

TITLE

[0001] Blood Drawing Device and Method of Collecting Blood Sample

CROSS-REFERENCE TO RELATED APPLICATIONS

5 [0002] This application claims benefit to U.S. Provisional Patent Application No. 62/656,321 filed June 5, 2024, entitled "Blood Drawing Device and Method of Collecting Blood Sample", and U.S. Provisional Patent Application No. 63/609,818 filed December 13, 2023, entitled "Blood Drawing Device", which are each incorporated by reference herein in their entirety.

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TECHNICAL FIELD

[0003] The present disclosure generally relates to a blood drawing device for collecting a blood sample from a patient and methods for collecting a blood sample from a patient.

SUMMARY

15 [0004] In one embodiment, there is a method of collecting a blood sample from a target area of a subject using a blood drawing device having a cutting element and a fluid collection chamber, the method including the steps of applying a heat source to the target area of the subject for a first time period and/or applying a cooling source to the target area of the subject for a second time period, puncturing the target area with the cutting element of the blood drawing device, and collecting a
20 volume of blood in the fluid collection chamber.

[0005] In some embodiments, the method further includes the steps of filling a first fluid collection chamber to a first predetermined volume, replacing the first fluid collection chamber with a second fluid collection chamber, and filling the second fluid collection chamber to a second predetermined volume. In some embodiments, an absorption apparatus is applied to the target area
25 as the first fluid collection chamber is replaced by the second fluid collection chamber. In some embodiments, the absorption apparatus is disposed between the first fluid collection chamber and the second fluid collection chamber and where the absorption apparatus is dragged across the target area as the first fluid collection chamber is replaced by the second fluid collection chamber.

[0006] In some embodiments, the heat source is at least one of a heating element, a warm towel
30 and an infrared light. In some embodiments, the heating element is a Peltier element. In some embodiments, the heat source has a temperature between approximately 40° to 55° Celsius. In some embodiments, the cooling source is at least one of a cooling element, an ice pack and a cold

compress. In some embodiments, the cooling element is a Peltier element. In some embodiments, the cooling source has a temperature between approximately -20° to +15° Celsius.

[0007] In some embodiments, the heat source and the cooling source are applied to the target area after the cutting element punctures the target area. In some embodiments, the heat source and the cooling source are alternated during collection of the blood sample. In some embodiments, the heat source and the cooling source are both applied and are applied one after the other. In some embodiments, the cooling source is applied to the target area before the heat source. In some embodiments, the cooling source is applied for the second time period followed by the heat source for the first time period.

[0008] In some embodiments, the method further includes the step of applying a vacuum to the target area to facilitate flow of blood into the fluid collection chamber. In some embodiments, the vacuum is applied to the target area while the cutting element of the blood drawing device is puncturing the target area.

[0009] In some embodiments, the method further includes the step of applying a vacuum to the target area to facilitate flow of blood into the fluid collection chamber. In some embodiments, the vacuum is applied to the target area after the cutting element of the blood drawing device is puncturing the target area but not during.

[0010] In some embodiments the first time period is between approximately 10 seconds to 5 minutes. In some embodiments, the second time period is at least between approximately 10 seconds to 3 minutes. In some embodiments, the cutting element punctures the target area during the second time period. In some embodiments, the cutting element punctures the target area during the first time period. In some embodiments, the cutting element punctures the target area before the second time period. In some embodiments, the cutting element is a blade. In some embodiments, the heat source covers the target area. In some embodiments, the cooling source covers the target area.

[0011] In some embodiments, the blood drawing device includes a disposable collection cartridge having a housing, the housing having a proximal end and a distal end extending along a longitudinal axis and a first side and a second side extending along a lateral axis, and at least one aperture extending therethrough. In some embodiments, the cutting element is slidably coupled to the housing, the cutting element having a distal end and a proximal end, and movable between a pre-firing position and a post-firing position in which the distal end of the cutting element is completely contained within the housing, and an extended position in which the distal end of the cutting element extends through the aperture. In some embodiments, the blood drawing device includes an energy source coupled to the housing and the cutting element and configured to move the cutting element

relative to the housing from the pre-firing position to the extended position to the post-firing position, and the fluid collection chamber removably coupled to the housing. In some embodiments, the cutting element includes a lancing end extending from the distal end thereof. In some embodiments, the lancing end moves in a single direction along the lateral axis and both directions
5 along the longitudinal axis when the cutting element is moved from the pre-firing position to the extended position to the post-firing position.

[0012] In another embodiment, there is a method of collecting a blood sample from a target area of a subject using a blood drawing device having a cutting element and a fluid collection chamber, the method including the steps of applying a heat source to the target area of the subject for a first
10 time period and/or applying a cooling source to the target area of the subject for a second time period, puncturing the target area with the cutting element of the blood drawing device, collecting a volume of blood in the fluid collection chamber, filling a first fluid collection chamber to a first predetermined volume, replacing the first fluid collection chamber with a second fluid collection chamber, and filling the second fluid collection chamber to a second predetermined volume. In some
15 embodiments, an absorption apparatus is applied to the target area as the first fluid collection chamber is replaced by the second fluid collection chamber.

[0013] In another embodiment, there is a blood drawing device for collecting a blood sample from a subject, the blood drawing device including a disposable collection cartridge having a housing, the housing having a proximal end and a distal end extending along a longitudinal axis and
20 a first side and a second side extending along a lateral axis, and at least one aperture extending therethrough, at least one slicing element slidably coupled to the housing, the at least one slicing element having a distal end and a proximal end, and movable between a pre-firing position and a post-firing position in which the distal end of the at least one slicing element is completely contained within the housing, and an extended position in which the distal end of the at least one
25 slicing element extends through the aperture, an energy source coupled to the housing and the at least one slicing element and configured to move the at least one slicing element relative to the housing from the pre-firing position to the extended position to the post-firing position, and at least one fluid collection chamber removably coupled to the housing. In some embodiments, the at least one slicing element includes a lancing end extending from the distal end thereof. In some
30 embodiments, the lancing end moves in a single direction along the lateral axis and both directions along the longitudinal axis when the at least one slicing element is moved from the pre-firing position to the extended position to the post-firing position.

[0014] In some embodiments, the housing further including an interior and a latch pivotably coupled to the interior of the housing and pivotable between a blocking position and a triggering position. In some embodiments, the blood drawing device further including a reusable actuation device releasably coupled to the disposable collection cartridge, the reusable actuation device having
5 a controller in electronic communication with the disposable collection cartridge, a power source in electronic communication with the disposable collection cartridge, and a vacuum source in fluid communication with the disposable collection cartridge. In some embodiments, the housing further includes a heating element and a cooling element, the heating element and the cooling element coupled to the distal end of the housing proximate the aperture.

10 [0015] In some embodiments, the reusable actuation device has a controller, the controller configured to control the vacuum source, a mechanical actuation system configured to move the latch, a temperature sensor coupled to the heating element, a pressure sensor disposed within the disposable collection cartridge, and a sample detection sensor disposed within the fluid collection chamber. In some embodiments, the temperature sensor is coupled to the controller, and the
15 controller is configured to adjust a temperature of the heating element based on a temperature detected by the temperature sensor and a desired temperature.

[0016] In some embodiments, the vacuum source is a vacuum pump configured to provide vacuum proximate a target area while the slicing element is in a retracted pre-firing position and during movement of the slicing element into an extended fired position. In some embodiments, the
20 heating element and the cooling element are a Peltier element configured to create a temperature difference in response to an electric current provided by the reusable actuation device. In some embodiments, the latch prevents movement of the at least one slicing element in the blocking position. In some embodiments, the latch into the triggering position allows the at least one slicing element to move from the pre-firing position to the fired position.

25 [0017] In some embodiments, the latch has an interference surface. In some embodiments, the interference surface engages the at least one slicing element in the blocking position and disengages the at least one slicing element in the triggering position. In some embodiments, the at least one slicing element includes a first slicing element and a second slicing element. In some embodiments, the latch comprises a first interference arm and a second interference arm. In some embodiments,
30 the first interference arm engages a first slicing element in the blocking position and the second interference arm engages a second slicing element in the blocking position. In some embodiments, movement of the latch from the blocking position to the triggering position disengages the first interference arm from the first slicing element at a first time and disengages the second interference

arm from the second slicing element at a second time, and wherein the first time is before the second time.

[0018] In some embodiments, the housing includes a guide extending generally along the lateral axis, the guide having two parallel guide rails spaced apart from each other. In some embodiments, the at least one slicing element has a slicing element protrusion extending therefrom, the slicing element protrusion disposed in the guide and slidable along the guide when the at least one slicing element is moved. In some embodiments, the slicing element protrusion extends from the at least one slicing element proximate the proximal end.

[0019] In some embodiments, the at least one fluid collection chamber comprises a plurality of fluid collection chambers. In some embodiments, the plurality of fluid collection chambers are each movable relative to the aperture between a filling position and a standby position. In some embodiments, the filling position is spaced apart from the standby position. In some embodiments, the housing includes a housing protrusion extending therefrom, the housing protrusion slidably received in a slicing element guide defined on the at least one slicing element and slidable along the slicing element guide when the at least one slicing element is moved. In some embodiments, the at least one fluid collection chamber extends at least partially through the at least one aperture. In some embodiments, the energy source is a torsion spring. In some embodiments, the pre-firing position is different than the post-firing position.

[0020] In another embodiment, there is a blood drawing device for collecting a blood sample from a subject, the blood drawing device including a disposable collection cartridge having a housing, the housing having a proximal end and a distal end extending along a longitudinal axis and a first side and a second side extending along a lateral axis, at least one aperture extending therethrough, and a guide extending along the lateral axis, the guide having two parallel guide rails spaced apart from each other, at least one slicing element slidably coupled to the housing, the at least one slicing element having a distal end and a proximal end, and movable between a pre-firing position and a post-firing position in which the distal end of the at least one slicing element is completely contained within the housing, and an extended position in which the distal end of the at least one slicing element extends through the aperture, an energy source rotatably coupled to the housing and the at least one slicing element and configured to move the at least one slicing element relative to the housing from the pre-firing position to the extended position to the post-firing position. In some embodiments, the at least one slicing element includes a lancing end extending from the distal end thereof. In some embodiments, the lancing end moves in a single direction along the lateral axis and both directions along the longitudinal axis when the at least one slicing element

is moved from the pre-firing position to the extended position to the post-firing position. In some embodiments, the at least one slicing element has a slicing element protrusion extending therefrom, the slicing element protrusion disposed in the guide and slidable along the guide when the at least one slicing element is moved.

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BRIEF DESCRIPTION OF THE DRAWINGS

[0021] The following detailed description of embodiments of the blood drawing device will be better understood when read in conjunction with the appended drawings of exemplary embodiments. It should be understood, however, that the invention is not limited to the precise arrangements and instrumentalities shown.

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[0022] In the drawings:

[0023] Fig. 1 is a top perspective view of a blood drawing device in accordance with a first exemplary embodiment of the present invention;

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[0024] Fig. 2 is a bottom perspective view of a disposable collection cartridge of the blood drawing device of Fig. 1;

[0025] Fig. 3 is a top perspective view of the disposable collection cartridge of the blood drawing device of Fig. 1 shown with a transparent housing to illustrate the interior components in a pre-firing position;

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[0026] Fig. 4 is a top perspective view of the disposable collection cartridge of the blood drawing device of Fig. 1 shown with a transparent housing to illustrate the interior components in an extended position;

[0027] Fig. 5 is a top perspective view of the disposable collection cartridge of the blood drawing device of Fig. 1 shown with a transparent housing to illustrate the interior components in a post-firing position;

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[0028] Fig. 6 is a bottom perspective view of the housing of the disposable collection cartridge of the blood drawing device of Fig. 1;

[0029] Fig. 7 is a top perspective view of a cutting element of the disposable collection cartridge of the blood drawing device of Fig. 1;

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[0030] Fig. 8A is a front partial view of the cutting element of the disposable collection cartridge of the blood drawing device of Fig. 1 in the pre-firing position shown with a transparent housing to illustrate the interior components;

[0031] Fig. 8B is a front partial view of the cutting element of Fig. 8A in the extended position;

- [0032] Fig. 9A is a top partial view of the cutting element of Fig. 8A to illustrate a lancing end with a more ovular lancing path;
- [0033] Fig. 9B is a top partial view of the cutting element of Fig. 8A to illustrate a lancing end with a more circular lancing path;
- 5 [0034] Fig. 10 is a top perspective view of a blood drawing device in accordance with a second exemplary embodiment of the present invention;
- [0035] Fig. 11 is a bottom perspective view of a disposable collection cartridge of the blood drawing device of Fig. 10;
- [0036] Fig. 12 is a top view of the disposable collection cartridge of the blood drawing device of
10 Fig. 10 shown with a transparent housing to illustrate the interior components;
- [0037] Fig. 13 is a perspective view of a blood drawing device in accordance with a third exemplary embodiment of the present invention;
- [0038] Fig. 14 is a front perspective view of the blood drawing device of Fig. 13 with a partially transparent housing;
- 15 [0039] Fig. 15 is a rear perspective view of the blood drawing device of Fig. 13 shown with a partially transparent housing to illustrate the interior components;
- [0040] Fig. 16 is a rear perspective view of the blood drawing device of Fig. 13 shown with a partially transparent housing to illustrate the interior components;
- [0041] Fig. 17 is a top view of the blood drawing device of Fig. 13 shown with a partially
20 transparent housing to illustrate the interior components in a pre-firing position;
- [0042] Fig. 18 is a top view of the blood drawing device of Fig. 13 shown with a partially transparent housing to illustrate the interior components in an extended position;
- [0043] Fig. 19 is a top view of the blood drawing device of Fig. 13 shown with a partially transparent housing to illustrate the interior components in a post-firing position;
- 25 [0044] Fig. 20 is a bottom cross-sectional view of the housing of the blood drawing device of Fig. 13;
- [0045] Fig. 21 is a partial rear perspective and exploded view of the blood drawing device of Fig. 13;
- [0046] Fig. 22 is a front perspective view of the blood drawing device of Fig. 13 in a first filling
30 position;
- [0047] Fig. 23 is a front perspective view of the blood drawing device of Fig. 13 in a second filling position;

[0048] Fig. 24 is a top view of a blood drawing device shown with a partially transparent housing to illustrate the interior components in a pre-firing position in accordance with a fourth exemplary embodiment of the present disclosure;

[0049] Fig. 25 is a top view of the blood drawing device of Fig. 24 shown with a partially transparent housing to illustrate the interior components in an extended position;

[0050] Fig. 26 is a top view of the blood drawing device of Fig. 24 shown with a partially transparent housing to illustrate the interior components in a swinging position; and

[0051] Fig. 27 is a top view of the blood drawing device of Fig. 24 shown with a partially transparent housing to illustrate the interior components in a post-firing position.

DETAILED DESCRIPTION

[0052] Blood sampling and analysis are indispensable parts of a patient's diagnostics. Blood quality is often the metric that is of utmost importance in clinical chemistry/pathology. Traditional methods of blood extraction are based on decades-old technologies such as the venipuncture (phlebotomy). But the phlebotomy process can be traumatic and inconvenient for some patients. Some approaches, such as a finger prick (using a lancet), allow drawing blood without the need for phlebotomy. This method is the most common method for checking blood glucose levels. For neonates, a heel prick is used to extract a small blood sample for a select few screening tests. The chief shortcoming of these methods is that the volume of blood extracted is limited by the amount of blood available in the capillary blood vessels that have been severed as a result of the lancing process before the repair process is initiated by the body. Repeated squeezing (milking) can be used to slightly increase the volume of expelled blood, but it is quite uncomfortable and laborious.

[0053] Some existing approaches to collecting capillary blood, as opposed to venous blood, allow collecting larger volumes of blood. Thus, some approaches allow creating several puncture wounds for collecting about 200 μ L of blood from capillaries after several minutes of use. However, one of the concerns with testing capillary blood is the fact that this method of extraction of blood has adverse effects on some blood parameters, which would then result in misdiagnosis of a patient. The parameters that are most susceptible are white blood cell (WBC) count, red blood cell (RBC) count, platelet count, and potassium, more generally complete blood count (CBC) and electrolyte panels. The CBC and electrolyte panels are two of the most commonly requisitioned panels and these parameters are some of the most important parameters considered by physicians to determine the overall health of a patient. Thus, any deviation from the actual values can lead to misdiagnosis and therefore mistreatment of the patient.

[0054] Non-phlebotomy approaches to blood collection, as compared to phlebotomy-based approaches, are complicated due to the increase in WBC count (which can be caused by the body's response to managing the wound as well as potential clumping of platelets that are mistakenly counted as WBCs), decrease in RBC count (the destruction of these fragile cells via the hemolysis process as a result of shear forces while the blood is being forced through the flesh wound), decrease in platelet count (these cells are responsible for blood coagulation and they clump and attempt to stop the bleeding when they come in contact with air and also as a result of shear forces as the blood is being forced through the flesh wound), and increase in potassium concentration (a side effect of hemolysis as RBCs carry a large amount of potassium that is not indicative of the true concentration of potassium).

[0055] In general, capillary blood collection methods have not been able to address the above issues and therefore have limited clinical utility as general-purpose blood extraction methods. In addition to the blood quality issues, lancing the finger may be an uncomfortable and painful process, as there are many nerve endings at the tip of fingers. The amount of blood available for collection is also limited, which means that the finger will have to be "milked" in order to increase the sample volume, which reduces the quality of the extracted blood.

[0056] Other approaches, such as controlled temperature modulation, can provide benefits over existing blood collection methods. Providing heat to the skin can induce vasodilation, promoting increased blood flow to the surface without causing discomfort or damage. This process can increase the availability of capillary blood, facilitating easier and more efficient collection of a sample. Following the warming phase, cooling the skin can induce vasoconstriction and help to minimize platelet activation by decreasing the skin and blood temperature, thereby slowing down the enzymatic reactions involved in coagulation. This reduction in platelet activity can decrease clot formation in the collected sample, thereby improving the accuracy and reliability of the blood parameters measured. Such temperature modulation techniques can significantly enhance the quality and volume of capillary blood samples, making non-phlebotomy methods more viable for a broader range of clinical applications.

[0057] Referring to the drawings in detail, wherein like reference numerals indicate like elements throughout, there is shown in Figs. 1-9B a blood drawing device, generally designated 100, in accordance with a first exemplary embodiment of the present invention. The blood drawing device 100 may include two main components, a reusable actuation device 102 and a disposable collection cartridge 104. Because the reusable actuation device 102 does not contact a patient's blood or blood sample, one reusable actuation device 102 may be used with two or more disposable collection

cartridges 104. Before and after collection of the blood sample, the disposable collection cartridge 104 may be separated from the reusable actuation device 102. During collection of the blood sample, the disposable collection cartridge 104 may be coupled to the reusable actuation device 102, which may control the operation of the components in the disposable collection cartridge 104.

5 [0058] By separating the blood drawing device 100 into multiple pieces, it may be possible to enhance the blood draw process by applying active control systems that may be configured to adjust the blood draw parameters based on the patient's needs. By including the active elements in the reusable actuation device 102, it may be possible to reduce the waste and costs associated with including these features in traditional single-use blood drawing devices.

10 [0059] Referring to Fig. 2, the disposable collection cartridge 104 may include a housing 106. The housing 106 may contain the components of the disposable collection cartridge 104 therein. The housing 106 may be illustrated with broken lines as if transparent. The housing 106 may have a proximal end 108 and a distal end 110 opposite the proximal end 108. A longitudinal axis (A_{LO}) may extend between the proximal end 108 and the distal end 110. The housing 106 may have a first side
15 112 and a second side 114 opposite the first side 112. A lateral axis (A_{LA}) may extend between the first side 112 and the second side 114.

[0060] Referring to Figs. 2-5, the disposable collection cartridge 104 may include a bottom surface 118 removably coupled to the housing 106. The bottom surface 118 may be shaped and sized to fit in an upper opening 120 of the housing 106. The upper opening 120 may be defined by a shelf 122
20 on a lower end and a housing rim 124. The bottom surface 118 may include a bottom surface aperture 119 extending therethrough. The bottom surface aperture 119 may be a generally rectangular shape and may be shaped and sized to receive a tool (e.g., a flathead screwdriver) therein. The bottom surface aperture 119 may enable a user to remove the bottom surface 118 from the housing 106.

[0061] The bottom surface 118 may include a membrane 126 on an upper end thereof. The
25 membrane 126 may be deformable and may engage the shelf 122 to prevent air from passing between the bottom surface 118 and the housing 106 when the bottom surface 118 is coupled thereto. The membrane 126 may be a rubber or soft plastic member. In some embodiments, the membrane 126 engages the shelf 122 and the upper opening 120 to prevent air from passing therethrough. Referring to Fig. 6, the shelf 122 may include at least one shelf extension 142 extending away from the housing
30 into the disposable collection cartridge 104. The shelf extension 142 may provide additional surface area for the membrane 126 to engage.

[0062] The disposable collection cartridge 104 may include a housing beam 140 coupled thereto. The housing beam 140 extends along the lateral axis A_{LA} between the first side 112 and the second

side 114. The housing beam 140 may be coupled to at least one shelf extension 142. The housing beam 140 may be spaced apart from the shelf 122 so as to not interfere with the engagement of the shelf 122 and the bottom surface 118. In some embodiments, the housing beam 140 is coupled directly to the housing 106.

5 [0063] Referring to Figs. 1-5, the housing 106 may include at least one aperture 116 extending therethrough. The aperture 116 may extend through the front or distal end 110 of the housing 106. The aperture 116 may be shaped and sized to allow one or more components from the disposable collection cartridge 104 to pass therethrough. The aperture 116 may have a generally rectangular body with an angled portion at a lower end thereof. The angled portion may be a generally triangular
10 shape. In some embodiments, the angled position may be a rounded shape.

[0064] Referring to Fig. 2, the disposable collection cartridge 104 may include a port or accessory hub 162 extending from the housing 106. The accessory hub 162 may be a generally tubular member with a tapered tip 164. The tip may be shaped and sized to removably couple to an accessory (e.g., a vacuum pump) during use. The accessory hub 162 may be in fluid communication with the interior
15 of the housing 106. While shown toward the distal end 110 of the housing 106, the accessory hub 162 may extend from any part of the housing 106.

[0065] The disposable collection cartridge 104 may include a trigger button 166 extending from the housing 106. The trigger button may extend through the bottom surface 118 to engage a latch disposed within the housing, as described in more detail below. The trigger button 166 may engage
20 the membrane 126 to move the latch, thereby maintaining the airtight seal provided by the membrane 126. The trigger button 166 may have an engagement surface 168 on an end thereof. The engagement surface may have a circumference or diameter larger than the trigger button 166 to allow a user to easily locate and move the trigger button 166. In some embodiments, the trigger button 166 is electronically moved by a controller, as described below.

25 [0066] The disposable collection cartridge 104 may include a heating element 186. The heating element 186 may be coupled to the distal end 110 of the housing 106 proximate the aperture 116. The heating element 186 may apply heat proximate the target area of the patient's skin before and during collection of the blood sample. By applying heat proximate the target area, the thermal energy may cause the blood in that area of the skin to flow more rapidly, which may allow for more blood to be
30 collected. The heating element 186 may apply a constant heat throughout collection of the sample. In some embodiments, the heating element 186 may apply variable heat according to a predetermined interval.

[0067] The heating element 186 may be configured to apply a temperature between 25-50 degrees Celsius proximate the target area. The heating element 186 may be configured to apply a temperature between 30-45 degrees Celsius proximate the target area. The heating element 186 may be configured to apply a temperature of approximately 25 degrees Celsius proximate the target area. The heating
5 element 186 may be configured to apply a temperature of approximately 30 degrees Celsius proximate the target area. The heating element 186 may be configured to apply a temperature of approximately 35 degrees Celsius proximate the target area. The heating element 186 may be configured to apply a temperature of approximately 40 degrees Celsius proximate the target area. The heating element 186 may be configured to apply a temperature of approximately 45 degrees Celsius proximate the target
10 area. The heating element 186 may be configured to apply a temperature of approximately 50 degrees Celsius proximate the target area.

[0068] In some embodiments, the heating element 186 includes a flexible printed circuit board (PCB). The heating element 186 may include a disposable restrictive circuit on the flexible PCB. The heating element 186 may include a compliant layer 202. The compliant layer 202 may provide a
15 cushion to soften the surface that contacts the patient's skin. The compliant layer 202 may also distribute the heat produced by the heating element 186 to improve the temperature uniformity proximate the target area. In some embodiments, the compliant layer 202 is a closed cell foam. In some embodiments, the compliant layer 202 is approximately 3 mm in thickness. In some embodiments, the compliant layer 202 is less than 5 mm in thickness. In some embodiments, the compliant layer 202 is less than 3 mm in thickness. In some embodiments, the compliant layer 202 is
20 between 0.5 mm and 3 mm in thickness. In some embodiments, the heating element 186 includes a non-compliant layer for distributing the heat and contacting the skin surface.

[0069] Referring to Figs. 3-7, the disposable collection cartridge 104 may include at least one cutting element 128 disposed therein. As described below in more detail, the cutting element 128 may
25 be a slicing element, such as a blade, that is slidably coupled to the housing 106. A cutting element 128 designed to slice instead of stab offers distinct advantages in blood sampling. The slicing action creates a longer and narrower incision, promoting a more controlled blood flow and potentially reducing pain for the individual. Furthermore, the elongated wound may facilitate increased blood draw volume, providing healthcare professionals with a larger sample for diagnostic purposes. In
30 other embodiments, the cutting element 128 can be a puncture element such as a needle or some other device that can cut, puncture or otherwise open the skin to extract blood such as an ultrasonic device.

[0070] The cutting element 128 may have a distal end 132 and a proximal end 130 opposite the distal end 132. The cutting element 128 may be an elongate member extending between the distal

end 132 and the proximal end 130. The cutting element 128 may include an energy source receiver 134 defined thereon. The energy source receiver 134 may be located proximate the proximal end 130 of the cutting element 128. The energy source receiver 143 may be shaped and sized to receive at least a portion of an energy source 136 therein. The cutting element 128 may include a sliding surface 138 defined thereon. The sliding surface 138 may be located proximate the proximal end 130 of the cutting element 128. The sliding surface 138 may be shaped and sized to engage the housing beam 140 when the cutting element 128 is moved relative to the housing 106.

[0071] The cutting element 128 may include a lancing end 144 extending from the distal end 132 thereof. The lancing end 144 may extend from the distal end 132 generally along a plane extending between the proximal end 130 and the distal end 132. The lancing end 144 may be a lancet or blade configured to make a small incision in a patient's flesh. The cutting element 128 may include a cutting element guide 146 defined thereon. The cutting element guide 146 may be located proximate the distal end 132 of the cutting element 128. The cutting element guide 146 may be defined on the cutting element 128 and may extend at least partially therethrough. The cutting element guide 146 may extend from the distal end 132 at least partially to the proximal end 130. The cutting element guide 146 may be a rectangular shape with a rounded proximal end.

[0072] Referring to Figs. 8A-8B, the cutting element 128 may be movable between a pre-firing position and a post-firing position in which the distal end 132 of the at least one cutting element 128 is completely contained within the housing 106. The cutting element 128 may also be movable to an extended position in which the distal end 132 of the at least one cutting element 128 extends through the aperture 116. As described in more detail below, the pre-firing position may be different than the post-firing position.

[0073] Referring to Figs. 3-5, the disposable collection cartridge 104 may include the energy source 136. The energy source 136 may be configured to translate stored mechanical energy into controlled force, thereby moving the cutting element 128 from the pre-firing position to the extended position to the post-firing position. The energy source 136 may facilitate precise and efficient slicing action, ensuring a reliable collection of a blood sampling.

[0074] The energy source 136 may be rotatably coupled to the housing 106 and the at least one cutting element 128. In some embodiments, the energy source 136 is rotatably coupled to the housing beam 140. The energy source 136 may have a first arm 148 and a second arm 150 extending from an energy source body 152. The first arm 148 may be coupled to the housing 106 and may be fixed relative to the housing 106. The second arm 150 may be coupled to the cutting element 128 and may

be configured to move the cutting element 128 relative to the housing 106 from the pre-firing position to the extended position to the post-firing position. The energy source 136 may be a torsion spring.

[0075] Referring to Figs. 1-5, the disposable collection cartridge 104 may include at least one fluid collection chamber 154 removably coupled to the housing 106. The fluid collection chamber 154 may efficiently capture the fluid sample as it is released from the incision site during collection of a sample. As described below in more detail, the location of the fluid collection chamber 154 and the shape of the fluid collection chamber 154 may minimize the risk of spillage and contamination of the same, thereby promoting accurate test results.

[0076] The fluid collection chamber 154 may be coupled to the disposable collection cartridge 104 by a threaded coupling. The housing 106 may include a threaded receiver shaped and sized to receive the fluid collection chamber 154. Rotation of the fluid collection chamber 154 in a first direction relative to the housing 106 may secure the fluid collection chamber 154 to the housing 106. Rotation of the fluid collection chamber 154 in a second direction that is opposite the first direction relative to the housing 106 may release the fluid collection chamber 154 from the housing 106.

[0077] The fluid collection chamber 154 may be at an oblique angle relative to the proximal end 108 of the housing 106. The fluid collection chamber 154 may extend at least partially through the aperture 116 in the proximal end 108 of the housing 106. A lip 160 defined on an end of the fluid collection chamber 154 may extend through the aperture 116. In some embodiments, the fluid collection chamber 154 is contained entirely within the housing 106.

[0078] In some embodiments, the fluid collection chamber 154 holds between 10 μ L and 1 mL of blood. The fluid collection chamber 154 may be configured to hold up to 1 mL of blood. The fluid collection chamber 154 may be configured to hold up to 900 μ L of blood. The fluid collection chamber 154 may be configured to hold up to 800 μ L of blood. The fluid collection chamber 154 may be configured to hold up to 700 μ L of blood. The fluid collection chamber 154 may be configured to hold up to 600 μ L of blood. The fluid collection chamber 154 may be configured to hold up to 500 μ L of blood. The fluid collection chamber 154 may be configured to hold up to 400 μ L of blood. The fluid collection chamber 154 may be configured to hold up to 350 μ L of blood. The fluid collection chamber 154 may be configured to hold up to 300 μ L of blood. The fluid collection chamber 154 may be configured to hold up to 250 μ L of blood. The fluid collection chamber 154 may be configured to hold up to 200 μ L of blood. The fluid collection chamber 154 may be configured to hold up to 150 μ L of blood. The fluid collection chamber 154 may be configured to hold up to 100 μ L of blood. The fluid collection chamber 154 may be configured to hold up to 50 μ L of blood.

[0079] Referring to Figs. 3-5, the fluid collection chamber 154 may include a collar 158 radially extending from at least a portion thereof. The collar 158 may extend around a circumference of the fluid collection chamber 154. In some embodiments, the collar 158 may extend around a portion of the circumference of the fluid collection chamber 154. The collar 158 may engage the housing 106 to prevent the fluid collection chamber 154 from moving past a predetermined point such that the lip 160 may extend through the aperture 116. The collar 158 may be a generally flat collar.

[0080] During a cutting event, the lancing end 144 of the cutting element 128 may move in a single direction along the lateral axis A_{LA} . For example, the lancing end 144 may move toward the first side 112 only when the cutting element 128 is moved from the pre-firing position to the extended position to the post-firing position. During a cutting event, the lancing end 144 of the cutting element 128 may move in both directions along the longitudinal axis A_{LO} . For example, the lancing end 144 may move toward the distal end 110 and toward the proximal end 108 when the cutting element 128 is moved from the pre-firing position to the extended position to the post-firing position. The cutting element 128 may travel along a single plane during a cutting event.

[0081] The housing 106 may include a guide 170 extending along the lateral axis A_{LA} . The guide 170 may extend at least partially between the first side 112 and the second side 114. The guide 170 may have two parallel guide rails 172 spaced apart from each other along a length of the guide 170. The cutting element 128 may have a cutting element protrusion 174 extending therefrom. The cutting element protrusion 174 may be a generally cylindrical member extending from the cutting element 128 proximate the proximal end 130. The cutting element protrusion 174 may be disposed in the guide 170 and may be slidable along the guide when the cutting element 128 is moved. As such, the proximal end 130 moves generally along the lateral axis A_{LA} when the cutting element 128 is moved from the pre-firing position to the extended position to the post-firing position.

[0082] The housing 106 may include a housing protrusion 176 extending therefrom. The housing protrusion 176 may be received in the cutting element guide 146. As discussed above, the cutting element guide 146 may be defined on the cutting element 128 proximate the distal end 132. The housing protrusion 176 may be slidable along the cutting element guide 146 when the cutting element 128 is moved from the pre-firing position to the extended position to the post-firing position. The interaction between the housing protrusion 176 and the cutting element guide 146 may limit the movement of the distal end 132 along the lateral axis A_{LA} while allowing movement along the longitudinal axis A_{LO} .

[0083] Referring to Figs. 8A-8B, the lancing end 144 of the cutting element 128 may move in a generally ovalar path when the cutting element 128 is moved from the pre-firing position to the

extended position to the post-firing position. The movement of the proximal end 130 along the guide may force the distal end 132 to pivot and slide about the housing protrusion 176 while the lancing end 144 extends through the aperture 116 as the proximal end 130 reaches a central portion of the guide, thereby moving the cutting element 128 into the extended position. Movement of the proximal end 130 along the guide may force the distal end 132 to pivot and slide about the housing protrusion 176 while the lancing end 144 recedes into the housing 106 as the proximal end 130 reaches an end of the guide 170 closest to the second side 114, thereby moving the cutting element 128 into the post-firing position.

[0084] Referring to Figs. 9A-9B, it is shown that the lancing end 144 may be adjusted relative to the cutting element 128 to adjust the depth and width of a cut produced by the lancing end. For example, in Fig. 9A the lancing end 144 is disposed farther in the distal end 132 compared to the lancing end 144 shown in Fig. 9B. The lancing end 144 in Fig. 9A may produce a cut with less depth and width than that of the lancing end 144 of Fig. 9B.

[0085] Referring to Figs. 9A-9B, a lancing path P1, P2 is shown. The lancing path P1, P2 may represent the path that the lancing end 144 travels when the cutting element 128 is moved from the pre-firing position to the extended position to the post-firing position. The lancing path P1, P2 may be a generally rounded or ovular shape. Referring to Fig. 9A, a lancing end that is disposed farther in the distal end 132 may form a more ovular lancing path P1. Referring to Fig. 9B, a lancing end that extends farther from the distal end 132 may have a more circular lancing path P2. The positioning of the lancing end 144 relative to the cutting element 128 may be modulated for use in various applications.

[0086] Referring to Figs. 3-5, the disposable collection cartridge 104 may include a latch 178 pivotably coupled to an interior of the housing 106. The latch 178 may be a generally cuboidal shape and may extend at least partially between the first side 112 and the second side 114. The latch 178 is shown in Figs. 3-5 as being pivotably coupled to the second side 114. In some embodiments, the latch 178 is pivotably coupled to the first side 112. The latch 178 may extend only partially between the second side 114 and the first side 112.

[0087] The latch 178 may be pivotable between a blocking position (or locked position) and a triggering position (or activation position). The trigger button 166 may engage the latch 178 at a location that is spaced apart from the end pivotably coupled with the housing 106. Movement of the trigger button 166 may cause the latch 178 to pivot about the end that is pivotably coupled to the housing 106. The latch 178 may prevent movement of the cutting element 128 in the blocking position. Movement of the latch 178 from the blocking position into the trigger position may allow

the cutting element 128 to move from the pre-firing position to the extended position to the post-firing position.

[0088] Referring to Figs. 3-5, the latch 178 may include at least one interference arm 180 extending therefrom. The interference arm 180 may engage the cutting element 128 in the blocking position. The guide rail 172 may include an arm recess 182 defined therein. The arm recess 182 may be shaped and sized to receive the interference arm 180 therein. Movement of the latch 178 from the blocking position into the trigger position may allow the interference arm 180 to move into the arm recess 182. The interference arm 180 may disengage the cutting element 128 in the triggering position when the interference arm 180 is disposed in the arm recess 182.

[0089] The reusable actuation device 102 may be releasably coupled to the disposable collection cartridge 104. The reusable actuation device 102 may have a controller 184 in electronic communication with the disposable collection cartridge 104. The reusable actuation device 102 may comprise a controller 184 in electronic communication with the disposable collection cartridge 104, a power source 188 in electronic communication with the disposable collection cartridge 104, and a vacuum source 190 in fluid communication with the disposable collection cartridge 104 via the accessory hub 162. In some embodiments, the accessory hub 162 is a pneumatic tube, pipe, or other conduit. The reusable actuation device 102 may be powered by a battery. In some embodiments, the reusable actuation device 102 is powered by a power cord plugged into an energy source.

[0090] In some embodiments, the controller 184 is configured to control the vacuum source 190. In some embodiments, the vacuum source 190 is a vacuum pump. The controller 184 may be disposed in a control housing 185. The control housing 185 may be a generally cuboidal member that may sit on a surface (e.g., a table) during use. The control housing 185 may be coupled to the reusable actuation device 102 by a conduit 187. The conduit 187 may include one or more lines disposed therein. As described below in more detail, the conduit 187 may include electrical lines providing power to the reusable actuation device 102, tubing enabling fluid communication between the control housing 185 and the reusable actuation device 102, data cables carrying data to and from sensors disposed in the reusable actuation device 102 and the controller 184 in the control housing 185, and any other appropriate line to enable the operation of the reusable actuation device 102.

[0091] In some embodiments, the controller 184 is configured to control a mechanical actuation system 192 that actuates the latch 178 when the disposable collection cartridge 104 is coupled to the reusable actuation device 102. In some embodiments, the controller 184 is configured to control a temperature sensor 194 coupled to the heating element 186 when the disposable collection cartridge 104 is coupled to the reusable actuation device 102. In some embodiments, the controller 184 is

configured to control a pressure sensor 196 disposed within the housing 106 when the disposable collection cartridge 104 is coupled to the reusable actuation device 102. In some embodiments, the pressure sensor 196 is disposed within the reusable actuation device 102. The pressure sensor 196 may be disposed within the accessory hub 162 of the reusable actuation device 102.

5 [0092] The temperature sensor 194 may be coupled to the heating element 186. In some embodiments, the temperature sensor 194 is electrically coupled to the controller 184. The controller 184 may be configured to adjust the temperature of the heating element 186 based on a difference between a temperature detected by the temperature sensor 194 and a desired temperature. In some
10 embodiments, the temperature sensor 194 provides feedback to the controller 184 as a means to perform active temperature control throughout the blood draw process to maintain the provided temperature within a predetermined tolerable range. In some embodiments, it is necessary and useful to implement different temperature profiles within the system to optimize blood flow throughout the blood draw process. The reusable actuation device 102 may include an adjustable knob 198 (not shown) coupled to the controller 184. In some embodiments, the user can manipulate the adjustable
15 knob 198 to control a temperature of the heating element 186. In some embodiments, the temperature sensor 194 detects a user's heat profile and provides feedback to the controller 184 in order to activate the vacuum source 190 as a result of the disposable collection cartridge 104 being pressed against the patient's skin.

[0093] In some embodiments, the controller 184 is configured to control a sample detection sensor
20 200 disposed within the fluid collection chamber 154 when the disposable collection cartridge 104 is coupled to the reusable actuation device 102. The fluid collection chamber 154 may be any container with an internal space that is configured to hold a collected fluid. The fluid collection chamber 154 may also be referred to as a collection tube. In some embodiments, the sample detection sensor 200 is disposed within the reusable actuation device 102. If the sample detection sensor 200 is disposed
25 within the reusable actuation device 102, the sample detection sensor 200 may detect the sample through, for example, a transparent window of the fluid collection chamber 154 (not shown).

[0094] In some embodiments, the vacuum source 190 is a vacuum pump configured to provide a vacuum in the housing 106 proximate a target area while the cutting element 128 is in the post-firing position. The vacuum source 190 may be a vacuum pump configured to provide a vacuum in the
30 housing 106 proximate a target area while the cutting element 128 is in the extended position. The vacuum source 190 may be a vacuum pump configured to provide a vacuum in the housing 106 proximate a target area while the cutting element 128 is in a pre-firing position. In some embodiments, the vacuum source 190 is applied proximate the target area while the cutting element 128 is puncturing

the target area. In some embodiments, the vacuum source 190 is applied proximate the target area after the cutting element is puncturing the target area. In some embodiments, the vacuum source 190 is not applied to the target area while the cutting element 128 is puncturing the target area. In some embodiments, the vacuum source 190 can be programmed to change the level at which the vacuum source 190 operates depending on the use of the blood drawing device 100. For example, the vacuum source 190 may operate at a low level while the cutting element 128 is puncturing the target area and then operate at a higher level after the cutting element 128 has punctured the target area. In one embodiment, the amount of vacuum force applied by the vacuum source 190 to the target area is based on the amount of blood collected. For example, a sensor could measure the amount of blood collected and if the amount of collected blood is high and/or filling rapidly, the vacuum force could be lowered and/or stopped. The pressure sensor 196 may provide feedback to the controller 46 as a means to perform active pressure control throughout the blood draw process.

[0095] Referring to Figs. 10-12, there is shown a second embodiment of the blood drawing device, generally designated 1100. The blood drawing device 1100 is similar to the first embodiment of the blood drawing device except that the blood drawing device 1100 may include two cutting elements 1128 and two fluid collection chambers 1154. The blood drawing device 1100 may include a first cutting element 1128a and a second cutting element 1128b.

[0096] Referring to Fig. 12, when there are two cutting elements it is important that the first cutting element 1128a moves before the second cutting element 1128b to prevent interference with the movement of both components. The latch 1178 may include a first interference arm 1180a and a second interference arm 1180b. The first interference arm 1180a may engage the first cutting element 1128a in the blocking position. The second interference arm 1180b may engage the second cutting element 1128b in the blocking position. Movement of the latch 1178 from the blocking position to the triggering position may disengage the first interference arm 1180a from the first cutting element 1128a at a first time. Movement of the latch 1178 from the blocking position to the triggering position may disengage the second interference arm 1180b from the second cutting element 1128b at a second time.

[0097] The first time may be before the second time. The first time may be approximately 1 msec before the second time. In some embodiments, the first time is approximately 2 msec, approximately 3 msec, approximately 4 msec, approximately 5 msec, approximately 6 msec, approximately 7 msec, approximately 8 msec, approximately 9 msec, approximately 10 msec, approximately 15 msec or approximately 20 msec before the second time. The first time may be at least 1 msec before the second time. In some embodiments, the first time is at least 2 msec, at least 3 msec, at least 4 msec, at

least 5 msec, at least 6 msec, at least 7 msec, at least 8 msec, at least 9 msec, at least 10 msec, at least 15 msec or at least 20 msec before the second time. In some embodiments, the first time is between 1 msec and 20 msec, between 2 msec and 15 msec, between 3 msec and 10 msec, between 4 msec and 9 msec, between 5 msec and 8 msec, or between 6 msec and 7 msec before the second time.

5 [0098] Referring to Figs. 10-12, the blood drawing device 1100 may include a first fluid collection chamber 1154a and a second fluid collection chamber 1154b. The first fluid collection chamber 1154a and the second fluid collection chamber 1154b may be fixed relative to the housing 1106. In some embodiments, the first fluid collection chamber 1154a and the second fluid collection chamber 1154b are movable relative to each other. In some embodiments, a single aperture 1116 (not shown) may
10 extend through the housing 1106. The first fluid collection chamber 1154a and the second fluid collection chamber 1154b may be movable relative to the aperture 1116 between a filling position and a standby position. The filling position may be spaced apart from the standby position. The filling position may position the fluid collection chamber 1154 proximate the aperture 1116.

[0099] In one embodiment, the blood drawing device includes one or more computers having one
15 or more processors and memory (e.g., one or more nonvolatile storage devices). In some embodiments, a memory or computer readable storage medium of memory stores programs, modules and data structures, or a subset thereof, for a processor to control and run the various systems and methods disclosed herein. In one embodiment, a non-transitory computer readable storage medium has stored thereon computer-executable instructions that, when executed by a processor, perform one
20 or more of the methods disclosed herein.

[00100] Referring to Figs. 13-23, there is shown a third embodiment of the blood drawing device, generally designated 2100. The blood drawing device 2100 is similar to the first embodiment of the blood drawing device 100 and the second embodiment of the blood drawing device 1100 except that the blood drawing device 2100 may include a collection assembly 2153 movable relative to the
25 housing 2106 having two fluid collection chambers 2154. The blood drawing device 2100 may include a temperature element 2186 configured to apply heating and/or cooling to the target area of the patient's skin before and/or during collection of a blood sample. In some embodiments, the heating and/or cooling methods and mechanisms are omitted.

[00101] The blood drawing device 2100 may include two main components, a reusable actuation
30 device 2102 and a disposable collection cartridge 2104. Because the reusable actuation device 2102 does not contact a patient's blood or blood sample, one reusable actuation device 2102 may be used with two or more disposable collection cartridges 2104. The disposable collection cartridge 2104 may be separated from the reusable actuation device 2102 after collection of a blood sample. During

collection of the blood sample, the disposable collection cartridge 2104 may be coupled to the reusable actuation device 2102, which may control the operation of the components in the disposable collection cartridge 2104, as described in more detail herein.

[00102] Referring to Fig. 13, the disposable collection cartridge 2104 may include a housing 2106.

5 The housing 2106 may contain the components of the disposable collection cartridge 2104 therein. The housing 2106 may have a proximal end 2108 and a distal end 2110 opposite the proximal end 2108. A longitudinal axis (A_{LO}) may extend between the proximal end 2108 and the distal end 2110. The housing 2106 may have a first side 2112 and a second side 2114 opposite the first side 2112. A lateral axis (A_{LA}) may extend between the first side 2112 and the second side 2114.

10 **[00103]** Referring to Fig. 13, the housing 2106 may include an aperture 2116 extending therethrough. The aperture 2116 may extend through the front end (distal end 2110) of the housing 2106. The aperture 2116 may be shaped and sized to allow one or more components from the disposable collection cartridge 2104 to pass therethrough. The aperture 2116 may include a slit 2117 defined along the lateral axis A_{LA} to allow at least a portion of the cutting element 2128 to extend
15 therethrough in the extended position (as described in more detail below). The aperture 2116 may include a rounded center 2119 to allow at least a portion of the fluid collection chamber 2154 to extend therethrough (as described in more detail below).

[00104] Referring to Fig. 13, the disposable collection cartridge 2104 may include a port or hub 2162 extending from the housing 2106. The hub 2162 may be a generally tubular member shaped
20 and sized to removably couple to the reusable actuation device 2102 during use. The hub 2162 may be in fluid communication with the interior of the housing 2106.

[00105] The disposable collection cartridge 2104 may include a slicing trigger 2166 and a chamber trigger 2167 extending therein to engage a respective latch disposed within the housing 2106, as described in more detail below. The slicing trigger 2166 and chamber trigger 2167 may include a
25 movable extension, 2166a and 2167a, respectively, that protrudes from an end of the respective trigger to move the respective latch. In some embodiments, the slicing trigger 2166 and chamber trigger 2167 are electronically moved by a controller, as described below.

[00106] The disposable collection cartridge 2104 may include a temperature element 2186. The temperature element 2186 may be coupled to the distal end 2110 of the housing 2106 proximate the
30 aperture 2116. In some embodiments, the temperature element 2186 is separated from the disposable collection cartridge 2104 and is applied directly to the target area of the patient's skin. The temperature element 2186 may be integral to the disposable collection cartridge 2104 and may be disposed after use. In some embodiments, the temperature element 2186 is a reusable component that

may be applied to the target area of the target prior to and/or during collection of the sample. In some embodiments, the temperature element 2186 is releasably attached to the disposable collection cartridge 2104. In some embodiments, the disposable collection cartridge 2104 is a separate member and is never coupled to the disposable collection cartridge 2104 or the reusable actuation device 2102.

5 [00107] The temperature element 2186 may apply heat proximate the target area of the patient's skin before and during collection of the blood sample. In some embodiments, the temperature element 2186 is a heating pad, a warm towel, infrared light or a Peltier element. By applying heat proximate the target area, the thermal energy may cause the blood in that area of the skin to flow more rapidly, which may allow for more blood to be collected. The temperature element 2186 may apply a constant
10 heat before and/or during collection of the sample. In some embodiments, the temperature element 2186 may apply variable heat according to a predetermined interval.

[00108] The temperature element 2186 may apply cooling proximate the target area of the patient's skin before and during collection of the blood sample. In some embodiments, the temperature element 2186 is a cooling pad, an ice pack, a cold compress or a Peltier element. By applying cooling
15 proximate the target area, the cooling energy may reduce the skin temperature and the temperature of the sub-skin region to a predetermined depth to reduce coagulation. The temperature gradient of the applied cooling may be non-linear. For example, the skin temperature may be reduced more by the temperature element 2186 when it is close to or touching the skin than when it is spaced apart from the skin.

20 [00109] The predetermined cooling depth may be between approximately 10 μm and 10 mm. In some embodiments, the predetermined depth is approximately 10 μm , approximately 20 μm , approximately 30 μm , approximately 40 μm , approximately 50 μm , approximately 60 μm , approximately 70 μm , approximately 80 μm , approximately 90 μm , approximately 100 μm , approximately 200 μm , approximately 300 μm , approximately 400 μm , approximately 500 μm ,
25 approximately 600 μm , approximately 700 μm , approximately 800 μm , approximately 900 μm , approximately 1 mm, approximately 1.5 mm, approximately 2 mm, approximately 2.5 mm, approximately 3 mm, approximately 3.5 mm, approximately 4 mm, approximately 4.5 mm, approximately 5 mm, approximately 5.5 mm, approximately 6 mm, approximately 6.5 mm, approximately 7 mm, approximately 7.5 mm, approximately 8 mm, approximately 8.5 mm,
30 approximately 9 mm, approximately 9.5 mm or approximately 10 mm. In some embodiments, the predetermined depth is at least 10 μm , at least 20 μm , at least 30 μm , at least 40 μm , at least 50 μm , at least 60 μm , at least 70 μm , at least 80 μm , at least 90 μm , at least 100 μm , at least 200 μm , at least 300 μm , at least 400 μm , at least 500 μm , at least 600 μm , at least 700 μm , at least 800 μm , at least

900 μm , at least 1 mm, at least 1.5 mm, at least 2 mm, at least 2.5 mm, at least 3 mm, at least 3.5 mm, at least 4 mm, at least 4.5 mm, at least 5 mm, at least 5.5 mm, at least 6 mm, at least 6.5 mm, at least 7 mm, at least 7.5 mm, at least 8 mm, at least 8.5 mm, at least 9 mm, at least 9.5 mm or at least 10 mm. In some embodiments, the predetermined depth is between approximately 10 μm and 10 mm, between approximately 20 μm and 9.5 mm, between approximately 30 μm and 9 mm, between approximately 40 μm and 8.5 mm, between approximately 50 μm and 8 mm, between approximately 60 μm and 7.5 mm, between approximately 70 μm and 7 mm, between approximately 80 μm and 6.5 mm, between approximately 90 μm and 6 mm, between approximately 100 μm and 5.5 mm, between approximately 200 μm and 5 mm, between approximately 300 μm and 4.5 mm, between approximately 400 μm and 4 mm, between approximately 500 μm and 3.5 mm, between approximately 600 μm and 3 mm, between approximately 700 μm and 2.5 mm, between approximately 800 μm and 2 mm, or between approximately 900 μm and 1.5 mm.

[00110] Applying cooling proximate the target area may reduce coagulation of the blood and allow for more blood to be collected. The temperature element 2186 may apply a constant cooling before and/or during collection of the sample. In some embodiments, the temperature element 2186 applies variable cooling according to a predetermined interval. In some embodiments, the temperature element 2186 applies variable heating and cooling before and/or during collection of the sample according to a predetermined interval.

[00111] The temperature element 2186 may be configured to apply heat between 30°C and 55°C proximate the target area. In some embodiments, the temperature element 2186 applies a temperature of approximately 30°C, approximately 31°C, approximately 32°C, approximately 33°C, approximately 34°C, approximately 35°C, approximately 36°C, approximately 37°C, approximately 38°C, approximately 39°C, approximately 40°C, approximately 41°C, approximately 42°C, approximately 43°C, approximately 44°C, approximately 45°C, approximately 46°C, approximately 47°C, approximately 48°C, approximately 49°C, approximately 50°C, approximately 51°C, approximately 52°C, approximately 53°C, approximately 54°C, or approximately 55°C. In some embodiments, the temperature element 2186 applies a temperature of at least 30°C, at least 31°C, at least 32°C, at least 33°C, at least 34°C, at least 35°C, at least 36°C, at least 37°C, at least 38°C, at least 39°C, at least 40°C, at least 41°C, at least 42°C, at least 43°C, at least 44°C, at least 45°C, at least 46°C, at least 47°C, at least 48°C, at least 49°C, at least 50°C, at least 51°C, at least 52°C, at least 53°C, at least 54°C, or at least 55°C. In some embodiments, the temperature element 2186 applies a temperature between approximately 30°C and 55°C, between approximately 31°C and 54°C, between approximately 32°C and 53°C, between approximately 33°C and 52°C, between

approximately 34°C and 51°C, between approximately 35°C and 50°C, between approximately 36°C and 49°C, between approximately 37°C and 48°C, between approximately 38°C and 47°C, between approximately 39°C and 46°C, between approximately 40°C and 45°C, between approximately 41°C and 44°C, or between approximately 42°C and 43°C.

- 5 **[00112]** The temperature element 2186 may be configured to apply cooling between -20°C and 15°C proximate the target area. In some embodiments, the temperature element 2186 applies a temperature of approximately -20°C, approximately -19°C, approximately -18°C, approximately -17°C, approximately -16°C, approximately -15°C, approximately -14°C, approximately -13°C, approximately -12°C, approximately -11°C, approximately -10°C, approximately -9°C,
- 10 approximately -8°C, approximately -7°C, approximately -6°C, approximately -5°C, approximately -4°C, approximately -3°C, approximately -2°C, approximately -1°C, approximately 0°C, approximately 1°C, approximately 2°C, approximately 3°C, approximately 4°C, approximately 5°C, approximately 6°C, approximately 7°C, approximately 8°C, approximately 9°C, approximately 10°C, approximately 11°C, approximately 12°C, approximately 13°C, approximately 14°C, or
- 15 approximately 15°C. In some embodiments, the temperature element 2186 applies a temperature of less than -20°C, less than -19°C, less than -18°C, less than -17°C, less than -16°C, less than -15°C, less than -14°C, less than -13°C, less than -12°C, less than -11°C, less than -10°C, less than -9°C, less than -8°C, less than -7°C, less than -6°C, less than -5°C, less than -4°C, less than -3°C, less than -2°C, less than -1°C, less than 0°C, less than 1°C, less than 2°C, less than 3°C, less than 4°C, less than 5°C,
- 20 less than 6°C, less than 7°C, less than 8°C, less than 9°C, less than 10°C, less than 11°C, less than 12°C, less than 13°C, less than 14°C, or less than 15°C. In some embodiments, the temperature element 2186 applies a temperature between approximately -20°C and 15°C, between approximately -19°C and 14°C, between approximately -18°C and 13°C, between approximately -17°C and 12°C, between approximately -16°C and 11°C, between approximately -15°C and 10°C, between
- 25 approximately -14°C and 9°C, between approximately -13°C and 8°C, between approximately -12°C and 7°C, between approximately -11°C and 6°C, between approximately -10°C and 5°C, between approximately -9°C and 4°C, between approximately -8°C and 3°C, between approximately -7°C and 2°C, between approximately -6°C and 1°C, between approximately -5°C and 0°C, between approximately -4°C and -1°C, or between approximately -3°C and -2°C.
- 30 **[00113]** In some embodiments, the temperature element 2186 includes a flexible PCB. The temperature element 2186 may include a disposable restrictive circuit on the flexible PCB. The temperature element 2186 may include a compliant layer 2202 (not shown). The compliant layer 2202 may provide a cushion to soften the surface that contacts the patient's skin. The compliant layer 2202

may also distribute the heat produced by the temperature element 2186 to improve the temperature uniformity proximate the target area. In some embodiments, the compliant layer 2202 is a closed cell foam. In some embodiments, the temperature element 2186 includes a non-compliant layer for distributing the heat and contacting the skin surface. The temperature element 2186 may cover the target area of the patient's skin.

[00114] Referring to Figs. 14-19, the disposable collection cartridge 2104 may include a base 2118, a cutting element 2128 and a collection assembly 2153 disposed within the housing 2106. The base 2118 may be fixed relative to the housing 2106 and the cutting element 2128 and the collection assembly 2153 may be moveably coupled to the base 2118.

[00115] Referring to Figs. 14-19, the base 2118 may be coupled to the housing 2106 and may have a generally flat and semicircular shape. The shape of the base 2118 may allow the fluid collection chamber 2154 to extend between the base 2118 and the housing 2106 and move relative to the base 2118. The base 2118 may have an upper side and a lower side opposite the upper side. The base 2118 may have an anchor 2121 defined thereon, the anchor 2121 configured to fix the base 2118 to the housing 2106. The anchor 2121 may extend from the upper side of the base 2118 and may be configured to receive a component of the housing 2106 therein. In some embodiments, the anchor 2121 extends from the lower side of the base 2118. The base 2118 may include a plurality of anchors 2121 configured to fix the base 2118 to the housing 2106 to prevent rotation of the base 2118 about the anchor 2121 during use. The base 2118 may include two anchors 2121.

[00116] Referring to Figs. 14-19, the slicing trigger 2166 and the chamber trigger 2167 may extend from the lower side of the base 2118. The slicing trigger 2166 and chamber trigger 2167 may be generally tubular members. In some embodiments, slicing trigger 2166 and the chamber trigger 2167 are flexible members. In some embodiments, the slicing trigger 2166 and the chamber trigger 2167 are rigid. The slicing trigger 2166 and the chamber trigger 2167 may include a sheath and an interior cable that is movable relative to the sheath. As described in more detail below, the interior cable may be a movable extension that protrudes from an end of the respective trigger to move a latch, as described in more detail below. The slicing trigger 2166 may include a slicing trigger extension 2169 that extends from the upper side of the base 2118 to position the cable of the slicing trigger 2166 proximate the slicing latch 2178. The chamber trigger 2167 may include a chamber trigger extension 2171 that extends from the upper side of the base 2118 to position the cable of the slicing trigger 2166 proximate the chamber latch 2179.

[00117] Referring to Figs. 14-19, the cutting element 2128 may be slidably coupled to the housing 2106. The cutting element 2128 may have a distal end 2132 and a proximal end 2130 opposite the

distal end 2132. The cutting element 2128 may be an elongate member extending between the distal end 2132 and the proximal end 2130. The cutting element 2128 may include an energy source receiver 2134 defined thereon. The energy source receiver 2134 may be located proximate the proximal end 2130 of the cutting element 2128. The energy source receiver 2143 may be shaped and sized to receive at least a portion of a cutting element energy source 2136 therein.

[00118] The cutting element 2128 may include a lancing end 2144 extending from the distal end 2132 thereof. The lancing end 2144 may extend from the distal end 2132 generally along a plane extending along a length of the cutting element 2128. The lancing end 2144 may be a lancet or blade configured to make an incision in a patient's flesh.

[00119] Referring to Figs. 17-19, the cutting element 2128 may be movable between a pre-firing position (Fig. 17) and a post-firing position (Fig. 19) in which the distal end 2132 of the cutting element 2128 is completely contained within the housing 2106. The cutting element 2128 may also be movable to an extended position (Fig. 18) in which the distal end 2132 of the cutting element 2128 extends through the aperture 2116. As described in more detail below, the pre-firing position may be different than the post-firing position.

[00120] Referring to Figs. 14-19, the disposable collection cartridge 2104 may include the cutting element energy source 2136. The cutting element energy source 2136 may be configured to translate stored mechanical energy into controlled force, thereby moving the cutting element 2128 from the pre-firing position to the extended position to the post-firing position. The cutting element energy source 2136 may facilitate precise and efficient slicing action, ensuring a reliable collection of a blood sampling.

[00121] The cutting element energy source 2136 may be rotatably coupled to the housing 2106 and the cutting element 2128. In some embodiments, the cutting element energy source 2136 is rotatably coupled to the base 2118. The cutting element energy source 2136 may have a first arm 2148 and a second arm 2150 extending from an energy source body 2152. The first arm 2148 may be coupled to the housing 2106 and may be fixed relative to the housing 2106. The second arm 2150 may be coupled to the cutting element 2128 and may be configured to move the cutting element 2128 relative to the housing 2106 from the pre-firing position to the extended position to the post-firing position. The cutting element energy source 2136 may be a torsion spring.

[00122] Referring to Figs. 14-19, the disposable collection cartridge 2104 may include a collection assembly 2153 disposed within the housing 2106. The collection assembly 2153 may have at least one fluid collection chamber 2154 removably coupled thereto. The collection assembly 2153 may have two fluid collection chambers 2154 removably coupled thereto. A first fluid collection chamber

2154a and a second fluid collection chamber 2154b may be removably coupled to a distal end of the collection assembly 2153. The first fluid collection chamber 2154a and the second fluid collection chamber 2154b may be fixed relative to the collection assembly 2153.

5 [00123] To avoid unnecessary lancing, it may be advantageous to make a single incision and position fluid collection chambers proximate the skin in succession. Referring to Figs. 21-23, the collection assembly 2153 may be rotatable about a collection pivot 2155. The collection pivot 2155 may be formed as part of the housing 2106. In some embodiments, the collection pivot 2155 extends from the upper side of the base 2118. The collection assembly 2153 may pivot about the collection pivot 2155 between a first filling position where the first fluid collection chamber 2154a is positioned proximate the aperture 2116 and a second filling position where the second fluid collection chamber 2154b is positioned proximate the aperture 2116.

[00124] The collection assembly 2153 may rotate approximately 30° about the collection pivot 2155 between the first filling position and the second filling position. In some embodiments, the collection assembly 2153 rotates approximately 20°, approximately 22°, approximately 24°, approximately 26°, approximately 28°, approximately 30°, approximately 32°, approximately 34°, approximately 36°, approximately 38°, or approximately 40° about the collection pivot 2155 between the first filling position and the second filling position. In some embodiments, the collection assembly 2153 rotates at least 20°, at least 22°, at least 24°, at least 26°, at least 28°, at least 30°, at least 32°, at least 34°, at least 36°, at least 38°, or at least 40° about the collection pivot 2155 between the first filling position and the second filling position. In some embodiments, the collection assembly 2153 rotates between approximately 20° and 40°, between approximately 22° and 38°, between approximately 24° and 36°, between approximately 26° and 34°, or between approximately 28° and 32° about the collection pivot 2155 between the first filling position and the second filling position.

25 [00125] Referring to Figs. 21-23, the first fluid collection chamber 2154a and the second fluid collection chamber 2154b may be movable relative to the aperture 2116 between an active position and a standby position. The active position may be spaced apart from the standby position. The active position may position the fluid collection chamber 2154 proximate the aperture 2116. The first fluid collection chamber 2154a may be in the active position when the collection assembly 2153 is in the first filling position and may be in the standby position when the collection assembly 2153 is in the second filling position. The second fluid collection chamber 2154b may be in the standby position when the collection assembly 2153 is in the first filling position and may be in the active position when the collection assembly 2153 is in the second filling position. In some embodiments, the first fluid collection chamber 2154a is positioned proximate the aperture 2116 in the second filling position

and the second fluid collection chamber 2154b is positioned proximate the aperture 2116 in the first filling position.

[00126] When moving the fluid collection assembly 2153 from the first filling position to the second filling position, the blood that is flowing from the target area of the subject may tend to collect on the area of the fluid collection assembly 2153 between the first fluid collection chamber 2154a and the second fluid collection chamber 2154b. This may cause the blood to continue to flow into the first fluid collection chamber 2154a when the fluid collection assembly 2153 is in the second collection position. Referring to Figs. 22-23, the fluid collection assembly 2153 may include an absorption apparatus 2173 disposed thereon to wipe the target area when moving the fluid collection assembly 2153 from the first filling position to the second filling position. The absorption apparatus 2173 may be configured to absorb any excess blood that flows from the target area when moving the fluid collection assembly 2153 from the first filling position to the second filling position. In some embodiments, the absorption apparatus 2173 may apply a pressure to the target area to temporarily slow or stop the flow of blood until the second fluid collection chamber 2154b is positioned proximate thereto.

[00127] Referring to Fig. 14, the fluid collection assembly 2153 may include a pad recess 2175 defined on a distal end thereof. The pad recess 2175 may be shaped and sized to receive at least a portion of the absorption apparatus 2173. The depth of the pad recess 2175 may be less than a thickness of the absorption apparatus 2173 to allow the absorption apparatus 2173 to protrude from the distal end of the fluid collection assembly 2153. In some embodiments, the absorption apparatus 2173 is fixed directly to the distal end of the fluid collection assembly 2153. The absorption apparatus 2173 may comprise a dry absorption material (e.g., composite dressing, charcoal dressing, gauze, non-adherent pad, foam, etc.) or a wet absorption material (e.g., super absorbent polymer (SAP), hydrocolloid dressing, alginate dressing, hydrogel, etc.) or a combination thereof. The absorption apparatus 2173 may have a generally uniform thickness and may be flexible so as to have the same curvature of the distal end of the fluid collection assembly 2153 when the absorption apparatus 2173 is coupled thereto.

[00128] Referring to Figs. 21-23, the disposable collection cartridge 2104 may include the collection assembly energy source 2137. The collection assembly energy source 2137 may be configured to translate stored mechanical energy into controlled force, thereby moving the collection assembly 2153 from the first filling position to the second filling position. The collection assembly energy source 2137 may be rotatably coupled to the housing 2106 and the collection assembly 2153. In some embodiments, the cutting element energy source 2136 is rotatably coupled to the base 2118

and the collection assembly 2153. The collection assembly energy source 2137 may have a first arm 2149 and a second arm 2151 extending from an energy source body 2156. The first arm 2149 may be coupled to the housing 2106 and may be fixed relative to the housing 2106. The second arm 2151 may be coupled to the collection assembly 2153 and may be configured to move the collection assembly 2153 relative to the housing 2106 from the first filling position to the second filling position. The collection assembly energy source 2137 may be a torsion spring.

[00129] Referring to Figs. 14-16, the fluid collection chamber 2154 may be coupled to the collection assembly 2153 by a threaded coupling. In some embodiments, the fluid collection chamber 2154 is coupled to the collection assembly 2153 by a snap-fit coupling. The fluid collection chamber 2154 may be at an oblique angle relative to the proximal end 2108 of the housing 2106. The fluid collection chamber 2154 may extend at least partially through the aperture 2116 in the proximal end 2108 of the housing 2106. A lip 2160 defined on an end of the fluid collection chamber 2154 may extend through the aperture 2116. In some embodiments, the fluid collection chamber 2154 is contained entirely within the housing 2106.

[00130] Referring to Figs. 17-19, during a cutting event, the lancing end 2144 of the cutting element 2128 may move in a single direction along the lateral axis A_{LA} . For example, the lancing end 2144 may move toward the first side 2112 only when the cutting element 2128 is moved from the pre-firing position to the extended position to the post-firing position. During a cutting event, the lancing end 2144 of the cutting element 2128 may move in both directions along the longitudinal axis A_{LO} . For example, the lancing end 2144 may move toward the distal end 2110 and toward the proximal end 2108 when the cutting element 2128 is moved from the pre-firing position to the extended position to the post-firing position. The cutting element 2128 may travel along a single plane that is generally parallel to the base 2118 during a cutting event.

[00131] Referring to Fig. 20, the housing 2106 may include a guide 2170 extending generally along the lateral axis A_{LA} . The guide 2170 may extend at least partially between the first side 2112 and the second side 2114. The guide 2170 may have two parallel guide rails 2172 spaced apart from each other along a length of the guide 2170. The cutting element 2128 may have a cutting element protrusion 2174 extending therefrom. The cutting element protrusion 2174 may be a generally cylindrical member extending from the cutting element 2128 proximate the proximal end 2130. The cutting element protrusion 2174 may be disposed in the guide 2170 and may be slidable along the guide 2170 when the cutting element 2128 is moved. As such, the proximal end 2130 moves generally along the lateral axis A_{LA} when the cutting element 2128 is moved from the pre-firing position to the extended position to the post-firing position. The guide 2170 may have a curved configuration where

a central portion of the guide 2170 is proximate relative to the end portions. The central portion of the guide 2170 may be in the form of an arc to facilitate a cut to the target area that has a target depth and target width. In some embodiments, the shape of the guide 2170 may be designed to facilitate a cut that has a maximum depth and minimum width. This configuration may urge the cutting element 2128 into the extended position where at least a portion of the cutting element 2128 extends from the housing 2106. In some embodiments, the guide 2170 may be generally straight.

[00132] Referring to Figs. 14-19, the disposable collection cartridge 2104 may include a slicing latch 2178 pivotably coupled to an interior of the housing 2106. The slicing latch 2178 may be a generally cuboidal shape and may extend at least partially between the second side 2114 and the first side 2112. The slicing latch 2178 is shown in Figs. 14-19 as being pivotably coupled to the second side 2114 of the housing 2106. In some embodiments, the slicing latch 2178 is pivotably coupled to the first side 2112 of the housing 2106. The slicing latch 2178 may extend only partially between the second side 2114 and the first side 2112.

[00133] The slicing latch 2178 may be pivotable between a blocking position (Fig. 15) and a triggering position (Fig. 22) in response to engagement by the slicing trigger 2166. The slicing trigger 2166 may engage the slicing latch 2178 at a location that is spaced apart from the end pivotably coupled to the housing 2106. Movement of the slicing trigger 2166 may cause the slicing latch 2178 to pivot from the blocking position to the triggering position. The slicing latch 2178 may prevent movement of the cutting element 2128 in the blocking position. Movement of the slicing latch 2178 from the blocking position into the trigger position may allow the cutting element 2128 to move from the pre-firing position to the extended position to the post-firing position.

[00134] Following the cutting event, the first fluid collection chamber 2154a may be filled with the subject's blood to a first predetermined volume. When the first fluid collection chamber 2154a is filled to the first predetermined volume, the collection assembly 2153 may be rotated about the collection pivot 2155 into the second filling position to position the second fluid collection chamber 2154b proximate the aperture 2116. As described above, the reusable actuation device 2102 may include a sensor that detects the volume of blood collection in the fluid collection chamber to initiate movement of the collection assembly 2153 from the first filling position to the second filling position. In some embodiments, movement of the collection assembly 2153 from the first filling position to the second filling position is initiated after a predetermined amount of time. In some embodiments, movement of the collection assembly 2153 from the first filling position to the second filling position is initiated by a user. The second fluid collection chamber 2154b may be filled with the subject's blood to a second predetermined volume. In some embodiments, the first fluid collection chamber

2154a and/or the second fluid collection chamber 2154b is a vacutainer blood collection tube or similar configured to facilitate increased flow of blood to increase the volume of blood to be collected.

[00135] The first predetermined volume may be between approximately 10 μ L and 10 ml. In some embodiments, the first predetermined volume is approximately 10 μ L, approximately 20 μ L, approximately 30 μ L, approximately 40 μ L, approximately 50 μ L, approximately 60 μ L, approximately 70 μ L, approximately 80 μ L, approximately 90 μ L, approximately 100 μ L, approximately 200 μ L, approximately 300 μ L, approximately 400 μ L, approximately 500 μ L, approximately 600 μ L, approximately 700 μ L, approximately 800 μ L, approximately 900 μ L, approximately 1 mL, approximately 1.5 mL, approximately 2 mL, approximately 2.5 mL, approximately 3 mL, approximately 3.5 mL, approximately 4 mL, approximately 4.5 mL, approximately 5 mL, approximately 5.5 mL, approximately 6 mL, approximately 6.5 mL, approximately 7 mL, approximately 7.5 mL, approximately 8 mL, approximately 8.5 mL, approximately 9 mL, approximately 9.5 mL or approximately 10 mL. In some embodiments, the first predetermined volume is at least 10 μ L, at least 20 μ L, at least 30 μ L, at least 40 μ L, at least 50 μ L, at least 60 μ L, at least 70 μ L, at least 80 μ L, at least 90 μ L, at least 100 μ L, at least 200 μ L, at least 300 μ L, at least 400 μ L, at least 500 μ L, at least 600 μ L, at least 700 μ L, at least 800 μ L, at least 900 μ L, at least 1 mL, at least 1.5 mL, at least 2 mL, at least 2.5 mL, at least 3 mL, at least 3.5 mL, at least 4 mL, at least 4.5 mL, at least 5 mL, at least 5.5 mL, at least 6 mL, at least 6.5 mL, at least 7 mL, at least 7.5 mL, at least 8 mL, at least 8.5 mL, at least 9 mL, at least 9.5 mL or at least 10 mL. In some embodiments, the first predetermined volume is between approximately 10 μ L and 10 mL, between approximately 20 μ L and 9.5 mL, between approximately 30 μ L and 9 mL, between approximately 40 μ L and 8.5 mL, between approximately 50 μ L and 8 mL, between approximately 60 μ L and 7.5 mL, between approximately 70 μ L and 7 mL, between approximately 80 μ L and 6.5 mL, between approximately 90 μ L and 6 mL, between approximately 100 μ L and 5.5 mL, between approximately 200 μ L and 5 mL, between approximately 300 μ L and 4.5 mL, between approximately 400 μ L and 4 mL, between approximately 500 μ L and 3.5 mL, between approximately 600 μ L and 3 mL, between approximately 700 μ L and 2.5 mL, between approximately 800 μ L and 2 mL, or between approximately 900 μ L and 1.5 mL.

[00136] The second predetermined volume may be between approximately 10 μ L and 10 ml. In some embodiments, the first predetermined volume is approximately 10 μ L, approximately 20 μ L, approximately 30 μ L, approximately 40 μ L, approximately 50 μ L, approximately 60 μ L, approximately 70 μ L, approximately 80 μ L, approximately 90 μ L, approximately 100 μ L, approximately 200 μ L, approximately 300 μ L, approximately 400 μ L, approximately 500 μ L,

approximately 600 μ L, approximately 700 μ L, approximately 800 μ L, approximately 900 μ L, approximately 1 mL, approximately 1.5 mL, approximately 2 mL, approximately 2.5 mL, approximately 3 mL, approximately 3.5 mL, approximately 4 mL, approximately 4.5 mL, approximately 5 mL, approximately 5.5 mL, approximately 6 mL, approximately 6.5 mL, approximately 7 mL, approximately 7.5 mL, approximately 8 mL, approximately 8.5 mL, approximately 9 mL, approximately 9.5 mL or approximately 10 mL. In some embodiments, the second predetermined volume is at least 10 μ L, at least 20 μ L, at least 30 μ L, at least 40 μ L, at least 50 μ L, at least 60 μ L, at least 70 μ L, at least 80 μ L, at least 90 μ L, at least 100 μ L, at least 200 μ L, at least 300 μ L, at least 400 μ L, at least 500 μ L, at least 600 μ L, at least 700 μ L, at least 800 μ L, at least 900 μ L, at least 1 mL, at least 1.5 mL, at least 2 mL, at least 2.5 mL, at least 3 mL, at least 3.5 mL, at least 4 mL, at least 4.5 mL, at least 5 mL, at least 5.5 mL, at least 6 mL, at least 6.5 mL, at least 7 mL, at least 7.5 mL, at least 8 mL, at least 8.5 mL, at least 9 mL, at least 9.5 mL or at least 10 mL. In some embodiments, the second predetermined volume is between approximately 10 μ L and 10 mL, between approximately 20 μ L and 9.5 mL, between approximately 30 μ L and 9 mL, between approximately 40 μ L and 8.5 mL, between approximately 50 μ L and 8 mL, between approximately 60 μ L and 7.5 mL, between approximately 70 μ L and 7 mL, between approximately 80 μ L and 6.5 mL, between approximately 90 μ L and 6 mL, between approximately 100 μ L and 5.5 mL, between approximately 200 μ L and 5 mL, between approximately 300 μ L and 4.5 mL, between approximately 400 μ L and 4 mL, between approximately 500 μ L and 3.5 mL, between approximately 600 μ L and 3 mL, between approximately 700 μ L and 2.5 mL, between approximately 800 μ L and 2 mL, or between approximately 900 μ L and 1.5 mL.

[00137] Referring to Figs. 21-23, following the cutting event, the distal end of the collection assembly 2153 may move in a single direction along the lateral axis A_{LA} . For example, the distal end of the collection assembly 2153 may move toward the first side 2112 only when the collection assembly 2153 is moved from the first filling position to the second filling position. The collection assembly 2153 may travel along a single plane that is generally parallel to the base 2118.

[00138] Referring to Fig. 21, the collection assembly 2153 may include a leg 2157 extending therefrom. The leg 2157 may extend generally downward. The leg 2157 may be configured to engage the base 2118 to ensure that movement of the collection assembly 2153 is along a single plane that is generally parallel to the base 2118. The leg 2157 may be configured to slide on the base 2118 when the collection assembly 2153 is moved. The base 2118 may include a stop 2159 defined thereon that engages the leg 2157 when the collection assembly 2153 is in the second filling position. The stop

2159 may be located proximate the anchor 2121. In some embodiments, the anchor 2121 is the stop 2159.

[00139] Referring to Figs. 21-23, the disposable collection cartridge 2104 may include a chamber latch 2179 pivotably coupled to an interior of the housing 2106. The chamber latch 2179 may be a generally cuboidal shape and may extend at least partially between the first side 2112 and the second side 2114. The chamber latch 2179 is shown in Figs. 21-23 as being pivotably coupled to the first side 2112 of the housing 2106. In some embodiments, the chamber latch 2179 is pivotably coupled to the second side 2114 of the housing 2106. The chamber latch 2179 may extend only partially between the first side 2112 and the second side 2114.

[00140] The chamber latch 2179 may be pivotable between a blocking position (Fig. 22) and a triggering position (Fig. 23) in response to engagement by the chamber trigger 2167. The chamber trigger 2167 may engage the chamber latch 2179 at a location that is spaced apart from the end pivotably coupled to the housing 2106. Movement of the chamber trigger 2167 may cause the chamber latch 2179 to pivot from the blocking position to the triggering position. The chamber latch 2179 may prevent movement of the collection assembly 2153 in the blocking position. Movement of the chamber latch 2179 from the blocking position into the trigger position may allow the collection assembly 2153 to move from the first filling position to the second filling position.

[00141] A method of collecting a blood sample from a target area of a subject using a blood drawing device 2100 may be disclosed. The blood drawing device 2100 may have a cutting element 2128 and a fluid collection chamber 2154. The method may include applying a heat source (temperature element 2186) to the target area of the subject for a first time period. Gently warming the target area where the capillary blood will be collected may cause vasodilation (widening of the blood vessels) without causing discomfort or damage to the skin. This may increase blood flow to the surface.

[00142] The first time period may be approximately 10 seconds to 5 minutes. In some embodiments, the first time period is approximately 10 seconds, approximately 15 seconds, approximately 20 seconds, approximately 25 seconds, approximately 30 seconds, approximately 35 seconds, approximately 40 seconds, approximately 45 seconds, approximately 50 seconds, approximately 55 seconds, approximately 60 seconds, approximately 70 seconds, approximately 80 seconds, approximately 90 seconds, approximately 100 seconds, approximately 110 seconds, approximately 120 seconds, approximately 130 seconds, approximately 140 seconds, approximately 150 seconds, approximately 160 seconds, approximately 170 seconds, approximately 180 seconds, approximately 2 minutes, approximately 2 minutes 30 seconds, approximately 3 minutes, approximately 3 minutes 30 seconds, approximately 4 minutes, approximately 4 minutes 30 seconds,

or approximately 5 minutes. In some embodiments, the first time period is at least 10 seconds, at least 15 seconds, at least 20 seconds, at least 25 seconds, at least 30 seconds, at least 35 seconds, at least 40 seconds, at least 45 seconds, at least 50 seconds, at least 55 seconds, at least 60 seconds, at least 70 seconds, at least 80 seconds, at least 90 seconds, at least 100 seconds, at least 110 seconds, at least 120 seconds, at least 130 seconds, at least 140 seconds, at least 150 seconds, at least 160 seconds, at least 170 seconds, at least 180 seconds, at least 2 minutes, at least 2 minutes 30 seconds, at least 3 minutes, at least 3 minutes 30 seconds, at least 4 minutes, at least 4 minutes 30 seconds, or at least 5 minutes. In some embodiments, the first time period is between approximately 10 seconds and 5 minutes, between approximately 15 seconds and 5 minutes, between approximately 20 seconds and 4 minutes 30 seconds, between approximately 25 seconds and 4 minutes, between approximately 30 seconds and 3 minutes 30 seconds, between approximately 35 seconds and 3 minutes, between approximately 40 seconds and 2 minutes 30 seconds, between approximately 45 seconds and 2 minutes, between approximately 50 seconds and 180 seconds, between approximately 60 seconds to 180 seconds, between approximately 70 seconds to 170 seconds, between approximately 80 seconds to 160 seconds, between approximately 90 seconds to 150 seconds, between approximately 100 seconds to 140 seconds, or between approximately 110 seconds to 130 seconds.

[00143] Applying the heat source for the first time period may be followed by applying a cooling source (temperature element 2186) to the target area of the subject for a second time period. Prompt cooling of the skin may induce vasoconstriction (narrowing of blood vessels), which can help trap more blood in the capillaries and can make them more accessible for blood collection. Prompt cooling of the skin may also reduce or delay platelet activation and coagulation. Cooling the skin rapidly after warming can help minimize platelet activation by decreasing the temperature of the blood and may slow down the enzymatic reactions involved in coagulation, thereby reducing the risk of clot formation in the collected sample. Preservation of blood sample integrity is vital for accurate test results, as clot formation can alter the composition of the sample and obstruct the capillary, making it difficult to collect an adequate volume of blood.

[00144] The second time period may be approximately 10 seconds to 5 minutes. In some embodiments, the second time period is approximately 10 seconds, approximately 15 seconds, approximately 20 seconds, approximately 25 seconds, approximately 30 seconds, approximately 40 seconds, approximately 50 seconds, approximately 60 seconds, approximately 70 seconds, approximately 80 seconds, approximately 90 seconds, approximately 100 seconds, approximately 110 seconds, approximately 120 seconds, approximately 130 seconds, approximately 140 seconds, approximately 150 seconds, approximately 160 seconds, approximately 170 seconds, approximately

180 seconds, approximately 2 minutes, approximately 2 minutes 30 seconds, approximately 3 minutes, approximately 3 minutes 30 seconds, approximately 4 minutes, approximately 4 minutes 30 seconds, or approximately 5 minutes. In some embodiments, the second time period is at least 10 seconds, at least 15 seconds, at least 20 seconds, at least 25 seconds, at least 30 seconds, at least 40 seconds, at least 50 seconds, at least 60 seconds, at least 70 seconds, at least 80 seconds, at least 90 seconds, at least 2 minutes, at least 2 minutes 30 seconds, at least 3 minutes, at least 3 minutes 30 seconds, at least 4 minutes, at least 4 minutes 30 seconds, or at least 5 minutes. In some embodiments, the first time period is between approximately 10 seconds and 5 minutes, between approximately 15 seconds and 5 minutes, between approximately 20 seconds and 4 minutes 30 seconds, between approximately 25 seconds and 4 minutes, between approximately 30 seconds and 3 minutes 30 seconds, between approximately 35 seconds and 3 minutes, between approximately 40 seconds and 2 minutes 30 seconds, between approximately 45 seconds and 2 minutes, between approximately 50 seconds and 180 seconds, between approximately 60 seconds to 180 seconds, between approximately 70 seconds to 170 seconds, between approximately 80 seconds to 160 seconds, between approximately 90 seconds to 150 seconds, between approximately 100 seconds to 140 seconds or between approximately 110 seconds to 130 seconds.

[00145] In some embodiments, the temperature element 2186 is a Peltier element. The Peltier element can be used as a heating and cooling source. By dynamically adjusting its operation between heating and cooling, the Peltier element can quickly heat the skin and then quickly cool it, ensuring optimal sample integrity and collection efficiency. In some embodiments, the temperature element 2186 is at least one of a heating element, a warm towel and an infrared light. In some embodiments, the temperature element 2186 is at least one of a cooling element, an ice pack and a cold compress.

[00146] Once the skin has been warmed and/or cooled, cutting element 2128 of the blood drawing device 2100 may be used to puncture the skin. The blood that is released from the target area of the subject may be collected in the fluid collection chamber 2154. The blood drawing device 2100 may include a vacuum source 190. Applying a vacuum to the target area may facilitate flow of blood into the fluid collection chamber.

[00147] The cutting element 2128 may puncture the target area following the second time period. In some embodiments, the cutting element 2128 punctures the target area during the second time period. In some embodiments, the cutting element 2128 punctures the target area during the first time period. In some embodiments, the cutting element 2128 punctures the target area after the first time period and before the second time period.

[00148] Alternative protocols of heat and cold may be applied to the target area of the subject to achieve desired blood collection results. In some embodiments, the heat source and the cooling source are applied to the target area after the cutting element 2128 punctures the target area. In some embodiments, the target area of the skin may be cooled during collection of the blood sample.

5 Prolonged skin cooling throughout the blood collection procedure may help maintain vasoconstriction by continually restricting blood flow, thereby increasing the volume of blood collected. Prolonged skin cooling during blood collection may also minimize the risk of platelet activation by slowing down the enzymatic reactions.

[00149] In some embodiments, the target area of the skin may be cooled during collection of the
10 blood sample. Warming during blood collection may help maintain optimal blood flow dynamics. This can be especially useful in situations where a person's skin temperature may have dropped, or due to other environmental factors (e.g., ambient temperature).

[00150] In some embodiments, the heat source and the cooling source may be alternated before and/or during collection of the blood sample. This dynamic modulation of temperature may increase
15 blood flow by periodically inducing vasodilation to replenish blood supply and then quickly promoting vasoconstriction to trap the blood in the capillaries. In some embodiments, the cooling source is applied to the target area before the heat source. The cooling source may be applied for the second time period followed by the heat source for the first time period. In some embodiments, the cooling source and the heat source are both applied to the target area.

[00151] The blood drawing device 2100 may include two fluid collection chambers 2154. The method may further include filling a first fluid collection chamber 2154a to the first predetermined volume. When the first fluid collection chamber 2154a has been filled to the first predetermined volume, the first fluid collection chamber 2154a may be replaced with a second fluid collection chamber 2154b. The method may further include filling the second fluid collection chamber 2154b
25 to the second predetermined volume.

[00152] Following the second fluid collection chamber 2154 being filled to the second predetermined volume, the blood drawing device 2100 may be separated from the subject and the first fluid collection chamber 2154a and the second fluid collection chamber 2154b may be removed therefrom to allow testing of the collected blood samples.

30 [00153] Referring to Figs. 24-27, there is shown a blood collection device, generally designated 3100, in accordance with a fourth embodiment of the present disclosure. The blood collection device 3100 may be generally the same as blood collection device 2100 discussed above except that cutting element 3128 has a shorter path as it moves from a pre-firing position to a post-firing position than

cutting element 2128. The cutting element 3128 having a shorter swipe path may increase the target area of the patient's skin during collection of the blood sample while limiting how deep the patient's skin is cut by lancing end 3144. Blood collection device 3100 may include disposable collection cartridge 3104 which is generally the same as disposable collection cartridge 2104. The cutting element 3128 illustrated in Figs. 24-27 may be movable between the pre-firing position (Fig. 24) and the post-firing position (Fig. 27) in which a distal end 3132 of the cutting element 3128 is completely contained in housing 3106. The cutting element 3128 may also be movable to an extended position as it swings from a second side 3114 to a first side 3112 (Figs. 25-26) in which the distal end 3132 of the cutting element 3128 extends out of the blood collection device 3100. The lancing end 3144 is generally the same as lancing end 2144 except that it extends a shorter length from the cutting element 3128 than lancing end 2144 extends from cutting element 2128.

[00154] Some embodiments or implementations are described with respect to the following clauses:

Clause A1. A method of collecting a blood sample from a target area of a subject using a blood drawing device having a cutting element and at least one fluid collection chamber, the method comprising the steps of:

- applying a heat source to the target area of the subject for a first time period;
 - applying a cooling source to the target area of the subject for a second time period;
 - puncturing the subject area with the cutting element of the blood drawing device;
 - applying a vacuum to the target area to facilitate flow of blood into a first fluid collection chamber;
 - filling the first fluid collection chamber to a first predetermined volume;
 - replacing the first fluid collection chamber with a second collection chamber; and
 - filling the second fluid collection chamber to a second predetermined volume,
- wherein the blood drawing device comprises:
- a disposable collection cartridge having a housing, the housing having a proximal end and a distal end extending along a longitudinal axis and a first side and a second side extending along a lateral axis, and at least one aperture extending therethrough,
 - the cutting element slidably coupled to the housing, the cutting element having a distal end and a proximal end, and movable between a pre-firing position and a post-firing position in which the distal end of the cutting element is completely contained within the housing, and an extended position in which the distal end of the cutting element extends through the aperture, and

an energy source coupled to the housing and the cutting element and configured to move the cutting element relative to the housing from the pre-firing position to the extended position to the post-firing position.

Clause A2. The method of clause A1, wherein the fluid collection chamber is removably coupled to the housing.

Clause A3. The method of clause A1, wherein the cutting element includes a lancing end extending from the distal end thereof, and wherein the lancing end moves in a single direction along the lateral axis and both directions along the longitudinal axis when the cutting element is moved from the pre-firing position to the extended position to the post-firing position.

Clause A4. The method of clause A1, wherein an absorption apparatus is applied to the target area as the first fluid collection chamber is replaced by the second fluid collection chamber.

Clause A5. The method of clause A4, wherein the absorption apparatus is disposed between the first fluid collection chamber and the second fluid collection chamber and where the absorption apparatus is dragged across the target area as the first fluid collection chamber is replaced by the second fluid collection chamber.

[00155] The term “about” or “approximately” is used herein to provide literal support for the exact number that it precedes, as well as a number that is near to or approximately the number that the term precedes. In determining whether a number is near to or approximately a specifically recited number, the near or approximating unrecited number may be a number that, in the context in which it is presented, provides the substantial equivalent of the specifically recited number. It should be appreciated that all numerical values and ranges disclosed herein are approximate values and ranges, whether “about” is used in conjunction therewith. It should also be appreciated that the term “about”, as used herein, in conjunction with a numeral refers to a value that may be $\pm 0.01\%$ (inclusive) of that numeral, $\pm 0.1\%$ (inclusive) of that numeral, $\pm 0.5\%$ (inclusive) of that numeral, $\pm 1\%$ (inclusive) of that numeral, $\pm 2\%$ (inclusive) of that numeral, $\pm 3\%$ (inclusive) of that numeral, $\pm 5\%$ (inclusive) of that numeral, $\pm 10\%$ (inclusive) of that numeral, or $\pm 15\%$ (inclusive) of that numeral. It should further be appreciated that when a numerical range is disclosed herein, any numerical value falling within the range is also specifically disclosed.

[00156] It will be appreciated by those skilled in the art that changes could be made to the exemplary embodiments shown and described above without departing from the broad inventive concepts thereof. It is to be understood that the embodiments and claims disclosed herein are not limited in their application to the details of construction and arrangement of the components set forth in the description and illustrated in the drawings. Rather, the description and the drawings provide

examples of the embodiments envisioned. The embodiments and claims disclosed herein are further capable of other embodiments and of being practiced and carried out in various ways.

[00157] Specific features of the exemplary embodiments may or may not be part of the claimed invention and various features of the disclosed embodiments may be combined. Unless specifically
5 set forth herein, the terms “a”, “an” and “the” are not limited to one element but instead should be read as meaning “at least one”. Finally, unless specifically set forth herein, a disclosed or claimed method should not be limited to the performance of its steps in the order written, and one skilled in the art can readily appreciate that the steps may be performed in any practical order.

CLAIMS

What is claimed is:

1. A method of collecting a blood sample from a target area of a subject using a blood drawing
5 device having a cutting element and a fluid collection chamber, the method comprising the steps of:
applying a heat source to the target area of the subject for a first time period and/or applying
a cooling source to the target area of the subject for a second time period;
puncturing the target area with the cutting element of the blood drawing device; and
collecting a volume of blood in the fluid collection chamber.
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2. The method of claim 1 further comprising the step of:
filling a first fluid collection chamber to a first predetermined volume;
replacing the first fluid collection chamber with a second fluid collection chamber; and
filling the second fluid collection chamber to a second predetermined volume.
15
3. The method of claim 2, wherein an absorption apparatus is applied to the target area as the
first fluid collection chamber is replaced by the second fluid collection chamber.
4. The method of claim 3, wherein the absorption apparatus is disposed between the first fluid
20 collection chamber and the second fluid collection chamber and where the absorption apparatus is
dragged across the target area as the first fluid collection chamber is replaced by the second fluid
collection chamber.
5. The method of claim 1, wherein the heat source is at least one of a heating element, a warm
25 towel and an infrared light.
6. The method of claim 5, wherein the heating element is a Peltier element.
7. The method of claim 5, wherein the heat source has a temperature between approximately
30 40° to 55° Celsius.
8. The method of claim 1, wherein the cooling source is at least one of a cooling element, an ice
pack and a cold compress.

9. The method of claim 8, wherein the cooling element is a Peltier element.
10. The method of claim 8, wherein the cooling source has a temperature between approximately
5 -20° to +15° Celsius.
11. The method of claim 1, wherein the heat source and the cooling source are applied to the target area after the cutting element punctures the target area.
- 10 12. The method of claim 11, wherein the heat source and the cooling source are alternated during collection of the blood sample.
13. The method of claim 1, wherein the heat source and the cooling source are both applied and are applied one after the other.
- 15 14. The method of claim 13, wherein the cooling source is applied to the target area before the heat source.
15. The method of claim 13, wherein the cooling source is applied for the second time period
20 followed by the heat source for the first time period.
16. The method of claim 1 further comprising the step of:
applying a vacuum to the target area to facilitate flow of blood into the fluid collection chamber,
25 wherein the vacuum is applied to the target area while the cutting element of the blood drawing device is puncturing the target area.
17. The method of claim 1 further comprising the step of:
applying a vacuum to the target area to facilitate flow of blood into the fluid collection
30 chamber,
wherein the vacuum is applied to the target area after the cutting element of the blood drawing device is puncturing the target area but not during.

18. The method of claim 1, wherein the first time period is between approximately 10 seconds to 5 minutes.
19. The method of claim 1, wherein the second time period is at least between approximately 10
5 seconds to 3 minutes.
20. The method of claim 1, wherein the cutting element punctures the target area during the second time period.
- 10 21. The method of claim 1, wherein the cutting element punctures the target area during the first time period.
22. The method of claim 1, wherein the cutting element punctures the target area before the second time period.
- 15 23. The method of claim 1, wherein the cutting element is a blade.
24. The method of claim 1, wherein the heat source covers the target area.
- 20 25. The method of claim 1, wherein the cooling source covers the target area.
26. The method of claim 1, wherein the blood drawing device comprises:
a disposable collection cartridge having a housing, the housing having a proximal end and a distal end extending along a longitudinal axis and a first side and a second side extending along a
25 lateral axis, and at least one aperture extending therethrough;
the cutting element slidably coupled to the housing, the cutting element having a distal end and a proximal end, and movable between a pre-firing position and a post-firing position in which the distal end of the cutting element is completely contained within the housing, and an extended position in which the distal end of the cutting element extends through the aperture;
30 an energy source coupled to the housing and the cutting element and configured to move the cutting element relative to the housing from the pre-firing position to the extended position to the post-firing position; and
the fluid collection chamber removably coupled to the housing,

wherein the cutting element includes a lancing end extending from the distal end thereof, and
 wherein the lancing end moves in a single direction along the lateral axis and both directions
 along the longitudinal axis when the cutting element is moved from the pre-firing position to the
 extended position to the post-firing position.

5

27. A method of collecting a blood sample from a target area of a subject using a blood drawing
 device having a cutting element and a fluid collection chamber, the method comprising the steps of:
 applying a heat source to the target area of the subject for a first time period and/or applying
 a cooling source to the target area of the subject for a second time period;

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puncturing the target area with the cutting element of the blood drawing device;

collecting a volume of blood in the fluid collection chamber;

filling a first fluid collection chamber to a first predetermined volume;

replacing the first fluid collection chamber with a second fluid collection chamber; and

filling the second fluid collection chamber to a second predetermined volume,

15

wherein an absorption apparatus is applied to the target area as the first fluid collection
 chamber is replaced by the second fluid collection chamber.

28. A blood drawing device for collecting a blood sample from a subject, the blood drawing
 device comprising:

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a disposable collection cartridge having a housing, the housing having a proximal end and a
 distal end extending along a longitudinal axis and a first side and a second side extending along a
 lateral axis, and at least one aperture extending therethrough;

at least one slicing element slidably coupled to the housing, the at least one slicing element
 having a distal end and a proximal end, and movable between a pre-firing position and a post-firing
 position in which the distal end of the at least one slicing element is completely contained within the
 housing, and an extended position in which the distal end of the at least one slicing element extends
 through the aperture;

25

an energy source coupled to the housing and the at least one slicing element and configured
 to move the at least one slicing element relative to the housing from the pre-firing position to the
 extended position to the post-firing position; and

30

at least one fluid collection chamber removably coupled to the housing,

wherein the at least one slicing element includes a lancing end extending from the distal end
 thereof, and

wherein the lancing end moves in a single direction along the lateral axis and both directions along the longitudinal axis when the at least one slicing element is moved from the pre-firing position to the extended position to the post-firing position.

5 29. The blood drawing device of claim 28, wherein the housing further comprises an interior and a latch pivotably coupled to the interior of the housing and pivotable between a blocking position and a triggering position.

30. The blood drawing device of claim 29 further comprising:
10 a reusable actuation device releasably coupled to the disposable collection cartridge, the reusable actuation device having a controller in electronic communication with the disposable collection cartridge;
a power source in electronic communication with the disposable collection cartridge; and
a vacuum source in fluid communication with the disposable collection cartridge.

15 31. The blood drawing device of claim 30, wherein the housing further comprises a heating element and a cooling element, the heating element and the cooling element coupled to the distal end of the housing proximate the aperture.

20 32. The blood drawing device of claim 31, wherein the reusable actuation device has a controller, the controller configured to control:
the vacuum source;
a mechanical actuation system configured to move the latch;
a temperature sensor coupled to the heating element;
25 a pressure sensor disposed within the disposable collection cartridge; and
a sample detection sensor disposed within the fluid collection chamber,
wherein the temperature sensor is coupled to the controller, and the controller is configured to adjust a temperature of the heating element based on a temperature detected by the temperature sensor and a desired temperature.

30 33. The blood drawing device of claim 31, wherein the vacuum source is a vacuum pump configured to provide vacuum proximate a target area while the slicing element is in a retracted pre-firing position and during movement of the slicing element into an extended fired position.

34. The blood drawing device of claim 31, wherein the heating element and the cooling element are a Peltier element configured to create a temperature difference in response to an electric current provided by the reusable actuation device.

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35. The blood drawing device of claim 29, wherein the latch prevents movement of the at least one slicing element in the blocking position, and

wherein movement of the latch into the triggering position allows the at least one slicing element to move from the pre-firing position to the fired position.

10

36. The blood drawing device of claim 35, wherein the latch has an interference surface, and wherein the interference surface engages the at least one slicing element in the blocking position and disengages the at least one slicing element in the triggering position.

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37. The blood drawing device of claim 35, wherein the at least one slicing element includes a first slicing element and a second slicing element,

wherein the latch comprises a first interference arm and a second interference arm, and

wherein the first interference arm engages a first slicing element in the blocking position and the second interference arm engages a second slicing element in the blocking position.

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38. The blood drawing device of claim 37, wherein movement of the latch from the blocking position to the triggering position disengages the first interference arm from the first slicing element at a first time and disengages the second interference arm from the second slicing element at a second time, and wherein the first time is before the second time.

25

39. The blood drawing device of claim 28, wherein the housing includes a guide extending generally along the lateral axis, the guide having two parallel guide rails spaced apart from each other.

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40. The blood drawing device of claim 39, wherein the at least one slicing element has a slicing element protrusion extending therefrom, the slicing element protrusion disposed in the guide and slidable along the guide when the at least one slicing element is moved.

41. The blood drawing device of claim 40, wherein the slicing element protrusion extends from the at least one slicing element proximate the proximal end.
42. The blood drawing device of claim 28, wherein the at least one fluid collection chamber
5 comprises a plurality of fluid collection chambers.
43. The blood drawing device of claim 42, wherein the plurality of fluid collection chambers are each movable relative to the aperture between a filling position and a standby position.
- 10 44. The blood drawing device of claim 43, wherein the filling position is spaced apart from the standby position.
45. The blood drawing device of claim 28, wherein the housing includes a housing protrusion extending therefrom, the housing protrusion slidably received in a slicing element guide defined on
15 the at least one slicing element and slidable along the slicing element guide when the at least one slicing element is moved.
46. The blood drawing device of claim 28, wherein the at least one fluid collection chamber extends at least partially through the at least one aperture.
- 20 47. The blood drawing device of claim 28, wherein the energy source is a torsion spring.
48. The blood drawing device of claim 28, wherein the pre-firing position is different than the post-firing position.
- 25 49. A blood drawing device for collecting a blood sample from a subject, the blood drawing device comprising:
a disposable collection cartridge having a housing, the housing having a proximal end and a distal end extending along a longitudinal axis and a first side and a second side extending along a
30 lateral axis, at least one aperture extending therethrough, and a guide extending along the lateral axis, the guide having two parallel guide rails spaced apart from each other;
at least one slicing element slidably coupled to the housing, the at least one slicing element having a distal end and a proximal end, and movable between a pre-firing position and a post-firing

position in which the distal end of the at least one slicing element is completely contained within the housing, and an extended position in which the distal end of the at least one slicing element extends through the aperture;

5 an energy source rotatably coupled to the housing and the at least one slicing element and configured to move the at least one slicing element relative to the housing from the pre-firing position to the extended position to the post-firing position; and

wherein the at least one slicing element includes a lancing end extending from the distal end thereof,

10 wherein the lancing end moves in a single direction along the lateral axis and both directions along the longitudinal axis when the at least one slicing element is moved from the pre-firing position to the extended position to the post-firing position, and

wherein the at least one slicing element has a slicing element protrusion extending therefrom, the slicing element protrusion disposed in the guide and slidable along the guide when the at least one slicing element is moved.

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