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(54) **APPARATUS FOR A MULTI-USE BODY FLUID SAMPLING DEVICE**

GERÄT FÜR EINE MEHRFACH VERWENDBARE VORRICHTUNG ZUR ENTNAHME VON KÖRPERFLÜSSIGKEITSPROBEN

APPAREIL POUR DISPOSITIF D'ECHANTILLONNAGE MULTI-FONCTION DE LIQUIDES ORGANIQUES

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Description

BACKGROUND OF THE INVENTION

[0001] Lancing devices are known in the medical health-care products industry for piercing the skin to produce blood for analysis. Typically, a drop of blood for this type of analysis is obtained by making a small incision in the fingertip, creating a small wound, which generates a small blood droplet on the surface of the skin.

[0002] Early methods of lancing included piercing or slicing the skin with a needle or razor. Current methods utilize lancing devices that contain a multitude of spring, cam and mass actuators to drive the lancet. These include cantilever springs, diaphragms, coil springs, as well as gravity plumbs used to drive the lancet. The device may be held against the skin and mechanically triggered to ballistically launch the lancet. Unfortunately, the pain associated with each lancing event using known technology discourages patients from testing. In addition to vibratory stimulation of the skin as the driver impacts the end of a launcher stop, known spring based devices have the possibility of firing lancets that harmonically oscillate against the patient tissue, causing multiple strikes due to recoil. This recoil and multiple strikes of the lancet is one major impediment to patient compliance with a structured glucose monitoring regime.

[0003] Another impediment to patient compliance is the lack of spontaneous blood flow generated by known lancing technology. In addition to the pain as discussed above, a patient may need more than one lancing event to obtain a blood sample since spontaneous blood generation is unreliable using known lancing technology. Thus the pain is multiplied by the number of attempts required by a patient to successfully generate spontaneous blood flow. Different skin thickness may yield different results in terms of pain perception, blood yield and success rate of obtaining blood between different users of the lancing device. Known devices poorly account for these skin thickness variations.

[0004] A still further impediment to improved compliance with glucose monitoring are the many steps and inconvenience associated with each lancing event. Many diabetic patients that are insulin dependent may need to self-test for blood glucose levels five to six times daily. The large number of steps required in traditional methods of glucose testing, ranging from lancing, to milking of blood, applying blood to a test strip, and getting the measurements from the test strip, discourages many diabetic patients from testing their blood glucose levels as often as recommended. Older patients and those with deteriorating motor skills encounter difficulty loading lancets into launcher devices, transferring blood onto a test strip, or inserting thin test strips into slots on glucose measurement meters. Additionally, the wound channel left on the patient by known systems may also be of a size that discourages those who are active with their hands or who are worried about healing of those wound channels from testing their glucose levels.

[0005] US 6228100 discloses a multi-use lancet device having a lancet receiving assembly containing at least two lancets disposed therein and structured to be independently moveable between a cocked and a fired orientation, and a firing assembly movably and operatively coupled with the lancet receiving assembly so as to be selectively and independently positioned in operative engagement with each of the lancets in order to define an active one of the lancets. The firing assembly is also structured to selectively move at least the active lancet between its cocked and its fired orientations.

[0006] EP 0985376 discloses a dispenser for lancets, used for drawing blood from a patient, that has a puncture instrument to hold a lancet, and a magazine with a supply of two or more lancets. The magazine has a mechanism to move the lancets, and an opening for the puncture instrument to be inserted and extract a lancet from the magazine. The protective shrouding for the lancet is discarded as the lancet is withdrawn from the magazine.

[0007] EP 0951939 discloses a stage container for holding analytical devices in respective chambers.

[0008] WO 02/00101 discloses an analyte monitoring device having a housing. The device comprises: a plurality of needles, each having a tip, a retracted position, a position wherein the tip is extended from the housing a distance adapted to pierce skin. An electrically or spring powered needle pushing apparatus is movable to separately engage each of the needles to move each from the retracted position to the extended position. An energy source is located within the housing. A plurality of analysis sites comprises an analysis preparation, each adapted to receive liquid from the needles to wet the analysis preparation. One or more light sources are adapted to direct light at the analysis sites. One or more light detectors are adapted to receive light from the analysis sites. The device further comprises a processor.

SUMMARY OF THE INVENTION

[0009] The present invention is defined by the appended claims.

[0010] A lancing system according to the present invention includes a cartridge. A plurality of penetrating members are coupled to the cartridge and are selectively actuatable to penetrate tissue. The penetrating members extend radially outward to penetrate tissue. An electrically powered drive force generator is operatively coupled to an active penetrating member to drive the penetrating member into a tissue site.

[0011] The system may include a penetrating member coupler attached the drive force generator, the coupler configured to establish a frictional coupling with an active one of the penetrating members.

[0012] The penetrating member coupler may be vertically movable.

[0013] The system may further include an actuator for rotating the radial cartridge.

[0014] The depth of penetration may be 100 to 2500 microns.

[0015] The depth of penetration may be 500 to 750 microns.

[0016] The depth of penetration may be no more than 1000 microns beyond a stratum corneum thickness of a skin surface.

[0017] The depth of penetration may be no more than 500 microns beyond a stratum corneum thickness of a skin surface.

[0018] The depth of penetration may be no more than 300 microns beyond a stratum corneum thickness of a skin surface.

[0019] The penetrating member sensor may be further configured to control velocity of a penetrating member.

[0020] The active penetrating member may move along a substantially linear path into the tissue. The active penetrating member may move along an at least partially curved path into the tissue.

[0021] The driver may be a voice coil drive force generator.

[0022] The driver may be a rotary voice coil drive force generator.

[0023] The system further comprises a processor, and the penetrating member sensor is coupled to this processor with control instructions for the penetrating member driver.

[0024] The processor includes a memory for storage and retrieval of a set of penetrating member profiles utilized with the penetrating member driver.

[0025] The processor may be utilized to monitor position and speed of a penetrating member as the penetrating member moves in a first direction.

[0026] The processor may be utilized to adjust an application of force to a penetrating member to achieve a desired speed of the penetrating member.

[0027] The processor may be utilized to adjust an application of force to a penetrating member when the penetrating member contacts a target tissue so that the penetrating member penetrates the target tissue within a desired range of speed.

[0028] The processor may be utilized to monitor position and speed of a penetrating member as the penetrating member moves in the first direction toward a target tissue, wherein the application of a launching force to the penetrating member is controlled based on position and speed of the penetrating member.

[0029] The processor may be utilized to control a withdraw force to the penetrating member so that the penetrating member moves in a second direction away from the target tissue.

[0030] The speed of a penetrating member in the first direction may be in the range of about 2.0 to 10.0 m/sec.

[0031] The average velocity of the penetrating member during a tissue penetration stroke in the first direction may be 100 to 1000 times greater than the average velocity of the penetrating member during a withdrawal stroke in a second direction.

BRIEF DESCRIPTION OF THE DRAWINGS

[0032]

Figure 1 is a perspective view illustrating a system, according to an embodiment for use in piercing skin to obtain a blood sample;

Figure 2 is a plan view of a portion of a replaceable penetrating member cartridge forming part of the system ;

Figure 3 is a cross-sectional end view on 3-3 in Figure 2;

Figure 4 is a cross-sectional end view on 4-4 in Figure 2;

Figure 5 is a perspective view of an apparatus forming part of the system and used for manipulating components of the cartridge, illustrating pivoting of a penetrating member accelerator in a downward direction;

Figure 6A is a view similar to Figure 5, illustrating how the cartridge is rotated or advanced;

Figure 6B is a cross-sectional side view illustrating how the penetrating member accelerator allows for the cartridge to be advanced;

Figure 7A and 7B are views similar to Figures 6A and 6B, respectively, illustrating pivoting of the penetrating member accelerator in an opposite direction to engage with a select one of the penetrating members in the cartridge ;

Figures 8A and 8B are views similar to Figures 7A and 7B, respectively, illustrating how the penetrating member accelerator moves the selected penetrating member to pierce skin;

Figures 9A and 9B are views similar to Figures 8A and 8B, respectively, illustrating how the penetrating member accelerator returns the penetrating member to its original position;

Figure 10 is a block diagram illustrating functional components of the apparatus; and

Figure 11 is an end view illustrating a cartridge according to an optional embodiment that allows for better adhesion of sterilization barriers.

DESCRIPTION OF THE SPECIFIC EMBODIMENTS

[0033] The present invention provides a multiple analyte detecting member solution for body fluid sampling. Specifically, some embodiments of the present invention provides a multiple analyte detecting member and multiple lancet solution to measuring analyte levels in the body.

[0034] The invention may use a high density design. It may use lancets of smaller size than known lancets. The device may be used for multiple lancing events without having to remove a disposable from the device. The invention may provide improved sensing capabilities. At least some of these and other objectives described herein will be met by embodiments of the present invention.

[0035] It is to be understood that both the foregoing general description and the following detailed description are exemplary and explanatory only and are not restrictive of the invention, as claimed. It must be noted that, as used in the specification and the appended claims, the singular forms"a", "an"and"the"include plural referents unless the context clearly dictates otherwise. Thus, for example, reference to"a material"may include mixtures of materials, reference to"a chamber"may include multiple chambers, and the like. In this specification and in the claims which follow, reference will be made to a number of terms which shall be defined to have the following meanings: "Optional"or"optionally"means that the subsequently described circumstance may or may not occur, so that the description includes instances where the circumstance occurs and instances where it does not. For example, if a device optionally contains a feature for analyzing a blood sample, this means that the analysis feature may or may not be present, and, thus, the description includes structures wherein a device possesses the analysis feature and structures wherein the analysis feature is not present.

[0036] "Analyte detecting member"refers to any use, singly or in combination, of chemical test reagents and methods, electrical test circuits and methods, physical test components and methods, optical test components and methods, and biological test reagents and methods to yield information about a blood sample. Such methods are well known in the art and may be based on teachings of, e. g. Tietz Textbook of Clinical Chemistry, 3d Ed. , Sec. V, pp. 776-78 (Burtis & Ashwood, Eds. , W. B. Saunders Company, Philadelphia, 1999) ; U. S. Pat. No. 5,997, 817 to Chrismore et al. (Dec. 7,1999) ; U. S. Pat. No. 5,059, 394 to Phillips et al. (Oct. 22, 1991) ; U. S.Pat. No. 5,001, 054 to Wagner et al. (Mar. 19, 1991) ; and U. S. Pat. No. 4,392, 933 to Nakamura et al. (July 12,1983). Analyte detecting member may include tests in the sample test chamber that test electrochemical properties of the blood, or they may include optical means for sensing optical properties of the blood (e. g. oxygen saturation level), or they may include biochemical reagents (e. g. antibodies) to sense properties (e. g. presence of antigens) of the blood. The analyte detecting member may comprise biosensing or reagent material that will react with an analyte in blood (e. g. glucose) or other body fluid so that an appropriate signal correlating with the presence of the analyte is generated and can be read by the reader apparatus. By way of example and not limitation, analyte detecting member may"associated with","mounted within", or "coupled to"a chamber or other structure when the analyte detecting member participates in the function of providing an appropriate signal about the blood sample to the reader device. Analyte detecting member may also include nanowire analyte detecting members as described herein.

[0037] Analyte detecting member may use potentiometric, coulometric, or other method useful for detection of analyte levels.

[0038] Figures 1-11 of the accompanying drawings illustrates one embodiment of a system 10 for piercing skin to obtain a blood sample. The system 10 may include a replaceable cartridge 12 and an apparatus 14 for removably receiving the cartridge 12 and for manipulating components of the cartridge 12.

[0039] Referring jointly to Figures 1 and 2, the cartridge 12 may include a plurality of penetrating members 18. The cartridge 12 may be in the form of a circular disc and has an outer circular surface 20 and an opening forming an inner circular surface 22. A plurality of grooves 24 are formed in a planar surface 26 of the cartridge 12. Each groove 24 is elongated and extends radially out from a center point of the cartridge 12. Each groove 24 is formed through the outer circular surface 20. Although not shown, it should be understood that the grooves 24 are formed over the entire circumference of the planar surface 26. As shown in Figures 3 and 4, each groove 24 is relatively narrow closer to the center point of the cartridge 12 and slightly wider further from the center point. These grooves 24 may be molded into the cartridge 12, machined into the cartridge, or formed using other methods useful in the manufacture of medical devices.

[0040] In the present embodiment, each penetrating member 18 has an elongated body 26 and a sharpened distal end 27 having a sharp tip 30. The penetrating member 18 may have a circular in cross-section with a diameter in this embodiment of about 0.315 mm. All outer surfaces of the penetrating member 18 may have the same coefficient of friction. The penetrating member may be , but is not necessarily, a bare lancet. The lancet is "bare", in the sense that no raised formations or molded parts are formed thereon that are complementarily engageable with another structure. Traditional lancets include large plastic molded parts that are used to facilitate engagement. Unfortunately, such attachments add size and cost. In the most basic sense, a bare lancet or bare penetrating member is an elongate wire having sharpened end. If it is of sufficiently small diameter, the tip may be penetrating without having to be sharpened. A bare lancet may be bent and still be considered a bare lancet. The bare lancet in one embodiment may be made of one material.

[0041] In the present embodiment, each penetrating member 18 is located in a respective one of the grooves 24. The penetrating members 18 have their sharpened distal ends 27 pointed radially out from the center point of the cartridge 12. A proximal end of each penetrating member 15 may engage in an interference fit with opposing sides of a respective groove 24 as shown in Figure 3. Other embodiments of the cartridge 12 may not use such an interference fit. For example, they may use a fracturable adhesive to releasably secure the penetrating member 18 to the cartridge 12. As shown in Figure 4, more distal portions of the penetrating member 18 are not engaged with the opposing sides of the groove 24 due to the larger spacing between the sides.

[0042] The cartridge 12 may further include a steriliza-

tion barrier 28 attached to the upper surface 26. The sterilization barrier 28 is located over the penetrating members 18 and serves to insulate the penetrating members 18 from external contaminants. The sterilization barrier 28 is made of a material that can easily be broken when an edge of a device applies a force thereto. The sterilization barrier 28 alone or in combination with other barriers may be used to create a sterile environment about at least the tip of the penetrating member prior to lancing or actuation. The sterilization barrier 28 may be made of a variety of materials such as but not limited to metallic foil, aluminum foil, paper, polymeric material, or laminates combining any of the above. Other details of the sterilization barrier are detailed herein.

[0043] In the present embodiment, the apparatus 14 may include a housing 30, an initiator button 32, a penetrating member movement subassembly 34, a cartridge advance subassembly 36, batteries 38, a capacitor 40, a microprocessor controller 42, and switches 44. The housing 30 may have a lower portion 46 and a lid 48. The lid 48 is secured to the lower portion 46 with a hinge 50. The lower portion 46 may have a recess 52. A circular opening 54 in the lower portion 46 defines an outer boundary of the recess 52 and a level platform 56 of the lower portion 46 defines a base of the recess 52.

[0044] In use, the lid 48 of the present embodiment is pivoted into a position as shown in Figure 1. The cartridge 12 is flipped over and positioned in the recess 52. The planar surface 26 rests against the level platform 56 and the circular opening 54 contacts the outer circular surface 20 to prevent movement of the cartridge 12 in a plane thereof. The lid 48 is then pivoted in a direction 60 and closes the cartridge 12.

[0045] Referring to the embodiment shown in Figure 5, the penetrating member movement subassembly 34 includes a lever 62, a penetrating member accelerator 64, a linear actuator 66, and a spring 68. Other suitable actuators including but not limited to rotary actuators are described in commonly assigned, copending U.S. Patent Application Ser. No. 10/127,395 (Attorney Docket No. 38187-2551) filed April 19, 2002. The lever 62 may be pivotably secured to the lower portion 46. The button 32 is located in an accessible position external of the lower portion 46 and is connected by a shaft 70 through the lower portion 46 to one end of the lever 62. The penetrating member accelerator 64 is mounted to an opposing end of the lever 62. A user depresses the button 32 in an upward direction 66 so that the shaft 70 pivots the end of the lever 62 to which it is connected in an upward direction. The opposing end of the lever pivots in a downward direction 66. The spring 46 is positioned between the button 32 and the base 40 and compresses when the button 32 is depressed to create a force that tends to move the button 32 down and pivot the penetrating member accelerator upward in a direction opposite to the direction 64.

[0046] Referring to Figures 6A and 6B in this particular embodiment, the movement of the button into the position shown in Figure 5 also causes contact between a terminal 74 on the shaft 20 with a terminal 70 secured to the lower portion 46. Contact between the terminals 74 and 76 indicates that the button 32 has been fully depressed. With the button 32 depressed, the cartridge 12 can be rotated without interference by the penetrating member actuator 64. To this effect, the cartridge advancer subsystem 36 includes a pinion gear 80 and a stepper motor 82. The stepper motor 82 is secured to the lower portion 46. The pinion gear 80 is secured to the stepper motor 82 and is rotated by the stepper motor 82. Teeth on the pinion gear 80 engage with teeth on the inner circular surface 22 of the cartridge 12. Rotation of the pinion gear 80 causes rotation of the cartridge 12 about the center point thereof. Each time that the terminals 74 and 76 make contact, the stepper motor 82 is operated to rotate the cartridge 12 through a discrete angle equal to an angular spacing from a centerline of one of the penetrating members 18 to a centerline of an adjacent penetrating member. A select penetrating member 18 is so moved over the penetrating member accelerator 64, as shown in Figure 6B. Subsequent depressions of the button 32 will cause rotation of subsequent adjacent penetrating members 18 into a position over the penetrating member accelerator 64.

[0047] The user then releases pressure from the button, as shown in Figure 7A. The force created by the spring 68 or other resilient member moves the button 32 in a downward direction 76. The shaft 70 is pivotably secured to the lever 62 so that the shaft 70 moves the end of the lever 62 to which it is connected down. The opposite end of the lever 62 pivots the penetrating member accelerator 64 upward in a direction 80. As shown in Figure 7B, an edge 82 of the penetrating member accelerator 64 breaks through a portion of the sterilization barrier 28 and comes in to physical contact with a lower side surface of the penetrating member 18.

[0048] Referring to Figure 8A, the linear actuator 66 includes separate advancing coils 86A and retracting coils 86B, and a magnetizable slug 90 within the coils 86A and 86B. The coils 86A and 86B are secured to the lower portion of 46, and the slug 90 can move within the coils 86A and 88B. Once the penetrating member accelerator 64 is located in the position shown in Figures 7A and 7B, electric current is provided to the advancing coils 86 only. The current in the advancing coils 86 creates a force in a direction 88 on the slug 90 according to conventional principles relating to electromagnetics.

[0049] A bearing 91 is secured to the lever and the penetrating member accelerator 64 has a slot 92 over the bearing 91. The slot 92 allows for the movement of the penetrating member accelerator 64 in the direction 88 relative to the lever 62, so that the force created on the slug moves the penetrating member accelerator 64 in the direction 88.

[0050] The spring 68 is not entirely relaxed, so that the spring 68, through the lever 62, biases the penetrating member accelerator 64 against the lower side surface of

the penetrating member 18 with a force F1. The penetrating member 18 rests against a base 88 of the cartridge 12. An equal and opposing force F2 is created by the base 88 on an upper side surface of the penetrating member 18.

[0051] The edge 82 of the penetrating member accelerator 64 has a much higher coefficient of friction than the base 88 of the cartridge 12. The higher coefficient of friction of the edge contributes to a relatively high friction force F3 on the lower side surface of the penetrating member 18. The relatively low coefficient of friction of the base 88 creates a relatively small friction force F4 on the upper side surface of the penetrating member 18. A difference between the force F3 and F4 is a resultant force that accelerates the penetrating member in the direction 88 relative to the cartridge 12. The penetrating member is moved out of the interference fit illustrated in Figure 3. The bare penetrating member 18 is moved without the need for any engagement formations on the penetrating member. Current devices, in contrast, often make use a plastic body molded onto each penetrating member to aid in manipulating the penetrating members. Movement of the penetrating member 18 moves the sharpened end thereof through an opening 90 in a side of the lower portion 46. The sharp end 30 of the penetrating member 18 is thereby moved from a retracted and safe position within the lower portion 46 into a position wherein it extends out of the opening 90. Accelerated, high-speed movement of the penetrating member is used so that the sharp tip 30 penetrates skin of a person. A blood sample can then be taken from the person, typically for diabetic analysis.

[0052] Reference is now made to Figures 9A and 9B. After the penetrating member is accelerated (for example, but not limitation, less than .25 seconds thereafter), the current to the accelerating coils 86A is turned off and the current is provided to the retracting coils 86B. The slug 90 moves in an opposite direction 92 together with the penetrating member accelerator 64. The penetrating member accelerator 64 then returns the used penetrating member into its original position, i.e., the same as shown in Figure 7B.

[0053] Subsequent depression of the button as shown in Figure 5 will then cause one repetition of the process described, but with an adjacent sterile penetrating member. Subsequent sterile penetrating members can so be used until all the penetrating members have been used, i.e., after one complete revolution of the cartridge 12. In this embodiment, a second revolution of the cartridge 12 is disallowed to prevent the use of penetrating members that have been used in a previous revolution and have become contaminated. The only way in which the user can continue to use the apparatus 14 is by opening 'the lid 48 as shown in Figure 1, removing the used cartridge 12, and replacing the used cartridge with another cartridge. A analyte detecting member (not shown) detects whenever a cartridge is removed and replaced with another cartridge. Such a analyte detecting member may be but is not limited to an optical analyte detecting member, an electrical contact analyte detecting member, a bar code reader, or the like.

[0054] Figure 10 illustrates the manner in which the electrical components may be functionally interconnected for the present embodiment. The battery 38 provides power to the capacitor 40 and the controller 42. The terminal 76 is connected to the controller 42 so that the controller recognizes when the button 32 is depressed. The capacitor to provide power (electric potential and current) individually through the switches (such as field-effect transistors) to the advancing coils 86A, retracting coils 86B and the stepper motor 82. The switches 44A, B, and C are all under the control of the controller 42. A memory 100 is connected to the controller. A set of instructions is stored in the memory 100 and is readable by the controller 42. Further functioning of the controller 42 in combination with the terminal 76 and the switches 44A, B, and C should be evident from the foregoing description.

[0055] Figure 11 illustrates a configuration for another example of a cartridge having penetrating members. The cartridge 112 has a corrugated configuration and a plurality of penetrating members 118 in grooves 124 formed in opposing sides of the cartridge 112. Sterilization barriers 126 and 128 are attached over the penetrating members 118 at the top and the penetrating members 118 at the bottom, respectively. Such an arrangement provides large surfaces for attachment of the sterilization barriers 126 and 128. All the penetrating members 118 on the one side are used first, whereafter the cartridge 112 is turned over and the penetrating members 118 on the other side are used.

Claims

1. A lancing system (10) comprising:

a cartridge (12);

a plurality of penetrating members (18) coupled to said cartridge and selectively actuatable to penetrate tissue, said penetrating members extending radially outward to penetrate tissue; and

characterised by

an electrically powered drive force generator (66) configured to be coupled to an active one of the penetrating members and to drive said active penetrating member into a tissue site, and

further comprising a penetrating member sensor positioned to monitor said active penetrating member, the penetrating member sensor being configured to provide information relative to a depth of penetration of a penetrating member through a skin surface, and

further comprising a processor (42) with control instructions for the penetrating member drive force generator, wherein the penetrating member sensor is coupled to said processor (42),

wherein the processor includes a memory (100) for storage and retrieval of a set of penetrating member profiles utilized with the penetrating member driver.

2. The system of any preceding claim, further comprising a penetrating member coupler (250) attached to the drive force generator (66), the coupler being configured to establish a frictional coupling with an active penetrating member (18).

3. The system of claim 2, wherein said penetrating member coupler (250) is vertically movable.

4. The system of any preceding claim, further comprising an actuator for rotating said cartridge.

5. The system of any preceding claim, wherein the depth of penetration is 100 to 2500 microns, and preferably wherein the depth of penetration is 500 to 750 microns.

6. The system of any preceding claim, wherein the depth of penetration is no more than (i) 1000 microns beyond a stratum corneum thickness of a skin surface; (ii) 500 microns beyond a stratum corneum thickness of a skin surface; or (iii) 300 microns beyond a stratum corneum thickness of a skin surface.

7. The system of any preceding claim, wherein the penetrating member sensor is further configured to control velocity of a penetrating member.

8. The system of any preceding claim, wherein the active penetrating member moves along a substantially linear path into the tissue.

9. The system of any of claims 1-7, wherein the active penetrating member moves along an at least partially curved path into the tissue.

10. The system of any preceding claim, wherein the drive force generator is (i) a voice coil drive force generator; or (ii) a rotary voice coil drive force generator.

11. The system of claim 1, wherein the processor (42) is operable to be utilized to monitor position and speed of a penetrating member as the penetrating member moves in a first direction toward a target tissue, , wherein the application of a launching force to the penetrating member is controlled based on position and speed of the penetrating member.

12. The system of claim 1, wherein the processor is operable to be utilized to (i) adjust an application of force to a penetrating member to achieve a desired speed of the penetrating member; or (ii) control a withdraw force to the penetrating member so that the penetrating member moves in a second direction away from the target tissue.

13. The system of claim 11, operable such that a speed of a penetrating member in the first direction is the range of about 2.0 to 10.0 m/sec.

14. The system of claim 12, operable such that the average velocity of the penetrating member during a tissue penetration stroke in the first direction is between 100 and 1000 times greater than the average velocity of the penetrating member during a withdrawal stroke in a second direction.

Patentansprüche

1. Lanzettensystem (10), umfassend:

eine Kartusche (12);
eine Vielzahl von Penetrationselementen (18), die mit der Kartusche verbunden sind und zur Penetration von Gewebe selektiv betätigt werden können, wobei sich die Penetrationselemente zur Penetration von Gewebe radial nach außen erstrecken;

und **gekennzeichnet durch**

einen elektrisch angetriebenen Antriebskraftgenerator (66), der ausgelegt ist, um mit einem aktiven der Penetrationselemente verbunden zu werden und das aktive Penetrationselement in eine Gewebestelle zu treiben, und
ferner umfassend einen Penetrationselementsensor, der zur Überwachung des aktiven Penetrationselements angeordnet ist, wobei der Penetrationselementsensor ausgelegt ist, Informationen bezüglich einer Penetrationstiefe eines Penetrationselements **durch** eine Hautoberfläche bereitzustellen,
und
ferner umfassend einen Prozessor (42) mit Kontrollanweisungen für den Antriebskraftgenerator der Penetrationselemente,
wobei der Penetrationselementsensor mit dem Prozessor (42) verbunden ist, und
wobei der Prozessor einen Speicher (100) zum Speichern und Abrufen eines Satzes von Penetrationselementprofilen, die mit dem Penetrationselementantrieb verwendet werden, aufweist.

2. System nach einem der vorhergehenden Ansprüche, ferner umfassend ein Penetrationselementverbindungsglied (250), das an dem Antriebskraftgenerator (66) befestigt ist, wobei das Verbindungsglied ausgelegt ist, um eine Reibungskupplung mit einem

aktiven Penetrationselement (18) herzustellen.

3. System nach Anspruch 2, wobei das Penetrationselementverbindungsglied (250) vertikal beweglich ist.

4. System nach einem der vorhergehenden Ansprüche, ferner umfassend ein Betätigungsglied zur Drehung der Kartusche.

5. System nach einem der vorhergehenden Ansprüche, wobei die Penetrationstiefe 100 bis 2500 Mikron beträgt und wobei die Penetrationstiefe vorzugsweise 500 bis 750 Mikron beträgt.

6. System nach einem der vorhergehenden Ansprüche, wobei die Penetrationstiefe nicht mehr als (i) 1000 Mikron über eine Dicke des Stratum corneum einer Hautoberfläche hinaus; (ii) 500 Mikron über eine Dicke des Stratum corneum einer Hautoberfläche hinaus; oder (iii) 300 Mikron über eine Dicke des Stratum corneum einer Hautoberfläche hinaus beträgt.

7. System nach einem der vorhergehenden Ansprüche, wobei der Penetrationselementsensor ferner zur Kontrolle der Geschwindigkeit eines Penetrationselements ausgelegt ist.

8. System nach einem der vorhergehenden Ansprüche, wobei sich das aktive Penetrationselement entlang eines im Wesentlichen linearen Wegs in das Gewebe bewegt.

9. System nach einem der Ansprüche 1-7, wobei sich das aktive Penetrationselement entlang eines wenigstens teilweise gebogenen Wegs in das Gewebe bewegt.

10. System nach einem der vorhergehenden Ansprüche, wobei der Antriebskraftgenerator (i) ein Schwingspulen-Antriebskraftgenerator; oder (ii) ein drehender Schwingspulen Antriebskraftgenerator ist.

11. System nach Anspruch 1, wobei der Prozessor (42) betätigt werden kann, um zur Überwachung der Position und Geschwindigkeit eines Penetrationselements verwendet zu werden, wenn sich das Penetrationselement in eine erste Richtung zu einem Zielgewebe hin bewegt, wobei das Aufbringen einer Startkraft auf das Penetrationselement auf Basis der Position und Geschwindigkeit des Penetrationselements gesteuert wird.

12. System nach Anspruch 1, wobei der Prozessor betätigt werden kann, um (i) zur Einstellung des Aufbringens einer Kraft auf eine Penetrationselement zur Erzielung einer gewünschten Geschwindigkeit des Penetrationselements; oder (ii) zur Kontrolle einer Rückzugskraft auf das Penetrationselement verwendet zu werden, so dass sich das Penetrationselement in eine zweite Richtung von dem Zielgewebe weg bewegt.

13. System nach Anspruch 11, das so betätigbar ist, dass eine Geschwindigkeit eines Penetrationselements in die erste Richtung im Bereich von ungefähr 2,0 bis 10,0 m/Sek liegt.

14. System nach Anspruch 12, das so betätigbar ist, dass die durchschnittliche Geschwindigkeit des Penetrationselements während eines Gewebepenetrationshubs in die erste Richtung zwischen 100 und 1000 Mal größer als die durchschnittliche Geschwindigkeit des Penetrationselements während eines Rückzugshubs in eine zweite Richtung ist.

Revendications

1. Système d'auto-piquage (10) comprenant :

une cartouche (12) ;
une pluralité d'organes de pénétration (18) accouplés à ladite cartouche et pouvant être actionnés, de manière sélective, de façon à pénétrer dans un tissu, lesdits organes de pénétration s'étendant radialement vers l'extérieur afin de pénétrer dans un tissu ; et
caractérisé par
un générateur de force d'enfoncement électrique (66) configuré pour être accouplé à un organe actif parmi les organes de pénétration et pour enfoncer ledit organe de pénétration actif dans un site tissulaire, et
comprenant en outre un capteur d'organe de pénétration positionné de façon à surveiller ledit organe de pénétration actif, le capteur d'organe de pénétration étant configuré pour fournir des informations concernant une profondeur de pénétration d'un organe de pénétration à travers une surface de la peau, et comprenant en outre un processeur (42) avec des instructions de commande pour le générateur de force d'enfoncement d'organe de pénétration, le capteur d'organe de pénétration étant raccordé audit processeur (42), et le processeur comprenant une mémoire (100) servant au stockage et à l'extraction d'un ensemble de profils d'organe de pénétration utilisés avec le dispositif d'enfoncement d'organe de pénétration.

2. Système selon l'une quelconque des revendications précédentes, comprenant en outre un dispositif d'accouplement d'organe de pénétration (250) attaché

au générateur de force d'enfoncement (66), le dispositif d'accouplement étant configuré pour établir un accouplement par frottement avec un organe de pénétration actif (18).

3. Système selon la revendication 2, dans lequel ledit dispositif d'accouplement d'organe de pénétration (250) peut être déplacé verticalement.

4. Système selon l'une quelconque des revendications précédentes, comprenant en outre un dispositif d'actionnement servant à faire tourner ladite cartouche.

5. Système selon l'une quelconque des revendications précédentes, dans lequel la profondeur de pénétration est de 100 à 2500 micromètres, et de préférence dans lequel la profondeur de pénétration est de 500 à 750 micromètres.

6. Système selon l'une quelconque des revendications précédentes, dans lequel la profondeur de pénétration est d'au plus (i) 1000 micromètres au-delà d'une épaisseur de couche cornée d'une surface de la peau ; (ii) 500 micromètres au-delà d'une épaisseur de couche cornée d'une surface de la peau ; ou (iii) 300 micromètres au-delà d'une épaisseur de couche cornée d'une surface de la peau.

7. Système selon l'une quelconque des revendications précédentes, dans lequel le capteur d'organe de pénétration est configuré en outre pour réguler la vélocité d'un organe de pénétration.

8. Système selon l'une quelconque des revendications précédentes, dans lequel l'organe de pénétration actif se déplace le long d'une trajectoire essentiellement linéaire dans le tissu.

9. Système selon l'une quelconque des revendications 1 à 7, dans lequel l'organe de pénétration actif se déplace le long d'une trajectoire au moins partiellement courbe dans le tissu.

10. Système selon l'une quelconque des revendications précédentes, dans lequel le générateur de force d'enfoncement est (i) un générateur de force d'enfoncement à bobine acoustique ; ou (ii) un générateur de force d'enfoncement à bobine acoustique rotatif.

11. Système selon la revendication 1, dans lequel le processeur (42) peut être mis en oeuvre pour être utilisé afin de surveiller la position et la vitesse d'un organe de pénétration à mesure que l'organe de pénétration se déplace dans une première direction vers un tissu cible, dans lequel l'application d'une force d'impulsion à l'organe de pénétration est régulée en fonction de la position et de la vitesse de l'organe de pénétration.

12. Système selon la revendication 1, dans lequel le processeur peut être mis en oeuvre pour être utilisé afin (i) d'ajuster une application de force à un organe de pénétration pour obtenir une vitesse souhaitée de l'organe de pénétration ; ou (ii) de réguler une force de retrait appliquée à l'organe de pénétration de telle sorte que l'organe de pénétration se déplace dans une seconde direction s'éloignant du tissu cible.

13. Système selon la revendication 11, pouvant être mis en oeuvre de telle sorte qu'une vitesse d'un organe de pénétration dans la première direction se situe dans la plage d'environ 2 à 10 m/s.

14. Système selon la revendication 12, pouvant être mis en oeuvre de telle sorte que la vélocité moyenne de l'organe de pénétration lors d'un mouvement de pénétration dans un tissu dans la première direction soit entre 100 et 1000 fois supérieure à la vélocité moyenne de l'organe de pénétration lors d'un mouvement de retrait dans une seconde direction.

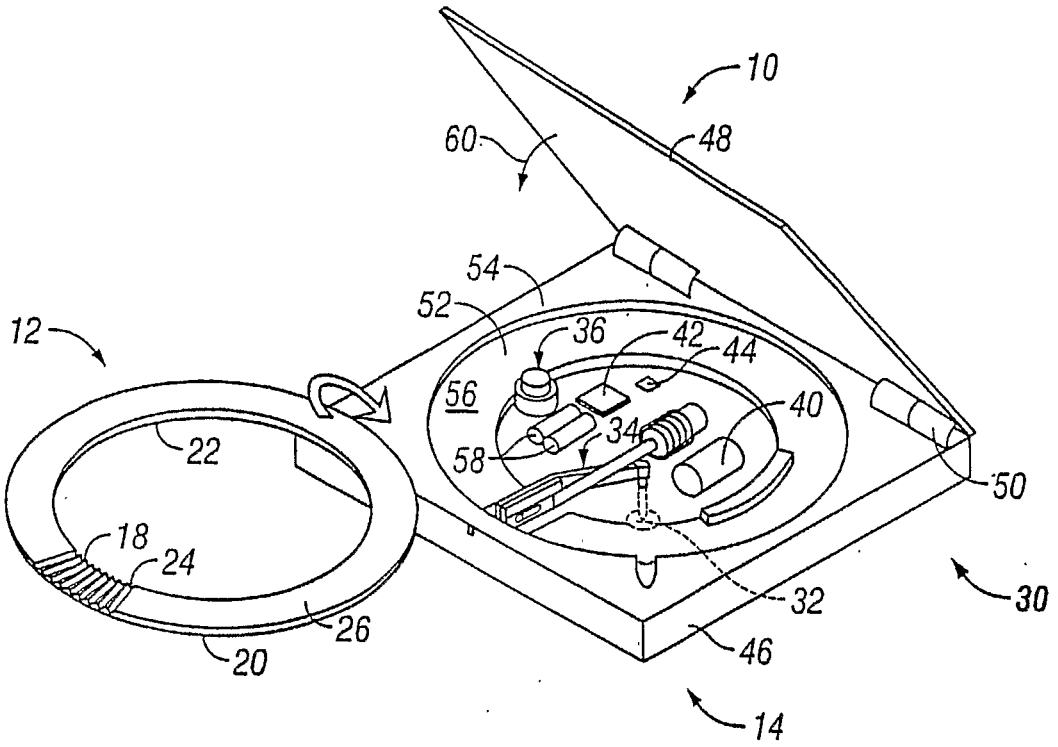


FIG. 1

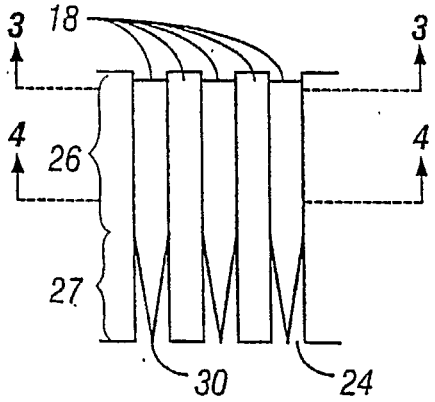
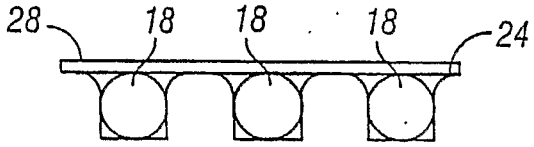


FIG. 2



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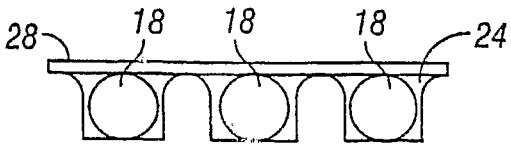


FIG. 4

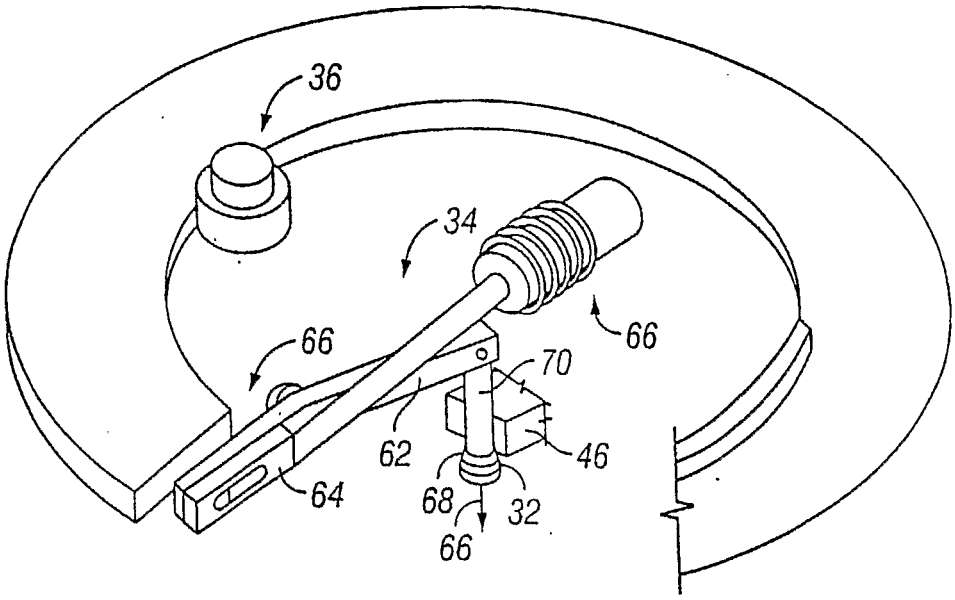


FIG. 5

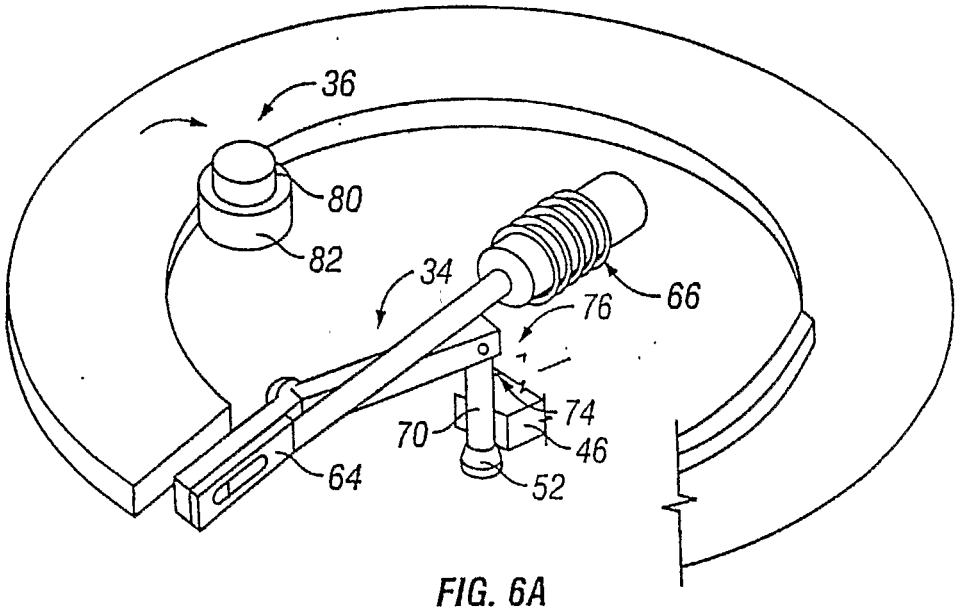


FIG. 6A

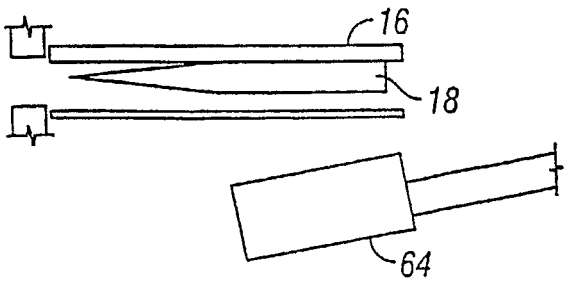


FIG. 6B

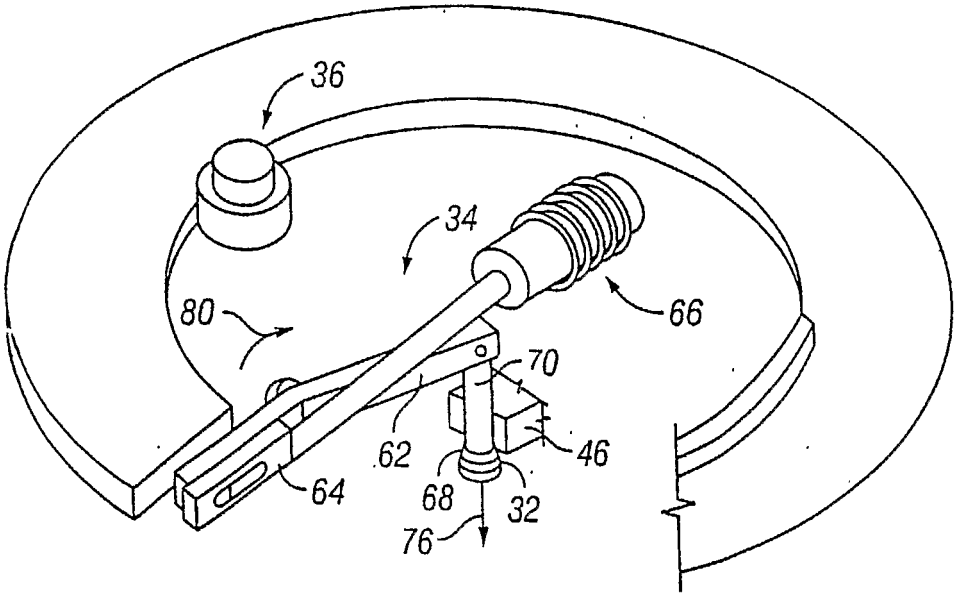
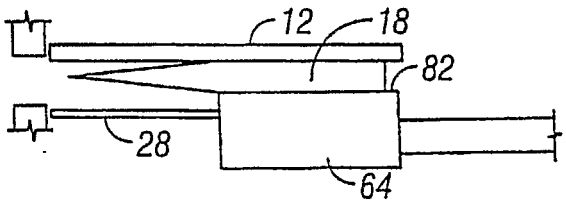
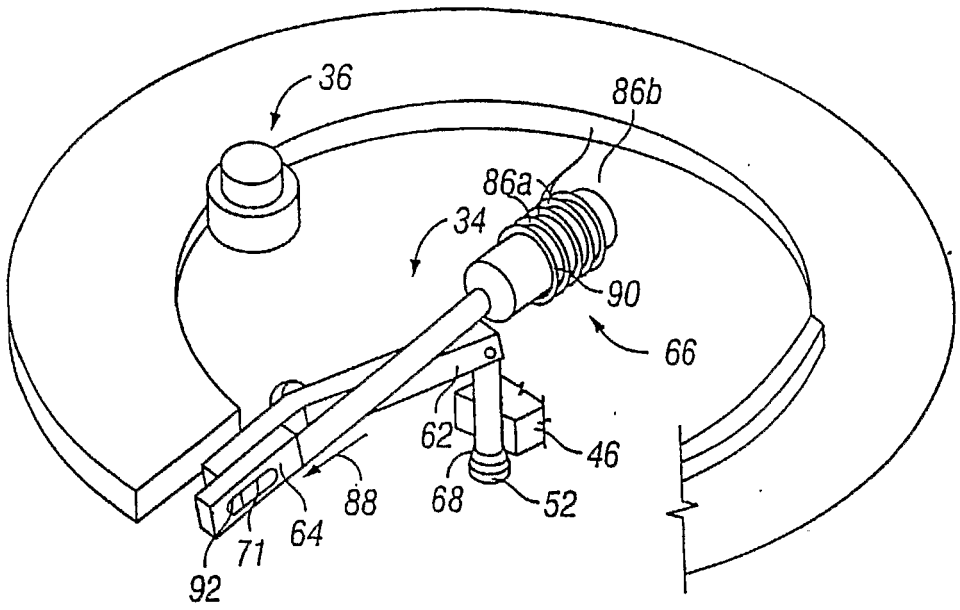


FIG. 7A

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86b
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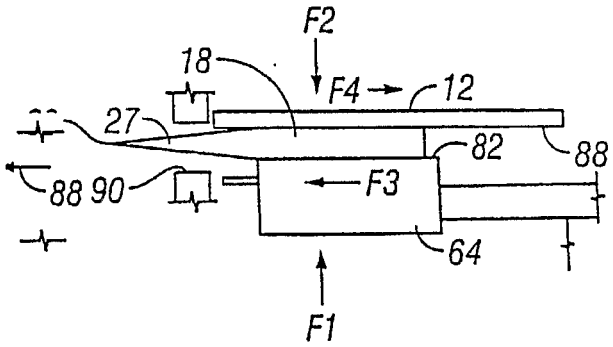
71
92

FIG. 8A


F2
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F3
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F1

FIG. 8B

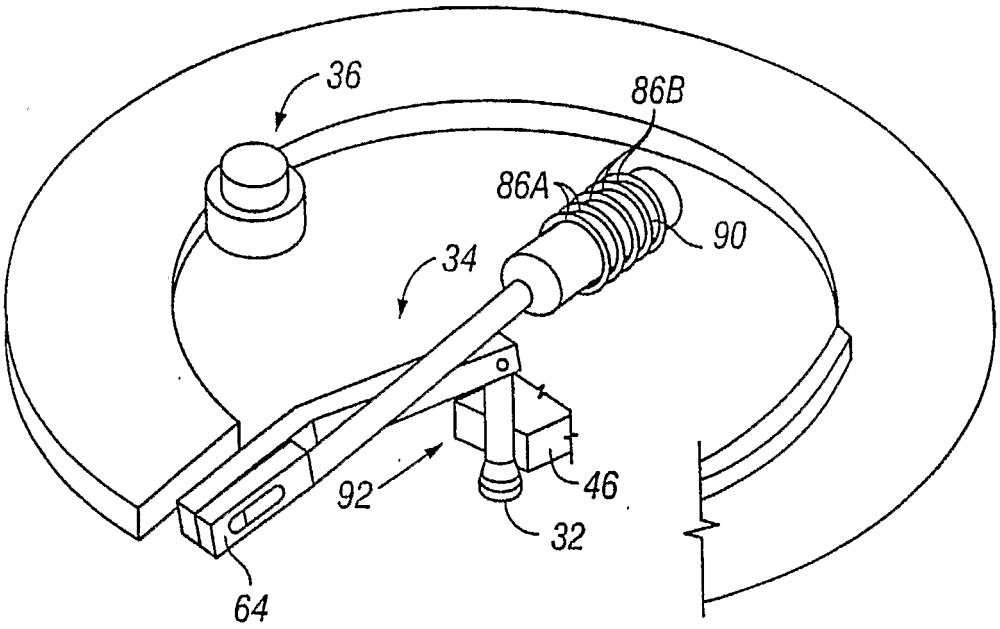


FIG. 9A

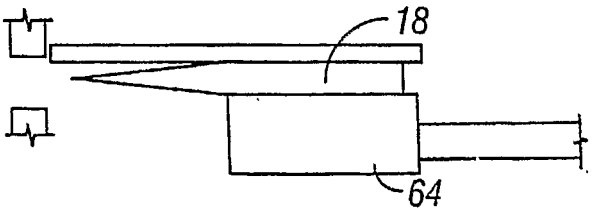
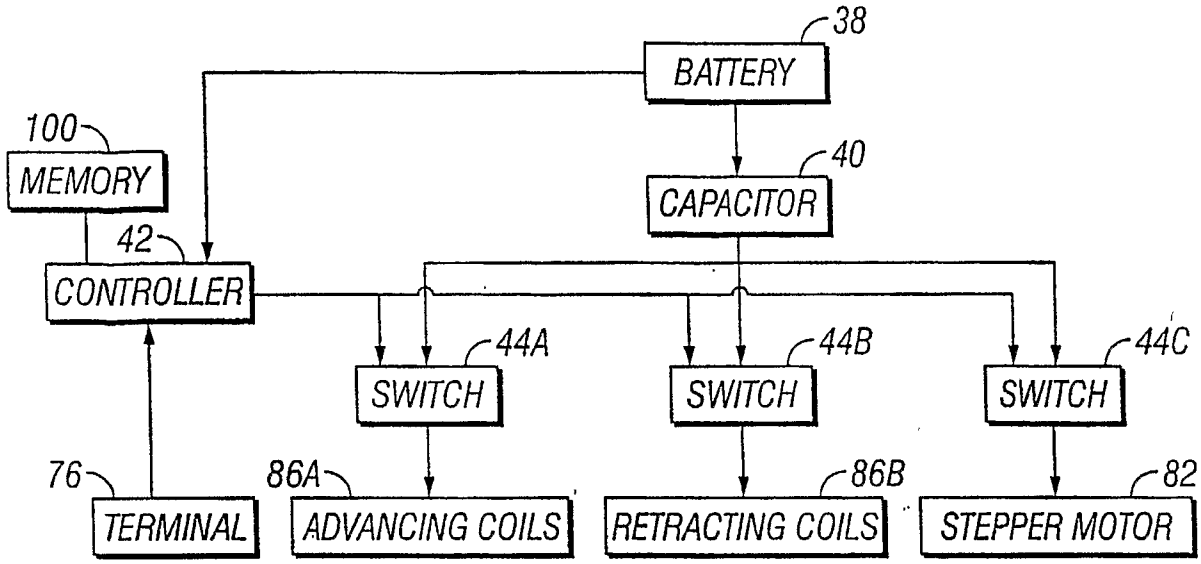


FIG. 9B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MEMORY
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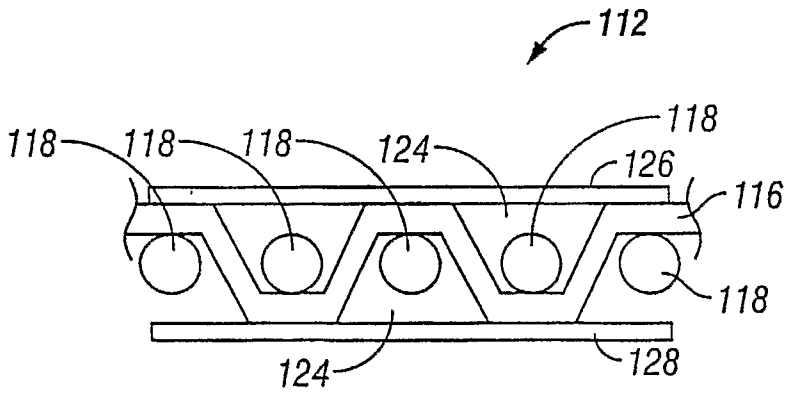
CAPACITOR
42
CONTROLLER
44A
SWITCH
44B
SWITCH
44C
SWITCH
76
TERMINAL
86A
ADVANCING COILS
86B
RETRACTING COILS
82
STEPPER MOTOR

FIG. 10


112
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128

FIG. 11

REFERENCES CITED IN THE DESCRIPTION

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专利名称(译)	用于多用途体液采样装置的装置		
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[标]申请(专利权)人(译)	佩利坎技术公司		
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IPC分类号	A61B5/145 A61B5/1455 A61B5/1486 A61B5/15 A61B5/151 A61B5/155 G01N33/483 A61B5/00 A61B5/1459 A61B5/157 G01N37/00		
CPC分类号	A61B5/1411 A61B5/1427 A61B5/14532 A61B5/14546 A61B5/1455 A61B5/1486 A61B5/150022 A61B5/150152 A61B5/150167 A61B5/150175 A61B5/150221 A61B5/150358 A61B5/150412 A61B5/150427 A61B5/150503 A61B5/150519 A61B5/150572 A61B5/150664 A61B5/150824 A61B5/15087 A61B5/150916 A61B5/151 A61B5/15113 A61B5/15117 A61B5/15123 A61B5/1513 A61B5/15146 A61B5/15151 A61B5/15153 A61B5/15161 A61B5/15163 A61B5/15169 A61B5/15171 A61B5/15178 A61B5/15182 A61B5/15184 A61B5/15186 A61B5/157 A61M37/0015		
代理机构(译)	MCDOUGALL，JAMES		
优先权	10/335218 2002-12-31 US 10/335212 2002-12-31 US 10/237261 2002-09-05 US 60/428084 2002-11-20 US 60/424429 2002-11-06 US 10/335241 2002-12-31 US 60/393706 2002-07-01 US 10/335211 2002-12-31 US 10/335073 2002-12-31 US 10/335182 2002-12-31 US 10/335217 2002-12-31 US 10/335219 2002-12-31 US 60/422988 2002-11-01 US 10/335257 2002-12-31 US 10/335259 2002-12-31 US 10/127395 2002-04-19 US		

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其他公开文献	EP1501409A1 EP1501409A4
外部链接	Espacenet

摘要(译)

本发明的这些和其他目的在一种用于组织部位的体液采样系统中得以实现，该体液采样系统包括电动驱动力发生器。 穿透构件可操作地联接至力产生器。 力产生器沿着路径将构件从具有穿透构件出口的壳体移出到组织部位中，在组织部位中停下来，并退出组织部位。 分析物检测构件被定位成从由穿透构件产生的伤口接收流体。 检测构件被配置成使用小于1μL的流体的样品来确定流体中的分析物的浓度。 用户界面被配置为中继穿透构件性能或穿透构件设置中的至少一项。

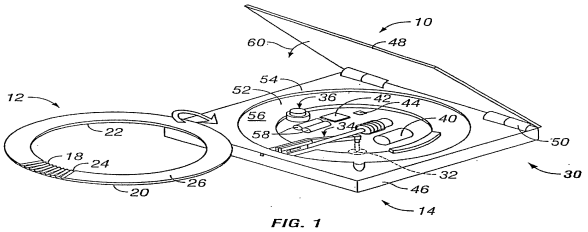

FIG. 1

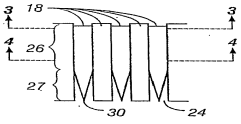

FIG. 2

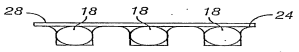

FIG. 3

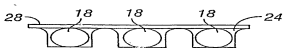

FIG. 4