

(12) STANDARD PATENT
(19) AUSTRALIAN PATENT OFFICE

(11) Application No. AU 2011229159 C1

(54) Title
Diagnostic system

(51) International Patent Classification(s)
A61B 5/151 (2006.01) **A61J 1/05** (2006.01)

(21) Application No: **2011229159** (22) Date of Filing: **2011.03.18**

(87) WIPO No: **WO11/113114**

(30) Priority Data

(31) Number
2010901175 (32) Date
2010.03.19 (33) Country
AU

(43) Publication Date: **2011.09.22**
(44) Accepted Journal Date: **2012.12.13**
(44) Amended Journal Date: **2018.01.04**

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(56) Related Art
US 5 249584 A
US 5714390 A
WO 1988/000812 A1
WO 2004/078232 A2
US 6264619 B1
US 2003/0013121 A1
WO 2008/085052 A2
WO 2002/078533 A2
US 4637403 A

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau(43) International Publication Date
22 September 2011 (22.09.2011)(10) International Publication Number
WO 2011/113114 A1(51) International Patent Classification:
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(21) International Application Number:

PCT/AU2011/000315

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(22) International Filing Date:

18 March 2011 (18.03.2011)

(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PE, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

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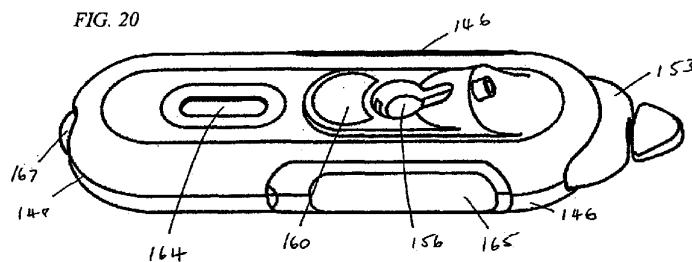
(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— with international search report (Art. 21(3))

(54) Title: DIAGNOSTIC SYSTEM

FIG. 20



(57) Abstract: A composite diagnostic system comprising a support member having a membrane penetration element; a bodily fluid collection point positioned for collection of a bodily fluid released by application of the membrane penetration element to a user's body; a test material positioned in the support member such that in use the bodily fluid is brought into contact with the test material.

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DIAGNOSTIC SYSTEM

Technical Field

The present disclosure broadly relates to an integrated system for diagnostics in humans and animals.

Background of the Disclosure

Systems for performing relatively immediate tests, assays or diagnoses with relative ease are known. However, personally performing these relatively immediate tests, assays or diagnoses can require complicated instruction and multiple devices.

Summary of the Disclosure

Disclosed is a composite diagnostic system comprising a support member having: a membrane penetration element; a test component positioned within the support member; a bodily fluid collection point comprising a capillary tube positioned on the support member for collection of a bodily fluid released by application of the membrane penetration element to a human and adapted in use to take up and conduct the bodily fluid into contact with the test component; an internal reservoir located within the support member and adapted to contain a solution for use with the test component; and a solution delivery actuator wherein in use, actuation of the solution delivery actuator causes the solution to be released from the reservoir and brought into contact with the test component after the bodily fluid has been brought into contact with the test component.

In one form the test material comprises a test strip positioned in the composite diagnostic system. In one form the test material comprises a test cassette positioned in the composite diagnostic system. In one form the test material comprises a cartridge. In one form the test material comprises an integrated circuit positioned within the diagnostic system. In one form the test material comprises a reagent tube. In one form the test material is removably positioned within the diagnostic system.

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In one form the membrane penetration element comprises a lancet or lancing system comprising a lancet tip, the lancet being moveable between a rest position in which the lancet tip is situated within the support member and an actuated position in which the lancet tip extends beyond the support member.

In one form the system further comprises a lancet activator, wherein the lancet is moveable between the rest position and the actuated position by actuation of the lancet activator.

In one form the lancet is removably connected with the support member. In one form the lancet is incorporated into the support member.

In one form the lancet activator is connected with the support member.

In one form the system further comprises a reservoir adapted to contain a physiologically acceptable solution, the reservoir being adapted such that in use the physiologically acceptable solution is brought into contact with the test material along with the bodily fluid.

In one form the reservoir is incorporated into the support member.

In one form the support member further comprises a solution delivery actuator, actuation of the solution delivery actuator causing the physiologically acceptable solution to be delivered to the test material.

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In one form the physiologically acceptable solution is a buffer.

In one form the system further comprises a swab locator or feature in the support member adapted for associating an alcohol swab with the system. In one form the swab locator comprises indicia; in one form the swab locator comprises a depression; in one form the swab locator comprises a recessed enclosure or alternative retainer.

In one form the system further comprises a drying pad locator or feature positioned in the support member for associating a drying pad with the system.

In one form the system further comprises an adhesive bandage feature located on a surface or within the support member, adapted for associating an adhesive bandage with the system. In one form the adhesive bandage feature comprises a depression or recessed enclosure to house and retain the bandage.

In one form the system further comprises indicia denoting a method of using the system.

In one form the system is sized to be hand-held. In one form the system is adapted to be held in a single hand. In one form the system is adapted for self testing.

In a second aspect, disclosed is a composite diagnostic system adapted to be handheld and comprising two or more of a membrane penetration element, a bodily fluid collection point positioned for collection of a bodily

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fluid released by application of the membrane penetration element to a user's body and a test material positioned in the support member such that in use the bodily fluid is brought into contact with the test material.

In one form a portion of the body comprising the membrane penetration element and bodily fluid collection point is detachable from a portion of the body comprising the test material.

In a third aspect, disclosed is a composite diagnostic system, further comprising an interface element adapted to allow the system to interface with diagnostic equipment.

In one form the interface element comprises a removable portion of the system adapted to engage with diagnostic equipment.

In one form the removable portion comprises the test material.

In one form the interface element comprises an opening adapted to allow diagnostic equipment to interface with the system.

In one form the opening is positioned such that the test material can interface with the diagnostic equipment through the opening.

Brief Description of the Drawings

Preferred embodiments will now be described by way of example only, with reference to the accompanying drawings in which:

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Figure 1 shows an isometric view of one embodiment of the system;

Figure 2 shows a side view of the embodiment of figure 1;

Figure 3 shows a second side view of the embodiment of figure 1;

Figure 4 shows a third side view of the embodiment of figure 1;

Figure 5 shows a fourth side view of the embodiment of figure 1;

Figure 6 shows an isometric view of a second embodiment of the present system;

Figure 7 shows a top view of the embodiment of figure 6;

Figure 8 shows an isometric view of a third embodiment of the present system;

Figure 9 shows a side view of the embodiment of figure 8;

Figure 10 shows a second side view of the embodiment of figure 8;

Figure 11 shows a third side view of the embodiment of figure 8;

Figure 12 shows a fourth side view of the embodiment of figure 8;

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Figure 13 shows a top view of a fourth embodiment of the present system;

Figure 14 shows a side view of the embodiment of figure 13;

Figure 15 shows a bottom view of the embodiment of figure 13;

Figure 16 shows a top view of a fifth embodiment of the present system;

Figure 17 shows an isometric view of the embodiment of figure 16;

Figure 18 shows an isometric view of the embodiment of figure 16 in a closed position;

Figure 19 shows a top view of a sixth embodiment of the present system;

Figure 20 shows a perspective view of the embodiment of figure 19;

Figure 21 shows a cross sectional view of the embodiment of figure 19;

Figure 22 shows a perspective view of a seventh embodiment of the present system in a first position;

Figure 23 shows a top view of the embodiment of figure 22;

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Figure 24 shows a cross sectional view of the embodiment of figure 22;

Figure 25 shows a perspective view of the embodiment of figure 22 in a second position;

Figure 26 shows a top view of the embodiment of figure 22 in a second position;

Figure 27 shows a perspective view of an eighth embodiment of the present system in a closed position;

Figure 28 shows a perspective view of the embodiment of figure 27 in use;

Figure 29 shows a perspective view of the embodiment of figure 27 in use.

Detailed Description of the Preferred Embodiments

Referring to Figures 1 through 5, disclosed is a composite diagnostic system (10). The diagnostic system (10) comprises a support member (20) which is made up of a body (21) in the form of a housing having six sides. The body (21) comprises top face (22) bottom face (23) and sides (24).

Embodiments described are in a form which is sized to be hand-held by a user. However a person skilled in the art will be aware that the system may be designed for use on a table top or any alternative positioning and orientation and later embodiments are described for use table top use.

The diagnostic system further comprises an integrated lancet (28). The integrated lancet is positioned in one side (24) of the body (21). The integrated lancet (28) is positioned such that a finger pad aperture (29) is adjacent the integrated lancet (28). The integrated lancet comprises a lancet tip (not illustrated) which is moveable between a rest position in which the lancet tip is enclosed within the body (21) and an actuated position in which the lancet tip extends from the body. In the actuated position, the lancet tip extends from the body such that a finger positioned in the finger pad aperture is pierced by the lancet upon the lancet moving between the rest position and the actuated position.

In use, activation of the lancet between the rest position and the actuated position occurs through depression of a lancet activator (30) which is positioned on the body. Contact with the lancet activator (30) moves the lancet tip into the finger pad aperture (29) to pierce a finger or alternative body part positioned in that aperture.

Upon a user's finger being pierced by the lancet, the user or clinician moves the user's finger over the blood collection window (32) and bodily fluid, in this case blood, is collected at fluid collection window (32). The fluid collection window (32) is positioned proximal to the aperture (29) to allow a user to easily move the pierced finger between the aperture (29) and the fluid collection window (32) without depositing fluid other than in the window.

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The diagnostic system further comprises a physiologically acceptable solution such as a buffer for supporting the blood or other bodily fluid. A solution delivery actuator (35) is positioned on the diagnostic system. Contact with the solution delivery actuator releases the buffer solution from an internal reservoir and delivers it to a test material incorporated into the diagnostic system (10). The test material may comprise a lateral flow test strip, a vertical flow test strip, solid phase test material, agglutination test material, a cartridge or reagent tube or any element which incorporates a reagent adapted to be mixed with the bodily fluid, a card incorporating a fluid sample retention material, an assay, a test strip or an integrated electrical circuit or any material adapted for retaining a sample and allowing a diagnostic test to be performed thereon.

The diagnostic system further includes a results window (41) which is positioned for easy viewing of the results of any diagnostic test performed.

An alcohol swab locator (45) in the form of a depression in which alcohol swabs and dry wipes can be inserted is positioned in side (24). The depression (45) is covered by a seal (46) such as a foil seal or plastic seal.

An adhesive bandage locator (48) is positioned in a further side of the diagnostic system. The adhesive bandage locator is in a form of a depression which fits adhesive bandages such as Band-Aids TM.

The sides of the diagnostic system (10) are labelled with indicia (72) indicating the order in which the sides are

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to be used. This simplifies the process of utilizing the system and allows an at home user to confidently proceed through the necessary steps. The positioning of the finger pad aperture (29), the fluid collection window (32), the solution delivery actuator (35) the alcohol swab locator (45) and the adhesive bandage locator (48) allow for a simple movement through the steps of the process. This allows for an intuitive movement about the surfaces of the system (10). Thus the lancet activator (30) is adjacent the fluid collection window (32) which is adjacent the solution delivery actuator (35) which is positioned adjacent the adhesive Band-Aid locator (48) allowing for sequential motion about the system (10) when following the steps in the order indicated by the indicia (72).

In a second embodiment of the present diagnostic system, shown in Figures 6 - 7, the diagnostic system (50) comprises a body (51) in the form of a substantially H-shaped housing.

In the illustrated form, the housing includes an integrated lancet (52) which extends substantially through the housing (51). The lancet (52) is moveable between a rest position in which the lancet tip is enclosed within the body (51) and an actuated position in which the lancet tip extends from the body (51). The lancet (52) is actuated by a lancet activator (53) positioned at one end of the body (51).

While the illustrated form includes a membrane penetration element in the form of a lancet, persons skilled in the art will be aware that the membrane penetration element could be any piercing, slicing, cutting, puncturing or

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pricking element which allows a user to penetrate a membrane such as the skin to allow a fluid sample to be released.

The diagnostic system further comprises a blood collection window (54) in which a user places their pricked finger in order to collect blood expelled from the finger after the lancet pierces the finger. The blood collection window is positioned in line with a test material which is incorporated into the diagnostic system (50). A receptacle for buffer solution (55) is positioned on the diagnostic system (50). The receptacle (55) is in the form of a sachet of buffer solution which can be manually added to the blood in the blood collection window (54).

The lateral flow test strip (56) extends across one portion of the diagnostic system such that the blood collection window (54) and a results window (57) are both positioned above the lateral flow test strip (56). Buffer (55) is added to a blood collection window (54) and results appear in the results window (57).

In use, a user will peel foil (60) positioned over an alcohol swab and dry wipe (61 and 62). These will then clean their finger with the alcohol swab (61) and dry it with the dry wipes (62). The user will then place the pad of the finger against the integrated lancet (52) at point (63).

Lancet activation is brought about by contact with button (53). In the illustrated form, lancet activation comprises extension of the penetrating element of the lancet and retraction of the same into a housing to provide for safe storage and disposal. In the extended

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position, the penetrating element is adapted to lance, pierce, slice, prick or otherwise penetrate the user's finger positioned at point (63). Blood is then collected at blood collection window (54). The receptacle of physiologically acceptable (55) is then removed from the body and the solution is added to the blood collection window (54). The lateral flow test strip extends across the body (51) at lateral flow test strip (56) allowing results to be read in the results window (57).

In a third embodiment a diagnostic system (70) comprises a body (71) in the form of a housing having six sides. The sides are labelled with indicia (72) indicating the order of which the sides are to be used. A user will initially peel foil (73) from over an alcohol swab and dry wipe (74 and 75) which are positioned within an alcohol swab locator in the form of a depression (76) in one side of the diagnostic system (70). The user will clean their finger with the alcohol swab and then will insert their finger into finger pad depression (78) on a second side of the diagnostic system (70). An integrated lancet (79) is positioned within this side and actuated by lancet activator (80). Once the user has contacted lancet activator (80) the lancet tip extends from the body (71) to pierce a finger in the aperture (78). The lancet tip then retracts. The user then allows their blood to be collected at blood collection window (82) on a third side of the diagnostic system (70).

A solution delivery actuator (84) is positioned on the same side of the diagnostic system (70) as the blood collection window (82). Depression of the solution delivery actuator delivers a physiologically acceptable solution or buffer to the lateral flow test strip.

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The lateral flow test strip is incorporated into the diagnostic system (70) although it is not visible from the outside of the system. The blood collected at blood collection window (82) and the buffer solution released upon depression of solution delivery actuator (84) combine to allow the test strip or other test material to provide results in the results window (86). The user then peels an adhesive strip from the adhesive bandage locator (87) located in the fourth side of the system. The adhesive bandage can then be used to bandage the pierced finger.

A fourth embodiment is shown in figures 13-15. In this embodiment a diagnostic system (100) comprises a body (101) in the form of an elongate housing. The body (101) includes a finger pad aperture (102) which is positioned adjacent a lancet (103). The lancet (103) is integrated into the body (101) and is moveable between a position in which the lancet tip is enclosed within the body (101) and a position in which the lancet tip extends from the body into the finger pad aperture (102).

The diagnostic system further comprises a lancet activator (104) which is actuated to move the lancet between the rest position in which it is enclosed in the body (101) and the actuator position in which it extends into the finger pad depression point (102). The reverse side of the body (101) comprises a solution delivery actuator in the form of a push button (106), along with a blood collection window (107) and results window (108). In use, a user inserts their finger into the finger pad aperture (102) with the finger pad pressing against the integrated lancet (103). The user then actuates the lancet (103) by pressing lancet actuator (104). This acts to pierce the finger. The user then collects blood in blood collection

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window (107) and presses solution delivery actuator (106) to allow buffer solution or other physiologically acceptable solution to contact the blood in blood collection window (107) and the lateral flow test strip which is incorporated into the diagnostic system. The lateral flow test strip then provides a result at results window (108).

A fifth embodiment of the present diagnostic system is shown in figures 16-18. In this form the system is in kit form and the support member comprises a hard cover case (110). The hard cover case is hinged along a central hinge (111) and opens to reveal a removable lancing system (112), an alcohol swab, and dry wipe locator (113) a blood collection window, (114) a lateral flow test strip, (115) a results window, (116) a solution delivery actuator, (117) and an adhesive bandage locator (118).

In use, a user removes the foil from alcohol swab and dry wipe locator (113) to clean a finger for use. The user then removes the removable lancet (112) from the hard cover case (110) and positions their finger at the piercing end (118) of the integrated lancet (112). The user then depresses lancet actuator (119) to pierce the finger.

Blood is collected at blood collection window (114) above test strip (115). A buffer solution reservoir (120) is located in the body and is connected with the test strip (115) by a channel (121). The user slides solution delivery actuator (117) forward to direct the buffer to the test strip and results are provided in the results window (116).

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In a sixth embodiment, shown in figures 19 through 21, disclosed is a composite diagnostic system (140). The diagnostic system 140 may in one form be hand held. Alternatively the system may be sized to be utilised as a table top system. The diagnostic system (140) comprises a support member (142) which is made up of a body (143) in the form of a housing having an elongated oval shape. The body (143) comprises top face (144) bottom face (145) and sides (146) and extends from a distal end (147) at which the lancet is positioned to a proximal end (148).

The diagnostic system further comprises an integrated lancet (149). The integrated lancet is positioned in the distal end (147) of the body (143) and is surrounded by the external walls of the body. A lancet tip (151) is positioned in a rest position internally to the body (142). The lancet tip (151) is positioned to extend from the body (142) when the lancet is actuated. In the actuated position, the lancet tip (151) extends from the body such that a finger positioned at the distal end is pierced by the lancet upon the lancet moving between the rest position and the actuated position. The lancet tip (151) then retracts into the body (143).

In use, activation of the lancet between the rest position and the actuated position occurs through depression of a lancet activator (153) which extends from the distal end (147). A user places their finger against a protruding end (155) of the lancet (149) and this contact results in depression of the lancet activator (153) moving the lancet tip (151) to pierce a finger or alternative body part positioned at the distal end (147).

Upon a user's finger being pierced by the lancet, the user or clinician moves the user's finger over the fluid collection element (156) which, in the illustrated form, is in the form of a window. Bodily fluid, in this case blood, is collected at fluid collection element (156). The fluid collection element (156) is positioned proximal to the distal end (147) to allow a user to easily move the pierced finger to the fluid collection element (156) without depositing fluid other than in the element.

While the fluid collection element (156) has been described in the form of a window into which fluid is deposited, the collection element (156) could alternatively be in the form of a capillary tube which may be adapted to retain and deposit quantifiable amounts of fluid, an alternate opening or depression, a loop adapted to retain and deposit small amounts of fluid, a well or any alternative embodiment which allows for deposit of fluid and transfer or movement or placement onto the test material within the system.

The diagnostic system further comprises a physiologically acceptable solution such as a buffer stored in a buffer sachet (159) for supporting the blood or other bodily fluid. A solution delivery actuator (160) is positioned on the diagnostic system. Contact with the solution delivery actuator (160) releases the buffer solution from the sachet (159).

A test material in the form of a test strip (162) is positioned beneath the buffer sachet (159) and the fluid collection window (156). The test material in the illustrated form comprises a lateral flow test strip

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however it may comprise a vertical flow test strip, solid phase test material, agglutination test material, a cartridge or reagent tube or any element which incorporates a reagent adapted to be mixed with the bodily fluid, a card incorporating a fluid sample retention material, an assay, a test strip or an integrated electrical circuit.

The diagnostic system further includes a results window (164) which is positioned on the same side as the fluid collection window (156) for easy viewing of the results of any diagnostic test performed.

An alcohol swab locator (165) in the form of indicia or a depression or other location feature in which alcohol swabs and dry wipes can be inserted or attached is positioned in a surface of the support member such as in the illustrated form in side (146).

An adhesive bandage locator (167) is positioned in the proximal end (148) of the diagnostic system (140). The adhesive bandage locator is in a form of a slit extending into the body (142) of the system (140) which fits adhesive bandages such as Band-Aids TM.

In a seventh embodiment shown in figures 22 through 26 disclosed is a composite diagnostic system (140). The diagnostic system (140) comprises a support member (142) which is made up of a body (143) in the form of a housing having an elongated oval shape. The body (143) comprises top face (144) bottom face (145) and sides (146) and extends from a distal end (147) at which a lancet is located to a proximal end (148).

The diagnostic system further comprises an integrated lancet (149). The integrated lancet is positioned in the distal end (147) of the body (143) and is surrounded by the external walls of the body. A lancet tip (not illustrated in this form) is positioned in a rest position internally to the body (142). The lancet tip is positioned to extend from the body (142) when the lancet is actuated. In the actuated position, the lancet tip extends from the body such that a finger positioned at the distal end is pierced by the lancet upon the lancet moving between the rest position and the actuated position. The lancet tip thereafter retracts into the body (143) to allow for safe storage or disposal of the system.

In use, activation of the lancet between the rest position and the actuated position occurs through depression of a lancet activator (153) which extends from the distal end (147). A user places their finger against a protruding end (155) of the lancet (149) and this contact results in depression of the lancet activator (153) moving the lancet tip to pierce a finger or alternative body part positioned at the distal end (147).

Upon a user's finger being pierced by the lancet, the user or clinician moves the user's finger over the fluid collection element (156) which, in the illustrated form, is in the form of a window. Bodily fluid, in this case blood, is collected at fluid collection element (156). The fluid collection element (156) is positioned proximal to the distal end (147) to allow a user to easily move the pierced finger to the fluid collection element (156) without depositing fluid other than in the element.

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While the fluid collection element (156) has been described in the form of a window into which fluid is deposited, the collection element (156) could alternatively be in the form of a capillary tube which may be adapted to retain and deposit quantifiable amounts of fluid, an alternate opening or depression, a loop adapted to retain and deposit small amounts of fluid, a well or any alternative embodiment which allows for deposit of fluid and transfer or movement or placement onto a test material.

The diagnostic system further comprises a physiologically acceptable solution such as a buffer stored in a buffer sachet (159) for supporting the blood or other bodily fluid. A solution delivery actuator (160) in the form of a slide is positioned on the diagnostic system. Sliding the solution delivery actuator (160) into an actuated position (shown in figures 25 and 26) releases the buffer solution from the sachet (159).

A test material in the form of a test strip (162) is positioned beneath the buffer sachet (159) and the fluid collection window (156). The test material in the illustrated form comprises a lateral flow test strip however it may alternatively comprise a vertical flow test strip, solid phase test material, agglutination test material, a cartridge or reagent tube or any element which incorporates a reagent adapted to be mixed with the bodily fluid, a card incorporating a fluid sample retention material, an assay, a test strip or an integrated electrical circuit.

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In one form the test material is adapted to interface with diagnostic equipment to provide a diagnosis. In one form the test material is removably engaged with the diagnostic system and is adapted upon removal to interface with diagnostic equipment for diagnosis. For example, a test strip may be removable and able to be inserted into diagnostic equipment for analysis. In another form a portion of the system such as a cartridge containing the test material or a fluid retainer is removable from the system to interface with diagnostic equipment.

Alternatively the system may include a port or platform for engagement with diagnostic equipment. The port may be in the form of a window or opening in contact with the test material. The diagnostic system can then interface with diagnostic equipment to be analysed and provide a diagnosis.

The diagnostic system further includes a results window (164) which is positioned on the same side as the fluid collection window (156) for easy viewing of the results of any diagnostic test performed. The results window (164) in this embodiment is positioned under the solution delivery actuator (160) when it is in a rest position (shown in figures 22 and 23) and is revealed when the solution delivery actuator (160) is in an actuated position (shown in figures 25 and 26). In the actuated position the fluid collection window (156) is covered by the solution delivery actuator (160).

An alcohol swab locator (165) in the form of a depression in which alcohol swabs and dry wipes can be inserted is positioned on the top face (144).

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An adhesive bandage locator (167) is positioned in the distal end (148) of the diagnostic system (140). The adhesive bandage locator is in a form of a slit extending into the body (142) of the system (140) which fits adhesive bandages such as Band-Aids TM.

Figures 27 through 29 show an eighth embodiment of a diagnostic system. The diagnostic system (180) comprises a body (181) composed of a sampling section (183) and a diagnostic section (184). The sampling section (183) and the diagnostic section (184) are removably engaged with one another. In the illustrated form the diagnostic section (184) caps the sampling section (183) and is engaged by means of a connector, clip, interference fit, snap fit or other engagement method.

The sampling section (183) comprises a sampling body (186). The sampling body (186) is adapted to be held in one hand, although the body (186) could alternatively be rested on a surface. A membrane penetration element (not illustrated in this form) in the form of a lancet is largely enclosed in the body (186). A lancet tip (not illustrated) is positioned to extend from the body through a lancet opening (187) in an actuated position and retract back into the body thereafter. Actuation of the lancet occurs through pressure on a lancet actuation element (188).

In the illustrated form the membrane penetration element has been described in terms of a lancet, however any other piercing, pricking, slicing, or otherwise penetrating element may be utilised.

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The sampling section (183) further includes a fluid collection element (190). In the illustrated form the fluid collection element (190) is in the form of a loop (191) although the fluid collection element may comprise a well, window, capillary tube or any alternative element for fluid collection.

A user positions a body part such as a finger adjacent the lancet opening (187) and actuates the lancet through pressure on the lancet actuation element (188). The lancet penetrates a membrane on the body part releasing a fluid, in this case blood. The user positions the body part in contact with the loop (191) and deposits a sample of blood therein.

The diagnostic section (184) comprises a body (193) which in this form is placed on a surface. The body includes a fluid deposit opening (194) into which the fluid collection element (190) on the sampling section (183) can be inserted to deposit fluid from the loop (191).

A test material (not illustrated) is positioned within the body (193) such that fluid from the sampling section (183) interacts with the test material.

In the illustrated form the test material is in the form of an integrated lateral flow test strip, test strip, cassette, cartridge, integrated circuit or other diagnostic or pre-diagnostic element.

The diagnostic section (184) further includes a test result window (196) through which results of a diagnostic test can be displayed.

The illustrated form shows an integrated test material resulting in an on-site diagnosis, however a person skilled in the art will be aware that the test material could be adapted to be analyzed elsewhere and a diagnosis provided by separate diagnostic equipment.

As shown best in the first and third embodiments, indicia (72) are incorporated onto the system to visibly cue a user to perform a sequence of steps in order. In the illustrated embodiment the indicia are in the form of numbers, however it will be clear that graphic, pictorial, text or alternative indicia could effectively present the sequence of steps to cue a user. In the first embodiment, the indicia (72) instruct the user to first perform the step on the side labeled "1", that is, clean and dry the area of skin in preparation for lancing. The user then rotates the system to find step "2", in which the user inserts a finger into the finger pad aperture (29) for lancing. The user then activates the lancet (28). The user rotates the system to find step "3" in which the user deposits blood at the blood collection window (32). The physiologically acceptable solution and blood contact the test material and the results show in the results window on the front face. The user then rotates the system to perform step 4, placing an adhesive bandage on the finger.

In the third embodiment the steps are much the same, however the step of delivering physiologically acceptable solution to the test material is performed by actuating an actuator (84) positioned adjacent the blood collection window (82).

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In one not illustrated form, a detachable patient information card or label is affixed to the support member.

In one not illustrated form, the diagnostic system is modular, comprising a body incorporating the membrane penetration element and a cartridge, the cartridge incorporating the fluid collection element and test material and, in some forms, a physiologically acceptable solution such as a buffer and a test results window. In this form, manufacture comprises separately manufacturing the body incorporating, for example, a lancet and the cartridge. Separate manufacture allows selection of specific cartridges for use in a given order. In the claims which follow and in the preceding description of the device, except where the context requires otherwise due to express language or necessary implication, the word "comprise" or variations such as "comprises" or "comprising" is used in an inclusive sense, i.e. to specify the presence of the stated features but not to preclude the presence or addition of further features in various embodiments of the invention.

Claims:

1. A composite diagnostic system comprising a support member having:
 - a membrane penetration element;
 - a test component positioned within the support member;
 - a bodily fluid collection point comprising a capillary tube positioned on the support member for collection of a bodily fluid released by application of the membrane penetration element to a human and adapted in use to take up and conduct the bodily fluid into contact with the test component;
 - an internal reservoir located within the support member and adapted to contain a solution for use with the test component; and
 - a solution delivery actuator wherein in use, actuation of the solution delivery actuator causes the solution to be released from the reservoir and brought into contact with the test component after the bodily fluid has been brought into contact with the test component.
2. A composite diagnostic system as defined in claim 1, wherein the solution delivery actuator is adapted to be manually operated.
3. A composite diagnostic system as defined in claim 1 or claim 2, wherein the solution delivery actuator is operated automatically upon a step in ordinary use of the system being performed.
4. A composite diagnostic system as defined in any one of the preceding claims, wherein the solution is a buffer.

5. A composite diagnostic system as defined in any one of the preceding claims, wherein the test component comprises a test strip positioned in the composite diagnostic system.
6. A composite diagnostic system as defined in any one of the preceding claims, wherein the test component is removably positioned within the diagnostic system.
7. A composite diagnostic system as defined in any of the preceding claims, wherein the membrane penetration element comprises a lancet or lancing system comprising a lancet tip, the lancet being moveable between a rest position in which the lancet tip is situated within the support member and an actuated position in which the lancet tip extends beyond the exterior of the support member.
8. A composite diagnostic system as defined in claim 7, the system further comprising a lancet activator, wherein the lancet is moveable between the rest position and the actuated position by actuation of the lancet activator.
9. A composite diagnostic system as defined in any of the preceding claims, the system further comprising indicia denoting a method of using the system.
10. A composite diagnostic system as defined in any of the preceding claims, wherein at least one of the reservoir and solution delivery actuator is adapted to release a controlled amount of solution.
11. A composite diagnostic system as defined in claim 10, wherein the solution delivery actuator is adapted to release a controlled amount of solution from the reservoir.
12. A composite diagnostic system as defined in claim 10 or 11, wherein the release of solution is effected by displacement.
13. A composite diagnostic system as defined in claim 10 or 11, wherein the release of solution is effected by a pressure differential.
14. A composite diagnostic system as defined in claim 10 or 11, wherein the release of solution is effected by capillary forces.

15. A composite diagnostic system as defined in any of the preceding claims, wherein the system is sized to be hand-held.
16. A composite diagnostic system as defined in any of the preceding claims, wherein the system is adapted to be held in a single hand.
17. A composite diagnostic system as defined in any of the preceding claims, further comprising an interface element adapted to allow the system to interface with diagnostic equipment.
18. A composite diagnostic system as defined in claim 17, wherein the interface element comprises a removable portion of the system adapted to engage with diagnostic equipment.
19. A composite diagnostic system as defined in claim 18, wherein the removable portion comprises the test component.
20. A composite diagnostic system as defined in any of the preceding claims, wherein the system comprises a plurality of reservoirs adapted to contain discrete solutions.
21. A composite diagnostic system as defined in any of the preceding claims, wherein the reservoir comprises a removable reservoir adapted to be engaged with the support member.
22. A composite diagnostic system comprising a support member having:
 - a membrane penetration element;
 - a bodily fluid collection point positioned for collection of a bodily fluid released by application of the membrane penetration element to a human;
 - a locator adapted to locate a reservoir containing a solution; and
 - a solution delivery actuator, actuation of the solution delivery actuator causes the solution to be released from the reservoir when the reservoir is located on the locator.

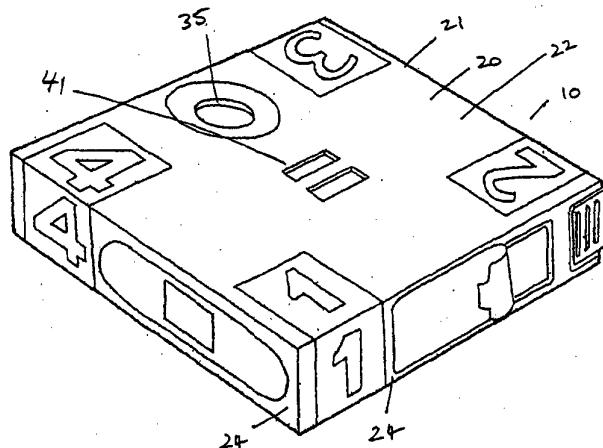


FIG. 1

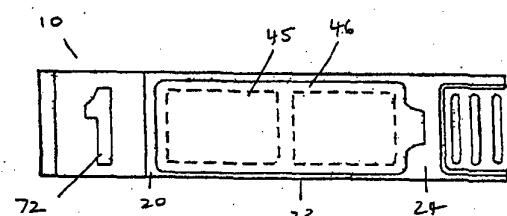


FIG. 2

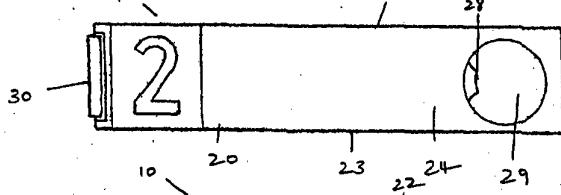


FIG. 3

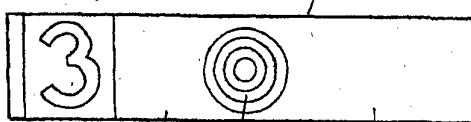


FIG. 4

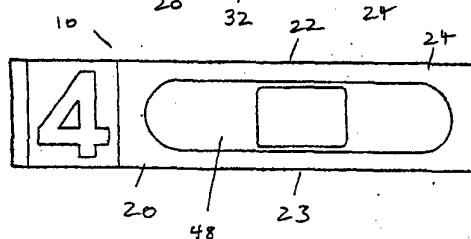


FIG. 5

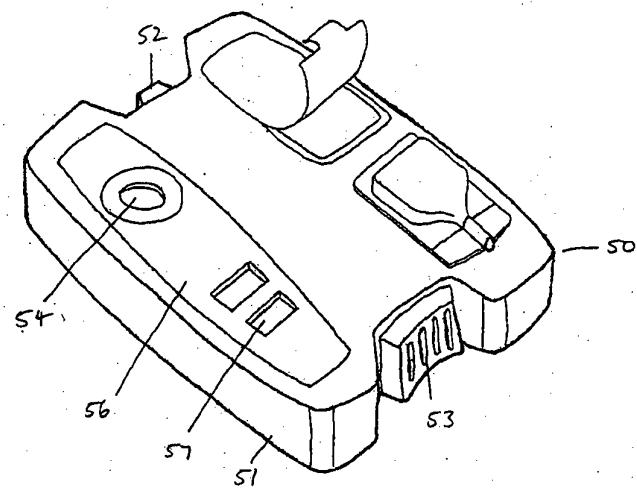


FIG. 6

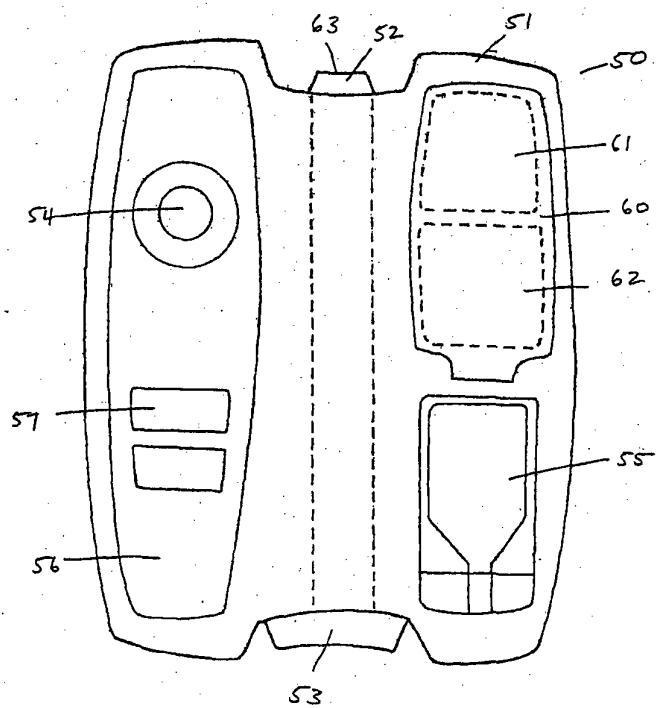


FIG. 7

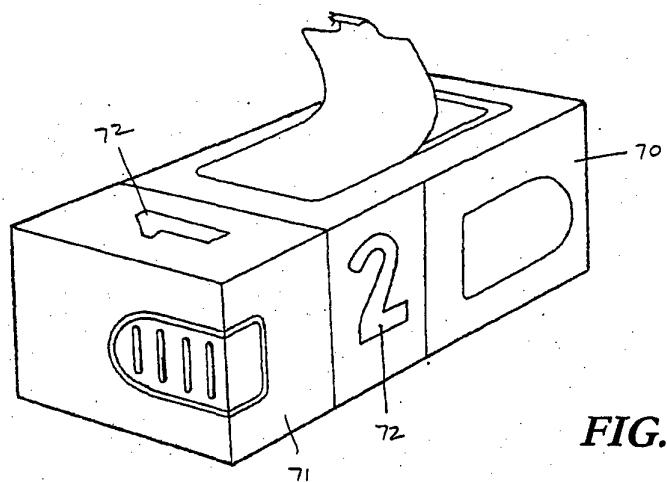


FIG. 8

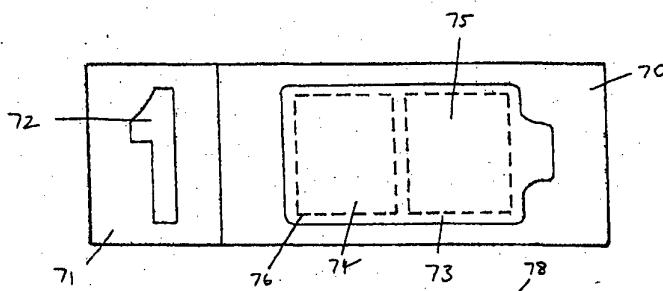


FIG. 9

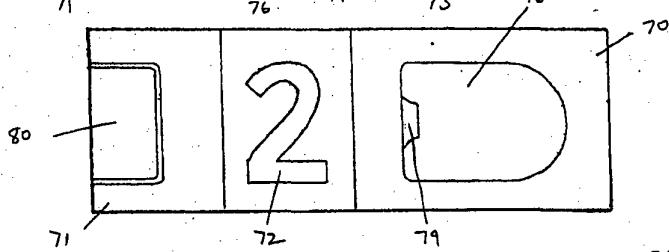


FIG. 10

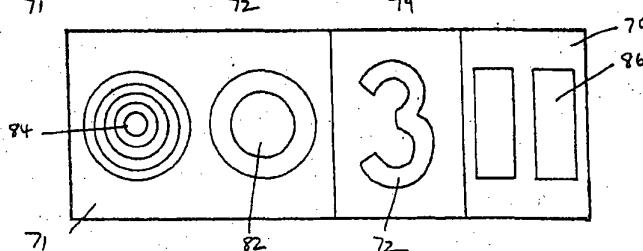


FIG. 11

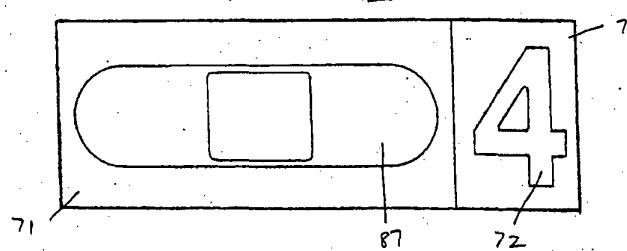


FIG. 12

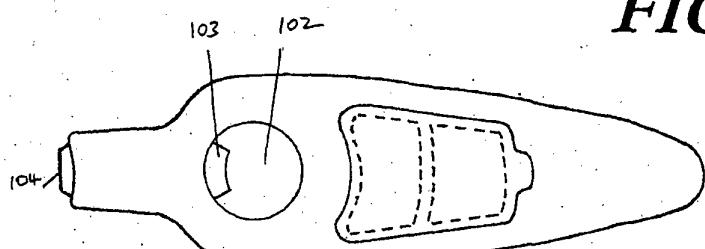
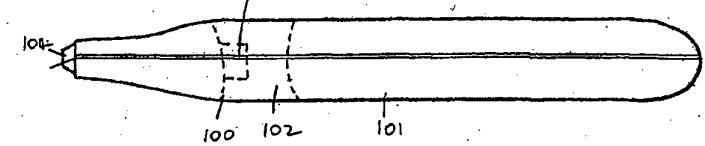
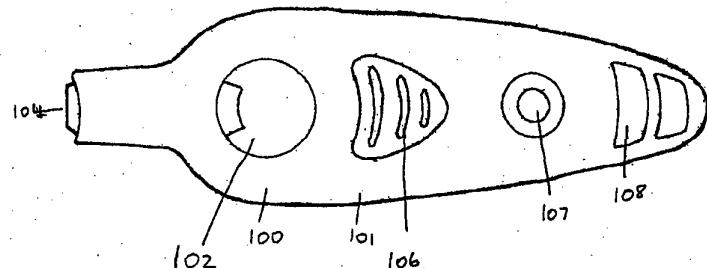
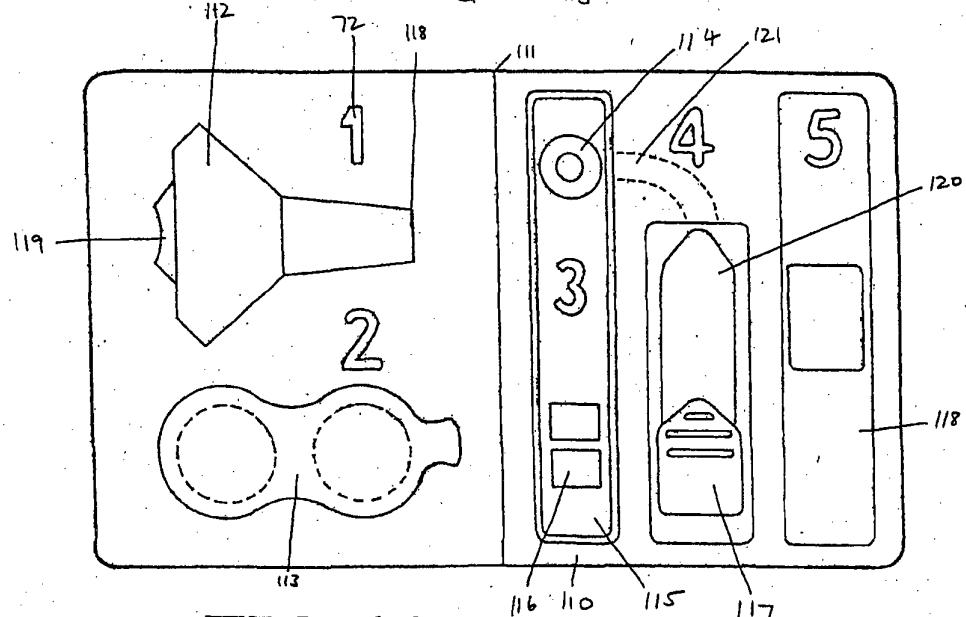
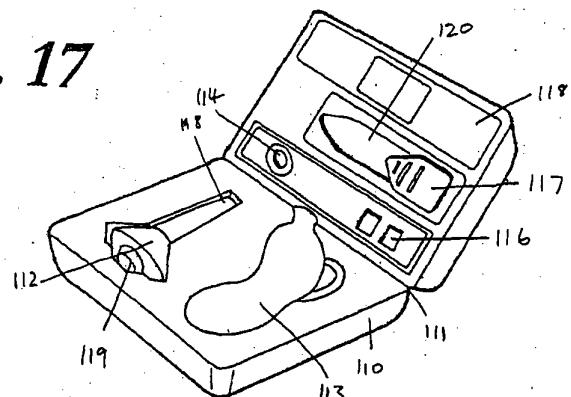
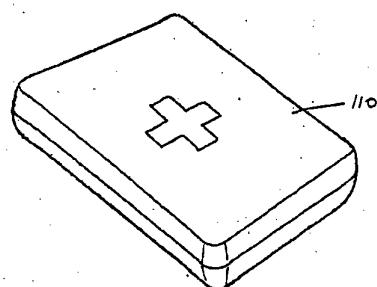
FIG. 13**FIG. 14****FIG. 15**

FIG. 17**FIG. 16****FIG. 18**

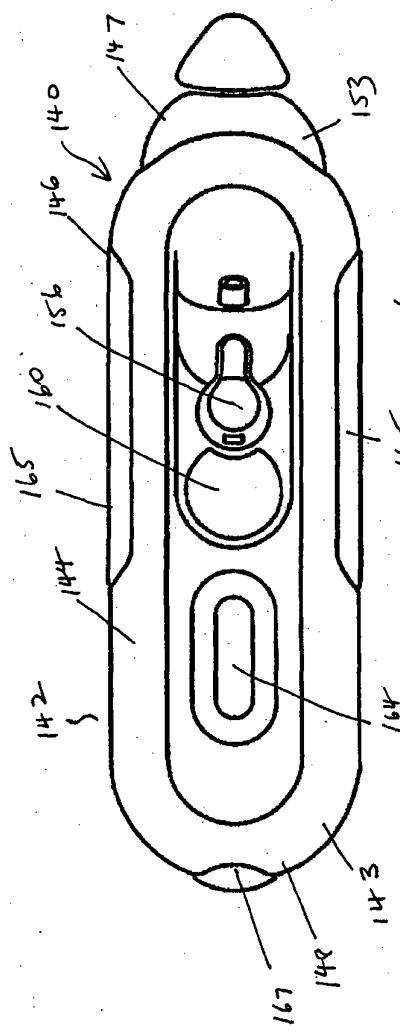


FIG. 19

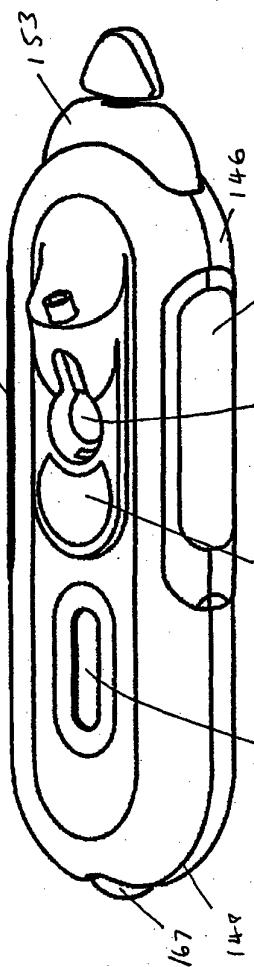


FIG. 20

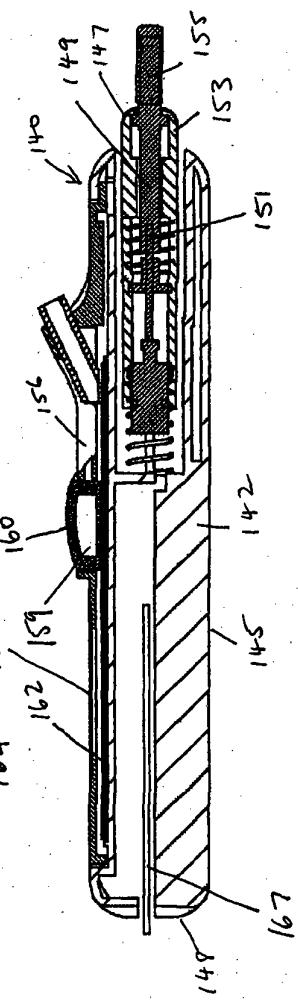
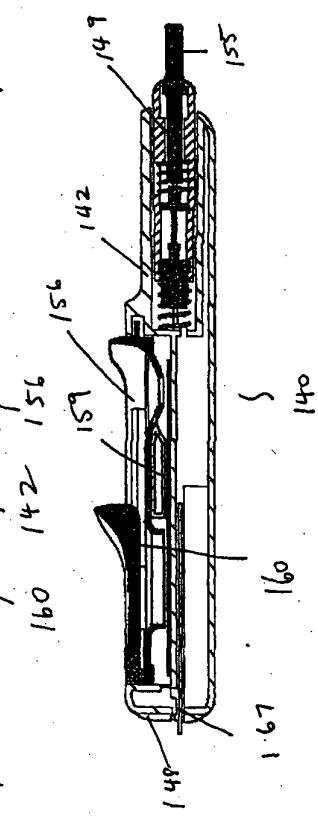
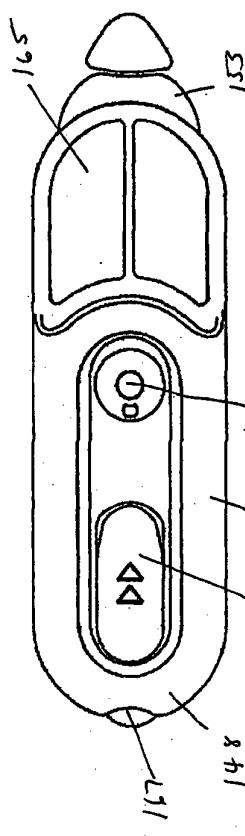
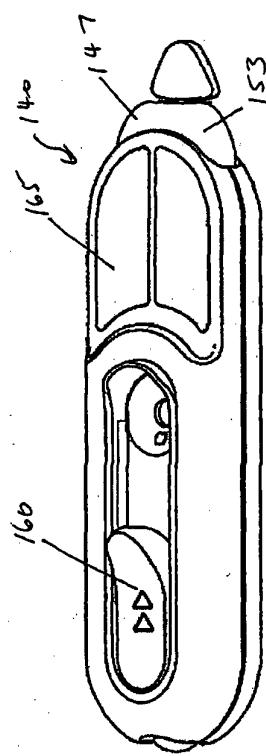


FIG. 21.



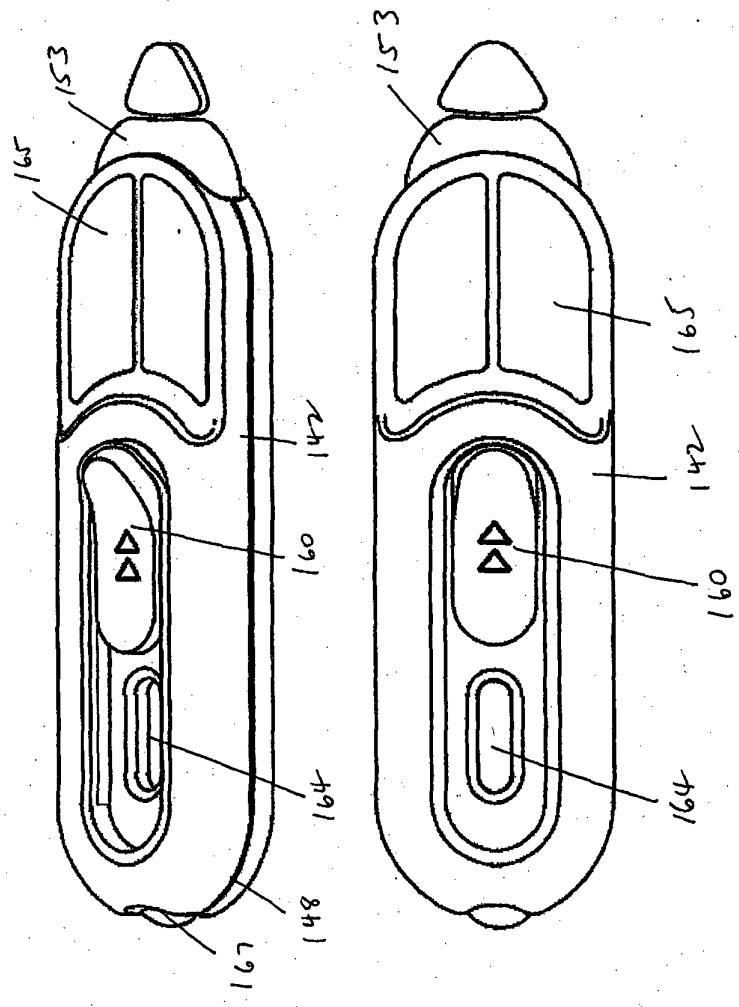


FIG. 25

FIG. 26

FIG. 27

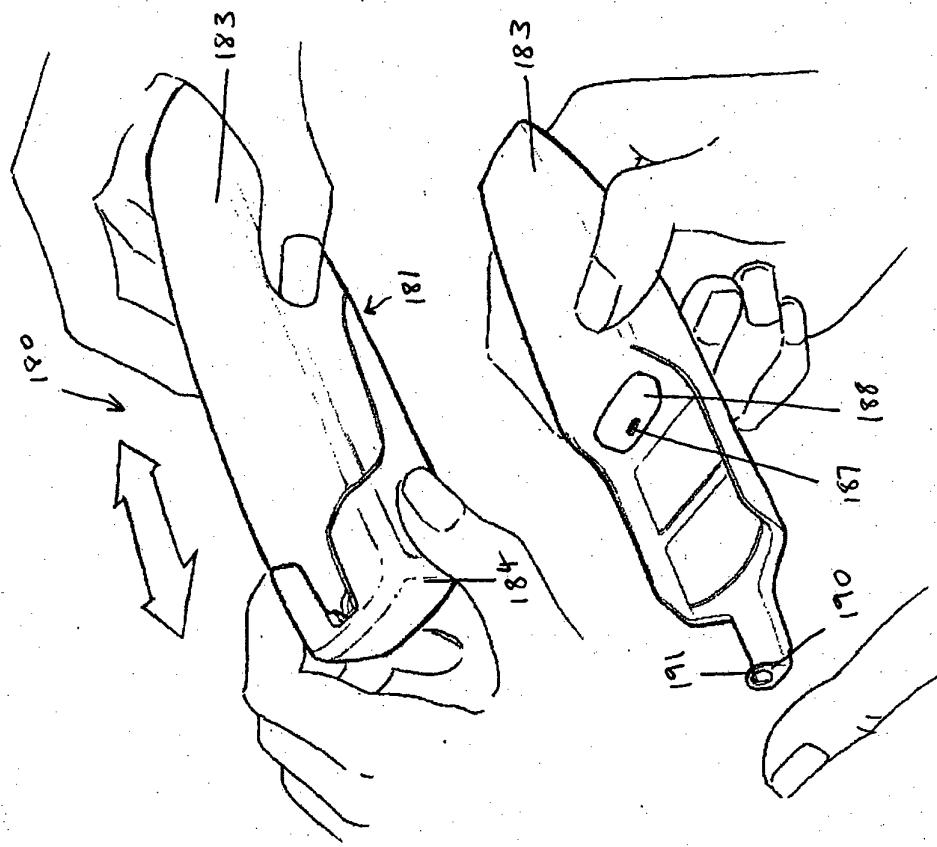


FIG. 28

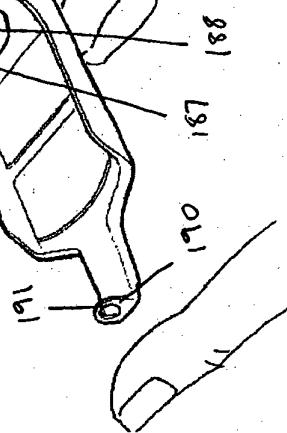


FIG. 29

