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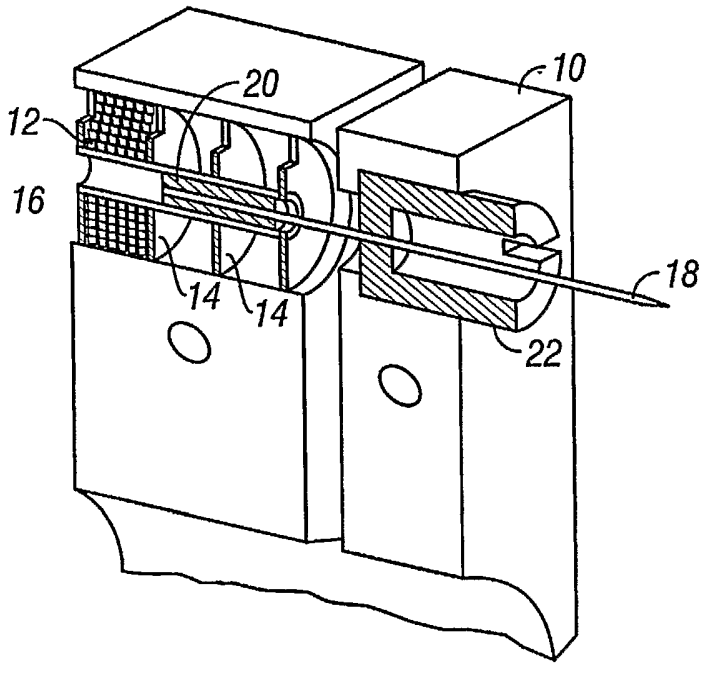
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(54) **Title:** IMPROVED PENETRATING MEMBER CONTROL USING AUTO-PRE-TENT



(57) **Abstract:** A body fluid sampling device is provided. The device comprises a pre-tent aperature front end configured to engage tissue, wherein the pre-tent aperture shapes a tissue site prior to lancing to minimize patient-to-patient tenting differences, the front end staying in place during penetrating member withdrawal to control tissue decompression. The use of the pre-tenting front end improves spontaneous blood generation for a wound on the patient.

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IMPROVED PENETRATING MEMBER CONTROL USING AUTO-PRE-TENT

BACKGROUND OF THE INVENTION

Field of the Invention

The invention relates to the collection of body fluid and specifically, to devices and methods for improving spontaneous body fluid generation during a lancing event.

Description of Related Art

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.

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.

Electric drive devices may be used to drive a lancet for fluid sampling. One example of an electric drive device includes a voice coil actuator. Although sufficient for some other applications, known voice coils fail to provide sufficient performance capability for use in an improved lancing device. The known devices are also unable to be controlled to provide an configurable velocity profile.

Additionally, tenting of skin being penetrated also influences the accuracy of lancing depth control. When a lancet penetrates the skin, the skin "dimples" or "tents" as

the lancet cuts the skin. This tenting makes it difficult to determine how deep the lancet is penetrating into the skin. Tenting is not a predictable parameter since the site of lancing, hydration, skin thickness and other factors affect the amount of tenting distance.

SUMMARY OF THE INVENTION

The present invention provides solutions for at least some of the drawbacks discussed above. Specifically, some embodiments of the present invention provide a voice coil based actuation devices for driving a penetrating member. Intelligent control of the velocity profile of the penetrating member will increase the likelihood of spontaneous blood generation. At least some of these and other objectives described herein will be met by embodiments of the present invention.

In one aspect of the present invention, the invention relates to using the electronic tissue penetration device to drive a penetrating member into the skin to a predetermined depth, and then hold the penetrating member in the extended position for a configurable period of time "tent-and-hold. The invention also allows fort he penetrating member to control the relaxation of the skin from maximum penetrating member displacement "tent-and-damped-hold". Optimizing this skin relaxation characteristic is directly related to success and spontaneous blood yield or "blood sufficiency".

A lancing device, which controls the advancement and retraction of a lancet by monitoring the position of the lancet in conjunction with a velocity control system in the form of a feedback loop, has been described (38187-2551 Tissue Penetration Device). The feedback loop can modulate the lancet driver to follow a predetermined velocity versus position profile. Inbound velocity, braking and retraction can be controlled. When the lancet is fully extended, it can be specifically instructed to maintain position, or hold the lancet out in the skin for period of time. This keeps the skin in a state of tension or "tenting". This tent and hold activity increases spontaneous blood without significant increase in pain.

In another embodiment of the present invention, the pre-tent-aperture may be a movable device inside the currently employed 5mm aperture through which the penetrating member could move freely. By way of example and not limitation, some embodiments may use 6mm, 4mm, or 3mm aperatures. The pre-tent aperture may shape the wound site prior to lancing to minimize patient to patient tenting differences and stay

in place during penetrating member withdrawal to help control tissue decompression and could be withdrawn for sample collection, or sample collection could happen behind it, or if constructed as a spreader it could spread the wound to prevent wound collapsing after penetrating member withdrawal. Relevant techniques includes the shape of wound site and maintaining or changing that shape during controlled lancet withdrawal as compression and decompression of tissue may be strong factors in spontaneous blood sample generation from a relatively small puncture wound.

In another embodiment of the present invention, a device is provided for body fluid sampling. The device comprises a housing and a pre-tent aperture front end on the housing configured to engage tissue. The pre-tent aperture shapes a tissue site prior to lancing to minimize patient-to-patient tenting differences, said front end staying in place during penetrating member withdrawal to control tissue decompression.

The aperture front end may be movable relative to the housing and is withdrawn from the tissue site after lancing for fluid sample collection. The aperture front end may be movable and is held is place during sample collection wherein sample fluid pass through an opening in said aperture front end. The aperture front end may be configured as a spreader in a manner sufficient to spread the wound to prevent wound collapsing after penetrating member withdrawal. The velocity profile may be a "tent-and-hold" profile wherein a penetrating member is held in place in the skin for a calculated period of time. The velocity profile may be a "tent-and-damped-hold" wherein the penetrating member applies a force only great enough to slow the relaxation of the skin, but not to hold the relaxation of the skin. In one embodiment, the front end is funnel shaped. The front end may be movable from a first position to a second position where the front end deforms target tissue to pre-tent the tissue (as seen in Figure 9).

In another embodiment of the present invention, a system is provided for body fluid sampling on a patient. The system comprises a housing and a pre-tent aperture front end on the housing configured to engage tissue. The pre-tent aperture may shape a tissue site prior to lancing to minimize patient-to-patient tenting differences, said front end staying in place during penetrating member withdrawal to control tissue decompression; The system may also include at least one penetrating member contained in the housing and an electrical driver with a gripper for engaging and advancing said penetrating member into a target tissue.

The system may have an aperture front end is configured as a spreader in a manner sufficient to spread the wound to prevent wound collapsing after penetrating member withdrawal. A radial cartridge may be included inside the housing for supporting the at least one penetrating member. The system may use a front end on a housing so that pre-tenting the wound site and maintaining the tented-in shape of the wound site during penetrating member withdrawal improves spontaneous blood flow from the wound. A front end on a housing may be included so that the pre-tent aperture is used to spread open the wound. The system may also include a radial cartridge inside the housing for supporting the at least one penetrating member and coupled to at least one analyte detecting member positioned to receive body fluid from a would created on the patient by the penetrating member.

In another embodiment of the present invention, a method is provided for body fluid sampling. The method comprises pre- tenting the tissue prior to lancing; determining at least one of the following characteristics based on relationship of power used by a penetrating member driver to tent-and-hold, or damp-and-hold: skin characteristics e.g. hydration, possibly stratum corneum thickness. Power is used to retract the penetrating member from a given depth or given skin. Wound stabilization characteristics are used to get the blood out –reorientation of collagen fibers to keep the channel patent.

In yet another embodiment of the present invention, a method is provided for controlling depth of penetrating member motion into a patient. The method comprises pre-tenting the target tissue; measuring the amount of skin or tissue tenting of an individual lancing event by actuating said penetrating member into the tissue, measuring a first penetration position, removing all actuation force, measuring a relaxed position, and determining the difference to determine the tenting. The method may include correcting the desired penetration depth by the amount of tenting. The method may also include advancing said penetrating member after measuring the amount of tenting and while the penetrating member remains in the patient, to continue the lancing event in order to achieve a desired depth into the tissue. The penetrating member may be advanced to continue the lancing event in order to achieve a desired depth into the tissue. A tent and hold velocity profile may be used to allow blood reperfusion after initial penetrating member impact on tissue, which is due to the delayed deformation of the skin

tissue immediately around a penetrating member target site unloading the peripheral skin tissue vasculature, wherein the vasculature functions as a pressure system, forcing blood towards the penetrating member after a delay that is related to the force of impact and is one factor in increasing spontaneous blood generation. Some embodiment may use a front end on a housing so that pre-tenting the wound site and maintaining the tented-in shape of the wound site during penetrating member withdrawal improves spontaneous blood flow from the wound. A front end on a housing may be used so that the pre-tent aperture is used to spread open the wound.

A further understanding of the nature and advantages of the invention will become apparent by reference to the remaining portions of the specification and drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 illustrates an embodiment of a controllable force driver in the form of a cylindrical electric penetrating member driver using a coiled solenoid -type configuration.

Figure 2A illustrates a displacement over time profile of a penetrating member driven by a harmonic spring/mass system.

Figure 2B illustrates the velocity over time profile of a penetrating member driver by a harmonic spring/mass system.

Figure 2C illustrates a displacement over time profile of an embodiment of a controllable force driver.

Figure 2D illustrates a velocity over time profile of an embodiment of a controllable force driver.

Figure 3 is a diagrammatic view illustrating a controlled feed-back loop.

Figure 4 is a perspective view of a tissue penetration device having features of the invention.

Figure 5 is an elevation view in partial longitudinal section of the tissue penetration device of Figure 4.

Figure 6A shows one embodiment of a device which may use the present invention.

Figure 6B shows one embodiment of a cartridge according to the present invention.

Figure 7 is a schematic showing blood location at a target site on a patient during a lancing event.

Figure 8 is a schematic showing a cross-sectional view of a penetrating member piercing skin.

Figure 9 shows a movable front end according to the present invention.

Figures 10 and 11 show other embodiments according to the present invention.

Figure 12 shows a still further embodiment of the present invention.

DESCRIPTION OF THE SPECIFIC EMBODIMENTS

The present invention provides a solution for body fluid sampling. Specifically, some embodiments of the present invention provides a method for improving spontaneous blood generation. The invention may use a high density penetrating member design. It may use penetrating members of smaller size, such as but not limited to diameter or length, than those of lancets known in the art. 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.

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 may 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. References cited herein are hereby incorporated by reference in their entirety, except to the extent that they conflict with teachings explicitly set forth in this specification.

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.

The present invention may be used with a variety of different penetrating member drivers. It is contemplated that these penetrating member drivers may be spring based, solenoid based, magnetic driver based, nanomuscle based, or based on any other mechanism useful in moving a penetrating member along a path into tissue. It should be noted that the present invention is not limited by the type of driver used with the penetrating member feed mechanism. One suitable penetrating member driver for use with the present invention is shown in Figure 1. This is an embodiment of a solenoid type electromagnetic driver that is capable of driving an iron core or slug mounted to the penetrating member assembly using a direct current (DC) power supply. The electromagnetic driver includes a driver coil pack that is divided into three separate coils along the path of the penetrating member, two end coils and a middle coil. Direct current is alternated to the coils to advance and retract the penetrating member. Although the driver coil pack is shown with three coils, any suitable number of coils may be used, for example, 4, 5, 6, 7 or more coils may optionally be used.

Referring to the embodiment of Figure 1, the stationary iron housing 10 may contain the driver coil pack with a first coil 12 flanked by iron spacers 14 which concentrate the magnetic flux at the inner diameter creating magnetic poles. The inner insulating housing 16 isolates the penetrating member 18 and iron core 20 from the coils and provides a smooth, low friction guide surface. The penetrating member guide 22 further centers the penetrating member 18 and iron core 20. The penetrating member 18 is protracted and retracted by alternating the current between the first coil 12, the middle coil, and the third coil to attract the iron core 20. Reversing the coil sequence and attracting the core and penetrating member back into the housing retracts the penetrating member. The penetrating member guide 22 also serves as a stop for the iron core 20 mounted to the penetrating member 18.

As discussed above, tissue penetration devices which employ spring or cam driving methods have a symmetrical or nearly symmetrical actuation displacement and velocity profiles on the advancement and retraction of the penetrating member as shown in Figures 2 and 3. In most of the available penetrating member devices, once the launch is initiated, the stored energy determines the velocity profile until the energy is dissipated.

Controlling impact, retraction velocity, and dwell time of the penetrating member within the tissue can be useful in order to achieve a high success rate while accommodating variations in skin properties and minimize pain. Advantages can be achieved by taking into account of the fact that tissue dwell time is related to the amount of skin deformation as the penetrating member tries to puncture the surface of the skin and variance in skin deformation from patient to patient based on skin hydration.

In this embodiment, the ability to control velocity and depth of penetration may be achieved by use of a controllable force driver where feedback is an integral part of driver control. Such drivers can control either metal or polymeric penetrating members or any other type of tissue penetration element. The dynamic control of such a driver is illustrated in Figure. 2C which illustrates an embodiment of a controlled displacement profile and Figure 2D which illustrates an embodiment of a the controlled velocity profile. These are compared to Figures 2A and 2B, which illustrate embodiments of displacement and velocity profiles, respectively, of a harmonic spring/mass powered driver. Reduced pain can be achieved by using impact velocities of greater than about 2 m/s entry of a tissue penetrating element, such as a penetrating member, into tissue. Other suitable embodiments of the penetrating member driver are described in commonly assigned, copending U.S. Patent Application Ser. No. 10/127,395, (Attorney Docket No. 38187-2551) filed April 19, 2002 and previously incorporated herein.

Figure 3 illustrates the operation of a feedback loop using a processor 60. The processor 60 stores profiles 62 in non-volatile memory. A user inputs information 64 about the desired circumstances or parameters for a lancing event. The processor 60 selects a driver profile 62 from a set of alternative driver profiles that have been preprogrammed in the processor 60 based on typical or desired tissue penetration device performance determined through testing at the factory or as programmed in by the operator. The processor 60 may optionally customize by either scaling or modifying the profile based on additional user input information 64. Once the processor has chosen and customized the profile, the processor 60 is ready to modulate the power from the power supply 66 to the penetrating member driver 68 through an amplifier 70. The processor 60 may measure the location of the penetrating member 72 using a position sensing mechanism 74 through an analog to digital converter 76 linear encoder or other such transducer. Examples of position sensing mechanisms have been described in the

embodiments above and may be found in the specification for commonly assigned, copending U.S. Patent Application Ser. No. 10/127,395, (Attorney Docket No. 38187-2551) filed April 19, 2002 and previously incorporated herein. The processor 60 calculates the movement of the penetrating member by comparing the actual profile of the penetrating member to the predetermined profile. The processor 60 modulates the power to the penetrating member driver 68 through a signal generator 78, which may control the amplifier 70 so that the actual velocity profile of the penetrating member does not exceed the predetermined profile by more than a preset error limit. The error limit is the accuracy in the control of the penetrating member.

After the lancing event, the processor 60 can allow the user to rank the results of the lancing event. The processor 60 stores these results and constructs a database 80 for the individual user. Using the database 79, the processor 60 calculates the profile traits such as degree of painlessness, success rate, and blood volume for various profiles 62 depending on user input information 64 to optimize the profile to the individual user for subsequent lancing cycles. These profile traits depend on the characteristic phases of penetrating member advancement and retraction. The processor 60 uses these calculations to optimize profiles 62 for each user. In addition to user input information 64, an internal clock allows storage in the database 79 of information such as the time of day to generate a time stamp for the lancing event and the time between lancing events to anticipate the user's diurnal needs. The database stores information and statistics for each user and each profile that particular user uses.

In addition to varying the profiles, the processor 60 can be used to calculate the appropriate penetrating member diameter and geometry suitable to realize the blood volume required by the user. For example, if the user requires about 1-5 microliter volume of blood, the processor 60 may optionally select a 200 micron diameter penetrating member to achieve these results. For each class of penetrating member, both diameter and penetrating member tip geometry, is stored in the processor 60 to correspond with upper and lower limits of attainable blood volume based on the predetermined displacement and velocity profiles.

The lancing device is capable of prompting the user for information at the beginning and the end of the lancing event to more adequately suit the user. The goal is to either change to a different profile or modify an existing profile. Once the profile is

set, the force driving the penetrating member is varied during advancement and retraction to follow the profile. The method of lancing using the lancing device comprises selecting a profile, lancing according to the selected profile, determining lancing profile traits for each characteristic phase of the lancing cycle, and optimizing profile traits for subsequent lancing events.

Figure 4 illustrates an embodiment of a tissue penetration device, more specifically, a lancing device 80 that includes a controllable driver 179 coupled to a tissue penetration element. The lancing device 80 has a proximal end 81 and a distal end 82. At the distal end 82 is the tissue penetration element in the form of a penetrating member 83, which is coupled to an elongate coupler shaft 84 by a drive coupler 85. The elongate coupler shaft 84 has a proximal end 86 and a distal end 87. A driver coil pack 88 is disposed about the elongate coupler shaft 84 proximal of the penetrating member 83. A position sensor 91 is disposed about a proximal portion 92 of the elongate coupler shaft 84 and an electrical conductor 94 electrically couples a processor 93 to the position sensor 91. The elongate coupler shaft 84 driven by the driver coil pack 88 controlled by the position sensor 91 and processor 93 form the controllable driver, specifically, a controllable electromagnetic driver.

Referring to Figure 5, the lancing device 80 can be seen in more detail, in partial longitudinal section. The penetrating member 83 has a proximal end 95 and a distal end 96 with a sharpened point at the distal end 96 of the penetrating member 83 and a drive head 98 disposed at the proximal end 95 of the penetrating member 83. A penetrating member shaft 201 is disposed between the drive head 98 and the sharpened point 97. The penetrating member shaft 201 may optionally be comprised of stainless steel, or any other suitable material or alloy and have a transverse dimension of about 0.1 to about 0.4 mm. The penetrating member shaft may optionally have a length of about 3 mm to about 50 mm, specifically, about 15 mm to about 20 mm. The drive head 98 of the penetrating member 83 is an enlarged portion having a transverse dimension greater than a transverse dimension of the penetrating member shaft 201 distal of the drive head 98. This configuration allows the drive head 98 to be mechanically captured by the drive coupler 85. The drive head 98 may have a transverse dimension of about 0.5 to about 2 mm.

A magnetic member 102 is secured to the elongate coupler shaft 84 proximal of the drive coupler 85 on a distal portion 203 of the elongate coupler shaft 84. The

magnetic member 102 is a substantially cylindrical piece of magnetic material having an axial lumen 204 extending the length of the magnetic member 102. The magnetic member 102 has an outer transverse dimension that allows the magnetic member 102 to slide easily within an axial lumen 105 of a low friction, possibly lubricious, polymer guide tube 105' disposed within the driver coil pack 88. The magnetic member 102 may have an outer transverse dimension of about 1.0 to about 5.0 mm, specifically, about 2.3 to about 2.5 mm. The magnetic member 102 may have a length of about 3.0 to about 5.0 mm, specifically, about 4.7 to about 4.9 mm. The magnetic member 102 can be made from a variety of magnetic materials including ferrous metals such as ferrous steel, iron, ferrite, or the like. The magnetic member 102 may be secured to the distal portion 203 of the elongate coupler shaft 84 by a variety of methods including adhesive or epoxy bonding, welding, crimping or any other suitable method.

Proximal of the magnetic member 102, an optical encoder flag 206 is secured to the elongate coupler shaft 84. The optical encoder flag 206 is configured to move within a slot 107 in the position sensor 91. The slot 107 of the position sensor 91 is formed between a first body portion 108 and a second body portion 109 of the position sensor 91. The slot 107 may have separation width of about 1.5 to about 2.0 mm. The optical encoder flag 206 can have a length of about 14 to about 18 mm, a width of about 3 to about 5 mm and a thickness of about 0.04 to about 0.06 mm.

The optical encoder flag 206 interacts with various optical beams generated by LEDs disposed on or in the position sensor body portions 108 and 109 in a predetermined manner. The interaction of the optical beams generated by the LEDs of the position sensor 91 generates a signal that indicates the longitudinal position of the optical flag 206 relative to the position sensor 91 with a substantially high degree of resolution. The resolution of the position sensor 91 may be about 200 to about 400 cycles per inch, specifically, about 350 to about 370 cycles per inch. The position sensor 91 may have a speed response time (position/time resolution) of 0 to about 120,000 Hz, where one dark and light stripe of the flag constitutes one Hertz, or cycle per second. The position of the optical encoder flag 206 relative to the magnetic member 102, driver coil pack 88 and position sensor 91 is such that the optical encoder 91 can provide precise positional information about the penetrating member 83 over the entire length of the penetrating member's power stroke.

An optical encoder that is suitable for the position sensor 91 is a linear optical incremental encoder, model HEDS 9200, manufactured by Agilent Technologies. The model HEDS 9200 may have a length of about 20 to about 30 mm, a width of about 8 to about 12 mm, and a height of about 9 to about 11 mm. Although the position sensor 91 illustrated is a linear optical incremental encoder, other suitable position sensor embodiments could be used, provided they posses the requisite positional resolution and time response. The HEDS 9200 is a two channel device where the channels are 90 degrees out of phase with each other. This results in a resolution of four times the basic cycle of the flag. These quadrature outputs make it possible for the processor to determine the direction of penetrating member travel. Other suitable position sensors include capacitive encoders, analog reflective sensors, such as the reflective position sensor discussed above, and the like.

A coupler shaft guide 111 is disposed towards the proximal end 81 of the lancing device 80. The guide 111 has a guide lumen 112 disposed in the guide 111 to slidingly accept the proximal portion 92 of the elongate coupler shaft 84. The guide 111 keeps the elongate coupler shaft 84 centered horizontally and vertically in the slot 102 of the optical encoder 91.

The driver coil pack 88, position sensor 91 and coupler shaft guide 111 are all secured to a base 113. The base 113 is longitudinally coextensive with the driver coil pack 88, position sensor 91 and coupler shaft guide 111. The base 113 can take the form of a rectangular piece of metal or polymer, or may be a more elaborate housing with recesses, which are configured to accept the various components of the lancing device 80.

As discussed above, the magnetic member 102 is configured to slide within an axial lumen 105 of the driver coil pack 88. The driver coil pack 88 includes a most distal first coil 114, a second coil 115, which is axially disposed between the first coil 114 and a third coil 116, and a proximal-most fourth coil 117. Each of the first coil 114, second coil 115, third coil 116 and fourth coil 117 has an axial lumen. The axial lumens of the first through fourth coils are configured to be coaxial with the axial lumens of the other coils and together form the axial lumen 105 of the driver coil pack 88 as a whole. Axially adjacent each of the coils 114-117 is a magnetic disc or washer 118 that augments completion of the magnetic circuit of the coils 114-117 during a lancing cycle of the device 80. The magnetic washers 118 of the embodiment of Figure 5 are made of ferrous

steel but could be made of any other suitable magnetic material, such as iron or ferrite. The outer shell 89 of the driver coil pack 88 is also made of iron or steel to complete the magnetic path around the coils and between the washers 118. The magnetic washers 118 have an outer diameter commensurate with an outer diameter of the driver coil pack 88 of about 4.0 to about 8.0 mm. The magnetic washers 118 have an axial thickness of about 0.05, to about 0.4 mm, specifically, about 0.15 to about 0.25 mm.

Wrapping or winding an elongate electrical conductor 121 about an axial lumen until a sufficient number of windings have been achieved forms the coils 114-117. The elongate electrical conductor 121 is generally an insulated solid copper wire with a small outer transverse dimension of about 0.06 mm to about 0.88 mm, specifically, about 0.3 mm to about 0.5 mm. In one embodiment, 32 gauge copper wire is used for the coils 114-117. The number of windings for each of the coils 114-117 of the driver pack 88 may vary with the size of the coil, but for some embodiments each coil 114-117 may have about 30 to about 80 turns, specifically, about 50 to about 60 turns. Each coil 114-117 can have an axial length of about 1.0 to about 3.0 mm, specifically, about 1.8 to about 2.0 mm. Each coil 114-117 can have an outer transverse dimension or diameter of about 4.0, to about 2.0 mm, specifically, about 9.0 to about 12.0 mm. The axial lumen 105 can have a transverse dimension of about 1.0 to about 3.0 mm.

It may be advantageous in some driver coil 88 embodiments to replace one or more of the coils with permanent magnets, which produce a magnetic field similar to that of the coils when the coils are activated. In particular, it may be desirable in some embodiments to replace the second coil 115, the third coil 116 or both with permanent magnets. In addition, it may be advantageous to position a permanent magnet at or near the proximal end of the coil driver pack in order to provide fixed magnet zeroing function for the magnetic member (Adams magnetic Products 23A0002 flexible magnet material (800) 747-7543).

Referring now to Figures 6A and 6B, yet another embodiment of the present invention will now be described. It should be understood that this embodiment may be adapted for use with devices described in commonly assigned copending U.S. Patent Applications Ser. No. 10/323,624 (Attorney Docket No. 38187-2608) filed December 18, 2002. Figure 6A shows a device that may use a cartridge as shown in Figure 6B. Figure 6B shows a radial cartridge 220. The cartridge 220 may include a sterility barrier 232 and

a substrate 250 having a plurality of analyte detecting members 226. In this embodiment, the cartridge 220 is designed so that blood will enter the fluid chamber 228 and be held there for analysis.

Figure 6B shows the radial cartridge 220 may be used with a lancing device 230. The radial cartridge 220 may be sealed with a sterility barrier 232 and be coupled to analyte detecting members mounted on a substrate 234. A suitable device is described in commonly assigned, copending U.S. Patent Application No. 10/429,196 (Attorney Docket No. 38187-2662) fully incorporated herein by reference for all purposes. It should be understood that in some embodiments, the layer 234 may be removed and the bottom layer of the cartridge 220 sealed. Instead, a ring 252 with a plurality of analyte detecting members 254 (such as those shown in Figures 7 to 21) may optionally be in a ring configuration around the penetrating member cartridge 220. This orients one analyte detecting member 254 for each penetrating member in cartridge 220. Some embodiments may optionally have portions of the ring 254 fold underneath the cartridge 220 in an L-configuration when viewed from a side cross-sectional.

Referring now to Figure 7, another aspect of the present invention will now be described. Figure 7 shows a schematic representation of the reperfusion of skin after impact with a tent and hold motion profile is shown. For ease of illustration, this figure is not to scale, and does not describe depth. This is a top down schematic view onto the skin or tissue. Penetrating member strikes perpendicularly to the skin in area A. Blood is initially forced out to an area D. Blood will quickly return from D to C as the skin settles after the shock of impact. Tent and hold allows blood reperfusion from C to B and is due to the delayed deformation of the skin tissue immediately around A, unloading the peripheral skin tissue vasculature. The vasculature also functions as a pressure system, forcing blood towards the penetrating member after a delay that is related to the force of impact. This pressuring is one factor in increasing spontaneous blood generation.

Referring now to Figure 8, two components of retraction profile are shown: As a nonlimiting example, reference letter A shows a "hold-to-neutral" position or range - when skin-penetrating member interface migrates together, and the skin settles naturally after the impact force tents the tissue. Perfusion acts as three-dimensional function of the pressure. Pressure distribution and perfusion is cone-shaped, as illustrated by the blue

triangle below. Reference letter B shows neutral to exit position or range where the actuator retracts the penetrating member from the skin.

Spontaneous blood yield can be achieved by a lancing motion profile that holds the penetrating member at maximum extension for a prolonged period of time. The viscoelastic of the skin may allow for a momentary tissue deflection that would rebound immediately after the penetrating member was retracted. A tent and hold lancing profile counteracts this natural property of the skin. In one embodiment, the penetrating member driver can maintain an extended position for about 2-8ms, and then make a controlled retraction out of the finger. The skin will slide up the penetrating member shaft as the collagen matrix in the reticular layer inelastically deforms. In this nonlimiting example, the penetrating member continues to cut, but only as a result of the relaxation of the surrounding tissue. This deformation during the hold happens radially as well as axially to the penetrating member shaft. With tissue compressed more evenly around the lanced area, the resulting wound maintains it shape longer before it collapses into a thin line that would resist blood spontaneously rising to the surface. The wound shape may exhibit increased blood sufficiency by counteracting tissue rebound characteristics using the tent and hold profile.

In one embodiment of the present invention, to achieve a "tent-and-hold" event, the penetrating member penetrates to the intended depth and then may maintain the position in the skin to prevent or retard the relaxation of the tissue, which would naturally return at approximately 1 m/s. In one nonlimiting example, holding the penetrating member in the skin between about 2 to 100 milliseconds appears be ideal to achieve spontaneous blood yield. Deeper lances will require more "hold" time. In one embodiment, hold may be achieved by removing the drive force from the penetrating member while letting the skin or tissue relax and reposition the penetrating member. In other embodiments, hold may involve placing the penetrating member at a fixed depth and maintaining that depth for the desired period. Although not limited by the following, motion profiles for which the hold time is longer than about 1 second may introduce a deleterious physical reaction from the patient or unnecessary pain. It may also use more power from the motor to maintain the position of the penetrating member for an extended period of time.

Some advantages of a "tent-and-hold" motion profile or trajectory waveform include:

1. Integrity of the wound channel by decreasing the effect of distension in the wound channel. The viscoelasticity of the skin may allow for a momentary tissue deflection that would rebound immediately after the penetrating member was retracted. A tent and hold lancing profile may counteract this natural property of the skin. This behavior can be directly observed when the penetrating member is held for greater than 200 microseconds. The skin will slide up the penetrating member shaft as the collagen matrix in the stratum reticulare layer inelastically deforms. The penetrating member continues to cut, but only as a result of the relaxation of the surrounding tissue. This deformation during the hold happens radially as well as axially to the penetrating member shaft. With tissue compressed more evenly around the lanced area, the resulting wound maintains it shape longer before it collapses into a thin line, which may resist blood spontaneously rising to the surface.

2. A limited amount of pinching and subsequent binding of the venuoles (at deeper lancing depths) by surrounding tissue at the target depth. In one nonlimiting example, a strike with the best yield would involve the larger venuoles at higher depths filling the channel with blood. As the blood moves with the retracting penetrating member up the channel, the inside of the channel is coated with blood, allowing the blood in smaller venuoles with higher pressures to overcome to use the advantage of the bloods natural surface tension to lower the pressure threshold that would prevent blood spontaneously coming to the surface. The momentum that a well-executed tent and hold with an appropriate retraction rate would build in the lancing channel not only decreases the number of sticks or lancing events with no spontaneous blood, but decrease the number of spontaneous sticks that are spontaneous but would require milking of the finger to gather a sufficient sample. This increase in the yield/depth ratio would thereby reduce pain/yield, as an optimal retraction speed profile would reduce the depth sufficient to gather a sufficient sample.

3. The force of the impact evacuates the blood from the area around the penetrating member channel. This lack of movement after the impact allows for reperfusion into the area of the strike before any significant movement occurs. If the pressure is too high in the tented tissue area, the blood may not return until the retraction

is performed. However, the coherence and focus of the tissue reperfusion is greater with the device-controlled relaxation of the penetrating member.

Once the penetrating member holds a certain period of time, there are two components of the retraction profile that influences blood spontaneously reaching the surface of the skin. The held-to-neutral subcomponent, (which may be at a speed), which facilitates a focused and optimal reperfusion of the lanced area; and the neutral-to-exit subcomponent, which allows the penetrating member to perform at least one of the following:

- Travel without binding or damaging the wound channel.
- Prevent the channel from closing up abruptly, enabling blood to displace the penetrating member as it performs a controlled exit.

The power requirement to hold a penetrating member may vary. Variations may be due in part to type of drive device such as but not limited to solenoid or voice coil and the like. In another embodiment, the penetrating member may apply a force only great enough to slow the relaxation of the skin, but not to hold the relaxation of the skin. The relationship of the power to tent-and-hold, or damp-and-hold may be related to: the skin characteristics e.g. hydration, possibly stratum corneum thickness. The power used to retract the penetrating member from a given depth or given skin may be used to relate characteristics of the skin. The wound stabilization characteristics required to get the blood out, reorientation of collagen fibers to keep the channel patent, may depend on the velocity profile used. By way of example and not limitation, the processor 93 may be used to process these characteristics and to set and execute the various velocity profiles.

Referring now to Figure 9, a shaped front end 400 of the tissue penetrating device is used to engage and pre-shape the tissue T to be lanced. In this embodiment, the housing 402 has also engaged the tissue to stabilize it. It should be understood that pre-tenting the wound site and maintaining the tented-in shape of the wound site during penetrating member 404 withdrawal will improve spontaneous blood flow from the wound. This pre-tent aperture 400 could also be used to spread open the wound. The front end 400 may optionally be adapted for use with a cartridge such as but not limited to that shown in Figure 6B.

Some embodiments of the present invention may optionally have the pre-tent aperture 400 fixed mounted on the housing and some may optionally have it movable as

shown in Figure 9. Figure 10 shows an embodiment with a fixed aperture 400 on a housing. A radial cartridge such as that shown in Figure 6B may be inside the housing of Figure 10. Figure 11 shows that the aperture may be movable as indicated by arrow 420 relative to a housing.

Referring now to Figure 12, in some embodiments where the aperture had two parts shaped like a pincer end 429, the aperture 430 could spread open a wound. This may also help with spontaneous blood generation.

While the invention has been described and illustrated with reference to certain particular embodiments thereof, those skilled in the art will appreciate that various adaptations, changes, modifications, substitutions, deletions, or additions of procedures and protocols may be made without departing from the spirit and scope of the invention. For example, with any of the above embodiments, the location of the penetrating member drive device may be varied, relative to the penetrating members or the cartridge. With any of the above embodiments, the penetrating member tips may be uncovered during actuation (i.e. penetrating members do not pierce the penetrating member enclosure or protective foil during launch). With any of the above embodiments, the penetrating members may be a bare penetrating member during launch. With any of the above embodiments, the penetrating members may be bare penetrating members prior to launch as this may allow for significantly tighter densities of penetrating members. In some embodiments, the penetrating members may be bent, curved, textured, shaped, or otherwise treated at a proximal end or area to facilitate handling by an actuator. The penetrating member may be configured to have a notch or groove to facilitate coupling to a gripper. The notch or groove may be formed along an elongate portion of the penetrating member. With any of the above embodiments, the cavity may be on the bottom or the top of the cartridge, with the gripper on the other side. In some embodiments, analyte detecting members may be printed on the top, bottom, or side of the cavities. The front end of the cartridge maybe in contact with a user during lancing. The same driver may be used for advancing and retraction of the penetrating member. The penetrating member may have a diameters and length suitable for obtaining the blood volumes described herein. The penetrating member driver may also be in substantially the same plane as the cartridge. The driver may use a through hole or other opening to engage a proximal end of a penetrating member to actuate the penetrating member along

a path into and out of the tissue. It should be understood that pre-tenting may be adapted for use with any embodiments of the inventions disclosed herein. The present invention may include a processor for controlling an electrical driver as described herein to execute various tent and hold and other controlled velocity profiles. The present application is related U.S. Provisional Application Ser. No. 60/534,003 (Attorney Docket No. 38187-2727).

The publications discussed or cited herein are provided solely for their disclosure prior to the filing date of the present application. Nothing herein is to be construed as an admission that the present invention is not entitled to antedate such publication by virtue of prior invention. Further, the dates of publication provided may be different from the actual publication dates which may need to be independently confirmed. All publications, patents, and patent applications mentioned herein are incorporated herein by reference to disclose and describe the structures and/or methods in connection with which the publications are cited.

Where a range of values is provided, it is understood that each intervening value, to the tenth of the unit of the lower limit unless the context clearly dictates otherwise, between the upper and lower limit of that range and any other stated or intervening value in that stated range is encompassed within the invention. The upper and lower limits of these smaller ranges may independently be included in the smaller ranges is also encompassed within the invention, subject to any specifically excluded limit in the stated range. Where the stated range includes one or both of the limits, ranges excluding either both of those included limits are also included in the invention.

Expected variations or differences in the results are contemplated in accordance with the objects and practices of the present invention. It is intended, therefore, that the invention be defined by the scope of the claims which follow and that such claims be interpreted as broadly as is reasonable.

WHAT IS CLAIMED IS:

1. A body fluid sampling device for use on a patient, the device comprising:

a pre-tent aperture front end configured to engage tissue;

wherein the pre-tent aperture shapes a tissue site prior to lancing.

2. A body fluid sampling device comprising:

a housing; and

a pre-tent aperture front end on the housing configured to engage tissue;

wherein the pre-tent aperture shapes a tissue site prior to lancing to minimize patient-to-patient tenting differences, said front end staying in place during penetrating member withdrawal to control tissue decompression.

3. The device of claim 1 wherein the aperture front end is movable relative to the housing and is withdrawn from the tissue site after lancing for fluid sample collection.

4. The device of claim 1 wherein the aperture front end is movable and is held is place during sample collection wherein sample fluid pass through an opening in said aperture front end.

5. The device of claim 1 wherein the aperture front end is configured as a spreader in a manner sufficient to spread the wound to prevent wound collapsing after penetrating member withdrawal.

6. The device of claim 1 wherein the velocity profile is "tent-and-hold" wherein a penetrating member is held in place in the skin for a calculated period of time.

7. The device of claim 1 comprising "tent-and-damped-hold" wherein the penetrating member applies a force only great enough to slow the relaxation of the skin, but not to hold the relaxation of the skin.

8. The device of claim 1 wherein the front end is funnel shaped.

9. The device of claim 1 wherein the front end is moved from a first position to a second position where the front end deforms target tissue to pre-tent the tissue.

10. A body fluid sampling system for use on a patient, the system comprising:

a housing;

a pre-tent aperture front end on the housing configured to engage tissue;

wherein the pre-tent aperture shapes a tissue site prior to lancing to minimize patient-to-patient tenting differences, said front end staying in place during penetrating member withdrawal to control tissue decompression;

at least one penetrating member contained in said housing;

an electrical driver with a gripper for engaging and advancing said penetrating member into a target tissue.

11. The system of claim 10 wherein the aperture front end is configured as a spreader in a manner sufficient to spread the wound to prevent wound collapsing after penetrating member withdrawal.

12. The system of claim 10 further comprising a radial cartridge inside the housing for supporting the at least one penetrating member.

13. The system of claim 10 comprising using a front end on a housing so that pre-tenting the wound site and maintaining the tented-in shape of the wound site during penetrating member withdrawal improves spontaneous blood flow from the wound.

14. The system of claim 10 comprising using a front end on a housing so that the pre-tent aperture is used to spread open the wound.

15. The system of claim 10 further comprising a radial cartridge inside the housing for supporting the at least one penetrating member and coupled to at least one analyte detecting member positioned to receive body fluid from a would created on the patient by the penetrating member.

16. A method of body fluid sampling, the method comprising:

pretenting the tissue prior to lancing;

determining at least one of the following characteristics based on relationship of power used by a penetrating member driver to tent-and-hold, or damp-and-hold: skin characteristics e.g. hydration, possibly stratum corneum thickness

using power to launch the penetrating member to a given depth or given skin;

using power to retract the penetrating member from a given depth or given skin; and

using wound stabilization characteristics to get the blood out – reorientation of collagen fibers to keep the channel patent.

17. A method for controlling depth of penetrating member motion into a patient, said method comprising:

pre-tenting the target tissue;

measuring the amount of skin or tissue tenting of an individual lancing event by actuating said penetrating member into the tissue, measuring a first penetration position, removing all actuation force, measuring a relaxed position, and determining the difference to determine the tenting.

18. The method of claim 17 comprising correcting the desired penetration depth by the amount of tenting.

19. The method of claim 17 comprising advancing said penetrating member after measuring the amount of tenting and while the penetrating member remains in the patient, to continue the lancing event in order to achieve a desired depth into the tissue.

20. The method of claim 17 comprising advancing said penetrating member to continue the lancing event in order to achieve a desired depth into the tissue.

21. The method of claim 17 comprising using a tent and hold velocity profile to allow blood reperfusion after initial penetrating member impact on tissue, which is due to the delayed deformation of the skin tissue immediately around a penetrating member target site unloading the peripheral skin tissue vasculature;

wherein the vasculature functions as a pressure system, forcing blood towards the penetrating member after a delay that is related to the force of impact and is one factor in increasing spontaneous blood generation.

22. The method of claim 17 comprising using a front end on a housing so that pre-tenting the wound site and maintaining the tented-in shape of the wound site during penetrating member withdrawal improves spontaneous blood flow from the wound.

23. The method of claim 17 comprising using a front end on a housing so that the pre-tent aperture is used to spread open the wound.

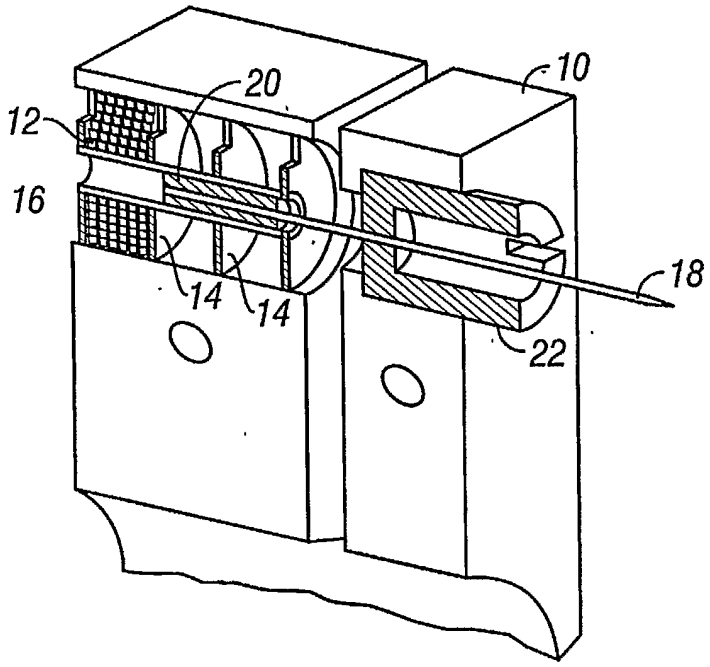


FIG. 1

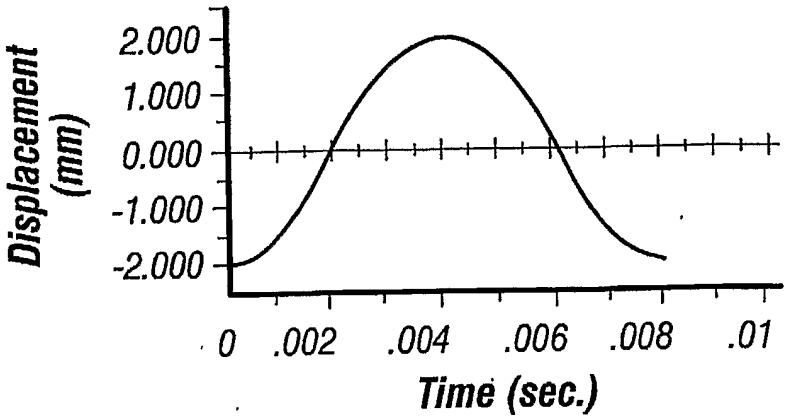

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.006
.008
.01
Time (sec.)

FIG. 2A

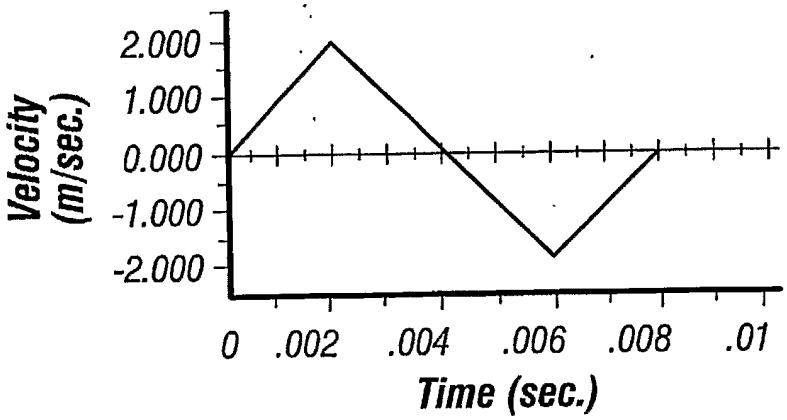

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FIG. 2B

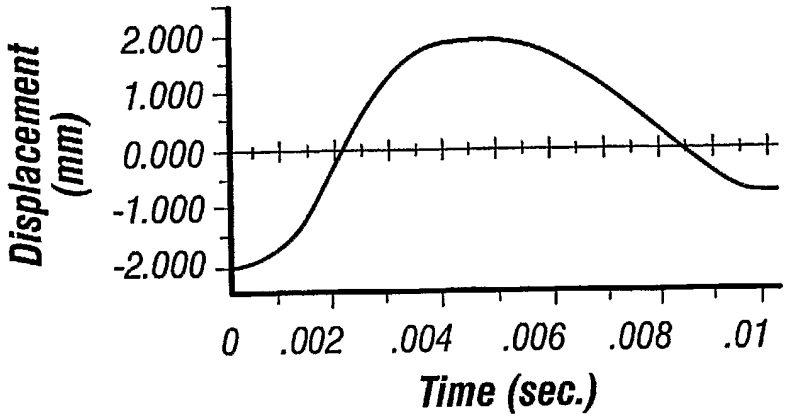

Displacement (mm)
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FIG. 2C

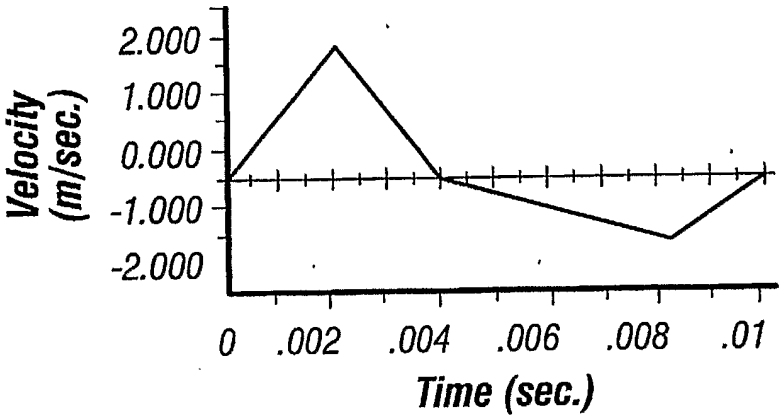

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FIG. 2D

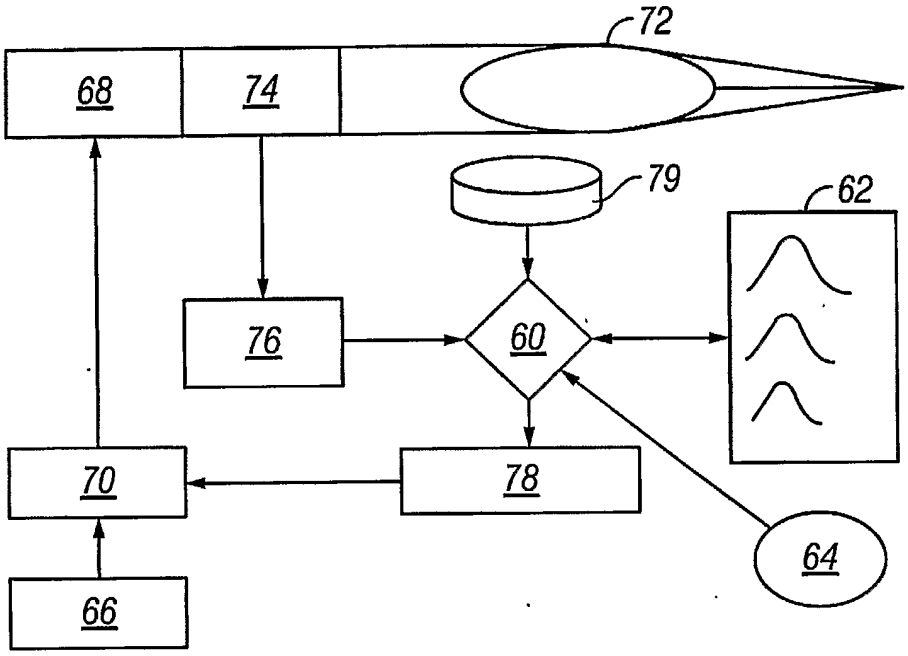


FIG. 3

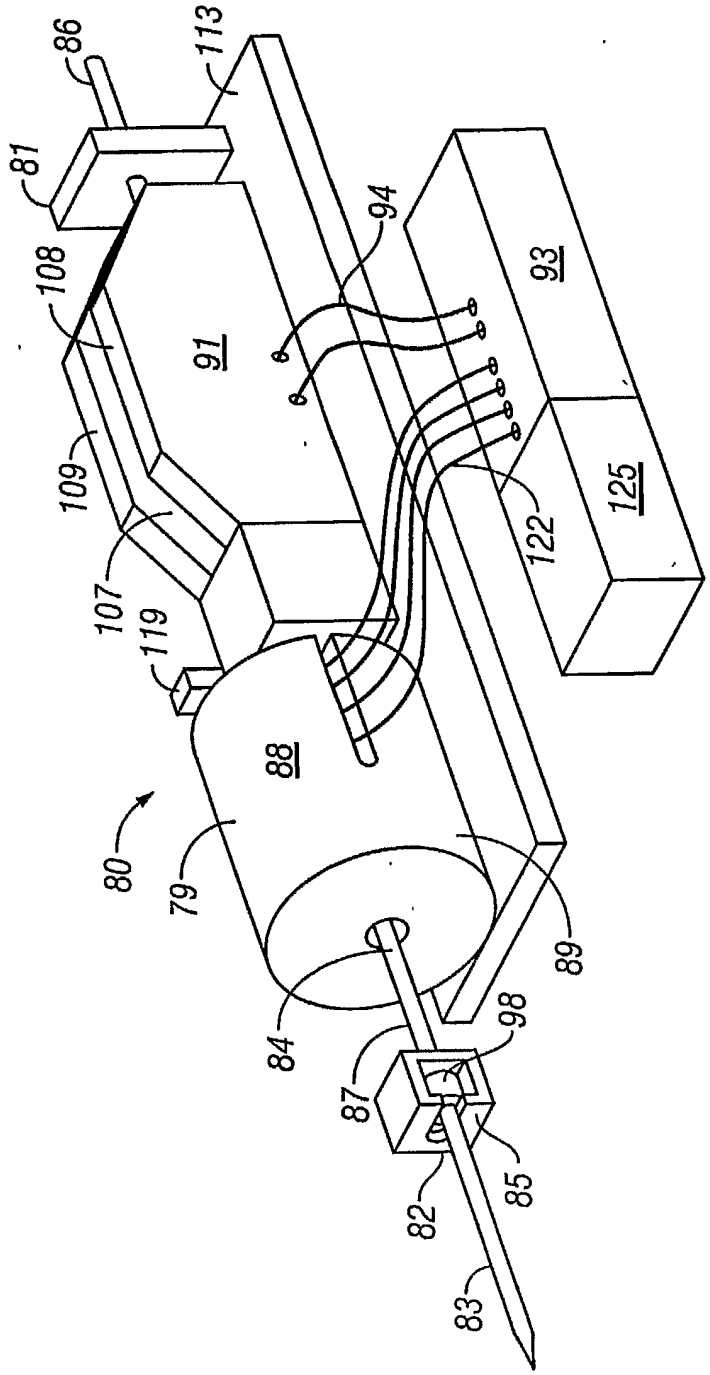

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FIG. 4

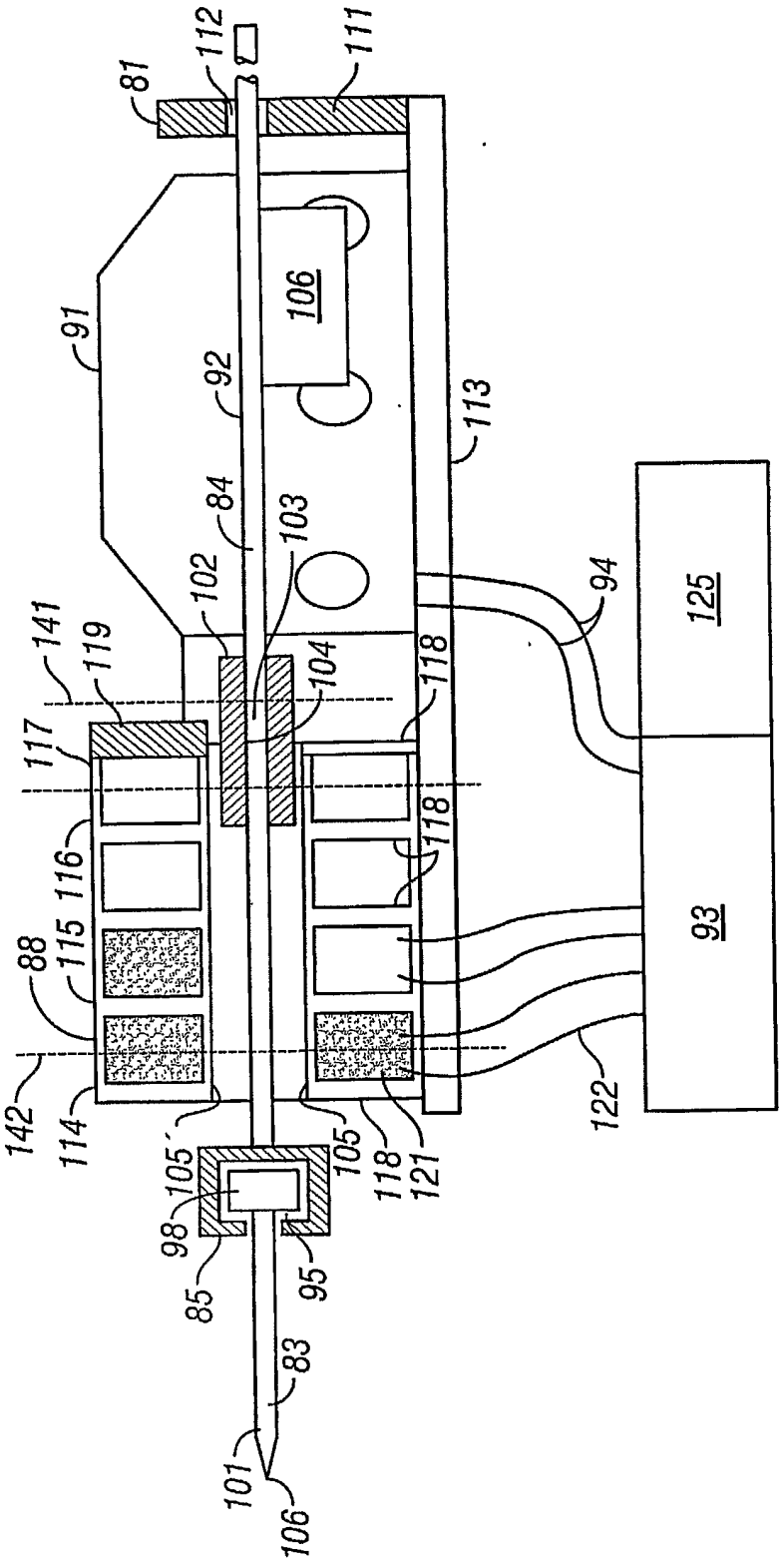

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FIG. 5

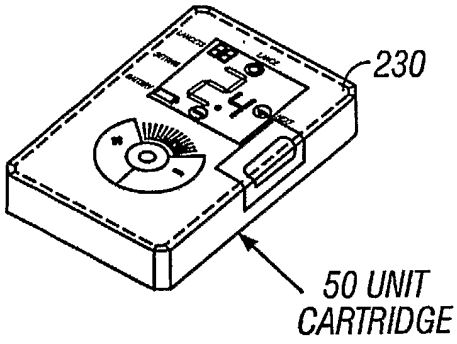

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CARTRIDGE

FIG. 6A

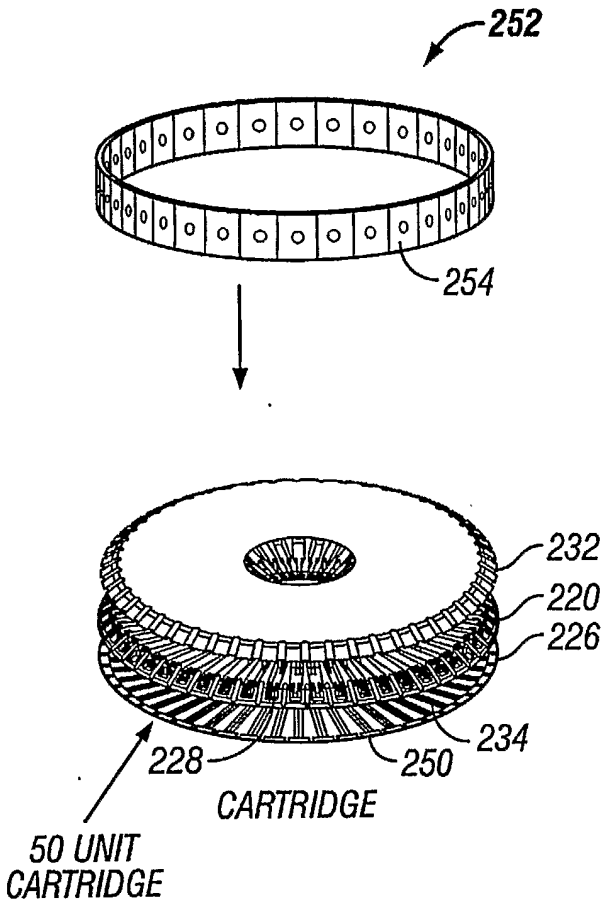

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CARTRIDGE

FIG. 6B

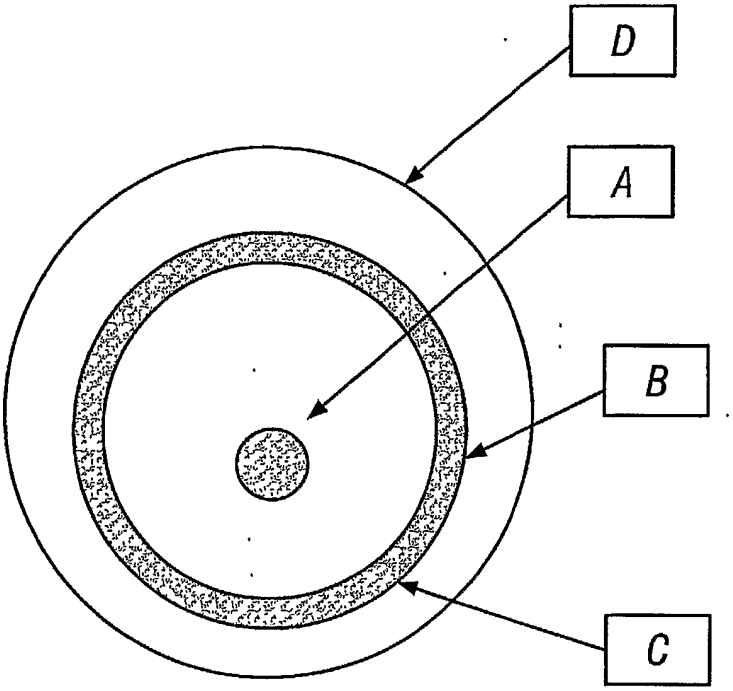


FIG. 7

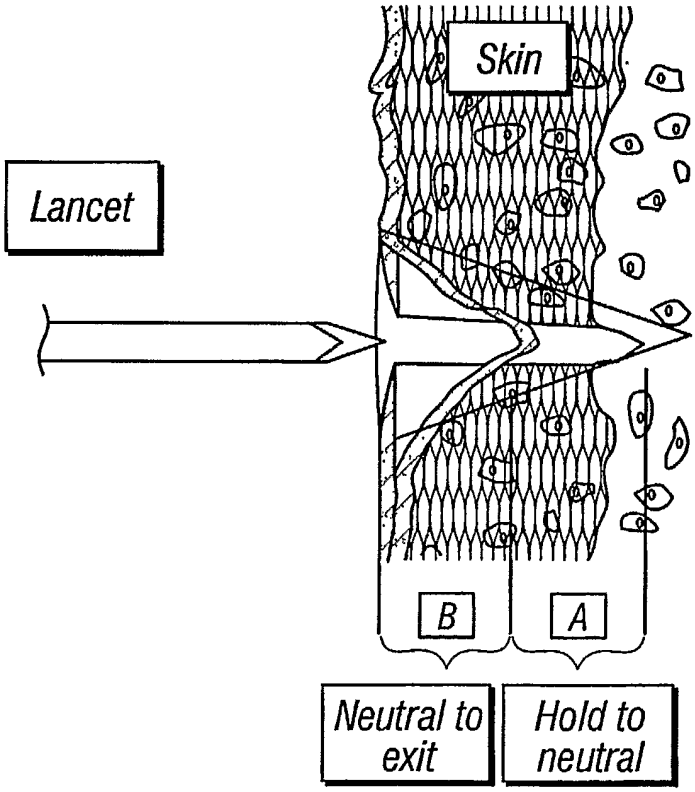


FIG. 8

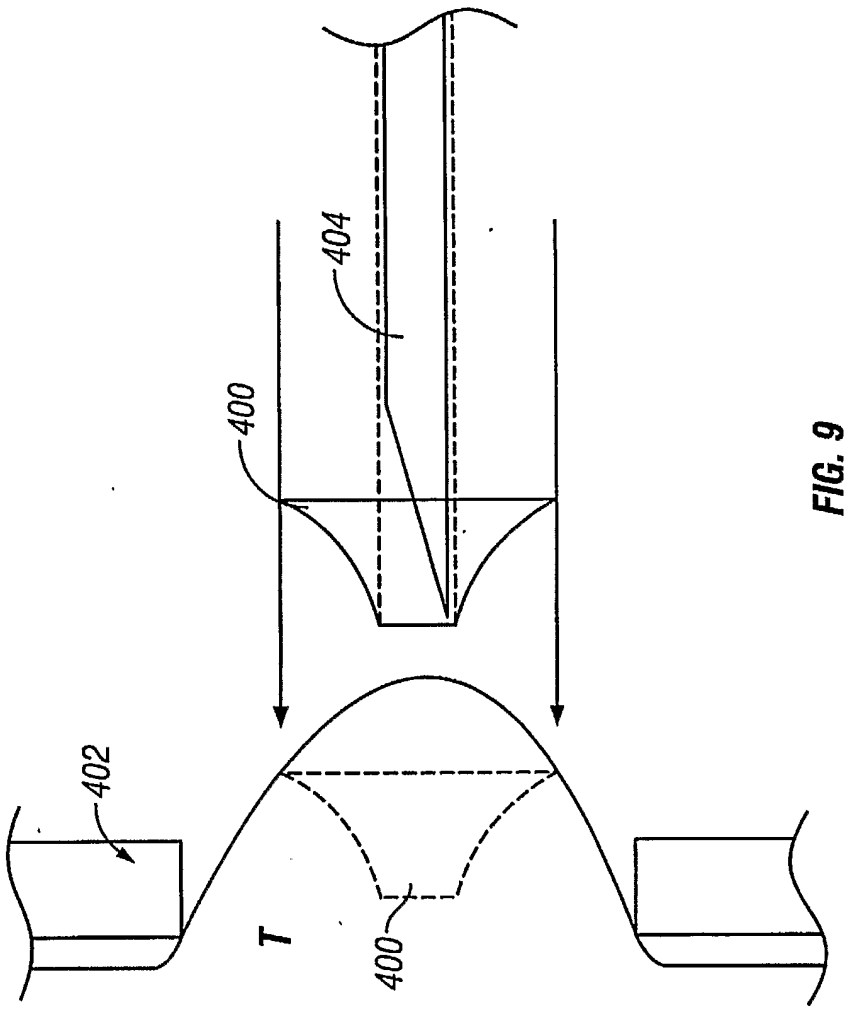


FIG. 9

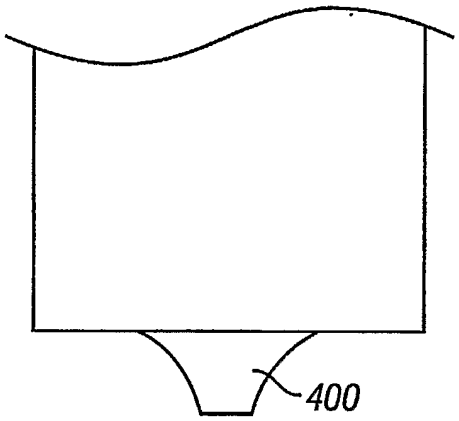


FIG. 10

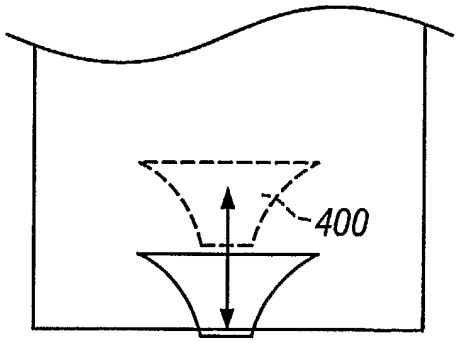


FIG. 11

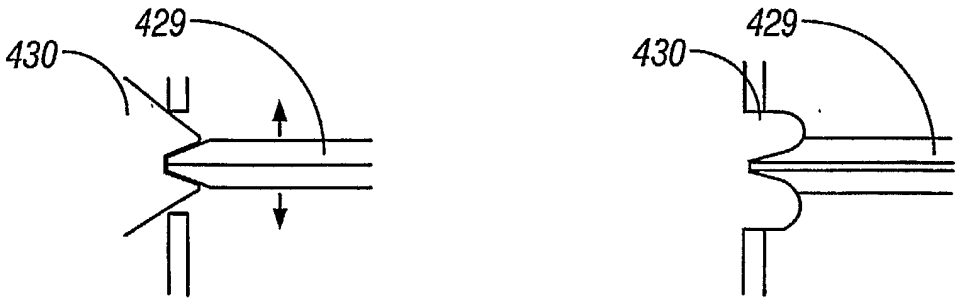


FIG. 12