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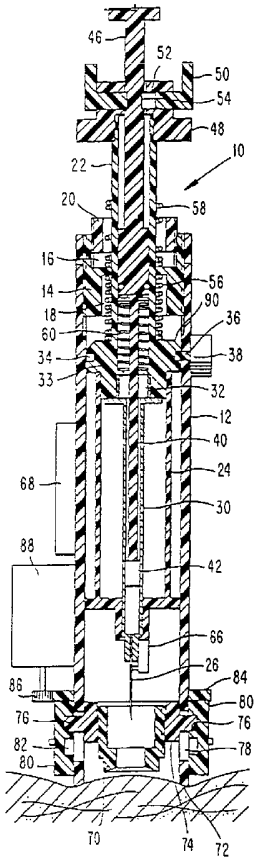

(57) Abstract: Bodily fluid is sampled by causing a syringe mounted in a housing to be displaced toward a skin surface. A suction element disposed on the housing is utilized to create a suction in the area to be incised causing bodily fluid to pool. Additionally, the suction mechanism may be utilized to create a suction in the tube for drawing in bodily fluid through the piercing element and into the tube. The syringe remains in the resulting incision while the surrounding body tissue is stimulated by a stimulator ring to urge bodily fluid toward the incision. Simultaneously, the syringe may be moved relative to the incision to keep the incision open. Such movement of the syringe may comprise reciprocation in the longitudinal or lateral directions, or both. Alternatively, the movement of the syringe may comprise rotation about a longitudinal center line of the syringe, with the pointed end of the syringe being in the shape of one-half of a cone segment. The suction may then be applied to the area being incised to promote further pooling of bodily fluid. After the bodily fluid has been pooled, suction may be created in a collection tube disposed in communication with the syringe, to draw bodily fluid inwardly through the syringe.

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METHOD AND APPARATUS FOR SAMPLING BODILY FLUID

PRIOR APPLICATIONS

This application claims benefit to U.S. Provisional Applications: Ser. No. 60/296,950, 60/297,045, and 60/297,098 each filed June 8, 2001; 60/263,533 filed January 22, 2001; and U.S. Patent Applications Ser. No. 09/528,097 filed March 17, 2000; US97/08401 file May 16, 1997; US97/08400 filed May 16, 1997; 09/887,574 filed June 21, 2001; 09/586,969 filed June 5, 2000; 09/180,839 filed November 16, 1998; 09/542,040 filed March 31, 2000; 09/567,054 filed May 8, 2000; The entireties of each of which are herein incorporated by reference.

FIELD OF THE INVENTION

The present invention relates to lancing devices and methods for obtaining samples of blood and other fluids from a body for analysis or processing.

BACKGROUND OF THE INVENTION

Many medical procedures in use today require a relatively small sample of blood, in the range of 3-50 milliliters. It is more cost effective and less traumatic to the patient to obtain such a sample by lancing or piercing the skin at a selected location, such as the finger, to enable the collection of 1 or 2 drops of blood, than by using a phlebotomist to draw a tube of venous blood. With the advent of home use tests such as self monitoring of blood glucose, there is a requirement for a simple procedure which can be performed in any setting by a person needing to test.

Lancets in conventional use generally have a rigid body and a sterile needle which protrudes from one end. The lancet may be used to pierce the skin, thereby

enabling the collection of a blood sample from the opening created. The blood is transferred to a test device or collection device. Blood is most commonly taken from the fingertips, where the supply is generally excellent. However, because the patient must perform multiple tests daily, the fingertips become sensitive or calloused thereby making it difficult to obtain a sample. Additionally, the nerve density in this region causes significant pain in many patients. Therefore alternate sampling sites, such as earlobes and limbs, is sometimes practiced to access a bodily fluid sample.

To reduce the anxiety of piercing the skin and the associated pain, many spring loaded devices have been developed. The following two patents are representative of the devices which were developed in the 1980's for use with home diagnostic test products.

U.S. Pat. No. 4,503,856, Cornell et al., describes a spring loaded lancet injector. The reusable device interfaces with a disposable lancet. The lancet holder may be latched in a retracted position. When the user contacts a release, a spring causes the lancet to pierce the skin at high speed and then retract. The speed is important to reduce the pain associated with the puncture.

Levin et al. U.S. Pat. No. 4,517,978 describes a blood sampling instrument. This device, which is also spring loaded, uses a standard disposable lancet. The design enables easy and accurate positioning against a fingertip so the impact site can be readily determined. After the lancet pierces the skin, a bounce back spring retracts the lancet to a safe position within the device.

In institutional settings, it is often desirable to collect the sample from the patient and then introduce the sample to a test device in a controlled fashion. Some blood glucose monitoring systems, for example, require that the blood sample be

applied to a test device which is in contact with a test instrument. In such situations, bringing the finger of a patient directly to the test device poses some risk of contamination from blood of a previous patient. With such systems, particularly in hospital settings, it is common to lance a patient, collect a sample in a micropipette via capillary action and then deliver the sample from the pipette to the test device.

Haynes U.S. Pat. No. 4,920,977 describes a blood collection assembly with lancet and microcollection tube. This device incorporates a lancet and collection container in a single device. The lancing and collection are two separate activities, but the device is a convenient single disposable unit for situations when sample collection prior to use is desirable. Similar devices are disclosed in Sarrine U.S. Pat. No. 4,360,016, and O'Brien U.S. Pat. No. 4,924,879.

Jordan et al. U.S. Pat. No. 4,850,973 and No. 4,858,607, disclose a combination device which may be alternatively used as a syringe-type injection device and a lancing device with disposable solid needle lancet, depending on configuration.

Lange et al. U.S. Pat. No. 5,318,584 describes a blood lancet device for withdrawing blood for diagnostic purposes. This invention uses a rotary/sliding transmission system to reduce the pain of lancing. The puncture depth is easily and precisely adjustable by the user.

Suzuki et al. U.S. Pat. No. 5,368,047, Dombrowski U.S. Pat. No. 4,654,513 and Ishibashi et al. U.S. Pat. No. 5,320,607 each describe suction-type blood samplers. These devices develop suction between the lancing site and the end of the device when the lancet holding mechanism withdraws after piercing the skin. A flexible gasket around the end of the device helps seal the end around the puncture site until adequate sample is drawn from the puncture site or the user pulls back on the device.

Garcia et al. U.S. Pat. No. 4,637,403 and Haber et al. U.S. Pat. No. 5,217,480, disclose combination lancing and blood collection devices which use a diaphragm to create a vacuum over the wound site.

Erickson et al. U.S. Pat. No. 5,582,184 describes a means of collecting and measuring bodily fluids. This system uses a coaxial syringe and capillary tube disposed within a spacer member. The spacer member limits the depth of syringe penetration, and compresses body tissue around the syringe while the syringe is in the skin, for improving the flow of interstitial fluid to the syringe. A suction device draws bodily fluid through the syringe and into the capillary tube.

Single use devices have also been developed for single use tests, i.e. home cholesterol testing, and for institutional use to eliminate cross-patient contamination multi-patient use. Crossman et al. U.S. Pat. No. 4,869,249, and Swierczek U.S. Pat. No. 5,402,798, also disclose disposable, single use lancing devices. U.S. Pat. No. 5,421,816; 5,445,611; and 5,458,140 disclose, as a replacement for invasive sampling, the use of ultrasound to act as a pump for expressing interstitial fluid directly through intact (non-lanced) skin. The amount of fluid which can be obtained in that way is very limited, however.

The disclosures of the above patents are incorporated herein by reference.

Even with the many improvements which have been made, the pain associated with lancing remains a significant issue for many patients. The need for blood sampling and the fear of the associated pain is also a major obstacle for the millions of diagnosed diabetics, who do not adequately monitor their blood glucose due to the pain involved. Moreover, lancing to obtain a blood sample for other diagnostic applications is becoming more commonplace, and a less painful, minimally invasive device is needed to enhance those applications and make those technologies more acceptable.

An object of the present invention therefore, is to provide a device and a method for obtaining a sample of bodily fluid through the skin which is virtually pain free and minimally invasive.

Therefore, it is another object of the invention to provide a lancet carrier which eliminates the above-mentioned shortcomings.

Another object of this invention is to provide a method which can result in a sample of either blood or interstitial fluid, depending on the sample site and the penetration depth utilized. While there are no commercially available devices utilizing interstitial fluid (ISF) at this time, there are active efforts to establish the correlation of analytes, such as glucose, in ISF compared to whole blood. If ISF could be readily obtained and correlation is established, ISF may be preferable as a sample since there is no interference of red blood cells or hematocrit adjustment required.

Another object of this invention is to provide a method which can draw a small but adjustable sample, i.e. 3 microliters for one test device and 8 microliters for another test device, as appropriate.

Another object of this invention is to provide a method by which the drawn sample is collected and may be easily presented to a testing device, regardless of the location of the sample site on the body. This approach helps with infection control in that multiple patients are not brought in contact with a single test instrument; only the sampling device with a disposable patient-contact portion is brought to the test instrument. Alternatively, the disposable portion of a test device may be physically coupled with the sampler so the sample can be brought directly into the test device during sampling. The test device may then be read in a test instrument if appropriate or the testing system can be integrated into the sampler and the test device can provide direct results displayed for the patient.

It is a further object of the invention is to provide a device for minimally invasive sampling comprising a reusable sampler and disposable sample collection.

Yet another object of the present invention is to provide a method of increasing the amount of bodily fluid available for sampling.

SUMMARY OF THE INVENTION

These and other objects are achieved by the present invention, one aspect of which relates to a method for sampling blood comprising the steps of placing a forward end of a housing against a skin surface, advancing a hollow piercing element forwardly to cut an incision through the skin surface, and depressing a ring of body tissue in surrounding relationship to the incision to spread apart sides of the incision while urging bodily fluid toward and into the incision. Simultaneously, the piercing element is moved within the incision to keep the incision open. A suction may be applied to the skin to aid the pooling of bodily fluid in the area of the incision. Additionally, a suction may be applied to the piercing element to draw in bodily fluid from the incision and into a tube communicating with the piercing element.

Another aspect of the present invention relates to a sampling device for sampling bodily fluid. The sampling device comprises a housing, a piercing element carrier mounted in the housing and carrying a hollow piercing element. A tube communicates with the piercing element. A driver mechanism mounted in the housing drives the syringe carrier forwardly to cut an incision in the skin and maintain and end of the piercing element in the incision. A stimulator mechanism disposed on the housing depresses a ring of body tissue in surrounding relationship to the incision to spread apart sides of the incision while urging bodily fluid toward the incision. A syringe-moving mechanism disposed on the housing moves the end of the piercing element relative to the incision to maintain the incision open while the stimulator mechanism urges bodily fluid thereto. A suction mechanism disposed on the housing creates a suction to cause bodily fluid to pool in the area to be incised, as will be described in greater detail below. Additionally, the suction element may be applied to the tube and utilized for drawing in bodily fluid through the piercing element and into the tube.

Still another aspect of the invention relates to a device for obtaining a

sampling of a bodily fluid through the skin comprising a housing member containing a hollow piercing element for piercing the skin. A first spring member disposed in the housing urges the piercing element to protrude from a forward end of the housing sufficient to cut an incision through the skin. A stop member defines a maximum penetration depth of the piercing element. A second spring disposed in the housing partially retracts the piercing element while maintaining a front end of the piercing element in the incision. A tube communicates with a rear end of the piercing element. A suction mechanism creates a suction in the tube for drawing in bodily fluid through the piercing element.

BRIEF DESCRIPTION OF THE DRAWINGS

The objects and advantages of the invention will become apparent from the following detailed description of preferred embodiments thereof in connection with the accompanying drawings in which like numerals designate like elements and in which:

FIG. 1 is a longitudinal sectional view taken through a sampling device according to the present invention, with a syringe thereof in an armed state;

FIG. 2 is a view similar to FIG. 1 after the syringe has been triggered and forms an incision in a skin surface;

FIGS. 3 is a view similar to FIG. 2 after a suction mechanism has been actuated to draw in bodily fluid through the syringe;

FIG. 3A is a sectional view taken along the line 3A--3A in FIG. 3;

FIG. 4 is a schematic view of a syringe being reciprocated longitudinally within an incision according to the present invention;

FIG. 5 is a schematic view of a syringe being reciprocated laterally within an incision according to the present invention;

FIG. 6 is a schematic view of a syringe being oscillated in an elliptical direction according to the present invention;

FIG. 7 is a schematic view of a syringe being rotated within an incision according to the present invention;

FIG. 8 is a longitudinal sectional view of a lower portion of a modified

sampling device according to the present invention, with a syringe disposed in a retracted state;

FIG. 9 is a view similar to FIG. 8 after the syringe has been urged forwardly;

FIG. 10 is a side elevational view of a lower end of a syringe having a stop member fixed thereto according to the present invention; and

FIG. 11 is a sectional view taken along the line 11-11 in FIG. 10;

FIG. 12 is a top view of a integrated testing/lancing apparatus according to one embodiment of the present invention;

FIG. 13 is a cross-sectional side view illustrating an integrated lancet and test strip holder according to the present invention; and

FIG. 14 is a side view illustrating the anti-coring needle in accordance with a lancing device of the present invention.

DESCRIPTION OF PREFERRED EMBODIMENTS

For the purposes of promoting an understanding of the principles of the invention, reference will now be made to the embodiments illustrated and specific language will be used to describe the same. It will nevertheless be understood that no limitation of the scope of the invention is thereby intended, such alterations, modifications, and further applications of the principles of the invention being contemplated as would normally occur to one skilled in the art to which the invention relates.

Depicted in FIGS. 1-3 is a bodily fluid sampling device 10 comprising an outer cylindrical housing 12. Screwed into an upper end of the housing 12 is a fixing sleeve 14 in which are formed upper and lower recesses 16, 18. The upper recess 16 has an internal screw thread connected to an externally threaded stop ring 20 which can be adjusted to a selected vertical position relative to the housing.

Slidably disposed for longitudinal movement within the fixing sleeve 14 is a hollow drive rod 22. Screwed onto a lower end of the drive rod 22 is a syringe carrier 24. Mounted in a lower end of the carrier 24 is a syringe 26 of the type which includes a longitudinal capillary passage 28 (see FIG. 4). That passage is preferably offset laterally with respect to a center axis of the syringe. In lieu of a syringe, any suitable type of hollow piercing element can be employed, such as a needle or sharp cannula, for example. An upper end of the syringe communicates with a sampling tube 30, an upper end of the tube fitting into a lower recess 32 formed in the drive rod 22.

Intermediate its upper and lower ends, the drive rod 22 includes a radial enlargement 33 in which an outwardly open, annular groove 34 is formed that is sized to receive a pin 36 of a first trigger 38.

Slidably mounted within the sampling tube 30 is a plunger 40 having a soft tip 42 that snugly (sealingly) engages an inner surface of the tube 30. An upper end

of the plunger 40 is fixed to the lower end of a drawbar 46 which slides within a center bore of the drive rod 22.

Screwed to an upper end of the drive rod 22 is a mounting sleeve 48 in which a second trigger 50 is mounted for lateral sliding movement. Formed in the second trigger 50 is a center hole 52 that is larger than the outer diameter of the drawbar 46. The drawbar 46 has a recess 54 sized to receive respective sides of the hole 52.

A drive spring 56 in the form of a coil compression spring acts between the enlargement 33 and the fixing sleeve 14. Resting on the fixing sleeve 14 is a retraction spring 58 in the form of a coil compression spring. Acting between the enlargement 33 and the top of the plunger 40 is a suction spring 60 in the form of a coil compression spring.

Mounted on the syringe carrier 24 is a piezoelectric transducer 66 which is electrically connected to a battery 68. Piezoelectric transducers are conventional types of vibrators which can be oriented to produce vibrations in any desired direction. A lower end of the piezoelectric transducer 66 is in contact with the syringe for vibrating the syringe, i.e., either vertically (longitudinally), laterally, or elliptically (a combination of vertical and lateral vibrations).

Disposed at a lower end of the housing 12 is a stimulator sleeve 70. That sleeve has an annular lower face 72 of frusto-conical shape, and is screwed into a sleeve carrier 74. Projecting from diametrically opposite positions of the sleeve carrier 74 are pins 76 which are slidably disposed in respective vertical slots 78 formed in the housing 12.

Rotatably mounted on diametrically opposite sides of the housing 12 are a pair of identical drive gears 80 (see also FIG. 3A). Formed in an inner surface of each drive gear 80 is a cam groove 82 in which a respective pin 76 projects.

Mounted above the drive gear for rotation about a central longitudinal axis of the housing is a ring gear 84 which is rotated by an output pinion 86 of an electric motor 88. The underside of the ring gear 84 is formed with teeth that mesh with teeth formed around the outer peripheries of the drive gears 80. Therefore, rotation of the pinion gear 86 is transmitted to the drive gears 80 to rotate the drive gears. The accompanying rotation of the eccentric grooves 82 of the drive gears causes the pins 76, and thus the sleeve carrier 74, to reciprocate vertically, along with the stimulator sleeve.

The operation of the sampling device 10 will now be explained. To arm the device, the mounting sleeve 48 is pulled upwardly by a user until a beveled face 90 of the enlargement 33 of the drive rod 22 cams the first trigger 38 laterally outwardly. When the groove 34 of the enlargement becomes aligned with the cammed-out first trigger 38, the first trigger is urged inwardly by a spring (not shown) to insert the pin 36 into the groove 34 for retaining the drive rod 22 in the armed state (FIG. 1). Simultaneously, the drive spring 56 is compressed from a relaxed state, and the syringe carrier 24, together with the syringe 26, is raised. The drawbar 46 is retained by the second trigger 50, with the suction spring 60 disposed in a compressed state.

The lower end 72 of the housing 12 is placed against the skin surface S, preferably at a portion of the body having fewer nerve endings than, say the fingertip. A forearm would be a suitable location. Suction may be applied to the skin surface S at this time. The suction may be applied and held, or applied and released prior to the syringe cutting the skin. The trigger 38 is then pulled out against a spring bias to release the drive rod 22 and the compressed drive spring 56. As a result, the drive rod 22, the syringe carrier 24, and syringe 26 are driven downwardly, so that the syringe cuts an incision I through the skin surface S, as shown in FIG. 2.

During downward movement of the drive rod 22, the mounting sleeve 48

engages an upper end of the retraction spring 58 and then abuts the stop ring 20, thereby limiting the incision depth and slightly compressing the retraction spring 58. The retraction spring 58 then moves the drive rod 22 slightly upwardly, but not enough to completely remove the syringe 26 from the incision I. Then, the motor 88 is actuated, either manually, or automatically in response to the firing of the syringe, to vertically reciprocate the stimulator sleeve 70. Consequently, the lower face 72 repeatedly depresses a ring of skin and body tissue which surrounds the incision. Each depression of that ring causes the incision to bulge and the sides of the incision to be spread apart, and urges bodily fluid such as blood or interstitial fluid toward and outwardly through the incision I, as explained also in commonly assigned U.S Patents No. 5,879,311, and 5,591,493.

In order to enable the inwardly urged bodily fluid to pool at the incision (for subsequent sampling), the syringe 26 is vibrated relatively slowly by the piezoelectric transducer 66 to keep the incision open. As noted earlier, the direction of vibration can be determined by the particular orientation of the transducer 66. In one embodiment, the direction of vibration is longitudinal or vertical (FIG. 4); in another embodiment the vibration is lateral (FIG. 5); in another embodiment the vibration is a combination of lateral and vertical, i.e., generally elliptical oscillation (FIG. 6).

It will be appreciated that if the syringe were not moved within the incision, the presence of a stationary syringe within the incision could result in a closing of the incision by collagen in the skin, whereby bodily fluid could not pool at the incision.

After a short period, sufficient to allow an ample amount of bodily fluid to pool at the incision, the second trigger 50 is manually actuated to release the drawbar 46, causing the spring 60 to raise the plunger 40 within the tube 30. That produces a suction in the tube 30 below the plunger 40, which draws in a sample 91 of bodily fluid through the syringe 26 (FIG. 3).

Then, the device can be removed from the skin, and the sample delivered to a suitable test site. Alternatively, the device may contain a test device in conjunction with the sampling device described above. Suitable test devices which may be incorporated with the sampler described above are shown and described in co-pending U.S. Patent Application No. (Insert)

As an alternative to the reciprocation of the syringe, the syringe can be rotated about its own center axis while disposed in the incision I. In that regard, a rotatable syringe 92 as shown in FIG. 7 can be utilized in a device 10' shown in FIGS. 8 and 9. That device 10' is similar to that depicted in FIGS. 1-3 with the addition of a rotary gear 94 that is driven by a pinion 95 of a second motor 96. The gear 94 includes an upwardly open recess 98 sized to receive, with a snug fit, a lower end 100 of the tube 30 in which the syringe 92 is disposed. Thus, when the syringe carrier 24' is driven toward the skin, the lower portion 100 of the tube 30 enters the recess 98 to create a frictional engagement between the tube 30 and the gear 94 (see FIG. 9). By then rotating the pinion 95, the gear 94, the tube 30, and the syringe 92 are rotated relative to the carrier 24' about an axis coinciding with a center axis of the syringe 92. The syringe 92 includes a pointed end 102 in the form of one-half of a cone. As the syringe rotates about its own axis, the semi-conical segment 102 cuts a conical recess 104 in the incision and keeps the incision open as the stimulator sleeve 70 reciprocates.

Any of the syringes described thus far can be provided with a stop which would replace the stop ring 20. Such a stop 110 is shown in FIGS. 10 and 11 in connection with the syringe 92. The stop 110 comprises a disc fixed to the syringe. When the disc contacts the skin surface, no further entry of the syringe into the skin can occur. The stop ring 20 could also be used to open and close the incision to promote bodily fluid pooling.

It will be appreciated that the present invention minimizes the pain

experienced by a user, because it can be used to provide a sample of bodily fluid at an area of the body which contains fewer nerve endings than in an area such as the finger tips. By stimulating the body tissue surrounding the incision, while moving the syringe relative to the incision, bodily fluid is caused to pool in the incision, thereby providing an ample sample to be sucked through the syringe and into a collection tube. Thus, an area of the body less sensitive to pain can be used as a source of bodily fluid.

Although the stimulator member 70 is disclosed as having a generally annular skin contacting surface, i.e., a surface which is symmetric about the center axis thereof, the member 70 could instead have an elliptical or polygonal end face whereby the ring of body tissue depressed thereby would have a corresponding shape.

An alternative method according to the present invention includes the use of a suction device prior to use of the lancing device. The lower end of the housing 12 is placed against the skin surface S, preferably at a portion of the body where the sample is to be taken from. For example, a forearm would be a suitable location. A vacuum source is activated whereupon the skin S adjacent the lower end of the housing 12 is drawn into the frusto-conical shaped distal tip. The suction causes bodily fluid beneath the skin to pool in the area of skin S in contact with the testing device 10. The vacuum is released thereby releasing the skin. The trigger 38 is then pulled out against a spring bias to release the drive rod 22 and the compressed drive spring 56. As a result, the drive rod 22, the syringe carrier 24, and syringe 26 are driven downwardly, so that he syringe cuts an incision I through the skin surface S. During the downward movement of the drive rod 22, the mounting sleeve 48 engages an upper end of the retraction spring 58 and then abuts the stop ring 20, thereby limiting the incision depth and slightly compressing the retraction spring 58. The retraction spring 58 then moves the drive rod 22 slightly upwardly, but not enough to completely remove the syringe 26 from the incision I. Then, the motor 88 is actuated, either manually, or automatically in response to the

firing of the syringe, to vertically reciprocate the stimulator sleeve 70. Consequently, the lower face 72 repeatably depresses a ring of skin and body tissue which surrounds the incision. The depression of the ring causes the skin adjacent the incision to bulge and the sides of the incision spread apart, such that bodily fluid is urged from the incision in response to the applied force.

After a short period, sufficient to allow an ample amount of bodily fluid to pool at the incision, the second trigger 50 is manually actuate to release the drawbar 46, causing the spring 60 to raise the plunger 40 within the tube 30. This produces suction in the tube 30 below the plunger 40, which draws in a sample 91 of bodily fluid through the syringe. The sample may then be delivered to an appropriate test media or testing device as described above.

Additionally, as described above, the vacuum may be repeatedly applied to the skin prior to deployment of the needle to form the incision I. By repeatably applying a vacuum source to the skin S this encourages bodily fluid to pool in the location adjacent to where the incision is to be made. Because bodily fluid is pooled in this area prior to formation of the incision I, once the incision I is formed the a sample is bodily fluid is easily collected because of the large volume of fluid available within the area.

It is further contemplated that the vacuum mechanism may be activated after the incision is formed to further express fluid from the incision. In addition to the vacuum source, it is also contemplated that a vibratory force, a heat force, and/or an ultrasonic force may be applied to the area to be lanced to further the expression of bodily fluid. Additionally, the vacuum may be repeatedly applied to the skin after the formation of incision I. Repeated application of a vacuum after the incision is formed encourages bodily fluid to continue to pool in the area adjacent to the incision, thereby aiding collection of the bodily fluid.

Referring now to Figure 12 there is shown yet another alternative

embodiment of the present invention. As shown in Figure 12 the test device 100 comprises a main body 120, a test strip holder/tip assembly 130, and a lancing device 150. The functions of the testing device 100 are similar to that as described above with reference to testing device 10. The testing device 100 is prepared for use by first inserting a disposable lancet/test strip holder and test strip into the lancing device 150. The lancing device 150 is then prepared for use by pulling up on a driving mechanism (not shown) thereby compressing a driving spring (not shown). The device 100 is placed over an area to be lanced, wherein a vacuum mechanism disposed within the main body 120 and in communication with the tip assembly 130 is then activated. Skin S is drawn into the distal end of the device 100. The vacuum mechanism may then be deactivated thereby releasing the vacuum force on the skin, or repeatedly activated and deactivated.

After the vacuum device has been utilized, device 100 releases the driving spring, wherein a lancet is advanced through the patient's skin to form an incision I therein. The lancet may then be retracted from the incision I. Alternatively, it may be desirable to leave the lancet within or directly adjacent the incision for the reasons described above. Additionally, the vacuum device may be activated, activated and deactivated, or repeatedly activated and deactivated after forming the incision. Furthermore, a vibratory force may be applied to the lancet, the vibratory force may be applied vertically, horizontally, or any combination thereof.

A sample of bodily fluid may then be withdrawn from the incision and transported to a test area. The sample may be withdrawn from the incision through a capillary tube having one end disposed within the end of the test device 100 and the other end in communication with a chemical pad of a test strip and or electrochemical measuring device. Alternatively, the test strip may include capillary means such as a capillary tube or a cascading capillary. In yet another alternative embodiment, the test strip may be disposed adjacent to the distal end of the testing device wherein the lancet passes through an aperture in the test strip. The test strip may further include a gasket and/or a deep dermal constriction

device. Furthermore, by placing the strip against the patient's skin and lancing there through this eliminates the need for a capillary to transport the bodily fluid from the incision to the test strip. This may lead to shorter sample times and/or lessen the likelihood of a failed test due to inadequate sample delivery.

In yet an additional alternative embodiment as shown in Figures 13 and 14, the test device 200 may include a test strip (not pictured) and lancet 220 which may be formed as an integrated unit. The lancet 220 may be embodied in the form of an anti-coring needle having a pre-bent radius of curvature R and a fluid inlet 223 such as that described in co-pending provisional patent application no. 60/297,098 filed on June 8, 2001, the entirety of which is herein incorporated by reference. In this embodiment, the test device is placed over the area to be lanced, a vacuum is drawn on the skin thereby increasing the amount of bodily fluid adjacent the test device. The vacuum is release and the lancet is advanced thereby forming an incision within the patient's skin. Bodily fluid may then be withdrawn from the incision. The bodily fluid is then collected using one of the devices described above. After a sufficiently sized sample has been collected, the test device may be removed from the patient's skin, this may be prompted by a audible and/or visual marker. The test device will then deliver to the patient a visual indication of the test results.

While the invention has been illustrated and described in detail in the drawings and foregoing description, the same is to be considered as illustrative and not restrictive in character, it being understood that only the preferred embodiment has been shown and described and that all changes and modifications that come within the spirit of the invention are desired to be protected.

What is claimed is:

1. A method of expressing bodily fluid from an incision in the skin, the method comprising:

disposing a testing device against the skin at a location from which the bodily fluid sample is to be taken, the testing device including a distal end portion forming a seal with the skin;

activating a vacuum source communicating with the distal end portion of the testing device and drawing the skin in the area into the distal end portion of the testing device;

deactivating the vacuum source;

forming an incision in the skin with a hollow piercing element; and

collecting the bodily fluid for testing using the hollow piercing element.

2. The method according to claim 1, wherein the testing device includes the vacuum source.

3. The method according to claim 1, wherein the vacuum source is applied before forming the incision.

4. The method according to claim 1, wherein the vacuum source is applied after the forming the incision.

5. The method according to claim 1, wherein the vacuum source is applied before and after the forming the incision.

6. The method according to claim 1, wherein the step of deactivating the vacuum source further includes releasing the vacuum between the testing device and the area of the skin to be lanced.

7. The method according to claim 1, wherein the testing device further includes a hollow fluid transport member having one end in fluid communication with the hollow piercing element and a second end in fluid communication with a

test strip.

8. The method according to claim 7, wherein the vacuum source creates a vacuum in the hollow fluid transport member.

9. The method according to claim 7, wherein the test strip is chemical based.

10. The method according to claim 7, wherein the test strip is electrochemical.

11. The method according to claim 1, wherein the method further includes drawing the sample of bodily fluid from the incision to a test strip, determining the level of glucose in the bodily fluid, and displaying the level on a display included on the testing device.

12. The method according to claim 1, wherein the testing device further includes a stimulating device disposed about the distal end of the testing device, the method further including stimulating the area of the skin to be lanced with the stimulating device to pucker the skin.

13. The method according to claim 1, wherein the method further includes vibrating the hollow piercing element after forming the incision.

14. The method according to claim 1, wherein the method further includes rotating the hollow piercing element after forming the incision.

15. The method according to claim 5, wherein the testing device further includes a stimulating device disposed about the distal end of the testing device, wherein the method further includes oscillating the stimulating to cause the area of the skin to be lanced to pucker, said method further including oscillating the hollow piercing element after forming the incision.

16. A hand-held apparatus for extracting bodily fluid from an incision in the skin, comprising:

a body having a distal end, the distal end being positionable against the skin surrounding an incision location;

a suction means coupled with said body for applying a suction to the distal end of said body;

a cutting member connected with said body and movable between a first position displaced from the skin and a second position extending into the skin at an incision location; and

a fluid extraction member positioned to receive bodily fluid from the incision location.

17. The invention of claim 16 wherein said suction means is for applying the suction prior to said cutting member contacting the skin.

18. The invention of claim 17 wherein said suction means is further for releasing the suction prior to said cutting member contacting the skin.

19. The invention of claim 16 wherein said suction means is for applying the suction after said cutting member contacts the skin.

20. The invention of claim 19 wherein said suction member is for first applying the suction and then subsequently releasing the suction.

21. The invention of claim 16 wherein said body further includes means for vibrating said cutting member after contacting the skin.

22. The invention of claim 16 wherein said body includes means for rotating said cutting member after contacting the skin.

23. The invention of claim 16 wherein said suction means is for applying the suction to said fluid extraction member.

24. The invention of claim 16 in which said body further includes a testing member wherein said fluid extraction member is configured to deposit extracted fluid onto said testing member.

25. The invention of claim 16 wherein said cutting member is hollow.

26. The invention of claim 16 wherein said body further includes means for oscillating the distal end.

27. The invention of claim 21 in which said body further includes a testing member, said fluid extraction member being configured to deposit extracted fluid onto said testing member, said body further including means for oscillating the distal end.

28. The invention of claim 21 wherein said cutting member is hollow and is in fluid communication with said fluid extraction member, said suction means being for applying suction to said fluid extraction member, said body further including means for oscillating the distal end.

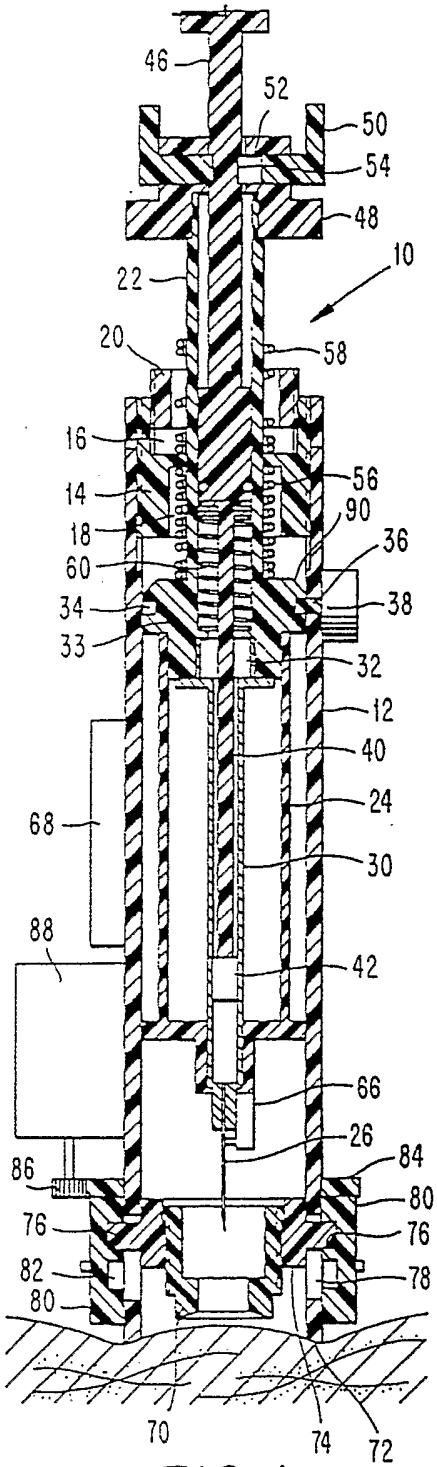
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FIG. 1

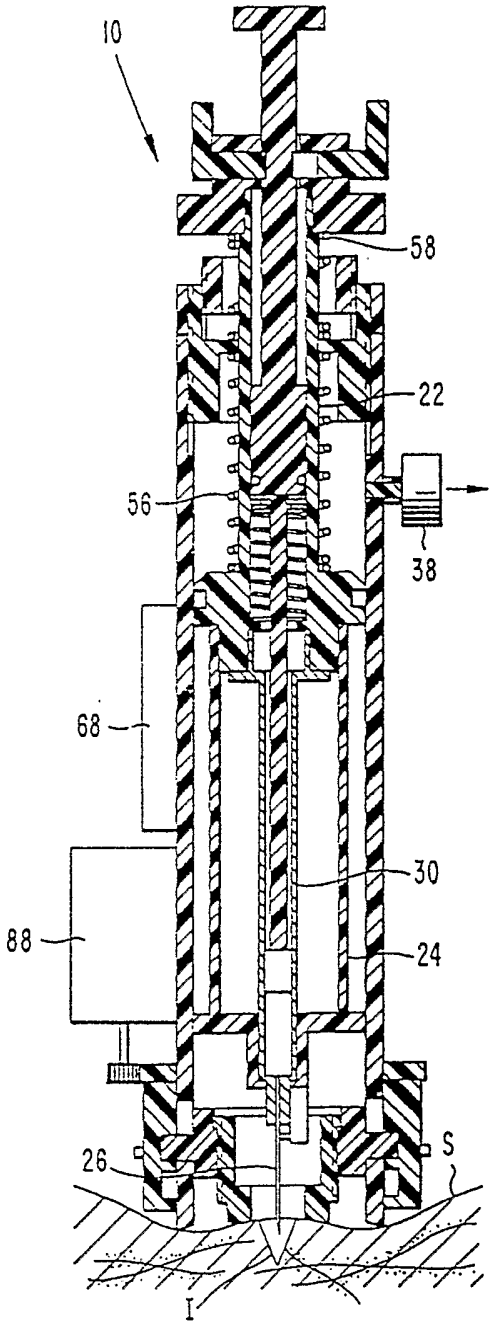
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FIG. 2

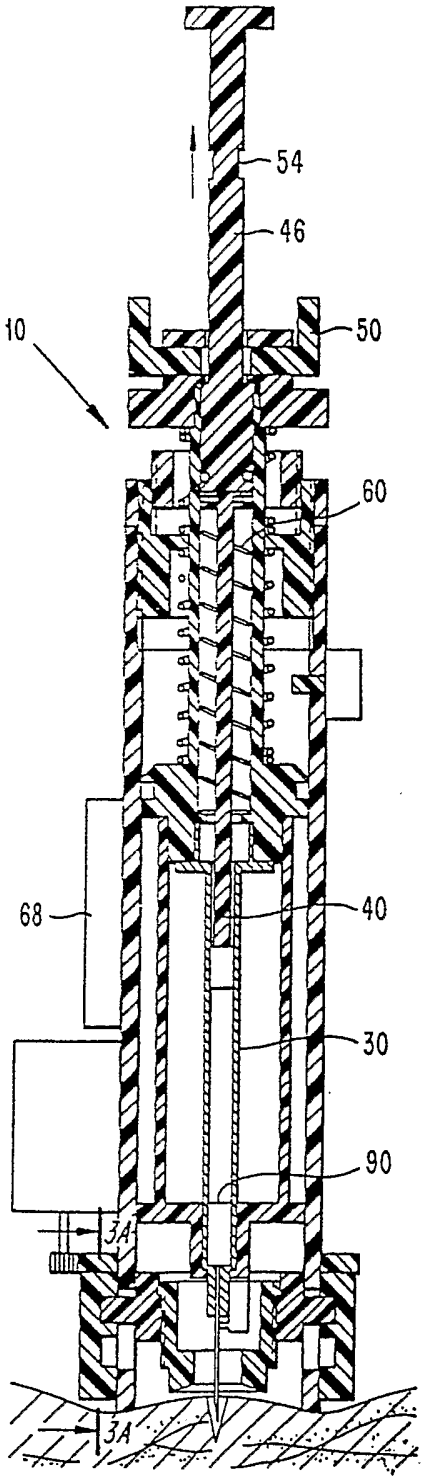

FIG. 3

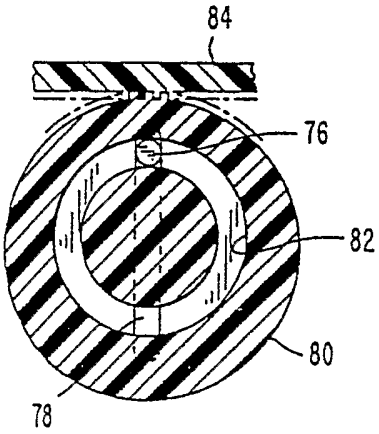

FIG. 3A

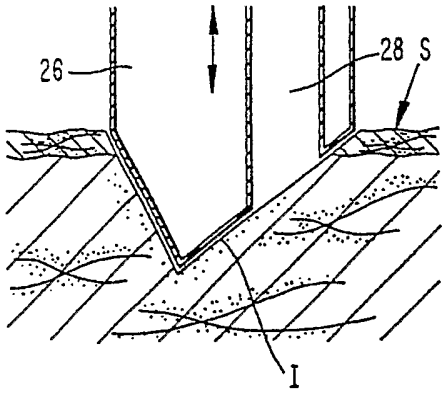

FIG. 4

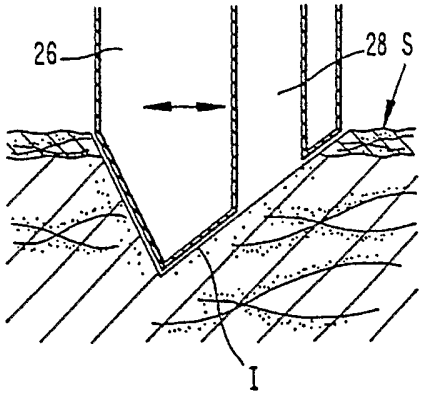

FIG. 5

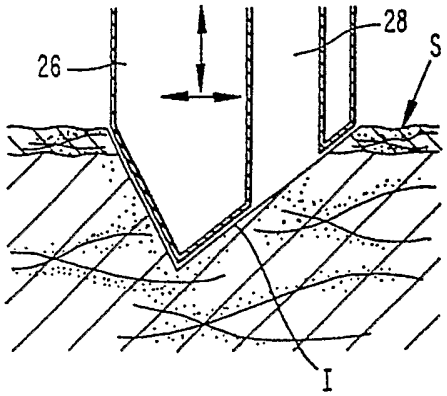

FIG. 6

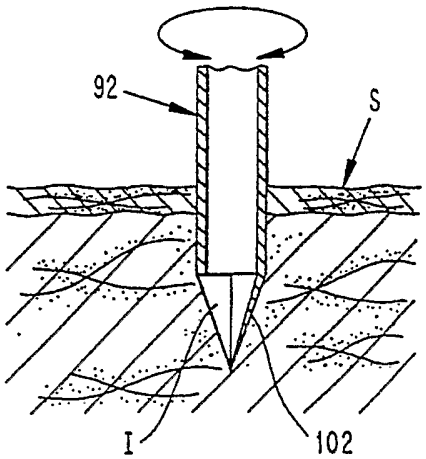

FIG. 7

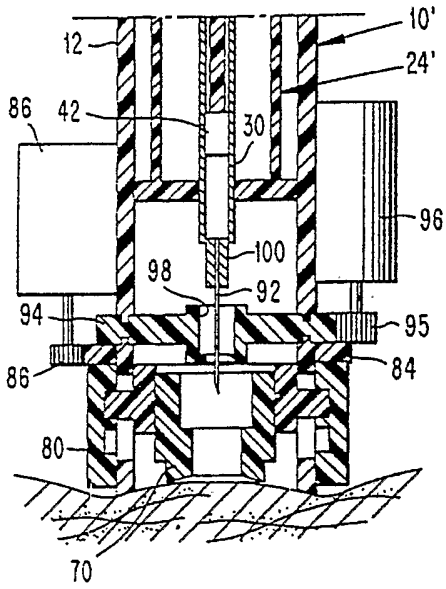

FIG. 8

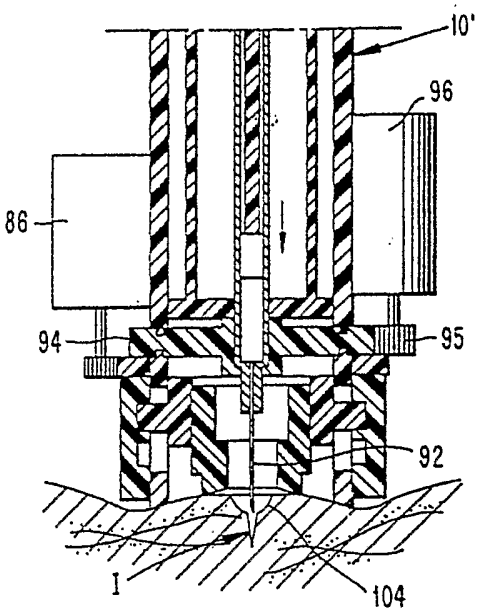

FIG. 9

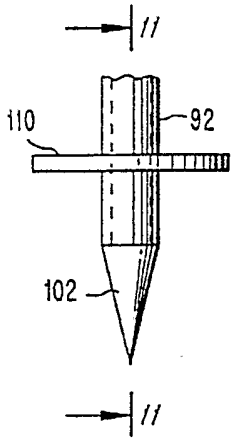

FIG. 10

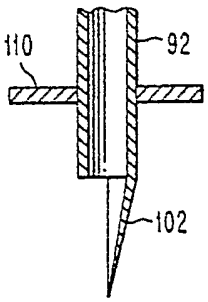

FIG. 11

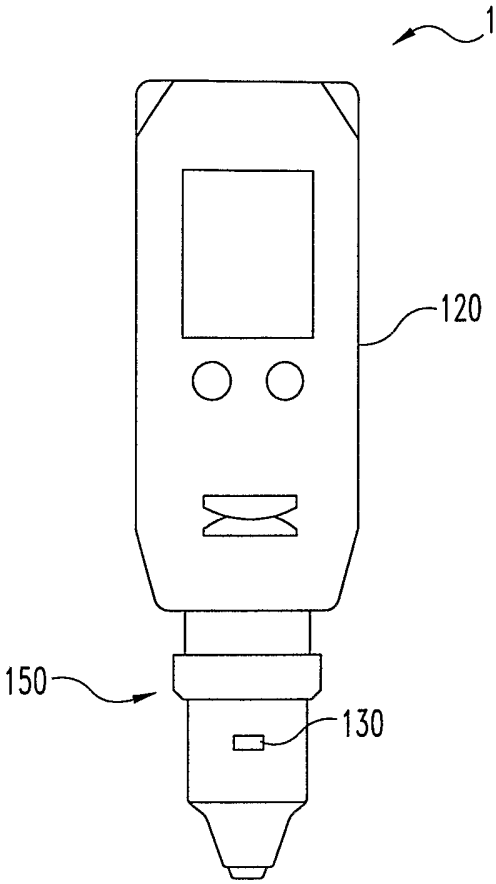

FIG. 12

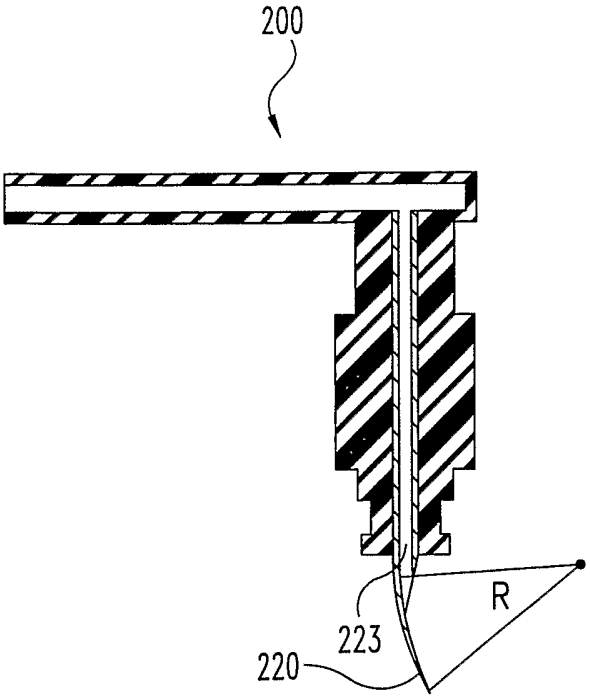

FIG. 13

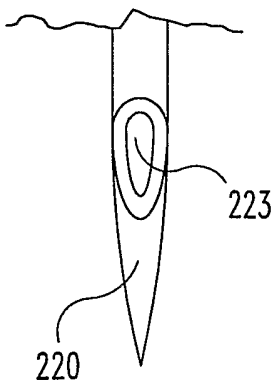

FIG. 14

INTERNATIONAL SEARCH REPORT

Int ›nal Application No
PCT/US 02/30531

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B5/15 A61B10/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	EP 1 112 717 A (ABBOTT LAB) 4 July 2001 (2001-07-04) page 4, line 34 -page 5, line 30 page 8, line 40 - line 58 page 10, line 16 -page 11, line 2 page 15, line 24 - line 34 page 16, line 43 -page 17, line 3; claims 1,7-9; figures 2,3,29A-D ---	16-20, 23,24 21,22, 25-28
Y	US 6 015 392 A (RADWANSKI RYSZARD ET AL) 18 January 2000 (2000-01-18) column 3, line 66 -column 4, line 29 column 5, line 60 - line 67 column 6, line 60 -column 7, line 21; claims 1,3; figures 3-7 abstract --- -/--	21,22, 25-28

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
14 February 2003	06/03/2003

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Rick, K

INTERNATIONAL SEARCH REPORT

International Application No
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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4 895 147 A (BODICKY RAYMOND O ET AL) 23 January 1990 (1990-01-23) column 1, line 67 -column 2, line 35 column 6, line 25 - line 56 column 7, line 16 - line 68; claims 4,8,10,11,13-15,20,21,25-27,30,32 ---	16-20, 23,24
X	US 6 086 545 A (ROE JEFFREY N ET AL) 11 July 2000 (2000-07-11) column 4, line 25 - line 49 column 6, line 25 -column 7, line 14; claims 1,2,4; figures 1-6 -----	16,19, 20,23

INTERNATIONAL SEARCH REPORT

national application No.
PCT/US 02/30531

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 1-15
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 02/30531

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