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(54) LANCET-INTEGRATED SENSOR AND MEASURER FOR LANCET-INTEGRATED SENSOR

SENSOR MIT INTEGRIERTER LANZETTE UND MESSGERÄT DAFÜR

CAPTEUR A LANCETTE INTEGREE ET DISPOSITIF DE MESURE AVEC CAPTEUR A LANCETTE INTEGREE

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Description

TECHNICAL FIELD

[0001] The present invention relates to a lancet-integrated sensor for extracting bodily fluid of a man or an animal, and easily analyzing the characteristics of the bodily fluid and, more particularly, to an improved lancet-integrated sensor that is characterized by a construction in which a lancet for lancing skin to extract bodily fluid is integrated with a sensor for collecting the bodily fluid extracted at the surface of the skin to analyze it.

[0002] Further, the present invention relates to a measuring device for measuring components of bodily fluid such as blood sugar and, more particularly, to an improved measuring device for a lancet-integrated sensor.

[0003] Furthermore, the present invention relates to an improved cartridge for housing biosensors of this type.

BACKGROUND ART

[0004] Conventionally, as a device for easily analyzing the characteristics of bodily fluid of a man or an animal, for example, a device for electrochemically measuring blood sugar has already been put to practical use.

[0005] US patents 5,791,941 and 6,071,294 disclose a sensor with an integrated lancet to be used with a glucose monitoring device. After the lancet has been driven into the skin of the patient, a blood sample is collected at the distal end of the sensor housing.

[0006] Japanese patent application publication JP 2000-185034 A discloses a sensor with a needle attached to the distal end of the sensor, and a blood collection space inside the sensor housing.

[0007] US patent 4,637,403 discloses a glucose monitor to which a cartridge comprising a needle can be attached. Blood is drawn through the needle to an analysis section by capillary action.

[0008] Japanese patent application publication JP 9-294737 A discloses a sensor to which a lancet may be attached. This combination is also to be used with a glucose monitoring device. However, this document does not disclose a lancet integrated into a sensor.

[0009] A biosensor is a device of this type, and hereinafter, a biosensor and a measuring device to be combined with the biosensor will be described.

[0010] Figure 21 shows a long and narrow strip-shaped sensor 31 for collecting blood, which is set in a sensor insertion slot 31a of a measuring device 32. The sensor 31 is provided with a cavity (not shown) for collecting blood, in its semi-circular front end that protrudes from the measuring device 32 in the state where the sensor 31 is housed in the measuring device 32. Further, the sensor 31 is provided with, in the cavity, a reagent layer containing an enzyme, an electron carrier, and the like, and electrodes.

[0011] The measuring device 32 contains an electric circuit for measuring a current value according to the concentration of glucose in blood, which current is generated by a reaction between the glucose in blood and the reagent layer, by applying a voltage to the electrode, and the measured blood sugar is displayed on a display 33 which is placed on the upper surface of the measuring device 32.

[0012] For every measurement, a new sensor 31 is inserted into the sensor insertion slot on the side surface of the measuring device 32, and blood of a patient is applied onto the sensor 31 to perform measurement. The sensor 31 after measurement is discarded for hygienic reasons.

[0013] Usually, the skin of a body part, such as a fingertip, is lanced with a lancet device 34 as shown in figure 22(a) to extract a very small quantity of blood, and the blood is collected in the cavity of the sensor 31.

[0014] In the lancet device 34 whose internal structure is shown in figure 22(b), a force is elastically applied to a lancet 35 by a spring coil 36. When an operation button 37 is pushed, an engagement member 37a which is united with the operation button 37 is disengaged from a ring-shaped groove 35a of the lancet 35, whereby the force applied to the lancet 35 by the spring 36 is released, and the tip of a needle 35b of the lancet 35 forcibly projects from the front end of an approximately cylindrical-shaped case 38. The lancet 35 comprises the needle 35b which is made of metal, and a holder 35c for holding the needle 35b, which is made of plastic. Usually, the lancet 35 is replaced with a new one at every measurement, for hygienic reasons.

[0015] Further, a biosensor to be used for analyzing bodily fluid extracted from a man or an animal is usually preserved in the state where it is wrapped with an aluminum wrapper or the like, or in the state where it is contained in a plastic case. When the biosensor is used, it is taken out of the aluminum wrapper or the plastic case.

[0016] Figure 23(a) is a diagram illustrating the state where a biosensor 110 having a reagent layer (not shown) for analyzing bodily fluid, and an electrode (not shown) for taking out an electric signal according to the result of analysis, is hermetically wrapped with an aluminum wrapper 120. To be specific, a biosensor 110 which comprises an approximately rectangle-shaped plate member having a shorter side of an approximately semi-circular shape is wrapped with an aluminum wrapper 120 having a rectangle shape that is a little larger than the biosensor 110. Figure 23(b) shows the state where a plurality of biosensors 110, which are arranged with their approximately-semi-circular-shaped ends turning upward and their surfaces being in contact with each other, are hermetically contained in a cylindrical plastic case 130 with a lid.

[0017] When performing measurement, the biosensor 110 which is preserved as shown in figure 23(a) or 23(b) is taken out, and the other shorter side of the biosensor 110, which is not the approximately-semi-circular-shaped side, is inserted in a biosensor insertion slot 114a of a measuring device 114 to prepare for measurement

as shown in figure 24.

[0018] Since the conventional biosensor and measuring device-thereof are constructed as described above, when preparing for measurement, a patient sets a new lancet 35 in the lancet device 34 as described above. Then, the patient sets a new sensor 31 in the measuring device 32, whereby preparation for measurement is completed. Thereafter, the patient operates the lancet device 34 to take blood from his/her fingertip or the like, and applies it onto the front end of the sensor 31 that is set in the measuring device 32 to perform measurement. In this way, the patient must perform replacement of the lancet and replacement of the sensor separately for every measurement, resulting in complicated operation.

[0019] Further, since it is necessary to monitor blood sugar a few times a day, the sizes of these devices are reduced in consideration of portability. In the conventional system, however, the patient must carry the sensor 31, the measuring device 32, the lancet 35, and the lancet device 34 together, resulting in a voluminous system as a whole. Further, since the patient must manage the sensor 31 and the lancet 35 separately, operation and measurement are troublesome, resulting in poor usability.

[0020] The present invention is made to solve the above-mentioned problems and has for its object to provide a lancet-integrated sensor in which a sensor and a lancet are integrated to facilitate operation and management, and improve portability, as well as a measuring device to be combined with the lancet-integrated sensor.

[0021] Further, with respect to the conventional biosensors, as described above, each biosensor is wrapped with an aluminum wrapper, or plural biosensors are stored in a plastic case with a lid, whereby the biosensors are prevented from contamination due to moisture.

[0022] However, when preparing for measurement, the patient must break the aluminum wrapper 120 to take the biosensor 110 or open the lid 130a of the plastic case 130 to take the biosensors 110 one by one. Further, the patient must insert the taken biosensor 110 toward the sensor insertion slot 114a of the measuring device 114. Therefore, preparation for measurement is troublesome, and the usability is poor.

[0023] The present invention is made to solve the above-mentioned problems and has for its object to provide a biosensor cartridge by which a biosensor stored in a case is easily inserted into a measuring device without troublesome operation.

DISCLOSURE OF THE INVENTION

[0024] To be specific, in order to solve the above-mentioned conventional problems, a lancet-integrated sensor according to Claim 1 of the present invention is provided. Further advantageous features of this lancet-integrated sensor are defined in claims 2-16. The lancet-integrated sensor may be detachably attached to a measuring device according to claim 17.

[0025] Further advantageous features of the measuring device are defined in claims 18-25.

BRIEF DESCRIPTION OF THE DRAWINGS

[0026]

Figures 1(a) and 1(b) are diagrams illustrating a lancet-integrated sensor according to a first embodiment of the present invention, wherein figure 1(a) is a perspective view of the whole, and figure 1(b) is an exploded perspective view thereof.

Figures 2(a)-2(d) are plan views for explaining the operation of the lancet-integrated sensor, wherein figure 2(a) shows the state where a needle tip, which is covered with a protection cover, protrudes from the sensor, figure 2(b) shows the state where the needle tip, which is covered with the protection cover, is housed in the sensor, figure 2(c) shows the state where the needle tip, from which the protection cover is removed, protrudes from the sensor, and figure 2(d) shows the state where the needle tip, from which the protection cover is removed, is housed in the sensor.

Figures 3(a) and 3(b) are perspective views of a measuring device to be combined with the lancet-integrated sensor according to the first embodiment of the invention, wherein figure 3(a) shows its upper surface, and figure 3(b) shows its lower surface.

Figures 4(a) and 4(b) are diagrams for explaining the internal structure of the measuring device, wherein figure 4(a) is an exploded perspective view of its lower half side, and figure 4(b) is a cross-sectional view of its side surface.

Figures 5(a)-5(c) are diagrams for explaining the operation for attaching the lancet-integrated sensor to the measuring device, wherein figure 5(a) is a sectional side elevation view at starting of the attachment, figure 5(b) is a sectional side elevation view at completion of the attachment, and figure 5(c) is a sectional view in the vicinity an operation button.

Figures 6(a) and 6(b) are diagrams illustrating a protection cover of the lancet-integrated sensor according to the first embodiment of the invention, wherein figure 6(a) shows the state where the protection cover is fitted when the needle tip protrudes, and figure 6(b) shows the state where the protection cover is fitted to a front end of the sensor when the needle tip is housed.

Figure 7 is a perspective view of a measuring device to be combined with the lancet-integrated sensor according to the first embodiment of the invention.

Figures 8(a) and 8(b) are diagrams illustrating a lancet-integrated sensor according to a first example illustrating the invention, wherein figure 8(a) shows a perspective view of the whole, and figure 8(b) is an exploded perspective view thereof.

Figures 9(a) and 9(b) are diagrams illustrating the lancet-integrated sensor according to the first exam-

ple illustrating the invention and a measuring device for the lancet-integrated sensor, wherein figure 9(a) is a perspective view of the measuring device in the state where the sensor is attached thereto, and figure 9(b) is a cross-sectional view of the measuring device in the state where the sensor is attached thereto.

Figure 10 is a diagram for explaining engagement of a fine concave portion provided in the lancet with a fine convex portion provided in the sensor.

Figures 11(a) and 11(b) are diagrams illustrating the appearance of a measuring device for a lancet-integrated sensor according to a second example illustrating the invention, wherein figure 11(a) shows the state where a holder is attached, and figure 11(b) shows the state where the holder body is removed.

Figures 12(a)-12(c) are diagrams illustrating the appearance of the holder of the measuring device for a lancet-integrated sensor according to the second example illustrating the invention, wherein figure 12 (a) is an elevational view in the state where the holder is attached to the measuring device, figure 12 (b) is a cross-sectional view when the holder attached to the measuring device is viewed from above, and figure 12(c) is a cross-sectional view when the holder to be.removed from the measuring device is viewed from above.

Figures 13(a) and 13(b) are diagrams illustrating the internal structure of the measuring device which uses a lancet-integrated sensor according to the second example illustrating the invention, and another construction of a lancet-integrated sensor, wherein figure 13(a) is a cross-sectional view of the measuring device in the state where the holder is attached, and figure 13(b) is a partially cutaway cross-sectional view of the measuring device in the state where the holder is attached.

Figure 14 is a diagram illustrating the appearance of a measuring device which uses a lancet-integrated sensor according to a third example illustrating the invention.

Figure 15 is a cross-sectional view illustrating the internal structure of the measuring device according to the third example illustrating the invention.

Figure 16 is a cross-sectional view illustrating a biosensor cartridge according to a fourth example illustrating the invention.

Figures 17(a) and 17(b) are diagrams illustrating the state where a sensor stored in the biosensor cartridge according to the fourth example illustrating the invention is inserted into a measuring device, wherein figure 17(a) shows the state where the sensor is inserted, and figure 17(b) shows the state before the sensor is inserted.

Figures 18(a)-18(c) are diagrams illustrating a biosensor cartridge according to a first modification of the fourth example illustrating the invention, wherein figure 18 (a) is a perspective view illustrating the state where a lid is opened, figure 18(b) is a side view illustrating the state wherein the lid is closed, and figure 18(c) is a cross-sectional view illustrating the state where the lid is closed.

Figure 19 is a diagram illustrating a biosensor cartridge according to a second modification of the fourth example illustrating the invention.

Figures 20(a) and 20(b) are diagrams for explaining attachment of a lancet-integrated sensor to a measuring device in the biosensor cartridge according to the second modification of the fourth example illustrating the invention, wherein figure 20(a) is a diagram illustrating the state where the sensor is attached, and figure 20(b) is a diagram illustrating the state before the sensor is attached.

Figure 21 is a perspective view illustrating an example of a conventional measuring device for a biosensor.

Figures 22(a) and 22(b) are diagrams illustrating a conventional lancet device, wherein figure 22(a) is a perspective view thereof, and figure 22(b) is a perspective view thereof in the state where a part of the lancet device is seen through.

Figures 23(a) and 23(b) are diagrams illustrating a conventional manner of housing biosensors, wherein figure 23(a) shows the state where a biosensor is wrapped with a wrapper, and figure 23(b) shows the state where plural biosensors are stored in a plastic container.

Figure 24 is a diagram illustrating the state where a biosensor is inserted into a measuring device.

BEST MODE TO EXECUTE THE INVENTION

(Embodiment 1)

[0027] Hereinafter, a first embodiment of the present invention will be specifically described taking, as an example, a blood sugar sensor for electrochemically measuring blood sugar, with reference to the drawings.

[0028] The first embodiment relates to a lancet-integrated sensor in which a lancet and a sensor are integrated to facilitate management and carrying, and a measuring device for driving the lancet-integrated sensor, and performing measurement using the sensor. This first embodiment corresponds to Claims 1 to 25 of the present invention.

[0029] That is, in the lancet-integrated sensor according to the first embodiment, a long and narrow strip-shaped sensor and a lancet are integrated with each other and, more specifically, the lancet is horizontally movable along the longitudinal direction of the sensor.

[0030] The measuring device, to which the lancet-integrated sensor is fitted, is provided with a lancet driving function of the conventional lancet device. That is, the measuring device is provided with a driving means for driving the lancet of the lancet-integrated sensor that is fitted thereto.

[0031] In this construction, a patient sets a new lan-

cet-integrated sensor onto the measuring device every time he/she performs measurement. Then, the patient grips the measuring device, and turns on the lancet driving means to lance his/her fingertip with the lancet. Subsequently, the patient drops blood onto the sensor to measure blood sugar or the like.

[0032] Hereinafter, the lancet-integrated sensor and the measuring device will be described more specifically.

[0033] Figures 1(a) and 1(b) are a perspective view and an exploded perspective view of a lancet-integrated sensor according to the first embodiment of the invention, respectively. With reference to figure 1(a), numeral 10 denotes a lancet-integrated sensor, wherein numeral 1 denotes a long and narrow strip-shaped sensor, and numeral 2 denotes a lancet, a greater part of which is housed in a hollow (space) 1a in the sensor 1, and the lancet 2 is supported by the sensor (sensor body) 1 so as to be slidable in the longitudinal direction of the sensor 1.

[0034] Reference numeral 3 denotes a protection cover into which the needle tip of the lancet 2 is pressed, thereby protecting the needle tip. This cover 3 is removed during measurement. Reference numeral 4 denotes electrode terminals for making electrical connection to a measuring device which is later described. Reference numeral 5 denotes a cavity provided at the semi-circular front end of the sensor. 1.

[0035] As shown in figure 1(b), the construction of the sensor 1 is obtained by bonding a cover (plate) 6 to a substrate (plate) 7 together, which are made of a resin such as polyethylene terephthalate. Further, the lancet 2 comprises a metal needle 2a, and a connector (end portion) 2b which has the needle 2a at its front end, and holds the needle 2a. A rear end portion of the approximately strip-shaped connector 2b projects from the rear end of the sensor 1 to be engaged with the driving means of the measuring device which is described later.

[0036] At the lower surface of the cover 6, concave portions which conform to the shape of the lancet 2 are provided. More specifically, there are provided a groove (concave portion) 6a which conforms to the outline of the connector 2b so that the connector 2b is slidably housed in it along its longitudinal direction, and a long and narrow groove (concave portion) 6b in which the needle 2a is housed. The groove 6b in which the needle 2a is housed is extended to the front end of the sensor 1. Further, a pair of electrodes 8 leading to the electrode terminals 4 are formed on the surface of the substrate 7, and a reagent layer (not shown) is formed on the surface of the electrodes 8.

[0037] In this way, the lancet-integrated sensor is obtained by bonding the cover 6 and the substrate 7 together, with the lancet 2 being placed between them. Accordingly, the cavity 5 also serves as the long and narrow groove 6b in which the needle 2a is housed. Further, portions of the electrodes 8 and the reagent layer are exposed in the cavity 5.

[0038] As described above, the lancet 2 is movable along the longitudinal direction of the sensor 1, and its motion will be described hereinafter with reference to a plan view shown in figure 2.

[0039] Figure 2(a) shows a state where the position of the lancet 2 is closest to the front end of the sensor 1. That is, each of fine projections 2c, which are formed so as to project from the connector 2b in the direction perpendicular to the longer side of the connector 2b within the same plane as the main surface of the connector 2b, abuts on a side wall 60b at an end of a wide concave groove (concave portion) 60a on the topmost side of the sensor 1, which groove 60a is formed in the cover 6. In this state, a longest portion of the needle 2a of the lancet 2 projects from the front end of the sensor 1. Figure 2(b) shows a state where each of the fine projections 2c of the connector 2b abuts on a side wall 60c at an end of the concave groove 60a on the rearmost side of the sensor 1. In this state, the needle of the lancet 2 is completely housed in the sensor 1.

[0040] As shown in figures 2(a) and 2(b), the shape of the groove 60a is curved such that, at the end where the fine projection 2c is positioned, the width of the groove 60a is a little narrower than the width of the connector 2b including the fine projection 2c. Accordingly, at the end of the concave groove 60a, the connector 2b is latched by the sensor 1 due to the mutual pressing or friction.

[0041] The construction of the lancet-integrated sensor is as described above, and the protection cover 3 is removed for measurement, and a fingertip or the like is lanced with the tip of the needle 2a of the lancet 2 which projects from the opening of the cavity 5, as shown in figure 2(c). When blood is dropped onto the sensor 1 and sucked into the cavity 5 to measure blood sugar as shown in figure 2(d), the needle tip of the lancet 2 is positioned in the groove 6a which is apart from the cavity 5 so that the needle does not contact the blood sucked into the cavity 5.

MEASURING DEVICE

[0042] Next, an example of a measuring device to be connected with the above-described lancet-integrated sensor will be described with reference to the drawings.

[0043] Figures 3(a) and 3(b) are perspective views of a measuring device 11 to which a lancet-integrated sensor is fitted, and figure 3(a) mainly shows its upper surface while figure 3(b) mainly shows its lower surface. Reference numeral 12 denotes a display (display means) for displaying the result of measurement and the like, and numeral 13 denotes a slot into which the lancet-integrated sensor is inserted. Reference numeral 14 denotes a push button (unlocking member) for driving the lancet that is fitted to the measuring device 11 such that the lancet forcibly projects to lance a fingertip or the like. Further, reference numeral 15 denotes a slide button (ejection member, operation button) for ejecting the used lancet-integrated sensor from the measuring device 11. Further, reference numeral 16 denotes an adjustment

button (lancet projection amount adjuster) for adjusting the amount of projection of the needle tip of the lancet.

[0044] Figure 4(a) is a perspective view of the measuring device 11 in the state where an upper portion of a package case is removed to show the internal structure of the measuring device 11, and figure 4(a) specifically shows the connection terminal to be electrically connected with the sensor, and the driving means to be engaged with the connector of the lancet. Further, figure 4(b) is a side view of the measuring device.

[0045] Reference numeral 17 denotes a pair of guides having connection terminals to be electrically connected with the electrode terminals of the sensor. The guides 17 are planted on the substrate 11a at the bottom of the package case by resin molding so as to have approximately-L-shaped cross sections, and connection terminals are formed on the ceilings of the guides 17. Further, at an end of each guide 17, which is opposite to a connector receiver 19 , a termination member 17a is planted to make a dead-end, excluding a space between the guides 17. When fitting the lancet-integrated sensor to the measuring device, the sensor 10 is guided by the guides 17 to be set.

[0046] Reference numeral 18 denotes a coil spring (lancet pushing member) for driving the lancet 2, and numeral 19 denotes a connect receiver (lancet pushing member) which is engaged with the connector 2b of the lancet 2. The connector receiver 19 is slidably supported by a pair of approximately-inverse-L-shaped supporting members 24 which are planted on the substrate 11a, and an end of the coil spring 18 is fixed onto a side of the connector receiver 19, which is opposite to the side that is engaged with the sensor 10. The other end of the coil spring 18 is supported by a spring stopper (lancet pushing member) 23. When the lancet 2 is engaged with the connector receiver ,19 and the lancet 2 is pushed into the measuring device 11, the coil spring 18 is compressed, whereby a force for driving the lancet 2 is applied to the coil spring 18.

[0047] Reference numeral 20 denotes a driving lever having a tapered projection 20a which is engaged with a tapered projection 11c that is positioned in front of the push button 14. When the lancet 2 is set up to a predetermined position, the driving lever 20 latches the connector receiver 19 to hold the driving force. This latching is canceled by pushing the push button 14, and the lancet 2 is driven by the pressing force from the spring 18.

[0048] Reference numeral 21 denotes a torsion spring for restricting the position of the connector receiver 19, and the torsion spring 21 is fixed by a shaft member 25 that is planted in the vicinity of a side surface parallel.with the insertion path of the sensor 10. The torsion spring 21 pushes the connector receiver 19 that is not latched by the driving lever 20, in the direction against the elasticity of the coil spring 18. The torsion spring 21 restricts the position of the connector receiver 19, in balance with the elasticity of the coil spring 18, so that the needle tip of the lancet 2 is positioned apart from the cavity 5 to prevent the needle chip from contacting the blood drawn into the cavity 5.

[0049] Reference numeral 22 denotes an ejection lever which is united with the slide button 15, and the ejection lever 22 pushes the rear end of the sensor 1 to eject the sensor 1 from the measuring device when the slide button 15 is operated in the direction indicated by an arrow a.

MEASURING OPERATION

[0050] Hereinafter, a description will be given of a series of measuring operations, with respect to the lancet-integrated sensor and the measuring device, which are constructed as described above.

[0051] Initially, an operation for fitting the lancet-integrated sensor to the measuring device will be described. The lancet-integrated sensor is in the state shown in figure 2(a) when it is not used. That is, the needle tip of the lancet 2 projects from the sensor 1, and is covered with the protection cover 3. A patient grips a wide grip part 3a of the protection cover 3, and inserts the lancet 2, from the connector 2b side, into the insertion slot 13 of the measuring device 11.

[0052] The patient further pushes the grip part 3a of the protection cover 3 to insert the sensor 1 and the lancet 2 deeper into the measuring device 11. Thereby, as shown in figure 5(a), the sensor 1 is guided by the guide 17 to advance into a case 11b. As the sensor 1 continues to advance into the case, the shorter side of the sensor 1, which is opposite to the semi-circular side thereof, touches the termination member 17a of the guide 17 to be set at a fixed position where the advance of the sensor 1 into the case 11b is restricted, whereby the electrode terminals 4 of the sensor 1 are connected to the connection terminals (not shown) of the measuring device 11. In order to make figure 5(a) easy to see, only the sensor 1 of the lancet-integrated sensor is shown, and a part corresponding to the lancet 2 is omitted.

[0053] Although the advance of the sensor 1 is stopped at this point of time, since the motion of the lancet 2 is not restricted by the termination member 17a of the guide 17 as shown in figure 5(c), the lancet 2 can be inserted deeper into the case 11b.

[0054] That is, by the pressing force of the protection cover 3, the engagement of the fine projection 2c with the concave groove 60a is released at the position shown in figure 2(a). Then, as shown in figure 2(b), the tube 3b of the protection cover 3, which protects the needle 2a, is pushed into the sensor 1, and a side of the grip part 3a of the protection cover 3 touches the front end of the sensor 1.

[0055] When the patient pushes the protection cover 3 deeper than the state shown in figure 5(a), the connector 2b of the lancet 2 is engaged with the concave portion 19a of the connector receiver 19 and, as shown in figure 5 (b), the coil spring 18 is compressed, whereby the tapered projection 20a of the driving lever 20 of the con-

nector receiver 19 is latched by the tapered projection 11c in front of the push button 14 to complete fitting of the sensor 10.

[0056] Next, a blood collecting operation and a blood dropping operation will be described. Figure 3(a) shows the state where fitting of the lancet-integrated sensor to the measuring device is completed. The patient holds the measuring device 11, and lightly pushes the front end of the sensor 10 against a portion of his/her body from which blood is to be extracted, such as a fingertip.

[0057] When the patient pushes the push button 14, the lancet 2 is driven, and the needle tip forcibly projects from the front end of the sensor 10 to lance the skin of the patient. At this time, the amount of projection of the needle tip from the sensor is variable by sliding the adjustment button 16 in the horizontal direction. To be specific, the torsion spring 21 is moved in the horizontal direction in the measuring device 11 by sliding the adjustment button 16 in the horizontal direction, thereby to adjust the spring force. Alternatively, the distance between the connector receiver 19 that is engaged with the push button 14, and the spring stopper 23 is increased or reduced by driving a mechanism (not shown) for converting the motion of the adjustment button 16 in the horizontal direction into the to-and-fro motion of the spring stopper 23 along the driving direction of the lancet 2. The amount of projection can be displayed on the display unit 12 by converting the amount of sliding of the adjustment button 16 to the amount of projection using a CPU or the like of the measuring device.

[0058] The patient drops a small amount of blood that is oozing from the lanced fingertip, onto the front end of the sensor 10, and the dropped blood is drawn into the cavity 5 by capillary phenomenon. The measuring device 11 measures blood sugar with the internal electronic circuit, and displays the result on the display unit 12. When the result of measurement is displayed to end the measurement, the patient slides the slide button 15 in the direction toward which the lancet 2 projects, whereby the lancet-integrated sensor is ejected from the measuring device 11, and the ejected lancet-integrated sensor is disposed of.

[0059] At this point of time, the connector 2b of the lancet 2 is engaged with the connector receiver 19 of the measuring device 11 although the ejection lever 22 pushes the rear end of the sensor 1. Since the sensor 1 is ejected firstly, the positional relationship between the sensor 1 and the lancet 2 goes into the state shown in figure 2(d). Then, the fine projection 2c of the lancet 2 is engaged with the concave groove 60a, and the lancet-integrated sensor is ejected from the measuring device 11 with the needle tip of the lancet 2 being completely housed in the sensor 1. Therefore, it is possible to prevent injury or infectious disease caused by that the needle tip protrudes from the sensor.

[0060] As described above, according to the first embodiment of the invention, since the sensor and the lancet are integrated with each other, management thereof is facilitated, and the trouble of separately replacing the sensor and the lancet at every use is saved. Further, since the sensor and the lancet can be simultaneously set in the measuring device, setting is facilitated, and the whole unit is reduced in size and easy to carry.

[0061] When the lancet-integrated sensor is ejected, in order to prevent injury and infectious disease more reliably, a semi-circular space that conforms to the shape of the front end of the sensor 1 is formed on a side of the grip part 3a of the protection cover 3 as shown in figure 6(a), and the lancet-integrated sensor may be ejected with the sensor 1 being covered with the protection cover 3 as shown in figure 6(b).

[0062] Further, while the lancet-integrated sensor according to the first embodiment is provided with the protection cover that covers the tip of the lancet, the lancet-integrated sensor may be provided with a holder which covers the periphery of the lancet-integrated sensor and the protection cover to hold them. In this case, fitting of the lancet-integrated sensor to the measuring device and ejection of the sensor from the measuring device can be carried out with the sensor being covered with the holder, and the operation is eased for patients with manual impairments.

[0063] When the holder is formed of a transparent material to make it easy to see the internal lancet-integrated sensor, the operability is further enhanced.

[0064] Furthermore, while in the first embodiment the lancet-integrated sensor uses the space in which the needle tip of the lancet moves, also as the cavity into which blood is drawn, the space and the cavity may be separated. Further, while in this first embodiment the sensor is a thin plate in shape, the shape of the sensor is not restricted thereto, and the sensor may be cylindrical in shape.

[0065] Furthermore, as shown in figure 7, the slide button 15 of the measuring device 11 may have wave-shaped projections and depressions on its upper surface to prevent the finger from slipping, and the shape of the sensor insertion slot 13 may be approached to rectangle.

(Example 1)

[0066] According to a the invention, when the lancet-integrated sensor is disconnected from the measuring device, the tip of the needle 2a is reliably housed in the sensor to prevent the possibility that a finger of another person touches the needle 2a onto which the bodily fluid remains, or a person pricks his/her finger with the needle 2a by mistake, thereby avoiding infectious disease as well as problems in terms of safety.

[0067] Hereinafter, a description will be given of a lancet-integrated sensor, and a measuring device which performs a measurement using the lancet-integrated sensor.

[0068] Figure 8 (a) is a perspective view illustrating such a lancet-integrated sensor according to the first ex-

ample illustrating the invention.

[0069] With reference to figure 8(a), reference numeral 2 denotes a lancet for lancing the skin of a man or an animal to extract bodily fluid. The lancet 2 is composed of a connector 2b which is made of an approximately rectangle-shaped plate member, and a needle 2a for lancing the skin, which is provided at the head of the connector 2b, i.e., in the vicinity of the center of a semi-circular-shaped shorter side of the connector 2b having two shorter sides. In the vicinity of the center of two longer sides of the connector 2b, small-sized fine projections 2c are formed at right angles from the respective longer sides, and these fine projections 2c have, on their upper surfaces, fine concave portions 21a and 21b (concave portions for locking; locking members) which are somewhat long from side to side and have semicylindrical-shaped bottom surfaces. Reference numeral 1 denotes a sensor for analyzing the extracted bodily fluid. The sensor 1 has an internal cavity 1a in which the lancet 2 is slidably housed. The sensor 1 has, at the ceiling of the cavity 1a, fine convex portions 61a and 61b (convex portions for locking, locking members) which are somewhat long from side to side and have semicylindrical-shaped surfaces, to be engaged with the fine concave portions 21a and 21b provided on the fine projections 2c of the lancet 2, respectively. Reference numeral 1a denotes a cavity formed in the sensor 1. The cavity 1a has a width a little larger than the width of the lancet 2, and has a pair of concave grooves 60a that project from two longer sides of the cavity 1a, in the width direction, correspondingly to the fine projections 2c of the lancet 2. Reference numeral 2a denotes a needle for lancing the skin, which is provided at a front end 2e of the lancet 2, i.e., in the vicinity of the center of a somewhat-rounded shorter side (head side) of two shorter sides of the lancet 2. Reference numeral 10 denotes a lancet-integrated sensor, in which the lancet 2 and the sensor 1 are integrated with each other.

[0070] Figure 8(b) is an exploded perspective view illustrating an example of such a lancet-integrated sensor.

[0071] As shown in figure 8(b), the lancet-integrated sensor 10 is constituted by placing the lancet 2 between a cover 6 and a substrate 7 which are components of the sensor 1, and bonding the cover 6 and the substrate 7 together.

[0072] The cover 6 has a groove 6a whose outline shape is a little larger than the lancet 2, and the groove 6a forms a cavity 1a in which the lancet 2 is to be housed slidably along its longitudinal direction. In the groove 6a, concave grooves 60a for restricting a region where the lancet 2 is slidable are formed on the rear of the longer sides of the groove 6a so that a part with the concave grooves 60a becomes a little wider than the other part of the groove 6a, and the length of each concave groove 60a in the transverse direction is set according to the length of the fine projection 2c of the lancet 2.

[0073] Further, as described above, the fine concave portions 21a and 21b of the lancet 2 are formed on the upper surfaces of the fine projections 2c which are formed in the vicinity of the center of the longer sides of the lancet 2, in positions most distant from the needle 2a, i.e., in the vicinity of the edges of the projections 2c on the opposite side from the needle 2a. The fine convex portions 61a and 61b of the sensor 1 are formed in the ceilings of the concave grooves (hollows) 60a of the cover 6, in positions most distant from the needle 2a when the lancet-integrated sensor is assembled, i.e., in the vicinity of the edges of the concave grooves 60a on the opposite side from the needle 2a.

[0074] Although the positional relationship between the fine concave portions 21a and 21b and the fine convex portions 61a and 61b may be other than mentioned above, these portions must be arranged with a predetermined positional relationship such that the needle 2a of the lancet 2 is housed in the sensor 1 when the fine concave portions 21a and 21b of the lancet 1 are engaged with the fine convex portions 61a and 61b of the concave grooves 60a of the cover 6.

[0075] Further, the front end of the cover 6, i.e., the shorter side of the cover 6 facing the needle 2a of the lancet 2, is semi-circular in shape, and a groove 6b an end of which is connected to the groove 6a is formed at the front end of the cover 6 so that the needle 2a at the front end 2e projects from the sensor 1, and the other end of the connecting groove 6b is an opening 6d of the front end of the sensor 1. An opening 6c is also formed on the rear end of the cover 6, i.e., an end of the cover 6 on the side opposite to the needle 2a of the lancet 2, so that the connector 2b of the lancet 2 projects from the sensor 1, and notches 21a and 21b are formed at two corners of the rear end of the cover 6 so that the electrodes 4 are exposed.

[0076] Although the front end of the substrate 7 is semi-circular in shape like the cover 6, the substrate 7 has no notches on the the rear end unlike the cover 6. On the surface of the substrate 7, two electrode terminals 4 are formed at the two corners of the rear ends of the longer sides, and a pair of electrodes 8 connected to the electrode terminals 4 by wiring are formed in the vicinity of the center of the semi-circular part on the front end of the substrate 7. Further, a reagent layer (not shown) is formed on the surface of the electrodes 8. The lancet-integrated sensor 10 is completed by bonding the cover 6 to the substrate 7, with the lancet 2 being housed in the groove 6a of the cover 6 as described above.

[0077] A protection cover 3 is fitted to the lancet-integrated sensor according to the first example illustrating the invention as shown in figures 2(a) and 2(b). Further, the measuring device for the lancet-integrated sensor according to the first example illustrating the invention has the same outward shape as that shown in figure 3. The internal structure of the measuring device is the same as that shown in figures 4(a) and 4(b) and figures 5(a), 5(b), and 5(c).

[0078] Next, a series of measuring operations of the lancet-integrated sensor and the measuring device

which are completed as described above, will be described.

[0079] Initially, an operation of attaching the lancet-integrated sensor to the measuring device will be described. In the state where the lancet-integrated sensor is not used, the lancet 2 is placed in such a position that the needle tip projects from the sensor 1, and the needle tip is covered with the protection cover 3, as shown in figure 2(a). The protection cover 3 is composed of a tube 3b as a needle housing part, and an approximately-square-shaped grip part 3a. The user holds the wide grip part 3a of the protection cover 3, and inserts the rear end of the connector 2b of the lancet 2 (the end of the lancet 2 opposite to the needle) from the opening 13a of the insertion slot 13 of the measuring device 11, as shown in figure 2(a)).

[0080] At this time, as shown in figure 5(a), the rear end of the connector 2b of the lancet 2 is guided by the guide (guide member) 17 in the measuring device 11, and goes toward the concave portion 19a of the front end of the connector receiver 19. The connector receiver (lancet pushing member) 19 is pressed in opposite directions by the coil spring 18 and the torsion spring 21, and stands still in the position where the pressing forces are balanced.

[0081] As the user continues to insert the lancet-integrated sensor 10 with the lancet 2 being covered with the protection cover 3, initially the lancet 2 is gradually inserted together with the sensor 1 to reach the position where it contacts the ejection lever 15 that is united with the slide button 14. Thereafter, when the slide button 14 reaches the end of its movable range (display 13 side) that is restricted by the termination member 17a of the guide 17, the sensor 1 stops its backward movement. On the other hand, the lancet 2 moves back in the sensor 1 while the user pushes the protection cover 3.

[0082] When the lancet 2 reaches an end of its movable range in the sensor 1, the fine concave portions 21a and 21b of the lancet 2 are engaged with the fine convex portions 61a and 61b of the cover 6 of the sensor 1 as shown in figure 2(b), whereby the lancet 2 is locked with respect to the sensor 1. At this time, the rear end of the lancet 2 is engaged with the concave portion 19a of the connector receiver 19, and the connector receiver 19 moves back as the user continues to push the protection cover 3, and the tapered projection 20a of the driving lever 20 that is fixed to the connector receiver 19 is engaged with the tapered projection 11a that is provided at the ceiling in the measuring device 11 as shown in figure 5(b), whereby the connector receiver 19 is locked. In this state, attachment of the lancet-integrated sensor 10 to the measuring device 11 is completed.

[0083] Next, a blood collecting operation and a blood dropping operation will be described. When attachment of the lancet-integrated sensor to the measuring device is completed, the vicinity of the semi-circular head portion of the sensor 10 is slightly exposed from the holder 13 as shown in figure 3(a). The user holds the measuring device 11, and lightly presses the front end of the sensor 10 against a portion of his/her body from which blood is to be extracted, such as a fingertip.

[0084] When the user pushes the push button (unlocking member) 14, the tapered projection 20a of the driving lever 20 and the tapered projection 11c of the measuring device 11 are disengaged from each other, and the lancet 2 and the sensor 1 are unlocked by extension of the coil spring 18, whereby the lancet 2 is driven (refer to figure 10) and, as shown in figure 2(c), the needle tip projects from the front end of the sensor 1 to lance the skin. At this time, the amount of projection of the needle tip from the sensor is variable by the adjustment button 16 shown in figure 3 (b). To be specific, the torsion spring 21 is moved in the horizontal direction in the measuring device 11 by sliding the adjustment button 16 in the horizontal direction, thereby to adjust the spring force. Alternatively, the distance between the connector receiver 19 that is engaged with the push button 14, and the spring stopper 23 is increased or reduced by driving a mechanism (not shown) for converting the motion of the adjustment button 16 in the horizontal direction into the to-and-fro motion of the spring stopper 23 along the driving direction of the lancet 2. The amount of projection can be displayed on the display unit 12 by converting the amount of sliding of the adjustment button 16 to the amount of projection, with the CPU or the like of the measuring device.

[0085] A small amount of blood that is oozing from the lanced fingertip of a patient or a person being tested is dropped onto the front end of the sensor 1, and the blood is drawn into the cavity 5. The measuring device 11 measures blood sugar by the internal electronic circuit, and displays the result on the display unit 12. When the result of measurement is displayed to complete the measurement, the user operates the slide button (ejection member) 15 to eject the lancet-integrated sensor 10 from the measuring device 11, and the ejected lancet-integrated sensor 10 is disposed of.

[0086] At this time, the ejection lever (ejection member) 22 that is united with the slide button 15 pushes the sensor 1 from its rear end. At the beginning of pushing, the connector 2b at the rear end of the lancet 2 is engaged with the concave portion 19a of the connector receiver 19 of the measuring device 11. Therefore, the sensor 1 is ejected before the lancet 2 by operating the slide button 15. Accordingly, the positional relationship between the sensor 1 and the lancet 2 becomes as shown in figure 5(b). That is, the fine concave portions 21a and 21b of the lancet 2 are engaged with the fine convex portions 61a and 61b of the concave grooves 60a and 60b of the sensor 1, and the lancet 2 is locked in the state where its needle tip does not project from the sensor 1. When the slide button 14 is further pushed, the lancet 2 with the needle tip 2a being locked in the sensor 1 is ejected together with the sensor 1 from the measuring device 11. Therefore, the needle 2a of the lancet 2 is not exposed from the sensor 1, thereby preventing injury or infectious disease caused by the needle tip being exposed.

[0087] As described above, according to the first example illustrating the invention, the lancet-integrated sensor is ejected in the state where the lancet 2 and the sensor 1 are reliably locked with each other. At this time, the lancet 2 and the sensor 1 are locked with the needle 2a of the lancet 2 being housed in the sensor 1. Therefore, when taking the lancet-integrated sensor 10 out of the measuring device, there is no possibility that the user touches the needle 2a of the lancet 2 with his/her finger, or pricks the finger with the needle 2a by mistake, thereby preventing infectious diseases. As a result, a lancet-integrated sensor which can be safely ejected from the measuring device is obtained.

[0088] Furthermore, it is possible to obtain a measuring device for a lancet-integrated sensor, which can measure bodily fluid with such a safely-detachable lanced-integrated sensor, and can eject the lancet-integrated sensor with the lancet being locked in the state where the needle of the lancet is housed in the sensor, when measurement is ended.

[0089] While in this first example a concave portion is provided on the upper surface of the lancet and a convex portion that is engaged with the concave portion is provided on the sensor 2, the positions where the concave portion and convex portion are provided may be arbitrarily set as long as the lancet and the sensor are locked by engagement of the concave portion with the convex portion after end of measurement, and the needle of the lance is housed in the sensor.

(Example 3)

[0090] According to a second example illustrating the present invention, a holder for guiding the lancet-integrated sensor into the measuring device is detachable from the measuring device to enable cleaning or the like of the holder.

[0091] To be specific, when a patient extracts bodily fluid using the measuring device with the lancet-integrated sensor according to the first embodiment or the first example, the patient must apply his/her finger or upper arm to the holder-shaped insertion slot 13 of the measuring device 11 to lance the skin, and the bodily fluid of the patient sometimes sticks to the insertion slot 13 of the measuring device 11.

[0092] However, since, in the measuring device according to the first embodiment or the first example, the measuring device 1 is united with the insertion slot 13, the insertion slot 13 cannot be cleaned or replaced after the measurement. Therefore, if another patient performs measurement with the measuring device in which the other's bodily fluid remains on the insertion slot 13, the bodily fluid of the patient might contact the other's bodily fluid, resulting in the fear of infectious diseases or the like. Accordingly, the measuring device of the first embodiment or the first example can be used for personal measurement only.

[0093] On the other hand, the measuring device for the lancet-integrated sensor according to the third embodiment enables the user to clean or replace the insertion-slot-shaped holder to which the bodily fluid sticks, whereby the user can handle the measuring device safely and cleanly.

[0094] Figures 11 and 12 are diagrams illustrating the construction of the measuring device for the lancet-integrated sensor, according to the second example illustrating the invention.

[0095] In figure 11, figure 11(a) is a perspective view of a lancet-integrated sensor and a measuring device to be combined with the sensor, and figure 11(b) shows the state when a holder is disconnected.

[0096] In figure 11, reference numeral 11 denotes a measuring device for a lancet-integrated sensor (hereinafter referred to as a measuring device) for measuring blood sugar or the like with a lancet-integrated sensor 2 that is fitted to it, and reference numeral 10 denotes a lancet-integrated sensor.

[0097] The measuring device 11 has a holder attachment part 47 on a side wall where the lancet lances the skin, and a holder body 43 for holding an end portion of the lancet-integrated sensor 10 in the vicinity of the side where the lancet lances the skin is detachably attached to the holder attachment part 47. Further, the measuring device 11 has an operation button 14 for driving the lancet that is fitted to it, a display 12 for displaying the measurement result or the like, a slide button 15 for ejecting the lancet-integrated sensor 10 from the measuring device 11, and a holder attachment part 47 to which the holder body 43 is attached.

[0098] As shown in figure 11(b), the holder body 43 is detachable from the measuring device 11 so that the bodily fluid that sticks to the holder body 43 can be washed away or the holder body 43 can be replaced with another one after completion of measurement.

[0099] Further, as already described above, the lancet-integrated sensor 10 is constituted by integrating the lancet 2 for lancing the skin of a man or an animal to extract bodily fluid, and the sensor 1 for analyzing the extracted bodily fluid.

[0100] Hereinafter, the constructions of the holder body 43 and the holder attachment part 47 will be described in more detail, with reference to figure 12.

[0101] Figure 12 is a diagram for explaining attachment/detachment of the holder body 43 to/from the holder attachment part 47.

[0102] With reference to figure 12(a), reference numerals 43a and 43b denote hinge-shaped stoppers possessed by the holder body 43. These stoppers are formed by bending plate members, which are extended forward from the both ends of the holder body 43, i.e., in the direction opposite to the direction along which the lancet-integrated sensor is inserted, backward at approximately 180°. The stoppers 43a and 43b have, at their front ends, clip parts 43e and 43f which serve as retainers of the stoppers 43a and 43b, and perform positioning when the holder body 43 is stopped at the opening 47c, respec-

tively. The inner sides of the hinge-shaped stoppers are fixed onto the holder body 43, and the outer sides of the hinge-shaped stoppers are engaged with engagement parts of the holder attachment part 47, whereby the holder body 43 is stopped by connecting it to the measuring device 11. That is, the holder body 43 is stopped, with its spring force, at holes (small openings) 47a and 47b which are formed at two shorter sides of the holder attachment part 47 having an opening shape approximately equal to the outer shape of the holder body 43 so as to increase the width of the holder attachment part 47 to some extent. The holes 47a and 47b may be formed at two longer sides of the opening 47a of the approximately-rectangle holder attachment part 47.

[0103] The holder body 43 can be attached to the holder attachment part 47 of the measuring device 11 by inserting the stoppers 43a and 43b of the holder body 43 into the holes 47b and 47b of the holder attachment part 47, respectively. As shown in figure 12(a), the holes 47a and 47b of the holder attachment part 47 have different sizes and the stoppers 43a and 43b of the holder body 43 have different sizes, whereby the holder body 43 cannot be inserted upside down. The reason is as follows. If the lancet-integrated sensor 10 is inserted upside down into the measuring device 11, electrical connection between the lancet-integrated sensor 10 and the measuring device 11 cannot be made. In order to avoid this problem, the right and left holes of the holder attachment part 47 are formed in different shapes and the right and left stoppers of the holder body 43 are also formed in different shapes, so that the holder body 43 can be inserted into the holder attachment part 47 only when its up-to-down direction is a certain direction, i.e., a normal direction, whereby the lancet-integrated sensor 10 cannot be inserted upside down.

[0104] Figure 12(b) and figure 12(c) are cross-sectional views in the case where the holder body 43 is stopped by connecting it to the measuring device 11. Figure 12(b) shows the state where the hinge-shaped stoppers 43a and 43b of the holder body 43 are engaged with the holes 47a and 47b of the measuring device 11. Further, figure 12(c) shows the state where the user tries to detach the holder body 43 by pressing the clip portions 43e and 43f of the stoppers 43a and 43b with fingers to replace the holder body 43, after measurement is completed or when another person uses the measuring device 11.

[0105] Since the holder for attaching the lancet-integrated sensor, which is possessed by the measuring device, is detachable as described above, the holder body onto which bodily fluid sticks can be replaced with an unused one or washed, whereby the measuring device can be used not only by a specific user but also by anyone other than the user, without the fear of infectious diseases or the like. Therefore, the measuring device for the lancet-integrated sensor can be used safely and cleanly.

[0106] Further, since the holder body is provided with the hinge-shaped stoppers to be engaged with the holder attachment part, fixation and attachment/detachment of the holder body can easily carried out.

[0107] Furthermore, since the holes of the holder attachment part have different shapes and the stoppers of the holder body also have different shapes, the holder body can always be attached in the normal direction to the measuring device, thereby preventing the lancet-integrated sensor from being inserted upside down into the measuring device.

[0108] While in this second example the shapes of the left and right stoppers 43a and 43b of the holder body 43 are different. from each other and the shapes of the left and right holes 47a and 47b of the holder attachment part 47 are also different from each other, these engagement parts of the holder body and the holder attachment part may have arbitrary shapes as long as the respective engagement parts are asymmetrical in the vertical or horizontal direction so that the holder body can be attached to the holder attachment part only when the holder body is inserted in a predetermined direction.

[0109] Furthermore, the spring stopper 23 of the measuring device 11 may be fixed to the ceiling of the measuring device 11 as shown in figure 13(a), and the coil spring 18 may be attached to a shaft 56a that is fixed onto the spring stopper 23.

[0110] Furthermore, the lancet-integrated sensor 10 may have a shape that is a little shorter in the longitudinal direction as shown in figure 13(b).

(Example 3)

[0111] According to a third example illustrating the present invention, the amount of projection of the needle tip from the lancet-integrated biosensor can be easily adjusted. Further, when the lancet is driven so as to project out forcibly, if the drive is stopped halfway due to some trouble, the lancet can easily be returned to the state before being driven.

[0112] To be specific, in the measuring device for the lancet-integrated sensor according to the first embodiment or the first example, when extraction of bodily fluid is carried out, the driving means 100 is operated by pushing down the operation button 14 to drive the lancet 2 so that the needle 2a lances a fingertip or upper arm, and the extracted blood is dropped onto the sensor 1 to perform measurement of it. However, when extraction of bodily fluid cannot be carried out due to some trouble such as insufficient lancing of the lancet, the lancet 2 must be reset to the state where the lancet 2 can be driven again.

[0113] However, in order to reset the once driven lancet 2 to the state where it can be driven again, the lancet-integrated sensor 10 must be once ejected by using the slide button 15 and, thereafter, reattached to the measuring device 11. It is sometimes necessary to replace the lancet-integrated sensor 10 itself.

[0114] Further, since the lancet-integrated sensor according to the first embodiment or the first example is not provided with an effective means for adjusting the

amount of projection of the needle tip of the lancet, it is difficult to adjust the amount of bodily fluid oozing from the patient or reduce pain of the patient.

[0115] On the other hand, the measuring device for the lancet-integrated sensor according to the third example can easily adjust the amount of projection of the needle tip of the lancet, and it can perform re-preparation for measurement when bodily fluid cannot be extracted due to some trouble such as insufficient lancing of the lancet.

[0116] Hereinafter, the measuring device for the lancet-integrated sensor according to the third example will be described.

[0117] Figure 14 is a diagram illustrating an example of the measuring device according to the third example illustrating the present invention.

[0118] With reference to figure 14, reference numeral 11 denotes a measuring device for a lancet-integrated sensor (hereinafter referred to as a measuring device) according to the third example illustrating the invention. Reference numeral 13 denotes an insertion slot into which the lancet-integrated sensor is inserted, and the insertion slot is applied to a finger or upper arm of a patient when measurement is carried out; numeral 14 denotes an operation button for driving the lancet that is fitted to the measuring device 11; numeral 12 denotes a display for displaying the result of measurement or the like; numeral 15 denotes a slide button for ejecting the lancet-integrated sensor from the measuring device 11; numeral 56 denotes a pull stick for returning the lancet-integrated sensor back to the stand-by position where measurement can be performed with the lancet-integrated sensor being fitted to the measuring device 11, by pulling the lancet-integrated sensor in the direction opposite to the lancet driving direction, i.e., in the direction shown by an arrow A in figure 14, when some trouble occurs in extracting bodily fluid; and numeral 57 denotes a lancet projection amount adjuster for adjusting the amount of projection of.the needle tip of the lancet, which also serves as a stopper of the pull stick 56.

[0119] Figure 15 is a cross-sectional view taken along a line X-X', of the measuring device for the lancet-integrated sensor shown in figure 14. In figure 15, the pull stick 56 has a handle part 56d. The same constituents as those described with respect to figure 14 are given the same reference numerals to omit description thereof.

[0120] In figure 15, reference numeral 10 denotes a lancet-integrated sensor fitted to the measuring device 11, which is constituted by integrating the lancet 2 for lancing the skin of a man or an animal to extract bodily fluid, and the sensor 1 for analyzing the extracted bodily fluid.

[0121] Further, reference numeral 19 denotes a connector receiver having a concave portion 19a that is engaged with a connector 2b possessed by the lancet 2 as a component of the lancet-integrated sensor 10. Reference numeral 56a denotes a shaft, and the connector receiver 19 for receiving an end of the lancet 2, which end is opposed to the side where the skin is lanced, is fixed to an end of the shaft 56a, which end is opposite to the side where the skin is lanced. An end (slip-out prevention member) 56b of the shaft 56a, which is positioned within the pull stick 56, has a diameter larger than the diameter of an opening 56c of the pull stick 56. Reference numeral 20 denotes a driving lever which is provided on the connector receiver 19, and the driving lever.20 stops the move of the connector receiver 19 against a force by which the connector receiver 19 is moved in the direction along which the lancet 2 lances the skin, by the spring 18 which is fitted to the shaft 56a that is unlocked by pressing the operation button 14 for starting the operation of the driving means 100. The operation button 14, the pull stick 56, the lancet projection amount adjuster 57, the shaft 56a, and the connector receiver 19 constitute the driving means 100 which drives the lancet 2 from its stand-by position along the longitudinal direction of the sensor 1, i.e., the direction along which it lances the skin and, thereafter, returns the lancet back to the stand-by position, with the lancet-integrated sensor 10 being fitted to the measuring device 11.

[0122] Next, the operation will be described.

[0123] First of all, the patient pushes the lancet-integrated sensor 10 into the sensor insertion slot 13 of the measuring device 11, whereby the connector 2b possessed by the lancet 2 of the lancet-integrated sensor 10 is engaged with the concave portion 19a of the connector receiver 19, and a tapered projection (claw portion) 20a of the driving lever 20 fixed to the connector receiver 19 is engaged with a tapered projection (claw portion) 11c of the measuring device 11 so that the lancet 2 can be shot by pressing down the operation button 14.

[0124] Thereafter, the patient applies the insertion slot 13 of the measuring device 11 to his/her finger or upper arm, and presses the operation button 14, whereby the tapered projection 20a of the connector receiver 19 is disengaged from the tapered projection 11c of the measuring device 11, and the lancet 2 is shot from the tip of the center 10.

[0125] At this time, if the lancet 2 fails to lance the skin or measurement does not go well due to some trouble, the user picks the pull stick 56 and pulls it in the direction of the arrow shown in figure 14, i.e., upward in the figure, whereby the end 56b of the shaft 56a is pulled up, and the connector receiver 19 holding the connector 2b of the lancet 2 is operated in synchronization with the shaft 56a. Thus, the tapered projection 20a provided on the connector receiver 19 can be re-engaged with the tapered projection 11c just before the operation button 14.

[0126] Further, when the lancet 2 is shot, the lancet 2 moves along the longitudinal direction of the sensor 1, and the pull stick 56 that is operated in synchronization with the lancet 1 moves until reaching the opposed surface of the lancet projection amount adjuster 57. The lancet projection amount adjuster 57, which serves as a stopper for the pull stick 56, has a structure of a screw thread to be screwed into a screw hole 11d that is formed on a side of the measuring device 11 opposite to the

insertion slot 13. The lancet projection amount adjuster 57 can be moved along the lancet moving direction by rotating it clockwise or counterclockwise.

[0127] Therefore, the measurer adjusts the position of the lancet projection amount adjuster 57 in advance of driving the lancet 2, and adjusts the spring force by adjusting the distance between the connector receiver 19 and the spring stopper (supporting member) 23, thereby setting the amount of projection of the needle 2a of the lancet 2 to a desired amount. Thus, the shot lancet 2 moves until the pull stick 56 hits the lancet projection amount adjuster 57 to stop, whereby the amount of projection of the needle tip of the lancet 2 from the sensor can be adjusted.

[0128] As described above, according to the third example, even when the lancet 2 fails to lance the skin or measurement does not go well due to some trouble, preparation for re-measurement can be easily carried out using the pull stick 56 which set the connector receiver 19 holding the connector 2b of the lancet 2, beneath the operation button 14 again to bring the measuring device into the state where measurement can be carried out.

[0129] Furthermore, since the measuring device 11 is provided with the lancet projection amount adjuster which can adjust the mount of projection of the lancet, the amount of bodily fluid oozing from the patient can be adjusted, or pain of the patient can be reduced.

(Example 4)

[0130] A fourth example illustrating the present invention provides a biosensor cartridge, by which a biosensor or a lancet-integrated sensor can be fitted to a measuring device without a troublesome operation.

[0131] Hereinafter, a biosensor cartridge according to the fourth example illustrating the invention will be described taking, as an example, a cartridge which houses biosensors for electrochemically measuring blood sugar, with reference to the drawings.

[0132] Figure 16 is a diagram illustrating a biosensor cartridge according to the fourth example illustrating the invention.

[0133] In figure 16, reference numeral 1 denotes biosensors for measuring blood sugar, and each biosensor 1 is formed of a plate member that is approximately rectangle in shape, and one of two shorter sides of the rectangle biosensor 1 is semi-circular in shape. Reference numeral 11 denotes a measuring device for measuring blood sugar with the biosensor 1 attached thereto. Reference numeral 63 denotes a biosensor cartridge comprising plastic or the like, and the cartridge 63 has an approximately-rectangular-parallelepiped housing box (cartridge body) 63c, and plural housing sections 63b which are slits each conforming to the shape of the biosensor 1. The housing sections 63b can hold plural biosensors 1 separately, by perpendicularly supporting the biosensors 1 with their end portions to be inserted into the measuring device 11 turning up. The spacing between the housing sections (slits) 63b for housing the biosensors 1 should be sufficiently large so that the insertion slot 11a of the measuring device 11 can be pressed onto one of the separately housed biosensors 1. That is, when inserting a target biosensor 1 into the insertion slot 11a of the measuring device 11, this spacing prevents the insertion slot 11a from contacting the biosensors adjacent to the target biosensor. Reference numeral 63a denotes a lid (lid part) of the biosensor cartridge 63. The lid 63a is hollow and approximately rectangular-parallelepiped in shape, and the lid 63a is opened or closed by rotating it at about 90 degrees about a hinge 63h that is provided on a side of the housing box 63c.

[0134] Figure 17 is a diagram illustrating the state where one of the biosensors housed in the biosensor cartridge of the fourth example is inserted into the measuring device.

[0135] Attachment of the biosensor 1 to the measuring device 11 is carried out as follows. After the lid 63a of the biosensor cartridge 63 is opened as shown in figure 16, the biosensor 1, which is stored in the biosensor cartridge 63 with its semi-circular end turning up, is inserted into the biosensor insertion slot 11a of the measuring device 11 as shown in figures 17(a) and 17(b).

[0136] At this time, the spacing between the housing sections 63b for housing the biosensors 1 is set so that, when a target biosensor 1 is inserted into the insertion slot 11a of the measuring device 11, the insertion slot 11a does not contact the biosensors adjacent to the target biosensor. Therefore, the target biosensor 1 can be easily attached to the measuring device 11 without damaging other biosensors 1.

[0137] As described above, according to the biosensor cartridge of the fourth example, the spacing between the respective housing sections provided in the biosensor cartridge is sufficiently large so that one of the separately stored biosensors 1 can be inserted into the insertion slot 11a of the measuring device 11. Therefore, the biosensor 1 can be inserted into the measuring device 11 with a single touch, whereby preparation for measurement can be easily carried out. Consequently, one of the biosensors stored in the cartridge can be inserted into the measuring device 11 without a troublesome operation, and it is possible to minimize such accident that the insertion slot 11a of the measuring device contacts the biosensors adjacent to the target biosensor thereby to damage the biosensors.

(Modification 1 of Example 4)

[0138] Hereinafter, a biosensor cartridge according to a first modification of the fourth example will be described. The biosensor cartridge according to this first modification is characterized in the manner of hermetically sealing the cartridge. Since other constituents are identical to those described for the fourth example, the same reference numerals are given to the constituents to omit de-

scription thereof.

[0139] Figure 18 is a diagram illustrating a biosensor cartridge according to the first modification of the fourth example.

[0140] As shown in figure 18(a), in the biosensor cartridge 63, an approximately-rectangular-parallelepiped lid 63a having a hollow inside is rotatably fixed onto an approximately-rectangular-parallelepiped housing box 63c with a hinge whose rotation axis is slidable in the longitudinal direction of the lid 63a.

[0141] The hinge is composed of a pair of axial projections 63g which project in the vertical direction with respect to the side surfaces forming the longer sides of the lid 63a from the vicinities of the both ends of the shorter side of the opening of the lid 63a; a side-to-side-long bearing 63i which extends within the same plane as the side surfaces along the longer sides of the opening of the housing box 63c from the vicinities of the both ends of the shorter side of the opening; and a bearing hole 63i which is formed in the bearing 63i in an oval shape, with which the axial projections 63g are engaged.

[0142] Then, four reverse-L-shaped projections 63d which are formed at the edges of the respective sides of the opening of the lid 63a are positioned at four notches 63e formed in an projection part (peripheral edge part) 63f which is formed at the edges of the respective sides of the upper surface of the housing box 63c of the biosensor cartridge 63, and the projections 63d are crawled into the notches 63e. Then, the lid 63a is rotated at 90° in the direction indicated by an arrow (i.e., counterclockwise) and, thereafter, slightly slid in the radial direction (i.e., left forward direction in the figure), whereby the L-shaped projections 63d are engaged with the.projection part 63f in the vicinity of the notches 63e, and the lid 63a seals the housing box 63c having the plural housing slits, of the biosensor cartridge 63. Figure 18(b) is a side view illustrating the state where the housing box is sealed with the lid, from the state shown in figure 18(a).

[0143] Further, figure 18(c) is a cross-sectional view illustrating the state where an elastic member (sealing member) 64 is disposed on the part where the housing box 63c and the lid 63a are closely contact with each other (i.e., on the peripheral edge part of the opening of the lid 63a) to hermetically seal the container. The elastic member 64 is a member having a large elasticity such as rubber. In this way, the hermeticity of the biosensor cartridge can be increased by integrally forming the elastic member 64.

[0144] Although the shape of the biosensor housing part is not particularly described above, plural slits, each conforming to the shape of the biosensor, may be formed at regular intervals in the member that fills the concave portion of the approximately-rectangular-parallelepiped housing box 63c. Thereby, the biosensors can be perpendicularly supported at regular intervals so that, when inserting the target biosensor 1 into the insertion slot 2a of the measuring device 2 as in the fourth example, the insertion slot 2a does not contact the adjacent biosensors.

[0145] As described above, according to the first modification of the fourth example, the elastic member 64 or the like is formed integrally with the engagement part of the housing box 63c and the lid 63a of the biosensor cartridge 63, and the housing box 63c is covered with the lid 63a. Thereafter, the L-shaped projections 63d provided on the lid 63a are crawled into the notches 63e of the projection part 63f of the biosensor cartridge, and the L-shaped projections 63d are slid to be engaged with the notches 63e, thereby hermetically sealing the container. Therefore, the hermeticity of the container is increased, and the moisture in the container is reduced, whereby the sensor is prevented from being contaminated by the moisture, leading to improvement in accuracy of the sensor.

[Modification 2 of Example 4]

[0146] Figure 19 is a diagram illustrating a biosensor cartridge according to a second modification of the fourth example illustrating the present invention.

[0147] In figure 19, reference numeral 10 denotes a lancet-integrated sensor which is constituted by integrating a lancet for lancing the skin of a man or an animal to extract bodily fluid and a sensor for analyzing the extracted bodily fluid; reference numeral 11 denotes a measuring device for measuring blood sugar or the like with a lancet-integrated sensor 5 that is attached thereto; and reference numeral 63 denotes a biosensor cartridge comprising plastic or the like, which is composed of an approximately-rectangular-parallelepiped lid 63a and an approximately-rectangular-parallelepiped housing box 63c. The housing box 63c is provided with lower grooves 630a, intermediate grooves 630b, and upper grooves 630c so as to support the lancet-integrated sensors 10, each having a protection cover (protector) 3 on its bottom surface, perpendicularly at regular intervals. To be specific, the lower grooves 630a, into which the protection covers 3 of the lancet-integrated sensors 10 are inserted to be supported, are formed at the side nearest to the bottom of the member that fills up the concave portion of the housing box 63c. The intermediate grooves 630b, into which portions of the lancet-integrated sensors 10 are inserted to be supported, are formed above the lower grooves. The upper grooves 630c are formed above the intermediate grooves, and lowermost portions of the upper grooves 630c are a little rounded to increase the widths of the grooves, and approximately whole portions thereof are wider than the widths of the sensors of the lancet-integrated sensors 10. A single housing part (groove) 63b is formed of a lower groove (first groove) 630a, an intermediate groove (second groove) 630b, and an upper groove (third groove) 630c which are connected with each other. In the housing box 63a, the lancet-integrated sensors 10 are respectively housed in the plural housing parts 63b at regular intervals, with the portions to be inserted to the measuring device 11 turning up.

[0148] The spacing between the housing parts for housing the lancet-integrated sensors should be sufficiently large so that the insertion slot 11a of the measuring device 11 can be pressed onto one of the separately stored lancet-integrated sensors 10. As an example of the lancet-integrated sensor, the lancet-integrated sensor which has already been described for the first embodiment or the first example may be employed.

[0149] Figure 20(a) is a constitutional diagram for explaining attachment of a lancet-integrated sensor to a measuring device, and figure 20(b) is a perspective view thereof.

[0150] Figure 20(a) shows a lancet-integrated sensor having a needle storage part that is a little wider than those shown in figure 1 and other figures.

[0151] Attachment of the lancet-integrated sensor 10 to the measuring device 11 is performed as follows. After the lid 63a of the biosensor cartridge 63 is opened as shown in figure 19, the lancet-integrated sensor insertion slot 11a of the measuring device 11 is pressed onto the lancet-integrated sensor 1 that is stored in the biosensor cartridge 63 as shown in figure 20(b).

[0152] As described above, according to the fourth example, the spacing between the respective storage parts of the biosensor cartridge is sufficiently large so that the insertion slot 11a of the measuring device 11 can be pressed onto one of the lancet-integrated sensors 10 that are stored separately, whereby the lancet-integrated sensor 10 can be inserted into the measuring device 11 by a single touch, and preparation for measurement can be easily carried out as compared with the measuring device for the sensor having no lancet. Therefore, one of the biosensors stored in the housing case can be inserted into the measuring device 11 without performing a troublesome operation, and the insertion slot 11a of the measuring device 11 is prevented from contacting the biosensors adjacent to the target biosensor thereby to damage the biosensors.

[0153] Although the biosensors are perpendicularly supported in the first or second modification of the fourth example, when the height of the biosensor cartridge should be reduced, the biosensors may be supported in a slanting direction. Also in this case, the same effects as mentioned above are achieved by providing biosensor storage parts at regular intervals with which the insertion slot of the measuring device can pressed onto the target biosensor without damaging the adjacent biosensors.

APPLICABILITY IN INDUSTRY

[0154] As described above, according to a lancet-integrated sensor of the present invention and a measuring device to be combined with the sensor, a sensor and a lancet are integrated, and a measuring device for measuring the characteristics of bodily fluid is provided with a function of driving the lancet. Therefore, as compared with the conventional system comprising a sensor, a lancet, a measuring device, and a lancet device, the number of components is reduced, whereby management is facilitated. Especially, it is not necessary to manage the number of disposal sensors and lancets separately. Further, when carrying these devices, the volume is reduced, resulting in a convenience of portability.

[0155] Further, when preparing for measurement, it is not necessary to set a sensor on a measuring device and a lancet on a lancet device, respectively, as conventional, and preparation for measurement can be completed by only a single operation of setting a lancet-integrated sensor on a measuring device. Further, the trouble of replacing a used sensor with a new one is reduced by half.

[0156] Furthermore, since a lancet is locked with its needle tip being housed in a sensor, an accident due to careless exposure of the needle tip is avoided.

[0157] Moreover, since a cartridge for housing plural sensors can support the sensors at regular intervals, it is possible to avoid such an accident that, when a sensor is attached to a measuring device, the measuring device damages other sensors.

Claims

1. A lancet-integrated sensor (10) which is constituted by integrating a lancet (2) for lancing the skin of a subject to extract its bodily fluid, and a sensor body (1) for analyzing the extracted bodily fluid, wherein
the sensor body (1) has a shape of a long and narrow strip,
the lancet (2) is configured so as to be driven along the longitudinal direction of the sensor body (1) by an external driving means, thereby lancing the skin,
the sensor body (1) has an internal space (1a) through which the lancet (2) can pass, and holds the lancet (2) in the space (1a),
the space (1a) in the sensor body (1) is adapted to house the lancet (2) and also serves as a cavity (5) for collecting the bodily fluid, and
an inlet of the cavity (5) for collecting the bodily fluid is provided at an end of the sensor (1) from which the needle tip (2a) of the lancet (2) is projected, and a reagent adapted to react with the collected bodily fluid is provided in the cavity (5).

2. A lancet-integrated sensor as defined In Claim 1, wherein
the space (1a) is long and narrow for housing the lancet (2).

3. A lancet-integrated sensor as defined in any of Claims 1 to 2, wherein
the sensor body (1) is obtained by bonding two thin plates (6. 7) together, and at least one of the two plates (6, 7) has a concave portion (6a); and
the space (1a) is formed by the concave portion (6a) of the two plates (6, 7) bonded together.

4. A lancet-integrated sensor as defined in any of Claims 1 to 3, wherein when the lancet (2) lances the skin to extract the bodily fluid, the lancet (2) is configured so as to project from the inside of the sensor body (1) in which its needle tip (2a) is stored.

5. A lancet-integrated sensor as defined in any of Claims 1 to 4, wherein
the sensor body (1) has, in the cavity (5), an electrode (8) for outputting the analysis result of the characteristics of the bodily fluid,

6. A lancet-integrated sensor as defined in Claim 5, wherein
a connection terminal (4) to be connected with an external measuring device (11) to electrically measure the characteristics of the bodily fluid is provided at an end of the sensor body (1) having the cavity (5).

7. A lancet-integrated sensor as defined in any of Claims 1 to 6, wherein
the lancet (2) is configured such that
an end of the lancet (2) on the side opposite to the needle tip (2a) projects from the sensor body (1); and
the projecting end is engaged with the driving means of the external measuring device (11), whereby the lancet (2) is driven to perform the skin lancing operation.

8. A lancet-integrated sensor as defined in Claim 7, wherein
a connector (2b) to be engaged with the driving means of the external measuring device (11) is provided at the end of the lancet (2) on the opposite side to the needle tip (2a); and
the connector (2b) is configured so as to be engaged with the driving means, whereby the lancet (2) performs the skin lancing operation.

9. A lancet-integrated sensor as defined in Claim 8, wherein
the connector (2b) is made of a resin, and has a diameter larger than that of the lancet (2).

10. A lancet-integrated sensor as defined in any of Claims 1 to 9,
wherein
a detachable protection cover (3) is fitted to the needle tip (2a) of the lancet (2); and
the protection cover (3) is configured so as to be removed during the skin lancing operation of the lancet (2).

11. A lancet-integrated sensor as defined in Claim 10, wherein
the protection cover (3) has a tube part (3b) for housing the needle tip (2a) in it, and a wide grip part (3a) for facilitating removal of the protection cover (3) from the lancet (2), which grip part (3a) is provided on the needle tip side of the tube part (3b).

12. A lancet-integrated sensor as defined in Claim 10, said lancet-integrated sensor (10) being configured such that the engagement of the lancet (2) and the driving means and the attachment of the sensor body (1) integrated with the lancet (2) to the measuring device (11) are performed with holding the grip part (3a) of the protection cover (3).

13. A lancet-integrated sensor as defined in Claim 10, wherein
a semi-circular space in which the front end of the sensor body (1) can be housed is formed in the grip part (3a).

14. A lancet-integrated sensor as defined in any of Claims 1 to 13 being provided with a holder which covers the periphery of the integrated sensor body (1) and lancet (2) to hold them.

15. A lancet-integrated sensor as defined in Claim 14, wherein the holder is made of a transparent material.

16. A lancet-integrated sensor as defined in any of Claims 1 to 15 being of a disposable type, which is adapted to be discarded after performing collection and analysis of the bodily blood one time.

17. A measuring device (11) comprising a lancet-integrated sensor (10) as defined in claims 1 to 16 detachably attached, for measuring the characteristics of the bodily fluid collected by the lancet-integrated sensor (10), said measuring device (11) including:

a lancet driving means for driving, after the lancet-integrated sensor (10) is attached to the measuring device (11), the lancet (2) so as to lance the skin.

18. A measuring device as defined in Claim 17, wherein at least one end of the lancet-integrated sensor (10) is projected from the measuring device (11) when attachment of the lancet-integrated sensor (10) to the measuring device (11) is completed.

19. A measuring device as defined in Claim 17 or 18, wherein
the lancet driving means is adapted to drive the lancet (2) of the lancet-integrated sensor (10) so that the needle tip (2a) of the lancet (2) is projected from the sensor (1) only when it lances the skin to collect the bodily fluid and, at all other times, the needle tip (2a) is housed in the sensor (1).

20. A measuring device as defined in Claim 19 being provided with guides (17) for maintaining electrical

connection with an electrode terminal (4) that is placed at an end of the sensor body (1) of the lancet-integrated sensor (10), to measure the characteristics of the collected bodily fluid by an internal electric circuit.

21. A measuring device as defined in any of Claims 17 to 20, wherein the lancet driving means drives the lancet (2) when it is engaged with an end of the lancet (2) on the opposite side to the needle tip (2a).

22. A measuring device as defined in Claim 21, wherein the lancet driving means has a spring (18) for applying a force to the lancet (2) in the longitudinal direction of the sensor (1), and the force of the spring (18) is released by a press button (14) that is provided on the measuring device (11) to project the lancet (2).

23. A measuring device as defined in any of Claims 17 to 22, wherein
a lancet-integrated sensor (10) as defined in any of Claims 10 to 13 is detachably attached to the measuring device (11); and
attachment of the lancet-integrated sensor (10) to the measuring device (11) is carried out with the tip (2a) of the lancet (2) being covered with a protection cover (3), the sensor (1) is held by guides (17) of the measuring device (11), and an end of the lancet (2) on the opposite side to the needle tip (2a) is supported by a connector receiver (19).

24. A measuring device as defined in any of Claims 17 to 23, wherein
a lancet-integrated sensor (10) which has been used is adapted to be ejected from the measuring device (11) body without being touched with hands, by operating an operation button (15) that is provided on the measuring device (11) body.

25. A measuring device as defined in any of Claims 17 to 24, wherein the amount of projection of the needle tip (2a) of the lancet (2) from the front end of the sensor (1) is adapted to be displayed on a display means (12) that is provided on the measuring device (11) body.

Patentansprüche

1. Lanzettenintegrierter Sensor (10), der durch Integrieren einer Lanzette (2) zum Aufstechen der Haut einer Person zum Entnehmen ihrer Körperflüssigkeit und eines Sensorkörpers (1) zum Analysieren der entnommenen Körperflüssigkeit gebildet ist, wobei
der Sensorkörper (1) eine Form eines langen und schmalen Streifens aufweist,
die Lanzette (2) derart konfiguriert ist, dass sie entlang der Längsrichtung des Sensorkörpers (1) durch ein externes Antriebsmittel angetrieben wird, wodurch sie die Haut aufsticht,
der Sensorkörper (1) einen Innenraum (1a) aufweist, den die Lanzette (2) durchlaufen kann, und die Lanzette (2) in dem Raum (1a) hält,
der Raum (1a) in dem Sensorkörper (1) dazu geeignet ist, die Lanzette (2) aufzunehmen, und außerdem als Hohlraum (5) zum Sammeln der Körperflüssigkeit dient, und
ein Einlass des Hohlraums (5) zum Sammeln der Körperflüssigkeit an einem Ende des Sensors (1) vorgesehen ist, von dem die Nadelspitze (2a) der Lanzette (2) vorsteht, und ein Reagens, das dazu geeignet ist, mit der gesammelten Körperflüssigkeit zu regieren, in dem Hohlraum (5) vorgesehen ist.

2. Lanzettenintegrierter Sensor nach Anspruch 1, wobei
der Raum (1a) lang und schmal zum Aufnehmen der Lanzette (2) ist.

3. Lanzettenintegrierter Sensor nach einem der Ansprüche 1 bis 2, wobei
der Sensorkörper (1) durch Verbinden von zwei dünnen Platten (6, 7) miteinander erhalten ist, und zumindest eine der zwei Platten (6, 7) einen konkaven Abschnitt (6a) aufweist; und
der Raum (1a) durch den konkaven Abschnitt (6a) der zwei Platten (6, 7), die miteinander verbunden sind, ausgebildet ist.

4. Lanzettenintegrierter Sensor nach einem der Ansprüche 1 bis 3, wobei,
wenn die Lanzette (2) die Haut zum Entnehmen der Körperflüssigkeit aufsticht, die Lanzette (2) zum Vorstehen von der Innenseite des Sensorkörpers (1), in dem die Nadelspitze (2a) aufbewahrt ist, konfiguriert ist.

5. Lanzettenintegrierter Sensor nach einem der Ansprüche 1 bis 4, wobei
der Sensorkörper (1) in dem Hohlraum (5) eine Elektrode (8) zum Ausgeben des Analyseergebnisses der Kennzeichen der Körperflüssigkeit aufweist.

6. Lanzettenintegrierter Sensor nach Anspruch 5, wobei
ein Verbindungsanschluss (4) zur Verbindung mit einer externen Messvorrichtung (11) zum elektrischen Messen der Kennzeichen der Körperflüssigkeit an einem Ende des Sensorkörpers (1) mit dem Hohlraum (5) vorgesehen ist.

7. Lanzettenintegrierter Sensor nach einem der Ansprüche 1 bis 6, wobei
die Lanzette (2) derart konfiguriert ist, dass
ein Ende der Lanzette (2) auf der Seite gegenüber der Nadelspitze (2a) von dem Sensorkörper (1) vor-

steht; und
das vorstehende Ende mit dem Antriebsmittel der externen Messvorrichtung (11) in Eingriff gebracht ist, wodurch die Lanzette (2) zum Durchführen des Hautaufstechvorgangs angetrieben ist.

8. Lanzettenintegrierter Sensor nach Anspruch 7, wobei
ein Verbinder (2b) zur Ineingriffnahme mit dem Antriebsmittel der externen Messvorrichtung (11) an dem Ende der Lanzette (2) auf der gegenüberliegenden Seite zur Nadelspitze (2a) vorgesehen ist; und
der Verbinder (2b) dazu konfiguriert ist, mit dem Antriebsmittel in Eingriff gebracht zu sein, wodurch die Lanzette (2) den Hautaufstechvorgang durchführt.

9. Lanzettenintegrierter Sensor nach Anspruch 8, wobei
der Verbinder (2b) aus einem Harz hergestellt ist und einen Durchmesser aufweist, der größer als der der Lanzette (2) ist.

10. Lanzettenintegrierter Sensor nach einem der Ansprüche 1 bis 9, wobei
eine abnehmbare Schutzabdeckung (3) auf die Nadelspitze (2a) der Lanzette (2) gepasst ist; und
die Schutzabdeckung (3) dazu konfiguriert ist, während des Hautaufstechvorgangs der Lanzette (2) abgenommen zu sein.

11. Lanzettenintegrierter Sensor nach Anspruch 10, wobei
die Schutzabdeckung (3) ein Röhrenteil (3b) zum Aufnehmen der Nadelspitze (2a) darin und ein breites Griffteil (3a) zum Erleichtern des Abnehmens der Schutzabdeckung (3) von der Lanzette (2) aufweist, wobei das Griffteil (3a) auf der Nadelspitzenseite des Röhrenteils (3b) vorgesehen ist.

12. Lanzettenintegrierter Sensor nach Anspruch 10, wobei
der lanzettenintegrierte Sensor (10) derart konfiguriert ist, dass die Ineingriffnahme der Lanzette (2) und des Antriebsmittels und die Anbringung des Sensorkörpers (1), der mit der Lanzette (2) integriert ist, an der Messvorrichtung (11) durch Halten des Griffteils (3a) der Schutzabdeckung (3) durchgeführt werden.

13. Lanzettenintegrierter Sensor nach Anspruch 10, wobei
ein halbkreisförmiger Raum, in dem das vordere Ende des Sensorkörpers (1) aufgenommen sein kann, in dem Griffteil (3a) ausgebildet ist.

14. Lanzettenintegrierter Sensor nach einem der Ansprüche 1 bis 13, versehen mit einem Halter, der den Umfang des integrierten Sensorkörpers (1) und der Lanzette (2) abdeckt, um sie zu halten.

15. Lanzettenintegrierter Sensor nach Anspruch 14, wobei der Halter aus transparentem Material hergestellt ist.

16. Lanzettenintegrierter Sensor nach einem der Ansprüche 1 bis 15 von einer Einwegart, die zum Wegwerfen nach dem Durchführen von einmaliger Sammlung und Analyse der Körperflüssigkeit konfiguriert ist.

17. Messvorrichtung (11), umfassend einen abnehmbar angebrachten lanzettenintegrierter Sensor (10) nach einem der Ansprüche 1 bis 16 zum Messen der Kennzeichen der Körperflüssigkeit, die von dem lanzettenintegrierten Sensor (10) gesammelt ist, die Messvorrichtung (11) enthaltend:

ein Lanzettenantriebsmittel zum Antreiben der Lanzette (2) zum Aufstechen der Haut nach dem Anbringen des lanzettenintegrierten Sensors (10) an der Messvorrichtung (11).

18. Messvorrichtung nach Anspruch 17, wobei
zumindest ein Ende des lanzettenintegrierten Sensors (10) von der Messvorrichtung (11) vorsteht, wenn die Anbringung des lanzettenintegrierten Sensors (10) an der Messvorrichtung (11) abgeschlossen ist.

19. Messvorrichtung nach einem der Ansprüche 17 oder 18, wobei
das Lanzettenantriebsmittel dazu geeignet ist, die Lanzette (2) des lanzettenintegrierten Sensors (10) derart anzutreiben, dass die Nadelspitze (2a) der Lanzette (2) nur dann von dem Sensor (1) vorsteht, wenn sie die Haut zum Sammeln der Körperflüssigkeit aufsticht, und die Nadelspitze (2a) ansonsten in dem Sensor (1) aufgenommen ist.

20. Messvorrichtung nach Anspruch 19, versehen mit Führungen (17) zum Erhalten von elektrischer Verbindung mit einem Elektrodenanschluss (4), der an einem Ende des Sensorkörpers (1) des lanzettenintegrierten Sensors (10) angeordnet ist, zum Messen der Kennzeichen der gesammelten Körperflüssigkeit durch einen internen Stromkreis.

21. Messvorrichtung nach einem der Ansprüche 17 bis 20, wobei
das Lanzettenantriebsmittel die Lanzette (2) antreibt, wenn es mit einem Ende der Lanzette (2) auf der gegenüberliegenden Seite zur Nadelspitze (2a) in Eingriff steht.

22. Messvorrichtung nach Anspruch 21, wobei
das Lanzettenantriebsmittel eine Feder (18) zum

Ausüben einer Kraft auf die Lanzette (2) in der Längsrichtung des Sensors (1) aufweist und die Kraft der Feder (18) durch einen Druckknopf (14) ausgelöst wird, der an der Messvorrichtung (11) zum Vorstehenlassen der Lanzette (2) vorgesehen ist.

23. Messvorrichtung nach einem der Ansprüche 17 bis 22, wobei
ein lanzettenintegrierter Sensor (10) nach einem der Ansprüche 10 bis 13 abnehmbar an der Messvorrichtung (11) angebracht ist; und
die Anbringung des lanzettenintegrierten Sensors (10) an der Messvorrichtung (11) mit der mit einer Schutzabdeckung (3) abgedeckten Spitze (2a) der Lanzette (2) durchgeführt wird, der Sensor (1) durch Führungen (17) der Messvorrichtung (11) gehalten ist und ein Ende der Lanzette (2) auf der gegenüberliegenden Seite zur Nadelspitze (2a) durch einen Verbinderaufnehmer (19) gestützt ist.

24. Messvorrichtung nach einem der Ansprüche 17 bis 23, wobei
ein lanzettenintegrierter Sensor (10), der benutzt wurde, dazu geeignet ist, durch Betätigen eines Betätigungsknopfs (15), der an der Messvorrichtung (11) vorgesehen ist, aus der Messvorrichtung (11) ausgestoßen zu werden, ohne mit den Händen berührt zu werden.

25. Messvorrichtung nach einem der Ansprüche 17 bis 24, wobei
wobei die Vorstandsmenge der Nadelspitze (2a) der Lanzette (2) vom vorderen Ende des Sensors (1) dazu geeignet ist, auf einem Anzeigemittel (12) angezeigt zu sein, das am Körper der Messvorrichtung (11) vorgesehen ist.

Revendications

1. Capteur à lancette intégrée (10) qui est constitué par l'intégration d'une lancette (2) destinée à piquer la peau d'un sujet pour extraire son fluide corporel, et un corps de capteur (1) pour analyser le fluide corporel extrait, où
le corps de capteur (1) a la forme d'une bande longue et étroite,
la lancette (2) est configurée pour être entraînée le long de la direction longitudinale du corps de capteur (1) par un moyen d'entraînement externe, ce qui permet ainsi de piquer la peau,
le corps de capteur (1) possède un espace interne (1a) à travers lequel la lancette (2) peut passer, et maintient la lancette (2) dans l'espace (1a),
l'espace (1a) dans le corps de capteur (1) est adapté pour recevoir la lancette (2) et sert également de cavité (5) pour collecter le liquide corporel ; et
une entrée de la cavité (5) destinée à collecter le fluide corporel est prévue au niveau d'une extrémité du capteur (1) à partir de laquelle la pointe d'aiguille (2a) de la lancette (2) est projetée, et un réactif adapté pour réagir avec le fluide corporel collecté est prévu dans la cavité (5).

2. Capteur à lancette intégrée tel que défini dans la revendication 1, dans lequel
l'espace (1a) est long et étroit pour recevoir la lancette (2).

3. Capteur à lancette intégrée tel que défini dans l'une des revendications 1 à 2, dans lequel
le corps de capteur (1) est obtenu par collage de deux plaques minces (6, 7) ensemble, et au moins l'une des deux plaques (6, 7) présente une partie concave (6a) ; et
l'espace (1a) est formé par la partie concave (6a) des deux plaques (6, 7) collées l'une à l'autre.

4. Capteur à lancette intégrée tel que défini dans l'une des revendications 1 à 3, dans lequel
lorsque la lancette (2) pique la peau pour extraire le fluide corporel, la lancette (2) est configurée pour se projeter depuis l'intérieur du corps de capteur (1) dans lequel sa pointe d'aiguille (2a) est stockée.

5. Capteur à lancette intégrée tel défini dans l'une des revendications 1 à 4, dans lequel
le corps de capteur (1) comporte, dans la cavité (5), une électrode (8) destinée à délivrer en sortie le résultat de l'analyse des caractéristiques du fluide corporel.

6. Capteur à lancette intégrée tel que défini dans la revendication 5, dans lequel
une borne de connexion (4) destinée à être connectée à un dispositif de mesure externe (11) pour mesurer électriquement les caractéristiques du fluide corporel est prévue au niveau d'une extrémité du corps de capteur (1) ayant la cavité (5).

7. Capteur à lancette intégrée tel que défini dans l'une des revendications 1 à 6, dans lequel
la lancette (2) est configurée de sorte que
une extrémité de la lancette (2) sur le côté opposé à la pointe d'aiguille (2a) se projette depuis le corps de capteur (1) ; et
l'extrémité projetée soit engagée avec le moyen d'entraînement du dispositif de mesure externe (11), moyennant quoi la lancette (2) est entraînée pour effectuer l'opération de piqûre de la peau.

8. Capteur à lancette intégrée tel que défini dans la revendication 7, dans lequel
un connecteur (2b) devant être engagé avec le moyen d'entraînement du dispositif de mesure externe (11) est prévu au niveau de l'extrémité de la

lancette (2) sur le côté opposé à la pointe d'aiguille (2a) ; et
le connecteur (2b) est configuré pour être engagé avec le moyen d'entraînement, moyennant quoi la lancette (2) effectue l'opération de piqûre de la peau.

9. Capteur à lancette intégrée tel que défini dans la revendication 8, dans lequel
le connecteur (2b) est réalisé en une résine, et a un diamètre plus grand que celui de la lancette (2).

10. Capteur à lancette intégrée tel que défini dans l'une des revendications 1 à 9, dans lequel
un couvercle de protection amovible (3) est ajusté à la pointe d'aiguille (2a) de la lancette (2) ; et
le couvercle de protection (3) est configuré pour être retiré lors de l'opération de piqûre de la peau de la lancette (2).

11. Capteur à lancette intégrée tel que défini dans la revendication 10, dans lequel
le couvercle de protection (3) comporte une partie de tube (3b) pour y recevoir la pointe de l'aiguille (2a), et une partie de préhension large (3a) pour faciliter le retrait du couvercle de protection (3) de la lancette (2), laquelle partie de préhension (3a) est prévue sur le côté pointe d'aiguille de la partie de tube (3b).

12. Capteur à lancette intégrée tel que défini dans la revendication 10, dans lequel
ledit capteur à lancette intégrée (10) étant configuré de sorte que l'engagement de la lancette (2) et du moyen d'entraînement et la fixation du corps de capteur (1) intégré à la lancette (2) au dispositif de mesure (11) soient effectués avec maintien de la partie de préhension (3a) du couvercle de protection (3).

13. Capteur à lancette intégrée tel que défini dans la revendication 10, dans lequel
un espace semi-circulaire, dans lequel l'extrémité avant du corps de capteur (1) peut être reçue, est formé dans la partie de préhension (3a).

14. Capteur à lancette intégrée tel que défini dans l'une des revendications 1 à 13 étant pourvu d'un support qui couvre la périphérie du corps de capteur intégré (1) et de la lancette (2) afin de les maintenir.

15. Capteur à lancette intégrée tel que défini dans la revendication 14, dans lequel le support est réalisé en un matériau transparent.

16. Capteur à lancette intégrée tel que défini dans l'une des revendications 1 à 15 étant du type jetable, qui est adapté pour être jeté après la réalisation de la collecte et de l'analyse du sang corporel une fois.

17. Dispositif de mesure (11) comprenant un capteur à lancette intégrée (10) tel que défini dans les revendications 1 à 16 fixé de manière amovible, pour mesurer les caractéristiques du fluide corporel collecté par le capteur à lancette intégrée (10), ledit dispositif de mesure (11) comportant :

un moyen d'entraînement de lancette destiné à entraîner la lancette (2) de manière à piquer la peau, après que le capteur à lancette intégrée (10) est fixé au dispositif de mesure (11).

18. Dispositif de mesure tel que défini dans la revendication 17, dans lequel
au moins une extrémité du capteur à lancette intégrée (10) est projetée à partir du dispositif de mesure (11) lorsque la fixation du capteur à lancette intégrée (10) au dispositif de mesure (11) est achevée.

19. Dispositif de mesure tel que défini dans la revendication 17 ou 18, dans lequel
le moyen d'entraînement de lancette est adapté pour entraîner la lancette (2) du capteur à lancette intégrée (10) de sorte que la pointe d'aiguille (2a) de la lancette (2) ne soit projetée à partir du capteur (1) que lorsqu'elle pique la peau pour collecter le fluide corporel et, à tout autre moment, la pointe d'aiguille (2a) est reçue dans le capteur (1).

20. Dispositif de mesure tel que défini dans la revendication 19 étant pourvu de guides (17) permettant de maintenir une connexion électrique avec une borne d'électrode (4) qui est placée au niveau d'une extrémité du corps de capteur (1) du capteur à lancette intégrée (10), afin de mesurer les caractéristiques du fluide corporel collecté par un circuit électrique interne.

21. Dispositif de mesure tel que défini dans l'une des revendications 17 à 20, dans lequel
le moyen d'entraînement de lancette entraîne la lancette (2) lorsqu'il est engagé avec une extrémité de la lancette (2) sur le côté opposé à la pointe d'aiguille (2a).

22. Dispositif de mesure tel que défini dans la revendication 21, dans lequel
le moyen d'entraînement de lancette comporte un ressort (18) destiné à appliquer une force à la lancette (2) dans la direction longitudinale du capteur (1), et la force du ressort (18) est libérée par un bouton-poussoir (14) qui est prévu sur le dispositif de mesure (11) pour projeter la lancette (2).

23. Dispositif de mesure tel que défini dans l'une des revendications 17 à 22, dans lequel
un capteur à lancette intégrée (10) tel que défini dans l'une des revendications 10 à 13 est fixé de manière

amovible au dispositif de mesure (11) ; et
la fixation du capteur à lancette intégrée (10) au dispositif de mesure (11) est effectuée avec la pointe (2a) de la lancette (2) qui est recouverte d'un couvercle de protection (3), le capteur (1) est maintenu par des guides (17) du dispositif de mesure (11), et une extrémité de la lancette (2) sur le côté opposé à la pointe d'aiguille (2a) est supportée par un récepteur de connecteur (19).

24. Dispositif de mesure tel que défini dans l'une des revendications 17 à 23, dans lequel
un capteur à lancette intégrée (10) qui a été utilisé est adapté pour être éjecté à partir du corps de dispositif de mesure (11) sans être touché avec les mains, par l'actionnement d'un bouton d'actionnement (15) qui est prévu sur le corps du dispositif de mesure (11).

25. Dispositif de mesure tel que défini dans l'une des revendications 17 à 24, dans lequel
la quantité de projection de la pointe d'aiguille (2a) de la lancette (2) partir de l'extrémité avant du capteur (1) est adaptée pour être affichée sur un moyen d'affichage (12) qui est prévu sur le corps du dispositif de mesure (11).

Fig.1 (a)

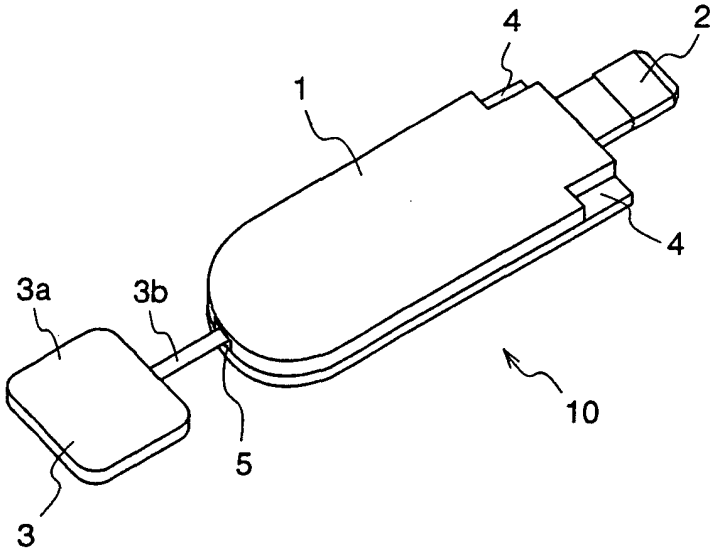


Fig.1 (b)

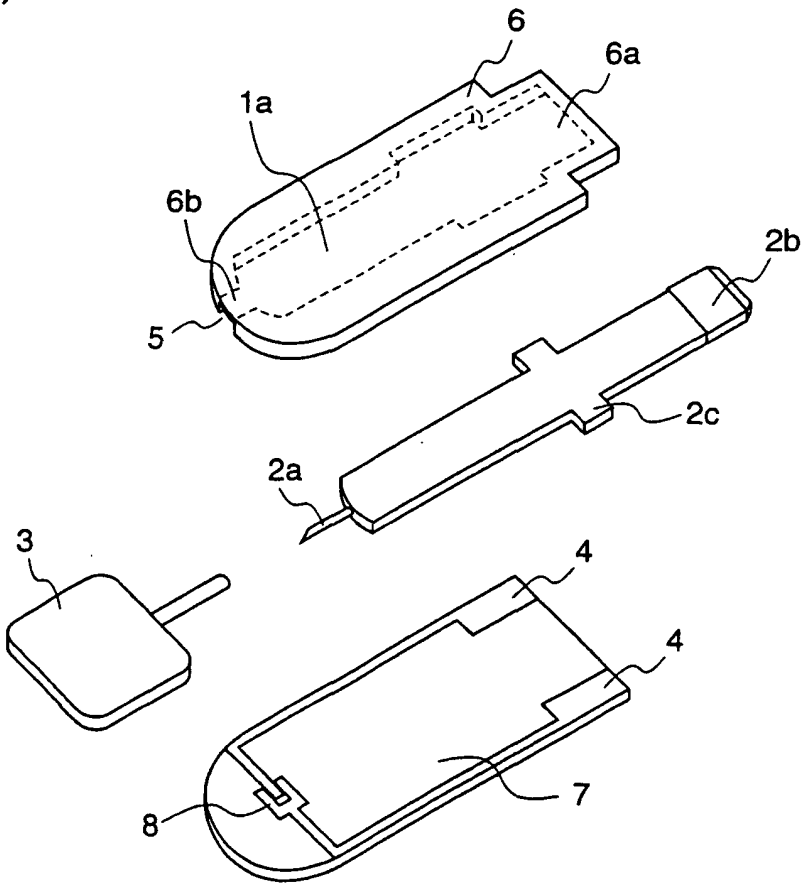


Fig.2 (a)

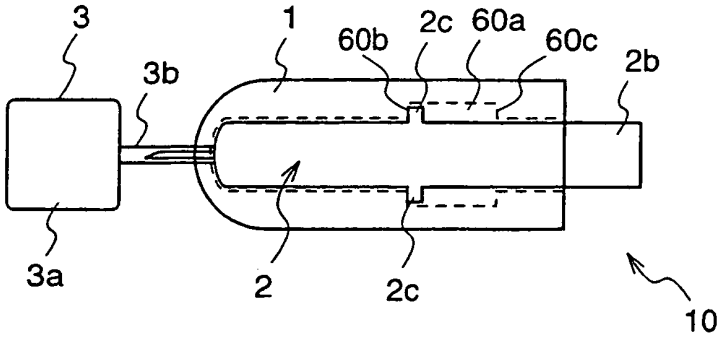


Fig.2 (b)

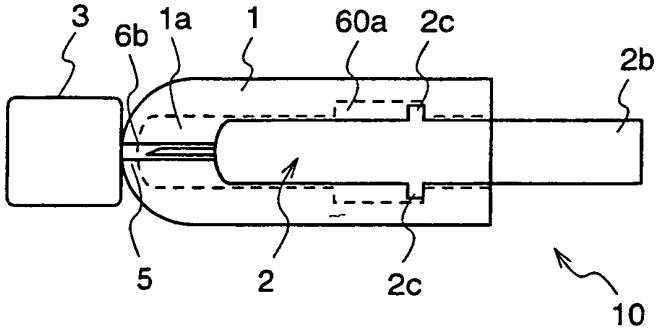


Fig.2 (c)

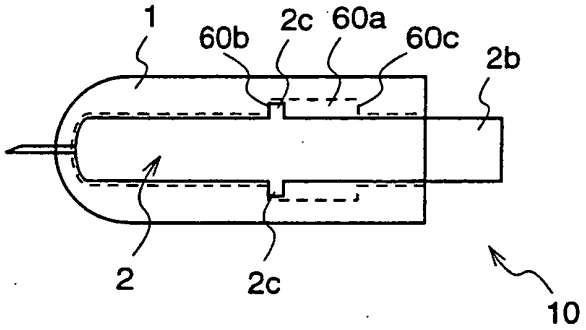


Fig.2 (d)

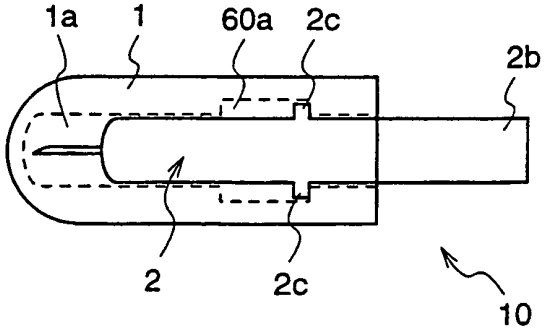


Fig.3 (a)

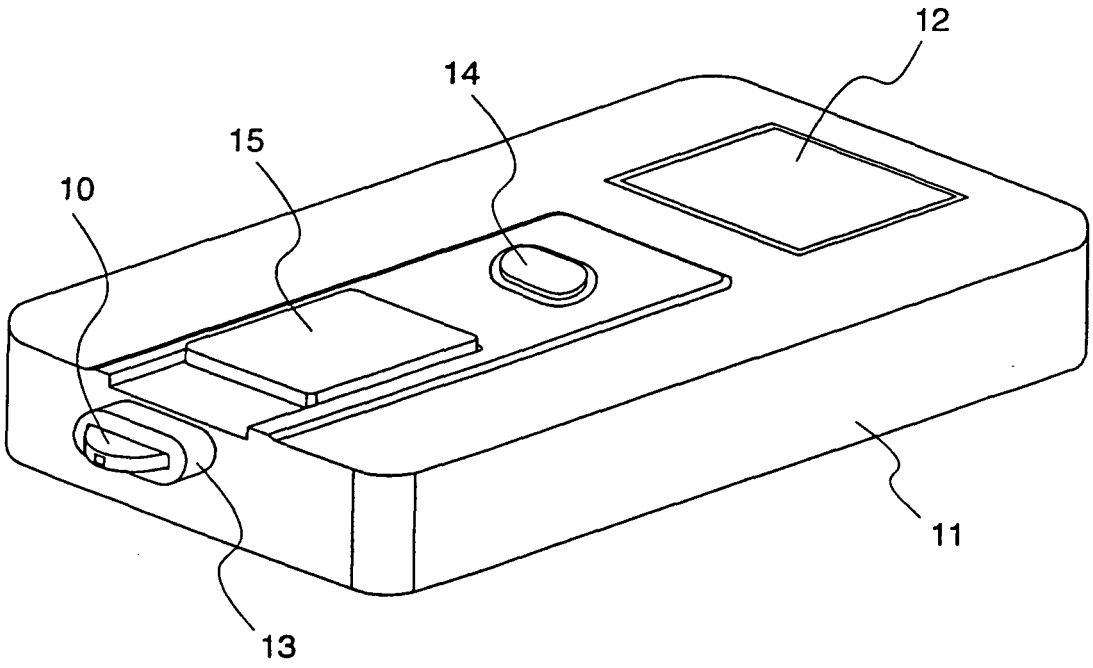


Fig.3 (b)

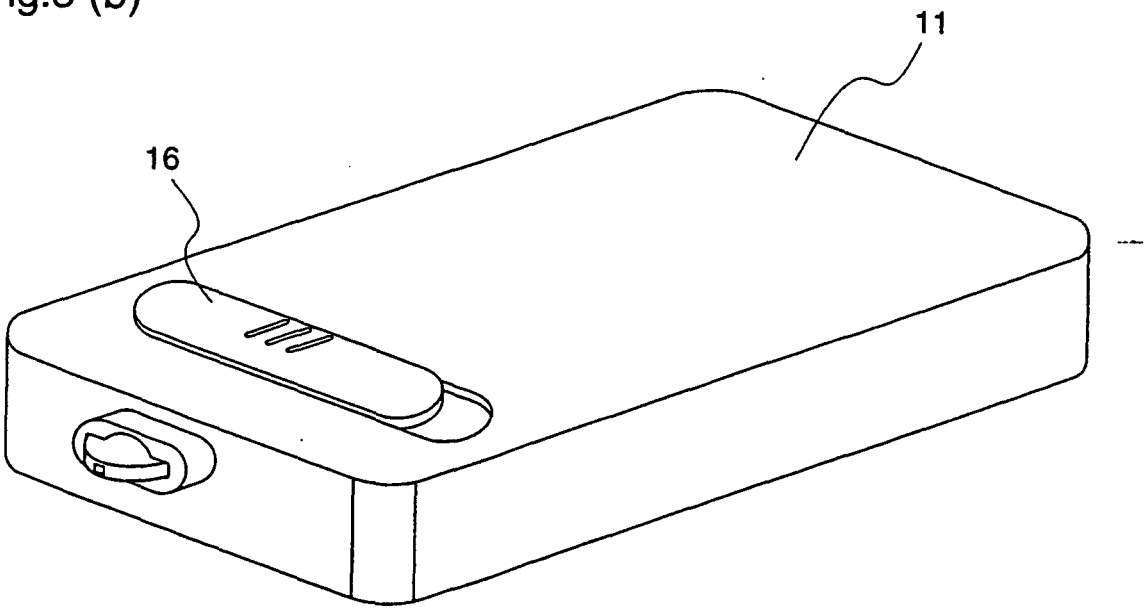


Fig.4 (a)

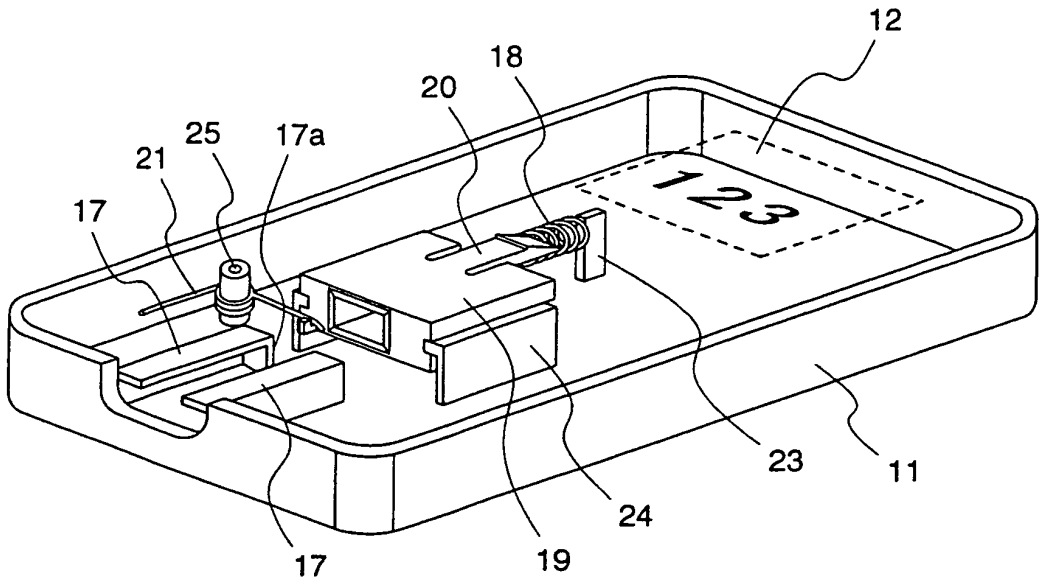

12
18
20
25
17a
21
17
1 2 3
23
11
24
17
19

Fig.4 (b)

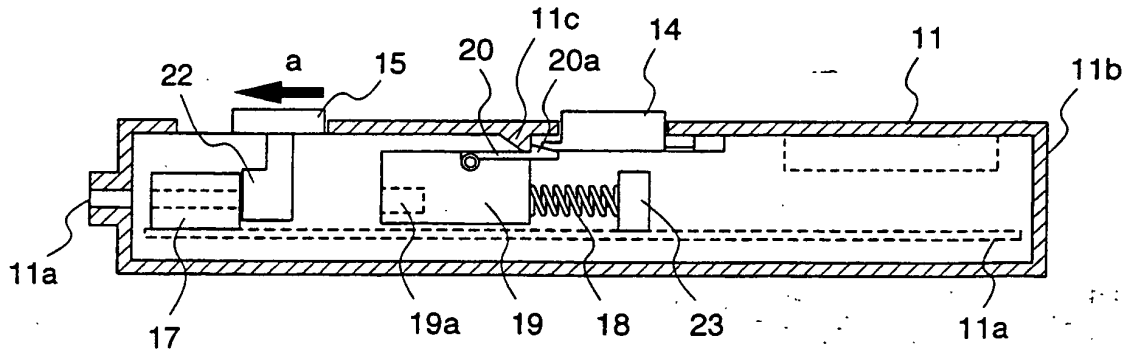

11c
14
11
22
a
15
20
20a
11b
11a
17
19a
19
18
23
11a

Fig.5 (a)

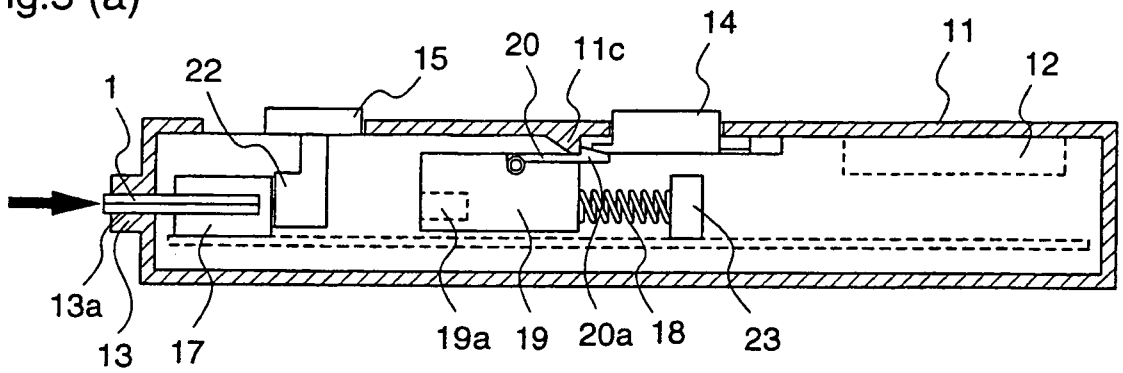


Fig.5 (b)

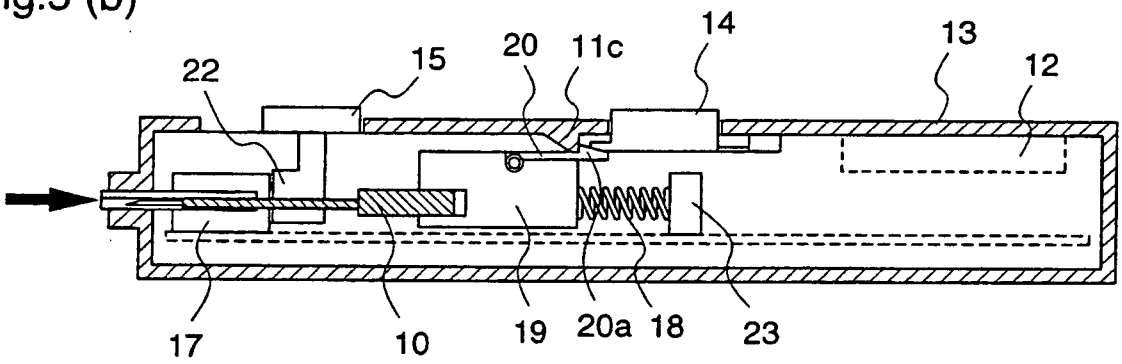


Fig.5 (c)

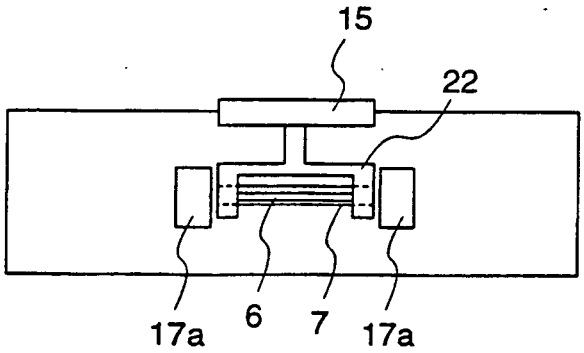


Fig.6 (a)

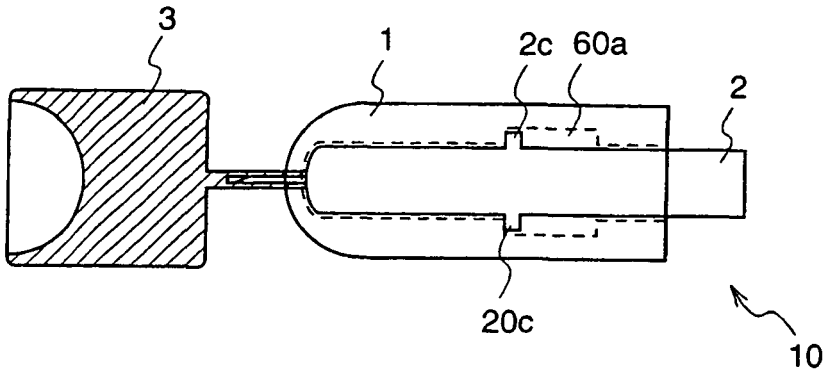


Fig.6 (b)

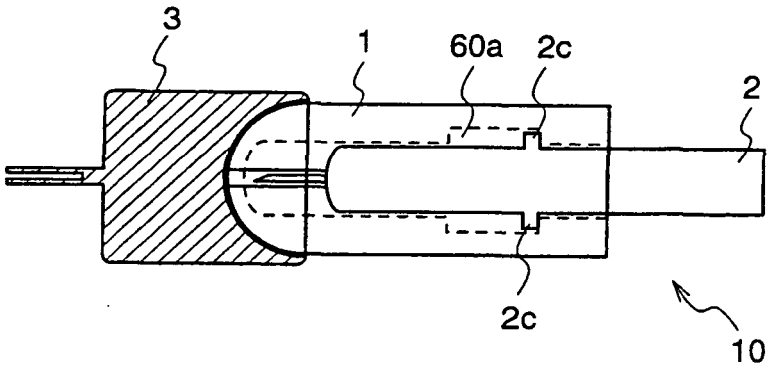


Fig.7

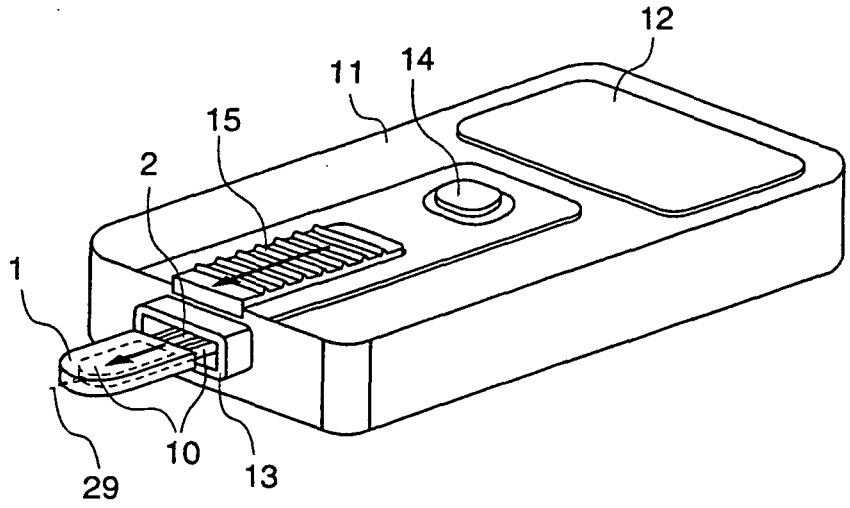
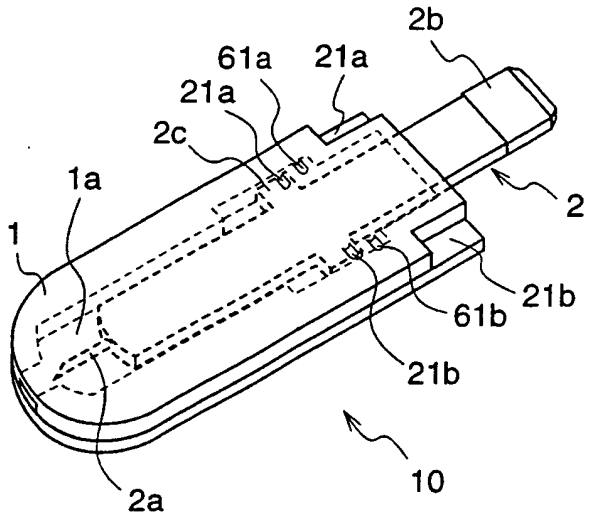


Fig.8 (a)


2b
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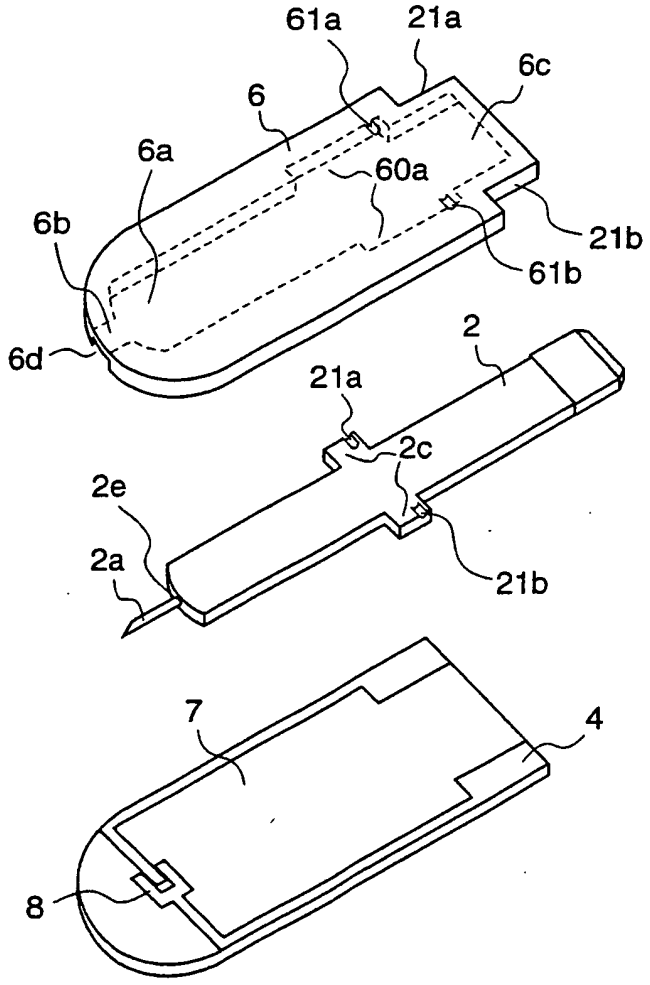
21a
21a
2c
1a
2
1
21b
61b
21b
10
2a

Fig.8 (b)


61a
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6c
6
6a
60a
6b
21b
61b
2
6d
21a
2c
2e
2a
21b
7
4
8

Fig.9 (a)

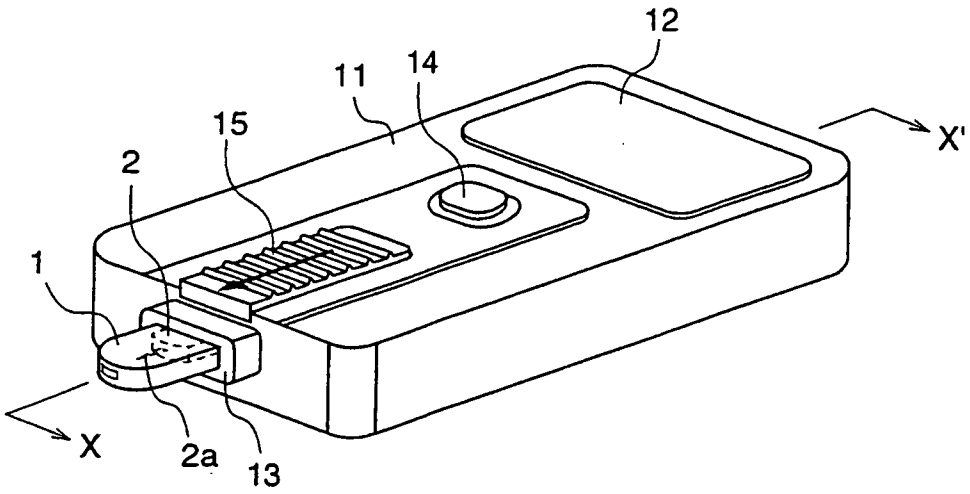


Fig.9 (b)

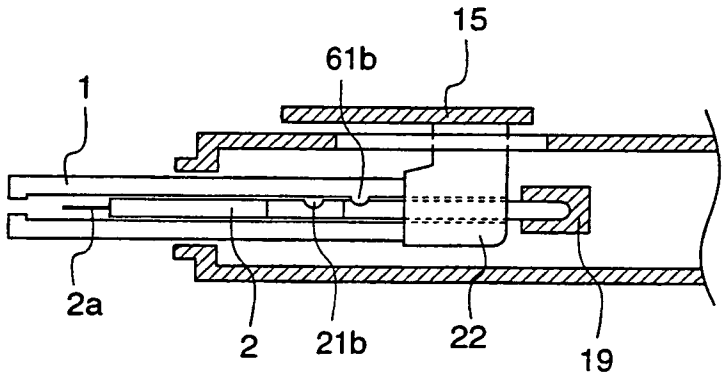


Fig.10

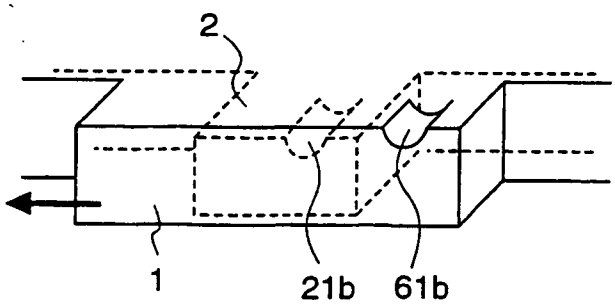


Fig.11 (a)

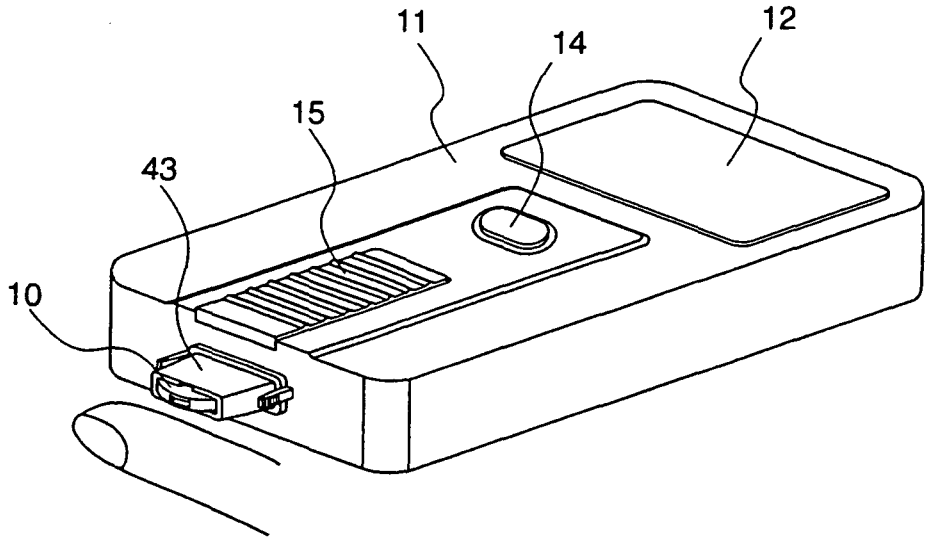


Fig.11 (b)

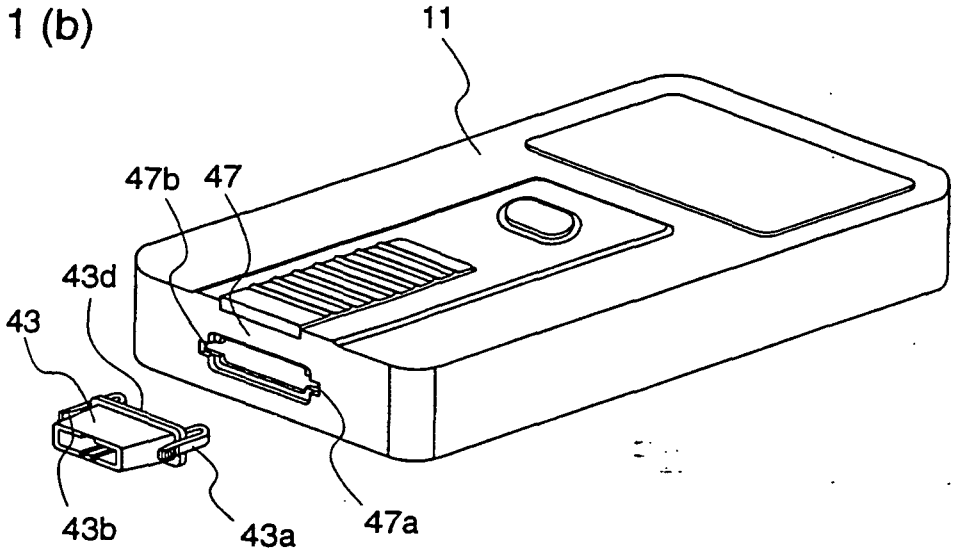


Fig.12 (a)

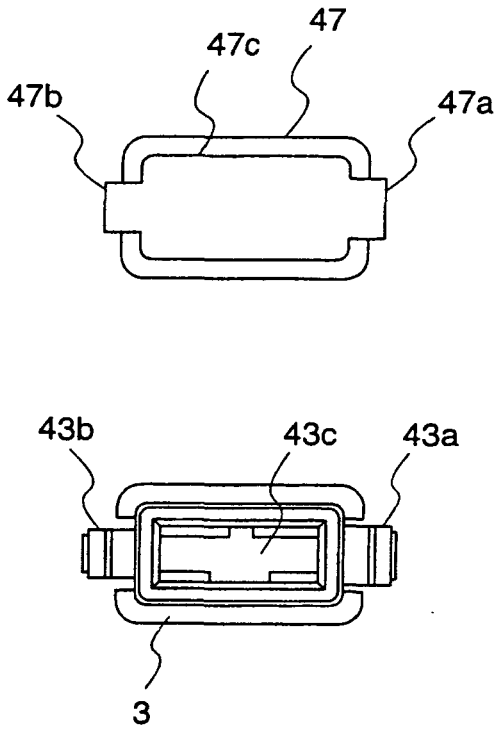


Fig.12 (b)

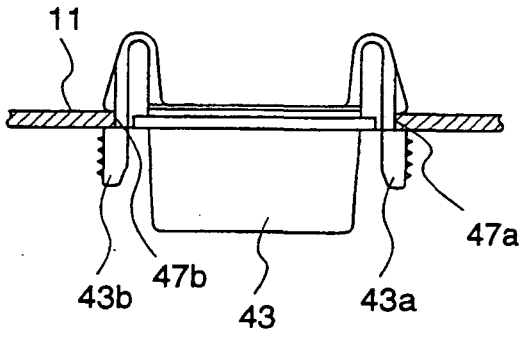


Fig.12 (c)

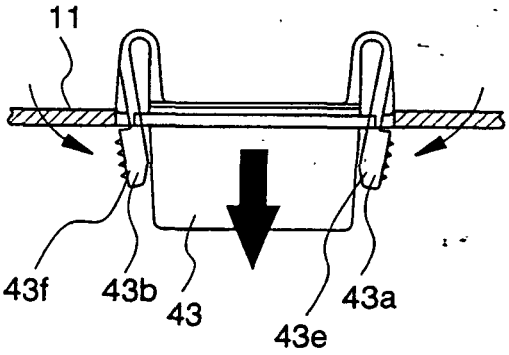


Fig.13 (a)

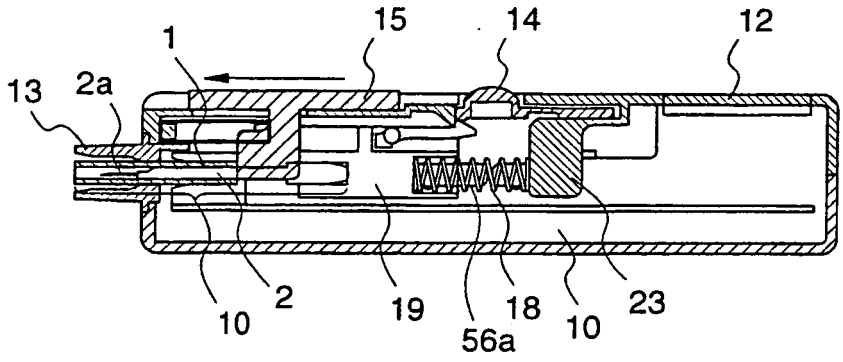


Fig.13 (b)

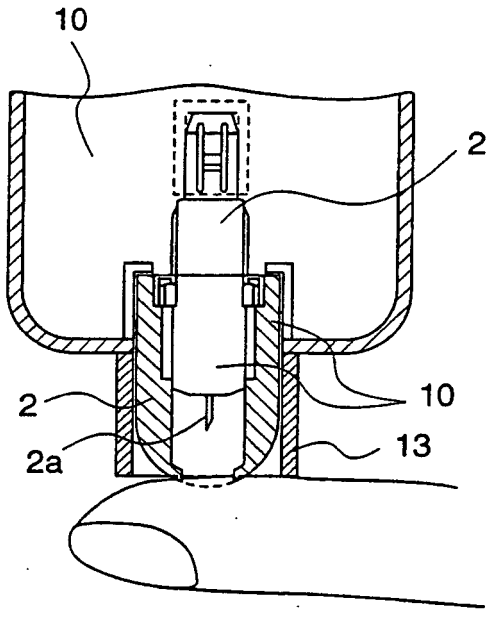
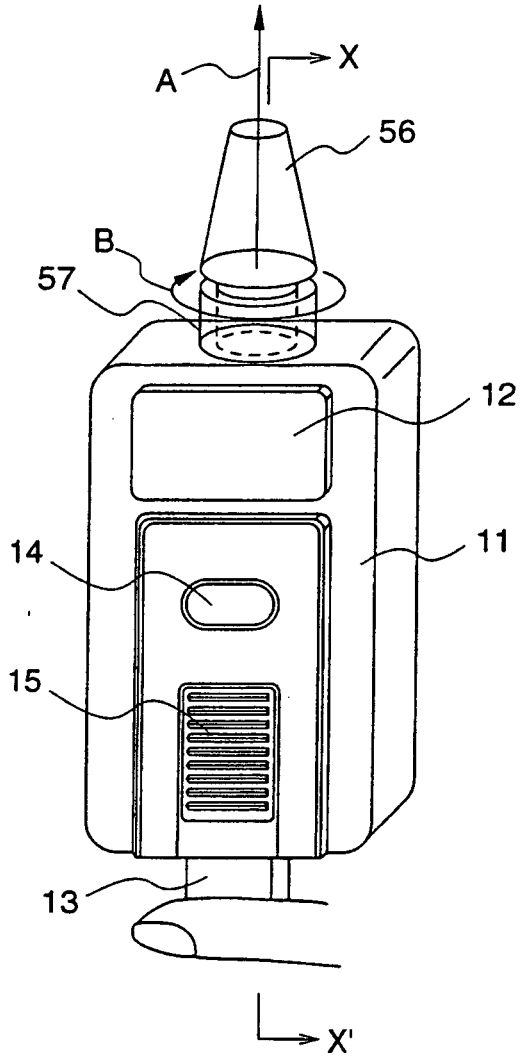


Fig.14


A
X
56
B
57
12
11
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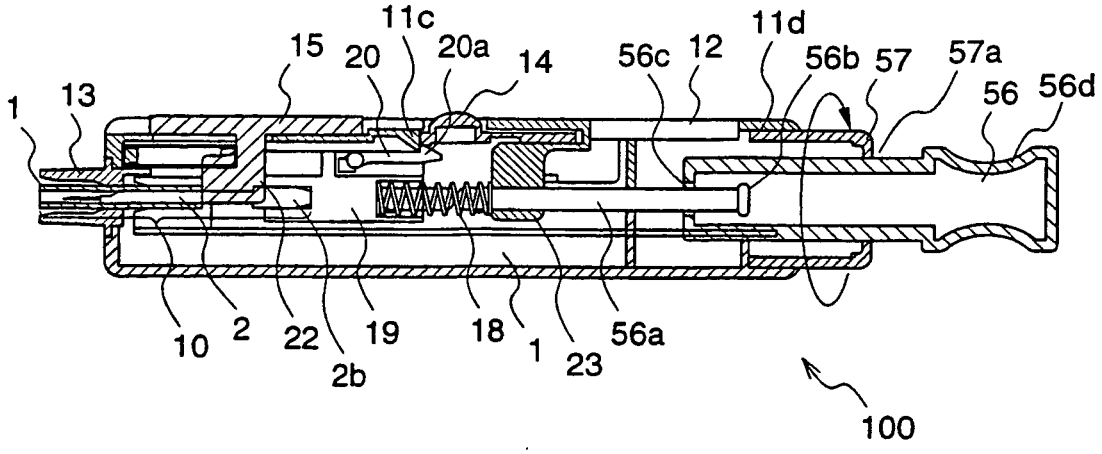
15
13
X'

Fig.15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56a
100

Fig.16

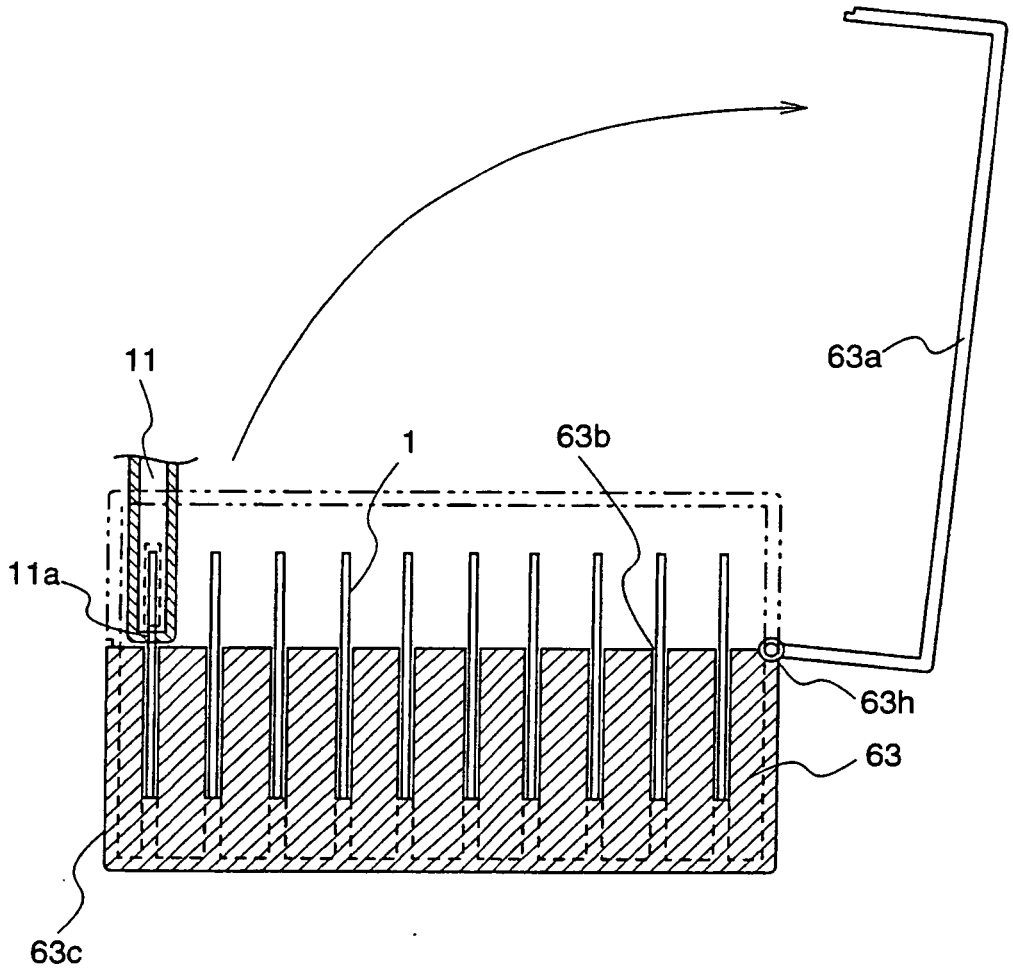


Fig.17 (a)

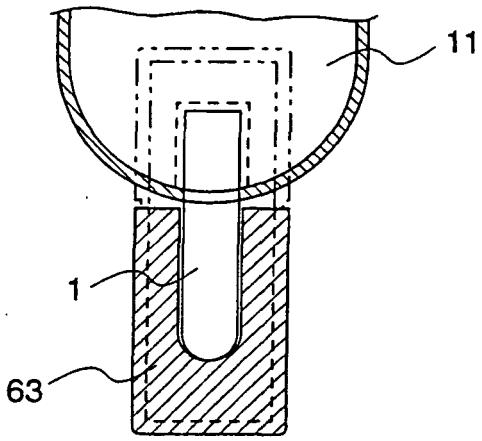


Fig.17 (b)

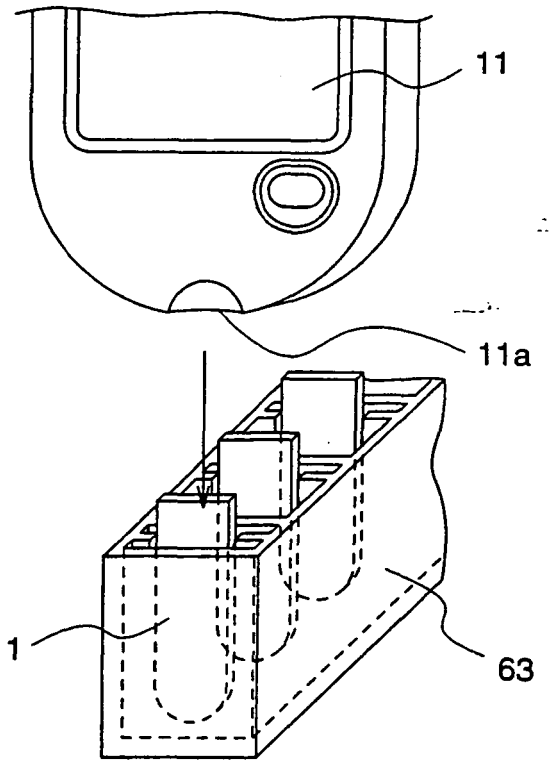


Fig.18 (a)

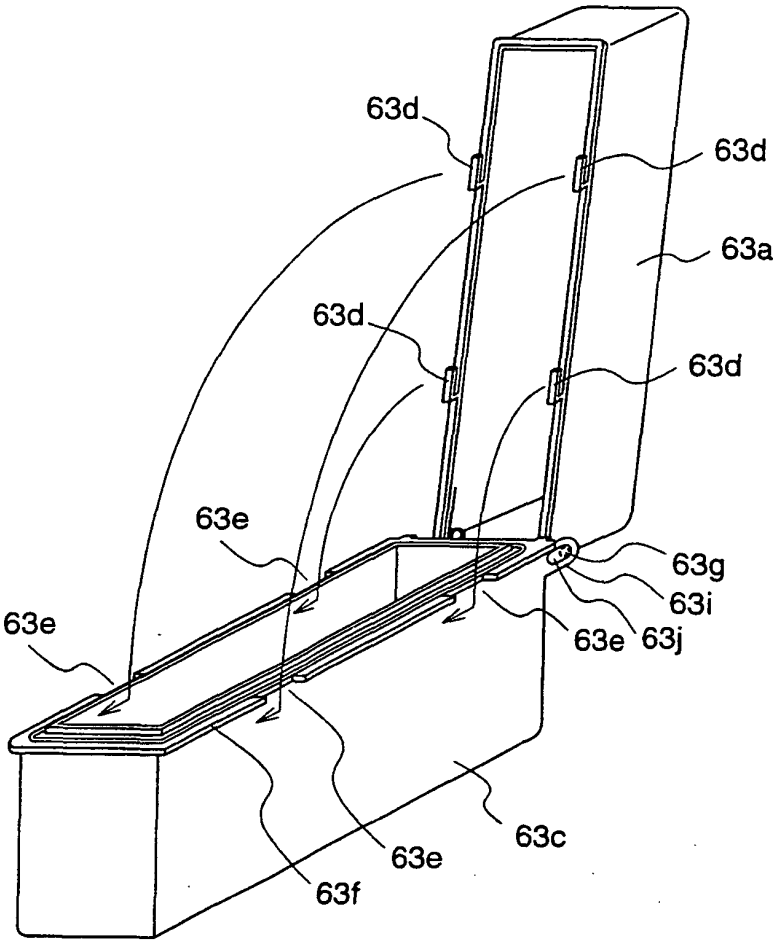


Fig.18 (b)

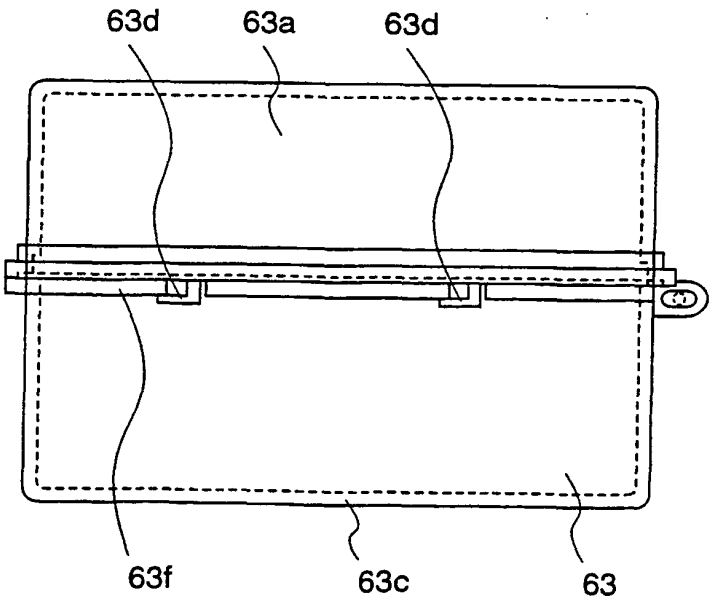


Fig.18 (c)

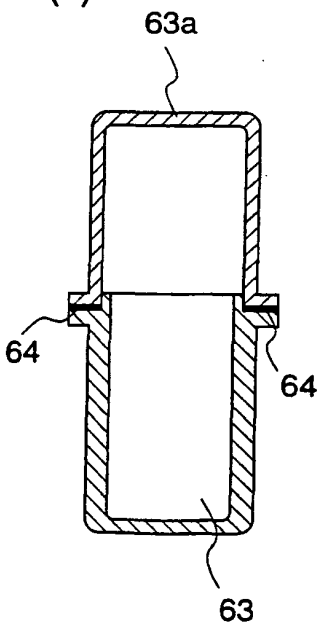


Fig.19

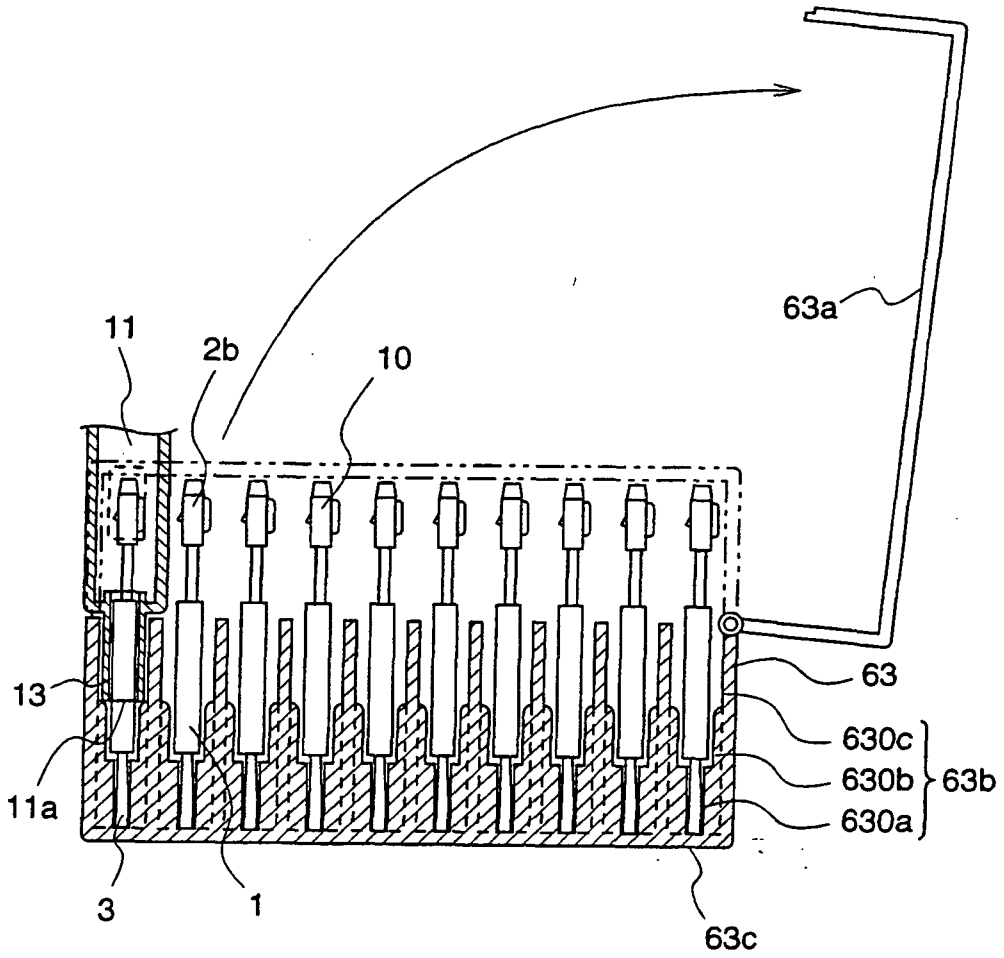


Fig.20 (a)

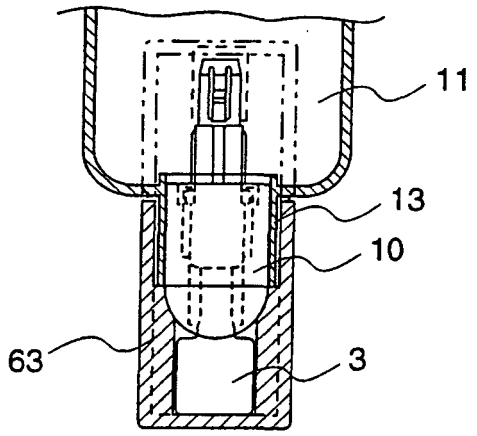


Fig.20 (b)

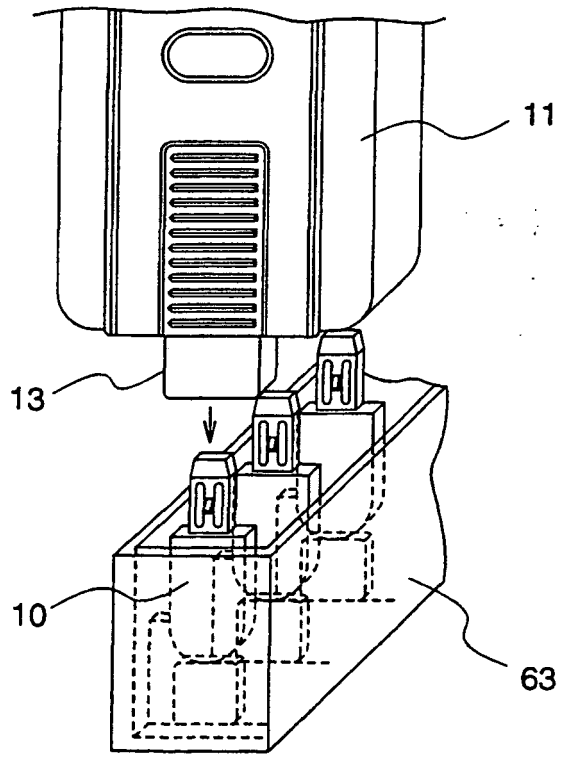


Fig.21

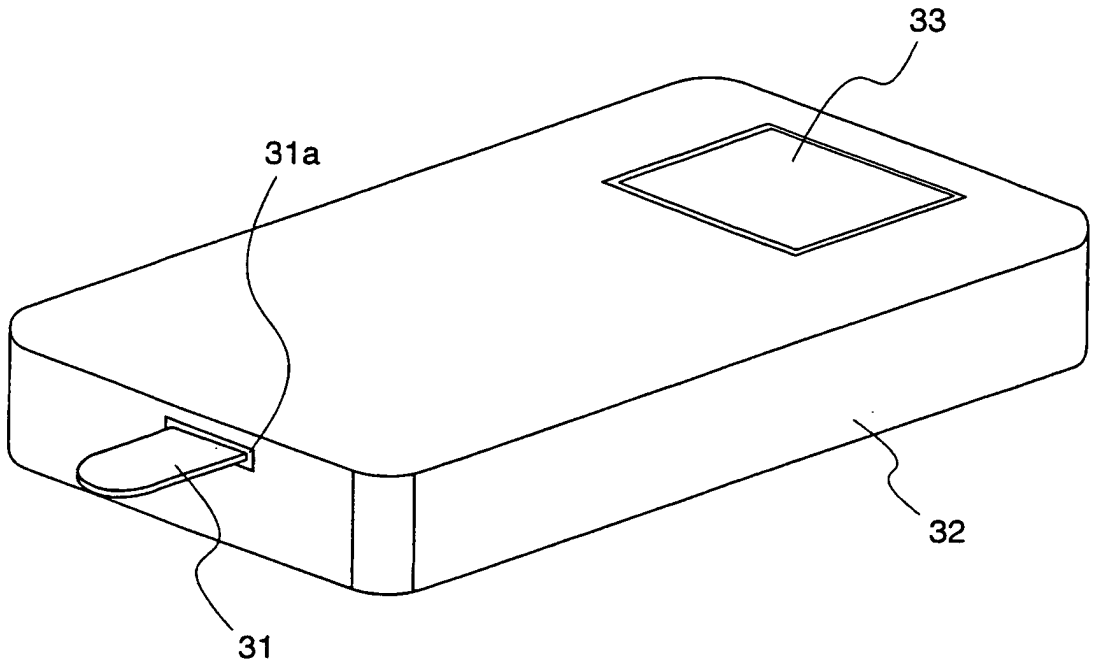


Fig.22 (a)

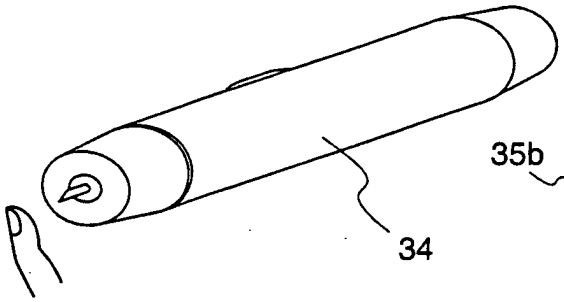


Fig.22 (b)

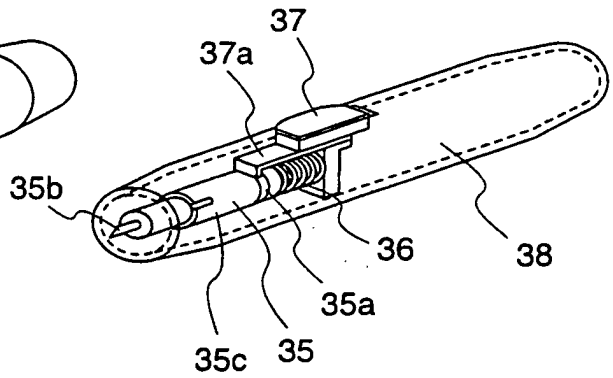


Fig.23 (a)

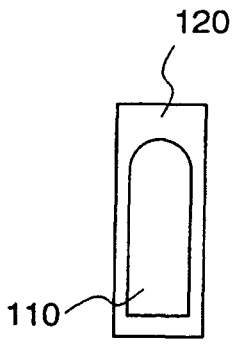


Fig.23 (b)

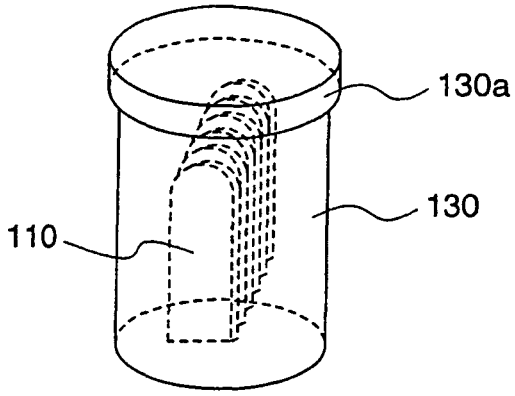
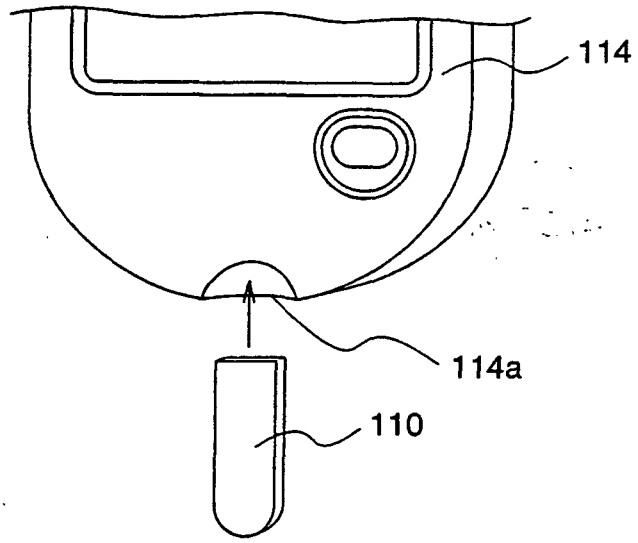


Fig.24



REFERENCES CITED IN THE DESCRIPTION

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Patent documents cited in the description

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- US 6071294 A **[0005]**
- JP 2000185034 A **[0006]**
- US 4637403 A **[0007]**
- JP 9294737 A **[0008]**

专利名称(译)	柳叶刀集成传感器和测量仪，用于柳叶刀集成传感器		
公开(公告)号	EP1285629B1	公开(公告)日	2013-05-22
申请号	EP2002710317	申请日	2002-01-21
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当前申请(专利权)人(译)	松下电器产业株式会社		
[标]发明人	KOJIMA SHINICHI TOKUNO YOSHINOBU		
发明人	KOJIMA, SHINICHI TOKUNO, YOSHINOBU		
IPC分类号	A61B5/145 A61B5/151 A61B5/00 A61B5/15		
CPC分类号	A61B5/0006 A61B5/14532 A61B5/150022 A61B5/150259 A61B5/150412 A61B5/150519 A61B5/150564 A61B5/150717 A61B5/150725 A61B5/15113 A61B5/15117 A61B5/1513 A61B5/1519 A61B5/15194 A61B5/157 A61B2562/0295		
优先权	2001011275 2001-01-19 JP		
其他公开文献	EP1285629A1 EP1285629A4		
外部链接	Espacenet		

摘要(译)

传感器和刺血针彼此集成以便于其更换和管理，并且进一步提高了其便携性。也就是说，薄带状传感器（1）和刺血针（2）一体化，使得刺血针（2）沿着传感器（1）的纵向平行移动。另一方面，安装有集成式刺血针和传感器10的测量装置具有驱动所安装的刺血针的功能。

Fig.1 (a)

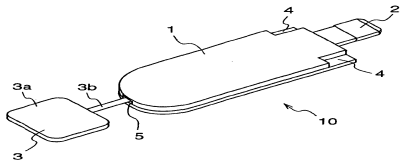

Fig.1 (b)