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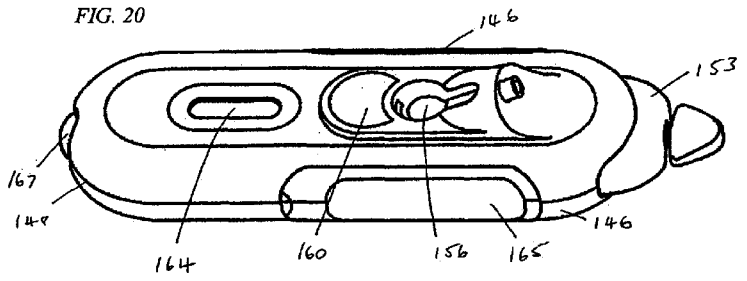
(54) Title: DIAGNOSTIC SYSTEM

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.

WO 2011/113114 A1

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, the support member having a membrane penetration element; a bodily fluid collection element positioned for collection of a bodily 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 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.

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.

In one form the physiologically acceptable solution is a buffer.

In one form the system further comprises a swab locator of 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

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:

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;

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;

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.

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

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

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

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.

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

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).

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

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.

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.

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).

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.

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).

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 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.

2. A composite diagnostic system as defined in claim 1, wherein the test material comprises a test strip positioned in the composite diagnostic system.

3. A composite diagnostic system as defined in claim 1, wherein the test material comprises a test cassette positioned in the composite diagnostic system.

4. A composite diagnostic system as defined in claim 1, wherein the test material comprises a cartridge.

5. A composite diagnostic system as defined in claim 1, wherein the test material comprises an integrated circuit positioned within the diagnostic system.

6. A composite diagnostic system as defined in claim 1, wherein the test material comprises a reagent tube.

7. A composite diagnostic system as defined in any of the preceding claims, wherein the test material is removably positioned within the diagnostic system.

8. A composite diagnostic system as defined in any of the preceding claims, wherein the piercing arrangement

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.

9. A composite diagnostic system as defined in claim 8, 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.

10. A composite diagnostic system as defined in claim 8 or 9, wherein the lancet is removably connected with the support member.

11. A composite diagnostic system as defined in claim 8 or 9, wherein the lancet is incorporated into the support member.

12. A composite diagnostic system as defined in claim 9, wherein the lancet activator is connected with the support member.

13. A composite diagnostic system as defined in any of the preceding claims, wherein the system further comprises 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.

14. A composite diagnostic system as defined in claim 13, wherein the reservoir is incorporated into the support member.

15. A composite diagnostic system as defined in claim 13 or 14, the support member further comprising a solution delivery actuator, actuation of the solution delivery actuator causing the physiologically acceptable solution to be delivered to the test material.

16. A composite diagnostic system as defined in any one of claims 13 - 16, wherein the physiologically acceptable solution is a buffer.

17. A composite diagnostic system as defined in any of the preceding claims, the system further comprising a swab locator located in the support member and adapted for associating an alcohol swab with the system.

18. A composite diagnostic system as defined in claim 17, wherein the swab locator comprises indicia or a depression.

19. A composite diagnostic system as defined in any of the preceding claims, the system further comprising a drying pad locator positioned in the support member for associating a drying pad with the system.

20. A composite diagnostic system as defined in any of the preceding claims, the system further comprising an adhesive bandage locator in the support member, adapted for associating an adhesive bandage with the system.

21. A composite diagnostic system as defined in claim 20 wherein the adhesive bandage locator comprises a slit extending into the support.

22. A composite diagnostic system as defined in any of the preceding claims, the system further comprising indicia denoting a method of using the system.

23. A composite diagnostic system as defined in any of the preceding claims, wherein the system is sized to be hand-held.

24. A composite diagnostic system as defined in any of the preceding claims, wherein the system is adapted to be held in a single hand.

25. A composite diagnostic system as defined in any of claims 1 - 22, wherein 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.

26. 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 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.

27. 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.

28. A composite diagnostic system as defined in claim 27, wherein the interface element comprises a removable portion of the system adapted to engage with diagnostic equipment.

29. A composite diagnostic system as defined in claim 28, wherein the removable portion comprises the test material.

30. A composite diagnostic system as defined in claim 27 wherein the interface element comprises an opening adapted to allow diagnostic equipment to interface with the system.

31. A composite diagnostic system as defined in claim 30, wherein the opening is positioned such that the test material can interface with the diagnostic equipment through the opening.

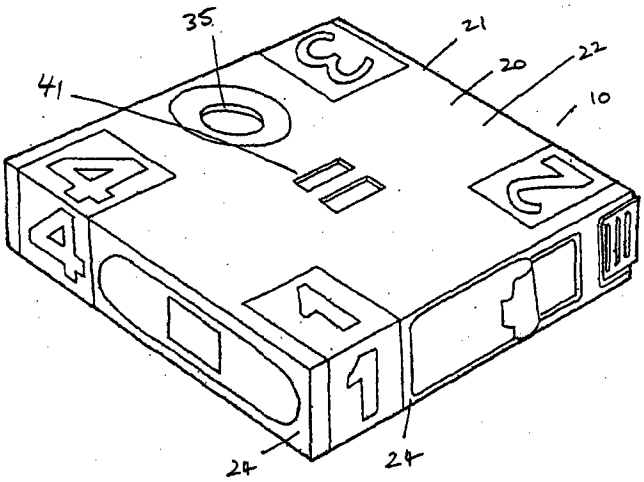


FIG. 1

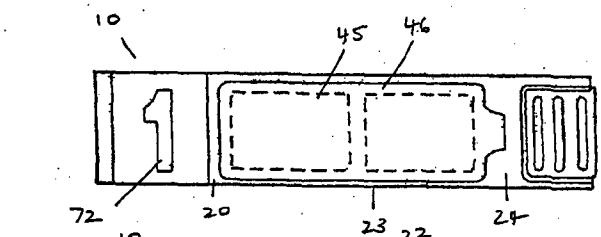


FIG. 2

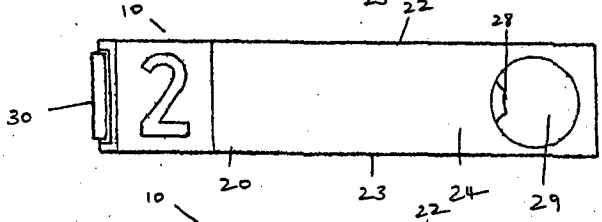


FIG. 3

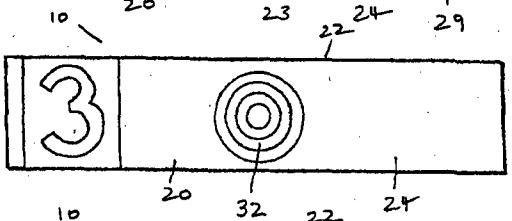


FIG. 4

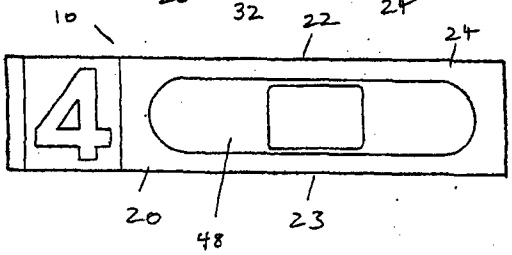


FIG. 5

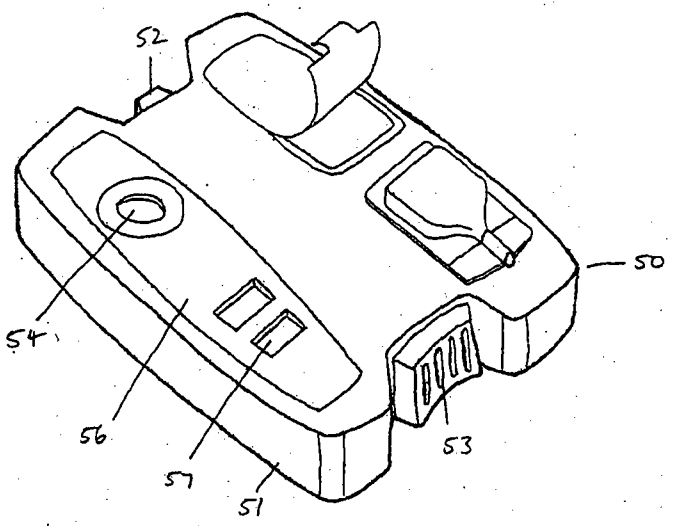


FIG. 6

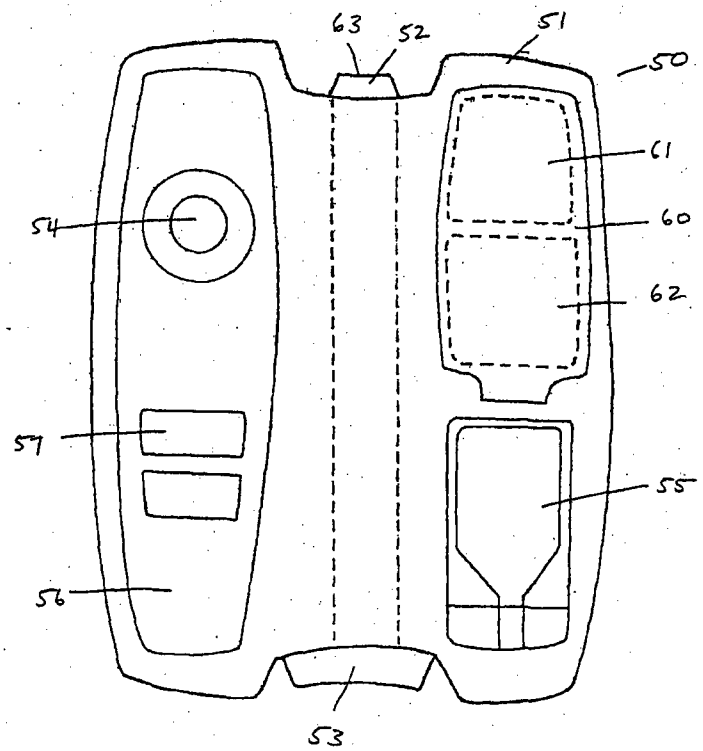


FIG. 7

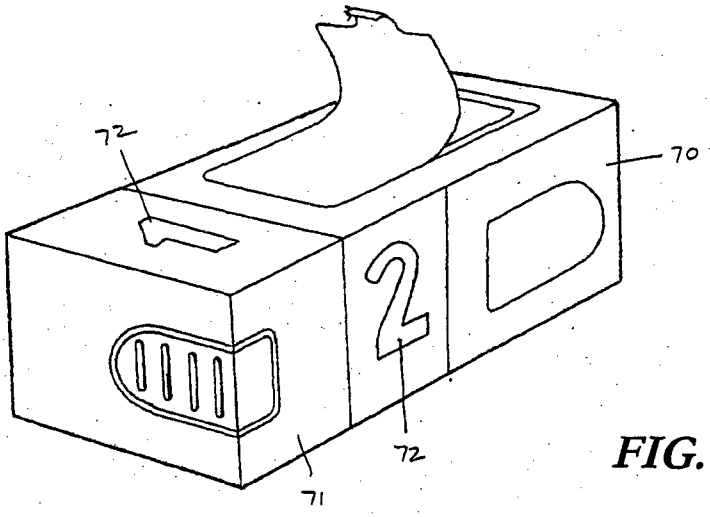


FIG. 8

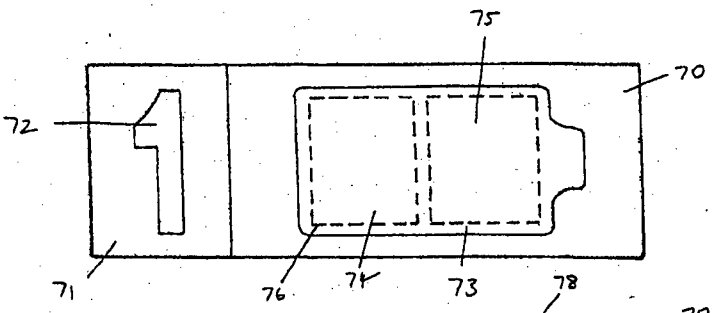


FIG. 9

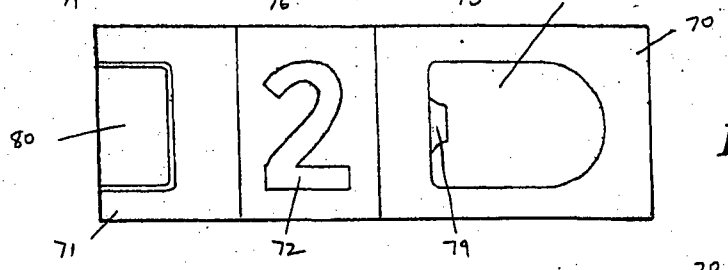


FIG. 10

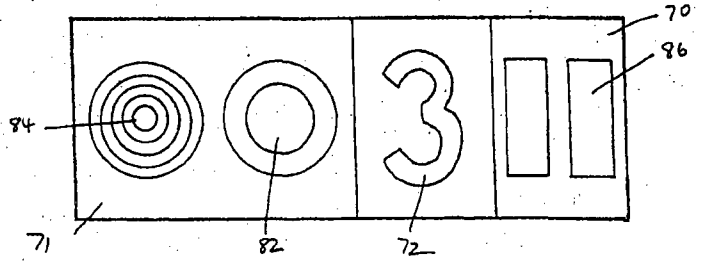


FIG. 11

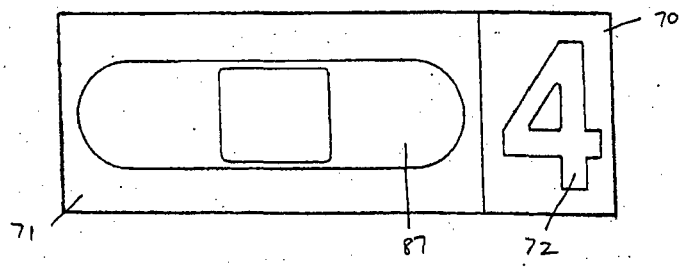


FIG. 12

FIG. 13

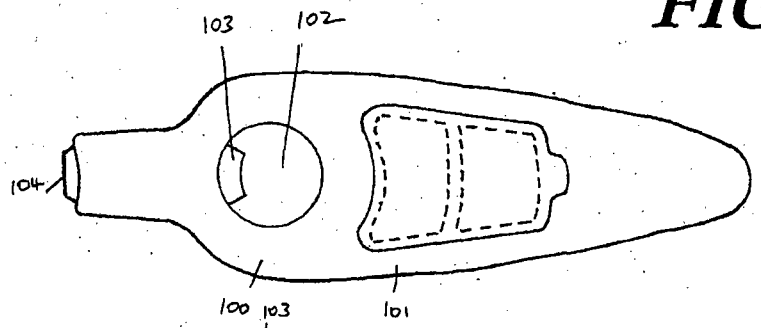


FIG. 14

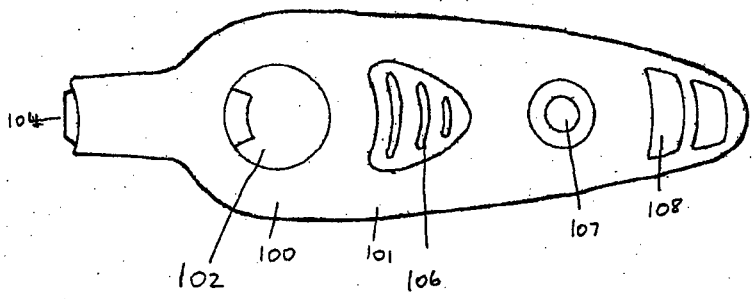
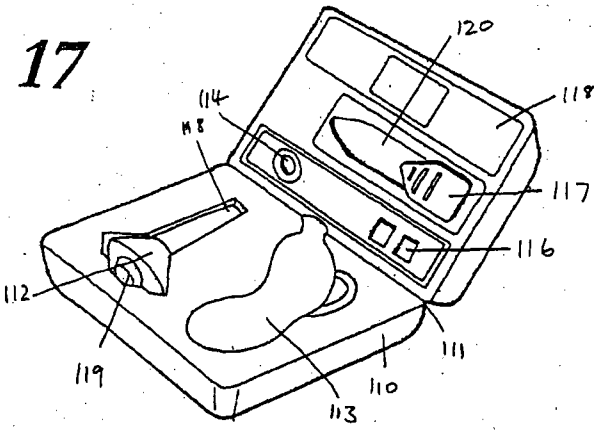


FIG. 15

FIG. 17



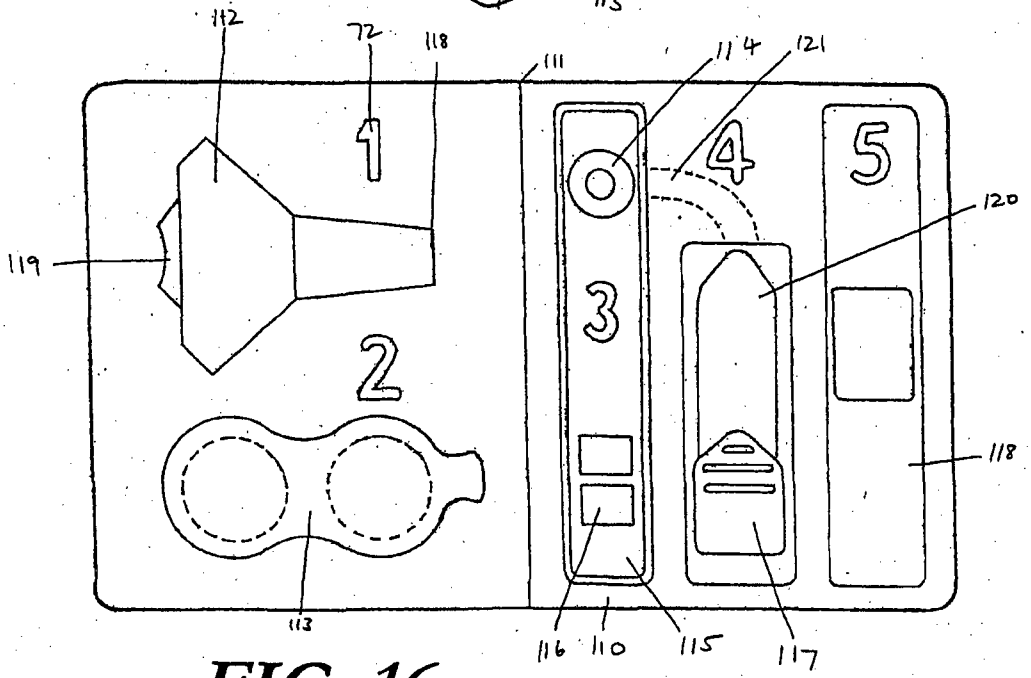


FIG. 16

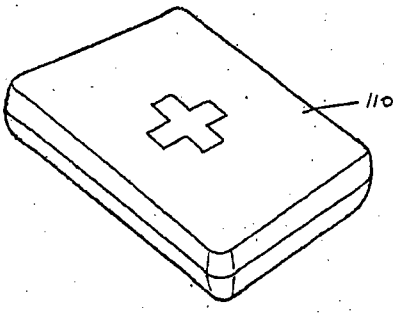


FIG. 18

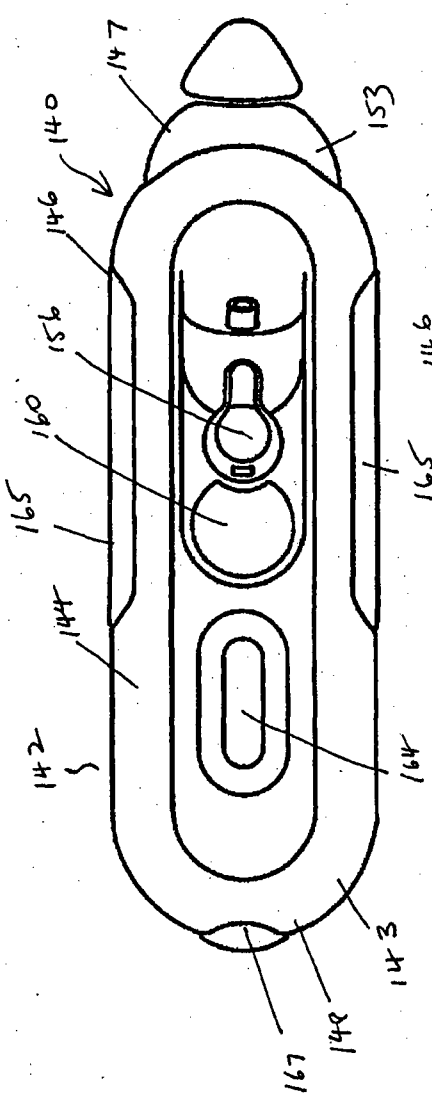


FIG. 19

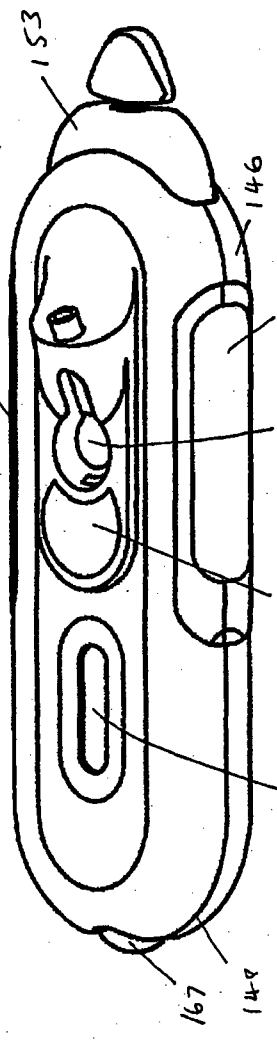


FIG. 20

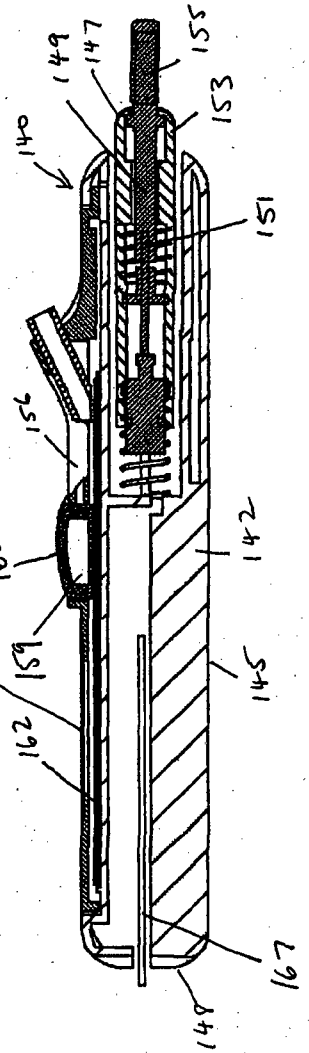


FIG. 21

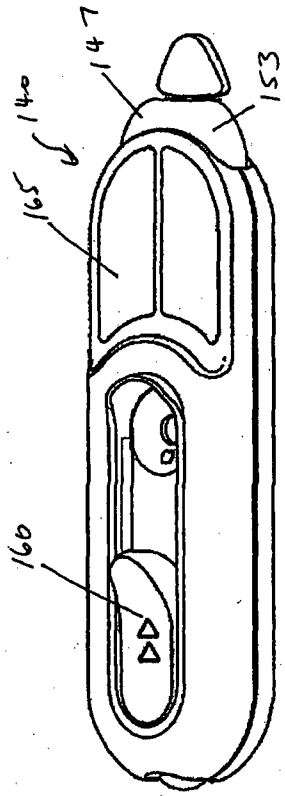


FIG. 22

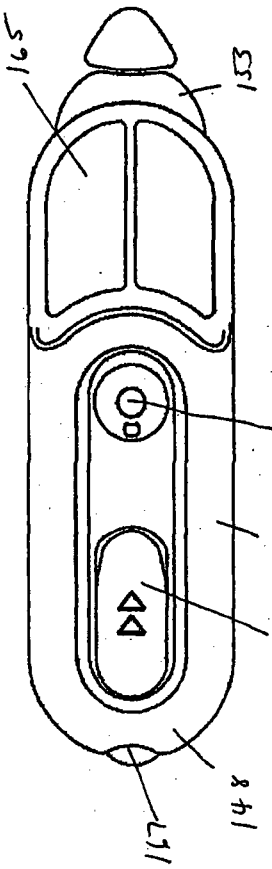


FIG. 23

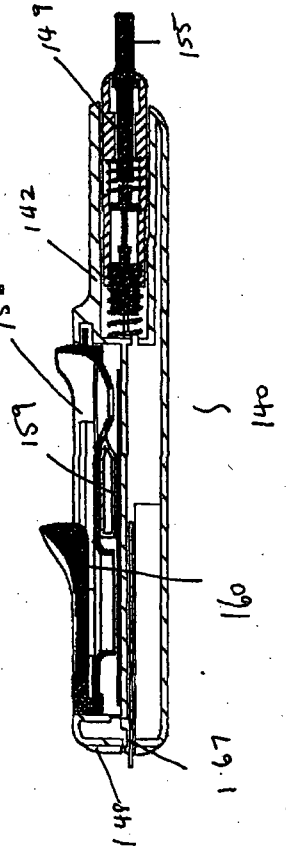


FIG. 24

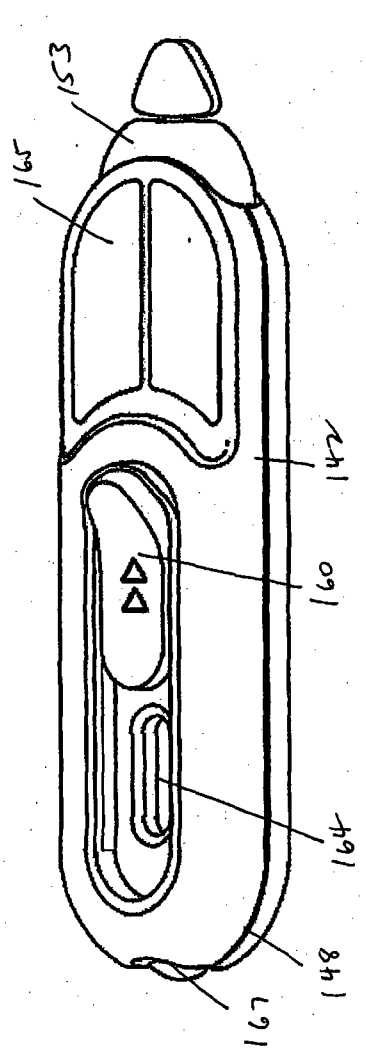


FIG. 25

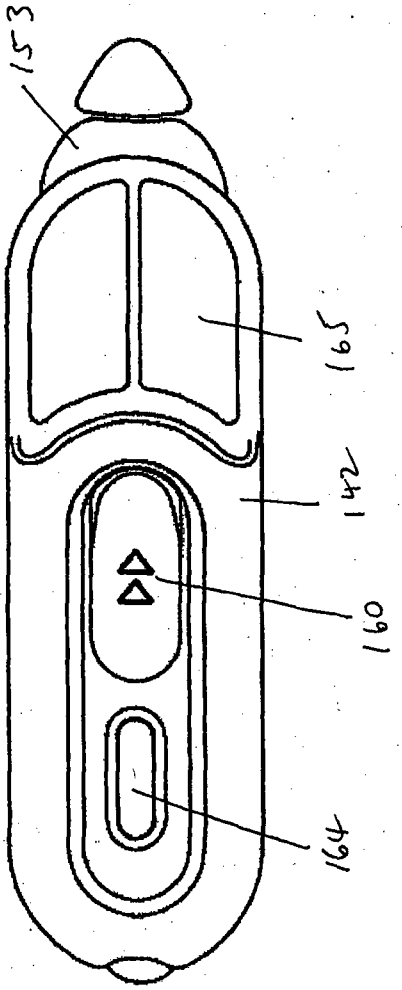


FIG. 26

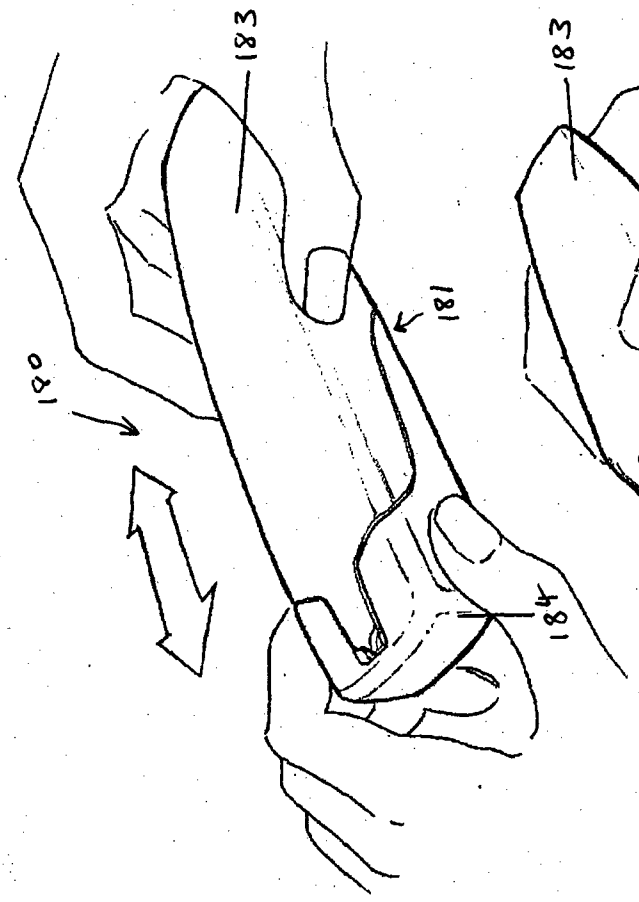


FIG. 27

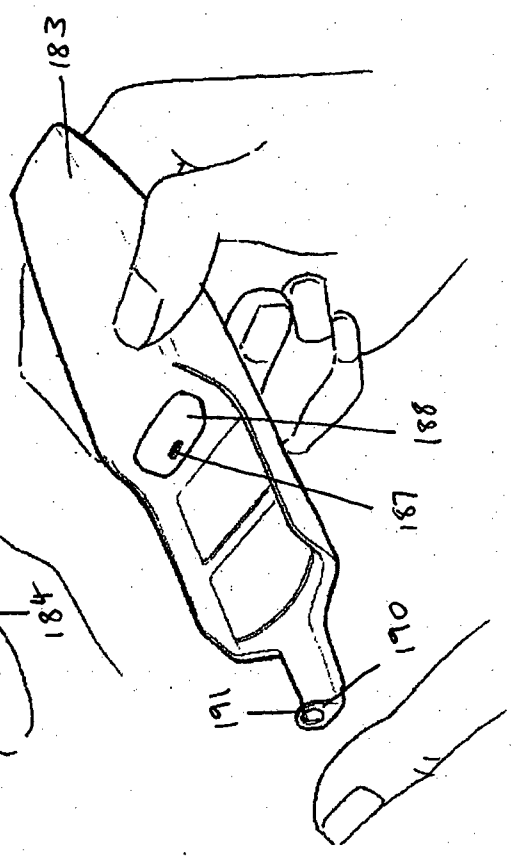


FIG. 28

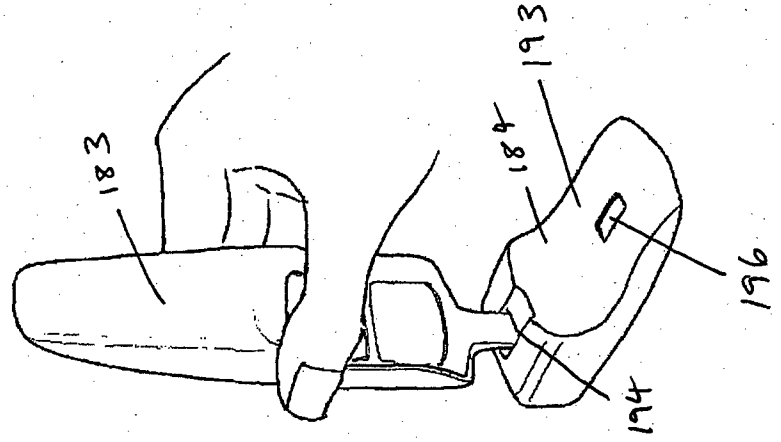


FIG. 29

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2011/000315

A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl.

A61B 5/151 (2006.01) ***A61J 1/05*** (2006.01)

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
WPI, EPODOC, IPC G01N C12Q A61 using keywords (test, assay, diagnos+, monitor, sampl+, analys+, meter, personal, self, contained, hand_held, module, pocket, easy, portable, bandage, plaster, swab, alcohol, syringe, needle, lanc+, prick, glucose, diabet+, blood, and like terms)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4637403 A (GARCIA et al.) 20 January 1987 Abstract; figures 2, 4-5, 9-15; column 6, lines 17-19; column 16, lines 16-17, 18-27; claim 1-3.	1, 2, 5, 7-12, 22-24, 26, 27
X	WO 2008/085052 A2 (KLAPWIJK) 17 July 2008 Abstract; figures 1-6; page 2, line 31; page 16, lines 5-8; claim 1 and 7.	1-4, 7-12, 23-28
X	WO 2002/078533 A2 (INVERNESS MEDICAL LIMITED et al.) 10 October 2002 Abstract; figures 1-3, 28, 30; page 8, lines 3-4; page 3, lines 10-12; page 4, lines 14-15; page 15, lines 23-31; page 16, lines 20-25; claims 19, 26, 54.	1-5, 7-12, 22-26

[X] Further documents are listed in the continuation of Box C [X] See patent family annex

* Special categories of cited documents:

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

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

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
13 May 2011	14 JUN 2011
Name and mailing address of the ISA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. +61 2 6283 7999	Authorized officer **STUART ASH** AUSTRALIAN PATENT OFFICE (ISO 9001 Quality Certified Service) Telephone No : (03) 9935 9633

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2003/0013121 A1 (KHAN) 16 January 2003 Figures 2, 3-6; paragraphs [0025]; [0029]; [0022-24]; [0026-28]; and [0008]; claim 8.	1, 2, 4, 6-8, 10, 11, 13, 14, 16, 17, 22-26
X	US 6264619 B1 (FERGUSON) 24 July 2001 Figure 1; column 4, line 11; column 3, line 34; column 3, lines 14-15; claim 3; claim 5	1, 2, 6-8, 10, 11, 13, 14, 16-20, 23, 24, 26
X	WO 2004/078232 A2 BECTON DICKINSON AND COMPANY) 16 September 2004 figure 1, paragraphs [0011], [0026], [0027], [0034], [0036]	1, 3-5, 7, 8, 11, 23-31
X	WO 1988/000812 A1 (GARID, INC) 11 February 1998 abstract, figures 3, 6A, 6B, page 27, page 21 line 12 to page 23 line 26, page 29 lines 10 to 26	1, 2, 8, 9, 11, 12, 23, 24, 26, 27, 30, 31
X	US 5 714 390 A (HALLOWITZ et al) 3 February 1998 figures 1 to 3, column 3 lines 20 to 34, whole of document	1, 6, 13, 14, 16, 23, 24, 26
X	US 5 249 584 A (KARKAR et al) 5 October 1993 abstract, column 12 line 15 to 50, figures 1 and 2	26, 27, 30, 31

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2011/000315

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

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

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

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

See Supplemental Box I.

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☒ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

Supplemental Box I
(To be used when the space in any of Boxes I to IV is not sufficient)

Continuation of Box No: III

This International Application does not comply with the requirements of unity of invention because it does not relate to one invention or to a group of inventions so linked as to form a single general inventive concept.

This Authority has found that there are different inventions based on the following features that separate the claims into distinct groups:

- Claim 2 (completely) and claims 1, 7 and 22 to 25 (partially) are directed to composite diagnostic system comprising a support member having a membrane penetration element, a bodily fluid collection point and a test material wherein the test material comprises a test strip positioned in the composite diagnostic system. The feature of the diagnostic test strip is specific to this group of claims.

- Claims 3 and 4 (completely) and claims 1, 7 and 22 to 25 (partially) are directed to composite diagnostic system comprising a support member having a membrane penetration element, a bodily fluid collection point and a test material wherein the test material comprises a cassette or cartridge. The feature of the test material comprising a cassette or cartridge is specific to this group of claims.

- Claim 5 (completely) and claims 1, 7 and 22 to 25 (partially) are directed to composite diagnostic system comprising a support member having a membrane penetration element, a bodily fluid collection point and a test material wherein the test material comprises an integrated circuit positioned within the diagnostic system. The feature of the test material comprising an integrated circuit is specific to this group of claims.

- Claim 6 (completely) and claims 1, 7 and 22 to 25 (partially) are directed to composite diagnostic system comprising a support member having a membrane penetration element, a bodily fluid collection point and a test material wherein the test material comprises a reagent tube. The feature of the test material comprising a reagent tube is specific to this group of claims.

- Claims 8 to 12 (completely) and claims 1, 7 and 22 to 25 (partially) are directed to composite diagnostic system comprising a support member having a membrane penetration element, a bodily fluid collection point and a test material wherein the piercing arrangement comprises a lancet, lancing system or lancet tip being moveable between a rest position and an actuated position. The feature of the piercing arrangement being a lancet, lancing system or lancet tip moveable between a rest position and an actuated position is specific to this group of claims.

- Claims 13 to 16 (completely) and claims 1, 7 and 22 to 25 (partially) are directed to composite diagnostic system comprising a support member having a membrane penetration element, a bodily fluid collection point and a test material wherein the system further comprises a reservoir containing a physiologically acceptable solution which is brought into contact with the test material along with the bodily fluid. The feature of the reservoir containing the physiologically acceptable solution is specific to this group of claims.

- Claims 17 and 18 (completely) and claims 1, 7 and 22 to 25 (partially) are directed to composite diagnostic system comprising a support member having a membrane penetration element, a bodily fluid collection point and a test material wherein the system further comprises a swab locator located in the support member for associating an alcohol swab with the system. The feature of the swab locator is specific to this group of claims.

.../continued in Supplemental Box II

Supplemental Box II
(To be used when the space in any of Boxes I to VIII is not sufficient)

Continuation of Supplemental Box I

- Claim 19 (completely) and claims 1, 7 and 22 to 25 (partially) are directed to composite diagnostic system comprising a support member having a membrane penetration element, a bodily fluid collection point and a test material wherein the system further comprises a drying pad locator positioned in the support member for associating a drying pad with the system. The feature of the drying pad locator is specific to this group of claims.

- Claims 20 and 21 (completely) and claims 1, 7 and 22 to 26 (partially) are directed to composite diagnostic system comprising a support member having a membrane penetration element, a bodily fluid collection point and a test material wherein the system includes an adhesive bandage locator in the support member for associating an adhesive bandage with the system. The feature of the adhesive bandage support member is specific to this group of claims.

- Claims 27 to 31 (completely) and claims 1, 7 and 22 to 26 (partially) are directed to composite diagnostic system comprising at least two of a membrane penetration element, a bodily fluid collection point and a test material wherein the system further comprises an interface element adapted to allow the system to interface with diagnostic equipment. The feature of the interface element is specific to this group of claims.

PCT Rule 13.2, first sentence, states that unity of invention is only fulfilled when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features. PCT Rule 13.2, second sentence, defines a special technical feature as a feature which makes a contribution over the prior art.

In the above groups of claims, the identified features may have the potential to make a contribution over the prior art but are not common to all the claims and therefore cannot provide the required technical relationship. The only feature common to all of the claims is the composite diagnostic system comprising a membrane penetration element, a bodily fluid collection point and a test material. However this feature does not make a contribution over the prior art as it is disclosed in a large number of documents such as:

D1: US 4637403 A
D2: WO 2008/085052 A2
D3: WO 2002/078533 A2
D4: US 2003/0013121 A1
D5: US 6264619 B1
D6 WO 2004/0758232 A2
D7 WO 1998/000812 A1
D8 US 5714390A

Therefore in this light this common feature cannot be a special technical feature. Therefore there is no special technical feature present in the claims and the requirements for unity of invention are consequently not satisfied a posteriori.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
PCT/AU2011/000315

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member					
US	4637403	AU	56990/86	AU	73691/91	AU	77505/87
		CA	2036431	DK	589486	EP	0199484
		EP	0449525	JP	6339473	JP	61286738
		US	4627445	US	4787398	US	5279294
		WO	8605966	WO	8800812		
WO	2008085052	NONE					
WO	02078533	AU	2007203157	CA	2410812	CN	1501788
		CZ	20023861	EP	1328192	MX	PA02011934
		NO	20025699	PL	368047	RU	2002135614
		US	2003191415				
US	2003/0013121	CA	2390761	US	2005227372		
US	6264619	NONE					
WO	2004078232	US	2004176704				
WO	8800812	AU	56990/86	AU	73691/91	AU	77505/87
		CA	2036431	DK	589486	EP	0199484
		EP	0449525	JP	6339473	JP	61286738
		US	4627445	US	4637403	US	4787398
		US	5279294	WO	8605966		
US	5714390	AU	42494/00	AU	43688/00	AU	48224/97
		AU	71643/01	AU	92937/98	BR	9806149
		CA	2269785	CA	2371661	EP	0933989
		EP	0935629	EP	1173763	US	5817458
		US	6127490	US	2002037498	US	6461809
		US	2002098476	US	7521176	US	2001039007
		WO	0065355	WO	0065356	WO	0203064
		WO	9816101	WO	9910405	ZA	9807756
US	5249584	US	5066859	WO	9310424		

Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.

END OF ANNEX