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(54) **ANALYZING APPARATUS, PIERCING ELEMENT INTEGRALLY INSTALLED BODY FOR TEMPERATURE MEASURING DEVICE WITH ANALYZING APPARATUS, AND BODY FLUID SAMPLING APPARATUS**

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(52) **U.S. Cl.** **600/583; 600/584**

(57) **ABSTRACT**

The present invention relates to an analyzing instrument (1A) which includes a capillary (31), a fluid feed port (20) for introducing a sample liquid to the capillary (31), and a fluid feed promoter (6) for promoting the introduction of the sample liquid into the feed port (20). The capillary (31) of the analyzer (1A) maybe formed on a substrate (2) for example. The fluid feed promoter (6) may include at least one of a water-absorbing layer having a higher water-absorbing capacity than the substrate (2) and an adhesive layer having a greater adhesion to the skin than the substrate (2).

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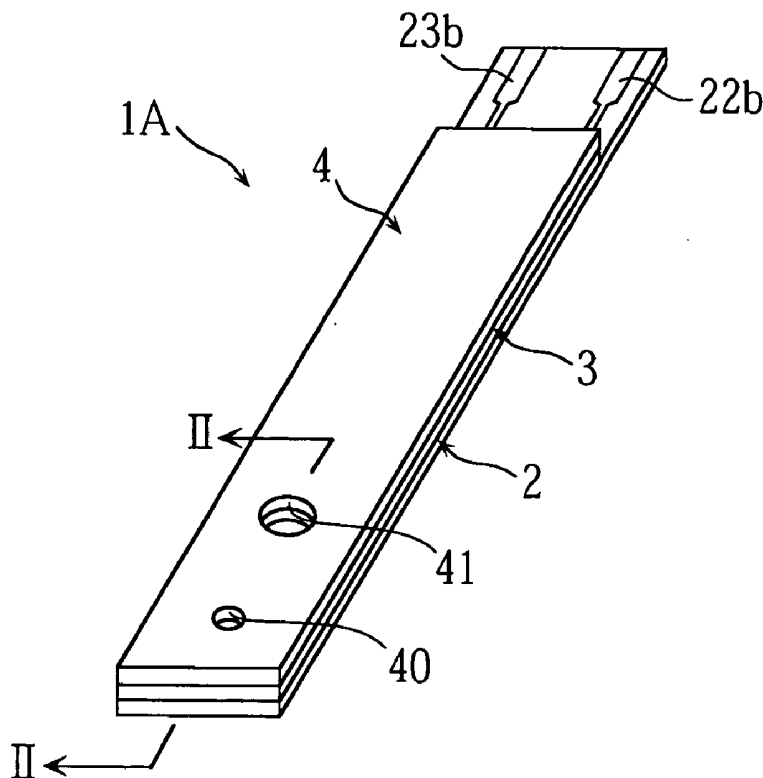


FIG. 1

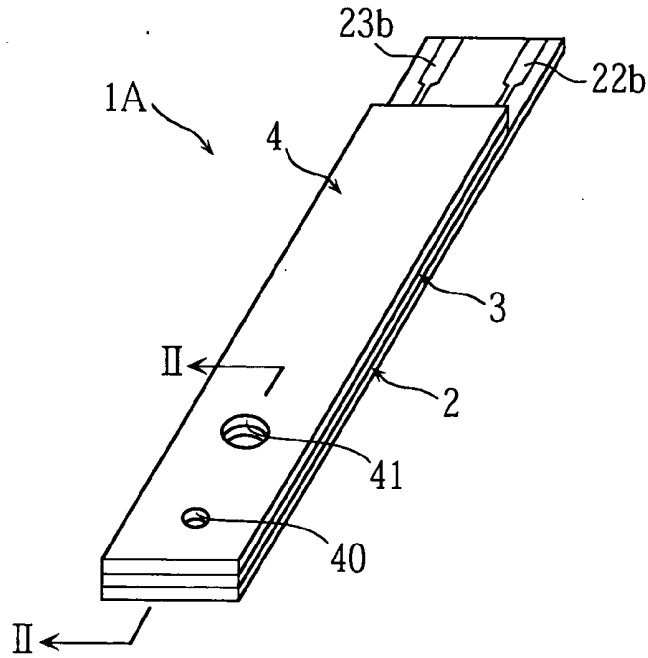


FIG. 2

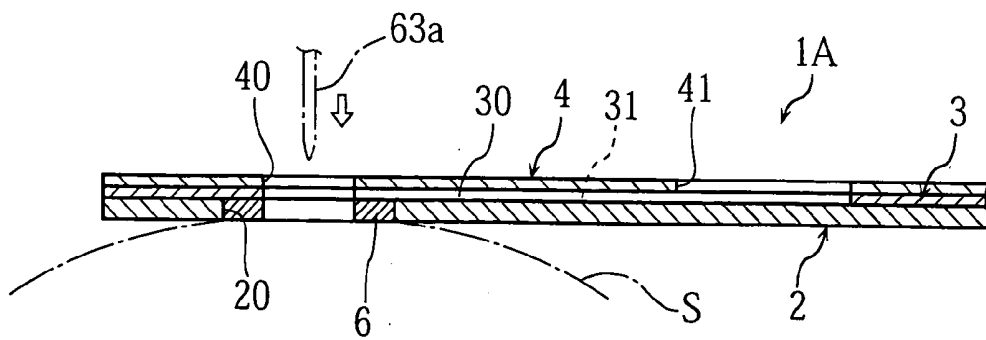


FIG.3

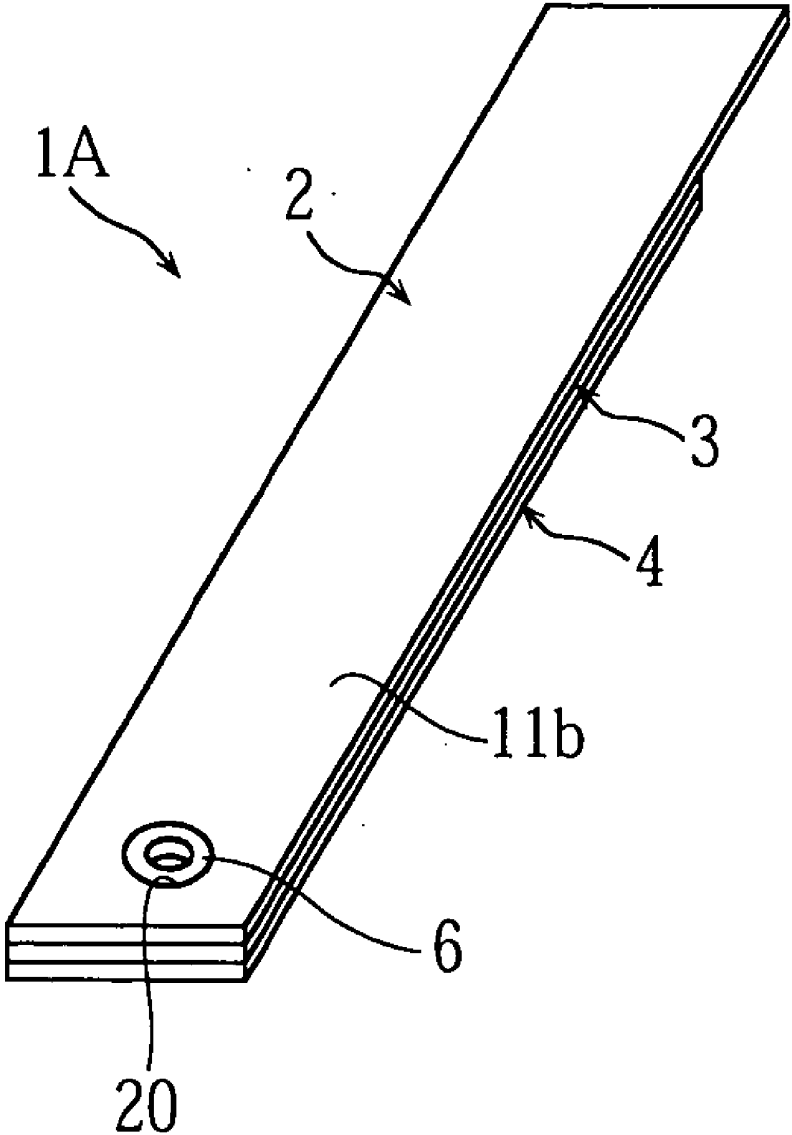


FIG. 4

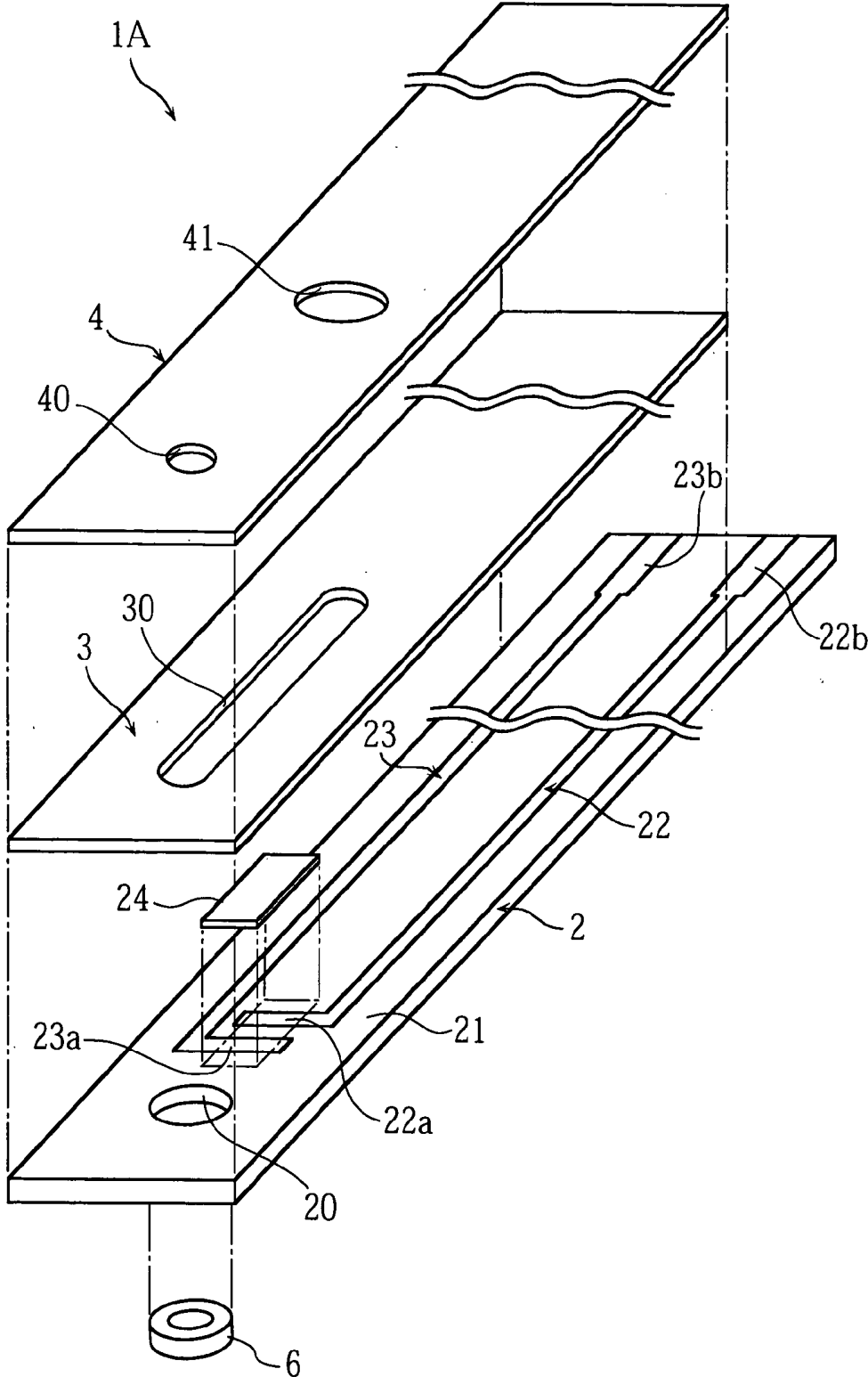


FIG. 5

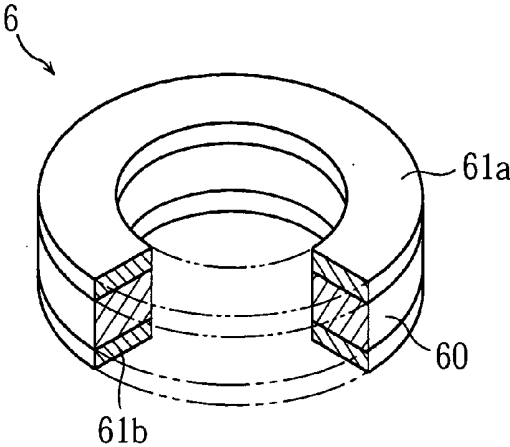


FIG. 6

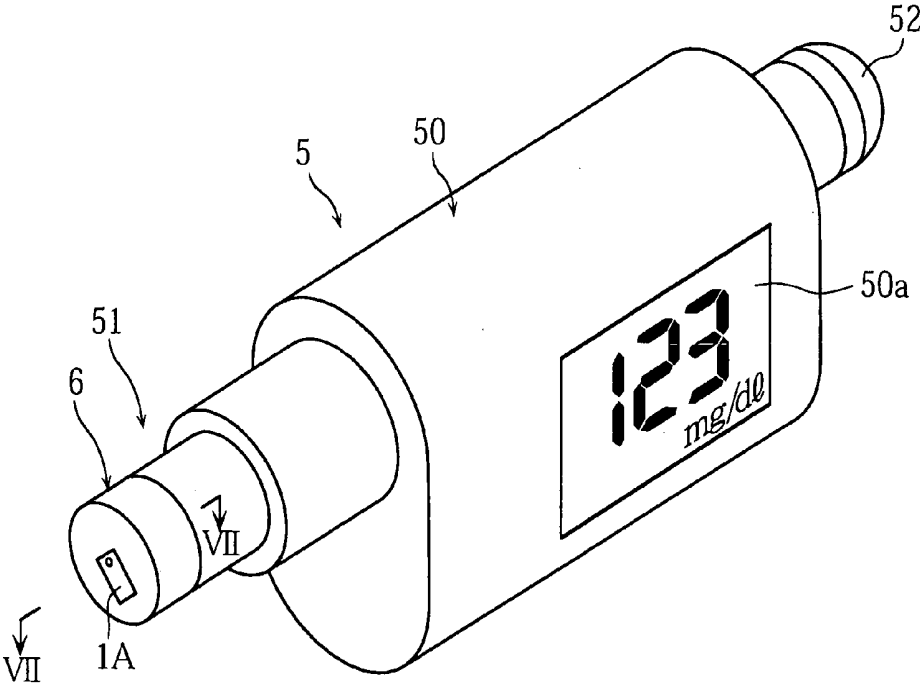


FIG. 7

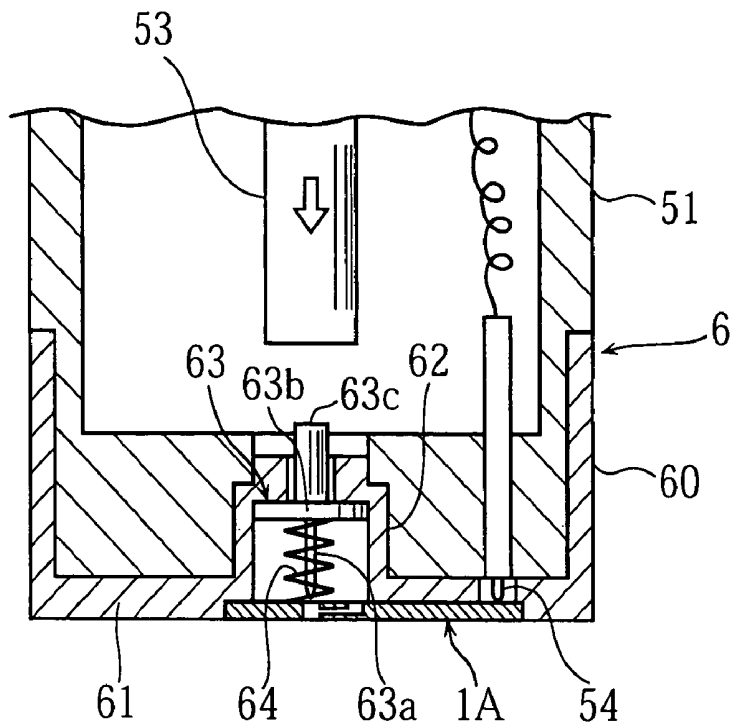


FIG. 8

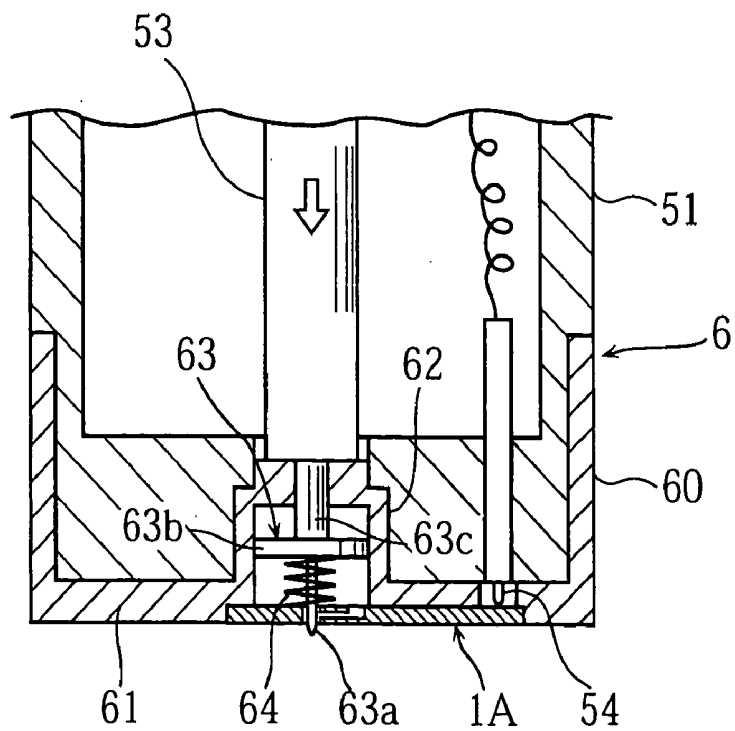


FIG.9

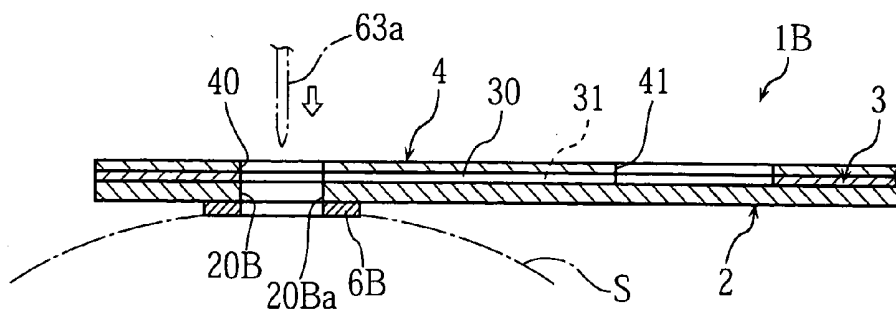


FIG.10

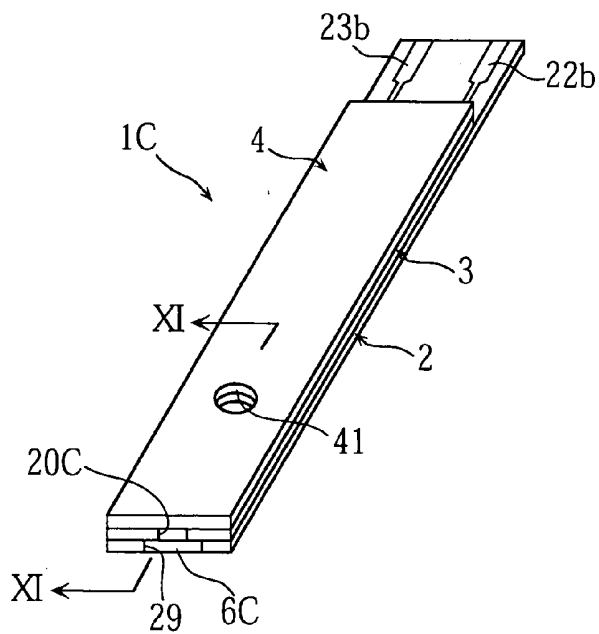


FIG.11

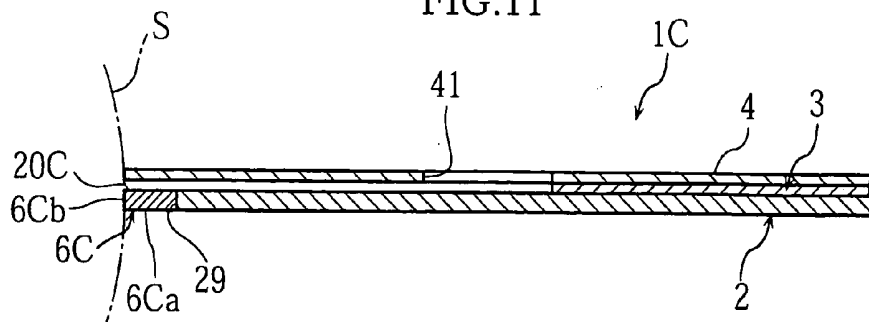
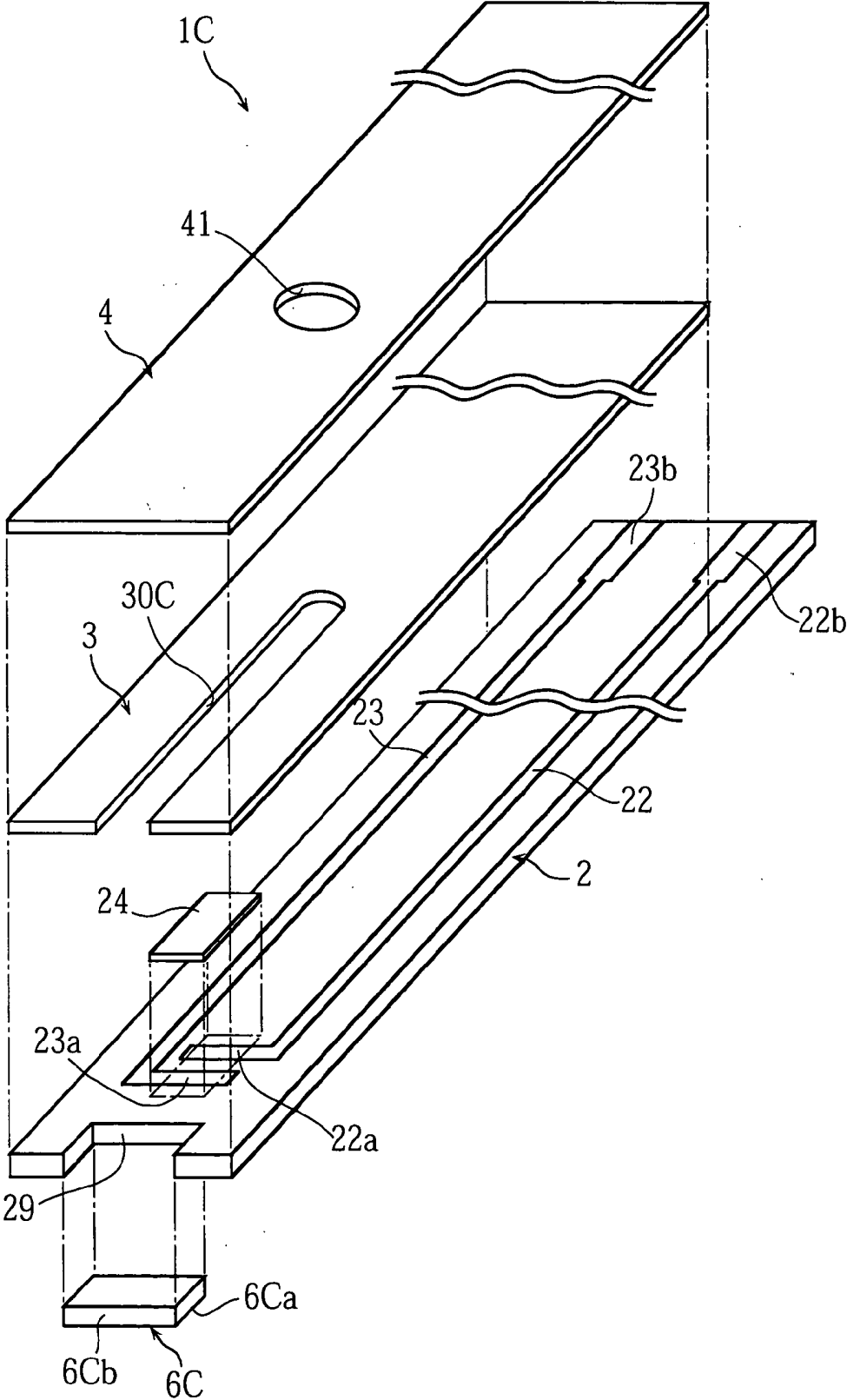


FIG.12



**ANALYZING APPARATUS, PIERCING ELEMENT
INTEGRALLY INSTALLED BODY FOR
TEMPERATURE MEASURING DEVICE WITH
ANALYZING APPARATUS, AND BODY FLUID
SAMPLING APPARATUS**

TECHNICAL FIELD

[0001] The present invention relates to an analyzing instrument used for measuring the concentration (e.g. glucose level) of a specific component in a sample liquid. The invention also relates to a lancet-integrated attachment, which, in use, is attached to a concentration measuring device, and which includes an analyzing instrument and a lancet.

BACKGROUND ART

[0002] Simple blood-sugar measuring devices have been in practical use for conveniently measuring the blood-sugar level at or away from home.

[0003] A blood-sugar measuring device is known wherein an attachment including a biosensor and a lancing needle is mounted to a tip portion of the measuring device for performing concentration measurement with respect to body fluid, as disclosed in JP-A 2000-231 for example. While a fluid feed port of the biosensor is pressed against the skin, the lancing needle of the blood-sugar measuring device is caused to protrude beyond the biosensor into the skin for bleeding. The blood bleeding from the skin is supplied to a reacting portion via a capillary of the biosensor to form a liquid phase reaction system. The blood-sugar measuring device calculates the blood-sugar level based on the value of a response current measured when a voltage is applied across the liquid phase reaction system.

[0004] However, the attachment incorporating the biosensor may fail to properly introduce blood via the sample feed port because if the skin contacts the biosensor improperly to create a gap between the biosensor and the skin, the blood may flow out along the biosensor and/or the skin via the gap. As a result, the reacting portion may fail to be supplied with an enough amount of blood needed for proper measurement.

[0005] Proposals have been made to solve the above problem by applying a water-repellent coating around the fluid feed port of the biosensor for blood leakage prevention or by arranging the feed port near the reacting portion. However, these countermeasures have turned out still insufficient for preventing blood leakage on lancing.

DISCLOSURE OF THE INVENTION

[0006] An object of the present invention is to enable concentration measurement which utilizes a capillary analyzing instrument and wherein it is possible to reliably supply the capillary with an enough amount of sample liquid needed for sample analysis.

[0007] An analyzing instrument according to a first aspect of the present invention comprises a capillary, a fluid feed port for introducing a sample liquid into the capillary, and a fluid feed promoter for promoting the introduction of the sample liquid through the fluid feed port.

[0008] The capillary of the analyzing instrument may be formed on a substrate for example. In this case, the fluid feed

promoter may preferably include at least one of a water-absorbing layer having higher water-absorbing capacity than the substrate and an adhesive layer that has greater adhesion to a skin than the substrate. Further, the fluid feed promoter may preferably have higher elasticity than the substrate.

[0009] The analyzing instrument may further comprise a substrate on which a cover plate is laminated via a spacer, and a through-hole may penetrate thicknesswise through the substrate, the spacer, and the cover board. In this case, the fluid feed port may comprise the through-hole, and the fluid feed promoter may be fitted in the fluid feed port. The fluid feed promoter may be disposed around the fluid feed port. In other words, the fluid feed promoter may be preferably arranged near the fluid feed port for assisting the introduction of the sample liquid into the fluid feed port. The fluid feed promoter may preferably comprise a ring, but it may also be arcuate or otherwise shaped.

[0010] The substrate may be provided with a notch which is open at a side of the substrate for holding the body fluid feed promoter. In this case, the fluid feed port may be preferably open at said side. Again, the fluid feed promoter may include at least one of a water-absorbing layer having higher water-absorbing capacity than the substrate and an adhesive layer having greater adhesion to skin than the substrate.

[0011] A second aspect of the present invention provides a lancet-integrated attachment which comprises a lancet and an analyzing instrument for use as mounted to a concentration measuring device. The analyzing instrument comprises a capillary, a fluid feed port for introducing a sample liquid into the capillary, and a fluid feed promoter for promoting the introduction of the sample liquid through the fluid feed port.

[0012] The capillary of the analyzing instrument according to this aspect may be formed on a substrate for example. In this case, the fluid feed promoter may preferably include at least one of a water-absorbing layer having higher water-absorbing capacity than the substrate and an adhesive layer that has greater adhesion to a skin than the substrate. Further, the fluid feed promoter may have higher elasticity than the substrate.

[0013] The analyzing instrument according to this aspect may further comprise a substrate on which a cover plate is laminated via a spacer, and a through-hole may penetrate thicknesswise through the substrate, the spacer, and the cover board for allowing insertion of the lancet. In this case, the fluid feed port may comprise the through-hole, and the fluid feed promoter may be fitted in the fluid feed port. The fluid feed promoter may preferably comprise a ring. The fluid feed promoter may be disposed around the fluid feed port.

[0014] A third aspect of the present invention provides a body fluid sampling instrument which comprises a capillary, a fluid feed port for introducing body fluid into the capillary, and a fluid feed promoter for promoting the introduction of the body fluid through the fluid feed port.

[0015] The body fluid sampling instrument according to this aspect is used for sampling blood bleeding from skin. For blood sampling, the fluid feed promoter is brought into contact with a target bleeding portion of the skin

[0016] The capillary of the blood sampling tool may be formed on a substrate for example. In this case, the fluid feed promoter may preferably include at least one of a water-absorbing layer having higher water-absorbing capacity than the substrate and an adhesive layer that has greater adhesion to a skin than the substrate. Further, the fluid feed promoter may preferably have higher elasticity than the substrate.

BRIEF DESCRIPTION OF THE DRAWINGS

[0017] FIG. 1 is an overall perspective view of a biosensor according to a first embodiment.

[0018] FIG. 2 is a sectional view taken along lines II-II in FIG. 1.

[0019] FIG. 3 is an overall perspective view of the biosensor shown in FIG. 1 as seen from the rear side.

[0020] FIG. 4 is an exploded perspective view of the biosensor shown in FIG. 1.

[0021] FIG. 5 is a perspective view of a ring as partially cut away.

[0022] FIG. 6 is an overall perspective view of a blood-sugar measuring device.

[0023] FIG. 7 is a sectional view taken along lines VII-VII of FIG. 6.

[0024] FIG. 8 is a sectional view similar to FIG. 7 with a lancet advanced to a protruding position.

[0025] FIG. 9 is a sectional view showing a principal part of the biosensor according to a second embodiment.

[0026] FIG. 10 is an overall perspective view of a biosensor according to a third embodiment.

[0027] FIG. 11 is a sectional view taken along lines XI-XI of FIG. 10.

[0028] FIG. 12 is an exploded perspective view of the biosensor shown in FIG. 10.

BEST MODE FOR CARRYING OUT THE INVENTION

[0029] An analyzer according to the present invention is described below taking a biosensor used for measuring blood-sugar level as an example.

[0030] A biosensor according to a first embodiment is described referring to FIGS. 1 through 4.

[0031] A biosensor 1A includes a substrate 2, a spacer 3, and a cover plate 4. In use, the biosensor 1A is attached to a blood-sugar measuring device 5 (refer to FIGS. 7 and 8) that is described below.

[0032] The substrate 2 is rectangular and has a blood feed port 20. The blood feed port 20 is fitted with a ring 6 for helping to introduce blood.

[0033] The ring 6 has a thickness of e.g. about 70 μm which is nearly equal to the thickness of the substrate 2. As shown in FIG. 5, the ring 6 includes a water-absorbing layer 60 sandwiched between a pair of adhesive layers 61a, 61b. The water-absorbing layer 60 is a membrane which is about 50 μm in thickness formed of nonwoven fabric or the like to have a water-absorbing capacity of 2-3 g/g. The adhesive

layers 61a, 61b provide suitable adhesion to the skin. The adhesive layers 61a, 61b are preferably formed of a blood-permeable material.

[0034] As shown in FIG. 4, the substrate 2 has an upper surface 21 formed with a working electrode 22, a counter electrode 23, and a reacting portion 24. The working electrode 22 and the counter electrode 23 have L-bent front terminals 22a, 23a. The reacting portion 24 is a solid part containing a redox enzyme and an electron carrier for example. The redox enzyme maybe glucose oxydase or glucose dehydrogenase for example. The electron carrier may be potassium ferricyanide for example.

[0035] As shown in FIGS. 1 through 4, the spacer 3 and the cover plate 4 which are laminated on the substrate 2 are rectangular but shorter than the substrate 2 for exposing the rear terminals 22b, 23b of the working electrode 22 and the counter electrode 23.

[0036] The spacer 3 is formed with a slit 30 communicating with the blood feed port 20. The slit 30 functions as a capillary 31 when the spacer 3 and the cover plate 4 are laminated on the upper surface 21 of the substrate 2. The slit 30 has an end disposed right over the blood feed port 20. The width of the slit 30 is smaller than the inner diameter of the blood feed port 20. As seen from FIGS. 2 and 5, the ring 6 is adhered to the spacer 3 via the adhesive layer 61a when fitted into the blood feed port 20. Such adhesive fixation of the ring 6 can be performed easily only by inserting the ring 6 into the blood feed port 20.

[0037] The cover plate 4 is formed with a lancing needle insertion port 40 and an air vent hole 41. As shown in FIG. 2, the lancing needle insertion port 40 is arranged right over the blood feed port 20 for inserting a lancing needle 63a of the blood-sugar measuring device 5 (refer to FIGS. 7 and 8). Consequently, the biosensor 1A is formed with a space that extends through the substrate 2, the spacer 3, and the cover plate 4 so that the lancing needle 63a can pass through the biosensor 1A. On the other hand, the air vent hole 41 communicates with the blood feed port 20 via the capillary 31. Thus, the blood introduced from the blood feed port 20 proceeds toward the air vent hole 41 in the capillary 31 due to the capillary phenomenon. In the course of such process, the blood dissolves the reacting portion 24, whereby the redox enzyme oxidizes the glucose in the blood while reducing the electron carrier.

[0038] The biosensor 1A described above may be a part of an attachment to be mounted to a blood-sugar measuring device for use in measuring the blood-sugar level.

[0039] As shown in FIG. 6, the blood-sugar measuring device 5 includes a main body 50, a mount 51, and a presser 52. The main body 50 is provided with a display 50a. The display 50a includes an LCD or the like for displaying the measurement. The mount 51, to which an attachment 6 is mounted, extends from the main body 50. The presser 52 is used for advancing the lancing needle 63a (refer to FIGS. 7 and 8).

[0040] As shown in FIG. 7, the attachment 6 includes a cylinder 60 and a bottom wall 61. The cylinder 60 is fitted around the tip end of the mount 51. The bottom wall 61 is provided with an upwardly concave recess 62. The recess 62 holds a lancet 63 and has a mouth closed by the biosensor 1A that is affixed to the bottom wall 61. The lancet 63

includes, besides the lancing needle **63a**, a flange **63b** and a head **63c**. The recess **62** receives a coil spring **64** biased between the flange **63b** and the biosensor **1A**.

[0041] The blood-sugar measuring device **5** is further provided with a pressing rod **53** and a pair of connector pins **54**. The pressing rod **53** is driven toward the tip end of the blood-sugar measuring device by operating the presser **52**. The pressing rod **53** is driven, for example, by a known latch mechanism or electromagnetic drive mechanism. The pair of connector pins **54** are connected to a non-illustrated electrical circuit while being held in contact with the rear terminals **22b**, **23b** of the biosensor **1** when the attachment **6** is mounted to the blood-sugar measuring device **5**.

[0042] In measuring the blood-sugar level, the attachment is attached to the mount **51** of the blood-sugar measuring device **5**. In this state, as shown in **FIG. 2**, the lancing needle **63a** is disposed right over the lancing needle insertion port **40** of the biosensor **1A**, while the connector pins **54** contact the rear terminals **22b**, **23b** of the biosensor **1A**.

[0043] Next, the tip end of the blood-sugar measuring device is pressed against the skin **S** of an examinee so that the skin **S** intimately contacts the ring **6** of the biosensor **1A** (refer to **FIG. 2**). In this state, as seen in **FIGS. 2 and 5**, the skin **S** sticks intimately to the ring **6** or the biosensor **1A** due to the adhesive layer **61b** at the surface of the ring **6**.

[0044] Subsequently, the presser **52** is operated for lancing. As shown in **FIG. 8**, the operation of the presser **52** causes the pressing rod **53** to move toward the tip end of the mount **51**, whereby the pressing rod **53** contacts the head **63c** of the attachment **6**. As a result, the lancet **63** is pushed forward. Since the lancing needle insertion port **40**, the slit **30**, and the blood feed port **20** of the biosensor **1A** communicate with each other to provide a penetrating path thicknesswise of the biosensor **1A**, the movement of the lancet **63** causes the lancing needle **63a** to pass through the biosensor **1A**. As a result, the tip end of the lancing needle **63a** protrudes beyond the biosensor **1A**, so that the lancing needle **63a** lances the skin **S** to promote bleeding out of the skin **S**. Due to the through-hole of the ring **6**, the movement of the lancing needle **63a** is not hindered by the ring **6** during this lancing operation even if the ring **6** is fitted in the blood feed port **20**.

[0045] After the lancing operation, the pressing rod **53** of the blood-sugar measuring device **5** is preferably spaced from the lancet **63** due to the elastic force of a spring or the like. Thus, the lancet **63** returns to the position shown in **FIG. 7** under the elastic force of the coil spring **64**. As a result, the lancing needle **63a** is prevented from pushing into the skin **S** for a needlessly long time, thereby reducing pain to the examinee.

[0046] When the blood from the skin **S** is introduced to the blood feed port **20**, most of the blood is retained in the water-absorbing layer **60** of the ring **6**. Since the ring **6** sticks intimately to the skin **S**, the blood once introduced to the blood feed port **20** is prevented from leaking outside. Further, the absorption provided by the water-absorbing layer **60** also contributes to the prevention of blood leakage from the blood feed port **20**. Even if the ring **6** fails to stick intimately to the skin **S** while the blood is pooled temporarily in the ring **6**, it is expected that the blood in a gap between the ring **6** and the skin **S** is exposed to the air to

clot, thereby clogging the gap. Thus, blood leakage may also be prevented in this way. On the other hand, the blood absorption provided by the water-absorbing layer **60** promotes bleeding from the skin **S**. As a result, enough blood for measurement can be sampled by the promotion of bleeding from the skin **S** as well as by the prevention of the blood leakage.

[0047] The blood introduced into the blood feed port **20** moves through the capillary **31** due to the capillary phenomenon for desolving the reacting portion **24** to create a liquid phase reaction system. The blood feed port **20** first pools an amount of blood before feeding to the capillary **31**. As described above, an enough quantity of blood is retained in the biosensor **1A** due to the prevention of blood leakage. Thus, an enough quantity of blood is reliably supplied to the capillary **31** and to the reacting portion **24**.

[0048] A voltage is applied across the liquid phase reaction system through the connector pin **54**, the working electrode **22**, and the counter electrode **23**. The quantity of electrons flowing between the liquid phase reaction system and the working electrode **22** is measured as an electric current at the electric circuit of the blood-sugar measuring device **5**. The electric circuit determines the blood-sugar level based on the measured electric current.

[0049] Next, a biosensor according to a second embodiment is described below referring to **FIG. 9**. In **FIG. 9**, members and elements identical or similar to those in the biosensor **1A** described already are given the same reference numbers, and duplicated description will be omitted.

[0050] The biosensor **1B** shown in **FIG. 9** includes a blood feed port **20B** having an open mouth **20Ba** surrounded by a ring **6B**. The ring **6B** includes a water-absorbing layer sandwiched between a pair of adhesive layers for example. The ring **6B** may dispense with either of the water-absorbing layer and the adhesive layers.

[0051] The biosensor **1B** provides the same advantages as the biosensor **1A** that is previously described.

[0052] The biosensors **1A**, **1B** according to the first and second embodiments are not limited by the description and figures above but may be variously modified.

[0053] For example, the ring may dispense with either of the water-absorbing layer and the adhesive layers. Even in this case, blood leakage is prevented, and bleeding is promoted for reliably introducing blood into the capillary.

[0054] Further, the ring may be elastic. Due to the elasticity, the ring may provide more intimate contact with the skin when pressed against the examinee's skin, thereby preventing blood leakage more reliably. This advantage may be obtained even if dust or hairs exist between the ring and the skin.

[0055] The ring may be made elastic by adopting a highly elastic material for the water-absorbing layer and/or the adhesive layers, or by providing a highly elastic layer in addition to the water-absorbing layer and the adhesive layer. Examples of highly elastic materials include elastomers (silicone resin, acrylic resin, rubber, or the like) and gels.

[0056] The ring may be replaced with a non-perforated fluid feed promoter fitted in the blood feed port. In this case, the fluid feed promoter should have at least a needle-

piercing portion which is made of a readily penetratable material or is otherwise designed to facilitate needle lancing. For example, the fluid feed promoter may include a first member provided with a through-hole and a second member to be fitted in the through-hole, or may be a sheet made from a single material. Further, the fluid feed promoter may be arcuate. Thus, the configuration and the material of the fluid feed promoter are not limitative as long as the above-described functions and advantages can be obtained.

[0057] Next, a biosensor according to a third embodiment is described referring to **FIGS. 10 through 12**. In these figures, members and elements identical or similar to those in the previously described biosensors are given the same reference numbers, and duplicated description will be omitted.

[0058] The biosensor **1C** does not form a part of the attachment shown in **FIG. 7** for mounting to the blood-sugar measuring device. Instead, the biosensor **1C** is mounted alone for use in the blood-sugar measuring device.

[0059] The biosensor **1C** includes a slit **30C** which is open at a side to form a blood feed port **20C**. As shown in **FIG. 11**, the thus designed biosensor **1C** introduces blood when the blood feed port **1C** is pressed against the bleeding skin **S**.

[0060] Similarly, a board **2** is formed with a notch **29** which is open at a side, and a fluid feed promoter **6C** is fitted in the notch **29**. The fluid feed promoter **6C** has a bottom surface **6Ca** and a side surface **6Cb** both of which are exposed. The fluid feed promoter **6C** is water-absorptive, whereas the side surface **6Cb** may be adherent.

[0061] The biosensor **1C** also prevents blood leakage upon blood introduction while promoting bleeding from the skin **S** for reliable blood introduction.

[0062] Though the first through third embodiments have been described taking a biosensor as an example in, the idea of the present invention may be also applied to a body fluid sampling tool used only for sampling body fluid (e.g. blood). An example of such a body fluid sampling tool may have the same structure as the biosensor shown in **FIGS. 1 through 4** except that the working electrode **22**, the counter electrode **23**, and the reacting portion **24** are omitted.

1. An analyzing instrument comprising:

a capillary,

a fluid feed port for introducing a sample liquid into the capillary, and

a fluid feed promoter for promoting the introduction of the sample liquid through the fluid feed port.

2. The analyzing instrument according to claim 1, wherein the capillary is formed on a substrate, the fluid feed promoter including a water-absorbing layer having higher water-absorbing capacity than the substrate.

3. The analyzing instrument according to claim 1, wherein the capillary is formed on a substrate, the fluid feed promoter including an adhesive layer having greater adhesion to a skin than the substrate.

4. The analyzing instrument according to claim 1, wherein the capillary is formed on a substrate, the fluid feed promoter having higher elasticity than the substrate.

5. The analyzing instrument according to claim 1, further comprising a substrate on which a cover plate is laminated via a spacer, wherein a through-hole penetrates thicknesswise through the substrate, the spacer, and the cover board.

6. The analyzing instrument according to claim 5, wherein the fluid feed port is formed in the board and comprises the through-hole.

7. The analyzing instrument according to claim 6, wherein the fluid feed promoter is fitted in the fluid feed port.

8. The analyzing instrument according to claim 7, wherein the fluid feed promoter comprises a ring.

9. The analyzing instrument according to claim 6, wherein the fluid feed promoter is disposed around the fluid feed port.

10. The analyzing instrument according to claim 1, further comprising a substrate on which a cover plate is laminated via a spacer, wherein the substrate is provided with a notch which is open at a side of the substrate, the notch holding the body fluid feed promoter.

11. The analyzing instrument according to claim 10, wherein the capillary is formed on the substrate, the fluid feed promoter including at least one of a water-absorbing layer having higher water-absorbing capacity than the substrate and an adhesive layer having greater adhesion to skin than the substrate.

12. A lancet-integrated attachment comprising a lancet and an analyzing instrument for use as mounted to a concentration measuring device,

wherein the analyzing instrument comprises a capillary, a fluid feed port for introducing a sample liquid into the capillary, and a fluid feed promoter for promoting the introduction of the sample liquid through the fluid feed port.

13. The lancet-integrated attachment according to claim 12, wherein the capillary is formed on the substrate, the fluid feed promoter including at least one of a water-absorbing layer having higher water-absorbing capacity than the substrate and an adhesive layer having greater adhesion to skin than the substrate.

14. The lancet-integrated attachment according to claim 13, further comprising a substrate on which a cover plate is laminated via a spacer, wherein a through-hole penetrates thicknesswise through the substrate, the spacer, and the cover board for allowing insertion of the lancet.

15. The lancet-integrated attachment according to claim 14, wherein the fluid feed port is formed in the substrate and comprises the through-hole.

16. The lancet-integrated attachment according to claim 15, wherein the fluid feed promoter comprises a ring.

17. A body fluid sampling instrument comprising:

a capillary,

a fluid feed port for introducing body fluid into the capillary, and

a fluid feed promoter for promoting the introduction of the body fluid through the fluid feed port.

18. The body fluid sampling instrument according to claim 17, which is used for sampling blood bleeding from skin, wherein the fluid feed promoter is brought into contact with a target bleeding portion of the skin for blood sampling.

专利名称(译)	分析装置，穿刺元件，用于具有分析装置的温度测量装置的整体安装体，以及体液采样装置		
公开(公告)号	US20040171968A1	公开(公告)日	2004-09-02
申请号	US10/483443	申请日	2002-07-11
[标]申请(专利权)人(译)	胜木KOJI 坂田tetabuya 草香泰秀		
申请(专利权)人(译)	胜木KOJI 坂田TETSUYA 草香泰秀		
当前申请(专利权)人(译)	ARKRAY, INC.		
[标]发明人	KATSUKI KOJI SAKATA TETSUYA KUSAKA YASUhide		
发明人	KATSUKI, KOJI SAKATA, TETSUYA KUSAKA, YASUhide		
IPC分类号	A61B5/00 G01N33/487 G01N27/327		
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其他公开文献	US7879211		
外部链接	Espacenet USPTO		

摘要(译)

分析仪器 (1A) 技术领域本发明涉及一种分析仪器 (1A)，其包括毛细管 (31)，用于将样品液体引入毛细管 (31) 的流体供给口 (20)，以及用于促进引入的流体供给促进器 (6)。样品液体进入进料口 (20)。分析器 (1A) 的毛细管 (31) 可以形成在例如基板 (2) 上。流体进料促进剂 (6) 可包括具有比基材 (2) 更高的吸水能力的吸水层和与基材 (2) 相比对皮肤具有更大粘附性的粘合剂层中的至少一种。

