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Inventor(s)	CARSE; Paul D. et al.

DEVICES AND SYSTEMS FOR AUTOMATED COLLECTION OF BLOOD INTO TUBE STORED AT ATMOSPHERIC PRESSURE AND MIXING OF THE BLOOD WITH ADDITIVES IN THE TUBE

Abstract

A blood collection tube comprises: 1) a body including a proximal end and a distal end, and defining an axial extent between the proximal end and the distal end; 2) a chamber within the body, the chamber including a plurality of mixing ribs; 3) a vacuum port; and 4) a cap arranged on the proximal end, wherein the cap comprises: a) a top face including a first septum; b) a first conduit having an inlet extending from the first septum and an outlet in fluid communication with the chamber; c) a lateral face including a second septum; d) a second conduit extending radially from the second septum to the first conduit; and a plurality of mixing ribs; wherein, when a fluid source is fluidically connected to the first septum or the second septum, and a vacuum is applied at the vacuum port, the vacuum draws fluid from the fluid source, through the first or second septum, and into the first conduit; and when the tube is rotated around an axis defined by the axial extent, the mixing ribs of the cap and the mixing ribs of the chamber cause fluids therein to swirl, thereby effecting mixing of the fluids therein.

Inventors:	**CARSE; Paul D. (Milford, NJ), OGREN; Cordelia A. (Milford, NJ), DUNCAN; Kelly Gail (Bethlehem, PA), CARR; William (Phillipsburg, NJ), TAVOR; David (Hod Hasharon, IL), BALJI; Rachel Jessica (Mahwah, NJ)**
Applicant:	**P5 Designers, LLC.** (Milford, NJ)

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Background/Summary

FIELD OF THE INVENTION

[0001] The present Application relates to the collection of blood into blood collection tubes for testing and, more specifically, but not exclusively, to a blood collection tube, blood collection device, and method for collecting blood into tubes stored at atmospheric pressure.

BACKGROUND OF THE INVENTION

[0002] Analysis of blood samples is one of the most important diagnostic tools available for detecting and treating diseases. Blood samples are obtained by a process known as venipuncture. During venipuncture, a cannula is inserted into a vein, and blood is drawn through tubing attached to the cannula into one or more blood collection tubes. The blood collection tubes may have one or more additives to prevent coagulation or isolate specific blood components.

[0003] For over 70 years, the industry standard for blood collection tubes has been the evacuated blood collection tube, such as the Vacutainer® manufactured by Becton Dickinson. An evacuated blood collection tube is prepared by adding a blood additive into the tube, stopping the tube, applying a vacuum to the tube, and storing the tube in internal vacuum conditions. Evacuated blood collection tubes account for nearly 1% of global medical supply sales, and it is estimated that annual global sales of evacuated blood collection tubes exceed $1.7 billion.

[0004] International Patent Publication WO2022/038616, entitled “Devices and Systems for Automated Collection of Blood into Tube Stored at Atmospheric Pressure,” and assigned to the same assignee as the present disclosure, discloses a blood collection system that is designed to withdraw blood at micro-vacuum, to tubes that are not evacuated. The contents of that application are incorporated by reference as if fully set forth herein.

SUMMARY OF THE INVENTION

[0005] The present disclosure builds upon the disclosure of the aforementioned International Patent Publication WO2022/038616 to provide additional embodiments of blood collection systems that are designed to withdraw blood at micro-vacuum. A blood collection tube has a first septum for the input of blood, a second septum for the input of a blood additive, and a vacuum port. A blood collection device includes a vacuum pump and a plurality of reservoirs containing blood additives. When the blood collection tube is inserted into the blood collection device, the vacuum pump applies a vacuum through the vacuum port. The applied vacuum draws into the blood collection tube both an aliquot of the concentrated blood additive and a predefined blood volume. Optionally, the additive may be added by other means, such as an injector. The blood additive and blood are

then mixed in the blood collection tube. Prior to the collection, the phlebotomist confirms the patient's identity, labels the collection tubes, and orders the blood collection tubes, e.g., with a scanner built into the blood collection device. The blood collection is performed at a low vacuum and draws the minimum required quantity of blood, with virtually no risk of misidentification of patients, incorrect ordering of collection tubes, or mislabeling of specimens.

[0006] In particular, the blood collection tube and the cap include mixing ribs. The mixing ribs are designed to induce the mixing of the blood and the additive when the tube is rotated. Furthermore, as an alternative to adhesive paper labeling mentioned previously, the blood collection device may include a laser for etching, and the tube is made of a material susceptible to laser etching (such as polycarbonate). The tube may also include sizing (e.g., a glaze or surface coating) to increase contrast during the printing. Optionally, the sizing material may also serve to protect the contents of the tube during the etching process. During the rotation of the tube for mixing, a laser is applied to the tube to imprint patient identification. Advantageously, mixing through rotation, with the operation of the mixing ribs, provides thorough mixing between the blood and the additive, which is especially necessary when small volumes of the blood and additive are employed. Furthermore, the laser etching process is quick, reliable, automated, and uses less consumable materials than printed labels. The laser etching process may be synchronized with the mixing process, enabling timely completion of the blood collection process.

[0007] According to a first aspect, a blood collection tube is disclosed. The blood collection tube includes a body including a proximal end and a distal end, and defining an axial extent between the proximal end and the distal end; a chamber within the body, the chamber including a plurality of mixing ribs; a vacuum port; and a cap arranged on the proximal end. The cap includes a top face including a first septum; a first conduit having an inlet extending from the first septum and an outlet in fluid communication with the chamber; a lateral face including a second septum; a second conduit extending radially from the second septum to the first conduit; and a plurality of mixing ribs. When a fluid source is fluidically connected to the first septum or the second septum, and a vacuum is applied at the vacuum port, the vacuum draws fluid from the fluid source through the first or second septum, and into the first conduit, and when the tube is rotated around an axis defined by the axial extent, the mixing ribs of the cap and the mixing ribs of the chamber cause fluids therein to swirl, thereby effecting mixing of the fluids therein.

[0008] In another implementation, according to the first aspect, the tube includes a relief channel configured to enable air to escape from the chamber during blood filling.

[0009] In another implementation according to the first aspect, a system for collecting blood includes the blood collection tube and a device for collecting blood into said blood collection tube. The device includes: a first slot for securing a blood collection tube therein, and a set of gears arranged at an end of the first slot for rotating the blood collection tube; a vacuum pump; a second slot for securing a needle therein; a plurality of conduits, each conduit connected at a distal end thereof to a reservoir; and a processor configured to specify a predetermined volume of additive to be delivered into a blood collection tube from one of the plurality of reservoirs and a predetermined volume of blood to be delivered into the blood collection tube via the needle. The vacuum pump, a plurality of conduits, and a second slot are arranged around the first slot such that when a blood collection tube having a vacuum port, first septum, and second septum is inserted into the first slot, the vacuum pump is configured to draw a vacuum through the vacuum port; each conduit is fluidically connectable to an interior of the blood collection tube via the second septum; and a needle secured within the second slot is fluidically connectable to an interior of the blood collection tube via the first septum. The processor is configured to control a vacuum delivered from the vacuum pump to draw the predetermined volumes of additive and blood into the blood collection tube. Following the drawing of the predetermined volumes of additive and blood into the blood collection tube, the processor is configured to operate the gears to rotate the blood collection tube a plurality of rotations within the first slot, thereby mixing the additive and blood within the blood

collection tube.
[0010] Optionally, the device further includes a laser etching tool situated parallel to the axial extent of the blood collection tube and, wherein, during rotation of the blood collection tube, the laser etching tool is configured to etch patient information onto the axial extent of the blood collection tube.
[0011] Optionally, the blood collection tube further includes a coating of sizing in a region onto which the laser etching is applied.
[0012] Optionally, the device further comprises a gyroscope for measuring orientation, and the processor is configured to permit the operation of the vacuum only when the device's orientation is within a prescribed range.
[0013] Optionally, the device further includes an ultraviolet light for internal sterilization.
[0014] Optionally, the device further includes an empty blood tube magazine and a full blood tube storage compartment and means for transferring an empty blood collection tube from the magazine to the first slot and for transferring a filled blood collection tube from the first slot to the storage compartment.
[0015] According to a second aspect, a method of collecting blood into a blood collection tube is disclosed. The blood collection tube comprises a tube body including a proximal end and a distal end, and defining an axial extent between the proximal end and the distal end; a chamber within the tube body; mixing ribs within the chamber; a vacuum port; and a cap arranged on the proximal end, wherein the cap comprises: a top face including a first septum; a first conduit having an inlet extending from the first septum and an outlet in fluid communication with the chamber; mixing ribs in fluid communication with the chamber, a lateral face including a second septum; and a second conduit extending radially from the second septum to the first conduit. The method comprises: drawing, with a vacuum, a volume of blood additive into the blood collection tube via the second septum through the second conduit; and drawing, with a vacuum, a volume of blood into the blood collection tube via the first septum through the first conduit; and rotating the blood collection tube a plurality of times along an axial extent thereof, to thereby swirl the blood and additive around the mixing ribs of the cap and of the chamber and thereby mix the blood and additive.
[0016] Optionally, the rotating step comprises rotating the blood collection tube at least ten times.
[0017] Optionally, the method further includes etching patient information on an axial extent of the tube with a laser etching device.

Description

BRIEF DESCRIPTION OF THE DRAWINGS
[0018] FIG. **1**A is an isometric view of a blood collection tube with the cap on, according to embodiments of the present disclosure;
[0019] FIG. **1**B is a cross-section view of the blood collection tube in FIG. **1**A with the cap on, according to embodiments of the present disclosure;
[0020] FIG. **2**A illustrates a bottom view of the cap, showing the mixing ribs therein, according to embodiments of the present disclosure;
[0021] FIG. **2**B illustrates a top view of the blood collection tube, illustrating the mixing ribs therein, according to embodiments of the present disclosure;
[0022] FIG. **3** is an exploded view of the cap, showing a polyolefin outer layer and a molded inner layer, according to embodiments of the present disclosure;
[0023] FIG. **4**A illustrates a path of insertion of a blood additive into the blood collection tube of FIG. **1**B, according to embodiments of the present disclosure;
[0024] FIG. **4**B illustrates a path of insertion of blood into the blood collection tube of FIG. **1**B,

according to embodiments of the present disclosure;
[0025] FIG. **5**A is a cross-section view of a vacuum pump tube applied to a vacuum port of the blood collection tube, according to embodiments of the present disclosure;
[0026] FIG. **5**B illustrates the operation of a valve and a moisture non-permeable membrane at the vacuum port for sequestering blood from the vacuum port, according to embodiments of the present disclosure;
[0027] FIGS. **6**A-**6**C illustrate the filling of a prior art blood collection tube and the blood collection tube of FIGS. **1**A-**1**B filled with blood, according to embodiments of the present disclosure;
[0028] FIG. **7**A is an upper perspective view of a blood collection device, according to embodiments of the present disclosure;
[0029] FIG. **7**B is an upper perspective view of the blood collection device of FIG. **7**A with a blood collection tube and a blood needle contained therein, according to embodiments of the present disclosure;
[0030] FIG. **7**C is a lower perspective view of the blood collection device of FIG. **7**A, according to embodiments of the present disclosure;
[0031] FIG. **7**D is an upper perspective view of the blood collection device of FIG. **7**A with its casing and certain internal components removed, according to embodiments of the present disclosure;
[0032] FIG. **7**E is a lower perspective view of the blood collection device of FIG. **7**A with its cover and certain internal components removed, according to embodiments of the present disclosure;
[0033] FIG. **8**A is a depiction of a second embodiment of a blood collection device, including gears for rotation of the blood collection tube for mixing, according to embodiments of the present disclosure;
[0034] FIG. **8**B illustrates the mixing of blood and additive through rotation of the blood collection tube, according to embodiments of the present disclosure;
[0035] FIG. **9** is a perspective view of the vacuum pump of the blood collection device connecting with a vacuum port on the blood collection tube, according to embodiments of the present disclosure;
[0036] FIG. **10** is a perspective view of a battery and a corresponding battery slot of the blood collection device, according to embodiments of the present disclosure;
[0037] FIG. **11**A is a lower perspective view of a system for delivering blood additives from a plurality of liquid reservoirs to a septum of the blood collection tube, according to embodiments of the present disclosure;
[0038] FIG. **11**B is an illustration of a needle from a blood additive reservoir injecting a blood additive into a blood collection tube, according to embodiments of the present disclosure;
[0039] FIG. **12** depicts steps of a method of collecting blood according to embodiments of the present disclosure;

DETAILED DESCRIPTION OF THE INVENTION

[0040] The present Application relates to the collection of blood for testing and, more specifically, but not exclusively, to a blood collection tube, blood collection device, and method for collecting volumes of blood into collection tubes that are stored at atmospheric pressure.
[0041] Before explaining at least one embodiment in detail, it is to be understood that the invention is not necessarily limited in its application to the details of construction and the arrangement of components and/or methods set forth in the following description and/or illustrated in the drawings. The invention is capable of other embodiments or of being practiced or carried out in various ways.
[0042] FIGS. **1**A and **1**B illustrate blood collection tube **100**, according to embodiments of the present disclosure. FIG. **1**A is an isometric view of the blood collection tube and FIG. **1**B is a cross-section view of the tube of FIG. **1**A, cut along axis “A.” Blood collection tube **100** includes body **102**, defining a chamber therein, and a cap **103**. Body **102** defines a proximal end, at cap **103**,

a distal end, at the bottom of the body **102**, and an axial extent therebetween.
[0043] In preferred embodiments, the outer dimensions of body **102** and cap **103** are geometrically identical to those of conventional blood collection tubes. For example, the axial length of tube **100** may be 75 mm, and the diameter of the cap **103** may be 13 mm. Advantageously, tube **100** is accordingly compatible with existing equipment for storing blood collection tubes and sampling blood collected in blood collection tubes. In addition, a technician using tube **100** will be comfortable with its shape and size.
[0044] Body **102** includes chamber **112** having a funnel-shaped geometry, which defines the contours of chamber **112**. Chamber **112** includes a substantially conical upper portion and a substantially cylindrical lower portion with a narrower diameter than the upper portion. The funnel-shaped chamber **112** is used to make the blood height within the chamber compatible with the height of blood in chambers of conventional blood collection tubes. The conventional tubes collect far more blood than necessary and thus have larger volumes than chamber **112**. Tube **100** is designed to collect volumes of between 300 µl and 1 ml, whereas conventional tubes are designed to collect between 3 and 5 ml. Without a funnel-shaped geometry, blood collected in tube **100** would pool at the very bottom of body **102**, causing difficulty in accessing the collected blood for analysis. For this reason, funnel- shaped chamber **112** limits the effective volume of the blood collection tube **100** and also ensures that the collected blood is accessible at an equivalent height compared to blood collected in a conventional tube. The body further includes a relief channel **125**. The relief channel **125** is an indentation along the axis of the tube that allows air to escape as blood enters the tube. This enables uniform blood flow within the tube and prevents the occurrence of an "air jam."
[0045] While the structure of tube **100** is particularly advantageous for the collection of micro-volumes of blood, there is no technical impediment in the use of tube **100** for the collection of larger volumes. For example, the collected blood volume may be as high as 10 ml, as in currently used vacuum blood collection tubes. The shape of chamber **112** may be adjusted as needed to define a desired volume.
[0046] At a distal end of body **102** (i.e., at an end further from cap **103**), tube **100** includes a vacuum port **114**. Vacuum port **114** is a substantially cylindrical opening configured to interface with tubing from a vacuum pump to draw a vacuum through chamber **112**. In the illustrated embodiment, port **114** is at the distal end of body **102**; in alternative embodiments, vacuum port **114** is configured along the axial extent of body **102**. Between the vacuum port **114** and chamber **112** are liquid-impervious membrane **116** (shown in FIG. **5**B) and valve **118**, the functions of which will be described further herein.
[0047] Optionally, a rupture disk is placed within chamber **112**. The rupture disk may be situated toward the top of the chamber and may include a peripheral pathway for the transfer of the blood and the additive therethrough, as well as a central area through which a needle may be inserted during the blood collection. In the illustrated embodiments, no rupture disk is employed, and the blood is retained.
[0048] Cap **103** is of a standard size and shape. As seen in FIG. **3**, cap **103** consists of an outer shell **109** with an over-molded or inserted septum **106** at a top face. The shell may be made of a polyolefin, while the septum **106** is made of an elastomeric material. This elastomeric material serves as a septum, and a self-sealing gasket, keeping the collected blood and additives secure within the tube until it is desired to remove the blood from the tube. Septum **106** is configured to receive a needle carrying blood from a patient, as well as receive a probe for removing the mixed blood and additive from the tube. Cap **103** further includes septum **108** at a lateral face for receiving an injection of an aliquot of blood additive. Septum **108** optionally includes several defined entry regions **110**. Entry regions **110** are locations where the blood additive is inserted into the septum **108**. In certain embodiments, entry regions **110** extend through the entire thickness of septum **108**, and blood additives are drawn through entry regions **110** by a force of vacuum. In

alternative embodiments, entry regions **110** are approximate locations where a needle may be inserted through septum **108**, and the additives are inserted via a needle that is extended through the entire thickness of septum **108**. The entry regions **110** may be separate, as illustrated, or may be a single large orifice suitable for receipt therein of a multi-lumen needle.

[0049] Septum **106** is significantly thinner than an equivalent prior-art septum. Because tube **100** is not stored under vacuum, a thick septum is not necessary to maintain a pressure differential within the chamber.

[0050] In preferred embodiments, body **102** further includes mixing ribs **107** at a proximal end thereof, as seen in FIG. **1**B and FIG. **2**B. The cap **103** may further include optional mixing ribs **105**, as seen in FIG. **2**A. The mixing ribs may be formed integrally with the septum of the same elastomeric material. Mixing ribs **105** and **107** promote swirling of liquid within the cap **103** and chamber **102** when the tube is rotated around its axial extent. This swirling ensures that the additive and blood collected into tube **100** are mixed effectively. Although, in the illustrated embodiments, three mixing ribs are used, more or fewer mixing ribs may also be employed, as desired.

[0051] Referring to FIGS. **4**A and **4**B, insertion of additive and blood into tube **100** proceeds in two stages. As shown in FIG. **4**A, a needle **131** is inserted through the septum, and the additive is deposited in the chamber through the second conduit **122**. In preferred embodiments, this needle is a tri-lumen needle. Each lumen is connected to a reservoir for one particular additive, and that additive is pumped through its lumen into the septum. Referring to FIG. **4**B, after insertion of the additive, blood is injected through septum **106** and into first conduit **120** via needle **132**.

[0052] After the introduction of the additive and the blood, the blood and the additive are mixed. In a preferred embodiment, the blood and additive are mixed in an active mixing process through rotation of tube **100** around the axis A-A thereof. To effect this mixing, the tube is rotated through the operation of gears within the blood collection device, which will be described further herein. The mixing process causes the blood and additive to mix a suitable amount of times, such as ten times. The mixing ribs promote swirling within the tube. In conventional blood collection systems, the phlebotomist manually inverts a blood collection tube up to ten times to mix the blood and the additive. The combination of the mixing ribs with rotational action replaces this manual mixing with an automatic mixing process.

[0053] In the illustrated embodiment, three mixing ribs are located in tube **100**, in addition to the three mixing ribs in cap **103**. This number of mixing ribs is merely exemplary, and a greater or lesser number of mixing ribs may also be employed.

[0054] FIGS. **5**A and **5**B illustrate the insertion of vacuum tube **146** into an interior region **148** of vacuum port **114** and various components of the distal end of tube **100**. Membrane **116** is configured between vacuum port **114** and chamber **112**. Membrane **116** is configured to permit vacuum to be drawn therethrough but is non-permeable to liquid. For example, membrane **116** may be made of polytetrafluoroethylene (PTFE) or a thin silicone membrane. One-way valve **118** is configured between a distal end of chamber **112** and membrane **116**. Valve **118** is made of a material approved by regulatory agencies for contacting blood samples, such as silicone. Valve **118** is controlled by the force of a vacuum applied at port **114**. Region **150** is defined between valve **118** and membrane **116**. When a vacuum is applied to vacuum port **114**, blood is drawn through valve **118** and fills region **150**, as shown in FIG. **6**B. This blood is sequestered from the distal end of the chamber by the valve. Advantageously, sequestering the blood in region **150** from the rest of the blood in the chamber prevents any contamination of the blood by the membrane **116**, which could affect the accuracy of an assay of the blood.

[0055] FIGS. **6**A-**6**C illustrate a process of blood withdrawal from the chamber, and illustrate how the same tools may be used to withdraw blood from the chamber of tube **100** compared to conventional tubes. In FIG. **6**A, a conventional tube **60** is illustrated. The tube is filled with blood, and a probe **52** is inserted to withdraw the blood. In FIGS. **6**B and **6**C, blood collection tube **100** is filled with blood. A probe **152** is inserted through septum **106** and accesses the blood within

chamber **112**. In FIG. **6**C, only 300 μl of blood is collected in chamber **112**. Chamber **112** is shaped such that the cylindrical-shaped lower section holds less than the collected 300 μl, and accordingly, at least a portion of the collected blood is in the cone-shaped upper section of chamber **112**. Because of the smaller volume of chamber **112** compared to that of the conventional tube, the height of the blood is similar, even though much less blood is collected. As a result, probe **152** is easily able to collect blood from the upper section of chamber **112** without having to be longer or thinner than probe **52**.

[0056] Referring now to FIGS. **7**A-**11**B, blood collection device **200** is configured to withdraw blood and additives into blood collection tube **100**. FIG. **7**A depicts an upper perspective view of device **200** without a tube therein and FIG. **7**B depicts the same view of device **200**, with tube **100** therein. FIG. **7**C depicts a lower perspective view of device **200**.

[0057] Device **200** includes casing **201** and has an upper face **202** and a lower face **204**. Casing **201** is ergonomically shaped for multiple grip positions for both right-handed and left-handed users.

[0058] Cover **206** is attached to casing **201**, for example, via a hinged connection. Cover **206** covers the first slot **208** and a second slot **210**. Cover **206** may be opened to permit the insertion or removal of tube **100** and is closed and optionally locked during the operation of device **200**.

[0059] First slot **208** is configured for receiving therein tube **200**, and second slot **210** is arranged for receiving therein needle **304**. Needle **304** is part of a phlebotomy assembly **300**, including a venipuncture cannula (not shown), tubing **302** extending from the venipuncture cannula, needle **304**, and connector **306** for connecting the needle **304** with tubing **302**. A divider **207** is configured between the first slot **208** and the second slot **210**. The divider **207** has a central aperture **209** for permitting needle **304** to pass therethrough. Similarly, cover **206** has an aperture **211** parallel to aperture **209**, for permitting the needle **304** to pass therethrough, even when the cover **206** is closed. An optical sensor (not shown) may be arranged at divider **207** or central aperture **209**. The optical sensor may be used to confirm whether blood has entered needle **304**, for example, during a priming process of tubing **302** and needle **304**.

[0060] Optionally, the needle **304** includes a blood metering sensor **308**. The blood metering sensor measures a volume of blood that passes through the needle **304**. This is especially relevant during a priming process, as the connector **306** is initially filled with air, and the air needs to be evacuated before a volume of blood may be drawn with accuracy. The blood metering sensor measures the blood passing through the needle, thereby determining that the blood volume matches the expected volume. The blood metering sensor may perform these sensations through any specific measuring technique known to those of skill in the art, such as measuring sound or light.

[0061] Second slot **210** further includes a locking slot **219**. Locking slot **219** is shaped to receive connector **306** and needle **304** and is slidable within the second slot **210**. The second slot **210** may also have a locking tube **213** for receiving the needle **304** therein. When the needle **304** is received in locking slot **219** and locking tube **213**, and the needle **304** is advanced relative to the second slot **210**, the locking slot **219** and locking tube **213** advance with it. The advancing locking tube **213** pushes tube **100** within the first slot **208**. Tube **100** is pushed sufficiently forward by locking tube **213** to be flush with vacuum adapter **242**. In alternative embodiments without a locking tube **213**, a similar pushing function may be performed by the needle **304** or connector **306** itself. The locking slot **219** may be locked into place with a spring-loaded mechanism attached to a sensor (not shown).

[0062] Optionally, locking slot **219** and needle **304** may be advanced, locked, and retracted in an automated fashion between three positions: a rest position, in which the tube **100** is not flush with vacuum adapter **242**; a vacuum position, in which the tube **100** is flush with vacuum adapter **242** but the needle **302** is not piercing septum **106**; and a drawing position, in which the needle **302** is advanced so that it is piercing septum **106**. The locking slot **219** may be controlled by any suitable motor, such as a servo motor. The needle **304**, locking slot **219**, and tube **100** stay in place until completion of a blood collection process, at which point the locking slot **219** is automatically

released, causing automatic retraction of locking slot **219** and ejection of the needle **304** from tube **100**. The view of FIG. **8**B shows tube **100**, locking slot **219**, and locking tube **213** in this released position. The foregoing descriptions of locking slot **219** and locking tube **213** are merely exemplary, and any other suitable mechanism may be employed for releasably locking the needle **304** and tube **100** in place.

[0063] Screen **212** is also visible within upper face **202**. Screen **212** may be a touch screen. The touch screen **212** may be any standard screen or display suitable for implementation in a mobile computing device, such as LCD, OLED, AMOLED, Super AMOLED, TFT, or IPS. The screen displays a graphic user interface **500** for the operation of device **200**.

[0064] Screen **212** is integrated with a processor (not shown) for controlling the operations of device **200**. The processor includes memory and circuitry for executing computer-readable program instructions stored in the memory. The memory is a non-transitory storage medium having stored thereon code instructions that, when executed by the processor, cause the performance of various steps. The storage medium may be, for example, an electronic storage device, a magnetic storage device, an optical storage device, a semiconductor storage device, or any suitable combination of the foregoing. In particular, the functions described herein may be programmed by a computer program product installed on the non-transitory computer-readable medium of the processor. In exemplary embodiments, the screen **212** functions as an input interface for the processor, including for confirming predetermined volumes of blood additive and blood to be delivered into tube **100**.

[0065] In addition, the processor preferably includes wireless communication hardware, such as Wi-Fi or Bluetooth, for transmitting information between the device **200** and an external device, such as a facility computer system, a smartphone, or a tablet. Alternatively or in addition, device **200** includes a manual data port, such as a USB connection, for interfacing between the processor and the external device. Through the link to the facility system, the processor is used to control patient information, sample collection compliance, specimen quality optimization, documentation compliance, and to provide complete inventory and storage management. The data link may also be used to provide programming, maintenance, and software updates to device **200**. A computer program product for controlling and documenting patient blood draws may be installed on both the facility computer system and on device **200**, for ease of compatibility and information transfer.

[0066] Optionally, the screen **212** and processor are part of a tablet computer that is installable within and removable from device **200**. Alternatively, the screen **212** and processor may be permanently fixed within device **200**.

[0067] The processor is connected to various sensors in device **200**, including a sensor for determining whether cover **206** is open or closed, a sensor for determining whether locking tube **213** is in a locked or unlocked position, a gyroscope sensor for determining if the orientation level is acceptable, and other sensors that will be described further herein.

[0068] Device **200** further includes battery **214**, which is stored within battery case **215** (shown in FIG. **10**). Battery case cover **216** secures battery **214** within battery case **215**. Battery **214** may be any battery known to those skilled in the art, such as lead-acid, nickel cadmium, nickel-metal hydride, lithium-ion, lithium-ion polymer, or an alkaline battery. In advantageous embodiments, battery **214** is rechargeable. Because device **200** is battery-powered, device **200** is fully portable. Battery **214** is configured to last throughout a typical user's workday.

[0069] In addition to being portable, in preferred embodiments, device **200** is handheld. That is, the device **200** can be held by a technician during use. In further advantageous embodiments, the device **200** may be held with a single hand, so a technician may use one hand to hold the device **200** and another to insert or remove a needle or collection tube. In preferred embodiments, the size of device **200** is comparable to that of handheld printers currently known to those of skill in the art, for example, Zebra® printers.

[0070] FIGS. **7**D and **7**E depict device **200** with casing **201** and certain other internal components removed. In the view of FIG. **7**D, top side **204** is on the top, and bottom side **206** is on the bottom;

in the view of FIG. **7**E, these orientations are reversed.
[0071] Reservoirs **220***a*, **220***b*, and **220***c* store blood additives. Although in most examples described below, reservoirs **220** contain liquid additives, the term "reservoir" encompasses a store of a solid additive. Typically, each reservoir **220***a-c* stores a different additive. For example, reservoir **220***a* may store a concentrated solution of sodium heparin or lithium heparin; reservoir **220***b* may store a concentrated solution of potassium EDTA, and reservoir **220***c* may store a concentrated sodium citrate solution. The number of reservoirs and the type of additive in each reservoir may be modified without departing from the scope of the present disclosure. A plurality of conduits **222***a*, **222***b*, and **222***c* are respectively connected to a corresponding reservoir **220***a*, **220***b*, **220***c*. Each conduit **222** extends from a respective reservoir **220** toward septum **108** of tube **100**. The specific mechanism for delivery of a blood additive from reservoir **220** through conduit **222** will be described further in connection with FIGS. **11**A-**11**B.
[0072] Also visible in FIGS. **7**D and **7**E is printer **230**, whose location is indicated schematically. Printer **230** may be, for example, a thermal printer or a color micro printer. A roll of adhesive-backed labels **234** is arranged adjacent to printer **230**. A single label **232** extends upward from roll **234** toward tube **100**. Roller **236** is used to advance roll **234** as the printer **230** is printing.
[0073] FIG. **8**A illustrates another embodiment of device **200** with casing **201** and certain other internal components removed. In this embodiment, the printer is not present, and instead, a laser etching device **275**, whose location is schematically indicated, is used to imprint patient information directly on the tubes, as discussed. In addition, gears **271** and **273** are configured to rotate the tube **100** following insertion of the additive and blood to mix the additive and the blood, as discussed. Suction fitment **275** secures the end of tube **100** during rotation thereof. Although, in the illustrated embodiments, the tube rotation is described as along the long A-A axis and is performed through the operation of gears **271** and **273**, other methods of implementation are possible for the mixing process. For example, the mixing may take place through vibration or anti-axial methods (i.e., back-and-forth movement in a perpendicular direction to the axial extent).
[0074] Referring to FIG. **9**, device **200** further includes vacuum pump **240**. Vacuum pump **240** may be a micro-diaphragm gas sampling pump. Vacuum pump **240** includes adapter **242** for receiving the bottom of tube **100** and making a vacuum-tight seal therewith. The interaction between pump **240** and tube **200** is further shown in FIG. **9**. The tube **100** rests on stands **252** and **254**, with the bottom **104** at a rear portion of the device **200**. Vacuum tube **146** extends from adapter **242** and is insertable into the vacuum port **114** of tube **100** in the manner discussed above. The specific vacuum drawn by the vacuum pump through vacuum tube **146** may be controlled by the processor, for example, through the use of sequencing valves.
[0075] Optionally, vacuum pump **240** is connected to a vacuum reservoir or staging chamber **244** to store a vacuum. The stored vacuum may be used to enable a quicker or more controlled vacuum application to tube **100**.
[0076] Referring to FIG. **10**, device **200** further includes a barcode scanner **205**, whose location is schematically indicated within casing **201**. Barcode scanner **205** is used to scan a barcode on a patient's armband to verify the patient's identity. Other sensors may alternatively be used to confirm patient identity, including, for example, image sensors, facial recognition technology, or digital capture technology. Device **200** also includes a removable cover **203** for inserting and removing reservoirs **220***a*-**220***c*, as well as for inserting and removing ink cartridges for printer **230**.
[0077] Other optional components of the device **200** include an internal ultraviolet light for sterilization of the interior of the device **200** in between patients, a gyroscope for determining the orientation level of the device, and for enabling the use of the device only when the device is at a proper orientation for optimal performance; a tube magazine, for enabling the possibility of collection of multiple tubes without operator intervention, a storage area for the completed and labeled tubes, and means for transporting the empty and full tubes before and after blood collection (e.g., pick and place arms, conveyor belts, or magnetic grippers).

[0078] FIGS. **11**A-**11**B illustrate in greater detail the system for delivering blood additives from the reservoirs **220***a*-**220***c*, through conduits **222***a*-**222***c*, and into septum **108** of tube **100**, according to embodiments of the present disclosure. As shown in FIG. **11**A, valve assembly **224** is configured between each respective reservoir and an outlet of each conduit **222***a*, **222***b*, **222***c*. Valve assembly **224** contains, for example, a plurality of solenoid valves, each configured to control fluid flow through a respective conduit **222**. The system further includes an air intake **226** and a sensor **228** configured to monitor fluid flow through each valve in valve assembly **224**. Sensor **228** may be, for example, any type of flow meter known to those of skill in the art. As shown in FIG. **11**B, each conduit **222***a*-**222***c* terminates in a needle **225***a*-**225***c*. Each needle **225***a*-**225***c* is operatively connected to a motor, such as a servo motor having a position encoder configured to extend and retract the needle. The needles **225***a*-**225***c* may alternatively be part of an integrated multi-lumen needle, as discussed, in which case a single servo motor operates the multi-lumen needle.
[0079] A process of drawing a blood additive from a reservoir **220** into a tube **100** using vacuum pump **240** is as follows. First, an identity and volume of blood additive to be drawn is set with the processor. Upon determination of a volume of fluid to be delivered from a particular reservoir **220**, the processor directs the operation of the servo motor so that the needle **225** corresponding to that reservoir **220** extends and penetrates the septum **108**, as shown in FIG. **11**B. The processor further directs the opening of a valve within valve assembly **224** corresponding to the selected additive. The opening of the valve permits an additive to be drawn out of the selected reservoir **220**. A vacuum is applied by vacuum pump **240**, drawing a vacuum through tube **100**, including through first conduit **120** and second conduit **122**, through needle **225**, and through conduit **222**. As a result, the additive is drawn from reservoir **220**. When sensor **228** determines that the predetermined volume of the additive has passed through valve **224**, the processor directs the closure of the valve and opens air intake **226**. Air intake **226** delivers a small pocket of air behind the aliquot of concentrated blood additive to help drive the aliquot through conduits **222**, needles **225**, and first and second conduits **120** and **122** of the tube. The vacuum is then turned off, and the needle **225** is removed from septum **108**.
[0080] Alternative additive delivery methods from reservoir **220** include piezo or inkjet delivery.
[0081] In the above-described embodiments, the blood additives are provided as highly concentrated liquid solutions. The concentration is determined such that a quantity of up to around a 10 µl aliquot of the solution is sufficient for providing additive to a blood draw of up to 1 ml. For example, lithium heparin may be delivered either at 15.8 USP (United States Pharmacopeia units) per unit or pulled as a 10 µl aliquot from a solution that has an equivalent 1580 USP. EDTA may be provided in a super concentrate that contains 180 mg of EDTA for every 10 uµl aliquot. These concentrations are merely exemplary, and other concentrations may also be employed.
[0082] One advantage of using concentrated liquid solutions is that the blood additives are removed from needles **225** without requiring any liquid or outside material to contact the tips of needles **225**. As a result, it is possible to use the same delivery system to deliver blood additives to multiple tubes **100** without any risk of contamination. In addition, because there are separate conduits **222** for each blood additive and separate regions **110** on septum **108** for receiving the different additives therethrough, there is no possibility of contamination of any particular reservoir **220** or conduit **222** with a blood additive from a different reservoir or conduit.
[0083] In alternative embodiments, the blood additives may be delivered as solids. For example, the blood additives may be delivered with a screw conveyor system, wherein the tip of each screw conveyor is configured as a needle that is insertable into septum **110**. The device may also use a combination of liquid and solid delivery as needed, with the liquid and solid additives being delivered from separate reservoirs **220**.
[0084] In addition, in alternative embodiments, instead of using vacuum pump **240** to withdraw the blood additives, a separate delivery system is implemented for them. For example, the separate delivery system may include a vacuum push-pull system configured at reservoir **220**.

[0085] In a preferred embodiment, patient information is supplied onto the tube through laser etching. The etched information may include, for example, a patient's name, identification number, barcode, QR code, etc. The tube is rotated through operations of gears, for example (illustrated in FIG. **8**A) during the etching process. For the etching to be effective, the tubes are made of a material susceptible to laser etching, such as polycarbonate. Optionally, each tube is coated with a layer of sizing around the etching region to increase the contrast during the laser etching. The sizing may also serve to protect the blood within the tube from the laser etching. Advantageously, compared to printing, the use of laser etching reduces the volume of consumables (such as toner and labels) that are required to be supplied to the device **200** during the operation of the device.
[0086] In alternative embodiments, patient information is supplied through label printing, as discussed at length in application WO2022/038616.
[0087] While device **200** is depicted in the illustrated embodiments as a standalone device, it is also possible to integrate it into a larger device. For example, a robotic surgery device, whether for general surgery or orthopedic surgery, may include a blood sampling module with all of the operative components of device **200**.
[0088] Referring now to FIG. **12**, a method **400** of drawing blood into tube **100** with device **200** is disclosed.
[0089] At step **401**, a user scans a bar code associated with a patient. The bar code may be printed on an armband worn by the patient. The processor determines patient information based on the scanned bar code, for example, the patient's name and current location. The processor compares the patient information to stored patient information previously downloaded to the device **200**. For example, the processor may have stored thereon a list of patients and bar code information for which blood drawing is required. The processor may allow proceeding to the next step of blood collection only when the patient's name and scanned bar code information match one of the names and bar codes on the list. This prevents errors due to misidentification.
[0090] At step **402**, device **200** displays information regarding how much blood to collect from the patient, which blood additives to include in each tube, in which order, and any special instructions associated with that patient, such as drawing at an especially low vacuum. The volumes of blood and additives to be collected are predetermined. For example, a physician may order a list of assays, and the laboratory information system or the processor of device **200** sets the volume of blood required to be collected to perform such assays. The processor or computer program may further calculate a predetermined volume of blood additive necessary to add to each blood sample to preserve the blood for testing.
[0091] At step **403**, the technician inserts a blood collection tube into first slot **208** and closes cover **206**. Because the blood collection tubes **100** are all interchangeable, this step may be performed before any of the preceding steps. Blood collection tube **100** is maintained at atmospheric pressure prior to insertion into first slot **208**. As used in the present disclosure, “atmospheric pressure” refers to the ambient pressure of an environment where the blood drawing process is performed.
[0092] Optionally, if the door is not closed and locked into place, an error message appears, and the screen does not proceed to the remaining steps. Additionally, there may be an indicator of the acceptable range of level orientation. For example, the indicator may be green if the device is in the acceptable range and red if the device is outside the acceptable range. If the indicator is red, the device needs to be repositioned before proceeding with the collection. The device will not function if the indicator is red.
[0093] At step **404**, the user inserts an intravenous cannula into a vein. The user may perform this step manually in a manner known to those with skill in the art. For example, the technician may insert a winged needle set into the vein. The cannulation and drawing of blood may alternatively be performed by a phlebotomy robot.
[0094] At step **405**, the technician inserts the needle **304** into the second slot **211**. The technician locks needle **304** into place using locking slot **213** and/or locking tube **219**.

[0095] At step **406**, the user primes the system. The priming may occur automatically or in response to user instruction. The optical sensor determines that the system is primed by sensing the presence of blood in tubing **302** or needle **304**.
[0096] At step **407**, device **200** draws a volume of blood additive solution from the appropriate reservoir into blood collection tube **100** by applying a vacuum at the vacuum port **114**. This step may be performed in the manner described above in connection with FIGS. **11**A-**11**B. Specifically, a vacuum is applied to blood collection tube **100** while cap **103** of blood collection tube **100** is fluidically connected to reservoir **220** containing the blood additive.
[0097] The volume of blood additive is added to the tube according to a predetermined ratio of additive to blood. The ratio may be, for example, about 1:100. Thus, for a 500 µl sample of blood, 5 uµl of additive is added. It is possible to deviate to some degree from the predetermined ratio without compromising the accuracy of the blood tests.
[0098] The vacuum is applied for a particular period of time. Specifically, the vacuum is applied for a sufficient amount of time to withdraw the blood additive into the second conduit **122** and first conduit **120**, but not to withdraw the blood additive further into blood collection tube **100**. Because a very small volume of blood additive is drawn, it is possible to fit the entire volume of drawn blood additive in the second conduit **122** or first conduit **120**.
[0099] At step **408**, device **200** draws a volume of blood from needle **304** into blood collection tube **100**. This drawing step is thus performed by applying a vacuum to the blood collection tube at vacuum port **114**, while cap **103** of the blood collection tube is fluidically connected to an intravenous cannula. One advantage of inserting the blood only after insertion of the additives is that there is no potential for contaminating the remaining additives in reservoirs **220** and conduits **222** with blood.
[0100] In exemplary embodiments, the applied vacuum may be approximately 120-150 mm Hg. The specific applied vacuum may be selected based on various factors, such as the desired time required for blood collection. The volume of withdrawn blood may be, for example, between 300 and 1,000 µl or more pending usage. The vacuum is applied until the predetermined volume of blood is collected, at which point the vacuum ceases automatically.
[0101] Typically, steps **407** and **408** are performed in very close proximity, i.e., within a few seconds of each other. Theoretically, steps **407** and **408** can happen simultaneously, so long as the needle delivering the additive is not contaminated by blood. This may be ensured through various mechanisms, including controlling the insertion depth of the needle containing the additive and the needle containing the blood.
[0102] The drawing of the additive and blood proceeds automatically once the user initiates the priming process. Throughout the collection process, a technician may be able to execute an emergency stop to abort the collection. The technician may also control the amount of vacuum applied if he or she determines this is necessary. This vacuum adjustment is recorded by the processor and associated with the patient's electronic medical record.
[0103] At step **409**, device **200** mixes the blood and additive together. This mixing is performed through the rotation of the tube within the device **200** and through the operation of the mixing ribs. The tube is rotated a number of times, which forces the blood to be mixed with the additive. As illustrated in FIG. **8**B, the rotational motion makes the blood fold over itself, utilizing the internal ribs/fins incorporated in the chamber. The mixing step preferably includes mixing the blood and additives at least ten times. Advantageously, this degree of mixing corresponds to a degree of mixing that would be performed manually by a user on a prior art tube.
[0104] At step **410**, device **200** etches patient information onto the blood collection tube **100** using a laser etching tool. As discussed, the patient information may include the patient name and ID, as well as the additive type, the date, the time, and the technician ID. The laser etching may be performed substantially at the same time as the mixing by applying the laser etching during the rotation of the tube for mixing. Alternatively, instead of laser etching, the patient information may

be supplied by printing and affixing a label.
[0105] At step **411**, the needle **304** is removed from blood collection tube **100**. Optionally, this step is performed automatically by releasing a locking mechanism holding the needle and blood collection tube in place, as described above in connection with FIGS. **7**A and **7**B. The processor uploads information regarding the blood collection to the facility's computer system. This information includes the date and time of collection and the identity of the phlebotomist who collected the sample. A button on the graphic user interface instructs the technician to remove tube **100**.
[0106] Each of the steps **408**-**411** are controlled by device **200** with forced compliance and are documented with traceability.
[0107] At step **412**, optionally, if the patient requires more than one type of blood assay, a new blood tube is inserted, and steps **407**-**411** are repeated. The graphic user interface may prompt the user to load the next tube, or alternatively, a new tube is conveyed via the tube magazine. Upon sensing the locking of the needle into the locking slot again, the processor may prompt the user to select or confirm values for the predetermined volumes of fluid and blood. In the alternative, the volumes of blood and additive may be set for multiple blood collection tubes prior to the first collection of blood and additive. The process is continued until all required tubes are complete.
[0108] When all required tubes are complete, a message may be displayed on the graphic user interface. The message may indicate that collection is complete and instruct the user to remove the needle from the patient and bandage the incision point. Another button may appear, prompting the user to “Upload Collection Information.” When this button is activated, all details of the successful collection are uploaded to the laboratory information system. The patient list is updated with either “complete” (if all tubes are collected) or “partial” (if only some of the requested tubes were collected.
[0109] Finally, at step **413**, a user withdraws a sample from the blood collection tube for analysis. This user is a lab technician rather than a phlebotomist. Optionally, instead of removing the cap **103** of blood collection tube **100**, the user may insert a probe **152** into the cap **103**. The probe **152** passes through septum **108** and first conduit **120** to reach the collected blood for sampling, as described above in connection with FIGS. **6**B-**6**C.

Claims

1. A blood collection tube, comprising: a body including a proximal end and a distal end, and defining an axial extent between the proximal end and the distal end; a chamber within the body, the chamber including a plurality of mixing ribs; a vacuum port; and a cap arranged on the proximal end, wherein the cap comprises: a top face including a first septum; a first conduit having an inlet extending from the first septum and an outlet in fluid communication with the chamber; a lateral face including a second septum; a second conduit extending radially from the second septum to the first conduit; and a plurality of mixing ribs; wherein, when a fluid source is fluidically connected to the first septum or the second septum, and a vacuum is applied at the vacuum port, the vacuum draws fluid from the fluid source, through the first or second septum, and into the first conduit; and when the tube is rotated around an axis defined by the axial extent, the mixing ribs of the cap and the mixing ribs of the chamber cause fluids therein to swirl, thereby effecting mixing of the fluids therein.
2. The blood collection tube of claim 1, further comprising a relief channel configured to enable air to escape from the chamber during filling of blood into the chamber.
3. A system for collecting blood, comprising the blood collection tube of claim 1, and a device for collecting blood into said blood collection tube, the device comprising: a first slot for securing a blood collection tube therein, and a set of gears arranged at an end of the first slot, for rotating the blood collection tube; a vacuum pump; a second slot for securing a needle therein; a plurality of

conduits, each conduit connected at a distal end thereof to a reservoir; a processor configured to specify a predetermined volume of additive to be delivered into a blood collection tube from one of the plurality of reservoirs and a predetermined volume of blood to be delivered into the blood collection tube via the needle; wherein, the vacuum pump, plurality of conduits, and second slot are arranged around the first slot such that when a blood collection tube having a vacuum port, first septum, and second septum is inserted into the first slot: the vacuum pump is configured to draw a vacuum through the vacuum port; each conduit is fluidically connectable to an interior of the blood collection tube via the second septum; and a needle secured within the second slot is fluidically connectable to an interior of the blood collection tube via the first septum; the processor is configured to control a vacuum delivered from the vacuum pump so as to draw the predetermined volumes of additive and blood into the blood collection tube; and wherein, following drawing of the predetermined volumes of additive and blood into the blood collection tube, the processor is configured to operate the gears so as to rotate the blood collection tube a plurality of rotations within the first slot, thereby mixing the additive and blood within the blood collection tube.

4. The system of claim 3, wherein the device further comprises a laser etching tool situated parallel to the axial extent of the blood collection tube, and, wherein, during rotation of the blood collection tube, the laser etching tool is configured to etch patient information onto the axial extent of the blood collection tube.

5. The system of claim 4, wherein the blood collection tube further includes a coating of sizing in a region onto which the laser etching is applied.

6. The system of claim 3, wherein the device further comprises a gyroscope for measuring orientation, and the processor is configured to permit operation of the vacuum only when the orientation of the device is within a prescribed range.

7. The system of claim 3, wherein the device further comprises an ultraviolet light for internal sterilization.

8. The system of claim 3, wherein the device further comprises an empty blood tube magazine and a full blood tube storage compartment, and means for transferring an empty blood collection tube from the magazine to the first slot and for transferring a filled blood collection tube from the first slot to the storage compartment.

9. A method of collecting blood into a blood collection tube, wherein the blood collection tube comprises a tube body including a proximal end and a distal end, and defining an axial extent between the proximal end and the distal end; a chamber within the tube body; mixing ribs within the chamber; a vacuum port; and a cap arranged on the proximal end, wherein the cap comprises: a top face including a first septum; a first conduit having an inlet extending from the first septum and an outlet in fluid communication with the chamber; mixing ribs in fluid communication with the chamber, a lateral face including a second septum; and a second conduit extending radially from the second septum to the first conduit; and the method comprises: drawing, with a vacuum, a volume of blood additive into the blood collection tube via the second septum through the second conduit; and drawing, with a vacuum, a volume of blood into the blood collection tube via the first septum through the first conduit; and rotating the blood collection tube a plurality of times along an axial extent thereof, to thereby swirl the blood and additive around the mixing ribs of the cap and of the chamber and thereby mix the blood and additive.

10. The method of claim 9, wherein the rotating step comprises rotating the blood collection tube at least ten times.

11. The method of claim 10, further comprising etching patient information on an axial extent of the tube with a laser etching device.