to contamination than secondary and other subsequent portion of the blood sample or subsequent draws. Since the sequestration chamber has an air-permeable blood barrier through which air can be displaced by blood pushed from the patient's vein, such blood will naturally and automatically flow into the sequestration chamber before it is drawn into or otherwise enters into a Vacutainer or other bottle for receiving and storing a blood sample.

[0065] When the sequestration chamber fills, the blood will gather at or otherwise make contact with the air permeable blood barrier, which will inhibit or prevent blood from passing therethrough. At 706, when the blood comes into contact with the entire internal surface area of the air permeable blood barrier, the air permeable blood barrier is then closed and air no longer flows out or in. At 708, the clinician may be provided an indictor or can see the full chamber, to indicate the evacuated blood collection tube, such as a Vacutainer™ can be attached. The indicator can include visibility into the primary chamber to see whether it is full, the blood barrier changing color, for example, or other indicator. The fill time of the sequestration chamber may be substantially instantaneous, so such indicator, if present, may be only that the sequestration chamber is filled.

[0066] Prior to an evacuated blood collection tube being attached, communication between the needle, sampling channel, and the sequestration chamber is restricted by the sealing of the sequestration chamber blood barrier thereby not permitting air to reenter the system through the sequestration. Sealing the communication path could also be accomplished with a mechanical twist or other movement, a small orifice or tortuous pathway, eliminating the need for a separate valve or mechanical movement or operation by the clinician. At 710, once the evacuated blood collection tube is removed, the self-sealing membrane closes the sample needle, and at 712, additional subsequent evacuated blood collection tubes may be attached. Once samples have been taken, at 714 the device is removed from the patient and discarded.

[0067] FIGS. 8A – 8E illustrate an exemplary blood sample optimization system 800 for non-contaminated blood sampling, in accordance with some implementations. The blood sample optimization system 800 includes an inlet port 802 that can be connected to tubing, a patient needle (or both), or other vascular or venous access device, and a pathway splitter 804 having a first outlet to a sequestration chamber tubing 806 and a second outlet to sample collection tubing 808. One or both of the sequestration chamber tubing 806 and the sample collection tubing 808 can be formed of tubing. In some implementations, the sequestration chamber tubing 806 is sized so as to contain a particular volume of initial blood sample. The sample collection tubing 808 will receive a blood sample once the sequestration chamber tubing 806 is filled. The sample collection tubing 808 can be connected to a Vacutainer™ base or housing 810, or other blood sample collection device.

[0068] The blood sequestration system 800 further includes a blood sequestration device 812 which, as shown in more detail in FIGS. 8B – 8D, includes a housing 818 that includes a sampling channel 820 defining a pathway for the non-contaminated sample collection tubing 808 or connected at either end to the non-contaminated sample collection tubing 808. The sampling channel 820 can be curved through the housing 818 so as to better affix and stabilize the housing 818 at a location along the non-contaminated sample collection tubing 808.

[0069] The blood sequestration device 812 further includes a sequestration chamber 822 connected with the sequestration chamber tubing 806 or other chamber. The sequestration chamber 822 terminates at an air permeable blood barrier 824. The air permeable blood barrier 824 can also include a coloring agent that turns a different color upon full contact with blood, as an indicator that the regular collection of blood samples (i.e. the non-contaminated blood samples) can be initiated. Other indicators may be used, such as a small light, a sound generation mechanism, or the like. In some implementations, the air permeable

blood barrier is positioned at a right angle from the direction of sequestration chamber 822, but can be positioned at any distance or orientation in order to conserve space and materials used for the housing 818. The housing 818 and its contents can be formed of any rigid or semi-rigid material or set of materials.

[0070] FIG. 9 illustrates a pathway splitter 900 for use in a blood sequestrations system, such as those shown in FIGS. 8A – 8E, for example. The pathway splitter 900 includes an inlet port 902, a main line outlet port 904, and a sequestration channel outlet port 906. The inlet port 902 can be connected to main tubing that is in turn connected to a patient needle system, or directly to a patient needle. The main line outlet port 904 can be connected to main line tubing to a blood sampling system, such as a vacutainer base or housing, or directly to such blood sampling system. The sequestration channel outlet port 906 can be connected to sequestration tubing for receiving and sequestering a first sample of blood, up to a measured amount or predetermined threshold. Alternatively, the sequestration channel outlet port 906 can be connected to a sequestration chamber. The sequestration channel outlet port 906 is preferably 20-70 degrees angled from the main line outlet port 904, which in turn is preferably in-line with the inlet port 902. Once the predetermined amount of initial blood sample is sequestered in the sequestration tubing or chamber, in accordance with mechanisms and techniques described herein, follow-on blood samples will flow into the inlet port 902 and directly out the main line outlet port 904, without impedance.

[0071] FIGS. 10A – 10D illustrate a blood sequestration device 1000 in accordance with alternative implementations. The blood sequestration device 1000 includes an inlet port 1002, a main outlet port 1004, and a sequestration channel port 1006. The inlet port 1002 can be connected to a patient needle or related tubing. The main outlet port 1004 can be connected to a blood sample collection device such as a Vacutainer, associated tubing, or a Luer activated valve, or the like. The sequestration channel port 1006 splits off from the main outlet port 1004 to a

sequestration chamber 1008. In some implementations, the sequestration chamber 1008 is formed as a helical channel within a housing or other container 1001.

[0072] The sequestration chamber 1008 is connected at the distal end to an air permeable blood barrier 1010, substantially as described above. Air in the sequestration chamber 1008 is displaced through the air permeable blood barrier 1010 by an initial aliquot of blood that is guided into the sequestration channel port 1006. Once the sequestration chamber 1008 is filled, further blood draws through the main outlet port 1004 can be accomplished, where these samples will be non-contaminated.

[0073] FIGS. 11A – 11E illustrate a blood sequestration device 1100 in accordance with other alternative implementations. The blood sequestration device 1100 includes an inlet port 1102, similar to the inlet ports described above, a main outlet port 1104, and a sequestration channel port 1106 that splits off from the main outlet port 1104 and inlet port 1102. The sequestration channel port is connected to a sequestration chamber 1108. In the implementation shown in FIGS. 11A – 11E, the blood sequestration device includes a base member 1101 having a channel therein, which functions as the sequestration chamber 1108. The channel can be formed as a tortuous path through the base member 1101, which is in turn shaped and formed to rest on a limb of a patient.

[0074] A portion of the sequestration chamber 1108 can protrude from the base member or near a top surface of the base member, just before exiting to an air permeable blood barrier 1110, to serve as a blood sequestration indicator 1109. The indicator 1109 can be formed of a clear material, or a material that changes color when in contact with blood.

[0075] In some implementations, the blood sequestration device 1100 can include a blood sampling device 1120 such as a normally closed needle, Vacutainer™ shield or other collection device. The blood sampling device 1120 can

be manufactured and sold with the blood sequestration device 1100 for efficiency and convenience, so that a first aliquot of blood that may be contaminated by a patient needle insertion process can be sequestered. Thereafter, the blood sampling device 1120 can draw non-contaminated blood samples to reduce the risk of false positive testing and ensure a non-contaminated sample.

[0076] FIGS. 12A-12D illustrate a blood sample optimization system 1200 in accordance with yet other alternative implementations. The system 1200 includes a blood sequestration device 1202 for attaching to a blood sampling device 1204, such as a Vacutainer™ or other collection and sampling device. The blood sequestration device 1202 is configured and arranged to receive, prior to a Vacutainer™ container or vial being attached to a collection needle of the blood sampling device 1204, a first aliquot or amount of blood, and sequester that first aliquot or amount in a sequestration channel of the blood sequestration device 1202.

[0077] In some implementations, the blood sequestration device 1202 can include an inlet port 1212, a main outlet port, and a sequestration channel port. The inlet port 1212 can be connected to a patient needle or related tubing. The main outlet port 1214 can be connected to a normally closed needle or device to enable connection with an evacuated blood collection container or other collection device such as a Vacutainer™, associated tubing, luer connectors, syringe, a Luer activated valve, or the like. The sequestration channel port splits off from the main outlet port to a sequestration chamber 1218.

[0078] In some implementations, the sequestration chamber 1218 is formed as a channel within the body of a sequestration device 1202. The sequestration chamber 1218 can be a winding channel, such as a U-shaped channel, an S-shaped channel, a helical channel, or any other winding channel. The sequestration device 1202 can include a housing or other containing body, and one or more channels formed therein. As shown in FIGS. 12A and 12B, the sequestration device 1202 includes a main body 1206 and a cap 1208. The main body 1206 is formed with

one or more cavities or channels, which are further formed with one or more arms 1210 that extend from the cap 1208, and which abut the cavities or channels in the main body 1206 to form the primary collection port and main outlet port.

[0079] FIGS. 13A-13D illustrate a blood sample optimization system 1300 in accordance with yet other alternative implementations. The system 1300 includes a blood sequestration device 1302 for attaching to a blood sampling device 1304, such as a Vacutainer or other bodily fluid collection and sampling device. The blood sequestration device 1302 is configured and arranged to receive, prior to a Vacutainer container or vial being attached to a collection needle of the blood sampling device 1304, a first aliquot or amount of blood, and to sequester that first aliquot or amount of blood or other bodily fluid in a sequestration channel of the blood sequestration device 1302.

[0080] The blood sequestration device 1302 includes a housing 1301 having an inlet port 1314, a main outlet port 1312, and a sequestration channel port 1316. The inlet port 1314 can be connected to a patient needle or associated tubing. The main outlet port 1312 can be connected to a normally closed needle or device to enable connection with an evacuated blood collection container or other collection device such as a Vacutainer™, associated tubing, luer connectors, syringe, a Luer activated valve, or the like. The sequestration channel port 1316 splits off from the main inlet port 1314 to a sequestration chamber 1318.

[0081] In the implementation shown in FIGS. 13A-D, the sequestration chamber 1318 is formed as a cavity or chamber within housing 1301 or formed by walls that define housing 1301. The sequestration chamber 1318 can be a winding channel, such as a U-shaped channel, an S-shaped channel, a helical channel, or any other winding channel, that is defined by the cooperation and connection of housing 1301 with cap 1307 which cap 1307 can include a protrusion 1305 that provides one or more walls or directors for the winding channel in the sequestration chamber 1318. The protrusion 1305 from the cap 1307 can be straight or curved,

and may have various channels, apertures or grooves embedded therein, and can extend from the cap 1307 any angle or orientation. When the cap 1307 is connected with the housing 1301 to complete the formation of the sequestration chamber 1318, the protrusion 1305 forms at least part of the winding channel to sequester a first aliquot or amount of blood or other bodily fluid in a sequestration channel formed in the sequestration chamber 1318 and by the winding channel.

[0082] The sequestration chamber 1318 includes an air permeable blood barrier 1310, substantially as described above. Air in the sequestration chamber 1318 is displaced through the air permeable blood barrier 1310 by an initial aliquot of blood that is provided into the sequestration chamber 1318 by the blood pressure of the patient. Once the sequestration chamber 1318 is filled and the air in the sequestration chamber 1318 displaced, the blood pressure of the patient will be insufficient to drive or provide further blood into the blood sequestration device 1302, and in particular the outlet port 1312, until a force such as a vacuum or other pressure, such as provided by the blood sample collection device like Vacutainer is provided to draw out a next aliquot or amount of blood or bodily fluid. Further blood draws through the main outlet port 1312 can be accomplished, where these samples will be non-contaminated since any contaminants would be sequestered in the sequestration chamber 1318 with the first aliquot of blood.

[0083] FIGS. 14A-14E illustrate yet another implementation of a blood sampling system 1400 to sequester contaminates of an initial aliquot or sample to reduce false positives in blood cultures or tests performed on a patient's blood sample. The blood sampling system 1400 includes a blood sequestration device 1401 that can be connected between a blood sample collection device 1403 and a patient needle (not shown). The blood sample collection device 1403 can be a Vacutainer or the like. The blood sequestration device 1401 includes an inlet port 1402 that can be connected with a patient needle that is inserted into a patient's vascular system for access to and withdrawing of a blood sample. The inlet port

1402 may also be connected with tubing or other conduit that is in turn connected with the patient needle.

[0084] The inlet port 1402 defines an opening into the blood sequestration device 1401, which opening can be the same cross sectional dimensions as tubing or other conduit connected with the patient needle or the patient needle itself. For instance, the opening can be circular with a diameter of approximately 0.114 cm (0.045 inches), but can have a diameter of between 0.0254 cm (0.01 inches) or less to 0.508 cm (0.2 inches) or more. The blood sequestration device 1401 further includes an outlet port 1404, which defines an opening out of the blood sequestration device 1401 and to the blood sample collection device 1403. The outlet port 1404 may also be connected with tubing or other conduit that is in turn connected with the blood sequestration device 1403. The outlet port 1404 can further include a connector device such as a threaded cap, a Luer connector (male or female), a non threaded interference or glue joint fitting for attachment of various devices including but not limited to tubing, or the like.

[0085] The blood sequestration device 1401 further includes a sampling channel 1406 between the inlet port 1402 and the outlet port 1404, and which functions as a blood sample pathway once a first aliquot of blood has been sequestered. The sampling channel 1406 can be any sized, shaped or configured channel, or conduit. In some implementations, the sampling channel 1406 has a substantially similar cross sectional area as the opening of the inlet port 1402. In other implementations, the sampling channel 1406 can gradually widen from the inlet port 1402 to the outlet port 1404.

[0086] The blood sequestration device 1401 further includes a sequestration chamber 1408 that is connected to and split off or diverted from the sampling channel 1406 at any point between the inlet port 1402 and the outlet port 1404, but preferably from a proximal end of the sampling channel 1406 near the inlet port 1402. The sequestration chamber 1408 is at first maintained at atmospheric pressure, and includes an air outlet 1412 at or near a distal end of the sequestration

chamber 1408 opposite the diversion point from the sampling channel 1406. The air outlet 1412 includes an air permeable blood barrier 1412. As shown in FIG. 14B, the air permeable blood barrier 1412 can be overlaid with a protective cover 1416. The protective cover 1416 can be sized and configured to inhibit a user from touching the air permeable blood barrier 1412 with their finger or other external implement, while still allowing air to exit the air permeable blood barrier 1412 as the air is displaced from the sequestration chamber 1408 by blood being forced into the sequestration chamber 1408 by a patient's own blood pressure. In addition the protective cover 1416 can be constructed to inhibit or prevent accidental exposure of the air permeable blood barrier to environmental fluids or splashes. This can be accomplished in a variety of mechanical ways including but not limited to the addition of a hydrophobic membrane to the protective cover.

[0087] As shown in FIGS. 14C and 14D, the sampling channel 1406 can be cylindrical or frusto-conical in shape, going from a smaller diameter to a larger diameter, to minimize a potential to lyse red blood cells. Likewise, the sampling channel 1406 is formed with a minimal amount of or no sharp turns or edges, which can also lyse red blood cells. The sampling channel 1406 splits off to the sequestration chamber 1408 near the inlet port 1402 via a diversion pathway 1409. The diversion pathway 1409 can have any cross-sectional shape or size, but is preferably similar to the cross-sectional shape of at least part of the inlet port 1402.

[0088] In some implementations, the sampling channel 1406 and the sequestration chamber 1408 are formed by grooves, channels, locks or other pathways formed in housing 1414. The housing 1414 can be made of plastic, metal or other rigid or semi-rigid material. The housing 1414 can have a bottom member that sealably mates with a top member. One or both of the bottom member and the top member can include the sampling channel 1406 and the sequestration chamber 1408, as well as the diversion pathway 1409, the inlet port 1402, and the outlet port 1404. In some other implementations, one or more of the diversion

pathway 1409, the inlet port 1402, and/or the outlet port 1404 can be at least partially formed by a cap member that is connected to either end of the housing 1414. In some implementations, the top member and the bottom member, as well as the cap member(s), can be coupled together by laser welding, heat sealing, gluing, snapping, screwing, bolting, or the like. In other implementations, some or all of the interior surface of the diversion pathway 1409 and/or sequestration chamber 1408 can be coated or loaded with an agent or substance, such as a decontaminate, solidifying agent, or the like. For instance, a solidifying agent can be provided at the diversion pathway 1409 such that when the sequestration chamber 1408 is filled and the initial aliquot of blood backs up to the diversion pathway 1409, that last amount of sequestered blood could solidify, creating a barrier between the sequestration chamber 1408 and the sampling channel 1406.

[0089] FIGS. 15A-15G illustrate a blood sequestration device 1500. The blood sequestration device 1500 can be connected to a normally closed needle or device to enable connection with an evacuated blood collection container or other collection device such as a Vacutainer™, associated tubing, luer connectors, syringe, a Luer activated valve, or the like.

[0090] The blood sequestration device 1500 includes an inlet port 1502 that can be connected with a patient needle that is inserted into a patient's vascular system for access to and withdrawing of a blood sample. The inlet port 1502 may also be connected with tubing or other conduit that is in turn connected with the patient needle. The inlet port 1502 defines an opening into the blood sequestration device 1500, which opening may be the same cross sectional dimensions as tubing or other conduit connected with the patient needle or the patient needle itself. For instance, the opening can be circular with a diameter of approximately 0.114 cm (0.045 inches), but can have a diameter of between 0.0254 cm (0.01 inches) or less to 0.508 cm (0.2 inches) or more.

[0091] The inlet port 1502 can also include a sealing or fluid-tight connector or connection, such as threading or Luer fitting, or the like. In some

implementations, tubing or other conduit associated with the patient needle can be integral with the inlet port 1502, such as by co-molding, gluing, laser weld, or thermally bonding the parts together. In this manner, the blood sequestration device 1500 can be fabricated and sold with the patient needle as a single unit, eliminating the need for connecting the patient needle to the blood sequestration device 1500 at the time of blood draw or sampling.

[0092] The blood sequestration device 1500 further includes an outlet port 1504, which defines an opening out of the blood sequestration device 1500 and to the blood sample collection device. The outlet port 1504 may also be connected with tubing or other conduit that is in turn connected with the blood sequestration device, and may also include a sealing or fluid-tight connector or connection, such as threading or Luer fitting, or the like. Accordingly, as discussed above, the blood sequestration device 1500 can be fabricated and sold with the patient needle and/or tubing and the blood sample collection device as a single unit, eliminating the need for connecting the patient needle and the blood sample collection device to the blood sequestration device 1500 at the time of blood draw or sampling.

[0093] The blood sequestration device 1500 further includes a sampling channel 1506 between the inlet port 1502 and the outlet port 1504, and which functions as a blood sample pathway once a first aliquot of blood has been sequestered. The sampling channel 1506 can be any sized, shaped or configured channel or conduit. In some implementations, the sampling channel 1506 has a substantially similar cross sectional area as the opening of the inlet port 1502. In other implementations, the sampling channel 1506 can gradually widen from the inlet port 1502 to the outlet port 1504.

[0094] The blood sequestration device 1500 further includes a sequestration chamber 1508 that is connected to and split off or diverted from the sampling channel 1506 at any point between the inlet port 1502 and the outlet port 1504, but preferably from a proximal end of the sampling channel 1506 near the inlet port

1502. In some implementations, the diversion includes a Y-shaped junction. The sequestration chamber 1508 is preferably maintained at atmospheric pressure, and includes a vent 1510 at or near a distal end of the sequestration chamber 1508. The vent 1510 includes an air permeable blood barrier 1512. FIG. 15C illustrates the blood sequestration device 1500 with the sequestration chamber 1508 filled with a first aliquot or sample of blood from the patient.

[0095] The air permeable blood barrier 1512 can be covered with a protective cover 1516. The protective cover 1516 can be sized and configured to inhibit a user from touching the air permeable blood barrier 1512 with their finger or other external implement, while still allowing air to exit the air permeable blood barrier 1512 as the air is displaced from the sequestration chamber 1508 by blood being forced into the sequestration chamber 1508 by a patient's own blood pressure. The protective cover 1516 can be constructed to inhibit or prevent accidental exposure of the filter to environmental fluids or splashes. This can be accomplished in a variety of mechanical ways including but not limited to the addition of a hydrophobic membrane to the protective cover.

[0096] FIG. 15B is a perspective view of the blood sequestration device 1500 from the outlet port 1504 and top side of a housing 1501 of the blood sequestration device 1500 that includes the vent 1510, and illustrating an initial aliquot of blood filling sequestration chamber 1508 while the sampling channel 1506 is empty, before a sample collection device is activated. FIG. 15G is a perspective view of the blood sequestration device 1500 from the outlet port 1504 and bottom side of the housing 1501 of the blood sequestration device 1500, and illustrating the initial aliquot of blood filling sequestration chamber 1508 while the sampling channel 1506 is empty, before the sample collection device is activated. FIG. 15C is another perspective view of the blood sequestration device 1500 from the inlet port 1502 and top side of a housing 1501 of the blood sequestration device 1500 that includes the vent 1510, and illustrating blood now being drawn through sampling channel

1506 while the sequestered blood remains substantially in the sequestration chamber 1508.

[0097] FIG. 15D is a cross section of the blood sequestration device 1500 in accordance with some implementations, showing the housing 1501 that defines the sampling channel 1506 and the sequestration chamber 1508. FIGS. 15E and 15F illustrate various form factors of a housing for a blood sequestration device, in accordance with one or more implementations described herein.

[0098] The sequestration chamber 1508 can have a larger cross-sectional area than the sampling channel 1506, and the cross-sectional area and length can be configured for a predetermined or specific volume of blood to be sequestered or locked. The sampling channel 1506 can be sized to be compatible with tubing for either or both of the patient needle tubing or the blood collection device tubing.

[0099] The housing 1501 can be formed of multiple parts or a single, unitary part. In some implementations, and as illustrated in FIG. 15D, the housing 1501 includes a top member 1520 and a bottom member 1522 that are mated together, one or both of which having grooves, channels, locks, conduits or other pathways pre-formed therein, such as by an injection molding process or by etching, cutting, drilling, etc. The top member 1520 can be connected with the bottom member 1522 by any mating or connection mechanism, such as by laser welding, thermal bonding, ultrasonic welding, gluing, using screws, rivets, bolts, or the like, or by other mating mechanisms such as latches, grooves, tongues, pins, flanges, or the like.

[00100] In some implementations, such as shown in FIG. 15D, the top member 1520 can include the grooves, channels, locks, conduits or other pathways, while the bottom member 1522 can include a protrusion 1524 that is sized and adapted to fit into at least one of the grooves, channels, locks or other pathways of the top member 1520. The protrusion 1524 can provide a surface feature, such as a partial

groove or channel, for instance, to complete the formation of either the sampling channel 1506 and/or the sequestration chamber 1508. In some implementations, the protrusion 1524 can be formed with one or more angled sides or surfaces for a tighter fit within the corresponding groove, channel, lock or other pathway. In yet other implementations, both the top member 1520 and the bottom member can include grooves, channels, locks or other pathways, as well as one or more protrusions 1524.

[00101] In some implementations, the sampling channel 1506 and the sequestration chamber 1508 are formed by grooves, channels, locks or other pathways formed in housing 1501. The housing 1501 can be made of any suitable material, including rubber, plastic, metal or other material. The housing 1501 can be formed of a clear or translucent material, or of an opaque or non-translucent material. In other implementations, the housing 1501 can be mostly opaque or non-translucent, while the housing surface directly adjacent to the sampling channel 1506 and/or the sequestration chamber 1508 is clear or translucent, giving a practitioner a visual cue or sign that the sequestration chamber 1508 is first filled to the extent necessary or desired, and/or then a visual cue or sign that the sequestered blood remains sequestered while a clean sample of blood is drawn through the sampling channel 1506. Other visual cues or signs of the sequestration can include, without limitation: the air permeable blood barrier 1512 turning a different color upon contact, saturation, or partial saturation with blood; a color-coded tab or indicator at any point along or adjacent to the sequestration chamber; an audible signal; a vibratory signal; or other signal.

[00102] After a venipuncture by a patient needle of a patient (not shown, not claimed),

which could gather a number of pathogens from the patient's skin, a first amount of the patient's blood with those pathogens will make its way into the input port 1502 blood sequestration device 1500 and flow into the sequestration chamber 1508 by following the path of least resistance, as the patient's own blood pressure

overcomes the atmospheric pressure in the sequestration chamber 1508 to displace air therein through the air permeable blood barrier 1512. The patient's blood pressure will not be sufficient to overcome the air pressure that builds up in the sealed sampling channel 1506. Eventually, the sequestration chamber 1508, which has a predetermined volume, is filled with blood that displaces air through the air permeable blood barrier 1512. Once the blood hits the air permeable blood barrier, the blood interacts with the air permeable blood barrier 1512 material to completely or partially seal the vent 1510. A signal or indication may be provided that the practitioner can now utilize the Vacutainer capsule or other blood sample collection device to acquire a next amount of the patient's blood for sampling. The blood in the sequestration chamber 1508 is now effectively sequestered in the sequestration chamber.

[00103] Upon filling the blood sequestration pathway 1508 but prior to use of the Vacutainer or other blood sample collection device, the patient's blood pressure may drive compression of the air in the sampling channel 1506, possibly resulting in a small amount of blood moving past the diversion point to the sequestration chamber 1508 and into the sampling channel 1506, queuing up the uncontaminated blood to be drawn through the sampling channel 1506.

[00104] FIGS. 16-19 illustrate yet another implementation of a blood sequestration device. FIGS. 16A-16D illustrate a blood sequestration device 1600 that can be connected between a blood sample collection device, such as an evacuated blood collection container like a Vacutainer™ (not shown), and a patient needle (not shown) and/or associated tubing. FIG. 17 illustrates a bottom member of the blood sequestration device, and FIG. 18 illustrates a top member of the blood sequestration device, which top member and bottom member can be mated together to form an input port, and output port, a sequestration chamber and a sampling channel, as explained more fully below. FIGS. 19A and B show the top member and bottom member mated together. It should be understood that FIGS.

16-19 illustrate one exemplary manner of constructing a blood sequestration device as described herein, and other forms of construction are possible.

[00105] Referring to FIGS. 16A – D, the blood sequestration device 1600 includes an inlet port 1602 that can be connected with a patient needle that is inserted into a patient's vascular system for access to and withdrawing of a blood sample. The inlet port 1602 may also be connected with tubing or other conduit that is in turn connected with the patient needle. The inlet port 1602 defines an opening into the blood sequestration device 1600, which opening can be the same cross sectional dimensions as tubing or other conduit connected with the patient needle or the patient needle itself. For instance, the opening can be circular with a diameter of approximately 0.114 cm (0.045 inches), but can have a diameter of between 0.0254 cm (0.01 inches) or less to 0.508 cm (0.2 inches) or more.

[00106] The inlet port 1602 can also include a sealing or fluid-tight connector or connection, such as threading or Luer fitting, or the like. In some implementations, tubing or other conduit associated with the patient needle can be integral with the inlet port 1602, such as by co-molding, gluing, laser weld, or thermally bonding the parts together. In this manner, the blood sequestration device 1600 can be fabricated and sold with the patient needle and/or tubing as a single unit, eliminating the need for connecting the patient needle to the blood sequestration device 1600 at the time of blood draw or sampling.

[00107] The blood sequestration device 1600 further includes an outlet port 1604, which defines an opening out of the blood sequestration device 1600 and to the blood sample collection device. The outlet port 1604 may also be connected with tubing or other conduit that is in turn connected with the blood sequestration device, and may also include a sealing or fluid-tight connector or connection, such as threading or Luer fitting, or the like. Accordingly, as discussed above, the blood sequestration device 1600 can be fabricated and sold with the patient needle and/or tubing and the blood sample collection device as a single unit, eliminating the need

for connecting the patient needle and the blood sample collection device to the blood sequestration device 1600 at the time of blood draw or sampling.

[00108] The blood sequestration device 1600 further includes a sampling channel 1606 between the inlet port 1602 and the outlet port 1604, and a sequestration chamber 1608 that is connected to and split off or diverted from the sampling channel 1606 at any point between the inlet port 1602 and the outlet port 1604. The sampling channel 1606 functions as a blood sampling pathway once a first aliquot of blood has been sequestered in the sequestration chamber 1608. The sampling channel 1606 can be any sized, shaped or configured channel, or conduit. In some implementations, the sampling channel 1606 has a substantially similar cross sectional area as the opening of the inlet port 1602. In other implementations, the sampling channel 1606 can gradually widen from the inlet port 1602 to the outlet port 1604. The sequestration chamber 1608 may have a larger cross section to form a big reservoir toward the sequestration channel path so that the blood will want to enter the reservoir first versus entering a smaller diameter on the sampling channel 1606, as is shown more fully in FIGS. 17 and 19.

[00109] In some exemplary implementations, the diversion between the sampling channel 1606 and the sequestration chamber 1608 is by diverter junction 1607. Diverter junction 1607 may be a substantially Y-shaped, T-shaped, or U-shaped. In some preferred exemplary implementations, and as shown in FIG. 17A – 17B, the diverter junction 1607 is configured such that the flow out of the inlet port 1602 is preferentially directed toward the sequestration chamber 1608. The sequestration chamber 1608 may also include or form a curve or ramp to direct the initial blood flow toward and into the sequestration chamber 1608.

[00110] The sequestration chamber 1608 is preferably maintained at atmospheric pressure, and includes a vent 1610 at or near a distal end of the sequestration chamber 1608. The vent 1610 may include an air permeable blood barrier 1612 as described above.

[00111] The blood sequestration device 1600 can include a housing 1601 that can be formed of multiple parts or a single, unitary part. In some implementations, and as illustrated in FIGS. 17A – 17D and FIGS. 18A – 18F, the housing 1601 includes a top member 1620 and a bottom member 1622 that are mated together. The blood sequestration device 1600 can also include a gasket or other sealing member (not shown) so that when the top member 1620 is mechanically attached with the bottom member 1622, the interface between the two is sealed by the gasket or sealing member. The FIGS. 17A – 17D illustrate a bottom member 1622 of a housing for a blood sequestration device 1600. The bottom member 1622 can include grooves, channels, locks, conduits or other pathways pre-formed therein, such as by an injection molding process or by etching, cutting, drilling, etc., to form the sampling channel 1606, the sequestration chamber 1608, and diverter junction 1607.

[00112] The sequestration chamber 1608 may have a larger cross section than the sampling channel 1606 so that the blood will preferentially move into the sequestration chamber first versus entering a smaller diameter on the sampling channel 1606.

[00113] FIGS. 18A – 18F illustrate the top member 1620, which can be connected with the bottom member 1622 by any mating or connection mechanism, such as by laser welding, thermal bonding, gluing, using screws, rivets, bolts, or the like, or by other mating mechanisms such as latches, grooves, tongues, pins, flanges, or the like. The top member 1620 can include some or all of the grooves, channels, locks, conduits or other pathways to form the sampling channel 1606, the sequestration chamber 1608, and the diverter junction 1607. In yet other implementations, both the top member 1620 and the bottom member 1622 can include the grooves, channels, locks or other pathways.

[00114] In some implementations, the sampling channel 1606 and the sequestration chamber 1608 are formed by grooves, channels, locks or other

pathways formed in housing 1601. The housing 1601 can be made of rubber, plastic, metal or any other suitable material. The housing 1601 can be formed of a clear or translucent material, or of an opaque or non-translucent material. In other implementations, the housing 1601 can be mostly opaque or non-translucent, while the housing surface directly adjacent to the sampling channel 1606 and/or the sequestration chamber 1608 may be clear or translucent, giving a practitioner a visual cue or sign that the sequestration chamber 1608 is first filled to the extent necessary or desired, and/or then a visual cue or sign that the sequestered blood remains sequestered while a clean sample of blood is drawn through the sampling channel 1606. Other visual cues or signs of the sequestration can include, without limitation: the air permeable blood barrier 1612 turning a different color upon contact, saturation, or partial saturation with blood; a color-coded tab or indicator at any point along or adjacent to the sequestration chamber; an audible signal; a vibratory signal; or other signal.

[00115] As shown in FIGS. 18A – 18F, the air permeable blood barrier 1612 can be covered with, or surrounded by, a protective member 1616. The protective member 1616 can be sized and configured to inhibit a user from touching the air permeable blood barrier 1612 with their finger or other external implement, while still allowing air to exit the air permeable blood barrier 1612 as the air is displaced from the sequestration chamber 1608. In some implementations, the protective member 1616 includes a protrusion that extends up from a top surface of the top member 1620 and around the air permeable blood barrier 1612. The protective cover 1616 can be constructed to inhibit or prevent accidental exposure of the filter to environmental fluids or splashes. This can be accomplished in a variety of mechanical ways including but not limited to the addition of a hydrophobic membrane to the protective cover.

[00116] In use (neither use nor method is claimed), the blood sequestration device 1600 includes a sampling channel 1606 and a sequestration chamber 1608. Both pathways are initially air-

filled at atmospheric pressure, but the sampling channel 1606 is directed to an output port 1604 that will be initially sealed by a Vacutainer or other such sealed blood sampling device, and the sequestration chamber 1608 terminates at a vent 1610 to atmosphere that includes an air permeable blood barrier 1612.

[00117] After a venipuncture by a patient needle of a patient (not shown), which could gather a number of pathogens from the patient's skin, a first amount of the patient's blood with those pathogens will pass through input port 1602 of blood sequestration device 1600. This initial volume of potentially contaminated blood will preferentially flow into the sequestration chamber 1608 by finding the path of least resistance. The patient's own blood pressure overcomes the atmospheric pressure in the vented sequestration chamber 1608 to displace air therein through the air permeable blood barrier 1612, but is not sufficient to overcome the air pressure that builds up in the sealed sampling channel 1606. In various exemplary embodiments, the sequestration chamber 1608 and sampling channel 1606 can be configured such that the force generated by the patient's blood pressure is sufficient to overcome any effect of gravity, regardless of the blood sequestration device's orientation.

[00118] Eventually, the sequestration chamber 1608 fills with blood that displaces air through the air permeable blood barrier 1612. Once the blood contacts the air permeable blood barrier, the blood interacts with the air permeable blood barrier 1612 material to completely or partially seal the vent 1610. A signal or indication may be provided that the practitioner can now utilize the Vacutainer or other blood sampling device.

[00119] Upon filling the blood sequestration pathway 1608 but prior to use of the Vacutainer or other blood sample collection device, the patient's blood pressure may drive compression of the air in the sampling channel 1606, possibly resulting in a small amount of blood moving past the diversion point into the sampling channel 1606, queuing up the uncontaminated blood to be drawn through the sampling channel 1606.

[00120] FIG. 19A is a side view, and FIG. 19B is a cross-sectional view, of the blood sequestration device 1600, illustrating the top member 1620 mated with the bottom member 1622.

[00121] FIG. 20 shows a blood sample optimization system 2000 that includes a patient needle 2002 for vascular access to a patient's bloodstream, a blood sample collection device 2004 to facilitate the collecting of one or more blood samples, and a conduit 2006 providing a fluid connection between the patient needle 2002 and the blood sample collection device 2004. In some implementations, the blood sample collection device 2004 includes a protective shield that includes a sealed collection needle on which a sealed vacuum-loaded container is placed, which, once pierced by the collection needle, draws in a blood sample under vacuum pressure or force through the conduit 2006 from the patient needle 2002.

[00122] The blood sample optimization system 2000 further includes a blood sequestration device 2008, located at any point on the conduit 2006 between the patient needle 2002 and the blood sample collection device 2004 as described herein.

[00123] FIG. 21 illustrates a non-vented blood sequestration device 2100 using a wicking material chamber. The blood sequestration device 2100 includes a housing 2101 that has a sampling channel 2104 that is at least partially surrounded or abutted by a sequestration chamber 2102 that is filled with a wicking material. An initial aliquot of blood is drawn in from the patient needle into the sampling channel 2104 where it is immediately wicked into the wicking material of the sequestration chamber 2102. The wicking material and/or sequestration chamber 2102 is sized and adapted to receive and hold a predetermined amount of blood, such that follow-on or later blood draws pass by the wicking material and flow straight through the sampling channel 2104 to a sampling device such as a Vacutainer. The wicking material can include a substance such as a solidifier, a decontaminate, or other additive.

[00124] As described herein, an air permeable blood barrier may be created using a wide variety of different structures and materials. As shown in FIGS. 22A and B, an air permeable blood barrier 2202 of a blood sequestration device 2200 can include a polymer bead matrix 2204, in which at least some beads are treated to make them hydrophilic. The air permeable blood barrier 2202 further includes a self-sealing material 2206, such as carboxymethyl cellulose (CMC) or cellulose gum, or other sealing material. The air permeable blood barrier 2202 can further include voids 2208 that permit air flow before contact or during partial contact with a fluid such as blood. As shown in FIG. 22B, contact with a fluid causes the self-sealing material 2206 to swell and close off the voids 2208, occluding air flow through the voids 2208 and creating a complete or partial seal.

[00125] FIGS. 23A and B illustrate yet another implementation of a blood sequestration device 2300, having an inlet port 2302 to connect with a patient needle, an outlet port 2304 to connect with a blood sample collection device, a sequestration chamber 2306, and a sampling channel 2308 that bypasses the sequestration chamber 2306 once the sequestration chamber is filled to an initial aliquot of potentially contaminated blood to be sequestered. The sequestration chamber 2306 includes a hydrophobic plug 2312 at a distal end of the sequestration chamber 2306 that is farthest from the inlet port 2302. A vacuum or other drawing force applied from the outlet port 2304, such as from a Vacutainer or the like, draws in blood into the inlet port 2302 and directly into the sequestration chamber 2306, where the initial aliquot of blood will contact the hydrophobic plug 2312 and cause the initial aliquot of blood to back up into the sequestration chamber 2306 and be sequestered there. A small amount of blood may make its way into the sampling channel 2308, which is initially closed off by valve 2308. Upon release of the valve 2308, and under further force of the vacuum or other force, follow-on amounts of blood will flow into inlet port 2302, bypass the sequestration chamber 2306, and flow into and through sampling channel 2308 toward the outlet port 2304 and to the collection device.

Amended claims

1. A blood sequestration device (1500) comprising;

an inlet port (1502);

a junction (1607) connected with the inlet port (1502);

a sequestration chamber (1508) having a vent (1510) comprising an air permeable blood barrier (1512);

a sampling channel (1506) having a proximal end connected with the inlet port (1502) via the junction (1607), and a distal end connected with an outlet port (1504); and

a housing (1501) that houses and defines the inlet port (1502), the junction (1607), the sequestration chamber (1508), the sampling channel (1506), and the outlet port (1504),

wherein the sequestration chamber (1508) is connected with the inlet port (1502) via the junction (1607) which is configured to direct a first portion of blood to the sequestration chamber (1508),

characterized in that the air permeable blood barrier (1512) includes an air permeable material that seals at least partially upon contact with a portion of the first portion of blood.

2. The blood sequestration device (1500) in accordance with claim 1, wherein the sequestration chamber (1508) includes a sequestration channel defined in the housing (1501).

3. The blood sequestration device (1500) in accordance with claim 1 or 2, further comprising a blood sampling pathway connected with the inlet port (1502) opposite the junction (1607), and

wherein the inlet port (1502) defined by the housing (1501) has a cross-sectional geometry consistent with the blood sampling pathway.

4. The blood sequestration device (1500) in accordance with one of the preceding claims, wherein the sampling channel (1506) defined by the housing (1501) has a cross-sectional geometry consistent with the inlet port (1502).

5. The blood sequestration device (1500) in accordance with one of claims 2 to 4, wherein the housing (1501) comprises a bottom member (1522) mated with a top member (1520), each of the bottom member (1522) and the top member (1520)

defining a part of each of the inlet port (1502), the outlet port (1504), the sequestration chamber (1508), and the sampling channel (1506).

6. A system of a blood sequestration device (1500), a blood sampling pathway having a patient needle, and a sample collection device, the blood sequestration device (1500) comprising;

an inlet port (1502) connected with the patient needle;

a junction (1607) connected with the inlet port (1502) opposite the blood sampling pathway;

a sequestration chamber (1508) having a vent (1510) comprising an air permeable blood barrier (1512);

a sampling channel (1506) having a proximal end connected with the inlet port (1502); and

an outlet port (1504) connected with a distal end of the sampling channel (1506) and with the sample collection device; and a housing (1501) that houses and defines the inlet port (1502), the outlet port (1504), the sequestration chamber (1508), and the sampling channel (1506),

characterized in that the sequestration chamber (1508) is connected with the inlet port (1502) and the air permeable blood barrier (1512) includes an air permeable material that seals at least partially upon contact with blood.

7. The system in accordance with claim 6, wherein the inlet port (1502) is connected with the patient needle via a first portion of the blood sampling pathway.

8. The system in accordance with claim 6 or 7, wherein the outlet port (1504) is connected with the sample collection device via a second portion of the blood sampling pathway.

9. The system in accordance with one of claims 6 to 8, wherein the sequestration chamber (1508) includes a sequestration channel defined in the housing (1501).

10. The system in accordance with claim 9, wherein the sequestration channel has a proximal end connected with the inlet port (1502), and a distal end having the vent (1510) comprising an air permeable blood barrier (1512).

11. The system in accordance with one of claims 6 to 10, wherein the sequestration chamber (1508) and the sampling channel (1506) are connected with

the inlet port (1502) by the junction (1607) that is configured to direct a first portion of blood to the sequestration chamber (1508).

12. The system in accordance with one of claims 6 to 11, wherein the sampling channel (1506) has a substantially uniform cross-sectional geometry that is consistent with the blood sampling pathway.

13. The system in accordance with claim 12, wherein the sequestration chamber (1506) includes a sequestration chamber that has a cross-sectional area that is larger than the cross-sectional geometry of the sampling channel (1506).

14. The system in accordance with claim 7, member (1520), wherein the housing (1501) comprises a bottom member (1522) mated with a top member (1520), each of the bottom member (1522) and the top member (1520) defining a part of each of the inlet port (1502), the outlet port (1504), the sequestration chamber (1508), and the sampling channel (1506).

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EPA-148 105
01.10.2019

1/50

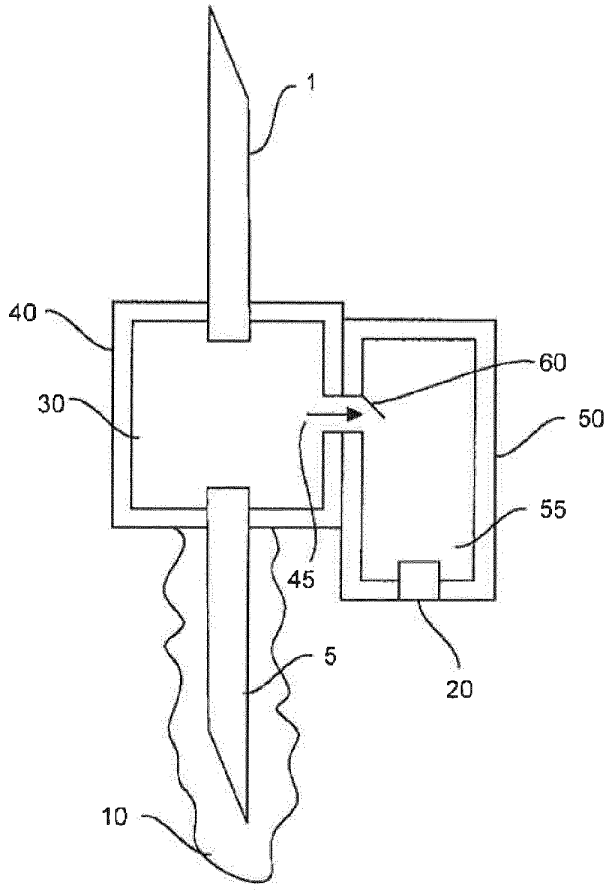


FIG. 1

2/50

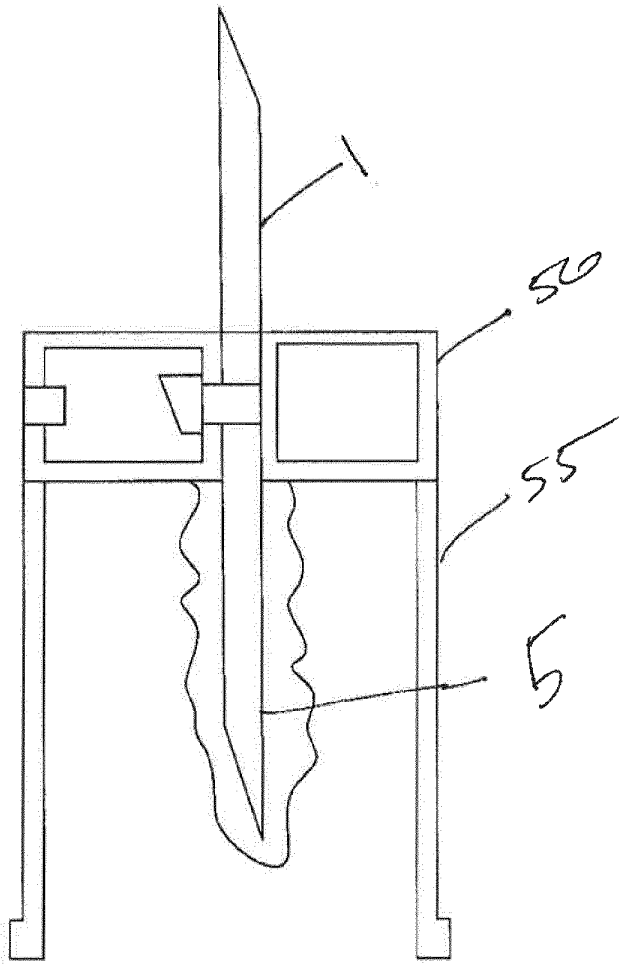


FIG. 2

KURIN, INC.

EPA-148 105
01.10.2019

3/50

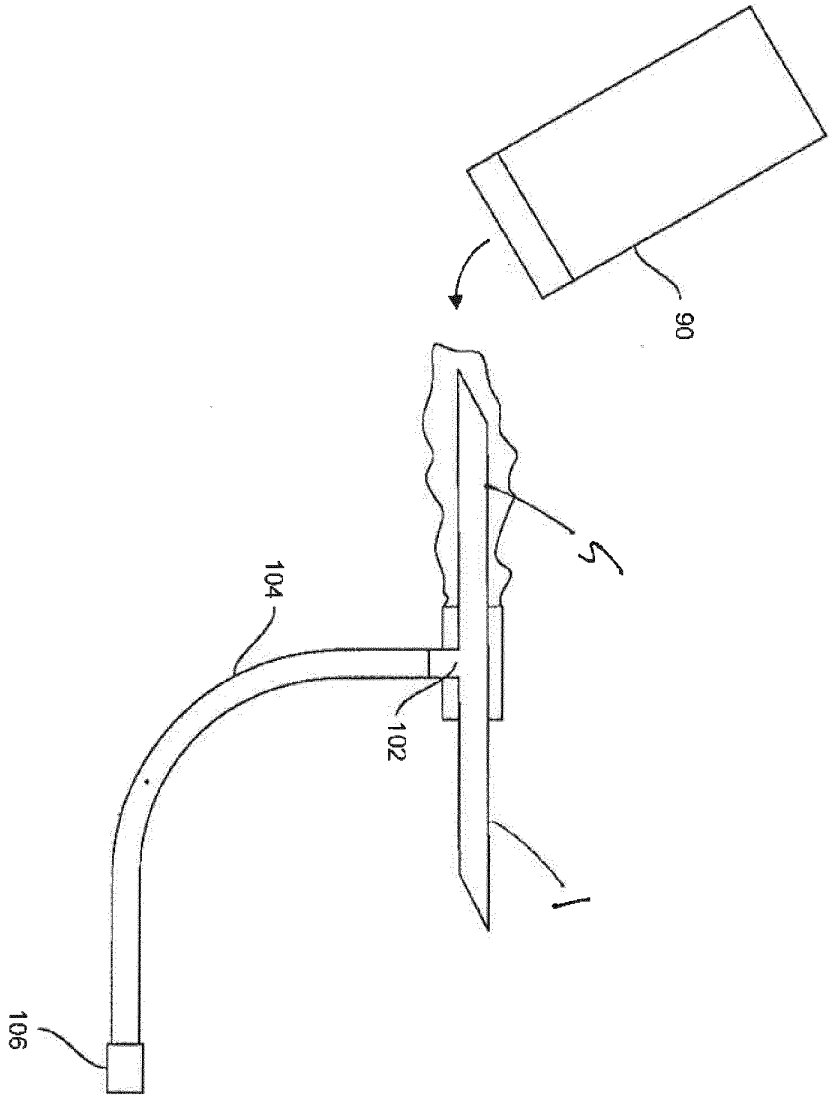


FIG. 3

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EPA-148 105
01.10.2019

4/50

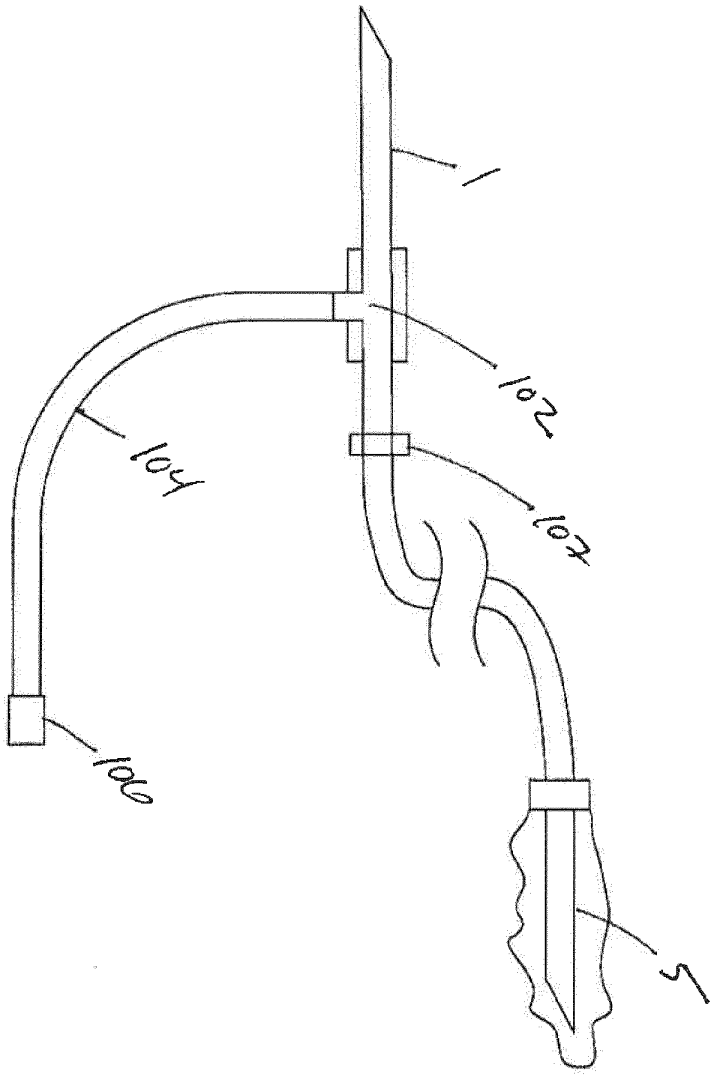


FIG. 4

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EPA-148 105
01.10.2019

5/50

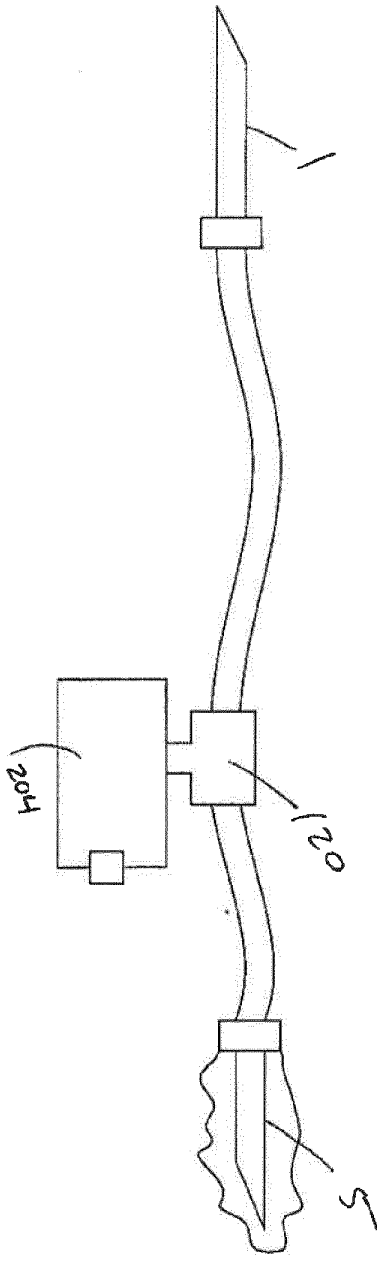


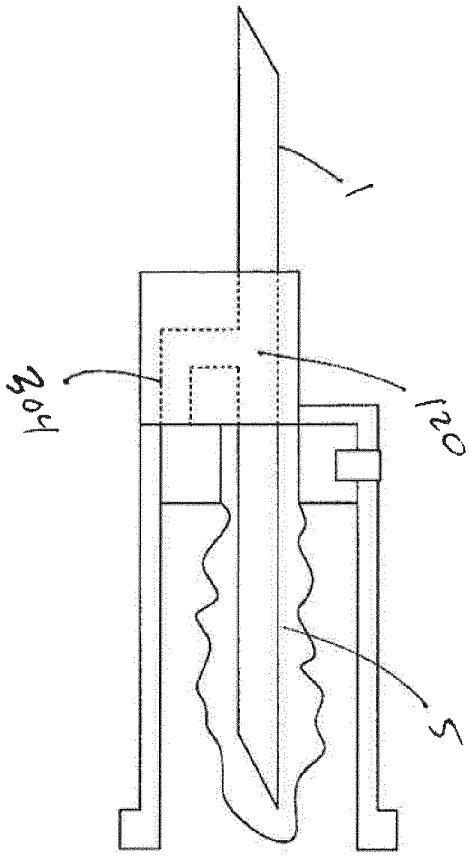
FIG. 5

KURIN, INC.

EPA-148 105
01.10.2019

6/50

FIG. 6



7/50

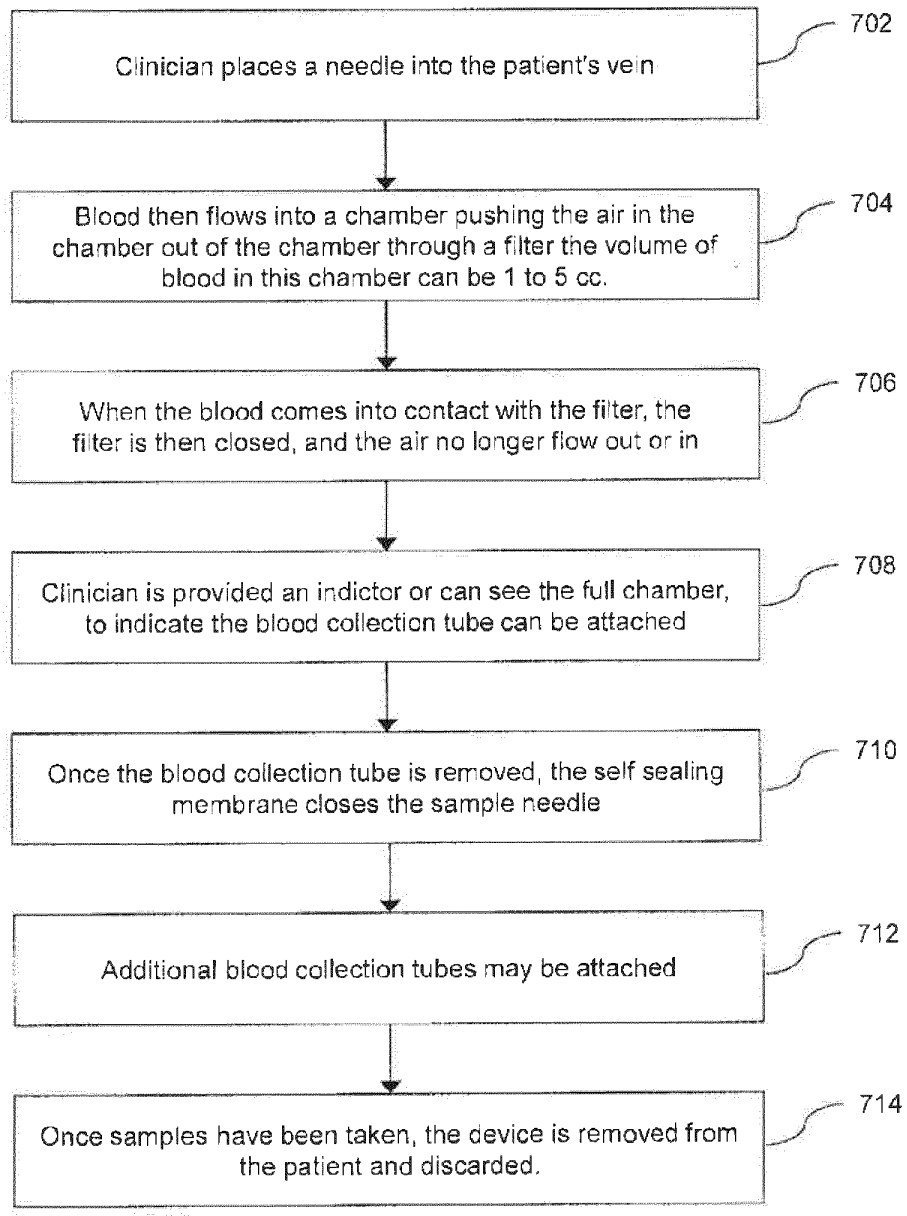
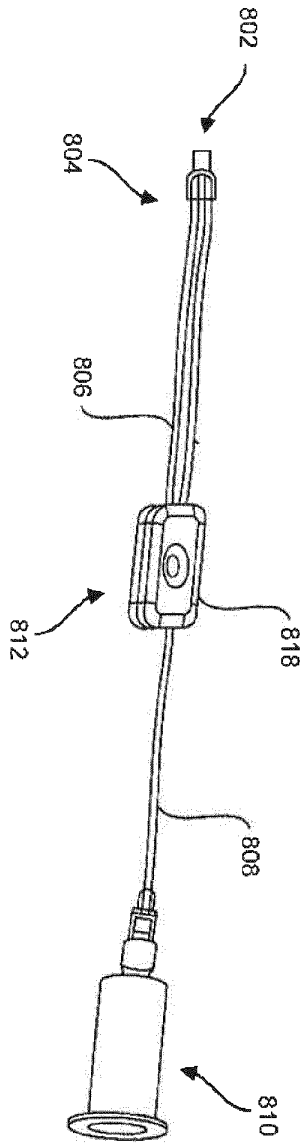

Clinician places a needle into the patient's vein
702
Blood then flows into a chamber pushing the air in the chamber out of the chamber through a filter the volume of blood in this chamber can be 1 to 5 cc.
704
When the blood comes into contact with the filter, the filter is then closed, and the air no longer flow out or in
706
Clinician is provided an indictor or can see the full chamber, to indicate the blood collection tube can be attached
708
Once the blood collection tube is removed, the self sealing membrane closes the sample needle
710
Additional blood collection tubes may be attached
712
Once samples have been taken, the device is removed from the patient and discarded.
714

FIG. 7

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EPA-148 105
01.10.2019

8/50



800

FIG. 8A

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EPA-148 105
01.10.2019

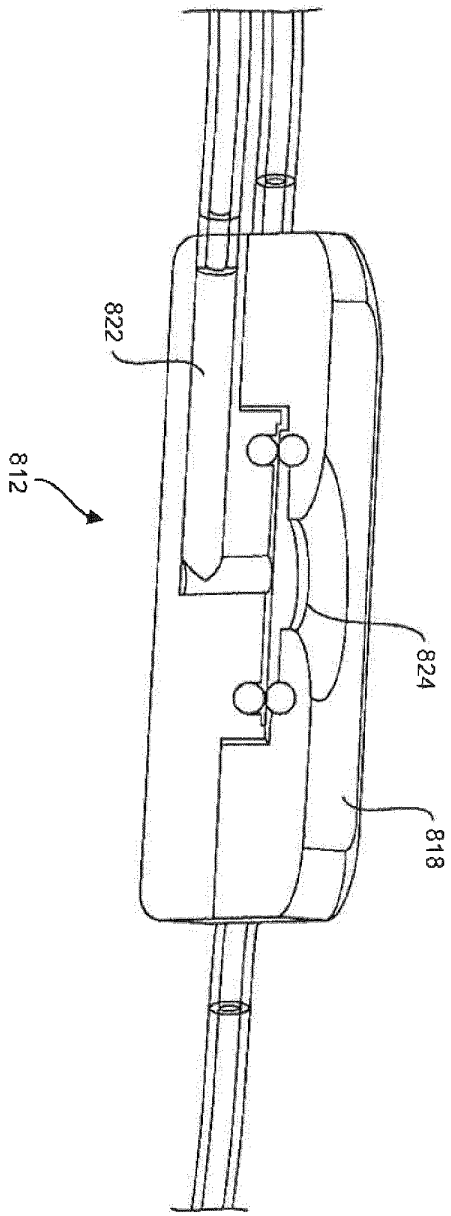


FIG. 8B

KURIN, INC.

EPA-148 105
01.10.2019

10/50

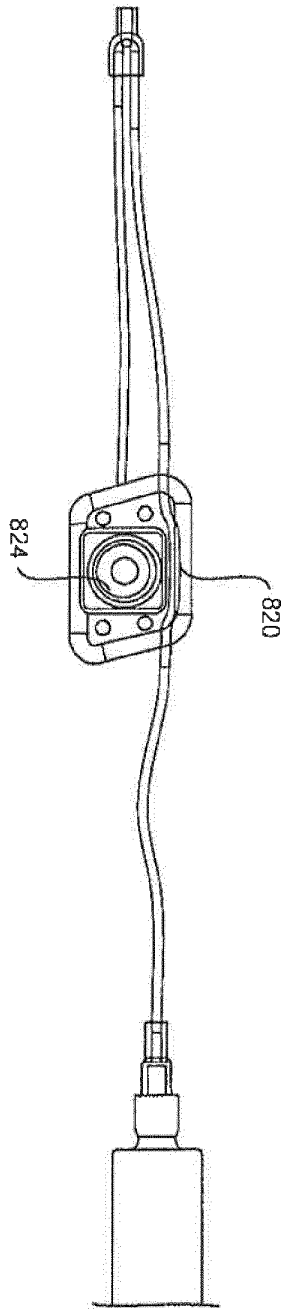
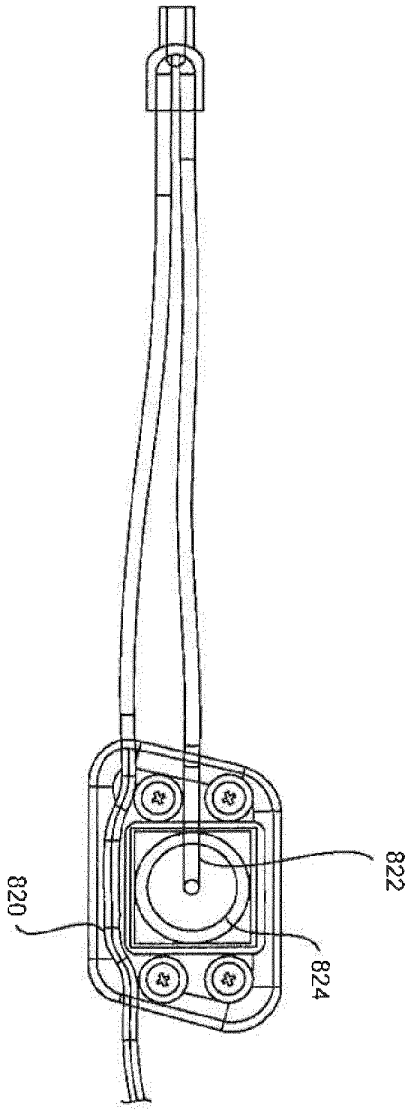


FIG. 8C

FIG. 8D



KURIN, INC.

EPA-148 105
01.10.2019

12/50

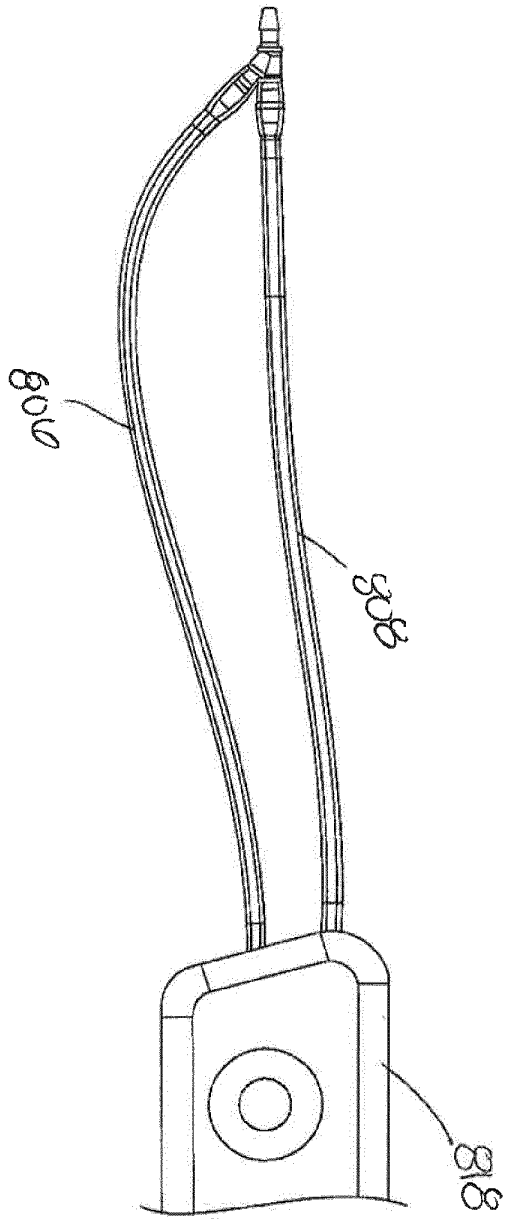


FIG. 8E

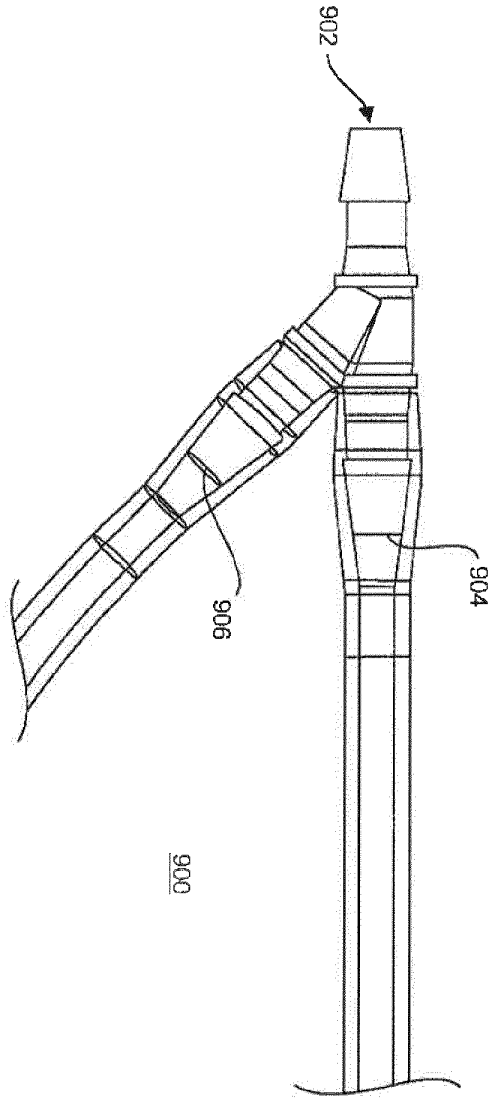


FIG. 9

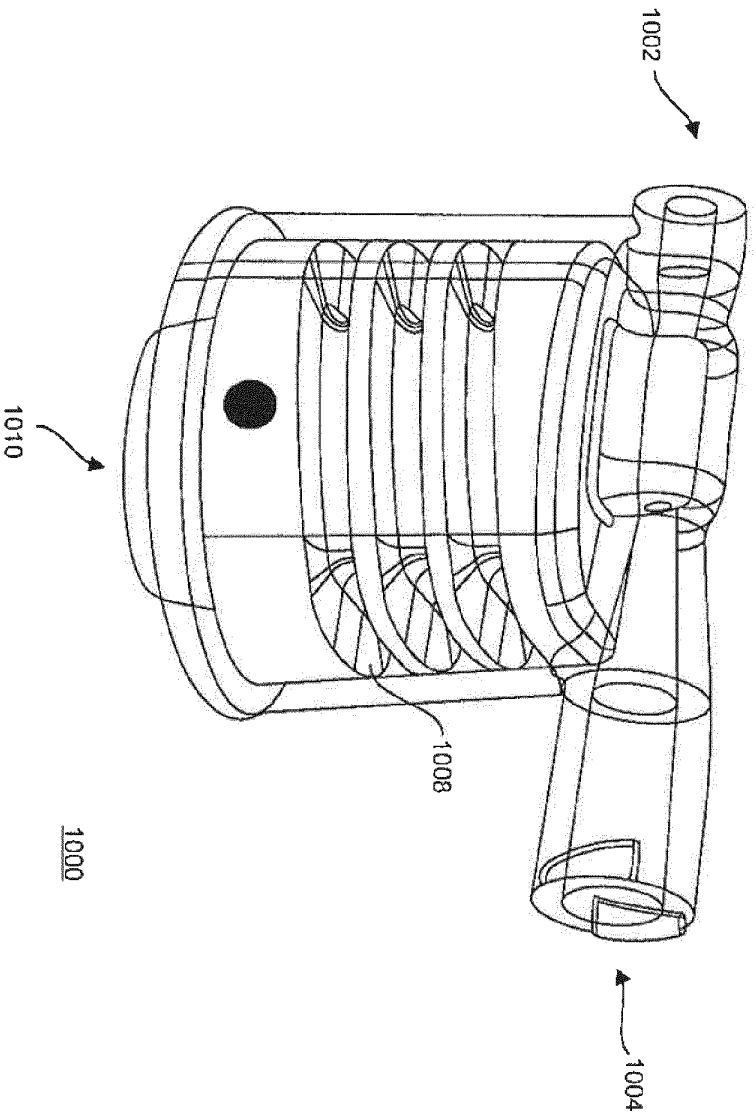


FIG. 10A

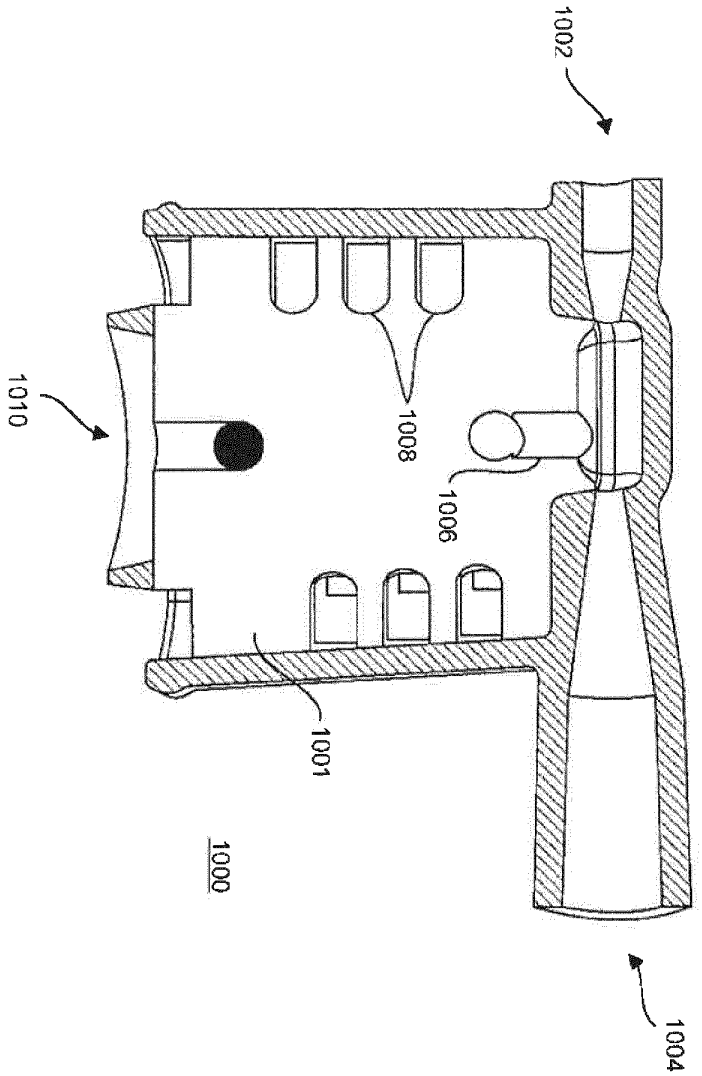


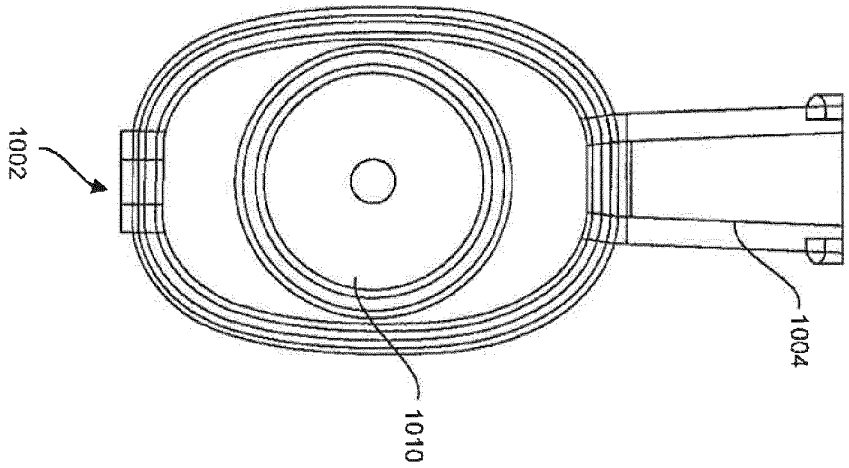
FIG. 10B

KURIN, INC.

EPA-148 105
01.10.2019

16/50

FIG. 10C



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EPA-148 105
01.10.2019

17/50

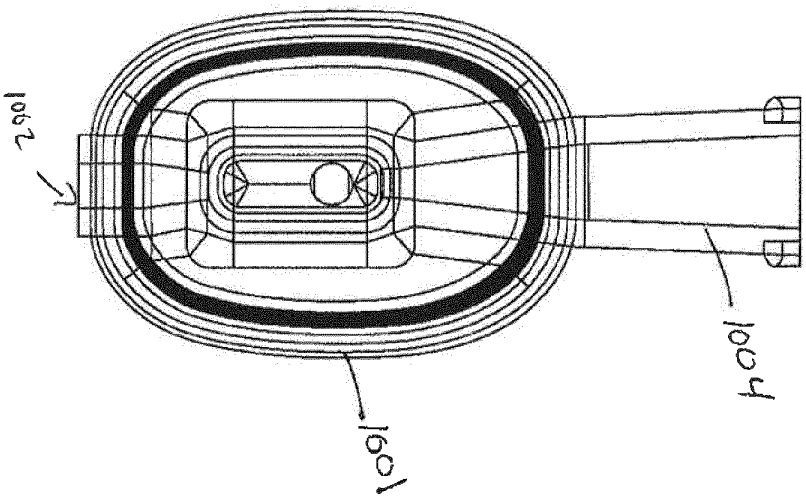


FIG. 10D

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EPA-148 105
01.10.2019

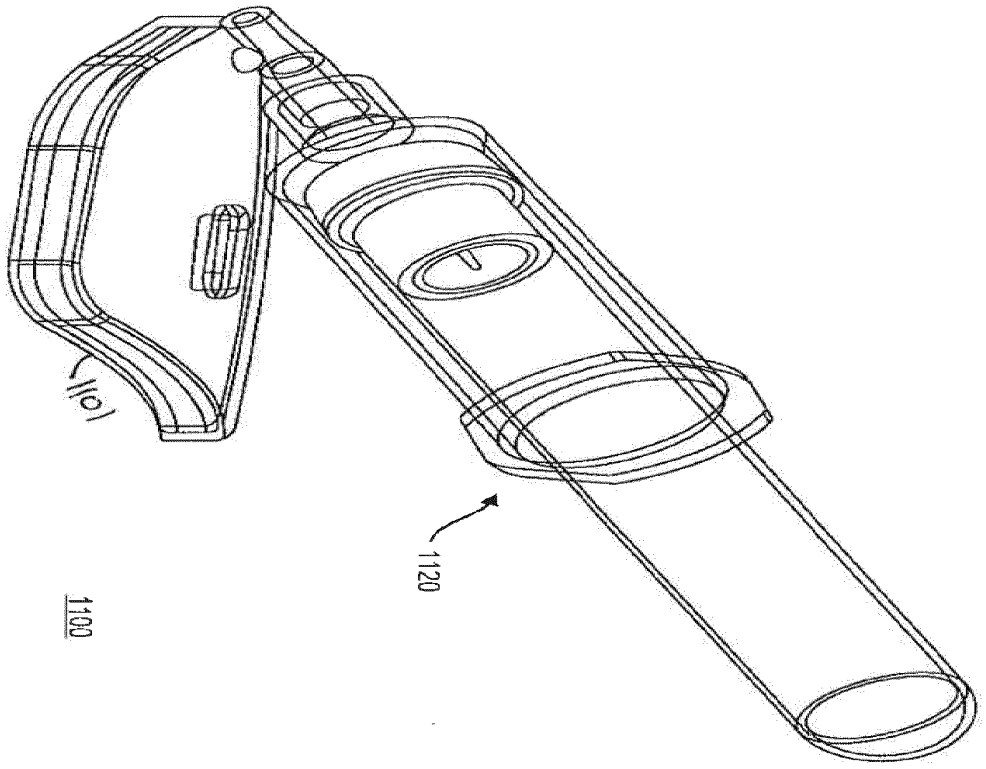


FIG. 11A

KURIN, INC.

EPA-148 105
01.10.2019

19/50

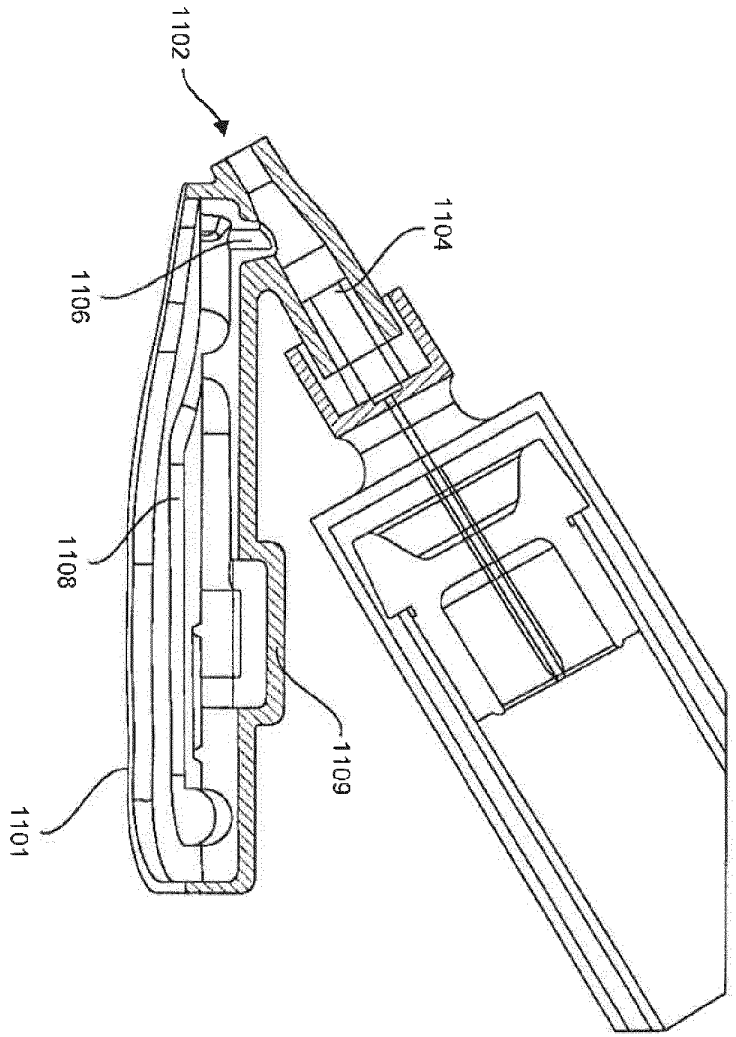


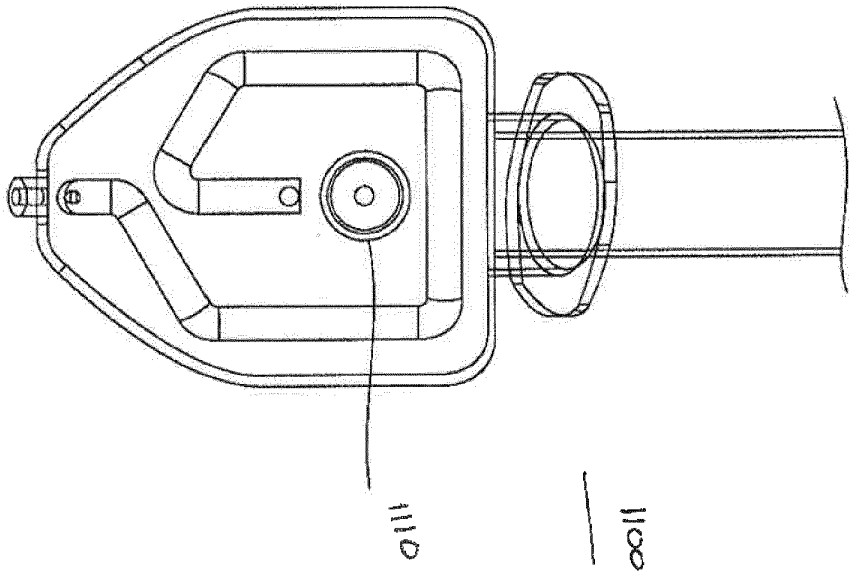
FIG. 11B

KURIN, INC.

EPA-148 105
01.10.2019

20/50

FIG. 11C

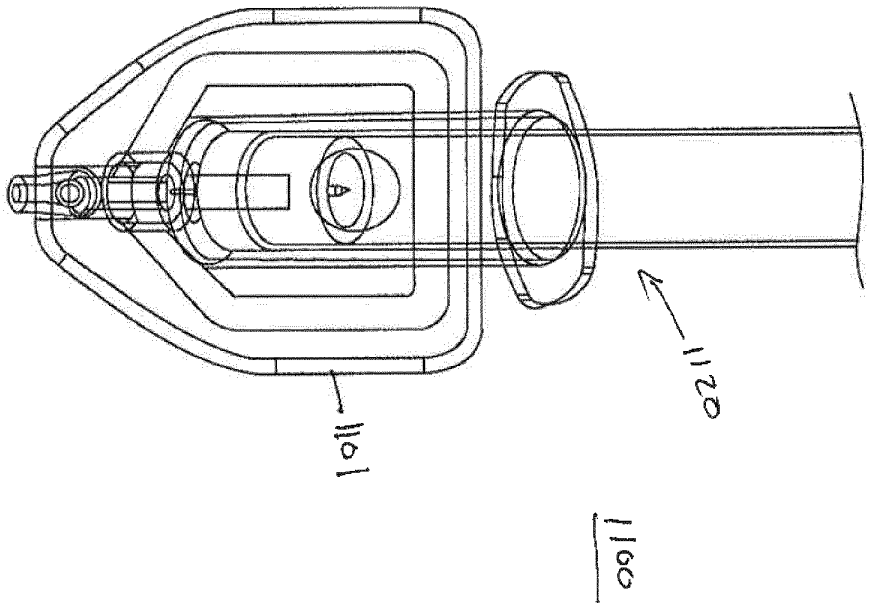


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EPA-148 105
01.10.2019

21/50

FIG. 11D



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EPA-148 105
01.10.2019

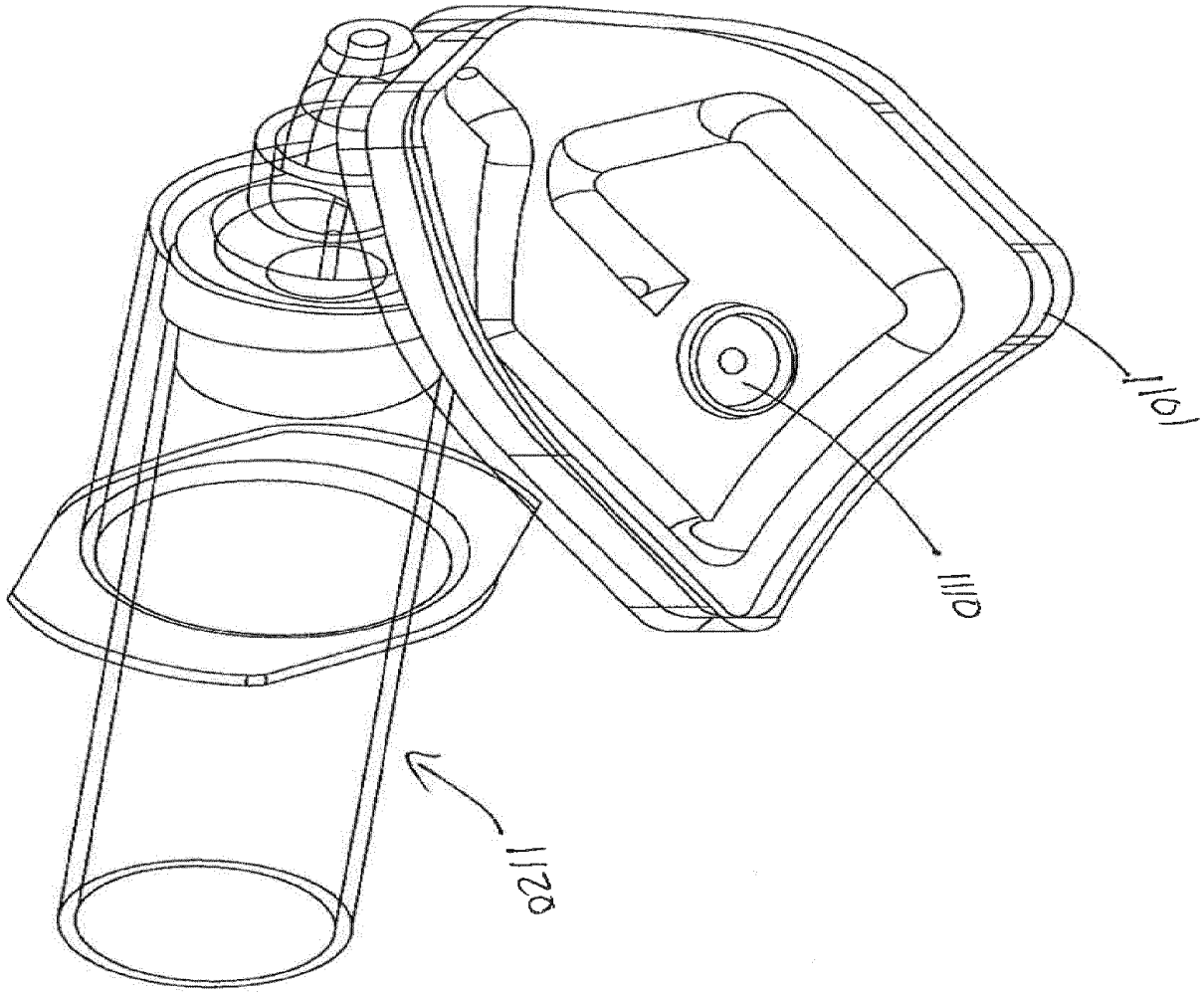


FIG. 11E

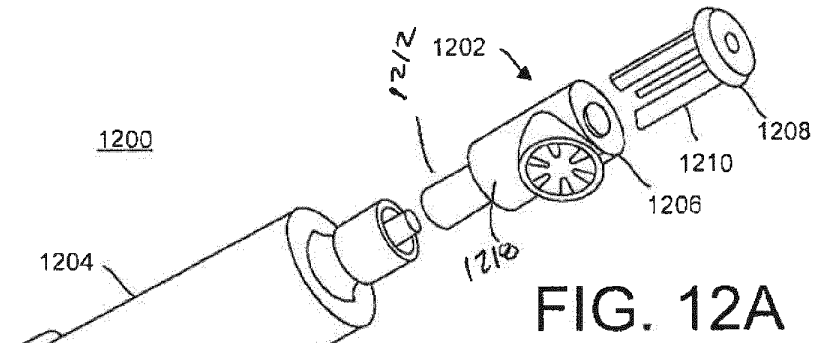


FIG. 12A

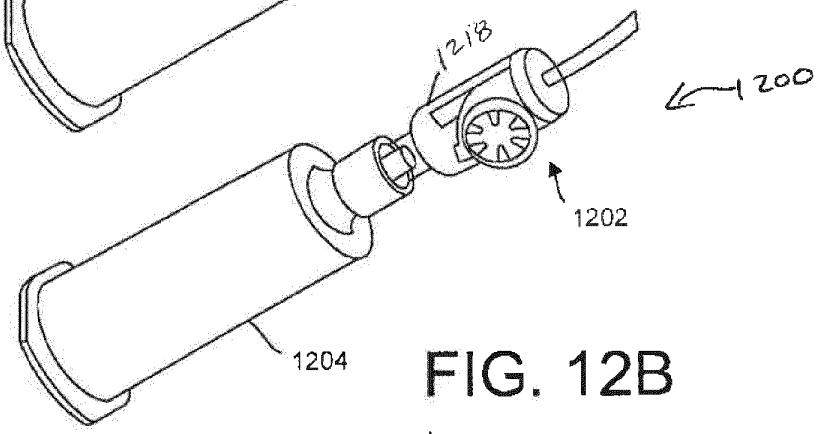


FIG. 12B

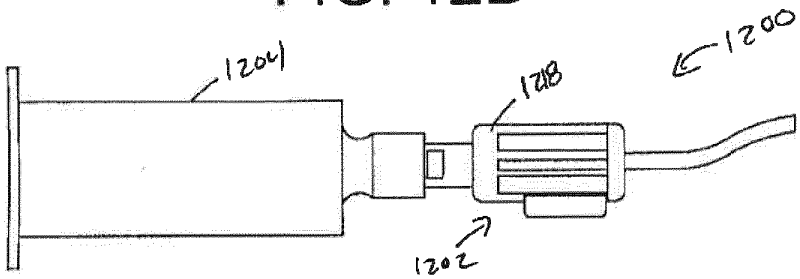


FIG. 12C

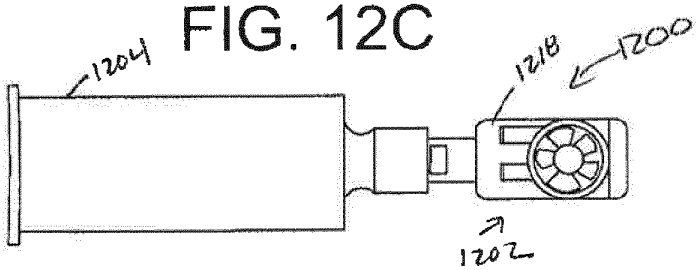


FIG. 12D

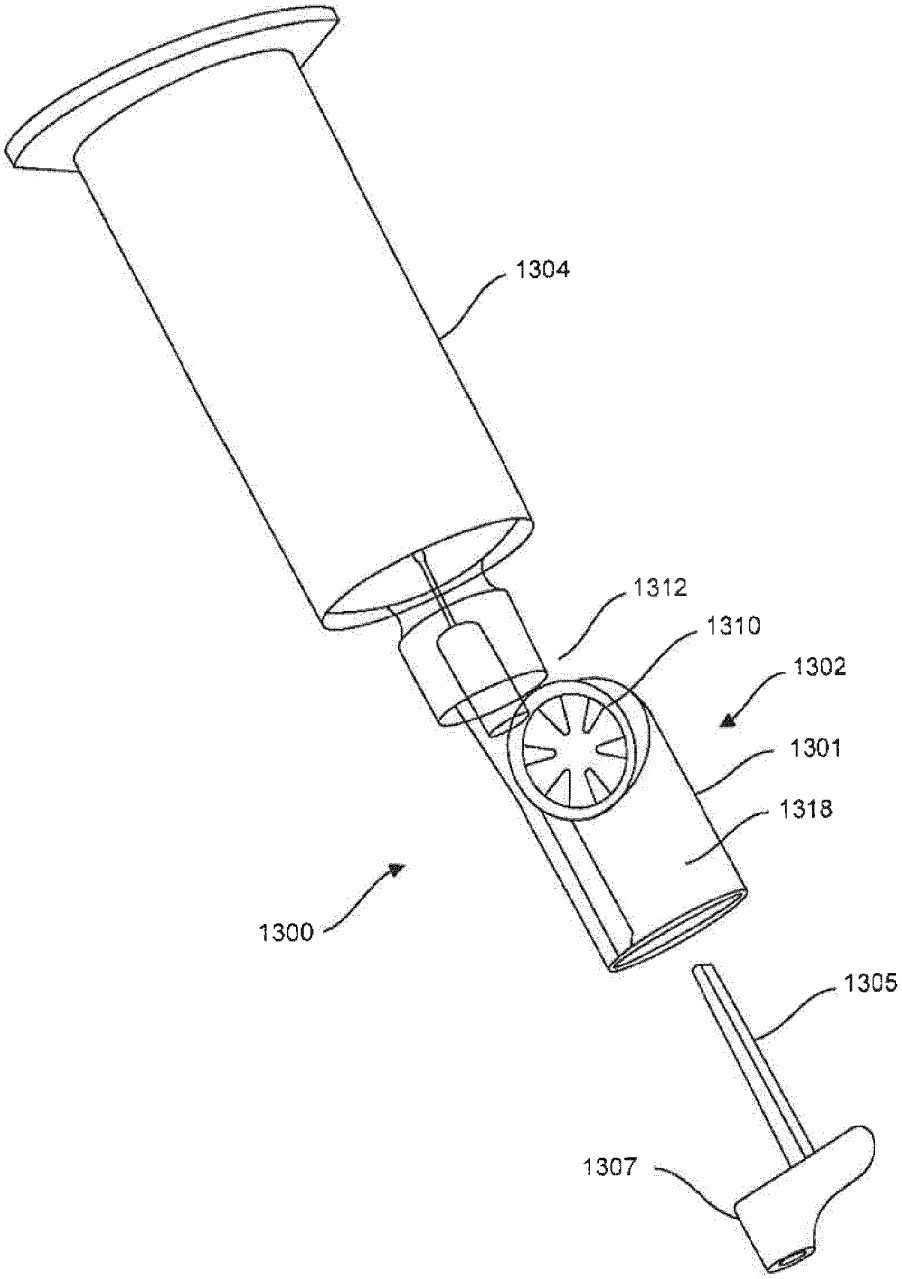


FIG. 13A

25/50

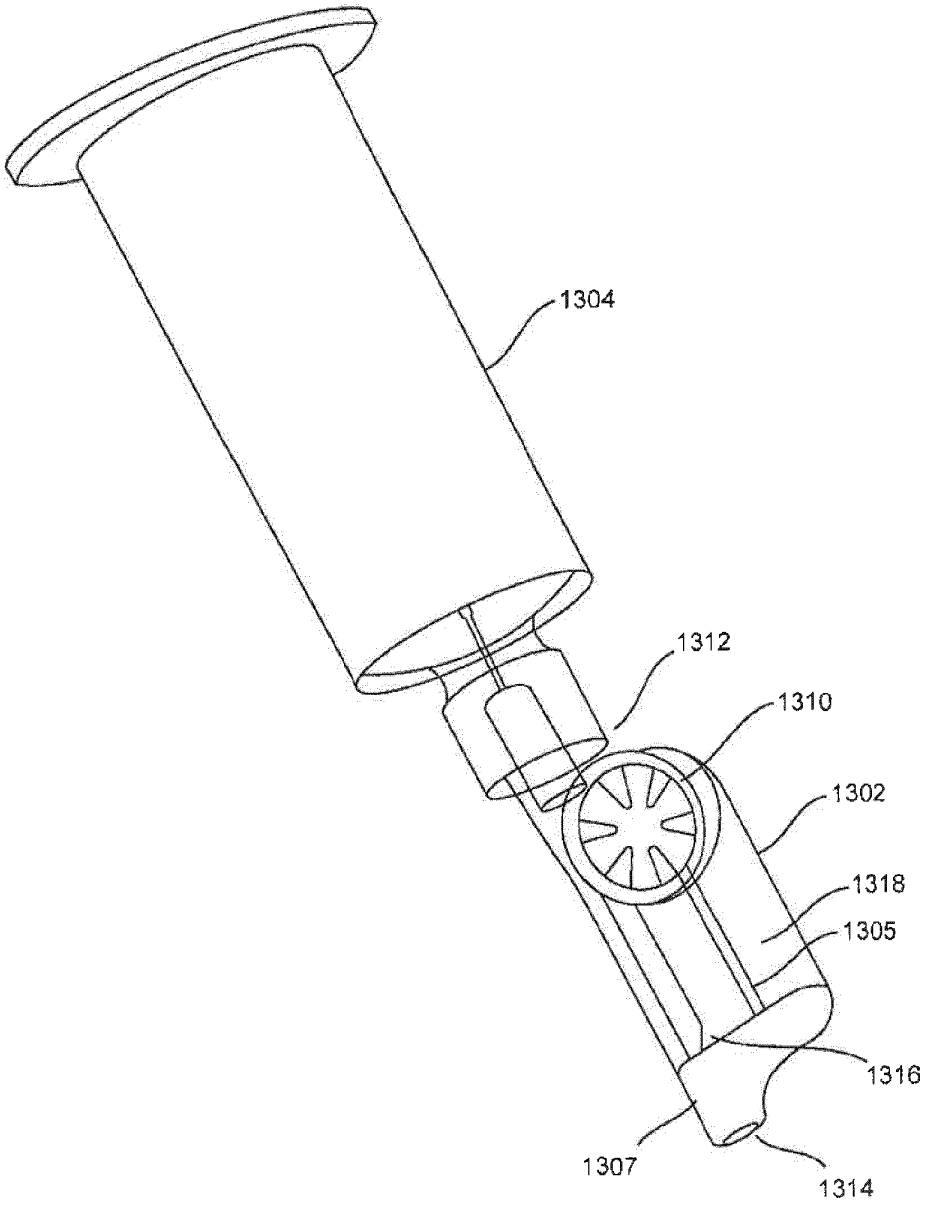


FIG. 13B

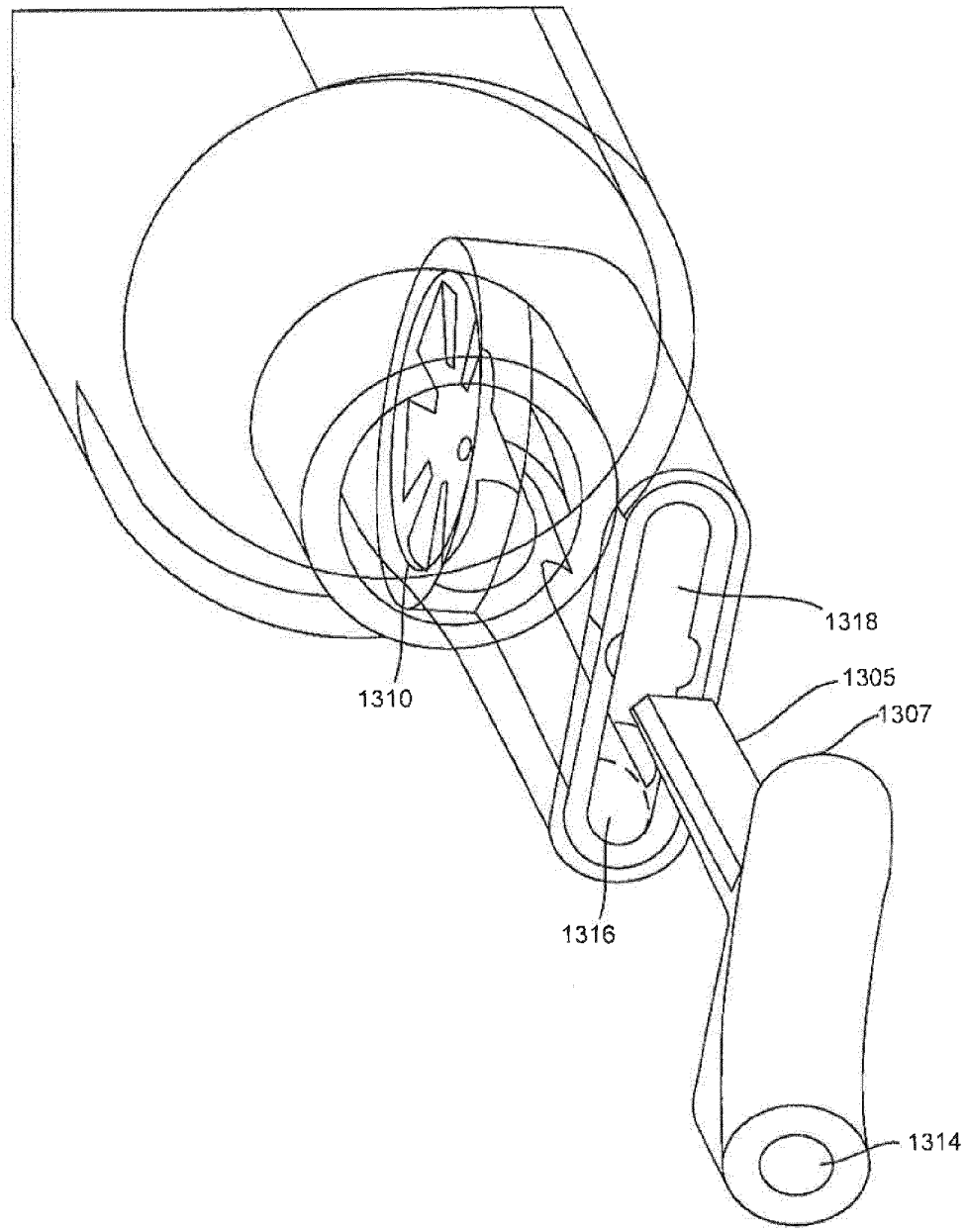


FIG. 13C

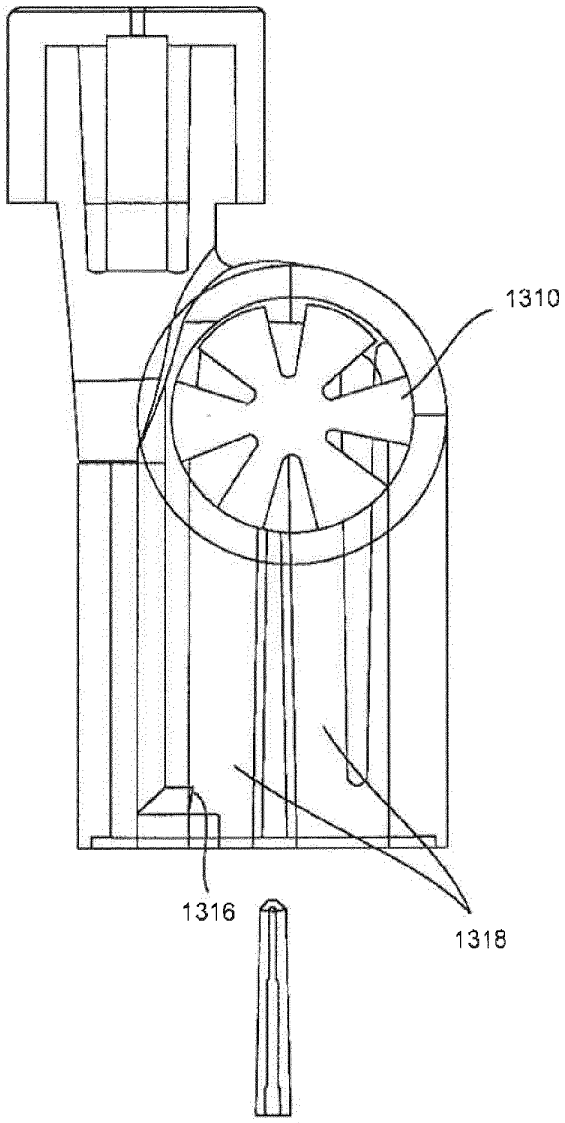


FIG. 13D

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EPA-148 105
01.10.2019

28/50

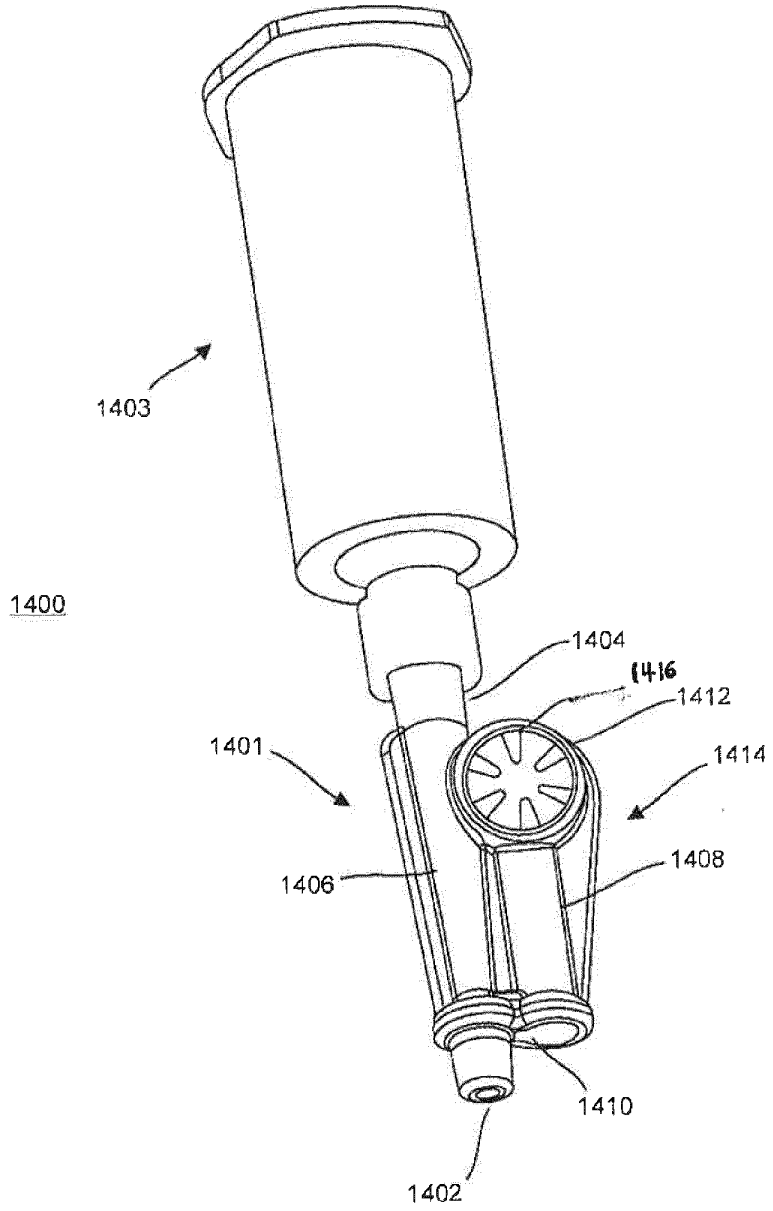


FIG. 14A

KURIN, INC.

EPA-148 105
01.10.2019

29/50

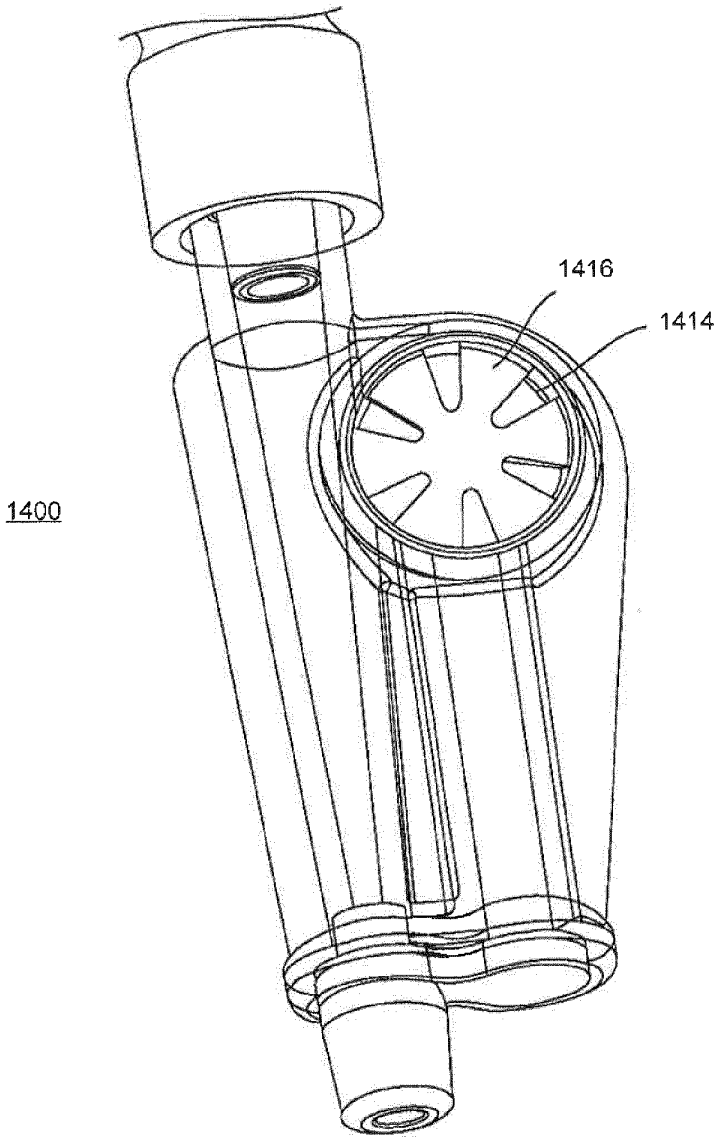


FIG. 14B

KURIN, INC.

EPA-148 105
01.10.2019

30/50

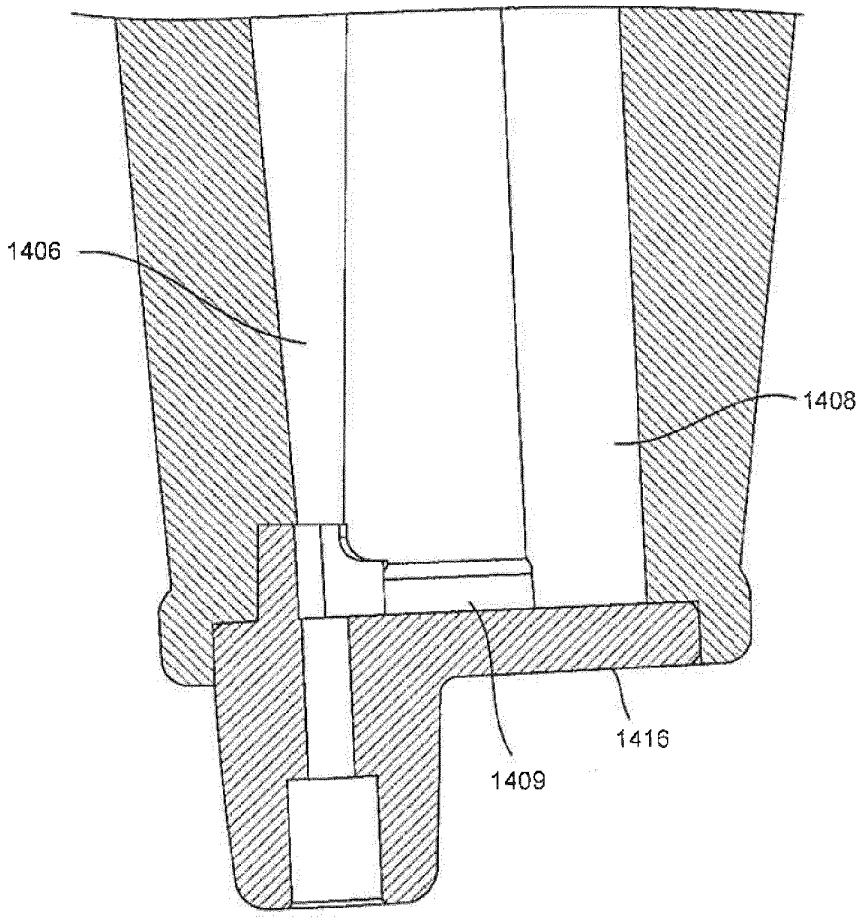


FIG. 14C

31/50

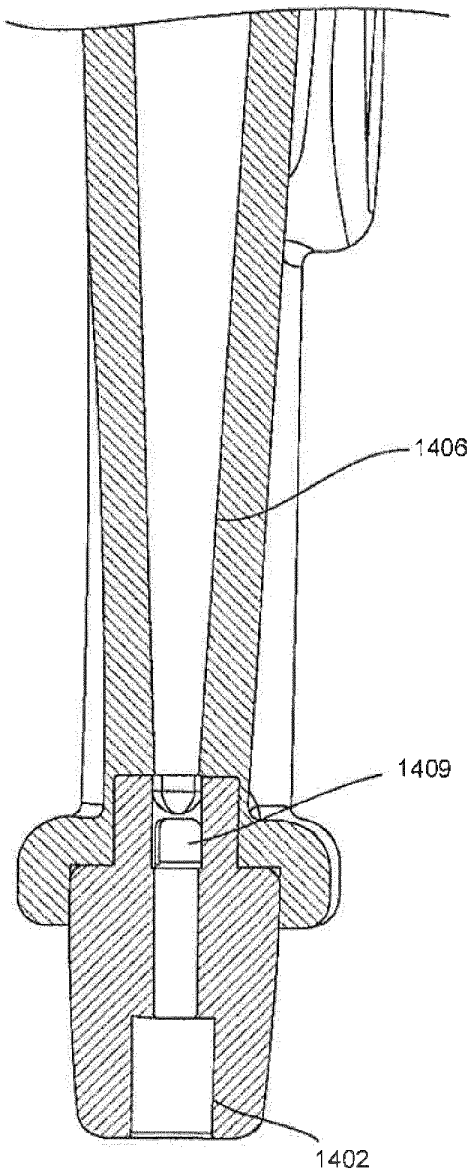


FIG. 14D

KURIN, INC.

EPA-148 105
01.10.2019

32/50

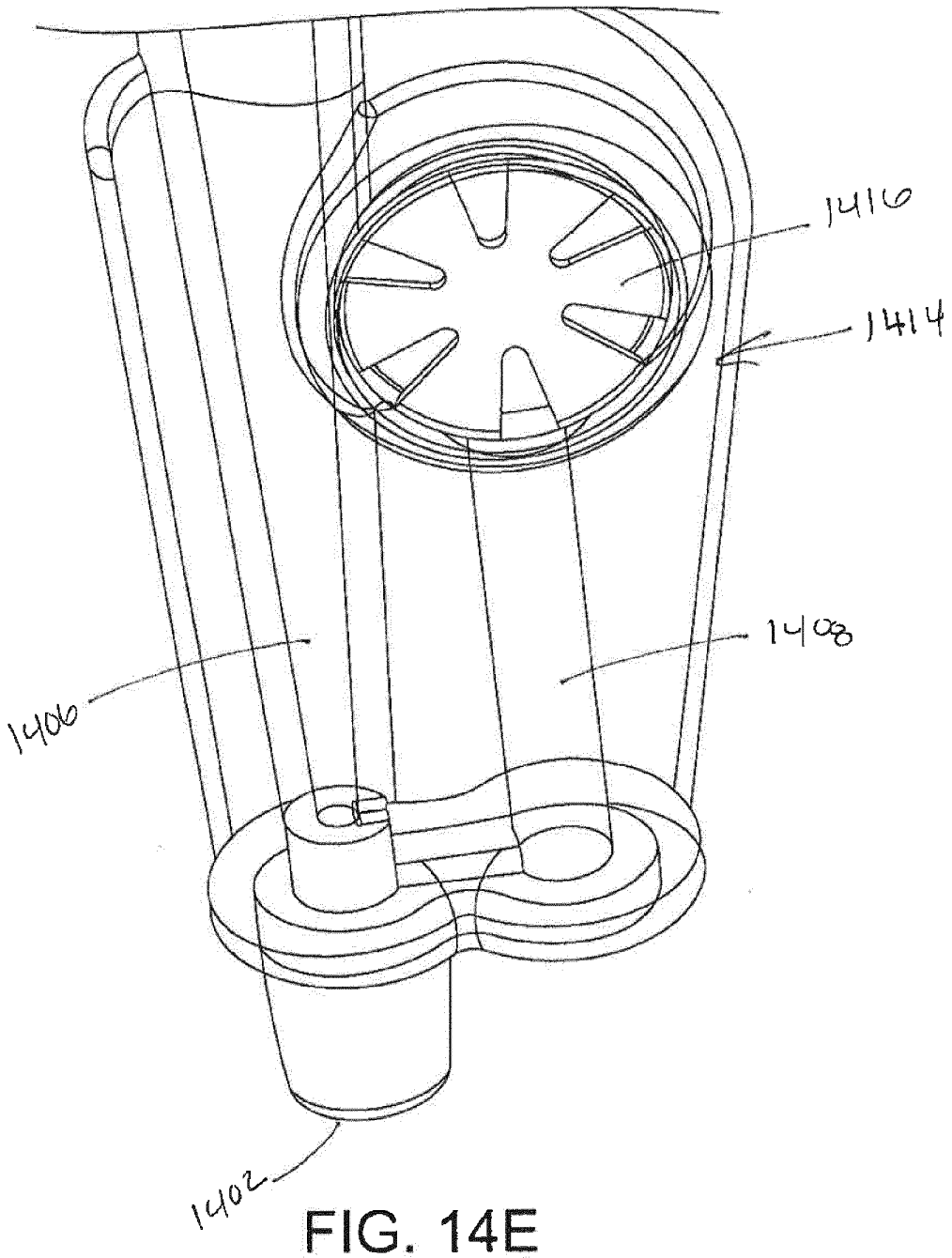


FIG. 14E

KURIN, INC.

EPA-148 105
01.10.2019

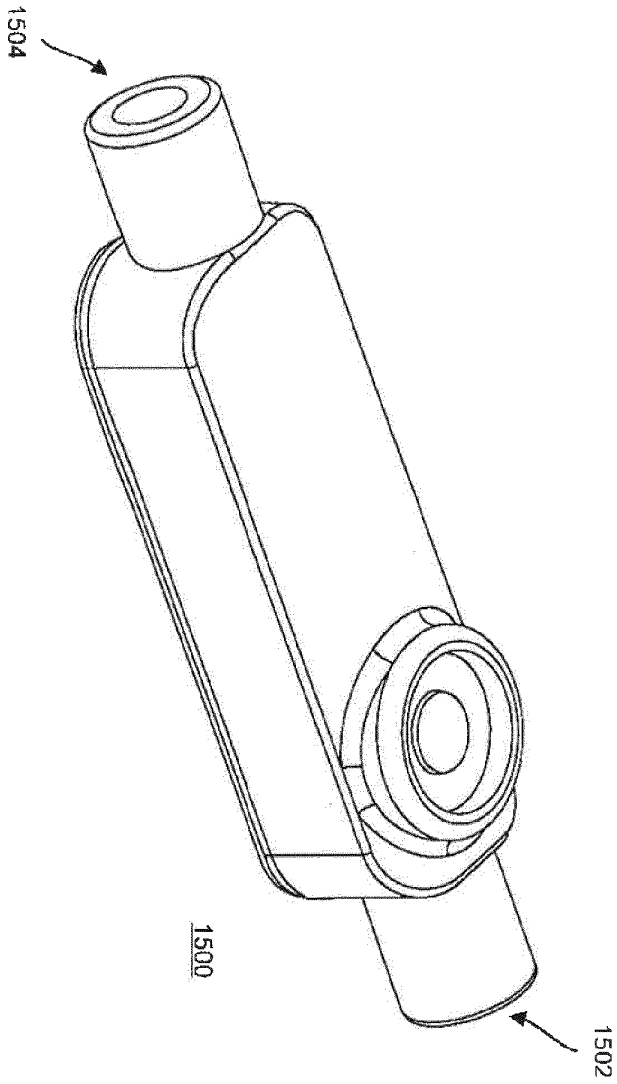


FIG. 15A

KURIN, INC.

EPA-148 105
01.10.2019

34/50

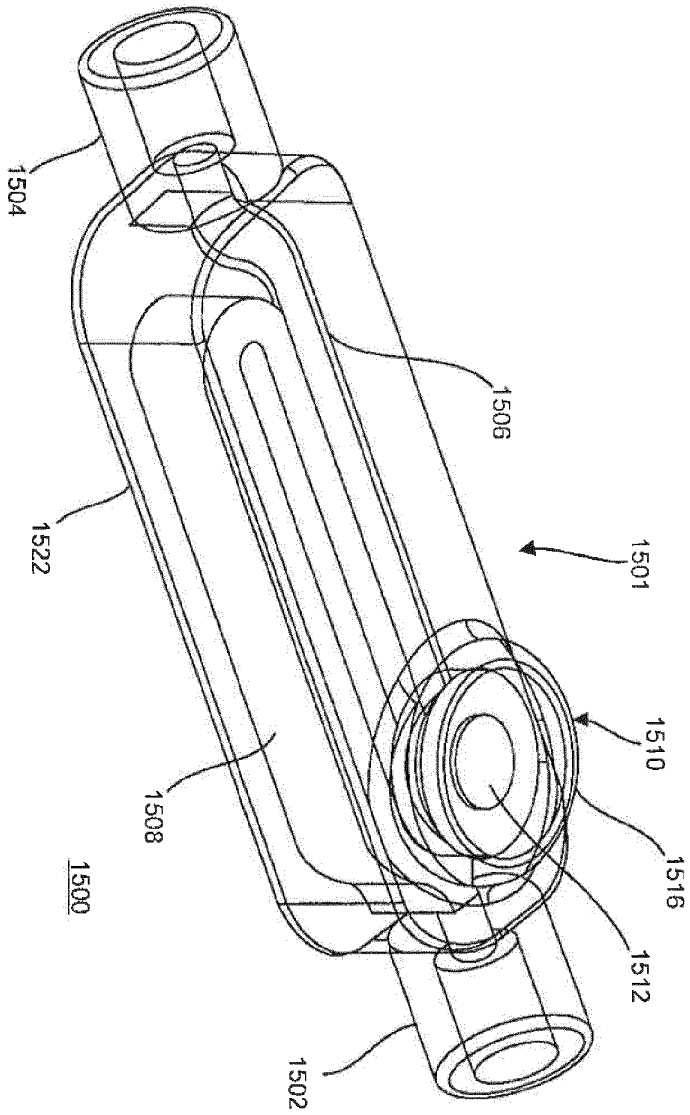


FIG. 15B

KURIN, INC.

EPA-148 105
01.10.2019

35/50

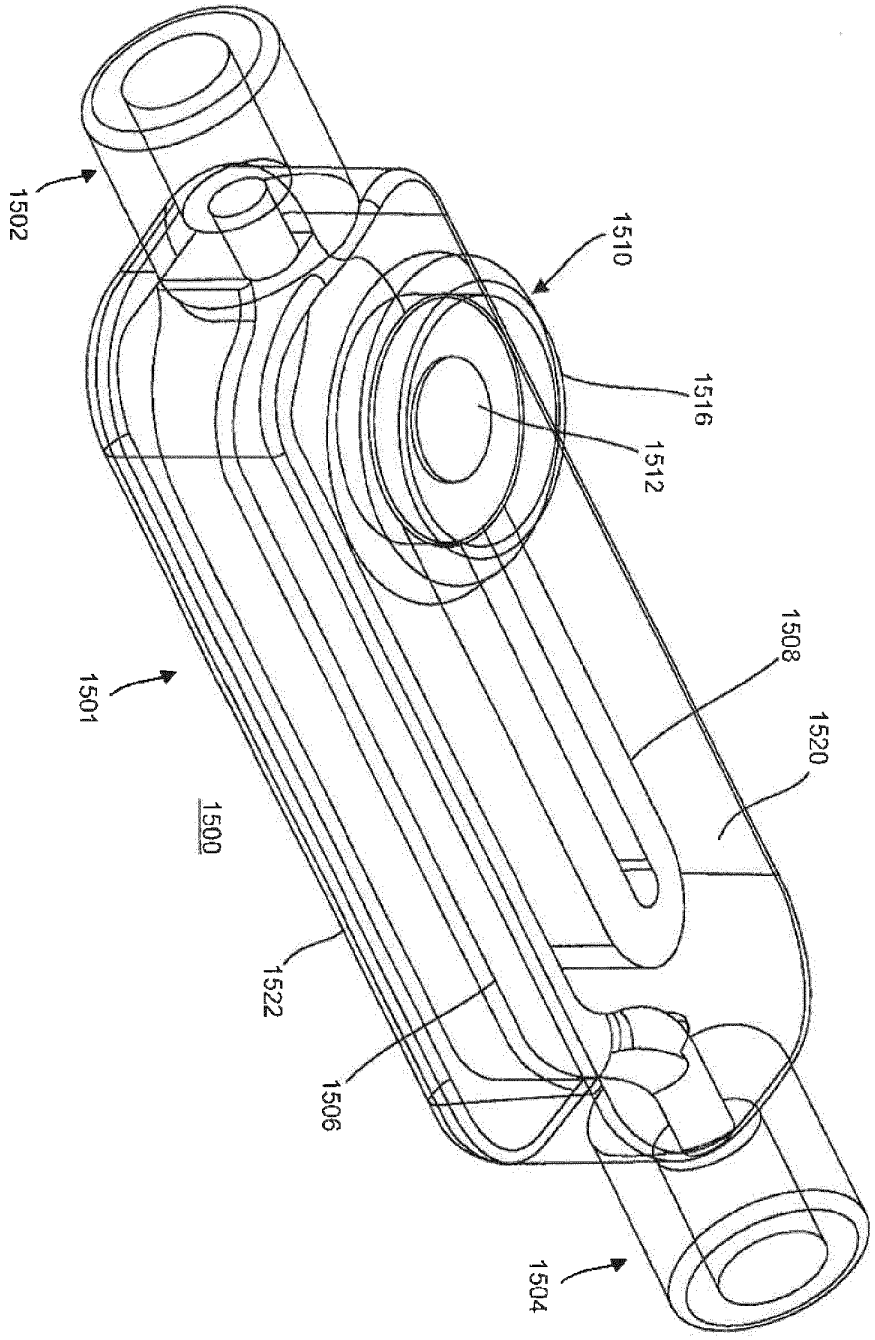


FIG. 15C

KURIN, INC.

EPA-148 105
01.10.2019

36/50

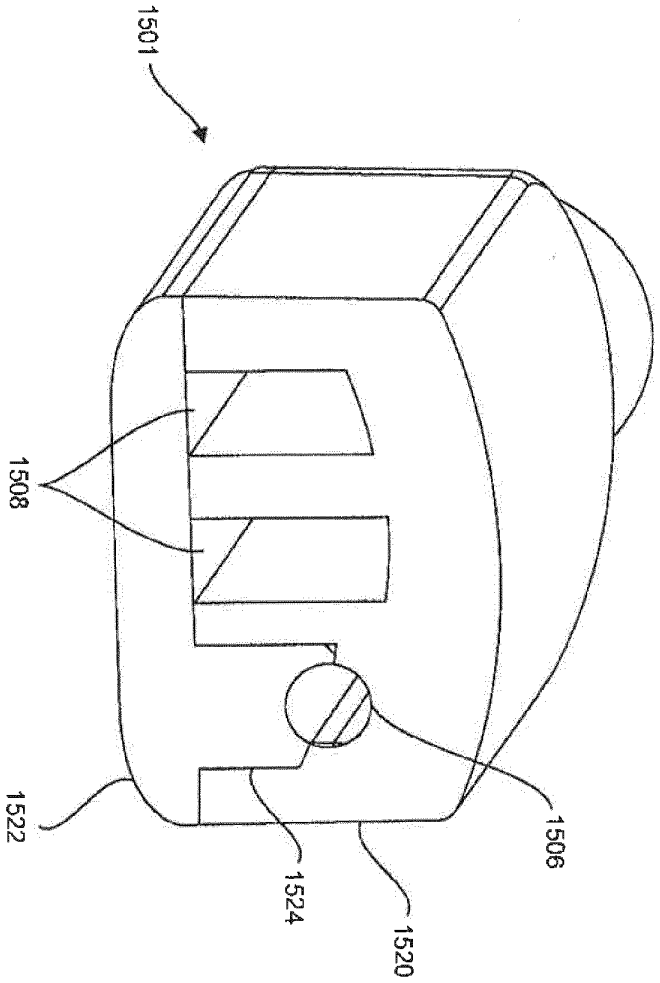


FIG. 15D

KURIN, INC.

EPA-148 105
01.10.2019

37/50

FIG. 15E

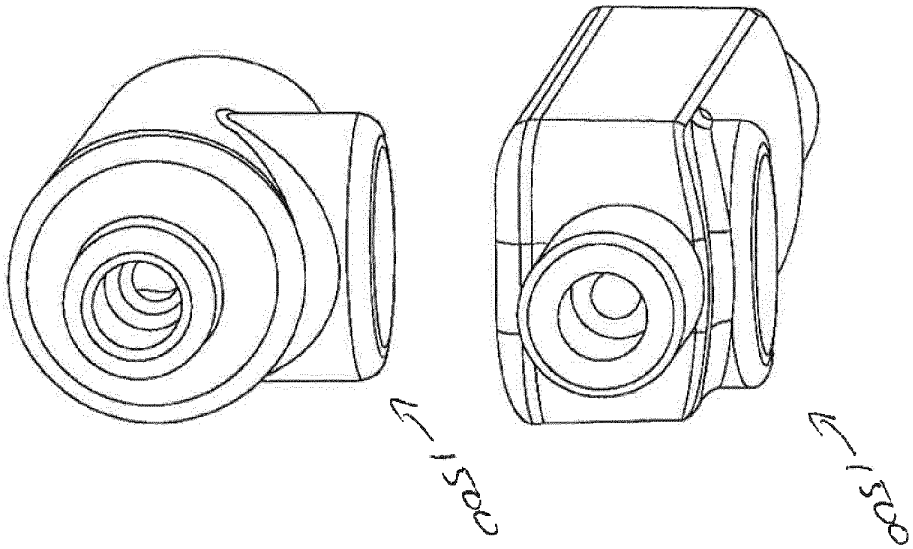
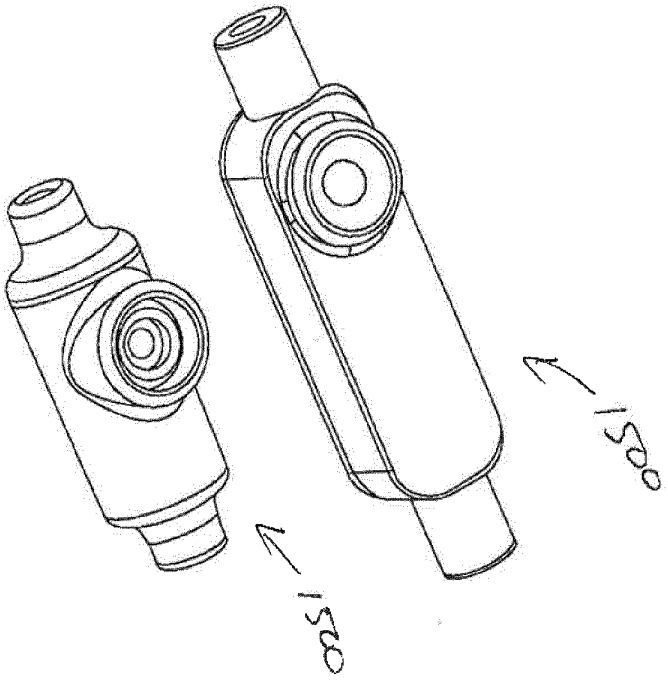


FIG. 15F



KURIN, INC.

EPA-148 105
01.10.2019

38/50

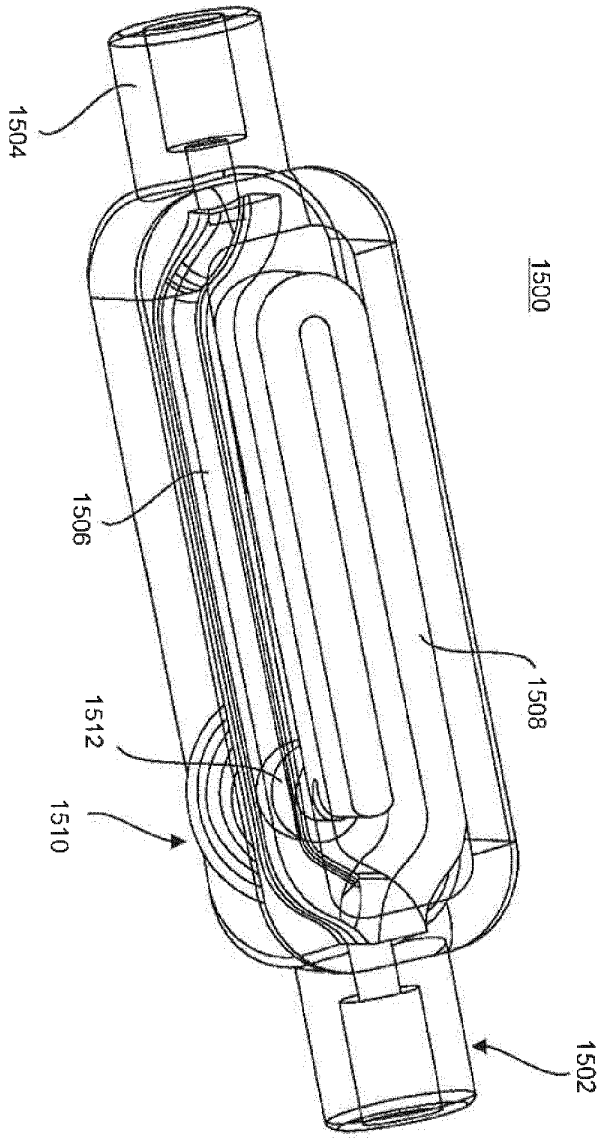


FIG. 15G

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EPA-148 105
01.10.2019

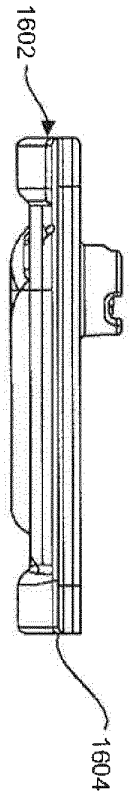


FIG. 16B

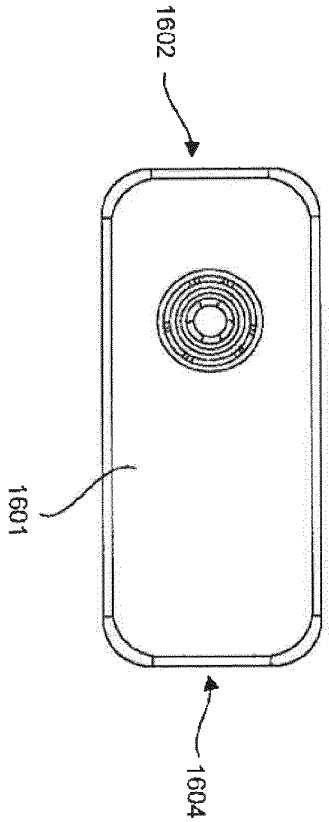


FIG. 16A

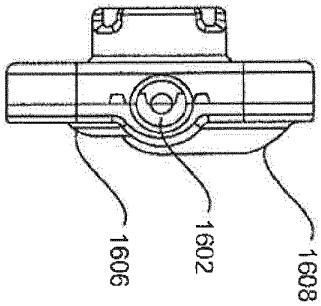


FIG. 16C

KURIN, INC.

EPA-148 105
01.10.2019

40/50

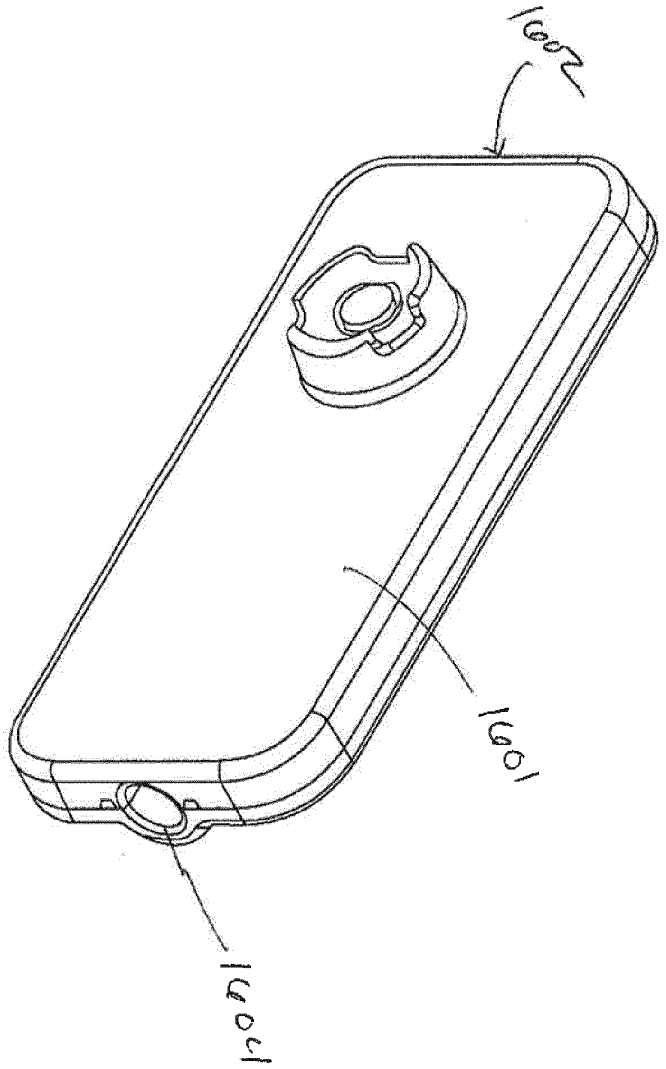


FIG. 16D

KURIN, INC.

EPA-148 105
01.10.2019

41/50

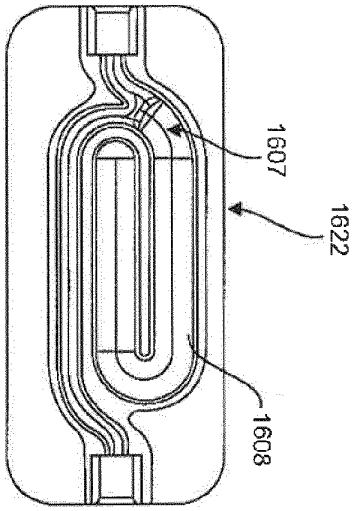


FIG. 17A

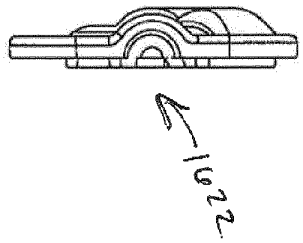


FIG. 17C

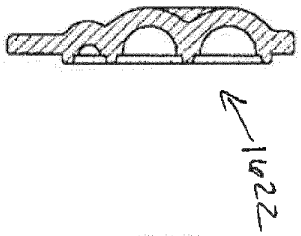


FIG. 17D

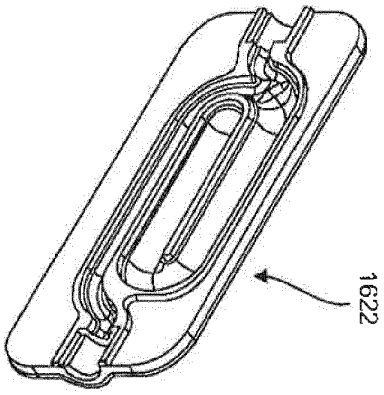


FIG. 17B

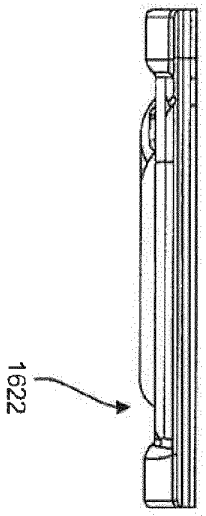


FIG. 17E

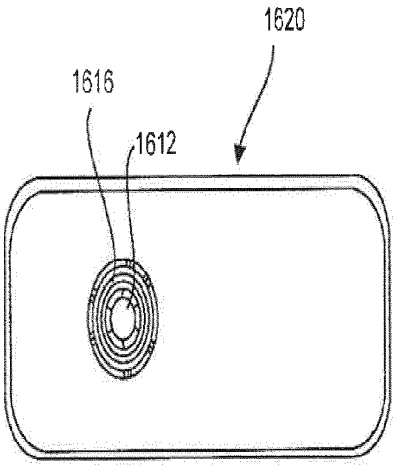


FIG. 18A

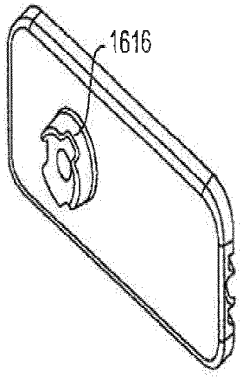


FIG. 18B

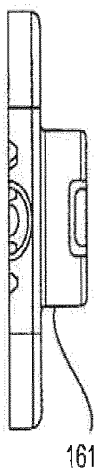


FIG. 18C

42/50

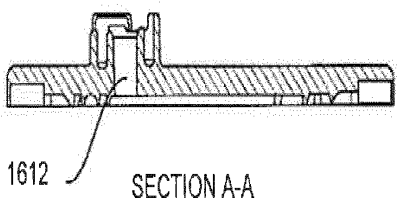


FIG. 18D

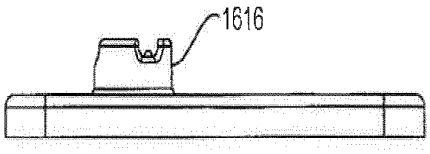


FIG. 18E

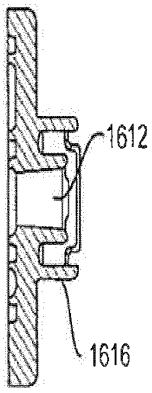


FIG. 18F

43/50

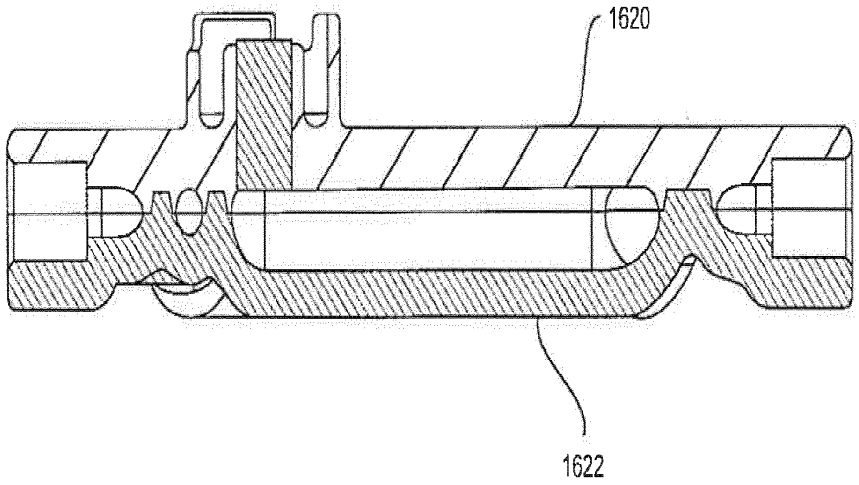


FIG. 19A

KURIN, INC.

EPA-148 105
01.10.2019

44/50

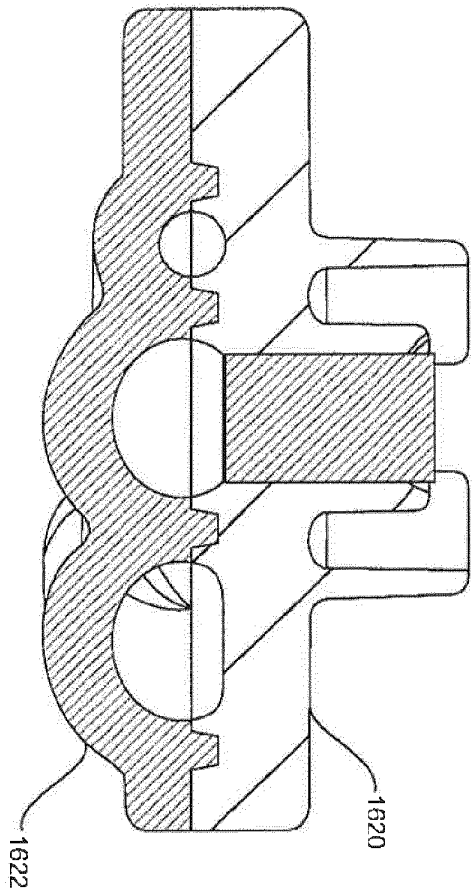


FIG. 19B

KURIN, INC.

EPA-148 105
01.10.2019

45/50

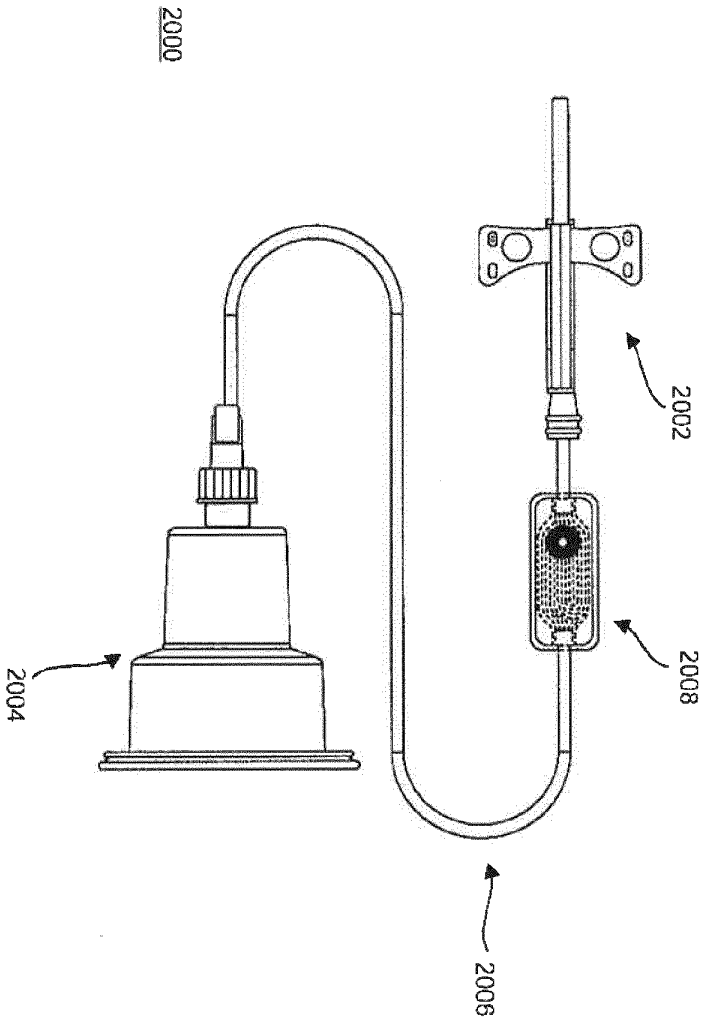


FIG. 20

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EPA-148 105
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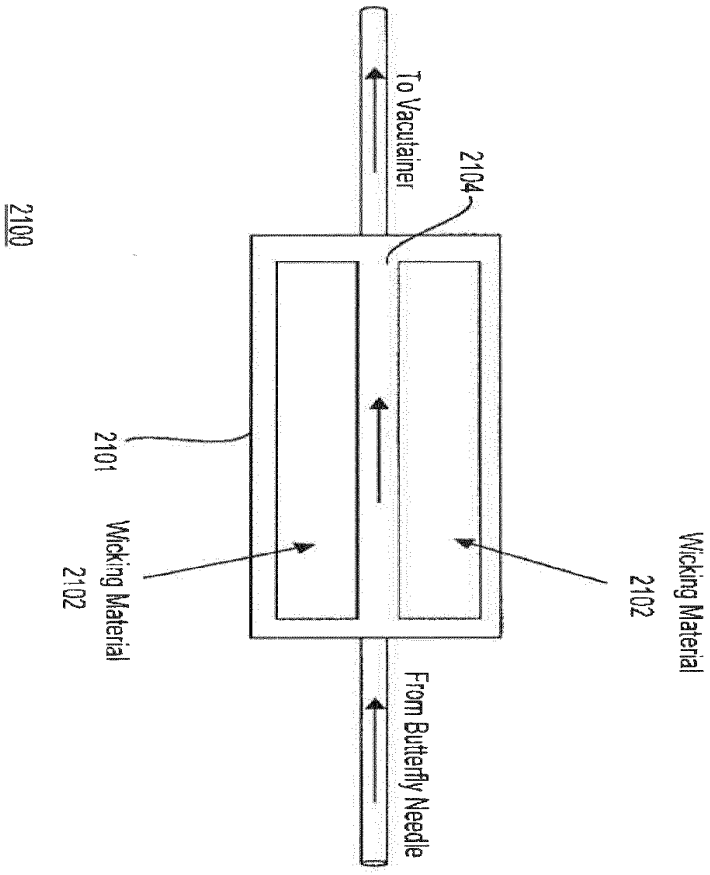


FIG. 21

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EPA-148 105
01.10.2019

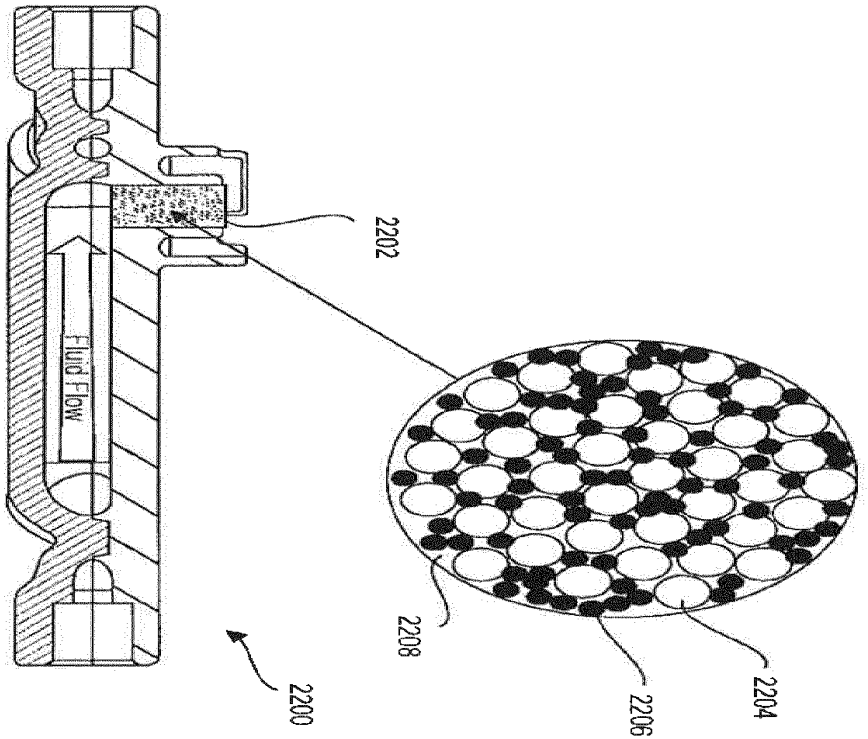


FIG. 22A

KURIN, INC.

EPA-148 105
01.10.2019

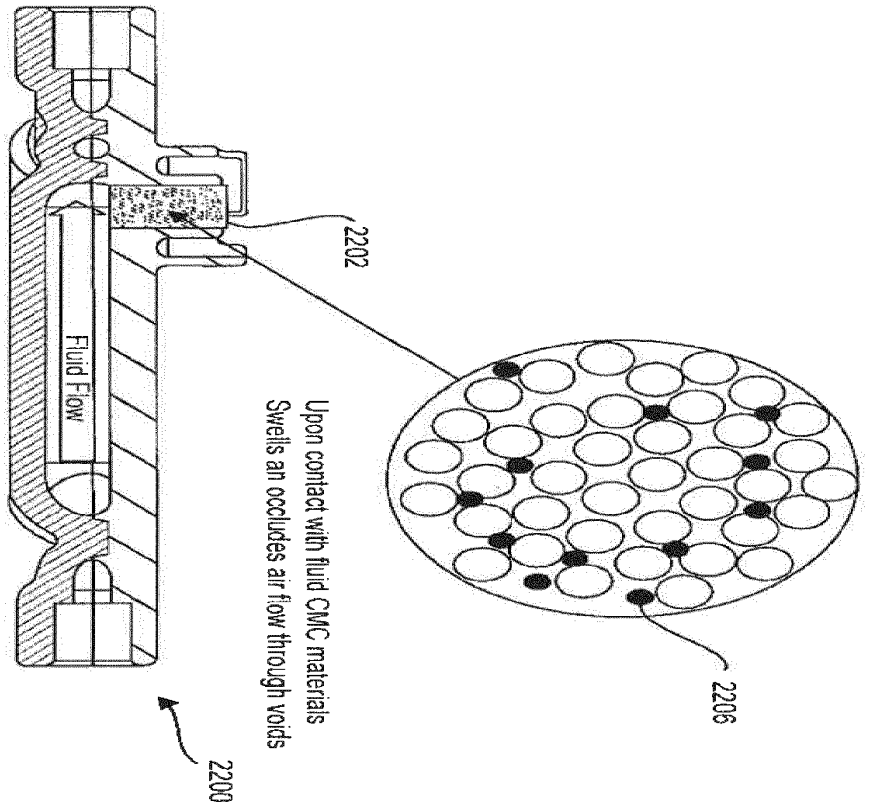


FIG. 22B

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EPA-148 105
01.10.2019

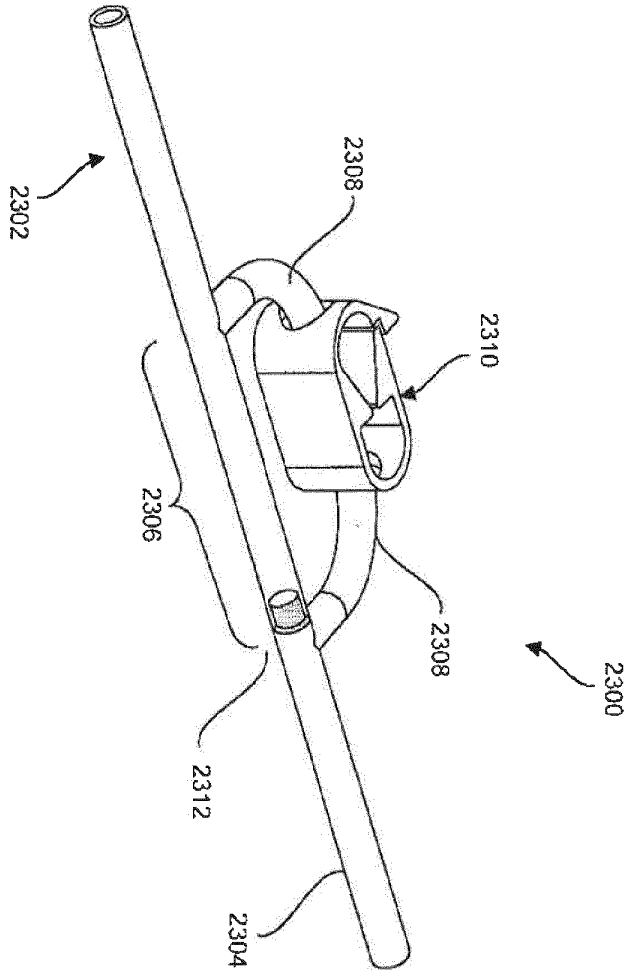


FIG. 23A

KURIN, INC.

EPA-148 105
01.10.2019

50/50

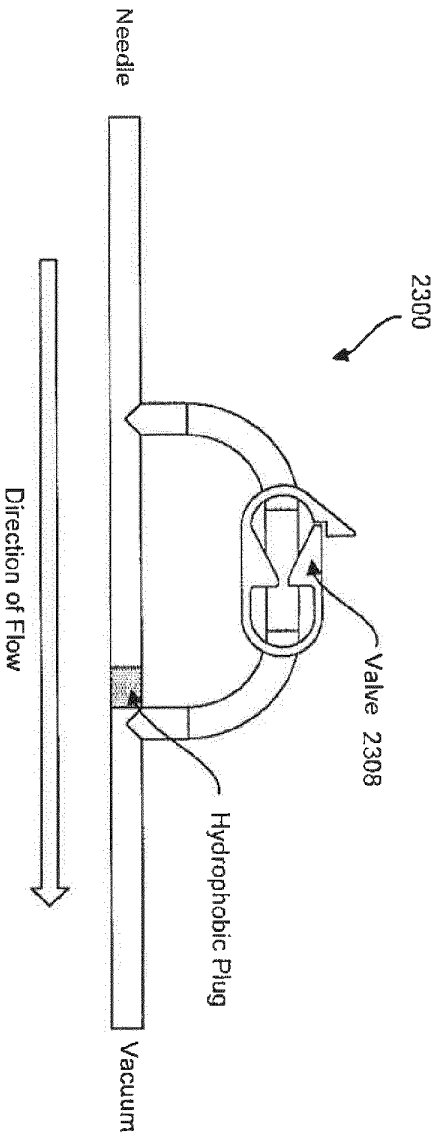


FIG. 23B

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Carroll, Christopher P.
Burns & Levinson London LLP
4-12 Regent Street, 4th Floor
London SW1Y 4PE
ROYAUME UNI

Date: 26.07.2023

Reference	Application No./Patent No.
KUR-002EP3	23155927.9 - 1122 / 4215114
Applicant/Proprietor: Kurin, Inc.	

Communication

The extended European search report is enclosed.

The extended European search report includes, pursuant to Rule 62 EPC, the European search report (R. 61 EPC) or the partial European search report/ declaration of no search (R. 63 EPC) and the European search opinion.

Copies of documents cited in the European search report are attached.

☒ 0 additional set(s) of copies of such documents is (are) enclosed as well.

The following have been approved:

☐ Abstract ☐ Title

☒ The Abstract was modified and the definitive text is attached to this communication.

The following figure(s) will be published together with the abstract: 23B

Refund of search fee
If applicable under Article 9 Rules relating to fees, a separate communication from the Receiving Section on the refund of the search fee will be sent later.

Should you wish to further prosecute this application in the examination phase, your attention is drawn to the provisions of Rule 70a EPC. An invitation to respond to the extended European search report will be issued once the date of publication of the European search report has been mentioned in the European Patent Bulletin (R. 69(1), R. 70(2) EPC).

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The examination is being carried out on the **following application documents**

Description, Pages

1-35 as originally filed

Claims, Numbers

1-16 filed in electronic form on 20-02-2023

Drawings, Sheets

1/50-50/50 as originally filed

Reference is made to the following document; the numbering will be adhered to in the rest of the procedure.

D1 WO 96/05875 A1 (BAXTER INT [US]) 29 February 1996 (1996-02-29)

1. The amendments filed with the letter dated 20-02-2023 introduce subject-matter which extends beyond the content of the application as filed, contrary to Article 123(2) EPC. The amendments concerned are the following: claims 1-16 relate to a device while the application as filed as well as in particular paragraphs [0051],[0125],[0126] relate to a blood sequestration device.

2. The present application does not meet the requirements of Article 52(1) EPC because the subject-matter of claim 1 is not new within the meaning of Article 54(1) and (2) EPC.

D1 discloses a device (10) comprising:
an inlet port (14);
an outlet port (42);
a chamber (22) connected with the inlet port (14) and configured to receive a first portion of blood the chamber (22) including an air permeable material (30) that seals at least partially upon contact with a portion of the first portion of blood (see p.7 l.172-174); and
a sampling channel (36) having a proximal end connected with the inlet port (14, see fig. 1) and a distal end connected with the outlet port (42, see fig.1).

The subject-matter of claim 1 is therefore not new (Article 54(1) and (2) EPC).

3. Dependent claims 2-16 do not appear to contain any additional features which, in combination with the features of any claim to which they refer, meet the requirements of the EPC with respect to novelty and/or inventive step.

3.1 The features of claims 2,9,10,13,15 are merely some straightforward possibilities which the skilled person would select, depending on the circumstances, without exercising inventive skill, in order to solve the problem posed.

3.2 The subject matter of claim 3 is already known from D1 (p.7 l.172-174).

3.3 The subject matter of claim 4 is already known from D1 (p.7 l.188,189).

3.4 The subject matter of claim 5 is already known from D1 (fig. 1).

3.5 The subject matter of claims 6,7 is already known from D1 (p.5 l.2).

3.6 The subject matter of claim 8 is already known from D1 (p.4 l.25: adsorbing material 24).

3.7 The subject matter of claims 11,12,14 is already known from D1 (fig.1).

3.8 The subject matter of claim 16 is already known from D1 (fig.2).

4. The applicant **should bring the description into conformity** with the claims on file (Article 84 EPC). In particular should features that are present in the independent claim(s) not be referred to as options in the form of e.g. "in some instances", "in some embodiments", "in a preferred embodiment" and so forth, but be clearly identified as forming part of the invention. **This applies to the description as a whole**, not only to the introductory part. The "Summary of The Invention" should likewise be amended, i.e. recitation of superseded claims be removed or adapted to the wording of the new claims. Please also note that no method is claimed.

5. To meet the requirements of Rule 42(1)(b) EPC, the document D1 should be identified in the description and the relevant background art disclosed therein should be briefly discussed, observing that references to the prior art introduced after filing must be purely factual.

6. In order to meet the requirements of Rule 43(1) EPC, the independent claim should be properly cast in the two-part form, with those features which in combination are part of the prior art being placed in the preamble (see Guidelines F-IV, 2.2).Arguments in support of inventive step should be presented in an accompanying letter.

If the applicant is of the opinion that a two-part form of claim would be inappropriate he is invited to provide reasons in his reply. In addition, the applicant should ensure that it is clear from the description which features of the subject-matter of the independent claim are known from the prior art (see Guidelines F-IV, 2.3.2).

7. The vague and imprecise statements used in the description at paragraph [0128] imply that the subject-matter for which protection is sought may be different to that defined by the claims, thereby resulting in lack of clarity of the claims (Article 84 EPC) when used to interpret them (see the Guidelines, F-IV, 4.4). These statements should therefore be amended to remove this inconsistency.

8. "Incorporation by reference" is not an option in the European procedure; the description thus requires amendments in this respect at paragraph.

9. The unit inch expressed in paragraphs [0084],[0090],[0105] does not meet the requirements of Rule 49(10) EPC and should be replaced by the appropriate SI unit (see Guidelines F-II, Annex 2). The present expression should, however, be retained in parentheses after the replacement expression.

10. Care should be taken during revision, especially of the introductory portion and any statements of problem or advantage**, not to add subject-matter which extends beyond the content of the application as originally filed (Article 123(2) EPC).**

11. In order to facilitate the examination of the conformity of the amended application with the requirements of Article 123(2) EPC, the applicant should **clearly identify the amendments made**, irrespective of whether they concern amendments by addition, replacement or deletion, and indicate the passages of the application as filed on which these amendments are based (**see Guidelines H-IV**).

If the applicant considers it appropriate, these indications could be submitted in handwritten form on a copy of the relevant parts of the application as filed.

12. Any information the applicant may wish to submit concerning the subject-matter of the invention, for example further details of its advantages or of the problem it solves, and for which there is no basis in the application as filed, should be confined to the letter of reply and not be incorporated into the application (Article 123(2) EPC and the Guidelines H-V, 2.2 to 2.5).

13. Amendments should be made by filing replacement pages. Unnecessary recasting of the description should be avoided. An amended abstract is not required. The applicant should also take account of the requirements of Rule 50(1) EPC. According to Rule 50(1) in conjunction with Rule 49(8) EPC, amendments shall be typed or printed. Handwritten amendments may only be made in documents other than those replacing application documents (Rule 50(2) EPC); they may, for example, be used to fulfil the requirements of Rule 137(4) EPC (identifying amendments and indicating basis for them).

14. In order to expedite the procedure, the applicant is requested to deal with all of the raised objections and to **perform all necessary amendments along with the first response to this communication**.

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EUROPEAN SEARCH REPORT

Application Number
EP 23 15 5927

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
X	WO 96/05875 A1 (BAXTER INT [US]) 29 February 1996 (1996-02-29) * the whole document *	1-16	INV. A61B5/15 A61B5/153 A61B5/154
A	WO 2011/162772 A1 (CLEARVIEW PATIENT SAFETY TECHNOLOGIES LLC [US]; FISCHEL LLOYD [US]; BR) 29 December 2011 (2011-12-29) * paragraph [0070] * * figure 15 * * abstract *	1-16	
A	US 2009/227953 A1 (TAN CHEE LEONG [SG] ET AL) 10 September 2009 (2009-09-10) * the whole document *	1-16	
A	JP H08 257018 A (NISSHO KK) 8 October 1996 (1996-10-08) * abstract; figures *	1-16	
A	US 4 416 291 A (KAUFMAN JOSEPH [US]) 22 November 1983 (1983-11-22) * column 5, line 40 - line 52; figure 7 *	1-16	TECHNICAL FIELDS SEARCHED (IPC) A61B

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
The Hague	18 July 2023	Coja, Michael

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
Y : particularly relevant if combined with another document of the same category
A : technological background
O : non-written disclosure
P : intermediate document

T : theory or principle underlying the invention
E : earlier patent document, but published on, or after the filing date
D : document cited in the application
L : document cited for other reasons

& : member of the same patent family, corresponding document

1

EPO FORM 1503 03.82 (P04C01)

ANNEX TO THE EUROPEAN SEARCH REPORT ON EUROPEAN PATENT APPLICATION NO. EP 23 15 5927

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report. The members are as contained in the European Patent Office EDP file on
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18-07-2023

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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		ZA 822891 B	30-03-1983
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EPO FORM P0459

For more details about this annex : see Official Journal of the European Patent Office, No. 12/82

Information on Search Strategy

The type of information contained in this sheet may change during the pilot for improving the usefulness of this new service.

Application Number

EP 23 15 5927

TITLE: BLOOD SAMPLE CONTAMINANT SEQUESTRATION DEVICE

APPLICANT: Kurin, Inc.

IPC CLASSIFICATION: A61B5/15, A61B5/153, A61B5/154

EXAMINER: Coja, Michael

CONSULTED DATABASES: EPODOC, WPI, COMBI, TXT+

CLASSIFICATION SYMBOLS DEFINING EXTENT OF THE SEARCH:

IPC:

CPC: A61B5/15003, A61B5/150213, A61B5/150389, A61B5/150473, A61B5/150572, A61B5/153, A61B5/154, A61B5/150251

FI/F-TERMS:

KEYWORDS OR OTHER ELEMENTS FEATURING THE INVENTION:

EPO FORM P04A42

UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/538,990	11/30/2021	Bobby E. ROGERS	069366-0572201_KUR2C03US	3420

27500 7590 10/04/2023

PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
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P.O BOX 10500
McLean, VA 22102

EXAMINER	
ABOUELELA, MAY A	

ART UNIT	PAPER NUMBER
3791	

NOTIFICATION DATE	DELIVERY MODE
10/04/2023	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Docket_IP@pillsburylaw.com

Office Action Summary	Application No. 17/538,990	Applicant(s) ROGERS et al.	
	Examiner MAY A ABOUELELA	Art Unit 3791	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 11/30/2021.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL.** 2b) ☑ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 1-20 is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 1-20 is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to **PPHfeedback@uspto.gov.**

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☑ The drawing(s) filed on 11/30/2011 is/are: a)☑ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☑ Notice of References Cited (PTO-892)

2) ☑ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

Notice of Pre-AIA or AIA Status

1. The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 05/16/2023. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Objections

3. Claim 1 is objected to because of the following informalities: the phrase “blood” in lines 8 and 10 should be amended to read –the blood--. Appropriate correction is required.

4. Claim 1 is objected to because of the following informalities: the phrase “the junction being sized” in lines 7-8 should be amended to read –wherein the junction being sized--. Appropriate correction is required.

5. Claim 2 is objected to because of the following informalities: the phrase “blood” in line 3 should be amended to read –the blood--. Appropriate correction is required.

6. Claim 11 is objected to because of the following informalities: the phrase "an curved channel" in line 2 should be amended to read –the curved channel--. Appropriate correction is required.

7. Claim 12 is objected to because of the following informalities: the phrase "an air permeable blood barrier" in line 2 should be amended to read –the air permeable blood barrier--. Appropriate correction is required.

8. Claim 13 is objected to because of the following informalities: the phrase "the chamber" in line 9 should be amended to read –wherein the chamber--. Appropriate correction is required.

9. Claim 13 is objected to because of the following informalities: the phrase "bodily fluid" in lines 9-10, 12 and 13 should be amended to read –the bodily fluid--. Appropriate correction is required.

10. Claim 13 is objected to because of the following informalities: the phrase "from the inlet to bypass the chamber" in line 13 should be amended to read –to be directed from the inlet to bypass the chamber--. Appropriate correction is required.

11. Claim 16 is objected to because of the following informalities: the phrase "bodily fluid" in line 3 should be amended to read –the bodily fluid--. Appropriate correction is required.

Claim Interpretation

12. The following is a quotation of 35 U.S.C. 112(f):

> (f) Element in Claim for a Combination. – An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

The following is a quotation of pre-AIA 35 U.S.C. 112, sixth paragraph:

> An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

The claims in this application are given their broadest reasonable interpretation using the plain meaning of the claim language in light of the specification as it would be understood by one of ordinary skill in the art. The broadest reasonable interpretation of a claim element (also commonly referred to as a claim limitation) is limited by the description in the specification when 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is invoked.

As explained in MPEP § 2181, subsection I, claim limitations that meet the following three-prong test will be interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph:

(A) the claim limitation uses the term "means" or "step" or a term used as a substitute for "means" that is a generic placeholder (also called a nonce term or a non-structural term having no specific structural meaning) for performing the claimed function;

(B) the term "means" or "step" or the generic placeholder is modified by functional language, typically, but not always linked by the transition word "for" (e.g.,

"means for") or another linking word or phrase, such as "configured to" or "so that"; and

(C) the term "means" or "step" or the generic placeholder is not modified by sufficient structure, material, or acts for performing the claimed function.

Use of the word "means" (or "step") in a claim with functional language creates a rebuttable presumption that the claim limitation is to be treated in accordance with 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph. The presumption that the claim limitation is interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is rebutted when the claim limitation recites sufficient structure, material, or acts to entirely perform the recited function.

Absence of the word "means" (or "step") in a claim creates a rebuttable presumption that the claim limitation is not to be treated in accordance with 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph. The presumption that the claim limitation is not interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is rebutted when the claim limitation recites function without reciting sufficient structure, material or acts to entirely perform the recited function.

Claim limitations in this application that use the word "means" (or "step") are being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, except as otherwise indicated in an Office action. Conversely, claim limitations in this application that do not use the word "means" (or "step") are not being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, except as otherwise indicated in an Office action.

This application includes one or more claim limitations that do not use the word "means," but are nonetheless being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, because the claim limitation(s) uses a generic placeholder that is coupled with functional language without reciting sufficient structure to perform the recited function and the generic placeholder is not preceded by a structural modifier. Such claim limitation(s) is/are:

Limitation "junction" in claims 1, 6 and 13, the claims does not recite enough structure that corresponds to the claimed "junction", the specification disclose (junction 1607. Diverter junction 1607 may be a substantially Y-shaped, T-shaped, or U-shaped. In some preferred exemplary implementations, and as shown in FIG. 17A-17B, the diverter junction 1607 is configured such that the flow out of the inlet port 1602 is preferentially directed toward the sequestration chamber 1608. The sequestration chamber 1608 may also include or form a curve or ramp to direct the initial blood flow toward and into the sequestration chamber 1608, par.0109) which can be interpreted as the structure that corresponds to the claimed "junction".

Because this/these claim limitation(s) is/are being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, it/they is/are being interpreted to cover the corresponding structure described in the specification as performing the claimed function, and equivalents thereof.

If applicant does not intend to have this/these limitation(s) interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, applicant may: (1) amend the claim limitation(s) to avoid it/them being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph (e.g., by reciting sufficient structure to perform the

claimed function); or (2) present a sufficient showing that the claim limitation(s) recite(s) sufficient structure to perform the claimed function so as to avoid it/them being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph.

Claim Rejections - 35 USC § 112

13. The following is a quotation of 35 U.S.C. 112(b):
(b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph:
The specifications hall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12 are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor (or for applications subject to pre-AIA 35 U.S.C. 112, the applicant), regards as the invention.

14. Claim 1 recites the limitation "the patient" in line2. There is insufficient antecedent basis for this limitation in the claim.

15. Claim 6 recites the limitation "the blood control device" in line 2. There is insufficient antecedent basis for this limitation in the claim.

16. Claim 6 recites the limitation "the sequestration chamber" in line 10. There is insufficient antecedent basis for this limitation in the claim. Examiner respectfully notes that the phrase “the sequestration chamber” is also recite in claim 7.

17. Claim 8 recites the limitation "the blood sampling pathway" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim.

18. Claim 9 recites the limitation "the blood sampling pathway" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim.

Double Patenting

19. The statutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the claims at issue are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).
A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a statutory double patenting ground provided the reference application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of

activities undertaken within the scope of a joint research agreement. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO internet Web site contains terminal disclaimer forms which may be used. Please visit http://www.uspto.gov/forms/. The filing date of the application will determine what form should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to http://www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp.

Claims 1-20 are non-provisionally rejected on the ground of statutory double patenting as being unpatentable over claims 1-20 of U.S Patent Application No.11311219, claims 1-16 of U.S Patent Application No. 9820682, claims 1-23 of U.S Patent Application No.10143412, and claims 1-26 of U.S Patent Application No.11185266.

Also, claim 1-20 are provisionally rejected on the ground of non-statutory double patenting as being unpatentable over claims 1-20 of U.S pending Application No.17/730118, and claims 1-18 and 20 of U.S pending Application No.17/094692.

Although the claims at issue are not identical, they are not patentably distinct from each other because the U.S Patent applications, pending applications and the instance application are claiming a common subject matter including: a blood sample device comprising; an inlet, an outlet; a chamber having a vent that includes an air permeable blood barrier; a sampling channel; and a junction connected between the inlet, the

chamber and the sampling channel, wherein the junction being sized and configured such that a first portion of blood conveyed from the patient flows into the chamber to displace air therein through the air permeable blood barrier, and such that a second portion of blood is allowed to bypass the chamber and the first portion of blood at least temporarily contained therein to be directed into the sampling channel toward the outlet.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MAY A ABOUELELA whose telephone number is (571)270-7917. The examiner can normally be reached 8-5.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JACQUELINE CHENG can be reached on 5712725596. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: https://patentcenter.uspto.gov. Visit https://www.uspto.gov/patents/apply/patent-center for more information about Patent Center and

https://www.uspto.gov/patents/docx for information about filing in DOCX format. For additional questions, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MAY A ABOUELELA/
Primary Examiner, Art Unit 3791

Notice of References Cited	Application/Control No. 17/538,990	Applicant(s)/Patent Under Reexamination ROGERS et al.	
	Examiner MAY A ABOUELELA	Art Unit 3791	Page 1 of 4

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
*	A	US-20080319346-A1	12-2008	Crawford; Jamieson	A61B5/150656	600/576
*	B	US-4412548-A	11-1983	Hoch; Louis	A61B5/150213	600/577
*	C	US-5222502-A	06-1993	Kurose; Katsutoshi	A61B5/150732	600/584
*	D	US-5520193-A	05-1996	Suzuki; Issei	A61B5/1545	604/126
*	E	US-20100057004-A1	03-2010	Christensen; Kelly D.	A61M39/22	604/122
*	F	US-20070088279-A1	04-2007	Shue; Ming-Jeng	A61M25/0693	604/168.01
*	G	US-20080145933-A1	06-2008	Patton; Richard G.	A61B5/154	435/379
*	H	US-20040054333-A1	03-2004	Theeuwes, Felix	A61M5/14276	604/248
*	I	US-9022951-B2	05-2015	Bullington; Gregory	A61B5/150221	600/576
*	J	US-6569117-B1	05-2003	Ziv; David	A61M39/02	604/246
*	K	US-3741197-A	06-1973	Sanz; Manuel C.	A61B5/150267	600/583
*	L	US-20100010372-A1	01-2010	BROWN; LEROY R.	A61B5/15003	600/573
*	M	US-8603009-B2	12-2013	Tan; Alvin Chee Leong	A61B5/150251	600/573

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	CPC Classification
	N					
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NON-PATENT DOCUMENTS

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*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
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	Examiner MAY A ABOUELELA	Art Unit 3791	Page 2 of 4

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*	B	US-20080167577-A1	07-2008	Weilbacher; Eugene E.	A61B5/1545	600/576
*	C	US-20080086085-A1	04-2008	Brown; Leroy R.	A61B5/150389	604/122
*	D	US-9877675-B2	01-2018	Baid; Rishi	A61B5/150389	1/1
*	E	US-4444203-A	04-1984	Engelman; Allan	A61B5/150496	600/576
*	F	US-20070083162-A1	04-2007	O'Reagan; James	A61M39/26	604/167.03
*	G	US-6398743-B1	06-2002	Halseth; Thor R.	A61B5/15003	604/164.12
*	H	US-9022950-B2	05-2015	Bullington; Gregory	A61B5/150251	600/576
*	I	US-9155495-B2	10-2015	Bullington; Gregory J.	A61B5/1405	1/1
*	J	US-20160008579-A1	01-2016	Burkholz; Jonathan Karl	A61M5/158	604/164.08
*	K	US-20120016266-A1	01-2012	Burkholz; Jonathan Karl	A61B5/150992	600/581
*	L	US-4436098-A	03-1984	Kaufman; Joseph	A61B5/1545	604/199
*	M	US-20130317391-A1	11-2013	Bullington; Gregory J.	A61B5/15003	600/578

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	Examiner MAY A ABOUELELA	Art Unit 3791	Page 3 of 4

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*	B	US-8568371-B2	10-2013	Siopes; William	A61M39/06	251/903
*	C	US-8540663-B2	09-2013	Davey; Christopher T.	A61M1/30	604/93.01
*	D	US-8523826-B2	09-2013	Layton, Jr.; Russell K.	A61M39/16	604/533
*	E	US-20160174888-A1	06-2016	Berthier; Erwin	A61B5/150503	600/573
*	F	US-8197420-B2	06-2012	Patton; Richard G.	A61B5/150503	600/573
*	G	US-4057050-A	11-1977	Sarstedt; Walter	A61B5/150351	604/125
*	H	US-20050240161-A1	10-2005	Crawford, Jamieson William McLean	A61B5/150572	604/264
*	I	US-20040147855-A1	07-2004	Marsden, Stewart	A61B5/150496	600/576
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*	K	US-8535241-B2	09-2013	Bullington; Gregory	A61B5/150946	604/249
*	L	US-20040073171-A1	04-2004	Rogers, Bobby E.	A61M39/26	604/164.13
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*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
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*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
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Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	17538990
Filing Date	2021-11-30
First Named Inventor	Bobby E. ROGERS
Art Unit	OPAP
Examiner Name	CENTRAL, DOCKET
Attorney Docket Number	069366-0572201_KUR2C03US

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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2023-05-16
Name/Print	Benjamin F. Hudson	Registration Number	71,474

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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	Attorney Docket Number	069366-0572201_KUR2C03US

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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2]	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
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That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

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See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2023-05-16
Name/Print	Benjamin F. Hudson	Registration Number	71,474

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2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.A.A/

Europäisches Patentamt
European Patent Office
Office européen des brevets

European Patent Office
80298 MUNICH
GERMANY

Questions about this communication?
Contact Customer Services at www.epo.org/contact

Carroll, Christopher P.
Burns & Levinson London LLP
4-12 Regent Street, 4th Floor
London SW1Y 4PE
ROYAUME UNI

Date 26.07.2023

Reference	Application No./Patent No.
KUR-002EP3	23155927.9 - 1122 / 4215114
Applicant/Proprietor	
Kurin, Inc.	

Communication

The extended European search report is enclosed.

The extended European search report includes, pursuant to Rule 62 EPC, the European search report (R. 61 EPC) or the partial European search report/ declaration of no search (R. 63 EPC) and the European search opinion.

Copies of documents cited in the European search report are attached.

☒ 0 additional set(s) of copies of such documents is (are) enclosed as well.

The following have been approved:

☐ Abstract ☐ Title

☒ The Abstract was modified and the definitive text is attached to this communication.

The following figure(s) will be published together with the abstract: 23B

Refund of search fee
If applicable under Article 9 Rules relating to fees, a separate communication from the Receiving Section on the refund of the search fee will be sent later.

Should you wish to further prosecute this application in the examination phase, your attention is drawn to the provisions of Rule 70a EPC. An invitation to respond to the extended European search report will be issued once the date of publication of the European search report has been mentioned in the European Patent Bulletin (R. 69(1), R. 70(2) EPC).

Europäisches Patentamt • European Patent Office • Office européen des brevets

The examination is being carried out on the **following application documents**

Description, Pages

1-35 as originally filed

Claims, Numbers

1-16 filed in electronic form on 20-02-2023

Drawings, Sheets

1/50-50/50 as originally filed

Reference is made to the following document; the numbering will be adhered to in the rest of the procedure.

D1 WO 96/05875 A1 (BAXTER INT [US]) 29 February 1996 (1996-02-29)

1. The amendments filed with the letter dated 20-02-2023 introduce subject-matter which extends beyond the content of the application as filed, contrary to Article 123(2) EPC. The amendments concerned are the following: claims 1-16 relate to a device while the application as filed as well as in particular paragraphs [0051],[0125],[0126] relate to a blood sequestration device.

2. The present application does not meet the requirements of Article 52(1) EPC because the subject-matter of claim 1 is not new within the meaning of Article 54(1) and (2) EPC.

D1 discloses a device (10) comprising:
an inlet port (14);
an outlet port (42);
a chamber (22) connected with the inlet port (14) and configured to receive a first portion of blood the chamber (22) including an air permeable material (30) that seals at least partially upon contact with a portion of the first portion of blood (see p.7 l.172-174); and
a sampling channel (36) having a proximal end connected with the inlet port (14, see fig. 1) and a distal end connected with the outlet port (42, see fig.1).

The subject-matter of claim 1 is therefore not new (Article 54(1) and (2) EPC).

3. Dependent claims 2-16 do not appear to contain any additional features which, in combination with the features of any claim to which they refer, meet the requirements of the EPC with respect to novelty and/or inventive step.

3.1 The features of claims 2,9,10,13,15 are merely some straightforward possibilities which the skilled person would select, depending on the circumstances, without exercising inventive skill, in order to solve the problem posed.

3.2 The subject matter of claim 3 is already known from D1 (p.7 l.172-174).

3.3 The subject matter of claim 4 is already known from D1 (p.7 l.188,189).

3.4 The subject matter of claim 5 is already known from D1 (fig. 1).

3.5 The subject matter of claims 6,7 is already known from D1 (p.5 l.2).

3.6 The subject matter of claim 8 is already known from D1 (p.4 l.25: adsorbing material 24).

3.7 The subject matter of claims 11,12,14 is already known from D1 (fig.1).

3.8 The subject matter of claim 16 is already known from D1 (fig.2).

4. The applicant **should bring the description into conformity** with the claims on file (Article 84 EPC). In particular should features that are present in the independent claim(s) not be referred to as options in the form of e.g. "in some instances", "in some embodiments", "in a preferred embodiment" and so forth, but be clearly identified as forming part of the invention. **This applies to the description as a whole**, not only to the introductory part. The "Summary of The Invention" should likewise be amended, i.e. recitation of superseded claims be removed or adapted to the wording of the new claims. Please also note that no method is claimed.

5. To meet the requirements of Rule 42(1)(b) EPC, the document D1 should be identified in the description and the relevant background art disclosed therein should be briefly discussed, observing that references to the prior art introduced after filing must be purely factual.

6. In order to meet the requirements of Rule 43(1) EPC, the independent claim should be properly cast in the two-part form, with those features which in combination are part of the prior art being placed in the preamble (see Guidelines F-IV, 2.2).Arguments in support of inventive step should be presented in an accompanying letter.

If the applicant is of the opinion that a two-part form of claim would be inappropriate he is invited to provide reasons in his reply. In addition, the applicant should ensure that it is clear from the description which features of the subject-matter of the independent claim are known from the prior art (see Guidelines F-IV, 2.3.2).

7. The vague and imprecise statements used in the description at paragraph [0128] imply that the subject-matter for which protection is sought may be different to that defined by the claims, thereby resulting in lack of clarity of the claims (Article 84 EPC) when used to interpret them (see the Guidelines, F-IV, 4.4). These statements should therefore be amended to remove this inconsistency.

8. "Incorporation by reference" is not an option in the European procedure; the description thus requires amendments in this respect at paragraph.

9. The unit inch expressed in paragraphs [0084],[0090],[0105] does not meet the requirements of Rule 49(10) EPC and should be replaced by the appropriate SI unit (see Guidelines F-II, Annex 2). The present expression should, however, be retained in parentheses after the replacement expression.

10. Care should be taken during revision, especially of the introductory portion and any statements of problem or advantage**, not to add subject-matter which extends beyond the content of the application as originally filed (Article 123(2) EPC).**

11. In order to facilitate the examination of the conformity of the amended application with the requirements of Article 123(2) EPC, the applicant should **clearly identify the amendments made**, irrespective of whether they concern amendments by addition, replacement or deletion, and indicate the passages of the application as filed on which these amendments are based (**see Guidelines H-IV**).

If the applicant considers it appropriate, these indications could be submitted in handwritten form on a copy of the relevant parts of the application as filed.

12. Any information the applicant may wish to submit concerning the subject-matter of the invention, for example further details of its advantages or of the problem it solves, and for which there is no basis in the application as filed, should be confined to the letter of reply and not be incorporated into the application (Article 123(2) EPC and the Guidelines H-V, 2.2 to 2.5).

13. Amendments should be made by filing replacement pages. Unnecessary recasting of the description should be avoided. An amended abstract is not required. The applicant should also take account of the requirements of Rule 50(1) EPC. According to Rule 50(1) in conjunction with Rule 49(8) EPC, amendments shall be typed or printed. Handwritten amendments may only be made in documents other than those replacing application documents (Rule 50(2) EPC); they may, for example, be used to fulfil the requirements of Rule 137(4) EPC (identifying amendments and indicating basis for them).

14. In order to expedite the procedure, the applicant is requested to deal with all of the raised objections and to **perform all necessary amendments along with the first response to this communication**.

Europäisches Patentamt
European Patent Office
Office européen des brevets

EUROPEAN SEARCH REPORT

Application Number
EP 23 15 5927

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
X	WO 96/05875 A1 (BAXTER INT [US]) 29 February 1996 (1996-02-29) * the whole document *	1-16	INV. A61B5/15 A61B5/153 A61B5/154
A	WO 2011/162772 A1 (CLEARVIEW PATIENT SAFETY TECHNOLOGIES LLC [US]; FISCHEL LLOYD [US]; BR) 29 December 2011 (2011-12-29) * paragraph [0070] * * figure 15 * * abstract *	1-16	
A	US 2009/227953 A1 (TAN CHEE LEONG [SG] ET AL) 10 September 2009 (2009-09-10) * the whole document *	1-16	
A	JP H08 257018 A (NISSHO KK) 8 October 1996 (1996-10-08) * abstract; figures *	1-16	
A	US 4 416 291 A (KAUFMAN JOSEPH [US]) 22 November 1983 (1983-11-22) * column 5, line 40 - line 52; figure 7 *	1-16	TECHNICAL FIELDS SEARCHED (IPC) A61B

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
The Hague	18 July 2023	Coja, Michael

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
Y : particularly relevant if combined with another document of the same category
A : technological background
O : non-written disclosure
P : intermediate document

T : theory or principle underlying the invention
E : earlier patent document, but published on, or after the filing date
D : document cited in the application
L : document cited for other reasons

& : member of the same patent family, corresponding document

1

EPO FORM 1503 03.82 (P04C01)

ANNEX TO THE EUROPEAN SEARCH REPORT ON EUROPEAN PATENT APPLICATION NO. EP 23 15 5927

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report. The members are as contained in the European Patent Office EDP file on
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

18-07-2023

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9605875 A1	29-02-1996	AT 208640 T	15-11-2001
		AU 686450 B2	05-02-1998
		CA 2173331 A1	29-02-1996
		DE 69523887 T2	29-08-2002
		EP 0725658 A1	14-08-1996
		JP H09504726 A	13-05-1997
		US 5947932 A	07-09-1999
		WO 9605875 A1	29-02-1996
WO 2011162772 A1	29-12-2011	NONE	
US 2009227953 A1	10-09-2009	US 2009227953 A1	10-09-2009
		US 2010262038 A1	14-10-2010
		US 2012330187 A1	27-12-2012
JP H08257018 A	08-10-1996	NONE	
US 4416291 A	22-11-1983	AU 549400 B2	23-01-1986
		BR 8202753 A	19-04-1983
		EP 0070356 A2	26-01-1983
		ES 8307509 A1	01-07-1983
		JP S649011 B2	16-02-1989
		JP S5825146 A	15-02-1983
		MX 151907 A	02-05-1985
		NZ 200914 A	31-05-1984
		US 4416291 A	22-11-1983
		ZA 822891 B	30-03-1983
		ZA 822892 B	30-03-1983

EPO FORM P0459

For more details about this annex : see Official Journal of the European Patent Office, No. 12/82

Information on Search Strategy

The type of information contained in this sheet may change during the pilot for improving the usefulness of this new service.

Application Number

EP 23 15 5927

TITLE: BLOOD SAMPLE CONTAMINANT SEQUESTRATION DEVICE

APPLICANT: Kurin, Inc.

IPC CLASSIFICATION: A61B5/15, A61B5/153, A61B5/154

EXAMINER: Coja, Michael

CONSULTED DATABASES: EPODOC, WPI, COMBI, TXT+

CLASSIFICATION SYMBOLS DEFINING EXTENT OF THE SEARCH:

IPC:

CPC: A61B5/15003, A61B5/150213, A61B5/150389, A61B5/150473, A61B5/150572, A61B5/153, A61B5/154, A61B5/150251

FI/F-TERMS:

KEYWORDS OR OTHER ELEMENTS FEATURING THE INVENTION:

EPO FORM P04A42

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18 March 2022

Examination report No. 1 for standard patent application

Griffith Hack
GPO Box 4164
Sydney NSW 2001
Australia

Your reference:	P108089.AU.1
Application number:	2021202622
Applicant name:	KURIN, INC.
Earliest priority date:	24 July 2015

Final date for acceptance:	**18 March 2023**
Date of this report:	18 March 2022
Examination request date:	6 July 2021

Dear Griffith Hack,

Your application has been examined under *section 45 of the Patents Act 1990*.

You have **12 months** from the date of this report to overcome all my objection(s) otherwise this application will lapse.

You will also need to pay any annual continuation fees that apply. Your next continuation fee is due on **22 July 2022**.

While the application is otherwise in order for acceptance, it cannot be accepted because there is a current postponement of acceptance in place.

You must respond to this report in order to gain acceptance. The Commissioner will only proceed to accept the application if you file a clear and unambiguous statement requesting the postponement be withdrawn with sufficient time for the request to be processed. If the application is not accepted by **18 March 2023**, your application will lapse.

Details of this patent application can be viewed on Auspat, our Australian patent search database.

Yours sincerely,

Kevin Sivieng
Section: MECH 4 - MEDICAL DEVICES
Phone: +61 2 6283 2609

Alternate contact: Vijay Singh
Phone: +61 2 6283 2665

Report details

Basis of the report

In examining this application I have considered:

- the specification as filed.
- allowed and/or proposed amendment/s under S104 including amendment item number 1, filed on 4 May 2021.

Summary of novelty, inventive step and patentable subject matter

	Satisfy requirements?	*Claim numbers*
Novelty/inventive step	**Yes**	1-16
	No	NONE
Patentable subject matter	**Yes**	1-16
	No	NONE

Detailed objections on issues that have been identified

Documents cited or considered relevant

D1: WO 2011162772 A1 (CLEARVIEW PATIENT SAFETY TECHNOLOGIES LLC [US], et al) 29 December 2011 [1]
Category: A

D2: WO 1996005875 A1 (BAXTER INT [US]) 29 February 1996 [2]
Category: A

D3: US 20130317391 A1 (BULLINGTON GREGORY J [US], et al) 28 November 2013 [3]
Category: A

D4: US 4207870 A (ELDRIDGE WILLIAM N [US]) 17 June 1980 [3]
Category: A

D5: US 4416291 A (KAUFMAN) 22 November 1983 [4]
& JP S 5825146 A
Category: A

D6: US 20080145933 A1 (PATTON RICHARD G [US]) 19 June 2008 [5]
Category: A

D7: JP 2001000424 A (NISSHO KK) 9 January 2001, English translation retrieved from Espacenet [5]
Category: A

[1] Cited in the search/examination report of WO 2017/019552 A1

[2] Cited in the search/examination report of EP 3622890

[3] Cited in the search/examination report of US 2017/0020427 A1

[4] Cited in the search/examination report of JP 2018525191

[5] Cited in the search/examination report of JP 2020192333

Special categories of cited documents:

A: Document defining the general state of the art which is not considered to be of particular relevance.
&: Document member of the same patent family.

END OF REPORT

Japanese Patent Application No. 2020-118498
Your Ref: KURIN2JP-DIV2
Our Ref: TS/KRN-C0137JP03
March 28, 2022

Translation of "Notice of Reasons for Rejection"

Patent Application Number: JP 2020-118498
Date of Delivery: February 15, 2022
Applied Provision: Patent Law Article 29(2)

The present application should be rejected for the following reasons. The applicant may present an argument against the reasons within three months from the date of delivery of this notice.

Reasons

1. The inventions of the following claims should not be granted a patent under Patent Law Article 29(2) as lacking inventive step over the documents listed below.

Remarks (See the Document List below)

- Reason 1 (Inventive step)
- Claims 1 to 10
- Documents D1 to D4

[Claim 1]

D1 ([0019]-[0055], Figs. 5-8) discloses

a blood sample optimization system (sample-procurement system; [0038], etc.) for optimizing a blood sample ([0020], etc.) collected by a blood collector (sample vessels 506; [0038], etc.), the system comprising:

a patient needle (first needle 508; [0038], etc.) configured for a venipuncture of a patient to access a sample of blood of a patient, the sample of blood including a first portion containing contaminants ([0021], etc.) and a second portion following the first portion;

a blood sampling pathway connected with the patient needle configured for conveying the sample of blood (see Fig. 5, etc.); and

a sample needle configured for receiving the blood collector to collect a second portion of the sample of blood(see suggestions in Fig. 5, etc.); and

a blood sequestration device connected on the blood sampling pathway between the patient needle and the sample needle, the blood sequestration device comprising;

an inlet port (sterile input tubing 514; [0039], etc.) configured for receiving the sample of blood;

a sequestration chamber (pre-sample reservoirs 504; [0038], etc.) connected with the inlet port, the sequestration chamber configured for receiving the first portion of the sample of blood to contain the contaminants in the first portion of the blood sample; and

a sampling channel (second sterile output tubing 518; [0038], Fig. 5, etc.) having a proximal end connected with the inlet port, configured for receiving the second portion of the

sample of blood,

the sequestration chamber, the sampling channel and the inlet port being configured to allow the second portion of the sample of blood to bypass the sequestration chamber and direct the second portion of the sample of blood toward an outlet port that is configured to output the second portion of the sample of blood to the blood collector ([0038], etc.).

As explained in the previous Notice of Reasons for Rejection, D2 ([0012]-[0013] etc.) discloses arts in a blood sample optimization system (blood sampling needle) of configuring a sequestration chamber having a vent comprising an air permeable blood barrier (air permeable blood impermeable member 23) to displace air in the sequestration chamber through the vent, and of configuring a housing (needle tube support 2) that houses and defines ports, the sequestration chamber and a channel.

In addition, newly cited D3 (see pages 5-6, FIG. 1, etc.) discloses arts in a blood sample optimization system (closed system blood sampling device) of configuring a sequestration chamber (blood disposal chamber 22) having a vent comprising an air permeable blood barrier (air permeable hydrophobic membrane 30) to displace air in the sequestration chamber through the vent, and of configuring a housing that houses and defines ports, the sequestration chamber and a channel (see FIG. 1, etc.).

Further, D4 ([0042], etc.) also discloses art of configuring a sequestration chamber having a vent comprising an air permeable blood barrier to displace air in the sequestration chamber through the vent.

And, as supported by the disclosure of D2 to D4 described above, in a blood sample optimization system, configuring a sequestration chamber having a vent comprising an air permeable blood barrier to displace air in the sequestration chamber through the vent, and configuring a housing that houses and defines ports, the sequestration chamber and a channel are both well-known arts.

The system disclosed in D1 and the well-known arts disclosed in D2 to D4 belong to the same technical field called the blood collection field.

Configuring the system disclosed in D1 to have an air permeable blood barrier and a housing similar to the invention of claim 1 of the present application with reference to the well-known arts disclosed in D2 to D4 is easy for those skilled in the art, or a matter that those skill in the art could have made as appropriate.

[Claims 2 and 4]

See [0012]-[0013] of D2.

[Claim 3]

Placing a seal on the sample needle can be said to be a design matter.

[Claim 5]

See [0011] of D2.

[Claim 6]

See Fig. 5 of D1.

[Claims 7-10]

See the above explanations including the descriptions of D1 to D4.

Document List

D1: US 2008/0145933A

D2: JP 2001-000424A

D3: JP H09-504726A (newly cited; document disclosing well-known art)

D4: US 2006/0009713A (newly cited; document disclosing well-known art)

Record of the Result of Prior Art Search

Technical field(s) searched	IPC A61B 5/00-5/398
Prior art document(s)	JP S58-025146A
	JP H02-224742A
	US 2011/0306899A

This record is not a component of the reasons for rejection.

פ.ק 26

תאריך : י״ח כסלו תשפ״ב
22/11/2021
מספרכם : 1000-016-01

לכבוד
כץ, פרזנטי ושות׳
דרך אבא הלל 14, ת.ד.
רמת גן, מיקוד 52506

א. ג. נ.,

הנדון : **<u>הודעה על ליקויים בבקשת פטנט מספר 286030</u>**
סימוכין : מכתבכם מיום 15/11/2021

לתשומת לבכם : מקום בו הנכם מופנים לחוק, הכוונה היא לחוק הפטנטים, התשכ״ז – 1967. מקום בו הנכם מופנים לתקנות, הכוונה היא לתקנות הפטנטים (נוהלי הרשות, סדרי דין, מסמכים ואגרות), התשכ״ח – 1968. עליכם להשיב על הודעה זו תוך ארבעה חודשים מתאריכה, אך הנכם רשאים לבקש את הארכת התקופה, עם בקשת הארכה שתוגש יש לשלם אגרה בסך 203.00 ש״ח בעד כל חודש או חלק ממנו. **לא יינתנו יותר מארבעה חודשי ארכה בגין כל הודעה על ליקויים וסך כל תקופות הארכה במהלך הבחינה לא יעלה על 12 חודשים** בהתאם לכללים שנקבעו בחוזר הרשם 035/2017-פטנטים.

<u>הודעה זו מבוססת על המסמכים הבאים :</u>
שרטוטים מתאריך : 01/09/2021
פרטי הבקשה מתאריך : 01/09/2021
תביעות מתאריך : 01/09/2021

<u>ההפניות בהודעה זו מתייחסות לפרסומים הבאים :</u>

D1: WO 2011162772 A1 [CLEARVIEW PATIENT SAFETY TECHNOLOGIES LLC [US]] - 29/12/2011

<u>הסתייעות הבוחן בדוח בינלאומי</u>

מערכת התביעות שבבקשה שבפניי זהה / זהה בחלקה למערכת התביעות בבקשה הבין-לאומית PCT/US/2016/043709 שנבחנה על ידי רשות חיפוש ובחינה בין-לאומית. לאחר עיון בדוח הבין-לאומי ולאור הזהות בתביעות כאמור, החלטתי כי הליקויים שפורטו בדוח הבין-לאומי חלים על הבקשה שבפניי כמפורט בהמשך הודעה זו.

<u>בהתאם למפורט בהמשך הודעה זו להלן סיכום עמדתי לעניין כשירות התביעות לפטנט :</u>

בתביעה/ות מס׳ 1-4 נמצאו ליקויים.
ראה הנימוקים בהמשך הודעה זו.

בהתאם להוראות **תקנה 41** הנני להודיעכם כי נמצאו בבקשה הנ״ל הליקויים המפורטים להלן :

1. <u>בחינת הבקשה מבוססת על ההודעות הבאות:</u>

1.1 הריני להודיעכם כי:

(א) תאריך הבקשה הנוכחית, שהינה בקשת חלוקה מן הבקשה מס' 257137, הוקדם לתאריך 22/07/2016, שהוא תאריך הבקשה ההורה, וזאת בהתאם ל**סעיף 24(ג) לחוק**;

(ב) הבקשה הנוכחית זכאית לאותו(ם) תאריך(כי) בכורה אשר עליו(הם) הושתתה הבקשה ההורה.

2. <u>חידוש והתקדמות המצאתית</u>

2.1 תביעה 1 אינה מגדירה אמצאה חדשה כהגדרתה ב**סעיף 4 לחוק**, לאור פרסום: D1.

תביעה 1 שבבקשה שבפניי תואמת לתביעה 17 בבקשה AU2016297849 שנבחנה על ידי IP Australia והופק עבורה דוח בחינה בתאריך 29/04/2020. לאחר עיון בדוח הבחינה האמור ולאור תאימות התביעות, מצאתי כי הליקוי שפורט בנוגע לחוסר חידוש חל גם על התביעות שבפניי לפי חוק הפטנטים הישראלי.

2.2 תביעות 2-4 אינן מגדירות אמצאה שיש בה התקדמות המצאתית כהגדרתה ב**סעיף 5 לחוק**, לאור פרסום: D1.

תביעות 2-4 שבבקשה שבפניי תואמות לתביעות 18-20 בבקשה AU2016297849 שנבחנה על ידי IP Australia והופק עבורה דוח בחינה בתאריך 29/04/2020. לאחר עיון בדוח הבחינה האמור ולאור תאימות התביעות, מצאתי כי הליקוי שפורט בנוגע לחוסר התקדמות המצאתית חל גם על התביעות שבפניי לפי חוק הפטנטים הישראלי.

3. <u>התביעות</u>

3.1 תביעה מס' 1 (התואמת לתביעה 17 בבקשה הבין-לאומית) אינה עונה לדרישות **סעיף 13 לחוק** ו**תקנה 20(א)(3)** מאחר והיא לא בהירה ו/או תמציתית, כמפורט בדוח הבחינה הבין-לאומי.

<u>חובת המבקש לעדכן את הרשות</u>

תשומת לבכם ל**סעיף 18א לחוק** לעניין חובת המבקשת לעדכן את הרשות על כל שינוי שחל ברשימת האסמכתאות או הפרסומים כאמור ב**סעיף 18(א) לחוק** ול**סעיף 18ג לחוק** בדבר אמצעי האכיפה.

<u>הגשת תיקונים לפירוט במהלך בחינת הבקשה</u>

באם יבוצעו תיקונים בבקשת הפטנט, תשומת לבכם מופנית **לתקנה 22(א)**. יש לשלוח לרשות עותק מלא של חלק הבקשה שבו הוכנסו התיקונים תוך סימונם באופן ברור. יש לסמן תוספות בקו תחתי (כך: <u>דוגמה</u>) והשמטות בקו חוצה (כך: ~~דוגמה~~). **אין להגיש מחדש קבצים שלא תוקנו.**

לתשומת לבכם:

א) בהתאם לתקנות 22(ב) ו-42 במידה שהנכם מתקנים את הפירוט כדי להתגבר על הליקויים בהודעה זו, עליכם לפרט את הליקויים שהתיקונים באים לסלקם, לנמק כיצד תיקון הפירוט מתקן את הליקוי ולגבי תיקון בתביעות, כיצד עומד התיקון בתנאי סעיף 13 לחוק.

ב) בהתאם להוראות חוזר רשם 034/2017-פטנטים, במידה שבחינת הבקשה החלה לאחר 27.03.2017, תיקון

פירוט בדרך של החלפת האמצאה שנבחנה ואשר לגביה הועלה ליקוי, באמצאה אחרת, בין אם היא הופיעה בתביעות מלכתחילה ובין אם תוארה בלבד, גם אם היא נובעת מהתיאור, אינו מהווה תיקון הליקוי ויביא לשליחת הודעה לפני סירוב.

ניתן לעיין בפרטי תיק הבקשה באתר הרשות בקישור:

https://israelpatents.justice.gov.il/#/en/patent-file/details/286030

<u>ראיון עם בוחן</u>

בהתאם לה.ע. 23.3, המפורסמת באתר הרשות, ניתן לקיים ראיון עם הבוחן באמצעות פגישה במשרדי הרשות או בשיחה טלפונית.

רשות הפטנטים מעודדת קיום של קשר ישיר בין הבוחן למבקש או בא-כוחו באמצעות שירות זה.

קיום ראיון עם בוחן מאפשר לרוב את ייעול וקיצור זמן הבחינה ואף לחיסכון בעלויות בתהליך הבחינה והאישור של בקשה לפטנט.

במסגרת הראיון ניתן לדון עם הבוחן בנושאים הקשורים לתיאור האמצאה והגדרתה, בליקויים שהועלו במהלך הבחינה ואף בתיקונים אפשריים לליקויים אלה.

תיאום הראיון יתבצע ישירות מול הבוחן (פרטי הקשר מופיעים מטה) וילווה בהודעה כתובה של יוזם הראיון שתפרט את הנושאים לדיון ואת הטיעונים העיקריים לגביהם.

לתשומת לבכם, בקשה לקיום ראיון אינה מהווה תשובה להודעת הליקויים כמשמעה בתקנה 42.

<u>השגה בפני הרשם</u>

על פי **סעיף 161 לחוק**, הנכם רשאים להשיג על החלטתי בפני רשם הפטנטים תוך ארבעה חודשים ממועד משלוח ההודעה.

בכבוד רב

אלברט אקרמן
בוחן פטנטים בכיר
טלפון: 073-3927233
דואר אלקטרוני: albertak@justice.gov.il
ראש צוות: מוריה שלמה לוי

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/730,118	04/26/2022	Bobby E. ROGERS	069366-0572186_KUR3C01US	1667

27500 7590 09/23/2024

PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
ATTENTION: DOCKETING DEPARTMENT
P.O BOX 10500
McLean, VA 22102

EXAMINER	
NGUYEN, HUONG Q	

ART UNIT	PAPER NUMBER
3791	

NOTIFICATION DATE	DELIVERY MODE
09/23/2024	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Docket_IP@pillsburylaw.com

Office Action Summary	Application No. 17/730,118	Applicant(s) ROGERS et al.	
	Examiner Huong Q NGUYEN	Art Unit 3791	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 4/26/2022.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL.** 2b) ☑ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 1 is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 1 is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to **PPHfeedback@uspto.gov.**

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☑ The drawing(s) filed on 4/26/2022 is/are: a)☐ accepted or b)☑ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☑ Notice of References Cited (PTO-892)

2) ☑ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

DETAILED ACTION

Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Claim Interpretation

The following is a quotation of 35 U.S.C. 112(f):

> (f) Element in Claim for a Combination. – An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

The following is a quotation of pre-AIA 35 U.S.C. 112, sixth paragraph:

> An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

The claims in this application are given their broadest reasonable interpretation using the plain meaning of the claim language in light of the specification as it would be understood by one of ordinary skill in the art. The broadest reasonable interpretation of a claim element (also commonly referred to as a claim limitation) is limited by the description in the specification when 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is invoked.

As explained in MPEP § 2181, subsection I, claim limitations that meet the following three-prong test will be interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph:

(A) the claim limitation uses the term "means" or "step" or a term used as a substitute for "means" that is a generic placeholder (also called a nonce term or a non-structural term having no specific structural meaning) for performing the claimed function;

(B) the term "means" or "step" or the generic placeholder is modified by functional language, typically, but not always linked by the transition word "for" (e.g., "means for") or another linking word or phrase, such as "configured to" or "so that"; and

(C) the term "means" or "step" or the generic placeholder is not modified by sufficient structure, material, or acts for performing the claimed function.

Use of the word "means" (or "step") in a claim with functional language creates a rebuttable presumption that the claim limitation is to be treated in accordance with 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph. The presumption that the claim limitation is interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is rebutted when the claim limitation recites sufficient structure, material, or acts to entirely perform the recited function.

Absence of the word "means" (or "step") in a claim creates a rebuttable presumption that the claim limitation is not to be treated in accordance with 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph. The presumption that the claim limitation is not interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is rebutted when the claim limitation recites function without reciting sufficient structure, material or acts to entirely perform the recited function.

Claim limitations in this application that use the word "means" (or "step") are being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, except as

otherwise indicated in an Office action. Conversely, claim limitations in this application that do not use the word "means" (or "step") are not being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, except as otherwise indicated in an Office action.

No claim elements are interpreted under 112(f).

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the junction of Claim 1 (referred to element 3007 in the specification 00160, which is not shown), the vent of Claim 1 (referred to as element 3010 in the spec 00161, which is not shown), and the air vent (Claim 1) must be shown with reference numbers in the claimed embodiment of Figure 30 or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or

"New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "3012" has been used to designate both fulcrum (0166 – published spec) and semi permeable barrier (0166 – published spec). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference characters "3017" and "2\3008" have both been used to designate "the seal" (0166 – published spec), while "3008" has also been used to designate the sequestration chamber (0166 – published spec). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement

Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

Claim 1 is objected to because of the following informalities: "insludes" should be "includes."

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of 35 U.S.C. 112(b):
(b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor (or for applications subject to pre-AIA 35 U.S.C. 112, the applicant), regards as the invention.

The recitation of "and includes one or more air vents" is indefinite because it is unclear if the air vents are part of the wall or the air permeable blood barrier. It is assumed the air vents are part of the wall, however, clarification is requested.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on nonstatutory double patenting provided the reference application or patent either is shown to be commonly owned with the examined application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. See MPEP § 717.02 for applications subject to

examination under the first inventor to file provisions of the AIA as explained in MPEP § 2159. See MPEP § 2146 *et seq.* for applications not subject to examination under the first inventor to file provisions of the AIA. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO Internet website contains terminal disclaimer forms which may be used. Please visit www.uspto.gov/patent/patents-forms. The filing date of the application in which the form is filed determines what form (e.g., PTO/SB/25, PTO/SB/26, PTO/AIA/25, or PTO/AIA/26) should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp.

Claim 1 is rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-5, or 7, 9, 10, 11, 12 of U.S. Patent No. 10827964 in view of Eldridge et al (US Pat No. 4207870).

Although the claims at issue are not identical, they are not patentably distinct from each other because both recite a blood sequestration device comprising; an inlet port; an outlet port; a sequestration chamber connected with the inlet port, the sequestration chamber having a vent that includes an air permeable blood barrier, the vent being defined by an outer wall that at least partially circumscribes the air permeable blood barrier and includes one or more air vents (aperture in claim 3, 10 of Patent), the vent further including a cap that at least partially covers the wall and a one-way seal (flexible sheet, plug in claim 3, 10 of Patent)

abutting (claim 3, 12 of Patent) the air permeable blood barrier that inhibits air from entering the sequestration chamber; and a sampling channel having a proximal end connected with the inlet port, and a distal end connected with the outlet port; the sequestration chamber, the sampling channel and the junction being sized and configured such that a first portion of blood flows into the sequestration chamber toward the air permeable blood barrier for sequestration therein, and a second portion of blood bypasses the sequestration chamber and the first portion of blood sequestered therein and is directed into the sampling channel toward the outlet port.

However, the patent doesn't expressly disclose the sequestration chamber connected to the inlet port via a junction. Eldridge et al teach that it is well-known in the art to provide an analogous blood sequestration device comprising inlet port (in hub 10 where cannula 14 is connected Col.2: 50-55), outlet port (cannula 18 in hub 12, Col.2: 50-55), sequestration chamber (28 and 30, Col.2: 63-65), the sequestration chamber connected to the inlet port via a junction (valve 20, Col.2: 57-6), and proximal end of sampling channel (32, Col.3: 52-54) connected to the inlet port via the junction, best seen in Figure 1 and 3, as an effective manner of connecting the inlet port to the sequestration chamber for controlled blood flow in the desired direction. Therefore, it would have been obvious to one of ordinary skill in the art at the time of filing to modify the invention of the Patent such that the sequestration chamber is connected to the inlet port via a junction as taught by Eldridge, to provide an effective manner of connecting the two for controlled blood flow in the desired direction.

Claim 1 is rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1, 8, or 15 of U.S. Patent No. 11311219 (Parent case of instant application) in view of Fischel (US Pub No. 20110306899).

Although the claims at issue are not identical, they are not patentably distinct from each other because both recite a blood sequestration device comprising; an inlet port; an outlet port; a sequestration chamber connected with the inlet port via the junction, the sequestration chamber having a vent that includes an air permeable blood barrier, the vent being defined by an outer wall that at least partially circumscribes the air permeable blood barrier, the vent further including a cap that at least partially covers the wall and a one-way seal abutting the air permeable blood barrier that inhibits air from entering the sequestration chamber; and a sampling channel having a proximal end connected with the inlet port via the junction, and a distal end connected with the outlet port; the sequestration chamber, the sampling channel and the junction being sized and configured such that a first portion of blood flows into the sequestration chamber toward the air permeable blood barrier for sequestration therein, and a second portion of blood bypasses the sequestration chamber and the first portion of blood sequestered therein and is directed into the sampling channel toward the outlet port.

However, the Patent does not disclose one or more air vents. Fischel teach that it is well-known in the art to provide an analogous blood collection device comprising both an air permeable blood barrier 160 (0043 – "member 160 may be constructed out of any material which is capable of substantially preventing blood from passing through it while permitting air to vent through it") as well as one or more air vents 336 that leads to ambient, best seen in Figure 16, as an effective configuration for the desired blood flow

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Huong Q NGUYEN whose telephone number is (571)272-8340. The examiner can normally be reached on 10 am - 6 pm.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert (Tse) Chen can be reached at 5712723672. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H.Q.N/
Examiner, Art Unit 3791

/RENE T TOWA/
Primary Examiner, Art Unit 3791

Notice of References Cited	Application/Control No. 17/730,118	Applicant(s)/Patent Under Reexamination ROGERS et al.	
	Examiner Huong Q NGUYEN	Art Unit 3791	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date YYYY-MM-DD	Name	CPC Classification	US Classification
*	A	US-20110306899-A1	2011-12-15	BROWN; LEROY R.	A61B5/150572	600/581
	B					
	C					
	D					
	E					
	F					
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Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-22)
Approved for use through 05/31/2024. OMB 0651-0031
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	17730118
Filing Date	2022-04-26
First Named Inventor	Bobby E. ROGERS
Art Unit	3791
Examiner Name	NGUYEN, HUONG Q
Attorney Docket Number	069366-0572186_KUR3C01US

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	1	European Patent Office, Extended European Search Report for European Patent Application 20197213.0-1132, dated Dec. 9, 2020, 6 pages.	☐
	2	European Patent Office; Communication pursuant to Article 94(3) EPC, dated Oct. 31, 2018; 11 pages.	☐
	3	Examination Report No. 1 dated Apr. 29, 2020, for Australian Patent Application No. 2016297849. 3 pages.	☐
	4	Japanese Patent Office, Notice of Reasons for Rejection dated Jun. 15, 2021, Application No. JP 2019-534792, 6 pages.	☐
	5	Japanese Patent Office, Notice of Reasons for Rejection, Japanese patent application No. JP2018-523384, dated Jul. 23, 2019, 5 pages.	☐

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☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

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A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2024-06-27
Name/Print	Benjamin F. Hudson	Registration Number	71,474

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7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

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First Named Inventor	Bobby E. ROGERS
Art Unit	OPAP
Examiner Name	CENTRAL, DOCKET
Attorney Docket Number	069366-0572186_KUR3C01US

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	1	BD Diagnostics, "Venous Blood Collection, BD Vacutainer Passive Shielding Blood Collection Needle " literature (2005) 2 pages.	
	2	Barnard, Dorothy R., et al. "Fibronectin (cold insoluble globulin) in the neonate," The Journal of Pediatrics, Vol. 102, Issue 3, March 1983, Pages 453-455.	
	3	Mayer, G.A. "A Method for the Reliable Determination of Clotting Time in Whole Blood," Canadian Medical Association Journal, June 15, 1955, Vol. 72, Pages 927-929.	
	4	Ziegler, R., et al. "Controlled Clinical Laboratory Comparison of Two Supplemented Aerobic and Anaerobic Media Used in Automated Blood Culture Systems to Detect Bloodstream Infections," Journal of Clinical Microbiology, Mar. 1998, p. 657-661.	
	5	Pall Medical, "Leukotrap Filtration Systems for Whole Blood Derived Platelets, Leukotrap RC PL and Leukotrap PL Systems" literature, (2005) 8 pages.	
	6	Meissner, George F. , et al., "The Standard Clotting Time, A Method Based on the Use of Whole Venous Blood in Capillary Tubes," The American Journal of Clinical Pathology, Vol. 39, No. 3., pp. 321-323, March 1963.	
	7	Sheppard, et al., Bacterial Contamination of Platelets for Transfusion: Recent Advances and Issues, LABMEDICINE, Vol. 36, No. 12, Dec. 2005 ("Sheppard 2005").	

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Examiner Signature	/H Q NGUYEN/	Date Considered	09/17/2024

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Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2023-05-17
Name/Print	Benjamin F. Hudson	Registration Number	71,474

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	1	Notice of Allowance mailed 07-04-2024; Attorney Docket No. 069366-0572164_KUR7N01JP. 9 pages.	☐
	2	Office Action mailed 05-21-2024; Attorney Docket No. 069366-0572161_KUR7N01IL. 6 pages.	☐
	3	European Patent Office, Examination Report for European Patent Application 20781928.5, dated July 31, 2024, pages 1-6.	☐

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FEE

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☐ An identification of an earlier application pursuant to 37 CFR 1.98 (d) (1) is attached.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	17730118
Filing Date	2022-04-26
First Named Inventor	Bobby E. ROGERS
Art Unit	3791
Examiner Name	NGUYEN, HUONG Q
Attorney Docket Number	069366-0572186_KUR3C01US

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	6126643		2000-10-03	VAILLANCOUERT VINCENT L	
	2	9764891		2017-09-19	AVILES VICTOR M	
	3	5147329		1992-09-15	BRANNON JAMES K	
	4	5518005		1996-05-21	BRANNON JAMES K	
	5	62845767		2019-05-09	BREWER MICHAEL	

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	1	20150314105		2015-11-05	GASPARYAN LEVON	

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	Art Unit	3791
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	Attorney Docket Number	069366-0572186_KUR3C01US

	2	20150359473		2015-12-17	GARRETT CHAD	
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	4	20160325085		2016-11-10	CHELAK TODD	
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	Attorney Docket Number	069366-0572186_KUR3C01US

	1	S5643474	JP		1981-10-12			☐
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	1	Office Action (Final Rejection) dated 08/25/2023 for US App. No. 18113710 (pages 1-50)	☐
	2	Notice of Allowance mailed 09-08-2023; Attorney Docket No. 069366-0574153_KUR2C04US. 35 page.	☐
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	4	Office Action (Non-Final Rejection) dated 10/04/2023 for US App. No. 17538990 (pages 1-47)	☐
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	6	Office Action (Notice of Section 18) dated 12/20/2023 for IL App No. 309380 (pages 1-5).	☐
	7	Notice of Allowance mailed 01-17-2024; Attorney Docket No. 069366-0572201_KUR2C03US. 16 pages.	☐
	8	JP Office Action mailed 02/27/2024; Attorney Docket No. 069366-0575273_KUR2D03JP. 11 pages.	☐
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	10	Office Action (Non-Final Rejection) dated 04/25/2023 for US App. 16838017 (pages 1-20).	☐
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	14	Office Action (Non-Final Rejection) dated 04/16/2024 for US App. 16838017 (pages 1-19).	☐

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	15	Office Action (Non-Final Rejection) dated 05/21/2024 for IL App. 286812 (pages 1-3).	☐
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	17	First Office Action (Non-Final Rejection) dated 09/27/2023 for CN App. 202080000666.0 (pages 1-11).	☐
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	20	Australian Patent Office, Examination Report No. 1 for for Australian Patent Application 2021202622, dated March 18, 2022, 3 pages.	☐
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	24	Office Action (Non-Final Rejection) dated 02/21/2023 for US Application No. 17893079, pages 1-32.	☐
	25	Office Action (Final Rejection) dated 07/19/2023 for US Application No. 17893079, pages 1-21.	☐

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	26	Advisory Action dated 09/29/2023 for US Application 17893079, pages 1-24.	☐
	27	European Patent Office, Extended European Search Report for European Patent Application 20781928.5-1122 dated October 28, 2022, pages 1-10.	☐
	28	Rule 70(a) Communication for European Application No. 20781928.5-1122 dated November 15, 2022, 1 page.	☐
	29	International Search Report and Written Opinion dated 19 March 2020 for PCT application no. PCT/US2020/023617. pages.	☐
	30	International Search Report and Written Opinion dated 28 September 2021 for PCT application no. PCT/ US2021/035294. 7 pages.	☐
	31	European Patent Office, Extended European Search Report for European Patent Application 22181212.6-1122 dated October 24, 2022, pages 1-10.	☐
	32	Australian Patent Office, Australian Examination Report No. 1 for Application No. 2021120 622 dated March 18, 2022, 3 pages.	☐
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	37	Office Action (Non-Final Rejection) dated 03/28/2022 for Japanese Application No. 2020-118498, pages 1-3.	☐
	38	Office Action (Non-Final Rejection) dated 09/01/2022 for Japanese Application No. 2020-118498, pages 1-4.	☐
	39	Notice of Allowance mailed 04-04-2023; Attorney Docket No. 069366-0572230_KUR2D02JP. 6 pages.	☐
	40	Rule 71(3) Communication and Text for Grant mailed 08/31/2022 for European Application No. 19200766.4-1122. 189 pages.	☐
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	42	Notice of Allowance mailed 02-14-2023; Attorney Docket No. 069366-0572429_KUR3N01IL. 122 pages.	☐
	43	Office Action (Non-Final Rejection) mailed 11/29/2022 for Application No. 2021-214177, pages 1-3.	☐
	44	Office Action (Non-Final Rejection) mailed 11/4/2022 for Application No. 17094692, pages 1-50.	☐
	45	Notice of Allowance mailed 04-20-2023; Attorney Docket No. 069366-0572169_KUR4C01US. 36 pages.	☐
	46	Office Action (Non-Final Rejection) mailed 08/04/2022 for Application No. 16819033, pages 1-35.	☐
	47	Notice of Allowance mailed 11-28-2022; Attorney Docket No. 069366-0572168_KUR4002US. 9 pages.	☐

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Examiner Signature	/H Q NGUYEN/	Date Considered	09/18/2024

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	Attorney Docket Number	069366-0572186_KUR3C01US

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

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☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

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A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2024-06-27
Name/Print	Benjamin F. Hudson	Registration Number	71,474

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	1	5200325		1993-04-06	BLATT JOEL M	
	2	5432084		1995-07-11	BRUBAKER DANIEL B	
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	4	6187347		2001-02-13	PATTERSON JAMES A	
	5	6599474		2003-07-29	EVTODIENKO VLADIMIR	
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	7	8535241		2013-09-17	BULLINGTON GREGORY	
	8	9060724		2015-06-23	BULLINGTON GREGORY J	

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	Examiner Name	CENTRAL, DOCKET
	Attorney Docket Number	069366-0572186_KUR3C01US

	9	9155495		2015-10-13	BULLINGTON GREGORY J	
	10	4412548		1983-11-01	HOCH LOUIS	
	11	5222502		1993-06-29	KUROSE KATSUTOSHI	
	12	5520193		1996-05-28	SUZUKI ISSEI	
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	14	6569117		2003-05-27	ZIV DAVID	
	15	3741197		1973-06-26	SANZ M	
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	17	4207870		1980-06-17	ELDRIDGE WILLIAM N	
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	19	4444203		1984-04-24	ENGELMAN ALLAN	

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	20	6398743		2002-06-04	HALSETH THOR R	
	21	9022950		2015-05-05	BULLINGTON GREGORY	
	22	4436098		1984-03-13	KAUFMAN JOSEPH	
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	27	4057050		1977-11-08	SARSTEDT WALTER	
	28	8864684		2014-10-21	BULLINGTON GREGORY J	
	29	5749857		1998-05-12	CUPPY MICHAEL J	
	30	9204864		2015-12-08	BULLINGTON GREGORY J	

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	31	3874367		1975-04-01	AYRES WALDEMAR A	
	32	3886930		1975-06-03	RYAN GEORGE R	
	33	4106497		1978-08-15	PERCARPIO EDWARD P	
	34	4154229		1979-05-15	NUGENT EDWARD L	
	35	4980297		1990-12-25	HAYNES JOHN L	
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Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2023-05-17
Name/Print	Benjamin F. Hudson	Registration Number	71,474

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First Named Inventor	Bobby E. ROGERS
Art Unit	3791
Examiner Name	NGUYEN, HUONG Q
Attorney Docket Number	069366-0572186_KUR3C01US

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	1	4416291		1983-11-22	KAUFMAN JOSEPH	
	2	10299713		2019-05-28	PATTON RICHARD G	
	3	10265007		2019-04-23	BULLINGTON GREGORY	
	4	11395612		2022-07-26	BULLINGTON GREGORY J	
	5	10881343		2021-01-05	BULLINGTON GREGORY J	
	6	10596315		2020-03-24	BULLINGTON GREGORY J	
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	9	11737693		2023-08-29	BULLINGTON GREGORY J	
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	1	20220151525		2022-05-19	BULLINGTON GREGORY J	
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Examiner Signature	/H Q NGUYEN/	Date Considered	09/17/2024

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /H.Q.N/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	17730118
	Filing Date	2022-04-26
	First Named Inventor	Bobby E. ROGERS
	Art Unit	OPAP
	Examiner Name	CENTRAL, DOCKET
	Attorney Docket Number	069366-0572186_KUR3C01US

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2024-02-06
Name/Print	Benjamin F. Hudson	Registration Number	71,474

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /H.Q.N/

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /H.Q.N/

Reference No.: 0575273
Mailing No.: 092516
Mailing Date: February 27, 2024

Non-final Office Action
(Translation)

Application No.	Japanese Patent Application No. 2023-076490
Drafting Date	February 26, 2024
Examiner	Yoshinori TAKA 9813 2Q00
Representative	Satoshi MURAKOSHI
Applied Articles	Japanese Patent Act, Section 36, Paragraph 6, Item 2 (clearness)
	Japanese Patent Act, Section 36, Paragraph 6, Item 1 (support requirement)
	Japanese Patent Act, Section 29, Paragraph 1, Item 3 (novelty)
	Japanese Patent Act, Section 29, Paragraph 2 (inventive step)

This application has been rejected for the grounds stated below. Applicant is invited to file a Response within three months from the mailing date of this notice.

Grounds

<Ground 1>

(Clearness) This application does not conform to Section 36, Paragraph 6, Item 2 of the Japanese Patent Act in the following points.

<Ground 2>

(Support requirement) This application does not conform to Section 36, Paragraph 6, Item 1 of the Japanese Patent Act in the following points.

<Ground 3>

(Novelty) The claim(s) of this application set forth below was/were anticipated by the invention(s) disclosed in the publication(s) below distributed in Japan or foreign countries or the invention(s) made available to the public through electrical communication lines prior to the filing of this application. Therefore, the claim(s) is/are not entitled to obtain a patent under Section 29, Paragraph 1, Item 3 of the Japanese Patent Act.

<Ground 4>

(Inventive step) The claim(s) of this application set forth below would have been obvious to one ordinarily skilled in the art prior to the filing of this application, based on the invention(s) disclosed in the publication(s) below distributed in Japan or foreign countries or the invention(s) made available to the public through electrical communication lines prior to the filing of this application. Therefore, the claim(s) is/are unpatentable under Section 29, Paragraph 2 of the Japanese Patent Act.

Examiner Notes (the cited references are listed in Reference List below)

• As to Ground 1 (clearness) and Ground 2 (support requirement)

(1) Claims 1 to 15

In claims 1 to 15, the following points are not clear.

(A) The device includes a first junction that connects the inlet port with the sampling channel and the chamber.

(B) The device includes a second junction, different from the first junction, that connects the outlet port with the sampling channel and the chamber.

Thus, the technical relationship is unclear among the inlet port, the outlet port, the sampling channel, and the chamber.

Claim 1 recites that the chamber is "connected with the inlet port and the outlet port." This recitation could only specify that the chamber fluidically communicates with the inlet port and the outlet port (therefore, as in Reference 2 cited below, this recitation encompasses the case where the chamber is connected at only one location with a channel connecting between the inlet port and the outlet port).

Claim 1 also recites that the sampling channel is "connected with the inlet port." This recitation does not indicate that the sampling channel is "connected with the inlet port and the outlet port."

Further, a device lacking in the above features (A) and (B) is not at all described in the Detailed Description of the Invention.

Accordingly, claims 1 to 15 lacking in the above features (A) and (B) are unclear (Ground 1) and are not described in the Detailed Description of the Invention (Ground 2).

If the above features (A) and (B) are clearly recited, "the junction" recited in claim 11 should rightly be "the first junction and the second junction."

(2) Claims 1 to 15

Claim 1 recites that the chamber is "connected with the inlet port and the outlet port." This recitation specifies that the chamber is connected with the outlet port as well as with the inlet port.

According to the Detailed Description of the Invention, the chamber is connected with the outlet port as well as with the inlet port for the purpose that the device is configured such that,

(C) "when a drawing force is applied at the outlet port, blood is drawn into the inlet port and into the chamber."

The technical significance of the chamber being connected with the outlet port as well as with the inlet port is clear only when it is specified that the device achieves the above operation (C). The Detailed Description of the Invention does not at all describe a device having a chamber "connected with the inlet port and the outlet port" but not achieving the above operation (C).

The Detailed Description of the Invention describes the following feature for the device to achieve the above operation (C).

(D) "A material that is air permeable and blood impermeable is located at a distal end of the chamber." The Detailed Description of the Invention does not at all describe a device achieving the above operation (C) but lacking in the above feature (D).

However, claim 1 and claims 2 to 15 depending on claim 1 do not specify that the device achieves the above operation (C) and satisfies the above feature (D). Thus, these claims are unclear (Ground 1) and are not described in the Detailed Description of the Invention (Ground 2).

(3) Claim 14

Claim 14 recites "the housing comprises a bottom member mated with a top member." This recitation does not indicate that the housing comprises the top member. If the housing does not comprise the top member, claim 14 is not described in the Detailed Description of the Invention. It is unclear whether this recitation is intended to mean "the housing comprises a top member and a bottom member mated therewith."

Accordingly, claim 14 is unclear (Ground 1) and is not described in the Detailed Description of the Invention (Ground 2).

• As to Ground 3 (novelty) and Ground 4 (inventive step)

- As to Claims: 1, 4, 8, 10, 11, and 15
- Reference cited: Reference 1
- Notes:

Reference 1 (page 3, lower left column, line 15 to page 7, upper left column, line 20 and Figs. 1 to 9) discloses the following.

A device comprising:

an inlet port (an inner end (inner opening 30) of a first puncture needle 14 that communicates with a chamber 28, or an inner end 39 of a second puncture needle 15 protruding into the chamber 28) for receiving a blood sample;

an outlet port (a tip end of an outer extension portion of the second puncture needle 15);

a chamber (the space containing the porous plug (porous member that is gas permeable and liquid impermeable) 52 and the space between the hole 48 and the porous plug 52, in the inner cavity 51 of the second puncture needle 15) connected with the inlet port and the outlet port, and configured to collect a first portion of the blood sample, the chamber including a material that is air permeable and blood impermeable (the porous plug (porous member that is gas permeable and liquid impermeable) 52); and

a sampling channel (cavity 46) connected with the inlet port and configured to convey a subsequent portion of the blood sample to the outlet port while bypassing the chamber.

As to claim 8, the sleeve valve 41 of Reference 1 corresponds to the "valve" of claim 8.

As to claims 10 and 11, the location of the hole 48 of the inner cavity 51 corresponds to the "junction" of claims 10 and 11.

As to claim 15, the first puncture needle 14 of Reference 1 corresponds to the "patient needle" of claim 15, and the vessel holder 19 and the vacuum blood collection vessel 16 of Reference 1 correspond to the "sample collection device" of claim 15.

Accordingly, claims 1, 4, 8, 10, 11, and 15 are disclosed in Reference 1.

Also, claims 1, 4, 8, 10, 11, and 15 could have been readily devised by those skilled in the art

bead on Reference 1.

- As to Claims: 1, 4 to 6, 8, 13, and 15
- Reference cited: Reference 2
- Notes:

Reference 2 (paragraphs 0004 to 0015, Figs. 1 to 4, and the claims) discloses the following.

A device comprising:

an inlet port (one end 1a of the needle tube 1) for receiving a blood sample;

an outlet port (the other end 1b of the needle tube 1);

a chamber (the passage 21 in the needle tube support 2) connected with the inlet port and the outlet port, and configured to collect a first portion of the blood sample, the chamber including a material that is air permeable and blood impermeable (air permeable and blood impermeable member 23); and

a sampling channel (the needle tube 1) connected with the inlet port and configured to convey a subsequent portion of the blood sample to the outlet port while bypassing the chamber.

For the features recited in claims 5 and 6, see Reference 2 (in particular, paragraph 0011).

As to claim 8, the rubber cap 4 or (D) that covers and seals the edge surface of the other end 1b of the needle tube 1 in Reference 2 (paragraphs 0014 and 0006) corresponds to the "valve" of claim 8.

As to claim 13, the needle tube support 2 of Reference 2 corresponds to the "housing" of claim 13.

As to claim 15, the needle tube 1 of Reference 2 corresponds to the "patient needle" of claim 15, and the vacuum blood collection tube of Reference 2 (paragraphs 0004, 0005, and 0012) corresponds to the "sample collection device" of claim 15.

Accordingly, claims 1, 4 to 6, 8, 13, and 15 are disclosed in Reference 2.

Also, claims 1, 4 to 6, 8, 13, and 15 could have been readily devised by those skilled in the art based on Reference 2.

• As to Ground 4 (inventive step)

- As to Claims: 9 and 12 to 14
- Reference cited: Reference 1
- Notes:

The features of claims 9 and 12 to 14 could have been devised as necessary by those skilled in the art, and thus claims 9 and 12 to 14 could have been readily devised by those skilled in the art based on Reference 1.

- As to Claims: 5 to 7
- References cited: References 1 to 3
- Notes:

In a blood sample collection device, use of an air permeable and blood impermeable material that is hydrophobic or hydrophilic is conventional. See Reference 2 (disclosing the hydrophobic material

in paragraph 0011 and a hydrophilic material in paragraph 0013) and Reference 3 (paragraph 0023 and Fig. 3). Claims 5 to 7 could have been readily devised by those skilled in the art based on References 1 to 3.

- As to Claims: 9, 12, and 14
- Reference cited: Reference 2
- Notes:

The features of claims 9, 12, and 14 could have been devised as necessary by those skilled in the art, and thus claims 9, 12, and 14 could have been readily devised by those skilled in the art based on Reference 2.

- As to Claim: 7
- References cited: References 2 and 3
- Notes:

In a blood sample collection device, use of an air permeable and blood impermeable material that is hydrophilic is conventional. See Reference 2 (disclosing a hydrophilic material in paragraph 0013) and Reference 3 (paragraph 0023 and Fig. 3). Claim 7 could have been readily devised by those skilled in the art based on References 2 and 3.

<Reference List>

1. Japanese Patent Application Publication No. Sho 58-25146
2. Japanese Patent Application Publication No. 2001-424
3. Japanese Patent Application Publication No. 2013-240628

Record of Search for Prior Art Literature

- Searched Field IPC A61B 5/06 – 5/22
- Prior Art Literature

U.S. Patent Application Publication No. 2008/0145933

This record of search for prior art literatures does not constitute grounds for refusal.

拒絶理由通知書

特許出願の番号	特願２０２３－０７６４９０
起案日	令和　６年　２月２６日
特許庁審査官	▲高▼　芳徳　　９８１３　２Ｑ００
特許出願人代理人	村越　智史　様
適用条文	第３６条第６項第２号（明確性） 第３６条第６項第１号（サポート要件） 第２９条第１項第３号（新規性） 第２９条第２項（進歩性）

この出願は、次の理由によって拒絶をすべきものです。これについて意見がありましたら、この通知書の発送の日から３か月以内に意見書を提出してください。

理由

１．（明確性）この出願は、特許請求の範囲の記載が下記の点で、特許法第３６条第６項第２号に規定する要件を満たしていない。
２．（サポート要件）この出願は、特許請求の範囲の記載が下記の点で、特許法第３６条第６項第１号に規定する要件を満たしていない。
３．（新規性）この出願の下記の請求項に係る発明は、その出願前に日本国内又は外国において、頒布された下記の刊行物に記載された発明又は電気通信回線を通じて公衆に利用可能となった発明であるから、特許法第２９条第１項第３号に該当し、特許を受けることができない。
４．（進歩性）この出願の下記の請求項に係る発明は、その出願前に日本国内又は外国において、頒布された下記の刊行物に記載された発明又は電気通信回線を通じて公衆に利用可能となった発明に基いて、その出願前にその発明の属する技術の分野における通常の知識を有する者が容易に発明をすることができたものであるから、特許法第２９条第２項の規定により特許を受けることができない。

記　　（引用文献等については引用文献等一覧参照）

●理由１（明確性）および理由２（サポート要件）について

（１）請求項１～１５
　請求項１～１５において、

（A）装置が、入口ポートとサンプリング流路とチャンバとを接続する第１の分岐点を備えること
（B）装置が、出口ポートとサンプリング流路とチャンバとを接続する、前記第１の分岐点とは異なる第２の分岐点を備えること
が明らかでなく、入口ポート、出口ポート、サンプリング流路、チャンバの間の技術的な関係が明らかでない。
請求項１における、チャンバに関する「前記入口ポートと前記出口ポートとに接続され」との記載は、チャンバが、前記入口ポートと前記出口ポートとに流体的に連通していれば足りる（したがって、後出の引用文献２のように、入口ポートと出口ポートとを結ぶ流路上に、チャンバが、１箇所のみで接続される場合を含む）との疑義を生じている。
また、請求項１における、サンプリング流路に関する「前記入口ポートと接続されており」との記載からは、そもそも、サンプリング流路が「前記入口ポートと前記出口ポートとに接続されて」いることが明らかでない。
また、上記（A）および（B）の事項を欠く装置は、発明の詳細な説明に何ら記載されていない。
したがって、上記（A）および（B）の事項を欠く請求項１～１５に係る発明は、明確でない（理由１）と共に、発明の詳細な説明に記載されたものとはいえない（理由２）。
尚、上記（A）および（B）の点を明確化した場合、請求項１１における「前記分岐点」は、正しくは、「前記第１の分岐点および前記第２の分岐点」であるものと認められる。

（２）請求項１～１５
請求項１には、チャンバに関して、「前記入口ポートと前記出口ポートとに接続され」と記載されており、チャンバが、前記入口ポートのみならず、前記出口ポートにも接続されていることが特定されている。
発明の詳細な説明によれば、チャンバが入口ポートのみならず出口ポートにも接続されているのは、装置が、
（C）「出口ポートで吸引力が加えられると、血液が入口ポートに吸い込まれ、チャンバ内に流入する」
という動作を実現するためであり、装置が上記（C）の動作を実現することを特定することにより、はじめて、チャンバが入口ポートのみならず出口ポートにも接続されていることの技術的意味が明らかになる。また、発明の詳細な説明には、チャンバが「前記入口ポートと前記出口ポートとに接続され」る装置として、上記（C）の動作を実現しないものは、何ら記載されていない。
また、装置が上記（C）の動作を実現するための構成として、発明の詳細な説明には、
（D）「空気透過性であり血液不透過性である材料が、チャンバの遠位端に配置

されること」
が記載されており、上記（C）の動作を実現する装置として、上記（D）の事項を欠くものは、発明の詳細な説明に何ら記載されていない。
しかしながら、請求項１とこれに従属する請求項２～１５に係る発明は、装置が上記（C）の動作を実現すること、および、上記（D）の事項を満足することが特定されておらず、明確でない（理由１）と共に、発明の詳細な説明に記載されたものとはいえない（理由２）。

（３）請求項１４
請求項１４における、「前記ハウジングは、上部部材と嵌合する下部部材を備え・・・」との記載からは、ハウジングが上部部材を備えることが明らかでない。また、ハウジングが上部部材を備えない場合の請求項１４に係る発明は、発明の詳細な説明に記載されたものとはいえない。「前記ハウジングは、上部部材とこれに嵌合する下部部材とを備え・・・」ということなのか。
したがって、請求項１４に係る発明は、明確でない（理由１）と共に、発明の詳細な説明に記載されたものとはいえない（理由２）。

●理由３（新規性）および理由４（進歩性）について

・請求項：１，４，８，１０，１１，１５
・引用文献等：１
・備考：
引用文献１（第３頁左下欄第１５行～第７頁左上欄第２０行、第１～９図）には、
血液サンプルを受け入れるための入口ポート（室２８に連通する第１の穿刺針１４の内方端（内部開口３０）、または、室２８に突出する第２の穿刺針１５の内方端３９）と、
出口ポート（第２の穿刺針１５の外方延長部の尖端）と、
前記入口ポートと前記出口ポートとに接続され、前記血液サンプルの第１の部分を集めるように構成されたチャンバ（第２の穿刺針１５の内腔５１のうち、多孔性プラグ（ガス透過性液不透過性の多孔性部材）５２が置かれたスペース、および、孔４８と多孔性プラグ５２との間のスペース）であって、空気透過性であり血液不透過性である材料（多孔性プラグ（ガス透過性液不透過性の多孔性部材）５２）を含む、チャンバと、
前記入口ポートと接続されており、前記チャンバを迂回しながら前記出口ポートに前記血液サンプルの後続の部分を運ぶように構成されたサンプリング流路（キャビティー４６）と、
を備える装置

が記載されている。

請求項８に関して、引用文献１におけるスリーブ弁４１が、請求項８でいう「弁」に相当する。

請求項１０，１１に関して、引用文献１における、内腔５１の孔４８がある位置が、請求項１０，１１でいう「分岐点」に相当する。

請求項１５に関して、引用文献１における第１の穿刺針１４が、請求項１５でいう「患者針」に相当し、引用文献１における容器ホルダー１９および真空血液収集容器１６が、請求項１５でいう「サンプル採取装置」に相当する。

したがって、請求項１，４，８，１０，１１，１５に係る発明は、引用文献１に記載された発明である。

また、請求項１，４，８，１０，１１，１５に係る発明は、引用文献１に基づき、当業者が容易に想到し得るものである。

・請求項：１，４～６，８，１３，１５
・引用文献等：２
・備考：

引用文献２（［０００４］～［００１５］、図１～４、特許請求の範囲）には、

血液サンプルを受け入れるための入口ポート（針管１の一端１ａ）と、

出口ポート（針管１の他端１ｂ）と、

前記入口ポートと前記出口ポートとに接続され、前記血液サンプルの第１の部分を集めるように構成されたチャンバ（針管支持体２内の通路２１）であって、空気透過性であり血液不透過性である材料（空気透過性血液不透過性部材２３）を含む、チャンバと、

前記入口ポートと接続されており、前記チャンバを迂回しながら前記出口ポートに前記血液サンプルの後続の部分を運ぶように構成されたサンプリング流路（針管１）と、

を備える装置

が記載されている。

請求項５，６の限定事項については、引用文献２の特に［００１１］を参照のこと。

請求項８に関して、引用文献２における、針管１の他端１ｂの刃面を密封的に覆うゴム状キャップ４または（D）（［００１４］、［０００６］）が、請求項８でいう「弁」に相当する。

請求項１３に関して、引用文献２における針管支持体２が、請求項１３でいう「ハウジング」に相当する。

請求項１５に関して、引用文献２における針管１が、請求項１５でいう「患者針」に相当し、引用文献２における真空採血管（［０００４］、［０００５］、［００１２］）が、請求項１５でいう「サンプル採取装置」に相当する。

したがって、請求項１，４～６，８，１３，１５に係る発明は、引用文献２に記載された発明である。

また、請求項１，４～６，８，１３，１５に係る発明は、引用文献２に基づき、当業者が容易に想到し得るものである。

●理由４（進歩性）について

・請求項：９，１２～１４
・引用文献等：１
・備考：

請求項９，１２～１４の限定事項は、いずれも、当業者が適宜なし得ることであり、　請求項９，１２～１４に係る発明は、引用文献１に基づき、当業者が容易に想到し得るものである。

・請求項：５～７
・引用文献等：１～３
・備考：

血液サンプル収集装置において、空気透過性かつ血液不透過性の材料を、疎水性または親水性とすることは、引用文献２（［００１１］には、前記材料を疎水性とすることが記載されており、［００１３］に記載された材料は、親水性である。）、引用文献３（［００２３］、図３）に記載のとおり、通常のことであり、請求項５～７に係る発明は、引用文献１～３に基づき、当業者が容易に想到し得るものである。

・請求項：９，１２，１４
・引用文献等：２
・備考：

請求項９，１２，１４の限定事項は、いずれも、当業者が適宜なし得ることであり、　請求項９，１２，１４に係る発明は、引用文献２に基づき、当業者が容易に想到し得るものである。

・請求項：７
・引用文献等：２，３
・備考：

血液サンプル収集装置において、空気透過性かつ血液不透過性の材料を、親水性とすることは、引用文献２（［００１３］に記載された材料は、親水性である。）、引用文献３（［００２３］、図３）に記載のとおり、通常のことであり、請求項７に係る発明は、引用文献２，３に基づき、当業者が容易に想到し得るも

のである。

＜引用文献等一覧＞

１．特開昭５８－２５１４６号公報
２．特開２００１－４２４号公報
３．特開２０１３－２４０６２８号公報

－－－－－－－－－－－－－－－－－－－－－－－－－－－－－－－－－－－－

＜先行技術文献調査結果の記録＞

・調査した分野　　ＩＰＣ　Ａ６１Ｂ　　５／０６　　－　　５／２２
・先行技術文献　　米国特許出願公開第２００８／０１４５９３３号明細書

この先行技術文献調査結果の記録は、拒絶理由を構成するものではありません。

この拒絶理由通知の内容に関する問い合せ先は以下のとおりです。補正案等の送付を希望される際は、その旨を事前にご連絡ください。

電子メールにて連絡する際は、氏名、所属、出願番号、電話番号、下記審査官名を記載していただき、下記メールアドレス（※）までご連絡ください。電子メールの連絡内容について不明な点等がある場合、電話で確認させていただく場合があります。

審査第一部　分析診断（医学診断）高　芳徳　（たか　よしのり）
ＴＥＬ．０３－３５８１－１１０１内線３２９１
※ ●●●●@jpo.go.jp （上記「●●●●」に置き換えて、「PA2J」と入力ください。）

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/538,990	11/30/2021	Bobby E. ROGERS	069366-0572201_KUR2C03US	3420

27500 7590 10/04/2023

PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
ATTENTION: DOCKETING DEPARTMENT
P.O BOX 10500
McLean, VA 22102

EXAMINER	
ABOUELELA, MAY A	

ART UNIT	PAPER NUMBER
3791	

NOTIFICATION DATE	DELIVERY MODE
10/04/2023	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Docket_IP@pillsburylaw.com

Office Action Summary	Application No. 17/538,990	Applicant(s) ROGERS et al.	
	Examiner MAY A ABOUELELA	Art Unit 3791	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 11/30/2021.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL.** 2b) ☑ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 1-20 is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 1-20 is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to **PPHfeedback@uspto.gov.**

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☑ The drawing(s) filed on 11/30/2011 is/are: a)☑ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☑ Notice of References Cited (PTO-892)

2) ☑ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

Notice of Pre-AIA or AIA Status

1. The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 05/16/2023. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Objections

3. Claim 1 is objected to because of the following informalities: the phrase "blood" in lines 8 and 10 should be amended to read –the blood--. Appropriate correction is required.

4. Claim 1 is objected to because of the following informalities: the phrase "the junction being sized" in lines 7-8 should be amended to read –wherein the junction being sized--. Appropriate correction is required.

5. Claim 2 is objected to because of the following informalities: the phrase "blood" in line 3 should be amended to read –the blood--. Appropriate correction is required.

6. Claim 11 is objected to because of the following informalities: the phrase "an curved channel" in line 2 should be amended to read –the curved channel--. Appropriate correction is required.

7. Claim 12 is objected to because of the following informalities: the phrase "an air permeable blood barrier" in line 2 should be amended to read –the air permeable blood barrier--. Appropriate correction is required.

8. Claim 13 is objected to because of the following informalities: the phrase "the chamber" in line 9 should be amended to read –wherein the chamber--. Appropriate correction is required.

9. Claim 13 is objected to because of the following informalities: the phrase "bodily fluid" in lines 9-10, 12 and 13 should be amended to read –the bodily fluid--. Appropriate correction is required.

10. Claim 13 is objected to because of the following informalities: the phrase "from the inlet to bypass the chamber" in line 13 should be amended to read –to be directed from the inlet to bypass the chamber--. Appropriate correction is required.

11. Claim 16 is objected to because of the following informalities: the phrase "bodily fluid" in line 3 should be amended to read –the bodily fluid--. Appropriate correction is required.

Claim Interpretation

12. The following is a quotation of 35 U.S.C. 112(f):

> (f) Element in Claim for a Combination. – An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

The following is a quotation of pre-AIA 35 U.S.C. 112, sixth paragraph:

> An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

The claims in this application are given their broadest reasonable interpretation using the plain meaning of the claim language in light of the specification as it would be understood by one of ordinary skill in the art. The broadest reasonable interpretation of a claim element (also commonly referred to as a claim limitation) is limited by the description in the specification when 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is invoked.

As explained in MPEP § 2181, subsection I, claim limitations that meet the following three-prong test will be interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph:

(A) the claim limitation uses the term "means" or "step" or a term used as a substitute for "means" that is a generic placeholder (also called a nonce term or a non-structural term having no specific structural meaning) for performing the claimed function;

(B) the term "means" or "step" or the generic placeholder is modified by functional language, typically, but not always linked by the transition word "for" (e.g.,

"means for") or another linking word or phrase, such as "configured to" or "so that"; and

(C) the term "means" or "step" or the generic placeholder is not modified by sufficient structure, material, or acts for performing the claimed function.

Use of the word "means" (or "step") in a claim with functional language creates a rebuttable presumption that the claim limitation is to be treated in accordance with 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph. The presumption that the claim limitation is interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is rebutted when the claim limitation recites sufficient structure, material, or acts to entirely perform the recited function.

Absence of the word "means" (or "step") in a claim creates a rebuttable presumption that the claim limitation is not to be treated in accordance with 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph. The presumption that the claim limitation is not interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is rebutted when the claim limitation recites function without reciting sufficient structure, material or acts to entirely perform the recited function.

Claim limitations in this application that use the word "means" (or "step") are being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, except as otherwise indicated in an Office action. Conversely, claim limitations in this application that do not use the word "means" (or "step") are not being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, except as otherwise indicated in an Office action.

This application includes one or more claim limitations that do not use the word "means," but are nonetheless being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, because the claim limitation(s) uses a generic placeholder that is coupled with functional language without reciting sufficient structure to perform the recited function and the generic placeholder is not preceded by a structural modifier. Such claim limitation(s) is/are:

Limitation "junction" in claims 1, 6 and 13, the claims does not recite enough structure that corresponds to the claimed "junction", the specification disclose (junction 1607. Diverter junction 1607 may be a substantially Y-shaped, T-shaped, or U-shaped. In some preferred exemplary implementations, and as shown in FIG. 17A-17B, the diverter junction 1607 is configured such that the flow out of the inlet port 1602 is preferentially directed toward the sequestration chamber 1608. The sequestration chamber 1608 may also include or form a curve or ramp to direct the initial blood flow toward and into the sequestration chamber 1608, par.0109) which can be interpreted as the structure that corresponds to the claimed "junction".

Because this/these claim limitation(s) is/are being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, it/they is/are being interpreted to cover the corresponding structure described in the specification as performing the claimed function, and equivalents thereof.

If applicant does not intend to have this/these limitation(s) interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, applicant may: (1) amend the claim limitation(s) to avoid it/them being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph (e.g., by reciting sufficient structure to perform the

claimed function); or (2) present a sufficient showing that the claim limitation(s) recite(s) sufficient structure to perform the claimed function so as to avoid it/them being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph.

Claim Rejections - 35 USC § 112

13. The following is a quotation of 35 U.S.C. 112(b):
(b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph:
The specifications hall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12 are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor (or for applications subject to pre-AIA 35 U.S.C. 112, the applicant), regards as the invention.

14. Claim 1 recites the limitation "the patient" in line2. There is insufficient antecedent basis for this limitation in the claim.

15. Claim 6 recites the limitation "the blood control device" in line 2. There is insufficient antecedent basis for this limitation in the claim.

16. Claim 6 recites the limitation "the sequestration chamber" in line 10. There is insufficient antecedent basis for this limitation in the claim. Examiner respectfully notes that the phrase “the sequestration chamber” is also recite in claim 7.

17. Claim 8 recites the limitation "the blood sampling pathway" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim.

18. Claim 9 recites the limitation "the blood sampling pathway" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim.

Double Patenting

19. The statutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the claims at issue are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).
A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a statutory double patenting ground provided the reference application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of

activities undertaken within the scope of a joint research agreement. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO internet Web site contains terminal disclaimer forms which may be used. Please visit http://www.uspto.gov/forms/. The filing date of the application will determine what form should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to http://www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp.

Claims 1-20 are non-provisionally rejected on the ground of statutory double patenting as being unpatentable over claims 1-20 of U.S Patent Application No.11311219, claims 1-16 of U.S Patent Application No. 9820682, claims 1-23 of U.S Patent Application No.10143412, and claims 1-26 of U.S Patent Application No.11185266.

Also, claim 1-20 are provisionally rejected on the ground of non-statutory double patenting as being unpatentable over claims 1-20 of U.S pending Application No.17/730118, and claims 1-18 and 20 of U.S pending Application No.17/094692.

Although the claims at issue are not identical, they are not patentably distinct from each other because the U.S Patent applications, pending applications and the instance application are claiming a common subject matter including: a blood sample device comprising; an inlet, an outlet; a chamber having a vent that includes an air permeable blood barrier; a sampling channel; and a junction connected between the inlet, the

chamber and the sampling channel, wherein the junction being sized and configured such that a first portion of blood conveyed from the patient flows into the chamber to displace air therein through the air permeable blood barrier, and such that a second portion of blood is allowed to bypass the chamber and the first portion of blood at least temporarily contained therein to be directed into the sampling channel toward the outlet.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MAY A ABOUELELA whose telephone number is (571)270-7917. The examiner can normally be reached 8-5.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JACQUELINE CHENG can be reached on 5712725596. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: https://patentcenter.uspto.gov. Visit https://www.uspto.gov/patents/apply/patent-center for more information about Patent Center and

https://www.uspto.gov/patents/docx for information about filing in DOCX format. For additional questions, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MAY A ABOUELELA/
Primary Examiner, Art Unit 3791

Notice of References Cited	Application/Control No. 17/538,990	Applicant(s)/Patent Under Reexamination ROGERS et al.	
	Examiner MAY A ABOUELELA	Art Unit 3791	Page 1 of 4

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
*	A	US-20080319346-A1	12-2008	Crawford; Jamieson	A61B5/150656	600/576
*	B	US-4412548-A	11-1983	Hoch; Louis	A61B5/150213	600/577
*	C	US-5222502-A	06-1993	Kurose; Katsutoshi	A61B5/150732	600/584
*	D	US-5520193-A	05-1996	Suzuki; Issei	A61B5/1545	604/126
*	E	US-20100057004-A1	03-2010	Christensen; Kelly D.	A61M39/22	604/122
*	F	US-20070088279-A1	04-2007	Shue; Ming-Jeng	A61M25/0693	604/168.01
*	G	US-20080145933-A1	06-2008	Patton; Richard G.	A61B5/154	435/379
*	H	US-20040054333-A1	03-2004	Theeuwes, Felix	A61M5/14276	604/248
*	I	US-9022951-B2	05-2015	Bullington; Gregory	A61B5/150221	600/576
*	J	US-6569117-B1	05-2003	Ziv; David	A61M39/02	604/246
*	K	US-3741197-A	06-1973	Sanz; Manuel C.	A61B5/150267	600/583
*	L	US-20100010372-A1	01-2010	BROWN; LEROY R.	A61B5/15003	600/573
*	M	US-8603009-B2	12-2013	Tan; Alvin Chee Leong	A61B5/150251	600/573

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	CPC Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Notice of References Cited	Application/Control No. 17/538,990	Applicant(s)/Patent Under Reexamination ROGERS et al.	
	Examiner MAY A ABOUELELA	Art Unit 3791	Page 2 of 4

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
*	A	US-4207870-A	06-1980	Eldridge; William N.	A61B5/150732	604/167.03
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	Examiner MAY A ABOUELELA	Art Unit 3791	Page 3 of 4

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Doc code: IDS
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First Named Inventor	Bobby E. ROGERS
Art Unit	OPAP
Examiner Name	CENTRAL, DOCKET
Attorney Docket Number	069366-0572201_KUR2C03US

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Examiner Signature	/MAY A ABOUELELA/	Date Considered	07/05/2023

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Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

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A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2023-05-16
Name/Print	Benjamin F. Hudson	Registration Number	71,474

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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	48	BD Diagnostics, "Venous Blood Collection, BD Vacutainer Passive Shielding Blood Collection Needle " literature (2005) 2 pages.	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	17538990
	Filing Date	2021-11-30
	First Named Inventor	Bobby E. ROGERS
	Art Unit	OPAP
	Examiner Name	CENTRAL, DOCKET
	Attorney Docket Number	069366-0572201_KUR2C03US

	49	Barnard, Dorothy R., et al. "Fibronectin (cold insoluble globulin) in the neonate," The Journal of Pediatrics, Vol. 102, Issue 3, March 1983, Pages 453-455.

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature	/MAY A ABOUELELA/	Date Considered	07/05/2023

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[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

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	Attorney Docket Number	069366-0572201_KUR2C03US

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Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2023-05-16
Name/Print	Benjamin F. Hudson	Registration Number	71,474

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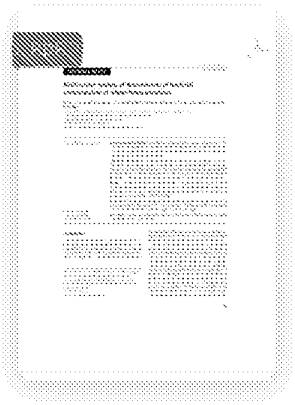
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A Multivariate analysis of determinants of bacterial contamination of whole-blood donations



Multivariate analysis of determinants of bacterial contamination of whole-blood donations

Vox Sanguinis, 2002

Luc Noel P. Perez Paul Pérez

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Vox Sanguinis (2002) 82, 55–60
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ORIGINAL PAPER

Multivariate analysis of determinants of bacterial contamination of whole-blood donations

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Vox Sanguinis

Background and Objectives Introduction of bacteria into blood components at the collection stage seems to be a frequent occurrence. We therefore assessed determinants of bacterial contamination of whole-blood donations to gain insight into contamination mechanisms and direct prevention.

Materials and Methods A cross-sectional study was carried out on donors accepted for whole-blood donation in four French blood banks. Each blood bank used its own two-stage procedure for phlebotomy site preparation. Contamination was identified by culturing two 15-ml samples (collected aseptically at the outset of donation) in a BacT/Alert 240® system. Determinants were assessed by logistic regression analysis.

Results Bacterial contamination, mainly by skin flora, occurred in 76 (2·2%) out of 3385 donations. Significant determinants were as follows: the blood bank (odds ratio (OR) range = 3·0–5·6, $P < 0·001$); lack of repetition of scrub (OR = 2·7, $P = 0·032$); and donor age > 35 years (OR = 1·8, $P = 0·036$).

Conclusion Systematic scrub repetition should be implemented to reduce bacterial contamination by skin flora at the collection stage. Further research is required to clarify the role of different antiseptic agents and of donor age.

Received: 14 May 2001, revised: 16 October 2001, accepted: 25 October 2001

Key words: adverse effects, bacterial infections, blood donors, blood transfusion, logistic models, prevention, risk factors.

A Multivariate analysis of determinants of bacterial contamination of whole-blood donations

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Introduction

Transfusion-associated bacterial contamination (TABC) is a potentially serious transfusion adverse event, reported to be responsible for 10% of transfusion-related fatalities reported in the USA from 1976 to 1999 [1], and for 22% in France from 1994 to 1999 [2]. TABC was considered by the United States [illegible] ing transfusion safety [3] and has been recently acknowledged as the most frequent transfusion-transmitted infection [4].

The most effective measures for preventing TABC would be systematic culture of every blood component or the application of bacterial inactivation steps during manufacture. However, bacterial inactivation methods are still under development [5], and techniques currently available for aseptic sampling and culture of cellular blood components may need further validation [6]. Other possible interventions may be aimed at avoiding or reducing the introduction of bacteria from all possible sources [7]. Contamination sources are rarely found, but that most frequently reported is the blood donor [7,8]. Bacteria may come from the bloodstream of infected but asymptomatic donors, or from the donor skin [8]. Despite well-conducted antisepsis, high concentrations of bacteria

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may remain on the skin surface [9,10]. Moreover, a core of deeper skin layers, which might not be adequately disinfected, may enter the needle during collection and introduce bacteria into the donation [7]. Pilot studies have reported that 0·3–0·6% of whole-blood donations are contaminated by bacteria, probably of skin origin [11,12].

Research on factors contributing to bacterial contamination at the collection stage may help to identify contamination mechanisms and consequently lead to the development of new interventions to improve the safety of blood transfusion. Possible factors favouring bacterial multiplication might include a high ambient temperature (leading to sweating) and poor skin hygiene. In addition, factors leading to a higher possibility of unintentional inclusion of bacteria from the phlebotomy site might be important; these factors include: skin lesions (because of their possible infectious origin); hairs (because hair follicles, rich in bacteria, may be touched by the needle); and scars (already reported to contain higher concentrations of bacteria than healthy skin) [13].

The objective of our study was to assess determinants associated with bacterial contamination of whole-blood donations.

Subjects and methods

Data collection

This cross-sectional study was nested in a study implemented to assess the efficacy of diverting the first 15 ml of blood collection to reduce bacterial contamination of whole-blood donations [14]. The study was carried out from March to December 1997 in four French volunteer blood banks: Etablissement Français du Sang (EFS) Centre-Atlantique (Tours); Centre de Transfusion Sanguine des Armées Jean Julliard (Clamart); EFS Alpes-Méditerranée (Marseille); and EFS Île-de-France (Versailles). To culture blood samples on the day of donation, collection sites were selected if they collected whole-blood donations in the morning. Donors were included if they had been accepted for donation after a medical selection complying with French regulations [15] and had given their informed consent to participate.

The phlebotomy site was prepared according to a two-stage procedure complying with the French Blood Agency recommendations [16]. This involved preparation of an area of skin of ≈ 3·5 cm in all directions around the intended phlebotomy site. The site was then scrubbed with a gauze pad soaked with an antiseptic or detergent agent (the regulations recommend that this stage is to be repeated 'if needed'). The second stage involved application of an antiseptic agent compatible with the one used in the first stage. The skin was then allowed to dry for the time recommended by the manufacturer of the antiseptic agent. Different antiseptic agents were used by each of the participating blood banks. However, all of the blood banks used the same agent for both stages of skin preparation. The scrub duration was 5–10 seconds. Application times were 5–10 seconds in all blood banks except in blood bank 4 where the second gauze pad soaked with antiseptic was left on the intended phlebotomy site for 30 seconds before being used to wipe the site. Drying times after application varied according to the antiseptic agent used: more than 15–20 seconds for iodine tincture in blood bank 1; more than 30 s for Hibisprint® (chlorhexidine) in blood bank 2; and 1 min for non-alcoholic Betadine® (povidone-iodine) in blood bank 3. Blood bank 4 used Bisseptine® (chlorhexidine, benzalkonium chloride, benzylic alcohol) and did not recommend any drying time. An additional drying time of 30 seconds between stages 1 and 2 was applied in blood bank 2.

The age and gender of the donor, the time since the last meal (as stated by the donor), and the site, date and hour of collection, were recorded by the physician. The skin at the phlebotomy site was carefully inspected by the nurse who recorded the presence of hairs, scars from previous phlebotomies, or skin lesions less than 10 cm away from the phlebotomy site. The requirement to repeat the scrub stage when the first gauze pad was dirty, and the ease of phlebotomy, were also recorded.

Blood was collected into standard Maco Pharma packs (Maco Pharma, Tourcoing, France), specially equipped with two small sample bags into which the first (S1) and second (S2) 15 ml of donation were aseptically collected, before blood was allowed to enter the unit bag. At the end of donation, the two sample bags were separated from the rest of the pack by double welding, placed into an isothermal box and brought to the bacteriology laboratory within 6 h.

Bacteriological methods

Samples were cultured in a BacT/Alert® 240 automated system (Organon Teknika, Durham, NC). Each sample bag was equipped with a needle allowing direct inoculation through the rubber cap of an anaerobic then an aerobic FAN culture bottle. Bottles were incubated in the BacT/Alert® for 7 days at 35 °C, according to the manufacturer's instructions.

A sample from each bottle detected as positive was subcultured onto trypticase–soy 5% blood agar (for aerobic culture) and onto Columbia blood agar (for anaerobic culture), both at 37 °C. When a subculture was positive, bacteria were identified according to standard microbiological methods and stored. A donation was defined as contaminated with bacteria if at least one aerobic or anaerobic bottle inoculated with S1 or S2 was culture positive.

The correct functioning of the automated culture systems was verified by inoculation and incubation of positive controls in the same conditions as study samples. One out of four strains was cultured each week in each centre, alternately: *Staphyloccocus aureus* CIP 53·156 (American Type Culture Collection [ATCC] 6538P; ATCC, Rockville, MD), *Clostridium sporogenes* CIP 79·03 (ATCC 19404), *Propionibacterium*

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acnes CIP 53·117T (ATCC 6919) and *Pseudomonas aeruginosa* CIP 76·110 (ATCC 27853). Bottles were expected to be culture positive within 10–24 h, depending on the strain of bacteria used. The rate of secondary contamination related to handling or inoculation was estimated by culturing the anticoagulant from 189 S1 and 189 S2 sample bags which were not used for donation, but which were transported, inoculated and incubated under the same experimental conditions as the study samples.

Data management and analysis

For each donation, information regarding blood collection was recorded on a report form. Culture results were recorded on a separate form at the laboratory and transferred to the corresponding donation form. Data were entered in each centre on the EPI INFO software (6·04b French version, January 1997, ENSP – Epiconcept) and files were transmitted to the Institut de Santé Publique, d'Epidémiologie et de Développement (Université Victor Segalen Bordeaux 2). Donations were excluded from analysis if clots or welding problems were reported during collection or inoculation, or if the blood volumes collected in S1 or S2 or inoculated in FAN bottles, were less than 5 ml.

The bacterial contamination rates of donations were estimated by the proportion of donations for which S1 or S2 was culture positive and its exact binomial 95% confidence intervals (95% CI). Comparisons were based upon standard tests [17]. The association between a variable and donation contamination was estimated by the odds ratio (OR) [18]. To analyse the simultaneous effect of several variables on the risk of contamination, a logistic regression model was used [19]. All variables were included in the multivariate model, regardless of their association with bacterial contamination in univariate analysis. A stepwise backward procedure was used to remove variables that were less significantly associated with donation contamination, according to Wald or the likelihood ratio test [19]. Statistical analysis was conducted using the STATA software (Stata 5·0; Stata Corporation, College Station, TX).

Results

Study population

Among 3441 whole-blood donations, collected from March through December 1997, 56 (1·6%) were excluded because of clots, welding problems or insufficient collection or culture volumes. Most donations were collected during mobile sessions (premises, 50%; vehicle, 37%), and before 14·00 h (99·4%); the time since the last meal was less than 3 h in 60·4% of the donors. A high percentage of the donors were male (73·3%) and their median age was 39 years (first quartile: 27 years; third quartile: 48 years). The presence of hairs at the phlebotomy site was reported in 29·5% of men and 2·0% of women; skin lesions close to the phlebotomy site were present in 2·3% of donors; and scars were present in 14·3% (minor signs, 10·6%; multiple scars, 2·9%; dimpled skin, 0·7%). The scrub stage of antisepsis was repeated in 8·5% of donations, and phlebotomy was reported as easy in 43·3%.

Bacteriological results

All positive controls were detected by the automated culture system. One negative control out of 378 (0·26%) was culture positive for coagulase negative staphylococci (CNS).

Seventy-nine bacteria were cultured from samples originating from 76 donations. The most common bacterial species were Gram-positive cocci, which accounted for 81% of the bacterial species and were mostly CNS (66%). Gram-positive bacilli, mostly Bacillus species and *P. acnes*, accounted for 14%, and Gram-negative bacilli for 5%, of species.

The overall prevalence rate of bacterial contamination was 2·2% (95% CI: 1·8–2·8%).

Determinants of bacterial contamination

In the univariate analysis, characteristics significantly associated with bacterial contamination were the blood bank, period of collection, time since last meal, donor age and the presence of hairs at the phlebotomy site (Table 1). As the rate of contamination was more than twofold higher when donors were > 35 years, this characteristic was used as a binary variable.

Characteristics significantly associated with bacterial contamination in the final multivariate model were the blood bank, a donor age > 35 years and the lack of repetition of the antisepsis scrub stage (Table 1).

Discussion

Our study confirmed the high frequency of bacterial contamination of whole-blood donations and revealed a strong protective role of repeating the antisepsis scrub stage. Other main determinants were the collecting blood bank and donor age. Contaminating bacteria, isolated after culture, were most likely to have a skin origin.

Our estimation of bacterial contamination rates of blood donations is higher than those previously reported in whole-blood units, but consistent with those of the first few ml collected [20] and with blood-culture contamination rates reported in clinical settings, where the same mechanisms may be implicated [21,22].

The major influence of the collecting blood bank may be related to the agent used for antisepsis. The risk of bacterial contamination was the highest in the blood bank using non-alcoholic povidone-iodine. This is consistent with studies

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Table 1 Univariate (3385 donations) and multivariate (3227 donations) analysis of associations between whole-blood donation characteristics and bacterial contamination in four French blood banks, March–December 1997

	Univariate analysis	Multivariate analysis (final model)

https://www.academia.edu/10154576/Multivariate_analysis_of_determinants_of_bacterial_contamination_of_whole-blood_donations 3/6

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Page 4335 of 6041

A Multivariate analysis of determinants of bacterial contamination of whole-blood donations

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1	1·59	2·71		2·05 (0·66–6·37)	
2	0·59	Ref.[d]		Ref.[d] (Ref.[d])	
3	3·92	6·87	< 0·001	5·63 (1·92–16·48)	0·0002
4	2·42	4·18		3·56 (1·16–10·91)	
Collection site					
Mobile session (premises)	2·74	1·58			
Mobile session (truck)	1·75	Ref.[d]	0·15		
Blood bank premises	1·77	1·01			
Period of collection					
March to May	1·59	Ref.[d]		Ref.[d] (Ref.[d])	
June to September	1·89	1·19	0·03	0·87 (0·41–1·86)	0·091
October to December	3·32	2·13		1·53 (0·70–3·36)	
Time since last meal (19 missing data)					
0 to 59 min	1·74	Ref.[d]		Ref.[d] (Ref.[d])	
1 h to 1 h 59 min	3·16	1·96		1·95 (0·87–4·36)	
2 h to 2 h 59 min	1·52	0·87	0·02	1·01 (0·43–2·37)	0·052
3 h to 3 h 59 min	1·57	0·90		1·01 (0·42–2·43)	
4 h or more	3·53	2·06		2·22 (0·98–5·02)	
Donor gender					
Male	2·14	Ref.[d]			
Female	2·55	1·20	0·47		
Donor age > 35 years					
No	1·43	Ref.[d]		Ref.[d] (Ref.[d])	
Yes	2·82	2.00	0·008	1·77 (1·02–3·07)	0·036
Phlebotomy site features					
Hairs (14 missing data)					
None	1·98	Ref.[d]		Ref.[d] (Ref.[d])	
Yes	3·21	1·64	0·05	1·51 (0·90–2·54)	0·125
Skin lesions (98 missing data)					
None	2·31	Ref.[d]			
Yes	2·60	1·13	0·87		
Scars					
None	2·31	Ref.[d]			
Minor signs	1·39	0·60			
Multiple scars	3·03	1·32	0·60		
Dimpled skin	4·00	1·76			
Scrub stage repeated (30 missing data)					
Yes	1·40	Ref.[d]		Ref.[d] (Ref.[d])	
No	2·35	1·68	0·32	2·72 (0·96–7·73)	0·032
Easiness of phlebotomy (29 missing data)					
Yes	1·72	Ref.[d]			
No	2·68	1·57	0·07		

[a]χ^2 or Fisher's exact test.
[b]CI: confidence interval of odds ratio (OR).
[c]Likelihood ratio test.
[d]Reference category for OR estimation.

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Japanese Patent Application No. 2020-118498
Your Ref: KURIN2JP-DIV2
Our Ref: TS/KRN-C0137JP03
September 2, 2021

Translation of "Notice of Reasons for Rejection"

Patent Application Number: JP 2020-118498
Date of Delivery: August 10, 2021
Applied Provision: Patent Law Articles 29(2), and 36

The present application should be rejected for the following reasons. The applicant may present an argument against the reasons within three months from the date of delivery of this notice.

Reasons

1. The inventions of the following claims should not be granted a patent under Patent Law Article 29(2) as lacking inventive step over the documents listed below.

2. The following claims do not comply with the requirements under Patent Law Article 36(6)(ii) as being unclear.

Remarks (See the Document List below)

- Reason 1 (Inventive step)
- Claims 1 to 10
- Documents D1 and D2

[Claim 1]

D1 ([0019]-[0055], Figs. 5-8) discloses

a blood sample optimization system (sample-procurement system; [0038], etc.) for optimizing a blood sample ([0020], etc.) collected by a blood collector (sample vessels 506; [0038], etc.), the system comprising:

a patient needle (first needle 508; [0038], etc.) configured for a venipuncture of a patient to access a sample of blood of a patient, at least a first portion of the sample of blood containing contaminants ([0021], etc.);

a blood sampling pathway connected with the patient needle configured for conveying the sample of blood (see Fig. 5, etc.); and

a sample needle configured for receiving the blood collector to collect a second portion of the sample of blood(see suggestions in Fig. 5, etc.); and

a blood sequestration device connected on the blood sampling pathway between the patient needle and the sample needle, the blood sequestration device comprising;

an inlet port (sterile input tubing 514; [0039], etc.) configured for receiving the sample of blood;

a sequestration chamber (pre-sample reservoirs 504; [0038], etc.) connected with the inlet port, the sequestration chamber configured for receiving the first portion of the sample of

blood to contain the contaminants in the first portion of the blood sample; and

a sampling channel (second sterile output tubing 518; [0038], Fig. 5, etc.) having a proximal end connected with the inlet port, configured for receiving the second portion of the sample of blood,

the sequestration chamber, the sampling channel and the inlet port being configured to allow the second portion of the sample of blood to bypass the sequestration chamber and direct the second portion of the sample of blood toward an outlet port that is configured to output the second portion of the sample of blood to the blood collector ([0038], etc.).

D2 ([0012]-[0013] etc.) discloses arts in a blood sample optimization system (blood sampling needle) of configuring a sequestration chamber having a vent comprising an air permeable blood barrier (air permeable blood impermeable member 23) to displace air in the sequestration chamber through the vent, and of configuring a housing (needle tube support 2) that houses and defines ports, the sequestration chamber and a channel.

Those disclosed in D1 and D2 belong to the same technical field called the blood collection field. It is easy for those skilled in the art to configure the one disclosed in D1 to have an air permeable blood barrier and a housing similar to the invention of claim 1 of the present application, with reference to the arts disclosed in D2.

[Claims 2 and 4]

See [0012]-[0013] of D2.

[Claim 3]

Placing a seal on the sample needle can be said to be a design matter.

[Claim 5]

See [0011] of D2.

[Claim 6]

See Fig. 5 of D1.

[Claims 7-10]

See the above explanations including the descriptions of D1 and D2.

- Reason 2 (Clarity)
- Claims 1 to 10

The recitations of claims 1-10 are unclear in the following points. Therefore, the

inventions of claims 1-10 are unclear.

(1) Claim 1

The recitation of "a sample of blood of a patient, at least a first portion of the sample of blood containing contaminants" is unclear in Japanese as to whether "at least containing contaminants" is related to the "a sample of blood" or to the "a first portion of the sample of blood". The same applies to the claims referring to claim 1.

(2) Claims 4 and 7

The recitation of "subsequent portion of the blood sample" is unclear as to what portion the "subsequent portion" follows. The same applies to the claims referring to claim 4 or 7.

Document List

D1: US 2008/0145933A

D2: JP 2001-000424A

Record of the Result of Prior Art Search

Technical field(s) searched	IPC A61B 5/00-5/398
Prior art document(s)	JP S58-025146A
	JP H09-504726A
	JP H02-224742A
	US 2011/0306899A

This record is not a component of the reasons for rejection.

拒絶理由通知書

特許出願の番号	特願２０２０－１１８４９８
起案日	令和　３年　８月　２日
特許庁審査官	岡▲さき▼　潤　　３３３０　２Ｑ００
特許出願人代理人	三好　秀和（ほか　３名）　様
適用条文	第２９条第２項（進歩性） 第３６条第６項第２号（明確性）

この出願は、次の理由によって拒絶をすべきものです。これについて意見がありましたら、この通知書の発送の日から３か月以内に意見書を提出してください。

理由

１．（進歩性）この出願の下記の請求項に係る発明は、その出願前に日本国内又は外国において、頒布された下記の刊行物に記載された発明又は電気通信回線を通じて公衆に利用可能となった発明に基いて、その出願前にその発明の属する技術の分野における通常の知識を有する者が容易に発明をすることができたものであるから、特許法第２９条第２項の規定により特許を受けることができない。

２．（明確性）この出願は、特許請求の範囲の記載が下記の点で、特許法第３６条第６項第２号に規定する要件を満たしていない。

記　　（引用文献等については引用文献等一覧参照）

●理由１（進歩性）について

・請求項　１－１０

・引用文献等　１－２

・備考

[請求項１について]

引用文献１（[0019]-[0055],図5-8）には、

採血器（sample vessels 506;[0038]等）によって集められる血液サンプル（[0020]等）を最適化するための血液サンプル最適化システム（sample-procurement system;[0038]等）であって、

患者の血液サンプル、少なくとも汚染物質を含む（[0021]等）前記血液サンプルの第１の部分を取り出せるようにするために患者の静脈穿刺用に構成された患者針（first needle 508;[0038]等）と、

前記患者針に接続され、前記血液サンプルを運ぶように構成された採血経路と（図5等参照）、

前記血液サンプルの第２の部分を集めるために前記採血器を受け入れるように構成されたサンプル針（図5等の示唆参照）と、

前記患者針と前記サンプル針との間の前記採血経路に接続された血液隔離装置であって、

前記血液サンプルを受け入れるように構成された入口ポート（sterile input tubing 514;[0039]等）と、

前記入口ポートに接続され、隔離チャンバであって、前記血液サンプルの第１の部分を受け入れ、前記血液サンプルの第１の部分に汚染物質を含むように構成された隔離チャンバ（pre-sample reservoirs 504;[0038]等）と、

前記入口ポートに接続される近位端を有し、前記血液サンプルの第２の部分を受け入れるように構成されたサンプリング流路と（second sterile output tubing 518;[0038],図5等）を含み、

前記隔離チャンバ、前記サンプリング流路及び前記入口ポートは、前記血液サンプルの第２の部分が前記隔離チャンバを迂回することを可能にし、前記血液サンプルの第２の部分を前記出口ポートに向かわせるように構成され、前記出口ポートは、前記血液サンプルの第２の部分を前記採血器に排出するように構成される（[0038]等）、血液隔離装置とを含む、血液サンプル最適化システム、

が記載されている。

引用文献２（[0012]-[0013]等）には、血液サンプル最適化システム（採血針）において、空気透過性血液バリア（空気透過性血液不透過性部材２３）を含む通気口を有する隔離チャンバであって、通気口を通して隔離チャンバ内の空気を追い出す隔離チャンバを構成する技術、ポート、隔離チャンバ及び流路を収容及び画定するハウジング（針管支持体２）を構成する技術、が開示されている。

引用文献１－２に記載のものは、採血分野という同一の技術分野に属する。

引用文献１に記載のものにおいて、引用文献２に記載の技術を参考として、本願の請求項１に係る発明と同様の空気透過性血液バリアとハウジングを具備するよう構成することは、当業者にとって容易である。

[請求項２，４について]

引用文献２の[0012]-[0013]を参照。

[請求項３について]

サンプル針に密封材を配置することは、設計的な事項といえる。

[請求項５について]

引用文献２の[0011]参照。

[請求項６について]

引用文献１の図5を参照。

[請求項７－１０について]

引用文献１－２の記載を含め既述の説示を参照。

●理由２（明確性）について

・請求項　１－１０

請求項１－１０の記載は、以下の点で不明確である。よって、請求項１－１０に係る発明は、明確でない。

（１）請求項１の記載について

請求項１の「患者の血液サンプル、少なくとも汚染物質を含む前記血液サンプルの第１の部分」との記載は、「少なくとも汚染物質を含む」ことが「血液サンプル」に係っているのか、「前記血液サンプルの第１の部分」に係っているのか、日本語として不明確である。引用項においても同様。

（２）請求項４，７の記載について

請求項４，７の「前記血液サンプルの後続の部分」との記載は、いかなる部分に「後続」するものを特定しているのか不明確である。引用項においても同様。

＜引用文献等一覧＞

１．米国特許出願公開第２００８／０１４５９３３号明細書

２．特開２００１－０００４２４号公報

－－－－－－－－－－－－－－－－－－－－－－－－－－－－－－－－－－－－

＜先行技術文献調査結果の記録＞

・調査した分野　　ＩＰＣ　Ａ６１Ｂ　　５／００　－　５／３９８

ＤＢ名

・先行技術文献　　特開昭５８－０２５１４６号公報

特表平０９－５０４７２６号公報

特開平０２－２２４７４２号公報

米国特許出願公開第２０１１／０３０６８９９号明細書

この先行技術文献調査結果の記録は、拒絶理由を構成するものではありません

。

＜補正をする際の注意＞
（１）明細書、特許請求の範囲について補正をする場合は、補正により記載を変更した個所に下線を引いてください（特許法施行規則様式第１３備考６、７）。
（２）補正は、この出願の外国語書面の翻訳文（又は誤訳訂正書による補正後の明細書、特許請求の範囲若しくは図面）に記載した事項の範囲内で行わなければなりません。また、意見書で、各補正事項について補正が適法なものである理由を、根拠となる翻訳文（又は誤訳訂正書による補正後の明細書、特許請求の範囲若しくは図面）の記載箇所を明確に示したうえで主張してください。
（３）特許請求の範囲について補正をする際には、特許法第１７条の２第４項に違反する補正とならないよう、注意してください。

この拒絶理由通知の内容に関するお問合せ又は面接のご希望がありましたら、次の連絡先までご連絡ください。電子メール等で補正案等の送付を希望される場合は、その旨を電話でお知らせください。

審査第一部分析診断（医学診断）　岡崎　潤
ＴＥＬ．０３－３５８１－１１０１　内線３２９１

(Translation)

Reference No.: D1163JP02 Letter No.: 309696 Mailing Date: June 20, 2023 1

Notice of Allowance

(Divisional)

Application Serial No.:	2021-214177
Drafting Date:	June 16, 2023
Examiner:	Naoya TAKAGI 3611 2Q00
Title of the Invention:	BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD
Number of Claims:	20
Applicant(s):	KURIN, INC.
Agent:	MURAKOSHI, Satoshi

A decision is hereby made to grant patent right to the above identified patent application on the ground that no cause for rejecting the application has been found in the examination.

This is to certify that all the above-referenced items are identical to the JPO's official record.
Certificated: June 19, 2023
Administrative Official of Ministry of Economy, Trade and Industry, Takashi SATO

Note: Applicant must pay Issue Fee within 30 days from the mailing date indicated above.

(Translation)

- Type of Application: Divisional Application
- Cited References: Yes
- Grace Period under Patent Act Article 30: No
- Amendment to Title of the Invention: No
- Deposit of Biological Material : N/A

(Translation)

Reference No.: D1163JP02 Letter No.: 309696 Mailing Date: June 20, 2023 3/E

Reference Information

Application Serial No.: 2021-214177

- FI

  A61B 5/15 200

- Search Fields (IPC, DB Name):

  A61B 5/15-5/157

- References Cited :

  Japanese Patent Application Publication No.2013-240628 (JP,A)
  Japanese Patent Application Publication No.2016-504075 (JP,A)
  International Patent Application Publication No.2014/058945 (WO,A1)
  US Patent Application Publication No.2005/0245885 (US,A1)

- Non-patent literatures:

特許査定

（分割）

特許出願の番号	特願２０２１－２１４１７７
起案日	令和　５年　６月１６日
特許庁審査官	▲高▼木　尚哉　３６１１　２Ｑ００
発明の名称	流体分流デバイス、及び流体分流サンプリングシステム
請求項の数	２０
特許出願人	クリン　インコーポレイテッド
代理人	村越　智史（ほか　４名）

この出願については、拒絶の理由を発見しないから、特許査定をします。

上記はファイルに記録されている事項と相違ないことを認証する。
認証日　令和 5年 6月19日　経済産業事務官　佐藤　隆

注意：この書面を受け取った日から３０日以内に特許料の納付が必要です。

・出願種別　分割
・参考文献　有
・特許法第３０条適用　無
・発明の名称の変更　無

・菌寄託

参考情報

特許出願の番号　特願２０２１－２１４１７７

・ＦＩ

Ａ６１Ｂ　５／１５　２００

・調査した分野（ＩＰＣ，ＤＢ名）

Ａ６１Ｂ　５／１５－５／１５７

・参考特許文献

特開２０１３－２４０６２８	（ＪＰ，Ａ）
特表２０１６－５０４０７５	（ＪＰ，Ａ）
国際公開第２０１４／０５８９４５	（WO，Ａ１）
米国特許出願公開第２００５／０２４５８８５	（ＵＳ，Ａ１）

・参考図書雑誌

UNITED STATES PATENT AND TRADEMARK OFFICE

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www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/113,710	02/24/2023	Bobby E. ROGERS	069366-0574153_KUR2C04US	2715

27500 7590 08/25/2023

PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
ATTENTION: DOCKETING DEPARTMENT
P.O BOX 10500
McLean, VA 22102

EXAMINER	
ABOUELELA, MAY A	

ART UNIT	PAPER NUMBER
3791	

NOTIFICATION DATE	DELIVERY MODE
08/25/2023	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Docket_IP@pillsburylaw.com

Office Action Summary	Application No. 18/113,710	Applicant(s) ROGERS et al.	
	Examiner MAY A ABOUELELA	Art Unit 3791	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 08/09/2023.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☑ This action is **FINAL.** 2b) ☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 1-13 and 16-31 is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☑ Claim(s) 17-31 is/are allowed.

7) ☑ Claim(s) 1-13 and 16 is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to **PPHfeedback@uspto.gov.**

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☑ Notice of References Cited (PTO-892)

2) ☑ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

Notice of Pre-AIA or AIA Status

1. The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 08/09/2023, and 05/10/2023. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a)(1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention.

Claim(s) 1, 5, 8-13 and 16 is/are rejected under 35 U.S.C. 102(1)(a) as being anticipated by Christensen et al (US 20100057004).

As to claim 1, Christensen discloses a device comprising:

an inlet port (catheter 14 and the frontal inlet port of device 10 where catheter 14 is connected/inserted therein, par.41-43 and par.47, fig.1-4);

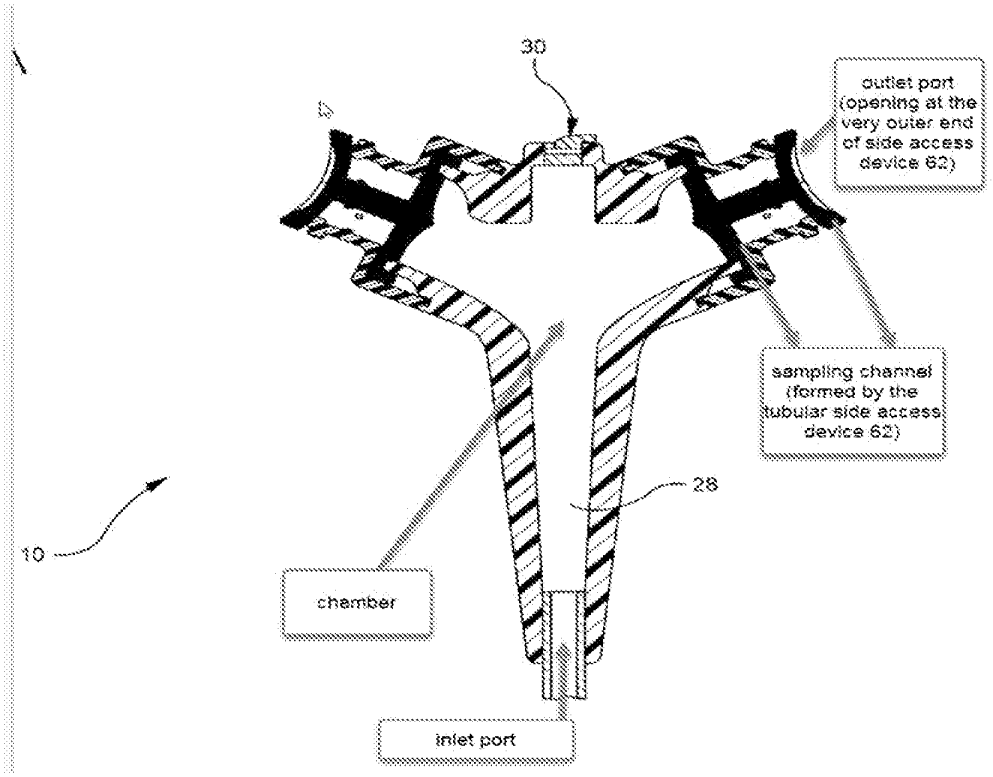
an outlet port (outlet opening at the very outer end of side access device 62 of device 10 where tube 16 is connected to and/or outlet port at the end of tube 16 connected to Y-adapter 18, par.41-43, par.53, fig.1-5);

a chamber (a fluid path 28 filling the interior of the extravascular system 10, par.47, fig.1-4) connected with the inlet port (fluid path 28 within the interior of device 10 is connected to catheter 14 and the frontal inlet port of device 10, fig.1-5) and configured to receive a first portion of blood (operator will insert the needle 12 into the vasculature of a patient and wait for flashback of blood to travel into the system 10 to confirm that the needle 12 is properly located within the vasculature of the patient, par.7, par.42, and blood travels into and along the catheter 14 and extension tubing 16 because a vent plug 22 permits air to escape the system 10 as blood enters the system 10, par.43)(The Examiner respectfully notes that flashback of blood, is considered the initial portion of blood),

the chamber including an air permeable material (venting material in vent 30, par.48-50, a removable filter plug 50 and a re-seal elastomer 52 in vent 30, par.51-53, or 114 that expands when exposed to liquid from bath 28, and thus seals the vent, par.71-72, fig.1-16, and/or curing material 108 of the vent 30 described with reference to FIGS. 13 and 14 provides a vent capable of venting gas from the system 10 without permitting the escape of liquid after the liquid has come into contact with the material 108, par.69, a porous membrane 110, par.70) that seals at least partially upon contact with a portion of the first portion of blood (par.48-53); and

a sampling channel (tubular channel formed by side access device 62 of device 10 and integrated extension tube 16, par.41-42, fig.1-6) having a proximal end connected with

the inlet port and a distal end connected with the outlet port (tubular channel formed by side access device 62 of device 10 having proximal end connected to frontal inlet port of device 10 at catheter 14, and having a distal end connected to the outlet opening at the very outer end of side access device 62 of device 10, as best seen in fig.1-6)(Examiner respectfully notes that since blood travels into and along the catheter 14 and extension tubing 16 because a vent plug 22 permits air to escape the system 10 as blood enters the system 10, par.43, so tubular channel formed by side access device 62 is configured to sample and convey blood to tubing 16).



As to claim 5, Christensen discloses the device, wherein the air permeable material is located at a distal end of the chamber (a vent may be placed at or near the start of the fluid path, or the vent may be placed at any point in between the start or end of the fluid path of the extravascular system, par.45, as best seen in fig.1-3).

As to claim 8, Christensen discloses the device, wherein the air permeable material is a hydrophilic membrane (vent 30 includes an expandable vent material 114 that is hydrophilic, par.71, fig.16).

As to claim 9, Christensen discloses the device, wherein the sampling channel further comprises a valve configured to close off the sampling channel (side clamp 20, par.41, slide clamp 20 on the integrated extension tubing 16 is provided to eliminate blood exposure when the vent plug 22 is replaced with another vascular access device, par.42, fig.1).

As to claim 10, Christensen discloses the device, wherein the valve is a clip (clamp 20, par.41, fig.1)

As to claim 11, Christensen discloses the device, further comprising a junction configured to direct an initial blood flow into the chamber (the longitudinal shape at the beginning of fluid path 28 formed in the interior of device 10 forces the flashback blood to enter the interior of device 10, par.43-48, and/or vent 30, vent 30 may be placed at or near the terminus of the system 10 in order to allow fluid, including gas, blood, saline,

and water, to fill the internal chamber of the fluid path directly adjacent any vascular access devices of the system 10, par.51-52, fig.1-6).

As to claim 12, Christensen discloses the device, further comprising a junction configured such that flow out of the inlet port is preferentially directed toward the chamber (the longitudinal shape at the beginning of fluid path 28 formed in the interior of device 10 forces the flashback blood to enter the interior of device 10, par.43-48, and/or vent 30, vent 30 may be placed at or near the terminus of the system 10 in order to allow fluid, including gas, blood, saline, and water, to fill the internal chamber of the fluid path directly adjacent any vascular access devices of the system 10, par.51-52, fig.1-6).

As to claim 13, Christensen discloses the device, wherein the chamber has a larger cross-sectional area than the sampling channel (the cross-sectional area of fluid path 28 of the interior of device 10 is larger than the side tubular channel and tube 16, as best seen in fig.1-3).

As to claim 16, Christensen discloses the device, further comprising a patient needle (needle 12, par.41-43, fig.1) and a sample collection device (Luer access device or port 24, par.41)(Examiner respectfully notes that the luer access device is a device that is connected to obtain blood sample in a sampling container, see link: https://www.medline.com/product/Blood-Transfer-and-Luer-Lock-Access-Device/Z05-PF253812#:~:text=Luer%20lock%20access%20devices%20%28LLAD%20and%20AC

SD%29%20are,reduce%20the%20risk%20of%20transfer-

related%20injuries%20and%20infections).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim(s) 2-4, 6 and 7 is/are rejected under 35 U.S.C. 103 as being obvious over Christensen et al (US 20100057004), in view of Weilbacher et al (US 2008/0167577).

As to claims 2-4, 6 and 7, Christensen discloses the device, wherein the device is further configured such that an initial aliquot of blood will contact the air permeable material and back up into the chamber (operator will insert the needle 12 into the vasculature of a patient and wait for flashback of blood to travel into the system 10 to confirm that the needle 12 is properly located within the vasculature of the patient. The blood travels into and along the catheter 14 and extension tubing The fluid path 28 is in communication with a vent 30, and the vent 30 is capable of venting gas from the fluid path 28 of the system 10, par.47 and par.53), wherein the device is further configured such that follow-on amounts of blood will flow through the sampling channel towards the outlet port (blood travels into and along the catheter 14 and extension tubing 16

because a vent plug 22 permits air to escape the system 10 as blood enters the system 10, par.43).

Christensen discloses the invention substantially as above, but failed to explicitly teach wherein the device is configured such that, when a drawing force is applied at the outlet port, blood is drawn into the inlet port and into the chamber, and wherein the air permeable material is a hydrophobic plug/membrane.

However Weilbacher discloses an analogous vascular access needle assembly (abstract, fig.1-3), when a drawing force is applied at the outlet port, blood is drawn into the inlet port and into the chamber (collection tube 17 is maintained at a vacuum such that when distal needle portion 20 is properly positioned in a vein 38 of a patient and collection tube 17 is positioned within cavity 34 OF BODY 30, blood will flow through needle 10 into blood collection tube 17, par.33, fig.1)(the Examiner respectfully notes the vacuum applies blood drawing force), and wherein the air permeable material is a hydrophobic plug/membrane (filter material 116 disposed in chamber 112, wherein material includes a hydrophobic material. In an alternate embodiment, the material includes a hydrophilic wicking material. In yet another embodiment, the material includes a hydrophobic plug, par.11 and par.35, fig.2).

As these types of blood drawing force are well-known in the art, so it would have been obvious to one having an ordinary skill in the art before the effective filing date of the invention to maintain blood collection devices and/or luer accesses devices connected to port 24 taught by Christensen's invention under vacuum, as tube 17 taught by

Weilbacher's invention, to facilitated blood sampling and prevent unwanted blood exposure/spilling, as taught by Weilbacher's invention (par.33).

Still, as the hydrophobic air permeable filter/material are well known in the art to vent air, so it would have been obvious to one having an ordinary skill in the art before the effective filing date of the invention to substitute the hydrophilic material taught by Christensen's invention, with the hydrophobic material taught by Weilbacher's invention, for the same reason of venting air from sampling chamber, as taught by Weilbacher's invention (par.11 and par.35-36).

Allowable Subject Matter

5. Claims 17-31 are allowed.

6. The following is an examiner's statement of reasons for allowance: the most pertinent prior art Christensen et al (US 2010/0057004) teaches a device comprising: an inlet port for receiving a blood sample; an outlet port; a chamber connected with the inlet port and the outlet port, and configured to collect a first portion of the blood sample, the chamber including a material that is air permeable and blood impermeable.

The prior art does not teach, disclose and/or fairly suggest a sampling channel connected with the inlet port and configured to convey a subsequent portion of the blood sample to the outlet port while bypassing the chamber.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Response to Arguments

7. Applicant's arguments claim objections/rejections and double patenting have been fully considered and are persuasive. The claim objections/rejections and double patenting have been withdrawn.

8. Applicant's arguments regarding Christensen's invention does not teach the claimed subject matter "an air permeable material that seals at least partially upon contact with a portion of the first portion of blood" in claim 1 have been fully considered but they are not persuasive, because Christensen's invention explicitly teaches hydrophilic air permeable material 114 that allows air to pass through vent 30, and then expands when exposed to liquid from fluid path 28, and thus seals the vent (par.71-72), similarly materials 108 and 110, par.69-70.

So, Christensen's invention explicitly teaches the claimed subject matter "an air permeable material that seals at least partially upon contact with a portion of the first portion of blood" in claim 1.

9. Still, regarding the Applicant's arguments that Christensen's invention does not teach "a sampling channel having a proximal end connected with the inlet port and a distal end connected with the outlet port" in claim 1 because Christensen's invention is not taking samples. Instead Christensen's invention is used for infusion therapy (see arguments page 5) have been fully considered but are not persuasive, because claim 1 broadly claims "A device comprising" in the preamble, and does not claim a blood sampling/collecting device. Under the broadest reasonable interpretation the claimed

subject matter "sampling channel" may be interpreted as sampling any type of tissue, fluid and/or infusion agents, and does not necessarily means sampling blood.

Device 10 taught by Christensen's invention comprises a fluid path 28 filling the interior of the extravascular system 10 (par.47) configured to receive a portion of blood (operator will insert the needle 12 into the vasculature of a patient and wait for flashback of blood to travel into fluid path 28 to confirm that the needle 12 is properly located within the vasculature of the patient (par.7, par.42), and blood travels into and along the catheter 14 and extension tubing 16 because a vent plug 22 permits air to escape the system 10 as blood enters the system 10 (par.43).

Examiner respectfully notes that since blood travels into and along the catheter 14 and extension tubing 16, so tubular channel formed by side access device 62 is configured to sample and convey blood to tubing 16.

So, it can be fairly interpreted that the tubular channel is a sampling channel that samples blood to and from tubing 16, as claimed in claim 1.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure Burkholz et al (US 20120/016266).

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MAY A ABOUELELA whose telephone number is (571)270-7917. The examiner can normally be reached 8-5.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JACQUELINE CHENG can be reached on 5712725596. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MAY A ABOUELELA/
Primary Examiner, Art Unit 3791

Notice of References Cited	Application/Control No. 18/113,710	Applicant(s)/Patent Under Reexamination ROGERS et al.	
	Examiner MAY A ABOUELELA	Art Unit 3791	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
*	A	US-20160325085-A1	11-2016	Chelak; Todd	F16K7/20	1/1
*	B	US-20160262677-A1	09-2016	EBETSBERGER; Franz	A61B5/150251	1/1
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Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

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Art Unit	-
Examiner Name	
Attorney Docket Number	069366-0574153_KUR2C04US

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	4416291		1983-11-22	KAUFMAN JOSEPH	

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☒ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

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A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2023-08-09
Name/Print	Benjamin F. Hudson	Registration Number	71,474

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Art Unit	-
Examiner Name	
Attorney Docket Number	069366-0574153_KUR2C04US

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	Examiner Name	
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	1	Ziegler, R., et al. "Controlled Clinical Laboratory Comparison of Two Supplemented Aerobic and Anaerobic Media Used in Automated Blood Culture Systems to Detect Bloodstream Infections," Journal of Clinical Microbiology, Mar. 1998, p. 657-661.	
	2	Pall Medical, "Leukotrap Filtration Systems for Whole Blood Derived Platelets, Leukotrap RC PL and Leukotrap PL Systems" literature, (2005) 8 pages.	
	3	Meissner, George F. , et al., "The Standard Clotting Time, A Method Based on the Use of Whole Venous Blood in Capillary Tubes," The American Journal of Clinical Pathology, Vol. 39, No. 3., pp. 321-323, March 1963.	
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	5	6599474		2003-07-29	EVTODIENKO VLADIMIR	
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	18113710
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	First Named Inventor	Bobby E. ROGERS
	Art Unit	-
	Examiner Name	
	Attorney Docket Number	069366-0574153_KUR2C04US

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	10	4412548		1983-11-01	HOCH LOUIS	
	11	5222502		1993-06-29	KUROSE KATSUTOSHI	
	12	5520193		1996-05-28	SUZUKI ISSEI	
	13	9022951		2015-05-05	BULLINGTON GREGORY	
	14	6569117		2003-05-27	ZIV DAVID	
	15	3741197		1973-06-26	SANZ M	
	16	8603009		2013-12-10	TAN ALVIN CHEE LEONG	
	17	4207870		1980-06-17	ELDRIDGE WILLIAM N	
	18	9877675		2018-01-30	BAID RISHI	
	19	4444203		1984-04-24	ENGELMAN ALLAN	

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	Art Unit	-
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	Attorney Docket Number	069366-0574153_KUR2C04US

	20	6398743		2002-06-04	HALSETH THOR R	
	21	9022950		2015-05-05	BULLINGTON GREGORY	
	22	4436098		1984-03-13	KAUFMAN JOSEPH	
	23	9138572		2015-09-22	ZEYTOONIAN PAUL	
	24	8568371		2013-10-29	SIOPES WILLIAM	
	25	8540663		2013-09-24	DAVEY CHRISTOPHER T	
	26	8523826		2013-09-03	LAYTON JR RUSSELL K	
	27	4057050		1977-11-08	SARSTEDT WALTER	
	28	8864684		2014-10-21	BULLINGTON GREGORY J	
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	Attorney Docket Number	069366-0574153_KUR2C04US

	31	3874367		1975-04-01	AYRES WALDEMAR A	
	32	3886930		1975-06-03	RYAN GEORGE R	
	33	4106497		1978-08-15	PERCARPIO EDWARD P	
	34	4154229		1979-05-15	NUGENT EDWARD L	
	35	4980297		1990-12-25	HAYNES JOHN L	
	36	9820682		2017-11-21	ROGERS BOBBY E	
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	Art Unit	-
	Examiner Name	
	Attorney Docket Number	069366-0574153_KUR2C04US

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	43	3648684		1972-03-14	BARNWELL CLEORA W	
	44	4056101		1977-11-01	GEISSLER ULRICH C	
	45	4416290		1983-11-22	LUTKOWSKI LAWRENCE	
	46	8070725		2011-12-06	CHRISTENSEN KELLY D	
	47	4349035		1982-09-14	THOMAS JOSEPH J	
	48	4813433		1989-03-21	DOWNEY JOHN M	
	49	5401262		1995-03-28	KARWOSKI THEODORE	
	50	3859998		1975-01-14	THOMAS JOSEPH JOHN	
	51	4373535		1983-02-15	MARTELL MICHAEL D	
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	Art Unit	-
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	53	5097842		1992-03-24	BONN GINA B	
	54	5865803		1999-02-02	MAJOR MIKLOS	
	55	5873841		1999-02-23	BRANNON JAMES K	
	56	6013037		2000-01-11	BRANNON JAMES K	
	57	6913580		2005-07-05	STONE BENJAMIN CURTIS	
	58	11213232		2022-01-04	IVOSEVIC MILAN	
	59	6626884		2003-09-30	DILLON JAGMOHANBIR SINGH	
	60	4904240		1990-02-27	HOOVER ROCKLIN L	
	61	4673386		1987-06-16	GORDON MARK G	
	62	7461671		2008-12-09	EHWALD RUDOLF	
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	Art Unit	-
	Examiner Name	
	Attorney Docket Number	069366-0574153_KUR2C04US

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	65	3848579		1974-11-19	VILLA REAL A	
	66	6106509		2000-08-22	LOUBSER PAUL G	
	67	3494352		1970-02-10	RUSSO RONALD D	
	68	6224561		2001-05-01	SWENDSON DAVID L	
	69	7055401		2006-06-06	PRYBELLA JOHN R	
	70	5135489		1992-08-04	JEPSON STEVEN C	
	71	5811658		1998-09-22	VAN DRIEL MICHAEL R	
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	73	5772608		1998-06-30	DHAS V VARAPRABHU	
	74	4150089		1979-04-17	LINET MICHAEL S	

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	Art Unit	-
	Examiner Name	
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	76	4193400		1980-03-18	LOVELESS JAMES C	
	77	6843775		2005-01-18	HYUN DONGCHUL D	
	78	7666166		2010-02-23	EMMERT MICHAEL	
	79	7479131		2009-01-20	MATHIAS JEAN-MARIE	
	80	8377040		2013-02-19	BURKHOLZ JONATHAN KARL	
	81	5417673		1995-05-23	GORDON MARK G	
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	Art Unit	-
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	Attorney Docket Number	069366-0574153_KUR2C04US

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	87	6860871		2005-03-01	KURACINA THOMAS C	
	88	6945948		2005-09-20	BAINBRIDGE MARLENE	
	89	7306736		2007-12-11	COLLINS GREGORY R	
	90	5691486		1997-11-25	BEHRINGER BRUCE E	
	91	5980830		1999-11-09	SAVAGE DOUGLAS ROBERT	
	92	5045185		1991-09-03	OHNAKA YUKIHIRO	
	93	5632906		1997-05-27	ISHIDA NOBORU	
	94	6695004		2004-02-24	RAYBUCK JOHN L	
	95	6733433		2004-05-11	FELL CLAUDE	
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	Art Unit	-
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	98	5439450		1995-08-08	HAEDT LORI E	
	99	6905483		2005-06-14	NEWBY C MARK	
	100	5431811		1995-07-11	TUSINI ANDREA	
	101	6736783		2004-05-18	BLAKE KEVIN R	
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	Art Unit	-
	Examiner Name	
	Attorney Docket Number	069366-0574153_KUR2C04US

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	4	20040116830		2004-06-17	TRUDEAU WILLIAM M	
	5	20090299253		2009-12-03	HURSEY FRANCIS X	
	6	20130158506		2013-06-20	HARRIS ADRIENNE ROSE	
	7	20150246352		2015-09-03	BULLINGTON GREGORY J	
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	9	20160361006		2016-12-15	BULLINGTON GREGORY J	
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	11	20180140240		2018-05-24	BULLINGTON GREGORY J	
	12	20140112841		2014-04-24	SCHOEN CHRISTIAN	
	13	20180271425		2018-09-27	ROGERS BOBBY E	

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	Art Unit	-
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	Attorney Docket Number	069366-0574153_KUR2C04US

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	15	20100057004		2010-03-04	CHRISTENSEN KELLY D	
	16	20070088279		2007-04-19	SHUE MING-JENG	
	17	20080145933		2008-06-19	PATTON RICHARD G	
	18	20040054333		2004-03-18	THEEUWES FELIX	
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	20	20080167577		2008-07-10	WEILBACHER EUGENE E	
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	Art Unit	-
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	Attorney Docket Number	069366-0574153_KUR2C04US

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	27	20050240161		2005-10-27	CRAWFORD JAMIESON W M	
	28	20040147855		2004-07-29	MARSDEN STEWART	
	29	20040073171		2004-04-15	ROGERS BOBBY E	
	30	20050004524		2005-01-06	NEWBY C MARK	
	31	20030105414		2003-06-05	LEONG ALVIN TAN CHEE	
	32	20020004647		2002-01-10	LEONG ALVIN TAN CHEE	
	33	20140155781		2014-06-05	BULLINGTON GREGORY J	
	34	20030208151		2003-11-06	KRAUS MENACHEM	
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	Art Unit	-
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	Attorney Docket Number	069366-0574153_KUR2C04US

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	40	20140039348		2014-02-06	BULLINGTON GREGORY J	
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	44	20160017488		2016-01-21	KOBAYASHI MASAYUKI	
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	Art Unit	-
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	49	20110306899		2011-12-15	BROWN LEROY R	
	50	20130116599		2013-05-09	BULLINGTON GREGORY J	
	51	20050273019		2005-12-08	CONWAY HUGH	
	52	20150351678		2015-12-10	BULLINGTON GREGORY	
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	Art Unit	-
	Examiner Name	
	Attorney Docket Number	069366-0574153_KUR2C04US

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	Art Unit	-
	Examiner Name	
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NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T5
	1	International Search Report and Written Opinion dated Nov. 5, 2015, for PCT application No. PCT/US2015/035870. 6 pages.	
	2	International Search Report and VVritten Opinion dated 16 July 2020 for PCT application no. PCT/US2020/026276. 9 pages.	
	3	Bullington, et al., Systems and Methods for Sample Collection with Reduced Hemolysis, Exhibit H in U.S. Appl. No. 62/517,681, dated Jun. 9, 2017, 131 pages.	
	4	Communication Under Rule 71(3) EPC dated Apr. 22, 2020 for EP application No. 17840467.9. 125 pages.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.A.A/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	18113710
	Filing Date	2023-02-24
	First Named Inventor	Bobby E. ROGERS
	Art Unit	-
	Examiner Name	
	Attorney Docket Number	069366-0574153_KUR2C04US

	5	European Patent Application No. EP19200766.4 extended European Search Report dated Dec. 2, 2019, 11 pages.	
	6	European Patent Office, Extended European Search Report for European Patent Application 20197213.0-1132, dated Dec. 9, 2020, 6 pages.	
	7	European Patent Office; Communication pursuant to Article 94(3) EPC; dated Oct. 31, 2018; 11 pages.	
	8	Examination Report No. 1 dated Apr. 29, 2020, for Australian Patent Application No. 2016297849. 3 pages.	
	9	International Search Report and Written Opinion dated Jun. 19, 2020, for PCT application No. PCTUS2020/023617. 12 pages.	
	10	European Patent Office, International Search Report and Written Opinion for PCT/US16/43709, dated Oct. 19, 2016, 14 pages.	
	11	International Search Report/Written Opinion for PCT/US17/68569 dated Apr. 25, 2018. 9 pages.	
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	14	Retractable Techs., Inc. v. Becton Dickinson & Co., CA No. 2:07-CV-250, Claim Construction Order (E.D. Tex., Jan. 20, 2009). 20 pages.	
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	Attorney Docket Number	069366-0574153_KUR2C04US

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	Art Unit	-
	Examiner Name	
	Attorney Docket Number	069366-0574153_KUR2C04US

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	First Named Inventor	Bobby E. ROGERS
	Art Unit	-
	Examiner Name	
	Attorney Docket Number	069366-0574153_KUR2C04US

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EXAMINER SIGNATURE

Examiner Signature	/MAY A ABOUELELA/	Date Considered	08/22/2023

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99**)	Application Number	18113710
	Filing Date	2023-02-24
	First Named Inventor	Bobby E. ROGERS
	Art Unit	-
	Examiner Name	
	Attorney Docket Number	069366-0574153_KUR2C04US

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2023-05-10
Name/Print	Benjamin F. Hudson	Registration Number	71,474

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

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Application No.	Ref.	Date
22 181 212.6 - 1122	KUR-19212-P-EP	28.09.2023
Applicant: Kurin, Inc.		

Communication pursuant to Article 94(3) EPC

The examination of the above-identified application has revealed that it does not meet the requirements of the European Patent Convention for the reasons enclosed herewith. If the deficiencies indicated are not rectified the application may be refused pursuant to Article 97(2) EPC.

You are invited to file your observations and in sofar as the deficiencies are such as to be rectifiable, to correct the indicated deficiencies within a period

of 4 months

from the notification of this communication, this period being computed in accordance with Rules 126(2) and 131(2) and (4) EPC. One set of amendments to the description, claims and drawings is to be filed within the said period on separate sheets (R. 50(1) EPC).

If filing amendments, you must identify them and indicate the basis for them in the application as filed. Failure to meet either requirement may lead to a communication from the Examining Division requesting that you correct this deficiency (R. 137(4) EPC).

In case you withdraw the application within the above-mentioned period, the examination fee will be refunded at a rate of 50% (Art. 11(b) RFees).

Failure to comply with this invitation in due time will result in the application being deemed to be withdrawn (Art. 94(4) EPC).

Registered Letter

Nielsen, Michael
Primary Examiner
For the Examining Division

Enclosure(s): 3 page/s reasons (EPO Form 2906)

The examination is being carried out on the **following application documents**

Description, Pages

1, 2, 4-46	as originally filed	
3, 3a, 3b	filed in electronic form on	19-05-2023

Claims, Numbers

1-8	filed in electronic form on	19-05-2023

Drawings, Sheets

1/69-69/69	as originally filed

1). The applicants arguments with regard to neither of the documents cited hinting to "a chamber connected with the inlet port and the outlet port, and configured to collect a first portion of the blood sample, **the chamber including a material that is air permeable and blood impermeable**" are agreed upon.

Applicants arguments with regard support for the claims on file, their novelty and inventiveness are likewise agreed upon.

Therefore:

2). The applicant should **bring the description into conformity** with the claims of the present divisional application (Article 84 EPC). In particular should features that are present in the independent claim not be referred to as options in the form of e.g. "in some instances", "in some embodiments", "in a preferred embodiment", "in one implementation" and so forth, but be clearly identified as forming part of the invention. T**his applies to the description as a whole**, not only to the introductory part. The "Summary of The Invention" should likewise be amended, i.e. **recitation of superseded claims and subject-matter be removed or adapted** to the wording of the claims on file.

Anything referred to as "**embodiment**" or "**implementation**" and which is not covered by the claims on file should be **excised or clearly referred to as examples not covered by the invention**. This throughout the description and drawings.

- The technical field of the invention (Rule 42(1)(a) EPC; Guidelines F-II.4.2) must correspond to the amended set of claims.

- The summary of the invention (Rule 42(1)(c) EPC; Guidelines F-II.4.5) must correspond to the amended set of claims. Where appropriate, statements such as "The invention is set out in the appended set of claims" or "The invention is as defined in claim X" may be used instead of repeating the claims verbatim.
- **Embodiments which are no longer covered by the claims must be** deleted, unless they can reasonably be considered to be useful for highlighting specific aspects of the amended subject-matter. If this is the case, they must be clearly marked as not being part of the present invention (T 1808/06 and Guidelines F-IV, 4.3)]:
  - Any combinations of features which do not fall under the scope of the amended independent claims must be clearly marked as not being part of the present invention.
  - Statements such as "The following examples/aspects/embodiments X, Y, Z are not according to the invention and are present for illustration purposes only" may be used **at the start of the description or in the list of figures**.
- The technical features of the independent claims may not be presented as optional in the description. Where they precede a feature of an independent claim, terms such as "for example", "may", "can", "exemplary", "optionally", "preferably" and the like must be removed.
- The **"claim-like" clauses** in paragraphs [0014] to [0023] and at pages 43 to 46 **must be deleted prior to grant**. Claim-like clauses are clauses present in the description which use claim language such as "according to the preceding clause" or "characterised in that" (Guidelines F-IV, 4.4). Claim-like clauses include examples, embodiments or aspects which are presented as claim-like clauses. The simple conversion of these clauses into separate optional features will not be admitted either.

3). The unit inches expressed in paragraphs [0099], [00115] and [00156] does not meet the requirements of Rule 49(10) EPC and should be replaced by the appropriate SI unit (see Guidelines F-II, Annex, 2). The present expression should, however, be retained in parentheses after the replacement expression.

4). Care should be taken during revision, especially of the introductory portion and any statements of problem or advantage, not to add subject-matter which extends beyond the content of the application as originally filed (Articles 76(1) and 123(2) EPC).

5). Any information the applicant may wish to submit concerning the subject-matter of the invention, for example further details of its advantages or of the problem it solves, and for which there is no basis in the application as filed, should be confined to the letter of reply and not be incorporated into the application (Articles 76(1) and 123(2) EPC and the Guidelines H-V, 2.2 to 2.5).

CARTRIDGE AND TEST INFORMATION

i-STAT® sensors are available in a variety of panel configurations. Sensors are contained in cartridges with microfluidic components and, in some cartridges, calibration solution. i-STAT cartridges are used with the i-STAT 1 Analyzer* for the simultaneous quantitative determination of specific analytes and coagulation parameters in whole blood.

CARTRIDGE SPECIFICATIONS

Shelf Life:

Refrigerated at 2 to 8 °C (35 to 46 °F) until expiration date.

Refer to the cartridge box for room temperature storage requirements.

Preparation for Use:

Individual cartridges may be used after standing five minutes at room temperature. An entire box of cartridges should stand at room temperature for one hour.

All cartridges should be used immediately after opening pouch. If the pouch has been punctured, the cartridge should not be used.

Sample Type:

Fresh whole blood from arterial, venous, or skin punctures.

(Note: Skin puncture is NOT a recommended sample type for ACT, cTnI, CK-MB, ß-hCG or BNP testing.)

cTnI, ß-hCG and CK-MB cartridges require the use of heparinized whole blood or plasma, or non-heparinized whole blood tested within one minute of patient draw.

BNP cartridges require the use of EDTA whole blood or plasma samples.

Sample Volume:

17 µL, 20 µL, 40 µL, 65 µL, or 95 µL depending on cartridge type.

Test Timing:

Immediately after collection

- Samples for the measurement of ACT, PT/INR and Lactate

Within 3 minutes after collection

- Samples collected in capillary tubes with balanced heparin anticoagulant
- Samples collected in evacuated or non-evacuated tubes and syringes without anticoagulant

Within 10 minutes after collection

- Samples collected with anticoagulant for the measurement of pH, PCO_2, PO_2 and iCa. Maintain anaerobic conditions. Remix before filling cartridge.

Within 30 minutes after collection

- Sodium, potassium, chloride, glucose, BUN/urea, creatinine, hematocrit, troponin I, CK-MB, ß-hCG and BNP. Remix thoroughly before testing.

Abbott Point of Care

Art: 714258-01O Rev. Date: 15-Aug-16

* The cTnI, CK-MB, ß-hCG and BNP cartridges can only be used with the i-STAT 1 analyzer bearing the  symbol.

Analysis Time:

- ACT cartridge: to detection of end point - up to 1000 sec (16.7 min)
- PT/INR cartridge: to detection of end point – up to 300 sec (5 min)
- cTnI, ß-hCG and BNP cartridges: 600 sec (10 min)
- CK-MB cartridge: 300 sec (5 min)
- Other cartridges: typically 130 to 200 sec

Cartridges	Collection Options			
	Syringes	**Evacuated Tubes**	**Capillary Tubes**	**Directly from Skin Puncture**
Cartridges which measure ionized calcium	• Without anticoagulant • With balanced heparin anticoagulant (syringe must be filled to labeled capacity)	• Without anticoagulant • With lithium heparin anticoagulant (tubes must be filled to capacity)	• With balanced heparin anticoagulant	• Not recommended • Not recommended for blood gas analysis; arterial specimens are preferred
Cartridges which perform ACT	• Without anticoagulant ONLY • Syringes must be plastic	• Without anticoagulant, clot activators, or serum separators ONLY • Tubes must be plastic • Devices used to transfer sample to cartridge must be plastic	• Not recommended	• Not recommended
Cartridges which perform PT/INR	• Without anticoagulant ONLY • Syringes must be plastic	• Without anticoagulant, clot activators, or serum separators ONLY • Tubes must be plastic • Devices used to transfer sample to cartridge must be plastic	• Not recommended	• Recommended
Cartridges which measure Troponin I or CK-MB	• With sodium or lithium heparin anticoagulant (syringe must be filled to labeled capacity) • Without anticoagulant if tested within one minute of patient draw	• With sodium or lithium heparin anticoagulant (tubes must be filled to capacity) • Without anticoagulant if tested within one minute of patient draw	• Not recommended	• Not recommended

Cartridges	Collection Options			
	Syringes	Evacuated Tubes	Capillary Tubes	Directly from Skin Puncture
Cartridges which measure Total ß-hCG	• With sodium or lithium anticoagulant (syringe must be filled to labeled capacity) • Without anticoagulant if tested within one minute of patient draw • Syringes must be plastic	• With sodium or lithium heparin anticoagulant (tubes must be filled to capacity)	• Not recommended	• Not recommended
Cartridges which measure BNP	• With EDTA anticoagulant (syringe must be filled to labeled capacity) • Syringes must be plastic	• With EDTA anticoagulant (tubes must be filled to capacity) • Tubes must be plastic	• Not recommended	• Not recommended
All other cartridges	• Without anticoagulant • With lithium or balanced heparin anticoagulant (syringe must be filled to labeled capacity)	• Without anticoagulant • With lithium heparin anticoagulant (tubes must be filled to capacity)	• With balanced heparin anticoagulant • With lithium heparin if labeled for the measurement of electrolytes	• While a sample can be transferred directly from a skin puncture to a cartridge, a capillary tube is preferred • Not recommended for blood gas analysis; arterial specimens are preferred

Note Regarding System Reliability

The i-STAT System automatically runs a comprehensive set of quality checks of analyzer and cartridge performance each time a sample is tested. This internal quality system will suppress results if the analyzer or cartridge does not meet certain internal specifications (see Quality Control section in System Manual for detailed information). To minimize the probability of delivering a result with medically significant error the internal specifications are very stringent. It is typical for the system to suppress a very small percentage of results in normal operation given the stringency of these specifications. If however the analyzer or cartridges have been compromised, results may be persistently suppressed, and one or the other must be replaced to restore normal operating conditions. **Where unavailability of results while awaiting replacement of analyzers or cartridges is unacceptable, APOC recommends maintaining both a backup i-STAT System analyzer and cartridges from an alternate lot number.**

EXPECTED VALUES

Measured:

TEST	UNITS	REPORTABLE RANGE	REFERENCE RANGE (arterial)	REFERENCE RANGE (venous)
Sodium/Na	mmol/L (mEq/L)	100 – 180	138 – 146	138 – 146
Potassium/K	mmol/L (mEq/L)	2.0 – 9.0	3.5 – 4.9	3.5 – 4.9
Chloride/Cl	mmol/L (mEq/L)	65 – 140	98 – 109	98 – 109
Glucose/Glu	mmol/L mg/dL g/L	1.1 – 38.9 20 – 700 0.20 – 7.00	3.9 – 5.8 70 – 105 0.70 – 1.05	3.9 – 5.8 70 – 105 0.70 – 1.05
Lactate/Lac	mmol/L mg/dL	0.30 – 20.00 2.7 – 180.2	0.36 – 1.25 3.2 – 11.3	0.90 – 1.70 8.1 – 15.3
Creatinine/Crea	mg/dL µmol/L	0.2 – 20.0 18 – 1768	0.6 – 1.3 53 – 115	0.6 – 1.3 53 – 115
pH		6.5 – 8.2	7.35 – 7.45	7.31 – 7.41
***P*CO$_2$**	mmHg kPa	5 – 130 0.67 – 17.33	35 – 45 4.67 – 6.00	41 – 51 5.47 – 6.80
TCO$_2$ (on the CHEM8+ cartridge only)	mmol/L (mEq/L)	5 – 50	23 – 27	24 – 29
***P*O$_2$**	mmHg kPa	5 – 800 0.7 – 106.6	80 – 105 10.7 – 14.0	
Ionized Calcium/iCa	mmol/L mg/dL	0.25 – 2.50 1.0 – 10.0	1.12 – 1.32 4.5 – 5.3	1.12 – 1.32 4.5 – 5.3
Urea Nitrogen/BUN **Urea**	mg/dL mmol/L mg/dL g/L	3 – 140 1 – 50 6 – 300 0.06 – 3.00	8 – 26 2.9 – 9.4 17 – 56 0.17 – 0.56	8 – 26 2.9 – 9.4 17 – 56 0.17 – 0.56
Hematocrit/Hct	%PCV Fraction	15 – 75 0.15 – 0.75	38 – 51 0.38 – 0.51	38 – 51 0.38 – 0.51
Celite Activated Clotting Time / ^{Celite}ACT *The range from 80 - 1000 seconds has been verified through method comparison studies.*	seconds	50 – 1000	74 – 125 (Prewarm) 84 – 139 (Nonwarm)	74 – 125 (Prewarm) 84 – 139 (Nonwarm)
Kaolin Activated Clotting Time / ^{Kaolin}ACT *The range from 77 - 1000 seconds has been verified through method comparison studies.*	seconds	50 – 1000	74 – 137 (Prewarm) 82 – 152 (Nonwarm)	74 – 137 (Prewarm) 82 – 152 (Nonwarm)
Prothrombin Time / PT *Performance characteristics have not been established for INRs above 6.0.*	INR	0.9 – 8.0		
Troponin I / cTnI	ng/mL (µg/L)	0.00 – 50.00		0.00 – 0.03* 0.00 – 0.08**
Performance characteristics have not been established for cTnI values above 35.00 ng/mL. ** Represents the 0 to 97.5% range of results.* *** Represents the 0 to 99% range of results.*				
Creatine Kinase MB / CK-MB ****Represents the 0 to 95% range of results.*	ng/mL (µg/L)	0.0 – 150.0		0.0 – 3.5***

EXPECTED VALUES (CONT.)

Measured: (CONT.)

TEST	UNITS	REPORTABLE RANGE	REFERENCE RANGE (arterial)	REFERENCE RANGE (venous)
B-Type Natriuretic Peptide / BNP	pg/mL (ng/L)	15 – 5000		<15 – 50#
# Represents the 0 to 95% range of results.				
Total Beta-Human Chorionic Gonadotropin /ß-hCG	IU/L	5.0 – 2000.0		<5.0

Calculated:

TEST	UNITS	REPORTABLE RANGE	REFERENCE RANGE (arterial)	REFERENCE RANGE (venous)
Hemoglobin/Hb	g/dL	5.1 – 25.5	12 – 17	12 – 17
	g/L	51 – 255	120 – 170	120 – 170
	mmol/L	3.2 – 15.8	7 – 11	7 – 11
TCO_2 (on all cartridges but the CHEM8+)	mmol/L (mEq/L)	5 – 50	23 – 27	24 – 29
HCO_3	mmol/L (mEq/L)	1.0 – 85.0	22 – 26	23 – 28
BE	mmol/L (mEq/L)	(-30) – (+30)	(-2) – (+3)	(-2) – (+3)
Anion Gap/AnGap	mmol/L (mEq/L)	(-10) – (+99)	10 – 20	10 – 20
sO_2	%	0 – 100	95 – 98	

CARTRIDGE CONFIGURATIONS AND SAMPLE VOLUME

i-STAT $^{EC}8^{+}$ (65µL)
Sodium (Na)
Potassium (K)
Chloride (Cl)
pH
PCO_2
Urea Nitrogen (BUN)/Urea
Glucose (Glu)
Hematocrit (Hct)
TCO_2*
HCO_3*
BE*
Anion Gap* (Angap)
Hemoglobin* (Hb)

i-STAT 6^{+} (65µL)
Sodium (Na)
Potassium (K)
Chloride (Cl)
Urea Nitrogen (BUN)/Urea
Glucose (Glu)
Hematocrit (Hct)
Hemoglobin* (Hb)

i-STAT $^{EC}4^{+}$ (65µL)
Sodium (Na)
Potassium (K)
Glucose (Glu)
Hematocrit (Hct)
Hemoglobin* (Hb)

i-STAT $^{E}3^{+}$ (65µL)
Sodium (Na)
Potassium (K)
Hematocrit (Hct)
Hemoglobin* (Hb)

i-STAT *G* (65µL)
Glucose (Glu)

i-STAT *CREA* (65µL)
Creatinine (Crea)

i-STAT $^{EG}7^{+}$ (95µL)
Sodium (Na)
Potassium (K)
Ionized Calcium (iCa)
Hematocrit (Hct)
pH
PCO_2
PO_2
TCO_2*
HCO_3*
BE*
sO_2*
Hemoglobin* (Hb)

i-STAT $^{EG}6^{+}$ (95µL)
Sodium (Na)
Potassium (K)
Hematocrit (Hct)
pH
PCO_2
PO_2
TCO_2*
HCO_3*
BE*
sO_2*
Hemoglobin* (Hb)

i-STAT $^{G}3^{+}$ (95µL)
pH
PCO_2
PO_2
TCO_2*
HCO_3*
BE*
sO_2*

i-STAT $^{CG}4^{+}$ (95µL)
pH
PCO_2
PO_2
Lactate
TCO_2*
HCO_3*
BE*
sO_2*

i-STAT *TOTAL ß-hCG* (17µL)
Total Beta-Human Chorionic Gonadotropin

**Calculated*

i-STAT $^{CG}8^{+}$ (95µL)
Sodium (Na)
Potassium (K)
Ionized Calcium (iCa)
Glucose (Glu)
Hematocrit (Hct)
pH
PCO_2
PO_2
TCO_2*
HCO_3*
BE*
sO_2*
Hemoglobin* (Hb)

i-STAT ^{Celite}*ACT* (40µL)
Celite® ACT

i-STAT ^{KAOLIN}*ACT* (40µL)
Kaolin ACT

i-STAT *PT/INR* (20µL)
Prothrombin Time

i-STAT *cTnI* (17 µL)
Troponin I

i-STAT *CK-MB* (17µL)
Creatine Kinase MB

i-STAT *BNP* (17µL)
B-type Natriuretic Peptide

i-STAT *CHEM8+* (95µL)
Sodium (Na)
Potassium (K)
Chloride (Cl)
Urea Nitrogen (BUN)/Urea
Glucose (Glu)
Creatinine (Crea)
Ionized Calcium (iCa)
TCO_2
Hematocrit (Hct)
Anion Gap* (Angap)
Hemoglobin* (Hb)

Celite is a registered trademark of Celite Corporation, Santa Barbara, CA, for its diatomaceous earth products.

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Date
28.10.2022

Reference	Application No./Patent No.
KUR-18996-P-EP	20781928.5 - 1122 / 3948211 PCT/US2020026276
Applicant/Proprietor	
Kurin, Inc.	

Communication

The extended European search report is enclosed.

The extended European search report includes, pursuant to Rule 62 EPC, the supplementary European search report (Art. 153(7) EPC) and the European search opinion.

Copies of documents cited in the European search report are attached.

☒ 0 additional set(s) of copies of such documents is (are) enclosed as well.

Refund of the search fee
If applicable under Article 9 Rules relating to fees, a separate communication from the Receiving Section on the refund of the search fee will be sent later.

Should you wish to further prosecute this application in the examination phase, your attention is drawn to the provisions of Rule 70a EPC. An invitation to respond to the extended European search report will be issued shortly (R. 70(2) EPC).

Europäisches Patentamt • European Patent Office • Office européen des brevets

The examination is being carried out on the **following application documents**

Description, Pages

1-28 as published

Claims, Numbers

1-20 as published

Drawings, Sheets

1/16-16/16 as published

Reference is made to the following documents; the numbering will be adhered to in the rest of the procedure.

D1 US 2018/271425 A1 (ROGERS BOBBY E [US] ET AL) 27 September 2018 (2018-09-27)

D2 EP 3 324 845 A1 (KURIN INC [US]) 30 May 2018 (2018-05-30)

D3 WO 2019/232196 A1 (MAGNOLIA MEDICAL TECHNOLOGIES INC [US]) 5 December 2019 (2019-12-05)

D4 WO 2019/055487 A1 (MAGNOLIA MEDICAL TECHNOLOGIES INC [US]) 21 March 2019 (2019-03-21)

1. The application does not meet the requirements of Article 84 EPC, because claims 1, 6 and 14 are not clear.

Claims 1, 6 and 14 have been drafted as separate independent claims.

Under Article 84 in combination with Rule 43(2) EPC, an application may contain more than one independent claim in a particular category only if the subject-matter claimed falls within one or more of the exceptional situations set out in paragraph (a), (b) or (c) of Rule 43(2) EPC. However, this is not the case in the present application.

2. The present application does not meet the requirements of Article 52(1) EPC because the subject-matter of claims 1, 6 and 14 is not new within the meaning of Article 54(1) and (2) EPC.

2.1 D1 discloses **a fluid sample optimization device** (see fig.23,24, par. [0141]-[0149]:"blood sample optimization system 2400") **for optimizing a fluid sample collected by a fluid collection device from a fluid source, a first portion of the fluid sample potentially having contaminants** (see par. [0141]:" a sampling channel 2308 that bypasses the sequestration chamber 2306 once the sequestration chamber is filled to an initial aliquot of potentially contaminated blood to be sequestered"), **the fluid sample optimization device comprising:**

an inlet ("inlet port 2412") **configured to connect with the fluid source;**

an outlet ("outlet port 2414") **configured to connect with the fluid collection device;**

a sample path ("blood sample channel 2422") **connected between the inlet and the outlet; and**

a contaminant containment reservoir ("blood sequestration chamber 2418 ") **connected between the inlet and the outlet, the contaminant containment reservoir having an air permeable fluid resistor** ("air permeable blood barrier 2420") **proximate the outlet, the contaminant containment reservoir being arranged to receive, when a pressure differential is applied between the inlet and the outlet, a first portion of the fluid sample from the fluid source to displace air therein through the air permeable fluid resistor and the outlet, such that upon receipt of the first portion of the fluid sample and containment of the contaminants in the contaminant containment reservoir, subsequent portions of the fluid sample can be conveyed by the sample path from the inlet to the outlet when subsequent pressure differentials are applied between the inlet and the outlet** (see par. [0148]:"As the initial aliquot of blood flows into the blood sequestration chamber, it displaces air therein and eventually the blood contacts the blood barrier 2420, forcing the inner chamber housing to the second position.","Once in the second position, the initial aliquot of blood is sequestered in the blood sequestration chamber 2418 and the one or more apertures 2424 are opened to create a pathway from the inlet port 2412 to the blood sampling channel 2422, bypassing and/or flowing around the blood sequestration chamber 2418.".

The subject-matter of claim 1 is therefore not new (Article 54(1) and (2) EPC).

2.2 D1 discloses a fluid sample optimization device for optimizing a fluid sample collected by a fluid collection device from a fluid source (see fig.23,24, par. [0141]-[0149]:"blood sample optimization system 2400"), a first portion of the fluid sample potentially having contaminants (see par. [0141]:" a sampling channel 2308 that

bypasses the sequestration chamber 2306 once the sequestration chamber is filled to an initial aliquot of potentially contaminated blood to be sequestered"), the fluid sample optimization device comprising:

an inlet ("inlet port 2412") configured to connect with the fluid source;

an outlet ("outlet port 2414") configured to connect with the fluid collection device;

a sample path ("blood sample channel 2422") connected between the inlet and the outlet, the sample path further having a resistive plug ("apertures 2424") that is configured to inhibit at least a part of the first portion of the fluid sample and the contaminants from entering the sample path (see par.[0141]:"the inner chamber housing 2419 is in the first position toward the inlet port 2412, such that the one or more apertures 2424 are closed, and the blood sequestration chamber 2418 is in a direct path from the patient needle."); and

a contaminant containment reservoir ("blood sequestration chamber 2418 ") connected between the inlet and the outlet, the contaminant containment reservoir further having an air permeable fluid resistor ("air permeable blood barrier 2420") proximate the outlet, the contaminant containment reservoir being arranged to receive, when a pressure differential is applied between the inlet and the outlet, the first portion of the fluid sample from the fluid source to displace air therein through the air permeable fluid resistor and the outlet, such that upon receipt of the first portion of the fluid sample and containment of the contaminants in the contaminant containment reservoir, subsequent portions of the fluid sample can be forced through the resistive plug and conveyed by the sample path from the inlet to the outlet when subsequent pressure differentials are applied between the inlet and the outlet (see par.[0148]:"As the initial aliquot of blood flows into the blood sequestration chamber, it displaces air therein and eventually the blood contacts the blood barrier 2420, forcing the inner chamber housing to the second position.","Once in the second position, the initial aliquot of blood is sequestered in the blood sequestration chamber 2418 and the one or more apertures 2424 are opened to create a pathway from the inlet port 2412 to the blood sampling channel 2422, bypassing and/or flowing around the blood sequestration chamber 2418.").

The subject-matter of claim 6 is therefore not new (Article 54(1) and (2) EPC).

2.3 The subject-matter of claim 14, which comprises for essentially the same features as the subject matter of claim 1, is for essentially the same reasons as those given above (see point 2.1) also not new (Article 54(1) and (2) EPC).

2.4 Furthermore, the documents D2-D3 also disclose all the features of claim 1, 6 and 14. For further details, see the relevant parts thereof as cited in the Search Report.

3. The dependent claims 2 to 5, 7 to 13 and 15 to 20 and seem not to contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the EPC in respect of novelty and/or inventive step, defining either features already known from any of D1-D3 or straightforward possibilities from which the person skilled in the art would select, in accordance with circumstances, without the exercise of inventive skill, in order to solve the problem posed.

4. Independent claims are not in the two-part form in accordance with Rule 43(1) EPC, which in the present case would be appropriate, with those features known in combination from the prior art being placed in the preamble (Rule 43(1)(a) EPC) and the remaining features being included in the characterising part (Rule 43(1)(b) EPC).

5. The features of the claims should be provided with reference signs placed in parentheses to increase the intelligibility of the claims (Rule 43(7) EPC). This applies to both the preamble and characterising portion (see Guidelines F-IV, 4.18).

6. The applicant is invited to file new claims which take account of the above comments.

In order to comply with the requirements of Rule 137(4) EPC, the applicant should clearly identify the amendments made, irrespective of whether they concern amendments by addition, replacement or deletion, and indicate the passages of the application as filed on which these amendments are based (see Guidelines H III, 2.1).

If the applicant considers it appropriate, these indications could be submitted in handwritten form on a copy of the relevant parts of the application as filed or in documents with tracked changes.

When filing amended claims the applicant should at the same time bring the description into conformity with the amended claims. Care should be taken during revision, especially of the introductory portion and of any statements of problem or advantage, not to add subject-matter which extends beyond the content of the application as originally filed (Article 123(2) EPC).

Information on Search Strategy - Pilot phase (see OJ 2015, A86)
The type of information contained in this sheet may change during the pilot for improving the usefulness of this new service.

Application Number
EP 20 78 1928

TITLE: NON-VENTING BODILY FLUID SAMPLE OPTIMIZATION DEVICE AND SYSTEM

APPLICANT: Kurin, Inc.

IPC CLASSIFICATION: G01N1/10, G01N1/02, A61B5/15, A61B5/154

EXAMINER: Coja, Michael

CONSULTED DATABASES: EPODOC, WPI

CLASSIFICATION SYMBOLS DEFINING EXTENT OF THE SEARCH:

IPC:

CPC: A61B5/15003, A61B5/150213, A61B5/150221, A61B5/150251

FI/F-TERMS:

KEYWORDS OR OTHER ELEMENTS FEATURING THE INVENTION:

EPO FORM P04A42

Europäisches Patentamt
European Patent Office
Office européen des brevets

SUPPLEMENTARY EUROPEAN SEARCH REPORT

Application Number
EP 20 78 1928

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
X	US 2018/271425 A1 (ROGERS BOBBY E [US] ET AL) 27 September 2018 (2018-09-27) * the whole document *	1-20	INV. G01N1/10 G01N1/02 A61B5/15
X	EP 3 324 845 A1 (KURIN INC [US]) 30 May 2018 (2018-05-30) * paragraph [0104]; figure 23 *	1-20	A61B5/154
X,P	WO 2019/232196 A1 (MAGNOLIA MEDICAL TECHNOLOGIES INC [US]) 5 December 2019 (2019-12-05) * paragraphs [0074], [0099], [0120], [0141]; figures 1-14 *	1,6,14	
A	WO 2019/055487 A1 (MAGNOLIA MEDICAL TECHNOLOGIES INC [US]) 21 March 2019 (2019-03-21) * paragraph [1179]; figures 35-37 *	1-20	

TECHNICAL FIELDS SEARCHED (IPC)

A61B

The supplementary search report has been based on the last set of claims valid and available at the start of the search.

Place of search	Date of completion of the search	Examiner
The Hague	20 October 2022	Coja, Michael

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
Y : particularly relevant if combined with another document of the same category
A : technological background
O : non-written disclosure
P : intermediate document

T : theory or principle underlying the invention
E : earlier patent document, but published on, or after the filing date
D : document cited in the application
L : document cited for other reasons

& : member of the same patent family, corresponding document

1

EPO FORM 1503 03.82 (P04C04)

ANNEX TO THE EUROPEAN SEARCH REPORT ON EUROPEAN PATENT APPLICATION NO. EP 20 78 1928

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report. The members are as contained in the European Patent Office EDP file on
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

20-10-2022

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2018271425 A1	27-09-2018	US 2018271425 A1	27-09-2018
		US 2021145336 A1	20-05-2021
EP 3324845 A1	30-05-2018	AU 2016297849 A1	22-02-2018
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WO 2019055487 A1	21-03-2019	AU 2018334138 A1	12-03-2020
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		US 2019076074 A1	14-03-2019
		US 2022175284 A1	09-06-2022
		WO 2019055487 A1	21-03-2019

EPO FORM P0459

For more details about this annex : see Official Journal of the European Patent Office, No. 12/82

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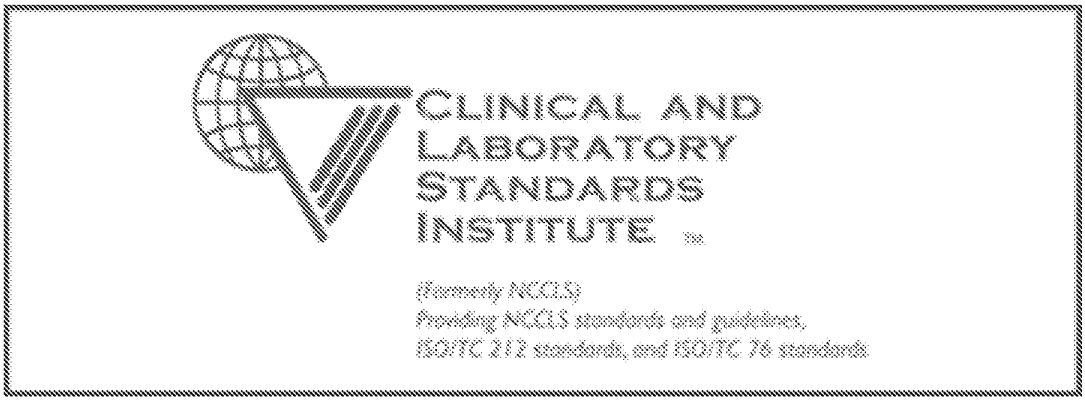
Application No.: 20781928.5

The search has started on 19.10.22 (see Notice from the European Patent Office dated 03/2013, OJ EPO 2013, 153).

Receiving Section

H3-A5
Vol. 23 No. 32
Replaces H3-A4
Vol. 18 No. 7

Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard—Fifth Edition



This document provides procedures for the collection of diagnostic specimens by venipuncture, including line draws, blood culture collection, and venipuncture in children.

A standard for global application developed through the NCCLS consensus process.

NCCLS

NCCLS...

Serving the World's Medical Science Community Through Voluntary Consensus

NCCLS is an international, interdisciplinary, nonprofit, standards-developing, and educational organization that promotes the development and use of voluntary consensus standards and guidelines within the healthcare community. It is recognized worldwide for the application of its unique consensus process in the development of standards and guidelines for patient testing and related healthcare issues. NCCLS is based on the principle that consensus is an effective and cost-effective way to improve patient testing and healthcare services.

In addition to developing and promoting the use of voluntary consensus standards and guidelines, NCCLS provides an open and unbiased forum to address critical issues affecting the quality of patient testing and health care.

PUBLICATIONS

An NCCLS document is published as a standard, guideline, or committee report.

Standard A document developed through the consensus process that clearly identifies specific, essential requirements for materials, methods, or practices for use in an unmodified form. A standard may, in addition, contain discretionary elements, which are clearly identified.

Guideline A document developed through the consensus process describing criteria for a general operating practice, procedure, or material for voluntary use. A guideline may be used as written or modified by the user to fit specific needs.

Report A document that has not been subjected to consensus review and is released by the Board of Directors.

CONSENSUS PROCESS

The NCCLS voluntary consensus process is a protocol establishing formal criteria for:

- the authorization of a project
- the development and open review of documents
- the revision of documents in response to comments by users
- the acceptance of a document as a consensus standard or guideline.

Most NCCLS documents are subject to two levels of consensus—"proposed" and "approved." Depending on the need for field evaluation or data collection, documents may also be made available for review at an intermediate (i.e., "tentative") consensus level.

Proposed An NCCLS consensus document undergoes the first stage of review by the healthcare community as a proposed standard or guideline. The document should receive a wide and thorough technical review, including an overall review of its scope, approach, and utility, and a line-by-line review of its technical and editorial content.

Tentative A tentative standard or guideline is made available for review and comment only when a recommended method has a well-defined need for a field evaluation or when a recommended protocol requires that specific data be collected. It should be reviewed to ensure its utility.

Approved An approved standard or guideline has achieved consensus within the healthcare community. It should be reviewed to assess the utility of the final document, to ensure attainment of consensus (i.e., that comments on earlier versions have been satisfactorily addressed), and to identify the need for additional consensus documents.

NCCLS standards and guidelines represent a consensus opinion on good practices and reflect the substantial agreement by materially affected, competent, and interested parties obtained by following NCCLS's established consensus procedures. Provisions in NCCLS standards and guidelines may be more or less stringent than applicable regulations. Consequently, conformance to this voluntary consensus document does not relieve the user of responsibility for compliance with applicable regulations.

COMMENTS

The comments of users are essential to the consensus process. Anyone may submit a comment, and all comments are addressed, according to the consensus process, by the NCCLS committee that wrote the document. All comments, including those that result in a change to the document when published at the next consensus level and those that do not result in a change, are responded to by the committee in an appendix to the document. Readers are strongly encouraged to comment in any form and at any time on any NCCLS document. Address comments to the NCCLS Executive Offices, 940 West Valley Road, Suite 1400, Wayne, PA 19087, USA.

VOLUNTEER PARTICIPATION

Healthcare professionals in all specialties are urged to volunteer for participation in NCCLS projects. Please contact the NCCLS Executive Offices for additional information on committee participation.

H3-A5
ISBN 1-56238-515-1
Volume 23 Number 32 ISSN 0273-3099

Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard—Fifth Edition

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Abstract

H3-A5—*Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard—Fifth Edition* provides a descriptive, stepwise procedure for the collection of diagnostic blood specimens by venipuncture. Special considerations for venipuncture in children, line draws, blood culture collection, and venipuncture in isolation situations are included.

NCCLS. *Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard—Fifth Edition*. NCCLS document H3-A5 (ISBN 1-56238-515-1). NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2003.

THE NCCLS consensus process, which is the mechanism for moving a document through two or more levels of review by the healthcare community, is an ongoing process. Users should expect revised editions of any given document. Because rapid changes in technology may affect the procedures, methods, and protocols in a standard or guideline, users should replace outdated editions with the current editions of NCCLS documents. Current editions are listed in the *NCCLS Catalog*, which is distributed to member organizations, and to nonmembers on request. If your organization is not a member and would like to become one, and to request a copy of the *NCCLS Catalog*, contact the NCCLS Executive Offices. Telephone: 610.688.0100; Fax: 610.688.0700; E-Mail: exoffice@nccls.org; Website: www.nccls.org



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Contents

Abstract i

Committee Membership iii

Foreword vii

1 Scope 1

2 Introduction 1

3 Standard Precautions 1

4 Definitions 1

5 Factors That Affect Laboratory Values 2

6 Facilities 2

6.1 Venipuncture Chairs 2
6.2 Hospital Area 3

7 Supplies 3

7.1 Utility Carts 3
7.2 Blood Collecting Trays 3
7.3 Gloves 3
7.4 Needles and Holders 4
7.5 Sterile Syringes 4
7.6 Venous Blood Collection Tubes 4
7.7 Tourniquets 4
7.8 Antiseptics 5
7.9 Gauze Pads 5
7.10 Puncture-Resistant Disposal Container 5
7.11 Ice 5
7.12 Adhesive Bandages 5
7.13 Warming Devices 5
7.14 Test Reference Manual 5

8 Venipuncture Procedure 5

8.1 Step 1: Prepare Accession Order 6
8.2 Step 2: Approach and Identify the Patient 6
8.3 Step 3: Verify Patient Diet Restrictions and Latex Sensitivity 8
8.4 Step 4: Assemble Supplies 8
8.5 Step 5: Position Patient 9
8.6 Step 6: Apply Tourniquet 10
8.7 Step 7: Put on Gloves 13
8.8 Step 8: Cleanse Venipuncture Site 13
8.9 Step 9: Perform Venipuncture 13
8.10 Step 10: Order of Draw 17
8.11 Step 11: Release the Tourniquet 17
8.12 Step 12: Place the Gauze Pad 17
8.13 Step 13: Remove and Dispose of the Needle 18
8.14 Step 14: Bandage the Arm 18

Contents (Continued)

8.15 Step 15: Label Blood Collection Tubes and Record Time of Collection 18
8.16 Step 16: Chill the Specimen 19
8.17 Step 17: Send Blood Collection Tubes to the Proper Laboratories 19

9 Venipuncture in Children and Difficult Collections 19

9.1 Procedure 19
9.2 Equipment 19

10 Additional Considerations 19

10.1 Monitoring Blood Volume Collected 19
10.2 Hematoma 20
10.3 Hemolysis 20

11 Special Situations 20

11.1 Timed Intervals 20
11.2 Specific Collection Techniques 20
11.3 Indwelling Lines or VADs 21
11.4 Heparin or Saline Locks 22
11.5 Fistula 22
11.6 Intravenous Fluids 22
11.7 Isolation 23
11.8 Emergency Situations 24

References 26

Summary of Comments and Subcommittee Responses 27

Summary of Delegate Comments and Working Group Responses 28

The Quality System Approach 34

Related NCCLS Publications 35

KUR-MAG-DE005090

Foreword

The errors that can occur during the collection and handling of blood specimens are potentially numerous (e.g., inaccurate identification of specimens, specimen hemolysis, the improper handling of anticoagulants, the formation of hematomas, hemoconcentration). Standards for venipuncture can reduce or alleviate many of these errors in much the same way that quality control standards have reduced errors within the laboratory.

Reducing errors during blood collecting will result in biologically representative specimens that are comparable from one institution to another. A well-planned, attractive environment in which to perform venipunctures will reduce patient anxiety and increase the efficiency and accuracy of the phlebotomist. Phlebotomists need a complete assortment of equipment at their fingertips so they can judiciously select the most appropriate materials for each patient. Standards governing the processing of paperwork will reduce errors and save time. Without question, a comprehensive training program is needed to produce efficient, well-trained phlebotomists. Finally, standards for the actual venipuncture procedure are needed to help eliminate the many errors that can occur during blood collection. Biologically representative specimens for laboratory testing will be obtained if national venipuncture standards are used.

Various comments received on the previous edition of this standard have been reviewed and incorporated where appropriate. All comments and the subcommittee's responses are summarized at the end of the document.

This document replaces the fourth edition approved standard, H3-A4, which was published in 1998. Several changes have been made in this edition; chief among them is the revised order of draw (Section 8.10.2), which reflects the increased use of plastic blood collection tubes. This standard also contains revised recommendations regarding collection of blood specimens in relation to intravenous sites (Section 11.6). The recommendations regarding the collection of coagulation specimens (Section 8.10.3) have been revised for consistency with NCCLS document H21—*Collection, Transport, and Processing of Blood Specimens for Coagulation Testing and General Performance of Coagulation Assays.*

Key Words

Accession, blood specimen, phlebotomist, sample, venipuncture

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Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard—Fifth Edition

1 Scope[a]

This document establishes criteria for the correct collection of blood specimens by venipuncture. These procedures are intended to be a suitable model for adoption by all healthcare providers responsible for the collection and handling of blood specimens in both outpatient and inpatient settings.

2 Introduction

Since 1977, NCCLS has progressively recognized the quality requirement that significant attention be directed towards the preanalytical components of laboratory testing, specifically, the correct collection and handling of blood specimens. Highly sophisticated testing technology cannot produce a good result from a poor specimen. Proper specimen collection and handling are of the utmost importance because significant errors occur in the preanalytical phase of laboratory testing.[1]

Preanalytical errors have the potential to be numerous: incorrect patient ID, incorrect order-of-draw, incorrect use of additive tubes, labeling errors, incorrect timing of collection, clerical errors, etc. Standard procedures and protocols are intended to prevent these problems and protect patient results quality.

3 Standard Precautions

Because it is often impossible to know what might be infectious, all human blood specimens are to be treated as infectious and handled according to "standard precautions." Standard precautions are guidelines that combine the major features of "universal precautions and body substance isolation" practices. Standard precautions cover the transmission of any pathogen and thus are more comprehensive than universal precautions which are intended to apply only to transmission of blood-borne pathogens. Standard precaution and universal precaution guidelines are available from the U.S. Centers for Disease Control and Prevention (*Guideline for Isolation Precautions in Hospitals*. Infection Control and Hospital Epidemiology. CDC. 1996;Vol 17;1:53-80), (MMWR 1987;36[suppl 2S]2S-18S), and (MMWR 1988;37:377-382, 387-388). For specific precautions for preventing the laboratory transmission of blood-borne infection from laboratory instruments and materials and for recommendations for the management of blood-borne exposure, refer to the most current edition of NCCLS document M29—*Protection of Laboratory Workers from Occupationally Acquired Infections.*

4 Definitions

In the context of this publication, the terms listed below are defined as follows:

Accession – The steps required to ensure that a specific patient specimen and the accompanying documentation are unmistakably identified as referring to a specific person.

Angle of insertion – The angle formed by the surface of the arm and the needle entering the arm.

[a] This standard reflects recent revisions to OSHA's Blood Borne Pathogens Standard (29 CFR 1910.1030). Therefore, all references to needles/winged blood collection sets indicate sharps with engineered safety features. This also encompasses safety accessories used in combination with conventional needles.

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(Patient) sample – A sample taken from the patient specimen and used to obtain information by means of a specific laboratory test.

(Patient) specimen – The discrete portion of a body fluid or tissue taken for examination, study, or analysis of one or more quantities or characteristics to determine the character of the whole.

Pre-evacuation – The creation of a vacuum (in a collection tube), induced by either the manufacturer or by the user immediately before a liquid specimen is taken.

Vascular access device (VAD) – A device inserted into a vein or artery to allow access to the circulatory system for the administration of intravenous fluids and/or medications.

Venipuncture – The puncture of a vein for surgical, or therapeutic, purposes, or for collecting blood specimens for analysis.

5 Factors That Affect Laboratory Values

Interpretation of laboratory data has assumed new importance and attracted increased attention with both more frequent testing and multiple testing. The increased use of laboratories predictably yields abnormal unsolicited data that requires interpretation and may lead to costly, unproductive, and unnecessary sequential testing. Even when an analytical procedure has been performed correctly and precisely, variables can affect the test result. Knowledge of these variables and standardization of laboratory testing procedures are essential for correct interpretation and optimal use of the data.

Major causes of "laboratory error" can be related to nonanalytical factors such as specimen collection, handling, and transport. Nonbiological factors—such as patient misidentification, and biological factors—such as patient posture and the time a specimen is drawn, all contribute to the total "laboratory error."

Physiological factors that influence results include age, activity, bed rest, food ingestion, alcohol ingestion, menstrual cycle, obesity, oral contraceptives, posture, pregnancy, race, gender, smoking, and time of day. All biological phenomena exhibit rhythms, with the circadian rhythm (the change in a 24-hour period) being the most important to laboratory testing. Many factors with documented effects on laboratory values have been published.[2-6]

6 Facilities

The venipuncture should be performed in a clean, quiet, and private environment. Reasonably soundproof rooms for pediatric patients should be considered.

The room should have facilities to allow the phlebotomist to wash his/her hands between patients. Washing with soap and running water is recommended; however, any standard detergent product acceptable to personnel may be used. In settings where water is not available, alcohol-based gels or liquids, hand-wipe towelettes, and cleansing foams can be used.[b]

6.1 Venipuncture Chairs

Venipuncture chairs should be designed for the maximum comfort and safety of the patient. Consideration should be given to the ergonomic comfort plus easy accessibility to the patient for the phlebotomist. Both armrests of the chairs should be adjustable so that the best venipuncture position for

[b] In the U.S., employees must wash their hands with soap and running water as soon as feasible thereafter.

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each patient can be achieved. The chair should have a safety device to prevent patients from falling if feeling faint.

6.2 Hospital Area

A central venipuncture area should be designed to include the following features.

6.2.1 Central Desk

The central desk is a location for a telephone system used to handle emergency request calls, facilities for processing daily and future requests, and a paging system for contacting the phlebotomist who is collecting specimens outside of the central area.

6.2.2 Cart Area

The cart area is constructed to allow easy access to the supplies.

6.2.3 Storage Area

The storage area should be large enough to accommodate the necessary supplies.

6.2.4 Counter Space

Counter space should be adequate for efficient sorting and dispatching of specimens.

6.2.5 Sampling Time Recorder

The sampling time recorder (i.e., time stampers, bar codes, or information system) should be located for convenient time recording of venipuncture paperwork.

7 Supplies

The following supplies should be available at any location where venipunctures are performed routinely.

7.1 Utility Carts

Utility carts, designed to roll smoothly and silently over all types of surfaces, may be useful. The phlebotomist may also find it very useful to have a specially designed rack on the top shelf for storing supplies.

7.2 Blood Collecting Trays

Blood collecting trays or carts may be used. The trays should be lightweight and easy to handle with enough space and compartments for the various supplies that are needed.

7.3 Gloves

Latex, vinyl, or nitrile gloves provide barrier protection. Disposable latex, vinyl, or nitrile gloves are available from hospital suppliers.

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Some workers may develop dermatitis from wearing latex gloves for long periods of time. These workers should experiment with nitrile, polyethylene or other gloves of various composition or gloves without powdered lubricant or they may wear cotton gloves under latex or plastic gloves.

Severe hypersensitivity has been reported and cases of anaphylactic shock have occurred. In such hypersensitive individuals, latex gloves must be avoided.

7.4 Needles and Holders

Needles/holders should be compatible with the tubes selected for use. For more information on venous blood collection tubes and additives, refer to the most current edition of NCCLS document H1—*Evacuated Tubes and Additives for Blood Specimen Collection.*

Needles and winged blood collection sets are individually color-coded according to their respective gauge sizes. The gauge number indicates the size of the needle. A large gauge number indicates a small needle, while a small gauge number indicates a large needle. The sizes for venipuncture range from 19 through 23. Needles must always be sterile.

In order to prevent potential worker exposure, the needle safety feature should be activated immediately after specimen collection and discarded without disassembly into a sharps container.[c]

7.5 Sterile Syringes

In general, venipuncture using a needle and syringe should be avoided for safety reasons; however, it may be suitable under some circumstances to have sterile syringes of the appropriate size available.

7.6 Venous Blood Collection Tubes

Venous blood collection tubes are manufactured to withdraw a predetermined volume of blood. At present, venous blood collection tubes used in venipuncture are designated sterile. It is recommended that information regarding the venous blood collection tubes selected for general use be clearly displayed in venipuncture areas for easy reference. Similar information should also be made available to all personnel who collect blood. Instructions furnished in the package insert by the manufacturer of venous blood collection tubes and needles should be available. (See also the most current version of NCCLS document H1—*Evacuated Tubes and Additives for Blood Specimen Collection* for information on venous blood collection tubes.)

7.7 Tourniquets

Tourniquets or products for use as tourniquets should be available. Examples include:

- Single-use disposable tourniquet, preferably latex-free.
- Blood pressure cuff inflated to 40 mmHg.
- Rubber/fabric-type tourniquets with closure tape, plastic clip, buckle, or similar type of fastening.

Tourniquets must be discarded immediately when contaminated with blood or body fluids or must be discarded if contamination is suspected.

[c] In the U.S., refer to OSHA's Bloodborne Pathogens Standard (29 CFR 1910.1030), the safe practice of phlebotomy and blood tube holder use (CPL2-2.9 at XIII.D.5).

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7.8 Antiseptics

Antiseptics for skin preparation are necessary. The following are some examples:

- Isopropyl or ethyl alcohol: 70%
- 1 to 10% povidone-iodine as swab sticks or chlorhexidine gluconate for blood cultures[7] (see Section 8.8.2).
- Nonalcohol-based cleanser for blood alcohol specimens (e.g., chlorhexidine).

7.9 Gauze Pads

Small prepackaged gauze pads, (i.e., 2 x 2 in or 3 x 3 in [5.0 x 5.0 cm or 7.5 x 7.5 cm]) should be available. Cotton balls are not recommended because of the possibility of dislodging the platelet plug at the venipuncture site.

7.10 Puncture-Resistant Disposal Container

An approved puncture-resistant disposal container that is compliant with OSHA regulations must be available.

7.11 Ice

Ice or refrigerant should be available.

7.12 Adhesive Bandages

Adhesive bandages and/or gauze pads should be available. Hypoallergenic adhesives should also be available.

7.13 Warming Devices

Warming devices may be used to increase blood flow.

7.14 Test Reference Manual

A test manual which explains which tube is to be used, that also indicates minimum volume requirements, special handling, and precautions to be taken should be consulted.

8 Venipuncture Procedure

The venipuncture procedure is complex and requires both knowledge and skill (refer to Sections 8.1 to 8.17 for detailed information on the procedure). When drawing a blood specimen, the trained phlebotomist must:

Step 1. Prepare accession order.
Step 2. Approach and identify the patient.
Step 3. Verify patient's diet restrictions, as appropriate, and inquire if patient has a latex sensitivity. Select appropriate gloves and tourniquet.
Step 4. Assemble necessary supplies and select appropriate tubes according to test requests.
Step 5. Position the patient.
Step 6. Apply the tourniquet, ensure the patient's hand is closed, and select the vein site.
Step 7. Put on gloves.

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Step 8. Cleanse the venipuncture site.
Step 9. Perform venipuncture; once blood flow begins, request patient to open hand.
Step 10. Use the correct order of draw.
Step 11. Release and remove the tourniquet.
Step 12. Place the gauze pad over the puncture site.
Step 13. Remove the needle, activating any safety feature according to manufacturers' instructions.
Step 14. Apply pressure to the site, making sure bleeding has stopped, and then bandage the arm.
Step 15. Label the tubes and record the time of collection.
Step 16. Chill the specimen (if required).
Step 17. Send properly labeled blood collection tubes to the appropriate laboratories.

8.1 Step 1: Prepare Accession Order

Each request for a blood specimen must be accessioned to identify all paperwork and supplies associated with each patient. An organized system will ensure prompt and accurate processing of the various forms required when performing a venipuncture and analyzing the results. Record all information on the test request form.

8.1.1 Information for Test Request Form

The following information should be included:

- The patient's name and age from identification plate
- An identification number
- The date and time the specimen is to be obtained
- An accessioning number
- The doctor's name
- The department or location for which the work is being done
- Other information as needed (e.g., special comments: intravenous site, sampling site if other than arm).

8.2 Step 2: Approach and Identify the Patient

The phlebotomist should identify himself or herself, establish a rapport, and gain the patient's confidence. Information given to the patient regarding the testing to be performed and specimen to be drawn must be in accordance with institutional policy. The phlebotomist must **NOT** perform blood collection against the patient's or guardian's consent. Instead, report the patient's objections to the physician's/nurse's station.

8.2.1 Identify Patient

Identification of the patient is crucial. The phlebotomist must ensure that the blood specimen is being drawn from the individual designated on the request form. The phlebotomist must not rely on a bed tag, or on charts or records placed on the bed, nearby tables, or equipment. The following steps are a suggested sequence for ensuring patient identification, regardless of the clinical setting.

8.2.2 Patient Who Is Conscious

The suggested sequence of steps for a patient who is conscious:

(1) Ask outpatients to give full name, address, identification number, and/or birth date.

(2) Compare this information with the information on the request form.

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(3) Ask inpatients for the same information and compare this information with the information on the request form and the patient's identification bracelet, which must be attached to the patient.

(4) Report any discrepancy, however minor, to the responsible person in the area (as determined by institutional policy) and have the patient identified by name and identification number before drawing any specimen.

8.2.3 Patient Who Is Semiconscious, Comatose, or Sleeping

The phlebotomist must take special care when drawing blood from semiconscious, comatose, or sleeping patients to anticipate any unexpected movements or jerks either while introducing the needle, or while it is in place in the arm. Sleeping patients should be awakened before drawing blood. A gauze pad should be readily available and the tourniquet quickly released in the event the needle is violently removed or repositioned. If the needle accidentally goes much deeper into the arm, the phlebotomist must inform the doctor's/nurse's station. If unable to identify the patient, then contact the nurse or physician.

8.2.4 Patient Who Is Unconscious, Too Young, Mentally Incompetent, or Does Not Speak the Language of the Phlebotomist

In any of these circumstances, the phlebotomist should follow this suggested sequence of steps:

(1) Ask the nurse, a relative, or a friend to identify the patient by name, address, identification number, and/or birth date. If unable to identify the patient, then contact the nurse or physician.

(2) Compare these data with the information on the request form and the patient's identification bracelet, which must be attached to the patient.

(3) Report any discrepancy, however minor, to the responsible person in the area (as determined by institutional policy) and have the patient identified by name and identification number before drawing any specimen.

8.2.5 Procedure for Identifying Unidentified Emergency Patients

Identification standards established by the American Association of Blood Banks (AABB) provide clear guidelines for unidentified emergency patients.[8]

The patient must be positively identified when the blood specimen is collected. The unidentified emergency patient should be given some temporary but clear designation until positive identification can be made. For a person who cannot be identified immediately, it is necessary to:

- Assign a master identification number (temporary) to the patient in accord with institutional policy.
- Select the appropriate test request forms and record with master identification number.
- Complete the necessary labels either by hand or by computer and apply the labels to the test request forms and specimens.
- When a permanent identification number is assigned to the patient, make sure the temporary identification number is cross-referenced to the permanent number to ensure correct identification and correlation of patient and test result information.

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In all cases, the name and permanent or temporary identification designation must be attached to the patient's body either by wristband or some similar device. Except in the case of isolation patients, bed labels must not be used in place of wristbands.

8.2.6 Physician Relationship

The physician has priority with the patient. The phlebotomist should not enter the room without permission while the physician or nurse is consulting with the patient. If the order is stat or the specimen is a "timed" specimen, the phlebotomist should request permission to draw the blood specimen.

8.3 Step 3: Verify Patient Diet Restrictions and Latex Sensitivity

Some tests require the patient to fast and/or eliminate certain foods from the diet before the blood is drawn. Time and diet restrictions vary according to the test. Such restrictions are necessary to ensure accurate test results.

The procedure for holding meals and notifying appropriate personnel that the patient has been drawn should be according to institutional policy.

Please refer to Section 7.3 for information regarding latex sensitivity to gloves and to Section 7.7 for tourniquets.

8.4 Step 4: Assemble Supplies

8.4.1 Supplies[d]

It is important that phlebotomy devices used reflect the most current local and regional safety regulations.[9]

Inspect all supplies for possible defects and applicable expiration dates. The following supplies should be available at any location where venipunctures are performed routinely:

- Blood collection tubes/blood culture bottles
- Needle
- Single-use tube/needle holder
- Syringe
- Syringe transfer device
- A tourniquet
- Alcohol prep pads
- 1 to 10% povidone-iodine pads, tincture iodine, or chlorhexidine compounds if blood culture is to be drawn
- Nonalcohol-based cleanser if blood alcohol is to be drawn
- Gauze pads, adhesive bandages, or tape (including hypoallergenic adhesives)
- Gloves
- Sharps container, consistent with OSHA regulations

8.4.2 Needles

The phlebotomist must select the appropriate needle gauge based on the physical characteristics of the vein, location of the vein, and the volume of blood to be drawn.

[d] In the U.S., OSHA mandates the use of engineering and work practice controls that eliminate occupational exposure or reduce it to the lowest feasible extent (e.g., safety needles, shielded needle devices, etc.).

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8.4.3 Syringes

The plunger must be moved within the barrel of the syringe to show syringe and needle patency and freedom of plunger movement.

8.4.4 System

The phlebotomist must select the appropriate blood collection system according to the patient's physical characteristics.

8.4.4.1 Venous Blood Collection Systems

When venous blood collection tubes are used, the phlebotomist must:

- Select the correct types and sizes of venous blood collection tubes. (Color-coded closures and labels make it easy to perform this step.)
- Apply a label to each of the necessary tubes and all test forms immediately after blood specimen has been drawn
- Refer to institutional policy.

All tubes should be labeled immediately *after* the blood specimen has been drawn. The completed label must be attached to the tube before leaving the side of the patient, and there must be a mechanism to identify the person who drew the blood.[8] If preprinted labels are not available, complete patient information can be handwritten on the tube label. This procedure eliminates the possibility of mixing up the blood specimens.

It is recommended that blood specimens be collected by venipuncture using a blood collection system that collects the blood directly into tubes. (For greater detail on venous blood collection tubes and additives, refer to the most current edition of NCCLS document H1—*Evacuated Tubes and Additives for Blood Specimen Collection.)* If the components are from different manufacturers, they should be checked to ensure compatibility.

8.4.4.2 Plastic Syringe

In general, the use of a syringe and needle should be avoided for safety reasons. If a syringe is used, a safety syringe shielded transfer device should be used to transfer blood to the appropriate venous blood collection tube.

8.4.4.3 Blood Collection Set

The blood collection set (i.e., winged blood collection set) is described in Section 9.2.

8.5 Step 5: Position Patient

8.5.1 Procedure for Seating Patient

(1) Ask the patient to be seated comfortably in a chair suitable for venipuncture. The chair should have arms to provide support and prevent falls if the patient loses consciousness. Chairs without arms do not provide adequate support for the arm or protect fainting patients from falls.

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(2) Have the patient position his/her arm on the slanting armrest and extend the arm to form a straight line from the shoulder to the wrist. The arm should be supported firmly by the armrest and should not be significantly bent at the elbow. A slight bend may be important in avoiding hyperextension of the arm.

8.5.2 Procedure for Having Patient Lie Down

(1) Ask the patient to lie on his/her back in a comfortable position.

(2) If additional support is needed, place a pillow under the arm from which the specimen is being drawn.

(3) Have the patient extend his/her arm to form a straight line from the shoulder to the wrist.

8.5.3 Foreign Objects in Mouth

No food or liquid, chewing gum, or thermometer should be in the patient's mouth at the time the specimen is drawn.

8.6 Step 6: Apply Tourniquet

A tourniquet is used to increase venous filling. This makes the veins more prominent and easier to enter. (See Section 7.7).

8.6.1 Precautions When Using a Tourniquet

Tourniquet application for preliminary vein selection should not exceed one minute as localized stasis with hemoconcentration and infiltration of blood into tissue can occur. This may result in erroneously high values for all protein-based analytes, packed cell volume, and other cellular elements. If the patient has a skin problem, the tourniquet should be applied over the patient's gown or a piece of gauze pad or paper tissue should be used so that the skin is not pinched.

8.6.2 Tourniquet Location

Wrap the tourniquet around the arm 3 to 4 inches (7.5 to 10.0 cm) above the venipuncture site.

8.6.3 Blood Pressure Cuff

If a blood pressure cuff is used as a tourniquet, inflate it to 40 mm Hg.

8.6.4 Ensure Patient's Hand Is Closed

The veins become more prominent and easier to enter when the patient forms a fist. There must not be vigorous hand exercise ("pumping"). Vigorous hand pumping can cause changes in the concentration of certain analytes in the blood.

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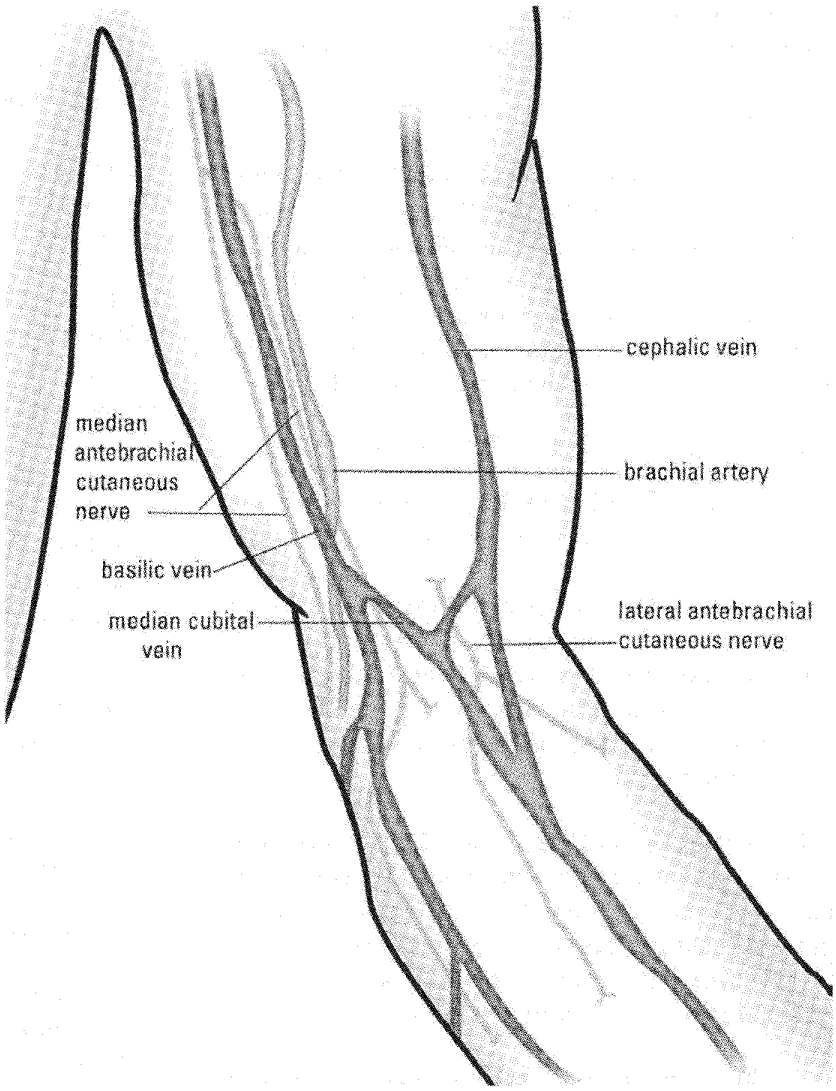


Figure 1. Superficial Veins of the Anterior Surface of the Upper Extremity (From Ernst DJ, Ernst C. Phlebotomy tools of the trade: Part 2—Surveying the antecubital area. *Home Healthcare Nurse.* 2002;20:402-403. Reprinted with permission from Lippincott Williams & Wilkins.)

8.6.5 Select Vein

Refer to Figure 1 for a description of the superficial veins of the anterior surface of the upper extremity.

8.6.5.1 Caution

It is important to select the vein carefully for blood collection because the veins also provide an avenue of entry for transfusion, infusion, and therapeutic agents. Because the brachial artery passes through the antecubital area, caution must be exercised to avoid the artery. If, during the procedure, arterial puncture is suspected, direct forceful pressure must be applied to the puncture site for a minimum of five minutes upon removal of the needle or until active bleeding has ceased. The nursing staff and physician are to be notified immediately thereafter.

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8.6.6 Preferred Veins

Arterial punctures should not be considered as an alternative to venipuncture for difficult draws. If this appears to be the only alternative, consult with the physician.

Although the larger and fuller median cubital and cephalic veins (see Figure 1) are used most frequently, veins on the back of the hand are also acceptable for venipuncture. Veins on the underside of the wrist must not be used.

Draws to the median cubital veins are preferred because they are typically closer to the surface of the skin, more stationary, less painful upon needle insertion, and less likely to injure nerves if needle placement is not accurate. Attempt to locate the median cubital vein on either arm before considering alternative veins. Due to the proximity of the basilic vein to the brachial artery and the median nerve, this vein should only be considered if no other vein is more prominent. Above all, phlebotomists should be aware of the potential for injury associated with each vein and select the vein that brings the greatest degree of confidence of being accessed successfully without risking nerve or arterial involvement. (See Figure 1.)

Alternative sites such as ankles or lower extremities must not be used without the permission of the physician because of the potential for significant medical complications (e.g., phlebitis, thrombosis, tissue necrosis, etc.)[10-12]

8.6.7 Factors in Site Selection

8.6.7.1 Extensive Scarring

Healed burn areas are to be avoided.

8.6.7.2 Mastectomy

A physician must be consulted before drawing blood from the side on which a mastectomy was performed because of the potential for complications due to lymphostasis.

8.6.7.3 Hematoma

Specimens collected through a hematoma area may cause erroneous test results. Phlebotomy must not be performed on any size hematoma. If another vein site is not available, the specimen is collected distal to the hematoma.

8.6.7.4 Intravenous Therapy

Preferably, specimens should not be collected from an arm with an intravenous site. (See Section 11.6).[13]

8.6.7.5 Cannula, Fistula, Vascular Graft

A cannulated arm is used only after consulting the attending physician.

8.6.8 Procedure for Vein Selection

8.6.8.1 Locating Veins

To locate veins, it is necessary to palpate and trace the path of veins several times with the index finger. Unlike veins, arteries pulsate, are more elastic, and have a thick wall. Thrombosed veins lack resilience,

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feel cord-like, roll easily, and should not be used. A tourniquet must be used to aid in the selection of a vein site unless specific tests require tourniquets not be used (e.g., lactate). If a tourniquet must be applied for the preliminary vein selection, it should be released and reapplied after two minutes.

8.7 Step 7: Put on Gloves

The phlebotomist must put gloves on before the venipuncture is performed, for each patient, with consideration for latex sensitivity as discussed in Section 7.3.

8.8 Step 8: Cleanse Venipuncture Site

The puncture site must be cleansed to prevent microbiological contamination of either the patient or the specimen.

8.8.1 Cleansing Method for Venipuncture

(1) Use a gauze pad with 70% isopropyl alcohol solution, or a commercially prepared alcohol pad.

(2) Cleanse the site with a circular motion from the center to the periphery.

(3) *Allow the area to air dry* to prevent hemolysis of the specimen and to prevent the patient from experiencing a burning sensation when the venipuncture is performed.

8.8.2 For Blood Culture Collection

For blood cultures, it is necessary to carefully disinfect the venipuncture site. Chlorhexidine gluconate is recommended for infants two months and older and patients with iodine sensitivity. Cleanse the site with 70% alcohol, then swab concentrically, starting at the middle of the site with a 1 to 10% povidone-iodine solution (0.1 to 1% available iodine) or chlorhexidine gluconate. Allow the site to air dry, then remove the iodine or chlorhexidine from the skin with alcohol.[8]

When specimens are obtained for blood cultures, disinfect the culture bottle stopper according to the manufacturer's instructions.

8.8.3 Touching the Site After Cleansing

If the venipuncture proves difficult and the vein must be touched again to draw blood, the site should be cleansed again.

8.9 Step 9: Perform Venipuncture

8.9.1 Venipuncture Procedure When Venous Blood Collection Tubes Are Used

There are several different blood collection systems available that collect blood samples using different principles. For example, there are evacuated tube systems and systems that have a flexible/dual collection technique that employ either a vacuum—user evacuates the tube immediately prior to use referred to as pre-evacuation—or aspiration principle of collection. For the proper venipuncture technique using the blood collection system selected refer to the manufacturers' instructions for use.

(1) If pre-evacuation is required, and the blood collection tubes are not evacuated by the manufacturer, evacuate the tubes immediately prior to use according to the manufacturer's instructions.

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(2) If not preassembled by the manufacturer, thread the appropriate needle into the holder until it is secure.

(3) When drawing blood for cultures, wipe the stopper with a suitable antiseptic solution. Make certain the stopper is dry before performing the venipuncture.

(4) Make sure the patient's arm or other venipuncture site is in a downward position to prevent reflux or "backflow."

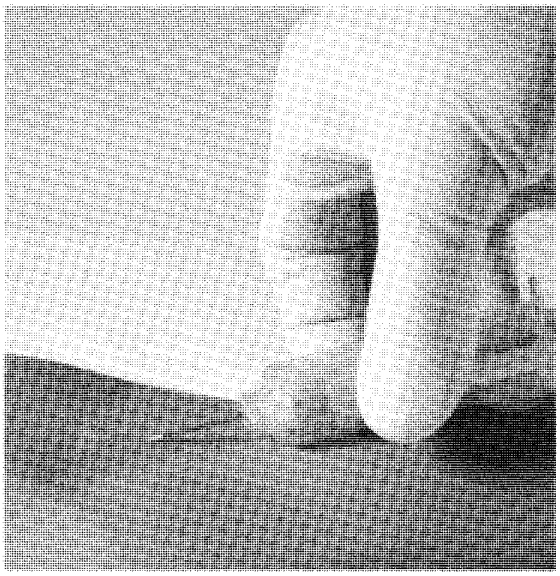


Figure 2. Proper Angle of Insertion (Figure contributed by the Center for Phlebotomy Education, Inc.)

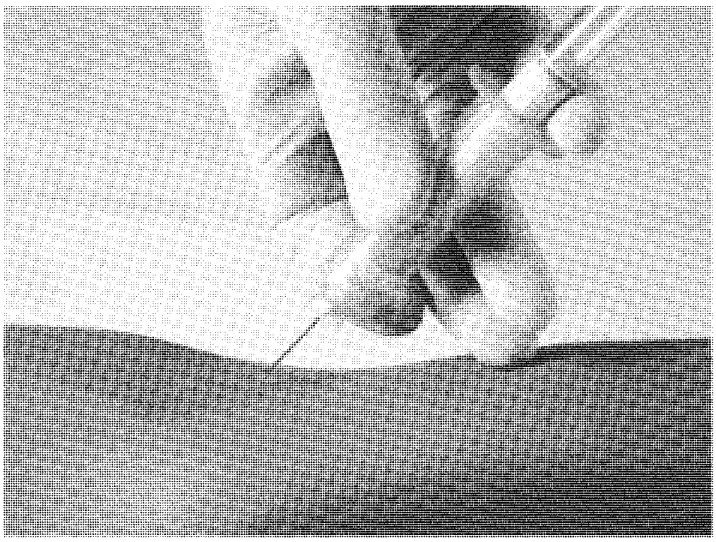


Figure 3. Improper Angle of Insertion (Figure contributed by the Center for Phlebotomy Education, Inc.)

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(5) Prior to venipuncture, if required, assemble the tube to the needle/holder according to the manufacturer's instructions.

(6) Hold the patient's arm firmly distal to the intended puncture site. The phlebotomist's thumb should be used to draw the skin taut. This anchors the vein. The thumb should be 1 to 2 inches (2.5 to 5.0 cm) below the venipuncture site.

(7) To prepare the patient, inform him or her that the venipuncture is about to occur. **NOTE:** From this point on, be prepared to react to a sudden and unexpected loss of consciousness.

(8) With the bevel up, puncture the vein with the needle at an angle of insertion of 30 degrees or less (See Figure 2). Keeping the needle as stable as possible in the vein, push/connect the first tube onto the needle. Maintain the tube below the site when the needle is in the vein.

(9) Release the tourniquet as soon as possible after the blood begins to flow. Do not change the position of the tube until it is removed from the needle. During the collection, do not allow the contents of the tube to contact the closure. Movement of the blood back and forth in the tube can cause reflux into the venous system and possible adverse patient reaction.

(10) Allow the tube to fill until the vacuum is exhausted and blood flow ceases. For tubes that contain additives, this will ensure there is a correct ratio of blood to additive.

NOTE: For systems that collect blood using an aspiration principle of collection rather than a vacuum, gently pull back on the piston rod until the piston reaches the base of the tube. This will ensure there is a correct ratio of blood to additive.

(11) When the blood ceases to flow, remove/disconnect the tube from the needle/holder. The sleeve re-covers the needlepoint that pierces the tube closure, stopping blood flow until the next tube is inserted/connected to the needle/holder. To obtain additional specimens, insert/connect the next tube to the needle/holder and repeat the collection procedure. Always remove the last tube collected from the needle/holder prior to withdrawing the needle from the vein. If only one tube is collected this must be removed prior to withdrawing the needle from the vein.

(12) Immediately after drawing each tube that contains an additive mix the blood gently and thoroughly by inverting the tube five to ten times. To avoid hemolysis, do not mix vigorously. For tubes that have been drawn using an aspiration principle, lock the piston into the base of the tube and snap off the piston rod after mixing.

8.9.2 Venipuncture Procedure Using Needle and Syringe

In general, venipuncture using a needle and syringe should be avoided for safety reasons. If conditions require a syringe draw, the following procedure is recommended:

(1) Assemble the needle and syringe.

(2) Hold the patient's arm firmly distal to the intended puncture site. The phlebotomist's thumb should be used to draw the skin taut. This anchors the vein. The phlebotomist's thumb should be 1 or 2 inches (2.5 cm or 5.0 cm) below the venipuncture site.

(3) Prepare the patient by informing him or her that the venipuncture is about to occur.

(4) With the bevel up, puncture the vein with the needle at an angle of insertion of 30 degrees or less (see Figure 2).

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(5) Keeping the needle as stable as possible in the vein, slowly withdraw the desired amount of blood.

(6) Release the tourniquet as soon as possible, after the blood begins to flow.

8.9.3 Fill the Tubes If Syringe and Needle Are Used

Syringe method of drawing venous blood is not recommended since it is much safer and easier to use a closed, venous blood collection tube system. If it is necessary to use a syringe, proceed with the following recommendations to transfer the blood from a syringe to a blood collection tube:

- Use the same "order of draw" as for a venous blood collection tube system (see Section 8.10.2).
- Rubber stoppers should not be removed from venous blood collection tubes to transfer blood to multiple tubes.
- To transfer the blood from the syringe to a venous blood collection tube, activate the safety feature of the needle or winged blood collection set used to withdraw the specimen, remove and discard the needle or winged collection set, and apply a safety transfer device.
- The stopper is pierced with the needle and the tube is allowed to fill (without applying any pressure to the plunger) until flow ceases. This technique helps to maintain the correct ratio of blood to additive if an additive tube is being used.
- Mix additive tubes by inversion.

8.9.4 Blood Specimen That Cannot Be Obtained

When a blood specimen cannot be obtained, it may be necessary to:

- Change the position of the needle. If the needle has penetrated too far into the vein, pull it back a bit. If it has not penetrated far enough, advance it farther into the vein. Rotate the needle half a turn. Lateral needle relocation should never be attempted in an effort to access the basilic vein, since nerves and the brachial artery are in close proximity.
- Try another tube to ensure the tube selected is not defective.
- Manipulation other than that recommended above is considered probing. Probing is not recommended. Probing is painful to the patient. In most cases another puncture in a site below the first site, or use of another vein on the other arm, is advisable.
- It is not advisable to attempt a venipuncture more than twice. If possible, have another person attempt to draw the specimen or notify the physician.

8.9.5 Ensure Patient's Hand Is Open

Opening the patient's hand reduces the amount of venous pressure as muscles relax. The patient must not be allowed to pump the hand.

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8.10 Step 10: Order of Draw

8.10.1 Additive Tubes

Gel separator tubes with clotting activators or anticoagulants are classified as additive tubes.[14] (For further information, refer to the most current edition of NCCLS document H18— *Procedures for the Handling and Processing of Blood Specimens*). These tubes should be drawn after the coagulation tube (blue stopper) and before other additive tubes (green, lavender, gray). All additive tubes should have a complete draw (see Section 8.9.1[10]).

8.10.2 Glass and Plastic Venous Blood Collection Tubes

The following order-of-draw is recommended when drawing multiple specimens for clinical laboratory testing during a single venipuncture. Its purpose is to avoid possible test result error due to cross contamination from tube additives.[15] This procedure should be followed for both glass and plastic venous blood collection tubes.

(1) Blood culture tube
(2) Coagulation tube (e.g., blue closure)
(3) Serum tube with or without clot activator, with or without gel (e.g., red closure)
(4) Heparin tube with or without gel plasma separator (e.g., green closure)
(5) EDTA (e.g., lavender closure)
(6) Glycolytic inhibitor (e.g., gray closure)

NOTE: The order of draw has been revised to reflect the increased use of plastic blood collection tubes. Plastic serum tubes containing a clot activator may cause interference in coagulation testing. Glass non-additive serum tubes may be drawn before the coagulation tube.

NOTE: When using a winged blood collection set for venipuncture and a coagulation tube is the first tube to be drawn, a discard tube should be drawn first. The discard tube must be used to fill the blood collection tubing dead space and to assure maintenance of the proper anticoagulant/blood ratio and need not be completely filled. The discard tube should be a nonadditive or a coagulation tube.

8.10.3 Coagulation Testing

Studies have shown that the PT (INR) and APTT results are not affected if tested on the first tube drawn.[16-18] Since it is not known whether other coagulation testing is affected, it may be advisable to draw a second tube for other coagulation assays. When a syringe system is used and a large specimen is taken, part of the blood from the second syringe should be used for the coagulation specimen. In the case of any unexplained abnormal coagulation test result, a new specimen should be obtained and the test repeated. If heparin contamination is suspected, the test should be repeated after the specimen is treated with a method that removes or neutralizes heparin. For more detailed descriptions of collection for coagulation testing, see the most current edition of NCCLS document H21—*Collection, Transport, and Processing of Blood Specimens for Coagulation Testing and General Performance of Coagulation Assays*.

8.11 Step 11: Release the Tourniquet

Release the tourniquet as soon as possible after the blood begins to flow.

8.12 Step 12: Place the Gauze Pad

A clean gauze pad should be placed lightly over the venipuncture site. Cotton balls are not recommended because of the possibility of dislodging the platelet plug at the venipuncture site.

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8.13 Step 13: Remove and Dispose of the Needle

Remove the needle and activate the safety mechanism according to the device manufacturer's instructions. Safely dispose of the unit into an easily accessible sharps container, consistent with OSHA regulations. Needles should not be resheathed, bent, broken, or cut, nor should they be removed from disposable syringes unless attaching a safety transfer device prior to disposal. Phlebotomists should anticipate a loss of consciousness and be prepared to react according to institutional policy. The use of ammonia inhalants may be associated with untoward effects and is not recommended. (See Section 11.8.1).

8.14 Step 14: Bandage the Arm

8.14.1 Normal Conditions

Under normal conditions, the phlebotomist should:

(1) Place the gauze pad over the site, continuing mild pressure.

(2) Check that bleeding has ceased, observe for hematoma, and apply an adhesive or gauze bandage over the venipuncture site. It is recommended that hypoallergenic adhesives be available.

(3) Tell patient to leave the bandage on for at least 15 minutes.

8.14.2 Continued Bleeding

The phlebotomist should watch for excessive bleeding. If a hematoma develops or bleeding persists longer than five minutes, a nurse should be alerted so that the attending physician can be notified. Pressure, applied with a gauze pad, must continue at the site as long as necessary to stop the bleeding. Wrap a gauze bandage tightly around the arm to keep the pad in place and tell the patient to leave the bandage on the site for at least 15 minutes.

8.15 Step 15: Label Blood Collection Tubes and Record Time of Collection

The patient and the patient's blood specimen must be positively identified at the time of collection. Blood specimens must be obtained in tubes identified with a firmly attached label bearing at least the following:

- The patient's first and last names
- An identification number
- The date
- The time (as required, e.g., therapeutic drug monitoring)
- The identification of the person collecting specimen.

The completed label must be attached to the tube before leaving the side of the patient, and there must be a mechanism to identify the person who drew the blood.[8] Alternatively, the manufacturer's tube label can be inscribed with the patient's complete information. Blood bank specimens must be labeled according to the standards set by the American Association of Blood Banks (AABB).

If an encoded (bar code) label is used, attach the label according to established institutional policy.

A permanent record is needed by the physician who must know exactly when each specimen was drawn to correlate the results with any change in the patient's condition. The laboratory also must document the

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time when the specimen was collected. If unable to obtain specimens, a record of the reasons and initials of the venipuncturist are necessary.

8.16 Step 16: Chill the Specimen (This is done only for certain specimens.)

Some tests require that blood specimens be cooled immediately following the venipuncture to slow down metabolic processes which may alter some test results. For more information on blood specimen handling and processing, see the most current edition of NCCLS document H18—*Procedures for the Handling and Processing of Blood Specimens*.

Examples of tests requiring chilling the specimen are:[19]

- Gastrin
- Ammonia
- Lactic acid
- Catecholamines
- pH/blood gas
- Parathyroid hormone (PTH).

8.17 Step 17: Send Blood Collection Tubes to the Proper Laboratories

Appropriately labeled blood collection tubes should be sent to appropriate laboratories designated to perform the required testing procedures. (See Section 8.15 for recommendations for labeling of tubes.)

9 Venipuncture in Children and Difficult Collections

If a venipuncture is requested on a child younger than one year of age, the phlebotomist should consult with the physician or follow institutional policy. For information on skin puncture blood collection, refer to the most current edition of NCCLS document H4—*Procedures and Devices for the Collection of Diagnostic Blood Specimens by Skin Puncture.*

9.1 Procedure

Except where indicated below, the procedure for venipuncture of adults as described in Section 8 should be followed for pediatric venipuncture.

9.2 Equipment

Venipunctures should be performed using equipment that can help to reduce the stress exerted on a vein to prevent vascular collapse. Examples include a venous blood collection system with a 22- to 23-gauge needle, or a 22- to 23-gauge (winged) blood collection set with attached tubing and venous blood collection tube holder. For pediatric patients, through the age of 16, larger gauge needles may be appropriate.

10 Additional Considerations

10.1 Monitoring Blood Volume Collected

It is recommended that a mechanism be in place to monitor the amount of blood drawn for pediatric and critically ill patients to avoid phlebotomy-induced anemia.

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10.2 Hematoma

To prevent a hematoma when performing a venipuncture, the phlebotomist should:

- Make sure the needle fully penetrates the uppermost wall of the vein (partial penetration may allow blood to leak into the soft tissue surrounding the vein by way of the needle bevel).
- Remove the tourniquet before removing the needle.
- Use the major superficial veins.
- Hold the venous blood collection assembly still while collecting the specimen.
- Before bandaging, ensure that the puncture to the vein has sealed by observing for hematoma formation after pressure is released.
- Apply a small amount of pressure to the area with the gauze pad when bandaging the arm.

10.3 Hemolysis

To prevent hemolysis when performing a venipuncture, the phlebotomist should:

- After cleansing, allow the venipuncture site to air dry.
- Never draw blood through a hematoma.
- If using a syringe, make sure the needle is fitted securely on a syringe to avoid frothing.
- When using a syringe and needle, avoid drawing the plunger back too forcibly.
- Gently invert the blood collection tube to mix additive specimens as recommended by the manufacturer.

11 Special Situations

11.1 Timed Intervals

Some specimens must be drawn at timed intervals because of medications, fasting requirements, and/or biological variations (circadian rhythm). It is important that collection of specimens for timed tests be obtained at the precisely specified interval. Directions should be given to the venipuncture team to obtain these specimens accurately.

11.1.1 Examples of Tests Requiring Timed Specimens

- Tolerance tests (e.g., two-hour postprandial glucose and three-hour glucose tolerance test), cortisol
- Therapy monitoring (e.g., prothrombin time, APTT, digoxin, and other drugs)

11.1.2 Documentation

For therapeutic drug monitoring, the dose of the medication and the time of the last dose given, as well as the time of the specimen collection, should be recorded accurately on the request slip.

11.2 Specific Collection Techniques

11.2.1 Blood Alcohol

When drawing a blood specimen for alcohol testing, a nonalcohol-based cleanser should be used to cleanse the venipuncture site (e.g., soap). (See the most current edition of NCCLS document T/DM6—*Blood Alcohol Testing in the Clinical Laboratory* for further information.)

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11.2.2 Legal Specimens

Appropriate chain-of-custody procedure should be followed. (See NCCLS document T/DM6—*Blood Alcohol Testing in the Clinical Laboratory*.)

11.2.3 Blood Culture Specimens

There are time and temperature requirements to be followed in collection, transport and storage of specimens for blood culture. In addition, there are variations in the volume of blood needed for culture. In general, adult blood cultures require 10 to 20 mL/set and infant blood cultures are done on 1 to 2 mL/set.[7] Please refer to the manufacturer's instructions for specific blood volume requirements. These requirements may vary considerably depending on the device.

11.2.4 Trace Elements

For collection of blood for trace elements testing (e.g., zinc) special, metal-free collection containers should be used. (See the most current edition of NCCLS document C38—*Control of Preanalytical Variation in Trace Element Determinations*, for more information.)

11.2.5 Immunohematology Specimens

Gel separator tubes must not be used for immunohematology specimens.[8] It is important to refer to manufacturer's package inserts for collection tubes and for test methods for other possible gel tube application limitations.

11.3 Indwelling Lines or VADs

A line is a piece of tubing inserted into a patient's vein or artery for administering fluids and medications, monitoring pressures, and obtaining blood samples for diagnostic tests. Without complete, thorough and documented training, it is not recommended that phlebotomists draw blood from indwelling cardiovascular (arterial, central venous) or umbilical lines. Institutional policy should be followed.

NOTE: Under certain circumstances, blood specimens for clinical laboratory testing may be drawn from a vascular access device (VAD) using a blood collection system or a syringe. When obtaining a blood specimen from a VAD, the components of the blood collection system (VAD, connecting device, syringe, needle, and collection device) should be checked to ensure compatibility to avoid air leaks, which may cause hemolysis and incorrect draw volumes. Collection of the blood through lines that have been previously flushed with heparin should be avoided, if possible. If the blood must be drawn through a VAD, possible heparin contamination and specimen dilution should be considered. The line should be flushed with 5 mL of saline, and the first 5 mL of blood or six dead space volumes of the VAD discarded.

11.3.1 Potential Error

Obtaining blood specimens from indwelling lines or VADs may be a problem and a potential source of test error because of incomplete flushing of collection site resulting in contamination and/or dilution of the specimen contributing to inaccurate results.[20-22]

11.3.2 Flushing Lines

Because it is normal practice to flush lines with a solution to reduce the risk of thrombosis, lines must be cleared of this fluid before blood specimens can be drawn for diagnostic testing. An adequate amount of blood must be withdrawn from the line and discarded before drawing a specimen to ensure that the actual specimen is not diluted or contaminated with the flush solution. Discard volume is dependent on the dead

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space volume of the particular line. Discarding two times the dead-space volume is recommended for noncoagulation testing, and 5 mL or six times the dead-space volume for coagulation tests.[20,23-25] (For additional information, please refer to the most current edition of NCCLS document H21—*Collection, Transport, and Processing of Blood Specimens for Coagulation Testing and General Performance of Coagulation Assays.*) See the "NOTE" in Section 11.3 for specific recommendations for coagulation testing specimens with line draws.

11.4 Heparin or Saline Locks

An indwelling winged infusion set can be successfully left in a vein from 36 to 48 hours for intravenous administration of medication or as a vein source to obtain a blood specimen. This procedure, known as a "heparin or saline lock," has become more common in hospitals to "save" veins for therapeutic use and also to cause less trauma to the patient. With this system, it is not necessary to keep the vein open with a continuous intravenous infusion, thus allowing the patient more comfort and mobility.

11.5 Fistula

A fistula is an artificial shunt connection done by a surgical procedure to fuse the vein and artery together. It is used for dialysis only.

An arm with a fistula should not be used routinely for blood drawing. When possible, specimens should be drawn from the opposite arm. Care must be taken of the fistula, as it is permanent.

11.6 Intravenous Fluids

Skin puncture is recommended when venous access is not readily available. (See the most current edition of NCCLS document H4—*Procedures and Devices for the Collection of Diagnostic Blood Specimens by Skin Puncture* for more information.)

When an intravenous fluid (including transfused blood products) is being administered in a patient's arm, blood should not be drawn from that arm if at all possible. Test results from this blood may be erroneous and thus misleading to the physician.

Satisfactory specimens may be drawn distal to the intravenous infusion site. If this is not possible, a specimen may be obtained from a proximal site.[13,26] However, it has been shown that blood drawn proximal to the intravenous site can be contaminated with the fluid being administered. Facilities should establish their own policy. The collection procedure is as follows:

(1) Ask the responsible caregiver for the intravenous infusion to be turned off for at least two minutes before venipuncture. Care should be taken to ensure that the flow has been completely discontinued.

(2) Apply the tourniquet. When drawing distal to the intravenous infusion site, apply the tourniquet between the intravenous and the intended venipuncture site.

(3) Perform the venipuncture.

It must be documented that the venipuncture was performed proximal or distal to an infusion site and from which arm.

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11.7 Isolation

Patients are isolated to prevent disease from spreading to other patients, visitors, or employees.[27] Some hospitals may also provide a different, protective isolation for patients who could be placed at increased risk from outside contamination.

11.7.1 Isolation Systems

Each hospital determines the system which best provides for their particular mix of patients, visitors, and employees. In most cases, a color-coded card placed just outside the patient's room describes the type of isolation and the precautions to be taken by those entering the room. It is important to understand and use the appropriate precautions.

11.7.1.1 Types of Isolation

Recent guidance emphasizes two tiers of infection control precautions[27]:

- standard, to be used for all patients, and
- transmission-based.

There are three types of transmission based isolation precautions[23]:

- airborne,
- droplet, and
- contact.

Hospitals have protocols for isolation procedures available through their infection control practitioner, infection control committee, or hospital epidemiologist. The example given in Sections 11.7.1.2 through 11.7.2 is an example of such a protocol. Some hospitals may provide for disinfection, dedication or disposal of equipment used in isolation rooms.

11.7.1.2 Clean Area

Gowns, gloves, masks, etc., are kept in a clean area. In some hospitals, a stand containing these supplies is kept outside the room. The new modern hospital often has an anteroom which serves as the "clean area." Here, the person entering the room can gown and apply other protective barriers as necessary before entering the patient's room. Doctors' suit coats, jackets, and other apparel are left here.

11.7.2 Isolation Room

11.7.2.1 Procedures to Follow Before Entering the Isolation Room

(1) Read the isolation sign on the door. It will explain the type of isolation, protective clothing to be worn, and the procedure to follow. Follow these instructions carefully.

(2) Check the orders and assemble an adequate amount of necessary equipment for the patient.

NOTE: Any supplies taken into the room must be left there, or discarded.

(3) Never take trays into the isolation room.

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11.7.2.2 Procedures to Follow in an Isolation Room

(1) Place paper towels on the table and place the equipment on one or two towels that have been spread open.

(2) Wash hands.

(3) Put on gloves.

(4) Obtain blood specimens in the usual manner, avoiding any unnecessary contact with the patient and bed.

(5) After mixing, place the filled tubes on a clean paper towel.

(6) Dispose of blood collection assembly into an easily accessible, approved puncture resistant disposal container, consistent with OSHA regulations, according to institutional policy.

NOTE: Recapping of needle is not recommended. (See the most current edition of NCCLS publication M29—*Protection of Laboratory Workers from Occupationally Acquired Infections*.)

(7) Dispose of the tourniquet in the proper container.

(8) Remove gown and gloves and dispose of them in the proper container.

(9) Wash hands.

(10) Turn off the faucet with a clean paper towel so that hands are not contaminated.

(11) Pick up the tubes from the paper towel and clean the outside of the tube with 1:10 dilution of bleach. Place tubes in a secondary container, which will contain the specimen if the primary container breaks or leaks in transit to the laboratory. A plastic bag with a sealable, leakproof closure can be used.

(12) If blood smears were made, place the smears on two clean paper towels. When ready to leave, wrap the smears and tubes in the top paper towel and discard the bottom paper towel and place in a secondary container.

11.7.3 Exposure

The phlebotomist must immediately report an accidental needlestick or contamination of a break in the skin by blood or excreta to a supervisor, and follow institutional guidelines. (See also NCCLS document M29—*Protection of Laboratory Workers from Occupationally Acquired Infections*.)

11.8 Emergency Situations

At least one member of available on-site healthcare personnel should have extensive first aid training, including special training in cardiopulmonary resuscitation, so that medical attention can be given to a needy patient while the physician on call is en route. This individual should be identified to phlebotomists. Emergency numbers should be posted in phlebotomy drawing areas.

11.8.1 Syncope (Fainting) or Unexpected Nonresponsiveness

The procedure for dealing with a patient who has fainted or is unexpectedly nonresponsive is to:

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EXAMINER	
NGUYEN, HUONG Q	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Docket_IP@pillsburylaw.com

Office Action Summary	Application No. 17/893,079	Applicant(s) ROGERS et al.	
	Examiner Huong Q NGUYEN	Art Unit 3791	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 8/22/2022.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL.** 2b) ☑ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 1-30 is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 1-30 is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to **PPHfeedback@uspto.gov.**

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☑ The drawing(s) filed on 8/22/02022 is/are: a)☐ accepted or b)☑ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☑ Notice of References Cited (PTO-892)

2) ☐ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

DETAILED ACTION

It noted that there are two claims numbered 15. The second of which has been renumbered as Claim 16, and all others following have been renumbered accordingly. Thus, there are 31 claims in total and the claims are referred to by the new numbering.

Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Information Disclosure Statement

It is noted that no IDS has been submitted. Applicant is reminded of the duty to disclose all known prior art resulting from all prior art searches.

Drawings

The drawings are objected to under 37 CFR 1.83(a) because they fail to show the structural components to enable the fluid controller to move from a first to a second position as described in the specification and in **Claims 6, 9, 24, and 27**. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended

drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Interpretation

The following is a quotation of 35 U.S.C. 112(f):

> (f) Element in Claim for a Combination. – An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

The following is a quotation of pre-AIA 35 U.S.C. 112, sixth paragraph:

> An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

The claims in this application are given their broadest reasonable interpretation using the plain meaning of the claim language in light of the specification as it would be understood by one of ordinary skill in the art. The broadest reasonable interpretation of a claim element

(also commonly referred to as a claim limitation) is limited by the description in the specification when 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is invoked.

As explained in MPEP § 2181, subsection I, claim limitations that meet the following three-prong test will be interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph:

(A) the claim limitation uses the term "means" or "step" or a term used as a substitute for "means" that is a generic placeholder (also called a nonce term or a non-structural term having no specific structural meaning) for performing the claimed function;

(B) the term "means" or "step" or the generic placeholder is modified by functional language, typically, but not always linked by the transition word "for" (e.g., "means for") or another linking word or phrase, such as "configured to" or "so that"; and

(C) the term "means" or "step" or the generic placeholder is not modified by sufficient structure, material, or acts for performing the claimed function.

Use of the word "means" (or "step") in a claim with functional language creates a rebuttable presumption that the claim limitation is to be treated in accordance with 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph. The presumption that the claim limitation is interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is rebutted when the claim limitation recites sufficient structure, material, or acts to entirely perform the recited function.

Absence of the word "means" (or "step") in a claim creates a rebuttable presumption that the claim limitation is not to be treated in accordance with 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph. The presumption that the claim limitation is not interpreted under

35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is rebutted when the claim limitation recites function without reciting sufficient structure, material or acts to entirely perform the recited function.

Claim limitations in this application that use the word "means" (or "step") are being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, except as otherwise indicated in an Office action. Conversely, claim limitations in this application that do not use the word "means" (or "step") are not being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, except as otherwise indicated in an Office action.

This application includes one or more claim limitations that do not use the word "means," but are nonetheless being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, because the claim limitation(s) uses a generic placeholder that is coupled with functional language without reciting sufficient structure to perform the recited function and the generic placeholder is not preceded by a structural modifier. Such claim limitation(s) is/are:

First flow controller (Claim 9, 12, 26, 27 – defined in specification by air permeable blood barrier 0060)

Second flow controller that is movable between first and second position (Claim 6, 9, 13, 23, 26, 28 – Figure 24, element 2419).

Because this/these claim limitation(s) is/are being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, it/they is/are being interpreted to cover the corresponding structure described in the specification as performing the claimed function, and equivalents thereof.

If applicant does not intend to have this/these limitation(s) interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, applicant may: (1) amend the claim limitation(s) to avoid it/them being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph (e.g., by reciting sufficient structure to perform the claimed function); or (2) present a sufficient showing that the claim limitation(s) recite(s) sufficient structure to perform the claimed function so as to avoid it/them being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112(a):

> (a) IN GENERAL.—The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.

The following is a quotation of the first paragraph of pre-AIA 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6, 8, 9, 13, 24, and 26-31 are rejected under 35 U.S.C. 112(a) or 35 U.S.C. 112 (pre-AIA), first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor or a joint inventor, or

for applications subject to pre-AIA 35 U.S.C. 112, the inventor(s), at the time the application was filed, had possession of the claimed invention.

In regard to Claims 6, 9, 24, 27, per the drawing objections and 112(b) rejection below, it is unclear that applicant has proper support for the entire structural mechanism of the flow controller that is movable from a first position to a second position through a pressure differential.

While Figure 24B shows inner chamber housing 2419 that is movable from a first position to second position (0141), it is unclear both from the drawings and the limited disclosure how this occurs structurally. For example, there are no details provided or explanation of the structural connection between the inner chamber housing 2419, the apertures 2424, and the housing 2416 that enable movement of said inner chamber housing 2419 *from the first position*. Further, though paragraph 0142 states that as the blood contacts blood barrier 2420, this forces the inner chamber housing 2419 to the second position, it is again unclear how the inner chamber housing 2419 structurally moves to the second position from the first. Again, while paragraph 0143 describes tangs 2421 to stop the inner chamber housing 2419 in the second position, this does not provide any information about how the chamber moved from the first position.

Claims 8, 13, 26, and 29 recite that a pressure differential moves the inner chamber housing. However, as elaborated above, the details of this have not been provided to sufficiently describe the mechanics of said movement from the first position to the second position. As this mechanism is the crux of the embodiment in Figure 24 which are recited in the claims, the claims are therefore not properly supported by the disclosure.

> The following is a quotation of 35 U.S.C. 112(b):
> (b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.
>
> The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph:
> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-31 are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor (or for applications subject to pre-AIA 35 U.S.C. 112, the applicant), regards as the invention.

In regard to Claims 1 and 18, the recitation of "an air permeable bodily fluid resistor" is indefinite. Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999).

The term "resistor" in claims 1 and 18 is used by the claim to mean "an air permeable blood barrier" (see paragraph 0060 of publication – listed as known in the art to include membranes, coatings, mesh, filter, valve, etc.) while the accepted meaning is "a specific electrical circuit component" The term is indefinite because the specification does not clearly redefine the term. In fact, the specification does not use the term "resistor" at all. Therefore, the use of the term above is unclear because a skilled artisan would not reasonably be able to ascertain its desired meaning from the limitation.

In the rejection that follows, it is assumed that the term "an air permeable bodily fluid resistor" refers to the air permeable blood barrier as disclosed in the specification. However, clarification and correction are required.

In regard to Claims 6, 9, 23, 26, per the drawing objections and 112(a) rejection above, it is unclear how the flow controller that is movable from a first position to a second position through a pressure differential is structured to enable such functioning.

While Figure 24B shows inner chamber housing 2419 that movable from a first position to second position (0141), it is unclear both from the drawings and the limited disclosure how this occurs structurally. For example, there are no details provided or explanation of the structural connection between the inner chamber housing 2419, the apertures 2424, and the housing 2416 that enable movement of said inner chamber housing 2419 *from the first position*. Further, though paragraph 0142 states that as the blood contacts blood barrier 2420, this forces the inner chamber housing 2419 to the second position, it is again unclear how the inner chamber 2419 structurally moves to the second position from the first. Again, while paragraph 0143 describes tangs 2421 to stop the inner chamber housing 2419 in the second position, this does not provide any information about how the chamber moved from the first position.

Claims 8, 13, 25, and 28 recite that a pressure differential moves the inner chamber housing. However, as elaborated above, the details of this have not been provided to sufficiently describe the mechanics of said movement from the first position to the second position. As this mechanism is the crux of the embodiment in Figure 24 which are recited in the

claims, the claims are therefore indefinite because a skilled artisan cannot ascertain how the invention operates as claimed.

In regard to Claims 4, 6, 21, and 23, the recitation of "the connection" between the sample path and the inlet lacks proper antecedent basis. Correction is requested.

In regard to Claims 18 and 26, the recitation of "a bodily fluid source comprising a venipuncture device" is indefinite because it is unclear how a venipuncture device may provide a body fluid source as claimed. As known to a skilled artisan in the art, venipuncture devices are used to collect blood from human veins but the devices themselves are not sources of fluid. The specification also does not appear to provide support for a structure within the venipuncture device that provides a source of body fluid other than from the human body itself. Furthermore, applicant is reminded that it is human body parts are not eligible subject matter. Clarification is requested.

It is also noted that there are two claims numbered 15. The second of which has been renumbered as Claim 16, and all others following have been renumbered accordingly. Thus, there are 31 claims in total. Correction of the misnumbering including claim dependencies is requested.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a)(1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention.

Claim(s) 1-5 and 19-23 is/are rejected under 35 U.S.C. 102(a)(1) as being anticipated by Haynes et al (US Pat No. 4980297).

In regard to Claim 1, Haynes et al disclose a bodily fluid sample optimization device for optimizing a bodily fluid sample collected by a bodily fluid collection device 63 from a bodily fluid source (vein Figure 16-17), a first portion of the bodily fluid sample potentially having contaminants, the bodily fluid sample optimization device comprising:

an inlet 61 configured to connect with the bodily fluid source, best seen in Figure 9 (Col.7: 15-Col.8: 68);

an outlet 62 configured to connect with the bodily fluid collection device 63, best seen in Figure 9 (Col.7: 15-Col.8: 68; Col.9: 3-46);

a sample path 54 between the inlet and the outlet, best seen in Figure 17 (Col.7: 15-Col.8: 68; Col.9: 3-46); and

a contaminant containment reservoir 55/55a between the inlet and the outlet, the contaminant containment reservoir having an air permeable bodily fluid resistor 112 (Figure 24) proximate the outlet, best seen in Figure 15-18 and 24 (Col.7: 15-Col.8: 68; Col.12: 38-Col.13: 17),

the contaminant containment reservoir being arranged to receive, when a pressure differential is applied between the inlet and the outlet (vacuum force – Col.9: 3-46), a first portion of the bodily fluid sample from the bodily fluid source via the inlet to displace air in the

contaminant containment reservoir through the air permeable bodily fluid resistor and the outlet (Col.9: 3-46; Col.11: 18-50; Col.12: 38-Col.13: 17),

such that upon receipt of the first portion of the bodily fluid sample and containment of the contaminants in the contaminant containment reservoir, subsequent portions of the bodily fluid sample can be conveyed by the sample path from the inlet to the outlet 62 and to the bodily fluid collection device 63, best seen in Figure 15-18 (Col.9: 3-46).

2, 20. The bodily fluid sample optimization device in accordance with claim 1, further including a housing 48, 49 that defines the inlet 61 and the outlet 62, and contains the sample path 54 and the contaminant containment reservoir 55, and wherein the housing does not vent to atmosphere when the outlet is connected with the bodily fluid collection device, best seen in Figure 9 and 15-18 (Col.7: 15-Col.8: 68; Col.9: 3-46; Col.11: 18-50; Col.12: 38-Col.13: 17).

3, 21. The bodily fluid sample optimization device in accordance with claim 1, wherein the pressure differential applied between the inlet 61 and the outlet 62 is applied by a vacuum of the bodily fluid collection device relative to a pressure of the bodily fluid source (Col.9: 3-46).

4, 22. The bodily fluid sample optimization device in accordance with claim 1, wherein the connection between the sample path 54 and the inlet 61 is made when the contaminant containment reservoir 55 receives the first portion of the bodily fluid sample (Col.9: 3-46).

5, 23. The bodily fluid sample optimization device in accordance with claim 1, wherein once the first portion is received in the contaminant containment reservoir 55, a resistance to a flow of the subsequent portions of the bodily fluid sample in the contaminant containment reservoir is higher than a resistance in the sample path due to the pressure (Col.9: 3-46).

In regard to Claim 19, Haynes et al disclose a patient bodily fluid sample optimization system comprising:

a bodily fluid source comprising a venipuncture device 58 configured for venipuncture of the patient, best seen in Figure 15-18;

a bodily fluid collection device 63 comprising a sealed collection needle 69 (Figures 21-22 show sleeve 105 – Col.11: 18-50) on which an evacuated tube 63, 80 can be placed to draw the patient bodily fluid with a pressure differential between the evacuated tube and the patient (Col.7: 15-Col.8: 68; Col.9: 3-46; Col.11: 18-50; Col.12: 38-Col.13: 17); and

a bodily fluid sample optimization device comprising:

an inlet 61 configured to connect with the bodily fluid source, best seen in Figure 9 (Col.7: 15-Col.8: 68);

an outlet 62 configured to connect with the bodily fluid collection device, best seen in Figure 9 (Col.7: 15-Col.8: 68; Col.9: 3-46);

a sample path 54 between the inlet and the outlet, best seen in Figure 17 (Col.7: 15-Col.8: 68; Col.9: 3-46); and

a contaminant containment reservoir 55/55a between the inlet and the outlet, the contaminant containment reservoir having an air permeable bodily fluid resistor 112 (Figure 24) proximate the outlet, best seen in Figure 15-18 and 24 (Col.7: 15-Col.8: 68; Col.12: 38-Col.13: 17),

the contaminant containment reservoir being arranged to receive, when the pressure differential is formed between the inlet and the outlet (vacuum force – Col.9: 3-46), a first portion of the bodily fluid sample from the bodily fluid source via the inlet to displace air in the

contaminant containment reservoir through the air permeable bodily fluid resistor and the outlet (Col.9: 3-46; Col.11: 18-50; Col.12: 38-Col.13: 17),

such that upon receipt of the first portion of the bodily fluid sample and containment of the contaminants in the contaminant containment reservoir, subsequent portions of the bodily fluid sample can be conveyed by the sample path from the inlet to the outlet 62and to the bodily fluid collection device 63, best seen in Figure 15-18 (Col.9: 3-46).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries for establishing a background for determining obviousness under 35 U.S.C. 103 are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims the examiner presumes that the subject matter of the various claims was commonly owned as of the effective filing date of the claimed invention(s) absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and effective filing dates of each claim that was not commonly owned as of the effective filing date of the later invention in order for the examiner to consider the applicability of 35 U.S.C. 102(b)(2)(C) for any potential 35 U.S.C. 102(a)(2) prior art against the later invention.

Claim(s) 6-8 and 24-26 is/are rejected under 35 U.S.C. 103 as being unpatentable over Haynes et al as applied to claims 1 and 18 above, further in view of Eldridge (US Pat No. 4207870).

Haynes et al disclose the invention above but do not expressly disclose a flow controller that is movable from a first position to a second position.

Eldridge teach an analogous fluid sampling device comprising a flow controller 22 that is movable from a first position to a second position to effectively enable flow of the body fluid only once the evacuated tube has been attached as well as preventing backflow of the body fluid once the sampling has concluded, best seen in Figure 1 and 3 (Col.2: 57-Col.3: 62).

6, 24. The bodily fluid sample optimization device in accordance with claim 4, wherein the contaminant containment reservoir includes a flow controller 22 that is movable from a first position to enable the contaminant containment reservoir to receive, when the pressure differential is applied between the inlet and the outlet, the first portion of the bodily fluid

sample from the bodily fluid source via the inlet, to a second position to open the connection between the sample path and the inlet to allow the subsequent portions of the bodily fluid sample to be conveyed by the sample path from the inlet to the outlet and to the bodily fluid collection device, best seen in Figure 1 and 3 (Col.2: 57-Col.3: 62).

7, 25. The bodily fluid sample optimization device in accordance with claim 6, wherein movement of the flow controller exposes at least one aperture between the inlet and the sample path (after valve skirt 22 opens), best seen in Figure 1 and 3 (Col.2: 57-Col.3: 62).

8, 26. The bodily fluid sample optimization device in accordance with claim 6, wherein the flow controller is movable by the pressure differential, best seen in Figure 1 and 3 (Col.2: 57-Col.3: 62).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of filing to modify Haynes et al such that there is included a flow controller that is movable from a first position to a second position as taught by Eldridge above to effectively enable flow of the body fluid only once the evacuated tube has been attached as well as preventing backflow of the body fluid once the sampling has concluded.

Claim(s) 9-12, 14-18, 27-28, and 30-31 is/are rejected under 35 U.S.C. 103 as being unpatentable over Haynes et al in view of Bullington et al (US Pub No. 20140155781).

In regard to Claim 9, Haynes et al disclose a bodily fluid control device comprising:

an inlet 61 fluidically coupleable to a bodily fluid source (vein, Figure 16-17), best seen in Figure 9 (Col.7: 15-Col.8: 68);

an outlet 62 fluidically coupleable to a bodily fluid sample collection device 63, and to allow a negative pressure differential between the outlet and the inlet when the outlet is fluidically coupled to the bodily fluid sample collection device, best seen in Figure 9 (Col.7: 15-Col.8: 68; Col.9: 3-46);

a sampling channel 54 between the inlet and the outlet, best seen in Figure 17 (Col.7: 15-Col.8: 68; Col.9: 3-46);

a containment chamber 55/55a between the inlet and the outlet, the containment chamber having a first flow controller 112 (Figure 24) that allows air to flow from the containment chamber to the outlet by the negative pressure differential between the outlet and the inlet, best seen in Figure 15-18 and 24 (Col.7: 15-Col.8: 68; Col.12: 38-Col.13: 17),

such that a first volume of bodily fluid is drawn from the inlet into the containment chamber, and to prevent the first volume of bodily fluid from flowing to the outlet (plasma in receiving portion 55/55a is collected by tube 80, not 63), best seen in Figure 15-18 (Col.9: 3-46).

However, Haynes et al do not expressly disclose a second flow controller that is movable from a first position as the first volume of bodily fluid is drawn from the inlet into the containment chamber, to a second position to allow subsequent volumes of bodily fluid from the inlet to bypass the containment chamber via the sampling channel and to the outlet and the bodily fluid sample collection device.

Bullington et al teach that it is well-known in the art to provide an analogous body sampling device comprising a flow controller 120, 130, 140 that is movable from a first position

as the first volume of bodily fluid is drawn from the inlet into a containment chamber 170, to a second position to allow subsequent volumes of bodily fluid from the inlet to bypass the containment chamber via the sampling channel and to the outlet and the bodily fluid sample collection device 180 (0006, 0054). Bullington et al teach that in the second position, fluid is directed into a second reservoir 180 and bypassing a first reservoir 170, which must be used first. This enables controlled sampling to reduce contamination of the sample by requiring isolation of the first volume of the collected body fluid in the first reservoir initially. (0002-0004).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of filing to modify Haynes et al such that there is included a second flow controller that is movable from a first position as the first volume of bodily fluid is drawn from the inlet into the containment chamber, to a second position to allow subsequent volumes of bodily fluid from the inlet to bypass the containment chamber via the sampling channel and to the outlet and the bodily fluid sample collection device, as taught by Bullington et al to effectively reduce contamination of the sample by requiring isolation of the first volume of the collected body fluid in the first reservoir initially.

10. Haynes et al disclose the bodily fluid control device in accordance with claim 9, wherein the bodily fluid source includes a patient needle 58, best seen in Figure 15-19.

11. Haynes et al disclose the bodily fluid control device in accordance with claim 9, wherein the bodily fluid sample collection device includes a sealed collection needle 69 (Figures

21-22 show sleeve 105 – Col.11: 18-50) on which an evacuated tube 63, 80 can be placed (Col.7: 15-Col.8: 68; Col.9: 3-46; Col.11: 18-50; Col.12: 38-Col.13: 17).

12. Haynes et al disclose the bodily fluid control device in accordance with claim 9, wherein the first flow controller 112 includes an air permeable blood barrier that seals upon contact with bodily fluid, best seen in Figure 24 (Col.12: 38-Col.13: 17).

14. Haynes et al disclose the bodily fluid control device in accordance with claim 9, further including a housing 48, 49 that defines the inlet 61 and the outlet 62, and wherein the housing contains the containment chamber 55 and the sampling channel 54, best seen in Figure 9 and 17 (Col.7: 15-Col.8: 68; Col.9: 3-46).

15. Haynes et al disclose the bodily fluid control device in accordance with claim 14, wherein the housing 48, 49 does not vent to atmosphere when the inlet 61 is fluidically coupleable to the bodily fluid source and the outlet 62 is fluidically coupled to the bodily fluid sample collection device 63 (Col.7: 15-Col.8: 68; Col.9: 3-46).

16. Haynes et al disclose the bodily fluid control device in accordance with claim 9, wherein the negative pressure differential applied between the inlet 61 and the outlet 62 is applied by a vacuum of the bodily fluid sample collection device relative to a pressure of the bodily fluid source (Col.9: 3-46).

17. Haynes et al disclose the bodily fluid control device in accordance with claim 9, wherein a fluidic coupling between the sample path 54 and the inlet 61 is made only after the containment chamber 55 receives the first volume of the bodily fluid (Col.7: 15-Col.8: 68; Col.9: 3-46; Col.11: 18-50; Col.12: 38-Col.13: 17).

18. Haynes et al disclose the bodily fluid control device in accordance with claim 1, wherein once the first portion is received in the containment chamber 55, a resistance to a flow of the subsequent volumes of the bodily fluid in the containment chamber is higher than a resistance in the sampling channel due to the pressure (Col.9: 3-46).

In regard to Claim 27, Haynes et al disclose a patient bodily fluid control system comprising:

a bodily fluid source comprising venipuncture device 58 for venipuncture to the patient, best seen in Figure 9;

a bodily fluid sample collection device 63, 80 comprising a sealed collection needle 69 (Figures 21-22 show sleeve 105 – Col.11: 18-50) on which an evacuated tube 63, 80 can be placed to draw the patient bodily fluid with a pressure differential between the evacuated tube and the patient (Col.7: 15-Col.8: 68; Col.9: 3-46; Col.11: 18-50; Col.12: 38-Col.13: 17); and

a bodily fluid control device comprising:

an inlet 61 fluidically coupleable to the bodily fluid source, best seen in Figure 9 (Col.7: 15-Col.8: 68);

an outlet 62 fluidically coupleable to a bodily fluid sample collection device, and to allow a negative pressure differential between the outlet and the inlet when the outlet is fluidically coupled to the bodily fluid sample collection device, best seen in Figure 9 and 15-18 (Col.7: 15-Col.8: 68; Col.9: 3-46);

a sampling channel 54 between the inlet and the outlet, best seen in Figure 17 (Col.7: 15-Col.8: 68; Col.9: 3-46);

a containment chamber 55/55a between the inlet and the outlet, the containment chamber having a first flow controller 112 (Figure 24) that allows air to flow from the containment chamber to the outlet by the negative pressure differential between the outlet and the inlet, best seen in Figure 15-18 and 24 (Col.7: 15-Col.8: 68; Col.12: 38-Col.13: 17),

such that a first volume of bodily fluid is drawn from the inlet into the containment chamber, and to prevent the first volume of bodily fluid from flowing to the outlet (plasma in receiving portion 55/55a is collected by tube 80, not 63), best seen in Figure 15-18 (Col.9: 3-46).

However, Haynes et al do not expressly disclose a second flow controller that is movable from a first position as the first volume of bodily fluid is drawn from the inlet into the containment chamber, to a second position to allow subsequent volumes of bodily fluid from the inlet to bypass the containment chamber via the sampling channel and to the outlet and the bodily fluid sample collection device.

Bullington et al teach that it is well-known in the art to provide an analogous body sampling device comprising a flow controller 120, 130, 140 that is movable from a first position as the first volume of bodily fluid is drawn from the inlet into the containment chamber 170, to a second position to allow subsequent volumes of bodily fluid from the inlet to bypass the containment chamber via the sampling channel and to the outlet and the bodily fluid sample collection device 180 (0006, 0054). Bullington et al teach that in the second position, fluid is directed into a second reservoir 180 and bypassing a first reservoir 170, which must be used first. This enables controlled sampling to reduce contamination of the sample by requiring

isolation of the first volume of the collected body fluid in the first reservoir initially. (0002-0004).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of filing to modify Haynes et al such that there is included a second flow controller that is movable from a first position as the first volume of bodily fluid is drawn from the inlet into the containment chamber, to a second position to allow subsequent volumes of bodily fluid from the inlet to bypass the containment chamber via the sampling channel and to the outlet and the bodily fluid sample collection device, as taught by Bullington et al to effectively reduce contamination of the sample by requiring isolation of the first volume of the collected body fluid in the first reservoir initially.

28. Haynes et al disclose the bodily fluid control system in accordance with claim 26, wherein the first flow controller includes an air permeable blood barrier 112 that seals upon contact with bodily fluid, best seen in Figure 24.

30. Haynes et al disclose the bodily fluid control system in accordance with claim 26, further including a housing 48, 49 that defines the inlet 61 and the outlet 62, and wherein the housing contains the containment chamber 55 and the sampling channel 54, best seen in Figure 9 and 15-18 (Col.7: 15-Col.8: 68).

31. Haynes et al disclose the bodily fluid control system in accordance with claim 29, wherein the housing 48, 49 does not vent to atmosphere when the inlet 61 is fluidically coupleable to the bodily fluid source and the outlet 62 is fluidically coupled to the bodily fluid sample collection device 63 (Col.7: 15-Col.8: 68; Col.12: 38-Col.13: 17).

Claim(s) 13 and 29 is/are rejected under 35 U.S.C. 103 as being unpatentable over Haynes et al in view of Bullington et al as applied to Claim 9 above, further in view of Eldridge.

Haynes et al in combination with Bullington et al disclose the invention above but do not expressly disclose the second flow controller that is movable from a first position to a second position by the pressure differential.

Eldridge teach an analogous fluid sampling device comprising a flow controller 22 that is movable from a first position to a second position by a pressure differential to effectively enable flow of the body fluid only once the evacuated tube has been attached as well as preventing backflow of the body fluid once the sampling has concluded, best seen in Figure 1 and 3 (Col.2: 57-Col.3: 62).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of filing to modify Haynes et al as modified by Bullington et al such that the second flow controller is movable from a first position to a second position by the pressure differential as taught by Eldridge above to effectively enable flow of the body fluid only once the evacuated tube has been attached as well as preventing backflow of the body fluid once the sampling has concluded.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on nonstatutory double patenting provided the reference application or patent either is shown to be commonly owned with the examined application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. See MPEP § 717.02 for applications subject to examination under the first inventor to file provisions of the AIA as explained in MPEP § 2159. See MPEP § 2146 *et seq.* for applications not subject to examination under the first inventor to file provisions of the AIA. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO Internet website contains terminal disclaimer forms which may be used. Please visit www.uspto.gov/patent/patents-forms. The filing date of the application in which the form is filed determines what form (e.g., PTO/SB/25, PTO/SB/26, PTO/AIA/25, or PTO/AIA/26) should be used. A web-based eTerminal Disclaimer may be filled out completely

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Claim 1 is rejected on the ground of nonstatutory double patenting as being unpatentable over claim 5 of U.S. Patent No. 9820682.

Although the claims at issue are not identical, they are not patentably distinct from each other because both recite a bodily fluid sample optimization device for optimizing a bodily fluid sample collected by a bodily fluid collection device from a bodily fluid source, a first portion of the bodily fluid sample potentially having contaminants, the bodily fluid sample opti mization device comprising: an inlet configured to connect with the bodily fluid source; an outlet configured to connect with the bodily fluid collection device; a sample path between the inlet and the outlet; and a contaminant containment reservoir between the inlet and the outlet, the contaminant containment reservoir having an air permeable bodily fluid resistor proximate the outlet, the contaminant containment reservoir being arranged to receive, when a pressure differential is applied between the inlet and the outlet (functional use), a first portion of the bodily fluid sample from the bodily fluid source via the inlet to displace air in the contaminant containment reservoir through the air permeable bodily fluid resistor and the outlet (displacement of air necessarily occurs), such that upon receipt of the first portion of the bodily fluid sample and containment of the contaminants in the contaminant containment reservoir, subsequent portions of the bodily fluid sample can be conveyed by the sample path from the inlet to the outlet and to the bodily fluid collection device.

Claims 1 and 18 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 10010282.

Although the claims at issue are not identical, they are not patentably distinct from each other because both recite a patient bodily fluid sample optimization system comprising: a bodily fluid source comprising a venipuncture device configured for venipuncture of the patient; a bodily fluid collection device comprising a sealed collection needle on which an evacuated tube can be placed to draw the patient bodily fluid with a pressure differential between the evacuated tube and the patient; and a bodily fluid sample optimization device comprising: an inlet configured to connect with the bodily fluid source; an outlet configured to connect with the bodily fluid collection device; a sample path between the inlet and the outlet; and a contaminant containment reservoir between the inlet and the outlet, the contaminant containment reservoir having an air permeable bodily fluid resistor proximate the outlet, the contaminant containment reservoir being arranged to receive, when the pressure differential is formed between the inlet and the outlet, a first portion of the bodily fluid sample from the bodily fluid source via the inlet to displace air in the contaminant containment reservoir through the air permeable bodily fluid resistor and the outlet, such that upon receipt of the first portion of the bodily fluid sample and containment of the contaminants in the contaminant containment reservoir, subsequent portions of the bodily fluid sample can be conveyed by the sample path from the inlet to the outlet and to the bodily fluid collection device, wherein air is necessarily displaced in such configuration.

Claim 1 is rejected on the ground of nonstatutory double patenting as being unpatentable over claim 18 of U.S. Patent No. 10143412.

Although the claims at issue are not identical, they are not patentably distinct from each other because both recite a bodily fluid sample optimization device for optimizing a bodily fluid sample collected by a bodily fluid collection device from a bodily fluid source, a first portion of the bodily fluid sample potentially having contaminants, the bodily fluid sample opti mization device comprising: an inlet configured to connect with the bodily fluid source; an outlet configured to connect with the bodily fluid collection device; a sample path between the inlet and the outlet; and a contaminant containment reservoir between the inlet and the outlet, the contaminant containment reservoir having an air permeable bodily fluid resistor proximate the outlet, the contaminant containment reservoir being arranged to receive, when a pressure differential is applied between the inlet and the outlet (functional use), a first portion of the bodily fluid sample from the bodily fluid source via the inlet to displace air in the contaminant containment reservoir through the air permeable bodily fluid resistor and the outlet, such that upon receipt of the first portion of the bodily fluid sample and containment of the contaminants in the contaminant containment reservoir, subsequent portions of the bodily fluid sample can be conveyed by the sample path from the inlet to the outlet and to the bodily fluid collection device.

Claim 1 is rejected on the ground of nonstatutory double patenting as being unpatentable over claim 20 of U.S. Patent No. 11185266.

Although the claims at issue are not identical, they are not patentably distinct from each other because both recite a bodily fluid sample optimization device for optimizing a bodily fluid sample collected by a bodily fluid collection device from a bodily fluid source, a first portion of the bodily fluid sample potentially having contaminants, the bodily fluid sample optimization device comprising: an inlet configured to connect with the bodily fluid source; an outlet configured to connect with the bodily fluid collection device; a sample path between the inlet and the outlet; and a contaminant containment reservoir between the inlet and the outlet, the contaminant containment reservoir having an air permeable bodily fluid resistor proximate the outlet, the contaminant containment reservoir being arranged to receive, when a pressure differential is applied between the inlet and the outlet (functional use), a first portion of the bodily fluid sample from the bodily fluid source via the inlet to displace air in the contaminant containment reservoir through the air permeable bodily fluid resistor and the outlet (displacement of air necessarily occurs), such that upon receipt of the first portion of the bodily fluid sample and containment of the contaminants in the contaminant containment reservoir, subsequent portions of the bodily fluid sample can be conveyed by the sample path from the inlet to the outlet and to the bodily fluid collection device.

Claim 1 is rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-2 of U.S. Patent No. 10827964.

Although the claims at issue are not identical, they are not patentably distinct from each other because both recite a bodily fluid sample optimization device for optimizing a bodily fluid

sample collected by a bodily fluid collection device from a bodily fluid source, a first portion of the bodily fluid sample potentially having contaminants, the bodily fluid sample optimization device comprising: an inlet configured to connect with the bodily fluid source; an outlet configured to connect with the bodily fluid collection device (functional use); a sample path between the inlet and the outlet; and a contaminant containment reservoir between the inlet and the outlet, the contaminant containment reservoir having an air permeable bodily fluid resistor proximate the outlet, the contaminant containment reservoir being arranged to receive, when a pressure differential is applied between the inlet and the outlet (functional use), a first portion of the bodily fluid sample from the bodily fluid source via the inlet to displace air in the contaminant containment reservoir through the air permeable bodily fluid resistor and the outlet (displacement of air necessarily occurs), such that upon receipt of the first portion of the bodily fluid sample and containment of the contaminants in the contaminant containment reservoir, subsequent portions of the bodily fluid sample can be conveyed by the sample path from the inlet to the outlet and to the bodily fluid collection device when the bodily fluid collection device is connected.

Claim 1 is rejected on the ground of nonstatutory double patenting as being unpatentable over claim 8 of U.S. Patent No. 11311219.

Although the claims at issue are not identical, they are not patentably distinct from each other because both recite a bodily fluid sample optimization device for optimizing a bodily fluid sample collected by a bodily fluid collection device from a bodily fluid source, a first portion of the bodily fluid sample potentially having contaminants, the bodily fluid sample optimization

device comprising: an inlet configured to connect with the bodily fluid source; an outlet configured to connect with the bodily fluid collection device; a sample path between the inlet and the outlet; and a contaminant containment reservoir between the inlet and the outlet, the contaminant containment reservoir having an air permeable bodily fluid resistor proximate the outlet, the contaminant containment reservoir being arranged to receive, when a pressure differential is applied between the inlet and the outlet (functional use), a first portion of the bodily fluid sample from the bodily fluid source via the inlet to displace air in the contaminant containment reservoir through the air permeable bodily fluid resistor and the outlet (displacement of air necessarily occurs), such that upon receipt of the first portion of the bodily fluid sample and containment of the contaminants in the contaminant containment reservoir, subsequent portions of the bodily fluid sample can be conveyed by the sample path from the inlet to the outlet and to the bodily fluid collection device.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Huong Q NGUYEN whose telephone number is (571)272-8340. The examiner can normally be reached on 10 am - 6 pm.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert (Tse) Chen can be reached at 5712723672. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

H.Q. NGUYEN
Examiner
Art Unit 3791

/TSE W CHEN/
Supervisory Patent Examiner, Art Unit 3791

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Application Number	18898239
Filing Date	2024-09-26
First Named Inventor	Bobby E. Rogers
Art Unit	
Examiner Name	
Attorney Docket Number	069366-0581370_KUR2C07US

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	Examiner Name	
	Attorney Docket Number	069366-0581370_KUR2C07US

	1	European Patent Application No. EP23155927.9 extended European Search Report dated Jul. 26, 2023, 8 pages.	☐
	2	Office Action (Final Rejection) dated 08/25/2023 for US App. No. 18113710 (pages 1-50)	☐
	3	Notice of Allowance mailed 09-08-2023; Attorney Docket No. 069366-0574153_KUR2C04US. 35 page.	☐
	4	Notice of Allowance mailed 09-14-2023; Attorney Docket No. 069366-0574152_KUR2D02IL. 90 pages.	☐
	5	Office Action (Non-Final Rejection) dated 10/04/2023 for US App. No. 17538990 (pages 1-47)	☐
	6	JP Notice of Allowance mailed 06-20-2023; Attorney Docket No. 069366-0572231_KUR3D01JP. 6 pages.	☐
	7	Examination Report dated Sep. 28, 2023, for European Patent Application No. 22181212.6. 5 pages.	☐
	8	Office Action (Notice of Section 18) dated 12/20/2023 for IL App No. 309380 (pages 1-5).	☐
	9	Notice of Allowance mailed 01-17-2024; Attorney Docket No. 069366-0572201_KUR2C03US. 16 pages.	☐
	10	JP Office Action mailed 02/27/2024; Attorney Docket No. 069366-0575273_KUR2D03JP. 11 pages.	☐
	11	Office Action (Non-Final Rejection) dated 01/25/2024 for IL App. 302893 (pages 1-3).	☐

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	17	Australian Patent Office, Examination Report No. 1 for for Australian Patent Application 2021202622, dated March 18, 2022, 3 pages.	☐
	18	Office Action (Final Rejection) dated 08/25/2023 for US Application No. 18113710 (pages 1-50).	☐
	19	European Patent Office, Extended European Search Report for European Patent Application 23155927.9-1122, dated July 26, 2023, pages 1-8.	☐
	20	Notice of Allowance mailed 04-17-2024; Attorney Docket No. 069366-0572201_KUR2C03US. 16 pages.	☐
	21	Office Action (Non-Final Rejection) mailed 10/04/2023 for US Application No. 17538900 (1-47).	☐
	22	First Office Action (Non-Final Rejection) dated 08-03-2023 for CN Application No. 202010300942.7. 21 pages.	☐

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	23	Office Action (Non-Final Rejection) dated 02/21/2023 for US Application No. 17893079, pages 1-32.	☐
	24	Office Action (Final Rejection) dated 07/19/2023 for US Application No. 17893079, pages 1-21.	☐
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	30	First Office Action dated 11/24/2021 for IL Application No. 286030, pages 1-3.	☐
	31	Notice of Allowance mailed 01-29-2023; Attorney Docket No. 069366-0572425_KUR2D01IL. 87 pages.	☐
	32	Office Action (Non-Final Rejection) dated 08/10/2021 for Japanese Application No. 2020-118498, pages 1-7.	☐
	33	Office Action (Non-Final Rejection) dated 03/28/2022 for Japanese Application No. 2020-118498, pages 1-3.	☐

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	Attorney Docket Number	069366-0581370_KUR2C07US

	34	Office Action (Non-Final Rejection) dated 09/01/2022 for Japanese Application No. 2020-118498, pages 1-4.	☐
	35	Notice of Allowance mailed 04-04-2023; Attorney Docket No. 069366-0572230_KUR2D02JP. 6 pages.	☐
	36	Rule 71(3) Communication and Text for Grant mailed 08/31/2022 for European Application No. 19200766.4-1122. 189 pages.	☐
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	38	Notice of Allowance mailed 02-14-2023; Attorney Docket No. 069366-0572429_KUR3N01IL. 122 pages.	☐
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	43	Office Action (Non-Final Rejection) mailed 08/04/2022 for Application No. 16819033, pages 1-35.	☐
	44	Notice of Allowance mailed 11-28-2022; Attorney Docket No. 069366-0572168_KUR4002US. 9 pages.	☐

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	Examiner Name	
	Attorney Docket Number	069366-0581370_KUR2C07US

	45	Office Action (Non-Final Rejection) mailed 04/16/2024 for Application No. 16838017, pages 1-19.	☐
	46	Office Action (Non-Final Rejection) dated 9/24/2024 for U.S. Application No. 18/783,173 ; Attorney Docket No. 069366-0580420_KUR3C03US (pages 1-62).	☐
	47	Office Action (Non-Final Rejection) dated 9/17/2024 for U.S. Application No. 17/893,079 ; Attorney Docket No. 069366-0572192_KUR3C02US (pages 1-50).	☐
	48	Office Action (Non-Final Rejection) dated 9/23/2024 for U.S. Application No. 17/730,118 ; Attorney Docket No. 069366-0572186_KUR3C01US (pages 1-73).	☐
	49	Office Action (Non-Final Rejection) dated 9/17/2024 for U.S. Application No. 18/783,088 ; Attorney Docket No. 069366-0580418_KUR2C06US (pages 1-60).	☐
	50	Meissner, George F. , et al., "The Standard Clotting Time, A Method Based on the Use of Whole Venous Blood in Capillary Tubes," The American Journal of Clinical Pathology, vol. 39, No. 3., pp. 321-323, Mar. 1963.	☐

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

PC 6.1.24

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	18898239
	Filing Date	2024-09-26
	First Named Inventor	Bobby E. Rogers
	Art Unit	
	Examiner Name	
	Attorney Docket Number	069366-0581370_KUR2C07US

CERTIFICATION STATEMENT

Please see 37 CFR 1.97(e) to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☒ A certification statement is not submitted herewith.

FEE

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

COPIES

☐ An identification of an earlier application pursuant to 37 CFR 1.98 (d) (1) is attached.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2024-09-27
Name/Print	Benjamin F. Hudson	Registration Number	71,474

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

PC 6.1.24

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

27500 7590 01/17/2024

PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
ATTENTION: DOCKETING DEPARTMENT
P.O BOX 10500
McLean, VA 22102

EXAMINER	
ABOUELELA, MAY A	
ART UNIT	PAPER NUMBER
3791	

DATE MAILED: 01/17/2024

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/538,990	11/30/2021	Bobby E. ROGERS	069366-0572201_KUR2C03US	3420

TITLE OF INVENTION: BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$480	$0.00	$0.00	$480	04/17/2024

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 40% the amount of undiscounted fees, and micro entity fees are 20% the amount of undiscounted fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Maintenance fees are due in utility patents issuing on applications filed on or after Dec. 12, 1980. It is patentee's responsibility to ensure timely payment of maintenance fees when due. More information is available at www.uspto.gov/PatentMaintenanceFees.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), by mail or fax, or via the USPTO patent electronic filing system.

By mail, send to: Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

By fax, send to: (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications. **Because electronic patent issuance may occur shortly after issue fee payment, any desired continuing application should preferably be filed prior to payment of this issue fee in order not to jeopardize copendency.**

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

27500 7590 01/17/2024
PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
ATTENTION: DOCKETING DEPARTMENT
P.O BOX 10500
McLean, VA 22102

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being transmitted to the USPTO via the USPTO patent electronic filing system or by facsimile to (571) 273-2885, on the date below.

(Typed or printed name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/538,990	11/30/2021	Bobby E. ROGERS	069366-0572201_KUR2C03US	3420

TITLE OF INVENTION: BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$480	$0.00	$0.00	$480	04/17/2024

EXAMINER	ART UNIT	CLASS-SUBCLASS
ABOUELELA, MAY A	3791	600-573000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

❑ Change of correspondence address (or Change of Correspondence Address form PTO/AIA/122 or PTO/SB/122) attached.

❑ "Fee Address" indication (or "Fee Address" Indication form PTO/AIA/47 or PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 _____
2 _____
3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ❑ Individual ❑ Corporation or other private group entity ❑ Government

4a. Fees submitted: ❑ Issue Fee ❑ Publication Fee (if required)

4b. Method of Payment: *(Please first reapply any previously paid fee shown above)*

❑ Electronic Payment via the USPTO patent electronic filing system ❑ Enclosed check ❑ Non-electronic payment by credit card (Attach form PTO-2038)

❑ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. _____

5. **Change in Entity Status** (from status indicated above)

❑ Applicant certifying micro entity status. See 37 CFR 1.29

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

❑ Applicant asserting small entity status. See 37 CFR 1.27

NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

❑ Applicant changing to regular undiscounted fee status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/538,990	11/30/2021	Bobby E. ROGERS	069366-0572201_KUR2C03US	3420

27500 7590 01/17/2024

PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
ATTENTION: DOCKETING DEPARTMENT
P.O BOX 10500
McLean, VA 22102

EXAMINER	
ABOUELELA, MAY A	

ART UNIT	PAPER NUMBER
3791	

DATE MAILED: 01/17/2024

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. The United States Patent and Trademark Office (USPTO) collects the information in this record under authority of 35 U.S.C. 2. The USPTO's system of records is used to manage all applicant and owner information including name, citizenship, residence, post office address, and other information with respect to inventors and their legal representatives pertaining to the applicant's/ owner's activities in connection with the invention for which a patent is sought or has been granted. The applicable Privacy Act System of Records Notice for the information collected in this form is COMMERCE/PAT-TM-7 Patent Application Files, available in the Federal Register at 78 FR 19243 (March 29, 2013).
https://www.govinfo.gov/content/pkg/FR-2013-03-29/pdf/2013-07341.pdf

Routine uses of the information in this record may include disclosure to:

1) law enforcement, in the event that the system of records indicates a violation or potential violation of law;
2) a federal, state, local, or international agency, in response to its request;
3) a contractor of the USPTO having need for the information in order to perform a contract;
4) the Department of Justice for determination of whether the Freedom of Information Act (FOIA) requires disclosure of the record;
5) a Member of Congress submitting a request involving an individual to whom the record pertains, when the individual has requested the Member's assistance with respect to the subject matter of the record;
6) a court, magistrate, or administrative tribunal, in the course of presenting evidence, including disclosures to opposing counsel in the course of settlement negotiations;
7) the Administrator, General Services Administration (GSA), or their designee, during an inspection of records conducted by GSA under authority of 44 U.S.C. 2904 and 2906, in accordance with the GSA regulations and any other relevant (i.e., GSA or Commerce) directive, where such disclosure shall not be used to make determinations about individuals;
8) another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c));
9) the Office of Personnel Management (OPM) for personnel research purposes; and
10) the Office of Management and Budget (OMB) for legislative coordination and clearance.

If you do not furnish the information requested on this form, the USPTO may not be able to process and/or examine your submission, which may result in termination of proceedings, abandonment of the application, and/or expiration of the patent.

Notice of Allowability	Application No. 17/538,990	Applicant(s) ROGERS et al.	
	Examiner MAY A ABOUELELA	Art Unit 3791	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☑ This communication is responsive to 12/20/2023.
   ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

3. ☑ The allowed claim(s) is/are 1-20 . As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see **http://www.uspto.gov/patents/init_events/pph/index.jsp** or send an inquiry to **PPHfeedback@uspto.gov.**

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

   Certified copies:

   a) ☐ All b) ☐ Some* c) ☐ None of the:

   1. ☐ Certified copies of the priority documents have been received.
   2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
   3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____ .

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____ .

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☑ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____.
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material _____.
4. ☑ Interview Summary (PTO-413), Paper No./Mail Date. 10/08/2024.
5. ☑ Examiner's Amendment/Comment
6. ☑ Examiner's Statement of Reasons for Allowance
7. ☐ Other _____.

/MAY A ABOUELELA/
Primary Examiner, Art Unit 3791

Notice of Pre-AIA or AIA Status

1. The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 12/20/2023. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Terminal Disclaimer

3. The terminal disclaimer filed on 12/20/2023 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S Patent Applications No. 9820682, 10143412 and 11185266 has been reviewed and is accepted. The terminal disclaimer has been recorded.

EXAMINER'S AMENDMENT

4. Authorization for this examiner's amendment was given in an interview with BEN HUDSON on 01/08/2024.

Claim 5 should be amended as follow:

5. (Currently Amended) The blood sample control device in accordance with claim **3** ~~2~~, wherein the housing comprises a bottom member mated with a top member, each of the

bottom member and the top member defining a part of each of the inlet, the outlet, the chamber, and the sampling channel.

Claim 10 should be amended as follow:

10. (**Currently Amended**) The bodily fluid control device in accordance with claim 6, wherein the air permeable blood barrier includes an air permeable material that at least partially seals upon contact with **the bodily fluid** ~~blood~~.

Claim 13 should be amended as follow:

13. (Currently Amended) A bodily fluid control device comprising;

an inlet;

a junction connected with the inlet;

an outlet;

a chamber connected with the inlet via the junction, the chamber having a vent that includes an air permeable bodily fluid barrier that at least partially seals upon contact with a first portion of bodily fluid;

a housing that houses and defines the inlet, the outlet, and the chamber; and

wherein the chamber and the junction **are** ~~being~~ configured to direct the first portion of the bodily fluid from the inlet into the chamber toward the air permeable bodily fluid barrier and to displace air in the chamber, whereupon at least partially sealing of the air permeable bodily fluid barrier enables at least temporary containment of the first portion of the bodily fluid in the chamber, and enables a second portion of the bodily fluid from the inlet to bypass the chamber via the junction and be directed toward the outlet.

Allowable Subject Matter

5. Claims 1-20 are allowed.

6. The following is an examiner's statement of reasons for allowance: the most pertinent prior art Eldridge et al (U.S 4,207,870) teaches a blood sample device for sampling blood conveyed from a patient, the blood device comprising; an inlet port configured to receive the blood conveyed from the patient; an outlet port; a chamber; and a sampling channel having a distal end connected with the outlet port; a junction connected between the inlet port, the chamber and the sampling channel, the junction being sized and configured such that a first portion of blood conveyed from the patient flows into the chamber to displace air therein through the air permeable blood barrier and to be sequestered in the chamber.

The prior art does not teach, disclose and/or fairly suggest the chamber having a vent that includes an air permeable blood barrier, and wherein the junction is configured to allow a second portion of blood to bypass the chamber and the first portion of blood sequestered therein to be directed into the sampling channel toward the outlet port.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MAY A ABOUELELA whose telephone number is (571)270-7917. The examiner can normally be reached 8-5.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JACQUELINE CHENG can be reached on 5712725596. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/MAY A ABOUELELA/
Primary Examiner, Art Unit 3791

Examiner-Initiated Interview Summary	**Application No.** 17/538,990	**Applicant(s)** ROGERS et al.		
	Examiner MAY A ABOUELELA	**Art Unit** 3791	**AIA (First Inventor to File) Status** Yes	**Page** 1 of 1

All Participants (applicant, applicants representative, PTO personnel)	**Title**	**Type**
MAY A ABOUELELA	Primary Examiner	Telephonic
BEN HUDSON	Attorney of Record	

Date of Interview: 08 January 2024

Issues Discussed:

35 U.S.C. 112

Applicant and Examiner discussed the claims set mailed on 12/20/2023. Applicant and Examiner discussed the claim language with respect to the applied prior art and the disclosure. Applicant and Examiner discussed proposed claim amendments represented by the Examiner to overcome 112 rejection for claims 5, 10 and 13. The Applicant has authorized the Examiner to amend the claims.

/MAY A ABOUELELA/ Primary Examiner, Art Unit 3791	

Applicant is reminded that a complete written statement as to the substance of the interview must be made of record in the application file. It is the applicants responsibility to provide the written statement, unless the interview was initiated by the Examiner and the Examiner has indicated that a written summary will be provided. See MPEP 713.04
Please further see:
MPEP 713.04
Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews, paragraph (b)
37 CFR § 1.2 Business to be transacted in writing

Applicant recordation instructions: It is not necessary for applicant to provide a separate record of the substance of interview.

Examiner recordation instructions: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.

Doc code: IDS
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	17538990
Filing Date	2021-11-30
First Named Inventor	Bobby E. ROGERS
Art Unit	OPAP
Examiner Name	CENTRAL, DOCKET
Attorney Docket Number	069366-0572201_KUR2C03US

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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	2	10299713		2019-05-28	PATTON RICHARD G	
	3	10265007		2019-04-23	BULLINGTON GREGORY	
	4	11395612		2022-07-26	BULLINGTON GREGORY J	
	5	10881343		2021-01-05	BULLINGTON GREGORY J	
	6	10596315		2020-03-24	BULLINGTON GREGORY J	
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	9	11737693		2023-08-29	BULLINGTON GREGORY J	
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	11	11589843		2023-02-28	BULLINGTON GREGORY J	
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	4	20210275068		2021-09-09	MIAZGA JAY M	
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EXAMINER SIGNATURE

Examiner Signature	/MAY A ABOUELELA/	Date Considered	01/08/2024

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	Art Unit	OPAP
	Examiner Name	CENTRAL, DOCKET
	Attorney Docket Number	069366-0572201_KUR2C03US

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☒ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2023-12-20
Name/Print	Benjamin F. Hudson	Registration Number	71,474

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(1) Notify the designated first-aid trained personnel.

(2) Where practical, lay the patient flat or lower his/her head and arms, if the patient is sitting.

(3) Loosen tight clothing.

(4) The use of ammonia inhalants may be associated with untoward effects and is not recommended.

11.8.2 Nausea

The procedure for dealing with a patient who is experiencing nausea is to:

(1) Make the patient as comfortable as possible.

(2) Instruct the patient to breathe deeply and slowly.

(3) Apply cold compresses to the patient's forehead.

(4) Notify the designated first-aid trained personnel.

11.8.3 Vomiting

The procedure for dealing with a patient who vomits is to:

(1) Give the patient an emesis basin or carton, and have tissues ready.

(2) Give the patient water to rinse out his/her mouth.

(3) Notify the designated first-aid trained personnel.

11.8.4 Convulsions

The procedure for dealing with a patient who is having convulsions is to:

(1) Prevent the patient from injuring himself/herself. Do not restrain the movements of the patient's extremities completely, but try to prevent him/her from being injured.

(2) Notify the designated first-aid trained personnel.

11.8.5 Incident Reports

Incident reports should be filed according to institutional policy.

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Summary of Comments and Subcommittee Responses

H3-A4: *Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard—Fourth Edition*

General

1. NCCLS has inconsistencies in their own publications (H3 and H21) when it comes to the order of draw for coagulation testing relative to tissue thromboplastin contamination and procurement of a "discard tube." In performing intra-laboratory studies at our institution and sister institutions, results showed no significant clinical or statistical significance on any of the assays between each of the specimen tubes performed at each individual laboratory. Also, our results indicated that NCCLS guidelines for obtaining a second tube when performing coagulation testing should be eliminated when the revised document is published.

- **The text has been revised (see Section 8.10.2), including the order of draw, and several notes have been added to address the use of discard tubes for coagulation test collection. The next version of H21—*Collection, Transport, and Processing of Blood Specimens for Coagulation Testing and General Performance of Coagulation Assays* is due to be released by the end of 2003. The documents are now consistent.**

Section 7.9.3.4, Intravenous Therapy (Now Section 8.6.7.4)

2. The text of this section states, "Optimally, specimens should not be collected from an arm with an intravenous site. If this is impossible the attending physician should be consulted (see Section 10.3). Blood should never be collected from above any active intravenous site (see Section 10.6). We would like a clearer definition of what is considered to be "active." What defining factors are present that would classify an "active" intravenous site?

- **The term "active" has been removed from the text. The text in Sections 8.6.7.4 and 11.6 has been revised to describe the procedure for specimen collection in relation to intravenous fluids.**

Section 7.13.3.3, Coagulation Testing (Now Section 8.10.3)

3. The text of this section states, "if only a coagulation tube is drawn for routine coagulation testing (APTT and PT tests) the first tube drawn may be used for testing." This statement has raised some discussion regarding the definition of the phrase "routine coagulation testing." Does this include coumadin patient samples?

- **Specimens collected from patients on warfarin sodium (Coumadin™) are considered for routine coagulation testing.**

Section 10, Special Situations (Now Section 11)

4. H3-A4 does not list recommendations for obtaining venipuncture specimens during blood transfusions. Information on this topic would be greatly appreciated.

- **The directions outlined in Section 11.6 should be followed during transfusions as it is described for intravenous fluids.**

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Summary of Delegate Comments and Working Group Responses

H3-A5: *Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard—Fifth Edition*

General

1. Nothing was included about pain management (EMLA, coldspray, etc.) or age-specific consideration on developmental stages of children. I can send you what we have if you like.

- **The working group recognizes the availability of pain reducing techniques. Topical sprays and treatments are available and are used at the discretion of each institution.**

  Age-specific considerations are outside the scope of this document. Please refer to the current edition of NCCLS document H4—*Procedures and Devices for the Collection of Diagnostic Blood Specimens by Skin Puncture.*

2. Add a Section 11.2.6, RNA Specimen. Since RNA is unstable, the whole blood should be transported to the laboratory at 2 to 25 °C within six hours of collection.

   References: de Gerbehaye A-I, et al. Stable hepatitis C virus RNA detection by RT-PCR during four days storage. *BMC Infectious Diseases.* 2002;2:22, and Halfon P, et al. Impact of various handling and storage conditions on quantitative defection of hepatitis C virus RNA. *J Hepatol.* 1996;25:307-311.

- **This comment is more related to specimen handling than collection and is beyond the scope of this document. This comment will be considered during the revision of NCCLS document H18-A2—*Procedures for the Handling and Processing of Blood Specimens; Approved Guideline.***

Foreword

3. Page vii should include hemolysis and clotting of samples, as these are common problems with hematology or coagulation samples. "The errors that can occur during the collection and handling of blood specimens are potentially numerous (e.g., inaccurate identification of specimens, the use of incorrect anticoagulant, the formation of hematomas, hemoconcentration)."

- **The text has been revised to include specimen hemolysis and improper handling of anticoagulants.**

Section 8, Venipuncture Procedure

4. Consider switching steps 14 and 15 so that bandaging occurs after specimens are labeled, not before. This helps assure that specimen labeling will occur before leaving the patient's side. It also accommodates situations in which the patient assists in applying pressure while the phlebotomist labels tubes.

- **The working group appreciates the comment; we believe, however, that the order is correct as written. The text in Section 8.15 emphasizes the need to label the tube before leaving the side of the patient.**

5. Between steps 5 and 6, add the following: "Inquire as to patient's sensitivity to latex products." Step 7, change as follows: "Put on appropriate gloves based on patient's response to Step 6."

- **The working group agrees with the comment. The text of step 3 has been revised as follows: "Verify patient's diet restrictions, as appropriate, and inquire if the patient has a latex sensitivity. Select appropriate gloves and tourniquet."**

6. Modify step 6 to new "step 6: Inquire on patient's allergy to latex products." Also add: "Due to the prevalence of latex sensitivity, the phlebotomist should inquire as the patient's sensitivity to latex products (tourniquet and gloves.)"

- **The text of Step 3 and Section 8.3 has been revised to include asking the patient if he/she has a latex sensitivity. The text in Section 8.6 has been revised to refer the reader to Section 7.7.**

7. The patient should be asked to open his/her hand just when entering the vein, therefore eliminating some of the pain a tense closed fist may cause. Also, recommend performing venipuncture using the correct order of draw.

- **In response to this comment, the text of step 9 has been revised as follows: "Perform venipuncture; once blood flow begins, request patient to open hand." Step 10 has been revised to recommend the use of the correct order of draw.**

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8. Following the removal of the needle, pressure should be applied to the venipuncture site (either by the patient or phlebotomist).

- **In response to this comment, the text of step 14 has been revised as follows: "Apply pressure to the site, making sure bleeding has stopped, and then bandage the arm."**

Section 8.1.1, Information for Test Request Form

9. "May include" should be utilized.

- **The working group believes that the test request form information listed should be included.**

Section 8.1.2, Accessioning Blood Bank Specimens

10. Neither AABB nor CAP requires "time of collection" on the specimen tube label.

- **Time of collection is important for some specimens (e.g., therapeutic drug monitoring). The subcommittee confirmed that AABB does not require "time of collection" on the specimen tube label. The text, "Blood bank specimens must be labeled according to the standards set by the American Association of Blood Banks (AABB)," has been incorporated into Section 8.15, Label Blood Collection Tubes and Record Time of Collection. The remainder of Section 8.1.2 has been deleted.**

11. This passage is more about patient identification and labeling specimens than accessioning. Passages are important, but seem out of place. Consider moving the passage on identifying blood bank patients to Section 8.2 ("Step 2: Approach and Identify the Patient.") and the passage about labeling to Section 8.15 ("Step 15: Label Blood Collection Tubes and Record Time of Collection").

- **See response to comment 10.**

Section 8.2.3, Patient Who Is Semiconscious, Comatose, or Sleeping

12. This passage does not address identification and is out of place. Consider moving to Section 8.5.4.

- **The location of this text is appropriate. Section 8.2 addresses both approaching and identifying the patient. The following has been added to the end of the paragraph: "If unable to identify the patient, then contact the nurse or physician."**

Section 8.2.4, Patient Who Is Unconscious, Too Young, Mentally Incompetent, or Does Not Speak the Language of the Phlebotomist

13. The first bullet states, "Ask the nurse, a relative, or a friend to identify the patient by name, address, and identification number and/or birth date." This is inconsistent with Section 8.2.2, re: asking for patient's address and identification number. Suggest changing "and" to "or" for consistency with step 1 of 8.2.2.

- **The text in Section 8.2.4 has been revised for consistency with Section 8.2.2.**

Section 8.4.1, Supplies

14. "Inspect all supplies for possible defects" should include inspection of expiration dates on blood collection tubes.

- **The text has been revised to include applicable expiration dates during inspection of supplies.**

15. Supplies, sharps, or other disposal container is missing from the list (as discussed in Section 8.13). This should be available at the bedside for safe disposal.

- **The following bullet point has been added to the list: "Sharps container, consistent with OSHA regulations."**

16. Supplies such as tubes and needles should be checked before use to ensure they are not outdated. Sterile conditions or tube vacuum could be lost in old supplies. NCCLS document H4-A discusses tube stability and dating; H1-A4 discusses expiration date. Therefore, this step should be added to the collection procedure.

- **See response to comment 13.**

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Section 8.6.3, Blood Pressure Cuff

17. In Section 7.7 the blood pressure cuff is said to be inflated to 40 mmHg. However, in Section 8.6.3 it is said that a blood pressure is taken first (an activity performed by NO phlebotomists I know) and maintained below the diastolic pressure of the patient. I would recommend using the specific 40 mm Hg found in Section 7.7 and replace the language in Section 8.6.3 with the same.

- **The text has been revised as recommended. The following text has been added to replace the previous text: "If a blood pressure cuff is used as a tourniquet, inflate it to 40 mm Hg."**

Section 8.6.5, Select Vein

18. "Brachial" is misspelled in Figure 1.

- **The spelling error in Figure 1 has been corrected.**

Section 8.7, Step 7: Put on Gloves

19. Step 7: Add the following after the existing sentence: "…is performed. The type of gloves (latex, vinyl or nitrile) used for venipuncture will depend on the patient's and/or phlebotomist's sensitivity to latex products." General note—As both a patient and laboratorian, I know the importance of covering the issue of latex sensitivity with both patients and the phlebotomists. I highly recommend that you incorporate the information presented here into the document.

- **The text has been revised as follows: "The phlebotomist must put gloves on before the venipuncture is performed, for each patient, with consideration for latex sensitivity as discussed in Section 7.3."**

Section 8.9.1, Venipuncture Procedure When Venous Blood Collection Tubes Are Used

20. The illustration on page 14 is very primitive and would be improved if the proper angle included a view of the needle bevel up just as the needle enters the skin.

- **The illustrations (Figures 2 and 3) have been replaced with comparable photographs.**

Section 8.9.3, Fill the Tubes If Syringe and Needle Are Used

21. The third bullet suggests a straight needle be applied to the syringe after removing the winged collection set. Consider substituting "attach a 19- to 21-gauge sterile needle" with "attach a safety transfer device."

- **The text of the third bullet has been revised as follows: "To transfer the blood from the syringe to a venous blood collection tube, activate the safety feature of the needle or winged blood collection set used to withdraw the specimen, remove and discard the needle or winged collection set, and apply a safety transfer device."**

22. The fourth bullet seems to define the third bullet. Consider combining the two.

- **The working group agrees with the comment and has deleted the fourth bullet.**

23. The fifth bullet is not necessary in light of the third bullet. If standards are being followed, a transfer device protects the user, and holding the tubes should be safe.

- **The fifth bullet has been deleted as suggested.**

Section 8.9.4, Blood Specimen That Cannot Be Obtained

24. Consider making the passage about trying another tube into a bullet. Consider differentiating between probing and a calculated needle relocation in an additional bullet so that the section is rewritten as follows:

   ► Try another tube to ensure the tube selected is not defective.
   ► Change the position of the needle. If the needle has penetrated too far into the vein, pull it back a bit. If it has not penetrated far enough, advance it farther into the vein. Rotate the needle half a turn.
   ► Lateral needle relocation should be attempted only if the phlebotomist has a high degree of confidence that so doing will access the vein successfully without risking injury to the patient. Lateral needle relocation should never be attempted in an effort to access the basilic vein, since nerves and the brachial artery are in close proximity.

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- ► Manipulation other than that recommended above is considered probing. Probing is not recommended. Probing is painful to the patient. In most cases, another puncture in a site below the first site (or use of another vein on the other arm) is advisable.
- ► It is not advisable to attempt a venipuncture more than twice. If possible, have another person attempt to draw the specimen or notify the physician.

- **The following text has been added to the first bullet point: "Lateral needle relocation should never be attempted in an effort to access the basilic vein, since nerves and the brachial artery are in close proximity."**

Section 8.10.2, Glass and Plastic Venous Blood Collection Tubes

25. Consider deleting tube 4: gel serum separator tube. Since gel does not carryover, its presence or absence should not affect the order of draw. It seems more fitting for the second italicized paragraph to immediately follow the order of draw than the first paragraph.

- **Gel serum separator tube has been deleted from the fourth position on the order of draw. The third position has been revised as follows: "Serum tube with or without clot activator, with or without gel (e.g., red closure)."**

  The italicized paragraphs have been reorganized as suggested; the note regarding the revised order of draw appears immediately following the order of draw.

Section 8.13, Step 13: Remove and Dispose of the Needle

26. Removal of a needle (after the safety feature is activated) is necessary and acceptable to OSHA if applying a safety transfer device. Consider modifying to read: "Needles should not be resheathed, bent, broken, or cut, nor should they be removed from disposable syringes unless attaching a safety transfer device…"

- **The text of the third sentence has been revised as follows: "Needles should not be resheathed, bent, broken, or cut, nor should they be removed from disposable syringes unless attaching a safety transfer device prior to disposal."**

Section 8.14.2, Continued Bleeding

27. "When a patient continues to bleed," indicates that it is inevitable. Consider revising to "If a patient continues to bleed or a hematoma develops, …"

- **The text has been revised as recommended. The first paragraph now reads as follows: "If a hematoma develops or bleeding persists longer than five minutes, a nurse should be alerted so that the attending physician can be notified."**

Section 8.15, Step 15: Label Blood Collection Tubes and Record Time of Collection

28. Step 15: Consider revising the paragraph after the bullet list to accommodate handwritten identification of tubes. Suggested revision: "The label must be attached to the tube or the tube inscribed with complete information before leaving the side of the patient …."

- **The text has been revised as recommended. The following text has been added to the second paragraph: "Alternatively, the manufacturer's tube label can be inscribed with the patient's complete information."**

29. Tubes should be labeled in accordance with the laboratory requirements. These may not meet all requirements for all laboratories.

- **The text in this section has been revised in response to comment 9.**

Section 9, Venipuncture in Children and Difficult Collections

30. Passage states, "If a venipuncture is done on a child younger than one year of age, the site should be limited to superficial veins." As opposed to what? This statement is unclear.

- **The first sentence has been revised for clarity. The revision is as follows: "If a venipuncture is requested on a child younger than one year of age, the phlebotomist should consult with the physician or follow institutional policy."**

Section 9.2, Equipment

31. Consider modifying the range of needles to be used on pediatrics from 20-23 to 22-23 for patient comfort unless platelet aggregation studies are required.

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- **The needle gauge range has been revised as suggested. The following text has also been added: "For pediatric patients, through the age of 16, larger gauge needles may be appropriate."**

Section 11.6, Intravenous Fluids

32. Add the following reference: Savage R, ed. Q&A column. *CAP Today*. 2002:16(4):102-103.

- **The recommended reference, regarding performance of venipunctures above intravenous sites, has been added as suggested.**

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The Quality System Approach

NCCLS subscribes to a quality system approach in the development of standards and guidelines, which facilitates project management; defines a document structure via a template; and provides a process to identify needed documents through a gap analysis. The approach is based on the model presented in the most current edition of NCCLS HS1—*A Quality System Model for Health Care.* The quality system approach applies a core set of "quality system essentials (QSEs)," basic to any organization, to all operations in any healthcare service's path of workflow. The QSEs provide the framework for delivery of any type of product or service, serving as a manager's guide. The quality system essentials (QSEs) are:

Documents & Records	Equipment	Information Management	Process Improvement
Organization	Purchasing & Inventory	Occurrence Management	Service & Satisfaction
Personnel	Process Control	Assessment	Facilities & Safety

H3-A5 addresses the quality system essentials (QSEs) indicated by an "X." For a description of the other NCCLS documents listed in the grid, please refer to the Related NCCLS Publications section on the next page.

Documents & Records	Organization	Personnel	Equipment	Purchasing & Inventory	Process Control	Information Management	Occurrence Management	Assessment	Process Improvement	Service & Satisfaction	Facilities & Safety
				X H1	X TDM6						X M29

Adapted from NCCLS document HS1— *A Quality System Model for Health Care.*

Path of Workflow

A path of workflow is the description of the necessary steps to deliver the particular product or service that the organization or entity provides. For example, GP26-A2 defines a clinical laboratory path of workflow which consists of three sequential processes: preanalytical, analytical, and postanalytical. All clinical laboratories follow these processes to deliver the laboratory's services, namely quality laboratory information.

H3-A5 addresses the clinical laboratory path of workflow steps indicated by an "X." For a description of the other NCCLS documents listed in the grid, please refer to the Related NCCLS Publications section on the next page.

Preanalytic					**Analytic**		**Postanalytic**	
Patient Assessment	Test Request	Specimen Collection	Specimen Transport	Specimen Receipt	Testing Review	Laboratory Interpretation	Results Report	Post-test Specimen Management
X	X	X C38 H4 H11 H21	X C38 H4 H11 H21	X H18	X TDM6			

Adapted from NCCLS document HS1— *A Quality System Model for Health Care.*

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Related NCCLS Publications*

C38-A **Control of Analytic Variation in Trace Element Analysis; Approved Guideline (1997).** This document provides guidelines for patient preparation, specimen collection, transport, and processing for the analysis of trace metals in a variety of biological matrices.

H1-A4 **Evacuated Tubes and Additives for Blood Specimen Collection—Fourth Edition; Approved Standard (1996).** This document provides requirements for blood collection tubes and additives.

H4-A4 **Procedures and Devices for the Collection of Diagnostic Blood Specimens by Skin Puncture; Approved Standard—Fourth Edition (1999).** A consolidation of H4-A3 and H14-A2, this standard provides detailed descriptions and explanations of proper collection techniques, as well as hazards to patients from inappropriate specimen collection by skin puncture procedures.

H11-A3 **Procedure for the Collection of Arterial Blood Specimens; Approved Standard—Third Edition (1999).** *American National Standard.* This standard describes principles of collecting, handling, and transporting arterial blood specimens. The document is aimed at reducing collection hazards and ensuring integrity of the arterial specimen.

H18-A2 **Procedures for the Handling and Processing of Blood Specimens; Second Edition—Approved Guideline (1999).** This guideline addresses multiple factors associated with handling and processing specimens, as well as factors that can introduce imprecision of systematic bias into results.

H21-A3 **Collection, Transport, and Processing of Blood Specimen for Coagulation Testing and General Performance of Coagulation Assays; Approved Guideline—Third Edition (1998).** This guideline contains procedures for collecting, transporting, and storing blood; processing blood specimens; storing plasma for coagulation testing; and provides general recommendations for performing the tests.

M29-A2 **Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline—Second Edition (2001).** This document provides guidance on the risk of transmission of hepatitis viruses and human immunodeficiency viruses in any laboratory setting; specific precautions for preventing the laboratory transmission of blood-borne infection from laboratory instruments and materials; and recommendations for the management of blood-borne exposure.

T/DM6-A **Blood Alcohol Testing in the Clinical Laboratory; Approved Guideline (1997).** This document gives technical and administrative guidance on laboratory procedures related to blood alcohol testing.

* Proposed- and tentative-level documents are being advanced through the NCCLS consensus process; therefore, readers should refer to the most recent edition.

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Washington Adventist Hospital (MD)
Washoe Medical Center Laboratory (NV)
Waterford Regional Hospital (Ireland)
Wellstar Health Systems (GA)
West Jefferson Medical Center (LA)
West Shore Medical Center (MI)
Wilford Hall Medical Center (TX)
William Beaumont Army Medical Center (TX)
William Beaumont Hospital (MI)
William Osler Health Centre (Brampton, ON, Canada)
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פ.ק 26

תאריך : י״ח שבט תשפ״ב
20/01/2022
מספרכם : 1000-018-01

לכבוד
כץ, פרזנטי ושות׳
דרך אבא הלל 14, ת.ד.
רמת גן, מיקוד 52506

א. ג. נ.,

הנדון : **<u>הודעה על ליקויים בבקשת פטנט מספר 267684</u>**
סימוכין : מכתבכם מיום

לתשומת לבכם : מקום בו הנכם מופנים לחוק, הכוונה היא לחוק הפטנטים, התשכ״ז – 1967. מקום בו הנכם מופנים לתקנות, הכוונה היא לתקנות הפטנטים (נוהלי הרשות, סדרי דין, מסמכים ואגרות), התשכ״ח – 1968. עליכם להשיב על הודעה זו תוך ארבעה חודשים מתאריכה, אך הנכם רשאים לבקש את הארכת התקופה, עם בקשת הארכה שתוגש יש לשלם אגרה בסך 208.00 ש״ח בעד כל חודש או חלק ממנו. **לא יינתנו יותר מארבעה חודשי ארכה בגין כל הודעה על ליקויים וסך כל תקופות הארכה במהלך הבחינה לא יעלה על 12 חודשים** בהתאם לכללים שנקבעו בחוזר הרשם 035/2017-פטנטים.

<u>הודעה זו מבוססת על המסמכים הבאים:</u>
שרטוטים מתאריך : 26/06/2019
פרטי הבקשה מתאריך : 26/06/2019
תביעות מתאריך : 26/06/2019

<u>בהתאם למפורט בהמשך הודעה זו להלן סיכום עמדתי לעניין כשירות התביעות לפטנט :</u>

בתביעה/ות מס׳ 1-20 נמצאו ליקויים.
ראה הנימוקים בהמשך הודעה זו.

בהתאם להוראות **תקנה 41** הנני להודיעכם כי נמצאו בבקשה הנ״ל הליקויים המפורטים להלן :

1. <u>חידוש והתקדמות המצאתית</u>

1.1 תביעה/ות 1-20 עונה/ות על דרישות **סעיפים 4 ו-5 לחוק**, מאחר והאמצאה המוגדרת בתביעה/ות זו/אלה לא נתפרסמה בפומבי לפני תאריך הבקשה ויש בה התקדמות המצאתית.

2. <u>התביעות</u>

2.1 תביעות מס׳ 1-20 אינן עומדות בהוראות **סעיף 13(א) לחוק** היות שהן אינן כוללות את כל יסודות האמצאה הדרושים לביצועה כפי שנלמד מהתיאור.

לגבי התביעות הבלתי תביעות 1,8,15, בלשון תביעות אלו מופיע הביטוי :

״the vent being defined by an outer wall that at least partially circumscribes the air permeable blood barrier **and includes one or more air vents**״

שיוצר אי בהירות האם ה- vents הנוספים הם חלק מה- vent השייך ל- sequestration chamber או

שהם חלק מה- outer wall.

כמו כן, בלשון תביעות 1,8,15 מופיע הביטוי:

"the vent further including a cap that at least partially covers the wall **and a one-way seal**"

שיוצר אי בהירות האם ה- cap מכסה גם את ה- one-way seal או שאותו one-way seal הוא חלק מה- vent עצמו.

התביעות התלויות 2-7,9-14,16-20 אינן עומדות בהוראות **סעיף 13(א)** לחוק עקב תלותן בתביעות 1,8,15 בהתאמה.

2.2 בניגוד ל**תקנה 20(א)(3)**, תביעות 4,11,18 אינן ברורות מאחר שהביטוי/המונח "the inner wall" המופיע בתביעות אלו זו מחוסר התייחסות קודמת (antecedence) בתביעה/ות קודמת/ות מתאימה/ות.

<u>חובת המבקש לעדכן את הרשות</u>

תשומת לבכם ל**סעיף 18א לחוק** לעניין חובת המבקשת לעדכן את הרשות על כל שינוי שחל ברשימת האסמכתאות או הפרסומים כאמור ב**סעיף 18(א) לחוק** ול**סעיף 18ג לחוק** בדבר אמצעי האכיפה.

<u>הגשת תיקונים לפירוט במהלך בחינת הבקשה</u>

באם יבוצעו תיקונים בבקשת הפטנט, תשומת לבכם מופנית **לתקנה 22(א)**. יש לשלוח לרשות עותק מלא של חלק הבקשה שבו הוכנסו התיקונים תוך סימונם באופן ברור. יש לסמן תוספות בקו תחתי (כך: <u>דוגמה</u>) והשמטות בקו חוצה (כך: ~~דוגמה~~). **אין להגיש מחדש קבצים שלא תוקנו**.

לתשומת לבכם:

א) בהתאם לתקנות 22(ב) ו-42 במידה שהנכם מתקנים את הפירוט כדי להתגבר על הליקויים בהודעה זו, עליכם לפרט את הליקויים שהתיקונים באים לסלקם, לנמק כיצד תיקון הפירוט מתקן את הליקוי ולגבי תיקון בתביעות, כיצד עומד התיקון בתנאי סעיף 13 לחוק.

ב) בהתאם להוראות חוזר רשם 034/2017-פטנטים, במידה שבחינת הבקשה החלה לאחר 27.03.2017, תיקון פירוט בדרך של החלפת האמצאה שנבחנה ואשר לגביה הועלה ליקוי, באמצאה אחרת, בין אם היא הופיעה בתביעות מלכתחילה ובין אם תוארה בלבד, גם אם היא נובעת מהתיאור, אינו מהווה תיקון הליקוי ויביא לשליחת הודעה לפני סירוב.

ניתן לעיין בפרטי תיק הבקשה באתר הרשות בקישור:

https://israelpatents.justice.gov.il/#/en/patent-file/details/267684

<u>ראיון עם בוחן</u>

בהתאם לה.ע. 23.3, המפורסמת באתר הרשות, ניתן לקיים ראיון עם הבוחן באמצעות פגישה במשרדי הרשות או בשיחה טלפונית.

רשות הפטנטים מעודדת קיום של קשר ישיר בין הבוחן למבקש או בא-כוחו באמצעות שירות זה.

קיום ראיון עם בוחן מאפשר לרוב את ייעול וקיצור זמן הבחינה ואף לחיסכון בעלויות בתהליך הבחינה והאישור של בקשה לפטנט.

במסגרת הראיון ניתן לדון עם הבוחן בנושאים הקשורים לתיאור האמצאה והגדרתה, בליקויים שהועלו במהלך הבחינה ואף בתיקונים אפשריים לליקויים אלה.

תיאום הראיון יתבצע ישירות מול הבוחן (פרטי הקשר מופיעים מטה) וילווה בהודעה כתובה של יוזם הראיון שתפרט את הנושאים לדיון ואת הטיעונים העיקריים לגביהם.

לתשומת לבכם, בקשה לקיום ראיון אינה מהווה תשובה להודעת הליקויים כמשמעה בתקנה 42.

<u>השגה בפני הרשם</u>

על פי **סעיף 161 לחוק**, הנכם רשאים להשיג על החלטתי בפני רשם הפטנטים תוך ארבעה חודשים ממועד משלוח ההודעה.

בכבוד רב

אלברט אקרמן
בוחן פטנטים בכיר
טלפון: 073-3927233
דואר אלקטרוני: albertak@justice.gov.il
ראש צוות: מוריה שלמה לוי

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NOTICE OF ALLOWANCE AND FEE(S) DUE

27500 7590 04/20/2023

PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
ATTENTION: DOCKETING DEPARTMENT
P.O BOX 10500
McLean, VA 22102

EXAMINER
ABOUELELA, MAY A

ART UNIT	PAPER NUMBER
3791	

DATE MAILED: 04/20/2023

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/094,692	11/10/2020	Bobby E. ROGERS	069366-0572169_KUR4C01US	8012

TITLE OF INVENTION: BLOOD CONTAMINANT SEQUESTRATION DEVICE WITH ONE-WAY AIR VALVE AND AIR-PERMEABLE BLOOD BARRIER WITH CLOSURE MECHANISM

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$480	$0.00	$0.00	$480	07/20/2023

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 40% the amount of undiscounted fees, and micro entity fees are 20% the amount of undiscounted fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Maintenance fees are due in utility patents issuing on applications filed on or after Dec. 12, 1980. It is patentee's responsibility to ensure timely payment of maintenance fees when due. More information is available at www.uspto.gov/PatentMaintenanceFees.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), by mail or fax, or via EFS-Web.

By mail, send to: Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

By fax, send to: (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications. **Because electronic patent issuance may occur shortly after issue fee payment, any desired continuing application should preferably be filed prior to payment of this issue fee in order not to jeopardize copendency.**

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27500 7590 04/20/2023
PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
ATTENTION: DOCKETING DEPARTMENT
P.O BOX 10500
McLean, VA 22102

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being transmitted to the USPTO via EFS-Web or by facsimile to (571) 273-2885, on the date below.

(Typed or printed name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/094,692	11/10/2020	Bobby E. ROGERS	069366-0572169_KUR4C01US	8012

TITLE OF INVENTION: BLOOD CONTAMINANT SEQUESTRATION DEVICE WITH ONE-WAY AIR VALVE AND AIR-PERMEABLE BLOOD BARRIER WITH CLOSURE MECHANISM

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$480	$0.00	$0.00	$480	07/20/2023

EXAMINER	ART UNIT	CLASS-SUBCLASS
ABOUELELA, MAY A	3791	600-573000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

❑ Change of correspondence address (or Change of Correspondence Address form PTO/AIA/122 or PTO/SB/122) attached.

❑ "Fee Address" indication (or "Fee Address" Indication form PTO/AIA/47 or PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 _____
2 _____
3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ❑ Individual ❑ Corporation or other private group entity ❑ Government

4a. Fees submitted: ❑ Issue Fee ❑ Publication Fee (if required)

4b. Method of Payment: *(Please first reapply any previously paid fee shown above)*

❑ Electronic Payment via Patent Center or EFS-Web ❑ Enclosed check ❑ Non-electronic payment by credit card (Attach form PTO-2038)

❑ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. _____

5. **Change in Entity Status** (from status indicated above)

❑ Applicant certifying micro entity status. See 37 CFR 1.29

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

❑ Applicant asserting small entity status. See 37 CFR 1.27

NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

❑ Applicant changing to regular undiscounted fee status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

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UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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27500 7590 04/20/2023

PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
ATTENTION: DOCKETING DEPARTMENT
P.O BOX 10500
McLean, VA 22102

EXAMINER	
ABOUELELA, MAY A	
ART UNIT	PAPER NUMBER
3791	

DATE MAILED: 04/20/2023

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Notice of Allowability	Application No. 17/094,692	Applicant(s) ROGERS et al.	
	Examiner MAY A ABOUELELA	Art Unit 3791	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☑ This communication is responsive to 04/04/2023.
   ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

3. ☑ The allowed claim(s) is/are See Continuation Sheet . As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see **http://www.uspto.gov/patents/init_events/pph/index.jsp** or send an inquiry to **PPHfeedback@uspto.gov.**

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

   Certified copies:

   a) ☐ All b) ☐ Some* c) ☐ None of the:

   1. ☐ Certified copies of the priority documents have been received.
   2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
   3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____ .

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____ .

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☑ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____.
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material _____.
4. ☐ Interview Summary (PTO-413), Paper No./Mail Date. _____.
5. ☐ Examiner's Amendment/Comment
6. ☑ Examiner's Statement of Reasons for Allowance
7. ☐ Other _____.

/MAY A ABOUELELA/
Primary Examiner, Art Unit 3791

Continuation of 3. The allowed claim(s) is/are: 1,3-8,10-14,16-18 and 20-47

Notice of Pre-AIA or AIA Status

1. The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 04/10/2023. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Allowable Subject Matter

3. Claims 1, 3-8, 10-14, 16-18 and 20-47 are allowed.

4. The following is an examiner's statement of reasons for allowance: the most pertinent art Cuppy et al (US 5,749,857) teaches a blood sampling device, comprising inlet and outlet port, a chamber connected to the inlet port; a sampling channel connected to the outlet; and a housing that houses and defines the inlet port, the outlet port, the chamber, and the sampling channel.

The prior art failed to teach, disclose and/or fairly suggest the chamber connected with the inlet port via a junction, and the sampling channel having a proximal end connected with the inlet port via the junction and a distal end connected to the outlet port, the sampling channel being configured to convey subsequent portions of blood to the outlet port after the first portion of blood has entered the chamber.

The other pertinent prior art Patton et al (US 2008/0145933) teaches the chamber connected with the inlet port via a junction, and the sampling channel having a

proximal end connected with the inlet port via the junction and a distal end connected to the outlet port, the sampling channel being configured to convey subsequent portions of blood to the outlet port after the first portion of blood has entered the chamber, but failed to teach and/or suggest a housing that houses and defines the inlet port, the junction, the outlet port, the chamber, and the sampling channel.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MAY A ABOUELELA whose telephone number is (571)270-7917. The examiner can normally be reached 8-5.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JACQUELINE CHENG can be reached on 5712725596. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is

available to registered users. To file and manage patent submissions in Patent Center, visit: https://patentcenter.uspto.gov. Visit https://www.uspto.gov/patents/apply/patent-center for more information about Patent Center and https://www.uspto.gov/patents/docx for information about filing in DOCX format. For additional questions, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MAY A ABOUELELA/
Primary Examiner, Art Unit 3791

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (02-18)
Approved for use through 11/30/2020. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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(Not for submission under 37 CFR 1.99)

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Filing Date	2020-11-10
First Named Inventor	Bobby E. ROGERS
Art Unit	3791
Examiner Name	ABOUELELA, MAY A
Attorney Docket Number	069366-0572169_KUR4C01US

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

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	Examiner Name	ABOUELELA, MAY A
	Attorney Docket Number	069366-0572169_KUR4C01US

	1	Weinbaum, Fredric I., et al. "Doing it right the first time: quality improvement and the contaminant blood culture." Journal of Clinical Microbiology 35.3 (1997): 563-565.	
	2	Weinstein, Melvin P. "Blood culture contamination: persisting problems and partial progress." Journal of clinical microbiology 41.6 (2003): 2275-2278.	
	3	Weinstein, Melvin P. "Current blood culture methods and systems: clinical concepts, technology, and interpretation of results." Clinical infectious diseases 23.1 (1996): 40-46.	
	4	Weinstein, Melvin P., et al. "The clinical significance of positive blood cultures in the 1990s: a prospective comprehensive evaluation of the microbiology, epidemiology, and outcome of bacteremia and fungemia in adults." Clinical Infectious Diseases 24.4 (1997): 584-602.	
	5	Ziegler, R., et al. "Controlled Clinical Laboratory Comparison of Two Supplemented Aerobic and Anaerobic Media Used in Automated Blood Culture Systems to Detect Bloodstream Infections," Journal of Clinical Microbiology, Mar. 1998, p. 657-661.	
	6	Zimmon, David S. et al. "Effect of portal venous blood flow diversion on portal pressure." The Journal of Clinical Investigation 65.6 (1980): 1388-1397.	

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature	/MAY A ABOUELELA/	Date Considered	04/11/2023

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

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	Examiner Name	ABOUELELA, MAY A
	Attorney Docket Number	069366-0572169_KUR4C01US

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

☒ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2023-04-10
Name/Print	Benjamin F. Hudson	Registration Number	71,474

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.A.A/

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

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Doc code: IDS
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PTO/SB/08a (02-18)
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First Named Inventor	Bobby E. ROGERS
Art Unit	3791
Examiner Name	ABOUELELA, MAY A
Attorney Docket Number	069366-0572169_KUR4C01US

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	3382865		1968-05-14	WORRALL JR ASHTON L	
	2	3494352		1970-02-10	RUSSO RONALD D	
	3	3604410		1971-09-14	WHITACRE GARY L	
	4	3648684		1972-03-14	BARNWELL CLEORA W	
	5	3817240		1974-06-18	AYRES W	
	6	3835835		1974-09-17	THOMPSON R	
	7	3848579		1974-11-19	VILLA REAL A	
	8	3859998		1975-01-14	THOMAS JOSEPH JOHN	

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	9	3945380		1976-03-23	DABNEY WILLIAM C	
	10	4056101		1977-11-01	GEISSLER ULRICH C	
	11	4150089		1979-04-17	LINET MICHAEL S	
	12	4193400		1980-03-18	LOVELESS JAMES C	
	13	4257416		1981-03-24	PRAGER DAVID	
	14	4349035		1982-09-14	THOMAS JOSEPH J	
	15	4373535		1983-02-15	MARTELL MICHAEL D	
	16	4416290		1983-11-22	LUTKOWSKI LAWRENCE	
	17	4673386		1987-06-16	GORDON MARK G	
	18	4690154		1987-09-01	WOODFORD TIMOTHY	
	19	4813433		1989-03-21	DOWNEY JOHN M	

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	20	4904240		1990-02-27	HOOVER ROCKLIN L	
	21	4980297		1990-12-25	HAYNES JOHN L	
	22	5045185		1991-09-03	OHNAKA YUKIHIRO	
	23	5097842		1992-03-24	BONN GINA B	
	24	5100394		1992-03-31	DUDAR THOMAS E	
	25	5135489		1992-08-04	JEPSON STEVEN C	
	26	5200325		1993-04-06	BLATT JOEL M	
	27	5401262		1995-03-28	KARWOSKI THEODORE	
	28	5417673		1995-05-23	GORDON MARK G	
	29	5431811		1995-07-11	TUSINI ANDREA	
	30	5432084		1995-07-11	BRUBAKER DANIEL B	

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	31	5439450		1995-08-08	HAEDT LORI E	
	32	5632906		1997-05-27	ISHIDA NOBORU	
	33	5691486		1997-11-25	BEHRINGER BRUCE E	
	34	5772608		1998-06-30	DHAS V VARAPRABHU	
	35	5811658		1998-09-22	VAN DRIEL MICHAEL R	
	36	5865803		1999-02-02	MAJOR MIKLOS	
	37	5873841		1999-02-23	BRANNON JAMES K	
	38	5972294		1999-10-26	SMITH JOHN L	
	39	5980830		1999-11-09	SAVAGE DOUGLAS ROBERT	
	40	6013037		2000-01-11	BRANNON JAMES K	
	41	6106509		2000-08-22	LOUBSER PAUL G	

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	42	6187347		2001-02-13	PATTERSON JAMES A	
	43	6224561		2001-05-01	SWENDSON DAVID L	
	44	6506182		2003-01-14	ESTABROOK BRIAN K	
	45	6599474		2003-07-29	EVTODIENKO VLADIMIR	
	46	6626884		2003-09-30	DILLON JAGMOHANBIR SINGH	
	47	6638252		2003-10-28	MOULTON WILLIAM G	
	48	6695004		2004-02-24	RAYBUCK JOHN L	
	49	6733433		2004-05-11	FELL CLAUDE	
	50	6736783		2004-05-18	BLAKE KEVIN R	
	51	6843775		2005-01-18	HYUN DONGCHUL D	
	52	6860871		2005-03-01	KURACINA THOMAS C	

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	53	6905483		2005-06-14	NEWBY C MARK	
	54	6913580		2005-07-05	STONE BENJAMIN CURTIS	
	55	6945948		2005-09-20	BAINBRIDGE MARLENE	
	56	7052603		2006-05-30	SCHICK KARL G	
	57	7055401		2006-06-06	PRYBELLA JOHN R	
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	59	7306736		2007-12-11	COLLINS GREGORY R	
	60	7461671		2008-12-09	EHWALD RUDOLF	
	61	7479131		2009-01-20	MATHIAS JEAN-MARIE	
	62	7666166		2010-02-23	EMMERT MICHAEL	
	63	8070725		2011-12-06	CHRISTENSEN KELLY D	

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	64	8349254		2013-01-08	HOSHINO YOSHITERU	
	65	8377040		2013-02-19	BURKHOLZ JONATHAN KARL	
	66	8574203		2013-11-05	STOUT MARTY L	
	67	8827958		2014-09-09	BIERMAN STEVEN F	
	68	9820682		2017-11-21	ROGERS BOBBY E	
	69	10010282		2018-07-03	ROGERS BOBBY E	
	70	10143412		2018-12-04	ROGERS BOBBY E	
	71	10827964		2020-11-10	ROGERS BOBBY E	
	72	11185266		2021-11-30	ROGERS BOBBY E	
	73	11213232		2022-01-04	IVOSEVIC MILAN	
	74	11311219		2022-04-26	ROGERS BOBBY E	

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	Examiner Name	ABOUELELA, MAY A
	Attorney Docket Number	069366-0572169_KUR4C01US

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	2	20030082074		2003-05-01	JURIK FRANKLIN A	
	3	20030185707		2003-10-02	IWAKI YOSHIHIDE	
	4	20030208151		2003-11-06	KRAUS MENACHEM	
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	11	20070119508		2007-05-31	WEST RICHARD L	
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Examiner Signature	/MAY A ABOUELELA/	Date Considered	04/11/2023

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CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

☒ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2023-04-10
Name/Print	Benjamin F. Hudson	Registration Number	71,474

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.A.A/

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/094,692	11/10/2020	Bobby E. ROGERS	KURIN4CON	8012

158174 7590 11/04/2022

Kurin, Inc.
P.O. Box 371710
San Diego, CA 92137

EXAMINER	
ABOUELELA, MAY A	

ART UNIT	PAPER NUMBER
3791	

NOTIFICATION DATE	DELIVERY MODE
11/04/2022	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

eofficeaction@appcoll.com
jsnolan1@hotmail.com
kurin@virtualipsupport.com

Office Action Summary	Application No. 17/094,692	Applicant(s) ROGERS et al.	
	Examiner MAY A ABOUELELA	Art Unit 3791	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 02/04/2021.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL.** 2b) ☑ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 1-18 and 20 is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 1-18 and 20 is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to **PPHfeedback@uspto.gov.**

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☑ The drawing(s) filed on 11/10/2020 is/are: a)☑ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☑ Notice of References Cited (PTO-892)

2) ☐ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

Notice of Pre-AIA or AIA Status

1. The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Claim Objections

2. Claim 14 is objected to because of the following informalities: the phrase "into chamber" in line 8 should be amended to read –into the chamber--. Appropriate correction is required.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the claims at issue are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the reference application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO internet Web site contains terminal disclaimer forms which may be used. Please visit http://www.uspto.gov/forms/. The filing date of the application will determine what form should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to http://www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp.

Claims 1-18 and 20 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-20 of U.S Patent Application No. 10827964. Although the claims at issue are not identical, they are not patentably distinct from each other because the U.S Patent Application and the instance application are claiming a common subject matter including: a blood sequestration/optimization device comprising; an inlet port; an outlet port; a chamber connected with the inlet port, the sequestration chamber having a vent configured to allow air to be displaced by a first portion of blood entering the inlet port and into sequestration chamber; a plug/closure to enclose the vent to inhibit air from reentering the sequestration chamber; a sampling

channel having a proximal end connected with the inlet port and a distal end connected with the outlet port, the sampling channel being configured to convey subsequent portions of blood past the sequestration chamber and to the outlet port after the first portion of blood has entered the sequestration chamber; and a housing that houses and defines the inlet port, the outlet port, the sequestration chamber, and the sampling channel.

This is a provisional nonstatutory double patenting rejection because the patentably indistinct claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MAY A ABOUELELA whose telephone number is (571)270-7917. The examiner can normally be reached 8-5.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JACQUELINE CHENG can be reached on 5712725596. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is

available to registered users. To file and manage patent submissions in Patent Center, visit: https://patentcenter.uspto.gov. Visit https://www.uspto.gov/patents/apply/patent-center for more information about Patent Center and https://www.uspto.gov/patents/docx for information about filing in DOCX format. For additional questions, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MAY A ABOUELELA/
Primary Examiner, Art Unit 3791

Notice of References Cited	Application/Control No. 17/094,692	Applicant(s)/Patent Under Reexamination ROGERS et al.	
	Examiner MAY A ABOUELELA	Art Unit 3791	Page 1 of 4

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
*	A	US-20080319346-A1	12-2008	Crawford; Jamieson	A61B5/150389	600/576
*	B	US-4412548-A	11-1983	Hoch; Louis	A61B5/150213	600/577
*	C	US-5222502-A	06-1993	Kurose; Katsutoshi	A61B5/150732	600/584
*	D	US-5520193-A	05-1996	Suzuki; Issei	A61B5/1545	604/126
*	E	US-20100057004-A1	03-2010	Christensen; Kelly D.	A61M39/22	604/122
*	F	US-20070088279-A1	04-2007	Shue; Ming-Jeng	A61M25/0693	604/168.01
*	G	US-20080145933-A1	06-2008	Patton; Richard G.	A61B5/154	435/379
*	H	US-20040054333-A1	03-2004	Theeuwes, Felix	A61M5/14276	604/248
*	I	US-9022951-B2	05-2015	Bullington; Gregory	A61B10/0048	600/576
*	J	US-6569117-B1	05-2003	Ziv; David	A61M39/02	604/246
*	K	US-3741197-A	06-1973	Sanz; Manuel C.	A61B5/150267	600/583
*	L	US-20100010372-A1	01-2010	BROWN; LEROY R.	A61B5/15003	600/573
*	M	US-8603009-B2	12-2013	Tan; Alvin Chee Leong	A61B5/150664	600/573

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	CPC Classification
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Notice of References Cited	Application/Control No. 17/094,692	Applicant(s)/Patent Under Reexamination ROGERS et al.	
	Examiner MAY A ABOUELELA	Art Unit 3791	Page 2 of 4

U.S. PATENT DOCUMENTS

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*	A	US-4207870-A	06-1980	Eldridge; William N.	A61B5/150732	604/167.03
*	B	US-20080167577-A1	07-2008	Weilbacher; Eugene E.	A61B5/1545	600/576
*	C	US-20080086085-A1	04-2008	Brown; Leroy R.	A61B5/150389	604/122
*	D	US-9877675-B2	01-2018	Baid; Rishi	A61B5/150389	1/1
*	E	US-4444203-A	04-1984	Engelman; Allan	A61B5/150496	600/576
*	F	US-20070083162-A1	04-2007	O'Reagan; James	A61M39/26	604/167.03
*	G	US-6398743-B1	06-2002	Halseth; Thor R.	A61B5/15003	604/164.12
*	H	US-9022950-B2	05-2015	Bullington; Gregory	A61B5/150389	600/576
*	I	US-9155495-B2	10-2015	Bullington; Gregory J.	A61B5/150633	1/1
*	J	US-20160008579-A1	01-2016	Burkholz; Jonathan Karl	A61M5/158	604/164.08
*	K	US-20120016266-A1	01-2012	Burkholz; Jonathan Karl	A61B5/150992	600/581
*	L	US-4436098-A	03-1984	Kaufman; Joseph	A61B5/1545	604/199
*	M	US-20130317391-A1	11-2013	Bullington; Gregory J.	A61B5/15003	600/578

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Notice of References Cited	Application/Control No. 17/094,692	Applicant(s)/Patent Under Reexamination ROGERS et al.	
	Examiner MAY A ABOUELELA	Art Unit 3791	Page 3 of 4

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
*	A	US-9138572-B2	09-2015	Zeytoonian; Paul	A61M39/26	1/1
*	B	US-8568371-B2	10-2013	Siopes; William	A61M39/26	251/903
*	C	US-8540663-B2	09-2013	Davey; Christopher T.	A61M1/30	604/93.01
*	D	US-8523826-B2	09-2013	Layton, Jr.; Russell K.	A61M39/16	604/533
*	E	US-20160174888-A1	06-2016	Berthier; Erwin	A61B5/150503	600/573
*	F	US-8197420-B2	06-2012	Patton; Richard G.	A61B5/150503	600/573
*	G	US-4057050-A	11-1977	Sarstedt; Walter	A61B5/150351	604/125
*	H	US-20050240161-A1	10-2005	Crawford, Jamieson William McLean	A61B5/150572	604/264
*	I	US-20040147855-A1	07-2004	Marsden, Stewart	A61B5/150496	600/576
*	J	US-8864684-B2	10-2014	Bullington; Gregory J.	A61B10/0048	600/576
*	K	US-8535241-B2	09-2013	Bullington; Gregory	A61B5/150946	604/249
*	L	US-20040073171-A1	04-2004	Rogers, Bobby E.	A61M39/26	604/164.13
*	M	US-20050004524-A1	01-2005	Newby, C. Mark	A61B5/150648	604/164.08

FOREIGN PATENT DOCUMENTS

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Notice of References Cited	Application/Control No. 17/094,692	Applicant(s)/Patent Under Reexamination ROGERS et al.	
	Examiner MAY A ABOUELELA	Art Unit 3791	Page 4 of 4

U.S. PATENT DOCUMENTS

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*	A	US-20030105414-A1	06-2003	Leong, Alvin Tan Chee	A61B5/15003	600/576
*	B	US-5749857-A	05-1998	Cuppy; Michael J.	A61M25/0606	604/161
*	C	US-9060724-B2	06-2015	Bullington; Gregory J.	A61B5/150099	1/1
*	D	US-9204864-B2	12-2015	Bullington; Gregory J.	A61B10/0096	1/1
*	E	US-20020004647-A1	01-2002	Leong, Alvin Tan Chee	A61B5/1545	604/168.01
*	F	US-3817240-A	06-1974	Ayres; Waldemar A.	A61B5/150221	600/584
*	G	US-3874367-A	04-1975	Ayres; Waldemar A.	A61B5/15003	600/577
*	H	US-3886930-A	06-1975	Ryan; George R.	A61B5/15003	600/584
*	I	US-4106497-A	08-1978	Percarpio; Edward P.	A61B5/150389	600/579
*	J	US-4154229-A	05-1979	Nugent; Edward L.	A61B5/150473	600/577
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Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/094,692	ROGERS et al.
	Examiner	**Art Unit**
	MAY A ABOUELELA	3791

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

CLAIMS

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	10/13/2022								
	1	✓								
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	16	✓								
	17	✓								
	18	✓								
	19	-								
	20	✓								

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/094,692	ROGERS et al.
	Examiner	Art Unit
	MAY A ABOUELELA	3791

CPC - Searched*		
Symbol	Date	Examiner
A61B5/150213 OR A61B5/15003 OR A61B5/150221 OR A61B5/150251 OR A61B5/150732 OR A61B5/15074 OR A61B5/150992 OR A61B5/153 OR A61B5/150389 OR A61B5/150503	10/13/2022	MA

CPC Combination Sets - Searched*		
Symbol	Date	Examiner

US Classification - Searched*			
Class	Subclass	Date	Examiner

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	Date	Examiner
class/subclass search, text search, inventor name search	10/13/2022	MA

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner

/MAY A ABOUELELA/ Primary Examiner, Art Unit 3791	

PE2E SEARCH - Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
L1	0	("15140443").PN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2016/12/20 11:05 PM
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L3	1	("14055232").PN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2016/12/21 11:39 AM
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L13	852	L4 and (blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2016/12/21 05:47 PM
L14	46	L10 and (blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2016/12/21 05:47 PM
L15	1	("8197420").PN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2016/12/21 06:29 PM
L16	1	("20130317391").PN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2016/12/21 06:42 PM
L17	1254	(600/583).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2016/12/21 06:43 PM
L18	1070	L17 and (blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2016/12/21 06:43 PM
L19	265030	(blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2016/12/21 07:09 PM
L20	5653	L19 AND ((A61B10/0096 OR A61B5/150022).CPC.)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2016/12/21 07:10 PM
L21	207	L20 and (seal near4 air)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2016/12/21 07:10 PM
L22	23	"2004087258"	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2016/12/21 08:59 PM
L23	1	("20050004524").PN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2017/04/11 08:23 PM
L24	1	("20030105414").PN.	(US-PGPUB; USPAT;	OR	ON	ON	2017/04/11

			USOCR)				08:24 PM
L25	1	("5749857").PN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2017/04/11 08:26 PM
L26	13	("20040073171"|"20040147855"|"20050240161"|"20130317391"|"20160174888"|"4057050"|"8197420"|"8523826"|"8535241"|"8540663"|"8568371"|"8864684"|"9138572").PN.	(US-PGPUB; USPAT)	OR	OFF	OFF	2017/04/11 08:39 PM
L27	1	("15140443").PN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2017/04/11 09:43 PM
L28	0	("4and(bloodnear4air)").PN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2017/04/11 10:01 PM
L29	3	L26 and (blood near4 air)	(US-PGPUB; USPAT)	OR	OFF	OFF	2017/04/11 10:01 PM
L30	6	L26 and vent$4	(US-PGPUB; USPAT)	OR	OFF	OFF	2017/04/11 10:02 PM
L31	5	("2013/0317391").URPN.	(USPAT)	OR	OFF	OFF	2017/04/11 10:06 PM
L32	48	("2005/0004524").URPN.	(USPAT)	OR	OFF	OFF	2017/04/11 10:17 PM
L33	1	("20120170037").PN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2017/04/12 04:11 PM
L34	1	("6139540").PN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2017/04/13 12:52 PM
L35	1	("20040116878").PN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2017/04/13 12:54 PM
L36	1	("20100152752").PN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2017/04/13 01:16 PM
L37	1	("6395003").PN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2017/04/13 01:20 PM
L38	5	("2013/0317391").URPN.	(USPAT)	OR	OFF	OFF	2017/04/13 01:43 PM
L39	1	("4444203").PN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2017/04/13 01:44 PM
L40	1	("20020004647").PN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2017/04/13 01:48 PM
L41	1	("3817240").PN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2017/04/13 01:57 PM
L42	1	("3874367").PN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2017/04/13 01:57 PM
L43	1	("3886930").PN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2017/04/13 01:58 PM
L44	1	("4106497").PN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2017/04/13 01:59 PM
L45	1	("4154229").PN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2017/04/13 01:59 PM
L46	1	("4207870").PN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2017/04/13 02:00 PM

L47	292	("2913000" | "3817240" | "3859998" | "3864979" | "4016879" | "4046144").PN. OR ("4207870").URPN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2017/04/13 02:01 PM
L48	1	("4412548").PN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2017/04/13 02:04 PM
L49	1	("5222502").PN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2017/04/13 02:11 PM
L50	1	("5520193").PN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2017/04/13 02:15 PM
L51	1	("20100057004").PN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2017/04/13 02:16 PM
L52	1	("20070088279").PN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2017/04/13 02:29 PM
L53	1733	(600/573).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2017/04/13 03:29 PM
L54	13	L53 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2017/04/13 03:52 PM
L55	1255	(600/583).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2017/04/13 04:23 PM
L56	4	L55 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2017/04/13 04:23 PM
L57	272301	(blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2017/04/13 04:29 PM
L58	5898	L57 AND ((A61B10/0096 OR A61B5/150022).CPC.)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2017/04/13 04:29 PM
L59	114	L58 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2017/04/13 04:29 PM
L60	2	("2007/0088279").URPN.	(USPAT)	OR	OFF	OFF	2017/04/13 05:58 PM
L61	1	("6358217").PN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2017/04/21 02:02 PM
L62	6	("2002/0004647").URPN.	(USPAT)	OR	OFF	OFF	2017/09/27 12:48 PM
L63	2	("14493796").PN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2017/09/27 01:21 PM
L64	2	("14494208").PN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2017/09/27 01:23 PM
L65	1	("15140443").PN.	(US-PGPUB; USPAT)	OR	ON	ON	2017/09/27 01:28 PM
L66	1	("20080145933").PN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2017/09/27 01:51 PM
L67	9	("2008/0145933").URPN.	(USPAT)	OR	OFF	OFF	2017/09/27 01:55 PM
L68	1	("20040054333").PN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2017/09/27 01:59 PM

L69	1	("20120109034").PN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2017/09/27 02:37 PM
L70	1	("20100228206").PN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2017/09/27 02:39 PM
L71	3	("2010/0228206").URPN.	(USPAT)	OR	OFF	OFF	2017/09/27 02:47 PM
L72	66	(("ROGERS") near3 ("Bobby")).INV.	(US-PGPUB; USPAT)	OR	OFF	OFF	2017/09/28 01:41 PM
L73	4	L72 and (blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2017/09/28 01:42 PM
L74	1733	(600/573).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2017/09/28 01:58 PM
L75	845	L74 and (blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2017/09/28 01:58 PM
L76	9	L75 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2017/09/28 01:59 PM
L77	86	("2007/0083162").URPN.	(USPAT)	OR	OFF	OFF	2017/09/28 01:59 PM
L78	1	("15140443").PN.	(US-PGPUB; USPAT)	OR	ON	ON	2017/09/28 01:59 PM
L79	9	("2008/0145933").URPN.	(USPAT)	OR	OFF	OFF	2017/09/28 02:04 PM
L80	1258	(600/583).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2017/09/28 02:20 PM
L81	1071	L80 and (blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2017/09/28 02:20 PM
L82	78	L81 and (vent$4 near4 air)	(US-PGPUB; USPAT)	OR	OFF	OFF	2017/09/28 02:21 PM
L83	282596	(blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2017/09/28 04:01 PM
L84	6183	L83 AND ((A61B10/0096 OR A61B5/150022).CPC.)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2017/09/28 04:01 PM
L85	387	L84 and (vent$4 near4 air)	(US-PGPUB; USPAT)	OR	OFF	OFF	2017/09/28 04:01 PM
L86	362	L85 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2017/09/28 04:02 PM
L87	12	("2005/0010189").URPN.	(USPAT)	OR	OFF	OFF	2017/09/28 04:03 PM
L88	1363	(604/164.01).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2017/09/28 04:04 PM
L89	74	L88 and (blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2017/09/28 04:05 PM
L90	21	("3965910" | "3996923"	(US-PGPUB; USPAT;	OR	OFF	OFF	2017/09/28

		| "4131127" | "4301811" | "4450854" | "4506691" | "4819684" | "5147333" | "5393035" | "5636975").PN. OR ("6569117").URPN.	USOCR)				04:09 PM
L91	499	(435/294.1).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2017/09/28 04:12 PM
L92	18	L91 and (blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2017/09/28 04:12 PM
L93	9	("2008/0145933").URPN.	(USPAT)	OR	OFF	OFF	2017/09/28 04:13 PM
L95	67	(("ROGERS") near3 ("Bobby")).INV.	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/01/09 04:23 PM
L96	1258	(600/583).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2018/01/09 04:25 PM
L97	4	L96 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/01/09 04:25 PM
L98	3	L97 and (blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/01/09 04:26 PM
L99	1733	(600/573).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2018/01/09 04:50 PM
L100	13	L99 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/01/09 04:50 PM
L101	255	("1779451" | "2004050" | "2700385" | "2836942" | "2854976" | "2953243" | "3021942" | "3073307" | "3074542" | "3255873" | "3294231" | "3323523" | "3329146" | "3333682" | "3367488" | "3382865" | "3485239" | "3537452" | "3585984" | "3610240" | "3658061" | "3664879" | "3817240" | "3828775" | "3859998" | "3874367" | "3886930" | "3890971" | "3904033" | "3934722" | "3968876" | "4106497" | "4108175" | "4113090" | "4139009" | "4154229" | "4166450" | "4175008" | "4193400" | "4207870" | "4269186" | "4300678" | "4312362" | "4317445" | "4340068" | "4375849" | "4398544" | "4409990" | "4412548" | "4416290" | "4416291" | "4418703" | "4430082" | "4436098" | "4444203" | "4592744"	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2018/01/09 04:51 PM

		| "4634428" | "4643722" | "4659330" | "4664249" | "4664654" | "4671408" | "4679571" | "4681567" | "4695274" | "4702738" | "4723943" | "4728320" | "4728321" | "4731059" | "4735311" | "4735618" | "4737144" | "4738663" | "4743233" | "4746008" | "4747836" | "4747837" | "4772272" | "4778453" | "4781697" | "4782841" | "4788986" | "4790828" | "4793484" | "4795432" | "4795443" | "4801295" | "4804372" | "4813426" | "4816022" | "4816024" | "4819659" | "4820277" | "4826490" | "4826491" | "4838871" | "4842587" | "4844089" | "4846796" | "4850968" | "4850976" | "4850977" | "4850978" | "4850994" | "4850996" | "4858607" | "4863434" | "4863435" | "4863436" | "4865592" | "4867746" | "4872552" | "4874383" | "4874384" | "4883469" | "4886072" | "4886503" | "4888001" | "4892107" | "4892521" | "4894052" | "4900309" | "4909791" | "4909792").PN. OR ("4921096" | "4927018" | "4944397" | "4966591" | "4971068" | "4976699" | "4982842" | "5011475" | "5011479" | "5030207" | "5032116" | "5033476" | "5055102" | "5069225" | "5078693" | "5078698" | "5092845" | "5112327" | "5116325" | "5120319" | "5122121" | "5135509" | "5137518" | "5139489" | "5151089" | "5154285" | "5181523" | "5188611" | "5197954" | "5201794" | "5207653" | "5217025" | "5222502" | "5232454" | "5232455" | "5242411" | "5242417" | "5277311" | "5290246" | "5295969" | "5303713" | "5306259" | "5312369" | "5401251" | "5405332" | "5423765"					

		| "5450856" | "5462534" | "5485854" | "5486163" | "5490841" | "5496281" | "5509907" | "5520193" | "5533984" | "5542932" | "5584816" | "5599313" | "5599318" | "5603699" | "5632732" | "5643219" | "5662617" | "5665075" | "5669889" | "5693022" | "5697914" | "5702369" | "5733265" | "5755701" | "5807351" | "5830190" | "5836920" | "5885249" | "5893844" | "5913846" | "5984895" | "5993426" | "6059737" | "6077244" | "6077253" | "6080137" | "6096006" | "6110160" | "6120482" | "6156010" | "6190370" | "6261263" | "6511439" | "6533760" | "6964658" | "7160267" | "RE31086").PN. OR ("7615033").URPN.					
L102	215	L101 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/01/09 04:51 PM
L103	1347	(604/164.01).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2018/01/09 05:11 PM
L104	17	L103 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/01/09 05:11 PM
L105	19	("2009/0312711").URPN.	(USPAT)	OR	OFF	OFF	2018/01/09 05:11 PM
L106	11	("2007/0106220").URPN.	(USPAT)	OR	OFF	OFF	2018/01/09 05:11 PM
L107	288967	(blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2018/01/09 05:16 PM
L108	6321	L107 AND ((A61B10/0096 OR A61B5/150022).CPC.)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2018/01/09 05:16 PM
L109	121	L108 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/01/09 05:17 PM
L110	448	(435/294.1).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2018/01/09 05:31 PM
L111	6	L110 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/01/09 05:31 PM
L113	71	(("ROGERS") near3 ("Bobby")).INV.	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/07/24 01:31 PM
L114	0	("15140443").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2018/07/24 01:38 PM

L115	2	(15/140443).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2018/07/24 01:38 PM
L116	2	(15/140448).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2018/07/24 01:40 PM
L117	1735	(600/573).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2018/07/24 01:56 PM
L118	854	L117 and (blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/07/24 01:56 PM
L119	91	L118 and (vent$4 near4 air)	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/07/24 01:57 PM
L120	1258	(600/583).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2018/07/24 02:06 PM
L121	1074	L120 and (blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/07/24 02:06 PM
L122	80	L121 and (vent$4 near4 air)	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/07/24 02:06 PM
L123	301210	(blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2018/07/24 02:11 PM
L124	6556	L123 AND ((A61B10/0096 OR A61B5/150022).CPC.)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2018/07/24 02:11 PM
L125	3664	L124 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/07/24 02:12 PM
L126	12749	"19" and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/07/24 02:12 PM
L127	117	L125 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/07/24 02:12 PM
L128	1348	(604/164.01).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2018/07/24 02:16 PM
L129	75	L128 and (blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/07/24 02:17 PM
L130	1	("20120291564").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2018/07/24 02:21 PM
L131	448	(435/294.1).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2018/07/24 02:25 PM
L132	18	L131 and (blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/07/24 02:25 PM
L133	98	("20020002349" | "20020183651" | "20030055381" | "20030208151" | "20040010228" | "20040054333" | "20040147855" | "20050004524" |	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2018/07/24 02:44 PM

		"20050240161" | "20050245885" | "20050281713" | "20060287639" | "20080108954" | "20080145933" | "2707953" | "3013557" | "3098016" | "3382865" | "3405706" | "3494351" | "3577980" | "3648684" | "3848579" | "3937211" | "4057050" | "4133863" | "4166450" | "4340067" | "4370987" | "4444203" | "4459997" | "4509534" | "4657160" | "4676256" | "4865583" | "4890627" | "4988339" | "5009847" | "5097842" | "5108927" | "5122129" | "5269317" | "5330464" | "5360011" | "5429610" | "5450856" | "5507299" | "5577513" | "5762633" | "5865812" | "5882318" | "5922551" | "6016712" | "6057105" | "6159164" | "6210909" | "6364890" | "6387086" | "6403381" | "6626884" | "6692479" | "6746420" | "6913580" | "7044941" | "7087047" | "7335188" | "7744573" | "8197420" | "8231546" | "8337418").PN. OR ("8535241").URPN.					
L134	307	("2913000" | "3817240" | "3859998" | "3864979" | "4016879" | "4046144").PN. OR ("4207870").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2018/07/24 02:47 PM
L135	23	("4166450").PN. OR ("4412548").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2018/07/24 02:48 PM
L136	307	("2913000" | "3817240" | "3859998" | "3864979" | "4016879" | "4046144").PN. OR ("4207870").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2018/07/24 02:48 PM
L137	4	("2007/0088279").URPN.	(USPAT)	OR	ON	ON	2018/07/24 02:48 PM
L138	1	(14/990763).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2018/07/24 02:58 PM
L139	9	(blood and sequest$5 and junction and first and portion and sampl$4).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2018/07/24 03:07 PM

L140	1	(15/287421).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2018/07/25 09:39 PM
L141	2	(14/055232).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2018/07/26 11:56 AM
L142	2	(15/140443).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/07 03:24 PM
L143	1	(15/893518).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/07 03:25 PM
L144	34	("20020004647"|"20030105414"|"20040054333"|"20040073171"|"20040147855"|"20050004524"|"20050240161"|"20070088279"|"20080145933"|"20100057004"|"20130317391"|"20160174888"|"3817240"|"3874367"|"3886930"|"4057050"|"4106497"|"4154229"|"4207870"|"4412548"|"5222502"|"5520193"|"5749857"|"6569117"|"8197420"|"8523826"|"8535241"|"8540663"|"8568371"|"8864684"|"9022951"|"9060724"|"9138572"|"9204864").PN.	(US-PGPUB; USPAT)	OR	ON	ON	2019/11/07 05:53 PM
L145	272	((("ROGERS") near3 ("Bobby")) OR (("KANG") near3 ("Gino")) OR (("STROUP") near3 ("David")) OR (("COCHRAN") near3 ("Jonas")) OR (("DEPTALA") near3 ("Arthur")) OR (("DETLOFF") near3 ("John")) OR (("POGUE") near3 ("Lonnie")) OR (("MACOWSKI") near3 ("Brian")) OR (("GARRETT") near3 ("Chad"))).INV.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2019/11/07 05:57 PM
L146	9	L145 and (blood near4 sequest$5)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 05:58 PM
L147	34	("20020004647"|"20030105414"|"20040054333"|"20040073171"|"20040147855"|"20050004524"|"20050240161"|"20070088279"|"20080145933"|"20100057004"|"20130317391"|"20160174888"|"3817240"|"38743	(US-PGPUB; USPAT)	OR	ON	ON	2019/11/07 06:26 PM

		67"|"3886930"|"4057050"|"4106497"|"4154229"|"4207870"|"4412548"|"5222502"|"5520193"|"5749857"|"6569117"|"8197420"|"8523826"|"8535241"|"8540663"|"8568371"|"8864684"|"9022951"|"9060724"|"9138572"|"9204864").PN.					
L148	5	L147 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 06:29 PM
L149	6	("2010/0057004").URPN.	(USPAT)	OR	ON	ON	2019/11/07 06:40 PM
L150	0	L149 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 07:20 PM
L151	1258	(600/583).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2019/11/07 07:21 PM
L152	4	L151 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 07:21 PM
L153	1766	(600/573).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/07 07:21 PM
L154	13	L153 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 07:21 PM
L155	811	(600/576).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/07 07:22 PM
L156	48	L155 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 07:22 PM
L157	1351	(604/164.01).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2019/11/07 07:43 PM
L158	17	L157 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 07:43 PM
L159	448	(435/294.1).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2019/11/07 07:43 PM
L160	6	L159 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 07:44 PM
L161	333030	(blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2019/11/07 07:44 PM
L162	6981	L161 AND ((A61B10/0096 OR A61B5/150022).CPC.)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2019/11/07 07:44 PM
L163	139	L162 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 07:44 PM
L164	117	L163 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 07:45 PM
L165	1	L146 and (enclos$3 near4 mechanism)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 07:51 PM
L166	1	("7637875").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/08 04:57 PM

L167	1	(15/139716).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/11 12:09 PM
L168	1	(15/520430).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/12 11:02 AM
L169	1	("7637875").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/12 12:11 PM
L170	1	("20120253321").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/12 12:13 PM
L171	1	(15/861959).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/12 12:14 PM
L172	1	("4207870").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/12/09 02:17 PM
L173	1	("5749857").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/12/09 03:14 PM
L174	1	("20080167577").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/12/09 03:19 PM
L175	4	("2008/0167577").URPN.	(USPAT)	OR	ON	ON	2019/12/09 03:30 PM
L176	1	("8197420").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/12/09 03:31 PM
L177	39	(US-20040073171-$ or US-20160174888-$ or US-20050240161-$ or US-20040147855-$ or US-20130317391-$ or US-20050004524-$ or US-20030105414-$ or US-20020004647-$ or US-20100057004-$ or US-20070088279-$ or US-20080145933-$ or US-20040054333-$ or US-20100010372-$ or US-20080319346-$ or US-20080167577-$).did. or (US-9138572-$ or US-8568371-$ or US-8540663-$ or US-8523826-$ or US-8197420-$ or US-4057050-$ or US-8864684-$ or US-8535241-$ or US-5749857-$ or US-9060724-$ or US-9204864-$ or US-3817240-$ or US-3874367-$ or US-3886930-$ or US-4106497-$ or US-4154229-$ or US-4207870-$ or US-4412548-$ or US-5222502-$ or US-5520193-$ or US-	(US-PGPUB; USPAT)	OR	ON	ON	2019/12/09 03:37 PM

		9022951-$ or US-6569117-$ or US-3741197-$ or US-8603009-$).did.					
L178	8	("20040054333"|"8197420"|"9855001"|"9861306"|"10045724"|"10028687"|"8337418"|"10028689").PN.	(US-PGPUB; USPAT)	OR	ON	ON	2019/12/09 03:42 PM
L179	100	("20020002349" | "20020183651" | "20030055381" | "20040010228" | "20040054333" | "20040147855" | "20050004524" | "20050240161" | "20050245885" | "20050281713" | "20060287639" | "2707953" | "3013557" | "3098016" | "3382865" | "3405706" | "3494351" | "3577980" | "3648684" | "3848579" | "3937211" | "4057050" | "4133863" | "4166450" | "4340067" | "4370987" | "4444203" | "4459997" | "4509534" | "4676256" | "4865583" | "4890627" | "4988339" | "5009847" | "5097842" | "5108927" | "5122129" | "5269317" | "5360011" | "5429610" | "5450856" | "5507299" | "5577513" | "5762633" | "5882318" | "5922551" | "6016712" | "6057105" | "6159164" | "6210909" | "6364890" | "6387086" | "6403381" | "6692479" | "6746420" | "6913580" | "7044941" | "7087047").PN. OR ("8197420").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2019/12/09 03:43 PM
L180	70	L179 and (blood near4 (sequest$5 or sampl$4 or flash$4))	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2019/12/09 03:43 PM
L181	43	L180 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 03:44 PM
L182	270	((("BULLINGTON") near3 ("Gregory")) OR (("PATTON") near3 ("Richard")) OR (("MIAZGA") near3	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2019/12/09 04:13 PM

		("Jay")) OR (("GAW") near3 ("Shan"))).INV.					
L183	335813	(blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2019/12/09 04:22 PM
L184	7259	L183 AND ((A61B10/0096 OR A61B5/150022).CPC.)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2019/12/09 04:22 PM
L185	325	("2913000" | "3817240" | "3859998" | "3864979" | "4016879" | "4046144").PN. OR ("4207870").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2019/12/09 04:33 PM
L186	594	L184 and (flash$6 and seal$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 04:40 PM
L187	476	L186 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 04:40 PM
L188	1735	(600/573).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2019/12/09 05:14 PM
L189	1123	L188 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:15 PM
L190	1013	L189 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:15 PM
L191	10	L190 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:16 PM
L192	1259	(600/583).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/12/09 05:23 PM
L193	1143	L192 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:23 PM
L194	1038	L193 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:23 PM
L195	3	L194 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:23 PM
L196	811	(600/576).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/12/09 05:24 PM
L197	618	L196 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:24 PM
L198	557	L197 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:24 PM
L199	1	(15/854273).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/12/09 05:25 PM
L200	1351	(604/164.01).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2019/12/09 05:31 PM
L201	219	L200 and ((blood or	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09

		fluid$4) near4 (sequest$5 or sampl$4 or flash$4))					05:33 PM
L202	199	L201 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:33 PM
L203	448	(435/294.1).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2019/12/09 05:36 PM
L204	44	L203 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:37 PM
L205	1	(15/508871).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/12/10 11:58 AM
L206	342199	(blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2020/03/16 12:53 PM
L207	4239	L206 AND ((A61B10/0096 OR A61B5/150022).CPC.)	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 12:53 PM
L208	146	L207 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 12:54 PM
L209	101	L208 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 12:55 PM
L210	1735	(600/573).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2020/03/16 01:38 PM
L211	1123	L210 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:38 PM
L212	1013	L211 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:39 PM
L213	22	L212 and (((vent$4 or open$5 or hole or aperture) near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:39 PM
L214	108	("20020193748" | "20030093009" | "20030105414" | "20030220614" | "20030229315" | "20040059302" | "20040092872" | "20040193120" | "20050004524" | "20050065482" | "20050124944" | "20050187493" | "20050245868" | "20050245869" | "20050245870" | "20050245879" | "20050245885" |	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2020/03/16 01:46 PM

		"20060036219" | "20060224122" | "20070106220" | "20070106224" | "20070167914" | "20080086085" | "20080177202" | "20080319345" | "20080319346" | "20090204026" | "20100262038" | "4106497" | "4207870" | "4305406" | "4572210" | "4573976" | "4641663" | "4795443" | "4840619" | "4894055" | "4900307" | "4994046" | "5015241" | "5195985" | "5215534" | "5222502" | "5242417" | "5246428" | "5256153" | "5295970" | "5303713" | "5312372" | "5336199" | "5348544" | "5356392" | "5411492" | "5439449" | "5466223" | "5501675" | "5542932" | "5599313" | "5662617" | "5665075" | "5672161" | "5676658" | "5702369" | "5704920" | "5733265" | "5755522" | "5957892" | "5984899" | "6149629" | "6224576" | "6254575" | "6261263" | "6298541" | "6344032" | "6436086" | "6440104" | "6524277" | "6533760" | "6592556" | "6623456" | "6635032" | "6648855" | "6695819" | "6699217" | "6712792" | "6780169" | "6837877" | "6869415" | "6984223" | "7001363" | "7128726" | "7147624" | "7160267" | "7163526" | "7223258" | "7226432" | "7396343" | "7428773" | "7537581" | "7766879" | "D422700" | "D442280" | "D604836" | "D604837" | "D604838" | "D604839" | "D605287").PN. OR ("8603009").URPN.					
L215	26	L214 and (((vent$4 or open$5 or hole or aperture) near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:47 PM

L216	27	("2008/0319346").URPN.	(USPAT)	OR	ON	ON	2020/03/16 01:47 PM
L217	23	("2003/0105414").URPN.	(USPAT)	OR	ON	ON	2020/03/16 01:48 PM
L218	1258	(600/583).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2020/03/16 01:52 PM
L219	1143	L218 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:52 PM
L220	25	L219 and (((vent$4 or open$5 or hole or aperture) near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:52 PM
L221	353695	((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:54 PM
L222	3643	L221 and (((vent$4 or open$5 or hole or aperture) near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:55 PM
L223	1926	L222 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:55 PM
L224	785	L223 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:56 PM
L225	7046	(600/300).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/03/16 02:32 PM
L226	14	L225 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 02:35 PM
L227	1352	(604/164.01).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2020/03/16 02:36 PM
L228	135	L227 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 02:36 PM
L229	19	L228 and (((vent$4 or open$5 or hole or aperture) near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 02:36 PM
L230	448	(435/294.1).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2020/03/16 02:47 PM
L231	3	L230 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 02:47 PM
L232	19	("2008/0145933").URPN.	(USPAT)	OR	ON	ON	2020/03/16 02:48 PM
L233	795	(600/576).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2020/03/16 02:58 PM
L234	71	L233 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 02:58 PM

L235	57	L234 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 02:59 PM
L236	371	(600/577).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/03/16 03:12 PM
L237	11	L236 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 03:12 PM
L238	45	("20040054333"|"20050240161"|"4412548"|"5749857"|"8197420"|"9855001"|"9861306"|"20020004647"|"20100057004"|"3741197"|"20040073171"|"3874367"|"4057050"|"4106497"|"8197420"|"8535241"|"8540663"|"8603009"|"8864684"|"10045724"|"3817240"|"10028687"|"20030105414"|"5222502"|"5520193"|"6569117"|"8568371"|"20040147855"|"20070088279"|"20080145933"|"20100010372"|"3886930"|"8523826"|"9060724"|"9204864"|"8337418"|"20050004524"|"20080167577"|"20080319346"|"20130317391"|"4154229"|"9022951"|"10028689"|"20160174888"|"4207870"|"9138572").PN.	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 03:13 PM
L239	6	("2008/0167577").URPN.	(USPAT)	OR	ON	ON	2020/03/16 03:13 PM
L240	118	("3500828" | "3670729" | "3714945" | "3977400" | "3994293" | "3995619" | "4106491" | "4200096" | "4468224" | "4531987" | "4549554" | "4735215" | "4828548" | "4874373" | "4893635" | "4894052" | "4907599" | "4944308" | "4994042" | "5129884" | "5400798").PN. OR ("5749857").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2020/03/16 03:15 PM
L241	6	("2008/0167577").URPN.	(US-PGPUB; USPAT)	OR	ON	ON	2020/03/16 03:15 PM
L242	274	((("BULLINGTON") near3 ("Gregory")) OR (("PATTON") near3 ("Richard")) OR (("MIAZGA") near3 ("Jay")) OR (("GAW") near3 ("Shan"))).INV.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2020/03/16 03:25 PM

L243	61	L242 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 03:25 PM
L244	1	(15/854273).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/03/16 03:47 PM
L245	0	(14/502498).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/03/16 04:11 PM
L246	1	("20110082383").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/03/16 04:24 PM
L247	1	("8150506").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/03/16 04:24 PM
L252	1	(15/057214).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/03/17 11:28 AM
L253	348964	(blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2020/06/10 05:22 PM
L254	7453	L253 AND ((A61B10/0096 OR A61B5/150022).CPC.)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2020/06/10 05:22 PM
L255	155	L254 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 05:23 PM
L256	77	(("ROGERS") near3 ("Bobby")).INV.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 05:35 PM
L257	343953	(blood same (sequest$5 or sampl$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 05:40 PM
L258	11	L256 and (blood same (sequest$5 or sampl$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 05:41 PM
L259	1	("5749857").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 05:50 PM
L260	121	("3500828" | "3670729" | "3714945" | "3977400" | "3994293" | "3995619" | "4106491" | "4200096" | "4468224" | "4531987" | "4549554" | "4735215" | "4828548" | "4874373" | "4893635" | "4894052" | "4907599" | "4944308" | "4994042" | "5129884" | "5400798").PN. OR ("5749857").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2020/06/10 06:19 PM
L261	32	L260 and (blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:20 PM
L262	1	("3648684").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 06:38 PM
L263	1	("4056101").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 06:38 PM
L264	329	(600/577).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2020/06/10

							06:39 PM
L265	11	L264 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:39 PM
L266	29	("2008/0319346").URPN.	(USPAT)	OR	ON	ON	2020/06/10 06:40 PM
L267	812	(600/576).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 06:40 PM
L268	72	L267 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:40 PM
L269	1767	(600/573).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 06:44 PM
L270	31	L269 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:45 PM
L271	77	("4676249" | "4787891" | "4850960" | "4874382" | "4886067" | "4886500" | "4900307" | "4904242" | "4917102" | "4950252" | "4955862" | "5046508" | "5116353" | "5125718" | "5129884" | "5163911" | "5217435" | "5290244" | "5295974" | "5314503" | "5318585" | "5330432" | "5360410" | "5366441" | "5376075" | "5395337" | "5531692" | "5695475" | "5695479" | "5702367" | "5735813" | "5749857" | "5788654" | "5800395" | "5846226" | "5871470" | "5882342" | "5919172" | "5935108" | "5935113" | "5989220" | "6050976" | "6077244" | "6099504" | "6126641" | "6162195").PN. OR ("6398743").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2020/06/10 06:46 PM
L272	18	L271 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:46 PM
L273	1	(15/893518).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 06:48 PM
L274	7050	(600/300).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 06:49 PM
L275	14	L274 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:49 PM
L276	1259	(600/583).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 06:51 PM
L277	7	L276 and ((blood or	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10

		fluid$4) near4 (sequest$5 or flash$4))					06:51 PM
L278	1368	(604/164.01).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 06:52 PM
L279	135	L278 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:52 PM
L280	499	(435/294.1).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 07:08 PM
L281	3	L280 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 07:08 PM
L282	20	("2008/0145933").URPN.	(USPAT)	OR	ON	ON	2020/06/10 07:08 PM
L286	1	("10045704").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 08:56 PM
L287	1	("10143412").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/01 09:16 PM
L288	1	("10010282").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/01 09:17 PM
L289	100	((("ROGERS") near3 ("Bobby")) OR (("KANG") near3 ("Gino")) OR (("DETLOFF") near3 ("John"))).INV.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2021/03/01 09:17 PM
L290	2	(15/140443).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/01 09:36 PM
L291	1	(15/855439).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/01 09:39 PM
L292	180	(("ROGERS") near3 ("Bobby")).INV.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2021/03/02 12:19 PM
L293	11	L292 and (blood near4 sequest$5)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 12:20 PM
L294	2	(15/140443).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 12:47 PM
L295	1	(15/855439).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 12:49 PM
L296	1	("20020048170").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 01:36 PM
L297	1	("20040174525").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 01:49 PM
L298	1	("10045704").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 03:09 PM
L299	27321	(A61B5/150992 or A61B5/15003 or A61B5/150213 or A61B5/150389 or A61B5/150473 or A61B5/150572 or	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2021/03/02 03:17 PM

		A61B5/154 or A61B5/153 or A61M39/0693 or A61M39/04 or A61B5/150221 or A61M2039/0633 or A61M2039/0202 or A61M2039/068).cpc.					
L300	4594	L299 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 03:27 PM
L301	3762	L300 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 03:28 PM
L302	257	L301 and (air near4 permeab$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 03:29 PM
L303	420	L301 and ((air or gas$4) near4 permeab$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 03:29 PM
L304	1	("20110167658").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 03:30 PM
L305	5	("2015/0306288").URPN.	(USPAT)	OR	ON	ON	2021/03/02 04:15 PM
L306	1	(16/208559).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 04:32 PM
L307	2	("2009/0043225").URPN.	(USPAT)	OR	ON	ON	2021/03/02 04:49 PM
L308	1736	(600/573).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2021/03/02 05:00 PM
L309	1363	L308 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:00 PM
L310	73	L309 and ((air or gas$4) near4 permeab$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:01 PM
L311	73	L310 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:01 PM
L312	812	(600/576).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 05:34 PM
L313	711	L312 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:34 PM
L314	58	L313 and ((air or gas$4) near4 permeab$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:34 PM
L315	58	L314 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:34 PM
L316	371	(600/577).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 05:42 PM
L317	277	L316 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:42 PM

L318	20	L317 and ((air or gas$4) near4 permeab$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:43 PM
L319	336	("2913000" | "3817240" | "3859998" | "3864979" | "4016879" | "4046144").PN. OR ("4207870").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/03/02 05:44 PM
L320	210	L319 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:44 PM
L321	196	L320 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:44 PM
L322	1259	(600/583).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 05:48 PM
L323	1208	L322 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:48 PM
L324	73	L323 and ((air or gas$4) near4 permeab$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:48 PM
L325	73	L324 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:49 PM
L326	1368	(604/164.01).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 05:59 PM
L327	271	L326 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 06:00 PM
L328	10	L327 and ((air or gas$4) near4 permeab$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 06:00 PM
L329	268	L327 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 06:00 PM
L330	182	(("ROGERS") near3 ("Bobby")).INV.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2021/07/08 02:22 PM
L331	27660	(A61B5/150992 or A61B5/15003 or A61B5/150213 or A61B5/150389 or A61B5/150473 or A61B5/150572 or A61B5/154 or A61B5/153 or A61M39/0693 or A61M39/04 or A61B5/150221 or A61M2039/0633 or A61M2039/0202 or A61M2039/068).cpc.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2021/07/08 03:27 PM
L332	4684	L331 and ((blood or fluid$4) near4	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 03:28 PM

		(sequest$5 or sampl$4 or flash$4 or collect$4))					
L333	3769	L332 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 03:29 PM
L334	579	L333 and (vent$4 near4 air)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 03:29 PM
L335	1	("9820682").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/07/08 03:54 PM
L336	1	("4207870").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/07/08 03:56 PM
L337	337	("2913000" | "3817240" | "3859998" | "3864979" | "4016879" | "4046144").PN. OR ("4207870").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/07/08 04:19 PM
L338	211	L337 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:19 PM
L339	196	L338 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:19 PM
L340	37	L339 and (vent$4 near4 air)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:19 PM
L341	221	("20010021827" | "20020004650" | "20020055716" | "20020072715" | "20020103464" | "20020103465" | "20020107488" | "20020151856" | "20020193748" | "20030028171" | "20030036730" | "20030050608" | "20030055385" | "20030078544" | "20030093009" | "20030105414" | "20030114797" | "20030120222" | "20030176842" | "20030181873" | "20030191438" | "20030199827" | "20030216687" | "20030220614" | "20030229315" | "20030229316" | "20040024370" | "20040059302" | "20040092872" | "20040102740" | "20040111068" | "20040193120" |	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/07/08 04:21 PM

		"20040204681" | "20040210197" | "20050004524" | "20050059936" | "20050065482" | "20050124944" | "20050165353" | "20050187493" | "20050228345" | "20050245868" | "20050245869" | "20050245870" | "20050245879" | "20050245885" | "20050283093" | "20060015073" | "20060036217" | "20060036219" | "20060079847" | "20060129064" | "20060189934" | "20060189936" | "20060224122" | "20060270947" | "20060276756" | "20070021724" | "20070027430" | "20070106220" | "20070106224" | "20070167914" | "20070282275" | "20080015513" | "20080086085" | "20080177202" | "20080221528" | "20080269691" | "20080306452" | "20080319345" | "20080319346" | "20090204026" | "20090227896" | "20100063455" | "20100191189" | "20100262038" | "20110118674" | "4106497" | "4207870" | "4305406" | "4572210" | "4573976" | "4641663" | "4795443" | "4813426" | "4840619" | "4887998" | "4894055" | "4900307" | "4923477" | "4994046" | "5015241" | "5195985" | "5215534" | "5219333" | "5222502" | "5242417" | "5246428" | "5256153").PN. OR ("5295970" | "5295975"				

		| "5303713" | "5312372" | "5318547" | "5336199" | "5344408" | "5348544" | "5356392" | "5389085" | "5403286" | "5411492" | "5439449" | "5466223" | "5501675" | "5542932" | "5549558" | "5595566" | "5599313" | "5607402" | "5662617" | "5665075" | "5669889" | "5672161" | "5676658" | "5681295" | "5685855" | "5687740" | "5688241" | "5695474" | "5702369" | "5704920" | "5718239" | "5733265" | "5755522" | "5769826" | "5795336" | "5879337" | "5893845" | "5910130" | "5921964" | "5957892" | "5984899" | "6149629" | "6171284" | "6183445" | "6224576" | "6254575" | "6261263" | "6261265" | "6298541" | "6344032" | "6419658" | "6436086" | "6440104" | "6471677" | "6475191" | "6485469" | "6524277" | "6533760" | "6554807" | "6575939" | "6592556" | "6623456" | "6623461" | "6635032" | "6641555" | "6648855" | "6648856" | "6659983" | "6695819" | "6699217" | "6712792" | "6716199" | "6761704" | "6773419" | "6780169" | "6805689" | "6811545" | "6835190" | "6837877" | "6846302" | "6860872" | "6869415" | "6905483" | "6918891" | "6958054" | "6974423" | "6984223" | "6997913" | "7001363" | "7083600" | "7101355" | "7128726" | "7147624" | "7160267" | "7163526" | "7201740" | "7211065" | "7223258" | "7226432" | "7361159" | "7396343" | "7428773" | "7524308" | "7537581" | "7670320" | "7727190" | "7766879" | "7938808" | "8066679" | "8282605" | "8795198" | "D422700" | "D442280" | "D604836" | "D604837"				

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L342	115	("20020193748" | "20030093009" | "20030105414" | "20030220614" | "20030229315" | "20040059302" | "20040092872" | "20040193120" | "20050004524" | "20050065482" | "20050124944" | "20050187493" | "20050245868" | "20050245869" | "20050245870" | "20050245879" | "20050245885" | "20060036219" | "20060224122" | "20070106220" | "20070106224" | "20070167914" | "20080086085" | "20080177202" | "20080319345" | "20080319346" | "20090204026" | "20100262038" | "4106497" | "4207870" | "4305406" | "4572210" | "4573976" | "4641663" | "4795443" | "4840619" | "4894055" | "4900307" | "4994046" | "5015241" | "5195985" | "5215534" | "5222502" | "5242417" | "5246428" | "5256153" | "5295970" | "5303713" | "5312372" | "5336199" | "5348544" | "5356392" | "5411492" | "5439449" | "5466223" | "5501675" | "5542932" | "5599313" | "5662617" | "5665075" | "5672161" | "5676658" | "5702369" | "5704920" | "5733265" | "5755522" | "5957892" | "5984899" | "6149629" | "6224576" | "6254575" | "6261263" | "6298541" | "6344032" | "6436086" | "6440104" | "6524277" | "6533760" |	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/07/08 04:21 PM

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L343	148	("20020193748" | "20030105414" | "20030229315" | "20040059302" | "20040092872" | "20050004524" | "20050187493" | "20050245868" | "20050245869" | "20050245870" | "20050245885" | "20060036219" | "20070106220" | "20070167914" | "20080086085" | "20080177202" | "4106497" | "4207870" | "4305406" | "4573976" | "4641663" | "4795443" | "4840619" | "4894055" | "4900307" | "4994046" | "5015241" | "5195985" | "5215534" | "5222502" | "5242417" | "5256153" | "5295970" | "5303713" | "5312372" | "5336199" | "5348544" | "5356392" | "5411492" | "5439449" | "5466223" | "5501675" | "5542932" | "5672161" | "5676658" | "5702369" | "5704920" | "5755522" | "5984899" | "6149629" | "6261263" | "6298541" | "6436086" | "6440104" | "6524277" | "6533760" | "6592556" | "6623456" | "6635032" | "6648855" | "6699217" | "6712792" | "6780169" | "6837877" | "6869415" | "6984223" |	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/07/08 04:21 PM

		"7001363" | "7128726" | "7147624" | "7160267" | "7163526" | "7223258" | "7226432" | "7396343" | "7428773" | "D422700" | "D442280").PN. OR ("7766879").URPN.					
L344	41	("2735430" | "2798487" | "3187749" | "3240209" | "3585984" | "3817240" | "4166450" | "4207870" | "4295477" | "4312362").PN. OR ("4436098").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/07/08 04:22 PM
L345	163	L341 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:22 PM
L346	163	L345 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:23 PM
L347	22	("2005/0283093").URPN.	(USPAT)	OR	ON	ON	2021/07/08 04:23 PM
L348	163	L345 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:27 PM
L349	163	L348 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:27 PM
L350	1736	(600/573).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2021/07/08 04:37 PM
L351	1363	L350 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:37 PM
L352	1346	L351 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:38 PM
L353	136	L352 and (vent$4 near4 air)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:38 PM
L354	812	(600/576).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/07/08 04:41 PM
L355	711	L354 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:41 PM
L356	699	L355 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:41 PM
L357	123	L356 and (vent$4 near4 air)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:41 PM
L358	371	(600/577).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/07/08 04:44 PM
L359	277	L358 and ((blood or fluid$4) near4 (sequest$5 or sampl$4	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:45 PM

		or flash$4 or collect$4))					
L360	260	L359 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:45 PM
L361	1259	(600/583).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/07/08 04:46 PM
L362	1208	L361 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:46 PM
L363	1194	L362 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:47 PM
L364	1194	L363 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:47 PM
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L367	319	((("BULLINGTON") near3 ("Gregory")) OR (("PATTON") near3 ("Richard")) OR (("MIAZGA") near3 ("Jay")) OR (("GAW") near3 ("Shan"))).INV.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2022/02/02 03:14 PM
L368	1	(16/376745).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:35 PM
L369	190	(("ROGERS") near3 ("Bobby")).INV.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2022/02/02 03:36 PM
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L381	1	("10010282").PN.	(US-PGPUB; USPAT;	OR	OFF	OFF	2022/02/02

			USOCR)				03:49 PM
L382	1	(16/376745).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:50 PM
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L384	276	(600/579).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:52 PM
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L386	37427	(A61B5/150221 or A61B5/15003 or A61B5/150236 or A61B5/150244 or A61B5/150251 or A61B5/150389 or A61B5/150503 or A61B5/150992 or A61B5/153 or A61B5/155 or A61B10/0048 or A61B10/0051 or A61B10/007 or A61B2010/0061 or A61B2010/0077 or A61B2010/008).cpc.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2022/02/02 04:35 PM
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L389	874	L388 and (seal$4 near4 (member or mechanism$4 or vent$4 or elastic$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/02/02 04:38 PM
L390	26	("2008/0145933").URPN.	(USPAT)	OR	ON	ON	2022/02/02 04:52 PM
L391	44	("2008/0319346").URPN.	(USPAT)	OR	ON	ON	2022/02/02 04:59 PM
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L393	171	L392 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/02/02 05:28 PM
L394	355	(604/103).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 05:52 PM
L395	7	L394 and ((blood or fluid) near4 (seal$4 near4 (member or mechanism$4 or vent$4 or elastic$4)))	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/02/02 05:52 PM

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L398	8	"20130062845"	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/02/04 04:17 PM
L399	14	"2013021595"	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/02/04 04:18 PM
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L402	0	(17/388440).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/07 09:34 AM
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L407	16	L406 and (junct$4 or bypass$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/05/18 03:09 PM
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L411	3810	L410 and @ad<"20170210"	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/05/18 03:56 PM
L412	820	L411 and ((vent$4 or	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/05/18

		open$4 or apertur$4) near4 air)					03:57 PM
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L414	4603	L413 and ((blood or fluid$4 or chamber) same (sequest$5 or sampl$4 or flash$4 or collect$4 or flush$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/05/18 05:51 PM
L415	511	L414 and ((junct$4 or bypass$4 or divert$4) near4 (blood or fluid))	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/05/18 05:52 PM
L416	355	L415 and @ad<"20170210"	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/05/18 05:53 PM
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L418	1	(17/094692).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/05/18 06:25 PM
L419	1	(17/538990).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/05/18 06:25 PM
L420	1	("11311219").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/05/18 06:27 PM
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L422	1	("10143412").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/05/18 06:31 PM
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L424	252	(("ROGERS") near3 ("Bobby")).INV.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2022/10/13 01:41 PM
L425	38	424 AND (closur$4 OR enclos$4)	(US-PGPUB; USPAT)	OR	ON	ON	2022/10/13 01:42 PM

L426	42781	(A61B5/150213 OR A61B5/15003 OR A61B5/150221 OR A61B5/150251 OR A61B5/150732 OR A61B5/15074 OR A61B5/150992 OR A61B5/153 OR A61B5/150389 OR A61B5/150503).cpc.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/10/13 01:47 PM
L427	5205	426 AND @ad<"20170210"	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/10/13 01:50 PM
L428	4803	427 AND ((blood OR fluid$4) near4 (sequest$5 OR sampl$4 OR flash$4 OR collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/10/13 01:51 PM
L429	519	428 AND ((closur$4 OR enclos$4 OR pug$4) near5 (vent OR open$4 OR air))	(US-PGPUB; USPAT)	OR	ON	ON	2022/10/13 01:54 PM
L430	169	"5749857"	(US-PGPUB; USPAT)	OR	ON	ON	2022/10/13 02:14 PM
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L432	346	427 AND ((junct$4 OR bypass$4 OR divert$4) near4 (blood OR fluid))	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/10/13 02:18 PM
L433	186	("3500828" | "3670729" | "3714945" | "3977400" | "3994293" | "3995619" | "4106491" | "4200096" | "4468224" | "4531987" | "4549554" | "4735215" | "4828548" | "4874373" | "4893635" | "4894052" | "4907599" | "4944308" | "4994042" | "5129884" | "5400798").pn. OR ("5749857").urpn. AND (PGPB | USPT | USOC).dbnm.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/10/13 02:32 PM
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L435	1	("5749857").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2022/10/13

							02:34 PM

PE2E SEARCH - Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
N94	1	(port and sequest$5 and junction and chamber and sampl$4 and vent and barrier).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2017/09/28 04:15 PM
N112	3	(port and sequest$5 and chamber and sampl$4 and vent and barrier).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/01/09 05:39 PM
N248	4	(blood and fluid$4 and inlet and outlet and port and reservoir and allow and initial$4 and sequest$5).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 03:30 PM
N249	4	(blood and fluid$4 and inlet and outlet and port and reservoir and allow$4 and initial$4 and sequest$5).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 03:30 PM
N250	495	(blood and fluid$4 and allow$4 and initial$4).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 03:31 PM
N251	107	(blood and fluid$4 and allow$4 and initial$4 and subsequent$4).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 03:31 PM
N283	9	((blood or fluid$4) and sequestrat$4 and chamber and sampl$4 and vent$4 and air$4).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:31 PM
N284	530	((blood or fluid$4) and chamber and sampl$4 and vent$4 and air$4).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:31 PM
N285	84	((blood or fluid$4) and chamber and cap and sampl$4 and vent$4 and air$4).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:32 PM
N365	6	(port and sequest$5 and junction and chamber and sampl$4 and vent and barrier).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:49 PM

Bibliographic Data

Application No: 17/094,692

Foreign Priority claimed: ○ Yes ◉ No

35 USC 119 (a-d) conditions met: ☐ Yes ☑ No ☐ Met After Allowance

Verified and Acknowledged: /MAY A ABOUELELA/ Examiner's Signature | Initials

Title: BLOOD CONTAMINANT SEQUESTRATION DEVICE WITH ONE-WAY AIR VALVE AND AIR-PERMEABLE BLOOD BARRIER WITH CLOSURE MECHANISM

FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
11/10/2020	600	3791	KURIN4CON
RULE			

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CONTINUING DATA

This application is a CON of 15893518 02/09/2018 PAT 10827964

15893518 has PRO of 62467016 03/03/2017

15893518 has PRO of 62457764 02/10/2017

FOREIGN APPLICATIONS

IF REQUIRED, FOREIGN LICENSE GRANTED**

02/02/2021

**** SMALL ENTITY ****

STATE OR COUNTRY

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/783,173	07/24/2024	Bobby E. ROGERS	069366-0580420_KUR3C03US	1561

27500 7590 09/24/2024

PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
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McLean, VA 22102

EXAMINER	
NGUYEN, HUONG Q	

ART UNIT	PAPER NUMBER
3791	

NOTIFICATION DATE	DELIVERY MODE
09/24/2024	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Docket_IP@pillsburylaw.com

Office Action Summary	Application No. 18/783,173	Applicant(s) ROGERS et al.	
	Examiner Huong Q NGUYEN	Art Unit 3791	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 7/24/2024.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL.** 2b) ☑ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 1-30 is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 1-30 is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to **PPHfeedback@uspto.gov.**

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☑ The drawing(s) filed on 7/24/2024 is/are: a)☐ accepted or b)☑ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☑ Notice of References Cited (PTO-892)

2) ☑ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

DETAILED ACTION

Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, valve to close off the sampling channel along with the moving part that moves from a first position to a second position to allow travel to the sampling channel of **Claims 10-12 and 25-27** must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the

applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Interpretation

The following is a quotation of 35 U.S.C. 112(f):

> (f) Element in Claim for a Combination. – An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

The following is a quotation of pre-AIA 35 U.S.C. 112, sixth paragraph:

> An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

The claims in this application are given their broadest reasonable interpretation using the plain meaning of the claim language in light of the specification as it would be understood by one of ordinary skill in the art. The broadest reasonable interpretation of a claim element (also commonly referred to as a claim limitation) is limited by the description in the specification when 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is invoked.

As explained in MPEP § 2181, subsection I, claim limitations that meet the following three-prong test will be interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph:

(A) the claim limitation uses the term “means” or “step” or a term used as a substitute for “means” that is a generic placeholder (also called a nonce term or a non-structural term having no specific structural meaning) for performing the claimed function;

(B) the term "means" or "step" or the generic placeholder is modified by functional language, typically, but not always linked by the transition word "for" (e.g., "means for") or another linking word or phrase, such as "configured to" or "so that"; and

(C) the term "means" or "step" or the generic placeholder is not modified by sufficient structure, material, or acts for performing the claimed function.

Use of the word "means" (or "step") in a claim with functional language creates a rebuttable presumption that the claim limitation is to be treated in accordance with 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph. The presumption that the claim limitation is interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is rebutted when the claim limitation recites sufficient structure, material, or acts to entirely perform the recited function.

Absence of the word "means" (or "step") in a claim creates a rebuttable presumption that the claim limitation is not to be treated in accordance with 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph. The presumption that the claim limitation is not interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is rebutted when the claim limitation recites function without reciting sufficient structure, material or acts to entirely perform the recited function.

Claim limitations in this application that use the word "means" (or "step") are being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, except as otherwise indicated in an Office action. Conversely, claim limitations in this application that do not use the word "means" (or "step") are not being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, except as otherwise indicated in an Office action.

No claim elements are interpreted under 112(f).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112(a):

> (a) IN GENERAL.—The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.

The following is a quotation of the first paragraph of pre-AIA 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10-12 and 25-27 are rejected under 35 U.S.C. 112(a) or 35 U.S.C. 112 (pre-AIA), first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor or a joint inventor, or for applications subject to pre-AIA 35 U.S.C. 112, the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 10-12 and 25-27 recite a valve to initially close off the sampling channel. This appears to be disclosed in the embodiment of Figure 23A-E. However, the independent claims recite an embodiment with a moving part configured to be movable from a first position to a

second position to allow the blood sample to flow to the sampling channel (and bypass the chamber), which appears disclosed in the embodiment Figure 24A-D.

However, the embodiment in Figure 23 does not disclose said moving part *in addition* to the valve to allow the bypass as claimed. Therefore, it appears that said claims improperly mix embodiments, which constitutes new matter. However, if an embodiment which contains both structures exists, applicant is requested to point out the portions of the specification disclosing such. Also see Drawing Objection above.

> The following is a quotation of 35 U.S.C. 112(b):
> (b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.
>
> The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph:
> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7, 12, 22, and 27 are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor (or for applications subject to pre-AIA 35 U.S.C. 112, the applicant), regards as the invention.

In regard to Claim 7 and 22, the recitation of blood impermeable membrane causes the first portion of the blood sample “to back up” into the chamber is indefinite because it is unclear what specific meaning or function this is meant to convey. In the rejection that follows it is assumed to be normal fluid flow. Clarification is requested.

In regard to Claim 12 and 27, the recitation of "otherwise close off the outlet" is indefinite because it is unclear what mechanisms are included in said limitation to close off the outlet, which are also supported by the disclosure.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a)(1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention.

Claim(s) 1-5, 13-20, and 28-30 is/are rejected under 35 U.S.C. 102(a)(1) as being anticipated by Bullington et al (US Pub No. 20140163419).

In regard to Claims 1 and 16, Bullington et al disclose a device comprising:

an inlet port 405 for receiving a blood sample, best seen in Figure 12 (0081, 0089);

an outlet port 475 (proximal end of lumen 475), best seen in Figure 13-15 (0085);

a chamber 480 connected with the inlet port, and configured to collect a first portion of the blood sample when under a drawing force applied from the outlet port from a blood sample collection device 451, best seen in Figure 14 (0079, 0091-0092 – "a bodily-fluid is drawn through the port 405, the first lumen 432 defined by the flow control mechanism 430, and the first lumen 406 defined by the diverter 409 and into the fluid reservoir 480. In some embodiments, the bodily-fluid can contain undesirable microbes such as, for example, dermally-residing microbes and/or other external contaminants");

a sampling channel 433 connected with the inlet port and configured to convey a subsequent portion of the blood sample to the outlet port, best seen in Figure 15 (0095); and

a moving part 430, 431, 435 (flow control mechanism first member 431 controlled by member 435), moving part also defined by plunger 476 (0084 – Figure 13-15),

configured to be movable from a first position to a second position to allow the blood sample to flow to the sampling channel –

in the first position, moving member 435 rotates first member 431 such that lumen 433 (sampling channel) is fluidically isolated, due to lumen 432 of the flow control mechanism aligned with the inlet port 405, which leads through lumen 406 in diverter 409 and into chamber 480 – thus the inlet port 405 is in fluid communication with the chamber 480, best seen in Figure 14 (0081, 0092);

in the second position, moving member 435 rotates first member 431 such that lumen 433 is aligned with inlet port 405 such that "a desired amount of bodily-fluid is drawn through the port 405, the second lumen 433 of the flow control mechanism 430, the second lumen 407 of the diverter 409, and the lumen 475 [defining the outlet port] defined by the shunt tube 471 and into the second reservoir 490. Moreover, the bodily-fluid disposed within the second reservoir 490 is fluidically isolated from the first, predetermined amount of bodily-fluid contained within the first reservoir 480," best seen in Figure 15 (0082, 0083, 0095, 0097) – thus creates a pathway from the inlet port 405 to the outlet port 475.

2, 17. The device in accordance with claim 1, wherein the first position allows the collection of the first portion of the blood sample in the chamber 480, best seen in Figure 14.

3, 18. The device in accordance with claim 1, wherein the moving part 430, 431, 435 is configured to move from the first position to the second position after the first portion of the blood sample flows into the chamber 480 – sample flow into the chamber 480 occurs first, best seen in Figure 14, followed by moving member 435 rotating first member 431 such that lumen 433 is aligned with inlet port 405 is aligned with the outlet port 475, into second reservoir 490, best seen in Figure 15 (0082, 0083, 0095, 0097).

4, 19. The device in accordance with claim 1, the device further comprising a locking mechanism 474 configured to maintain the moving part 476 in the first position (Figure 14) until the chamber 480 is filled with the first portion of the blood sample – protrusion 474 enables proximal movement of plunger 476 to create chamber 480 for the first portion of the blood sample, best seen in Figure 13-14 (0085, 0091, 0096).

5, 20. The device in accordance with claim 1, wherein the moving part 430, 431, 476 is an inner chamber housing, best seen in Figure 13-15.

13, 28. The device in accordance with claim 1, further comprising a patient needle – "a user can engage the transfer device 400 to couple the port 405 to a proximal end portion of a lumen-defining device (not shown) such as, for example, a butterfly needle, a cannula assembly, a trocar (which in some cases is used to insert a catheter into a patient), or the like" (0089) and

a sample collection device – "with the desired amount of bodily-fluid disposed within the second fluid reservoir 490, the transfer device 400 can be removed from the portion of the patient and disposed above or in a container (e.g., a vile, a test tube, a petri dish, a culture medium, a test apparatus, or the like) such that a portion of the second amount of bodily-fluid can be tested" (0099).

14, 29. The device in accordance with claim 1, the chamber having a volume sufficient to collect the first portion of the blood sample that is more prone to contamination and also to minimize an amount of blood to be sequestered (0092).

15, 30. The device in accordance with claim 1, wherein the chamber 480 has a volume of less than 1.5 cubic centimeters, e.g. 0.1 mL (0094).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries for establishing a background for determining obviousness under 35 U.S.C. 103 are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims the examiner presumes that the subject matter of the various claims was commonly owned as of the effective filing date of the claimed invention(s) absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and effective filing dates of each claim that was not commonly owned as of the effective filing date of the later invention in order for the examiner to consider the applicability of 35 U.S.C. 102(b)(2)(C) for any potential 35 U.S.C. 102(a)(2) prior art against the later invention.

Claim(s) 6-12 and 21-27 is/are rejected under 35 U.S.C. 103 as being unpatentable over Bullington et al as applied to claim 1 above, and further in view of Percarpio (US Pat No. 4106497 – cited by applicant).

In regard to Claims 6-9 and 21-24, Bullington et al disclose the invention above but do not expressly disclose a blood impermeable membrane is configured to facilitate the chamber collecting the first portion of the blood sample.

Percarpio teach that it is well-known in the art to provide an analogous blood sampling device comprising an inlet port 22 for receiving a blood sample, an outlet port 42, 44, a

chamber to collect a first portion of the blood sample (indicator area), and a sampling channel 28 connecting the inlet and the outlet, including a blood impermeable membrane 90 to enable necessary venting of air for the desired flow of the blood first to the chamber before directing it to the outlet (Col.4: 16-39). Percarpio teach a housing 40, 56 separate from the blood impermeable membrane 90, best seen in Figure 3-4, as an effective configuration for the location of said blood impermeable membrane.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the of filing to modify Bullington et al to include a blood impermeable membrane causes the first portion of the blood sample to back up into the chamber following application of the drawing force applied from the outlet port as taught by Percarpio by enabling necessary venting of air from the device during the desired flow of blood such that, when the drawing force is applied at the outlet port, the first portion of the blood sample is drawn into the chamber in the manner taught by Bullington et al to contact a material that is blood impermeable to enable the venting of air, wherein the blood impermeable membrane is separate from the housing, as taught by Percarpio as an effective configuration for said blood impermeable membrane.

In regard to Claims 10-12 and 25-27, Bullington et al disclose the invention above but do not expressly disclose a valve configured to initially close off the sampling channel.

Percarpio teach that it is well-known in the art to provide an analogous blood sampling device comprising an inlet port 22 for receiving a blood sample, an outlet port 42, 44, a chamber to collect a first portion of the blood sample (indicator area), and a sampling channel

28 connecting the inlet and the outlet, including a blood impermeable membrane 90 to enable necessary venting of air for the desired flow of the blood first to the chamber before directing it to the outlet (Col.4: 16-39). Percarpio teach a valve 78 (check valve) that is configured to initially close off access to the outlet until the first portion of the blood sample is in the chamber, best seen in Figure 3, and is further configured such that, upon release, follow-on amounts of the blood sample will bypass the chamber and flow through the sampling channel toward the outlet port, best seen in Figure 4 (Col.3: 61-Col.4: 15, 64-Col.5: 47). Percarpio also teach the valve is configured to pinch, shunt, bend or otherwise close off the outlet before the first portion of the blood sample is collected in the chamber, best seen in Figure 3-4 (Col.3: 61-Col.4: 15, 64-Col.5: 47).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of filing to modify Bullington et al to include a valve to pinch, shunt, bend or otherwise close off the outlet in the manner above as taught by Percarpio to effectively seal off the outlet before the blood is properly in the chamber of Bullington et al, wherein it would have been obvious to a skilled artisan to place the valve such that it closes off the sampling channel and not just the outlet, to effectively block the flow of blood upstream before it reaches the outlet, prior to being drawn into the chamber as taught by Bullington et al, as well as Percarpio.

Also see 112 rejection above.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Huong Q NGUYEN whose telephone number is (571)272-8340. The examiner can normally be reached on 10 am - 6 pm.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert (Tse) Chen can be reached at 5712723672. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H.Q.N/
Examiner, Art Unit 3791

/RENE T TOWA/
Primary Examiner, Art Unit 3791

Notice of References Cited	Application/Control No. 18/783,173	Applicant(s)/Patent Under Reexamination ROGERS et al.	
	Examiner Huong Q NGUYEN	Art Unit 3791	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date YYYY-MM-DD	Name	CPC Classification	US Classification
*	A	US-20140163419-A1	2014-06-12	Bullington; Gregory J.	A61B5/153	600/575
	B					
	C					
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	E					
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Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	18783173
Filing Date	2024-07-24
First Named Inventor	Bobby E. ROGERS
Art Unit	OPAP
Examiner Name	DOCKET CENTRAL
Attorney Docket Number	069366-0580420_KUR3C03US

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	1	Meissner, George F. , et al., "The Standard Clotting Time, A Method Based on the Use of Whole Venous Blood in Capillary Tubes," The American Journal of Clinical Pathology, vol. 39, No. 3., pp. 321-323, Mar. 1963.	☐
	2	European Patent Application No. EP23155927.9 extended European Search Report dated Jul. 26, 2023, 8 pages.	☐
	3	Office Action (Final Rejection) dated 08/25/2023 for US App. No. 18113710 (pages 1-50)	☐
	4	Notice of Allowance mailed 09-08-2023; Attorney Docket No. 069366-0574153_KUR2C04US. 35 page.	☐
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	Attorney Docket Number	069366-0580420_KUR3C03US

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	Attorney Docket Number	069366-0580420_KUR3C03US

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	30	Office Action (Final Rejection) dated 08/25/2023 for US Application No. 18113710 (pages 1-50).	☐
	31	European Patent Office, Extended European Search Report for European Patent Application 23155927.9-1122, dated July 26, 2023, pages 1-8.	☐
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	33	Office Action (Non-Final Rejection) mailed 10/04/2023 for US Application No. 17538900 (1-47).	☐
	34	First Office Action (Non-Final Rejection) dated 08-03-2023 for CN Application No. 202010300942.7. 21 pages.	☐
	35	Office Action (Non-Final Rejection) dated 02/21/2023 for US Application No. 17893079, pages 1-32.	☐
	36	Office Action (Final Rejection) dated 07/19/2023 for US Application No. 17893079, pages 1-21.	☐
	37	Advisory Action dated 09/29/2023 for US Application 17893079, pages 1-24.	☐
	38	European Patent Office, Examination Report for European Patent Application 22181212.6-1122, dated September 28, 2023, pages 1-5.	☐
	39	European Patent Office, Extended European Search Report for European Patent Application 20781928.5-1122 dated October 28, 2022, pages 1-10.	☐
	40	Rule 70(a) Communication for European Application No. 20781928.5-1122 dated November 15, 2022, 1 page.	☐

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	Filing Date	2024-07-24
	First Named Inventor	Bobby E. ROGERS
	Art Unit	OPAP
	Examiner Name	DOCKET CENTRAL
	Attorney Docket Number	069366-0580420_KUR3C03US

	41	International Search Report and Written Opinion dated 19 March 2020 for PCT application no. PCT/US2020/023617. pages.	☐
	42	International Search Report and Written Opinion dated 28 September 2021 for PCT application no. PCT/ US2021/035294. 7 pages.	☐
	43	European Patent Office, Extended European Search Report for European Patent Application 22181212.6-1122 dated October 24, 2022, pages 1-10.	☐
	44	Australian Patent Office, Australian Examination Report No. 1 for Application No. 2021120 622 dated March 18, 2022, 3 pages.	☐
	45	Notice of Allowance mailed 03-01-2023; Attorney Docket No. 069366-0572419_KUR2D01AU. 3 pages.	☐
	46	First Office Action dated 11/24/2021 for IL Application No. 286030, pages 1-3.	☐
	47	Notice of Allowance mailed 01-29-2023; Attorney Docket No. 069366-0572425_KUR2D01IL. 87 pages.	☐
	48	Office Action (Non-Final Rejection) dated 08/10/2021 for Japanese Application No. 2020-118498, pages 1-7.	☐
	49	Office Action (Non-Final Rejection) dated 03/28/2022 for Japanese Application No. 2020-118498, pages 1-3.	☐
	50	Office Action (Non-Final Rejection) dated 09/01/2022 for Japanese Application No. 2020-118498, pages 1-4.	☐

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	Attorney Docket Number	069366-0580420_KUR3C03US

EXAMINER SIGNATURE			
Examiner Signature	/H Q NGUYEN/	Date Considered	09/09/2024

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CERTIFICATION STATEMENT

Please see 37 CFR 1.97(e) to make the appropriate selection(s):

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☐ See attached certification statement.

☒ A certification statement is not submitted herewith.

FEE

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

COPIES

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SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2024-08-26
Name/Print	Benjamin F. Hudson	Registration Number	71,474

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7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

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Doc description: Information Disclosure Statement (IDS) Filed

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Application Number	18783173
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First Named Inventor	Bobby E. ROGERS
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Examiner Name	DOCKET CENTRAL
Attorney Docket Number	069366-0580420_KUR3C03US

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	1	Notice of Allowance mailed 04-04-2023; Attorney Docket No. 069366-0572230_KUR2D02JP. 6 pages.	☐
	2	Rule 71(3) Communication and Text for Grant mailed 08/31/2022 for European Application No. 19200766.4-1122. 189 pages.	☐
	3	Office Action (Non-Final Rejection) mailed 01/21/2022 for Israeli Application No. 267684. 3 pages.	☐
	4	Notice of Allowance mailed 02-14-2023; Attorney Docket No. 069366-0572429_KUR3N01IL. 122 pages.	☐
	5	Office Action (Non-Final Rejection) mailed 11/29/2022 for Application No. 2021-214177, pages 1-3.	☐
	6	Notice of Allowance mailed 06-20-2023; Attorney Docket No. 069366-0572231_KUR3D01JP. 6 pages.	☐
	7	Office Action (Non-Final Rejection) mailed 11/4/2022 for Application No. 17094692, pages 1-50.	☐
	8	Notice of Allowance mailed 04-20-2023; Attorney Docket No. 069366-0572169_KUR4C01US. 36 pages.	☐
	9	Office Action (Non-Final Rejection) mailed 08/04/2022 for Application No. 16819033, pages 1-35.	☐
	10	Notice of Allowance mailed 11-28-2022; Attorney Docket No. 069366-0572168_KUR4002US. 9 pages.	☐
	11	Office Action (Non-Final Rejection) mailed 04/16/2024 for Application No. 16838017, pages 1-19.	☐

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	12	Second Office Action dated 04/28/2024 for CN Application No. 202080000666.0, pages 1-28.	☐
	13	Notice of Allowance mailed 07-04-2024; Attorney Docket No. 069366-0572164_KUR7N01JP. 9 pages.	☐
	14	Office Action mailed 05-21-2024; Attorney Docket No. 069366-0572161_KUR7N01IL. 6 pages.	☐
	15	European Patent Office, Examination Report for European Patent Application 21818838.1, dated April 22, 2024, pages 1-11.	☐
	16	European Patent Office, Examination Report for European Patent Application 20781928.5, dated July 31, 2024, pages 1-6.	☐
	17	Ziegler, R., et al. "Controlled Clinical Laboratory Comparison of Two Supplemented Aerobic and Anaerobic Media Used in Automated Blood Culture Systems to Detect Bloodstream Infections," Journal of Clinical Microbiology, Mar. 1998, p. 657-661.	☐
	18	Pall Medical, "Leukotrap Filtration Systems for Whole Blood Derived Platelets, Leukotrap RC PL and Leukotrap PL Systems" literature, (2005) 8 pages.	☐

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Examiner Signature	/H Q NGUYEN/	Date Considered	09/09/2024

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☐ See attached certification statement.

☒ A certification statement is not submitted herewith.

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Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2024-08-26
Name/Print	Benjamin F. Hudson	Registration Number	71,474

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	5200325		1993-04-06	BLATT JOEL M	
	2	5432084		1995-07-11	BRUBAKER DANIEL B	
	3	5972294		1999-10-26	SMITH JOHN L	
	4	6187347		2001-02-13	PATTERSON JAMES A	
	5	6599474		2003-07-29	EVTODIENKO VLADIMIR	
	6	8197420		2012-06-12	PATTON RICHARD G	
	7	8535241		2013-09-17	BULLINGTON GREGORY	
	8	9060724		2015-06-23	BULLINGTON GREGORY J	

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	Art Unit	OPAP
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	Attorney Docket Number	069366-0580420_KUR3C03US

	9	9155495		2015-10-13	BULLINGTON GREGORY J	
	10	4412548		1983-11-01	HOCH LOUIS	
	11	5222502		1993-06-29	KUROSE KATSUTOSHI	
	12	5520193		1996-05-28	SUZUKI ISSEI	
	13	9022951		2015-05-05	BULLINGTON GREGORY	
	14	6569117		2003-05-27	ZIV DAVID	
	15	3741197		1973-06-26	SANZ M	
	16	8603009		2013-12-10	TAN ALVIN CHEE LEONG	
	17	4207870		1980-06-17	ELDRIDGE WILLIAM N	
	18	9877675		2018-01-30	BAID RISHI	
	19	4444203		1984-04-24	ENGELMAN ALLAN	

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	20	6398743		2002-06-04	HALSETH THOR R	
	21	9022950		2015-05-05	BULLINGTON GREGORY	
	22	4436098		1984-03-13	KAUFMAN JOSEPH	
	23	9138572		2015-09-22	ZEYTOONIAN PAUL	
	24	8568371		2013-10-29	SIOPES WILLIAM	
	25	8540663		2013-09-24	DAVEY CHRISTOPHER T	
	26	8523826		2013-09-03	LAYTON JR RUSSELL K	
	27	4057050		1977-11-08	SARSTEDT WALTER	
	28	8864684		2014-10-21	BULLINGTON GREGORY J	
	29	5749857		1998-05-12	CUPPY MICHAEL J	
	30	9204864		2015-12-08	BULLINGTON GREGORY J	

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	31	3874367		1975-04-01	AYRES WALDEMAR A	
	32	3886930		1975-06-03	RYAN GEORGE R	
	33	4106497		1978-08-15	PERCARPIO EDWARD P	
	34	4154229		1979-05-15	NUGENT EDWARD L	
	35	4980297		1990-12-25	HAYNES JOHN L	
	36	9820682		2017-11-21	ROGERS BOBBY E	
	37	10010282		2018-07-03	ROGERS BOBBY E	
	38	10143412		2018-12-04	ROGERS BOBBY E	
	39	11185266		2021-11-30	ROGERS BOBBY E	
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	Attorney Docket Number	069366-0580420_KUR3C03US

	42	3817240		1974-06-18	AYRES W	
	43	3648684		1972-03-14	BARNWELL CLEORA W	
	44	4056101		1977-11-01	GEISSLER ULRICH C	
	45	4416290		1983-11-22	LUTKOWSKI LAWRENCE	
	46	8070725		2011-12-06	CHRISTENSEN KELLY D	
	47	4349035		1982-09-14	THOMAS JOSEPH J	
	48	4813433		1989-03-21	DOWNEY JOHN M	
	49	5401262		1995-03-28	KARWOSKI THEODORE	
	50	3859998		1975-01-14	THOMAS JOSEPH JOHN	
	51	4373535		1983-02-15	MARTELL MICHAEL D	
	52	4690154		1987-09-01	WOODFORD TIMOTHY	

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	53	5097842		1992-03-24	BONN GINA B	
	54	5865803		1999-02-02	MAJOR MIKLOS	
	55	5873841		1999-02-23	BRANNON JAMES K	
	56	6013037		2000-01-11	BRANNON JAMES K	
	57	6913580		2005-07-05	STONE BENJAMIN CURTIS	
	58	11213232		2022-01-04	IVOSEVIC MILAN	
	59	6626884		2003-09-30	DILLON JAGMOHANBIR SINGH	
	60	4904240		1990-02-27	HOOVER ROCKLIN L	
	61	4673386		1987-06-16	GORDON MARK G	
	62	7461671		2008-12-09	EHWALD RUDOLF	
	63	6506182		2003-01-14	ESTABROOK BRIAN K	

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	64	3382865		1968-05-14	WORRALL JR ASHTON L	
	65	3848579		1974-11-19	VILLA REAL A	
	66	6106509		2000-08-22	LOUBSER PAUL G	
	67	3494352		1970-02-10	RUSSO RONALD D	
	68	6224561		2001-05-01	SWENDSON DAVID L	
	69	7055401		2006-06-06	PRYBELLA JOHN R	
	70	5135489		1992-08-04	JEPSON STEVEN C	
	71	5811658		1998-09-22	VAN DRIEL MICHAEL R	
	72	3604410		1971-09-14	WHITACRE GARY L	
	73	5772608		1998-06-30	DHAS V VARAPRABHU	
	74	4150089		1979-04-17	LINET MICHAEL S	

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	75	4257416		1981-03-24	PRAGER DAVID	
	76	4193400		1980-03-18	LOVELESS JAMES C	
	77	6843775		2005-01-18	HYUN DONGCHUL D	
	78	7666166		2010-02-23	EMMERT MICHAEL	
	79	7479131		2009-01-20	MATHIAS JEAN-MARIE	
	80	8377040		2013-02-19	BURKHOLZ JONATHAN KARL	
	81	5417673		1995-05-23	GORDON MARK G	
	82	6638252		2003-10-28	MOULTON WILLIAM G	
	83	3945380		1976-03-23	DABNEY WILLIAM C	
	84	5100394		1992-03-31	DUDAR THOMAS E	
	85	8827958		2014-09-09	BIERMAN STEVEN F	

PC 6.1.24

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	86	8574203		2013-11-05	STOUT MARTY L	
	87	6860871		2005-03-01	KURACINA THOMAS C	
	88	6945948		2005-09-20	BAINBRIDGE MARLENE	
	89	7306736		2007-12-11	COLLINS GREGORY R	
	90	5691486		1997-11-25	BEHRINGER BRUCE E	
	91	5980830		1999-11-09	SAVAGE DOUGLAS ROBERT	
	92	5045185		1991-09-03	OHNAKA YUKIHIRO	
	93	5632906		1997-05-27	ISHIDA NOBORU	
	94	6695004		2004-02-24	RAYBUCK JOHN L	
	95	6733433		2004-05-11	FELL CLAUDE	
	96	7241281		2007-07-10	COELHO PHILIP H	

PC 6.1.24

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	97	8349254		2013-01-08	HOSHINO YOSHITERU	
	98	5439450		1995-08-08	HAEDT LORI E	
	99	6905483		2005-06-14	NEWBY C MARK	
	100	5431811		1995-07-11	TUSINI ANDREA	
	101	6736783		2004-05-18	BLAKE KEVIN R	
	102	7052603		2006-05-30	SCHICK KARL G	
	103	3835835		1974-09-17	THOMPSON R	
	104	4416291		1983-11-22	KAUFMAN JOSEPH	
	105	10299713		2019-05-28	PATTON RICHARD G	
	106	10265007		2019-04-23	BULLINGTON GREGORY	
	107	11395612		2022-07-26	BULLINGTON GREGORY J	

PC 6.1.24

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	108	10881343		2021-01-05	BULLINGTON GREGORY J	
	109	10596315		2020-03-24	BULLINGTON GREGORY J	
	110	11660030		2023-05-30	BULLINGTON GREGORY J	
	111	11259727		2022-03-01	BULLINGTON GREGORY J	
	112	11737693		2023-08-29	BULLINGTON GREGORY J	
	113	11439332		2022-09-13	BULLINGTON GREGORY J	
	114	11589843		2023-02-28	BULLINGTON GREGORY J	
	115	11612340		2023-03-28	BULLINGTON GREGORY J	
	116	11234626		2022-02-01	BULLINGTON GREGORY J	
	117	10624977		2020-04-21	BULLINGTON GREGORY J	
	118	11653863		2023-05-23	BULLINGTON GREGORY J	

PC 6.1.24

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	119	11419531		2022-08-23	BULLINGTON GREGORY J	
	120	11786155		2023-10-17	BULLINGTON GREGORY J	
	121	11789017		2023-10-17	BULLINGTON GREGORY J	
	122	3848581		1974-11-19	CINQUALBRE P	
	123	6126643		2000-10-03	VAILLANCOUERT VINCENT L	
	124	9764891		2017-09-19	AVILES VICTOR M	
	125	5147329		1992-09-15	BRANNON JAMES K	
	126	5518005		1996-05-21	BRANNON JAMES K	
	127	62845767		2019-05-09	BREWER MICHAEL	

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PC 6.1.24

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	1	20010044615		2001-11-22	AMANO YOSHIKAZU	
	2	20030082074		2003-05-01	JURIK FRANKLIN A	
	3	20030185707		2003-10-02	IWAKI YOSHIHIDE	
	4	20040116830		2004-06-17	TRUDEAU WILLIAM M	
	5	20090299253		2009-12-03	HURSEY FRANCIS X	
	6	20130158506		2013-06-20	HARRIS ADRIENNE ROSE	
	7	20150246352		2015-09-03	BULLINGTON GREGORY J	
	8	20150342510		2015-12-03	BULLINGTON GREGORY J	
	9	20160361006		2016-12-15	BULLINGTON GREGORY J	
	10	20170065733		2017-03-09	BULLINGTON GREGORY J	
	11	20180140240		2018-05-24	BULLINGTON GREGORY J	

PC 6.1.24

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	12	20140112841		2014-04-24	SCHOEN CHRISTIAN	
	13	20180271425		2018-09-27	ROGERS BOBBY E	
	14	20080319346		2008-12-25	CRAWFORD JAMIESON	
	15	20100057004		2010-03-04	CHRISTENSEN KELLY D	
	16	20070088279		2007-04-19	SHUE MING-JENG	
	17	20080145933		2008-06-19	PATTON RICHARD G	
	18	20040054333		2004-03-18	THEEUWES FELIX	
	19	20100010372		2010-01-14	BROWN LEROY R	
	20	20080167577		2008-07-10	WEILBACHER EUGENE E	
	21	20080086085		2008-04-10	BROWN LEROY R	
	22	20070083162		2007-04-12	OREAGAN JAMES	

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	23	20160008579		2016-01-14	BURKHOLZ JONATHAN KARL	
	24	20120016266		2012-01-19	BURKHOLZ JONATHAN KARL	
	25	20130317391		2013-11-28	BULLINGTON GREGORY J	
	26	20160174888		2016-06-23	BERTHIER ERWIN	
	27	20050240161		2005-10-27	CRAWFORD JAMIESON W M	
	28	20040147855		2004-07-29	MARSDEN STEWART	
	29	20040073171		2004-04-15	ROGERS BOBBY E	
	30	20050004524		2005-01-06	NEWBY C MARK	
	31	20030105414		2003-06-05	LEONG ALVIN TAN CHEE	
	32	20020004647		2002-01-10	LEONG ALVIN TAN CHEE	
	33	20140155781		2014-06-05	BULLINGTON GREGORY J	

PC 6.1.24

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	34	20030208151		2003-11-06	KRAUS MENACHEM	
	35	20090227953		2009-09-10	TAN CHEE LEONG	
	36	20170020428		2017-01-26	ROGERS BOBBY E	
	37	20170020427		2017-01-26	ROGERS BOBBY E	
	38	20050005635		2005-01-13	LE METAIS MARC	
	39	20050007524		2005-01-13	LUO FANG-CHEN	
	40	20140039348		2014-02-06	BULLINGTON GREGORY J	
	41	20140107564		2014-04-17	BULLINGTON GREGORY J	
	42	20140155782		2014-06-05	BULLINGTON GREGORY J	
	43	20140276578		2014-09-18	BULLINGTON GREGORY J	
	44	20160017488		2016-01-21	KOBAYASHI MASAYUKI	

PC 6.1.24

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	45	20180177445		2018-06-28	ROGERS BOBBY E	
	46	20180353117		2018-12-13	BULLINGTON GREGORY J	
	47	20190159711		2019-05-30	ROGERS BOBBY E	
	48	20050245885		2005-11-03	BROWN LEROY	
	49	20110306899		2011-12-15	BROWN LEROY R	
	50	20130116599		2013-05-09	BULLINGTON GREGORY J	
	51	20050273019		2005-12-08	CONWAY HUGH	
	52	20150351678		2015-12-10	BULLINGTON GREGORY	
	53	20220160271		2022-05-26	IVOSEVIC MILAN	
	54	20050161112		2005-07-28	EHWALD RUDOLF	
	55	20070119508		2007-05-31	WEST RICHARD L	

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	56	20220304600		2022-09-29	HAMMER JEREMY	
	57	20220151525		2022-05-19	BULLINGTON GREGORY J	
	58	20220151527		2022-05-19	BULLINGTON GREGORY J	
	59	20200289039		2020-09-17	BULLINGTON GREGORY J	
	60	20210275068		2021-09-09	MIAZGA JAY M	
	61	20220304664		2022-09-29	HAMMER JEREMY	
	62	20160073937		2016-03-17	BURKHOLZ JONATHAN KARL	
	63	20150314105		2015-11-05	GASPARYAN LEVON	
	64	20150359473		2015-12-17	GARRETT CHAD	
	65	20160262677		2016-09-15	EBETSBERGER FRANZ	
	66	20160325085		2016-11-10	CHELAK TODD	

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	67	20070031283		2007-02-08	DAVIS CHARLES Q	
	68	20190365303		2019-12-05	BULLINGTON GREGORY J	
	69	20180297303		2018-10-18	SEKIGUCHI TAKUMI	
	70	20190175087		2019-06-13	BULLINGTON GREGORY J	
	71	20210145336		2021-05-20	ROGERS BOBBY E	
	72	20060009713		2006-01-12	FLAHERTY PATRICE	

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	2	2009131273A	JP		2009-06-18	CSL BEHRING GMBH		☒
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PC 6.1.24

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	4	2013082301A1	WO		2013-06-06	TELEFLEX MEDICAL INC		☐
	5	1378602A	GB		1974-12-27	BECTON DICKINSON CO		☐
	6	2019055487A1	WO		2019-03-21	MAGNOLIA MEDICAL TECHNOLOGIES INC		☐
	7	2019232196A1	WO		2019-12-05	MAGNOLIA MEDICAL TECHNOLOGIES INC		☐
	8	1665986	EP		2006-06-07	BECTON DICKINSON CO		☐
	9	2011162772A1	WO		2011-12-29	CLEARVIEW PATIENT SAFETY TECHNOLOGIES LLC		☐
	10	2993646	CA		2017-02-02	KURIN INC		☐
	11	3324845A1	EP		2018-05-30	KURIN INC		☐
	12	3562397A1	EP		2019-11-06	KURIN INC		☐
	13	3622890A1	EP		2020-03-18	KURIN INC		☐
	14	5789869B2	JP		2015-10-07	TOHO ENGINEERING KK,		☒

PC 6.1.24

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	15	5867238B2	JP		2016-02-24	FUJITSU LTD,		☒
	16	6643474B2	JP		2020-02-12	クリン インコーポレイテッド		☒
	17	6734490	JP		2020-08-05	クリン インコーポレイテッド		☒
	18	2001000424	JP		2001-01-09	NISSHO KK		☒
	19	2012016496A	JP		2012-01-26	TERUMO CORP		☒
	20	2016504075	JP		2016-02-12	マグノリア メディカル テクノロジーズ , インコーポレイテッド		☒
	21	2019534792A	JP		2019-12-05	プライメタルズ・テクノロジーズ・オーストリア・ゲーエムベーハー		☒
	22	H09504726A	JP		1997-05-13	BAXTER INT		☒
	23	9605875A1	WO		1996-02-29	BAXTER INT		☐
	24	2013181352A1	WO		2013-12-05	MAGNOLIA MEDICAL TECHNOLOGIES INC		☐
	25	2014058945	WO		2014-04-17	BULLINGTON GREGORY J		☐

PC 6.1.24

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	26	2017019552A1	WO		2017-02-02	KURIN INC		☐
	27	2018125929A1	WO		2018-07-05	KURIN INC		☐
	28	S5825146A	JP		1983-02-15	BECTON DICKINSON CO		☒
	29	S5867238A	JP		1983-04-21	BECTON DICKINSON CO		☒
	30	5643474	JP		2014-12-17	ヴェロシス，インク．		☒
	31	5825146B2	JP		2015-12-02	JVC KENWOOD CORP,		☒
	32	2020000340A	JP		2020-01-09	TOSHO INC		☒
	33	2013240628	JP		2013-12-05	COVIDIEN LP		☒
	34	H02224742	JP		1990-09-06	SPACELABS INC		☒
	35	S5789869	JP		1982-06-04	BECTON DICKINSON CO		☒
	36	2005349196	JP		2005-12-22	BECTON DICKINSON CO		☒

PC 6.1.24

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	37	10243129	DE		2004-04-01	RITTER GMBH		☒
	38	7203008	DE		1972-05-10	IMMUNO AG FUER CHEM-MED PROD		☒
	39	10038026	DE		2001-02-22	ZIERDEN PETER		☒
	40	29913417	DE		2000-12-28	ZIERDEN PETER		☒
	41	10134913	DE		2003-02-20	HIBERNA AG		☒
	42	10134913C2	DE		2003-06-26	HIBERNA AG		☒
	43	2541494	DE		1977-03-31	GUERRA LUIS A		☒
	44	2008101025	WO		2008-08-21	EDWARDS LIFESCIENCES CORP		☐
	45	0448795A2	EP		1991-10-02	BECTON DICKINSON CO		☐
	46	2007033319A1	WO		2007-03-22	EDWARDS LIFESCIENCES CORP		☐
	47	199216144	WO		1992-10-01	GOLDSPILL PTY. LTD.		☐

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	18783173
	Filing Date	2024-07-24
	First Named Inventor	Bobby E. ROGERS
	Art Unit	OPAP
	Examiner Name	DOCKET CENTRAL
	Attorney Docket Number	069366-0580420_KUR3C03US

	48	S5643474	JP		1981-10-12	TORAY INDUSTRIES		☐
	49	H08257018	JP		1996-10-08	NISSHO KK		☒
	50	1996005875	WO		1996-02-29	BAXTER INT		☒

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NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1	International Search Report and Written Opinion dated Nov. 5, 2015, for PCT application No. PCT/US2015/035870. 6 pages.	☐
	2	International Search Report and Written Opinion dated 16 July 2020 for PCT application no. PCT/US2020/026276. 9 pages.	☐
	3	Bullington, et al., Systems and Methods for Sample Collection with Reduced Hemolysis, Exhibit H in U.S. Appl. No. 62/517,681, dated Jun. 9, 2017, 131 pages.	☐
	4	Communication Under Rule 71(3) EPC dated Apr. 22, 2020 for EP application No. 17840467.9. 125 pages.	☐
	5	European Patent Application No. EP19200766.4 extended European Search Report dated Dec. 2, 2019, 11 pages.	☐
	6	European Patent Office, Extended European Search Report for European Patent Application 20197213.0-1132, dated Dec. 9, 2020, 6 pages.	☐

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	7	European Patent Office; Communication pursuant to Article 94(3) EPC, dated Oct. 31, 2018; 11 pages.	☐
	8	Examination Report No. 1 dated Apr. 29, 2020, for Australian Patent Application No. 2016297849. 3 pages.	☐
	9	International Search Report and Written Opinion dated Jun. 19, 2020, for PCT application No. PCTUS2020/023617. 12 pages.	☐
	10	European Patent Office, International Search Report and Written Opinion for PCT/US16/43709, dated Oct. 19, 2016, 14 pages.	☐
	11	International Search Report/Written Opinion for PCT/US17/68569 dated Apr. 25, 2018. 9 pages.	☐
	12	Japanese Patent Office, Notice of Reasons for Rejection dated Jun. 15, 2021, Application No. JP 2019-534792, 6 pages.	☐
	13	Japanese Patent Office, Notice of Reasons for Rejection for JP Application No. JP 2020-118498 date Aug. 10, 2021.	☐
	14	Japanese Patent Office, Notice of Reasons for Rejection, Japanese patent application No. JP2018-523384, dated Jul. 23, 2019, 5 pages.	☐
	15	European Patent Office, International Search Report/Written Opinion for PCT/US17/068569 dated Apr. 25, 2018, 9 pages.	☐
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	17	Retractable Techs., Inc. v. Becton Dickinson & Co., CA No. 2:07-CV-250, Claim Construction Order (E.D. Tex., Jan. 20, 2009). 20 pages.	☐

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	18	Hillyer, Christopher D., et al. “Bacterial Contamination of Blodd Components: Risks, Strategies and Regulation,” Hematology, 2003, pp. 575-589.	☐
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	29	Norberg, Alonna, et al. “Contamination rates of blood cultures obtained by dedicated phlebotomy vs intravenous catheter.” Jama 289.6 (2003): 726-729.	☐
	30	Quilici, Nathalie, et al. “Differential quantitative blood cultures in the diagnosis of catheter-related sepsis in intensive care units.” Clinical infectious diseases 25.5 (1997): 1066-1070.	☐
	31	Napolitano, Marcello, et al. “Quality control of bacterial contamination of blood components: the feasibility of diversion system testing.” Blood Transfus 2 (2004): 231-232.	☐
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	48	Mayer, G.A. "A Method for the Reliable Determination of Clotting Time in Whole Blood," Canadian Medical Association Journal, June 15, 1955, Vol. 72, Pages 927-929.	☐

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EXAMINER SIGNATURE

Examiner Signature	/H Q NGUYEN/	Date Considered	09/09/2024

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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	Attorney Docket Number	069366-0580420_KUR3C03US

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

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CERTIFICATION STATEMENT

Please see 37 CFR 1.97(e) to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☒ A certification statement is not submitted herewith.

FEE

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

COPIES

☐ An identification of an earlier application pursuant to 37 CFR 1.98 (d) (1) is attached.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2024-08-26
Name/Print	Benjamin F. Hudson	Registration Number	71,474

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/783,088	07/24/2024	Bobby E. ROGERS	069366-0580418_KUR2C06US	2051

27500 7590 09/17/2024

PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
ATTENTION: DOCKETING DEPARTMENT
P.O BOX 10500
McLean, VA 22102

EXAMINER	
ABOUELELA, MAY A	

ART UNIT	PAPER NUMBER
3791	

NOTIFICATION DATE	DELIVERY MODE
09/17/2024	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Docket_IP@pillsburylaw.com

Office Action Summary	Application No. 18/783,088	Applicant(s) ROGERS et al.	
	Examiner MAY A ABOUELELA	Art Unit 3791	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 07/24/2024.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL.** 2b) ☑ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 1-26 is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 1-9,11-22 and 24-26 is/are rejected.

8) ☑ Claim(s) 10 and 23 is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to **PPHfeedback@uspto.gov.**

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☑ The drawing(s) filed on 07/24/2024 is/are: a)☑ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☑ Notice of References Cited (PTO-892)

2) ☑ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

Notice of Pre-AIA or AIA Status

1. The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 08/26/2024. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Objections

3. Claim 11 is objected to because of the following informalities: the phrase "a sample collection device" in line 2 should be amended to read –the blood sample collection device--. Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a)(1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention.

Claim(s) 1, 6-9, 11, 12, 14, 19-22, 24 and 25 is/are rejected under 35 U.S.C. 102(a)(1) as being anticipated by Patton et al (US 2008/0145933).

As to claims 1 and 14, Patton discloses a device (blood sampling device 500, par.38-40, fig.5) comprising:

an inlet port for receiving a blood sample (inlet/opening connecting needle 508 to input tubing 514, par.38-40, fig.5);

an outlet port (needle 510, fig.5);

a chamber (tubing 516 and reservoir 504, par.38-40, fig.5) comprising a flexible material (flexible material of tubing 516 and reservoir 504), wherein the chamber is connected with the inlet port (516 and 504 are connected to inlet of tubing 514, as best seen in fig.5) and configured to collect a first portion of the blood sample (diversion mechanism 512 can be initially adjusted to divert blood to the one or more pre-sample reservoirs 504 until the one or more pre-sample reservoirs 504 are filled, par.40, fig.5) when under a drawing force applied from the outlet port from a blood sample collection device (pre vacuumed effect of vessel 506 withdraws blood, first needle 508 can be inserted into a patient to procure a blood sample. In FIG. 5, the first needle 508 is shown inserted into a vein 520. The second needle 510 is shown inserted into the one or more sample vessels 506 that have been vacuum-sealed. The vacuum in each of the one or more sample vessels 506 causes blood to pass from the vein 520 to the diversion mechanism 512, par.40); and

a sampling channel (tubings 514 and 518 connected with inlet of tubing 214, par.38-40, as best seen in fig.4) connected with the inlet port and configured to convey a subsequent portion of the blood sample to the outlet port (which point the diversion mechanism 512 can be adjusted to divert the flow of blood to the one or more sample vessels 506, ar.38-40, fig.5).

As to claims 6 and 19, Patton discloses the device, further comprising a valve (diversion mechanism 512 having valve 60, par.38-41, fig.5) configured to initially close off the sampling channel (diversion mechanism 512 can be initially adjusted to divert blood to the one or more pre-sample reservoirs 504 until the one or more pre-sample reservoirs 504 are filled, or a desired amount of blood has been withdrawn, at which point the diversion mechanism 512 can be adjusted to divert the flow of blood to the one or more sample vessels 506, par.40).

As to claims 7 and 20, Patton discloses the device, further comprising a valve configured to initially close off the sampling channel until the first portion of the blood sample is in the chamber (diversion mechanism 512 can be initially adjusted to divert blood to the one or more pre-sample reservoirs 504 until the one or more pre-sample reservoirs 504 are filled, or a desired amount of blood has been withdrawn, at which point the diversion mechanism 512 can be adjusted to divert the flow of blood to the one or more sample vessels 506, par.40).

As to claims 8 and 21, Patton discloses the device, further comprising a valve that is configured to initially close off the sampling channel until the first portion of the blood sample is in the chamber and is further configured such that, upon release, follow-on amounts of the blood sample will bypass the chamber and flow through the sampling channel toward the outlet port (diversion mechanism 512 can be initially adjusted to divert blood to the one or more pre-sample reservoirs 504 until the one or more pre-sample reservoirs 504 are filled, or a desired amount of blood has been withdrawn, at

which point the diversion mechanism 512 can be adjusted to divert the flow of blood to the one or more sample vessels 506, par.40, as best seen from fig.5 the subsequent blood will bypass reservoir 504 and flows straight from inlet of 502 to tubings 514 and 518).

As to claims 9 and 22, Patton discloses the device, wherein the valve is configured to pinch, shunt, bend or otherwise close off the sampling channel before the first portion of the blood sample is collected in the chamber (diversion mechanism 512 can be initially adjusted to divert blood to the one or more pre-sample reservoirs 504 until the one or more pre-sample reservoirs 504 are filled, or a desired amount of blood has been withdrawn, at which point the diversion mechanism 512 can be adjusted to divert the flow of blood to the one or more sample vessels 506, par.40, fig.5).

As to claims 11 and 24, Patton discloses the device, further comprising a patient needle (patient needle 508, par.38-40, fig.5) and a sample collection device (sample vessel 506, par.38-40, fig.5).

As to claims 12 and 25, Patton discloses the device, the chamber having a volume sufficient to collect the first portion of the blood sample that is more prone to contamination and also to minimize an amount of blood to be sequestered (the data suggests that fewer false positive test results for the presence of microbes in blood are obtained over conventional methods when initially-drawn volumes of blood are not used in microbial testing, par.54).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim(s) 2-5 and 15-18 is/are rejected under 35 U.S.C. 103 as being obvious over Patton et al (US 2008/0145933) in view of Flaherty et al (US 2006/0009713).

As to claims 2-5 and 15-18, Patton discloses the invention substantially above, wherein a housing of the diverting mechanism is separate from a blood impermeable membrane, but failed to explicitly teach a blood impermeable membrane is configured to facilitate the chamber collecting the first portion of the blood sample, and causes the first portion of the blood sample to back up into the chamber following application of the drawing force applied from the outlet port, and wherein the device is configured such that, when the drawing force is applied at the outlet port, the first portion of the blood sample is drawn into the chamber to contact a material that is blood impermeable.

However, Flaherty discloses an analogous blood sampling device, wherein the blood sampling chamber comprises (liquid impenetrable, air-permeable membrane 45, par.39, fig.8-10), wherein blood flows into the blood collection chamber 39, air is displaced from the blood collection chamber 39, through the membrane 45 and air opening or openings 46, respectively. This facilitates the substantially continual and unhindered flow of blood from the patient 106 and into the blood collection chamber 39

to collect the desired quantity of blood into the blood collection chamber 39 (par.40, fig.8-10).

Since blood impermeable membrane is well-known in the art, so it would have been obvious to one having an ordinary skill in the art before the effective filing date of the invention to include a blood impermeable membrane in reservoir 504 taught by Patton's invention, as blood impermeable membrane 45 taught by Flaherty's invention to facilitate the continual and unhindered flow of blood from the patient and into the blood collection chamber, as taught by Flaherty's invention (par.40).

6. Claim(s) 13 and 26 is/are rejected under 35 U.S.C. 103 as being obvious over Patton et al (US 2008/0145933).

As to claims 13 and 26, Patton discloses the volume of blood withdrawn into the one or more pre-sample reservoirs 504 is at least equal to the collective volumes of the first needle 508, the flexible, sterile input tubing 516, the diversion mechanism 512, and the first sterile output tubing 516 (par.40), but failed to explicitly teach he chamber has a volume of less than 1.5 cubic centimeters. However, it would have been obvious to one having an ordinary skill in the art at the time the invention was made to allow reservoir 504 to collect blood volume less than 1.5 cubic centimeters, since it has been that discovering the optimum value of a result of effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215(CCPA 1980).

Allowable Subject Matter

7. Claims 10 and 23 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MAY A ABOUELELA whose telephone number is (571)270-7917. The examiner can normally be reached 8-5.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JACQUELINE CHENG can be reached on 5712725596. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: https://patentcenter.uspto.gov. Visit https://www.uspto.gov/patents/apply/patent-center for more information about Patent Center and https://www.uspto.gov/patents/docx for information about filing in DOCX format. For

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Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MAY A ABOUELELA/
Primary Examiner, Art Unit 3791

Notice of References Cited	Application/Control No. 18/783,088	Applicant(s)/Patent Under Reexamination ROGERS et al.	
	Examiner MAY A ABOUELELA	Art Unit 3791	Page 1 of 5

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	Examiner MAY A ABOUELELA	Art Unit 3791	Page 2 of 5

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Notice of References Cited	Application/Control No. 18/783,088	Applicant(s)/Patent Under Reexamination ROGERS et al.	
	Examiner MAY A ABOUELELA	Art Unit 3791	Page 3 of 5

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	Examiner MAY A ABOUELELA	Art Unit 3791	Page 4 of 5

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	Examiner MAY A ABOUELELA	Art Unit 3791	Page 5 of 5

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Filing Date	2024-07-24
First Named Inventor	Bobby E. ROGERS
Art Unit	OPAP
Examiner Name	DOCKET CENTRAL
Attorney Docket Number	069366-0580418_KUR2C06US

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PC 6.1.24

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Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2024-08-26
Name/Print	Benjamin F. Hudson	Registration Number	71,474

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	1	Meissner, George F. , et al., "The Standard Clotting Time, A Method Based on the Use of Whole Venous Blood in Capillary Tubes," The American Journal of Clinical Pathology, vol. 39, No. 3., pp. 321-323, Mar. 1963.	☐
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	4	Notice of Allowance mailed 09-08-2023; Attorney Docket No. 069366-0574153_KUR2C04US. 35 page.	☐
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	11	Notice of Allowance mailed 01-17-2024; Attorney Docket No. 069366-0572201_KUR2C03US. 16 pages.	☐
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☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☒ A certification statement is not submitted herewith.

FEE

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

COPIES

☐ An identification of an earlier application pursuant to 37 CFR 1.98 (d) (1) is attached.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2024-08-26
Name/Print	Benjamin F. Hudson	Registration Number	71,474

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.A.A/

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.A.A/

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-22)
Approved for use through 05/31/2024. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	18783088
Filing Date	2024-07-24
First Named Inventor	Bobby E. ROGERS
Art Unit	OPAP
Examiner Name	DOCKET CENTRAL
Attorney Docket Number	069366-0580418_KUR2C06US

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1							☐

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NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

PC 6.1.24

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.A.A/

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	Application Number	18783088
	Filing Date	2024-07-24
	First Named Inventor	Bobby E. ROGERS
	Art Unit	OPAP
	Examiner Name	DOCKET CENTRAL
	Attorney Docket Number	069366-0580418_KUR2C06US

	1	Notice of Allowance mailed 04-04-2023; Attorney Docket No. 069366-0572230_KUR2D02JP. 6 pages.	☐
	2	Rule 71(3) Communication and Text for Grant mailed 08/31/2022 for European Application No. 19200766.4-1122. 189 pages.	☐
	3	Office Action (Non-Final Rejection) mailed 01/21/2022 for Israeli Application No. 267684. 3 pages.	☐
	4	Notice of Allowance mailed 02-14-2023; Attorney Docket No. 069366-0572429_KUR3N01IL. 122 pages.	☐
	5	Office Action (Non-Final Rejection) mailed 11/29/2022 for Application No. 2021-214177, pages 1-3.	☐
	6	Notice of Allowance mailed 06-20-2023; Attorney Docket No. 069366-0572231_KUR3D01JP. 6 pages.	☐
	7	Office Action (Non-Final Rejection) mailed 11/4/2022 for Application No. 17094692, pages 1-50.	☐
	8	Notice of Allowance mailed 04-20-2023; Attorney Docket No. 069366-0572169_KUR4C01US. 36 pages.	☐
	9	Office Action (Non-Final Rejection) mailed 08/04/2022 for Application No. 16819033, pages 1-35.	☐
	10	Notice of Allowance mailed 11-28-2022; Attorney Docket No. 069366-0572168_KUR4002US. 9 pages.	☐
	11	Office Action (Non-Final Rejection) mailed 04/16/2024 for Application No. 16838017, pages 1-19.	☐

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	First Named Inventor	Bobby E. ROGERS
	Art Unit	OPAP
	Examiner Name	DOCKET CENTRAL
	Attorney Docket Number	069366-0580418_KUR2C06US

	12	Second Office Action dated 04/28/2024 for CN Application No. 202080000666.0, pages 1-28.	☐
	13	Notice of Allowance mailed 07-04-2024; Attorney Docket No. 069366-0572164_KUR7N01JP. 9 pages.	☐
	14	Office Action mailed 05-21-2024; Attorney Docket No. 069366-0572161_KUR7N01IL. 6 pages.	☐
	15	European Patent Office, Examination Report for European Patent Application 21818838.1, dated April 22, 2024, pages 1-11.	☐
	16	European Patent Office, Examination Report for European Patent Application 20781928.5, dated July 31, 2024, pages 1-6.	☐
	17	Ziegler, R., et al. "Controlled Clinical Laboratory Comparison of Two Supplemented Aerobic and Anaerobic Media Used in Automated Blood Culture Systems to Detect Bloodstream Infections," Journal of Clinical Microbiology, Mar. 1998, p. 657-661.	☐

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature	/MAY A ABOUELELA/	Date Considered	09/16/2024

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

PC 6.1.24

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	Attorney Docket Number	069366-0580418_KUR2C06US

CERTIFICATION STATEMENT

Please see 37 CFR 1.97(e) to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

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Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2024-08-26
Name/Print	Benjamin F. Hudson	Registration Number	71,474

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The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

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3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

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6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

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9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.A.A/

Date: 20 December 2023

Your ref: 1000-016-04

Attn.

Katz, Presenti & Co.

14 Abba Hillel Rd.

Ramat Gan 52506

Greetings,

Re: **Notice prior to an Examination of Patent Application no. 309380 pursuant to Section 18 of the Law and Regulation 36 of the Regulations**

Please be advised: any reference to the Law, shall mean a reference to the Patents Law, 5727-1967; any reference to the Regulations, shall mean a reference to the Patents Regulations (Office Practices, Rules of Procedure, Documents and Fees), 5728-1968.

Please note: you must reply to this notice (even if all the answers are negative) within 4 months from the date hereof; however, you may request to extend the period in accordance with the rules prescribed in the Patents Registrar's Circular 035/2017-Patents. **In accordance with this circular, an extension of up to six months shall be granted for a notice prior to an examination.** Upon filing such an application prior to the end of the period, a fee at the sum of NIS 208 shall be paid for each month of delay or any part thereof.

1. List of References and Publications

Pursuant to the provisions of Section 18 of the Law and Regulation 36 of the Regulations, the following documents must be provided to the Patent Office:

a) The list of references relied on by the patent offices of the countries in which patent applications were filed with respect to the invention subject of the application contemplated herein during their examination of such applications (Section 18(a)(1) of the Law).

The applicant must enclose a copy of publications that are neither patents nor patent applications, which are specified in the list above mentioned.

b) In a separate list, publications that were published prior to the application date, which are known to the applicant and pertain directly to the invention. It is not required to include in this list any publications explicitly mentioned in the patent application (Section 18(a)(2) of the Law).

Pursuant to the provisions of Patents Registrar's Circular 035-2017-Patents, the following should also be specified as part of the said list:

- Any publications published or submitted by the applicant itself or by its predecessor in holding the right of ownership, including patent applications, patents and researches that directly pertain to the claimed invention;
- In the event of filing an application in Israel while claiming a priority right under an application of continuation or continuation in part (as the same are known in the U.S.), it will be required to submit a notice to the Patent Office regarding the publication dates of the applications in the chain of the applications of continuation or continuation in part and the numbers of such applications.

c) A list of the countries in which protection was sought for the invention subject of the application, by the applicant or by its predecessor in holding the right of ownership and the numbers of the applications filed in the said countries (**Regulation 36 of the Regulations**).

Please note: pursuant to Regulation 36(4) of the Regulations, if the applicant failed to respond to this requirement, it shall be deemed to have failed to remove deficiencies for which it was given notice under Section 20 of the Law.

2) **The Details of the Application**

a) **Please be advised:** each claim beyond the first 50 claims shall require a payment of an additional fee. If the application includes more than 50 claims, you must pay the fee; alternatively, you may reduce the number of claims. If the said fees have not been paid or if the number of claims was not reduced, this notice shall be deemed a notice of deficiencies. An applicant who fails to rectify the said deficiency upon filing its response to this notice will receive a notice prior to abandonment of the application, and if no payment was made - the application will be abandoned (the Patents Registrar notice dated December 3, 2012).

b) With respect to patent applications in the field of biotechnology, you must submit the list of sequences in a *.txt file only, and in accordance with the WIPO ST.25 standard. If the sequences file has already been submitted to the Patent Office in a *.txt file as of the application submission date, there is no need to submit it again.

c) Please be advised: in accordance with the provisions of the Patents Registrar Circular 0034/2017-Patents, if it will be determined that more than one invention was claimed under the application, the examiner will examine the first one among them according to the order of claims.

With respect to some fields, it is possible that the examination of the application shall not commence immediately after the Patent Office's requirements listed herein have been satisfied.

Please be advised: the examination of this application may be accelerated based on a parallel application, for which a positive report/patent was granted by an equivalent patent authority that has entered into a PPH arrangement vis-à-vis the Israeli Patent Office, thus free of any additional fees. For further details, please review the PPH webpage (the Patent Department) on the Israeli Patent Office website.

Respectfully,
Cohen Carmela
On behalf of the Patents Registrar

תאריך: ח' טבת תשפ"ד
20/12/2023
סימוכין: 1000-016-04

לכבוד
כץ, פרזנטי ושות'
דרך אבא הלל 14,
רמת גן, מיקוד 52506

א.ג.נ.,

<u>הודעה לפני בחינת הבקשה לפטנט מס' 309380 בהתאם לסעיף 18 לחוק ותקנה 36 לתקנות</u>

לתשומת לבכם: מקום בו הנכם מופנים לחוק, הכוונה היא לחוק הפטנטים, התשכ"ז – 1967.
מקום בו הנכם מופנים לתקנות, הכוונה היא לתקנות הפטנטים (נוהלי הרשות , סדרי דין, מסמכים ואגרות), התשכ"ח – 1968.
<u>הערה:</u> עליכם להשיב על הודעה זו (אף אם כל התשובות הן שליליות) תוך ארבעה חודשים מתאריכה, אך הנכם רשאים לבקש את הארכת התקופה בהתאם לכללים שנקבעו בחוזר הרשם 035/2017 – פטנטים. **בהתאם לחוזר זה לא יינתנו יותר משישה חודשי ארכה בגין הודעה לפני בחינה.** עם בקשה כאמור שתוגש לפני תום התקופה יש לשלם אגרה בסך 218 בעד כל חודש איחור או חלק ממנו.

1. רשימת פירסומים

בהתאם לאמור בסעיף 18 לחוק ובתקנה 36 לתקנות, יש להמציא לרשות את המסמכים הבאים:

(א) רשימת פירסומים (אסמכתאות) עליהם הסתמכו רשויות הפטנטים בארצות בהן הוגשו בקשות לפטנט על האמצאה מושא הבקשה דנן בשעת הבחינה של בקשות אלה (סעיף 18 (א)(1) לחוק).
על המבקש לצרף עותק של פרסומים שאינם פטנטים או בקשות לפטנט המצוינים ברשימה הנ"ל.

(ב) ברשימה נפרדת, פרסומים שפורסמו לפני תאריך הבקשה, הידועים למבקש והנוגעים במישרין לאמצאה. אין צורך לכלול ברשימה זו פרסומים שאוזכרו במפורש בבקשת הפטנט (סעיף 18(א)(2) לחוק).
על פי הוראות חוזר רשם 035/2017 - פטנטים במסגרת רשימה זו יש להודיע בין היתר גם על:

- פרסומים שפרסם או הגיש המבקש עצמו או מי שקדם לו בזכות בעלות, לרבות בקשות לפטנט, פטנטים, מחקרים הנוגעים במישרין לאמצאה הנתבעת;
- בקשה שהוגשה בישראל תוך תביעת דין קדימה מבקשת המשך או המשך בחלקה (Continuation, Continuation In Part כפי שאלה נעשות בארה"ב) תחייב הודעה לרשות אודות תאריכי הפרסום של הבקשות בשרשרת בקשות ההמשך או בקשות המשך בחלקן ומספרי הבקשות.

(ג) רשימת הארצות שבהן נתבקשה הגנה על האמצאה נושא הבקשה על ידי המבקש או מי שקדם לו בזכות בעלות ואת מספרי הבקשות שהוגשו באותן ארצות **(תקנה 36 לתקנות).**

לתשומת לבכם, בהתאם לתקנה 36(4) לתקנות אם לא השיב המבקש על דרישה זו, יהיה דינו כדין מי שלא סילק ליקויים שעליהם נמסרה לו הודעה לפי סעיף 20 לחוק.

2. פירוט הבקשה

(א) **תשומת לבכם** כי כל תביעה שמעבר ל-50 התביעות הראשונות מחייבת בתשלום אגרה נוספת. ככל שהבקשה כוללת מעל 50 תביעות עליכם לשלם את האגרה, לחלופין באפשרותכם לצמצם את מספר התביעות. לא שולמה האגרה כאמור או לא צומצם מספר התביעות, יראו בהודעה זו מכתב ליקויים. מבקש שלא יתקן את הליקוי האמור במועד תשובתו להודעה זו יקבל הודעה לפני סגירת הבקשה ובהעדר תשלום תיסגר הבקשה (הודעת הרשם מיום 3/12/2012).

(ב) בבקשה לפטנט בתחום הביוטכנולוגיה הכוללת רשימת רצפים:
עבור בקשה שתאריכה מאוחר מ- 1/7/2022 עליכם להגיש את רשימת הרצפים בקובץ מסוג XML ערוך בהתאם לתקן ST.26 של WIPO;
עבור בקשה שתאריכה מוקדם מתאריך זה עליכם להגיש את רשימת הרצפים בקובץ מסוג TXT ערוך בהתאם לתקן ST.25 של WIPO;
במידה וקובץ הרצפים הוגש לרשות בסוג הקובץ הנדרש במועד הגשת הבקשה, אין צורך להגישו בשנית.

(ג) **לתשומת לבכם בהתאם להוראות חוזר רשם 0034/2017 - פטנטים, באם יקבע כי נתבעו בבקשה יותר מאמצאה אחת, הבוחן יבחן את <u>הראשונה</u> מביניהן לפי סדר התביעות.**

ייתכן כי בתחומים מסויימים בחינתה של בקשה לא תחל מייד עם מילוי דרישות הרשות המפורטות בהודעה זו.

נבקש לידע שניתן לזרז את בחינת בקשה זו על סמך בקשה מקבילה אשר קיבלה דוח חיובי/פטנט ברשות מקבילה שיש לה הסדר PPH עם רשות הפטנטים הישראלית וזאת ללא צורך בתשלום אגרה נוספת. לפרטים נוספים נא לפנות לדף ה-PPH (מחלקת פטנטים) באתר רשות הפטנטים.

בכבוד רב,
רשות הפטנטים

טופס פר' 34 (12) 15.05.2023

פ.ק 13

תאריך : כ״ח אלול תשפ״ג
14/09/2023
מספרכם : 1000-016-03

לכבוד
כץ, פרזנטי ושות׳
דרך אבא הלל 14,
רמת גן, מיקוד 52506

א. ג. נ.,

הנדון : **<u>הודעה לפני קיבול בקשת פטנט מספר 300848</u>**

סימוכין : מכתבכם מיום 14/07/2023

לתשומת לבכם : מקום בו הנכם מופנים ל״חוק״, הכוונה היא לחוק הפטנטים, התשכ״ז – 1967. מקום בו הנכם מופנים ל״תקנות״, הכוונה היא לתקנות הפטנטים (נוהלי הרשות, סדרי דין, מסמכים ואגרות), התשכ״ח – 1968. בהתאם לחוזר רשם 035/2017 – פטנטים **לא ניתן להשהות פרסום בקשות פטנט לפי סעיף 26 לחוק.**

<u>הודעה זו מבוססת על המסמכים הבאים :</u>

שרטוטים מתאריך : 21/02/2023
תביעות מתאריך : 27/07/2023
פרטי הבקשה מתאריך : 27/07/2023

<u>הריני להודיעכם כי בחינת הבקשה הנ״ל הושלמה לפי הוראות סעיף 48ו(ג)(1) ו- (2) לחוק.</u>

1. <u>בחינת הבקשה מבוססת על ההודעות הבאות :</u>

1.1 הריני להודיעכם כי :

תאריך הבקשה הנוכחית, שהינה בקשת חלוקה מן הבקשה מס׳ 286030, הוקדם לתאריך 22/07/2016 , שהוא תאריך הבקשה ההורה, וזאת בהתאם ל**סעיף 24(ג) לחוק**.

<u>תשלום אגרת קיבול</u>

1. הבקשה תתקבל בהתאם לסעיף 26 לחוק לאחר תשלום אגרת הקיבול.
2. יש לשלם את האגרה תוך 3 חודשים מתאריך הודעה זו.
3. סכום האגרה נכון למועד הודעה זו הינו 764.00 ש״ח. הסכום כפוף לעדכונו על פי המדד בהתאם לתקנה 6א.

<u>הפניה בפירוט למסמך הבכורה</u>

לפי הוראות **סעיף 20 לחוזר הרשם 034/2017-פטנטים** במידה ופירוט הבקשה מכיל הפניה למסמך בכורה באמצעות הביטוי ״incorporated by reference״ ובמידה וחלפו 14 חודשים ממועד דין הקדימה (אם נדרש) לא

ניתן עוד להוסיף דבר מתוך מסמך הבכורה והמבקש לא יכול להסתמך על האמור במסמך הבכורה לצורך סעיפים 12 ו-13 לחוק.

<u>עדכון רשימות האסמכתאות והפרסומים לפי סעיף 18א לחוק</u>

לתשומת לבכם, בהתאם להוראות פרק ג' בחוזר רשם 035/2017-פטנטים חובת המבקש לעדכן את הרשות בכל שינוי שחל ברשימת הפרסומים בהתאם לסעיף 18 לחוק נמשכת עד קיבול הבקשה.

באם ברצונכם להחזיר את הבקשה לבחינה בעקבות שינוי ברשימת הפרסומים שהתרחש מאז עדכנתם לאחרונה את תשובתכם לדרישה לפי סעיף 18 לחוק , עליכם להגיש בקשה לבחינה חוזרת בה עליכם לציין מהו השינוי ברשימת הפרסומים ומתי נודע על שינוי זה.

בקשה לבחינה חוזרת יש להגיש באמצעות פניה ל-"בקשה לתיקונים לאחר פ.ק. 13".

<u>הגשת בקשות חלוקה</u>

בהתאם להוראות סעיף 24(א) לחוק זכאי המבקש כל עוד לא קובלה הבקשה לדרוש את חלוקת הבקשה לבקשות אחדות. לפיכך, באם ברצונכם להגיש בקשות חלוקה מבקשה זו עליכם לעשות זאת בטרם מועד הקיבול. לא נוכל להכיר בבקשות שיוגשו לאחר מועד הקיבול של הבקשה הנוכחית כבקשות חלוקה לעניין סעיף 24(ג) לחוק.

<u>בדיקה פורמלית</u>

להודעה הנוכחית מצורף העתק פירוט הבקשה המעודכן - אם נפלו טעויות נא להודיע עליהן לרשות לפני מועד תשלום אגרת הקיבול.

לצורך אימות פרטי הפרסום בהתאם לסעיף 26 לחוק ניתן לעיין בנסח הבקשה באתר הרשות בקישור הבא:

https://israelpatents.justice.gov.il/#/en/patent-extract/300848

ניתן לעיין בפרטי תיק הבקשה באתר הרשות בקישור:

https://israelpatents.justice.gov.il/#/en/patent-file/details/300848

בכבוד רב

אלברט אקרמן
בוחן פטנטים בכיר
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דואר אלקטרוני: albertak@justice.gov.il
ראש צוות: מוריה שלמה לוי

Claims

1. A device comprising:

an inlet port for receiving a blood sample;

an outlet port;

a chamber connected with the inlet port and the outlet port, and configured to collect a first portion of the blood sample, the chamber including a material that is air permeable and blood impermeable; and

a sampling channel connected with the inlet port and configured to convey a subsequent portion of the blood sample to the outlet port while bypassing the chamber.

2. The device in accordance with claim 1, wherein the device is configured such that, when a drawing force is applied at the outlet port, blood is drawn into the inlet port and into the chamber.

3. The device in accordance with claim 2, wherein the device is further configured such that an initial aliquot of blood will contact the material and back up into the chamber.

4. The device in accordance with claim 1, wherein the material is located at a distal end of the chamber.

5. The device in accordance with claim 1, wherein the material is a hydrophobic plug.

6. The device in accordance with claim 1, wherein the material is a hydrophobic membrane.

7. The device in accordance with claim 1, wherein the material is a hydrophilic membrane.

8. The device in accordance with claim 1, wherein the sampling channel further comprises a valve configured to close off the sampling channel.

9. The device in accordance with claim 8, wherein the valve is a clip.

10. The device in accordance with claim 1, further comprising a junction connecting the inlet port and the sampling channel and the chamber.

11. The device in accordance with claim 10, wherein the junction is configured to convey the subsequent portion of the blood sample to the outlet port while bypassing the chamber.

12. The device in accordance with claim 1, wherein the chamber has a larger cross-sectional area than the sampling channel.

13. The device in accordance with claim 1, further comprising a housing that defines the chamber and the sampling channel.

14. The device in accordance with claim 13, wherein the housing comprises a bottom member mated with a top member, each of the bottom member and the top member defining a part of each of the inlet port, the outlet port, the chamber, and the sampling channel.

15. The device in accordance with claim 1, further comprising a patient needle and a sample collection device.

BLOOD SAMPLE OPTIMIZATION DEVICE

ABSTRACT

Blood sample optimization systems and methods are described that reduce or eliminate contaminates in collected blood samples, which in turn reduces or eliminates false positive readings in blood cultures or other testing of collected blood samples. A blood sample optimization system can include a blood sequestration device located between a patient needle and a sample needle. The blood sequestration device can include a sequestration chamber for sequestering an initial, potentially contaminated aliquot of blood, and may further include a sampling channel that bypasses the sequestration chamber to convey likely uncontaminated blood between the patient needle and the sample needle after the initial aliquot of blood is sequestered in the sequestration chamber.

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of priority of U.S. Non-Provisional Application Serial No. 15/140,443, filed on April 27, 2016 and titled "BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD" and U.S. Non-Provisional Application Serial No. 15/140,448, filed on April 27, 2016 and titled "BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD", both of which claim priority to U.S. Provisional Application Serial No. 62/196,797, filed on July 24, 2015 and titled "BLOOD CULTURE IMPROVEMENT SYSTEM AND METHOD"; U.S. Provisional Application Serial No. 62/238,636, filed on October 7, 2015 and titled "BLOOD SEQUESTRATION SYSTEM FOR NON-CONTAMINATED BLOOD SAMPLING"; and U.S. Provisional Application Serial No. 62/318,194, filed on April 4, 2016 and titled "BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD," the disclosures of which are incorporated by reference in their entirety.

BACKGROUND

[0002] Bacteraemia is the presence of microorganisms in the blood. Sepsis, on the other hand, is bacteraemia in the presence of clinical symptoms and signs such as fever, tachycardia, tachypnea and hypotension. Bacteraemia and sepsis are associated with a high mortality and an increased incidence and duration of hospital stay and associated costs. Many bacteraemias, sepsis, fungaemias and other pathogens actually occur within a hospital or other healthcare settings with catheters and venipunctures being a source of contamination as potential carriers of these pathogens.

[0003] Blood cultures are the standard test used to detect microbial pathogens related to bacteraemia and sepsis in a patient's blood. The term blood culture refers to a single venipuncture, either from a peripheral site or central or arterial line, with the blood inoculated into one or more blood culture bottles or containers. One bottle is considered a blood culture where two or more are considered a set. Multiple sets may be obtained from multiple venipunctures and are associated with different sites on the patient.

[0004] These methods allow for microbial identification and susceptibility testing to be performed, which is a critical component to managing sepsis, however the lack of rapid results and decreased sensitivity for fastidious pathogens has led to the development of improved systems and adjunctive molecular or proteomic testing.

[0005] Collection of blood samples for conducting blood cultures is a critical component of modern patient care and can either positively affect the patient outcome by providing an accurate diagnosis, or can adversely affect the outcome by prolonging unnecessary antimicrobial therapy, the length of hospital stays, and increasing costs.

[0006] One outcome of collection of blood cultures is contamination. Blood culture contamination can lead to a false positive culture result and/or significant increase in healthcare related costs. Sources of blood culture contamination include improper skin antisepsis, improper collection tube disinfection, and contamination of the initial blood draw which may then skew results.

[0007] Blood culture collection kits generally consist of a "butterfly" set, infusion set, or other type of venipuncture device as offered by companies like BD, Smiths, B. Braun and others, and aerobic and anaerobic blood culture bottles. Various different bottles are also available depending on the test requirements. These bottles are specifically designed to optimize recovery of both aerobic and anaerobic organisms. In conventional kits, a bottle used is known generally as a "Vacutainer," which is a blood collection tube formed of a sterile glass or plastic tube with a closure that is evacuated to create a vacuum inside the tube to facilitate the draw of a predetermined volume of liquid such as blood.

[0008] False positive blood cultures are typically a result of poor sampling techniques. They cause the use of antibiotics when not needed, increasing hospital costs and patient anxiety. Blood cultures are drawn from a needlestick into the skin, and then a Vacutainer is attached to capture a sample of blood. Contamination may occur from improper or incomplete disinfection of the skin area in and around the puncture site. It may also occur from the coring of the skin by the needle during insertion, with the cored skin cells and any associated contamination being pulled into the sample.

[0009] Blood flow through a hypodermic needle is laminar, and as such, a velocity gradient can be developed over the flow tube as a pressure drop is applied to the hypodermic needle. Either forceful aspiration of blood, or using a very small hypodermic needle, can cause lysis and a release of potassium from the red blood cells, thereby rendering the blood samples abnormal.

[0010] In other instances, some patients have delicate veins that can collapse under a pressure drop or vacuum, particularly as applied by a syringe's plunger that is drawn too quickly for the patient's condition. Since such condition is impossible to know beforehand, such vein collapses are a risk and very difficult to control.

[0011] Various strategies have been implemented to decrease blood culture contamination rates, e.g. training staff with regard to aseptic collection technique, feedback with regard to contamination rates and implementation of blood culture collection kits. Although skin antisepsis can reduce the burden of contamination, 20% or more of skin organisms are located deep within the dermis and are unaffected by

antisepsis. Changing needles before bottle inoculation is not advisable as it increases the risk to acquire needle stick injuries without decreasing contamination rates.

[0012] Some conventional systems and techniques for reducing blood culture contamination include discarding the initial aliquot of blood taken from central venous catheters, venipunctures, and other vascular access systems. However, these systems require the user to mechanically manipulate an intravascular device, or require a complex series of steps that are difficult to ensure being followed.

SUMMARY

[0013] This document presents systems and methods for reducing blood culture contamination, lysing of cells, and vein collapse. In some implementations, a system and method can eliminate user variability in disinfection, and also eliminate the risk of skin cells getting into the blood culture sample. The systems and methods disclosed herein do not require a change in existing clinical processes, other than to potentially indicate when a vacutainer or other blood collection device (i.e., syringe) should be attached for drawing contaminant-free blood samples.

[0014] In some implementations of the systems and methods disclosed herein the withdrawal of blood is accomplished passively by use of the patient's own blood pressure, thereby reducing the risk of vein collapse and eliminating any additional user steps over current practice. The systems and methods can be applied to accommodate short-path direct stick or butterfly venipuncture systems. They can also be used with samples drawn through a catheter.

[0015] In one aspect, a blood sequestration device is presented. The blood sequestration device includes an inlet port and an outlet port. The blood sequestration device further includes a sequestration chamber connected with the inlet port, the sequestration chamber having a vent comprising an air permeable blood barrier. The blood sequestration device further includes a sampling channel having a proximal end connected with the inlet port and a distal end connected with the outlet port.

[0016] In another aspect, a blood sequestration device connected with a blood sampling pathway is described. The blood sampling pathway has a patient needle and a sample collection device. The blood sequestration device includes an inlet port

connected with the patient needle, and a sequestration chamber connected with the inlet port, the sequestration chamber having a vent comprising an air permeable blood barrier. The blood sequestration device further includes a sampling channel having a proximal end connected with the inlet port, and an outlet port connected with a distal end of the sampling channel and with the sample collection device.

[0017] In yet another aspect, a blood sequestration device connected with a blood sampling system is described. The blood sampling system includes a patient needle for accessing a blood sample from a patient, and a sample needle that is sealed and adapted for receiving an evacuated blood collection tube. The blood sequestration device includes an inlet port connected with the patient needle to receive the blood sample from the patient. The blood sequestration device further includes a sequestration chamber connected with the inlet port and having a vent comprising an air permeable blood barrier, the sequestration chamber for receiving and sequestering a first portion of the blood sample prior to the sample needle being unsealed by the evacuated blood collection tube. The blood sequestration device further includes a sampling channel having a proximal end connected with the inlet port, the sampling channel for conveying a subsequent portion of the blood sample once the sample needle is unsealed by the evacuated blood collection tube. The blood sequestration device further includes an outlet port connected with a distal end of the sampling channel for conveying the subsequent portion of the blood sample to the sample needle.

[0018] In yet another aspect, a blood sample optimization system is disclosed and described. The blood sample optimization system includes a blood sampling system for accessing and acquiring one or more samples of a patient's blood, and a blood sequestration device for receiving and sequestering a first portion of the one or more samples of the patient's blood which might be contaminated by a venipuncture process and which could result in a false positive identification of a pathogen in the patient's blood.

[0019] The blood sampling system includes a patient needle configured for a venipuncture of a patient to access a sample of blood of a patient, a blood sampling pathway connected with the patient needle for conveying the sample of blood, and a

sample needle configured for receiving an evacuated blood collection container to collect and contain a subsequent portion of the sample of blood.

[0020] In yet another aspect, a blood sequestration device is disclosed and described. In some implementations, the blood sequestration device can include an inlet port, an outlet port connected with the inlet port, and a sequestration chamber connected with the inlet port. The sequestration chamber can have a vent comprising an air permeable blood barrier.

[0021] The blood sequestration device is connected along the blood sampling pathway between the patient needle and the sample needle, and includes an inlet port for receiving the sample of blood. The blood sequestration device further includes a sequestration chamber connected with the inlet port for receiving a first amount of the sample of blood, the sequestration chamber having a vent comprising an air permeable blood barrier for sequestering at least a first portion of the first amount of the sample of blood. The blood sequestration device may further include a sampling channel having a proximal end connected with the inlet port, the sampling channel conveying a subsequent amount of the sample of blood to the evacuated blood collection container upon the sequestration chamber sequestering at least the first portion of the first amount of the sample of blood. The blood sequestration device further includes an outlet port connected with a distal end of the sampling channel, the outlet port for outputting the subsequent amount of the sample of blood.

[0022] The details of one or more embodiments are set forth in the accompanying drawings and the description below. Other features and advantages will be apparent from the description and drawings, and from the claims.

BRIEF DESCRIPTION OF THE DRAWINGS

[0023] These and other aspects will now be described in detail with reference to the following drawings.

[0024] FIG. 1 illustrates a blood sample optimization system.

[0025] FIG. 2 illustrates a blood sample optimization system in accordance with an alternative implementation.

[0026] FIG. 3 illustrates a blood sample optimization system in accordance with another alternative implementation.

[0027] FIG. 4 illustrates a blood sample optimization system in accordance with another alternative implementation.

[0028] FIG. 5 illustrates a blood sample optimization system in accordance with another alternative implementation.

[0029] FIG. 6 illustrates a blood sample optimization system in accordance with an alternative implementation.

[0030] FIG. 7 is a flowchart of a method for optimizing a quality of a blood culture.

[0031] FIGS. 8A – 8E illustrate a blood sequestration system for non-contaminated blood sampling, in accordance with some implementations.

[0032] FIG. 9 illustrates a pathway splitter for use in a blood sequestrations system.

[0033] FIGS. 10A – 10D illustrate a blood sequestration system for non-contaminated blood sampling, in accordance with alternative implementations.

[0034] FIGS. 11A – 11E illustrate a blood sequestration system for non-contaminated blood sampling, in accordance with other alternative implementations.

[0035] FIGS. 12A-12D illustrate a blood sample optimization system including a blood sequestration device in accordance with yet other alternative implementations.

[0036] FIGS. 13A-13D illustrate a blood sample optimization system 1300 in accordance with yet another alternative implementations.

[0037] FIGS. 14A-14E illustrate yet another implementation of a blood sampling system to sequester contaminates of an initial aliquot or sample to reduce false positives in blood cultures or tests performed on a patient's blood sample.

[0038] FIGS. 15A-15G illustrate a blood sequestration device and method of using the same, in accordance with yet another implementation.

[0039] FIGS. 16A-16D illustrate a blood sequestration device in accordance with yet another implementation.

[0040] FIGS. 17A – 17E illustrate a bottom member of a housing for a blood sequestration device.

[0041] FIGS. 18A – 18F illustrate a top member of a housing for a blood sequestration device.

[0042] FIGS. 19A and 19B illustrate a blood sequestration device having a top member mated with a bottom member.

[0043] FIG. 20 shows a blood sample optimization system including a blood sequestration device.

[0044] FIG. 21 illustrates a non-vented blood sequestration device using a wicking material chamber.

[0045] FIGS. 22A and 22B illustrate a material makeup of a filter for sequestering blood in a sequestration chamber of a blood sequestration device.

[0046] FIGS. 23A and 23B illustrate another implementation of a blood sequestration device that uses a vacuum force from a blood collection device.

[0047] Like reference symbols in the various drawings indicate like elements.

DETAILED DESCRIPTION

[0048] This document describes blood sample optimization systems and methods for reducing or eliminating contaminates in collected blood samples, which in turn reduces or eliminates false positive readings in blood cultures or other testing of collected blood samples. In some implementations, a blood sample optimization system includes a patient needle for vascular access to a patient's bloodstream, a sample needle for providing a blood sample to a blood collection container, such as an evacuated blood collection container or tube like a Vacutainer™ or the like, or other

sampling device, and a blood sequestration device located between the patient needle and the sample needle. The blood sequestration device includes a sequestration chamber for sequestering an initial, potentially contaminated aliquot of blood, and may further include a sampling channel that bypasses the sequestration chamber to convey likely uncontaminated blood between the patient needle and the sample needle after the initial aliquot of blood is sequestered in the sequestration chamber.

[0049] FIG. 1 illustrates a blood sample optimization system in accordance with some implementations. The system includes a patient needle 1 to puncture the skin of a patient to access the patient's vein and blood therein. The system further includes a sample needle (i.e., a resealably closed needle for use with Vacutainers™ or the like) 5, which may be contained within and initially sealed by a resealable boot 10, a Luer activated valve, or another collection interface or device. The resealable boot 10 can be pushed aside or around the sample needle 5 by application of a Vacutainer™ bottle (not shown) for drawing the patient's blood. The system can further include a low volume chamber 30 that leads to the sample needle 5, but also includes an orifice or one or more channels 45 that lead to a sequestration chamber 55 formed by a housing 50.

[0050] The sequestration chamber 55 is a chamber, channel, pathway, lock, or other structure for receiving and holding a first aliquot of the patient's blood, which may be in a predetermined or measured amount, depending on a volume of the sequestration chamber 55. The first draw of blood typically contains or is more susceptible to containing organisms that cause bacteraemia and sepsis or other pathogens than subsequent blood draws. The sequestration chamber 55 can be a vessel encased in a solid housing, formed in or defined by the housing itself, or can be implemented as tubing or a lumen. The sequestration chamber 55, regardless how formed and implemented, may have a predetermined volume. In some implementations, the predetermined volume may be based on a volume of the patient needle, i.e. ranging from less than the volume of the patient needle to any volume up to or greater than 20 times or more of the volume of the patient needle. The predetermined volume of the sequestration chamber 55 may also be established to economize or minimize an amount of blood to be sequestered and disposed of.

[0051] The sequestration chamber 55 can be formed, contained or housed in a chamber housing 50, and can be made of plastic, rubber, steel, aluminum or other suitable material. For example, the sequestration chamber 55 could be formed of flexible tubing or other elastomeric materials. The sequestration chamber 55 further includes an air permeable blood barrier 20 that allows air to exit the sequestration chamber 55. As used herein the term "air permeable blood barrier" means an air permeable but substantially blood impermeable substance, material, or structure. Examples may include hydrophobic membranes and coatings, a hydrophilic membrane or coating combined with a hydrophobic membrane or coating, mesh, a filter, a mechanical valve, antimicrobial material, or any other means of allowing air to be displaced from the sequestration chamber 55 as it is filled with blood. In various exemplary embodiments, an air permeable blood barrier may be formed by one or more materials that allow air to pass through until contacted by a liquid, such material then becomes completely or partially sealed to prevent or inhibit the passage of air and/or liquid. In other words, prior to contact with liquid, the material forms a barrier that is air permeable. After contact with a liquid, the material substantially or completely prevents the further passage of air and/or liquid.

[0052] The orifice or channel 45 can be any desired length, cross-sectional shape or size, and/or can be formed to depart from the low volume chamber 30 at any desired angle or orientation. The orifice or channel 45 may also include a one-way flap or valve 60 that maintains an initial aliquot of blood sample within the sequestration chamber 55. In some specific implementations, the orifice or channel 45 can include a "duck bill" or flapper valve 60, or the like, for one-way flow of blood from low volume chamber 30 to the sequestration chamber 55. The air permeable blood barrier 20 can also be constructed of a material that allows air to exit but then seals upon contact with blood, thereby not allowing external air to enter sequestration chamber 55. This sealing would eliminate the need for a valve.

[0053] Valve 60 can be any type of valve or closing mechanism. Chamber 30 is designed to hold virtually no residual blood, and can be designed to be adapted to hold or allow pass-through of a particular volume or rate of blood into sequestration chamber 55. Likewise, sequestration chamber 55 may also include any type of

coating, such as an anti-microbial coating, or a coating that aids identification and/or diagnosis of components of the first, sequestered blood draw.

[0054] Housing 50 and 40 can be formed of any suitable material, including plastic, such as acrylonitrile butadiene styrene (ABS) or other thermoplastic or polymeric material, rubber, steel, or aluminum. The air permeable blood barrier 20 can include a color-providing substance, or other signaling mechanism, that is activated upon contact with blood from the initial blood draw, or when air displacement is stopped, or any combination of events with blood in the sequestration chamber 55. The air permeable barrier may also include an outer layer such as a hydrophobic membrane or cover that inhibits or prevents the inadvertent or premature sealing of the filter by an external fluid source, splash etc. Sequestration chamber 55 can also be translucent or clear to enable a user to visually confirm the chamber is filled.

[0055] FIG. 2 illustrates a blood sample optimization system in accordance with some alternative implementations. In the implementation shown in FIG. 2, a sequestration chamber 55, or waste chamber, surrounds the patient needle 1, with an open-ended cuff or housing connected with the waste chamber and encircling the sample needle housing base and housing. The patient needle 1 and sample needle 5 are connected together by a boot 56, which forms a continuous blood draw channel therethrough. The boot 56 includes a single orifice or channel leading from the blood draw channel into sequestration chamber 55. The device can include more than one single orifice or channel, in other implementations. Each orifice or channel can include a one-way valve, and can be sized and adapted for predetermined amount of blood flow.

[0056] The sequestration chamber 55 includes an air permeable blood barrier. The filter can further include a sensor or indicator to sense and/or indicate, respectively, when a predetermined volume of blood has been collected in the sequestration chamber 55. That indication will alert a user to attach an evacuated blood collection tube or bottle, such as a Vacutainer™ to the sample needle 5. The housing for the sequestration chamber 55 can be any size or shape, and can include any type of material to define an interior space or volume therein. The interior space is initially filled only with air, but can also be coated with an agent or substance, such

as a decontaminate, solidifying agent, or the like. Once evacuated blood collection tube is attached to the sample needle 5, blood will flow automatically into the patient needle 1, through the blood draw channel and sample needle 5, and into the bottle. The sample needle 5 is covered by a resealable boot, coating or membrane that seals the sample needle when a blood collection bottle is not attached thereon or thereto.

[0057] FIG. 3 illustrates a blood sample optimization system in accordance with some alternative implementations. In the implementation shown, a sample needle 5 is surrounded by a resealable boot or membrane, and is further connected with a patient needle 1. A blood flow channel is formed through the sample needle and the patient needle. The connection between the sample needle and patient needle includes a "T" or "Y" connector 102, which includes a channel, port or aperture leading out from the main blood flow channel to a sequestration chamber 104.

[0058] The T or Y connector 102 may include a flap or one-way valve, and have an opening that is sized and adapted for a predetermined rate of flow of blood. The sequestration chamber 104 can be formed from tubing, or be formed by a solid housing, and is initially filled with air. The sequestration chamber 104 will receive blood that flows out of a patient automatically, i.e. under pressure from the patient's own blood pressure. The sequestration chamber 104 includes an air permeable blood barrier 106, preferably at the distal end of tubing that forms the sequestration chamber 104, and which is connected at the proximal end to the T or Y connector 102. The T or Y connector 102 can branch off at any desired angle for most efficient blood flow, and can be formed so as to minimize an interface between the aperture and channel and the main blood flow channel, so as to minimize or eliminate mixing of the initial aliquot of blood with main blood draw samples.

[0059] In some alternative implementations, the sample needle may be affixed to a tubing of any length, as shown in FIG. 4, connecting at its opposite end to the T or Y connector 102. The sequestration chamber 104 can be any shape or volume so long as it will contain a predetermined amount of blood sample in the initial aliquot. The T or Y connector 102 may also include an opening or channel that is parallel to the main blood flow channel. The air permeable blood barrier may further include an indicator 107 or other mechanism to indicate when a predetermined amount of blood has been collected in the sequestration chamber, or when air being expelled reaches a

certain threshold, i.e. to zero. The tubing can also include a clip 109 that can be used to pinch off and prevent fluid flow therethrough.

[0060] Once the air permeable blood barrier and primary chamber are sealed the initial aliquot of blood is trapped in the sequestration chamber 104, an evacuated blood collection tube, such as a Vacutainer™ bottle may be attached to the sample needle 5 to obtain the sample. The blood collection tube can be removed, and the sample needle 5 will be resealed. Any number of follow-on blood collection tubes can then be attached for further blood draws or samples. Upon completion of all blood draws, the system can be discarded, with the initial aliquot of blood remaining trapped in the sequestration chamber 104.

[0061] FIG. 5 illustrates a blood sample optimization system in accordance with some alternative implementations. In the implementation shown, a sample needle 5 is connected with a patient needle by tubing. A "T" or "Y" connector 120 is added along the tubing at any desired location, and includes an aperture, port or channel leading to a sequestration chamber 204, substantially as described above.

[0062] FIG. 6 illustrates a blood sample optimization system in accordance with some alternative implementations, in which a sequestration chamber 304, formed as a primary collection channel, receives an initial aliquot of blood, and is provided adjacent to the blood sampling channel. The sequestration chamber 304 can encircle the blood sampling channel, the patient needle 1, and/or the sample needle 5. The primary collection channel can include a T or Y connector 120, or other type of aperture or channel. The sequestration chamber 304 includes an air permeable blood barrier, which can also include an indicator of being contacted by a fluid such as blood, as described above.

[0063] In some implementations, either the patient needle 1 or the sample needle 5, or both, can be replaced by a Luer lock male or female connector. However, in various implementations, the connector at a sample needle end of the blood sample optimization system is initially sealed to permit the diversion of the initial aliquot of blood to the sequestration chamber, which is pressured at ambient air pressure and includes the air outlet of the air permeable blood barrier. In this way, the system passively and automatically uses a patient's own blood pressure to overcome the

ambient air pressure of the sequestration chamber to push out air through the air permeable blood barrier and displace air in the sequestration chamber with blood.

[0064] FIG. 7 is a flowchart of an exemplary method for optimizing the quality of a blood culture. At 702, a clinician places a needle into a patient's vein. At 704, blood then flows into a sequestration chamber, pushing the air in the sequestration chamber out of the sequestration chamber through an air permeable blood barrier. In some implementations, the volume of the sequestration chamber is less than 0.1 to more than 5 cubic centimeters (cc's), or more. The sequestration chamber is sized and adapted to collect a first portion of a blood sample, which is more prone to contamination than secondary and other subsequent portion of the blood sample or subsequent draws. Since the sequestration chamber has an air-permeable blood barrier through which air can be displaced by blood pushed from the patient's vein, such blood will naturally and automatically flow into the sequestration chamber before it is drawn into or otherwise enters into a Vacutainer or other bottle for receiving and storing a blood sample.

[0065] When the sequestration chamber fills, the blood will gather at or otherwise make contact with the air permeable blood barrier, which will inhibit or prevent blood from passing therethrough. At 706, when the blood comes into contact with the entire internal surface area of the air permeable blood barrier, the air permeable blood barrier is then closed and air no longer flows out or in. At 708, the clinician may be provided an indictor or can see the full chamber, to indicate the evacuated blood collection tube, such as a Vacutainer™ can be attached. The indicator can include visibility into the primary chamber to see whether it is full, the blood barrier changing color, for example, or other indicator. The fill time of the sequestration chamber may be substantially instantaneous, so such indicator, if present, may be only that the sequestration chamber is filled.

[0066] Prior to an evacuated blood collection tube being attached, communication between the needle, sampling channel, and the sequestration chamber is restricted by the sealing of the sequestration chamber blood barrier thereby not permitting air to reenter the system through the sequestration. Sealing the communication path could also be accomplished with a mechanical twist or other movement, a small orifice or tortuous pathway, eliminating the need for a separate

valve or mechanical movement or operation by the clinician. At 710, once the evacuated blood collection tube is removed, the self-sealing membrane closes the sample needle, and at 712, additional subsequent evacuated blood collection tubes may be attached. Once samples have been taken, at 714 the device is removed from the patient and discarded.

[0067] FIGS. 8A – 8E illustrate an exemplary blood sample optimization system 800 for non-contaminated blood sampling, in accordance with some implementations. The blood sample optimization system 800 includes an inlet port 802 that can be connected to tubing, a patient needle (or both), or other vascular or venous access device, and a pathway splitter 804 having a first outlet to a sequestration chamber tubing 806 and a second outlet to sample collection tubing 808. One or both of the sequestration chamber tubing 806 and the sample collection tubing 808 can be formed of tubing. In some implementations, the sequestration chamber tubing 806 is sized so as to contain a particular volume of initial blood sample. The sample collection tubing 808 will receive a blood sample once the sequestration chamber tubing 806 is filled. The sample collection tubing 808 can be connected to a Vacutainer™ base or housing 810, or other blood sample collection device.

[0068] The blood sequestration system 800 further includes a blood sequestration device 812 which, as shown in more detail in FIGS. 8B – 8D, includes a housing 818 that includes a sampling channel 820 defining a pathway for the non-contaminated sample collection tubing 808 or connected at either end to the non-contaminated sample collection tubing 808. The sampling channel 820 can be curved through the housing 818 so as to better affix and stabilize the housing 818 at a location along the non-contaminated sample collection tubing 808.

[0069] The blood sequestration device 812 further includes a sequestration chamber 822 connected with the sequestration chamber tubing 806 or other chamber. The sequestration chamber 822 terminates at an air permeable blood barrier 824. The air permeable blood barrier 824 can also include a coloring agent that turns a different color upon full contact with blood, as an indicator that the regular collection of blood samples (i.e. the non-contaminated blood samples) can be initiated. Other indicators may be used, such as a small light, a sound generation mechanism, or the like. In some implementations, the air permeable blood barrier is positioned at a right angle

from the direction of sequestration chamber 822, but can be positioned at any distance or orientation in order to conserve space and materials used for the housing 818. The housing 818 and its contents can be formed of any rigid or semi-rigid material or set of materials.

[0070] FIG. 9 illustrates a pathway splitter 900 for use in a blood sequestrations system, such as those shown in FIGS. 8A – 8E, for example. The pathway splitter 900 includes an inlet port 902, a main line outlet port 904, and a sequestration channel outlet port 906. The inlet port 902 can be connected to main tubing that is in turn connected to a patient needle system, or directly to a patient needle. The main line outlet port 904 can be connected to main line tubing to a blood sampling system, such as a vacutainer base or housing, or directly to such blood sampling system. The sequestration channel outlet port 906 can be connected to sequestration tubing for receiving and sequestering a first sample of blood, up to a measured amount or predetermined threshold. Alternatively, the sequestration channel outlet port 906 can be connected to a sequestration chamber. The sequestration channel outlet port 906 is preferably 20-70 degrees angled from the main line outlet port 904, which in turn is preferably in-line with the inlet port 902. Once the predetermined amount of initial blood sample is sequestered in the sequestration tubing or chamber, in accordance with mechanisms and techniques described herein, follow-on blood samples will flow into the inlet port 902 and directly out the main line outlet port 904, without impedance.

[0071] FIGS. 10A – 10D illustrate a blood sequestration device 1000 in accordance with alternative implementations. The blood sequestration device 1000 includes an inlet port 1002, a main outlet port 1004, and a sequestration channel port 1006. The inlet port 1002 can be connected to a patient needle or related tubing. The main outlet port 1004 can be connected to a blood sample collection device such as a Vacutainer, associated tubing, or a Luer activated valve, or the like. The sequestration channel port 1006 splits off from the main outlet port 1004 to a sequestration chamber 1008. In some implementations, the sequestration chamber 1008 is formed as a helical channel within a housing or other container 1001.

[0072] The sequestration chamber 1008 is connected at the distal end to an air permeable blood barrier 1010, substantially as described above. Air in the

sequestration chamber 1008 is displaced through the air permeable blood barrier 1010 by an initial aliquot of blood that is guided into the sequestration channel port 1006. Once the sequestration chamber 1008 is filled, further blood draws through the main outlet port 1004 can be accomplished, where these samples will be non-contaminated.

[0073] FIGS. 11A – 11E illustrate a blood sequestration device 1100 in accordance with other alternative implementations. The blood sequestration device 1100 includes an inlet port 1102, similar to the inlet ports described above, a main outlet port 1104, and a sequestration channel port 1106 that splits off from the main outlet port 1104 and inlet port 1102. The sequestration channel port is connected to a sequestration chamber 1108. In the implementation shown in FIGS. 11A – 11E, the blood sequestration device includes a base member 1101 having a channel therein, which functions as the sequestration chamber 1108. The channel can be formed as a tortuous path through the base member 1101, which is in turn shaped and formed to rest on a limb of a patient.

[0074] A portion of the sequestration chamber 1108 can protrude from the base member or near a top surface of the base member, just before exiting to an air permeable blood barrier 1110, to serve as a blood sequestration indicator 1109. The indicator 1109 can be formed of a clear material, or a material that changes color when in contact with blood.

[0075] In some implementations, the blood sequestration device 1100 can include a blood sampling device 1120 such as a normally closed needle, Vacutainer™ shield or other collection device. The blood sampling device 1120 can be manufactured and sold with the blood sequestration device 1100 for efficiency and convenience, so that a first aliquot of blood that may be contaminated by a patient needle insertion process can be sequestered. Thereafter, the blood sampling device 1120 can draw non-contaminated blood samples to reduce the risk of false positive testing and ensure a non-contaminated sample.

[0076] FIGS. 12A-12D illustrate a blood sample optimization system 1200 in accordance with yet other alternative implementations. The system 1200 includes a blood sequestration device 1202 for attaching to a blood sampling device 1204, such as a Vacutainer™ or other collection and sampling device. The blood sequestration

device 1202 is configured and arranged to receive, prior to a Vacutainer™ container or vial being attached to a collection needle of the blood sampling device 1204, a first aliquot or amount of blood, and sequester that first aliquot or amount in a sequestration channel of the blood sequestration device 1202.

[0077] In some implementations, the blood sequestration device 1202 can include an inlet port 1212, a main outlet port, and a sequestration channel port. The inlet port 1212 can be connected to a patient needle or related tubing. The main outlet port 1214 can be connected to a normally closed needle or device to enable connection with an evacuated blood collection container or other collection device such as a Vacutainer™, associated tubing, luer connectors, syringe, a Luer activated valve, or the like. The sequestration channel port splits off from the main outlet port to a sequestration chamber 1218.

[0078] In some implementations, the sequestration chamber 1218 is formed as a channel within the body of a sequestration device 1202. The sequestration chamber 1218 can be a winding channel, such as a U-shaped channel, an S-shaped channel, a helical channel, or any other winding channel. The sequestration device 1202 can include a housing or other containing body, and one or more channels formed therein. As shown in FIGS. 12A and 12B, the sequestration device 1202 includes a main body 1206 and a cap 1208. The main body 1206 is formed with one or more cavities or channels, which are further formed with one or more arms 1210 that extend from the cap 1208, and which abut the cavities or channels in the main body 1206 to form the primary collection port and main outlet port.

[0079] FIGS. 13A-13D illustrate a blood sample optimization system 1300 in accordance with yet other alternative implementations. The system 1300 includes a blood sequestration device 1302 for attaching to a blood sampling device 1304, such as a Vacutainer or other bodily fluid collection and sampling device. The blood sequestration device 1302 is configured and arranged to receive, prior to a Vacutainer container or vial being attached to a collection needle of the blood sampling device 1304, a first aliquot or amount of blood, and to sequester that first aliquot or amount of blood or other bodily fluid in a sequestration channel of the blood sequestration device 1302.

[0080] The blood sequestration device 1302 includes a housing 1301 having an inlet port 1314, a main outlet port 1312, and a sequestration channel port 1316. The inlet port 1314 can be connected to a patient needle or associated tubing. The main outlet port 1312 can be connected to a normally closed needle or device to enable connection with an evacuated blood collection container or other collection device such as a Vacutainer™, associated tubing, luer connectors, syringe, a Luer activated valve, or the like. The sequestration channel port 1316 splits off from the main inlet port 1314 to a sequestration chamber 1318.

[0081] In the implementation shown in FIGS. 13A-D, the sequestration chamber 1318 is formed as a cavity or chamber within housing 1301 or formed by walls that define housing 1301. The sequestration chamber 1318 can be a winding channel, such as a U-shaped channel, an S-shaped channel, a helical channel, or any other winding channel, that is defined by the cooperation and connection of housing 1301 with cap 1307 which cap 1307 can include a protrusion 1305 that provides one or more walls or directors for the winding channel in the sequestration chamber 1318. The protrusion 1305 from the cap 1307 can be straight or curved, and may have various channels, apertures or grooves embedded therein, and can extend from the cap 1307 any angle or orientation. When the cap 1307 is connected with the housing 1301 to complete the formation of the sequestration chamber 1318, the protrusion 1305 forms at least part of the winding channel to sequester a first aliquot or amount of blood or other bodily fluid in a sequestration channel formed in the sequestration chamber 1318 and by the winding channel.

[0082] The sequestration chamber 1318 includes an air permeable blood barrier 1310, substantially as described above. Air in the sequestration chamber 1318 is displaced through the air permeable blood barrier 1310 by an initial aliquot of blood that is provided into the sequestration chamber 1318 by the blood pressure of the patient. Once the sequestration chamber 1318 is filled and the air in the sequestration chamber 1318 displaced, the blood pressure of the patient will be insufficient to drive or provide further blood into the blood sequestration device 1302, and in particular the outlet port 1312, until a force such as a vacuum or other pressure, such as provided by the blood sample collection device like Vacutainer is provided to draw out a next aliquot or amount of blood or bodily fluid. Further blood draws through the main

outlet port 1312 can be accomplished, where these samples will be non-contaminated since any contaminants would be sequestered in the sequestration chamber 1318 with the first aliquot of blood.

[0083] FIGS. 14A-14E illustrate yet another implementation of a blood sampling system 1400 to sequester contaminates of an initial aliquot or sample to reduce false positives in blood cultures or tests performed on a patient's blood sample. The blood sampling system 1400 includes a blood sequestration device 1401 that can be connected between a blood sample collection device 1403 and a patient needle (not shown). The blood sample collection device 1403 can be a Vacutainer or the like. The blood sequestration device 1401 includes an inlet port 1402 that can be connected with a patient needle that is inserted into a patient's vascular system for access to and withdrawing of a blood sample. The inlet port 1402 may also be connected with tubing or other conduit that is in turn connected with the patient needle.

[0084] The inlet port 1402 defines an opening into the blood sequestration device 1401, which opening can be the same cross sectional dimensions as tubing or other conduit connected with the patient needle or the patient needle itself. For instance, the opening can be circular with a diameter of approximately 0.045 inches, but can have a diameter of between 0.01 inches or less to 0.2 inches or more. The blood sequestration device 1401 further includes an outlet port 1404, which defines an opening out of the blood sequestration device 1401 and to the blood sample collection device 1403. The outlet port 1404 may also be connected with tubing or other conduit that is in turn connected with the blood sequestration device 1403. The outlet port 1404 can further include a connector device such as a threaded cap, a Luer connector (male or female), a non threaded interference or glue joint fitting for attachment of various devices including but not limited to tubing, or the like.

[0085] The blood sequestration device 1401 further includes a sampling channel 1406 between the inlet port 1402 and the outlet port 1404, and which functions as a blood sample pathway once a first aliquot of blood has been sequestered. The sampling channel 1406 can be any sized, shaped or configured channel, or conduit. In some implementations, the sampling channel 1406 has a substantially similar cross sectional area as the opening of the inlet port 1402. In

other implementations, the sampling channel 1406 can gradually widen from the inlet port 1402 to the outlet port 1404.

[0086] The blood sequestration device 1401 further includes a sequestration chamber 1408 that is connected to and split off or diverted from the sampling channel 1406 at any point between the inlet port 1402 and the outlet port 1404, but preferably from a proximal end of the sampling channel 1406 near the inlet port 1402. The sequestration chamber 1408 is at first maintained at atmospheric pressure, and includes an air outlet 1412 at or near a distal end of the sequestration chamber 1408 opposite the diversion point from the sampling channel 1406. The air outlet 1412 includes an air permeable blood barrier 1412. As shown in FIG. 14B, the air permeable blood barrier 1412 can be overlaid with a protective cover 1416. The protective cover 1416 can be sized and configured to inhibit a user from touching the air permeable blood barrier 1412 with their finger or other external implement, while still allowing air to exit the air permeable blood barrier 1412 as the air is displaced from the sequestration chamber 1408 by blood being forced into the sequestration chamber 1408 by a patient's own blood pressure. In addition the protective cover 1416 can be constructed to inhibit or prevent accidental exposure of the air permeable blood barrier to environmental fluids or splashes. This can be accomplished in a variety of mechanical ways including but not limited to the addition of a hydrophobic membrane to the protective cover.

[0087] As shown in FIGS. 14C and 14D, the sampling channel 1406 can be cylindrical or frusto-conical in shape, going from a smaller diameter to a larger diameter, to minimize a potential to lyse red blood cells. Likewise, the sampling channel 1406 is formed with a minimal amount of or no sharp turns or edges, which can also lyse red blood cells. The sampling channel 1406 splits off to the sequestration chamber 1408 near the inlet port 1402 via a diversion pathway 1409. The diversion pathway 1409 can have any cross-sectional shape or size, but is preferably similar to the cross-sectional shape of at least part of the inlet port 1402.

[0088] In some implementations, the sampling channel 1406 and the sequestration chamber 1408 are formed by grooves, channels, locks or other pathways formed in housing 1414. The housing 1414 can be made of plastic, metal or other rigid or semi-rigid material. The housing 1414 can have a bottom member that

sealably mates with a top member. One or both of the bottom member and the top member can include the sampling channel 1406 and the sequestration chamber 1408, as well as the diversion pathway 1409, the inlet port 1402, and the outlet port 1404. In some other implementations, one or more of the diversion pathway 1409, the inlet port 1402, and/or the outlet port 1404 can be at least partially formed by a cap member that is connected to either end of the housing 1414. In some implementations, the top member and the bottom member, as well as the cap member(s), can be coupled together by laser welding, heat sealing, gluing, snapping, screwing, bolting, or the like. In other implementations, some or all of the interior surface of the diversion pathway 1409 and/or sequestration chamber 1408 can be coated or loaded with an agent or substance, such as a decontaminate, solidifying agent, or the like. For instance, a solidifying agent can be provided at the diversion pathway 1409 such that when the sequestration chamber 1408 is filled and the initial aliquot of blood backs up to the diversion pathway 1409, that last amount of sequestered blood could solidify, creating a barrier between the sequestration chamber 1408 and the sampling channel 1406.

[0089] FIGS. 15A-15G illustrate a blood sequestration device 1500. The blood sequestration device 1500 can be connected to a normally closed needle or device to enable connection with an evacuated blood collection container or other collection device such as a Vacutainer™, associated tubing, luer connectors, syringe, a Luer activated valve, or the like.

[0090] The blood sequestration device 1500 includes an inlet port 1502 that can be connected with a patient needle that is inserted into a patient's vascular system for access to and withdrawing of a blood sample. The inlet port 1502 may also be connected with tubing or other conduit that is in turn connected with the patient needle. The inlet port 1502 defines an opening into the blood sequestration device 1500, which opening may be the same cross sectional dimensions as tubing or other conduit connected with the patient needle or the patient needle itself. For instance, the opening can be circular with a diameter of approximately 0.045 inches, but can have a diameter of between 0.01 inches or less to 0.2 inches or more.

[0091] The inlet port 1502 can also include a sealing or fluid-tight connector or connection, such as threading or Luer fitting, or the like. In some implementations,

tubing or other conduit associated with the patient needle can be integral with the inlet port 1502, such as by co-molding, gluing, laser weld, or thermally bonding the parts together. In this manner, the blood sequestration device 1500 can be fabricated and sold with the patient needle as a single unit, eliminating the need for connecting the patient needle to the blood sequestration device 1500 at the time of blood draw or sampling.

[0092] The blood sequestration device 1500 further includes an outlet port 1504, which defines an opening out of the blood sequestration device 1500 and to the blood sample collection device. The outlet port 1504 may also be connected with tubing or other conduit that is in turn connected with the blood sequestration device, and may also include a sealing or fluid-tight connector or connection, such as threading or Luer fitting, or the like. Accordingly, as discussed above, the blood sequestration device 1500 can be fabricated and sold with the patient needle and/or tubing and the blood sample collection device as a single unit, eliminating the need for connecting the patient needle and the blood sample collection device to the blood sequestration device 1500 at the time of blood draw or sampling.

[0093] The blood sequestration device 1500 further includes a sampling channel 1506 between the inlet port 1502 and the outlet port 1504, and which functions as a blood sample pathway once a first aliquot of blood has been sequestered. The sampling channel 1506 can be any sized, shaped or configured channel or conduit. In some implementations, the sampling channel 1506 has a substantially similar cross sectional area as the opening of the inlet port 1502. In other implementations, the sampling channel 1506 can gradually widen from the inlet port 1502 to the outlet port 1504.

[0094] The blood sequestration device 1500 further includes a sequestration chamber 1508 that is connected to and split off or diverted from the sampling channel 1506 at any point between the inlet port 1502 and the outlet port 1504, but preferably from a proximal end of the sampling channel 1506 near the inlet port 1502. In some implementations, the diversion includes a Y-shaped junction. The sequestration chamber 1508 is preferably maintained at atmospheric pressure, and includes a vent 1510 at or near a distal end of the sequestration chamber 1508. The vent 1510 includes an air permeable blood barrier 1512. FIG. 15C illustrates the blood

sequestration device 1500 with the sequestration chamber 1508 filled with a first aliquot or sample of blood from the patient.

[0095] The air permeable blood barrier 1512 can be covered with a protective cover 1516. The protective cover 1516 can be sized and configured to inhibit a user from touching the air permeable blood barrier 1512 with their finger or other external implement, while still allowing air to exit the air permeable blood barrier 1512 as the air is displaced from the sequestration chamber 1508 by blood being forced into the sequestration chamber 1508 by a patient's own blood pressure. The protective cover 1516 can be constructed to inhibit or prevent accidental exposure of the filter to environmental fluids or splashes. This can be accomplished in a variety of mechanical ways including but not limited to the addition of a hydrophobic membrane to the protective cover.

[0096] FIG. 15B is a perspective view of the blood sequestration device 1500 from the outlet port 1504 and top side of a housing 1501 of the blood sequestration device 1500 that includes the vent 1510, and illustrating an initial aliquot of blood filling sequestration chamber 1508 while the sampling channel 1506 is empty, before a sample collection device is activated. FIG. 15G is a perspective view of the blood sequestration device 1500 from the outlet port 1504 and bottom side of the housing 1501 of the blood sequestration device 1500, and illustrating the initial aliquot of blood filling sequestration chamber 1508 while the sampling channel 1506 is empty, before the sample collection device is activated. FIG. 15C is another perspective view of the blood sequestration device 1500 from the inlet port 1502 and top side of a housing 1501 of the blood sequestration device 1500 that includes the vent 1510, and illustrating blood now being drawn through sampling channel 1506 while the sequestered blood remains substantially in the sequestration chamber 1508.

[0097] FIG. 15D is a cross section of the blood sequestration device 1500 in accordance with some implementations, showing the housing 1501 that defines the sampling channel 1506 and the sequestration chamber 1508. FIGS. 15E and 15F illustrate various form factors of a housing for a blood sequestration device, in accordance with one or more implementations described herein.

[0098] The sequestration chamber 1508 can have a larger cross-sectional area than the sampling channel 1506, and the cross-sectional area and length can be configured for a predetermined or specific volume of blood to be sequestered or locked. The sampling channel 1506 can be sized to be compatible with tubing for either or both of the patient needle tubing or the blood collection device tubing.

[0099] The housing 1501 can be formed of multiple parts or a single, unitary part. In some implementations, and as illustrated in FIG. 15D, the housing 1501 includes a top member 1520 and a bottom member 1522 that are mated together, one or both of which having grooves, channels, locks, conduits or other pathways pre-formed therein, such as by an injection molding process or by etching, cutting, drilling, etc. The top member 1520 can be connected with the bottom member 1522 by any mating or connection mechanism, such as by laser welding, thermal bonding, ultrasonic welding, gluing, using screws, rivets, bolts, or the like, or by other mating mechanisms such as latches, grooves, tongues, pins, flanges, or the like.

[00100] In some implementations, such as shown in FIG. 15D, the top member 1520 can include the grooves, channels, locks, conduits or other pathways, while the bottom member 1522 can include a protrusion 1524 that is sized and adapted to fit into at least one of the grooves, channels, locks or other pathways of the top member 1520. The protrusion 1524 can provide a surface feature, such as a partial groove or channel, for instance, to complete the formation of either the sampling channel 1506 and/or the sequestration chamber 1508. In some implementations, the protrusion 1524 can be formed with one or more angled sides or surfaces for a tighter fit within the corresponding groove, channel, lock or other pathway. In yet other implementations, both the top member 1520 and the bottom member can include grooves, channels, locks or other pathways, as well as one or more protrusions 1524.

[00101] In some implementations, the sampling channel 1506 and the sequestration chamber 1508 are formed by grooves, channels, locks or other pathways formed in housing 1501. The housing 1501 can be made of any suitable material, including rubber, plastic, metal or other material. The housing 1501 can be formed of a clear or translucent material, or of an opaque or non-translucent material. In other implementations, the housing 1501 can be mostly opaque or non-translucent, while the housing surface directly adjacent to the sampling channel 1506 and/or the

sequestration chamber 1508 is clear or translucent, giving a practitioner a visual cue or sign that the sequestration chamber 1508 is first filled to the extent necessary or desired, and/or then a visual cue or sign that the sequestered blood remains sequestered while a clean sample of blood is drawn through the sampling channel 1506. Other visual cues or signs of the sequestration can include, without limitation: the air permeable blood barrier 1512 turning a different color upon contact, saturation, or partial saturation with blood; a color-coded tab or indicator at any point along or adjacent to the sequestration chamber; an audible signal; a vibratory signal; or other signal.

[00102] After a venipuncture by a patient needle of a patient (not shown), which could gather a number of pathogens from the patient's skin, a first amount of the patient's blood with those pathogens will make its way into the input port 1502 blood sequestration device 1500 and flow into the sequestration chamber 1508 by following the path of least resistance, as the patient's own blood pressure overcomes the atmospheric pressure in the sequestration chamber 1508 to displace air therein through the air permeable blood barrier 1512. The patient's blood pressure will not be sufficient to overcome the air pressure that builds up in the sealed sampling channel 1506. Eventually, the sequestration chamber 1508, which has a predetermined volume, is filled with blood that displaces air through the air permeable blood barrier 1512. Once the blood hits the air permeable blood barrier, the blood interacts with the air permeable blood barrier 1512 material to completely or partially seal the vent 1510. A signal or indication may be provided that the practitioner can now utilize the Vacutainer capsule or other blood sample collection device to acquire a next amount of the patient's blood for sampling. The blood in the sequestration chamber 1508 is now effectively sequestered in the sequestration chamber.

[00103] Upon filling the blood sequestration pathway 1508 but prior to use of the Vacutainer or other blood sample collection device, the patient's blood pressure may drive compression of the air in the sampling channel 1506, possibly resulting in a small amount of blood moving past the diversion point to the sequestration chamber 1508 and into the sampling channel 1506, queuing up the uncontaminated blood to be drawn through the sampling channel 1506.

[00104] FIGS. 16-19 illustrate yet another implementation of a blood sequestration device. FIGS. 16A-16D illustrate a blood sequestration device 1600 that can be connected between a blood sample collection device, such as an evacuated blood collection container like a Vacutainer™ (not shown), and a patient needle (not shown) and/or associated tubing. FIG. 17 illustrates a bottom member of the blood sequestration device, and FIG. 18 illustrates a top member of the blood sequestration device, which top member and bottom member can be mated together to form an input port, and output port, a sequestration chamber and a sampling channel, as explained more fully below. FIGS. 19A and B show the top member and bottom member mated together. It should be understood that FIGS. 16-19 illustrate one exemplary manner of constructing a blood sequestration device as described herein, and other forms of construction are possible.

[00105] Referring to FIGS. 16A – D, the blood sequestration device 1600 includes an inlet port 1602 that can be connected with a patient needle that is inserted into a patient's vascular system for access to and withdrawing of a blood sample. The inlet port 1602 may also be connected with tubing or other conduit that is in turn connected with the patient needle. The inlet port 1602 defines an opening into the blood sequestration device 1600, which opening can be the same cross sectional dimensions as tubing or other conduit connected with the patient needle or the patient needle itself. For instance, the opening can be circular with a diameter of approximately 0.045 inches, but can have a diameter of between 0.01 inches or less to 0.2 inches or more.

[00106] The inlet port 1602 can also include a sealing or fluid-tight connector or connection, such as threading or Luer fitting, or the like. In some implementations, tubing or other conduit associated with the patient needle can be integral with the inlet port 1602, such as by co-molding, gluing, laser weld, or thermally bonding the parts together. In this manner, the blood sequestration device 1600 can be fabricated and sold with the patient needle and/or tubing as a single unit, eliminating the need for connecting the patient needle to the blood sequestration device 1600 at the time of blood draw or sampling.

[00107] The blood sequestration device 1600 further includes an outlet port 1604, which defines an opening out of the blood sequestration device 1600 and to the

blood sample collection device. The outlet port 1604 may also be connected with tubing or other conduit that is in turn connected with the blood sequestration device, and may also include a sealing or fluid-tight connector or connection, such as threading or Luer fitting, or the like. Accordingly, as discussed above, the blood sequestration device 1600 can be fabricated and sold with the patient needle and/or tubing and the blood sample collection device as a single unit, eliminating the need for connecting the patient needle and the blood sample collection device to the blood sequestration device 1600 at the time of blood draw or sampling.

[00108] The blood sequestration device 1600 further includes a sampling channel 1606 between the inlet port 1602 and the outlet port 1604, and a sequestration chamber 1608 that is connected to and split off or diverted from the sampling channel 1606 at any point between the inlet port 1602 and the outlet port 1604. The sampling channel 1606 functions as a blood sampling pathway once a first aliquot of blood has been sequestered in the sequestration chamber 1608. The sampling channel 1606 can be any sized, shaped or configured channel, or conduit. In some implementations, the sampling channel 1606 has a substantially similar cross sectional area as the opening of the inlet port 1602. In other implementations, the sampling channel 1606 can gradually widen from the inlet port 1602 to the outlet port 1604. The sequestration chamber 1608 may have a larger cross section to form a big reservoir toward the sequestration channel path so that the blood will want to enter the reservoir first versus entering a smaller diameter on the sampling channel 1606, as is shown more fully in FIGS. 17 and 19.

[00109] In some exemplary implementations, the diversion between the sampling channel 1606 and the sequestration chamber 1608 is by diverter junction 1607. Diverter junction 1607 may be a substantially Y-shaped, T-shaped, or U-shaped. In some preferred exemplary implementations, and as shown in FIG. 17A – 17B, the diverter junction 1607 is configured such that the flow out of the inlet port 1602 is preferentially directed toward the sequestration chamber 1608. The sequestration chamber 1608 may also include or form a curve or ramp to direct the initial blood flow toward and into the sequestration chamber 1608.

[00110] The sequestration chamber 1608 is preferably maintained at atmospheric pressure, and includes a vent 1610 at or near a distal end of the

sequestration chamber 1608. The vent 1610 may include an air permeable blood barrier 1612 as described above.

[00111] The blood sequestration device 1600 can include a housing 1601 that can be formed of multiple parts or a single, unitary part. In some implementations, and as illustrated in FIGS. 17A – 17D and FIGS. 18A – 18F, the housing 1601 includes a top member 1620 and a bottom member 1622 that are mated together. The blood sequestration device 1600 can also include a gasket or other sealing member (not shown) so that when the top member 1620 is mechanically attached with the bottom member 1622, the interface between the two is sealed by the gasket or sealing member. The FIGS. 17A – 17D illustrate a bottom member 1622 of a housing for a blood sequestration device 1600. The bottom member 1622 can include grooves, channels, locks, conduits or other pathways pre-formed therein, such as by an injection molding process or by etching, cutting, drilling, etc., to form the sampling channel 1606, the sequestration chamber 1608, and diverter junction 1607.

[00112] The sequestration chamber 1608 may have a larger cross section than the sampling channel 1606 so that the blood will preferentially move into the sequestration chamber first versus entering a smaller diameter on the sampling channel 1606.

[00113] FIGS. 18A – 18F illustrate the top member 1620, which can be connected with the bottom member 1622 by any mating or connection mechanism, such as by laser welding, thermal bonding, gluing, using screws, rivets, bolts, or the like, or by other mating mechanisms such as latches, grooves, tongues, pins, flanges, or the like. The top member 1620 can include some or all of the grooves, channels, locks, conduits or other pathways to form the sampling channel 1606, the sequestration chamber 1608, and the diverter junction 1607. In yet other implementations, both the top member 1620 and the bottom member 1622 can include the grooves, channels, locks or other pathways.

[00114] In some implementations, the sampling channel 1606 and the sequestration chamber 1608 are formed by grooves, channels, locks or other pathways formed in housing 1601. The housing 1601 can be made of rubber, plastic, metal or any other suitable material. The housing 1601 can be formed of a clear or translucent

material, or of an opaque or non-translucent material. In other implementations, the housing 1601 can be mostly opaque or non-translucent, while the housing surface directly adjacent to the sampling channel 1606 and/or the sequestration chamber 1608 may be clear or translucent, giving a practitioner a visual cue or sign that the sequestration chamber 1608 is first filled to the extent necessary or desired, and/or then a visual cue or sign that the sequestered blood remains sequestered while a clean sample of blood is drawn through the sampling channel 1606. Other visual cues or signs of the sequestration can include, without limitation: the air permeable blood barrier 1612 turning a different color upon contact, saturation, or partial saturation with blood; a color-coded tab or indicator at any point along or adjacent to the sequestration chamber; an audible signal; a vibratory signal; or other signal.

[00115] As shown in FIGS. 18A – 18F, the air permeable blood barrier 1612 can be covered with, or surrounded by, a protective member 1616. The protective member 1616 can be sized and configured to inhibit a user from touching the air permeable blood barrier 1612 with their finger or other external implement, while still allowing air to exit the air permeable blood barrier 1612 as the air is displaced from the sequestration chamber 1608. In some implementations, the protective member 1616 includes a protrusion that extends up from a top surface of the top member 1620 and around the air permeable blood barrier 1612. The protective cover 1616 can be constructed to inhibit or prevent accidental exposure of the filter to environmental fluids or splashes. This can be accomplished in a variety of mechanical ways including but not limited to the addition of a hydrophobic membrane to the protective cover.

[00116] In use, the blood sequestration device 1600 includes a sampling channel 1606 and a sequestration chamber 1608. Both pathways are initially air-filled at atmospheric pressure, but the sampling channel 1606 is directed to an output port 1604 that will be initially sealed by a Vacutainer or other such sealed blood sampling device, and the sequestration chamber 1608 terminates at a vent 1610 to atmosphere that includes an air permeable blood barrier 1612.

[00117] After a venipuncture by a patient needle of a patient (not shown), which could gather a number of pathogens from the patient's skin, a first amount of the patient's blood with those pathogens will pass through input port 1602 of blood

sequestration device 1600. This initial volume of potentially contaminated blood will preferentially flow into the sequestration chamber 1608 by finding the path of least resistance. The patient's own blood pressure overcomes the atmospheric pressure in the vented sequestration chamber 1608 to displace air therein through the air permeable blood barrier 1612, but is not sufficient to overcome the air pressure that builds up in the sealed sampling channel 1606. In various exemplary embodiments, the sequestration chamber 1608 and sampling channel 1606 can be configured such that the force generated by the patient's blood pressure is sufficient to overcome any effect of gravity, regardless of the blood sequestration device's orientation.

[00118] Eventually, the sequestration chamber 1608 fills with blood that displaces air through the air permeable blood barrier 1612. Once the blood contacts the air permeable blood barrier, the blood interacts with the air permeable blood barrier 1612 material to completely or partially seal the vent 1610. A signal or indication may be provided that the practitioner can now utilize the Vacutainer or other blood sampling device.

[00119] Upon filling the blood sequestration pathway 1608 but prior to use of the Vacutainer or other blood sample collection device, the patient's blood pressure may drive compression of the air in the sampling channel 1606, possibly resulting in a small amount of blood moving past the diversion point into the sampling channel 1606, queuing up the uncontaminated blood to be drawn through the sampling channel 1606.

[00120] FIG. 19A is a side view, and FIG. 19B is a cross-sectional view, of the blood sequestration device 1600, illustrating the top member 1620 mated with the bottom member 1622.

[00121] FIG. 20 shows a blood sample optimization system 2000 that includes a patient needle 2002 for vascular access to a patient's bloodstream, a blood sample collection device 2004 to facilitate the collecting of one or more blood samples, and a conduit 2006 providing a fluid connection between the patient needle 2002 and the blood sample collection device 2004. In some implementations, the blood sample collection device 2004 includes a protective shield that includes a sealed collection needle on which a sealed vacuum-loaded container is placed, which, once pierced by

the collection needle, draws in a blood sample under vacuum pressure or force through the conduit 2006 from the patient needle 2002.

[00122] The blood sample optimization system 2000 further includes a blood sequestration device 2008, located at any point on the conduit 2006 between the patient needle 2002 and the blood sample collection device 2004 as described herein.

[00123] FIG. 21 illustrates a non-vented blood sequestration device 2100 using a wicking material chamber. The blood sequestration device 2100 includes a housing 2101 that has a sampling channel 2104 that is at least partially surrounded or abutted by a sequestration chamber 2102 that is filled with a wicking material. An initial aliquot of blood is drawn in from the patient needle into the sampling channel 2104 where it is immediately wicked into the wicking material of the sequestration chamber 2102. The wicking material and/or sequestration chamber 2102 is sized and adapted to receive and hold a predetermined amount of blood, such that follow-on or later blood draws pass by the wicking material and flow straight through the sampling channel 2104 to a sampling device such as a Vacutainer. The wicking material can include a substance such as a solidifier, a decontaminate, or other additive.

[00124] As described herein, an air permeable blood barrier may be created using a wide variety of different structures and materials. As shown in FIGS. 22A and B, an air permeable blood barrier 2202 of a blood sequestration device 2200 can include a polymer bead matrix 2204, in which at least some beads are treated to make them hydrophilic. The air permeable blood barrier 2202 further includes a self-sealing material 2206, such as carboxymethyl cellulose (CMC) or cellulose gum, or other sealing material. The air permeable blood barrier 2202 can further include voids 2208 that permit air flow before contact or during partial contact with a fluid such as blood. As shown in FIG. 22B, contact with a fluid causes the self-sealing material 2206 to swell and close off the voids 2208, occluding air flow through the voids 2208 and creating a complete or partial seal.

[00125] FIGS. 23A and B illustrate yet another implementation of a blood sequestration device 2300, having an inlet port 2302 to connect with a patient needle, an outlet port 2304 to connect with a blood sample collection device, a sequestration chamber 2306, and a sampling channel 2308 that bypasses the sequestration chamber

2306 once the sequestration chamber is filled to an initial aliquot of potentially contaminated blood to be sequestered. The sequestration chamber 2306 includes a hydrophobic plug 2312 at a distal end of the sequestration chamber 2306 that is farthest from the inlet port 2302. A vacuum or other drawing force applied from the outlet port 2304, such as from a Vacutainer or the like, draws in blood into the inlet port 2302 and directly into the sequestration chamber 2306, where the initial aliquot of blood will contact the hydrophobic plug 2312 and cause the initial aliquot of blood to back up into the sequestration chamber 2306 and be sequestered there. A small amount of blood may make its way into the sampling channel 2308, which is initially closed off by valve 2308. Upon release of the valve 2308, and under further force of the vacuum or other force, follow-on amounts of blood will flow into inlet port 2302, bypass the sequestration chamber 2306, and flow into and through sampling channel 2308 toward the outlet port 2304 and to the collection device.

[00126] The sampling channel 2308 can have any suitable geometry and can be formed of plastic tubing or any other suitable material. Valve 2308 can be a clip or other enclosing device to pinch, shunt, bend or otherwise close off the sampling channel before the initial aliquot of blood is sequestered in the sequestration chamber 2306.

[00127] Although a variety of embodiments have been described in detail above, other modifications are possible. Other embodiments may be within the scope of the following claims.

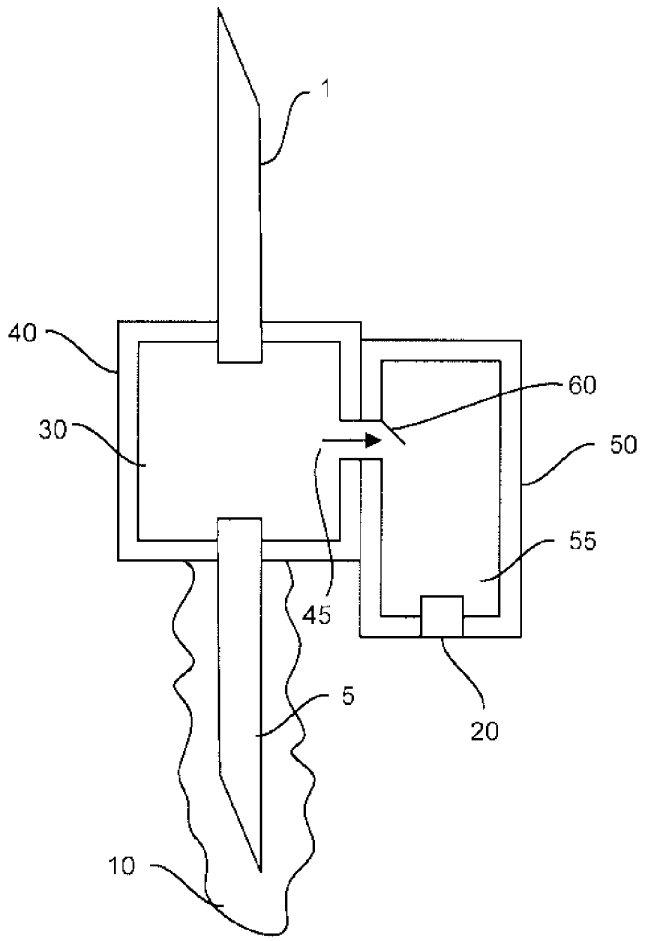


FIG. 1

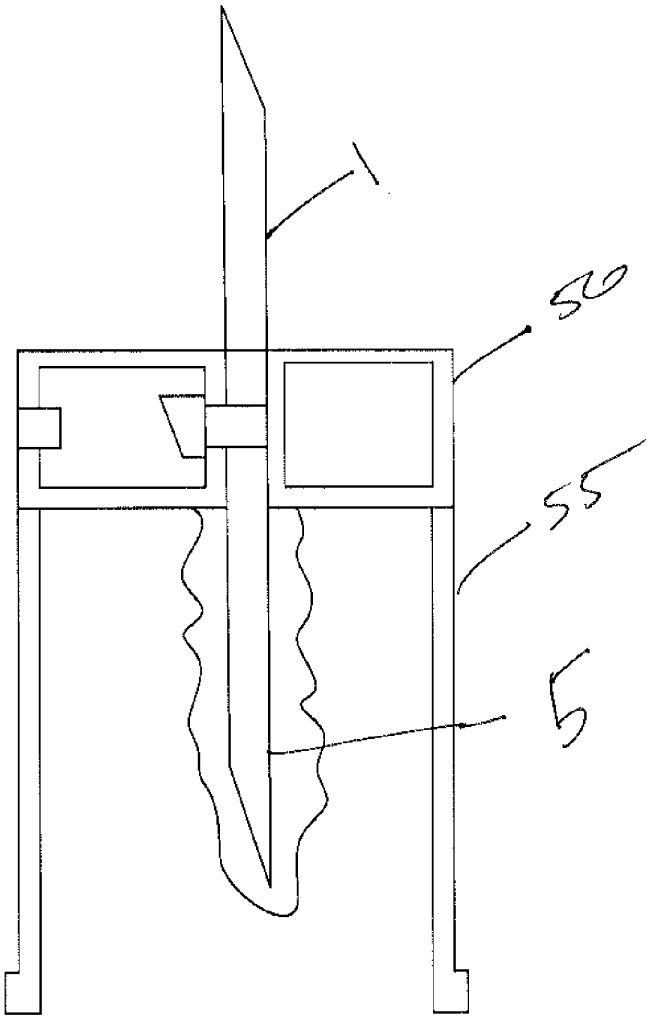


FIG. 2

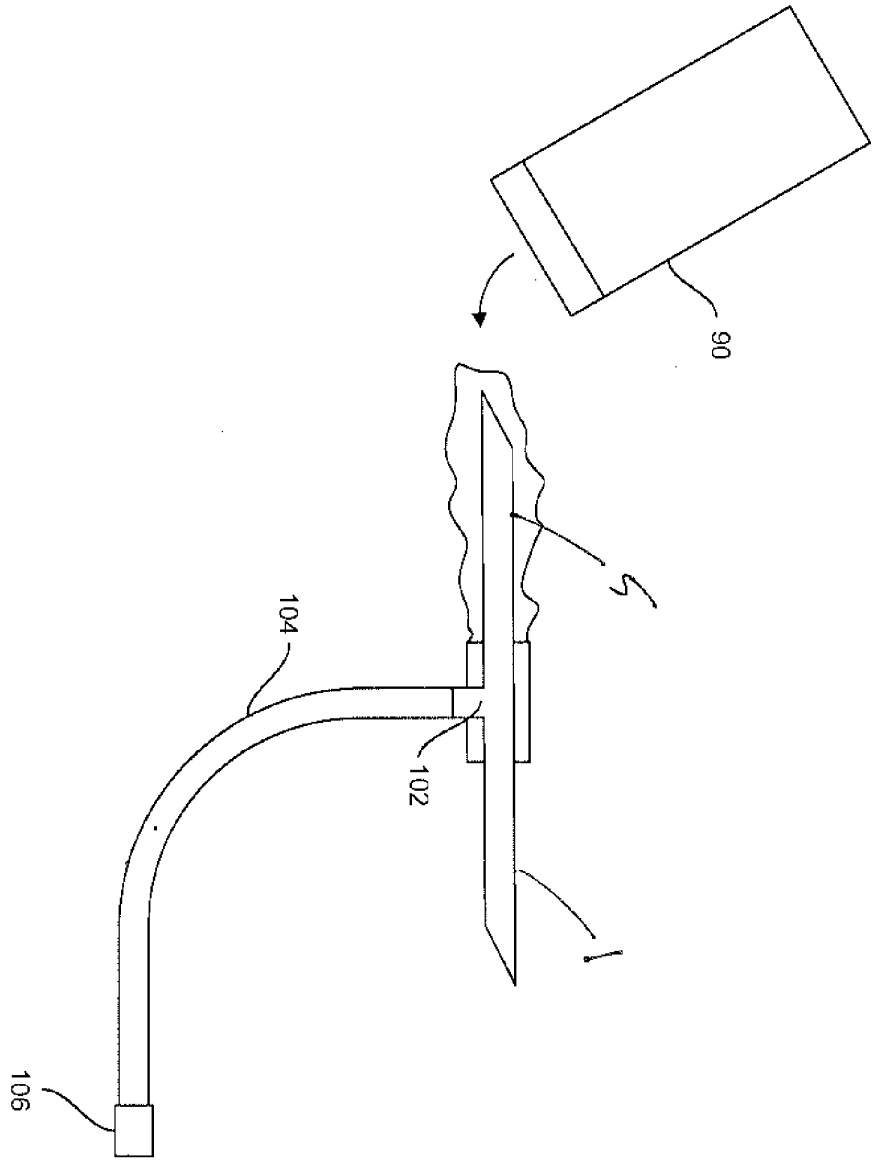


FIG. 3

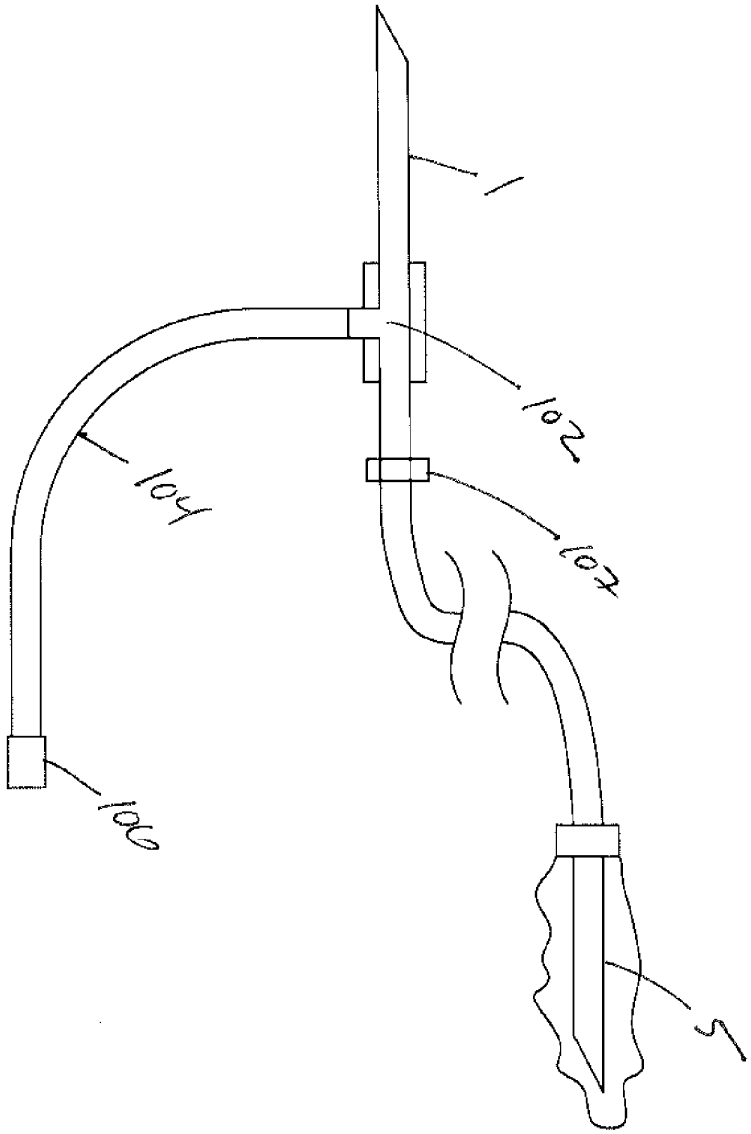


FIG. 4

FIG. 5

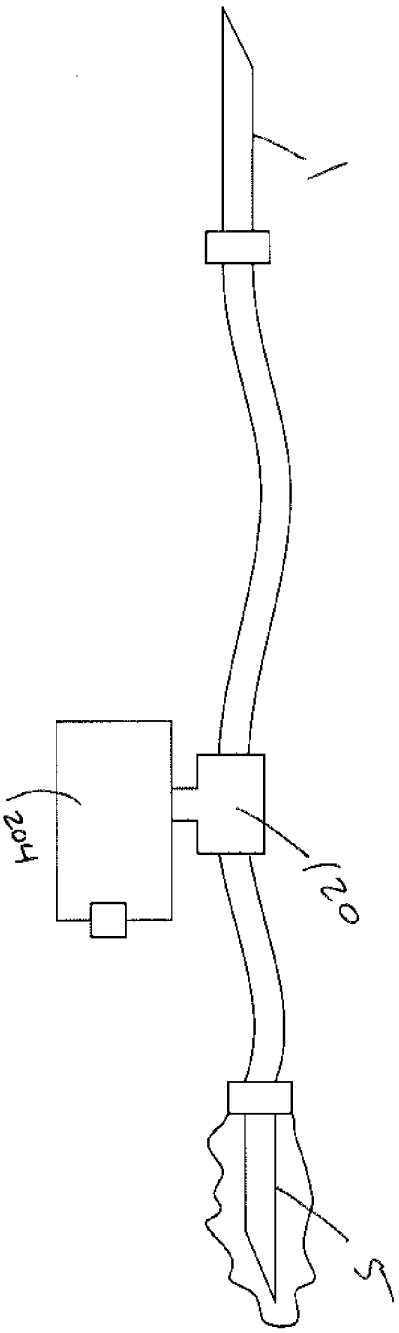
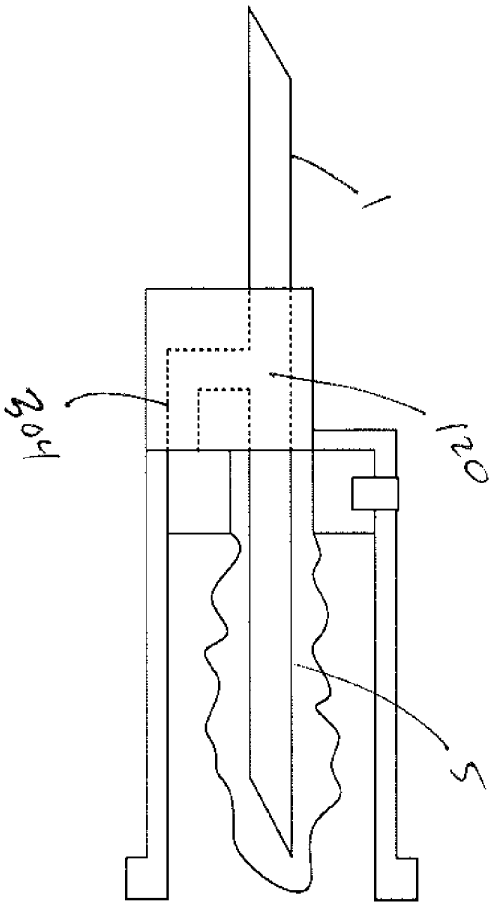


FIG. 6



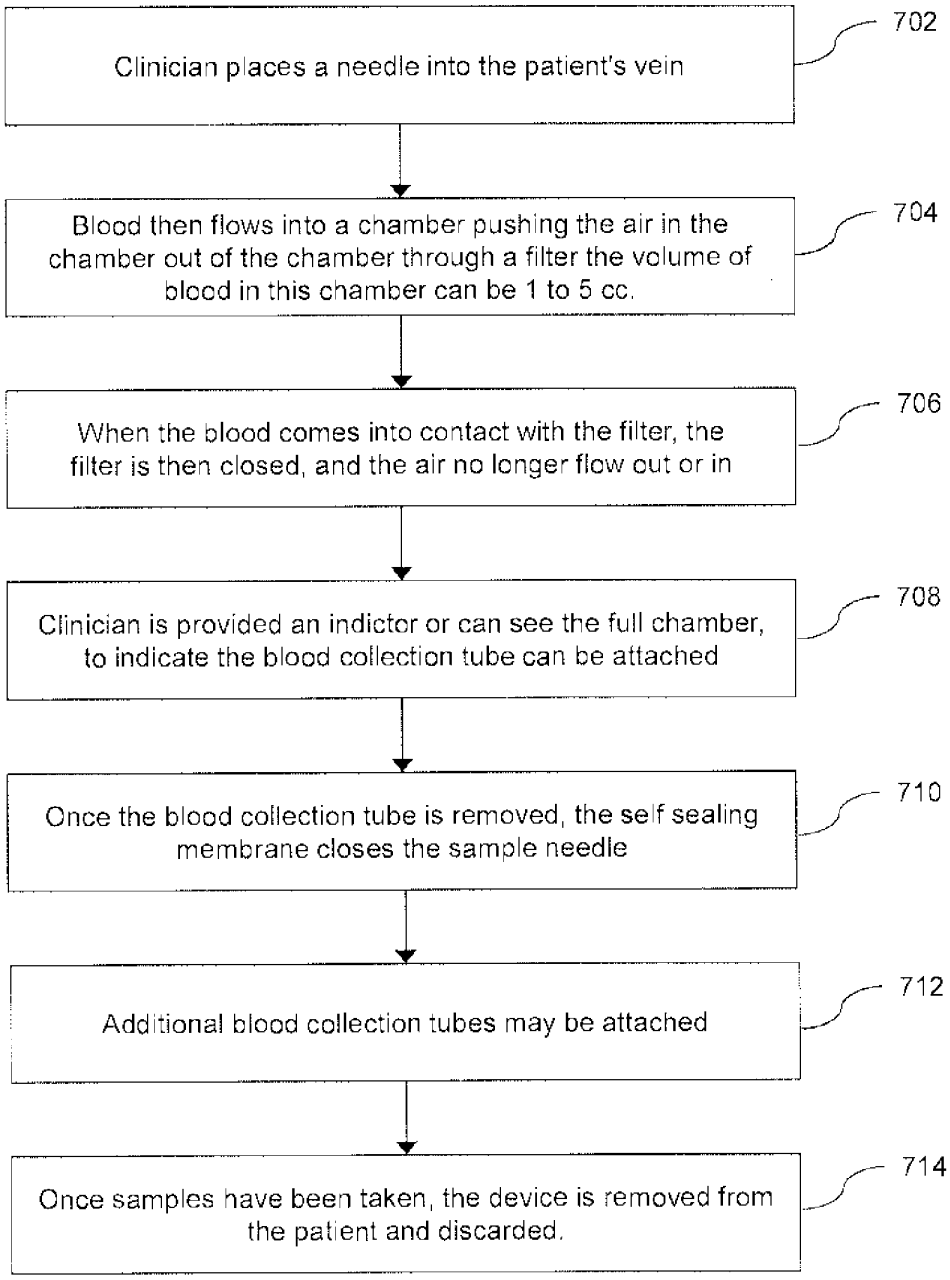

Clinician places a needle into the patient's vein
702
Blood then flows into a chamber pushing the air in the chamber out of the chamber through a filter the volume of blood in this chamber can be 1 to 5 cc.
704
When the blood comes into contact with the filter, the filter is then closed, and the air no longer flow out or in
706
Clinician is provided an indictor or can see the full chamber, to indicate the blood collection tube can be attached
708
Once the blood collection tube is removed, the self sealing membrane closes the sample needle
710
Additional blood collection tubes may be attached
712
Once samples have been taken, the device is removed from the patient and discarded.
714

FIG. 7

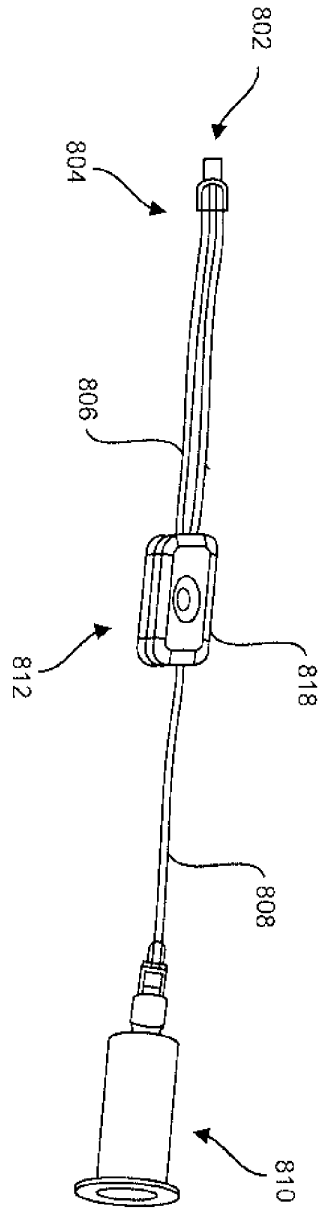


FIG. 8A

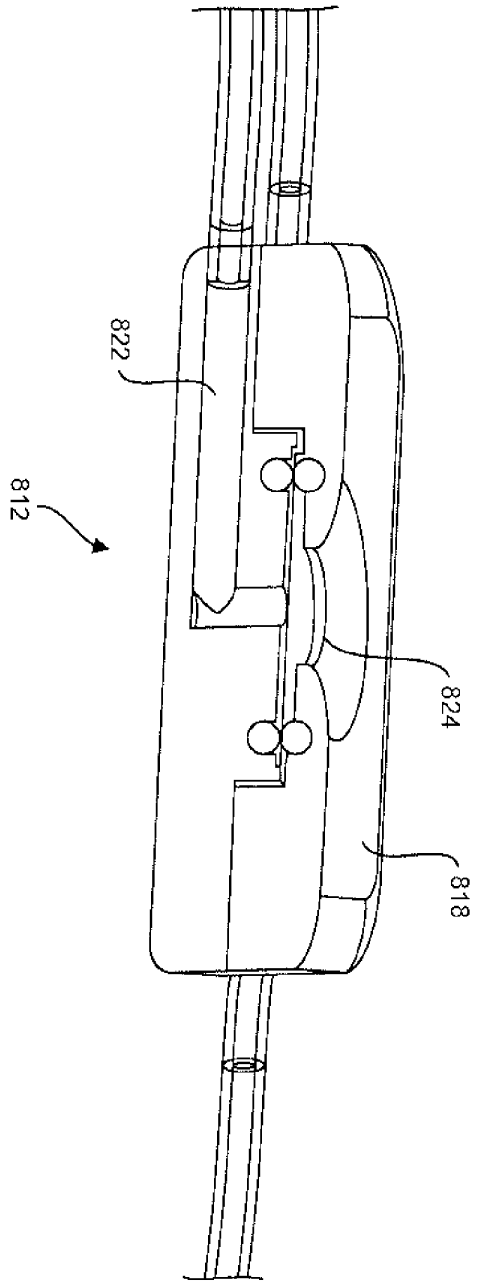


FIG. 8B

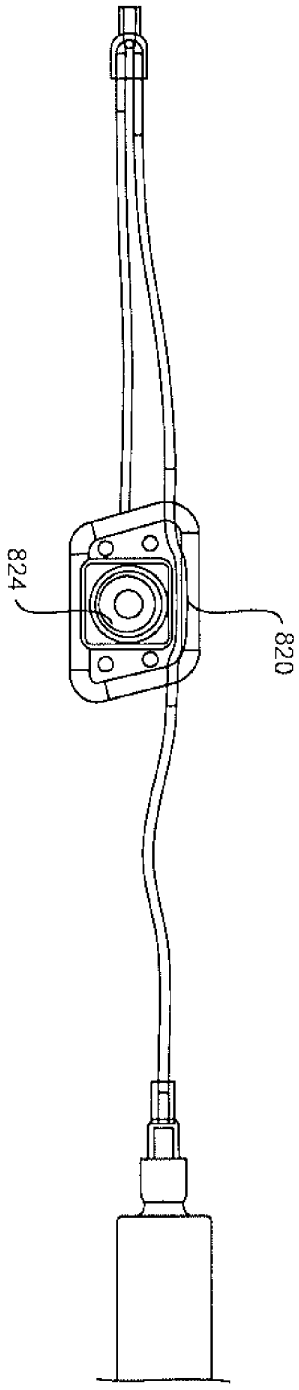


FIG. 8C

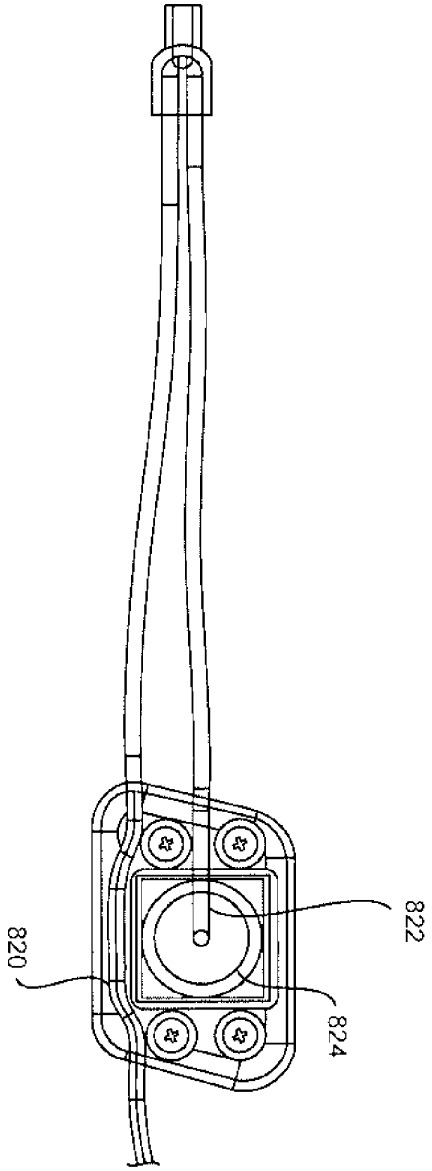


FIG. 8D

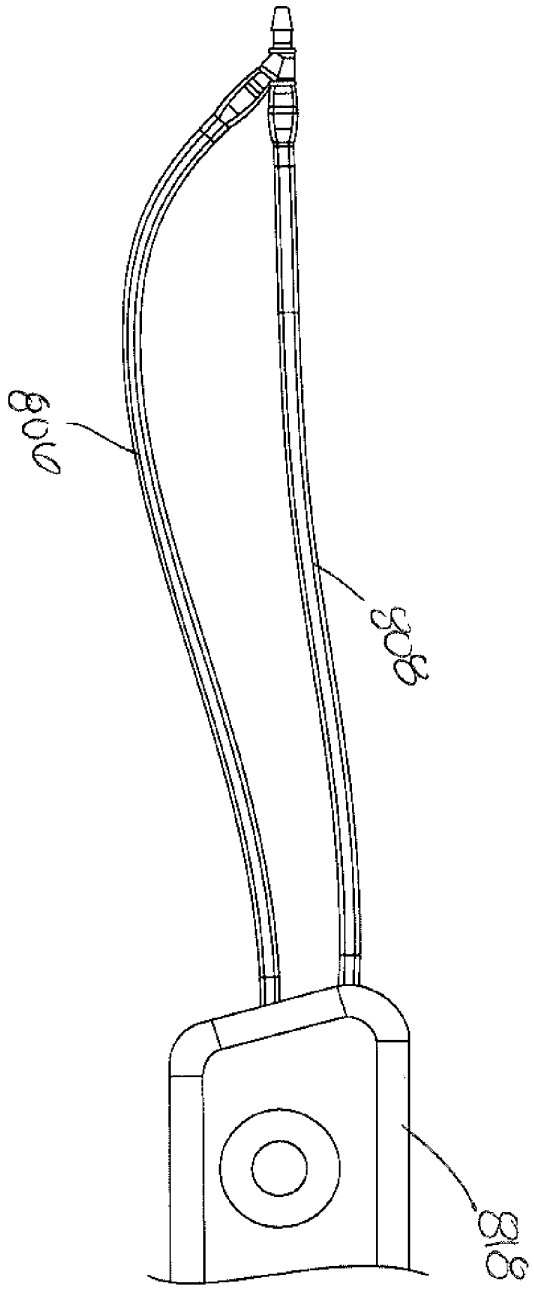


FIG. 8E

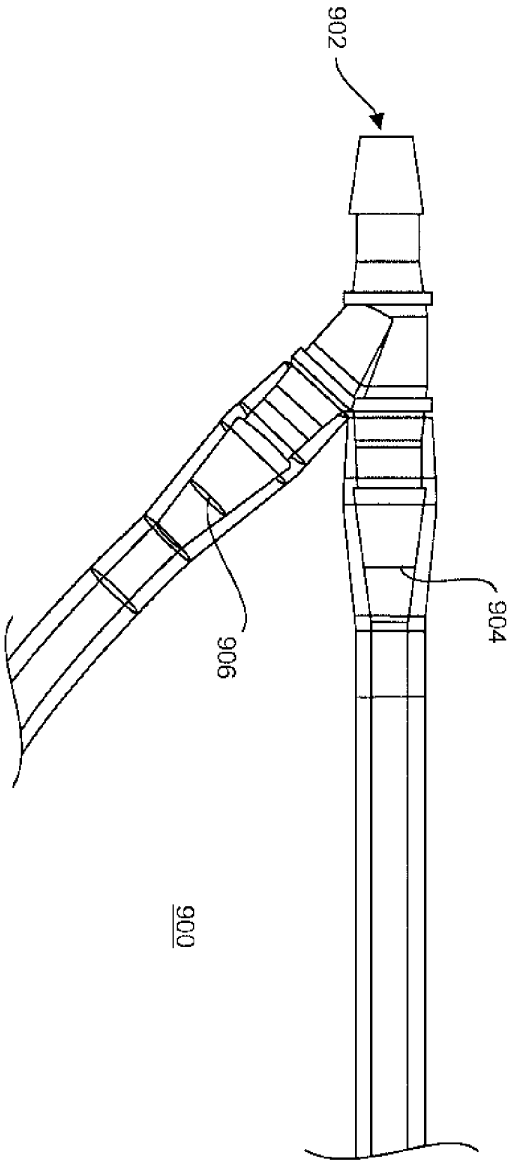


FIG. 9

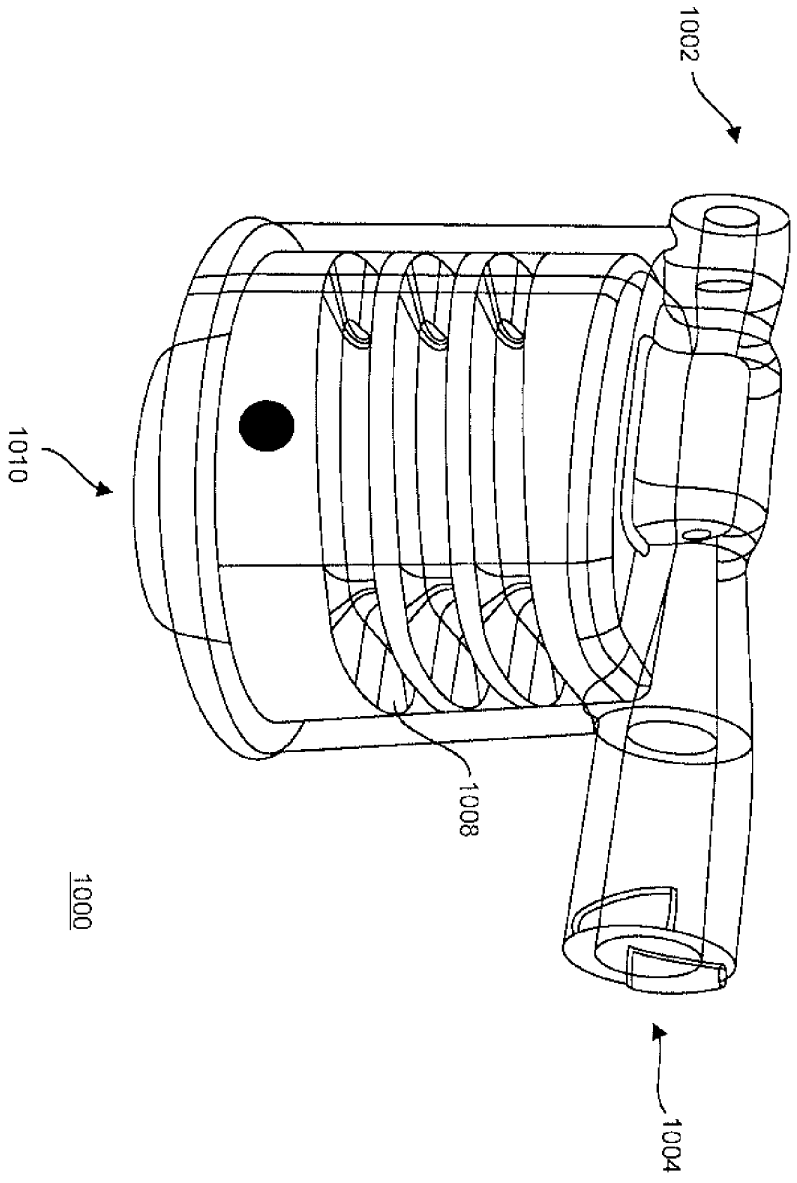


FIG. 10A

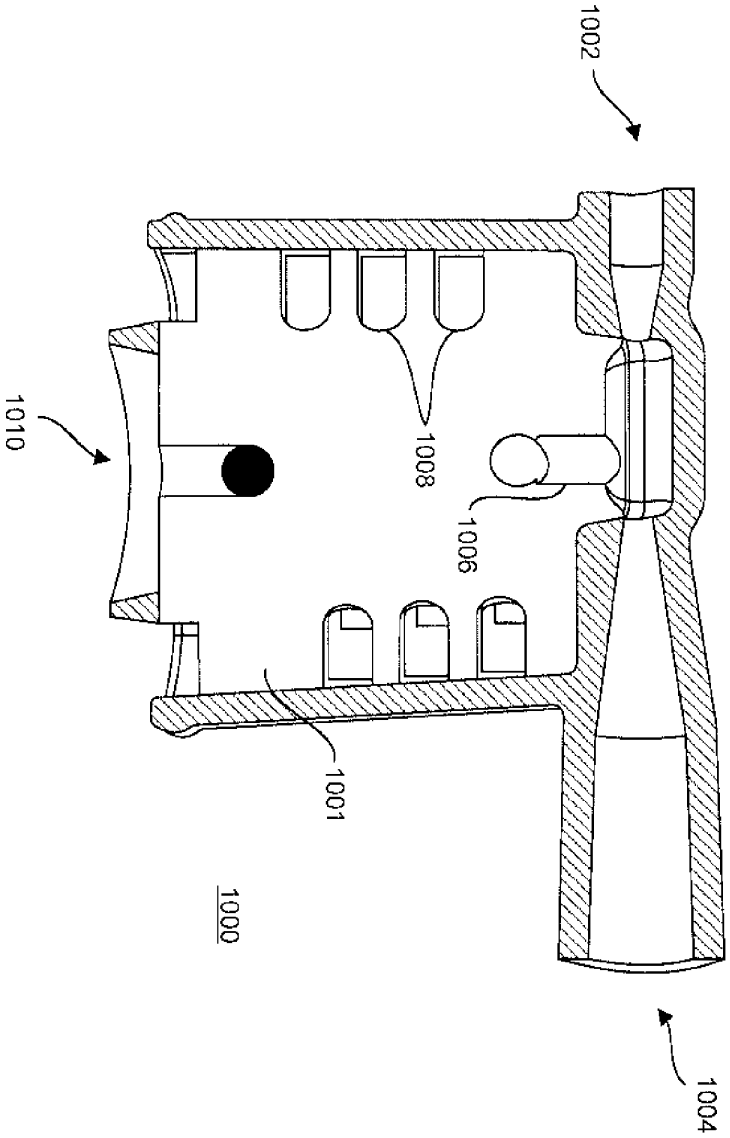


FIG. 10B

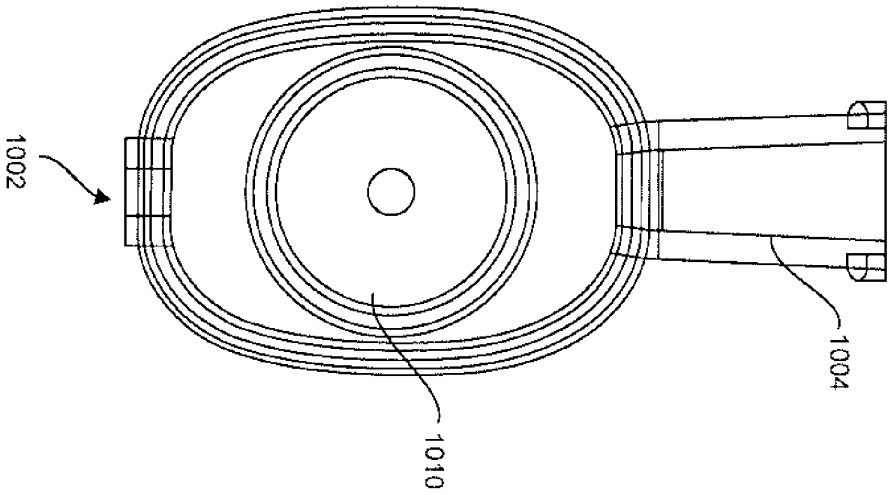


FIG. 10C

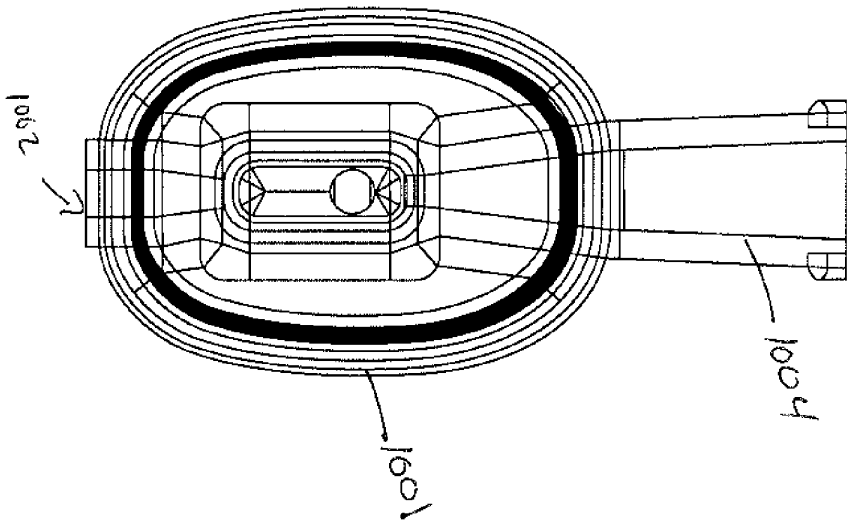


FIG. 10D

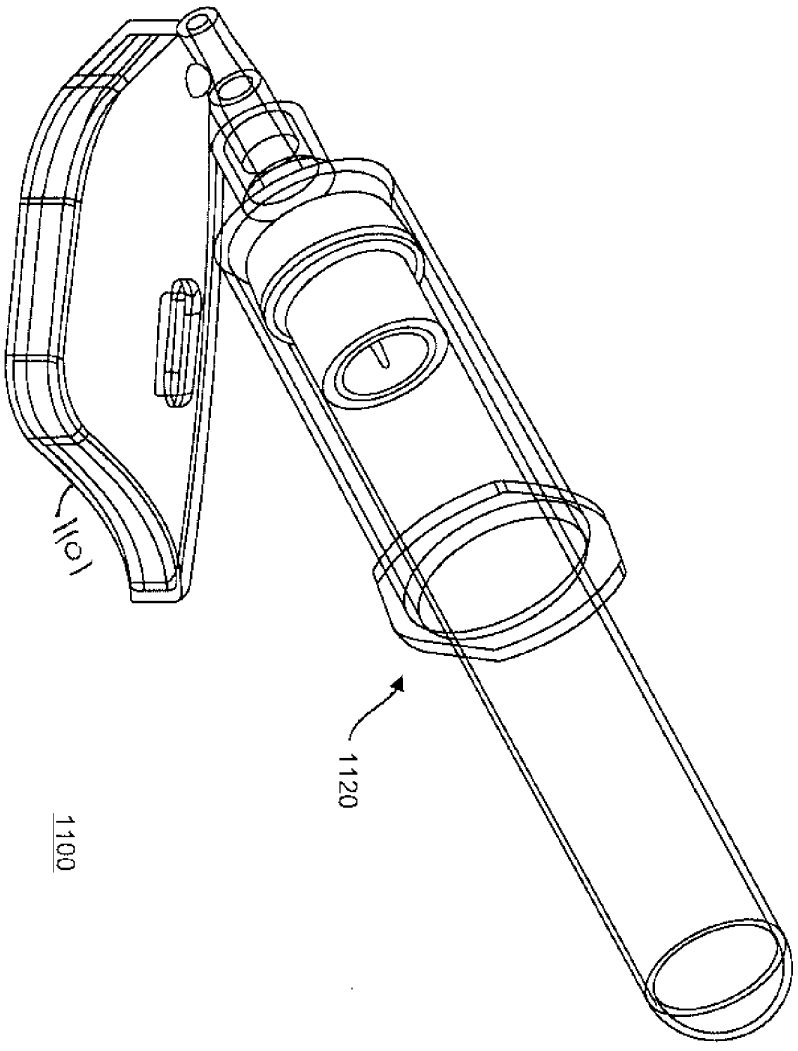


FIG. 11A

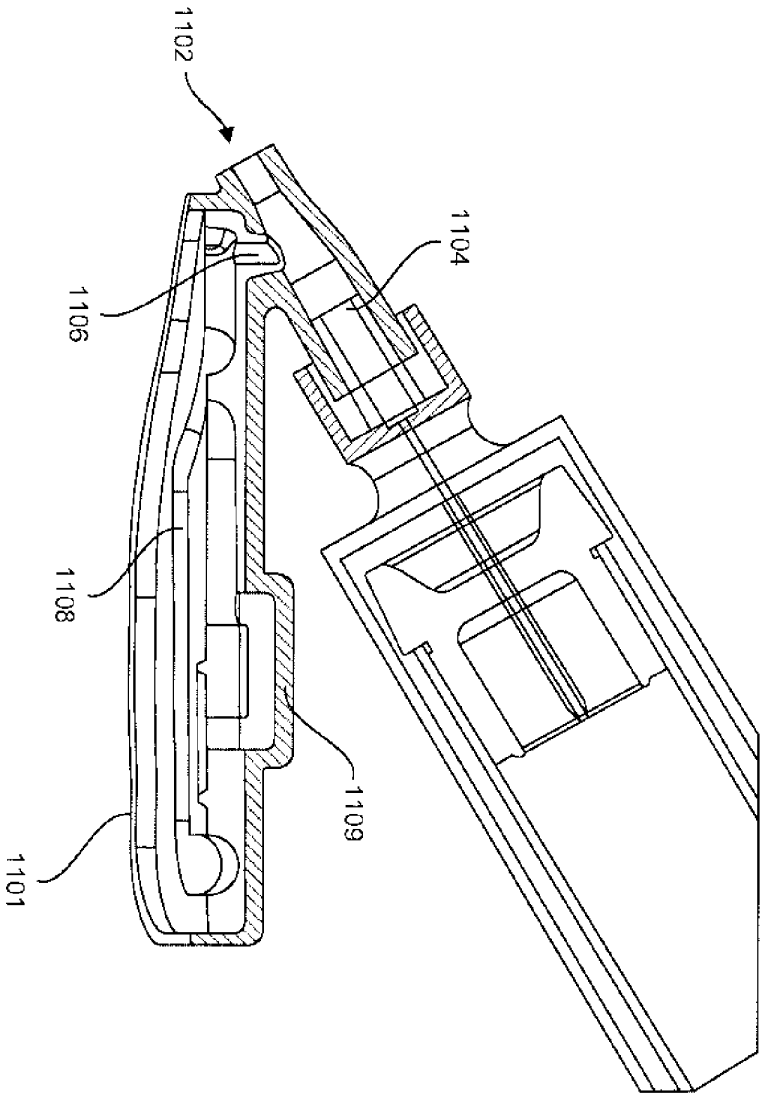


FIG. 11B

FIG. 11C

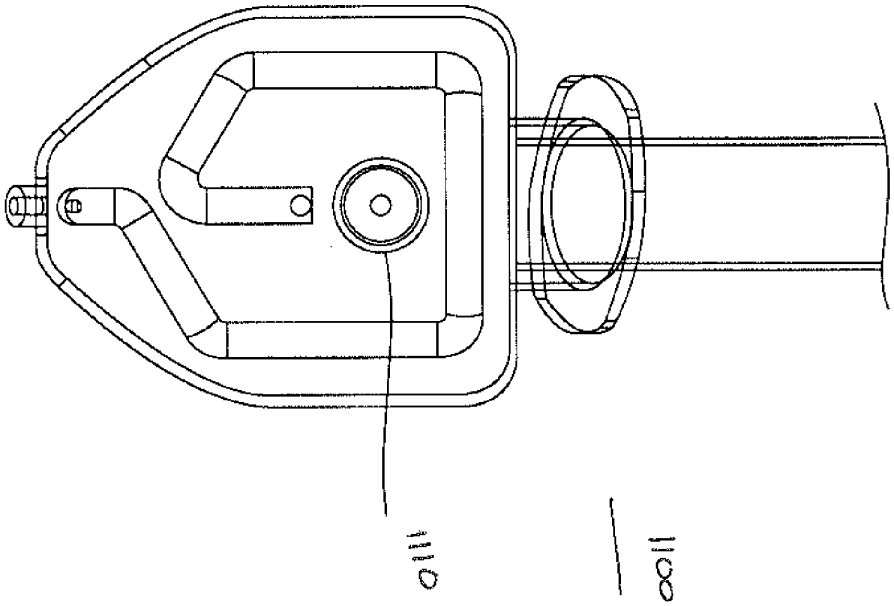
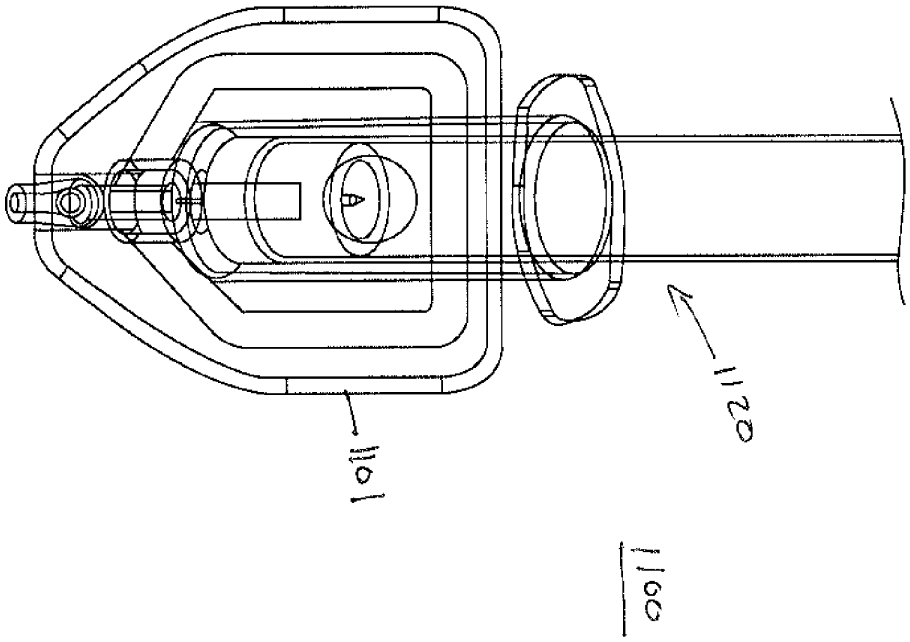


FIG. 11D



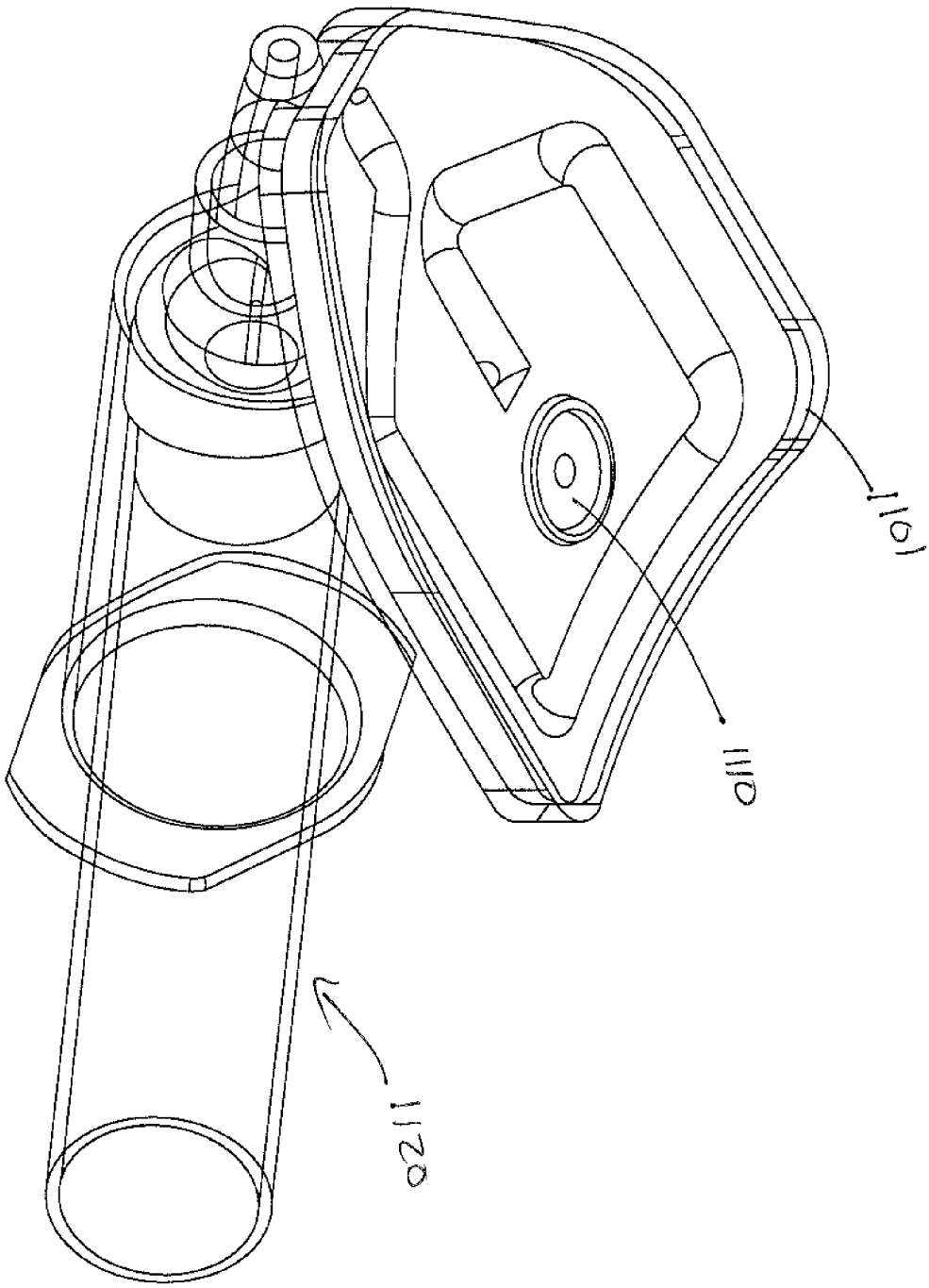


FIG. 11E

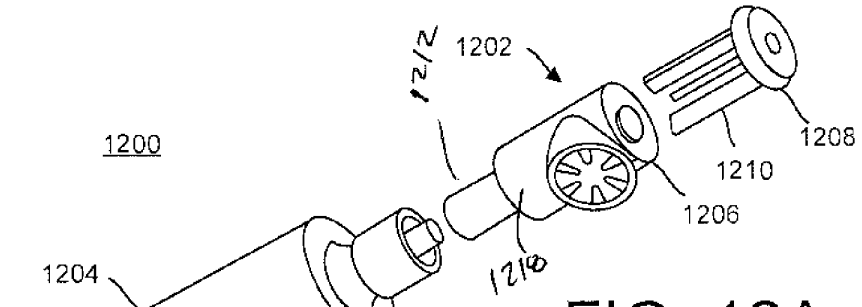


FIG. 12A

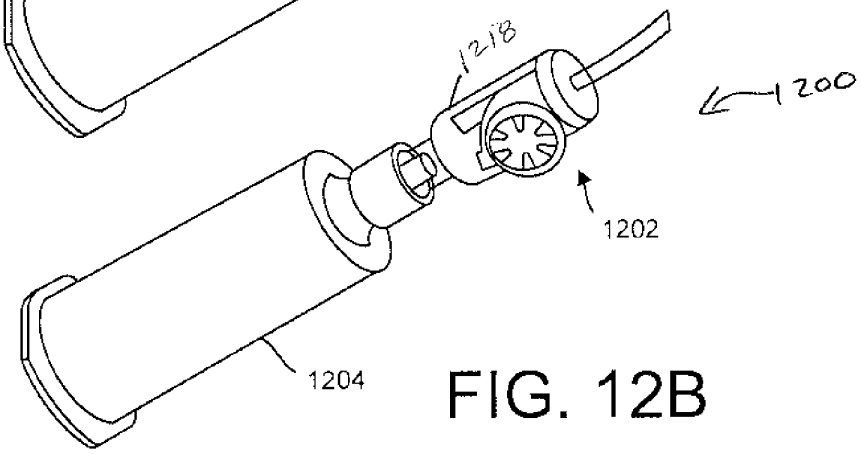


FIG. 12B

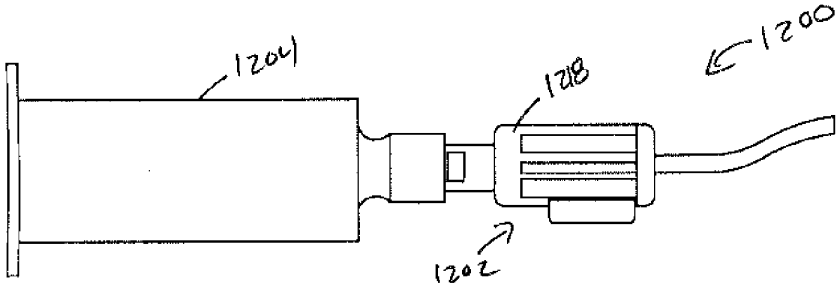


FIG. 12C

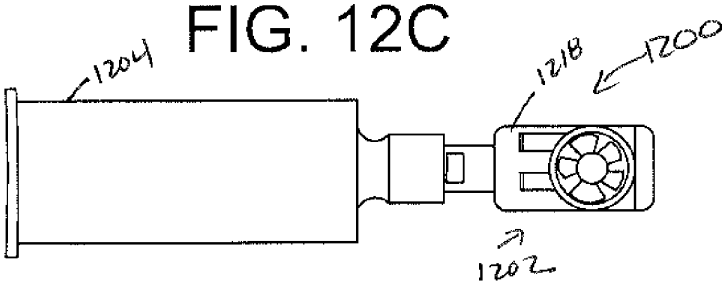


FIG. 12D

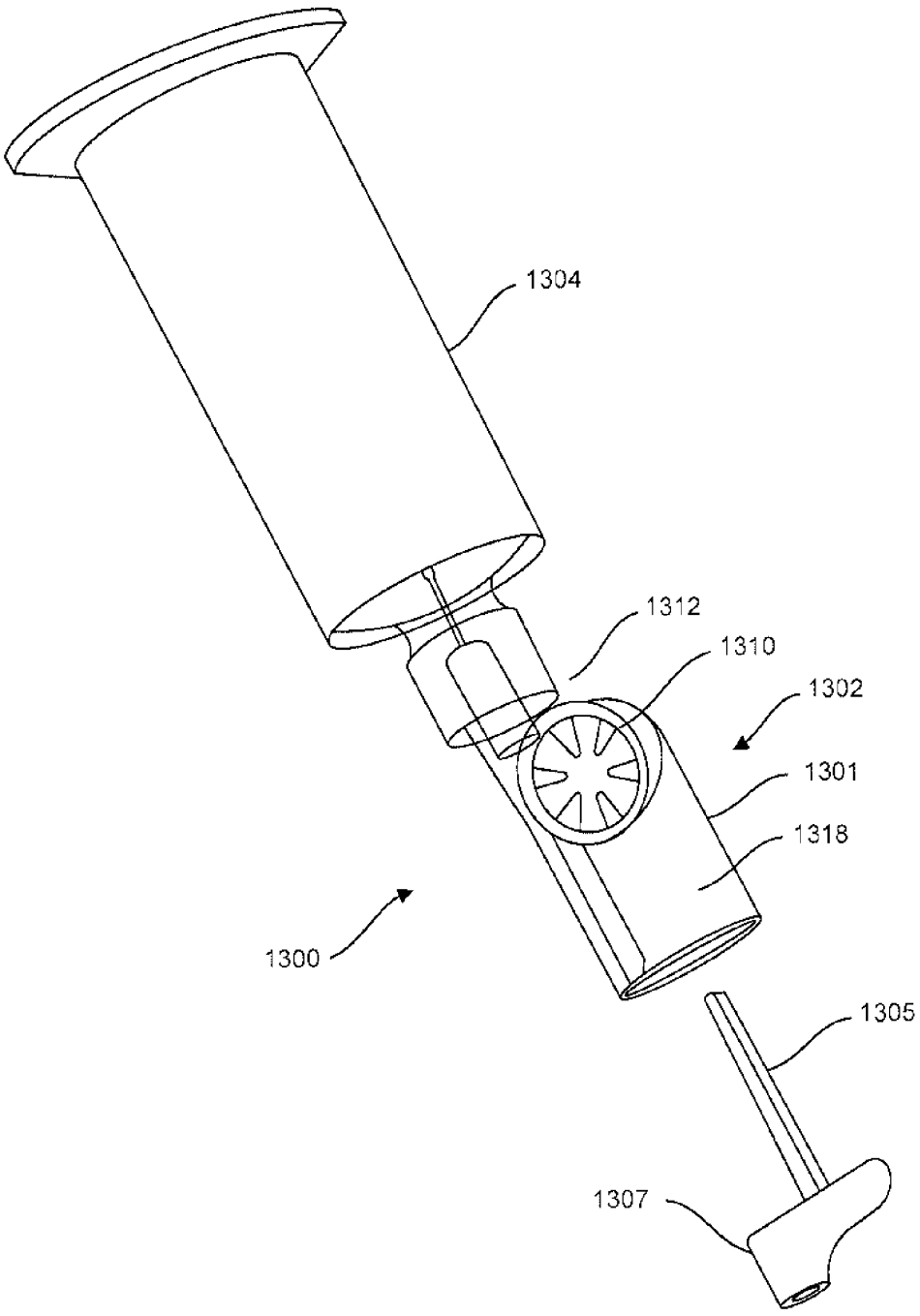


FIG. 13A

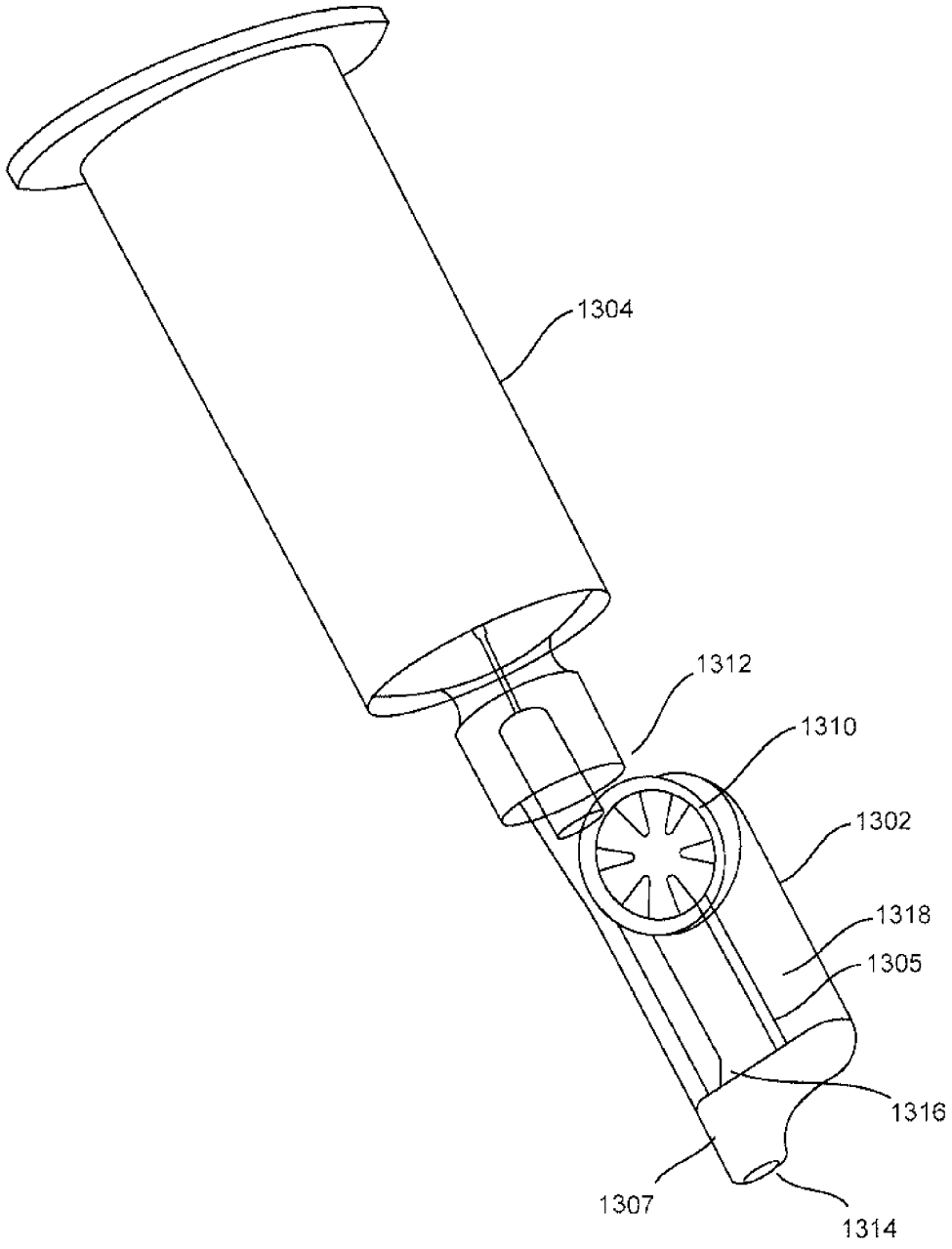


FIG. 13B

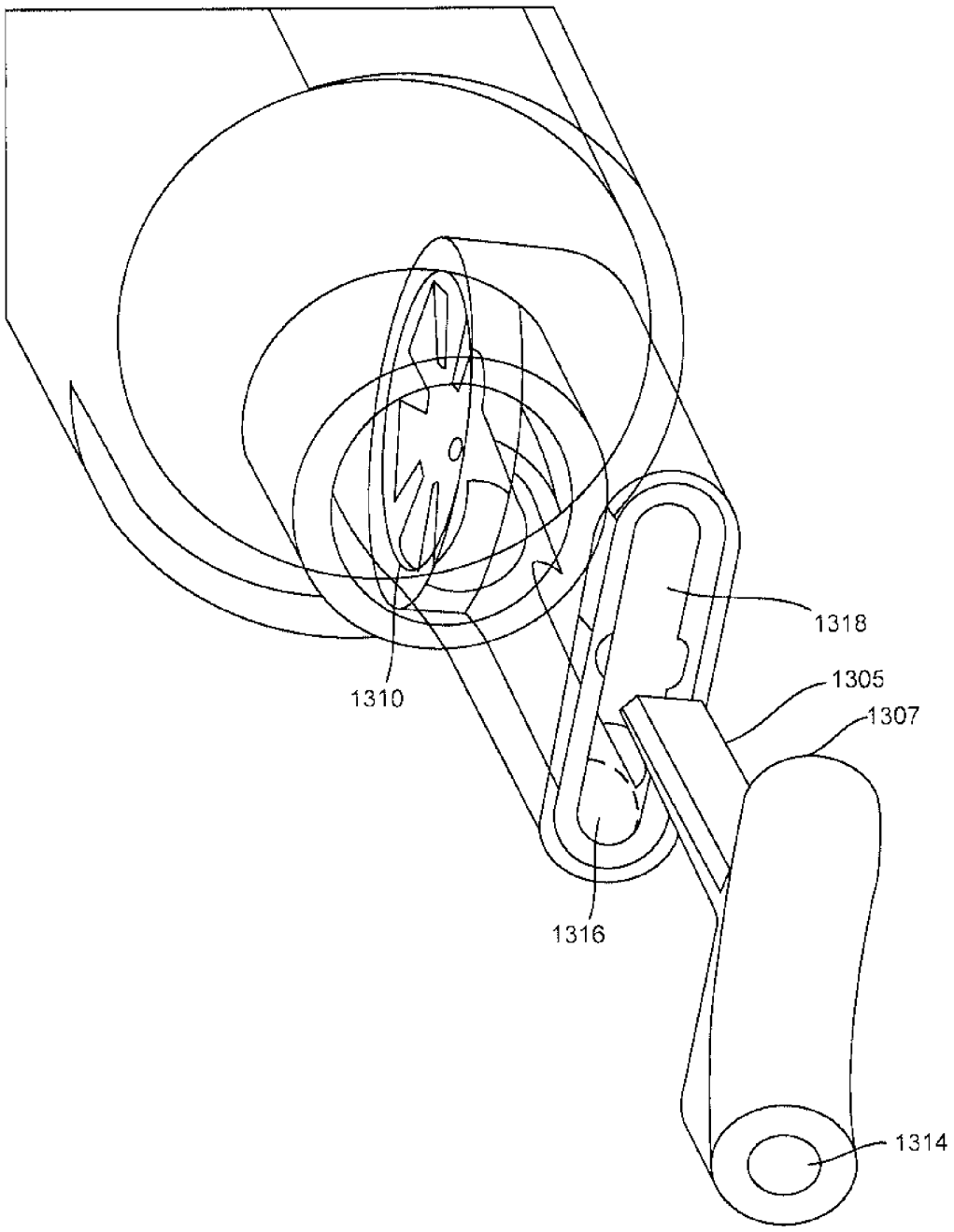


FIG. 13C

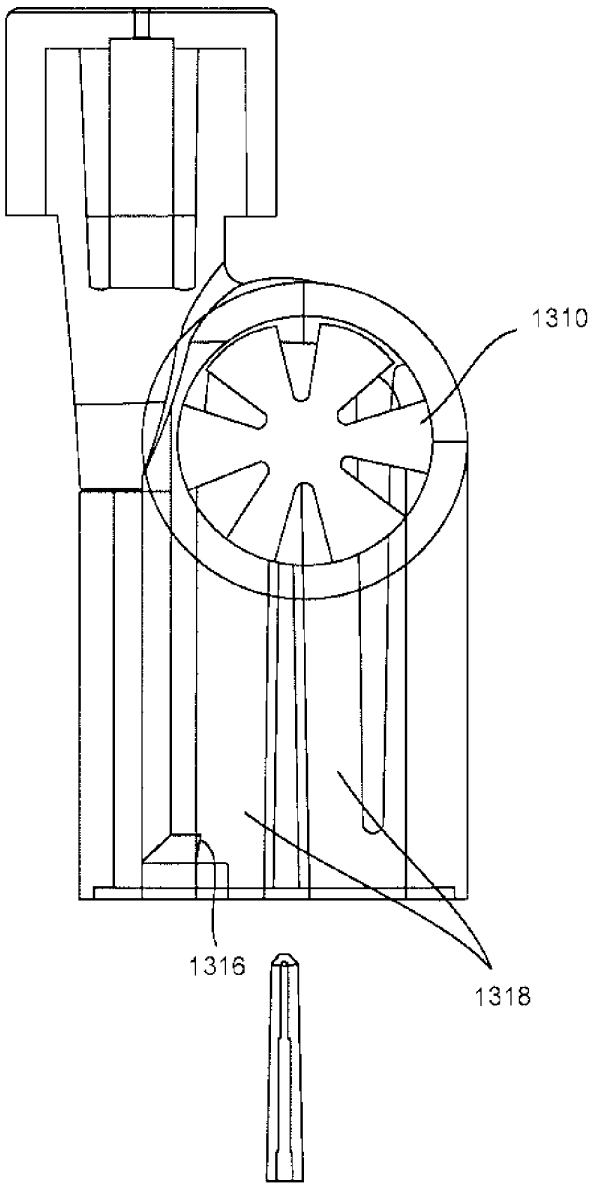


FIG. 13D

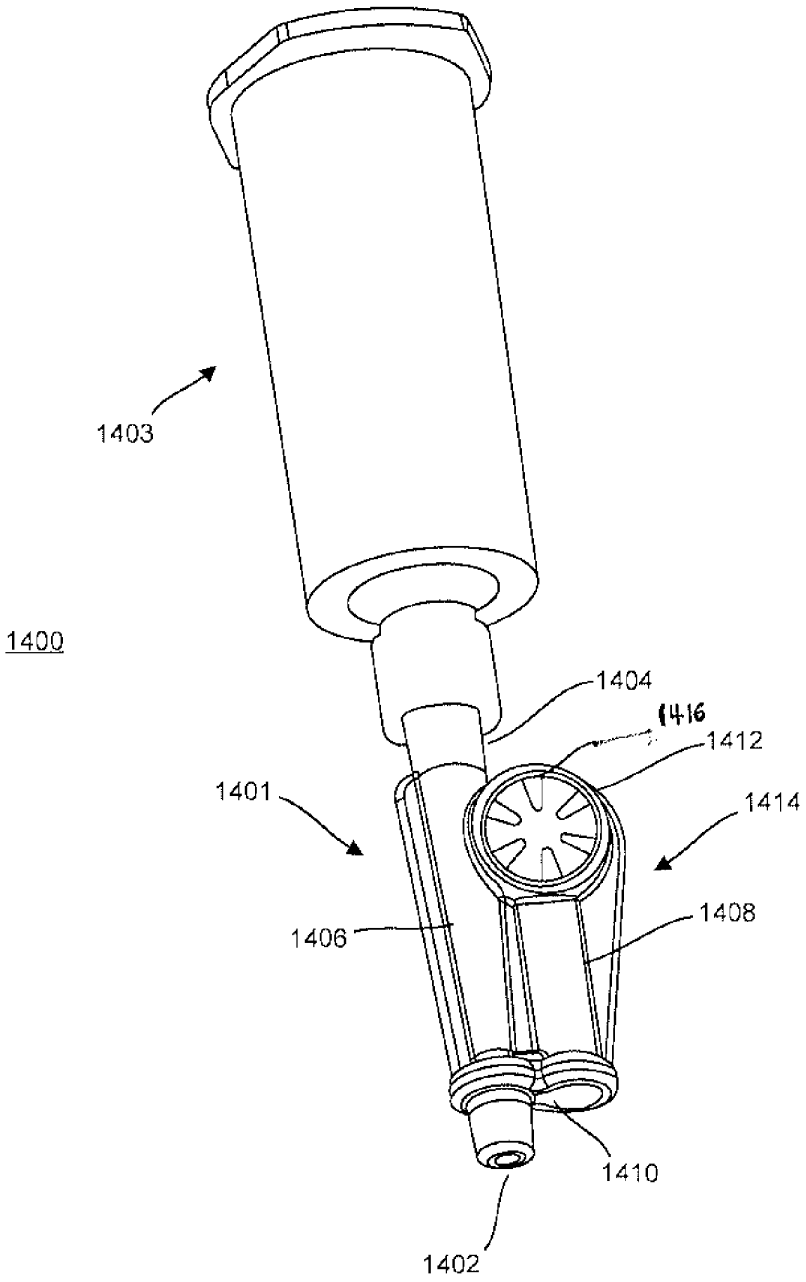


FIG. 14A

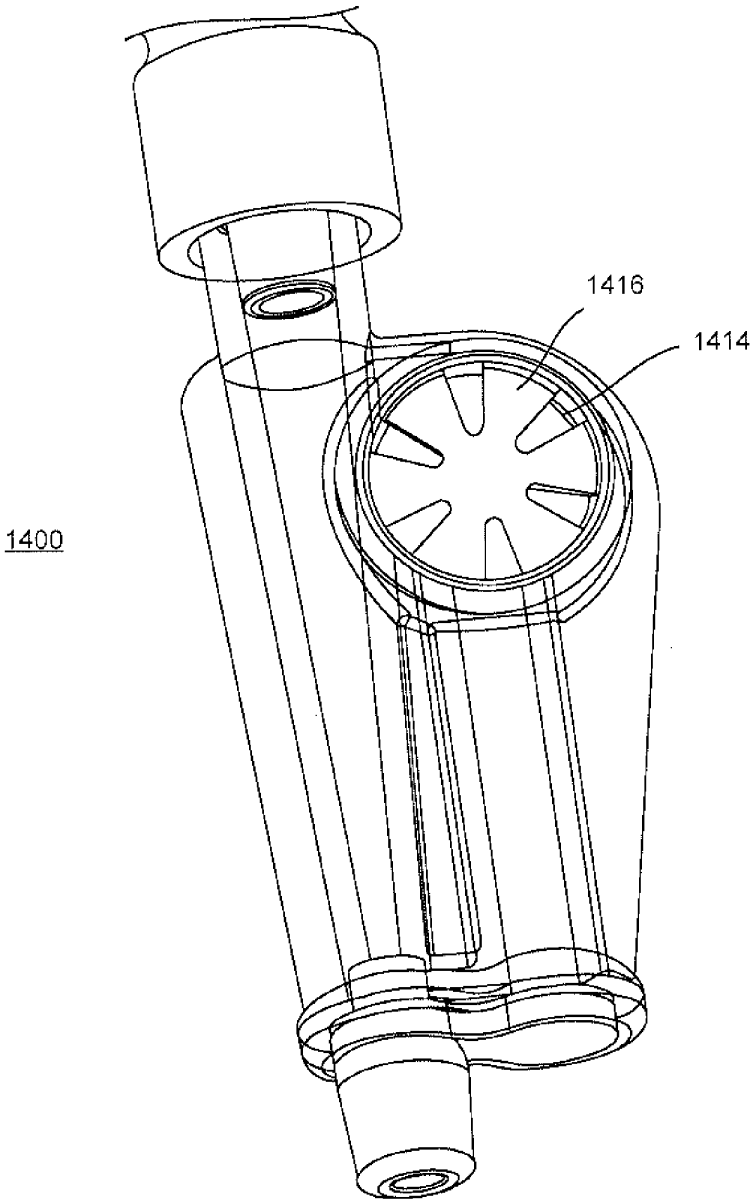


FIG. 14B

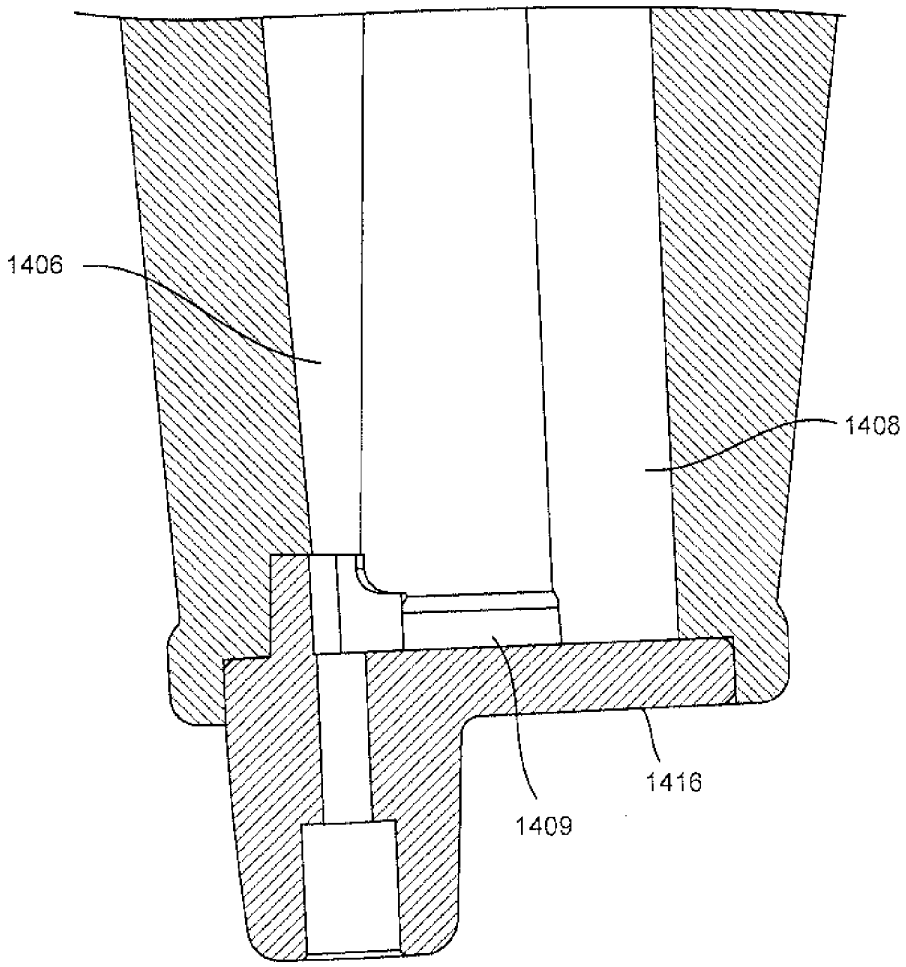


FIG. 14C

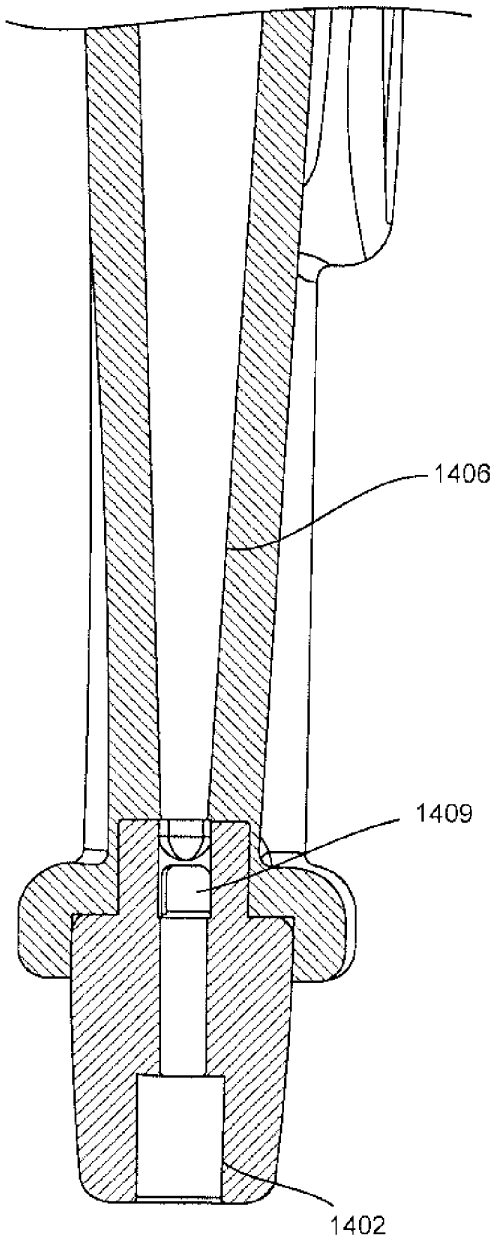


FIG. 14D

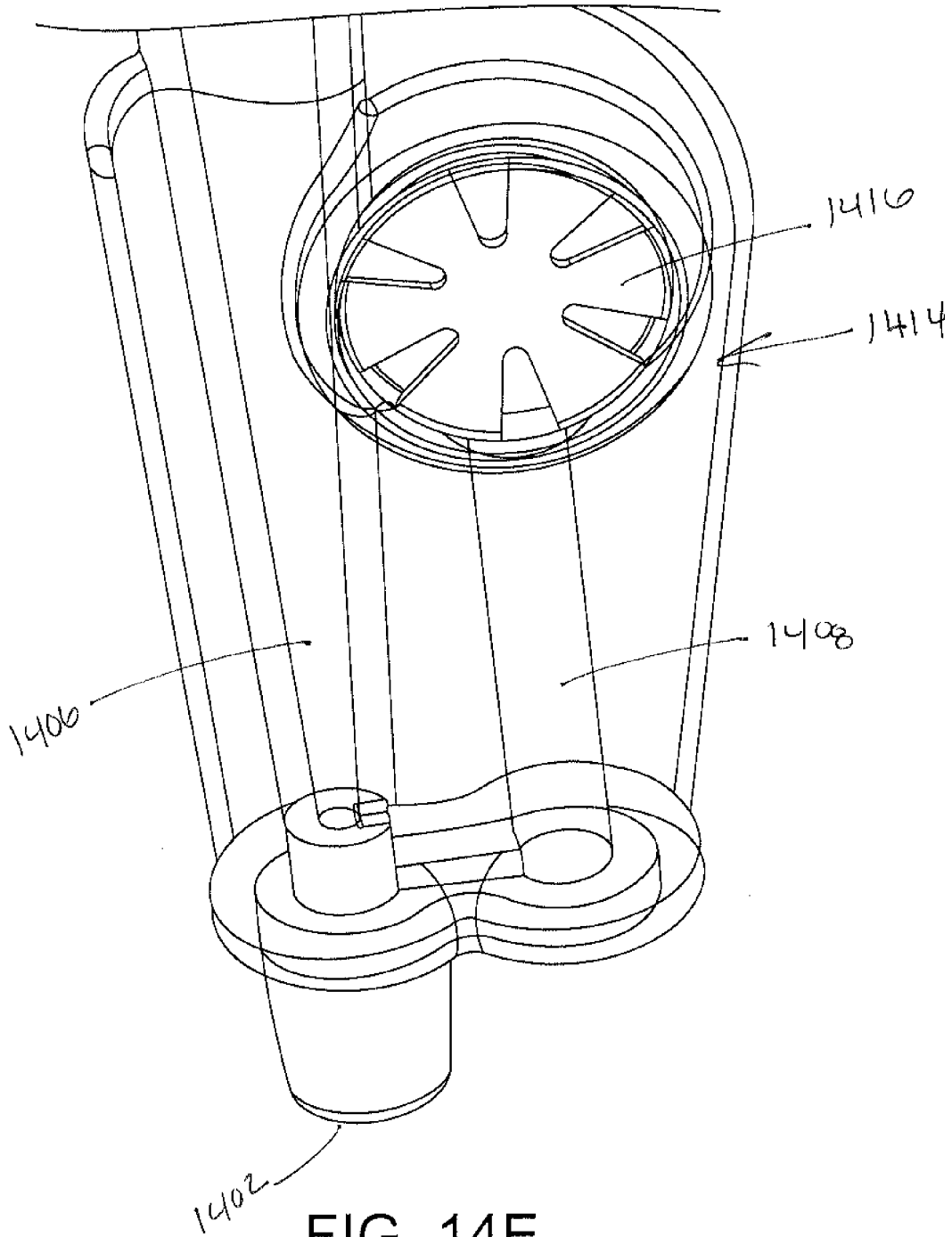


FIG. 14E

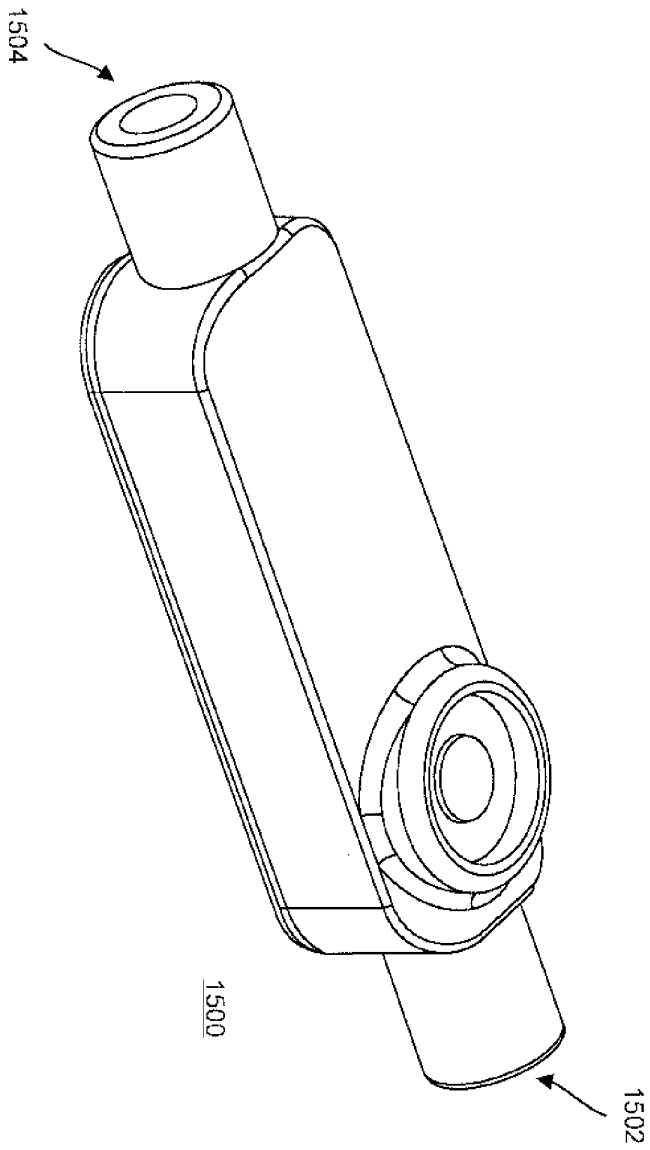


FIG. 15A

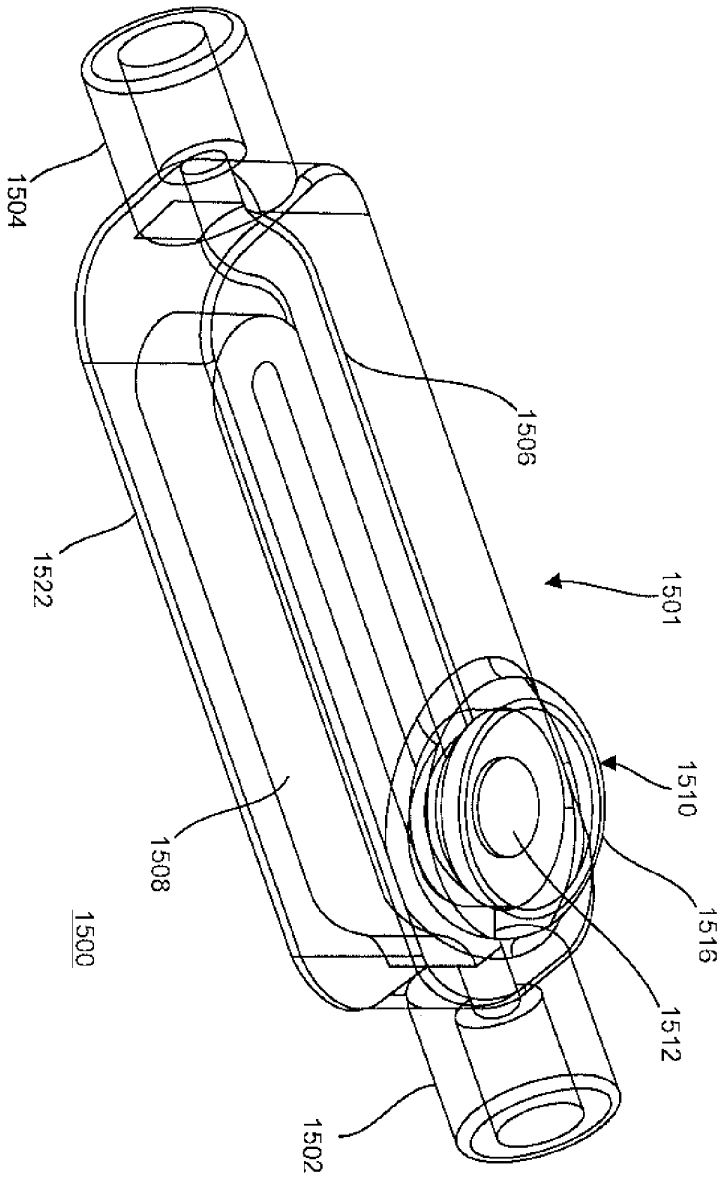


FIG. 15B

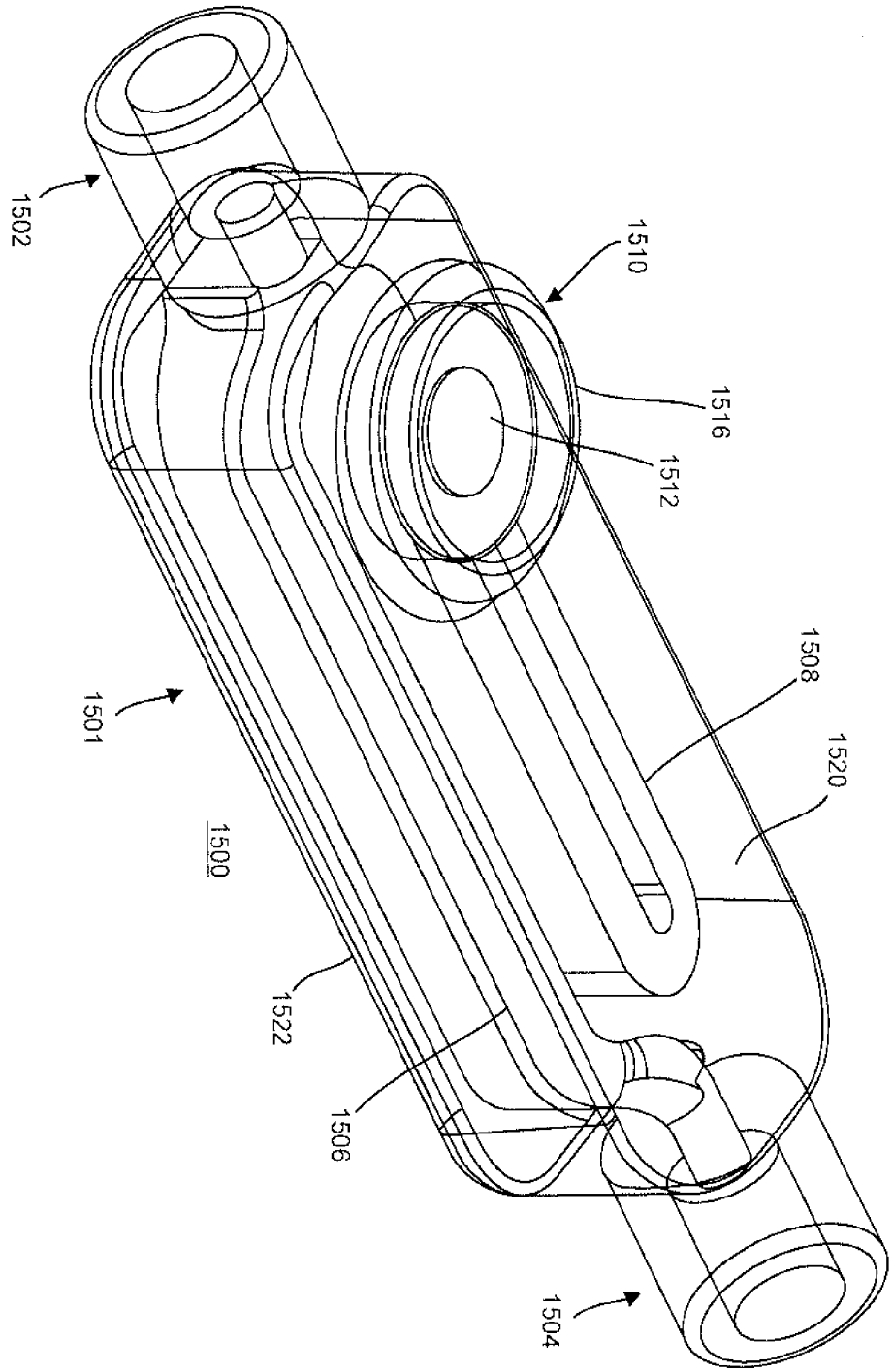


FIG. 15C

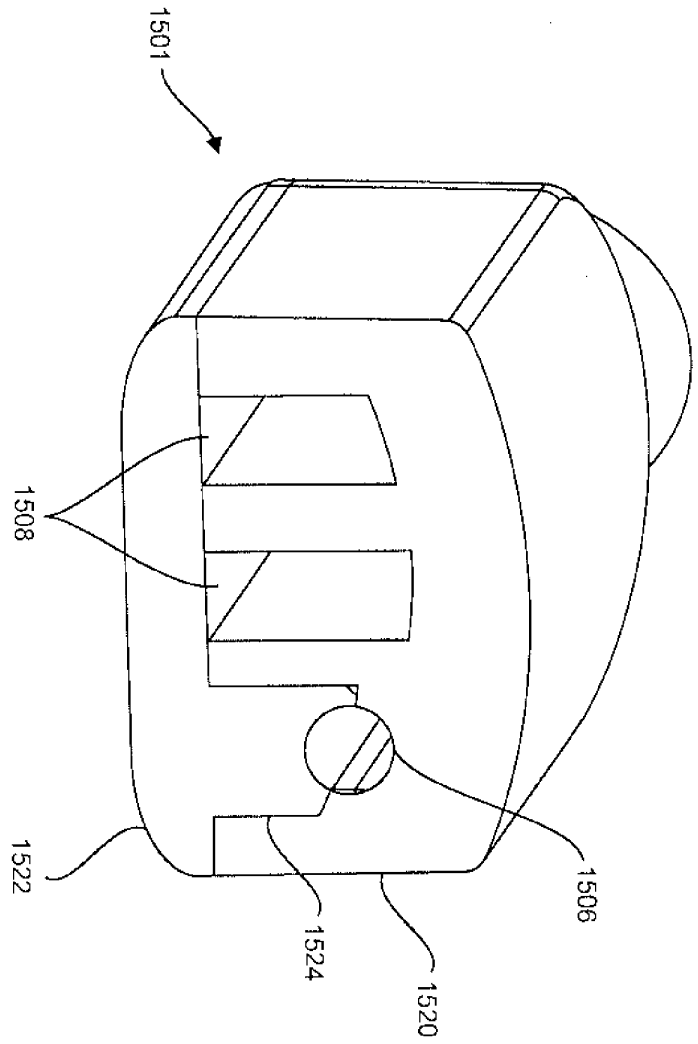


FIG. 15D

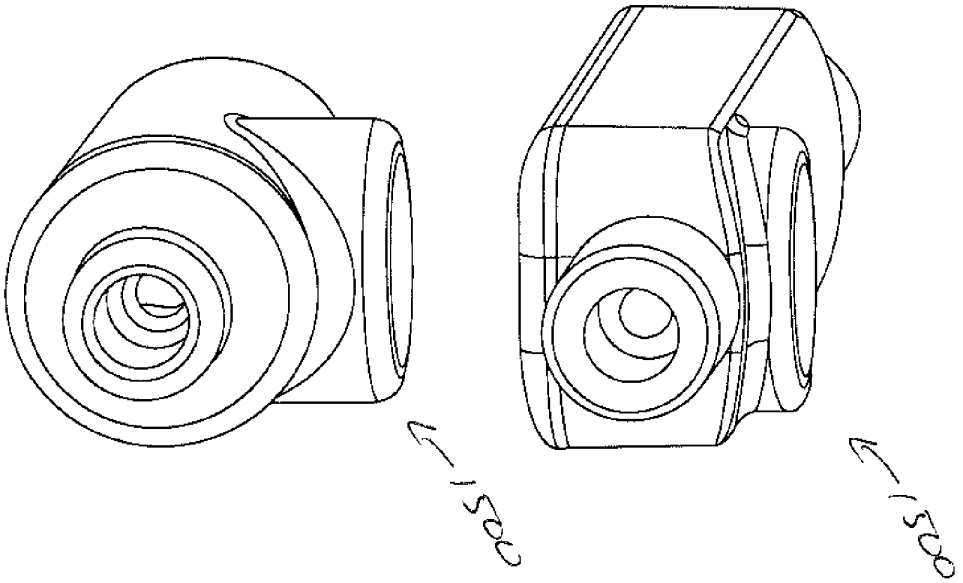


FIG. 15E

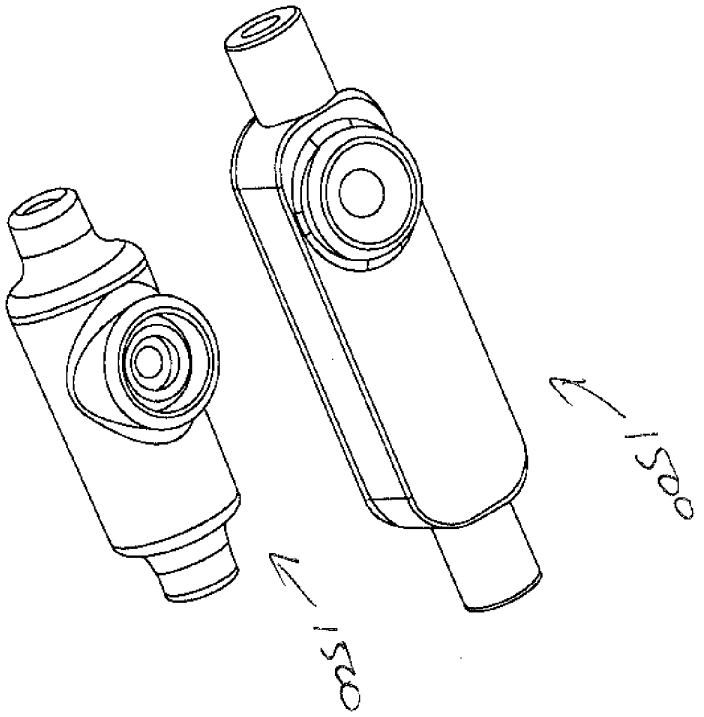


FIG. 15F

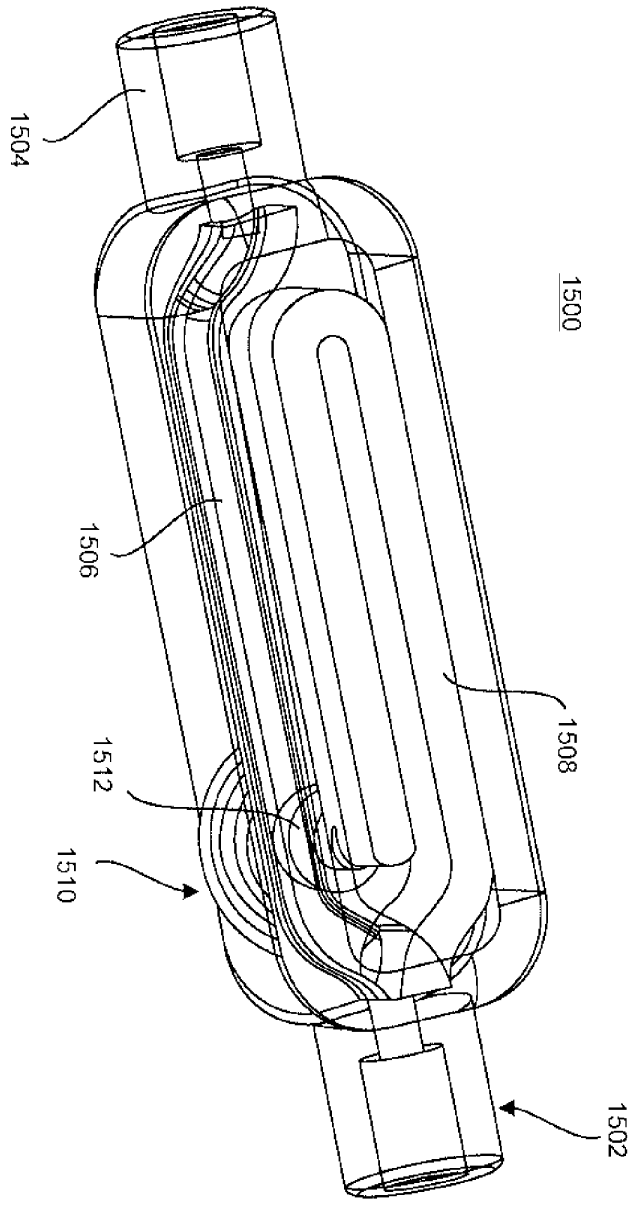


FIG. 15G



FIG. 16B

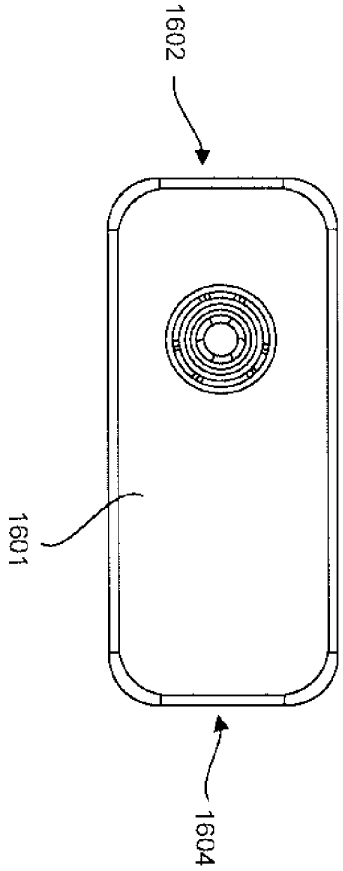


FIG. 16A

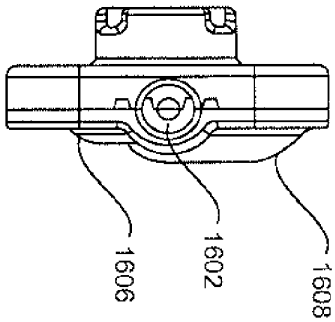


FIG. 16C

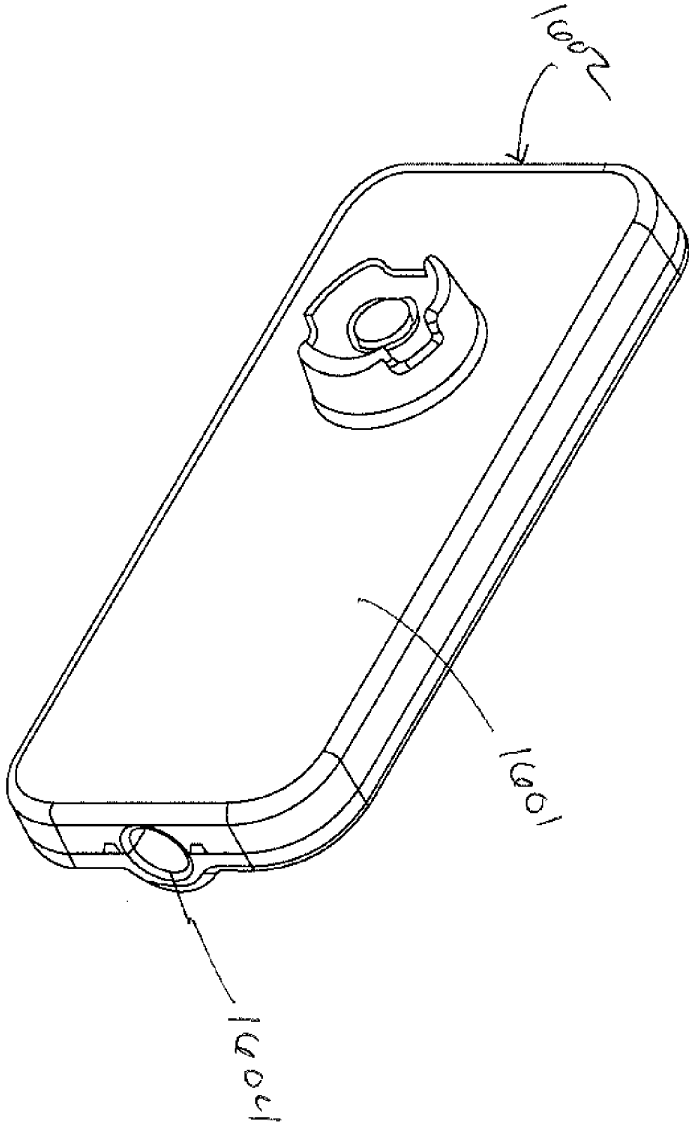


FIG. 16D

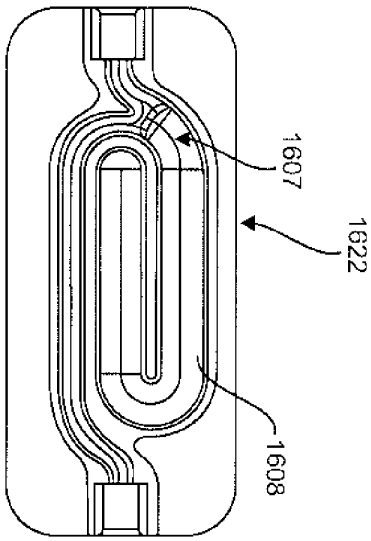


FIG. 17A

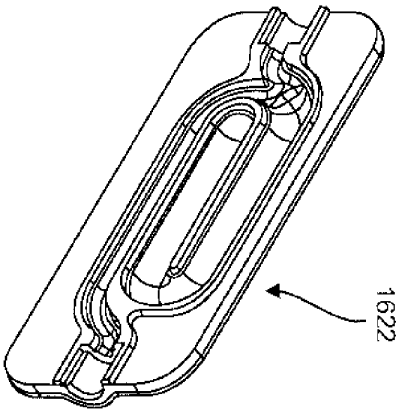


FIG. 17B

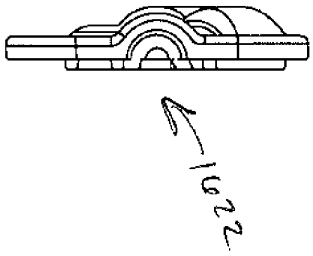


FIG. 17C

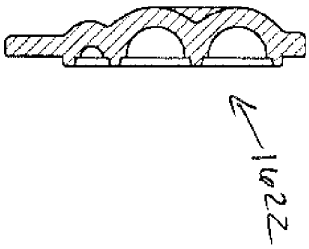


FIG. 17D

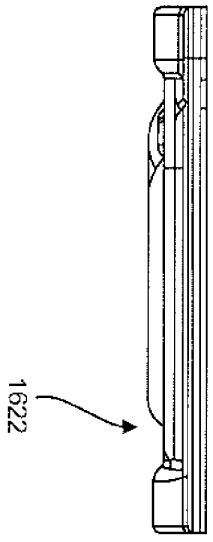


FIG. 17E

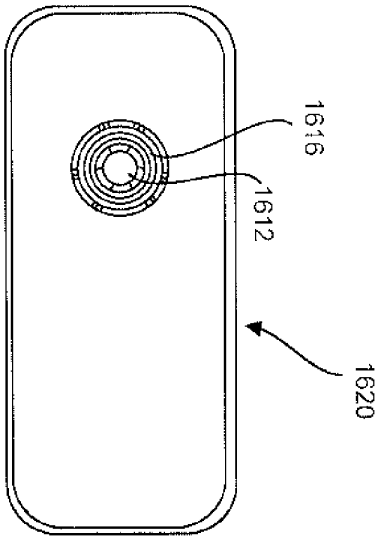


FIG. 18A

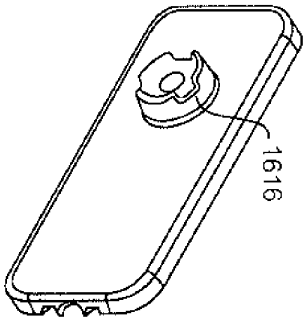


FIG. 18B

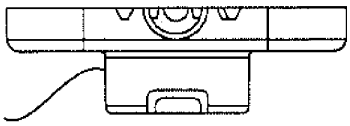


FIG. 18C

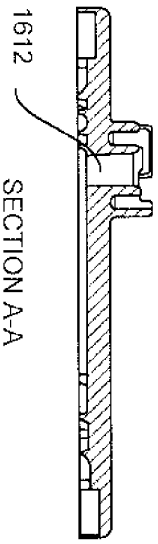


FIG. 18D

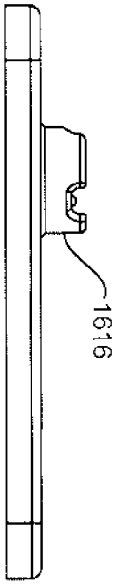


FIG. 18E

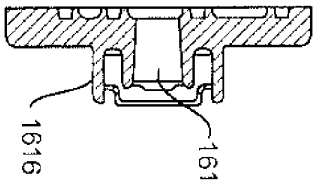


FIG. 18F

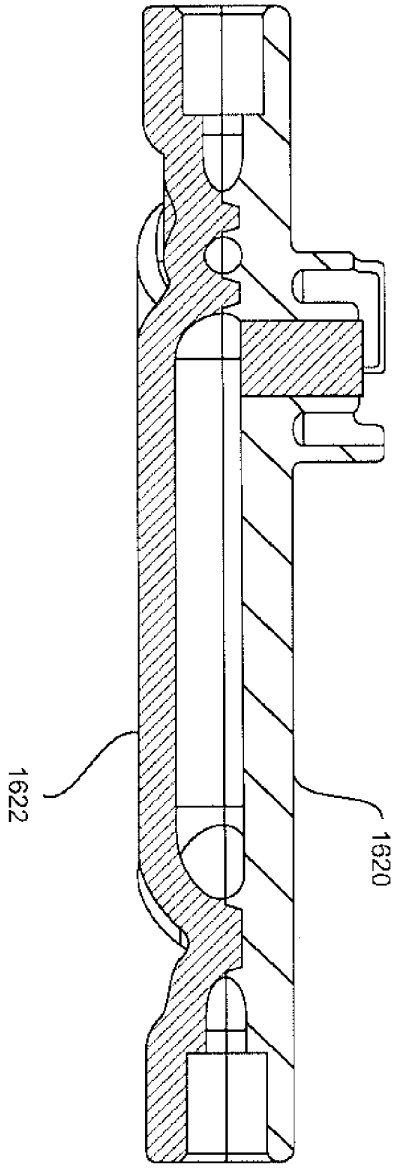


FIG. 19A

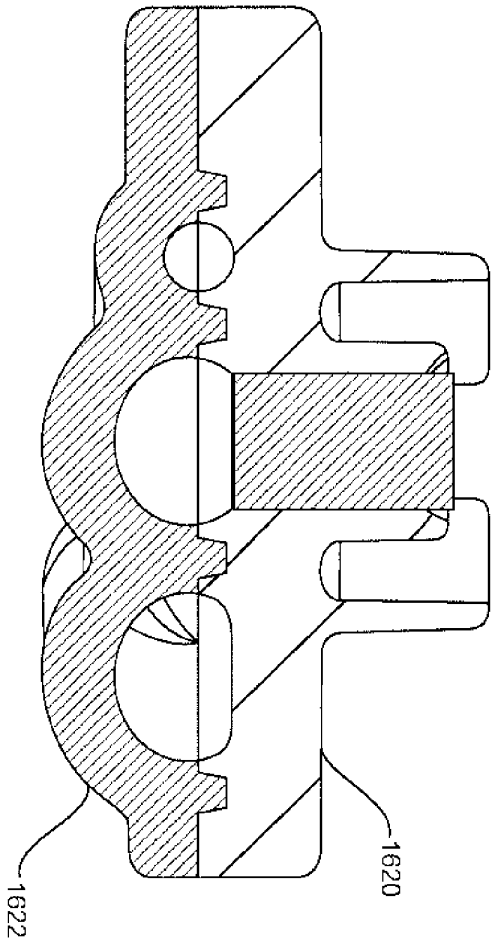


FIG. 19B

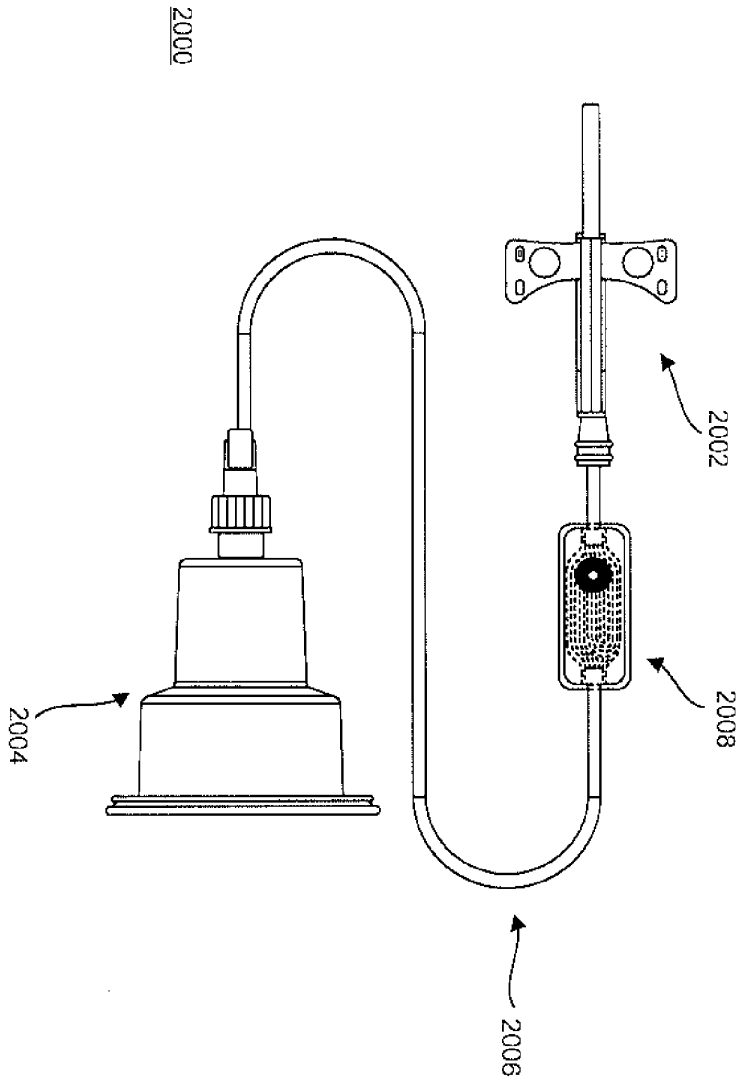


FIG. 20

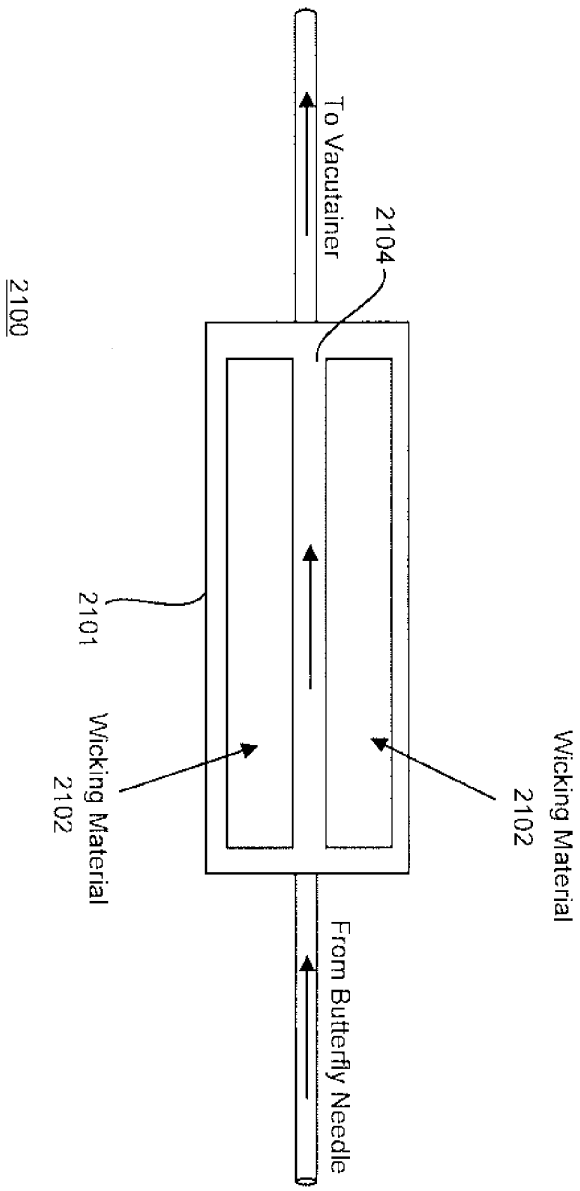

2100
To Vacutainer
2104
2101
Wicking Material
2102
Wicking Material
2102
From Butterfly Needle

FIG. 21

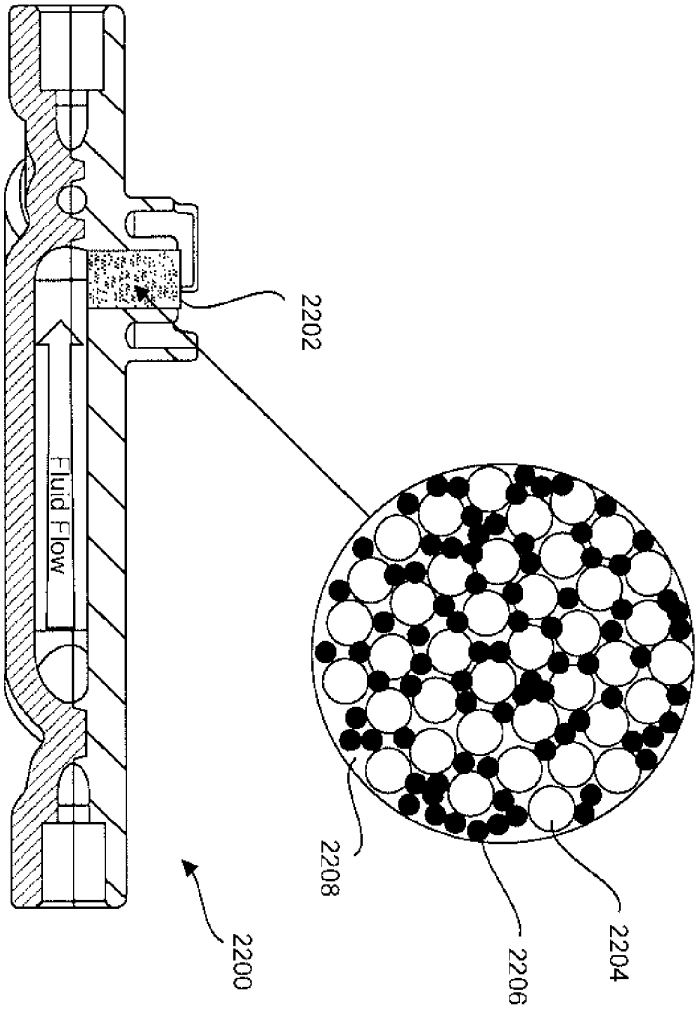


FIG. 22A

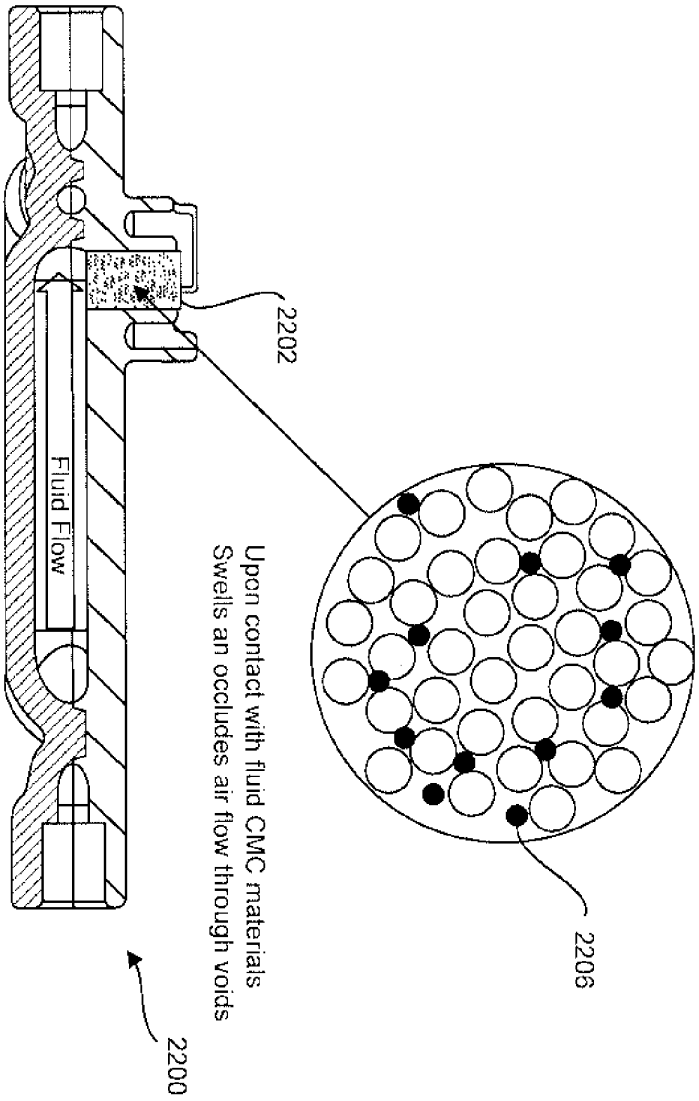

2202
Fluid Flow
Upon contact with fluid CMC materials
Swells an occludes air flow through voids
2206
2200

FIG. 22B

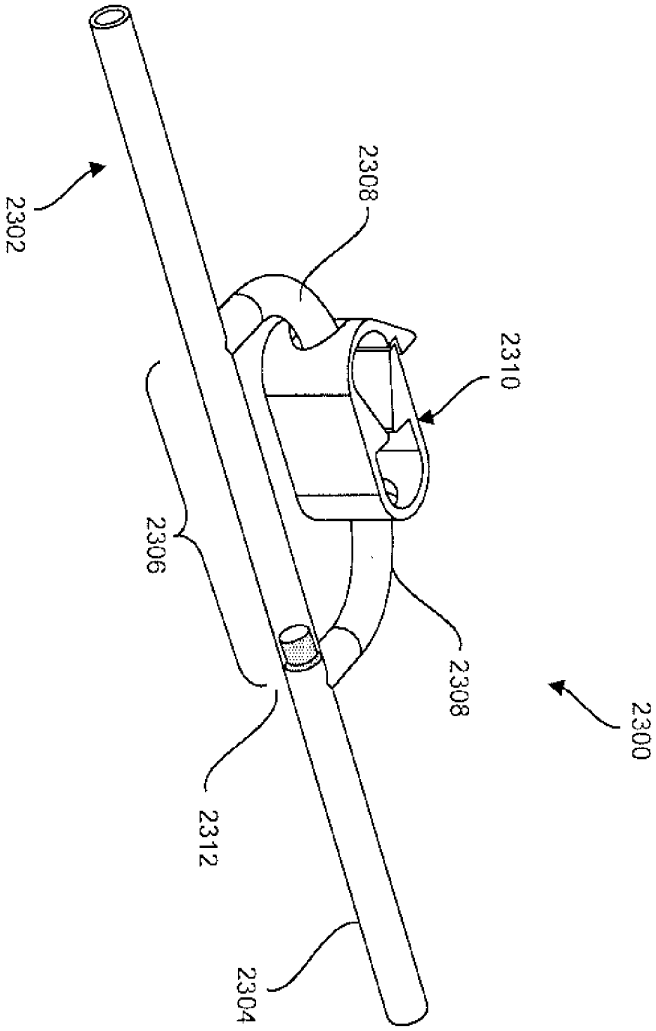


FIG. 23A

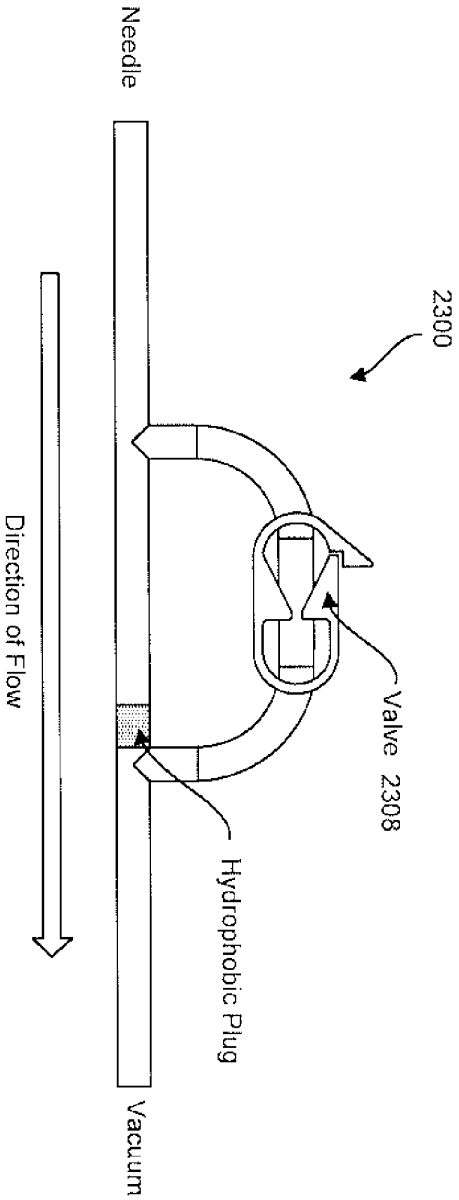

Needle
2300
Valve 2308
Hydrophobic Plug
Vacuum
Direction of Flow

FIG. 23B

katz Presenti & CO

14 September 2023

PILLSBURY WINTHROP SHAW PITTMAN, LLP
P.O. BOX 10500
McLean, VA 22102
USA

By Email Only:
james.conley@pillsburylaw.com
benjamin.hudson@pillsburylaw.com
suzanne.simpson@pillsburylaw.com
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To the attention of Jim Conley

P.K. 13 - Notice of Acceptance of:

IL Patent Application No.: 300848
a divisional application of IL 286030
Title: BLOOD SAMPLE OPTIMIZATION DEVICE
Filing Date: 21 February 2023
App. date: 22 July 2016
IL NP of PCT Patent Application No.: PCT/US2016/043709
Applicant(s): KURIN, INC.

Dear Jim:

1

We are pleased to report that the above identified Israel Patent Application has been accepted by the Israel Patent Office (ILPO), which issued the herein attached Notice before allowance dated **14 September 2023**.

The Applicant is now required to pay the Allowance Fee, by the due date of **14 December 2023**.

After the payment of the allowance fee the application shall be published for 3rd party opposition for a period of 3 months, after which if no opposition is filed the Certificate of patent will be issued.

This notice of acceptance is based on the following documents:

Drawings dated 21 February 2023
Claims dated 27 July 2023
Description dated 27 July 2023

1. The examination of the above application was based on the following points:
   1.1. The date of the present application, which is a divisional application of IL 286030, has been put forward to the date of 22 July 2016, which is the application

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+972-3-9326393 | +972-3-9093614 | info@patents-il.com | 14 Abba Hillel Rd. Beit OZ, 11th floor, Ramat Gan 5250607, Israel
www.patents-il.com

date of the parent application. And this in accordance with Section 24(3) of the law.

Attached for your kind attention are:

- The allowed Description
- The allowed Claims
- The allowed Drawings

Please review the attached documents, namely the allowed description, claims and drawings before authorizing us to pay the allowance fee. Of course, we will review the documents as well.

We additionally remind you of the continuing responsibility of the Applicant to update the ILPO with information of cited art and/or opposition procedure and/or cancellation procedures in corresponding Applications under Section 18 of the Israel Patent Law - until the payment of the allowance fee. When the Applicant becomes aware of publications or other citations that may be relevant information/material to the examination of this application, such information/material must be forwarded to us for reporting to the ILPO. Failure to disclose such information to the ILPO may result in cancellation of an issued IL patent.

2

Publications filed after this notice will not be reviewed but will be on record. Should the applicant wish to receive continued examination based on new publications, a request to file for re-examination must be filed along with an update of the list of publications.

Divisional Applications

Please be advised that pursuant to Art. 24(a) of the Act, divisional applications may be filed after the payment of the Allowance fee but before the publication. We highly recommend filng divisional applications before the payment of the allowance fee.

We look forward to receiving your instructions in due course.

Yours sincerely,

Ronen Presenti

רח' אבא הלל סילבר 14, בית עתן, קומה 11, רמת-גן, 5250607 | info@patents-il.com | 03-9093614 | 03-9326393
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Submitted herewith

> The original notice in Hebrew.

> The publication documents, namely, Description, Claims, Drawings.

> Our invoice number 3264.

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ABN: 38 113 072 755

1 March 2023

Notice of acceptance for patent application

Griffith Hack
Level 15, 376-390 Collins Street
Melbourne VIC 3000
Australia

Your reference	P108089.AU.1
Application number	2021202622
Applicant name	KURIN, INC.

Dear Griffith Hack,

This patent application was accepted on 21 February 2023. The accepted specification incorporates the following amendments:

S104 amendments up to and including item number: 4

The total number of claims at acceptance has been reported as: 15

Notice of the acceptance will appear in the Australian Official Journal of Patents on 16 March 2023.

Please review the acceptance details attached to this letter to ensure that they are correct. If you wish to amend any details prior to the grant please do so within 3 months of the advertisement of acceptance.

An Invitation to Pay (ITP) the acceptance fee will be issued to you. This fee will include an additional component if the number of claims exceeds 20.

Details of this patent application can be viewed on AusPat, our Australian patent search database.

Yours sincerely,

IP Australia

Acceptance summary

Standard patent details

Patent number:	2021202622
Title:	Blood sample optimization system and blood contaminant sequestration device and method
Your reference:	P108089.AU.1
Number of claims at acceptance:	15

Applicant and inventor details

Applicant name(s) and address(es) *(as it will appear on certificate/s)* **:**

KURIN, INC. of 10755 Scripps Poway Parkway, No. 257 San Diego CA 92131 United States of America

Inventor name(s):	ROGERS, Bobby KANG, Gino DETLOFF, John

Agent details

Agent Name	Griffith Hack
Address for correspondence:	Level 15, 376-390 Collins Street Melbourne VIC 3000 Australia
Address for legal service:	Level 15, 376-390 Collins Street Melbourne VIC 3000 Australia

Prior art details

Prior art documents:
WO 2011/162772 A1
WO 96/05875 A1
US 2013/0317391 A1
US 4207870 A
US 4416291 A
US 2008/0145933 A1
JP 2001000424 A

Priority details

Divisional of:	2016297849

Your reference	P108089.AU.1
Application number	2021202622

International classification

A61B 5/15 (2006.01)
A61B 5/153 (2006.01)
A61B 5/154 (2006.01)

Relevant dates

Acceptance date:	21 February 2023
Acceptance to be advertised:	16 March 2023
Complete filing date:	28 April 2021
OPI date:	27 May 2021
Continuation fee due date:	22 July 2023
Date of patent:	22 July 2016
Expiry date:	22 July 2036
National phase entry date:	Not Applicable

פ.ק 26

תאריך : י״ב תשרי תשפ״ה
14/10/2024
מספרכם : 1000-016-04

To
KATZ, PRESENTI AND CO.
11 Menachem Begin St. Rogovin-Tidhar Tower, 31st Floor Ramat Gan 5268104,

Dear Sir / Madam

Subject: Notice of Deficiencies for Patent Application 309380
Ref: Your letter dated 26/07/2024

Please note: any reference made to the "Law" shall mean the Patent Law 5727 - 1967, and any reference made to the "Regulations" shall mean the Patent Regulations (Office Practice, Rules of Procedure, Documents and Fees) 5728 - 1968. You shall reply to this Notice within four months. However, you are entitled to request an extension. **According to the rules set forth in Commissioner's Circular 035/2017-Patents, a maximum extension of 4 months will be allowed per Notice of Deficiencies, while the total period for all extensions approved during the examination shall not exceed 12 months.** With the filed request for extension, a fee of 226.00 NIS shall be paid per month of extension or part of it.

This Notice is based on the following documents:
Description (Date: 13/12/2023)
Drawings (Date: 13/12/2023)
Claims (Date: 26/07/2024)

Reference is made to the following document/s:
D1: US 2014309558 A1 [BECTON DICKINSON CO [US]] - 16/10/2014
D2: US 2014073990 A1 [THERANOS INC [US]] - 13/03/2014

As detailed below, my decision regarding the allowability of the claims is as follows:
Claim/s 1-26 is/are not allowable according to Section 17(a) of the Law, due to deficiencies.
Please see the reasoning below.

According to **Regulation 41,** I hereby inform you that the application contains the following deficiencies:

1. **The examination is based on the following notices:**

1.1 I hereby inform you that:

According to **Section 24(c) of the Law**, the date of the present application, which is a divisional application of application number 300848, is deemed to be the same (22/07/2016) as that of the parent application.

2. Novelty and Inventive step

2.1 Claims 1-2,4,6-15,17,19-26 do not meet the requirements of **Section 5 of the Law,** since the subject matter of the claims does not involve an inventive step in view of documents: D1 ,D2.

Independent Claim 1:
D1 discloses a blood sampling device with:

- An inlet port (Fig. 5-6 element 40; [0037])
- An outlet port (Fig. 5-6 elements 45-48; [0038])
- A chamber (Fig. 1; [0037]) connected to the inlet port
- A sampling channel (Fig. 1, element 42; [0037]) connected to the inlet port and configured to convey a subsequent portion of the blood sample to the outlet port

D1 also mentions that the chamber collects an initial portion of blood ([0017]). However, D1 does not explicitly disclose that the chamber collects the first portion "when under a drawing force applied from the outlet port from a blood sample collection device."
In a similar field of endeavour, D2 teaches a blood sampling system where a drawing force from a blood collection device is used to draw blood through the system ([0164,0186,0188]).

It would have been obvious to a person of ordinary skill in the art to modify the device of D1 to use a drawing force from the outlet port as taught by D2. This modification would provide the advantage of using a single force to both collect the initial portion in the chamber and draw the subsequent portion through the sampling channel, simplifying the blood collection process.

Independent Claim 14:
Starting from D1 as the closest prior art, the differences are:

1. The chamber is made of flexible material
2. The chamber collects blood under a drawing force from the outlet port

Regarding difference 1, D2 teaches a blood sampling device with a flexible reservoir for collecting a portion of blood ([0251]). It would have been obvious to use a flexible material

for the chamber in D1 to allow for visual or tactile indication of when the chamber is filled. Regarding difference 2, as discussed for claim 1, this would have been obvious in view of D2.

Claims 2 and 15:
D1 disclose a blood impermeable membrane facilitating the chamber collecting the first portion of the blood sample ([0035]).

Claims 4 and 17:
A separate housing is a common feature in medical devices and would have been obvious to include.

Claims 6-9 and 19-22:
Valves for controlling fluid flow are common in the art (see D2: [0043],[0166]).

Claims 10 and 23:
A housing defining the ports and channels is a common feature in medical devices and would have been obvious to include.

Claims 11 and 24:
Including a patient needle and sample collection device would have been obvious for a complete blood sampling system.

Claims 12-13 and 25-26:
None of D1-D4 explicitly disclose the claimed volume ranges. However, optimizing the volume of a sampling chamber is routine experimentation and thus and would have been obvious to include.

Therefore, the subject matter of claims 1-2,4,6-15,17,19-26 lacks inventive step.

2.2 Claims 3,5,16,18 meet the requirements of **Sections 4 and 5 of the Law**, because the invention defined in the claims was not published prior to the application date and it involves an inventive step.

3. <u>The claims</u>

3.1 Claims 1-26 do not meet the requirements of **Section 13(a) of the Law**, since the claimed subject matter is not reasonably supported by the specification.

Independent Claim 1:

- The specification primarily describes the sequestration chamber filling due to the patient's blood pressure, not a drawing force from the outlet port. While vacuum force is mentioned (paragraph [0046]), it's not the primary mechanism described for filling the sequestration chamber in most embodiments.
- The specification doesn't explicitly describe the chamber as "configured to collect a first portion of the blood sample when under a drawing force applied from the outlet port."

Independent Claim 14:

- While flexible materials are mentioned, the specification doesn't explicitly describe the chamber itself as being made of a flexible material in most embodiments. The primary descriptions involve rigid or semi-rigid housings.
- As with Claim 1, the specification doesn't focus on using a drawing force from the outlet port as the primary mechanism for filling the sequestration chamber.

Claims 2-4,15-17 introduce a "blood impermeable membrane." While the specification describes air permeable blood barriers, it doesn't explicitly use the term "blood impermeable membrane" in the same context.

The volume specification in claims 13 and 26 (less than 1.5 cubic centimeters) is not explicitly supported in the specification, which mentions volumes ranging from less than the volume of the patient needle to 20 times or more of the volume of the patient needle (paragraph [0050]).

Claims 5-12,18-25 is not reasonably supported by the specification due to their dependency on claims 1 and 14, respectively.

3.2 Claims 1-3,13-14,16,26 do not meet the requirements of **Regulation 20(a)(3)**, since the subject matter of the claims is not clear or concise.

Independent Claim 1:

- The term "drawing force" is unclear. It's not immediately evident what constitutes a "drawing force" or how it's applied "from the outlet port."
- The phrase "from a blood sample collection device" is ambiguous. It's not clear if this refers to the drawing force or the outlet port.

Independent Claim 14:

- The relative term "flexible material" is unclear without further definition or context of what kind of flexibility is refered to.
- The "drawing force" issue noted in Claim 1 applies here as well.

Claims 2 and 15 introduce a "blood impermeable membrane" without clear context of its relationship to other elements.

Claims 3 and 16 use the phrase "causes the first portion of the blood sample to back up", which lack clarity.

Claims 13 and 26 specify a volume "less than 1.5 cubic centimeters" without clear context of what this volume refers to.

3.3 Claims 12,25 do not meet the requirements of **Regulation 20(a)(3)**, since the subject matter of the claims is not clear regarding the relative term "sufficient". Please note that the description does not include a clear definition for this term. Therefore, to meet the requirements of **Regulation 20(a)(3)**, this term must be replaced with a clear term, based on a reasonable support by the description of the present application.

Applicant's duty to notify the office according Section 18 of the Law

Please note: according to **Section 18A of the Law,** it is the applicant's duty to notify the Office on any change occurring in the list of citations or publications according to **Section 18(a) of the Law.** Attention is drawn to **Section 18C of the Law** regarding means of enforcement with respect to applicant's duty under **Section 18 of the Law**.

Filing amendments to the specification during examination

If amendments are made to the specification, please refer to **Regulation 22(a)**. A full copy of the amended part of the application must be sent to the Office, in which the amendments are clearly marked. Additions should be underlined (i.e. example) and deletions noted by strikethrough (i.e. ~~example~~). **Parts of the specification that have not been amended should not be resubmitted**.

Please note:

a) According to Regulations 22(b) and 42, if amendments to the specification are made to rectify the deficiencies stated in this Notice, you must specify the deficiencies for which these

amendments are intended to rectify, explain how the amendments rectify them, and, regarding amendments made to the claims, how they satisfy the requirements of Section 13 of the Law.
b) According to the provisions of Circular 034/2017-Patents, amending the specification by replacing an already examined invention, and for which objection was raised, with another invention, even if it the latter was previously claimed or only described and even if it is supported by the specification as originally filed, will not be considered as overcoming the objection, and it will lead to issuing a Notice before Refusal.

The application documents can be accessed at the following link:
https://israelpatents.justice.gov.il/#/en/patent-file/details/309380

Interview with the examiner

According to the Examination Guidelines published on the ILPO's website, an interview may be held with the examiner either at the ILPO or alternatively by telephone or videoconference. The ILPO encourages direct contact using this service between the examiner and the applicant or the representative. Conducting an interview with the examiner generally allows for a streamlined examination process and for cost saving measures throughout the overall process. During the interview, the applicant has the opportunity to explain and clarify the invention and to discuss the objections raised during the examination and the possible amendments that may be made in order to overcome them.
The interviews need to be coordinated directly with the examiner (please see the contact details below), and should include a written notice from the person initiating the interview, specifying the topics to be discussed and the main arguments pertaining to these topics.
Please note that a request for an interview does not constitute a response to a Notice of Deficiencies according to Regulation 42.

Objection before the Commissioner

According to **Section 161 of the Law**, the applicant is entitled to object to my decision before Commissioner within four months from the date of this Notice.

With hope for better, peaceful and safer days ahead.

Sincerely



Albert Akerman
Senior Patent Examiner
Phone: 073-3927233
Email: albertak@justice.gov.il
Team Leader: Moria Shlomo Levi

INFORMATION DISCLOSURE STATEMENT BY APPLICANT		
	Application Number	18/898,239
	Filing Date	09/26/2024
	First Named Inventor	Bobby E. Rogers
	Art Unit	
	Client Number	069366
Page 1 of 1	**Matter Number**	0581370_KUR2C07US

GENERAL

Pursuant to 37 C.F.R. 1.97 and 1.98 and to the duty of disclosure set forth in 37 C.F.R. 1.56, the Examiner in charge of the above-identified application is requested to consider and make of record the references listed herewith. A copy of each listed reference, other than U.S. patents/applications and references cited in a parent application, is enclosed.

Although the information submitted herewith may be "material" to the Examiner's consideration of the subject application, this submission is not intended to constitute an admission that such information is "prior art" as to the claimed invention, nor is it intended to constitute an admission that such information is "analogous prior art".

In accordance with 37 C.F.R. 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.

TIMING

In accordance with 37 CFR 1.97(b), this Information Disclosure Statement is being filed within three months of the filing of a national application other than a continued prosecution application under 37 CFR 1.53(d); within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 in an international application; before the mailing of a first Office Action on the merits; or before the mailing of a first Office Action after the filing of a request for continued examination under 37 CFR 1.114.

CERTIFICATION STATEMENT

No certification statement is required. This Information Disclosure Statement is being filed in accordance with 37 CFR 1.97(b).

FEE

No fee is required. This Information Disclosure Statement is being filed in accordance with 37 CFR 1.97(b).

ADDITIONAL COMMENTS

SIGNATURE

Signature	/Benjamin F. Hudson/	**Date**	2024-10-16
Name	Benjamin F. Hudson	**Registration Number**	71,474

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PTO/SB/08a (01-22)
Approved for use through 05/31/2024. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	18898239
	Filing Date	2024-09-26
	First Named Inventor	Bobby E. Rogers
	Art Unit	
	Examiner Name	
	Attorney Docket Number	069366-0581370_KUR2C07US

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					

If you wish to add additional U.S. Patent citation information please click the Add button. Add

U.S.PATENT APPLICATION PUBLICATIONS Remove

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20140309558		2014-10-16	FLETCHER GARY D	
	2	20140073990		2014-03-13	HOLMES ELIZABETH A	
	3	20140323911		2014-10-30	SLOAN DEBORAH	
	4	20040112808		2004-06-17	TAKAGI YOSHIKI	

If you wish to add additional U.S. Published Application citation information please click the Add button. Add

FOREIGN PATENT DOCUMENTS Remove

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] ¡	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]

PC 6.1.24

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	18898239
	Filing Date	2024-09-26
	First Named Inventor	Bobby E. Rogers
	Art Unit	
	Examiner Name	
	Attorney Docket Number	069366-0581370_KUR2C07US

	1							☐

If you wish to add additional Foreign Patent Document citation information please click the Add button Add

NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1	Office Action (Notice of Deficiencies) dated 10/14//2023 for IL App No. 309380 (pages 1-7).	☐

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	18898239
	Filing Date	2024-09-26
	First Named Inventor	Bobby E. Rogers
	Art Unit	
	Examiner Name	
	Attorney Docket Number	069366-0581370_KUR2C07US

CERTIFICATION STATEMENT

Please see 37 CFR 1.97(e) to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☒ A certification statement is not submitted herewith.

FEE

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

COPIES

☐ An identification of an earlier application pursuant to 37 CFR 1.98 (d) (1) is attached.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2024-10-16
Name/Print	Benjamin F. Hudson	Registration Number	71,474

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

UNITED STATES
PATENT AND TRADEMARK OFFICE

P.O. Box 1450
Alexandria, VA 22313 - 1450
www.uspto.gov

ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
18/898,239	**10/16/2024 03:06:28 PM Z ET**	**069366-0581370_KUR2C07US**

Title of Invention

BLOOD SAMPLE OPTIMIZATION DEVICE

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	7801	FILED BY	Trent Tercenio
PATENT CENTER #	67592582	FILING DATE	-
CUSTOMER #	27500	FIRST NAMED INVENTOR	Bobby E. Rogers
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	Benjamin Hudson

Documents

TOTAL DOCUMENTS: 3

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
069366-0581370_KUR2C07US_Transmittal-Letter.pdf	1	Transmittal Letter	493 KB
069366-0581370_KUR2C07US_PTO_IDS-Form.pdf	4	Information Disclosure Statement (IDS) Form (SB08)	1272 KB
069366-0581370_KUR2C07US-NPL-001.pdf	7	Non Patent Literature	4168 KB

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)

069366-0581370_KUR2C07US_Transmittal-Letter.pdf	636A35CB54D8BD6B047BA76EFDADFCB2ED85AD07857ACD87B582B3C703D5252DC320F35578B98B24BD74A56603DF8BB1A7B6C3544D285D64FCF50B346E225E03
069366-0581370_KUR2C07US_PTO_IDS-Form.pdf	BC14257785CD42422CD8AEE11789A0D66FF8E80B7DCBC42A32A9DDB087676997EA8AFF6DA1B0438E65AB13585CA431623EBECA373206EF7F25457075CAF9C7FD
069366-0581370_KUR2C07US-NPL-001.pdf	F549969621B94689DE598C3ACEBAB475954F40FA021634C54F45C4E25863B61C755B7D476712F1F40ACD5CC2A828BF7E2BFE698466803265425D23E5537768C8

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
18/898,239	09/26/2024		824	069366-0581370_KUR2C07US	24	2

CONFIRMATION NO. 7801

27500
PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
ATTENTION: DOCKETING DEPARTMENT
P.O BOX 10500
McLean, VA 22102

FILING RECEIPT

OC000000079453941

Date Mailed: 10/18/2024

Receipt is acknowledged of this non-provisional utility patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF FIRST INVENTOR, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection.

Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please submit a written request for a corrected Filing Receipt, including a properly marked-up ADS showing the changes with strike-through for deletions and underlining for additions. If you received a "Notice to File Missing Parts" or other Notice requiring a response for this application, please submit any request for correction to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections provided that the request is grantable.

Inventor(s)

Bobby E. Rogers, Park City, CA;
Gino Kang, Irvine, CA;
John Detloff, San Diego, CA;

Applicant(s)

Kurin, Inc., San Diego, CA;

Assignment For Published Patent Application

Kurin, Inc., San Diego, CA

Power of Attorney: None

Domestic Priority data as claimed by applicant

This application is a CON of 18/783,088 07/24/2024
which is a CON of 18/494,622 10/25/2023
which is a CON of 18/113,710 02/24/2023 PAT 11,832,944
which is a CON of 17/538,990 11/30/2021 PAT 11,963,769
which is a CON of 16/208,559 12/04/2018 PAT 11,185,266
which is a CON of 15/994,559 05/31/2018 PAT 10,143,412
which is a CON of 15/140,448 04/27/2016 PAT 10,010,282
which claims benefit of 62/318,194 04/04/2016
and claims benefit of 62/238,636 10/07/2015
and claims benefit of 62/196,797 07/24/2015

Foreign Applications for which priority is claimed (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see http://www.uspto.gov for more information.) - None.
Foreign application information must be provided in an Application Data Sheet in order to constitute a claim to foreign priority. See 37 CFR 1.55 and 1.76.

Permission to Access Application via Priority Document Exchange: Yes

Permission to Access Search Results: Yes

Applicant may provide or rescind an authorization for access using Form PTO/SB/39 or Form PTO/SB/69 as appropriate.

If Required, Foreign Filing License Granted: 10/17/2024

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 18/898,239**

Projected Publication Date: 01/23/2025

Non-Publication Request: No

Early Publication Request: No
**** SMALL ENTITY ****
Title

BLOOD SAMPLE OPTIMIZATION DEVICE

Preliminary Class

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: No

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

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Title 37, Code of Federal Regulations, 5.11 & 5.15

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PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number: 18/898,239

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY FEE($)
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	64		N/A	
SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	280		N/A	
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	320		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	24 minus 20 =	* 4	x 40 =	160	OR		
INDEPENDENT CLAIMS (37 CFR 1.16(h))	2 minus 3 =	*	x =	0			
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			0			
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				0			
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	824		TOTAL	

APPLICATION AS AMENDED - PART II

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY ADDITIONAL FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE($)
AMENDMENT A	Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE($)	ADDITIONAL FEE($)	OR	RATE($)	ADDITIONAL FEE($)
AMENDMENT B	Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

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Kathi Vidal

Kathi Vidal
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

Derrick Brent
Deputy Under Secretary of Commerce for Intellectual Property and
Deputy Director of the United States Patent and Trademark Office

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/898,239	09/26/2024	Bobby E. Rogers	069366-0581370_KUR2C07US	7801

27500 7590 11/06/2024

PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
ATTENTION: DOCKETING DEPARTMENT
P.O BOX 10500
McLean, VA 22102

EXAMINER
CENTRAL, DOCKET

ART UNIT	PAPER NUMBER
OPAP	

NOTIFICATION DATE	DELIVERY MODE
11/06/2024	ELECTRONIC

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Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Docket_IP@pillsburylaw.com

PTOL-90A (Rev. 04/07)

Decision Granting Request for Prioritized Examination (Track I)	**Application No.** 18/898,239	**Applicant(s)** Rogers et al.	
	Examiner FIKIRTE A GEREMEW	**Art Unit** OMBL	**AIA (FITF) Status** Yes

1. THE REQUEST FILED 26 September 2024 IS **GRANTED** .

The above-identified application has met the requirements for prioritized examination

A. ☑ for an original nonprovisional application (Track I).
B. ☐ for an application undergoing continued examination (RCE).

2. **The above-identified application will undergo prioritized examination**. The application will be accorded special status throughout its entire course of prosecution until one of the following occurs:

A. filing a **petition for extension of time** to extend the time period for filing a reply;

B. filing an **amendment to amend the application to contain more than four independent claims, more than thirty total claims** , or a multiple dependent claim;

C. filing a **request for continued examination** ;

D. filing a notice of appeal;

E. filing a request for suspension of action;

F. mailing of a notice of allowance;

G. mailing of a final Office action;

H. completion of examination as defined in 37 CFR 41.102; or

I. abandonment of the application.

Telephone inquiries with regard to this decision should be directed to FIKIRTE GEREMEW at (703) 756-1930. In his/her absence, calls may be directed to Petition Help Desk at (571) 272-3282.

/FIKIRTE A GEREMEW/ PROGRAM SUPPORT SPECIALIST, OMBL	

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FROM: noreply@uspto.gov
CC: patentcenter_eofficeaction@uspto.gov
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Fri Oct 18 05:00:19 EDT 2024

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Application	Document	Mailroom Date	Attorney Docket No.
18898239	APP.FILE.REC	10/18/2024	069366-0581370_KUR2C07US
18898239	WELCOME.LET	10/18/2024	069366-0581370_KUR2C07US

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McLean,VIRGINIA,22102
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Application	Document	Mailroom Date	Attorney Docket No.
18898239	TRACK1.GRANT	11/06/2024	069366-0581370_KUR2C07US

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/898,239	09/26/2024	Bobby E. Rogers	069366-0581370_KUR2C07US	7801

27500 7590 11/22/2024

PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
ATTENTION: DOCKETING DEPARTMENT
P.O BOX 10500
McLean, VA 22102

EXAMINER	
ABOUELELA, MAY A	

ART UNIT	PAPER NUMBER
3791	

NOTIFICATION DATE	DELIVERY MODE
11/22/2024	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

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Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 18/898,239	Applicant(s) Rogers et al.	
	Examiner MAY A ABOUELELA	Art Unit 3791	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 09/26/2024.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL.** 2b) ☑ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 1-9,11-22 and 24-26 is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 1-9,11-22 and 24-26 is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to **PPHfeedback@uspto.gov.**

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☑ The drawing(s) filed on 09/26/2024 is/are: a)☑ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☑ Notice of References Cited (PTO-892)

2) ☑ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

Notice of Pre-AIA or AIA Status

1. The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 09/27/2024 and 10/16/2024. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a)(1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention.

Claim(s) 1, 6-9, 11, 12, 14, 19-22, 24 and 25 is/are rejected under 35 U.S.C. 102(a)(1) as being anticipated by Patton et al (US 2008/0145933).

As to claims 1 and 14, Patton discloses a device (blood sampling device 500, par.38-40, fig.5) comprising:

an inlet port for receiving a blood sample (inlet/opening connecting needle 508 to input tubing 514, par.38-40, fig.5);

an outlet port (needle 510, fig.5);

a chamber (tubing 516 and reservoir 504, par.38-40, fig.5) comprising a flexible material (flexible material of tubing 516 and reservoir 504), wherein the chamber is connected with the inlet port (516 and 504 are connected to inlet of tubing 514, as best seen in fig.5) and configured to collect a first portion of the blood sample (diversion mechanism 512 can be initially adjusted to divert blood to the one or more pre-sample reservoirs 504 until the one or more pre-sample reservoirs 504 are filled, par.40, fig.5) when under a drawing force applied from the outlet port from a blood sample collection device (pre vacuumed effect of vessel 506 withdraws blood, first needle 508 can be inserted into a patient to procure a blood sample. In FIG. 5, the first needle 508 is shown inserted into a vein 520. The second needle 510 is shown inserted into the one or more sample vessels 506 that have been vacuum-sealed. The vacuum in each of the one or more sample vessels 506 causes blood to pass from the vein 520 to the diversion mechanism 512, par.40); and

a sampling channel (tubings 514 and 518 connected with inlet of tubing 214, par.38-40, as best seen in fig.4) connected with the inlet port and configured to convey a subsequent portion of the blood sample to the outlet port (which point the diversion mechanism 512 can be adjusted to divert the flow of blood to the one or more sample vessels 506, ar.38-40, fig.5).

As to claims 6 and 19, Patton discloses the device, further comprising a valve (diversion mechanism 512 having valve 60, par.38-41, fig.5) configured to initially close off the sampling channel (diversion mechanism 512 can be initially adjusted to divert blood to the one or more pre-sample reservoirs 504 until the one or more pre-sample reservoirs

504 are filled, or a desired amount of blood has been withdrawn, at which point the diversion mechanism 512 can be adjusted to divert the flow of blood to the one or more sample vessels 506, par.40).

As to claims 7 and 20, Patton discloses the device, further comprising a valve configured to initially close off the sampling channel until the first portion of the blood sample is in the chamber (diversion mechanism 512 can be initially adjusted to divert blood to the one or more pre-sample reservoirs 504 until the one or more pre-sample reservoirs 504 are filled, or a desired amount of blood has been withdrawn, at which point the diversion mechanism 512 can be adjusted to divert the flow of blood to the one or more sample vessels 506, par.40).

As to claims 8 and 21, Patton discloses the device, further comprising a valve that is configured to initially close off the sampling channel until the first portion of the blood sample is in the chamber and is further configured such that, upon release, follow-on amounts of the blood sample will bypass the chamber and flow through the sampling channel toward the outlet port (diversion mechanism 512 can be initially adjusted to divert blood to the one or more pre-sample reservoirs 504 until the one or more pre-sample reservoirs 504 are filled, or a desired amount of blood has been withdrawn, at which point the diversion mechanism 512 can be adjusted to divert the flow of blood to the one or more sample vessels 506, par.40, as best seen from fig.5 the subsequent blood will bypass reservoir 504 and flows straight from inlet of 502 to tubings 514 and 518).

As to claims 9 and 22, Patton discloses the device, wherein the valve is configured to pinch, shunt, bend or otherwise close off the sampling channel before the first portion of the blood sample is collected in the chamber (diversion mechanism 512 can be initially adjusted to divert blood to the one or more pre-sample reservoirs 504 until the one or more pre-sample reservoirs 504 are filled, or a desired amount of blood has been withdrawn, at which point the diversion mechanism 512 can be adjusted to divert the flow of blood to the one or more sample vessels 506, par.40, fig.5).

As to claims 11 and 24, Patton discloses the device, further comprising a patient needle (patient needle 508, par.38-40, fig.5) and a sample collection device (sample vessel 506, par.38-40, fig.5).

As to claims 12 and 25, Patton discloses the device, the chamber having a volume sufficient to collect the first portion of the blood sample that is more prone to contamination and also to minimize an amount of blood to be sequestered (the data suggests that fewer false positive test results for the presence of microbes in blood are obtained over conventional methods when initially-drawn volumes of blood are not used in microbial testing, par.54).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have

> been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim(s) 2-5 and 15-18 is/are rejected under 35 U.S.C. 103 as being obvious over Patton et al (US 2008/0145933) in view of Flaherty et al (US 2006/0009713).

As to claims 2-5 and 15-18, Patton discloses the invention substantially above, wherein a housing of the diverting mechanism is separate from a blood impermeable membrane, but failed to explicitly teach a blood impermeable membrane is configured to facilitate the chamber collecting the first portion of the blood sample, and causes the first portion of the blood sample to back up into the chamber following application of the drawing force applied from the outlet port, and wherein the device is configured such that, when the drawing force is applied at the outlet port, the first portion of the blood sample is drawn into the chamber to contact a material that is blood impermeable.

However, Flaherty discloses an analogous blood sampling device, wherein the blood sampling chamber comprises (liquid impenetrable, air-permeable membrane 45, par.39, fig.8-10), wherein blood flows into the blood collection chamber 39, air is displaced from the blood collection chamber 39, through the membrane 45 and air opening or openings 46, respectively. This facilitates the substantially continual and unhindered flow of blood from the patient 106 and into the blood collection chamber 39 to collect the desired quantity of blood into the blood collection chamber 39 (par.40, fig.8-10).

Since blood impermeable membrane is well-known in the art, so it would have been obvious to one having an ordinary skill in the art before the effective filing date of the invention to include a blood impermeable membrane in reservoir 504 taught by Patton's invention, as blood impermeable membrane 45 taught by Flaherty's invention to

facilitate the continual and unhindered flow of blood from the patient and into the blood collection chamber, as taught by Flaherty's invention (par.40).

5. Claim(s) 13 and 26 is/are rejected under 35 U.S.C. 103 as being obvious over Patton et al (US 2008/0145933).

As to claims 13 and 26, Patton discloses the volume of blood withdrawn into the one or more pre-sample reservoirs 504 is at least equal to the collective volumes of the first needle 508, the flexible, sterile input tubing 516, the diversion mechanism 512, and the first sterile output tubing 516 (par.40), but failed to explicitly teach he chamber has a volume of less than 1.5 cubic centimeters. However, it would have been obvious to one having an ordinary skill in the art at the time the invention was made to allow reservoir 504 to collect blood volume less than 1.5 cubic centimeters, since it has been that discovering the optimum value of a result of effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215(CCPA 1980).

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the claims at issue are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s)

because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the reference application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO internet Web site contains terminal disclaimer forms which may be used. Please visit http://www.uspto.gov/forms/. The filing date of the application will determine what form should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to http://www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp.

Claims 1-9, 11-22 and 24-26 are non-provisionally rejected on the ground of non-statutory double patenting as being unpatentable over claims 1-24 of U.S Patent No. 12,138,052. Although the claims at issue are not identical, they are not patentably

distinct from each other because the U.S Patent Application and the instance application are claiming a common subject matter including: a device comprising: an inlet port for receiving a blood sample; an outlet port; a chamber connected with the inlet port and configured to collect a first portion of the blood sample when under a drawing force applied from the outlet port from a blood sample collection device; and a sampling channel connected with the inlet port and configured to convey a subsequent portion of the blood sample to the outlet port.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MAY A ABOUELELA whose telephone number is (571)270-7917. The examiner can normally be reached 8-5.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JACQUELINE CHENG can be reached on 5712725596. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center,

visit: https://patentcenter.uspto.gov. Visit https://www.uspto.gov/patents/apply/patent-center for more information about Patent Center and https://www.uspto.gov/patents/docx for information about filing in DOCX format. For additional questions, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MAY A ABOUELELA/
Primary Examiner, Art Unit 3791

Notice of References Cited	Application/Control No. 18/898,239	Applicant(s)/Patent Under Reexamination Rogers et al.	
	Examiner MAY A ABOUELELA	Art Unit 3791	Page 1 of 4

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*	B	US-4412548-A	1983-11-01	Hoch; Louis	A61B5/150213	600/577
*	C	US-5222502-A	1993-06-29	Kurose; Katsutoshi	A61B5/150732	600/584
*	D	US-5520193-A	1996-05-28	Suzuki; Issei	A61B5/1545	604/126
*	E	US-20100057004-A1	2010-03-04	Christensen; Kelly D.	A61M25/0606	604/122
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*	G	US-20080145933-A1	2008-06-19	Patton; Richard G.	A61B10/0051	435/379
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*	L	US-20100010372-A1	2010-01-14	BROWN; LEROY R.	A61B5/15003	600/573
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Notice of References Cited	Application/Control No. 18/898,239	Applicant(s)/Patent Under Reexamination Rogers et al.	
	Examiner MAY A ABOUELELA	Art Unit 3791	Page 2 of 4

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*	G	US-6398743-B1	2002-06-04	Halseth; Thor R.	A61B5/15003	604/164.12
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*	K	US-20120016266-A1	2012-01-19	Burkholz; Jonathan Karl	A61B5/150992	600/581
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Notice of References Cited	Application/Control No. 18/898,239	Applicant(s)/Patent Under Reexamination Rogers et al.	
	Examiner MAY A ABOUELELA	Art Unit 3791	Page 3 of 4

U.S. PATENT DOCUMENTS

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*	L	US-20130317391-A1	2013-11-28	Bullington; Gregory J.	A61B5/15003	600/578
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Notice of References Cited	Application/Control No. 18/898,239	Applicant(s)/Patent Under Reexamination Rogers et al.	
	Examiner MAY A ABOUELELA	Art Unit 3791	Page 4 of 4

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*	B	US-5749857-A	1998-05-12	Cuppy; Michael J.	A61M25/0606	604/161
*	C	US-9060724-B2	2015-06-23	Bullington; Gregory J.	A61B5/150221	1/1
*	D	US-9204864-B2	2015-12-08	Bullington; Gregory J.	A61B10/0096	1/1
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*	F	US-3817240-A	1974-06-18	Ayres; Waldemar A.	A61B5/150221	600/584
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*	K	US-20160325085-A1	2016-11-10	Chelak; Todd	F16K7/20	1/1
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Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	18/898,239	Rogers et al.
	Examiner	Art Unit
	MAY A ABOUELELA	3791

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

CLAIMS

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	11/13/2024								
	1	✓								
	2	✓								
	3	✓								
	4	✓								
	5	✓								
	6	✓								
	7	✓								
	8	✓								
	9	✓								
	10	-								
	11	✓								
	12	✓								
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	14	✓								
	15	✓								
	16	✓								
	17	✓								
	18	✓								
	19	✓								
	20	✓								
	21	✓								
	22	✓								
	23	-								
	24	✓								
	25	✓								
	26	✓								

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	18/898,239	Rogers et al.
	Examiner	Art Unit
	MAY A ABOUELELA	3791

CPC - Searched*		
Symbol	Date	Examiner
(A61B5/150992 or A61B5/15003 or A61B5/150213 or A61B5/150221 or A61B5/150389 or A61B5/150473 or A61B5/150572 or A61B5/153 or A61B5/154 or A61M39/04 or A61M39/0693 or A61M2039/0202 or A61M2039/0633 or A61M2039/068).cpc.	11/13/2024	MA

CPC Combination Sets - Searched*		
Symbol	Date	Examiner

US Classification - Searched*			
Class	Subclass	Date	Examiner

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	Date	Examiner
inventor name search, class/subclass search, text search	11/13/2024	MA

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner

/MAY A ABOUELELA/ Primary Examiner, Art Unit 3791	

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	18898239
	Filing Date	2024-09-26
	First Named Inventor	Bobby E. Rogers
	Art Unit	
	Examiner Name	
	Attorney Docket Number	069366-0581370_KUR2C07US

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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	2	5432084		1995-07-11	BRUBAKER DANIEL B	
	3	5972294		1999-10-26	SMITH JOHN L	
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	Attorney Docket Number	069366-0581370_KUR2C07US

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	10	4412548		1983-11-01	HOCH LOUIS	
	11	5222502		1993-06-29	KUROSE KATSUTOSHI	
	12	5520193		1996-05-28	SUZUKI ISSEI	
	13	9022951		2015-05-05	BULLINGTON GREGORY	
	14	6569117		2003-05-27	ZIV DAVID	
	15	3741197		1973-06-26	SANZ M	
	16	8603009		2013-12-10	TAN ALVIN CHEE LEONG	
	17	4207870		1980-06-17	ELDRIDGE WILLIAM N	
	18	9877675		2018-01-30	BAID RISHI	
	19	4444203		1984-04-24	ENGELMAN ALLAN	

PC 6.1.24

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	21	9022950		2015-05-05	BULLINGTON GREGORY	
	22	4436098		1984-03-13	KAUFMAN JOSEPH	
	23	9138572		2015-09-22	ZEYTOONIAN PAUL	
	24	8568371		2013-10-29	SIOPES WILLIAM	
	25	8540663		2013-09-24	DAVEY CHRISTOPHER T	
	26	8523826		2013-09-03	LAYTON JR RUSSELL K	
	27	4057050		1977-11-08	SARSTEDT WALTER	
	28	8864684		2014-10-21	BULLINGTON GREGORY J	
	29	5749857		1998-05-12	CUPPY MICHAEL J	
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PC 6.1.24

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	32	3886930		1975-06-03	RYAN GEORGE R	
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PC 6.1.24

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	54	5865803		1999-02-02	MAJOR MIKLOS	
	55	5873841		1999-02-23	BRANNON JAMES K	
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	57	6913580		2005-07-05	STONE BENJAMIN CURTIS	
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	65	3848579		1974-11-19	VILLA REAL A	
	66	6106509		2000-08-22	LOUBSER PAUL G	
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	68	6224561		2001-05-01	SWENDSON DAVID L	
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PC 6.1.24

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	Art Unit	
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	Attorney Docket Number	069366-0581370_KUR2C07US

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	18898239
	Filing Date	2024-09-26
	First Named Inventor	Bobby E. Rogers
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	First Named Inventor	Bobby E. Rogers
	Art Unit	
	Examiner Name	
	Attorney Docket Number	069366-0581370_KUR2C07US

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	Application Number	18898239
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	Examiner Name	
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	Art Unit	
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	Application Number	18898239
	Filing Date	2024-09-26
	First Named Inventor	Bobby E. Rogers
	Art Unit	
	Examiner Name	
	Attorney Docket Number	069366-0581370_KUR2C07US

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	Examiner Name	
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PC 6.1.24

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.A.A/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	18898239
	Filing Date	2024-09-26
	First Named Inventor	Bobby E. Rogers
	Art Unit	
	Examiner Name	
	Attorney Docket Number	069366-0581370_KUR2C07US

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	Filing Date	2024-09-26
	First Named Inventor	Bobby E. Rogers
	Art Unit	
	Examiner Name	
	Attorney Docket Number	069366-0581370_KUR2C07US

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	18898239
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	First Named Inventor	Bobby E. Rogers
	Art Unit	
	Examiner Name	
	Attorney Docket Number	069366-0581370_KUR2C07US

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[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	18898239
	Filing Date	2024-09-26
	First Named Inventor	Bobby E. Rogers
	Art Unit	
	Examiner Name	
	Attorney Docket Number	069366-0581370_KUR2C07US

CERTIFICATION STATEMENT

Please see 37 CFR 1.97(e) to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☒ A certification statement is not submitted herewith.

FEE

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

COPIES

☐ An identification of an earlier application pursuant to 37 CFR 1.98 (d) (1) is attached.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2024-09-27
Name/Print	Benjamin F. Hudson	Registration Number	71,474

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

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7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

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PE2E SEARCH - Search History (Prior Art)

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L84	6183	L83 AND ((A61B10/0096 OR A61B5/150022).CPC.)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2017/09/28 04:01 PM
L85	387	L84 and (vent$4 near4 air)	(US-PGPUB; USPAT)	OR	OFF	OFF	2017/09/28 04:01 PM
L86	362	L85 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2017/09/28 04:02 PM
L87	12	("2005/0010189").URPN.	(USPAT)	OR	OFF	OFF	2017/09/28 04:03 PM
L88	1363	(604/164.01).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2017/09/28 04:04 PM
L89	74	L88 and (blood near4 (sequest$5 or	(US-PGPUB; USPAT)	OR	OFF	OFF	2017/09/28 04:05 PM

		sampl$4))					
L90	21	("3965910" | "3996923" | "4131127" | "4301811" | "4450854" | "4506691" | "4819684" | "5147333" | "5393035" | "5636975").PN. OR ("6569117").URPN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2017/09/28 04:09 PM
L91	499	(435/294.1).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2017/09/28 04:12 PM
L92	18	L91 and (blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2017/09/28 04:12 PM
L93	9	("2008/0145933").URPN.	(USPAT)	OR	OFF	OFF	2017/09/28 04:13 PM
L95	67	(("ROGERS") near3 ("Bobby")).INV.	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/01/09 04:23 PM
L96	1258	(600/583).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2018/01/09 04:25 PM
L97	4	L96 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/01/09 04:25 PM
L98	3	L97 and (blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/01/09 04:26 PM
L99	1733	(600/573).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2018/01/09 04:50 PM
L100	13	L99 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/01/09 04:50 PM
L101	255	("1779451" | "2004050" | "2700385" | "2836942" | "2854976" | "2953243" | "3021942" | "3073307" | "3074542" | "3255873" | "3294231" | "3323523" | "3329146" | "3333682" | "3367488" | "3382865" | "3485239" | "3537452" | "3585984" | "3610240" | "3658061" | "3664879" | "3817240" | "3828775" | "3859998" | "3874367" | "3886930" | "3890971" | "3904033" | "3934722" | "3968876" | "4106497" | "4108175" | "4113090" | "4139009" | "4154229" | "4166450" | "4175008" | "4193400" | "4207870" | "4269186" | "4300678" | "4312362" | "4317445" | "4340068" | "4375849" | "4398544" | "4409990" | "4412548" | "4416290" | "4416291" | "4418703"	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2018/01/09 04:51 PM

		| "4430082" | "4436098" | "4444203" | "4592744" | "4634428" | "4643722" | "4659330" | "4664249" | "4664654" | "4671408" | "4679571" | "4681567" | "4695274" | "4702738" | "4723943" | "4728320" | "4728321" | "4731059" | "4735311" | "4735618" | "4737144" | "4738663" | "4743233" | "4746008" | "4747836" | "4747837" | "4772272" | "4778453" | "4781697" | "4782841" | "4788986" | "4790828" | "4793484" | "4795432" | "4795443" | "4801295" | "4804372" | "4813426" | "4816022" | "4816024" | "4819659" | "4820277" | "4826490" | "4826491" | "4838871" | "4842587" | "4844089" | "4846796" | "4850968" | "4850976" | "4850977" | "4850978" | "4850994" | "4850996" | "4858607" | "4863434" | "4863435" | "4863436" | "4865592" | "4867746" | "4872552" | "4874383" | "4874384" | "4883469" | "4886072" | "4886503" | "4888001" | "4892107" | "4892521" | "4894052" | "4900309" | "4909791" | "4909792").PN. OR ("4921096" | "4927018" | "4944397" | "4966591" | "4971068" | "4976699" | "4982842" | "5011475" | "5011479" | "5030207" | "5032116" | "5033476" | "5055102" | "5069225" | "5078693" | "5078698" | "5092845" | "5112327" | "5116325" | "5120319" | "5122121" | "5135509" | "5137518" | "5139489" | "5151089" | "5154285" | "5181523" | "5188611" | "5197954" | "5201794" | "5207653" | "5217025" | "5222502" | "5232454" | "5232455" | "5242411" | "5242417" | "5277311" | "5290246" | "5295969" | "5303713" | "5306259"					

		| "5312369" | "5401251" | "5405332" | "5423765" | "5450856" | "5462534" | "5485854" | "5486163" | "5490841" | "5496281" | "5509907" | "5520193" | "5533984" | "5542932" | "5584816" | "5599313" | "5599318" | "5603699" | "5632732" | "5643219" | "5662617" | "5665075" | "5669889" | "5693022" | "5697914" | "5702369" | "5733265" | "5755701" | "5807351" | "5830190" | "5836920" | "5885249" | "5893844" | "5913846" | "5984895" | "5993426" | "6059737" | "6077244" | "6077253" | "6080137" | "6096006" | "6110160" | "6120482" | "6156010" | "6190370" | "6261263" | "6511439" | "6533760" | "6964658" | "7160267" | "RE31086").PN. OR ("7615033").URPN.					
L102	215	L101 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/01/09 04:51 PM
L103	1347	(604/164.01).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2018/01/09 05:11 PM
L104	17	L103 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/01/09 05:11 PM
L105	19	("2009/0312711").URPN.	(USPAT)	OR	OFF	OFF	2018/01/09 05:11 PM
L106	11	("2007/0106220").URPN.	(USPAT)	OR	OFF	OFF	2018/01/09 05:11 PM
L107	288967	(blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2018/01/09 05:16 PM
L108	6321	L107 AND ((A61B10/0096 OR A61B5/150022).CPC.)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2018/01/09 05:16 PM
L109	121	L108 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/01/09 05:17 PM
L110	448	(435/294.1).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2018/01/09 05:31 PM
L111	6	L110 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/01/09 05:31 PM
L113	71	(("ROGERS") near3 ("Bobby")).INV.	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/07/24 01:31 PM
L114	0	("15140443").PN.	(US-PGPUB; USPAT;	OR	OFF	OFF	2018/07/24

			USOCR)				01:38 PM
L115	2	(15/140443).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2018/07/24 01:38 PM
L116	2	(15/140448).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2018/07/24 01:40 PM
L117	1735	(600/573).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2018/07/24 01:56 PM
L118	854	L117 and (blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/07/24 01:56 PM
L119	91	L118 and (vent$4 near4 air)	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/07/24 01:57 PM
L120	1258	(600/583).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2018/07/24 02:06 PM
L121	1074	L120 and (blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/07/24 02:06 PM
L122	80	L121 and (vent$4 near4 air)	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/07/24 02:06 PM
L123	301210	(blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2018/07/24 02:11 PM
L124	6556	L123 AND ((A61B10/0096 OR A61B5/150022).CPC.)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2018/07/24 02:11 PM
L125	3664	L124 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/07/24 02:12 PM
L126	12749	"19" and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/07/24 02:12 PM
L127	117	L125 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/07/24 02:12 PM
L128	1348	(604/164.01).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2018/07/24 02:16 PM
L129	75	L128 and (blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/07/24 02:17 PM
L130	1	("20120291564").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2018/07/24 02:21 PM
L131	448	(435/294.1).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2018/07/24 02:25 PM
L132	18	L131 and (blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/07/24 02:25 PM
L133	98	("20020002349" | "20020183651" | "20030055381" | "20030208151" | "20040010228" | "20040054333" |	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2018/07/24 02:44 PM

		"20040147855" | "20050004524" | "20050240161" | "20050245885" | "20050281713" | "20060287639" | "20080108954" | "20080145933" | "2707953" | "3013557" | "3098016" | "3382865" | "3405706" | "3494351" | "3577980" | "3648684" | "3848579" | "3937211" | "4057050" | "4133863" | "4166450" | "4340067" | "4370987" | "4444203" | "4459997" | "4509534" | "4657160" | "4676256" | "4865583" | "4890627" | "4988339" | "5009847" | "5097842" | "5108927" | "5122129" | "5269317" | "5330464" | "5360011" | "5429610" | "5450856" | "5507299" | "5577513" | "5762633" | "5865812" | "5882318" | "5922551" | "6016712" | "6057105" | "6159164" | "6210909" | "6364890" | "6387086" | "6403381" | "6626884" | "6692479" | "6746420" | "6913580" | "7044941" | "7087047" | "7335188" | "7744573" | "8197420" | "8231546" | "8337418").PN. OR ("8535241").URPN.					
L134	307	("2913000" | "3817240" | "3859998" | "3864979" | "4016879" | "4046144").PN. OR ("4207870").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2018/07/24 02:47 PM
L135	23	("4166450").PN. OR ("4412548").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2018/07/24 02:48 PM
L136	307	("2913000" | "3817240" | "3859998" | "3864979" | "4016879" | "4046144").PN. OR ("4207870").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2018/07/24 02:48 PM
L137	4	("2007/0088279").URPN.	(USPAT)	OR	ON	ON	2018/07/24 02:48 PM
L138	1	(14/990763).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2018/07/24 02:58 PM
L139	9	(blood and sequest$5 and junction and first	(US-PGPUB; USPAT)	OR	ON	ON	2018/07/24 03:07 PM

		and portion and sampl$4).clm.					
L140	1	(15/287421).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2018/07/25 09:39 PM
L141	2	(14/055232).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2018/07/26 11:56 AM
L142	2	(15/140443).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/07 03:24 PM
L143	1	(15/893518).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/07 03:25 PM
L144	34	("20020004647"|"20030105414"|"20040054333"|"20040073171"|"20040147855"|"20050004524"|"20050240161"|"20070088279"|"20080145933"|"20100057004"|"20130317391"|"20160174888"|"3817240"|"3874367"|"3886930"|"4057050"|"4106497"|"4154229"|"4207870"|"4412548"|"5222502"|"5520193"|"5749857"|"6569117"|"8197420"|"8523826"|"8535241"|"8540663"|"8568371"|"8864684"|"9022951"|"9060724"|"9138572"|"9204864").PN.	(US-PGPUB; USPAT)	OR	ON	ON	2019/11/07 05:53 PM
L145	272	((("ROGERS") near3 ("Bobby")) OR (("KANG") near3 ("Gino")) OR (("STROUP") near3 ("David")) OR (("COCHRAN") near3 ("Jonas")) OR (("DEPTALA") near3 ("Arthur")) OR (("DETLOFF") near3 ("John")) OR (("POGUE") near3 ("Lonnie")) OR (("MACOWSKI") near3 ("Brian")) OR (("GARRETT") near3 ("Chad"))).INV.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2019/11/07 05:57 PM
L146	9	L145 and (blood near4 sequest$5)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 05:58 PM
L147	34	("20020004647"|"20030105414"|"20040054333"|"20040073171"|"20040147855"|"20050004524"|"20050240161"|"20070088279"|"200801459	(US-PGPUB; USPAT)	OR	ON	ON	2019/11/07 06:26 PM

		33"|"20100057004"|"20130317391"|"20160174888"|"3817240"|"3874367"|"3886930"|"4057050"|"4106497"|"4154229"|"4207870"|"4412548"|"5222502"|"5520193"|"5749857"|"6569117"|"8197420"|"8523826"|"8535241"|"8540663"|"8568371"|"8864684"|"9022951"|"9060724"|"9138572"|"9204864").PN.					
L148	5	L147 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 06:29 PM
L149	6	("2010/0057004").URPN.	(USPAT)	OR	ON	ON	2019/11/07 06:40 PM
L150	0	L149 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 07:20 PM
L151	1258	(600/583).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2019/11/07 07:21 PM
L152	4	L151 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 07:21 PM
L153	1766	(600/573).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/07 07:21 PM
L154	13	L153 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 07:21 PM
L155	811	(600/576).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/07 07:22 PM
L156	48	L155 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 07:22 PM
L157	1351	(604/164.01).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2019/11/07 07:43 PM
L158	17	L157 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 07:43 PM
L159	448	(435/294.1).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2019/11/07 07:43 PM
L160	6	L159 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 07:44 PM
L161	333030	(blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2019/11/07 07:44 PM
L162	6981	L161 AND ((A61B10/0096 OR A61B5/150022).CPC.)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2019/11/07 07:44 PM
L163	139	L162 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 07:44 PM
L164	117	L163 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 07:45 PM
L165	1	L146 and (enclos$3	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07

		near4 mechanism)					07:51 PM
L166	1	("7637875").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/08 04:57 PM
L167	1	(15/139716).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/11 12:09 PM
L168	1	(15/520430).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/12 11:02 AM
L169	1	("7637875").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/12 12:11 PM
L170	1	("20120253321").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/12 12:13 PM
L171	1	(15/861959).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/12 12:14 PM
L172	1	("4207870").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/12/09 02:17 PM
L173	1	("5749857").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/12/09 03:14 PM
L174	1	("20080167577").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/12/09 03:19 PM
L175	4	("2008/0167577").URPN.	(USPAT)	OR	ON	ON	2019/12/09 03:30 PM
L176	1	("8197420").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/12/09 03:31 PM
L177	39	(US-20040073171-$ or US-20160174888-$ or US-20050240161-$ or US-20040147855-$ or US-20130317391-$ or US-20050004524-$ or US-20030105414-$ or US-20020004647-$ or US-20100057004-$ or US-20070088279-$ or US-20080145933-$ or US-20040054333-$ or US-20100010372-$ or US-20080319346-$ or US-20080167577-$).did. or (US-9138572-$ or US-8568371-$ or US-8540663-$ or US-8523826-$ or US-8197420-$ or US-4057050-$ or US-8864684-$ or US-8535241-$ or US-5749857-$ or US-9060724-$ or US-9204864-$ or US-3817240-$ or US-3874367-$ or US-3886930-$ or US-4106497-$ or US-4154229-$ or US-	(US-PGPUB; USPAT)	OR	ON	ON	2019/12/09 03:37 PM

		4207870-$ or US-4412548-$ or US-5222502-$ or US-5520193-$ or US-9022951-$ or US-6569117-$ or US-3741197-$ or US-8603009-$).did.					
L178	8	("20040054333"|"8197420"|"9855001"|"9861306"|"10045724"|"10028687"|"8337418"|"10028689").PN.	(US-PGPUB; USPAT)	OR	ON	ON	2019/12/09 03:42 PM
L179	100	("20020002349" | "20020183651" | "20030055381" | "20040010228" | "20040054333" | "20040147855" | "20050004524" | "20050240161" | "20050245885" | "20050281713" | "20060287639" | "2707953" | "3013557" | "3098016" | "3382865" | "3405706" | "3494351" | "3577980" | "3648684" | "3848579" | "3937211" | "4057050" | "4133863" | "4166450" | "4340067" | "4370987" | "4444203" | "4459997" | "4509534" | "4676256" | "4865583" | "4890627" | "4988339" | "5009847" | "5097842" | "5108927" | "5122129" | "5269317" | "5360011" | "5429610" | "5450856" | "5507299" | "5577513" | "5762633" | "5882318" | "5922551" | "6016712" | "6057105" | "6159164" | "6210909" | "6364890" | "6387086" | "6403381" | "6692479" | "6746420" | "6913580" | "7044941" | "7087047").PN. OR ("8197420").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2019/12/09 03:43 PM
L180	70	L179 and (blood near4 (sequest$5 or sampl$4 or flash$4))	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2019/12/09 03:43 PM
L181	43	L180 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 03:44 PM
L182	270	((("BULLINGTON")	(US-PGPUB; USPAT;	OR	ON	ON	2019/12/09

		near3 ("Gregory")) OR (("PATTON") near3 ("Richard")) OR (("MIAZGA") near3 ("Jay")) OR (("GAW") near3 ("Shan"))).INV.	USOCR; EPO; JPO; DERWENT)				04:13 PM
L183	335813	(blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2019/12/09 04:22 PM
L184	7259	L183 AND ((A61B10/0096 OR A61B5/150022).CPC.)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2019/12/09 04:22 PM
L185	325	("2913000" | "3817240" | "3859998" | "3864979" | "4016879" | "4046144").PN. OR ("4207870").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2019/12/09 04:33 PM
L186	594	L184 and (flash$6 and seal$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 04:40 PM
L187	476	L186 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 04:40 PM
L188	1735	(600/573).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2019/12/09 05:14 PM
L189	1123	L188 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:15 PM
L190	1013	L189 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:15 PM
L191	10	L190 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:16 PM
L192	1259	(600/583).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/12/09 05:23 PM
L193	1143	L192 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:23 PM
L194	1038	L193 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:23 PM
L195	3	L194 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:23 PM
L196	811	(600/576).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/12/09 05:24 PM
L197	618	L196 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:24 PM
L198	557	L197 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:24 PM
L199	1	(15/854273).APP.	(US-PGPUB; USPAT;	OR	OFF	OFF	2019/12/09

			USOCR)				05:25 PM
L200	1351	(604/164.01).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2019/12/09 05:31 PM
L201	219	L200 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:33 PM
L202	199	L201 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:33 PM
L203	448	(435/294.1).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2019/12/09 05:36 PM
L204	44	L203 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:37 PM
L205	1	(15/508871).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/12/10 11:58 AM
L206	342199	(blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2020/03/16 12:53 PM
L207	4239	L206 AND ((A61B10/0096 OR A61B5/150022).CPC.)	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 12:53 PM
L208	146	L207 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 12:54 PM
L209	101	L208 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 12:55 PM
L210	1735	(600/573).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2020/03/16 01:38 PM
L211	1123	L210 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:38 PM
L212	1013	L211 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:39 PM
L213	22	L212 and (((vent$4 or open$5 or hole or aperture) near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:39 PM
L214	108	("20020193748" | "20030093009" | "20030105414" | "20030220614" | "20030229315" | "20040059302" | "20040092872" | "20040193120" | "20050004524" | "20050065482" | "20050124944" | "20050187493" | "20050245868" |	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2020/03/16 01:46 PM

		"20050245869" | "20050245870" | "20050245879" | "20050245885" | "20060036219" | "20060224122" | "20070106220" | "20070106224" | "20070167914" | "20080086085" | "20080177202" | "20080319345" | "20080319346" | "20090204026" | "20100262038" | "4106497" | "4207870" | "4305406" | "4572210" | "4573976" | "4641663" | "4795443" | "4840619" | "4894055" | "4900307" | "4994046" | "5015241" | "5195985" | "5215534" | "5222502" | "5242417" | "5246428" | "5256153" | "5295970" | "5303713" | "5312372" | "5336199" | "5348544" | "5356392" | "5411492" | "5439449" | "5466223" | "5501675" | "5542932" | "5599313" | "5662617" | "5665075" | "5672161" | "5676658" | "5702369" | "5704920" | "5733265" | "5755522" | "5957892" | "5984899" | "6149629" | "6224576" | "6254575" | "6261263" | "6298541" | "6344032" | "6436086" | "6440104" | "6524277" | "6533760" | "6592556" | "6623456" | "6635032" | "6648855" | "6695819" | "6699217" | "6712792" | "6780169" | "6837877" | "6869415" | "6984223" | "7001363" | "7128726" | "7147624" | "7160267" | "7163526" | "7223258" | "7226432" | "7396343" | "7428773" | "7537581" | "7766879" | "D422700" | "D442280" | "D604836" | "D604837" | "D604838" | "D604839" | "D605287").PN. OR ("8603009").URPN.					

L215	26	L214 and (((vent$4 or open$5 or hole or aperture) near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:47 PM
L216	27	("2008/0319346").URPN.	(USPAT)	OR	ON	ON	2020/03/16 01:47 PM
L217	23	("2003/0105414").URPN.	(USPAT)	OR	ON	ON	2020/03/16 01:48 PM
L218	1258	(600/583).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2020/03/16 01:52 PM
L219	1143	L218 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:52 PM
L220	25	L219 and (((vent$4 or open$5 or hole or aperture) near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:52 PM
L221	353695	((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:54 PM
L222	3643	L221 and (((vent$4 or open$5 or hole or aperture) near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:55 PM
L223	1926	L222 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:55 PM
L224	785	L223 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:56 PM
L225	7046	(600/300).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/03/16 02:32 PM
L226	14	L225 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 02:35 PM
L227	1352	(604/164.01).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2020/03/16 02:36 PM
L228	135	L227 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 02:36 PM
L229	19	L228 and (((vent$4 or open$5 or hole or aperture) near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 02:36 PM
L230	448	(435/294.1).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2020/03/16 02:47 PM
L231	3	L230 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 02:47 PM
L232	19	("2008/0145933").URPN.	(USPAT)	OR	ON	ON	2020/03/16 02:48 PM
L233	795	(600/576).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2020/03/16

							02:58 PM
L234	71	L233 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 02:58 PM
L235	57	L234 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 02:59 PM
L236	371	(600/577).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/03/16 03:12 PM
L237	11	L236 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 03:12 PM
L238	45	("20040054333"|"20050240161"|"4412548"|"5749857"|"8197420"|"9855001"|"9861306"|"20020004647"|"20100057004"|"3741197"|"20040073171"|"3874367"|"4057050"|"4106497"|"8197420"|"8535241"|"8540663"|"8603009"|"8864684"|"10045724"|"3817240"|"10028687"|"20030105414"|"5222502"|"5520193"|"6569117"|"8568371"|"20040147855"|"20070088279"|"20080145933"|"20100010372"|"3886930"|"8523826"|"9060724"|"9204864"|"8337418"|"20050004524"|"20080167577"|"20080319346"|"20130317391"|"4154229"|"9022951"|"10028689"|"20160174888"|"4207870"|"9138572").PN.	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 03:13 PM
L239	6	("2008/0167577").URPN.	(USPAT)	OR	ON	ON	2020/03/16 03:13 PM
L240	118	("3500828" | "3670729" | "3714945" | "3977400" | "3994293" | "3995619" | "4106491" | "4200096" | "4468224" | "4531987" | "4549554" | "4735215" | "4828548" | "4874373" | "4893635" | "4894052" | "4907599" | "4944308" | "4994042" | "5129884" | "5400798").PN. OR ("5749857").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2020/03/16 03:15 PM
L241	6	("2008/0167577").URPN.	(US-PGPUB; USPAT)	OR	ON	ON	2020/03/16 03:15 PM
L242	274	((("BULLINGTON") near3 ("Gregory")) OR	(US-PGPUB; USPAT; USOCR; EPO; JPO;	OR	ON	ON	2020/03/16 03:25 PM

		(("PATTON") near3 ("Richard")) OR (("MIAZGA") near3 ("Jay")) OR (("GAW") near3 ("Shan"))).INV.	DERWENT)				
L243	61	L242 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 03:25 PM
L244	1	(15/854273).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/03/16 03:47 PM
L245	0	(14/502498).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/03/16 04:11 PM
L246	1	("20110082383").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/03/16 04:24 PM
L247	1	("8150506").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/03/16 04:24 PM
L252	1	(15/057214).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/03/17 11:28 AM
L253	348964	(blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2020/06/10 05:22 PM
L254	7453	L253 AND ((A61B10/0096 OR A61B5/150022).CPC.)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2020/06/10 05:22 PM
L255	155	L254 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 05:23 PM
L256	77	(("ROGERS") near3 ("Bobby")).INV.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 05:35 PM
L257	343953	(blood same (sequest$5 or sampl$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 05:40 PM
L258	11	L256 and (blood same (sequest$5 or sampl$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 05:41 PM
L259	1	("5749857").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 05:50 PM
L260	121	("3500828" | "3670729" | "3714945" | "3977400" | "3994293" | "3995619" | "4106491" | "4200096" | "4468224" | "4531987" | "4549554" | "4735215" | "4828548" | "4874373" | "4893635" | "4894052" | "4907599" | "4944308" | "4994042" | "5129884" | "5400798").PN. OR ("5749857").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2020/06/10 06:19 PM
L261	32	L260 and (blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:20 PM

L262	1	("3648684").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 06:38 PM
L263	1	("4056101").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 06:38 PM
L264	329	(600/577).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2020/06/10 06:39 PM
L265	11	L264 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:39 PM
L266	29	("2008/0319346").URPN.	(USPAT)	OR	ON	ON	2020/06/10 06:40 PM
L267	812	(600/576).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 06:40 PM
L268	72	L267 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:40 PM
L269	1767	(600/573).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 06:44 PM
L270	31	L269 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:45 PM
L271	77	("4676249" | "4787891" | "4850960" | "4874382" | "4886067" | "4886500" | "4900307" | "4904242" | "4917102" | "4950252" | "4955862" | "5046508" | "5116353" | "5125718" | "5129884" | "5163911" | "5217435" | "5290244" | "5295974" | "5314503" | "5318585" | "5330432" | "5360410" | "5366441" | "5376075" | "5395337" | "5531692" | "5695475" | "5695479" | "5702367" | "5735813" | "5749857" | "5788654" | "5800395" | "5846226" | "5871470" | "5882342" | "5919172" | "5935108" | "5935113" | "5989220" | "6050976" | "6077244" | "6099504" | "6126641" | "6162195").PN. OR ("6398743").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2020/06/10 06:46 PM
L272	18	L271 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:46 PM
L273	1	(15/893518).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 06:48 PM
L274	7050	(600/300).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 06:49 PM

L275	14	L274 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:49 PM
L276	1259	(600/583).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 06:51 PM
L277	7	L276 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:51 PM
L278	1368	(604/164.01).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 06:52 PM
L279	135	L278 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:52 PM
L280	499	(435/294.1).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 07:08 PM
L281	3	L280 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 07:08 PM
L282	20	("2008/0145933").URPN.	(USPAT)	OR	ON	ON	2020/06/10 07:08 PM
L286	1	("10045704").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 08:56 PM
L287	1	("10143412").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/01 09:16 PM
L288	1	("10010282").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/01 09:17 PM
L289	100	((("ROGERS") near3 ("Bobby")) OR (("KANG") near3 ("Gino")) OR (("DETLOFF") near3 ("John"))).INV.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2021/03/01 09:17 PM
L290	2	(15/140443).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/01 09:36 PM
L291	1	(15/855439).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/01 09:39 PM
L292	180	(("ROGERS") near3 ("Bobby")).INV.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2021/03/02 12:19 PM
L293	11	L292 and (blood near4 sequest$5)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 12:20 PM
L294	2	(15/140443).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 12:47 PM
L295	1	(15/855439).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 12:49 PM
L296	1	("20020048170").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 01:36 PM
L297	1	("20040174525").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 01:49 PM
L298	1	("10045704").PN.	(US-PGPUB; USPAT;	OR	OFF	OFF	2021/03/02

			USOCR)				03:09 PM
L299	27321	(A61B5/150992 or A61B5/15003 or A61B5/150213 or A61B5/150389 or A61B5/150473 or A61B5/150572 or A61B5/154 or A61B5/153 or A61M39/0693 or A61M39/04 or A61B5/150221 or A61M2039/0633 or A61M2039/0202 or A61M2039/068).cpc.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2021/03/02 03:17 PM
L300	4594	L299 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 03:27 PM
L301	3762	L300 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 03:28 PM
L302	257	L301 and (air near4 permeab$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 03:29 PM
L303	420	L301 and ((air or gas$4) near4 permeab$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 03:29 PM
L304	1	("20110167658").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 03:30 PM
L305	5	("2015/0306288").URPN.	(USPAT)	OR	ON	ON	2021/03/02 04:15 PM
L306	1	(16/208559).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 04:32 PM
L307	2	("2009/0043225").URPN.	(USPAT)	OR	ON	ON	2021/03/02 04:49 PM
L308	1736	(600/573).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2021/03/02 05:00 PM
L309	1363	L308 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:00 PM
L310	73	L309 and ((air or gas$4) near4 permeab$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:01 PM
L311	73	L310 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:01 PM
L312	812	(600/576).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 05:34 PM
L313	711	L312 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:34 PM
L314	58	L313 and ((air or gas$4) near4 permeab$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:34 PM
L315	58	L314 and	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02

		@ad<"20150724"					05:34 PM
L316	371	(600/577).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 05:42 PM
L317	277	L316 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:42 PM
L318	20	L317 and ((air or gas$4) near4 permeab$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:43 PM
L319	336	("2913000" | "3817240" | "3859998" | "3864979" | "4016879" | "4046144").PN. OR ("4207870").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/03/02 05:44 PM
L320	210	L319 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:44 PM
L321	196	L320 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:44 PM
L322	1259	(600/583).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 05:48 PM
L323	1208	L322 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:48 PM
L324	73	L323 and ((air or gas$4) near4 permeab$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:48 PM
L325	73	L324 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:49 PM
L326	1368	(604/164.01).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 05:59 PM
L327	271	L326 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 06:00 PM
L328	10	L327 and ((air or gas$4) near4 permeab$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 06:00 PM
L329	268	L327 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 06:00 PM
L330	182	(("ROGERS") near3 ("Bobby")).INV.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2021/07/08 02:22 PM
L331	27660	(A61B5/150992 or A61B5/15003 or A61B5/150213 or A61B5/150389 or A61B5/150473 or A61B5/150572 or A61B5/154 or A61B5/153 or	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2021/07/08 03:27 PM

		A61M39/0693 or A61M39/04 or A61B5/150221 or A61M2039/0633 or A61M2039/0202 or A61M2039/068).cpc.					
L332	4684	L331 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 03:28 PM
L333	3769	L332 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 03:29 PM
L334	579	L333 and (vent$4 near4 air)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 03:29 PM
L335	1	("9820682").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/07/08 03:54 PM
L336	1	("4207870").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/07/08 03:56 PM
L337	337	("2913000" | "3817240" | "3859998" | "3864979" | "4016879" | "4046144").PN. OR ("4207870").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/07/08 04:19 PM
L338	211	L337 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:19 PM
L339	196	L338 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:19 PM
L340	37	L339 and (vent$4 near4 air)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:19 PM
L341	221	("20010021827" | "20020004650" | "20020055716" | "20020072715" | "20020103464" | "20020103465" | "20020107488" | "20020151856" | "20020193748" | "20030028171" | "20030036730" | "20030050608" | "20030055385" | "20030078544" | "20030093009" | "20030105414" | "20030114797" | "20030120222" | "20030176842" | "20030181873" | "20030191438" | "20030199827" | "20030216687" |	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/07/08 04:21 PM

		"20030220614" | "20030229315" | "20030229316" | "20040024370" | "20040059302" | "20040092872" | "20040102740" | "20040111068" | "20040193120" | "20040204681" | "20040210197" | "20050004524" | "20050059936" | "20050065482" | "20050124944" | "20050165353" | "20050187493" | "20050228345" | "20050245868" | "20050245869" | "20050245870" | "20050245879" | "20050245885" | "20050283093" | "20060015073" | "20060036217" | "20060036219" | "20060079847" | "20060129064" | "20060189934" | "20060189936" | "20060224122" | "20060270947" | "20060276756" | "20070021724" | "20070027430" | "20070106220" | "20070106224" | "20070167914" | "20070282275" | "20080015513" | "20080086085" | "20080177202" | "20080221528" | "20080269691" | "20080306452" | "20080319345" | "20080319346" | "20090204026" | "20090227896" | "20100063455" | "20100191189" | "20100262038" | "20110118674" | "4106497" | "4207870" | "4305406" | "4572210" | "4573976" | "4641663" | "4795443" | "4813426" |				

		"4840619" | "4887998" | "4894055" | "4900307" | "4923477" | "4994046" | "5015241" | "5195985" | "5215534" | "5219333" | "5222502" | "5242417" | "5246428" | "5256153").PN. OR ("5295970" | "5295975" | "5303713" | "5312372" | "5318547" | "5336199" | "5344408" | "5348544" | "5356392" | "5389085" | "5403286" | "5411492" | "5439449" | "5466223" | "5501675" | "5542932" | "5549558" | "5595566" | "5599313" | "5607402" | "5662617" | "5665075" | "5669889" | "5672161" | "5676658" | "5681295" | "5685855" | "5687740" | "5688241" | "5695474" | "5702369" | "5704920" | "5718239" | "5733265" | "5755522" | "5769826" | "5795336" | "5879337" | "5893845" | "5910130" | "5921964" | "5957892" | "5984899" | "6149629" | "6171284" | "6183445" | "6224576" | "6254575" | "6261263" | "6261265" | "6298541" | "6344032" | "6419658" | "6436086" | "6440104" | "6471677" | "6475191" | "6485469" | "6524277" | "6533760" | "6554807" | "6575939" | "6592556" | "6623456" | "6623461" | "6635032" | "6641555" | "6648855" | "6648856" | "6659983" | "6695819" | "6699217" | "6712792" | "6716199" | "6761704" | "6773419" | "6780169" | "6805689" | "6811545" | "6835190" | "6837877" | "6846302" | "6860872" | "6869415" | "6905483" | "6918891" | "6958054" | "6974423" | "6984223" | "6997913" | "7001363" | "7083600" | "7101355" | "7128726" | "7147624" | "7160267" | "7163526" | "7201740" | "7211065" | "7223258"					

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L342	115	("20020193748" | "20030093009" | "20030105414" | "20030220614" | "20030229315" | "20040059302" | "20040092872" | "20040193120" | "20050004524" | "20050065482" | "20050124944" | "20050187493" | "20050245868" | "20050245869" | "20050245870" | "20050245879" | "20050245885" | "20060036219" | "20060224122" | "20070106220" | "20070106224" | "20070167914" | "20080086085" | "20080177202" | "20080319345" | "20080319346" | "20090204026" | "20100262038" | "4106497" | "4207870" | "4305406" | "4572210" | "4573976" | "4641663" | "4795443" | "4840619" | "4894055" | "4900307" | "4994046" | "5015241" | "5195985" | "5215534" | "5222502" | "5242417" | "5246428" | "5256153" | "5295970" | "5303713" | "5312372" | "5336199" | "5348544" | "5356392" | "5411492" | "5439449" | "5466223" | "5501675" | "5542932" | "5599313" |	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/07/08 04:21 PM

		"5662617" | "5665075" | "5672161" | "5676658" | "5702369" | "5704920" | "5733265" | "5755522" | "5957892" | "5984899" | "6149629" | "6224576" | "6254575" | "6261263" | "6298541" | "6344032" | "6436086" | "6440104" | "6524277" | "6533760" | "6592556" | "6623456" | "6635032" | "6648855" | "6695819" | "6699217" | "6712792" | "6780169" | "6837877" | "6869415" | "6984223" | "7001363" | "7128726" | "7147624" | "7160267" | "7163526" | "7223258" | "7226432" | "7396343" | "7428773" | "7537581" | "7766879" | "D422700" | "D442280" | "D604836" | "D604837" | "D604838" | "D604839" | "D605287").PN. OR ("8603009").URPN.					
L343	148	("20020193748" | "20030105414" | "20030229315" | "20040059302" | "20040092872" | "20050004524" | "20050187493" | "20050245868" | "20050245869" | "20050245870" | "20050245885" | "20060036219" | "20070106220" | "20070167914" | "20080086085" | "20080177202" | "4106497" | "4207870" | "4305406" | "4573976" | "4641663" | "4795443" | "4840619" | "4894055" | "4900307" | "4994046" | "5015241" | "5195985" | "5215534" | "5222502" | "5242417" | "5256153" | "5295970" | "5303713" | "5312372" | "5336199" | "5348544" | "5356392" | "5411492" | "5439449" | "5466223" | "5501675" | "5542932" | "5672161" |	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/07/08 04:21 PM

		"5676658" | "5702369" | "5704920" | "5755522" | "5984899" | "6149629" | "6261263" | "6298541" | "6436086" | "6440104" | "6524277" | "6533760" | "6592556" | "6623456" | "6635032" | "6648855" | "6699217" | "6712792" | "6780169" | "6837877" | "6869415" | "6984223" | "7001363" | "7128726" | "7147624" | "7160267" | "7163526" | "7223258" | "7226432" | "7396343" | "7428773" | "D422700" | "D442280").PN. OR ("7766879").URPN.					
L344	41	("2735430" | "2798487" | "3187749" | "3240209" | "3585984" | "3817240" | "4166450" | "4207870" | "4295477" | "4312362").PN. OR ("4436098").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/07/08 04:22 PM
L345	163	L341 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:22 PM
L346	163	L345 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:23 PM
L347	22	("2005/0283093").URPN.	(USPAT)	OR	ON	ON	2021/07/08 04:23 PM
L348	163	L345 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:27 PM
L349	163	L348 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:27 PM
L350	1736	(600/573).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2021/07/08 04:37 PM
L351	1363	L350 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:37 PM
L352	1346	L351 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:38 PM
L353	136	L352 and (vent$4 near4 air)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:38 PM
L354	812	(600/576).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/07/08 04:41 PM
L355	711	L354 and ((blood or fluid$4) near4 (sequest$5 or sampl$4	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:41 PM

		or flash$4 or collect$4))					
L356	699	L355 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:41 PM
L357	123	L356 and (vent$4 near4 air)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:41 PM
L358	371	(600/577).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/07/08 04:44 PM
L359	277	L358 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:45 PM
L360	260	L359 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:45 PM
L361	1259	(600/583).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/07/08 04:46 PM
L362	1208	L361 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:46 PM
L363	1194	L362 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:47 PM
L364	1194	L363 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:47 PM
L366	1	("9820682").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:05 PM
L367	319	((("BULLINGTON") near3 ("Gregory")) OR (("PATTON") near3 ("Richard")) OR (("MIAZGA") near3 ("Jay")) OR (("GAW") near3 ("Shan"))).INV.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2022/02/02 03:14 PM
L368	1	(16/376745).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:35 PM
L369	190	(("ROGERS") near3 ("Bobby")).INV.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2022/02/02 03:36 PM
L370	2	(15/140448).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:41 PM
L371	1	("9820682").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:42 PM
L372	1	("9060725").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:42 PM
L373	1	("9060724").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:43 PM
L374	1	("9022950").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:45 PM
L375	1	("9022951").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:45 PM
L376	1	("10292633").PN.	(US-PGPUB; USPAT;	OR	OFF	OFF	2022/02/02

			USOCR)				03:46 PM
L377	1	("10433779").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:47 PM
L378	1	("10436554").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:48 PM
L379	1	("10736554").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:49 PM
L380	1	("10912506").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:49 PM
L381	1	("10010282").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:49 PM
L382	1	(16/376745).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:50 PM
L383	1	("9820682").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:51 PM
L384	276	(600/579).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:52 PM
L385	204	L384 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/02/02 03:53 PM
L386	37427	(A61B5/150221 or A61B5/15003 or A61B5/150236 or A61B5/150244 or A61B5/150251 or A61B5/150389 or A61B5/150503 or A61B5/150992 or A61B5/153 or A61B5/155 or A61B10/0048 or A61B10/0051 or A61B10/007 or A61B2010/0061 or A61B2010/0077 or A61B2010/008).cpc.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2022/02/02 04:35 PM
L387	7279	L386 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/02/02 04:36 PM
L388	4442	L387 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/02/02 04:36 PM
L389	874	L388 and (seal$4 near4 (member or mechanism$4 or vent$4 or elastic$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/02/02 04:38 PM
L390	26	("2008/0145933").URPN.	(USPAT)	OR	ON	ON	2022/02/02 04:52 PM
L391	44	("2008/0319346").URPN.	(USPAT)	OR	ON	ON	2022/02/02 04:59 PM
L392	385	L386 and ((blood or fluid) near4 (seal$4 near4 (member or	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/02/02 05:28 PM

		mechanism$4 or vent$4 or elastic$4)))					
L393	171	L392 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/02/02 05:28 PM
L394	355	(604/103).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 05:52 PM
L395	7	L394 and ((blood or fluid) near4 (seal$4 near4 (member or mechanism$4 or vent$4 or elastic$4)))	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/02/02 05:52 PM
L396	1	(16/328127).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/03 12:00 PM
L397	0	"1020130062845"	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/02/04 04:17 PM
L398	8	"20130062845"	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/02/04 04:17 PM
L399	14	"2013021595"	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/02/04 04:18 PM
L400	2	(14/055232).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/04 07:10 PM
L401	1	(15/746656).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/05 11:48 AM
L402	0	(17/388440).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/07 09:34 AM
L403	1	("20050048465").PN.	(US-PGPUB; USPAT)	OR	ON	ON	2022/02/07 09:34 AM
L404	196	(("ROGERS") near3 ("Bobby")).INV.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2022/05/18 03:08 PM
L405	16	L404 and (blood near4 sequest$5)	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/05/18 03:08 PM
L406	16	L404 and ((blood or chamber) near4 sequest$5)	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/05/18 03:08 PM
L407	16	L406 and (junct$4 or bypass$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/05/18 03:09 PM
L408	16	L406 and junct$4	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/05/18 03:09 PM
L409	22445	(A61B5/150992 or A61B5/15003 or A61B5/150213 or A61B5/150221 or A61B5/150389 or A61B5/150473 or	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2022/05/18 03:54 PM

		A61B5/150572 or A61B5/154 or A61B5/15074).cpc.					
L410	4525	L409 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4 or flush$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/05/18 03:55 PM
L411	3810	L410 and @ad<"20170210"	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/05/18 03:56 PM
L412	820	L411 and ((vent$4 or open$4 or apertur$4) near4 air)	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/05/18 03:57 PM
L413	22445	(A61B5/150992 or A61B5/15003 or A61B5/150213 or A61B5/150221 or A61B5/150389 or A61B5/150473 or A61B5/150572 or A61B5/154 or A61B5/15074).cpc.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2022/05/18 05:51 PM
L414	4603	L413 and ((blood or fluid$4 or chamber) same (sequest$5 or sampl$4 or flash$4 or collect$4 or flush$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/05/18 05:51 PM
L415	511	L414 and ((junct$4 or bypass$4 or divert$4) near4 (blood or fluid))	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/05/18 05:52 PM
L416	355	L415 and @ad<"20170210"	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/05/18 05:53 PM
L417	1	(16/819033).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/05/18 06:10 PM
L418	1	(17/094692).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/05/18 06:25 PM
L419	1	(17/538990).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/05/18 06:25 PM
L420	1	("11311219").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/05/18 06:27 PM
L421	1	("11185266").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/05/18 06:30 PM
L422	1	("10143412").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/05/18 06:31 PM
L423	1	("9820682").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/05/18 06:32 PM
L424	331	((("BULLINGTON") near3 ("Gregory")) OR (("PATTON") near3 ("Richard")) OR (("MIAZGA") near3 ("Jay")) OR (("GAW") near3 ("Shan"))).INV.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2022/06/06 03:44 PM

L425	8944	(A61B5/150221 OR A61B5/15003 OR A61B5/150236 OR A61B5/150244 OR A61B5/150251 OR A61B5/150389 OR A61B5/150503 OR A61B5/150992 OR A61B5/153 OR A61B5/155 OR A61B10/0048 OR A61B10/0051 OR A61B10/007 OR A61B2010/0061 OR A61B2010/0077 OR A61B2010/008).cpc.	(US-PGPUB; USPAT)	OR	ON	ON	2022/06/06 05:17 PM
L426	58747	(A61B5/150221 OR A61B5/15003 OR A61B5/150236 OR A61B5/150244 OR A61B5/150251 OR A61B5/150389 OR A61B5/150503 OR A61B5/150992 OR A61B5/153 OR A61B5/155 OR A61B10/0048 OR A61B10/0051 OR A61B10/007 OR A61B2010/0061 OR A61B2010/0077 OR A61B2010/008).cpc.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/06/06 05:17 PM
L427	7420	426 AND ((blood OR fluid$4) near4 (sequest$5 OR sampl$4 OR flash$4 OR collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/06/06 05:18 PM
L428	4441	427 AND @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/06/06 05:18 PM
L429	846	428 AND (seal$4 near4 (member OR mechanism$4 OR vent$4 OR elastic$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/06/06 05:20 PM
L430	2	"17525682"	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/06/06 05:46 PM
L431	547	426 AND (((blood OR fluid$4) near4 (sequest$5 OR bypass$4 OR flash$4)) AND seal$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/06/06 05:50 PM
L432	231	431 AND @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/06/06 05:50 PM
L433	1	18/113710	(US-PGPUB; USPAT)	OR	ON	ON	2023/08/22 02:58 PM
L434	209	(("ROGERS") near3	(US-PGPUB; USPAT;	OR	OFF	OFF	2023/08/22

		("Bobby")).INV.	USOCR; FPRS; EPO; JPO; DERWENT)				03:09 PM
L435	21	434 AND (((blood OR fluid$4) near4 (sequest$5 OR bypass$4 OR flash$4)) AND seal$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/08/22 03:09 PM
L436	9	"20100057004"	(US-PGPUB; USPAT)	OR	ON	ON	2023/08/22 03:11 PM
L437	49165	(A61B5/150992 OR A61B5/15003 OR A61B5/150213 OR A61B5/150221 OR A61B5/150389 OR A61B5/150473 OR A61B5/150572 OR A61B5/153 OR A61B5/154 OR A61M39/04 OR A61M39/0693 OR A61M2039/0202 OR A61M2039/0633 OR A61M2039/068 OR A61B5/150251).cpc.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/08/22 03:49 PM
L438	33727	(A61B5/150992 OR A61B5/15003 OR A61B5/150213 OR A61B5/150389 OR A61B5/150473 OR A61B5/150572 OR A61B5/154 OR A61B5/153 OR A61M39/0693 OR A61M39/04 OR A61B5/150221 OR A61M2039/0633 OR A61M2039/0202 OR A61M2039/068 OR A61B5/150251).cpc.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/08/22 03:51 PM
L439	36143	438 AND @ad<"20150724"	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2023/08/22 03:52 PM

L440	3944	439 AND ((blood OR fluid$4) near4 (sequest$5 OR bypass$4 OR flash$4 OR collect$4 OR sampl$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/08/22 03:52 PM
L441	1473	440 AND (seal$4 near4 (member OR mechanism$4 OR vent$4 OR elastic$4 OR filter$4 OR material$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/08/22 03:53 PM
L442	8	"20080167577"	(US-PGPUB; USPAT)	OR	ON	ON	2023/08/22 04:42 PM
L443	115	440 AND (seal$4 near4(expos$4 OR contact$4) near5 (blood OR fluid))	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/08/22 04:58 PM
L444	116	440 AND (seal$4 near4(expos$4 OR contact$4 OR absorb$4) near5 (blood OR fluid))	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/08/22 04:59 PM
L445	1	18/317558	(US-PGPUB; USPAT)	OR	ON	ON	2024/05/06 02:44 PM
L446	303	((("ROGERS") near3 ("Bobby")) OR (("KANG") near3 ("Gino")) OR (("STROUP") near3 ("David")) OR (("COCHRAN") near3 ("Jonas")) OR (("DEPTALA") near3 ("Arthur")) OR (("DETLOFF") near3 ("John")) OR (("POGUE") near3 ("Lonnie")) OR (("MACOWSKI") near3 ("Brian"))).INV.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2024/05/06 02:45 PM
L447	127	446 AND ((blood OR fluid$4) near4 (sequest$5 OR bypass$4 OR flash$4 OR collect$4 OR sampl$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2024/05/06 02:54 PM
L448	122	447 AND (((vent$4 OR open$5 OR hole OR aperture) near5 air) sam (clos$4 OR plug$4 OR cap$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2024/05/06 02:56 PM
L449	3	17/094692	(US-PGPUB; USPAT)	OR	ON	ON	2024/05/06 03:07 PM

L450	46753	(A61B5/150213 OR A61B5/15003 OR A61B5/150221 OR A61B5/150251 OR A61B5/150732 OR A61B5/15074 OR A61B5/150992 OR A61B5/153 OR A61B5/150389 OR A61B5/150503).cpc.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/05/06 03:08 PM
L451	37283	450 AND @ad<"20170210"	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2024/05/06 03:09 PM
L452	4944	451 AND ((blood OR fluid$4) near5 (sequest$5 OR sampl$4 OR flash$4 OR collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2024/05/06 03:14 PM
L453	511	452 AND (((vent$4 OR open$5 OR hole OR aperture) near5 air) SAME (clos$4 OR plug$4 OR cap$4 OR seal$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2024/05/06 03:15 PM
L454	1	("5749857").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/05/06 03:25 PM
L455	233	("3500828" | "3670729" | "3714945" | "3977400" | "3994293" | "3995619" | "4106491" | "4200096" | "4468224" | "4531987" | "4549554" | "4735215" | "4828548" | "4874373" | "4893635" | "4894052" | "4907599" | "4944308" | "4994042" | "5129884" | "5400798").pn. OR	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2024/05/06 03:37 PM

		("5749857").urpn. AND (PGPB | USPT | USOC).dbnm.					
L456	228	455 AND @ad<"20170210"	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2024/05/06 03:37 PM
L457	14	456 AND (((vent$4 OR open$5 OR hole OR aperture) near5 air) SAME (clos$4 OR plug$4 OR cap$4 OR seal$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2024/05/06 03:37 PM
L458	8	"20080145933"	(US-PGPUB; USPAT)	OR	ON	ON	2024/05/06 03:57 PM
L459	387	452 AND (((vent$4 OR open$5 OR hole OR aperture) near5 air) near5 (chamber OR hous$4 OR contain$4 OR tub$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2024/05/06 04:01 PM
L460	601	452 AND (air near5 (displac$4 OR mov$4 OR substit$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2024/05/06 04:22 PM
L461	346	452 AND (air near5 (displac$4 OR substit$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2024/05/06 04:22 PM
L462	1	17/250875	(US-PGPUB; USPAT)	OR	ON	ON	2024/05/06 04:58 PM
L463	1	("5376100").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/05/06 07:06 PM
L464	19	"20140276233"	(US-PGPUB; USPAT)	OR	ON	ON	2024/05/06 07:07 PM
L465	13	"20120101508"	(US-PGPUB; USPAT)	OR	ON	ON	2024/05/06 07:08 PM
L466	2	"20070179473"	(US-PGPUB; USPAT)	OR	ON	ON	2024/05/06 07:09 PM
L467	6	"20060073538"	(US-PGPUB; USPAT)	OR	ON	ON	2024/05/06 07:56 PM
L468	1	18/079528	(US-PGPUB; USPAT)	OR	ON	ON	2024/05/07 01:22 PM

L469	9	"20080145933"	(US-PGPUB; USPAT)	OR	ON	ON	2024/09/30 02:35 PM
L470	122	((("ROGERS") near3 ("Bobby")) OR (("KANG") near3 ("Gino")) OR (("DETLOFF") near3 ("John"))).INV.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2024/09/30 02:39 PM
L471	34	470 AND ((blood OR fluid$4) near4 (sequest$5 OR bypass$4 OR flash$4 OR collect$4 OR sampl$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2024/09/30 02:40 PM
L472	53	("20020004647"|"20030105414"|"20040054333"|"20040073171"|"20040147855"|"20050004524"|"20050240161"|"20060009713"|"20070083162"|"20070088279"|"20080086085"|"20080145933"|"20080167577"|"20080319346"|"20100010372"|"20100057004"|"20120016266"|"20130317391"|"20150314105"|"20150359473"|"20160008579"|"20160073937"|"20160174888"|"3741197"|"3817240"|"3874367"|"3886930"|"4057050"|"4106497"|"4154229"|"4207870"|"4412548"|"4436098"|"4444203"|"5222502"|"5520193"|"5749857"|"6398743"|"6569117"|"8197420"|"8523826"|"8535241"|"8540663"|"8568371"|"8603009"|"8864684"|"9022950"|"9022951"|"9060724"|"9138572"|"9155495"|"9204864"|"9877675").PN.	(US-PGPUB; USPAT)	OR	ON	ON	2024/09/30 02:50 PM
L473	50987	(A61B5/150992 OR A61B5/15003 OR A61B5/150213 OR A61B5/150221 OR A61B5/150389 OR A61B5/150473 OR A61B5/150572 OR A61B5/153 OR A61B5/154 OR A61M39/04 OR A61M39/0693 OR	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO,	OR	ON	ON	2024/09/30 02:57 PM

		A61M2039/0202 OR A61M2039/0633 OR A61M2039/068).cpc.	RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)				
L474	203	455 AND @ad<"20150724"	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2024/09/30 02:58 PM
L475	36038	473 AND @ad<"20150724"	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2024/09/30 02:59 PM
L476	22627	475 AND ((collect$4 OR sampl$4 OR draw$4 OR withdraw$4) near5 (blood OR fluid))	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/09/30 03:02 PM
L477	499	476 AND ((blood OR fluid$4) NEAR (sequest$5 OR	(US-PGPUB; USPAT)	OR	OFF	OFF	2024/09/30 03:02 PM

		bypass$4 OR flash$4 OR subsequent$4))					
L478	0	18/783088	(US-PGPUB; USPAT)	OR	ON	ON	2024/09/30 03:24 PM
L479	3918	475 AND ((blood OR fluid$4) near5 (sequest$5 OR bypass$4 OR flash$4 OR collect$4 OR sampl$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2024/09/30 03:27 PM
L480	648	479 AND ((pump$4 OR vacuum) near5 (draw$4 OR withdraw$4 OR forc$4) near5 blood)	(US-PGPUB; USPAT)	OR	OFF	OFF	2024/09/30 03:30 PM
L481	7	("2014/0309557").urpn. AND (PGPB | USPT | USOC).dbnm.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2024/09/30 03:56 PM
L482	0	476 AND (blood near5 (impereamble OR impenetrat$4))	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/09/30 04:07 PM
L483	122	((("ROGERS") near3 ("Bobby")) OR (("KANG") near3 ("Gino")) OR (("DETLOFF") near3 ("John"))).INV.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2024/10/16 02:28 PM
L484	34	483 AND ((blood OR fluid$4) near5 (sequest$5 OR bypass$4 OR flash$4 OR collect$4 OR sampl$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2024/10/16 02:28 PM
L485	53	("20020004647"|"20030105414"|"20040054333"|"20040073171"|"20040147855"|"20050004524"|"20050240161"|"20060009713"|"20070083162"|"20070088279"|"20080086085"|"20080145933"|"20080167577"|"20080319346"|"2010001	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2024/10/16 02:33 PM

		0372"|"20100057004"|"20120016266"|"20130317391"|"20150314105"|"20150359473"|"20160008579"|"20160073937"|"20160174888"|"3741197"|"3817240"|"3874367"|"3886930"|"4057050"|"4106497"|"4154229"|"4207870"|"4412548"|"4436098"|"4444203"|"5222502"|"5520193"|"5749857"|"6398743"|"6569117"|"8197420"|"8523826"|"8535241"|"8540663"|"8568371"|"8603009"|"8864684"|"9022950"|"9022951"|"9060724"|"9138572"|"9155495"|"9204864"|"9877675").PN.					
L486	27	("2016/0073937").urpn. AND (PGPB | USPT | USOC).dbnm.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2024/10/16 02:42 PM
L487	0	18/783088	(US-PGPUB; USPAT)	OR	ON	ON	2024/10/16 03:06 PM
L488	52227	(A61B5/150992 OR A61B5/15003 OR A61B5/150213 OR A61B5/150221 OR A61B5/150389 OR A61B5/150473 OR A61B5/150572 OR A61B5/153 OR A61B5/154 OR A61M39/04 OR A61M39/0693 OR A61M2039/0202 OR A61M2039/0633 OR A61M2039/068 OR A61B5/150251).cpc.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/10/16 03:08 PM
L489	36429	488 AND @ad<"20150724"	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO;	OR	OFF	OFF	2024/10/16 03:08 PM

			JPO; DERWENT; IBM_TDB)				
L490	3974	489 AND ((blood OR fluid$4) near5 (sequest$5 OR bypass$4 OR flash$4 OR collect$4 OR sampl$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2024/10/16 03:08 PM
L491	0	490 AND (blood near5 (impereamble OR impenetrat$4))	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/10/16 03:09 PM
L492	0	489 AND (blood near5 (impereamble OR impenetrat$4))	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/10/16 03:10 PM
L493	22949	489 AND ((collect$4 OR sampl$4 OR draw$4 OR withdraw$4) near5 (blood OR fluid))	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/10/16 03:10 PM

L494	0	493 AND (blood near5 (impeream$5 OR impenetrat$4))	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/10/16 03:11 PM
L495	944	493 AND ((vent$4 OR open$4 OR apertur$4) near5 air)	(US-PGPUB; USPAT)	OR	OFF	OFF	2024/10/16 03:12 PM
L496	1406	493 AND (blood near5 (member$4 OR mechanism$4 OR vent$4 OR elastic$4 OR flexibl$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2024/10/16 03:28 PM
L497	671	493 AND ((pump$4 OR vacuum) near5 (draw$4 OR withdraw$4 OR forc$4) near5 blood)	(US-PGPUB; USPAT)	OR	OFF	OFF	2024/10/16 06:17 PM
L498	9	"20080145933"	(US-PGPUB; USPAT)	OR	ON	ON	2024/10/16 07:03 PM
L499	38	("2008/0145933").urpn. AND (PGPB | USPT | USOC).dbnm.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2024/10/16 07:04 PM
L500	1	17/513796	(US-PGPUB; USPAT)	OR	ON	ON	2024/10/17 06:00 PM
L501	9	"20080145933"	(US-PGPUB; USPAT)	OR	ON	ON	2024/10/17 06:05 PM
L502	3	"20160066953"	(US-PGPUB; USPAT)	OR	ON	ON	2024/10/17 06:08 PM
L503	34	"20100174157"	(US-PGPUB; USPAT)	OR	ON	ON	2024/10/17 06:08 PM
L504	8	"20150073238"	(US-PGPUB; USPAT)	OR	ON	ON	2024/10/17 06:22 PM
L505	14	"20140243844"	(US-PGPUB; USPAT)	OR	ON	ON	2024/10/17 06:27 PM
L506	1	17/250875	(US-PGPUB; USPAT)	OR	ON	ON	2024/10/18 02:36 PM
L507	1	("11589782").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/10/21 02:40 PM
L508	1	("9782077").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/10/21 02:58 PM
L509	1	("10952614").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/10/21 02:58 PM

L510	1	("11877824").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/10/21 02:59 PM
L511	11	"20020055680"	(US-PGPUB; USPAT)	OR	ON	ON	2024/10/21 03:00 PM
L512	24	"20110015496"	(US-PGPUB; USPAT)	OR	ON	ON	2024/10/21 03:03 PM
L513	127743	(A61B5/0051 OR A61B5/4884 OR A61B5/6843 OR A61B2562/0219 OR A61B5/00 OR A61B5/6801).cpc.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/10/21 03:56 PM
L514	4440	513 AND @ad<"20110817"	(US-PGPUB; USPAT)	OR	ON	ON	2024/10/21 03:56 PM
L515	63	514 AND (accelerom$4) SAME (modulat$4 near5 signal$4)	(US-PGPUB; USPAT)	OR	ON	ON	2024/10/21 03:57 PM
L516	1	18/537615	(US-PGPUB; USPAT)	OR	ON	ON	2024/10/21 04:11 PM
L517	161	(accelerom$4) SAME ((modulat$4 OR enhanc$4) near5 (introduc$4 OR apply$4 OR add$8) WITH signal$4)	(US-PGPUB; USPAT)	OR	ON	ON	2024/10/21 04:26 PM
L518	29	517 AND @ad<"20110817"	(US-PGPUB; USPAT)	OR	ON	ON	2024/10/21 04:26 PM
L519	50	"2628064"	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/10/21 05:53 PM
L520	17	"20150216448"	(US-PGPUB; USPAT)	OR	ON	ON	2024/10/21

							06:28 PM
L521	1	17/554418	(US-PGPUB; USPAT)	OR	ON	ON	2024/10/21 06:35 PM
L522	3	"20190267003"	(US-PGPUB; USPAT)	OR	ON	ON	2024/10/21 06:47 PM
L523	0	18/661927	(US-PGPUB; USPAT)	OR	ON	ON	2024/10/21 07:48 PM
L524	1	18/229971	(US-PGPUB; USPAT)	OR	ON	ON	2024/10/21 07:48 PM
L525	1	("12138052").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/11/12 04:46 PM
L526	0	18/898239	(US-PGPUB; USPAT)	OR	ON	ON	2024/11/12 04:48 PM
L527	1	"18783088"	(US-PGPUB; USPAT)	OR	ON	ON	2024/11/12 04:48 PM
L528	123	((("ROGERS") near3 ("Bobby")) OR (("KANG") near3 ("Gino")) OR (("DETLOFF") near3 ("John"))).INV.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2024/11/13 03:02 PM
L529	35	528 AND ((blood OR fluid$4) near5 (sequest$5 OR bypass$4 OR flash$4 OR collect$4 OR sampl$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2024/11/13 03:03 PM
L530	10	"20080145933"	(US-PGPUB; USPAT)	OR	ON	ON	2024/11/13 03:48 PM
L531	10	"20060009713"	(US-PGPUB; USPAT)	OR	ON	ON	2024/11/13 03:57 PM
L532	20	("2006/0009713").urpn. AND (PGPB | USPT | USOC).dbnm.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2024/11/13 03:58 PM
L533	1	("12138052").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/11/13 04:04 PM
L534	102	("20020004647"|"20030105414"|"20040054333"|"20040073171"|"20040147855"|"20050004524"|"20050240161"|"20060009713"|"20070083162"|"20070088279"|"20080086085"|"20080145933"|"20080167577"|"20080319346"|"20100010372"|"20100057004"|"20120016266"|"20130317391"|"20150314105"|"20150359473"|"20160008579"|"20160073937"|"20160174888"|"3741197"|"3817240"|"38743	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN))	OR	ON	ON	2024/11/13 04:05 PM

		67"|"3886930"|"4057050"|"4106497"|"4154229"|"4207870"|"4412548"|"4436098"|"4444203"|"5222502"|"5520193"|"5749857"|"6398743"|"6569117"|"8197420"|"8523826"|"8535241"|"8540663"|"8568371"|"8603009"|"8864684"|"9022950"|"9022951"|"9060724"|"9138572"|"9155495"|"9204864"|"9877675").PN.					
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L536	53530	(A61B5/150992 OR A61B5/15003 OR A61B5/150213 OR A61B5/150221 OR A61B5/150389 OR A61B5/150473 OR A61B5/150572 OR A61B5/153 OR A61B5/154 OR A61M39/04 OR A61M39/0693 OR A61M2039/0202 OR A61M2039/0633 OR A61M2039/068).cpc.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/11/13 04:21 PM
L537	5102	536 AND @ad<"20150724"	(US-PGPUB; USPAT)	OR	ON	ON	2024/11/13 04:22 PM
L538	3922	537 AND ((blood OR fluid$4) near5 (sequest$5 OR bypass$4 OR flash$4 OR collect$4 OR sampl$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2024/11/13 04:23 PM
L539	900	538 AND ((pump$4 OR vacuum) near5 (draw$4 OR withdraw$4 OR forc$4) near5 (blood OR fluid))	(US-PGPUB; USPAT)	OR	OFF	OFF	2024/11/13 04:24 PM
L540	0	538 AND (blood near5 (impeream$5 OR impenetrat$4))	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL,	OR	ON	ON	2024/11/13 04:50 PM

			PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)				
L541	0	538 AND ((blood OR fluid) WITH (impeream$5 OR impenetrat$4))	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/11/13 04:50 PM
L542	776	538 AND ((blood OR fluid) WITH (impermeab$5 OR impenetrat$4))	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/11/13 04:51 PM
L543	417	538 AND (blood near5(impermeab$5 OR impenetrat$4))	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/11/13 04:51 PM

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
N94	1	(port and sequest$5 and junction and chamber and sampl$4 and vent and barrier).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2017/09/28 04:15 PM
N112	3	(port and sequest$5 and chamber and sampl$4 and vent and barrier).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/01/09 05:39 PM
N248	4	(blood and fluid$4 and inlet and outlet and port and reservoir and allow and initial$4 and sequest$5).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 03:30 PM
N249	4	(blood and fluid$4 and inlet and outlet and port and reservoir and allow$4 and initial$4 and sequest$5).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 03:30 PM
N250	495	(blood and fluid$4 and allow$4 and initial$4).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 03:31 PM
N251	107	(blood and fluid$4 and allow$4 and initial$4 and subsequent$4).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 03:31 PM
N283	9	((blood or fluid$4) and sequestrat$4 and chamber and sampl$4 and vent$4 and air$4).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:31 PM
N284	530	((blood or fluid$4) and chamber and sampl$4 and vent$4 and air$4).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:31 PM
N285	84	((blood or fluid$4) and chamber and cap and sampl$4 and vent$4 and air$4).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:32 PM
N365	6	(port and sequest$5 and junction and chamber and sampl$4 and vent and barrier).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:49 PM
N366	0	(blood AND seal$4 AND sampl$4 AND state AND transfrer$4).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2022/06/06 03:50 PM
N367	41	(blood AND seal$4 AND bypass$4 AND transfer$4).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2022/06/06 03:51 PM
N368	396	(blood AND seal$4 AND sampl$4 AND	(US-PGPUB; USPAT)	OR	ON	ON	2022/06/06 05:13 PM

		transfer$4).clm.					
N369	172	(blood AND seal$4 AND sampl$4 AND transfer$4 AND volume).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2022/06/06 05:13 PM
N370	5	(blood AND seal$4 AND sampl$4 AND transfer$4 AND volume AND bypass$4).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2022/06/06 05:14 PM
N371	8944	(A61B5/150221 OR A61B5/15003 OR A61B5/150236 OR A61B5/150244 OR A61B5/150251 OR A61B5/150389 OR A61B5/150503 OR A61B5/150992 OR A61B5/153 OR A61B5/155 OR A61B10/0048 OR A61B10/0051 OR A61B10/007 OR A61B2010/0061 OR A61B2010/0077 OR A61B2010/008).cpc.	(US-PGPUB; USPAT)	OR	ON	ON	2022/06/06 05:16 PM
N372	22	(chamber AND inlet AND outlet AND channel AND forc$4 AND draw$4 AND blood).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2024/09/30 04:09 PM
N373	8	(chamber AND inlet AND outlet AND channel AND forc$4 AND draw$4 AND blood AND hous$4).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2024/09/30 04:10 PM

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-22)
Approved for use through 05/31/2024. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	18898239
Filing Date	2024-09-26
First Named Inventor	Bobby E. Rogers
Art Unit	
Examiner Name	
Attorney Docket Number	069366-0581370_KUR2C07US

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PC 6.1.24

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.A.A/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	18898239
	Filing Date	2024-09-26
	First Named Inventor	Bobby E. Rogers
	Art Unit	
	Examiner Name	
	Attorney Docket Number	069366-0581370_KUR2C07US

	1	European Patent Application No. EP23155927.9 extended European Search Report dated Jul. 26, 2023, 8 pages.	☐
	2	Office Action (Final Rejection) dated 08/25/2023 for US App. No. 18113710 (pages 1-50)	☐
	3	Notice of Allowance mailed 09-08-2023; Attorney Docket No. 069366-0574153_KUR2C04US. 35 page.	☐
	4	Notice of Allowance mailed 09-14-2023; Attorney Docket No. 069366-0574152_KUR2D02IL. 90 pages.	☐
	5	Office Action (Non-Final Rejection) dated 10/04/2023 for US App. No. 17538990 (pages 1-47)	☐
	6	JP Notice of Allowance mailed 06-20-2023; Attorney Docket No. 069366-0572231_KUR3D01JP. 6 pages.	☐
	7	Examination Report dated Sep. 28, 2023, for European Patent Application No. 22181212.6. 5 pages.	☐
	8	Office Action (Notice of Section 18) dated 12/20/2023 for IL App No. 309380 (pages 1-5).	☐
	9	Notice of Allowance mailed 01-17-2024; Attorney Docket No. 069366-0572201_KUR2C03US. 16 pages.	☐
	10	JP Office Action mailed 02/27/2024; Attorney Docket No. 069366-0575273_KUR2D03JP. 11 pages.	☐
	11	Office Action (Non-Final Rejection) dated 01/25/2024 for IL App. 302893 (pages 1-3).	☐

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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.A.A/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	18898239
	Filing Date	2024-09-26
	First Named Inventor	Bobby E. Rogers
	Art Unit	
	Examiner Name	
	Attorney Docket Number	069366-0581370_KUR2C07US

	12	Li, Yiwen, et al. "Direct labeling and visualization of blood vessels with lipophilic carbocyanine dye DiI." Nature protocols 3.11 (2008): 1703-1708.	☐
	13	Abbott Point of Care, Cartridge and Test Information, Art: 714258-010; Rev. Date: 15-Aug-16,1-6 pages.	☐
	14	NCCLS. Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard—Fifth dition. H3-A5, vol. 23, No. 32. Replaces H3-A4; vol. 18, No. 7. 1-52 pages. http://demo.nextlab.ir/Organization/ Documents/CLSI-Standards/CLSI-H3-A5.aspx.	☐
	15	Perez, P., et al. "Multivariate analysis of determinants of bacterial contamination of whole-blood donations." Vox Sanguinis 82.2 (2002): 55-60.	☐
	16	Sheppard, et al., Bacterial Contamination of Platelets for Transfusion: Recent Advances and Issues, LABMEDICINE, vol. 36, No. 12, Dec. 2005 ("Sheppard 2005").	☐
	17	Australian Patent Office, Examination Report No. 1 for for Australian Patent Application 2021202622, dated March 18, 2022, 3 pages.	☐
	18	Office Action (Final Rejection) dated 08/25/2023 for US Application No. 18113710 (pages 1-50).	☐
	19	European Patent Office, Extended European Search Report for European Patent Application 23155927.9-1122, dated July 26, 2023, pages 1-8.	☐
	20	Notice of Allowance mailed 04-17-2024; Attorney Docket No. 069366-0572201_KUR2C03US. 16 pages.	☐
	21	Office Action (Non-Final Rejection) mailed 10/04/2023 for US Application No. 17538900 (1-47).	☐
	22	First Office Action (Non-Final Rejection) dated 08-03-2023 for CN Application No. 202010300942.7. 21 pages.	☐

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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.A.A/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	18898239
	Filing Date	2024-09-26
	First Named Inventor	Bobby E. Rogers
	Art Unit	
	Examiner Name	
	Attorney Docket Number	069366-0581370_KUR2C07US

	23	Office Action (Non-Final Rejection) dated 02/21/2023 for US Application No. 17893079, pages 1-32.	☐
	24	Office Action (Final Rejection) dated 07/19/2023 for US Application No. 17893079, pages 1-21.	☐
	25	Advisory Action dated 09/29/2023 for US Application 17893079, pages 1-24.	☐
	26	European Patent Office, Examination Report for European Patent Application 22181212.6-1122, dated September 28, 2023, pages 1-5.	☐
	27	European Patent Office, Extended European Search Report for European Patent Application 22181212.6-1122 dated October 24, 2022, pages 1-10.	☐
	28	Australian Patent Office, Australian Examination Report No. 1 for Application No. 2021120 622 dated March 18, 2022, 3 pages.	☐
	29	Notice of Allowance mailed 03-01-2023; Attorney Docket No. 069366-0572419_KUR2D01AU. 3 pages.	☐
	30	First Office Action dated 11/24/2021 for IL Application No. 286030, pages 1-3.	☐
	31	Notice of Allowance mailed 01-29-2023; Attorney Docket No. 069366-0572425_KUR2D01IL. 87 pages.	☐
	32	Office Action (Non-Final Rejection) dated 08/10/2021 for Japanese Application No. 2020-118498, pages 1-7.	☐
	33	Office Action (Non-Final Rejection) dated 03/28/2022 for Japanese Application No. 2020-118498, pages 1-3.	☐

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	Filing Date	2024-09-26
	First Named Inventor	Bobby E. Rogers
	Art Unit	
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	Attorney Docket Number	069366-0581370_KUR2C07US

	34	Office Action (Non-Final Rejection) dated 09/01/2022 for Japanese Application No. 2020-118498, pages 1-4.	☐
	35	Notice of Allowance mailed 04-04-2023; Attorney Docket No. 069366-0572230_KUR2D02JP. 6 pages.	☐
	36	Rule 71(3) Communication and Text for Grant mailed 08/31/2022 for European Application No. 19200766.4-1122. 189 pages.	☐
	37	Office Action (Non-Final Rejection) mailed 01/21/2022 for Israeli Application No. 267684. 3 pages.	☐
	38	Notice of Allowance mailed 02-14-2023; Attorney Docket No. 069366-0572429_KUR3N01IL. 122 pages.	☐
	39	Office Action (Non-Final Rejection) mailed 11/29/2022 for Application No. 2021-214177, pages 1-3.	☐
	40	Notice of Allowance mailed 06-20-2023; Attorney Docket No. 069366-0572231_KUR3D01JP. 6 pages.	☐
	41	Office Action (Non-Final Rejection) mailed 11/4/2022 for Application No. 17094692, pages 1-50.	☐
	42	Notice of Allowance mailed 04-20-2023; Attorney Docket No. 069366-0572169_KUR4C01US. 36 pages.	☐
	43	Office Action (Non-Final Rejection) mailed 08/04/2022 for Application No. 16819033, pages 1-35.	☐
	44	Notice of Allowance mailed 11-28-2022; Attorney Docket No. 069366-0572168_KUR4002US. 9 pages.	☐

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	First Named Inventor	Bobby E. Rogers
	Art Unit	
	Examiner Name	
	Attorney Docket Number	069366-0581370_KUR2C07US

	45	Office Action (Non-Final Rejection) mailed 04/16/2024 for Application No. 16838017, pages 1-19.	☐
	46	Office Action (Non-Final Rejection) dated 9/24/2024 for U.S. Application No. 18/783,173 ; Attorney Docket No. 069366-0580420_KUR3C03US (pages 1-62).	☐
	47	Office Action (Non-Final Rejection) dated 9/17/2024 for U.S. Application No. 17/893,079 ; Attorney Docket No. 069366-0572192_KUR3C02US (pages 1-50).	☐
	48	Office Action (Non-Final Rejection) dated 9/23/2024 for U.S. Application No. 17/730,118 ; Attorney Docket No. 069366-0572186_KUR3C01US (pages 1-73).	☐
	49	Office Action (Non-Final Rejection) dated 9/17/2024 for U.S. Application No. 18/783,088 ; Attorney Docket No. 069366-0580418_KUR2C06US (pages 1-60).	☐
	50	Meissner, George F. , et al., "The Standard Clotting Time, A Method Based on the Use of Whole Venous Blood in Capillary Tubes," The American Journal of Clinical Pathology, vol. 39, No. 3., pp. 321-323, Mar. 1963.	☐

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	Filing Date	2024-09-26
	First Named Inventor	Bobby E. Rogers
	Art Unit	
	Examiner Name	
	Attorney Docket Number	069366-0581370_KUR2C07US

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Please see 37 CFR 1.97(e) to make the appropriate selection(s):

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FEE

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Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2024-09-27
Name/Print	Benjamin F. Hudson	Registration Number	71,474

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6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

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9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

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Bibliographic Data

Application No: 18/898,239

Foreign Priority claimed: ○ Yes ◉ No

35 USC 119 (a-d) conditions met: ☐ Yes ☑ No ☐ Met After Allowance

Verified and Acknowledged: /MAY A ABOUELELA/ Examiner's Signature | Initials

Title: BLOOD SAMPLE OPTIMIZATION DEVICE

FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
09/26/2024	600	3791	069366-0581370_KUR2C07US
RULE			

APPLICANTS

Kurin, Inc., San Diego, CA, UNITED STATES

INVENTORS

Bobby E. Rogers, Park City, CA, UNITED STATES

Gino Kang, Irvine, CA, UNITED STATES

John Detloff, San Diego, CA, UNITED STATES

CONTINUING DATA

This application is a CON of 18783088 07/24/2024 PAT 12138052

18783088 is a CON of 18494622 10/25/2023

18494622 is a CON of 18113710 02/24/2023 PAT 11832944

18113710 is a CON of 17538990 11/30/2021 PAT 11963769

17538990 is a CON of 16208559 12/04/2018 PAT 11185266

16208559 is a CON of 15994559 05/31/2018 PAT 10143412

15994559 is a CON of 15140448 04/27/2016 PAT 10010282

15140448 has PRO of 62318194 04/04/2016

15140448 has PRO of 62238636 10/07/2015

15140448 has PRO of 62196797 07/24/2015

FOREIGN APPLICATIONS

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P.O BOX 10500
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UNITED STATES

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Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

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First Named Inventor	Bobby E. Rogers
Art Unit	
Examiner Name	
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	1	20140309558		2014-10-16	FLETCHER GARY D	
	2	20140073990		2014-03-13	HOLMES ELIZABETH A	
	3	20140323911		2014-10-30	SLOAN DEBORAH	
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	Attorney Docket Number	069366-0581370_KUR2C07US

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	1	Office Action (Notice of Deficiencies) dated 10/14//2023 for IL App No. 309380 (pages 1-7).	☐

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EXAMINER SIGNATURE

Examiner Signature	/MAY A ABOUELELA/	Date Considered	11/13/2024

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Name/Print	Benjamin F. Hudson	Registration Number	71,474

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Application	Document	Mailroom Date	Attorney Docket No.
18898239	CTNF	11/22/2024	069366-0581370_KUR2C07US
18898239	892	11/22/2024	069366-0581370_KUR2C07US
18898239	1449	11/22/2024	069366-0581370_KUR2C07US
18898239	1449	11/22/2024	069366-0581370_KUR2C07US
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APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
18/898,239	**12/11/2024 04:28:30 PM Z ET**	**069366-0581370_KUR2C07US**

Title of Invention

BLOOD SAMPLE OPTIMIZATION DEVICE

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	7801	FILED BY	Trent Tercenio
PATENT CENTER #	68326063	FILING DATE	09/26/2024
CUSTOMER #	27500	FIRST NAMED INVENTOR	Bobby E. Rogers
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	Benjamin Hudson

Documents

TOTAL DOCUMENTS: 1

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
069366-0581370_KUR2C07US_POA-for-filing.pdf	2	Power of Attorney	384 KB

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
069366-0581370_KUR2C07US_POA-for-filing.pdf	82B216C0560EFFD616BA9C4212C71F8871F588EE98F40FEFB3F1C5FA2F2C490855A283A7F07087118913E8471D36E408D8BD21590142DD5B626DA35AAA666FCA

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If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Doc Code: PA..
Document Description: Power of Attorney

PTO/AIA/82A (07-13)
Approved for use through 09/30/2025. OMB 0651-0035
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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TRANSMITTAL FOR POWER OF ATTORNEY TO ONE OR MORE REGISTERED PRACTITIONERS

NOTE: This form is to be submitted with the Power of Attorney by Applicant form (PTO/AIA/82B) to identify the application to which the Power of Attorney is directed, in accordance with 37 CFR 1.5, unless the application number and filing date are identified in the Power of Attorney by Applicant form. If neither form PTO/AIA/82A nor form PTO/AIA82B identifies the application to which the Power of Attorney is directed, the Power of Attorney will not be recognized in the application.

Application Number	18/898,239
Filing Date	September 26, 2024
First Named Inventor	Bobby E. Rogers
Title	BLOOD SAMPLE OPTIMIZATION DEVICE
Art Unit	3791
Examiner Name	May A. Abouelela
Attorney Docket Number	069366-0581370_KUR2C07US

SIGNATURE of Applicant or Patent Practitioner

Signature	/Ben Hudson/	Date (Optional)	
Name	Benjamin F. Hudson	Registration Number	71,474
Title (if Applicant is a juristic entity)	Patent Practitioner		
Applicant Name (if Applicant is a juristic entity)			

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications. If more than one applicant, use multiple forms.

☐ *Total of _____ forms are submitted.

A Federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with an information collection subject to the requirements of the Paperwork Reduction Act of 1995, unless the information collection has a currently valid OMB Control Number. The OMB Control Number for this information collection is 0651-0035. Public burden for this form is estimated to average 3 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information collection. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden to the Chief Administrative Officer, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450 or email InformationCollection@uspto.gov. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS.** If filing this completed form by mail, send to: **Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Doc Code: PA..
Document Description: Power of Attorney

PTO/AIA/82B (07-13)
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U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
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POWER OF ATTORNEY BY APPLICANT

I hereby revoke all previous powers of attorney given in the application identified in either the attached transmittal letter or the boxes below.

Application Number	Filing Date

(Note: The boxes above may be left blank if information is provided on form PTO/AIA/82A.)

☑ I hereby appoint the Patent Practitioner(s) associated with the following Customer Number as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the application referenced in the attached transmittal letter (form PTO/AIA/82A) or identified above: 27500

OR

☐ I hereby appoint Practitioner(s) named in the attached list (form PTO/AIA/82C) as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the patent application referenced in the attached transmittal letter (form PTO/AIA/82A) or identified above. (Note: Complete form PTO/AIA/82C.)

Please recognize or change the correspondence address for the application identified in the attached transmittal letter or the boxes above to:

☑ The address associated with the above-mentioned Customer Number

OR

☐ The address associated with Customer Number:

OR

☐ Firm or Individual Name					
Address					
City		State		Zip	
Country					
Telephone		Email			

I am the Applicant (if the Applicant is a juristic entity, list the Applicant name in the box):

Kurin, Inc.

☐ Inventor or Joint Inventor (title not required below)

☐ Legal Representative of a Deceased or Legally Incapacitated Inventor (title not required below)

☑ Assignee or Person to Whom the Inventor is Under an Obligation to Assign (provide signer's title if applicant is a juristic entity)

☐ Person Who Otherwise Shows Sufficient Proprietary Interest (e.g., a petition under 37 CFR 1.46(b)(2) was granted in the application or is concurrently being filed with this document) (provide signer's title if applicant is a juristic entity)

SIGNATURE of Applicant for Patent

The undersigned (whose title is supplied below) is authorized to act on behalf of the applicant (e.g., where the applicant is a juristic entity).

Signature		Date (Optional)	
Name	Bobby E. Rogers		
Title	CEO		

NOTE: Signature - This form must be signed by the applicant in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. If more than one applicant, use multiple forms.

☐ Total of forms are submitted.

This collection of information is required by 37 CFR 1.131, 1.32, and 1.33. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
18/898,239	09/26/2024	Bobby E. Rogers	069366-0581370_KUR2C07US

CONFIRMATION NO. 7801

27500
PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
ATTENTION: DOCKETING DEPARTMENT
P.O BOX 10500
McLean, VA 22102

POA ACCEPTANCE LETTER

OC00000001249857

Date Mailed: 12/17/2024

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 12/11/2024.

The Power of Attorney in this application is accepted. Correspondence in this application will be mailed to the above address as provided by 37 CFR 1.33.

Questions about the contents of this notice and the requirements it sets forth should be directed to the Office of Data Management, Application Assistance Unit, at **(571) 272-4000** or **(571) 272-4200** or **1-888-786-0101**.

/dtdinh/

TO: Docket_IP@pillsburylaw.com
FROM: noreply@uspto.gov
CC: patentcenter_eofficeaction@uspto.gov
SUBJECT: USPTO: Patent Electronic System - Correspondence Notification for Customer Number 27500

Tue Dec 17 05:00:24 EST 2024

Dear Patent Center Customer:

Correspondence Address:

PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
ATTENTION: DOCKETING DEPARTMENT
P.O BOX 10500
McLean,VIRGINIA,22102
UNITED STATES

This is a courtesy notification regarding the following USPTO patent application(s) associated with your Customer Number, 27500, that have new outgoing correspondence. This correspondence is now available for viewing in Patent Center.

The official date of notification of the outgoing correspondence will be indicated on the form (e.g., PTOL-90) accompanying the correspondence.

Disclaimer:
The list of documents shown below are provided as a courtesy and is not part of the official file wrapper. The content of the images shown in the Image File Wrapper is the official record.

Application	Document	Mailroom Date	Attorney Docket No.
18898239	N570	12/17/2024	069366-0581370_KUR2C07US

To view your correspondence online, please sign in to Patent Center and then select Workbench/View correspondence. To update your email address(es), select Manage/Manage customer numbers.

If you have any questions, please contact the Patent Electronic Business Center (EBC) at ebc@uspto.gov or 866-217-9197 Monday – Friday, 6 a.m. to midnight ET.

Please do not reply to this email as it was sent from an unmonitored mailbox.

Sincerely,

The Patent Center Team

UNITED STATES
PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313 - 1450
www.uspto.gov

APPROVAL LETTER

APPLICATION #	FILING DATE	APPLICANT/PATENT UNDER REEXAMINATION
18/898,239	09/26/2024	Bobby Rogers

Title of Invention

BLOOD SAMPLE OPTIMIZATION DEVICE

Electronic terminal disclaimer filed on 12/17/2024

☑ Approved

This patent is subject to a Terminal Disclaimer

Approved / Disapproved by: Electronic Terminal Disclaimer automatically approved

UNITED STATES
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ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
18/898,239	**12/17/2024 05:14:34 PM Z ET**	**069366-0581370_KUR2C07US**

Title of Invention

BLOOD SAMPLE OPTIMIZATION DEVICE

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	7801	FILED BY	Trent Tercenio
PATENT CENTER #	68405178	FILING DATE	09/26/2024
CUSTOMER #	27500	FIRST NAMED INVENTOR	Bobby E. Rogers
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	Benjamin Hudson

Documents

TOTAL DOCUMENTS: 2

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
petition-request.pdf	3	Terminal Disclaimer-Filed (Electronic)	44 KB
grantLetter.pdf	1	Terminal Disclaimer-Electronic-Approved	18 KB

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
petition-request.pdf	96F82D25EAAB1740B2C1D5DEDDC664277462333D671DA7592C436A2CA33A2644E454ADBCA89CC032483C74AD2708E6BD7EF94B326FB36F4295E9513600552F94
grantLetter.pdf	14A96C7141DE181C2A467CBB22A7163C97D66A8E9ED986261

8114F568C19111F0BC87912F2CAC25D38C13A618CF32AA382
6AB61823015D86F3F7DB38A7921B2F

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

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P.O. Box 1450
Alexandria, VA 22313 - 1450
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TERMINAL DISCLAIMER TO OBVIATE A DOUBLE PATENTING REJECTION OVER A PRIOR PATENT

APPLICATION #	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET #
18898239	**09/26/2024**	**Bobby Rogers**	**069366-0581370_KUR2C07US**

Title of Invention

BLOOD SAMPLE OPTIMIZATION DEVICE

✓	Filing of terminal disclaimer does not obviate requirement for response under 37 CFR 1.111 to outstanding Office Action
✓	This electronic Terminal Disclaimer is not being used for a Joint Research Agreement.

Owner	Percent interest
Kurin, Inc.	100%
Total	**100%**

The owner(s) of percent interest listed above in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term of any patent granted on pending reference Application Number(s)

Application #	Filing Date

as the term of any patent granted on said reference application may be shortened by any terminal disclaimer filed prior to the grant of any patent on the pending reference application. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and any patent granted on the reference application are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.
In making the above disclaimer, the owner does not disclaim the terminal part of any patent granted on the instant application that would extend to the expiration date of the full statutory term of any patent granted on said reference application, "as the term of any patent granted on said reference application may be shortened by any terminal disclaimer filed prior to the grant of any patent on the pending reference application," in the event that any such patent granted on the pending reference application: expires for failure to pay a maintenance fee, is held unenforceable, is found invalid by a court of competent jurisdiction, is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321, has all claims canceled by a reexamination certificate, is reissued, or is in any manner terminated prior to the expiration of its full statutory term as shortened by any terminal disclaimer filed prior to its grant.

The owner(s) of percent interest listed above in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term of prior patent number(s)

Patent #
12138052

as the term of said prior patent is presently shortened by any terminal disclaimer. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the prior patent are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.
In making the above disclaimer, the owner does not disclaim the terminal part of the term of any patent granted on the instant application that would extend to the expiration date of the full statutory term of the prior patent, "as the term of said prior patent is presently shortened by any terminal disclaimer," in the event that said prior patent later:
- expires for failure to pay a maintenance fee;
- is held unenforceable;
- is found invalid by a court of competent jurisdiction;
- is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321;
- has all claims canceled by a reexamination certificate;
- is reissued; or
- is in any manner terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer.



Terminal disclaimer fee under 37 CFR 1.20(d) included with Electronic Terminal Disclaimer request.

Applicant claims the following entity status:
Small

I hereby declare that all statements made herein of my own knowledge are true and that all statemnts made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

I certify, in accordance with 37 CFR 1.4(d)(4) that I am: An attorney or agent registered to practice before the Patent and Trademark Office who is of record in this application

Signature	Name	Registration #
/Ben Hudson/	Benjamin Hudson	71474

* Statement under 37 CFR 3.73(b) is required if terminal disclaimer is signed by the assignee (owner). Form PTO/SB/96 may be used for making this certification. See MPEP 324.

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ELECTRONIC PAYMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
18/898,239	**12/17/2024 05:14:34 PM Z ET**	**069366-0581370_KUR2C07US**

Title of Invention

BLOOD SAMPLE OPTIMIZATION DEVICE

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	7801	FILED BY	Trent Tercenio
PATENT CENTER #	68405178	AUTHORIZED BY	Benjamin Hudson
CUSTOMER #	27500	FILING DATE	09/26/2024
CORRESPONDENCE ADDRESS	-	FIRST NAMED INVENTOR	Bobby E. Rogers

Payment Information

PAYMENT METHOD	PAYMENT TRANSACTION ID	PAYMENT AUTHORIZED BY
DA / 033975	**E2024BGH15029237**	**Benjamin Hudson**

FEE CODE	DESCRIPTION	ITEM PRICE($)	QUANTITY	ITEM TOTAL($)
2814	STATUTORY DISCLAIMER, INCLUDING TERMINAL DISCLAIMER	170.00	1	170.00
			TOTAL AMOUNT:	**$170.00**

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C.

371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

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United States Patent and Trademark Office
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/783,173	07/24/2024	Bobby E. ROGERS	069366-0580420_KUR3C03US	1561

27500 7590 11/04/2024

PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
ATTENTION: DOCKETING DEPARTMENT
P.O BOX 10500
McLean, VA 22102

EXAMINER	
NGUYEN, HUONG Q	

ART UNIT	PAPER NUMBER
3791	

NOTIFICATION DATE	DELIVERY MODE
11/04/2024	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Docket_IP@pillsburylaw.com

Office Action Summary	Application No. 18/783,173	Applicant(s) ROGERS et al.	
	Examiner Huong Q NGUYEN	Art Unit 3791	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 9/27/2024.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☑ This action is **FINAL.** 2b) ☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 1-30 is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 1-30 is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to **PPHfeedback@uspto.gov.**

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☑ The drawing(s) filed on 7/24/2024 is/are: a)☑ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☑ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

DETAILED ACTION

This office action is responsive to the response filed 9/27/2024. Claims 1-30 remain pending and under prosecution.

Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Claim Interpretation

The following is a quotation of 35 U.S.C. 112(f):

> (f) Element in Claim for a Combination. – An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

The following is a quotation of pre-AIA 35 U.S.C. 112, sixth paragraph:

> An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

The claims in this application are given their broadest reasonable interpretation using the plain meaning of the claim language in light of the specification as it would be understood by one of ordinary skill in the art. The broadest reasonable interpretation of a claim element (also commonly referred to as a claim limitation) is limited by the description in the specification when 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is invoked.

As explained in MPEP § 2181, subsection I, claim limitations that meet the following three-prong test will be interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph:

(A) the claim limitation uses the term "means" or "step" or a term used as a substitute for "means" that is a generic placeholder (also called a nonce term or a non-structural term having no specific structural meaning) for performing the claimed function;

(B) the term "means" or "step" or the generic placeholder is modified by functional language, typically, but not always linked by the transition word "for" (e.g., "means for") or another linking word or phrase, such as "configured to" or "so that"; and

(C) the term "means" or "step" or the generic placeholder is not modified by sufficient structure, material, or acts for performing the claimed function.

Use of the word "means" (or "step") in a claim with functional language creates a rebuttable presumption that the claim limitation is to be treated in accordance with 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph. The presumption that the claim limitation is interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is rebutted when the claim limitation recites sufficient structure, material, or acts to entirely perform the recited function.

Absence of the word "means" (or "step") in a claim creates a rebuttable presumption that the claim limitation is not to be treated in accordance with 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph. The presumption that the claim limitation is not interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is rebutted when the claim limitation

recites function without reciting sufficient structure, material or acts to entirely perform the recited function.

Claim limitations in this application that use the word "means" (or "step") are being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, except as otherwise indicated in an Office action. Conversely, claim limitations in this application that do not use the word "means" (or "step") are not being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, except as otherwise indicated in an Office action.

No claim elements are interpreted under 112(f).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a)(1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention.

Claim(s) 1-5, 13-20, and 28-30 is/are rejected under 35 U.S.C. 102(a)(1) as being anticipated by Bullington et al (US Pub No. 20140163419).

In regard to Claims 1 and 16, Bullington et al disclose a device comprising:

an inlet port 405 for receiving a blood sample, best seen in Figure 12 (0081, 0089);

an outlet port 475 (proximal end of lumen 475), best seen in Figure 13-15 (0085);

a chamber 480 connected with the inlet port, and configured to collect a first portion of the blood sample when under a drawing force applied from the outlet port from a blood sample collection device 451, best seen in Figure 14 (0079, 0091-0092 – "a bodily-fluid is drawn through the port 405, the first lumen 432 defined by the flow control mechanism 430, and the first lumen 406 defined by the diverter 409 and into the fluid reservoir 480. In some embodiments, the bodily-fluid can contain undesirable microbes such as, for example, dermally-residing microbes and/or other external contaminants");

a sampling channel 433 connected with the inlet port and configured to convey a subsequent portion of the blood sample to the outlet port, best seen in Figure 15 (0095); and

a moving part 430, 431, 435 (flow control mechanism first member 431 controlled by member 435), moving part also defined by plunger 476 (0084 – Figure 13-15),

configured to be movable from a first position to a second position to allow the blood sample to flow to the sampling channel –

in the first position, moving member 435 rotates first member 431 such that lumen 433 (sampling channel) is fluidically isolated, due to lumen 432 of the flow control mechanism aligned with the inlet port 405, which leads through lumen 406 in diverter 409 and into chamber 480 – thus the inlet port 405 is in fluid communication with the chamber 480, best seen in Figure 14 (0081, 0092);

in the second position, moving member 435 rotates first member 431 such that lumen 433 is aligned with inlet port 405 such that "a desired amount of bodily-fluid is drawn through the port 405, the second lumen 433 of the flow control mechanism 430, the second lumen 407 of the diverter 409, and the lumen 475 [defining the outlet port] defined by the shunt tube 471

and into the second reservoir 490. Moreover, the bodily-fluid disposed within the second reservoir 490 is fluidically isolated from the first, predetermined amount of bodily-fluid contained within the first reservoir 480," best seen in Figure 15 (0082, 0083, 0095, 0097) – thus creates a pathway from the inlet port 405 to the outlet port 475.

2, 17. The device in accordance with claim 1, wherein the first position allows the collection of the first portion of the blood sample in the chamber 480, best seen in Figure 14.

3, 18. The device in accordance with claim 1, wherein the moving part 430, 431, 435 is configured to move from the first position to the second position after the first portion of the blood sample flows into the chamber 480 – sample flow into the chamber 480 occurs first, best seen in Figure 14, followed by moving member 435 rotating first member 431 such that lumen 433 is aligned with inlet port 405 is aligned with the outlet port 475, into second reservoir 490, best seen in Figure 15 (0082, 0083, 0095, 0097).

4, 19. The device in accordance with claim 1, the device further comprising a locking mechanism 474 configured to maintain the moving part 476 in the first position (Figure 14) until the chamber 480 is filled with the first portion of the blood sample – protrusion 474 enables proximal movement of plunger 476 to create chamber 480 for the first portion of the blood sample, best seen in Figure 13-14 (0085, 0091, 0096).

5, 20. The device in accordance with claim 1, wherein the moving part 430, 431, 476 is an inner chamber housing, best seen in Figure 13-15.

13, 28. The device in accordance with claim 1, further comprising a patient needle – "a user can engage the transfer device 400 to couple the port 405 to a proximal end portion of a lumen-defining device (not shown) such as, for example, a butterfly needle, a cannula assembly, a trocar (which in some cases is used to insert a catheter into a patient), or the like" (0089) and

a sample collection device – "with the desired amount of bodily-fluid disposed within the second fluid reservoir 490, the transfer device 400 can be removed from the portion of the patient and disposed above or in a container (e.g., a vile, a test tube, a petri dish, a culture medium, a test apparatus, or the like) such that a portion of the second amount of bodily-fluid can be tested" (0099).

14, 29. The device in accordance with claim 1, the chamber having a volume sufficient to collect the first portion of the blood sample that is more prone to contamination and also to minimize an amount of blood to be sequestered (0092).

15, 30. The device in accordance with claim 1, wherein the chamber 480 has a volume of less than 1.5 cubic centimeters, e.g. 0.1 mL (0094).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries for establishing a background for determining obviousness under 35 U.S.C. 103 are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims the examiner presumes that the subject matter of the various claims was commonly owned as of the effective filing date of the claimed invention(s) absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and effective filing dates of each claim that was not commonly owned as of the effective filing date of the later invention in order for the examiner to consider the applicability of 35 U.S.C. 102(b)(2)(C) for any potential 35 U.S.C. 102(a)(2) prior art against the later invention.

Claim(s) 6-12 and 21-27 is/are rejected under 35 U.S.C. 103 as being unpatentable over Bullington et al as applied to claim 1 above, and further in view of Percarpio (US Pat No. 4106497 – cited by applicant).

In regard to Claims 6-9 and 21-24, Bullington et al disclose the invention above but do not expressly disclose a blood impermeable membrane is configured to facilitate the chamber collecting the first portion of the blood sample.

Percarpio teach that it is well-known in the art to provide an analogous blood sampling device comprising an inlet port 22 for receiving a blood sample, an outlet port 42, 44, a chamber to collect a first portion of the blood sample (indicator area), and a sampling channel 28 connecting the inlet and the outlet, including a blood impermeable membrane 90 to enable necessary venting of air for the desired flow of the blood first to the chamber before directing it to the outlet (Col.4: 16-39). Percarpio teach a housing 40, 56 separate from the blood impermeable membrane 90, best seen in Figure 3-4, as an effective configuration for the location of said blood impermeable membrane.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the of filing to modify Bullington et al to include a blood impermeable membrane causes the first portion of the blood sample to back up into the chamber following application of the drawing force applied from the outlet port as taught by Percarpio by enabling necessary venting of air from the device during the desired flow of blood such that, when the drawing force is applied at the outlet port, the first portion of the blood sample is drawn into the chamber in the manner taught by Bullington et al to contact a material that is blood impermeable to enable the venting

of air, wherein the blood impermeable membrane is separate from the housing, as taught by Percarpio as an effective configuration for said blood impermeable membrane.

In regard to Claims 10-12 and 25-27, Bullington et al disclose the invention above but do not expressly disclose a valve configured to initially close off the sampling channel.

Percarpio teach that it is well-known in the art to provide an analogous blood sampling device comprising an inlet port 22 for receiving a blood sample, an outlet port 42, 44, a chamber to collect a first portion of the blood sample (indicator area), and a sampling channel 28 connecting the inlet and the outlet, including a blood impermeable membrane 90 to enable necessary venting of air for the desired flow of the blood first to the chamber before directing it to the outlet (Col.4: 16-39). Percarpio teach a valve 78 (check valve) that is configured to initially close off access to the outlet until the first portion of the blood sample is in the chamber, best seen in Figure 3, and is further configured such that, upon release, follow-on amounts of the blood sample will bypass the chamber and flow through the sampling channel toward the outlet port, best seen in Figure 4 (Col.3: 61-Col.4: 15, 64-Col.5: 47). Percarpio also teach the valve is configured to pinch, shunt, bend or otherwise close off the outlet before the first portion of the blood sample is collected in the chamber, best seen in Figure 3-4 (Col.3: 61-Col.4: 15, 64-Col.5: 47).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of filing to modify Bullington et al to include a valve to pinch, shunt, bend or otherwise close off the outlet in the manner above as taught by Percarpio to effectively seal off the outlet before

the blood is properly in the chamber of Bullington et al, wherein it would have been obvious to a skilled artisan to place the valve such that it closes off the sampling channel and not just the outlet, to effectively block the flow of blood upstream before it reaches the outlet, prior to being drawn into the chamber as taught by Bullington et al, as well as Percarpio.

Response to Arguments

Applicant's arguments filed have been fully considered but they are not persuasive. Applicant contends that Bullington et al do not disclose a chamber connected with the inlet port, and configured to collect a first portion of the blood "when under a drawing force applied from the outlet port" because Bullington's pre-sample reservoir for collecting the first portion of blood is instead isolated from any drawing force applied at the outlet (Remarks pg. 11). Applicant contends that chamber 480 "is never able to receive a drawing force from lumen 475" which defines the outlet port.

It is noted that applicant appears to be implicitly narrowly interpreting the term "drawing force" to mean something specific such as a vacuum force, which is disclosed in the specification. However, it is noted that the term "drawing force" as claimed is broadly and reasonably interpreted as the movement of plunger 451, which is attached to outlet port 475, by the withdrawal of plunger 451 relative to housing 401, which creates the space for the chamber 480 and thus constitutes a drawing force applied from the outlet port as broadly as has been claimed, best seen in Figure 13-14. Figure 13 shows the initial position of plunger 451 before applying a drawing force and Figure 14 shows withdrawal of the plunger, which then creates chamber 480. Furthermore, the withdrawal of plunger 451 creates a negative pressure

within chamber 480, which enables the fluid to flow into chamber 480 through the rotary valve. Thus, Bullington et al disclose the invention as broadly as has been claimed and the rejection is maintained.

The previous 112 rejections and Drawing objections are withdrawn in light of applicant's amendments.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Huong Q NGUYEN whose telephone number is (571)272-8340. The examiner can normally be reached on 10 am - 6 pm.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert (Tse) Chen can be reached at 5712723672. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H.Q.N/
Examiner, Art Unit 3791

/RENE T TOWA/
Primary Examiner, Art Unit 3791

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-22)
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	18783173
Filing Date	2020-04-01
First Named Inventor	Bobby E. Rogers
Art Unit	3791
Examiner Name	Jairo H. Portillo
Attorney Docket Number	069366-0580420_KUR3C03US

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	4312362		1982-01-26	KAUFMAN JOSEPH	

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PC 6.1.24

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /H.Q.N/

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	2	Office Action (Non-Final Rejection) dated 9/23/2024 for U.S. Application No. 17/730,118 ; Attorney Docket No. 069366-0572186_KUR3C01US (pages 1-73).	☐
	3	Office Action (Non-Final Rejection) dated 9/17/2024 for U.S. Application No. 18/783,088 ; Attorney Docket No. 069366-0580418_KUR2C06US (pages 1-60).	☐

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	Examiner Name	Jairo H. Portillo
	Attorney Docket Number	069366-0580420_KUR3C03US

CERTIFICATION STATEMENT

Please see 37 CFR 1.97(e) to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☒ A certification statement is not submitted herewith.

FEE

☒ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

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SIGNATURE

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Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2024-09-27
Name/Print	Benjamin F. Hudson	Registration Number	71,474

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

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7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

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Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-22)
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	Filing Date	2024-07-24
	First Named Inventor	Bobby ROGERS
	Art Unit	3791
	Examiner Name	HUONG Q NGUYEN
	Attorney Docket Number	069366-0580420_KUR3C03US

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	1	20140163419		2014-06-12	BULLINGTON GREGORY J	
	2	20140309558		2014-10-16	FLETCHER GARY D	
	3	20140073990		2014-03-13	HOLMES ELIZABETH A	
	4	20140323911		2014-10-30	SLOAN DEBORAH	
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	1	Office Action (Non-Final Rejection) dated 9/17/2024 for U.S. Application No. 17/893,079 ; Attorney Docket No. 069366-0572192_KUR3C02US (pages 1-50).	☐
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	4	Office Action (Notice of Deficiencies) dated 10/14//2023 for IL App No. 309380 (pages 1-7).	☐

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	Attorney Docket Number	069366-0580420_KUR3C03US

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☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☒ A certification statement is not submitted herewith.

FEE

☒ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

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Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2024-10-16
Name/Print	Benjamin F. Hudson	Registration Number	71,474

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

PC 6.1.24

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /H.Q.N/

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /H.Q.N/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT		
	Application Number	18/898,239
	Filing Date	09/26/2024
	First Named Inventor	Bobby E. Rogers
	Art Unit	
	Client Number	069366
Page 1 of 1	**Matter Number**	0581370_KUR2C07US

GENERAL

Pursuant to 37 C.F.R. 1.97 and 1.98 and to the duty of disclosure set forth in 37 C.F.R. 1.56, the Examiner in charge of the above-identified application is requested to consider and make of record the references listed herewith. A copy of each listed reference, other than U.S. patents/applications and references cited in a parent application, is enclosed.

Although the information submitted herewith may be "material" to the Examiner's consideration of the subject application, this submission is not intended to constitute an admission that such information is "prior art" as to the claimed invention, nor is it intended to constitute an admission that such information is "analogous prior art".

In accordance with 37 C.F.R. 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.

TIMING

In accordance with 37 CFR 1.97(c), this Information Disclosure Statement is being filed after the period specified in 37 CFR 1.97(b) and before the mailing date of a Final Action under 37 CFR 1.113, a Notice of Allowance under 37 CFR 1.311, or an Action that otherwise closes prosecution in the application.

CERTIFICATION STATEMENT

No certification statement is required. This Information Disclosure Statement is being filed in accordance with 37 CFR 1.97(c) and is accompanied by the fee set forth in 37 CFR 1.17(p).

FEE

This Information Disclosure Statement is being filed in accordance with 37 CFR 1.97(c), and is not accompanied by one of the certification statements of 37 CFR 1.97(e). Therefore, this Information Disclosure Statement is subject to the $104 (small entity) PTO Timing Fee set forth in 37 CFR 1.17(p).

ADDITIONAL COMMENTS

SIGNATURE

Signature	/Benjamin F. Hudson/	**Date**	2024-12-17
Name	Benjamin F. Hudson	**Registration Number**	71,474

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UNITED STATES
PATENT AND TRADEMARK OFFICE

P.O. Box 1450
Alexandria, VA 22313 - 1450
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ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
18/898,239	**12/17/2024 05:34:54 PM Z ET**	**069366-0581370_KUR2C07US**

Title of Invention

BLOOD SAMPLE OPTIMIZATION DEVICE

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	7801	FILED BY	Trent Tercenio
PATENT CENTER #	68405127	FILING DATE	09/26/2024
CUSTOMER #	27500	FIRST NAMED INVENTOR	Bobby E. Rogers
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	Benjamin Hudson

Documents

TOTAL DOCUMENTS: 9

DOCUMENT		PAGES	DESCRIPTION	SIZE (KB)
069366-0581370_KUR2C07US_Response_to_Non-Final_Office_Action_rcvd_22NOV2024_4874-6969-2671_v1.pdf		12	-	221 KB
069366-0581370_KUR2C07US_Response_to_Non-Final_Office_Action_rcvd_22NOV2024_4874-6969-2671_v1-A....pdf	(1-1)	1	Amendment/Request for Reconsideration-After Non-Final Rejection	96 KB
069366-0581370_KUR2C07US_Response_to_Non-	(2-6)	5	Claims	125 KB

Final_Office_Action_rcvd_22NOV2024_4874-6969-2671_v1-CLM.pdf				
069366-0581370_KUR2C07US_Response_to_Non-Final_Office_Action_rcvd_22NOV2024_4874-6969-2671_v1-REM.pdf	(7-12)	6	Applicant Arguments/Remarks Made in an Amendment	181 KB
069366-0581370_KUR2C07US-NPL-003.pdf		8	Non Patent Literature	277 KB
069366-0581370_KUR2C07US_Transmittal-Letter.pdf		1	Transmittal Letter	493 KB
069366-0581370_KUR2C07US-NPL-001.pdf		22	Non Patent Literature	971 KB
069366-0581370_KUR2C07US-NPL-004.pdf		62	Non Patent Literature	2532 KB
069366-0581370_KUR2C07US-NPL-002.pdf		62	Non Patent Literature	3538 KB
069366-0581370_KUR2C07US_PTO_IDS-Form.pdf		4	Information Disclosure Statement (IDS) Form (SB08)	1272 KB

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
069366-0581370_KUR2C07US_Response_to_Non-Final_Office_Action_rcvd_22NOV2024_4874-6969-2671_v1.pdf	4247FA0897C6360E88E801C9A1EAA9A53F1EFE3C1A598362025D9E6E263CC3E6943550E2584C410B687975975B871C7EAA9D53025A14DAC88798C901220A27FD
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069366-0581370_KUR2C07US_Response_to_Non-Final_Office_Action_rcvd_22NOV2024_4874-6969-2671_v1-REM.pdf	7BBE0D6D849ACFD2AA84897EFC898CB1156C0DC0436CD36FDFEF98071471A81BB9AD5D516BC0EB206EEC77B1F37423170C99EC6AD8DE17C45D2432491AD6C6E1
069366-0581370_KUR2C07US-NPL-003.pdf	54FD5F82FDF06E98692624A1C50B837731EE9E4CF11D5F2852BB8579E30A18D33CCDDFC9499F04DAFDB666325B6FBAB47A9A0002167C62718D1073B232558B87
069366-0581370_KUR2C07US_Transmittal-Letter.pdf	57D1E359DAB354DAAFE0B6BAA594C0881FF47F34571CCB7E87536368D21F2F45C1CA9F181194405CB318DEEBE602B9E1D736143AD523462E6833A61EEB24E83B
069366-0581370_KUR2C07US-NPL-001.pdf	88B16E78BB224A47EE9FCDB40B64F4EE093F0C307DF5D90FD47A048C68DE8A748170A4176CDF442DDEEC88266A0D73E26CCCBBE0B9CEF7DDD0D1912B380CD946
069366-0581370_KUR2C07US-NPL-004.pdf	ABE45DD5733F0BDD358DDC0501857953783AB44A8B0A016F6AE05FDA4893114E27F13E8A2B91ED61EE2183FF1C49DB1F4B36992A655E5018A59F924695AD8A63
069366-0581370_KUR2C07US-NPL-002.pdf	42EFC06FDD8C8BCF921C0795647608EEC1F89C96CDAFCDB092423F1FC620D91167B11393265CD6E6F708ADF724A813B8CF7AF874EDFF3CA746AD91EE64C84B3C
069366-0581370_KUR2C07US_PTO_IDS-Form.pdf	E5A967397AC361BD9932A07D42BE5CAD5DEC1943D6BC6C92D31FDBCDD50BA807ECD999018F99F818A1D7A8ACE1BCB1CCD27F79838F4CC54522CB87EA69DCB047

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

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UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/317,558	05/15/2023	Bobby E. ROGERS	069366-0575710_KUR4C02US	8048

27500 7590 10/22/2024

PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
ATTENTION: DOCKETING DEPARTMENT
P.O BOX 10500
McLean, VA 22102

EXAMINER	
ABOUELELA, MAY A	

ART UNIT	PAPER NUMBER
3791	

NOTIFICATION DATE	DELIVERY MODE
10/22/2024	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Docket_IP@pillsburylaw.com

Office Action Summary	Application No. 18/317,558	Applicant(s) ROGERS et al.	
	Examiner MAY A ABOUELELA	Art Unit 3791	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 05/15/2023.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL.** 2b) ☑ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 1 is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 1 is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to **PPHfeedback@uspto.gov.**

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☑ The drawing(s) filed on 05/15/2023 is/are: a)☑ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☑ Notice of References Cited (PTO-892)

2) ☑ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

Notice of Pre-AIA or AIA Status

1. The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 04/23/2023, 06/27/2024, 08/26/2024 and 10/16/2024. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the claims at issue are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the reference application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO internet Web site contains terminal disclaimer forms which may be used. Please visit http://www.uspto.gov/forms/. The filing date of the application will determine what form should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to http://www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp.

Claim 1 is non-provisionally rejected on the ground of non-statutory double patenting as being unpatentable over claims 1-20 of U.S Patent No. 10827964, and claims 1-43 of U.S Patent No. 11744494. Although the claims at issue are not identical, they are not patentably distinct from each other because the U.S Patent Applications and the instance application are claiming a common subject matter including: a blood sequestration device comprising; an inlet port; an outlet port; a sequestration chamber connected with the inlet port, the sequestration chamber having a vent configured to allow air to be displaced by a first portion of blood entering the inlet port and into the sequestration chamber; a closure to enclose the vent to inhibit air from entering the

sequestration chamber after the first portion of blood has displaced the air in the sequestration chamber; a sampling channel having a proximal end connected with the inlet port and a distal end connected with the outlet port, the sampling channel being configured to convey subsequent portions of blood to the outlet port after the first portion of blood has entered the sequestration chamber; and a housing that houses and defines the inlet port, the outlet port, the sequestration chamber, and the sampling channel.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MAY A ABOUELELA whose telephone number is (571)270-7917. The examiner can normally be reached 8-5.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JACQUELINE CHENG can be reached on 5712725596. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: https://patentcenter.uspto.gov. Visit https://www.uspto.gov/patents/apply/patent-

center for more information about Patent Center and

https://www.uspto.gov/patents/docx for information about filing in DOCX format. For

additional questions, contact the Electronic Business Center (EBC) at 866-217-9197

(toll-free). If you would like assistance from a USPTO Customer Service

Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MAY A ABOUELELA/
Primary Examiner, Art Unit 3791

Notice of References Cited	Application/Control No. 18/317,558	Applicant(s)/Patent Under Reexamination ROGERS et al.	
	Examiner MAY A ABOUELELA	Art Unit 3791	Page 1 of 4

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date YYYY-MM-DD	Name	CPC Classification	US Classification
*	A	US-20080319346-A1	2008-12-25	Crawford; Jamieson	A61B5/150656	600/576
*	B	US-4412548-A	1983-11-01	Hoch; Louis	A61B5/150213	600/577
*	C	US-5222502-A	1993-06-29	Kurose; Katsutoshi	A61B5/150732	600/584
*	D	US-5520193-A	1996-05-28	Suzuki; Issei	A61B5/1545	604/126
*	E	US-20100057004-A1	2010-03-04	Christensen; Kelly D.	A61M25/0606	604/122
*	F	US-20070088279-A1	2007-04-19	Shue; Ming-Jeng	A61M25/0693	604/168.01
*	G	US-20080145933-A1	2008-06-19	Patton; Richard G.	A61B5/154	435/379
*	H	US-20040054333-A1	2004-03-18	Theeuwes, Felix	A61M5/14276	604/248
*	I	US-9022951-B2	2015-05-05	Bullington; Gregory	A61B5/150221	600/576
*	J	US-6569117-B1	2003-05-27	Ziv; David	A61M39/02	604/246
*	K	US-3741197-A	1973-06-26	Sanz; Manuel C.	A61B5/150267	600/583
*	L	US-20100010372-A1	2010-01-14	BROWN; LEROY R.	A61B5/15003	600/573
*	M	US-8603009-B2	2013-12-10	Tan; Alvin Chee Leong	A61B5/150251	600/573

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date YYYY-MM-DD	Country	Name	CPC Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in YYYY-MM-DD format are publication dates. Classifications may be US or foreign.

Notice of References Cited	Application/Control No. 18/317,558	Applicant(s)/Patent Under Reexamination ROGERS et al.	
	Examiner MAY A ABOUELELA	Art Unit 3791	Page 2 of 4

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date YYYY-MM-DD	Name	CPC Classification	US Classification
*	A	US-9138572-B2	2015-09-22	Zeytoonian; Paul	A61M39/26	1/1
*	B	US-20080167577-A1	2008-07-10	Weilbacher; Eugene E.	A61B5/1545	600/576
*	C	US-20080086085-A1	2008-04-10	Brown; Leroy R.	A61B5/150389	604/122
*	D	US-9877675-B2	2018-01-30	Baid; Rishi	A61B5/150389	1/1
*	E	US-4444203-A	1984-04-24	Engelman; Allan	A61B5/150496	600/576
*	F	US-20070083162-A1	2007-04-12	O'Reagan; James	A61M39/26	604/167.03
*	G	US-6398743-B1	2002-06-04	Halseth; Thor R.	A61B5/15003	604/164.12
*	H	US-9022950-B2	2015-05-05	Bullington; Gregory	A61B5/150251	600/576
*	I	US-9155495-B2	2015-10-13	Bullington; Gregory J.	A61B10/0045	1/1
*	J	US-20160008579-A1	2016-01-14	Burkholz; Jonathan Karl	A61M5/158	604/164.08
*	K	US-20120016266-A1	2012-01-19	Burkholz; Jonathan Karl	A61B5/150992	600/581
*	L	US-4436098-A	1984-03-13	Kaufman; Joseph	A61B5/1545	604/199
*	M	US-4154229-A	1979-05-15	Nugent; Edward L.	A61B5/154	600/577

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date YYYY-MM-DD	Country	Name	CPC Classification
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Notice of References Cited	Application/Control No. 18/317,558	Applicant(s)/Patent Under Reexamination ROGERS et al.	
	Examiner MAY A ABOUELELA	Art Unit 3791	Page 3 of 4

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*	A	US-20040073171-A1	2004-04-15	Rogers, Bobby E.	A61M39/26	604/164.13
*	B	US-8568371-B2	2013-10-29	Siopes; William	A61M39/06	251/903
*	C	US-8540663-B2	2013-09-24	Davey; Christopher T.	A61M25/0029	604/93.01
*	D	US-8523826-B2	2013-09-03	Layton, Jr.; Russell K.	A61M39/16	604/533
*	E	US-20160174888-A1	2016-06-23	Berthier; Erwin	A61B5/150503	600/573
*	F	US-8197420-B2	2012-06-12	Patton; Richard G.	A61B5/150503	600/573
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*	J	US-8864684-B2	2014-10-21	Bullington; Gregory J.	A61B10/0048	600/576
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*	B	US-5749857-A	1998-05-12	Cuppy; Michael J.	A61M25/0606	604/161
*	C	US-9060724-B2	2015-06-23	Bullington; Gregory J.	A61B5/150221	1/1
*	D	US-9204864-B2	2015-12-08	Bullington; Gregory J.	A61B10/0096	1/1
*	E	US-20020004647-A1	2002-01-10	Leong, Alvin Tan Chee	A61B5/15003	604/168.01
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*	I	US-4106497-A	1978-08-15	Percarpio; Edward P.	A61B5/150389	600/579
*	J	US-4207870-A	1980-06-17	Eldridge; William N.	A61B5/150732	604/167.03
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	18317558
	Filing Date	2023-05-15
	First Named Inventor	Bobby E. ROGERS
	Art Unit	3791
	Examiner Name	ABOUELELA, MAY A
	Attorney Docket Number	069366-0572186_KUR4C02US

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	4312362		1982-01-26	KAUFMAN JOSEPH	

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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20140163419		2014-06-12	BULLINGTON GREGORY J	
	2	20140309558		2014-10-16	FLETCHER GARY D	
	3	20140073990		2014-03-13	HOLMES ELIZABETH A	
	4	20140323911		2014-10-30	SLOAN DEBORAH	
	5	20040112808		2004-06-17	TAKAGI YOSHIKI	

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	1	Office Action (Non-Final Rejection) dated 9/24/2024 for U.S. Application No. 18/783,173 ; Attorney Docket No. 069366-0580420_KUR3C03US (pages 1-62).	☐
	2	Office Action (Non-Final Rejection) dated 9/17/2024 for U.S. Application No. 17/893,079 ; Attorney Docket No. 069366-0572192_KUR3C02US (pages 1-50).	☐
	3	Office Action (Non-Final Rejection) dated 9/23/2024 for U.S. Application No. 17/730,118 ; Attorney Docket No. 069366-0572186_KUR3C01US (pages 1-73).	☐
	4	Office Action (Non-Final Rejection) dated 9/17/2024 for U.S. Application No. 18/783,088 ; Attorney Docket No. 069366-0580418_KUR2C06US (pages 1-60).	☐
	5	Office Action (Notice of Deficiencies) dated 10/14//2023 for IL App No. 309380 (pages 1-7).	☐

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	Art Unit	3791
	Examiner Name	ABOUELELA, MAY A
	Attorney Docket Number	069366-0572186_KUR4C02US

CERTIFICATION STATEMENT

Please see 37 CFR 1.97(e) to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

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☐ See attached certification statement.

☒ A certification statement is not submitted herewith.

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☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

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☐ An identification of an earlier application pursuant to 37 CFR 1.98 (d) (1) is attached.

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A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2024-10-16
Name/Print	Benjamin F. Hudson	Registration Number	71,474

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First Named Inventor	Bobby E. ROGERS
Art Unit	3791
Examiner Name	ABOUELELA, MAY A
Attorney Docket Number	069366-0572186_KUR4C02US

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	2	9764891		2017-09-19	AVILES VICTOR M	
	3	5147329		1992-09-15	BRANNON JAMES K	
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	5	62845767		2019-05-09	BREWER MICHAEL	

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	1	20150314105		2015-11-05	GASPARYAN LEVON	

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	2	20150359473		2015-12-17	GARRETT CHAD	
	3	20160262677		2016-09-15	EBETSBERGER FRANZ	
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	6	20190365303		2019-12-05	BULLINGTON GREGORY J	
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	2	0448795	EP		1991-02-10			☒
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	4	104107054	CN		2014-10-22	BECTON DICKINSON CO		☒
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	1	Office Action (Non-Final Rejection) dated 04/25/2023 for US App. 16838017 (pages 1-20).	☐
	2	Office Action (Final Rejection) dated 01/29/2024 for US App. 16838017 (pages 1-44).	☐

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	3	"Membrane Definition & Meaning," Merriam-Webster, Merriam-Webster, 22 Apr. 2009, www.merriam-webster.com/ dictionary/ membrane. (Year: 2009).	☐
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	6	Office Action (Non-Final Rejection) dated 05/21/2024 for IL App. 286812 (pages 1-3).	☐
	7	First Office Action (Non-Final Rejection) dated 01/16/2024 for JP App. 2021-558648 (pages 1-6).	☐
	8	First Office Action (Non-Final Rejection) dated 09/27/2023 for CN App. 202080000666.0 (pages 1-11).	☐
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	10	European Patent Office, Extended European Search Report for European Patent Application 21818838.1-1122, dated April 22, 2024, 11 pages.	☐
	11	Australian Patent Office, Examination Report No. 1 for for Australian Patent Application 2021202622, dated March 18, 2022, 3 pages.	☐
	12	Office Action (Final Rejection) dated 08/25/2023 for US Application No. 18113710 (pages 1-50).	☐
	13	European Patent Office, Extended European Search Report for European Patent Application 23155927.9-1122, dated July 26, 2023, pages 1-8.	☐

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	14	Office Action (Non-Final Rejection) mailed 10/04/2023 for US Application No. 17538900 (1-47).	☐
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	17	Office Action (Final Rejection) dated 07/19/2023 for US Application No. 17893079, pages 1-21.	☐
	18	Advisory Action dated 09/29/2023 for US Application 17893079, pages 1-24.	☐
	19	European Patent Office, Examination Report for European Patent Application 22181212.6-1122, dated September 28, 2023, pages 1-5.	☐
	20	European Patent Office, Extended European Search Report for European Patent Application 20781928.5-1122 dated October 28, 2022, pages 1-10.	☐
	21	Rule 70(a) Communication for European Application No. 20781928.5-1122 dated November 15, 2022, 1 page.	☐
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	26	First Office Action dated 11/24/2021 for IL Application No. 286030, pages 1-3.	☐
	27	Notice of Allowance mailed 01-29-2023; Attorney Docket No. 069366-0572425_KUR2D01IL. 87 pages.	☐
	28	Office Action (Non-Final Rejection) dated 08/10/2021 for Japanese Application No. 2020-118498, pages 1-7.	☐
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	30	Office Action (Non-Final Rejection) dated 09/01/2022 for Japanese Application No. 2020-118498, pages 1-4.	☐
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	33	Office Action (Non-Final Rejection) mailed 01/21/2022 for Israeli Application No. 267684. 3 pages.	☐
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	18317558
	Filing Date	2023-05-15
	First Named Inventor	Bobby E. ROGERS
	Art Unit	3791
	Examiner Name	ABOUELELA, MAY A
	Attorney Docket Number	069366-0572186_KUR4C02US

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EXAMINER SIGNATURE

Examiner Signature	/MAY A ABOUELELA/	Date Considered	10/17/2024

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

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CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2024-06-27
Name/Print	Benjamin F. Hudson	Registration Number	71,474

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

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First Named Inventor	Bobby E. ROGERS
Art Unit	OPAP
Examiner Name	CENTRAL, DOCKET
Attorney Docket Number	069366-0572186_KUR4C02US

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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	2	8827958		2014-09-09	BIERMAN STEVEN F	
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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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	Attorney Docket Number	069366-0572186_KUR4C02US

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	19	20170020428		2017-01-26	ROGERS BOBBY E	
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	54	20070119508		2007-05-31	WEST RICHARD L	
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	61	20220304664		2022-09-29	HAMMER JEREMY	
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CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2024-04-23
Name/Print	Benjamin F. Hudson	Registration Number	71,474

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-22)
Approved for use through 05/31/2024. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	18317558
Filing Date	2023-05-15
First Named Inventor	Bobby E. ROGERS
Art Unit	3791
Examiner Name	ABOUELELA, MAY A
Attorney Docket Number	069366-0572186_KUR4C02US

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
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PC 6.1.24

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	Attorney Docket Number	069366-0572186_KUR4C02US

	1	Notice of Allowance mailed 07-04-2024; Attorney Docket No. 069366-0572164_KUR7N01JP. 9 pages.	☐
	2	Office Action mailed 05-21-2024; Attorney Docket No. 069366-0572161_KUR7N01IL. 6 pages.	☐
	3	European Patent Office, Examination Report for European Patent Application 20781928.5, dated July 31, 2024, pages 1-6.	☐

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EXAMINER SIGNATURE

Examiner Signature	/MAY A ABOUELELA/	Date Considered	10/17/2024

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

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	Examiner Name	ABOUELELA, MAY A
	Attorney Docket Number	069366-0572186_KUR4C02US

CERTIFICATION STATEMENT

Please see 37 CFR 1.97(e) to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☒ A certification statement is not submitted herewith.

FEE

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

COPIES

☐ An identification of an earlier application pursuant to 37 CFR 1.98 (d) (1) is attached.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2024-08-26
Name/Print	Benjamin F. Hudson	Registration Number	71,474

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

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	1	Office Action (Non-Final Rejection) dated 10/04/2023 for US App. No. 17538990 (pages 1-47)	☐
	2	Notice of Allowance mailed 01-17-2024; Attorney Docket No. 069366-0572201_KUR2C03US. 16 pages.	☐
	3	JP Office Action mailed 02/27/2024; Attorney Docket No. 069366-0575273_KUR2D03JP. 11 pages.	☐

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Bobby E. Rogers, et al.

Confirmation No: 7801

Application No.: 18/898,239

Art Unit: 3791

Filed: September 26, 2024

Examiner: May A. Abouelela

For: BLOOD SAMPLE OPTIMIZATION DEVICE

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE TO NON-FINAL OFFICE ACTION

Dear Examiner Abouelela:

This reply is responsive to the Non-Final Office Action mailed November 22, 2024, in the above-referenced matter (hereinafter "the Office Action"). Reconsideration and allowance of the application is requested in view of the following:

Listing of Claims beginning on page 2.

Remarks beginning on page 7.

LISTING OF CLAIMS

This listing of claims replaces all prior versions of claims in the application:

1. (Original) A device comprising:

an inlet port for receiving a blood sample;

an outlet port;

a chamber connected with the inlet port and configured to collect a first portion of the blood sample when under a drawing force applied from the outlet port from a blood sample collection device; and

a sampling channel connected with the inlet port and configured to convey a subsequent portion of the blood sample to the outlet port.

2. (Original) The device in accordance with claim 1, wherein a blood impermeable membrane is configured to facilitate the chamber collecting the first portion of the blood sample.

3. (Original) The device in accordance with claim 1, wherein a blood impermeable membrane causes the first portion of the blood sample to back up into the chamber following application of the drawing force applied from the outlet port.

4. (Original) The device in accordance with claim 2, further comprising a housing, separate from the blood impermeable membrane.

5. (Original) The device in accordance with claim 1, wherein the device is configured such that, when the drawing force is applied at the outlet port, the first portion of the blood sample is drawn into the chamber to contact a material that is blood impermeable.

6. (Original) The device in accordance with claim 1, further comprising a valve configured to initially close off the sampling channel.

7. (Original) The device in accordance with claim 1, further comprising a valve configured to initially close off the sampling channel until the first portion of the blood sample is in the chamber.

8. (Original) The device in accordance with claim 1, further comprising a valve that is configured to initially close off the sampling channel until the first portion of the blood sample is in the chamber and is further configured such that, upon release, follow-on amounts of the blood sample will bypass the chamber and flow through the sampling channel toward the outlet port.

9. (Original) The device in accordance with claim 6, wherein the valve is configured to pinch, shunt, bend or otherwise close off the sampling channel before the first portion of the blood sample is collected in the chamber.

10. (Cancelled)

11. (Previously Presented) The device in accordance with claim 1, further comprising a patient needle and the blood sample collection device.

12. (Original) The device in accordance with claim 1, the chamber having a volume sufficient to collect the first portion of the blood sample that is more prone to contamination and also to minimize an amount of blood to be sequestered.

13. (Original) The device in accordance with claim 1, wherein the chamber has a volume of less than 1.5 cubic centimeters.

14. (Original) A device comprising:

an inlet port for receiving blood;

an outlet port;

a chamber comprising a flexible material, the chamber connected with the inlet port and configured to collect a first portion of the blood when under a drawing force applied from the outlet port; and

a sampling channel connected with the inlet port and configured to convey a subsequent portion of the blood to the outlet port.

15. (Original) The device in accordance with claim 14, wherein the flexible material is a blood impermeable membrane configured to facilitate the chamber collecting the first portion of the blood.

16. (Original) The device in accordance with claim 14, wherein the flexible material is a blood impermeable membrane causes the first portion of the blood to back up into the chamber following application of the drawing force applied from the outlet port.

17. (Original) The device in accordance with claim 15, further comprising a housing, separate from the blood impermeable membrane.

18. (Original) The device in accordance with claim 14, wherein the device is configured such that, when the drawing force is applied at the outlet port, the first portion of the blood is drawn into the chamber to contact a material that is blood impermeable.

19. (Original) The device in accordance with claim 14, further comprising a valve configured to initially close off the sampling channel.

20. (Original) The device in accordance with claim 14, further comprising a valve configured to initially close off the sampling channel until the first portion of the blood is in the chamber.

21. (Original) The device in accordance with claim 14, further comprising a valve that is configured to initially close off the sampling channel until the first portion of the blood is in the chamber and is further configured such that, upon release, follow-on amounts of the blood will bypass the chamber and flow through the sampling channel toward the outlet port.

22. (Original) The device in accordance with claim 19, wherein the valve is configured to pinch, shunt, bend or otherwise close off the sampling channel before the first portion of the blood is collected in the chamber.

23. (Cancelled)

24. (Original) The device in accordance with claim 14, further comprising a patient needle and a sample collection device.

25. (Original) The device in accordance with claim 14, the chamber having a volume sufficient to collect the first portion of the blood that is more prone to contamination and also to minimize an amount of blood to be sequestered.

26. (Original) The device in accordance with claim 14, wherein the chamber has a volume of less than 1.5 cubic centimeters.

REMARKS

Claim Summary: Prior to this response, Claims 1-9, 11-22, and 24-26 were pending. No amendments are made with this response. No new matter is added with this amendment. Reconsideration and allowance of the current application are requested in light of the following remarks.

Summary of Rejections: The Office rejects Claims 1-9, 11-22, and 24-26 on the grounds of non-statutory double patenting over Claims 1-24 of U.S. Patent No. 12,138,052; rejects Claims 1, 6-9, 11, 12, 14, 19-22, 24, and 25 under 35 U.S.C. §102(a)(1) as allegedly being anticipated by Patton, et al. (U.S. 2008/0145933), hereinafter "Patton;" rejects Claims 2-5 and 15-18 as allegedly being unpatentable under 35 U.S.C. §103 over Patton in view of Flaherty, et al. (U.S. 2006/0009713), hereinafter "Flaherty;" and rejects Claims 13 and 26 as allegedly being unpatentable under 35 U.S.C. §103 over Patton.

No Change in Scope of Claims: The Office is respectfully reminded that the scope of at least one claim has remained unchanged in this Response. If new grounds of rejection for an unchanged claim are presented in a subsequent action, per MPEP§706.07(a), that subsequent action cannot properly be made final.

Request for Interview: The present response is believed to be sufficient to overcome the pending rejections. However, if this paper is not deemed sufficient to result in a notice of allowance, or if any remaining issues can be more efficiently handled by telephone, the Examiner is respectfully requested to contact the undersigned by either phone or e-mail to schedule an interview at a mutually convenient time.

Rejections for Non-Statutory Double Patenting

The Office Action rejects Claims 1-9, 11-22, and 24-26 on the grounds of non-statutory obviousness-type double patenting as allegedly being unpatentable over Claims 1-24 of U.S. Patent No. 12,138,052. In order to further prosecution of the present application and obtain allowance of the pending claims, Applicant submits herewith a terminal disclaimer to overcome the rejections. In so doing, Applicant does not indicate agreement with the propriety of the rejections.

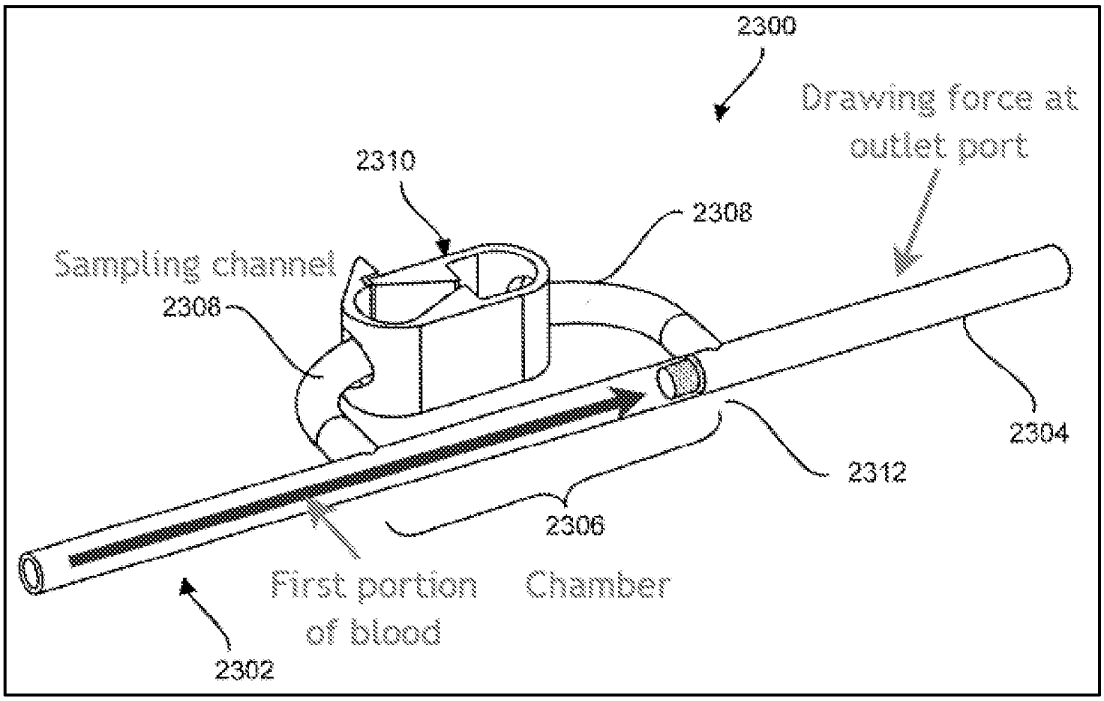
Rejections under 35 U.S.C. § 102/103

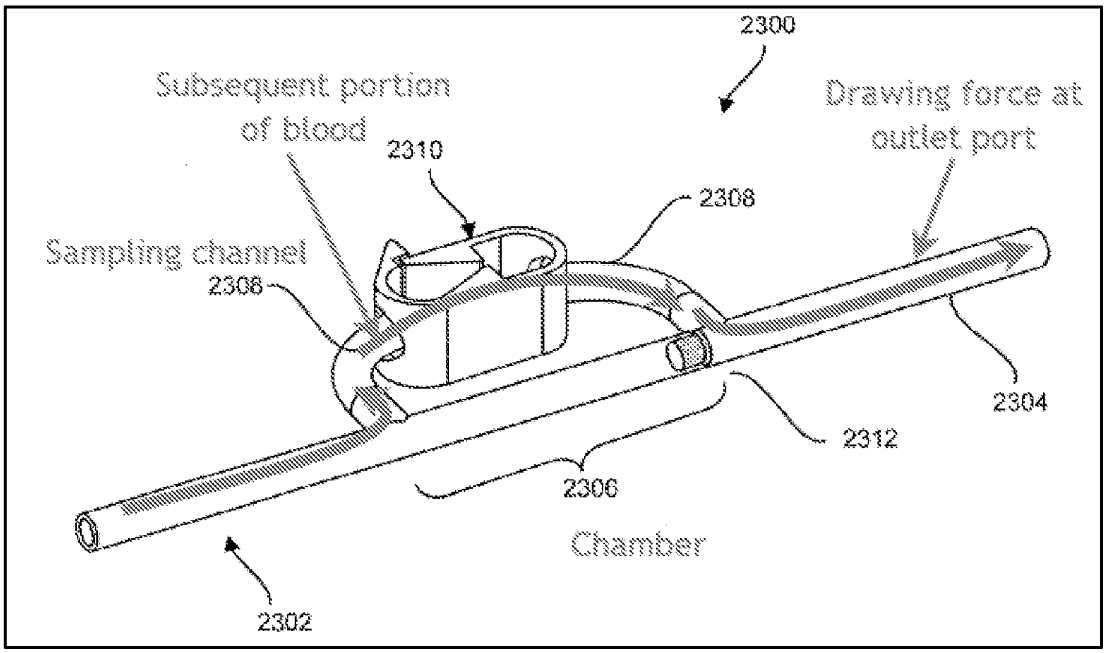
Claim 1

The Office Action rejected Claim 1 as allegedly anticipated under 35 U.S.C. § 102 in view of Patton (U.S. Publication 2008/0145933). However, Patton fails to disclose or suggest at least the following elements of Claim 1:

> "a chamber connected with the inlet port and configured **to collect a first portion of the blood sample when under a drawing force applied from the outlet port** from a blood sample collection device; and
>
> a sampling channel connected with the inlet port and configured to convey a **subsequent** portion of the blood sample to **the outlet port**."

As an illustrative example of the features of Claim 1, below are annotated versions of the instant application's Figure 23A. The first figure shows an example of the **first** portion of blood going into chamber 2306 due to **a drawing force applied from outlet port 2304**. The next diagram shows the same drawing force bringing a **subsequent** portion of blood through sample channel 2308 to **the same outlet port 2304**.





In contrast, the first portion of blood in the cited Patton reference, which fills a "pre-sample reservoir 504," is not drawn in by a force applied from outlet port 510, as claimed, but

rather by a vacuum in the pre-sample reservoir (e.g., from a vacutainer). See, e.g., Paragraph [0024] and Figure 5:

> "For example, in at least some embodiments, **the pre-sample reservoirs 104 are BD Vacutainers™** with buffered citrate, manufactured by Becton Dickenson."

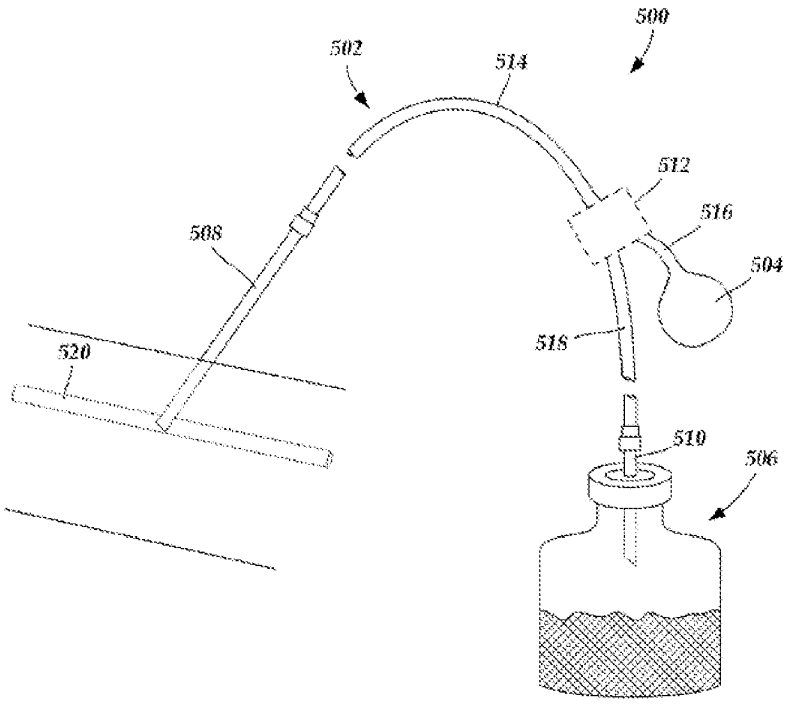


Fig. 5

It is clear from the configuration of Patton that a drawing force at its **outlet** 510 cannot "collect a **first** portion of the blood sample" in its alleged **chamber 504**. As such, Claim 1 is not anticipated by Patton.

Claim 14

The same arguments apply to the similar limitation in independent Claim 14, which is also rejected as allegedly anticipated by Patton.

For at least the reasons given above, the art of record fails to disclose or suggest each of

the elements of Claim 1 and Claim 14 and thus should not be rejected under §102 or §103.

Each of the remaining pending claims depends from one of independent Claims 1 or 14 and thus each is likewise patentable for at least the reasons discussed above.

CONCLUSION

On the basis of the foregoing remarks and/or amendments, allowance of the pending claims is respectfully requested. It is believed that all the pending rejections have been addressed in this paper. However, failure to address a specific rejection, issue or comment, does not signify agreement with or concession of that rejection, issue or comment. In addition, because any arguments made above are not intended to be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed. Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper.

No additional fees are believed to be due, however the Commissioner is authorized to charge any fees that may be due, or credit any overpayment of same, to Deposit Account 033975, Reference No. 069366-0581370_KUR2C07US. If there are any questions regarding this submission, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

Respectfully submitted,
PILLSBURY WINTHROP SHAW PITTMAN LLP

Date: December 17, 2024 By: /Ben Hudson/
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4874-6969-2671.v1

Reference No.: 0575273
Mailing No.: 531664
Mailing Date: November 5, 2024

Rejection Decision
(Translation)

Application No.	Japanese Patent Application No. 2023-076490	
Drafting Date	October 29, 2024	
Examiner	Yoshinori Koh	9813 2Q00
Title	BLOOD SAMPLE OPTIMIZATION DEVICE	
Applicant	Kurin Inc.	
Representative	Satoshi MURAKOSHI	

The rejections on the Grounds 3 and 4 stated in the Office Action drafted on February 26, 2024 (mailed on February 27, 2024) have been maintained.

The Response and Amendment submitted by the Applicant have been considered but are not sufficiently persuasive to overcome the rejections.

Notes:

●Ground 3 (Section 29, Paragraph 1, Item 3 of the Japanese Patent Act) and Ground 4 (Section 29, Paragraph 2 of the Japanese Patent Act)

- Claims: 1, 4, 8 and 13
- Cited References: 1

The term "sambling channel" in claim 1 is hypothetically interpreted as meaning "sampling channel."

Reference 1 (Page 3, Lower Left Section, Line 15 to Page 7, Upper Left Section, Line 20, Figs. 1 to 9) discloses a device comprising:

an inlet port for receiving a blood sample (an inner end (inner opening 30) of a first puncture needle 14 that communicates with a chamber 28, or an inner end 39 of a second puncture needle 15 protruding into the chamber 28);

an outlet port (a tip end of an outer extension portion of the second puncture needle 15);

a chamber (the space containing the porous plug (porous member that is gas permeable and liquid impermeable) 52 and the space between the hole 48 and the porous plug 52, in the inner cavity 51 of the second puncture needle 15) connected with the inlet port and the outlet port, and configured to collect a first portion of the blood sample, the chamber including a material (the porous plug (porous member that is gas permeable and liquid impermeable) 52) that is air permeable and blood impermeable; and

a sampling channel (cavity 46) connected with the inlet port and the chamber at a first junction

(the site in the inner cavity 51 where the hole 48 is located) and connected with the outlet port and the chamber at a second junction (the site in the inner cavity 51 where the hole 50 is located) different than the first junction, the sampling channel being configured to convey a subsequent portion of the blood sample to the outlet port.

In regard with claim 8, the feature "valve" is equivalent to the sleeve valve 41 disclosed in Reference 1.

In regard with claim 13, the feature "patient needle" is equivalent to the first puncture needle 14 disclosed in Reference 1, and the feature "sample collection device" is equivalent to the vessel holder 19 and the vacuum blood collection vessel 16 disclosed in Reference 1.

For the reasons stated above, claims 1, 4, 8 and 13 are anticipated by the disclosure of Reference 1.

Additionally, claims 1, 4, 8 and 13 are obvious to the person skilled in the art based on Reference 1.

The Applicant argued in the Argument as follows.

(a) Referring to Reference 1, the collected blood may be blocked by the porous plug 52 prior to attaching of the vacuum blood collection vessel to the puncture needle 15, but the blocked blood can be collected into the vacuum blood collection vessel once the vacuum blood collection vessel is attached to the puncture needle 15. According to the technique disclosed in Reference 1, the blood sample blocked by the porous plug 52 is entirely, including the first portion, collected into the vessel through the cavity 46, which forms a detour in communication with the hole 48.

In light of the above, the present invention is different from the invention disclosed in Reference 1 at least in terms of the following point.

• Difference A1: While the present invention includes "the chamber configured to collect a first portion of the blood sample" and "the sampling channel configured to convey a subsequent portion of the blood sample to the outlet port," the invention disclosed in Reference 1 does not mention the feature equivalent to the chamber configured to collect the first portion of the blood.

Therefore, the present invention is novel over the invention disclosed in Reference 1.

(b) As discussed above, Reference 1 neither discloses nor suggests that the chamber configured to collect the first portion of the blood be provided separately from the channel configured to convey the subsequent portion of the blood. Furthermore, according to the invention disclosed in Reference 1, the blood blocked by the porous plug 52 is entirely collected into the vessel, including the first portion of the blood sample, while the first portion is more likely to contain contaminants than the subsequent portion. Therefore, unlike the present invention, the invention disclosed in Reference 1 can not reduce contaminants in blood cultures.

For the reasons stated above, the present invention is not obvious to the person skilled in the art due to the difference A1.

According to the invention disclosed in Reference 1, however, the blood reserved in the partial space in the inner cavity 51 of the second puncture needle 15, specifically, the space between the hole 48 and the porous plug 52, is at least partially left in the space between the hole 48 and the porous plug 52 even after the puncture needle 15 penetrates the penetratable stopper 21. The disclosure of

Reference 1 is not interpreted as indicating that "the blood sample blocked by the porous plug 52 is entirely, including the first portion, collected into the vessel through the cavity 46, which forms the detour in communication with the hole 48."

Here, it may be assumed that the blood reserved in the partial space in the inner cavity 51 of the second puncture needle 15, specifically, the space between the hole 48 and the porous plug 52, is "entirely" collected into the vessel through the cavity 46, which forms the detour in communication with the hole 48. If so, in the corresponding embodiment of the present invention disclosed in the paragraphs [0125], [0126] and Figs. 23A and 23B, a vacuum or other drawing force applied from the outlet port 2304 would also cause the entire blood reserved in the sequestration chamber 2306 to flow toward the outlet port 2304, to be conveyed into the collection device. This means that the present invention can not be practiced.

As a consequence, the assertions (a) and (b) made by the Applicant in Argument are both dismissed.

●Ground 4 (Section 29, Paragraph 2 of the Japanese Patent Act)

•Claims: 9 to 12
•Cited References: 1

The limitations set forth in claims 9 to 12 are all matters of design choice for the person skilled in the art, and claims 9 to 12 are all obvious to the person skilled in the art on the basis of Reference 1.

•Claims: 5 to 7
•Cited References: 1 to 3

As disclosed in Reference 2 (Paragraph [0011] discloses that the material can be hydrophobic, and Paragraph [0013] discloses a hydrophilic material) and Reference 3 (see Paragraph [0023] and Fig. 3), it is normally done in the field of blood sample collection devices to employ hydrophobic or hydrophilic materials as the air permeable and blood impermeable materials. Thus, claims 5 to 7 are obvious to the person skilled in the art on the basis of References 1 to 3.

(Additional Notes) Although not constituting the present Rejection Decision, another ground for rejection (Ground A) is discussed in the following.

●Ground A (Section 36, Paragraph 6, Item 2 of the Japanese Patent Act)

•Claims 1 to 13

It is not clear what is indicated by the term "sambling channel" in claim 1. It may mean "sampling channel." For this reason, claim 1 and the dependent claims 2 to 13 are rejected as being indefinite.

<List of Cited References>

1. Japanese Patent Application Publication No. Sho 58-025146
2. Japanese Patent Application Publication No. 2001-000424
3. Japanese Patent Application Publication No. 2013-240628

If the Applicant is dissatisfied with this final decision, the Applicant is allowed to file an appeal with Commissioner of JPO within three months (or four months for residents abroad) from the delivery date of this Rejection Decision (Japanese Patent Law, Section 121, Paragraph 1).

(Note pursuant to Japanese Administrative Case Litigation Law, Section 46, Paragraph 2)

The Applicant is not allowed to commence any action for the revocation of this Rejection Decision. The Applicant is only allowed to file a revocation action against a trial decision by the JPO Appeal Board on the appeal against this Rejection Decision (Japanese Patent Law, Section 178, Paragraph 6).

拒絶査定

特許出願の番号	特願２０２３－０７６４９０
起案日	令和　６年１０月２９日
特許庁審査官	▲高▼　芳徳　　９８１３　２Ｑ００
発明の名称	血液サンプル最適化装置
特許出願人	クリン　インコーポレイテッド
代理人	村越　智史

この出願については、令和６年２月２６日付け起案（令和６年２月２７日付け発送）の拒絶理由通知書に記載した理由３および理由４によって、拒絶をすべきものです。

なお、意見書および手続補正書の内容を検討しましたが、拒絶理由を覆すに足りる根拠が見いだせません。

備考：

●理由３（特許法第２９条第１項第３号）および理由４（特許法第２９条第２項）について

・請求項：１，４，８，１３
・引用文献等：１

請求項１中の記載「・・・サンブリング流路であって・・・」における「サンブリング流路」は、「サンプリング流路」を意味するものと仮定する。

引用文献１（第３頁左下欄第１５行～第７頁左上欄第２０行、第１～９図）には、

血液サンプルを受け入れるための入口ポート（室２８に連通する第１の穿刺針１４の内方端（内部開口３０）、または、室２８に突出する第２の穿刺針１５の内方端３９）と、

出口ポート（第２の穿刺針１５の外方延長部の尖端）と、

前記入口ポートと前記出口ポートとに接続され、前記血液サンプルの第１の部分を集めるように構成されたチャンバ（第２の穿刺針１５の内腔５１のうち、多孔性プラグ（ガス透過性液不透過性の多孔性部材）５２が置かれたスペース、および、孔４８と多孔性プラグ５２との間のスペース）であって、空気透過性であ

り血液不透過性である材料（多孔性プラグ（ガス透過性液不透過性の多孔性部材）５２）を含む、チャンバと、
第１の分岐点（内腔５１の孔４８がある位置）において前記入口ポートと前記チャンバとに接続されており、前記第１の分岐点とは異なる第２の分岐点（内腔５１の孔５０がある位置）において前記出口ポートと前記チャンバとに接続されたサンプリング流路（キャビティー４６）であって、前記出口ポートに前記血液サンプルの後続の部分を運ぶように構成されたサンプリング流路（キャビティー４６）と
を備える装置
が記載されている。
請求項８に関して、引用文献１におけるスリーブ弁４１が、請求項８でいう「弁」に相当する。
請求項１３に関して、引用文献１における第１の穿刺針１４が、請求項１３でいう「患者針」に相当し、引用文献１における容器ホルダー１９および真空血液収集容器１６が、請求項１３でいう「サンプル採取装置」に相当する。
したがって、請求項１，４，８，１３に係る発明は、引用文献１に記載された発明である。
また、請求項１，４，８，１３に係る発明は、引用文献１に基づき、当業者が容易に想到し得るものである。

出願人は意見書において、
（ａ）引用文献１において、穿刺針１５に真空血液収集容器を取付ける前においては、多孔性フラグ５２によって採取された血液がブロックされるが、穿刺針１５に真空血液収集容器を取付けることによって、ブロックされた血液は真空血液収集容器内に収集される。したがって、引用文献１においては、多孔性フラグ５２によってブロックされていた血液サンプルは第１の部分も含む全てが、孔４８と連通された迂回路であるキャビティー４６を介して容器内に収集される。
したがって、本願発明と引用文献１に記載の発明とを対比すると、両者は少なくとも以下の点において異なる。
・相違点Ａ１：本願発明は、「前記血液サンプルの第１の部分を集めるように構成されたチャンバ」と「前記出口ポートに前記血液サンプルの後続の部分を運ぶように構成されたサンプリング流路」とを備えるのに対し、引用文献１に記載の発明においては、血液の第１の部分を集めるチャンバに相当する構成は記載されていないこと
したがって、本願発明は引用文献１に記載の発明に対して新規性を有する。
（ｂ）上記のとおり、引用文献１には、血液の後続の部分を運ぶ流路とは別に、血液の第１の部分を集めるチャンバを設けることは記載も示唆も一切されていない。また、引用文献１に記載に発明においては、多孔性プラグ５２にブロックされた血液は、後続の部分よりも汚染しやすい血液サンプルの第１部分も含めて全

て容器に収集されるから、本願発明のように血液培養の汚染を低減することはできない。

したがって、当業者は、本願発明の相違点Ａ１の構成に容易に想到することはできなかった。

旨主張する。

しかしながら、第２の穿刺針１５の内腔５１のうち、孔４８と多孔性プラグ５２との間のスペースに溜まっていた血液の少なくとも一部は、穿刺針１５が貫通可能ストッパ２１を貫通した後も、孔４８と多孔性プラグ５２との間のスペースにとどまるものと認められるのであって、「多孔性フラグ５２によってブロックされていた血液サンプルは第１の部分も含む全てが、孔４８と連通された迂回路であるキャビティー４６を介して容器内に収集される」とは認められない。

尚、仮に、引用文献１において、第２の穿刺針１５の内腔５１のうち、孔４８と多孔性プラグ５２との間のスペースに溜まっていた血液の「全て」が、「孔４８と連通された迂回路であるキャビティー４６を介して容器内に収集される」ものとすると、本願発明に対応する［０１２５］、［０１２６］、図２３Ａ、図２３Ｂの実施形態においても、出口ポート２３０４から加えられる真空力又はその他の吸引力により、隔離チャンバ２３０６内に溜まっていた血液の全てが、出口ポート２３０４に向かって流れ、採取装置に送られることになり、本願発明を実施することはできないものと認められる。

したがって、意見書における出願人の上記主張（ａ）および（ｂ）はいずれも採用できない。

●理由４（特許法第２９条第２項）について

・請求項：９～１２
・引用文献等：１

請求項９～１２の限定事項は、いずれも、当業者が適宜なし得ることであり、

請求項９～１２に係る発明は、引用文献１に基づき、当業者が容易に想到し得るものである。

・請求項：５～７
・引用文献等：１～３

血液サンプル収集装置において、空気透過性かつ血液不透過性の材料を、疎水性または親水性とすることは、引用文献２（［００１１］には、前記材料を疎水性とすることが記載されており、［００１３］に記載された材料は、親水性である。）、引用文献３（［００２３］、図３）に記載のとおり、通常のことであり

、請求項５～７に係る発明は、引用文献１～３に基づき、当業者が容易に想到し得るものである。

（付記）本拒絶査定の理由を構成するものではないが、その他の拒絶理由（理由Ａ）について、以下に述べる。

●理由Ａ（特許法第３６条第６項第２号）について

・請求項１～１３
　請求項１中の記載「・・・サンブリング流路であって・・・」における「サンブリング流路」の意味内容が明らかでない。「サンプリング流路」のことなのか。よって、請求項１とこれに従属する請求項２～１３に係る発明は明確でない。

＜引用文献等一覧＞
１．特開昭５８－２５１４６号公報
２．特開２００１－４２４号公報
３．特開２０１３－２４０６２８号公報

　この査定に不服があるときは、この査定の謄本の送達があった日から３月以内（在外者にあっては、４月以内）に、特許庁長官に対して、拒絶査定不服審判を請求することができます（参照条文：特許法第１２１条第１項）。
＜行政事件訴訟法第４６条第２項に基づく教示＞
　この査定に対しては取消訴訟を提起することはできません。この査定についての審判請求に対する審決に対してのみ取消訴訟を提起することができます（参照条文：特許法第１７８条第６項）。

上記はファイルに記録されている事項と相違ないことを認証する。
認証日　令和 6年11月 1日　経済産業事務官　圷　政光

PTO/SB/08a (01-22)
Approved for use through 05/31/2024. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	18898239
Filing Date	2024-09-26
First Named Inventor	Bobby E. Rogers
Art Unit	
Examiner Name	
Attorney Docket Number	069366-0581370_KUR2C07US

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	11744494		2023-09-05	ROGERS BOBBY E	

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PC 6.1.24

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	18898239
	Filing Date	2024-09-26
	First Named Inventor	Bobby E. Rogers
	Art Unit	
	Examiner Name	
	Attorney Docket Number	069366-0581370_KUR2C07US

	1	Office Action (Final Rejection) dated 11/4/2024 for U.S. Application No. 18/783,173; Attorney Docket No. 069366-0580420_KUR3C03US (pages 1-22).	☐
	2	Office Action (Non-Final Rejection) dated 09/24/2024 for U.S. Application No. 18/783,173; Attorney Docket No. 069366-0580420_KUR3C03US (pages 1-62).	☐
	3	Office Action (Rejection Decision) dated 11/5/2024 for JP Application No. 2023-076490; Attorney Docket No. 069366-0575273_KUR2D03JP (pages 1-8).	☐
	4	Office Action (Non-Final Rejection) dated 10/22/2024 for U.S. Application No. 18/783,173; Attorney Docket No. 069366-0580420_KUR3C03US (pages 1-62).	☐

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

PC 6.1.24

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	18898239
	Filing Date	2024-09-26
	First Named Inventor	Bobby E. Rogers
	Art Unit	
	Examiner Name	
	Attorney Docket Number	069366-0581370_KUR2C07US

CERTIFICATION STATEMENT

Please see 37 CFR 1.97(e) to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☒ A certification statement is not submitted herewith.

FEE

☒ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

COPIES

☐ An identification of an earlier application pursuant to 37 CFR 1.98 (d) (1) is attached.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2024-12-17
Name/Print	Benjamin F. Hudson	Registration Number	71,474

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

PC 6.1.24

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

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2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

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5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

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ELECTRONIC PAYMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
18/898,239	**12/17/2024 05:34:54 PM Z ET**	**069366-0581370_KUR2C07US**

Title of Invention

BLOOD SAMPLE OPTIMIZATION DEVICE

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	7801	FILED BY	Trent Tercenio
PATENT CENTER #	68405127	AUTHORIZED BY	Benjamin Hudson
CUSTOMER #	27500	FILING DATE	09/26/2024
CORRESPONDENCE ADDRESS	-	FIRST NAMED INVENTOR	Bobby E. Rogers

Payment Information

PAYMENT METHOD	PAYMENT TRANSACTION ID	PAYMENT AUTHORIZED BY
DA / 033975	**E2024BGH35216372**	**Trent Tercenio**

FEE CODE	DESCRIPTION	ITEM PRICE($)	QUANTITY	ITEM TOTAL($)
2806	SUBMISSION OF AN INFORMATION DISCLOSURE STATEMENT	104.00	1	104.00
			TOTAL AMOUNT:	**$104.00**

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C.

371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/783,173	07/24/2024	Bobby E. ROGERS	069366-0580420_KUR3C03US	1561

27500 7590 09/24/2024

PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
ATTENTION: DOCKETING DEPARTMENT
P.O BOX 10500
McLean, VA 22102

EXAMINER	
NGUYEN, HUONG Q	

ART UNIT	PAPER NUMBER
3791	

NOTIFICATION DATE	DELIVERY MODE
09/24/2024	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Docket_IP@pillsburylaw.com

Office Action Summary	**Application No.** 18/783,173	**Applicant(s)** ROGERS et al.	
	Examiner Huong Q NGUYEN	**Art Unit** 3791	**AIA (FITF) Status** Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 7/24/2024.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL.** 2b) ☑ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 1-30 is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 1-30 is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to **PPHfeedback@uspto.gov.**

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☑ The drawing(s) filed on 7/24/2024 is/are: a)☐ accepted or b)☑ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☑ Notice of References Cited (PTO-892)

2) ☑ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

DETAILED ACTION

Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, valve to close off the sampling channel along with the moving part that moves from a first position to a second position to allow travel to the sampling channel of **Claims 10-12 and 25-27** must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the

applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Interpretation

The following is a quotation of 35 U.S.C. 112(f):

> (f) Element in Claim for a Combination. – An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

The following is a quotation of pre-AIA 35 U.S.C. 112, sixth paragraph:

> An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

The claims in this application are given their broadest reasonable interpretation using the plain meaning of the claim language in light of the specification as it would be understood by one of ordinary skill in the art. The broadest reasonable interpretation of a claim element (also commonly referred to as a claim limitation) is limited by the description in the specification when 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is invoked.

As explained in MPEP § 2181, subsection I, claim limitations that meet the following three-prong test will be interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph:

(A) the claim limitation uses the term “means” or “step” or a term used as a substitute for “means” that is a generic placeholder (also called a nonce term or a non-structural term having no specific structural meaning) for performing the claimed function;

(B) the term "means" or "step" or the generic placeholder is modified by functional language, typically, but not always linked by the transition word "for" (e.g., "means for") or another linking word or phrase, such as "configured to" or "so that"; and

(C) the term "means" or "step" or the generic placeholder is not modified by sufficient structure, material, or acts for performing the claimed function.

Use of the word "means" (or "step") in a claim with functional language creates a rebuttable presumption that the claim limitation is to be treated in accordance with 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph. The presumption that the claim limitation is interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is rebutted when the claim limitation recites sufficient structure, material, or acts to entirely perform the recited function.

Absence of the word "means" (or "step") in a claim creates a rebuttable presumption that the claim limitation is not to be treated in accordance with 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph. The presumption that the claim limitation is not interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is rebutted when the claim limitation recites function without reciting sufficient structure, material or acts to entirely perform the recited function.

Claim limitations in this application that use the word "means" (or "step") are being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, except as otherwise indicated in an Office action. Conversely, claim limitations in this application that do not use the word "means" (or "step") are not being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, except as otherwise indicated in an Office action.

No claim elements are interpreted under 112(f).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112(a):

> (a) IN GENERAL.—The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.

The following is a quotation of the first paragraph of pre-AIA 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10-12 and 25-27 are rejected under 35 U.S.C. 112(a) or 35 U.S.C. 112 (pre-AIA), first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor or a joint inventor, or for applications subject to pre-AIA 35 U.S.C. 112, the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 10-12 and 25-27 recite a valve to initially close off the sampling channel. This appears to be disclosed in the embodiment of Figure 23A-E. However, the independent claims recite an embodiment with a moving part configured to be movable from a first position to a

second position to allow the blood sample to flow to the sampling channel (and bypass the chamber), which appears disclosed in the embodiment Figure 24A-D.

However, the embodiment in Figure 23 does not disclose said moving part *in addition* to the valve to allow the bypass as claimed. Therefore, it appears that said claims improperly mix embodiments, which constitutes new matter. However, if an embodiment which contains both structures exists, applicant is requested to point out the portions of the specification disclosing such. Also see Drawing Objection above.

> The following is a quotation of 35 U.S.C. 112(b):
> (b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.
>
> The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph:
> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7, 12, 22, and 27 are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor (or for applications subject to pre-AIA 35 U.S.C. 112, the applicant), regards as the invention.

In regard to Claim 7 and 22, the recitation of blood impermeable membrane causes the first portion of the blood sample “to back up” into the chamber is indefinite because it is unclear what specific meaning or function this is meant to convey. In the rejection that follows it is assumed to be normal fluid flow. Clarification is requested.

In regard to Claim 12 and 27, the recitation of "otherwise close off the outlet" is indefinite because it is unclear what mechanisms are included in said limitation to close off the outlet, which are also supported by the disclosure.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a)(1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention.

Claim(s) 1-5, 13-20, and 28-30 is/are rejected under 35 U.S.C. 102(a)(1) as being anticipated by Bullington et al (US Pub No. 20140163419).

In regard to Claims 1 and 16, Bullington et al disclose a device comprising:

an inlet port 405 for receiving a blood sample, best seen in Figure 12 (0081, 0089);

an outlet port 475 (proximal end of lumen 475), best seen in Figure 13-15 (0085);

a chamber 480 connected with the inlet port, and configured to collect a first portion of the blood sample when under a drawing force applied from the outlet port from a blood sample collection device 451, best seen in Figure 14 (0079, 0091-0092 – "a bodily-fluid is drawn through the port 405, the first lumen 432 defined by the flow control mechanism 430, and the first lumen 406 defined by the diverter 409 and into the fluid reservoir 480. In some embodiments, the bodily-fluid can contain undesirable microbes such as, for example, dermally-residing microbes and/or other external contaminants");

a sampling channel 433 connected with the inlet port and configured to convey a subsequent portion of the blood sample to the outlet port, best seen in Figure 15 (0095); and

a moving part 430, 431, 435 (flow control mechanism first member 431 controlled by member 435), moving part also defined by plunger 476 (0084 – Figure 13-15),

configured to be movable from a first position to a second position to allow the blood sample to flow to the sampling channel –

in the first position, moving member 435 rotates first member 431 such that lumen 433 (sampling channel) is fluidically isolated, due to lumen 432 of the flow control mechanism aligned with the inlet port 405, which leads through lumen 406 in diverter 409 and into chamber 480 – thus the inlet port 405 is in fluid communication with the chamber 480, best seen in Figure 14 (0081, 0092);

in the second position, moving member 435 rotates first member 431 such that lumen 433 is aligned with inlet port 405 such that "a desired amount of bodily-fluid is drawn through the port 405, the second lumen 433 of the flow control mechanism 430, the second lumen 407 of the diverter 409, and the lumen 475 [defining the outlet port] defined by the shunt tube 471 and into the second reservoir 490. Moreover, the bodily-fluid disposed within the second reservoir 490 is fluidically isolated from the first, predetermined amount of bodily-fluid contained within the first reservoir 480," best seen in Figure 15 (0082, 0083, 0095, 0097) – thus creates a pathway from the inlet port 405 to the outlet port 475.

2, 17. The device in accordance with claim 1, wherein the first position allows the collection of the first portion of the blood sample in the chamber 480, best seen in Figure 14.

3, 18. The device in accordance with claim 1, wherein the moving part 430, 431, 435 is configured to move from the first position to the second position after the first portion of the blood sample flows into the chamber 480 – sample flow into the chamber 480 occurs first, best seen in Figure 14, followed by moving member 435 rotating first member 431 such that lumen 433 is aligned with inlet port 405 is aligned with the outlet port 475, into second reservoir 490, best seen in Figure 15 (0082, 0083, 0095, 0097).

4, 19. The device in accordance with claim 1, the device further comprising a locking mechanism 474 configured to maintain the moving part 476 in the first position (Figure 14) until the chamber 480 is filled with the first portion of the blood sample – protrusion 474 enables proximal movement of plunger 476 to create chamber 480 for the first portion of the blood sample, best seen in Figure 13-14 (0085, 0091, 0096).

5, 20. The device in accordance with claim 1, wherein the moving part 430, 431, 476 is an inner chamber housing, best seen in Figure 13-15.

13, 28. The device in accordance with claim 1, further comprising a patient needle – "a user can engage the transfer device 400 to couple the port 405 to a proximal end portion of a lumen-defining device (not shown) such as, for example, a butterfly needle, a cannula assembly, a trocar (which in some cases is used to insert a catheter into a patient), or the like" (0089) and

a sample collection device – "with the desired amount of bodily-fluid disposed within the second fluid reservoir 490, the transfer device 400 can be removed from the portion of the patient and disposed above or in a container (e.g., a vile, a test tube, a petri dish, a culture medium, a test apparatus, or the like) such that a portion of the second amount of bodily-fluid can be tested" (0099).

14, 29. The device in accordance with claim 1, the chamber having a volume sufficient to collect the first portion of the blood sample that is more prone to contamination and also to minimize an amount of blood to be sequestered (0092).

15, 30. The device in accordance with claim 1, wherein the chamber 480 has a volume of less than 1.5 cubic centimeters, e.g. 0.1 mL (0094).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries for establishing a background for determining obviousness under 35 U.S.C. 103 are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims the examiner presumes that the subject matter of the various claims was commonly owned as of the effective filing date of the claimed invention(s) absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and effective filing dates of each claim that was not commonly owned as of the effective filing date of the later invention in order for the examiner to consider the applicability of 35 U.S.C. 102(b)(2)(C) for any potential 35 U.S.C. 102(a)(2) prior art against the later invention.

Claim(s) 6-12 and 21-27 is/are rejected under 35 U.S.C. 103 as being unpatentable over Bullington et al as applied to claim 1 above, and further in view of Percarpio (US Pat No. 4106497 – cited by applicant).

In regard to Claims 6-9 and 21-24, Bullington et al disclose the invention above but do not expressly disclose a blood impermeable membrane is configured to facilitate the chamber collecting the first portion of the blood sample.

Percarpio teach that it is well-known in the art to provide an analogous blood sampling device comprising an inlet port 22 for receiving a blood sample, an outlet port 42, 44, a

chamber to collect a first portion of the blood sample (indicator area), and a sampling channel 28 connecting the inlet and the outlet, including a blood impermeable membrane 90 to enable necessary venting of air for the desired flow of the blood first to the chamber before directing it to the outlet (Col.4: 16-39). Percarpio teach a housing 40, 56 separate from the blood impermeable membrane 90, best seen in Figure 3-4, as an effective configuration for the location of said blood impermeable membrane.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the of filing to modify Bullington et al to include a blood impermeable membrane causes the first portion of the blood sample to back up into the chamber following application of the drawing force applied from the outlet port as taught by Percarpio by enabling necessary venting of air from the device during the desired flow of blood such that, when the drawing force is applied at the outlet port, the first portion of the blood sample is drawn into the chamber in the manner taught by Bullington et al to contact a material that is blood impermeable to enable the venting of air, wherein the blood impermeable membrane is separate from the housing, as taught by Percarpio as an effective configuration for said blood impermeable membrane.

In regard to Claims 10-12 and 25-27, Bullington et al disclose the invention above but do not expressly disclose a valve configured to initially close off the sampling channel.

Percarpio teach that it is well-known in the art to provide an analogous blood sampling device comprising an inlet port 22 for receiving a blood sample, an outlet port 42, 44, a chamber to collect a first portion of the blood sample (indicator area), and a sampling channel

28 connecting the inlet and the outlet, including a blood impermeable membrane 90 to enable necessary venting of air for the desired flow of the blood first to the chamber before directing it to the outlet (Col.4: 16-39). Percarpio teach a valve 78 (check valve) that is configured to initially close off access to the outlet until the first portion of the blood sample is in the chamber, best seen in Figure 3, and is further configured such that, upon release, follow-on amounts of the blood sample will bypass the chamber and flow through the sampling channel toward the outlet port, best seen in Figure 4 (Col.3: 61-Col.4: 15, 64-Col.5: 47). Percarpio also teach the valve is configured to pinch, shunt, bend or otherwise close off the outlet before the first portion of the blood sample is collected in the chamber, best seen in Figure 3-4 (Col.3: 61-Col.4: 15, 64-Col.5: 47).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of filing to modify Bullington et al to include a valve to pinch, shunt, bend or otherwise close off the outlet in the manner above as taught by Percarpio to effectively seal off the outlet before the blood is properly in the chamber of Bullington et al, wherein it would have been obvious to a skilled artisan to place the valve such that it closes off the sampling channel and not just the outlet, to effectively block the flow of blood upstream before it reaches the outlet, prior to being drawn into the chamber as taught by Bullington et al, as well as Percarpio.

Also see 112 rejection above.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Huong Q NGUYEN whose telephone number is (571)272-8340. The examiner can normally be reached on 10 am - 6 pm.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert (Tse) Chen can be reached at 5712723672. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/H.Q.N/
Examiner, Art Unit 3791

/RENE T TOWA/
Primary Examiner, Art Unit 3791

Notice of References Cited	Application/Control No. 18/783,173	Applicant(s)/Patent Under Reexamination ROGERS et al.	
	Examiner Huong Q NGUYEN	Art Unit 3791	Page 1 of 1

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*		Document Number Country Code-Number-Kind Code	Date YYYY-MM-DD	Name	CPC Classification	US Classification
*	A	US-20140163419-A1	2014-06-12	Bullington; Gregory J.	A61B5/153	600/575
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Attorney Docket Number	069366-0580420_KUR3C03US

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	2	European Patent Application No. EP23155927.9 extended European Search Report dated Jul. 26, 2023, 8 pages.	☐
	3	Office Action (Final Rejection) dated 08/25/2023 for US App. No. 18113710 (pages 1-50)	☐
	4	Notice of Allowance mailed 09-08-2023; Attorney Docket No. 069366-0574153_KUR2C04US. 35 page.	☐
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	Attorney Docket Number	069366-0580420_KUR3C03US

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A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2024-08-26
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
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	Filing Date	2024-07-24
	First Named Inventor	Bobby E. ROGERS
	Art Unit	OPAP
	Examiner Name	DOCKET CENTRAL
	Attorney Docket Number	069366-0580420_KUR3C03US

	12	Second Office Action dated 04/28/2024 for CN Application No. 202080000666.0, pages 1-28.	☐
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	17	Ziegler, R., et al. "Controlled Clinical Laboratory Comparison of Two Supplemented Aerobic and Anaerobic Media Used in Automated Blood Culture Systems to Detect Bloodstream Infections," Journal of Clinical Microbiology, Mar. 1998, p. 657-661.	☐
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Examiner Signature	/H Q NGUYEN/	Date Considered	09/09/2024

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	Attorney Docket Number	069366-0580420_KUR3C03US

CERTIFICATION STATEMENT

Please see 37 CFR 1.97(e) to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☒ A certification statement is not submitted herewith.

FEE

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

COPIES

☐ An identification of an earlier application pursuant to 37 CFR 1.98 (d) (1) is attached.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2024-08-26
Name/Print	Benjamin F. Hudson	Registration Number	71,474

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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Doc code: IDS
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Art Unit	OPAP
Examiner Name	DOCKET CENTRAL
Attorney Docket Number	069366-0580420_KUR3C03US

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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	10	4412548		1983-11-01	HOCH LOUIS	
	11	5222502		1993-06-29	KUROSE KATSUTOSHI	
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	13	9022951		2015-05-05	BULLINGTON GREGORY	
	14	6569117		2003-05-27	ZIV DAVID	
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	23	9138572		2015-09-22	ZEYTOONIAN PAUL	
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	Art Unit	OPAP
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CERTIFICATION STATEMENT

Please see 37 CFR 1.97(e) to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☒ A certification statement is not submitted herewith.

FEE

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

COPIES

☐ An identification of an earlier application pursuant to 37 CFR 1.98 (d) (1) is attached.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2024-08-26
Name/Print	Benjamin F. Hudson	Registration Number	71,474

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /H.Q.N/

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/898,239	09/26/2024	Bobby E. Rogers	069366-0581370_KUR2C07US	7801

27500 7590 01/06/2025

PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
ATTENTION: DOCKETING DEPARTMENT
P.O BOX 10500
McLean, VA 22102

EXAMINER	
ABOUELELA, MAY A	

ART UNIT	PAPER NUMBER
3791	

NOTIFICATION DATE	DELIVERY MODE
01/06/2025	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Docket_IP@pillsburylaw.com

Office Action Summary	**Application No.** 18/898,239	**Applicant(s)** Rogers et al.	
	Examiner MAY A ABOUELELA	**Art Unit** 3791	**AIA (FITF) Status** Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 12/17/2024.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☑ This action is **FINAL.** 2b) ☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 1-9,11-22 and 24-26 is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 1-9,11-22 and 24-26 is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to **PPHfeedback@uspto.gov.**

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☑ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

Notice of Pre-AIA or AIA Status

1. The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 12/17/2024. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Terminal Disclaimer

3. The terminal disclaimer filed on 12/17/2024 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S Patent No. 12,138,052 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a)(1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention.

Claim(s) 1, 6-9, 11, 12, 14, 19-22, 24 and 25 is/are rejected under 35 U.S.C. 102(a)(1) as being anticipated by Patton et al (US 2008/0145933).

As to claims 1 and 14, Patton discloses a device (blood sampling device 500, par.38-40, fig.5) comprising:

an inlet port for receiving a blood sample (inlet/opening connecting needle 508 to input tubing 514, par.38-40, fig.5);

an outlet port (needle 510, fig.5);

a chamber (tubing 516 and reservoir 504, par.38-40, fig.5) comprising a flexible material (flexible material of tubing 516 and reservoir 504), wherein the chamber is connected with the inlet port (516 and 504 are connected to inlet of tubing 514, as best seen in fig.5) and configured to collect a first portion of the blood sample (diversion mechanism 512 can be initially adjusted to divert blood to the one or more pre-sample reservoirs 504 until the one or more pre-sample reservoirs 504 are filled, par.40, fig.5) when under a drawing force applied from the outlet port from a blood sample collection device (pre vacuumed effect of vessel 506 withdraws blood, first needle 508 can be inserted into a patient to procure a blood sample. In FIG. 5, the first needle 508 is shown inserted into a vein 520. The second needle 510 is shown inserted into the one or more sample vessels 506 that have been vacuum-sealed. The vacuum in each of the one or more sample vessels 506 causes blood to pass from the vein 520 to the diversion mechanism 512, par.40); and

a sampling channel (tubings 514 and 518 connected with inlet of tubing 214, par.38-40, as best seen in fig.4) connected with the inlet port and configured to convey a subsequent portion of the blood sample to the outlet port (which point the diversion mechanism 512 can be adjusted to divert the flow of blood to the one or more sample vessels 506, ar.38-40, fig.5).

As to claims 6 and 19, Patton discloses the device, further comprising a valve (diversion mechanism 512 having valve 60, par.38-41, fig.5) configured to initially close off the sampling channel (diversion mechanism 512 can be initially adjusted to divert blood to the one or more pre-sample reservoirs 504 until the one or more pre-sample reservoirs 504 are filled, or a desired amount of blood has been withdrawn, at which point the diversion mechanism 512 can be adjusted to divert the flow of blood to the one or more sample vessels 506, par.40).

As to claims 7 and 20, Patton discloses the device, further comprising a valve configured to initially close off the sampling channel until the first portion of the blood sample is in the chamber (diversion mechanism 512 can be initially adjusted to divert blood to the one or more pre-sample reservoirs 504 until the one or more pre-sample reservoirs 504 are filled, or a desired amount of blood has been withdrawn, at which point the diversion mechanism 512 can be adjusted to divert the flow of blood to the one or more sample vessels 506, par.40).

As to claims 8 and 21, Patton discloses the device, further comprising a valve that is configured to initially close off the sampling channel until the first portion of the blood sample is in the chamber and is further configured such that, upon release, follow-on amounts of the blood sample will bypass the chamber and flow through the sampling channel toward the outlet port (diversion mechanism 512 can be initially adjusted to divert blood to the one or more pre-sample reservoirs 504 until the one or more pre-sample reservoirs 504 are filled, or a desired amount of blood has been withdrawn, at

which point the diversion mechanism 512 can be adjusted to divert the flow of blood to the one or more sample vessels 506, par.40, as best seen from fig.5 the subsequent blood will bypass reservoir 504 and flows straight from inlet of 502 to tubings 514 and 518).

As to claims 9 and 22, Patton discloses the device, wherein the valve is configured to pinch, shunt, bend or otherwise close off the sampling channel before the first portion of the blood sample is collected in the chamber (diversion mechanism 512 can be initially adjusted to divert blood to the one or more pre-sample reservoirs 504 until the one or more pre-sample reservoirs 504 are filled, or a desired amount of blood has been withdrawn, at which point the diversion mechanism 512 can be adjusted to divert the flow of blood to the one or more sample vessels 506, par.40, fig.5).

As to claims 11 and 24, Patton discloses the device, further comprising a patient needle (patient needle 508, par.38-40, fig.5) and a sample collection device (sample vessel 506, par.38-40, fig.5).

As to claims 12 and 25, Patton discloses the device, the chamber having a volume sufficient to collect the first portion of the blood sample that is more prone to contamination and also to minimize an amount of blood to be sequestered (the data suggests that fewer false positive test results for the presence of microbes in blood are obtained over conventional methods when initially-drawn volumes of blood are not used in microbial testing, par.54).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim(s) 2-5 and 15-18 is/are rejected under 35 U.S.C. 103 as being obvious over Patton et al (US 2008/0145933) in view of Flaherty et al (US 2006/0009713).

As to claims 2-5 and 15-18, Patton discloses the invention substantially above, wherein a housing of the diverting mechanism is separate from a blood impermeable membrane, but failed to explicitly teach a blood impermeable membrane is configured to facilitate the chamber collecting the first portion of the blood sample, and causes the first portion of the blood sample to back up into the chamber following application of the drawing force applied from the outlet port, and wherein the device is configured such that, when the drawing force is applied at the outlet port, the first portion of the blood sample is drawn into the chamber to contact a material that is blood impermeable.
However, Flaherty discloses an analogous blood sampling device, wherein the blood sampling chamber comprises (liquid impenetrable, air-permeable membrane 45, par.39, fig.8-10), wherein blood flows into the blood collection chamber 39, air is displaced from the blood collection chamber 39, through the membrane 45 and air opening or openings 46, respectively. This facilitates the substantially continual and unhindered flow of blood

from the patient 106 and into the blood collection chamber 39 to collect the desired quantity of blood into the blood collection chamber 39 (par.40, fig.8-10).

Since blood impermeable membrane is well-known in the art, so it would have been obvious to one having an ordinary skill in the art before the effective filing date of the invention to include a blood impermeable membrane in reservoir 504 taught by Patton's invention, as blood impermeable membrane 45 taught by Flaherty's invention to facilitate the continual and unhindered flow of blood from the patient and into the blood collection chamber, as taught by Flaherty's invention (par.40).

6. Claim(s) 13 and 26 is/are rejected under 35 U.S.C. 103 as being obvious over Patton et al (US 2008/0145933).

As to claims 13 and 26, Patton discloses the volume of blood withdrawn into the one or more pre-sample reservoirs 504 is at least equal to the collective volumes of the first needle 508, the flexible, sterile input tubing 516, the diversion mechanism 512, and the first sterile output tubing 516 (par.40), but failed to explicitly teach he chamber has a volume of less than 1.5 cubic centimeters. However, it would have been obvious to one having an ordinary skill in the art at the time the invention was made to allow reservoir 504 to collect blood volume less than 1.5 cubic centimeters, since it has been that discovering the optimum value of a result of effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215(CCPA 1980).

Response to Arguments

5. Applicant's arguments with respect to double patenting rejection have been fully considered and are persuasive. The double patenting rejection has been withdrawn.

6. Applicant's arguments regarding Patton's invention does not teach the claimed subject matter "collect a first portion of the blood sample when under a drawing force applied from the outlet port" in claims 1 and 14 have been fully considered but they are not persuasive, because under the broadest reasonable interpretation the claimed "drawing force applied" may be interpreted as any type of drawing force that is able to draw blood, such as, vacuum force as a result of a pressure differential created by removing air from a closed space/Vacutainer, or force from a pump, or the like. The claims dose not recite any specific type of drawing force and/or the outlet port is the drawing force itself.

The Applicant argues that first portion of blood in the cited Patton reference, which fills a "pre- sample reservoir 504," is not drawn in by a force applied from outlet port 510, as claimed, but rather by a vacuum in the pre-sample reservoir (e.g., from a vacutainer), see arguments pages 9-10. While, the Applicant's own specification discloses (A vacuum or other drawing force applied from the outlet port 2304, such as from a Vacutainer or the like, draws in blood into the inlet port 2302 and directly into the sequestration chamber 2306, par.00125). The Examiner is not really sure how the Applicant is arguing their own teaching from their own specification, because Patton's invention teaches the use of the same type of drawing force applied to the outlet port, which is vacuum force from a Vacutainer.

Since Patton teaches first needle 508 can be inserted into a patient to procure a blood sample and outlet port 510 is inserted into vacuum-sealed vessel 506, the blood flows from needle 508 to valve 512 and eventually to chamber/reservoir 504 due to the vacuum force applied to outlet port 510 from vacuum-sealed vessel 506. Then, blood flow is diverted to flow to vessel 506 due to the same vacuum force applied to outlet port 510, so it can be fairly interpreted that Patton's inventio teaches the claimed subject matter "collect a first portion of the blood sample when under a drawing force applied from the outlet port" in claims 1 and 14.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MAY A ABOUELELA whose telephone number is (571)270-7917. The examiner can normally be reached 8-5.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JACQUELINE CHENG can be reached on 5712725596. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: https://patentcenter.uspto.gov. Visit https://www.uspto.gov/patents/apply/patent-center for more information about Patent Center and https://www.uspto.gov/patents/docx for information about filing in DOCX format. For additional questions, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MAY A ABOUELELA/
Primary Examiner, Art Unit 3791

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	18/898,239	Rogers et al.
	Examiner	Art Unit
	MAY A ABOUELELA	3791

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

CLAIMS

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☑ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	11/13/2024	12/23/2024							
	1	✓	✓							
	2	✓	✓							
	3	✓	✓							
	4	✓	✓							
	5	✓	✓							
	6	✓	✓							
	7	✓	✓							
	8	✓	✓							
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	11	✓	✓							
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	23	-	-							
	24	✓	✓							
	25	✓	✓							
	26	✓	✓							

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	18/898,239	Rogers et al.
	Examiner	Art Unit
	MAY A ABOUELELA	3791

CPC - Searched*		
Symbol	**Date**	**Examiner**
(A61B5/150992 or A61B5/15003 or A61B5/150213 or A61B5/150221 or A61B5/150389 or A61B5/150473 or A61B5/150572 or A61B5/153 or A61B5/154 or A61M39/04 or A61M39/0693 or A61M2039/0202 or A61M2039/0633 or A61M2039/068).cpc.	11/13/2024	MA
updated as above	12/23/2024	MA

CPC Combination Sets - Searched*		
Symbol	**Date**	**Examiner**

US Classification - Searched*			
Class	**Subclass**	**Date**	**Examiner**

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	**Date**	**Examiner**
inventor name search, class/subclass search, text search	11/13/2024	MA
updated as above	12/23/2024	MA

Interference Search			
US Class/CPC Symbol	**US Subclass/CPC Group**	**Date**	**Examiner**

/MAY A ABOUELELA/ Primary Examiner, Art Unit 3791	

PE2E SEARCH - Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
L1	0	("15140443").PN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2016/12/20 11:05 PM
L2	1	("20020099309").PN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2016/12/21 11:38 AM
L3	1	("14055232").PN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2016/12/21 11:39 AM
L4	1763	(600/573).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2016/12/21 05:18 PM
L5	63	(("ROGERS") near3 ("Bobby")).INV.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2016/12/21 05:19 PM
L6	28	("2004/0073171").URPN.	(USPAT)	OR	OFF	OFF	2016/12/21 05:36 PM
L7	0	("1and(bloodnear4sequest$5)").PN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2016/12/21 05:41 PM
L8	5225	1and (blood near4 sequest$5)	(US-PGPUB; USPAT)	OR	OFF	OFF	2016/12/21 05:42 PM
L9	7	L4 and (blood near4 sequest$5)	(US-PGPUB; USPAT)	OR	OFF	OFF	2016/12/21 05:42 PM
L10	73	("20020002349" | "20020183651" | "20030055381" | "20040010228" | "20040054333" | "20040147855" | "20050004524" | "20050240161" | "20050245885" | "20050281713" | "20060287639" | "2707953" | "3013557" | "3098016" | "3382865" | "3405706" | "3494351" | "3577980" | "3648684" | "3848579" | "3937211" | "4057050" | "4133863" | "4166450" | "4340067" | "4370987" | "4444203" | "4459997" | "4509534" | "4676256" | "4865583" | "4890627" | "4988339" | "5009847" | "5097842" | "5108927" | "5122129" | "5269317" | "5360011" | "5429610" | "5450856" | "5507299" | "5577513" | "5762633" | "5882318" | "5922551" | "6016712" | "6057105" | "6159164" | "6210909" | "6364890" |	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2016/12/21 05:43 PM

		"6387086" | "6403381" | "6692479" | "6746420" | "6913580" | "7044941" | "7087047").PN. OR ("8197420").URPN.					
L11	2	L10 and (blood near4 sequest$5)	(US-PGPUB; USPAT)	OR	OFF	OFF	2016/12/21 05:44 PM
L12	77	("0453322" | "0577682" | "0729011" | "1074965" | "1110189" | "1450016" | "1521890" | "2218899" | "2688325" | "2895773" | "3176595" | "3214069" | "3236268" | "3263874" | "3486503" | "3577980" | "3754644" | "3794221" | "3834387" | "3855997" | "3937211" | "3958570").PN. OR ("4057050").URPN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2016/12/21 05:47 PM
L13	852	L4 and (blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2016/12/21 05:47 PM
L14	46	L10 and (blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2016/12/21 05:47 PM
L15	1	("8197420").PN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2016/12/21 06:29 PM
L16	1	("20130317391").PN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2016/12/21 06:42 PM
L17	1254	(600/583).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2016/12/21 06:43 PM
L18	1070	L17 and (blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2016/12/21 06:43 PM
L19	265030	(blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2016/12/21 07:09 PM
L20	5653	L19 AND ((A61B10/0096 OR A61B5/150022).CPC.)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2016/12/21 07:10 PM
L21	207	L20 and (seal near4 air)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2016/12/21 07:10 PM
L22	23	"2004087258"	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2016/12/21 08:59 PM
L23	1	("20050004524").PN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2017/04/11 08:23 PM

L24	1	("20030105414").PN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2017/04/11 08:24 PM
L25	1	("5749857").PN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2017/04/11 08:26 PM
L26	13	("20040073171"|"20040147855"|"20050240161"|"20130317391"|"20160174888"|"4057050"|"8197420"|"8523826"|"8535241"|"8540663"|"8568371"|"8864684"|"9138572").PN.	(US-PGPUB; USPAT)	OR	OFF	OFF	2017/04/11 08:39 PM
L27	1	("15140443").PN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2017/04/11 09:43 PM
L28	0	("4and(bloodnear4air)").PN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2017/04/11 10:01 PM
L29	3	L26 and (blood near4 air)	(US-PGPUB; USPAT)	OR	OFF	OFF	2017/04/11 10:01 PM
L30	6	L26 and vent$4	(US-PGPUB; USPAT)	OR	OFF	OFF	2017/04/11 10:02 PM
L31	5	("2013/0317391").URPN.	(USPAT)	OR	OFF	OFF	2017/04/11 10:06 PM
L32	48	("2005/0004524").URPN.	(USPAT)	OR	OFF	OFF	2017/04/11 10:17 PM
L33	1	("20120170037").PN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2017/04/12 04:11 PM
L34	1	("6139540").PN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2017/04/13 12:52 PM
L35	1	("20040116878").PN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2017/04/13 12:54 PM
L36	1	("20100152752").PN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2017/04/13 01:16 PM
L37	1	("6395003").PN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2017/04/13 01:20 PM
L38	5	("2013/0317391").URPN.	(USPAT)	OR	OFF	OFF	2017/04/13 01:43 PM
L39	1	("4444203").PN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2017/04/13 01:44 PM
L40	1	("20020004647").PN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2017/04/13 01:48 PM
L41	1	("3817240").PN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2017/04/13 01:57 PM
L42	1	("3874367").PN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2017/04/13 01:57 PM
L43	1	("3886930").PN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2017/04/13 01:58 PM
L44	1	("4106497").PN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2017/04/13 01:59 PM
L45	1	("4154229").PN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2017/04/13 01:59 PM

L46	1	("4207870").PN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2017/04/13 02:00 PM
L47	292	("2913000" | "3817240" | "3859998" | "3864979" | "4016879" | "4046144").PN. OR ("4207870").URPN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2017/04/13 02:01 PM
L48	1	("4412548").PN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2017/04/13 02:04 PM
L49	1	("5222502").PN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2017/04/13 02:11 PM
L50	1	("5520193").PN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2017/04/13 02:15 PM
L51	1	("20100057004").PN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2017/04/13 02:16 PM
L52	1	("20070088279").PN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2017/04/13 02:29 PM
L53	1733	(600/573).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2017/04/13 03:29 PM
L54	13	L53 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2017/04/13 03:52 PM
L55	1255	(600/583).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2017/04/13 04:23 PM
L56	4	L55 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2017/04/13 04:23 PM
L57	272301	(blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2017/04/13 04:29 PM
L58	5898	L57 AND ((A61B10/0096 OR A61B5/150022).CPC.)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2017/04/13 04:29 PM
L59	114	L58 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2017/04/13 04:29 PM
L60	2	("2007/0088279").URPN.	(USPAT)	OR	OFF	OFF	2017/04/13 05:58 PM
L61	1	("6358217").PN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2017/04/21 02:02 PM
L62	6	("2002/0004647").URPN.	(USPAT)	OR	OFF	OFF	2017/09/27 12:48 PM
L63	2	("14493796").PN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2017/09/27 01:21 PM
L64	2	("14494208").PN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2017/09/27 01:23 PM
L65	1	("15140443").PN.	(US-PGPUB; USPAT)	OR	ON	ON	2017/09/27 01:28 PM
L66	1	("20080145933").PN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2017/09/27 01:51 PM
L67	9	("2008/0145933").URPN.	(USPAT)	OR	OFF	OFF	2017/09/27 01:55 PM

L68	1	("20040054333").PN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2017/09/27 01:59 PM
L69	1	("20120109034").PN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2017/09/27 02:37 PM
L70	1	("20100228206").PN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2017/09/27 02:39 PM
L71	3	("2010/0228206").URPN.	(USPAT)	OR	OFF	OFF	2017/09/27 02:47 PM
L72	66	(("ROGERS") near3 ("Bobby")).INV.	(US-PGPUB; USPAT)	OR	OFF	OFF	2017/09/28 01:41 PM
L73	4	L72 and (blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2017/09/28 01:42 PM
L74	1733	(600/573).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2017/09/28 01:58 PM
L75	845	L74 and (blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2017/09/28 01:58 PM
L76	9	L75 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2017/09/28 01:59 PM
L77	86	("2007/0083162").URPN.	(USPAT)	OR	OFF	OFF	2017/09/28 01:59 PM
L78	1	("15140443").PN.	(US-PGPUB; USPAT)	OR	ON	ON	2017/09/28 01:59 PM
L79	9	("2008/0145933").URPN.	(USPAT)	OR	OFF	OFF	2017/09/28 02:04 PM
L80	1258	(600/583).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2017/09/28 02:20 PM
L81	1071	L80 and (blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2017/09/28 02:20 PM
L82	78	L81 and (vent$4 near4 air)	(US-PGPUB; USPAT)	OR	OFF	OFF	2017/09/28 02:21 PM
L83	282596	(blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2017/09/28 04:01 PM
L84	6183	L83 AND ((A61B10/0096 OR A61B5/150022).CPC.)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2017/09/28 04:01 PM
L85	387	L84 and (vent$4 near4 air)	(US-PGPUB; USPAT)	OR	OFF	OFF	2017/09/28 04:01 PM
L86	362	L85 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2017/09/28 04:02 PM
L87	12	("2005/0010189").URPN.	(USPAT)	OR	OFF	OFF	2017/09/28 04:03 PM
L88	1363	(604/164.01).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2017/09/28 04:04 PM
L89	74	L88 and (blood near4 (sequest$5 or	(US-PGPUB; USPAT)	OR	OFF	OFF	2017/09/28 04:05 PM

		sampl$4))					
L90	21	("3965910" | "3996923" | "4131127" | "4301811" | "4450854" | "4506691" | "4819684" | "5147333" | "5393035" | "5636975").PN. OR ("6569117").URPN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2017/09/28 04:09 PM
L91	499	(435/294.1).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2017/09/28 04:12 PM
L92	18	L91 and (blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2017/09/28 04:12 PM
L93	9	("2008/0145933").URPN.	(USPAT)	OR	OFF	OFF	2017/09/28 04:13 PM
L95	67	(("ROGERS") near3 ("Bobby")).INV.	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/01/09 04:23 PM
L96	1258	(600/583).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2018/01/09 04:25 PM
L97	4	L96 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/01/09 04:25 PM
L98	3	L97 and (blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/01/09 04:26 PM
L99	1733	(600/573).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2018/01/09 04:50 PM
L100	13	L99 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/01/09 04:50 PM
L101	255	("1779451" | "2004050" | "2700385" | "2836942" | "2854976" | "2953243" | "3021942" | "3073307" | "3074542" | "3255873" | "3294231" | "3323523" | "3329146" | "3333682" | "3367488" | "3382865" | "3485239" | "3537452" | "3585984" | "3610240" | "3658061" | "3664879" | "3817240" | "3828775" | "3859998" | "3874367" | "3886930" | "3890971" | "3904033" | "3934722" | "3968876" | "4106497" | "4108175" | "4113090" | "4139009" | "4154229" | "4166450" | "4175008" | "4193400" | "4207870" | "4269186" | "4300678" | "4312362" | "4317445" | "4340068" | "4375849" | "4398544" | "4409990" | "4412548" | "4416290" | "4416291" | "4418703"	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2018/01/09 04:51 PM

		| "4430082" | "4436098" | "4444203" | "4592744" | "4634428" | "4643722" | "4659330" | "4664249" | "4664654" | "4671408" | "4679571" | "4681567" | "4695274" | "4702738" | "4723943" | "4728320" | "4728321" | "4731059" | "4735311" | "4735618" | "4737144" | "4738663" | "4743233" | "4746008" | "4747836" | "4747837" | "4772272" | "4778453" | "4781697" | "4782841" | "4788986" | "4790828" | "4793484" | "4795432" | "4795443" | "4801295" | "4804372" | "4813426" | "4816022" | "4816024" | "4819659" | "4820277" | "4826490" | "4826491" | "4838871" | "4842587" | "4844089" | "4846796" | "4850968" | "4850976" | "4850977" | "4850978" | "4850994" | "4850996" | "4858607" | "4863434" | "4863435" | "4863436" | "4865592" | "4867746" | "4872552" | "4874383" | "4874384" | "4883469" | "4886072" | "4886503" | "4888001" | "4892107" | "4892521" | "4894052" | "4900309" | "4909791" | "4909792").PN. OR ("4921096" | "4927018" | "4944397" | "4966591" | "4971068" | "4976699" | "4982842" | "5011475" | "5011479" | "5030207" | "5032116" | "5033476" | "5055102" | "5069225" | "5078693" | "5078698" | "5092845" | "5112327" | "5116325" | "5120319" | "5122121" | "5135509" | "5137518" | "5139489" | "5151089" | "5154285" | "5181523" | "5188611" | "5197954" | "5201794" | "5207653" | "5217025" | "5222502" | "5232454" | "5232455" | "5242411" | "5242417" | "5277311" | "5290246" | "5295969" | "5303713" | "5306259"					

		| "5312369" | "5401251" | "5405332" | "5423765" | "5450856" | "5462534" | "5485854" | "5486163" | "5490841" | "5496281" | "5509907" | "5520193" | "5533984" | "5542932" | "5584816" | "5599313" | "5599318" | "5603699" | "5632732" | "5643219" | "5662617" | "5665075" | "5669889" | "5693022" | "5697914" | "5702369" | "5733265" | "5755701" | "5807351" | "5830190" | "5836920" | "5885249" | "5893844" | "5913846" | "5984895" | "5993426" | "6059737" | "6077244" | "6077253" | "6080137" | "6096006" | "6110160" | "6120482" | "6156010" | "6190370" | "6261263" | "6511439" | "6533760" | "6964658" | "7160267" | "RE31086").PN. OR ("7615033").URPN.					
L102	215	L101 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/01/09 04:51 PM
L103	1347	(604/164.01).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2018/01/09 05:11 PM
L104	17	L103 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/01/09 05:11 PM
L105	19	("2009/0312711").URPN.	(USPAT)	OR	OFF	OFF	2018/01/09 05:11 PM
L106	11	("2007/0106220").URPN.	(USPAT)	OR	OFF	OFF	2018/01/09 05:11 PM
L107	288967	(blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2018/01/09 05:16 PM
L108	6321	L107 AND ((A61B10/0096 OR A61B5/150022).CPC.)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2018/01/09 05:16 PM
L109	121	L108 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/01/09 05:17 PM
L110	448	(435/294.1).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2018/01/09 05:31 PM
L111	6	L110 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/01/09 05:31 PM
L113	71	(("ROGERS") near3 ("Bobby")).INV.	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/07/24 01:31 PM
L114	0	("15140443").PN.	(US-PGPUB; USPAT;	OR	OFF	OFF	2018/07/24

			USOCR)				01:38 PM
L115	2	(15/140443).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2018/07/24 01:38 PM
L116	2	(15/140448).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2018/07/24 01:40 PM
L117	1735	(600/573).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2018/07/24 01:56 PM
L118	854	L117 and (blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/07/24 01:56 PM
L119	91	L118 and (vent$4 near4 air)	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/07/24 01:57 PM
L120	1258	(600/583).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2018/07/24 02:06 PM
L121	1074	L120 and (blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/07/24 02:06 PM
L122	80	L121 and (vent$4 near4 air)	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/07/24 02:06 PM
L123	301210	(blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2018/07/24 02:11 PM
L124	6556	L123 AND ((A61B10/0096 OR A61B5/150022).CPC.)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2018/07/24 02:11 PM
L125	3664	L124 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/07/24 02:12 PM
L126	12749	"19" and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/07/24 02:12 PM
L127	117	L125 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/07/24 02:12 PM
L128	1348	(604/164.01).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2018/07/24 02:16 PM
L129	75	L128 and (blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/07/24 02:17 PM
L130	1	("20120291564").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2018/07/24 02:21 PM
L131	448	(435/294.1).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2018/07/24 02:25 PM
L132	18	L131 and (blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/07/24 02:25 PM
L133	98	("20020002349" | "20020183651" | "20030055381" | "20030208151" | "20040010228" | "20040054333" |	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2018/07/24 02:44 PM

		"20040147855" | "20050004524" | "20050240161" | "20050245885" | "20050281713" | "20060287639" | "20080108954" | "20080145933" | "2707953" | "3013557" | "3098016" | "3382865" | "3405706" | "3494351" | "3577980" | "3648684" | "3848579" | "3937211" | "4057050" | "4133863" | "4166450" | "4340067" | "4370987" | "4444203" | "4459997" | "4509534" | "4657160" | "4676256" | "4865583" | "4890627" | "4988339" | "5009847" | "5097842" | "5108927" | "5122129" | "5269317" | "5330464" | "5360011" | "5429610" | "5450856" | "5507299" | "5577513" | "5762633" | "5865812" | "5882318" | "5922551" | "6016712" | "6057105" | "6159164" | "6210909" | "6364890" | "6387086" | "6403381" | "6626884" | "6692479" | "6746420" | "6913580" | "7044941" | "7087047" | "7335188" | "7744573" | "8197420" | "8231546" | "8337418").PN. OR ("8535241").URPN.					
L134	307	("2913000" | "3817240" | "3859998" | "3864979" | "4016879" | "4046144").PN. OR ("4207870").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2018/07/24 02:47 PM
L135	23	("4166450").PN. OR ("4412548").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2018/07/24 02:48 PM
L136	307	("2913000" | "3817240" | "3859998" | "3864979" | "4016879" | "4046144").PN. OR ("4207870").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2018/07/24 02:48 PM
L137	4	("2007/0088279").URPN.	(USPAT)	OR	ON	ON	2018/07/24 02:48 PM
L138	1	(14/990763).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2018/07/24 02:58 PM
L139	9	(blood and sequest$5 and junction and first	(US-PGPUB; USPAT)	OR	ON	ON	2018/07/24 03:07 PM

		and portion and sampl$4).clm.					
L140	1	(15/287421).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2018/07/25 09:39 PM
L141	2	(14/055232).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2018/07/26 11:56 AM
L142	2	(15/140443).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/07 03:24 PM
L143	1	(15/893518).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/07 03:25 PM
L144	34	("20020004647"|"20030105414"|"20040054333"|"20040073171"|"20040147855"|"20050004524"|"20050240161"|"20070088279"|"20080145933"|"20100057004"|"20130317391"|"20160174888"|"3817240"|"3874367"|"3886930"|"4057050"|"4106497"|"4154229"|"4207870"|"4412548"|"5222502"|"5520193"|"5749857"|"6569117"|"8197420"|"8523826"|"8535241"|"8540663"|"8568371"|"8864684"|"9022951"|"9060724"|"9138572"|"9204864").PN.	(US-PGPUB; USPAT)	OR	ON	ON	2019/11/07 05:53 PM
L145	272	((("ROGERS") near3 ("Bobby")) OR (("KANG") near3 ("Gino")) OR (("STROUP") near3 ("David")) OR (("COCHRAN") near3 ("Jonas")) OR (("DEPTALA") near3 ("Arthur")) OR (("DETLOFF") near3 ("John")) OR (("POGUE") near3 ("Lonnie")) OR (("MACOWSKI") near3 ("Brian")) OR (("GARRETT") near3 ("Chad"))).INV.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2019/11/07 05:57 PM
L146	9	L145 and (blood near4 sequest$5)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 05:58 PM
L147	34	("20020004647"|"20030105414"|"20040054333"|"20040073171"|"20040147855"|"20050004524"|"20050240161"|"20070088279"|"200801459	(US-PGPUB; USPAT)	OR	ON	ON	2019/11/07 06:26 PM

		33"|"20100057004"|"20130317391"|"20160174888"|"3817240"|"3874367"|"3886930"|"4057050"|"4106497"|"4154229"|"4207870"|"4412548"|"5222502"|"5520193"|"5749857"|"6569117"|"8197420"|"8523826"|"8535241"|"8540663"|"8568371"|"8864684"|"9022951"|"9060724"|"9138572"|"9204864").PN.					
L148	5	L147 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 06:29 PM
L149	6	("2010/0057004").URPN.	(USPAT)	OR	ON	ON	2019/11/07 06:40 PM
L150	0	L149 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 07:20 PM
L151	1258	(600/583).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2019/11/07 07:21 PM
L152	4	L151 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 07:21 PM
L153	1766	(600/573).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/07 07:21 PM
L154	13	L153 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 07:21 PM
L155	811	(600/576).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/07 07:22 PM
L156	48	L155 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 07:22 PM
L157	1351	(604/164.01).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2019/11/07 07:43 PM
L158	17	L157 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 07:43 PM
L159	448	(435/294.1).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2019/11/07 07:43 PM
L160	6	L159 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 07:44 PM
L161	333030	(blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2019/11/07 07:44 PM
L162	6981	L161 AND ((A61B10/0096 OR A61B5/150022).CPC.)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2019/11/07 07:44 PM
L163	139	L162 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 07:44 PM
L164	117	L163 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 07:45 PM
L165	1	L146 and (enclos$3	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07

		near4 mechanism)					07:51 PM
L166	1	("7637875").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/08 04:57 PM
L167	1	(15/139716).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/11 12:09 PM
L168	1	(15/520430).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/12 11:02 AM
L169	1	("7637875").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/12 12:11 PM
L170	1	("20120253321").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/12 12:13 PM
L171	1	(15/861959).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/12 12:14 PM
L172	1	("4207870").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/12/09 02:17 PM
L173	1	("5749857").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/12/09 03:14 PM
L174	1	("20080167577").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/12/09 03:19 PM
L175	4	("2008/0167577").URPN.	(USPAT)	OR	ON	ON	2019/12/09 03:30 PM
L176	1	("8197420").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/12/09 03:31 PM
L177	39	(US-20040073171-$ or US-20160174888-$ or US-20050240161-$ or US-20040147855-$ or US-20130317391-$ or US-20050004524-$ or US-20030105414-$ or US-20020004647-$ or US-20100057004-$ or US-20070088279-$ or US-20080145933-$ or US-20040054333-$ or US-20100010372-$ or US-20080319346-$ or US-20080167577-$).did. or (US-9138572-$ or US-8568371-$ or US-8540663-$ or US-8523826-$ or US-8197420-$ or US-4057050-$ or US-8864684-$ or US-8535241-$ or US-5749857-$ or US-9060724-$ or US-9204864-$ or US-3817240-$ or US-3874367-$ or US-3886930-$ or US-4106497-$ or US-4154229-$ or US-	(US-PGPUB; USPAT)	OR	ON	ON	2019/12/09 03:37 PM

		4207870-$ or US-4412548-$ or US-5222502-$ or US-5520193-$ or US-9022951-$ or US-6569117-$ or US-3741197-$ or US-8603009-$).did.					
L178	8	("20040054333"|"8197420"|"9855001"|"9861306"|"10045724"|"10028687"|"8337418"|"10028689").PN.	(US-PGPUB; USPAT)	OR	ON	ON	2019/12/09 03:42 PM
L179	100	("20020002349" | "20020183651" | "20030055381" | "20040010228" | "20040054333" | "20040147855" | "20050004524" | "20050240161" | "20050245885" | "20050281713" | "20060287639" | "2707953" | "3013557" | "3098016" | "3382865" | "3405706" | "3494351" | "3577980" | "3648684" | "3848579" | "3937211" | "4057050" | "4133863" | "4166450" | "4340067" | "4370987" | "4444203" | "4459997" | "4509534" | "4676256" | "4865583" | "4890627" | "4988339" | "5009847" | "5097842" | "5108927" | "5122129" | "5269317" | "5360011" | "5429610" | "5450856" | "5507299" | "5577513" | "5762633" | "5882318" | "5922551" | "6016712" | "6057105" | "6159164" | "6210909" | "6364890" | "6387086" | "6403381" | "6692479" | "6746420" | "6913580" | "7044941" | "7087047").PN. OR ("8197420").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2019/12/09 03:43 PM
L180	70	L179 and (blood near4 (sequest$5 or sampl$4 or flash$4))	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2019/12/09 03:43 PM
L181	43	L180 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 03:44 PM
L182	270	((("BULLINGTON")	(US-PGPUB; USPAT;	OR	ON	ON	2019/12/09

		near3 ("Gregory")) OR (("PATTON") near3 ("Richard")) OR (("MIAZGA") near3 ("Jay")) OR (("GAW") near3 ("Shan"))).INV.	USOCR; EPO; JPO; DERWENT)				04:13 PM
L183	335813	(blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2019/12/09 04:22 PM
L184	7259	L183 AND ((A61B10/0096 OR A61B5/150022).CPC.)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2019/12/09 04:22 PM
L185	325	("2913000" | "3817240" | "3859998" | "3864979" | "4016879" | "4046144").PN. OR ("4207870").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2019/12/09 04:33 PM
L186	594	L184 and (flash$6 and seal$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 04:40 PM
L187	476	L186 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 04:40 PM
L188	1735	(600/573).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2019/12/09 05:14 PM
L189	1123	L188 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:15 PM
L190	1013	L189 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:15 PM
L191	10	L190 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:16 PM
L192	1259	(600/583).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/12/09 05:23 PM
L193	1143	L192 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:23 PM
L194	1038	L193 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:23 PM
L195	3	L194 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:23 PM
L196	811	(600/576).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/12/09 05:24 PM
L197	618	L196 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:24 PM
L198	557	L197 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:24 PM
L199	1	(15/854273).APP.	(US-PGPUB; USPAT;	OR	OFF	OFF	2019/12/09

			USOCR)				05:25 PM
L200	1351	(604/164.01).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2019/12/09 05:31 PM
L201	219	L200 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:33 PM
L202	199	L201 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:33 PM
L203	448	(435/294.1).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2019/12/09 05:36 PM
L204	44	L203 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:37 PM
L205	1	(15/508871).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/12/10 11:58 AM
L206	342199	(blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2020/03/16 12:53 PM
L207	4239	L206 AND ((A61B10/0096 OR A61B5/150022).CPC.)	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 12:53 PM
L208	146	L207 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 12:54 PM
L209	101	L208 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 12:55 PM
L210	1735	(600/573).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2020/03/16 01:38 PM
L211	1123	L210 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:38 PM
L212	1013	L211 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:39 PM
L213	22	L212 and (((vent$4 or open$5 or hole or aperture) near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:39 PM
L214	108	("20020193748" | "20030093009" | "20030105414" | "20030220614" | "20030229315" | "20040059302" | "20040092872" | "20040193120" | "20050004524" | "20050065482" | "20050124944" | "20050187493" | "20050245868" |	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2020/03/16 01:46 PM

		"20050245869" | "20050245870" | "20050245879" | "20050245885" | "20060036219" | "20060224122" | "20070106220" | "20070106224" | "20070167914" | "20080086085" | "20080177202" | "20080319345" | "20080319346" | "20090204026" | "20100262038" | "4106497" | "4207870" | "4305406" | "4572210" | "4573976" | "4641663" | "4795443" | "4840619" | "4894055" | "4900307" | "4994046" | "5015241" | "5195985" | "5215534" | "5222502" | "5242417" | "5246428" | "5256153" | "5295970" | "5303713" | "5312372" | "5336199" | "5348544" | "5356392" | "5411492" | "5439449" | "5466223" | "5501675" | "5542932" | "5599313" | "5662617" | "5665075" | "5672161" | "5676658" | "5702369" | "5704920" | "5733265" | "5755522" | "5957892" | "5984899" | "6149629" | "6224576" | "6254575" | "6261263" | "6298541" | "6344032" | "6436086" | "6440104" | "6524277" | "6533760" | "6592556" | "6623456" | "6635032" | "6648855" | "6695819" | "6699217" | "6712792" | "6780169" | "6837877" | "6869415" | "6984223" | "7001363" | "7128726" | "7147624" | "7160267" | "7163526" | "7223258" | "7226432" | "7396343" | "7428773" | "7537581" | "7766879" | "D422700" | "D442280" | "D604836" | "D604837" | "D604838" | "D604839" | "D605287").PN. OR ("8603009").URPN.					

L215	26	L214 and (((vent$4 or open$5 or hole or aperture) near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:47 PM
L216	27	("2008/0319346").URPN.	(USPAT)	OR	ON	ON	2020/03/16 01:47 PM
L217	23	("2003/0105414").URPN.	(USPAT)	OR	ON	ON	2020/03/16 01:48 PM
L218	1258	(600/583).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2020/03/16 01:52 PM
L219	1143	L218 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:52 PM
L220	25	L219 and (((vent$4 or open$5 or hole or aperture) near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:52 PM
L221	353695	((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:54 PM
L222	3643	L221 and (((vent$4 or open$5 or hole or aperture) near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:55 PM
L223	1926	L222 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:55 PM
L224	785	L223 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:56 PM
L225	7046	(600/300).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/03/16 02:32 PM
L226	14	L225 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 02:35 PM
L227	1352	(604/164.01).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2020/03/16 02:36 PM
L228	135	L227 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 02:36 PM
L229	19	L228 and (((vent$4 or open$5 or hole or aperture) near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 02:36 PM
L230	448	(435/294.1).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2020/03/16 02:47 PM
L231	3	L230 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 02:47 PM
L232	19	("2008/0145933").URPN.	(USPAT)	OR	ON	ON	2020/03/16 02:48 PM
L233	795	(600/576).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2020/03/16

							02:58 PM
L234	71	L233 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 02:58 PM
L235	57	L234 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 02:59 PM
L236	371	(600/577).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/03/16 03:12 PM
L237	11	L236 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 03:12 PM
L238	45	("20040054333"|"20050240161"|"4412548"|"5749857"|"8197420"|"9855001"|"9861306"|"20020004647"|"20100057004"|"3741197"|"20040073171"|"3874367"|"4057050"|"4106497"|"8197420"|"8535241"|"8540663"|"8603009"|"8864684"|"10045724"|"3817240"|"10028687"|"20030105414"|"5222502"|"5520193"|"6569117"|"8568371"|"20040147855"|"20070088279"|"20080145933"|"20100010372"|"3886930"|"8523826"|"9060724"|"9204864"|"8337418"|"20050004524"|"20080167577"|"20080319346"|"20130317391"|"4154229"|"9022951"|"10028689"|"20160174888"|"4207870"|"9138572").PN.	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 03:13 PM
L239	6	("2008/0167577").URPN.	(USPAT)	OR	ON	ON	2020/03/16 03:13 PM
L240	118	("3500828" | "3670729" | "3714945" | "3977400" | "3994293" | "3995619" | "4106491" | "4200096" | "4468224" | "4531987" | "4549554" | "4735215" | "4828548" | "4874373" | "4893635" | "4894052" | "4907599" | "4944308" | "4994042" | "5129884" | "5400798").PN. OR ("5749857").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2020/03/16 03:15 PM
L241	6	("2008/0167577").URPN.	(US-PGPUB; USPAT)	OR	ON	ON	2020/03/16 03:15 PM
L242	274	((("BULLINGTON") near3 ("Gregory")) OR	(US-PGPUB; USPAT; USOCR; EPO; JPO;	OR	ON	ON	2020/03/16 03:25 PM

		(("PATTON") near3 ("Richard")) OR (("MIAZGA") near3 ("Jay")) OR (("GAW") near3 ("Shan"))).INV.	DERWENT)				
L243	61	L242 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 03:25 PM
L244	1	(15/854273).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/03/16 03:47 PM
L245	0	(14/502498).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/03/16 04:11 PM
L246	1	("20110082383").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/03/16 04:24 PM
L247	1	("8150506").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/03/16 04:24 PM
L252	1	(15/057214).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/03/17 11:28 AM
L253	348964	(blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2020/06/10 05:22 PM
L254	7453	L253 AND ((A61B10/0096 OR A61B5/150022).CPC.)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2020/06/10 05:22 PM
L255	155	L254 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 05:23 PM
L256	77	(("ROGERS") near3 ("Bobby")).INV.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 05:35 PM
L257	343953	(blood same (sequest$5 or sampl$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 05:40 PM
L258	11	L256 and (blood same (sequest$5 or sampl$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 05:41 PM
L259	1	("5749857").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 05:50 PM
L260	121	("3500828" | "3670729" | "3714945" | "3977400" | "3994293" | "3995619" | "4106491" | "4200096" | "4468224" | "4531987" | "4549554" | "4735215" | "4828548" | "4874373" | "4893635" | "4894052" | "4907599" | "4944308" | "4994042" | "5129884" | "5400798").PN. OR ("5749857").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2020/06/10 06:19 PM
L261	32	L260 and (blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:20 PM

L262	1	("3648684").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 06:38 PM
L263	1	("4056101").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 06:38 PM
L264	329	(600/577).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2020/06/10 06:39 PM
L265	11	L264 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:39 PM
L266	29	("2008/0319346").URPN.	(USPAT)	OR	ON	ON	2020/06/10 06:40 PM
L267	812	(600/576).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 06:40 PM
L268	72	L267 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:40 PM
L269	1767	(600/573).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 06:44 PM
L270	31	L269 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:45 PM
L271	77	("4676249" | "4787891" | "4850960" | "4874382" | "4886067" | "4886500" | "4900307" | "4904242" | "4917102" | "4950252" | "4955862" | "5046508" | "5116353" | "5125718" | "5129884" | "5163911" | "5217435" | "5290244" | "5295974" | "5314503" | "5318585" | "5330432" | "5360410" | "5366441" | "5376075" | "5395337" | "5531692" | "5695475" | "5695479" | "5702367" | "5735813" | "5749857" | "5788654" | "5800395" | "5846226" | "5871470" | "5882342" | "5919172" | "5935108" | "5935113" | "5989220" | "6050976" | "6077244" | "6099504" | "6126641" | "6162195").PN. OR ("6398743").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2020/06/10 06:46 PM
L272	18	L271 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:46 PM
L273	1	(15/893518).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 06:48 PM
L274	7050	(600/300).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 06:49 PM

L275	14	L274 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:49 PM
L276	1259	(600/583).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 06:51 PM
L277	7	L276 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:51 PM
L278	1368	(604/164.01).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 06:52 PM
L279	135	L278 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:52 PM
L280	499	(435/294.1).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 07:08 PM
L281	3	L280 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 07:08 PM
L282	20	("2008/0145933").URPN.	(USPAT)	OR	ON	ON	2020/06/10 07:08 PM
L286	1	("10045704").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 08:56 PM
L287	1	("10143412").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/01 09:16 PM
L288	1	("10010282").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/01 09:17 PM
L289	100	((("ROGERS") near3 ("Bobby")) OR (("KANG") near3 ("Gino")) OR (("DETLOFF") near3 ("John"))).INV.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2021/03/01 09:17 PM
L290	2	(15/140443).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/01 09:36 PM
L291	1	(15/855439).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/01 09:39 PM
L292	180	(("ROGERS") near3 ("Bobby")).INV.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2021/03/02 12:19 PM
L293	11	L292 and (blood near4 sequest$5)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 12:20 PM
L294	2	(15/140443).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 12:47 PM
L295	1	(15/855439).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 12:49 PM
L296	1	("20020048170").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 01:36 PM
L297	1	("20040174525").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 01:49 PM
L298	1	("10045704").PN.	(US-PGPUB; USPAT;	OR	OFF	OFF	2021/03/02

			USOCR)				03:09 PM
L299	27321	(A61B5/150992 or A61B5/15003 or A61B5/150213 or A61B5/150389 or A61B5/150473 or A61B5/150572 or A61B5/154 or A61B5/153 or A61M39/0693 or A61M39/04 or A61B5/150221 or A61M2039/0633 or A61M2039/0202 or A61M2039/068).cpc.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2021/03/02 03:17 PM
L300	4594	L299 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 03:27 PM
L301	3762	L300 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 03:28 PM
L302	257	L301 and (air near4 permeab$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 03:29 PM
L303	420	L301 and ((air or gas$4) near4 permeab$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 03:29 PM
L304	1	("20110167658").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 03:30 PM
L305	5	("2015/0306288").URPN.	(USPAT)	OR	ON	ON	2021/03/02 04:15 PM
L306	1	(16/208559).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 04:32 PM
L307	2	("2009/0043225").URPN.	(USPAT)	OR	ON	ON	2021/03/02 04:49 PM
L308	1736	(600/573).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2021/03/02 05:00 PM
L309	1363	L308 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:00 PM
L310	73	L309 and ((air or gas$4) near4 permeab$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:01 PM
L311	73	L310 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:01 PM
L312	812	(600/576).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 05:34 PM
L313	711	L312 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:34 PM
L314	58	L313 and ((air or gas$4) near4 permeab$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:34 PM
L315	58	L314 and	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02

		@ad<"20150724"					05:34 PM
L316	371	(600/577).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 05:42 PM
L317	277	L316 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:42 PM
L318	20	L317 and ((air or gas$4) near4 permeab$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:43 PM
L319	336	("2913000" | "3817240" | "3859998" | "3864979" | "4016879" | "4046144").PN. OR ("4207870").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/03/02 05:44 PM
L320	210	L319 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:44 PM
L321	196	L320 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:44 PM
L322	1259	(600/583).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 05:48 PM
L323	1208	L322 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:48 PM
L324	73	L323 and ((air or gas$4) near4 permeab$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:48 PM
L325	73	L324 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:49 PM
L326	1368	(604/164.01).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 05:59 PM
L327	271	L326 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 06:00 PM
L328	10	L327 and ((air or gas$4) near4 permeab$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 06:00 PM
L329	268	L327 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 06:00 PM
L330	182	(("ROGERS") near3 ("Bobby")).INV.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2021/07/08 02:22 PM
L331	27660	(A61B5/150992 or A61B5/15003 or A61B5/150213 or A61B5/150389 or A61B5/150473 or A61B5/150572 or A61B5/154 or A61B5/153 or	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2021/07/08 03:27 PM

		A61M39/0693 or A61M39/04 or A61B5/150221 or A61M2039/0633 or A61M2039/0202 or A61M2039/068).cpc.					
L332	4684	L331 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 03:28 PM
L333	3769	L332 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 03:29 PM
L334	579	L333 and (vent$4 near4 air)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 03:29 PM
L335	1	("9820682").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/07/08 03:54 PM
L336	1	("4207870").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/07/08 03:56 PM
L337	337	("2913000" | "3817240" | "3859998" | "3864979" | "4016879" | "4046144").PN. OR ("4207870").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/07/08 04:19 PM
L338	211	L337 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:19 PM
L339	196	L338 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:19 PM
L340	37	L339 and (vent$4 near4 air)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:19 PM
L341	221	("20010021827" | "20020004650" | "20020055716" | "20020072715" | "20020103464" | "20020103465" | "20020107488" | "20020151856" | "20020193748" | "20030028171" | "20030036730" | "20030050608" | "20030055385" | "20030078544" | "20030093009" | "20030105414" | "20030114797" | "20030120222" | "20030176842" | "20030181873" | "20030191438" | "20030199827" | "20030216687" |	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/07/08 04:21 PM

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		"5676658" | "5702369" | "5704920" | "5755522" | "5984899" | "6149629" | "6261263" | "6298541" | "6436086" | "6440104" | "6524277" | "6533760" | "6592556" | "6623456" | "6635032" | "6648855" | "6699217" | "6712792" | "6780169" | "6837877" | "6869415" | "6984223" | "7001363" | "7128726" | "7147624" | "7160267" | "7163526" | "7223258" | "7226432" | "7396343" | "7428773" | "D422700" | "D442280").PN. OR ("7766879").URPN.					
L344	41	("2735430" | "2798487" | "3187749" | "3240209" | "3585984" | "3817240" | "4166450" | "4207870" | "4295477" | "4312362").PN. OR ("4436098").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/07/08 04:22 PM
L345	163	L341 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:22 PM
L346	163	L345 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:23 PM
L347	22	("2005/0283093").URPN.	(USPAT)	OR	ON	ON	2021/07/08 04:23 PM
L348	163	L345 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:27 PM
L349	163	L348 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:27 PM
L350	1736	(600/573).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2021/07/08 04:37 PM
L351	1363	L350 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:37 PM
L352	1346	L351 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:38 PM
L353	136	L352 and (vent$4 near4 air)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:38 PM
L354	812	(600/576).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/07/08 04:41 PM
L355	711	L354 and ((blood or fluid$4) near4 (sequest$5 or sampl$4	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:41 PM

		or flash$4 or collect$4))					
L356	699	L355 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:41 PM
L357	123	L356 and (vent$4 near4 air)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:41 PM
L358	371	(600/577).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/07/08 04:44 PM
L359	277	L358 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:45 PM
L360	260	L359 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:45 PM
L361	1259	(600/583).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/07/08 04:46 PM
L362	1208	L361 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:46 PM
L363	1194	L362 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:47 PM
L364	1194	L363 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:47 PM
L366	1	("9820682").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:05 PM
L367	319	((("BULLINGTON") near3 ("Gregory")) OR (("PATTON") near3 ("Richard")) OR (("MIAZGA") near3 ("Jay")) OR (("GAW") near3 ("Shan"))).INV.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2022/02/02 03:14 PM
L368	1	(16/376745).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:35 PM
L369	190	(("ROGERS") near3 ("Bobby")).INV.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2022/02/02 03:36 PM
L370	2	(15/140448).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:41 PM
L371	1	("9820682").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:42 PM
L372	1	("9060725").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:42 PM
L373	1	("9060724").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:43 PM
L374	1	("9022950").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:45 PM
L375	1	("9022951").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:45 PM
L376	1	("10292633").PN.	(US-PGPUB; USPAT;	OR	OFF	OFF	2022/02/02

			USOCR)				03:46 PM
L377	1	("10433779").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:47 PM
L378	1	("10436554").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:48 PM
L379	1	("10736554").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:49 PM
L380	1	("10912506").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:49 PM
L381	1	("10010282").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:49 PM
L382	1	(16/376745).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:50 PM
L383	1	("9820682").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:51 PM
L384	276	(600/579).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:52 PM
L385	204	L384 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/02/02 03:53 PM
L386	37427	(A61B5/150221 or A61B5/15003 or A61B5/150236 or A61B5/150244 or A61B5/150251 or A61B5/150389 or A61B5/150503 or A61B5/150992 or A61B5/153 or A61B5/155 or A61B10/0048 or A61B10/0051 or A61B10/007 or A61B2010/0061 or A61B2010/0077 or A61B2010/008).cpc.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2022/02/02 04:35 PM
L387	7279	L386 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/02/02 04:36 PM
L388	4442	L387 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/02/02 04:36 PM
L389	874	L388 and (seal$4 near4 (member or mechanism$4 or vent$4 or elastic$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/02/02 04:38 PM
L390	26	("2008/0145933").URPN.	(USPAT)	OR	ON	ON	2022/02/02 04:52 PM
L391	44	("2008/0319346").URPN.	(USPAT)	OR	ON	ON	2022/02/02 04:59 PM
L392	385	L386 and ((blood or fluid) near4 (seal$4 near4 (member or	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/02/02 05:28 PM

		mechanism$4 or vent$4 or elastic$4)))					
L393	171	L392 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/02/02 05:28 PM
L394	355	(604/103).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 05:52 PM
L395	7	L394 and ((blood or fluid) near4 (seal$4 near4 (member or mechanism$4 or vent$4 or elastic$4)))	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/02/02 05:52 PM
L396	1	(16/328127).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/03 12:00 PM
L397	0	"1020130062845"	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/02/04 04:17 PM
L398	8	"20130062845"	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/02/04 04:17 PM
L399	14	"2013021595"	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/02/04 04:18 PM
L400	2	(14/055232).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/04 07:10 PM
L401	1	(15/746656).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/05 11:48 AM
L402	0	(17/388440).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/07 09:34 AM
L403	1	("20050048465").PN.	(US-PGPUB; USPAT)	OR	ON	ON	2022/02/07 09:34 AM
L404	196	(("ROGERS") near3 ("Bobby")).INV.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2022/05/18 03:08 PM
L405	16	L404 and (blood near4 sequest$5)	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/05/18 03:08 PM
L406	16	L404 and ((blood or chamber) near4 sequest$5)	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/05/18 03:08 PM
L407	16	L406 and (junct$4 or bypass$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/05/18 03:09 PM
L408	16	L406 and junct$4	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/05/18 03:09 PM
L409	22445	(A61B5/150992 or A61B5/15003 or A61B5/150213 or A61B5/150221 or A61B5/150389 or A61B5/150473 or	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2022/05/18 03:54 PM

		A61B5/150572 or A61B5/154 or A61B5/15074).cpc.					
L410	4525	L409 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4 or flush$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/05/18 03:55 PM
L411	3810	L410 and @ad<"20170210"	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/05/18 03:56 PM
L412	820	L411 and ((vent$4 or open$4 or apertur$4) near4 air)	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/05/18 03:57 PM
L413	22445	(A61B5/150992 or A61B5/15003 or A61B5/150213 or A61B5/150221 or A61B5/150389 or A61B5/150473 or A61B5/150572 or A61B5/154 or A61B5/15074).cpc.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2022/05/18 05:51 PM
L414	4603	L413 and ((blood or fluid$4 or chamber) same (sequest$5 or sampl$4 or flash$4 or collect$4 or flush$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/05/18 05:51 PM
L415	511	L414 and ((junct$4 or bypass$4 or divert$4) near4 (blood or fluid))	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/05/18 05:52 PM
L416	355	L415 and @ad<"20170210"	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/05/18 05:53 PM
L417	1	(16/819033).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/05/18 06:10 PM
L418	1	(17/094692).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/05/18 06:25 PM
L419	1	(17/538990).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/05/18 06:25 PM
L420	1	("11311219").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/05/18 06:27 PM
L421	1	("11185266").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/05/18 06:30 PM
L422	1	("10143412").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/05/18 06:31 PM
L423	1	("9820682").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/05/18 06:32 PM
L424	252	(("ROGERS") near3 ("Bobby")).INV.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS,	OR	OFF	OFF	2022/10/13 01:41 PM

			IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)				
L425	38	424 AND (closur$4 OR enclos$4)	(US-PGPUB; USPAT)	OR	ON	ON	2022/10/13 01:42 PM
L426	42781	(A61B5/150213 OR A61B5/15003 OR A61B5/150221 OR A61B5/150251 OR A61B5/150732 OR A61B5/15074 OR A61B5/150992 OR A61B5/153 OR A61B5/150389 OR A61B5/150503).cpc.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/10/13 01:47 PM
L427	5205	426 AND @ad<"20170210"	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/10/13 01:50 PM
L428	4803	427 AND ((blood OR fluid$4) near4 (sequest$5 OR sampl$4 OR flash$4 OR collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/10/13 01:51 PM
L429	519	428 AND ((closur$4 OR enclos$4 OR pug$4) near5 (vent OR open$4 OR air))	(US-PGPUB; USPAT)	OR	ON	ON	2022/10/13 01:54 PM
L430	169	"5749857"	(US-PGPUB; USPAT)	OR	ON	ON	2022/10/13 02:14 PM
L431	1	("5749857").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2022/10/13 02:14 PM
L432	346	427 AND ((junct$4 OR bypass$4 OR divert$4) near4 (blood OR fluid))	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/10/13 02:18 PM
L433	186	("3500828" | "3670729" | "3714945" | "3977400" | "3994293" | "3995619" | "4106491" | "4200096" | "4468224" | "4531987" | "4549554" | "4735215" | "4828548" | "4874373" | "4893635" | "4894052" | "4907599" | "4944308" | "4994042" | "5129884"	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/10/13 02:32 PM

		| "5400798").pn. OR ("5749857").urpn. AND (PGPB | USPT | USOC).dbnm.					
L434	124	433 AND ((blood OR fluid$4) near4 (sequest$5 OR sampl$4 OR flash$4 OR collect$4 OR optimiz$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/10/13 02:34 PM
L435	1	("5749857").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2022/10/13 02:34 PM
L436	1	17/138056	(US-PGPUB; USPAT)	OR	ON	ON	2022/10/19 11:35 AM
L437	253	(("ROGERS") near3 ("Bobby")).INV.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2022/11/16 03:25 PM
L438	39	437 AND (closur$4 OR enclos$4)	(US-PGPUB; USPAT)	OR	ON	ON	2022/11/16 03:25 PM
L439	35391	(A61B5/150992 OR A61B5/15003 OR A61B5/150213 OR A61B5/150221 OR A61B5/150389 OR A61B5/150473 OR A61B5/150572 OR A61B5/154 OR A61B5/15074).cpc.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2022/11/16 03:46 PM
L440	4100	439 AND @ad<"20170210"	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/11/16 03:48 PM
L441	3875	440 AND ((blood OR fluid$4 OR urine) SAME (sequest$5 OR sampl$4 OR flash$4 OR collect$4 OR	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/11/16 03:49 PM

		optimiz$5))					
L442	368	441 AND ((junct$4 OR bypass$4 OR divert$4) near5 (blood OR fluid OR urine))	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/11/16 03:50 PM
L443	7	"10827964"	(US-PGPUB; USPAT)	OR	ON	ON	2022/11/16 04:13 PM
L444	1	16/819033	(US-PGPUB; USPAT)	OR	ON	ON	2022/11/16 04:48 PM
L445	359	"4207870"	(US-PGPUB; USPAT)	OR	ON	ON	2022/11/16 05:07 PM
L446	1	("4207870").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2022/11/16 05:07 PM
L447	3814	440 AND ((blood OR fluid$4 OR urine) near5(sequest$5 OR sampl$4 OR flash$4 OR collect$4 OR optimiz$5))	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/11/16 05:17 PM
L448	366	447 AND ((junct$4 OR bypass$4 OR divert$4) near5 (blood OR fluid OR urine))	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/11/16 05:17 PM
L449	89	(("ROGERS") near3 ("Bobby")).INV.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2023/04/11 01:13 PM
L450	24	449 AND ((blood OR fluid$4 OR urine) near5(sequest$5 OR sampl$4 OR flush$4 OR collect$4 OR optimiz$5or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/04/11 01:14 PM
L451	24	449 AND ((blood OR fluid$4 OR urine) near5(sequest$5 OR sampl$4 OR flush$4 OR collect$4 OR optimiz$5 OR flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/04/11 01:14 PM
L452	6634	(A61B5/150213 OR A61B5/15003 OR A61B5/150221 OR A61B5/150251 OR A61B5/150732 OR A61B5/15074 OR A61B5/150992 OR A61B5/153 OR A61B5/150389 OR A61B5/150503).cpc.	(US-PGPUB; USPAT)	OR	ON	ON	2023/04/11 01:32 PM
L453	5326	452 AND @ad<"20170210"	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/04/11 01:32 PM
L454	4928	453 AND ((blood OR fluid$4 OR urine) near5(sequest$5 OR sampl$4 OR flush$4	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/04/11 01:32 PM

		OR collect$4 OR optimiz$5 OR flash$4))					
L455	371	454 AND ((junct$4 OR bypass$4 OR divert$4) near5 (blood OR fluid OR urine))	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/04/11 01:33 PM
L456	11	("2016/0361006").urpn. AND (PGPB | USPT | USOC).dbnm.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2023/04/11 03:03 PM
L457	1	17/094692	(US-PGPUB; USPAT)	OR	ON	ON	2023/04/11 03:11 PM
L458	49	("20020004647"|"20030105414"|"20040054333"|"20040073171"|"20040147855"|"20050004524"|"20050240161"|"20070083162"|"20070088279"|"20080086085"|"20080145933"|"20080167577"|"20080319346"|"20100010372"|"20100057004"|"20120016266"|"20130317391"|"20160008579"|"20160174888"|"3741197"|"3817240"|"3874367"|"3886930"|"4057050"|"4106497"|"4154229"|"4207870"|"4412548"|"4436098"|"4444203"|"5222502"|"5520193"|"5749857"|"6398743"|"6569117"|"8197420"|"8523826"|"8535241"|"8540663"|"8568371"|"8603009"|"8864684"|"9022950"|"9022951"|"9060724"|"9138572"|"9155495"|"9204864"|"9877675").PN.	(US-PGPUB; USPAT)	OR	ON	ON	2023/04/11 03:18 PM
L459	13	458 AND ((junct$4 OR bypass$4 OR divert$4) near5 (blood OR fluid OR urine))	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/04/11 03:18 PM
L460	155	("2707953" | "2992974" | "3013557" | "3098016" | "3382865" | "3405706" | "3494351" | "3577980" | "3635798" | "3648684" | "3848579" | "3890203" | "3937211" | "4057050" | "4133863" | "4166450" | "4340067" | "4370987" | "4425235" | "4444203" | "4459997" | "4509534" | "4657160" | "4676256" | "4865583" | "4890627"	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2023/04/11 03:21 PM

		| "4988339" | "5009847" | "5097842" | "5108927" | "5122129" | "5269317" | "5330464" | "5360011" | "5429610" | "5450856" | "5454786" | "5485854" | "5507299" | "5577513" | "5762633" | "5865812" | "5882318" | "5922551" | "6016712" | "6057105" | "6159164" | "6210909" | "6328726" | "6364890" | "6387086" | "6403381" | "6520948" | "6626884" | "6692479" | "6716187" | "6746420" | "6913580" | "7044941" | "7087047" | "7335188" | "7384416" | "7744573" | "8197420" | "8231546" | "8337418" | "8535241" | "8647286" | "8864684" | "8876734" | "20020002349" | "20020183651" | "20030055381" | "20030208151" | "20040010228" | "20040054283" | "20040054333" | "20040147855" | "20050004524" | "20050240161" | "20050245885" | "20050281713" | "20060287639" | "20080108954" | "20080145933" | "20100152681" | "20120095367" | "20120215131" | "20130079604" | "20130116599" | "20130317391" | "20140081172").pn. OR ("9060724").urpn. AND (PGPB | USPT | USOC).dbnm.					
L461	31	("2008/0145933").urpn. AND (PGPB | USPT | USOC).dbnm.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2023/04/11 03:30 PM
L462	1	("5749857").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/04/11 03:46 PM
L463	13	459 AND ((junct$4 OR bypass$4 OR divert$4) near5 (blood OR fluid OR urine))	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/04/11 03:47 PM

L464	4994	453 AND ((blood OR fluid$4 OR urine OR semen) SAME (sequest$5 OR sampl$4 OR flush$4 OR collect$4 OR optimiz$5 OR flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/04/11 03:58 PM
L465	968	464 AND ((junct$4 OR bypass$4 OR diver$5) SAME (blood OR fluid OR urine OR semen))	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/04/11 03:59 PM
L466	707	465 AND housing	(US-PGPUB; USPAT)	OR	ON	ON	2023/04/11 04:50 PM
L467	2911	464 AND ((blood OR fluid$4 OR urine OR semen) near5 (first OR second OR subsequent$4 OR bypass))	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/04/11 04:52 PM
L468	2954	464 AND ((blood OR fluid$4 OR urine OR semen) near5 (first OR second OR subsequent$4 OR convey$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/04/11 04:52 PM
L469	2891	464 AND ((blood OR fluid$4 OR urine OR semen) near5 (first OR second OR subsequent$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/04/11 04:52 PM
L470	790	469 AND ((junct$4 OR bypass$4 OR diver$5) SAME (blood OR fluid OR urine OR semen))	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/04/11 04:53 PM
L471	1	17/538990	(US-PGPUB; USPAT)	OR	ON	ON	2023/05/08 12:35 PM
L472	164	(("ROGERS") near3 ("Bobby")).INV.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2023/05/08 02:18 PM
L473	1	("4207870").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/05/08 03:23 PM
L474	1	("10827964").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/05/08

							03:31 PM
L475	1	("11311219").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/05/08 03:32 PM
L476	1	"17094692"	(US-PGPUB; USPAT)	OR	ON	ON	2023/05/08 03:34 PM
L477	2	"17730118"	(US-PGPUB; USPAT)	OR	ON	ON	2023/05/08 03:34 PM
L478	1	("10012828").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/05/08 03:36 PM
L479	1	("10010282").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/05/08 03:36 PM
L480	48138	(A61B5/150992 OR A61B5/15003 OR A61B5/150213 OR A61B5/150221 OR A61B5/150389 OR A61B5/150473 OR A61B5/150572 OR A61B5/153 OR A61B5/154 OR A61M39/04 OR A61M39/0693 OR A61M2039/0202 OR A61M2039/0633 OR A61M2039/068).cpc.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/05/08 03:59 PM
L481	5081	480 AND @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/05/08 04:15 PM
L482	3947	481 AND ((blood OR fluid$4 OR urine) near5(sequest$5 OR sampl$4 OR flush$4 OR collect$4 OR optimiz$5 OR flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/05/08 04:17 PM
L483	1	17/538990	(US-PGPUB; USPAT)	OR	ON	ON	2023/05/08 04:17 PM
L484	1069	482 AND (air near5 (filter$4 OR material$4 OR membrane OR permeab$4 OR vent$4))	(US-PGPUB; USPAT)	OR	ON	ON	2023/05/08 04:32 PM
L485	203	("3500828" | "3670729" | "3714945" | "3977400" | "3994293" | "3995619" | "4106491" | "4200096" | "4468224" | "4531987" | "4549554" | "4735215" | "4828548" | "4874373" | "4893635" | "4894052" | "4907599" | "4944308" | "4994042" | "5129884" | "5400798").pn. OR ("5749857").urpn. AND	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/05/08 04:51 PM

		(PGPB | USPT | USOC).dbnm.					
L486	606	484 AND ((pressure OR vacuum) near5 (draw OR forc$4 OR withdraw OR flow$4)) SAME (blood OR fluid)	(US-PGPUB; USPAT)	OR	ON	ON	2023/05/08 05:32 PM
L487	24	("2010/0057004").urpn. AND (PGPB | USPT | USOC).dbnm.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/05/08 05:35 PM
L488	3	487 AND @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/05/08 05:55 PM
L489	49	((US-20080319346-A1 OR US-20100057004-A1 OR US-20070088279-A1 OR US-20080145933-A1 OR US-20040054333-A1 OR US-20100010372-A1 OR US-20080167577-A1 OR US-20080086085-A1 OR US-20070083162-A1 OR US-20160008579-A1 OR US-20120016266-A1 OR US-20130317391-A1 OR US-20160174888-A1 OR US-20050240161-A1 OR US-20040147855-A1 OR US-20040073171-A1 OR US-20050004524-A1 OR US-20030105414-A1 OR US-20020004647-A1).did. AND PGPB.dbnm.) OR ((US-4412548-A OR US-5222502-A OR US-5520193-A OR US-9022951-B2 OR US-6569117-B1 OR US-3741197-A OR US-8603009-B2 OR US-4207870-A OR US-9877675-B2 OR US-4444203-A OR US-6398743-B1 OR US-9022950-B2 OR US-9155495-B2 OR US-4436098-A OR US-9138572-B2 OR US-8568371-B2 OR US-	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/05/08 06:07 PM

		8523826-B2 OR US-8197420-B2 OR US-4057050-A OR US-8864684-B2 OR US-8535241-B2 OR US-5749857-A OR US-9060724-B2 OR US-9204864-B2 OR US-3817240-A OR US-3874367-A OR US-3886930-A OR US-4106497-A OR US-4154229-A).did. AND USPT.dbnm.)					
L490	25	489 AND (air near5 (filter$4 OR material$4 OR membrane OR permeab$4 OR vent$4))	(US-PGPUB; USPAT)	OR	ON	ON	2023/05/08 06:07 PM
L491	204	482 AND (hous$4 SAME (inlet AND outlet AND channel))	(US-PGPUB; USPAT)	OR	ON	ON	2023/05/08 06:29 PM
L492	118	491 AND (hous$4 near5 ((top OR upper) AND (lower OR bottom)))	(US-PGPUB; USPAT)	OR	ON	ON	2023/05/08 06:33 PM
L493	1	489 AND (hous$4 near5 ((top OR upper) AND (lower OR bottom)))	(US-PGPUB; USPAT)	OR	ON	ON	2023/05/08 06:39 PM
L494	0	489 AND (hous$4 near5 ((top OR upper) SAME (lower OR bottom)))	(US-PGPUB; USPAT)	OR	ON	ON	2023/05/08 06:39 PM
L495	27	492 AND (hous$4 near5 ((top OR upper) SAME (lower OR bottom)))	(US-PGPUB; USPAT)	OR	ON	ON	2023/05/08 06:39 PM
L496	172	484 AND (hous$4 near5 ((top OR upper) SAME (lower OR bottom)))	(US-PGPUB; USPAT)	OR	ON	ON	2023/05/08 06:41 PM
L497	113	((("ROGERS") near3 ("Bobby")) OR (("KANG") near3 ("Gino")) OR (("DETLOFF") near3 ("John"))).INV.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2023/07/05 01:58 PM
L498	26	497 AND ((blood OR fluid$4 OR urine) near5(sequest$5 OR sampl$4 OR flush$4 OR collect$4 OR optimiz$5 OR flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/07/05 01:58 PM

L499	4	15/855439	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/05 03:12 PM
L500	48306	(A61B5/150992 OR A61B5/15003 OR A61B5/150213 OR A61B5/150221 OR A61B5/150389 OR A61B5/150473 OR A61B5/150572 OR A61B5/153 OR A61B5/154 OR A61M39/04 OR A61M39/0693 OR A61M2039/0202 OR A61M2039/0633 OR A61M2039/068).cpc.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/07/05 03:36 PM
L501	5081	500 AND @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/07/05 03:36 PM
L502	3947	501 AND ((blood OR fluid$4 OR urine) near5(sequest$5 OR sampl$4 OR flush$4 OR collect$4 OR optimiz$5 OR flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/07/05 03:37 PM
L503	1069	502 AND (air near5 (filter$4 OR material$4 OR membrane OR permeab$4 OR vent$4))	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/05 03:37 PM
L504	3871	501 AND ((blood OR fluid$4 OR urine) near5(divert$4 OR direct$4 OR flow$4 OR bypass$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/07/05 05:18 PM
L505	3030	501 AND ((blood OR fluid$4 OR urine) near5(divert$4 OR direct$4 OR flow$4 OR bypass$4 OR allow$4)) SAME (channel$4 OR chamber OR junct$4 OR inlet OR outlet OR path$4 OR contain$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/07/05 05:20 PM
L506	921	503 AND ((blood OR fluid$4 OR urine) near5(divert$4 OR direct$4 OR flow$4 OR bypass$4 OR allow$4)) SAME (channel$4 OR chamber OR junct$4 OR inlet OR outlet OR path$4 OR contain$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/07/05 05:20 PM
L507	1	17/538990	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/05

							06:04 PM
L508	1	16/961875	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/05 08:21 PM
L509	7	"20070148624"	(US-PGPUB; USPAT)	OR	ON	ON	2023/08/31 01:02 PM
L510	43469	(A61B5/150992 OR A61B5/15003 OR A61B5/150213 OR A61B5/150221 OR A61B5/150389 OR A61B5/150473 OR A61B5/150572 OR A61B5/153 OR A61B5/154 OR A61M39/04 OR A61M39/0693 OR A61M2039/0202 OR A61M2039/0633 OR A61M2039/068).cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO)	OR	ON	ON	2023/08/31 01:28 PM
L511	5081	510 AND @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/08/31 01:32 PM
L512	3947	511 AND ((blood OR fluid$4 OR urine) near5(sequest$5 OR sampl$4 OR flush$4 OR collect$4 OR optimiz$5 OR flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/08/31 01:32 PM
L513	2653	512 AND ((blood OR fluid$4 OR urine) near5(divert$4 OR direct$4 OR flow$4 OR bypass$4 OR allow$4)) SAME (channel$4 OR chamber OR junct$4 OR inlet OR outlet OR path$4 OR contain$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/08/31 01:32 PM
L514	921	513 AND (air near5 (filter$4 OR material$4 OR membrane OR permeab$4 OR vent$4))	(US-PGPUB; USPAT)	OR	ON	ON	2023/08/31 01:33 PM
L515	1	18/113710	(US-PGPUB; USPAT)	OR	ON	ON	2023/08/31 02:05 PM
L516	372	((("BULLINGTON") near3 ("Gregory")) OR (("PATTON") near3 ("Richard")) OR (("MIAZGA") near3 ("Jay")) OR (("GAW") near3 ("Shan"))).INV.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2023/11/20 02:30 PM
L517	172	516 AND ((blood OR fluid$4 OR urine) near5(sequest$5 OR	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/11/20 02:41 PM

		sampl$4 OR flush$4 OR collect$4 OR optimiz$5 OR flash$4 OR divert$4 OR bypass$4))					
L518	165	516 AND ((blood OR fluid$4 OR urine) near5(sequest$5 OR flush$4 OR optimiz$5 OR flash$4 OR divert$4 OR bypass$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/11/20 02:42 PM
L519	165	516 AND ((blood OR fluid$4 OR urine) near5(sequest$5 OR flush$4 OR optimiz$5 OR flash$4 OR diver$5 OR bypass$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/11/20 02:42 PM
L520	1	("11395612").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/20 02:43 PM
L521	1	("11395611").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/20 02:45 PM
L522	1	("10292633").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/20 02:46 PM
L523	1	("9022950").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/20 02:52 PM
L524	11	"10736554"	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/20 02:55 PM
L525	1	("10736554").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/20 02:55 PM
L526	1	("10912506").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/20 02:55 PM
L527	1	("10010282").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/20 02:56 PM
L528	1	("9820682").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/20 02:58 PM
L529	67080	(A61B5/150221 OR A61B5/15003 OR A61B5/150236 OR A61B5/150244 OR A61B5/150251 OR A61B5/150389 OR A61B5/150503 OR A61B5/150992 OR A61B5/153 OR A61B5/155 OR A61B10/0048 OR A61B10/0051 OR A61B10/007 OR A61B2010/0061 OR A61B2010/0077 OR A61B2010/008).cpc.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/11/20 03:05 PM
L530	1791	529 AND ((blood OR fluid$4 OR urine)	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/11/20 03:05 PM

		near5(sequest$5 OR flush$4 OR optimiz$5 OR flash$4 OR diver$5 OR bypass$4))					
L531	322	530 AND (flow$4 OR control$4 OR divert$4 OR mechanism) near5 rotat$4	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/20 03:07 PM
L532	420	530 AND (flow$4 OR control$4 OR divert$4 OR mechanism OR valve) near5 rotat$4	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/20 03:07 PM
L533	0	("2021/0128037").urpn. AND (PGPB | USPT | USOC).dbnm.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/11/20 03:39 PM
L534	1267	530 AND (flow$4 OR control$4 OR divert$4 OR mechanism OR valve) near5 (chamber OR reservoir OR hous$4 OR container)	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/20 03:56 PM
L535	1142	530 AND (flow$4 OR control$4 OR divert$4 OR mechanism OR valve) near5 (chamber OR reservoir OR container)	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/20 03:56 PM
L536	1	17/863605	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/20 04:48 PM
L537	1	("10292633").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/20 05:19 PM
L538	505	530 AND (flow$4 OR control$4 OR divert$4 OR mechanism OR valve) near5 (multiple OR pluarlit$4 OR first OR second) near5 (lumen OR channel OR path$4)	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/20 05:25 PM
L539	8	"20080077183"	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/21 01:29 PM
L540	1	15/933356	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/21 01:47 PM
L541	7	("20060074354"|"20080077183"|"20100131454"|"20140228714"|"20150196247"|"20200129380"|"9974476").PN.	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/21 02:08 PM
L542	6	541 AND (suck$4 near5 pressure)	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/21 02:09 PM
L543	146297	(A61B5/4542 OR A61B5/7242 OR A61B5/7246 OR	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY,	OR	ON	ON	2023/11/21 02:17 PM

		A61B5/7257 OR A61B5/7267 OR A61B5/7282 OR A61B2503/045 OR A61B2562/0247 OR A61B5/038 OR A61B5/002).cpc.	CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)				
L544	16368	543 AND @ad<"20170322"	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/21 02:17 PM
L545	15	544 AND (determin$4 OR measur$4 OR detect$4 OR process$4) near5(suck$4 near5 pressure)	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/21 02:18 PM
L546	120	544 AND (determin$4 OR measur$4 OR detect$4 OR process$4 OR estimat$4) near5((suck$4 OR feed$4) near5 pressure)	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/21 02:20 PM
L547	15	544 AND (determin$4 OR measur$4 OR detect$4 OR process$4 OR estimat$4) near5((suck$4) near5 pressure)	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/21 02:20 PM
L548	1868	(determin$4 OR measur$4 OR detect$4 OR process$4 OR estimat$4) near5(suck$4 near5 pressure)	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/21 02:27 PM
L549	1387	548 AND @ad<"20170322"	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/21 02:27 PM
L550	48	(determin$4 OR measur$4 OR detect$4 OR process$4 OR estimat$4) near5(suck$4 near5 pressure) AND (nutrit$4 SAME feed$4)	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/21 02:34 PM
L551	39	550 AND (baseline OR threshold OR predetermin$4)	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/21 02:35 PM
L552	16	"20150011874"	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/21 02:55 PM
L553	5	"20140288398"	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/21

							02:55 PM
L554	6	"20140120531"	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/21 03:01 PM
L555	1	("9060724").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/21 03:45 PM
L556	1	("10433779").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/21 03:49 PM
L557	12	"10736554"	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/21 03:50 PM
L558	1	("10912506").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/21 03:54 PM
L559	0	18/381369	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/21 05:01 PM
L560	21	(Artificial Intelligence) More like doc: US-10912506-B2 Text: (US-20200359951-A1 OR US-11395611-B2 OR US-20220071533-A1 OR US-20180116577-A1 OR US-11395612-B2 OR US-20220079482-A1 OR US-10736554-B2 OR US-10433779-B2 OR US-20150351679-A1 OR US-20140155781-A1 OR US-9060724-B2 OR US-20150011910-A1 OR US-9022951-B2 OR US-20210361206-A1 OR US-20150011911-A1 OR US-9022950-B2 OR US-20150257691-A1 OR US-20200060595-A1 OR US-10292633-B2 OR US-20230172502-A1).did.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/11/21 07:16 PM
L561	0	("10912506").urpn. AND (PGPB | USPT | USOC).dbnm.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/11/21 07:16 PM
L562	273	("2707953" | "2992974" | "3013557" | "3098016" | "3382865" | "3405706" | "3467095" | "3494351" | "3494352" | "3577980" | "3604410" | "3635798" | "3648684" | "3730168" | "3741197" | "3777773" | "3803810" | "3817240" | "3834372" | "3835835" | "3848579" | "3848581"	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/11/21 07:16 PM

		| "3874367" | "3886930" | "3890203" | "3890968" | "3937211" | "3945380" | "3978846" | "4056101" | "4057050" | "4063460" | "4077395" | "4106497" | "4133863" | "4150089" | "4154229" | "4166450" | "4190426" | "4193400" | "4207870" | "4212308" | "4238207" | "4257416" | "4275730" | "4298358" | "4340067" | "4340068" | "4349035" | "4370987" | "4398544" | "4412548" | "4416290" | "4425235" | "4444203" | "4459997" | "4509534" | "4608996" | "4654027" | "4657027" | "4657160" | "4673386" | "4676256" | "4679571" | "4705497" | "4714461" | "4772273" | "4865583" | "4879098" | "4886072" | "4890627" | "4904240" | "4980297" | "4988339" | "5009847" | "5027827" | "5032116" | "5045185" | "5066284" | "5084034" | "5097842" | "5100394" | "5108927" | "5116323" | "5122129" | "5135489" | "5222502" | "5269317" | "5330464" | "5417673" | "5431811" | "5439450" | "5450856" | "5466228" | "5472605" | "5485854" | "5507299" | "5520193" | "5575777" | "5603700" | "5632906" | "5649912" | "5691486" | "5749857" | "5772608" | "5811658" | "5824001" | "5865812" | "5871699" | "5911705" | "5961472" | "5971956" | "5980830" | "6001307" | "6010633" | "6106509" | "6210909" | "6224561" | "6325975" | "6328726" | "6364890" | "6387086" | "6403381" | "6506182" | "6520948" | "6569117" | "6626884" | "6638252" | "6648835" | "6692479" | "6695004" | "6716187" | "6733433" | "6736783" | "6746420" | "6843775" | "6860871" | "6905483"					

		| "6913580" | "6945948" | "7044941" | "7052603" | "7055401" | "7087047" | "7141097" | "7241281" | "7306736" | "7314452" | "7316662" | "7335188" | "7384416" | "7461671" | "7479131" | "7614857" | "7615033" | "7618407" | "7648491" | "7666166" | "7744573" | "7766879" | "8070725" | "8197420" | "8231546" | "8337418" | "8349254" | "8377040" | "8382712" | "8383044" | "8412300" | "8523826" | "8535241" | "8540663" | "8568371" | "8574203" | "8603009" | "8647286" | "8795198" | "8827958" | "8864684" | "8876734" | "9022950" | "9022951" | "D731643" | "9060724" | "9060725" | "9138572" | "9149576" | "9155495" | "9204864" | "9314201" | "9855001" | "9855002" | "9855386" | "9861306" | "9872645" | "9877675" | "9895092" | "9950084" | "9999383" | "10028687" | "10028689" | "10045724" | "10251590" | "10736554" | "20010039058" | "20020002349" | "20020004647" | "20020183651" | "20020193751" | "20030013991" | "20030055381" | "20030069543" | "20030105414" | "20030208151" | "20040009542" | "20040010228" | "20040054283" | "20040054333" | "20040127816" | "20040147855" | "20050004524" | "20050148993" | "20050161112" | "20050199077" | "20050240161" | "20050245885" |				

		"20050273019" | "20050281713" | "20060251622" | "20060287639" | "20070088279" | "20070100250" | "20070119508" | "20070287948" | "20080086085" | "20080108954" | "20080167577" | "20080185056" | "20080319346" | "20090050213" | "20090306601" | "20100010372" | "20100042048" | "20100057004" | "20100094171" | "20100152681" | "20100268118" | "20110306899" | "20120035540" | "20120265099" | "20120265128" | "20140066880" | "20150018715" | "20150342510" | "20150351679" | "20160174888" | "20160213294" | "20170071519" | "20180160958" | "20180353117" | "20190076074" | "20190175087" | "20200060595" | "20200060596").pn. OR ("10912506").urpn. AND (PGPB | USPT | USOC).dbnm.					
L563	303	((("ROGERS") near3 ("Bobby")) OR (("KANG") near3 ("Gino")) OR (("DETLOFF") near3 ("John"))).INV.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/01/08 02:52 PM

L564	26	563 AND ((blood OR fluid$4 OR urine) near5(sequest$5 OR flush$4 OR optimiz$5 OR flash$4 OR diver$5 OR bypass$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2024/01/08 02:55 PM
L565	33645	(A61B5/150992 OR A61B5/15003 OR A61B5/150213 OR A61B5/150221 OR A61B5/150389 OR A61B5/150473 OR A61B5/150572 OR A61B5/153 OR A61B5/154 OR A61M39/04 OR A61M39/0693 OR A61M2039/0202 OR A61M2039/0633 OR A61M2039/068).cpc.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/01/08 03:06 PM
L566	5091	565 AND @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2024/01/08 03:09 PM
L567	1014	566 AND ((blood OR fluid$4 OR urine) near5(sequest$5 OR flush$4 OR optimiz$5 OR flash$4 OR diver$5 OR bypass$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2024/01/08 03:09 PM
L568	828	567 AND (flow$4 OR control$4 OR divert$4 OR mechanism OR valve OR junct$4) near5 (chamber OR reservoir OR container OR hous$4 OR inlet OR outlet OR channel OR port)	(US-PGPUB; USPAT)	OR	ON	ON	2024/01/08 03:15 PM
L569	51	("20020004647"|"20030105414"|"20040054333"|"20040073171"|"20040147855"|"20050004524"|"20050240161"|"20070083162"|"20070088279"|"20080086085"|"20080145933"|"20080167577"|"20080319346"|"20100010372"|"20100057004"|"20120016266"|"20130317391"|"20150314105"|"20150359473"|"20160008579"|"20160174888"|"3741197"|"3817240"|"3874367"|"3886930"|"4057050"|"4106497"|"4154229"|"4207870"|"4412548"|"443609	(US-PGPUB; USPAT)	OR	ON	ON	2024/01/08 03:40 PM

		8"|"4444203"|"5222502"|"5520193"|"5749857"|"6398743"|"6569117"|"8197420"|"8523826"|"8535241"|"8540663"|"8568371"|"8603009"|"8864684"|"9022950"|"9022951"|"9060724"|"9138572"|"9155495"|"9204864"|"9877675").PN.					
L570	35	569 AND ((blood OR fluid$4 OR urine) near5(sequest$5 OR flush$4 OR optimiz$5 OR flash$4 OR diver$5 OR bypass$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2024/01/08 03:40 PM
L571	353	567 AND (air near5 (filter$4 OR material$4 OR membrane OR permeab$4 OR vent$4))	(US-PGPUB; USPAT)	OR	ON	ON	2024/01/08 04:09 PM
L572	3	17/538990	(US-PGPUB; USPAT)	OR	ON	ON	2024/01/08 04:12 PM
L573	1	17/110651	(US-PGPUB; USPAT)	OR	ON	ON	2024/01/08 04:28 PM
L574	16	"20150011874"	(US-PGPUB; USPAT)	OR	ON	ON	2024/01/08 05:23 PM
L575	5	"20140288398"	(US-PGPUB; USPAT)	OR	ON	ON	2024/01/08 05:26 PM
L576	7	"20140120531"	(US-PGPUB; USPAT)	OR	ON	ON	2024/01/08 05:27 PM
L577	2	"20140135604"	(US-PGPUB; USPAT)	OR	ON	ON	2024/01/09 02:26 PM
L578	1	("10624616").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/01/09 02:27 PM
L579	7	"20090118628"	(US-PGPUB; USPAT)	OR	ON	ON	2024/01/09 02:27 PM
L580	1	("10687811").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/01/09 02:27 PM
L581	2	"20060287603"	(US-PGPUB; USPAT)	OR	ON	ON	2024/01/09 02:41 PM
L582	1	18/494622	(US-PGPUB; USPAT)	OR	ON	ON	2024/09/16 05:48 PM
L583	1	("11832944").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/09/16 05:49 PM
L584	21	"20100057004"	(US-PGPUB; USPAT)	OR	ON	ON	2024/09/16 05:51 PM
L585	24	"20080167577"	(US-PGPUB; USPAT)	OR	ON	ON	2024/09/16 06:00 PM
L586	1	("11963769").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/09/16 06:26 PM
L587	1	("11185266").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/09/16

							06:26 PM
L588	1	("10143412").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/09/16 06:27 PM
L589	1	("10010282").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/09/16 06:28 PM
L590	122	((("ROGERS") near3 ("Bobby")) OR (("KANG") near3 ("Gino")) OR (("DETLOFF") near3 ("John"))).INV.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2024/09/16 06:52 PM
L591	25	590 AND (flow$4 OR control$4 OR divert$4 OR mechanism OR valve) near5 (chamber OR reservoir OR container) AND (blood near5 impermeable)	(US-PGPUB; USPAT)	OR	ON	ON	2024/09/16 06:54 PM
L592	50925	(A61B5/150992 OR A61B5/15003 OR A61B5/150213 OR A61B5/150221 OR A61B5/150389 OR A61B5/150473 OR A61B5/150572 OR A61B5/153 OR A61B5/154 OR A61M39/04 OR A61M39/0693 OR A61M2039/0202 OR A61M2039/0633 OR A61M2039/068).cpc.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/09/16 07:03 PM
L593	5094	592 AND @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2024/09/16 07:03 PM
L594	1015	593 AND ((blood OR fluid$4 OR urine) near5(sequest$5 OR flush$4 OR optimiz$5 OR flash$4 OR diver$5 OR bypass$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2024/09/16 07:04 PM
L595	6	594 AND (blood near5 (filter OR impermeabl$4 OR membrane)) WITH (facilitat$4 OR caus$4) near5 (withdraw$4 OR draw$4 OR sampl$4 OR collect$4)	(US-PGPUB; USPAT)	OR	ON	ON	2024/09/16 07:06 PM
L596	0	594 AND (blood near5 (filter OR impermeabl$4 OR membrane)) WITH (facilitat$4 near5 (withdraw$4 OR draw$4 OR sampl$4 OR	(US-PGPUB; USPAT)	OR	ON	ON	2024/09/16 07:07 PM

		collect$4))					
L597	2	594 AND (blood near5 (filter OR impermeabl$4 OR membrane)) SAME (facilitat$4 near5 (withdraw$4 OR draw$4 OR sampl$4 OR collect$4))	(US-PGPUB; USPAT)	OR	ON	ON	2024/09/16 07:08 PM
L598	66	593 AND (flow$4 OR control$4 OR divert$4 OR mechanism OR valve) near5 (chamber OR reservoir OR container) AND (blood near5 impermeable)	(US-PGPUB; USPAT)	OR	ON	ON	2024/09/16 07:20 PM
L599	0	18/783088	(US-PGPUB; USPAT)	OR	ON	ON	2024/09/16 07:35 PM
L600	1	18/494622	(US-PGPUB; USPAT)	OR	ON	ON	2024/09/16 08:32 PM
L601	1	("11832944").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/09/16 08:32 PM
L602	1	18/549438	(US-PGPUB; USPAT)	OR	ON	ON	2024/09/17 01:14 PM
L603	326	((("ROGERS") near3 ("Bobby")) OR (("KANG") near3 ("Gino")) OR (("DETLOFF") near3 ("John"))).INV.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/12/23 03:36 PM
L604	32	603 AND ((blood OR fluid$4 OR urine) near5(sequest$5 OR flush$4 OR optimiz$5 OR flash$4 OR diver$5 OR bypass$4 OR subsequent$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2024/12/23 03:37 PM
L605	1635	593 AND ((blood OR fluid$4 OR urine) near5(sequest$5 OR flush$4 OR optimiz$5 OR flash$4 OR diver$5 OR bypass$4 OR subsequent$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2024/12/23 03:40 PM
L606	33	605 AND (blood near5	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/23

		(filter OR impermeabl$4 OR membrane)) WITH (facilitat$4 OR caus$4) near5 (withdraw$4 OR draw$4 OR sampl$4 OR collect$4)					03:41 PM
L607	1189	605 AND (flow$4 OR control$4 OR collect$4 OR sampl$4) near5 (force OR pressure OR pump$4 OR vacuum$4)	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/23 03:59 PM
L608	700	605 AND (flow$4 OR control$4 OR collect$4 OR sampl$4) near5 (force OR pressure OR pump$4 OR vacuum$4) WITH (chamber OR channel OR container OR port)	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/23 04:00 PM
L609	11	"20080145933"	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/23 04:12 PM

PE2E SEARCH - Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
N94	1	(port and sequest$5 and junction and chamber and sampl$4 and vent and barrier).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2017/09/28 04:15 PM
N112	3	(port and sequest$5 and chamber and sampl$4 and vent and barrier).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/01/09 05:39 PM
N248	4	(blood and fluid$4 and inlet and outlet and port and reservoir and allow and initial$4 and sequest$5).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 03:30 PM
N249	4	(blood and fluid$4 and inlet and outlet and port and reservoir and allow$4 and initial$4 and sequest$5).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 03:30 PM
N250	495	(blood and fluid$4 and allow$4 and initial$4).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 03:31 PM
N251	107	(blood and fluid$4 and allow$4 and initial$4 and subsequent$4).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 03:31 PM
N283	9	((blood or fluid$4) and sequestrat$4 and chamber and sampl$4	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:31 PM

		and vent$4 and air$4).clm.					
N284	530	((blood or fluid$4) and chamber and sampl$4 and vent$4 and air$4).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:31 PM
N285	84	((blood or fluid$4) and chamber and cap and sampl$4 and vent$4 and air$4).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:32 PM
N365	6	(port and sequest$5 and junction and chamber and sampl$4 and vent and barrier).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:49 PM
N366	9	(blood AND fluid$4 AND inlet AND outlet AND junct$4 AND inhibit$4).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/11/16 05:31 PM
N367	84	((blood OR fluid$4) AND chamber AND sampl$4 AND junction AND (inhibit$4 OR prevent$4)).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/11/16 05:36 PM
N368	25	(blood AND chamber AND sampl$4 AND junction AND inlet AND outlet AND port AND first).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2023/04/11 04:48 PM
N369	4	(blood AND chamber AND sampl$4 AND junction AND inlet AND outlet AND port AND first AND hous$4 AND subsequent).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2023/04/11 04:49 PM
N370	64902	"465" AND housing	(US-PGPUB; USPAT)	OR	ON	ON	2023/04/11 04:50 PM
N371	6	(inlet AND outlet AND junct$4 AND channel AND sampl$4 AND fluid$4 AND vent AND air AND permeab$4).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/05 05:51 PM
N372	167	(inlet AND outlet AND junct$4 AND channel AND sampl$4 AND fluid$4).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/05 05:52 PM
N373	23	(inlet AND outlet AND junct$4 AND channel AND sampl$4 AND fluid$4 AND bypass$4).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/05 05:53 PM
N374	33	(inlet AND outlet AND chamber AND blood	(US-PGPUB; USPAT)	OR	ON	ON	2023/08/31 02:35 PM

		AND sampl$4 AND bypass).clm.					
N375	18	(inlet AND outlet AND chamber AND blood AND sampl$4 AND bypass AND air AND permeable).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2023/08/31 02:36 PM
N376	14	(inlet AND outlet AND chamber AND (blood OR fluid OR urine) AND sampl$4 AND bypass AND air AND permeable AND junct$4).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2024/01/08 04:24 PM
N377	14	(inlet AND outlet AND chamber AND (blood OR fluid OR urine) AND sampl$4 AND bypass AND air AND permeable AND junct$4 AND channel).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2024/01/08 04:25 PM
N378	14	(inlet AND outlet AND chamber AND (blood OR fluid OR urine) AND sampl$4 AND bypass AND air AND permeable AND junct$4 AND channel AND vent).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2024/01/08 04:25 PM

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-22)
Approved for use through 05/31/2024. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	18898239
Filing Date	2024-09-26
First Named Inventor	Bobby E. Rogers
Art Unit	
Examiner Name	
Attorney Docket Number	069366-0581370_KUR2C07US

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	11744494		2023-09-05	ROGERS BOBBY E	

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	1					

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	1							☐

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Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

PC 6.1.24

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.A.A/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	18898239
	Filing Date	2024-09-26
	First Named Inventor	Bobby E. Rogers
	Art Unit	
	Examiner Name	
	Attorney Docket Number	069366-0581370_KUR2C07US

	1	Office Action (Final Rejection) dated 11/4/2024 for U.S. Application No. 18/783,173; Attorney Docket No. 069366-0580420_KUR3C03US (pages 1-22).	☐
	2	Office Action (Non-Final Rejection) dated 09/24/2024 for U.S. Application No. 18/783,173; Attorney Docket No. 069366-0580420_KUR3C03US (pages 1-62).	☐
	3	Office Action (Rejection Decision) dated 11/5/2024 for JP Application No. 2023-076490; Attorney Docket No. 069366-0575273_KUR2D03JP (pages 1-8).	☐
	4	Office Action (Non-Final Rejection) dated 10/22/2024 for U.S. Application No. 18/783,173; Attorney Docket No. 069366-0580420_KUR3C03US (pages 1-62).	☐

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature	/MAY A ABOUELELA/	Date Considered	12/23/2024

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

PC 6.1.24

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
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	Examiner Name	
	Attorney Docket Number	069366-0581370_KUR2C07US

CERTIFICATION STATEMENT

Please see 37 CFR 1.97(e) to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☒ A certification statement is not submitted herewith.

FEE

☒ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

COPIES

☐ An identification of an earlier application pursuant to 37 CFR 1.98 (d) (1) is attached.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2024-12-17
Name/Print	Benjamin F. Hudson	Registration Number	71,474

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

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2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

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5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

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CC: patentcenter_eofficeaction@uspto.gov
SUBJECT: USPTO: Patent Electronic System - Correspondence Notification for Customer Number 27500

Mon Jan 06 05:00:09 EST 2025

Dear Patent Center Customer:

Correspondence Address:

PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
ATTENTION: DOCKETING DEPARTMENT
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Application	Document	Mailroom Date	Attorney Docket No.
18898239	CTFR	01/06/2025	069366-0581370_KUR2C07US
18898239	1449	01/06/2025	069366-0581370_KUR2C07US

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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
18/898,239	09/26/2024	Bobby E. Rogers	069366-0581370_KUR2C07US

CONFIRMATION NO. 7801

27500
PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
ATTENTION: DOCKETING DEPARTMENT
P.O BOX 10500
McLean, VA 22102

PUBLICATION NOTICE

OC00000000834048841

Date Mailed: 01/23/2025

Title:BLOOD SAMPLE OPTIMIZATION DEVICE

Publication No.US-2025-0025079-A1
Publication Date:01/23/2025

NOTICE OF PUBLICATION OF APPLICATION

The above-identified application will be electronically published as a patent application publication pursuant to 37 CFR 1.211, et seq. The patent application publication number and publication date are set forth above.

The publication may be viewed using the USPTO's publicly available Searchable Databases via the Patent Public Search tool at www.uspto.gov. The direct link to access the Patent Public Search tool is currently https://ppubs.uspto.gov/pubwebapp/static/pages/ppubsbasic.html.

The publication process established by the Office does not provide for mailing a copy of the publication to applicant. A copy of the publication may be obtained from the Office upon payment of the appropriate fee set forth in 37 CFR 1.19(a)(1). Orders for copies of patent application publications are handled by the USPTO's Public Records Division. The Public Records Division can be reached by telephone at (571) 272-3150 or (800) 972-6382, by facsimile at (571) 273-3250, by mail addressed to the United States Patent and Trademark Office, Public Records Division, Alexandria, VA 22313-1450 or via the Internet.

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FROM: noreply@uspto.gov
CC: patentcenter_eofficeaction@uspto.gov
SUBJECT: USPTO: Patent Electronic System - Correspondence Notification for Customer Number 27500

Thu Jan 23 05:00:24 EST 2025

Dear Patent Center Customer:

Correspondence Address:

PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
ATTENTION: DOCKETING DEPARTMENT
P.O BOX 10500
McLean,VIRGINIA,22102
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Application	Document	Mailroom Date	Attorney Docket No.
18898239	NTC.PUB	01/23/2025	069366-0581370_KUR2C07US

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/893,079	08/22/2022	Bobby E. ROGERS	069366-0572192_KUR3C02US	6240

27500 7590 06/04/2025

PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
ATTENTION: DOCKETING DEPARTMENT
P.O BOX 10500
McLean, VA 22102

EXAMINER	
NGUYEN, HUONG Q	

ART UNIT	PAPER NUMBER
3791	

NOTIFICATION DATE	DELIVERY MODE
06/04/2025	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	**Application No.** 17/893,079	**Applicant(s)** ROGERS et al.	
	Examiner Huong Q NGUYEN	**Art Unit** 3791	**AIA (First Inventor to File) Status** Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 3/20/2025.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL.** 2b) ☑ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 1-2,6-7 and 32-39 is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 1-2,6-7 and 32-39 is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to **PPHfeedback@uspto.gov.**

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☑ The drawing(s) filed on 8/22/02022 is/are: a)☑ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☑ Notice of References Cited (PTO-892)

2) ☑ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/20/2025 has been entered.

Claims 1-2, 6-7, and 32-39 remain pending and under prosecution.

Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Claim Interpretation

The following is a quotation of 35 U.S.C. 112(f):

> (f) Element in Claim for a Combination. – An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

The following is a quotation of pre-AIA 35 U.S.C. 112, sixth paragraph:

> An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

The claims in this application are given their broadest reasonable interpretation using the plain meaning of the claim language in light of the specification as it would be understood by one of ordinary skill in the art. The broadest reasonable interpretation of a claim element (also commonly referred to as a claim limitation) is limited by the description in the specification when 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is invoked.

As explained in MPEP § 2181, subsection I, claim limitations that meet the following three-prong test will be interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph:

(A) the claim limitation uses the term "means" or "step" or a term used as a substitute for "means" that is a generic placeholder (also called a nonce term or a non-structural term having no specific structural meaning) for performing the claimed function;

(B) the term "means" or "step" or the generic placeholder is modified by functional language, typically, but not always linked by the transition word "for" (e.g., "means for") or another linking word or phrase, such as "configured to" or "so that"; and

(C) the term "means" or "step" or the generic placeholder is not modified by sufficient structure, material, or acts for performing the claimed function.

Use of the word "means" (or "step") in a claim with functional language creates a rebuttable presumption that the claim limitation is to be treated in accordance with 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph. The presumption that the claim limitation is interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is rebutted when the claim limitation recites sufficient structure, material, or acts to entirely perform the recited function.

Absence of the word "means" (or "step") in a claim creates a rebuttable presumption that the claim limitation is not to be treated in accordance with 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph. The presumption that the claim limitation is not interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is rebutted when the claim limitation recites function without reciting sufficient structure, material or acts to entirely perform the recited function.

Claim limitations in this application that use the word "means" (or "step") are being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, except as otherwise indicated in an Office action. Conversely, claim limitations in this application that do not use the word "means" (or "step") are not being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, except as otherwise indicated in an Office action.

No elements are interpreted under 112(f).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries for establishing a background for determining obviousness under 35 U.S.C. 103 are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims the examiner presumes that the subject matter of the various claims was commonly owned as of the effective filing date of the claimed invention(s) absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and effective filing dates of each claim that was not commonly owned as of the effective filing date of the later invention in order for the examiner to consider the applicability of 35 U.S.C. 102(b)(2)(C) for any potential 35 U.S.C. 102(a)(2) prior art against the later invention.

Claims 1-2, 6-7, and 32-39 are rejected under 35 U.S.C. 103 as being unpatentable over Zdeb et al (US Pat No. 4874366) in view of Browka et al (US Pub No. 20170209644).

In regard to Claims 1 and 34, Zdeb discloses a device comprising:

an inlet port 94, 76a for receiving a blood sample – the device is capable of receiving a blood sample for transfusion to the patient (abst), best seen in Figure 3 (Col.9: 29-61);

an outlet port 96, 76b, best seen in Figure 3 (Col.9: 29-61);

a chamber 106 connected at a proximal end (top near element 114) with the inlet port and at a distal end (bottom near element 112) with the outlet port, best seen in Figure 3-4, and configured to collect a first portion of the blood sample – when cartridge 82 is connected to

housing 78, the blood sample flows into chamber 106 for mixing, best seen in Figure 4 (Col.10: 56-67);

a sampling channel 134 connected with the inlet port and configured to convey a subsequent portion of the blood sample to the outlet port while bypassing the chamber – when cartridge 82 is removed, the blood sample bypasses the chamber and thus flows into the sampling channel 134, best seen in Figure 3 (Col.10: 46-55); and

a housing 78, 82 that fully encloses the inlet port, the outlet port, the chamber, and the sampling channel, best seen in Figure 4 when cartridge 82 is connected to housing 78.

However, Zdeb et al do not expressly disclose the chamber including a material that is air permeable and blood impermeable/air permeable blood barrier. It is noted the Zdeb et al teaches the use of air eliminating membrane 86 that is air permeable (and known in the art for being blood impermeable/a blood barrier) to remove air that is trapped in the device, best seen in Figure 1 (Col.9: 1-8). It is also noted that Zdeb et al teaches said air permeable membrane can be disposed within the housing but is often disposed outside said housing, best seen in Figure 1 – "it is possible for the air eliminating membrane to be disposed within the housing" (Col.11: 60-Col.12: 9).

Browka et al teach that it is well-known in the art to provide an analogous device with two chambers for infusion of fluids such as blood comprising two interconnected chambers 202, 200 and including a material that is air permeable and blood or fluid impermeable/air permeable blood barrier 224 positioned on the left chamber 202, best seen in Figure 2 – "A filter 224 may be provided in the vent 222 to prevent contaminants from flowing into or out of

chamber 202 and to prevent dump liquid from being ejected from the chamber while permitting air to exit. Exit of air through vent 222. prevents a pressure build up in the dump chamber. Filter 224 may be, for example… a hydrophobic/hydrophilic membrane or the like that prevents loss of fluid from chamber 202 while allowing air to exit from chamber 202" (0034). It is noted that fluid in Browka et al first flows into chamber 200 and then into chamber 202. Thus chamber 202 of Browka et al corresponds to the chamber in Zdeb et al as it is "the second" chamber into which the fluid flows from chamber 200 of Browka et al, best seen in Figure 4 (0034).

Since Zdeb et al already disclose the use of an air permeable material in housing 78 (which corresponds to chamber 200 of Browka et al), it would have been obvious to one of ordinary skill in the art at the time of filing to modify Zdeb et al such that the air permeable and blood impermeable is included in the chamber of Zdeb et al (which corresponds to chamber 202 of Browka et al) as an effective location for the air permeable blood barrier to expectedly provide the effect of allowing trapped air to escape, as already taught by Zdeb et al and as is well known in the art.

2, 35. Zdeb et al disclose the material 86 is configured to seal upon contact with the first portion of the blood sample as is known in the art, best seen in Figure 1 (Col.9: 1-8; Col.11: 60-Col.12: 9).

6, 36. Zdeb et al disclose the device is configured with a moving part 148 – which is considered movable when the user connects or disconnects cartridge 82 from housing 78 – that is movable

from a first position (connected to housing 78 in Figure 4) to a second position (disconnected from housing 78 in Figure 3) to allow blood to bypass the chamber 106 and go through the sampling channel 134 (Col.9: 62-Col.10: 67).

7, 37. Zdeb et al disclose the moving part 148 further configured to move from the first position to the second position as defined after the first portion of blood flows into the chamber – the user can disconnect cartridge 82 from housing 78 after the first portion of the blood flows into chamber 106.

32, 38. Zdeb et al disclose the moving part 148 is an inner chamber housing, best seen in Figure 3-4.

33, 39. Zdeb et al disclose a locking mechanism 126, 168 configured to maintain the moving part 148 in the first position until the chamber 106 is filled, providing force to overcome the locking mechanism to enable movement of the moving part to the second position – injection sites 126, 168 maintain the moving part 148 in the first position (connected to housing 78 in Figure 4), and then the user provides a force to overcome the locking mechanism to move the moving part to the second position (disconnected from housing 78 in Figure 3) (Col.9: 62-Col.10: 67).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on nonstatutory double patenting provided the reference application or patent either is shown to be commonly owned with the examined application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. See MPEP § 717.02 for applications subject to examination under the first inventor to file provisions of the AIA as explained in MPEP § 2159. See MPEP § 2146 *et seq.* for applications not subject to examination under the first inventor to file provisions of the AIA. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The filing of a terminal disclaimer by itself is not a complete reply to a nonstatutory double patenting (NSDP) rejection. A complete reply requires that the terminal disclaimer be accompanied by a reply requesting reconsideration of the prior Office action. Even where the NSDP rejection is provisional the reply must be complete. See MPEP § 804, subsection I.B.1. For a reply to a non-final Office action, see 37 CFR 1.111(a). For a reply to final Office action, see 37 CFR 1.113(c). A request for reconsideration while not provided for in 37 CFR 1.113(c) may be filed after final for consideration. See MPEP §§ 706.07(e) and 714.13.

The USPTO Internet website contains terminal disclaimer forms which may be used. Please visit www.uspto.gov/patent/patents-forms. The actual filing date of the application in which the form is filed determines what form (e.g., PTO/SB/25, PTO/SB/26, PTO/AIA/25, or PTO/AIA/26) should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to www.uspto.gov/patents/apply/applying-online/eterminal-disclaimer.

Claim 1 and 34 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 12 and 18 of U.S. Patent No. 11617525 in view of Zdeb et al (US Pat No. 4874366).

The Patent discloses an inlet port for receiving a blood sample; an outlet port; a chamber connected at the inlet port and configured to collect a first portion of the blood sample, the chamber including a material that is air permeable and blood impermeable/air permeable blood barrier; a sampling channel connected with the inlet port and the outlet port

and configured to convey a subsequent portion of the blood sample to the outlet port while bypassing the chamber; and a housing that fully encloses the inlet port, the outlet port, the chamber, and the sampling channel.

However, the Patent does not expressly disclose the chamber connected at a proximal end with the inlet port and at a distal end with the outlet port.

Zdeb et al teach that it is well-known in the art to provide an analogous device with a chamber connected at a proximal end (top near element 114) with the inlet port 94, 76a and at a distal end (bottom near element 112) with the outlet port 96, 76b, best seen in Figure 3-4, as an effective configuration to connect to the chamber to the rest of the device for the desired fluid flow.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of filing to modify the Patent such that the chamber is connected at a proximal end with the inlet port and at a distal end with the outlet port as taught by Zdeb et al as an effective configuration for the desired fluid flow.

Claim 1 and 34 are rejected on the ground of nonstatutory double patenting as being unpatentable over claim 1 of U.S. Patent No. 12257051 in view of Zdeb et al (US Pat No. 4874366).

The Patent discloses an inlet port for receiving a blood sample; an outlet port; a chamber connected at the inlet port and configured to collect a first portion of the blood sample, the chamber including a material that is air permeable and blood impermeable/air permeable blood barrier; a sampling channel connected with the inlet port and the outlet port

and configured to convey a subsequent portion of the blood sample to the outlet port while bypassing the chamber; and a housing that defines the inlet port, the outlet port, the chamber, and the sampling channel.

However, the Patent does not expressly disclose the chamber connected at a proximal end with the inlet port and at a distal end with the outlet port, nor the housing fully encloses the inlet port, the outlet port, the chamber, and the sampling channel.

Zdeb et al teach that it is well-known in the art to provide an analogous device with a chamber 106 connected at a proximal end (top near element 114) with the inlet port 94, 76a and at a distal end (bottom near element 112) with the outlet port 96, 76b, best seen in Figure 3-4, as an effective configuration to connect to the chamber to the rest of the device for the desired fluid flow.

Zdeb et al also disclose the housing 78, 82 fully encloses the inlet port, the outlet port, the chamber, and the sampling channel 134, best seen in Figure 3-4.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of filing to modify the Patent such that the chamber is connected at a proximal end with the inlet port and at a distal end with the outlet port as well as the housing fully encloses the inlet port, the outlet port, the chamber, and the sampling channel as taught by Zdeb et al as an effective configuration for the desired fluid flow.

Claim 1 and 34 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-2 of U.S. Patent No. 10827964 in view of Zdeb et al (US Pat No. 4874366).

The Patent discloses an inlet port for receiving a blood sample; an outlet port; a chamber connected at the inlet port and configured to collect a first portion of the blood sample, the chamber including a material that is air permeable and blood impermeable/air permeable blood barrier; a sampling channel connected with the inlet port and the outlet port and configured to convey a subsequent portion of the blood sample to the outlet port while bypassing the chamber; and a housing that defines the inlet port, the outlet port, the chamber, and the sampling channel.

However, the Patent does not expressly disclose the chamber connected at a proximal end with the inlet port and at a distal end with the outlet port, nor the housing fully encloses the inlet port, the outlet port, the chamber, and the sampling channel.

Zdeb et al teach that it is well-known in the art to provide an analogous device with a chamber 106 connected at a proximal end (top near element 114) with the inlet port 94, 76a and at a distal end (bottom near element 112) with the outlet port 96, 76b, best seen in Figure 3-4, as an effective configuration to connect to the chamber to the rest of the device for the desired fluid flow.

Zdeb et al also disclose the housing 78, 82 fully encloses the inlet port, the outlet port, the chamber, and the sampling channel 134, best seen in Figure 3-4.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of filing to modify the Patent such that the chamber is connected at a proximal end with the inlet port and at a distal end with the outlet port as well as the housing fully encloses the inlet port, the outlet port, the chamber, and the sampling channel as taught by Zdeb et al as an effective configuration for the desired fluid flow.

Claim 1 and 34 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 11744494 in view of Zdeb et al (US Pat No. 4874366).

The Patent discloses an inlet port for receiving a blood sample; an outlet port; a chamber connected at the inlet port and configured to collect a first portion of the blood sample, the chamber including a material that is air permeable and blood impermeable/air permeable blood barrier; a sampling channel connected with the inlet port and the outlet port and configured to convey a subsequent portion of the blood sample to the outlet port while bypassing the chamber; and a housing that defines the inlet port, the outlet port, the chamber, and the sampling channel.

However, the Patent does not expressly disclose the chamber connected at a proximal end with the inlet port and at a distal end with the outlet port, nor the housing fully encloses the inlet port, the outlet port, the chamber, and the sampling channel.

Zdeb et al teach that it is well-known in the art to provide an analogous device with a chamber 106 connected at a proximal end (top near element 114) with the inlet port 94, 76a and at a distal end (bottom near element 112) with the outlet port 96, 76b, best seen in Figure 3-4, as an effective configuration to connect to the chamber to the rest of the device for the desired fluid flow.

Zdeb et al also disclose the housing 78, 82 fully encloses the inlet port, the outlet port, the chamber, and the sampling channel 134, best seen in Figure 3-4.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of filing to modify the Patent such that the chamber is connected at a proximal end with the inlet port and at a distal end with the outlet port as well as the housing fully encloses the inlet port, the outlet port, the chamber, and the sampling channel as taught by Zdeb et al as an effective configuration for the desired fluid flow.

Claim 1 and 34 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 13 and 16 of U.S. Patent No. 11963769 in view of Zdeb et al (US Pat No. 4874366).

The Patent discloses an inlet port for receiving a bodily fluid that is capable of being a blood sample; an outlet port; a chamber connected at the inlet port and configured to collect a first portion of the blood sample, the chamber including a material that is air permeable and blood impermeable/air permeable blood barrier; a sampling channel connected with the inlet port and the outlet port and configured to convey a subsequent portion of the blood sample to the outlet port while bypassing the chamber; and a housing that defines the inlet port, the outlet port, the chamber, and the sampling channel.

However, the Patent does not expressly disclose the chamber connected at a proximal end with the inlet port and at a distal end with the outlet port, nor the housing fully encloses the inlet port, the outlet port, the chamber, and the sampling channel.

Zdeb et al teach that it is well-known in the art to provide an analogous device with a chamber 106 connected at a proximal end (top near element 114) with the inlet port 94, 76a and at a distal end (bottom near element 112) with the outlet port 96, 76b, best seen in Figure

3-4, as an effective configuration to connect to the chamber to the rest of the device for the desired fluid flow.

Zdeb et al also disclose the housing 78, 82 fully encloses the inlet port, the outlet port, the chamber, and the sampling channel 134, best seen in Figure 3-4.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of filing to modify the Patent such that the chamber is connected at a proximal end with the inlet port and at a distal end with the outlet port as well as the housing fully encloses the inlet port, the outlet port, the chamber, and the sampling channel as taught by Zdeb et al as an effective configuration for the desired fluid flow.

Claim 1 and 34 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1 and 13-14 of U.S. Patent No. 11832944 in view of Zdeb et al (US Pat No. 4874366).

The Patent discloses an inlet port for receiving a blood sample; an outlet port; a chamber connected at the inlet port and configured to collect a first portion of the blood sample, the chamber including a material that is air permeable and blood impermeable/air permeable blood barrier; a sampling channel connected with the inlet port and the outlet port and configured to convey a subsequent portion of the blood sample to the outlet port while bypassing the chamber; and a housing that defines the inlet port, the outlet port, the chamber, and the sampling channel.

However, the Patent does not expressly disclose the chamber connected at a proximal end with the inlet port and at a distal end with the outlet port, nor the housing fully encloses the inlet port, the outlet port, the chamber, and the sampling channel.

Zdeb et al teach that it is well-known in the art to provide an analogous device with a chamber 106 connected at a proximal end (top near element 114) with the inlet port 94, 76a and at a distal end (bottom near element 112) with the outlet port 96, 76b, best seen in Figure 3-4, as an effective configuration to connect to the chamber to the rest of the device for the desired fluid flow.

Zdeb et al also disclose the housing 78, 82 fully encloses the inlet port, the outlet port, the chamber, and the sampling channel 134, best seen in Figure 3-4.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of filing to modify the Patent such that the chamber is connected at a proximal end with the inlet port and at a distal end with the outlet port as well as the housing fully encloses the inlet port, the outlet port, the chamber, and the sampling channel as taught by Zdeb et al as an effective configuration for the desired fluid flow.

Claim 1 and 34 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 13 and 16 of U.S. Patent No. 11185266 in view of Zdeb et al (US Pat No. 4874366).

The Patent discloses an inlet port for receiving a bodily fluid capable of being a blood sample; an outlet port; a chamber connected at the inlet port and configured to collect a first portion of the blood sample, the chamber including a material that is air permeable and blood

impermeable/air permeable blood barrier; a sampling channel connected with the inlet port and the outlet port and configured to convey a subsequent portion of the blood sample to the outlet port while bypassing the chamber; and a housing that defines the inlet port, the outlet port, the chamber, and the sampling channel.

However, the Patent does not expressly disclose the chamber connected at a proximal end with the inlet port and at a distal end with the outlet port, nor the housing fully encloses the inlet port, the outlet port, the chamber, and the sampling channel.

Zdeb et al teach that it is well-known in the art to provide an analogous device with a chamber 106 connected at a proximal end (top near element 114) with the inlet port 94, 76a and at a distal end (bottom near element 112) with the outlet port 96, 76b, best seen in Figure 3-4, as an effective configuration to connect to the chamber to the rest of the device for the desired fluid flow.

Zdeb et al also disclose the housing 78, 82 fully encloses the inlet port, the outlet port, the chamber, and the sampling channel 134, best seen in Figure 3-4.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of filing to modify the Patent such that the chamber is connected at a proximal end with the inlet port and at a distal end with the outlet port as well as the housing fully encloses the inlet port, the outlet port, the chamber, and the sampling channel as taught by Zdeb et al as an effective configuration for the desired fluid flow.

Claim 1 and 34 are rejected on the ground of nonstatutory double patenting as being unpatentable over claim 5 of U.S. Patent No. 10143412 in view of Zdeb et al (US Pat No. 4874366).

The Patent discloses an inlet port for receiving a blood sample; an outlet port; a chamber connected at the inlet port and configured to collect a first portion of the blood sample, the chamber including a material that is air permeable and blood impermeable/air permeable blood barrier; a sampling channel connected with the inlet port and the outlet port and configured to convey a subsequent portion of the blood sample to the outlet port while bypassing the chamber; and a housing that defines the inlet port, the outlet port, the chamber, and the sampling channel.

However, the Patent does not expressly disclose the chamber connected at a proximal end with the inlet port and at a distal end with the outlet port, nor the housing fully encloses the inlet port, the outlet port, the chamber, and the sampling channel.

Zdeb et al teach that it is well-known in the art to provide an analogous device with a chamber 106 connected at a proximal end (top near element 114) with the inlet port 94, 76a and at a distal end (bottom near element 112) with the outlet port 96, 76b, best seen in Figure 3-4, as an effective configuration to connect to the chamber to the rest of the device for the desired fluid flow.

Zdeb et al also disclose the housing 78, 82 fully encloses the inlet port, the outlet port, the chamber, and the sampling channel 134, best seen in Figure 3-4.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of filing to modify the Patent such that the chamber is connected at a proximal end with the inlet

port and at a distal end with the outlet port as well as the housing fully encloses the inlet port, the outlet port, the chamber, and the sampling channel as taught by Zdeb et al as an effective configuration for the desired fluid flow.

Claim 1 and 34 are rejected on the ground of nonstatutory double patenting as being unpatentable over claim 1 of U.S. Patent No. 10010282 in view of Zdeb et al (US Pat No. 4874366).

The Patent discloses an inlet port for receiving a blood sample; an outlet port; a chamber connected at the inlet port and configured to collect a first portion of the blood sample, the chamber including a material that is air permeable and blood impermeable/air permeable blood barrier; a sampling channel connected with the inlet port and the outlet port and configured to convey a subsequent portion of the blood sample to the outlet port while bypassing the chamber; and a housing that defines the inlet port, the outlet port, the chamber, and the sampling channel.

However, the Patent does not expressly disclose the chamber connected at a proximal end with the inlet port and at a distal end with the outlet port, nor the housing fully encloses the inlet port, the outlet port, the chamber, and the sampling channel.

Zdeb et al teach that it is well-known in the art to provide an analogous device with a chamber 106 connected at a proximal end (top near element 114) with the inlet port 94, 76a and at a distal end (bottom near element 112) with the outlet port 96, 76b, best seen in Figure 3-4, as an effective configuration to connect to the chamber to the rest of the device for the desired fluid flow.

Zdeb et al also disclose the housing 78, 82 fully encloses the inlet port, the outlet port, the chamber, and the sampling channel 134, best seen in Figure 3-4.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of filing to modify the Patent such that the chamber is connected at a proximal end with the inlet port and at a distal end with the outlet port as well as the housing fully encloses the inlet port, the outlet port, the chamber, and the sampling channel as taught by Zdeb et al as an effective configuration for the desired fluid flow.

Claim 1 and 34 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 13-14 of U.S. Patent No. 12138052 in view of Zdeb et al (US Pat No. 4874366).

The Patent discloses an inlet port for receiving a blood sample; an outlet port; a chamber connected at the inlet port and configured to collect a first portion of the blood sample, the chamber including a material that blood impermeable/blood barrier; a sampling channel connected with the inlet port and the outlet port and configured to convey a subsequent portion of the blood sample to the outlet port while bypassing the chamber; and a housing that defines the inlet port, the outlet port, and the sampling channel.

However, the Patent does not expressly disclose the chamber connected at a proximal end with the inlet port and at a distal end with the outlet port, nor the housing fully encloses the inlet port, the outlet port, the chamber, and the sampling channel, nor the blood impermeable material is air permeable.

Zdeb et al teach that it is well-known in the art to provide an analogous device with a chamber 106 connected at a proximal end (top near element 114) with the inlet port 94, 76a and at a distal end (bottom near element 112) with the outlet port 96, 76b, best seen in Figure 3-4, as an effective configuration to connect to the chamber to the rest of the device for the desired fluid flow.

Zdeb et al also disclose the housing 78, 82 fully encloses the inlet port, the outlet port, the chamber, and the sampling channel 134, best seen in Figure 3-4.

Zdeb et al also disclose air permeable material 86 to allow air to escape as necessary (Col.9: 1-8).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of filing to modify the Patent such that the chamber is connected at a proximal end with the inlet port and at a distal end with the outlet port as well as the housing fully encloses the inlet port, the outlet port, the chamber, and the sampling channel as taught by Zdeb et al as an effective configuration for the desired fluid flow. Therefore, it would have been obvious to one of ordinary skill in art at the time of filing to modify the Patent such that the the blood impermeable material is air permeable as taught by Zdeb et al to effectively air to escape as necessary.

Claim 1 and 34 are rejected on the ground of nonstatutory double patenting as being unpatentable over claim 1 of U.S. Patent No. 11311219 in view of Zdeb et al (US Pat No. 4874366).

The Patent discloses an inlet port for receiving a blood sample; an outlet port; a chamber connected at the inlet port and configured to collect a first portion of the blood sample, the chamber including a material that air permeable and blood impermeable/air permeable blood barrier; a sampling channel connected with the inlet port and the outlet port and configured to convey a subsequent portion of the blood sample to the outlet port while bypassing the chamber; and a housing that defines the inlet port, the outlet port, and the sampling channel.

However, the Patent does not expressly disclose the chamber connected at a proximal end with the inlet port and at a distal end with the outlet port, nor the housing fully encloses the inlet port, the outlet port, the chamber, and the sampling channel.

Zdeb et al teach that it is well-known in the art to provide an analogous device with a chamber 106 connected at a proximal end (top near element 114) with the inlet port 94, 76a and at a distal end (bottom near element 112) with the outlet port 96, 76b, best seen in Figure 3-4, as an effective configuration to connect to the chamber to the rest of the device for the desired fluid flow.

Zdeb et al also disclose the housing 78, 82 fully encloses the inlet port, the outlet port, the chamber, and the sampling channel 134, best seen in Figure 3-4.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of filing to modify the Patent such that the chamber is connected at a proximal end with the inlet port and at a distal end with the outlet port as well as the housing fully encloses the inlet port, the outlet port, the chamber, and the sampling channel as taught by Zdeb et al as an effective configuration for the desired fluid flow.

Response to Arguments

Applicant's arguments with respect to claim(s) above have been considered but are moot because the new ground of rejection does not rely on any reference applied in the prior rejection of record for any teaching or matter specifically challenged in the argument.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Huong Q NGUYEN whose telephone number is (571)272-8340. The examiner can normally be reached 10 am - 6 pm.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jennifer Robertson can be reached on (571)272-5001. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: https://patentcenter.uspto.gov. Visit https://www.uspto.gov/patents/apply/patent-center for

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/H.Q.N/
Examiner, Art Unit 3791

/JENNIFER ROBERTSON/
Supervisory Patent Examiner, Art Unit 3791

Notice of References Cited	Application/Control No. 17/893,079	Applicant(s)/Patent Under Reexamination ROGERS et al.	
	Examiner Huong Q NGUYEN	Art Unit 3791	Page 1 of 1

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*		Document Number Country Code-Number-Kind Code	Date YYYY-MM-DD	Name	CPC Classification	US Classification
*	A	US-4874366-A	1989-10-17	Zdeb; Brian	A61M5/1409	604/518
*	B	US-20170209644-A1	2017-07-27	BROWKA; Edward	A61M5/1409	1/1
	C					
	D					
	E					
	F					
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FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date YYYY-MM-DD	Country	Name	CPC Classification
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Dates in YYYY-MM-DD format are publication dates. Classifications may be US or foreign.

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Application Number	17893079
Filing Date	2022-08-22
First Named Inventor	Gino KANG
Art Unit	3791
Examiner Name	NGUYEN, HUONG Q
Attorney Docket Number	069366-0572192_KUR3C02US

U.S. PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Inventor of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
	1	4312362		1982-01-26	KAUFMAN JOSEPH	
	2	11744494		2023-09-05	ROGERS BOBBY E	

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	1	20140163419		2014-06-12	BULLINGTON GREGORY J	
	2	20140309558		2014-10-16	FLETCHER GARY D	
	3	20140073990		2014-03-13	HOLMES ELIZABETH A	
	4	20140323911		2014-10-30	SLOAN DEBORAH	

PC.1.19.25

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /H.Q.N/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT		
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	First Named Inventor	Gino KANG
	Art Unit	3791
	Examiner Name	NGUYEN, HUONG Q
	Attorney Docket Number	069366-0572192_KUR3C02US

	5	20040112808		2004-06-17	TAKAGI YOSHIKI	
	6	20150018715		2015-01-15	WALTERSPIEL JUAN NEPOMUC	
	7	20160161511		2016-06-09	XU XIN	

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Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1	Office Action (Non-Final Rejection) dated 9/24/2024 for U.S. Application No. 18/783,173 ; Attorney Docket No. 069366-0580420_KUR3C03US (pages 1-62).	☐
	2	Office Action (Non-Final Rejection) dated 9/23/2024 for U.S. Application No. 17/730,118 ; Attorney Docket No. 069366-0572186_KUR3C01US (pages 1-73).	☐
	3	Office Action (Non-Final Rejection) dated 9/17/2024 for U.S. Application No. 18/783,088 ; Attorney Docket No. 069366-0580418_KUR2C06US (pages 1-60).	☐

PC.1.19.25

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /H.Q.N/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT		
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	Filing Date	2022-08-22
	First Named Inventor	Gino KANG
	Art Unit	3791
	Examiner Name	NGUYEN, HUONG Q
	Attorney Docket Number	069366-0572192_KUR3C02US

	4	Office Action (Notice of Deficiencies) dated 10/14/2024 for IL App No. 309380 (pages 1-7).	☐
	5	Office Action (Final Rejection) dated 11/4/2024 for U.S. Application No. 18/783,173; Attorney Docket No. 069366-0580420_KUR3C03US (pages 1-22).	☐
	6	Office Action (Non-Final Rejection) dated 09/24/2024 for U.S. Application No. 18/783,173; Attorney Docket No. 069366-0580420_KUR3C03US (pages 1-62).	☐
	7	Office Action (Rejection Decision) dated 11/5/2024 for JP Application No. 2023-076490; Attorney Docket No. 069366-0575273_KUR2D03JP (pages 1-8).	☐
	8	Office Action (Non-Final Rejection) dated 10/22/2024 for U.S. Application No. 18/783,173; Attorney Docket No. 069366-0580420_KUR3C03US (pages 1-62).	☐
	9	Office Action (Non-Final Rejection) mailed 11/22/2024 for U.S. Application No. 18/898,239; Attorney Docket No. 069366-0581370_KUR2C07US (pages 1-57).	☐
	10	Office Action (Non-Final Rejection) dated 11/26/2024 for JP Application No. 2024-121200; Attorney Docket No. 069366-0580493_KUR3C03JP (pages 1-11).	☐
	11	Office Action (Final Rejection) dated 01/06/2025 for U.S. Application No. 18/898,239; Attorney Docket No. 069366-0581370_KUR2C07US (pages 1-15).	☐
	12	Office Action (Non-Final Rejection) dated 12/02/2024 for U.S. Application No. 18/494,622; Attorney Docket No. 069366-0577657_KUR2C05US (pages 1-70).	☐
	13	Office Action (Non-Final Rejection) dated 02/11/2025 for U.S. Application No. 18/783,173; Attorney Docket No. 069366-0580420_KUR3C03US (pages 1-70).	☐
	14	Office Action (Final Rejection) dated 02/12/2025 for U.S. Application No. 17/793,118; Attorney Docket No. 069366-0572186_KUR3C01US (pages 1-19).	☐

PC.1.19.25

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /H.Q.N/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT		
	Application Number	17893079
	Filing Date	2022-08-22
	First Named Inventor	Gino KANG
	Art Unit	3791
	Examiner Name	NGUYEN, HUONG Q
	Attorney Docket Number	069366-0572192_KUR3C02US

If you wish to add additional non-patent literature document citation information, please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature	/H Q NGUYEN/	Date Considered	03/27/2025

*EXAMINER: Initial if reference considered and whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

PC.1.19.25

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /H.Q.N/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT		
	Application Number	17893079
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	Examiner Name	NGUYEN, HUONG Q
	Attorney Docket Number	069366-0572192_KUR3C02US

TIMING STATEMENT

Please see 37 CFR 1.97(e) to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached timing statement under 37 CFR 1.97(e).

☒ A timing statement under 37 CFR 1.97(e) is not submitted herewith.

TIMING FEE

☐ The fee set forth in 37 CFR 1.17(p) has been submitted herewith.

COPIES

☐ An identification of an earlier application pursuant to 37 CFR 1.98(d)(1) is attached.

SIZE FEE ASSERTION

Please see 37 CFR 1.17(v) and the IDS Auto-Load Instructions for completing this form to make the appropriate selection of an assertion under 37 CFR 1.98. For the information disclosure statement (IDS) submitted herewith, the applicant or patent owner certifies the following with respect to the cumulative number of applicant-provided or patent-owner provided items of information submitted to date including those in the accompanying IDS (select only one):

☒ No IDS size fee is required under 37 CFR 1.17(v) at this time.

☐ The IDS is accompanied by the IDS size fee under 37 CFR 1.17(v)(1).

☐ The IDS is accompanied by the IDS size fee under 37 CFR 1.17(v)(2).

☐ The IDS is accompanied by the IDS size fee under 37 CFR 1.17(v)(3).

SIGNATURE

A signature of the applicant or representative is required in accordance with 37 CFR 1.33 and 11.18. Please see 37 CFR 1.4(d) for the form of the signature.

Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2025-03-20
Name/Print	Benjamin F. Hudson	Registration Number	71,474

PC.1.19.25

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /H.Q.N/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT		
	Application Number	17893079
	Filing Date	2022-08-22
	First Named Inventor	Gino KANG
	Art Unit	3791
	Examiner Name	NGUYEN, HUONG Q
	Attorney Docket Number	069366-0572192_KUR3C02US

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /H.Q.N/

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /H.Q.N/

Reference No.: 0572492
Mailing No.: 100290
Mailing Date: March 11, 2025

Non-final Office Action
(Translation)

Application No.	Japanese Patent Application No. 2022-572789	
Drafting Date	March 4, 2025	
Examiner	Satoshi ABE	4635 2Q00
Representative	Satoshi MURAKOSHI	
Applied Articles	Japanese Patent Act, Section 29, Paragraph 1, Item 3 (novelty)	
	Japanese Patent Act, Section 29, Paragraph 2 (inventive step)	
	Japanese Patent Act, Section 36, Paragraph 6, Item 1 (support requirement)	
	Japanese Patent Act, Section 36, Paragraph 6, Item 2 (clearness)	

This application has been rejected for the grounds stated below. Applicant is invited to file a Response within three months from the mailing date of this notice.

Grounds

<Ground 1>

(Novelty) The claim(s) of this application set forth below was/were anticipated by the invention(s) disclosed in the publication(s) below distributed in Japan or foreign countries or the invention(s) made available to the public through electrical communication lines prior to the filing of this application. Therefore, the claim(s) is/are not entitled to obtain a patent under Section 29, Paragraph 1, Item 3 of the Japanese Patent Act.

<Ground 2>

(Inventive step) The claim(s) of this application set forth below would have been obvious to one ordinarily skilled in the art prior to the filing of this application, based on the invention(s) disclosed in the publication(s) below distributed in Japan or foreign countries or the invention(s) made available to the public through electrical communication lines prior to the filing of this application. Therefore, the claim(s) is/are unpatentable under Section 29, Paragraph 2 of the Japanese Patent Act.

<Ground 3>

(Support requirement) This application does not conform to Section 36, Paragraph 6, Item 1 of the Japanese Patent Act in the following points.

<Ground 4>

(Clearness) This application does not conform to Section 36, Paragraph 6, Item 2 of the Japanese Patent Act in the following points.

Examiner Notes (the cited references are listed in Reference List below)

• As to Ground 1 (novelty) and Ground 2 (inventive step)

- As to Claims: 1 to 4, 9, 11, 12, 15, and 18 to 22
- Reference cited: Reference 1
- Notes:

As to claim 1:

Reference 1 (paragraphs 0113 to 0132 and Figs. 4 to 7) discloses a fluid control device including:

an inlet 412 ("an inlet" of the present application); an outlet 416 ("an outlet" of the present application); a fluid path 454 ("a sample path" of the present application); a sequestration chamber 414 ("a chamber" of the present application); a flow controller 415 ("an air permeable fluid resistor" of the present application); and a flow restrictor 431 ("a displaceable plug" of the present application),

wherein the flow controller 415 allows movement of gases and prevents movement of liquids, and

wherein the fluid control device includes an external actuator, controller, or adjuster configured to control the amount of flow through the flow restrictor 431 by adjusting the inner diameter of the flow restrictor 431, and the structure of the flow restrictor 431 can be manipulated to modulate the degree of negative pressure.

As to claim 2:

In addition to the above, Reference 1 (paragraphs 0133 to 0160 and Figs. 13 and 14) discloses that a barrier 775, a diaphragm 776, and an actuator 778 (one or more of these correspond to the "displaceable plug" of the present application) are received in the sequestration chamber and a fluid path 754 ("a recess" of the present application).

As to claim 3:

Reference 1 (Figs. 4 and 13) discloses that a flow path (a part of the "chamber" of the present application) continuous to the sequestration chamber is tortuous.

As to claim 4:

The Actuator 778 of Reference 1 forms a water-tight seal with the barrier 774. Thus, when the actuator 778 tries to move, a frictional force should occur between them.

As to claim 9:

The diaphragm 776 of Reference 1 should be an elastic material. Alternatively, it can be readily accomplished to form the diaphragm 776 of Reference 1 from an elastic material.

As to claim 11:

Figs. 13 and 14 of Reference 1 show that the left and right ends of the diaphragm 776 are received by a wall ("a protrusion" of the present application) protruding upward in the drawing.

As to claim 12:

The diaphragm 776 of Reference 1 has a curved bottom surface.

As to claim 15:

The barrier 775 of Reference 1 is movable ("collapsible" in the present application) by the actuator 778, which is actuated by a pressure, to a position where it does not block the flow path.

Alternatively, see Figs. 9 to 12 of Reference 1, which show that the barrier 675 is broken. It can be readily accomplished to break the barrier 775 in the same manner.

As to claim 18:

The diaphragm 776 of Reference 1 corresponds to "an enlarged diameter shoulder" of the present application.

As to claim 19:

In Fig. 14 of Reference 1, the part of the fluid path 754 that receives the actuator 778 corresponds to "a screen or gate" of the present application.

As to claim 20:

In Reference 1, the flow path 754 extends in the direction substantially perpendicular to the operating direction of the actuator 778. Thus, the flow path 754 "has a shape that changes to not allow traversal of the displaceable plug along a length of the sample path," as in the present application.

As to claims 21 and 22:

The features of these claims are also found in Reference 1.

• As to Ground 2 (inventive step)

- As to Claims: 4 to 8, 10, 13, 14, 16, and 17
- Reference cited: Reference 1 or 1 and 2
- Notes:

As to claim 4:

Reference 2 (paragraphs 1106 to 1118 and Figs. 9 and 10) discloses an actuator 450 of the fluid control device 400, wherein plungers 460 and 461 should be initially secured by a friction-fit with the seal 465.

References 1 and 2 are both related to a fluid (blood) control device.

Therefore, those skilled in the art could have readily applied the technical matter of Reference 2 to Reference 1 such that the flow restrictor 431 and the actuator 778 (the "displaceable plug" of the present application) are initially secured by a friction-fit.

As to claims 5 to 7:

It is a design matter to provide Reference 1 with a seat such as an elastomeric O-ring to stably secure the flow restrictor 431 and the actuator 778 (the "displaceable plug" of the present application) in the initial state.

As to claim 8:

The diaphragm 776 of Reference 1 corresponds to "a membrane" of the present application.

As to claim 10:

It is a design matter to form the diaphragm 776 of Reference 1 of a rigid polymer.

It is a design matter to provide a seat for positioning the diaphragm 776 of Reference 1 in the initial state.

In addition, as shown in Figs. 13 and 14, the diaphragm 776 allows deflection of the walls causing displacement from a seat.

As to claims 13, 14, 16, and 17:

The shape of the actuator 778 of Reference 1 can be selected as appropriate.

• As to Ground 3 (support requirement)

- As to Claims: 13 and 14

Claims 13 and 14 respectively recite "the displaceable plug is hollowed out towards the sample path" and "the displaceable plug is hollowed out away from the sample path." However, the Detailed Description of the Invention does not describe that the displaceable plug is hollowed out towards the sample path or hollowed out away from the sample path.

• As to Ground 4 (clearness)

- As to Claim: 10

The recitation "a rigid polymer" is unclear as to the criterion of the rigidity or the degree of the rigidity.

- As to Claim: 12

Claim 12 of the present application recites "the conduit," but this term lacks antecedent basis.

In addition, the recitation "curved to facilitate displacement from the conduit" is unclear as to how the bottom surface is curved.

Therefore, claim 12 is unclear.

- As to Claim: 18

Claim 18 of the present application recites "the second pressure differential," but this term lacks

antecedent basis.

Therefore, claim 18 is unclear.

<Reference List>

1. International Publication No. WO 2019/232196
2. International Publication No. WO 2019/055487

Record of Search for Prior Art Literature

- Searched Field IPC A61B 5/00 – 5/398

This record of search for prior art literatures does not constitute grounds for refusal.

拒絶理由通知書

特許出願の番号	特願２０２２－５７２７８９
起案日	令和　７年　３月　４日
特許庁審査官	阿部　知　　４６３５　２Ｑ００
特許出願人代理人	村越　智史　様
適用条文	第２９条第１項第３号（新規性） 第２９条第２項（進歩性） 第３６条第６項第１号（サポート要件） 第３６条第６項第２号（明確性）

この出願は、次の理由によって拒絶をすべきものです。これについて意見がありましたら、この通知書の発送の日から３か月以内に意見書を提出してください。

理由

１．（新規性）この出願の下記の請求項に係る発明は、その出願前に日本国内又は外国において、頒布された下記の刊行物に記載された発明又は電気通信回線を通じて公衆に利用可能となった発明であるから、特許法第２９条第１項第３号に該当し、特許を受けることができない。

２．（進歩性）この出願の下記の請求項に係る発明は、その出願前に日本国内又は外国において、頒布された下記の刊行物に記載された発明又は電気通信回線を通じて公衆に利用可能となった発明に基いて、その出願前にその発明の属する技術の分野における通常の知識を有する者が容易に発明をすることができたものであるから、特許法第２９条第２項の規定により特許を受けることができない。

３．（サポート要件）この出願は、特許請求の範囲の記載が下記の点で、特許法第３６条第６項第１号に規定する要件を満たしていない。

４．（明確性）この出願は、特許請求の範囲の記載が下記の点で、特許法第３６条第６項第２号に規定する要件を満たしていない。

記　　（引用文献等については引用文献等一覧参照）

●理由１（新規性）、理由２（進歩性）について

・請求項　１～４、９、１１、１２、１５、１８～２２
・引用文献等　１
・備考

（請求項１について）
引用文献１には、流体制御装置について、［０１１３］～［０１３２］、図４～７には、
入口４１２（本願の「入口」）、出口４１６（本願の「出口」）、流体流路４５４（本願の「サンプル経路」）、隔離室４１４（本願の「チャンバ」）、流れコントローラ４１５（本願の「空気透過性流体抵抗体」）、流れリストリクタ４３１（本願の「可動栓」）を備えること、
流れコントローラ４１５は、気体の移動を可能とし、液体の移動を防止すること、
流れリストリクタ４３１の内径を調整して、流れリストリクタ４３１を通る流れの量を制御する、外部アクチュエータ、コントローラ、または、アジャスタを有すること、流れリストリクタ４３１の構造を操作して負圧の程度を調整すること、
などが記載されている。

（請求項２について）
上記に加えて、引用文献１の［０１３３］～［０１６０］、図１３、１４には、バリア７７５,ダイヤフラム７７６,アクチュエータ７７８（左記のいずれか１つ又は複数は、本願の「可動栓」に相当）は、隔離室や流路７５４（本願の「凹部」）に受容されていること、が記載されている。

（請求項３について）
引用文献１の図４、１３には、隔離室に続く流路（本願の「チャンバ」の一部）が蛇行している様子が図示されている。

（請求項４について）
引用文献１に記載のアクチュエータ７７８は、バリア７７４と水密なシールを形成しており、アクチュエータ７７８が変位しようとした際には、両者の間には摩擦力が働くものと認められる。

（請求項９について）
引用文献１に記載のダイヤフラム７７６は、弾性材料であるものと認められる。または、引用文献１に記載のダイヤフラム７７６を、弾性材料から構成することは適宜なし得る事項である。

（請求項１１について）
　引用文献１の図１３、１４を見ると、ダイヤフラム７７６の左右端は、紙面上方に突出した壁部（本願の「突起」）に受容されている。

（請求項１２について）
　引用文献１に記載のダイヤフラム７７６の底面は、湾曲している。

（請求項１５について）
　引用文献１に記載のバリア７７５は、圧力により作動したアクチュエータ７７８により流路を遮断しない位置に移動（本願の「崩壊」）している。
　または、引用文献１の図９～１２など参照。バリア６７５等が破壊されており、バリア７７５が同様に破壊されるものとすることは、適宜なし得る事項である。

（請求項１８について）
　引用文献１に記載のダイヤフラム７７６は、本願の「拡径された肩部」に相当する。

（請求項１９について）
　引用文献１の図１４において、アクチュエータ７７８を受け止めている、流路７５４の部分は、本願の「スクリーンまたはゲート」に相当する。

（請求項２０について）
　引用文献１に記載の発明においては、アクチュエータ７７８の動作方向と略垂直方向に流路７５４が延びており、本願でいうところの「前記サンプル経路の長さ方向に沿う前記可動栓の横断を許容しないように変化する形状を有」する。

（請求項２１、２２について）
　引用文献１に記載の発明も備える構成である。

●理由２（進歩性）について

・請求項　４～８、１０、１３、１４、１６、１７
・引用文献等　１又は１、２
・備考

（請求項４について）
　引用文献２（［１１０６］～［１１１８］、図９、１０など）には、流体制御

装置４００のアクチュエータ４５０について記載されており、各プランジャ４６０、４６１は、シール４６５により、初期状態では、摩擦嵌合によって固定されているものと認められる。
　引用文献１、２に記載の発明は、いずれも流体（血液）制御装置に関するものである。
　してみると、引用文献１に記載の発明に、引用文献２に記載の技術事項を適用して、流れリストリクタ４３１やアクチュエータ７７８（本願の「可動栓」）を、初期状態では、摩擦嵌合によって固定することは、当業者であれば容易になし得ることである。

（請求項５～７について）
　引用文献１に記載の流れリストリクタ４３１やアクチュエータ７７８（本願の「可動栓」）を、初期状態にて、安定して固定するために、弾性Ｏリング等の座部を設けることは、設計事項である。

（請求項８について）
　引用文献１に記載のダイヤフラム７７６は、本願の「膜」に相当する。

（請求項１０について）
　引用文献１に記載のダイヤフラム７７６を、剛性の高いポリマーにて形成することは、設計事項である。
　また、引用文献１に記載のダイヤフラム７７６の、初期状態を位置決めする座部を設けることは、設計事項である。
　そして、ダイヤフラム７７６は、図１３、１４のとおり、座部からの変位を引き起こす壁のたわみを可能としている。

（請求項１３、１４、１６、１７について）
　引用文献１に記載のアクチュエータ７７８の形状は適宜選択し得る事項である。

●理由３（サポート要件）について

・請求項　１３、１４

　請求項１３、１４には、「前記可動栓は、前記サンプル経路に向かってくりぬかれている」「前記可動栓は、前記サンプル経路から離れる方向にくりぬかれている」と記載されているが、発明の詳細な説明には、可動栓を、サンプル経路に向かってくりぬくことや、サンプル経路から離れる方向にくりぬくことが、記載されているとは認められない。

●理由４（明確性）について

・請求項　１０

「剛性の高いポリマー」と記載されているが、何と比較して剛性が高いのか、または、どの程度を剛性が高いとするのか、明確でない。

・請求項　１２

本願の請求項１２には「前記導管」との記載があるが、この記載よりも前に「導管」の記載が無く、「前記導管」が何を指し示しているのかが不明確である。

また、「導管からの変位を容易にするように湾曲した」と記載されているが、どのように湾曲することを意図しているのか、明確でない。

よって、請求項１２に係る発明は明確でない。

・請求項　１８

本願の請求項１８には「前記第２の圧力差」との記載があるが、この記載よりも前に「第２の圧力差」の記載が無く、「前記第２の圧力差」が何を指し示しているのかが不明確である。

よって、請求項１８に係る発明は明確でない。

＜引用文献等一覧＞

１．国際公開第２０１９／２３２１９６号

２．国際公開第２０１９／０５５４８７号

－－－－－－－－－－－－－－－－－－－－－－－－－－－－－－－－－－－－－－－

＜先行技術文献調査結果の記録＞

・調査した分野　　ＩＰＣ　Ａ６１Ｂ　５／００　－　５／３９８

この先行技術文献調査結果の記録は、拒絶理由を構成するものではありません。

この拒絶理由通知の内容に関するお問合せ又は面接のご希望がありましたら、次の連絡先までご連絡ください。補正案等の送付を希望される際は、その旨を事前にご連絡ください。

電子メールにて連絡する際は、氏名、所属、出願番号、電話番号、下記審査官（補）名を記載していただき、下記メールアドレス（※）までご連絡ください。電子メールの連絡内容について不明な点等がある場合、電話で確認させていただく場合があります。

審査第一部分析診断（医学診断）　阿部　知（あべ　さとし）
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/893,079	08/22/2022	Bobby E. ROGERS	069366-0572192_KUR3C02US	6240

27500 7590 12/31/2024

PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
ATTENTION: DOCKETING DEPARTMENT
P.O BOX 10500
McLean, VA 22102

EXAMINER	
NGUYEN, HUONG Q	

ART UNIT	PAPER NUMBER
3791	

NOTIFICATION DATE	DELIVERY MODE
12/31/2024	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Docket_IP@pillsburylaw.com

Office Action Summary	Application No. 17/893,079	Applicant(s) ROGERS et al.	
	Examiner Huong Q NGUYEN	Art Unit 3791	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 12/11/2024.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☑ This action is **FINAL.** 2b) ☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 1-2,6-7 and 32-39 is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 1-2,6-7 and 32-39 is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to **PPHfeedback@uspto.gov.**

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☑ The drawing(s) filed on 8/22/02022 is/are: a)☑ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☑ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

DETAILED ACTION

This office action is responsive to the amendment filed 12/11/2024. Claims 1-2, 6-7, and 32-39 remain pending and under prosecution.

Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Claim Interpretation

The following is a quotation of 35 U.S.C. 112(f):

> (f) Element in Claim for a Combination. – An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

The following is a quotation of pre-AIA 35 U.S.C. 112, sixth paragraph:

> An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

The claims in this application are given their broadest reasonable interpretation using the plain meaning of the claim language in light of the specification as it would be understood by one of ordinary skill in the art. The broadest reasonable interpretation of a claim element (also commonly referred to as a claim limitation) is limited by the description in the specification when 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is invoked.

As explained in MPEP § 2181, subsection I, claim limitations that meet the following three-prong test will be interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph:

(A) the claim limitation uses the term "means" or "step" or a term used as a substitute for "means" that is a generic placeholder (also called a nonce term or a non-structural term having no specific structural meaning) for performing the claimed function;

(B) the term "means" or "step" or the generic placeholder is modified by functional language, typically, but not always linked by the transition word "for" (e.g., "means for") or another linking word or phrase, such as "configured to" or "so that"; and

(C) the term "means" or "step" or the generic placeholder is not modified by sufficient structure, material, or acts for performing the claimed function.

Use of the word "means" (or "step") in a claim with functional language creates a rebuttable presumption that the claim limitation is to be treated in accordance with 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph. The presumption that the claim limitation is interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is rebutted when the claim limitation recites sufficient structure, material, or acts to entirely perform the recited function.

Absence of the word "means" (or "step") in a claim creates a rebuttable presumption that the claim limitation is not to be treated in accordance with 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph. The presumption that the claim limitation is not interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is rebutted when the claim limitation

recites function without reciting sufficient structure, material or acts to entirely perform the recited function.

Claim limitations in this application that use the word "means" (or "step") are being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, except as otherwise indicated in an Office action. Conversely, claim limitations in this application that do not use the word "means" (or "step") are not being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, except as otherwise indicated in an Office action.

No elements are interpreted under 112(f).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a)(1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention.

Claim(s) 1-2, 6-7, 32, and 34-38 is/are rejected under 35 U.S.C. 102(a)(1) as being anticipated by Percarpio (US Pat No. 4106497 – cited by applicant).

In regard to Claim 1, Percarpio discloses a device comprising:

an inlet port (corresponding to location of needle 22) for receiving a blood sample, best seen in Figure 3 (Col.2: 58-Col.3: 23);

an outlet port 42, 44 (central passageway, opening -- Col.2: 58-Col.3: 23) – Figure 3;

a chamber (one channel) 92 connected with the inlet port and the outlet port, and configured to collect a first portion of the blood sample ("by capturing the blood within the indicator area including channels 92, there is no danger of contamination of blood being collected into chamber 32 and ultimately into an evacuated container through the passageway interconnected with rear needle 50" – Col.4: 16-39) – Figure 3,

the chamber including a material 90 that is air permeable (due to vents) and blood impermeable ("film of water expansible material 90… Three spaced channels 92 are formed in the film to provide air passageways for facilitating venting of the assembly and flow of blood into the indicator area where film 90 is located. The number of channels is a matter of choice. Thereafter, expansion of the film due to contact with the liquid closes channels 92 and locks the blood into the area of the location of the film" – Col.4: 16-39) – Figure 3;

a sampling channel 28 (extends through valve 78) connected with the inlet port and configured to convey a subsequent portion of the blood sample to the outlet port while bypassing the chamber – after blood is collected in channel 92 and the water expansible material forming the from expands to close channel 92 and stops the blood flow to channel 92, tube 94 is then advanced in holder 62 until the pointed end 54 of needle 50 pierces the stopper 96 and enters the evacuated tube…The difference in pressure caused by the vacuum within tube 94 causes the flaps of check valve 82 and 84 to separate permitting flow of blood through the check valve 78 and through passageway 42 and communicating needle 50 into the evacuated tube 94 for blood collection purposes (Col.5: 1-47), best seen in Figure 4; and

a housing (defined by hub 26 and adapter 40) that fully encloses the inlet port, the outlet port, the chamber, and the sampling channel, best seen in Figure 3.

2. (Previously Presented) The device in accordance with claim 1, wherein the material is configured to seal upon contact with the first portion of the blood sample (Col.4: 16-39; Col.5: 1-47).

6. (Previously Presented) The device in accordance with claim 1, wherein the device is configured with a moving part – 78 check valve with flaps 82, 84 – that is movable from a first position (closed) to a second position (open) to allow blood to bypass the chamber 92 and go through the sampling channel 28 – "The difference in pressure caused by the vacuum within tube 94 causes the flaps of check valve 82 and 84 to separate permitting flow of blood through the check valve 78 and through passageway 42 and communicating needle 50 into the evacuated tube 94 for blood collection purposes" (Col.5: 1-47), best seen in Figure 2 and 4.

7. (Previously Presented) The device in accordance with claim 6, the moving part 78, 82, 84 further configured to move from the first position to the second position after the first portion of blood flows into the chamber 92 – "tube 94 is then advanced in holder 62 until the pointed end 54 of needle 50 pierces the stopper 96 and enters the evacuated tube…The difference in pressure caused by the vacuum within tube 94 causes the flaps of check valve 82 and 84 to separate permitting flow of blood through the check valve 78 and through passageway 42 and communicating needle 50 into the evacuated tube 94 for blood collection purposes" (Col.5: 1-47).

32. (Previously Presented) The device in accordance with claim 6, wherein the moving part 78, 82, 84 is an inner chamber housing, best seen in Figure 3-4.

In regard to Claim 34, Percarpio discloses a device comprising:

an inlet port (corresponding to location of needle 22) for receiving a blood sample, best seen in Figure 3 (Col.2: 58-Col.3: 23);

an outlet port 42, 44 (central passageway, opening -- Col.2: 58-Col.3: 23) – Figure 3;

a chamber (one channel) 92 connected with the inlet port and the outlet port, and configured to collect a first portion of the blood sample ("by capturing the blood within the indicator area including channels 92, there is no danger of contamination of blood being collected into chamber 32 and ultimately into an evacuated container through the passageway interconnected with rear needle 50" – Col.4: 16-39) – Figure 3,

the chamber including an air permeable blood barrier due to vents ("Three spaced channels 92 are formed in the film to provide air passageways for facilitating venting of the assembly and flow of blood into the indicator area where film 90 is located. The number of channels is a matter of choice – Col.4: 16-39) – Figure 3;

a sampling channel 28 (extends through valve 78) connected with the inlet port and the outlet port, the sampling channel and chamber configured to convey a subsequent portion of the blood sample through the sampling channel to the outlet port – after blood is collected in channel 92 and the water expansible material forming the from expands to close channel 92 and stops the blood flow to channel 92, tube 94 is then advanced in holder 62 until the pointed end 54 of needle 50 pierces the stopper 96 and enters the evacuated tube…The difference in

pressure caused by the vacuum within tube 94 causes the flaps of check valve 82 and 84 to separate permitting flow of blood through the check valve 78 and through passageway 42 and communicating needle 50 into the evacuated tube 94 for blood collection purposes (Col.5: 1-47), best seen in Figure 4; and

a housing (defined by hub 26 and adapter 40) that fully encloses the inlet port, the outlet port, the chamber, and the sampling channel, best seen in Figure 3.

35. (Previously Presented) The device in accordance with claim 34, wherein the air permeable blood barrier is configured to seal upon contact with the first portion of the blood sample (Col.4: 16-39; Col.5: 1-47).

36. (Previously Presented) The device in accordance with claim 34, wherein the device is configured with a moving part – 78 check valve with flaps 82, 84 – that is movable from a first position (closed) to a second position (open) to allow blood to bypass the chamber 92 and go through the sampling channel 28 – "The difference in pressure caused by the vacuum within tube 94 causes the flaps of check valve 82 and 84 to separate permitting flow of blood through the check valve 78 and through passageway 42 and communicating needle 50 into the evacuated tube 94 for blood collection purposes" (Col.5: 1-47), best seen in Figure 2 and 4.

37. (Previously Presented) The device in accordance with claim 36, the moving part 78, 82, 84 further configured to move from the first position to the second position after the first portion of blood flows into the chamber 92 -- after blood is collected in channel 92 and the water

expansible material forming the from expands to close channel 92 and stops the blood flow to channel 92, tube 94 is then advanced in holder 62 until the pointed end 54 of needle 50 pierces the stopper 96 and enters the evacuated tube…The difference in pressure caused by the vacuum within tube 94 causes the flaps of check valve 82 and 84 to separate permitting flow of blood through the check valve 78 and through passageway 42 and communicating needle 50 into the evacuated tube 94 for blood collection purposes (Col.5: 1-47), best seen in Figure 4.

38. (Previously Presented) The device in accordance with claim 36, wherein the moving part 78, 82, 84 is an inner chamber housing, best seen in Figure 3-4.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries for establishing a background for determining obviousness under 35 U.S.C. 103 are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims the examiner presumes that the subject matter of the various claims was commonly owned as of the effective filing date of the claimed invention(s) absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and effective filing dates of each claim that was not commonly owned as of the effective filing date of the later invention in order for the examiner to consider the applicability of 35 U.S.C. 102(b)(2)(C) for any potential 35 U.S.C. 102(a)(2) prior art against the later invention.

Claim(s) 33 and 39 is/are rejected under 35 U.S.C. 103 as being unpatentable over Percarpio in view of Kaufman (US Pat No. 4312362).

Percarpio discloses the invention above but do not expressly disclose the device further comprising a locking mechanism configured to maintain the moving part in the first until the chamber is filled, providing force to overcome the locking mechanism to enable movement of the moving part to the second position.

Kaufman teach that it is well-known in the art to provide a blood sampling device comprising a locking mechanism that maintain the moving part 26 in the first position (so that hole 48 is free) which allows air to escape (similar to in Percarpio), and then providing force to overcome the locking mechanism to enable movement of the moving part to the second position (to free hole 49), which enables collection of the blood into evacuated tube 16 when said tube is connected also similarly to Percarpio, best seen in Figure 2 and 7 (Col.6: 44-Col.7:

50). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention of filing to modify Percarpio such that the device further comprising a locking mechanism configured to maintain the moving part in the first until the chamber is filled, providing force to overcome the locking mechanism to enable movement of the moving part to the second position as taught by Kaufman to effectively maintain the moving part in the first position until the chamber is filled, providing force to overcome the locking mechanism to enable movement of the moving part to the second position.

Response to Arguments

Applicant's arguments filed have been fully considered but they are not persuasive. Applicant contends that Percarpio does not disclose chamber 92 (channels) connected to outlet 40/42 because Percarpio discloses the channels 92 providing communication between the chamber 32 and the atmosphere. Applicant contends that the claimed invention does not vent to atmosphere. However, it is noted that such distinction has not been currently recited in the claims. Furthermore, it is noted that channel 92 is connected to chamber 32, which is fluidly connected to outlet 40/42. Thus, Percarpio disclose chamber 92 (channels) connected to outlet 40/42 as broadly as has been claimed. It is noted that applicant appears to be reading limitations into the claims such that the flow of blood through the chamber leads in the direction of the outlet. However, it is noted that the claims do not specify the direction of the blood flow into the chamber relative to the outlet. Therefore, the rejection is maintained.

The previous 112 rejections and drawing objections are moot in light of applicant's cancellation of Claims 3-4 and 40-41.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Huong Q NGUYEN whose telephone number is (571)272-8340. The examiner can normally be reached 10 am - 6 pm.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jennifer Robertson can be reached on (571)272-5001. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: https://patentcenter.uspto.gov. Visit https://www.uspto.gov/patents/apply/patent-center for more information about Patent Center and https://www.uspto.gov/patents/docx for information about filing in DOCX format. For additional questions, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H.Q.N/
Examiner, Art Unit 3791

/RENE T TOWA/
Primary Examiner, Art Unit 3791

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-22)
Approved for use through 05/31/2024. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	17893079
	Filing Date	2022-08-22
	First Named Inventor	Gino KANG
	Art Unit	3791
	Examiner Name	NGUYEN, HUONG Q
	Attorney Docket Number	069366-0572192_KUR3C02US

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	4312362		1982-01-26	KAUFMAN JOSEPH	
	2	11744494		2023-09-05	ROGERS BOBBY E	

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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20140163419		2014-06-12	BULLINGTON GREGORY J	
	2	20140309558		2014-10-16	FLETCHER GARY D	
	3	20140073990		2014-03-13	HOLMES ELIZABETH A	
	4	20140323911		2014-10-30	SLOAN DEBORAH	

PC 6.1.24

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /H.Q.N/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	17893079
	Filing Date	2022-08-22
	First Named Inventor	Gino KANG
	Art Unit	3791
	Examiner Name	NGUYEN, HUONG Q
	Attorney Docket Number	069366-0572192_KUR3C02US

	5	20040112808		2004-06-17	TAKAGI YOSHIKI	

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	3	Office Action (Non-Final Rejection) dated 9/17/2024 for U.S. Application No. 18/783,088 ; Attorney Docket No. 069366-0580418_KUR2C06US (pages 1-60).	☐
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	5	Office Action (Final Rejection) dated 11/4/2024 for U.S. Application No. 18/783,173; Attorney Docket No. 069366-0580420_KUR3C03US (pages 1-22).	☐

PC 6.1.24

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	17893079
	Filing Date	2022-08-22
	First Named Inventor	Gino KANG
	Art Unit	3791
	Examiner Name	NGUYEN, HUONG Q
	Attorney Docket Number	069366-0572192_KUR3C02US

	6	Office Action (Non-Final Rejection) dated 09/24/2024 for U.S. Application No. 18/783,173; Attorney Docket No. 069366-0580420_KUR3C03US (pages 1-62).	☐
	7	Office Action (Rejection Decision) dated 11/5/2024 for JP Application No. 2023-076490; Attorney Docket No. 069366-0575273_KUR2D03JP (pages 1-8).	☐
	8	Office Action (Non-Final Rejection) dated 10/22/2024 for U.S. Application No. 18/783,173; Attorney Docket No. 069366-0580420_KUR3C03US (pages 1-62).	☐

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
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Bibliographic data: WO2019055487 (A1) — 2019-03-21

FLUID CONTROL DEVICES AND METHODS OF USING THE SAME

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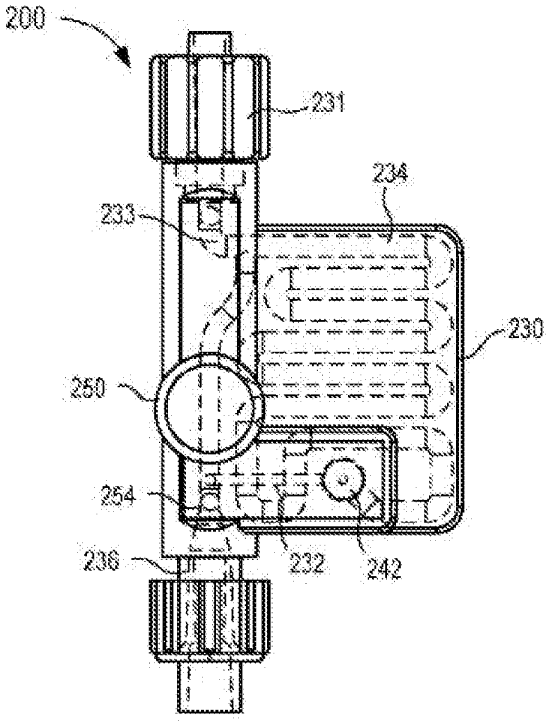
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Abstract of WO2019055487 (A1)

A fluid control device includes an inlet configured to be placed directly or indirectly in fluid communication with a bodily fluid source and an outlet configured to be placed in fluid communication with a fluid collection device. The fluid control device has a first state in which a negative pressure differential produced from an external source such as the fluid collection device is applied to the fluid control device to draw an initial volume of bodily fluid from the bodily fluid source, through the inlet, and into a sequestration portion of the fluid control device. The fluid control device has a second state in which (1) the sequestration portion sequesters the initial volume, and (2) the negative pressure differential draws a subsequent volume of bodily fluid, being substantially free of contaminants, from the bodily fluid source, through the fluid control device, and into the fluid collection device.


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(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, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JO, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

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(54) Title: FLUID CONTROL DEVICES AND METHODS OF USING THE SAME

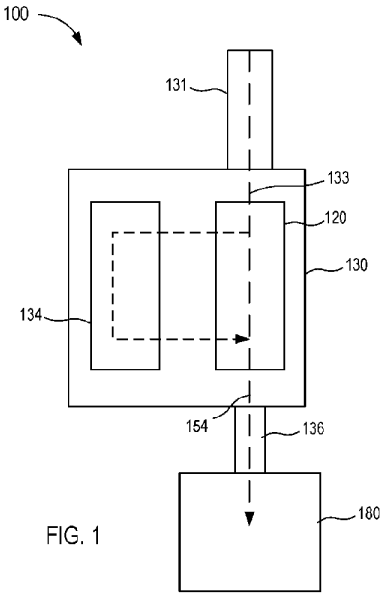


FIG. 1

(57) Abstract: A fluid control device includes an inlet configured to be placed directly or indirectly in fluid communication with a bodily fluid source and an outlet configured to be placed in fluid communication with a fluid collection device. The fluid control device has a first state in which a negative pressure differential produced from an external source such as the fluid collection device is applied to the fluid control device to draw an initial volume of bodily fluid from the bodily fluid source, through the inlet, and into a sequestration portion of the fluid control device. The fluid control device has a second state in which (1) the sequestration portion sequesters the initial volume, and (2) the negative pressure differential draws a subsequent volume of bodily fluid, being substantially free of contaminants, from the bodily fluid source, through the fluid control device, and into the fluid collection device.

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[Continued on next page]

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— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*

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FLUID CONTROL DEVICES AND METHODS OF USING THE SAME

Cross-Reference to Related Applications

[1001] This application claims priority to and the benefit of U.S. Provisional Patent Application Serial No. 62/557,530 entitled, "Fluid Control Devices and Methods of Using the Same," filed September 12, 2017, the disclosure of which is incorporated herein by reference in its entirety.

[1002] This application also claims priority to and the benefit of U.S. Provisional Patent Application Serial No. 62/634,569 entitled, "Fluid Control Devices and Methods of Using the Same," filed February 23, 2018, the disclosure of which is incorporated herein by reference in its entirety.

[1003] This application also claims priority to and the benefit of U.S. Provisional Patent Application Serial No. 62/678,632 entitled, "Fluid Control Devices and Methods of Using the Same," filed May 31, 2018, the disclosure of which is incorporated herein by reference in its entirety.

Background

[1004] The invention relates generally to the parenteral procurement of bodily fluid samples, and more particularly to fluid diversion, sequestration, and/or isolation devices and methods for procuring bodily fluid samples with reduced contaminants such as dermally residing microbes and/or other contaminants exterior to the bodily fluid source.

[1005] Health care practitioners routinely perform various types of microbial as well as other broad diagnostic tests on patients using parenterally obtained bodily fluids. As advanced diagnostic technologies evolve and improve, the speed, accuracy (both sensitivity and specificity), and value of information that can be provided to clinicians continues to improve. Maintaining the integrity of the bodily fluid sample during and/or after collection also ensures that analytical diagnostic results are representative of the in vivo conditions of a patient. Examples of diagnostic technologies that are reliant on high quality, non-contaminated, and/or unadulterated bodily fluid samples include but are not limited to microbial detection, molecular diagnostics, genetic sequencing (e.g., deoxyribonucleic acid (DNA), ribonucleic acid (RNA), next-generation sequencing (NGS), etc.), biomarker identification, and the like. When biological matter, which can include cells external to the intended source for sample procurement, and/or other external contaminants are inadvertently included in the bodily fluid

sample that is to be analyzed, there is an opportunity for inaccurate test results to be derived. In short, when the purity of the sample intended to be derived or collected from a specific bodily fluid source is compromised during the specimen procurement process, resultant analytical test results may be inaccurate, distorted, adulterated, falsely positive, falsely negative, and/or otherwise not representative of the actual condition of the patient, which in turn, can inform faulty, inaccurate, confused, unsure, low-confidence, and/or otherwise undesired clinical decision making.

[1006] In some instances, patient samples (e.g., bodily fluids) are tested for the presence of one or more potentially undesirable microbes, such as bacteria, fungi, or yeast (e.g., Candida). In some instances, microbial testing may include incubating patient samples in one or more sterile and/or non-sterile vessels that may contain culture media, common additives, and/or other types of solutions that are conducive to microbial growth. In other instances, the sample in the vessel may be analyzed directly (i.e., not incubated) and may not contain culture media or additives associated with incubating the specimen. In still other instances, various technologies can be employed to assist in the detection of the presence of microbes as well as other types of biological matter, specific types of cells, biomarkers, proteins, antigens, enzymes, blood components, and/or the like during diagnostic testing. Examples include but are not limited to molecular polymerase chain reaction (PCR), magnetic resonance and other magnetic analytical platforms, automated microscopy, spatial clone isolation, flow cytometry, whole blood ("culture free") specimen analysis (e.g. NGS) and associated technologies, morphokinetic cellular analysis, and/or other common or evolving and advanced technologies utilized in the clinical laboratory environment to characterize patient specimens and/or to detect, identify, type, categorize, and/or characterize specific organisms, antibiotic susceptibilities, and/or the like.

[1007] In some instances, the detection of the presence of microbes includes allowing the microbes and/or organisms to grow for an amount of time (e.g., a variable amount of time from less than an hour to a few hours to several days – which can be longer or shorter depending on the diagnostic technology employed). The microbe and/or organism growth can then be detected by automated, continuous monitoring, and/or other methods specific to the analytical platform and technology used for detection, identification, and/or the like.

[1008] In culture testing, for example, when microbes are present in the patient sample, the microbes flourish over time in the culture medium and, in some instances, automated monitoring technologies can detect carbon dioxide produced by organism growth. The presence of microbes in the culture medium (as indicated by observation of carbon dioxide

and/or via other detection methods) suggests the presence of the same microbes in the patient sample which, in turn, suggests the presence of the same microbes in the bodily fluid of the patient from whom the sample was obtained. Accordingly, when microbes are determined to be present in the culture medium (or more generally in the sample used for testing), the patient may be diagnosed and prescribed one or more antibiotics or other treatments specifically designed to treat or otherwise remove the undesired microbes from the patient.

[1009] Patient samples, however, can become contaminated during procurement and/or otherwise can be susceptible to false positive or false negative results. For example, microbes from a bodily surface (e.g., dermally residing microbes) that are dislodged during the specimen procurement process (which can include needle insertion into a patient, specimen procurement via a lumen-containing device such as a peripheral IV catheter (PIV), a central line (PICC) and/or other indwelling catheter(s), collection with a syringe or any other suitable means employed to collect a patient specimen), either directly or indirectly via tissue fragments, hair follicles, sweat glands, and other skin adnexal structures, can be subsequently transferred to a culture medium, test vial, or other suitable specimen collection or transfer vessel with the patient sample and/or included in the specimen that is to be analyzed for non-culture based testing. Another possible source of contamination is from the person drawing the patient sample (e.g., a doctor, phlebotomist, nurse, technician, etc.). Specifically, equipment, supplies, and/or devices used during a patient sample procurement process often include multiple fluidic interfaces (by way of example, but not limited to, patient to needle, needle to transfer adapter, transfer adapter to sample vessel, catheter hub to syringe, syringe to transfer adapter, needle/tubing to sample vessels, and/or any other fluidic interface or any combination thereof) that can each introduce points of potential contamination. In some instances, such contaminants may thrive in a culture medium and/or may be identified by another non-culture based diagnostic technology and eventually may yield a false positive and/or a false negative microbial test result, which may inaccurately reflect the presence or lack of such microbes within the patient (i.e., in vivo).

[1010] Such inaccurate results because of contamination and/or other sources of adulteration that compromise the purity of the sample are a concern when attempting to diagnose or treat a wide range of suspected illnesses, diseases, infections, patient conditions or other maladies of concern. For example, false negative results from microbial tests may result in a misdiagnosis and/or delayed treatment of a patient illness, which, in some cases, could result in the death of the patient. Conversely, false positive results from microbial tests may result in the patient being unnecessarily subjected to one or more anti-microbial therapies,

which may cause serious side effects to the patient including, for example, death, as well as produce an unnecessary burden and expense to the health care system due to extended length of patient stay and/or other complications associated with erroneous treatments. The use of diagnostic imaging equipment attributable to these false positive results is also a concern from both a cost as well as patient safety perspective as unnecessary exposure to concentrated radiation associated with a variety of imaging procedures (e.g., CT scans) has many known adverse impacts on long-term patient health.

[1011] In some instances, devices and/or systems can be used to reduce the likelihood of contamination, adulteration, and/or the like of bodily fluid samples for testing. For example, some known devices can be configured to collect, divert, separate, and/or isolate or sequester an initial volume of bodily fluid that may be more likely to contain contaminants such as dermally residing microbes or the like. Some such devices, however, can be cumbersome, non-intuitive, perceived as difficult to use, inappropriate or unusable as intended for the target patient population, etc. In addition, some such devices can require training, user observation, intervention by more than one user, and/or can otherwise present challenges that can lead to limited efficacy based on variables including environmental, educational, clinician skill, patient condition, and/or the like. In some instances, such challenges can complicate the collection of consistently high quality samples that are non-contaminated, sterile, unadulterated, etc., which in turn, can impact the validity of test result outcomes.

[1012] On the other hand, some known passive diversion devices and/or systems (e.g., systems that do not specifically utilize or rely on direct user intervention, interaction, manipulation, and/or the like) may fail to adequately divert, sequester, and/or isolate a clinically desired and efficacious pre-sample volume of bodily fluid due to clinical realities such as, for example, the time required to fill a sequestration reservoir with a meaningful volume of fluid. In some instances, the operation of some known passive devices is dependent on a positive pressure applied by a bodily fluid source (e.g., a patient's blood pressure). The positive pressure applied by the bodily fluid source, however, may be insufficient to result in flow dynamics and/or flow rates that makes use of such devices practical in various clinical settings (including emergency rooms and other intensive settings). For example, the patient population with symptoms requiring diagnostic testing noted above commonly are in such physical condition that attaining vascular access and/or collection of bodily fluid samples can be difficult due to a hypotensive state (i.e., low blood pressure), hypovolemic state (i.e., low blood volume), and/or other physical challenges (e.g., severe dehydration, obesity, difficult and/or inaccessible vasculature, etc.). Such states or physical conditions can result in difficulty

in providing sufficient blood flow and/or pressure to achieve passive filling of a sequestration chamber, channel, reservoir, container (or other diversion volume) consistently with sufficient volume to meet clinically validated, evidence-based efficacy and results in diverting, sequestering, and/or isolating contaminants which otherwise can lead to distorted, inaccurate, falsely positive, falsely negative, and/or otherwise adulterated diagnostic test results. The challenges associated with this approach (e.g., relying on a positive pressure differential applied by the bodily fluid source without utilizing a specific external energy source and/or negative pressure to facilitate collection of an appropriate and clinically efficacious initial volume of bodily fluid) can render it impractical as failure rates can be unacceptably high for the fragile patient population from whom these samples are collected.

[1013] As such, a need exists for fluid diversion devices and methods for procuring bodily fluid samples with reduced contaminants such as dermally residing microbes and/or other contaminants exterior to the bodily fluid source that result in consistent bodily fluid collection (e.g., from a general patient population and/or a challenging patient population). Some such devices and methods can include, for example, bodily fluid collection with the assistance of various sources of external energy and/or negative pressure. Furthermore, a need exists for such devices that are user-friendly, demonstrate consistent efficacy, and address the challenges associated with collecting samples from patients with challenging health circumstances and/or physical characteristics that impact the ability to collect bodily fluid samples.

Summary

[1014] Devices and methods for procuring bodily fluid samples with reduced contaminants such as dermally residing microbes and/or other contaminants exterior to the bodily fluid source are described herein. In some embodiments, a system includes a housing, a flow controller, and a fluid collection device. The housing has an inlet and an outlet, and forms a sequestration portion. The inlet is configured to be placed in fluid communication with a bodily fluid source. The sequestration portion is configured to receive an initial volume of bodily fluid from the bodily fluid source. The flow controller is at least partially disposed in the sequestration portion of the housing and is configured to transition from a first state to a second state. The fluid collection device is configured to be fluidically coupled to the outlet to produce a negative pressure differential within at least a portion of the housing. The negative pressure differential is operable to draw the initial volume of bodily fluid into the sequestration portion when the flow controller is in the first state and is operable to draw the sample volume of bodily

fluid through the outlet and into the fluid collection device when the flow controller is in the second state.

Brief Description of the Drawings

[1015] FIG. 1 is a schematic illustration of a fluid control device according to an embodiment.

[1016] FIGS. 2-5 are various views of a fluid control device according to an embodiment.

[1017] FIGS. 6-8 are various views of a fluid control device according to an embodiment.

[1018] FIGS. 9 and 10 are front view illustrations of a fluid control device in a first operating mode and a second operating mode, respectively, according to an embodiment.

[1019] FIGS. 11 and 12 are front view illustrations of a fluid control device in a first operating mode and a second operating mode, respectively, according to an embodiment.

[1020] FIGS. 13-15B are various views of a fluid control device according to an embodiment.

[1021] FIGS. 16-18 are various views of a fluid control device according to an embodiment.

[1022] FIGS. 19-25 are various views of a fluid control device according to an embodiment.

[1023] FIGS. 26-28 are each a perspective view of a fluid control device according to different embodiments.

[1024] FIGS. 29-34 are various views of a fluid control device according to an embodiment.

[1025] FIGS. 35-40 are various views of a fluid control device according to an embodiment.

[1026] FIGS. 41-44 are various views of a fluid control device according to an embodiment.

[1027] FIGS. 45-50 are various views of a fluid control device according to an embodiment.

[1028] FIGS. 51 and 52 are cross-sectional views of a fluid control device according to an embodiment.

[1029] FIG. 53 is a flowchart illustrating a method of using a fluid control device according to an embodiment.

Detailed Description

[1030] Devices and methods for collecting, diverting, sequestering, isolating, etc. an initial volume of bodily fluid to reduce contamination in subsequently procured bodily fluid samples are described herein. Any of the fluid control devices described herein can be configured to receive, procure, and/or transfer a flow, bolus, volume, etc., of bodily fluid. A first reservoir, channel, flow path, or portion of the device can receive an initial amount of the bodily fluid flow, which then can be substantially or fully sequestered (e.g., contained or retained, circumvented, isolated, segregated, vapor-locked, separated, and/or the like) in or by the first reservoir or first portion of the device. In some instances, contaminants such as dermally residing microbes or the like can be included and/or entrained in the initial amount of the bodily fluid and likewise are sequestered in or by the first reservoir or first portion of the device. Once the initial amount is sequestered, any subsequent amount of the bodily fluid flow can be diverted, channeled, directed, flow controlled (e.g., manually, automatically, and/or semi-automatically) to a second reservoir, second portion of the device, and/or any additional flow path(s). Thus, with the initial amount sequestered, any additional and/or subsequent amount(s) of bodily fluid flow are substantially free from contaminants that may otherwise produce inaccurate, distorted, adulterated, falsely positive, falsely negative, etc., results in some diagnostics and/or testing. In some instances, the initial amount of bodily fluid also can be used, for example, in other testing such as those less affected by the presence of contaminants, can be discarded as a waste volume, can be infused back into the patient, and/or can be used for any other suitable clinical application.

[1031] In some embodiments, a feature of the fluid control devices and/or methods described herein is the use of an external negative pressure source (e.g., provided by a fluid collection device or any other suitable means) to (1) overcome physical patient challenges which can limit and/or prevent a sufficient pressure differential (e.g., a differential in blood pressure to ambient air pressure) to fully engage the sequestration chamber and/or to transition fluid flow to the fluid collection device; (2) result in proper filling of the sequestration chamber with a clinically validated and/or desirable volume of bodily fluid; (3) result in efficient, timely, and/or user-accepted consistency with bodily fluid collection process; and/or (4) provide a means of manipulating and/or automatically transitioning fluid flow (e.g., movement of physical components of the system or changing, switching, engaging, and/or otherwise employing or achieving desired fluid flow dynamics) to enable sequestration and/or isolation of the initial sample and collection of a subsequent sample.

[1032] In some embodiments, a fluid control device includes an inlet and an outlet. The inlet is configured to be placed in fluid communication with a bodily fluid source or an intermediary bodily fluid transfer device and the outlet is configured to be placed in fluid communication with a fluid collection device such as, for example, a sample reservoir, a syringe, a lumen-containing device, and/or any other suitable bodily fluid collection and/or transfer device. The fluid control device has a first state in which a negative pressure differential produced from an external source (e.g., the fluid collection device such as a sample reservoir, a syringe, a vessel, and/or any suitable intermediary fluid reservoir) is applied to the fluid control device to draw an initial volume of bodily fluid from the bodily fluid source, through the inlet, and into a sequestration and/or diversion portion of the fluid control device (which can be formed by or in the fluid control device or coupled thereto). The fluid control device has a second state in which (1) the sequestration chamber sequesters the initial volume, and (2) the negative pressure differential draws a subsequent volume of bodily fluid, being substantially free of contaminants, from the bodily fluid source, through the fluid control device, and into the fluid collection device.

[1033] In some embodiments, a system includes a housing, a flow controller, and a fluid collection device. The housing has an inlet and an outlet, and forms a sequestration portion. The inlet is configured to be placed in fluid communication with a bodily fluid source. The sequestration portion is configured to receive an initial volume of bodily fluid from the bodily fluid source. The flow controller is at least partially disposed in the sequestration portion of the housing and is configured to transition from a first state to a second state. The fluid collection device is configured to be fluidically coupled to the outlet to produce a negative pressure differential within at least a portion of the housing. The negative pressure differential is operable to draw the initial volume of bodily fluid into the sequestration portion when the flow controller is in the first state and is operable to draw the sample volume of bodily fluid through the outlet and into the fluid collection device when the flow controller is in the second state.

[1034] In some embodiments, an apparatus includes a housing and an actuator coupled to the housing. The housing has an inlet configured to be placed in fluid communication with a bodily fluid source and an outlet configured be placed in fluid communication with a fluid collection device. The housing forms a sequestration portion that is configured to receive an initial volume of bodily fluid from the bodily fluid source. The actuator has a first configuration in which a first fluid flow path places the inlet in fluid communication with the sequestration portion and a second configuration in which a second fluid flow path places the

inlet in fluid communication with the outlet. The fluid collection device is configured to be placed in fluid communication with the outlet to produce a negative pressure differential (1) within the first fluid flow path that is operable to draw the initial volume of bodily fluid into the sequestration portion when the actuator is in the first configuration, and (2) within the second fluid flow path that is operable to draw a sample volume of bodily fluid into the fluid collection device when the actuator is in the second configuration.

[1035] In some embodiments, a method of using a fluid control device to obtain a bodily fluid sample with reduced contamination includes establishing fluid communication between a bodily fluid source and an inlet of the fluid control device. A fluid collection device is coupled to an outlet of the fluid control device and is configured to produce a negative pressure differential within at least a portion of the fluid control device. An initial volume of bodily fluid is received from the inlet and into a sequestration portion of the fluid control device in response to the negative pressure differential. In response to contact with a portion of the initial volume of bodily fluid, a flow controller disposed in the sequestration portion is transitioned from a first state in which the flow controller allows a flow of a gas through the flow controller and prevents a flow of bodily fluid through the flow controller, to a second state in which the flow controller prevents a flow of gas and bodily fluid through the flow controller. The initial volume of bodily fluid is sequestered in the sequestration portion after the flow controller is transitioned to the second state and a subsequent volume of bodily fluid is transferred from the inlet to an outlet in fluid communication with a fluid collection device.

[1036] As used in this specification and the claims, the singular forms "a," "an" and "the" include plural referents unless the context clearly dictates otherwise. Thus, for example, the term "a member" is intended to mean a single member or a combination of members, "a material" is intended to mean one or more materials, or a combination thereof.

[1037] As used herein, the terms "about," "approximate," and/or "substantially" when used in connection with stated value and/or other geometric relationships is intended to convey that the structure so defined is nominally the value stated and/or the geometric relationship described. In some instances, the terms "about," "approximately," and/or "substantially" can generally mean and/or can generally contemplate plus or minus 10% of the value or relationship stated. For example, about 0.01 would include 0.009 and 0.011, about 0.5 would include 0.45 and 0.55, about 10 would include 9 to 11, and about 1000 would include 900 to 1100. While a value stated may be desirable, it should be understood that some variance may occur as a result of, for example, manufacturing tolerances or other practical considerations (such as, for example, the pressure or force applied through a portion of a device, conduit,

lumen, etc.). Accordingly, the terms "about," "approximately," and/or "substantially" can be used herein to account for such tolerances and/or considerations.

[1038] As used herein, "bodily fluid" can include any fluid obtained directly or indirectly from a body of a patient. For example, "bodily fluid" includes, but is not limited to, blood, cerebrospinal fluid, urine, bile, lymph, saliva, synovial fluid, serous fluid, pleural fluid, amniotic fluid, mucus, sputum, vitreous, air, and the like, or any combination thereof.

[1039] As used herein, the words "proximal" and "distal" refer to the direction closer to and away from, respectively, a user who would place the device into contact with a patient. Thus, for example, the end of a device first touching the body of the patient would be the distal end, while the opposite end of the device (e.g., the end of the device being manipulated by the user) would be the proximal end of the device.

[1040] As described in further detail herein, any of the devices and methods can be used to procure bodily fluid samples with reduced contamination by, for example, diverting a "pre-sample" volume of bodily fluid prior to collecting a "sample" volume of bodily fluid. Each of the terms "pre-sample," "first," and/or "initial," can be used interchangeably to describe and/or refer to an amount, portion, or volume of bodily fluid that is transferred, diverted, and/or sequestered prior to procuring the "sample" volume. In some embodiments, the terms "pre-sample," "first," and/or "initial" can refer to a predetermined, defined, desired, or given volume, portion, or amount of bodily fluid. For example, in some embodiments, a predetermined and/or desired pre-sample volume of bodily fluid can be about 0.1 milliliter (mL), about 0.2 mL, about 0.3 mL, about 0.4 mL, about 0.5 mL, about 1.0 mL, about 2.0 mL, about 3.0 mL, about 4.0 mL, about 5.0 mL, about 10.0 mL, about 20 mL, about 50 mL, and/or any volume or fraction of a volume therebetween. In other embodiments, the pre-sample volume can be greater than 50 mL or less than 0.1 mL. In some specific embodiments, a predetermined and/or desired pre-sample volume can be between about 0.1 mL and about 5.0 mL. In other embodiments, the pre-sample volume can be, for example, a drop of bodily fluid, a few drops of bodily fluid, a combined volume of any number of lumen that form, for example, a flow path (or portion thereof) from the bodily fluid source to an initial collection chamber, portion, reservoir, etc. (e.g., a sequestration chamber).

[1041] On the other hand, the terms "sample," "second," and/or "subsequent" when used in the context of a volume of bodily fluid can refer to a volume, portion, or amount of bodily fluid that is either a random volume or a predetermined or desired volume of bodily fluid collected after transferring, diverting, sequestering, and/or isolating the pre-sample volume of bodily fluid. For example, in some embodiments, a desired sample volume of bodily fluid can

be about 10 mL to about 60 mL. In other embodiments, a desired sample volume of bodily fluid can be less than 10 mL or greater than 60 mL. In some embodiments, for example, a sample volume can be at least partially based on one or more tests, assays, analyses, and/or processes to be performed on the sample volume.

[1042] The embodiments described herein can be configured to selectively transfer bodily fluid to one or more fluid collection device(s). In some embodiments, a fluid collection device can include, but is not limited to, any suitable vessel, container, reservoir, bottle, adapter, dish, vial, syringe, device, diagnostic and/or testing machine, and/or the like. By way of specific example, in some instances, any of the embodiments and/or methods described herein can be used to transfer a sample volume into a sample reservoir such as any of those described in detail in U.S. Patent No. 8,197,420 entitled, "Systems and Methods for Parenterally Procuring Bodily-Fluid Samples with Reduced Contamination," filed December 13, 2007 ("the '420 Patent"), the disclosure of which is incorporated herein by reference in its entirety.

[1043] In some embodiments, a sample reservoir can be a sample or culture bottle such as, for example, an aerobic culture bottle or an anaerobic culture bottle. In this manner, the culture bottle can receive a bodily fluid sample, which can then be tested (e.g., via in vitro diagnostic (IVD) tests, and/or any other suitable test) for the presence of, for example, Gram-Positive bacteria, Gram-Negative bacteria, yeast, fungi, and/or any other organism. In some instances, the culture bottle can receive a bodily fluid sample and the culture medium (disposed therein) can be tested for the presence of any suitable organism. If such a test of the culture medium yields a positive result, the culture medium can be subsequently tested using a PCR-based system to identify a specific organism. Moreover, as described in further detail herein, in some instances, diverting a pre-sample or initial volume of bodily fluid can reduce and/or substantially eliminate contaminants in the bodily fluid sample that may otherwise lead to inaccurate test results.

[1044] Any of the sample containers, reservoirs, bottles, dishes, vials, etc., described herein can be devoid of contents prior to receiving a sample volume of bodily fluid or can include, for example, any suitable additive, culture medium, substances, enzymes, oils, fluids, and/or the like. For example, in some embodiments, a sample reservoir can include an aerobic or anaerobic culture medium (e.g., a nutrient rich and/or environmentally controlled medium to promote growth, and/or other suitable medium(s)), which occupies at least a portion of the inner volume defined by the sample reservoir. In some embodiments, a sample reservoir can include, for example, any suitable additive or the like such as, heparin, citrate, ethylenediaminetetraacetic acid (EDTA), oxalate, SPS, and/or the like, which similarly

occupies at least a portion of the inner volume defined by the sample reservoir. In other embodiments, a sample reservoir can be any suitable container used to collect a specimen.

[1045] While the term "culture medium" can be used to describe a substance configured to react with organisms in a bodily fluid (e.g., microorganisms such as bacteria) and the term "additive" can be used to describe a substance configured to react with portions of the bodily fluid (e.g., constituent cells of blood, serum, synovial fluid, etc.), it should be understood that a sample reservoir can include any suitable substance, liquid, solid, powder, lyophilized compound, gas, etc. Moreover, when referring to an "additive" within a sample reservoir, it should be understood that the additive could be a culture medium, such as an aerobic culture medium and/or an anaerobic culture medium contained in a culture bottle, an additive and/or any other suitable substance or combination of substances contained in a culture bottle and/or any other suitable reservoir such as those described above. That is to say, the embodiments described herein can be used with any suitable fluid reservoir or the like containing any suitable substance. Furthermore, any of the embodiments and/or methods described herein can be used to transfer a volume of bodily fluid to a reservoir (or the like) that does not contain a culture medium, additive, and/or any other substance prior to receiving a flow of bodily fluid.

[1046] While some of the embodiments are described herein as being used for procuring bodily fluid for one or more culture sample testing, it should be understood that the embodiments are not limited to such a use. Any of the embodiments and/or methods described herein can be used to transfer a flow of bodily fluid to any suitable device that is placed in fluid communication therewith. Thus, while specific examples are described herein, the devices, methods, and/or concepts are not intended to be limited to such specific examples.

[1047] The embodiments described herein and/or portions thereof can be formed or constructed of one or more biocompatible materials. In some embodiments, the biocompatible materials can be selected based on one or more properties of the constituent material such as, for example, stiffness, toughness, durometer, bioreactivity, etc. Examples of suitable biocompatible materials include metals, glasses, ceramics, or polymers. Examples of suitable metals include pharmaceutical grade stainless steel, gold, titanium, nickel, iron, platinum, tin, chromium, copper, and/or alloys thereof. A polymer material may be biodegradable or non-biodegradable. Examples of suitable biodegradable polymers include polylactides, polyglycolides, polylactide-co-glycolides (PLGA), polyanhydrides, polyorthoesters, polyetheresters, polycaprolactones, polyesteramides, poly(butyric acid), poly(valeric acid), polyurethanes, and/or blends and copolymers thereof. Examples of non-biodegradable polymers include nylons, polyesters, polycarbonates, polyacrylates, polymers of ethylene-vinyl

acetates and other acyl substituted cellulose acetates, non-degradable polyurethanes, polystyrenes, polyvinyl chloride, polyvinyl fluoride, poly(vinyl imidazole), chlorosulphonate polyolefins, polyethylene oxide, and/or blends and copolymers thereof.

[1048] The embodiments described herein and/or portions thereof can include components formed of one or more parts, features, structures, etc. When referring to such components it should be understood that the components can be formed by a singular part having any number of sections, regions, portions, and/or characteristics, or can be formed by multiple parts or features. For example, when referring to a structure such as a wall or chamber, the structure can be considered as a single structure with multiple portions, or multiple, distinct substructures or the like coupled to form the structure. Thus, a monolithically constructed structure can include, for example, a set of substructures. Such a set of substructures may include multiple portions that are either continuous or discontinuous from each other. A set of substructures can also be fabricated from multiple items or components that are produced separately and are later joined together (e.g., via a weld, an adhesive, or any suitable method).

[1049] Referring now to the drawings, FIG. 1 is a schematic illustration of a fluid control device 100 according to an embodiment. Generally, the fluid control device 100 (also referred to herein as "control device" or "device") is configured to withdraw bodily fluid from a patient. A first portion or amount (e.g., an initial amount) of the withdrawn bodily fluid is sequestered from a second portion or amount (e.g., a subsequent amount) of the withdrawn bodily fluid which can be subsequently used for additional testing, discarded, and/or reinfused into the patient. In this manner, contaminants or the like can be sequestered within the first portion or amount, leaving the second portion or amount substantially free of contaminants. The second portion or amount of bodily fluid can then be used as a biological sample in one or more tests for the purpose of medical diagnosis and/or treatment (e.g., a blood culture test or the like), as described in more detail herein. The first portion or amount of bodily fluid can be discarded as waste or can be used in any suitable test that is less likely to produce false, inaccurate, distorted, inconsistent, and unreliable results as a result of potential contaminants contained therein. In other instances, the first portion or amount of bodily fluid can be infused back into the patient.

[1050] The control device 100 includes a housing 130 that has and/or forms an inlet 131, at least one outlet 136, and a sequestration chamber 134. The inlet 131 is configured to fluidically couple to a lumen-containing device, which in turn, can place the housing 130 in fluid communication with a bodily fluid source. For example, the housing 130 can be coupled to and/or can include a lumen-containing device that is in fluid communication with the inlet

131 and that is configured to be percutaneously disposed in a patient (e.g., a butterfly needle, intravenous (IV) catheter, peripherally inserted central catheter (PICC), syringe, sterile tubing, intermediary lumen-containing device, and/or bodily-fluid transfer device or the like). Thus, bodily fluid can be transferred from the patient and/or other bodily fluid source to the housing 130 via the inlet 131, as described in further detail herein. The outlet(s) 136 can be placed in fluid communication with a fluid collection device 180 (e.g., a fluid or sample reservoir, syringe, evacuated container, etc.). As such, the control device 100 can be used and/or manipulated to selectively transfer a volume of bodily fluid from a bodily fluid source, through the inlet 131, the housing 130, and the outlet(s) 136 to the fluid collection device 180, as described in further detail herein.

[1051] The housing 130 defines one or more fluid flow paths 133 between the inlet 131 and the sequestration chamber 134 and/or one or more fluid flow paths 154 between the inlet 131 and the outlet 136. The housing 130 of the device 100 can be any suitable shape, size, and/or configuration. For example, in some embodiments, the housing 130 can have a size that is at least partially based on a volume of bodily fluid at least temporarily stored, for example, in the sequestration chamber 134. As described in further detail herein, the control device 100 and/or the housing 130 can be configured to transition between operating modes such that bodily fluid flows through at least one of the fluid flow paths 133 and/or 154. Moreover, the control device 100 and/or the housing 130 can be configured to transition automatically (e.g., based on pressure differential, time, electronically, saturation of a membrane, an absorbent and/or barrier material, etc.) or via intervention (e.g., user intervention, mechanical intervention, or the like).

[1052] The sequestration chamber 134 is at least temporarily placed in fluid communication with the inlet 131 via the fluid flow path(s) 133. As described in further detail herein, the sequestration chamber 134 is configured to (1) receive a flow and/or volume of bodily fluid from the inlet 131 and (2) sequester (e.g., separate, segregate, contain, retain, isolate, etc.) the flow and/or volume of bodily fluid therein. The sequestration chamber 134 can have any suitable arrangement such as, for example, those described herein with respect to specific embodiments. It should be understood, however, that the control device 100 and/or the housing 130 can have a sequestration chamber 134 in any suitable arrangement and is not intended to be limited to those shown and described herein. For example, in some embodiments, the sequestration chamber 134 can be at least partially formed by the housing 130. In other embodiments, the sequestration chamber 134 can be a reservoir placed and/or disposed within a portion of the housing 130. In other embodiments, the sequestration chamber

134 can be formed and/or defined by a portion of the fluid flow path 133. That is to say, the housing 130 can define one or more lumens and/or can include one or more lumen defining device(s) configured to receive a flow of bodily fluid from the inlet 131, thereby defining the fluid flow path 133. In such embodiments, at least a portion of the lumen and/or a portion of the lumen defining device(s) can form and/or can define the sequestration chamber 134.

[1053] The sequestration chamber 134 can have any suitable volume and/or fluid capacity. For example, in some embodiments, the sequestration chamber 134 can have a volume and/or fluid capacity between about 0.25 mL and about 5.0 mL. In some embodiments, the sequestration chamber 134 can have a volume measured in terms of an amount of bodily fluid (e.g., the initial or first amount of bodily fluid) configured to be transferred in the sequestration chamber 134. For example, in some embodiments, the sequestration chamber 134 can have a volume sufficient to receive an initial volume of bodily fluid as small as a microliter or less of bodily fluid (e.g., a volume as small as 20 drops of bodily fluid, 10 drops of bodily fluid, 5 drops of bodily fluid, a single drop of bodily fluid, or any suitable volume therebetween). In other embodiments, the sequestration chamber 134 can have a volume sufficient to receive an initial volume of bodily fluid up to, for example, about 5.0 mL, 10.0 mL, 15 mL, 20 mL, 30 mL, 40 mL, 50 mL, or more. In some embodiments, the sequestration chamber 134 can have a volume that is equal to a fraction of and/or a multiple of at least some of the volumes of one or more lumen(s) placing the sequestration chamber 134 in fluid communication with the bodily fluid source.

[1054] Although not shown in FIG. 1, in some embodiments, the sequestration chamber 134 can include any suitable arrangement, configuration, and/or feature, and/or can be formed of one or more materials configured to interact with a portion of the bodily fluid transferred into the sequestration chamber 134. For example, in some embodiments, the housing 130 can include an absorbent and/or hydrophilic material disposed within the sequestration chamber 134. Accordingly, when bodily fluid is transferred into the sequestration chamber 134, the absorbent and/or hydrophilic material can absorb, attract, retain, expand, and/or otherwise interact with at least a portion of the bodily fluid, which in turn, can sequester and/or retain at least an initial portion of the bodily fluid within the sequestration chamber 134, as described in further detail herein. In other embodiments, the sequestration chamber 134 can include and/or can be formed of an expandable or collapsible material configured to transition between a first state (e.g., while an initial portion of the bodily fluid is being transferred into the sequestration chamber 134) to a second state (e.g., after the initial portion of the bodily fluid is transferred into the sequestration chamber 134). In some embodiments, a force associated with and/or

resulting from such a material expanding or collapsing can be operable to transition the housing 130 and/or the device 100 from a first state, position, configuration, etc. to a second state, position, configuration, etc. In some embodiments, the sequestration chamber 134 and/or any other suitable portion of the housing 130 can include one or more chemicals, compounds, and/or the like configured to chemically interact with bodily fluid transferred through a portion of the housing 130, which can be operable to transition the control device 100 and/or the housing 130 between the first state and the second state (e.g., via a force or any other suitable means).

[1055] In some embodiments, the control device 100 and/or the housing 130 can include and/or define a flow controller 120 configured to selectively control a flow of fluids (e.g., gas or liquids) through a portion of the control device 100. For example, in some embodiments, the flow controller 120 can control a flow of bodily fluid through the control device 100 (or housing 130) and/or otherwise selectively control a flow of bodily fluid through at least one of the fluid flow paths 133 and/or 154. The flow controller 120 can be, for example, a valve, a membrane, a diaphragm, a restrictor, a vent, a selectively permeable member (e.g., a fluid impermeable barrier or seal that at least selectively allows the passage of air or gas therethrough), a port, a junction, an actuator, and/or the like, or any suitable combination thereof. In some embodiments, the flow controller 120 can be configured to selectively control (at least in part) a flow of fluids into and/or out of the sequestration chamber 134 and/or any other suitable portion of the housing 130. In this context, the flow of fluids, for example, can be a liquid such as water, oil, dampening fluid, bodily fluid, and/or any other suitable liquid, and/or can be a gas such as air, oxygen, carbon dioxide, helium, nitrogen, ethylene oxide, and/or any other suitable gas. For example, in some embodiments, a wall or structure of the housing 130 can define an opening, aperture, port, orifice, and/or the like that is in fluid communication with the sequestration chamber 134. In such embodiments, the flow controller 120 can be, for example, a semi-permeable member or membrane disposed in or about the opening to selectively allow a flow of air or gas through the opening while limiting or substantially preventing a flow of fluid (e.g., bodily fluid such as blood) through the opening.

[1056] In some embodiments, one or more flow controllers 120 or the like can be configured to facilitate air (or other fluid) displacement through one or more portions of the control device 100, which in some instances, can result in a pressure differential across one or more portions of the control device 100 or can result in and/or allow for a pressure equalization across one or more portions of the housing 130. In some embodiments, the control device 100 can be configured to selectively transfer a volume of bodily fluid to the sequestration chamber

134 or to the outlet 136 based at least in part on a pressure differential between two or more portions of the control device 100. In some embodiments, the pressure differential can result from fluidically coupling the outlet 136 to the fluid collection device 180, which can define and/or can be configured to produce a negative pressure (e.g., an evacuated reservoir, a syringe, a pressure charged canister, and/or other source or potential energy to create a vacuum or pressure differential). In other embodiments, the pressure differential can result from a change in volume and/or temperature. In still other embodiments, the pressure differential can result from at least a portion of the control device 100, the housing 130, and/or other portions of the flow path being evacuated and/or charged (e.g., the sequestration chamber 134 and/or any other suitable portion). In some embodiments, the pressure differential can be established automatically or via direct or indirect intervention (e.g., by the user).

[1057] Moreover, a flow of a fluid (e.g., gas and/or liquid) resulting from a pressure differential can be selectively controlled via one or more flow controllers 120 that can, for example, transition between one or more operating conditions to control the fluid flow. In some embodiments, for example, the flow controller 120 can be an actuator or the like configured to transition between one or more operating conditions or states to establish fluid communication between one or more portions of the control device 100 and/or configured to sequester one or more portions of the control device 100 (e.g., the sequestration chamber 134). In some embodiments, the flow controller 120 can be member or device formed of an absorbent material configured to selectively allow fluid flow therethrough. For example, such an absorbent material can be transitioned from a first state in which the material allows a flow of gas (e.g., air) therethrough but prevents a flow of liquid (e.g., bodily fluid) therethrough, to a second state in which the material substantially prevents a flow of gas and liquid therethrough. In other embodiments, the flow controller 120 can include one or more valves, membranes, diaphragms, and/or the like. In some embodiments, the flow controller 120 can include any suitable combination of devices, members, and/or features. It should be understood that the flow controllers included in the embodiments described herein are presented by way of example and not limitation. Thus, while specific flow controllers are described herein, it should be understood that fluid flow can be controlled through the control device 100 by any suitable means.

[1058] The outlet(s) 136 is/are in fluid communication with and/or is/are configured to be placed in fluid communication with the fluid flow paths 133 and/or 154. As shown in FIG. 1, the outlet 136 can be any suitable outlet, opening, port, stopcock, lock, seal, coupler, valve (e.g. one-way, check valve, duckbill valve, umbrella valve, and/or the like), etc. and is configured

to be fluidically coupled to the fluid collection device 180 (e.g., a fluid reservoir, culture sample bottle, syringe, container, vial, dish, receptacle, pump, adapter, and/or any other suitable collection or transfer device). In some embodiments, the outlet 136 can be monolithically formed with the fluid collection device 180. In other embodiments, the outlet 136 can be at least temporarily coupled to the fluid collection device 180 via an adhesive, a resistance fit, a mechanical fastener, a threaded coupling, a piercing or puncturing arrangement, any number of mating recesses, and/or any other suitable coupling or combination thereof. Similarly stated, the outlet 136 can be physically (e.g., mechanically) and/or fluidically coupled to the fluid collection device 180 such that an interior volume defined by the fluid collection device 180 is in fluid communication with the outlet 136. In still other embodiments, the outlet 136 can be operably coupled to the fluid collection device 180 via an intervening structure (not shown in FIG. 1), such as a flexible sterile tubing. In some embodiments, the arrangement of the outlet 136 can be such that the outlet 136 is physically and/or fluidically sealed prior to coupling to the fluid collection device 180. In some embodiments, the outlet 136 can be transitioned from a sealed configuration to an unsealed configuration in response to being coupled to the fluid collection device 180 and/or in response to a negative pressure differential between an environment within the outlet 136 and/or housing 130 and an environment within the fluid collection device 180.

[1059] The fluid collection device 180 can be any suitable device for at least temporarily containing a bodily fluid, such as, for example, any of those described in detail above. For example, in some embodiments, the fluid collection device 180 can be a single-use disposable collection tube(s), a syringe, a vacuum-based collection tube(s), an intermediary bodily-fluid transfer device, and/or the like. In some embodiments, the fluid collection device 180 can be substantially similar to or the same as known sample containers such as, for example, a Vacutainer® (manufactured by BD), a BacT/ALERT ® SN or BacT/ALERT ® FA (manufactured by Biomerieux, Inc.), and/or any suitable reservoir, vial, microvial, microliter vial, nanoliter vial, container, microcontainer, nanocontainer, and/or the like. In some embodiments, the fluid collection device 180 can be a sample reservoir that includes a vacuum seal that maintains negative pressure conditions (vacuum conditions) inside the sample reservoir, which in turn, can facilitate withdrawal of bodily fluid from the patient, through the control device 100, and into the sample reservoir, via a vacuum or suction force, as described in further detail herein. In embodiments in which the fluid collection device 180 is an evacuated container or the like, the user can couple the fluid collection device 180 to the outlet 136 to initiate a flow of bodily fluid from the patient such that a first or initial portion of the

bodily fluid is transferred into and sequestered by the sequestration chamber 134 and such that any subsequent portion or volume of bodily fluid bypasses and/or is otherwise diverted away from the sequestration chamber 134 and flows into the fluid collection device 180, as described in further detail herein.

[1060] Although the outlet 136 of the control device 100 and/or the housing 130 is described above as being fluidically coupled to and/or otherwise placed in fluid communication with the fluid collection device 180, in other embodiments, the control device 100 can be used in conjunction with any suitable bodily fluid collection device and/or system. For example, in some embodiments, the control device 100 described herein can be used in any suitable fluid transfer device such as those described in U.S. Patent Publication No. 2015/0342510 entitled, "Sterile Bodily-Fluid Collection Device and Methods," filed June 2, 2015 (referred to herein as the "'510 publication"), the disclosure of which is incorporated herein by reference in its entirety. More particularly, the control device 100 can be used in an "all-in-one" or pre-assembled device (e.g., such as those described in the '510 publication) to receive and sequester an initial volume of bodily fluid such that contaminants in subsequent volumes of bodily fluid are reduced and/or eliminated.

[1061] As described above, the device 100 can be used to procure a bodily fluid sample having reduced contamination from microbes such as, for example, dermally residing microbes, and/or the like. For example, in some instances, a user such as a doctor, physician, nurse, phlebotomist, technician, etc. can manipulate the device 100 to establish fluid communication between the inlet 131 and the bodily fluid source (e.g., a vein of a patient, cerebral spinal fluid (CSF) from the spinal cavity, urine collection, and/or the like). As a specific example, in some instances, the inlet 131 can be coupled to and/or can include a needle or the like that can be manipulated to puncture the skin of the patient and to insert at least a portion of the needle in the vein of the patient, thereby placing the inlet 131 in fluid communication with the bodily fluid source (e.g., the vein, an IV catheter, a PICC, etc.).

[1062] In some embodiments, once the inlet 131 is placed in fluid communication with the bodily fluid source (e.g., the portion of the patient), the outlet 136 can be fluidically coupled to the fluid collection device 180. As described above, in some embodiments, the fluid collection device 180 can be any suitable reservoir, container, and/or device configured to receive a volume of bodily fluid. For example, the fluid collection device 180 can be an evacuated reservoir or container that defines a negative pressure and/or can be a syringe that can be manipulated to produce a negative pressure. In some instances, coupling the outlet 136 to the fluid collection device 180 selectively exposes at least a portion of the fluid flow paths 133

and/or 154 to the negative pressure, thereby resulting in a negative pressure differential operable in drawing bodily fluid from the bodily fluid source (e.g., the patient), through the inlet 131, and into the housing 130.

[1063] In some embodiments, the arrangement of the housing 130 is such that when a volume of bodily fluid is transferred to and/or through the inlet 131, an initial portion of the volume of bodily fluid (also referred to herein as an "initial volume" or a "first volume") flows from the inlet 131, through at least a portion of the fluid flow path 133, and into the sequestration chamber 134. That is to say, in some embodiments, the control device 100 and/or the housing 130 can be in first or initial state in which the initial portion or volume of bodily fluid can flow in or through at least a portion the fluid flow path 133 and into the sequestration chamber 134. For example, in some embodiments, the initial state of the control device 100 and/or the housing 130 can be one in which one or more flow controllers 120 (e.g., valves, membranes, diaphragms, restrictors, vents, air permeable and fluid impermeable barriers, ports, actuators, and/or the like, or a combination thereof) are in a first state in which the fluid flow path 133 is exposed to the negative pressure differential via the sequestration chamber 134. In other words, the negative pressure within or created by the fluid collection device 180 can result in a negative pressure (or negative pressure differential) within at least a portion of the sequestration chamber 134 that is operable in drawing an initial flow of bodily fluid into the sequestration chamber 134 when one or more flow controllers 120 is/are in a first or initial state.

[1064] For example, in some embodiments, the flow controller 120 can be an actuator or the like that includes a valve (e.g. one-way valve, check valve, duckbill valve, umbrella valve, and/or the like), a selectively permeable member (e.g., a fluid impermeable barrier or seal that allows at least selective passage of gas or air), a selectively permeable membrane, a diaphragm, and/or the like that is at least temporarily fluidically coupled to a flow path between the fluid collection device 180 and the sequestration chamber 134 (e.g., at least a portion of the fluid flow path 154). While in some embodiments the flow controller 120 examples noted above can be, for example, known off-the-shelf components that are used in medical devices to control the flow of fluids and air, in other embodiments, the flow controller 120 can be a custom, proprietary, and/or specifically tailored component integrated into the device 100. When the flow controller 120 is in the first or initial state, the flow controller 120 can allow a flow of fluid therethrough in response to the negative pressure of the fluid collection device 180. In some embodiments, the flow controller 120 or a portion or component thereof is configured to allow only a flow of air or gas through the flow controller 120 and is configured

to limit and/or substantially prevent a flow of liquid (e.g., bodily fluid) through the flow controller 120. As such, the fluid collection device 180 can produce a negative pressure differential within the sequestration chamber 134 that is operable to draw an initial portion and/or amount of bodily fluid into the sequestration chamber 134 when the flow controller 120 is in a first or initial state without allowing the initial portion of bodily fluid to flow into the fluid flow path 154 and/or otherwise out of the sequestration chamber 134.

[1065] Although not shown in FIG. 1, in some embodiments, the control device 100 and/or the housing 130 can include a member, device, mechanism, feature, etc. configured to modulate a magnitude of the negative pressure to which the sequestration chamber 134 is exposed. For example, in some embodiments, a housing can include a valve, a membrane, a porous material, a restrictor, an orifice, and/or any other suitable member, device, and/or feature configured to modulate pressure. In some embodiments, modulating and/or controlling a magnitude of the pressure to which the sequestration chamber 134 is exposed can, in turn, modulate a magnitude of pressure exerted on the bodily fluid and/or within a vein of a patient. In some instances, such pressure modulation can reduce, for example, hemolysis of a blood sample and/or a likelihood of collapsing a vein (e.g., which is particularly important in fragile patients needing microbial and/or other diagnostic testing associated with use of the control device 100). In addition, the modulation of the negative pressure can, for example, at least partially control a rate at which the control device 100 transitions between a first configuration or state and a second configuration or state. In some embodiments, modulating the negative pressure can act like a timer. For example, a time between the introduction of the negative pressure differential and the transitioning of the control device 100 from the first state to the second state can be known, predetermined, calculated, and/or controlled. As such, in some instances, modulating the negative pressure can at least partially control an amount or volume of bodily fluid transferred into the sequestration chamber 134 (i.e., can control a volume of the initial amount of bodily fluid).

[1066] The initial portion and/or amount of bodily fluid can be any suitable volume of bodily fluid, as described above. For example, in some instances, the control device 100 and/or the housing 130 can remain in the first state until a predetermined and/or desired volume (e.g., the initial volume) of bodily fluid is transferred to the sequestration chamber 134. In some embodiments, the initial volume can be associated with and/or at least partially based on a volume of the sequestration chamber 134. In other embodiments, the initial volume can be associated with and/or at least partially based on an amount or volume of bodily fluid that can be absorbed by an absorbent material, an expandable material, a hydrophilic material, a

wicking material, and/or other suitable material disposed in the sequestration chamber 134. In other embodiments, the initial volume of bodily fluid can be associated with and/or at least partially based on an amount or volume of bodily fluid that can be transferred into the sequestration chamber 134 in a predetermined time. In still other embodiments, the initial volume can be associated with and/or at least partially based on an amount or volume of bodily fluid that is sufficient to fully wet or saturate a semi-permeable member or membrane otherwise configured to selectively expose the sequestration chamber 134 to the negative pressure of the fluid collection device 180 (i.e., the flow controller 120 such as an air permeable and liquid impermeable member or membrane). In other words, in some embodiments, the initial volume of bodily fluid can be a volume sufficient to transition one or more flow controllers 120 to a second state (e.g., a saturated or fully wetted state). In still other embodiments, the control device 100 and/or the housing 130 can be configured to transfer a volume of bodily fluid (e.g., the initial volume) into the sequestration chamber 134 until a pressure differential between the sequestration chamber 134 and the fluid flow path 133 and/or the bodily fluid source is brought into substantial equilibrium and/or is otherwise reduced below a desired threshold.

[1067] After the initial volume of bodily fluid is transferred and/or diverted into the sequestration chamber 134, the initial volume is sequestered, segregated, retained, contained, isolated, etc. in the sequestration chamber 134. For example, in some embodiments, the transitioning of the one or more flow controllers 120 from a first state to a second state can be operable to sequester and/or retain the initial portion of the bodily fluid in the sequestration chamber 134. As described in further detail herein, in some instances, contaminants such as, for example, dermally residing microbes or the like dislodged during the venipuncture event, other external sources of contamination, colonization of catheters and PICC lines that are used to collect samples, and/or the like can be entrained and/or included in the initial volume of the bodily fluid and thus, are sequestered in the sequestration chamber 134 when the initial volume is sequestered therein.

[1068] With the initial volume transferred and/or diverted into the sequestration chamber 134, the device 100 can transition to the second state in which a subsequent volume(s) of bodily fluid can flow through at least a portion the fluid flow paths 133 and/or 154 from the inlet 131 to the outlet 136. In some embodiments, the control device 100 and/or the housing 130 can passively and/or automatically transition (e.g., without user intervention) from the first state to the second state once the initial volume of bodily fluid is sequestered in the sequestration chamber 134. For example, in some embodiments, filling the sequestration chamber 134 to capacity and/or fully saturating, wetting, and/or impregnating an absorbent or similar material

disposed between the sequestration chamber 134 and the fluid collection device 180 can be such that further transfer of bodily fluid into the sequestration chamber 134 is limited and/or substantially prevented due to a removal or diversion of the negative pressure. In other embodiments, the control device 100 and/or the housing 130 can be manually transitioned or transitioned in response to at least an indirect interaction by a user. For example, in some embodiments, a user can transition the control device 100 and/or the housing 130 from the first state to the second state by actuating an actuator or the like (e.g., actuating the flow controller 120 or a portion thereof). In still other embodiments, at least a portion of the initial volume of bodily fluid can transition the control device 100 and/or the housing 130 from the first state to the second state. For example, the control device 100 can include a flow controller 120 that is and/or that includes a bodily fluid activated switch, valve, port, and/or the like. In other embodiments, a volume of bodily fluid can move and/or displace one or more flow controller 120 (e.g., actuators or the like) that can, for example, open a port, flow path, and/or outlet. In still other embodiments, a user can manipulate such a flow controller 120 (e.g., switch, valve, port, actuator, etc.) to transition the control device 100 and/or the housing 130 from the first state to the second state.

[1069] With the fluid collection device 180 fluidically coupled to the outlet 136 and with the control device 100 and/or the housing 130 being in the second state (e.g., the initial volume of bodily fluid is sequestered in or by the sequestration chamber 134), any subsequent volume(s) of the bodily fluid can flow from the inlet 131, through at least one of the fluid flow paths 133 and/or 154, through the outlet 136, and into the fluid collection device 180. Thus, as described above, sequestering the initial volume of bodily fluid in the sequestration chamber 134 prior to collecting or procuring one or more sample volumes of bodily fluid reduces and/or substantially eliminates an amount of contaminants in the one or more sample volumes. Moreover, in some embodiments, the arrangement of the control device 100 and/or the housing 130 can be such that the control device 100 and/or the housing 130 cannot transition to the second state prior to collecting and sequestering the initial volume in the sequestration chamber 134.

[1070] FIGS. 2-5 illustrate a fluid control device 200 according to an embodiment. The fluid control device 200 can be similar in at least form and/or function to the fluid control device 100 described above with reference to FIG. 1. Accordingly, portions of the fluid control device 200 that can be similar to portions of the fluid control device 100 are not described in further detail herein.

[1071] As shown in FIGS. 2-5, the fluid control device 200 (also referred to herein as "control device" or "device") includes a housing 230 having an inlet 231, an outlet 236, and an actuator 250. As described above with reference to the control device 100, the inlet 231 is configured to be placed in fluid communication with a bodily fluid source to receive a flow of bodily fluid therefrom (e.g., via a lumen-containing device such as a needle, IV catheter, PICC line, or the like). The outlet 236 is configured to be fluidically coupled to a fluid collection device such as, for example, a sample reservoir, a syringe, and/or other intermediary bodily fluid transfer device or vessel (e.g., a transfer device similar to those described in the '510 publication), and/or the like.

[1072] As described above with reference to the housing 130, the housing 230 defines one or more fluid flow paths 233 between the inlet 231 and a sequestration chamber 234 and/or one or more fluid flow paths 254 between the inlet 231 and the outlet 236. The housing 230 of the device 200 can be any suitable shape, size, and/or configuration. For example, in some embodiments, the housing 230 can be substantially similar in at least form and/or function to the housing 130 described above with reference to FIG. 1. The sequestration chamber 234 of the housing 230 is at least temporarily placed in fluid communication with the inlet 231 via the fluid flow path(s) 233. Moreover, the sequestration chamber 234 can be selectively placed in fluid communication with the fluid flow path 254 such that at least air or gas can be transferred therebetween, as described in further detail herein.

[1073] As described in further detail herein, the sequestration chamber 234 is configured to (1) receive a flow and/or volume of bodily fluid from the inlet 231 and (2) sequester (e.g., separate, segregate, contain, retain, isolate, etc.) the flow and/or volume of bodily fluid therein. The sequestration chamber 234 can have any suitable shape, size, and/or configuration. For example, in some embodiments, the sequestration chamber 234 can have any suitable size, volume, and/or fluid capacity such as, for example, those described above with reference to the sequestration chamber 134. In the embodiment shown in FIGS. 2-5, the sequestration chamber 234 can be at least partially formed by the housing 230 that defines a lumen or flow path. In some embodiments, at least a portion of the fluid flow path 233 can extend through a portion of the housing 230 to form and/or define at least a portion of the sequestration chamber 234. As shown in FIGS. 2-5, the sequestration chamber 234 and/or a portion of the fluid flow path 233 forming the sequestration chamber 234 can have a serpentine configuration or the like. In other embodiments, the sequestration chamber 234 can have any suitable arrangement. For example, in some embodiments, a housing can include a sequestration chamber that is formed by a flexible tubing or the like that can be arranged in any suitable shape and/or configuration.

[1074] In some embodiments, the housing 230 and/or the sequestration chamber 234 can include, form, and/or define a flow controller 242. The flow controller 242 can be, for example, a valve, membrane, diaphragm, restrictor, vent, a selectively permeable member (e.g., a fluid impermeable barrier or seal that allows at least selective passage of gas or air such as, for example, a blood barrier and/or the like), port, etc. (collectively referred to herein as a "flow controller") configured to selectively control (at least in part) a flow of fluids into and/or out of the sequestration chamber 234 and/or any other suitable portion of the housing 230. More particularly, in the embodiment shown in FIGS. 2-5, the flow controller 242 is a selectively permeable fluid barrier (e.g., a blood barrier) that includes and/or is formed of a porous material configured to selectively allow a flow of gas therethrough but to prevent a flow of a liquid therethrough.

[1075] As shown, the flow controller 242 is positioned within the housing 230 to selectively establish fluid communication between the sequestration chamber 234 and the fluid flow path 254. Thus, with the flow controller 242 being configured as a semi-permeable member, the flow controller 242 can be configured to at least temporarily allow a gas or air to transfer between the fluid flow path 254 and the sequestration chamber 234 and can be configured to substantially prevent a flow of liquid between the fluid flow path 254 and the sequestration chamber 234, as described in further detail herein.

[1076] The outlet 236 of the housing 230 is in fluid communication with and/or is configured to be placed in fluid communication with the fluid flow paths 233 and/or 254. As shown in FIGS. 2-5, the outlet 236 can be any suitable outlet, opening, port, lock, seal, coupler, etc. and is configured to be fluidically coupled to a fluid collection device such as a sample reservoir, a syringe, container, and/or other sample vessel. In some embodiments, the outlet 236 can be monolithically formed with the fluid collection device or can be at least temporarily coupled to the fluid collection device, as described above with reference to the outlet 136 of the housing 130. The fluid collection device can be any suitable reservoir, container, and/or device for containing a bodily fluid, such as, for example, any of those described in detail above with reference to the fluid collection device 180. More particularly, in some embodiments, the outlet 236 can be configured to couple to an evacuated sample reservoir. As such, the user can couple the sample reservoir to the outlet 236 to initiate a flow of bodily fluid from the patient such that a first or initial portion of the bodily fluid is transferred into and sequestered by the sequestration chamber 234 and such that any subsequent portion or volume of bodily fluid bypasses and/or is otherwise diverted away from the sequestration chamber 234 and flows into the sample reservoir.

[1077] As shown in FIGS. 3-5, the housing 230 includes and/or is coupled to the actuator 250 configured to selectively control a flow of bodily fluid through the housing 230. More particularly, the actuator 250 is disposed, for example, between a portion of the fluid flow path 233 and a portion of the fluid flow path 254. While the actuator 250 is shown in FIGS. 3-5 as being positioned apart from, away from, and/or downstream of a junction between the fluid flow path 233 and the sequestration chamber 234, in other embodiments, the actuator 250 can be disposed at any suitable position within the housing 230. For example, in some embodiments, the actuator 250 can be positioned at and/or can form at least a portion of a junction between the fluid flow path 233, the sequestration chamber 234, and the fluid flow path 254.

[1078] The actuator 250 can be any suitable shape, size, and/or configuration. For example, in some embodiments, the actuator 250 can be any suitable member or device configured to transition between a first state and a second state. In the embodiment shown in FIGS. 2-5, the actuator 250 is configured to isolate, sequester, separate, and/or otherwise prevent fluid communication between the fluid flow path 233 and the fluid flow path 254 when in the first state and is configured to place the fluid flow path 233 in fluid communication with the fluid flow path 254 when in the second state. In some embodiments, for example, the actuator 250 can be a valve, plunger, seal, membrane, flap, plate, and/or the like. As shown, for example, in FIG. 5, the actuator 250 can include one or more seals 265 configured to selectively establish fluid communication between the fluid flow channels 233 and 254 when the actuator 250 is transitioned from a first state to a second state (e.g., pressed, rotated, moved, activated, switched, slid, etc.).

[1079] Although the actuator 250 is particularly shown in FIGS. 2-5 and described above, in other embodiments, the control device 200 can include any suitable actuator or device configured to selectively establish fluid communication between the fluid flow path 233 and 254. Thus, while particularly shown in FIGS. 2-5, it should be understood that the control device 200 is presented by way of example only and not limitation. For example, while the actuator 250 is shown in FIGS. 2-5 as being disposed in a given position, in other embodiments, the actuator 250 can be placed at any suitable position along the housing 230. By way of example, in some embodiments, the actuator 250 can be disposed at the junction between the fluid flow path 233, the sequestration chamber 234, and the inlet 231. In such embodiments, a flow of bodily fluid can flow directly from the inlet 231 and into the sequestration chamber 234 when the actuator 250 is in the first state and can flow directly from the inlet 231 to the fluid flow path 254 when the actuator 250 is in the second state. In other words, the actuator

250 can form a portion of the sequestration chamber 234 such that when the actuator 250 is in the first state, bodily fluid flows from the inlet directly into the sequestration chamber 234. When the actuator 250 is actuated, placed, and/or transitioned to the second state, the actuator 250 can, for example, allow bodily fluid to flow directly from the inlet 231 to the fluid flow path 233. In such embodiments, the actuator 250 can prevent the formation of a junction between the inlet 231, the sequestration chamber 234, and the fluid flow path 233. Moreover, when in the second state, the actuator 250 can be operable in at least partially sequestering the sequestration chamber 234 from the inlet 231 and/or the fluid flow path 233.

[1080] In addition, the actuator 250 can be actuated and/or transitioned in any suitable manner. For example, in some embodiments, the actuator 250 can transition between the first and the second state in response to a manual actuation by the user (e.g., exerting a manual force on a button, slider, switch, rotational member, etc.). In other embodiments, the actuator 250 can be configured to automatically transition between the first state and the second state in response to a pressure differential (or lack thereof), a change in potential or kinetic energy, a change in composition or configuration (e.g., a portion of the actuator could at least partially dissolve or transform), and/or the like. In still other embodiments, the actuator 250 can be mechanically and/or electrically actuated or transitioned based on a predetermined time, volumetric flow rate, flow velocity, etc. While examples of actuators and/or ways in which an actuator can transition are provided herein, it should be understood that they have been presented by way of example only and not limitation. Thus, a control device 200 can include any suitable actuator configured to transition in any suitable manner.

[1081] As described above, the device 200 can be used to procure a bodily fluid sample having reduced contamination from microbes such as, for example, dermally residing microbes, and/or the like. For example, in some instances, a user such as a doctor, physician, nurse, phlebotomist, technician, etc. can manipulate the device 200 to establish fluid communication between the inlet 231 and the bodily fluid source (e.g., a vein of a patient). Once the inlet 231 is placed in fluid communication with the bodily fluid source (e.g., the portion of the patient), the outlet 236 can be fluidically coupled to the fluid collection device. As described above, in the embodiment shown in FIGS. 2-5, the fluid collection device can be, for example, an evacuated reservoir or container that defines a negative pressure and/or can be any other suitable negative pressure source.

[1082] Coupling the outlet 236 to the fluid collection device selectively exposes at least a portion of the fluid flow path 254 to the negative pressure within the fluid collection device. As described above, the flow controller 242 is in fluid communication with the fluid flow path

254 and the sequestration chamber 234. Thus, coupling the outlet 236 to the fluid collection device exposes the sequestration chamber to the negative pressure of the fluid collection device, thereby resulting in a negative pressure differential operable in drawing bodily fluid from the bodily fluid source (e.g., the patient), through the inlet 231, and into the housing 230. As described above with reference to the control device 100, the arrangement of the housing 230 is such that when a volume of bodily fluid is transferred to and/or through the inlet 231, an initial portion of the volume of bodily fluid (also referred to herein as an "initial volume" or a "first volume") flows from the inlet 231, through at least a portion of the fluid flow path 233, and into the sequestration chamber 234. That is to say, in some embodiments, the control device 200 and/or the housing 230 can be in first or initial state in which the initial portion or volume of bodily fluid can flow in or through at least a portion the fluid flow path 233 and into the sequestration chamber 234.

[1083] As described above, the housing 230 and/or the control device 200 can be in the initial state when the flow controller 242 and the actuator 250 are in a first state, position, configuration, etc. As such, the actuator 250 isolates, separates, segregates, sequesters and/or otherwise prevents direct fluid communication between the fluid flow paths 233 and 254. In addition, the inlet 231 is exposed to the negative pressure differential via the sequestration chamber 234. In other words, the negative pressure within the fluid collection device can result in a negative pressure (or negative pressure differential) within at least a portion of the sequestration chamber 234 that is operable in drawing an initial flow of bodily fluid from the inlet 233 into the sequestration chamber 234 when the housing 230 and/or control device 200 is in the first or initial state.

[1084] When the flow controller 242 is in the first or initial state, the flow controller 242 can allow a flow of fluid (e.g., a gas or air) therethrough in response to the negative pressure of the fluid collection device (e.g., a sample reservoir, a syringe, or other source of potential energy used to create negative pressure), as described above with reference to the housing 130. In some instances, it may be desirable to modulate and/or control a magnitude of the negative pressure differential. In the embodiment shown in FIGS. 2-5, for example, the housing 230 defines a restricted flow path 232 that places the flow controller 242 in fluid communication with the fluid flow path 254. More specifically, the restricted flow path 232 is a fluid flow path having a smaller diameter than at least the fluid flow path 254.

[1085] For example, in some embodiments, the restricted flow path 232 can have a diameter of about 0.0005", about 0.001", about 0.003", about 0.005", about 0.01", about 0.1", about 0.5" or more. In other embodiments, the restricted flow path 232 can have a diameter

less than 0.0005" or greater than 0.5". In some embodiments, the restricted flow path 232 can have a predetermined and/or desired length of about 0.01", about 0.05", about 0.1", about 0.15", about 0.2", about 0.5", or more. In other embodiments, the restricted flow path 232 can have a predetermined and/or desired length that is less than 0.01" or more than about 0.5". Moreover, in some embodiments, a restricted flow path 232 can have any suitable combination of diameter and length to allow for and/or to provide a desired flow characteristic through at least a portion of the control device 200.

[1086] In this embodiment, the restricted flow path 232 having a smaller diameter results in a lower magnitude of negative pressure being applied through the sequestration chamber than a magnitude of negative pressure when the restricted flow path has a larger diameter. In some instances, modulating a magnitude of negative pressure can control a rate at which bodily fluid is transferred into the sequestration chamber 234. For example, in some embodiments, a fluid collection device and/or other suitable negative pressure source may produce a negative pressure differential having a magnitude (e.g., a negative magnitude) of about 0.5 pounds per square inch (PSI), about 1.0 PSI, about 2.0 PSI, about 3.0 PSI, about 4.0 PSI, about 5.0 PSI, about 10 PSI, about 12.5 PSI, or about 14.7 PSI (e.g., at or substantially at atmospheric pressure at about sea level). In some embodiments, a fluid collection device such as an evacuated container or the like can have a predetermined negative pressure of about 12.0 PSI. Accordingly, by controlling the diameter and/or length of the restricted flow path 232, the amount of negative pressure to which the sequestration chamber 234 is exposed and/or the rate at which the negative pressure is applied can be controlled, reduced, and/or otherwise modulated. In some instances, the use of the restricted flow path 232 can result in a delay or ramp up of the negative pressure exerted on or in the sequestration chamber.

[1087] Moreover, in this embodiment, the restricted flow path 232 is, for example, a gas flow path configured to receive a flow of gas or air but not a flow of a liquid (e.g., bodily fluid). In some embodiments, the diameter of the restricted flow path 232 can be sufficiently small to limit and/or prevent a flow of a liquid therethrough. In addition, the arrangement of the restricted flow path 232 being disposed between the fluid flow path 254 and the flow controller 242 is such that a flow of bodily fluid and/or any other liquid is substantially prevented by the flow controller 242 (e.g., a selectively permeable barrier or seal).

[1088] Although the pressure modulation is described above as being based on a diameter of the restricted flow path 232 (i.e., a single restricted flow path), it should be understood that this is presented by way of example only and not limitation. Other means of modulating the magnitude of negative pressure to which the sequestration chamber is exposed can include, for

example, a porous material, a valve, a membrane, a diaphragm, a specific restriction, a vent, a deformable member or flow path, and/or any other suitable means. In other embodiments, a control device can include any suitable number of restricted flow paths, each of which can have substantially the same diameter or can have varied diameters. For example, in some embodiments, a control device can include up to 100 restricted flow paths or more. In such embodiments, each of the restricted flow paths can have a diameter of between about 0.0005" and about 0.1", between about 0.0005" and about 0.05", or between about 0.0005" and about 0.01". In some embodiments, multiple restricted flow paths can be configured to (1) selectively provide a flow path between the outlet 236 and the sequestration chamber 234 that exposes the sequestration chamber 234 to the negative pressure differential, and (2) act as a flow controller configured to selectively allow the passage of a gas and/or air while substantially preventing the passage of a liquid (e.g., bodily fluid).

[1089] In some embodiments, modulating and/or controlling a magnitude of the pressure to which the sequestration chamber 234 is exposed can, in turn, modulate a magnitude of pressure exerted on the bodily fluid and/or within a vein of a patient. In some instances, such pressure modulation can reduce, for example, hemolysis of a blood sample and/or a likelihood of collapsing a vein. In some instances, the ability to modulate and/or control an amount or magnitude of negative pressure can allow the control device 200 to be used across a large spectrum of patients that may have physiological challenges whereby negative pressure is often needed to facilitate collection of bodily fluid such as, for example, blood (i.e. pressure differential between atmospheric pressure and a patient's vascular pressure is not sufficient to facilitate consistent and sufficiently forceful flow) but not so much pressure that a rapid force flattens, collapses, caves-in, and/or otherwise inhibits patency and ability to collect blood.

[1090] The initial portion and/or amount of bodily fluid can be any suitable volume of bodily fluid, as described in detail above with reference to the control device 100. For example, in some instances, the initial volume can be associated with and/or at least partially based on an amount or volume of bodily fluid that is sufficient to fully wet or saturate the flow controller 242. In other words, in some embodiments, the initial volume of bodily fluid can be a volume sufficient to transition the flow controller 242 to a second state (e.g., a saturated or fully wetted state). In some embodiments, the flow controller 242 is placed in a sealed configuration when transitioned to the second state. That is to say, saturating and/or fully wetting the flow controller 242 (e.g., the semi-permeable material) places the flow controller 242 in a sealed configuration in which the flow controller 242 substantially prevents a flow of a liquid and a gas therethrough. Thus, transitioning the flow controller 242 to the second state sequesters,

blocks, isolates, separates, segregates, and/or otherwise prevents flow through the flow controller 242 between the restricted flow path 232 and the sequestration chamber 234.

[1091] After the initial volume of bodily fluid is transferred and/or diverted into the sequestration chamber 234, the control device 200 and/or the housing 230 can be transitioned to its second state or operating mode to sequester, segregate, retain, contain, isolate, etc. the initial volume in the sequestration chamber 234. For example, as described above, the flow controller 242 is placed in the sealed configuration. In addition, the actuator 250 can be actuated to transition from its first state to its second state to establish fluid communication between the fluid flow paths 233 and 254. As such, the negative pressure otherwise exerted on or through the sequestration chamber 234 is now exerted on or through the fluid flow paths 233 and 254. In response, bodily fluid can flow from the inlet 231, through the fluid flow paths 233 and 254, through the outlet 236, and into the fluid collection device. In some embodiments, the transitioning of the flow controller 242 and the actuator 250 from their respective first states to their respective second states is operable to sequester and/or retain the initial portion of the bodily fluid in the sequestration chamber 234. As described in further detail herein, in some instances, contaminants such as, for example, dermally residing microbes or the like dislodged during the venipuncture event, can be entrained and/or included in the initial volume of the bodily fluid and thus, are sequestered in the sequestration chamber 234 when the initial volume is sequestered therein.

[1092] With the fluid collection device fluidically coupled to the outlet 236 and with the control device 200 and/or the housing 230 being in the second state (e.g., the initial volume of bodily fluid is sequestered in or by the sequestration chamber 234), any subsequent volume(s) of the bodily fluid can flow from the inlet 231, through the fluid flow paths 233 and 254, through the outlet 236, and into the fluid collection device. Thus, as described above, sequestering the initial volume of bodily fluid in the sequestration chamber 234 prior to collecting or procuring one or more sample volumes of bodily fluid reduces and/or substantially eliminates an amount of contaminants in the one or more sample volumes. Moreover, in some embodiments, the arrangement of the control device 200 and/or the housing 230 can be such that the control device 200 and/or the housing 230 cannot transition to the second state prior to collecting and sequestering the initial volume in the sequestration chamber 234.

[1093] While the control device 200 is described above with reference to FIGS. 2-5 as including the actuator 250 configured to be moved (e.g., via a force applied by a user) between the first state and the second state, in other embodiments, a control device can include any suitable member, device, mechanism, etc. configured to selectively establish fluid

communication between two or more fluid flow paths. For example, FIGS. 6-8 illustrate a fluid control device 300 according to an embodiment. The fluid control device 300 can be similar in at least form and/or function to the fluid control device 100 described above with reference to FIG. 1 and/or the fluid control device 200 described above with reference to FIGS. 2-5. Accordingly, portions of the fluid control device 300 that can be similar to portions of the fluid control devices 100 and/or 200 are not described in further detail herein.

[1094] As shown in FIGS. 6-8, the fluid control device 300 (also referred to herein as "control device" or "device") includes a housing 330 having an inlet 331 and an outlet 336, and including or being coupled to an actuator 350. As described above with reference to the control devices 100 and/or 200, the inlet 331 is configured to be placed in fluid communication with a bodily fluid source to receive a flow of bodily fluid therefrom (e.g., via a lumen-containing device such as a needle or the like). The outlet 336 is configured to be fluidically coupled to a fluid collection device (not shown in FIGS. 6-8).

[1095] As described above with reference to the housings 130 and/or 230, the housing 330 defines one or more fluid flow paths 333, 354A, and 354B configured to selectively place the inlet 331 in fluid communication with the sequestration chamber 334 and/or the outlet 336. The housing 330 of the device 300 can be any suitable shape, size, and/or configuration. For example, in some embodiments, the housing 330 can be substantially similar in at least form and/or function to the housings 130 and/or 230 described above. In some embodiments, the housing 330 can have a size that is at least partially based on a volume of bodily fluid at least temporarily stored, for example, in the sequestration chamber 334. The sequestration chamber 334 of the housing 330 is at least temporarily placed in fluid communication with the inlet 331 via the fluid flow path(s) 333. Moreover, the sequestration chamber 334 can be selectively placed in fluid communication with the fluid flow path 354A such that at least air or gas can be transferred therebetween, as described in further detail herein.

[1096] As described in further detail herein, the sequestration chamber 334 is configured to (1) receive a flow and/or volume of bodily fluid from the inlet 331 and (2) sequester (e.g., separate, segregate, contain, retain, isolate, etc.) the flow and/or volume of bodily fluid therein. The sequestration chamber 334 can have any suitable shape, size, and/or configuration. For example, in some embodiments, the sequestration chamber 334 can be substantially similar to the sequestration chamber 234 described above with reference to FIGS. 2-5 and thus, is not described in further detail herein. Likewise, the housing 330 and/or the sequestration chamber 334 include, form, and/or define a flow controller 342 that can be substantially similar to the flow controller 242 described above. As such, the flow controller 342 is positioned within the

housing 330 to selectively establish fluid communication between the sequestration chamber 334 and the fluid flow path 354A, as described in further detail herein.

[1097] The outlet 336 of the housing 330 is in fluid communication with and/or is configured to be placed in fluid communication with the fluid flow paths 333, 354A, and/or 354B. In addition, the outlet 336 is configured to be fluidically coupled to a fluid collection device such as, for example, a sample reservoir, container, vial, negative pressure source, syringe, and/or intermediate control and/or transfer device (not shown in FIGS. 6-8). The outlet 336 and the fluid collection device can each be substantially similar to the outlet 236 and fluid collection device, respectively, described above with reference to the control device 200. Thus, the outlet 336 and fluid collection device are not described in further detail herein.

[1098] As shown in FIGS. 6-8, the housing 330 includes and/or is coupled to the actuator 350, which is configured to selectively control a flow of bodily fluid through the housing 330. In some embodiments, the actuator 350 can be substantially similar in at least function to the actuator 250 described above with reference to FIGS. 2-5. In this embodiment, however, the actuator 350 is arranged as a plunger and includes a set of seals 365 disposed along an outer surface of the plunger. Moreover, the actuator 350 has a substantially annular shape and is configured to at least temporarily receive and/or otherwise be disposed about a portion of the flow controller 342, as shown in FIG. 8. As described above with reference to the actuator 250, the actuator 350 is configured to isolate, sequester, separate, and/or otherwise prevent fluid communication between the fluid flow path 333 and the fluid flow path 354B when in the first state and is configured to place the fluid flow path 333 in fluid communication with the fluid flow path 354B when in the second state.

[1099] As described above, the device 300 can be used to procure a bodily fluid sample having reduced contamination from microbes such as, for example, dermally residing microbes, and/or the like. For example, in some instances, a user such as a doctor, physician, nurse, phlebotomist, technician, etc. can manipulate the device 300 to establish fluid communication between the inlet 331 and the bodily fluid source (e.g., a vein of a patient). Once the inlet 331 is placed in fluid communication with the bodily fluid source (e.g., the portion of the patient), the outlet 336 can be fluidically coupled to the fluid collection device. As described above, in the embodiment shown in FIGS. 6-8, the fluid collection device can be, for example, an evacuated reservoir, a syringe, and/or any container that defines a negative pressure.

[1100] Coupling the outlet 336 to the fluid collection device selectively exposes at least a portion of the fluid flow paths 354A and 354B to the negative pressure within and/or produced

by the fluid collection device. The arrangement of the actuator 350 when in its first state, configuration, and/or position is such that the actuator 350 isolates the fluid flow path 354B from the fluid flow path 333 and as such, the fluid flow path 333 is not exposed to the negative pressure differential produced by the fluid collection device. As described above, the flow controller 342 is in fluid communication with the fluid flow path 354A and the sequestration chamber 334. More particularly, the annular arrangement of the actuator 350 allows the flow controller 342 to be in fluid communication with the fluid flow path 354A (see e.g., FIG. 8). Thus, coupling the outlet 336 to the fluid collection device exposes the sequestration chamber 334 to the negative pressure of the fluid collection device, thereby resulting in a negative pressure differential operable in drawing bodily fluid from the bodily fluid source (e.g., the patient), through the inlet 331, and into the housing 330. As described above with reference to the control devices 100 and 200, the arrangement of the housing 330 is such that when a volume of bodily fluid is transferred to and/or through the inlet 331, an initial portion of the volume of bodily fluid (also referred to herein as an "initial volume" or a "first volume") flows from the inlet 331 and into the sequestration chamber 334. That is to say, in some embodiments, the housing 330 can be in first or initial state in which the initial portion or volume of bodily fluid can flow from the inlet 331 and into the sequestration chamber 334.

[1101] As described above, the housing 330 and/or the control device 300 can be in the initial state when the flow controller 342 and the actuator 350 are in a first state, position, configuration, etc. As such, the actuator 350 isolates, separates, segregates, sequesters and/or otherwise prevents direct fluid communication between the fluid flow paths 333 and 354B. In addition, the inlet 331 is exposed to the negative pressure differential via the sequestration chamber 334. In other words, the negative pressure within or produced by the fluid collection device can result in a negative pressure (or negative pressure differential) within at least a portion of the sequestration chamber 334 that is operable in drawing an initial flow of bodily fluid from the inlet 331 into the sequestration chamber 334 when the housing 330 and/or control device 300 is in the first or initial state. As described in detail above, in some instances, it may be desirable to modulate and/or control a magnitude of the negative pressure differential by any suitable means such as those described herein.

[1102] The initial portion and/or amount of bodily fluid can be any suitable volume of bodily fluid, as described in detail above with reference to the control devices 100 and/or 200. For example, in some instances, the initial volume can be associated with and/or at least partially based on an amount or volume of bodily fluid that is sufficient to fully wet or saturate the flow controller 342. In other words, in some embodiments, the initial volume of bodily

fluid can be a volume sufficient to transition the flow controller 342 to a second state (e.g., a saturated or fully wetted state). As described above with reference to the flow controller 242, the flow controller 342 is placed in a sealed configuration when transitioned to the second state. Thus, transitioning the flow controller 342 to the second state sequesters, blocks, isolates, separates, segregates, and/or otherwise prevents flow through the flow controller 342.

[1103] After the initial volume of bodily fluid is transferred and/or diverted into the sequestration chamber 334, the control device 300 and/or the housing 330 can be transitioned to its second state or operating mode to sequester, segregate, retain, contain, isolate, etc. the initial volume in the sequestration chamber 334. As described above, the flow controller 342 is placed in the sealed configuration and thus, substantially prevents a flow of fluid therethrough. In this embodiment, the arrangement of the actuator 350 is such that when the flow controller 342 is placed in the sealed configuration, at least a portion of the negative pressure otherwise being exerted through the flow controller 342 is instead exerted on the actuator 350, which in turn, is sufficient to transition the actuator 350 from its first state to its second state. For example, in some embodiments, the negative pressure is operable to move the actuator 350 from a first position (e.g., the first state) to a second position (e.g., the second state), thereby establishing fluid communication between the fluid flow paths 333 and 354B.

[1104] More particularly, moving the actuator 350 to its second position (or otherwise transitioning the actuator 350 to its second state), moves and/or transitions the seals 365 relative to the fluid flow paths 333 and 354B such that fluid communication is established therebetween. As such, the negative pressure otherwise exerted on or through the sequestration chamber 334 is now exerted on or through the fluid flow paths 333 and 354B. In response, bodily fluid can flow from the inlet 331, through the fluid flow paths 333 and 354B, through the outlet 336, and into the fluid collection device. In some embodiments, the transitioning of the flow controller 342 and the actuator 350 from their respective first states to their respective second states is operable to sequester and/or retain the initial portion of the bodily fluid in the sequestration chamber 334. As described in further detail herein, in some instances, contaminants such as, for example, dermally residing microbes or the like dislodged during the venipuncture event, can be entrained and/or included in the initial volume of the bodily fluid and thus, are sequestered in the sequestration chamber 334 when the initial volume is sequestered therein.

[1105] With the fluid collection device fluidically coupled to the outlet 336 and with the control device 300 and/or the housing 330 being in the second state (e.g., the initial volume of bodily fluid is sequestered in or by the sequestration chamber 334), any subsequent volume(s)

of the bodily fluid can flow from the inlet 331, through the fluid flow paths 333 and 354B, through the outlet 336, and into the fluid collection device. Thus, as described above, sequestering the initial volume of bodily fluid in the sequestration chamber 334 prior to collecting or procuring one or more sample volumes of bodily fluid reduces and/or substantially eliminates an amount of contaminants in the one or more sample volumes. Moreover, in some embodiments, the arrangement of the housing 330 can be such that housing 330 cannot transition to the second state prior to collecting and sequestering the initial volume in the sequestration chamber 334.

[1106] FIGS. 9 and 10 illustrate a fluid control device 400 according to an embodiment. The fluid control device 400 can be similar in at least form and/or function to the fluid control device 100 described above with reference to FIG. 1, the fluid control device 200 described above with reference to FIGS. 2-5, and/or the fluid control device 300 described above with reference to FIGS. 6-8. Accordingly, portions of the fluid control device 400 that can be similar to portions of the fluid control devices 100, 200, and/or 300 are not described in further detail herein.

[1107] As shown in FIGS. 9 and 10, the fluid control device 400 (also referred to herein as "control device" or "device") includes a housing 430 having an inlet 431 and an outlet 436, and having and/or being coupled to an actuator 450. As described above with reference to the control devices 100, 200, and/or 300, the inlet 431 is configured to be placed in fluid communication with a bodily fluid source to receive a flow of bodily fluid therefrom (e.g., via a lumen-containing device such as a needle or the like). The outlet 436 is configured to be fluidically coupled to a fluid collection device (not shown in FIGS. 9 and 10).

[1108] As described above, the housing 430 of the control device 400 is configured to (1) receive a flow and/or volume of bodily fluid via the inlet 431 and (2) sequester (e.g., separate, segregate, contain, retain, isolate, etc.) the flow and/or volume of bodily fluid within the sequestration chamber 434. The housing 430 can be any suitable shape, size, and/or configuration. In some embodiments, the housing 430 can have a size that is at least partially based on a volume of bodily fluid at least temporarily stored, for example, in the sequestration chamber 434. For example, in the embodiment shown in FIGS. 9 and 10, the housing 430 is arranged (at least in part) as a syringe-like device or the like, as described in further detail herein.

[1109] The housing 430 defines fluid flow paths 433 and 454 that are selectively in fluid communication with the outlet 436 and that selectively receive a flow of fluid therethrough (e.g., a liquid and/or a gas). The outlet 436 of the housing 430 is in fluid communication with

and/or is configured to be placed in fluid communication with the fluid flow paths 433 and/or 454. In addition, the outlet 436 is configured to be fluidically coupled to a fluid collection device (not shown in FIGS. 9 and 10). The outlet 436 and the fluid collection device can each be substantially similar to the outlet 236 and fluid collection device, respectively, described above with reference to the control device 200. Thus, the outlet 436 and fluid collection device are not described in further detail herein.

[1110] The housing 430 includes and/or is coupled to the actuator 450 configured to selectively control a flow of bodily fluid through the housing 430. In this embodiment, the actuator 450 includes a first plunger 460 and a second plunger 461 movably disposed within the housing 430 and configured to at least partially define the sequestration chamber 434. More specifically, the actuator 450 is configured to move between a first state in which the inlet 431 is placed in fluid communication with the sequestration chamber 434 (FIG. 9) and a second state in which the inlet 431 is placed in fluid communication with the outlet 436 via the fluid flow path 454 (FIG. 10). In this embodiment, when the actuator 450 and/or housing 430 is in the first state, the inlet 431 is in fluid communication with a portion of the housing 430 defined between the first plunger 460 and the second plunger 461.

[1111] When in the first state, the first plunger 460 is disposed in a position such that a dampening chamber 437 is defined by the housing 430 on a side of the first plunger 460 opposite the sequestration chamber 434. As shown, the dampening chamber 437 is configured to be placed in fluid communication with the fluid flow path 433 via a port 435. The port 435 can be an opening, a valve, a membrane, a diaphragm, and/or any other suitable flow controller or the like configured to at least selectively establish fluid communication between the fluid flow path 433 and the dampening chamber 437. Furthermore, when the actuator 450 and/or the housing 430 is in the first state, the dampening chamber 437 includes and/or contains a dampening fluid 456 such as a gas (compressed or uncompressed) and/or a liquid (e.g., water, oil, dampening fluid, and/or any other suitable liquid).

[1112] When the actuator 450 and/or housing 430 are in the first state, the second plunger 461 is disposed in a position within the housing 430 such that one or more seals 465 formed by or coupled to the second plunger 461 fluidically isolate, separate, and/or sequester the inlet 431 from the fluid flow path 454. In addition, the second plunger 461 and/or the seals 465 formed by or coupled thereto fluidically isolate the fluid flow path 454 from the sequestration chamber 434. Thus, when the actuator 450 and/or control device 400 are in the first state, the inlet 431 is in fluid communication with the sequestration chamber 434 and is fluidically isolated from the fluid flow paths 433 and 454 as well as the outlet 436 (see FIG. 9). As

described in further detail herein, the actuator 450 and/or the control device 400 can be configured to transition to the second state in which the sequestration chamber 434 is sequestered within the housing 430 and the inlet 431 is placed in fluid communication with the fluid flow path 454 (see FIG. 10).

[1113] As described above, the device 400 can be used to procure a bodily fluid sample having reduced contamination from microbes such as, for example, dermally residing microbes, and/or the like. For example, in some instances, a user such as a doctor, physician, nurse, phlebotomist, technician, etc. can manipulate the device 400 to establish fluid communication between the inlet 431 and the bodily fluid source (e.g., a vein of a patient). Once the inlet 431 is placed in fluid communication with the bodily fluid source (e.g., the portion of the patient), the outlet 436 can be fluidically coupled to the fluid collection device. As described above, in the embodiment shown in FIGS. 9 and 10 the fluid collection device can be, for example, an evacuated reservoir or container that defines a negative pressure.

[1114] As shown in FIG. 9, the actuator 450 and/or the control device 400 can be in a first or initial state prior to coupling the outlet 436 to the fluid collection device. Thus, the fluid flow path 433 is in fluid communication with the dampening chamber 437 and the fluid flow path 454 is fluidically isolated from the inlet 431 and the sequestration chamber 434 (e.g., via the second plunger 461). As described above, coupling the outlet 436 to the fluid collection device exposes at least a portion of the fluid flow paths 433 and 454 to the negative pressure within the fluid collection device. When the actuator 450 and/or the control device 400 are in the first state, the second plunger 461 isolates the housing 430 and/or the sequestration chamber 434 from the negative pressure exerted via the fluid flow path 454. Conversely, the negative pressure exerted through the fluid flow path 433 can be operable in exerting at least a portion of the negative pressure on the dampening chamber 437 (e.g., via the port 435). In some embodiments, for example, the port 435 can be transitioned from a closed configuration to an open configuration in response to the negative pressure.

[1115] The negative pressure exerted through the fluid flow path 433 is operable in transitioning the actuator 450 from a first state to a second state. For example, in some embodiments, the negative pressure differential draws the dampening fluid 456 from the dampening chamber 437 and into the fluid flow path 433 or a secondary chamber or the like. Moreover, the negative pressure urges the first plunger 460 to transition and/or move relative to the housing 430 from a first configuration or position to a second configuration or position. In some embodiments, the transitioning and/or moving of the first plunger 460 can be such that a volume of the housing 430 defined between the first plunger 460 and the second plunger 461

is increased (i.e., a volume of the sequestration chamber 434 is increased). In some embodiments, the increase in the volume of the sequestration chamber 434 results in a negative pressure therein, which in turn, can be operable in drawing an initial volume of bodily fluid through the inlet 431 and into the sequestration chamber 434. In other words, the negative pressure of the fluid collection device indirectly results in a negative pressure differential between the inlet 431 and the sequestration chamber 434 that is operable in drawing the initial volume of bodily fluid into the sequestration chamber 434.

[1116] As shown in FIG. 10, movement of the first plunger 460 results in a similar movement of the second plunger 461. For example, in some embodiments, the arrangement of the actuator 450 is such that after the first plunger 460 has moved a predetermined amount (and/or after the volume of the sequestration chamber 434 has been increased a predetermined amount) and an initial volume of bodily fluid has been drawn into the sequestration chamber 434, the second plunger 461 is moved or transitioned from a first position and/or configuration to a second position and/or configuration. As such, the actuator 450 is placed in its second state in which the sequestration chamber 434 is sequestered from the inlet 431. In addition, the second plunger 461 and/or the seals 465 coupled thereto place the inlet 431 in fluid communication with the fluid flow path 454. Thus, the negative pressure otherwise exerted on or through the fluid flow path 433 is now exerted on or through the fluid flow path 454. In response, bodily fluid can flow from the inlet 431, through the fluid flow path 454, through the outlet 436, and into the fluid collection device.

[1117] In some embodiments, the transitioning of the actuator 450 from the first state to the second state is operable to sequester and/or retain the initial portion of the bodily fluid in the sequestration chamber 434. As described in further detail herein, in some instances, contaminants such as, for example, dermally residing microbes or the like dislodged during the venipuncture event, can be entrained and/or included in the initial volume of the bodily fluid and thus, are sequestered in the sequestration chamber 434 when the initial volume is sequestered therein. Thus, as described above, sequestering the initial volume of bodily fluid in the sequestration chamber 434 prior to collecting or procuring one or more sample volumes of bodily fluid reduces and/or substantially eliminates an amount of contaminants in the one or more sample volumes. Moreover, in some embodiments, the arrangement of the housing 430 can be such that housing 430 cannot transition to the second state prior to collecting and sequestering the initial volume in the sequestration chamber 434.

[1118] As described above with reference to the control devices 100, 200, and/or 300, the control device 400 is configured to modulate an amount of negative pressure exerted on the

first plunger 460 when the actuator 450 is in the first state. Specifically, in this embodiment, the dampening fluid 456 disposed in the dampening chamber 437 reduces a magnitude of the negative pressure exerted on the first plunger 460. As such, the rate at which the actuator 450 and/or control device 400 is transitioned from the first state to the second state can be controlled. Moreover, in some instances, exposing the housing 430 to the full magnitude of the negative pressure may result transitioning the actuator 450 and/or the control device 400 from the first state to the second state prior to receiving the initial volume of bodily fluid in the sequestration chamber 434. Thus, modulating the magnitude of the pressure can ensure a desired volume of bodily fluid is transferred into the sequestration chamber 434. Although shown in FIGS. 9 and 10 as modulating the negative pressure via the dampening fluid 456, it should be understood that this is presented by way of example only and not limitation. Any other suitable means of dampening and/or modulating a magnitude of the negative pressure can be used to control the transitioning of the actuator 450 and/or housing 430.

[1119] Although the housing 430 is shown in FIGS. 9 and 10 and described above as including the plungers 460 and 461 and being in a syringe-like configuration, in other embodiments, a housing can include any other suitable means for controlling fluid flow therethrough. For example, FIG. 11 and 12 illustrate a fluid control device 500 according to an embodiment. The fluid control device 500 can be similar in at least form and/or function to any of the fluid control devices 100, 200, 300, and/or 400. Accordingly, portions of the fluid control device 500 that can be similar to portions of the fluid control devices 100, 200, 300, and/or 400 are not described in further detail herein. As shown in FIGS. 11 and 12, the fluid control device 500 (also referred to herein as "control device" or "device") includes a housing 530 having an inlet 531 and an outlet 536, and having and/or being coupled to an actuator 550. As described above with reference to the control devices 100, 200, 300, and/or 400, the inlet 531 is configured to be placed in fluid communication with a bodily fluid source to receive a fluid of bodily fluid therefrom (e.g., via a lumen-containing device such as a needle or the like). The outlet 536 is configured to be fluidically coupled to a fluid collection device (not shown in FIGS. 11 and 12). The inlet 531, the outlet 536, and the fluid collection device can be substantially similar to those described above and thus, are not described in further detail herein.

[1120] As described above, the housing 530 of the control device 500 is configured to (1) receive a flow and/or volume of bodily fluid via the inlet 531 and (2) sequester (e.g., separate, segregate, contain, retain, isolate, etc.) the flow and/or volume of bodily fluid within the sequestration chamber 534. The housing 530 can be any suitable shape, size, and/or

configuration. In some embodiments, the housing 530 can have a size that is at least partially based on a volume of bodily fluid at least temporarily stored, for example, in the sequestration chamber 534. For example, in the embodiment shown in FIGS. 11 and 12, the housing 530 can be arranged in a substantially similar manner as the housing 430 described above with reference to FIGS. 9 and 10. As described in further detail herein, the housing 530 can differ from the housing 430, by arranging the actuator 550 as, for example, a diaphragm rather than one or more plungers.

[1121] The housing 530 defines a set of fluid flow paths 533 and 554 in fluid communication with the outlet 536 and configured to selectively receive a flow of fluid therethrough (e.g., a liquid and/or a gas). The housing 530 includes and/or is coupled to the actuator 550 configured to selectively control a flow of bodily fluid through the housing 530. In this embodiment, the actuator 550 includes a diaphragm 576 movably disposed within the housing 530 and configured to at least partially define the sequestration chamber 534. More specifically, the actuator 550 is configured to move between a first state in which the inlet 531 is placed in fluid communication with the sequestration chamber 534 (FIG. 11) and a second state in which the inlet 531 is placed in fluid communication with the outlet 536 via the fluid flow path 554 (FIG. 12).

[1122] As shown in FIG. 11, when the actuator 550 and/or control device 500 is in the first state, the inlet 531 is in fluid communication with a portion of the housing 530 defined between the diaphragm 576 and one or more seals 565. Moreover, the diaphragm 576 is disposed in a first state such that a dampening chamber 537 is defined by the housing 530 on a side of the diaphragm 576 opposite the sequestration chamber 534, as described above with reference to the housing 430. As shown, the dampening chamber 537 is configured to be placed in fluid communication with the fluid flow path 533 via a port 535. The port 535 can be an opening, a valve, a membrane, a diaphragm, and/or any other suitable flow controller or the like configured to at least selectively establish fluid communication between the fluid flow path 533 and the dampening chamber 537. Furthermore, when the actuator 550 and/or the control device 500 is in the first state, the dampening chamber 537 includes and/or contains a dampening fluid such as a gas (compressed or uncompressed) and/or a liquid (e.g., water, oil, dampening fluid, and/or any other suitable liquid). As described above with reference to the control devices 400, the arrangement of the dampening chamber 537, the dampening fluid, and the port 535 can be configured to modulate an amount of negative pressure exerted on the diaphragm 576 when the actuator 550 is in the first state. Although shown in FIGS. 11 and 12 as modulating the negative pressure via the dampening fluid, it should be understood that this

is presented by way of example only and not limitation. Any other suitable means of dampening and/or modulating a magnitude of the negative pressure can be used to control the transitioning of the actuator 550 and/or the control device 500.

[1123] As described above with reference to the actuator 450, when the actuator 550 and/or the control device 500 are in the first state, the one or more seals 565 are disposed in a position within the housing 530 such that the one or more seals 565 fluidically isolate, separate, and/or sequester the inlet 531 from the fluid flow path 554. In addition, the one or more seals 565 fluidically isolate the fluid flow path 554 from the sequestration chamber 534. Thus, when the actuator 550 and/or the control device 500 are in the first state, the inlet 531 is in fluid communication with the sequestration chamber 534 and fluidically isolated from the fluid flow paths 533 and 554 as well as the outlet 536 (see FIG. 11). As described in further detail herein, the actuator 550 and/or the control device 500 housing 530 can be configured to transition to the second state in which the sequestration chamber 534 is sequestered within the housing 530 and the inlet 531 is placed in fluid communication with the fluid flow path 554 (see FIG. 12).

[1124] As described in detail above, the device 500 can be used to procure a bodily fluid sample having reduced contamination from microbes such as, for example, dermally residing microbes, and/or the like. For example, in some instances, a user can place the inlet 531 in fluid communication with the bodily fluid source (e.g., the portion of the patient) and can fluidically couple the outlet 536 to the fluid collection device. As shown in FIG. 11, the actuator 550 and/or the device 500 can be in a first or initial state prior to coupling the outlet 536 to the fluid collection device. Thus, the fluid flow path 533 is in fluid communication with the dampening chamber 537 and the fluid flow path 554 is fluidically isolated from the inlet 531 and the sequestration chamber 534 (e.g., via the one or more seals 565), as described in detail above with reference to the control device 400 of FIGS. 9 and 10.

[1125] Coupling the outlet 536 to the fluid collection device selectively exposes at least a portion of the fluid flow paths 533 and 554 to the negative pressure within and/or produced by the fluid collection device. When the actuator 550 and/or the device 500 are in the first state, the one or more seals 565 isolate the housing 530 and/or the sequestration chamber 534 from the negative pressure exerted via the fluid flow path 554. Conversely, the negative pressure exerted through the fluid flow path 533 can be operable in exerting at least a portion of the negative pressure on the dampening chamber 537 (e.g., via the port 535). In some embodiments, for example, the port 535 can be transitioned from a closed configuration to an open configuration in response to the negative pressure. The negative pressure exerted through the fluid flow path 533 is operable in transitioning the actuator 550 from a first state to a second

state. For example, in some embodiments, the negative pressure differential draws the dampening fluid from the dampening chamber 537 and into the fluid flow path 533. Moreover, the negative pressure urges the diaphragm 576 to transition, flip, move, switch, deform, etc., from a first configuration or state (FIG. 11) to a second configuration or state (FIG. 12). As described above with reference to the actuator 450, the transitioning of the diaphragm 576 from the first state to the second state can be such that a volume of the housing 530 defined between the diaphragm 576 and the one or more seals 565 is increased (i.e., a volume of the sequestration chamber 534 is increased), which in turn, results in a negative pressure therein that can be operable in drawing an initial volume of bodily fluid through the inlet 531 and into the sequestration chamber 534.

[1126] As shown in FIG. 12, movement of the diaphragm 576 results in a similar movement of the one or more seals 565 such that the one or more seals 565 are disposed on the same side of the inlet 531 as the diaphragm 576. Thus, the sequestration chamber 534 is sequestered within the housing 530. In addition, moving the one or more seals 565 is such that fluid communication is established between the inlet 531 and the fluid flow path 554. Thus, the negative pressure otherwise exerted on or through the fluid flow path 533 is now exerted on or through the fluid flow path 554. In response, bodily fluid can flow from the inlet 531, through the fluid flow path 554, through the outlet 536, and into the fluid collection device, as described in detail above. In some embodiments, the transitioning of the actuator 550 from the first state to the second state is operable to sequester and/or retain the initial portion of the bodily fluid in the sequestration chamber 534, which can include contaminants such as, for example, dermally residing microbes or the like dislodged during the venipuncture event. Thus, as described above, sequestering the initial volume of bodily fluid in the sequestration chamber 534 prior to collecting or procuring one or more sample volumes of bodily fluid reduces and/or substantially eliminates an amount of contaminants in the one or more sample volumes. Moreover, in some embodiments, the arrangement of the control device 500 and/or the housing 530 can be such that the control device 500 and/or the housing 530 cannot transition to the second state prior to collecting and sequestering the initial volume in the sequestration chamber 534.

[1127] FIGS. 13-15 illustrate a fluid control device 600 according to an embodiment. The fluid control device 600 can be similar in at least form and/or function to any of the fluid control devices 100, 200, 300, 400, and/or 500. Accordingly, portions of the fluid control device 600 that can be similar to portions of the fluid control devices 100, 200, 300, 400, and/or 500 are not described in further detail herein. As shown in FIGS. 13-15, the fluid control device 600

(also referred to herein as "control device" or "device") includes a housing 630 having an inlet 631 and an outlet 636, and having and/or being coupled to an actuator 650. As described above with reference to the control devices 100, 200, 300, 500, and/or 500, the inlet 631 is configured to be placed in fluid communication with a bodily fluid source to receive a fluid of bodily fluid therefrom (e.g., via a lumen-containing device such as a needle or the like). The outlet 636 is configured to be fluidically coupled to a fluid collection device (not shown in FIGS. 13-15). The inlet 631, the outlet 636, and the fluid collection device can be substantially similar to those described above and thus, are not described in further detail herein.

[1128] As described above, the housing 630 of the control device 600 is configured to (1) receive a flow and/or volume of bodily fluid via the inlet 631 and (2) sequester (e.g., separate, segregate, contain, retain, isolate, etc.) the flow and/or volume of bodily fluid within a sequestration chamber 634 included in and/or at least partially formed by the housing 630. The housing 630 can be any suitable shape, size, and/or configuration. In some embodiments, the housing 630 can have a size that is at least partially based on a volume of bodily fluid at least temporarily stored, for example, in the sequestration chamber 634. For example, in the embodiment shown in FIGS. 13-15, the housing 630 can be arranged in a substantially similar manner as the housing 530 described above with reference to FIGS. 11 and 12. That is to say, the housing 630 includes an actuator 650 that is arranged as a diaphragm.

[1129] The housing 630 defines a set of fluid flow paths 633 and 654 in fluid communication with the outlet 636 and configured to selectively receive a flow of fluid therethrough (e.g., a liquid and/or a gas). The housing 630 includes and/or is coupled to the actuator 650 configured to selectively control a flow of bodily fluid through the housing 630. In this embodiment, the actuator 650 includes a diaphragm 676 movably disposed within the housing 630 and configured to at least partially define the sequestration chamber 634. More specifically, the actuator 650 is configured to move between a first state in which the inlet 631 is placed in fluid communication with the sequestration chamber 634 and a second state in which the inlet 631 is placed in fluid communication with the outlet 636 via the fluid flow path 654, as described in detail above with reference to the control device 500.

[1130] As shown in FIGS. 14 and 15, when the actuator 650 and/or the device 600 is in the first state, the inlet 631 is in fluid communication with a portion of the housing 630 defined between the diaphragm 676 and one or more seals 665. Moreover, the diaphragm 676 is disposed in a first state such that a dampening chamber 637 is defined by the housing 630 on a side of the diaphragm 676 opposite the sequestration chamber 634, as described above with reference to the housing 530. As shown, the dampening chamber 637 is configured to be placed

in fluid communication with the fluid flow path 654 via a port 635 (such as those described above). Although not shown, when the actuator 650 and/or the device 600 is in the first state, the dampening chamber 637 includes and/or contains a dampening fluid such as a gas (compressed or uncompressed) and/or a liquid (e.g., water, oil, dampening fluid, and/or any other suitable liquid), that can be configured to modulate an amount of negative pressure exerted on the diaphragm, as described in detail above with reference to the control device 500. Although described as modulating the negative pressure via the dampening fluid, it should be understood that this is presented by way of example only and not limitation. Any other suitable means of dampening and/or modulating a magnitude of the negative pressure can be used to control the transitioning of the actuator 650 and/or device 600.

[1131] As described above with reference to the actuator 550, when the actuator 650 and/or the device 600 are in the first state, the seal 665 is disposed in a position within the housing 630 such that the seal 665 fluidically isolates, separates, and/or sequesters the inlet 631 from the fluid flow path 654. In addition, the seal 665 fluidically isolates the fluid flow path 654 from the sequestration chamber 634. Thus, when the actuator 650 and/or the device 600 are in the first state, the inlet 631 is in fluid communication with the sequestration chamber 634 and fluidically isolated from the fluid flow path 654 as well as the outlet 636. The actuator 650 and/or the device 600 can be configured to transition to the second state in which the sequestration chamber 634 is sequestered within the housing 630 and the inlet 631 is placed in fluid communication with the fluid flow path 654. Accordingly, the device 600 can be used to procure a bodily fluid sample having reduced contamination from microbes (e.g., dermally residing microbes and/or the like), in a substantially similar manner as the device 500 described above with reference to FIGS. 11 and 12. Thus, the functioning of the device 600 is not described in further detail herein.

[1132] FIGS. 16-18 illustrate a fluid control device 700 according to an embodiment. The fluid control device 700 can be similar in at least form and/or function to any of the fluid control devices 100, 200, 300, 400, 500, and/or 600. Accordingly, portions of the fluid control device 700 that can be similar to portions of the fluid control devices 100, 200, 300, 400, 500, and/or 600 are not described in further detail herein. As shown in FIGS. 16-18, the fluid control device 700 (also referred to herein as "control device" or "device") includes a housing 730 having an inlet 731 and an outlet 736, and having or being coupled to an actuator 750. As described above with reference to the control devices 100, 200, 300, 400, 500, and/or 600, the inlet 731 is configured to be placed in fluid communication with a bodily fluid source to receive a fluid of bodily fluid therefrom (e.g., via a lumen-containing device such as a needle or the

like). The outlet 736 is configured to be fluidically coupled to a fluid collection device (not shown in FIGS. 16-18). The inlet 731, the outlet 736, and the fluid collection device can be substantially similar to those described above and thus, are not described in further detail herein.

[1133] As described above, the housing 730 of the control device 700 is configured to (1) receive a flow and/or volume of bodily fluid via the inlet 731 and (2) sequester (e.g., separate, segregate, contain, retain, isolate, etc.) the flow and/or volume of bodily fluid within the sequestration chamber 734. The housing 730 can be any suitable shape, size, and/or configuration. In some embodiments, the housing 730 can have a size that is at least partially based on a volume of bodily fluid at least temporarily stored, for example, in the sequestration chamber 734. For example, in the embodiment shown in FIGS. 16-18, the housing 730 can be arranged in a substantially similar manner as the housings 530 and/or 630. That is to say, the housing 530 includes and/or is coupled to the actuator 750 that is arranged as a diaphragm.

[1134] The housing 730 defines a set of fluid flow paths 733 and 754 in fluid communication with the outlet 736 (see e.g., FIGS. 17A and 17B) and configured to selectively receive a flow of fluid therethrough (e.g., a liquid and/or a gas). The housing 730 includes and/or is coupled to the actuator 750 configured to selectively control a flow of bodily fluid through the housing 730. In this embodiment, the actuator 750 includes a diaphragm 776 movably disposed within the housing 730 and configured to at least partially define the sequestration chamber 734. More specifically, the actuator 750 is configured to move between a first state in which the inlet 731 is placed in fluid communication with the sequestration chamber 734 and a second state in which the inlet 731 is placed in fluid communication with the outlet 736 via the fluid flow path 754, as described in detail above with reference to the control device 500.

[1135] In the embodiment shown in FIGS. 16-18, when the actuator 750 and/or the device 700 are in the first state, the inlet 731 is in fluid communication with the sequestration chamber 734 formed by a portion of the housing 730 defined between the diaphragm 776 and a flow controller 742 (e.g., a selectively permeable fluid barrier or seal, and/or any other flow controller such as any of those described above). Moreover, the diaphragm 776 is disposed in a first state such that the fluid flow path 733 is in fluid communication with the sequestration chamber 734. As described above with reference to the actuator 550, when in the actuator 750 and/or device 700 are in the first state, the diaphragm 776 and/or the seal 765 are disposed in a position within the housing 730 such that the diaphragm 776 and/or the seal 765 fluidically isolate, separate, and/or sequester the inlet 731 from the fluid flow path 754. In addition, the

diaphragm 776 and/or the seal 765 fluidically isolate the fluid flow path 754 from the sequestration chamber 734. Thus, when the actuator 750 and/or the device 700 are in the first state, the inlet 731 is in fluid communication with the sequestration chamber 734 and fluidically isolated from the fluid flow path 754.

[1136] As described above with reference to, for example, the control device 200, when the actuator 750 and/or the device 700 are in the first state, a negative pressure differential within the sequestration chamber 734 can result from the coupling of the fluid collection device to the outlet 736. More specifically, the fluid flow path 733 can be in fluid communication with the outlet 736 and the flow controller 742. When the flow controller 742 is in a first state, the flow controller 742 can allow a gas or air to pass therethrough. Thus, the negative pressure differential within the sequestration chamber 734 can result from the coupling of the fluid collection device to the outlet 736.

[1137] As shown in FIG. 18, the actuator 750 and/or the device 700 can be configured to transition to the second state in which the sequestration chamber 734 is sequestered within the housing 730 and the inlet 731 is placed in fluid communication with the fluid flow path 754, as described in detail above with reference to the control device 600. More particularly, an initial volume of bodily fluid can be transferred into the sequestration chamber 734, which in turn, can saturate, can wet, and/or otherwise can transition the flow controller 742 from the first or open state to a second or closed state. In some embodiments, the transitioning of the flow controller 742 from the first state to the second state is operable in isolating the fluid flow path 733 from the outlet 736. As such, a negative pressure exerted through the fluid flow path 754 can be operable in transitioning, switching, flipping, moving, deforming, and/or otherwise reconfiguring the diaphragm 776 such that the actuator 750 is placed in its second state. As such, the negative pressure of the fluid collection device can draw bodily fluid from the inlet 731, through the housing 730 (bypassing the sequestration chamber 734), through the fluid flow path 754 and the outlet 736, and into the fluid collection device, as described in detail above. Accordingly, the device 700 can be used to procure a bodily fluid sample having reduced contamination from microbes (e.g., dermally residing microbes and/or the like), in a manner substantially similar to one or more of the control devices 100, 200, 300, 400, 500, and/or 600 described in detail above. Thus, the functioning of the device 700 is not described in further detail herein.

[1138] In some embodiments, any of the control devices 100, 200, 300, 400, 500, 600, and/or 700 can be formed from any suitable components that can be manufactured, assembled, sterilized, and packaged as an assembly or integrated device. In such embodiments, a user can,

for example, open a packaging containing such an assembly or integrated device and can use the device as described above with reference to the control devices 100, 200, 300, 400, 500, 600, and/or 700. In some embodiments, any of the control devices can be monolithically formed in whole or at least in part.

[1139] In some embodiments any of the control devices can be physically coupled, attached, formed, and/or otherwise mated to a fluid collection device (e.g., a sample reservoir, a syringe, a blood culture bottle, a collection vial, a fluid transfer container, and/or any other suitable reservoir, collection device, and/or transfer device) during a manufacturing process. This can be done prior to sterilization so the collection pathway(s) and connection interface(s) (e.g., where the control device couples to the fluid collection device) maintain a closed-system, mechanical diversion device within a sterile environment that is not subject to touch-point contamination from external sources. In this manner, in order for a user to transfer a sample volume to the fluid collection device, the user would be forced first to sequester, segregate, and/or isolate at least a portion of the initial bodily fluid volume or flow. In some embodiments, the coupling, mating, and/or attachment of the fluid control device to the fluid collection device can be executed such that the control device can be removed (physically decoupled, removed with a specific "key," and/or any other approach used to separate the control device from the fluid collection device) after use to allow access to the fluid collection device, which can then be placed in an incubator and/or any other type of analytical machine, and accessed for analysis and/or otherwise further processed. In some embodiments, such decoupling may be blocked, limited, and/or substantially prevented prior to use and unblocked or allowed after use. In other embodiments, the fluid control device and the fluid collection device can be permanently coupled and/or monolithically formed (at least in part) to prevent such decoupling.

[1140] While described above as being coupled and/or assembled, for example, during manufacturing, in other embodiments, however, a control device can include one or more modular components that can be selected by a user based on a desired use, preference, patient, etc. In such embodiments, the user can couple one or more modular components (packaged together or packaged separately) to form the desired fluid control device. For example, FIGS. 19-25 illustrate a modular fluid control device 800 according to an embodiment. The fluid control device 800 can be similar in at least form and/or function to the fluid control devices described herein. More specifically, portions of the fluid control device 800 can be similar to and/or substantially the same as corresponding portions of the fluid control device 200 described above with reference to FIGS. 2-5. Accordingly, such portions of the fluid control device 800 are not described in further detail herein.

[1141] The fluid control device 800 (also referred to herein as "control device" or "device") includes a housing 830 and an actuator 850. As described above, the control device 800 can be at least partially monolithically formed or can be otherwise preassembled during manufacturing. In other embodiments, the control device 800 can be at least partially modular such that a user can physically and fluidically couple the housing 830 and the actuator 850 to form the control device 800. The housing 830 of the device 800 can be any suitable shape, size, and/or configuration. For example, in the embodiment shown in FIGS. 19-25, the housing 830 can be, for example, relatively thin and substantially rectangular. In some embodiments, portions of the housing 830 can be substantially similar in at least form and/or function to the housing 230 described above with reference to FIGS. 2-5. Thus, while such portions are identified, similar components, features, and/or functions are not described in further detail herein.

[1142] As shown in FIGS. 19 and 20, the housing 830 forms and/or defines a sequestration chamber 834 that is in selective fluid communication with a first port 845 and a second port 846. The first port 845 and the second port 846 are configured to be at least fluidically coupled to a portion of the actuator 850 to allow for selective fluid flow between the housing 830 and the actuator 850. As described in further detail herein, the sequestration chamber 834 is configured (1) to receive a selective flow and/or volume of bodily fluid from a portion of the actuator 850 via the first port 845, and (2) to sequester (e.g., separate, segregate, contain, retain, isolate, etc.) the flow and/or volume of bodily fluid (e.g., an initial or first flow and/or volume of bodily fluid or any portion thereof) within the sequestration chamber 834. The sequestration chamber 834 can have any suitable shape, size, and/or configuration. For example, in some embodiments, the sequestration chamber 834 can have any suitable size, volume, and/or fluid capacity such as, for example, those described above with reference to the sequestration chamber 134. In the embodiment shown in FIGS. 19-25, the sequestration chamber 834 can be, for example, a fluid flow path that extends through and/or that is defined by at least a portion of the housing 830. In some embodiments, the sequestration chamber 834 can be substantially similar in at least form and/or function to the sequestration chamber 234 described above with reference to FIGS. 2-5 and thus, is not described in further detail herein.

[1143] As shown in FIG. 20, the housing 830 includes and/or defines a flow controller 842 and a restricted flow path 832. The flow controller 842 can be, for example, a valve, membrane, diaphragm, restrictor, vent, a selectively permeable member, port, etc. configured to selectively control (at least in part) a flow of fluids into and/or out of the sequestration chamber 834 and/or any other suitable portion of the housing 830. For example, the flow controller 842 can be a

selectively permeable fluid barrier (e.g., a blood barrier) that includes and/or is formed of a porous material configured to selectively allow a flow of gas therethrough but to prevent a flow of a liquid therethrough. In some embodiments, the flow controller 842 can be substantially similar to the flow controller 242 described in detail above with reference to FIGS. 2-5 and thus, is not described in further detail herein.

[1144] As shown, the restricted flow path 832 defined by the housing 830 is in fluid communication with the second port 846 and is positioned between the second port 846 and the flow controller 842 (or a portion of the housing 830 receiving or housing the flow controller 842). As described above with reference to the restricted flow path 232 shown in FIGS. 2-5, the restricted flow path 832 is a fluid flow path having a smaller diameter than, for example, one or more other flow paths defined by the housing 830 and/or actuator 850. For example, in some embodiments, the restricted flow path 832 can have a diameter between about 0.0005" to about 0.5" and can have a length between about 0.01" and about 0.5", as described above with reference to the restricted flow path 232. As described above, the smaller diameter of the restricted flow path 832 results in a lower magnitude of negative pressure being applied through the sequestration chamber 834 than a magnitude of negative pressure when the restricted flow path 832 has a larger diameter. In other words, the restricted flow path 832 can be configured to modulate an amount of negative pressure to which the sequestration chamber 834 is exposed. In some instances, modulating the amount of negative pressure can control a rate at which bodily fluid is transferred into the sequestration chamber 834. Moreover, in this embodiment, the restricted flow path 832 is, for example, a gas flow path configured to receive a flow of gas or air but not a flow of a liquid (e.g., bodily fluid), which can allow for a negative pressure differential sufficient to successfully collect the initial volume of bodily fluid and/or sufficient to transition at least a portion of the control device 800 to a second state, while limiting and/or substantially preventing a portion of the initial or first volume of bodily fluid from being drawn through the sequestration chamber 834 and the second port 846.

[1145] As shown in FIGS. 19-24, the actuator 850 includes a body 851 and an actuator rod 862. The body 851 of the actuator 850 includes an inlet 852 and an outlet 853. The inlet 852 and the outlet 853 can be substantially similar in at least form and/or function to the inlet 231 and the outlet 236, respectively, described above with reference to FIGS. 2-5. Thus, the inlet 852 is configured to be placed in fluid communication with a bodily fluid source to receive a flow of bodily fluid therefrom (e.g., via a lumen-containing device such as a needle, IV catheter, PICC line, or the like). The outlet 853 is configured to be fluidically coupled to a fluid collection device 880 such as, for example, a sample reservoir, a syringe, and/or other

intermediary bodily fluid transfer device, adapter, or vessel (see e.g., FIG. 25) such as, for example, a transfer device similar to those described in the '510 publication.

[1146] As shown in FIG. 21, the body 851 of the actuator 850 includes and/or defines a first port 858 and a second port 859. The first port 858 is in fluid communication with the inlet 852 and the second port 859 is in fluid communication with the outlet 853. In addition, the first port 858 and the second port 859 are configured to be at least fluidically coupled to the first port 845 and the second port 846, respectively, of the housing 830. As described in further detail herein, the actuator 850 can be transitioned between a first operating mode or state and a second operating mode or state to selectively control fluid flow through the ports 858 and 859 of the actuator 850 and the ports 845 and 846 of the housing 830, which in turn, can selectively control a flow of bodily fluid into and/or out of the sequestration chamber 834 of the housing 830.

[1147] In some embodiments, the arrangement of the ports 858 and 859 of the actuator 850 and the ports 845 and 846 of the housing 830 can allow for and/or otherwise can provide a means of physically coupling the housing 830 to the actuator 850 as well as fluidically coupling the housing 830 to the actuator 850. For example, in some embodiments, the ports 858 and 859 of the actuator 850 and the ports 845 and 846 of the housing 830 can form a friction fit, a press fit, an interference fit, and/or the like. In other embodiments, the ports 858 and 859 of the actuator 850 can be coupled to the ports 845 and 846, respectively, of the housing 830 via an adhesive, a mechanical fastener, an elastomeric coupling, a gasket, an o-ring(s), and/or any other suitable coupling means. In still other embodiments, the ports 858 and 859 of the actuator 850 can be physically and fluidically coupled to the ports 845 and 846, respectively, of the housing 830 via an intervening structure such as, for example, one or more sterile, flexible tubing(s). As such, the device 800 can be and/or can have, for example, a modular configuration in which the housing 830 can be at least fluidically coupled to the actuator 850.

[1148] In some embodiments, such a modular arrangement can allow a user to select a housing (or actuator) with one or more desired characteristics based on, for example, the intended purpose and/or use of the assembled device. In other embodiments, the modular arrangement can allow and/or facilitate one or more components with desired characteristics to be coupled and/or assembled during manufacturing. For example, in some instances, it may be desirable to select a housing that includes and/or defines a sequestration chamber having a particular or desired volume. As a specific example, when the device is being used to procure bodily fluid from a pediatric patient and/or a very sick patient (for example), it may be desirable to select a housing that defines and/or includes a sequestration chamber with a smaller volume

than may otherwise be selected when the device is being used to procure bodily fluid from a seemingly healthy adult patient. Accordingly, such a modular arrangement can allow a user (e.g., a doctor, physician, nurse, technician, phlebotomist, etc.) to select a housing or an actuator having one or more desired characteristics based on, for example, the intended use of the device. In other instances, the modular arrangement can allow or facilitate assembly of a housing or an actuator having one or more desired characteristics during manufacturing without making significant changes to one or more manufacturing processes.

[1149] The actuator rod 862 of the actuator 850 is movably disposed within a portion of the body 851. The actuator rod 862 includes a first end portion 863 and a second end portion 864, at least one of which extends beyond the body 851 of the actuator 850 with the actuator rod 862 is disposed within the body 851 (see e.g., FIGS. 23 and 24). A portion of the actuator rod 862 includes and/or is coupled to a set of seals 865. The seals 865 can be, for example, o-rings, elastomeric over-molds, proud or raised dimensions or fittings, and/or the like. The arrangement of the actuator 862 and the body 851 of the actuator 850 can be such that an inner portion of the seals 865 forms a fluid tight seal with a surface of the actuator rod 862 and an outer portion of the seals 865 forms a fluid tight seal with an inner surface of the body 851. In other words, the seals 865 form one or more fluid tight seals between the actuator rod 862 and the inner surface of the body 851. As shown in FIGS. 23 and 24, the actuator rod 862 includes and/or is coupled to three seals 865 which form and/or define a first fluid flow path 833 within the body 851 of the actuator 850 and a second fluid flow path 854 within the body 851 of the actuator 850.

[1150] The actuator rod 862 is configured to be moved or transitioned relative to the body 851 between a first position or configuration and a second position or configuration. For example, in some instances, a force can be exerted on the first end portion 863 of the actuator rod 862 to place the actuator rod 862 in its first position and/or configuration, as shown in FIG. 23. The force exerted on the first end portion 863 of the actuator rod 862 can come from any suitable source. For example, a user can create the force with his or her hand or finger, a syringe, a positive or negative pressure source, and/or any other external energy source. When in the first position and/or configuration, the inlet 852 of the actuator 850 is in fluid communication with the first fluid flow path 833 and the outlet 853 of the actuator 850 is in fluid communication with the second fluid flow path 854. In some instances, a force can be exerted on the second end portion 864 of the actuator rod 862 to place the actuator rod 862 in its second position and/or configuration, as shown in FIG. 24. When in the second position and/or configuration, the inlet 852 and the outlet 853 of the actuator 850 are each in fluid

communication with the second fluid flow path 854 while the first fluid flow path is sequestered, isolated, and/or otherwise not in fluid communication with the inlet 852 and the outlet 853. Although not shown, the first port 858 of the actuator 850 is in fluid communication with the first fluid flow path 833 and the second port 859 of the actuator 850 is in fluid communication with the second fluid flow path 854. As such, moving and/or transitioning the actuator rod 862 (or the actuator 850 in general) between the first position and the second position can be operable in selectively controlling a flow of fluid (e.g., bodily fluid) between the inlet 852 of the actuator 850 and the housing 830, or between the inlet 852 of the actuator 850 and the outlet 853 of the actuator 850, as described in further detail herein.

[1151] As described above, the device 800 can be used to procure a bodily fluid sample having reduced contamination from microbes such as, for example, dermally residing microbes, microbes external to the bodily fluid source, and/or the like. For example, in some instances, a user such as a doctor, physician, nurse, phlebotomist, technician, etc. can manipulate the device 800 to establish fluid communication between the inlet 852 and the bodily fluid source (e.g., a vein of a patient). Once the inlet 852 is placed in fluid communication with the bodily fluid source (e.g., the portion of the patient), the outlet 853 can be fluidically coupled to the fluid collection device 880. In the embodiment shown in FIGS. 19-25, the fluid collection device 880 can be, for example, a syringe (as shown in FIG. 25), and/or any other suitable container or device configured to define or produce a negative pressure or energy source.

[1152] As described in detail above with reference to, for example, the device 200, coupling the outlet 853 to the fluid collection device 880 selectively exposes at least a portion of the control device 800 to a negative pressure within and/or produced by the fluid collection device 880. More specifically, in the embodiment shown in FIGS. 19-25, coupling the outlet 853 to the fluid collection device 880 exposes the outlet 853 of the actuator 850 and the second fluid flow path 854 to the negative pressure within and/or produced by the fluid collection device 880. In addition, the second port 859 of the actuator 850 is in fluid communication with the second fluid flow path 854 and the second port 846 of the housing 830. The second port 846 of the housing 830, in turn, is in selective fluid communication with the sequestration chamber 834 via the flow controller 842 and the restricted flow path 832. For example, the device 800 and/or the flow controller 842 can be in a first operating state or mode in which the flow controller 842 allows a flow of gas (e.g., air) through the flow controller 842 while limiting and/or preventing a flow of liquid (e.g., bodily fluid such as blood) through the flow controller 842. Thus, coupling the fluid collection device 880 to the outlet 853 results in a

negative pressure differential between the fluid collection device 880 (and/or any suitable negative pressure source) and the sequestration chamber 834.

[1153] As described above, the control device 800 can be in a first or initial state when the flow controller 842 and/or the actuator 850 are in a first state, position, configuration, etc. As such, the actuator rod 862 can be in its first position and/or configuration in which the first fluid flow path 833 is in fluid communication with the inlet 852. In addition, the first port 858 of the actuator 850 and the first port 845 of the housing 830 establish fluid communication between the sequestration chamber 834 and the first fluid flow path 833. Thus, the negative pressure within the fluid collection device 880 can result in a negative pressure (or negative pressure differential) within at least a portion of the sequestration chamber 834 that is operable in drawing an initial flow, portion, amount, or volume of bodily fluid from the inlet 852, through the first fluid flow path 833, and into the sequestration chamber 834 when the actuator 850 and/or control device 800 is in the first or initial state (e.g., when the actuator rod 862 is in its first state, position, and/or configuration). In some instances, the arrangement of the flow controller 842 and/or the restricted flow path 832 can be configured to restrict, limit, control, and/or otherwise modulate an amount or magnitude of negative pressure exerted on or through the sequestration chamber 834, as described in detail above with reference to the device 200.

[1154] The initial portion and/or amount of bodily fluid can be any suitable volume of bodily fluid, as described in detail above with reference to the control device 100. For example, in some instances, the initial volume can be associated with and/or at least partially based on an amount or volume of bodily fluid that is sufficient to fully wet or saturate the flow controller 842. In other words, in some embodiments, the initial volume of bodily fluid can be a volume sufficient to transition the flow controller 842 from a first state to a second state (e.g., a saturated or fully wetted state). In some embodiments, the flow controller 842 is placed in a sealed configuration when transitioned to the second state. That is to say, saturating and/or fully wetting the flow controller 842 (e.g., the semi-permeable material) places the flow controller 842 in a sealed configuration in which the flow controller 842 substantially prevents a flow of a liquid and a gas therethrough. Thus, transitioning the flow controller 842 to the second state sequesters, blocks, isolates, separates, segregates, and/or otherwise prevents flow through the flow controller 842 between the restricted flow path 832 and the sequestration chamber 834.

[1155] After the initial volume of bodily fluid is transferred and/or diverted into the sequestration chamber 834, the control device 800 and/or the actuator 850 can be transitioned to its second state or operating mode to sequester, segregate, retain, contain, isolate, etc. the

initial volume in the sequestration chamber 834. For example, the actuator 850 can be actuated to transition from its first state to its second state, for example, by exerting a force on the second end portion 864 of the actuator rod 862. As such, the actuator rod 862 is moved and/or transitioned to its second state, position, and/or configuration in which the first fluid flow path 833 is sequestered and/or isolated from the inlet 852. With the flow controller 842 in the sealed configuration in response to the initial volume of bodily fluid being disposed in the sequestration chamber 834 and with the initial fluid flow path 833 sequestered and/or isolated from the inlet 852, the initial volume of bodily fluid is sequestered in the sequestration chamber 834. As described in detail above, in some instances, contaminants such as, for example, dermally residing microbes or the like dislodged during the venipuncture event, can be entrained and/or included in the initial volume of the bodily fluid and thus, are sequestered in the sequestration chamber 834 when the initial volume is sequestered therein.

[1156] As shown in FIG. 24, moving and/or transitioning the control device 800 and/or the actuator 850 to its second state or configuration establishes fluid communication between the inlet 852 and the outlet 853 via the second fluid flow path 854. As such, the negative pressure otherwise exerted on or through the sequestration chamber 834 is now exerted on or through the fluid flow path 854. In response, bodily fluid can flow from the inlet 852, through the fluid flow path 854, through the outlet 853, and into the fluid collection device 880. Thus, as described above, sequestering the initial volume of bodily fluid in the sequestration chamber 834 prior to collecting or procuring one or more sample volumes of bodily fluid reduces and/or substantially eliminates an amount of contaminants in the one or more sample volumes. Moreover, in some embodiments, the arrangement of the control device 800 can be such that the control device 800 cannot transition to the second state prior to collecting and sequestering the initial volume in the sequestration chamber 834, thereby reducing the likelihood of contaminants being transferred to the fluid collection device 880.

[1157] In some instances, it may be desirable to isolate the negative pressure source (e.g., the fluid collection device 880 from the inlet 853 such as, for example, if it is desirable to collect multiple samples of bodily fluid using multiple fluid collection device 880 (e.g., syringes). For example, in some instances, after filling the fluid collection device 880 the user can engage the actuator 850 and exert a force on the first end portion 863 of the actuator rod 862 to move and/or transition the actuator rod 862 from its second position and/or configuration toward its first position and/or configuration. As such, the second fluid flow path 854 no longer places the inlet 852 in fluid communication with the outlet 853. Moreover, the flow controller 842 can remain in the sealed state or configuration (e.g., fully saturated, wetted, and/or

otherwise preventing flow therethrough) such that the outlet 853 is substantially sequestered or isolated from the rest of the control device 800. In some instances, the user can then remove the filled fluid collection device 880 (e.g., syringe) and can couple a new fluid collection device 880 (e.g., syringe) to the outlet 853. With the new fluid collection device 880 coupled to the outlet 853, the user can, for example, exert a force on the second end portion 864 of the actuator rod 862 to move and/or transition the actuator rod 862 back to its second position, state, and/or configuration, as described above.

[1158] While the fluid collection device 880 coupled to the device 800 is shown in FIG. 25 as being a syringe, in other embodiments, a control device can be physically and/or fluidically coupled to any suitable collection device. For example, FIG. 26 illustrates a fluid control device 900. As described above with reference to the control device 800, the fluid control device 900 includes a housing 930 and an actuator 950, which can be arranged, for example, in a modular configuration or the like. The actuator 950 includes an inlet 952 configured to be placed in fluid communication with a bodily fluid source and an outlet 953 configured to be coupled to a fluid collection device 980. In the embodiment shown in FIG. 26, the fluid collection device 980 is a transfer adapter configured to be coupled to one or more reservoirs such as, for example, an evacuated container, a sample bottle, a culture bottle, etc. In such embodiments, the reservoir can be sealed prior to being coupled to the transfer adapter (i.e., the fluid collection device 980) and once coupled the seal can be punctured, displaced, deformed, and/or otherwise unsealed to expose the outlet 953 to the negative pressure within the reservoir. Thus, the fluid control device 900 can function in a substantially similar manner to the control device 800 described above with reference to FIGS. 19-25.

[1159] While the fluid control device 800 is shown as including the actuator rod 862 that includes the first end portion 863 and the second portion 864 on which a force can be exerted to transition the device 800 between its first and second configurations, states, and/or positions, in other embodiments, a control device can include an actuator having any suitable configuration. For example, the fluid control device 900 includes an actuator rod 962 having only a single end portion that extends beyond the body 951 of the actuator 950, as shown in FIG. 26. In such embodiments, the device 900 can be used to fill a fluid collection device such as, for example, a sample reservoir, container, bottle, etc. and if it is desirable for more than one sample to be collected, the user can, for example, decouple the inlet 952 from a lumen-containing device and/or any suitable device otherwise placing the inlet 952 in fluid communication with the bodily fluid source. Once decoupled, the user can couple the inlet of a new control device 900 to the lumen-containing device and/or the like and can collect one or

more additional samples in a manner similar to that described above with reference to the control device 800.

[1160] As described above, some fluid control device described herein can be and/or can have a modular configuration in which one or more components can be coupled to collectively form a fluid control device having a desired set of characteristics or the like. For example, the fluid control device 800 shown in FIGS. 19-25 includes the housing 830 and the actuator 850 in one modular arrangement. It should be understood, however, that a control device can have any suitable modular arrangement. For example, FIG. 27 illustrates a modular fluid control device 1000 according to an embodiment. The fluid control device (also referred to herein as "device") includes a housing 1030 forming and/or defining a sequestration chamber 1034, and an actuator 1050 forming and/or having an inlet 1052 and an outlet 1053. The device 1000 can be substantially similar to the control device 800 described in detail above but can be arranged such that housing 1030 is disposed in different position and/or orientation relative to the actuator 1050. In some embodiments, varying the arrangement may, for example, enhance usability, visibility, and/or the like and/or may otherwise allow for a more compact design.

[1161] As another example, FIG. 28 illustrates a modular fluid control device 1100 according to an embodiment. The fluid control device (also referred to herein as "device") includes a housing 1130 forming and/or defining a sequestration chamber 1134, and an actuator 1150 forming and/or having an inlet 1152 and an outlet 1153. The device 1100 can be substantially similar to the control device 800 described in detail above but can be arranged such that housing 1130 is disposed in different position and/or orientation relative to the actuator 1150. Moreover, as shown in FIG. 28, the actuator 1150 can be arranged such that the inlet 1152 and the outlet 1153 are disposed in substantially perpendicular positions relative to one another. As described above, in some embodiments, varying the arrangement may, for example, enhance usability, visibility, and/or the like and/or may otherwise allow for a more compact design. While examples of modular fluid control devices are shown herein, it should be understood that such embodiments are presented by way of example and not limitation. Thus, while specific arrangements and/or orientations may be described herein, the devices and/or concepts described herein are not intended to be limited to those shown herein.

[1162] While the housings 230, 330, 830, 930, 1030, and 1130 have been shown and described herein as including and/or defining a sequestration chamber that is arranged in a serpentine-like configuration, in other embodiments, a housing and/or any other suitable portion of a control device can include and/or can define a sequestration chamber having any suitable configuration. For example, FIGS. 29-34 illustrate a fluid control device 1200

according to an embodiment. The fluid control device 1200 can be similar in at least form and/or function to the fluid control devices described herein. More specifically, portions of the fluid control device 1200 can be similar to and/or substantially the same as corresponding portions of the fluid control devices 200, 300, 800, 900, 1000, and/or 1100 described above. Accordingly, such portions of the fluid control device 1200 are not described in further detail herein.

[1163] The fluid control device 1200 (also referred to herein as "control device" or "device") includes a housing 1230 and an actuator 1250. As described above with reference to the control device 800, the control device 1200 can be arranged in a modular configuration such that the housing 1230 and the actuator 1250 can be physically and fluidically coupled to form the control device 1200. In other embodiments, the control device 1200 need not be modular. That is to say, in some embodiments, the control device 1200 can be assembled during manufacturing and delivered to a supplier and/or end user as an assembled device. In other embodiments, the control device can be monolithically formed and/or coupled to a fluid collection device in any suitable manner, as described in detail above.

[1164] The housing 1230 of the control device 1200 can be any suitable shape, size, and/or configuration. For example, in some embodiments, the housing 1230 can be substantially similar in at least form and/or function to the housing 830 described in detail above. Accordingly, such similar portions of the housing 1230 are identified below but may not be described in further detail herein.

[1165] As shown in FIGS. 29-31, the housing 1230 forms and/or defines a sequestration chamber 1234 that is in selective fluid communication with a first port 1245 and a second port 1246. The second port 1246 is configured to receive, include, and/or define a flow controller 1242 (see e.g., FIG. 30) and a restricted flow path 1232 (see e.g., FIG. 31). Although shown as including the restricted flow path 1232, in other embodiments, a housing need not include or receive a restricted flow path (e.g., when excessive negative pressure being applied to the sequestration chamber 1234 is unlikely or otherwise not intended such as when a fluid collection device is a syringe or the like). The first port 1245 and the second port 1246 are configured to be at least fluidically coupled to a portion of the actuator 1250 to allow for selective fluid flow between the housing 1230 and the actuator 1250. As described in further detail herein, the sequestration chamber 1234 is configured (1) to receive a selective flow and/or volume of bodily fluid from a portion of the actuator 1250 via the first port 1245, and (2) to sequester (e.g., separate, segregate, contain, retain, isolate, etc.) the flow and/or volume

of bodily fluid (e.g., an initial or first flow and/or volume of bodily fluid or any portion thereof) within the sequestration chamber 1234.

[1166] The sequestration chamber 1234 can have any suitable shape, size, and/or configuration. For example, in some embodiments, the sequestration chamber 1234 can have any suitable size, volume, and/or fluid capacity such as, for example, those described above with reference to the sequestration chamber 134. In the embodiment shown in FIGS. 29-34, the sequestration chamber 1234 can be, for example, a fluid flow path that extends through and/or that is defined by at least a portion of the housing 1230. In some embodiments, the sequestration chamber 1234 can be substantially similar in at least form and/or function to the sequestration chamber 834 described above with reference to FIGS. 19-25. The sequestration chamber 1234 and/or the housing 1230 can differ from the sequestration chamber 834 and/or the housing 830 by being arranged in a spiral configuration with the first port 1245 being in fluid communication with, for example, an inner portion of the spiraled sequestration chamber 1234 and the second port 1246 being in fluid communication with, for example, an outer portion of the spiraled sequestration chamber, as shown in FIG. 30. In some embodiments, the sequestration chamber 1234 can be, for example, a channel or the like formed in a portion of the housing 1230.

[1167] In some embodiments, the channel forming at least a portion of the sequestration chamber 1234 can have a relatively small cross-sectional shape and/or size that can reduce and/or substantially prevent a mixing of an initial volume of bodily fluid drawn into the sequestration chamber 1234 (channel) and a volume of air within the sequestration chamber 1234 (e.g., a volume of air that has not been vented or purged, as described in further detail herein). For example, in some instances, the relatively small cross-sectional shape and/or size of the sequestration chamber 1234 (channel), a surface tension associated with the bodily fluid flowing into the sequestration chamber 1234, and a contact angle between a surface of the housing 1230 forming the sequestration chamber 1234 and the bodily fluid flowing into the sequestration chamber 1234 can collectively limit and/or substantially prevent a mixing of the bodily fluid and a volume of air within the sequestration chamber 1234.

[1168] As shown in FIG. 30, the housing 1230 can include and/or can be coupled to a cover 1238 configured to enclose the channel, thereby forming the sequestration chamber 1234. The cover 1238 can be coupled to the housing 1230 in any suitable manner (e.g., via a friction fit, snap fit, interference fit, an adhesive, one or more mechanical fasteners, laser welding, ultrasonic welding, plasma techniques, annealing, heat boding and/or any other suitable coupling means or combination thereof). In other embodiments, the cover 1238 is

monolithically formed with and/or coupled to the housing 1230. Moreover, in some embodiments, the cover 1238 can be at least partially transparent to allow a user to visualize a flow of bodily fluid through the sequestration chamber 1234. In some embodiments, the arrangement of the housing 1230 and the cover 1238 can, for example, facilitate one or more manufacturing processes and/or can facilitate use of the control device 1200.

[1169] As shown in FIG. 30, the housing 1230 includes and/or defines a flow controller 1242 and a restricted flow path 1232. The flow controller 1242 can be, for example, a valve, membrane, diaphragm, restrictor, vent, a selectively permeable member, port, etc. configured to selectively control (at least in part) a flow of fluids into and/or out of the sequestration chamber 1234 and/or any other suitable portion of the housing 1230. For example, the flow controller 1242 can be a selectively permeable fluid barrier (e.g., a blood barrier) that includes and/or is formed of a porous material configured to selectively allow a flow of gas therethrough but to prevent a flow of a liquid therethrough. As such, the flow controller 1242 can be configured to vent and/or purge a volume of air within the sequestration chamber 1234 through the flow controller 1242 in response to a negative pressure differential within a portion of the control device 1200. Such a venting and/or purging of the volume of air within the sequestration chamber 1234 can result in a suction force and/or negative pressure differential being exerted and/or applied in or on the sequestration chamber 1234 that is operable to draw in the initial volume of bodily fluid. Moreover, the use of a selectively permeable fluid barrier can allow for the venting and/or purging of air without allowing a volume of bodily fluid to pass through the flow controller 1242. Accordingly, in some embodiments, the flow controller 1242 can be substantially similar to the flow controller 242 described in detail above with reference to FIGS. 2-5 and thus, is not described in further detail herein.

[1170] The actuator 1250 of the control device 1200 can be any suitable shape, size, and/or configuration. For example, in some embodiments, the actuator 1250 can be substantially similar in at least form and/or function to the actuator 850 described in detail above. Accordingly, such similar portions of the actuator 1250 are identified below but may not be described in further detail herein.

[1171] As shown in FIGS. 32-34, the actuator 1250 includes a body 1251 and an actuator rod 1262. The body 1251 of the actuator 1250 includes an inlet 1252 and an outlet 1253. The inlet 1252 and the outlet 1253 can be substantially similar in at least form and/or function to the inlet 852 and the outlet 853, respectively, described above with reference to FIGS. 19-25. Thus, the inlet 1252 is configured to be placed in fluid communication with a bodily fluid source to receive a flow of bodily fluid therefrom (e.g., via a lumen-containing device such as

a needle, IV catheter, PICC line, or the like). The outlet 1253 is configured to be fluidically coupled to a fluid collection device (not shown in FIGS. 29-34) such as, for example, a sample reservoir, a syringe, and/or other intermediary bodily fluid transfer device, adapter, or vessel such as, for example, a transfer device similar to those described in the '510 publication. In some embodiments, such a transfer device can provide a negative pressure and/or can act as an external energy source to enable desired functionality and fluid flow path dynamics/characteristics of the control device 1200.

[1172] The body 1251 of the actuator 1250 includes and/or defines a first port 1258 and a second port 1259. The first port 1258 is in fluid communication with the inlet 1252 and the second port 1259 is in fluid communication with the outlet 1252. In addition, the first port 1258 and the second port 1259 are configured to be at least fluidically coupled to the first port 1245 and the second port 1246, respectively, of the housing 1230. In some embodiments, the arrangement of the ports 1258 and 1259 of the actuator 1250 and the ports 1245 and 1246 of the housing 1230 can allow for and/or otherwise can provide a means of physically coupling the housing 1230 to the actuator 1250 as well as fluidically coupling the housing 1230 to the actuator 1250. That is to say, in some embodiments, the arrangement of the ports 1258 and 1259 of the actuator 1250 and the ports 1245 and 1246 of the housing 1230 can allow for a modular configuration or arrangement as described above with reference to the control device 800. In other embodiments, the housing 1230 and/or actuator 1250 need not be modular.

[1173] In some embodiments, the body 1251 and the actuator rod 1262 collectively include and/or collectively form a lock configured to at least temporarily lock the actuator 1250. For example, in some embodiments, the body 1251 and the actuator rod 1262 can each define an opening 1257 in or through which a locking member can be disposed. In such embodiments, when the locking member (not shown in FIG. 32) is disposed in the openings 1257, the locking member can limit and/or substantially prevent the actuator rod 1262 from being moved relative to the body 1251. On the other hand, removing the locking member from the openings 1257 can allow the actuator rod 1262 to be moved relative to the body 1251. While described as forming a lock, in some embodiments, the body 1251 and the actuator rod 1262 collectively include and/or collectively form a feature and/or arrangement that can limit and/or substantially prevent the actuator rod 1262 from being pulled out of the body 1251. In such embodiments, the feature can be a snap, a lock, a catch, and/or any other suitable feature and/or arrangement.

[1174] As shown in FIGS. 33 and 34, a portion of the actuator rod 1262 includes and/or is coupled to a set of seals 1265. The seals 1265 can be, for example, o-rings, over-molded elastomeric material, raised protrusions, and/or the like. The arrangement of the actuator 1262

and the body 1251 of the actuator 1250 can be such that the seals 1265 form one or more fluid tight seals between the actuator rod 1262 and the inner surface of the body 1251, as described above with reference to the actuator 850. In the embodiment shown in FIGS. 33 and 34, the actuator rod 1262 includes and/or is coupled to three seals 1265 which form and/or define a first fluid flow path 1233 within the body 1251 of the actuator 1250 and a second fluid flow path 1254 within the body 1251 of the actuator 1250. In other embodiments, any number of seals may be used to achieve desired performance.

[1175] As described above with reference to the device 800, the device 1200 can be used to procure a bodily fluid sample having reduced contamination from microbes such as, for example, dermally residing microbes, microbes external to the bodily fluid source, and/or the like. For example, the actuator rod 1262 is configured to be moved or transitioned relative to the body 1251 between a first position or configuration and a second position or configuration. In some embodiments, the transition of the actuator rod 1262 can be achieved by and/or can otherwise result from user interaction and manipulation of the actuator rod 1262, automatically in response to negative pressure and associated flow dynamics within the device 1200, and/or enacted by or in response to an external energy source which creates dynamics that result in the transitioning of the actuator rod 1262. As shown in FIG. 33, when in the first position and/or configuration, the inlet 1252 of the actuator 1250 is in fluid communication with the first fluid flow path 1233, which in turn, is in fluid communication with the first port 1258. The outlet 1253 of the actuator 1250 is in fluid communication with the second fluid flow path 1254, which in turn, is in fluid communication with the second port 1259. Thus, when in the actuator 1250 and/or actuator rod 1262 is in the first position and/or configuration (e.g., when the control device 1200 is in a first state or operating mode), the negative pressure within the fluid collection device (not shown in FIGS. 29-34) can result in a negative pressure (or negative pressure differential) within at least a portion of the sequestration chamber 1234 that is operable in drawing at least a portion of an initial flow, amount, or volume of bodily fluid from the inlet 1252, through the first fluid flow path 1233, and into the sequestration chamber 1234. Moreover, in some instances, the initial volume and/or flow of bodily fluid can be transferred into the sequestration chamber 1234 until, for example, the bodily fluid disposed within the sequestration chamber 1234 transitions the flow controller 1242 from an open or unsealed configuration or state (e.g., one in which a flow of gas or air can be drawn therethrough) to a sealed configuration or state (e.g., one in which a flow of gas and liquid cannot be drawn therethrough).

[1176] In some instances, a force can be exerted on the end portion 1263 of the actuator rod 1262 to place the actuator rod 1262 and/or actuator 1250 in its second position and/or configuration, as shown in FIG. 34. As described above, in some instances, prior to exerting the force on the end portion 1263 of the actuator rod 1262, the actuator 1250 may be transitioned from a locked configuration or state to an unlocked configuration or state. When the actuator rod 1262 and/or the actuator 1250 is placed in its second position and/or configuration (e.g., when the control device 1200 is transitioned to a second state or operating mode), the inlet 1252 and the outlet 1253 of the actuator 1250 are each in fluid communication with the second fluid flow path 1254 while the first fluid flow path 1233 is sequestered, isolated, and/or otherwise not in fluid communication with the inlet 1252 and the outlet 1253. As described in detail above, in some instances, contaminants such as, for example, dermally residing microbes or the like dislodged during the venipuncture event or throughout the bodily fluid collection process, can be entrained and/or included in the initial volume of the bodily fluid and thus, are sequestered in the sequestration chamber 1234 when the initial volume is sequestered therein. As such, the negative pressure otherwise exerted on or through the sequestration chamber 1234 is now exerted on or through the second fluid flow path 1254. In response, bodily fluid can flow from the inlet 1252, through the second fluid flow path 1254, through the outlet 1253, and into the fluid collection device coupled to the outlet 1253. Accordingly, the device 1200 can function in a manner substantially similar to that of the device 800 and thus, the function of the device 1200 is not described in further detail herein.

[1177] FIGS. 35-40 illustrate a fluid control device 1300 according to an embodiment. The fluid control device 1300 can be similar in at least form and/or function to the fluid control devices described herein. More specifically, portions of the fluid control device 1300 can be similar to and/or substantially the same as corresponding portions of the fluid control devices 200, 300, 800, 900, 1000, 1100, and/or 1200 described above. Accordingly, such portions of the fluid control device 1300 are not described in further detail herein.

[1178] The fluid control device 1300 (also referred to herein as "control device" or "device") includes a housing 1330 and an actuator 1350. As described above with reference to the control devices 800, the control device 1300 can be arranged in a modular configuration such that the housing 1330 and the actuator 1350 can be physically and fluidically coupled to form the control device 1300. In other embodiments, the control device 1300 need not be modular. That is to say, in some embodiments, the control device 1300 can be assembled during manufacturing and delivered to a supplier and/or end user as an assembled device. In

other embodiments, the device 1300 can be monolithically formed and/or collectively formed with, for example, a fluid collection device, as described above.

[1179] The housing 1330 of the control device 1300 can be any suitable shape, size, and/or configuration. As shown in FIGS. 35-37, the housing 1330 forms and/or defines a sequestration chamber 1334 that is in selective fluid communication with a first port 1345 and a second port 1346. The second port 1346 is configured to receive, include, and/or define a flow controller 1342 (see e.g., FIG. 36) and a restricted flow path 1332 (see e.g., FIG. 37). The first port 1345 and the second port 1346 are configured to be at least fluidically coupled to a portion of the actuator 1350 to allow for selective fluid flow between the housing 1330 and the actuator 1350. As described in further detail herein, the sequestration chamber 1334 is configured (1) to receive a selective flow and/or volume of bodily fluid from a portion of the actuator 1350 via the first port 1345, and (2) to sequester (e.g., separate, segregate, contain, retain, isolate, etc.) the flow and/or volume of bodily fluid (e.g., at least a portion of an initial or first flow and/or volume of bodily fluid) within the sequestration chamber 1334. The sequestration chamber 1334 can have any suitable shape, size, and/or configuration. For example, in some embodiments, the sequestration chamber 1334 can be, for example, a channel or the like formed in a portion of the housing 1330 and the housing 1330 can include and/or can be coupled to a cover 1338 configured to enclose the channel, thereby forming the sequestration chamber 1334. In some embodiments, the housing 1330 can be substantially similar in at least form and/or function to the housing 1230 described in detail above with reference to FIGS. 29-34. Accordingly, the housing 1330 is not described in further detail herein.

[1180] The actuator 1350 of the control device 1300 can be any suitable shape, size, and/or configuration. For example, in some embodiments, the actuator 1350 can be substantially similar in at least form and/or function to the actuators 850 and/or 1250 described in detail above. Accordingly, such similar portions of the actuator 1350 are identified below but may not be described in further detail herein.

[1181] As shown in FIGS. 38-40, the actuator 1350 includes a body 1351 and an actuator rod 1362. The body 1351 of the actuator 1350 includes an inlet 1352 and an outlet 1353. The inlet 1352 and the outlet 1353 can be substantially similar in at least form and/or function to the inlet 852 and the outlet 853, respectively, described above with reference to FIGS. 19-25. Thus, the inlet 1352 is configured to be placed in fluid communication with a bodily fluid source to receive a flow of bodily fluid therefrom (e.g., via a lumen-containing device such as a needle, IV catheter, surgical tubing, other standard bodily-fluid transfer device, PICC line, or

the like). The outlet 1353 is configured to be fluidically coupled to a fluid collection device (not shown in FIGS. 35-40) such as, for example, a sample reservoir, a syringe, and/or other intermediary bodily fluid transfer device, adapter, or vessel such as, for example, a transfer device similar to those described in the '510 publication.

[1182] The body 1351 of the actuator 1350 includes and/or defines a first port 1358 and a second port 1359. The first port 1358 is in fluid communication with the inlet 1352 and the second port 1359 is in fluid communication with the outlet 1353. In addition, the first port 1358 and the second port 1359 are configured to be at least fluidically coupled to the first port 1345 and the second port 1346, respectively, of the housing 1330. In some embodiments, the arrangement of the ports 1358 and 1359 of the actuator 1350 and the ports 1345 and 1346 of the housing 1330 can allow for and/or otherwise can provide a means of physically coupling the housing 1330 to the actuator 1350 as well as fluidically coupling the housing 1330 to the actuator 1350. That is to say, in some embodiments, the arrangement of the ports 1358 and 1359 of the actuator 1350 and the ports 1345 and 1346 of the housing 1330 can allow for a modular configuration or arrangement as described above with reference to the control device 800. In other embodiments, the housing 1330 and/or actuator 1350 need not be modular.

[1183] As shown in FIGS. 39 and 40, a portion of the actuator rod 1362 includes and/or is coupled to a set of seals 1365. The seals 1365 can be, for example, o-rings, elastomeric material, silicone or any other suitable material or configuration as described above with reference to the seals 1265. The arrangement of the actuator 1362 and the body 1351 of the actuator 1350 can be such that the seals 1365 form one or more fluid tight seals between the actuator rod 1362 and the inner surface of the body 1351, as described above with reference to the actuator 850. In the embodiment shown in FIGS. 33 and 34, the actuator rod 1362 includes and/or is coupled to three seals 1365 which form and/or define a first fluid flow path 1333 within the body 1351 of the actuator 1350 and a second fluid flow path 1354 within the body 1351 of the actuator 1350.

[1184] As described above with reference to the device 800, the device 1300 can be used to procure a bodily fluid sample having reduced contamination from microbes such as, for example, dermally residing microbes, microbes external to the bodily fluid source, and/or the like. For example, the actuator rod 1362 is configured to be moved or transitioned relative to the body 1351 between a first position or configuration and a second position or configuration. As shown in FIG. 39, when in the first position and/or configuration, the inlet 1352 of the actuator 1350 is in fluid communication with the first fluid flow path 1333, which in turn, is in fluid communication with the first port 1358. The outlet 1353 of the actuator 1350 is in fluid

communication with the second fluid flow path 1354, which in turn, is in fluid communication with the second port 1359. Thus, when in the actuator 1350 and/or actuator rod 1362 is in the first position and/or configuration (e.g., when the control device 1300 is in a first state or operating mode), the negative pressure within the fluid collection device (not shown in FIGS. 35-40) can result in a negative pressure (or negative pressure differential) within at least a portion of the sequestration chamber 1334 that is operable in drawing at least a portion of an initial flow, amount, or volume of bodily fluid from the inlet 1352, through the first fluid flow path 1333, and into the sequestration chamber 1334. Moreover, in some instances, the initial volume and/or flow of bodily fluid can be transferred into the sequestration chamber 1334 until, for example, the bodily fluid disposed within the sequestration chamber 1334 transitions the flow controller 1342 from an open or unsealed configuration or state (e.g., one in which a flow of gas or air can be drawn therethrough) to a sealed configuration or state (e.g., one in which a flow of gas and liquid cannot be drawn therethrough).

[1185] In some instances, a force can be exerted on a first end portion 1363 of the actuator rod 1362 to place the actuator rod 1362 and/or actuator 1350 in its second position, state, operating mode, and/or configuration, as shown in FIG. 35. As described above, in some instances, prior to exerting the force on the first end portion 1363 of the actuator rod 1362, the actuator 1350 may be transitioned from a locked configuration or state to an unlocked configuration or state. In some embodiments, the transition of the actuator rod 1362 can be achieved by and/or can otherwise result from user interaction and manipulation of the actuator rod 1362, automatically in response to negative pressure and associated flow dynamics within the device 1300, and/or enacted by or in response to an external energy source which creates dynamics that result in the transitioning of the actuator rod 1362.

[1186] When the actuator rod 1362 and/or the actuator 1350 is placed in its second position and/or configuration (e.g., when the control device 1300 is transitioned to a second state or operating mode), the inlet 1352 and the outlet 1353 of the actuator 1350 are each in fluid communication with the second fluid flow path 1354 while the first fluid flow path 1333 is sequestered, isolated, and/or otherwise not in fluid communication with the inlet 1352 and the outlet 1353. As described in detail above, in some instances, contaminants such as, for example, dermally residing microbes or the like dislodged during the venipuncture event or throughout the bodily-fluid collection process, can be entrained and/or included in the initial volume of the bodily fluid and thus, are sequestered in the sequestration chamber 1334 when the initial volume is sequestered therein. As such, the negative pressure otherwise exerted on or through the sequestration chamber 1334 is now exerted on or through the second fluid flow

path 1354. In response, bodily fluid can flow from the inlet 1352, through the second fluid flow path 1354, through the outlet 1353, and into the fluid collection device coupled to the outlet 1353. Accordingly, the device 1300 can function in a manner substantially similar to that of the device 800 and thus, the function of the device 1300 is not described in further detail herein.

[1187] In some instances, it may be desirable to isolate the negative pressure source (e.g., the fluid collection device from the inlet 1353 such as, for example, if it is desirable to collect multiple samples of bodily fluid using multiple fluid collection devices (e.g., syringes or the like). For example, in some instances, after filling the fluid collection device the user can engage the actuator 1350 and exert a force on a second end portion 1364 of the actuator rod 1362 to move and/or transition the actuator rod 1362 from its second position and/or configuration toward its first position and/or configuration. As such, the second fluid flow path 1354 no longer places the inlet 1352 in fluid communication with the outlet 1353. Moreover, the flow controller 1342 can remain in the sealed state or configuration (e.g., fully saturated, wetted, and/or otherwise preventing flow therethrough) such that the outlet 1353 is substantially sequestered or isolated from the rest of the control device 1300. In some instances, the user can then remove the filled fluid collection device and can couple a new fluid collection device to the outlet 1353. With the new fluid collection device coupled to the outlet 1353, the user can, for example, exert a force on the first end portion 1363 of the actuator rod 1362 to move and/or transition the actuator rod 1362 back to its second position, state, and/or configuration, as described above with reference to the actuator 850.

[1188] FIGS. 41-44 illustrate a fluid control device 1400 according to an embodiment. The fluid control device 1400 can be similar in at least form and/or function to the fluid control devices described herein. More specifically, portions of the fluid control device 1400 can be similar to and/or substantially the same as corresponding portions of the fluid control devices 200, 300, 800, 900, 1000, 1100, 1200, and/or 1300 described above. Accordingly, such portions of the fluid control device 1400 are not described in further detail herein.

[1189] The fluid control device 1400 (also referred to herein as "control device" or "device") includes a housing 1430 and an actuator 1450. As described above with reference to the control device 800, the control device 1400 can be arranged in a modular configuration such that the housing 1430 and the actuator 1450 can be physically and fluidically coupled to form the control device 1400. In other embodiments, the control device 1400 need not be modular. That is to say, in some embodiments, the control device 1400 can be assembled during manufacturing and delivered to a supplier and/or end user as an assembled device. In

other embodiments, the device 1400 can be monolithically formed and/or collectively formed with, for example, a fluid collection device, as described above.

[1190] The housing 1430 of the control device 1400 can be any suitable shape, size, and/or configuration. The housing 1430 is configured to be in selective fluid communication with a portion of the actuator 1450 via a first port 1458 and a second port 1459. As shown in FIGS. 43 and 44, the housing 1430 includes a bladder 1478 that can be transitioned from a first configuration and/or state to a second configuration and/or state to form and/or define a sequestration chamber 1434. As described in further detail herein, the bladder 1478 is configured to transition from the first configuration and/or state (FIG. 43) to the second configuration and/or state (FIG. 44) to form and/or define the sequestration chamber 1434, which in turn, is configured to receive a selective flow and/or volume of bodily fluid from a portion of the actuator 1450 via the first port 1458. After the bladder 1478 is placed in the second configuration and/or state, the sequestration chamber 1434 can sequester (e.g., separate, segregate, contain, retain, isolate, etc.) the flow and/or volume of bodily fluid (e.g., at least a portion of an initial or first flow and/or volume of bodily fluid) within the sequestration chamber 1434.

[1191] While the bladder 1478 is particularly shown in FIGS. 43 and 44, in other embodiments, the bladder 1478 can be any suitable shape, size, and/or configuration. Similarly, the bladder 1478 can be formed of any suitable material (e.g., any suitable biocompatible material such as those described herein and/or any other suitable material). In some embodiments, the bladder 1478 can be arranged and/or configured as, for example, a bellows, an expandable bag, a flexible pouch, and/or any other suitable reconfigurable container or the like. In addition, the sequestration chamber 1434 formed by the bladder 1478 can have any suitable shape, size, and/or configuration. In some embodiments, the housing 1430 can be substantially similar in at least form and/or function to the housing 1230 and/or 1330 described in detail above with reference to FIGS. 29-34 and FIGS. 35-40, respectively. Accordingly, the housing 1430 is not described in further detail herein.

[1192] The actuator 1450 of the control device 1400 can be any suitable shape, size, and/or configuration. For example, in some embodiments, the actuator 1450 can be substantially similar in at least form and/or function to the actuators 850, 1250, and/or 1350 described in detail above. Accordingly, such similar portions of the actuator 1450 are identified below but may not be described in further detail herein.

[1193] As shown in FIGS. 41-44, the actuator 1450 includes a body 1451 and an actuator rod 1462. The body 1451 of the actuator 1450 includes an inlet 1452 and an outlet 1453. The

inlet 1452 and the outlet 1453 can be substantially similar in at least form and/or function to the inlet 1252 and the outlet 1253, respectively, described above with reference to FIGS. 29-34. Thus, the inlet 1452 is configured to be placed in fluid communication with a bodily fluid source to receive a flow of bodily fluid therefrom (e.g., via a lumen-containing device such as a needle, IV catheter, surgical tubing, other standard bodily-fluid transfer device, PICC line, or the like). The outlet 1453 is configured to be fluidically coupled to a fluid collection device (not shown in FIGS. 41-44) such as, for example, a sample reservoir, a syringe, and/or other intermediary bodily fluid transfer device, adapter, or vessel such as, for example, a transfer device similar to those described in the '510 publication.

[1194] The body 1451 of the actuator 1450 includes and/or defines the first port 1458 and the second port 1459. Although not shown, the first port 1458 is configured to be in fluid communication with the inlet 1452 and the second port 1459 is configured to be in fluid communication with the outlet 1453. In addition, the first port 1458 is configured to be in fluid communication with the housing 1430 and more particularly, an inner volume or an inlet side of the bladder 1478 that forms the sequestration chamber 1434. The second port 1459 is configured to be in fluid communication with a portion of the housing 1430 defined between an inner surface of the housing 1430 and an outer surface of the bladder 1478. In other words, the second port 1459 is in fluid communication with a portion of the housing 1430 that is isolated and/or sequestered from the inner volume of the bladder 1478 that forms the sequestration chamber 1434. In some embodiments, the arrangement of the ports 1458 and 1459 of the actuator 1450 can allow for and/or otherwise can provide a means of physically coupling the housing 1430 to the actuator 1450 as well as fluidically coupling the housing 1430 to the actuator 1450. That is to say, in some embodiments, the arrangement of the ports 1458 and 1459 of the actuator 1450 can allow for a modular configuration or arrangement as described above with reference to the control device 800. In other embodiments, the housing 1430 and/or actuator 1450 need not be modular.

[1195] Although not shown in FIGS. 41-44, a portion of the actuator rod 1462 includes and/or is coupled to a set of seals. The seals can be, for example, o-rings, elastomeric material, silicone or any other suitable material or configuration as described above with reference to the seals 1265 and/or 1365. The arrangement of the actuator rod 1462 and the body 1451 of the actuator 1450 can be such that the seals form one or more fluid tight seals between the actuator rod 1462 and the inner surface of the body 1451, as described above with reference to the actuators 850, 1250, and/or 1350. Moreover, as described above with reference to the actuators 1250 and/or 1350, the actuator rod 1462 can include and/or can be coupled to a set seals which

selectively form and/or define a first fluid flow path configured to place the inlet 1452 of the actuator 1450 in fluid communication with the first port 1458 (e.g., when in a first position, state, operating mode, and/or configuration) and a second fluid flow path configured to place the inlet 1452 in fluid communication with the outlet 1453 (e.g., when in a second position, state, operating mode, and/or configuration).

[1196] As described above with reference to the devices 800, 1200, and/or 1300, the device 1400 can be used to procure a bodily fluid sample having reduced contamination from microbes such as, for example, dermally residing microbes, microbes external to the bodily fluid source, and/or the like. For example, as described above with reference to the devices 1200 and/or 1300, the actuator rod 1462 can be configured to be moved or transitioned relative to the body 1451 between a first position or configuration and a second position or configuration. When in the first position and/or configuration, the inlet 1452 of the actuator 1450 is in fluid communication with, for example, the first fluid flow path, which in turn, is in fluid communication with the first port 1458 (not shown in FIGS. 41-44). The outlet 1453 of the actuator 1450 is in fluid communication with the second fluid flow path 1454, which in turn, is in fluid communication with the second port 1459. Thus, when in the actuator 1450 and/or actuator rod 1462 is in the first position and/or configuration (e.g., when the control device 1400 is in a first state or operating mode), the negative pressure within the fluid collection device (not shown in FIGS. 41-44) can result in a negative pressure (or negative pressure differential) within the portion of the housing 1430 defined between the inner surface of the housing 1430 and the outer surface of the bladder 1478.

[1197] As shown in FIG. 43, the bladder 1478 can be in a first state and/or configuration prior to the fluid collection device being coupled to the outlet 1453. In some embodiments, for example, the bladder 1478 can have a flipped, inverted, collapsed, and/or empty configuration prior to coupling the fluid collection device to the outlet 1453. As shown in FIG. 44, the bladder 1478 can be configured to transition from the first state and/or configuration to a second state and/or configuration in response to the negative pressure differential resulting from the coupling of the fluid collection device to the outlet 1453. In other words, the negative pressure differential can be operable to transition the bladder 1478 from a collapsed or unexpanded configuration and/or state to an expanded configuration and/or state. For example, in some embodiments, the transitioning of the bladder 1478 can be similar to the transitioning and/or "flipping" of the diaphragm 576, described above with reference to FIGS. 11 and 12.

[1198] As described above, the bladder 1478 can be configured to transition from the first configuration and/or state to the second configuration and/or state to form and/or define the

sequestration chamber 1434. In some embodiments, the transitioning of the bladder 1478 results in an increase in an inner volume of the bladder 1478 (i.e., the sequestration chamber 1434). The increase in the inner volume can, in turn, result in a negative pressure differential between the sequestration chamber 1434 defined by the bladder 1478 and the inlet 1452 that is operable in drawing at least a portion of an initial flow, amount, or volume of bodily fluid from the inlet 1452, through the first port 1458, and into the sequestration chamber 1434. Moreover, in some instances, the initial volume and/or flow of bodily fluid can be transferred into the sequestration chamber 1434 until, for example, the bladder 1478 is fully expanded, and/or until the negative pressure differential is reduced and/or equalized.

[1199] Having transferred the initial volume of bodily fluid into the sequestration chamber 1434, a force can be exerted on a first end portion 1463 of the actuator rod 1462 to place the actuator rod 1462 and/or actuator 1450 in its second position, state, operating mode, and/or configuration, as described in detail above with reference to the devices 1200 and/or 1300. As described above, in some instances, prior to exerting the force on the first end portion 1463 of the actuator rod 1462, the actuator 1450 may be transitioned from a locked configuration or state to an unlocked configuration or state. In some embodiments, the transition of the actuator rod 1462 can be achieved by and/or can otherwise result from user interaction and manipulation of the actuator rod 1462, automatically in response to negative pressure and associated flow dynamics within the device 1400, and/or enacted by or in response to an external energy source which creates dynamics that result in the transitioning of the actuator rod 1462.

[1200] When the actuator rod 1462 and/or the actuator 1450 is placed in its second position and/or configuration (e.g., when the control device 1400 is transitioned to a second state or operating mode), the inlet 1452 and the outlet 1453 of the actuator 1450 are placed in fluid communication (e.g., via the second fluid flow path (not shown)) while the first fluid flow path (not shown) and/or the first port 1458 is sequestered, isolated, and/or otherwise not in fluid communication with the inlet 1452 and/or the outlet 1453. As described in detail above, in some instances, contaminants such as, for example, dermally residing microbes or the like dislodged during the venipuncture event or throughout the bodily-fluid collection process, can be entrained and/or included in the initial volume of the bodily fluid and thus, are sequestered in the sequestration chamber 1434 when the initial volume is sequestered therein. As such, the negative pressure otherwise exerted on or through the housing 1430 is now exerted on or through the outlet 1453 and the inlet 1452 via, for example, the second fluid flow path (not shown). In response, bodily fluid can flow from the inlet 1452, through the body 1451 of the actuator 1450, through the outlet 1453, and into the fluid collection device coupled to the outlet

1453. Accordingly, the device 1400 can function in a manner substantially similar to that of the devices 800, 1200, and/or 1300 and thus, the function of the device 1400 is not described in further detail herein.

[1201] While the device 1400 is described above as including the housing 1430 and the actuator 1450, in other embodiments, a fluid control device can have, for example, at least a partially integrated design. For example, FIGS. 45-50 illustrate a fluid control device 1500 according to an embodiment. The fluid control device 1500 can be similar in at least form and/or function to the fluid control devices described herein. More specifically, portions of the fluid control device 1500 can be similar to and/or substantially the same as corresponding portions of at least the fluid control device 1400 described above with reference to FIGS. 41-44. Accordingly, such portions of the fluid control device 1500 are not described in further detail herein.

[1202] The fluid control device 1500 (also referred to herein as "control device" or "device") includes an actuator 1550 having an actuator body 1551 and an actuator rod 1562. The actuator 1550 can be any suitable shape, size, and/or configuration. For example, in some embodiments, the actuator 1550 can be substantially similar in at least form and/or function to the actuators 850, 1250, 1350, and/or 1450 described in detail above. Accordingly, such similar portions of the actuator 1550 are identified below but may not be described in further detail herein.

[1203] As shown in FIGS. 45-50, the actuator 1550 includes an inlet 1552 and an outlet 1553, each of which is in fluid communication with the body 1551. The inlet 1552 and the outlet 1553 can be substantially similar in at least form and/or function to the inlet 1252 and the outlet 1253, respectively, described above with reference to FIGS. 29-34. Thus, the inlet 1552 is configured to be placed in fluid communication with a bodily fluid source to receive a flow of bodily fluid therefrom (e.g., via a lumen-containing device such as a needle, IV catheter, surgical tubing, other standard bodily-fluid transfer device, PICC line, or the like). The outlet 1553 is configured to be fluidically coupled to a fluid collection device (not shown in FIGS. 45-50) such as, for example, a sample reservoir, a syringe, and/or other intermediary bodily fluid transfer device, adapter, or vessel such as, for example, a transfer device similar to those described in the '510 publication.

[1204] As shown in FIGS. 48-50, the actuator 1550 includes a bladder 1578 that can be transitioned from a first configuration and/or state (FIG. 48) to a second configuration and/or state (FIG. 49) to form and/or define a sequestration chamber 1534. As described in further detail herein, the bladder 1578 is configured to transition from the first configuration and/or

state (FIG. 48) to the second configuration and/or state (FIGS. 49 and 50) to form and/or define the sequestration chamber 1534, which in turn, is configured to receive a selective flow and/or volume of bodily fluid from the inlet 1552. After the bladder 1578 is placed in the second configuration and/or state, the sequestration chamber 1534 can sequester (e.g., separate, segregate, contain, retain, isolate, etc.) the flow and/or volume of bodily fluid (e.g., at least a portion of an initial or first flow and/or volume of bodily fluid) within the sequestration chamber 1534. As such, the bladder 1578 can be substantially similar in at least form and/or function to the bladder 1478 described above with reference to FIGS. 41-44 and thus, is not described in further detail herein.

[1205] As shown in FIGS. 46 and 48-50, the body 1551 of the actuator 1550 includes and/or defines a port 1559 configured to be in fluid communication with the outlet 1553. In addition, the port 1559 defines a fluid flow path that is configured to be in fluid communication with a portion of the actuator 1550 defined between an inner surface of the body 1551 and an outer surface of the bladder 1578. In other words, the port 1559 is in fluid communication with a portion of the actuator 1550 that is isolated and/or sequestered from the inner volume of the bladder 1578 that forms and/or that is configured to form the sequestration chamber 1534.

[1206] As described above with reference to the devices 1200, 1300, and/or 1400, a portion of the actuator rod 1562 includes and/or is coupled to a set of seals 1565. The seals 1565 can be, for example, o-rings, elastomeric material, silicone or any other suitable material or configuration as described above with reference to the seals 1265 and/or 1365. The arrangement of the actuator rod 1562 and the body 1551 of the actuator 1550 can be such that the seals 1565 form one or more fluid tight seals between the actuator rod 1562 and the inner surface of the body 1551, as described above with reference to the actuators 850, 1250, and/or 1350. Moreover, as described above with reference to the actuators 1250 and/or 1350, the set seals 1565 can be arranged along the actuator rod 1562 to selectively form and/or define a fluid flow path 1554 that is sequestered from and/or fluidically isolated from the inlet 1552 when the actuator rod 1562 is in a first position and/or configuration and that is configured to place the inlet 1552 in fluid communication with the outlet 1553 when the actuator rod 1562 is in a second position and/or configuration.

[1207] As described above with reference to the devices 800, 1200, 1300, and/or 1400, the device 1500 can be used to procure a bodily fluid sample having reduced contamination from microbes such as, for example, dermally residing microbes, microbes external to the bodily fluid source, and/or the like. For example, as described above with reference to the devices 1200, 1300, and/or 1400, the actuator rod 1562 can be configured to be moved or transitioned

relative to the body 1551 between the first position or configuration and the second position or configuration. When in the first position and/or configuration, the inlet 1552 of the actuator 1550 is in fluid communication with a fluid flow path, which in turn, is in fluid communication with a portion of the body 1551 that is disposed on an inlet side of the bladder 1578. In other words, the fluid flow path establishes fluid communication between the inlet 1553 and the bladder 1578 and/or the sequestration chamber 1534 at least partially defined by the bladder 1578 when the bladder 1578 is transitioned to the second configuration and/or state. The outlet 1553 of the actuator 1550 is in fluid communication with the port 1559. Thus, when in the actuator 1550 and/or actuator rod 1562 is in the first position and/or configuration (e.g., when the control device 1500 is in a first state or operating mode), the negative pressure within the fluid collection device (not shown in FIGS. 45-50) can result in a negative pressure (or negative pressure differential) within the portion of the actuator body 1551 defined between the inner surface of the body 1551 and the outer surface of the bladder 1578, as described above with reference to the device 1400.

[1208] As shown in FIG. 48, the bladder 1578 can be in a first state and/or configuration prior to the fluid collection device being coupled to the outlet 1553. In some embodiments, for example, the bladder 1578 can have a flipped, inverted, collapsed, and/or empty configuration prior to coupling the fluid collection device to the outlet 1553. Moreover, when the actuator rod 1562 is in the first position and/or configuration, the fluid flow path 1554 is fluidically isolated from the inlet 1552. Accordingly, as shown in FIG. 49, the bladder 1578 can be configured to transition from the first state and/or configuration to a second state and/or configuration in response to the negative pressure differential resulting from the coupling of the fluid collection device to the outlet 1553. In other words, the negative pressure differential can be operable to transition the bladder 1578 from a collapsed or unexpanded configuration and/or state to an expanded configuration and/or state. For example, in some embodiments, the transitioning of the bladder 1578 can be similar to the transitioning and/or "flipping" of the diaphragm 576, described above with reference to FIGS. 11 and 12. In other embodiments, the bladder 1578 can be configured to transition between a first state and/or configuration to a second state and/or configuration in any suitable manner such as any of those described herein.

[1209] As described above, the bladder 1578 can be configured to transition from the first configuration and/or state to the second configuration and/or state to form and/or define the sequestration chamber 1534. In some embodiments, the transitioning of the bladder 1578 results in an increase in an inner volume of the bladder 1578 (i.e., the sequestration chamber 1534). The increase in the inner volume can, in turn, result in a negative pressure differential

between the sequestration chamber 1534 defined by the bladder 1578 and the inlet 1552 that is operable in drawing at least a portion of an initial flow, amount, or volume of bodily fluid from the inlet 1552 and a portion of the actuator body 1551, and into the sequestration chamber 1534. Moreover, in some instances, the initial volume and/or flow of bodily fluid can be transferred into the sequestration chamber 1534 until, for example, the bladder 1578 is fully expanded, and/or until the negative pressure differential is reduced and/or equalized.

[1210] Having transferred the initial volume of bodily fluid into the sequestration chamber 1534, a force can be exerted on a first end portion 1563 of the actuator rod 1562 to place the actuator rod 1562 and/or actuator 1550 in its second position, state, operating mode, and/or configuration, as described in detail above with reference to the devices 1200 and/or 1300. As described above, in some instances, prior to exerting the force on the first end portion 1563 of the actuator rod 1562, the actuator 1550 may be transitioned from a locked configuration or state to an unlocked configuration or state. In some embodiments, the transition of the actuator rod 1562 can be achieved by and/or can otherwise result from user interaction and manipulation of the actuator rod 1562, automatically in response to negative pressure and associated flow dynamics within the device 1500, and/or enacted by or in response to an external energy source which creates dynamics that result in the transitioning of the actuator rod 1562.

[1211] When the actuator rod 1562 and/or the actuator 1550 is placed in its second position and/or configuration (e.g., when the control device 1500 is transitioned to a second state or operating mode), the inlet 1552 and the outlet 1553 of the actuator 1550 are placed in fluid communication via the fluid flow path 1554 while the sequestration chamber 1534 is sequestered, isolated, and/or otherwise not in fluid communication with the inlet 1552 and/or the outlet 1553. As described in detail above, in some instances, contaminants such as, for example, dermally residing microbes or the like dislodged during the venipuncture event or throughout the bodily-fluid collection process, can be entrained and/or included in the initial volume of the bodily fluid and thus, are sequestered in the sequestration chamber 1534 when the initial volume is sequestered therein.

[1212] As described above with reference to the devices 1200 and/or 1300, transitioning the actuator rod 1562 to the second position and/or configuration is such that the fluid flow path 1554 places the inlet 1552 in fluid communication with the outlet 1553. For example, transitioning the actuator rod 1562 to the second position and/or configuration can move the seals 1565 relative to the inlet 1552 such that the fluid flow path 1554 is placed in fluid communication with both the inlet 1552 and the outlet 1553. As such, the negative pressure otherwise exerted on the outer surface of the bladder 1578 is now exerted on or through the

outlet 1553 and the inlet 1552 via the fluid flow path 1554. In response, bodily fluid can flow from the inlet 1552, through the fluid flow path 1554, through the outlet 1553, and into the fluid collection device coupled to the outlet 1553. Accordingly, the device 1500 can function in a manner substantially similar to that of the devices 800, 1200, 1300, and/or 1400 and thus, the function of the device 1500 is not described in further detail herein.

[1213] While the actuators 850, 1250, 1350, 1450, and 1550 have been described in detail above as being transitioned in response to an external force such as, for example, a force exerted by a user, in other embodiments, a fluid control device can include one or more actuators that can be transitioned in response to any suitable force, input, change of state or configuration, etc. For example, FIGS. 51 and 52 illustrate a portion of a fluid control device 1600 according to an embodiment. The fluid control device 1600 can be similar in at least form and/or function to the fluid control devices described herein. More specifically, portions of the fluid control device 1600 can be similar to and/or substantially the same as corresponding portions of at least the fluid control devices 500, 600, and/or 700 described above. Accordingly, such portions of the fluid control device 1600 are not described in further detail herein.

[1214] As shown in FIGS. 51 and 52, the fluid control device 1600 (also referred to herein as "control device" or "device") includes a housing 1630 having an inlet 1631 and an outlet 1636, and having and/or being coupled to an actuator 1650. As described in further detail herein, the housing 1630 defines a set of fluid flow paths 1633 and 1654 configured to establish fluid communication between one or more portions of the housing 1630 to selectively receive a flow of fluid therethrough (e.g., a liquid and/or a gas). The inlet 1631 is configured to be placed in fluid communication with a bodily fluid source to receive a flow of bodily fluid therefrom (e.g., via a lumen-containing device such as a needle or the like, as described in detail above). The outlet 1636 is configured to be fluidically coupled to a fluid collection device (not shown in FIGS. 51 and 52). The inlet 1631, the outlet 1636, and the fluid collection device can be substantially similar to those described above and thus, are not described in further detail herein.

[1215] The housing 1630 can be any suitable shape, size, and/or configuration. In some embodiments, the housing 1630 can have a size that is at least partially based on a volume of bodily fluid configured to be at least temporarily stored within one or more portions of the housing 1630. As described above, the housing 1630 of the control device 1600 is configured to (1) receive a flow and/or volume of bodily fluid via the inlet 1631 and (2) sequester (e.g., separate, segregate, contain, retain, isolate, etc.) the flow and/or volume of bodily fluid within a sequestration chamber 1634 included in and/or at least partially formed by the housing 1630.

In some embodiments, aspects of the housing 1630 can be substantially similar, for example, to aspects of the housings 630, 730, and/or 830. Accordingly, some portions and/or aspects of the housing 1630 are not described in further detail herein.

[1216] The housing 1630 includes and/or is coupled to the actuator 1650 configured to selectively control a flow of bodily fluid through the housing 1630. In this embodiment, the actuator 1650 includes a diaphragm 1676 and an actuator rod 1662 having a set of seals (e.g., seals 1665 and 1666). As described in further detail herein, the diaphragm 1676 and the actuator rod 1662 are configured to transition, move, and/or otherwise reconfigure within the housing 1630 in response to a negative pressure differential within at least a portion of the device. More specifically, the actuator 1650 is configured to move between a first state in which the inlet 1631 is placed in fluid communication with the sequestration chamber 1634 and a second state in which the inlet 1631 is placed in fluid communication with the outlet 1636 via the fluid flow path 1654, as described in detail above with reference to the control device 500.

[1217] In some embodiments, the diaphragm 1676 can be similar to, for example, the diaphragms 576, 676, and/or 776 described in detail above. Accordingly, the diaphragm 1676 can be at least partially disposed in a sequestration portion of the housing 1630 to define and/or to form at least a portion of the sequestration chamber 1634. As described in detail above, the diaphragm 1676 can be configured to transition, move, flip, and/or otherwise reconfigure from a first state to a second state in response to a negative pressure differential, which can be operable to draw an initial volume of bodily fluid into the sequestration chamber 1634 and/or to sequester the initial volume of bodily fluid in the sequestration chamber 1634 once disposed therein. Moreover, as shown in FIGS. 51 and 52, the diaphragm 1676 can include and/or can be coupled to a flow controller 1642. The flow controller 1642 can be any suitable flow controller such as any of those described herein. For example, in some embodiments, the flow controller 1642 can be a semi-permeable member or membrane such as an air permeable/liquid impermeable barrier (e.g., a blood barrier).

[1218] As described in detail above, the flow controller 1642 can be configured to transition from a first state in which the flow controller 1642 allows a flow of gas (e.g., air) to pass through the flow controller 1642 while preventing a flow of liquid (e.g., bodily fluid) to pass therethrough, to a second state in which the flow controller 1642 limits and/or substantially prevents a flow of gas and liquid to pass through the flow controller 1642. In some embodiments, the flow controller 1642 can be configured to transition from the first state to the second state in response to contact with, for example, the initial volume of bodily fluid

(e.g., at least a portion of the initial volume of bodily fluid can wet or saturate the flow controller 1642 to place the flow controller 1642 in the second state).

[1219] While the diaphragms 576, 676, and 776 are shown and described above as including a pin, rod, post, and/or the like that include and/or are coupled to one or more seals (e.g., the seals 565, 665, and 765, respectively), in the embodiment shown in FIGS. 51 and 52, the diaphragm 1676 includes a pin 1677 (e.g., a rod, an extension, a protrusion, a latch, a lock, and/or any other suitable feature, member, and/or mechanism) that does not include and/or is not coupled to a seal. For example, in this embodiment, the pin 1677 extends through a portion of the housing 1630 to selectively engage a portion of the actuator rod 1662, which in turn includes one or more seals (e.g., the seals 1665 and 1666), as described in further detail herein.

[1220] As shown in FIGS. 51 and 52, the actuator rod 1662 is movably disposed in, for example, an actuator portion 1639 of the housing 1630. The actuator rod 1662 includes a first seal 1665 and a second seal 1666 and is in contact with an energy storage member 1667 such as a spring or the like disposed within the actuator portion 1639 of the housing 1630. In the embodiment shown in FIGS. 51 and 52, the arrangement of the actuator 1650 can be such that a first end portion of the actuator rod 1662 is in selective contact with the pin 1677 of the diaphragm 1676 and a second end portion of the actuator rod 1662 (opposite the first end portion) is in contact with and/or otherwise is engaged with the energy storage member 1667.

[1221] As shown in FIG. 51, when the actuator 1650 is in a first state, the pin 1677 of the diaphragm 1676 can engage the actuator rod 1662 to maintain the actuator rod 1662 in a first or initial state and/or position in which the energy storage member 1667 has a relatively high potential energy (e.g., the energy storage member 1667 can be a spring maintained and/or held in a compressed state when in the first state). Furthermore, the first seal 1665 coupled to and/or disposed on the actuator 1662 is in a first or initial position in which the fluid flow path 1633 establishes fluid communication between the inlet 1631 and the sequestration chamber 1634 when the actuator 1650 is in the first state. As shown, the second seal 1666 coupled to and/or disposed on the actuator rod 1662 is likewise in a first or initial position in which the second seal 1666 is spaced apart from a seal surface 1640 formed by at least a portion of the actuator portion 1639 of the housing 1630.

[1222] In some embodiments, the separation of the second seal 1666 from the seal surface 1640 can be such that the fluid flow path 1654 places the outlet 1636 in fluid communication with the sequestration chamber 1634 via a restricted flow path 1632 (see FIG. 52). In some embodiments, the restricted flow path 1632 can be similar in at least form and/or function to any of the restricted flow paths described herein (e.g., the restricted flow paths 232, 832, 1232,

and/or 1332). As such, the restricted flow path 1632 can be configured to modulate a magnitude of a negative pressure differential applied on or in the sequestration chamber 1634 and/or a rate at which a negative pressure differential increases within the sequestration chamber 1634. In other embodiments, the outlet 1636 can be in fluid communication with the sequestration chamber 1634 via any suitable flow path, port, opening, valve, etc. In other words, in some embodiments, the control device 1600 need not include the restricted flow path 1632.

[1223] As shown in FIG. 51, when the actuator 1650 is in the first state, the actuator rod 1662 can be maintained in a first state or position in which the fluid flow path 1633 places the inlet 1631 in fluid communication with the sequestration chamber 1634, and the fluid flow path 1654 places the outlet 1636 in fluid communication with the sequestration chamber 1634 via the restricted flow path 1632. Accordingly, when a fluid collection device (such as those described herein) is coupled to the outlet 1636, a negative pressure defined in and/or otherwise produced by the fluid collection device can be operable to draw the initial volume of bodily fluid into the sequestration chamber 1634.

[1224] As described in detail above, the actuator 1650 can be transitioned to a second state and/or configuration in response to the initial volume being transferred into the sequestration chamber 1634. For example, in some embodiments, the initial volume of bodily fluid can be drawn into the sequestration chamber 1634 in response to a negative pressure being exerted through the flow controller 1642 (e.g., the selectively permeable membrane). In some instances, at least a portion of the bodily fluid drawn into the sequestration chamber 1634 can come into contact with the flow controller 1642, which in turn, can transition the flow controller 1642 from the first state to the second state (e.g., the flow controller 1642 limits and/or substantially prevents a flow of gas and liquid therethrough). As such, a negative pressure exerted on a surface of the diaphragm 1676 can build and can become sufficient to transition, move, and/or flip the diaphragm from a first state and/or configuration to a second state and/or configuration (see FIG. 52). In some embodiments, the transitioning of the diaphragm 1676 can correspond with and/or can be in response to the flow controller 1642 being transitioned from the first state to the second state (e.g., becoming fully wetted or the like, as described in detail above). In other embodiments, the diaphragm 1676 can transition before or after the flow controller 1642 has transitioned from the first state to the second state. In still other embodiments, the control device 1600 need not include the flow controller 1642 and the diaphragm 1676 can be configured to transition in response to being exposed to the negative pressure differential produced by the fluid collection device. In some such embodiments, the

diaphragm 1676 (and/or at least a portion thereof) can be configured to act in a similar manner to the flow controller 1642 by transitioning from the first state to the second state in a predictable and/or predetermined manner after being exposed to a predetermined negative pressure differential or a predetermined rate of change in negative pressure. Moreover, the transitioning of the diaphragm 1676 can be automatic (e.g., is not a result of user intervention).

[1225] As shown in FIG. 52, when the diaphragm 1676 is transitioned, moved, flipped, etc., the pin 1677 can be moved within the housing 1630 and relative to the actuator rod 1662. More particularly, the transitioning of the diaphragm 1676 can move the pin 1677 a sufficient amount that the pin 1677 is disengaged from the actuator rod 1662. As such, the energy storage member 1667 (e.g., spring) can be configured to release and/or convert at least a portion of its potential energy. As a specific example, in this embodiment, moving the pin 1677 can allow the spring 1667 to expand from a first or compressed state to a second or substantially uncompressed state. The transitioning of the energy storage member 1667 (e.g., spring) from the first state to the second state, in turn, moves the actuator rod 1662 within the actuator portion 1639 from a first state and/or position to a second state and/or position.

[1226] As shown in FIG. 52, when the actuator rod 1662 is in the second state and/or position, the first seal 1665 can be placed in a second or subsequent position in which the first seal 1665 sequesters the sequestration chamber 1634 from the inlet 1631. Similarly, the second seal 1666 can be placed in a second or subsequent position in which the second seal 1666 is pushed (e.g., by the energy storage member 1667) against the seal surface 1640, which in turn, sequesters the flow controller 1642 from the fluid flow path 1654. Furthermore, the placement of the first seal 1665 and the second seal 1666 when the actuator rod 1662 is in the second state and/or position is such that the fluid flow path 1633 is placed in fluid communication with the fluid flow path 1654. Thus, a negative pressure differential produced by the fluid collection device coupled to the outlet 1636 can be operable to draw a subsequent volume of bodily fluid from the inlet 1631, through the fluid flow path 1633 and 1654, through the outlet 1636, and into the fluid collection device. Moreover, the collecting and sequestering of the initial volume of bodily fluid can result in the subsequent volume(s) of bodily fluid being substantially free from contaminants, as described in detail above.

[1227] Referring now to FIG. 53, a flowchart is presented illustrating a method 10 of using a fluid control device to obtain a bodily fluid sample with reduced contamination according to an embodiment. The fluid control device can be similar to and/or substantially the same as any of the fluid control devices described in detail above. The method 10 includes establishing fluid communication between a bodily fluid source and an inlet of the fluid collection device,

at 11. For example, in some embodiments, a user can manipulate the fluid control device to physically and/or fluidically couple the inlet to a lumen-containing device (e.g., a needle, IV, PICC line, etc.) in fluid communication with a patient.

[1228] A fluid collection device is coupled to an outlet of the fluid control device, at 12. The coupling of the fluid collection device to the outlet is configured to produce a negative pressure differential within at least a portion of the fluid control device, as described in detail above. In some embodiments, for example, the fluid collection device can be a sample bottle or container that defines a negative pressure. In other embodiments, the fluid collection device can be a syringe or the like that can be manipulated to produce a negative pressure. Accordingly, a negative pressure differential can be produced within one or more portions of the fluid control device, as described above with reference to the control devices 100, 200, 300, 400, 500, 600, 700, 800, 900, 1000, 1100, 1200, 1300, 1400, 1500, and/or 1600.

[1229] An initial volume of bodily fluid is received from the inlet and into a sequestration portion of the fluid control device in response to the negative pressure differential, at 13. For example, in some embodiments, the sequestration portion can be similar to and/or substantially the same as the sequestration chamber 1234 described above with reference to FIGS. 29-34. In other embodiments, the sequestration portion can be similar to and/or substantially the same as the sequestration chamber 1634. In still other embodiments, the sequestration portion can be similar to and/or substantially the same as any of the sequestration chambers described herein. Furthermore, in some instances, the initial volume of bodily fluid can include contaminants entrained therein, which may otherwise result in false results during testing of a bodily fluid sample.

[1230] In response to contact with at least a portion of the initial volume of bodily fluid, a flow controller disposed in the sequestration portion is transitioned from a first state in which the flow controller allows a flow of a gas through the flow controller and prevents a flow of bodily fluid through the flow controller, to a second state in which the flow controller prevents a flow of gas and bodily fluid through the flow controller, at 14. For example, in some embodiments, the flow controller can be a selectively permeable member or membrane (e.g., a fluid or blood barrier and/or the like), as described above with reference to the flow controller 242. In other embodiments, the flow controller can be similar to and/or substantially the same as any of the flow controllers described herein. Thus, in some embodiments, the contact with at least the portion of the initial volume of bodily fluid can, for example, wet or saturate the flow controller such that the flow controller limits and/or substantially prevents a flow of gas and liquid (e.g., bodily fluid) therethrough. In other embodiments, the flow controller can be

a bladder and/or diaphragm that is configured to be transitioned in response to a negative pressure differential. For example, in such embodiments, a flow controller can be a substantially impermeable bladder or diaphragm that can transition from a first state to a second state when a negative pressure differential applied to a surface of the bladder and/or diaphragm exceeds a threshold amount of negative pressure.

[1231] The initial volume of bodily fluid is sequestered in the sequestration portion after the flow controller is transitioned to the second state, at 15. For example, in some embodiments, the fluid control device can include an actuator and/or any other suitable feature or mechanism configured to transition after the flow controller is placed in its second configuration to sequester the initial volume of bodily fluid. In some embodiments, the actuator can transition from a first state to a second state to automatically sequester the initial volume of bodily fluid in the sequestration portion, as described above with reference to, for example, the actuator 1650. In other embodiments, the actuator can transition from a first state to a second state in response to a force exerted by a user, as described above with reference to, for example, the actuator 850. In still other embodiments, the fluid control device can sequester the initial volume of bodily fluid in the sequestration portion in any suitable manner such as those described herein.

[1232] After sequestering the initial volume of bodily fluid, a subsequent volume of bodily fluid is transferred from the inlet, through the outlet, and into the fluid collection device, at 16. As described in detail above, in some instances, sequestering the initial volume of bodily fluid in the sequestration portion of the fluid control device can likewise sequester contaminants contained in the initial volume. Accordingly, contaminants in the subsequent volume of bodily fluid can be reduced or substantially eliminated.

[1233] While various embodiments have been described above, it should be understood that they have been presented by way of example only, and not limitation. Where schematics and/or embodiments described above indicate certain components arranged in certain orientations or positions, the arrangement of components may be modified. While the embodiments have been particularly shown and described, it will be understood that various changes in form and details may be made. For example, while the control devices 100, 200, 300, 400, 500, 600, 700, 800, 900, 1000, 1100, 1200, 1300, 1400, and/or 1500 are described as transferring a bodily fluid into the device as a result of a negative pressure within a fluid collection device, in other embodiments, the devices described herein can be used with any suitable device configured to establish a pressure differential (e.g., a negative pressure differential). For example, in some embodiments, an outlet of a control device can be coupled

to a syringe or pump. In other embodiments, a control device can include a pre-charged sequestration chamber, a vented sequestration chamber, a manually activated device configured to produce a negative pressure, an energy source (e.g., a chemical energy source, a kinetic energy source, and/or the like), and/or any other suitable means of defining and/or forming a pressure differential within a portion of the control device. Moreover, as described above, the control devices can be coupled to such collection devices by a user (e.g., doctor, nurse, technician, physician, etc.) or can be coupled or assembled during manufacturing. In some embodiments, pre-assembling a control device and a collection device (e.g., a sample container or syringe) can, for example, force compliance with a sample procurement protocol that calls for the sequestration of an initial amount of bodily fluid prior to collecting a sample volume of bodily fluid.

[1234] While some of the embodiments described above include a flow controller and/or an actuator having a particular configuration and/or arrangement, in other embodiments, a fluid control device can include any suitable flow controller and/or actuator configured to selectively control a flow of bodily fluid through one or more portions of the fluid control device. For example, while some embodiments include an actuator such as a diaphragm or the like having one or more seals arranged as an O-ring or an elastomeric over-mold, which is/are moved with the diaphragm and relative to a portion of the device (e.g., the inlet, the outlet, or any other suitable portion) when the diaphragm is transitioned or flipped from a first state to a second state, in other embodiments, a fluid control device can include one or more seals having any suitable configuration. For example, in some embodiments, a fluid control device can include one or more seals arranged as an elastomeric sheet or the like that is/are fixedly coupled to a portion of the control device. In such embodiments, a portion of an actuator such as a pin or rod extending from a diaphragm (see e.g., FIGS. 11 and 12) can extend through an opening defined in the one or more elastomeric sheets, which in turn, form a substantially fluid tight seal with an outer surface of the pin or rod. As such, when the actuator (e.g., diaphragm) is transitioned from a first state to a second state, the portion of the actuator (e.g., the pin or rod) can move through one or more of the elastomeric sheets. In other words, the portion of the actuator moves relative to the one or more elastomeric sheets, which in turn, remain in a substantially fixed position relative to the portion of the control device. In some embodiments, the removal or the portion of the actuator can allow a flow of fluid through the opening defined by the one or more elastomeric sheets that was otherwise occluded by the portion of the actuator. Accordingly, the one or more elastomeric sheets can function in a similar manner as any of the seals described herein. Moreover, in some embodiments, such an arrangement may,

for example, reduce an amount of friction associated with forming the desired fluid tight seals, which in turn, may obviate the use of a lubricant otherwise used to facilitate the movement of the seals within the control device.

[1235] While the diaphragms (e.g., diaphragms 576, 676, and 776) are described herein as being configured to transition, move, flip, and/or otherwise reconfigure in response to an amount of negative pressure exerted on a surface of the diaphragm exceeding a threshold amount of negative pressure, in other embodiments, a fluid control device can include any suitable actuator or the like configured to transition, move, flip, and/or otherwise reconfigure in response to being exposed to a desired and/or predetermined amount of negative pressure. For example, in some embodiments, a fluid control device can include an actuator including and/or arranged as a movable member, plug, plunger, occlusion member, seal, and/or the like configured to selectively control a flow of fluid through at least a portion of the fluid control device. More particularly, the movable member or the like can be transitioned from a first state and/or position in which the movable member or the like is disposed in and/or otherwise occludes an opening, to a second state and/or position in which the movable member or the like is removed from the opening. In such embodiments, a negative pressure can be exerted through a portion of the device to transfer, for example, an initial volume of bodily fluid into a sequestration portion and/or chamber.

[1236] As described in detail above, in some embodiments, a device can include a flow controller such as a selectively permeable member or membrane, that can be configured to transition from a first state to a second state in response to being wetted (or otherwise transitioned) by the initial volume of bodily fluid. After transferring the initial volume of bodily fluid and after the flow controller is transitioned to its second state, an amount of negative pressure exerted on a surface of the movable member or the like may build until a magnitude of the negative pressure is sufficient to pull or move the movable member out of the opening, thereby allowing a flow of bodily fluid through the opening that was otherwise occluded by the movable member. In this manner, the movable member can function similar to any of the diaphragms described herein (e.g., the diaphragm 576, 676, and/or 776) that are configured to transition or flip from a first state to a second state. In such embodiments, the movable member can be, for example, an elastomeric plug, cork, plunger, and/or any other suitable member that can be moved or "popped" out of such an opening or portion of a flow path.

[1237] While some of the embodiments described above include a flow controller and/or actuator that selectively establishes fluid communication between a sequestration chamber and

a fluid collection device (e.g., a sample reservoir, a syringe, and/or any other suitable source of negative pressure) in other embodiments, a control device can be arranged to transfer a flow of bodily fluid in response to negative pressure differentials resulting from any suitable portion(s) of the device. For example, while the control device 200 is described above as including the flow controller 242 and the restricted flow path 232 that selectively place the sequestration chamber 234 in fluid communication with the sample reservoir until the flow controller 242 is transitioned to a sealed or closed state (e.g., until the flow controller 242 is sufficiently wetted), in other embodiments, a control device can include a sequestration chamber that is a pre-sealed evacuated and/or charged chamber such that establishing fluid communication between an inlet and the sequestration chamber results in a negative pressure differential that is sufficient to draw an initial volume of bodily fluid into the sequestration chamber. In such embodiments, the control device can be configured to transfer bodily fluid to the sequestration chamber until the pressure differential is sufficiently reduced and/or until pressures otherwise substantially equalize. Moreover, in some such embodiments, the sequestration chamber and/or the inlet can include a coupler, an actuator, a needle, a septum, a port, and/or any other suitable member that can establish fluid communication therebetween (e.g., that can transition the sequestration chamber from a sealed to an unsealed configuration).

[1238] While some of the embodiments described above include a flow controller and/or actuator that physically and/or mechanically sequesters one or more portions of a fluid control device, in other embodiments, a fluid control device need not physically and/or mechanically sequester one or more portions of the fluid control device. For example, in some embodiments, an actuator such as the actuator 1250 can be transitioned from a first state in which an initial volume of bodily fluid can flow from an inlet to a sequestration chamber or portion, to a second state in which (1) the sequestration chamber or portion is physically and/or mechanically sequestered and (2) the inlet is in fluid communication with an outlet of the fluid control device. In other embodiments, however, an actuator and/or any other suitable portion of a fluid control device can transition from a first state in which an initial volume of bodily fluid can flow from an inlet to a sequestration chamber or portion, to a second state in which the inlet is placed in fluid communication with the outlet without physically and/or mechanically sequestering (or isolating) the sequestration chamber or portion. When such a control device is in the second state, one or more features and/or geometries of the control device can result in a preferential flow of bodily fluid from the inlet to the outlet and the initial volume of bodily fluid can be retained in the sequestration chamber or portion without physically and/or mechanically being sequestered or isolated.

[1239] While the restricted flow path 232 is described above as modulating and/or controlling a magnitude of negative pressure applied on or through at least a portion of the device 200, in other embodiments, a control device can include any suitable feature, mechanism, and/or device configured to modulate, create, and/or otherwise control one or more pressure differentials through at least a portion of the control device. For example, in some embodiments, a user can transition and/or move an actuator to change (e.g., reduce or increase) the size of one or more portions of a fluid flow path or fluid flow interface within a portion of the control device to manually modulate and/or otherwise control an amount or magnitude of negative pressure within one or more portions of a control device.

[1240] Although various embodiments have been described as having particular features, concepts, and/or combinations of components, other embodiments are possible having any combination or sub-combination of any features, concepts, and/or components from any of the embodiments described herein. For example, as described above, the device 700 includes concepts, features, and/or elements of the devices 200 and 600. As another example, any of the embodiments described herein can include a lock or other suitable feature configured to at least temporarily maintain one or more components in a desired position, state, arrangement, and/or configuration. As another example, any of the embodiments described herein can include and/or can define a sequestration chamber and/or portion that is configured similar to, for example, the sequestration chamber 1234 described above with reference to FIG. 30. In other words, any of the fluid control devices described herein can include a sequestration chamber that is arranged and/or formed as a channel. In some embodiments, a channel forming at least a portion of a sequestration chamber can have a relatively small cross-sectional shape and/or size that can reduce and/or substantially prevent mixing of air and bodily fluid as the initial volume of bodily fluid is drawn into the channel, as described above with reference to the sequestration chamber 1234. Moreover, such a channel can have a spiral shape and/or configuration similar to the sequestration chamber 1234 described above and/or can have any other suitable shape and/or configuration.

[1241] As another example, any of the control devices described herein can include a flow controller arranged as a selectively permeable member or membrane as described above, for example, with reference to the flow controller 242. More particularly, while the control device 600 is not described as including a flow controller, in other embodiments, a portion of the diaphragm 676 can include and/or can form a flow controller formed, at least in part, of a selectively permeable material. In such embodiments, the flow controller can be configured to allow a volume of the sequestration chamber and/or portion 634 to be vented in response to

being exposed to the negative pressure differential (as described above). In other words, a volume of air can be drawn out of (e.g., vented from or purged from) the sequestration chamber 634 via the flow controller in response to the negative pressure differential within a portion of the fluid control device 600. In some instances, such an arrangement can allow for a reduction in a size and/or volume of the sequestration chamber 634 because a volume of air otherwise occupying a portion of the sequestration chamber 634 is vented or purged through the flow controller in response to the negative pressure differential.

[1242] By way of another example, any of the embodiments described herein can include any suitable actuator and/or flow controller configured to selectively control fluid flow through at least a portion of the device. Specifically, a flow controller or the like can be one or more of a selectively permeable material or membrane, a valve, a diaphragm, and/or any other suitable flow controller. While some of the embodiments have been described as including an actuator rod configured to be transitioned from a first configuration or position to a second configuration or position (e.g., the actuator rod 1262 of the actuator 1250), in other embodiments, any actuator described herein can include an actuator rod configured to transition from between a first position and second position to at least temporarily isolate an outlet of the device from one or more other portions of the device (e.g., as described above with reference to the actuators 850 and/or 1350). In some embodiments, such an actuator can be configured for use with a given and/or predetermined collection device such as, for example, a syringe. In other embodiments, such an actuator can be used with any suitable collection device.

[1243] In some embodiments, the specific configurations of the various components can also be varied. For example, the size and specific shape of the various components can be different from the embodiments shown, while still providing the functions as described herein. For example, while a portion of the actuator body 1551, sequestration chamber 1534, and/or the bladder 1578 are shown in FIGS. 45-50 as being substantially tubular having a round or substantially semi-circular end portion, in other embodiments, the portion of the actuator body 1551, sequestration chamber 1534, and/or bladder 1578 can have any suitable shape and/or size. In some embodiments, varying the size and/or shape of such components may reduce an overall size of the device 1500 and/or may increase the ergonomics of the device 1500 without changing the function of the device 1500. As a specific example, a housing, sequestration chamber, and/or bladder may have a substantially cylindrical shape with a relatively flat end portion or the like. Moreover, in some embodiments, a control device can include a bladder that is configured to "flip" similar to the diaphragms described above in response to being exposed to a negative pressure differential. In other embodiments, a bladder can be configured

to gradually transition (e.g., unroll, unfold, unfurl, and/or otherwise reconfigure) from the first state to the second state. In some instances, controlling a rate at which a bladder is transitioned may allow for a modulation and/or control of a negative pressure differential produced within the sequestration chamber.

[1244] In other embodiments, a device may include a bladder (similar in form and/or function to the bladders 1478 and/or 1578) disposed in a housing having a size, shape, and/or profile similar to the housings 1230 and/or 1330. In some such embodiments, the bladder can define a volume that is similar in shape and/or size the overall size, and/or shape of the housing (e.g., cylindrical with a relatively low profile or height). In some instances, such an arrangement can allow at least a portion of an initial volume of bodily fluid to remain in contact with a surface of the bladder (or diaphragm or other actuator), which can provide a visual indication to the user regarding the bodily fluid being transferred into the sequestration chamber. In other embodiments, a housing similar to the housing 1230 can define a spiral channel or any other suitable channel and can include a bladder disposed within at least a portion of that channel. In such embodiments, the bladder can function similarly to the bladder 1578 in which the bladder expands, opens, and/or otherwise increases in volume in response to being exposed to a negative pressure differential. In some embodiments, a bladder can define an enclosed volume configured to receive an initial volume of bodily fluid. In other embodiments, the bladder and a portion of the housing (e.g., a surface defining the sequestration chamber and/or channel) can collectively define the volume configured to receive the initial volume of bodily fluid. In this manner, a fluid control device can include a bladder configured to conform to any suitable shape, feature, channel, and/or configuration of a housing in which it is disposed. In some embodiments, the size and shape of the various components can be specifically selected for a desired rate and/or volume of bodily fluid flow into a fluid reservoir.

[1245] In some embodiments, the size and/or shape of the various components can be specifically selected for a desired or intended usage. For example, in some embodiments, a device such as those described herein can be configured for use with or on seemingly healthy adult patients. In such embodiments, the device can include a sequestration chamber that has a first volume (e.g., about 0.5 ml to about 5.0 ml). In other embodiments, a device such as those described herein can be configured for use with or on, for example, very sick patients and/or pediatric patients. In such embodiments, the device can include a sequestration chamber that has a second volume that is less than the first volume (e.g., less than about 0.5 ml). Thus, it should be understood that the size, shape, and/or arrangement of the embodiments and/or

components thereof can be adapted for a given use unless the context explicitly states otherwise.

[1246] Although not shown, any of the devices described herein can include an opening, port, coupler, septum, Luer-Lok, gasket, valve, threaded connecter, standard fluidic interface, etc. (referred to for simplicity as a "port") in fluid communication with the sequestration chamber. In some such embodiments, the port can be configured to couple to any suitable device, reservoir, pressure source, etc. For example, in some embodiments, the port can be configured to couple to a reservoir, which in turn, can allow a greater volume of bodily fluid to be diverted and/or transferred into the sequestration chamber. In other embodiments, the port can be coupled to a negative pressure source such as an evacuated container, a pump, a syringe, and/or the like to collect a portion of or the full volume of bodily fluid in the sequestration chamber, channel, reservoir, etc. and use that volume of bodily fluid (e.g., the pre-sample volume) for additional clinical and/or in vitro diagnostic testing purposes. In other embodiments, the port can be configured to receive a probe, sampling tool, testing device, and/or the like that can be used to perform one or more tests (e.g., tests not sensitive to potential contamination) on the initial volume while the initial volume is disposed or sequestered in the sequestration chamber. In still other embodiments, the port can be coupled to any suitable pressure source or infusion device configured to infuse the initial volume of bodily fluid sequestered in the sequestration chamber back into the patient and/or bodily fluid source (e.g., in the case of pediatric patients, very sick patients, patients having a low blood volume, and/or the like). In other embodiments, the sequestration channel, chamber, and/or reservoir can be configured with the addition of other diagnostic testing components integrated into the chamber (e.g., a paper test) such that the initial bodily fluid is used for that test.

[1247] In still other embodiments, the sequestration chamber, channel, and/or reservoir can be designed, sized, and configured to be removable and compatible with testing equipment and/or specifically accessible for other types of bodily fluid tests commonly performed on patients with suspected conditions. By way of example, a patient with suspected sepsis commonly has blood samples collected for lactate testing, procalcitonin testing, and blood culture testing. All of the fluid control devices described herein can be configured such that the sequestration chamber, channel, reservoir, etc. can be removed (e.g., after receiving the initial volume of bodily fluid) and the bodily fluid contained therein can be used for these additional testing purposes before or after the subsequent sample is collected for microbial testing.

[1248] Although not shown, in some embodiments, a fluid control device can include one or more lumen, channels, flow paths, etc. configured to selectively allow for a "bypass" flow of bodily fluid, where an initial amount or volume of bodily fluid can flow from the inlet, through the lumen, cannel, flow path, etc. to bypass the sequestration chamber, and into the collection device. In some embodiments, the fluid control device can include an actuator having, for example, at least three states – a first in which bodily fluid can flow from the inlet to the sequestration chamber, a second in which bodily fluid can flow from the inlet to the outlet after the initial volume is sequestered in the sequestration chamber, and a third in which bodily fluid can flow from the inlet, through the bypass flow path, and to the outlet. In other embodiments, the control device can include a first actuator configured to transition the device between a first and second state, as described in detail above with reference to specific embodiments, and can include a second actuator configured to transition the device to a bypass configuration or the like. In still other embodiments, the control device can include any suitable device, feature, component, mechanism, actuator, controller, etc. configured to selectively place the fluid control device in a bypass configuration or state.

[1249] Any of the embodiments described herein can be used in conjunction with any suitable fluid transfer, fluid collection, and/or fluid storage device such as, for example, the fluid reservoirs described in the '420 patent. In some instances, any of the embodiments described herein can be used in conjunction with any suitable transfer adapter, fluid transfer device, fluid collection device, and/or fluid storage devices such as, for example, the devices described in the '510 Publication and/or any of the devices described in U.S. Patent Publication No. 2015/0246352 entitled, "Apparatus and Methods for Disinfection of a Specimen Container," filed March 3, 2015; U.S. Patent No. 8,535,241 entitled, "Fluid Diversion Mechanism for Bodily-Fluid Sampling," filed October 12, 2012; U.S. Patent No. 9,060,724 entitled, "Fluid Diversion Mechanism for Bodily-Fluid Sampling," filed May 29, 2013; U.S. Patent No. 9,155,495 entitled, "Syringe-Based Fluid Diversion Mechanism for Bodily-Fluid Sampling," filed December 2, 2013; U.S. Patent Publication No. 2016/0361006 entitled, "Devices and Methods for Syringe Based Fluid Transfer for Bodily-Fluid Sampling," filed June 13, 2016; U.S. Patent Publication No. 2018/0140240 entitled, "Systems and Methods for Sample Collection with Reduced Hemolysis," filed November 20, 2017; and/or U.S. Patent Publication No. 2017/0065733 entitled, "Apparatus and Methods for Maintaining Sterility of a Specimen Container," filed September 6, 2016, the disclosures of each of which are incorporated herein by reference in their entireties.

[1250] In some embodiments, a method of using a fluid control device such as those described herein can include the ordered steps of establishing fluid communication between a bodily fluid source (e.g., a vein of a patient or the like) and an inlet of a fluid control device. An outlet of the fluid control device is then placed in fluid communication with and/or otherwise engages a negative pressure source. Such a negative pressure source can be a sample reservoir, a syringe, an evacuated container, an intermediate transfer device, and/or the like. The fluid control device can be in a first state or operating mode when the outlet is coupled to the negative pressure source and, as such, a negative pressure differential is applied through the fluid control device that draws an initial volume of bodily fluid into a sequestration chamber of the fluid control device. For example, a negative pressure within a sample reservoir can be operable in drawing an initial volume of bodily fluid from a patient and into the sequestration chamber. Once the initial volume of bodily fluid is disposed in the sequestration chamber, the fluid control device is transitioned, either automatically or via user intervention, from the first state or operating mode to a second state or operating mode such that (1) the initial volume is sequestered in the sequestration chamber and (2) the fluid communication is established between the inlet and the outlet. The sequestration of the initial volume can be such that contaminants entrained in the flow of the initial volume are likewise sequestered within the sequestration chamber. With the initial volume of bodily fluid sequestered in the sequestration chamber and with fluid communication established between the inlet and the outlet, subsequent volumes of bodily fluid that are substantially free of contamination can be collected in one or more sample reservoirs.

[1251] While the method of using the fluid control device is explicitly described as including the recited ordered steps, in other embodiments, the ordering of certain events and/or procedures in any of the methods or processes described herein may be modified and such modifications are in accordance with the variations of the invention. Additionally, certain events and/or procedures may be performed concurrently in a parallel process when possible, as well as performed sequentially as described above. Certain steps may be partially completed or may be omitted before proceeding to subsequent steps. For example, while the devices are described herein as transitioning from a first state to a second state in a discrete operation or the like, it should be understood that the devices described herein can be configured to automatically and/or passively transition from the first state to the second state and that such a transitioning may occur over a period of time. In other words, the transitioning from the first state to the second state may, in some instances, be relatively gradual such that as a last portion of the initial volume of bodily fluid is being transferred into the sequestration chamber, the

housing begins to transition from the first state to the second state. In some instances, the rate of change when transitioning from the first state to the second state can be selectively controlled to achieve one or more desired characteristics associated with the transition. Moreover, in some such instances, the inflow of the last portion of the initial volume can limit and/or substantially prevent bodily fluid already disposed in the sequestration chamber from escaping therefrom. Accordingly, while the transitioning from the first state to the second state may occur over a given amount of time, the sequestration chamber can nonetheless sequester the volume of bodily fluid disposed therein.

What is claimed:

1. A system, comprising:

a housing having an inlet and an outlet, the inlet configured to be placed in fluid communication with a bodily fluid source, the housing forming a sequestration portion configured to receive an initial volume of bodily fluid from the bodily fluid source;

a flow controller at least partially disposed in the sequestration portion of the housing and configured to transition from a first state to a second state; and

a fluid collection device configured to be fluidically coupled to the outlet to produce a negative pressure differential within at least a portion of the housing, the negative pressure differential produced by the fluid collection device operable to draw the initial volume of bodily fluid into the sequestration portion when the flow controller is in the first state, the negative pressure differential produced by the fluid collection device operable to draw the sample volume of bodily fluid through the outlet and into the fluid collection device when the flow controller is in the second state.

2. The system of claim 1, wherein the flow controller is configured to transition from the first state to the second state automatically.

3. The system of claim 1, wherein the flow controller is configured to transition from the first state to the second state in response to contact with a portion of the initial volume of bodily fluid disposed in the sequestration portion.

4. The system of claim 1, wherein the flow controller includes a selectively permeable material.

5. The system of claim 4, wherein prior to being placed in the second state, the flow controller is configured to allow a flow of a gas through the flow controller and to prevent a flow of bodily fluid through the flow controller.

6. The system of claim 5, wherein the flow controller is configured to prevent a flow of gas and bodily fluid through the flow controller when in the second state.

7. The system of claim 6, wherein the flow controller is configured to be placed in the second state in response to a portion of the initial volume of bodily fluid saturating the selectively permeable material.

8. The system of claim 1, wherein the flow controller is configured to modulate a magnitude of negative pressure exerted on the sequestration portion of the housing prior to the flow controller transitioning to the second state.

9. The system of claim 1, wherein the fluid collection device is a sample reservoir that defines a negative pressure operable to produce the negative pressure differential within at least the portion of the housing when fluidically coupled to the outlet.

10. The system of claim 1, wherein the fluid collection device is a syringe configured to be manipulated by a user after being fluidically coupled to the outlet to produce the negative pressure differential within at least the portion of the housing.

11. The system of claim 1, wherein the housing defines a first fluid flow path and a second fluid flow path, the negative pressure differential is operable to draw the initial volume of bodily fluid through the first fluid flow path from the inlet to the sequestration portion when the flow controller is in the first state, the negative pressure differential is operable to draw the sample volume of bodily fluid through the second fluid flow path from the inlet to the outlet when the flow controller is in the second state.

12. The system of claim 11, further comprising:

an actuator coupled to the housing, the actuator having a first actuator state in which the negative pressure differential is applied to the first fluid flow path and a second actuator state in which the negative pressure differential is applied to the second fluid flow path.

13. The system of claim 12, wherein the actuator is in the first actuator state when the flow controller is in the first state, the actuator is configured to be transitioned from the first actuator state to the second actuator state after the flow controller is transitioned to the second state.

14. The system of claim 13, wherein the negative pressure differential automatically transitions the actuator from the first actuator state to the second actuator state after the flow controller is transitioned to the second state.

15. An apparatus, comprising:

a housing having an inlet configured to be placed in fluid communication with a bodily fluid source and an outlet configured be placed in fluid communication with a fluid collection device, the housing forming a sequestration portion configured to receive an initial volume of bodily fluid from the bodily fluid source; and

an actuator coupled to the housing, the actuator having a first configuration in which a first fluid flow path places the inlet in fluid communication with the sequestration portion and a second configuration in which a second fluid flow path places the inlet in fluid communication with the outlet,

wherein the fluid collection device is configured to be placed in fluid communication with the outlet to produce a negative pressure differential (1) within the first fluid flow path operable to draw the initial volume of bodily fluid into the sequestration portion when the actuator is in the first configuration, and (2) within the second fluid flow path operable to draw a sample volume of bodily fluid into the fluid collection device when the actuator is in the second configuration.

16. The apparatus of claim 15, wherein the initial volume of bodily fluid is sequestered in the sequestration portion when the actuator is in the second configuration.

17. The apparatus of claim 15, wherein sequestering the initial volume in the sequestration portion reduces contamination in the sample volume.

18. The apparatus of claim 15, wherein the fluid collection device is a sample reservoir that defines a negative pressure operable to produce the negative pressure differential within the first fluid flow path and the second fluid flow path.

19. The apparatus of claim 15, wherein the fluid collection device is a syringe configured to be manipulated by a user after being placed in fluid communication with the outlet to produce the negative pressure differential within the first fluid flow path and the second fluid flow path.

20. The apparatus of claim 15, wherein the actuator is configured to transition from the first configuration to the second configuration in response to a force applied by a user on a portion of the actuator.

21. The apparatus of claim 15, wherein the actuator includes at least one seal configured to define a portion of the first fluid flow path when the actuator is in the first configuration, the at least one seal is configured to define a portion of the second fluid flow path when the actuator is in the second configuration.

22. The apparatus of claim 15, wherein the actuator includes a diaphragm configured to transition from a first state to a second state when a negative pressure differential within a portion of the first fluid flow path is greater than a threshold amount of negative pressure.

23. The apparatus of claim 22, wherein the diaphragm is coupled to at least one seal configured to define a portion of the first fluid flow path when the diaphragm is in the first state and configured to define a portion of the second fluid flow path when the diaphragm is in the second state.

24. The apparatus of claim 15, further comprising:

a flow controller at least partially disposed in the sequestration portion of the housing, the flow controller is configured to establish selective fluid communication between the sequestration portion and the actuator.

25. The apparatus of claim 24, wherein the flow controller includes a selectively permeable material.

26. The apparatus of claim 25, wherein the flow controller is configured to transition from a first state in which the selective permeable material allows a flow of a gas through the flow controller and prevents a flow of bodily fluid through the flow controller, to a second state in which the selectively permeable material prevents a flow of gas and bodily fluid through the flow controller.

27. The apparatus of claim 26, wherein the flow controller is configured to be placed in the second state in response to at least a portion of the initial volume of bodily fluid saturating the selectively permeable material.

28. The apparatus of claim 26, wherein the actuator is configured to be transitioned to the second configuration after the flow controller is transitioned to the second state.

29. A method of using a fluid control device to obtain a bodily fluid sample with reduced contamination, the method comprising:

establishing fluid communication between a bodily fluid source and an inlet of the fluid control device;

coupling a fluid collection device to an outlet of the fluid control device, the coupling of the fluid collection device to the outlet configured to produce a negative pressure differential within at least a portion of the fluid control device;

receiving an initial volume of bodily fluid from the inlet and into a sequestration portion of the fluid control device in response to the negative pressure differential;

transitioning, in response to contact with at least a portion of the initial volume of bodily fluid, a flow controller disposed in the sequestration portion from a first state in which the flow controller allows a flow of a gas through the flow controller and prevents a flow of bodily fluid through the flow controller, to a second state in which the flow controller prevents a flow of gas and bodily fluid through the flow controller;

sequestering the initial volume of bodily fluid in the sequestration portion after the flow controller is transitioned to the second state; and

transferring a subsequent volume of bodily fluid from the inlet, through the outlet, and into the fluid collection device.

30. The method of claim 29, wherein the flow controller includes a selectively permeable material.

31. The method of claim 29, wherein the flow controller is configured to be placed in the second state in response to at least a portion of the initial volume of bodily fluid saturating the selectively permeable material.

32. The method of claim 29, wherein the flow controller is configured to automatically transition from the first state to the second state in response to contact with at least the portion of the initial volume of bodily fluid.

33. The method of claim 29, wherein the coupling the fluid collection device to the outlet includes coupling a fluid reservoir to the outlet to produce the negative pressure differential within at least the portion of the fluid control device, the fluid reservoir defining a negative pressure prior to the fluid reservoir being coupled to the outlet.

34. The method of claim 29, wherein coupling the fluid collection device to the outlet includes coupling a syringe to the outlet, the method further comprising:

manipulating the syringe, after coupling the syringe to the outlet, to produce the negative pressure differential within at least the portion of the fluid control device.

35. The method of claim 29, further comprising:

transitioning an actuator of the fluid control device from a first configuration to a second configuration after transitioning the flow controller from the first state to the second state, the actuator defining at least a portion of a first fluid flow path between the inlet and the sequestration portion when in the first configuration, the actuator defining at least a portion of a second fluid flow path between the inlet and the outlet when in the second configuration.

36. The method of claim 29, wherein the sequestering of the initial volume of bodily fluid sequesters contaminants within the sequestration portion such that the subsequent volume of bodily fluid is substantially free of contaminants.

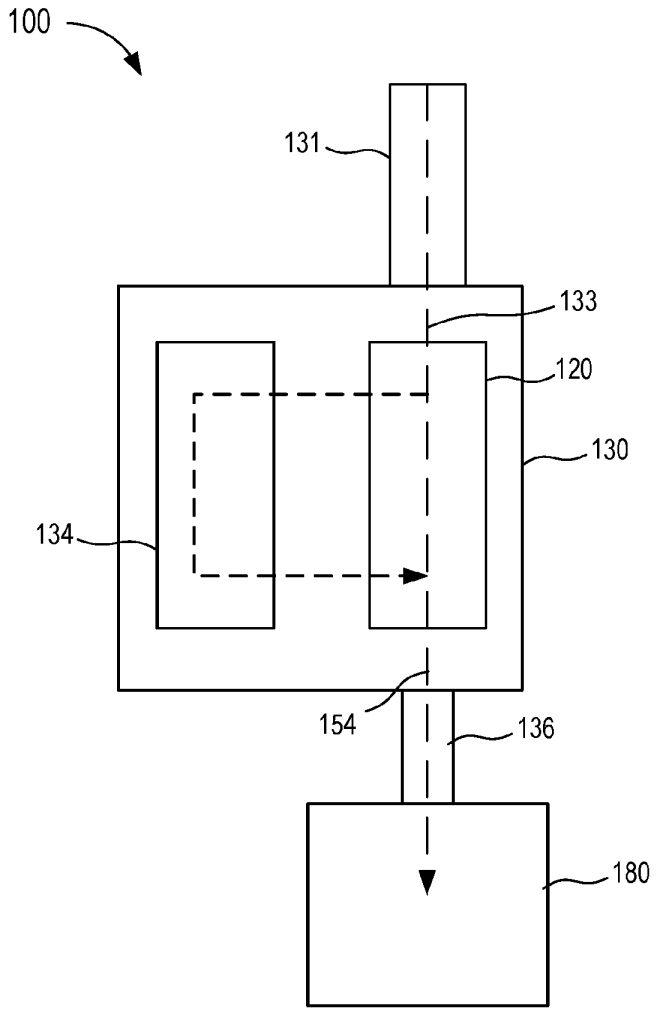


FIG. 1

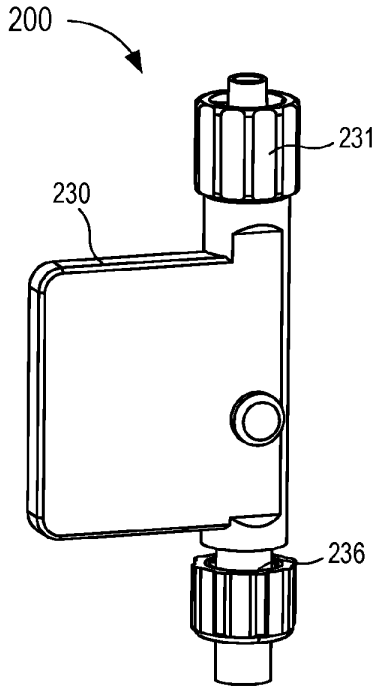


FIG. 2

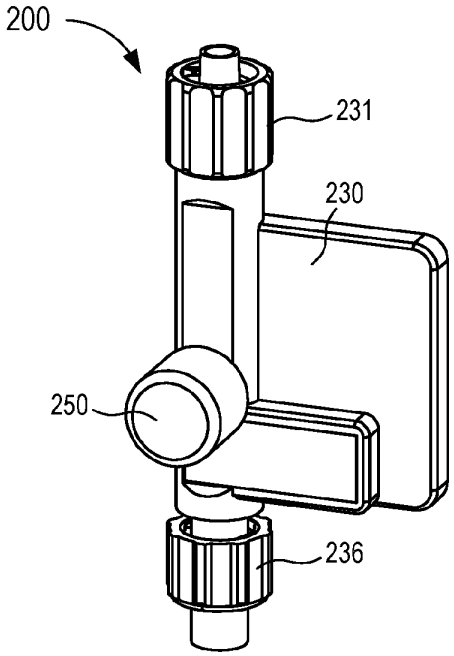


FIG. 3

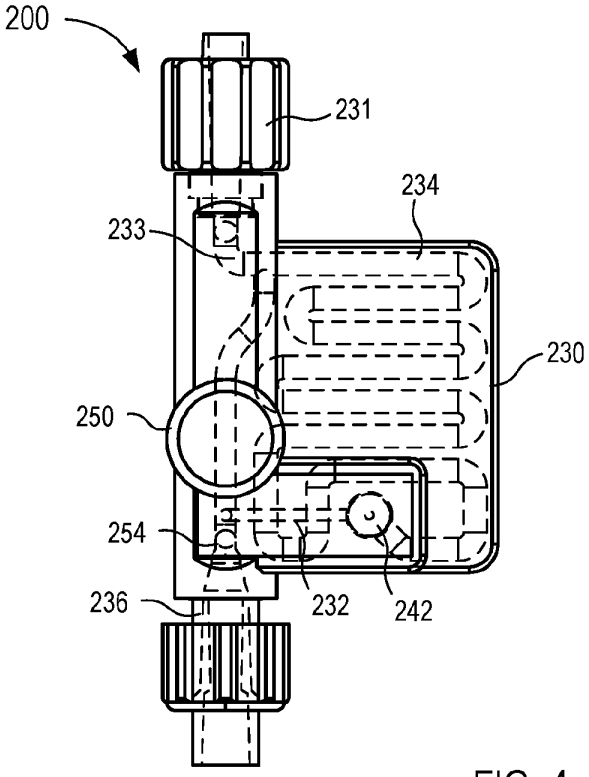


FIG. 4

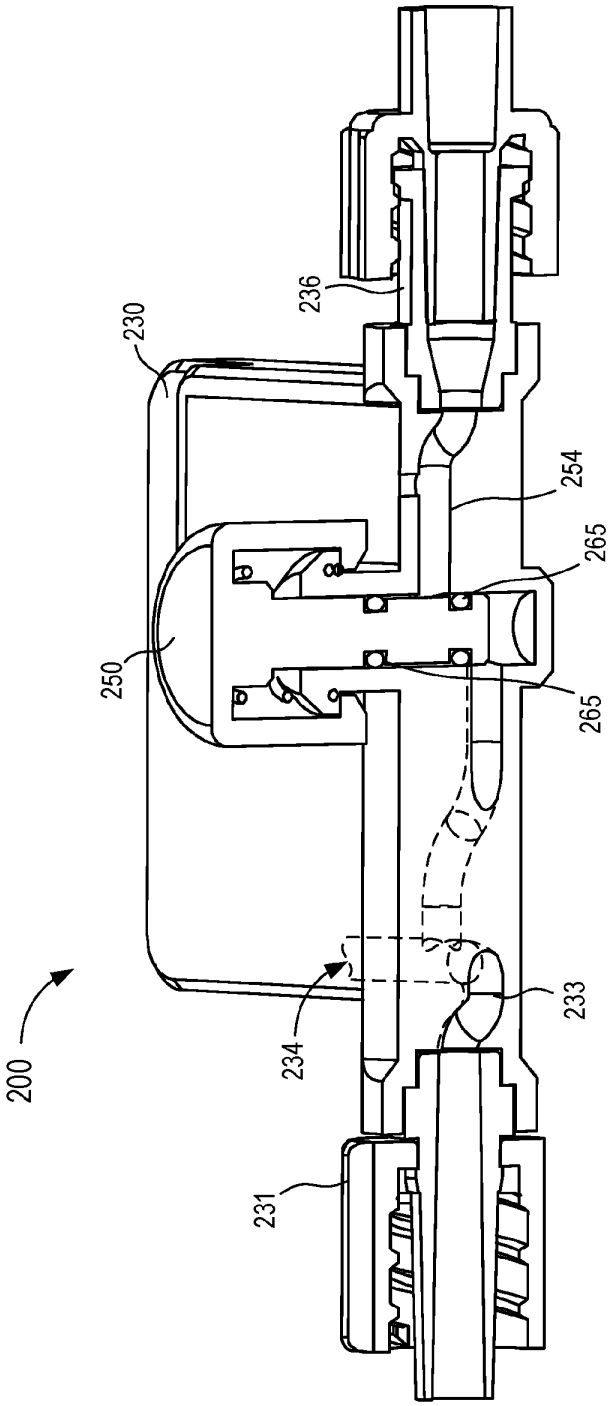


FIG. 5

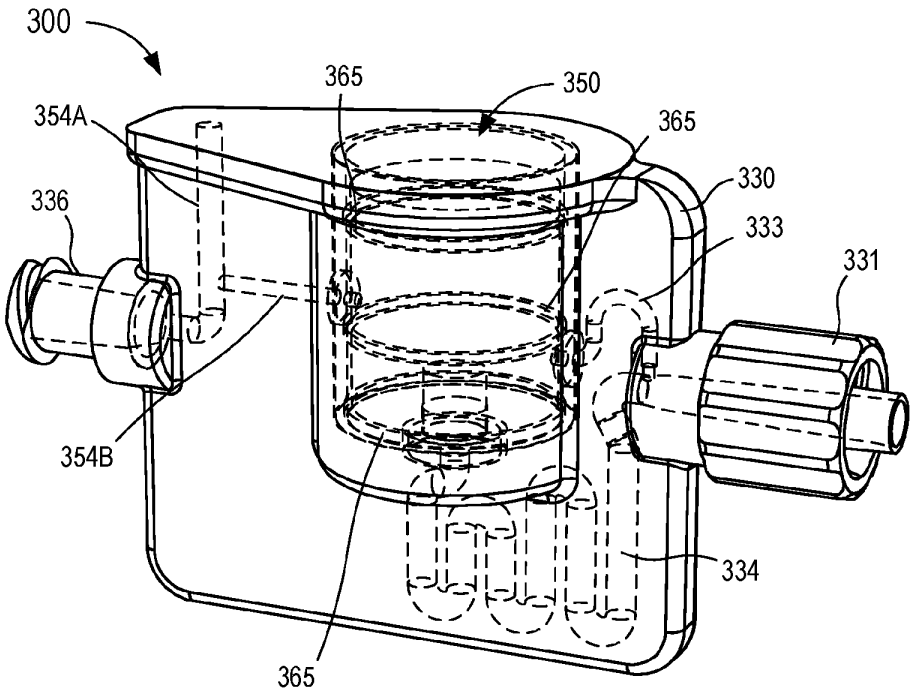

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FIG. 6

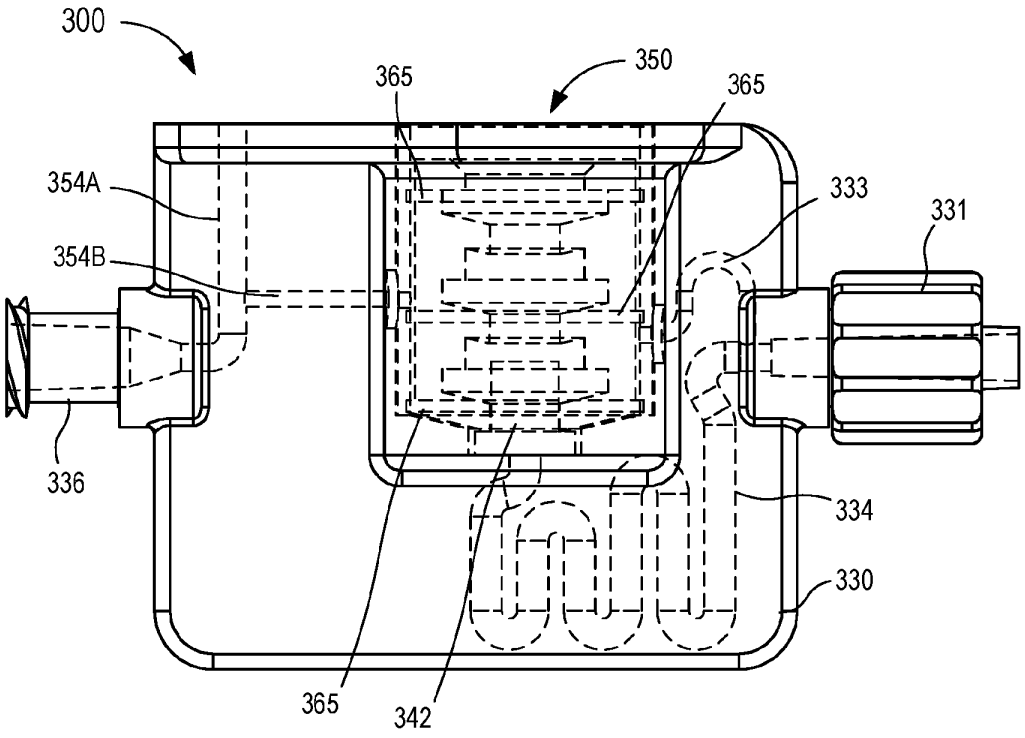

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FIG. 7

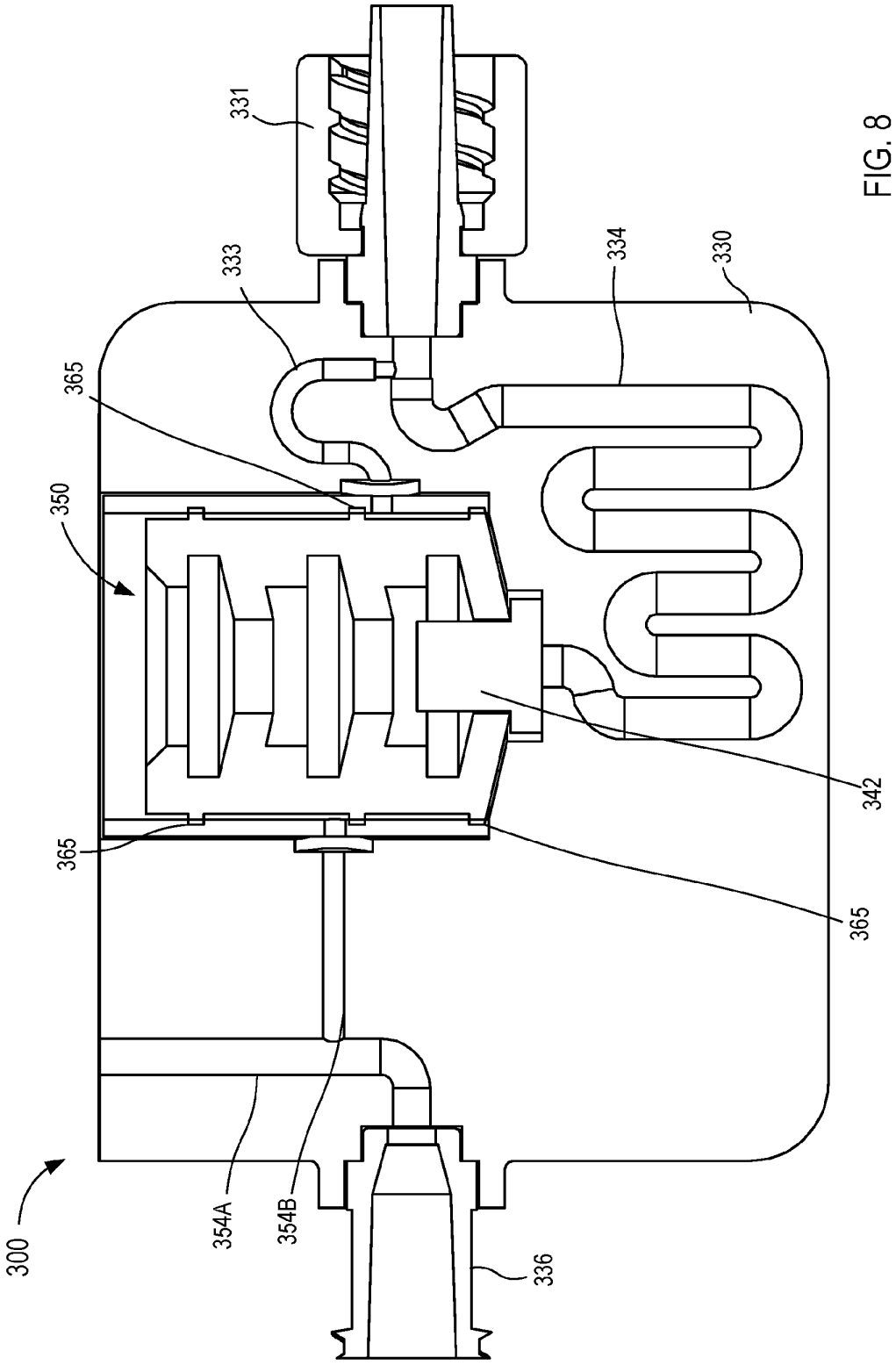


FIG. 8

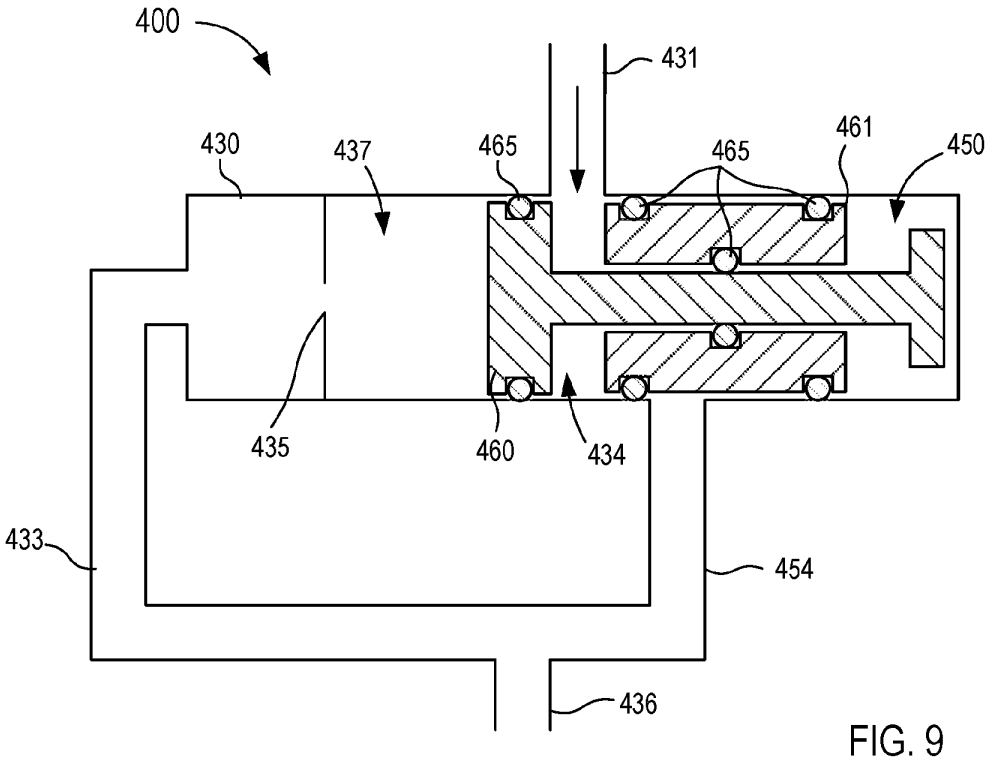

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FIG. 9

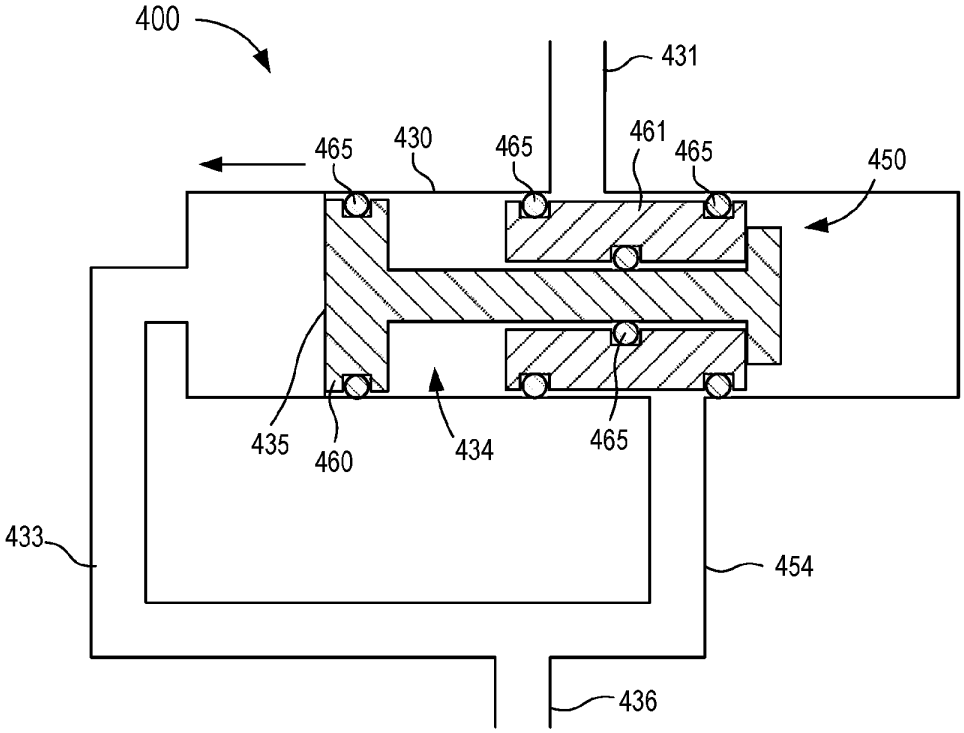

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FIG. 10

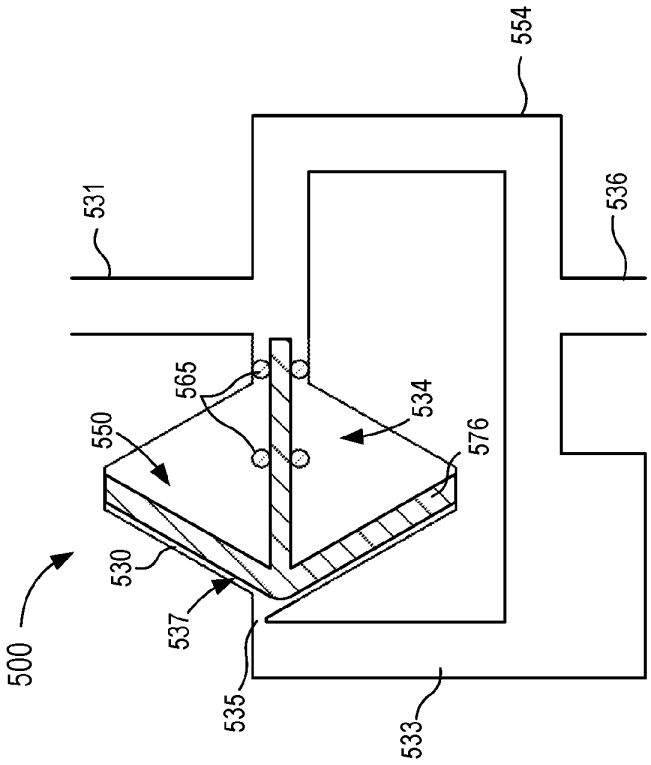

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FIG. 12

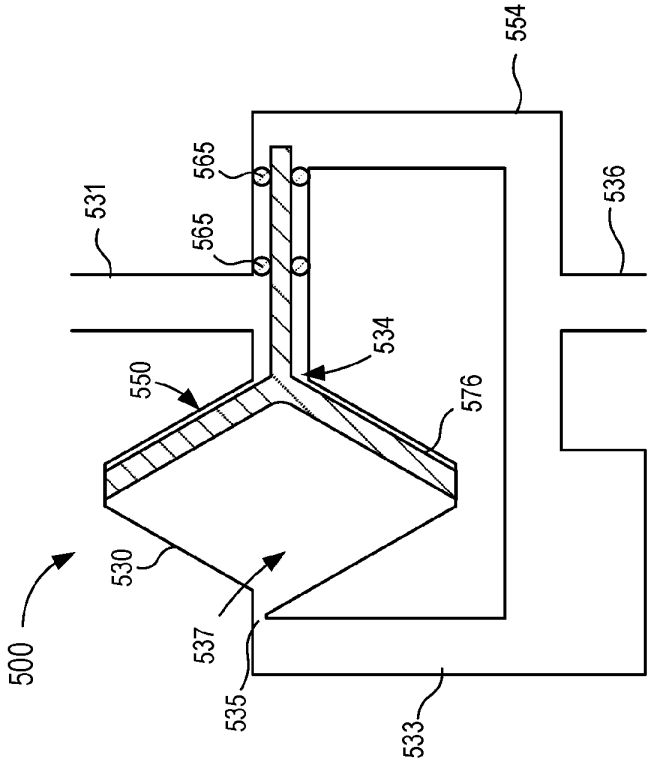

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FIG. 11

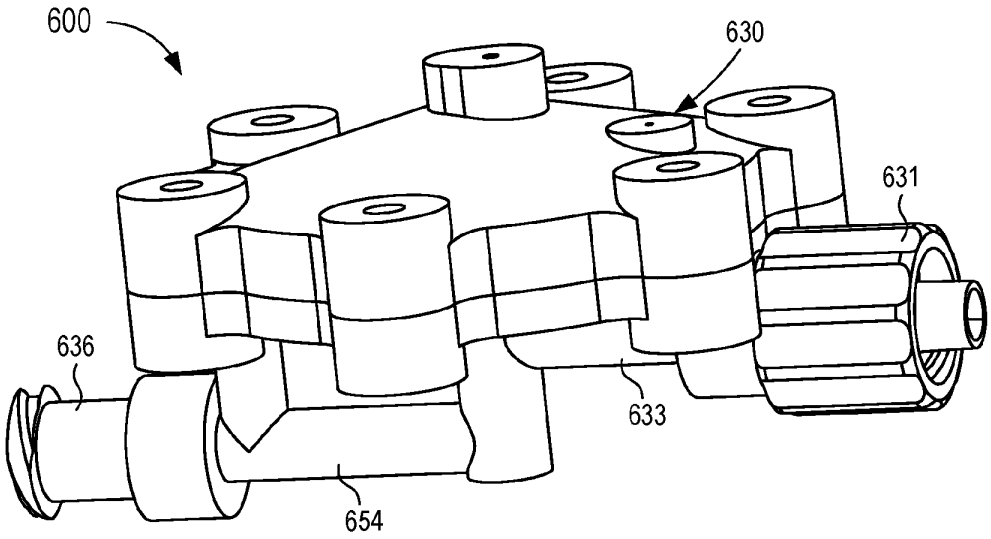

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FIG. 13

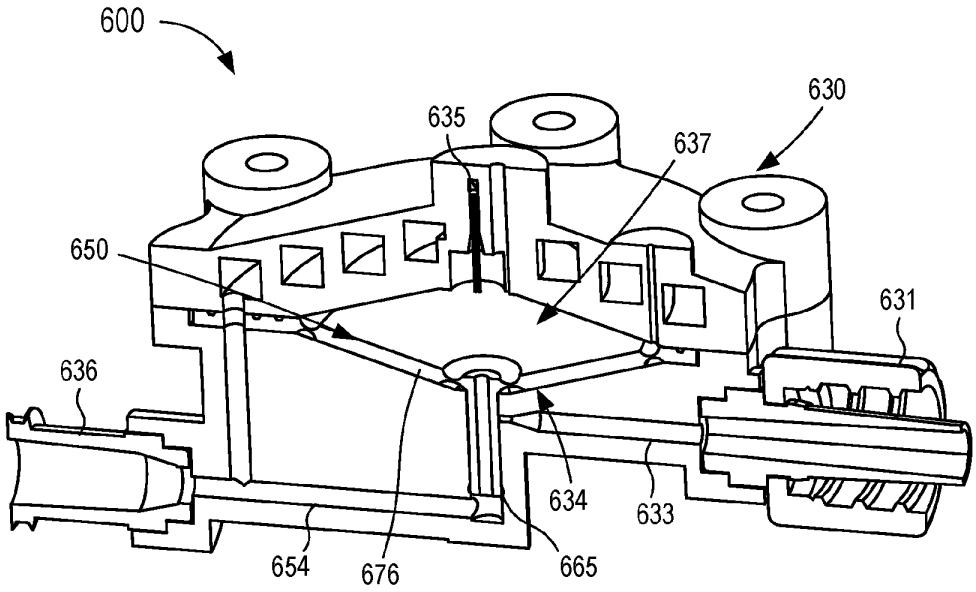

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FIG. 14

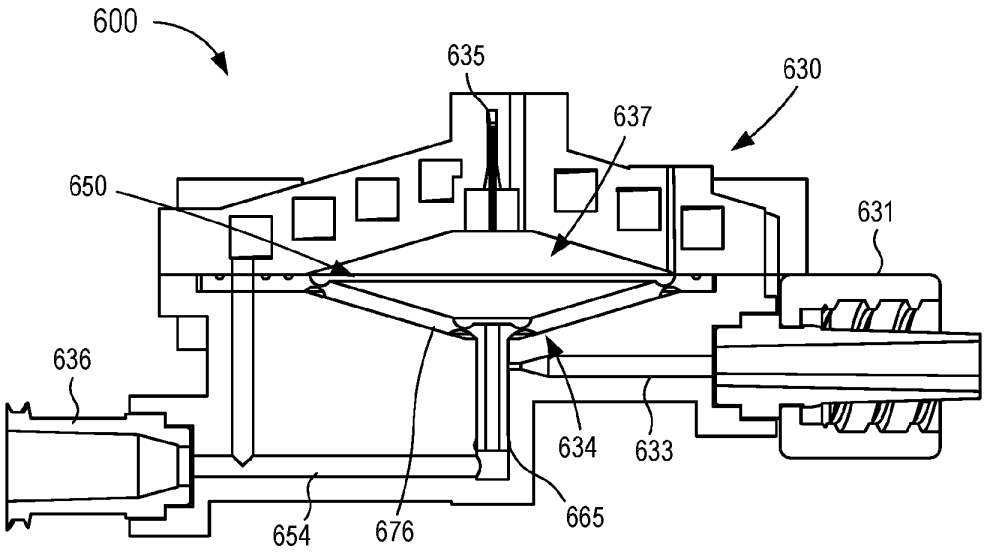


FIG. 15A

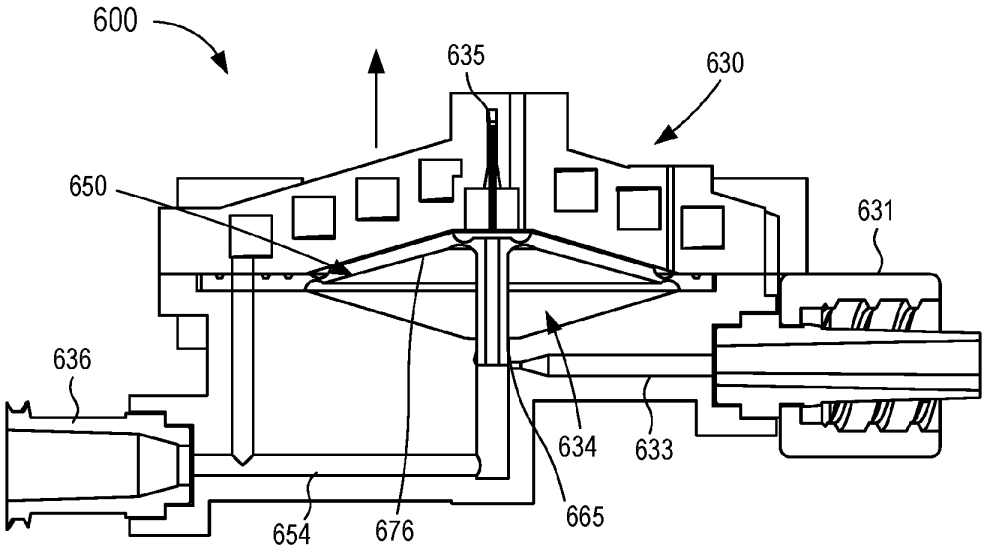


FIG. 15B

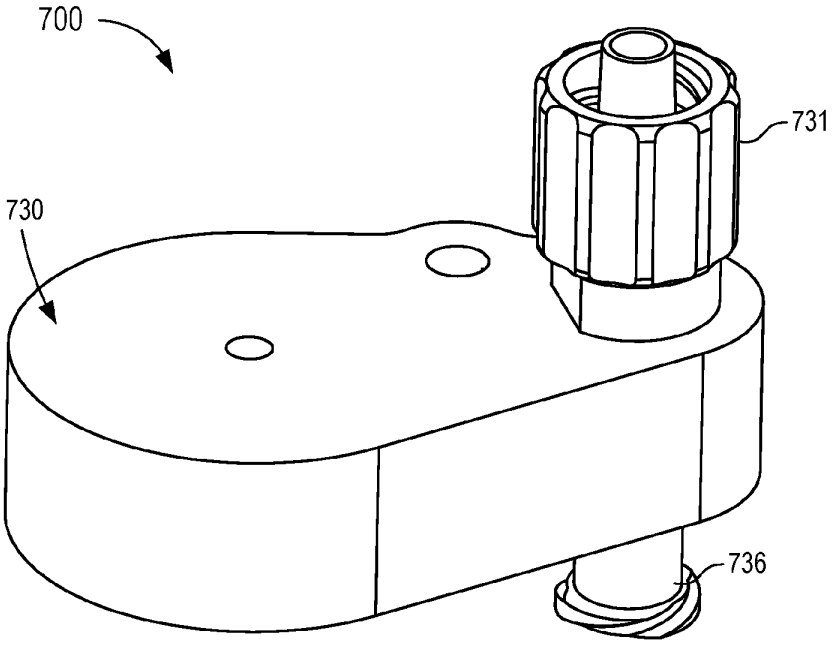


FIG. 16

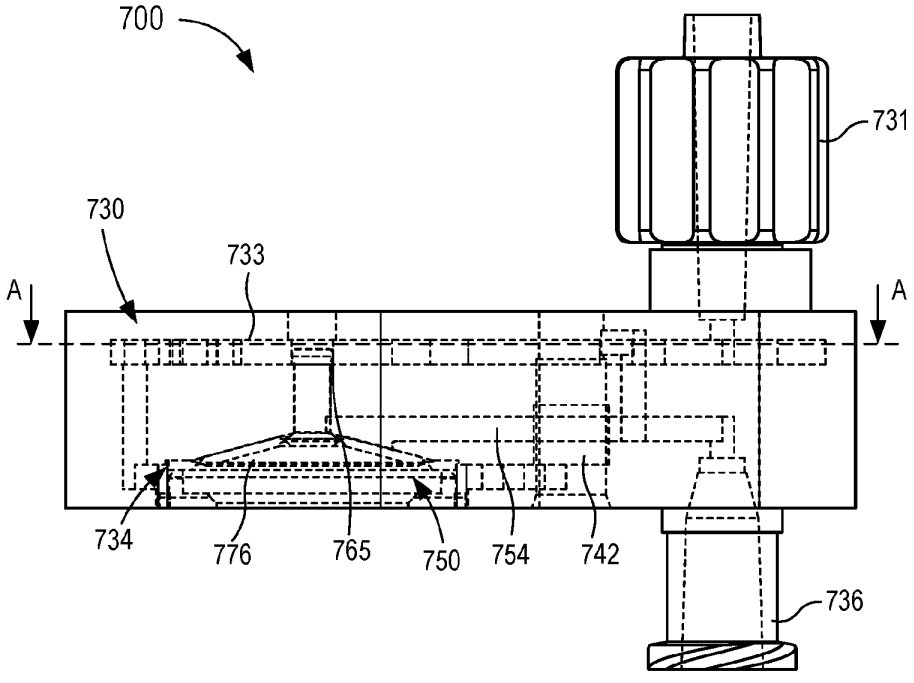


FIG. 17A

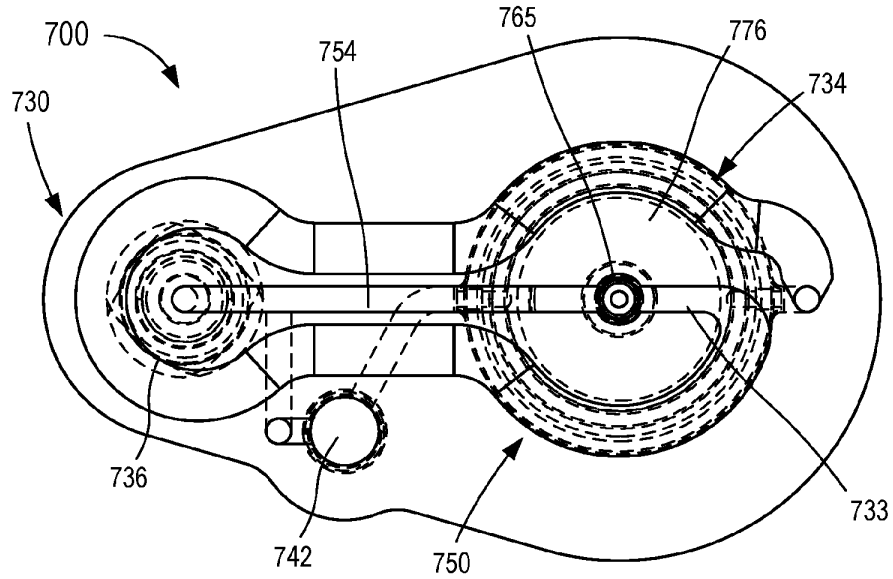


FIG. 17B

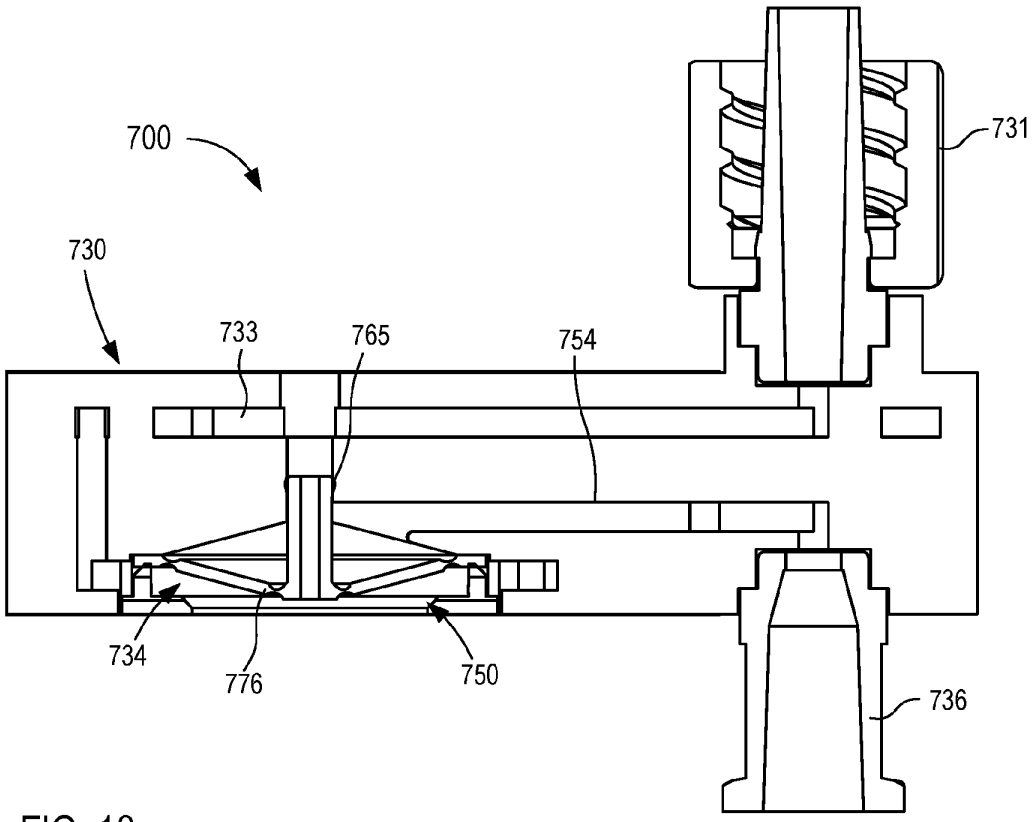


FIG. 18

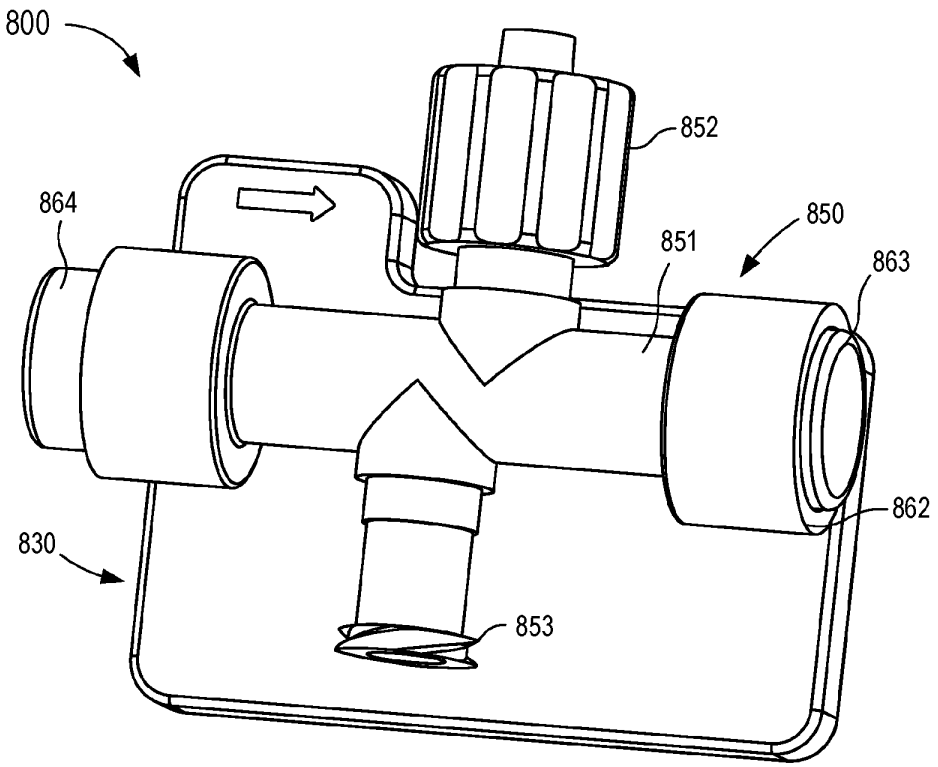


FIG. 19

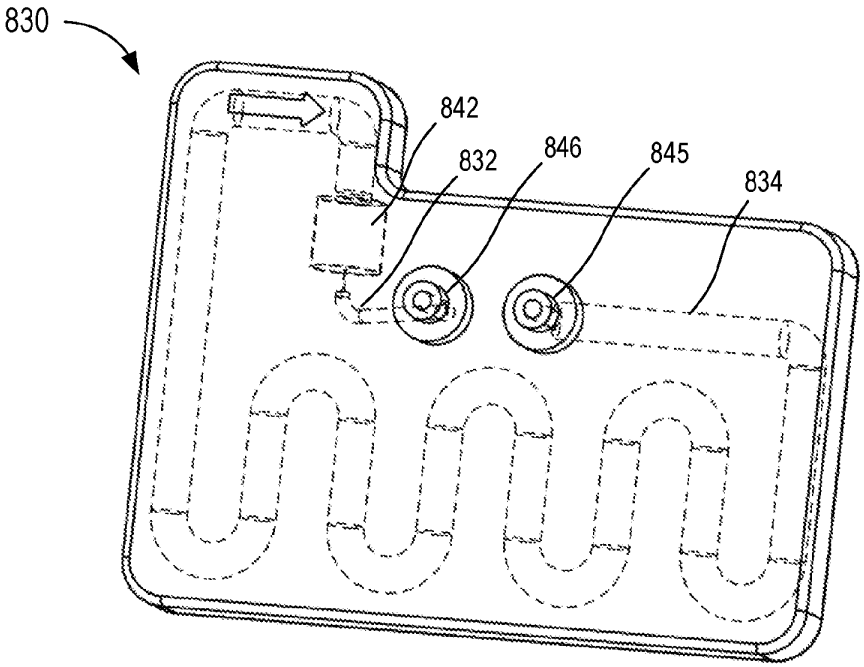


FIG. 20

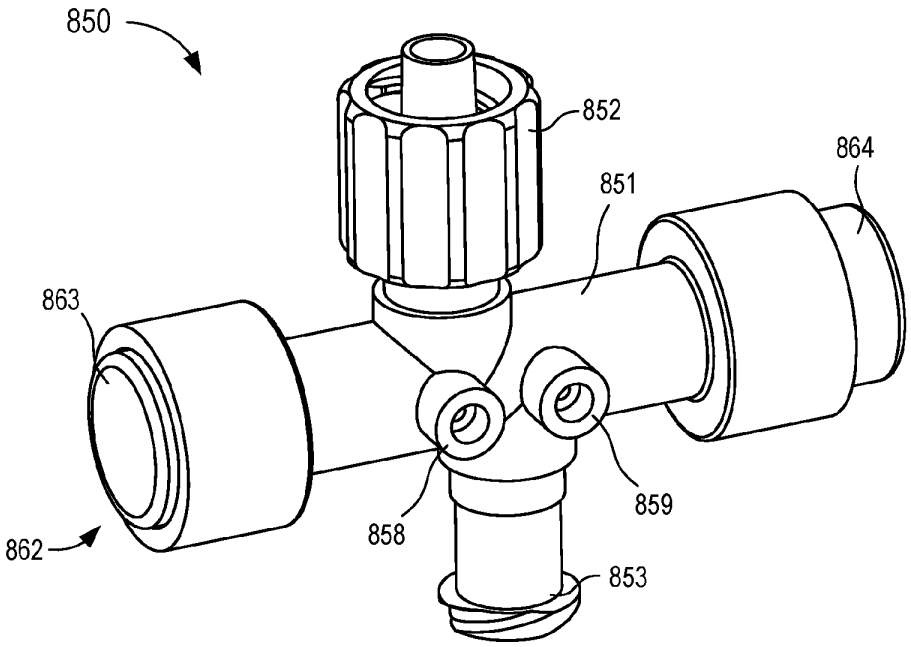


FIG. 21

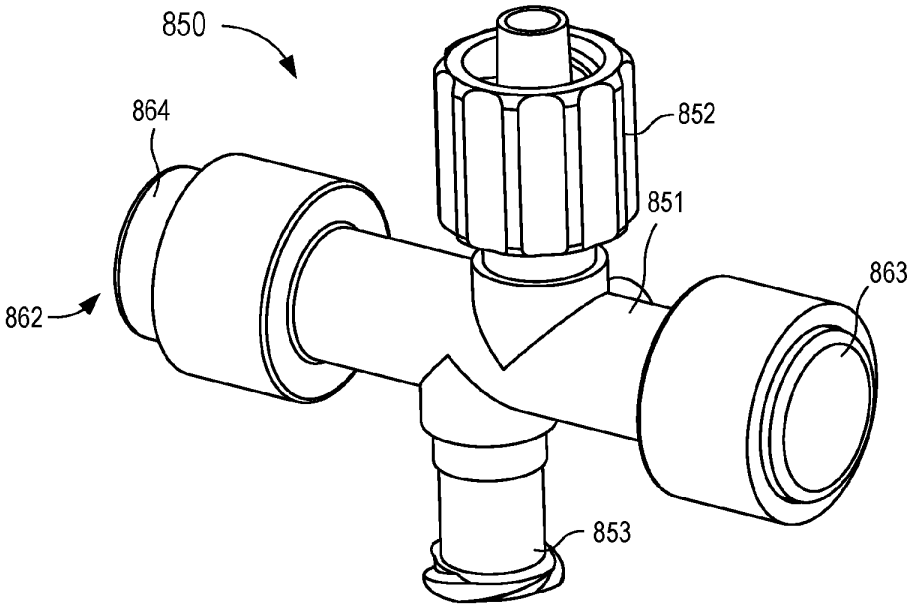


FIG. 22

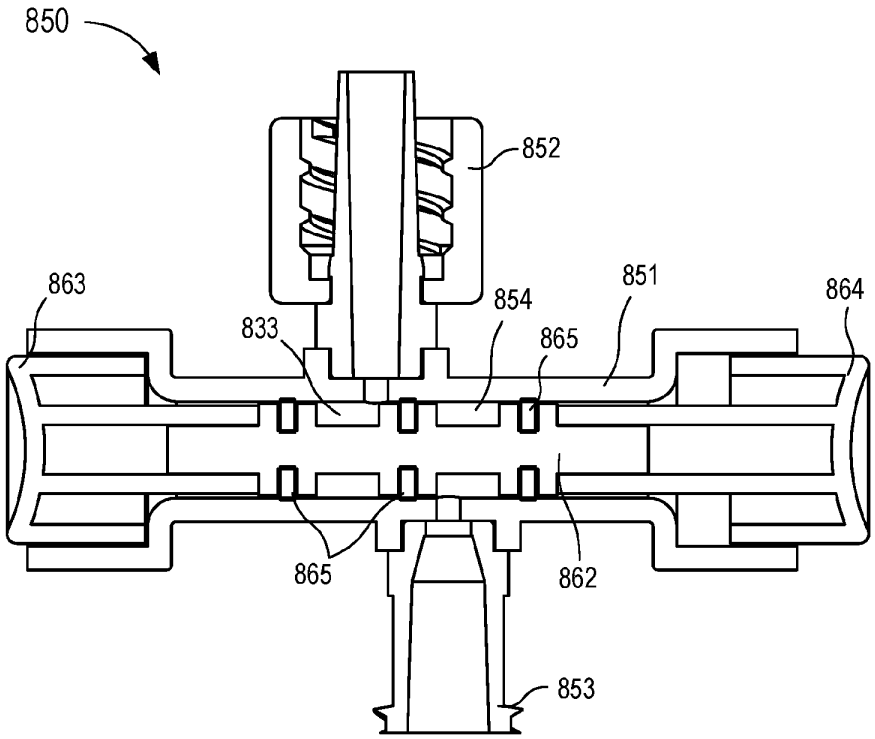

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FIG. 23

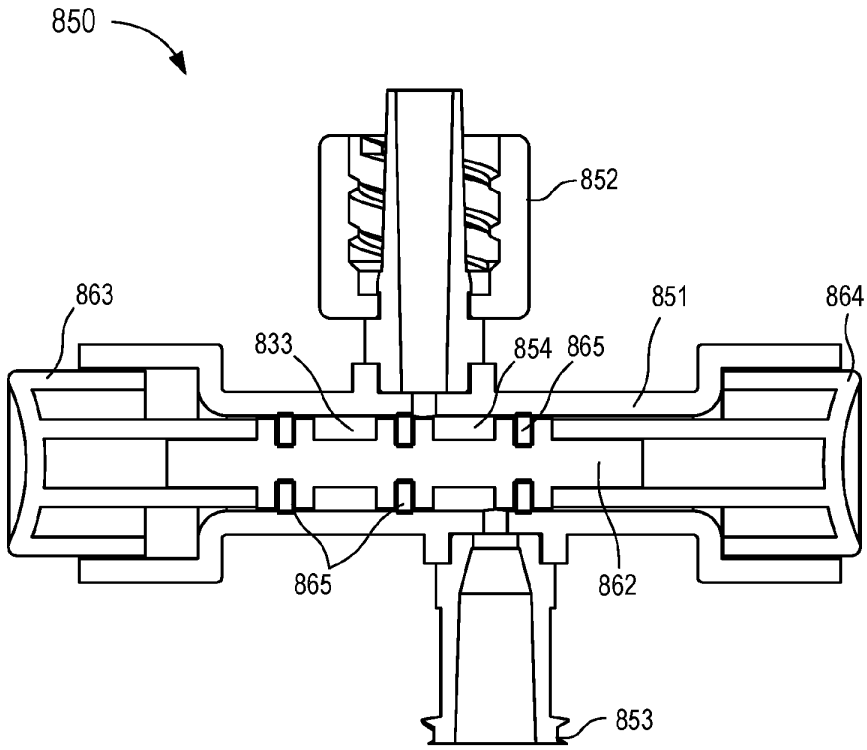

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FIG. 24

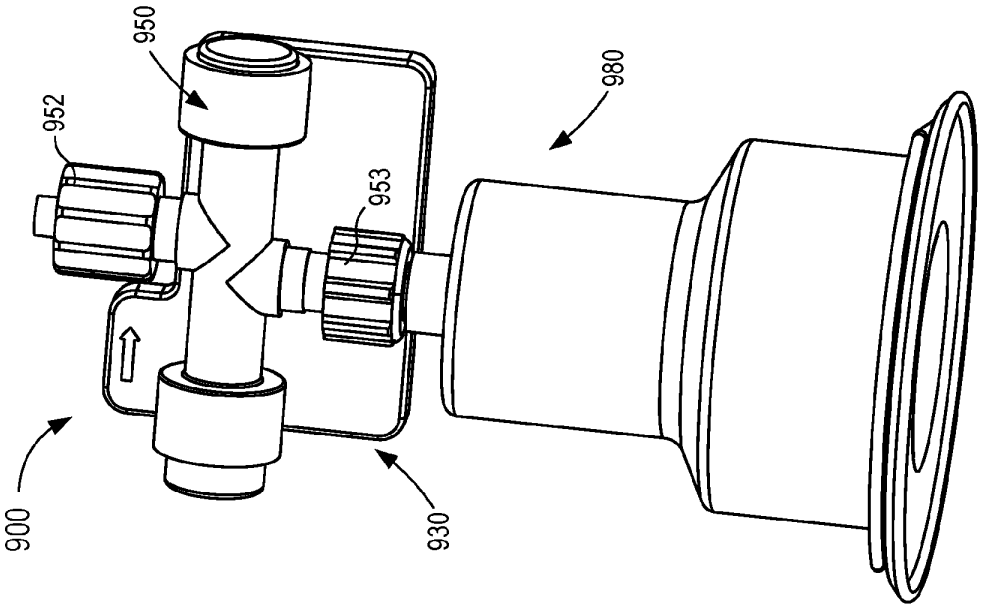


FIG. 26

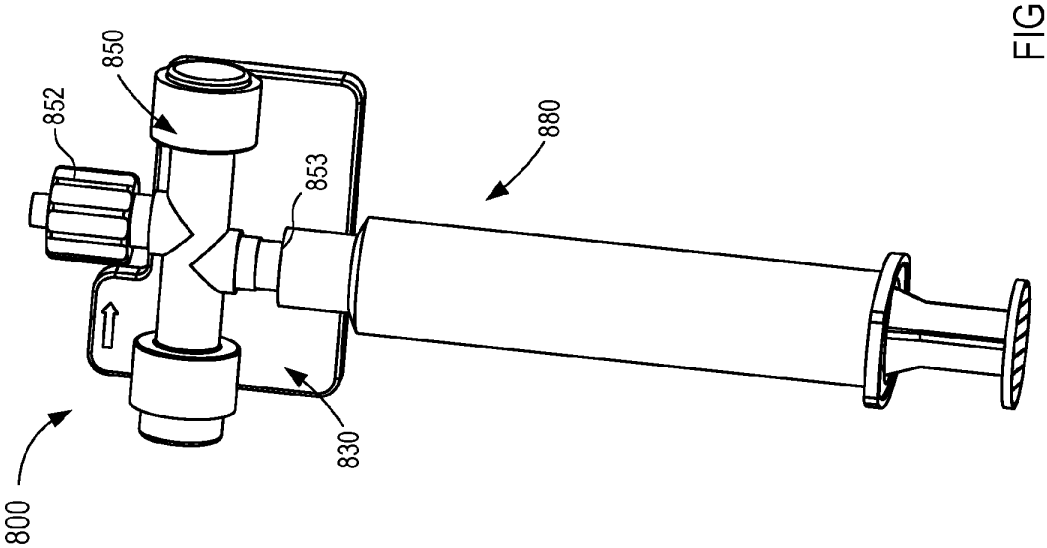


FIG. 25

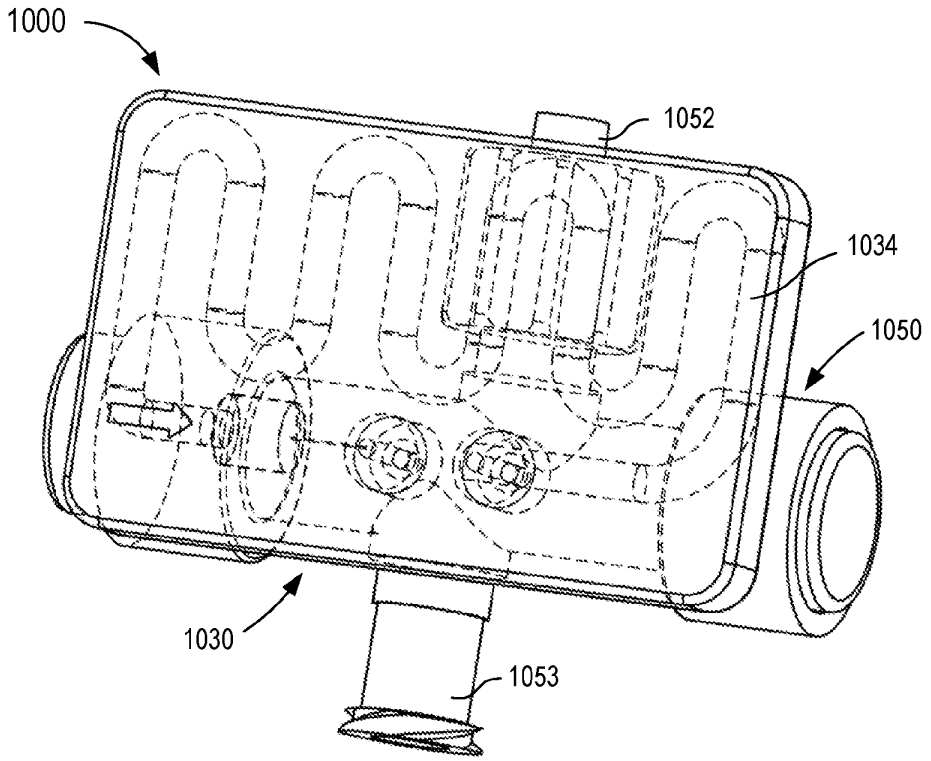


FIG. 27

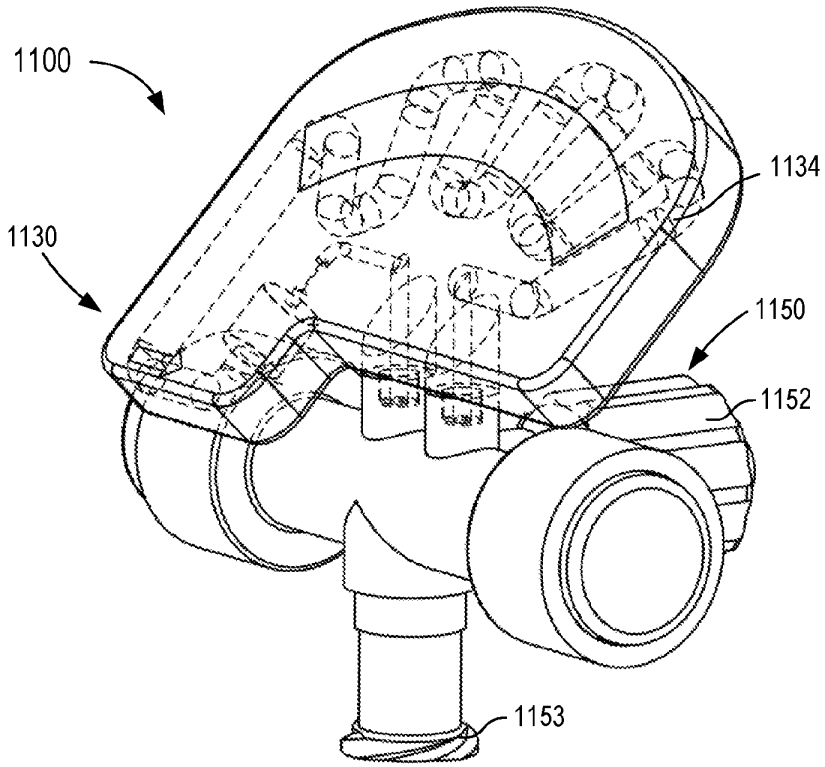


FIG. 28

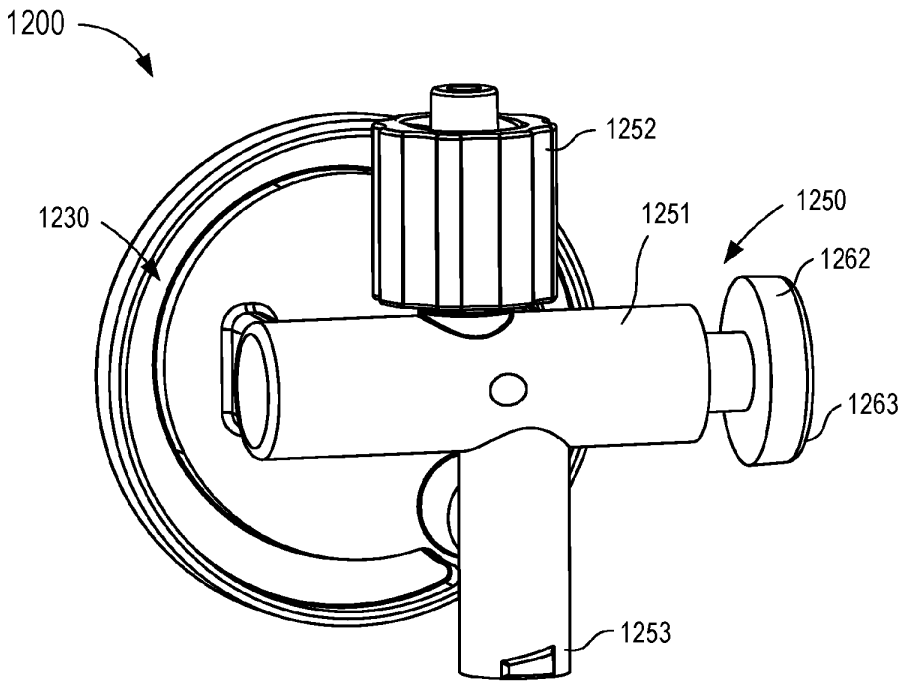

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FIG. 29

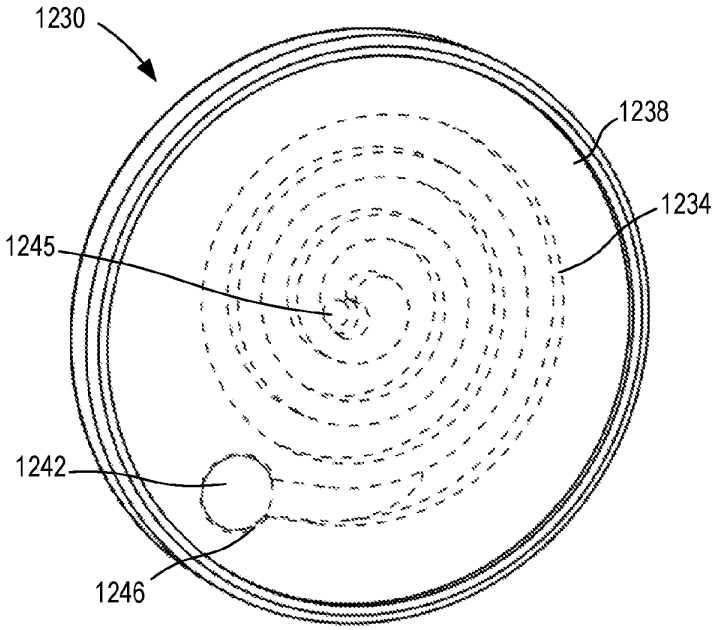

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FIG. 30

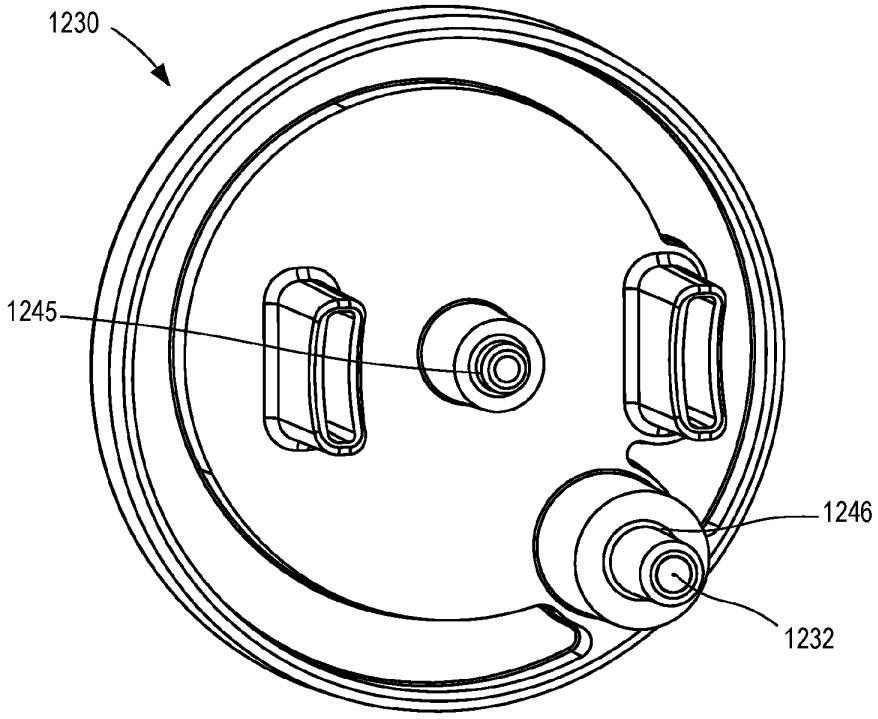

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FIG. 31

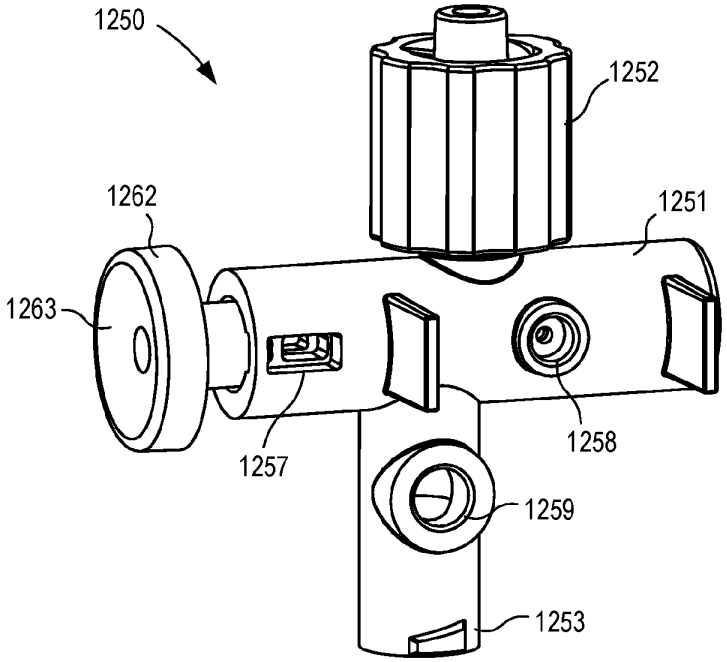

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FIG. 32

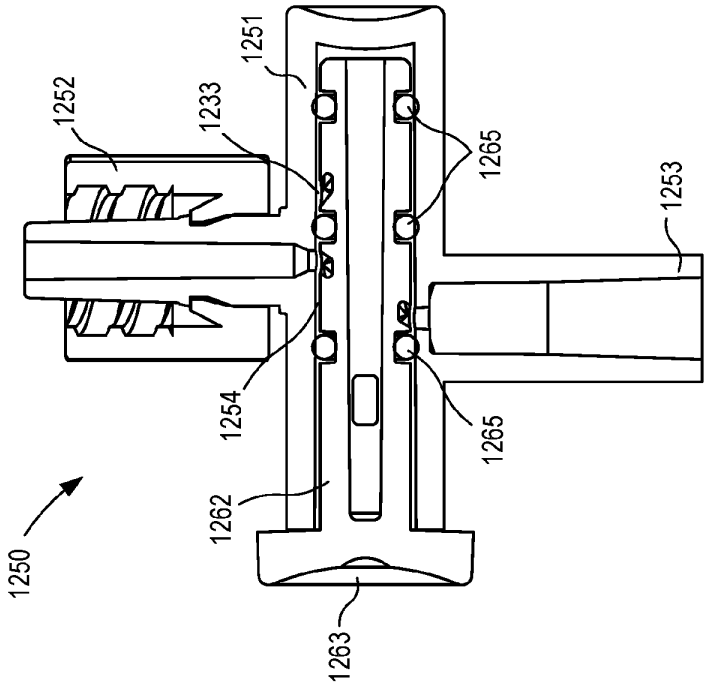

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FIG. 34

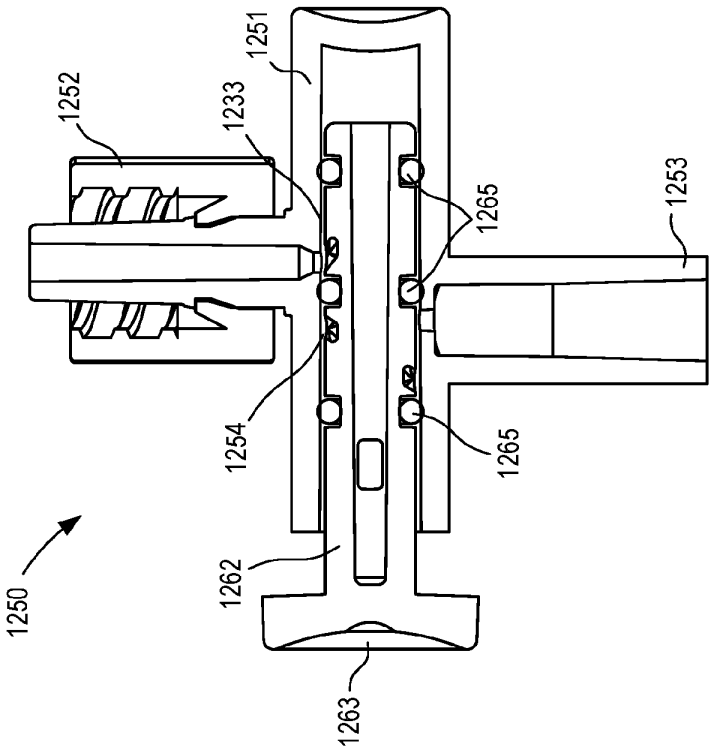

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FIG. 33

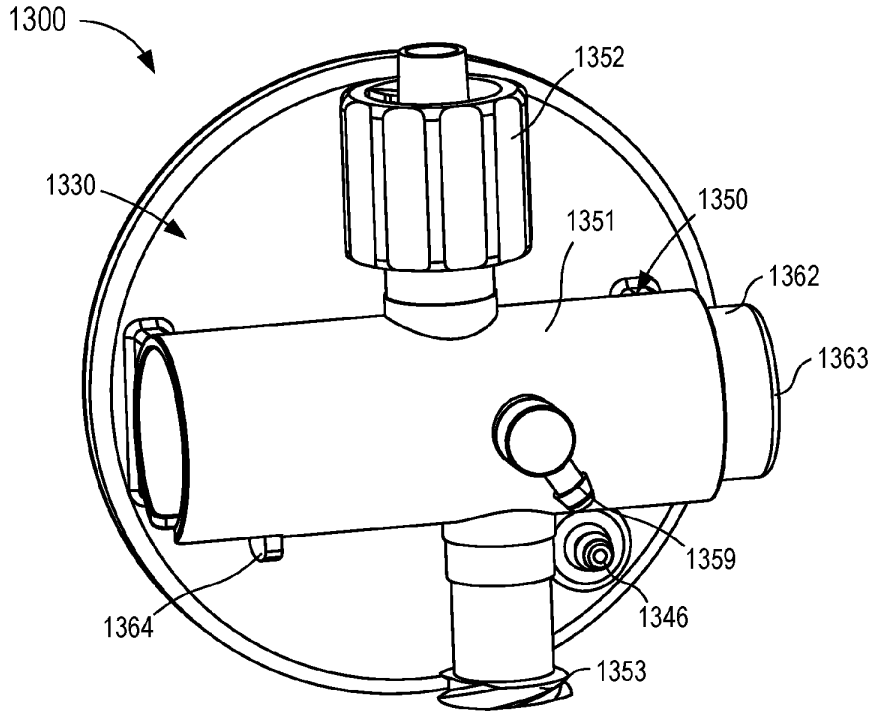

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FIG. 35

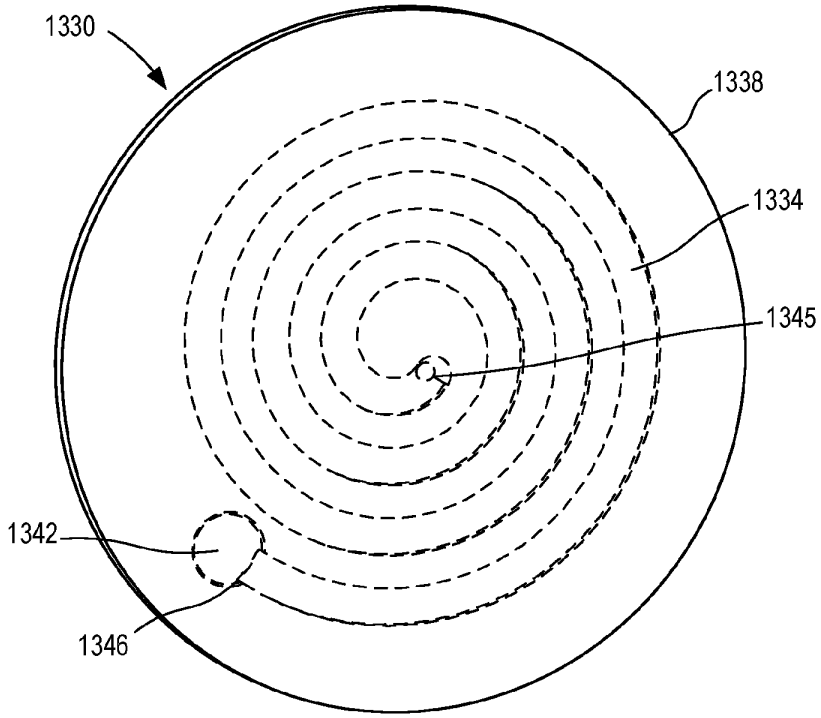

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FIG. 36

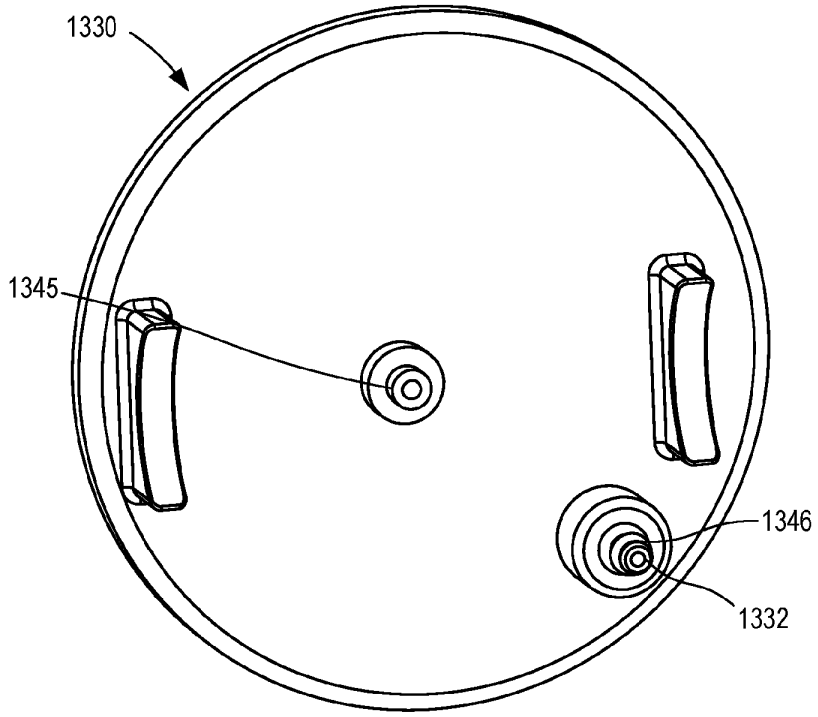


FIG. 37

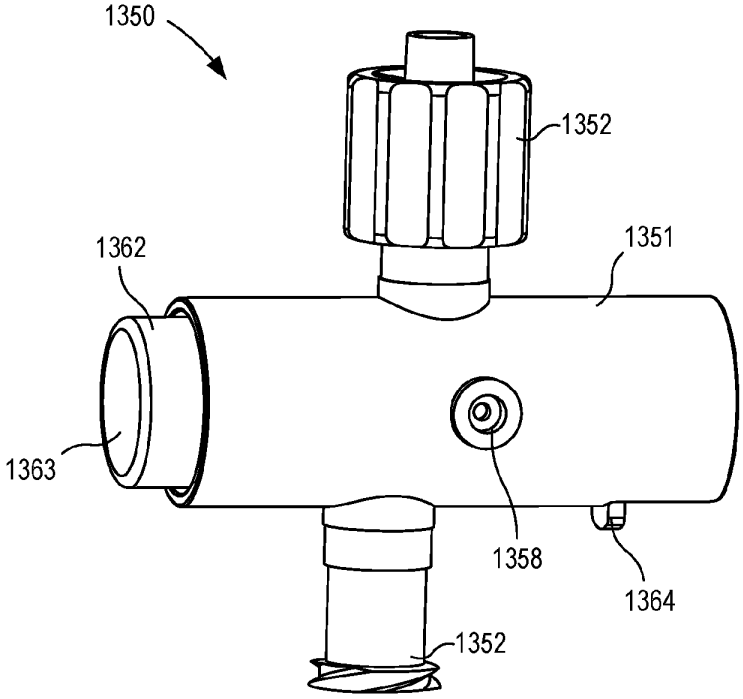


FIG. 38

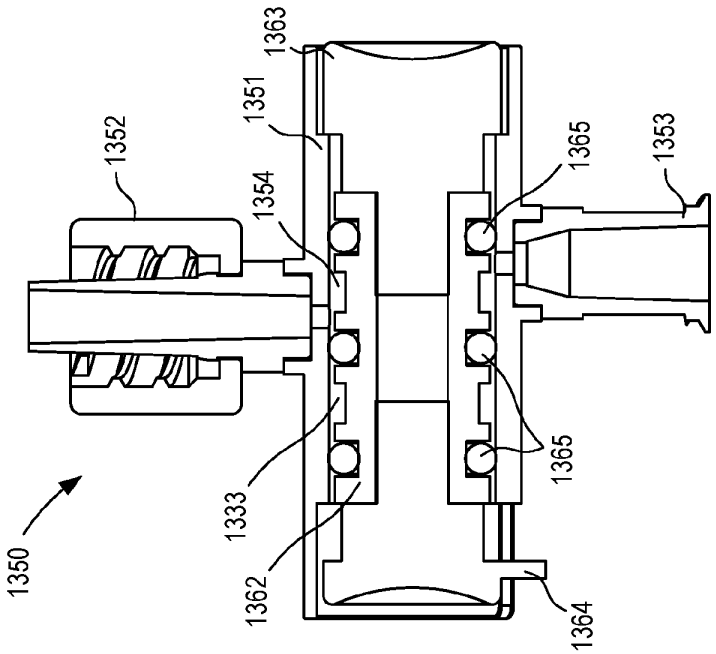

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FIG. 40

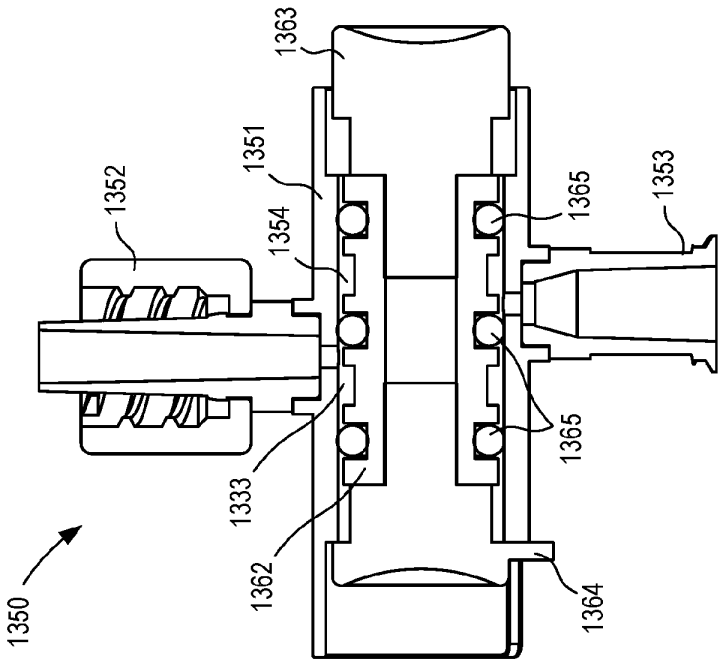

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FIG. 39

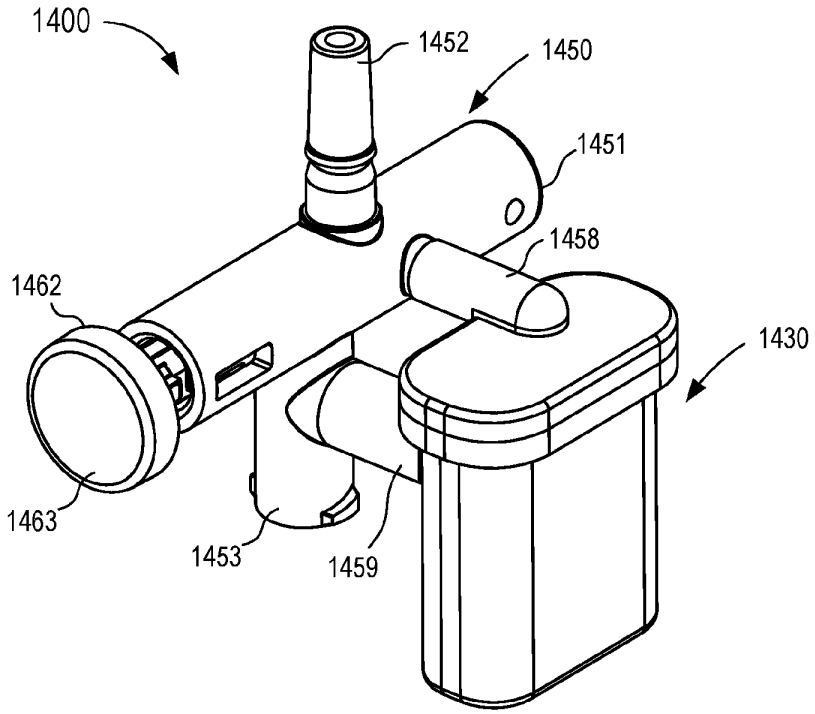

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FIG. 41

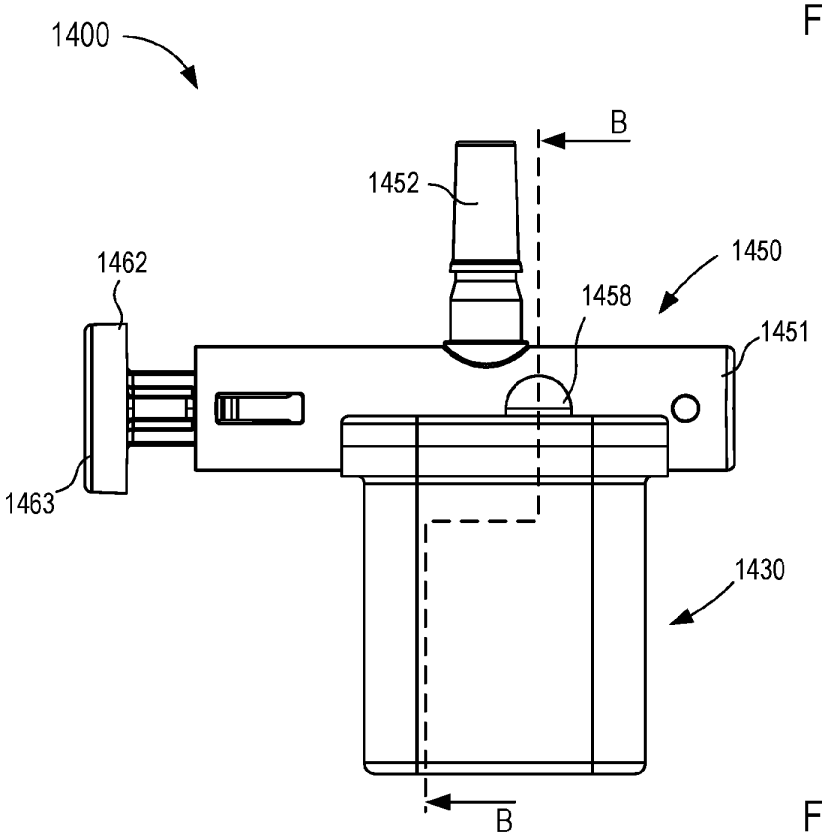

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FIG. 42

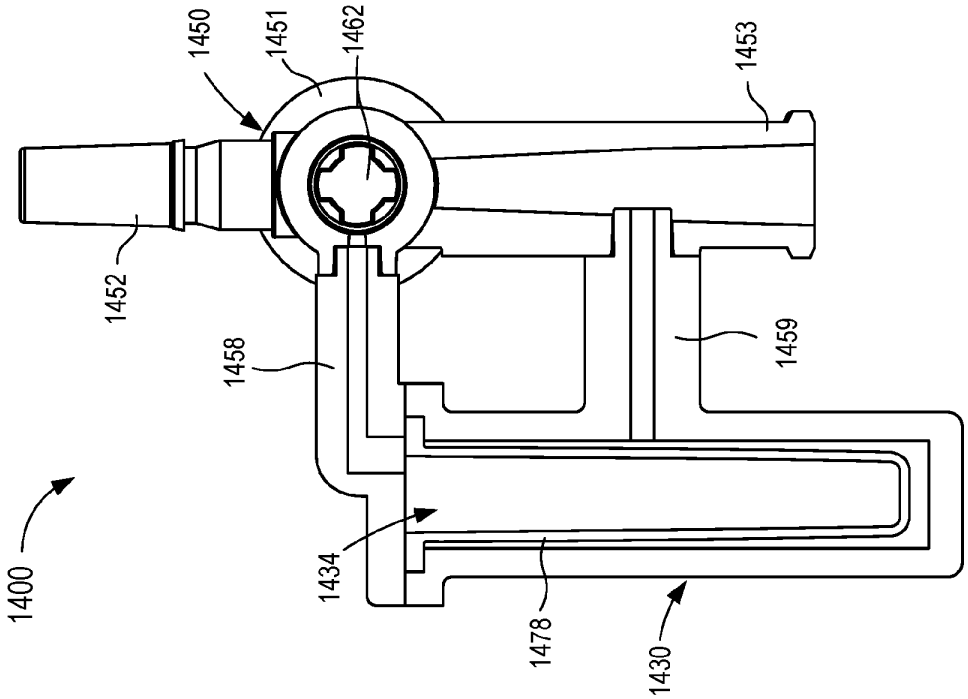

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SECTION B-B

FIG. 44

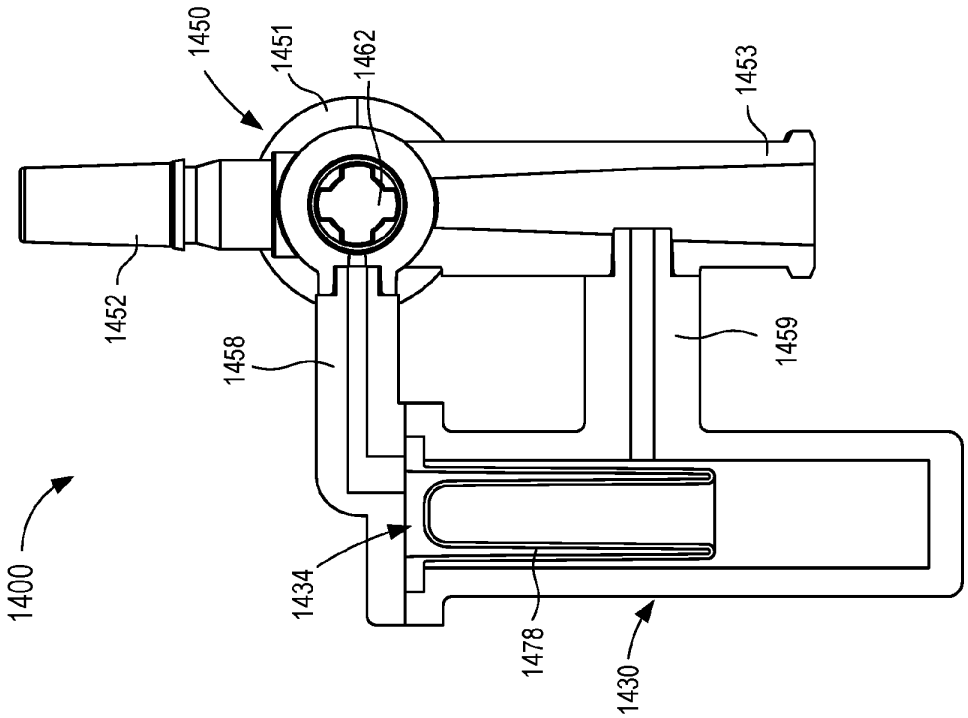

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SECTION B-B

FIG. 43

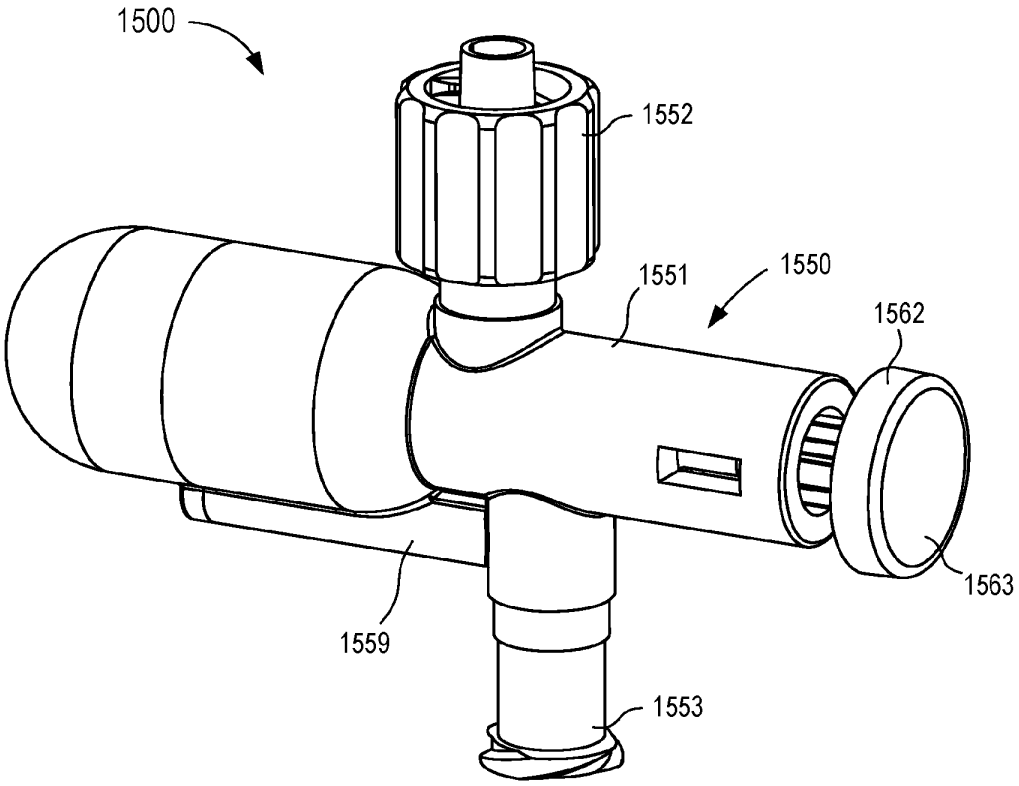

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FIG. 45

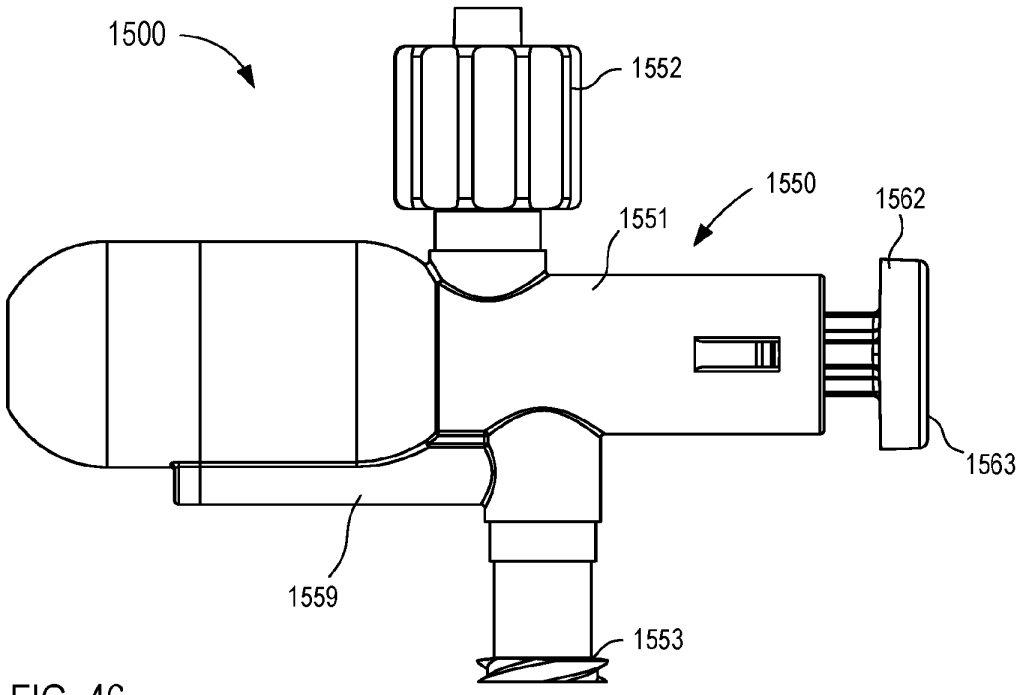

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FIG. 46

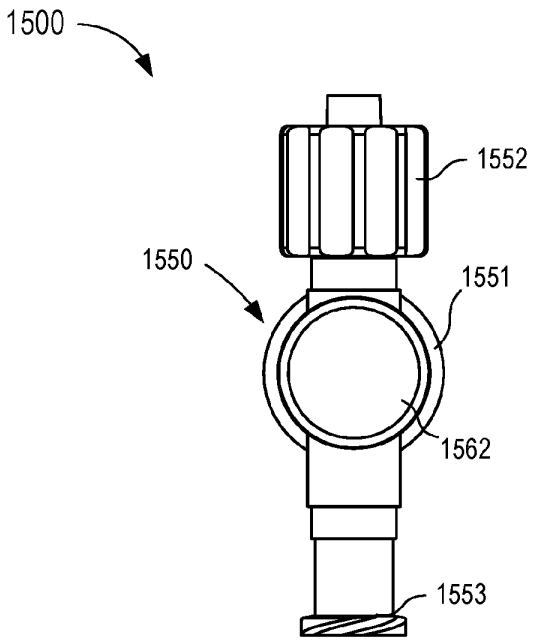

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FIG. 47

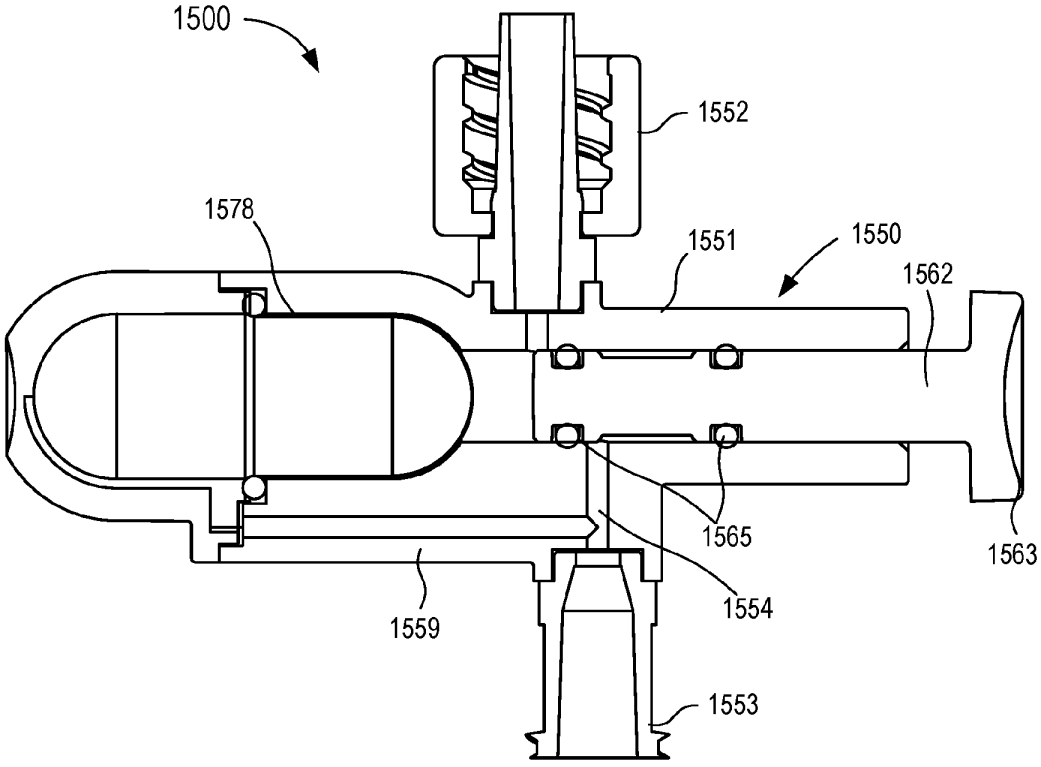

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FIG. 48

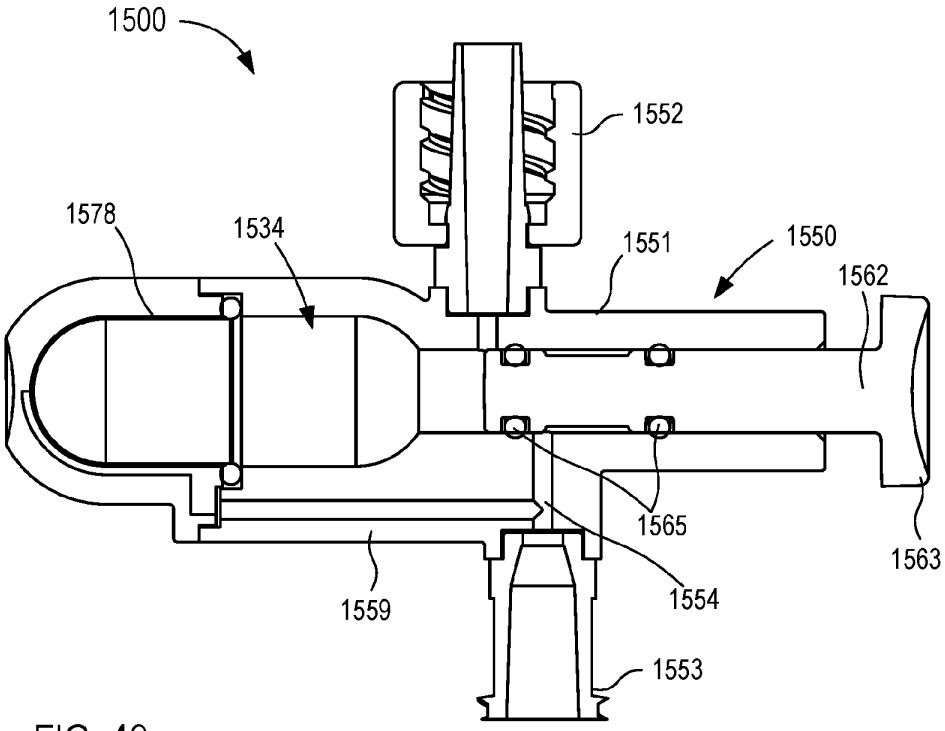

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FIG. 49

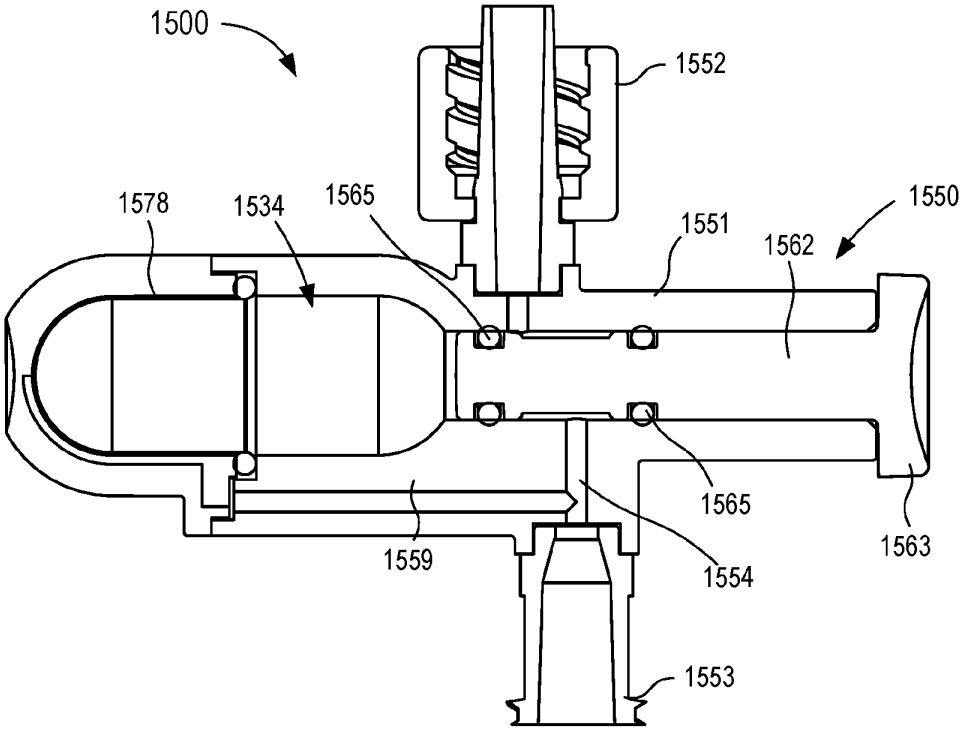

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FIG. 50

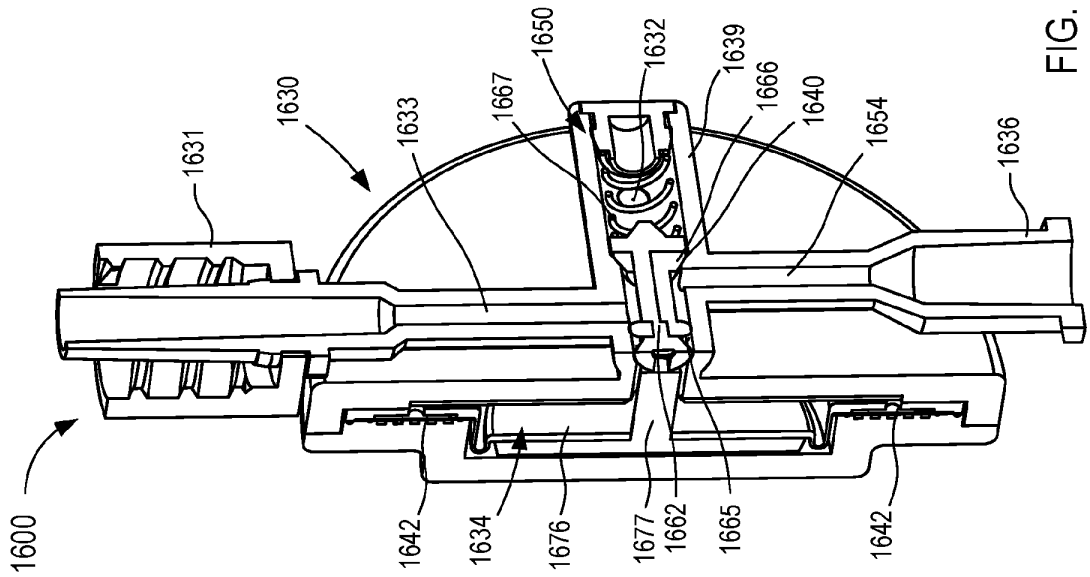

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FIG. 52

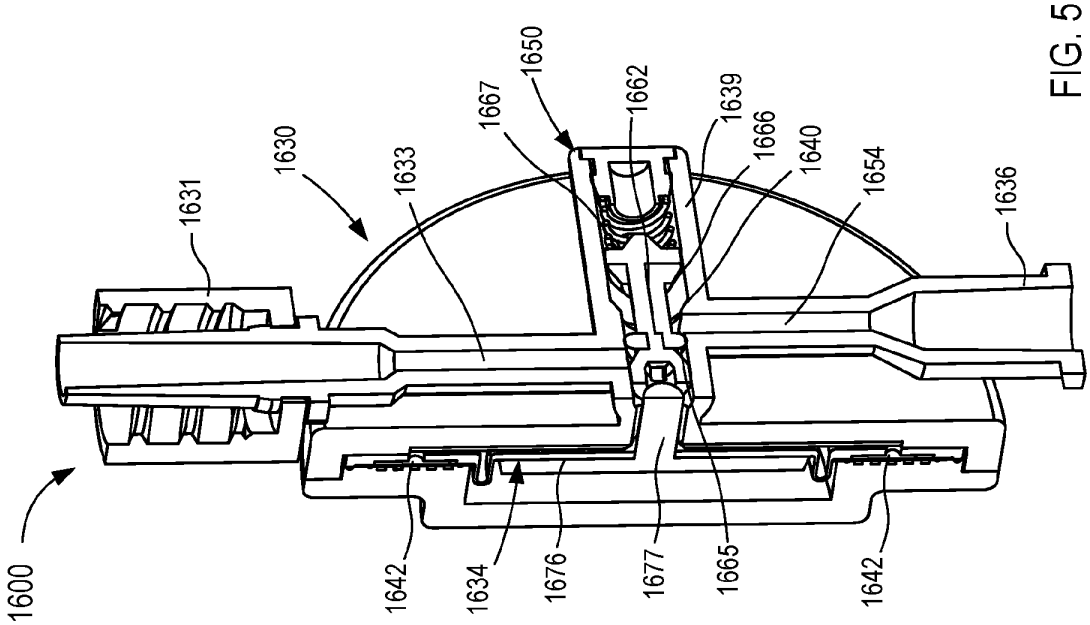

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FIG. 51

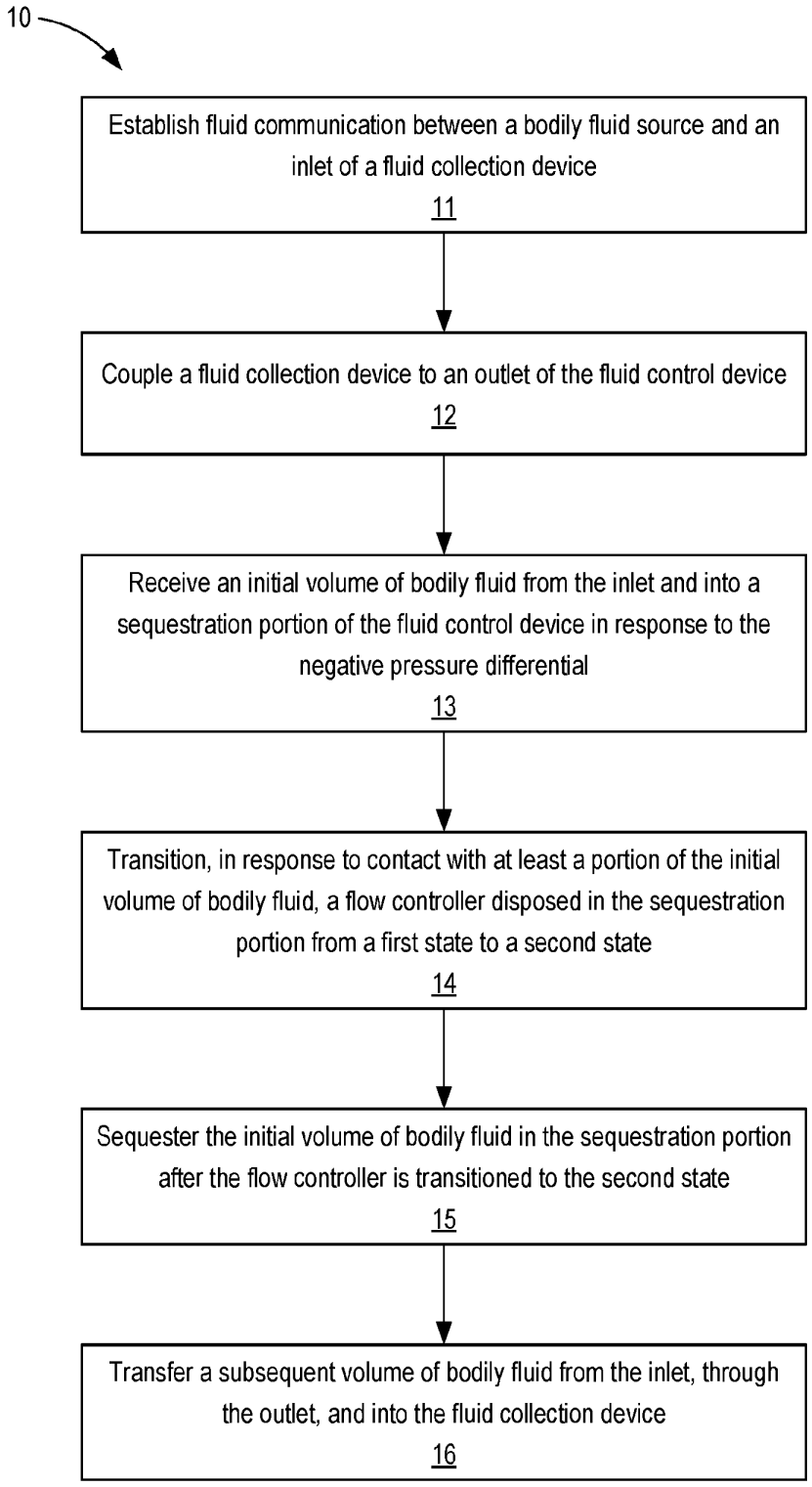

10
Establish fluid communication between a bodily fluid source and an inlet of a fluid collection device
11
Couple a fluid collection device to an outlet of the fluid control device
12
Receive an initial volume of bodily fluid from the inlet and into a sequestration portion of the fluid control device in response to the negative pressure differential
13
Transition, in response to contact with at least a portion of the initial volume of bodily fluid, a flow controller disposed in the sequestration portion from a first state to a second state
14
Sequester the initial volume of bodily fluid in the sequestration portion after the flow controller is transitioned to the second state
15
Transfer a subsequent volume of bodily fluid from the inlet, through the outlet, and into the fluid collection device
16

FIG. 53

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 18/50621

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61B 5/00, A61B 17/00, A61M 1/00, A61M 39/00 (2018.01)

CPC - A61B 5/00, A61B 5/02, A61B 5/03, A61B 5/06, A61B 5/14, A61B 5/1405, A61B 5/145, A61B 5/15, A61B 5/150007, A61B 5/150099, A61B 5/150206, A61B 5/150221, A61B 5/150251, A61B 5/150755, A61B 5/153, A61B 5/154, A61B 5/155, A61B 5/157, A61M 1/00, A61M 1/0001, A61M 1/0031, A61M 1/0035, A61M 1/0058, A61M 1/0066, A61M 1/10, A61M 1/1037, A61M 1/1086, A61M 1/34, A61M 1/36, A61M 39/00

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)

See Search History Document

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

See Search History Document

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

See Search History Document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y --- A	US 2014/0163419 A1 (MAGNOLIA MEDICAL TECHNOLOGIES, INC.) 12 June 2014 (12.06.2014), entire document, especially Figs. 11-15; paras [0079]-[0099])	1-3, 8-21, 24, 29, 32-36 --- 4-5, 25, 30 --- 6-7, 22-23, 26-28, 31
Y --- A	US 6,511,439 B1 (TABATA et al.) 28 January 2003 (28.01.2003), entire document, especially Fig. 1; col 4, ln 48-51; col 9; ln 48-51	4-5, 25, 30 --- 6-7, 22-23, 26-28, 31
A	US 8,876,734 B2 (MAGNOLIA MEDICAL TECHNOLOGIES, INC.) 4 November 2014 (04.11.2014), entire document	1-36
A	US 2014/0107564 A1 (MAGNOLIA MEDICAL TECHNOLOGIES, INC.) 17 April 2014 (17.04.2014), entire document	1-36
A	US 2013/0116599 A1 (BULLIUNGTON et al.) 9 May 2013 (09.05.2013), entire document	1-36
A	US 2015/0018715 A1 (WALTERSPIEL) 15 January 2015 (15.01.2015), entire document	1-36
A	US 2017/0020428 A1 (CALLIOPE SOLUTIONS, INC.) 26 January 2017 (26.01.2017), entire document	1-36

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
5 November 2018	26 NOV 2018
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Authorized officer: Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (January 2015)

PTO/SB/08a (01-25)
Approved for use through 11/30/2027. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Application Number	18898239
Filing Date	2024-09-26
First Named Inventor	Bobby E. Rogers
Art Unit	3791
Examiner Name	ABOUELELA, MAY A
Attorney Docket Number	069366-0581370_KUR2C07US

U.S. PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Inventor of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
	1	4874366		1989-10-17	ZDEB BRIAN	

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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Inventor or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
	1	20150018715		2015-01-15	WALTERSPIEL JUAN NEPOMUC	
	2	20160161511		2016-06-09	XU XIN	
	3	20080145933		2008-06-19	PATTON RICHARD G	
	4	20170020428		2017-01-26	ROGERS BOBBY E	
	5	20170209644		2017-07-27	BROWKA EDWARD	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT		
	Application Number	18898239
	Filing Date	2024-09-26
	First Named Inventor	Bobby E. Rogers
	Art Unit	3791
	Examiner Name	ABOUELELA, MAY A
	Attorney Docket Number	069366-0581370_KUR2C07US

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] ¡	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1	2019232196A1	WO		2019-12-05	MAGNOLIA MEDICAL TECHNOLOGIES INC		☐
	2	2019055487A1	WO		2019-03-21	MAGNOLIA MEDICAL TECHNOLOGIES INC		☐

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NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1	Office Action (Non-Final Rejection) dated 12/02/2024 for U.S. Application No. 18/494,622; Attorney Docket No. 069366-0577657_KUR2C05US (pages 1-70).	☐
	2	Office Action (Advisory Action) dated 11/22/2024 for U.S. Application No. 18/783,173; Attorney Docket No. 069366-0580420_KUR3C03US (pages 1-3).	☐
	3	Office Action (Non-Final Rejection) dated 2/11/2025 for U.S. Application No. 18/783,173; Attorney Docket No. 069366-0580420_KUR3C03US (pages 1-23).	☐
	4	Office Action (Final Rejection) dated 12/31/2024 for U.S. Application No. 18/783,173; Attorney Docket No. 069366-0572192_KUR3C02US (pages 1-19).	☐
	5	Office Action (Advisory Action) dated 3/12/2025 for U.S. Application No. 17/893,079; Attorney Docket No. 069366-0572192_KUR3C02USUS (pages 1-5).	☐
	6	Office Action (Final Rejection) dated 2/12/2025 for U.S. Application No. 17/730,118; Attorney Docket No. 069366-0572186_KUR3C01US (pages 1-28).	☐

INFORMATION DISCLOSURE STATEMENT BY APPLICANT		
	Application Number	18898239
	Filing Date	2024-09-26
	First Named Inventor	Bobby E. Rogers
	Art Unit	3791
	Examiner Name	ABOUELELA, MAY A
	Attorney Docket Number	069366-0581370_KUR2C07US

	7	Notice of Allowance mailed 1/23/2025; Attorney Docket No. 069366-0575784_KUR3D01IL, 121 pages.	☐
	8	Office Action (Non-Final Rejection) dated 11/26/2024 for JP Application No. 2024-121200; Attorney Docket No. 069366-0580493_KUR3D03JP (pages 1-11).	☐
	9	Office Action (Non-Final Rejection) dated 10/22/2024 for U.S. Application No. 18/317,558; Attorney Docket No. 069366-0575710_KUR4C02US (pages 1-62).	☐
	10	Notice of Allowance mailed 11/15/2024; Attorney Docket No. 069366-0575710_KUR4C02US, 9 pages.	☐
	11	Office Action (Final Rejection) mailed 10/09/2024 for Application No. 16838017, pages 1-27.	☐
	12	Office Action (Grounds) mailed 03/11/2025 for Application No. 2022-572789, pages 1-11; Attorney Docket No. 069366-0572492_KUR8001JP.	☐
	13	Office Action (Restriction Requirement) mailed 03/18/2025 for Application No. 17/336,178, pages 1-7; Attorney Docket No. 069366-0572194_KUR8001US.	☐
	14	Notice of Allowance mailed 07-02-2024; Attorney Docket No. 069366-0575784_KUR3D01IL.	☐
	15	Office Action (Non-Final Rejection) mailed 06/04/2025 for Application No. 17/893,079, pages 1-34; Attorney Docket No. 069366-0572192_KUR3C02US.	☐

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Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered and whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

PC.1.19.25

INFORMATION DISCLOSURE STATEMENT BY APPLICANT		
	Application Number	18898239
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	First Named Inventor	Bobby E. Rogers
	Art Unit	3791
	Examiner Name	ABOUELELA, MAY A
	Attorney Docket Number	069366-0581370_KUR2C07US

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT		
	Application Number	18898239
	Filing Date	2024-09-26
	First Named Inventor	Bobby E. Rogers
	Art Unit	3791
	Examiner Name	ABOUELELA, MAY A
	Attorney Docket Number	069366-0581370_KUR2C07US

TIMING STATEMENT

Please see 37 CFR 1.97(e) to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached timing statement under 37 CFR 1.97(e).

☒ A timing statement under 37 CFR 1.97(e) is not submitted herewith.

TIMING FEE

☐ The fee set forth in 37 CFR 1.17(p) has been submitted herewith.

COPIES

☐ An identification of an earlier application pursuant to 37 CFR 1.98(d)(1) is attached.

SIZE FEE ASSERTION

Please see 37 CFR 1.17(v) and the IDS Auto-Load Instructions for completing this form to make the appropriate selection of an assertion under 37 CFR 1.98. For the information disclosure statement (IDS) submitted herewith, the applicant or patent owner certifies the following with respect to the cumulative number of applicant-provided or patent-owner provided items of information submitted to date including those in the accompanying IDS (select only one):

☒ No IDS size fee is required under 37 CFR 1.17(v) at this time.

☐ The IDS is accompanied by the IDS size fee under 37 CFR 1.17(v)(1).

☐ The IDS is accompanied by the IDS size fee under 37 CFR 1.17(v)(2).

☐ The IDS is accompanied by the IDS size fee under 37 CFR 1.17(v)(3).

SIGNATURE

A signature of the applicant or representative is required in accordance with 37 CFR 1.33 and 11.18. Please see 37 CFR 1.4(d) for the form of the signature.

Signature	/Ben Hudson/	Date (YYYY-MM-DD)	2025-07-02
Name/Print	Benjamin F. Hudson	Registration Number	71,474

PC.1.19.25

INFORMATION DISCLOSURE STATEMENT BY APPLICANT		
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This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/730,118	04/26/2022	Bobby E. ROGERS	069366-0572186_KUR3C01US	1667

27500 7590 02/12/2025

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EXAMINER	
NGUYEN, HUONG Q	

ART UNIT	PAPER NUMBER
3791	

NOTIFICATION DATE	DELIVERY MODE
02/12/2025	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Docket_IP@pillsburylaw.com

PTOL-90A (Rev. 04/07)

Office Action Summary	Application No. 17/730,118	Applicant(s) ROGERS et al.	
	Examiner Huong Q NGUYEN	Art Unit 3791	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 10/31/2024.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☑ This action is **FINAL.** 2b) ☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 2-23 is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 2-23 is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to **PPHfeedback@uspto.gov.**

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☑ The drawing(s) filed on 4/26/2022 is/are: a)☑ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☑ Notice of References Cited (PTO-892)

2) ☑ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

DETAILED ACTION

This office action is responsive to the amendment filed

Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Claim Interpretation

The following is a quotation of 35 U.S.C. 112(f):

> (f) Element in Claim for a Combination. – An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

The following is a quotation of pre-AIA 35 U.S.C. 112, sixth paragraph:

> An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

The claims in this application are given their broadest reasonable interpretation using the plain meaning of the claim language in light of the specification as it would be understood by one of ordinary skill in the art. The broadest reasonable interpretation of a claim element (also commonly referred to as a claim limitation) is limited by the description in the specification when 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is invoked.

As explained in MPEP § 2181, subsection I, claim limitations that meet the following three-prong test will be interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph:

(A) the claim limitation uses the term "means" or "step" or a term used as a substitute for "means" that is a generic placeholder (also called a nonce term or a non-structural term having no specific structural meaning) for performing the claimed function;

(B) the term "means" or "step" or the generic placeholder is modified by functional language, typically, but not always linked by the transition word "for" (e.g., "means for") or another linking word or phrase, such as "configured to" or "so that"; and

(C) the term "means" or "step" or the generic placeholder is not modified by sufficient structure, material, or acts for performing the claimed function.

Use of the word "means" (or "step") in a claim with functional language creates a rebuttable presumption that the claim limitation is to be treated in accordance with 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph. The presumption that the claim limitation is interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is rebutted when the claim limitation recites sufficient structure, material, or acts to entirely perform the recited function.

Absence of the word "means" (or "step") in a claim creates a rebuttable presumption that the claim limitation is not to be treated in accordance with 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph. The presumption that the claim limitation is not interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is rebutted when the claim limitation

recites function without reciting sufficient structure, material or acts to entirely perform the recited function.

Claim limitations in this application that use the word "means" (or "step") are being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, except as otherwise indicated in an Office action. Conversely, claim limitations in this application that do not use the word "means" (or "step") are not being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, except as otherwise indicated in an Office action.

No claim elements are interpreted under 112(f).

Claim Rejections - 35 USC § 112

The following is a quotation of 35 U.S.C. 112(b):
(b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 12 rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor (or for applications subject to pre-AIA 35 U.S.C. 112, the applicant), regards as the invention.

The recitation of the term "approximately" is a relative term which renders the claim indefinite. The term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention thus rendering the metes and bounds of the invention unclear. Therefore, use of the terms introduces indefiniteness because one skilled in the art cannot determine the exact boundaries of the limitations of approximately 20 times as claimed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a)(1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention.

Claim(s) 2-3, 9-10, 17-20, and 22-23 is/are rejected under 35 U.S.C. 102(a)(1) as being anticipated by Bullington et al (US Pub No. 20140163419).

In regard to Claims 2 and 17, Bullington et al disclose a device comprising:

an inlet port 405 for receiving a blood sample, best seen in Figure 12 (0081, 0089);

an outlet port 402 (proximal end portion of housing 401), best seen in Figure 13-15 (0085);

a chamber 480 connected with the inlet port, and configured to collect a first portion of the blood sample, the chamber having a volume sufficient to collect the first portion of the blood sample that is more prone to contamination and also to minimize an amount of blood to be collected, best seen in Figure 14 (0079, 0091 – "the proximal motion of the second member 451 moves the plunger 476 of the first member 470 in the proximal direction relative to the shunt tube 471… increases the volume of the portion of the inner volume 411 of the housing 401 that is distal of the plunger 476, thereby defining the first reservoir 480, as shown in FIG. 14. With the plunger 476 forming a fluid tight seal with the inner surface of the walls defining the inner volume 411 and with the shunt tube 471 about which the plunger 476 is disposed, the volume increase of the portion of the inner volume 411 can produce a negative pressure within the first reservoir 480"; 0092 – "Expanding further, the negative pressure within the first reservoir 480 produced by the movement of the plunger 476 (as indicated by the arrow II) introduces a suction force within the portion of the patient. Thus, a bodily-fluid is drawn through the port 405, the first lumen 432 defined by the flow control mechanism 430, and the first lumen 406 defined by the diverter 409 and into the fluid reservoir 480. In some embodiments, the bodily-fluid can contain undesirable microbes such as, for example, dermally-residing microbes and/or other external contaminants"),

the chamber has a volume of less than 1.5 cubic centimeters – "the first reservoir 480 can be configured to contain from about 0.1 ml to about 3.0 ml" (0094); and

a sampling channel 433 connected with the inlet port and configured to convey a subsequent portion of the blood sample to the outlet port, best seen in Figure 15 (0095).

3, 20. The device, the chamber further configured to collect a first portion of the blood sample when under a drawing force applied from the outlet port from a blood sample collection device, best seen in Figure 14 (0079, 0091 – "the proximal motion of the second member 451 moves the plunger 476 of the first member 470 in the proximal direction relative to the shunt tube 471… increases the volume of the portion of the inner volume 411 of the housing 401 that is distal of the plunger 476, thereby defining the first reservoir 480, as shown in FIG. 14. With the plunger 476 forming a fluid tight seal with the inner surface of the walls defining the inner volume 411 and with the shunt tube 471 about which the plunger 476 is disposed, the volume increase of the portion of the inner volume 411 can produce a negative pressure within the first reservoir 480"; 0092 – "Expanding further, the negative pressure within the first reservoir 480 produced by the movement of the plunger 476 (as indicated by the arrow II) introduces a suction force within the portion of the patient. Thus, a bodily-fluid is drawn through the port 405, the first lumen 432 defined by the flow control mechanism 430, and the first lumen 406 defined by the diverter 409 and into the fluid reservoir 480. In some embodiments, the bodily-fluid can contain undesirable microbes such as, for example, dermally-residing microbes and/or other external contaminants").

9, 22. The device, further comprising a patient needle (0089) and a sample collection device 451, best seen in Figure 14 (0079).

10, 23. The device, further comprising a moving part 430, 431, 435 (flow control mechanism first member 431 controlled by member 435), moving part also defined by plunger 476 (0084 – Figure 13-15),

configured to be movable from a first position to a second position to allow the blood sample to flow to the sampling channel –

in the first position, moving member 435 rotates first member 431 such that lumen 433 (sampling channel) is fluidically isolated, due to lumen 432 of the flow control mechanism aligned with the inlet port 405, which leads through lumen 406 in diverter 409 and into chamber 480 – thus the inlet port 405 is in fluid communication with the chamber 480, best seen in Figure 14 (0081, 0092);

in the second position, moving member 435 rotates first member 431 such that lumen 433 is aligned with inlet port 405 such that "a desired amount of bodily-fluid is drawn through the port 405, the second lumen 433 of the flow control mechanism 430, the second lumen 407 of the diverter 409, and the lumen 475 defined by the shunt tube 471 and into the second reservoir 490. Moreover, the bodily-fluid disposed within the second reservoir 490 is fluidically isolated from the first, predetermined amount of bodily-fluid contained within the first reservoir 480," best seen in Figure 15 (0082, 0083, 0095, 0097) – thus creates a pathway from the inlet port 405 to the outlet port 402, which is adjacent to reservoir 490.

18. The device in accordance with claim 17, wherein the chamber 480 has a volume of less than 1.0 cubic centimeter – "the first reservoir 480 can be configured to contain from about 0.1 ml to about 3.0 ml" (0094).

19. The device in accordance with claim 17, wherein the chamber 480 has a volume from 0.5 cubic centimeters to 1.0 cubic centimeters – "the first reservoir 480 can be configured to contain from about 0.1 ml to about 3.0 ml" (0094).

Claim(s) 11-13 and 15-16 is/are rejected under 35 U.S.C. 102(a)(1) as anticipated by or, in the alternative, under 35 U.S.C. 103 as obvious over Bullington et al in view of Xu et al (US Pub No. 20160161511).

In regard to Claims 11-12, Bullington et al disclose a device comprising:

an inlet port 405 for receiving a blood sample, best seen in Figure 12 (0081, 0089);

a patient needle in fluid communication with the inlet port – "a user can engage the transfer device 400 to couple the port 405 to a proximal end portion of a lumen-defining device (not shown) such as, for example, a butterfly needle, a cannula assembly, a trocar (which in some cases is used to insert a catheter into a patient), or the like" (0089);

an outlet port 402 (proximal end portion of housing 401), best seen in Figure 13-15 (0085);

a chamber 480 connected with the inlet port, and configured to collect a first portion of the blood sample, the chamber having a volume sufficient to collect the first portion of the blood sample that is more prone to contamination and also to minimize an amount of blood to be collected, best seen in Figure 14 (0079, 0091 – "the proximal motion of the second member 451 moves the plunger 476 of the first member 470 in the proximal direction relative to the shunt tube 471… increases the volume of the portion of the inner volume 411 of the housing 401 that is distal of the plunger 476, thereby defining the first reservoir 480, as shown in FIG. 14. With the plunger 476 forming a fluid tight seal with the inner surface of the walls defining the inner volume 411 and with the shunt tube 471 about which the plunger 476 is disposed, the volume increase of the portion of the inner volume 411 can produce a negative pressure within the first reservoir 480"; 0092 – "Expanding further, the negative pressure within the first reservoir 480 produced by the movement of the plunger 476 (as indicated by the arrow II) introduces a suction force within the portion of the patient. Thus, a bodily-fluid is drawn through the port 405, the first lumen 432 defined by the flow control mechanism 430, and the first lumen 406 defined by the diverter 409 and into the fluid reservoir 480. In some embodiments, the bodily-fluid can contain undesirable microbes such as, for example, dermally-residing microbes and/or other external contaminants"); and

a sampling channel 433 connected with the inlet port and configured to convey a subsequent portion of the blood sample to the outlet port, best seen in Figure 15 (0095),

the chamber having a volume up to 20 times the volume of a patient needle – Bullington et al disclose chamber 480 configured to contain from about 0.1 ml to about 3.0 ml (0094), with 0.1 ml being up to 20 times the volume of a patient needle as typically found in the art.

Alternatively, Xu et al teach that it is well-known in the art that a sampling needle provides 10-50 microliter volume (0007). If the needle is said to have 50 microliters, then chamber 480 can have 0.1 ml (100 microliter), which is 20 times the volume of the patient needle. Therefore, it would have been obvious to one of ordinary skill in the art at the time of filing to have the patient needle of Bullington et al have a volume that allows the chamber having a volume up to 20 times the volume of the patient needle as taught by Xu et al as an effective and well-known size for the patient needle for sampling the blood.

13. Bullington et al disclose the device in accordance with Claim 11, the chamber further configured to collect a first portion of the blood sample when under a drawing force applied from the outlet port from a blood sample collection device, best seen in Figure 14 (0079, 0091 – "the proximal motion of the second member 451 moves the plunger 476 of the first member 470 in the proximal direction relative to the shunt tube 471… increases the volume of the portion of the inner volume 411 of the housing 401 that is distal of the plunger 476, thereby defining the first reservoir 480, as shown in FIG. 14. With the plunger 476 forming a fluid tight seal with the inner surface of the walls defining the inner volume 411 and with the shunt tube 471 about which the plunger 476 is disposed, the volume increase of the portion of the inner volume 411 can produce a negative pressure within the first reservoir 480"; 0092 – "Expanding further, the negative pressure within the first reservoir 480 produced by the movement of the

plunger 476 (as indicated by the arrow II) introduces a suction force within the portion of the patient. Thus, a bodily-fluid is drawn through the port 405, the first lumen 432 defined by the flow control mechanism 430, and the first lumen 406 defined by the diverter 409 and into the fluid reservoir 480. In some embodiments, the bodily-fluid can contain undesirable microbes such as, for example, dermally-residing microbes and/or other external contaminants").

15. Bullington et al disclose the device in accordance with claim 13, further comprising the patient needle (0089) and a sample collection device 451, best seen in Figure 14 (0079).

16. Bullington et al disclose the device in accordance of claim 13, further comprising a moving part 430, 431, 435 (flow control mechanism first member 431 controlled by member 435), moving part also defined by plunger 476 (0084 – Figure 13-15),

configured to be movable from a first position to a second position to allow the blood sample to flow to the sampling channel –

in the first position, moving member 435 rotates first member 431 such that lumen 433 (sampling channel) is fluidically isolated, due to lumen 432 of the flow control mechanism aligned with the inlet port 405, which leads through lumen 406 in diverter 409 and into chamber 480 – thus the inlet port 405 is in fluid communication with the chamber 480, best seen in Figure 14 (0081, 0092);

in the second position, moving member 435 rotates first member 431 such that lumen 433 is aligned with inlet port 405 such that "a desired amount of bodily-fluid is drawn through the port 405, the second lumen 433 of the flow control mechanism 430, the second lumen 407

of the diverter 409, and the lumen 475 defined by the shunt tube 471 and into the second reservoir 490. Moreover, the bodily-fluid disposed within the second reservoir 490 is fluidically isolated from the first, predetermined amount of bodily-fluid contained within the first reservoir 480," best seen in Figure 15 (0082, 0083, 0095, 0097) – thus creates a pathway from the inlet port 405 to the outlet port 402, which is adjacent to reservoir 490.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries for establishing a background for determining obviousness under 35 U.S.C. 103 are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims the examiner presumes that the subject matter of the various claims was commonly

owned as of the effective filing date of the claimed invention(s) absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and effective filing dates of each claim that was not commonly owned as of the effective filing date of the later invention in order for the examiner to consider the applicability of 35 U.S.C. 102(b)(2)(C) for any potential 35 U.S.C. 102(a)(2) prior art against the later invention.

Claim(s) 4-8, 14, and 21 is/are rejected under 35 U.S.C. 103 as being unpatentable over Bullington et al, further in view of Percarpio (US Pat No. 4106497 – cited by applicant).

In regard to Claims 4-7, Bullington et al disclose the invention above but do not expressly disclose a blood impermeable membrane is configured to facilitate the chamber collecting the first portion of the blood sample.

Percarpio teach that it is well-known in the art to provide an analogous blood sampling device comprising an inlet port 22 for receiving a blood sample, an outlet port 42, 44, a chamber to collect a first portion of the blood sample (indicator area), and a sampling channel 28 connecting the inlet and the outlet, including a blood impermeable membrane 90 to enable necessary venting of air for the desired flow of the blood first to the chamber before directing it to the outlet (Col.4: 16-39). Percarpio teach a housing 40, 56 separate from the blood impermeable membrane 90, best seen in Figure 3-4, as an effective configuration for the location of said blood impermeable membrane.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the of filing to modify Bullington et al to include a blood impermeable membrane causes the first

portion of the blood sample to back up into the chamber following application of the drawing force applied from the outlet port as taught by Percarpio by enabling necessary venting of air from the device during the desired flow of blood such that, when the drawing force is applied at the outlet port, the first portion of the blood sample is drawn into the chamber in the manner taught by Bullington et al to contact a material that is blood impermeable to enable the venting of air, wherein the blood impermeable membrane is separate from the housing, as taught by Percarpio as an effective configuration for said blood impermeable membrane.

In regard to Claims 8, 14, and 21, Bullington et al disclose the invention above but do not expressly disclose a valve configured to initially close off the sampling channel.

Percarpio teach that it is well-known in the art to provide an analogous blood sampling device comprising an inlet port 22 for receiving a blood sample, an outlet port 42, 44, a chamber to collect a first portion of the blood sample (indicator area), and a sampling channel 28 connecting the inlet and the outlet, including a blood impermeable membrane 90 to enable necessary venting of air for the desired flow of the blood first to the chamber before directing it to the outlet (Col.4: 16-39). Percarpio teach a valve 78 (check valve) that is configured to initially close off access to the outlet through sampling channel 38 until the first portion of the blood sample is in the chamber, best seen in Figure 3, and is further configured such that, upon release, follow-on amounts of the blood sample will bypass the chamber and flow through the sampling channel toward the outlet port, best seen in Figure 4 (Col.3: 61-Col.4: 15, 64-Col.5: 47). Percarpio also teach the valve is configured to pinch, shunt, bend or otherwise close off

the outlet before the first portion of the blood sample is collected in the chamber, best seen in Figure 3-4 (Col.3: 61-Col.4: 15, 64-Col.5: 47).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of filing to modify Bullington et al to include a valve that is configured to initially close off the sampling channel until the first portion of the blood sample is in the chamber and is further configured such that, upon release, follow-on amounts of the blood sample will bypass the chamber and flow through the sampling channel toward the outlet port, as taught by Percarpio above to effectively seal off the outlet before the blood is properly in the chamber of Bullington et al, to effectively block the flow of blood upstream before it reaches the outlet, prior to being drawn into the chamber as taught by Bullington et al for the reasons of reducing contamination in the sample, as well as Percarpio.

Response to Arguments

Applicant's arguments with respect to new claim(s) above have been considered but are moot because the new ground of rejection does not rely on any reference applied in the prior rejection of record for any teaching or matter specifically challenged in the argument.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any nonprovisional extension fee (37 CFR 1.17(a)) pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Huong Q NGUYEN whose telephone number is (571)272-8340. The examiner can normally be reached 10 am - 6 pm.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jennifer Robertson can be reached on (571)272-5001. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/H.Q.N/
Examiner, Art Unit 3791

/RENE T TOWA/
Primary Examiner, Art Unit 3791

Notice of References Cited	Application/Control No. 17/730,118	Applicant(s)/Patent Under Reexamination ROGERS et al.	
	Examiner Huong Q NGUYEN	Art Unit 3791	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date YYYY-MM-DD	Name	CPC Classification	US Classification
*	A	US-20140163419-A1	2014-06-12	Bullington; Gregory J.	A61B5/154	600/575
*	B	US-20160161511-A1	2016-06-09	Xu; Xin	G01N33/49	435/13
	C					
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FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date YYYY-MM-DD	Country	Name	CPC Classification
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Dates in YYYY-MM-DD format are publication dates. Classifications may be US or foreign.

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	17730118
	Filing Date	2022-04-26
	First Named Inventor	Bobby E. ROGERS
	Art Unit	3791
	Examiner Name	NGUYEN, HUONG Q
	Attorney Docket Number	069366-0572186_KUR3C01US

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	11744494		2023-09-05	ROGERS BOBBY E	

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	1	20150018715		2015-01-15	WALTERSPIEL JUAN NEPOMUC	

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	Attorney Docket Number	069366-0572186_KUR3C01US

	1	Office Action (Final Rejection) dated 11/4/2024 for U.S. Application No. 18/783,173; Attorney Docket No. 069366-0580420_KUR3C03US (pages 1-22).	☐
	2	Office Action (Non-Final Rejection) dated 09/24/2024 for U.S. Application No. 18/783,173; Attorney Docket No. 069366-0580420_KUR3C03US (pages 1-62).	☐
	3	Office Action (Rejection Decision) dated 11/5/2024 for JP Application No. 2023-076490; Attorney Docket No. 069366-0575273_KUR2D03JP (pages 1-8).	☐
	4	Office Action (Non-Final Rejection) dated 10/22/2024 for U.S. Application No. 18/783,173; Attorney Docket No. 069366-0580420_KUR3C03US (pages 1-62).	☐
	5	Office Action (Non-Final Rejection) mailed 11/22/2024 for U.S. Application No. 18/898,239; Attorney Docket No. 069366-0581370_KUR2C07US (pages 1-57).	☐
	6	Office Action (Non-Final Rejection) dated 11/26/2024 for JP Application No. 2024-121200; Attorney Docket No. 069366-0580493_KUR3C03JP (pages 1-11).	☐

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	Attorney Docket Number	069366-0572186_KUR3C01US

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Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2025-01-09
Name/Print	Benjamin F. Hudson	Registration Number	71,474

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7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

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Doc description: Information Disclosure Statement (IDS) Filed

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Filing Date	2022-04-26
First Named Inventor	Bobby E. ROGERS
Art Unit	3791
Examiner Name	NGUYEN, HUONG Q
Attorney Docket Number	069366-0572186_KUR3C01US

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	4312362		1982-01-26	KAUFMAN JOSEPH	

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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20140163419		2014-06-12	BULLINGTON GREGORY J	
	2	20140309558		2014-10-16	FLETCHER GARY D	
	3	20140073990		2014-03-13	HOLMES ELIZABETH A	
	4	20140323911		2014-10-30	SLOAN DEBORAH	
	5	20040112808		2004-06-17	TAKAGI YOSHIKI	

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	1	Office Action (Non-Final Rejection) dated 9/24/2024 for U.S. Application No. 18/783,173 ; Attorney Docket No. 069366-0580420_KUR3C03US (pages 1-62).	☐
	2	Office Action (Non-Final Rejection) dated 9/17/2024 for U.S. Application No. 17/893,079 ; Attorney Docket No. 069366-0572192_KUR3C02US (pages 1-50).	☐
	3	Office Action (Non-Final Rejection) dated 9/17/2024 for U.S. Application No. 18/783,088 ; Attorney Docket No. 069366-0580418_KUR2C06US (pages 1-60).	☐
	4	Office Action (Notice of Deficiencies) dated 10/14//2023 for IL App No. 309380 (pages 1-7).	☐

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Name/Print	Benjamin F. Hudson	Registration Number	71,474

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/783,173	07/24/2024	Bobby E. ROGERS	069366-0580420_KUR3C03US	1561

27500 7590 11/22/2024

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P.O BOX 10500
McLean, VA 22102

EXAMINER	
NGUYEN, HUONG Q	

ART UNIT	PAPER NUMBER
3791	

NOTIFICATION DATE	DELIVERY MODE
11/22/2024	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Docket_IP@pillsburylaw.com

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 18/783,173	**Applicant(s)** ROGERS et al.	
	Examiner Huong Q NGUYEN	**Art Unit** 3791	**AIA (FITF) Status** Yes

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 08 November 2024 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

NO NOTICE OF APPEAL FILED

1. ☑ The reply was filed after a final rejection. No Notice of Appeal has been filed. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114 if this is a utility or plant application. Note that RCEs are not permitted in design applications. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires ____ months from the mailing date of the final rejection.
   b) ☑ The period for reply expires on: (1) the mailing date of this Advisory Action; or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
   c) ☐ A prior Advisory Action was mailed more than 3 months after the mailing date of the final rejection in response to a first after-final reply filed within 2 months of the mailing date of the final rejection.The current period for reply expires ____ months from the mailing date of *the prior Advisory Action* or SIX MONTHS from the mailing date of the final rejection, whichever is earlier.
   Examiner Note: If box 1 is checked, check either box (a), (b) or (c). ONLY CHECK BOX (b) WHEN THIS ADVISORY ACTION IS THE FIRST RESPONSE TO APPLICANTS FIRST AFTER-FINAL REPLY WHICH WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. ONLY CHECK BOX (c) IN THE LIMITED SITUATION SET FORTH UNDER BOX (c). See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) or (c) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37CFR 41.37(a).

AMENDMENTS

3. ☑ The proposed amendments filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   a) ☑ They raise new issues that would require further consideration and/or search (see NOTE below);
   b) ☐ They raise the issue of new matter (see NOTE below);
   c) ☑ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.
   NOTE: See Continuation Sheet (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☑ Applicant's reply has overcome the following rejection(s): Current rejection under Bullington et al.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☑ For purposes of appeal, the proposed amendment(s):(a) ☑ will not be entered; or (b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____
9. ☐ The affidavit or other evidence filed after final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
10. ☐ The affidavit or other evidence filed after the date of filing the Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
11. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

12. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
13. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
14. ☐ Other: _____.

STATUS OF CLAIMS

15. The status of the claim(s) is (or will be) as follows:
    Claim(s) allowed:_____.
    Claim(s) objected to:_____.
    Claim(s) rejected:1-30.
    Claim(s) withdrawn from consideration:_____.

/H.Q.N/ Examiner, Art Unit 3791	/RENE T TOWA/ Primary Examiner, Art Unit 3791

Continuation of 3. NOTE: The amendment to the independent claims to recite a vacuum is applied from the outlet port to the chamber requires new search and consideration as narrowing the scope of the claims in a manner not previously claimed.

katz Presenti & CO

23 January 2025

PILLSBURY WINTHROP SHAW PITTMAN, LLP
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By Email Only:
james.conley@pillsburylaw.com
benjamin.hudson@pillsburylaw.com
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the attention of Jim Conley

P.K. 13 - Notice of Acceptance of:

IL Patent Application No.: 302893
(a divisional of IL 267684)
Title: BLOOD SAMPLE OPTIMIZATION DEVICE
Filing Date: 13 May 2023
App. date: 27 December 2017
IL NP of PCT Patent Application No.: PCT/US2017/068569
Applicant(s): KURIN, INC.

Dear Jim:

1

We are pleased to report that the above identified Israel Patent Application has been accepted by the Israel Patent Office (ILPO), which issued the herein attached Notice before allowance dated **23 January 2025**.

The Applicant is now required to pay the Allowance Fee, by the due date of **23 April 2025**.

After the payment of the allowance fee the application shall be published for 3rd party opposition for a period of 3 months, after which if no opposition is filed the Certificate of patent will be issued.

This notice before allowance is based on the following documents:

Drawings dated 13 May 2023
Claims dated 15 May 2024
Description dated 20 August 2023

The examiner has advised that the applicant must inform the ILPO should any opposition procedure or requests to cancel the parallel AU patent are filed before and up to the date of Grant of this application

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Attached for your kind attention are:

- The allowed Description
- The allowed Claims
- The allowed Drawings

Please review the attached documents, namely the allowed description, claims and drawings before authorizing us to pay the allowance fee. Of course, we will review the documents as well.

We additionally remind you of the continuing responsibility of the Applicant to update the ILPO with information of cited art and/or opposition procedure and/or cancellation procedures in corresponding Applications under Section 18 of the Israel Patent Law - until the payment of the allowance fee. When the Applicant becomes aware of publications or other citations that may be relevant information/material to the examination of this application, such information/material must be forwarded to us for reporting to the ILPO. Failure to disclose such information to the ILPO may result in cancellation of an issued IL patent.

2

Publications filed after this notice will not be reviewed but will be on record. Should the applicant wish to receive continued examination based on new publications, a request to file for re-examination must be filed along with an update of the list of publications.

Divisional Applications

Please be advised that pursuant to Art. 24(a) of the Act, divisional applications may be filed after the payment of the Allowance fee but before publication. We highly recommend filng divisional applications before the payment of the allowance fee.

We look forward to receiving your instructions in due course.

Yours sincerely,

Ronen Presenti
Manager

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Submitted herewith

> The original notice in Hebrew.

> The publication documents, namely, Description, Claims, Drawings.

> Our invoice number 3641.

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פ.ק 13

תאריך: כ"ג טבת תשפ"ה
23/01/2025
מספרכם: 1000-018-02

לכבוד
כץ, פרזנטי ושות'
מנחם בגין 11 מגדל רוגובין תדהר, קומה 31 רמת גן 5268104,
מיקוד

א. ג. נ.,

הנדון: **<u>הודעה לפני קיבול בקשת פטנט מספר 302893</u>**

סימוכין: מכתבכם מיום 15/05/2024, 15/01/2025

לתשומת לבכם: מקום בו הנכם מופנים ל"חוק", הכוונה היא לחוק הפטנטים, התשכ"ז – 1967. מקום בו הנכם מופנים ל"תקנות", הכוונה היא לתקנות הפטנטים (נוהלי הרשות, סדרי דין, מסמכים ואגרות), התשכ"ח – 1968. בהתאם לחוזר רשם 035/2017 – פטנטים **לא ניתן להשהות פרסום בקשות פטנט לפי סעיף 26 לחוק.**

<u>הודעה זו מבוססת על המסמכים הבאים:</u>

שרטוטים מתאריך: 13/05/2023
פרטי הבקשה מתאריך: 20/08/2023
תביעות מתאריך: 15/05/2024

<u>מענה לטיעוני המבקש</u>

מערכת התביעות המוצעת מתקבלת.

<u>הריני להודיעכם כי בחינת הבקשה הנ"ל הושלמה לפי הוראות סעיף 48ו(ג)(1) ו- (2) לחוק.</u>

<u>תשלום אגרת קיבול</u>

1. הבקשה תתקבל בהתאם לסעיף 26 לחוק לאחר תשלום אגרת הקיבול.
2. יש לשלם את האגרה תוך 3 חודשים מתאריך הודעה זו.
3. סכום האגרה נכון למועד הודעה זו הינו 820.00 ש"ח. הסכום כפוף לעדכונו על פי המדד בהתאם לתקנה 6א.

<u>הפניה בפירוט למסמך הבכורה</u>

לפי הוראות **סעיף 20 לחוזר הרשם 034/2017-פטנטים** במידה ופירוט הבקשה מכיל הפניה למסמך בכורה באמצעות הביטוי "incorporated by reference" ובמידה וחלפו 14 חודשים ממועד דין הקדימה (אם נדרש) לא ניתן עוד להוסיף דבר מתוך מסמך הבכורה והמבקש לא יכול להסתמך על האמור במסמך הבכורה, לצורך סעיפים 12 ו-13 לחוק.

<u>עדכון רשימות האסמכתאות והפרסומים לפי סעיף 18א לחוק</u>

לתשומת לבכם, בהתאם להוראות פרק ג' בחוזר רשם 035/2017-פטנטים חובת המבקש לעדכן את הרשות בכל שינוי שחל ברשימת הפרסומים בהתאם לסעיף 18 לחוק נמשכת עד קיבול הבקשה.

באם ברצונכם להחזיר את הבקשה לבחינה בעקבות שינוי ברשימת הפרסומים שהתרחש לאחר תשובתכם להודעת הליקויים האחרונה, עליכם להגיש בקשה לבחינה חוזרת בה עליכם לציין מהו השינוי ברשימת הפרסומים ומתי נודע על שינוי זה.

בקשה לבחינה חוזרת יש להגיש באמצעות פניה ל-"בקשה לתיקונים לאחר פ.ק. 13".

<u>הגשת בקשות חלוקה</u>

בהתאם להוראות סעיף 24(א) לחוק זכאי המבקש כל עוד לא קובלה הבקשה לדרוש את חלוקת הבקשה לבקשות אחדות. לפיכך, באם ברצונכם להגיש בקשות חלוקה מבקשה זו עליכם לעשות זאת בטרם מועד הקיבול. לא נוכל להכיר בבקשות שיוגשו לאחר מועד הקיבול של הבקשה הנוכחית כבקשות חלוקה לעניין סעיף 24(ג) לחוק.

<u>בדיקה פורמלית</u>

להודעה הנוכחית מצורף העתק פירוט הבקשה המעודכן - אם נפלו טעויות נא להודיע עליהן לרשות לפני מועד תשלום אגרת הקיבול.

לצורך אימות פרטי הפרסום בהתאם לסעיף 26 לחוק ניתן לעיין בנסח הבקשה באתר הרשות בקישור הבא:

https://israelpatents.justice.gov.il/#/en/patent-extract/302893

ניתן לעיין בפרטי תיק הבקשה באתר הרשות בקישור:

https://israelpatents.justice.gov.il/#/en/patent-file/details/302893

בכבוד רב

אלברט אקרמן
בוחן פטנטים בכיר
טלפון: 073-3927233
דואר אלקטרוני: albertak@justice.gov.il
ראש צוות: מוריה שלמה לוי

Claims:

1. A device comprising:

an inlet port for receiving a blood sample;

an outlet port;

a chamber connected with the inlet port and the outlet port, and configured to collect a first portion of the blood sample, the chamber including a material that is air permeable and blood impermeable;

a sampling channel connected with the inlet port and configured to convey a subsequent portion of the blood sample to the outlet port ; and

a housing that houses and defines the inlet port, the outlet port, the chamber, and the sampling channel.

2. The device in accordance with claim 1, wherein the device is configured such that, when a drawing force is applied at the outlet port, blood is drawn into the chamber to contact the air permeable blood barrier.

3. The device in accordance with claim 2, wherein the device is further configured such that an initial aliquot of blood will contact the material and back up into the chamber.

4. The device in accordance with claim 1, wherein the material is located at a distal end of the chamber.

5. The device in accordance with claim 1, wherein the material is a hydrophobic plug.

6. The device in accordance with claim 1, wherein the material is a hydrophobic membrane.

7. The device in accordance with claim 1, wherein the material is a hydrophilic membrane.

8. The device in accordance with claim 1, wherein the sampling channel further comprises a valve configured to close off the sampling channel.

9. The device in accordance with claim 8, wherein the valve is a clip.

10. The device in accordance with claim 1, further comprising a junction connecting the inlet port and the sampling channel and the chamber.

11. The device in accordance with claim 10, wherein the junction is configured to convey the subsequent portion of the blood sample to the outlet port .

12. The device in accordance with claim 1, wherein the chamber has a larger cross-sectional area than the sampling channel.

13. The device in accordance with claim 1, wherein the housing comprises a bottom member mated with a top member, each of the bottom member and the top member defining a part of each of the inlet port, the outlet port, the chamber, and the sampling channel.

14. The device in accordance with claim 1, further comprising a patient needle and a sample collection device.

15. The device in accordance with claim 1, wherein the device is configured with a moving part that is movable from a first position to a second position to allow blood to go through the sampling channel.

16. The device in accordance with claim 15, the moving part further configured to move from the first position to the second position after the first portion of blood flows into the chamber.

17. The device in accordance with claim 15, wherein the moving part is an inner chamber housing.

18. The device in accordance with claim 15, the device further comprising a locking mechanism configured to maintain the moving part in the first position until the chamber is filled, providing force to overcome the locking mechanism to enable movement of the moving part to the second position.

19. The device in accordance with claim 1, wherein the device is configured such that, when a drawing force is applied at the outlet port, blood is drawn into the chamber to contact the material that is air permeable and blood impermeable and causes an initial aliquot of blood to back up into the chamber.

BLOOD SAMPLE OPTIMIZATION DEVICE

ABSTRACT

Blood sample optimization systems and methods are described that reduce or eliminate contaminates in collected blood samples, which in turn reduces or eliminates false positive readings in blood cultures or other testing of collected blood samples. A blood sample optimization system can include a blood sequestration device located between a patient needle and a sample needle. The blood sequestration device can include a sequestration chamber for sequestering an initial, potentially contaminated aliquot of blood, and may further include a sampling channel that bypasses the sequestration chamber to convey likely uncontaminated blood between the patient needle and the sample needle after the initial aliquot of blood is sequestered in the sequestration chamber.

BACKGROUND

[0001] Bacteraemia is the presence of microorganisms in the blood. Sepsis, on the other hand, is bacteraemia in the presence of clinical symptoms and signs such as fever, tachycardia, tachypnea and hypotension. Bacteraemia and sepsis are associated with a high mortality and an increased incidence and duration of hospital stay and associated costs. Many bacteraemias, sepsis, fungaemias and other pathogens actually occur within a hospital or other healthcare settings with catheters and venipunctures being a source of contamination as potential carriers of these pathogens.

[0002] Blood cultures are the standard test used to detect microbial pathogens related to bacteraemia and sepsis in a patient's blood. The term blood culture refers to a single venipuncture, either from a peripheral site or central or arterial line, with the blood inoculated into one or more blood culture bottles or containers. One bottle is considered a blood culture where two or more are considered a set. Multiple sets may be obtained from multiple venipunctures and are associated with different sites on the patient.

[0003] These methods allow for microbial identification and susceptibility testing to be performed, which is a critical component to managing sepsis, however the lack of

rapid results and decreased sensitivity for fastidious pathogens has led to the development of improved systems and adjunctive molecular or proteomic testing.

[0004] Collection of blood samples for conducting blood cultures is a critical component of modern patient care and can either positively affect the patient outcome by providing an accurate diagnosis, or can adversely affect the outcome by prolonging unnecessary antimicrobial therapy, the length of hospital stays, and increasing costs.

[0005] One outcome of collection of blood cultures is contamination. Blood culture contamination can lead to a false positive culture result and/or significant increase in healthcare related costs. Sources of blood culture contamination include improper skin antisepsis, improper collection tube disinfection, and contamination of the initial blood draw which may then skew results.

[0006] Blood culture collection kits generally consist of a "butterfly" set, infusion set, or other type of venipuncture device as offered by companies like BD, Smiths, B. Braun and others, and aerobic and anaerobic blood culture bottles. Various different bottles are also available depending on the test requirements. These bottles are specifically designed to optimize recovery of both aerobic and anaerobic organisms. In conventional kits, a bottle used is known generally as a "Vacutainer," which is a blood collection tube formed of a sterile glass or plastic tube with a closure that is evacuated to create a vacuum inside the tube to facilitate the draw of a predetermined volume of liquid such as blood.

[0007] False positive blood cultures are typically a result of poor sampling techniques. They cause the use of antibiotics when not needed, increasing hospital costs and patient anxiety. Blood cultures are drawn from a needlestick into the skin, and then a Vacutainer is attached to capture a sample of blood. Contamination may occur from improper or incomplete disinfection of the skin area in and around the puncture site. It may also occur from the coring of the skin by the needle during insertion, with the cored skin cells and any associated contamination being pulled into the sample.

[0008] Blood flow through a hypodermic needle is laminar, and as such, a velocity gradient can be developed over the flow tube as a pressure drop is applied to the hypodermic needle. Either forceful aspiration of blood, or using a very small hypodermic

needle, can cause lysis and a release of potassium from the red blood cells, thereby rendering the blood samples abnormal.

[0009] In other instances, some patients have delicate veins that can collapse under a pressure drop or vacuum, particularly as applied by a syringe's plunger that is drawn too quickly for the patient's condition. Since such condition is impossible to know beforehand, such vein collapses are a risk and very difficult to control.

[0010] Various strategies have been implemented to decrease blood culture contamination rates, e.g. training staff with regard to aseptic collection technique, feedback with regard to contamination rates and implementation of blood culture collection kits. Although skin antisepsis can reduce the burden of contamination, 20% or more of skin organisms are located deep within the dermis and are unaffected by antisepsis. Changing needles before bottle inoculation is not advisable as it increases the risk to acquire needle stick injuries without decreasing contamination rates.

[0011] Some conventional systems and techniques for reducing blood culture contamination include discarding the initial aliquot of blood taken from central venous catheters, venipunctures, and other vascular access systems. However, these systems require the user to mechanically manipulate an intravascular device, or require a complex series of steps that are difficult to ensure being followed.

SUMMARY

[0012] This document presents systems and methods for reducing blood culture contamination, lysing of cells, and vein collapse. In some implementations, a system and method can eliminate user variability in disinfection, and also eliminate the risk of skin cells getting into the blood culture sample. The systems and methods disclosed herein do not require a change in existing clinical processes, other than to potentially indicate when a vacutainer or other blood collection device (i.e., syringe) should be attached for drawing contaminant-free blood samples.

[0013] In some implementations of the systems and methods disclosed herein the withdrawal of blood is accomplished passively by use of the patient's own blood pressure, thereby reducing the risk of vein collapse and eliminating any additional user steps over current practice. The systems and methods can be applied to accommodate

short-path direct stick or butterfly venipuncture systems. They can also be used with samples drawn through a catheter.

[0014] In one aspect, a blood sequestration device is presented. The blood sequestration device includes an inlet port and an outlet port. The blood sequestration device further includes a sequestration chamber connected with the inlet port, the sequestration chamber having a vent comprising an air permeable blood barrier. The blood sequestration device further includes a sampling channel having a proximal end connected with the inlet port and a distal end connected with the outlet port.

[0015] In another aspect, a blood sequestration device connected with a blood sampling pathway is described. The blood sampling pathway has a patient needle and a sample collection device. The blood sequestration device includes an inlet port connected with the patient needle, and a sequestration chamber connected with the inlet port, the sequestration chamber having a vent comprising an air permeable blood barrier. The blood sequestration device further includes a sampling channel having a proximal end connected with the inlet port, and an outlet port connected with a distal end of the sampling channel and with the sample collection device.

[0016] In yet another aspect, a blood sequestration device connected with a blood sampling system is described. The blood sampling system includes a patient needle for accessing a blood sample from a patient, and a sample needle that is sealed and adapted for receiving an evacuated blood collection tube. The blood sequestration device includes an inlet port connected with the patient needle to receive the blood sample from the patient. The blood sequestration device further includes a sequestration chamber connected with the inlet port and having a vent comprising an air permeable blood barrier, the sequestration chamber for receiving and sequestering a first portion of the blood sample prior to the sample needle being unsealed by the evacuated blood collection tube. The blood sequestration device further includes a sampling channel having a proximal end connected with the inlet port, the sampling channel for conveying a subsequent portion of the blood sample once the sample needle is unsealed by the evacuated blood collection tube. The blood sequestration device further includes an outlet port connected with a distal end of the sampling channel for conveying the subsequent portion of the blood sample to the sample needle.

[0017] In yet another aspect, a blood sample optimization system is disclosed and described. The blood sample optimization system includes a blood sampling system for accessing and acquiring one or more samples of a patient's blood, and a blood sequestration device for receiving and sequestering a first portion of the one or more samples of the patient's blood which might be contaminated by a venipuncture process and which could result in a false positive identification of a pathogen in the patient's blood.

[0018] The blood sampling system includes a patient needle configured for a venipuncture of a patient to access a sample of blood of a patient, a blood sampling pathway connected with the patient needle for conveying the sample of blood, and a sample needle configured for receiving an evacuated blood collection container to collect and contain a subsequent portion of the sample of blood.

[0019] In yet another aspect, a blood sequestration device is disclosed and described. In some implementations, the blood sequestration device can include an inlet port, an outlet port connected with the inlet port, and a sequestration chamber connected with the inlet port. The sequestration chamber can have a vent comprising an air permeable blood barrier.

[0020] The blood sequestration device, in one aspect can include an inlet port, an outlet port, a sequestration chamber connected with the inlet port via a junction, the sequestration chamber having a vent that includes an air permeable blood barrier, the vent being defined by an outer wall that at least partially circumscribes the air permeable blood barrier and includes one or more air vents, the vent further includes a cap that at least partially covers the wall and a one-way seal abutting the air permeable blood barrier that inhibits air from entering the sequestration chamber, and a sampling channel having a proximal end connected with the inlet port via the junction, and a distal end connected with the outlet port. In certain related aspects, the sequestration chamber, the sampling channel and the junction are sized and configured such that a first portion of blood flows into the sequestration chamber toward the air permeable blood barrier for sequestration therein, and a second portion of blood bypasses the sequestration chamber and the first portion of blood sequestered therein and is directed into the sampling channel toward the outlet port.

[0021] In another aspect, the sampling channel and the junction is sized and configured such that a first portion of blood flows into and fills the sequestration chamber to displace air therein through the vent, and such that a second portion of blood bypasses the sequestration chamber and the first portion of blood sequestered therein and is directed into the sampling channel toward the outlet port.

[0022] The blood sequestration and sampling system sequestration device, in certain aspects can include a blood sampling pathway having a patient needle on a proximal end and a sample collection device on a distal end; and a blood sequestration device attached on the blood sampling pathway between the proximal end and distal end of the blood sampling pathway. The blood sequestration device in one aspect can include an inlet port coupled with the blood sampling pathway toward the patient needle, an outlet port coupled with the blood sampling pathway toward the sample collection device, a sequestration chamber connected with the inlet port via a junction, which chamber has a vent that includes an air permeable blood barrier, the vent being defined by an outer wall that at least partially circumscribes the air permeable blood barrier and includes one or more air vents, the vent further including a cap that at least partially covers the wall and a one-way seal abutting the air permeable blood barrier that inhibits air from entering the sequestration chamber; and a sampling channel having a proximal end connected with the inlet port via the junction, and a distal end connected with the outlet port. In a certain related aspect, the sequestration chamber, the sampling channel and the junction can be sized and configured such that a first portion of blood flows into the sequestration chamber toward the air permeable blood barrier for sequestration therein, and a second portion of blood bypasses the sequestration chamber and the first portion of blood sequestered therein and is directed into the sampling channel toward the outlet port.

[0023] The blood sequestration device is connected along the blood sampling pathway between the patient needle and the sample needle, and includes an inlet port for receiving the sample of blood. The blood sequestration device further includes a sequestration chamber connected with the inlet port for receiving a first amount of the sample of blood, the sequestration chamber having a vent comprising an air permeable blood barrier for sequestering at least a first portion of the first amount of the sample of blood. The blood sequestration device may further include a sampling channel having a proximal end connected with the inlet port, the sampling channel conveying a subsequent amount of the sample of blood to the evacuated blood collection container upon the

sequestration chamber sequestering at least the first portion of the first amount of the sample of blood. The blood sequestration device further includes an outlet port connected with a distal end of the sampling channel, the outlet port for outputting the subsequent amount of the sample of blood.

[0024] The details of one or more embodiments are set forth in the accompanying drawings and the description below. Other features and advantages will be apparent from the description and drawings, and from the claims.

BRIEF DESCRIPTION OF THE DRAWINGS

[0025] These and other aspects will now be described in detail with reference to the following drawings.

[0026] FIG. 1 illustrates a blood sample optimization system.

[0027] FIG. 2 illustrates a blood sample optimization system in accordance with an alternative implementation.

[0028] FIG. 3 illustrates a blood sample optimization system in accordance with another alternative implementation.

[0029] FIG. 4 illustrates a blood sample optimization system in accordance with another alternative implementation.

[0030] FIG. 5 illustrates a blood sample optimization system in accordance with another alternative implementation.

[0031] FIG. 6 illustrates a blood sample optimization system in accordance with an alternative implementation.

[0032] FIG. 7 is a flowchart of a method for optimizing a quality of a blood culture.

[0033] FIGS. 8A – 8E illustrate a blood sequestration system for non-contaminated blood sampling, in accordance with some implementations.

[0034] FIG. 9 illustrates a pathway splitter for use in a blood sequestrations system.

[0035] FIGS. 10A – 10D illustrate a blood sequestration system for non-contaminated blood sampling, in accordance with alternative implementations.

[0036] FIGS. 11A – 11E illustrate a blood sequestration system for non-contaminated blood sampling, in accordance with other alternative implementations.

[0037] FIGS. 12A-12D illustrate a blood sample optimization system including a blood sequestration device in accordance with yet other alternative implementations.

[0038] FIGS. 13A-13D illustrate a blood sample optimization system 1300 in accordance with yet another alternative implementations.

[0039] FIGS. 14A-14E illustrate yet another implementation of a blood sampling system to sequester contaminates of an initial aliquot or sample to reduce false positives in blood cultures or tests performed on a patient's blood sample.

[0040] FIGS. 15A-15G illustrate a blood sequestration device and method of using the same, in accordance with yet another implementation.

[0041] FIGS. 16A-16D illustrate a blood sequestration device in accordance with yet another implementation.

[0042] FIGS. 17A – 17E illustrate a bottom member of a housing for a blood sequestration device.

[0043] FIGS. 18A – 18F illustrate a top member of a housing for a blood sequestration device.

[0044] FIGS. 19A and 19B illustrate a blood sequestration device having a top member mated with a bottom member.

[0045] FIG. 20 shows a blood sample optimization system including a blood sequestration device.

[0046] FIG. 21 illustrates a non-vented blood sequestration device using a wicking material chamber.

[0047] FIGS. 22A and 22B illustrate a material makeup of a filter for sequestering blood in a sequestration chamber of a blood sequestration device.

[0048] FIGS. 23A – 23E illustrate another implementation of a blood sequestration device that uses a vacuum force from a blood collection device.

[0049] FIGS. 24A – 24D illustrate another implementation of a blood optimization system and blood sequestration device.

[0050] FIGS. 25A – 25D illustrate another implementation of a blood optimization system and blood sequestration device.

[0051] FIGS. 26A – 26E illustrate another implementation of a blood optimization system and blood sequestration device.

[0052] FIGS. 27A – 27D illustrate another implementation of a blood optimization system and blood sequestration device.

[0053] FIGS. 28A – 28F illustrate another implementation of a blood optimization system and blood sequestration device.

[0054] FIGS. 29A – 29C illustrate another implementation of a blood optimization system and blood sequestration device.

[0055] FIGS. 30A – 30G illustrate another implementation of a blood optimization system and blood sequestration device.

[0056] Like reference symbols in the various drawings indicate like elements.

DETAILED DESCRIPTION

[0057] This document describes blood sample optimization systems and methods for reducing or eliminating contaminates in collected blood samples, which in turn reduces or eliminates false positive readings in blood cultures or other testing of collected blood samples. In some implementations, a blood sample optimization system includes a patient needle for vascular access to a patient's bloodstream, a sample needle for providing a blood sample to a blood collection container, such as an evacuated blood collection container or tube like a Vacutainer™ or the like, or other sampling device, and

a blood sequestration device located between the patient needle and the sample needle. The blood sequestration device includes a sequestration chamber for sequestering an initial, potentially contaminated aliquot of blood, and may further include a sampling channel that bypasses the sequestration chamber to convey likely uncontaminated blood between the patient needle and the sample needle after the initial aliquot of blood is sequestered in the sequestration chamber.

[0058] FIG. 1 illustrates a blood sample optimization system in accordance with some implementations. The system includes a patient needle 1 to puncture the skin of a patient to access the patient's vein and blood therein. The system further includes a sample needle (i.e., a resealably closed needle for use with Vacutainers™ or the like) 5, which may be contained within and initially sealed by a resealable boot 10, a Luer activated valve, or another collection interface or device. The resealable boot 10 can be pushed aside or around the sample needle 5 by application of a Vacutainer™ bottle (not shown) for drawing the patient's blood. The system can further include a low volume chamber 30 that leads to the sample needle 5, but also includes an orifice or one or more channels 45 that lead to a sequestration chamber 55 formed by a housing 50.

[0059] The sequestration chamber 55 is a chamber, channel, pathway, lock, or other structure for receiving and holding a first aliquot of the patient's blood, which may be in a predetermined or measured amount, depending on a volume of the sequestration chamber 55. The first draw of blood typically contains or is more susceptible to containing organisms that cause bacteraemia and sepsis or other pathogens than subsequent blood draws. The sequestration chamber 55 can be a vessel encased in a solid housing, formed in or defined by the housing itself, or can be implemented as tubing or a lumen. The sequestration chamber 55, regardless how formed and implemented, may have a predetermined volume. In some implementations, the predetermined volume may be based on a volume of the patient needle, i.e. ranging from less than the volume of the patient needle to any volume up to or greater than 20 times or more of the volume of the patient needle. The predetermined volume of the sequestration chamber 55 may also be established to economize or minimize an amount of blood to be sequestered and disposed of.

[0060] The sequestration chamber 55 can be formed, contained or housed in a chamber housing 50, and can be made of plastic, rubber, steel, aluminum or other suitable

material. For example, the sequestration chamber 55 could be formed of flexible tubing or other elastomeric materials. The sequestration chamber 55 further includes an air permeable blood barrier 20 that allows air to exit the sequestration chamber 55. As used herein the term "air permeable blood barrier" means an air permeable but substantially blood impermeable substance, material, or structure. Examples may include hydrophobic membranes and coatings, a hydrophilic membrane or coating combined with a hydrophobic membrane or coating, mesh, a filter, a mechanical valve, antimicrobial material, or any other means of allowing air to be displaced from the sequestration chamber 55 as it is filled with blood. In various exemplary embodiments, an air permeable blood barrier may be formed by one or more materials that allow air to pass through until contacted by a liquid, such material then becomes completely or partially sealed to prevent or inhibit the passage of air and/or liquid. In other words, prior to contact with liquid, the material forms a barrier that is air permeable. After contact with a liquid, the material substantially or completely prevents the further passage of air and/or liquid.

[0061] The orifice or channel 45 can be any desired length, cross-sectional shape or size, and/or can be formed to depart from the low volume chamber 30 at any desired angle or orientation. The orifice or channel 45 may also include a one-way flap or valve 60 that maintains an initial aliquot of blood sample within the sequestration chamber 55. In some specific implementations, the orifice or channel 45 can include a "duck bill" or flapper valve 60, or the like, for one-way flow of blood from low volume chamber 30 to the sequestration chamber 55. The air permeable blood barrier 20 can also be constructed of a material that allows air to exit but then seals upon contact with blood, thereby not allowing external air to enter sequestration chamber 55. This sealing would eliminate the need for a valve.

[0062] Valve 60 can be any type of valve or closing mechanism. Chamber 30 is designed to hold virtually no residual blood, and can be designed to be adapted to hold or allow pass-through of a particular volume or rate of blood into sequestration chamber 55. Likewise, sequestration chamber 55 may also include any type of coating, such as an anti-microbial coating, or a coating that aids identification and/or diagnosis of components of the first, sequestered blood draw.

[0063] Housing 50 and 40 can be formed of any suitable material, including plastic, such as acrylonitrile butadiene styrene (ABS) or other thermoplastic or polymeric material, rubber, steel, or aluminum. The air permeable blood barrier 20 can include a color-providing substance, or other signaling mechanism, that is activated upon contact with blood from the initial blood draw, or when air displacement is stopped, or any combination of events with blood in the sequestration chamber 55. The air permeable barrier may also include an outer layer such as a hydrophobic membrane or cover that inhibits or prevents the inadvertent or premature sealing of the filter by an external fluid source, splash etc. Sequestration chamber 55 can also be translucent or clear to enable a user to visually confirm the chamber is filled.

[0064] FIG. 2 illustrates a blood sample optimization system in accordance with some alternative implementations. In the implementation shown in FIG. 2, a sequestration chamber 55, or waste chamber, surrounds the patient needle 1, with an open-ended cuff or housing connected with the waste chamber and encircling the sample needle housing base and housing. The patient needle 1 and sample needle 5 are connected together by a boot 56, which forms a continuous blood draw channel therethrough. The boot 56 includes a single orifice or channel leading from the blood draw channel into sequestration chamber 55. The device can include more than one single orifice or channel, in other implementations. Each orifice or channel can include a one-way valve, and can be sized and adapted for predetermined amount of blood flow.

[0065] The sequestration chamber 55 includes an air permeable blood barrier. The filter can further include a sensor or indicator to sense and/or indicate, respectively, when a predetermined volume of blood has been collected in the sequestration chamber 55. That indication will alert a user to attach an evacuated blood collection tube or bottle, such as a Vacutainer™ to the sample needle 5. The housing for the sequestration chamber 55 can be any size or shape, and can include any type of material to define an interior space or volume therein. The interior space is initially filled only with air, but can also be coated with an agent or substance, such as a decontaminate, solidifying agent, or the like. Once evacuated blood collection tube is attached to the sample needle 5, blood will flow automatically into the patient needle 1, through the blood draw channel and sample needle 5, and into the bottle. The sample needle 5 is covered by a resealable boot, coating or membrane that seals the sample needle when a blood collection bottle is not attached thereon or thereto.

[0066] FIG. 3 illustrates a blood sample optimization system in accordance with some alternative implementations. In the implementation shown, a sample needle 5 is surrounded by a resealable boot or membrane, and is further connected with a patient needle 1. A blood flow channel is formed through the sample needle and the patient needle. The connection between the sample needle and patient needle includes a "T" or "Y" connector 102, which includes a channel, port or aperture leading out from the main blood flow channel to a sequestration chamber 104.

[0067] The T or Y connector 102 may include a flap or one-way valve, and have an opening that is sized and adapted for a predetermined rate of flow of blood. The sequestration chamber 104 can be formed from tubing, or be formed by a solid housing, and is initially filled with air. The sequestration chamber 104 will receive blood that flows out of a patient automatically, i.e. under pressure from the patient's own blood pressure. The sequestration chamber 104 includes an air permeable blood barrier 106, preferably at the distal end of tubing that forms the sequestration chamber 104, and which is connected at the proximal end to the T or Y connector 102. The T or Y connector 102 can branch off at any desired angle for most efficient blood flow, and can be formed so as to minimize an interface between the aperture and channel and the main blood flow channel, so as to minimize or eliminate mixing of the initial aliquot of blood with main blood draw samples.

[0068] In some alternative implementations, the sample needle may be affixed to a tubing of any length, as shown in FIG. 4, connecting at its opposite end to the T or Y connector 102. The sequestration chamber 104 can be any shape or volume so long as it will contain a predetermined amount of blood sample in the initial aliquot. The T or Y connector 102 may also include an opening or channel that is parallel to the main blood flow channel. The air permeable blood barrier may further include an indicator 107 or other mechanism to indicate when a predetermined amount of blood has been collected in the sequestration chamber, or when air being expelled reaches a certain threshold, i.e. to zero. The tubing can also include a clip 109 that can be used to pinch off and prevent fluid flow therethrough.

[0069] Once the air permeable blood barrier and primary chamber are sealed the initial aliquot of blood is trapped in the sequestration chamber 104, an evacuated blood collection tube, such as a Vacutainer™ bottle may be attached to the sample needle 5 to

obtain the sample. The blood collection tube can be removed, and the sample needle 5 will be resealed. Any number of follow-on blood collection tubes can then be attached for further blood draws or samples. Upon completion of all blood draws, the system can be discarded, with the initial aliquot of blood remaining trapped in the sequestration chamber 104.

[0070] FIG. 5 illustrates a blood sample optimization system in accordance with some alternative implementations. In the implementation shown, a sample needle 5 is connected with a patient needle by tubing. A "T" or "Y" connector 120 is added along the tubing at any desired location, and includes an aperture, port or channel leading to a sequestration chamber 204, substantially as described above.

[0071] FIG. 6 illustrates a blood sample optimization system in accordance with some alternative implementations, in which a sequestration chamber 304, formed as a primary collection channel, receives an initial aliquot of blood, and is provided adjacent to the blood sampling channel. The sequestration chamber 304 can encircle the blood sampling channel, the patient needle 1, and/or the sample needle 5. The primary collection channel can include a T or Y connector 120, or other type of aperture or channel. The sequestration chamber 304 includes an air permeable blood barrier, which can also include an indicator of being contacted by a fluid such as blood, as described above.

[0072] In some implementations, either the patient needle 1 or the sample needle 5, or both, can be replaced by a Luer lock male or female connector. However, in various implementations, the connector at a sample needle end of the blood sample optimization system is initially sealed to permit the diversion of the initial aliquot of blood to the sequestration chamber, which is pressured at ambient air pressure and includes the air outlet of the air permeable blood barrier. In this way, the system passively and automatically uses a patient's own blood pressure to overcome the ambient air pressure of the sequestration chamber to push out air through the air permeable blood barrier and displace air in the sequestration chamber with blood.

[0073] FIG. 7 is a flowchart of an exemplary method for optimizing the quality of a blood culture. At 702, a clinician places a needle into a patient's vein. At 704, blood then flows into a sequestration chamber, pushing the air in the sequestration chamber out

of the sequestration chamber through an air permeable blood barrier. In some implementations, the volume of the sequestration chamber is less than 0.1 to more than 5 cubic centimeters (cc's), or more. The sequestration chamber is sized and adapted to collect a first portion of a blood sample, which is more prone to contamination than secondary and other subsequent portion of the blood sample or subsequent draws. Since the sequestration chamber has an air-permeable blood barrier through which air can be displaced by blood pushed from the patient's vein, such blood will naturally and automatically flow into the sequestration chamber before it is drawn into or otherwise enters into a Vacutainer or other bottle for receiving and storing a blood sample.

[0074] When the sequestration chamber fills, the blood will gather at or otherwise make contact with the air permeable blood barrier, which will inhibit or prevent blood from passing therethrough. At 706, when the blood comes into contact with the entire internal surface area of the air permeable blood barrier, the air permeable blood barrier is then closed and air no longer flows out or in. At 708, the clinician may be provided an indictor or can see the full chamber, to indicate the evacuated blood collection tube, such as a Vacutainer™ can be attached. The indicator can include visibility into the primary chamber to see whether it is full, the blood barrier changing color, for example, or other indicator. The fill time of the sequestration chamber may be substantially instantaneous, so such indicator, if present, may be only that the sequestration chamber is filled.

[0075] Prior to an evacuated blood collection tube being attached, communication between the needle, sampling channel, and the sequestration chamber is restricted by the sealing of the sequestration chamber blood barrier thereby not permitting air to reenter the system through the sequestration. Sealing the communication path could also be accomplished with a mechanical twist or other movement, a small orifice or tortuous pathway, eliminating the need for a separate valve or mechanical movement or operation by the clinician. At 710, once the evacuated blood collection tube is removed, the self-sealing membrane closes the sample needle, and at 712, additional subsequent evacuated blood collection tubes may be attached. Once samples have been taken, at 714 the device is removed from the patient and discarded.

[0076] FIGS. 8A – 8E illustrate an exemplary blood sample optimization system 800 for non-contaminated blood sampling, in accordance with some implementations. The blood sample optimization system 800 includes an inlet port 802 that can be

connected to tubing, a patient needle (or both), or other vascular or venous access device, and a pathway splitter 804 having a first outlet to a sequestration chamber tubing 806 and a second outlet to sample collection tubing 808. One or both of the sequestration chamber tubing 806 and the sample collection tubing 808 can be formed of tubing. In some implementations, the sequestration chamber tubing 806 is sized so as to contain a particular volume of initial blood sample. The sample collection tubing 808 will receive a blood sample once the sequestration chamber tubing 806 is filled. The sample collection tubing 808 can be connected to a Vacutainer™ base or housing 810, or other blood sample collection device.

[0077] The blood sequestration system 800 further includes a blood sequestration device 812 which, as shown in more detail in FIGS. 8B – 8D, includes a housing 818 that includes a sampling channel 820 defining a pathway for the non-contaminated sample collection tubing 808 or connected at either end to the non-contaminated sample collection tubing 808. The sampling channel 820 can be curved through the housing 818 so as to better affix and stabilize the housing 818 at a location along the non-contaminated sample collection tubing 808.

[0078] The blood sequestration device 812 further includes a sequestration chamber 822 connected with the sequestration chamber tubing 806 or other chamber. The sequestration chamber 822 terminates at an air permeable blood barrier 824. The air permeable blood barrier 824 can also include a coloring agent that turns a different color upon full contact with blood, as an indicator that the regular collection of blood samples (i.e. the non-contaminated blood samples) can be initiated. Other indicators may be used, such as a small light, a sound generation mechanism, or the like. In some implementations, the air permeable blood barrier is positioned at a right angle from the direction of sequestration chamber 822, but can be positioned at any distance or orientation in order to conserve space and materials used for the housing 818. The housing 818 and its contents can be formed of any rigid or semi-rigid material or set of materials.

[0079] FIG. 9 illustrates a pathway splitter 900 for use in a blood sequestrations system, such as those shown in FIGS. 8A – 8E, for example. The pathway splitter 900 includes an inlet port 902, a main line outlet port 904, and a sequestration channel outlet port 906. The inlet port 902 can be connected to main tubing that is in turn connected to a

patient needle system, or directly to a patient needle. The main line outlet port 904 can be connected to main line tubing to a blood sampling system, such as a vacutainer base or housing, or directly to such blood sampling system. The sequestration channel outlet port 906 can be connected to sequestration tubing for receiving and sequestering a first sample of blood, up to a measured amount or predetermined threshold. Alternatively, the sequestration channel outlet port 906 can be connected to a sequestration chamber. The sequestration channel outlet port 906 is preferably 20-70 degrees angled from the main line outlet port 904, which in turn is preferably in-line with the inlet port 902. Once the predetermined amount of initial blood sample is sequestered in the sequestration tubing or chamber, in accordance with mechanisms and techniques described herein, follow-on blood samples will flow into the inlet port 902 and directly out the main line outlet port 904, without impedance.

[0080] FIGS. 10A – 10D illustrate a blood sequestration device 1000 in accordance with alternative implementations. The blood sequestration device 1000 includes an inlet port 1002, a main outlet port 1004, and a sequestration channel port 1006. The inlet port 1002 can be connected to a patient needle or related tubing. The main outlet port 1004 can be connected to a blood sample collection device such as a Vacutainer, associated tubing, or a Luer activated valve, or the like. The sequestration channel port 1006 splits off from the main outlet port 1004 to a sequestration chamber 1008. In some implementations, the sequestration chamber 1008 is formed as a helical channel within a housing or other container 1001.

[0081] The sequestration chamber 1008 is connected at the distal end to an air permeable blood barrier 1010, substantially as described above. Air in the sequestration chamber 1008 is displaced through the air permeable blood barrier 1010 by an initial aliquot of blood that is guided into the sequestration channel port 1006. Once the sequestration chamber 1008 is filled, further blood draws through the main outlet port 1004 can be accomplished, where these samples will be non-contaminated.

[0082] FIGS. 11A – 11E illustrate a blood sequestration device 1100 in accordance with other alternative implementations. The blood sequestration device 1100 includes an inlet port 1102, similar to the inlet ports described above, a main outlet port 1104, and a sequestration channel port 1106 that splits off from the main outlet port 1104 and inlet port 1102. The sequestration channel port is connected to a sequestration

chamber 1108. In the implementation shown in FIGS. 11A – 11E, the blood sequestration device includes a base member 1101 having a channel therein, which functions as the sequestration chamber 1108. The channel can be formed as a tortuous path through the base member 1101, which is in turn shaped and formed to rest on a limb of a patient.

[0083] A portion of the sequestration chamber 1108 can protrude from the base member or near a top surface of the base member, just before exiting to an air permeable blood barrier 1110, to serve as a blood sequestration indicator 1109. The indicator 1109 can be formed of a clear material, or a material that changes color when in contact with blood.

[0084] In some implementations, the blood sequestration device 1100 can include a blood sampling device 1120 such as a normally closed needle, Vacutainer™ shield or other collection device. The blood sampling device 1120 can be manufactured and sold with the blood sequestration device 1100 for efficiency and convenience, so that a first aliquot of blood that may be contaminated by a patient needle insertion process can be sequestered. Thereafter, the blood sampling device 1120 can draw non-contaminated blood samples to reduce the risk of false positive testing and ensure a non-contaminated sample.

[0085] FIGS. 12A-12D illustrate a blood sample optimization system 1200 in accordance with yet other alternative implementations. The system 1200 includes a blood sequestration device 1202 for attaching to a blood sampling device 1204, such as a Vacutainer™ or other collection and sampling device. The blood sequestration device 1202 is configured and arranged to receive, prior to a Vacutainer™ container or vial being attached to a collection needle of the blood sampling device 1204, a first aliquot or amount of blood, and sequester that first aliquot or amount in a sequestration channel of the blood sequestration device 1202.

[0086] In some implementations, the blood sequestration device 1202 can include an inlet port 1212, a main outlet port, and a sequestration channel port. The inlet port 1212 can be connected to a patient needle or related tubing. The main outlet port 1214 can be connected to a normally closed needle or device to enable connection with an evacuated blood collection container or other collection device such as a Vacutainer™,

associated tubing, luer connectors, syringe, a Luer activated valve, or the like. The sequestration channel port splits off from the main outlet port to a sequestration chamber 1218.

[0087] In some implementations, the sequestration chamber 1218 is formed as a channel within the body of a sequestration device 1202. The sequestration chamber 1218 can be a winding channel, such as a U-shaped channel, an S-shaped channel, a helical channel, or any other winding channel. The sequestration device 1202 can include a housing or other containing body, and one or more channels formed therein. As shown in FIGS. 12A and 12B, the sequestration device 1202 includes a main body 1206 and a cap 1208. The main body 1206 is formed with one or more cavities or channels, which are further formed with one or more arms 1210 that extend from the cap 1208, and which abut the cavities or channels in the main body 1206 to form the primary collection port and main outlet port.

[0088] FIGS. 13A-13D illustrate a blood sample optimization system 1300 in accordance with yet other alternative implementations. The system 1300 includes a blood sequestration device 1302 for attaching to a blood sampling device 1304, such as a Vacutainer or other bodily fluid collection and sampling device. The blood sequestration device 1302 is configured and arranged to receive, prior to a Vacutainer container or vial being attached to a collection needle of the blood sampling device 1304, a first aliquot or amount of blood, and to sequester that first aliquot or amount of blood or other bodily fluid in a sequestration channel of the blood sequestration device 1302.

[0089] The blood sequestration device 1302 includes a housing 1301 having an inlet port 1314, a main outlet port 1312, and a sequestration channel port 1316. The inlet port 1314 can be connected to a patient needle or associated tubing. The main outlet port 1312 can be connected to a normally closed needle or device to enable connection with an evacuated blood collection container or other collection device such as a Vacutainer™, associated tubing, luer connectors, syringe, a Luer activated valve, or the like. The sequestration channel port 1316 splits off from the main inlet port 1314 to a sequestration chamber 1318.

[0090] In the implementation shown in FIGS. 13A-D, the sequestration chamber 1318 is formed as a cavity or chamber within housing 1301 or formed by walls that define

housing 1301. The sequestration chamber 1318 can be a winding channel, such as a U-shaped channel, an S-shaped channel, a helical channel, or any other winding channel, that is defined by the cooperation and connection of housing 1301 with cap 1307 which cap 1307 can include a protrusion 1305 that provides one or more walls or directors for the winding channel in the sequestration chamber 1318. The protrusion 1305 from the cap 1307 can be straight or curved, and may have various channels, apertures or grooves embedded therein, and can extend from the cap 1307 any angle or orientation. When the cap 1307 is connected with the housing 1301 to complete the formation of the sequestration chamber 1318, the protrusion 1305 forms at least part of the winding channel to sequester a first aliquot or amount of blood or other bodily fluid in a sequestration channel formed in the sequestration chamber 1318 and by the winding channel.

[0091] The sequestration chamber 1318 includes an air permeable blood barrier 1310, substantially as described above. Air in the sequestration chamber 1318 is displaced through the air permeable blood barrier 1310 by an initial aliquot of blood that is provided into the sequestration chamber 1318 by the blood pressure of the patient. Once the sequestration chamber 1318 is filled and the air in the sequestration chamber 1318 displaced, the blood pressure of the patient will be insufficient to drive or provide further blood into the blood sequestration device 1302, and in particular the outlet port 1312, until a force such as a vacuum or other pressure, such as provided by the blood sample collection device like Vacutainer is provided to draw out a next aliquot or amount of blood or bodily fluid. Further blood draws through the main outlet port 1312 can be accomplished, where these samples will be non-contaminated since any contaminants would be sequestered in the sequestration chamber 1318 with the first aliquot of blood.

[0092] FIGS. 14A-14E illustrate yet another implementation of a blood sampling system 1400 to sequester contaminates of an initial aliquot or sample to reduce false positives in blood cultures or tests performed on a patient's blood sample. The blood sampling system 1400 includes a blood sequestration device 1401 that can be connected between a blood sample collection device 1403 and a patient needle (not shown). The blood sample collection device 1403 can be a Vacutainer or the like. The blood sequestration device 1401 includes an inlet port 1402 that can be connected with a patient needle that is inserted into a patient's vascular system for access to and withdrawing of a

blood sample. The inlet port 1402 may also be connected with tubing or other conduit that is in turn connected with the patient needle.

[0093] The inlet port 1402 defines an opening into the blood sequestration device 1401, which opening can be the same cross sectional dimensions as tubing or other conduit connected with the patient needle or the patient needle itself. For instance, the opening can be circular with a diameter of approximately 0.045 inches, but can have a diameter of between 0.01 inches or less to 0.2 inches or more. The blood sequestration device 1401 further includes an outlet port 1404, which defines an opening out of the blood sequestration device 1401 and to the blood sample collection device 1403. The outlet port 1404 may also be connected with tubing or other conduit that is in turn connected with the blood sequestration device 1403. The outlet port 1404 can further include a connector device such as a threaded cap, a Luer connector (male or female), a non threaded interference or glue joint fitting for attachment of various devices including but not limited to tubing, or the like.

[0094] The blood sequestration device 1401 further includes a sampling channel 1406 between the inlet port 1402 and the outlet port 1404, and which functions as a blood sample pathway once a first aliquot of blood has been sequestered. The sampling channel 1406 can be any sized, shaped or configured channel, or conduit. In some implementations, the sampling channel 1406 has a substantially similar cross sectional area as the opening of the inlet port 1402. In other implementations, the sampling channel 1406 can gradually widen from the inlet port 1402 to the outlet port 1404.

[0095] The blood sequestration device 1401 further includes a sequestration chamber 1408 that is connected to and split off or diverted from the sampling channel 1406 at any point between the inlet port 1402 and the outlet port 1404, but preferably from a proximal end of the sampling channel 1406 near the inlet port 1402. The sequestration chamber 1408 is at first maintained at atmospheric pressure, and includes an air outlet 1412 at or near a distal end of the sequestration chamber 1408 opposite the diversion point from the sampling channel 1406. The air outlet 1412 includes an air permeable blood barrier 1412. As shown in FIG. 14B, the air permeable blood barrier 1412 can be overlaid with a protective cover 1416. The protective cover 1416 can be sized and configured to inhibit a user from touching the air permeable blood barrier 1412 with their finger or other external implement, while still allowing air to exit the air

permeable blood barrier 1412 as the air is displaced from the sequestration chamber 1408 by blood being forced into the sequestration chamber 1408 by a patient's own blood pressure. In addition the protective cover 1416 can be constructed to inhibit or prevent accidental exposure of the air permeable blood barrier to environmental fluids or splashes. This can be accomplished in a variety of mechanical ways including but not limited to the addition of a hydrophobic membrane to the protective cover.

[0096] As shown in FIGS. 14C and 14D, the sampling channel 1406 can be cylindrical or frusto-conical in shape, going from a smaller diameter to a larger diameter, to minimize a potential to lyse red blood cells. Likewise, the sampling channel 1406 is formed with a minimal amount of or no sharp turns or edges, which can also lyse red blood cells. The sampling channel 1406 splits off to the sequestration chamber 1408 near the inlet port 1402 via a diversion pathway 1409. The diversion pathway 1409 can have any cross-sectional shape or size, but is preferably similar to the cross-sectional shape of at least part of the inlet port 1402.

[0097] In some implementations, the sampling channel 1406 and the sequestration chamber 1408 are formed by grooves, channels, locks or other pathways formed in housing 1414. The housing 1414 can be made of plastic, metal or other rigid or semi-rigid material. The housing 1414 can have a bottom member that sealably mates with a top member. One or both of the bottom member and the top member can include the sampling channel 1406 and the sequestration chamber 1408, as well as the diversion pathway 1409, the inlet port 1402, and the outlet port 1404. In some other implementations, one or more of the diversion pathway 1409, the inlet port 1402, and/or the outlet port 1404 can be at least partially formed by a cap member that is connected to either end of the housing 1414. In some implementations, the top member and the bottom member, as well as the cap member(s), can be coupled together by laser welding, heat sealing, gluing, snapping, screwing, bolting, or the like. In other implementations, some or all of the interior surface of the diversion pathway 1409 and/or sequestration chamber 1408 can be coated or loaded with an agent or substance, such as a decontaminate, solidifying agent, or the like. For instance, a solidifying agent can be provided at the diversion pathway 1409 such that when the sequestration chamber 1408 is filled and the initial aliquot of blood backs up to the diversion pathway 1409, that last amount of sequestered blood could solidify, creating a barrier between the sequestration chamber 1408 and the sampling channel 1406.

[0098] FIGS. 15A-15G illustrate a blood sequestration device 1500. The blood sequestration device 1500 can be connected to a normally closed needle or device to enable connection with an evacuated blood collection container or other collection device such as a Vacutainer™, associated tubing, luer connectors, syringe, a Luer activated valve, or the like.

[0099] The blood sequestration device 1500 includes an inlet port 1502 that can be connected with a patient needle that is inserted into a patient's vascular system for access to and withdrawing of a blood sample. The inlet port 1502 may also be connected with tubing or other conduit that is in turn connected with the patient needle. The inlet port 1502 defines an opening into the blood sequestration device 1500, which opening may be the same cross sectional dimensions as tubing or other conduit connected with the patient needle or the patient needle itself. For instance, the opening can be circular with a diameter of approximately 0.045 inches, but can have a diameter of between 0.01 inches or less to 0.2 inches or more.

[00100] The inlet port 1502 can also include a sealing or fluid-tight connector or connection, such as threading or Luer fitting, or the like. In some implementations, tubing or other conduit associated with the patient needle can be integral with the inlet port 1502, such as by co-molding, gluing, laser weld, or thermally bonding the parts together. In this manner, the blood sequestration device 1500 can be fabricated and sold with the patient needle as a single unit, eliminating the need for connecting the patient needle to the blood sequestration device 1500 at the time of blood draw or sampling.

[00101] The blood sequestration device 1500 further includes an outlet port 1504, which defines an opening out of the blood sequestration device 1500 and to the blood sample collection device. The outlet port 1504 may also be connected with tubing or other conduit that is in turn connected with the blood sequestration device, and may also include a sealing or fluid-tight connector or connection, such as threading or Luer fitting, or the like. Accordingly, as discussed above, the blood sequestration device 1500 can be fabricated and sold with the patient needle and/or tubing and the blood sample collection device as a single unit, eliminating the need for connecting the patient needle and the blood sample collection device to the blood sequestration device 1500 at the time of blood draw or sampling.

[00102] The blood sequestration device 1500 further includes a sampling channel 1506 between the inlet port 1502 and the outlet port 1504, and which functions as a blood sample pathway once a first aliquot of blood has been sequestered. The sampling channel 1506 can be any sized, shaped or configured channel or conduit. In some implementations, the sampling channel 1506 has a substantially similar cross sectional area as the opening of the inlet port 1502. In other implementations, the sampling channel 1506 can gradually widen from the inlet port 1502 to the outlet port 1504.

[00103] The blood sequestration device 1500 further includes a sequestration chamber 1508 that is connected to and split off or diverted from the sampling channel 1506 at any point between the inlet port 1502 and the outlet port 1504, but preferably from a proximal end of the sampling channel 1506 near the inlet port 1502. In some implementations, the diversion includes a Y-shaped junction. The sequestration chamber 1508 is preferably maintained at atmospheric pressure, and includes a vent 1510 at or near a distal end of the sequestration chamber 1508. The vent 1510 includes an air permeable blood barrier 1512. FIG. 15C illustrates the blood sequestration device 1500 with the sequestration chamber 1508 filled with a first aliquot or sample of blood from the patient.

[00104] The air permeable blood barrier 1512 can be covered with a protective cover 1516. The protective cover 1516 can be sized and configured to inhibit a user from touching the air permeable blood barrier 1512 with their finger or other external implement, while still allowing air to exit the air permeable blood barrier 1512 as the air is displaced from the sequestration chamber 1508 by blood being forced into the sequestration chamber 1508 by a patient's own blood pressure. The protective cover 1516 can be constructed to inhibit or prevent accidental exposure of the filter to environmental fluids or splashes. This can be accomplished in a variety of mechanical ways including but not limited to the addition of a hydrophobic membrane to the protective cover.

[00105] FIG. 15B is a perspective view of the blood sequestration device 1500 from the outlet port 1504 and top side of a housing 1501 of the blood sequestration device 1500 that includes the vent 1510, and illustrating an initial aliquot of blood filling sequestration chamber 1508 while the sampling channel 1506 is empty, before a sample collection device is activated. FIG. 15G is a perspective view of the blood sequestration

device 1500 from the outlet port 1504 and bottom side of the housing 1501 of the blood sequestration device 1500, and illustrating the initial aliquot of blood filling sequestration chamber 1508 while the sampling channel 1506 is empty, before the sample collection device is activated. FIG. 15C is another perspective view of the blood sequestration device 1500 from the inlet port 1502 and top side of a housing 1501 of the blood sequestration device 1500 that includes the vent 1510, and illustrating blood now being drawn through sampling channel 1506 while the sequestered blood remains substantially in the sequestration chamber 1508.

[00106] FIG. 15D is a cross section of the blood sequestration device 1500 in accordance with some implementations, showing the housing 1501 that defines the sampling channel 1506 and the sequestration chamber 1508. FIGS. 15E and 15F illustrate various form factors of a housing for a blood sequestration device, in accordance with one or more implementations described herein.

[00107] The sequestration chamber 1508 can have a larger cross-sectional area than the sampling channel 1506, and the cross-sectional area and length can be configured for a predetermined or specific volume of blood to be sequestered or locked. The sampling channel 1506 can be sized to be compatible with tubing for either or both of the patient needle tubing or the blood collection device tubing.

[00108] The housing 1501 can be formed of multiple parts or a single, unitary part. In some implementations, and as illustrated in FIG. 15D, the housing 1501 includes a top member 1520 and a bottom member 1522 that are mated together, one or both of which having grooves, channels, locks, conduits or other pathways pre-formed therein, such as by an injection molding process or by etching, cutting, drilling, etc. The top member 1520 can be connected with the bottom member 1522 by any mating or connection mechanism, such as by laser welding, thermal bonding, ultrasonic welding, gluing, using screws, rivets, bolts, or the like, or by other mating mechanisms such as latches, grooves, tongues, pins, flanges, or the like.

[00109] In some implementations, such as shown in FIG. 15D, the top member 1520 can include the grooves, channels, locks, conduits or other pathways, while the bottom member 1522 can include a protrusion 1524 that is sized and adapted to fit into at least one of the grooves, channels, locks or other pathways of the top member 1520. The

protrusion 1524 can provide a surface feature, such as a partial groove or channel, for instance, to complete the formation of either the sampling channel 1506 and/or the sequestration chamber 1508. In some implementations, the protrusion 1524 can be formed with one or more angled sides or surfaces for a tighter fit within the corresponding groove, channel, lock or other pathway. In yet other implementations, both the top member 1520 and the bottom member can include grooves, channels, locks or other pathways, as well as one or more protrusions 1524.

[00110] In some implementations, the sampling channel 1506 and the sequestration chamber 1508 are formed by grooves, channels, locks or other pathways formed in housing 1501. The housing 1501 can be made of any suitable material, including rubber, plastic, metal or other material. The housing 1501 can be formed of a clear or translucent material, or of an opaque or non-translucent material. In other implementations, the housing 1501 can be mostly opaque or non-translucent, while the housing surface directly adjacent to the sampling channel 1506 and/or the sequestration chamber 1508 is clear or translucent, giving a practitioner a visual cue or sign that the sequestration chamber 1508 is first filled to the extent necessary or desired, and/or then a visual cue or sign that the sequestered blood remains sequestered while a clean sample of blood is drawn through the sampling channel 1506. Other visual cues or signs of the sequestration can include, without limitation: the air permeable blood barrier 1512 turning a different color upon contact, saturation, or partial saturation with blood; a color-coded tab or indicator at any point along or adjacent to the sequestration chamber; an audible signal; a vibratory signal; or other signal.

[00111] After a venipuncture by a patient needle of a patient (not shown), which could gather a number of pathogens from the patient's skin, a first amount of the patient's blood with those pathogens will make its way into the inlet port 1502 blood sequestration device 1500 and flow into the sequestration chamber 1508 by following the path of least resistance, as the patient's own blood pressure overcomes the atmospheric pressure in the sequestration chamber 1508 to displace air therein through the air permeable blood barrier 1512. The patient's blood pressure will not be sufficient to overcome the air pressure that builds up in the sealed sampling channel 1506. Eventually, the sequestration chamber 1508, which has a predetermined volume, is filled with blood that displaces air through the air permeable blood barrier 1512. Once the blood hits the air permeable blood barrier, the blood interacts with the air permeable blood barrier 1512 material to completely or

partially seal the vent 1510. A signal or indication may be provided that the practitioner can now utilize the Vacutainer capsule or other blood sample collection device to acquire a next amount of the patient's blood for sampling. The blood in the sequestration chamber 1508 is now effectively sequestered in the sequestration chamber.

[00112] Upon filling the blood sequestration pathway 1508 but prior to use of the Vacutainer or other blood sample collection device, the patient's blood pressure may drive compression of the air in the sampling channel 1506, possibly resulting in a small amount of blood moving past the diversion point to the sequestration chamber 1508 and into the sampling channel 1506, queuing up the uncontaminated blood to be drawn through the sampling channel 1506.

[00113] In some instances, as shown in FIG. 15H, an inlet port 1532 can include a male luer connector for connecting to a removable patient needle, and an outlet port 11534 can include a female luer connector for connecting with a syringe. This implementation of the inlet port and outlet port can be used with any device described herein, for avoiding a propensity of a Vacutainer-type device collapsing a patient's vein. In this implementation, a clinician can use the syringe in a modulated fashion to obtain a blood sample. In operation, the syringe is attached to the outlet port 1004, and the needle is attached to the inlet port 1002. A venipuncture is performed with the needle, and without the clinician pulling on the syringe. An initial aliquot of blood fills a sequestration chamber, and then the syringe can be used to draw a sample of blood through the collection channel, bypassing the sequestered blood in the sequestration chamber.

[00114] FIGS. 16-19 illustrate yet another implementation of a blood sequestration device. FIGS. 16A-16D illustrate a blood sequestration device 1600 that can be connected between a blood sample collection device, such as an evacuated blood collection container like a Vacutainer™ (not shown), and a patient needle (not shown) and/or associated tubing. FIG. 17 illustrates a bottom member of the blood sequestration device, and FIG. 18 illustrates a top member of the blood sequestration device, which top member and bottom member can be mated together to form an inlet port, and outlet port, a sequestration chamber and a sampling channel, as explained more fully below. FIGS. 19A and B show the top member and bottom member mated together. It should be

understood that FIGS. 16-19 illustrate one exemplary manner of constructing a blood sequestration device as described herein, and other forms of construction are possible.

[00115] Referring to FIGS. 16A – D, the blood sequestration device 1600 includes an inlet port 1602 that can be connected with a patient needle that is inserted into a patient's vascular system for access to and withdrawing of a blood sample. The inlet port 1602 may also be connected with tubing or other conduit that is in turn connected with the patient needle. The inlet port 1602 defines an opening into the blood sequestration device 1600, which opening can be the same cross sectional dimensions as tubing or other conduit connected with the patient needle or the patient needle itself. For instance, the opening can be circular with a diameter of approximately 0.045 inches, but can have a diameter of between 0.01 inches or less to 0.2 inches or more.

[00116] The inlet port 1602 can also include a sealing or fluid-tight connector or connection, such as threading or Luer fitting, or the like. In some implementations, tubing or other conduit associated with the patient needle can be integral with the inlet port 1602, such as by co-molding, gluing, laser weld, or thermally bonding the parts together. In this manner, the blood sequestration device 1600 can be fabricated and sold with the patient needle and/or tubing as a single unit, eliminating the need for connecting the patient needle to the blood sequestration device 1600 at the time of blood draw or sampling.

[00117] The blood sequestration device 1600 further includes an outlet port 1604, which defines an opening out of the blood sequestration device 1600 and to the blood sample collection device. The outlet port 1604 may also be connected with tubing or other conduit that is in turn connected with the blood sequestration device, and may also include a sealing or fluid-tight connector or connection, such as threading or Luer fitting, or the like. Accordingly, as discussed above, the blood sequestration device 1600 can be fabricated and sold with the patient needle and/or tubing and the blood sample collection device as a single unit, eliminating the need for connecting the patient needle and the blood sample collection device to the blood sequestration device 1600 at the time of blood draw or sampling.

[00118] The blood sequestration device 1600 further includes a sampling channel 1606 between the inlet port 1602 and the outlet port 1604, and a sequestration chamber

1608 that is connected to and split off or diverted from the sampling channel 1606 at any point between the inlet port 1602 and the outlet port 1604. The sampling channel 1606 functions as a blood sampling pathway once a first aliquot of blood has been sequestered in the sequestration chamber 1608. The sampling channel 1606 can be any sized, shaped or configured channel, or conduit. In some implementations, the sampling channel 1606 has a substantially similar cross sectional area as the opening of the inlet port 1602. In other implementations, the sampling channel 1606 can gradually widen from the inlet port 1602 to the outlet port 1604. The sequestration chamber 1608 may have a larger cross section to form a big reservoir toward the sequestration channel path so that the blood will want to enter the reservoir first versus entering a smaller diameter on the sampling channel 1606, as is shown more fully in FIGS. 17 and 19.

[00119] In some exemplary implementations, the diversion between the sampling channel 1606 and the sequestration chamber 1608 is by diverter junction 1607. Diverter junction 1607 may be a substantially Y-shaped, T-shaped, or U-shaped. In some preferred exemplary implementations, and as shown in FIG. 17A – 17B, the diverter junction 1607 is configured such that the flow out of the inlet port 1602 is preferentially directed toward the sequestration chamber 1608. The sequestration chamber 1608 may also include or form a curve or ramp to direct the initial blood flow toward and into the sequestration chamber 1608.

[00120] The sequestration chamber 1608 is preferably maintained at atmospheric pressure, and includes a vent 1610 at or near a distal end of the sequestration chamber 1608. The vent 1610 may include an air permeable blood barrier 1612 as described above.

[00121] The blood sequestration device 1600 can include a housing 1601 that can be formed of multiple parts or a single, unitary part. In some implementations, and as illustrated in FIGS. 17A – 17E and FIGS. 18A – 18F, the housing 1601 includes a top member 1620 and a bottom member 1622 that are mated together. The blood sequestration device 1600 can also include a gasket or other sealing member (not shown) so that when the top member 1620 is mechanically attached with the bottom member 1622, the interface between the two is sealed by the gasket or sealing member. The FIGS. 17A – 17E illustrate a bottom member 1622 of a housing for a blood sequestration device 1600. The bottom member 1622 can include grooves, channels, locks, conduits or

other pathways pre-formed therein, such as by an injection molding process or by etching, cutting, drilling, etc., to form the sampling channel 1606, the sequestration chamber 1608, and diverter junction 1607.

[00122] The sequestration chamber 1608 may have a larger cross section than the sampling channel 1606 so that the blood will preferentially move into the sequestration chamber first versus entering a smaller diameter on the sampling channel 1606.

[00123] FIGS. 18A – 18F illustrate the top member 1620, which can be connected with the bottom member 1622 by any mating or connection mechanism, such as by laser welding, thermal bonding, gluing, using screws, rivets, bolts, or the like, or by other mating mechanisms such as latches, grooves, tongues, pins, flanges, or the like. The top member 1620 can include some or all of the grooves, channels, locks, conduits or other pathways to form the sampling channel 1606, the sequestration chamber 1608, and the diverter junction 1607. In yet other implementations, both the top member 1620 and the bottom member 1622 can include the grooves, channels, locks or other pathways.

[00124] In some implementations, the sampling channel 1606 and the sequestration chamber 1608 are formed by grooves, channels, locks or other pathways formed in housing 1601. The housing 1601 can be made of rubber, plastic, metal or any other suitable material. The housing 1601 can be formed of a clear or translucent material, or of an opaque or non-translucent material. In other implementations, the housing 1601 can be mostly opaque or non-translucent, while the housing surface directly adjacent to the sampling channel 1606 and/or the sequestration chamber 1608 may be clear or translucent, giving a practitioner a visual cue or sign that the sequestration chamber 1608 is first filled to the extent necessary or desired, and/or then a visual cue or sign that the sequestered blood remains sequestered while a clean sample of blood is drawn through the sampling channel 1606. Other visual cues or signs of the sequestration can include, without limitation: the air permeable blood barrier 1612 turning a different color upon contact, saturation, or partial saturation with blood; a color-coded tab or indicator at any point along or adjacent to the sequestration chamber; an audible signal; a vibratory signal; or other signal.

[00125] As shown in FIGS. 18A – 18F, the air permeable blood barrier 1612 can be covered with, or surrounded by, a protective member 1616. The protective member

1616 can be sized and configured to inhibit a user from touching the air permeable blood barrier 1612 with their finger or other external implement, while still allowing air to exit the air permeable blood barrier 1612 as the air is displaced from the sequestration chamber 1608. In some implementations, the protective member 1616 includes a protrusion that extends up from a top surface of the top member 1620 and around the air permeable blood barrier 1612. The protective member 1616 can be constructed to inhibit or prevent accidental exposure of the filter to environmental fluids or splashes. This can be accomplished in a variety of mechanical ways including but not limited to the addition of a hydrophobic membrane to the protective cover.

[00126] In use, the blood sequestration device 1600 includes a sampling channel 1606 and a sequestration chamber 1608. Both pathways are initially air-filled at atmospheric pressure, but the sampling channel 1606 is directed to an outlet port 1604 that will be initially sealed by a Vacutainer or other such sealed blood sampling device, and the sequestration chamber 1608 terminates at a vent 1610 to atmosphere that includes an air permeable blood barrier 1612.

[00127] After a venipuncture by a patient needle of a patient (not shown), which could gather a number of pathogens from the patient's skin, a first amount of the patient's blood with those pathogens will pass through inlet port 1602 of blood sequestration device 1600. This initial volume of potentially contaminated blood will preferentially flow into the sequestration chamber 1608 by finding the path of least resistance. The patient's own blood pressure overcomes the atmospheric pressure in the vented sequestration chamber 1608 to displace air therein through the air permeable blood barrier 1612, but is not sufficient to overcome the air pressure that builds up in the sealed sampling channel 1606. In various exemplary embodiments, the sequestration chamber 1608 and sampling channel 1606 can be configured such that the force generated by the patient's blood pressure is sufficient to overcome any effect of gravity, regardless of the blood sequestration device's orientation.

[00128] Eventually, the sequestration chamber 1608 fills with blood that displaces air through the air permeable blood barrier 1612. Once the blood contacts the air permeable blood barrier, the blood interacts with the air permeable blood barrier 1612 material to completely or partially seal the vent 1610. A signal or indication may be

provided that the practitioner can now utilize the Vacutainer or other blood sampling device.

[00129] Upon filling the blood sequestration pathway 1608 but prior to use of the Vacutainer or other blood sample collection device, the patient's blood pressure may drive compression of the air in the sampling channel 1606, possibly resulting in a small amount of blood moving past the diversion point into the sampling channel 1606, queuing up the uncontaminated blood to be drawn through the sampling channel 1606.

[00130] FIG. 19A is a side view, and FIG. 19B is a cross-sectional view, of the blood sequestration device 1600, illustrating the top member 1620 mated with the bottom member 1622.

[00131] FIG. 20 shows a blood sample optimization system 2000 that includes a patient needle 2002 for vascular access to a patient's bloodstream, a blood sample collection device 2004 to facilitate the collecting of one or more blood samples, and a conduit 2006 providing a fluid connection between the patient needle 2002 and the blood sample collection device 2004. In some implementations, the blood sample collection device 2004 includes a protective shield that includes a sealed collection needle on which a sealed vacuum-loaded container is placed, which, once pierced by the collection needle, draws in a blood sample under vacuum pressure or force through the conduit 2006 from the patient needle 2002.

[00132] The blood sample optimization system 2000 further includes a blood sequestration device 2008, located at any point on the conduit 2006 between the patient needle 2002 and the blood sample collection device 2004 as described herein.

[00133] FIG. 21 illustrates a non-vented blood sequestration device 2100 using a wicking material chamber. The blood sequestration device 2100 includes a housing 2101 that has a sampling channel 2104 that is at least partially surrounded or abutted by a sequestration chamber 2102 that is filled with a wicking material. An initial aliquot of blood is drawn in from the patient needle into the sampling channel 2104 where it is immediately wicked into the wicking material of the sequestration chamber 2102. The wicking material and/or sequestration chamber 2102 is sized and adapted to receive and hold a predetermined amount of blood, such that follow-on or later blood draws pass by the wicking material and flow straight through the sampling channel 2104 to a sampling

device such as a Vacutainer. The wicking material can include a substance such as a solidifier, a decontaminate, or other additive.

[00134] As described herein, an air permeable blood barrier may be created using a wide variety of different structures and materials. As shown in FIGS. 22A and B, an air permeable blood barrier 2202 of a blood sequestration device 2200 can include a polymer bead matrix 2204, in which at least some beads are treated to make them hydrophilic. The air permeable blood barrier 2202 further includes a self-sealing material 2206, such as carboxymethyl cellulose (CMC) or cellulose gum, or other sealing material. The air permeable blood barrier 2202 can further include voids 2208 that permit air flow before contact or during partial contact with a fluid such as blood. As shown in FIG. 22B, contact with a fluid causes the self-sealing material 2206 to swell and close off the voids 2208, occluding air flow through the voids 2208 and creating a complete or partial seal.

[00135] FIGS. 23A and B illustrate yet another implementation of a blood sequestration device 2300, having an inlet port 2302 to connect with a patient needle, an outlet port 2304 to connect with a blood sample collection device, a sequestration chamber 2306, and a sampling channel 2308 that bypasses the sequestration chamber 2306 once the sequestration chamber is filled to an initial aliquot of potentially contaminated blood to be sequestered. The sequestration chamber 2306 includes a hydrophobic plug 2312 at a distal end of the sequestration chamber 2306 that is farthest from the inlet port 2302. A vacuum or other drawing force applied from the outlet port 2304, such as from a Vacutainer or the like, draws in blood into the inlet port 2302 and directly into the sequestration chamber 2306, where the initial aliquot of blood will contact the hydrophobic plug 2312 and cause the initial aliquot of blood to back up into the sequestration chamber 2306 and be sequestered there. A small amount of blood may make its way into the sampling channel 2308, which is initially closed off by valve 2308. Upon release of the valve 2308, and under further force of the vacuum or other force, follow-on amounts of blood will flow into inlet port 2302, bypass the sequestration chamber 2306, and flow into and through sampling channel 2308 toward the outlet port 2304 and to the collection device.

[00136] The sampling channel 2308 can have any suitable geometry and can be formed of plastic tubing or any other suitable material. Valve 2308 can be a clip or other enclosing device to pinch, shunt, bend or otherwise close off the sampling channel 2308

before the initial aliquot of blood is sequestered in the sequestration chamber 2306. For instance, valve 2308 can also be formed as a flap, door or closable window or barrier within the sampling channel 2308.

[00137] FIGS. 23C – 23E illustrate an alternative implementation of the blood sequestration device 2300', in which a sequestration chamber 2320 branches off from a main collection channel 2322 between an inlet port 2316 to connect with a patient needle and an outlet port 2318 to connect with a blood sample collection device, such as a Vacutainer, a syringe, or the like. The sequestration chamber 2320 includes an air-permeable, blood impermeable blood barrier 2324, such as a hydrophobic plug of material, or a filter formed of one or more layers, for example. A valve 2324 closes off and opens the collection channel 2322, and the device 2300' can be used similarly as described above.

[00138] FIG. 24A – 24D illustrate a blood sample optimization system 2400 that includes a patient needle 2402 for vascular access to a patient's bloodstream, a blood sample collection device 2404 to facilitate the collecting of one or more blood samples for blood testing or blood cultures, and a conduit 2406 providing a fluid connection between the patient needle 2402 and the blood sample collection device 2404. In some implementations, the blood sample collection device 2404 includes a protective shield that includes a sealed collection needle on which a sealed vacuum-loaded container is placed, which, once pierced by the collection needle, draws in a blood sample under vacuum pressure or force through the conduit 2006 from the patient needle 2402.

[00139] The blood sample optimization system 2400 further includes a blood sequestration device 2408, located at any point on the conduit 2406 between the patient needle 2402 and the blood sample collection device 2404. The location of the blood sequestration device 2408 can be based on a length of the conduit between the blood sequestration device 2408 and the patient needle 2402, and the associated volume that length provides.

[00140] The blood sequestration device 2408 includes an inlet port 2412 for being connected to the conduit 2406 toward the patient needle 2402, and an outlet port 2414 for being connected to the conduit 2406 toward the blood sample collection device 2404, and a housing 2416. The housing 2416 can be any shape, although it is shown in FIGS. 24A

– D as being substantially cylindrical, and includes the inlet port 2412 and outlet port 2414, which can be located anywhere on the housing although shown as being located on opposite ends of the housing 2416.

[00141] The blood sequestration device 2408 further includes a blood sequestration chamber 2418 connected with the inlet port 2412. The blood sequestration chamber 2418 is defined by an inner chamber housing 2419 that is movable from a first position to receive and sequester a first aliquot of blood, to a second position to expose one or more apertures 2424 at a proximal end of the inner chamber housing 2419 to allow blood to bypass and/or flow around the inner chamber housing 2419 and through a blood sample channel 2422 defined by the outer surface of the inner chamber housing 2419 and the inner surface of the housing 2416. The blood sequestration chamber 2418 includes an air permeable blood barrier 2420 at a distal end of the blood sequestration chamber 2418.

[00142] In operation, the inner chamber housing 2419 is in the first position toward the inlet port 2412, such that the one or more apertures 2424 are closed, and the blood sequestration chamber 2418 is in a direct path from the patient needle. Upon venipuncture of a patient, and drawing of blood by way of a syringe or Vacutainer, or other blood collection device 2404, the initial aliquot of blood flows into the blood sequestration chamber 2418. As the initial aliquot of blood flows into the blood sequestration chamber, it displaces air therein and eventually the blood contacts the blood barrier 2420, forcing the inner chamber housing to the second position. The inner chamber housing 2419 and/or housing 2416 can include a locking mechanism of one or more small tabs, grooves, detents, bumps, ridges, or the like, to maintain the inner chamber housing 2419 in the first position until the blood sequestration chamber 2418 is filled, providing force to overcome the locking mechanism to enable movement of the inner chamber housing 2419 to the second position. Once in the second position, the initial aliquot of blood is sequestered in the blood sequestration chamber 2418 and the one or more apertures 2424 are opened to create a pathway from the inlet port 2412 to the blood sampling channel 2422, bypassing and/or flowing around the blood sequestration chamber 2418.

[00143] As described above, the housing 2416 and/or inner chamber housing 2419 can be formed as cylindrical and concentric, but can be any shape, such as squared, rectangular, elliptical, oval, or other cross-sectional shape. The outer surface of the distal

end of the inner chamber housing 2419 can have one or more outwardly projecting tangs 2421with gaps therebetween. The tangs 2421 contact the inner surface of the housing 2416 to help define the blood sampling channel 2422 therebetween, and to help stop the inner chamber housing 2419 in the second position. The gaps between the tangs 2421 enable blood to flow through the blood sampling channel 2422 and to the outlet port 2414. When the inner chamber housing 2419 is in the second position and the blood sequestration chamber 2418 is filled with the first aliquot of blood, further blood samples will automatically flow through the inlet port 2412, through the one or more apertures 2424, through the blood sampling channel 2422, through the gaps between the tangs 2421, and ultimately through the outlet port 2414 to be collected by a blood sampling device 2404.

[00144] FIGS. 25A – D show a blood optimization system 2500 and blood sequestration device 2502, formed substantially as described in FIGS. 15, 16, 17, 18 and 19, but being formed to inhibit a user or other object from touching or blocking an air venting mechanism from a blood sequestration chamber 2520. Air initially in the blood sequestration chamber 2520 is displaced by an initial aliquot of blood upon venipuncture, where a patient's blood pressure overcomes the ambient air pressure in the blood sequestration chamber 2520. The air venting mechanism includes an air permeable blood barrier 2506, such as a porous material or set of materials that allows air to escape but blocks blood from leaving the blood sequestration chamber 2520.

[00145] The air venting mechanism includes an inner wall 2516 that at least partially circumscribes or surrounds the air permeable blood barrier 2506, and an outer wall 2504 spaced apart from the inner wall 2516. The outer wall 2504 can have one or more air vents 2514 formed therein. The outer wall 2504 extends higher upward than the inner wall 2516, such that a lid 2510, such as a cap, plug, cover, etc., can be attached to the outer wall 2504 and be displaced by a small distance from the top of the inner wall 2516. A seal 2508 in the form of a silicone wafer, or other elastomeric material, fits within the outer wall 2504 to cover the air permeable blood barrier 2506 and abut the top of the inner wall 2516. The seal 2508 covers and seals the air permeable blood barrier 2506 and inhibits air from entering the blood sequestration chamber 2520 through the air permeable blood barrier 2506. A fulcrum 2512 on an underside of the lid 2510 allows the seal 2508 to flexibly disconnect from the top of the inner wall 2516 when pushed by air displaced from the blood sequestration chamber 2520, to allow air to vent from the air

permeable blood barrier 2506 and through the one or more air vents 2514 in the outer wall 2504.

[00146] FIG. 26A – E illustrate a blood sample optimization system 2600 that includes a patient needle 2602 for vascular access to a patient's bloodstream, a blood sample collection device 2604 to facilitate the collecting of one or more blood samples for blood testing or blood cultures, and a conduit 2606 providing a fluid connection between the patient needle 2602 and the blood sample collection device 2604. The conduit 2606 can include flexible tubing. In preferred implementations, the blood sample collection device 2604 includes a protective shield 2605 that includes a sealed collection needle on which a sealed vacuum-loaded container is placed, which, once pierced by the collection needle, draws in a blood sample under vacuum pressure or force through the conduit 2006 from the patient needle 2602.

[00147] The blood sample optimization system 2600 further includes a blood sequestration device 2608, located at any point on the conduit 2606 between the patient needle 2602 and the blood sample collection device 2604. The location of the blood sequestration device 2608 can be based on a length of the conduit between the blood sequestration device 2608 and the patient needle 2602, and the associated volume that length provides.

[00148] The blood sequestration device 2608 includes an inlet port 2612 for being connected to the conduit 2606 toward the patient needle 2602, and an outlet port 2614 for being connected to the conduit 2606 toward the blood sample collection device 2604. The blood sequestration device 2608 includes an outer housing 2616 and an inner housing 2617, both having a cylindrical form, and being connected concentrically. The outer housing 2616 includes an outer wall 2618 and an inner conduit 2620 that defines a blood sampling channel 2622 to convey blood through the conduit 2606 to the blood sampling device 2604. The inner housing 2617 fits snugly between the inner conduit 2620 and the outer wall 2618 of the outer housing, and is rotatable in relation to the outer housing 2616. The fit between the outer housing 2616 and the inner housing 2617 can be a friction fit that maintains the housings in a particular position. The inner housing 2617 defines a blood sequestration chamber 2624, preferably a helical or corkscrew channel around the outer surface of inner conduit 2620 of the outer housing 2616, and which

terminates at an air vent 2628 having an air permeable blood barrier, as shown in FIG. 26E.

[00149] The blood sequestration chamber 2624 is connected with the blood sampling channel 2622 via diversion junction 2624 formed in the inner conduit 2620, when the blood sequestration device in a first state, illustrated in FIG. 26C. The protective shield 2606 on the collection needle 2604 provides a block for air or blood, enabling a diversion of an initial aliquot of blood into the blood sequestration chamber 2624 as the patient's blood pressure overcomes the ambient air pressure in the blood sequestration channel 2624 to displace air therefrom through air vent 2628.

[00150] When the inner housing 2617 is rotated relative to the outer housing 2616, or vice versa, to a second state, as illustrated in FIG. 26D, the blood sequestration chamber 2624 is shut off from diversion junction 2624, enabling a direct path from the patient needle through the conduit 2606 to the collection needle 2604, via blood sampling channel 2622. The outer housing 2616 and/or inner housing 2617 can include ridges or grooves formed within a portion of their surfaces, to facilitate relative rotation from the first state to the second state.

[00151] FIGS. 27A – D illustrate a blood optimization system 2700 and blood sequestration device 2702, formed substantially as described with reference to at least FIGS. 15, 16, 17, 18, 19, and 25, but being formed to inhibit a user or other object from touching or blocking an air venting mechanism from a blood sequestration chamber 2720. Air initially in the blood sequestration chamber 2720 is displaced by an initial aliquot of blood upon venipuncture, where a patient's blood pressure overcomes the ambient air pressure in the blood sequestration chamber 2720. The air venting mechanism includes an air permeable blood barrier 2706, such as a porous material or set of materials that allows air to escape but blocks blood from leaving the blood sequestration chamber 2720.

[00152] The air venting mechanism includes an inner wall 2716 that at least partially circumscribes or surrounds the air permeable blood barrier 2706, and an outer wall 2704 spaced apart from the inner wall 2716. A cap 2722 is positioned on the air venting mechanism, preferably by having a lower cap wall 2728 that fits between the inner wall 2716 and the outer wall 2704 of the air venting mechanism, and frictionally abutting either the the inner wall 2716 or the outer wall 2704 or both. The cap 2722

further includes one or more vent holes 2724 or slits, apertures, openings, or the like, which extend through an upper surface of the cap 2722 around a downwardly extending plug 2726. The plug 2726 is sized and adapted to fit snugly within the space defined by inner wall 2716.

[00153] In a first position, as illustrated in FIG. 27C, the cap 2722 is extended from the air venting mechanism to allow air from the blood sequestration chamber 2720 to exit through the air permeable blood barrier 2706 and through the one or more vent holes 2724. Once the air from the blood sequestration chamber 2720 has been displaced, i.e., when the blood sequestration chamber 2720 is filled with the first aliquot of potentially tainted blood from the patient, then the cap 2722 can be pushed down on the air venting mechanism in a second position as shown in FIG. 27D, so that the plug 2726 fits within the inner wall 2716 over the air permeable blood barrier 2706 to seal the air venting mechanism. In either the first position or the second position, the cap 2722 protects the air permeable blood barrier 2706 from outside air or from being touched by a user.

[00154] FIGS. 28A – F illustrate a blood optimization system 2800 and blood sequestration device 2802, formed substantially as described with reference to at least FIGS. 15, 16, 17, 18, 19, 25 and 26, but utilizing a multi-layered filter, and in some implementations, a filter with trapped reactive material, for an air permeable blood barrier. As shown in FIGS. 28C and D, an air permeable blood barrier 2803 includes a first layer 2804 of an air permeable but blood impermeable material, and a second layer 2806 that includes a reactive material, such as a hydrophobic material, for repelling blood while still allowing air to pass through both layers. As shown in FIGS. 28E and F, the air permeable blood barrier 2803 can include any number of layers, such as a third layer 2808 formed of the same air permeable but blood impermeable material as first layer 2804, while a second layer 2806 includes trapped or embedded blood reactive material.

[00155] FIGS. 29A – C illustrate a blood optimization system 2900 and blood sequestration device 2902, formed substantially as described with reference to at least FIGS. 15, 16, 17, 18, 19, 25 and 26, but in which a blood sequestration chamber 2904 is at least partially filled with a blood-absorptive material 2906. The blood-absorptive material 2906 can act as a wicking material to further draw in blood to be sequestered upon venipuncture of the patient, and prior to use of a blood drawing device such as a Vacutainer™ or a syringe, or the like.

[00156] FIGS. 30A – G illustrate a blood optimization system 3000 and blood sequestration device 3002, formed substantially as described with reference to at least FIGS. 15, 16, 17, 18, 19, 25 and 26. The blood sequestration device 3000 includes an inlet port 3002 that can be connected with a patient needle that is inserted into a patient's vascular system for access to and withdrawing of a blood sample. The inlet port 3002 may also be connected with tubing or other conduit that is in turn connected with the patient needle. The inlet port 3002 defines an opening into the blood sequestration device 3000, which opening can be the same cross sectional dimensions as tubing or other conduit connected with the patient needle or the patient needle itself. For instance, the opening can be circular with a diameter of approximately 0.045 inches, but can have a diameter of between 0.01 inches or less to 0.2 inches or more.

[00157] The inlet port 3002 can also include a sealing or fluid-tight connector or connection, such as threading or Luer fitting, or the like. In some implementations, tubing or other conduit associated with the patient needle can be integral with the inlet port 3002, such as by co-molding, gluing, laser weld, or thermally bonding the parts together. In this manner, the blood sequestration device 3000 can be fabricated and sold with the patient needle and/or tubing as a single unit, eliminating the need for connecting the patient needle to the blood sequestration device 3000 at the time of blood draw or sampling.

[00158] The blood sequestration device 3000 further includes an outlet port 3004, which defines an opening out of the blood sequestration device 3000 and to the blood sample collection device. The outlet port 3004 may also be connected with tubing or other conduit that is in turn connected with the blood sequestration device, and may also include a sealing or fluid-tight connector or connection, such as threading or Luer fitting, or the like. Accordingly, as discussed above, the blood sequestration device 3000 can be fabricated and sold with the patient needle and/or tubing and the blood sample collection device as a single unit, eliminating the need for connecting the patient needle and the blood sample collection device to the blood sequestration device 3000 at the time of blood draw or sampling.

[00159] The blood sequestration device 3000 further includes a sampling channel 3006 between the inlet port 3002 and the outlet port 3004, and a sequestration chamber 3008 that is connected to and split off or diverted from the sampling channel 3006 at any

point between the inlet port 3002 and the outlet port 3004. The sampling channel 3006 functions as a blood sampling pathway once a first aliquot of blood has been sequestered in the sequestration chamber 3008. The sampling channel 3006 can be any sized, shaped or configured channel, or conduit. In some implementations, the sampling channel 3006 has a substantially similar cross sectional area as the opening of the inlet port 3002. In other implementations, the sampling channel 3006 can gradually widen from the inlet port 3002 to the outlet port 3004. The sequestration chamber 3008 may have a larger cross section to form a big reservoir toward the sequestration channel path so that the blood will want to enter the reservoir first versus entering a smaller diameter on the sampling channel 3006.

[00160] In some exemplary implementations, the diversion between the sampling channel 3006 and the sequestration chamber 3008 is by diverter junction 3007. Diverter junction 3007 may be a substantially Y-shaped, T-shaped, or U-shaped. In some preferred exemplary implementations, and as shown in FIG. 17A – 17B, the diverter junction 3007 is configured such that the flow out of the inlet port 3002 is preferentially directed toward the sequestration chamber 3008. The sequestration chamber 3008 may also include or form a curve or ramp to direct the initial blood flow toward and into the sequestration chamber 3008.

[00161] The sequestration chamber 3008 is preferably maintained at atmospheric pressure, and includes a vent 3010 at or near a distal end of the sequestration chamber 3008. The vent 3010 may include an air permeable blood barrier 3012 as described above.

[00162] The blood sequestration device 3000 can include a housing 3001 that can be formed of multiple parts or a single, unitary part. In some implementations, and as illustrated FIG. 30F, the housing 3001 includes a top member 3020 and a bottom member 3022 that are mated together. The blood sequestration device 3000 can also include a gasket or other sealing member (not shown) so that when the top member 3020 is mechanically attached with the bottom member 3022, the interface between the two is sealed by the gasket or sealing member. The bottom member 3022 can include grooves, channels, locks, conduits or other pathways pre-formed therein, such as by an injection molding process or by etching, cutting, drilling, etc., to form the sampling channel 3006, the sequestration chamber 3008, and diverter junction 3007.

[00163] The sequestration chamber 3008 may have a larger cross section than the sampling channel 3006 so that the blood will preferentially move into the sequestration chamber first versus entering a smaller diameter on the sampling channel 3006.

[00164] In some implementations, the sampling channel 3006 and the sequestration chamber 3008 are formed by grooves, channels, locks or other pathways formed in housing 3001. The housing 3001 can be made of rubber, plastic, metal or any other suitable material. The housing 3001 can be formed of a clear or translucent material, or of an opaque or non-translucent material. In other implementations, the housing 3001 can be mostly opaque or non-translucent, while the housing surface directly adjacent to the sampling channel 3006 and/or the sequestration chamber 3008 may be clear or translucent, giving a practitioner a visual cue or sign that the sequestration chamber 3008 is first filled to the extent necessary or desired, and/or then a visual cue or sign that the sequestered blood remains sequestered while a clean sample of blood is drawn through the sampling channel 3006. Other visual cues or signs of the sequestration can include, without limitation: the air permeable blood barrier 3012 turning a different color upon contact, saturation, or partial saturation with blood; a color-coded tab or indicator at any point along or adjacent to the sequestration chamber; an audible signal; a vibratory signal; or other signal.

[00165] The air permeable blood barrier 3012 can be covered with, or surrounded by, a cap 3032. The cap 3032 can be sized and configured to inhibit a user from touching the air permeable blood barrier 3012 with their finger or other external implement, while still allowing air to exit the air permeable blood barrier 3012 as the air is displaced from the sequestration chamber 3008. The cap 3032 can be constructed to inhibit or prevent accidental exposure of the filter to environmental fluids or splashes. This can be accomplished in a variety of mechanical ways including but not limited to the addition of a hydrophobic membrane to the protective cover.

[00166] The air venting mechanism includes a wall 3030 that at least partially circumscribes or surrounds the air permeable blood barrier 3012. The wall 3030 can have one or more air vents formed therein. The cap 3032 covers wall 3030 and can be snapped, glued, or otherwise attached in place. A seal 3017 in the form of a silicone wafer, or other elastomeric material, fits within the wall 3030 to cover the air permeable blood barrier 3012 and abut the top of the wall 3030. The seal 3017 covers and seals the

air permeable blood barrier 3012 and inhibits air from entering the blood sequestration chamber 3008 through the air permeable blood barrier 3012. A fulcrum 3012 on an underside of the cap 3032 allows the seal 3008 to flexibly disconnect from the top of the inner wall 3016 when pushed by air displaced from the blood sequestration chamber 3008, to allow air to vent from the air permeable blood barrier 3012 and through the one or more air vents in the wall 3030 and/or cap 3032.

[00167] In use, the blood sequestration device 3000 includes a sampling channel 3006 and a sequestration chamber 3008. Both pathways are initially air-filled at atmospheric pressure, but the sampling channel 3006 is directed to an outlet port 3004 that will be initially sealed by a Vacutainer or other such sealed blood sampling device, and the sequestration chamber 3008 terminates at a vent 3010 to atmosphere that includes an air permeable blood barrier 3012.

[00168] After a venipuncture by a patient needle of a patient (not shown), which could gather a number of pathogens from the patient's skin, a first amount of the patient's blood with those pathogens will pass through inlet port 3002 of blood sequestration device 3000. This initial volume of potentially contaminated blood will preferentially flow into the sequestration chamber 3008 by finding the path of least resistance. The patient's own blood pressure overcomes the atmospheric pressure in the vented sequestration chamber 3008 to displace air therein through the air permeable blood barrier 3012, but is not sufficient to overcome the air pressure that builds up in the sealed sampling channel 3006. In various exemplary embodiments, the sequestration chamber 3008 and sampling channel 3006 can be configured such that the force generated by the patient's blood pressure is sufficient to overcome any effect of gravity, regardless of the blood sequestration device's orientation.

[00169] Eventually, the sequestration chamber 3008 fills with blood that displaces air through the air permeable blood barrier 3012. Once the blood contacts the air permeable blood barrier, the blood interacts with the air permeable blood barrier 3012 material to completely or partially seal the vent 3010. A signal or indication may be provided that the practitioner can now utilize the Vacutainer or other blood sampling device.

[00170] Upon filling the blood sequestration pathway 3008 but prior to use of the Vacutainer or other blood sample collection device, the patient's blood pressure may drive compression of the air in the sampling channel 3006, possibly resulting in a small amount of blood moving past the diversion point into the sampling channel 3006, queuing up the uncontaminated blood to be drawn through the sampling channel 3006.

[00171] In yet another aspect, the blood sequestration chamber and/or blood sampling channel, or other component, of any of the implementations described herein, can provide a visually discernable warning or result in a component adapted for operative fluid communication with the flash chamber of an introducer for an intravenous catheter into a blood vessel of a patient. The device and method provides a visually discernable alert when blood from the patient communicates with a test component reactive to communicated blood plasma, to visually change. The reaction with the blood or the plasma occurs depending on one or a plurality of reagents positioned therein configured to test for blood contents, substances or threshold high or low levels thereof, to visually change in appearance upon a result.

[00172] In yet other aspects, the blood sequestration chamber and/or blood sampling channel can be sized and adapted to provide a particular volumetric flow of blood, either during the sequestration process and/or the sampling process.

[00173] Although a variety of embodiments have been described in detail above, other modifications are possible. Other embodiments may be within the scope of the following claims.

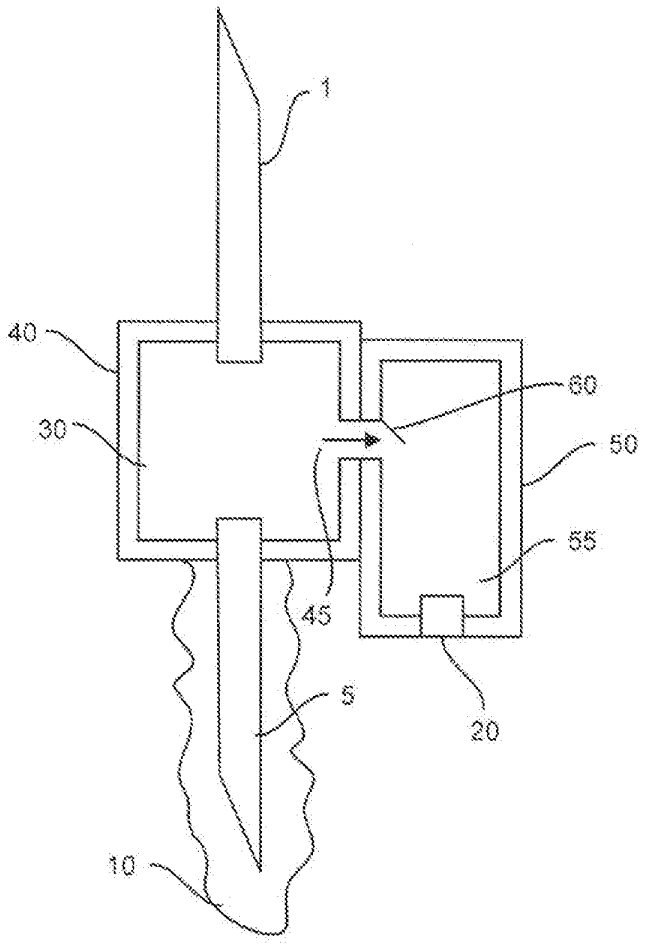


FIG. 1

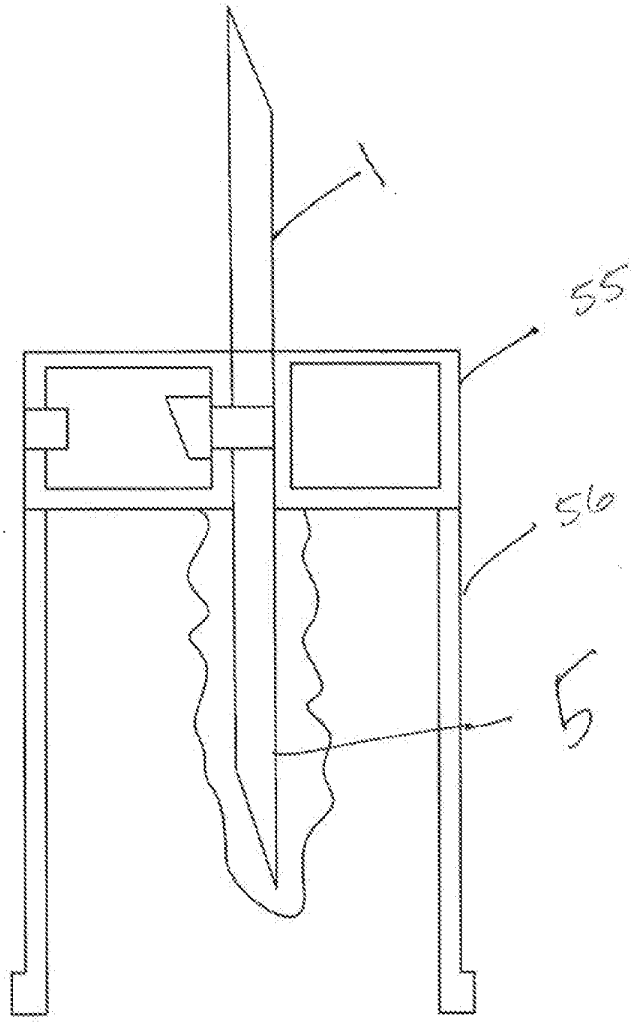


FIG. 2

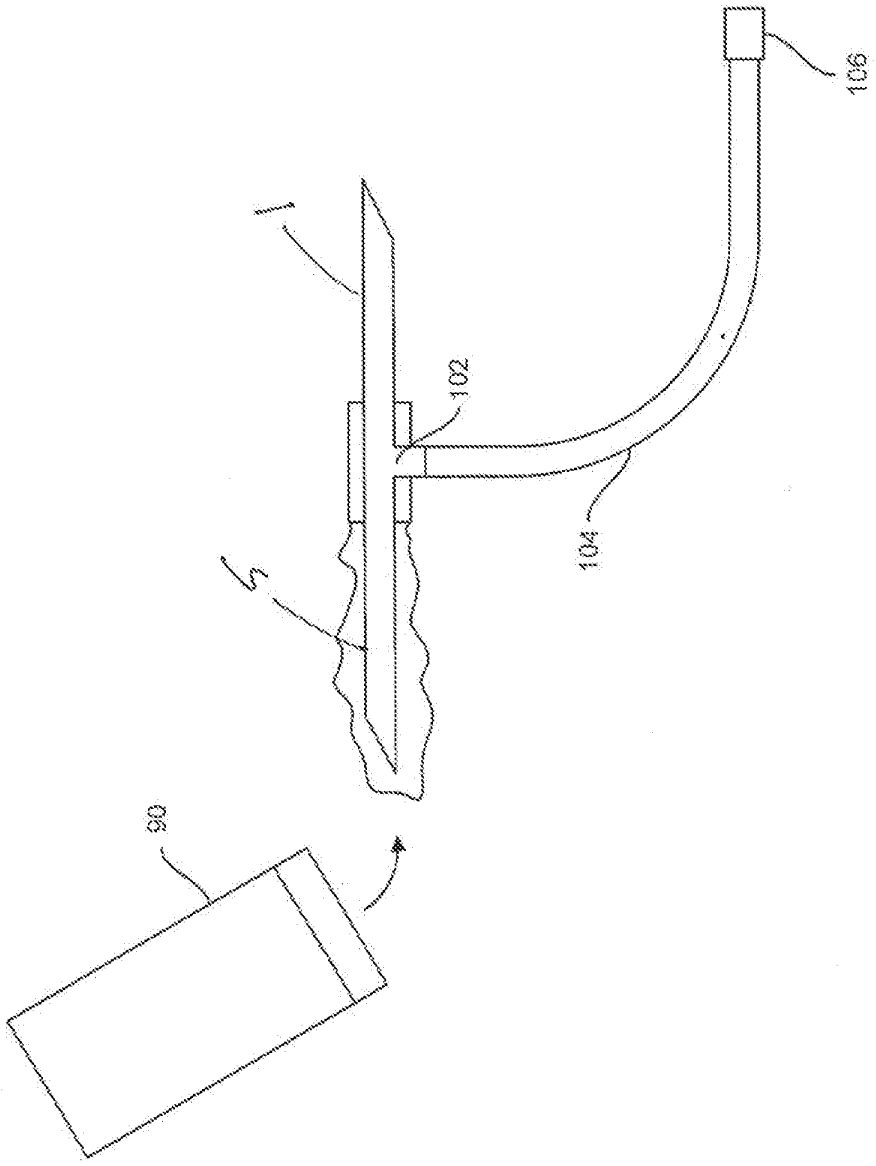


FIG. 3

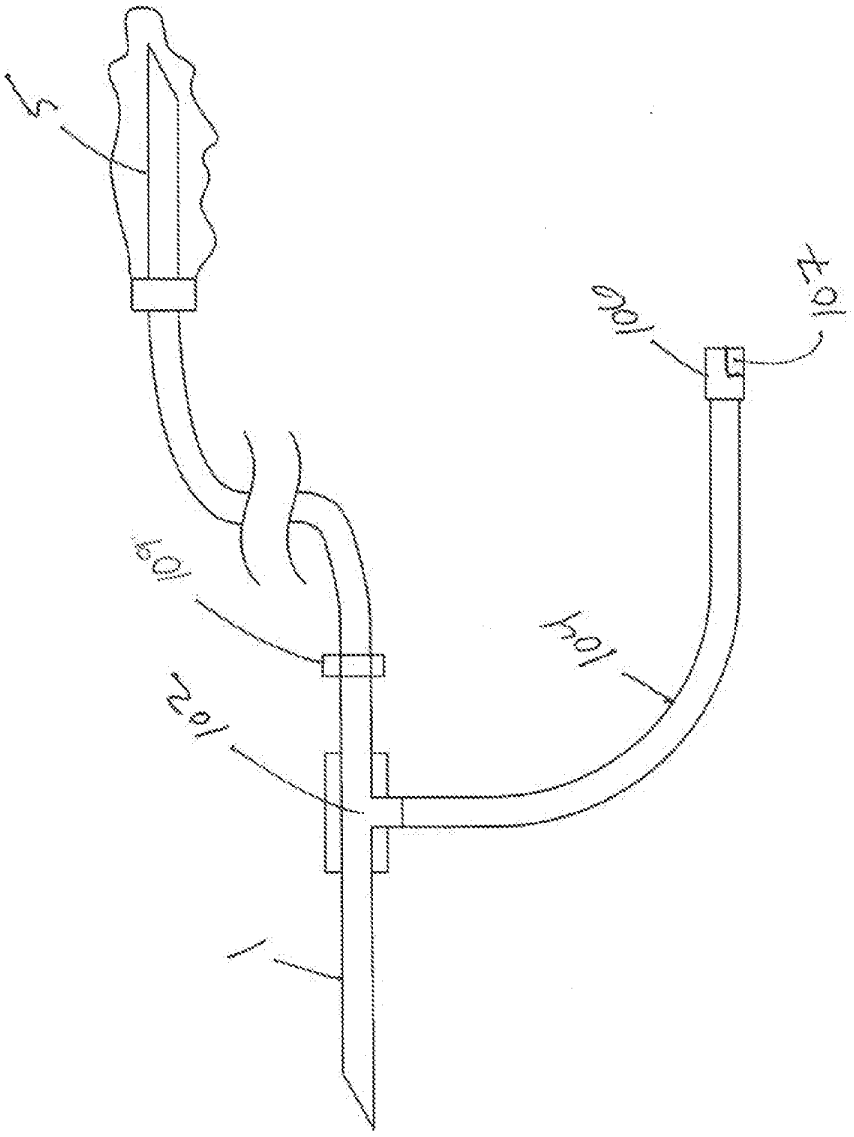


FIG. 4

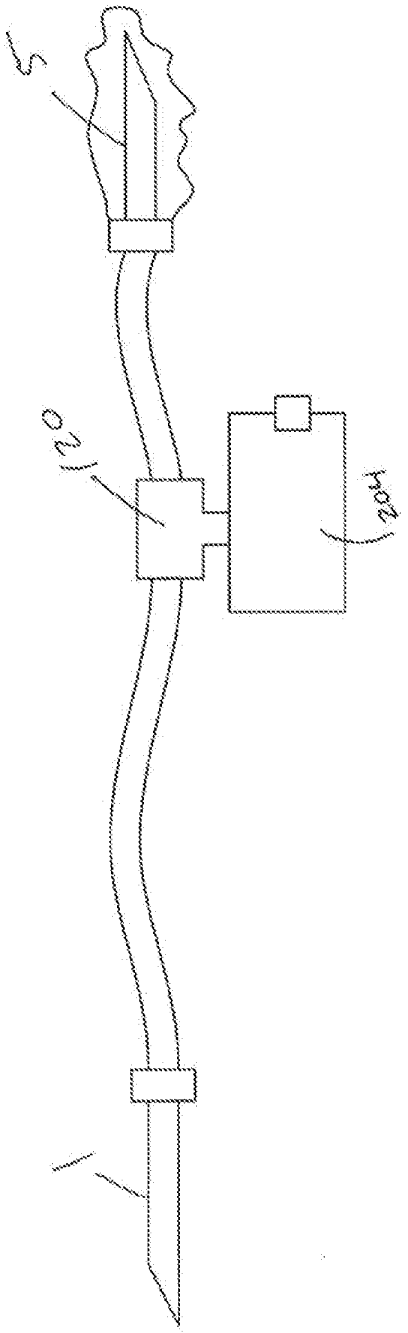


FIG. 5

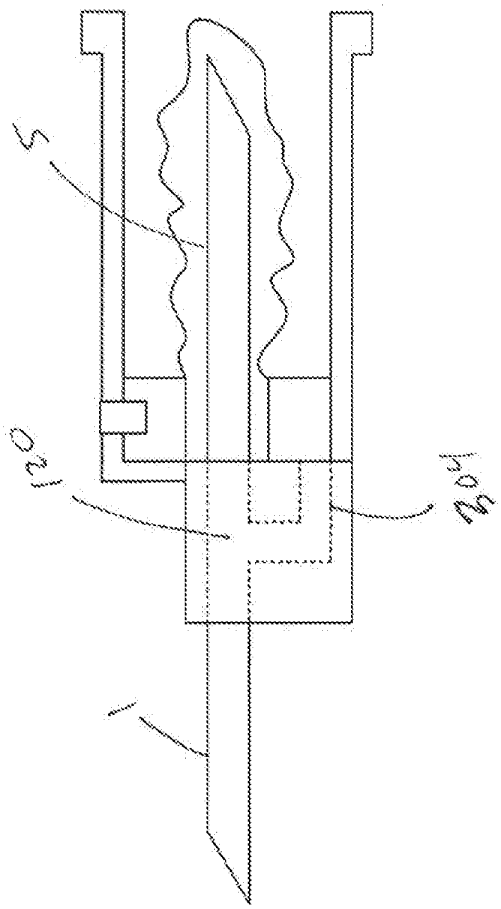


FIG. 6

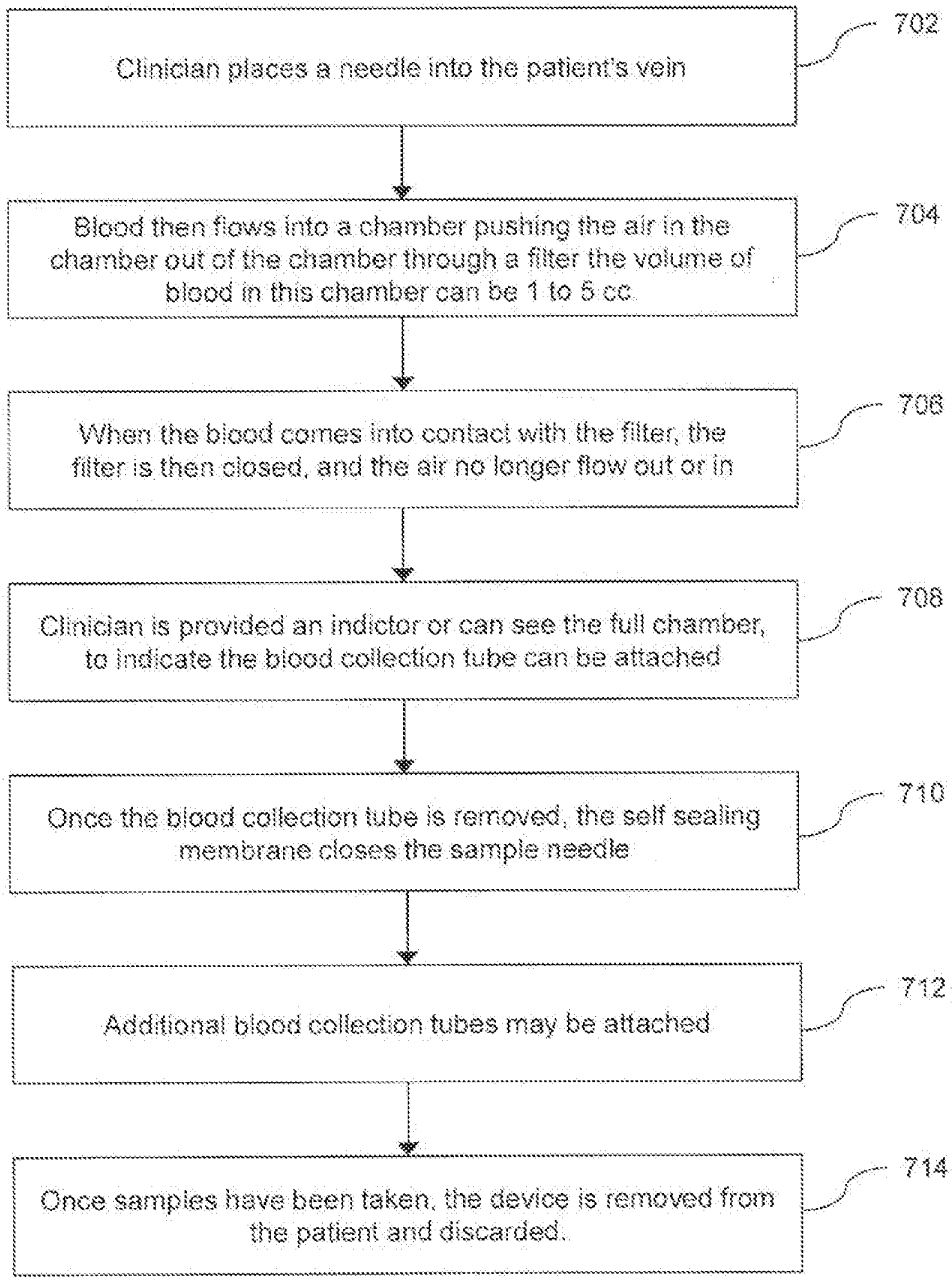

Clinician places a needle into the patient's vein
702
Blood then flows into a chamber pushing the air in the chamber out of the chamber through a filter the volume of blood in this chamber can be 1 to 5 cc
704
When the blood comes into contact with the filter, the filter is then closed, and the air no longer flow out or in
706
Clinician is provided an indictor or can see the full chamber, to indicate the blood collection tube can be attached
708
Once the blood collection tube is removed, the self sealing membrane closes the sample needle
710
Additional blood collection tubes may be attached
712
Once samples have been taken, the device is removed from the patient and discarded.
714

FIG. 7

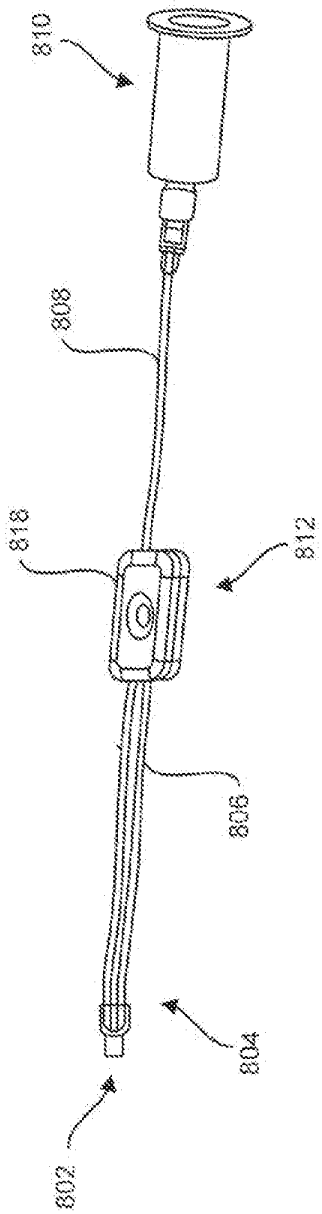


FIG. 8A

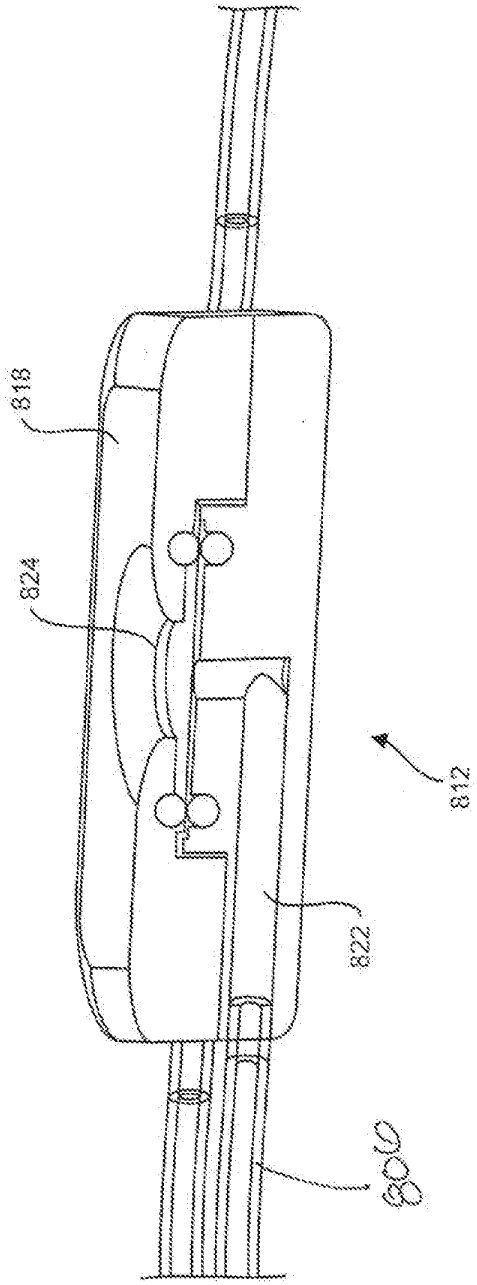


FIG. 8B

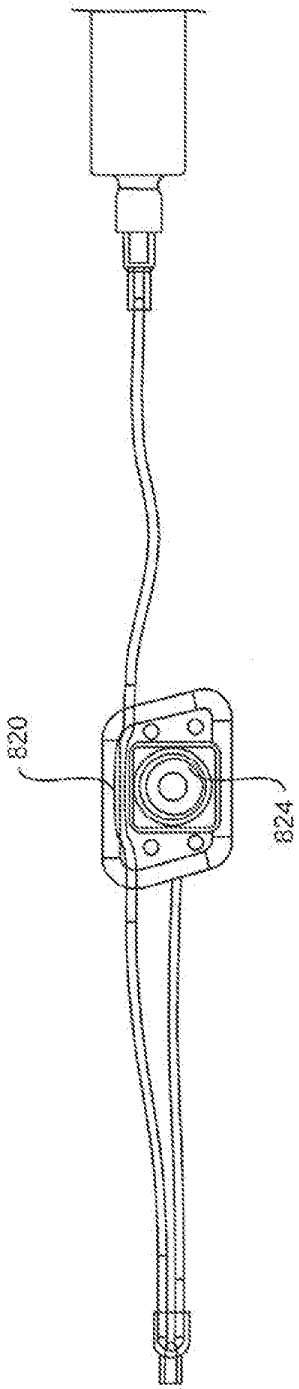


FIG. 8C

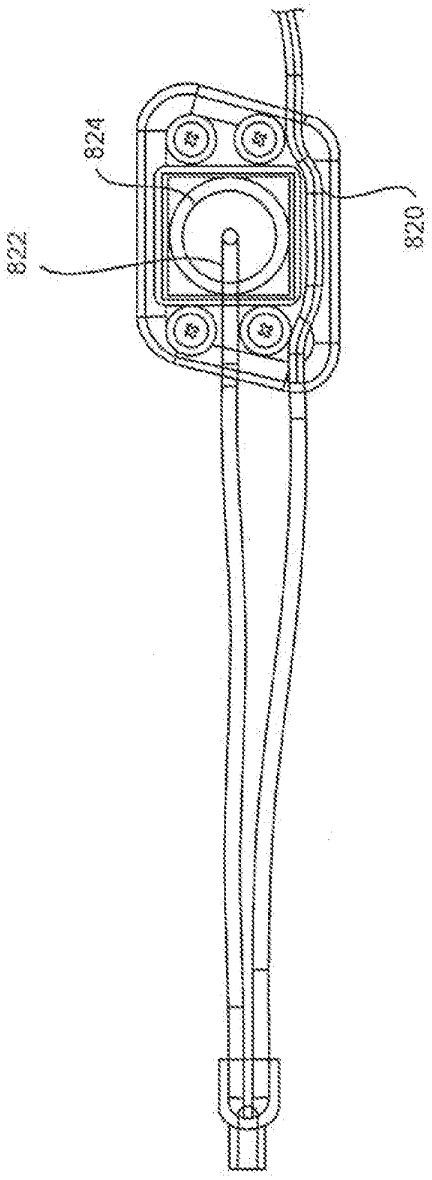


FIG. 8D

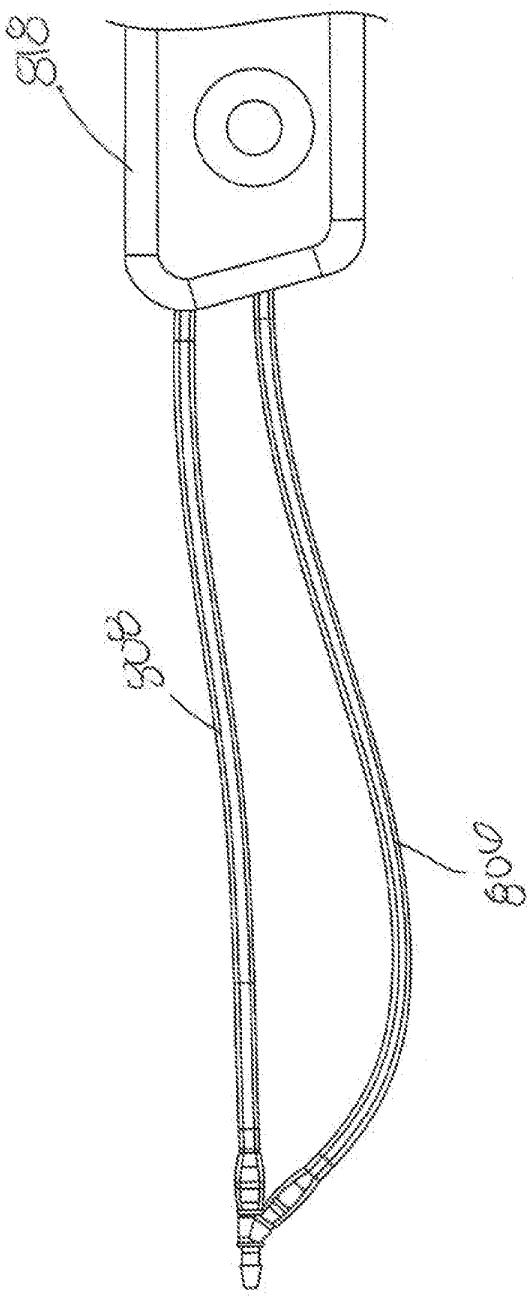


FIG. 8E

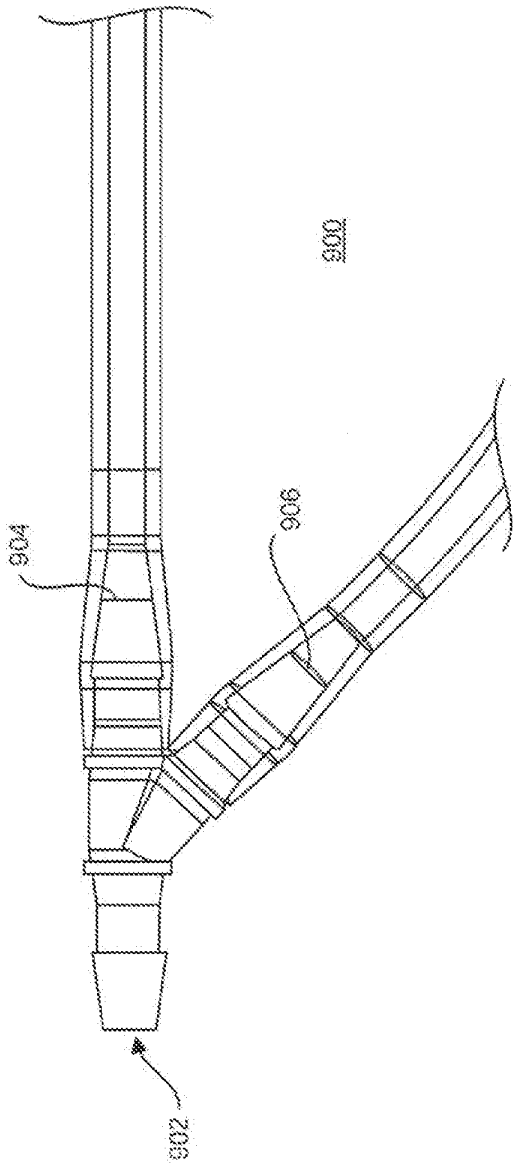


FIG. 9

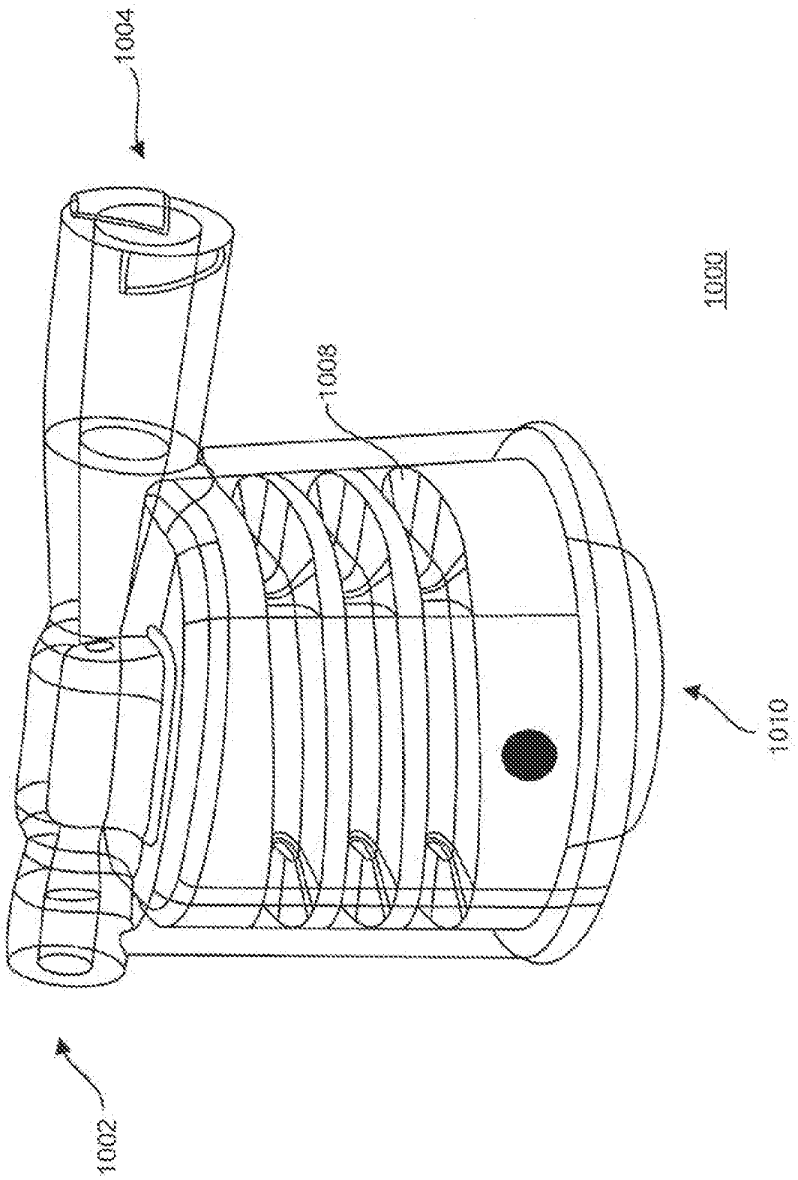


FIG. 10A

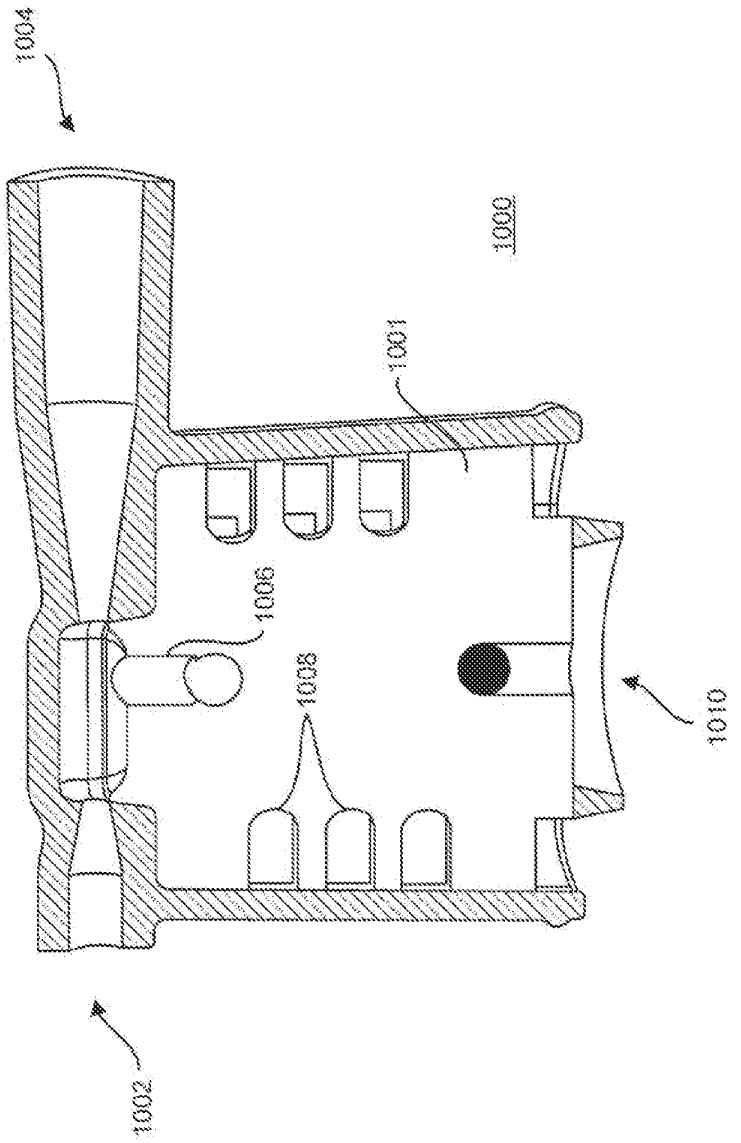


FIG. 10B

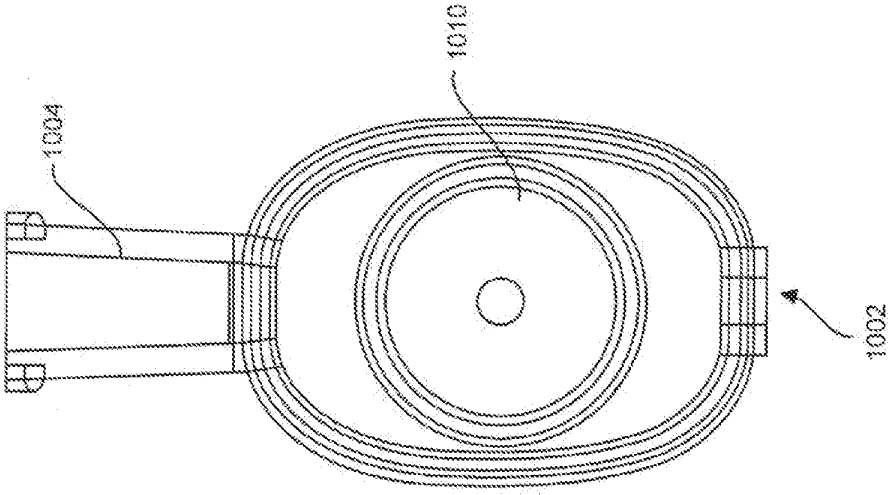


FIG. 10C

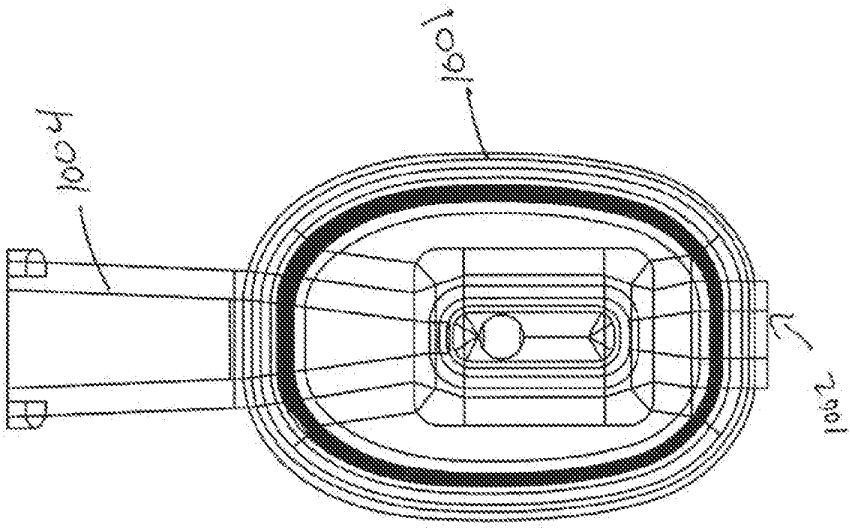


FIG. 10D

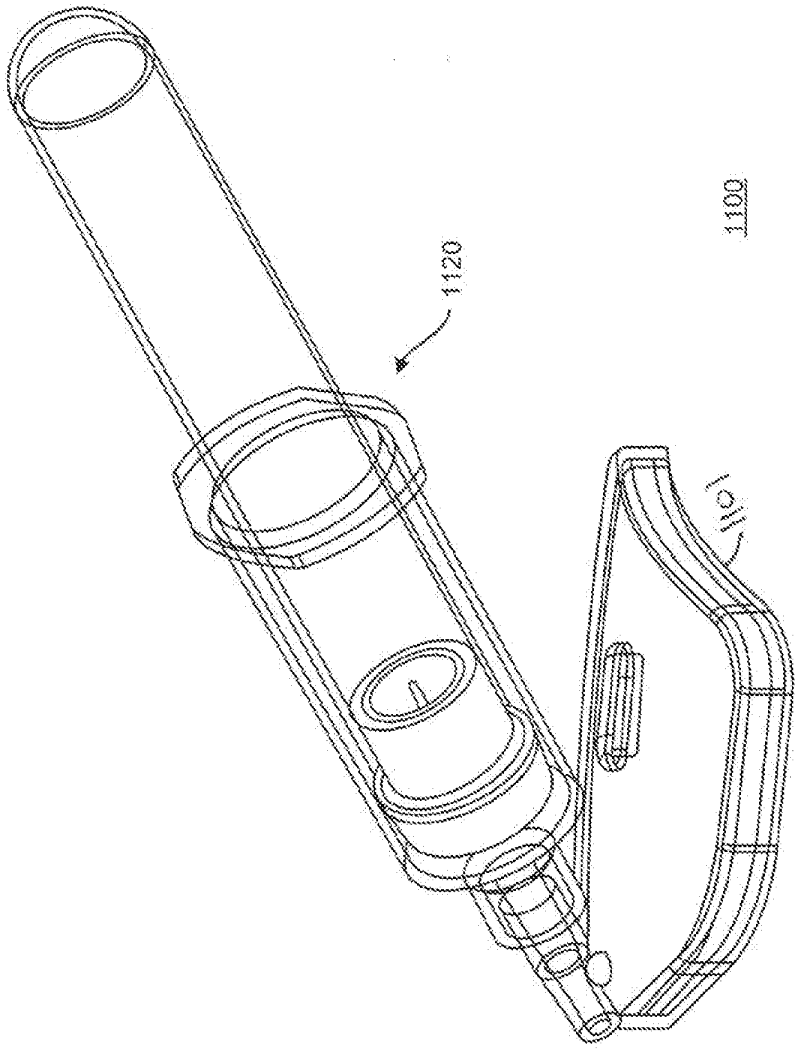


FIG. 11A

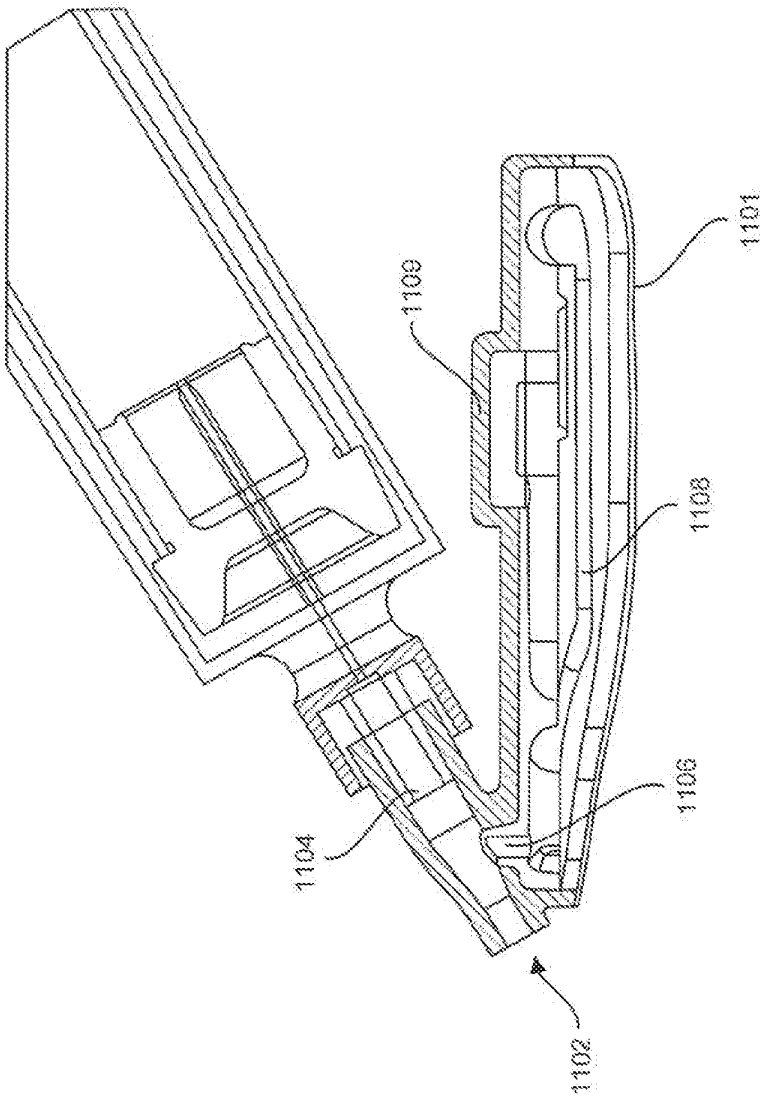


FIG. 11B

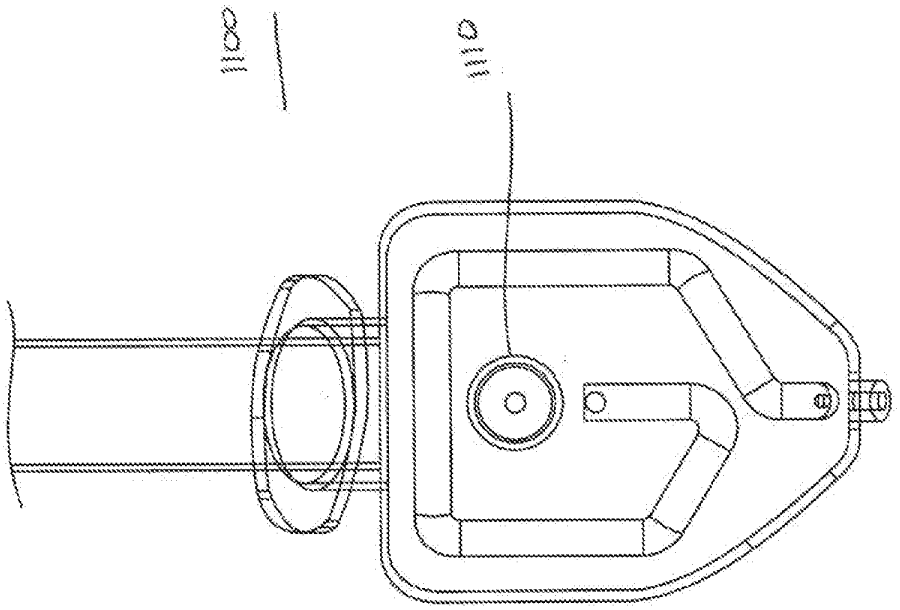


FIG. 11C

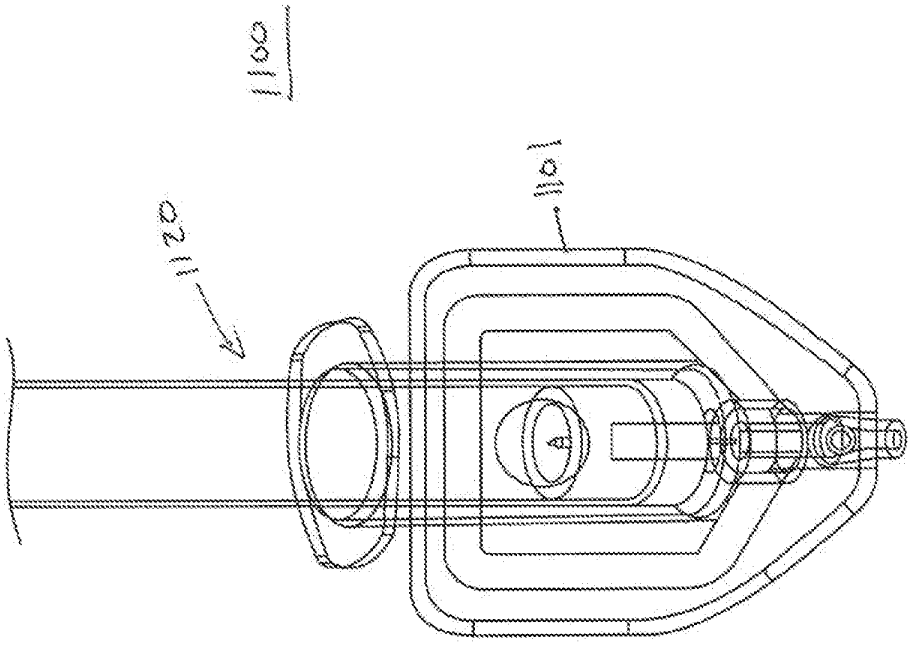


FIG. 11D

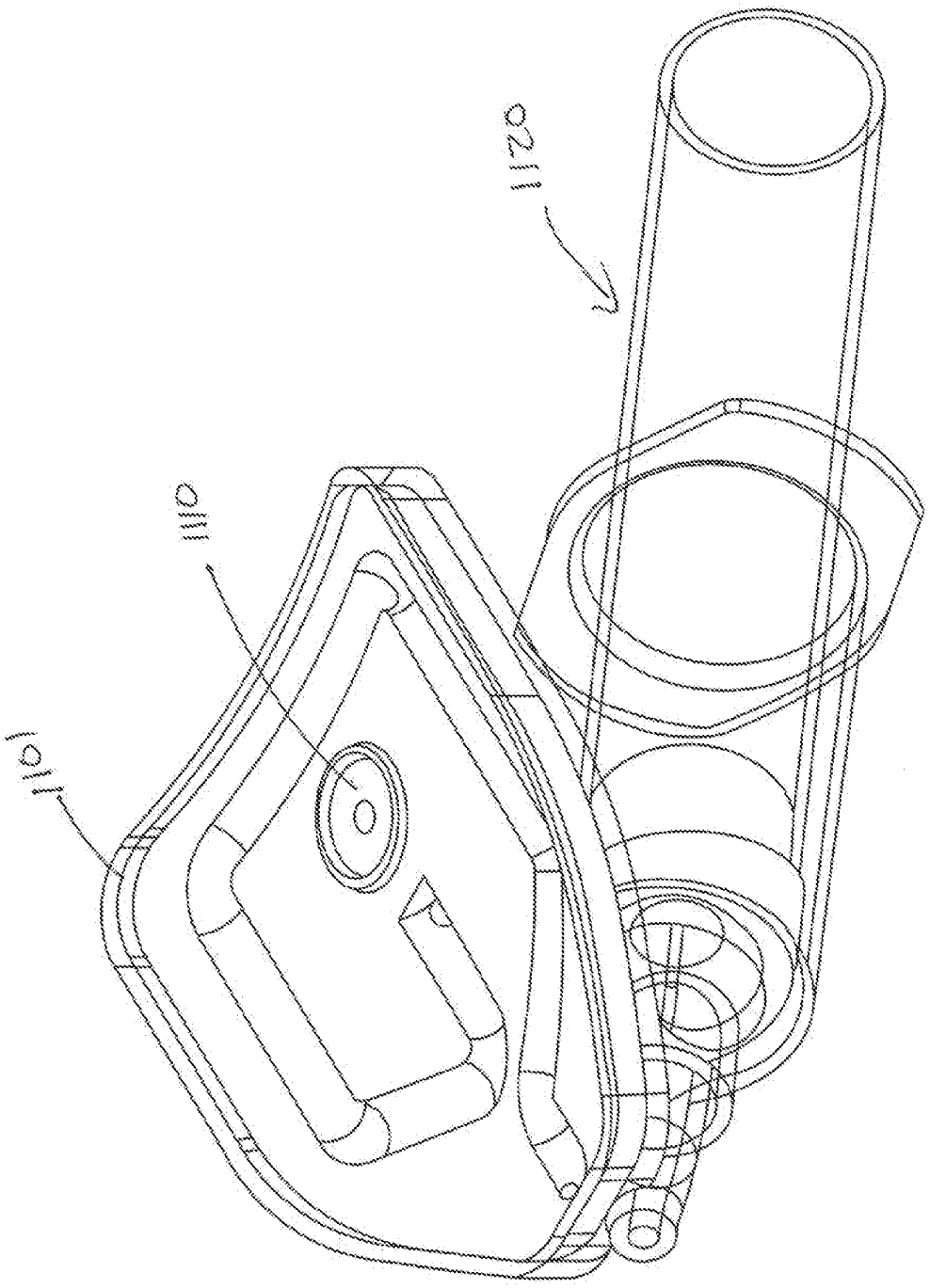


FIG. 11E

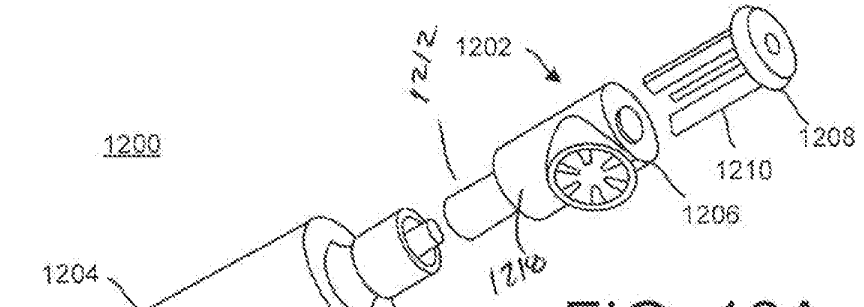


FIG. 12A

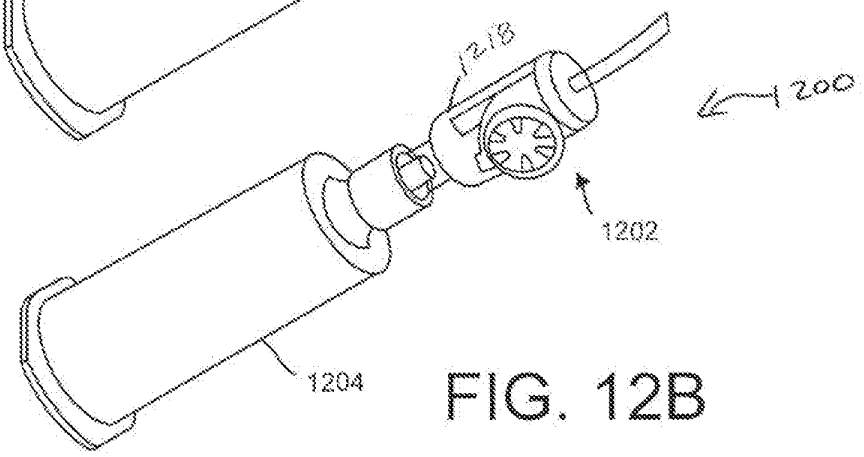


FIG. 12B

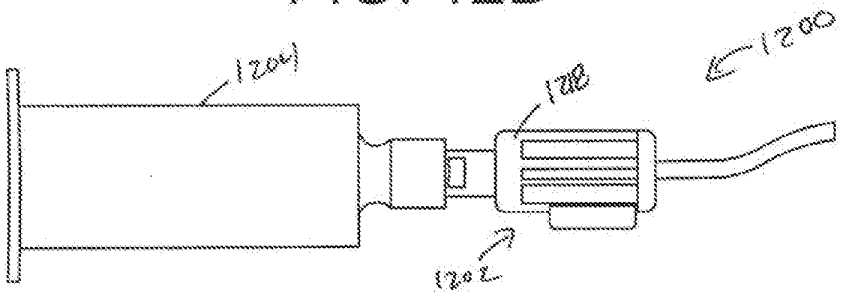


FIG. 12C

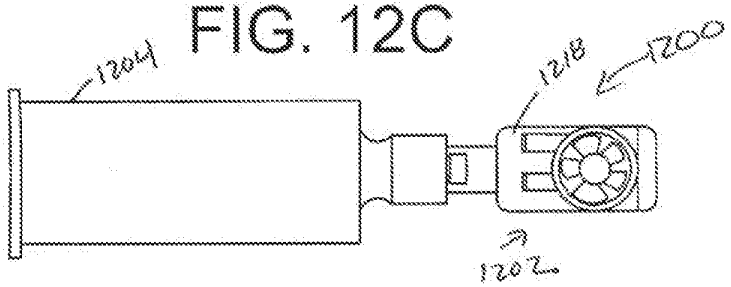


FIG. 12D

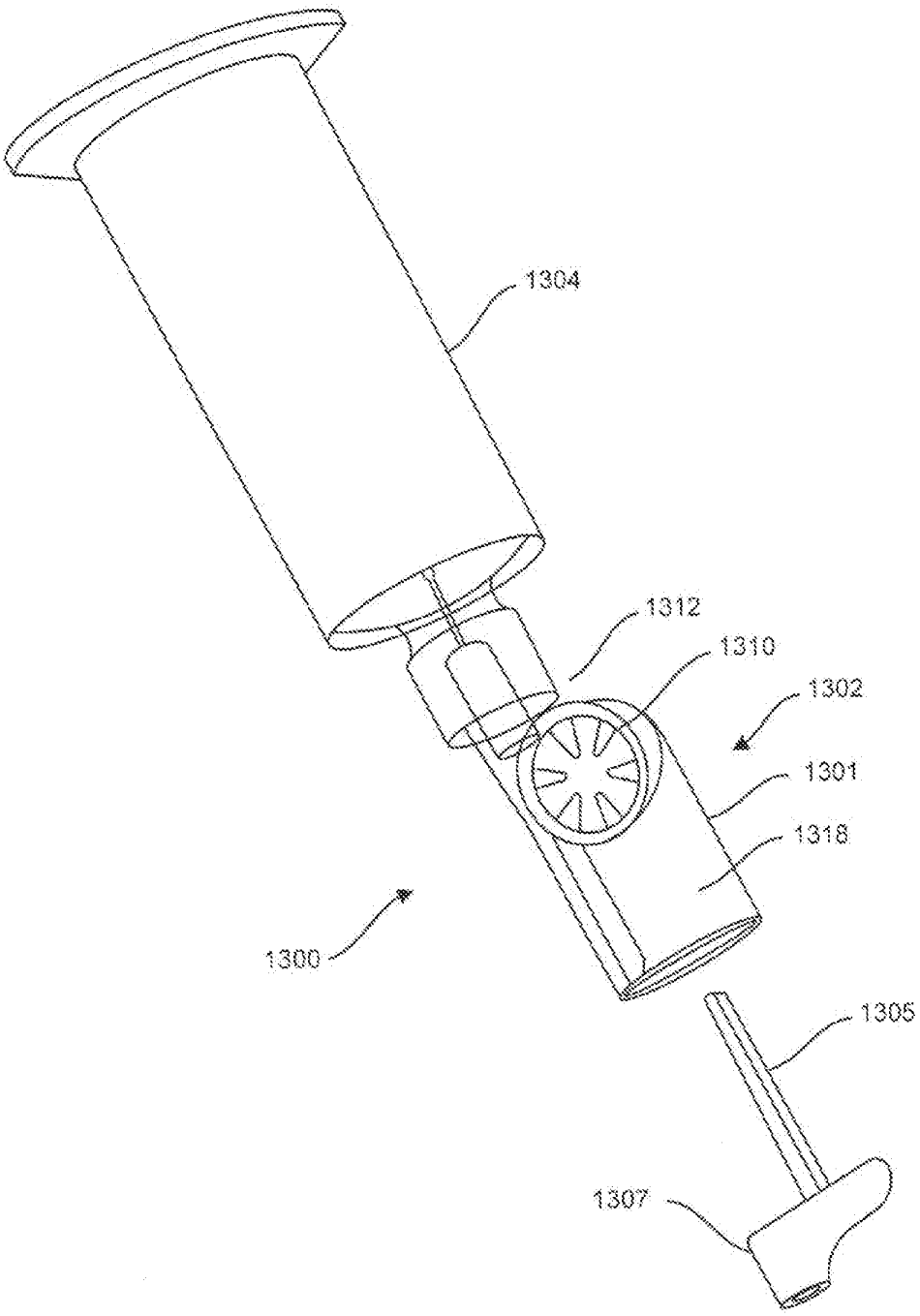


FIG. 13A

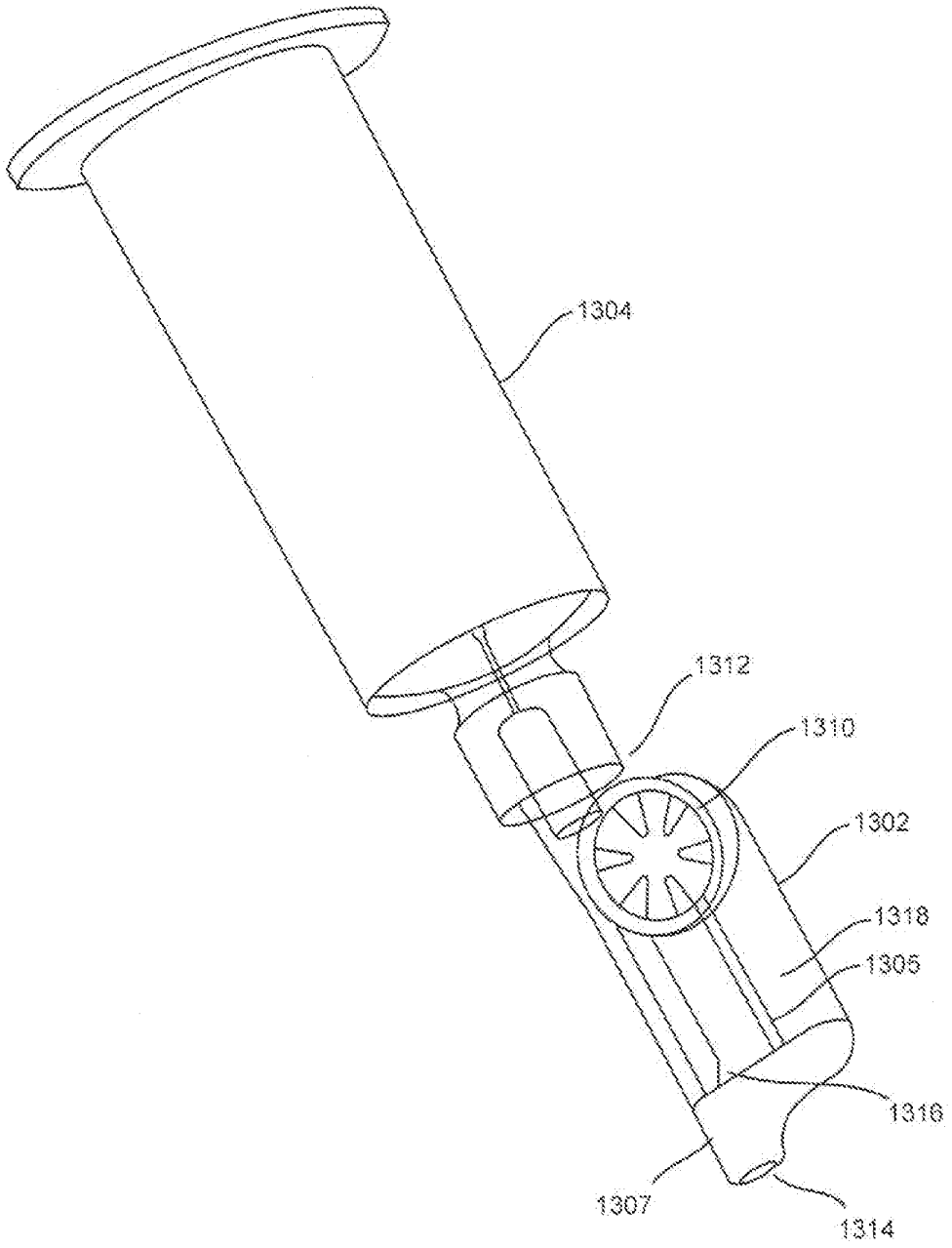


FIG. 13B

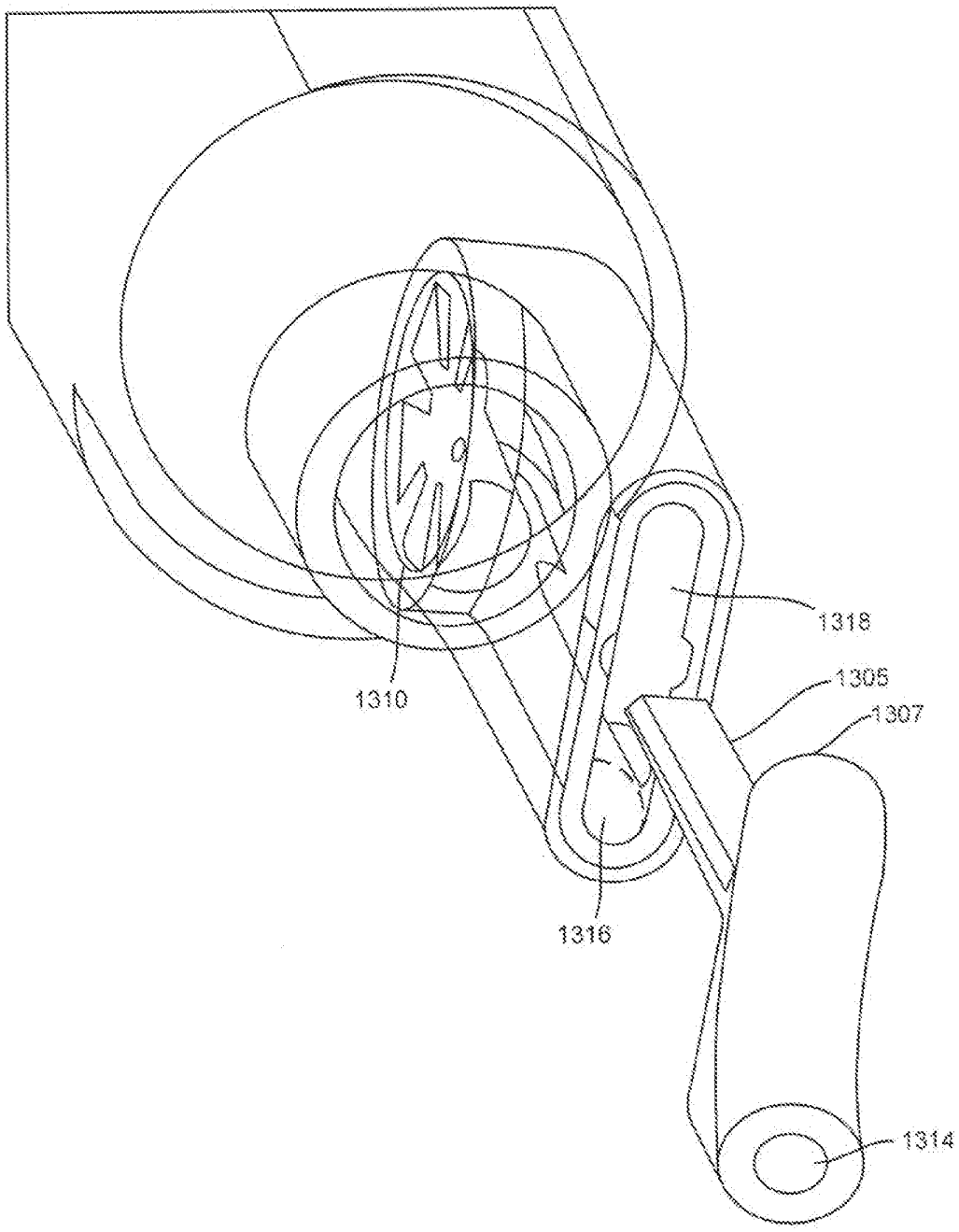


FIG. 13C

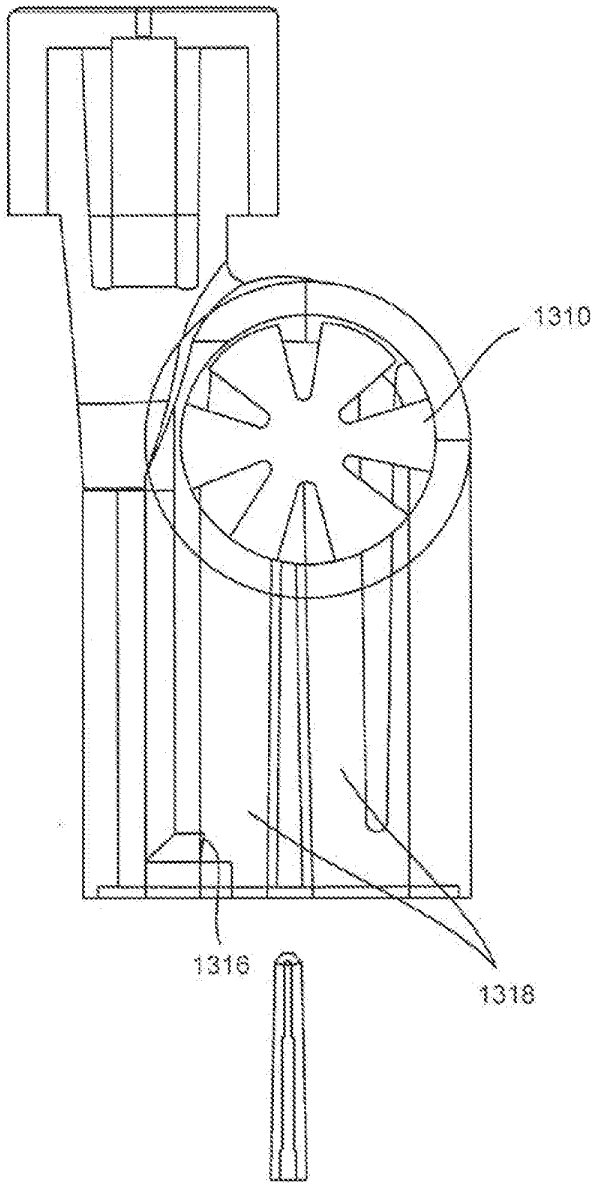


FIG. 13D

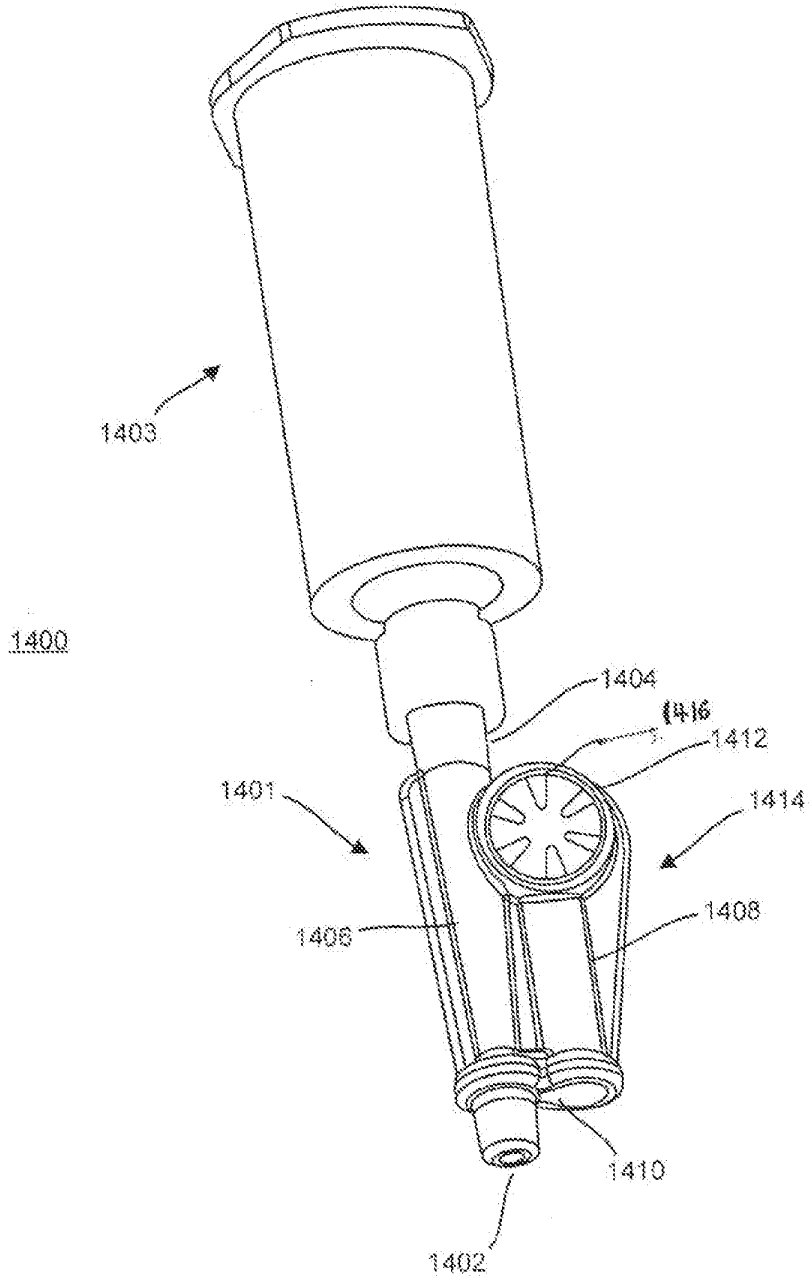


FIG. 14A

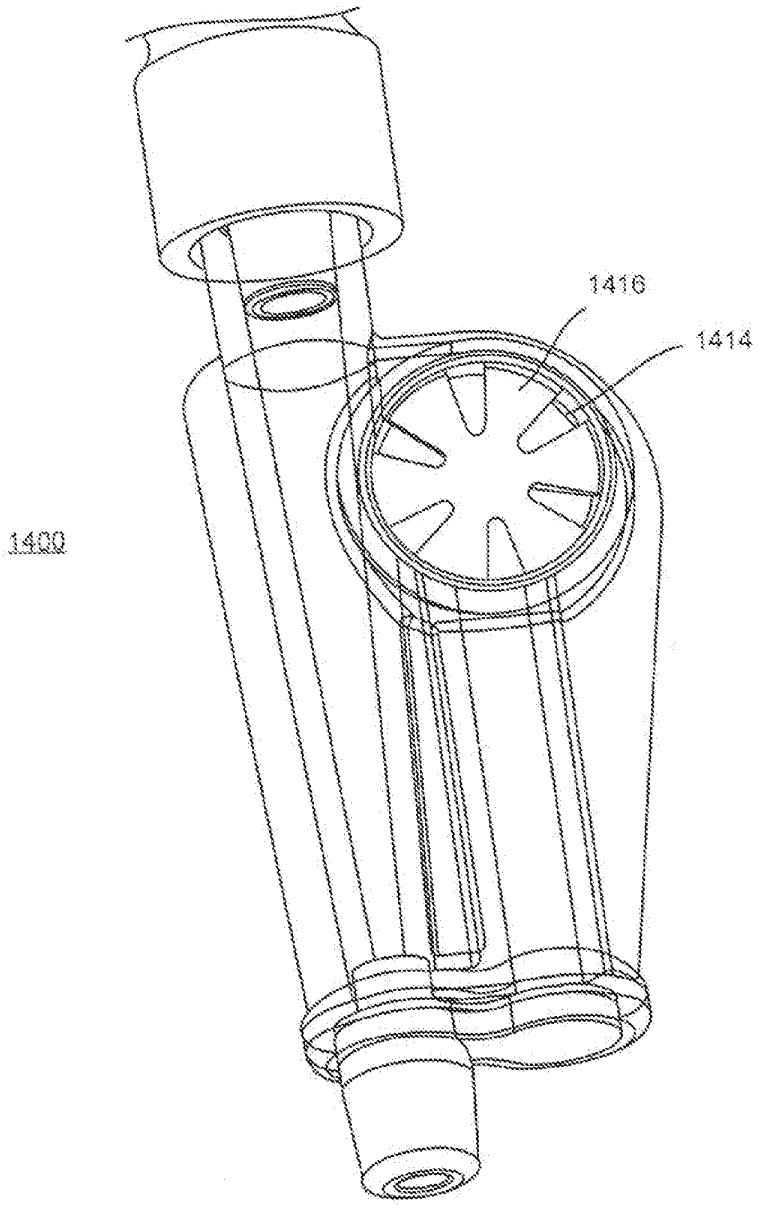


FIG. 14B

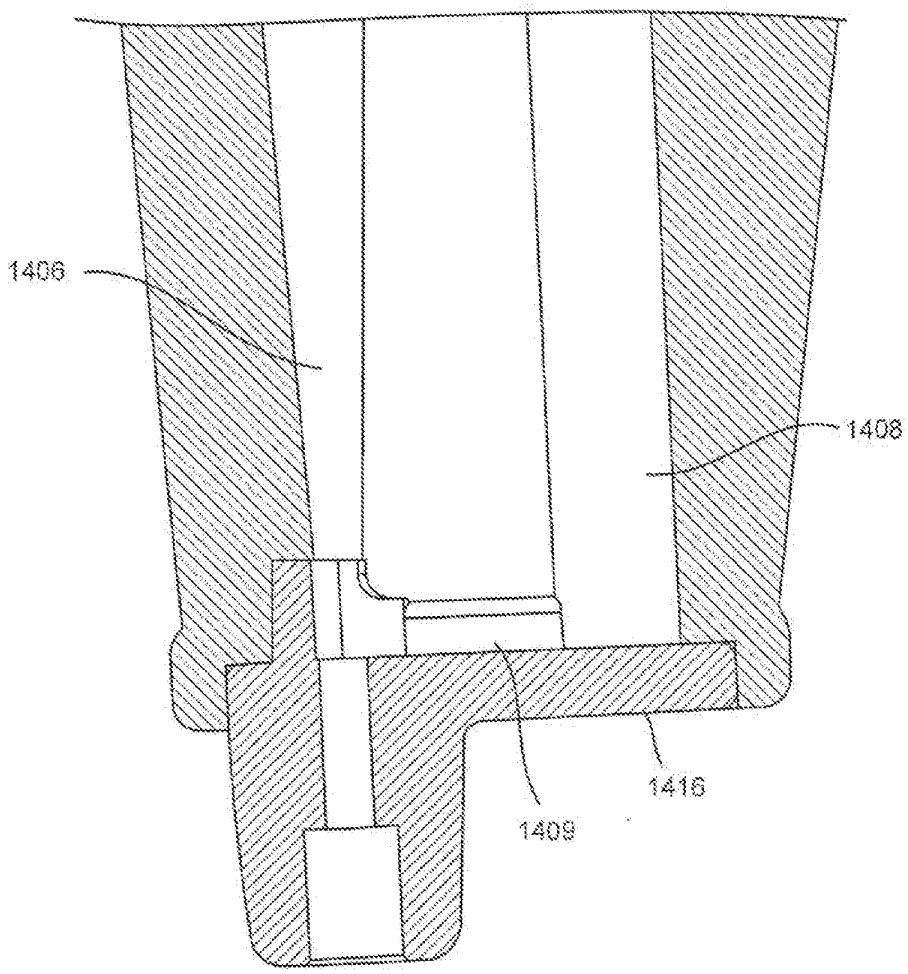


FIG. 14C

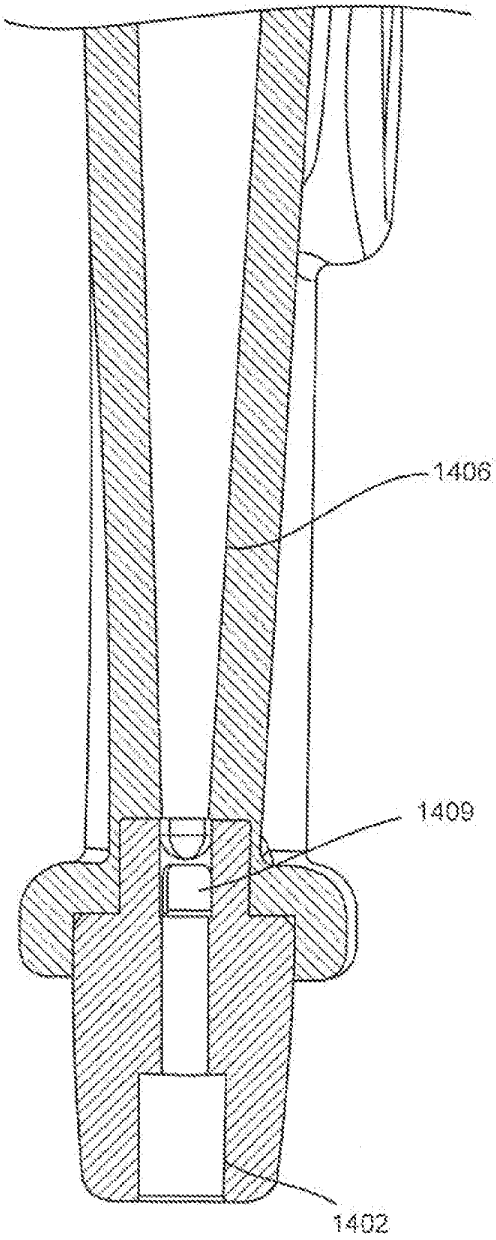


FIG. 14D

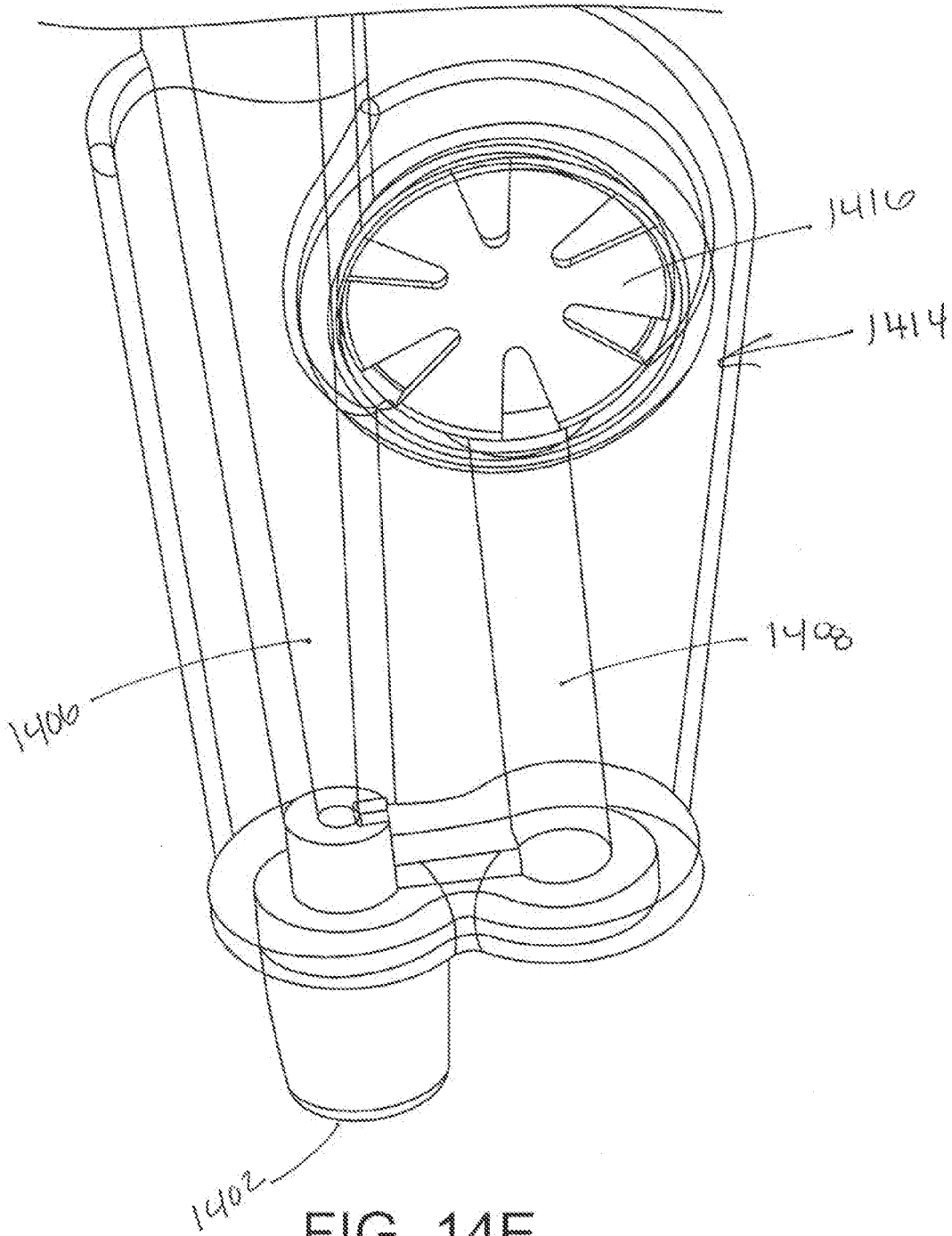


FIG. 14E

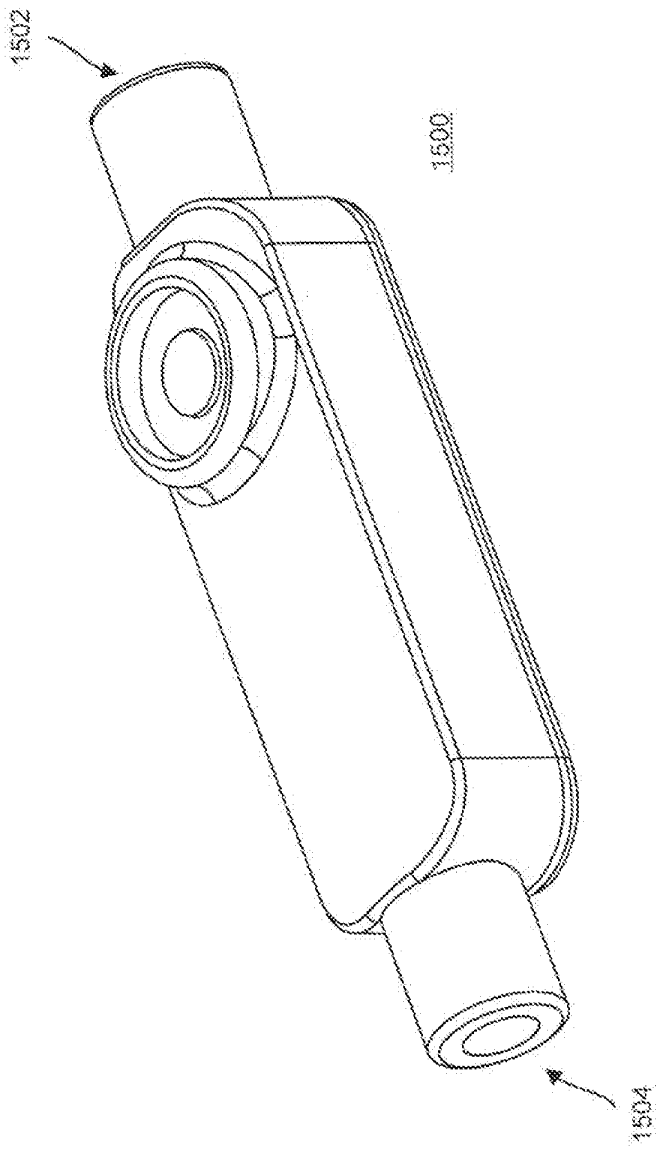


FIG. 15A

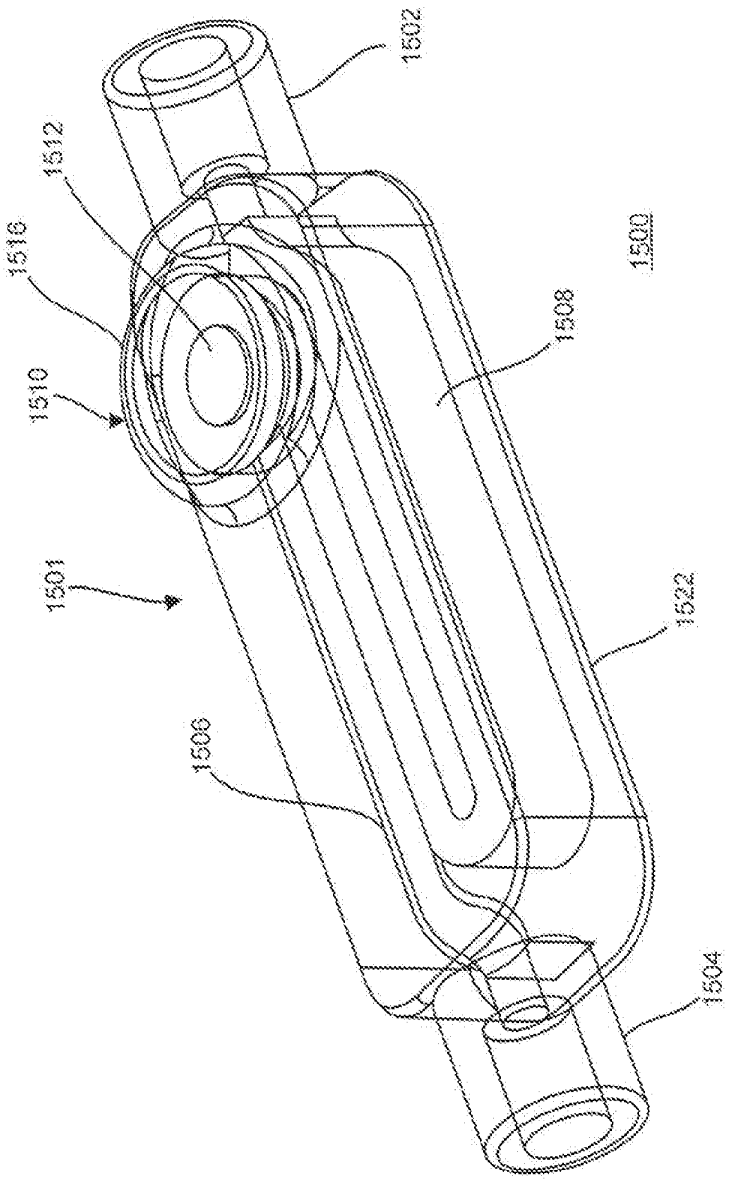


FIG. 15B

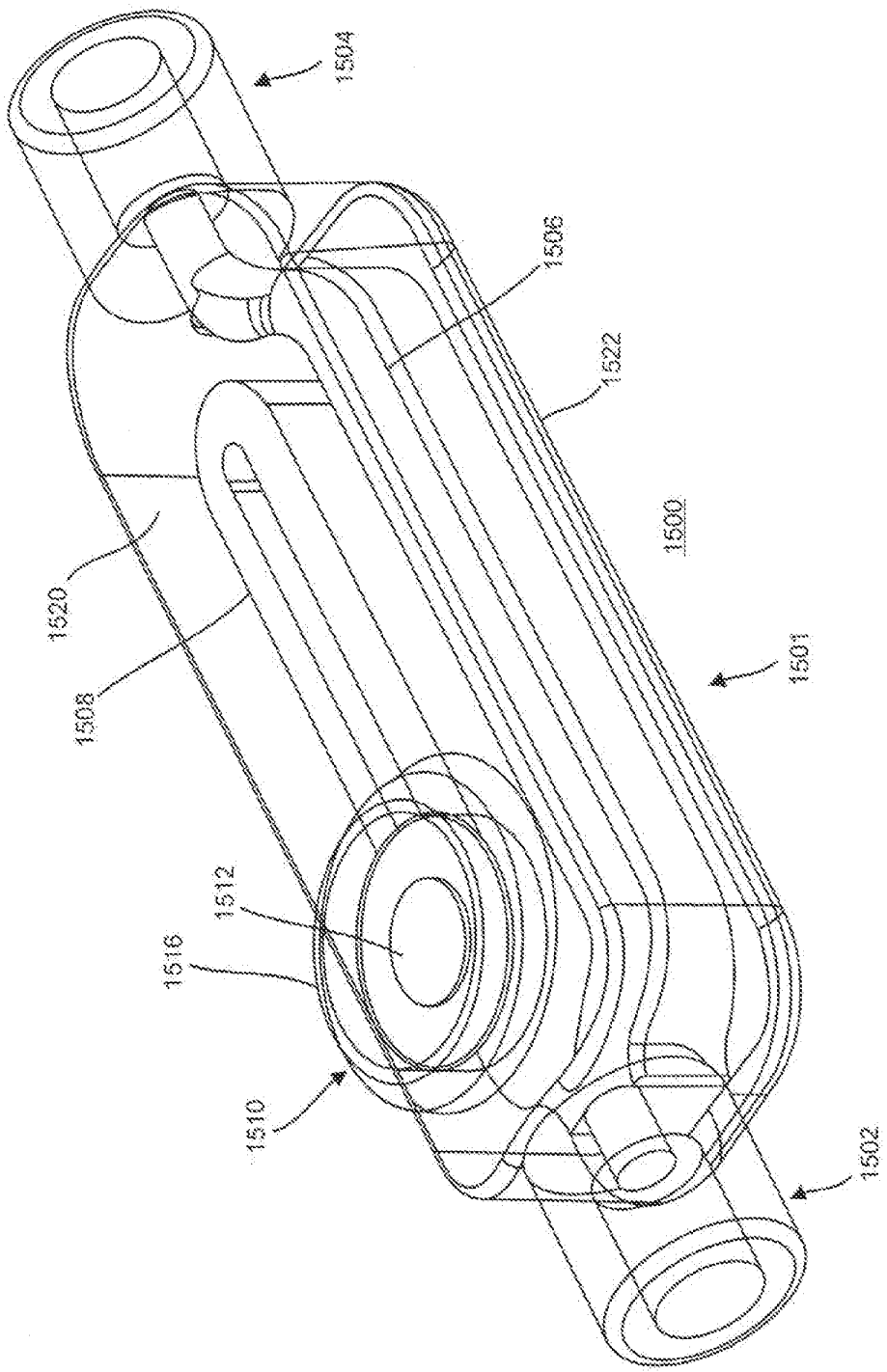


FIG. 15C

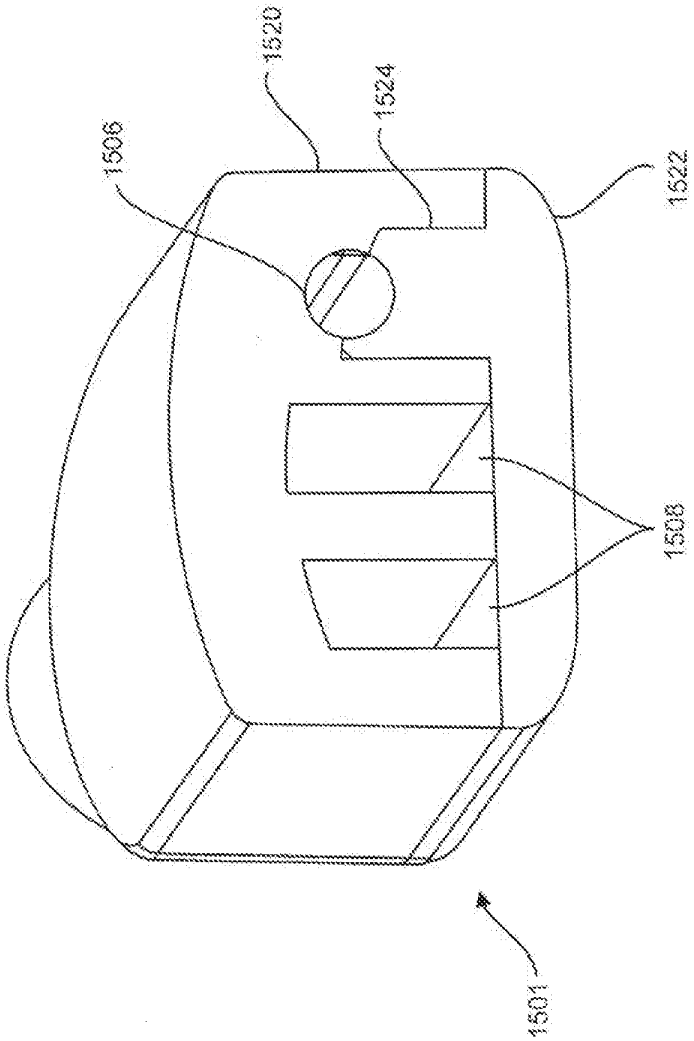


FIG. 15D

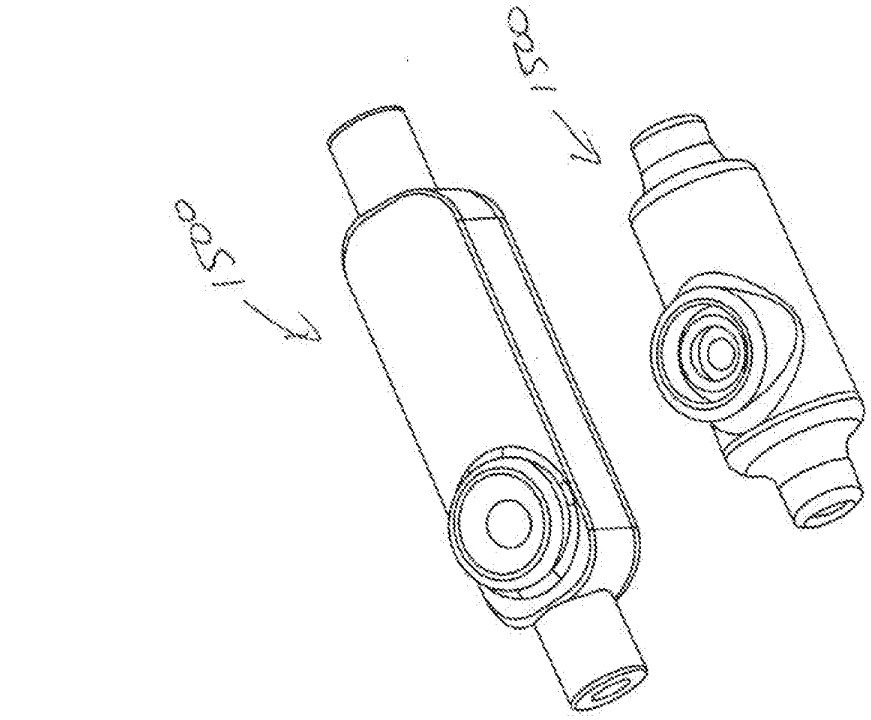


FIG. 15F

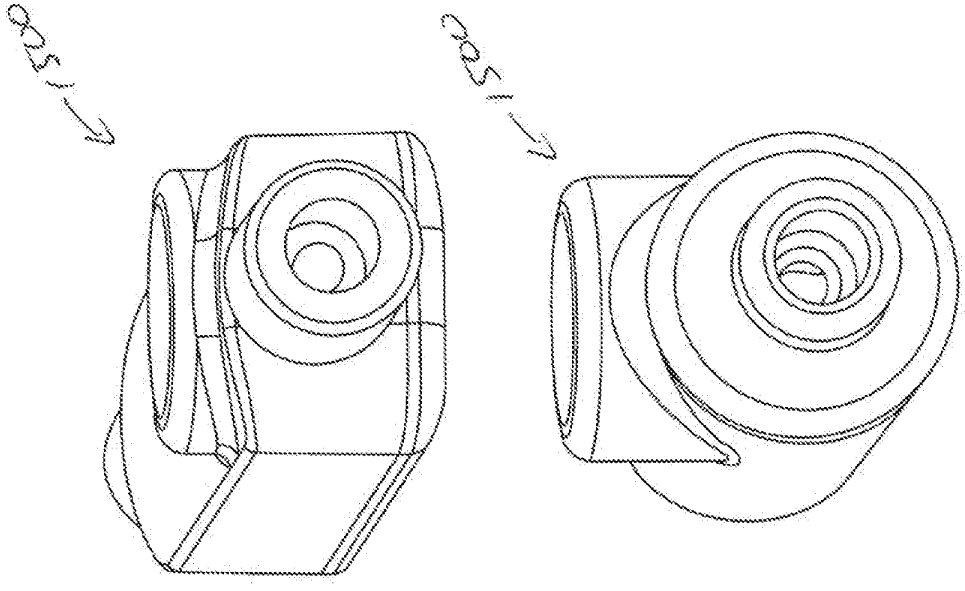


FIG. 15E

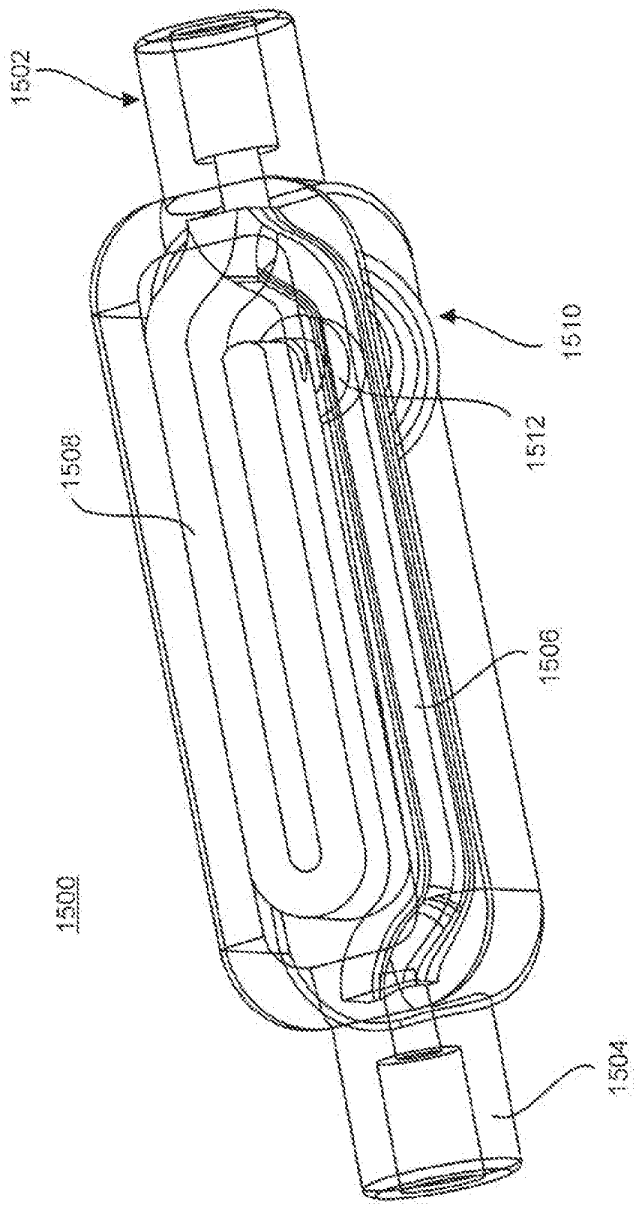


FIG. 15G

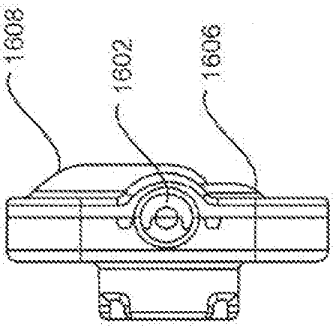


FIG. 16C

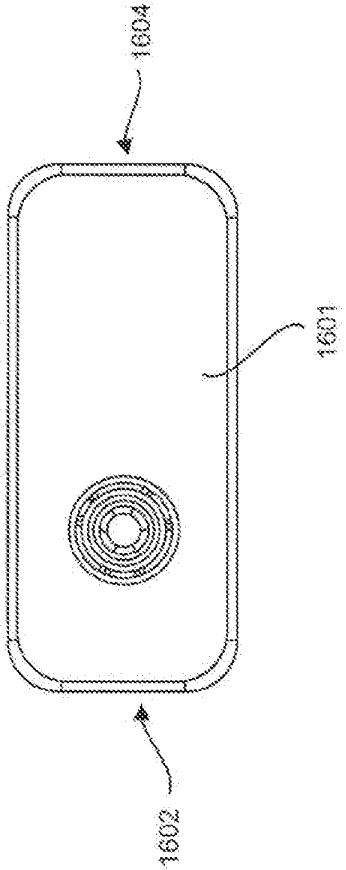


FIG. 16A

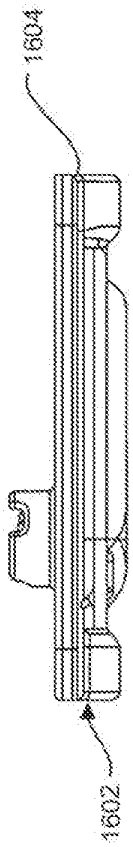


FIG. 16B

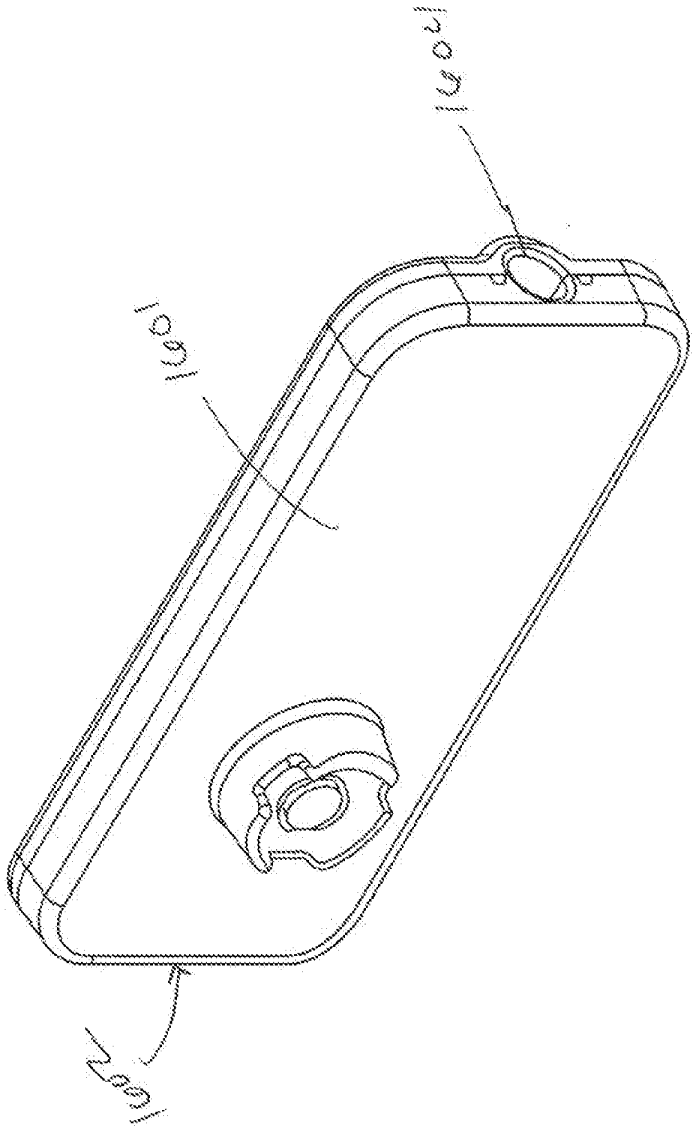


FIG. 16D

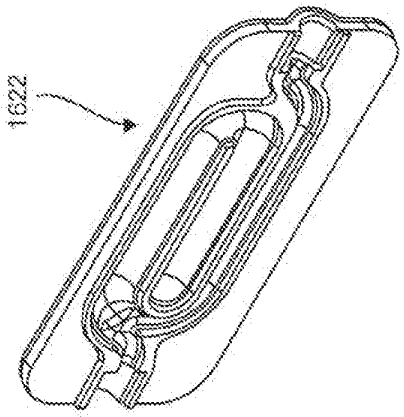


FIG. 17B

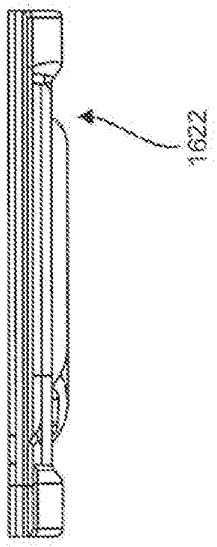


FIG. 17E

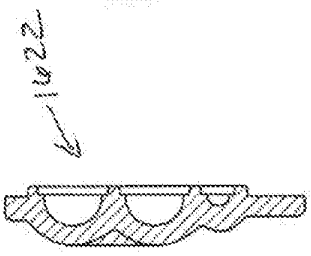


FIG. 17D

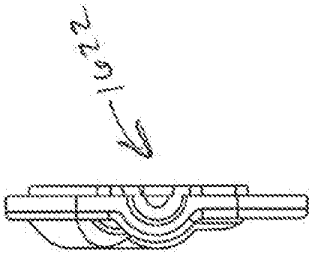


FIG. 17C

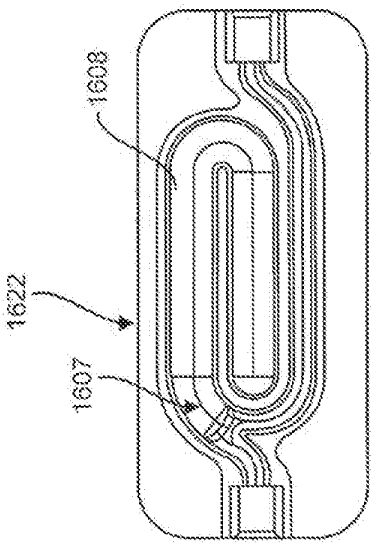


FIG. 17A

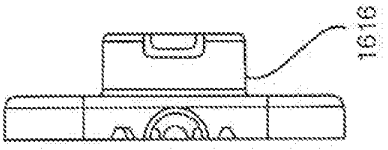


FIG. 18C

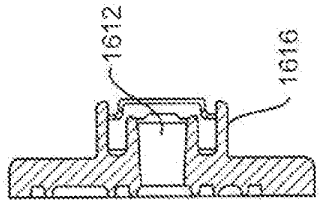


FIG. 18F

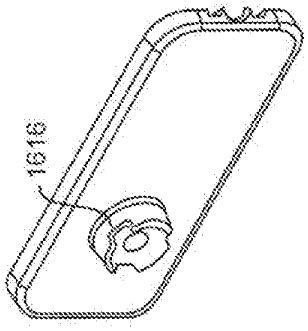


FIG. 18B

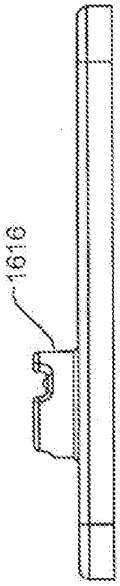


FIG. 18E

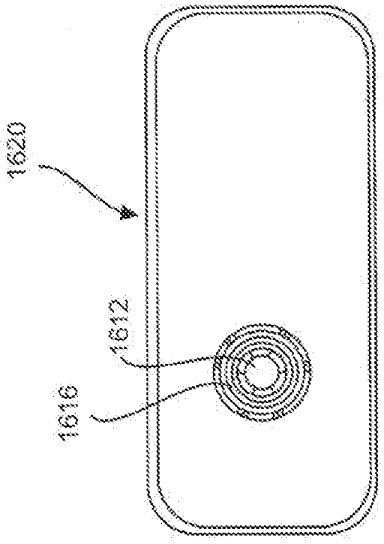


FIG. 18A

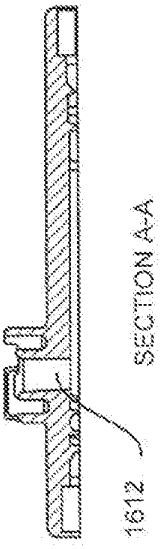


FIG. 18D

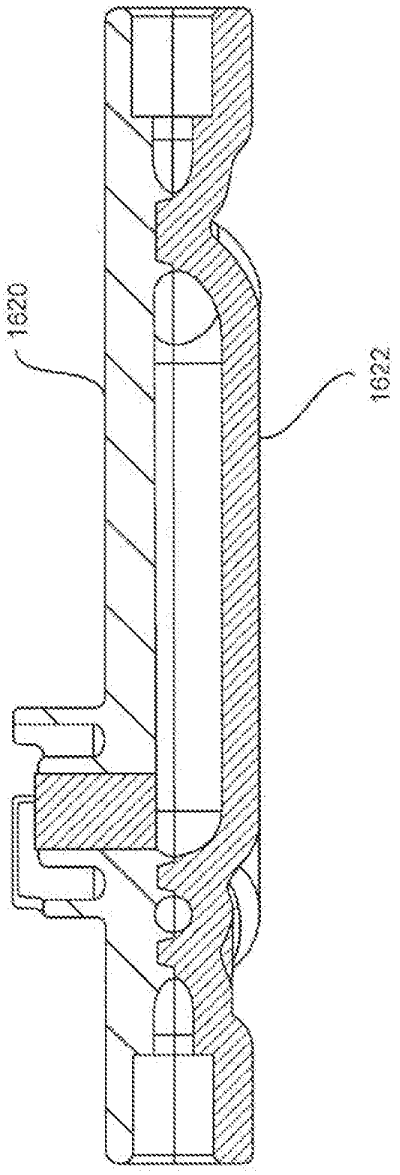


FIG. 19A

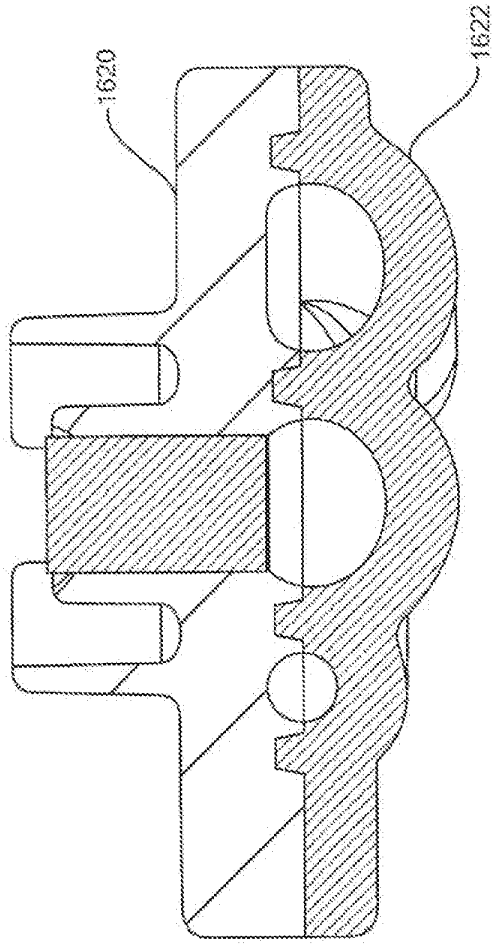


FIG. 19B

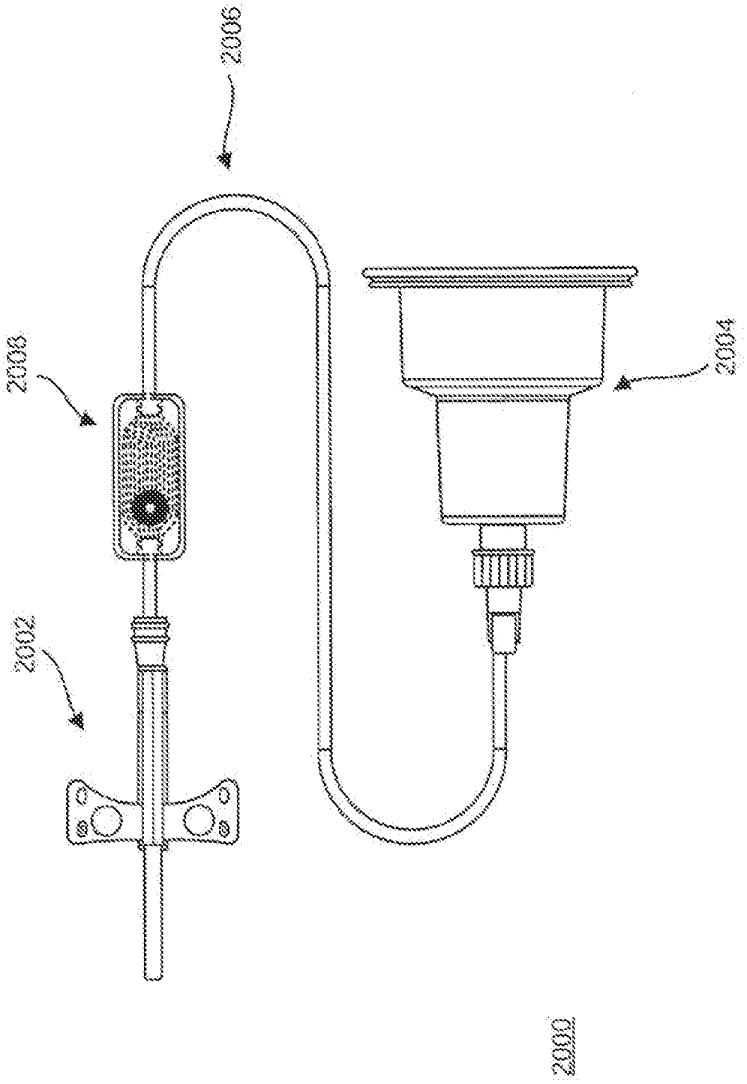


FIG. 20

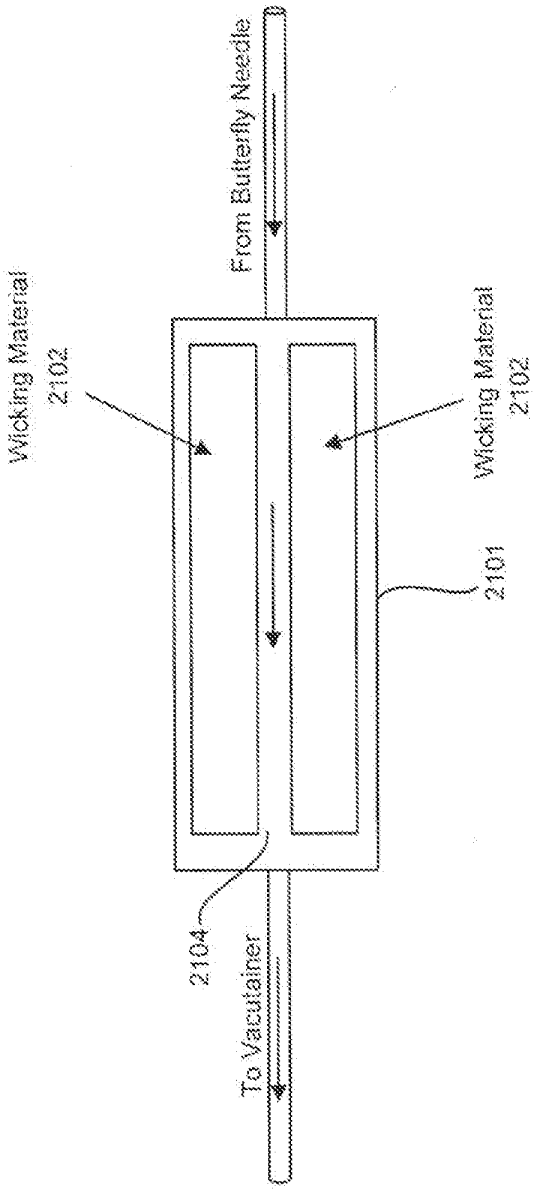

From Butterfly Needle
Wicking Material
2102
Wicking Material
2102
2101
2104
To Vacutainer
2100

FIG. 21

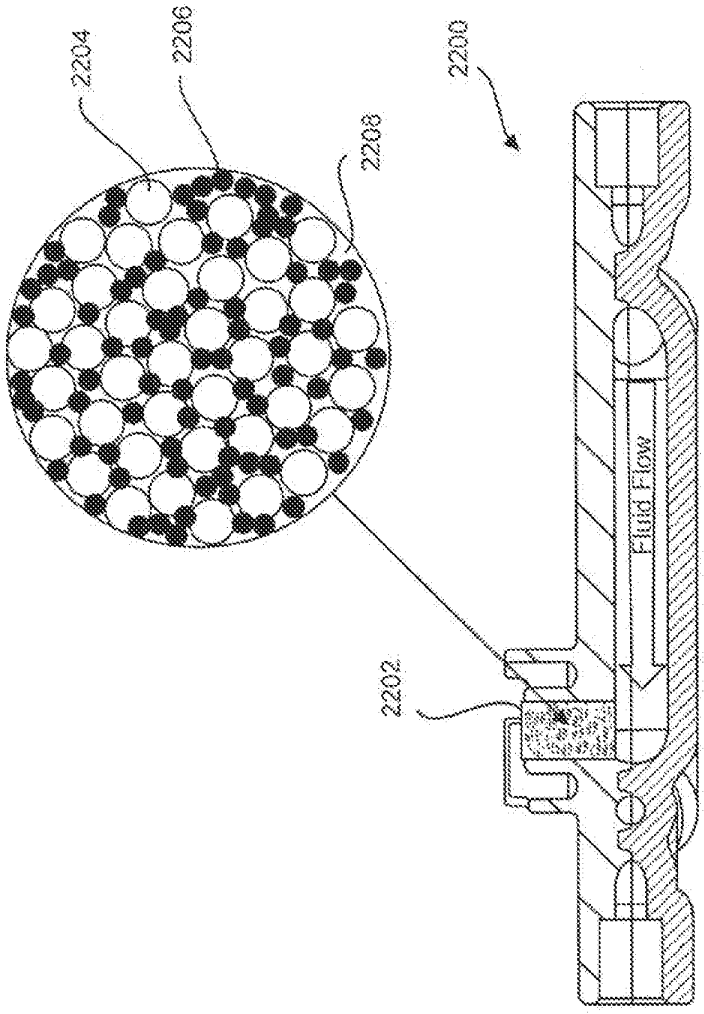


FIG. 22A

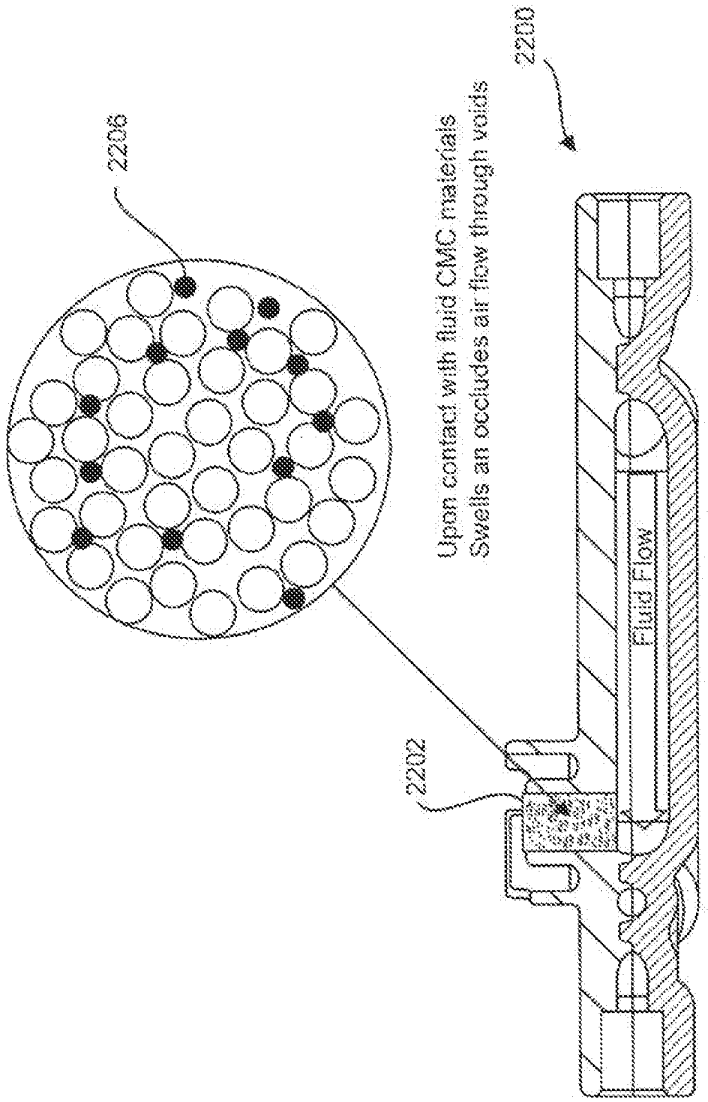

2206
Upon contact with fluid CMC materials
Swells an occludes air flow through voids
2200
Fluid Flow
2202

FIG. 22B

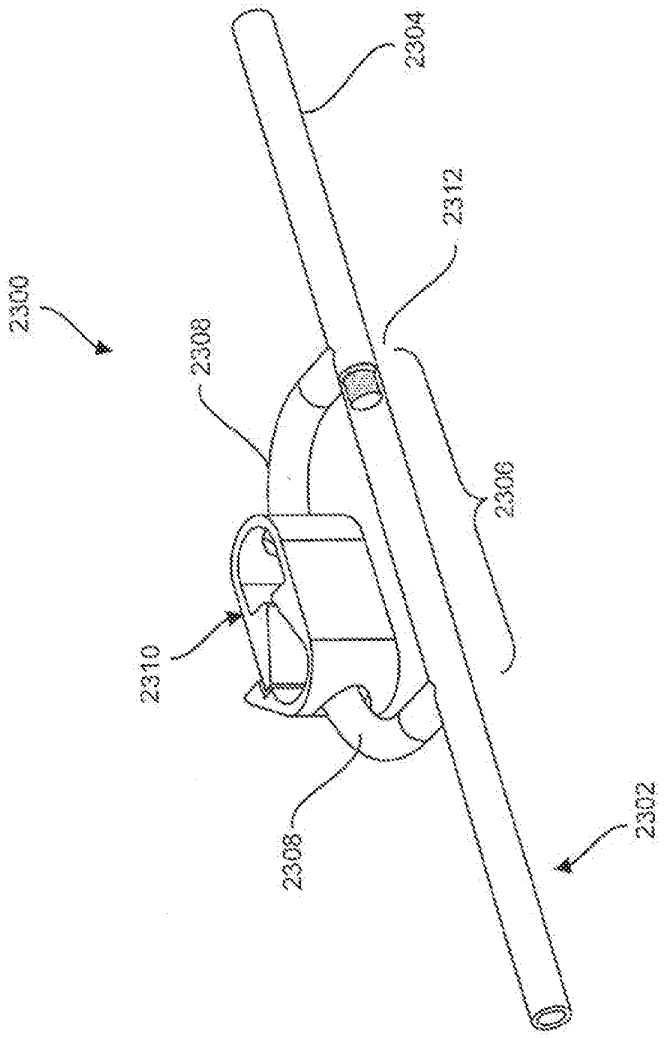


FIG. 23A

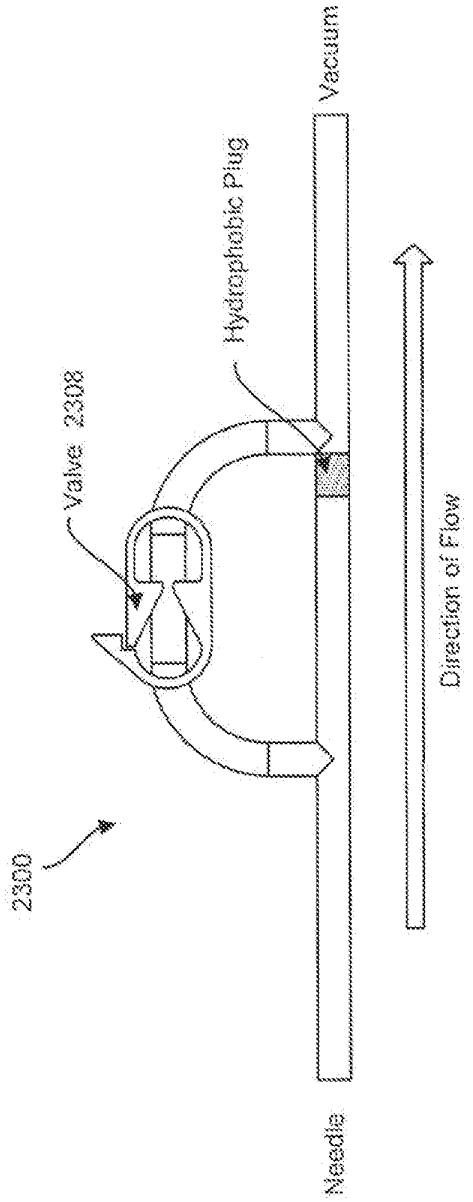

2300
Valve 2308
Hydrophobic Plug
Vacuum
Needle
Direction of Flow

FIG. 23B

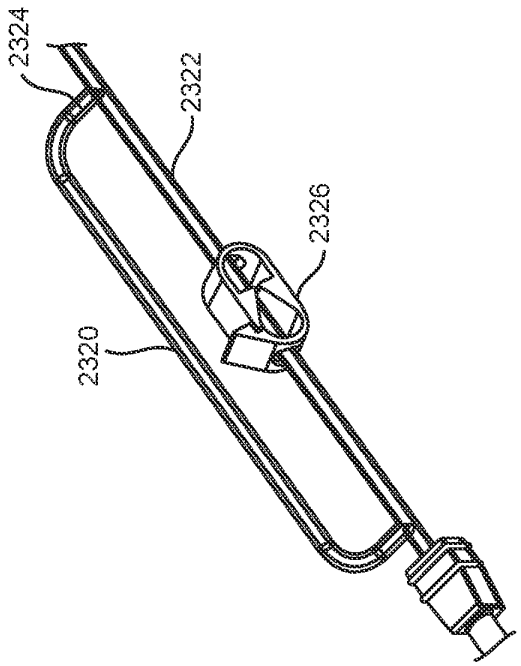


FIG. 23D

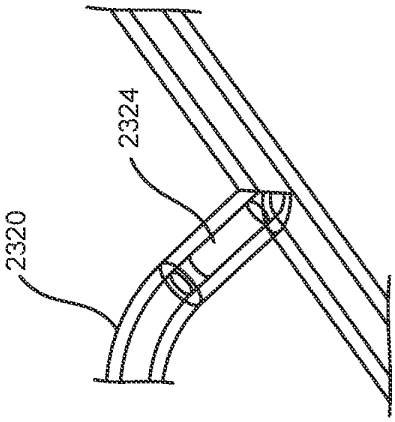


FIG. 23E

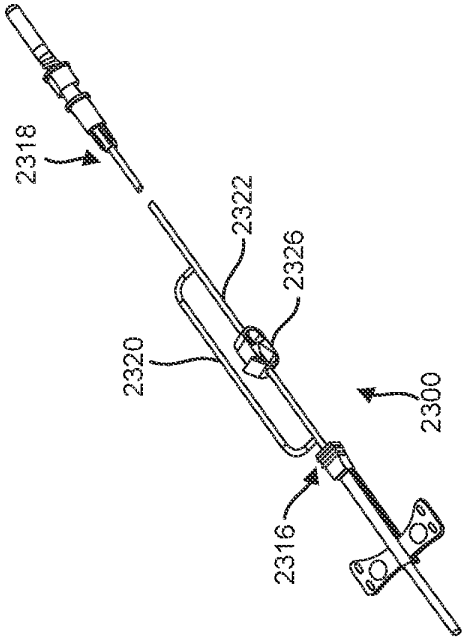


FIG. 23C

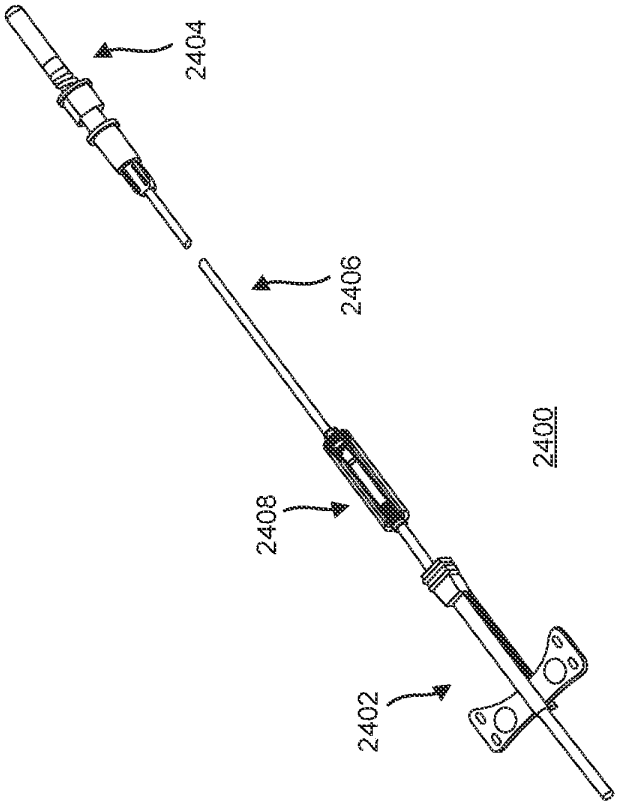


FIG. 24A

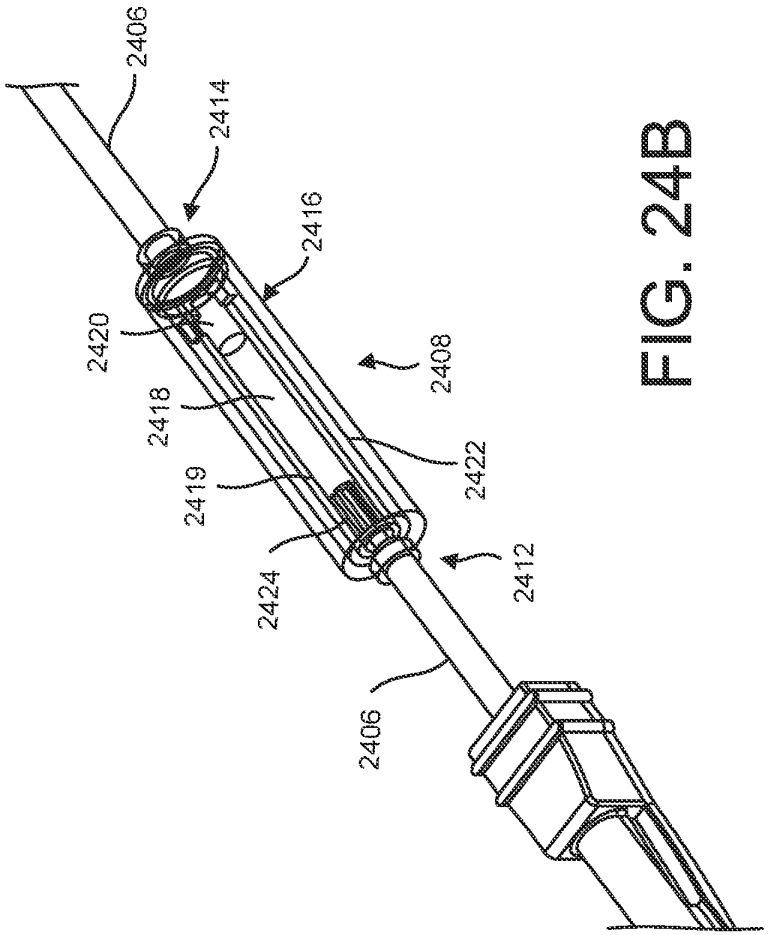


FIG. 24B

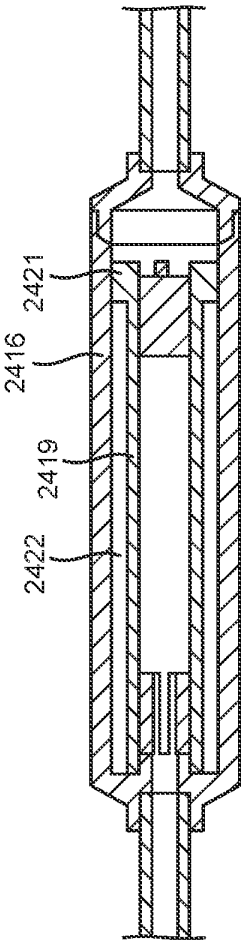


FIG. 24C

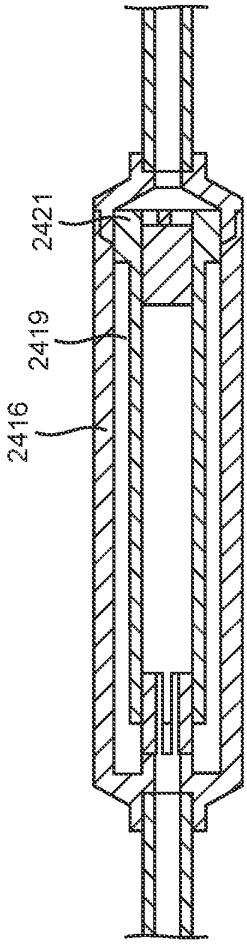


FIG. 24D

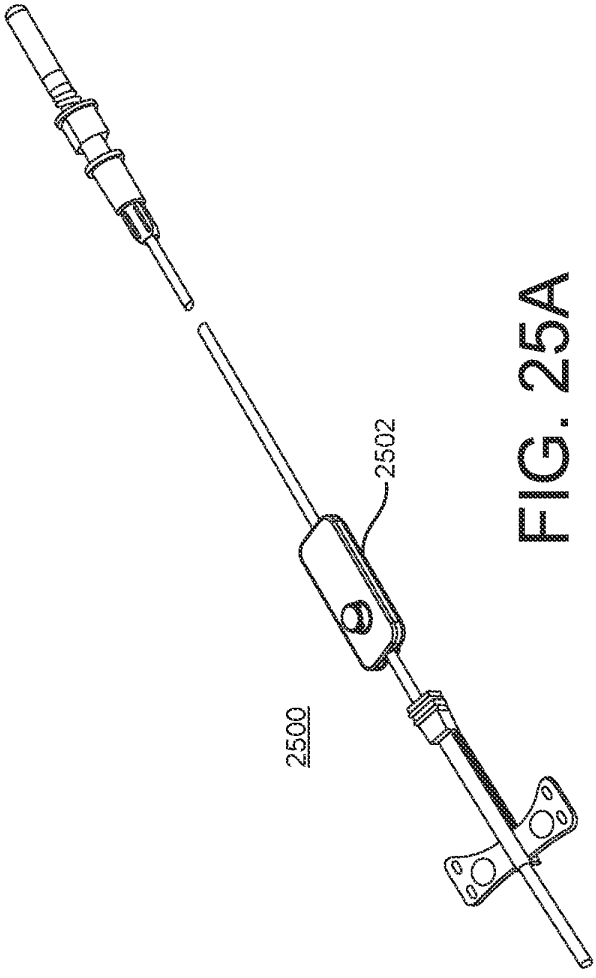


FIG. 25A

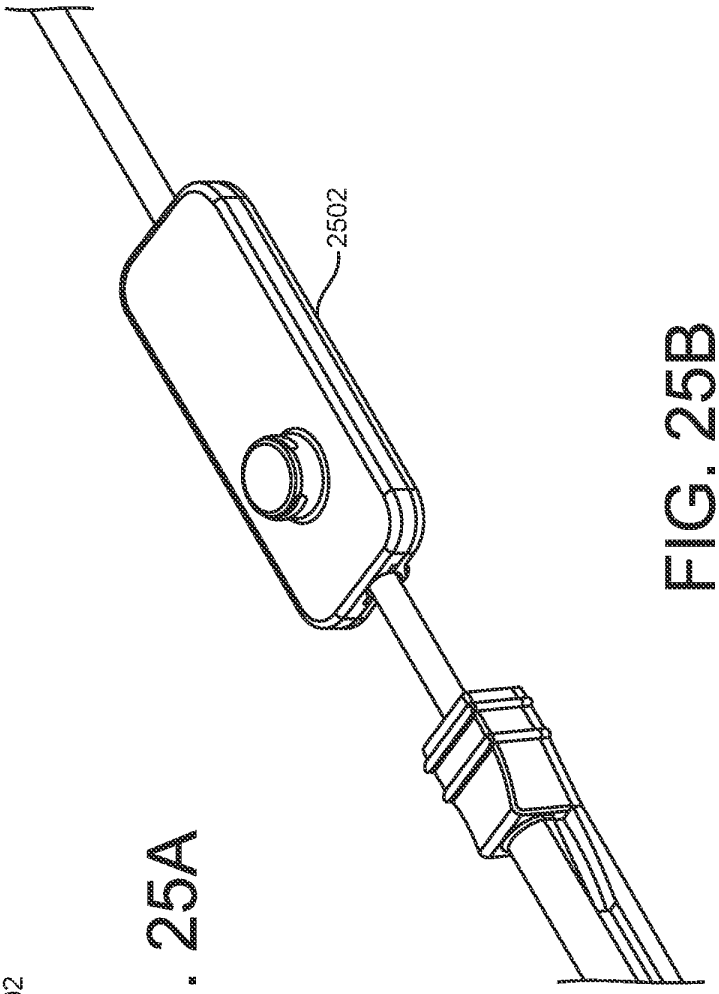


FIG. 25B

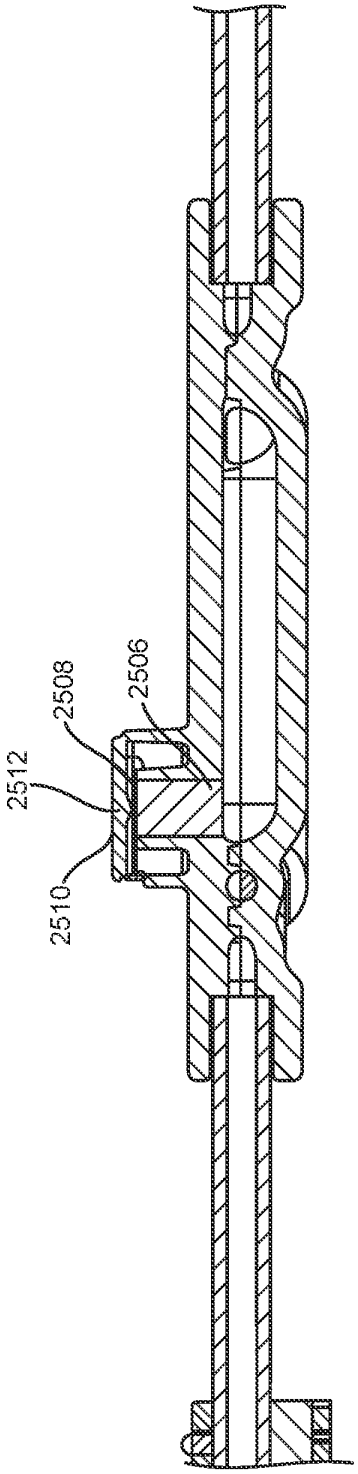


FIG. 25C

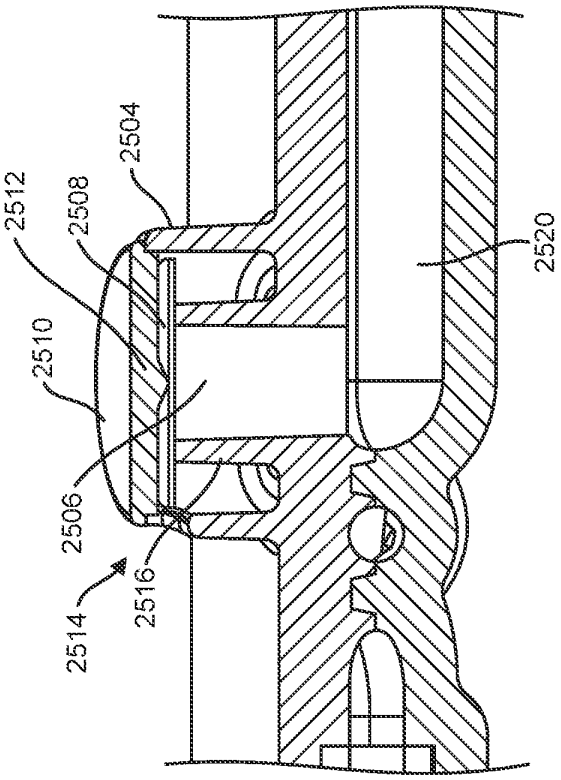


FIG. 25D

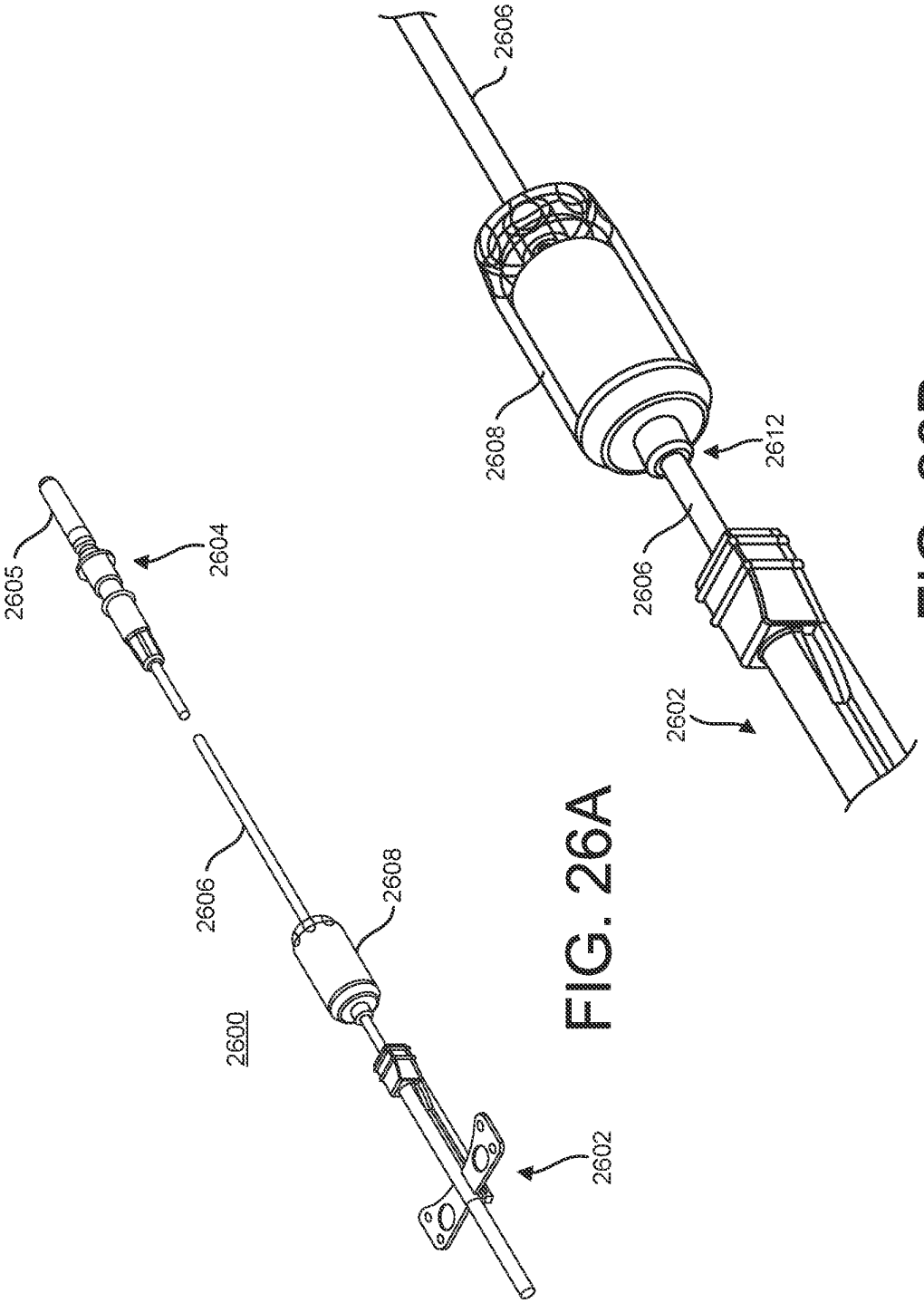


FIG. 26A

FIG. 26B

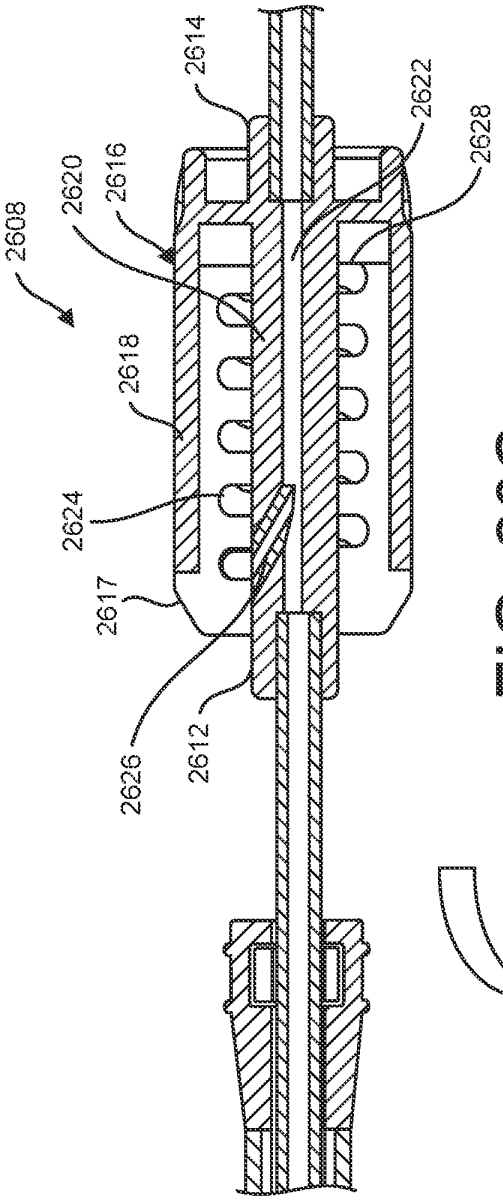


FIG. 26C

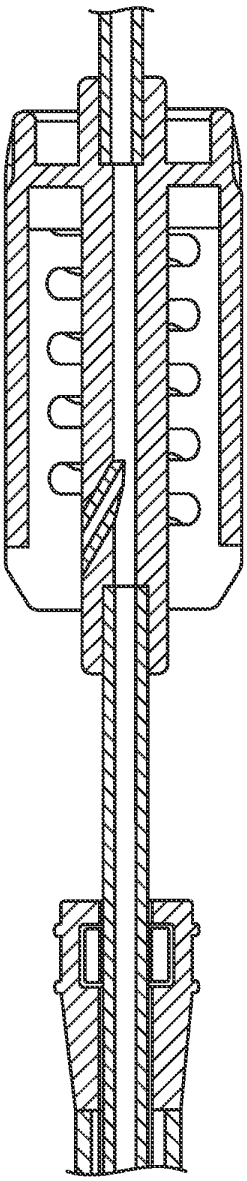


FIG. 26D

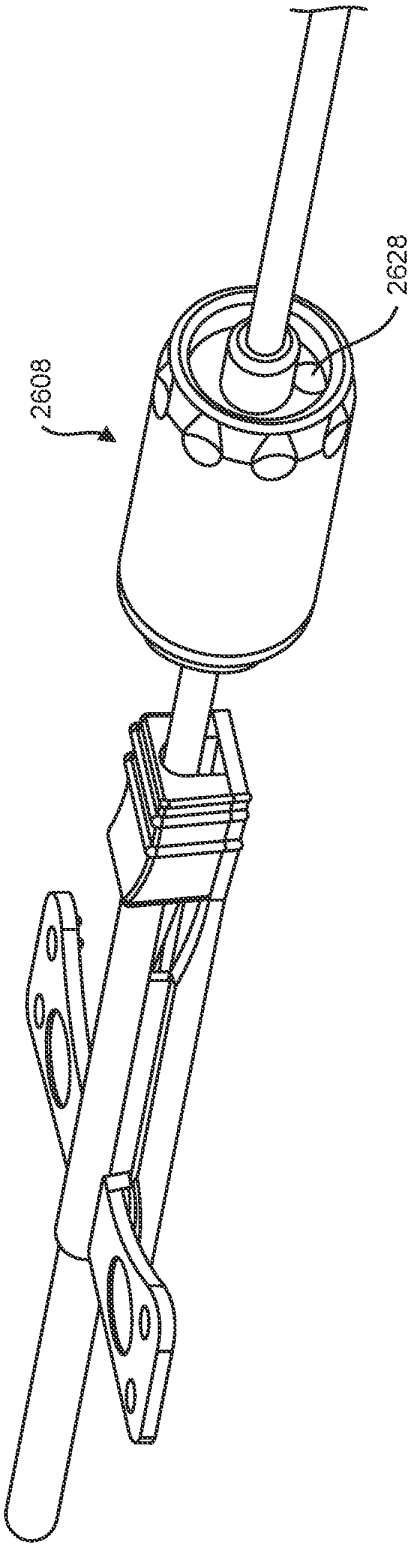


FIG. 26E

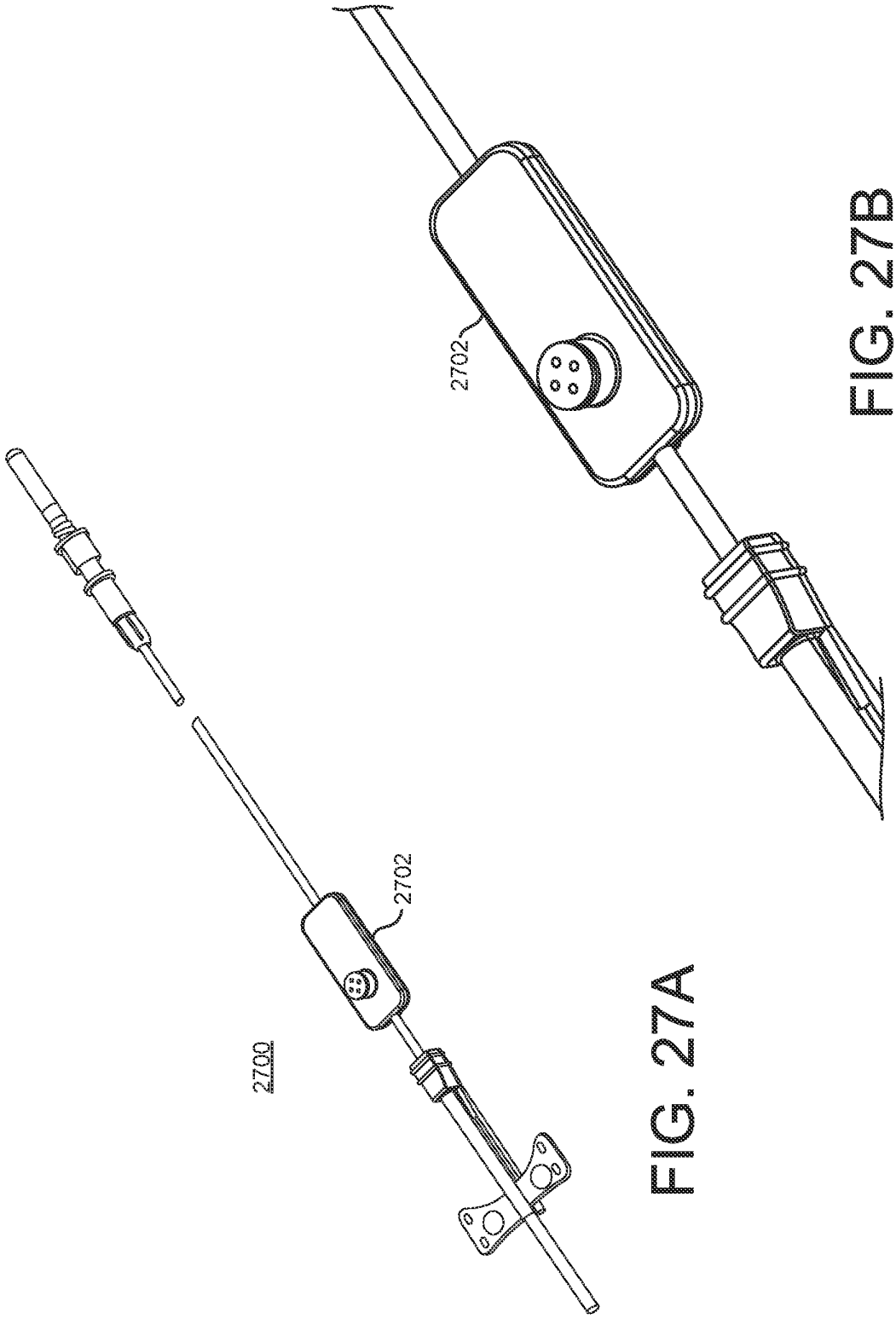


FIG. 27A

FIG. 27B

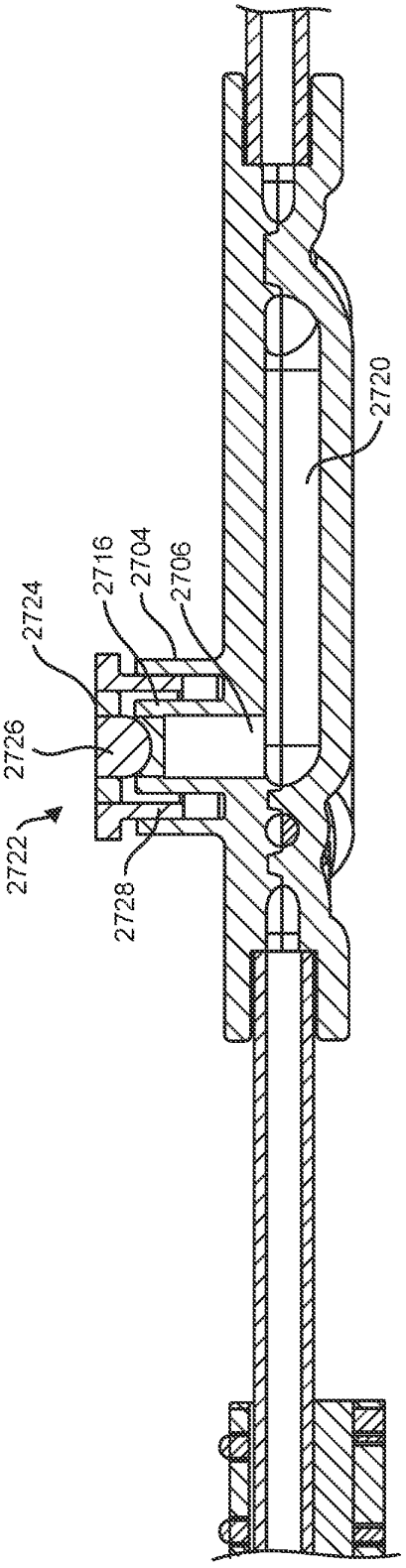


FIG. 27C

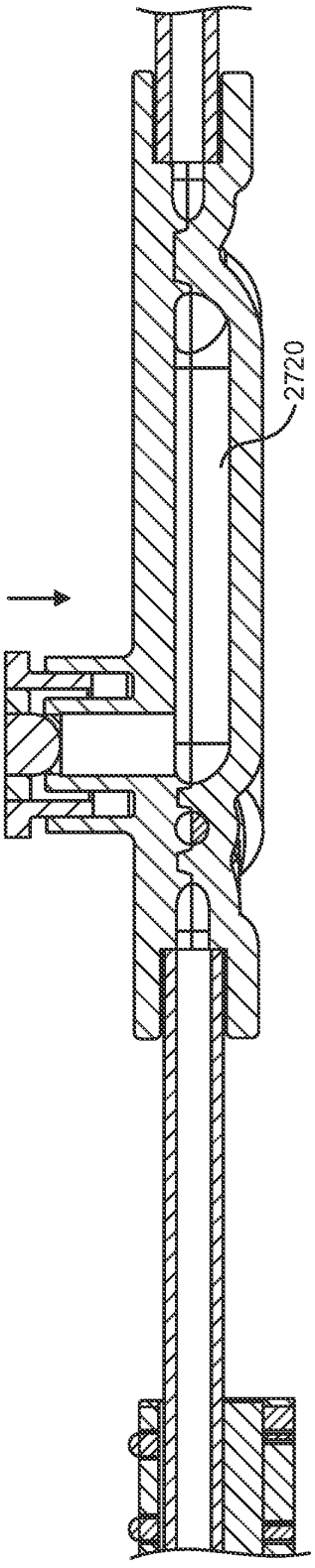


FIG. 27D

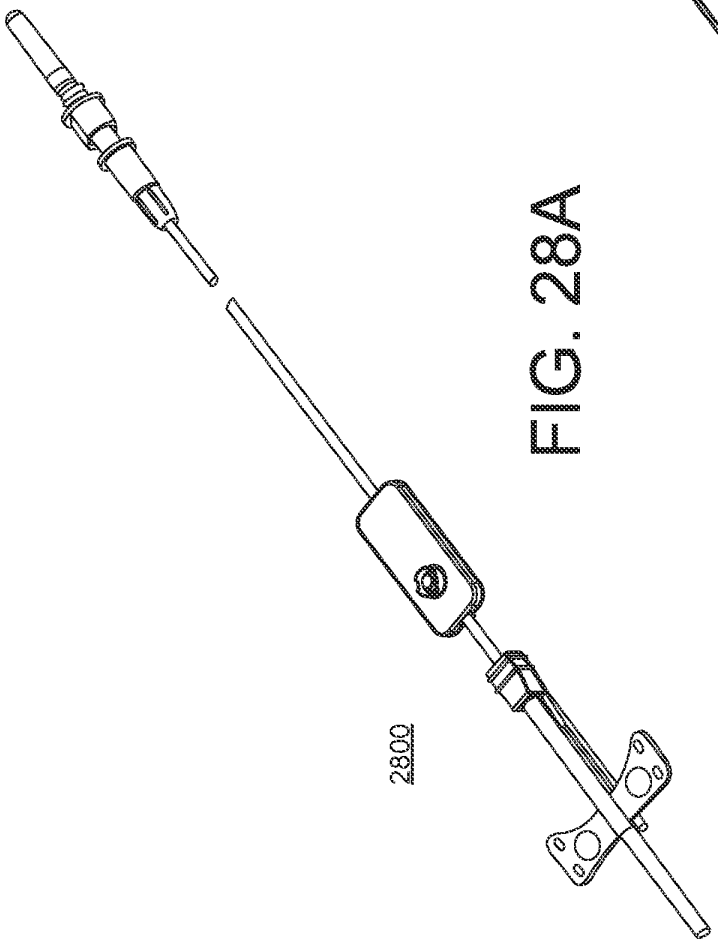


FIG. 28A

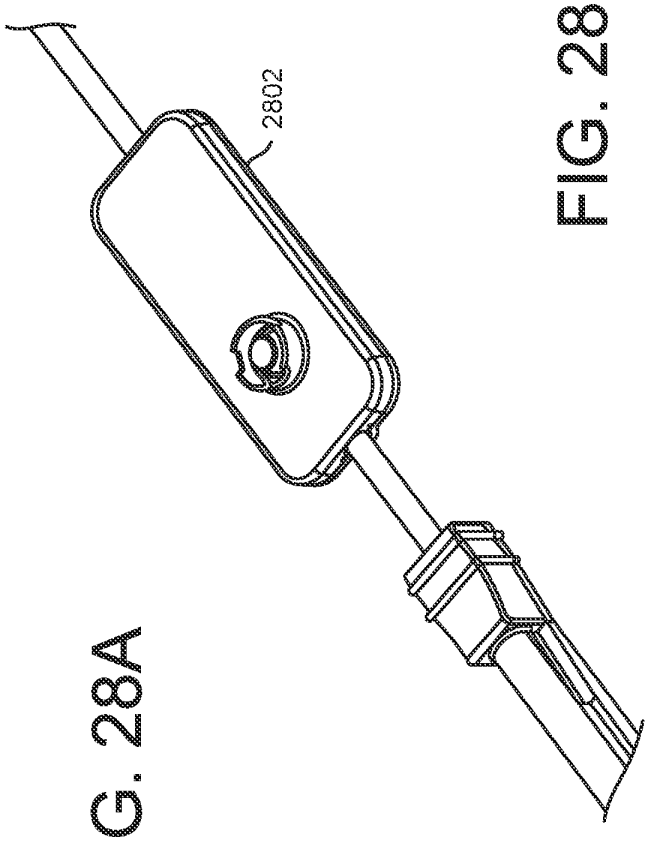


FIG. 28B

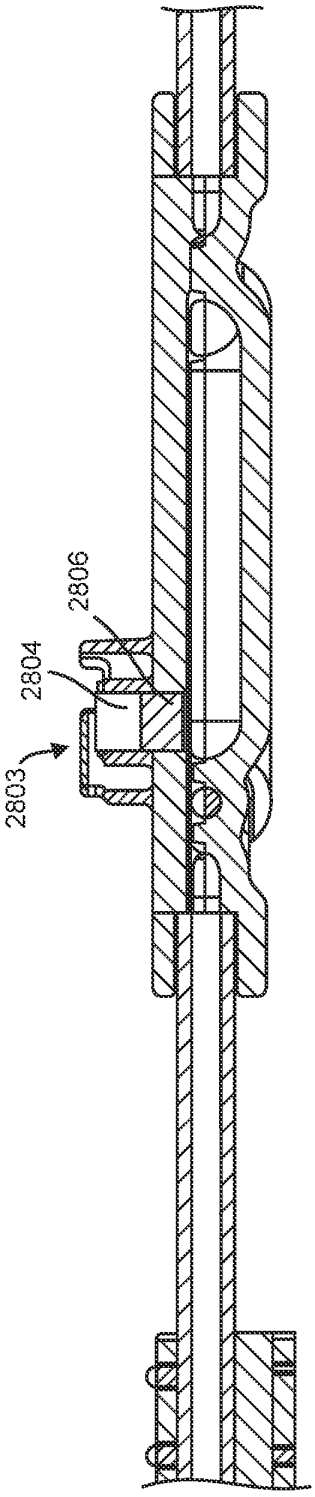


FIG. 28C

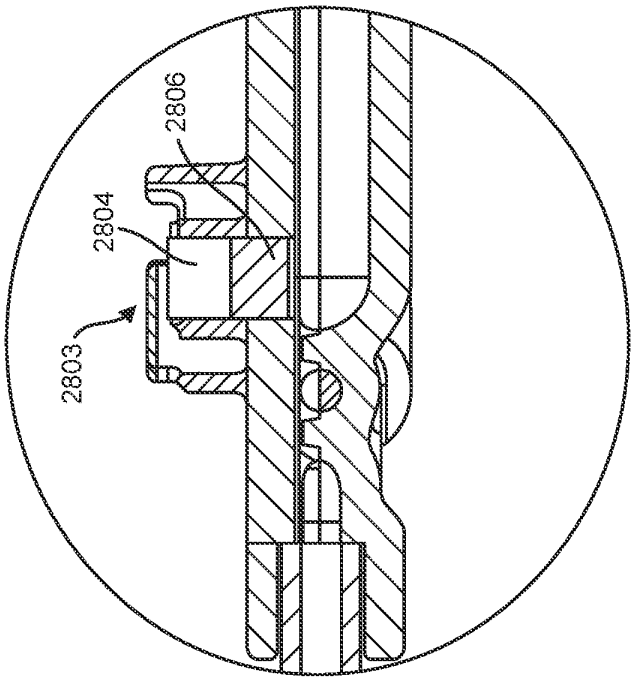


FIG. 28D

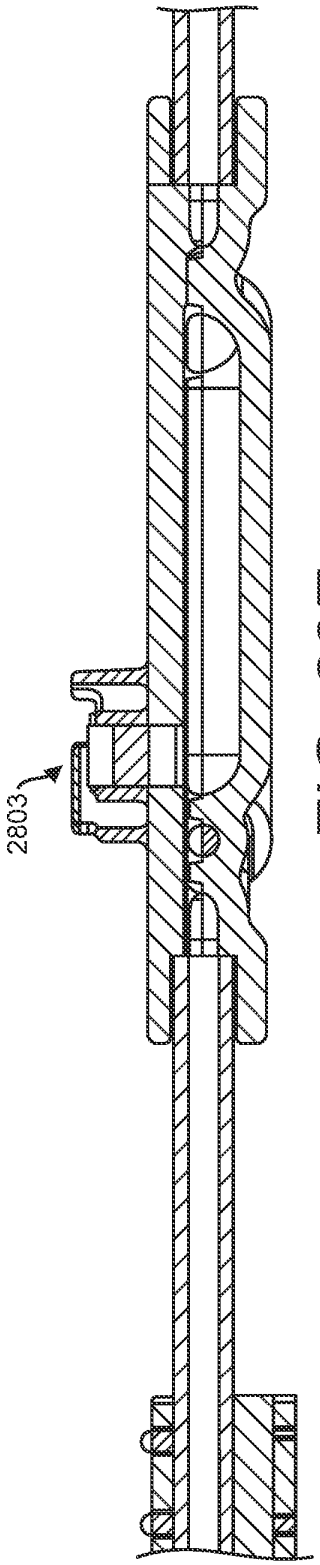


FIG. 28E

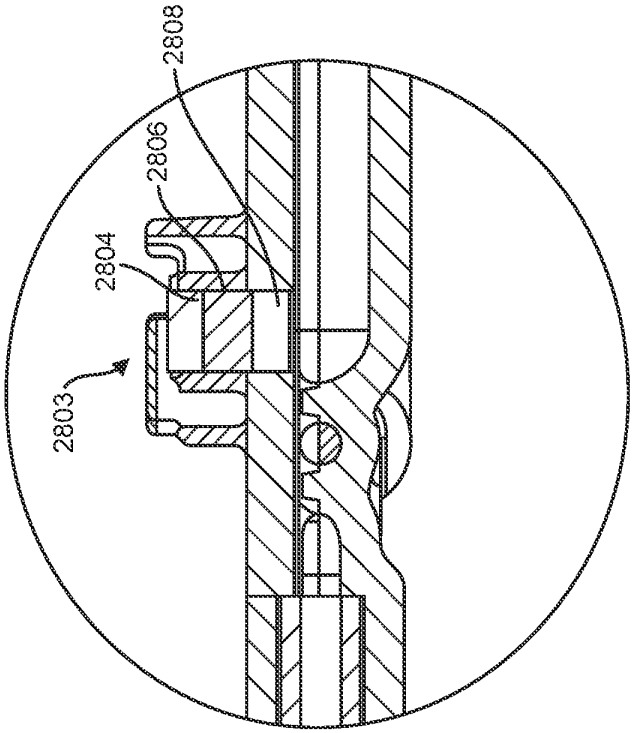


FIG. 28F

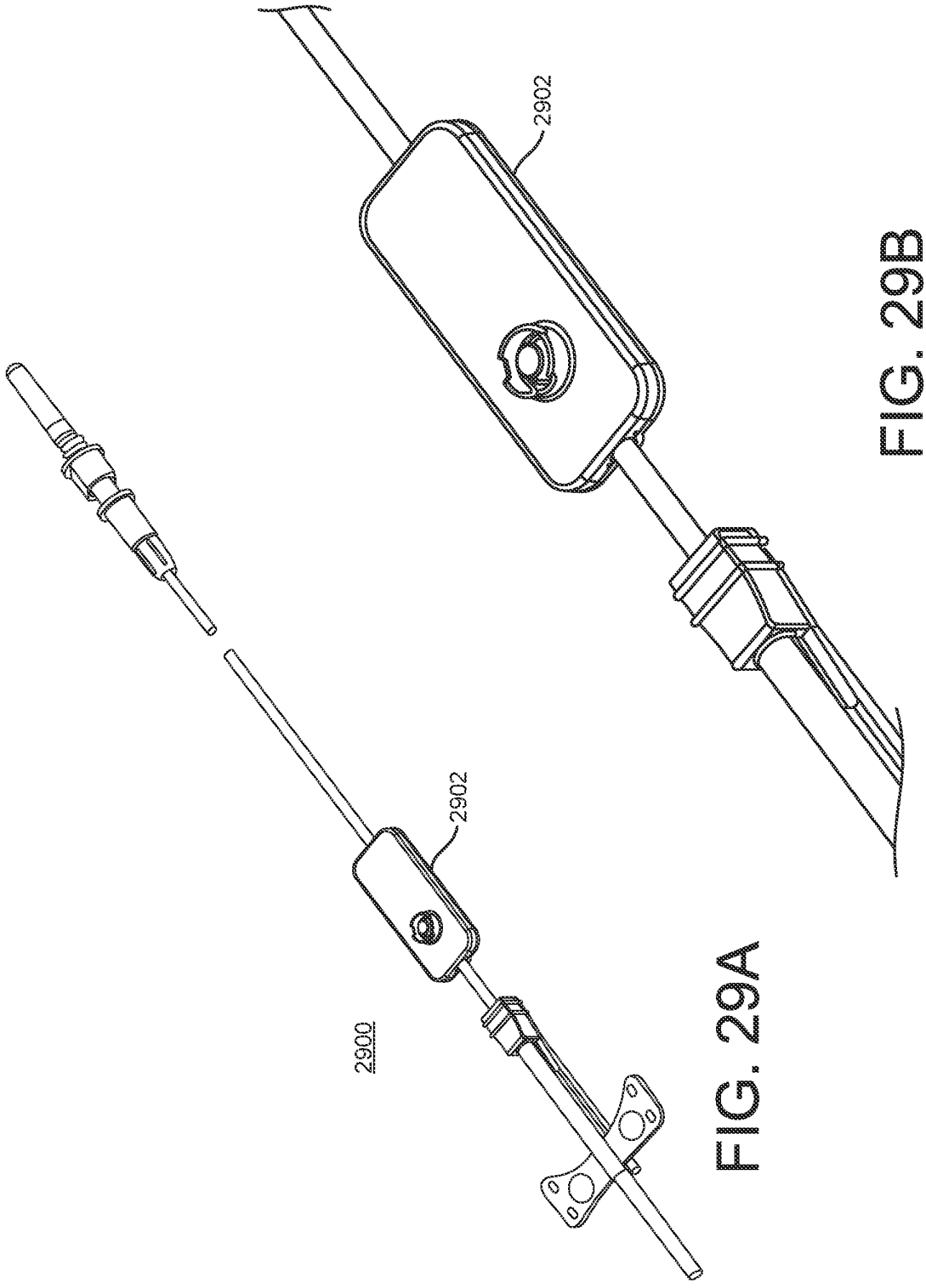


FIG. 29B

FIG. 29A

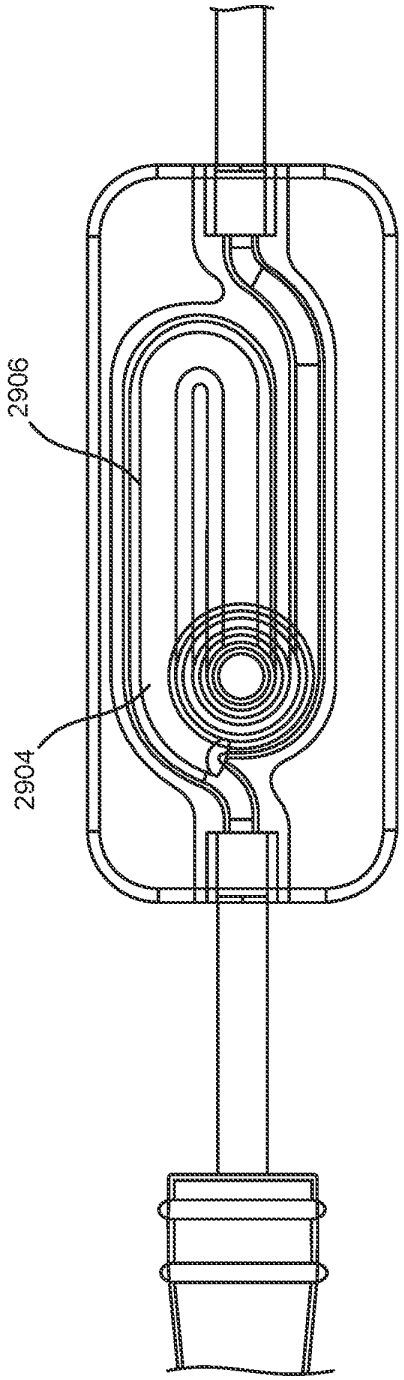


FIG. 29C

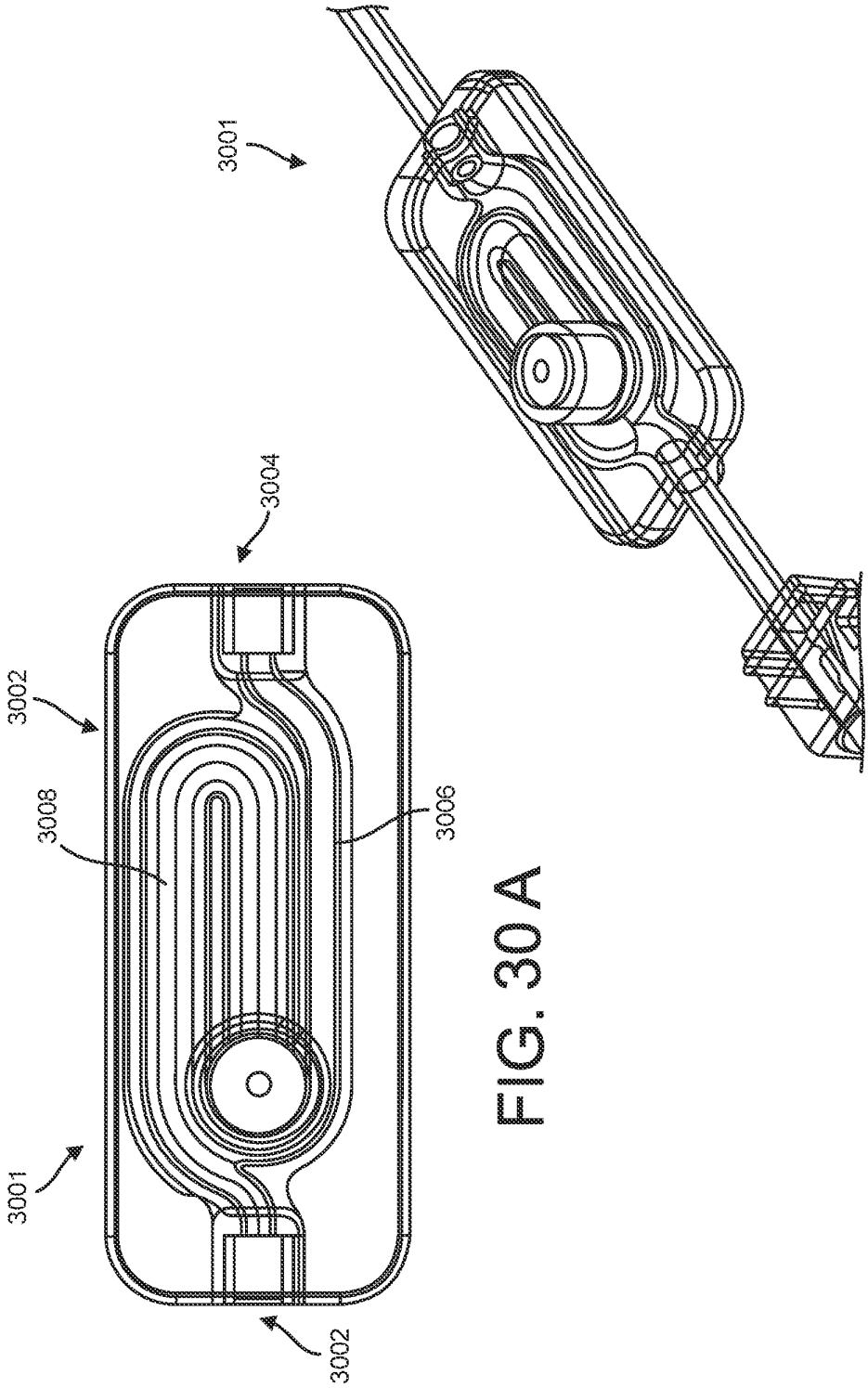


FIG. 30A

FIG. 30B

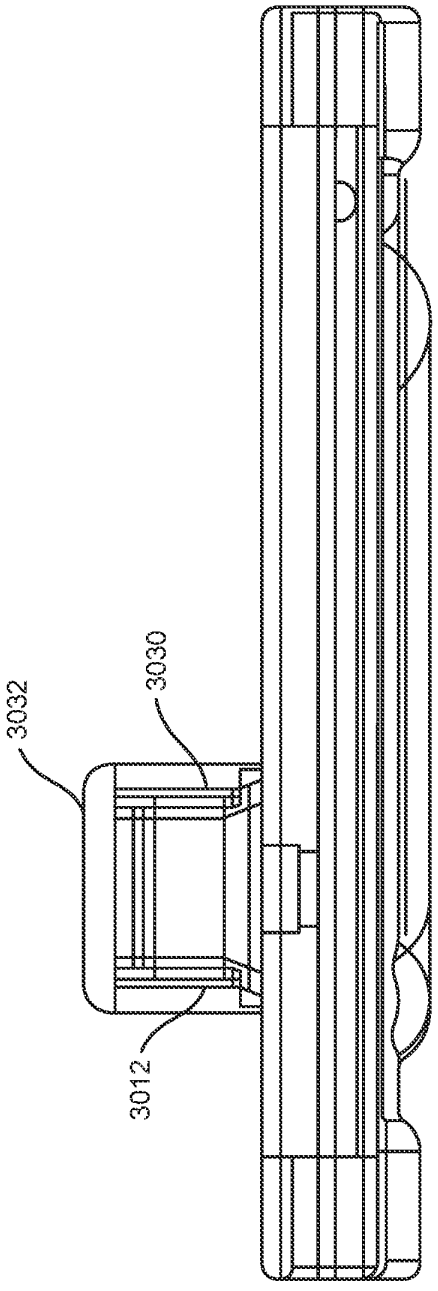


FIG. 30C

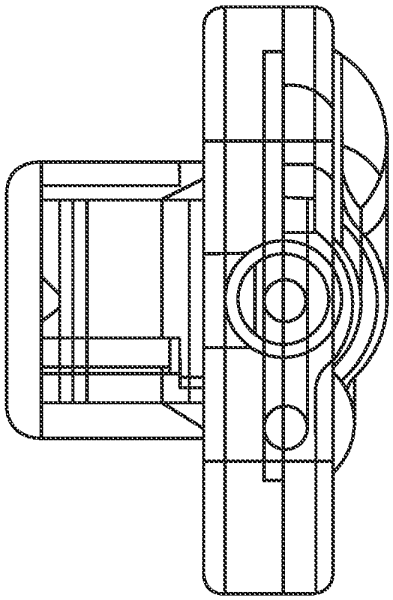


FIG. 30D

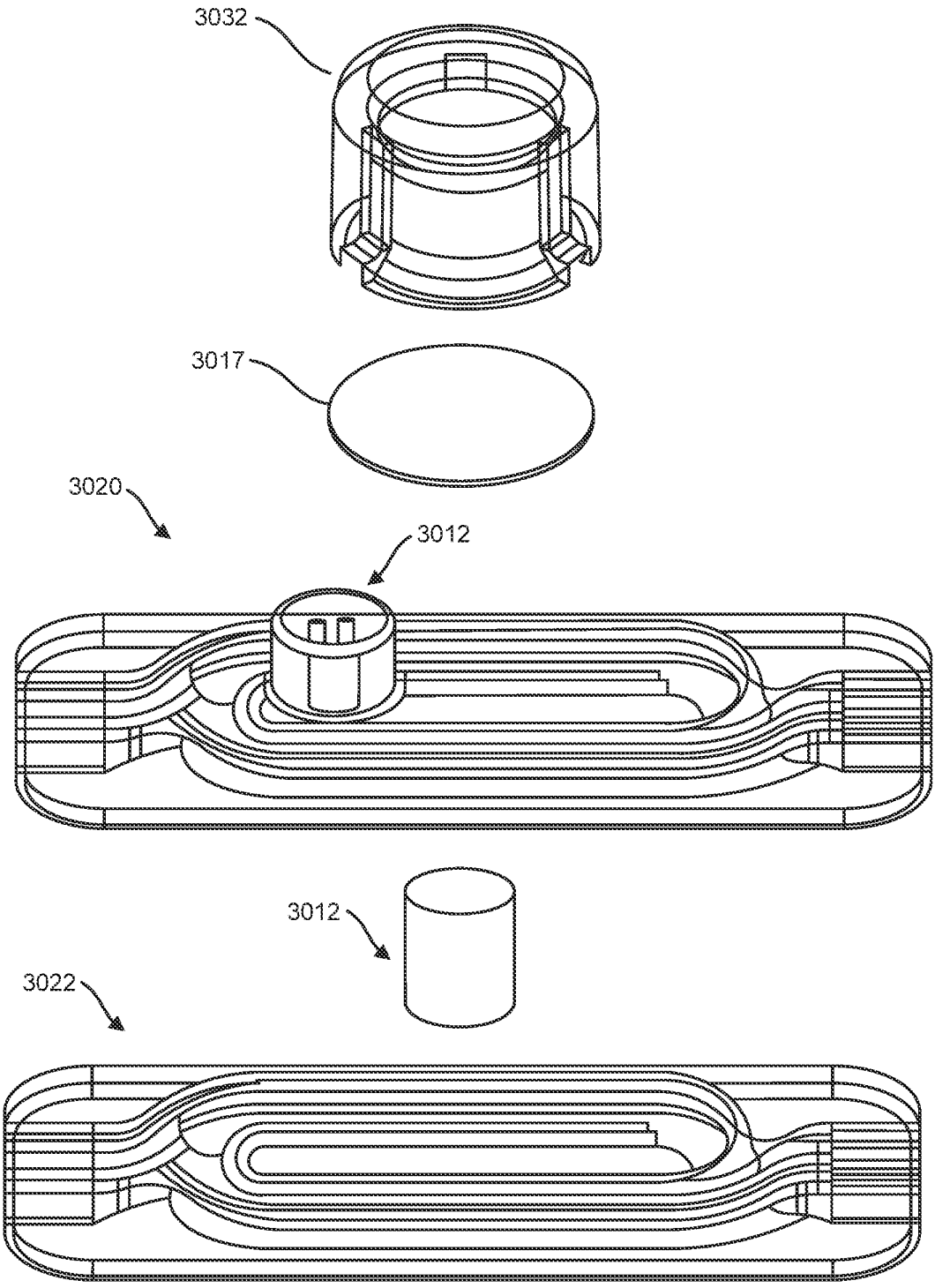


FIG. 30E

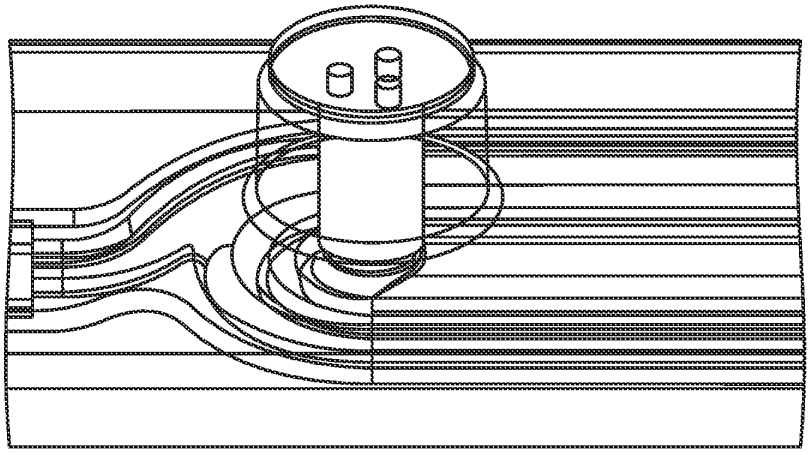


FIG. 30F

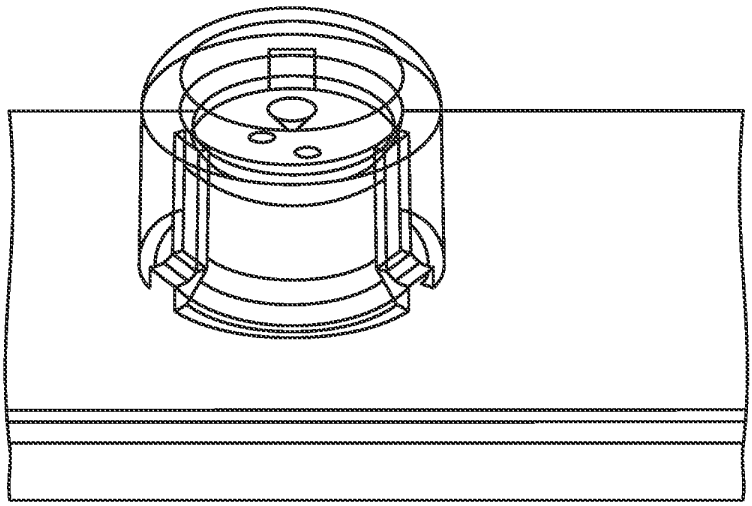


FIG. 30G

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/893,079	08/22/2022	Bobby E. ROGERS	069366-0572192_KUR3C02US	6240

27500 7590 03/12/2025

PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
ATTENTION: DOCKETING DEPARTMENT
P.O BOX 10500
McLean, VA 22102

EXAMINER	
NGUYEN, HUONG Q	

ART UNIT	PAPER NUMBER
3791	

NOTIFICATION DATE	DELIVERY MODE
03/12/2025	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Docket_IP@pillsburylaw.com

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 17/893,079	**Applicant(s)** ROGERS et al.	
	Examiner Huong Q NGUYEN	**Art Unit** 3791	**AIA (First Inventor to File) Status** Yes

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 28 February 2025 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

NO NOTICE OF APPEAL FILED

1. ☑ The reply was filed after a final rejection. No Notice of Appeal has been filed. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114 if this is a utility or plant application. Note that RCEs are not permitted in design applications. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires ____ months from the mailing date of the final rejection.
   b) ☑ The period for reply expires on: (1) the mailing date of this Advisory Action; or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
   c) ☐ A prior Advisory Action was mailed more than 3 months after the mailing date of the final rejection in response to a first after-final reply filed within 2 months of the mailing date of the final rejection.The current period for reply expires ____ months from the mailing date of *the prior Advisory Action* or SIX MONTHS from the mailing date of the final rejection, whichever is earlier.
   Examiner Note: If box 1 is checked, check either box (a), (b) or (c). ONLY CHECK BOX (b) WHEN THIS ADVISORY ACTION IS THE FIRST RESPONSE TO APPLICANTS FIRST AFTER-FINAL REPLY WHICH WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. ONLY CHECK BOX (c) IN THE LIMITED SITUATION SET FORTH UNDER BOX (c). See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) or (c) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendments filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   b) ☐ They raise the issue of new matter (see NOTE below);
   c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.
   NOTE: _____ (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☐ For purposes of appeal, the proposed amendment(s):(a)☐ will not be entered; or (b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____
9. ☐ The affidavit or other evidence filed after final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
10. ☐ The affidavit or other evidence filed after the date of filing the Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
11. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

12. ☑ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
13. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
14. ☐ Other: _____.

STATUS OF CLAIMS

15. The status of the claim(s) is (or will be) as follows:
    Claim(s) allowed:_____.
    Claim(s) objected to:_____.
    Claim(s) rejected:1-2,6-7 and 32-39.
    Claim(s) withdrawn from consideration:_____.

/RENE T TOWA/
Primary Examiner, Art Unit 3791

Continuation of REQUEST FOR RECONSIDERATION/OTHER 12. The request for reconsideration has been considered but does NOT place the application in condition for allowance because: Applicant's arguments have been fully considered but are not persuasive. Applicant contends that Percarpio does not disclose the chamber “connected with the inlet port and the outlet port” because Percarpio discloses that contaminated fluid in channel 92 does not go to the outlet, and thus the chamber (defined as channel 92) cannot be “fluidly connected” to outlet port 40/42 (Remarks pg. 6). However, it is noted that the fact that contaminated fluid in channel 92 does not go to the outlet is similar to applicant’s invention, which uses an air permeable blood barrier that allows air to vent from the sequestration chamber until it is contacted by the blood, “such material then becomes completely or partially sealed to prevent or inhibit the passage of air and/or liquid” (0060 of published spec). Thus, applicant’s own invention also does not allow fluid that has entered the chamber to flow into the outlet and thus cannot be an argument against Percarpio.

Additionally, applicant has misinterpreted the statement made in the Response to Arguments in the final dated 12/31/2024. As previously presented, it is submitted that “channel 92 is connected to chamber 32, which is fluidly connected to outlet 40/42. Thus, Percarpio disclose chamber 92 (channels) connected to outlet 40/42 as broadly as has been claimed” (Response to Arguments, 12/31/2024). The ability of channel 92 to “connect” to chamber 32, wherein chamber 32 is fluidly connected to outlet 40/42, is the reason channel 92 is considered “connected to the outlet port” as broadly as has been claimed. In other words, the office does not take the position that the chamber is “fluidly connected” to the outlet port, as such limitation has not been presented recited. It is submitted that since fluid can flow from the inlet, to chamber 32, and then to channel 92, with chamber 32 being in fluid communication with the outlet port, this satisfies the broad recitation of “the chamber connected to the outlet port.”

Applicant also contends that Percarpio’s chamber “does not exit to an outlet port” (Remarks pg. 6). However, it is noted that this limitation is not required by the claim, as the recitation of “connected to the outlet port” is much more broad and does not require “exit to the outlet port,” which implies direction of fluid flow. As previously submitted, the claims do not specify any particular direction or manner of fluid flow . Furthermore, it is noted that the given that the fluid first flows into the chamber 92 before flowing into the outlet port, as per applicant’s own invention, this sequence in the order of flow may be interpreted to mean that the chamber “exits” to an outlet port.

Applicant also contends that “it is not reasonable to interpret Claim 1’s two recited separate connections to inlet and outlet as met by a single connection in Percarpio” (Remarks pg. 6). This is not persuasive because it again appears that applicant is reading into the claims. The claims as currently presented do not provide any detail toward the nature of the connection of the outlet relative to the chamber nor precludes “a single connection” for the inlet vs. outlet. While it is noted that while applicant provides two separate flow paths, provided by distinct structures that define said separate flow paths, that enable the flow between the inlet to the chamber, and then subsequently, the inlet to the outlet (without requiring the fluid in the chamber to flow into the outlet), such distinction has not been claimed. Applicant confirms this interpretation in the following statement: “Said another way, a proper interpretation of the claimed device is one where the chamber reconnects with the outlet port similarly to sample channel 2308 (see, Fig. 23A above). That is, from the inlet port there are two paths (through the chamber or through the sampling channel) and these two paths reconnect to the outlet port. Percarpio is structurally different in that the exit of chamber 92 never reconnects with (outlet port) passageway 42” (Remarks pg. 8).

Again, the claim as broadly as have been recited do not require two structurally separate flow paths. Therefore, the claims do NOT require Percarpio to have a separate flow path from the chamber 92 to the outlet 40/42 from that used by the inlet to flow to the outlet. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See In re Van Geuns, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Lastly, it is noted that the film 90 has been interpreted as a part of the chamber 92 since, as disclosed by Percarpio, fluid flow from chamber 92 contacts film 90. While applicant contends that “were the Office inclined to consider the combined area containing Percarpio’s elements 90 and 92 as disclosing the claimed chamber including the material that is air permeable and blood impermeable, then it would be even more clear that such a chamber would not connect back to the alleged outlet port (element 40/42). Instead, the exit of such a chamber would be disclosed by Percarpio as venting to the outside — the stated purpose of film 90” (Remarks pg. 9), it is noted that this again constitutes applicant’s reading into the claims. As noted above, applicant’s own invention does not allow the air permeable blood barrier to enable blood to flow to the exit. The only difference is that the location of the air permeable blood barrier of the instant invention is positioned closer to the exit, unlike in Percarpio. However, this limitation is also not presently claimed.

CONSIDERED: /H.Q.N/

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Bobby E. Rogers, et al. **Confirmation No:** 6240

Application No.: 17/893,079 **Art Unit:** 3791

Filed: August 22, 2022 **Examiner:** Huong Q. Nguyen

For: BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE TO FINAL OFFICE ACTION

Dear Examiner Nguyen:

This reply is responsive to the Final Office Action mailed December 31, 2024, in the above-referenced matter (hereinafter "the Office Action"). Reconsideration and allowance of the application is requested in view of the following:

Listing of Claims beginning on page 2.

Remarks beginning on page 5.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/317,558	05/15/2023	Bobby E. ROGERS	069366-0575710_KUR4C02US	8048

27500 7590 10/22/2024

PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
ATTENTION: DOCKETING DEPARTMENT
P.O BOX 10500
McLean, VA 22102

EXAMINER	
ABOUELELA, MAY A	

ART UNIT	PAPER NUMBER
3791	

NOTIFICATION DATE	DELIVERY MODE
10/22/2024	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Docket_IP@pillsburylaw.com

Office Action Summary	Application No. 18/317,558	Applicant(s) ROGERS et al.	
	Examiner MAY A ABOUELELA	Art Unit 3791	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 05/15/2023.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL.** 2b) ☑ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 1 is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 1 is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to **PPHfeedback@uspto.gov.**

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☑ The drawing(s) filed on 05/15/2023 is/are: a)☑ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☑ Notice of References Cited (PTO-892)

2) ☑ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

Notice of Pre-AIA or AIA Status

1. The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 04/23/2023, 06/27/2024, 08/26/2024 and 10/16/2024. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the claims at issue are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the reference application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO internet Web site contains terminal disclaimer forms which may be used. Please visit http://www.uspto.gov/forms/. The filing date of the application will determine what form should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to http://www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp.

Claim 1 is non-provisionally rejected on the ground of non-statutory double patenting as being unpatentable over claims 1-20 of U.S Patent No. 10827964, and claims 1-43 of U.S Patent No. 11744494. Although the claims at issue are not identical, they are not patentably distinct from each other because the U.S Patent Applications and the instance application are claiming a common subject matter including: a blood sequestration device comprising; an inlet port; an outlet port; a sequestration chamber connected with the inlet port, the sequestration chamber having a vent configured to allow air to be displaced by a first portion of blood entering the inlet port and into the sequestration chamber; a closure to enclose the vent to inhibit air from entering the

sequestration chamber after the first portion of blood has displaced the air in the sequestration chamber; a sampling channel having a proximal end connected with the inlet port and a distal end connected with the outlet port, the sampling channel being configured to convey subsequent portions of blood to the outlet port after the first portion of blood has entered the sequestration chamber; and a housing that houses and defines the inlet port, the outlet port, the sequestration chamber, and the sampling channel.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MAY A ABOUELELA whose telephone number is (571)270-7917. The examiner can normally be reached 8-5.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JACQUELINE CHENG can be reached on 5712725596. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: https://patentcenter.uspto.gov. Visit https://www.uspto.gov/patents/apply/patent-

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/MAY A ABOUELELA/
Primary Examiner, Art Unit 3791

Notice of References Cited	Application/Control No. 18/317,558	Applicant(s)/Patent Under Reexamination ROGERS et al.	
	Examiner MAY A ABOUELELA	Art Unit 3791	Page 1 of 4

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*		Document Number Country Code-Number-Kind Code	Date YYYY-MM-DD	Name	CPC Classification	US Classification
*	A	US-20080319346-A1	2008-12-25	Crawford; Jamieson	A61B5/150656	600/576
*	B	US-4412548-A	1983-11-01	Hoch; Louis	A61B5/150213	600/577
*	C	US-5222502-A	1993-06-29	Kurose; Katsutoshi	A61B5/150732	600/584
*	D	US-5520193-A	1996-05-28	Suzuki; Issei	A61B5/1545	604/126
*	E	US-20100057004-A1	2010-03-04	Christensen; Kelly D.	A61M25/0606	604/122
*	F	US-20070088279-A1	2007-04-19	Shue; Ming-Jeng	A61M25/0693	604/168.01
*	G	US-20080145933-A1	2008-06-19	Patton; Richard G.	A61B5/154	435/379
*	H	US-20040054333-A1	2004-03-18	Theeuwes, Felix	A61M5/14276	604/248
*	I	US-9022951-B2	2015-05-05	Bullington; Gregory	A61B5/150221	600/576
*	J	US-6569117-B1	2003-05-27	Ziv; David	A61M39/02	604/246
*	K	US-3741197-A	1973-06-26	Sanz; Manuel C.	A61B5/150267	600/583
*	L	US-20100010372-A1	2010-01-14	BROWN; LEROY R.	A61B5/15003	600/573
*	M	US-8603009-B2	2013-12-10	Tan; Alvin Chee Leong	A61B5/150251	600/573

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*		Document Number Country Code-Number-Kind Code	Date YYYY-MM-DD	Country	Name	CPC Classification
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	Examiner MAY A ABOUELELA	Art Unit 3791	Page 2 of 4

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*	A	US-9138572-B2	2015-09-22	Zeytoonian; Paul	A61M39/26	1/1
*	B	US-20080167577-A1	2008-07-10	Weilbacher; Eugene E.	A61B5/1545	600/576
*	C	US-20080086085-A1	2008-04-10	Brown; Leroy R.	A61B5/150389	604/122
*	D	US-9877675-B2	2018-01-30	Baid; Rishi	A61B5/150389	1/1
*	E	US-4444203-A	1984-04-24	Engelman; Allan	A61B5/150496	600/576
*	F	US-20070083162-A1	2007-04-12	O'Reagan; James	A61M39/26	604/167.03
*	G	US-6398743-B1	2002-06-04	Halseth; Thor R.	A61B5/15003	604/164.12
*	H	US-9022950-B2	2015-05-05	Bullington; Gregory	A61B5/150251	600/576
*	I	US-9155495-B2	2015-10-13	Bullington; Gregory J.	A61B10/0045	1/1
*	J	US-20160008579-A1	2016-01-14	Burkholz; Jonathan Karl	A61M5/158	604/164.08
*	K	US-20120016266-A1	2012-01-19	Burkholz; Jonathan Karl	A61B5/150992	600/581
*	L	US-4436098-A	1984-03-13	Kaufman; Joseph	A61B5/1545	604/199
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*	B	US-8568371-B2	2013-10-29	Siopes; William	A61M39/06	251/903
*	C	US-8540663-B2	2013-09-24	Davey; Christopher T.	A61M25/0029	604/93.01
*	D	US-8523826-B2	2013-09-03	Layton, Jr.; Russell K.	A61M39/16	604/533
*	E	US-20160174888-A1	2016-06-23	Berthier; Erwin	A61B5/150503	600/573
*	F	US-8197420-B2	2012-06-12	Patton; Richard G.	A61B5/150503	600/573
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*	H	US-20050240161-A1	2005-10-27	Crawford, Jamieson William McLean	A61B5/150816	604/264
*	I	US-20040147855-A1	2004-07-29	Marsden, Stewart	A61B5/150496	600/576
*	J	US-8864684-B2	2014-10-21	Bullington; Gregory J.	A61B10/0048	600/576
*	K	US-8535241-B2	2013-09-17	Bullington; Gregory	A61B5/150251	604/249
*	L	US-20130317391-A1	2013-11-28	Bullington; Gregory J.	A61B5/15003	600/578
*	M	US-20050004524-A1	2005-01-06	Newby, C. Mark	A61B5/150648	604/164.08

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*	B	US-5749857-A	1998-05-12	Cuppy; Michael J.	A61M25/0606	604/161
*	C	US-9060724-B2	2015-06-23	Bullington; Gregory J.	A61B5/150221	1/1
*	D	US-9204864-B2	2015-12-08	Bullington; Gregory J.	A61B10/0096	1/1
*	E	US-20020004647-A1	2002-01-10	Leong, Alvin Tan Chee	A61B5/15003	604/168.01
*	F	US-3817240-A	1974-06-18	Ayres; Waldemar A.	A61B5/150221	600/584
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*	I	US-4106497-A	1978-08-15	Percarpio; Edward P.	A61B5/150389	600/579
*	J	US-4207870-A	1980-06-17	Eldridge; William N.	A61B5/150732	604/167.03
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Doc description: Information Disclosure Statement (IDS) Filed

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	18317558
	Filing Date	2023-05-15
	First Named Inventor	Bobby E. ROGERS
	Art Unit	3791
	Examiner Name	ABOUELELA, MAY A
	Attorney Docket Number	069366-0572186_KUR4C02US

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	4312362		1982-01-26	KAUFMAN JOSEPH	

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	1	20140163419		2014-06-12	BULLINGTON GREGORY J	
	2	20140309558		2014-10-16	FLETCHER GARY D	
	3	20140073990		2014-03-13	HOLMES ELIZABETH A	
	4	20140323911		2014-10-30	SLOAN DEBORAH	
	5	20040112808		2004-06-17	TAKAGI YOSHIKI	

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	Filing Date	2023-05-15
	First Named Inventor	Bobby E. ROGERS
	Art Unit	3791
	Examiner Name	ABOUELELA, MAY A
	Attorney Docket Number	069366-0572186_KUR4C02US

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	1	Office Action (Non-Final Rejection) dated 9/24/2024 for U.S. Application No. 18/783,173 ; Attorney Docket No. 069366-0580420_KUR3C03US (pages 1-62).	☐
	2	Office Action (Non-Final Rejection) dated 9/17/2024 for U.S. Application No. 17/893,079 ; Attorney Docket No. 069366-0572192_KUR3C02US (pages 1-50).	☐
	3	Office Action (Non-Final Rejection) dated 9/23/2024 for U.S. Application No. 17/730,118 ; Attorney Docket No. 069366-0572186_KUR3C01US (pages 1-73).	☐
	4	Office Action (Non-Final Rejection) dated 9/17/2024 for U.S. Application No. 18/783,088 ; Attorney Docket No. 069366-0580418_KUR2C06US (pages 1-60).	☐
	5	Office Action (Notice of Deficiencies) dated 10/14//2023 for IL App No. 309380 (pages 1-7).	☐

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Examiner Signature	/MAY A ABOUELELA/	Date Considered	10/17/2024

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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	Examiner Name	ABOUELELA, MAY A
	Attorney Docket Number	069366-0572186_KUR4C02US

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

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	Art Unit	3791
	Examiner Name	ABOUELELA, MAY A
	Attorney Docket Number	069366-0572186_KUR4C02US

CERTIFICATION STATEMENT

Please see 37 CFR 1.97(e) to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☒ A certification statement is not submitted herewith.

FEE

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

COPIES

☐ An identification of an earlier application pursuant to 37 CFR 1.98 (d) (1) is attached.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2024-10-16
Name/Print	Benjamin F. Hudson	Registration Number	71,474

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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The information provided by you in this form will be subject to the following routine uses:

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3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

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5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

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Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

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	1	6126643		2000-10-03	VAILLANCOUERT VINCENT L	
	2	9764891		2017-09-19	AVILES VICTOR M	
	3	5147329		1992-09-15	BRANNON JAMES K	
	4	5518005		1996-05-21	BRANNON JAMES K	
	5	62845767		2019-05-09	BREWER MICHAEL	

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	1	20150314105		2015-11-05	GASPARYAN LEVON	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	18317558
	Filing Date	2023-05-15
	First Named Inventor	Bobby E. ROGERS
	Art Unit	3791
	Examiner Name	ABOUELELA, MAY A
	Attorney Docket Number	069366-0572186_KUR4C02US

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	7	20180297303		2018-10-18	SEKIGUCHI TAKUMI	
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	1	Office Action (Non-Final Rejection) dated 04/25/2023 for US App. 16838017 (pages 1-20).	☐
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	Examiner Name	ABOUELELA, MAY A
	Attorney Docket Number	069366-0572186_KUR4C02US

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	Attorney Docket Number	069366-0572186_KUR4C02US

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Examiner Signature	/MAY A ABOUELELA/	Date Considered	10/17/2024

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	Attorney Docket Number	069366-0572186_KUR4C02US

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

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☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2024-06-27
Name/Print	Benjamin F. Hudson	Registration Number	71,474

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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	Attorney Docket Number	069366-0572186_KUR4C02US

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	Attorney Docket Number	069366-0572186_KUR4C02US

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	Application Number	18317558
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	Examiner Name	CENTRAL, DOCKET
	Attorney Docket Number	069366-0572186_KUR4C02US

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Examiner Signature	/MAY A ABOUELELA/	Date Considered	05/06/2024

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☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2024-04-23
Name/Print	Benjamin F. Hudson	Registration Number	71,474

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Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

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(Not for submission under 37 CFR 1.99)

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Filing Date	2023-05-15
First Named Inventor	Bobby E. ROGERS
Art Unit	3791
Examiner Name	ABOUELELA, MAY A
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	1	Notice of Allowance mailed 07-04-2024; Attorney Docket No. 069366-0572164_KUR7N01JP. 9 pages.	☐
	2	Office Action mailed 05-21-2024; Attorney Docket No. 069366-0572161_KUR7N01IL. 6 pages.	☐
	3	European Patent Office, Examination Report for European Patent Application 20781928.5, dated July 31, 2024, pages 1-6.	☐

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FEE

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☐ An identification of an earlier application pursuant to 37 CFR 1.98 (d) (1) is attached.

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Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2024-08-26
Name/Print	Benjamin F. Hudson	Registration Number	71,474

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	1	Office Action (Non-Final Rejection) dated 10/04/2023 for US App. No. 17538990 (pages 1-47)	☐
	2	Notice of Allowance mailed 01-17-2024; Attorney Docket No. 069366-0572201_KUR2C03US. 16 pages.	☐
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Name/Print	Benjamin F. Hudson	Registration Number	71,474

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.A.A/

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.A.A/

שירות התשלומים הממשלתי

אישור תשלום

התשלום בוצע בהצלחה

מספר אישור תשלום: 337169973
שם לקוח: Katz Presenti
תאריך התשלום: 11/02/2025 **שעה:** 08:57

פרטי האגרות

אגרת פטנטים

1. שם האגרה:
אגרת פטנטים
כמות:
1
מחיר:
820 ₪
שם היחידה:
רשות הפטנטים
מספר הסל:
459600
שם איש הקשר:
פרנצטי רונן
ת.ז של הלקוח:
027286277
מספר בקשה:
302893
תיאור תשלום:
אגרת קיבול בקשה לפי תקנה 52

פרטי התשלום

סה"כ שולם:
820 ₪
אישור מחברת האשראי/בנק:
0970567
סוג העסקה:
תשלום רגיל ISRAC
4 ספרות אחרונות / מזהה ארנק דיגיטלי:
2962
שימו לב!
לחזרה לאתר ההגשה של מחלקת הפטנטים לחצו כאן

כרטיס אדי – להציל חיים !!!
החתימה על כרטיס אדי מקנה קדימות בתור להשתלה לחותמים ולבני משפחתם מדרגה ראשונה.
מעוניינים לחתום? לחצו כאן

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

27500 7590 11/15/2024

PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
ATTENTION: DOCKETING DEPARTMENT
P.O BOX 10500
McLean, VA 22102

EXAMINER	
ABOUELELA, MAY A	
ART UNIT	PAPER NUMBER
3791	

DATE MAILED: 11/15/2024

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/317,558	05/15/2023	Bobby E. ROGERS	069366-0575710_KUR4C02US	8048

TITLE OF INVENTION: BLOOD CONTAMINANT SEQUESTRATION DEVICE WITH ONE-WAY AIR VALVE AND AIR-PERMEABLE BLOOD BARRIER WITH CLOSURE MECHANISM

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$480	$0.00	$0.00	$480	02/18/2025

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 40% the amount of undiscounted fees, and micro entity fees are 20% the amount of undiscounted fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Maintenance fees are due in utility patents issuing on applications filed on or after Dec. 12, 1980. It is patentee's responsibility to ensure timely payment of maintenance fees when due. More information is available at www.uspto.gov/PatentMaintenanceFees.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), by mail or fax, or via the USPTO patent electronic filing system.

By mail, send to: Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

By fax, send to: (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications. **Because electronic patent issuance may occur shortly after issue fee payment, any desired continuing application should preferably be filed prior to payment of this issue fee in order not to jeopardize copendency.**

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

27500 7590 11/15/2024

PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
ATTENTION: DOCKETING DEPARTMENT
P.O BOX 10500
McLean, VA 22102

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being transmitted to the USPTO via the USPTO patent electronic filing system or by facsimile to (571) 273-2885, on the date below.

(Typed or printed name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/317,558	05/15/2023	Bobby E. ROGERS	069366-0575710_KUR4C02US	8048

TITLE OF INVENTION: BLOOD CONTAMINANT SEQUESTRATION DEVICE WITH ONE-WAY AIR VALVE AND AIR-PERMEABLE BLOOD BARRIER WITH CLOSURE MECHANISM

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$480	$0.00	$0.00	$480	02/18/2025

EXAMINER	ART UNIT	CLASS-SUBCLASS
ABOUELELA, MAY A	3791	073-864910

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

❑ Change of correspondence address (or Change of Correspondence Address form PTO/AIA/122 or PTO/SB/122) attached.

❑ "Fee Address" indication (or "Fee Address" Indication form PTO/AIA/47 or PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 _____
2 _____
3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ❑ Individual ❑ Corporation or other private group entity ❑ Government

4a. Fees submitted: ❑ Issue Fee ❑ Publication Fee (if required)

4b. Method of Payment: *(Please first reapply any previously paid fee shown above)*

❑ Electronic Payment via the USPTO patent electronic filing system ❑ Enclosed check ❑ Non-electronic payment by credit card (Attach form PTO-2038)

❑ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. _____

5. **Change in Entity Status** (from status indicated above)

❑ Applicant certifying micro entity status. See 37 CFR 1.29

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

❑ Applicant asserting small entity status. See 37 CFR 1.27

NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

❑ Applicant changing to regular undiscounted fee status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/317,558	05/15/2023	Bobby E. ROGERS	069366-0575710_KUR4C02US	8048

27500 7590 11/15/2024

PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
ATTENTION: DOCKETING DEPARTMENT
P.O BOX 10500
McLean, VA 22102

EXAMINER	
ABOUELELA, MAY A	
ART UNIT	**PAPER NUMBER**
3791	

DATE MAILED: 11/15/2024

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. The United States Patent and Trademark Office (USPTO) collects the information in this record under authority of 35 U.S.C. 2. The USPTO's system of records is used to manage all applicant and owner information including name, citizenship, residence, post office address, and other information with respect to inventors and their legal representatives pertaining to the applicant's/ owner's activities in connection with the invention for which a patent is sought or has been granted. The applicable Privacy Act System of Records Notice for the information collected in this form is COMMERCE/PAT-TM-7 Patent Application Files, available in the Federal Register at 78 FR 19243 (March 29, 2013).
https://www.govinfo.gov/content/pkg/FR-2013-03-29/pdf/2013-07341.pdf

Routine uses of the information in this record may include disclosure to:

1) law enforcement, in the event that the system of records indicates a violation or potential violation of law;
2) a federal, state, local, or international agency, in response to its request;
3) a contractor of the USPTO having need for the information in order to perform a contract;
4) the Department of Justice for determination of whether the Freedom of Information Act (FOIA) requires disclosure of the record;
5) a Member of Congress submitting a request involving an individual to whom the record pertains, when the individual has requested the Member's assistance with respect to the subject matter of the record;
6) a court, magistrate, or administrative tribunal, in the course of presenting evidence, including disclosures to opposing counsel in the course of settlement negotiations;
7) the Administrator, General Services Administration (GSA), or their designee, during an inspection of records conducted by GSA under authority of 44 U.S.C. 2904 and 2906, in accordance with the GSA regulations and any other relevant (i.e., GSA or Commerce) directive, where such disclosure shall not be used to make determinations about individuals;
8) another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c));
9) the Office of Personnel Management (OPM) for personnel research purposes; and
10) the Office of Management and Budget (OMB) for legislative coordination and clearance.

If you do not furnish the information requested on this form, the USPTO may not be able to process and/or examine your submission, which may result in termination of proceedings, abandonment of the application, and/or expiration of the patent.

Notice of Allowability	Application No. 18/317,558	Applicant(s) ROGERS et al.	
	Examiner MAY A ABOUELELA	Art Unit 3791	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☑ This communication is responsive to 10/31/2024.
   ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

3. ☑ The allowed claim(s) is/are 2-7 . As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see **http://www.uspto.gov/patents/init_events/pph/index.jsp** or send an inquiry to **PPHfeedback@uspto.gov.**

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

   Certified copies:

   a) ☐ All b) ☐ Some* c) ☐ None of the:

   1. ☐ Certified copies of the priority documents have been received.
   2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
   3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____ .

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____ .

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____.
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material _____.
4. ☑ Interview Summary (PTO-413), Paper No./Mail Date. 11/04/2024.
5. ☑ Examiner's Amendment/Comment
6. ☑ Examiner's Statement of Reasons for Allowance
7. ☐ Other _____.

/MAY A ABOUELELA/
Primary Examiner, Art Unit 3791

Notice of Pre-AIA or AIA Status

1. The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Response to Arguments

2. Applicant's arguments with respect to Double Patenting rejection have been fully considered and are persuasive. The Double Patenting rejection has been withdrawn.

EXAMINER'S AMENDMENT

3. Authorization for this examiner's amendment was given in an interview with BENJAMIN F. HUDSON on 11/04/2024.

Claim 2 should be amended as follow:

2. (New) A device comprising:

an inlet port;

an outlet port;

a chamber connected with the inlet port, the chamber having a vent configured to allow air to be displaced through an air permeable blood barrier by a first portion of blood entering the inlet port and into **the** chamber;

a cap configured to inhibit a user from touching the air permeable blood barrier;

a sampling channel having a proximal end connected with the inlet port and a distal end connected with the outlet port, the sampling channel being configured to convey

subsequent portions of blood past the chamber and to the outlet port after the first portion of blood has entered the chamber; and

a housing that houses and defines the inlet port, the outlet port, the chamber, and the sampling channel.

Allowable Subject Matter

4. Claims 2-7 are allowed.

5. The following is an examiner's statement of reasons for allowance: the most pertinent prior art Cubby et al (U.S 5,749,857) teaches a device comprising: an inlet port; an outlet port; a chamber connected with the inlet port, the chamber having a vent configured to allow air to be displaced through an air permeable blood barrier by a first portion of blood entering the inlet port and into the chamber.

The prior art does not teach, disclose and/or fairly suggest a cap configured to inhibit a user from touching the air permeable blood barrier; a sampling channel having a proximal end connected with the inlet port and a distal end connected with the outlet port, the sampling channel being configured to convey subsequent portions of blood past the chamber and to the outlet port after the first portion of blood has entered the chamber; and a housing that houses and defines the inlet port, the outlet port, the chamber, and the sampling channel.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MAY A ABOUELELA whose telephone number is (571)270-7917. The examiner can normally be reached 8-5.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JACQUELINE CHENG can be reached on 5712725596. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: https://patentcenter.uspto.gov. Visit https://www.uspto.gov/patents/apply/patent-center for more information about Patent Center and https://www.uspto.gov/patents/docx for information about filing in DOCX format. For additional questions, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MAY A ABOUELELA/
Primary Examiner, Art Unit 3791

Examiner-Initiated Interview Summary	**Application No.** 18/317,558	**Applicant(s)** ROGERS et al.		
	Examiner MAY A ABOUELELA	**Art Unit** 3791	**AIA (First Inventor to File) Status** Yes	**Page** 1 of 1

All Participants (applicant, applicants representative, PTO personnel)	**Title**	**Type**
MAY A ABOUELELA	Primary Examiner	Telephonic
BENJAMIN F. HUDSON	Attorney of Record	

Date of Interview: 04 November 2024

Issues Discussed:

35 U.S.C. 112

Applicant and Examiner discussed the claims set mailed on 10/31/2024. Applicant and Examiner discussed the claim language with respect to the applied prior art and the disclosure. Applicant and Examiner discussed proposed claim amendments represented by the Examiner to overcome 112 rejection. For claim 2 The Applicant has authorized the Examiner to amend the claims.

/MAY A ABOUELELA/ Primary Examiner, Art Unit 3791	

Applicant is reminded that a complete written statement as to the substance of the interview must be made of record in the application file. It is the applicants responsibility to provide the written statement, unless the interview was initiated by the Examiner and the Examiner has indicated that a written summary will be provided. See MPEP 713.04
Please further see:
MPEP 713.04
Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews, paragraph (b)
37 CFR § 1.2 Business to be transacted in writing

Applicant recordation instructions: It is not necessary for applicant to provide a separate record of the substance of interview.

Examiner recordation instructions: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.

Reference No.: 0580493
Mailing No.: 566445
Mailing Date: November 26, 2024

Non-final Office Action KURD03JP
(Translation)

Application No.	Japanese Patent Application No. 2024-121200
Drafting Date	November 18, 2024
Examiner	Naoya TAKAGI 3611 2Q00
Representative	Satoshi MURAKOSHI
Applied Articles	Japanese Patent Act, Section 17(2), Paragraph 3 (new matter)
	Japanese Patent Act, Section 36, Paragraph 4, Item 1 (enablement requirement)
	Japanese Patent Act, Section 36, Paragraph 6, Item 2 (clearness)

This application has been rejected for the grounds stated below. Applicant is invited to file a Response within three months from the mailing date of this notice.

Grounds

<Ground 1>

(New Matter) The amendment made by the Amendment filed on August 5, 2024 is not within the scope of the translation of the foreign language text (or the specification, claims, or the drawings after the amendment by Correction of Mistranslation). Therefore, the amendment does not satisfy the requirement provided for in the Japanese Patent Act, Section 17(2), Paragraph 3.

<Ground 2>

(Enablement requirement) The Detail Description of the Invention of this application does not conform to Section 36, Paragraph 4, Item 1 of the Japanese Patent Act in the following points.

<Ground 3>

(Clearness) This application does not conform to Section 36, Paragraph 6, Item 2 of the Japanese Patent Act in the following points.

Examiner Notes (the cited references are listed in Reference List below)

• As to Ground 1 (new matter)

- As to Claims: 1 to 30
- Notes:

(1) The amendment made by the Amendment filed on August 5, 2024 added, to claim 1, an element of "a moving part configured to be movable from a first position to a second position to allow the blood sample to flow to the sampling channel."

Since claim 1 does not at all recite the relationship between "a chamber … configured to collect a first portion of the blood sample" and the "moving part," the "moving part" may be separate from the "chamber."

On the other hand, the specification as filed describes the "moving part" as follows.

"[0141] … The blood sequestration chamber 2418 is defined by an inner chamber housing 2419 that is movable from a first position to receive and sequester a first aliquot of blood, to a second position to expose one or more apertures 2424 at a proximal end of the inner chamber housing 2419 to allow blood to bypass and/or flow around the inner chamber housing 2419 and through a blood sample channel 2422 defined by the outer surface of the inner chamber housing 2419 and the inner surface of the housing 2416."

"[0142] … Upon venipuncture of a patient, and drawing of blood by way of a syringe or Vacutainer, or other blood collection device 2404, the initial aliquot of blood flows into the blood sequestration chamber 2418. As the initial aliquot of blood flows into the blood sequestration chamber, it displaces air therein and eventually the blood contacts the blood barrier 2420, forcing the inner chamber housing to the second position." (Underlined by the Examiner)

Taking into account the above description, the specification of the present application should describe that the "inner chamber housing" (corresponding to the "chamber … configured to collect a first portion of the blood sample" recited in claim 1) is movable from a first position to a second position, that is, the "moving part" in claim 1 is the "chamber … configured to collect a first portion of the blood sample."

However, the specification and the like of the present application does not at all describe the configuration in which the "moving part" is constituted by a member other than the "chamber … configured to collect a first portion of the blood sample."

In addition, such configuration is not obvious from the description in the as-filed specification or the like.

The same applies to claim 16.

(2) Claim 7 recites that "a blood impermeable membrane causes the first portion of the blood sample to back up into the chamber following application of the drawing force applied from the outlet port." However, this configuration is not at all described in the specification or the like of the present application. (In the Written Statement, the Applicant referred to paragraph 0135 as supporting this amendment, but this paragraph does not all describe the word "back up.")

(3) Claim 8 recites "… further comprising a housing, separate from the blood impermeable membrane." Since claim 8 depends on claim 1, the above recitation should specify that the aspect of claim 1 represented by paragraph 0141 and Fig. 24 "further includes a housing separate from the blood impermeable membrane." However, such configuration is not at all described.

The same applies to claim 23.

(4) Claim 10 recites "… further comprising a valve configured to initially close off the sampling channel." Since claim 10 depends on claim 1, the above recitation should specify that the aspect of claim 1 represented by paragraph 0141 and Fig. 24 "further includes a valve configured to initially close off the

sampling channel." However, such configuration is not at all described.

The same applies to claims 11 to 12 and 25 to 27.

(5) Claim 14 recites "the chamber having a volume sufficient to collect the first portion of the blood sample that is more prone to contamination and also to minimize an amount of blood to be sequestered." This configuration is not at all described in the specification or the like of the present application. (In the Written Statement, the Applicant referred to paragraphs 0059, 0073, and so on as supporting this amendment, but these paragraphs describes an aspect other than the aspect of claim 1 represented by paragraph 0141 and Fig. 24.)

The same applies to claim 29.

(6) Claim 15 recites that "the chamber has a volume of less than 1.5 cubic centimeters." This configuration is not at all described in the specification or the like of the present application. (In the Written Statement, the Applicant referred to paragraph 0073 as supporting this amendment, which paragraph describes that "the volume of the sequestration chamber is less than 0.1 to more than 5 cubic centimeters (cc's), or more." Thus, no reference is made to the numeric value of "1.5 cubic centimeters" or the configuration that "the chamber has a volume of less than 1.5 cubic centimeters.")

The same applies to claim 30.

The matters recited in the amended claims 1 to 30 obviously go beyond the scope of the translation of the foreign language text ((or the specification, claims, or the drawings after the amendment by Correction of Mistranslation), and therefore, these claims are not examined for patentability requirements such as novelty and inventive step.

• As to Ground 2 (enablement requirement)

- As to Claims: 1 to 30
- Notes:

The amendment made by the Amendment filed on August 5, 2024 added, to claim 1, an element of "a moving part configured to be movable from a first position to a second position to allow the blood sample to flow to the sampling channel."

On the other hand, the specification as filed describes the "moving part" as follows.

"[0141] ... The blood sequestration chamber 2418 is defined by an inner chamber housing 2419 that is movable from a first position to receive and sequester a first aliquot of blood, to a second position to expose one or more apertures 2424 at a proximal end of the inner chamber housing 2419 to allow blood to bypass and/or flow around the inner chamber housing 2419 and through a blood sample channel 2422 defined by the outer surface of the inner chamber housing 2419 and the inner surface of the housing 2416."

"[0142] ... Upon venipuncture of a patient, and drawing of blood by way of a syringe or Vacutainer, or other blood collection device 2404, the initial aliquot of blood flows into the blood sequestration chamber 2418. As the initial aliquot of blood flows into the blood sequestration chamber,

it displaces air therein and eventually the blood contacts the blood barrier 2420, forcing the inner chamber housing to the second position. … Once in the second position, the initial aliquot of blood is sequestered in the blood sequestration chamber 2418 and the one or more apertures 2424 are opened to create a pathway from the inlet port 2412 to the blood sampling channel 2422, bypassing and/or flowing around the blood sequestration chamber 2418." (Underlined by the Examiner)

However, the specification and the like of the present application do not describe in which member the "apertures 2424" are formed, and do not describe the mutual relationship between the member in which the "apertures 2424" are formed and the "inner chamber housing 2419." Therefore, it is unclear why the one or more apertures 2424 are opened when the "inner chamber housing" moves from the first position to the second position.

Thus, the Detailed Description of the Invention of the present application fails to provide clear and sufficient description for those skilled in the art to practice the invention of claim 1 (in particular, the feature of "a moving part configured to be movable from a first position to a second position to allow the blood sample to flow to the sampling channel").

The same applies to claim 16.

The same also applies to claims 2 to 15, depending on claim 1, and claims 17 to 30, depending on claim 16.

• As to Ground 3 (clearness)

- As to Claims: 6, 8, 14, 21, and 29
- Notes:

(1) Claim 6 recites that "a blood impermeable membrane is configured to facilitate the chamber collecting the first portion of the blood sample." This recitation is unclear as to what specific feature is provided to the "blood impermeable membrane" to "facilitate the chamber collecting the first portion of the blood sample." Thus, the scope of the aspect of the "blood impermeable membrane" is unclear.

The same applies to claim 21.

(2) Claim 14 recites "the chamber having a volume sufficient … to minimize an amount of blood to be sequestered." This recitation is unclear as to what is the "volume sufficient" for a minimized amount. Thus, the configuration of the "chamber" is unclear.

The same applies to claim 29.

Therefore, claims 6, 8, 14, 21, and 29 are unclear.

Record of Search for Prior Art Literature

- Searched Field IPC A61B 5/06 – 5/22
- Prior Art Literature

Japanese Patent Application Publication No. 2013-240628 [Weilbacher/Tycho Healthcare Group – PCT application is WO2008085393]

Japanese Translation of PCT International Patent Application No. 2016-504075 [Bullington/Magnolia – PCT application is WO2014089186]

Japanese Patent Application Publication No. Sho 57-089869 [Yuko provided – aka U.S. 4,312,362 / Becton Dickinson] [Very similar to Kaufman/BD reference used for rejection of optimized non-venting claims in KUR2D03JP U.S. 4,416,291 – different patent families]

U.S. Patent Application Publication No. 2015/0018715 [Walterspiel/No assign]

This record of search for prior art literatures does not constitute grounds for refusal.

拒絶理由通知書

特許出願の番号	特願２０２４－１２１２００
起案日	令和　６年１１月１８日
特許庁審査官	▲高▼木　尚哉　　３６１１　２Ｑ００
特許出願人代理人	村越　智史　様
適用条文	第１７条の２第３項（新規事項） 第３６条第４項第１号（実施可能要件） 第３６条第６項第２号（明確性）

この出願は、次の理由によって拒絶をすべきものです。これについて意見がありましたら、この通知書の発送の日から３か月以内に意見書を提出してください。

理由

１．（新規事項）令和６年８月５日付け手続補正書でした補正は、下記の点で外国語書面の翻訳文（又は誤訳訂正書による補正後の明細書、特許請求の範囲若しくは図面）に記載した事項の範囲内においてしたものでないから、特許法第１７条の２第３項に規定する要件を満たしていない。

２．（実施可能要件）この出願は、発明の詳細な説明の記載が下記の点で、特許法第３６条第４項第１号に規定する要件を満たしていない。

３．（明確性）この出願は、特許請求の範囲の記載が下記の点で、特許法第３６条第６項第２号に規定する要件を満たしていない。

記　　（引用文献等については引用文献等一覧参照）

●理由１（新規事項）について

・請求項　１－３０
・備考
（１）令和６年８月５日付け手続補正書でした補正により、請求項１には、「前記血液サンプルが前記サンプリング流路に流れることを可能とするように、第１の位置から第２の位置に移動可能に構成された可動部」を備えるとの事項が追加された。

そして、請求項１には、「血液サンプルの最初の部分を採取するように構成されたチャンバ」と「可動部」との関係について何ら記載されていないから、請求項１には、上記「チャンバ」とは別に構成されている「可動部」を備える構成が含まれる。

これに対して、出願当初の明細書には、「可動部」に関して、

「[0141]

・・・血液隔離チャンバ２４１８は、内側チャンバハウジング２４１９によって画定され、内側チャンバハウジング２４１９は、最初のアリコートの血液を受け入れて隔離する第１の位置から、血液が内側チャンバハウジング２４１９の周りで内側チャンバハウジング２４１９の外側表面とハウジング２４１６の内側表面とによって画定される血液サンプル流路２４２２を通って迂回しかつ／又は流れることを可能にするために内部チャンバハウジング２４１９の近位端にある１つ以上の開口部２４２４を露出させる第２の位置まで移動可能である。・・・。」

「[0142]

・・・患者の静脈穿刺、及び注射器もしくはバキュテナー（登録商標）又は他の採血デバイス２４０４による採血の際に、最初のアリコートの血液は血液隔離チャンバ２４１８に流れ込む。最初のアリコートの血液が血液隔離チャンバに流れ込むと、血液は血液隔離チャンバ内の空気に取って代わり、最終的に血液は血液バリア２４２０に接触し、内側チャンバハウジングを第２の位置に押しやる。・・・。」

と記載されている（下線は、関連箇所を示し、審査官が付記。）。

そして、上記記載を総合的に勘案すると、本願の明細書等には、「内側チャンバハウジング」（請求項１の「血液サンプルの最初の部分を採取するように構成されたチャンバ」が相当）が、第１の位置から第２の位置まで移動可能であること、すなわち、請求項１の「可動部」が、「血液サンプルの最初の部分を採取するように構成されたチャンバ」である構成が記載されていると認められる。

しかしながら、本願の明細書等には、「可動部」を、「血液サンプルの最初の部分を採取するように構成されたチャンバ」以外の部材で構成する点については何ら記載されていない。

また、当該構成が、当初明細書等の記載から自明な事項であるとも認められない。

請求項１６についても同様である。

（２）請求項７には、「血液不透過性膜が、前記出口ポートから加えられる前記吸引力の印加に続いて、前記血液サンプルの前記最初の部分を前記チャンバ内に逆流させる」ことが記載されているが、当該構成は、本願の明細書等に一切記載されていない。（出願人が上申書において、補正の根拠として挙げている段落[0

135]には、「逆流」について何ら記載されていない。）

（３）請求項８には、「前記血液不透過性膜とは別にハウジングをさらに備える」ことが記載されている。そして、請求項８は、請求項１を引用しているところ、本願の明細書等の記載を参酌すれば、上記記載は、段落[0141]等や図24で示される請求項1の実施態様において、「血液不透過性膜とは別にハウジングをさらに備える」ことを特定していると認められるが、そのような構成については何ら記載されていない。
　請求項２３についても同様である。

（４）請求項１０には、「最初は前記サンプリング流路を閉鎖するように構成された弁をさらに備える」ことが記載されている。そして、請求項１０は、請求項１を引用しているところ、本願の明細書等の記載を参酌すれば、上記記載は、段落[0141]等や図24で示される請求項1の実施態様において、「最初は前記サンプリング流路を閉鎖するように構成された弁をさらに備える」ことを特定していると認められるが、そのような構成については何ら記載されていない。
　請求項１１－１２、２５－２７についても同様である。

（５）請求項１４には、「チャンバは、汚染されやすい前記血液サンプルの前記最初の部分を採取し、また、隔離される血液の量を最小化するのに十分な容積を有する」ことが記載されているが、当該構成は、本願の明細書等に一切記載されていない。（出願人が上申書において、補正の根拠として挙げている段落[0059],[0073]等は、段落[0141]等や図24に示されている請求項１の実施態様とは別の実施態様である。）
　請求項２９についても同様である。

（６）請求項１５には、「チャンバは、１．５立方センチメートル未満の容積を有する」ことが記載されているが、当該構成は、本願の明細書等に一切記載されていない。（出願人が上申書において、補正の根拠として挙げている段落[0073]には、「隔離チャンバの容積は、０．１立方センチメートル（ｃｃ）未満から５立方センチメートル（ｃｃ）以上である。」と記載されているが、「１．５立方センチメートル」という数値が記載されていないだけでなく、「チャンバは、１．５立方センチメートル未満の容積を有する」構成についても記載されていない。）
　請求項３０についても同様である。

　なお、当該補正がなされた請求項１－３０に記載した事項は、外国語書面の翻訳文（又は誤訳訂正書による補正後の明細書、特許請求の範囲若しくは図面）に記載した事項の範囲内にないことが明らかであるから、当該請求項に係る発明に

ついては新規性、進歩性等の特許要件についての審査を行っていない。

●理由２（実施可能要件）について

・請求項　１－３０
・備考
　令和６年８月５日付け手続補正書でした補正により、請求項１には、「前記血液サンプルが前記サンプリング流路に流れることを可能とするように、第１の位置から第２の位置に移動可能に構成された可動部」を備えるとの事項が追加された。
　これに対して、出願当初の明細書には、「可動部」に関して、
「[0141]
　・・・血液隔離チャンバ２４１８は、内側チャンバハウジング２４１９によって画定され、内側チャンバハウジング２４１９は、最初のアリコートの血液を受け入れて隔離する第１の位置から、血液が内側チャンバハウジング２４１９の周りで内側チャンバハウジング２４１９の外側表面とハウジング２４１６の内側表面とによって画定される血液サンプル流路２４２２を通って迂回しかつ／又は流れることを可能にするために内部チャンバハウジング２４１９の近位端にある１つ以上の開口部２４２４を露出させる第２の位置まで移動可能である。・・・。
」
「[0142]
　・・・患者の静脈穿刺、及び注射器もしくはバキュテナー（登録商標）又は他の採血デバイス２４０４による採血の際に、最初のアリコートの血液は血液隔離チャンバ２４１８に流れ込む。最初のアリコートの血液が血液隔離チャンバに流れ込むと、血液は血液隔離チャンバ内の空気に取って代わり、最終的に血液は血液バリア２４２０に接触し、内側チャンバハウジングを第２の位置に押しやる。・・・。ひとたび第２の位置になると、最初のアリコートの血液は血液隔離チャンバ２４１８に隔離され、１つ以上の開口部２４２４が開かれて、血液隔離チャンバ２４１８を迂回しかつ／又は血液隔離チャンバ２４１８の周りを流れる入口ポート２４１２から採血流路２４２２への経路を生じる。」

　と記載されている（下線は、関連箇所を示し、審査官が付記。）。
　しかしながら、本願の明細書等には、「開口部２４２４」がいずれの部材に設けられているのか記載されておらず、「開口部２４２４」が設けられている部材と「内側チャンバハウジング２４１９」との相互関係も記載されていないため、「内側チャンバハウジング」が、第１の位置から第２の位置まで移動することによって、何故、１つ以上の開口部２４２４が開かれるのか把握することができない。
　そうすると、この出願の発明の詳細な説明は、当業者が請求項１（特に、「前

記血液サンプルが前記サンプリング流路に流れることを可能とするように、第１の位置から第２の位置に移動可能に構成された可動部」の構成）に係る発明を実施することができる程度に明確かつ十分に記載されたものでない。

請求項１６についても同様である。

請求項１を引用する請求項２－１５、請求項１６を引用する請求項１７－３０についても同様である。

●理由３（明確性）について

・請求項　６、８、１４、２１、２９
・備考
（１）請求項６には、「血液不透過性膜が、前記チャンバが前記血液サンプルの前記最初の部分を採取することを容易にするように構成される」ことが記載されているが、「チャンバが前記血液サンプルの前記最初の部分を採取することを容易にする」ために、「血液不透過性膜」が、具体的にどのような構成を備えているのか明らかでなく、「血液不透過性膜」として、どのような態様の膜が含まれるのか把握することができない。

請求項２１についても同様である。

（２）請求項１４には、「チャンバは、・・・隔離される血液の量を最小化するのに十分な容積を有する」ことが記載されているが、「最小化」するにも関わらず、「十分な容積を有する」とは、どのようなことを特定しようとしているのか明らかでなく、「チャンバ」の構成を把握することができない。

請求項２９についても同様である。

よって、請求項６、８、１４、２１、２９に係る発明は明確でない。

－－－－－－－－－－－－－－－－－－－－－－－－－－－－－－－－－－－－

＜先行技術文献調査結果の記録＞

・調査した分野　　ＩＰＣ　Ａ６１Ｂ５／０６－５／２２
・先行技術文献　　特開２０１３－２４０６２８号公報
特表２０１６－５０４０７５号公報
特開昭５７－０８９８６９号公報
米国特許出願公開第２０１５／００１８７１５号明細書

この先行技術文献調査結果の記録は、拒絶理由を構成するものではありません。

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/336,178	06/01/2021	Bobby E. ROGERS	069366-0572194_KUR8001US	6056

27500 7590 03/18/2025

PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
ATTENTION: DOCKETING DEPARTMENT
P.O BOX 10500
McLean, VA 22102

EXAMINER	
NGUYEN, HUONG Q	

ART UNIT	PAPER NUMBER
3791	

NOTIFICATION DATE	DELIVERY MODE
03/18/2025	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Docket_IP@pillsburylaw.com

Office Action Summary	**Application No.** 17/336,178	**Applicant(s)** ROGERS et al.	
	Examiner Huong Q NGUYEN	**Art Unit** 3791	**AIA (FITF) Status** Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 2 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 11/1/2024.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL.** 2b) ☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☐ Claim(s) _____ is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☐ Claim(s) _____ is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☑ Claim(s) 21-43 are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to **PPHfeedback@uspto.gov.**

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☐ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

DETAILED ACTION

Election/Restriction

This application contains claims directed to the following patentably distinct species:

1) Displaceable plug of Figure 32A-C with protrusion in the sample path to receive the plug after displacement
2) Displaceable plug of Figure 33A-D including vertical ribs to allow fluid flow after displacement of the plug
3) Displaceable plug of Figure 34A in a shape of ball or rounded shape with o-ring seat to hold the plug
4) Displaceable plug of Figure 34B in a shape of ball or rounded shape with thin sheet with hole/aperture seat to hold the plug
5) Displaceable plug of Figure 34C in a shape of ball or rounded shape with short segment of tubing seat to hold the plug
6) Displaceable plug of Figure 35A with enlarged diameter shoulder to hold the plug
7) Displaceable plug of Figure 35B having a rigid disk shoulder attached to a thin flexible sheet to hold the plug
8) Displaceable plug of Figure 36A having a thin elastomeric disk or membrane with o-ring member/gasket with greater thickness than the disk
9) Displaceable plug of Figure 36B having a hollowed out elastomeric stopper
10) Displaceable plug of Figure 36C being a soft compressible plug

11) Displaceable plug of Figure 37A-B with receptacle/recess formed on inner surface of the sample path by a divider to receive the displaced plug

The species are independent or distinct because each species has different and distinct structure as well as different modes of operation in terms of how the displaceable plug is held in the seat and/or received after being displaced. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, or a single grouping of patentably indistinct species, for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claim 21 is generic.

There is a serious search and/or examination burden for the patentably distinct species as set forth above because at least the following reason(s) apply: each species has different and distinct structural features and manner of operation in terms of how the displaceable plug is held in the seat and/or received after being displaced and thus requires different and distinct search queries.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species or grouping of patentably indistinct species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species or grouping of patentably indistinct species.

Should applicant traverse on the ground that the species, or groupings of patentably indistinct species from which election is required, are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing them to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 or pre-AIA 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

A telephone call was made to Ben Hudson on 3/11/2025 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is reminded that upon the cancelation of claims to a non-elected invention, the inventorship must be corrected in compliance with 37 CFR 1.48(a) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. A request to correct inventorship under 37 CFR 1.48(a) must be accompanied by an application data sheet in accordance with 37 CFR 1.76 that identifies each inventor by his or her legal name and by the processing fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Huong Q NGUYEN whose telephone number is (571)272-8340. The examiner can normally be reached 10 am - 6 pm.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jennifer Robertson can be reached at (571)272-5001. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: https://patentcenter.uspto.gov. Visit https://www.uspto.gov/patents/apply/patent-center for more information about Patent Center and https://www.uspto.gov/patents/docx for information about filing in DOCX format. For additional questions, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

H.Q. NGUYEN
Examiner

Art Unit 3791

/JENNIFER ROBERTSON/
Supervisory Patent Examiner, Art Unit 3791

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/838,017	04/01/2020	Bobby E. ROGERS	069366-0572158_KUR7001US	1044

27500 7590 10/09/2024

PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
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McLean, VA 22102

EXAMINER	
PORTILLO, JAIRO H	

ART UNIT	PAPER NUMBER
3791	

NOTIFICATION DATE	DELIVERY MODE
10/09/2024	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Docket_IP@pillsburylaw.com

Office Action Summary	Application No. 16/838,017	Applicant(s) ROGERS et al.	
	Examiner JAIRO H PORTILLO	Art Unit 3791	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 8/16/2024.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☑ This action is **FINAL.** 2b) ☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 1-4,6-9,14 and 16-18 is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 1-4,6-9,14 and 16-18 is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to **PPHfeedback@uspto.gov.**

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☑ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

DETAILED ACTION

Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim(s) 1-3, 6-8, 14, and 16-17 is/are rejected under 35 U.S.C. 103 as being unpatentable over **Bullington et al (US 2019/0365303) ("Bullington").**

Regarding Claim 1, while Bullington teaches a device for optimizing a fluid sample collected by a fluid collection device from a fluid source (Abstract, [0134]-[0135] Figs. 9 and 10), the device comprising:

an inlet configured to connect with the fluid source ([0135] Figs. 9 and 10, inlet 512);

an outlet configured to connect with the fluid collection device ([0135] Figs. 9 and 10, outlet 516);

a sample path connected between the inlet and the outlet ([0135] Figs. 9 and 10, sample path 554), the sample path further having a resistive plug ([0141] Figs, 9 and 10, barrier 574); and

a chamber connected between the inlet and the outlet ([0135] , Figs. 9 and 10, fluid control device 500), the chamber having an air permeable fluid resistor proximate the outlet ([0050] fluid control device utilizes air permeable resistors, [0143] air permeable fluid resistor

515), the chamber being arranged to receive, when a pressure differential is applied between the inlet and the outlet, a first portion of the fluid sample from the fluid source to displace air therein through the air permeable fluid resistor and the outlet, such that upon receipt of the first portion of the fluid sample in the chamber, subsequent portions of the fluid sample can be conveyed by the sample path from the inlet to the outlet ([0136]-[0140] pressure differentials applied between the inlet and outlet to lead a first portion of the fluid sample into sequestration chamber 514, [0145] with subsequent portions following the sample path 554 to the outlet),

the resistive plug including a membrane that is pierceable ([0141] Figs, 9 and 10, barrier 574, pierceable by the piercing member); and

a piercing member configured to pierce the membrane ([0141] Figs. 9 and 10, piercing member 578),

wherein the device is configured such that, once the chamber fills with the first portion of the fluid sample, pressure is exerted against a diaphragm of the piercing member causing the diaphragm to stretch and the piercing member to contact the membrane ([0141]-[0142]),

Bullington fails to teach

wherein the device is configured such that, once the chamber fills with the first portion of the fluid sample, pressure is exerted against the *membrane* causing the *membrane* to stretch and contact the *piercing member*.

It would have been obvious to one of ordinary skill in the art, before the effective filing date of the claimed invention, that Bullington teaches a piercing member, a resistive plug including a membrane that is pierceable, and a piercing action due to pressure exertion wherein a component stretches to bring the piercing member into contact with a pierceable membrane, is the same mechanism as the instant invention. The difference between the inventions is what component is stretching to facilitate the piercing action. If one were to reverse the stretching action from occurring at the diaphragm 576 to instead occur at the barrier 574, the claim limitations would be taught. Examiner recognizes this as a design choice, specifically a reversal

of parts [*In reGazda,* 219 F.2d 449, 104 USPQ 400 (CCPA 1955) (Prior art disclosed a clock fixed to the stationary steering wheel column of an automobile while the gear for winding the clock moves with steering wheel; mere reversal of such movement, so the clock moves with wheel, was held to be an obvious modification.).].

Regarding Claim 2, Bullington teaches the device in accordance with claim 1, further comprising a housing that houses and/or defines one or more of the inlet, the outlet, the sample path, and the chamber (*See Claim 1 Rejection,* housing of fluid control device 500).

Regarding Claim 3, Bullington teaches the device in accordance with claim 1, wherein the air permeable fluid resistor includes a material that seals upon contact with the first portion of the fluid sample ([0054] fluid resistor can perform this function by sealing upon contact with the first portion of the fluid sample).

Regarding Claim 6, Bullington teaches a device for optimizing a fluid sample collected by a fluid collection device from a fluid source (Abstract, [0134]-[0135] Figs. 9 and 10), the device comprising:

an inlet configured to connect with the fluid source ([0135] Figs. 9 and 10, inlet 512);

an outlet configured to connect with the fluid collection device ([0135] Figs. 9 and 10, outlet 516);

a sample path connected between the inlet and the outlet ([0135] Figs. 9 and 10, sample path 554), the sample path further having a resistive plug that is configured to inhibit at least a part of a first portion of the fluid sample from entering the sample path ([0141] Figs, 9 and 10, barrier 574 acts as resistive plug); and

a chamber connected between the inlet and the outlet ([0135] , Figs. 9 and 10, fluid control device 500), the chamber further having an air permeable fluid resistor proximate the outlet ([0050] fluid control device utilizes air permeable resistors, [0143] air permeable fluid resistor 515), the chamber being arranged to receive, when a pressure differential is applied

between the inlet and the outlet, the first portion of the fluid sample from the fluid source to displace air therein through the air permeable fluid resistor and the outlet, such that upon receipt of the first portion of the fluid sample in the chamber, subsequent portions of the fluid sample can be forced through the resistive plug and conveyed by the sample path from the inlet to the outlet ([0136]-[0140] pressure differentials applied between the inlet and outlet to lead a first portion of the fluid sample into sequestration chamber 514, [0145] with subsequent portions following the sample path 554 to the outlet, after piercing, subsequent portions of the fluid sample can be forced through the resistive plug and conveyed by the sample path from the inlet to the outlet),

the resistive plug including a membrane that is pierceable ([0141] Figs, 9 and 10, barrier 574); and

a piercing member configured to pierce the membrane ([0141] Figs. 9 and 10, piercing member 578),

wherein the device is configured such that, once the chamber fills with the first portion of the fluid sample, pressure is exerted against a diaphragm of the piercing member causing the diaphragm to stretch and the piercing member to contact the membrane ([0141]-[0142]),

Bullington fails to teach

wherein the device is configured such that, once the chamber fills with the first portion of the fluid sample, pressure is exerted against the *membrane* causing the *membrane* to stretch and contact the *piercing member*.

It would have been obvious to one of ordinary skill in the art, before the effective filing date of the claimed invention, that Bullington teaches a piercing member, a resistive plug including a membrane that is pierceable, and a piercing action due to pressure exertion wherein a component stretches to bring the piercing member into contact with a pierce able membrane, is the same mechanism as the instant invention. The difference between the inventions is what component is stretching to facilitate the piercing action. If one were to reverse the stretching

action from occurring at the diaphragm 576 to instead occur at the barrier 574, the claim limitations would be taught. Examiner recognizes this as a design choice, specifically a reversal of parts [*In reGazda,* 219 F.2d 449, 104 USPQ 400 (CCPA 1955) (Prior art disclosed a clock fixed to the stationary steering wheel column of an automobile while the gear for winding the clock moves with steering wheel; mere reversal of such movement, so the clock moves with wheel, was held to be an obvious modification.).].

Regarding Claim 7, Bullington teaches the device in accordance with claim 6, further comprising a housing that houses and/or defines one or more of the inlet, the outlet, the sample path, and the chamber (*See Claim 6 Rejection,* housing of fluid control device 500).

Regarding Claim 8, Bullington teaches the device in accordance with claim 6, wherein the air permeable fluid resistor includes a material that seals upon contact with the first portion of the fluid sample ([0054] fluid resistor can perform this function by sealing upon contact with the first portion of the fluid sample).

Regarding Claim 14, Bullington teaches a device for optimizing a fluid sample (Abstract, [0134]-[0135] Figs. 9 and 10), the device comprising:

an inlet ([0135] Figs. 9 and 10, inlet 512);

an outlet ([0135] Figs. 9 and 10, outlet 516);

a sample path connected between the inlet and the outlet ([0135] Figs. 9 and 10, sample path 554), and

a chamber connected between the inlet and the outlet ([0135] , Figs. 9 and 10, fluid control device 500), the chamber having an air permeable fluid resistor proximate the outlet ([0050] fluid control device utilizes air permeable resistors, [0143] air permeable fluid resistor 515), the chamber being arranged to receive, when a pressure differential is applied between the inlet and the outlet, a first portion of the fluid sample from the fluid source to displace air therein through the air permeable fluid resistor and the outlet, such that upon receipt of the first

portion of the fluid sample in the chamber, subsequent portions of the fluid sample can be conveyed by the sample path from the inlet to the outlet ([0136]-[0140] pressure differentials applied between the inlet and outlet to lead a first portion of the fluid sample into sequestration chamber 514, [0145] with subsequent portions following the sample path 554 to the outlet),

wherein the sample path further includes a resistive plug that is configured to inhibit at least a part of the first portion of the fluid sample from entering the sample path during receipt of the first portion of the fluid sample in the chamber ([0141] Figs. 9 and 10, barrier 574 acts as resistive plug),

the resistive plug including a membrane that is pierceable ([0141] Figs, 9 and 10, barrier 574); and

a piercing member configured to pierce the membrane ([0141] Figs. 9 and 10, piercing member 578),

wherein the device is configured such that, once the chamber fills with the first portion of the fluid sample, pressure is exerted against a diaphragm of the piercing member causing the diaphragm to stretch and the piercing member to contact the membrane ([0141]-[0142]),

Bullington fails to teach

wherein the device is configured such that, once the chamber fills with the first portion of the fluid sample, pressure is exerted against the *membrane* causing the *membrane* to stretch and contact the *piercing member*.

It would have been obvious to one of ordinary skill in the art, before the effective filing date of the claimed invention, that Bullington teaches a piercing member, a resistive plug including a membrane that is pierceable, and a piercing action due to pressure exertion wherein a component stretches to bring the piercing member into contact with a pierceable membrane, is the same mechanism as the instant invention. The difference between the inventions is what component is stretching to facilitate the piercing action. If one were to reverse the stretching action from occurring at the diaphragm 576 to instead occur at the barrier 574, the claim

limitations would be taught. Examiner recognizes this as a design choice, specifically a reversal of parts [*In reGazda,* 219 F.2d 449, 104 USPQ 400 (CCPA 1955) (Prior art disclosed a clock fixed to the stationary steering wheel column of an automobile while the gear for winding the clock moves with steering wheel; mere reversal of such movement, so the clock moves with wheel, was held to be an obvious modification.).].

Regarding Claim 16, Bullington teaches the device in accordance with claim 14, further comprising a housing that houses and/or defines one or more of the inlet, the outlet, the sample path, and the chamber (*See Claim 14 Rejection,* housing of fluid control device 500).

Regarding Claim 17, Bullington teaches the device in accordance with claim 14, wherein the air permeable fluid resistor includes a material that seals upon contact with the first portion of the fluid sample ([0054] fluid resistor can perform this function by sealing upon contact with the first portion of the fluid sample).

Claim(s) 4, 9, and 18 is/are rejected under 35 U.S.C. 103 as being unpatentable over **Bullington** in view of **Rogers et al (US 2017/0020428) ("Rogers").**

Regarding Claim 4, while Bullington teaches the device in accordance with claim 1, Bullington fails to teach wherein the chamber includes a tortuous path.

However Rogers teaches a device for optimizing a fluid sample collected by a fluid collection device from a fluid source (Abstract, [0072] Figs. 11A-11E) wherein a sequestration chamber includes a tortuous path ([0072]).

It would have been obvious to one of ordinary skill in the art, before the effective filing date of the claimed invention, to form the sequestration chamber of Bullington with a tortuous path as a simple substitution of one configuration for sequestration of a fluid sample for another configuration sequestration of a fluid sample to obtain predictable results of trapping initial contaminants.

Regarding Claim 9, while Bullington teaches the device in accordance with claim 6, Bullington fails to teach wherein the chamber includes a tortuous path.

However Rogers teaches a device for optimizing a fluid sample collected by a fluid collection device from a fluid source (Abstract, [0072] Figs. 11A-11E) wherein a sequestration chamber includes a tortuous path ([0072]).

It would have been obvious to one of ordinary skill in the art, before the effective filing date of the claimed invention, to form the sequestration chamber of Bullington with a tortuous path as a simple substitution of one configuration for sequestration of a fluid sample for another configuration sequestration of a fluid sample to obtain predictable results of trapping initial contaminants.

Regarding Claim 18, while Bullington teaches the device in accordance with claim 14, Bullington fails to teach wherein the chamber includes a tortuous path.

However Rogers teaches a device for optimizing a fluid sample collected by a fluid collection device from a fluid source (Abstract, [0072] Figs. 11A-11E) wherein a sequestration chamber includes a tortuous path ([0072]).

It would have been obvious to one of ordinary skill in the art, before the effective filing date of the claimed invention, to form the sequestration chamber of Bullington with a tortuous path as a simple substitution of one configuration for sequestration of a fluid sample for another configuration sequestration of a fluid sample to obtain predictable results of trapping initial contaminants.

Response to Arguments

Applicant's amendments and arguments filed 8/16/2024 with respect to the 35 USC 103 rejection of claims 1, 6, and 14 have been fully considered, but are not persuasive.

Applicant argues that should the design of Bullington be reversed, and the membrane stretch to reach the piercing member as taught by the Examiner, the contaminated blood would not be brought into the sequestration chamber 514 and instead go to the first portion 524, as the negative pressure differential cause by the expansion attracts the contaminants. Examiner respectfully disagrees. Examiner first notes that the device is broadly described as achieving the desired sequestration in a multitude of ways ([0140] "In some embodiments, the device **500** can include one or more flow controllers in addition to the flow controller **515** configured to selectively control, direct, divert, and/or manipulate fluid flow through at least a portion of the flow paths **513** and/or **554**." [0143] "Although not shown in FIGS. 8-10, in some embodiments, the device 500 can include any suitable device and/or mechanism configured to modulate the negative pressure to which the sequestration chamber 514 is exposed, as described in detail above."). Secondly, Bullington states in [0143]-[0144] that the flow controller's construction causes the initial flow passes through flow controller 515, thus ensuring the sequestration of an initial sample into the sequestration chamber. Paragraph [0146] of Bullington also confirms that the construction of the system must ensure before a second state transition (i.e. where a membrane moves so the piercing) the initial volume must be sequestered in the sequestration chamber. Thus one of ordinary skill in the art would understand that any form of creating a negative pressure differential is envisioned and not limited to the movement of the diaphragm in sequestration chamber 514. And they would understand that first and foremost, the initial volume with contaminants must be directed to the sequestration chamber and remain isolated there. With these ideas in mind, the movement of barrier 574 to a piercing membrane would

only occur after the initial volume is isolated in sequestration chamber, with no possibility that initial volume would then move to the first portion 524.

Applicant then argues that the capture of the first portion of the fluid sample is linked to the stretching of the membrane, one of ordinary skill in the art would not make the changes proposed by the Examiner. Examiner respectfully disagrees. Examiner asserts the capture of the first portion of the fluid sample is controlled by the flow controller 515. The stretching of the membrane is one way to create a negative pressure differential, but as stated above, Bullington affirms that any suitable form of creating a negative pressure differential may be applied. Thus the flow controller is what is critical for the operation of the claimed device.

The rejection stands.

Consequently, claims 2-4, 7-9, and 16-18 dependent off of independent claims 1, 6, and 14 remain rejected.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAIRO H PORTILLO whose telephone number is (571)272-1073. The examiner can normally be reached M-F 9:00 am - 5:15 pm.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jacqueline Cheng can be reached on (571)272-5596. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/JAIRO H. PORTILLO/
Examiner
Art Unit 3791

/JACQUELINE CHENG/
Supervisory Patent Examiner, Art Unit 3791

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

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Art Unit	3791
Examiner Name	PORTILLO, JAIRO H
Attorney Docket Number	069366-0572158_KUR7001US

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	1	3848581		1974-11-19	CINQUALBRE P	
	2	6126643		2000-10-03	VAILLANCOUERT VINCENT L	
	3	9764891		2017-09-19	AVILES VICTOR M	
	4	5147329		1992-09-15	BRANNON JAMES K	
	5	5518005		1996-05-21	BRANNON JAMES K	
	6	62845767		2019-05-09	BREWER MICHAEL	

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	1	20150314105		2015-11-05	GASPARYAN LEVON	
	2	20150359473		2015-12-17	GARRETT CHAD	
	3	20160262677		2016-09-15	EBETSBERGER FRANZ	
	4	20160325085		2016-11-10	CHELAK TODD	
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	6	20190365303		2019-12-05	BULLINGTON GREGORY J	
	7	20180297303		2018-10-18	SEKIGUCHI TAKUMI	
	8	20190175087		2019-06-13	BULLINGTON GREGORY J	
	9	20210145336		2021-05-20	ROGERS BOBBY E	
	10	20060009713		2006-01-12	FLAHERTY PATRICE	

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	1	S5643474	JP		1981-10-12	TORAY INDUSTRIES		☐
	2	1996005875	WO		1996-02-29	BAXTER INT		☒
	3	104107054	CN		2014-10-22	BECTON DICKINSON CO		☒
	4	104981203	CN		2015-10-14	MAGNOLIA MEDICAL TECHNOLOGIES INC		☒
	5	1717280	CN		2006-01-04	SECR DEFENCE		☒
	6	2015150742	WO		2015-10-08	UNIV HULL		☒

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	1	Office Action (Non-Final Rejection) dated 04/25/2023 for US App. 16838017 (pages 1-20).	☐
	2	Office Action (Final Rejection) dated 01/29/2024 for US App. 16838017 (pages 1-44).	☐

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	3	"Membrane Definition & Meaning," Merriam-Webster, Merriam-Webster, 22 Apr. 2009, www.merriam-webster.com/ dictionary/ membrane. (Year: 2009).	☐
	4	Office Action (Advisory Action) dated 02/09/2024 for US App. 16838017 (pages 1-6).	☐
	5	Office Action (Non-Final Rejection) dated 04/16/2024 for US App. 16838017 (pages 1-19).	☐
	6	Office Action (Non-Final Rejection) dated 05/21/2024 for IL App. 286812 (pages 1-3).	☐
	7	First Office Action (Non-Final Rejection) dated 01/16/2024 for JP App. 2021-558648 (pages 1-6).	☐
	8	First Office Action (Non-Final Rejection) dated 09/27/2023 for CN App. 202080000666.0 (pages 1-11).	☐
	9	Second Office Action (Non-Final Rejection dated 04/28/2024 for CN App. 202080000666.0 (pages 1-11).	☐
	10	European Patent Office, Extended European Search Report for European Patent Application 21818838.1-1122, dated April 22, 2024, 11 pages.	☐
	11	Australian Patent Office, Examination Report No. 1 for for Australian Patent Application 2021202622, dated March 18, 2022, 3 pages.	☐
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	14	Notice of Allowance mailed 04-17-2024; Attorney Docket No. 069366-0572201_KUR2C03US. 16 pages.	☐
	15	Office Action (Non-Final Rejection) mailed 10/04/2023 for US Application No. 17538900 (1-47).	☐
	16	First Office Action (Non-Final Rejection) dated 08-03-2023 for CN Application No. 202010300942.7. 21 pages.	☐
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	22	Rule 70(a) Communication for European Application No. 20781928.5-1122 dated November 15, 2022, 1 page.	☐
	23	International Search Report and Written Opinion dated 19 March 2020 for PCT application no. PCT/US2020/023617. pages.	☐
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	25	European Patent Office, Extended European Search Report for European Patent Application 22181212.6-1122 dated October 24, 2022, pages 1-10.	☐
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	27	Notice of Allowance mailed 03-01-2023; Attorney Docket No. 069366-0572419_KUR2D01AU. 3 pages.	☐
	28	First Office Action dated 11/24/2021 for IL Application No. 286030, pages 1-3.	☐
	29	Notice of Allowance mailed 01-29-2023; Attorney Docket No. 069366-0572425_KUR2D01IL. 87 pages.	☐
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	36	Notice of Allowance mailed 02-14-2023; Attorney Docket No. 069366-0572429_KUR3N01IL. 122 pages.	☐
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	42	Notice of Allowance mailed 11-28-2022; Attorney Docket No. 069366-0572168_KUR4002US. 9 pages.	☐
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	47	European Patent Office, Examination Report for European Patent Application 21818838.1, dated April 22, 2024, pages 1-11.	☐

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Please see 37 CFR 1.97(e) to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

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☒ A certification statement is not submitted herewith.

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☒ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

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☐ An identification of an earlier application pursuant to 37 CFR 1.98 (d) (1) is attached.

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A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2024-08-16
Name/Print	Benjamin F. Hudson	Registration Number	71,474

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[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /J.H.P/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	16838017
	Filing Date	2020-04-01
	First Named Inventor	Bobby E. ROGERS
	Art Unit	3791
	Examiner Name	PORTILLO, JAIRO H
	Attorney Docket Number	069366-0572158_KUR7001US

CERTIFICATION STATEMENT

Please see 37 CFR 1.97(e) to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☒ A certification statement is not submitted herewith.

FEE

☒ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

COPIES

☐ An identification of an earlier application pursuant to 37 CFR 1.98 (d) (1) is attached.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2024-08-26
Name/Print	Benjamin F. Hudson	Registration Number	71,474

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

PC 6.1.24

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /J.H.P/

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

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2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/494,622	10/25/2023	Bobby E. ROGERS	069366-0577657_KUR2C05US	9839

27500 7590 12/02/2024

PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
ATTENTION: DOCKETING DEPARTMENT
P.O BOX 10500
McLean, VA 22102

EXAMINER	
ABOUELELA, MAY A	

ART UNIT	PAPER NUMBER
3791	

NOTIFICATION DATE	DELIVERY MODE
12/02/2024	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Docket_IP@pillsburylaw.com

Office Action Summary	Application No. 18/494,622	Applicant(s) ROGERS et al.	
	Examiner MAY A ABOUELELA	Art Unit 3791	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 07/24/2024.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL.** 2b) ☑ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 2-31 is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 2-31 is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to **PPHfeedback@uspto.gov.**

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☑ The drawing(s) filed on 10/25/2023 is/are: a)☑ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☑ Notice of References Cited (PTO-892)

2) ☑ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

Notice of Pre-AIA or AIA Status

1. The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 04/23/2024, 06/27/2024, 08/26/2024 and 10/16/2024. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Objections

3. Claim 2 is objected to because of the following informalities: the phrase "an inlet port for receiving a blood sample" in line 2 should be amended to read –an inlet port configured for receiving a blood sample--. Appropriate correction is required.

4. Claim 3 is objected to because of the following informalities: the phrase "cause the first portion of the blood sample" in line 2 should be amended to read –configured to cause the first portion of the blood sample--. Appropriate correction is required.

5. Claim 7 is objected to because of the following informalities: the phrase "follow-on amounts of the blood sample" in lines 3-4 should be amended to read –the subsequent portion of the blood sample--. Appropriate correction is required.

6. Claim 11 is objected to because of the following informalities: the phrase "the chamber having a volume sufficient to collect the first portion of the blood sample" in

lines 1-2 should be amended to read -- the chamber having a volume configured to be sufficient to collect the first portion of the blood sample--. Appropriate correction is required.

7. Claim 13 is objected to because of the following informalities: the phrase "an inlet port for receiving a blood sample" in line 2 should be amended to read –an inlet port configured for receiving a blood sample--. Appropriate correction is required.

8. Claim 14 is objected to because of the following informalities: the phrase "cause the first portion of the blood sample" in line 2 should be amended to read –configured to cause the first portion of the blood sample--. Appropriate correction is required.

9. Claim 18 is objected to because of the following informalities: the phrase "follow-on amounts of the blood" in line 3 should be amended to read –the subsequent portion of the blood--. Appropriate correction is required.

10. Claim 21 is objected to because of the following informalities: the phrase "the chamber having a volume sufficient to collect the first portion of the blood sample" in lines 1-2 should be amended to read -- the chamber having a volume configured to be sufficient to collect the first portion of the blood sample--. Appropriate correction is required.

11. Claim 22 is objected to because of the following informalities: the phrase "an inlet port for receiving a blood sample" in line 2 should be amended to read –an inlet port configured for receiving a blood sample--. Appropriate correction is required.

12. Claim 23 is objected to because of the following informalities: the phrase "cause the first portion of the blood sample" in line 2 should be amended to read –configured to cause the first portion of the blood sample--. Appropriate correction is required.

13. Claim 26 is objected to because of the following informalities: the phrase "follow-on amounts of the blood" in line 3 should be amended to read –the subsequent portion of the blood--. Appropriate correction is required.

14. Claim 30 is objected to because of the following informalities: the phrase "the chamber having a volume sufficient to collect the first portion of the blood sample" in lines 1-2 should be amended to read -- the chamber having a volume configured to be sufficient to collect the first portion of the blood sample--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

15. The following is a quotation of 35 U.S.C. 112(b):

> (b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 4, 14, 15, 23 and 24 are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor (or for applications subject to pre-AIA 35 U.S.C. 112, the applicant), regards as the invention.

16. Claims 4, 15 and 24 recite the limitation “a material blood impermeable” this limitation is not defined by the claims, which renders the claims indefinite. One with ordinary skill in the art would not be able to know if the claimed “material that is blood impermeable” in claims 4, 15 and 24 is the same and/or different than the claimed “blood impermeable membrane” in claims 2, 13 and 22, respectively. The scope of the claim remains indeterminate because of the claimed “a material blood impermeable” in claims 4, 15 and 24.

17. Claim 3 recites the limitation "the drawing force" in line 3. There is insufficient antecedent basis for this limitation in the claim.

18. Claim 14 recites the limitation "the drawing force" in line 3. There is insufficient antecedent basis for this limitation in the claim.

19. Claim 23 recites the limitation "the drawing force" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

20. The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim(s) 2-8 and 10-31 is/are rejected under 35 U.S.C. 103 as being obvious over Patton et al (US 2008/0145933) in view of Flaherty et al (US 2006/0009713).

As to claims 2-4, 13-15 and 22-24, Patton discloses a device (blood sampling device 500, par.38-40, fig.5) comprising:

an inlet port for receiving a blood sample (inlet/opening connecting needle 508 to input tubing 514, par.38-40, fig.5);

an outlet port (needle 510, fig.5);

a chamber (tubing 516 and reservoir 504, par.38-40, fig.5) comprising a flexible material (flexible material of tubing 516 and reservoir 504), wherein the chamber is connected with the inlet port (516 and 504 are connected to inlet of tubing 514, as best seen in fig.5) and configured to collect a first portion of the blood sample (diversion mechanism 512 can be initially adjusted to divert blood to the one or more pre-sample reservoirs 504 until the one or more pre-sample reservoirs 504 are filled, par.40, fig.5); and

a sampling channel (tubing 514 and 518 connected with inlet of tubing 514, par.38-40, as best seen in fig.4) connected with the inlet port and configured to convey a subsequent portion of the blood sample to the outlet port (which point the diversion

mechanism 512 can be adjusted to divert the flow of blood to the one or more sample vessels 506, ar.38-40, fig.5),

wherein the device is configured such that, when a drawing force applied at the outlet port, the first portion of the blood sample is drawn into the chamber (pre vacuumed effect of vessel 506 withdraws blood, first needle 508 can be inserted into a patient to procure a blood sample. In FIG. 5, the first needle 508 is shown inserted into a vein 520. The second needle 510 is shown inserted into the one or more sample vessels 506 that have been vacuum-sealed. The vacuum in each of the one or more sample vessels 506 causes blood to pass from the vein 520 to the diversion mechanism 512, par.40).

Still, regarding claims 2-4, 13-15 and 22-24, Patton discloses the invention substantially above, wherein a housing of the diverting mechanism is separate from a blood impermeable membrane, but failed to explicitly teach the chamber having a blood impermeable membrane configured to facilitate the chamber collecting the first portion of the blood sample, and causes the first portion of the blood sample to back up into the chamber following application of the drawing force applied from the outlet port, and wherein the device is configured such that, when the drawing force is applied at the outlet port, the first portion of the blood sample is drawn into the chamber to contact a material that is blood impermeable.

However, Flaherty discloses an analogous blood sampling device, wherein the blood sampling chamber comprises (liquid impenetrable, air-permeable membrane 45, par.39, fig.8-10), wherein blood flows into the blood collection chamber 39, air is displaced from the blood collection chamber 39, through the membrane 45 and air opening or openings

46, respectively. This facilitates the substantially continual and unhindered flow of blood from the patient 106 and into the blood collection chamber 39 to collect the desired quantity of blood into the blood collection chamber 39 (par.40, fig.8-10).
Since blood impermeable membrane is well-known in the art, so it would have been obvious to one having an ordinary skill in the art before the effective filing date of the invention to include a blood impermeable membrane in reservoir 504 taught by Patton's invention, as blood impermeable membrane 45 taught by Flaherty's invention to facilitate the continual and unhindered flow of blood from the patient and into the blood collection chamber, as taught by Flaherty's invention (par.40).

As to claims 5, 16 and 25, Patton discloses the device, further comprising a valve (diversion mechanism 512 having valve 60, par.38-41, fig.5) configured to initially close off the sampling channel (diversion mechanism 512 can be initially adjusted to divert blood to the one or more pre-sample reservoirs 504 until the one or more pre-sample reservoirs 504 are filled, or a desired amount of blood has been withdrawn, at which point the diversion mechanism 512 can be adjusted to divert the flow of blood to the one or more sample vessels 506, par.40).

As to claims 6, 17 and 26, Patton discloses the device, further comprising a valve configured to initially close off the sampling channel until the first portion of the blood sample is in the chamber (diversion mechanism 512 can be initially adjusted to divert blood to the one or more pre-sample reservoirs 504 until the one or more pre-sample reservoirs 504 are filled, or a desired amount of blood has been withdrawn, at which

point the diversion mechanism 512 can be adjusted to divert the flow of blood to the one or more sample vessels 506, par.40).

As to claims 7, 18 and 27, Patton discloses the device, further comprising a valve that is configured to initially close off the sampling channel until the first portion of the blood sample is in the chamber and is further configured such that, upon release, follow-on amounts of the blood sample will bypass the chamber and flow through the sampling channel toward the outlet port (diversion mechanism 512 can be initially adjusted to divert blood to the one or more pre-sample reservoirs 504 until the one or more pre-sample reservoirs 504 are filled, or a desired amount of blood has been withdrawn, at which point the diversion mechanism 512 can be adjusted to divert the flow of blood to the one or more sample vessels 506, par.40, as best seen from fig.5 the subsequent blood will bypass reservoir 504 and flows straight from inlet of 502 to tubings 514 and 518).

As to claims 8, 19 and 28, Patton discloses the device, wherein the valve is configured to pinch, shunt, bend or otherwise close off the sampling channel before the first portion of the blood sample is collected in the chamber (diversion mechanism 512 can be initially adjusted to divert blood to the one or more pre-sample reservoirs 504 until the one or more pre-sample reservoirs 504 are filled, or a desired amount of blood has been withdrawn, at which point the diversion mechanism 512 can be adjusted to divert the flow of blood to the one or more sample vessels 506, par.40, fig.5).

As to claims 10, 20 and 29, Patton discloses the device, further comprising a patient needle (patient needle 508, par.38-40, fig.5) and a sample collection device (sample vessel 506, par.38-40, fig.5).

As to claims 11, 21 and 30, Patton discloses the device, the chamber having a volume sufficient to collect the first portion of the blood sample that is more prone to contamination and also to minimize an amount of blood to be sequestered (the data suggests that fewer false positive test results for the presence of microbes in blood are obtained over conventional methods when initially-drawn volumes of blood are not used in microbial testing, par.54).

As to claims 12 and 31, Patton/ Flaherty combination discloses the volume of blood withdrawn into the one or more pre-sample reservoirs 504 is at least equal to the collective volumes of the first needle 508, the flexible, sterile input tubing 516, the diversion mechanism 512, and the first sterile output tubing 516 (par.40), but failed to explicitly teach he chamber has a volume of less than 1.5 cubic centimeters. However, it would have been obvious to one having an ordinary skill in the art at the time the invention was made to allow reservoir 504 to collect blood volume less than 1.5 cubic centimeters, since it has been that discovering the optimum value of a result of effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215(CCPA 1980).

Double Patenting

21. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the claims at issue are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the reference application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO internet Web site contains terminal disclaimer forms which may be used. Please visit http://www.uspto.gov/forms/. The filing date of the application will determine what form should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all

requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to http://www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp.

Claims 2-31 are non-provisionally rejected on the ground of non-statutory double patenting as being unpatentable over claims 1-15 of U.S Patent Application No. 11,832,944 and are provisionally rejected on the ground of non-statutory double patenting as being unpatentable over claims 1-9, 11-22 and 24-26 of pending Application No.18/783088. Although the claims at issue are not identical, they are not patentably distinct from each other because the U.S Patent Application and the instance application are claiming a common subject matter including: a device comprising: an inlet port for receiving a blood sample; an outlet port; a chamber connected to the inlet port and being configured to collect a first portion of the blood sample, the chamber having a blood impermeable membrane configured to facilitate the chamber collecting the first portion of the blood sample; and a sampling channel connected with the inlet port and configured to convey a subsequent portion of the blood sample to the outlet port.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MAY A ABOUELELA whose telephone number is (571)270-7917. The examiner can normally be reached 8-5.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an

interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JACQUELINE CHENG can be reached on 5712725596. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: https://patentcenter.uspto.gov. Visit https://www.uspto.gov/patents/apply/patent-center for more information about Patent Center and https://www.uspto.gov/patents/docx for information about filing in DOCX format. For additional questions, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MAY A ABOUELELA/
Primary Examiner, Art Unit 3791

Notice of References Cited	Application/Control No. 18/494,622	Applicant(s)/Patent Under Reexamination ROGERS et al.	
	Examiner MAY A ABOUELELA	Art Unit 3791	Page 1 of 4

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date YYYY-MM-DD	Name	CPC Classification	US Classification
*	A	US-20080319346-A1	2008-12-25	Crawford; Jamieson	A61B5/150656	600/576
*	B	US-4412548-A	1983-11-01	Hoch; Louis	A61B5/150213	600/577
*	C	US-5222502-A	1993-06-29	Kurose; Katsutoshi	A61B5/150732	600/584
*	D	US-5520193-A	1996-05-28	Suzuki; Issei	A61B5/1545	604/126
*	E	US-20100057004-A1	2010-03-04	Christensen; Kelly D.	A61M25/0606	604/122
*	F	US-20070088279-A1	2007-04-19	Shue; Ming-Jeng	A61M25/0693	604/168.01
*	G	US-20080145933-A1	2008-06-19	Patton; Richard G.	A61B10/0051	435/379
*	H	US-20040054333-A1	2004-03-18	Theeuwes, Felix	A61M5/14276	604/248
*	I	US-9022951-B2	2015-05-05	Bullington; Gregory	A61B5/150992	600/576
*	J	US-6569117-B1	2003-05-27	Ziv; David	A61M39/02	604/246
*	K	US-3741197-A	1973-06-26	Sanz; Manuel C.	A61B5/150267	600/583
*	L	US-20100010372-A1	2010-01-14	BROWN; LEROY R.	A61B5/15003	600/573
*	M	US-8603009-B2	2013-12-10	Tan; Alvin Chee Leong	A61B5/150251	600/573

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date YYYY-MM-DD	Country	Name	CPC Classification
	N					
	O					
	P					
	Q					
	R					
	S					
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NON-PATENT DOCUMENTS

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Notice of References Cited	Application/Control No. 18/494,622	Applicant(s)/Patent Under Reexamination ROGERS et al.	
	Examiner MAY A ABOUELELA	Art Unit 3791	Page 2 of 4

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date YYYY-MM-DD	Name	CPC Classification	US Classification
*	A	US-9138572-B2	2015-09-22	Zeytoonian; Paul	A61M39/26	1/1
*	B	US-20080167577-A1	2008-07-10	Weilbacher; Eugene E.	A61B5/1545	600/576
*	C	US-20080086085-A1	2008-04-10	Brown; Leroy R.	A61B5/150389	604/122
*	D	US-9877675-B2	2018-01-30	Baid; Rishi	A61B5/150389	1/1
*	E	US-4444203-A	1984-04-24	Engelman; Allan	A61B5/150496	600/576
*	F	US-20070083162-A1	2007-04-12	O'Reagan; James	A61M39/26	604/167.03
*	G	US-6398743-B1	2002-06-04	Halseth; Thor R.	A61B5/15003	604/164.12
*	H	US-9022950-B2	2015-05-05	Bullington; Gregory	A61B5/153	600/576
*	I	US-9155495-B2	2015-10-13	Bullington; Gregory J.	A61B5/150389	1/1
*	J	US-20160008579-A1	2016-01-14	Burkholz; Jonathan Karl	A61M5/158	604/164.08
*	K	US-20120016266-A1	2012-01-19	Burkholz; Jonathan Karl	A61B5/150992	600/581
*	L	US-4436098-A	1984-03-13	Kaufman; Joseph	A61B5/1545	604/199
*	M	US-4154229-A	1979-05-15	Nugent; Edward L.	A61B5/154	600/577

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*		Document Number Country Code-Number-Kind Code	Date YYYY-MM-DD	Country	Name	CPC Classification
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	Examiner MAY A ABOUELELA	Art Unit 3791	Page 3 of 4

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date YYYY-MM-DD	Name	CPC Classification	US Classification
*	A	US-20040073171-A1	2004-04-15	Rogers, Bobby E.	A61M39/26	604/164.13
*	B	US-8568371-B2	2013-10-29	Siopes; William	A61M39/06	251/903
*	C	US-8540663-B2	2013-09-24	Davey; Christopher T.	A61M25/0029	604/93.01
*	D	US-8523826-B2	2013-09-03	Layton, Jr.; Russell K.	A61M39/16	604/533
*	E	US-20160174888-A1	2016-06-23	Berthier; Erwin	A61B5/150503	600/573
*	F	US-8197420-B2	2012-06-12	Patton; Richard G.	A61B10/0045	600/573
*	G	US-4057050-A	1977-11-08	Sarstedt; Walter	A61B5/150351	604/125
*	H	US-20050240161-A1	2005-10-27	Crawford, Jamieson William McLean	A61B5/150816	604/264
*	I	US-20040147855-A1	2004-07-29	Marsden, Stewart	A61B5/150496	600/576
*	J	US-8864684-B2	2014-10-21	Bullington; Gregory J.	A61B10/0048	600/576
*	K	US-8535241-B2	2013-09-17	Bullington; Gregory	A61B5/150251	604/249
*	L	US-20130317391-A1	2013-11-28	Bullington; Gregory J.	A61B5/15003	600/578
*	M	US-20050004524-A1	2005-01-06	Newby, C. Mark	A61B5/150648	604/164.08

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*	A	US-20030105414-A1	2003-06-05	Leong, Alvin Tan Chee	A61B5/15003	600/576
*	B	US-5749857-A	1998-05-12	Cuppy; Michael J.	A61M25/0606	604/161
*	C	US-9060724-B2	2015-06-23	Bullington; Gregory J.	A61B5/150221	1/1
*	D	US-9204864-B2	2015-12-08	Bullington; Gregory J.	A61B10/0096	1/1
*	E	US-20020004647-A1	2002-01-10	Leong, Alvin Tan Chee	A61B5/15003	604/168.01
*	F	US-3817240-A	1974-06-18	Ayres; Waldemar A.	A61B5/150221	600/584
*	G	US-3874367-A	1975-04-01	Ayres; Waldemar A.	A61B5/15003	600/577
*	H	US-3886930-A	1975-06-03	Ryan; George R.	A61B5/150351	600/584
*	I	US-4106497-A	1978-08-15	Percarpio; Edward P.	A61B5/150389	600/579
*	J	US-4207870-A	1980-06-17	Eldridge; William N.	A61B5/150732	604/167.03
*	K	US-20160325085-A1	2016-11-10	Chelak; Todd	F16K7/20	1/1
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Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	18494622
Filing Date	2023-10-25
First Named Inventor	Bobby ROGERS
Art Unit	OPAP
Examiner Name	CENTRAL, DOCKET
Attorney Docket Number	069366-0577657_KUR2C05US

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	4312362		1982-01-26	KAUFMAN JOSEPH	

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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20140163419		2014-06-12	BULLINGTON GREGORY J	
	2	20140309558		2014-10-16	FLETCHER GARY D	
	3	20140073990		2014-03-13	HOLMES ELIZABETH A	
	4	20140323911		2014-10-30	SLOAN DEBORAH	
	5	20040112808		2004-06-17	TAKAGI YOSHIKI	

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	Attorney Docket Number	069366-0577657_KUR2C05US

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	1	Office Action (Non-Final Rejection) dated 9/24/2024 for U.S. Application No. 18/783,173 ; Attorney Docket No. 069366-0580420_KUR3C03US (pages 1-62).	☐
	2	Office Action (Non-Final Rejection) dated 9/17/2024 for U.S. Application No. 17/893,079 ; Attorney Docket No. 069366-0572192_KUR3C02US (pages 1-50).	☐
	3	Office Action (Non-Final Rejection) dated 9/23/2024 for U.S. Application No. 17/730,118 ; Attorney Docket No. 069366-0572186_KUR3C01US (pages 1-73).	☐
	4	Office Action (Non-Final Rejection) dated 9/17/2024 for U.S. Application No. 18/783,088 ; Attorney Docket No. 069366-0580418_KUR2C06US (pages 1-60).	☐
	5	Office Action (Notice of Deficiencies) dated 10/14//2023 for IL App No. 309380 (pages 1-7).	☐

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Examiner Signature	/MAY A ABOUELELA/	Date Considered	11/26/2024

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	First Named Inventor	Bobby ROGERS
	Art Unit	OPAP
	Examiner Name	CENTRAL, DOCKET
	Attorney Docket Number	069366-0577657_KUR2C05US

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

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	Examiner Name	CENTRAL, DOCKET
	Attorney Docket Number	069366-0577657_KUR2C05US

CERTIFICATION STATEMENT

Please see 37 CFR 1.97(e) to make the appropriate selection(s):

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☐ See attached certification statement.

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FEE

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☐ An identification of an earlier application pursuant to 37 CFR 1.98 (d) (1) is attached.

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A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2024-10-16
Name/Print	Benjamin F. Hudson	Registration Number	71,474

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Application Number	18494622
Filing Date	2023-10-25
First Named Inventor	Bobby ROGERS
Art Unit	3791
Examiner Name	DOCKET CENTRAL
Attorney Docket Number	069366-0577657_KUR2C05US

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	Attorney Docket Number	069366-0577657_KUR2C05US

	1	Office Action (Non-Final Rejection) mailed 11/29/2022 for Application No. 2021-214177, pages 1-3.	☐
	2	Notice of Allowance mailed 06-20-2023; Attorney Docket No. 069366-0572231_KUR3D01JP. 6 pages.	☐
	3	Office Action (Non-Final Rejection) mailed 11/4/2022 for Application No. 17094692, pages 1-50.	☐
	4	Notice of Allowance mailed 04-20-2023; Attorney Docket No. 069366-0572169_KUR4C01US. 36 pages.	☐
	5	Office Action (Non-Final Rejection) mailed 08/04/2022 for Application No. 16819033, pages 1-35.	☐
	6	Notice of Allowance mailed 11-28-2022; Attorney Docket No. 069366-0572168_KUR4002US. 9 pages.	☐

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☐ See attached certification statement.

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☒ A certification statement is not submitted herewith.

SIGNATURE

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Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2024-06-27
Name/Print	Benjamin F. Hudson	Registration Number	71,474

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6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

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Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

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Application Number	18494622
Filing Date	2023-10-25
First Named Inventor	Bobby ROGERS
Art Unit	OPAP
Examiner Name	CENTRAL, DOCKET
Attorney Docket Number	069366-0577657_KUR2C05US

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	1	Notice of Allowance mailed 07-04-2024; Attorney Docket No. 069366-0572164_KUR7N01JP. 9 pages.	☐
	2	Office Action mailed 05-21-2024; Attorney Docket No. 069366-0572161_KUR7N01IL. 6 pages.	☐
	3	European Patent Office, Examination Report for European Patent Application 20781928.5, dated July 31, 2024, pages 1-6.	☐

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Examiner Signature	/MAY A ABOUELELA/	Date Considered	10/16/2024

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

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CERTIFICATION STATEMENT

Please see 37 CFR 1.97(e) to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☒ A certification statement is not submitted herewith.

FEE

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

COPIES

☐ An identification of an earlier application pursuant to 37 CFR 1.98 (d) (1) is attached.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2024-08-26
Name/Print	Benjamin F. Hudson	Registration Number	71,474

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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The information provided by you in this form will be subject to the following routine uses:

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3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

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First Named Inventor	Bobby E. ROGERS
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Attorney Docket Number	069366-0577657_KUR2C05US

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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	2	5432084		1995-07-11	BRUBAKER DANIEL B	
	3	5972294		1999-10-26	SMITH JOHN L	
	4	6187347		2001-02-13	PATTERSON JAMES A	
	5	6599474		2003-07-29	EVTODIENKO VLADIMIR	
	6	8197420		2012-06-12	PATTON RICHARD G	
	7	8535241		2013-09-17	BULLINGTON GREGORY	
	8	9060724		2015-06-23	BULLINGTON GREGORY J	

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	9	9155495		2015-10-13	BULLINGTON GREGORY J	
	10	4412548		1983-11-01	HOCH LOUIS	
	11	5222502		1993-06-29	KUROSE KATSUTOSHI	
	12	5520193		1996-05-28	SUZUKI ISSEI	
	13	9022951		2015-05-05	BULLINGTON GREGORY	
	14	6569117		2003-05-27	ZIV DAVID	
	15	3741197		1973-06-26	SANZ M	
	16	8603009		2013-12-10	TAN ALVIN CHEE LEONG	
	17	4207870		1980-06-17	ELDRIDGE WILLIAM N	
	18	9877675		2018-01-30	BAID RISHI	
	19	4444203		1984-04-24	ENGELMAN ALLAN	

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	Attorney Docket Number	069366-0577657_KUR2C05US

	20	6398743		2002-06-04	HALSETH THOR R	
	21	9022950		2015-05-05	BULLINGTON GREGORY	
	22	4436098		1984-03-13	KAUFMAN JOSEPH	
	23	9138572		2015-09-22	ZEYTOONIAN PAUL	
	24	8568371		2013-10-29	SIOPES WILLIAM	
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	26	8523826		2013-09-03	LAYTON JR RUSSELL K	
	27	4057050		1977-11-08	SARSTEDT WALTER	
	28	8864684		2014-10-21	BULLINGTON GREGORY J	
	29	5749857		1998-05-12	CUPPY MICHAEL J	
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	Examiner Name	
	Attorney Docket Number	069366-0577657_KUR2C05US

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	106	10265007		2019-04-23	BULLINGTON GREGORY	
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	2	20030082074		2003-05-01	JURIK FRANKLIN A	
	3	20030185707		2003-10-02	IWAKI YOSHIHIDE	
	4	20040116830		2004-06-17	TRUDEAU WILLIAM M	
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CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2024-04-23
Name/Print	Benjamin F. Hudson	Registration Number	71,474

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-22)
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	18494622
Filing Date	2023-10-25
First Named Inventor	Bobby ROGERS
Art Unit	3791
Examiner Name	DOCKET CENTRAL
Attorney Docket Number	069366-0577657_KUR2C05US

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	6126643		2000-10-03	VAILLANCOUERT VINCENT L	
	2	9764891		2017-09-19	AVILES VICTOR M	
	3	5147329		1992-09-15	BRANNON JAMES K	
	4	5518005		1996-05-21	BRANNON JAMES K	
	5	62845767		2019-05-09	BREWER MICHAEL	

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	1	20150314105		2015-11-05	GASPARYAN LEVON	

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	Attorney Docket Number	069366-0577657_KUR2C05US

	2	20150359473		2015-12-17	GARRETT CHAD	
	3	20160262677		2016-09-15	EBETSBERGER FRANZ	
	4	20160325085		2016-11-10	CHELAK TODD	
	5	20070031283		2007-02-08	DAVIS CHARLES Q	
	6	20190365303		2019-12-05	BULLINGTON GREGORY J	
	7	20180297303		2018-10-18	SEKIGUCHI TAKUMI	
	8	20190175087		2019-06-13	BULLINGTON GREGORY J	
	9	20210145336		2021-05-20	ROGERS BOBBY E	
	10	20060009713		2006-01-12	FLAHERTY PATRICE	

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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] ¡	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]

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	Art Unit	3791
	Examiner Name	DOCKET CENTRAL
	Attorney Docket Number	069366-0577657_KUR2C05US

	1	S5643474	JP		1981-10-12			☐
	2	0448795	EP		1991-02-10			☒
	3	1996005875	WO		1996-02-29	BAXTER INT		☒
	4	104107054	CN		2014-10-22	BECTON DICKINSON CO		☒
	5	104981203	CN		2015-10-14	MAGNOLIA MEDICAL TECHNOLOGIES INC		☒
	6	1717280	CN		2006-01-04	SECR DEFENCE		☒
	7	2015150742	WO		2015-10-08	UNIV HULL		☒

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Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1	JP Office Action mailed 02/27/2024; Attorney Docket No. 069366-0575273_KUR2D03JP. 11 pages.	☐
	2	Notice of Allowance mailed 01-17-2024; Attorney Docket No. 069366-0572201_KUR2C03US. 16 pages.	☐

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	Attorney Docket Number	069366-0577657_KUR2C05US

	3	Office Action (Notice of Section 18) dated 12/20/2023 for IL App No. 309380 (pages 1-5).	☐
	4	Examination Report dated Sep. 28, 2023, for European Patent Application No. 22181212.6. 5 pages.	☐
	5	JP Notice of Allowance mailed 06-20-2023; Attorney Docket No. 069366-0572231_KUR3D01JP. 6 pages.	☐
	6	Office Action (Non-Final Rejection) dated 10/04/2023 for US App. No. 17538990 (pages 1-47)	☐
	7	Notice of Allowance mailed 09-14-2023; Attorney Docket No. 069366-0574152_KUR2D02IL. 90 pages.	☐
	8	Notice of Allowance mailed 09-08-2023; Attorney Docket No. 069366-0574153_KUR2C04US. 35 page.	☐
	9	Office Action (Final Rejection) dated 08/25/2023 for US App. No. 18113710 (pages 1-50)	☐
	10	Japanese Patent Office, Notice of Reasons for Rejection for JP Application No. JP 2020-118498 date Aug. 10, 2021.	☐
	11	Japanese Patent Office, Notice of Reasons for Rejection dated Jun. 15, 2021, Application No. JP 2019-534792, 6 pages.	☐
	12	Japanese Patent Office, Notice of Reasons for Rejection, Japanese patent application No. JP2018-523384, dated Jul. 23, 2019, 5 pages.	☐
	13	European Patent Office; Communication pursuant to Article 94(3) EPC, dated Oct. 31, 2018; 11 pages.	☐

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	Attorney Docket Number	069366-0577657_KUR2C05US

	14	Examination Report No. 1 dated Apr. 29, 2020, for Australian Patent Application No. 2016297849. 3 pages.	☐
	15	European Patent Application No. EP19200766.4 extended European Search Report dated Dec. 2, 2019, 11 pages.	☐
	16	European Patent Office, Extended European Search Report for European Patent Application 20197213.0-1132, dated Dec. 9, 2020, 6 pages.	☐
	17	Communication Under Rule 71(3) EPC dated Apr. 22, 2020 for EP application No. 17840467.9. 125 pages.	☐
	18	Office Action (Non-Final Rejection) dated 01/25/2024 for IL App. 302893 (pages 1-3).	☐
	19	Office Action (Non-Final Rejection) dated 04/25/2023 for US App. 16838017 (pages 1-20).	☐
	20	Office Action (Final Rejection) dated 01/29/2024 for US App. 16838017 (pages 1-44).	☐
	21	"Membrane Definition & Meaning," Merriam-Webster, Merriam-Webster, 22 Apr. 2009, www.merriam-webster.com/ dictionary/ membrane. (Year: 2009).	☐
	22	Office Action (Advisory Action) dated 02/09/2024 for US App. 16838017 (pages 1-6).	☐
	23	Office Action (Non-Final Rejection) dated 04/16/2024 for US App. 16838017 (pages 1-19).	☐
	24	Office Action (Non-Final Rejection) dated 05/21/2024 for IL App. 286812 (pages 1-3).	☐

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	Attorney Docket Number	069366-0577657_KUR2C05US

	25	First Office Action (Non-Final Rejection) dated 01/16/2024 for JP App. 2021-558648 (pages 1-6).	☐
	26	First Office Action (Non-Final Rejection) dated 09/27/2023 for CN App. 202080000666.0 (pages 1-11).	☐
	27	Second Office Action (Non-Final Rejection dated 04/28/2024 for CN App. 202080000666.0 (pages 1-11).	☐
	28	European Patent Office, Extended European Search Report for European Patent Application 21818838.1-1122, dated April 22, 2024, 11 pages.	☐
	29	European Patent Office, Extended European Search Report for European Patent Application 23155927.9-1122, dated July 26, 2023, pages 1-8.	☐
	30	Office Action (Non-Final Rejection) mailed 10/04/2023 for US Application No. 17538900 (1-47).	☐
	31	First Office Action (Non-Final Rejection) dated 08-03-2023 for CN Application No. 202010300942.7. 21 pages.	☐
	32	Office Action (Non-Final Rejection) dated 02/21/2023 for US Application No. 17893079, pages 1-32.	☐
	33	Office Action (Final Rejection) dated 07/19/2023 for US Application No. 17893079, pages 1-21.	☐
	34	Advisory Action dated 09/29/2023 for US Application 17893079, pages 1-24.	☐
	35	European Patent Office, Extended European Search Report for European Patent Application 20781928.5-1122 dated October 28, 2022, pages 1-10.	☐

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	36	Rule 70(a) Communication for European Application No. 20781928.5-1122 dated November 15, 2022, 1 page.	☐
	37	International Search Report and Written Opinion dated 19 March 2020 for PCT application no. PCT/US2020/023617. pages.	☐
	38	International Search Report and Written Opinion dated 28 September 2021 for PCT application no. PCT/ US2021/035294. 7 pages.	☐
	39	European Patent Office, Extended European Search Report for European Patent Application 22181212.6-1122 dated October 24, 2022, pages 1-10.	☐
	40	Australian Patent Office, Australian Examination Report No. 1 for Application No. 2021120 622 dated March 18, 2022, 3 pages.	☐
	41	Notice of Allowance mailed 03-01-2023; Attorney Docket No. 069366-0572419_KUR2D01AU. 3 pages.	☐
	42	First Office Action dated 11/24/2021 for IL Application No. 286030, pages 1-3.	☐
	43	Notice of Allowance mailed 01-29-2023; Attorney Docket No. 069366-0572425_KUR2D01IL. 87 pages.	☐
	44	Office Action (Non-Final Rejection) dated 08/10/2021 for Japanese Application No. 2020-118498, pages 1-7.	☐
	45	Office Action (Non-Final Rejection) dated 03/28/2022 for Japanese Application No. 2020-118498, pages 1-3.	☐
	46	Office Action (Non-Final Rejection) dated 09/01/2022 for Japanese Application No. 2020-118498, pages 1-4.	☐

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	Attorney Docket Number	069366-0577657_KUR2C05US

	47	Notice of Allowance mailed 04-04-2023; Attorney Docket No. 069366-0572230_KUR2D02JP. 6 pages.	☐
	48	Rule 71(3) Communication and Text for Grant mailed 08/31/2022 for European Application No. 19200766.4-1122. 189 pages.	☐
	49	Office Action (Non-Final Rejection) mailed 01/21/2022 for Israeli Application No. 267684. 3 pages.	☐
	50	Notice of Allowance mailed 02-14-2023; Attorney Docket No. 069366-0572429_KUR3N01IL. 122 pages.	☐

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Examiner Signature	/MAY A ABOUELELA/	Date Considered	10/16/2024

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	Examiner Name	DOCKET CENTRAL
	Attorney Docket Number	069366-0577657_KUR2C05US

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

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☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

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A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2024-06-27
Name/Print	Benjamin F. Hudson	Registration Number	71,474

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ELECTRONIC PAYMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
18/898,239	**07/02/2025 06:44:57 PM Z ET**	**069366-0581370_KUR2C07US**

Title of Invention

BLOOD SAMPLE OPTIMIZATION DEVICE

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	7801	FILED BY	TRENT TERCENIO
PATENT CENTER #	71189265	AUTHORIZED BY	Benjamin Hudson
CUSTOMER #	27500	FILING DATE	09/26/2024
CORRESPONDENCE ADDRESS	-	FIRST NAMED INVENTOR	Bobby E. Rogers

Payment Information

PAYMENT METHOD	PAYMENT TRANSACTION ID	PAYMENT AUTHORIZED BY
DA / 033975	**E202572I45198008**	**TRENT TERCENIO**

FEE CODE	DESCRIPTION	ITEM PRICE($)	QUANTITY	ITEM TOTAL($)
2253	EXTENSION FOR RESPONSE WITHIN THIRD MONTH, EXCEPT PROVISIONAL APPLICATIONS	636.00	1	636.00
2801	REQUEST FOR CONTINUED EXAMINATION (RCE) - 1ST REQUEST (SEE 37 CFR 1.114)	600.00	1	600.00
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This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

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Receipt will establish the filing date of the application

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/783,173	07/24/2024	Bobby E. ROGERS	069366-0580420_KUR3C03US	1561

27500 7590 02/11/2025

PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
ATTENTION: DOCKETING DEPARTMENT
P.O BOX 10500
McLean, VA 22102

EXAMINER	
NGUYEN, HUONG Q	

ART UNIT	PAPER NUMBER
3791	

NOTIFICATION DATE	DELIVERY MODE
02/11/2025	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Docket_IP@pillsburylaw.com

Office Action Summary	Application No. 18/783,173	Applicant(s) ROGERS et al.	
	Examiner Huong Q NGUYEN	Art Unit 3791	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 11/25/2024.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL.** 2b) ☑ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 1-30 is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 1-30 is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to **PPHfeedback@uspto.gov.**

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☑ The drawing(s) filed on 7/24/2024 is/are: a)☑ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☑ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/25/2024 has been entered.

Claims 1-30 remain pending and under prosecution.

Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Claim Interpretation

The following is a quotation of 35 U.S.C. 112(f):

> (f) Element in Claim for a Combination. – An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

The following is a quotation of pre-AIA 35 U.S.C. 112, sixth paragraph:

> An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

The claims in this application are given their broadest reasonable interpretation using the plain meaning of the claim language in light of the specification as it would be understood by one of ordinary skill in the art. The broadest reasonable interpretation of a claim element (also commonly referred to as a claim limitation) is limited by the description in the specification when 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is invoked.

As explained in MPEP § 2181, subsection I, claim limitations that meet the following three-prong test will be interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph:

(A) the claim limitation uses the term "means" or "step" or a term used as a substitute for "means" that is a generic placeholder (also called a nonce term or a non-structural term having no specific structural meaning) for performing the claimed function;

(B) the term "means" or "step" or the generic placeholder is modified by functional language, typically, but not always linked by the transition word "for" (e.g., "means for") or another linking word or phrase, such as "configured to" or "so that"; and

(C) the term "means" or "step" or the generic placeholder is not modified by sufficient structure, material, or acts for performing the claimed function.

Use of the word "means" (or "step") in a claim with functional language creates a rebuttable presumption that the claim limitation is to be treated in accordance with 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph. The presumption that the claim limitation is interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is rebutted when the claim limitation recites sufficient structure, material, or acts to entirely perform the recited function.

Absence of the word "means" (or "step") in a claim creates a rebuttable presumption that the claim limitation is not to be treated in accordance with 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph. The presumption that the claim limitation is not interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is rebutted when the claim limitation recites function without reciting sufficient structure, material or acts to entirely perform the recited function.

Claim limitations in this application that use the word "means" (or "step") are being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, except as otherwise indicated in an Office action. Conversely, claim limitations in this application that do not use the word "means" (or "step") are not being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, except as otherwise indicated in an Office action.

No claim elements are interpreted under 112(f).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a)(1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention.

Claim(s) 1-5, 13-20, and 28-30 is/are rejected under 35 U.S.C. 102(a)(1) as being anticipated by Bullington et al (US Pub No. 20140163419).

In regard to Claims 1 and 16, Bullington et al disclose a device comprising:

an inlet port 405 for receiving a blood sample, best seen in Figure 12 (0081, 0089);

an outlet port 402 (proximal end portion of housing 401), best seen in Figure 13-15 (0085);

a chamber 480 connected with the inlet port, and configured to collect a first portion of the blood sample when under a vacuum is applied from the outlet port from a blood sample collection device 451, best seen in Figure 14 (0079, 0091 – "the proximal motion of the second member 451 moves the plunger 476 of the first member 470 in the proximal direction relative to the shunt tube 471… increases the volume of the portion of the inner volume 411 of the housing 401 that is distal of the plunger 476, thereby defining the first reservoir 480, as shown in FIG. 14. With the plunger 476 forming a fluid tight seal with the inner surface of the walls defining the inner volume 411 and with the shunt tube 471 about which the plunger 476 is disposed, the volume increase of the portion of the inner volume 411 can produce a negative pressure within the first reservoir 480"; 0092 – "Expanding further, the negative pressure within the first reservoir 480 produced by the movement of the plunger 476 (as indicated by the arrow II) introduces a suction force within the portion of the patient. Thus, a bodily-fluid is drawn through the port 405, the first lumen 432 defined by the flow control mechanism 430, and the first lumen 406 defined by the diverter 409 and into the fluid reservoir 480. In some embodiments, the bodily-fluid can contain undesirable microbes such as, for example, dermally-residing microbes and/or other external contaminants");

a sampling channel 433 connected with the inlet port and configured to convey a subsequent portion of the blood sample to the outlet port, best seen in Figure 15 (0095); and

a moving part 430, 431, 435 (flow control mechanism first member 431 controlled by member 435), moving part also defined by plunger 476 (0084 – Figure 13-15),

configured to be movable from a first position to a second position to allow the blood sample to flow to the sampling channel –

in the first position, moving member 435 rotates first member 431 such that lumen 433 (sampling channel) is fluidically isolated, due to lumen 432 of the flow control mechanism aligned with the inlet port 405, which leads through lumen 406 in diverter 409 and into chamber 480 – thus the inlet port 405 is in fluid communication with the chamber 480, best seen in Figure 14 (0081, 0092);

in the second position, moving member 435 rotates first member 431 such that lumen 433 is aligned with inlet port 405 such that "a desired amount of bodily-fluid is drawn through the port 405, the second lumen 433 of the flow control mechanism 430, the second lumen 407 of the diverter 409, and the lumen 475 defined by the shunt tube 471 and into the second reservoir 490. Moreover, the bodily-fluid disposed within the second reservoir 490 is fluidically isolated from the first, predetermined amount of bodily-fluid contained within the first reservoir 480," best seen in Figure 15 (0082, 0083, 0095, 0097) – thus creates a pathway from the inlet port 405 to the outlet port 402, which is adjacent to reservoir 490.

2, 17. The device in accordance with claim 1, wherein the first position allows the collection of the first portion of the blood sample in the chamber 480, best seen in Figure 14.

3, 18. The device in accordance with claim 1, wherein the moving part 430, 431, 435 is configured to move from the first position to the second position after the first portion of the blood sample flows into the chamber 480 – sample flow into the chamber 480 occurs first, best seen in Figure 14, followed by moving member 435 rotating first member 431 such that lumen 433 is aligned with inlet port 405 is aligned with the outlet port 402, into second reservoir 490, best seen in Figure 15 (0082, 0083, 0095, 0097).

4, 19. The device in accordance with claim 1, the device further comprising a locking mechanism 474 configured to maintain the moving part 476 in the first position (Figure 14) until the chamber 480 is filled with the first portion of the blood sample – protrusion 474 enables proximal movement of plunger 476 to create chamber 480 for the first portion of the blood sample, best seen in Figure 13-14 (0085, 0091, 0096).

5, 20. The device in accordance with claim 1, wherein the moving part 430, 431, 476 is an inner chamber housing, best seen in Figure 13-15.

13, 28. The device in accordance with claim 1, further comprising a patient needle – "a user can engage the transfer device 400 to couple the port 405 to a proximal end portion of a lumen-defining device (not shown) such as, for example, a butterfly needle, a cannula assembly, a trocar (which in some cases is used to insert a catheter into a patient), or the like" (0089) and

a sample collection device – "with the desired amount of bodily-fluid disposed within the second fluid reservoir 490, the transfer device 400 can be removed from the portion of the patient and disposed above or in a container (e.g., a vile, a test tube, a petri dish, a culture medium, a test apparatus, or the like) such that a portion of the second amount of bodily-fluid can be tested" (0099).

14, 29. The device in accordance with claim 1, the chamber having a volume sufficient to collect the first portion of the blood sample that is more prone to contamination and also to minimize an amount of blood to be sequestered (0092).

15, 30. The device in accordance with claim 1, wherein the chamber 480 has a volume of less than 1.5 cubic centimeters, e.g. 0.1 mL (0094).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries for establishing a background for determining obviousness under 35 U.S.C. 103 are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims the examiner presumes that the subject matter of the various claims was commonly owned as of the effective filing date of the claimed invention(s) absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and effective filing dates of each claim that was not commonly owned as of the effective filing date of the later invention in order for the examiner to consider the applicability of 35 U.S.C. 102(b)(2)(C) for any potential 35 U.S.C. 102(a)(2) prior art against the later invention.

Claim(s) 6-12 and 21-27 is/are rejected under 35 U.S.C. 103 as being unpatentable over Bullington et al as applied to claim 1 above, and further in view of Percarpio (US Pat No. 4106497 – cited by applicant).

In regard to Claims 6-9 and 21-24, Bullington et al disclose the invention above but do not expressly disclose a blood impermeable membrane is configured to facilitate the chamber collecting the first portion of the blood sample.

Percarpio teach that it is well-known in the art to provide an analogous blood sampling device comprising an inlet port 22 for receiving a blood sample, an outlet port 42, 44, a

chamber to collect a first portion of the blood sample (indicator area), and a sampling channel 28 connecting the inlet and the outlet, including a blood impermeable membrane 90 to enable necessary venting of air for the desired flow of the blood first to the chamber before directing it to the outlet (Col.4: 16-39). Percarpio teach a housing 40, 56 separate from the blood impermeable membrane 90, best seen in Figure 3-4, as an effective configuration for the location of said blood impermeable membrane.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the of filing to modify Bullington et al to include a blood impermeable membrane causes the first portion of the blood sample to back up into the chamber following application of the drawing force applied from the outlet port as taught by Percarpio by enabling necessary venting of air from the device during the desired flow of blood such that, when the drawing force is applied at the outlet port, the first portion of the blood sample is drawn into the chamber in the manner taught by Bullington et al to contact a material that is blood impermeable to enable the venting of air, wherein the blood impermeable membrane is separate from the housing, as taught by Percarpio as an effective configuration for said blood impermeable membrane.

In regard to Claims 10-12 and 25-27, Bullington et al disclose the invention above but do not expressly disclose a valve configured to initially close off the sampling channel.

Percarpio teach that it is well-known in the art to provide an analogous blood sampling device comprising an inlet port 22 for receiving a blood sample, an outlet port 42, 44, a chamber to collect a first portion of the blood sample (indicator area), and a sampling channel

28 connecting the inlet and the outlet, including a blood impermeable membrane 90 to enable necessary venting of air for the desired flow of the blood first to the chamber before directing it to the outlet (Col.4: 16-39). Percarpio teach a valve 78 (check valve) that is configured to initially close off access to the outlet until the first portion of the blood sample is in the chamber, best seen in Figure 3, and is further configured such that, upon release, follow-on amounts of the blood sample will bypass the chamber and flow through the sampling channel toward the outlet port, best seen in Figure 4 (Col.3: 61-Col.4: 15, 64-Col.5: 47). Percarpio also teach the valve is configured to pinch, shunt, bend or otherwise close off the outlet before the first portion of the blood sample is collected in the chamber, best seen in Figure 3-4 (Col.3: 61-Col.4: 15, 64-Col.5: 47).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of filing to modify Bullington et al to include a valve to pinch, shunt, bend or otherwise close off the outlet in the manner above as taught by Percarpio to effectively seal off the outlet before the blood is properly in the chamber of Bullington et al, wherein it would have been obvious to a skilled artisan to place the valve such that it closes off the sampling channel and not just the outlet, to effectively block the flow of blood upstream before it reaches the outlet, prior to being drawn into the chamber as taught by Bullington et al, as well as Percarpio.

Response to Arguments

Applicant's arguments filed have been fully considered but they are not persuasive. Applicant contends that Bullington et al do not disclose filling reservoir 480 by creating a vacuum at reservoir 480 (Remarks pg.8). However, this is patently not true. The blood sample

collection device being defined as member 451 and the outlet as 402 (proximal end portion of housing 401), Bullington et al explicitly state "the proximal motion of the second member 451 moves the plunger 476 of the first member 470 in the proximal direction relative to the shunt tube 471… increases the volume of the portion of the inner volume 411 of the housing 401 that is distal of the plunger 476, thereby defining the first reservoir 480, as shown in FIG. 14. With the plunger 476 forming a fluid tight seal with the inner surface of the walls defining the inner volume 411 and with the shunt tube 471 about which the plunger 476 is disposed, the volume increase of the portion of the inner volume 411 can produce a negative pressure within the first reservoir 480" (0091). Further, Bullington et al disclose "the negative pressure within the first reservoir 480 produced by the movement of the plunger 476 (as indicated by the arrow II) introduces a suction force within the portion of the patient. Thus, a bodily-fluid is drawn through the port 405, the first lumen 432 defined by the flow control mechanism 430, and the first lumen 406 defined by the diverter 409 and into the fluid reservoir 480. In some embodiments, the bodily-fluid can contain undesirable microbes such as, for example, dermally-residing microbes and/or other external contaminants."

Thus, Bullington et al clearly disclose a vacuum, e.g. negative pressure, is applied to the outlet port 402 through proximal motion of member 451 such that the chamber 480 when connected with the inlet port 405 is configured to collect a first portion of the blood, as claimed. Therefore, the rejection is maintained.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Huong Q NGUYEN whose telephone number is (571)272-8340. The examiner can normally be reached on 10 am - 6 pm.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jennifer Robertson can be reached on (571)272-5001. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H.Q.N/
Examiner, Art Unit 3791

/RENE T TOWA/
Primary Examiner, Art Unit 3791

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-22)
Approved for use through 05/31/2024. OMB 0651-0031
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	18783173
Filing Date	2024-07-24
First Named Inventor	Bobby ROGERS
Art Unit	3791
Examiner Name	NGUYEN, HUONG Q
Attorney Docket Number	069366-0580420_KUR3C03US

U.S.PATENTS Remove

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Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

PC 6.1.24

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /H.Q.N/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	18783173
	Filing Date	2024-07-24
	First Named Inventor	Bobby ROGERS
	Art Unit	3791
	Examiner Name	NGUYEN, HUONG Q
	Attorney Docket Number	069366-0580420_KUR3C03US

	1		☐

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature	/H Q NGUYEN/	Date Considered	01/26/2025

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

PC 6.1.24

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /H.Q.N/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	18783173
	Filing Date	2024-07-24
	First Named Inventor	Bobby ROGERS
	Art Unit	3791
	Examiner Name	NGUYEN, HUONG Q
	Attorney Docket Number	069366-0580420_KUR3C03US

CERTIFICATION STATEMENT

Please see 37 CFR 1.97(e) to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☒ A certification statement is not submitted herewith.

FEE

☒ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

COPIES

☐ An identification of an earlier application pursuant to 37 CFR 1.98 (d) (1) is attached.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2024-11-25
Name/Print	Benjamin F. Hudson	Registration Number	71,474

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /H.Q.N/

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

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Application Number	18783173
Filing Date	2024-07-24
First Named Inventor	Bobby ROGERS
Art Unit	3791
Examiner Name	NGUYEN, HUONG Q
Attorney Docket Number	069366-0580420_KUR3C03US

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	1	Office Action (Rejection Decision) dated 11/5/2024 for JP Application No. 2023-076490; Attorney Docket No. 069366-0575273_KUR2D03JP (pages 1-8).	☐
	2	Office Action (Non-Final Rejection) mailed 11/22/2024 for U.S. Application No. 18/898,239; Attorney Docket No. 069366-0581370_KUR2C07US (pages 1-57).	☐
	3	Office Action (Non-Final Rejection) dated 11/26/2024 for JP Application No. 2024-121200; Attorney Docket No. 069366-0580493_KUR3C03JP (pages 1-11).	☐

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	Examiner Name	NGUYEN, HUONG Q
	Attorney Docket Number	069366-0580420_KUR3C03US

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☐ An identification of an earlier application pursuant to 37 CFR 1.98 (d) (1) is attached.

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A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2025-01-09
Name/Print	Benjamin F. Hudson	Registration Number	71,474

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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(54) Title: FLUID CONTROL DEVICES AND METHODS OF USING THE SAME

(57) Abstract: A fluid control device (200) includes an inlet (212) configured to be placed in fluid communication with a bodily fluid source and an outlet (216) configured to be placed in fluid communication with a fluid collection device, which can produce a negative pressure differential between the outlet and the inlet. A sequestration portion (214) is in fluid communication with the inlet and includes a first flow controller (222) configured to transition from a first state to a second state to place the sequestration portion in fluid communication with the outlet when the negative pressure differential has a first magnitude. A sampling portion (224) is in fluid communication with an outlet and includes a second flow controller (221) configured to transition from a first state to a second state to place the sampling portion in fluid communication with the inlet when the negative pressure differential has a second magnitude greater than the first magnitude.

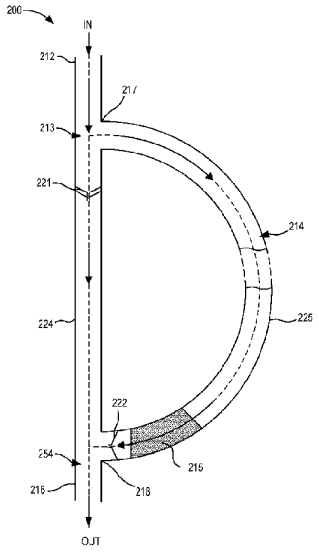


FIG. 2

WO 2019/232196 A1

[Continued on next page]

Declarations under Rule 4.17:

— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*

Published:

— *with international search report (Art. 21(3))*

FLUID CONTROL DEVICES AND METHODS OF USING THE SAME

Cross-Reference to Related Applications

[0001] This application claims priority to and the benefit of U.S. Provisional Patent Application Serial No. 62/678,637 entitled, "Fluid Control Devices and Methods of Using the Same," filed May 31, 2018, the disclosure of which is incorporated herein by reference in its entirety.

Background

[0002] Embodiments described herein relate generally to the procurement of bodily fluid samples, and more particularly to fluid diversion, sequestration, and/or isolation devices and methods for procuring bodily fluid samples with reduced contaminants such as dermally residing microbes and/or other contaminants exterior to the bodily fluid source.

[0003] Health care practitioners routinely perform various types of microbial as well as other broad diagnostic tests on patients using parenterally obtained bodily fluids. As advanced diagnostic technologies evolve and improve, the speed, accuracy (both sensitivity and specificity), and value of information that can be provided to clinicians continues to improve. Maintaining the integrity of the bodily fluid sample during and/or after collection also ensures that analytical diagnostic results are representative of the in vivo conditions of a patient. Examples of diagnostic technologies that are reliant on high quality, non-contaminated, and/or unadulterated bodily fluid samples include but are not limited to microbial detection, molecular diagnostics, genetic sequencing (e.g., deoxyribonucleic acid (DNA), ribonucleic acid (RNA), next-generation sequencing (NGS), etc.), biomarker identification, and/or the like.

[0004] Inaccurate results from such testing can be due to the presence biological matter including cells external to the intended sample source and/or other external contaminants that inadvertently are included in the bodily fluid sample being analyzed. In short, when the purity of the bodily fluid sample is compromised during the specimen procurement process, resultant analytical test results may be inaccurate, distorted, adulterated, falsely positive, falsely negative, and/or otherwise not representative of the actual condition of the patient. In turn, these results can lead to faulty, inaccurate, confused, unsure, low-confidence, and/or otherwise undesired clinical decision making.

[0005] In some instances, devices and/or systems can be used to reduce the likelihood of contamination, adulteration, and/or the like of bodily fluid samples for testing. For example, some known devices can be configured to collect, divert, separate, and/or sequester (e.g., isolate) an initial volume of bodily fluid that may be more likely to contain contaminants such as dermally residing microbes or the like. Some such devices, however, can be cumbersome, non-intuitive, perceived as difficult to use, inappropriate or unusable for a target patient population, etc. In addition, some such devices can require training, user observation, intervention by more than one user, and/or can otherwise present challenges that can lead to limited efficacy. In some instances, these and/or other challenges can complicate the collection of consistently high quality samples that are non-contaminated, sterile, unadulterated, etc., which in turn, can influence the validity of test result outcomes.

[0006] As such, a need exists for fluid control and/or diversion devices and methods for procuring bodily fluid samples with reduced contaminants such as dermally residing microbes and/or other contaminants exterior to the bodily fluid source that result in consistent bodily fluid collection (e.g., from a general patient population and/or a challenging patient population). In addition, a need exists for devices and methods that can include, for example, bodily fluid collection with the assistance of various sources of external energy and/or negative pressure.

Summary

[0007] Devices and methods for procuring bodily fluid samples with reduced contaminants such as dermally residing microbes and/or other contaminants exterior to the bodily fluid source are described herein. In some embodiments, a fluid control device includes an inlet and an outlet. The inlet is configured to be placed in fluid communication with a bodily fluid source and the outlet is configured to be placed in fluid communication with a fluid collection device. The coupling of the outlet to the fluid collection device can produce a negative pressure differential within the fluid control device between the outlet and the inlet. The fluid control device has a sequestration portion in fluid communication with the inlet and a sampling portion in fluid communication with the outlet. The sequestration portion includes a first flow controller configured to transition from a first state in which the sequestration portion is sequestered from the outlet to a second state in which the sequestration portion is in fluid communication with the outlet when the negative pressure differential has a first magnitude. The sampling portion includes a second flow controller configured to transition from a first

state in which the sampling portion is sequestered from the inlet to a second state in which the sampling portion is in fluid communication with the inlet when the negative pressure differential has a second magnitude greater than the first magnitude.

Brief Description of the Drawings

[0008] FIG. 1 is a schematic illustration of a fluid control device according to an embodiment.

[0009] FIG. 2 is a schematic illustration of a fluid control device according to an embodiment.

[0010] FIG. 3 is a schematic illustration of a fluid control device according to an embodiment.

[0011] FIG. 4 is a schematic illustration of a fluid control device according to an embodiment.

[0012] FIGS. 5-7 are each a schematic illustration of a flow controller included in a fluid control device according to various embodiments.

[0013] FIG. 8 is a schematic illustration of a fluid control device according to an embodiment.

[0014] FIGS. 9 and 10 are schematic cross-sectional illustrations of the fluid control device illustrated in FIG. 8, taken along the line A-A, and shown in a first state and a second state, respectively.

[0015] FIGS. 11 and 12 are schematic cross-sectional illustrations of a fluid control device in a first state and a second state, respectively, according to an embodiment.

[0016] FIGS. 13 and 14 are schematic cross-sectional illustrations of a fluid control device in a first state and a second state, respectively, according to an embodiment.

[0017] FIGS. 15 and 16 are flowcharts, each of which illustrates a method of using a fluid control device to divert an initial volume of bodily fluid to procure bodily fluid samples with reduced contamination, according to different embodiments.

Detailed Description

[0018] Devices and methods for collecting, diverting, sequestering, isolating, etc. an initial volume of bodily fluid to reduce contamination in subsequently procured bodily fluid samples

are described herein. Any of the fluid control devices described herein can be configured to receive, procure, and/or transfer a flow, bolus, volume, etc., of bodily fluid. A first reservoir, channel, flow path, chamber, and/or portion of the device can receive an initial amount of the bodily fluid flow, which then can be substantially or fully sequestered therein (e.g., contained or retained, circumvented, isolated, segregated, vapor-locked, separated, and/or the like). In some instances, contaminants such as dermally residing microbes or the like can be included and/or entrained in the initial amount of the bodily fluid and likewise are sequestered in or by the first reservoir, flow path, or portion of the device. Once the initial amount is sequestered, any subsequent amount of the bodily fluid flow can be diverted, channeled, directed, and/or otherwise allowed to flow to or through a second portion of the device and/or any additional flow path(s) thereof. Based at least in part on the initial amount being sequestered, subsequent amount(s) of bodily fluid can be substantially free from contaminants that may otherwise produce inaccurate, distorted, adulterated, and/or false results in some diagnostics and/or testing. In some instances, the initial amount of bodily fluid also can be used, for example, in other testing such as those less affected by the presence of contaminants, can be discarded as a waste volume, can be infused back into the patient, and/or can be used for any other suitable clinical application.

[0019] In some embodiments, a feature of the fluid control devices and/or methods described herein is the use of an external negative pressure source (e.g., provided by a fluid collection device or any other suitable means) that can (1) overcome physical patient challenges which can limit and/or prevent a sufficient pressure differential to fully engage the sequestration chamber or sequestration portion of the control device and/or to transition fluid flow to the fluid collection device; (2) result in proper filling of the sequestration chamber with a clinically validated and/or desirable volume of bodily fluid; (3) result in efficient, timely, and/or user-accepted consistency with bodily fluid collection process; and/or (4) provide a means of transitioning fluid flow (e.g., automatically or by manipulation to move any number of physical components of the system or by changing, switching, engaging, and/or otherwise providing desired fluid flow dynamics) to enable sequestration and/or isolation of the initial amount (e.g., pre-sample) and collection of a subsequent sample.

[0020] In some embodiments, a fluid control device includes an inlet and an outlet. The inlet is configured to be placed in fluid communication with a bodily fluid source and the outlet is configured to be placed in fluid communication with a fluid collection device. The coupling of the outlet to the fluid collection device can produce a negative pressure differential within

the fluid control device between the outlet and the inlet. The fluid control device has a sequestration portion in fluid communication with the inlet and a sampling portion in fluid communication with the outlet. The sequestration portion includes a first flow controller configured to transition from a first state in which the sequestration portion is sequestered from the outlet to a second state in which the sequestration portion is in fluid communication with the outlet when the negative pressure differential has a first magnitude. The sampling portion includes a second flow controller configured to transition from a first state in which the sampling portion is sequestered from the inlet to a second state in which the sampling portion is in fluid communication with the inlet when the negative pressure differential has a second magnitude greater than the first magnitude.

[0021] In some embodiments, a fluid control device includes a housing, a first flow controller, and a second flow controller. The housing has an inlet configured to establish fluid communication with a bodily fluid source and an outlet configured to be coupled to a fluid collection device. The housing defines a sequestration flow path that is in fluid communication with the inlet and a sampling flow path that is in fluid communication with the outlet. The first flow controller has a flow state in which the sequestration flow path is in fluid communication with the outlet and a non-flow state in which the sequestration flow path is sequestered from the outlet. The second flow controller has a flow state in which sampling flow path is in fluid communication with the inlet and a non-flow state in which the sampling flow path is sequestered from the inlet. The first flow controller configured to be in the flow state when a negative pressure differential generated by coupling the outlet to the fluid collection device has a first magnitude such that an initial volume of bodily fluid flows through the sequestration flow path toward the first flow controller. The first flow controller is configured to transition to the non-flow state when the initial volume of bodily fluid is received in the sequestration flow path such that (1) the sequestration flow path is sequestered from the outlet and (2) the negative pressure differential is increased to a second magnitude operable to transition the second flow controller from the non-flow state to the flow state.

[0022] In some embodiments, a method of using a fluid control device to obtain a bodily fluid sample with reduced contamination includes coupling a fluid collection device to an outlet of the fluid control device. The coupling of the fluid collection device to the outlet is configured to produce a negative pressure differential within at least a portion of the fluid control device. A first flow controller is transitioned from a first state to a second state when the negative pressure differential has a first magnitude. The first flow controller is configured

to sequester a sequestration portion of the fluid control device from the outlet when in the first state and to establish fluid communication between the sequestration portion and the outlet when in the second state. An initial volume of bodily fluid is received from an inlet of the fluid control device into the sequestration portion in response to the negative pressure differential when the first flow controller is in the second state. The first flow controller is configured to transition from the second state to a third state in response to the sequestration portion receiving the initial volume of bodily fluid. When the first flow controller is in the third state, the first flow controller sequesters the sequestration portion from the outlet the negative pressure differential increases from the first magnitude to a second magnitude. A second flow controller is transitioned from a first state to a second state when the negative pressure differential has the second magnitude. The second flow controller is configured to sequester a sampling portion of the fluid control device from the inlet when in the first state and to establish fluid communication between the sampling portion and the inlet when in the second state. A subsequent volume of bodily fluid is transferred from the inlet to the fluid collection device via the sampling portion and the outlet.

[0023] In some embodiments, a fluid control device includes an inlet and an outlet. The inlet is configured to be placed in fluid communication with a bodily fluid source or an intermediary bodily fluid transfer device. The outlet is configured to be placed in fluid communication with a fluid collection device such as, for example, a sample reservoir (bottle, container, dish, vial, etc.), a culture bottle, and evacuated container, a syringe, a lumen-containing device, and/or any other suitable bodily fluid collection and/or transfer device. The fluid control device has a first state in which a negative pressure differential produced from an external source (e.g., the fluid collection device such as a sample reservoir, a syringe, a vessel, and/or any suitable intermediary fluid reservoir) is applied to the fluid control device to draw an initial volume of bodily fluid from the bodily fluid source, through the inlet, and into a sequestration and/or diversion portion of the fluid control device (which can be formed by or in the fluid control device or coupled thereto). The fluid control device has a second state in which (1) the sequestration and/or diversion portion sequesters the initial volume, and (2) the negative pressure differential draws a subsequent volume of bodily fluid, being substantially free of contaminants, from the bodily fluid source, through the fluid control device, and into the fluid collection device.

[0024] Any of the embodiments and/or methods described herein can be used in the procurement of clean or substantially unadulterated bodily fluid samples such as, for example,

blood samples. In some instances, bodily fluid samples (e.g., blood samples) can be tested for the presence of one or more potentially undesirable microbes, such as bacteria (e.g., Gram-Positive bacteria and/or Gram-Negative bacteria), fungi, yeast (e.g., Candida), and/or other undesirable microbes. Various technologies can be employed to assist in the detection of the presence of microbes as well as other types of biological matter, specific types of cells, biomarkers, proteins, antigens, enzymes, blood components, and/or the like during diagnostic testing. Examples include but are not limited to molecular polymerase chain reaction (PCR), magnetic resonance and other magnetic analytical platforms, automated microscopy, spatial clone isolation, flow cytometry, whole blood ("culture free") specimen analysis (e.g., NGS) and associated technologies, morphokinetic cellular analysis, and/or other common or evolving and advanced technologies to characterize patient specimens and/or to detect, identify, type, categorize, and/or characterize specific organisms, antibiotic susceptibilities, and/or the like.

[0025] For example, in some instances, microbial testing and/or detection can include incubating blood samples in one or more vessels that may contain culture media (e.g., a nutrient rich and/or environmentally controlled medium to promote growth and/or any number of other mediums), common additives, and/or other types of solutions conducive to microbial growth. Any of the microbes and/or organisms present in the blood sample flourish and/or grow over time in the culture medium (e.g., a variable amount of time from less than an hour to more than several days – which can be longer or shorter depending on the diagnostic technology employed). The presence of the microbes and/or organisms can be detected by automated, continuous monitoring, and/or other methods specific to the analytical platform and/or technology used for detection, identification, and/or the like (e.g., by observing carbon dioxide levels and/or any other suitable methods of detection).

[0026] The presence of microbes and/or organisms in the culture medium suggests the presence of the same microbes and/or organisms in the blood sample, which in turn, suggests the presence of the same microbes and/or organisms in the bodily fluid of the patient from whom the sample was obtained. In other instances, a bodily fluid sample may be analyzed directed (i.e., not incubated) for the presence of the microbes and/or organisms. Accordingly, when the microbes and/or organisms are determined to be present in the blood sample, the patient may be diagnosed and prescribed one or more antibiotics or other treatments specifically designed to treat or otherwise remove the undesired microbes and/or organisms from the patient.

[0027] Patient samples, however, can become contaminated during procurement and/or otherwise can be susceptible to false results. For example, microbes from a bodily surface (e.g., dermally residing microbes) that are dislodged during the specimen procurement process (e.g., either directly or indirectly via tissue fragments, hair follicles, sweat glands, and other skin adnexal structures) can be subsequently transferred to a culture medium, test vial, or other suitable specimen collection or transfer vessel with the patient sample and/or otherwise included in the specimen that is to be analyzed. Another possible source of contamination is from the person drawing the patient sample (e.g., a doctor, phlebotomist, nurse, technician, etc.) and/or the equipment used for drawing the patient sample. For example, equipment, supplies, and/or devices used during a patient sample procurement process often include multiple fluidic interfaces (e.g., patient to needle, needle to transfer adapter, transfer adapter to sample vessel, catheter hub to syringe, syringe to transfer adapter, needle/tubing to sample vessels, and/or any other fluidic interface or any combination(s) thereof) that can each introduce points of potential contamination. In some instances, such contaminants may thrive in a culture medium and/or may be otherwise identified, thereby increasing a risk or likelihood of false, compromised, and/or erroneous microbial test results, which may inaccurately reflect the presence or lack of such microbes within the patient (i.e., in vivo).

[0028] Such inaccurate results because of contamination and/or any other sources of adulteration are a concern when attempting to diagnose or treat a wide range of suspected illnesses, diseases, infections, patient conditions, and/or other maladies. For example, false results from microbial tests may result in a misdiagnosis and/or delayed treatment of a patient illness (which could result in the harm to and/or death of the patient or, on the other hand, may result in the patient being unnecessarily subjected to one or more anti-microbial therapies, which may cause serious side effects to and/or consequences for the patient including, for example, death. As such, false results produce an unnecessary burden and expense on the health care system due to extended length of patient stay and/or other complications associated with erroneous treatments. The use of diagnostic imaging equipment to arrive at these false results is also a concern from both a cost perspective and a patient safety perspective as unnecessary exposure to concentrated radiation associated with a variety of imaging procedures (e.g., CT scans) has many known adverse effects on long-term patient health.

[0029] As used in this specification and/or any of the claims included herein, the singular forms "a," "an" and "the" include plural referents unless the context clearly dictates otherwise.

Thus, for example, the term "a member" is intended to mean a single member or a combination of members, "a material" is intended to mean one or more materials, or a combination thereof.

[0030] As used herein, the terms "about," "approximately," and/or "substantially" when used in connection with a stated value(s) and/or a geometric structure(s) or relationship(s) is intended to convey that the value or characteristic so defined is nominally the value stated and/or characteristic described. In some instances, the terms "about," "approximately," and/or "substantially" can generally mean and/or can generally contemplate a value or characteristic stated within a desirable tolerance (e.g., plus or minus 10% of the value or characteristic stated). For example, a value of about 0.01 would include 0.009 and 0.011, a value of about 0.5 would include 0.45 and 0.55, a value of about 10 would include 9 to 11, and a value of about 1000 would include 900 to 1100. While a value, structure, and/or relationship stated may be desirable, it should be understood that some variance may occur as a result of, for example, manufacturing tolerances or other practical considerations (such as, for example, the pressure or force applied through a portion of a device, conduit, lumen, etc.). Accordingly, the terms "about," "approximately," and/or "substantially" can be used herein to account for such tolerances and/or considerations.

[0031] As used herein, "bodily fluid" can include any fluid obtained directly or indirectly from a body of a patient. For example, "bodily fluid" includes, but is not limited to, blood, cerebrospinal fluid, urine, bile, lymph, saliva, synovial fluid, serous fluid, pleural fluid, amniotic fluid, mucus, sputum, vitreous, air, and the like, or any combination thereof.

[0032] As used herein, the words "proximal" and "distal" refer to the direction closer to and away from, respectively, a user who would place the device into contact with a patient. Thus, for example, the end of a device first touching the body of the patient would be the distal end, while the opposite end of the device (e.g., the end of the device being manipulated by the user) would be the proximal end of the device.

[0033] As used herein, the terms "pre-sample," "first," and/or "initial," can be used interchangeably to describe an amount, portion, or volume of bodily fluid that is collected and/or sequestered prior to procuring the "sample" volume. A "pre-sample," "first," and/or "initial" volume can refer to a predetermined, defined, desired, and/or given volume of bodily fluid. For example, a predetermined and/or desired pre-sample volume of bodily fluid can be a drop of bodily fluid, a few drops of bodily fluid, and/or a volume of bodily fluid equal to about 0.1 milliliter (mL), about 0.2 mL, about 0.3 mL, about 0.4 mL, about 0.5 mL, about 1.0

mL, about 2.0 mL, about 3.0 mL, about 4.0 mL, about 5.0 mL, about 10.0 mL, about 20.0 mL, about 50.0 mL, and/or any volume or fraction of a volume therebetween. Alternatively, a pre-sample volume can be greater than 50.0 mL or less than 0.1 mL. In some specific embodiments, a predetermined and/or desired pre-sample volume can be between about 0.1 mL and about 5.0 mL. In other embodiments, a pre-sample volume can be, for example, a combined volume of any number of lumen (e.g., lumen that form at least a portion of a flow path from the bodily fluid source to an initial collection chamber, portion, reservoir, etc...

[0034] As used herein, the terms "sample," "second," and/or "subsequent" can be used interchangeably to describe a volume, portion, or amount of bodily fluid that is used, for example, in one or more sample or diagnostic tests. A "sample" volume can be either a random volume or a predetermined or desired volume of bodily fluid collected after collecting, sequestering, and/or isolating a pre-sample volume of bodily fluid. A desired sample volume of bodily fluid can be, for example, between about 10.0 mL to about 60.0 mL. Alternatively, a desired sample volume of bodily fluid can be less than 10.0 mL or greater than 60.0 mL. In some embodiments, for example, a sample volume can be at least partially based on one or more tests, assays, analyses, and/or processes to be performed on the sample volume.

[0035] The embodiments described herein can be configured to transfer bodily fluid with reduced contamination and/or substantially free from contamination to one or more fluid collection device(s). In some embodiments, a fluid collection device can include, but is not limited to, any suitable vessel, container, reservoir, bottle, adapter, dish, vial, syringe, device, diagnostic and/or testing machine, and/or the like. In some embodiments, a fluid collection device can be substantially similar to or the same as known sample containers such as, for example, a Vacutainer ® (manufactured by Becton Dickinson and Company (BD)), a BacT/ALERT ® SN or BacT/ALERT ® FA (manufactured by Biomerieux, Inc.), and/or any suitable reservoir, vial, microvial, microliter vial, nanoliter vial, container, microcontainer, nanocontainer, and/or the like. In some embodiments, a fluid collection device can be similar to and/or substantially the same as any of those described in U.S. Patent No. 8,197,420 entitled, "Systems and Methods for Parenterally Procuring Bodily-Fluid Samples with Reduced Contamination," filed December 13, 2007 ("the '420 Patent"), the disclosure of which is incorporated herein by reference in its entirety.

[0036] In some embodiments, a fluid collection device can be devoid of contents prior to receiving a sample volume of bodily fluid. For example, in some embodiments, a fluid collection device or reservoir can define and/or can be configured to define or produce a

vacuum or suction such as, for example, a vacuum-based collection tube (e.g., a Vacutainer ®), a syringe, and/or the like. In some embodiments, a sample reservoir can include, for example, any suitable additives, substances, enzymes, oils, fluids, compounds, chemicals, etc. (e.g., heparin, citrate, acid citrate dextrose (ACD), ethylenediaminetetraacetic acid (EDTA), oxalate, sodium polyanethol sulfonate (SPS), and/or the like). In other embodiments, a sample reservoir can contain, for example, an aerobic culture medium or an anaerobic culture medium. The sample reservoir (e.g., culture bottle) can receive a bodily fluid sample, which can then be tested (e.g., after incubation via in vitro diagnostic (IVD) tests and/or any other suitable test) for the presence of, for example, Gram-Positive bacteria, Gram-Negative bacteria, yeast, fungi, and/or any other organism. If testing of the culture medium yields a positive result, the culture medium can be subsequently tested using, for example, a PCR-based system to identify a specific organism.

[0037] While the term "culture medium" can be used to describe a substance configured to react with organisms in a bodily fluid (e.g., microorganisms such as bacteria) and the term "additive" can be used to describe a substance configured to react with portions of the bodily fluid (e.g., constituent cells of blood, serum, synovial fluid, etc.), it should be understood that a sample reservoir can include any suitable substance, liquid, solid, powder, lyophilized compound, gas, etc. Moreover, when referring to an "additive" within a sample reservoir, it should be understood that the additive could be a culture medium, an additive, and/or any other suitable substance, and/or any combination(s) thereof. That is to say, the embodiments described herein can be used with any suitable fluid collection device, reservoir, and/or the like containing any suitable substance.

[0038] While some of the embodiments are described herein as being used for procuring bodily fluid for one or more culture sample testing, it should be understood that the embodiments are not limited to such a use. Any of the embodiments and/or methods described herein can be used to transfer a flow of bodily fluid to any suitable device that is placed in fluid communication therewith. Thus, while specific examples are described herein, the devices, methods, and/or concepts are not intended to be limited to such specific examples.

[0039] The embodiments described herein and/or portions thereof can be formed or constructed of one or more biocompatible materials. In some embodiments, the biocompatible materials can be selected based on one or more properties of the constituent material such as, for example, stiffness, toughness, durometer, bioreactivity, etc. Examples of suitable biocompatible materials include metals, glasses, ceramics, or polymers. Examples of suitable

metals include pharmaceutical grade stainless steel, gold, titanium, nickel, iron, platinum, tin, chromium, copper, and/or alloys thereof. A polymer material may be biodegradable or non-biodegradable. Examples of suitable biodegradable polymers include polylactides, polyglycolides, polylactide-co-glycolides (PLGA), polyanhydrides, polyorthoesters, polyetheresters, polycaprolactones, polyesteramides, poly(butyric acid), poly(valeric acid), polyurethanes, and/or blends and copolymers thereof. Examples of non-biodegradable polymers include nylons, polyesters, polycarbonates, polyacrylates, polysiloxanes (silicones), polymers of ethylene-vinyl acetates and other acyl substituted cellulose acetates, non-degradable polyurethanes, polystyrenes, polyvinyl chloride, polyvinyl fluoride, poly(vinyl imidazole), chlorosulphonate polyolefins, polyethylene oxide, and/or blends and copolymers thereof.

[0040] The embodiments described herein and/or portions thereof can include components formed of one or more parts, features, structures, etc. When referring to such components it should be understood that the components can be formed by a singular part having any number of sections, regions, portions, and/or characteristics, or can be formed by multiple parts or features. For example, when referring to a structure such as a wall or chamber, the structure can be considered as a single structure with multiple portions, or multiple, distinct substructures or the like coupled to form the structure. Thus, a monolithically constructed structure can include, for example, a set of substructures. Such a set of substructures may include multiple portions that are either continuous or discontinuous from each other. A set of substructures can also be fabricated from multiple items or components that are produced separately and are later joined together (e.g., via a weld, an adhesive, and/or any other suitable method).

[0041] Referring now to the drawings, FIG. 1 is a schematic illustration of a fluid control device 100 according to an embodiment. Generally, the fluid control device 100 (also referred to herein as "control device" or "device") is configured to withdrawal bodily fluid from a patient. A first portion or amount (e.g., an initial amount) of the withdrawn bodily fluid is sequestered from a second portion or amount (e.g., a subsequent amount) of the withdrawn bodily fluid which can be subsequently used for additional testing, discarded, and/or reinfused into the patient. In this manner, contaminants or the like can be sequestered within the first portion or amount, leaving the second portion or amount substantially free of contaminants. The second portion or amount of bodily fluid can then be used as a biological sample in one or more tests for the purpose of medical diagnosis and/or treatment (e.g., a blood culture test or the like), as described in more detail herein. The first portion or amount of bodily fluid can be

discarded as waste or can be used in any suitable test that is less likely to produce false, inaccurate, distorted, inconsistent, and unreliable results as a result of potential contaminants contained therein. In some circumstances, for example in patients with limited supply of the bodily fluid such as blood, the first portion or amount of bodily fluid can be reinfused back into the patient via any suitable method.

[0042] The control device 100 can be any suitable shape, size, and/or configuration. For example, in some embodiments, the control device 100 can have a size that is at least partially based on a volume of bodily fluid at least temporarily stored, for example, in a sequestration, diversion, isolation, and/or storage portion of the control device 100. As described in further detail herein, the control device 100 can be configured to transition between operating modes such that (1) the first portion or amount of bodily fluid selectively flows through at least a first portion of the fluid control device and is subsequently sequestered therein, and (2) the second portion or amount of bodily fluid selectively flows through at least a second portion of the fluid control device and into a fluid collection device or the like. In some embodiments, the control device 100 can be configured to transition between operating modes automatically (e.g., based on pressure differential, time, electronic signal or instruction, saturation of a membrane or member, an absorbent and/or barrier material, etc.) or via and/or in response to intervention (e.g., user intervention, mechanical intervention, or the like).

[0043] The control device 100 includes an inlet 112, at least one outlet 116, and a sequestration chamber 114. In addition, the control device 100 defines one or more fluid flow paths 113 between the inlet 112 and at least the sequestration chamber 114 and/or one or more fluid flow paths 154 between the inlet 112 and the outlet(s) 116.

[0044] The inlet 112 of the control device 100 is configured to be placed in fluid communication with a bodily fluid source such as, for example, the vasculature of a patient. In some embodiments, the inlet 112 can be coupled to and/or can include an inlet device such as, for example, an intravenous (IV) catheter, a needle, a peripherally inserted central catheter (PICC), a syringe, one or more pieces of sterile tubing, and/or any other suitable lumen-containing device and/or intermediary transfer device. In some embodiments, the inlet 112 can be a port, a valve, and/or the like such as, for example, a Luer Lok ® or any other suitable coupler. In such embodiments, the inlet 112 (e.g., port or coupler) can be configured to couple to an access or inlet device in fluid communication with a patient (e.g., a placed or indwelling IV catheter or needle). In some embodiments, the inlet 112 can be physically and fluidically coupled to the access or inlet device via a lock, coupler, port, etc. In other embodiments, the

inlet 112 can be in fluid communication with the access or inlet device via an intermediate lumen-containing device such as, for example, sterile tubing or the like. In still other embodiments, the inlet 112 of the control device 100 can form and/or can be integrally or monolithically formed with the access or inlet device.

[0045] The sequestration chamber 114 is at least temporarily placed in fluid communication with the inlet 112 via the fluid flow path(s) 113. As described in further detail herein, the sequestration chamber 114 is configured to (1) receive a flow and/or volume of bodily fluid from the inlet 112 and (2) sequester (e.g., separate, segregate, contain, retain, isolate, etc.) the flow and/or volume of bodily fluid therein.

[0046] Although not shown in FIG.1, in some embodiments, the fluid control device 100 can have one or more flow path(s) 113 that include one or more flow modulating features (e.g., flow restrictors, fluid flow retardants, etc.) that selectively modulate the flow of bodily fluid drawn therethrough. In some embodiments, the flow modulating features can be structural and built into the fluid control device 100. In other embodiments, the flow modulating features can be separately formed or can be a material that can be introduced within the fluid control device 100, for example within the sequestration chamber 114, as described in further detail herein.

[0047] The sequestration chamber 114 can be any suitable shape, size, and/or configuration. For example, in some embodiments, the sequestration chamber 114 can be at least partially formed by a body portion of the control device 100 (not shown in FIG. 1). In other embodiments, the sequestration chamber 114 can be a reservoir placed and/or disposed within a portion of the control device 100. In other embodiments, the sequestration chamber 114 can be formed and/or defined by a portion of the fluid flow path 113. That is to say, the control device 100 can define one or more lumen and/or can include one or more lumen-defining device(s) configured to receive a flow of bodily fluid from the inlet 112, thereby defining the fluid flow path 113. In such embodiments, at least a portion of the lumen and/or a portion of the lumen-defining device(s) can form and/or can define the sequestration chamber 114.

[0048] The sequestration chamber 114 can have any suitable volume and/or fluid capacity. For example, in some embodiments, the sequestration chamber 114 can have a volume and/or fluid capacity between about 0.25 milliliters (mL) and about 5.0 mL. In some embodiments, the sequestration chamber 114 can have a volume measured in volumes as small as a microliter or less of bodily fluid (e.g., a volume as small as 20 drops of bodily fluid, 10 drops of bodily

fluid, 5 drops of bodily fluid, a single drop of bodily fluid, or any suitable volume therebetween). In other embodiments, the sequestration chamber 114 can have a volume up to, for example, about 5.0 mL, 10.0 mL, 15.0 mL, 20.0 mL, 30.0 mL, 40.0 mL, 50.0 mL, or more. In some embodiments, the sequestration chamber 114 can have a volume that is equal to and/or that is based at least in part on the volumes of a lumen of the inlet device coupled to and/or included in the control device 100, the lumen of the inlet 112, and a portion of the fluid flow path 113 defined between the inlet 112 and the sequestration chamber 114 and/or any combination thereof. In other embodiments, the sequestration chamber 114 can have a volume that is equal to and/or that is based at least in part on the individual and/or combined volumes of a portion of the inlet device, the inlet 112 of the control device 100, and the portion of the fluid flow path 113 defined between the inlet 112 and the sequestration chamber 114.

[0049] Although not shown in FIG. 1, in some embodiments, the fluid control device 100 and/or the sequestration chamber 114 can include and/or can be formed of one or more features or materials configured to interact with a portion of the bodily fluid transferred into the sequestration chamber 114. For example, in some embodiments, the fluid control device 100 and/or the sequestration chamber 114 can include and/or define a valve, a membrane, a diaphragm, a restrictor, a vent, a selectively permeable member (e.g., a fluid impermeable barrier or seal that at least selectively allows the passage of air or gas therethrough), a port, a junction, an actuator, and/or the like, or any suitable combination thereof (collectively referred to herein as a "flow controller"). Such flow controllers can be configured to selectively control (at least in part) a flow of fluids into and/or out of the sequestration chamber 114 and/or any other suitable portion of the fluid control device 100. In this context, the flow of fluids, for example, can be a liquid such as water, oil, dampening fluid, bodily fluid, and/or any other suitable liquid, and/or can be a gas such as air, oxygen, carbon dioxide, helium, nitrogen, ethylene oxide, and/or any other suitable gas.

[0050] In some embodiments, one or more openings and/or one or more flow controllers can be configured to facilitate air displacement into or out of the sequestration chamber 114. In some embodiments, the air displacement from the sequestration chamber 114 as an initial portion of the bodily fluid is transferred into the sequestration chamber 114 can allow for a redistribution of pressure in the sequestration chamber 114 and/or between the sequestration chamber 114 and, for example, the fluid source and/or a portion of the fluid flow path outside of the sequestration chamber 114, or a pressure of an ambient environment into which the sequestration chamber 114 is vented. In some embodiments, the redistribution of pressure can

be a factor in determining and/or defining how bodily fluid flows through the control device 100 and/or the amount or volume of bodily fluid to be transferred into the sequestration chamber 114.

[0051] In other embodiments, the sequestration chamber 114 and/or control device 100 can include a flow controller operable to selectively control a flow of bodily fluid through the fluid flow paths 113 in any suitable manner. For example, in some embodiments, the control device 100 can be configured to selectively transfer a volume of bodily fluid to the sequestration chamber 114 or to the outlet 116 based at least in part on a pressure differential between two or more portions of the control device 100. In some embodiments, the pressure differential can result from fluidically coupling the outlet 116 to an evacuated fluid collection device 160 (e.g., a sample reservoir, a syringe, a pressure charged canister, and/or other source or potential energy to create a vacuum or pressure differential). In other embodiments, the pressure differential can result from a change in volume and/or temperature. In still other embodiments, the pressure differential can result from at least a portion of the control device 100, and/or other portions of the flow paths 113 and/or 154 being evacuated and/or charged (e.g., the sequestration chamber 114 and/or any other suitable portion). In some embodiments, the pressure differential can be established automatically or via direct or indirect intervention and/or manipulation (e.g., by the user). Moreover, a flow of a fluid (e.g., gas and/or liquid) resulting from a pressure differential can be selectively controlled via one or more flow controllers that can, for example, transition between one or more operating conditions to control the fluid flow. It should be understood that the flow controllers included in the embodiments described herein are presented by way of example and not limitation. Thus, while specific flow controllers are described herein, it should be understood that fluid flow can be controlled through the control device 100 by any suitable means.

[0052] In some embodiments, a wall or structure of the fluid control device 100 can define an opening, aperture, port, orifice, and/or the like that is in fluid communication with the sequestration chamber 114. In some embodiments, the control device 100 can include a semi-permeable member, film, membrane, or material such as a hydrophobic or hydrophilic membrane disposed in or about the opening or elsewhere in the flow paths 113 to selectively allow a flow of air or gas through the opening while limiting or substantially preventing a flow of fluid (e.g., bodily fluid such as blood) through the opening.

[0053] In some embodiments, for example, the control device 100 can include an absorbent and/or hydrophilic material disposed within the sequestration chamber 114. Accordingly,

when bodily fluid is transferred into the sequestration chamber 114, the absorbent and/or hydrophilic material can absorb, attract, retain, expand, and/or otherwise interact with at least a portion of the bodily fluid, which in turn, can sequester and/or retain at least an initial portion of the bodily fluid within the sequestration chamber 114, as described in further detail herein.

[0054] In some embodiments, the fluid control device 100 can include one or more self-sealing vent materials that permit the flow of air or air pressure (e.g., vacuum) but not the flow of fluid (i.e., liquid). For example, the self-sealing material when wetted or when in contact with a fluid may absorb or otherwise become saturated and transition to a sealed configuration such that the self-sealing material does not permit air or liquid therethrough. The transitioning of the self-sealing material (e.g., vent) may be associated with the fluid control device 100 moving from a first state (e.g., wherein an initial portion of the bodily fluid is being transferred into the sequestration chamber 114) to a second state (e.g., after the initial portion of the bodily fluid is transferred into the sequestration chamber 114).

[0055] In some embodiments, the sequestration chamber 114 or any other portion of the fluid control device 100 can include and/or can be formed of an expandable or collapsible material configured to transition between a first state (e.g., while an initial portion of the bodily fluid is being transferred into the sequestration chamber 114) to a second state (e.g., after the initial portion of the bodily fluid is transferred into the sequestration chamber 114). For example, the collapsible material can be in the form of a dissolvable substance that initially blocks the flow path 113 within which it is present and does not permit the flow of fluid (e.g., gas or liquid) therethrough. Upon coming into contact with a predetermined amount of fluid, however, the material can be dissolved or otherwise transitioned to a dissolved configuration to release the obstruction of the fluid flow path 113 in which the material is disposed. In some embodiments, the change in configuration resulting from such a material expanding, collapsing, dissolving, etc. can be operable to transition the control device 100 and/or any suitable portion of the control device 100 from a first state, mode, position, configuration, etc., to a second state, mode, position, configuration, etc., as described in further detail herein.

[0056] In some embodiments, the control device 100 and/or the sequestration chamber 114 can include a valve such as, for example, a duckbill valve, a butterfly valve, a one-way check valve, etc. and can be made from any suitable material with any suitable cracking pressure (e.g., an amount of pressure or force sufficient to open the valve) to be used to direct fluid flow as desired. For example, the fluid control device 100 can include two or more valves with varying cracking pressure such that they open sequentially with increasing pressure. Such a

configuration can be used, for example, in conjunction with a suitable source of negative pressure and suitable flow controllers to direct fluid flow.

[0057] The outlet(s) 116 is/are in fluid communication with and/or is/are configured to be placed in fluid communication with the fluid flow paths 113 and/or 154. The outlet 116 can be any suitable outlet, opening, port, stopcock, lock, seal, coupler, valve (e.g., a one-way check valve, duckbill valve, umbrella valve, and/or the like), etc. and is configured to be fluidically coupled to the fluid collection device 160. In some embodiments, the outlet 116 can be monolithically formed with the collection device 160, a syringe, and/or other intermediary bodily-fluid transfer device. In other embodiments, the outlet 116 can be at least temporarily coupled to the collection device 160 via an adhesive, a resistance fit, a mechanical fastener, a threaded coupling, a piercing or puncturing arrangement, any number of mating recesses, and/or any other suitable coupling or combination thereof. Similarly stated, the outlet 116 can be physically (e.g., mechanically) and/or fluidically coupled to the collection device 160 such that an interior volume defined by the collection device 160 is in fluid communication with the outlet 116. In still other embodiments, the outlet 116 can be operably coupled to the collection device 160 via an intervening structure (not shown in FIG. 1), such as a flexible sterile tubing. In still other embodiments, the outlet 116 can be fluidically coupled to a downstream source of negative pressure that suitably directs the flow of fluid into the collection device 160.

[0058] In some embodiments, the arrangement of the outlet 116 can be such that the outlet 116 is physically and/or fluidically sealed prior to coupling to the collection device 160. In some embodiments, the outlet 116 can be transitioned from a sealed configuration to an unsealed configuration in response to being coupled to the collection device 160 and/or in response to a negative pressure differential between an environment within the outlet 116 and/or control device 100 and an environment within the collection device 160.

[0059] The fluid collection device 160 can be any suitable device for at least temporarily containing a bodily fluid, such as, for example, those described above. For example, in some embodiments, the fluid collection device 160 can be a single-use disposable collection tube(s), a syringe, a vacuum-based collection tube(s), an intermediary bodily-fluid transfer device, and/or the like. In some embodiments, the fluid collection device 160 can be substantially similar to or the same as known sample containers such as, for example, a Vacutainer ®, a BacT/ALERT ® SN or BacT/ALERT ® FA, and/or any other suitable reservoir, vial, microvial, microliter vial, nanoliter vial, container, microcontainer, nanocontainer, and/or the like. In some embodiments, the collection device 160 can be a sample reservoir that includes

a vacuum seal that maintains negative pressure conditions (vacuum conditions) inside the sample reservoir, which in turn, can facilitate withdrawal of bodily fluid from the patient, through the fluid control device 100, and into the sample reservoir, via a vacuum or suction force, as described in further detail herein. In embodiments in which the fluid collection device 160 is an evacuated container or the like, the user can couple the collection device 160 to the outlet 116 to initiate a flow of bodily fluid from the patient such that a first or initial portion of the bodily fluid is transferred into and sequestered by the sequestration chamber 114 and such that any subsequent portion or volume of bodily fluid bypasses and/or is otherwise diverted away from the sequestration chamber 114 and flows into the fluid collection device 160.

[0060] Although the outlet 116 of the control device 100 is described above as being fluidically coupled to and/or otherwise placed in fluid communication with the fluid collection device 160 (e.g., a sample reservoir, syringe, etc.), in other embodiments, the control device 100 can be used in conjunction with any suitable bodily fluid collection device, system, and/or the like. For example, in some embodiments, the fluid control device 100 can be used in any suitable fluid transfer device such as those described in U.S. Patent Publication No. 2015/0342510 entitled, "Sterile Bodily-Fluid Collection Device and Methods," filed June 2, 2015 (referred to herein as the "'510 publication"), the disclosure of which is incorporated herein by reference in its entirety. More particularly, the control device 100 can be used in an "all-in-one" or pre-assembled device (e.g., such as those described in the '510 publication) to receive and sequester an initial volume of bodily fluid such that contaminants in subsequent volumes of bodily fluid are reduced and/or eliminated. In other embodiments, the outlet 116 can include and/or can be coupled to an adapter, outlet needle, and/or the like. For example, in some embodiments, the outlet 116 can be coupled to and/or can include a transfer adapter and/or the like such as, for example, the transfer adapters described in U.S. Patent Publication No. 2015/0246352 entitled, "Apparatus and Methods for Disinfection of a Specimen Container," filed March 3, 2015 (referred to henceforth as the "'352 publication"), the disclosure of which is incorporated herein by reference in its entirety.

[0061] As described above, the device 100 can be used to procure a bodily fluid sample having reduced contamination from microbes such as, for example, dermally residing microbes and/or the like. For example, in some instances, a user such as a doctor, physician, nurse, phlebotomist, technician, etc. can manipulate the device 100 to establish fluid communication between the inlet 112 and the bodily fluid source (e.g., a vein of a patient, cerebral spinal fluid (CSF) from the spinal cavity, urine collection, and/or the like). As a specific example, in some

instances, the inlet 112 can be coupled to and/or can include a needle or the like that can be manipulated to puncture the skin of the patient and to insert at least a portion of the needle in the vein of the patient, thereby placing the inlet 112 in fluid communication with the bodily fluid source (e.g., the vein, an IV catheter, a PICC, etc.).

[0062] In some embodiments, once the inlet 112 is placed in fluid communication with the bodily fluid source (e.g., the portion of the patient), the outlet 116 can be fluidically coupled to the collection device 160. As described above, the collection device 160 can be any suitable reservoir, container, and/or collection system configured to receive a volume of bodily fluid. More particularly, the collection device 160 can be, for example, an evacuated reservoir or container that defines a negative pressure and/or can be a syringe that can be manipulated to produce a negative pressure. In some instances, coupling the outlet 116 to the collection device 160 selectively exposes at least a portion of the fluid flow paths 113 and/or 154 to the negative pressure, thereby resulting in a negative pressure differential operable in drawing bodily fluid from the bodily fluid source (e.g., the patient), through the inlet 112, and into the fluid control device 100.

[0063] In some embodiments, the arrangement of the control device 100 is such that when a volume of bodily fluid is transferred to and/or through the inlet 112, an initial portion of the volume of bodily fluid (also referred to herein as an "initial volume" or a "first volume") flows from the inlet 112, through at least a portion of the fluid flow path 113, and into the sequestration chamber 114. That is to say, in some embodiments, the control device 100 can be in first or initial state in which the initial portion or volume of bodily fluid can flow in or through at least a portion the fluid flow path 113 and into the sequestration chamber 114. For example, in some embodiments, the initial state of the control device 100 can be one in which one or more flow controllers (e.g., valves, membranes, diaphragms, restrictors, vents, air permeable and fluid impermeable barriers, ports, and/or the like) are in a first state in which the fluid flow path 113 is exposed to the negative pressure differential via the sequestration chamber 114. In other words, the negative pressure within the sample reservoir 160 (or created by a syringe or other source of negative pressure) can result in a negative pressure (or negative pressure differential) within at least a portion of the sequestration chamber 114 that is operable in drawing an initial flow of bodily fluid into the sequestration chamber 114 when one or more flow controllers is in a first or initial state.

[0064] For example, in some embodiments, the control device 100 can include one or more flow controller(s) such as those described above that is at least temporarily fluidically coupled

to a flow path between the fluid collection device 160 and the sequestration chamber 114. In some embodiments, the flow controller(s) can be at least temporarily fluidically coupled to a flow path between the fluid collection device 160 and the inlet 112. While in some embodiments the flow controller examples noted above can be, for example, known off-the-shelf components that are used in medical devices to control the flow of fluids and air, in other embodiments, the flow controller can be a custom, proprietary, and/or specifically tailored component integrated into the device 100. When the flow controller is in the first or initial state, the flow controller can allow a flow of fluid therethrough in response to the negative pressure of the collection device 160. In some embodiments, the flow controller is configured to allow only a flow of air or gas through the flow controller and is configured to limit and/or substantially prevent a flow of liquid (e.g., bodily fluid) through the flow controller. As such, the collection device 160 can produce a negative pressure differential that is operable to draw an initial portion and/or amount of bodily fluid into the sequestration chamber 114 when the flow controller is in a first or initial state without allowing the initial portion of bodily fluid to flow into the fluid flow path 154 and/or otherwise out of the sequestration chamber 114.

[0065] Although not shown in FIG. 1, in some embodiments, the control device 100 can include a member, device, mechanism, etc. configured to modulate a magnitude of the negative pressure to which the sequestration chamber 114 is exposed. For example, in some embodiments, the control device 100 can include a valve, a membrane, a porous material, a restrictor, and/or any other suitable member and/or device configured to modulate pressure. In some embodiments, modulating and/or controlling a magnitude of the pressure to which the sequestration chamber 114 is exposed can, in turn, modulate a magnitude of pressure exerted on the bodily fluid and/or within a vein of a patient. In some instances, such pressure modulation can reduce, for example, hemolysis of a blood sample and/or a likelihood of collapsing a vein (e.g., which is particularly important in fragile patients needing microbial and/or other diagnostic testing associated with use of the control device 100). In addition, the modulation of the negative pressure can, for example, at least partially control a rate at which the fluid control device 100 transitions between a first configuration or state and a second configuration or state. In some embodiments, modulating the negative pressure can act like a timer. For example, a time between the introduction of the negative pressure differential and the transitioning of the diverter from the first state to the second state can be known, predetermined, calculated, and/or controlled. As such, in some instances, modulating the negative pressure can at least partially control an amount or volume of bodily fluid transferred

into the sequestration chamber 114 (e.g., can control a volume of the initial amount of bodily fluid).

[0066] The initial portion and/or amount of bodily fluid can be any suitable volume of bodily fluid, as described above. For example, in some instances, the control device 100 can remain in the first state until a predetermined and/or desired volume (e.g., the initial volume) of bodily fluid is transferred to the sequestration chamber 134. In some embodiments, the initial volume can be associated with and/or at least partially based on a volume of the sequestration chamber 114. In other embodiments, the initial volume can be associated with and/or at least partially based on an amount or volume of bodily fluid that can be transferred into the device prior to one or more portions of the control device 100 transitioning from a first operating state or mode to a second operating state or more (e.g., an amount of bodily fluid that can be absorbed by an absorbent, expandable, hydrophilic, and/or a wicking material, an amount of bodily fluid sufficient to fully wet or saturate a vent material or semi-permeable member or membrane, an amount sufficient to equalize one or more pressure differentials within the control device 100, an amount sufficient to transition a valve or actuator, and/or the like).

[0067] After the initial volume of bodily fluid is transferred and/or diverted into the sequestration chamber 114, the initial volume is sequestered, segregated, retained, contained, isolated, etc. in the sequestration chamber 114. For example, in some embodiments, the transitioning of the one or more flow controllers from a first state to a second state can be operable to sequester and/or retain the initial portion of the bodily fluid in the sequestration chamber 114. As described in further detail herein, in some instances, contaminants such as, for example, dermally residing microbes or the like dislodged during the venipuncture event, other external sources of contamination, colonization of catheters and PICC lines that are used to collect samples, and/or the like can be entrained and/or included in the initial volume of the bodily fluid and thus, are sequestered in the sequestration chamber 114 when the initial volume is sequestered therein.

[0068] With the initial volume transferred and/or diverted into the sequestration chamber 114, the device 100 can transition to the second state in which a subsequent volume(s) of bodily fluid can flow through at least a portion the fluid flow paths 113 and/or 154 from the inlet 112 to the outlet 116. In some embodiments, the control device 100 can passively and/or automatically transition (e.g., without user intervention) from the first state to the second state once the initial volume of bodily fluid is sequestered in the sequestration chamber 114. For

example, in some embodiments, filling the sequestration chamber 114 to capacity and/or fully saturating, wetting, and/or impregnating an absorbent or similar material disposed between the sequestration chamber 114 and the sample reservoir 160 can be such that further transfer of bodily fluid into the sequestration chamber 114 is limited and/or substantially prevented due to a removal or diversion of the negative pressure. In other embodiments, the control device 100 can be manually transitioned or transitioned in response to at least an indirect interaction by a user. For example, in some embodiments, a user can at least partially obstruct the opening and/or vent. In other embodiments, the user can actuate an actuator or the like (not shown in FIG. 1) to transition the control device 100 from the first state to the second state. In still other embodiments, at least a portion of the initial volume of bodily fluid can transition the control device 100 from the first state to the second state. For example, the control device 100 can include a bodily fluid activated switch, valve, port, and/or the like. In other embodiments, a volume of bodily fluid can move and/or displace one or more actuators or the like that can, for example, open a port, flow path, and/or outlet. In still other embodiments, a user can manipulate such a switch, valve, port, actuator, etc. to transition the control device 100 from the first state to the second state.

[0069] With the collection device 160 fluidically coupled to the outlet 116 and with the control device 100 being in the second state (e.g., the initial volume of bodily fluid is sequestered in or by the sequestration chamber 134), any subsequent volume(s) of the bodily fluid can flow from the inlet 112, through at least one of the fluid flow paths 113 and/or 154, through the outlet 116, and into the collection device 160. Thus, as described above, sequestering the initial volume of bodily fluid in the sequestration chamber 114 prior to collecting or procuring one or more sample volumes of bodily fluid reduces and/or substantially eliminates and amount of contaminants in the one or more sample volumes. Moreover, in some embodiments, the arrangement of the control device 100 can be such that the control device 100 cannot transition to the second state prior to collecting and sequestering the initial volume in the sequestration chamber 114.

[0070] FIG. 2 illustrates a cross-sectional side-view of a fluid control device 200 according to an embodiment. The fluid control device 200 can be similar in at least form and/or function to the fluid control device 100 described above with reference to FIG. 1. Accordingly, portions of the fluid control device 200 that can be similar to portions of the fluid control device 100 are not described in further detail herein.

[0071] As shown in FIG. 2, the fluid control device 200 (also referred to herein as "control device" or "device") includes an inlet 212, an outlet 216, and a sequestration chamber 214. As described above with reference to the control device 100, the inlet 212 is configured to be placed in fluid communication with a bodily fluid source to receive a flow of bodily fluid therefrom (e.g., via a lumen-containing device such as a needle, IV catheter, PICC line, or the like). The outlet 216 is configured to be fluidically coupled to a fluid collection device, a syringe, and/or other intermediary bodily fluid transfer device or vessel (not shown in FIG. 2) such as, for example, a transfer device similar to those described in the '510 publication.

[0072] As described above with reference to the fluid control device 100, the control device 200 includes one or more fluid flow paths 213 between the inlet 212 and a sequestration chamber 214 and/or one or more fluid flow paths 254 between the inlet 212 and the outlet 216. The device 200 can have any suitable shape, size, and/or configuration. For example, in some embodiments, the device 200 can be substantially similar in at least form and/or function to the device 100 described above with reference to FIG. 1. In some embodiments, the device 200 can include a first portion 224 and a second portion 225. As shown in FIG. 2, in some embodiments, the second portion 225 can be, for example, a bypass and/or diversion portion that is physically coupled to and selectively in fluid communication with the first portion 224. Moreover, the device 200 includes and/or forms a first junction 217 at a position where a first end (e.g., an inlet end) of the second portion 225 is coupled to the first portion 224 and includes and/or forms a second junction 218 at a position where a second end (e.g., an outlet end) of the second portion 225 is coupled to the first portion 224. That is to say, the device 200 can be configured to have and/or form a bifurcation (e.g., the second portion 225) at the first junction 217 which is rejoined at, for example, the second junction 218. In some embodiments, the second portion 225 can form and/or can have a D-shaped configuration and/or arrangement. In other embodiments, the first portion 224 and/or the second portion 225 can form and/or can have any suitable configuration and/or arrangement (e.g., a serpentine configuration, a looping configuration, a spiraled configuration, any suitable geometric configuration, and/or the like). In some embodiments, the first portion 224 and/or the second portion 225 of the device 200 can include and/or can be formed by flexible tubing or the like having any suitable shape and/or size and being reconfigurable or movable to be placed in any suitable configuration and/or arrangement.

[0073] In some embodiments, the sequestration chamber 214 of the device 200 can be formed by and/or included in the second portion 225 of the device 200. The coupling of the

second portion 225 to the first portion 224 (e.g., at the first junction 217) is such that the sequestration chamber 214 can be selectively placed in fluid communication with the inlet 212 via the fluid flow path 213 and the first junction 217. Similarly, the coupling of the second portion 225 to the first portion 224 (e.g., at the second junction 218) is such that the sequestration chamber 214 can be selectively placed in fluid communication with the outlet 216 and/or a fluid collection device coupled to the outlet 216 via the fluid flow path 254 and the second junction 218,.

[0074] As described in further detail herein, the sequestration chamber 214 is configured to (1) selectively receive a flow and/or volume of bodily fluid from the inlet 212 and (2) sequester (e.g., separate, segregate, contain, retain, isolate, etc.) the flow and/or volume of bodily fluid therein. The sequestration chamber 214 can have any suitable shape, size, and/or configuration. For example, in some embodiments, the sequestration chamber 214 can have any suitable size, volume, and/or fluid capacity such as, for example, those described above with reference to the sequestration chamber 114. In some embodiments, at least a portion of the fluid flow path 213 can extend through a portion of the device 200 and/or the first junction 217 to form and/or define at least a portion of the sequestration chamber 214. In other embodiments, the first junction 217 and/or the sequestration chamber 214 can include a flow control mechanism and/or the like that can at least temporarily separate the fluid flow path 213 from the sequestration chamber 214. In some embodiments, the device 200 can include, form, and/or define one or more flow controllers such as flow controllers 221, 222, and/or 215. The flow controllers 221, 222, and/or 215 can be, for example, a valve, membrane, diaphragm, restrictor, vent, a selectively permeable member (e.g., a fluid impermeable barrier or seal that allows at least selective passage of gas or air such as, for example, a blood barrier like Porex ®, and/or the like), port, etc. (collectively referred to herein as a "flow controller") placed in one or more desired positions and configured to selectively control (at least in part) a flow of fluids into and/or out of the sequestration chamber 214 and/or any other suitable portion of the device 200.

[0075] More particularly, in the embodiment shown in FIG. 2, the flow controllers 221 and 222 each can be a valve configured to have a specific, desired, and/or predetermined cracking pressure or the like. The valves 221 and/or 222 can be, for example, inline or Lined Pipe Insert (LP) valves that can configured to be suitably placed in any position along pipe or tubing systems. In some embodiments, the valves 221 and/or 222 can be configured to stay in a closed state, limiting or substantially preventing the flow of air or liquid, until a specific amount of

pressure greater than the cracking pressure is applied on the valves 221 and/or 222 to transition the valve 221 and/or 222, respectively, from a closed state to an open state.

[0076] In some embodiments, the valves 221 and/or 222 and other additional valves (not shown) each can be configured to have a variable cracking pressure and to be placed in any suitable position in and/or along the device 200. For example, in some embodiments, as shown in FIG.2, the valve 221 can be disposed in the first portion 224 of the device 200 and downstream of the first junction 217 and the valve 222 can be disposed in the second portion 225 of the device 200 upstream and/or before the second junction 218. In some embodiments, the device 200 can be configured such that the valve 221 has a greater cracking pressure than the valve 222 such that an applied vacuum source may be used to result in a sequential opening of the valves 221 and 222. For example, the cracking pressure of each of the valves 221 and 222 and the pressure exerted by the source of negative pressure can be collectively configured to achieve a sequential and/or otherwise desired first flow of bodily fluid towards and/or into the sequestration chamber 214 and then a desired second flow of bodily fluid towards the outlet 216 and the fluid collection device.

[0077] By way of specific example, in some embodiments, a source of negative pressure (e.g., a fluid collection device and/or the like) can define a vacuum having a magnitude of approximately 8 pounds per square inch (psi). Thus, when the source of negative pressure is coupled to the outlet 216, the pressure is communicated to both valves 221 and 222. In some embodiments, the valve 221 may have, for example, a cracking pressure of 3.4 psi and the valve 222 may have, for example, a cracking pressure of 0.017 psi. As such, the negative pressure differential produced as a result of coupling the negative pressure source to the outlet 216, in turn, can transition the valve 222 (having the lower cracking pressure) from a substantially closed configuration or state to a substantially open configuration or state prior to transitioning the valve 221 (having the higher cracking pressure) from a substantially closed configuration or state to a substantially open configuration or state. In some instances, this sequential opening of the valves (i.e., valve 222 before valve 221), can be operable to direct a flow of fluid (e.g., a first flow) towards the sequestration chamber 214 and then direct the flow of fluid (e.g., a second flow) towards the fluid collection device and/or negative pressure source coupled to the outlet 216, as described further below.

[0078] The device 200, can in some embodiments, include one or more flow controllers in the form of materials that are selectively permeable to air but impermeable or at least selectively permeable to fluid (e.g., liquid). For example, the device 200 can include one or

more membranes made of material that permit the flow of air or convey a vacuum from a source of negative pressure but do not permit or convey a flow of bodily fluid (e.g., hydrophobic). In some embodiment, the device 200 can include flow controllers that can be in a first or initial state or configuration before interaction with a bodily fluid or any other suitable form of actuation, and then transition and/or be transitioned to a second state or configuration upon interaction with the bodily fluid or a suitable form of actuation. For example, in some embodiments, such flow controllers can be in an initial or first state that selectively permits a flow of air therethrough while substantially limiting and/or preventing a flow of bodily fluid therethrough. Upon interaction with a bodily fluid (or any other suitable fluid), the flow controller can transition to a second state, in which the flow controller can be substantially impermeable to the flow of air and the flow of bodily fluid therethrough.

[0079] As shown in the embodiment illustrated in FIG.2, the device 200 can include a flow controller 215 in the form of a membrane, porous material, absorbent material, etc. The flow controller 215 can be any suitable shape, size, and/or configuration. In some embodiments, the flow controller 215 can be formed of a porous material having any suitable pore size to, for example, permit a flow of air therethrough while limiting and/or substantially preventing a flow of liquid therethrough. For example, in some embodiments, the flow controller 215 can be a membrane or the like having a diameter of about 17 mm and having a pore size of about 0.45 micrometers (μm). In other embodiments, the flow controller 215 can be a membrane and/or the like having any suitable diameter (e.g., 1 mm, 2 mm, 3 mm ,4 mm, 5 mm, 10 mm, 15 mm, 20 mm, 30 mm, or more, and/or any diameter therebetween). Likewise, in other embodiments, the flow controller 215 can be a membrane and/or the like having any suitable pore size. In some embodiments, a pore size for a flow controller, membrane, and/or the like can be based on, for example, the type of fluid (e.g., bodily fluid) to be withdrawn, collected, and/or sequestered, the amount or type of particulate matter expected in the fluid flow (e.g., in the flow of the bodily fluid and/or the flow of air), the vacuum source to be used and/or a magnitude of an expected negative pressure differential, and/or any other suitable factor or consideration.

[0080] As shown, the flow controller 215 is positioned within the device 200 to selectively establish fluid communication between the second portion 225 and/or the sequestration chamber 214 and the outlet 216 via the junction 218. Thus, with the flow controller 215 being configured as a semi-permeable member, the flow controller 215 can be configured to at least temporarily allow a gas or air to transfer from the second portion 225 of the device 200 and/or the sequestration chamber 214, through the flow controller 215 and the junction 218, and into

the fluid flow path 254 and can be configured to limit and/or substantially prevent a flow of liquid (e.g., bodily fluid) between the second portion 225 and/or the sequestration chamber and the fluid flow path 254 (e.g., via the junction 218), as described in further detail herein. Although not shown, in some embodiments, the device 200 can include one or more actuators or the like configured to control and/or transition the state of the flow controller 215. The outlet 216 of the device 200 is in fluid communication with and/or is configured to be placed in fluid communication with the fluid flow paths 213 and/or 254. The outlet 216 can be any suitable outlet, opening, port, lock, seal, coupler, etc. and is configured to be fluidically coupled to a fluid collection device, such as a sample reservoir, a syringe, container, and/or other sample vessel. In some embodiments, the outlet 216 can be monolithically formed with the fluid collection device or can be at least temporarily coupled to the fluid collection device, as described above with reference to the outlet 116 of the device 100. The fluid collection device can be any suitable collection system for containing a bodily fluid, such as, for example, any of those described in detail above with reference to the collection device 160. More particularly, in some embodiments, the outlet 216 can be configured to couple to an evacuated sample reservoir. In some other embodiments, the outlet 216 can be configured to couple to a source of negative pressure downstream of the outlet 216, while also coupled to the fluid collection device. As such, the user can couple the fluid collection device to the outlet 216 to initiate a flow of bodily fluid from the patient such that a first or initial portion of the bodily fluid is transferred into and sequestered by the sequestration chamber 214 and such that any subsequent portion or volume of bodily fluid bypasses and/or is otherwise diverted away from the sequestration chamber 214 and flows into the fluid collection device.

[0081] In operation, the device 200 can be used to procure a bodily fluid sample having reduced contamination from microbes such as, for example, dermally residing microbes and/or the like. For example, in some instances, a user such as a doctor, physician, nurse, phlebotomist, technician, etc. can manipulate the device 200 to establish fluid communication between the inlet 212 and the bodily fluid source (e.g., a vein of a patient). Once the inlet 212 is placed in fluid communication with the bodily fluid source (e.g., the portion of the patient), the outlet 216 can be fluidically coupled to the fluid collection device. As described above, in the embodiment shown in FIG. 2, the fluid collection device can be a negative pressure source and/or can be configured to produce a negative pressure differential. For example, the fluid collection device can be an evacuated reservoir or container that defines a negative pressure, a syringe, a pump, and/or any other negative pressure source. In other embodiments, the fluid

collection device can be a container, reservoir, or device configured to be coupled to a separate negative pressure source.

[0082] Coupling the outlet 216 to the fluid collection device and/or the source of negative pressure selectively exposes at least a portion of the fluid flow path 254 to the negative pressure within or passing through the fluid collection device. As described above, the flow controller 215 and/or the valves 221 and 222 can be configured to selectively control the flow of fluid through the device 200. More particularly, coupling the outlet 216 to the fluid collection device and/or source of negative pressure results in a negative pressure differential within the fluid flow path 254, which in turn, exposes the valves 221 and 222 to the negative pressure. As described above, in some embodiments, the valve 221 can have a greater cracking pressure (e.g., 3.4 psi) compared to that of the valve 222 (e.g., 0.017 psi). Furthermore, the flow controller 215 upstream of the valve 222 can be a membrane in an initial or first state, in which the flow controller 215 is permeable to a flow of air or gas. In some instances, such an arrangement results in the valve 222 being transitioned from a closed state to an open state such that the negative pressure is communicated through the valve 222 and the flow controller 215 and into the sequestration chamber 214.

[0083] Accordingly, a negative pressure differential is produced that is operable in drawing bodily fluid from the bodily fluid source (e.g., the patient), through the inlet 212, and into the fluid flow path 213. Moreover, with the valve 222 in the open state and the valve 221 in the closed state, the bodily fluid can flow through the fluid flow path 213 and into the sequestration chamber 214 (e.g., via the junction 217). As described above with reference to the control device 100, the arrangement of the device 200 is such that when a volume of bodily fluid is transferred to and/or through the inlet 212, an initial portion of the volume of bodily fluid (also referred to herein as an "initial volume" or a "first volume") flows from the inlet 212, through at least a portion of the fluid flow path 213 and/or the junction 217, and into the sequestration chamber 214. That is to say, in some embodiments, the control device 200 can be in first or initial state in which the initial portion or volume of bodily fluid can flow in or through at least a portion the fluid flow path 213 and/or junction 217 and into the sequestration chamber 214. When the device 200 is in the first or initial state, the valve 221 is in a closed state and as such, the bodily fluid does not pass through the valve 221 nor substantially enter the fluid flow path 254.

[0084] As described above, the control device 200 can be in the initial state when the flow controller 222 (valve) is in an open state, which in turn, allows the negative pressure differential

to draw the initial amount of bodily fluid into the sequestration chamber 214. In some instances, the bodily fluid can flow through the second portion 225 (e.g., the sequestration chamber 214) until the flow reaches the flow controller 215 (e.g., a selectively permeable membrane or member, as described above). The membrane 215 can be in its initial or first state and therefore can be permeable to air but impermeable to liquids. As such, the membrane 215 isolates, separates, segregates, sequesters and/or otherwise prevents direct liquid communication between the fluid flow paths 213 and the sequestration chamber 214. In addition, the inlet 212 is exposed to the negative pressure differential via the sequestration chamber 214. In other words, the negative pressure within the fluid collection device can result in a negative pressure (or negative pressure differential) within at least the second portion 225 of the device 200 (e.g., the sequestration chamber 214) that is operable in drawing an initial flow of bodily fluid from the inlet 212, through at least a portion of the fluid flow path 213 and/or the junction 217, and into the sequestration chamber 214 when the control device 200 is in the first or initial state.

[0085] When the flow controller 215 is in the first or initial state, the flow controller 215 can allow a flow of fluid (e.g., a gas or air) therethrough in response to the negative pressure of the sample reservoir (or a syringe or other source of potential energy used to create negative pressure), as described above with reference to the device 100. The flow controller 215 (e.g., selectively permeable membrane or member) can be configured to transition from the first state of being permeable to air and impermeable to liquid, to a second state of being impermeable to air and liquid in response to the flow of the initial amount of bodily fluid into the sequestration chamber 214. For example, the filling of the sequestration chamber 214 to capacity can correspond to and/or otherwise result in the bodily fluid saturating, wetting, and/or impregnating the flow controller 215 (e.g., membrane material), which can transition the flow controller 215 from the first state to the second state. In the second state the flow controller 215 is impermeable to air and liquid, thereby limiting and/or substantially preventing fluid communication between the sequestration chamber 214 and the source of negative pressure (e.g., the fluid collection device). In other words, the sequestration chamber 214 can be sequestered from the negative pressure source in response to initial volume of bodily fluid filling the sequestration chamber 214.

[0086] The initial portion and/or amount of bodily fluid can be any suitable volume of bodily fluid, as described in detail above with reference to the control device 100. For example, in some instances, the initial volume can be associated with and/or at least partially based on

an amount or volume of bodily fluid that is sufficient to fully wet or saturate the flow controller 215 (e.g., selectively permeable membrane or member). In other words, in some embodiments, the initial volume of bodily fluid can be a volume sufficient to transition the flow controller 215 to a second state (e.g., a saturated or fully wetted state). In some embodiments, the flow controller 215 is placed in a sealed configuration when transitioned to the second state. That is to say, saturating and/or fully wetting the flow controller 215 (e.g., the semi-permeable material) places the flow controller 215 in a sealed configuration in which the flow controller 215 substantially prevents a flow of a liquid and a gas therethrough.

[0087] After the initial volume of bodily fluid is transferred and/or diverted into the sequestration chamber 214, the control device 200 can be transitioned to its second state or operating mode to sequester, segregate, retain, contain, isolate, etc. the initial volume in the sequestration chamber 214. For example, as described above, the flow controller 215 is placed in the sealed configuration, which fluidically isolates the sequestration chamber 214 from the fluid flow path 254. In addition, the transitioning of the flow controller 215 can be in response to the initial amount of bodily fluid filling the sequestration chamber 214. Accordingly, the initial amount of bodily fluid in the sequestration chamber 214 can limit and/or substantially prevent further amounts of bodily fluid from being transferred into the sequestration chamber 214. Thus, the initial amount and/or portion of bodily fluid is sequestered and/or retained within the sequestration chamber 214. As described above, in some instances, contaminants such as, for example, dermally residing microbes or the like dislodged during the venipuncture event, can be entrained and/or included in the initial volume of the bodily fluid and thus, are sequestered in the sequestration chamber 214 when the initial volume of bodily fluid is sequestered therein.

[0088] With the flow controller 215 in the second state (e.g., an impermeable or sealed state), the negative pressure otherwise exerted on or through the sequestration chamber 214 is now exerted on or through the fluid flow path 254 and thus, on the flow controller 221. In some instances, a magnitude of the negative pressure can build and/or increase within the fluid flow path 254 until the negative pressure becomes sufficient to transition the flow controller 221 from its first state to its second state. More specifically, when the flow controller 221 is a valve, the negative pressure can increase until it becomes sufficient to overcome the cracking pressure of the valve 221. As such, when the valve is placed in its open state (and/or when the flow controller 221 is otherwise in its second state), the inlet 212 is exposed to the negative pressure differential via the fluid flow path 213. With the fluid collection device fluidically

coupled to the outlet 216 and with the control device 200 being in the second state (e.g., the initial volume of bodily fluid is sequestered in or by the sequestration chamber 214), any subsequent volume(s) of the bodily fluid can flow from the inlet 212, through the fluid flow paths 213 and 254, through the flow controller 221 (e.g., valve), through the outlet 216, and into the fluid collection device. Thus, as described above, sequestering the initial volume of bodily fluid in the sequestration chamber 214 prior to collecting or procuring one or more sample volumes of bodily fluid reduces and/or substantially eliminates and amount of contaminants in the one or more sample volumes. Moreover, in some embodiments, the arrangement of the control device 200 can be such that the control device 200 cannot transition to the second state prior to collecting and sequestering the initial volume in the sequestration chamber 214.

[0089] Although not shown in FIG. 2, in some embodiments, the control device 200 can include an actuator and/or the like configured to be moved (e.g., via a force applied by a user) between a first state and a second state. In other embodiments, a control device can include any suitable member, device, mechanism, etc. configured to selectively establish fluid communication between two or more fluid flow paths (e.g., the fluid flow paths 213 and 254).

[0090] In some instances, it may be desirable to modulate and/or control a magnitude of the negative pressure differential to which the sequestration chamber 214 is exposed. Although not shown in FIG. 2, the device 200 can include one or more means for reducing and/or controlling a magnitude of the negative pressure differential. For example, in some embodiments, the device 200 can include a restricted flow path path(s) or portions of flow path(s) having a smaller diameter than the fluid flow paths 213 and/or 254. For example, in some embodiments, the one or more restricted flow paths can have a diameter of about 1.0 micrometers (μm), about 10.0 μm, about 100.0 μm, about 1000.0 μm, about 10,000.0 μm, about 100,000.0 μm, and/or any suitable diameter therebetween. In other embodiments, the restricted flow path(s) can have a diameter smaller than 1.0 μm or larger than 100,000.0 μm. In such embodiments, a restricted flow path having a smaller diameter may result in a lower magnitude of negative pressure being applied through the sequestration chamber 214 than a magnitude of negative pressure when the restricted flow path has a larger diameter. Moreover, in some such embodiments, the one or more restricted flow paths can be, for example, gas flow path(s) configured to receive a flow of gas or air but not a flow of a liquid (e.g., bodily fluid). In some embodiments, the diameter of the restricted flow path can be sufficiently small to limit and/or prevent a flow of a liquid therethrough.

[0091] In some embodiments, the restricted flow path can be, for example, disposed between the junction 218 and the flow controller 215, such that a flow of bodily fluid and/or any other liquid is substantially prevented by the flow controller 215 (e.g., a selectively permeable barrier or seal). More specifically, in some embodiments, the restricted flow path can be disposed between, for example, the flow controller 222 (e.g., valve) and the flow controller 215 (e.g., selectively permeable membrane or member). Accordingly, the flow controller 222 can be exposed to a greater magnitude of negative pressure than the magnitude of negative pressure to which the flow controller 215 is exposed. In such embodiments, the greater magnitude of negative pressure can facilitate the transition of the flow controller 222 from its first state to its second state. For example, in some embodiments, when the flow controller 222 is a valve, this arrangement can allow for the valve to be exposed to a negative pressure differential that is sufficient to overcome the cracking pressure of the valve.

[0092] Although the pressure modulation is described above as being based on a diameter of a restricted flow path, it should be understood that this is presented by way of example only and not limitation. For example, in some embodiments, a control device can include any suitable number of restricted flow paths, each of which can have substantially the same diameter or can have varied diameters. For example, in some embodiments, a control device can include up to 100 restricted flow paths or more. In such embodiments, each of the restricted flow paths can have a diameter of between about 1.0 μm and about 100.0 μm, between about 1.0 μm and about 10.0 μm, or between about 1.0 μm and about 5.0 μm. In some embodiments, multiple restricted flow paths can be configured to (1) selectively provide a flow path between the outlet 216 and the sequestration chamber 214 that exposes the sequestration chamber 214 to the negative pressure differential, and (2) act as a flow controller configured to selectively allow the passage of a gas and/or air while substantially preventing the passage of a liquid (e.g., bodily fluid). Other means of modulating the magnitude of negative pressure to which the sequestration chamber is exposed can include, for example, a porous material, a valve, a membrane, a diaphragm, a specific restriction, a vent, a deformable member or flow path, and/or any other suitable means. In some embodiments, the flow controller 215 can be a selectively permeable membrane or member having a predetermined and/or desired porosity to provide the desired amount of negative pressure modulation.

[0093] In some embodiments, modulating and/or controlling a magnitude of the pressure to which the sequestration chamber 214 is exposed can, in turn, modulate a magnitude of pressure exerted on the bodily fluid and/or within a vein of a patient. In some instances, such

pressure modulation can reduce, for example, hemolysis of a blood sample and/or a likelihood of collapsing a vein. In some instances, the ability to modulate and/or control an amount or magnitude of negative pressure can allow the control device 200 to be used across a large spectrum of patients that may have physiological challenges whereby negative pressure is often needed to facilitate collection of bodily fluid such as, for example, blood (e.g., a pressure differential between atmospheric pressure and a patient's vascular pressure may not be sufficient to facilitate consistent and sufficiently forceful flow) but not so much pressure that a rapid force flattens, collapses, caves-in, and/or otherwise inhibits patency and ability to collect blood.

[0094] FIG. 3 illustrates a fluid control device 300 according to another embodiment. The fluid control device 300 (also referred to herein as "control device" or "device") can be of any suitable shape, size, and/or configuration. For example, in some embodiments, the fluid control device 300 can be similar in at least form and/or function to the fluid control device 100 described above with reference to FIG. 1 and/or the fluid control device 200 described above with reference to FIG. 2. Accordingly, portions of the fluid control device 300 that can be similar to portions of the fluid control devices 100 and/or 200 are not described in further detail herein.

[0095] As described above with reference to the fluid control device 200 shown in FIG. 2, the fluid control device 300 shown in FIG. 3 includes an inlet 312, an outlet 316, and a sequestration chamber 314. The inlet 312 is configured to be placed in fluid communication with a bodily fluid source to receive a flow of bodily fluid therefrom (e.g., via a lumen-containing device such as a needle, IV catheter, PICC line, or the like). The outlet 316 is configured to be fluidically coupled to a fluid collection device, a syringe, an evacuated container, and/or other intermediary bodily fluid transfer device or vessel (not shown in FIG. 3) such as, for example, a transfer device similar to those described in the '510 publication. Furthermore, the control device 300 includes and/or defines one or more fluid flow paths 313 between the inlet 312 and the sequestration chamber 314 and/or one or more fluid flow paths 354 between the inlet 312 and the outlet 316.

[0096] In some embodiments, the device 300 can include a first portion 324 and a second portion 325. As shown in FIG. 3, in some embodiments, the second portion 325 can be, for example, a bypass and/or diversion portion that is physically coupled to and selectively in fluid communication with the first portion 324. Moreover, the device 300 includes and/or forms a first junction 317 at a position where a first end (e.g., an inlet end) of the second portion 325 is

coupled to the first portion 324 and includes and/or forms a second junction 318 at a position where a second end (e.g., an outlet end) of the second portion 325 is coupled to the first portion 324. That is to say, the device 300 can be configured to have and/or form a bifurcation (e.g., the second portion 325) at the first junction 317 which is rejoined at, for example, the second junction 318. In some embodiments, the first portion 324 and/or the second portion 325 of the device 300 can include and/or can be formed by flexible tubing or the like having any suitable shape and/or size and being reconfigurable or movable to be placed in any suitable configuration and/or arrangement.

[0097] As described in further detail herein, the sequestration chamber 314 is configured to (1) receive a flow and/or volume of bodily fluid from the inlet 312 and (2) sequester (e.g., separate, segregate, contain, retain, isolate, etc.) the flow and/or volume of bodily fluid therein. The sequestration chamber 314 can have any suitable shape, size, and/or configuration. For example, in some embodiments, the sequestration chamber 314 can have any suitable size, volume, and/or fluid capacity such as, for example, those described above with reference to the sequestration chamber 114 and/or 214. In some embodiments, at least a portion of the fluid flow path 313 can extend through a portion of the device 300 to form and/or define at least a portion of the sequestration chamber 314. In some embodiments, the sequestration chamber 314 of the device 300 can be substantially similar in form and/or function to one or more of the sequestration chambers 114 and/or 214. Accordingly, portions of the sequestration chamber 314 may not be described in further detail herein.

[0098] As shown in FIG. 3, the sequestration chamber 314 can be formed by and/or included in the second portion 325 of the device 300 and can be selectively placed in fluid communication with (1) the inlet 312 via the fluid flow path 313 and the first junction 317, and (2) the outlet 316 via the fluid flow path 354 and the second junction 318. As such, the sequestration chamber 314 can be configured to (1) selectively receive a flow and/or volume of bodily fluid from the inlet 312 and (2) sequester (e.g., separate, segregate, contain, retain, isolate, etc.) the flow and/or volume of bodily fluid therein.

[0099] In some embodiment, the fluid control device 300 can include and/or define one or more flow controllers. Flow controllers can include for example, valves, membranes, diaphragms, restrictors, vents, selectively permeable members (e.g., a fluid impermeable barrier or seal that allows at least selective passage of gas or air such as, for example, a blood barrier like Porex ®, and/or the like), ports, etc. (collectively referred to herein as a "flow controller") placed suitably and configured to selectively control (at least in part) a flow of

fluids into and/or out of the sequestration chamber 314 and/or any other suitable portion of the device 300. Some embodiments of the device 300, as shown in FIG. 3, can include flow controllers such as a selectively permeable member 315, a check valve 322, and a dissolvable member 323 that are arranged to, under certain states of function and/or under certain conditions, permit, direct, control, and/or obstruct the flow of fluid in one or more specific directions.

[0100] As shown in FIG. 3, the second portion 325 of the device 300 can include the check valve 322 and the selectively permeable member 315. For example, in some embodiments, the check valve 322 and/or the selectively permeable member 315 can be disposed on, at, or near a proximal or second end of the sequestration chamber 314. In other words, the check valve 322 and the selectively permeable member 315 can be positioned at, on, or near an outlet or outlet portion of the sequestration chamber 314. Said another way, the check valve 322 and/or the selectively permeable member can be positioned at, on, or near an end portion of the sequestration chamber 314 that is closer to the second junction 318 than it is to the first junction 317. In some embodiments, the check valve 322 and/or the selectively permeable member 315 can be integrated into at least a portion of the second junction 318. In some embodiments, the check valve 322 can be substantially similar to the valve 222 described above with reference to the device 200. For example, in some embodiments, the check valve 322 can be configured to have a desired cracking pressure such as those described above with reference to the valve 222. Accordingly, the check valve 322 can be configured to selectively control a flow of fluid between, for example, the fluid flow path 354 and the sequestration chamber 314, as described above with reference to the device 200. As such, the check valve 322 is not described in further detail herein. Moreover, in some embodiments, the device 300 need not include a check valve and/or any other suitable valve.

[0101] The selectively permeable member can be any suitable shape, size, and/or configuration. For example, in some embodiments, the selectively permeable member 315 can be, for example, a membrane, a porous material, an absorbent material, a hydrophilic or hydrophobic material, a selectively permeable barrier, etc. In some embodiments, the selectively permeable member 315 can be substantially similar to the flow controller 215 (e.g., selectively permeable member and/or membrane) and thus, aspects of the selectively permeable member 315 are not described in further detail herein. The selectively permeable member 315 can be configured to at least temporarily allow a gas or air to transfer from the second portion 325 of the device 300 and/or the sequestration chamber 314, through the

selectively permeable member 315 and the junction 318, and into the fluid flow path 354 and can be configured to limit and/or substantially prevent a flow of liquid (e.g., bodily fluid) between the second portion 325 and/or the sequestration chamber and the fluid flow path 354 (e.g., via the junction 318). In some embodiments, the selectively permeable member 315 can be in a first or initial state, in which the selectively permeable member 315 allows a flow of air or gas to transfer therethrough, when the device 300 is in its first state and/or configuration. As described in further detail herein, the selectively permeable member 315 can be transitioned to and/or otherwise can be in a second state or configuration, in which the selectively permeable member 315 is substantially impermeable to all fluids (gasses and/or liquids), when the device 300 is in its second state and/or configuration.

[0102] In some embodiments, the dissolvable member 323 can be situated at a suitable position within the first portion of the device 300. For example, in some embodiments, the dissolvable member 323 can be positioned at and/or near the first junction 317, as shown in FIG. 3. In some embodiments, the dissolvable member 323 can be integrated into the junction 317 and/or at least a portion of the junction 317. As such, the dissolvable member 323 can be, for example, upstream of the selectively permeable member 315.

[0103] As described in further detail herein, the dissolvable member 323 can be configured to transition from a first or initial state to a second state in response to contact with a fluid such as, for example, bodily fluid. In some embodiments, for example, the dissolvable member 323 can be disposed within and/or near the first junction 317 to isolate the inlet 312 from the fluid flow path 354 when the device 300 is in the first or initial state. In response to and/or after transferring an initial volume of bodily fluid to the sequestration chamber 314, the device 300 can be transitioned from the first or initial state to the second state. In some embodiments, when the device 300 is in the second state, the dissolvable member 323 can be substantially dissolved, which in turn, can allow fluid communication to be established between the inlet 312 and the fluid flow path 354. In some instances, for example, a portion of the bodily fluid can contact the dissolvable member 323 as the initial volume of bodily fluid flows into the sequestration chamber 314. The contact with the bodily fluid can, in turn, begin to dissolve the dissolvable member 323 such that when the device 300 is transitioned to its second state and/or configuration, the dissolvable member 323 is at least substantially dissolved, thereby placing the inlet 312 in fluid communication with the fluid flow path 354, as described in further detail herein.

[0104] As described above, the device 300 can be used to procure a bodily fluid sample having reduced contamination from microbes such as, for example, dermally residing microbes and/or the like. For example, in some instances, a user such as a doctor, physician, nurse, phlebotomist, technician, etc. can manipulate the device 300 to establish fluid communication between the inlet 312 and the bodily fluid source (e.g., a vein of a patient). Once the inlet 312 is placed in fluid communication with the bodily fluid source (e.g., the portion of the patient), the outlet 316 can be fluidically coupled to the fluid collection device. As described above, in the embodiment shown in FIG. 3, the fluid collection device can be, for example, an evacuated reservoir, a syringe, and/or any container that defines a negative pressure, or is coupled to a downstream source of negative pressure.

[0105] Coupling the outlet 316 to the fluid collection device selectively exposes at least a portion of the fluid flow path 354 to the negative pressure within the fluid collection device. The arrangement of the device 300 when in its first or initial state includes one or more flow controllers in their first state or configuration. For example, the selectively permeable member 315, the check valve 322, and the dissolvable member 323 can each be in their first states and/or configurations when the outlet 316 is coupled to the fluid collection device. In response to the negative pressure, the check valve 322 can be configured to transition from a substantially closed state (e.g., its first configuration or state) to a substantially open state (e.g., its second configuration and/or state). For example, in some instances, establishing fluid communication between the outlet 316 and the fluid collection device can expose the check valve 322 to a negative pressure differential that exceeds, for example, a cracking pressure of the check valve 322. Thus, the check valve 322 can be placed in its second state and/or configuration. In other embodiments, the device 300 need not include a check valve and/or other suitable valve. In such embodiments, the negative pressure differential otherwise operable to transition the check valve 322 would instead be exerted on the selectively permeable member 315, which is substantially similar to when the check valve 322 is in the second or opened state.

[0106] As described above, the selectively permeable member 315 and the dissolvable member 323 are each in their first state or configuration when the outlet 316 is coupled to the fluid collection device. As such, the selectively permeable member 315 can be configured to permit a flow of air, gas, and/or negative pressure therethrough while blocking and/or preventing a flow of liquid therethrough, as described above with reference to the flow controller 215. Furthermore, with the dissolvable member 323 in its first state or configuration, the dissolvable member 323 can be configured to block, isolate, and/or obstruct fluid

communication between, for example, the inlet 312 and the fluid flow path 354 such that it does not permit any flow of fluid (air or liquid or negative pressure) therethrough. Thus, coupling the outlet 316 to the fluid collection device exposes the sequestration chamber 314 to the negative pressure of the fluid collection device, thereby resulting in a negative pressure differential operable in drawing bodily fluid from the bodily fluid source (e.g., the patient), through the inlet 312, and into the sequestration chamber 314.

[0107] As described above with reference to the control devices 100 and 200, the arrangement of the device 300 is such that when a volume of bodily fluid is transferred to and/or through the inlet 312, an initial portion of the volume of bodily fluid (also referred to herein as an "initial volume" or a "first volume") flows from the inlet 312 and into the sequestration chamber 314. That is to say, in some embodiments, the device 300 is in its first or initial state in which the initial portion or volume of bodily fluid can flow from the inlet 312 and into the sequestration chamber 314 in response to the negative pressure differential associated with the fluid collection device. In other words, the negative pressure within the fluid collection device can result in a negative pressure (or negative pressure differential) within at least a portion of the sequestration chamber 314 that is operable in drawing an initial flow of bodily fluid from the inlet 312 into the sequestration chamber 314 when the control device 300 is in the first or initial state. As described in detail above, in some instances, it may be desirable to modulate and/or control a magnitude of the negative pressure differential by any suitable means such as those described herein.

[0108] The initial portion and/or amount of bodily fluid can be any suitable volume of bodily fluid, as described in detail above with reference to the control devices 100 and/or 200. For example, in some instances, the initial volume can be associated with and/or at least partially based on an amount or volume of bodily fluid that is sufficient to fully wet or saturate the membrane 315. In other words, in some embodiments, the initial volume of bodily fluid can be a volume sufficient to transition the selectively permeable member 315 to a second state (e.g., a saturated or fully wetted state). As described above with reference to the flow controller 215, the selectively permeable member 315 is placed in a sealed configuration when transitioned to the second state. Thus, transitioning the selectively permeable member 315 to the second state sequesters, blocks, isolates, separates, segregates, and/or otherwise prevents flow through the selectively permeable member 315.

[0109] After the initial volume of bodily fluid is transferred and/or diverted into the sequestration chamber 314, the control device 300 can be transitioned to its second state or

operating mode to sequester, segregate, retain, contain, isolate, etc. the initial volume in the sequestration chamber 314. As described above, the selectively permeable member 315 is placed in the sealed configuration and thus, substantially prevents a flow of fluid therethrough. In this embodiment, the arrangement of the control device 300 is such that when the selectively permeable member 315 is placed in the sealed configuration, at least a portion of the negative pressure otherwise being exerted through the selectively permeable member 315 is instead exerted on and/or in the fluid flow path 354. The negative pressure, however, can be isolated within the fluid flow path 354 until the dissolvable member 323 is transitioned from its first state and/or configuration to its second state and/or configuration (e.g., until it is at least partially dissolved).

[0110] With the selectively permeable member 315 sealed in its second state and the filling of the sequestration chamber 314 to capacity by the initial volume of bodily fluid drawn, the amount of bodily fluid held at least temporarily at and/or near the junction 317 can place a sufficient amount of bodily fluid in contact with the dissolvable member 323 to transition the dissolvable member 323 from its first state to its second state. In other words, filing the sequestration chamber 314 can place a sufficient volume or amount of bodily fluid into contact with the dissolvable member 323 to substantially dissolve the dissolvable member 323, thereby transitioning it to its second state or configuration. The transition of the dissolvable member 323, in turn, is sufficient to transition the fluid control device 300 from its first state to its second state.

[0111] With the dissolvable member 323 in its second state and/or configuration (e.g., at least partially dissolved), the negative pressure within the fluid flow path 354 can be exerted on the fluid flow path 313 and/or the inlet 312. In some embodiments, the arrangement of the dissolvable member 323 can be such that as the dissolvable member 323 is dissolved, the inlet 312 is exposed to a greater amount and/or magnitude of negative pressure. In other words, the dissolvable member 323 can be configured to dissolve of a predetermined and/or desired period of time, which in turn, can modulate and/or control an amount of negative pressure to which the inlet 312 is exposed. In some embodiments, the dissolvable member 323 can include one or more characteristics that can be tuned, adjusted, and/or the like configured to adjust (e.g., increase or decrease) a rate at which the dissolvable member 323 transitions to its second state (e.g., dissolves). As the dissolvable member 323 is transitioned to its second state and/or configuration, the negative pressure within the fluid flow path 354, urges, draws, and/or induces a flow of bodily fluid from the inlet 312 and the first junction 317, through the fluid

flow path 354 and the outlet 316, and into the fluid collection device. Moreover, the sealed state of the selectively permeable member 315 and the presence of check valves 322 (or other suitable flow controller) can limit and/or substantially prevent flow of bodily fluid from the fluid flow path 354, through the second junction 318, and toward the sequestration chamber 314. In some embodiments, the transitioning of the selectively permeable member 315 and the dissolvable member 323 from their respective first states to their respective second states is operable to sequester and/or retain the initial portion of the bodily fluid in the sequestration chamber 314. As described in further detail herein, in some instances, contaminants such as, for example, dermally residing microbes or the like dislodged during the venipuncture event, can be entrained and/or included in the initial volume of the bodily fluid and thus, are sequestered in the sequestration chamber 314 when the initial volume is sequestered therein.

[0112] With the fluid collection device fluidically coupled to the outlet 316 and with the control device 300 in the second state (e.g., the initial volume of bodily fluid is sequestered in or by the sequestration chamber 314), any subsequent volume(s) of the bodily fluid can flow from the inlet 312, through the fluid flow paths 313 and 354, through the outlet 316, and into the fluid collection device. Thus, as described above, sequestering the initial volume of bodily fluid in the sequestration chamber 314 prior to collecting or procuring one or more sample volumes of bodily fluid reduces and/or substantially eliminates and amount of contaminants in the one or more sample volumes. Moreover, in some embodiments, the arrangement of the fluid control device 300 can be such that the device 300 cannot transition to the second state prior to collecting and sequestering the initial volume in the sequestration chamber 314.

[0113] FIG. 4 illustrates a fluid control device 400 according to an embodiment. The fluid control device 400 can be of any suitable shape, size, and/or configuration. For example, in some embodiments, the fluid control device 400 can be similar in at least form and/or function to one or more of the devices 100, 200, and/or 300 described above with reference to FIG. 1, FIG. 2, and FIG. 3, respectively. Accordingly, portions of the fluid control device 400 that can be similar to portions of the fluid control devices 100, 200, and/or 300 are not described in further detail herein.

[0114] As shown in FIG. 4, the fluid control device 400 (also referred to herein as "control device" or "device") includes an inlet 412, an outlet 416, and a sequestration chamber 414. As described above with reference to the control devices 100, 200, and/or 300, the inlet 412 is configured to be placed in fluid communication with a bodily fluid source to receive a flow of bodily fluid therefrom (e.g., via a lumen-containing device such as a needle, IV catheter, PICC

line, and/or the like). The outlet 416 is configured to be fluidically coupled to fluid collection device, a syringe, a transfer adapter, and/or the like (not shown in FIG. 4). Furthermore, the control device 400 includes and/or defines one or more fluid flow paths 413 between the inlet 412 and at least the sequestration chamber 414 and/or one or more fluid flow paths 454 between the inlet 412 and the outlet 416.

[0115] In some embodiments, the device 400 can include a first portion 424 and a second portion 425. As shown in FIG. 4, in some embodiments, the second portion 425 can be, for example, a bypass and/or diversion portion that is physically coupled to and selectively in fluid communication with the first portion 424. Moreover, the device 400 includes and/or forms a first junction 417 at a position where a first end (e.g., an inlet end) of the second portion 425 is coupled to the first portion 424 and includes and/or forms a second junction 418 at a position where a second end (e.g., an outlet end) of the second portion 425 is coupled to the first portion 424. That is to say, the device 400 can be configured to have and/or form a bifurcation (e.g., the second portion 425) at the first junction 417 which is rejoined at, for example, the second junction 418. In some embodiments, the first portion 424 and/or the second portion 425 of the device 400 can include and/or can be formed by flexible tubing or the like having any suitable shape and/or size and being reconfigurable or movable to be placed in any suitable configuration and/or arrangement.

[0116] The sequestration chamber 414 can have any suitable shape, size, and/or configuration. For example, in some embodiments, the sequestration chamber 414 can have any suitable size, volume, and/or fluid capacity such as, for example, those described above with reference to the sequestration chamber 114. In some embodiments, the sequestration chamber 414 of the device 400 can be substantially similar in form and/or function to one or more of the sequestration chambers 114, 214, and/or 314. Accordingly, portions of the sequestration chamber 414 may not be described in further detail herein.

[0117] As shown in FIG. 4, the sequestration chamber 414 can be formed by and/or included in the second portion 425 of the device 400 and can be selectively placed in fluid communication with (1) the inlet 412 via the fluid flow path 413 and the first junction 417, and (2) the outlet 416 via the fluid flow path 454 and the second junction 418. As such, the sequestration chamber 414 can be configured to (1) selectively receive a flow and/or volume of bodily fluid from the inlet 412 and (2) sequester (e.g., separate, segregate, contain, retain, isolate, etc.) the flow and/or volume of bodily fluid therein.

[0118] The second portion 425 of the device 400 and/or the sequestration chamber 414 specifically, can include, form, and/or define a flow controller 415 disposed on, at, or near a proximal or second end of the sequestration chamber 414. In other words, the flow controller 415 can be positioned at, on, or near an outlet or outlet portion of the sequestration chamber 414. Said another way, the flow controller can be positioned at, on, or near an end portion of the sequestration chamber 414 that is closer to the second junction 418 than it is to the first junction 417. In some embodiments, the flow controller 415 can be, for example, a membrane, a porous material, an absorbent material, a hydrophilic or hydrophobic material, a selectively permeable barrier, etc. The flow controller 415 can be any suitable shape, size, and/or configuration. In some embodiments, the flow controller 415 can be substantially similar to the flow controller 215 and/or the flow controller 315 and thus, is not described in further detail herein.

[0119] As described in detail above, the flow controller 415 is positioned within the second portion 425 of the device to selectively establish fluid communication between the second portion 425 and/or the sequestration chamber 414 and the outlet 416 via the junction 418. Thus, with the flow controller 415 configured to selectively control fluid flow therethrough (e.g., configured as a semi-permeable member), the flow controller 415 can be configured to at least temporarily allow a gas or air to transfer from the second portion 425 of the device 400 and/or the sequestration chamber 414, through the flow controller 415 and the junction 418, and into the fluid flow path 454 and can be configured to limit and/or substantially prevent a flow of liquid (e.g., bodily fluid) between the second portion 425 and/or the sequestration chamber and the fluid flow path 454 (e.g., via the junction 418), as described in further detail herein.

[0120] As described above with reference to the devices 100, 200, and/or 300, the device 400 can include one or more flow controllers that is/are configured to selectively control a flow of gas or liquid (e.g., air or bodily fluid, respectively) through the device 400. For example, in the embodiment illustrated in FIG. 4, the device 400 includes a first flow restrictor 431 and a second flow restrictor 432. The flow restrictors 431 and 432 (and/or any other suitable flow controllers that may be included but not illustrated in FIG. 4) can be included at predetermined and/or desired positions along the first portion 424 and/or the second portion 425 of the device 400 to control, manipulate, divert, and/or direct the flow of air, liquid (e.g., bodily fluid), and/or negative pressure. The flow restrictors 431 and 432 can be configured with varying flow permitting or flow obstructing properties. For example, in some embodiments, the flow restrictor 431 and/or the flow restrictor 432 can have and/or can define any suitable inner cross-

sectional shape, size, and/or configuration to selectively allow fluid flow therethrough, as described in further detail herein.

[0121] In the embodiment shown in FIG. 4, the flow restrictors 431 and 432 each can be a flow restrictor configured to define a flow path therethrough having one or more specific, desired, and/or predetermined characteristics. Moreover, in some embodiments, the second flow restrictor 432 (e.g., the flow restrictor positioned between the second junction 418 and the sequestration chamber 414) can have a flow path that is less restrictive than the flow path of the first flow restrictor 431 (e.g., the flow restrictor positioned between the outlet 416 and the first junction 417). In other words, a pressure differential sufficient to allow fluid (e.g., a gas or liquid) to pass through the second flow restrictor 432 can be less than a pressure differential sufficient to allow fluid (e.g., gas or liquid) to pass through the first flow restrictor 431. Accordingly, the first flow restrictor 431 and the second flow restrictor 431 can be similar to the first valve 221 and second valve 222 described above with reference to FIG. 2.

[0122] As described in further detail herein, the arrangement of the flow restrictors 431 and 432 can be such that when a source of negative pressure (e.g., a fluid collection device and/or the like) is coupled to the outlet 416, the negative pressure differential can result in a flow through the second flow restrictor 432 prior to a flow through the first flow restrictor 431. In some instances, this sequential opening of the flow restrictors (e.g., the flow restrictor 432 before the flow restrictor 431), can be operable to direct a flow of fluid (e.g., a first flow) towards the sequestration chamber 414 and then direct the flow of fluid (e.g., a second flow) towards the fluid collection device and/or negative pressure source coupled to the outlet 416. Said another way, in some embodiments, the device 400 can be configured to transition between a first state in which (1) the inlet 412 is placed in fluid communication with the second portion 425 of the device 400 (e.g., the sequestration chamber 414) and (2) the second flow restrictor 432 establishes selective fluid communication between the sequestration chamber 414 and the outlet 416, and a second state in which (1) the second flow restrictor 432 isolates the sequestration chamber 414 from the outlet 416 and (2) the first flow restrictor 431 establishes selective fluid communication between the inlet 412 and the first portion 424 of the device 400 and/or the outlet 416.

[0123] As described above, with respect to devices 100, 200, and 300, the device 400 can be used to procure a bodily fluid sample having reduced contamination. In some instances, a user such as a doctor, physician, nurse, phlebotomist, technician, etc. can manipulate the device 400 to establish fluid communication between the inlet 412 and the bodily fluid source (e.g., a

vein of a patient). For example, in some embodiments, the user can couple the inlet 412 to an inlet device, a needle, an indwelling catheter or IV, and/or any other suitable lumen-containing device. Once the inlet 412 is placed in fluid communication with the bodily fluid source (e.g., the portion of the patient), the outlet 416 can be fluidically coupled to the fluid collection device. As described herein, the fluid collection device can be any suitable reservoir, syringe, pump, and/or device configured to define and/or produce a negative pressure. In other embodiments, the outlet 416 can be coupled to the fluid collection device, which in turn, is coupled to a downstream source of negative pressure.

[0124] The control device 400 can be in a first or initial state prior to coupling the outlet 416 to the fluid collection device. Coupling the outlet 416 to the fluid collection device selectively exposes at least a portion of the fluid flow path 454 to the negative pressure within the fluid collection device. For example, with the device 400 in its initial or first state, the flow controller 415 can be in its first state or configuration such that the flow controller 415 is permeable to a flow of air or gas but impermeable to a flow of liquid (e.g., bodily fluid). Moreover, the arrangement of the flow restrictors 431 and 432 is such that the first flow restrictor 431 is more restrictive toward a flow of liquid or air therethrough than is the second flow restrictor 432.

[0125] The negative pressure differential defined and/or produced by the fluid collection device results in a suction or drawing of fluid (e.g., air or gas) from the fluid flow path 454. In other words, the negative pressure within and/or produced by the fluid collection device results in a negative pressure differential within the fluid flow path 454. The arrangement of the flow restrictors 431 and 432, and the flow controller 415 can be such that the negative pressure differential within the fluid flow path 454, results in a negative pressure differential through and/or across the outlet 416, the second junction 418, the second flow restrictor 432, the flow controller 415, and the sequestration chamber 414. Moreover, with the first flow restrictor 431 configured to be more restrictive than the second flow restrictor 432, the flow through the second flow restrictor 432 can at least partially maintain a magnitude of the negative pressure within the fluid flow path 454 below a threshold magnitude of negative pressure otherwise operable to induce a flow of fluid through the first flow restrictor 431. That is to say, when the device 400 is in the first state, the negative pressure within the fluid flow path 454 is sufficient to result in a flow through the second flow restrictor 432 but is insufficient to result in a flow through the first flow restrictor 431. Accordingly, the negative pressure within and/or produced by the fluid collection device (coupled to the outlet 416) can draw air and/or gas through the

flow controller 415 and the second flow restrictor 432 and into the fluid flow path 454. Although not shown in FIG. 4, in some embodiments, the device 400 can include a vent or one-way valve configured to allow the air or gas withdrawn from the sequestration chamber 414 to be vented to the atmosphere. In other embodiments, the air and/or gas can be transferred to the fluid collection device, which in turn, can directly or indirectly allow the air or gas to be vented. Thus, the negative pressure within and/or produced by the fluid collection device can result in a negative pressure (or negative pressure differential) within at least a portion of the sequestration chamber 414.

[0126] The negative pressure within the sequestration chamber 414 can be operable in drawing an initial flow of bodily fluid from the inlet 412, through the fluid flow path 413 and the first junction 417, and into the sequestration chamber 414 when the control device 400 is in the first or initial state. In some instances, it may be desirable to modulate and/or control a magnitude of the negative pressure differential by any suitable means such as those described herein, including manipulating the permissibility and/or permeability of flow restrictors 431 and/or 432 and/or the flow controller 415. In some embodiments, the flow restrictors 431 and/or 432 can be configured to have one or more external actuators, controllers, and/or adjusters configured to control the amount of flow through the flow restrictors 431 and/or 432 (e.g., by altering or adjusting an inner diameter of the flow restrictors 431 and/or 432). In some other embodiments, the flow restrictors 431 and/or 432 can be configured to adjust and/or alter their properties of permitting fluid flow therethrough based on time, interaction with one or more fluids, and/or any other suitable parameter. In some embodiments, the structure of the flow restrictors 431 and/or 432 can be manipulated (e.g., squeezed, squished, pinched, compressed, etc.) to modulate the degree of negative pressure.

[0127] In some embodiments, modulating and/or controlling a magnitude of the pressure to which the sequestration chamber 414 is exposed can, in turn, modulate a magnitude of pressure (i.e., negative pressure) exerted on the bodily fluid and/or within a vein of a patient. In some instances, such pressure modulation can reduce, for example, hemolysis of a blood sample and/or a likelihood of collapsing a vein. In some instances, the ability to modulate and/or control an amount or magnitude of negative pressure can allow the control device 400 to be used across a large spectrum of patients that may have physiological challenges whereby negative pressure is often needed to facilitate collection of bodily fluid such as, for example, blood but not so much pressure that a rapid force flattens, collapses, caves-in, and/or otherwise inhibits patency and ability to collect blood, as described above.

[0128] The initial portion and/or amount of bodily fluid can be any suitable volume of bodily fluid, as described in detail above with reference to the control devices 100, 200, and/or 300. For example, in some instances, the initial volume can be associated with and/or at least partially based on an amount or volume of bodily fluid that is sufficient to fully wet or saturate the flow controller 415. In other words, in some embodiments, the initial volume of bodily fluid can be a volume sufficient to transition the flow controller 415 to a second state (e.g., a saturated or fully wetted state or a sealed state), in which the flow controller 415 is placed in a sealed state and/or configuration. In some embodiments, transitioning the flow controller 415 to the second state sequesters, blocks, isolates, separates, segregates, and/or otherwise prevents a flow of air, gas, and/or liquid (e.g., bodily fluid) through the flow controller 415.

[0129] After the initial volume of bodily fluid is transferred and/or diverted into the sequestration chamber 414, the control device 400 can be in and/or can be placed in its second state or operating mode to sequester, segregate, retain, contain, isolate, etc. the initial volume in the sequestration chamber 414. As described above, the flow controller 415 in its second state or sealed state substantially prevents a flow of fluid including air and liquid therethrough (e.g., and into the second flow restrictor 432 and/or fluid flow path 454). Therefore, the sequestration chamber 414 is fluidically isolated from the fluid collection device and/or source of negative pressure, which in turn, can allow a pressure differential between the sequestration chamber 414 and, for example, the inlet 412 to equalize such that the flow of bodily fluid to the sequestration chamber 414 is limited and/or substantially stops.

[0130] As described previously, an amount of negative pressure sufficient to induce and/or allow a flow of fluid through the first flow restrictor 431 can be greater than an amount of negative pressure sufficient to induce and/or allow a flow of fluid through the second flow restrictor 432. In this embodiment, the arrangement of the control device 400 is such that when the flow controller 415 is placed in the second or sealed configuration, at least a portion of the negative pressure otherwise being exerted through the flow controller 415 builds and/or increases within the fluid flow path 454 to an extent sufficient to induce and/or allow a flow of fluid through the first flow restrictor 431. Thus, with the device 400 in its second state, the negative pressure exerted by the fluid collection device and/or negative pressure source can result in negative pressure within the fluid flow path 454 sufficient to allow bodily fluid to flow from the inlet 412, through the first flow restrictor 431, the fluid flow path 454, and the outlet 416, and into the fluid collection device. As described above, in some instances, contaminants such as, for example, dermally residing microbes or the like dislodged during the venipuncture

event, can be entrained and/or included in the initial volume of the bodily fluid and thus, are sequestered in the sequestration chamber 414. Moreover, as described for devices 100, 200, 300, in some embodiments, the arrangement of the fluid control device 400 can be such that the device cannot transition to the second state prior to collecting and sequestering the initial volume in the sequestration chamber 414.

[0131] While the flow restrictors 431 and 432 are particularly described above with reference to FIG. 4, in other embodiments, a fluid control device can include other forms of flow controllers and/or restrictors in addition to and/or instead of those described in association with device 400. In some embodiments, a fluid control device can include any other suitable means or combination of means for controlling fluid flow therethrough. For example, FIGS. 5-7 illustrate three different embodiments of flow controllers and/or flow restrictors, each according to a different embodiment. FIG. 5 shows a flow restrictor 433 defining an orifice or channel for the passage of air and/or fluid. In this embodiment, the fluid restrictor 433 can have a relatively large inner diameter and a relatively long length. FIG. 6, on the other hand, shows a flow restrictor 434 defining an orifice or channel having a relatively small inner diameter (e.g., smaller than the inner diameter of the flow restrictor 433) and a relatively short length (e.g., shorter than the length of the flow restrictor 433).

[0132] As will be understood, adjusting a length and/or diameter of an orifice or channel of a flow restrictor can allow for an adjusting of a magnitude of a pressure differential sufficient to induce and/or result in a flow of fluid (e.g., bodily fluid) through the orifice or channel. For example, in some embodiments, a flow restriction and/or a restricted flow path can have a diameter of about 1.0 micrometers (μm), about 10.0 μm, about 100.0 μm, about 1000.0 μm, about 10,000.0 μm, about 100,000.0 μm, and/or any suitable diameter therebetween. In other embodiments, the restricted flow path can have a diameter smaller than 1.0 μm or larger than 100,000.0 μm. In such embodiments, a restricted flow path having a smaller diameter may be designed such that a magnitude of a pressure (e.g., negative pressure) sufficient to induce or draw a flow of fluid through the restricted flow path is greater than a magnitude of a pressure sufficient to induce or draw a flow of fluid through a restricted flow path having a larger diameter. Similarly, a longer restricted flow path may be designed such that a magnitude of a pressure (e.g., negative pressure) sufficient to induce or draw a flow of fluid through the restricted flow path is greater than a magnitude of a pressure sufficient to induce or draw a flow of fluid through a restricted flow path having a shorter length.

[0133] FIG. 7 shows a flow controller 435 including a porous material 436 disposed within the flow controller 435. In such embodiments, a porosity and/or permeability of the porous material 436 can be adjusted to adjust a magnitude of a pressure differential sufficient to induce and/or result in a flow of fluid (e.g., bodily fluid) through the orifice or channel. Other examples of flow restrictors and/or flow controllers can include but are not limited to, flow controllers where the restricted or restrictive regions include regions with varying diameter of the cross-section permitting fluid flow or include structures (e.g., porous material) designed to selectively allow or deter fluid flow or air flow as desired. Other embodiments can include, for example, valves, actuators, selectively permeable membranes and/or materials, and/or the like.

[0134] FIGS. 8-10 illustrate a fluid control device 500 according to an embodiment. FIG. 8 shows, for example, a top view of the device 500 and FIGS. 9 and 10 each show a cross-sectional view of the device 500, in a first state and a second state, respectively. The fluid control device 500 can be similar in at least form and/or function to any of the fluid control devices 100, 200, 300, and/or 400. Accordingly, portions of the fluid control device 500 that can be similar to portions of the fluid control devices 100, 200, 300, and/or 400 are not described in further detail herein.

[0135] As shown in FIGS. 8-10, the fluid control device 500 (also referred to herein as "control device" or "device") includes an inlet 512 and an outlet 516, and a sequestration chamber 514. As described above with reference to the control devices 100, 200, 300, and/or 400, the inlet 512 is configured to be placed in fluid communication with a bodily fluid source to receive a fluid of bodily fluid therefrom (e.g., via a lumen-containing device such as a needle or the like). The outlet 516 is configured to be fluidically coupled to a fluid collection device (not illustrated). The inlet 512, the outlet 516, and the fluid collection device can be substantially similar to those described above and thus, are not described in further detail herein.

[0136] As described above, the control device 500 is configured to (1) receive an initial flow and/or volume of bodily fluid via the inlet 512 and (2) sequester (e.g., separate, segregate, contain, retain, isolate, etc.) the flow and/or volume of bodily fluid within the sequestration chamber 514. The device 500 can be any suitable shape, size, and/or configuration. In some embodiments, the device 500 can have a size that is at least partially based on a volume of bodily fluid at least temporarily stored, for example, in the sequestration chamber 514. For example, in the embodiment shown in FIGS. 8-10, the device 500 can be arranged in and/or

can have a substantially "inline" configuration in which portions of the device 500 are at least partially aligned.

[0137] The device 500 includes and/or defines one or more fluid flow paths 513 between the inlet 512 and at least the sequestration chamber 514 and/or one or more fluid flow paths 554 between the inlet 512 and the outlet 516. In some embodiments, the device 500 can include a first portion 524 and a second portion 525. As shown in FIGS. 9 and 10, in some embodiments, the second portion 525 can be, for example, a bypass and/or diversion portion that is physically coupled to and selectively in fluid communication with the first portion 524. Moreover, the device 500 includes and/or forms a junction 517 at a position where each of a first end (e.g., an inlet end) of the first portion 524 and a first end (e.g., an inlet end) of the second portion 525 couple to the inlet 512. In some embodiments, the first portion 524 and the second portion 525 can be collectively disposed in a housing or otherwise at least partially enclosed by a common structure. In other embodiments, the first portion 524 and/or the second portion 525 of the device 500 can include and/or can be formed by flexible tubing or the like having any suitable shape and/or size and being reconfigurable or movable to be placed in any suitable configuration and/or arrangement.

[0138] The sequestration chamber 514 can have any suitable shape, size, and/or configuration. For example, in some embodiments, the sequestration chamber 514 can have any suitable size, volume, and/or fluid capacity such as, for example, those described above with reference to the sequestration chamber 114. The sequestration chamber 514 can be formed by and/or included in the second portion 525 of the device 500 and can be selectively placed in fluid communication with (1) the inlet 512 via the fluid flow path 513 and the first junction 517, and (2) the outlet 516 via the fluid flow path 554 and a flow controller 515 (described in further detail herein). In some embodiments, the sequestration chamber 514 of the device 500 can be substantially similar in form and/or function to one or more of the sequestration chambers 114, 214, 314, and/or 414. Accordingly, portions of the sequestration chamber 514 may not be described in further detail herein.

[0139] As shown in FIGS. 9 and 10, the second portion 525 of the device 500 and/or the sequestration chamber 514 specifically, can include, form, and/or define the flow controller 515 disposed on, at, or near a proximal or second end of the sequestration chamber 514. In other words, the flow controller 515 can be positioned at, on, or near an outlet or outlet portion of the sequestration chamber 514 to establish selective fluid communication between the sequestration chamber 514 and the fluid flow path 554. The flow controller 515 can be any

suitable shape, size, and/or configuration. In some embodiments, the flow controller 515 can be, for example, a membrane, a porous material, an absorbent material, a hydrophilic or hydrophobic material, a selectively permeable barrier, etc. In some embodiments, the flow controller 515 can be configured to at least temporarily allow a gas or air to transfer from the second portion 525 of the device 500 and/or the sequestration chamber 514, through the flow controller 515, and into the fluid flow path 554 and can be configured to limit and/or substantially prevent a flow of liquid (e.g., bodily fluid) between the second portion 525 and/or the sequestration chamber 514 and the fluid flow path 554. In some embodiments, the flow controller 515 can be substantially similar in at least form and/or function to the flow controllers 215, 315, and/or 415 and thus, aspects of the flow controller 515 are not described in further detail herein.

[0140] In some embodiments, the device 500 can include one or more flow controllers in addition to the flow controller 515 configured to selectively control, direct, divert, and/or manipulate fluid flow through at least a portion of the flow paths 513 and/or 554. In some embodiments, such flow controllers can be configured to selectively control a flow of fluid through the device 500 in response to, for example, an external force or actuation (e.g., manual intervention by the user), or automatically (e.g., after a period of time and/or in response to a predetermined force, pressure, flow rate, volume of fluid, saturation level, etc. For example, in this embodiment, the device 500 includes a diaphragm 576 movably disposed within the body of the device 500 and configured to at least partially define the sequestration chamber 514. In some embodiments, the diaphragm 576 can be configured to transition, flip, move, switch, deform, etc., from a first configuration or state (FIG. 9) to a second configuration or state (FIG. 10) in response to a negative pressure differential within and/or across at least a portion of the device 500 (e.g., a negative pressure differential associated with and/or resulting from the coupling of the fluid collection device to the outlet 516).

[0141] In some embodiments, the diaphragm 576 can be coupled to a piercing member 578 and configured to move through at least a portion of the device 500 in response to movement of the diaphragm 576. As shown in FIGS. 9 and 10, the device 500 includes a film, barrier, and/or frangible member 574 (referred to herein as "barrier") configured to at least temporarily isolate, separate, and/or sequester the fluid flow path 513 (e.g., an inlet fluid flow path) from the fluid flow path 554 (e.g., an outlet fluid flow path). In some embodiments, the arrangement of the diaphragm 576 and/or the piercing member 578 can be such that as the diaphragm 576 is transitioned from its first state, configuration, and/or position to its second state,

configuration, and/or position, the piercing member 578 is transitioned and/or moved through a portion of the device 500 to pierce, puncture, rupture, break, and/or otherwise reconfigure the barrier 574.

[0142] More specifically, as shown in FIG. 9, the diaphragm 576 can have, for example, a concave shape relative to the barrier 574 when in its first or initial state and the piercing member 578 coupled to the diaphragm 576 is disengaged with and/or separated from the barrier 574. As such, the barrier 574 can be in a first or initial state in which the barrier 574 is sealed, unbroken, not punctured, and/or otherwise acting to fluidically isolate the fluid flow path 513 from the fluid flow path 554. As shown in FIG. 10, the diaphragm 576 can have, for example, a convex shape relative to the barrier 574 when in its second or subsequent state and the piercing member 578 coupled to the diaphragm 576 is engaged with, in contact with, and/or otherwise reconfiguring the barrier 574, thereby piercing through and/or defining an opening through the barrier 574. In other words, as illustrated in FIGS. 9 and 10 respectively, the device 500 and/or the diaphragm 576 is configured to move between a first or initial state in which the fluid flow path 513 is fluidically isolated and/or sequestered from the fluid flow path 554 such that a flow of fluid (e.g., bodily fluid) can flow from the inlet 512, through at least a portion of the fluid flow path 513, and into the sequestration chamber 514, and a second or subsequent state in which the fluid flow path 513 is in fluid communication with the fluid flow path 554 such that a flow of fluid (e.g., bodily fluid) can flow from the inlet 512, through the barrier 574 and the fluid flow path 554, and to the outlet 516. In some embodiments, the transitioning of the device 500 and/or diaphragm 576 from the first state to the second state can be such that a volume of the device 500 defined between the diaphragm 576, the flow controller 515, and the one or more walls of the sequestration chamber 514 is increased (i.e., a volume of the sequestration chamber 514 is increased), which in turn, results in a negative pressure therein that can be operable in drawing at least a portion of the initial volume of bodily fluid through the inlet 512 and into the sequestration chamber 514, as described further below.

[0143] As described above, with respect to devices 100, 200, 300, and/or 400, the device 500 can be used to procure a bodily fluid sample having reduced contamination. For example, in some instances, the control device 500 can be in the first or initial state and a user can manipulate the device 500 to establish fluid communication between the inlet 512 and the bodily fluid source (e.g., a vein of a patient) and to establish fluid communication between the outlet 516 and the fluid collection device (e.g., a sample vessel, syringe, reservoir, etc.). With the device 500 in its initial or first state, coupling the outlet 516 to the fluid collection device

selectively exposes at least a portion of the fluid flow path 554 to the negative pressure within the fluid collection device. Moreover, when the device 500 is in its initial or first state, the flow controller 515 can be in its first state or configuration such that the flow controller 515 is permeable to a flow of air or gas but impermeable to a flow of liquid (e.g., bodily fluid). The barrier 574 is also in its first or initial state such that the barrier 574 fluidically isolates the fluid flow path 513 from the fluid flow path 554. As such, the negative pressure differential defined and/or produced by the fluid collection device results in a suction force within the fluid flow path 554, which in turn, is exerted on or through the flow controller 515. Thus, coupling the outlet 516 to the fluid collection device exposes the sequestration chamber 514 to the negative pressure defined and/or produced by the fluid collection device, thereby resulting in a negative pressure differential operable in drawing the initial volume and/or amount of bodily fluid from the bodily fluid source (e.g., the patient's vasculature), through the inlet 512, at least a portion of the fluid flow path 513, and the junction 517, and into the sequestration chamber 514. Although not shown in FIGS. 8-10, in some embodiments, the device 500 can include any suitable device and/or mechanism configured to modulate the negative pressure to which the sequestration chamber 514 is exposed, as described in detail above.

[0144] The initial portion and/or amount of bodily fluid can be any suitable volume of bodily fluid, as described in detail above with reference to the control devices 100, 200, 300, and/or 400. For example, in some instances, the initial volume can be associated with and/or at least partially based on an amount or volume of bodily fluid that is sufficient to fully wet or saturate the flow controller 515 (e.g., transition the flow controller 515 from its first or selectively open state to its second or sealed state). With the flow controller 515 in its second state or sealed state, the flow controller 515 substantially prevents a flow of fluid including air and liquid therethrough, thereby sequestering and/or fluidically isolating the sequestration chamber 514 from the fluid flow path 554. As a result, in some instances, a pressure differential between, for example, the sequestration chamber 514 and the inlet 512 can equalize such that the flow of bodily fluid to the sequestration chamber 514 is limited and/or substantially stops.

[0145] In this embodiment, the arrangement of the control device 500 is such that when the flow controller 515 is placed in the second or sealed configuration, at least a portion of the negative pressure otherwise being exerted through the flow controller 515 builds and/or increases within the fluid flow path 554 to an extent sufficient to transition the diaphragm 576 from its first state or configuration (FIG. 9) to its second state or configuration (FIG. 10). In some embodiments, for example, the diaphragm 576 can flip and/or can be moved from a

concave configuration relative to the barrier 574 to a convex configuration relative to the barrier 574. Moreover, as described above, the transitioning of the diaphragm 576, in turn, moves the piercing member 578 such that the piercing member 578 engages, pierces, punctures, opens, breaks, and/or otherwise reconfigures the barrier 574, thereby placing the fluid flow path 513 in fluid communication with the fluid flow path 554. Thus, with the device 500 in its second state, the negative pressure exerted by the fluid collection device and/or negative pressure source can result in negative pressure within the fluid flow path 554 sufficient to allow bodily fluid to flow from the inlet 512, through the fluid flow path 513, barrier 574, fluid flow path 554, and outlet 516, and into the fluid collection device.

[0146] As described above, in some instances, contaminants such as, for example, dermally residing microbes or the like dislodged during the venipuncture event, can be entrained and/or included in the initial volume of the bodily fluid and thus, are sequestered in the sequestration chamber 514. Moreover, as described for devices 100, 200, 300, and/or 400, in some embodiments, the arrangement of the fluid control device 500 can be such that the device cannot transition to the second state prior to collecting and sequestering the initial volume in the sequestration chamber 514.

[0147] While the flow controller 515 is shown in FIGS. 8-10 as being in fluid communication with the fluid flow path 554 without a feature, device, mechanism, and/or means to modulate an amount of negative pressure disposed therebetween, in other embodiments, a fluid control device can include any suitable feature, device, mechanism, and/or means configured to modulate an amount or magnitude of negative pressure to which a flow controller is exposed. For example, FIGS. 11 and 12 are schematic illustrations of a fluid control device 600 in a first state and a second state, respectively, according to another embodiment. The fluid control device 600 (also referred to herein as "control device" or "device") can be any suitable shape, size, and/or configuration. For example, in some embodiments, the device 600 can be substantially similar in at least form and/or function to any of the devices 100, 200, 300, 400, and/or 500 described herein. More particularly, the device 600 can be substantially similar in at least form and/or function to the device 500 described above with reference to FIGS. 8-10. Accordingly, portions and/or aspects of the fluid control device 600 are not described in further detail herein.

[0148] As shown in FIGS. 11 and 12, the device 600 includes an inlet 612, an outlet 616, and a sequestration chamber 614. In addition, the device 600 includes and/or defines one or more fluid flow paths 613 between the inlet 612 and at least the sequestration chamber 614

and/or one or more fluid flow paths 654 between the inlet 612 and the outlet 616. The inlet 612 is configured to be placed in fluid communication with a bodily fluid source to receive a fluid of bodily fluid therefrom. The outlet 616 is configured to be fluidically coupled to a fluid collection device substantially similar to those described above. The sequestration chamber 614 can be included in and/or formed by a portion of the device 600 and can be selectively placed in fluid communication with (1) the inlet 612 via the fluid flow path 613, and (2) the outlet 616 via the fluid flow path 654 and a flow controller 615. The flow controller 615 can be any suitable shape, size, and/or configuration and can be configured to selectively control, permit, allow, and/or transfer a flow of fluid therethrough. For example, as described above, the flow controller 615 can be a selectively permeable member configured to be selectively permeable to a gas (e.g., air) and substantially impermeable to a liquid (e.g., bodily fluid). In some embodiments, the inlet 612, the outlet 616, the sequestration chamber 614, and the flow controller 615 can be substantially similar to the inlet 512, the outlet 516, the sequestration chamber 514, and the flow controller 515, respectively, described above with reference to the device 500 shown in FIGS. 8-10. Accordingly, portions and/or aspects of the inlet 612, the outlet 616, the sequestration chamber 614, and/or the flow controller 615 are not described in further detail herein.

[0149] In some embodiments, the device 600 can include a first portion 624 and a second portion 625. As shown in FIGS. 11 and 12, in some embodiments, the second portion 625 can be, for example, a bypass and/or diversion portion that (1) is physically coupled to and selectively in fluid communication with the first portion 624 and (2) includes and/or forms the sequestration chamber 614. Moreover, the device 600 includes and/or forms a junction 617 at a position where each of a first end (e.g., an inlet end) of the first portion 624 and a first end (e.g., an inlet end) of the second portion 625 couple to the inlet 612. In some embodiments, the first portion 624 and the second portion 625 can be collectively disposed in a housing or otherwise at least partially enclosed by a common structure. In other embodiments, the first portion 624 and/or the second portion 625 of the device 600 can include and/or can be formed by flexible tubing or the like having any suitable shape and/or size and being reconfigurable or movable to be placed in any suitable configuration and/or arrangement.

[0150] As described above with reference to the device 500, the device 600 includes a diaphragm 676 movably disposed within at least a portion of the device 600 and a piercing member 678 coupled to the diaphragm 676. In some embodiments, the diaphragm 676 can define at least a portion of the sequestration chamber 614. In some embodiments, the

diaphragm 676 and the piercing member 678 can be substantially similar in at least form and/or function to the diaphragm 576 and piercing member 578, respectively, of the device 500. For example, as described above with reference to the diaphragm 576 of the device 500, the diaphragm 676 is configured to transition between a first state, in which the fluid flow path 613 is fluidically isolated from the fluid flow path 654, and a second state, in which the fluid flow path 613 is in fluid communication with the fluid flow path 654, as described in further detail herein.

[0151] While the device 500 is shown and described above as including a single barrier 574 configured to selectively isolate and/or otherwise selectively prevent fluid communication between the fluid flow paths 513 and 554, in the embodiment shown in FIGS. 11 and 12, the device 600 includes a set of barriers configured to selectively prevent or selectively allow fluid flow through the device 600. For example, in some embodiments, the device 600 can include two barriers 674 and 675. Each of the barriers 674 and 675 can be substantially similar in at least form and/or function to the barrier 574 of the device 500 described above with reference to FIGS. 9 and 10. Accordingly, the arrangement of the device 600 can be such that when the diaphragm 676 is in its first state, the piercing member 678 can be disengaged and/or separated from the barriers 674 and 675, which in turn, remain in a sealed, closed, and/or substantially undeformed state (FIG. 11). As the diaphragm 676 is transitioned to its state, however, the piercing member 678 can be moved within the device 600 such that the piercing member 678 engages, contacts, pierces, punctures, and/or otherwise reconfigures each of the barriers 674 and 675, thereby transitioning the barriers 674 and 675 to an unsealed, opened, pierced, and/or deformed state (FIG. 12), as described in further detail herein.

[0152] As described above, the device 600 can include one or more features, mechanisms, devices, and/or means of modulating a negative pressure exerted through one or more portions of the device 600. For example, as shown in FIGS. 11 and 12, the device 600 includes and/or defines a restricted flow path 631 (also referred to herein as a "flow restrictor") configured to establish fluid communication between, for example, the flow controller 615 and the fluid flow path 654. As described above with reference to the flow restrictors 431 and 432 of the device 400 shown in FIG. 4, the flow restrictor 631 can be configured to define a restricted and/or limited flow path therethrough having one or more specific, desired, and/or predetermined characteristics. As described in further detail herein, the arrangement of the flow restrictor 631 can be such that when a source of negative pressure (e.g., a fluid collection device and/or the like) is coupled to the outlet 616, a negative pressure differential can result in a restricted and/or

modulated flow or suction force through the flow restrictor 631, which in turn, results in a restricted and/or modulated negative pressure being exerted on the flow controller 615. Accordingly, the flow restrictor 631 can be substantially similar in at least form and/or function to the flow restrictor 432 described above with reference to FIG. 4.

[0153] As described above with respect to devices 100, 200, 300, 400, and/or 500, the device 600 can be used to procure a bodily fluid sample having reduced contamination. For example, in some instances, the control device 600 can be in the first or initial state (see e.g., FIG. 11) and a user can manipulate the device 600 to establish fluid communication between the inlet 612 and the bodily fluid source (e.g., a vein of a patient) and to establish fluid communication between the outlet 616 and the fluid collection device (e.g., a sample vessel, syringe, reservoir, etc.). With the control device 600 in its first or initial state, coupling the outlet 616 to the fluid collection device selectively exposes at least a portion of the fluid flow path 654 to the negative pressure within the fluid collection device. When the control device 600 is in the first state, the diaphragm 676, the flow controller 615, and the barriers 674 and 675 each can be in their respective first states. Accordingly, the diaphragm 676 can be disposed in a position and/or state such that the piercing member 678 is separated and/or disengaged from the barriers 674 and 675. As such, the barriers 674 and 675 are in their first or sealed state such that the barrier 674 (e.g., a first barrier) fluidically isolates and/or sequesters the fluid flow path 613 from the flow restrictor 631 (e.g., restricted flow path) and such that the barrier 675 (e.g., a second barrier) fluidically isolates and/or sequesters the fluid flow path 613 (e.g., an inlet flow path) from the fluid flow path 654 (e.g., an outlet flow path), as shown in FIG. 11.

[0154] With the fluid collection device coupled to the outlet 616, the negative pressure within the fluid collection device can result in a negative pressure (or negative pressure differential) within at least a portion of the fluid flow path 654. As shown in FIG. 11, however, the barrier 675 fluidically isolates at least a portion of the fluid flow path 654 from other portions of the device 600 and thus, the negative pressure within the fluid flow path 654 is transferred and/or exerted through the flow restrictor 631. Accordingly, a modulated and/or desired portion of the negative pressure within and/or produced by the fluid collection device (coupled to the outlet 616) is transferred through the flow restrictor 631 and in turn, exerted on the flow controller 615. Moreover, with the flow controller 615 in its first state (e.g., a selectively permeable state), the modulated and/or desired portion of the negative pressure within and/or produced by the fluid collection device can result in a negative pressure (or

negative pressure differential) within at least a portion of the sequestration chamber 614 that is operable in drawing an initial flow of bodily fluid from the inlet 612, through at least a portion of the fluid flow path 613, and into the sequestration chamber 614, as described above with reference to, for example, the devices 100, 200, 300, 400, and/or 500.

[0155] The initial portion and/or amount of bodily fluid can be any suitable volume of bodily fluid, as described in detail above with reference to the control devices 100, 200, 300, 400, and/or 500. For example, in some instances, the initial volume can be associated with and/or at least partially based on an amount or volume of bodily fluid that is sufficient to fully wet or saturate the flow controller 615 (e.g., transition the flow controller 615 from its first or selectively open state to its second or sealed state). With the flow controller 615 in its second or sealed state, the flow controller 615 substantially sequesters, blocks, isolates, separates, segregates, and/or otherwise prevents a flow of fluid (e.g., gas and liquid) through the flow controller 615, thereby sequestering and/or fluidically isolating the sequestration chamber 614 from the fluid flow path 654. As a result, in some instances, a pressure differential between, for example, the sequestration chamber 614 and the inlet 612 can equalize such that the flow of bodily fluid to the sequestration chamber 614 is limited and/or substantially stops.

[0156] As described above with reference to the device 500, the arrangement of the control device 600 is such that when the flow controller 615 is placed in its second or sealed state, at least a portion of the negative pressure otherwise being exerted through the flow controller 615 is instead exerted on a concave side or surface of the diaphragm 676. The increased negative pressure on the concave side and/or surface of the diaphragm 676 can be operable to flip, switch, and/or transition the diaphragm 676 from its first state (e.g., a concave state relative to the barrier 674) to its second state (e.g., a convex state relative to the barrier 674). In some embodiments, the flow restrictor 631 can be configured to modulate and/or regulate a magnitude or change in magnitude of the negative pressure being exerted on the diaphragm 676 in substantially the same manner as the modulation and/or regulation of the negative pressure being exerted on or through the flow controller 615. In some instances, modulating the negative pressure exerted on the diaphragm 676 can in turn, modulate, reduce, and/or control a rate at which the diaphragm 676 is transitioned from its first state to its second state.

[0157] As described above, the transitioning of the diaphragm 676, in turn, moves the piercing member 678 coupled thereto such that the piercing member 678 engages, pierces, punctures, opens, breaks, and/or otherwise reconfigures each of the barriers 674 and 675 such that each barrier 674 and 675 is placed in an open state and/or otherwise defines an opening

through which fluid can flow. In other embodiments, the barrier 674 can be configured to form a substantially fluid tight seal with an outer surface of the piercing member 678 as the piercing member 678 extends therethrough. Moreover, as described above with reference to the device 500, the opening of the barrier 675 places the fluid flow path 613 in fluid communication with the fluid flow path 654. As such, the device 600 can be in and/or can be placed in its second state, and the negative pressure exerted by the fluid collection device and/or negative pressure source can result in negative pressure within the fluid flow path 654 sufficient to allow bodily fluid to flow from the inlet 612, through the fluid flow path 613, barrier 675, fluid flow path 654, and outlet 616, and into the fluid collection device (not shown). As described above, in some instances, contaminants such as, for example, dermally residing microbes or the like dislodged during the venipuncture event, can be entrained and/or included in the initial volume of the bodily fluid and thus, are sequestered in the sequestration chamber 614. Moreover, as described for devices 100, 200, 300, 400, and/or 500, in some embodiments, the arrangement of the fluid control device 600 can be such that the device cannot transition to the second state prior to collecting and sequestering the initial volume in the sequestration chamber 614.

[0158] While the device 600 is described above as including the piercing member 678 that pierces the barrier 675 to place the device 600 in the second state, in other embodiments, a device can include any suitable member configured to transition any suitable barrier. For example, FIGS. 13 and 14 illustrate a device 700 according to an embodiment. The device 700 can be substantially similar to the device 600 and thus, similar portions are not described in further detail herein. The device 700 (FIGS. 13 and 14) can differ from the device 600 (FIGS. 11 and 12), however, by including a diaphragm 776 that includes and/or that is coupled to a rod, a pusher, a plunger, an actuator, and/or the like (referred to herein for simplicity as an "actuator"). Moreover, rather than including the barriers 674 and 675 that are configured to be pierced, as described above with reference to the device 600), the device 700 includes barriers 774 and 775 that can have any suitable shape, size, and/or configuration and that can be transitioned, in some instances, in any suitable manner. For example, the barrier 774 can be configured and/or otherwise disposed to form a substantially fluid tight seal with one or more inner surfaces of the device 700 and with one or more outer surfaces of the actuator 778. In this manner, the barrier 774 can limit and/or substantially prevent bodily fluid from undesirably flowing out of a fluid flow path 754 and into other portions of the device 700 (e.g., in a manner similar to that described above with reference to the barrier 674).

[0159] As shown in FIG. 13, when the device 700 is in a first state, the diaphragm 776 can be in a first state (e.g., a non-flipped, unactuated, and/or initial state). Similarly, the actuator 778 coupled to the diaphragm 776 and the barrier 775 can be in a first or initial state. As described in detail above with reference to the device 600, when the barrier 775 is in the first state, a flow path 713 of the device 700 (e.g., an inlet flow path or the like) can be sequestered from the flow path 754 (e.g., an outlet flow path or the like). In other words, the barrier 775 (e.g., a flow controller) can be configured to sequester the flow path 713 from the flow path 754. Thus, when a negative pressure is generated within a portion of the device 700 (e.g., in response to coupling a fluid collection device to an outlet of the device 700), an initial volume of bodily fluid can flow into a sequestration chamber of the device 700 (e.g., a sequestration portion of the device 700, a sequestration flow path, a sequestration reservoir or container, etc.), as described in detail above with reference to the device 600.

[0160] After the initial volume of bodily fluid is received in the sequestration chamber, the arrangement of the device 700 can be such that the diaphragm 776 flips, actuates, moves, and/or otherwise transitions from the first state (FIG. 13) to a second state (FIG. 14). As described in detail above, the movement of the diaphragm can result in a similar movement of the actuator 778 such that the actuator 778 is placed in contact with and moves and/or otherwise transitions the barrier 775 within the device 700. For example, as shown in FIG. 14, the actuator 778 can move the barrier 775 in a substantially linear motion from a first position to a second position, which in turn, can be a position in which the barrier 775 no longer sequesters the flow path 713 from the flow path 754. Thus, a subsequent volume of bodily fluid that is substantially free of contaminants can flow through the device 700 and into the fluid collection device coupled thereto. In this manner, the device 700 can be substantially similar in at least form and/or function to the device 600 and thus, is not described in further detail herein.

[0161] Referring now to FIG. 15, a flowchart is shown illustrating a method 10 of using a fluid control device, such as those described herein, to divert an initial volume of bodily fluid to procure bodily fluid samples with reduced contamination, according to an embodiment. The fluid control device (also referred to herein as "control device") can be similar to and/or substantially the same as any of the control devices 100, 200, 300, 400, 500, 600, and/or 700 described herein.

[0162] The method 10 includes establishing fluid communication between a bodily fluid source and an inlet of the control device, at 11. In some instances, for example, the bodily fluid source can be a fluid source within a patient's body. More specifically, in some instances, the

bodily fluid source can be a vein and/or vascular structure in the patient's body. As described above, the control device can be configured to couple to and/or include an inlet device such as, for example, an intravenous catheter, a butterfly needle, and/or the like. In other embodiments, the inlet device can be any suitable coupler, port, etc. configured to fluidically couple to the bodily fluid source. As such, the inlet device can be manipulated to establish fluid communication between the bodily fluid source and the fluid control device, as described in detail above.

[0163] Having established fluid communication with the bodily fluid source, an initial volume of bodily fluid is transferred from the bodily fluid source to a sequestration chamber included in and/or defined by the control device when the control device is in a first state, at 12. In some embodiments, the control device or a portion thereof (e.g., the sequestration chamber, a junction, an actuator, a flow controller, etc.) is in a first state and/or configuration prior to use. As such, establishing fluid communication with the bodily fluid source automatically establishes fluid communication with the sequestration chamber. More particularly, in some embodiments, a flow controller such as, for example, a valve, a flow restrictor, a selectively permeable member, and/or the like can be in a first state and/or configuration such a flow of at least a gas can pass and/or can be conveyed therethrough.

[0164] As described in detail herein, the initial volume can be any suitable volume of bodily fluid. For example, in some instances, the initial volume can be as small as one drop of bodily fluid (or a relatively few drops of bodily fluid). In other instances, the initial volume can be, for example, up to about 30 mL, 40 mL, 50 mL, or more. Moreover, as described in detail above with reference to specific embodiments, the initial volume can be at least partially based on and/or can be associated with an amount of bodily fluid that can be contained and/or sequestered in the sequestration chamber. In some instances, the initial volume can be at least partially based on and/or associated with a desired amount of fluid sufficient to transition the control device from an initial or first state to a subsequent or second state, using a negative pressure differential defined and/or produced by a negative pressure source coupled to the outlet of the fluid control device. In some instances, the initial volume can be at least partially based on and/or associated with a desired amount of fluid sufficient to transition one or more flow controllers included in the fluid control device from its/their first state to its/their second state. For example, in some instances one or more flow controllers can be driven and/or transitioned by a pressure differential, a predetermined and/or desired fluid volume, a fluid contact, the passage of predetermined and/or desired time, and/or the like, as described herein.

In some instances, the initial volume can be a volume that is sufficient to entrain and/or contain substantially all the undesired microbes that may have been dislodged and/or the like as the fluid communication was being established between the bodily fluid source and the inlet device.

[0165] In response to the initial volume of bodily fluid being disposed in the sequestration chamber, the control device is transitioned (e.g., automatically, passively, or in response to an actuation) from the first state to the second state to sequester the initial volume of bodily fluid in the sequestration chamber, at 13. In some embodiments, for example, the initial volume of bodily fluid can fill the sequestration chamber such that any additional volume of bodily fluid is substantially prevented from entering and/or being contained in the sequestration chamber. In such embodiments, the filled sequestration chamber can form, for example, a fluid lock or the like that substantially prevents additional amounts of bodily fluid from entering the sequestration chamber and/or that substantially prevents bodily fluid from exiting the sequestration chamber. In some embodiments, the sequestration chamber can include a membrane or material interacting with the bodily fluid (e.g., a semi-permeable membrane or the like such as described above with reference to the control devices 100, 200, 300, 400, 500, 600, and/or 700). In some embodiments, the sequestration chamber and/or device can include one or more flow controllers that can be activated (e.g., diaphragms as described with reference to control device 500, 600, and/or 700, and/or any other suitable flow controller) that are activated using any suitable mechanism to draw, divert, and/or sequester bodily fluid. For example, such flow controllers can use a change in a pressure differential (e.g., a pressure differential that can occur when portions of the flow path are sealed and/or closed off from interacting with bodily fluid), as described with reference to control device 500, 600, and/or 700, or can be user activated or activated on the basis of other variables like time, gravity, or the like.

[0166] In some instances, two or more of these mechanisms can be used in combination. For example, in some embodiments, the diversion and/or sequestration of bodily fluid can be carried out using passive mechanisms (e.g., based on one or more pressure differentials and/or filling of the sequestration chamber). In other embodiments, the diversion and sequestration or fluid can also result from one or more active methods such as, for example, one or more actuators operated with or without user intervention. In some embodiments, one or more user mediated mechanisms, actuators, controllers, etc. can be included to provide additional control functions such as, for example, a supervisory or safety override function that may be used in

certain settings such as, for example, during training of personnel on the use of the control devices. In other embodiments, the sequestration chamber can retain and/or sequester the initial volume of bodily fluid in any suitable manner such as those described herein and/or any suitable combination(s) thereof.

[0167] With the control device being transitioned to the second state (e.g., passively or through user intervention), a subsequent volume of bodily fluid is transferred from the bodily fluid source to a fluid collection device (e.g., any of those described herein) in fluid communication with the control device, at 14. As described in detail above, the sequestering of the initial volume of bodily fluid in the sequestration chamber can be operable to sequester any contaminants contained in the initial volume of bodily fluid in the sequestration chamber. Accordingly, the subsequent volume of bodily fluid transferred to the fluid collection device is substantially free of contaminants.

[0168] Referring now to FIG. 16, a flowchart is shown illustrating a method 20 of using a fluid control device, such as those described herein, to divert an initial volume of bodily fluid to procure bodily fluid samples with reduced contamination, according to an embodiment. The fluid control device (also referred to herein as "control device") can be similar to and/or substantially the same as any of the control devices 100, 200, 300, 400, 500, 600, and/or 700 described herein. In some embodiments, for example, the fluid control device can include an inlet configured to be placed in fluid communication with a bodily fluid source and an outlet configured to be coupled to a fluid collection device. Moreover, the fluid control device can include a sequestration portion that is in fluid communication with the inlet and a sampling portion that is in fluid communication with the outlet.

[0169] The method 20 includes coupling a fluid collection device to the outlet of the fluid control device, at 21. The fluid collection device can be any of those described herein. For example, in some embodiments, the fluid collection device can be an evacuated container, sample bottle, syringe, and/or the like. Moreover, the coupling of the fluid collection device to the outlet can be such that a negative pressure differential is produced and/or generated within at least a portion of the fluid control device, as described in detail above.

[0170] A first flow controller of the fluid control device is transitioned from a first state to a second state when the negative pressure differential within the fluid control device has a first magnitude, at 22. As described above, the first flow controller can be a valve, selectively permeable material, restricted flow path, and/or the like configured to sequester the

sequestration portion of the fluid control device from the outlet when in the first state and to establish fluid communication between the sequestration portion and the outlet when in the second state, as described in detail above.

[0171] An initial volume of bodily fluid is received from the inlet of the fluid control device and into the sequestration portion of the fluid control device in response to the negative pressure differential when the first flow controller is in the second state, at 23. In some instances, for example, the inlet can be in fluid communication with a bodily fluid source such as a bodily fluid source within a patient's body (e.g., a vein and/or vascular structure in the patient's body). In some embodiments, for example, the inlet can be coupled to an inlet device such as, for example, an intravenous catheter, a butterfly needle, and/or the like, which in turn, is inserted into a portion of the patient. Thus, bodily fluid can flow from the bodily fluid source, through the inlet of the fluid control device, and into the sequestration portion.

[0172] The first flow controller is transitioned from the second state to a third state in response to the sequestration portion receiving the initial volume of bodily fluid, at 24. As described in detail herein, the initial volume can be any suitable volume such as, for example, a volume as small as one drop of bodily fluid (or a relatively few drops of bodily fluid) up to, for example, 50.0 mL or more. In some instances, the initial volume can be at least partially based on and/or associated with a desired amount of fluid sufficient to transition the first flow controller from the second state to the third state. In some instances, the initial volume can be a volume of bodily fluid that is transferred into the sequestration portion until a negative pressure differential (e.g., between the first flow controller and the inlet) is in substantial equilibrium or the like. In such instances, the first flow controller can automatically transitioned from the second state to the third state when the negative pressure differential operable to draw the initial volume of bodily fluid is in substantial equilibrium. In some embodiments, the first flow controller can include, for example, a selectively permeable material that can be saturated by at least a portion of the initial volume of bodily fluid to transition the first flow controller from the second state to the third state, as described in detail above. As such, the first flow controller can sequester the sequestration portion from the outlet when in the third state.

[0173] With the first flow controller in the third state, the negative pressure differential within a portion of the fluid control device can increase from the first magnitude to a second magnitude. When the negative pressure differential has the second magnitude, a second flow controller is transitioned from a first state to a second state, at 25. The second flow controller

can be configured to, for example, sequester the sampling portion of the fluid control device from the inlet when in the first state and is configured to establish fluid communication between the sampling portion and the inlet when in the second state. As described above with reference to specific embodiments, the second flow controller can be any suitable control device or mechanism such as, for example, a valve, a selectively permeable material, a restricted flow path, a dissolvable material, a frangible barrier, a movable barrier, and/or the like.

[0174] As described above, a pressure differential sufficient to transition the second flow controller from the first state (e.g., a non-flow state) to the second state (e.g., a flow state) is greater than a pressure differential sufficient to transition the first flow controller from the first state (e.g., a non-flow state) to the second state (e.g., a flow state). As such, the second flow controller can be configured to transition to the second state after the first flow controller has transitioned between its first, second, and third states. Thus, a subsequent volume of bodily fluid is transferred from the inlet to the fluid collection device via the sampling portion and the outlet, at 26. As described in detail above, receiving the initial volume of bodily fluid in the sequestration portion and sequestering the sequestration portion from the outlet can be operable to sequester any contaminants contained in the initial volume of bodily fluid in the sequestration portion of the fluid control device. Accordingly, the subsequent volume of bodily fluid transferred to the fluid collection device can have reduced contamination and/or can be substantially free of contaminants.

[0175] While various embodiments have been described above, it should be understood that they have been presented by way of example only, and not limitation. Where schematics and/or embodiments described above indicate certain components arranged in certain orientations or positions, the arrangement of components may be modified. While the embodiments have been particularly shown and described, it will be understood that various changes in form and details may be made. For example, while the control devices 100, 200, 300, 400, 500, 600, and/or 700, are described as transferring a bodily fluid into the device as a result of a negative pressure within a fluid collection device, in other embodiments, the devices described herein can be used with any suitable device configured to establish a pressure differential (e.g., a negative pressure differential). For example, in some embodiments, an outlet of a control device can be coupled to a syringe or pump. In other embodiments, a control device can include a pre-charged sequestration chamber, a vented sequestration chamber, a manually activated device configured to produce a negative pressure, an energy source, and/or

any other suitable means of defining and/or forming a pressure differential within a portion of the control device.

[0176] In some other embodiments, the source of negative pressure can be associated with but independent of the fluid collection device. For example, a source of negative pressure such as a syringe, a pump, a passive source like a gravity aided or structurally aided container, etc., can be placed downstream of the outlet of the fluid control device such that the negative pressure imparted is communicated to the fluid collection device and the outlet. For example the source of negative pressure may be in fluid communication with the outlet via the fluid collection device. In other embodiments, under some circumstances, the source of negative pressure may be placed in fluid communication with the outlet to impart the pressure differential and the outlet may then be placed in fluid communication with the collection device to collect the fluid drawn by the pressure differential imparted, as described in further detail herein.

[0177] In some embodiments, any of the fluid control devices described herein can be formed from any suitable components that can be manufactured, sterilized, and packaged as individual parts or components. In such embodiments, a user can, for example, open one or more packages containing one or more components, can assemble the components to form the fluid control device, and can use the fluid control device as described above. In other embodiments, any of the fluid control devices described herein can be formed from any suitable components that can be manufactured, sterilized, assembled, and packaged as an assembly or integrated device. In such embodiments, a user can, for example, open a packaging containing such an assembly or integrated device and can use the device as described above without further assembly of components. In some embodiments, any of the control devices can be monolithically formed in whole or at least in part.

[0178] In some embodiments, any of the control devices can be physically and/or fluidically coupled to a collection device (e.g., a sample reservoir, a syringe, a blood culture bottle, a collection vial, a fluid transfer container, and/or any other suitable reservoir, collection device, and/or transfer device) by a user prior to or during use, as described in detail above. In other embodiments, any of the control devices can be physically coupled, attached, formed, and/or otherwise mated to a fluid collection device during a manufacturing process. This can be done prior to sterilization so the collection pathway(s) and connection interface(s) (e.g., where the control device couples to the fluid collection device) maintain a closed-system,

mechanical diversion device within a sterile environment that is not subject to touch-point contamination from external sources.

[0179] In some embodiments, the pre-assembly of the control device and the collection device can be such that the user is forced first to sequester, segregate, and/or isolate at least a portion of the initial bodily fluid volume or flow prior to transferring a sample volume to the pre-assembled fluid collection device. For example, the control device can include an actuator that is configured to isolate an outlet from other portions of the control device, thereby isolating the collection device from such portions of the control device. Moreover, after transferring the initial volume of bodily fluid, the actuation of the actuator can result in sequestration of the initial volume of bodily fluid and the fluidic coupling of the outlet to additional portions of the control device (e.g., an inlet). In some embodiments, pre-assembling the control device and the collection device (e.g., during manufacturing) can, for example, force compliance with a sample procurement protocol that calls for the sequestration of an initial amount of bodily fluid prior to collecting a sample volume of bodily fluid.

[0180] In some embodiments, the coupling, mating, and/or attachment of the fluid control device to the fluid collection device (e.g., during manufacturing) can be executed such that the control device can be removed (physically decoupled, removed with a specific "key," and/or any other approach used to separate the control device from the fluid collection device) after use to allow access to the fluid collection device. After decoupling, the collection device can be placed in an incubator and/or any other type of analytical machine, and accessed for analysis and/or otherwise further processed. In some embodiments, such decoupling may be blocked, limited, and/or substantially prevented prior to use and unblocked or allowed after use. In other embodiments, the fluid control device and the fluid collection device can be permanently coupled and/or monolithically formed (at least in part) to prevent such decoupling.

[0181] Any of the embodiments described herein can be used in conjunction with any suitable fluid transfer, fluid collection, and/or fluid storage device such as, for example, the fluid reservoirs described in the '420 patent, the transfer devices described in the '510 publication, and/or the transfer adapters described in the '352 publication. In some embodiments, any of the embodiments described herein can be used in conjunction with fluid transfer, fluid collection, and/or fluid storage devices such as, for example, the devices described in U.S. Patent No. 8,535,241 entitled, "Fluid Diversion Mechanism for Bodily-Fluid Sampling," filed October 12, 2012; U.S. Patent No. 9,060,724 entitled, "Fluid Diversion Mechanism for Bodily-Fluid Sampling," filed May 29, 2013; U.S. Patent No. 9,155,495

entitled, "Syringe-Based Fluid Diversion Mechanism for Bodily-Fluid Sampling," filed December 2, 2013; U.S. Patent Publication No. 2016/0361006 entitled, "Devices and Methods for Syringe Based Fluid Transfer for Bodily-Fluid Sampling," filed June 13, 2016; U.S. Patent Publication No. 2018/0140240 entitled, "Systems and Methods for Sample Collection with Reduced Hemolysis," filed November 20, 2017; and/or U.S. Patent Publication No. 2017/0065733 entitled, "Apparatus and Methods for Maintaining Sterility of a Specimen Container," filed September 6, 2016, the disclosures of each of which are incorporated herein by reference in their entireties.

[0182] While some of the embodiments described above include a flow controller that selectively establishes fluid communication between a sequestration chamber and a fluid collection device (or other source of negative pressure) in other embodiments, a control device can be arranged to transfer a flow of bodily fluid in response to negative pressure differentials resulting from any suitable portion(s) of the device. For example, while the control device 200 is described above as including the flow controllers (e.g., the membrane 215, and/or the like) that place the sequestration chamber 214 in selective fluid communication with the fluid collection device (e.g., a sample reservoir or syringe) until the membrane 215 is transitioned to a sealed or closed state (e.g., until the membrane 215 is sufficiently wetted), in other embodiments, a control device can include a sequestration chamber that is a pre-sealed, evacuated, and/or pre-charged chamber such that establishing fluid communication between an inlet and the sequestration chamber results in a negative pressure differential that is sufficient to draw an initial volume of bodily fluid into the sequestration chamber. In such embodiments, the control device can be configured to transfer bodily fluid to the sequestration chamber until the pressure differential is sufficiently reduced and/or until pressures otherwise substantially equalize. Moreover, in some such embodiments, the sequestration chamber and/or the inlet can include a coupler, an actuator, a needle, a septum, a port, and/or any other suitable member that can establish fluid communication therebetween (e.g., that can transition the sequestration chamber from a sealed to an unsealed configuration).

[0183] While the embodiments have been described above as including particular means for modulating and/or controlling a magnitude of negative pressure applied on or through at least a portion of the device(s), in other embodiments, a control device can include any suitable feature, mechanism, and/or device configured to modulate, create, and/or otherwise control one or more pressure differentials through at least a portion of the control device. For example, in some embodiments, a user can transition and/or move an actuator to change (e.g., reduce or

increase) the size of one or more portions of a fluid flow path or fluid flow interface within a portion of the control device to manually modulate and/or otherwise control an amount or magnitude of negative pressure within one or more portions of a control device.

[0184] By way of another example, any of the embodiments described herein can include any suitable actuator and/or flow controller configured to selectively control fluid flow through at least a portion of the device. Specifically, a flow controller or the like can be one or more of a selectively permeable material or membrane, a valve, a diaphragm, and/or any other suitable flow controller. While some of the embodiments have been described as including an actuator rod configured to be transitioned from a first configuration or position to a second configuration or position, in other embodiments, any actuator described herein can include an actuator rod configured to transition from between a first position and second position to at least temporarily isolate an outlet from of the device from one or more other portions of the device. In some embodiments, such an actuator can be configured for use with a given and/or predetermined collection device such as, for example, a syringe. In other embodiments, such an actuator can be used with any suitable collection device.

[0185] While the embodiments have been described above as including or coupling to an inlet device such as a needle or the like that is configured to puncture the skin of a patient to place the lumen of the needle in fluid communication with a vein in the patient, in other embodiments, a fluid control device can include and/or can couple to any suitable inlet device. For example, in some embodiments, an inlet device can include a trocar or the like and a catheter. The trocar is configured to puncture the skin of a patient and then configured to be withdrawn from the patient, leaving the catheter of the inlet device placed within the patient. In other embodiments, the inlet device need not puncture the skin of a patient. For example, in some embodiments, the inlet device can include a needle or catheter that can be placed in a dish, well, sample volume, container, reservoir, etc. In still other embodiments, the inlet device can be and/or can include a coupler or port configured to couple to an indwelling needle or intravenous catheter. In other embodiments, such a coupler or port can be configured to couple to any suitable bodily fluid source (or port thereof) such as, for example, a syringe, a reservoir, a container, etc.

[0186] Accordingly, while the embodiments are described above as withdrawing and sequestering an initial volume of bodily fluid to sequester contaminants such as, for example, dermally-residing microbes, in other embodiments, the inlet device can be coupled to any suitable bodily fluid source and the control device can be configured to sequester an initial

volume of bodily fluid withdrawn from that bodily fluid source to sequester contaminants that may be present within the source and/or any an interface of the container or reservoir containing the bodily fluid. For example, in some embodiments, a needle of an inlet device can be configured to puncture a port or surface of a reservoir to place the needle in fluid communication with an interior volume of the container or device. In such embodiments, the devices described herein can be used to sequester an initial volume of bodily fluid from the bodily fluid source, which in turn, can sequester contaminants or the like that may have been present on the interface, port, or surface that was punctured. Thus, the devices and methods described herein can be used to procure bodily fluid samples having reduced contamination from any suitable bodily fluid source. Moreover, while some such contaminants are described herein as being dermally residing microbes, it should be understood that the contaminants can be any contaminant that is, for example, exterior to the bodily fluid source and/or otherwise that is or that includes any constituent component (e.g., microbe, virus, molecule, particle, element, etc.) that is otherwise foreign to the bodily fluid.

[0187] Although various embodiments have been described as having particular features, concepts, and/or combinations of components, other embodiments are possible having any combination or sub-combination of any features, concepts, and/or components from any of the embodiments described herein. For example, as described above, the device 700 includes concepts, features, and/or elements of the device 600, the device 600 includes concepts, features, and/or elements of the device 500, and the device 400 includes concepts, features, and/or elements of the devices 200 and 300. The specific configurations of the various components can also be varied. For example, the size and specific shape of the various components can be different from the embodiments shown, while still providing the functions as described herein. More specifically, the size and shape of the various components can be specifically selected for a desired rate and/or volume of bodily fluid flow into a fluid reservoir. Likewise, the size and/or shape of the various components can be specifically selected for a desired or intended usage. Thus, it should be understood that the size, shape, and/or arrangement of the embodiments and/or components thereof can be adapter for a given use unless the context explicitly states otherwise.

[0188] In some embodiments, the specific configurations of the various components can also be varied. For example, the size and specific shape of the various components can be different from the embodiments shown, while still providing the functions as described herein. More specifically, the size and shape of the various components can be specifically selected

for a desired rate and/or volume of bodily fluid flow into a fluid reservoir. Likewise, the size and/or shape of the various components can be specifically selected for a desired or intended usage. For example, in some embodiments, a device such as those described herein can be configured for use with or on seemingly healthy adult patients. In such embodiments, the device can include a sequestration chamber that has a first volume (e.g., about 0.5 ml to about 5.0 ml). In other embodiments, a device such as those described herein can be configured for use with or on, for example, very sick patients and/or pediatric patients. In such embodiments, the device can include a sequestration chamber that has a second volume that is less than the first volume (e.g., less than about 0.5 ml). Thus, it should be understood that the size, shape, and/or arrangement of the embodiments and/or components thereof can be adapted for a given use unless the context explicitly states otherwise.

[0189] Although not shown, any of the devices described herein can include an opening, port, coupler, septum, Luer-Lok, gasket, valve, threaded connecter, standard fluidic interface, etc. (referred to for simplicity as a "port") in fluid communication with the sequestration chamber. In some such embodiments, the port can be configured to couple to any suitable device, reservoir, pressure source, etc. For example, in some embodiments, the port can be configured to couple to a reservoir, which in turn, can allow a greater volume of bodily fluid to be diverted and/or transferred into the sequestration chamber. In other embodiments, the port can be coupled to a negative pressure source such as an evacuated container, a pump, a syringe, and/or the like to collect a portion of or the full volume of bodily fluid in the sequestration chamber, channel, reservoir, etc. and use that volume of bodily fluid (e.g., the pre-sample volume) for additional clinical and/or in vitro diagnostic testing purposes. In other embodiments, the port can be coupled to any suitable pressure source or infusion device configured to infuse the initial volume of bodily fluid sequestered in the sequestration chamber back into the patient and/or bodily fluid source (e.g., in the case of pediatric patients, very sick patients, patients having a low blood volume, and/or the like).

[0190] In some embodiments, the port can be configured to receive a probe, sampling tool, testing device, and/or the like that can be used to perform one or more tests (e.g., tests not sensitive to potential contamination) on the initial volume while the initial volume is disposed or sequestered in the sequestration chamber. In other embodiments, the sequestration channel, chamber, and/or reservoir can be configured with the addition of other diagnostic testing components integrated into the chamber (e.g., a paper test) such that the initial bodily fluid is used for that test. In still other embodiments, the sequestration chamber, channel, and/or

reservoir can be designed, sized and configured to be removable and compatible with testing equipment and/or specifically accessible for other types of bodily fluid tests commonly performed on patients with suspected conditions. By way of example, a patient with suspected sepsis commonly has blood samples collected for lactate testing, procalcitonin testing, and blood culture testing. All of the fluid control devices described herein can be configured such that the sequestration chamber, channel, reservoir, etc. can be removed (e.g., after receiving the initial volume of bodily fluid) and the bodily fluid contained therein can be used for these additional testing purposes before or after the subsequent sample is collected for microbial testing.

[0191] Although not shown, in some embodiments, a fluid control device can include one or more lumen, channels, flow paths, etc. configured to selectively allow for a "bypass" flow of bodily fluid, where an initial amount or volume of bodily fluid can flow from the inlet, through the lumen, cannel, flow path, etc. to bypass the sequestration chamber, and into the collection device. In some embodiments, the fluid control device can include an actuator having, for example, at least three states – a first in which bodily fluid can flow from the inlet to the sequestration chamber, a second in which bodily fluid can flow from the inlet to the outlet after the initial volume is sequestered in the sequestration chamber, and a third in which bodily fluid can flow from the inlet, through the bypass flow path, and to the outlet. In other embodiments, the control device can include a first actuator configured to transition the device between a first and second state, as described in detail above with reference to specific embodiments, and can include a second actuator configured to transition the device to a bypass configuration or the like. In still other embodiments, the control device can include any suitable device, feature, component, mechanism, actuator, controller, etc. configured to selectively place the fluid control device in a bypass configuration or state.

[0192] In some embodiments, a method of using a fluid control device employing an external negative pressure source can include the ordered steps of establishing fluid communication between a bodily fluid source (e.g., a vein of a patient or the like) and an inlet of the fluid control device. An outlet of the fluid control device is then placed in fluid communication with and/or otherwise engages a negative pressure source. Such a negative pressure source can be a sample reservoir, a syringe, an evacuated container, an intermediate transfer device, and/or the like. The fluid control device can be in a first state or operating mode when the outlet is coupled to the negative pressure source and, as such, a negative pressure differential is applied through at least a portion of the fluid control device that can be

operable to draw an initial volume of bodily fluid into a sequestration chamber of the fluid control device. Once the initial volume of bodily fluid is disposed in the sequestration chamber, the fluid control device is transitioned, either automatically or via user intervention, from the first state or operating mode to a second state or operating mode such that (1) the initial volume is sequestered in the sequestration chamber and (2) fluid communication is established between the inlet and the outlet. The sequestration of the initial volume can be such that contaminants entrained in the flow of the initial volume are likewise sequestered within the sequestration chamber. With the initial volume of bodily fluid sequestered in the sequestration chamber and with fluid communication established between the inlet and the outlet, subsequent volumes of bodily fluid that are substantially free of contamination can be collected in one or more sample reservoirs.

[0193] While the method of using the fluid control device is explicitly described as including the recited ordered steps, in other embodiments, the ordering of certain events and/or procedures in any of the methods or processes described herein may be modified and such modifications are in accordance with the variations of the invention. Additionally, certain events and/or procedures may be performed concurrently in a parallel process when possible, as well as performed sequentially as described above. Certain steps may be partially completed or may be omitted before proceeding to subsequent steps.

[0194] For example, while the devices are described herein as transitioning from a first state to a second state in a discrete operation or the like, it should be understood that the devices described herein can be configured to automatically and/or passively transition from the first state to the second state and that such a transitioning may occur over a period of time. In other words, the transitioning from the first state to the second state may, in some instances, be relatively gradual such that as a last portion of the initial volume of bodily fluid is being transferred into the sequestration chamber, the housing begins to transition from the first state to the second state. In some instances, the rate of change when transitioning from the first state to the second state can be selectively controlled to achieve one or more desired characteristics associated with the transition. Moreover, in some such instances, the inflow of the last portion of the initial volume can limit and/or substantially prevent bodily fluid already disposed in the sequestration chamber from escaping therefrom. Accordingly, while the transitioning from the first state to the second state may occur over a given amount of time, the sequestration chamber can nonetheless sequester the volume of bodily fluid disposed therein.

What is claimed:

1. A fluid control device, comprising:

an inlet configured to be placed in fluid communication with a bodily fluid source;

an outlet configured to be placed in fluid communication with a fluid collection device, a negative pressure differential being produced between the outlet and the inlet when the outlet is placed in fluid communication with the fluid collection device;

a sequestration portion in fluid communication with the inlet, the sequestration portion including a first flow controller configured to transition from a first state in which the sequestration portion is sequestered from the outlet to a second state in which the sequestration portion is in fluid communication with the outlet when the negative pressure differential has a first magnitude; and

a sampling portion in fluid communication with the outlet, the sampling portion including a second flow controller configured to transition from a first state in which the sampling portion is sequestered from the inlet to a second state in which the sampling portion is in fluid communication with the inlet when the negative pressure differential has a second magnitude greater than the first magnitude.

2. The system of claim 1, wherein the fluid collection device is a sample bottle, the sample bottle being at least partially evacuated such that coupling the outlet to the sample bottle generates the negative pressure differential.

3. The system of claim 1, wherein the fluid collection device is a syringe that is configured to be manipulated after the outlet is coupled to the syringe to generate the negative pressure differential.

4. The system of claim 1, wherein the first flow controller is configured to transition from the first state to the second state automatically.

5. The system of claim 1, wherein the second flow controller is configured to transition from the first state to the second state automatically.

6. The system of claim 1, wherein the sequestration portion is configured to receive an initial volume of bodily fluid withdrawn from the bodily fluid source in response to the first flow controller transitioning to the second state.

7. The system of claim 6, wherein the first flow controller has a third state in which the sequestration portion is sequestered from the outlet, the first flow controller configured to transition from the second state to the third state as a result of the sequestration portion receiving the initial volume of bodily fluid.

8. The system of claim 7, wherein the first flow controller being placed in the third state results in an increase in a magnitude of the negative pressure differential within the sampling portion from the first magnitude to the second magnitude.

9. The system of claim 7, wherein the first flow controller includes a selectively permeable material, the selectively permeable material configured to (1) allow a flow of a gas and prevent a flow of bodily fluid through the selectively permeable material when in a first state and (2) prevent a flow of gas and bodily fluid through the selectively permeable material when in a second state.

10. The system of claim 9, wherein the selectively permeable material is configured to transition from the first state to the second state as a result the initial volume of bodily fluid being received in the sequestration portion, thereby placing the first flow controller in the third state.

11. A fluid control device, comprising:

a housing having an inlet configured to establish fluid communication with a bodily fluid source and an outlet configured to be coupled to a fluid collection device, the coupling of the outlet to the fluid collection device resulting in a negative pressure differential within at least a portion of the housing, the housing defining a sequestration flow path in fluid communication with the inlet and a sampling flow path in fluid communication with the outlet;

a first flow controller having a flow state in which fluid communication is established between the sequestration flow path and the outlet and a non-flow state in which the sequestration flow path is sequestered from the outlet; and

a second flow controller having a flow state in which fluid communication is established between the sampling flow path and the inlet and a non-flow state in which the sampling flow path is sequestered from the inlet,

the first flow controller configured to be in the flow state when the negative pressure differential generated by coupling the outlet to the fluid collection device has a first magnitude

such that an initial volume of bodily fluid flows through the sequestration flow path toward the first flow controller, and

the first flow controller configured to transition to the non-flow state when the initial volume of bodily fluid is received in the sequestration flow path such that (1) the sequestration flow path is sequestered from the outlet and (2) the negative pressure differential is increased to a second magnitude operable to transition the second flow controller from the non-flow state to the flow state.

12. The system of claim 11, wherein the fluid collection device is a sample bottle, the sample bottle being at least partially evacuated such that coupling the outlet to the sample bottle generates the negative pressure differential.

13. The system of claim 11, wherein the fluid collection device is a syringe that is configured to be manipulated after the outlet is coupled to the syringe to generate the negative pressure differential.

14. The system of claim 11, wherein the first flow controller is configured to transition from the first state to the second state automatically.

15. The system of claim 11, wherein the second flow controller is configured to transition from the first state to the second state automatically.

16. The system of claim 11, wherein the first flow controller is at least one of a valve, a selectively permeable material, or a restricted flow path.

17. The system of claim 16, wherein the second flow controller is at least one of a valve, a selectively permeable material, a dissolvable material, a frangible barrier, a movable barrier, or a restricted flow path.

18. The system of claim 11, wherein the first flow controller includes a selectively permeable material configured to (1) allow a flow of a gas and prevent a flow of bodily fluid through the selectively permeable material when in a first state and (2) prevent a flow of gas and bodily fluid through the selectively permeable material when in a second state.

19. The system of claim 18, wherein the selectively permeable material is configured to transition from the first state to the second state as a result of the sequestration flow path receiving the initial volume of bodily fluid, the transitioning of the selectively permeable material from the first state to the second state places the first flow controller in the non-flow state.

20. The system of claim 19, wherein the first state of the selectively permeable material is an unsaturated state and the second state of the selectively permeable material is a saturated state.

21. A method of using a fluid control device to obtain a bodily fluid sample with reduced contamination, the method comprising:

coupling a fluid collection device to an outlet of the fluid control device, the coupling of the fluid collection device to the outlet configured to produce a negative pressure differential within at least a portion of the fluid control device;

transitioning a first flow controller from a first state to a second state when the negative pressure differential has a first magnitude, the first flow controller sequestering a sequestration portion of the fluid control device from the outlet when in the first state and establishing fluid communication between the sequestration portion and the outlet when in the second state;

receiving an initial volume of bodily fluid from an inlet of the fluid control device and into the sequestration portion in response to the negative pressure differential when the first flow controller is in the second state;

transitioning the first flow controller from the second state to a third state in response to the receiving, the first flow controller sequestering the sequestration portion from the outlet when in the third state, the negative pressure differential being increased from the first magnitude to a second magnitude when the first flow controller is in the third state;

transitioning a second flow controller from a first state to a second state when the negative pressure differential has the second magnitude, the second flow controller sequestering a sampling portion of the fluid control device from the inlet when in the first state and establishing fluid communication between the sampling portion and the inlet when in the second state; and

transferring a subsequent volume of bodily fluid from the inlet to the fluid collection device via the sampling portion and the outlet.

22. The method of claim 21, wherein the transitioning of the first flow controller from the first state to the second state includes automatically transitioning the first flow controller from the first state to the second state without manual intervention.

23. The method of claim 22, wherein the transitioning of the first flow controller from the second state to the third state includes automatically transitioning the first flow controller from the first state to the second state without manual intervention.

24. The method of claim 21, wherein the transitioning of the second flow controller from the first state to the second state includes automatically transitioning the second flow controller from the first state to the second state without manual intervention.

25. The method of claim 21, wherein the first flow controller includes a selectively permeable material configured to (1) allow a flow of a gas and prevent a flow of bodily fluid through the selectively permeable material when in a first state and (2) prevent a flow of gas and bodily fluid through the selectively permeable material when in a second state,

the transitioning of the first flow controller from the second state to the third state includes the selectively permeable material being placed in its second state.

26. The method of claim 21, further comprising:

establishing fluid communication between the inlet and a bodily fluid source, wherein the initial volume of bodily fluid contains contaminants associated with the establishing of fluid communication between the inlet and the bodily fluid source.

27. The method of claim 26, wherein the initial volume of bodily fluid and the contaminants are sequestered within the sequestration portion when the first flow controller is in the third state such that the subsequent volume of bodily fluid is substantially free of contaminants.

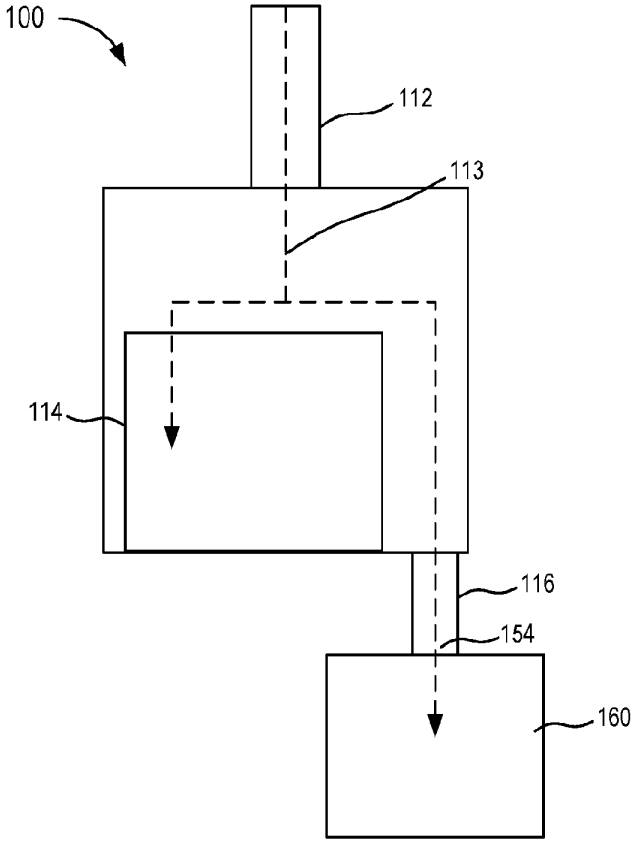


FIG. 1

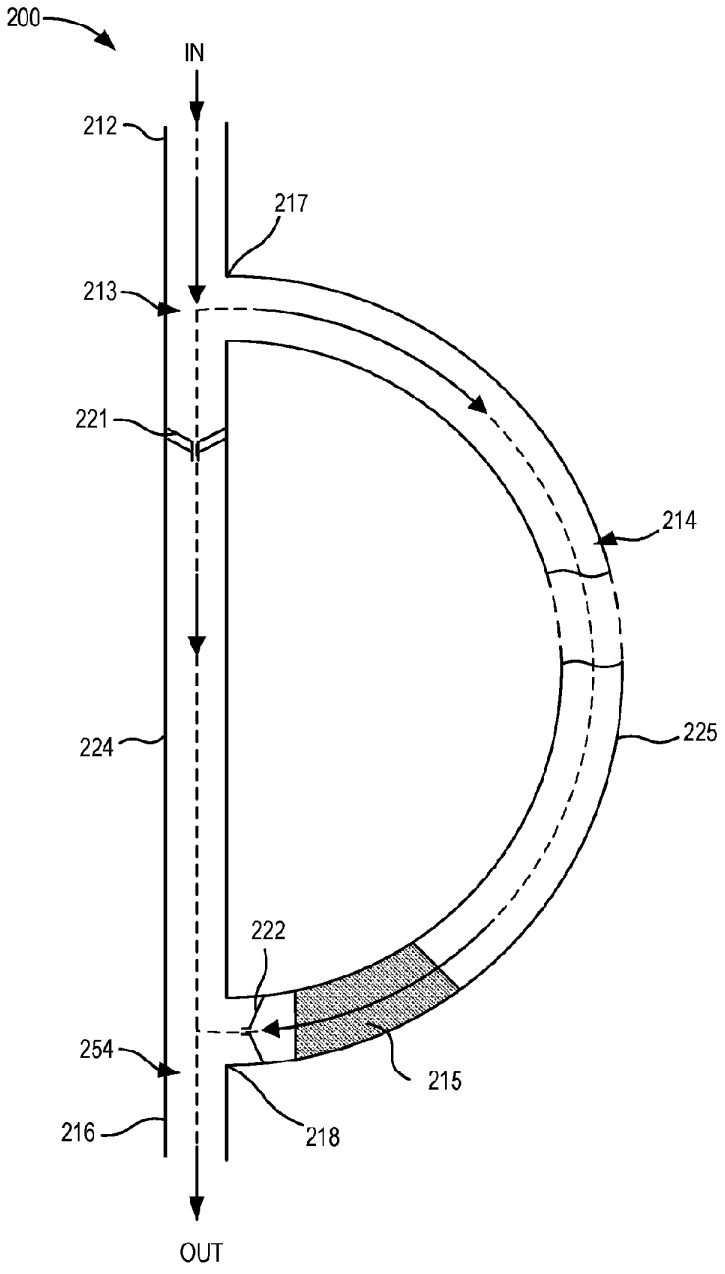


FIG. 2

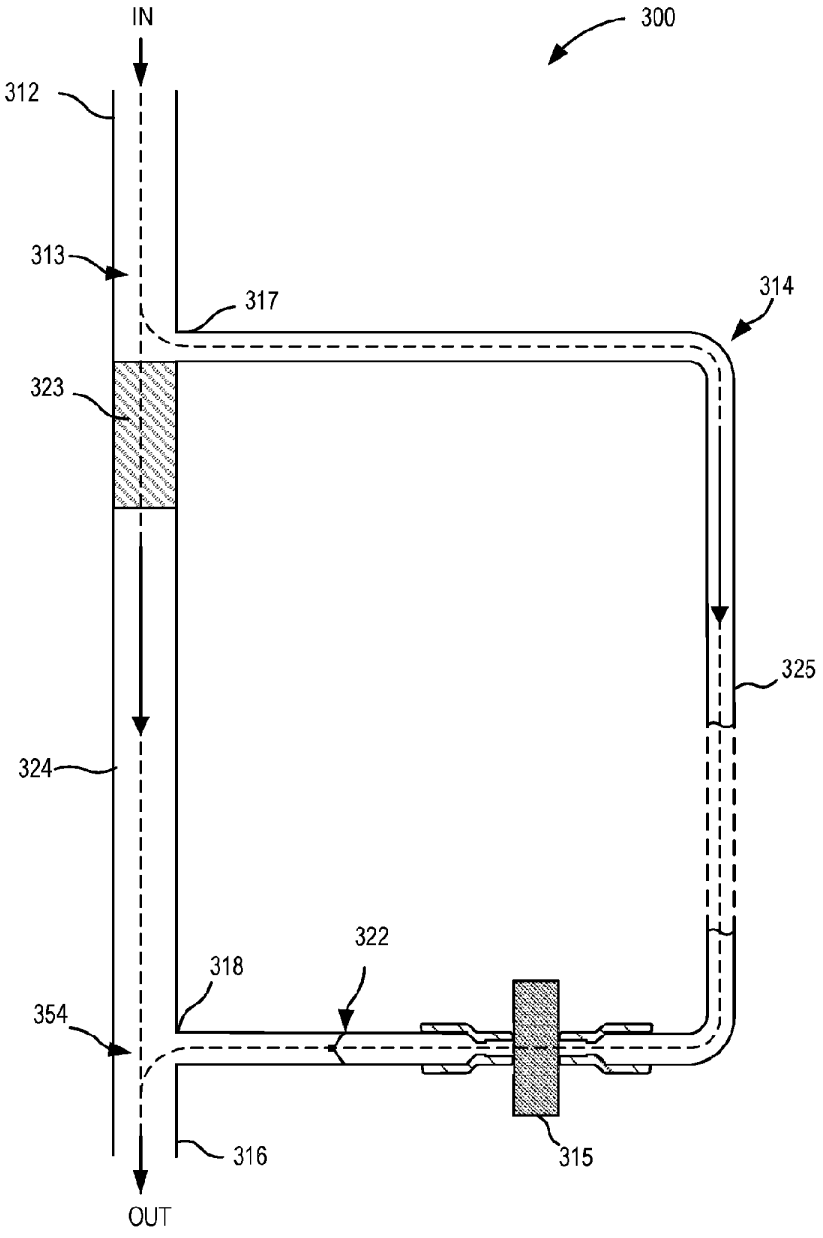


FIG. 3

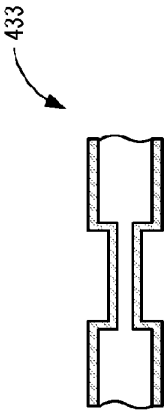


FIG. 5

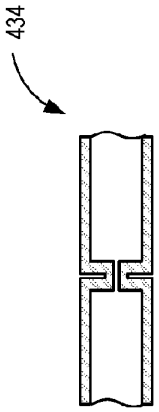


FIG. 6

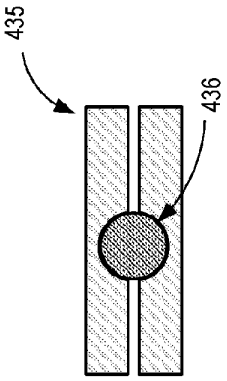


FIG. 7

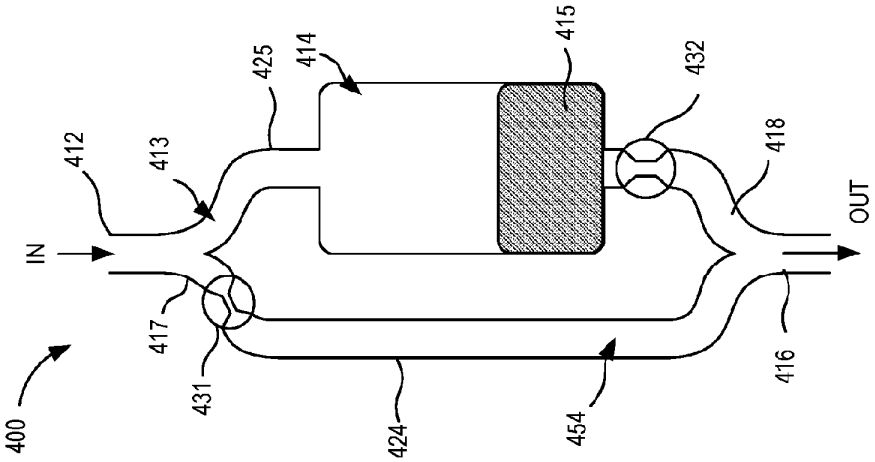


FIG. 4

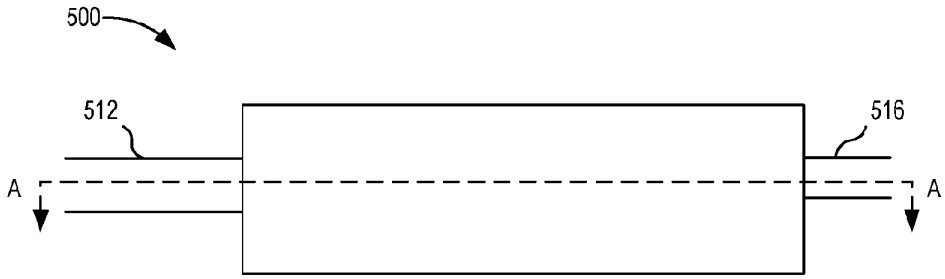


FIG. 8

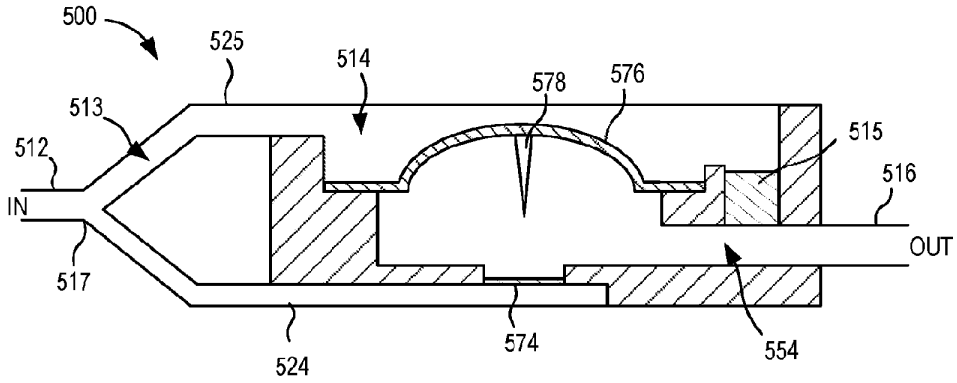


FIG. 9

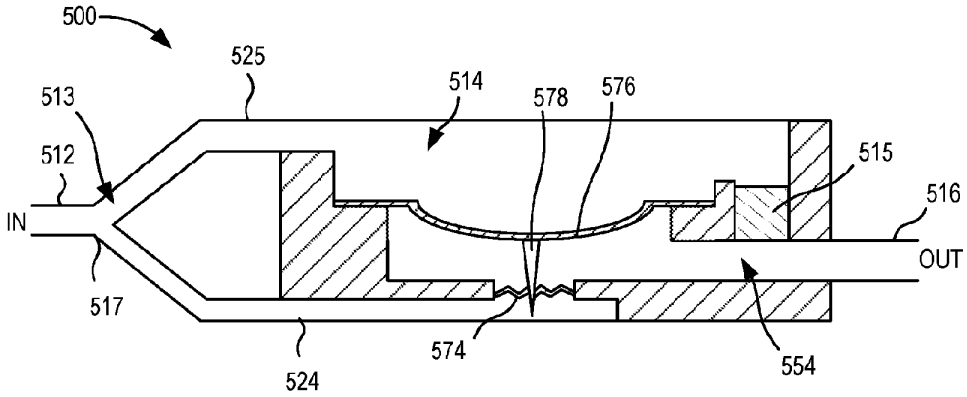


FIG. 10

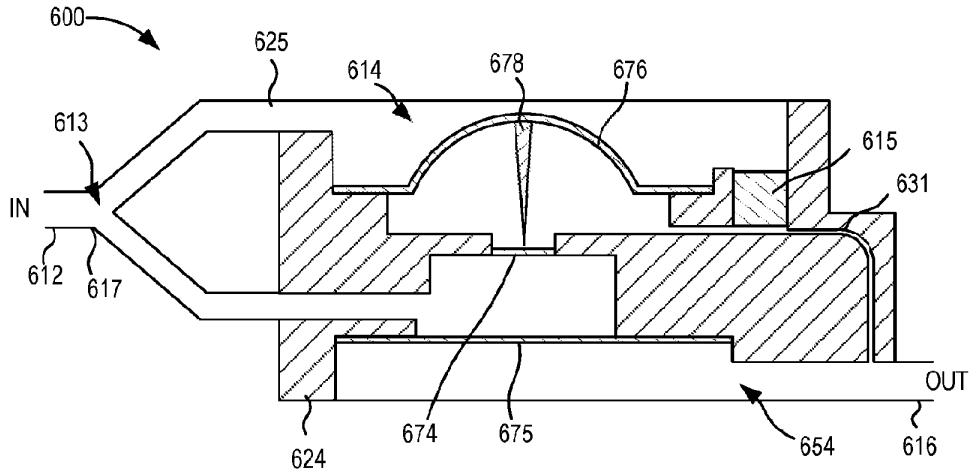

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FIG. 11

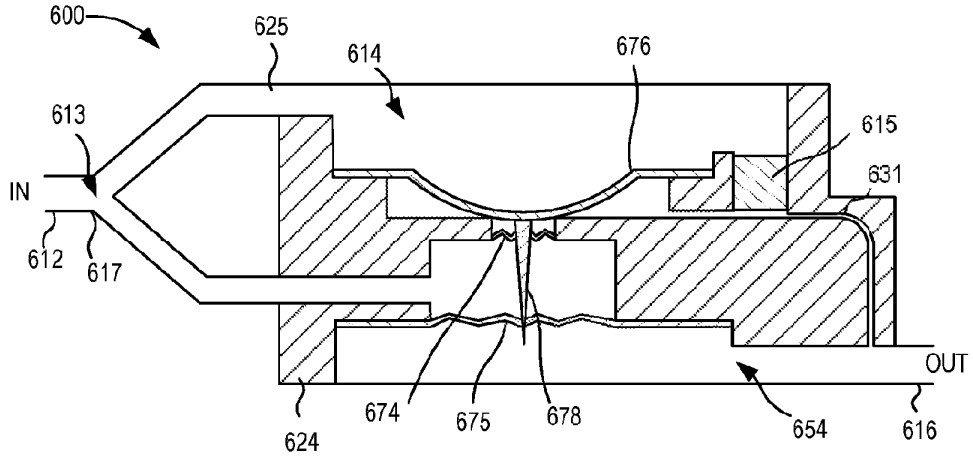

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FIG. 12

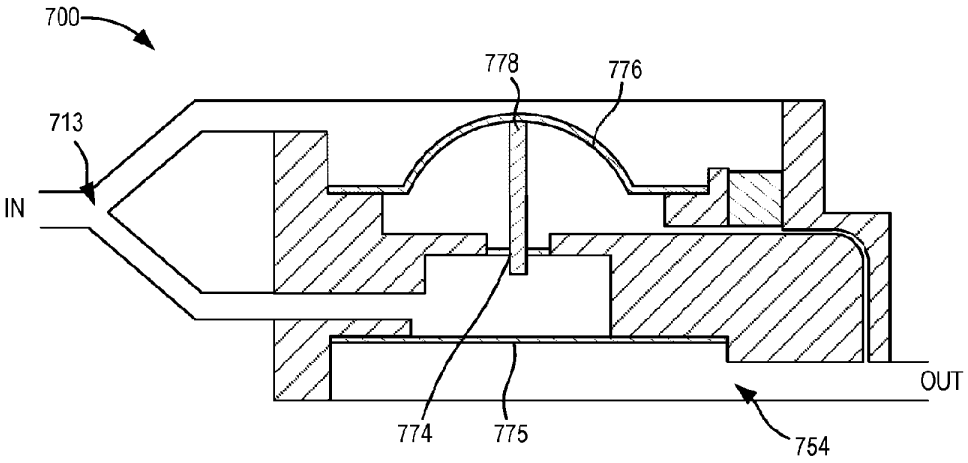

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FIG. 13

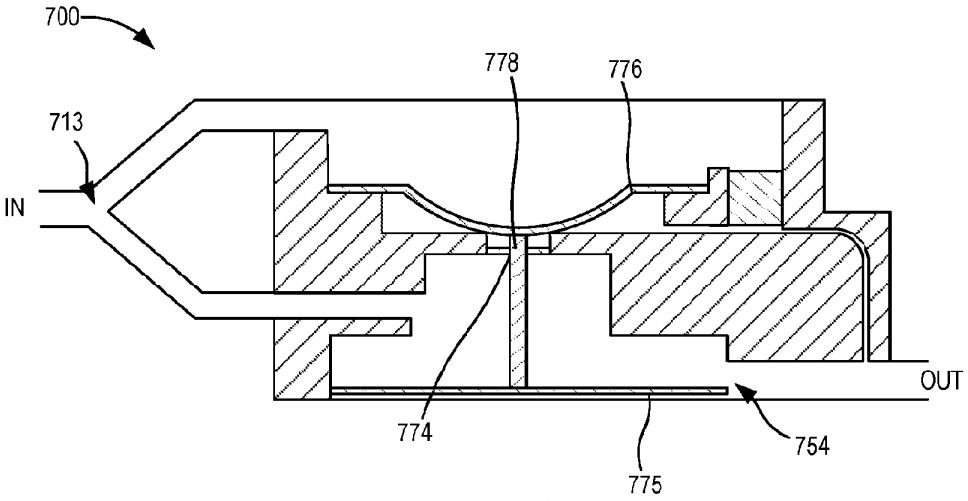

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FIG. 14

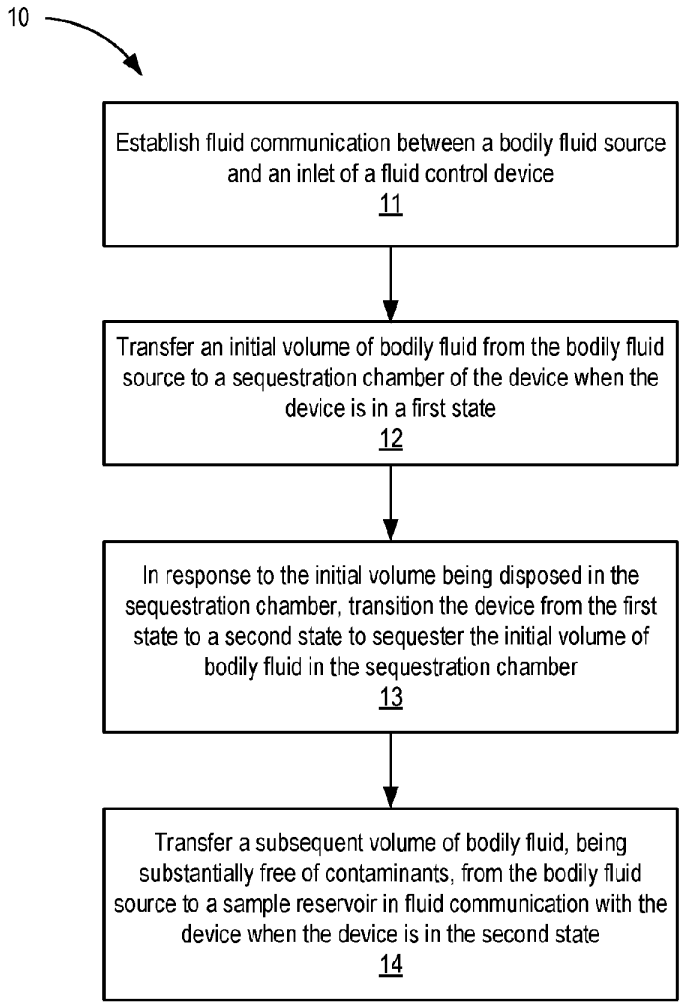

10
Establish fluid communication between a bodily fluid source and an inlet of a fluid control device
11
Transfer an initial volume of bodily fluid from the bodily fluid source to a sequestration chamber of the device when the device is in a first state
12
In response to the initial volume being disposed in the sequestration chamber, transition the device from the first state to a second state to sequester the initial volume of bodily fluid in the sequestration chamber
13
Transfer a subsequent volume of bodily fluid, being substantially free of contaminants, from the bodily fluid source to a sample reservoir in fluid communication with the device when the device is in the second state
14

FIG. 15

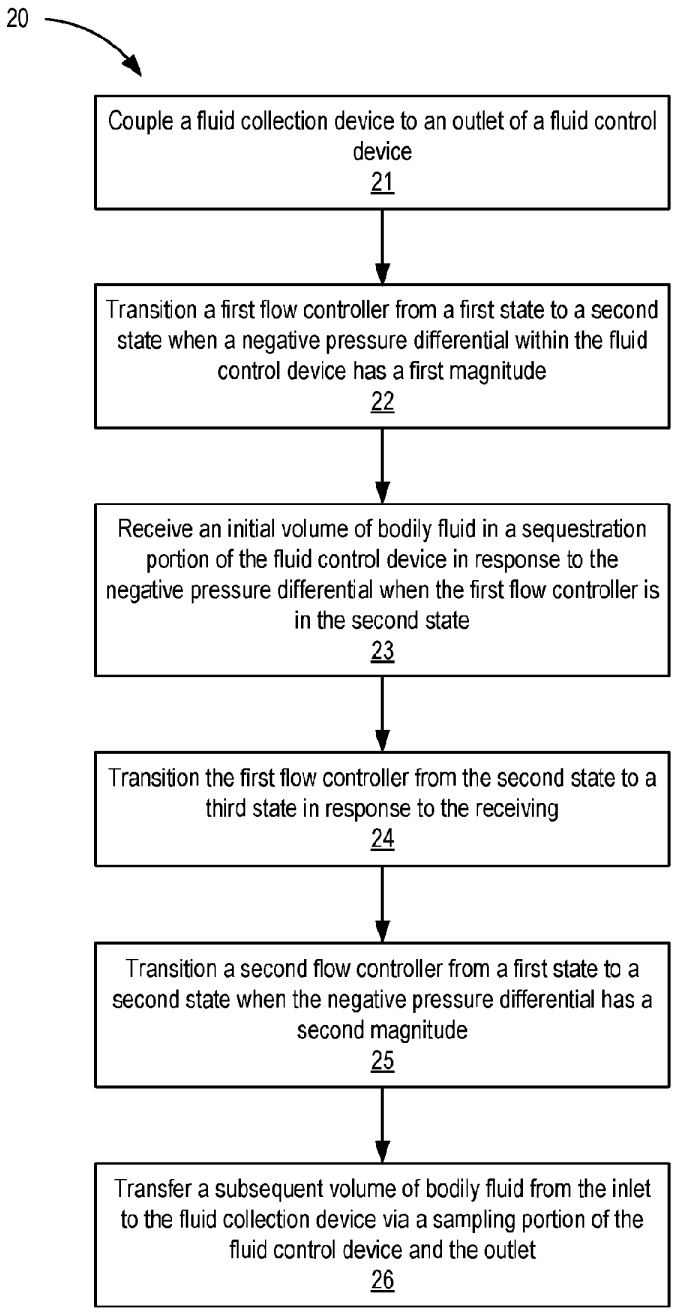

20
Couple a fluid collection device to an outlet of a fluid control device
21
Transition a first flow controller from a first state to a second state when a negative pressure differential within the fluid control device has a first magnitude
22
Receive an initial volume of bodily fluid in a sequestration portion of the fluid control device in response to the negative pressure differential when the first flow controller is in the second state
23
Transition the first flow controller from the second state to a third state in response to the receiving
24
Transition a second flow controller from a first state to a second state when the negative pressure differential has a second magnitude
25
Transfer a subsequent volume of bodily fluid from the inlet to the fluid collection device via a sampling portion of the fluid control device and the outlet
26

FIG. 16

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2019/034626

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B5/15 A61B5/153 A61B5/154
ADD.

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

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2017/020427 A1 (ROGERS BOBBY E [US] ET AL) 26 January 2017 (2017-01-26) paragraphs [0125], [0126] figures 23A, 23B	1-27
A	US 2016/361006 A1 (BULLINGTON GREGORY J [US] ET AL) 15 December 2016 (2016-12-15) cited in the application paragraphs [0040] - [0073] figures 1-7	1-27
A	US 2015/011910 A1 (BULLINGTON GREGORY [US] ET AL) 8 January 2015 (2015-01-08) paragraphs [0078] - [0104] figures 2-12	1-27

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[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
6 August 2019	22/08/2019

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Schultz, Ottmar

1

Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2019/034626

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2014/163419 A1 (BULLINGTON GREGORY J [US] ET AL) 12 June 2014 (2014-06-12) the whole document	1-27
A	US 8 535 241 B2 (BULLINGTON GREGORY [US]; PATTON RICHARD G [US] ET AL.) 17 September 2013 (2013-09-17) cited in the application the whole document	1-27

1

Form PCT/ISA/210 (continuation of second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2019/034626

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2017020427 A1	26-01-2017	AU 2016297849 A1	22-02-2018
		CA 2993646 A1	02-02-2017
		EP 3324845 A1	30-05-2018
		JP 2018525191 A	06-09-2018
		US 2017020427 A1	26-01-2017
		US 2017020428 A1	26-01-2017
		US 2018289304 A1	11-10-2018
		US 2019159711 A1	30-05-2019
		WO 2017019552 A1	02-02-2017
US 2016361006 A1	15-12-2016	EP 3307359 A1	18-04-2018
		US 2016361006 A1	15-12-2016
		WO 2016201406 A1	15-12-2016
US 2015011910 A1	08-01-2015	US 2015011910 A1	08-01-2015
		US 2015011911 A1	08-01-2015
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US 2014163419 A1	12-06-2014	CA 2931983 A1	05-06-2014
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		US 2015073348 A1	12-03-2015
		US 2016135724 A1	19-05-2016
		US 2019150818 A1	23-05-2019
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		GB 2560267 A	05-09-2018
		US 2013116599 A1	09-05-2013
		WO 2014099266 A2	26-06-2014

Form PCT/ISA/210 (patent family annex) (April 2005)

Doc Code: IDS.SIZEFEE
Document Description: Assertion of whether IDS Size Fee Due

PTO/SB/08C (01-25)
Approved for use through 01/31/2028. OMB 0651-0070
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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INFORMATION DISCLOSURE STATEMENT SIZE FEE – WRITTEN ASSERTION UNDER 37 CFR 1.98

Complete if Known

Application or Patent No.:	First Named Inventor:	Art Unit:
18898239	Bobby E. Rogers	3791
Filing Date:	**Attorney Docket Number:**	**Examiner:**
2024-09-26	069366-0581370_KUR2C07US	ABOUELELA, MAY A

Please see 37 CFR 1.17(v) and attached Instructions for completing this form to make the appropriate selection of an assertion under 37 CFR 1.98. For the information disclosure statement (IDS) submitted herewith, the applicant or patent owner certifies the following with respect to the cumulative number of applicant-provided or patent-owner provided items of information submitted to date including those in the accompanying IDS (select only one):

☑ No IDS size fee is required under 37 CFR 1.17(v) at this time.

☐ The IDS is accompanied by the IDS size fee under 37 CFR 1.17(v)(1).

☐ The IDS is accompanied by the IDS size fee under 37 CFR 1.17(v)(2).

☐ The IDS is accompanied by the IDS size fee under 37 CFR 1.17(v)(3).

NOTE: This form must be accompanied by PTO/SB/08a and/or PTO/SB/08b or equivalent.

DEPOSIT ACCOUNT

The Director is authorized to charge the fee indicated above in the amount of $ _____ for the IDS submitted herewith to deposit account _____.

SIGNATURE

This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications.

If applicant or patent owner is a juristic entity (e.g., an LLC or corporation), this form must be signed by a registered practitioner. See 37 CFR 1.31.

If applicant or patent owner is a person or persons, this form may be signed by either a registered practitioner, or the applicant or patentee. Note that if multiple people together are the applicant or patentee (e.g., there are joint inventors who together are the applicant), then a signature is required from each person who is an applicant or patentee. *Submit multiple forms if more than one signature is required, see below*.*

Signature	Date
/Ben Hudson/	2025-07-02
Name (Print/Typed)	**Practitioner Registration Number (if applicable)**
Benjamin F. Hudson	71,474

☐ * Total of _____ forms are submitted.

A Federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with an information collection subject to the requirements of the Paperwork Reduction Act of 1995, unless the information collection has a currently valid OMB Control Number. The OMB Control Number for this information collection is 0651-0070. Public burden for this form is estimated to average 2 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information collection. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden to the Office of the Chief Administrative Officer, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450 or email InformationCollection@uspto.gov. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Instructions for Filling out the
"Information Disclosure Statement Size Fee – Written Assertion Under 37 CFR 1.98" Form
(Not to be Submitted to the USPTO)

Note: This form is to be used when applicant or patent owner files an Information Disclosure Statement (IDS) for consideration by the examiner. This form must be accompanied by PTO/SB/08a and/or PTO/SB/08b or equivalent.

Determining the cumulative number of applicant-provided or patent owner-provided items of information

The IDS size fee is based on the cumulative number of items of information provided by an applicant or patent owner during the pendency of the application or reexamination proceeding. It is the applicant's and patent owner's responsibility to track the cumulative number of items of information provided in the application or proceeding and provide a written assertion of any applicable IDS size fee due.

In determining the applicable written assertion for the cumulative number of applicant-provided or patent owner-provided items of information, "provided" refers to the items cited on an IDS under 37 CFR 1.98(a)(1) by an applicant or patent owner, whether or not an actual copy of the cited item is submitted by the applicant or patent owner to the USPTO. If a particular item provided by an applicant or patent owner on an IDS was not considered because the item was non-compliant and that particular item is provided on an IDS a second time in the same application or patent, it will not be counted again.

An item of information that an applicant cited in a parent application will not be counted in a child application (e.g., a continuation, continuation-in-part, or divisional application) for the purpose of the IDS size fees unless it is resubmitted, i.e., provided by the applicant on an IDS in the child application. Applicants who wish to avoid paying the IDS size fees in a child application for items of information considered in a parent application may do so by not resubmitting the items. An item of information must be resubmitted in the continuing application if the applicant desires the item of information to be printed on the patent. See MPEP 609.02, subsection II.A.2.

The cumulative count is determined for each application or patent separately. Continuing, CPA, and reissue applications and post-issuance proceedings will start with a count of zero. A request for continued examination (RCE) is not the filing of a new application, and thus the count will not reset when an RCE is filed.

Written Assertion

Check "[ ] No IDS size fee is required under 37 CFR 1.17(v) at this time" on the above PTO/SB/08c form when the IDS does not cause the cumulative number of applicant-provided or patent owner-provided items in this application or proceeding to:

- exceed 50, 100, or 200 items of information.

Check "[ ] The IDS is accompanied by the IDS size fee under 1.17(v)(1)" on the above PTO/SB/08c form when the IDS causes the cumulative number of applicant-provided or patent owner-provided items in this application or proceeding to:

- exceed 50 items of information but not exceed 100 items of information.

Check "[ ] The IDS is accompanied by the IDS size fee under 1.17(v)(2)" on the above PTO/SB/08c form when the IDS causes the cumulative number of applicant-provided or patent owner-provided items in this application or proceeding to:

- exceed 100 items of information but not exceed 200 items of information.

Note: If a fee under 1.17(v)(1) was previously paid, the fee currently due is the difference between the 1.17(v)(2) fee and the previously paid 1.17(v)(1) fee.

Doc Code: IDS.SIZEFEE
Document Description: Assertion of whether IDS Size Fee Due

Check "[ ] The IDS is accompanied by the IDS size fee under 1.17(v)(3)" on the above PTO/SB/08c form when the IDS causes the cumulative number of applicant-provided or patent owner-provided items in this application or proceeding to:

- exceed 200 items of information.

Note: If a fee under 1.17(v)(1) or (v)(2) was previously paid, the fee currently due is the difference between the 1.17(v)(3) fee and the previously paid 1.17(v)(1) or (v)(2) fee.

Select only one assertion on the PTO/SB/08c form above.

Note: the cumulative count of items of information includes all items of information already of record in a pending application or proceeding that were submitted via IDS(s) including those submitted prior to January 19, 2025.

Method of Payment

This section should only be filled out if the IDS size fee is due. Fees may be paid by check or money order (made payable to the Director of the United States Patent and Trademark Office), credit card (Form PTO-2038), or deposit account. When paying by deposit account, the amount of the IDS size fee to be charged to the deposit account must be specified to comply with 37 CFR 1.98(a)(4). General authorizations to charge fees to a deposit account are not compliant written assertions. When paying by credit card, to protect your credit card information, do not submit Form PTO-2038 electronically through USPTO's patent electronic filing system or any other USPTO Web site.

Privacy Act Statement

The **Privacy Act of 1974 (P.L. 93-579)** requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

Routine uses of the information in this record may include disclosure to:

1) law enforcement, in the event that the system of records indicates a violation or potential violation of law;

2) a federal, state, local, or international agency, in response to its request;

3) a contractor of the USPTO having need for the information in order to perform a contract;

4) the Department of Justice for determination of whether the Freedom of Information Act (FOIA) requires disclosure of the record;

5) a Member of Congress submitting a request involving an individual to whom the record pertains, when the individual has requested the Member's assistance with respect to the subject matter of the record;

6) a court, magistrate, or administrative tribunal, in the course of presenting evidence, including disclosures to opposing counsel in the course of settlement negotiations;

7) the Administrator, General Services Administration (GSA), or their designee, during an inspection of records conducted by GSA under authority of 44 U.S.C. 2904 and 2906, in accordance with the GSA regulations and any other relevant (i.e., GSA or Commerce) directive, where such disclosure shall not be used to make determinations about individuals;

8) another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c));

9) the Office of Personnel Management (OPM) for personnel research purposes; and

10) the Office of Management and Budget (OMB) for legislative coordination and clearance.

If you do not furnish the information requested on this form, the USPTO may not be able to process and/or examine your submission, which may result in termination of proceedings, abandonment of the application, and/or expiration of the patent.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT		
	Application Number	18/898,239
	Filing Date	09/26/2024
	First Named Inventor	Bobby E. Rogers
	Art Unit	3791
	Client Number	069366
Page 1 of 1	**Matter Number**	0581370_KUR2C07US

GENERAL

Pursuant to 37 C.F.R. 1.97 and 1.98 and to the duty of disclosure set forth in 37 C.F.R. 1.56, the Examiner in charge of the above-identified application is requested to consider and make of record the references listed herewith. A copy of each listed reference, other than U.S. patents/applications and references cited in a parent application, is enclosed.

Although the information submitted herewith may be "material" to the Examiner's consideration of the subject application, this submission is not intended to constitute an admission that such information is "prior art" as to the claimed invention, nor is it intended to constitute an admission that such information is "analogous prior art".

In accordance with 37 C.F.R. 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.

TIMING

In accordance with 37 CFR 1.97(b), this Information Disclosure Statement is being filed within three months of the filing of a national application other than a continued prosecution application under 37 CFR 1.53(d); within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 in an international application; before the mailing of a first Office Action on the merits; or before the mailing of a first Office Action after the filing of a request for continued examination under 37 CFR 1.114.

CERTIFICATION STATEMENT

No certification statement is required. This Information Disclosure Statement is being filed in accordance with 37 CFR 1.97(b).

FEE

No PTO Timing Fee is required. This Information Disclosure Statement is being filed in accordance with 37 CFR 1.97(b).

If necessary, the Director is hereby authorized to charge or credit Deposit Account No. 033975 for any additional fees, or any underpayment or credit for overpayment in connection herewith. Please reference attorney docket number 069366-0581370_KUR2C07US for any such charge or credit.

No PTO IDS Size Fee under § 1.17(v) is due.

ADDITIONAL COMMENTS

SIGNATURE

Signature	/Ben Hudson/	**Date**	2025-07-02
Name	Benjamin F. Hudson	**Registration Number**	71,474

SyncIDS.com

PTO/SB/30EFS (01-22)
Approved for use through 05/31/2024. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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REQUEST FOR CONTINUED EXAMINATION(RCE)TRANSMITTAL
(Submitted Only via EFS-Web)

Application Number	18/898,239	Filing Date	2024-09-26	Docket Number (if applicable)	069366-0581370_KUR2C07U	Art Unit	3791
First Named Inventor	Bobby E. Rogers			Examiner Name	May A. Abouelela		

This is a Request for Continued Examination (RCE) under 37 CFR 1.114 of the above-identified application.
Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, or to any design application. The Instruction Sheet for this form is located at WWW.USPTO.GOV

SUBMISSION REQUIRED UNDER 37 CFR 1.114

Note: If the RCE is proper, any previously filed unentered amendments and amendments enclosed with the RCE will be entered in the order in which they were filed unless applicant instructs otherwise. If applicant does not wish to have any previously filed unentered amendment(s) entered, applicant must request non-entry of such amendment(s).

☐ Previously submitted. If a final Office action is outstanding, any amendments filed after the final Office action may be considered as a submission even if this box is not checked.

- ☐ Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____
- ☐ Other _____

☒ Enclosed

- ☒ Amendment/Reply
- ☒ Information Disclosure Statement (IDS)
- ☐ Affidavit(s)/ Declaration(s)
- ☐ Other _____

MISCELLANEOUS

☐ Suspension of action on the above-identified application is requested under 37 CFR 1.103(c) for a period of months _____
(Period of suspension shall not exceed 3 months; Fee under 37 CFR 1.17(i) required)

☐ Other _____

FEES

☒ **The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.**
The Director is hereby authorized to charge any underpayment of fees, or credit any overpayments, to Deposit Account No 033975

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

☒ Patent Practitioner Signature

☐ Applicant Signature

PTO/SB/30EFS (01-22)
Approved for use through 05/31/2024. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Signature of Registered U.S. Patent Practitioner			
Signature	/Ben Hudson/	Date (YYYY-MM-DD)	2025-07-02
Name	Benjamin F. Hudson	Registration Number	71,474

This collection of information is required by 37 CFR 1.114. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

UNITED STATES
PATENT AND TRADEMARK OFFICE

P.O. Box 1450
Alexandria, VA 22313 - 1450
www.uspto.gov

ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
18/898,239	**07/02/2025 06:44:57 PM Z ET**	**069366-0581370_KUR2C07US**

Title of Invention

BLOOD SAMPLE OPTIMIZATION DEVICE

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	7801	FILED BY	TRENT TERCENIO
PATENT CENTER #	71189265	FILING DATE	09/26/2024
CUSTOMER #	27500	FIRST NAMED INVENTOR	Bobby E. Rogers
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	Benjamin Hudson

Documents

TOTAL DOCUMENTS: 24

DOCUMENT		PAGES	DESCRIPTION	SIZE (KB)
069366-0581370_KUR2C07US FINAL Response to Final Office Action rcvd 06JAN2025 4934-1579-3490 v.1.pdf		12	-	175 KB
069366-0581370_KUR2C07US FINAL Response to Final Office Action rcvd 06JAN2025 4934-1579-3490 v.1-A.NE.pdf	(1-1)	1	Response After Final Action	96 KB
069366-0581370_KUR2C07US FINAL Response to Final	(2-6)	5	Claims	127 KB

Office Action rcvd 06JAN2025 4934-1579-3490 v.1-CLM.pdf				
069366-0581370_KUR2C07US FINAL Response to Final Office Action rcvd 06JAN2025 4934-1579-3490 v.1-REM.pdf	(7-12)	6	Applicant Arguments/Remarks Made in an Amendment	155 KB
069366-0581370_KUR2C07US-NPL-008.pdf		11	Non Patent Literature	326 KB
069366-0581370_KUR2C07US-NPL-010.pdf		9	Non Patent Literature	528 KB
069366-0581370_KUR2C07US-NPL-012.pdf		11	Non Patent Literature	303 KB
069366-0581370_KUR2C07US-NPL-006.pdf		28	Non Patent Literature	1151 KB
069366-0581370_KUR2C07US-NPL-013.pdf		7	Non Patent Literature	243 KB
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069366-0581370_KUR2C07US-NPL-014.pdf		1	Non Patent Literature	119 KB
069366-0581370_KUR2C07US-NPL-009.pdf		62	Non Patent Literature	2532 KB
069366-0581370_KUR2C07US-NPL-015.pdf		34	Non Patent Literature	1252 KB
069366-0581370_KUR2C07US-NPL-002.pdf		3	Non Patent Literature	135 KB
069366-0581370_KUR2C07US-NPL-		23	Non Patent Literature	972 KB

003.pdf			
069366-0581370_KUR2C07US-NPL-007.pdf	121	Non Patent Literature	5312 KB
069366-0581370_KUR2C07US-NPL-004.pdf	19	Non Patent Literature	706 KB
069366-0581370_KUR2C07US-NPL-001.pdf	70	Non Patent Literature	2845 KB
069366-0581370_KUR2C07US-NPL-005.pdf	5	Non Patent Literature	281 KB
069366-0581370_KUR2C07US-Foreign-001-FOR.pdf	92	Foreign Reference	5061 KB
069366-0581370_KUR2C07US-Foreign-002-FOR.pdf	132	Foreign Reference	6904 KB
069366-0581370_KUR2C07US_Transmittal-Letter.pdf	1	Transmittal Letter	501 KB
069366-0581370_KUR2C07US_PTO_IDS-Form.pdf	7	Information Disclosure Statement (IDS) Form (SB08)	1261 KB
069366-0581370_KUR2C07US RCE-1st.pdf	3	Request for Continued Examination (RCE)	1628 KB
069366-0581370_KUR2C07US_IDS-Size-Fee-Written-Assertion.pdf	4	Assertion regarding Information Disclosure Statement (IDS) Size Fee (SB/08C)	263 KB

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
069366-0581370_KUR2C07US FINAL Response to Final Office Action rcvd 06JAN2025 4934-1579-3490 v.1.pdf	A27A734DA1DB48E71AA806D104085702989403C44F662DD526DFB794789F5A6F7C3DF81CF4CDBDC268ECA25E2B770FCCE199F709961F1264E1F937CAAFA28CC0

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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

LISTING OF CLAIMS

This listing of claims replaces all prior versions of claims in the application:

1. (Original) A device comprising:

an inlet port for receiving a blood sample;

an outlet port;

a chamber connected with the inlet port and configured to collect a first portion of the blood sample when under a drawing force applied from the outlet port from a blood sample collection device; and

a sampling channel connected with the inlet port and configured to convey a subsequent portion of the blood sample to the outlet port.

2. (Original) The device in accordance with claim 1, wherein a blood impermeable membrane is configured to facilitate the chamber collecting the first portion of the blood sample.

3. (Original) The device in accordance with claim 1, wherein a blood impermeable membrane causes the first portion of the blood sample to back up into the chamber following application of the drawing force applied from the outlet port.

4. (Original) The device in accordance with claim 2, further comprising a housing, separate from the blood impermeable membrane.

5. (Original) The device in accordance with claim 1, wherein the device is configured such that, when the drawing force is applied at the outlet port, the first portion of the blood sample is drawn into the chamber to contact a material that is blood impermeable.

6. (Original) The device in accordance with claim 1, further comprising a valve configured to initially close off the sampling channel.

7. (Original) The device in accordance with claim 1, further comprising a valve configured to initially close off the sampling channel until the first portion of the blood sample is in the chamber.

8. (Original) The device in accordance with claim 1, further comprising a valve that is configured to initially close off the sampling channel until the first portion of the blood sample is in the chamber and is further configured such that, upon release, follow-on amounts of the blood sample will bypass the chamber and flow through the sampling channel toward the outlet port.

9. (Original) The device in accordance with claim 6, wherein the valve is configured to pinch, shunt, bend or otherwise close off the sampling channel before the first portion of the blood sample is collected in the chamber.

10. (Cancelled)

11. (Previously Presented) The device in accordance with claim 1, further comprising a patient needle and the blood sample collection device.

12. (Original) The device in accordance with claim 1, the chamber having a volume sufficient to collect the first portion of the blood sample that is more prone to contamination and also to minimize an amount of blood to be sequestered.

13. (Original) The device in accordance with claim 1, wherein the chamber has a volume of less than 1.5 cubic centimeters.

14. (Original) A device comprising:

an inlet port for receiving blood;

an outlet port;

a chamber comprising a flexible material, the chamber connected with the inlet port and configured to collect a first portion of the blood when under a drawing force applied from the outlet port; and

a sampling channel connected with the inlet port and configured to convey a subsequent portion of the blood to the outlet port.

15. (Original) The device in accordance with claim 14, wherein the flexible material is a blood impermeable membrane configured to facilitate the chamber collecting the first portion of the blood.

16. (Original) The device in accordance with claim 14, wherein the flexible material is a blood impermeable membrane causes the first portion of the blood to back up into the chamber following application of the drawing force applied from the outlet port.

17. (Original) The device in accordance with claim 15, further comprising a housing, separate from the blood impermeable membrane.

18. (Original) The device in accordance with claim 14, wherein the device is configured such that, when the drawing force is applied at the outlet port, the first portion of the blood is drawn into the chamber to contact a material that is blood impermeable.

19. (Original) The device in accordance with claim 14, further comprising a valve configured to initially close off the sampling channel.

20. (Original) The device in accordance with claim 14, further comprising a valve configured to initially close off the sampling channel until the first portion of the blood is in the chamber.

21. (Original) The device in accordance with claim 14, further comprising a valve that is configured to initially close off the sampling channel until the first portion of the blood is in the chamber and is further configured such that, upon release, follow-on amounts of the blood will bypass the chamber and flow through the sampling channel toward the outlet port.

22. (Original) The device in accordance with claim 19, wherein the valve is configured to pinch, shunt, bend or otherwise close off the sampling channel before the first portion of the blood is collected in the chamber.

23. (Cancelled)

24. (Original) The device in accordance with claim 14, further comprising a patient needle and a sample collection device.

25. (Original) The device in accordance with claim 14, the chamber having a volume sufficient to collect the first portion of the blood that is more prone to contamination and also to minimize an amount of blood to be sequestered.

26. (Original) The device in accordance with claim 14, wherein the chamber has a volume of less than 1.5 cubic centimeters.

REMARKS

Claim Summary: Prior to this response, Claims 1-9, 11-22, and 24-26 were pending. No claims are amended with this response. Reconsideration and allowance of the current application are requested in light of the following remarks.

Summary of Rejections: The Office rejects Claims 1, 6-9, 11, 12, 14, 19-22, 24 and 25 under 35 U.S.C. §102(a)(1) as allegedly being anticipated by Patton, et al. (U.S. 2008/0145933), hereinafter "Patton;" rejects Claims 2-5 and 15-18 as allegedly being unpatentable under 35 U.S.C. §103 over Patton in view of Flaherty, et al. (U.S. 2006/0009713), hereinafter "Flaherty;" and rejects Claims 13 and 26 under 35 U.S.C. §103 as allegedly being anticipated by Patton.

No Change in Scope of Claims: The Office is respectfully reminded that the scope of at least one claim has remained unchanged in this Response. If new grounds of rejection for an unchanged claim are presented in a subsequent action, per MPEP§706.07(a), that subsequent action cannot properly be made final.

Request for Interview: The present response is believed to be sufficient to overcome the pending rejections. However, if this paper is not deemed sufficient to result in a notice of allowance, or if any remaining issues can be more efficiently handled by telephone, the Examiner is respectfully requested to contact the undersigned by either phone or e-mail to schedule an interview at a mutually convenient time.

Rejections under 35 U.S.C. §102

The Office Action rejects Claim 1 as allegedly anticipated in view of Patton. However, Patton fails to disclose or suggest at least the following elements of Claim 1:

> "a chamber … configured to collect a first portion of the blood sample when under a drawing force **applied from the outlet port**."

The Office Action concludes that Patton discloses these elements, citing to Paragraph [0040] of the reference. However, Patton does not state that the vacuum from sample vessel 506 draws blood into the pre-sample reservoir 504. Paragraph [0040] only states that the drawing force at the outlet causes blood to pass **up to the diversion mechanism**. Patton's diversion mechanism then seals off the pre-sample reservoir from the drawing force at the outlet, preventing that drawing force from filling the pre-sample reservoir.

To keep contaminated blood isolated from a desired sample, Patton states that diversion mechanism 512 has two positions that each make a seal resulting in a path to the pre-sample reservoir 504 **or** sample vessel 506, **not both**. See, e.g., Figures 6A and 6B (annotated):

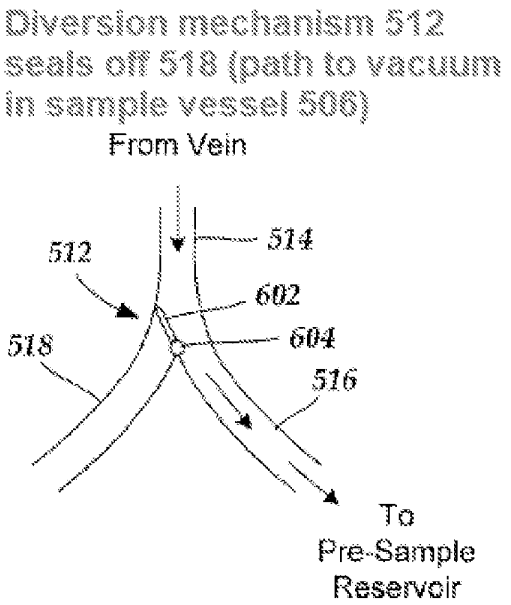


Fig. 6A

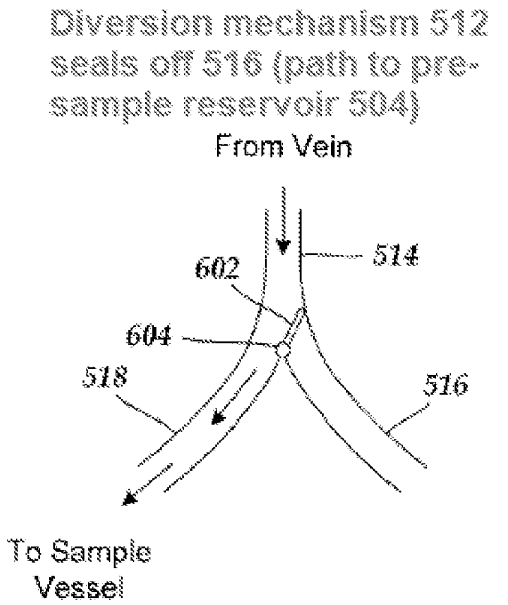


Fig. 6B

When switchable valve 602 is in the first position (Fig. 6A) it **creates a seal** disallowing the vacuum of sample vessel 506 from acting as a drawing force applied from an outlet port, as claimed. See, e.g., Paragraph [0041]:

> [0041] "…in a first position…switchable valve 602 **creates a seal** disallowing the flow of blood [to 518/510/506]…"

Accordingly, any vacuum provided by Patton's sample vessel 506 is **sealed off** from the pre-sample reservoir and **cannot** cause the pre-sample reservoir to collect a first portion of the blood sample, as claimed.

This understanding of Patton is further evidenced by its disclosure in Paragraph [0040] that blood flows to either the pre-sample reservoir or to the sample vessel:

> "The diversion mechanism 512 can be adjusted to divert the flow of blood to **either** the one or more pre-sample reservoirs 504 **or** to the … sample vessels 506."

In addition, Patton repeatedly discloses drawing blood into pre-sample reservoirs (e.g., vacutainers) by using their own vacuum rather than a drawing force applied from an outlet port, as claimed. See, e.g., Patton's Claim 1, Claim 15, and Paragraphs [0026] and [0030]:

> Claim 1: "**at least one vacuum-sealed pre-sample reservoir**, each of the at least one vacuum-sealed pre-sample reservoirs configured and arranged for collecting and storing patient bodily fluid withdrawn from the bodily-fluid withdrawing device; and
> at least one vacuum-sealed sample vessel…."
>
> Claim 15: "inserting the second sterile needle into a **vacuum-sealed pre-sample reservoir** and draining a predetermined amount of bodily fluids into the vacuum-sealed pre-sample reservoir;
> inserting the second sterile needle into a first vacuum-sealed sample vessel…"
>
> [0026] "Each of the one or more pre-sample reservoirs 104 is sterile and includes a septum 122 covering a mouth 124 of each of the pre-sample reservoirs 104. Each septum 122 seals the mouth 124 and maintains **an internal vacuum inside the pre-sample reservoir** 104."
>
> [0030] "The second needle 112 is inserted through the septum 122 and into the one or more **pre-sample reservoirs** 104, **which contains an internal vacuum**."

Accordingly, blood flow into the pre-sample reservoir is repeatedly described by Patton as being caused by a vacuum in the pre-sample reservoir and not by a vacuum applied from the outlet to

the sample vessel.

In summary, Patton:

- Fails to disclose that a vacuum from the outlet (sample vessel) is used to draw blood into the chamber (pre-sample vessel).
- Discloses instead that its diversion mechanism **seals off** the pre-sample reservoir from any vacuum in the sample vessel.
- Describes the scenario of the **pre-sample reservoir being a vacutainer** with its own vacuum to draw in blood.

Claim 14

The Office Action also rejects Claim 14 as allegedly anticipated in view of Patton. However, Patton fails to disclose or suggest at least the following elements of Claim 14:

"a **chamber** comprising a **flexible** material…"

In the rejection, the Office Action refers to "flexible material of tubing 516 and reservoir 504" (Office Action, p. 3) as allegedly disclosing the above elements by assuming that because tubing 516 is disclosed as flexible that reservoir 504 is also flexible. However, Patton never discloses that reservoir 504 comprises any flexible material. Instead, Patton discloses "flexible, sterile input **tubing** 516" as being a distinct element from reservoir 504 and merely used to couple reservoir 504 to diversion mechanism 512. See, e.g., Patton [0039]:

> "…the one or more **pre-sample reservoirs 504 are coupled** to the diversion mechanism 512 **via the one or more first sterile output tubing 516**."

Accordingly, Applicant respectfully disagrees with the assertion that pre-sample reservoir 504 is also disclosed as flexible.

Moreover, tubing 516 cannot even properly be considered as storing contaminated blood and thus cannot properly be used to (in part) anticipate the chamber of Claim 14. Patton explains that rather than relying on the volume of tubing 516 holding hold contaminated blood, it is

instead pre-sample reservoir 504 that specifically has a volume at least equal to the volumes of the components that come before it (including tubing 516) – presumably so contaminated blood does **not** need to be stored in tubing 516. See, e.g., Patton [0040]:

> "…the **volume of blood withdrawn into the one or more pre-sample reservoirs 504 is at least equal to** the collective volumes of the first needle 508, the flexible, sterile input tubing 516, the diversion mechanism 512, and **the first sterile output tubing 516**."

Accordingly, even though Patton discloses tubing 516, Patton does not disclose it as being part of pre-sample reservoir 504 and therefore cannot properly be said as anticipating the above elements of Claim 14.

For at least the reasons given above, the art of record fails to disclose or suggest each of the elements of Claim 1 and Claim 14 and thus withdrawal of the pending rejection under §102 is respectfully requested.

Each of the remaining pending claims depends from one of independent Claims 1 or 14 and thus each is likewise patentable for at least the reasons discussed above.

Applicant respectfully asserts that the additional references cited by the Office Action in the rejection of dependent Claims 2-5 fail to cure these deficiencies of Patton.

CONCLUSION

On the basis of the foregoing remarks and/or amendments, allowance of the pending claims is respectfully requested. It is believed that all the pending rejections have been addressed in this paper. However, failure to address a specific rejection, issue or comment, does not signify agreement with or concession of that rejection, issue or comment. In addition, because any arguments made above are not intended to be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed. Finally,

nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper.

Applicant is concurrently filing a petition and fee for a three-month extension of time along with a Request for Continued Examination. No additional fees are believed to be due, however the Commissioner is authorized to charge any fees that may be due, or credit any overpayment of same, to Deposit Account 033975, Reference No. 069366-0581370_KUR2C07US. If there are any questions regarding this submission, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

Respectfully submitted,
PILLSBURY WINTHROP SHAW PITTMAN LLP

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4934-2324-4045.v1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Bobby E. Rogers, et al.

Confirmation No: 7801

Application No.: 18/898,239

Art Unit: 3791

Filed: September 26, 2024

Examiner: May A. Abouelela

For: BLOOD SAMPLE OPTIMIZATION DEVICE

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE TO FINAL OFFICE ACTION

Dear Examiner Abouelela:

This reply is responsive to the Final Office Action mailed January 6, 2025, in the above-referenced matter (hereinafter "the Office Action"). Reconsideration and allowance of the application is requested in view of the following:

Listing of Claims beginning on page 2.

Remarks beginning on page 7.

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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 18/898,239	Filing Date 09/26/2024	☐ To be Mailed

ENTITY: ☐ LARGE ☑ SMALL ☐ MICRO

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA		RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A		N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A		N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*		x $40 =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*		x $ 192 =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).				
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))					
* If the difference in column 1 is less than zero, enter "0" in column 2.				TOTAL	

APPLICATION AS AMENDED - PART II

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT	07/02/2025	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 24	Minus	** 24	= 0		x $80 =	0
	Independent (37 CFR 1.16(h))	* 2	Minus	*** 3	= 0		x $240 =	0
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	0

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=		x $0 =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=		x $0 =	
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.	SLIE
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".	/SHEMICA K DOWNING/
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".	
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.	

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ABOUELELA, MAY A	
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3791	

DATE MAILED: 07/18/2025

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/898,239	09/26/2024	Bobby E. Rogers	069366-0581370_KUR2C07US	7801

TITLE OF INVENTION: BLOOD SAMPLE OPTIMIZATION DEVICE

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$516	$0.00	$0.00	$516	10/20/2025

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 40% the amount of undiscounted fees, and micro entity fees are 20% the amount of undiscounted fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Maintenance fees are due in utility patents issuing on applications filed on or after Dec. 12, 1980. It is patentee's responsibility to ensure timely payment of maintenance fees when due. More information is available at www.uspto.gov/PatentMaintenanceFees.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), by mail or fax, or via the USPTO patent electronic filing system.

By mail, send to: Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

By fax, send to: (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications. **Because electronic patent issuance may occur shortly after issue fee payment, any desired continuing application should preferably be filed prior to payment of this issue fee in order not to jeopardize copendency.**

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

27500 7590 07/18/2025

PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
ATTENTION: DOCKETING DEPARTMENT
P.O BOX 10500
McLean, VA 22102

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being transmitted to the USPTO via the USPTO patent electronic filing system or by facsimile to (571) 273-2885, on the date below.

(Typed or printed name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/898,239	09/26/2024	Bobby E. Rogers	069366-0581370_KUR2C07US	7801

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nonprovisional	SMALL	$516	$0.00	$0.00	$516	10/20/2025

EXAMINER	ART UNIT	CLASS-SUBCLASS
ABOUELELA, MAY A	3791	600-577000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

❑ Change of correspondence address (or Change of Correspondence Address form PTO/AIA/122 or PTO/SB/122) attached.

❑ "Fee Address" indication (or "Fee Address" Indication form PTO/AIA/47 or PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 _____
2 _____
3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ❑ Individual ❑ Corporation or other private group entity ❑ Government

4a. Fees submitted: ❑ Issue Fee ❑ Publication Fee (if required)

4b. Method of Payment: *(Please first reapply any previously paid fee shown above)*

❑ Electronic Payment via the USPTO patent electronic filing system ❑ Enclosed check ❑ Non-electronic payment by credit card (Attach form PTO-2038)

❑ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. _____

5. **Change in Entity Status** (from status indicated above)

❑ Applicant certifying micro entity status. See 37 CFR 1.29

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

❑ Applicant asserting small entity status. See 37 CFR 1.27

NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

❑ Applicant changing to regular undiscounted fee status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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27500 7590 07/18/2025

PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
ATTENTION: DOCKETING DEPARTMENT
P.O BOX 10500
McLean, VA 22102

EXAMINER	
ABOUELELA, MAY A	

ART UNIT	PAPER NUMBER
3791	

DATE MAILED: 07/18/2025

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. The United States Patent and Trademark Office (USPTO) collects the information in this record under authority of 35 U.S.C. 2. The USPTO's system of records is used to manage all applicant and owner information including name, citizenship, residence, post office address, and other information with respect to inventors and their legal representatives pertaining to the applicant's/ owner's activities in connection with the invention for which a patent is sought or has been granted. The applicable Privacy Act System of Records Notice for the information collected in this form is COMMERCE/PAT-TM-7 Patent Application Files, available in the Federal Register at 78 FR 19243 (March 29, 2013).
https://www.govinfo.gov/content/pkg/FR-2013-03-29/pdf/2013-07341.pdf

Routine uses of the information in this record may include disclosure to:

1) law enforcement, in the event that the system of records indicates a violation or potential violation of law;
2) a federal, state, local, or international agency, in response to its request;
3) a contractor of the USPTO having need for the information in order to perform a contract;
4) the Department of Justice for determination of whether the Freedom of Information Act (FOIA) requires disclosure of the record;
5) a Member of Congress submitting a request involving an individual to whom the record pertains, when the individual has requested the Member's assistance with respect to the subject matter of the record;
6) a court, magistrate, or administrative tribunal, in the course of presenting evidence, including disclosures to opposing counsel in the course of settlement negotiations;
7) the Administrator, General Services Administration (GSA), or their designee, during an inspection of records conducted by GSA under authority of 44 U.S.C. 2904 and 2906, in accordance with the GSA regulations and any other relevant (i.e., GSA or Commerce) directive, where such disclosure shall not be used to make determinations about individuals;
8) another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c));
9) the Office of Personnel Management (OPM) for personnel research purposes; and
10) the Office of Management and Budget (OMB) for legislative coordination and clearance.

If you do not furnish the information requested on this form, the USPTO may not be able to process and/or examine your submission, which may result in termination of proceedings, abandonment of the application, and/or expiration of the patent.

Notice of Allowability	Application No. 18/898,239	Applicant(s) Rogers et al.	
	Examiner MAY A ABOUELELA	Art Unit 3791	AIA (First Inventor to File) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☑ This communication is responsive to 07/02/2025.
   ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

3. ☑ The allowed claim(s) is/are 1-9,11-22 and 24-26 . As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information , please see **http://www.uspto.gov/patents/init_events/pph/index.jsp** or send an inquiry to **PPHfeedback@uspto.gov.**

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

   Certified copies:

   a) ☐ All b) ☐ Some* c) ☐ None of the:

   1. ☐ Certified copies of the priority documents have been received.
   2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
   3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____ .

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____ .

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☑ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____.
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material _____.
4. ☐ Interview Summary (PTO-413), Paper No./Mail Date. _____.
5. ☐ Examiner's Amendment/Comment
6. ☑ Examiner's Statement of Reasons for Allowance
7. ☐ Other _____.

/MAY A ABOUELELA/
Primary Examiner, Art Unit 3791

Notice of Pre-AIA or AIA Status

1. The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 07/02/2025 has been entered.

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on 07/02/2025. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Terminal Disclaimer

4. The terminal disclaimer filed on 12/17/2024 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S Patent No.12,138,052 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Response to Arguments

5. Applicant's arguments with respect to 102 and 103 rejections have been fully considered and are persuasive. The 102 and 103 rejections have been withdrawn.

Allowable Subject Matter

6. Claims 1-9, 11-22 and 24-26 are allowed.

7. The following is an examiner's statement of reasons for allowance: the combination of the most pertinent prior art (see Final Rejection mailed om 01/06/2025) teaches a device comprising: an inlet port for receiving a blood sample; an outlet port; a chamber connected with the inlet port and configured to collect a first portion of the blood sample; and a sampling channel connected with the inlet port and configured to convey a subsequent portion of the blood sample to the outlet port.

The prior art does not teach, disclose and/or fairly suggest the chamber connected with the inlet port and configured to collect a first portion of the blood sample when under a drawing force applied from the outlet port from a blood sample collection device.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MAY A ABOUELELA whose telephone number is (571)270-7917. The examiner can normally be reached 8-5.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JACQUELINE CHENG can be reached at 5712725596. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: https://patentcenter.uspto.gov. Visit https://www.uspto.gov/patents/apply/patent-center for more information about Patent Center and https://www.uspto.gov/patents/docx for information about filing in DOCX format. For additional questions, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MAY A ABOUELELA/
Primary Examiner, Art Unit 3791

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	18/898,239	Rogers et al.
	Examiner	Art Unit
	MAY A ABOUELELA	3791

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

CLAIMS

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☑ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	11/13/2024	12/23/2024	07/08/2025						
1	1	✓	✓	=						
2	2	✓	✓	=						
3	3	✓	✓	=						
4	4	✓	✓	=						
5	5	✓	✓	=						
6	6	✓	✓	=						
7	7	✓	✓	=						
8	8	✓	✓	=						
9	9	✓	✓	=						
	10	-	-	-						
10	11	✓	✓	=						
11	12	✓	✓	=						
12	13	✓	✓	=						
13	14	✓	✓	=						
14	15	✓	✓	=						
15	16	✓	✓	=						
16	17	✓	✓	=						
17	18	✓	✓	=						
18	19	✓	✓	=						
19	20	✓	✓	=						
20	21	✓	✓	=						
21	22	✓	✓	=						
	23	-	-	-						
22	24	✓	✓	=						
23	25	✓	✓	=						
24	26	✓	✓	=						

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	18/898,239	Rogers et al.
	Examiner	**Art Unit**
	MAY A ABOUELELA	3791

CPC						
Symbol					**Type**	**Version**
A61B	/	5	/	150992	F	2013-01-01
A61M	/	39	/	04	I	2013-01-01
A61B	/	5	/	150221	I	2013-01-01
A61B	/	5	/	15003	I	2013-01-01
A61B	/	5	/	150213	I	2013-01-01
A61B	/	5	/	150389	I	2013-01-01
A61B	/	5	/	150473	I	2013-01-01
A61B	/	5	/	150572	I	2013-01-01
A61B	/	5	/	154	I	2013-01-01
A61B	/	5	/	153	I	2013-01-01
A61M	/	39	/	0693	I	2013-01-01
A61M	/	2039	/	0202	A	2013-01-01
A61M	/	2039	/	068	A	2013-01-01
A61M	/	2039	/	0633	A	2013-01-01

CPC Combination Sets							
Symbol					**Type**	**Set**	**Ranking**	**Version**
	/		/					

NONE		**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	24	
/MAY A ABOUELELA/ Primary Examiner, Art Unit 3791	08 July 2025	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	23A

U.S. Patent and Trademark Office — Part of Paper No.: 20250708

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	18/898,239	Rogers et al.
	Examiner	**Art Unit**
	MAY A ABOUELELA	3791

INTERNATIONAL CLASSIFICATION					
CLAIMED					
A61B	/	5	/	00	

NON-CLAIMED					
	/		/		

US ORIGINAL CLASSIFICATION	
CLASS	**SUBCLASS**

CROSS REFERENCES(S)						
CLASS	**SUBCLASS (ONE SUBCLASS PER BLOCK)**					

NONE (Assistant Examiner) (Date)	**Total Claims Allowed:** 24	
/MAY A ABOUELELA/ Primary Examiner, Art Unit 3791 (Primary Examiner) 08 July 2025 (Date)	O.G. Print Claim(s) 1	O.G. Print Figure 23A

U.S. Patent and Trademark Office Part of Paper No.: 20250708

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
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	Examiner	**Art Unit**
	MAY A ABOUELELA	3791

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☑ T.D. ☐ R.1.47

CLAIMS

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
1	1		10	18	19										
2	2	10	11	19	20										
3	3	11	12	20	21										
4	4	12	13	21	22										
5	5	13	14		23										
6	6	14	15	22	24										
7	7	15	16	23	25										
8	8	16	17	24	26										
9	9	17	18												

NONE		**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	24	
/MAY A ABOUELELA/ Primary Examiner, Art Unit 3791	08 July 2025	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	23A

U.S. Patent and Trademark Office Part of Paper No.: 20250708

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	18/898,239	Rogers et al.
	Examiner	Art Unit
	MAY A ABOUELELA	3791

CPC - Searched*		
Symbol	**Date**	**Examiner**
(A61B5/150992 or A61B5/15003 or A61B5/150213 or A61B5/150221 or A61B5/150389 or A61B5/150473 or A61B5/150572 or A61B5/153 or A61B5/154 or A61M39/04 or A61M39/0693 or A61M2039/0202 or A61M2039/0633 or A61M2039/068).cpc.	11/13/2024	MA
updated as above	12/23/2024	MA
updated as above	07/08/2025	MA

CPC Combination Sets - Searched*		
Symbol	**Date**	**Examiner**

US Classification - Searched*			
Class	**Subclass**	**Date**	**Examiner**

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	**Date**	**Examiner**
inventor name search, class/subclass search, text search	11/13/2024	MA
updated as above	12/23/2024	MA
updated as above	07/08/2025	MA

Interference Search			
US Class/CPC Symbol	**US Subclass/CPC Group**	**Date**	**Examiner**
as above		07/08/2025	MA

/MAY A ABOUELELA/ Primary Examiner, Art Unit 3791	

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
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	Examiner	Art Unit
	MAY A ABOUELELA	3791

/MAY A ABOUELELA/ Primary Examiner, Art Unit 3791	

Bibliographic Data

Application No: 18/898,239

Foreign Priority claimed: ○ Yes ◉ No

35 USC 119 (a-d) conditions met: ☐ Yes ☑ No ☑ Met After Allowance

Verified and Acknowledged: /MAY A ABOUELELA/ (Examiner's Signature) | M.A.A (Initials)

Title: BLOOD SAMPLE OPTIMIZATION DEVICE

FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
09/26/2024	600	3791	069366-0581370_KUR2C07US
RULE			

APPLICANTS

Kurin, Inc., San Diego, CA, UNITED STATES

INVENTORS

Bobby E. Rogers, Park City, CA, UNITED STATES

Gino Kang, Irvine, CA, UNITED STATES

John Detloff, San Diego, CA, UNITED STATES

CONTINUING DATA

This application is a CON of 18783088 07/24/2024 PAT 12138052

18783088 is a CON of 18494622 10/25/2023 PAT 12357209

18494622 is a CON of 18113710 02/24/2023 PAT 11832944

18113710 is a CON of 17538990 11/30/2021 PAT 11963769

17538990 is a CON of 16208559 12/04/2018 PAT 11185266

16208559 is a CON of 15994559 05/31/2018 PAT 10143412

15994559 is a CON of 15140448 04/27/2016 PAT 10010282

15140448 has PRO of 62318194 04/04/2016

15140448 has PRO of 62238636 10/07/2015

15140448 has PRO of 62196797 07/24/2015

FOREIGN APPLICATIONS

IF REQUIRED, FOREIGN LICENSE GRANTED**

10/17/2024

** SMALL ENTITY **

STATE OR COUNTRY

UNITED STATES

ADDRESS

PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
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P.O BOX 10500
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PE2E SEARCH - Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
L1	0	("15140443").PN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2016/12/20 11:05 PM
L2	1	("20020099309").PN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2016/12/21 11:38 AM
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L120	1258	(600/583).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2018/07/24 02:06 PM
L121	1074	L120 and (blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/07/24 02:06 PM
L122	80	L121 and (vent$4 near4 air)	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/07/24 02:06 PM
L123	301210	(blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2018/07/24 02:11 PM
L124	6556	L123 AND ((A61B10/0096 OR A61B5/150022).CPC.)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2018/07/24 02:11 PM
L125	3664	L124 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/07/24 02:12 PM
L126	12749	"19" and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/07/24 02:12 PM
L127	117	L125 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/07/24 02:12 PM
L128	1348	(604/164.01).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2018/07/24 02:16 PM
L129	75	L128 and (blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/07/24 02:17 PM
L130	1	("20120291564").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2018/07/24 02:21 PM
L131	448	(435/294.1).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2018/07/24 02:25 PM
L132	18	L131 and (blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/07/24 02:25 PM
L133	98	("20020002349" | "20020183651" | "20030055381" | "20030208151" | "20040010228" | "20040054333" |	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2018/07/24 02:44 PM

		"20040147855" | "20050004524" | "20050240161" | "20050245885" | "20050281713" | "20060287639" | "20080108954" | "20080145933" | "2707953" | "3013557" | "3098016" | "3382865" | "3405706" | "3494351" | "3577980" | "3648684" | "3848579" | "3937211" | "4057050" | "4133863" | "4166450" | "4340067" | "4370987" | "4444203" | "4459997" | "4509534" | "4657160" | "4676256" | "4865583" | "4890627" | "4988339" | "5009847" | "5097842" | "5108927" | "5122129" | "5269317" | "5330464" | "5360011" | "5429610" | "5450856" | "5507299" | "5577513" | "5762633" | "5865812" | "5882318" | "5922551" | "6016712" | "6057105" | "6159164" | "6210909" | "6364890" | "6387086" | "6403381" | "6626884" | "6692479" | "6746420" | "6913580" | "7044941" | "7087047" | "7335188" | "7744573" | "8197420" | "8231546" | "8337418").PN. OR ("8535241").URPN.					
L134	307	("2913000" | "3817240" | "3859998" | "3864979" | "4016879" | "4046144").PN. OR ("4207870").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2018/07/24 02:47 PM
L135	23	("4166450").PN. OR ("4412548").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2018/07/24 02:48 PM
L136	307	("2913000" | "3817240" | "3859998" | "3864979" | "4016879" | "4046144").PN. OR ("4207870").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2018/07/24 02:48 PM
L137	4	("2007/0088279").URPN.	(USPAT)	OR	ON	ON	2018/07/24 02:48 PM
L138	1	(14/990763).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2018/07/24 02:58 PM
L139	9	(blood and sequest$5 and junction and first	(US-PGPUB; USPAT)	OR	ON	ON	2018/07/24 03:07 PM

		and portion and sampl$4).clm.					
L140	1	(15/287421).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2018/07/25 09:39 PM
L141	2	(14/055232).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2018/07/26 11:56 AM
L142	2	(15/140443).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/07 03:24 PM
L143	1	(15/893518).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/07 03:25 PM
L144	34	("20020004647"|"20030105414"|"20040054333"|"20040073171"|"20040147855"|"20050004524"|"20050240161"|"20070088279"|"20080145933"|"20100057004"|"20130317391"|"20160174888"|"3817240"|"3874367"|"3886930"|"4057050"|"4106497"|"4154229"|"4207870"|"4412548"|"5222502"|"5520193"|"5749857"|"6569117"|"8197420"|"8523826"|"8535241"|"8540663"|"8568371"|"8864684"|"9022951"|"9060724"|"9138572"|"9204864").PN.	(US-PGPUB; USPAT)	OR	ON	ON	2019/11/07 05:53 PM
L145	272	((("ROGERS") near3 ("Bobby")) OR (("KANG") near3 ("Gino")) OR (("STROUP") near3 ("David")) OR (("COCHRAN") near3 ("Jonas")) OR (("DEPTALA") near3 ("Arthur")) OR (("DETLOFF") near3 ("John")) OR (("POGUE") near3 ("Lonnie")) OR (("MACOWSKI") near3 ("Brian")) OR (("GARRETT") near3 ("Chad"))).INV.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2019/11/07 05:57 PM
L146	9	L145 and (blood near4 sequest$5)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 05:58 PM
L147	34	("20020004647"|"20030105414"|"20040054333"|"20040073171"|"20040147855"|"20050004524"|"20050240161"|"20070088279"|"200801459	(US-PGPUB; USPAT)	OR	ON	ON	2019/11/07 06:26 PM

		33"|"20100057004"|"20130317391"|"20160174888"|"3817240"|"3874367"|"3886930"|"4057050"|"4106497"|"4154229"|"4207870"|"4412548"|"5222502"|"5520193"|"5749857"|"6569117"|"8197420"|"8523826"|"8535241"|"8540663"|"8568371"|"8864684"|"9022951"|"9060724"|"9138572"|"9204864").PN.					
L148	5	L147 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 06:29 PM
L149	6	("2010/0057004").URPN.	(USPAT)	OR	ON	ON	2019/11/07 06:40 PM
L150	0	L149 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 07:20 PM
L151	1258	(600/583).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2019/11/07 07:21 PM
L152	4	L151 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 07:21 PM
L153	1766	(600/573).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/07 07:21 PM
L154	13	L153 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 07:21 PM
L155	811	(600/576).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/07 07:22 PM
L156	48	L155 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 07:22 PM
L157	1351	(604/164.01).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2019/11/07 07:43 PM
L158	17	L157 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 07:43 PM
L159	448	(435/294.1).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2019/11/07 07:43 PM
L160	6	L159 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 07:44 PM
L161	333030	(blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2019/11/07 07:44 PM
L162	6981	L161 AND ((A61B10/0096 OR A61B5/150022).CPC.)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2019/11/07 07:44 PM
L163	139	L162 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 07:44 PM
L164	117	L163 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 07:45 PM
L165	1	L146 and (enclos$3	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07

		near4 mechanism)					07:51 PM
L166	1	("7637875").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/08 04:57 PM
L167	1	(15/139716).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/11 12:09 PM
L168	1	(15/520430).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/12 11:02 AM
L169	1	("7637875").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/12 12:11 PM
L170	1	("20120253321").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/12 12:13 PM
L171	1	(15/861959).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/12 12:14 PM
L172	1	("4207870").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/12/09 02:17 PM
L173	1	("5749857").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/12/09 03:14 PM
L174	1	("20080167577").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/12/09 03:19 PM
L175	4	("2008/0167577").URPN.	(USPAT)	OR	ON	ON	2019/12/09 03:30 PM
L176	1	("8197420").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/12/09 03:31 PM
L177	39	(US-20040073171-$ or US-20160174888-$ or US-20050240161-$ or US-20040147855-$ or US-20130317391-$ or US-20050004524-$ or US-20030105414-$ or US-20020004647-$ or US-20100057004-$ or US-20070088279-$ or US-20080145933-$ or US-20040054333-$ or US-20100010372-$ or US-20080319346-$ or US-20080167577-$).did. or (US-9138572-$ or US-8568371-$ or US-8540663-$ or US-8523826-$ or US-8197420-$ or US-4057050-$ or US-8864684-$ or US-8535241-$ or US-5749857-$ or US-9060724-$ or US-9204864-$ or US-3817240-$ or US-3874367-$ or US-3886930-$ or US-4106497-$ or US-4154229-$ or US-	(US-PGPUB; USPAT)	OR	ON	ON	2019/12/09 03:37 PM

		4207870-$ or US-4412548-$ or US-5222502-$ or US-5520193-$ or US-9022951-$ or US-6569117-$ or US-3741197-$ or US-8603009-$).did.					
L178	8	("20040054333"|"8197420"|"9855001"|"9861306"|"10045724"|"10028687"|"8337418"|"10028689").PN.	(US-PGPUB; USPAT)	OR	ON	ON	2019/12/09 03:42 PM
L179	100	("20020002349" | "20020183651" | "20030055381" | "20040010228" | "20040054333" | "20040147855" | "20050004524" | "20050240161" | "20050245885" | "20050281713" | "20060287639" | "2707953" | "3013557" | "3098016" | "3382865" | "3405706" | "3494351" | "3577980" | "3648684" | "3848579" | "3937211" | "4057050" | "4133863" | "4166450" | "4340067" | "4370987" | "4444203" | "4459997" | "4509534" | "4676256" | "4865583" | "4890627" | "4988339" | "5009847" | "5097842" | "5108927" | "5122129" | "5269317" | "5360011" | "5429610" | "5450856" | "5507299" | "5577513" | "5762633" | "5882318" | "5922551" | "6016712" | "6057105" | "6159164" | "6210909" | "6364890" | "6387086" | "6403381" | "6692479" | "6746420" | "6913580" | "7044941" | "7087047").PN. OR ("8197420").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2019/12/09 03:43 PM
L180	70	L179 and (blood near4 (sequest$5 or sampl$4 or flash$4))	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2019/12/09 03:43 PM
L181	43	L180 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 03:44 PM
L182	270	((("BULLINGTON")	(US-PGPUB; USPAT;	OR	ON	ON	2019/12/09

		near3 ("Gregory")) OR (("PATTON") near3 ("Richard")) OR (("MIAZGA") near3 ("Jay")) OR (("GAW") near3 ("Shan"))).INV.	USOCR; EPO; JPO; DERWENT)				04:13 PM
L183	335813	(blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2019/12/09 04:22 PM
L184	7259	L183 AND ((A61B10/0096 OR A61B5/150022).CPC.)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2019/12/09 04:22 PM
L185	325	("2913000" | "3817240" | "3859998" | "3864979" | "4016879" | "4046144").PN. OR ("4207870").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2019/12/09 04:33 PM
L186	594	L184 and (flash$6 and seal$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 04:40 PM
L187	476	L186 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 04:40 PM
L188	1735	(600/573).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2019/12/09 05:14 PM
L189	1123	L188 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:15 PM
L190	1013	L189 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:15 PM
L191	10	L190 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:16 PM
L192	1259	(600/583).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/12/09 05:23 PM
L193	1143	L192 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:23 PM
L194	1038	L193 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:23 PM
L195	3	L194 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:23 PM
L196	811	(600/576).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/12/09 05:24 PM
L197	618	L196 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:24 PM
L198	557	L197 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:24 PM
L199	1	(15/854273).APP.	(US-PGPUB; USPAT;	OR	OFF	OFF	2019/12/09

			USOCR)				05:25 PM
L200	1351	(604/164.01).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2019/12/09 05:31 PM
L201	219	L200 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:33 PM
L202	199	L201 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:33 PM
L203	448	(435/294.1).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2019/12/09 05:36 PM
L204	44	L203 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:37 PM
L205	1	(15/508871).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/12/10 11:58 AM
L206	342199	(blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2020/03/16 12:53 PM
L207	4239	L206 AND ((A61B10/0096 OR A61B5/150022).CPC.)	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 12:53 PM
L208	146	L207 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 12:54 PM
L209	101	L208 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 12:55 PM
L210	1735	(600/573).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2020/03/16 01:38 PM
L211	1123	L210 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:38 PM
L212	1013	L211 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:39 PM
L213	22	L212 and (((vent$4 or open$5 or hole or aperture) near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:39 PM
L214	108	("20020193748" | "20030093009" | "20030105414" | "20030220614" | "20030229315" | "20040059302" | "20040092872" | "20040193120" | "20050004524" | "20050065482" | "20050124944" | "20050187493" | "20050245868" |	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2020/03/16 01:46 PM

		"20050245869" | "20050245870" | "20050245879" | "20050245885" | "20060036219" | "20060224122" | "20070106220" | "20070106224" | "20070167914" | "20080086085" | "20080177202" | "20080319345" | "20080319346" | "20090204026" | "20100262038" | "4106497" | "4207870" | "4305406" | "4572210" | "4573976" | "4641663" | "4795443" | "4840619" | "4894055" | "4900307" | "4994046" | "5015241" | "5195985" | "5215534" | "5222502" | "5242417" | "5246428" | "5256153" | "5295970" | "5303713" | "5312372" | "5336199" | "5348544" | "5356392" | "5411492" | "5439449" | "5466223" | "5501675" | "5542932" | "5599313" | "5662617" | "5665075" | "5672161" | "5676658" | "5702369" | "5704920" | "5733265" | "5755522" | "5957892" | "5984899" | "6149629" | "6224576" | "6254575" | "6261263" | "6298541" | "6344032" | "6436086" | "6440104" | "6524277" | "6533760" | "6592556" | "6623456" | "6635032" | "6648855" | "6695819" | "6699217" | "6712792" | "6780169" | "6837877" | "6869415" | "6984223" | "7001363" | "7128726" | "7147624" | "7160267" | "7163526" | "7223258" | "7226432" | "7396343" | "7428773" | "7537581" | "7766879" | "D422700" | "D442280" | "D604836" | "D604837" | "D604838" | "D604839" | "D605287").PN. OR ("8603009").URPN.					

L215	26	L214 and (((vent$4 or open$5 or hole or aperture) near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:47 PM
L216	27	("2008/0319346").URPN.	(USPAT)	OR	ON	ON	2020/03/16 01:47 PM
L217	23	("2003/0105414").URPN.	(USPAT)	OR	ON	ON	2020/03/16 01:48 PM
L218	1258	(600/583).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2020/03/16 01:52 PM
L219	1143	L218 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:52 PM
L220	25	L219 and (((vent$4 or open$5 or hole or aperture) near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:52 PM
L221	353695	((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:54 PM
L222	3643	L221 and (((vent$4 or open$5 or hole or aperture) near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:55 PM
L223	1926	L222 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:55 PM
L224	785	L223 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:56 PM
L225	7046	(600/300).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/03/16 02:32 PM
L226	14	L225 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 02:35 PM
L227	1352	(604/164.01).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2020/03/16 02:36 PM
L228	135	L227 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 02:36 PM
L229	19	L228 and (((vent$4 or open$5 or hole or aperture) near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 02:36 PM
L230	448	(435/294.1).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2020/03/16 02:47 PM
L231	3	L230 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 02:47 PM
L232	19	("2008/0145933").URPN.	(USPAT)	OR	ON	ON	2020/03/16 02:48 PM
L233	795	(600/576).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2020/03/16

							02:58 PM
L234	71	L233 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 02:58 PM
L235	57	L234 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 02:59 PM
L236	371	(600/577).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/03/16 03:12 PM
L237	11	L236 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 03:12 PM
L238	45	("20040054333"|"20050240161"|"4412548"|"5749857"|"8197420"|"9855001"|"9861306"|"20020004647"|"20100057004"|"3741197"|"20040073171"|"3874367"|"4057050"|"4106497"|"8197420"|"8535241"|"8540663"|"8603009"|"8864684"|"10045724"|"3817240"|"10028687"|"20030105414"|"5222502"|"5520193"|"6569117"|"8568371"|"20040147855"|"20070088279"|"20080145933"|"20100010372"|"3886930"|"8523826"|"9060724"|"9204864"|"8337418"|"20050004524"|"20080167577"|"20080319346"|"20130317391"|"4154229"|"9022951"|"10028689"|"20160174888"|"4207870"|"9138572").PN.	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 03:13 PM
L239	6	("2008/0167577").URPN.	(USPAT)	OR	ON	ON	2020/03/16 03:13 PM
L240	118	("3500828" | "3670729" | "3714945" | "3977400" | "3994293" | "3995619" | "4106491" | "4200096" | "4468224" | "4531987" | "4549554" | "4735215" | "4828548" | "4874373" | "4893635" | "4894052" | "4907599" | "4944308" | "4994042" | "5129884" | "5400798").PN. OR ("5749857").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2020/03/16 03:15 PM
L241	6	("2008/0167577").URPN.	(US-PGPUB; USPAT)	OR	ON	ON	2020/03/16 03:15 PM
L242	274	((("BULLINGTON") near3 ("Gregory")) OR	(US-PGPUB; USPAT; USOCR; EPO; JPO;	OR	ON	ON	2020/03/16 03:25 PM

		(("PATTON") near3 ("Richard")) OR (("MIAZGA") near3 ("Jay")) OR (("GAW") near3 ("Shan"))).INV.	DERWENT)				
L243	61	L242 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 03:25 PM
L244	1	(15/854273).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/03/16 03:47 PM
L245	0	(14/502498).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/03/16 04:11 PM
L246	1	("20110082383").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/03/16 04:24 PM
L247	1	("8150506").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/03/16 04:24 PM
L252	1	(15/057214).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/03/17 11:28 AM
L253	348964	(blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2020/06/10 05:22 PM
L254	7453	L253 AND ((A61B10/0096 OR A61B5/150022).CPC.)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2020/06/10 05:22 PM
L255	155	L254 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 05:23 PM
L256	77	(("ROGERS") near3 ("Bobby")).INV.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 05:35 PM
L257	343953	(blood same (sequest$5 or sampl$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 05:40 PM
L258	11	L256 and (blood same (sequest$5 or sampl$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 05:41 PM
L259	1	("5749857").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 05:50 PM
L260	121	("3500828" | "3670729" | "3714945" | "3977400" | "3994293" | "3995619" | "4106491" | "4200096" | "4468224" | "4531987" | "4549554" | "4735215" | "4828548" | "4874373" | "4893635" | "4894052" | "4907599" | "4944308" | "4994042" | "5129884" | "5400798").PN. OR ("5749857").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2020/06/10 06:19 PM
L261	32	L260 and (blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:20 PM

L262	1	("3648684").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 06:38 PM
L263	1	("4056101").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 06:38 PM
L264	329	(600/577).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2020/06/10 06:39 PM
L265	11	L264 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:39 PM
L266	29	("2008/0319346").URPN.	(USPAT)	OR	ON	ON	2020/06/10 06:40 PM
L267	812	(600/576).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 06:40 PM
L268	72	L267 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:40 PM
L269	1767	(600/573).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 06:44 PM
L270	31	L269 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:45 PM
L271	77	("4676249" | "4787891" | "4850960" | "4874382" | "4886067" | "4886500" | "4900307" | "4904242" | "4917102" | "4950252" | "4955862" | "5046508" | "5116353" | "5125718" | "5129884" | "5163911" | "5217435" | "5290244" | "5295974" | "5314503" | "5318585" | "5330432" | "5360410" | "5366441" | "5376075" | "5395337" | "5531692" | "5695475" | "5695479" | "5702367" | "5735813" | "5749857" | "5788654" | "5800395" | "5846226" | "5871470" | "5882342" | "5919172" | "5935108" | "5935113" | "5989220" | "6050976" | "6077244" | "6099504" | "6126641" | "6162195").PN. OR ("6398743").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2020/06/10 06:46 PM
L272	18	L271 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:46 PM
L273	1	(15/893518).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 06:48 PM
L274	7050	(600/300).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 06:49 PM

L275	14	L274 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:49 PM
L276	1259	(600/583).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 06:51 PM
L277	7	L276 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:51 PM
L278	1368	(604/164.01).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 06:52 PM
L279	135	L278 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:52 PM
L280	499	(435/294.1).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 07:08 PM
L281	3	L280 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 07:08 PM
L282	20	("2008/0145933").URPN.	(USPAT)	OR	ON	ON	2020/06/10 07:08 PM
L286	1	("10045704").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 08:56 PM
L287	1	("10143412").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/01 09:16 PM
L288	1	("10010282").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/01 09:17 PM
L289	100	((("ROGERS") near3 ("Bobby")) OR (("KANG") near3 ("Gino")) OR (("DETLOFF") near3 ("John"))).INV.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2021/03/01 09:17 PM
L290	2	(15/140443).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/01 09:36 PM
L291	1	(15/855439).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/01 09:39 PM
L292	180	(("ROGERS") near3 ("Bobby")).INV.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2021/03/02 12:19 PM
L293	11	L292 and (blood near4 sequest$5)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 12:20 PM
L294	2	(15/140443).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 12:47 PM
L295	1	(15/855439).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 12:49 PM
L296	1	("20020048170").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 01:36 PM
L297	1	("20040174525").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 01:49 PM
L298	1	("10045704").PN.	(US-PGPUB; USPAT;	OR	OFF	OFF	2021/03/02

			USOCR)				03:09 PM
L299	27321	(A61B5/150992 or A61B5/15003 or A61B5/150213 or A61B5/150389 or A61B5/150473 or A61B5/150572 or A61B5/154 or A61B5/153 or A61M39/0693 or A61M39/04 or A61B5/150221 or A61M2039/0633 or A61M2039/0202 or A61M2039/068).cpc.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2021/03/02 03:17 PM
L300	4594	L299 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 03:27 PM
L301	3762	L300 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 03:28 PM
L302	257	L301 and (air near4 permeab$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 03:29 PM
L303	420	L301 and ((air or gas$4) near4 permeab$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 03:29 PM
L304	1	("20110167658").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 03:30 PM
L305	5	("2015/0306288").URPN.	(USPAT)	OR	ON	ON	2021/03/02 04:15 PM
L306	1	(16/208559).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 04:32 PM
L307	2	("2009/0043225").URPN.	(USPAT)	OR	ON	ON	2021/03/02 04:49 PM
L308	1736	(600/573).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2021/03/02 05:00 PM
L309	1363	L308 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:00 PM
L310	73	L309 and ((air or gas$4) near4 permeab$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:01 PM
L311	73	L310 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:01 PM
L312	812	(600/576).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 05:34 PM
L313	711	L312 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:34 PM
L314	58	L313 and ((air or gas$4) near4 permeab$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:34 PM
L315	58	L314 and	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02

		@ad<"20150724"					05:34 PM
L316	371	(600/577).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 05:42 PM
L317	277	L316 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:42 PM
L318	20	L317 and ((air or gas$4) near4 permeab$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:43 PM
L319	336	("2913000" | "3817240" | "3859998" | "3864979" | "4016879" | "4046144").PN. OR ("4207870").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/03/02 05:44 PM
L320	210	L319 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:44 PM
L321	196	L320 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:44 PM
L322	1259	(600/583).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 05:48 PM
L323	1208	L322 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:48 PM
L324	73	L323 and ((air or gas$4) near4 permeab$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:48 PM
L325	73	L324 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:49 PM
L326	1368	(604/164.01).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 05:59 PM
L327	271	L326 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 06:00 PM
L328	10	L327 and ((air or gas$4) near4 permeab$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 06:00 PM
L329	268	L327 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 06:00 PM
L330	182	(("ROGERS") near3 ("Bobby")).INV.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2021/07/08 02:22 PM
L331	27660	(A61B5/150992 or A61B5/15003 or A61B5/150213 or A61B5/150389 or A61B5/150473 or A61B5/150572 or A61B5/154 or A61B5/153 or	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2021/07/08 03:27 PM

		A61M39/0693 or A61M39/04 or A61B5/150221 or A61M2039/0633 or A61M2039/0202 or A61M2039/068).cpc.					
L332	4684	L331 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 03:28 PM
L333	3769	L332 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 03:29 PM
L334	579	L333 and (vent$4 near4 air)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 03:29 PM
L335	1	("9820682").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/07/08 03:54 PM
L336	1	("4207870").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/07/08 03:56 PM
L337	337	("2913000" | "3817240" | "3859998" | "3864979" | "4016879" | "4046144").PN. OR ("4207870").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/07/08 04:19 PM
L338	211	L337 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:19 PM
L339	196	L338 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:19 PM
L340	37	L339 and (vent$4 near4 air)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:19 PM
L341	221	("20010021827" | "20020004650" | "20020055716" | "20020072715" | "20020103464" | "20020103465" | "20020107488" | "20020151856" | "20020193748" | "20030028171" | "20030036730" | "20030050608" | "20030055385" | "20030078544" | "20030093009" | "20030105414" | "20030114797" | "20030120222" | "20030176842" | "20030181873" | "20030191438" | "20030199827" | "20030216687" |	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/07/08 04:21 PM

		"20030220614" | "20030229315" | "20030229316" | "20040024370" | "20040059302" | "20040092872" | "20040102740" | "20040111068" | "20040193120" | "20040204681" | "20040210197" | "20050004524" | "20050059936" | "20050065482" | "20050124944" | "20050165353" | "20050187493" | "20050228345" | "20050245868" | "20050245869" | "20050245870" | "20050245879" | "20050245885" | "20050283093" | "20060015073" | "20060036217" | "20060036219" | "20060079847" | "20060129064" | "20060189934" | "20060189936" | "20060224122" | "20060270947" | "20060276756" | "20070021724" | "20070027430" | "20070106220" | "20070106224" | "20070167914" | "20070282275" | "20080015513" | "20080086085" | "20080177202" | "20080221528" | "20080269691" | "20080306452" | "20080319345" | "20080319346" | "20090204026" | "20090227896" | "20100063455" | "20100191189" | "20100262038" | "20110118674" | "4106497" | "4207870" | "4305406" | "4572210" | "4573976" | "4641663" | "4795443" | "4813426" |				

		"4840619" | "4887998" | "4894055" | "4900307" | "4923477" | "4994046" | "5015241" | "5195985" | "5215534" | "5219333" | "5222502" | "5242417" | "5246428" | "5256153").PN. OR ("5295970" | "5295975" | "5303713" | "5312372" | "5318547" | "5336199" | "5344408" | "5348544" | "5356392" | "5389085" | "5403286" | "5411492" | "5439449" | "5466223" | "5501675" | "5542932" | "5549558" | "5595566" | "5599313" | "5607402" | "5662617" | "5665075" | "5669889" | "5672161" | "5676658" | "5681295" | "5685855" | "5687740" | "5688241" | "5695474" | "5702369" | "5704920" | "5718239" | "5733265" | "5755522" | "5769826" | "5795336" | "5879337" | "5893845" | "5910130" | "5921964" | "5957892" | "5984899" | "6149629" | "6171284" | "6183445" | "6224576" | "6254575" | "6261263" | "6261265" | "6298541" | "6344032" | "6419658" | "6436086" | "6440104" | "6471677" | "6475191" | "6485469" | "6524277" | "6533760" | "6554807" | "6575939" | "6592556" | "6623456" | "6623461" | "6635032" | "6641555" | "6648855" | "6648856" | "6659983" | "6695819" | "6699217" | "6712792" | "6716199" | "6761704" | "6773419" | "6780169" | "6805689" | "6811545" | "6835190" | "6837877" | "6846302" | "6860872" | "6869415" | "6905483" | "6918891" | "6958054" | "6974423" | "6984223" | "6997913" | "7001363" | "7083600" | "7101355" | "7128726" | "7147624" | "7160267" | "7163526" | "7201740" | "7211065" | "7223258"					

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L342	115	("20020193748" | "20030093009" | "20030105414" | "20030220614" | "20030229315" | "20040059302" | "20040092872" | "20040193120" | "20050004524" | "20050065482" | "20050124944" | "20050187493" | "20050245868" | "20050245869" | "20050245870" | "20050245879" | "20050245885" | "20060036219" | "20060224122" | "20070106220" | "20070106224" | "20070167914" | "20080086085" | "20080177202" | "20080319345" | "20080319346" | "20090204026" | "20100262038" | "4106497" | "4207870" | "4305406" | "4572210" | "4573976" | "4641663" | "4795443" | "4840619" | "4894055" | "4900307" | "4994046" | "5015241" | "5195985" | "5215534" | "5222502" | "5242417" | "5246428" | "5256153" | "5295970" | "5303713" | "5312372" | "5336199" | "5348544" | "5356392" | "5411492" | "5439449" | "5466223" | "5501675" | "5542932" | "5599313" |	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/07/08 04:21 PM

		"5662617" | "5665075" | "5672161" | "5676658" | "5702369" | "5704920" | "5733265" | "5755522" | "5957892" | "5984899" | "6149629" | "6224576" | "6254575" | "6261263" | "6298541" | "6344032" | "6436086" | "6440104" | "6524277" | "6533760" | "6592556" | "6623456" | "6635032" | "6648855" | "6695819" | "6699217" | "6712792" | "6780169" | "6837877" | "6869415" | "6984223" | "7001363" | "7128726" | "7147624" | "7160267" | "7163526" | "7223258" | "7226432" | "7396343" | "7428773" | "7537581" | "7766879" | "D422700" | "D442280" | "D604836" | "D604837" | "D604838" | "D604839" | "D605287").PN. OR ("8603009").URPN.					
L343	148	("20020193748" | "20030105414" | "20030229315" | "20040059302" | "20040092872" | "20050004524" | "20050187493" | "20050245868" | "20050245869" | "20050245870" | "20050245885" | "20060036219" | "20070106220" | "20070167914" | "20080086085" | "20080177202" | "4106497" | "4207870" | "4305406" | "4573976" | "4641663" | "4795443" | "4840619" | "4894055" | "4900307" | "4994046" | "5015241" | "5195985" | "5215534" | "5222502" | "5242417" | "5256153" | "5295970" | "5303713" | "5312372" | "5336199" | "5348544" | "5356392" | "5411492" | "5439449" | "5466223" | "5501675" | "5542932" | "5672161" |	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/07/08 04:21 PM

		"5676658" | "5702369" | "5704920" | "5755522" | "5984899" | "6149629" | "6261263" | "6298541" | "6436086" | "6440104" | "6524277" | "6533760" | "6592556" | "6623456" | "6635032" | "6648855" | "6699217" | "6712792" | "6780169" | "6837877" | "6869415" | "6984223" | "7001363" | "7128726" | "7147624" | "7160267" | "7163526" | "7223258" | "7226432" | "7396343" | "7428773" | "D422700" | "D442280").PN. OR ("7766879").URPN.					
L344	41	("2735430" | "2798487" | "3187749" | "3240209" | "3585984" | "3817240" | "4166450" | "4207870" | "4295477" | "4312362").PN. OR ("4436098").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/07/08 04:22 PM
L345	163	L341 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:22 PM
L346	163	L345 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:23 PM
L347	22	("2005/0283093").URPN.	(USPAT)	OR	ON	ON	2021/07/08 04:23 PM
L348	163	L345 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:27 PM
L349	163	L348 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:27 PM
L350	1736	(600/573).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2021/07/08 04:37 PM
L351	1363	L350 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:37 PM
L352	1346	L351 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:38 PM
L353	136	L352 and (vent$4 near4 air)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:38 PM
L354	812	(600/576).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/07/08 04:41 PM
L355	711	L354 and ((blood or fluid$4) near4 (sequest$5 or sampl$4	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:41 PM

		or flash$4 or collect$4))					
L356	699	L355 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:41 PM
L357	123	L356 and (vent$4 near4 air)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:41 PM
L358	371	(600/577).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/07/08 04:44 PM
L359	277	L358 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:45 PM
L360	260	L359 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:45 PM
L361	1259	(600/583).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/07/08 04:46 PM
L362	1208	L361 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:46 PM
L363	1194	L362 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:47 PM
L364	1194	L363 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:47 PM
L366	1	("9820682").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:05 PM
L367	319	((("BULLINGTON") near3 ("Gregory")) OR (("PATTON") near3 ("Richard")) OR (("MIAZGA") near3 ("Jay")) OR (("GAW") near3 ("Shan"))).INV.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2022/02/02 03:14 PM
L368	1	(16/376745).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:35 PM
L369	190	(("ROGERS") near3 ("Bobby")).INV.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2022/02/02 03:36 PM
L370	2	(15/140448).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:41 PM
L371	1	("9820682").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:42 PM
L372	1	("9060725").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:42 PM
L373	1	("9060724").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:43 PM
L374	1	("9022950").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:45 PM
L375	1	("9022951").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:45 PM
L376	1	("10292633").PN.	(US-PGPUB; USPAT;	OR	OFF	OFF	2022/02/02

			USOCR)				03:46 PM
L377	1	("10433779").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:47 PM
L378	1	("10436554").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:48 PM
L379	1	("10736554").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:49 PM
L380	1	("10912506").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:49 PM
L381	1	("10010282").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:49 PM
L382	1	(16/376745).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:50 PM
L383	1	("9820682").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:51 PM
L384	276	(600/579).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:52 PM
L385	204	L384 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/02/02 03:53 PM
L386	37427	(A61B5/150221 or A61B5/15003 or A61B5/150236 or A61B5/150244 or A61B5/150251 or A61B5/150389 or A61B5/150503 or A61B5/150992 or A61B5/153 or A61B5/155 or A61B10/0048 or A61B10/0051 or A61B10/007 or A61B2010/0061 or A61B2010/0077 or A61B2010/008).cpc.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2022/02/02 04:35 PM
L387	7279	L386 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/02/02 04:36 PM
L388	4442	L387 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/02/02 04:36 PM
L389	874	L388 and (seal$4 near4 (member or mechanism$4 or vent$4 or elastic$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/02/02 04:38 PM
L390	26	("2008/0145933").URPN.	(USPAT)	OR	ON	ON	2022/02/02 04:52 PM
L391	44	("2008/0319346").URPN.	(USPAT)	OR	ON	ON	2022/02/02 04:59 PM
L392	385	L386 and ((blood or fluid) near4 (seal$4 near4 (member or	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/02/02 05:28 PM

		mechanism$4 or vent$4 or elastic$4)))					
L393	171	L392 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/02/02 05:28 PM
L394	355	(604/103).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 05:52 PM
L395	7	L394 and ((blood or fluid) near4 (seal$4 near4 (member or mechanism$4 or vent$4 or elastic$4)))	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/02/02 05:52 PM
L396	1	(16/328127).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/03 12:00 PM
L397	0	"1020130062845"	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/02/04 04:17 PM
L398	8	"20130062845"	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/02/04 04:17 PM
L399	14	"2013021595"	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/02/04 04:18 PM
L400	2	(14/055232).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/04 07:10 PM
L401	1	(15/746656).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/05 11:48 AM
L402	0	(17/388440).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/07 09:34 AM
L403	1	("20050048465").PN.	(US-PGPUB; USPAT)	OR	ON	ON	2022/02/07 09:34 AM
L404	196	(("ROGERS") near3 ("Bobby")).INV.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2022/05/18 03:08 PM
L405	16	L404 and (blood near4 sequest$5)	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/05/18 03:08 PM
L406	16	L404 and ((blood or chamber) near4 sequest$5)	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/05/18 03:08 PM
L407	16	L406 and (junct$4 or bypass$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/05/18 03:09 PM
L408	16	L406 and junct$4	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/05/18 03:09 PM
L409	22445	(A61B5/150992 or A61B5/15003 or A61B5/150213 or A61B5/150221 or A61B5/150389 or A61B5/150473 or	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2022/05/18 03:54 PM

		A61B5/150572 or A61B5/154 or A61B5/15074).cpc.					
L410	4525	L409 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4 or flush$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/05/18 03:55 PM
L411	3810	L410 and @ad<"20170210"	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/05/18 03:56 PM
L412	820	L411 and ((vent$4 or open$4 or apertur$4) near4 air)	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/05/18 03:57 PM
L413	22445	(A61B5/150992 or A61B5/15003 or A61B5/150213 or A61B5/150221 or A61B5/150389 or A61B5/150473 or A61B5/150572 or A61B5/154 or A61B5/15074).cpc.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2022/05/18 05:51 PM
L414	4603	L413 and ((blood or fluid$4 or chamber) same (sequest$5 or sampl$4 or flash$4 or collect$4 or flush$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/05/18 05:51 PM
L415	511	L414 and ((junct$4 or bypass$4 or divert$4) near4 (blood or fluid))	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/05/18 05:52 PM
L416	355	L415 and @ad<"20170210"	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/05/18 05:53 PM
L417	1	(16/819033).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/05/18 06:10 PM
L418	1	(17/094692).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/05/18 06:25 PM
L419	1	(17/538990).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/05/18 06:25 PM
L420	1	("11311219").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/05/18 06:27 PM
L421	1	("11185266").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/05/18 06:30 PM
L422	1	("10143412").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/05/18 06:31 PM
L423	1	("9820682").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/05/18 06:32 PM
L424	252	(("ROGERS") near3 ("Bobby")).INV.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS,	OR	OFF	OFF	2022/10/13 01:41 PM

			IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)				
L425	38	424 AND (closur$4 OR enclos$4)	(US-PGPUB; USPAT)	OR	ON	ON	2022/10/13 01:42 PM
L426	42781	(A61B5/150213 OR A61B5/15003 OR A61B5/150221 OR A61B5/150251 OR A61B5/150732 OR A61B5/15074 OR A61B5/150992 OR A61B5/153 OR A61B5/150389 OR A61B5/150503).cpc.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/10/13 01:47 PM
L427	5205	426 AND @ad<"20170210"	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/10/13 01:50 PM
L428	4803	427 AND ((blood OR fluid$4) near4 (sequest$5 OR sampl$4 OR flash$4 OR collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/10/13 01:51 PM
L429	519	428 AND ((closur$4 OR enclos$4 OR pug$4) near5 (vent OR open$4 OR air))	(US-PGPUB; USPAT)	OR	ON	ON	2022/10/13 01:54 PM
L430	169	"5749857"	(US-PGPUB; USPAT)	OR	ON	ON	2022/10/13 02:14 PM
L431	1	("5749857").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2022/10/13 02:14 PM
L432	346	427 AND ((junct$4 OR bypass$4 OR divert$4) near4 (blood OR fluid))	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/10/13 02:18 PM
L433	186	("3500828" | "3670729" | "3714945" | "3977400" | "3994293" | "3995619" | "4106491" | "4200096" | "4468224" | "4531987" | "4549554" | "4735215" | "4828548" | "4874373" | "4893635" | "4894052" | "4907599" | "4944308" | "4994042" | "5129884"	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/10/13 02:32 PM

		| "5400798").pn. OR ("5749857").urpn. AND (PGPB | USPT | USOC).dbnm.					
L434	124	433 AND ((blood OR fluid$4) near4 (sequest$5 OR sampl$4 OR flash$4 OR collect$4 OR optimiz$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/10/13 02:34 PM
L435	1	("5749857").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2022/10/13 02:34 PM
L436	1	17/138056	(US-PGPUB; USPAT)	OR	ON	ON	2022/10/19 11:35 AM
L437	253	(("ROGERS") near3 ("Bobby")).INV.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2022/11/16 03:25 PM
L438	39	437 AND (closur$4 OR enclos$4)	(US-PGPUB; USPAT)	OR	ON	ON	2022/11/16 03:25 PM
L439	35391	(A61B5/150992 OR A61B5/15003 OR A61B5/150213 OR A61B5/150221 OR A61B5/150389 OR A61B5/150473 OR A61B5/150572 OR A61B5/154 OR A61B5/15074).cpc.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2022/11/16 03:46 PM
L440	4100	439 AND @ad<"20170210"	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/11/16 03:48 PM
L441	3875	440 AND ((blood OR fluid$4 OR urine) SAME (sequest$5 OR sampl$4 OR flash$4 OR collect$4 OR	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/11/16 03:49 PM

		optimiz$5))					
L442	368	441 AND ((junct$4 OR bypass$4 OR divert$4) near5 (blood OR fluid OR urine))	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/11/16 03:50 PM
L443	7	"10827964"	(US-PGPUB; USPAT)	OR	ON	ON	2022/11/16 04:13 PM
L444	1	16/819033	(US-PGPUB; USPAT)	OR	ON	ON	2022/11/16 04:48 PM
L445	359	"4207870"	(US-PGPUB; USPAT)	OR	ON	ON	2022/11/16 05:07 PM
L446	1	("4207870").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2022/11/16 05:07 PM
L447	3814	440 AND ((blood OR fluid$4 OR urine) near5(sequest$5 OR sampl$4 OR flash$4 OR collect$4 OR optimiz$5))	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/11/16 05:17 PM
L448	366	447 AND ((junct$4 OR bypass$4 OR divert$4) near5 (blood OR fluid OR urine))	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/11/16 05:17 PM
L449	89	(("ROGERS") near3 ("Bobby")).INV.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2023/04/11 01:13 PM
L450	24	449 AND ((blood OR fluid$4 OR urine) near5(sequest$5 OR sampl$4 OR flush$4 OR collect$4 OR optimiz$5or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/04/11 01:14 PM
L451	24	449 AND ((blood OR fluid$4 OR urine) near5(sequest$5 OR sampl$4 OR flush$4 OR collect$4 OR optimiz$5 OR flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/04/11 01:14 PM
L452	6634	(A61B5/150213 OR A61B5/15003 OR A61B5/150221 OR A61B5/150251 OR A61B5/150732 OR A61B5/15074 OR A61B5/150992 OR A61B5/153 OR A61B5/150389 OR A61B5/150503).cpc.	(US-PGPUB; USPAT)	OR	ON	ON	2023/04/11 01:32 PM
L453	5326	452 AND @ad<"20170210"	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/04/11 01:32 PM
L454	4928	453 AND ((blood OR fluid$4 OR urine) near5(sequest$5 OR sampl$4 OR flush$4	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/04/11 01:32 PM

		OR collect$4 OR optimiz$5 OR flash$4))					
L455	371	454 AND ((junct$4 OR bypass$4 OR divert$4) near5 (blood OR fluid OR urine))	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/04/11 01:33 PM
L456	11	("2016/0361006").urpn. AND (PGPB | USPT | USOC).dbnm.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2023/04/11 03:03 PM
L457	1	17/094692	(US-PGPUB; USPAT)	OR	ON	ON	2023/04/11 03:11 PM
L458	49	("20020004647"|"20030105414"|"20040054333"|"20040073171"|"20040147855"|"20050004524"|"20050240161"|"20070083162"|"20070088279"|"20080086085"|"20080145933"|"20080167577"|"20080319346"|"20100010372"|"20100057004"|"20120016266"|"20130317391"|"20160008579"|"20160174888"|"3741197"|"3817240"|"3874367"|"3886930"|"4057050"|"4106497"|"4154229"|"4207870"|"4412548"|"4436098"|"4444203"|"5222502"|"5520193"|"5749857"|"6398743"|"6569117"|"8197420"|"8523826"|"8535241"|"8540663"|"8568371"|"8603009"|"8864684"|"9022950"|"9022951"|"9060724"|"9138572"|"9155495"|"9204864"|"9877675").PN.	(US-PGPUB; USPAT)	OR	ON	ON	2023/04/11 03:18 PM
L459	13	458 AND ((junct$4 OR bypass$4 OR divert$4) near5 (blood OR fluid OR urine))	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/04/11 03:18 PM
L460	155	("2707953" | "2992974" | "3013557" | "3098016" | "3382865" | "3405706" | "3494351" | "3577980" | "3635798" | "3648684" | "3848579" | "3890203" | "3937211" | "4057050" | "4133863" | "4166450" | "4340067" | "4370987" | "4425235" | "4444203" | "4459997" | "4509534" | "4657160" | "4676256" | "4865583" | "4890627"	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2023/04/11 03:21 PM

		| "4988339" | "5009847" | "5097842" | "5108927" | "5122129" | "5269317" | "5330464" | "5360011" | "5429610" | "5450856" | "5454786" | "5485854" | "5507299" | "5577513" | "5762633" | "5865812" | "5882318" | "5922551" | "6016712" | "6057105" | "6159164" | "6210909" | "6328726" | "6364890" | "6387086" | "6403381" | "6520948" | "6626884" | "6692479" | "6716187" | "6746420" | "6913580" | "7044941" | "7087047" | "7335188" | "7384416" | "7744573" | "8197420" | "8231546" | "8337418" | "8535241" | "8647286" | "8864684" | "8876734" | "20020002349" | "20020183651" | "20030055381" | "20030208151" | "20040010228" | "20040054283" | "20040054333" | "20040147855" | "20050004524" | "20050240161" | "20050245885" | "20050281713" | "20060287639" | "20080108954" | "20080145933" | "20100152681" | "20120095367" | "20120215131" | "20130079604" | "20130116599" | "20130317391" | "20140081172").pn. OR ("9060724").urpn. AND (PGPB | USPT | USOC).dbnm.					
L461	31	("2008/0145933").urpn. AND (PGPB | USPT | USOC).dbnm.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2023/04/11 03:30 PM
L462	1	("5749857").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/04/11 03:46 PM
L463	13	459 AND ((junct$4 OR bypass$4 OR divert$4) near5 (blood OR fluid OR urine))	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/04/11 03:47 PM

L464	4994	453 AND ((blood OR fluid$4 OR urine OR semen) SAME (sequest$5 OR sampl$4 OR flush$4 OR collect$4 OR optimiz$5 OR flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/04/11 03:58 PM
L465	968	464 AND ((junct$4 OR bypass$4 OR diver$5) SAME (blood OR fluid OR urine OR semen))	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/04/11 03:59 PM
L466	707	465 AND housing	(US-PGPUB; USPAT)	OR	ON	ON	2023/04/11 04:50 PM
L467	2911	464 AND ((blood OR fluid$4 OR urine OR semen) near5 (first OR second OR subsequent$4 OR bypass))	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/04/11 04:52 PM
L468	2954	464 AND ((blood OR fluid$4 OR urine OR semen) near5 (first OR second OR subsequent$4 OR convey$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/04/11 04:52 PM
L469	2891	464 AND ((blood OR fluid$4 OR urine OR semen) near5 (first OR second OR subsequent$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/04/11 04:52 PM
L470	790	469 AND ((junct$4 OR bypass$4 OR diver$5) SAME (blood OR fluid OR urine OR semen))	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/04/11 04:53 PM
L471	1	17/538990	(US-PGPUB; USPAT)	OR	ON	ON	2023/05/08 12:35 PM
L472	164	(("ROGERS") near3 ("Bobby")).INV.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2023/05/08 02:18 PM
L473	1	("4207870").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/05/08 03:23 PM
L474	1	("10827964").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/05/08

							03:31 PM
L475	1	("11311219").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/05/08 03:32 PM
L476	1	"17094692"	(US-PGPUB; USPAT)	OR	ON	ON	2023/05/08 03:34 PM
L477	2	"17730118"	(US-PGPUB; USPAT)	OR	ON	ON	2023/05/08 03:34 PM
L478	1	("10012828").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/05/08 03:36 PM
L479	1	("10010282").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/05/08 03:36 PM
L480	48138	(A61B5/150992 OR A61B5/15003 OR A61B5/150213 OR A61B5/150221 OR A61B5/150389 OR A61B5/150473 OR A61B5/150572 OR A61B5/153 OR A61B5/154 OR A61M39/04 OR A61M39/0693 OR A61M2039/0202 OR A61M2039/0633 OR A61M2039/068).cpc.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/05/08 03:59 PM
L481	5081	480 AND @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/05/08 04:15 PM
L482	3947	481 AND ((blood OR fluid$4 OR urine) near5(sequest$5 OR sampl$4 OR flush$4 OR collect$4 OR optimiz$5 OR flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/05/08 04:17 PM
L483	1	17/538990	(US-PGPUB; USPAT)	OR	ON	ON	2023/05/08 04:17 PM
L484	1069	482 AND (air near5 (filter$4 OR material$4 OR membrane OR permeab$4 OR vent$4))	(US-PGPUB; USPAT)	OR	ON	ON	2023/05/08 04:32 PM
L485	203	("3500828" | "3670729" | "3714945" | "3977400" | "3994293" | "3995619" | "4106491" | "4200096" | "4468224" | "4531987" | "4549554" | "4735215" | "4828548" | "4874373" | "4893635" | "4894052" | "4907599" | "4944308" | "4994042" | "5129884" | "5400798").pn. OR ("5749857").urpn. AND	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/05/08 04:51 PM

		(PGPB | USPT | USOC).dbnm.					
L486	606	484 AND ((pressure OR vacuum) near5 (draw OR forc$4 OR withdraw OR flow$4)) SAME (blood OR fluid)	(US-PGPUB; USPAT)	OR	ON	ON	2023/05/08 05:32 PM
L487	24	("2010/0057004").urpn. AND (PGPB | USPT | USOC).dbnm.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/05/08 05:35 PM
L488	3	487 AND @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/05/08 05:55 PM
L489	49	((US-20080319346-A1 OR US-20100057004-A1 OR US-20070088279-A1 OR US-20080145933-A1 OR US-20040054333-A1 OR US-20100010372-A1 OR US-20080167577-A1 OR US-20080086085-A1 OR US-20070083162-A1 OR US-20160008579-A1 OR US-20120016266-A1 OR US-20130317391-A1 OR US-20160174888-A1 OR US-20050240161-A1 OR US-20040147855-A1 OR US-20040073171-A1 OR US-20050004524-A1 OR US-20030105414-A1 OR US-20020004647-A1).did. AND PGPB.dbnm.) OR ((US-4412548-A OR US-5222502-A OR US-5520193-A OR US-9022951-B2 OR US-6569117-B1 OR US-3741197-A OR US-8603009-B2 OR US-4207870-A OR US-9877675-B2 OR US-4444203-A OR US-6398743-B1 OR US-9022950-B2 OR US-9155495-B2 OR US-4436098-A OR US-9138572-B2 OR US-8568371-B2 OR US-	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/05/08 06:07 PM

		8523826-B2 OR US-8197420-B2 OR US-4057050-A OR US-8864684-B2 OR US-8535241-B2 OR US-5749857-A OR US-9060724-B2 OR US-9204864-B2 OR US-3817240-A OR US-3874367-A OR US-3886930-A OR US-4106497-A OR US-4154229-A).did. AND USPT.dbnm.)					
L490	25	489 AND (air near5 (filter$4 OR material$4 OR membrane OR permeab$4 OR vent$4))	(US-PGPUB; USPAT)	OR	ON	ON	2023/05/08 06:07 PM
L491	204	482 AND (hous$4 SAME (inlet AND outlet AND channel))	(US-PGPUB; USPAT)	OR	ON	ON	2023/05/08 06:29 PM
L492	118	491 AND (hous$4 near5 ((top OR upper) AND (lower OR bottom)))	(US-PGPUB; USPAT)	OR	ON	ON	2023/05/08 06:33 PM
L493	1	489 AND (hous$4 near5 ((top OR upper) AND (lower OR bottom)))	(US-PGPUB; USPAT)	OR	ON	ON	2023/05/08 06:39 PM
L494	0	489 AND (hous$4 near5 ((top OR upper) SAME (lower OR bottom)))	(US-PGPUB; USPAT)	OR	ON	ON	2023/05/08 06:39 PM
L495	27	492 AND (hous$4 near5 ((top OR upper) SAME (lower OR bottom)))	(US-PGPUB; USPAT)	OR	ON	ON	2023/05/08 06:39 PM
L496	172	484 AND (hous$4 near5 ((top OR upper) SAME (lower OR bottom)))	(US-PGPUB; USPAT)	OR	ON	ON	2023/05/08 06:41 PM
L497	113	((("ROGERS") near3 ("Bobby")) OR (("KANG") near3 ("Gino")) OR (("DETLOFF") near3 ("John"))).INV.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2023/07/05 01:58 PM
L498	26	497 AND ((blood OR fluid$4 OR urine) near5(sequest$5 OR sampl$4 OR flush$4 OR collect$4 OR optimiz$5 OR flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/07/05 01:58 PM

L499	4	15/855439	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/05 03:12 PM
L500	48306	(A61B5/150992 OR A61B5/15003 OR A61B5/150213 OR A61B5/150221 OR A61B5/150389 OR A61B5/150473 OR A61B5/150572 OR A61B5/153 OR A61B5/154 OR A61M39/04 OR A61M39/0693 OR A61M2039/0202 OR A61M2039/0633 OR A61M2039/068).cpc.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/07/05 03:36 PM
L501	5081	500 AND @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/07/05 03:36 PM
L502	3947	501 AND ((blood OR fluid$4 OR urine) near5(sequest$5 OR sampl$4 OR flush$4 OR collect$4 OR optimiz$5 OR flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/07/05 03:37 PM
L503	1069	502 AND (air near5 (filter$4 OR material$4 OR membrane OR permeab$4 OR vent$4))	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/05 03:37 PM
L504	3871	501 AND ((blood OR fluid$4 OR urine) near5(divert$4 OR direct$4 OR flow$4 OR bypass$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/07/05 05:18 PM
L505	3030	501 AND ((blood OR fluid$4 OR urine) near5(divert$4 OR direct$4 OR flow$4 OR bypass$4 OR allow$4)) SAME (channel$4 OR chamber OR junct$4 OR inlet OR outlet OR path$4 OR contain$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/07/05 05:20 PM
L506	921	503 AND ((blood OR fluid$4 OR urine) near5(divert$4 OR direct$4 OR flow$4 OR bypass$4 OR allow$4)) SAME (channel$4 OR chamber OR junct$4 OR inlet OR outlet OR path$4 OR contain$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/07/05 05:20 PM
L507	1	17/538990	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/05

							06:04 PM
L508	1	16/961875	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/05 08:21 PM
L509	7	"20070148624"	(US-PGPUB; USPAT)	OR	ON	ON	2023/08/31 01:02 PM
L510	43469	(A61B5/150992 OR A61B5/15003 OR A61B5/150213 OR A61B5/150221 OR A61B5/150389 OR A61B5/150473 OR A61B5/150572 OR A61B5/153 OR A61B5/154 OR A61M39/04 OR A61M39/0693 OR A61M2039/0202 OR A61M2039/0633 OR A61M2039/068).cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO)	OR	ON	ON	2023/08/31 01:28 PM
L511	5081	510 AND @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/08/31 01:32 PM
L512	3947	511 AND ((blood OR fluid$4 OR urine) near5(sequest$5 OR sampl$4 OR flush$4 OR collect$4 OR optimiz$5 OR flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/08/31 01:32 PM
L513	2653	512 AND ((blood OR fluid$4 OR urine) near5(divert$4 OR direct$4 OR flow$4 OR bypass$4 OR allow$4)) SAME (channel$4 OR chamber OR junct$4 OR inlet OR outlet OR path$4 OR contain$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/08/31 01:32 PM
L514	921	513 AND (air near5 (filter$4 OR material$4 OR membrane OR permeab$4 OR vent$4))	(US-PGPUB; USPAT)	OR	ON	ON	2023/08/31 01:33 PM
L515	1	18/113710	(US-PGPUB; USPAT)	OR	ON	ON	2023/08/31 02:05 PM
L516	372	((("BULLINGTON") near3 ("Gregory")) OR (("PATTON") near3 ("Richard")) OR (("MIAZGA") near3 ("Jay")) OR (("GAW") near3 ("Shan"))).INV.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2023/11/20 02:30 PM
L517	172	516 AND ((blood OR fluid$4 OR urine) near5(sequest$5 OR	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/11/20 02:41 PM

		sampl$4 OR flush$4 OR collect$4 OR optimiz$5 OR flash$4 OR divert$4 OR bypass$4))					
L518	165	516 AND ((blood OR fluid$4 OR urine) near5(sequest$5 OR flush$4 OR optimiz$5 OR flash$4 OR divert$4 OR bypass$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/11/20 02:42 PM
L519	165	516 AND ((blood OR fluid$4 OR urine) near5(sequest$5 OR flush$4 OR optimiz$5 OR flash$4 OR diver$5 OR bypass$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/11/20 02:42 PM
L520	1	("11395612").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/20 02:43 PM
L521	1	("11395611").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/20 02:45 PM
L522	1	("10292633").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/20 02:46 PM
L523	1	("9022950").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/20 02:52 PM
L524	11	"10736554"	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/20 02:55 PM
L525	1	("10736554").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/20 02:55 PM
L526	1	("10912506").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/20 02:55 PM
L527	1	("10010282").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/20 02:56 PM
L528	1	("9820682").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/20 02:58 PM
L529	67080	(A61B5/150221 OR A61B5/15003 OR A61B5/150236 OR A61B5/150244 OR A61B5/150251 OR A61B5/150389 OR A61B5/150503 OR A61B5/150992 OR A61B5/153 OR A61B5/155 OR A61B10/0048 OR A61B10/0051 OR A61B10/007 OR A61B2010/0061 OR A61B2010/0077 OR A61B2010/008).cpc.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/11/20 03:05 PM
L530	1791	529 AND ((blood OR fluid$4 OR urine)	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/11/20 03:05 PM

		near5(sequest$5 OR flush$4 OR optimiz$5 OR flash$4 OR diver$5 OR bypass$4))					
L531	322	530 AND (flow$4 OR control$4 OR divert$4 OR mechanism) near5 rotat$4	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/20 03:07 PM
L532	420	530 AND (flow$4 OR control$4 OR divert$4 OR mechanism OR valve) near5 rotat$4	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/20 03:07 PM
L533	0	("2021/0128037").urpn. AND (PGPB | USPT | USOC).dbnm.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/11/20 03:39 PM
L534	1267	530 AND (flow$4 OR control$4 OR divert$4 OR mechanism OR valve) near5 (chamber OR reservoir OR hous$4 OR container)	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/20 03:56 PM
L535	1142	530 AND (flow$4 OR control$4 OR divert$4 OR mechanism OR valve) near5 (chamber OR reservoir OR container)	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/20 03:56 PM
L536	1	17/863605	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/20 04:48 PM
L537	1	("10292633").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/20 05:19 PM
L538	505	530 AND (flow$4 OR control$4 OR divert$4 OR mechanism OR valve) near5 (multiple OR pluarlit$4 OR first OR second) near5 (lumen OR channel OR path$4)	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/20 05:25 PM
L539	8	"20080077183"	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/21 01:29 PM
L540	1	15/933356	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/21 01:47 PM
L541	7	("20060074354"|"20080077183"|"20100131454"|"20140228714"|"20150196247"|"20200129380"|"9974476").PN.	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/21 02:08 PM
L542	6	541 AND (suck$4 near5 pressure)	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/21 02:09 PM
L543	146297	(A61B5/4542 OR A61B5/7242 OR A61B5/7246 OR	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY,	OR	ON	ON	2023/11/21 02:17 PM

		A61B5/7257 OR A61B5/7267 OR A61B5/7282 OR A61B2503/045 OR A61B2562/0247 OR A61B5/038 OR A61B5/002).cpc.	CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)				
L544	16368	543 AND @ad<"20170322"	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/21 02:17 PM
L545	15	544 AND (determin$4 OR measur$4 OR detect$4 OR process$4) near5(suck$4 near5 pressure)	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/21 02:18 PM
L546	120	544 AND (determin$4 OR measur$4 OR detect$4 OR process$4 OR estimat$4) near5((suck$4 OR feed$4) near5 pressure)	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/21 02:20 PM
L547	15	544 AND (determin$4 OR measur$4 OR detect$4 OR process$4 OR estimat$4) near5((suck$4) near5 pressure)	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/21 02:20 PM
L548	1868	(determin$4 OR measur$4 OR detect$4 OR process$4 OR estimat$4) near5(suck$4 near5 pressure)	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/21 02:27 PM
L549	1387	548 AND @ad<"20170322"	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/21 02:27 PM
L550	48	(determin$4 OR measur$4 OR detect$4 OR process$4 OR estimat$4) near5(suck$4 near5 pressure) AND (nutrit$4 SAME feed$4)	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/21 02:34 PM
L551	39	550 AND (baseline OR threshold OR predetermin$4)	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/21 02:35 PM
L552	16	"20150011874"	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/21 02:55 PM
L553	5	"20140288398"	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/21

							02:55 PM
L554	6	"20140120531"	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/21 03:01 PM
L555	1	("9060724").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/21 03:45 PM
L556	1	("10433779").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/21 03:49 PM
L557	12	"10736554"	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/21 03:50 PM
L558	1	("10912506").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/21 03:54 PM
L559	0	18/381369	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/21 05:01 PM
L560	21	(Artificial Intelligence) More like doc: US-10912506-B2 Text: (US-20200359951-A1 OR US-11395611-B2 OR US-20220071533-A1 OR US-20180116577-A1 OR US-11395612-B2 OR US-20220079482-A1 OR US-10736554-B2 OR US-10433779-B2 OR US-20150351679-A1 OR US-20140155781-A1 OR US-9060724-B2 OR US-20150011910-A1 OR US-9022951-B2 OR US-20210361206-A1 OR US-20150011911-A1 OR US-9022950-B2 OR US-20150257691-A1 OR US-20200060595-A1 OR US-10292633-B2 OR US-20230172502-A1).did.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/11/21 07:16 PM
L561	0	("10912506").urpn. AND (PGPB | USPT | USOC).dbnm.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/11/21 07:16 PM
L562	273	("2707953" | "2992974" | "3013557" | "3098016" | "3382865" | "3405706" | "3467095" | "3494351" | "3494352" | "3577980" | "3604410" | "3635798" | "3648684" | "3730168" | "3741197" | "3777773" | "3803810" | "3817240" | "3834372" | "3835835" | "3848579" | "3848581"	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/11/21 07:16 PM

		| "3874367" | "3886930" | "3890203" | "3890968" | "3937211" | "3945380" | "3978846" | "4056101" | "4057050" | "4063460" | "4077395" | "4106497" | "4133863" | "4150089" | "4154229" | "4166450" | "4190426" | "4193400" | "4207870" | "4212308" | "4238207" | "4257416" | "4275730" | "4298358" | "4340067" | "4340068" | "4349035" | "4370987" | "4398544" | "4412548" | "4416290" | "4425235" | "4444203" | "4459997" | "4509534" | "4608996" | "4654027" | "4657027" | "4657160" | "4673386" | "4676256" | "4679571" | "4705497" | "4714461" | "4772273" | "4865583" | "4879098" | "4886072" | "4890627" | "4904240" | "4980297" | "4988339" | "5009847" | "5027827" | "5032116" | "5045185" | "5066284" | "5084034" | "5097842" | "5100394" | "5108927" | "5116323" | "5122129" | "5135489" | "5222502" | "5269317" | "5330464" | "5417673" | "5431811" | "5439450" | "5450856" | "5466228" | "5472605" | "5485854" | "5507299" | "5520193" | "5575777" | "5603700" | "5632906" | "5649912" | "5691486" | "5749857" | "5772608" | "5811658" | "5824001" | "5865812" | "5871699" | "5911705" | "5961472" | "5971956" | "5980830" | "6001307" | "6010633" | "6106509" | "6210909" | "6224561" | "6325975" | "6328726" | "6364890" | "6387086" | "6403381" | "6506182" | "6520948" | "6569117" | "6626884" | "6638252" | "6648835" | "6692479" | "6695004" | "6716187" | "6733433" | "6736783" | "6746420" | "6843775" | "6860871" | "6905483"					

		| "6913580" | "6945948" | "7044941" | "7052603" | "7055401" | "7087047" | "7141097" | "7241281" | "7306736" | "7314452" | "7316662" | "7335188" | "7384416" | "7461671" | "7479131" | "7614857" | "7615033" | "7618407" | "7648491" | "7666166" | "7744573" | "7766879" | "8070725" | "8197420" | "8231546" | "8337418" | "8349254" | "8377040" | "8382712" | "8383044" | "8412300" | "8523826" | "8535241" | "8540663" | "8568371" | "8574203" | "8603009" | "8647286" | "8795198" | "8827958" | "8864684" | "8876734" | "9022950" | "9022951" | "D731643" | "9060724" | "9060725" | "9138572" | "9149576" | "9155495" | "9204864" | "9314201" | "9855001" | "9855002" | "9855386" | "9861306" | "9872645" | "9877675" | "9895092" | "9950084" | "9999383" | "10028687" | "10028689" | "10045724" | "10251590" | "10736554" | "20010039058" | "20020002349" | "20020004647" | "20020183651" | "20020193751" | "20030013991" | "20030055381" | "20030069543" | "20030105414" | "20030208151" | "20040009542" | "20040010228" | "20040054283" | "20040054333" | "20040127816" | "20040147855" | "20050004524" | "20050148993" | "20050161112" | "20050199077" | "20050240161" | "20050245885" |				

		"20050273019" | "20050281713" | "20060251622" | "20060287639" | "20070088279" | "20070100250" | "20070119508" | "20070287948" | "20080086085" | "20080108954" | "20080167577" | "20080185056" | "20080319346" | "20090050213" | "20090306601" | "20100010372" | "20100042048" | "20100057004" | "20100094171" | "20100152681" | "20100268118" | "20110306899" | "20120035540" | "20120265099" | "20120265128" | "20140066880" | "20150018715" | "20150342510" | "20150351679" | "20160174888" | "20160213294" | "20170071519" | "20180160958" | "20180353117" | "20190076074" | "20190175087" | "20200060595" | "20200060596").pn. OR ("10912506").urpn. AND (PGPB | USPT | USOC).dbnm.					
L563	303	((("ROGERS") near3 ("Bobby")) OR (("KANG") near3 ("Gino")) OR (("DETLOFF") near3 ("John"))).INV.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/01/08 02:52 PM

L564	26	563 AND ((blood OR fluid$4 OR urine) near5(sequest$5 OR flush$4 OR optimiz$5 OR flash$4 OR diver$5 OR bypass$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2024/01/08 02:55 PM
L565	33645	(A61B5/150992 OR A61B5/15003 OR A61B5/150213 OR A61B5/150221 OR A61B5/150389 OR A61B5/150473 OR A61B5/150572 OR A61B5/153 OR A61B5/154 OR A61M39/04 OR A61M39/0693 OR A61M2039/0202 OR A61M2039/0633 OR A61M2039/068).cpc.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/01/08 03:06 PM
L566	5091	565 AND @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2024/01/08 03:09 PM
L567	1014	566 AND ((blood OR fluid$4 OR urine) near5(sequest$5 OR flush$4 OR optimiz$5 OR flash$4 OR diver$5 OR bypass$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2024/01/08 03:09 PM
L568	828	567 AND (flow$4 OR control$4 OR divert$4 OR mechanism OR valve OR junct$4) near5 (chamber OR reservoir OR container OR hous$4 OR inlet OR outlet OR channel OR port)	(US-PGPUB; USPAT)	OR	ON	ON	2024/01/08 03:15 PM
L569	51	("20020004647"|"20030105414"|"20040054333"|"20040073171"|"20040147855"|"20050004524"|"20050240161"|"20070083162"|"20070088279"|"20080086085"|"20080145933"|"20080167577"|"20080319346"|"20100010372"|"20100057004"|"20120016266"|"20130317391"|"20150314105"|"20150359473"|"20160008579"|"20160174888"|"3741197"|"3817240"|"3874367"|"3886930"|"4057050"|"4106497"|"4154229"|"4207870"|"4412548"|"443609	(US-PGPUB; USPAT)	OR	ON	ON	2024/01/08 03:40 PM

		8"|"4444203"|"5222502"|"5520193"|"5749857"|"6398743"|"6569117"|"8197420"|"8523826"|"8535241"|"8540663"|"8568371"|"8603009"|"8864684"|"9022950"|"9022951"|"9060724"|"9138572"|"9155495"|"9204864"|"9877675").PN.					
L570	35	569 AND ((blood OR fluid$4 OR urine) near5(sequest$5 OR flush$4 OR optimiz$5 OR flash$4 OR diver$5 OR bypass$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2024/01/08 03:40 PM
L571	353	567 AND (air near5 (filter$4 OR material$4 OR membrane OR permeab$4 OR vent$4))	(US-PGPUB; USPAT)	OR	ON	ON	2024/01/08 04:09 PM
L572	3	17/538990	(US-PGPUB; USPAT)	OR	ON	ON	2024/01/08 04:12 PM
L573	1	17/110651	(US-PGPUB; USPAT)	OR	ON	ON	2024/01/08 04:28 PM
L574	16	"20150011874"	(US-PGPUB; USPAT)	OR	ON	ON	2024/01/08 05:23 PM
L575	5	"20140288398"	(US-PGPUB; USPAT)	OR	ON	ON	2024/01/08 05:26 PM
L576	7	"20140120531"	(US-PGPUB; USPAT)	OR	ON	ON	2024/01/08 05:27 PM
L577	2	"20140135604"	(US-PGPUB; USPAT)	OR	ON	ON	2024/01/09 02:26 PM
L578	1	("10624616").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/01/09 02:27 PM
L579	7	"20090118628"	(US-PGPUB; USPAT)	OR	ON	ON	2024/01/09 02:27 PM
L580	1	("10687811").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/01/09 02:27 PM
L581	2	"20060287603"	(US-PGPUB; USPAT)	OR	ON	ON	2024/01/09 02:41 PM
L582	1	18/494622	(US-PGPUB; USPAT)	OR	ON	ON	2024/09/16 05:48 PM
L583	1	("11832944").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/09/16 05:49 PM
L584	21	"20100057004"	(US-PGPUB; USPAT)	OR	ON	ON	2024/09/16 05:51 PM
L585	24	"20080167577"	(US-PGPUB; USPAT)	OR	ON	ON	2024/09/16 06:00 PM
L586	1	("11963769").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/09/16 06:26 PM
L587	1	("11185266").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/09/16

							06:26 PM
L588	1	("10143412").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/09/16 06:27 PM
L589	1	("10010282").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/09/16 06:28 PM
L590	122	((("ROGERS") near3 ("Bobby")) OR (("KANG") near3 ("Gino")) OR (("DETLOFF") near3 ("John"))).INV.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2024/09/16 06:52 PM
L591	25	590 AND (flow$4 OR control$4 OR divert$4 OR mechanism OR valve) near5 (chamber OR reservoir OR container) AND (blood near5 impermeable)	(US-PGPUB; USPAT)	OR	ON	ON	2024/09/16 06:54 PM
L592	50925	(A61B5/150992 OR A61B5/15003 OR A61B5/150213 OR A61B5/150221 OR A61B5/150389 OR A61B5/150473 OR A61B5/150572 OR A61B5/153 OR A61B5/154 OR A61M39/04 OR A61M39/0693 OR A61M2039/0202 OR A61M2039/0633 OR A61M2039/068).cpc.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/09/16 07:03 PM
L593	5094	592 AND @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2024/09/16 07:03 PM
L594	1015	593 AND ((blood OR fluid$4 OR urine) near5(sequest$5 OR flush$4 OR optimiz$5 OR flash$4 OR diver$5 OR bypass$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2024/09/16 07:04 PM
L595	6	594 AND (blood near5 (filter OR impermeabl$4 OR membrane)) WITH (facilitat$4 OR caus$4) near5 (withdraw$4 OR draw$4 OR sampl$4 OR collect$4)	(US-PGPUB; USPAT)	OR	ON	ON	2024/09/16 07:06 PM
L596	0	594 AND (blood near5 (filter OR impermeabl$4 OR membrane)) WITH (facilitat$4 near5 (withdraw$4 OR draw$4 OR sampl$4 OR	(US-PGPUB; USPAT)	OR	ON	ON	2024/09/16 07:07 PM

		collect$4))					
L597	2	594 AND (blood near5 (filter OR impermeabl$4 OR membrane)) SAME (facilitat$4 near5 (withdraw$4 OR draw$4 OR sampl$4 OR collect$4))	(US-PGPUB; USPAT)	OR	ON	ON	2024/09/16 07:08 PM
L598	66	593 AND (flow$4 OR control$4 OR divert$4 OR mechanism OR valve) near5 (chamber OR reservoir OR container) AND (blood near5 impermeable)	(US-PGPUB; USPAT)	OR	ON	ON	2024/09/16 07:20 PM
L599	0	18/783088	(US-PGPUB; USPAT)	OR	ON	ON	2024/09/16 07:35 PM
L600	1	18/494622	(US-PGPUB; USPAT)	OR	ON	ON	2024/09/16 08:32 PM
L601	1	("11832944").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/09/16 08:32 PM
L602	1	18/549438	(US-PGPUB; USPAT)	OR	ON	ON	2024/09/17 01:14 PM
L603	326	((("ROGERS") near3 ("Bobby")) OR (("KANG") near3 ("Gino")) OR (("DETLOFF") near3 ("John"))).INV.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/12/23 03:36 PM
L604	32	603 AND ((blood OR fluid$4 OR urine) near5(sequest$5 OR flush$4 OR optimiz$5 OR flash$4 OR diver$5 OR bypass$4 OR subsequent$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2024/12/23 03:37 PM
L605	1635	593 AND ((blood OR fluid$4 OR urine) near5(sequest$5 OR flush$4 OR optimiz$5 OR flash$4 OR diver$5 OR bypass$4 OR subsequent$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2024/12/23 03:40 PM
L606	33	605 AND (blood near5	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/23

		(filter OR impermeabl$4 OR membrane)) WITH (facilitat$4 OR caus$4) near5 (withdraw$4 OR draw$4 OR sampl$4 OR collect$4)					03:41 PM
L607	1189	605 AND (flow$4 OR control$4 OR collect$4 OR sampl$4) near5 (force OR pressure OR pump$4 OR vacuum$4)	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/23 03:59 PM
L608	700	605 AND (flow$4 OR control$4 OR collect$4 OR sampl$4) near5 (force OR pressure OR pump$4 OR vacuum$4) WITH (chamber OR channel OR container OR port)	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/23 04:00 PM
L609	11	"20080145933"	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/23 04:12 PM
L610	1	16/331180	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/25 01:18 PM
L611	12	2017/0065824	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/25 04:38 PM
L612	6	"20170065824"	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/25 04:38 PM
L613	3	"20010047198"	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/25 04:38 PM
L614	20	"20050154321"	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/25 04:53 PM
L615	1	"20050049689"	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/25 04:58 PM
L616	12	"20170290686"	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/25 05:03 PM
L617	30	"20160199204"	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/25 05:08 PM
L618	1	18/066515	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/26 12:43 PM
L619	22	"20160082222"	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/26 02:02 PM
L620	50	("20020004647"|"20030105414"|"20040054333"|"20040073171"|"20040147855"|"20050004524"|"20050240161"|"20070083162"|"20070088279"|"20080086085"|"20080145933"|"20080167577"|"20080319346"|"20100010372"|"20100057004"|"20120016266"|"20130317391"|"201600	(US-PGPUB; USPAT)	OR	ON	ON	2025/06/03 11:38 AM

		08579"|"20160174888"|"20160325085"|"3741197"|"3817240"|"3874367"|"3886930"|"4057050"|"4106497"|"4154229"|"4207870"|"4412548"|"4436098"|"4444203"|"5222502"|"5520193"|"5749857"|"6398743"|"6569117"|"8197420"|"8523826"|"8535241"|"8540663"|"8568371"|"8603009"|"8864684"|"9022950"|"9022951"|"9060724"|"9138572"|"9155495"|"9204864"|"9877675").PN.					
L621	128	((("ROGERS") near3 ("Bobby")) OR (("KANG") near3 ("Gino")) OR (("DETLOFF") near3 ("John"))).INV.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2025/06/03 01:19 PM
L622	35	621 AND ((blood OR fluid$4 OR urine) near5(sequest$5 OR flush$4 OR optimiz$5 OR flash$4 OR diver$5 OR bypass$4 OR subsequent$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2025/06/03 01:19 PM
L623	1	("12138052").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2025/06/03 01:24 PM
L624	1	("11963769").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2025/06/03 01:25 PM
L625	1	("11185266").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2025/06/03 01:25 PM
L626	1	("10143412").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2025/06/03 01:26 PM
L627	1	("10010282").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2025/06/03 01:26 PM
L628	55585	(A61B5/150992 OR A61B5/15003 OR A61B5/150213 OR A61B5/150221 OR A61B5/150389 OR A61B5/150473 OR A61B5/150572 OR A61B5/153 OR A61B5/154 OR A61M39/04 OR A61M39/0693 OR A61M2039/0202 OR A61M2039/0633 OR A61M2039/068 OR A61B5/150251).cpc.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2025/06/03 01:27 PM

L629	38203	628 AND @ad<"20150724"	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2025/06/03 01:28 PM
L630	4451	629 AND ((blood OR fluid$4 OR urine) near5(sequest$5 OR flush$4 OR optimiz$5 OR flash$4 OR diver$5 OR bypass$4 OR collect$4 OR sampl$4 OR draw$4 OR withdraw$4 OR receiv$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2025/06/03 01:29 PM
L631	2304	630 AND ((blood OR fluid$4 OR urine) near5(filter$4 OR material$4 OR membrane OR permeab$4 OR impermeab$4 OR vent$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2025/06/03 01:30 PM
L632	735	630 AND ((blood OR fluid$4 OR urine) near5(filter$4 OR permeab$4 OR impermeab$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2025/06/03 01:30 PM
L633	1047	629 AND ((blood OR fluid$4 OR urine) near5(sequest$5 OR flush$4 OR optimiz$5 OR flash$4 OR diver$5 OR bypass$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2025/06/03 02:15 PM
L634	345	633 AND ((blood OR fluid$4 OR urine) near5(filter$4 OR permeab$4 OR impermeab$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2025/06/03 02:16 PM
L635	1	17/785304	(US-PGPUB; USPAT)	OR	ON	ON	2025/06/04 12:33 PM
L636	128	((("ROGERS") near3 ("Bobby")) OR (("KANG") near3	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2025/07/08 03:38 PM

		("Gino")) OR ((("DETLOFF") near3 ("John"))).INV.					
L637	35	636 AND ((blood OR fluid$4 OR urine) near5(sequest$5 OR flush$4 OR optimiz$5 OR flash$4 OR diver$5 OR bypass$4 OR subsequent$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2025/07/08 03:39 PM
L638	1	18/898239	(US-PGPUB; USPAT)	OR	ON	ON	2025/07/08 04:03 PM
L639	50	("20020004647"|"20030105414"|"20040054333"|"20040073171"|"20040147855"|"20050004524"|"20050240161"|"20070083162"|"20070088279"|"20080086085"|"20080145933"|"20080167577"|"20080319346"|"20100010372"|"20100057004"|"20120016266"|"20130317391"|"20160008579"|"20160174888"|"20160325085"|"3741197"|"3817240"|"3874367"|"3886930"|"4057050"|"4106497"|"4154229"|"4207870"|"4412548"|"4436098"|"4444203"|"5222502"|"5520193"|"5749857"|"6398743"|"6569117"|"8197420"|"8523826"|"8535241"|"8540663"|"8568371"|"8603009"|"8864684"|"9022950"|"9022951"|"9060724"|"9138572"|"9155495"|"9204864"|"9877675").PN.	(US-PGPUB; USPAT)	OR	ON	ON	2025/07/08 04:12 PM
L640	55732	(A61B5/150992 OR A61B5/15003 OR A61B5/150213 OR A61B5/150221 OR A61B5/150389 OR A61B5/150473 OR A61B5/150572 OR A61B5/153 OR A61B5/154 OR A61M39/04 OR A61M39/0693 OR A61M2039/0202 OR A61M2039/0633 OR A61M2039/068 OR A61B5/150251).cpc.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2025/07/08 04:32 PM

L641	5164	640 AND @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2025/07/08 04:32 PM
L642	4453	641 AND ((blood OR fluid$4 OR urine) near5(sequest$5 OR flush$4 OR optimiz$5 OR flash$4 OR diver$5 OR bypass$4 OR collect$4 OR sampl$4 OR draw$4 OR withdraw$4 OR receiv$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2025/07/08 04:33 PM
L643	2386	642 AND ((blood OR fluid$4 OR urine) near5(forc$4 OR pump$4 OR vacuum$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2025/07/08 04:33 PM
L644	1300	642 AND ((blood OR fluid$4 OR urine) near5(forc$4 OR pump$4 OR vacuum$4)) near5 (draw$4 OR withdraw$4 OR sampl$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2025/07/08 04:34 PM

PE2E SEARCH - Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
N94	1	(port and sequest$5 and junction and chamber and sampl$4 and vent and barrier).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2017/09/28 04:15 PM
N112	3	(port and sequest$5 and chamber and sampl$4 and vent and barrier).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/01/09 05:39 PM
N248	4	(blood and fluid$4 and inlet and outlet and port and reservoir and allow and initial$4 and sequest$5).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 03:30 PM
N249	4	(blood and fluid$4 and inlet and outlet and port and reservoir and allow$4 and initial$4 and sequest$5).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 03:30 PM
N250	495	(blood and fluid$4 and allow$4 and initial$4).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 03:31 PM
N251	107	(blood and fluid$4 and allow$4 and initial$4 and subsequent$4).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 03:31 PM

N283	9	((blood or fluid$4) and sequestrat$4 and chamber and sampl$4 and vent$4 and air$4).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:31 PM
N284	530	((blood or fluid$4) and chamber and sampl$4 and vent$4 and air$4).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:31 PM
N285	84	((blood or fluid$4) and chamber and cap and sampl$4 and vent$4 and air$4).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:32 PM
N365	6	(port and sequest$5 and junction and chamber and sampl$4 and vent and barrier).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:49 PM
N366	9	(blood AND fluid$4 AND inlet AND outlet AND junct$4 AND inhibit$4).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/11/16 05:31 PM
N367	84	((blood OR fluid$4) AND chamber AND sampl$4 AND junction AND (inhibit$4 OR prevent$4)).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/11/16 05:36 PM
N368	25	(blood AND chamber AND sampl$4 AND junction AND inlet AND outlet AND port AND first).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2023/04/11 04:48 PM
N369	4	(blood AND chamber AND sampl$4 AND junction AND inlet AND outlet AND port AND first AND hous$4 AND subsequent).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2023/04/11 04:49 PM
N370	64902	"465" AND housing	(US-PGPUB; USPAT)	OR	ON	ON	2023/04/11 04:50 PM
N371	6	(inlet AND outlet AND junct$4 AND channel AND sampl$4 AND fluid$4 AND vent AND air AND permeab$4).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/05 05:51 PM
N372	167	(inlet AND outlet AND junct$4 AND channel AND sampl$4 AND fluid$4).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/05 05:52 PM
N373	23	(inlet AND outlet AND junct$4 AND channel AND sampl$4 AND fluid$4 AND	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/05 05:53 PM

		bypass$4).clm.					
N374	33	(inlet AND outlet AND chamber AND blood AND sampl$4 AND bypass).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2023/08/31 02:35 PM
N375	18	(inlet AND outlet AND chamber AND blood AND sampl$4 AND bypass AND air AND permeable).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2023/08/31 02:36 PM
N376	14	(inlet AND outlet AND chamber AND (blood OR fluid OR urine) AND sampl$4 AND bypass AND air AND permeable AND junct$4).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2024/01/08 04:24 PM
N377	14	(inlet AND outlet AND chamber AND (blood OR fluid OR urine) AND sampl$4 AND bypass AND air AND permeable AND junct$4 AND channel).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2024/01/08 04:25 PM
N378	14	(inlet AND outlet AND chamber AND (blood OR fluid OR urine) AND sampl$4 AND bypass AND air AND permeable AND junct$4 AND channel AND vent).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2024/01/08 04:25 PM
N379	156	(inlet AND outlet AND chamber AND (blood OR fluid OR urine) AND memb$5 AND impermeable AND channel).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2025/06/03 02:28 PM
N380	18	(inlet AND outlet AND chamber AND blood AND memb$5 AND impermeable AND channel).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2025/06/03 02:28 PM
N381	6	(inlet AND outlet AND chamber AND blood AND memb$5 AND impermeable AND channel AND force).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2025/07/08 05:00 PM

Doc Code: IDS.SIZEFEE
Document Description: Assertion of whether IDS Size Fee Due

PTO/SB/08C (01-25)
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INFORMATION DISCLOSURE STATEMENT SIZE FEE – WRITTEN ASSERTION UNDER 37 CFR 1.98

Complete if Known

Application or Patent No.:	First Named Inventor:	Art Unit:
18898239	Bobby E. Rogers	3791
Filing Date:	**Attorney Docket Number:**	**Examiner:**
2024-09-26	069366-0581370_KUR2C07US	ABOUELELA, MAY A

Please see 37 CFR 1.17(v) and attached Instructions for completing this form to make the appropriate selection of an assertion under 37 CFR 1.98. For the information disclosure statement (IDS) submitted herewith, the applicant or patent owner certifies the following with respect to the cumulative number of applicant-provided or patent-owner provided items of information submitted to date including those in the accompanying IDS (select only one):

☑ No IDS size fee is required under 37 CFR 1.17(v) at this time.

☐ The IDS is accompanied by the IDS size fee under 37 CFR 1.17(v)(1).

☐ The IDS is accompanied by the IDS size fee under 37 CFR 1.17(v)(2).

☐ The IDS is accompanied by the IDS size fee under 37 CFR 1.17(v)(3).

NOTE: This form must be accompanied by PTO/SB/08a and/or PTO/SB/08b or equivalent.

DEPOSIT ACCOUNT

The Director is authorized to charge the fee indicated above in the amount of $ _____ for the IDS submitted herewith to deposit account _____.

SIGNATURE

This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications.

If applicant or patent owner is a juristic entity (e.g., an LLC or corporation), this form must be signed by a registered practitioner. See 37 CFR 1.31.

If applicant or patent owner is a person or persons, this form may be signed by either a registered practitioner, or the applicant or patentee. Note that if multiple people together are the applicant or patentee (e.g., there are joint inventors who together are the applicant), then a signature is required from each person who is an applicant or patentee. *Submit multiple forms if more than one signature is required, see below*.*

Signature	Date
/Ben Hudson/	2025-07-02
Name (Print/Typed)	**Practitioner Registration Number (if applicable)**
Benjamin F. Hudson	71,474

☐ * Total of _____ forms are submitted.

A Federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with an information collection subject to the requirements of the Paperwork Reduction Act of 1995, unless the information collection has a currently valid OMB Control Number. The OMB Control Number for this information collection is 0651-0070. Public burden for this form is estimated to average 2 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information collection. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden to the Office of the Chief Administrative Officer, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450 or email InformationCollection@uspto.gov. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

/MAY A ABOUELELA/ 07/08/2025

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.A.A/

Instructions for Filling out the
"Information Disclosure Statement Size Fee – Written Assertion Under 37 CFR 1.98" Form
(Not to be Submitted to the USPTO)

Note: This form is to be used when applicant or patent owner files an Information Disclosure Statement (IDS) for consideration by the examiner. This form must be accompanied by PTO/SB/08a and/or PTO/SB/08b or equivalent.

Determining the cumulative number of applicant-provided or patent owner-provided items of information

The IDS size fee is based on the cumulative number of items of information provided by an applicant or patent owner during the pendency of the application or reexamination proceeding. It is the applicant's and patent owner's responsibility to track the cumulative number of items of information provided in the application or proceeding and provide a written assertion of any applicable IDS size fee due.

In determining the applicable written assertion for the cumulative number of applicant-provided or patent owner-provided items of information, "provided" refers to the items cited on an IDS under 37 CFR 1.98(a)(1) by an applicant or patent owner, whether or not an actual copy of the cited item is submitted by the applicant or patent owner to the USPTO. If a particular item provided by an applicant or patent owner on an IDS was not considered because the item was non-compliant and that particular item is provided on an IDS a second time in the same application or patent, it will not be counted again.

An item of information that an applicant cited in a parent application will not be counted in a child application (e.g., a continuation, continuation-in-part, or divisional application) for the purpose of the IDS size fees unless it is resubmitted, i.e., provided by the applicant on an IDS in the child application. Applicants who wish to avoid paying the IDS size fees in a child application for items of information considered in a parent application may do so by not resubmitting the items. An item of information must be resubmitted in the continuing application if the applicant desires the item of information to be printed on the patent. See MPEP 609.02, subsection II.A.2.

The cumulative count is determined for each application or patent separately. Continuing, CPA, and reissue applications and post-issuance proceedings will start with a count of zero. A request for continued examination (RCE) is not the filing of a new application, and thus the count will not reset when an RCE is filed.

Written Assertion

Check "[ ] No IDS size fee is required under 37 CFR 1.17(v) at this time" on the above PTO/SB/08c form when the IDS does not cause the cumulative number of applicant-provided or patent owner-provided items in this application or proceeding to:

- exceed 50, 100, or 200 items of information.

Check "[ ] The IDS is accompanied by the IDS size fee under 1.17(v)(1)" on the above PTO/SB/08c form when the IDS causes the cumulative number of applicant-provided or patent owner-provided items in this application or proceeding to:

- exceed 50 items of information but not exceed 100 items of information.

Check "[ ] The IDS is accompanied by the IDS size fee under 1.17(v)(2)" on the above PTO/SB/08c form when the IDS causes the cumulative number of applicant-provided or patent owner-provided items in this application or proceeding to:

- exceed 100 items of information but not exceed 200 items of information.

Note: If a fee under 1.17(v)(1) was previously paid, the fee currently due is the difference between the 1.17(v)(2) fee and the previously paid 1.17(v)(1) fee.

/MAY A ABOUELELA/ 07/08/2025

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.A.A/

Doc Code: IDS.SIZEFEE
Document Description: Assertion of whether IDS Size Fee Due

Check "[ ] The IDS is accompanied by the IDS size fee under 1.17(v)(3)" on the above PTO/SB/08c form when the IDS causes the cumulative number of applicant-provided or patent owner-provided items in this application or proceeding to:

- exceed 200 items of information.

Note: If a fee under 1.17(v)(1) or (v)(2) was previously paid, the fee currently due is the difference between the 1.17(v)(3) fee and the previously paid 1.17(v)(1) or (v)(2) fee.

Select only one assertion on the PTO/SB/08c form above.

Note: the cumulative count of items of information includes all items of information already of record in a pending application or proceeding that were submitted via IDS(s) including those submitted prior to January 19, 2025.

Method of Payment

This section should only be filled out if the IDS size fee is due. Fees may be paid by check or money order (made payable to the Director of the United States Patent and Trademark Office), credit card (Form PTO-2038), or deposit account. When paying by deposit account, the amount of the IDS size fee to be charged to the deposit account must be specified to comply with 37 CFR 1.98(a)(4). General authorizations to charge fees to a deposit account are not compliant written assertions. When paying by credit card, to protect your credit card information, do not submit Form PTO-2038 electronically through USPTO's patent electronic filing system or any other USPTO Web site.

/MAY A ABOUELELA/ 07/08/2025

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The **Privacy Act of 1974 (P.L. 93-579)** requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

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2) a federal, state, local, or international agency, in response to its request;

3) a contractor of the USPTO having need for the information in order to perform a contract;

4) the Department of Justice for determination of whether the Freedom of Information Act (FOIA) requires disclosure of the record;

5) a Member of Congress submitting a request involving an individual to whom the record pertains, when the individual has requested the Member's assistance with respect to the subject matter of the record;

6) a court, magistrate, or administrative tribunal, in the course of presenting evidence, including disclosures to opposing counsel in the course of settlement negotiations;

7) the Administrator, General Services Administration (GSA), or their designee, during an inspection of records conducted by GSA under authority of 44 U.S.C. 2904 and 2906, in accordance with the GSA regulations and any other relevant (i.e., GSA or Commerce) directive, where such disclosure shall not be used to make determinations about individuals;

8) another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c));

9) the Office of Personnel Management (OPM) for personnel research purposes; and

10) the Office of Management and Budget (OMB) for legislative coordination and clearance.

If you do not furnish the information requested on this form, the USPTO may not be able to process and/or examine your submission, which may result in termination of proceedings, abandonment of the application, and/or expiration of the patent.

/MAY A ABOUELELA/

07/08/2025

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.A.A/

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-25)
Approved for use through 11/30/2027. OMB 0651-0031
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Application Number	18898239
Filing Date	2024-09-26
First Named Inventor	Bobby E. Rogers
Art Unit	3791
Examiner Name	ABOUELELA, MAY A
Attorney Docket Number	069366-0581370_KUR2C07US

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Inventor of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
	1	4874366		1989-10-17	ZDEB BRIAN	

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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Inventor or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
	1	20150018715		2015-01-15	WALTERSPIEL JUAN NEPOMUC	
	2	20160161511		2016-06-09	XU XIN	
	3	20080145933		2008-06-19	PATTON RICHARD G	
	4	20170020428		2017-01-26	ROGERS BOBBY E	
	5	20170209644		2017-07-27	BROWKA EDWARD	

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FOREIGN PATENT DOCUMENTS Remove

PC.1.19.25

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.A.A/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT		
	Application Number	18898239
	Filing Date	2024-09-26
	First Named Inventor	Bobby E. Rogers
	Art Unit	3791
	Examiner Name	ABOUELELA, MAY A
	Attorney Docket Number	069366-0581370_KUR2C07US

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] ¡	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1	2019232196A1	WO		2019-12-05	MAGNOLIA MEDICAL TECHNOLOGIES INC		☐
	2	2019055487A1	WO		2019-03-21	MAGNOLIA MEDICAL TECHNOLOGIES INC		☐

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NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1	Office Action (Non-Final Rejection) dated 12/02/2024 for U.S. Application No. 18/494,622; Attorney Docket No. 069366-0577657_KUR2C05US (pages 1-70).	☐
	2	Office Action (Advisory Action) dated 11/22/2024 for U.S. Application No. 18/783,173; Attorney Docket No. 069366-0580420_KUR3C03US (pages 1-3).	☐
	3	Office Action (Non-Final Rejection) dated 2/11/2025 for U.S. Application No. 18/783,173; Attorney Docket No. 069366-0580420_KUR3C03US (pages 1-23).	☐
	4	Office Action (Final Rejection) dated 12/31/2024 for U.S. Application No. 18/783,173; Attorney Docket No. 069366-0572192_KUR3C02US (pages 1-19).	☐
	5	Office Action (Advisory Action) dated 3/12/2025 for U.S. Application No. 17/893,079; Attorney Docket No. 069366-0572192_KUR3C02USUS (pages 1-5).	☐
	6	Office Action (Final Rejection) dated 2/12/2025 for U.S. Application No. 17/730,118; Attorney Docket No. 069366-0572186_KUR3C01US (pages 1-28).	☐

PC.1.19.25

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.A.A/

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	Application Number	18898239
	Filing Date	2024-09-26
	First Named Inventor	Bobby E. Rogers
	Art Unit	3791
	Examiner Name	ABOUELELA, MAY A
	Attorney Docket Number	069366-0581370_KUR2C07US

	7	Notice of Allowance mailed 1/23/2025; Attorney Docket No. 069366-0575784_KUR3D01IL, 121 pages.	☐
	8	Office Action (Non-Final Rejection) dated 11/26/2024 for JP Application No. 2024-121200; Attorney Docket No. 069366-0580493_KUR3D03JP (pages 1-11).	☐
	9	Office Action (Non-Final Rejection) dated 10/22/2024 for U.S. Application No. 18/317,558; Attorney Docket No. 069366-0575710_KUR4C02US (pages 1-62).	☐
	10	Notice of Allowance mailed 11/15/2024; Attorney Docket No. 069366-0575710_KUR4C02US, 9 pages.	☐
	11	Office Action (Final Rejection) mailed 10/09/2024 for Application No. 16838017, pages 1-27.	☐
	12	Office Action (Grounds) mailed 03/11/2025 for Application No. 2022-572789, pages 1-11; Attorney Docket No. 069366-0572492_KUR8001JP.	☐
	13	Office Action (Restriction Requirement) mailed 03/18/2025 for Application No. 17/336,178, pages 1-7; Attorney Docket No. 069366-0572194_KUR8001US.	☐
	14	Notice of Allowance mailed 07-02-2024; Attorney Docket No. 069366-0575784_KUR3D01IL.	☐
	15	Office Action (Non-Final Rejection) mailed 06/04/2025 for Application No. 17/893,079, pages 1-34; Attorney Docket No. 069366-0572192_KUR3C02US.	☐

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EXAMINER SIGNATURE

Examiner Signature	/MAY A ABOUELELA/	Date Considered	07/08/2025

*EXAMINER: Initial if reference considered and whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.A.A/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT		
	Application Number	18898239
	Filing Date	2024-09-26
	First Named Inventor	Bobby E. Rogers
	Art Unit	3791
	Examiner Name	ABOUELELA, MAY A
	Attorney Docket Number	069366-0581370_KUR2C07US

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.A.A/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT		
	Application Number	18898239
	Filing Date	2024-09-26
	First Named Inventor	Bobby E. Rogers
	Art Unit	3791
	Examiner Name	ABOUELELA, MAY A
	Attorney Docket Number	069366-0581370_KUR2C07US

TIMING STATEMENT

Please see 37 CFR 1.97(e) to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached timing statement under 37 CFR 1.97(e).

☒ A timing statement under 37 CFR 1.97(e) is not submitted herewith.

TIMING FEE

☐ The fee set forth in 37 CFR 1.17(p) has been submitted herewith.

COPIES

☐ An identification of an earlier application pursuant to 37 CFR 1.98(d)(1) is attached.

SIZE FEE ASSERTION

Please see 37 CFR 1.17(v) and the IDS Auto-Load Instructions for completing this form to make the appropriate selection of an assertion under 37 CFR 1.98. For the information disclosure statement (IDS) submitted herewith, the applicant or patent owner certifies the following with respect to the cumulative number of applicant-provided or patent-owner provided items of information submitted to date including those in the accompanying IDS (select only one):

☒ No IDS size fee is required under 37 CFR 1.17(v) at this time.

☐ The IDS is accompanied by the IDS size fee under 37 CFR 1.17(v)(1).

☐ The IDS is accompanied by the IDS size fee under 37 CFR 1.17(v)(2).

☐ The IDS is accompanied by the IDS size fee under 37 CFR 1.17(v)(3).

SIGNATURE

A signature of the applicant or representative is required in accordance with 37 CFR 1.33 and 11.18. Please see 37 CFR 1.4(d) for the form of the signature.

Signature	/Ben Hudson/	Date (YYYY-MM-DD)	2025-07-02
Name/Print	Benjamin F. Hudson	Registration Number	71,474

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT		
	Application Number	18898239
	Filing Date	2024-09-26
	First Named Inventor	Bobby E. Rogers
	Art Unit	3791
	Examiner Name	ABOUELELA, MAY A
	Attorney Docket Number	069366-0581370_KUR2C07US

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

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TO: Docket_IP@pillsburylaw.com
FROM: noreply@uspto.gov
CC: patentcenter_eofficeaction@uspto.gov
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Fri Jul 18 05:00:16 EDT 2025

Dear Patent Center Customer:

Correspondence Address:

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ATTENTION: DOCKETING DEPARTMENT
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Application	Document	Mailroom Date	Attorney Docket No.
18898239	NOA	07/18/2025	069366-0581370_KUR2C07US
18898239	1449	07/18/2025	069366-0581370_KUR2C07US
18898239	1449	07/18/2025	069366-0581370_KUR2C07US

To view your correspondence online, please sign in to Patent Center and then select Workbench/View correspondence. To update your email address(es), select Manage/Manage customer numbers.

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Sincerely,

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UNITED STATES
PATENT AND TRADEMARK OFFICE

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ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
18/898,239	**07/30/2025 05:56:42 PM Z ET**	**069366-0581370_KUR2C07US**

Title of Invention

BLOOD SAMPLE OPTIMIZATION DEVICE

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	7801	FILED BY	TRENT TERCENIO
PATENT CENTER #	71620489	FILING DATE	09/26/2024
CUSTOMER #	27500	FIRST NAMED INVENTOR	Bobby E. Rogers
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	Benjamin Hudson

Documents

TOTAL DOCUMENTS: 2

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
069366-0581370_KUR2C07US Comments on Reasons for Allowance.pdf	2	Miscellaneous Incoming Letter	101 KB
069366-0581370_KUR2C07US Issue Fee Transmittal_PTOL-85.pdf	1	Issue Fee Payment (PTO-85B)	189 KB

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
069366-0581370_KUR2C07US	32F8315FDD611C9E657F1A6CF7C0A4B1EE3E81199CB38A1D

Comments on Reasons for Allowance.pdf	2406B5CE79C197CDB4BF3A84991CDDC32B5AE56AE7740795 4E08D0A5C45A30ABA653E9BB554B2109
069366-0581370_KUR2C07US Issue Fee Transmittal_PTOL-85.pdf	987298A1DB31D56FED504DE8AA4AB0304520A92461856CF67 4AA105BCB5FEC30E39A8FB4DD15EE974E60C59F1E6AA5666 DDA319158B156A89E14F8FFAE271D77

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

UNITED STATES
PATENT AND TRADEMARK OFFICE

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ELECTRONIC PAYMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
18/898,239	**07/30/2025 05:56:42 PM Z ET**	**069366-0581370_KUR2C07US**

Title of Invention

BLOOD SAMPLE OPTIMIZATION DEVICE

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	7801	FILED BY	TRENT TERCENIO
PATENT CENTER #	71620489	AUTHORIZED BY	Benjamin Hudson
CUSTOMER #	27500	FILING DATE	09/26/2024
CORRESPONDENCE ADDRESS	-	FIRST NAMED INVENTOR	Bobby E. Rogers

Payment Information

PAYMENT METHOD	PAYMENT TRANSACTION ID	PAYMENT AUTHORIZED BY
DA / 033975	**E20257TH58486019**	**TRENT TERCENIO**

FEE CODE	DESCRIPTION	ITEM PRICE($)	QUANTITY	ITEM TOTAL($)
2501	UTILITY ISSUE FEE	516.00	1	516.00
			TOTAL AMOUNT:	**$516.00**

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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application

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New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Bobby E. Rogers, et al.

Confirmation No: 7801

Application No.: 18/898,239

Art Unit: 3791

Filed: September 26, 2024

Examiner: May A. Abouelela

For: BLOOD SAMPLE OPTIMIZATION DEVICE

Mail Stop Issue Fee
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

COMMENTS ON EXAMINER'S STATEMENT OF REASONS FOR ALLOWANCE

Applicant thanks Examiner Abouelela for the Notice of Allowance and the Examiner's efforts in examining the above-referenced application.

Applicant received the Examiner's "Statement Of Reasons For Allowance" (hereafter the "Statement") along with the Notice and wishes to note that entry of this Statement should not be construed as Applicant necessarily agreeing with or acquiescing to the reasons stated therein.

Applicant recognizes that, in accordance with MPEP § 1302.14, the Statement need not set forth all of the details as to why claims are allowed and, respectfully, Applicant does not concede that the Statement contains the only reasons for which the pending claims are allowable. Each of the claims stands on its own merits and is patentable because of the combination it recites and not because of the presence or absence of any one particular element.

CONCLUSION

It is believed that no fees are due in connection with the filing of this paper. In the event that it is determined that fees are due, however, the Commissioner is hereby authorized to charge any fees that may be due, or credit any overpayment of same, to Deposit Account 033975, Reference No. 069366-0581370_KUR2C07US.

Respectfully submitted,
PILLSBURY WINTHROP SHAW PITTMAN LLP

Date: July 30, 2025 By: /Ben Hudson/
Benjamin F. Hudson, Ph.D.
Reg. No. 71,474

PO Box 10500
McLean, Virginia 22102
Telephone: (858) 509-4000
Customer No. 27500

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), by mail or fax, or via the USPTO patent electronic filing system.

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By fax, send to: (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications. **Because electronic patent issuance may occur shortly after issue fee payment, any desired continuing application should preferably be filed prior to payment of this issue fee in order not to jeopardize copendency.**

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27500 7590 07/18/2025
PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
ATTENTION: DOCKETING DEPARTMENT
P.O BOX 10500
McLean, VA 22102

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Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being transmitted to the USPTO via the USPTO patent electronic filing system or by facsimile to (571) 273-2885, on the date below.

(Typed or printed name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/898,239	09/26/2024	Bobby E. Rogers	069366-0581370_KUR2C07US	7801

TITLE OF INVENTION: BLOOD SAMPLE OPTIMIZATION DEVICE

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$516	$0.00	$0.00	$516	10/20/2025

EXAMINER	ART UNIT	CLASS-SUBCLASS
ABOUELELA, MAY A	3791	600-577000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

☐ Change of correspondence address (or Change of Correspondence Address form PTO/AIA/122 or PTO/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/AIA/47 or PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 Pillsbury Winthrop Shaw Pittman LLP
2
3

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE: Kurin, Inc.
(B) RESIDENCE: (CITY and STATE OR COUNTRY): San Diego, CA

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ☒ Corporation or other private group entity ☐ Government

4a. Fees submitted: ☒ Issue Fee ☐ Publication Fee (if required)

4b. Method of Payment: *(Please first reapply any previously paid fee shown above)*

☒ Electronic Payment via the USPTO patent electronic filing system ☐ Enclosed check ☐ Non-electronic payment by credit card (Attach form PTO-2038)

☒ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. 033975

5. **Change in Entity Status** (from status indicated above)

☐ Applicant certifying micro entity status. See 37 CFR 1.29
NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

☐ Applicant asserting small entity status. See 37 CFR 1.27
NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

☐ Applicant changing to regular undiscounted fee status.
NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature /Ben Hudson/ Date July 30, 2025

Typed or printed name Benjamin F. Hudson Registration No. 71,474

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APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/898,239	08/19/2025	12390137	069366-0581370_KUR2C07US	7801

27500 7590 08/06/2025

PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
ATTENTION: DOCKETING DEPARTMENT
P.O BOX 10500
McLean, VA 22102

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(application filed on or after May 29, 2000)

The Patent Term Adjustment is 0 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

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INVENTOR(s) (Please see PATENT CENTER site https://patentcenter.uspto.gov for additional inventors):

Bobby E. Rogers, Park City, CA;
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John Detloff, San Diego, CA;

APPLICANT(s) (Please see PATENT CENTER site https://patentcenter.uspto.gov for additional applicants):

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18898239	ISSUE.NTF	08/06/2025	069366-0581370_KUR2C07US

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/898,239	09/26/2024	Bobby E. Rogers	069366-0581370_KUR2C07US	7801

27500 7590 08/19/2025

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3791	

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APPLICATION NO.	ISSUE DATE	PATENT NO.
18/898,239	19-Aug-2025	12390137

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Application	Patent	Document	Mailroom Date	Attorney Docket No.
18898239	12390137	EGRANT.NTF	08/19/2025	069366-0581370_KUR2C07US

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