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(54) Title: BIOLOGICAL SAMPLE COLLECTION DEVICE PROVIDING FOR MECHANICAL SAMPLE HOMOGENIZATION USING A SAMPLE ALIQUOT UNIT

(57) Abstract: Devices and techniques for collecting and mechanically homogenizing biological samples by exchanging a collected biological sample between two degassed volumes, one of which is a sample aliquot unit, are discussed. The sample collection unit may be sized for use in a hospital environment, including pneumatic delivery systems.
BIological SAMPLE Collection DEVICE PROVIDING FOR MECHANICAL SAMPLE HOMOGENIZATION USING A SAMPLE ALIQUOT UNIT

BACKGROUND OF THE INVENTION

[0001] Biological sample collection in the hospital setting may occur in various ways depending on the nature of the sample to be collected. One device which is in widespread use is a Lukens trap, which is a cylindrical container with a screw-top lid. The Lukens lid includes two nipples which protrude out of the top of the lid. The first nipple exits the lid near the edge of the Lukens lid. The second nipple protrudes from the center of the Lukens lid and also extends into the volume of the Lukens container some distance when the Lukens lid is attached. A vacuum source is connected to the center nipple via a flexible hose, and a sample source is connected to the outer nipple using another flexible hose. The vacuum is used to draw the sample into the Lukens trap. After a desired quantity of sample is collected, the vacuum and sample sources are disconnected, and a short length of tubing is used to join both nipples and seal the Lukens trap against contamination of, or contagion from, the collected sample. In some Lukens trap implementations, rather than joining the nipples via a short length of tubing to seal the Lukens trap, the entire lid is removed and replaced with a lid without nipples or other leak paths. To remove the sample, the Lukens lid is typically unscrewed and the sample either poured out or withdrawn using a syringe or other instrument.

SUMMARY OF THE INVENTION

[0002] In one particular implementation, a biological sample collection unit (SCU) is provided. The SCU may include a housing substantially defining a sample collection volume (SCV). The SCV may be changeable in volume and have a first port and a second port. The first port may be in fluidic communication with the SCV and may be configured to be sealable with respect to the SCV, and the second port may be in fluidic communication with the SCV and may be configured to removably mount a sample aliquot unit (SAU) with a changeable internal volume such that, when the SAU is mounted to the second port, the SAU internal volume is in fluidic communication with the SCV via the second port, the SAU internal volume, the SCV, and the second port, while in fluidic communication with each other, are not in fluidic communication with an external environment, and the SCU is
configured to provide mechanical homogenization by providing a substantially equal and complementary volumetric change in the SCV in response to a volumetric change in the SAU internal volume.

[0003] In some further implementations, the SCU may also include the SAU removably mounted to the second port. In some further implementations, the SAU may be a syringe.

[0004] In another particular implementation, a biological sample collection device is provided. The biological sample collection device may include a sample collection unit (SCU) main body, with a first tubular region of a substantially constant cross section along an axis of the SCU main body and including a first inner surface and terminating at a first end and a second end opposite the first end. The biological sample collection device may also include an SCU plunger slidably engaged with the first inner surface to form a sliding seal with the first inner surface and configured to slide along the axis with respect to the SCU main body. The SCU plunger may include a first orifice. A sample collection volume (SCV) may be substantially defined by the first inner surface, the first end, and the SCU plunger, and the first orifice may provide a fluidic communication path from the SCV, through the SCU plunger, and away from the first end.

[0005] In some further implementations, the biological sample collection device may be provided partially or completely disassembled and in kit form.

[0006] In some further implementations, the SCU plunger may include a filter within the first orifice, the filter configured to filter all fluidic flow through the first orifice when present.

[0007] In some further implementations, the biological sample collection device may include an SCU lid with a mechanical interface configured to secure the SCU lid to the second end of the SCU main body and a sliding interface. The sliding interface may be configured to slidably engage with an external surface of the SCU plunger and the SCU plunger may be configured to slide along the axis with respect to the SCU lid when the SCU plunger is slidably engaged with the SCU lid and the SCU lid is secured to the second end of the SCU main body. The mechanical interface may be configured to form a seal between the SCU lid and the SCU main body when the SCU lid is secured to the second end, and the
sliding interface may be configured to form a seal between the SCU lid and the SCU plunger when the SCU plunger is slidably engaged with the SCU lid.

[0008] In some further implementations, the SCU lid may include a conical frustum which is configured to project into the SCU main body when the SCU lid is secured to the second end of the SCU main body. The conical frustum may include a through-hole, the sliding interface may be provided by at least a portion of the through-hole, and the conical frustum may engage with the SCU main body when the SCU lid is secured to the second end of the SCU body.

[0009] In some implementations, the biological sample collection device may include a sample aliquot unit (SAU) including an SAU plunger slidably engaged with an SAU main body, a first SAU end and a second SAU end located at opposite ends of the SAU main body, and an SAU port located at the first SAU end. The SAU port may be configured to interface with the first orifice and to form a seal between the SAU and the SCU plunger when the SAU is mounted to the first orifice. In some implementations, the SCU plunger and the filter may be configured such that the SAU port ruptures the filter when the SAU is mounted to the first orifice.

[0010] In some implementations, the biological sample collection device may include a Lukens lid including a mechanical interface configured to secure the Lukens lid to the second end of the SCU main body, a vacuum port, the vacuum port configured to extend away from the SCU main body when the Lukens lid is secured to the SCU main body, and a sample collection port, the sample collection port configured to extend away from the SCU main body when the Lukens lid is secured to the SCU main body, wherein the Lukens lid seals an internal volume of the SCU main body when secured to the second end of the SCU main body and the sample collection port and the vacuum port are the only fluidic communication paths out of the internal volume when the Lukens lid is secured to the SCU main body.

[0011] In some implementations, the SCU main body may include a second orifice at the first end of the SCU main body. In some further implementations, the biological sample collection device may further include an SCU cap configured to be installed on the second orifice and seal the second orifice when installed.
[0012] In some implementations, the SCU plunger may include an adapter interface including the first orifice, and the biological sample collection device may further include a vacuum port adapter including a vacuum port. The vacuum port adapter may include an interface configured to mate with, and seal to, the adapter interface, and may provide for fluidic communication between the SCV and an external environment when the SCU plunger is slidably engaged with the inner surface and the vacuum port adapter is mated with, and sealed to, the adapter interface. The biological sample collection device may also include a sample aliquot unit (SAU) adapter which includes an interface configured to mate with, and seal to, the adapter interface. The SAU adapter may include an SAU interface which provides a fluidic communication path between the SCV and an external environment when the SCU plunger is slidably engaged with the inner surface and the SAU adapter is mated with, and sealed to, the adapter interface, and a filter, the filter mounted within the SAU interface and configured to filter all fluidic flow through the SAU interface when present.

[0013] In some implementations, the biological sample collection device may include an SAU including an SAU plunger slidably engaged with an SAU main body, a first SAU end and a second SAU end located at opposite ends of the SAU main body, and an SAU port located at the first SAU end. The SAU port may be configured to interface with the SAU interface and to form a seal between the SAU and the SAU adapter when the SAU is mounted to SAU interface. In some further implementations, the SAU interface and the filter may be configured such that the SAU port ruptures the filter when the SAU is mounted to the SAU interface.

[0014] In one particular implementation, a biological sample collection device may be provided. The biological sample collection device may include a sample collection unit (SCU) main body, a base plunger, and an SCU lid. The SCU main body may include a first tubular region with a substantially constant cross section along an axis of the SCU main body, the first tubular region including a first inner surface and terminating at a first end and a second end opposite the first end. The base plunger may be slidably engaged with the first inner surface to form a sliding seal with the first inner surface and to slide along the axis with respect to the SCU main body. The SCU lid may include a mechanical interface configured to secure the SCU lid to the second end of the SCU main body, a vacuum port interface, and a sample port interface. The SCU lid may be secured to the SCU main body by the mechanical
interface, a sample collection volume (SCV) may be substantially defined by the first inner surface, the base plunger, and the SCU lid, and the vacuum port interface and the sample port interface are may be in fluidic communication with the SCV.

[0015] In some further implementations, the biological sample collection device may be provided partially or completely disassembled and in kit form.

[0016] In some implementations, the biological sample collection device may include a filter plug and a non-permeable plug. The filter plug may be sized to connect with the sample port interface and provide a filtered fluidic flow path from the SCV when the filter plug is connected with the sample port interface and the SCU lid is secured to the second end of the SCU main body. The non-permeable plug may be sized to connect with the vacuum port interface and prevent fluidic flow from the SCV via the vacuum port interface when the non-permeable plug is connected with the vacuum port interface and the SCU lid is secured to the second end of the SCU main body.

[0017] In some implementations, the biological sample collection device may further include a sample aliquot unit (SAU) including an SAU plunger slidably engaged with an SAU main body, a first SAU end and a second SAU end located at opposite ends of the SAU main body, and an SAU port located at the first SAU end. The SAU port may be configured to interface with the sample port interface and to form a seal between the SAU and the SCU lid when the SAU is mounted to the sample port interface.

[0018] In some implementations, the SCU lid may further include a first storage receptacle configured to store the filter plug and a second storage receptacle configured to store the non-permeable plug. In some implementations, the filter plug may be connected to the SCU lid by a first flexible tether, and the non-permeable plug may be connected to the SCU lid by a second flexible tether.

[0019] In some implementations, the base plunger may include a base housing and a base piston. The base piston may form the sliding seal with the first inner surface when the base plunger is inserted through the first end, and the base piston may be configured to be slidable along the axis of the SCU with respect to the SCU and the base plunger when the base plunger is inserted through the first end. In some further implementations, the base plunger may include a uni-directional ratchet mechanism and the SCU main body may
include features which interface with the uni-directional ratchet mechanism and prevent the base plunger from being withdrawn from the SCU main body when the base plunger is inserted through the first end.

[0020] In one particular implementation, a method is provided. The method may include collecting a biological sample in a first volume, bleeding, after the collecting, substantially all free gas from the first volume, and mechanically homogenizing, after the bleeding, the biological sample by transferring at least a portion of the biological sample between the first volume and a second volume fluidly removably connected with the first volume. The method may further include repeating the transference of the at least a portion of the biological sample between the first volume and the second volume a predetermined number of times. The method may further include transferring, after the transference of the at least a portion of the biological sample between the first volume and the second volume, at least some of the biological sample into the second volume and disconnecting the second volume from the first volume.

**BRIEF DESCRIPTION OF THE DRAWINGS**

[0021] Fig. 1 depicts a high-level conceptual diagram of an SCU where homogenization is provided, in part, using a detachable sample aliquot unit (SAU).

[0022] Fig. 2A depicts an isometric view of one implementation of an SCU.

[0023] Fig. 2B depicts an isometric exploded view of the SCU depicted in Fig. 2A.

[0024] Fig. 2C depicts an isometric exploded section view of the SCU depicted in Fig. 2A.

[0025] Fig. 2D depicts a side section view of the SCU depicted in Fig. 2A during sample collection.

[0026] Fig. 2E depicts a side section view of the SCU depicted in Fig. 2A after sample collection and during vacuum port adapter removal.

[0027] Fig. 2F depicts a side section view of the SCU depicted in Fig. 2A after SAU adapter installation.

[0028] Fig. 2G depicts a side section view of the SCU depicted in Fig. 2A after de-gassing.
[0029] Fig. 2H depicts a side section view of the SCU depicted in Fig. 2A after SAU installation.

[0030] Fig. 2I depicts a side section view of the SCU depicted in Fig. 2A during homogenization.

[0031] Fig. 3A depicts an isometric view of a second implementation of an SCU.

[0032] Fig. 3B depicts an isometric exploded view of the SCU depicted in Fig. 3A.

[0033] Fig. 3C depicts an isometric exploded section view of the SCU depicted in Fig. 3A.

[0034] Fig. 3D depicts a side section view of the SCU depicted in Fig. 3A during sample collection.

[0035] Fig. 3E depicts a side section view of the SCU depicted in Fig. 3A after sample collection and during Lukens lid removal.

[0036] Fig. 3F depicts a side section view of the SCU depicted in Fig. 3A after SCU lid installation.

[0037] Fig. 3G depicts a side section view of the SCU depicted in Fig. 3A after de-gassing.

[0038] Fig. 3H depicts a side section view of the SCU depicted in Fig. 3A after SAU installation.

[0039] Fig. 3I depicts a side section view of the SCU depicted in Fig. 3A during homogenization.

[0040] Fig. 4A depicts an isometric view of a third implementation of an SCU.

[0041] Fig. 4B depicts an isometric exploded view of the SCU depicted in Fig. 4A.

[0042] Fig. 4C depicts an isometric exploded section view of the SCU depicted in Fig. 4A.

[0043] Fig. 4D depicts a side section view of the SCU depicted in Fig. 4A during sample collection.

[0044] Fig. 4E depicts a side section view of the SCU depicted in Fig. 4A after sample collection.

[0045] Fig. 4F depicts a side section view of the SCU depicted in Fig. 4A after filter plug and solid plug installation.
[0046] Fig. 4G depicts a side section view of the SCU depicted in Fig. 4A after sealing of the SCU lid to the SCU main body.

[0047] Fig. 4H depicts a side section view of the SCU depicted in Fig. 4A after de-gassing.

[0048] Fig. 4I depicts a side section view of the SCU depicted in Fig. 4A after removal of the filter plug.

[0049] Fig. 4J depicts a side section view of the SCU depicted in Fig. 4A after SAU installation.

[0050] Fig. 4K depicts a side section view of the SCU depicted in Fig. 4A during homogenization.

[0051] Fig. 5 depicts a high-level flow diagram of one technique of using an SCU.

**DETAILED DESCRIPTION**

[0052] Reference will now be made in detail to specific implementations of the invention. Examples of the specific implementations are illustrated in the accompanying drawings. While the invention will be described in conjunction with these specific implementations, it will be understood that it is not intended to limit the invention to such specific implementations. On the contrary, it is intended to cover alternatives, modifications, and equivalents as may be included within the spirit and scope of the invention. In the following description, numerous specific details are set forth in order to provide a thorough understanding of the present invention. The present invention may be practiced without some or all of these specific details. In other instances, well known mechanical apparatuses and/or process operations have not been described in detail in order not to unnecessarily obscure the present invention.

[0053] It should also be understood that, unless a term is expressly defined in this patent using the sentence “As used herein, the term ‘________’ is hereby defined to mean...” or a similar sentence, there is no intent to limit the meaning of that term, either expressly or by implication, beyond its plain or ordinary meaning, and such term should not be interpreted to be limited in scope based on any statement made in any section of this patent (other than the language of the claims). To the extent that any term recited in the claims at the
end of this patent is referred to in this patent in a manner consistent with a single meaning, that is done for sake of clarity only so as to not confuse the reader, and it is not intended that such claim term be limited, by implication or otherwise, to that single meaning. Finally, unless a claim element is defined by reciting the word “means” and a function without the recital of any structure, it is not intended that the scope of any claim element be interpreted based on the application of 35 U.S.C. § 112, sixth paragraph.

[0054] It is to be understood that the term “fluidic” is used herein to refer to indicate a substance, such as a liquid, gas, or mixture thereof, that is capable of flowing, unless specifically or contextually indicated otherwise. For example, a passage which permits fluidic flow is a passage which allows for a fluidic substance to flow through it; there may be solids or particulates entrained within the fluidic substance which may also pass through such a passage as part of the flow. By way of further example, a collected biological sample may, in some cases, be generally described as “fluidic.” One such example is sputum, which may include saliva, water, or other fluids, as well as bubbles of air and small particles, such as cells or debris.

[0055] It is also to be understood that some of the claims based on this application may be “kit” claims which include one or more components which may be assembled or combined with each other or with components external to the kit to provide, for example, an SCU, but which may not necessarily need to be provided in assembled form. Such components may be described with reference to features of assembly, e.g., “component A has a hole with an axis parallel to the central axis of assembly A.” While such assembly features may not exist when the assembly is in a disassembled state, it is to be understood that the geometry of the component, unless otherwise indicated, is not affected by the assembly state of the assembly, and that such references are to be understood as including an implicit reference to the assembled assembly, e.g., “component A has a hole with an axis parallel to the central axis of assembly A [when component A is installed in assembly A].”

[0056] At a high level, biological sample collection unit (SCU) 100 may be provided for collecting biological samples, as shown in Fig. 1. SCU 100 may be used in a hospital setting and may be designed to be a single-use, disposable component. SCU 100 may include sample collection volume (SCV) 102 and sample aliquot unit (SAU) volume 104. SCV 102 may be fluidly connected with SAU volume 104 via passage 108; SAU volume 104 may be
connected with SCV 102 in a removable manner. Parting line 110 may represent the boundary between the SAU and the SCU, although, in practice, such a boundary may not be a straight line. SCV 102 may also fluidly connect with inlet port 106, which may be used to introduce the fluids, solids, or gases containing a biological sample to SCV 102.

[0057] For example, SCU 100 may be connected to a vacuum source via the passage and a sample source via inlet port 106 for sample collection; it may be necessary to remove the SAU, and SAU volume 104, from fluidic communication with passage 106 in order to connect the vacuum source to SCU 100. The vacuum source may be used to draw a sample into SCU 100, where the sample collects in SCV 102. After the sample is collected, the sample source and vacuum source may be disconnected, and the SAU may be, if needed, reinstalled or installed. SCV 102 may be degassed prior to SAU installation to remove free gas from SCV 102. When the SAU is installed, the collected biological sample may be reciprocated between SCV 102 and SAU volume 104 to mechanically homogenize the sample. Such an implementation may be used, for example, to collect sputum samples from a respiratory tract via a ventilator. In some other implementations, a sample may be introduced to SCV 102 manually, such as via a scoop, spatula, or other instrument. Such a configuration may be used, for example, for blood, urine, or stool samples, although such samples may also be collected in SCV 102 using other techniques as well.

[0058] SCU 100 may be configured to receive a collected biological sample at or near the site of collection, e.g., bedside, and provide for safe transport from the collection site to a remote analysis site, e.g., pathology lab. SCU 100 may also be configured to provide for mechanical homogenization of the collected biological sample at either the collection site, the analysis site, or during transit through repeated transfer of the collected biological sample between SCV 102 and SAU volume 102. It is to be understood that “mechanical homogenization,” as used herein, refers to rendering the biological sample more homogenous through forcing repetitive movement of the collected biological sample between SCV 102 and SAU volume 104 rather than, for example, using heat, chemicals, or other techniques to render the collected biological sample more homogenous. The biological sample, in the case of an SCU used to collect sputum, may include material such as clots of blood, phlegm, mucus, saliva, or other substances which may be found in a respiratory tract, for example. Such substances may take the form of a mucoidal, non-
homogenous fluid or mass. For example, mucus may be described as a viscous, slimy, non-homogenous mixture of mucins, water, electrolytes, epithelial cells, leukocytes, and other biological materials that is secreted by glands lining the nasal, esophageal, and other body cavities and serves primarily to protect and lubricate surfaces. Mucus may also include biological and non-biological materials which are not secreted by the organism, but which are foreign to the organism and entrained in the mucus. For example, mucus may include soot, dust, pollens, spores, etc. Depending on the conditions, mucus may also solidify wholly or partially due to moisture loss and other factors.

[0059] It is to be further understood that while a collected biological sample may be rendered somewhat more homogenous by simply shaking or otherwise manipulating the orientation or position of the vessel containing the sample, such actions do not constitute "mechanical homogenization" as used herein since the collected biological sample is not forced from one volume to another, and vice versa, in a repeated manner.

[0060] In some implementations, the various components of SCU 100 may be broken down into three separate groups, each of which moves in a different direction and/or at a different rate during mechanical homogenization. During mechanical homogenization in these implementations, the components in each group may move together, i.e., in the same direction, by the same amount, and at the same rate, and the components in another group may also move together, although each group may move in a different direction with respect to another group. For example, in Fig. 1, a first group of components may generally define most of SCV 102, most of SAU volume 104, and passage 108. A second group of components, however, may define a portion of SCV 102, and may be movable with respect to the first group of components. When the second group of components is moved with respect to the first group of components, SCV 102 may experience volumetric change. For example, SCV102 may expand to SCV 102', or contract to SCV 102'' when the second group of components is moved. A third group of components may define a portion of SAU volume 104, and may be movable with respect to the first group of components and the second group of components. For example, SAU volume 104 may contract to SAU volume 104', or expand to SAU volume 104'' when the third group of components is moved. If SCV 102 and SAU volume 104, linked by passage 108, represent a sealed system filled with a generally incompressible fluid or mixture of fluid and solids, such as a collected biological sample, the
third group of components may move with respect to the first group of components and the second group of components when the second group of components is moved with respect to the first group of components so as to maintain the overall system volume at a generally constant amount.

[0061] The amount of movement experienced of the second group of components with respect to the first group of components as compared with the amount of movement experienced by the third group of components with respect to the first group of components may be different if similar movement of the second group and the third group results in different volumetric changes in the volumes they define. For example, if SCV 102 and SAU volume 104 are generally cylindrical (and the cylinder axes correspond with the vertical direction on the drawing page), the second group of components may only need to move 25% of the distance that the third group of components may need to move (both with respect to the first group of components) in order to preserve the overall system volume. Thus, SAU volume 104' may correspond with SCV 102', and SAU volume 104" may correspond with SCV 102", since both pairs of volumes result in the same overall system volume.

[0062] By maintaining the overall system volume while transferring a generally incompressible biological sample between two different, and variable, volumes, one of which may be a removable SAU, the SCU allows for mechanical homogenization to be reliably performed without the significant, and needless, introduction of gas into the collected biological sample. Such SCU implementations may also provide for a portion of the mechanical homogenization equipment, such as the SAU, to be used not only for mechanical homogenization purposes, but for sample transfer during laboratory testing as well.

[0063] Fig. 2A shows an isometric view of one implementation of an SCU. Figs. 2B and 2C show an isometric exploded view and an isometric exploded section view, respectively, of the SCU of Fig. 2A. SCU 200 may include a variety of components, including SAU 202, SCU main body 210, SCU plunger 212, and SCU cap 218. Also shown are vacuum tube 222, sample tube 224, vacuum port adapter 220, and SAU adapter 230. The parts shown in Figs. 2A-2C may not all be used simultaneously, and may be combined in various manners to perform various tasks. In practice, the various parts used in some or all of the tasks
described below may be provided as a pre-assembled unit, or in kit form requiring some limited assembly by a user. For example, SCU 200 may be provided with SAU 202 unassembled (or without an SAU 202 at all, requiring that SAU 202 be separately procured—which may be a feasible option when SAU 202 is a standard syringe commonly found in medical facilities). Some such combinations and configurations of such parts are shown in Figs. 2D-2I, and are discussed below.

[0064] Fig. 2D shows SCU 200 configured for biological sample collection. As can be seen, vacuum tube 222 is connected to vacuum port adapter 220, which is, in turn, installed in SCU plunger 212. SCU plunger 212 includes SCU piston sleeve 216, which has SCU piston 214 encircling it. SCU piston sleeve 216 may provide a rigid or substantially non-compliant interface which supports vacuum port adapter 220 and provides a sealing surface for SCU plunger O-ring 256. SCU piston 214 may be made from a compliant material allowing it to seal against the inner surface of SCU main body 210 while simultaneously permitting SCU plunger 212 to slide along the central axis of SCU main body 210. Any of several techniques may be used to secure vacuum port adapter 220 to SCU piston sleeve 216, including threaded connections, connections modeled after Luer-type fittings, friction fits, bayonet type interfaces, etc.

[0065] SCU plunger 212 may take other forms as well. For example, SCU plunger 212 may be any of a variety of structures which form a sliding seal with the inner wall of SCU main body 210, contain a passage connecting the interior of SCU main body 210 with the environment on the side of SCU plunger 212 facing away from the interior of SCU main body 210, and provide for an interface with a suction source, SAU 202, or both. In some implementations, SCU plunger 212 may be a single piece, e.g., SCU piston sleeve 216 and SCU piston 214 may be a single, molded part featuring a compliant outer perimeter or compliant material throughout.

[0066] With SCU plunger 212 forming a sliding seal with SCU main body 210, and with vacuum port adapter 220 mounted in SCU plunger 212 and forming a seal with SCU plunger 212 via SCU plunger O-ring 256 and SCU piston sleeve 216, vacuum port 252 and sample port 254 are the only inlets or outlets from the interior of SCU 200. Vacuum tube 222 may be connected to vacuum port 252 and sample tube 224 may be connected to sample port 254. The other end of vacuum tube 222 may be connected to a suction source (not shown),
and the other end of sample tube 224 may be connected to a source of sample material, such as a patient’s lungs via a ventilator apparatus. Biological sample 201 may then be pulled through sample tube 224 and deposited within SCU main body 210. Chains of arrows are used to indicate flow direction for gases/liquids/solids being pulled through SCU 200. Black arrows are used to indicate flow prior to sample deposition within SCU 200, and white arrows are used to indicate flow after sample deposition within SCU 200. Similar conventions are used with respect to other depicted implementations herein.

[0067] The volume within SCU main body 210 bracketed between SCU plunger 212 and the end of SCU main body 210 featuring sample port 54 may be referred to as SCV 290. It is to be noted that SCV 290 may change in overall volume depending on the positioning of SCU plunger 212, as may be evident in the other figures. It is to be understood that other SCVs discussed with reference to other SCU implementations herein may be similarly variable in size depending on the configuration of components during various stages of SCU use.

[0068] When sufficient biological sample 201 has been collected within SCV 290 of SCU main body 210, sample tube 224 may be removed from sample port 254. Sample port 254 may then be sealed using SCU cap 218, as shown in Fig. 2E. Vacuum port adapter 220 may also be removed, as shown in Fig. 2E.

[0069] After vacuum port adapter 220 has been removed from SCU plunger 212, SAU adapter 230 may be installed, as shown in Fig. 2F. SAU adapter 230 and vacuum port adapter 220 may have similar features for interfacing with SCU plunger 212 and/or SCU plunger sleeve 216, and both may be secured to SCU plunger 212 in a similar manner. SAU adapter 230 may include SAU adapter O-ring 232 to form a seal between SAU adapter 230 and SCU piston sleeve 216. SAU adapter 230 may have, for example, SAU interface 236, which may be configured to receive SAU 202. SAU interface 236 may be a simple friction fit, such as a Luer-Slip™ style taper connection, or may include other interface types such as, for example, a Luer-Lok™ style of taper-type fitting or a threaded interface. SAU adapter 230 may also include filter 234 which filters fluidic flow through passage 238 of SAU adapter 230. Filter 234 may be a micropore filter configured to allow gaseous flow between SCV 290 and the environment on the opposite side of SCU plunger 212. Filter 234 may be selected to allow gaseous flow but prevent most liquid and particulate flow, such as flow of the biological sample 201. Filter 234 may be, for example, a 0.2 micron filter.
After SAU adapter 230 has been installed in SCU plunger 212, SAU adapter 230 and SCU plunger 212 may be pushed into SCU main body 212, as shown in Fig. 2G. Gases which are trapped within SCV 290 may escape through filter 234, allowing any pressure built up by pushing SAU adapter 230 and SCU plunger 212 into SCU main body 210 to bleed off. After substantially all of the free gas within SCV 290 has been bled off through filter 234, the remaining material within SCV 290 may be substantially composed of solid and liquid biological sample 201. SCV 290 may also, as a result of the translation of SAU adapter 230 and SCU plunger 212 within SCU main body 210, decrease in volume until SCV 290 is substantially coextensive in volume with the collected biological sample 201.

After the excess gas has been bled from SCV 290, SAU 202 may be installed in SAU adapter 230 by connecting SAU 202 with SAU interface 236, as shown in Fig. 2H. SAU interface 236 and SAU 202 form a seal and prevent ambient air from being drawn into SAU main body 206 when SAU plunger 204 is partially withdrawn from SAU main body 206. When SAU 202 is inserted into SAU interface 236, the tip of SAU 202 contacts filter 234 and ruptures filter 234. Because filter 234 no longer prevents fluids and solids in SCV 290 from flowing through passage 238, the collected biological sample 201 may be transferred between SCU main body 212 and SAU main body 206.

After filter 234 has been ruptured by installing SAU 202 into SAU interface 236, SAU plunger 204 may be reciprocated with respect to SAU main body 206. This causes collected biological sample 201 from SCV 290 to be drawn into SAU 202, as shown in Fig. 2I. Concurrently with the transfer of material from SCV 290 into SAU 202, SCU plunger 212 may be drawn further forward into SCU main body 210 to accommodate the reduction in volume of the collected biological sample 201 as the biological sample 201 flows into SAU 202. For example, if 1 cc of biological sample 201 is drawn into SAU 202, SCU plunger 212 may be drawn into SCU main body 210 sufficiently far enough to decrease SCV 290 by 1 cc. As can be seen in Fig. 2I, due to SCU plunger 212’s larger diameter as compared to SAU piston 208’s diameter, SCU plunger 212 may be displaced a relatively small distance compared to the displacement of SAU plunger 204. There may be some dead volume within the SAU which corresponds generally with the volume within the tip of the SAU—gas trapped within this volume may be trapped within the SCU system once SAU 202 is installed, and it may not be possible to bleed this trapped gas off. While such trapped dead-space gas may be a source
of compressible volume within SCU 200, this compressible volume may be negligible compared to the volume of collected biological sample 201, and it is to be understood that this minor compressible volume should not be viewed as affecting the overall generally incompressible nature of SCV 290 or biological sample 201 once degassing has occurred. Similar dead space volume may also exist in other SAUs used in other implementations, and a similar understanding is to be accorded in such other implementations as well.

[0073] As noted above, SAU plunger 204 may be reciprocated, which may draw biological sample 201 into SAU 202 from SCV 290 and then expel the biological sample 201 back out into SCV 290. This may cause turbulent flow and mixing in SCV 290 and within SAU 202, which may, if repeated a sufficient number of times, achieve a desired degree of mechanical homogenization. For example, 20-30 reciprocations may be performed in some implementations. In practice, a standard number, or range, of reciprocations may be specified for a given model of SCU and a range of different types of biological sample 201.

[0074] After sufficient reciprocations have been performed, a desired amount of biological sample 201 may be drawn into SAU 202 and SAU 202 may then be removed from SAU adapter 230. The withdrawn biological sample 201 may then be transferred to laboratory or pathology testing apparatuses for evaluation.

[0075] Another implementation of an SCU is shown in Figs. 3A-3I. Fig. 3A shows an isometric view of SCU 300. Figs. 3B and 3C show an isometric exploded view and an isometric exploded section view, respectively, of SCU 300 of Fig. 3A. SCU 300 may include a variety of components, including SAU 302, SCU main body 310, SCU plunger 312, and SCU lid 340. Also shown are vacuum tube 322, sample tube 324, and Lukens lid 350. The parts shown in Figs. 3A-3C may not all be used simultaneously, and may be combined in various manners to perform various tasks. Again, various components shown, or equivalent components, may be provided commercially in kit form, or partial kit form. Some combinations and configurations of the depicted parts are shown in Figs. 3D-3I, and are discussed below.

[0076] Fig. 3D shows SCU 300 configured for biological sample collection. As can be seen, vacuum tube 322 is connected to vacuum port 352 of Lukens lid 350, which is, in turn, installed on SCU main body 310. Lukens lid 350 may be secured to SCU main body 310
using, for example, a threaded connection similar to that used on standard Lukens traps. Main body 310 may be substantially similar in size and shape to a standard Lukens container, which many medical personnel find to be ergonomically sized. Sample tube 324 may be connected to sample port 354 on Lukens lid 350.

[0077] The other end of vacuum tube 322 may be connected to a suction source (not shown), and the other end of sample tube 324 may be connected to a source of sample material, such as a patient’s lungs, via a ventilator apparatus. Biological sample 301 may then be pulled through sample tube 324 and deposited within SCU main body 310 by the suction from the vacuum source.

[0078] When sufficient biological sample 301 has been collected within SCV 390 of SCU main body 310, Lukens lid 350 may be removed from SCU main body 310, as shown in Fig. 3E. SCU lid 340 may then be installed on SCU main body 310, using the same interface feature previously used to secure Lukens lid 350 to SCU main body 310, as shown in Fig. 3F. SCU lid 340 may include a central bore through which SCU plunger 312 passes. An annular ridge 360 may engage in a light interference fit with SCU plunger 312 and prevent SCU plunger 312 from translating with respect to SCU lid 340 without the application force on SCU plunger 312 along the bore axis. In some implementations, other techniques may be used to prevent undesired movement of SCU plunger 312 with respect to SCU lid 340. SCU lid 340 may also include a tapered interface region, the outer tapered surface of which engages with the interior wall of SCU main body 310, and the inner cylindrical surface of which slidably engages with SCU plunger 312. A shoulder on the interior cylindrical surface may engage with a shoulder on SCU plunger 312 and prevent SCU plunger 312 from being completely withdrawn from SCU lid 340. Some of these features, such as the shoulder or annular ridge 360, may be optional in some implementations.

[0079] After SCU lid 340 has been secured to SCU main body 310, excess gas within SCV 390 may be bled off by pushing SCU plunger 312 into SCU main body 310, as shown in Fig. 3G. After SCU plunger 312 is pushed an initial amount, SCU plunger 312 may slidably engage with the interior wall of SCU main body 310, which has a substantially constant cross section along the slide axis. In some implementations, SCU plunger 312 may be made from a substantially non-compliant material, such as plastic, and may be equipped with SCU plunger O-ring 356 to provide a compliant seal between SCU plunger 312 and SCU main
body 310. In some other implementations, SCU plunger 312 may itself be made from a compliant material and may provide a seal by virtue of its compliant nature. After SCU plunger 312 has engaged with SCU main body 310 to form a sliding seal, gases trapped within SCV 390 may be forced through filter 334 in passage 338. As SCU plunger 312 is pushed further into SCU main body 310, the remaining free gas trapped in SCV 390 is forced out through filter 334, leaving the collected biological sample 301 largely free of gas. When substantially all of the free gas has been bled off, the remaining biological sample 301 may be largely incompressible, and further translation of SCU plunger 312 into SCU main body 310 may be effectively blocked. Filter 334 may filter fluidic flow through passage 338 of SCU plunger 312. Filter 334 may be a micropore filter configured to allow gaseous flow between SCV 390 and the environment on the opposite side of SCU plunger 312. Filter 334 may be selected to allow gaseous flow but prevent most liquid and particulate flow, such as flow of the biological sample 301. Filter 334 may be, for example, a 0.2 micron filter. As with the implementation discussed with respect to Figs. 2A-2I, SCV 390 may be reduced in size as a result of the gas bleed-off process, and may be substantially coextensive in volume with the collected biological sample 301 after gas bleed-off has been performed.

[0080] After the excess gas has been bled from SCV 390, SAU 302 may be installed in SCU plunger 312 by connecting SAU 302 with SAU interface 336, as shown in Fig. 3H. SAU interface 336 and SAU 302 form a seal and prevent ambient air from being drawn into SAU main body 306 when SAU plunger 304 is partially withdrawn from SAU main body 306. When SAU 302 is inserted into SAU interface 336, the tip of SAU 302 contacts filter 334 and ruptures filter 334. Because filter 334 no longer prevents fluids and solids in SCV 390 from flowing through passage 338, the collected biological sample 301 may be transferred between SCU main body 310 and SAU main body 306. SAU interface 336 may be a simple friction fit, or may feature an interface with positive engagement, such as a Luer-Lok™ or threaded interface.

[0081] After filter 334 has been ruptured by installing SAU 302 into SAU interface 336, SAU plunger 304 may be reciprocated with respect to SAU main body 306. This causes collected biological sample 301 from SCV 390 to be drawn into SAU 302, as shown in Fig. 3I. Concurrently with the transfer of material from SCV 390 into SAU 302, SCU plunger 312 may be drawn further forward into SCU main body 310 to accommodate the reduction in volume
of the collected biological sample 301 as the biological sample 301 flows into SAU 302. For example, if 1 cc of biological sample 301 is drawn into SAU 302, SCU plunger 312 may be drawn into SCU main body 310 sufficiently far enough to decrease SCV 390 by 1 cc. As can be seen in Fig. 31, due to SCU plunger 312’s larger diameter as compared to SAU piston 308’s diameter, SCU plunger 312 may be displaced a relatively small distance compared to the displacement of SAU plunger 304.

[0082] As noted above, SAU plunger 304 may be reciprocated, which may draw the biological sample 301 into SAU 302 from SCV 390 and then propel the biological sample 301 back out into SCV 390. This may cause turbulent flow and mixing in SCV 390 and within SAU 302, which may, if repeated a sufficient number of times, achieve a desired degree of mechanical homogenization. For example, 20-30 reciprocations may be performed in some implementations. In practice, a standard number, or range, of reciprocations may be specified for a given model of SCU and a range of different types of biological sample 301.

[0083] After sufficient reciprocations have been performed, a desired amount of biological sample 301 may be drawn into SAU 302 and SAU 302 may then be removed from SCU plunger 312. The withdrawn biological sample 301 may then be transferred to laboratory or pathology testing apparatuses for evaluation.

[0084] Yet another implementation of an SCU is shown in Figs. 4A-4I. Fig. 4A shows an isometric view of SCU 400. Figs. 4B and 4C show an isometric exploded view and an isometric exploded section view, respectively, of SCU 400 of Fig. 4A. SCU 400 may include a variety of components, including SAU 402, SCU main body 410, SCU lid 440, SCU lid pass-through 470, and base 480. Also shown are vacuum tube 422, vacuum port 452, solid plug 474, sample tube 424, sample port 454, and filter plug 472. The parts shown in Figs. 4A-4C may not all be used simultaneously, and may be combined in various manners to perform various tasks. Again, various components shown, or equivalent components, may be provided commercially in kit form, or partial kit form. Some combinations and configurations of the depicted parts are shown in Figs. 4D-4I, and are discussed below.

[0085] Fig. 4D shows SCU 400 configured for biological sample collection. As can be seen, vacuum tube 422 is connected to vacuum port 452, which is installed in SCU lid pass-through 470. SCU lid pass-through 470 may be made of a compliant material and be
installed in SCU lid 440 to form an integrated assembly. In some implementations, SCU lid pass-through 470 and SCU lid 440 may be made of the same material, such as a non-compliant material, and as a single part. Sample tube 424 may be connected to sample port 454, which may be installed in SCU lid pass-through 470. Both sample port 454 and vacuum port 452 may be held in place using friction fits, light interference fits, or other suitable techniques. Solid plug 474 and filter plug 474 are not in use in Fig. 4D, but are visible in a stowed configuration within storage locations located in SCU lid pass-through 470.

[0086] The other end of vacuum tube 422 may be connected to a suction source (not shown), and the other end of sample tube 424 may be connected to a source of sample material, such as a patient’s lungs, via a ventilator apparatus. Biological sample 401 may then be pulled through sample tube 424 and deposited within SCU main body 410.

[0087] When sufficient biological sample 401 has been collected within SCV 490 of SCU main body 410, vacuum tube 422, vacuum port 452, sample tube 424, and sample port 454 may be removed from SCU lid pass-through 470, as shown in Fig. 4E. Filter plug 472 and solid plug 474 may then be removed from their storage receptacles and installed in SCU lid pass-through 470, as shown in Fig. 4F. Solid plug 474 may be substantially impermeable, e.g., a solid plug or a hollow plug with a solid wall at one end, but filter plug 472 may be hollow and may include filter 434.

[0088] SCU lid 440 may then be translated towards the bottom of SCU main body 410, either by pushing down on SCU lid 440, or, if SCU lid 440 is held onto SCU main body 410 using a threaded interface, by advancing the threads. SCU lid 440 is translated towards SCU main body 410 sufficiently far enough that a seal is formed between SCU lid pass-through 470 and the interior wall of SCU main body 410, as shown in Fig. 4G. Alternatively, such a seal may be formed between SCU lid 440 and the interior wall of SCU main body 410 if SCU lid 440 and SCU lid pass-through 470 are a single integrated component. An SCU O-ring 456 may be used to help provide the seal.

[0089] After the collected biological sample 401 has been sealed within SCU main body 410 by SCU lid pass-through 470 and/or SCU lid 440, free gas may be bled from SCV 490 by translating base 480 into SCU main body 410, as shown in Fig. 4H. This has the effect of
pushing the free gas through filter 434 and out into the ambient environment via filter plug 472. Filter 434 may filter fluidic flow through filter plug 472. Filter 434 may be a micropore filter configured to allow gaseous flow between SCV 490 and the environment on the opposite side of SCU lid 440 and/or SCU lid pass-through 470. Filter 434 may be selected to allow gaseous flow but prevent most liquid and particulate flow, such as flow of the biological sample 401. Filter 434 may be, for example, a 0.2 micron filter. As with the implementation discussed with respect to Figs. 2A-2I, SCV 490 may be reduced in size as a result of the gas bleed-off process, and may be substantially coextensive in volume with the collected biological sample 401 after gas bleed-off has been performed.

[0090] Base 480 may include a ratchet mechanism which only permits base 480 to be advanced into SCU main body 410 and which prevents base 480 from being withdrawn from SCU main body 410. For example, base 480 may include conical washer 484, which may snap into a circumferential groove located on an interior surface of base 480. The inner rim of conical washer 484 may engage with annular ridges spaced at various intervals along a portion of SCU main body 410. As base 480 is advanced into SCU main body 410, conical washer 484 may snap over each successive annular ridge. The annular ridges may prevent conical washer 484, and base 480, from retreating once the annular ridges have been passed over.

[0091] After the excess gas has been bled from SCV 490, filter plug 472 may be removed and re-stowed in the storage receptacle in SCU lid pass-through 470, as shown in Fig. 4I, or simply disposed of in an appropriate disposal container, e.g., a biological waste container. Once filter plug 472 has been removed, SAU 402 may be installed, as shown in Fig. 4J. The tip of SAU 402 may be in fluid contact with the de-gassed biological sample 401 and SCV 490. SAU 402 is held in place, in this implementation, by a friction fit between SAU main body 406 and SAU interface 436 on SCU lid pass-through 470. Other techniques for securing SAU 402 may be used as well. For example, techniques such as those used in the implementations shown in Figs. 2A-2I and 3A-3I may be used. SAU interface 436 and SAU 402 form a seal and prevent ambient air from being drawn into SAU main body 406 when SAU plunger 404 is partially withdrawn from SAU main body 406. Because filter 434 no longer prevents fluids and solids in SCV 490 from flowing through passage 438 due to the
removal of filter plug 472, the collected biological sample 401 may be transferred between SCU main body 410 and SAU main body 406.

[0092] SAU plunger 404 may then be reciprocated with respect to SAU main body 406, as shown in Fig. 4K. This causes collected biological sample 401 from SCV 490 to be drawn into SAU 402. Concurrently with the transfer of material from SCV 490 into SAU 402, base plunger 482 may be drawn further forward into SCU main body 410 to accommodate the reduction in volume of the collected biological sample 401 as the biological sample 401 flows into SAU 402. For example, if 1 cc of biological sample 401 is drawn into SAU 402, base plunger 482 may be drawn into SCU main body 410 sufficiently far enough to decrease SCV 490 by 1 cc. As can be seen in Fig. 4I, due to base plunger 482’s larger diameter as compared to SAU piston 408’s diameter, base plunger 482 may be displaced a relatively small distance compared to the displacement of SAU plunger 404. Base plunger 482 may be sealed to SCU main body 410 using an o-ring, as shown, or other compliant seal mechanism.

[0093] As noted above, SAU plunger 404 may be reciprocated, which may draw the biological sample 401 into SAU 402 from SCV 490 and then propel the biological sample 401 back out into SCV 490, which may move base plunger 282 back to its original position. This may cause turbulent flow and mixing in SCV 490 and within SAU 402, which may, if repeated a sufficient number of times, achieve a desired degree of mechanical homogenization. For example, 20-30 reciprocations may be performed in some implementations. In practice, a standard number, or range, of reciprocations may be specified for a given model of SCU and a range of different types of biological sample 401.

[0094] After sufficient reciprocations have been performed, a desired amount of biological sample 401 may be drawn into SAU 402 and SAU 402 may then be removed from SCU lid pass-through 470. The withdrawn biological sample 401 may then be transferred to laboratory or pathology testing apparatuses for evaluation.

[0095] The design concepts demonstrated in the above-described implementations may be selectively combined, as appropriate, to provide other implementations. For example, in the implementation depicted in Figs. 4A-4K, filter plug 472 may be designed to accommodate the installation of SAU 402 without requiring the removal of filter plug 472. Such an implementation may include features similar to, for example, SAU interface 236 and
filter 434 of filter adapter 230, as well as clearances sufficient to allow SAU 402 to be installed within filter plug 472. This allows SAU 402 installation to occur without exposing the de-gassed biological sample 401 to the ambient environment (or exposing medical personnel to the collected biological sample 401).

[0096] In some implementations, the change in volume of the SCV during the mechanical homogenization process, which may be caused by the withdrawal of the collected biological sample into the SAU, may be accommodated through compliant flexure of various components rather than through component translation. For example, the volumetric change in SCV 490 in Fig. 4K is accommodated by the translation of base plunger 482. However, an alternative implementation may not include a base plunger 482 capable of movement (or base plunger 482 and base housing 486 may be a single contiguous part). In such implementations, the volume of fluid which is drawn into SAU 402 may be sufficiently miniscule, e.g., on the order of 1cc, that the volumetric change in SCV 490 may be accommodated by compression, extension, or flexure of various components of SCU 400. For example, SCU lid pass-through 470 may distend into SCU main body 410 and decrease SCV 490. In some implementations, base plunger 482, if rigidly attached to base housing 486, may stretch (as opposed to freely translating) to accommodate some of the volumetric change in SCV 490. Additionally, gas which is still present within biological sample 401, such as entrained microbubbles, may allow biological sample 401 to “expand” in overall volume temporarily.

[0097] The SCUs shown and discussed above may be sized sufficiently small enough to be transported using pneumatic tube or capsule pipeline delivery systems used by some hospitals. These are systems in which payloads, such as the SCUs, may be loaded into capsules which are then introduced into a pneumatic tube. The pneumatic pressure in the tube causes the capsule to travel along the path of the tube until the final destination of the tube is reached. Hospitals may use such systems to allow for the rapid delivery of biological samples to a pathology lab.

[0098] In some implementations, if sufficient biological sample material has been collected in an SCU, one or more additional SAUs may be connected to the SCU to obtain further mechanically-homogenized samples after the initial mechanically-homogenized sample is withdrawn. Such additional samples may be collected until no further collectible
sample remains within the SCU. In some implementations, the SAU may be removed from the SCU after mechanical homogenization for direct access to the mechanically-homogenized sample. For example, a loop or pipette may be used to directly withdraw sample material from the mechanically-homogenized sample through the passage fluidically linking the SAU, were it installed, with the SCV. In some implementations, the SCU, or portions thereof, may be re-usable, for example, after autoclaving. In some other implementations, the SCU may not be re-usable and re-use of SCU may introduce a risk of cross-sample contamination.

[0099] The SCUs discussed herein may be made from a variety of materials. For example, the SCU main body may be made from any of a variety of plastics, such as polyethylene or polypropylene. Various compliant materials, such as buna-N or other rubbers may be used to manufacture parts which may seal against other parts, such as SCU lid pass-throughs, O-rings, plungers, etc. While the transparency/opacity of most of the materials used may be a matter of design choice, it may be desirable for some components, such as the SCU main body, to be transparent or translucent to allow sample collection/preparation personnel to easily observe the sample within the SCU.

[00100] Some implementations of SCUs may, in general, be configured for hand-held use, i.e., some SCUs may be compact enough to be used or operated while being held in the hand or hands. It is to be understood that while many objects are of sufficiently small size to be described as being capable of being held by a human hand or hands, not all such objects may be described as “handheld” because they are not designed for ease of carrying by hand. For example, most web cameras are small enough to be held by hand, but it would not be reasonable to describe most web cameras as “handheld” cameras since they are typically designed to clip onto a monitor or stand on a base structure. In contrast, it would be entirely reasonable to describe a compact point-and-shoot digital camera as a “handheld” camera, since it is designed to be held in a user’s hand while being operated. As mentioned elsewhere in this document, SCUs may also be configured to be compatible with pneumatic transport systems, which may place a further limit on their size and weight.

[00101] While SCUs may, in general, be configured for hand-held use, some implementations may be configured to be connected to a powered device which drives homogenization or degassing operations. For example, a degassing operation may be
performed using a motorized or powered press which compresses the SCV and drives out free air. In some implementations, the reciprocation of collected biological sample between the SCV and SAU may be driven by a motorized device which produces volumetric displacement within the SCV and the SAU. Such powered devices may utilize power derived from a facility electrical source, e.g., a wall outlet, or from batteries.

[00102] Some implementations of SCUs may also be configured to be easily portable, i.e., requiring no special carrying container or equipment for transport from one location to another. For example, an SCU may be lightweight, easily graspable in a human hand, and capable of withstanding minor mechanical insults, such as being dropped from the height of a hospital bed, without failure. Some implementations of an SCU may be easily manipulated by human hands in order to facilitate making connections to suction sources or sample collection sources. Some implementations of an SCU may require no external electrical or other power to perform mechanical homogenization, and may be entirely operated, after sample collection has occurred, by human effort applied directly to the SCU.

[00103] As mentioned previously, SCUs as described herein may frequently be provided in “kit” form. During normal operation, various components may be added and removed from an SCU, such as the SAU. As a result, the SCU may be supplied as a collection of 2 or more components which may, during normal use, be assembled during various phases of SCU use. In some implementations, some components may be standard medical facility equipment, such as a standard syringe which may be used as the SAU. In such situations, the kit may not include the standard equipment and may only include the non-standard equipment.

[00104] The SCU may also include various substances which are designed to interact with a collected biological sample. For example, chemical reagents which may help stabilize and preserve a collected sample may be pre-loaded into the SCU, or used to coat the interior walls of the SCU, before use. Such pre-loading may occur in a medical facility where the SCU is being used or earlier, such as at location in the manufacturing chain. Other examples of substances which may be loaded into the SCU prior to sample collection include reagents which indicate the presence of a biological organism or a particular chemical or molecule, substances which promote bacterial growth, and substances which may dilute or thin out the collected sample for ease of collection or mechanical homogenization.
[00105] The SCU may also be designed to be retained, with a collected sample, for a specified period of time. To that end, the SCU may include various chemicals or other substances which act to preserve collected sample material for a period of several hours or days to allow for delays between collection and testing.

[00106] While one technique for using an SCU has been outlined above with respect to the Figures discussed above, Fig. 5 provides a high-level flow diagram of an implementation of sample collection technique 500 using an SCU configured for collection of sputum samples. Initially, a sample port of the SCU may be connected to a sample collection source (502), such as a tube used to remove air and liquid from a patient’s lungs, e.g., a ventilator tube. A suction port of the SCU may be connected to a suction source (504), such as a facility vacuum source or a ventilator. After the above connections have been made, the suction, if not already active, may be engaged and biological sample collected within the SCU (506). After a desired amount of biological sample has been collected within the SCU (508), suction may be disengaged (510) and the SCU reconfigured for a de-gas operation, which may involve the introduction of a filter to one of the ports (512). The SCU may then be de-gassed or de-aired to remove free air from the SCU SCV (514). After de-gassing, an SAU may be installed in the SCU—installation of the SAU may rupture the filter, or the filter may be removed prior to SAU installation (516). After installing the SAU, the collected biological sample may be mechanically-homogenized by drawing the biological sample from the SCV of the SCU into the SAU (518) and expelling the biological sample from the SAU into the SCV of the SCU (520); blocks 518 and 520 may be repeated a desired number of times to ensure a desired degree of mechanical homogenization is achieved (522). After mechanical homogenization is completed, a desired amount of biological sample may be drawn into the SAU (524). After the SAU is filled to the desired level, the SAU may be removed (526). If additional samples are desired after removal of the aliquot, a new SAU may be installed in the SCU and 524-526 may be repeated as desired. In some implementations, additional sample material may be retrieved from the SCU using a pipette, loop, or other instrument (528). When sample collection is complete, the SCU may be discarded as appropriate for a biological sample container (530).

[00107] It is to be understood that the various components discussed within this paper may, in some implementations, be constructed differently. For example, in some
implementations, components which are shown as a single part may, absent any indication to the contrary, be made from multiple parts which may then be assembled into an assembly which provides functionality similar to that provided by the single part. Conversely, components which are shown or presented as consisting of multiple parts may, absent any indication to the contrary, be made as a single, integrated part in some implementations.

[00108] Although the foregoing invention has been described in some detail for purposes of clarity of understanding, it will be apparent that certain changes and modifications may be practiced within the scope of the invention. It should be noted that there are many alternative ways of implementing both the processes and apparatures of the present invention. Accordingly, the present implementations are to be considered as illustrative and not restrictive, and the invention is not to be limited to the details given herein.

[00109] It will be further understood that unless features in any of the particular preferred implementations are expressly identified as incompatible with one another or the surrounding context implies that they are mutually exclusive and not readily combinable in a complementary and/or supportive sense, the totality of this disclosure contemplates and envisions that specific features of those complementary implementations can be selectively combined to provide one or more comprehensive, but slightly different, technical solutions. It will therefore be further appreciated that the above description has been given by way of example only and that modifications in detail may be made within the scope of the invention.
CLAIMS

What is claimed is:

1. A biological sample collection unit (SCU) comprising:

   a housing, the housing substantially defining a sample collection volume (SCV), wherein the SCV is changeable in volume,

   a first port, and

   a second port, wherein:

      the first port is in fluidic communication with the SCV and configured to be sealable with respect to the SCV, and

      the second port is in fluidic communication with the SCV and configured to removably mount a sample aliquot unit (SAU) with a changeable internal volume such that, when the SAU is mounted to the second port:

      the SAU internal volume is in fluidic communication with the SCV via the second port,

      the SAU internal volume, the SCV, and the second port, while in fluidic communication with each other, are not in fluidic communication with an external environment, and

      the SCU is configured to provide mechanical homogenization by providing a substantially equal and complementary volumetric change in the SCV in response to a volumetric change in the SAU internal volume.

2. The SCU of claim 1, the SCU further comprising the SAU, wherein the SAU is removably mounted to the second port.

3. The SCU of claim 1, wherein the SAU is a syringe.

4. A biological sample collection device comprising:

   a sample collection unit (SCU) main body, wherein the SCU main body includes a first tubular region with a substantially constant cross section along an axis of the SCU main body, the first tubular region including a first inner surface and terminating at a first end and a second end opposite the first end; and

   an SCU plunger, wherein:
the SCU plunger is slidably engaged with the first inner surface to form a sliding seal with the first inner surface and configured to slide along the axis with respect to the SCU main body,

the SCU plunger includes a first orifice,

a sample collection volume (SCV) is substantially defined by the first inner surface, the first end, and the SCU plunger, and

the first orifice provides a fluidic communication path from the SCV, through the SCU plunger, and away from the first end.

5. A biological sample collection device kit including one or more components configured to be assembled into a sample collection unit (SCU), the kit comprising:

an SCU main body, wherein the SCU main body includes a first tubular region with a substantially constant cross section along an axis of the SCU, the first tubular region including a first inner surface and terminating at a first end and a second end opposite the first end; and

an SCU plunger, wherein:

the SCU plunger is configured to slidably engage with the first inner surface to form a sliding seal with the first inner surface and to slide along the axis with respect to the SCU main body when the SCU is assembled,

the SCU plunger includes a first orifice,

a sample collection volume (SCV) is substantially defined by the first inner surface, the first end, and the SCU plunger when the SCU plunger is slidably engaged with the first inner surface, and

the first orifice is configured to provide a fluidic communication path with the SCV through the SCU plunger when the SCU plunger is slidably engaged with the first inner surface.

6. The biological sample collection device kit of claim 5, wherein the SCU plunger includes a filter within the first orifice, the filter configured to filter all fluidic flow through the first orifice when present.

7. The biological sample collection device kit of claim 6, further comprising an SCU lid including:

a mechanical interface configured to secure the SCU lid to the second end of the SCU main body, and

a sliding interface, wherein:
the sliding interface is configured to slidably engage with an external surface of the SCU plunger and the SCU plunger is configured to slide along the axis with respect to the SCU lid when the SCU plunger is slidably engaged with the SCU lid and the SCU lid is secured to the second end of the SCU main body,

the mechanical interface is configured to form a seal between the SCU lid and the SCU main body when the SCU lid is secured to the second end, and

the sliding interface is configured to form a seal between the SCU lid and the SCU plunger when the SCU plunger is slidably engaged with the SCU lid.

8. The biological sample collection device kit of claim 7, wherein:

the SCU lid includes a conical frustum which is configured to project into the SCU main body when the SCU lid is secured to the second end of the SCU main body,

the conical frustum includes a through-hole,

the sliding interface is provided by at least a portion of the through-hole, and

the conical frustum engages with the SCU main body when the SCU lid is secured to the second end of the SCU body.

9. The biological sample collection device kit of claim 7, further comprising:

a sample aliquot unit (SAU), the SAU including:

an SAU plunger slidably engaged with an SAU main body,

a first SAU end and a second SAU end located at opposite ends of the SAU main body, and

an SAU port located at the first SAU end, wherein:

the SAU port is configured to interface with the first orifice and to form a seal between the SAU and the SCU plunger when the SAU is mounted to the first orifice.
10. The biological sample collection device kit of claim 9, wherein the SCU plunger and the filter are configured such that the SAU port ruptures the filter when the SAU is mounted to the first orifice.

11. The biological sample collection device kit of claim 7, further comprising a Lukens lid, the Lukens lid including:

   a mechanical interface configured to secure the Lukens lid to the second end of the SCU main body,

   a vacuum port, the vacuum port configured to extend away from the SCU main body when the Lukens lid is secured to the SCU main body,

   a sample collection port, the sample collection port configured to extend away from the SCU main body when the Lukens lid is secured to the SCU main body, wherein the Lukens lid seals an internal volume of the SCU main body when secured to the second end of the SCU main body and the sample collection port and the vacuum port are the only fluidic communication paths out of the internal volume when the Lukens lid is secured to the SCU main body.

12. The biological sample collection device kit of claim 5, wherein the SCU main body includes a second orifice at the first end of the SCU main body.

13. The biological sample collection device kit of claim 12, further comprising an SCU cap, the SCU cap configured to be installed on the second orifice and seal the second orifice when installed.

14. The biological sample collection device kit of claim 6, wherein the SCU plunger includes an adapter interface including the first orifice, the biological sample collection device kit further comprising:

   a vacuum port adapter including a vacuum port, wherein:

   the vacuum port adapter includes an interface configured to mate with, and seal to, the adapter interface, and

   the vacuum port provides for fluidic communication between the SCV and an external environment when the SCU plunger is slidably engaged with the inner surface and the vacuum port adapter is mated with, and sealed to, the adapter interface; and

   a sample aliquot unit (SAU) adapter, wherein:

   the SAU adapter includes an interface configured to mate with, and seal to, the adapter interface,
the SAU adapter includes an SAU interface, the SAU interface providing a fluidic communication path between the SCV and an external environment when the SCU plunger is slidably engaged with the inner surface and the SAU adapter is mated with, and sealed to, the adapter interface, and

a filter, the filter mounted within the SAU interface and configured to filter all fluidic flow through the SAU interface when present.

15. The biological sample collection device kit of claim 14, further comprising an SAU, the SAU including:

an SAU plunger slidably engaged with an SAU main body,

a first SAU end and a second SAU end located at opposite ends of the SAU main body, and

an SAU port located at the first SAU end, wherein:

the SAU port is configured to interface with the SAU interface and to form a seal between the SAU and the SAU adapter when the SAU is mounted to SAU interface

16. The biological sample collection device kit of claim 15, wherein the SAU interface and the filter are configured such that the SAU port ruptures the filter when the SAU is mounted to the SAU interface.

17. A biological sample collection device comprising:

a sample collection unit (SCU) main body including a first tubular region with a substantially constant cross section along an axis of the SCU main body, the first tubular region including a first inner surface and terminating at a first end and a second end opposite the first end;

a base plunger, slidably engaged with the first inner surface to form a sliding seal with the first inner surface and to slide along the axis with respect to the SCU main body; and

an SCU lid, the SCU lid including:

a mechanical interface configured to secure the SCU lid to the second end of the SCU main body,

a vacuum port interface, and

a sample port interface, wherein:
the SCU lid is secured to the SCU main body by the mechanical interface,

a sample collection volume (SCV) is substantially defined by the first inner surface, the base plunger, and the SCU lid, and

the vacuum port interface and the sample port interface are in fluidic communication with the SCV.

18. A biological sample collection device kit including one or more components configured to be assembled into a sample collection unit (SCU), the kit comprising:

an SCU main body, wherein the SCU main body includes a first tubular region with a substantially constant cross section along an axis of the SCU, the first tubular region including a first inner surface and terminating at a first end and a second end opposite the first end;

a base plunger, the base plunger configured to be inserted through the first end and slidably engage with the first inner surface to form a sliding seal with the first inner surface and to slide along the axis with respect to the SCU main body when the SCU is assembled; and

an SCU lid, the SCU lid including:

a mechanical interface configured to secure the SCU lid to the second end of the SCU main body,

a vacuum port interface, and

a sample port interface, wherein:

a sample collection volume (SCV) is substantially defined by the first inner surface, the base plunger, and the SCU lid when the base plunger is slidably engaged with the first inner surface and the SCU lid is secured to the second end of the SCU main body, and

the vacuum port interface and the sample port interface are configured to be in fluidic communication with the SCV when the SCU lid is secured to the second end of the SCU main body.

19. The biological sample collection device kit of claim 18, further comprising:

a filter plug; and

a non-permeable plug, wherein:
the filter plug is sized to connect with the sample port interface and provide a filtered fluidic flow path from the SCV when the filter plug is connected with the sample port interface and the SCU lid is secured to the second end of the SCU main body, and

the non-permeable plug is sized to connect with the vacuum port interface and prevent fluidic flow from the SCV via the vacuum port interface when the non-permeable plug is connected with the vacuum port interface and the SCU lid is secured to the second end of the SCU main body.

20. The biological sample collection device kit of claim 18, further comprising a sample aliquot unit (SAU), the SAU including:

an SAU plunger slidably engaged with an SAU main body,

a first SAU end and a second SAU end located at opposite ends of the SAU main body, and

an SAU port located at the first SAU end, wherein:

the SAU port is configured to interface with the sample port interface and to form a seal between the SAU and the SCU lid when the SAU is mounted to the sample port interface.

21. The biological sample collection device kit of claim 18, wherein the SCU lid further includes:

a first storage receptacle configured to store the filter plug; and

a second storage receptacle configured to store the non-permeable plug.

22. The biological sample collection device kit of claim 18, wherein:

the filter plug is connected to the SCU lid by a first flexible tether, and

the non-permeable plug is connected to the SCU lid by a second flexible tether.

23. The biological sample collection device kit of claim 18, wherein the base plunger includes:

a base housing, and

a base piston, wherein:

the base piston forms the sliding seal with the first inner surface when the base plunger is inserted through the first end, and
the base piston is configured to be slidable along the axis of the SCU with respect to the SCU and the base plunger when the base plunger is inserted through the first end.

24. The biological sample collection device kit of claim 18, wherein:

   the base plunger includes a uni-directional ratchet mechanism,

   the SCU main body includes features which interface with the uni-directional ratchet mechanism and prevent the base plunger from being withdrawn from the SCU main body when the base plunger is inserted through the first end.

25. A method comprising:

   a) collecting a biological sample in a first volume;

   b) bleeding, after the collecting, substantially all free gas from the first volume; and

   c) mechanically homogenizing, after the bleeding, the biological sample by transferring at least a portion of the biological sample between the first volume and a second volume fluidly removably connected with the first volume.

26. The method of claim 25, further comprising repeating step c) a predetermined number of times.

27. The method of claim 25, further comprising:

   d) transferring, after performing steps a) through e), at least some of the biological sample into the second volume; and

   e) disconnecting, after performing step f), the second volume from the first volume.
502
Connect SCU sample port to sample collection source

504
Connect SCU suction port to suction source

506
Introduce fluid sample into SCU by engaging suction

508
Allow fluid sample to accumulate to desired level

510
Disengage suction

512
Reconfigure SCU for de-gas

514
De-gas SCV

516
Install SAU

518
Draw sample into SAU from SCV

520
Expel sample from SAU into SCV

522
Repeat 518 and 520 desired number of times

524
Draw homogenized sample into SAU

526
Remove SAU

528
Obtain additional sample from aliquot port using loop or pipette

530
Discard SCU

Fig. 5