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(54) **LINE DRAW DEVICE FOR DIRECT ARTERIAL BLOOD SAMPLING**

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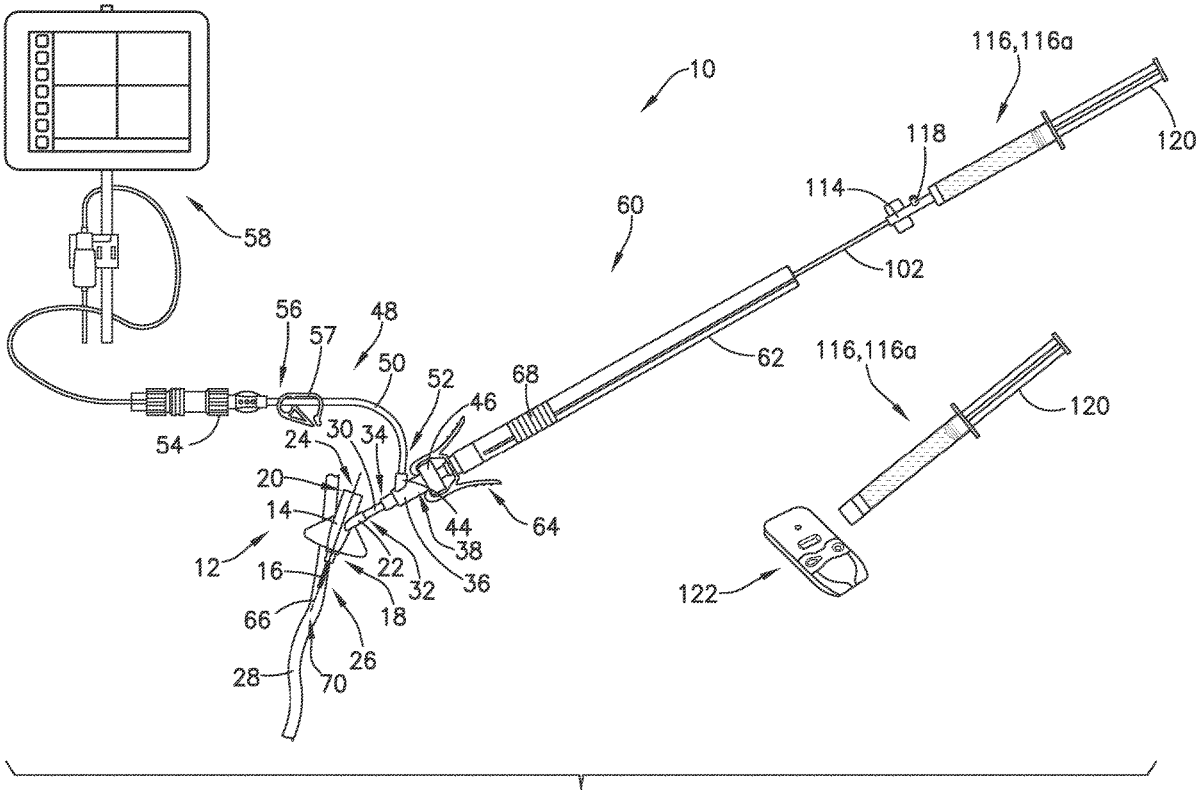
(57) **ABSTRACT**

A blood draw device for performing arterial blood collection includes a catheter tube, a housing configured to movably receive the catheter tube, and an advancement member movably coupled to the housing to move the catheter tube between first and second positions, with a distal end of the catheter tube disposed beyond a distal end of the housing and past a distal tip of the indwelling arterial catheter when in the second position. A secondary catheter is coupled to the advancement member and extends out proximally therefrom, with a collection device coupled to the secondary catheter so as to be in fluid communication with the catheter tube. The blood draw device is configured such that a fluid path formed by the catheter tube and secondary catheter has a controlled geometric factor, defined as a ratio of a length of the fluid path to an inner diameter of the fluid path.



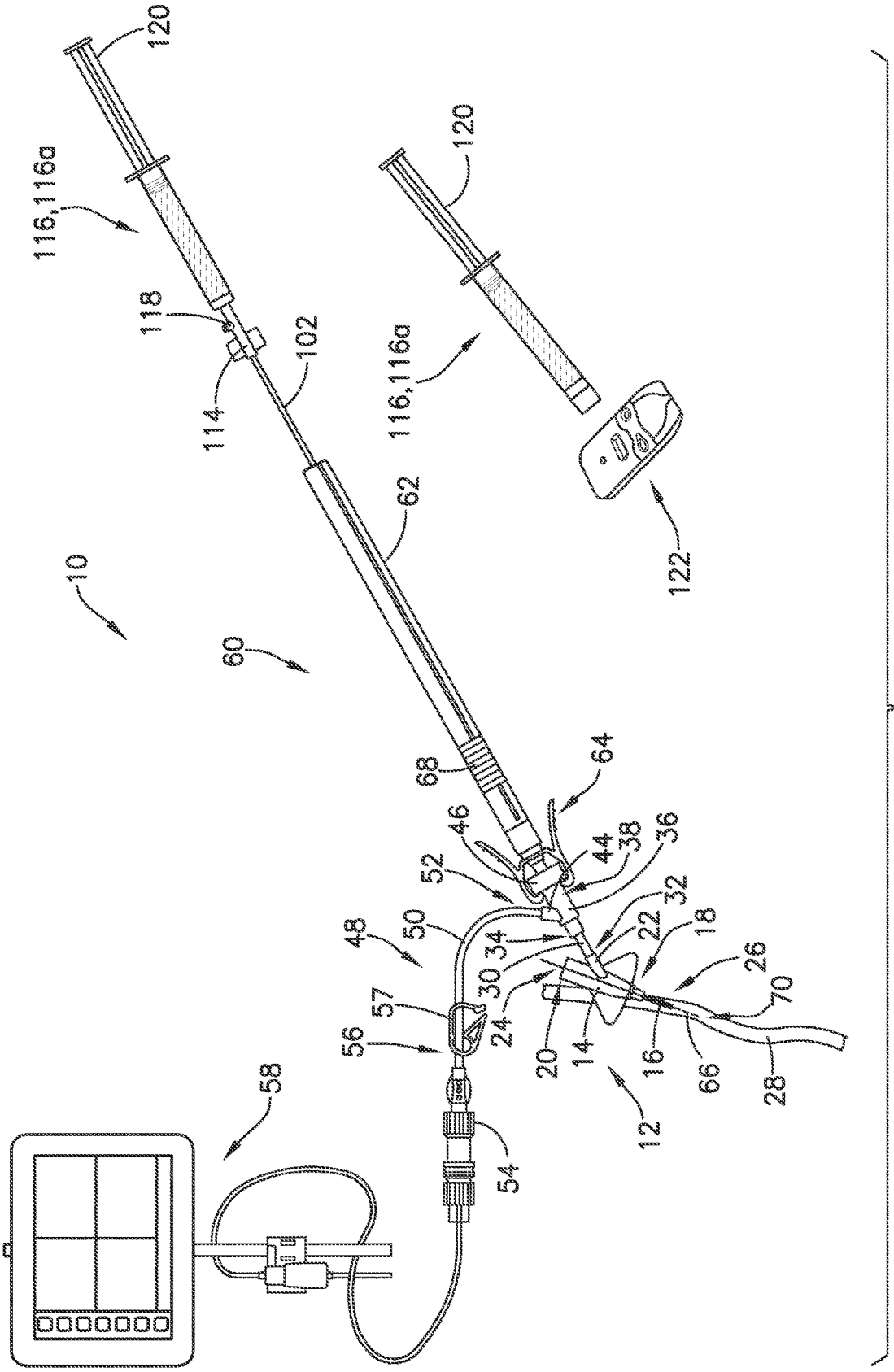

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FIG. 1

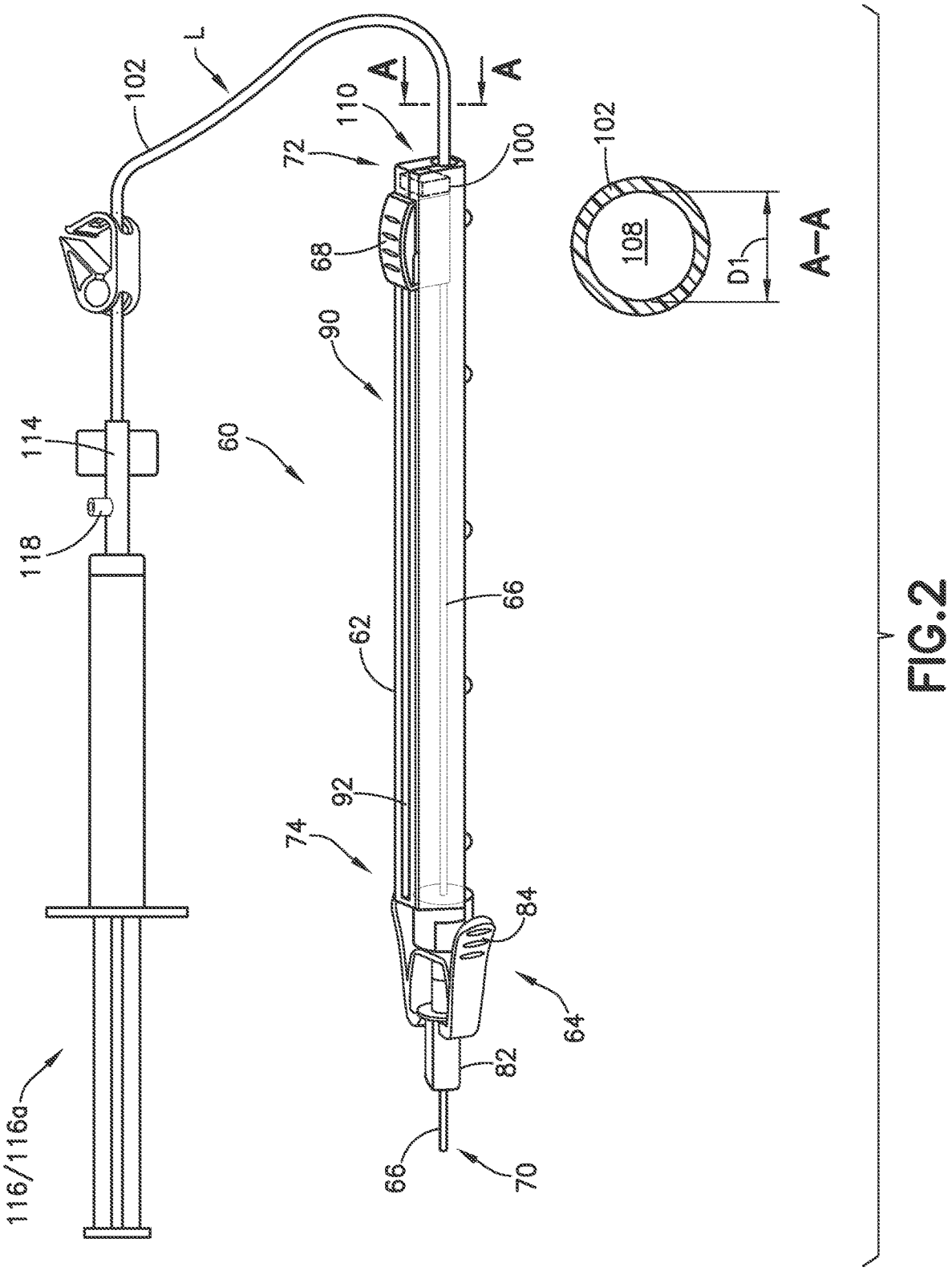
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FIG.2

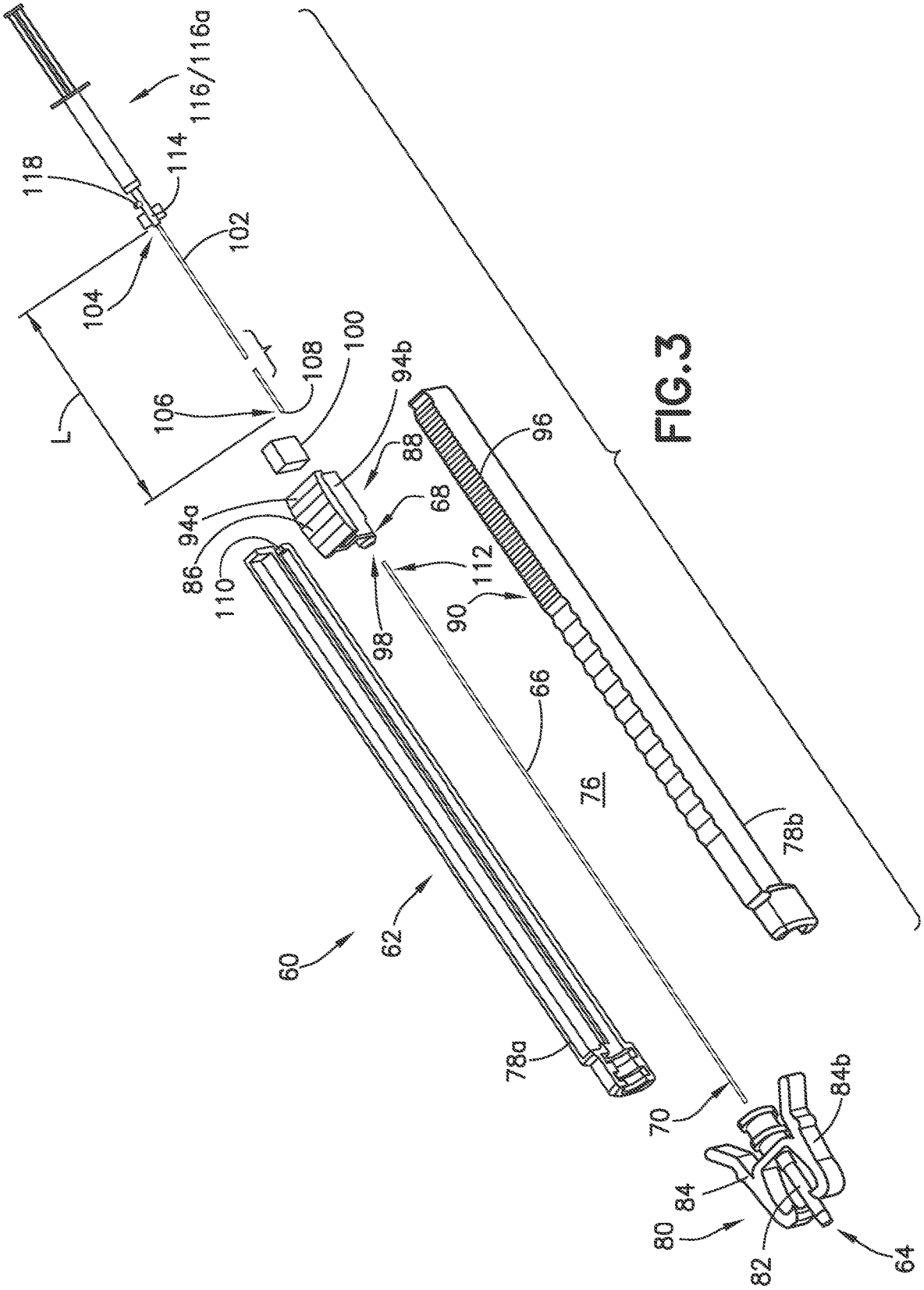
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FIG.3

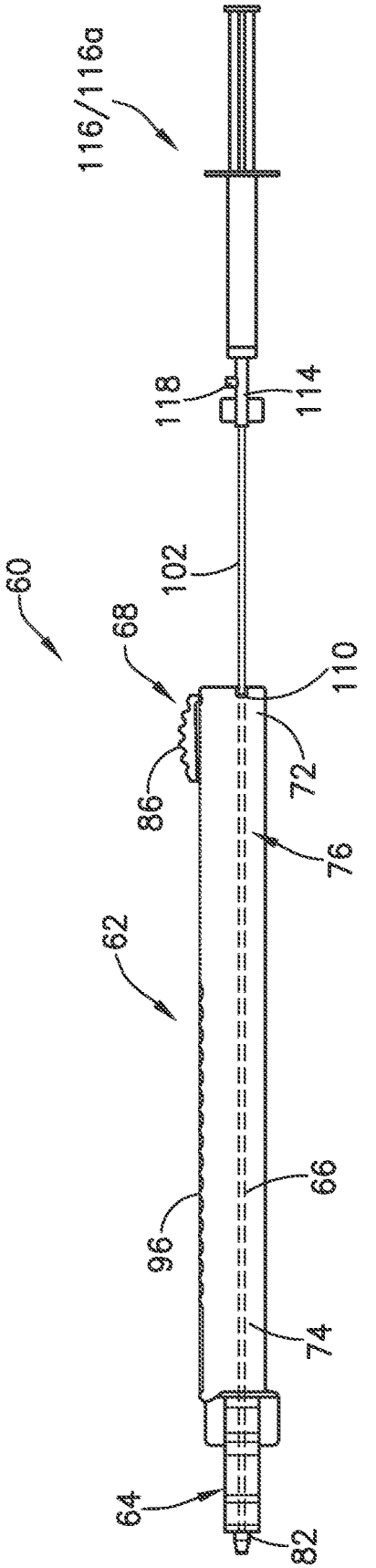
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FIG.4

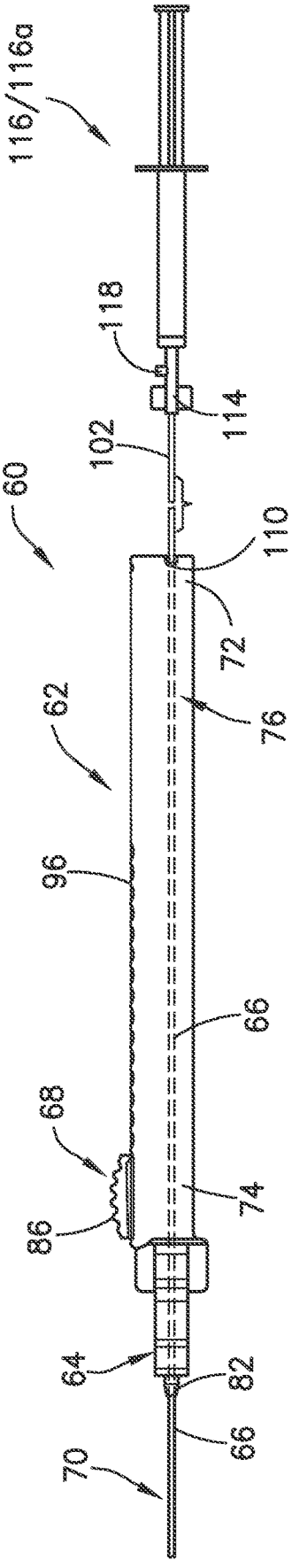
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FIG.5

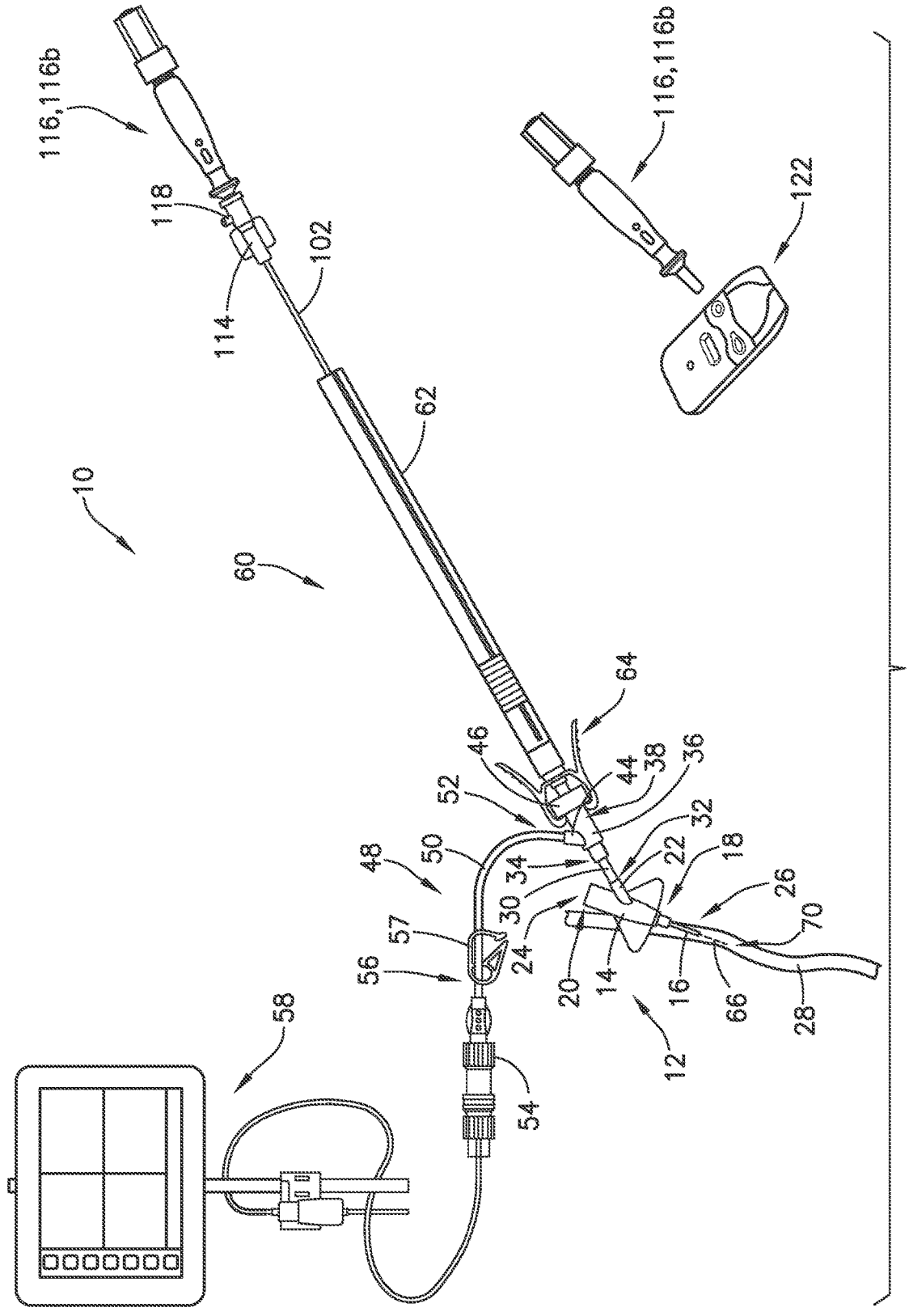
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FIG.6

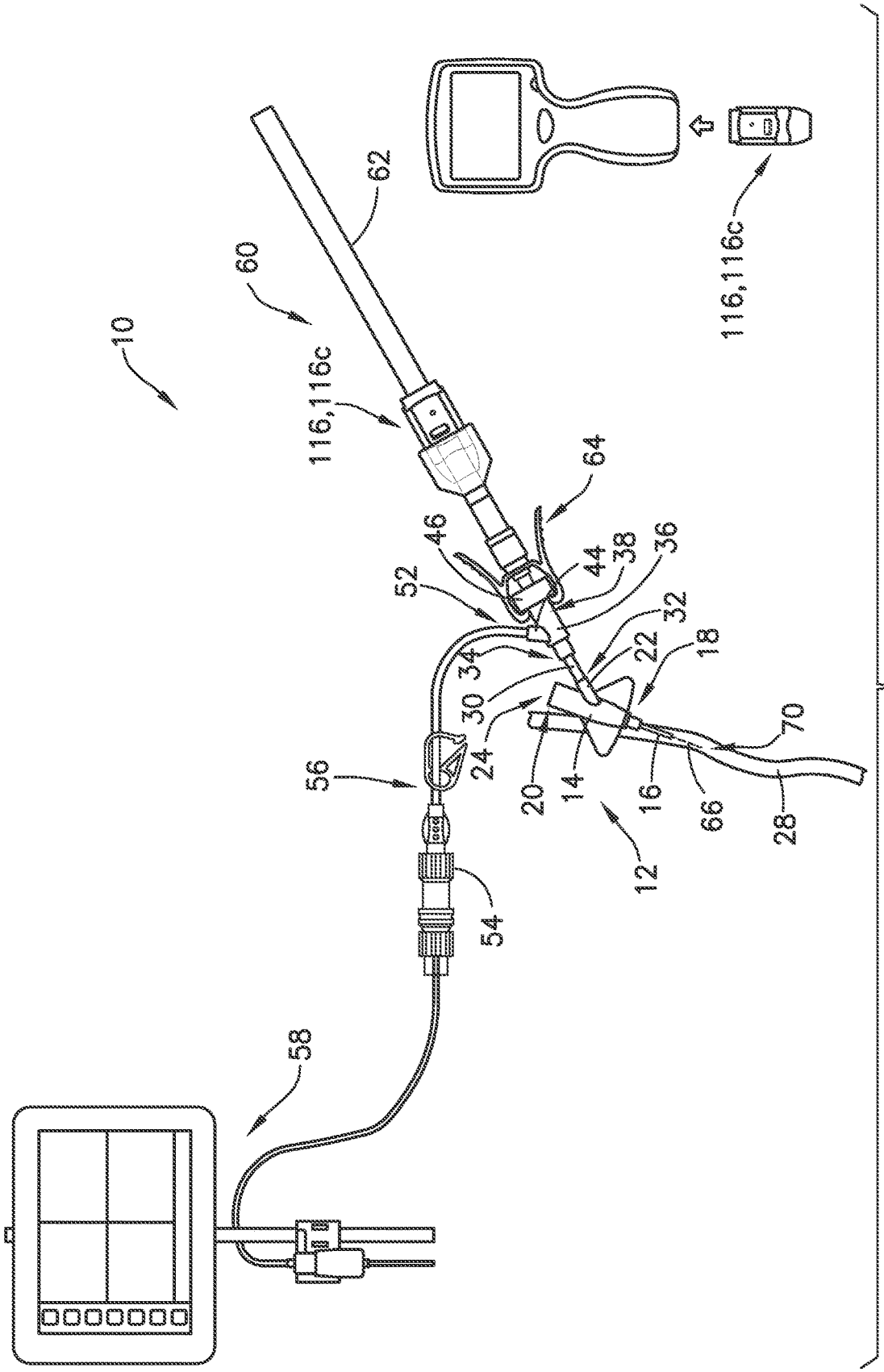
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FIG. 7

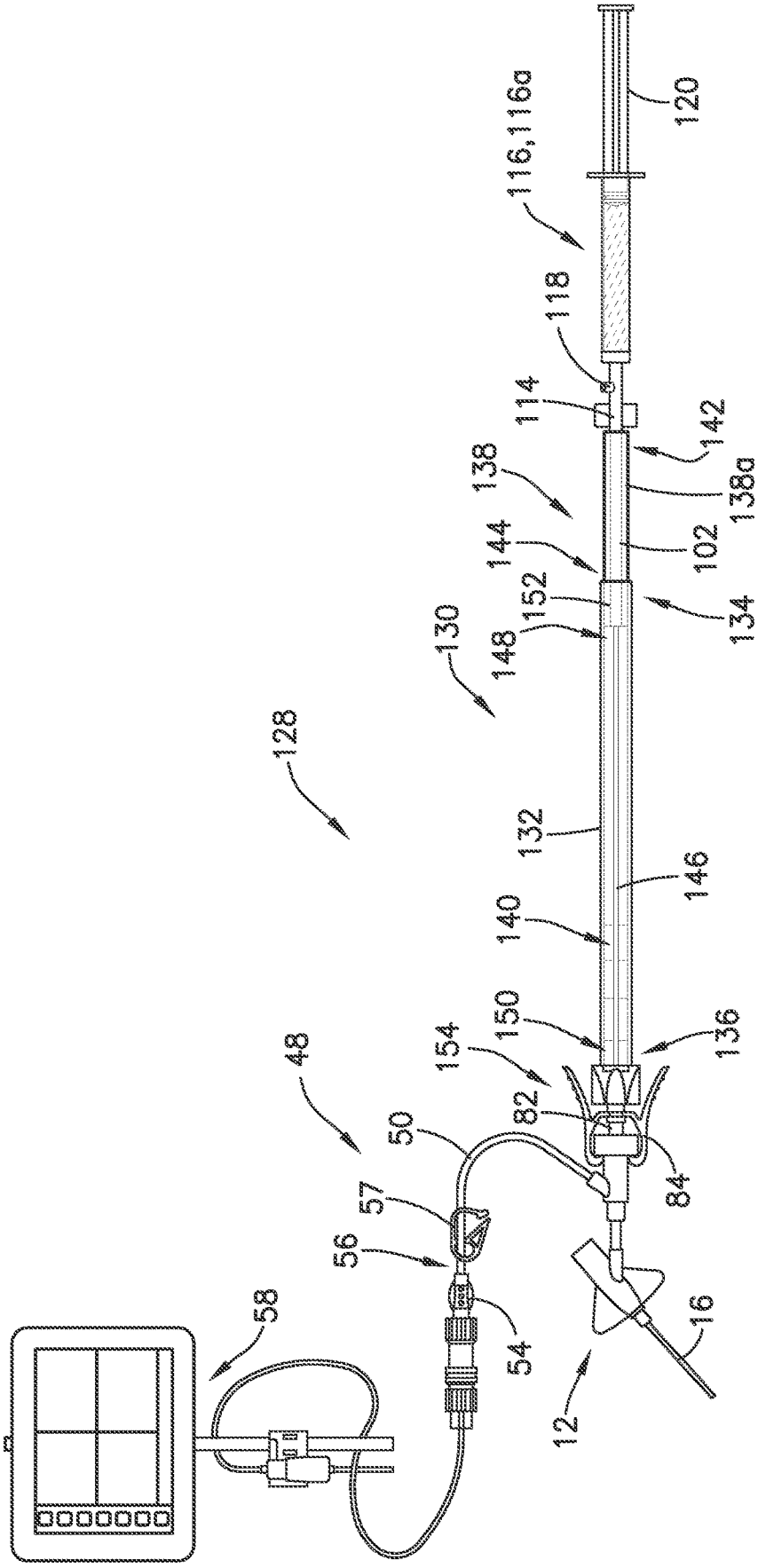
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FIG.8

LINE DRAW DEVICE FOR DIRECT ARTERIAL BLOOD SAMPLING

CROSS-REFERENCE TO RELATED APPLICATION

[0001] The present application claims priority to U.S. Provisional Application No. 63/452,025 entitled "Line Draw Device for Direct Arterial Blood Sampling" filed Mar. 24, 2023, the entire disclosure of which is hereby incorporated by reference.

BACKGROUND OF THE INVENTION

Field of the Invention

[0002] The present invention is directed to a blood draw device for direct arterial blood collection utilizing an indwelling arterial catheter.

BACKGROUND OF THE INVENTION

[0003] Arterial catheterization is a vital procedure that is used ubiquitously in the hospital setting, both in critically injured and perioperative patients. Arterial catheters are used to continuously monitor and measure blood pressure, heart rate, and pulse contour to allow for immediate recognition of aberrant hemodynamic events and initiation of appropriate treatment. Arterial catheters are also used to provide samples for blood gas analysis without the morbidity associated with repeat arterial puncture. In use, an arterial catheter is usually inserted into the radial artery in the wrist, but can also be inserted into the brachial artery at the elbow, into the femoral artery in the groin, into the dorsalis pedis artery in the foot, or into the ulnar artery in the wrist.

[0004] It is recognized that the use of current arterial catheters and associated arterial blood gas and blood sampling systems can be complicated, have numerous workflow procedure steps that can be simplified, and can result in difficult to flush IV lines and an interruption in hemodynamic monitoring. For example, current systems used with arterial catheters require pulling a large clearing volume of blood out of the patient and into a large, complex fluid extension set prior to sampling, with the system then sampling from the extension set, pushing the large volume of blood back into the patient, and then flushing the large fluid path volume to clear the blood out of the extension set.

[0005] Accordingly, a need exists for an arterial access system and device for facilitating improved arterial line blood collection for arterial blood gas sampling and continuous pressure monitoring that overcomes the aforementioned limitations of existing systems and devices. The system and device would enable the acquisition of a blood sample from within the arterial of the patient, while eliminating the complexity and complication that come with the current systems and approaches.

SUMMARY OF THE INVENTION

[0006] Provided herein is a blood draw device useable with an indwelling arterial catheter for performing arterial blood collection. The blood draw device includes a catheter tube, a housing having a proximal end portion and a distal end portion and defining an inner volume configured to movably receive the catheter tube, and an advancement member movably coupled to the housing and configured to move relative to the housing to move the catheter tube between a first position, in which the catheter tube is disposed within the housing, and a second position, in which a distal end of the catheter tube is disposed beyond the distal end portion of the housing and past a distal tip of the indwelling arterial catheter. The blood draw device also includes a secondary catheter coupled to the advancement member and extending out proximally therefrom and out through the proximal end portion of the housing, the secondary catheter in fluid communication with the catheter tube, and a collection device coupled to the proximal end of the secondary catheter, so as to be in fluid communication with the secondary catheter and the catheter tube. A fluid path formed by the catheter tube and the secondary catheter has a controlled geometric factor, Gf, defined as a ratio of a length of the fluid path, L, to an inner diameter of the fluid path, D.

[0007] In some embodiments, the blood draw device includes a coupler connected to a proximal end of the secondary catheter, and wherein the collection device is connected to the coupler.

[0008] In some embodiments, the collection device is a vacuum-assisted collection device.

[0009] In some embodiments, the collection device is a non-vacuum-assisted collection device.

[0010] In some embodiments, wherein the coupler includes a venting feature configured to selectively vent the non-vacuum-assisted collection device.

[0011] In some embodiments, the fluid path has a geometric factor, Gf, equal to or greater than $35/D_{min}^{3}$ for a non-vacuum-assisted collection device and between equal to or greater than $220/D_{min}^{3}$ for a vacuum-assisted collection device.

[0012] In some embodiments, for the secondary catheter having a constant inner diameter, the geometric factor, Gf, is defined as:

$$Gf = \frac{L}{D^4}.$$

[0013] In some embodiments, for the secondary catheter having have multiple sections with lengths **L1**, **L2**, **L3** and inner diameters of **D1**, **D2**, **D3**, the geometric factor, Gf, is defined as:

$$G_f = \frac{L1}{D1^4} + \frac{L2}{D2^4} + \frac{L3}{D3^4}.$$

[0014] In some embodiments, for the secondary catheter having a changing inside diameter over the length thereof, the geometric factor, Gf, is defined as:

$$G_f = \int_0^L \frac{dl}{D(l)^4}.$$

[0015] In some embodiments, the housing and/or the advancement member are configured such that, when the catheter tube is moved to the second position, the distal end of the catheter tube extends out 10 mm or less past the distal tip of the indwelling arterial catheter.

[0016] In some embodiments, the housing and/or the advancement member are configured such that, when the catheter tube is moved to the second position, the distal end of the catheter tube extends out between 3-10 mm past the distal tip of the indwelling arterial catheter.

[0017] In some embodiments, the housing has a length of 103-110 mm or 122-129 mm.

[0018] In some embodiments, comprising a spacer positioned within the inner volume of the housing and proximally from the advancement member, the spacer limiting movement of the advancement member along the housing.

[0019] Also provided is a method of manufacturing an arterial blood draw device operable to collect an arterial blood sample. The method includes providing a catheter tube, housing the catheter tube within an inner volume of a housing having a proximal end portion and a distal end portion such the catheter tube is movable within the housing, and coupling an advancement member to the catheter tube and to housing, with the advancement member movable relative to the housing, so as to cause a corresponding movement of the catheter tube between a first position, in which the catheter tube is disposed within the housing, and a second position, in which a distal end of the catheter tube is disposed beyond the distal end portion of the housing. The method also includes connecting a secondary catheter to the advancement member to extend proximally from the advancement member and out through the proximal end portion of the housing, the secondary catheter in fluid communication with the catheter tube, and connecting a collection device at a proximal end of the secondary catheter, the collection device comprising one of a vacuum-assisted collection device and a non-vacuum-assisted collection device. The method further includes configuring the catheter tube and the secondary catheter to collectively provide a fluid path having a geometric factor, Gf, defined as a ratio of a length of the fluid path, L, to an inner diameter of the fluid path, D, with the geometric factor, Gf, having a first value or value range when the collection device is a vacuum-assisted collection device and having a second value or value range when the collection device is a non-vacuum-assisted collection device.

[0020] In some embodiments, the geometric factor, Gf, equal to or greater than $35/D_{min}^3$ for a non-vacuum-assisted collection device and between equal to or greater than $220/D_{min}^3$ for a vacuum-assisted collection device.

[0021] In some embodiments, the housing and/or the advancement member are configured such that, when the catheter tube is moved to the second position, the distal end of the catheter tube extends out 10 mm or less past the distal tip of the indwelling arterial catheter.

[0022] In some embodiments, for the secondary catheter having a constant inner diameter, the geometric factor, Gf, is defined as:

$$Gf = \frac{L}{D^4}.$$

[0023] In some embodiments, for the secondary catheter having have multiple sections with lengths L1, L2, L3 and inner diameters of D1, D2, D3, the geometric factor, Gf, is defined as:

$$G_f = \frac{L1}{D1^4} + \frac{L2}{D2^4} + \frac{L3}{D3^4}.$$

[0024] In some embodiments, for the secondary catheter having a changing inside diameter over the length thereof, the geometric factor, Gf, is defined as:

$$G_f = \int_0^L \frac{dl}{D(l)^4}.$$

[0025] In some embodiments, the method of manufacturing the arterial blood draw device includes constructing the housing to have a length of 103-110 mm or 122-129 mm.

[0026] In some embodiments, constructing the housing and/or coupling the advancement member to the housing is performed such that, when the catheter tube is moved to the second position, the distal end of the catheter tube extends out 10 mm or less past the distal end portion of the housing.

BRIEF DESCRIPTION OF THE DRAWINGS

[0027] FIG. 1 is a perspective view of an arterial access system, with a syringe connected to a blood draw device thereof, in accordance with an aspect of the disclosure;

[0028] FIG. 2 is a perspective view of a blood draw device useable with the arterial access system of FIG. 1, in accordance with an aspect of the disclosure;

[0029] FIG. 3 is an exploded view of the blood draw of FIG. 2;

[0030] FIG. 4 is a side view of the blood draw device of FIG. 2, showing the catheter tube in a first, retracted position;

[0031] FIG. 5 is a side view of the blood draw device of FIG. 2, showing the catheter tube in a second, extended position;

[0032] FIG. 6 is a perspective view of an arterial access system, with a vacutainer connected to the blood draw device thereof, in accordance with an aspect of the disclosure;

[0033] FIG. 7 is a perspective view of an arterial access system, with a diagnostic cartridge connected to the blood draw device thereof, in accordance with an aspect of the disclosure; and

[0034] FIG. 8 is a perspective view of an arterial access system, in accordance with an aspect of the disclosure.

DESCRIPTION OF THE INVENTION

[0035] The following description is provided to enable those skilled in the art to make and use the described embodiments contemplated for carrying out the invention. Various modifications, equivalents, variations, and alternatives, however, will remain readily apparent to those skilled in the art. Any and all such modifications, variations, equivalents, and alternatives are intended to fall within the spirit and scope of the present invention.

[0036] As used in this specification, the words "proximal" and "distal" refer to the direction closer to and away from, respectively. a user who would place the device into contact with a patient. Thus, for example, the end of a device first touching the body of the patient would be the distal end,

while the opposite end of the device (e.g., the end of the device being manipulated by the user) would be the proximal end of the device.

[0037] Spatial or directional terms, such as "left", "right", "inner", "outer", "above", "below", and the like, are not to be considered as limiting as the invention can assume various alternative orientations.

[0038] For purposes of the description hereinafter, the terms "upper", "lower", "right", "left", "vertical", "horizontal", "top", "bottom", "lateral", "longitudinal", and derivatives thereof shall relate to the invention as it is oriented in the drawing figures. However, it is to be understood that the invention may assume various alternative variations, except where expressly specified to the contrary. It is also to be understood that the specific devices illustrated in the attached drawings, and described in the following specification, are simply exemplary aspects of the invention.

[0039] The terms "first", "second", and the like are not intended to refer to any particular order or chronology, but refer to different conditions, properties, or elements.

[0040] As used herein, "at least one of" is synonymous with "one or more of". For example, the phrase "at least one of A, B, and C" means any one of A, B, or C, or any combination of any two or more of A, B, or C. For example, "at least one of A, B, and C" includes one or more of A alone; or one or more of B alone; or one or more of C alone; or one or more of A and one or more of B; or one or more of A and one or more of C; or one or more of B and one or more of C; or one or more of all of A, B, and C.

[0041] The present invention is directed to an arterial access system having a blood draw device (alternatively, "line draw device"), along with a method of using the arterial blood draw device to advance a blood draw catheter tube into an indwelling arterial catheter and subsequently draw a blood sample from a patient.

[0042] Referring to FIG. **1**, shown is a non-limiting embodiment of an arterial access system **10** for facilitating improved arterial line blood collection for arterial blood gas sampling and continuous pressure monitoring. Arterial access system **10** may include a catheter assembly **12** having a catheter adapter **14** and associated catheter **16**. The catheter adapter **14** may include a distal end **18** and a proximal end **20**. In some embodiments, the catheter adapter **14** may include an additional adapter port **22** that may disposed between the distal end **18** and the proximal end **20** or disposed at the proximal end **20**. The catheter adapter **14** may include a first lumen **24** extending through the distal end **18** and the proximal end **20**, and the first lumen **24** may be sealed at proximal end **20** of catheter adapter **14**. The catheter **16** extends from the distal end **18** of catheter adapter **14** and may be configured as an arterial catheter that is placed into an artery of the patient, with a distal end or tip **26** of the catheter **16** positioned appropriately within an artery **28** to enable a blood draw from the patient. In some embodiments, the catheter **16** may be inserted into an artery such that the distal tip **26** (an opening therein) faces upstream and into the arterial blood flow. Catheter **16** may be formed of any suitable material and may be of any useful length, as known to those of skill in the art.

[0043] In some non-limiting embodiments or aspects, the catheter assembly **12** may include a first fluid conduit **30** extending from the port **22**. First fluid conduit **30** may be formed of any suitable material known to those of skill in the art and may have a distal end **32** and a proximal end **34**. The distal end **32** of first fluid conduit **30** is coupled to port **22**, while the proximal end **34** of first fluid conduit **30** may be coupled to a connector **36**. Connector **36** may be a t-connector (e.g., one side port arranged at a 90 degree angle relative to a longitudinal axis of connector **36**), a y-connector (e.g., one side port arranged at a 25, a 60, or a 75 degree angle relative to a longitudinal axis of connector **36**), or any other type of connector known in the art. The connector **36** includes a second lumen **38** therethrough, having any number of branches suitable for the type of connector, such as a branch extending between distal and proximal ends **40**, **42** of connector **36** and a branch provided to a port **44** of the connector **36**.

[0044] In some non-limiting embodiments or aspects, catheter assembly **12** may include a needleless access connector **46** coupled to the proximal end **42** of connector **36**, with the needleless access connector **46** providing an access port to the catheter assembly **12**. The needleless access connector **46** may be configured as a split-septum connector or self-healing septum connector, as examples. In the illustrated embodiment, the access port provided by needleless access connector **46** is a near-patient access port close to the insertion site of the catheter **16**, but it is recognized that an access port could be provided at other alternative locations close enough to the insertion site that allow for advancement of a blood draw catheter tube into the indwelling arterial catheter **16** and out beyond the distal tip thereof. For example, an access port that provides for advancement of a blood draw catheter tube into the indwelling arterial catheter **16** could be located on another connector, such as a proximal connector on an extension set (as described below) of the catheter assembly **12**.

[0045] In some non-limiting embodiments or aspects, catheter assembly **12** may also include an extension set **48** coupled to the port **44** of the connector **36**. The extension set **48** may include a second fluid conduit **50** coupled to port **44** at end **52** of the conduit **50** and a luer connection **54** at opposing end **56**, with a clamp **57** provided on second fluid conduit **50** that allows for occlusion thereof. The extension set **48** may be used to provide a fluid path from the catheter assembly **12** to a hemodynamic monitoring device **58** that monitors blood pressure, heart rate, and/or pulse contour of a patient, based on arterial blood drawn through the catheter assembly **12**. While the non-limiting embodiments of FIG. **1** shows a needleless access connector **46** arranged at connector **36**, those of skill in the art will appreciate that a suitable needleless access connector may also be arranged at luer **54** of extension set **48**.

[0046] Arterial access system **10** further includes a blood draw device **60** (alternatively, "line draw device") that may be operated to obtain a blood sample from the patient, with such a blood sample enabling blood gas analysis for example. As shown in FIG. **1** and in further detail in FIGS. **2-5**, according to a non-limiting embodiment, the blood draw device **60** includes at least a housing **62**, a coupling device **64**, a catheter tube **66**, and an advancement member **68**. As will be described in further detail below, the catheter tube **66** is moveable within the housing **62** so as to provide for advancement of a portion of the catheter tube **66** from a first or retracted position inside the housing **62** (FIG. **3**) to a second or advanced position outside of the housing **62** (FIG. **4**), such that a distal end thereof may be routed into the catheter assembly **12**. Once a portion of the catheter tube **66** has been routed into the catheter assembly **12** and out past

the distal tip **26** of indwelling catheter **16**, the catheter tube **66** may enable collection of a blood sample.

[0047] According to embodiments, the catheter tube **66** is sized to enable introduction thereof into the fluid path (i.e., into a lumen of catheter **16**, lumen **24** of catheter adapter **14**, and first fluid conduit **30**) of catheter assembly **12** and for advancement therethrough. Accordingly, the catheter tube **66** can have an outer diameter (e.g., between a 10-gauge and a 30-gauge) that is smaller than the smallest lumen of the catheter assembly fluid path. The catheter tube **66** can have a length that is sufficient to place a distal end **70** of the catheter tube **66** in a desired position within the fluid path of the arterial access system **10**. Thus, in one embodiment, the catheter tube **66** may have a length sufficient to provide for advancement of the distal end **70** thereof out from the housing **62** and through the catheter assembly (i.e., through connector **36**, fluid conduit **30**, catheter adapter **14** and catheter **16**), and all the way out past the distal tip **26** of catheter **16**.

[0048] In some embodiments, and in order to accommodate positioning of the catheter tube **66** within catheter **16** and advancement thereof out past the distal tip **26** of catheter **16**, the distal end **26** of the catheter **16** may include fenestrations formed therein. The fenestrations at the distal end **26** of the catheter **16** serve to maintain fluid continuity from the artery and through the catheter **16** to the hemodynamic monitoring device **58** connected to the proximal end of extension set **48**—i.e., the fenestrations prevent catheter tube **66** from occluding the catheter **16** at the distal tip **26** thereof and cutting off accurate pressure monitoring. The fenestrations in catheter **16** thus provide the ability to continue monitoring arterial pressure during a sampling procedure performed by blood draw device **60** as catheter tube **66** is advanced.

[0049] In accordance with aspects of the disclosure, it is recognized that the use of the blood draw device **60** with the indwelling arterial catheter **16** may differ from use of a blood draw device with an indwelling peripheral IV catheter. That is, unlike peripheral IV catheters that are used in the vein, arterial catheters have the distal end and opening facing upstream and into the oncoming arterial blood flow. The arterial blood flow is also typically at a higher flow rate and pressure and therefore, some of the challenges and complications seen with peripheral IV catheters do not appear with arterial catheters, such as thrombus development downstream from the catheter tip in the venous side, making aspiration and line draw difficult through the dwell period of a PIV. Accordingly, use of the blood draw device **60** with indwelling arterial catheter **16** includes different requirements, optimization targets and design considerations. For example, in accordance with some non-limiting embodiments of the disclosure, the blood draw device **60** may be configured to extend the distal end **70** of the catheter tube **66** out beyond the distal tip **26** of the indwelling arterial catheter **16** by a distance of less than 10 mm, and preferably between 3 to 10 mm, as such a distance may be sufficient to obtain a quality arterial blood sample due to the reasons provided above. In other embodiments, the blood draw device **60** may be configured to extend the distal end **70** of the catheter tube **66** out beyond the distal tip **26** of the indwelling arterial catheter **16** by a distance of up to 20 cm, 30 cm, or further, according to other non-limiting embodiments.

[0050] As shown in FIGS. **2-5**, the housing **62** of blood draw device **60** can be an elongate member having a proximal end **72** and a distal end **74** and defining an inner volume **76**. In some embodiments, the housing **62** may be formed of a pair of housing portions **78***a*, **78***b* that are coupled together to define the inner volume **76**. The housing **62** may include one or more features or surface finishes on an outer surface thereof that can be arranged to increase the ergonomics of the blood draw device **60**, which in some instances can allow a user to manipulate the blood draw device **60** with one hand (i.e., single-handed use).

[0051] The coupling device **64** of blood draw device **60** is provided at the distal end **74** of the housing **62**, with the coupling device **64** providing for reversible coupling of the blood draw device **60** to catheter assembly **12**, such as via needleless access connector **46** as shown in FIG. **1**. In some embodiments, the coupling device **64** is configured as a lock **80** that includes a blunted cannula **82** and locking arms **84** for coupling to the needleless access connector **46** of catheter assembly **12**, with the blunted cannula **82** and locking arms **84** forming three points of contact therewith. However, those of skill will appreciate that any connection or coupling, for example a luer, can be used, so long as the distal end **70** of catheter tube **66** may pass through the coupling device **64** to catheter assembly **12**.

[0052] The advancement member **68** of blood draw device **60** includes a first portion **86** and a second portion **88**. The first portion **86** is movably disposed along an upper surface **90** of the housing **62** and the second portion **88** is movably disposed within the inner volume **76** of the housing **62**. The arrangement of the advancement member **68** and the housing **62** is such that a connecting portion (not shown) of the advancement member **68** that joins the first and second portions **86**, **88** is seated within a slot **92** formed in the upper surface **90** of the housing **62**—the slot **92** generally extending between the proximal and distal ends **72**, **74** of the housing **62**. As the first and second portions **86**, **88** are joined together, movement of the first portion **86** along the upper surface **90** of the housing **62** results in a corresponding movement of the second portion **88** within the inner volume **76**.

[0053] As shown in FIGS. **2-5**, the first portion **86** of the advancement member **68** may be configured as a tab or tab having a contact surface **94***a* engageable by a user and an underside **94***b*that is in contact with the outer surface **90** of the housing **62**. In such embodiments, the upper surface **90** of the housing **62** can include a track **96**, for example, a set of ribs, ridges, bumps, grooves, and/or the like along which the underside **94***b* of tab or protrusion advances when the advancement member **68** is engaged by a user. In this manner, a user can engage the first portion **86** of the advancement member **68** and can move the advancement member **68** relative to the housing **62**.

[0054] As shown in FIGS. **2-5**, the second portion **88** includes an opening **98** extending therethrough that is configured to grip or retain a portion of the catheter tube **66**. Due to a portion of the catheter tube **66** being retained within the opening **98** of second portion, **94**, movement of the advancement member **68** relative to housing **62** causes a corresponding movement of the catheter tube **66** relative to the housing **62**. In this manner, the distal end **70** of the catheter tube **66** can be selectively moved out of or back into the inner volume **76** of the housing **62** as desired, such as advancing the distal end **70** of the catheter tube **66** out of the housing

62 when the blood draw device **60** has been coupled to the catheter assembly **12** and collection of an arterial blood sample is to be performed.

[0055] As indicated above, in advancing the distal end **70** of the catheter tube **66** out of the housing **62** and into the catheter assembly **12**, blood draw device **60** may be configured to extend the distal end **70** of the catheter tube **66** out beyond the distal tip **26** of the indwelling arterial catheter **16** by a distance of less than 10 mm, and preferably between 3 to 10 mm, as such a distance is sufficient to obtain a quality arterial blood sample due to the reasons provided above. Advancement of the catheter tube **66** by this distance allows for a reduction in the length of the catheter tube and housing **62** and/or a limitation of the movement of advancement member **68** relative to housing **62**. In some embodiments, introducer **62** may be configured to have a length L_{Intro} of between 103-110 mm, in association with the need for the extension length of catheter tube **66** to be less than what is typically required for use of a blood draw device with peripheral IV catheters. In some embodiments, housing **62** may be configured to have a length L_{Intro} of between 122-129 mm. In other embodiments, a spacer **100** (shown in phantom in FIG. **2**) may be provided within the inner volume **76** of housing **62** at a location proximal to advancement member **68** (i.e., at proximal end **72** of housing **62**), with the spacer **100** functioning to limit the path of travel of the advancement member **68** in association with the need for the extension length of catheter tube **66** to be less than what is typically required for use of a blood draw device with peripheral IV catheters.

[0056] As further shown in FIGS. **2-5**, blood collection device **60** includes a secondary catheter **102** provided at the proximal end **72** of the housing **62**. The secondary catheter **102** has a proximal end portion **104** and a distal end portion **106** and defines a lumen **108**. A portion of the secondary catheter **102** is disposed within and extends through an opening **110** formed in the proximal end **72** of housing **62**. As such, the proximal end portion **104** is at least partially disposed outside of the housing **62** and the distal end portion **106** is at least partially disposed within the housing **62**, with the distal end portion **106** coupled to the second portion **88** of the advancement member **68**. In some embodiments, the secondary catheter **102** can have a larger diameter than the catheter tube **66**, which can function to limit, reduce, and/or substantially prevent hemolysis of a volume of blood as the volume of blood flows through the catheter **66** and the secondary catheter **102**, as explained in further detail below. In this manner, when the blood draw device **60** is coupled to a syringe, evacuated container, etc., the secondary catheter **102** establishes fluid communication between the reservoir, source, pump, etc. and the catheter tube **66**, as explained further below.

[0057] According to embodiments of the disclosure, the proximal end portion **104** of the secondary catheter **102** is coupled to and/or otherwise includes a coupler **114** configured to mate with a collection device **116** that is useable with (or is considered part of) the blood draw device **60** to collect an arterial blood sample for subsequent analysis, such as blood gas analysis of the sample. According to some embodiments, the coupler **114** may be configured as a luer connection (i.e., a female luer connection) configured to mate with a corresponding luer connection (i.e., a male luer connection) of the collection device **116**. The coupler **114** physically and fluidically couples the secondary catheter **102** to the collection device **116**, which as described further here below, may be any suitable vacuum or non-vacuum assisted blood sample collection device **116**, such as a sampling syringe, vacutainer, luer lock access device (LLAD), a point-of-care (POC) sampling device, integrated POC cartridge, blood culture collection system, or the like. Non-limiting examples of vacuum or non-vacuum assisted blood sample collection devices may include a Vacutainer® Luer-Lok™ access device or Accustat™ device by Becton Dickinson and Company. In some embodiments, a venting feature **118** may be provided that functions to vent the vacuum or non-vacuum assisted collection device **116** prior to blood collection. As shown in the illustrated embodiment, the venting feature **118** may be provided on coupler **114**, but it is recognized that venting feature **118** could be provided anywhere along the sampling fluid path, although preferably near the proximal end portion **104** of the secondary catheter **102**.

[0058] As shown in FIGS. **1-5**, in accordance with one aspect of the disclosure, the collection device **116** that is connected to blood draw device **60** (via coupler **114**) is provided as a syringe **116***a*. In some embodiments, the syringe **116***a* may be pre-attached with a plunger **120** of the syringe **116***a* in an advanced position. When the catheter tube **66** of blood draw device **60** is advanced through the indwelling catheter **16** and into the artery **28**, the syringe plunger **120** may be retracted to pull an undiluted arterial blood sample into the syringe **116***a*. The syringe **116***a*may contain blood preservatives/stabilizers therein to help maintain a quality of the sample. In other embodiments, the syringe **116***a* may begin in a retracted position and have a selective venting feature (e.g., vent **118** on coupler **114**) via which the syringe **116***a* may be vented after the catheter tube **66** has been moved to the second, advanced position. Upon any venting of the syringe **116***a*and a subsequent sample collection and stabilization, the syringe **116***a* may be detached from the blood draw device **60** and the sample may then be dispensed to a POC blood diagnostic test cartridge **122** or provided to another blood analyzer test instrument.

[0059] Referring now to FIG. **6**, an arterial access system **10** is illustrated where the collection device **116** connected to blood draw device **60** (via coupler **114**) is provided as a vacutainer collection device **116***b*, or a simplified/modified vacutainer that is vented, not requiring the vacuum tube to drive sampling volume collection. The vacutainer **116***b* may contain blood preservatives/stabilizers therein to help maintain a quality of the sample. Upon filling of the vacutainer **116***b* and blood stabilization, the vacutainer **116***b* may be detached from the blood draw device **60** and a blood sample can then be dispensed onto a POC diagnostic test cartridge **122** or provided to another blood analyzer test instrument.

[0060] Referring now to FIG. **7**, an arterial access system **10** is illustrated where the collection device **116** connected to blood draw device **60** is provided as an onboarded POC diagnostic cartridge **116***c* (e.g., an iStat test cartridge from Abbott Labratories). The diagnostic cartridge **116***c*may be removably coupled to blood draw device **60** (i.e., coupled to housing **62**) for direct collection of a micro-sample of arterial blood. With the diagnostic cartridge **116***c*, the system requires selective venting of the cartridge micro-fluidic fluid path to prevent filling until the distal tip **70** of the catheter tube **66** is directly in the artery **28** for undiluted blood sampling. Upon filling of the diagnostic cartridge **116***c*, it

can be removed from the blood draw device **60** and inserted into a POC blood test instrument and analyzer.

[0061] As indicated above, the use of blood draw device **60** and collection device **116** with catheter assembly **12** enables a direct collection of an arterial blood sample. In accordance with aspects of the disclosure, the arterial blood draw can be performed either by connecting a vacuum-assisted blood sample collection device **116** (such as an evacuated syringe or LLAD with a vacutainer connected thereto), or by a non-vacuum-assisted blood sample collection device **116** (such as a vented syringe or other vented chamber). When using a non-vacuum assisted blood sample collection device **116** with the blood draw device **60**, the arterial pressure acts to fill the vented collection device chamber, with the blood flow driven by the constant arterial pressure. In the case of a vacuum-assisted blood draw, a pressure gradient across a fluid path of the blood draw device (i.e., across catheter tube **66** and secondary catheter **102**) is much higher, and thus shear driven hemolysis may affect the collection of the arterial blood sample.

[0062] Regarding the effect of shear driven hemolysis, max shear stress in a tubular fluid pathway (such as catheter tube **66** and secondary catheter **102**) is determined by the flow rate and the smallest hydraulic diameter of the tube. Fluid flow in a tubular fluid pathway therethrough can be analyzed using Poiseuille's equation:

$$Q = \frac{\pi D^4 \Delta P}{128 \mu L} = \frac{\Delta P}{Rf}$$

[0063] where ΔP is a change in pressure gradient across the length of the fluid pathway, D and L are the inner diameter and length, respectively, of the fluid pathway, μ is the viscosity of a fluid, and R_f=128 μL/πD^4 is the fluid resistance. Since u is the viscosity of the fluid and not part of the extension tube geometry, a geometric factor Gf is defined such that R_f (the fluid resistance) is R_f=(128 μL/π) *G_f, where G_f=L/D^4.

[0064] In some embodiments, the optimized fluid pathway may have multiple sections with lengths (L**1**, L**2**, L**3**, . . .) and inner diameters of (D**1**, D**2**, D**3**, . . .), the geometric factor is then:

$$G_f = \frac{L1}{D1^4} + \frac{L2}{D2^4} + \frac{L3}{D3^4}$$

[0065] In some embodiments, the optimized fluid pathway may have an inside diameter that changes over the length of the tube, the geometric factor is then:

$$G_f = \int_0^L \frac{dl}{D(l)^4}$$

[0066] In some embodiments, the optimized fluid pathway may have a cross section that has a non-circular inside diameter profile. The geometric factor can be determined by measuring the flow rate (Q) at given pressure (ΔP) with known viscosity (μ) fluid:

$$G_f = \frac{\pi \Delta P}{128 \mu Q}$$

[0067] Since, in the case of arterial blood collection, the Gf value of the optimized fluid pathway would be different for a syringe draw or vented chamber and a vacutainer draw, the Gf value of the optimized fluid pathway can be the higher value between the syringe draw and vacutainer draw. Alternatively, the Gf value of the optimized fluid pathway can be the lower value between the syringe draw and vacutainer draw, and an accessory in the form of an extension set or connector can be connected to the Luer in the case where a higher Gf value is needed. In another alternative embodiment, the proximal end of the extension tube (i.e., secondary catheter **102**) can consist of two ports where each port provides different Gf value.

[0068] In the case of a syringe draw or vented chamber, the blood draw occurs at constant flow rate due to constant driving arterial pressure. The max shear stress is constant where:

$$\tau_{max} = \frac{\Delta P}{4 G_f D \min^3}$$

where D_{min} is the minimum diameter of the fluid pathway defined by catheter tube **66** and secondary catheter **102**.

[0069] Based on the above, the G_f value of the optimized fluid pathway (i.e., catheter tube **66** and secondary catheter **102**) may be selected depending on the blood draw methodology. In the case of a vacuum-assisted vacutainer draw, the G_f value of the optimized fluid pathway may be selected to reduce the max shear stress to be the same or less than the max shear stress of a typical vacuum-assisted, push button blood collection set—with a G_f value of equal to or greater than 220/D_{min}^3 being desirable, in accordance with aspects of the disclosure. In the case of a syringe draw or other vented chamber (i.e., a non-vacuum assisted device), the G_f value of the optimized fluid pathway may again be selected to reduce the max shear stress to be the same or less than the average max shear stress of a typical vacuum-assisted, push button blood collection set-with a G_f value of equal to or greater than 35/D_{min}^3 being desirable, in accordance with aspects of the disclosure.

[0070] It is recognized that aspects of the disclosure are not limited to the specific blood draw device **60** shown and described in FIGS. **1-7**, and that blood draw devices with other suitable constructions may also incorporate aspects of the disclosure. Referring now to FIG. **8**, an arterial access system **128** is shown that includes a blood draw device **130** according to another embodiment of the disclosure. The blood draw device **130** includes a housing **132** having a proximal end **134** and a distal end **136**, and an advancement member **138** slideably received within housing **132** (i.e., within an inner volume **140** of housing **132**). In the illustrated embodiment, the advancement member **138** is provided as one or more telescopic cylinders **138***a* that are provided in a telescoping relationship with housing **132**, such that advancement member **138** may be slideably received entirely, or almost entirely, within the inner volume **140** of housing **132**. Advancement member **138** also includes a proximal end **142** and a distal end **144** and, in

non-limiting embodiments, advancement member **138** may have a variable diameter along its length. As one example, the distal end **144** of advancement member **138** may have a larger diameter than other portions of advancement member **138** such that, as advancement member **138** is retracted, one or more features on housing **132** may interact with the enlarged portion of advancement member **138** to prevent pulling advancement member **138** completely out of housing **132**. As another example, the distal end **144** of advancement member **138** may have a smaller diameter than other portions of advancement member **138**, to keep the advancement member **138** in position at a blood draw forward condition, so that a hand of the operator is freed up to manipulate additional components (e.g., a vacutainer tube).

[0071] Blood draw device **130** further includes a catheter tube **146** having a proximal end **148** and a distal end **150**. Catheter tube **146** is received within the inner volume **140** of housing **132**, and may be advanced and/or retracted relative to housing **132** by displacement of the advancement member **138** relative to the housing **132**. In some embodiments, the catheter tube **146** may be joined to advancement member **138** via a fitting **152** provided at the distal end **144** of advancement member **138**, such that displacement of the advancement member **138** relative to the housing **132** causes a corresponding displacement of catheter tube **146**. In non-limiting embodiments, catheter tube **146** may be advanced from a first positon in which distal end **150** of catheter tube **146** is within housing **132**, to a second position in which a distal end **150** of catheter tube **146** is positioned distally of housing **132** (and also positioned distally of catheter **16**), as previously described regarding blood draw device **60** and operation thereof.

[0072] Blood draw device also includes a coupling device **154** thereon which may be identical to the coupling device shown and described in the blood draw device of FIGS. **1-7**. That is, coupling device **154** is configured as a lock **80** that includes a blunted cannula **82** and locking arms **84** for coupling to the needleless access connector **46** of catheter assembly **12**, with the blunted cannula **82** and locking arms **84** forming three points of contact therewith. However, it is appreciated that alternative embodiments of blood draw device **130** may include a coupling device **154** of another type to secure blood draw device **130** to catheter assembly **12**, including luer connections, clips, blunt plastic cannulae, blunt metal cannulae, hybrid luers (e.g., with a cannula) friction fits, and the like.

[0073] According to aspects of the disclosure, a secondary catheter **102** may be routed through the telescopic cylinder **138***a* of advancement member **138**, with the secondary catheter **102** providing a fluid connection between the catheter tube **146** and a coupler **114** provided at the proximal end portion **104** of the secondary catheter **102**-with the coupler **114** configured to mate with a collection device **116**. Although shown in FIG. **8** as a syringe **116***a*, the collection device **116** may be configured as any of the collection devices **116** shown and described in FIGS. **1-7**, with the collection device **116** attached to blood draw device **130** to provide an arterial access system for facilitating improved arterial line blood collection for arterial blood gas sampling. That is, the blood draw device **130** may accommodate use of any of a number of different vacuum-assisted or non-vacuum-assisted blood collection devices **116** therewith for collection of the blood sample, with the blood draw device configurable to prevent hemolysis during the sample collection, such as by controlling the sizing of the device, including the geometric factor G_f of the device (i.e., of the fluid pathway therein).

[0074] Beneficially, embodiments of the disclosure thus provide an arterial access system for facilitating improved arterial line blood collection for arterial blood gas sampling and continuous pressure monitoring. The arterial access system includes a catheter assembly having a blood draw device attached thereto that may be used to directly collect an arterial blood sample from the patient via the indwelling arterial catheter, with such blood sample being used for blood gas analysis. The arterial access system simultaneously provides for continuous blood pressure monitoring via use of an extension set attachable to the catheter assembly and that provides arterial blood to hemodynamic monitoring system connected thereto. The blood draw device may accommodate use of any of a number of different vacuum-assisted or non-vacuum-assisted blood collection devices therewith for collection of the blood sample, with the blood draw device configurable to prevent hemolysis during the sample collection.

[0075] Although the present disclosure has been described in detail for the purpose of illustration based on what is currently considered to be the most practical and preferred embodiments or aspects, it is to be understood that such detail is solely for that purpose and that the present disclosure is not limited to the disclosed embodiments or aspects, but, on the contrary, is intended to cover modifications and equivalent arrangements that are within the spirit and scope of the appended claims. For example, it is to be understood that the present disclosure contemplates that, to the extent possible, one or more features of any embodiment may be combined with one or more features of any other embodiment.

The invention claimed is

1. A blood draw device useable with an indwelling arterial catheter for performing arterial blood collection, the blood draw device comprising:

a catheter tube;

a housing having a proximal end portion and a distal end portion and defining an inner volume configured to movably receive the catheter tube;

an advancement member movably coupled to the housing and configured to move relative to the housing to move the catheter tube between a first position, in which the catheter tube is disposed within the housing, and a second position, in which a distal end of the catheter tube is disposed beyond the distal end portion of the housing and past a distal tip of the indwelling arterial catheter;

a secondary catheter coupled to the advancement member and extending out proximally therefrom and out through the proximal end portion of the housing, the secondary catheter in fluid communication with the catheter tube; and

a collection device coupled to the proximal end of the secondary catheter, so as to be in fluid communication with the secondary catheter and the catheter tube;

wherein a fluid path comprising the catheter tube and the secondary catheter has a controlled geometric factor, Gf, defined as a ratio of a length of the fluid path, L, to an inner diameter of the fluid path, D.

2. The blood draw device of claim **1**, wherein the blood draw device comprises a coupler connected to a proximal

end of the secondary catheter, and wherein the collection device is connected to the coupler.

3. The blood draw device of claim **2**, wherein the collection device comprises a vacuum-assisted collection device.

4. The blood draw device of claim **2**, wherein the collection device comprises a non-vacuum-assisted collection device.

5. The blood draw device of claim **4**, wherein the coupler comprises a venting feature configured to selectively vent the non-vacuum-assisted collection device.

6. The blood draw device of claim **2**, wherein the geometric factor, Gf, is equal to or greater than $35/D_{min}^3$ for a non-vacuum-assisted collection device and between equal to or greater than $220/D_{min}^3$ for a vacuum-assisted collection device.

7. The blood draw device of claim **6**, wherein for the secondary catheter having a constant inner diameter, the geometric factor, Gf, is defined as:

$$Gf = \frac{L}{D^4}.$$

8. The blood draw device of claim **6**, wherein for the secondary catheter having have multiple sections with lengths L**1**, L**2**, L**3** and inner diameters of D**1**, D**2**, D**3**, the geometric factor, Gf, is defined as:

$$G_f = \frac{L1}{D1^4} + \frac{L2}{D2^4} + \frac{L3}{D3^4}.$$

9. The blood draw device of claim **6**, wherein for the secondary catheter having a changing inside diameter over the length thereof, the geometric factor, Gf, is defined as:

$$G_f = \int_0^L \frac{dl}{D(l)^4}.$$

10. The blood draw device of claim **1**, wherein the housing and/or the advancement member are configured such that, when the catheter tube is moved to the second position, the distal end of the catheter tube extends out 10 mm or less past the distal tip of the indwelling arterial catheter.

11. The blood draw device of claim **1**, wherein the housing and/or the advancement member are configured such that, when the catheter tube is moved to the second position, the distal end of the catheter tube extends out between 3-10 mm past the distal tip of the indwelling arterial catheter.

12. The blood draw device of claim **1**, wherein the housing has a length of 103-110 mm or 122-129 mm.

13. The blood draw device of claim **1**, comprising a spacer positioned within the inner volume of the housing and proximally from the advancement member, the spacer limiting movement of the advancement member along the housing.

14. A method of manufacturing an arterial blood draw device operable to collect an arterial blood sample, the method comprising:

providing a catheter tube;

housing the catheter tube within an inner volume of a housing having a proximal end portion and a distal end portion, the catheter tube movable within the housing;

coupling an advancement member to the catheter tube and to housing, with the advancement member movable relative to the housing, so as to cause a corresponding movement of the catheter tube between a first position, in which the catheter tube is disposed within the housing, and a second position, in which a distal end of the catheter tube is disposed beyond the distal end portion of the housing;

connecting a secondary catheter to the advancement member, the secondary catheter extending proximally from the advancement member and out through the proximal end portion of the housing, the secondary catheter in fluid communication with the catheter tube;

connecting a collection device at a proximal end of the secondary catheter, the collection device comprising one of a vacuum-assisted collection device and a non-vacuum-assisted collection device; and

configuring the catheter tube and the secondary catheter to collectively provide a fluid path having a geometric factor, Gf, defined as a ratio of a length of the fluid path, L, to an inner diameter of the fluid path, D, with the geometric factor, Gf, having a first value or value range when the collection device is a vacuum-assisted collection device and having a second value or value range when the collection device is a non-vacuum-assisted collection device.

15. The method of claim **14**, wherein the geometric factor, Gf, is equal to or greater than $35/D_{min}^3$ for a non-vacuum-assisted collection device and between equal to or greater than $220/D_{min}^3$ for a vacuum-assisted collection device.

16. The method of claim **14**, wherein the housing and/or the advancement member are configured such that, when the catheter tube is moved to the second position, the distal end of the catheter tube extends out 10 mm or less past the distal tip of the indwelling arterial catheter.

17. The method of claim **14**, wherein for the secondary catheter having a constant inner diameter, the geometric factor, Gf, is defined as:

$$Gf = \frac{L}{D^4}.$$

18. The method of claim **14**, wherein for the secondary catheter having have multiple sections with lengths L**1**, L**2**, L**3** and inner diameters of D**1**, D**2**, D**3**, the geometric factor, Gf, is defined as:

$$G_f = \frac{L1}{D1^4} + \frac{L2}{D2^4} + \frac{L3}{D3^4}.$$

19. The method of claim **14**, wherein for the secondary catheter a changing inside diameter over the length thereof, the geometric factor, Gf, is defined as:

$$G_f = \int_0^L \frac{dl}{D(l)^4}.$$

20. The method of claim **14**, further comprising constructing the housing to have a length of 103-110 mm or 122-129 mm.

21. The method of claim **20**, comprising constructing the housing and/or coupling the advancement member to the housing such that, when the catheter tube is moved to the second position, the distal end of the catheter tube extends out 10 mm or less past the distal end portion of the housing.

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