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(54) **Title:** METHOD AND APPARATUS FOR COLLECTING TEST DATA FROM USE OF A DISPOSABLE TEST KIT

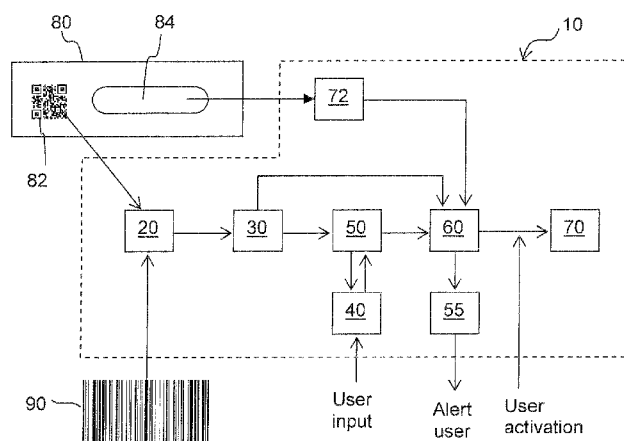


Fig. 1

(57) **Abstract:** A method of collecting test data from use of a disposable test kit, the method comprising the steps of: a code reader scanning a unique test identifier provided on the disposable test kit; an identification module identifying from the scanned unique test identifier a type of test performed by the disposable test kit; the code reader scanning a patient identifier; the identification module identifying from the scanned patient identifier a patient who has used the disposable test kit; a display and selection module automatically displaying on a display screen each of all possible distinct outcomes associated with the identified test as a selectable option; a user selecting one of the displayed all possible distinct outcomes for collection as test data; an association module automatically associating the test data with the patient; and the user activating storage of the test data to a data storer.

METHOD AND APPARATUS FOR COLLECTING TEST DATA FROM USE OF A DISPOSABLE TEST KIT

FIELD OF THE INVENTION

5 This invention relates to a method and apparatus for collecting test data from use of a disposable test kit.

BACKGROUND OF THE INVENTION

10 Disposable test kits such as home pregnancy test kits or laboratory test kits using bodily fluids such as urine or blood as an analyte to detect or diagnose disease or other medical conditions are in common use throughout the world. It is necessary to collect test data from using such disposable test kits, in order to monitor a patient's medical condition and/or for other purposes such as statistical data collection. However, mix-ups are known to occur when linking patients with their individual test data collected, and for healthcare
15 organisations and patients alike, the task of storing and organising vast volumes of test data collected would benefit from being as simple to perform and as streamlined as possible.

SUMMARY OF INVENTION

20 According to a first aspect, there is provided a method of collecting test data from use of a disposable test kit, the method comprising the steps of: a code reader scanning a unique test identifier provided on the disposable test kit; an identification module identifying from the scanned unique test identifier a type of test performed by the disposable test kit; the code reader scanning a patient identifier; the identification module identifying from the scanned patient identifier a patient who has used the disposable test kit; a display and selection
25 module automatically displaying on a display screen each of all possible distinct outcomes associated with the identified test as a selectable option; a user selecting one of the displayed all possible distinct outcomes for collection as test data; an association module automatically associating the test data with the patient; and the user activating storage of the test data to a data storer.

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The selecting one of the displayed all possible distinct outcomes for collection as test data may be such that the one of the displayed all possible distinct outcomes selected by the user corresponds to an actual outcome of the test arising from use of the disposable test kit by the patient.

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The method may further comprise the steps of: taking a photograph of the actual outcome of the test on the disposable test kit; automatically associating the photograph with the test data; and storing the photograph to the data storer.

- 5 The method may further comprise the step of: an alerting module automatically prompting the patient to perform a predetermined action based on the test data.

The automatically prompting the patient to perform a predetermined action based on the test data may include the alerting module comparing the test data with previously collected test data and selecting the predetermined action from a database of predetermined actions
10 according to results of the comparing.

The unique test identifier may comprise a quick response code having information about the type of test stored therein.
15

The data storer may be a database on a server made accessible to a healthcare organisation via a subscription service.

Each of all possible distinct outcomes may be displayed as an image corresponding to what the patient would see on the disposable test kit for each possible distinct outcome arising from use of the disposable test kit.
20

The method may further comprise automatically displaying on the display screen a distinct test result corresponding with the test data after the user has selected one of the displayed all possible distinct outcomes for collection as test data and before the user activates storage of the test data to the data storer.
25

According to a second aspect, there is provided an apparatus for collecting test data from use of a disposable test kit, the apparatus comprising: a code reader configured to scan a unique test identifier provided on the disposable test kit and further configured to scan a patient identifier; an identification module configured to identify from the scanned unique test identifier a type of test performed by the disposable test kit and further configured to identify
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from the scanned patient identifier a patient who has used the disposable test kit; a display screen; a display and selection module configured to automatically display on the display screen each of all possible distinct outcomes associated with the identified test as a selectable option for selection by a user such that only a selected one of the displayed all possible distinct outcomes is collected as test data; an association module configured to automatically associate the test data with the patient; and a data storer configured to automatically store the test data upon activation by the user.

The apparatus may further comprise a camera configured to take a photograph of an actual outcome of the test on the disposable test kit, wherein the association module is further configured to automatically associate the photograph with the test data, and wherein the data storer is further configured to automatically store the photograph in the data storer.

The apparatus may further comprise an alerting module configured to automatically prompt the identified patient to perform a predetermined action based on the test data.

The alerting module may be further configured to compare the test data with previously collected test data and to select the predetermined action from a database of predetermined actions according to different results of the comparing.

The unique test identifier may further comprise a quick response code having information about the type of test stored therein.

The data storer may be a database on a server made accessible to a healthcare organisation via a subscription service.

Each of all possible distinct outcomes may be displayed as an image corresponding to what the patient would see on the disposable test kit for each possible distinct outcome arising from use of the disposable test kit.

The display and selection module may be further configured to automatically display on the display screen a distinct test result corresponding with the test data.

According to a third aspect, there is provided a computer program stored on tangible computer readable medium, said program comprising computer readable code which, when executed on a processor, causes the processor to perform the steps of the method of the first aspect that are not performed by the user.

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According to a fourth aspect, there is provided a computer program product comprising a tangible computer readable medium and a computer program according to the third aspect, wherein the computer program is stored on the tangible computer readable medium.

10 BRIEF DESCRIPTION OF FIGURES

In order that the invention may be fully understood and readily put into practical effect there shall now be described by way of non-limitative example only exemplary embodiments of the present invention, the description being with reference to the accompanying illustrative drawings.

15 Fig. 1 is a an exemplary architectural diagram of an apparatus for collecting test data from a disposable test kit.

Fig. 2 is a schematic illustration of an exemplary display of all possible test outcomes during use of the apparatus and method.

Fig. 3 is a flow chart of an exemplary method of collecting test data from a disposable test kit.

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DETAILED DESCRIPTION

Exemplary embodiments of a method 100 and apparatus 10 for collecting test data from a disposable test kit will be described below with reference to Figs. 1 to 3, in which the same reference numerals are used to denote the same or similar parts.

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As shown in Fig. 1, the apparatus 10 for collecting test data from use of a disposable test kit 80 comprises a code reader 20 configured to scan a unique test identifier 82 provided on the disposable test kit 80 and to scan a patient identifier 90. In a preferred embodiment, the unique test identifier 82 is in the form of a quick response code while the patient identifier 90
30 is a bar code that may be provided on an identification card or a clinical record of the patient.

The apparatus 10 also comprises an identification module 30 configured to identify from the scanned unique test identifier 82 a type of test performed by the disposable test kit 80 and to identify from the scanned patient identifier 90 a patient who has used the disposable test kit
35 80, from whom the fluid analyte is obtained to run the test performed by the disposable test

kit 80. The test performed by the disposable test kit 80 is an immunoassay carried out by analysing a fluid analyte using a dipstick or lateral flow test strip provided in the disposable test kit 80.

5 Currently, different types of immunoassays are available to test for different medical conditions or to detect or diagnose disease. Examples of different types of tests that may be performed using a disposable test kit include: pregnancy test, human immunodeficiency virus (HIV) test, urine test, Malaria test, Dengue test, Leptospira test, Typhoid Fever test and so on. Appreciably, each test has its own specific possible distinct outcomes. For example,
10 in a pregnancy test, there may be four possible distinct outcomes: a negative outcome indicated by only one visible line shown in a result window 84 of the disposable test kit 80 at a 'control' location, a positive outcome indicated by two visible lines shown in the result window 84, and two invalid outcomes: a first invalid outcome indicated by no visible line at the 'control' location and a visible line at the 'test' location, and a second invalid outcome
15 indicated by no visible line at the 'control' location and no visible line at the 'test' location. The 'test' location may be marked by "T" to represent Test, and the 'control' location may be marked by "C" to represent Control in the result window 84.

The apparatus 10 further comprises a display screen 40 and a display and selection module
20 50 configured to automatically display on the display screen 40 each of all possible distinct outcomes associated with the identified test as a selectable option for selection by a user. This may be achieved by displaying each of the possible distinct outcomes 51, 52, 53, 54 on the screen together with its own option button 51b, 52b, 53b, 54bas shown in Fig. 2. Each option button 51b, 52b, 53b, 54b may be selected by touching that option button if the
25 display screen is a touch screen, or using a mouse to click on the option button if the display screen is connected to a computing device having a mouse input. Alternatively, each of the possible distinct outcomes may be displayed as a selectable item itself without any option buttons required so that selection is made by touching or mouse-clicking on one of the possible distinct outcomes directly.

30

In a preferred embodiment, each of the possible distinct outcomes is displayed as an image of a result window that corresponds with what the patient of the disposable test kit 80 would see in the result window for that particular outcome as arising from use of the disposable test kit 80. For example, if the disposable test kit was a pregnancy test having four possible
35 distinct outcomes, all four possible distinct outcomes would be displayed as: a first image of

a result window 84 showing one visible line at the 'control' location for a negative outcome 51, a second image of a result window showing two visible lines for a positive outcome 52, a third image of a result window showing one visible line at the 'test' location but no visible line at the 'control' location 53 for a first invalid outcome, and a fourth image of a result window showing no visible lines for a second invalid outcome 54. In this way, the user is presented with a multiple choice assessment in which the user can select an option that visually matches an actual outcome of the test that is visible on the disposable test kit after use of the disposable test kit by the patient.

The apparatus 10 is configured such that only the selected one of the displayed possible distinct outcomes is collected as test data.

In a preferred embodiment, the display and selection module 50 is further configured to automatically display on the display screen 40 a distinct test result corresponding with the test data after selection of one of the possible distinct outcomes by the user. In this way, the user does not need to mentally interpret the outcome of the test that is visible on the disposable test kit 80, but only needs to select a displayed image on the display screen that matches what is seen on the disposable test kit, and a distinct test result is automatically displayed. Continuing with the example of the disposable test kit 80 being a pregnancy test kit, upon the user selecting the second image 52 as shown in Fig. 2, a result such as "Pregnancy Positive" or the like will be displayed on the display screen. To facilitate this feature, the distinct test results that are known to correspond with the possible distinct outcomes of the test are stored in a library accessible to the display and selection module 50.

The apparatus 10 further comprises an association module 60 configured to automatically associate the test data with the identified patient. In this way, test data can be stored for each specific patient and mix-ups between patients and test outcomes can be eliminated.

The apparatus 10 also comprises a data storer 70 configured to automatically store the test data in the data storer 70 upon activation by the user. The data storer 70 may be one or more of an internal memory of a computing device such as a smart phone or hard disk of a computer, an external storage device such as an SD card or flash memory device, a cloud computing storage, a database on a server and so on. Additionally, test data in the data storer 70 may be configured to be made accessible to a healthcare organisation via a subscription service. Storage of the tested data to the data storer 70 is configured to be activated by the user, for example, by touching or clicking on a "save" icon displayed on the

display screen after selection of one of the possible distinct outcomes.

Optionally, the apparatus 10 may further comprise a camera 72 configured to take a photograph of an actual outcome of the test on the disposable test kit 80. In such an embodiment, the association module 60 is further configured to automatically associate the photograph with the test data, and the data storer 70 is further configured to automatically store the photograph. The photograph is intended to serve as evidence and as a back-up to check that the test data corresponds with the actual outcome of the test on the disposable test kit 80.

The apparatus 10 may also further comprise an alerting module 55 configured to automatically prompt the patient to perform a predetermined action based on the test data. For example, in the case where the type of test is a blood sugar level test, if the test data indicates that the blood sugar level is beyond a predetermined level, the alerting module may prompt the patient to see their doctor. Prompting the patient may be by means of sending an sms or an email to the patient, or displaying on the display screen an appropriate message. Additionally, the alerting module 55 may be further configured to compare the test data with previously collected test data and to select the predetermined action from a database of predetermined actions according to different results of the comparing. This is envisaged for test in which different magnitudes of change between the test data and previously collected test data require different actions to be taken. For example, where the apparatus 10 is configured as an HBA1c (refers to glycated haemoglobin (A1c), which identifies average plasma glucose concentration) glucose monitoring device, test data collected will be captured each time a user saves the latest test results. If the latest collected test data exceeds a predetermined difference when compared with the previously collected data, the patient will be prompted to take a predetermined appropriate action according to the magnitude of the difference.

One embodiment of the apparatus 10 is in the form of a smart phone (as already shown in Fig. 2) in which the code reader 20 is provided as an application making use of the camera provided in the smart phone, and the display screen 40 is the display screen of the smart phone. The identification module 30, the display and selection module 50, the association module 60 and the alerting module 55 (optional) are provided in an application configured to work with the operating system of the smart phone. The data storer 70 may include the internal memory of the smart phone as well as a database on a server that is accessed via

cloud computing. The smart phone embodiment is particularly suited for point-of-care use in which the user and the patient who uses the disposable test kit are expected to be the same person, or in which the user is a caregiver of the patient.

5 An alternative embodiment of the apparatus 10 is in the form of a computer (not shown) in which the code reader 20 is provided as a handheld or stationary laser barcode scanner and the display screen 40 is a monitor of the computer. The identification module 30, the display and selection module 50, the association module 60 and the alerting module 55 (optional) are provided as a software application configured to work with the operating system of the
10 computer. The data storer 70 may include the internal hard disk of the computer as well as a database on a network server to which the computer is connected. The computer embodiment is particularly suited for organisational use in which the user may be a staff member of the organisation facilitating the collection of test data from multiple patients each using a unique disposable test kit.

15

The method 100 of collecting test data from use of the disposable test kit will now be described with reference to Fig. 3. In the method 100, the code reader 20 is used to scan a unique test identifier 82 provided on the disposable test kit 80 (101) and from the scan, the identification module 30 identifies a type of test performed by the disposable test kit (102).

20 The code reader 20 is also used to scan a patient identifier 90 (103) from which the identification module 30 identifies the patient who used the disposable test kit (104). The display and selection module 50 then automatically displays each of all possible distinct outcomes associated with the identified test on the display screen 40 as a selectable option (105). The user selects one of the displayed outcomes for collection as test data (106). The
25 selecting step (106) should be such that the outcome selected by the user corresponds to an actual outcome of the test arising from use of the disposable test kit by the patient. The association module 60 then automatically associates the test data with the patient (107) and the user finally activates storage of the test data to the data storer 70 (108).

30 The method (100) may optionally further comprise taking a photograph of the actual outcome of the test on the disposable test kit, automatically associating the photograph with the test data and storing the photograph to the data storer. Storing of the photograph may be user activated or automatically performed.

35 Depending on the test data, the method may further automatically prompt the patient to

perform a predetermined action based on the test data. This may comprise sending an electronic message to the patient. The automatically prompting may include comparing the test data with previously collected test data and selecting the predetermined action from a database of predetermined actions according to results of the comparing.

5

The apparatus 10 and method 100 thus allow test data to be collected without requiring the user to mentally interpret what is seen on the disposable test kit 80. The user only needs to input into the apparatus 10 what the user sees on the disposable test kit 80 without having to interpret what the test outcome means. Interpretation is performed by the apparatus 10 according to the input test outcome that has been predetermined to correlate with a specific test result. This reduces one possible source of human error. At the same time, the apparatus 10 and method 100 do not rely on using the apparatus 10 to automatically read the test outcome shown by the disposable test kit 80, since it is the user who selects one of the possible distinct outcomes displayed by the apparatus 10 according to what the user
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sees on the disposable test kit 80. The method 100 and apparatus 10 thus combine the strengths of human and machine capabilities while reducing possibilities of human and machine error.

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Whilst there has been described in the foregoing description exemplary embodiments of the present invention, it will be understood by those skilled in the technology concerned that many variations in details of design, construction and/or operation may be made without departing from the present invention.

CLAIMS

1. A method of collecting test data from use of a disposable test kit, the method comprising the steps of:
 - 5 a) a code reader scanning a unique test identifier provided on the disposable test kit;
 - b) an identification module identifying from the scanned unique test identifier a type of test performed by the disposable test kit;
 - c) the code reader scanning a patient identifier;
 - d) the identification module identifying from the scanned patient identifier a patient who
10 has used the disposable test kit;
 - e) a display and selection module automatically displaying on a display screen each of all possible distinct outcomes associated with the identified test as a selectable option;
 - f) a user selecting one of the displayed all possible distinct outcomes for collection as
15 test data;
 - g) an association module automatically associating the test data with the patient; and
 - h) the user activating storage of the test data to a data storer.
2. The method of claim 1, wherein the selecting in step f) is such that the one of the
20 displayed all possible distinct outcomes selected by the user corresponds to an actual outcome of the test arising from use of the disposable test kit by the patient.
3. The method of claim 2, further comprising the steps of:
 - 25 i) taking a photograph of the actual outcome of the test on the disposable test kit;
 - j) automatically associating the photograph with the test data; and
 - k) storing the photograph to the data storer.
4. The method of any one of claims 1 to 3, further comprising the step of:
 - 30 l) an alerting module automatically prompting the patient to perform a predetermined action based on the test data.
5. The method of claim 4, wherein the automatically prompting in step l) includes the alerting module comparing the test data with previously collected test data and selecting the predetermined action from a database of predetermined actions according to results
35 of the comparing.

6. The method of any one of claims 1 to 5, wherein the unique test identifier comprises a quick response code having information about the type of test stored therein.

5 7. The method of any one of claims 1 to 6, wherein the data storer is a database on a server made accessible to a healthcare organisation via a subscription service.

8. The method of any one of claims 1 to 7, wherein each of all possible distinct outcomes is displayed as an image corresponding to what the patient would see on the disposable
10 test kit for each possible distinct outcome arising from use of the disposable test kit.

9. The method of any one of claims 1 to 8, further comprising: after step f) and before step h), automatically displaying on the display screen a distinct test result corresponding with the test data.

15

10. An apparatus for collecting test data from use of a disposable test kit, the apparatus comprising:

a code reader configured to scan a unique test identifier provided on the disposable test kit and further configured to scan a patient identifier;

20 an identification module configured to identify from the scanned unique test identifier a type of test performed by the disposable test kit and further configured to identify from the scanned patient identifier a patient who has used the disposable test kit;

a display screen;

25 a display and selection module configured to automatically display on the display screen each of all possible distinct outcomes associated with the identified test as a selectable option for selection by a user such that only a selected one of the displayed all possible distinct outcomes is collected as test data;

an association module configured to automatically associate the test data with the patient; and

30 a data storer configured to automatically store the test data upon activation by the user.

11. The apparatus of claim 10, further comprising a camera configured to take a photograph of an actual outcome of the test on the disposable test kit, wherein the association

module is further configured to automatically associate the photograph with the test data, and wherein the data storer is further configured to automatically store the photograph in the data storer.

- 5 12. The apparatus of claim 10 or 11, further comprising an alerting module configured to automatically prompt the identified patient to perform a predetermined action based on the test data.
- 10 13. The apparatus of claim 12, wherein the alerting module is further configured to compare the test data with previously collected test data and to select the predetermined action from a database of predetermined actions according to different results of the comparing.
14. The apparatus of any one of claims 10 to 13, wherein the unique test identifier comprises a quick response code having information about the type of test stored therein.
- 15 15. The apparatus of any one of claims 10 to 14, wherein the data storer is a database on a server made accessible to a healthcare organisation via a subscription service.
- 20 16. The apparatus of any one of claims 10 to 15, wherein each of all possible distinct outcomes is displayed as an image corresponding to what the patient would see on the disposable test kit for each possible distinct outcome arising from use of the disposable test kit.
- 25 17. The apparatus of any one of claims 10 to 16, wherein the display and selection module is further configured to automatically display on the display screen a distinct test result corresponding with the test data.
- 30 18. A computer program stored on tangible computer readable medium, said program comprising computer readable code which, when executed on a processor, causes the processor to perform the steps of claim 1 that are not performed by the user.
19. A computer program product comprising a tangible computer readable medium and a computer program according to claim 18, wherein the computer program is stored on the tangible computer readable medium.

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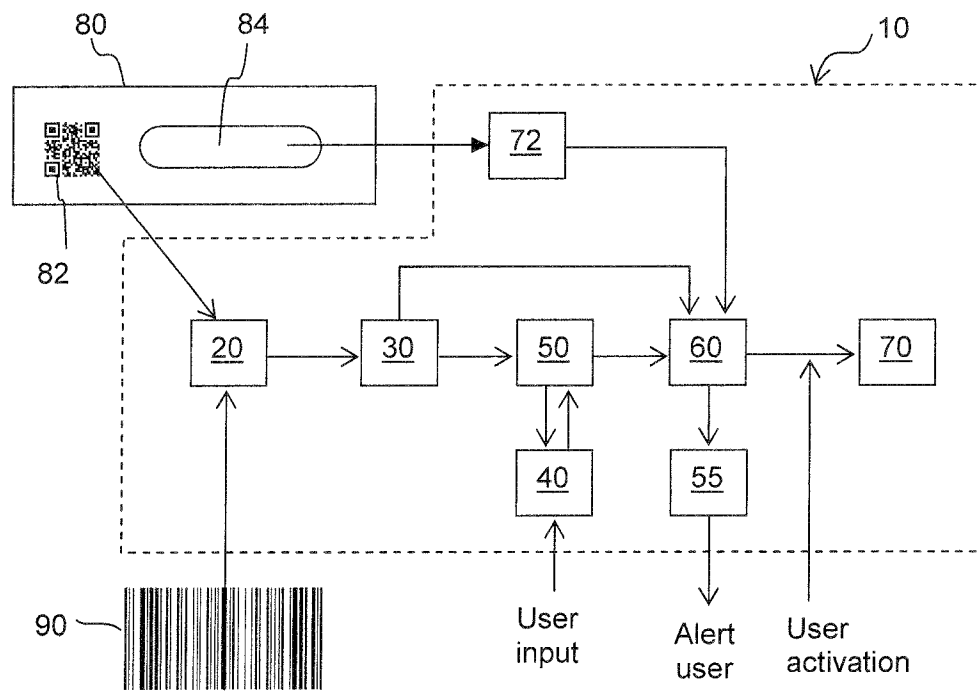


Fig. 1

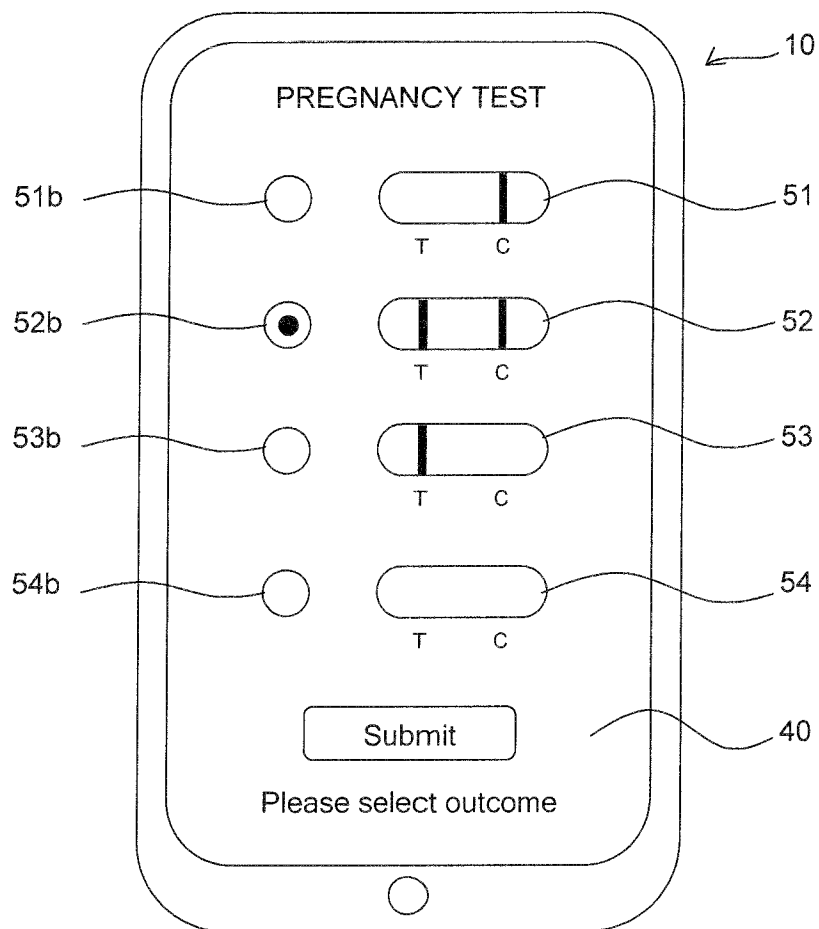


Fig. 2

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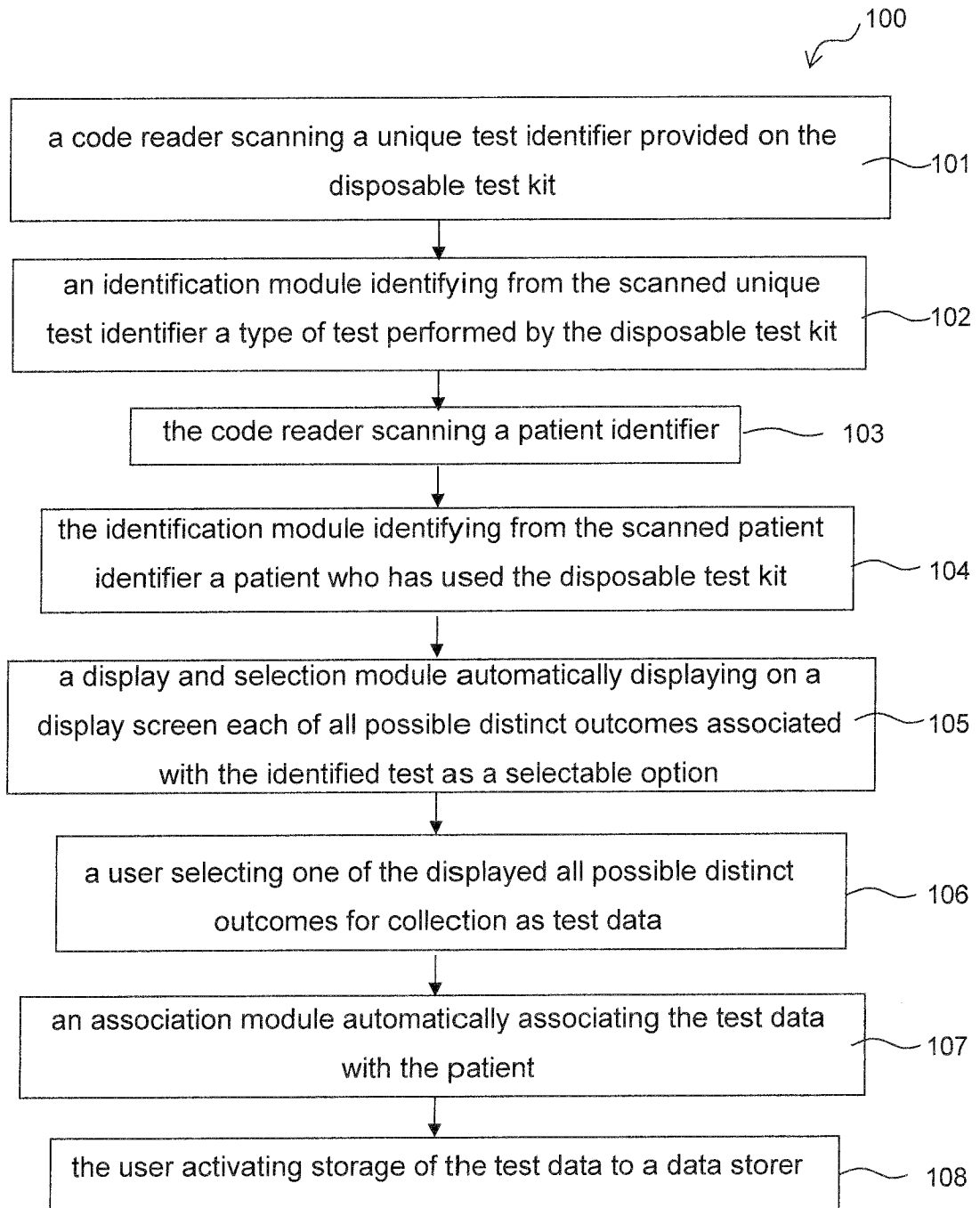


Fig. 3

INTERNATIONAL SEARCH REPORT

International application No.

PCT/SG2015/050185

A. CLASSIFICATION OF SUBJECT MATTER			
Int.Cl. G01N33/52 (2006.01) i, G01N33/543 (2006.01) i			
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)			
Int.Cl. G01N33/52, G01N33/543			
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched			
Published examined utility model applications of Japan 1922-1996 Published unexamined utility model applications of Japan 1971-2015 Registered utility model specifications of Japan 1996-2015 Published registered utility model applications of Japan 1994-2015			
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)			
JSTPlus/JMEDPlus/JST/580 (JDreamIII)			
C. DOCUMENTS CONSIDERED TO BE RELEVANT			
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.	
A	US 2012/0288851 A1 (ARKRAY, INC.) 2012.11.15, paragraphs [0043]-[0061], Figs. 1-8 & EP 2495570 A1 & WO 2012/070111 A1 & CN 102687022 A	1-19	
A	JP 2013-170835 A (Sharp Corporation) 2013.09.02, paragraphs [0002], [0103]-[0115], Fig. 1 & WO 2013/122121 A1	1-19	
A	US 2010/0196200 A1 (Jin Po Lee, KAIWOOD TECHNOLOGY CO., LTD) 2010.08.05, paragraphs [0001]-[0005], Figs. 1A-1C (Family: none)	1-19	
☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.			
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