specific devices and processes illustrated in the attached drawings, and described in the following specification, are simply exemplary embodiments of the invention. Hence, specific dimensions and other physical characteristics related to the embodiments disclosed herein are not to be considered as limiting.

[0019] Various point-of-care testing devices are known in the art. Such point-of-care testing devices include test strips, glass slides, diagnostic cartridges, or other testing devices for testing and analysis. Test strips, glass slides, and diagnostic cartridges are point-of-care testing devices that receive a blood sample and test that blood for one or more physiological and biochemical states. There are many point-of-care devices that use cartridge based architecture to analyze very small amounts of blood bedside without the need to send the sample to a lab for analysis. This saves time in getting results over the long run but creates a different set of challenges versus the highly routine lab environment. Examples of such testing cartridges include the i-STAT® testing cartridge from the Abbot group of companies. Testing cartridges such as the i-STAT® cartridges may be used to test for a variety of conditions including the presence of chemicals and electrolytes, hematology, blood gas concentrations, coagulation, or cardiac markers. The results of tests using such cartridges are quickly provided to the clinician.

[0020] However, the samples provided to such point-of-care testing cartridges are currently manually collected with an open system and transferred to the point-of-care testing cartridge in a manual manner that often leads to inconsistent results, or failure of the cartridge leading to a repeat of the sample collection and testing process, thereby negating the advantage of the point-of-care testing device. Accordingly, a need exists for a system for collecting and transferring a sample to a point-of-care testing device that provides safer, reproducible, and more accurate results. Accordingly, a point-of-care collecting and transferring system of the present disclosure will be described hereinafter. A system of the present disclosure enhances the reliability of the point-of-care testing device by: 1) incorporating a more closed type of sampling and transfer system; 2) minimizing open exposure of the sample; 3) improving sample quality; 4) improving the overall ease of use; and 5) separating the sample at the point of collection.

[0021] **Figs. 1-7** illustrate an exemplary embodiment of the present disclosure. The biological fluid sampling transfer device of the present disclosure incorporates the concepts of lancing, blood collection, and blood separation. Referring to **Figs. 1-7,** a biological fluid sampling transfer device **10,** such as a blood sampling transfer device, of the present disclosure is adapted to receive a blood sample **12** (**Figs. 6, 7,** and **9**) having a cellular portion **14** and a plasma portion **16.**

[0022] **Figs. 8-10** illustrate an exemplary embodiment of the present disclosure. Referring to **Figs. 8-10,** a biological fluid separation and testing system **20,** such as a blood separation and testing system, of the present disclosure for a blood sample **12** includes a blood sampling transfer device **10** adapted to receive a blood sample **12,** a blood separation device or centrifuge **22,** and a blood testing device or point-of-care testing device **24.** The centrifuge **22** is adapted to receive a portion of the blood sampling transfer device **10** such that with the blood sampling transfer device **10** received within the centrifuge **22** and a rotational force applied to the blood sampling transfer device **10,** a plasma portion **16** of the blood sample **12** is separated from a cellular portion **14** of the blood sample **12.** The blood testing device **24** is adapted to receive a portion of the blood sampling transfer device **10** to analyze the plasma portion **16** of the blood sample **12** and obtain test results.

[0023] Some of the advantages of the blood sampling transfer device and the blood separation and testing system of the present disclosure over prior systems are that it is a closed system which reduces blood sample exposure, it provides passive and fast mixing of the blood sample with a sample stabilizer, and it is capable of transferring pure plasma to the point-of-care testing device **24.** The clinician may collect and separate the blood sample and then immediately transfer the plasma portion to the point-of-care testing device **24** without further manipulation. This enables collection and transfer of plasma to the point-of-care testing device **24** without exposure to blood. Further, for tests which only require small amounts of blood, it eliminates the waste associated with blood collection and plasma separation with an evacuated tube. Also, the blood sampling transfer device **10** of the present disclosure incorporates the concepts of lancing, blood collection, and blood separation.

[0024] Referring to **Figs. 1-7,** the blood sampling transfer device **10** generally includes a housing **30** having an upper portion **32** and a lower portion **34** removably connectable to the upper portion **32.** With the lower portion **34** connected to the upper portion **32,** significant relative movement between the upper portion **32** and the lower

portion **34** is prevented. The housing **30** defines a central aperture **35** therethrough the upper portion **32** and the lower portion **34.** A lancet structure or lancet device **60** is positioned within the central aperture **35** as shown in **Figs. 1-6.** The housing **30** includes a lancet engagement portion **39** for securing the lancet structure **60** within the central aperture **35** as shown in **Figs. 5** and **6.**

[0025] The upper portion **32** includes a dome-shaped surface **36** and the lower portion **34** includes a bottom surface **38.** Referring to **Figs. 3, 5,** and **6,** the bottom surface **38** includes an adhesive **54** so that the blood sampling transfer device **10** can be secured onto a skin surface S of a patient where a blood sample will be accessed. In one embodiment, the adhesive **54** of the bottom surface **38** is protected by a peel-off layer, similar to an adhesive bandage, which would be removed before placing the blood sampling transfer device **10** on the skin surface S of the patient's body. A hydrogel or other layer could be included to provide some thickness to the bottom surface **38** of the lower portion **34** and help improve the stability of the adhesive seal. Additionally, in one embodiment, the adhesive **54** could include a chemistry to create a more liquid-tight seal, similar to painter's tape technology, where wetting from the paint itself causes a chemical reaction with the adhesive **54** to create a more water-tight barrier to prevent the paint from seeping under the tape.

[0026] The upper portion **32** is a resiliently deformable member that is transitionable between an undeformed position (**Figs. 3** and **6**) and a deformed position (**Figs. 4** and **5**) as will be discussed in more detail below. The upper portion **32** is formed of a flexible material such that the upper portion **32** can be depressed by pressure applied by a user. After the pressure is removed, the upper portion **32** returns to its original or undeformed position and its domed-shape. In one embodiment, the upper portion **32** of the housing **30** includes a vent or check valve **52** to allow air to be expelled upon depression of the dome-shaped upper portion **32.**

[0027] Referring to **Figs. 1-7,** the lower portion **34** of the housing **30** of the blood sampling transfer device **10** generally includes an inlet port **40** defined through the bottom surface **38** of the lower portion **34,** an entry reservoir **42** in fluid communication with the inlet port **40,** a flow channel or mixing channel **44** in fluid communication with the entry reservoir **42,** an exit reservoir **46** in fluid communication with the flow channel **44,** an exit port or outlet port **48** in fluid communication with the exit reservoir **46,** a valve **50** (**Figs. 11** and **12**) disposed in communication with the exit port **48,** a venting portion **51,** and a button portion **53.** In one embodiment, the plasma portion **16** contained within the exit reservoir **46** of the lower portion **34** can be transferred through the valve **50** to the point-of-care testing device **24** by pressing the button portion **53** of the lower portion **34** as discussed below.

[0028] The lower portion **34** of the housing **30** of the blood sampling transfer device **10** is adapted to contain a sample stabilizer to provide passive and fast mixing of a blood sample with the sample stabilizer. The sample stabilizer, can be an anticoagulant, or a substance designed to preserve a specific element within the blood such as, for example, RNA, protein analyte, or other element. In one embodiment, the sample stabilizer is provided within the flow channel **44.** In other embodiments, the sample stabilizer is provided in other areas of the lower portion **34** of the housing **30** of the blood sampling transfer device **10** such as the entry reservoir **42.**

[0029] In one embodiment, the flow channel **44** comprises a serpentine shape to promote efficient mixing of a blood sample **12** (**Figs. 6, 7,** and **9**) having a cellular portion **14** and a plasma portion **16.** As discussed below, a blood separation device **22** provides a rotational force applied to the lower portion **34** of the housing **30** to separate the plasma portion **16** from the cellular portion **14** through the flow channel **44.** In other embodiments, the flow channel **44** comprises other shapes to promote efficient mixing of a blood sample.

[0030] The valve **50** is transitionable between a closed position (**Fig. 11**) to seal a plasma portion **16** of the blood sample **12** within the exit reservoir **46** of the lower portion **34** of the housing **30** and an open position (**Fig. 12**) to allow a plasma portion **16** to flow through the exit port **48** to a point-of-care testing device **24** as shown in **Fig. 10.**

[0031] Referring to **Figs. 11** and **12,** the exit port or outlet port **48** of the lower portion **34** of the housing **30** of the blood sampling transfer device **10** may include a valve **50** that is transitionable between a closed position and an open position. With the valve **50** in an open position, the plasma portion **16** of the blood sample **12** may flow through the outlet port **48** to a blood testing device or a point-of-care testing device **24 (Fig. 10).**

[0032] In one embodiment, referring to **Figs. 11** and **12,** the valve **50** may generally include a transfer channel **90,** a bellows or deformable wall member **92,** and a septum or barrier **94** having a first barrier wall **96** and a second barrier wall **98.** Referring to **Fig. 11,** the valve **50** is in a closed position to prevent the plasma portion **16** of the blood sample **12** from flowing through the outlet port **48.** In this manner, the plasma portion **16** is sealed within the lower portion **34** of the housing **30** of the blood sampling transfer device **10.** Referring to **Fig. 12,** the valve **50** is in an open position so that the plasma portion **16** of the blood sample **12** may flow through the outlet port **48** to a blood testing device or a point-of-care testing device **24 (Fig. 10).**

[0033] Referring to **Fig. 11,** with the plasma portion **16** received within the exit reservoir **46** of the lower portion **34** of the blood sampling transfer device **10,** the outlet port **48** of the lower portion **34** of the blood sampling transfer device **10** is then positioned over a receiving port **26** of the point-of-care testing device **24.** Pushing down in the direction of arrow **B** compresses the deformable wall member **92** and opens up the first barrier wall **96** and the second barrier wall **98** of the septum **94** as shown in **Fig. 12.** With the valve **50** in the open position, the plasma portion **16** of the blood sample **12** is allowed to

flow through the receiving port **26** to the point-of-care testing device **24** in a closed manner reducing exposure to the clinician and the patient.

[0034] The valve **50** of the blood sampling transfer device **10** only opens when the outlet port **48** is pressed upon the receiving port **26** of the point-of-care testing device **24.** This releases the isolated plasma portion **16** directly into the receiving port **26** of the point-of-care testing device **24,** thus mitigating unnecessary exposure to the patient's blood.

[0035] Referring to **Figs. 1-6,** the blood sampling transfer device **10** also includes a lancet or lancet structure **60** that may be secured within the central aperture **35** of the housing **30.** The lancet **60** generally includes a first end **100,** a second end **102,** a top or handle portion **104** adjacent the first end **100,** a bottom or lancet portion **106** adjacent the second end **102,** and a housing engagement portion **108.** The housing engagement portion **108** engages the lancet engagement portion **39** of the housing for securing the lancet **60** to the housing **30** within central aperture **35** as shown in **Figs. 5** and **6.** Referring to **Figs. 5** and **6,** a portion of the lancet **60** is disposed within the housing **30** of the blood sampling transfer device **10.** The lancet portion **106** includes a puncturing element **110** having a puncturing end **112.** The puncturing end **112** is adapted for puncturing the skin surface S of a patient **(Fig. 5),** and may define a pointed end, a blade edge, or a similar cutting mechanism. The puncturing end **112** may include a preferred alignment orientation, such as with a pointed end of a blade aligned in a specific orientation.

[0036] The lancet **60** is adapted for movement between a pre-actuated position (**Figs. 3** and **6**) wherein the puncturing element **110** including the puncturing end **112** is retained within the housing **30** and a puncturing position (**Figs. 4** and **5**) wherein the puncturing end **112** of the puncturing element **110** extends through the inlet port **40** of the housing **30** to puncture a skin surface S of a patient to draw a blood sample as discussed in more detail below.

[0037] In one embodiment, the housing **30** of the blood sampling device **10** may include a self-sealing dock that would allow an external lancet to be removably received within the housing **30.** The external lancet could be either pre-integrated into the packaged device or introduced separately by a user before using the blood sampling transfer device **10** of the present disclosure.

[0038] Referring to **Fig. 8,** a blood separation device or centrifuge **22** of the present disclosure generally includes a receiving port **120** adapted to receive the lower portion **34** of the blood sampling transfer device **10** such that with the lower portion **34** received within the centrifuge **22** and a rotational force applied to the lower portion **34,** a plasma portion **16** of the blood sample **12** is separated from a cellular portion **14** of the blood sample **12 (Fig. 9).** The centrifuge **22** includes a receiving port **120** adapted to receive the lower portion **34** of the blood sampling transfer device **10,** a base or bottom portion **122,** a top portion **124** movably connected to the base portion **122** by a hinged portion **126,** and a rotational force element **128** contained within the base portion **122.** The top portion **124** is transitionable between an open position in which the lower portion **34** of the blood sampling transfer device **10** can be placed within the receiving port **120** as shown in **Fig. 8** and a closed position. With the lower portion **34** of the blood sampling transfer device **10** received within the centrifuge **22,** a rotational force is applied to the lower portion **34** of the blood sampling transfer device **10** to separate the plasma portion **16** from the cellular portion **14** as described in more detail below.

[0039] Referring to **Fig. 10,** a blood testing device or point-of-care testing device **24** includes a receiving port **26** for receiving the outlet port **48** of the lower portion **34** of the housing **30** of the blood sampling transfer device **10.** The blood testing device **24** is adapted to receive the lower portion **34** of the housing **30** to analyze the blood sample and obtain test results. The receiving port **26** of the point-of-care testing device **24** allows for the closed transfer of a blood sample from the lower portion **34** of the housing **30** to the point-of-care testing device **24.**

[0040] Referring to **Figs. 1-10,** use of a blood sampling transfer device of the present disclosure will now be described. Referring to **Figs. 3** and **6,** upon selecting a site, a clinician can adhere the adhesive **54** on the bottom surface **38** of the lower portion **34** of the housing **30** onto a skin surface S of a patient where a blood sample will be accessed over a selected sampling site.

[0041] Referring to **Figs. 3-6,** a user or an operator may then apply pressure to the dome-shaped surface **36** of the upper portion **32** of the housing **30** to actuate the upper portion **32** from the undeformed position (**Figs**. **3** and **6**) to the deformed position (**Figs. 4** and **5**). Actuation of the upper portion **32** from the undeformed position (**Figs. 3** and **6**) to the deformed position (**Figs. 4** and **5**) moves the lancet **60** from the pre-actuation position (**Figs. 3** and **6**) to the puncturing position (**Figs. 4** and **5**) thereby causing the lancing of the skin surface S of the patient by the puncturing end **112** of the lancet **60** as shown in **Fig. 5.** When the upper portion **32** of the housing **30** is depressed, the puncturing end **112** of the lancet **60** cuts into the skin surface S of the patient's body and capillary blood begins to flow into the inlet port **40** of the housing **30.**

[0042] After lancing and release of the pressure for the lancing action, the domed shape of the upper portion **32** begins to relax and returns to its original shape or undeformed position. This return of the upper portion **32** to its undeformed position creates a gentle vacuum during the process that helps to draw out the capillary blood through the inlet port **40** and to the entry reservoir **42** of the lower portion **34** of the housing **30.**

[0043] With the upper portion **32** of the housing **30** returned to its undeformed position and with the blood sample **12** received within the entry reservoir **42** as shown in **Fig. 6,** the clinician can remove the lower portion **34** of the housing **30** from the upper portion **32** as shown in

Fig. 7. When the lower portion **34** is removed from the upper portion **32,** the entry reservoir **42** and the flow channel **44** of the lower portion **34** is sealed from the external environment. Additionally, with the lower portion **34** removed from the upper portion **32,** the puncturing end **112** of the lancet **60** is contained within the upper portion **32** to shield the puncturing end **112.**

[0044] Referring to **Fig. 8,** the next step of the process involves manual insertion of the lower portion **34** into a blood separation device or centrifuge **22** designed specifically for the lower portion **34** of the housing **30.** The centrifuge **22** is designed to facilitate plasma separation by centrifugal force and to drive a blood sample through the mixing channel **44** of the lower portion **34.** The blood sample **12** contained within the lower portion **34** is quickly spun in the centrifuge **22** and due to the low volume is separated through the mixing channel **44** of the lower portion **34** within a few seconds such that the plasma portion **16** is collected within the exit reservoir **46** of the lower portion **34.** After separation, the lower portion **34** is removed manually from the centrifuge device **22.**

[0045] Thereafter, referring to **Fig. 10,** the collected plasma portion **16** of the blood sample **12** within the exit reservoir **46** of the lower portion **34** of the blood sampling transfer device **10** is transferred to the receiving port **26** of the point-of-care testing device **24** to analyze the collected plasma portion **16** and obtain test results for tests such as glucose, cholesterol, or other blood sample results. Referring to **Fig. 10,** the receiving port **26** of the point-of-care testing device **24** allows for the closed transfer of a portion of the plasma portion **16** of the blood sample **12** from the lower portion **34** to the point-of-care testing device **24.**

[0046] In one embodiment, the plasma portion **16** of the blood sample **12** within the exit reservoir **46** of the lower portion **34** is dispensed through the valve **50** of the exit port **48** of the lower portion **34** into a well or receiving port **26** of the point-of-care testing device **24** to perform the desired test. In one embodiment, the plasma portion **16** is transferred through the valve **50** to the point-of-care testing device **24** by pressing the button portion **53** of the lower portion **34.** In another embodiment, the lower portion **34** can be connected to the upper portion **32** and actuation of the upper portion **32** from the undeformed position to the deformed position transfers the plasma portion **16** of the blood sample **12** from the lower portion **34** of the blood sampling transfer device **10** to the blood testing device **24** via the outlet port **48.**

[0047] In one embodiment, the entry reservoir **42** and/or flow channel **44** of the lower portion **34** of the housing **30** contains the sample stabilizer to promote efficient mixing with the blood sample. Referring to **Fig. 5,** upon actuation of the lancet **60** to puncture the skin surface S, no or minimal blood will seep between the stick site and the housing **30** of the blood sampling transfer device **10,** and, importantly, any seeped blood will not subsequently enter the blood sampling transfer device **10.**

[0048] Some of the advantages of the blood sampling transfer device and the blood separation and testing system of the present disclosure over prior systems are that it is a closed system which reduces blood sample exposure, it provides passive and fast mixing of the blood sample with a sample stabilizer, and it is capable of transferring pure plasma to the point-of-care testing device **24.** The clinician may collect and separate the blood sample and then immediately transfer the plasma portion to the point-of-care testing device **24** without further manipulation. This enables collection and transfer of plasma to the point-of-care testing device **24** without exposure to blood. Further, for tests which only require small amounts of blood, it eliminates the waste associated with blood collection and plasma separation with an evacuated tube. Also, the blood sampling transfer device **10** of the present disclosure incorporates the concepts of lancing, blood collection, and blood separation.

[0049] While this disclosure has been described as having exemplary designs, the present disclosure can be further modified within the scope of this disclosure. This application is therefore intended to cover any variations, uses, or adaptations of the disclosure using its general principles. Further, this application is intended to cover such departures from the present disclosure as come within known or customary practice in the art to which this disclosure pertains and which fall within the limits of the appended claims.

Claims

1. A biological fluid sampling transfer device (10), comprising:

   a housing (30) having a resiliently deformable upper portion (32), wherein the upper portion (32) transitionable between an undeformed position and a deformed position; and
   a puncturing element (60), a portion of which is disposed within the housing (30) and adapted for movement between a pre-actuated position wherein the puncturing element (60) is retained within the housing (30) and a puncturing position,
   characterized in that the housing (30) having further a lower portion (34) removably connectable to the upper portion (32), the lower portion (34) having an inlet port (40), an outlet port (48), and a flow channel (44), the inlet port (40) and the outlet port (48) in fluid communication via the flow channel (44), wherein the puncturing element (60) extends through the inlet port (40) of the lower portion of the housing (30) in the puncturing position.

2. The biological fluid sampling transfer device of claim 1, wherein the biological fluid sampling transfer device is adapted to receive a multi-component blood

sample wherein preferably the multi-component blood sample comprises a first cellular component and a second plasma component.

3. The biological fluid sampling transfer device of claim 2, wherein the flow channel (44) is adapted to receive the blood sample via the inlet port (40).

4. The biological fluid sampling transfer device of claim 1, wherein actuation of the upper portion (32) from the undeformed position to the deformed position moves the puncturing element (60) from the pre-actuated position to the puncturing position.

5. The biological fluid sampling transfer device of claim 4, wherein after the puncturing element (60) moves to the puncturing position, the upper portion (32) returns to its undeformed position and returns the puncturing element (60) to the pre-actuated position.

6. The biological fluid sampling transfer device of claim 5, wherein with the blood sample received within the flow channel (44), the lower portion (34) is removable from the upper portion (32).

7. The biological fluid sampling transfer device of claim 1, further comprising an adhesive (54) disposed on an outside surface (38) of the lower portion (34).

8. The biological fluid sampling transfer device of claim 1, further comprising a check valve (50) in the upper portion (32).

9. A biological fluid separation and testing system for a multi-component blood sample, the biological fluid separation and testing system comprising:

the biological fluid sampling transfer device (10) of claim 1 and a blood testing device (24) having a receiving port (26) adapted to receive the outlet port (48) of the lower portion (34) of the housing (30) of the biological fluid sampling transfer device (10) for closed transfer of a portion of the blood sample from the biological fluid sampling transfer device (10) to the blood testing device (24) via the outlet port (48).

10. The biological fluid separation and testing system of claim 9, wherein the blood testing device comprises a point-of-care testing device (24).

11. The biological fluid separation and testing system of claim 9, wherein with the biological fluid sampling transfer device (10) received within the receiving port (26) of the blood testing device (24), actuation of the upper portion (32) from the undeformed position to the deformed position transfers the blood sample from the biological fluid sampling transfer device (10) to the blood testing device (24) via the outlet port (48).

12. The biological fluid separation and testing system of claim 9, wherein with the blood sample received within the flow channel (44), the lower portion (34) is removable from the upper portion (32).

13. The biological fluid separation and testing system of claim 12, further comprising a blood separation device (22), wherein with the lower portion (34) removed from the upper portion (32), the lower portion (34) is receivable within the blood separation device (22).

14. The biological fluid separation and testing system of claim 13, wherein with the lower portion (34) received within the blood separation device (22), the blood sample contained within the lower portion (34) is separated.

15. The biological fluid separation and testing system of claim 9, wherein a portion of the housing (30) includes a sample stabilizer.

Patentansprüche

1. Übertragungsvorrichtung für biologische Flüssigkeitsproben (10), mit:

einem Gehäuse (30), das einen elastisch verformbaren oberen Abschnitt (32) aufweist, wobei der obere Abschnitt (32) zwischen einer unverformten Position und einer verformten Position veränderbar ist; und
einem Punktierelement (60), von dem ein Abschnitt in dem Gehäuse (30) angeordnet ist und zur Bewegung zwischen einer voraktivierten Position, in der das Punktierelement (60) in dem Gehäuse (30) rückgehalten ist, und einer Punktierposition in der Lage ist,
dadurch gekennzeichnet, dass das Gehäuse (30) ferner einen unteren Abschnitt (34) aufweist, der abnehmbar mit dem oberen Abschnitt (32) verbunden ist, wobei der untere Abschnitt (34) einen Eingangs-Durchlass (40), einen Ausgangs-Durchlass (48) und einen Strömungskanal (44) aufweist, wobei der Eingangs-Durchlass (40) und der Auslass-Durchlass (48) über den Strömungskanal (44) in Flüssigkeitsverbindung miteinander stehen, wobei sich das Punktierelement (60) in der Punktierposition durch den Eingangs-Durchlass (40) des unteren Abschnitts des Gehäuses (30) ersttreckt.

2. Übertragungsvorrichtung für biologische Flüssigkeitsproben nach Anspruch 1, wobei die Übertra-

gungsvorrichtung für biologische Flüssigkeitsproben zur Aufnahme einer Mehrkomponenten-Blutprobe in der Lage ist, wobei die Mehrkomponenten-Blutprobe vorzugsweise eine erste, zelluläre Komponente und eine zweite, als Plasma-Komponente vorgesehene Komponente aufweist.

3. Übertragungsvorrichtung für biologische Flüssigkeitsproben nach Anspruch 2, bei der der Strömungskanal (44) zur Aufnahme der Blutprobe über den Eingangs-Durchlass (40) in der Lage ist.

4. Übertragungsvorrichtung für biologische Flüssigkeitsproben nach Anspruch 1, bei der durch Betätigung des oberen Abschnitts (32) zum Übergang von der unverformten Position in die verformte Position das Punktierelement (60) aus der voraktivierten Position in die Punktierposition bewegt wird.

5. Übertragungsvorrichtung für biologische Flüssigkeitsproben nach Anspruch 4, bei der, nachdem sich das Punktierelement (60) in die Punktierposition bewegt hat, der obere Abschnitt (32) in seine unverformte Position zurückkehrt und das Punktierelement (60) in die voraktivierte Position zurückführt.

6. Übertragungsvorrichtung für biologische Flüssigkeitsproben nach Anspruch 5, bei der im Zustand der Aufnahme der Blutprobe in dem Strömungskanal (44) der untere Abschnitt (34) von dem oberen Abschnitt (32) abnehmbar ist.

7. Übertragungsvorrichtung für biologische Flüssigkeitsproben nach Anspruch 1, ferner mit einem Haftvermittler (54), der an einer Außenfläche (38) des unteren Abschnitts (34) angeordnet ist.

8. Übertragungsvorrichtung für biologische Flüssigkeitsproben nach Anspruch 1, ferner mit einem Rückschlagventil (50) in dem oberen Abschnitt (32).

9. Trenn- und Testsystem für biologische Flüssigkeiten zur Verwendung für eine Mehrkomponenten-Blutprobe, wobei das Trenn- und Testsystem für biologische Flüssigkeiten aufweist:

die Übertragungsvorrichtung für biologische Flüssigkeitsproben (10) nach Anspruch 1 und eine Bluttestvorrichtung (24) mit einem Aufnahme-Durchlass (26), der zur Aufnahme des Ausgangs-Durchlasses (48) des unteren Abschnitts (34) des Gehäuses (30) der Übertragungsvorrichtung für biologische Flüssigkeitsproben (10) in der Lage ist, um über den Ausgangs-Durchlass (48) eine geschlossene Übertragung eines Teils der Blutprobe aus der Übertragungsvorrichtung für biologische Flüssigkeitsproben (10) in die Bluttestvorrichtung (24) zu ermöglichen.

10. Trenn- und Testsystem für biologische Flüssigkeiten nach Anspruch 9, bei der die Bluttestvorrichtung eine Point-of-care-Testvorrichtung (24) aufweist.

11. Trenn- und Testsystem für biologische Flüssigkeiten nach Anspruch 9, bei der im Zustand der Aufnahme der Übertragungsvorrichtung für biologische Flüssigkeitsproben (10) in dem Aufnahme-Durchlass (26) der Bluttestvorrichtung (24) eine Betätigung des oberen Abschnitts (32) zum Übergang von der unverformten Position in die verformte Position eine Übertragung der Blutprobe aus der Übertragungsvorrichtung für biologische Flüssigkeitsproben (10) über den Ausgangs-Durchlass (48) in die Bluttestvorrichtung (24) bewirkt.

12. Trenn- und Testsystem für biologische Flüssigkeiten nach Anspruch 9, bei der im Zustand der Aufnahme der Blutprobe in dem Strömungskanal (44) der untere Abschnitt (34) von dem oberen Abschnitt (32) abnehmbar ist.

13. Trenn- und Testsystem für biologische Flüssigkeiten nach Anspruch 12, ferner mit einer Bluttrennungsvorrichtung (22), wobei, wenn der untere Abschnitt (34) von dem oberen Abschnitt (32) abgenommen ist, der untere Abschnitt (34) von der Bluttrennungsvorrichtung (22) aufgenommen werden kann.

14. Trenn- und Testsystem für biologische Flüssigkeiten nach Anspruch 13, bei der im Zustand der Aufnahme des unteren Abschnitts (34) in der Bluttrennungsvorrichtung (22) die in dem unteren Abschnitt (34) enthaltene Blutprobe getrennt ist.

15. Trenn- und Testsystem für biologische Flüssigkeiten nach Anspruch 9, bei der ein Abschnitt des Gehäuses (30) einen Probenstabilisator aufweist.

Revendications

1. Dispositif de transfert d'échantillon de fluide biologique (10), comprenant :

un boîtier (30) ayant une partie supérieure élastiquement déformable (32), où la partie supérieure (32) peut effectuer une transition entre une position non déformée et une position déformée ; et
un élément de ponction (60), dont une partie est disposée dans le boîtier (30) et adaptée pour se déplacer entre une position pré-actionnée dans laquelle l'élément de ponction (60) est retenu dans le boîtier (30) et une position de ponction, **caractérisé en ce que** le boîtier (30) ayant en outre une partie inférieure (34) pouvant être reliée de manière amovible à la partie supérieure

(32), la partie inférieure (34) ayant un orifice d'entrée (40), un orifice de sortie (48) et un canal d'écoulement (44), l'orifice d'entrée (40) et l'orifice de sortie (48) étant en communication fluidique par l'intermédiaire du canal d'écoulement (44), où l'élément de ponction (60) s'étend à travers l'orifice d'entrée (40) de la partie inférieure du boîtier (30) dans la position de ponction.

2. Dispositif de transfert d'échantillon de fluide biologique de la revendication 1, dans lequel le dispositif de transfert d'échantillon de fluide biologique est adapté pour recevoir un échantillon de sang à composants multiples, où de préférence l'échantillon de sang à composants multiples comprend un premier composant cellulaire et un deuxième composant plasmatique.

3. Dispositif de transfert d'échantillon de fluide biologique de la revendication 2, dans lequel le canal d'écoulement (44) est adapté pour recevoir l'échantillon de sang par l'intermédiaire de l'orifice d'entrée (40).

4. Dispositif de transfert d'échantillon de fluide biologique de la revendication 1, dans lequel l'actionnement de la partie supérieure (32) de la position non déformée à la position déformée permet de déplacer l'élément de ponction (60) de la position pré-actionnée à la position de ponction.

5. Dispositif de transfert d'échantillon de fluide biologique de la revendication 4, dans lequel, après que l'élément de ponction (60) se déplace à la position de ponction, la partie supérieure (32) revient à sa position non déformée et renvoie l'élément de ponction (60) à la position pré-actionnée.

6. Dispositif de transfert d'échantillon de fluide biologique de la revendication 5, dans lequel, avec l'échantillon de sang reçu dans le canal d'écoulement (44), la partie inférieure (34) peut être retirée de la partie supérieure (32).

7. Dispositif de transfert d'échantillon de fluide biologique de la revendication 1, comprenant en outre un adhésif (54) disposé sur une surface extérieure (38) de la partie inférieure (34).

8. Dispositif de transfert d'échantillon de fluide biologique de la revendication 1, comprenant en outre un clapet anti-retour (50) dans la partie supérieure (32).

9. Système de séparation et de test de fluide biologique pour un échantillon de sang à composants multiples, le système de séparation et de test de fluide biologique comprenant :

le dispositif de transfert d'échantillon de fluide biologique (10) de la revendication 1 et un dispositif de test sanguin (24) ayant un orifice de réception (26) adapté pour recevoir l'orifice de sortie (48) de la partie inférieure (34) du boîtier (30) du dispositif de transfert d'échantillon de fluide biologique (10) pour assurer un transfert fermé d'une partie de l'échantillon de sang du dispositif de transfert d'échantillon de fluide biologique (10) au dispositif de test sanguin (24) par l'intermédiaire de l'orifice de sortie (48).

10. Système de séparation et de test de fluide biologique de la revendication 9, dans lequel le dispositif de test sanguin comprend un dispositif de test de point d'intervention (24).

11. Système de séparation et de test de fluide biologique de la revendication 9, dans lequel, avec le dispositif de transfert d'échantillon de fluide biologique (10) reçu dans l'orifice de réception (26) du dispositif de test sanguin (24), l'actionnement de la partie supérieure (32) de la position non déformée à la position déformée permet de transférer l'échantillon de sang du dispositif de transfert d'échantillon de fluide biologique (10) au dispositif de test sanguin (24) par l'intermédiaire de l'orifice de sortie (48).

12. Système de séparation et de test de fluide biologique de la revendication 9, dans lequel, avec l'échantillon de sang reçu dans le canal d'écoulement (44), la partie inférieure (34) peut être retirée de la partie supérieure (32).

13. Système de séparation et de test de fluide biologique de la revendication 12, comprenant en outre un dispositif de séparation de sang (22), où, avec la partie inférieure (34) retirée de la partie supérieure (32), la partie inférieure (34) peut être reçue dans le dispositif de séparation de sang (22).

14. Système de séparation et de test de fluide biologique de la revendication 13, dans lequel, avec la partie inférieure (34) reçue dans le dispositif de séparation de sang (22), l'échantillon de sang contenu dans la partie inférieure (34) est séparé.

15. Système de séparation et de test de fluide biologique de la revendication 9, dans lequel une partie du boîtier (30) comporte un stabilisateur d'échantillon.

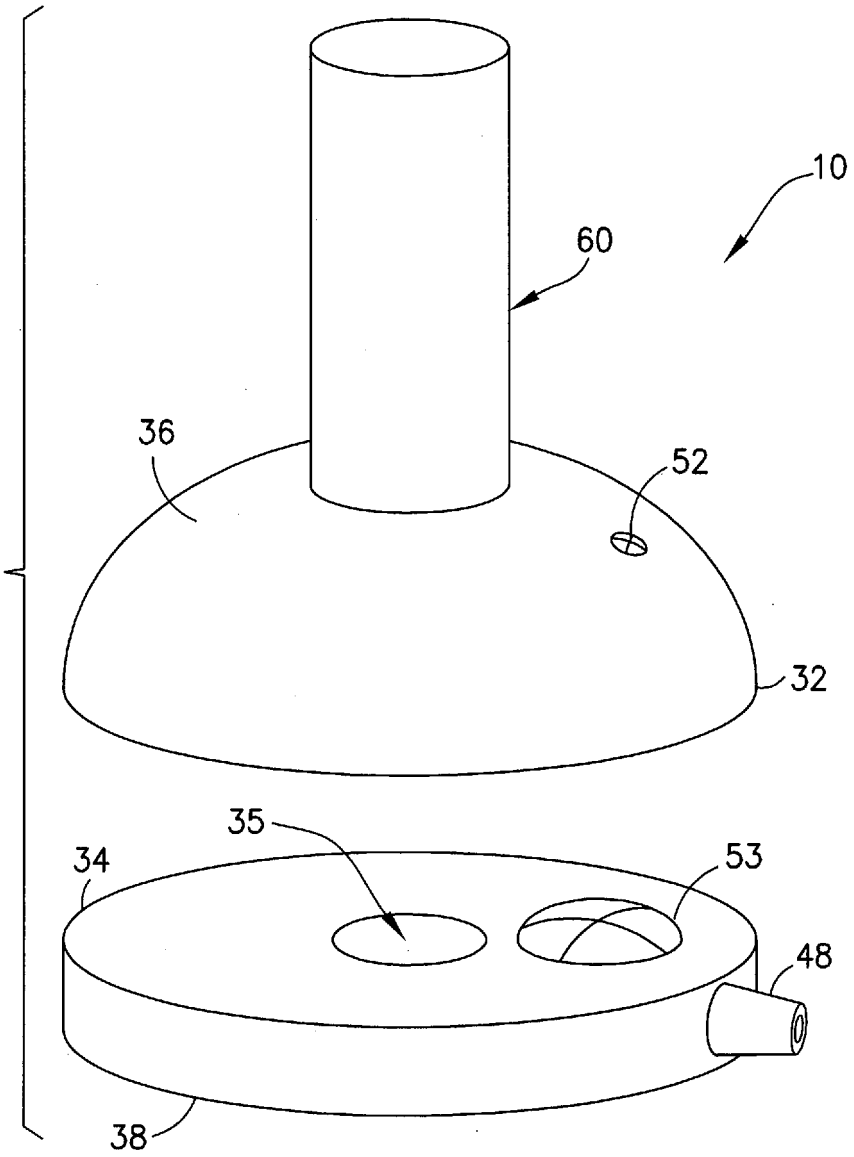


FIG. 1

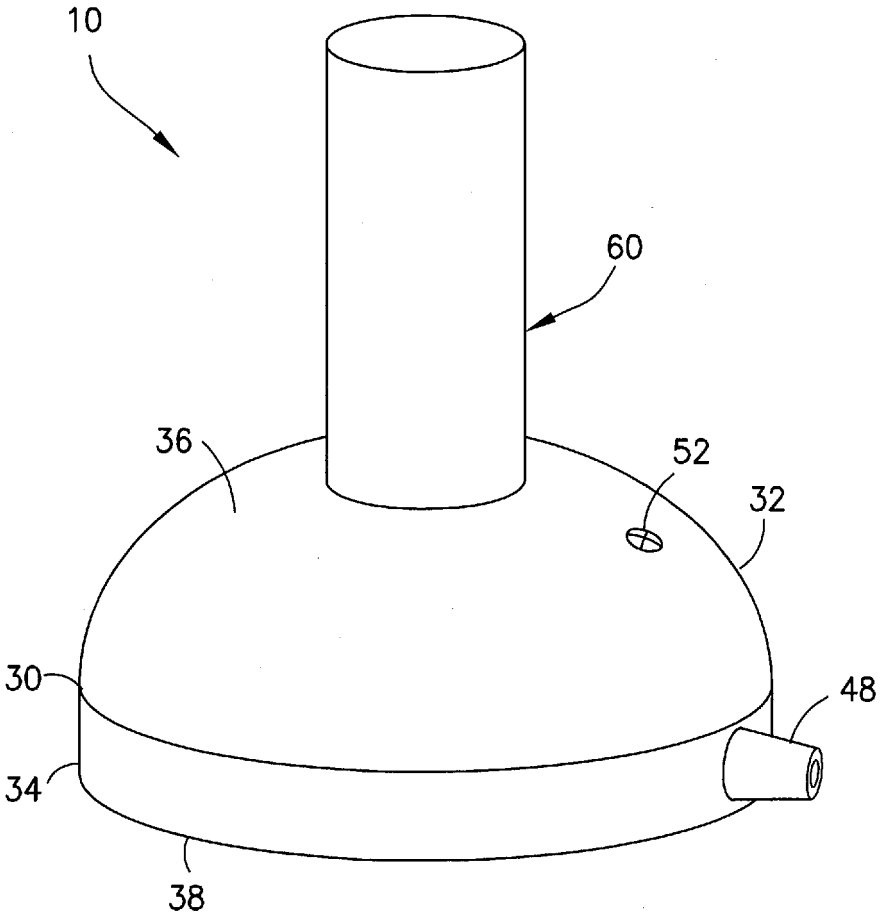


FIG.2

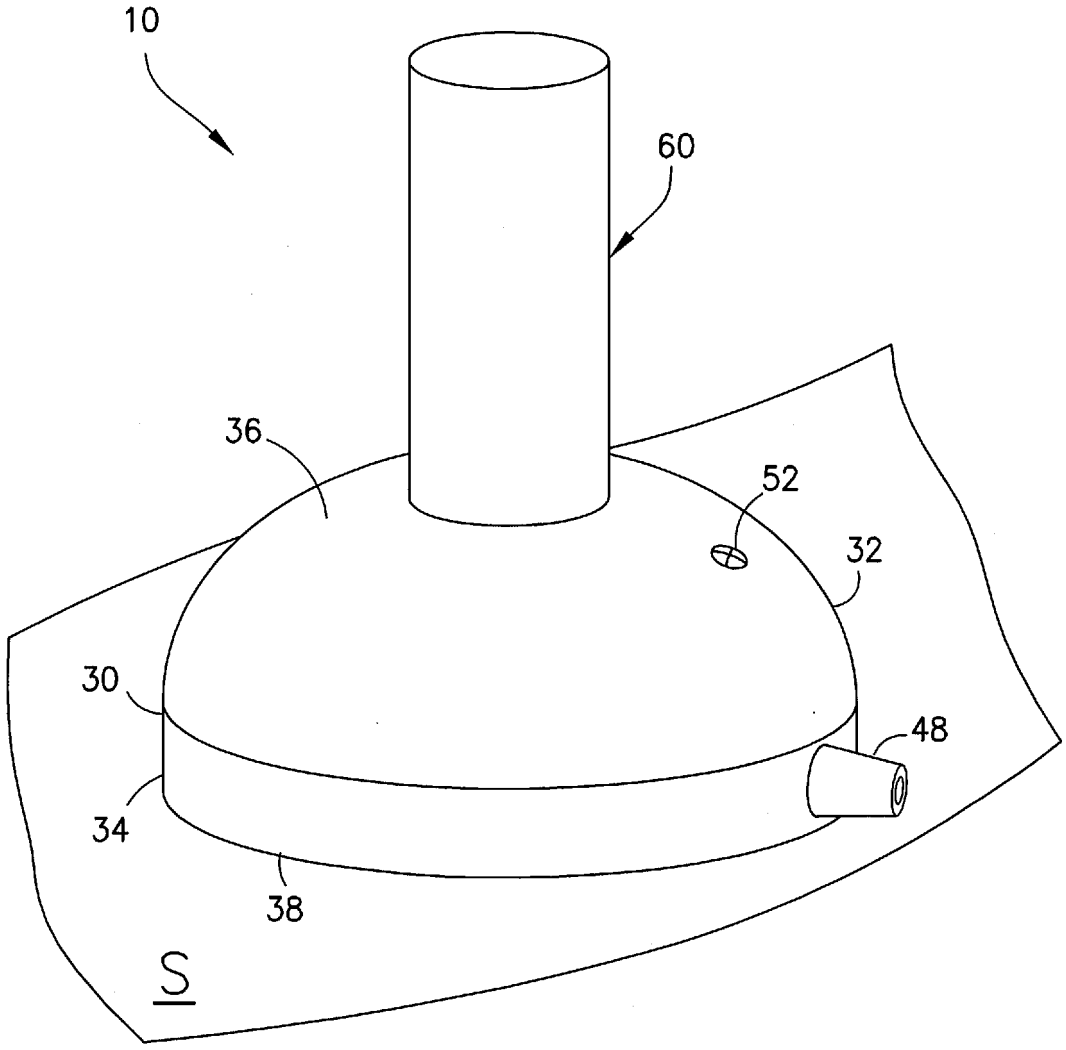


FIG.3

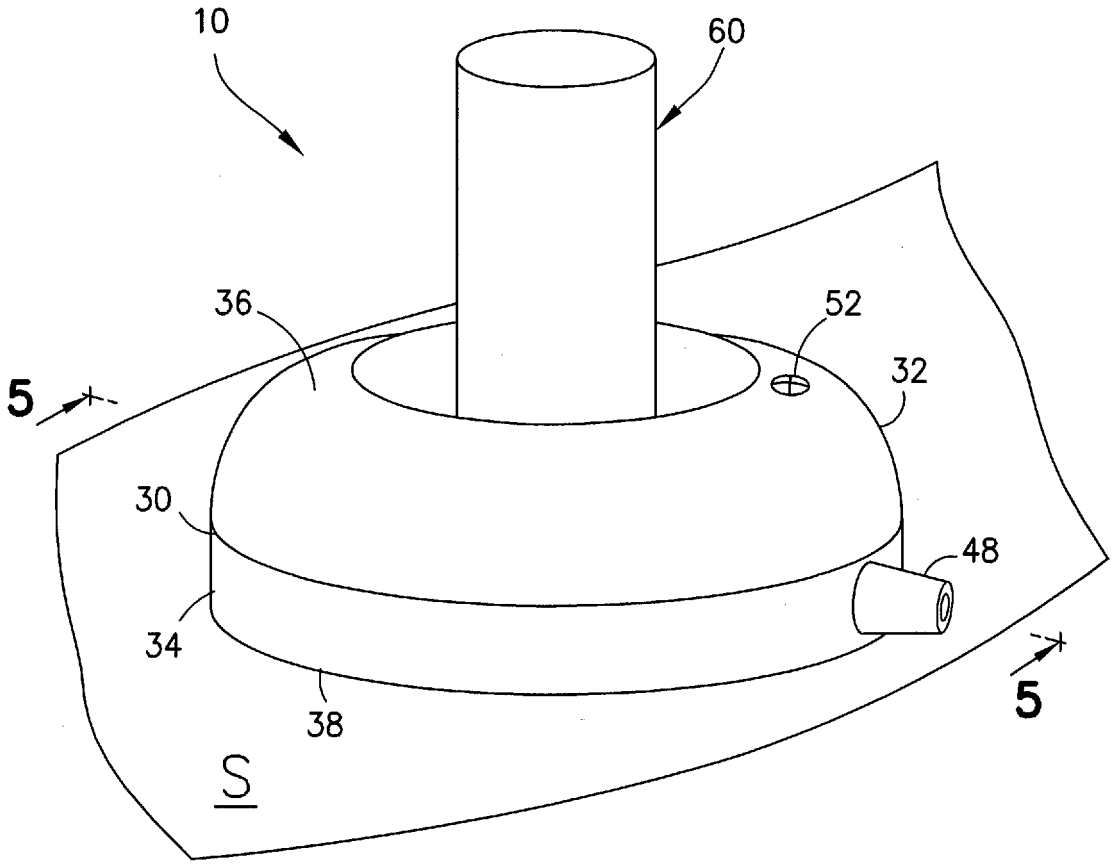
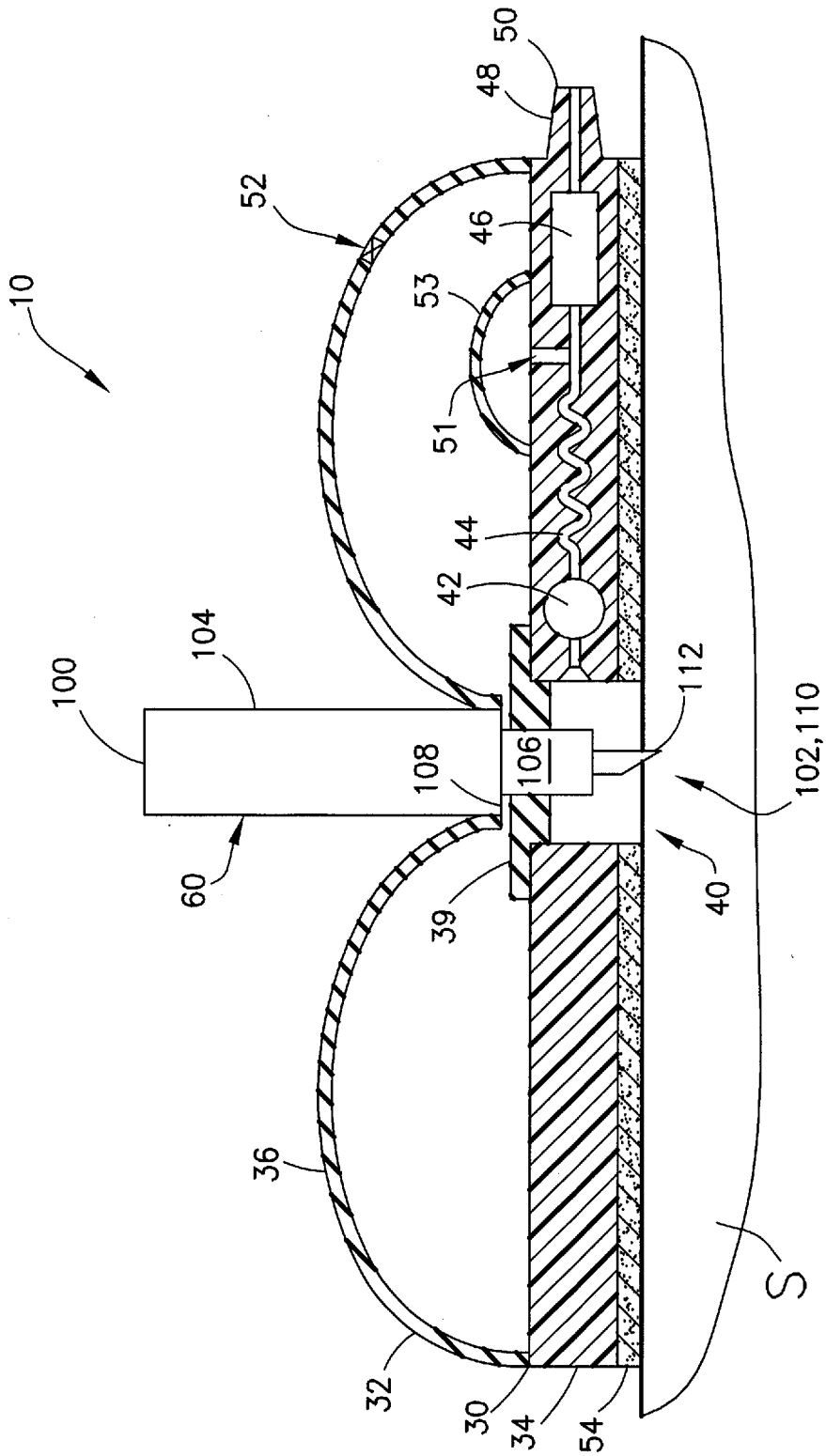


FIG.4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53
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S
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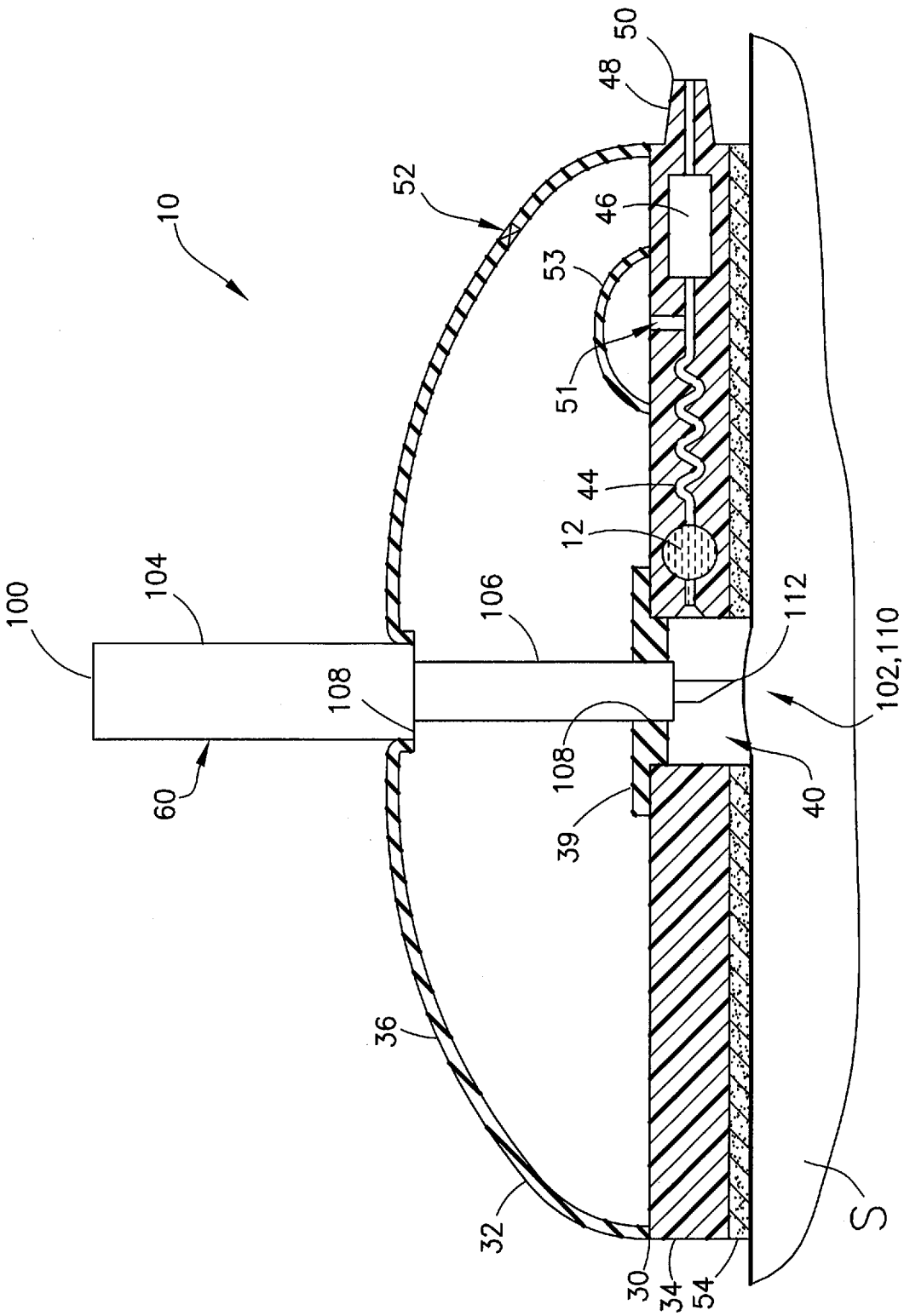
54

FIG.5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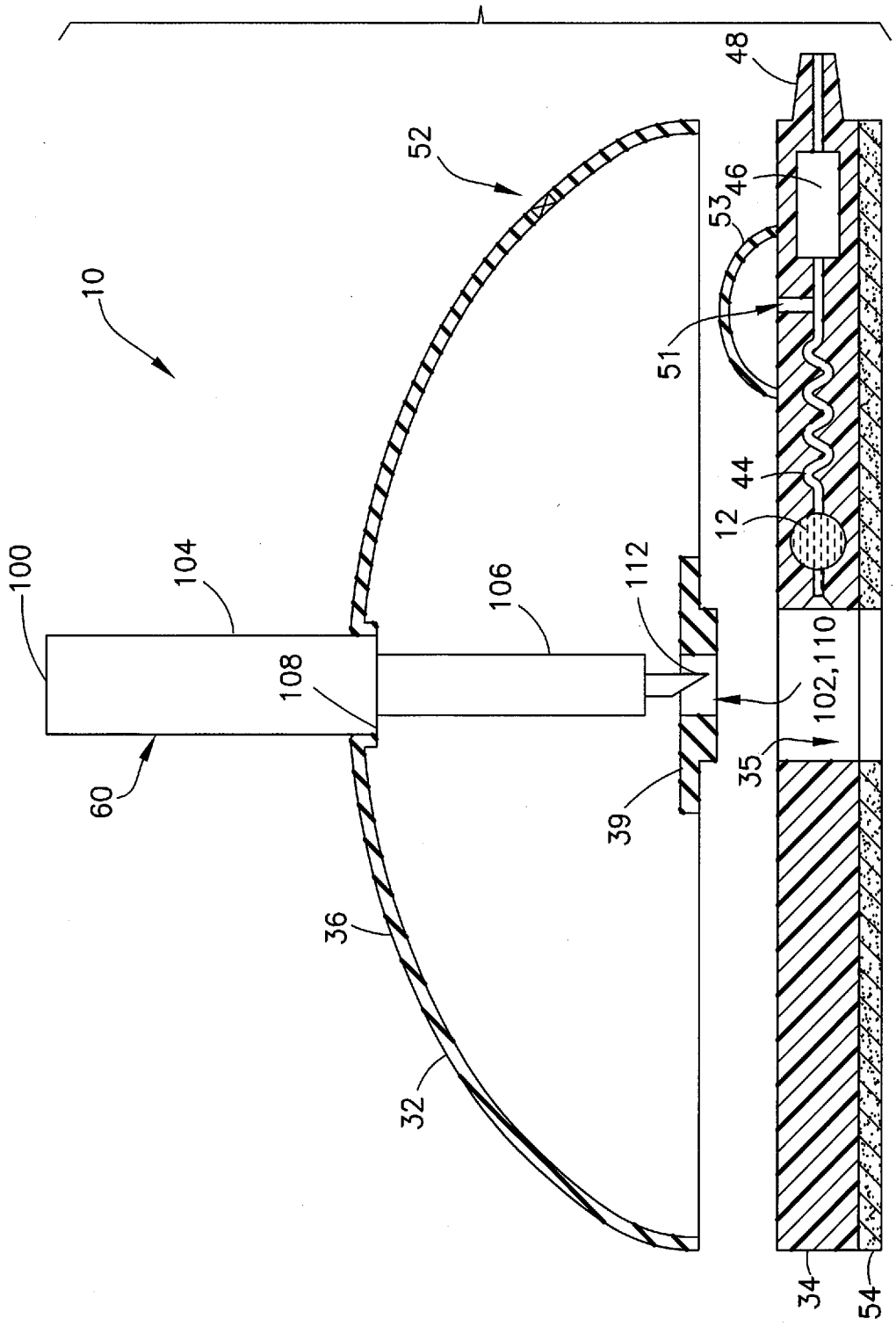
50

FIG.6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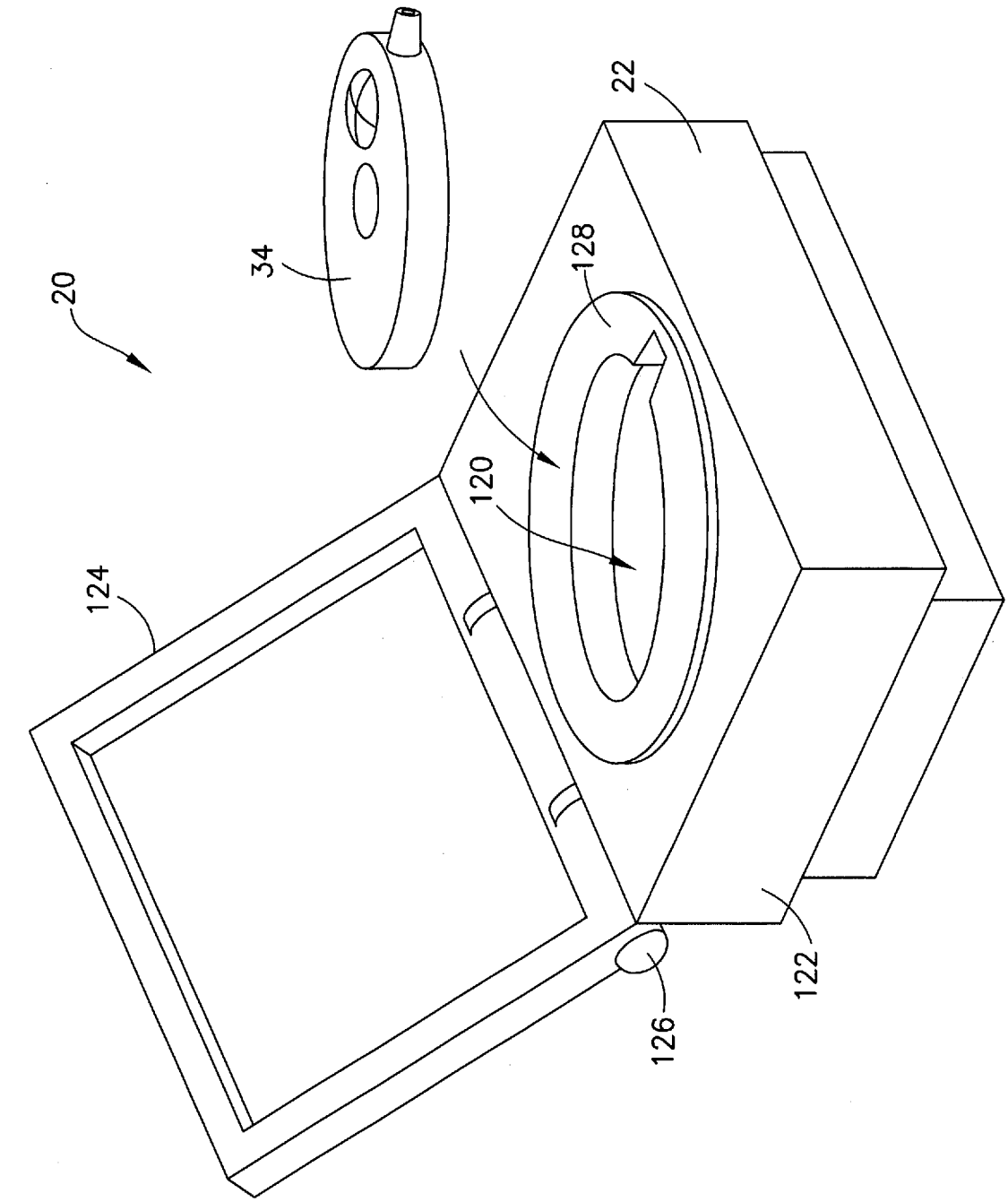
54

FIG.7

FIG.8



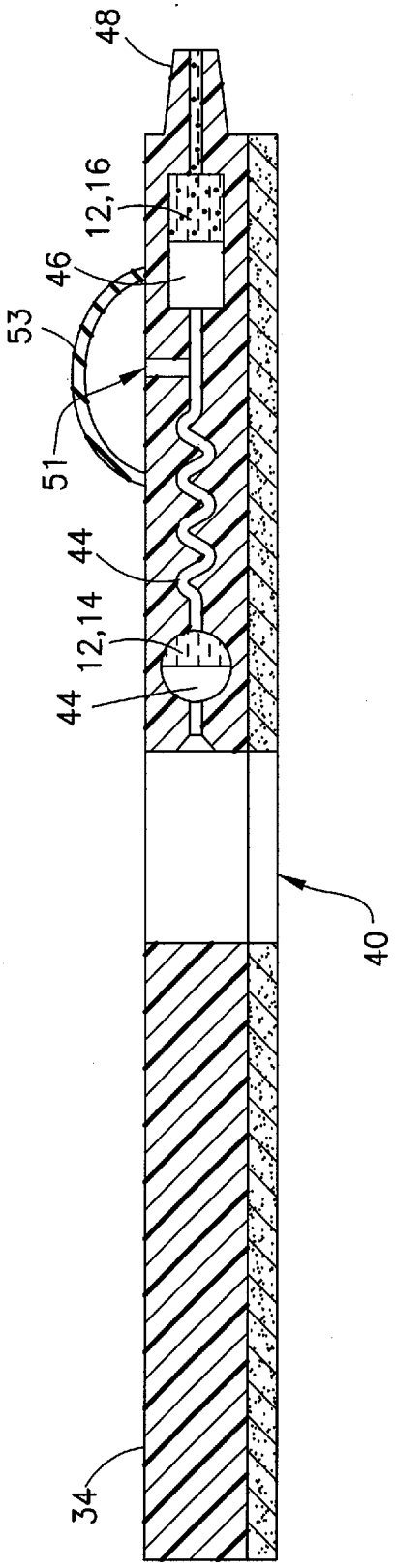


FIG.9

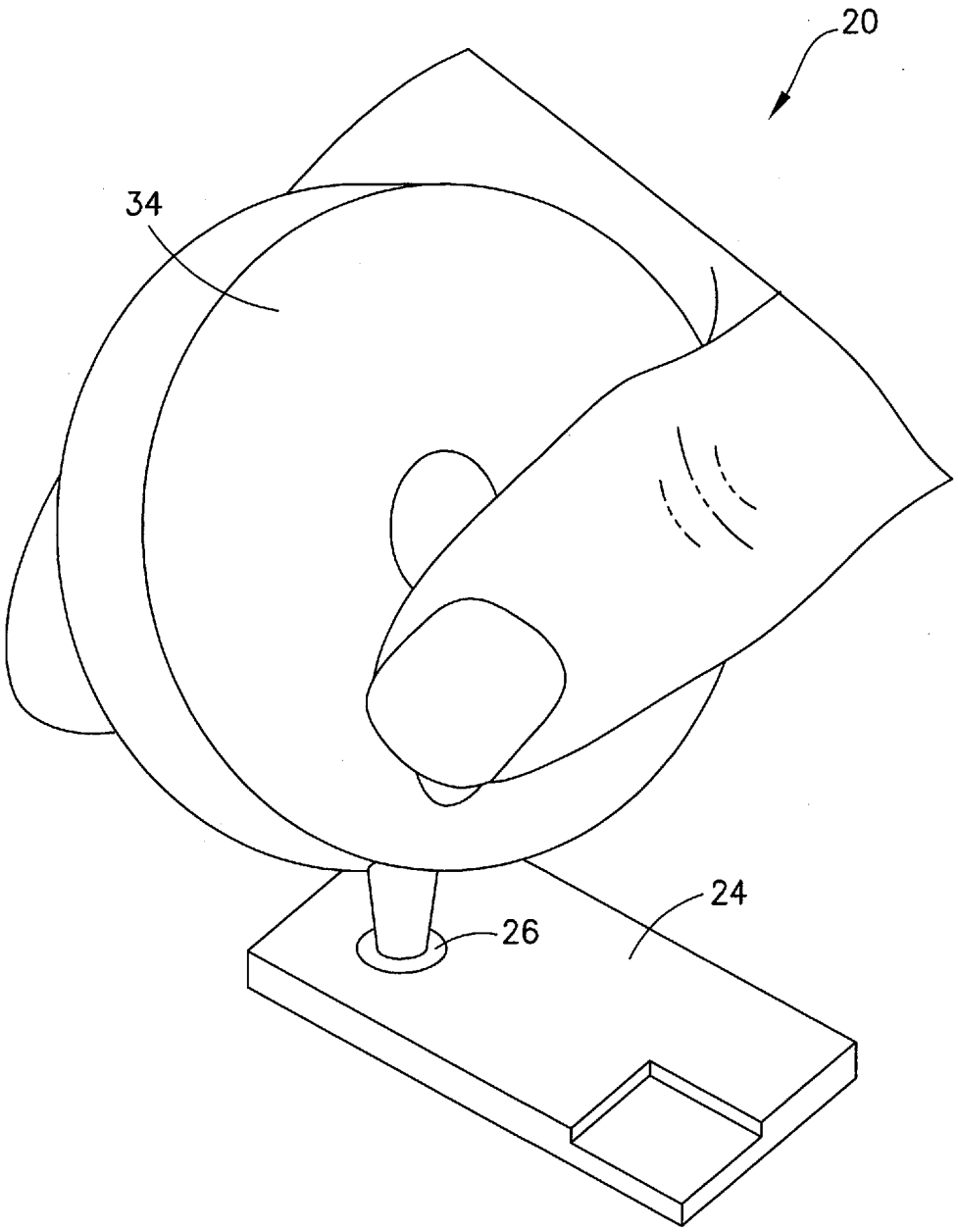


FIG. 10

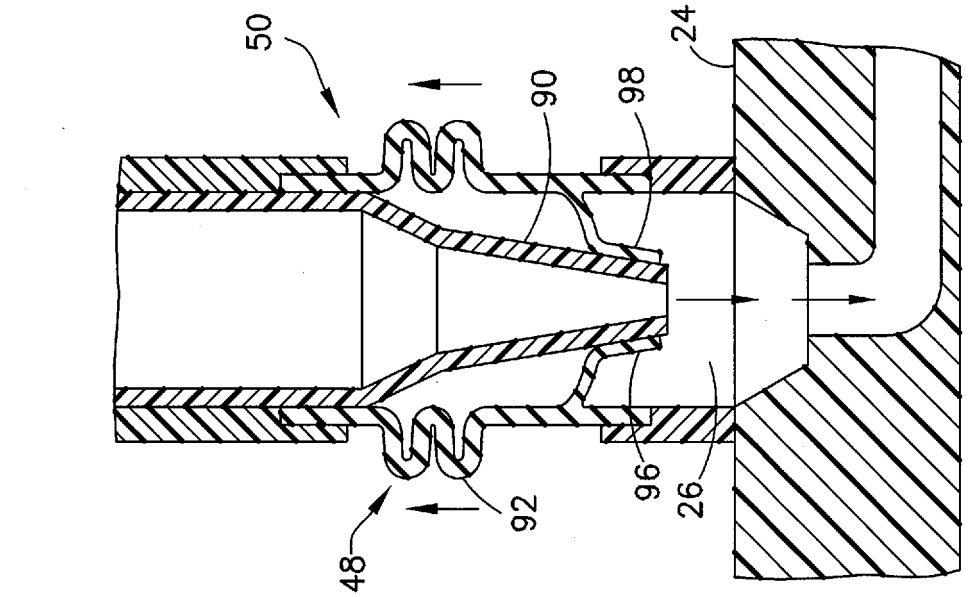


FIG.12

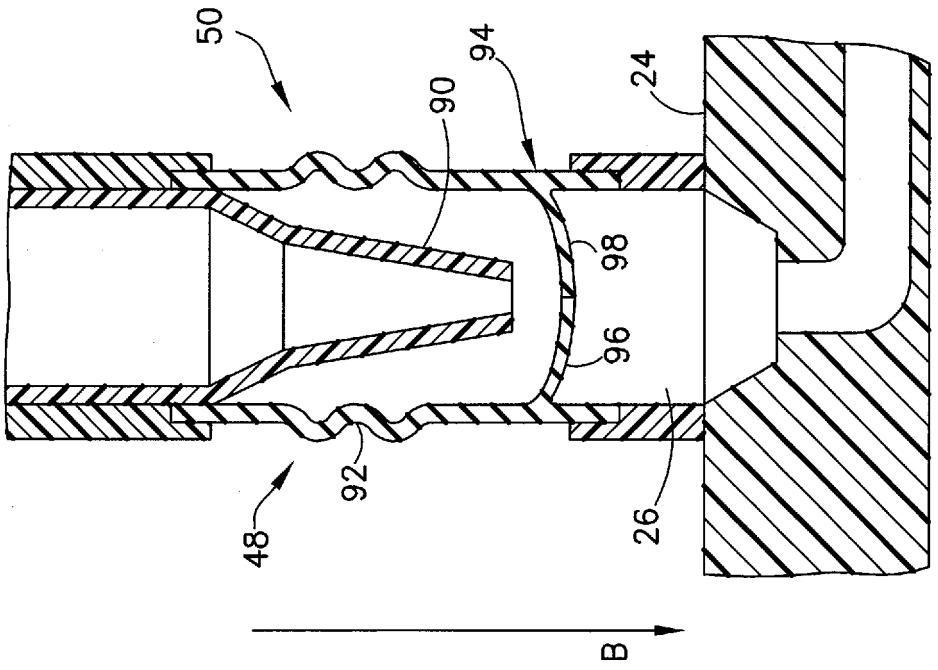


FIG.11

REFERENCES CITED IN THE DESCRIPTION

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