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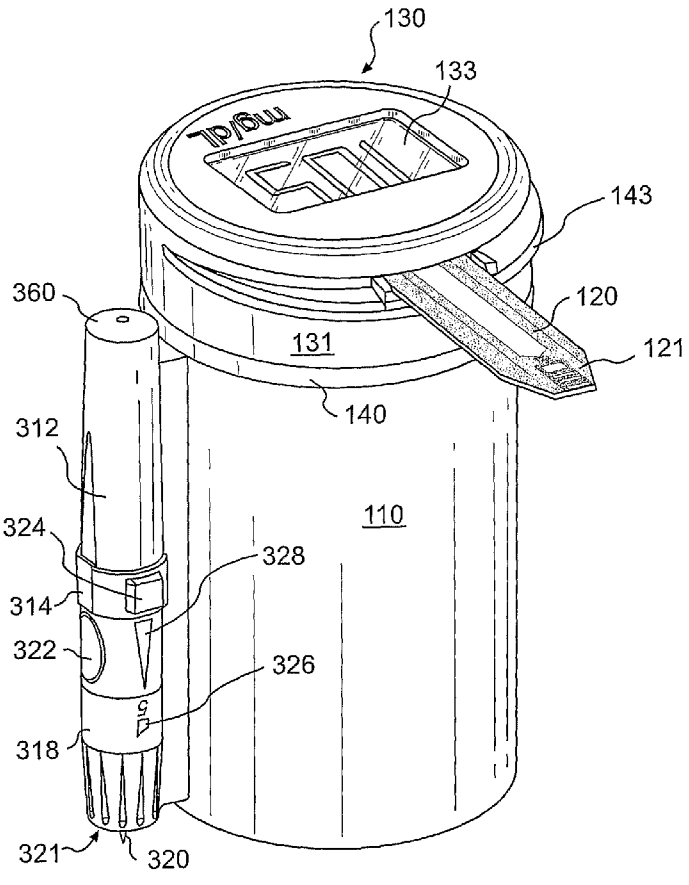
(54) Title: INTEGRATED DIAGNOSTIC TEST SYSTEM



(57) Abstract: A system for diagnostic testing may include a meter (130) for performing a diagnostic test on a sample applied to a test media (120) and a container (110) configured to contain test media compatible with the meter. The meter may include a closure portion (140) for selectively closing the opening of the container. The system may further provide a sampling device (360), such as a lancet, operable connected to the container. The system may also provide mechanisms to disable a power source, an auto-on function of the meter, a diagnostic testing function of the meter, or other function of the meter when it has been determined that a triggering event has occurred. The triggering event may be, e.g., the expiration of a certain expiration of a certain time period, passage of a certain date, performance of a certain quantity of diagnostic tests, or use of a certain quantity of test media.

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INTEGRATED DIAGNOSTIC TEST SYSTEM

DESCRIPTION

[001] The present application claims the benefit of copending Provisional U.S. Patent Application 60/533,557, entitled "TEST STRIP CONTAINER WITH INTEGRATED METER," filed December 31, 2003, and Utility U.S. Patent Application 10/857,917, entitled "INTEGRATED DIAGNOSTIC TEST SYSTEM", filed June 2, 2004, which are incorporated herein by reference in their entirety.

[002] The present invention is also related to copending U.S. Design Patent Applications 29/206,526 (Attorney Docket No. 06882.0111) and 29/206,525 (Attorney Docket No. 06882.0112), both entitled "METER FOR AN INTEGRATED DIAGNOSTIC TEST SYSTEM" and filed on even date herewith, which are incorporated herein by reference in their entirety.

Technical Field

[003] The present invention relates to the field of diagnostic testing and, more particularly, to diagnostic testing systems using electronic meters.

Background

[004] Diagnostic testing systems are commonly used to perform various types of diagnostic tests on various types of samples. The diagnostic test may be a qualitative or quantitative test to determine the presence, concentration or amount of one or more analytes in a sample. The analyte may be a medically significant analyte – e.g., glucose, ketones, cholesterol, triglycerides, human choriogonadotropin (HCG), hemoglobin A1C, fructosamine, carbohydrates, tumor markers, lead, anti-epilepsy drugs, bilirubin, liver function markers, toxins or their metabolites, controlled substances, blood coagulation factors (PT, ATPP), etc. –

contained in a biological sample – e.g., blood, urine, tissue, saliva, etc. However the diagnostic test is not limited to the medical field. For instance, the diagnostic test may determine the presence or quantity of an analyte in a water, soil or chemical sample.

[005] Such diagnostic testing systems may include a test media (e.g., a test strip, tab, disc, etc.) configured to react to the presence of the analyte in a sample, and a separate electronic meter configured to interface with the test media in order to conduct the diagnostic test and indicate the results of the diagnostic test to the user.

[006] In order to conduct the diagnostic test, a user must first obtain a sample test media, e.g., a test strip, from a container, then obtain a sample using a sampling device (e.g., by drawing blood using a lancet), and then apply the sample to the test media (either before or after inserting the test media into the meter interface). The meter then performs the diagnostic test on the sample and indicates the result to the user, e.g., using a numerical display.

[007] However, the diagnostic meter is often bulky. Further, because the user must pick up and put down the test media container, sampling device and meter in succession, the test media container, sampling device and meter are easily separated from each other, so that the user may find themselves without one or more of the components necessary to conduct the diagnostic test. Thus, it is inconvenient for the user to carry a separate test media container, electronic meter and sampling device.

[008] Further, test media from different brands or manufacturing lots may respond differently to the presence or concentration of analyte in the sample. In order to obtain more accurate results, the electronic meter may be calibrated with

respect to a given brand or lot of test strips by providing it with one or more brand- or lot-specific calibration parameters that correlate the response from particular a particular brand or lot of test media to a standardized reference.

[009] The user may be required to provide the meter with the appropriate calibration parameters in a separate "coding" step. For example, the test media container may display a code number from which the meter can determine the appropriate calibration information. The user may then manually enter the code number (e.g., using buttons or other user input devices on the meter) so as to provide the calibration data to the meter. Alternatively, the calibration data may be downloaded, e.g., from a manufacturer's website. In another approach, the test media container may be provided with an associated code chip in which the calibration data is stored electronically. The user may provide the calibration data to the meter by inserting the code chip into a corresponding port on the meter.

[010] This coding step can be inconvenient or difficult for the user. For example, elderly or infirm users may have difficulty downloading calibration data or inserting code chips. Further, users may forget to calibrate the meter for use with a new brand or lot of test media. Consequently, the user may enter incorrect calibration parameters or codes, or the user may use test media from one brand or lot with a meter calibrated for use with test media from a different brand or lot. However, once a meter is calibrated for a given lot of test media, the use of that meter with test media from another lot may lead to erroneous results that could have serious consequences for the user. For example, where the test is a self-test of blood glucose level, an erroneous result can misinform the user as to their blood glucose level, which may lead to the user having a diabetic seizure.

[011] Accordingly, there is a need for diagnostic testing systems that are convenient to carry and that minimize the chance that a user will use a diagnostic meter with test media from a brand or lot for which the meter has not been calibrated.

SUMMARY

[012] The present invention meets these and other needs by providing a system for diagnostic testing having a meter for performing a diagnostic test on a sample applied to a test media, a container configured to contain test media compatible with the meter, wherein the meter includes a closure portion for selectively closing the opening of the container. The present invention further provides a sampling device, such as a lancet, operable connected to the container such that that a user may use the sampling device to obtain a sample without disconnecting the sampling device from the container.

[013] The present invention also provides mechanisms to disable a power source, an auto-on function of the meter, a diagnostic testing function of the meter or other function of the meter when it has been determined that a triggering event has occurred. The triggering event may be, e.g., the expiration of a certain time period, passage of a certain date, performance of a certain quantity of diagnostic tests, or use of a certain quantity of test media. The present invention further provides mechanisms to reconfigure the meter to perform a new function when it has been determined that the triggering event has occurred.

[014] Additional aspects and advantages of the invention will be set forth in part in the description which follows, and in part will be obvious from the description, or may be learned by practice of the invention. The advantages of the

invention will be realized and attained by means of the elements and combinations particularly pointed out in the appended claims.

[015] It is to be understood that both the foregoing general description and the following detailed description are exemplary and explanatory only and are not restrictive of the invention, as claimed.

BRIEF DESCRIPTION OF THE DRAWINGS

[016] The accompanying drawings, which are incorporated in and constitute a part of this specification, illustrate several embodiments of the invention and together with the description, serve to explain the principles of the invention.

[017] Figure 1 is a perspective view of a first embodiment of an integrated system consistent with the present invention.

[018] Figure 2 is a perspective view of a second embodiment of an integrated system consistent with the present invention.

[019] Figure 3 is a perspective view of a third embodiment of an integrated system consistent with the present invention.

[020] Figure 4 is a block diagram illustrating the functional components of a diagnostic meter consistent with the present invention.

[021] Figure 5 is a cross-sectional view of an integrated fourth embodiment of an integrated system consistent with the present invention.

DESCRIPTION OF THE EMBODIMENTS

[022] Reference will now be made in detail to the exemplary embodiments of the invention, examples of which are illustrated in the accompanying drawings. Wherever possible, the same reference numbers will be used throughout the drawings to refer to the same or like parts.

[023] 1. The Integrated System

[024] Figure 1 shows an integrated system 100 for conducting a diagnostic test in accordance with an exemplary embodiment of the present invention. Exemplary integrated system 100 includes a container 110 for containing test media, such as test strips 120, and a meter 130 for performing a diagnostic test using the test strips 120 contained in container 110.

[025] In one illustrative embodiment, the diagnostic test is the determination of the amount of glucose in a sample of whole blood applied to a sample chamber 121 of test strip 120. For blood glucose testing, meter 130 may employ any of a variety of techniques. Preferably, the diagnostic test employs an electrochemical technique (e.g., coulometry, amperometry, potentiometry, etc.). Exemplary electrochemical systems are described in prior Application Ser. Nos. 10/286,648, filed November 1, 2002, and 10/420,995, filed April 21, 2003, both entitled "SYSTEM AND METHOD FOR BLOOD GLUCOSE TESTING" and both having assignee in common with the instant application, which are incorporated by reference herein in their entirety. Alternatively, meter 130 may employ a photometric technique (e.g., reflection, transmission, scattering, absorption, fluorescence, electro-chemiluminescence, etc.) to determine the amount of glucose in the sample. Exemplary photometric systems are described in U.S. Patent Nos. 6,201,607, 6,284,550 and 6,541,266, each having assignee in common with the instant application, which are incorporated by reference herein in their entirety. However, electrochemical techniques are currently preferred because, among other reasons, they require a smaller blood sample (on the order of 1 μL or less) than the photometric techniques (on the order of 1 μL or greater). Further, the instrumentation for the electrochemical techniques typically requires less power and

can typically be made more compactly than the instrumentation for the photometric techniques.

[026] Integrated system 100 will be illustrated with reference to a diagnostic test to determine the concentration of blood glucose using an electrochemical technique, with the understanding that the principles of the present invention are equally applicable to other types of diagnostic tests and techniques, such as those mentioned above. Further, although the present invention has been illustrated as utilizing test media in the form of test strips 120, exemplary embodiments of the present invention are not limited to a particular type of media and those of skill in the art will recognize that the principles of the present invention are equally applicable to diagnostic testing systems which employ test media in other forms, e.g., tabs, discs, etc.

[027] Meter 130 may be contained within a housing 131. The meter housing 131 is attached to or otherwise includes a closure portion 140 (bottom of meter 130 in Figure 1) which engages container 110 in order to selectively close an opening 111 of the container. Opening 111 may be the only opening in the container 110. In an illustrative embodiment, meter housing 131 has one side (e.g., the bottom of meter housing 131 in Figure 1) which is shaped to conform to the closure 140 and is affixed to the closure 140, e.g., by a mechanical attachment (clips, etc.), bonding, gluing, welding, etc. Alternatively, closure portion 140 may be formed integrally with the meter housing 131. The meter 130 and closure 140 together thus form a cap or lid for the container 110.

[028] The closure 140 may be configured to engage the container in a number of ways. In the closed position (see Figure 3), closure 140 closes opening 111 sufficiently to prevent loss or removal of the test media from container 110.

Accordingly, closure 140 is configured to engage container 110 so as to prevent test strips 120 from passing through opening 111 when closure 140 is in the closed position. Container 110 and closure 140 may also be configured to prevent the infiltration of light, liquid, vapor, and/or air into the container so as to prevent contamination or degradation of the test media. Where the test media is configured such that it is toxic or may present a choking hazard, closure 140 may optionally be configured to be child-resistant in order to prevent children from opening container 110 and accessing the test media. For example, closure 140 and container 110 may be configured in a manner similar to well known child-resistant containers for pharmaceuticals or household chemicals.

[029] Closure 140 may be configured as a twist-off cap, e.g., by providing inter-engaging threads (not shown) on the closure 140 and the container 110. Alternatively, closure 140 may be configured to slide over the opening, e.g., within grooves (not shown) beside the opening. As a further alternative, closure 140 may be provided with a catch (not shown), such as a detent, that engages container 110 (or vice versa). The catch may be released by a button. However, in an illustrative embodiment, the closure 140 is configured to form a press-fit seal with the container so as to seal the opening against the infiltration of light, liquid and vapor. For example, in Figure 1, closure 140 is configured with a recess (not shown) to press-fit to the outside of the opening 111, so that the rim of the opening 111 fits within the closure portion 140. Alternatively, closure 140 may be configured with a projection 241 shaped to engage the inside of the opening 111, as shown in Figure 2. However, it will be understood that the present invention is not limited to any particular configuration of the container and closure and that other configurations may be employed consistent with the principles of the present invention.

[030] For ease of manufacture, opening 111 may be made in the same shape as the container 110. The housing 131 of meter 130 is likewise preferably have an exterior shape similar to that of the container 110 so that the integrated system may be more comfortably held and carried, e.g., in a user's pocket. However, it will be understood that the container 110, meter 130 and opening 111 need not be of the same exterior shape, and the container and meter may be configured in different shapes without departing from the scope of the present invention.

[031] Preferably, the container 110 is generally a right circular cylinder and opening 111 has a circular shape as shown in Figures 1 and 2. A circular shape is one possible configuration for the opening because it allows a uniformly tight seal to be formed with a press-fit between the closure portion 140 and the container 110. As shows in Figures 1-3, meter 130 may also be generally circular and cylindrical and have a width similar to the width of the container so that the integrated meter 100 has an overall generally circular-cylindrical shape that is comfortable to hold and to carry, e.g., in a pants pocket. However, the container 110, meter 130 and opening 111 may be made in any of a number of other shapes. For example, the container may formed as a right oval, elliptical or rectangular cylinder in order to better conform to a user's shirt pocket.

[032] Container 110 and closure 140 may also be provided with corresponding flanges 112 and 242, respectively, that fit flush against each other when the closure portion is in the closed position in order to further prevent the infiltration of liquid and vapor. Closure 140 is also preferably provided with a protrusion 143 which extends beyond the side of container 110 sufficiently to aid to the user in opening and closing the container 110, e.g., by pushing upward with the

thumb against the protrusion 143. Protrusion 143 may be an extension of the flange 242, as shown in Figure 2. Alternatively, protrusion 143 may be formed directly on meter housing 131, as shown in Figure 3.

[033] As shown in Figure 1, container 110 may be opened by completely removing meter 130 and closure portion 140 from the container 110. Alternatively, meter 130 and/or closure 140 may be connected to container 110 in order to prevent the meter 130 from becoming separated from the container. Container 110 and meter 130 may be connected by, e.g., a hinge, lanyard or other flexible connector, such as a flexible plastic band or wire, etc. (not shown). In an illustrative embodiment, a hinge 251 connects the container 110 and the meter housing 131 and/or closure 140. Hinge 251 is positioned such that projection 241 fits within opening 111 in the closed position. The connector (e.g., hinge 251) may have one end connected to the container 110 and the other end connected to the closure 140 and/or meter housing 131. For example, container 110 and closure 140 may be integrally connected by a hinge, e.g., as shown in U.S. Patent No. 5,723,085, entitled "PROCESS AND APPARATUS FOR MAKING A LEAK PROOF CAP AND BODY ASSEMBLY," which is incorporated by reference herein in its entirety. Alternatively, one end of the connector (e.g., hinge 251) may be connected to a ring 252 that is sized to fit over container 110, as shown in Figure 2. Ring 252 may be configured to loosely frictionally engage container 110. As another alternative, ring 252 may be affixed to the container 110, e.g., by welding, gluing, etc.

[034] In an exemplary embodiment, container 110 and closure 140 are formed of polypropylene using an injection molding process. However, other materials and processes may be used without departing from the scope of the present invention.

[035] Integrated system 100 may further include a sampling device which the user may use to obtain a sample for testing. The sampling device may be adapted to obtain a biological sample. For instance, the sampling device may be a lancing device that the user may use to draw blood, e.g., for a diagnostic test of blood glucose level.

[036] An exemplary integrated system incorporating a lancing device 360 is shown in Figure 3. Exemplary lancing device 360 includes a rearward body 312, a finger cover 314, an exterior nozzle 318, an interior nozzle 322 and a trigger 324. Exemplary lancing device 360 further includes an internal spring (not shown) that is used to propel lancet 320 beyond contact surface 321 and through the skin to depth selected by the user.

[037] As shown in Figure 3, the exemplary lancing device 360 is connected to container 110. Lancing device 360 may be permanently connected to the container, for instance, by forming, e.g., rearward body 312, finger cover 314, exterior nozzle 318 or interior nozzle 322 integrally with the container 110, or by bonding one of these components to the container 110, e.g., by a mechanical attachment (clips, etc.), bonding, gluing, welding, etc. Alternatively, lancing device 360 may be releasably connected to the container 110 by providing corresponding releasable connectors on lancing device 360 and container 110. For example, lancing device 360 may be provided with one or more slots, holes or clips that engage corresponding structures on container 110, or vice versa. As further alternatives, lancing device 360 may be connected to housing 131 of meter 130, or to closure portion 140. Preferably only one of the rearward body 312, finger cover 314, exterior nozzle 318 or interior nozzle 322 is connected to the container 110 so

that lancing device 360 may be adjusted and used without disconnecting it from the container 110.

[038] In order to draw a sample using exemplary lancing device 360, the user may first select a desired depth of penetration of lancet 320 by rotating exterior nozzle 318 so that the desired depth indicator 326 on exterior nozzle 318 is aligned with arrow 328 on interior nozzle 322. Next, the user loads the internal spring by pulling interior nozzle 322 away from rearward body 312 and places contact surface 321 against the surface to be lanced. The user may then actuate trigger 324 to release the internal spring, which propels lancet 320 beyond contact surface 321 to the indicated depth, and thus into the skin. A blood sample can then be applied to the sample chamber 121 of test strip 120.

[039] Further details of exemplary lancing device 360 are shown in prior Application Ser. No. 10/757,776, entitled "LANCING DEVICE," filed January 15, 2004, having assignee in common with the instant application, which is incorporated by reference herein in its entirety. However, the present invention is not limited to any particular sampling device, and one of skill in the art will recognize that other sampling devices can be incorporated in a manner similar to the exemplary lancing device described above.

[040] 2. Meter Electronics

[041] Figure 4 shows is a block diagram illustrating functional components of exemplary meter 130. As shown in Figure 4, meter 130 may include controller function 400, media interface 410, power source 420, user control function 430, input/output function 440, indicator function 450, media dispensing mechanism 460, voice message function 470, and environmental sensors 480. In an illustrative embodiment, the functional components of meter 130 are contained within meter

housing 131. However, it will be understood that some or all of the components of a given function may be located elsewhere in integrated system 100.

[042] Controller 400 controls the operation of the functional components of the meter in accordance with its instructions 402, which may be provided as software or firmware. Controller 400 may include processor 404, memory 406, and clock 408 functions. In an illustrative embodiment of the invention, the processor 404, memory 406, and/or clock 408 functions may be implemented using an Application Specific Integrated Circuit (ASIC), which allows controller 400 to be reduced in size in comparison to standard integrated circuit technology. However, it will be understood that the controller may be implemented using standard integrated circuit technology, or other technology, without departing from the scope of the present invention.

[043] Processor function 404 executes instructions 402 used to control the functional components 410-480 of meter 130. In particular, processor 404 executes instructions 402 necessary to perform the diagnostic test (e.g., as set forth in Application Ser. Nos. 10/286,648 and 10/420,995, incorporated by reference above). The instructions 402 for the processor 404 may be stored in memory 406 or elsewhere. Memory function 406 may also store data, such as calibration data and other data used in the performance of the diagnostic test. In exemplary embodiments of the present invention, memory 406 is used to store results of the diagnostic test, together with a time stamp and/or associated voice message, for later review or uploading (discussed below).

[044] Clock function 408 regulates the processor's execution of the instructions 402 in time. In particular, clock function 408 is used to regulate the timing of steps in the diagnostic test. For instance, processor 404 may use clock

408 to regulate an incubation time period, or other time periods, necessary for the correct performance of the diagnostic test (e.g., as set forth in Application Ser. Nos. 10/286,648 and 10/420,995, incorporated by reference above). Clock function 408 may be implemented by a single system clock or by multiple clocks for different purposes.

[045] Media interface 410 accepts test media, such as test strips 120, for testing and includes a channel 411 to ensure that the test media is correctly positioned when inserted by a user or media dispensing mechanism 460. Interface 410 includes one or more media sensors for determining, e.g., whether a test strip 120 has been correctly inserted in the test port 410 (i.e., whether interface side 122 of test strip 120 is properly positioned with respect to the media sensors); whether an adequately-sized sample has been applied to the sample chamber on the sample side 121 of the test strip; and the presence or concentration of analyte in the sample. For meters using electrochemical techniques, the media sensors may include one or more electrical contacts corresponding to electrodes on the interface side 122 of test strip 120. For meters using photometric techniques, at least the presence or concentration of analyte in the sample is determined using an optical sensor, e.g., a light emitting diode and corresponding photo-detector.

[046] Power source 420 provides power to the electronic components of meter 130. In an illustrative embodiment, the power source is a lithium coin cell battery. However, other power sources, such as other types of batteries, solar cells, or AC/DC converters may be used without departing from the scope of the present invention. The output of the power source may be regulated, e.g., by a voltage regulator circuit.

[047] User control function 430 may include, for example, one or more buttons, switches, keys or other controls for controlling the functions of meter 130. In an illustrative embodiment, user control function 430 is implemented by one or more buttons 132 placed on the left side of meter housing 131 (see Figure 1). In this position, button 132 may be comfortably pressed with the right thumb or index finger while the integrated system 100 is held in the right hand, with display 133 in an upright position. However, user control 430 may be positioned elsewhere on meter 130. For example, button 132 may be placed on right hand side of the meter housing 131 in order to be more convenient for left handed users, or on the top of the meter, e.g., centered under display 133. As another example, user control function 430 may include a switch actuated when the user opens the closure 140, e.g., so that the meter 130 automatically turns on when the user opens container 110 to retrieve a test strip.

[048] In an exemplary embodiment of the present invention, user control function 430 is implemented using a single control, e.g., a single button 132, that is used to control a plurality of meter functions. For example, user control 430 may be used to control the input/output 440 function, indicator function 450, media dispensing mechanism 460, and/or voice message function 470 by providing commands to these functions directly or through controller 400. User control 430 may also be used to control the diagnostic test function of controller 400. For example, when a test is to be performed using a control solution (e.g., as set forth in Application Ser. Nos. 10/286,648 and 10/420,995, incorporated by reference above), button 132 may be held down to indicate to controller 400 that the current sample is of a control solution and, consequently, that controller 400 should perform a control test on the current strip.

[049] Alternatively, a plurality of user controls, e.g., a plurality of buttons 132, may be provided, with each button having different functions. For example, two buttons may be provided to allow a user to scroll through diagnostic test results stored in memory 406 in either forward or reverse directions. As an aid to the user, the function of the button or buttons 132 at the particular time may be dynamically indicated by indicator function 450. For example, when reviewing previous test results, indicator function 450, e.g., a display 133, may instruct the user to "PRESS BUTTON TO VIEW NEXT RESULT." Further, user controls 430 may have different functions at different times. For example, holding button 132 down upon the insertion of a test strip into media interface 410 may command the controller to perform a control test on that strip, while holding the button down without inserting a test strip may command the controller to display the result of the previous diagnostic test.

[050] Input/output function 440 provides for the downloading of data or instructions 402 to meter 130, and/or the uploading of data from meter 130. Input/output function 440 may be used, for example, to upload the results of a diagnostic test or tests so that they may be transferred to a storage device or to a third party, e.g., a medical care provider for use in treating the user. Alternatively, input/output function 440 may be used to download data (e.g., calibration data) or instructions 402 (e.g., updated software) to the meter 130. The uploading and downloading of data and/or instructions is further explained in prior Application Ser. No. 09/512,919, entitled "SYSTEMS AND METHODS FOR COMMUNICATING DATA FROM METERS," filed February 25, 2000, having assignee in common with the present application, which is incorporated by reference herein in its entirety. Input/output function 440 may be implemented using any conventional digital or

analog information interface, e.g., a serial port, a parallel port, an optical port, an infrared interface, etc.

[051] Indicator function 450 indicates the result of the diagnostic test to the user, e.g., as a numerical value together with the units of measurement. In addition to indicating the result of the diagnostic test, the indicator may present other information to the user. For example, the indicator 450 may indicate the average result of a plurality of tests, the time and/or date, remaining battery life, etc. (e.g., as set forth in Application Ser. Nos. 10/286,648 and 10/420,995, incorporated by reference above). Indicator 450 may also be used to prompt the user to perform certain steps of the diagnostic test, e.g., to apply the sample to the test strip 120. In an exemplary embodiment of the present invention (discussed below), indicator 450 indicates the number of test strips remaining in container 110, or the number of tests or the time remaining before meter 130 becomes inoperative.

[052] Indicator function 450 may present information in visible, audible or tactile form. For example, indicator 450 may include a display 133 for displaying information, e.g., using numerical values, words and/or icons. A number of different technologies may be used for display 133. For example, the display may be a liquid crystal display, a vacuum fluorescent display, an electroluminescent display, a light emitting diode display, a plasma display, etc. In an illustrative embodiment, display 134 is a liquid crystal display. Alternatively or in addition, indicator 450 may include an audible indicator configured to indicate information by sound. For example, indicator 450 may include a speaker connected to a voice and/or sound circuit that is configured to, e.g., speak the result of the diagnostic test or to beep to indicate that an error has occurred. As a further alternative, indicator 450 may be implemented as a dynamic Braille indicator for use by the blind.

[053] In an illustrative embodiment, indicator function 450 includes a display 133 as well as a speaker connected to a sound circuit (not shown). The display 133 may be placed on the top of meter housing 131 as shown in Figures 1 and 3. In this position, display 133 is conveniently visible when the meter is grasped in the hand with the thumb or index finger on button 132.

[054] Because the diagnostic test media, e.g., test strips 120, is typically very small, certain users may find it difficult to retrieve the test media from the container 110. Accordingly, a media dispensing mechanism may be used to provide for the automated dispensing of test media from the container.

[055] Figure 5 shows a cross-section of an exemplary integrated system having a media dispensing mechanism 460. In this embodiment, the container is configured as a spring-loaded magazine 510. A plurality of test strips 120 are stacked on top of one another in magazine 510. Magazine 510 may have an interior shape similar to that of the test media in order to maintain the alignment of the stack. For example, for the test strips 120 depicted in Figure 1, the interior of magazine 510 may be generally rectangular in cross-section.

[056] Spring 516 pushes the stack of test strips against the top 518 of magazine 510, where the top test strip 125 is operably positioned with respect to strip dispensing mechanism 460. Dispensing mechanism 460 dispenses the top test strip 125 in the stack using a linear and/or rotational mechanical action. The mechanical action may be executed manually (e.g., by the user pulling a slide or rotating a wheel) or by a motor (e.g., a stepper motor) actuated by user control function 430. The top test strip 125 is slid from the stack and through slot 520. The test media used with this embodiment may be modified by application of a non-

friction coating or film, such as TEFLON, to one or both sides in order to ensure smooth ejection.

[057] Where the particular diagnostic test requires that the test strip be inserted into the media interface 410 before the sample is applied, media dispensing mechanism 460 may position the interface side 122 of the ejected test strip 125 within media interface 410, e.g., with the interface side 122 of the test strip engaging the media sensors and the sample chamber 121 of the test strip projected outwardly from the meter 130 so as to allow application of a sample, as shown in Figure 5. Alternatively, media dispensing mechanism 460 may simply present either end of the top test strip 125 to the user, who may then manually insert the test strip 125 into media interface 410 (either before or after the sample is applied, depending on the requirements of the particular diagnostic test). Controller 400 may be instructed to count the number of test strips 120 dispensed by media dispensing mechanism 460 and cause indicator function 450 to indicate, e.g., the number of test strips 120 remaining in magazine 510.

[058] Voice message function 470 may be used to record a voice message associated with a given diagnostic test result. For self-testing of blood glucose level, for example, a user may use voice message function 470 to record information related to their diet around the time of the diagnostic test. The voice message may be recorded in memory 406 along with a pointer associating it with a particular test result. The use of the voice message function 470 is more fully explained in prior Application Ser. No. 10/764,974, entitled "MEDICAL DIAGNOSTIC TESTING DEVICE WITH VOICE MESSAGE CAPABILITY," filed January 26, 2004, having assignee in common with the present application, which is incorporated by reference herein in its entirety. At the end of the useful life of the

meter 130, meter 130 itself may be given or sent to the user's medical care provider. The medical care provider may then review the results of the diagnostic tests and/or associated voice messages for use in treating the user.

[059] Environmental sensing function 480 may include one or more environmental sensors used to gather data used in the performance of the diagnostic test. Such environmental sensors may include, e.g., a temperature sensor and/or a humidity sensor. For example, meter 130 may use a temperature reading to correct the diagnostic test result for temperature dependence (e.g., as set forth in Application Ser. Nos. 10/286,648 and 10/420,995, incorporated by reference above). As a further example, meter 130 may use a humidity reading to determine if the humidity level is too high to proceed with the diagnostic test.

[060] 3. Prevention of the Use of Incorrect Test Strips

[061] Meter 130 may be calibrated for use with a particular brand or manufacturer's lot of test media by customizing the diagnostic test performed by meter 130 with respect to the particular brand or lot using one or more calibration parameters. These calibration parameters may include environmental corrections (e.g., temperature corrections), timing period corrections (e.g., with respect to incubation time), voltage corrections (e.g., for use in electrochemical tests), color variations (e.g., for use in photometric tests), etc., that customize the diagnostic test function of controller 400 to the particular brand or lot of test media. See, e.g., Application Ser. Nos. 10/286,648 and 10/420,995, incorporated by reference above.

[062] In an illustrative embodiment of the present invention, integrated system 100 includes one or more containers 110 or magazines 510 of test strips 120 packaged together with a meter 130. The test strips 120 in the package are

from the same manufacturing lot or otherwise have the same characteristic reaction to blood glucose so that meter 130 may be calibrated once and thereafter used with any of the test strips 120 in the package without recalibration.

[063] The diagnostic test function of the packaged meter 130 may be precalibrated by the manufacturer or distributor, e.g., by providing instructions 402 and/or data customized to the associated test media. Alternatively, meter 130 may be calibrated at the user level by requiring the user to calibrate the meter with respect to a particular brand or lot of test media prior to using the meter to conduct diagnostic tests. For example, the user may use the user control 430 or input/output 440 functions to enter or download calibration data or a code from which controller 400 may derive calibration data. In another approach, each test media container 110 (or a co-packaged group of containers from the same lot) may be provided with a data storage device that stores the calibration data electronically. See, e.g., Application Ser. Nos. 10/286,648 and 10/420,995, incorporated by reference above. To calibrate the meter for the test media in the particular container 110 or package, the user simply plugs the corresponding data storage device into a connector (not shown) on meter 130. The controller 400 then obtains the necessary instructions 402 or data from the data storage device. However, it is from a distribution standpoint very efficient, and from a user's standpoint very convenient, when meter 130 is precalibrated for use with the co-packaged test strips 120 prior to distribution to the user.

[064] Because the use of meter 130 with test media from a brand or lot for which the meter 130 has not been calibrated may lead to errors, exemplary embodiments of the present invention minimize the chance that a user will mistakenly use meter 130 with test media from a brand or lot for which the meter

130 has not been calibrated. In an illustrative embodiment, the functional components of meter 130 are chosen and constructed such that meter 130 is economical to market as a disposable device. For example, the meter 130 may be constructed using low-cost components, or one or more of the functional components of exemplary meter 130 described above may be omitted in order to reduce the overall cost of the meter 130. For example, the meter may be constructed without, e.g., input/output function 440, media dispensing mechanism 460, voice message function 470, and/or environmental sensors 480. Further, the test media and meter 130 may be packaged together such that the user receives a new meter 130 with each purchase of test media. Consequently, the user is encouraged to dispose of their old meter 130 when the test media packaged with the meter (e.g., in container 110) has been used up. In this manner, exemplary embodiments of the present invention reduce the likelihood that a user will mistakenly use a meter 130 with test media from a brand or lot for which the meter 130 has not been calibrated.

[065] Illustrative embodiments of the present invention also provide one or more preventive measures that are configured to further minimize the chance that a user will mistakenly use test media for which their meter is not calibrated. These preventive measures may disable one or more functions of the meter upon the occurrence of certain triggering events. For example, the preventive measure may render meter 130 wholly inoperative after the meter 130 has been used for a certain period of time or quantity of tests, or with a certain quantity of test media. The meter 130 may then be simply disposed of or returned to the manufacturer for remanufacturing. Alternatively, the preventive measure may render only the diagnostic testing function of controller 400 inoperative, or simply prevent the meter

from displaying the result of a diagnostic test. The user may then retain meter 130 in order to use its remaining functions.

[066] A given preventive measure may be triggered by the occurrence of a triggering event, such as the expiration of a certain time period. The time period may be related to particular test media, e.g., a particular container 110 or lot of test strips 120 for which meter 130 has been calibrated or otherwise associated. For example, a preventive measure may be triggered if the current date is after an expiration date of test media associated with the meter 130, e.g., where the manufacturer indicates that the particular test media should not be used more than two years after its date of manufacture. Alternatively, the expiration date may be determined relative to a date a particular container was opened, e.g., where the manufacturer indicates that the test media should not be used more than 2 months after its container 110 has first been opened.

[067] The date a particular container 110 of test media has first been opened may be estimated or determined in a number of ways. Where meter 130 is precalibrated for use with a single container or lot of test strips, the date that the container has first been opened may be estimated by determining the date the meter was first turned on, e.g., by instructing controller 400 to save the date or start a timer when the meter 130 is first turned on. However, because the user may turn on the meter (e.g., to familiarize themselves with the functions of the meter or to calibrate the meter) an indeterminate time before actually using the meter to conduct a diagnostic test, it is envisioned that the date of first use of the meter be estimated by instructing controller 400 to save the date or start a timer when meter 130 is first used to run a diagnostic test. Similarly, where meter 130 is calibrated by the user, the date a particular container is opened may be estimated by instructing

controller 400 to save the date or start a timer when meter 130 is first used to conduct a diagnostic test after being calibrated or otherwise associated with a given plurality of test strips. Alternatively, where meter 130 is attached to a particular container 110, user control function 430 may include a switch actuated when the user opens the closure 140, e.g., so that the controller is informed when the container 110 is first opened.

[068] The time period need not be related to a particular lot or container of test media. A particular preventive measure may be triggered a predetermined time after manufacture or first use of meter 130, or first use of a particular meter function (e.g., performance of a diagnostic test), without regard to any characteristic of the test media. For example, a given preventive measure may be triggered three months after first use of the meter to conduct a diagnostic test. In any case, indicator function 450 may be used to indicate the time remaining until preventive measures are triggered.

[069] Alternatively or in addition, controller 400 may maintain a running count of the quantity of test media used or the quantity of diagnostic tests performed by the meter using the current calibration data. The quantity of test media used may be estimated by the number of times that test media have been inserted in media interface 410 or, preferably, the number of times a sample has been detected, e.g., by the media sensors. The running count may be compared to a quantity of tests or test media allowed before triggering of a preventive measure. The allowed quantity may relate to a quantity of test media that were originally packaged with meter 130 by the manufacturer or distributor, e.g., the quantity of test media originally contained in an associated container 110. As a further alternative, the allowed quantity may exceed the number of test strips contained in

the associated packaging or container 110 by a small amount, e.g., 10%. If the running count exceeds the operative quantity, then a preventive measure may be triggered. Indicator function 450 may be used to indicate the quantity of diagnostic tests or test media remaining before a preventive measure is activated.

[070] Information related to the trigger for the preventive measure (e.g., the allowed time period, the expiration date of the associated test media, the quantity of diagnostic tests, the quantity of diagnostic test strips, etc.) may be obtained in a manner similar to the calibration data. In an illustrative embodiment, controller 400 is distributed with the trigger information, e.g., encoded in memory 406 or elsewhere in controller 400. Alternatively, the trigger information may be entered by the user. For example, the trigger information may be appended to the calibration data that is entered or downloaded by the user. Alternatively, the user may enter or download the trigger information (or a code from which controller 400 may derive the trigger information) separately from the calibration data.

[071] Controller 400 may be instructed to periodically determine whether a particular preventive measure is triggered. For example, controller 400 may determine whether a preventive measure is triggered on a daily or weekly basis. Alternatively or in addition, controller 400 may be instructed to determine whether a given preventive measure is triggered whenever a certain event occurs. For example, controller 400 may be instructed to determine whether a preventive measure is triggered whenever a test strip 120 is inserted into test strip interface 110, whenever a sample is detected by the media sensors, whenever a diagnostic test is performed by the controller, whenever the result of a diagnostic test is displayed, or whenever a certain user control 430 or other function of meter 130 is actuated, etc.

[072] The preventive measures may take a number of forms. Where the power source 420 of the meter is finite (e.g., a battery), the preventive measure may manipulate the life of power source 420 so that the power source, e.g., a battery within housing 131, becomes inoperative soon after the preventive measure is triggered. For instance, controller 400 may increase the load on the power source when the preventive measure is triggered. The load may be increased, e.g., by raising the frequency of system clock 408 so that the rate power is consumed by the controller 400 and other electronic functions is increased. The power source 420, and thus meter 130, will then become inoperative in a relatively short period of time. Alternatively or in addition, controller 400 may be instructed to cause the meter 130 to remain in an "on" state once the preventive measure is triggered, thus draining the power source. As a further alternative, controller may be instructed to open a switch or blow a fuse so as to disconnect power source 420 from the electronic functions of the meter 130. For this embodiment, meter housing 131 may be constructed so that power source 420 is not replaceable. Indicator function 450 may indicate an estimation of the time remaining before the power source 420, and thus the meter 130, become inoperable.

[073] Another preventive measure may prevent a diagnostic test from being performed. For example, where meter 130 includes an auto-on function for initiating a diagnostic test upon insertion of a test strip 120 into interface 410 (e.g., as set forth in Application Ser. Nos. 10/286,648 and 10/420,995, incorporated by reference above), controller 400 may be instructed to disable the auto-on function when the preventive measure is triggered. Controller 400 may nevertheless allow the user to turn on the meter using user control function 430 so as to allow access to other functions of the meter. For instance, controller 400 may allow the user to

turn on the meter and review previous test results and/or associated voice messages stored in memory 406.

[074] As another alternative, the preventive measure may allow the a diagnostic test to be performed, but prevent the indicator function from indicating the result. Instead, the meter may display a message indicating that the meter is not calibrated and/or that the meter needs to be replaced. As before, controller 400 may still allow the user to review previous test results and any associated voice messages stored in memory 406. The meter 130 itself may then be given or sent to the user's medical care provider. The medical care provider may then review the results of the diagnostic tests and/or associated voice messages for use in treating the user.

[075] As a further preventive measure, controller 400 may be instructed to reconfigure the function of meter 130. For instance, controller 400 may instructed to reconfigure indicator function 450 to indicate other information in place of a result of a diagnostic test. For example, the indicator function 450 may be reconfigured to indicate the time and/or the date. Alternatively, indicator function 450 may be reconfigured to indicate readings from environmental sensors 480. For example, the meter 130 may indicate the temperature and/or humidity, together with the appropriate units, on display 133. As another alternative, controller may be instructed to reconfigure voice message function to allow voice messages to be recorded outside of the context of a diagnostic test.

[076] The user control function 430 may be reconfigured in accordance with the reconfiguration of the indicator function. For example, the indicator function 450 may be reconfigured to act as a timer, e.g., a kitchen timer. User control 430 may be correspondingly reconfigured to control the timer. For example,

user control 430 may be reconfigured to start and stop the timer. Alternatively, user control 430 may be reconfigured to switch between or adjust displays of the time, date, temperature and/or humidity.

[077] The meter may be provided with a fastener (e.g., a magnet, a VELCRO hook and loop fastener, an adhesive, etc.) on its back so as to allow the user to place the meter 130 where its new function will be useful. For example, the user may place the meter on their refrigerator. In this manner, the user may be reminded of the meter manufacturer's or distributor's name and/or logo (which may be placed next to the display 133) in a context outside of the use of the meter 130 for diagnostic testing.

[078] Other embodiments of the invention will be apparent to those skilled in the art from consideration of the specification and practice of the invention disclosed herein. It is intended that the specification and examples be considered as exemplary only, with a true scope and spirit of the invention being indicated by the following claims.

WHAT IS CLAIMED IS:

1. A system for diagnostic testing, the system comprising:

a meter for performing a diagnostic test on a sample applied to a test media; and

a container configured to contain test media compatible with the meter, the container having an opening;

wherein the meter comprises:

an interface for accepting test media in order to perform the diagnostic test;

a controller configured to perform the diagnostic test;

an indicator for indicating a result of the diagnostic test; and

a closure portion for selectively closing the opening of the container.

2. The system of claim 1, wherein the diagnostic test is for the analysis of a biological sample.

3. The system of claim 2, wherein the diagnostic test is for the determination of the presence, concentration or amount of one of: glucose, ketones, cholesterol, human choriogonadotropin, hemoglobin A1C, fructosamine, carbohydrates, a tumor marker, lead, an anti-epilepsy drug, bilirubin, a liver function marker, a toxin, a metabolite of a toxin, a controlled substance, and a blood coagulation factor.

4. The system of claim 1, wherein the diagnostic test employs a technique comprising at least one of: a photometric technique, reflection, transmission, scattering, absorption, fluorescence, electrochemiluminescence, an electrochemical technique, coulometry, amperometry, and potentiometry.

5. The system of claim 1, wherein meter further comprises a housing and the closure is either affixed to or integral with the housing.

6. The system of claim 1, further comprising test media contained in the container, the meter being configured to conduct the diagnostic test on a sample applied to the test media contained in the container.

7. The system of claim 6, wherein the meter is calibrated for use with the test media contained in the container.

8. The system of claim 1, wherein the closure is configured to seal the opening against the infiltration of at least one of liquid, vapor and air.

9. The system of claim 1, wherein the closure comprises one of: a press-fit closure, a twist-off closure, and a child-resistant closure.

10. The system of claim 1, wherein the meter is connected to the container by a flexible connector.

11. The system of claim 10, wherein the flexible connector is a hinge.

12. The system of claim 1, further comprising a sampling device operably connected to the container.

13. The system of claim 12, wherein the sampling device is a lancet.

14. The system of claim 13, wherein the lancet comprises a spring for propelling the lancet to puncture the skin and the lancet is operably connected to the container such that a user may load the spring and release the spring to draw a sample without disconnecting the lancet from the container.

15. The system of claim 13, wherein the lancet comprises a mechanism for adjusting the depth of penetration of the lancet and the lancet is operably connected to the container such that a user may operate the mechanism to adjust the depth of penetration of the lancet without disconnecting the lancet from the container.

16. The system of claim 1, further comprising a user control for controlling a function of the meter.

17. The system of claim 16, wherein the user control includes a button on a lateral side of the meter and the indicator includes a display on a top side of the meter.

18. The system of claim 1, further comprising a media dispensing mechanism for dispensing test media from the container.

19. The system of claim 18, wherein the media dispensing mechanism is configured to dispense test media into the interface.

20. The system of claim 1, wherein the system is configured to be hand held.

21. The system of claim 1, wherein the system further comprises:

data corresponding to at least one of: a time period, a date, a quantity of diagnostic tests, and a quantity of diagnostic test media;

wherein the controller is configured to examine the data to determine if a triggering event has occurred and to disable a function of the meter when it has been determined that a triggering event has occurred.

22. The system of claim 21, wherein the system further comprises a power source and the controller is configured to disable the power source when it has been determined that a triggering event has occurred.

23. The system of claim 22, wherein the controller is configured to disable the power source by increasing a load on the power source so as to drain the power source

24. The system of claim 23, wherein the meter comprises a clock and the controller is configured to increase the load on the power source by increasing the frequency of the clock.

25. The system of claim 22, wherein the controller is configured to disable the power source by disconnecting the power source.

26. The system of claim 21, wherein the controller further comprises an auto-on function for initiating a diagnostic test upon the insertion of test media into the interface; and the controller is configured to disable the auto-on function when it has been determined that a triggering event has occurred.

27. The system of claim 21, wherein the controller the controller is configured to disable the diagnostic testing function of the meter and to reconfigure the meter to perform a new function when it has been determined that a triggering event has occurred.

28. The system of claim 27, wherein the controller further comprises an auto-on function for initiating a diagnostic test upon the insertion of test media into the interface; and the controller is configured to disable the diagnostic testing function by disabling the auto-on function.

29. The system of claim 27, wherein the controller is configured to disable the diagnostic testing function by preventing the indicator from indicating the result of a diagnostic test.

30. The system of claim 27, wherein the controller is configured to reconfigure the function of the meter by causing the indicator to indicate information other than the result of a diagnostic test.

31. The system of claim 30, wherein the other information is at least one of: time, date, temperature, humidity, and a reading of an environmental sensor.

32. The system of claim 27, wherein the meter further comprises at least one user control and the controller is configured to reconfigure the function of the meter by reconfiguring the function of the at least one user control.

33. The system of claim 21, further comprising test media contained in the container, wherein the data is related to the test media contained in the container.

34. The system of claim 33, wherein the triggering event is related to one of: an expiration date, and a quantity of the test media contained in the container.

35. The system of claim 21, wherein the triggering event is related to one of: expiration of the time period, passage of the date, performance of the quantity of diagnostic tests, and use of the quantity of test media.

36. The system of claim 35, wherein the triggering event is related to the expiration of the time period relative to one of: a date of a first use of an operation of the meter, and a date of first use of an operation of the meter with an associated plurality of test strips.

37. The system of claim 36, wherein the operation of the meter is the performance of a diagnostic test.

38. A meter for performing a diagnostic test on a sample applied to a test media, the meter comprising:

an interface for accepting test media in order to perform the diagnostic test;

a controller configured to perform the diagnostic test;

an indicator for indicating a result of the diagnostic test; and

a closure portion for selectively closing an opening of a container configured to contain test media compatible with the meter.

39. A meter for performing a diagnostic test on a sample applied to a test media, the meter comprising:

an interface for accepting test media in order to perform the diagnostic test;

a controller configured to perform the diagnostic test;

an indicator for indicating a result of the diagnostic test; and

a housing, the housing having a portion configured to conform to a closure portion of a container configured to contain test media compatible with the meter.

40. A device comprising:

a container configured to contain test media for diagnostic testing of a sample;

a sampling device configured to obtain a sample compatible with the test media which the container is configured to contain;

wherein the sampling device is permanently affixed to the container such that a user may use the sampling device to obtain a sample.

41. The device of claim 40, wherein the sampling device is a lancet.

42. The device of claim 41, wherein the lancet comprises a spring for propelling the lancet to puncture the skin and the lancet is operably connected to the container such that a user may load the spring and release the spring to draw a sample.

43. The device of claim 13, wherein the lancet comprises a mechanism for adjusting the depth of penetration of the lancet and the lancet is operably connected to the container such that a user may operate the mechanism to adjust the depth of penetration of the lancet.

44. The device of claim 40, further comprising test media contained in the container.

45. The device of claim 44, wherein the test media comprises test strips for blood glucose testing.

46. A meter for performing a diagnostic test on a sample applied to a test media, the meter comprising:

a power source;

an interface for accepting test media in order to perform the diagnostic test;

a controller configured to perform the diagnostic test;

an indicator for indicating a result of the diagnostic test; and

data corresponding to at least one of: a time period, a date, a quantity of diagnostic tests, and a quantity of diagnostic test media;

wherein the controller is configured to examine the data to determine if a triggering event has occurred and to disable the power source when it has been determined that a triggering event has occurred.

47. The meter of claim 46, wherein the controller is configured to disable the power source by increasing a load on the power source so as to drain the power source

48. The meter of claim 47, wherein the meter comprises a clock and the controller is configured to increase the load on the power source by increasing the frequency of the clock.

49. The meter of claim 46, wherein the controller is configured to disable the power source by disconnecting the power source.

50. The meter of claim 46, wherein the triggering event is related to one of: expiration of the time period, passage of the date, performance of the quantity of diagnostic tests, and use of the quantity of test media.

51. The meter of claim 50, wherein the triggering event is related to the expiration of the time period relative to one of: a date of a first use of an operation of the meter, and a date of first use of an operation of the meter with an associated plurality of test strips.

52. The meter of claim 51, wherein the operation of the meter is the performance of a diagnostic test.

53. The meter of claim 46, wherein the data is related to an associated plurality of test media.

54. The meter of claim 53, wherein the associated plurality of test media is a brand or lot of test media for which the meter has been calibrated.

55. The meter of claim 53, wherein the triggering event is related to an expiration date of the associated plurality of test media.

56. The meter of claim 53, wherein the associated plurality of test media is for a plurality of test media with which the meter has been packaged.

57. The meter of claim 56, wherein the triggering event is related to one of: an expiration date of the of the test media contained in the package, and the quantity of test media contained in the package.

58. A meter for performing a diagnostic test on a sample applied to a test media, the meter comprising:

a power source;

an interface for accepting test media in order to perform the diagnostic test;

a controller configured to perform the diagnostic test, the controller comprising an auto-on function for initiating a diagnostic test upon the insertion of test media into the interface;

an indicator for indicating a result of the diagnostic test; and

data corresponding to at least one of: a time period, a date, a quantity of diagnostic tests, and a quantity of diagnostic test media;

wherein the controller is configured to examine the data to determine if a triggering event has occurred and to disable the disable the auto-on function when it has been determined that a triggering event has occurred.

59. The meter of claim 58, wherein the triggering event is related to one of: expiration of the time period, passage of the date, performance of the quantity of diagnostic tests, and use of the quantity of test media.

60. The meter of claim 59, wherein the triggering event is related to the expiration of the time period relative to one of: a date of a first use of an operation of the meter, and a date of first use of an operation of the meter with an associated plurality of test strips.

61. The meter of claim 59, wherein the operation of the meter is the performance of a diagnostic test.

62. The meter of claim 58, wherein the data is related to an associated plurality of test media.

63. The meter of claim 62, wherein the associated plurality of test media is a brand or lot of test media for which the meter has been calibrated.

64. The meter of claim 62, wherein the triggering event is related to an expiration date of the associated plurality of test media.

65. The meter of claim 62, wherein the associated plurality of test media is for a plurality of test media with which the meter has been packaged.

66. The meter of claim 65, wherein the triggering event is related to one of: an expiration date of the test media contained in the package, and the quantity of test media contained in the package.

67. A meter for performing a diagnostic test on a sample applied to a test media, the meter comprising:

a power source;

an interface for accepting test media in order to perform the diagnostic test;

a controller configured to perform the diagnostic test;

an indicator for indicating a result of the diagnostic test; and

data corresponding to at least one of: a time period, a date, a quantity of diagnostic tests, and a quantity of diagnostic test media;

wherein the controller is configured to examine the data to determine if a triggering event has occurred and to disable the diagnostic testing function of the meter and to reconfigure the meter to perform a new function when it has been determined that a triggering event has occurred.

68. The meter of claim 67, wherein the controller further comprises an auto-on function for initiating a diagnostic test upon the insertion of test media into the interface; and the controller is configured to disable the diagnostic testing function by disabling the auto-on function.

69. The meter of claim 67, wherein the controller is configured to disable the diagnostic testing function by preventing the indicator from indicating the result of a diagnostic test.

70. The meter of claim 67, wherein the controller is configured to reconfigure the function of the meter by causing the indicator to indicate information other than the result of a diagnostic test.

71. The meter of claim 70, wherein the other information is at least one of: time, date, temperature, humidity, and a reading of an environmental sensor.

72. The meter of claim 67, wherein the meter further comprises at least one user control and the controller is configured to reconfigure the function of the meter by reconfiguring the function of the at least one user control.

73. The meter of claim 67, wherein the triggering event is related to one of: expiration of the time period, passage of the date, performance of the quantity of diagnostic tests, and use of the quantity of test media.

74. The meter of claim 73, wherein the triggering event is related to the expiration of the time period relative to one of: a date of a first use of an operation of the meter, and a date of first use of an operation of the meter with an associated plurality of test strips.

75. The meter of claim 74, wherein the operation of the meter is the performance of a diagnostic test.

76. The meter of claim 67, wherein the data is related to an associated plurality of test media.

77. The meter of claim 76, wherein the associated plurality of test media is a brand or lot of test media for which the meter has been calibrated.

78. The meter of claim 76, wherein the triggering event is related to an expiration date of the associated plurality of test media.

79. The meter of claim 76, wherein the associated plurality of test media is for a plurality of test media with which the meter has been packaged.

80. The meter of claim 79, wherein the triggering event is related to one of: an expiration date of the test media contained in the package, and the quantity of test media contained in the package.

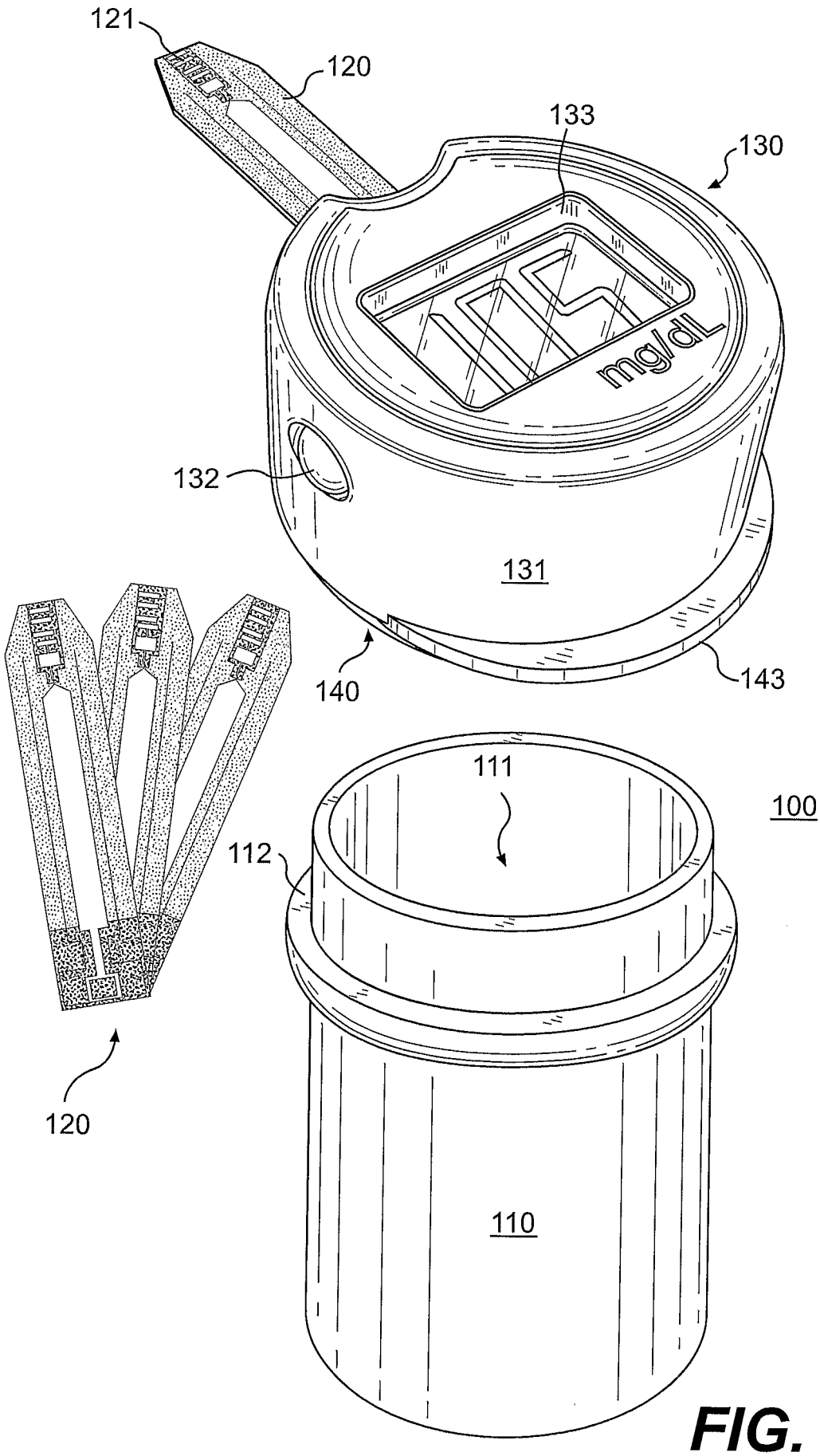


FIG. 1

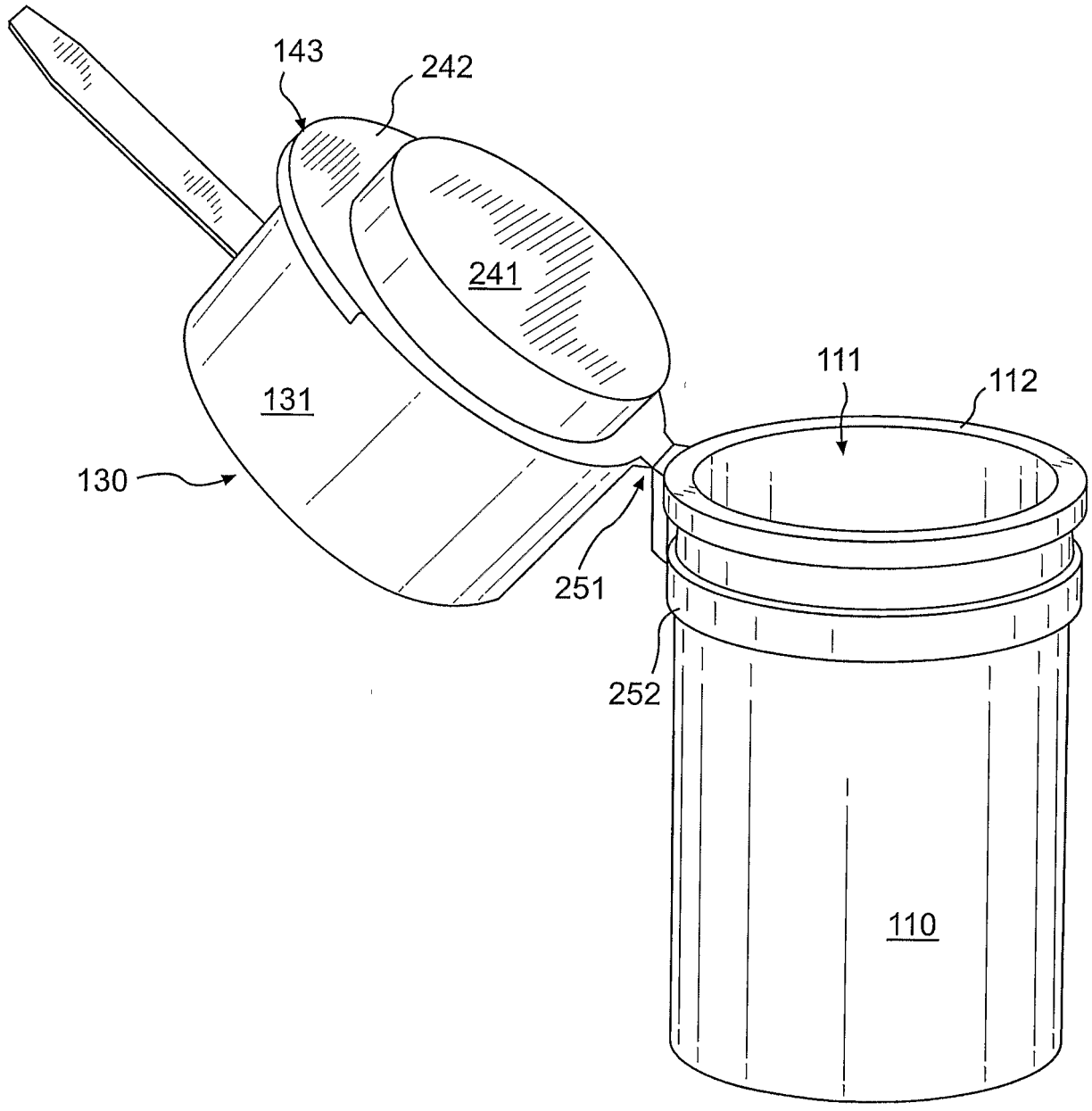
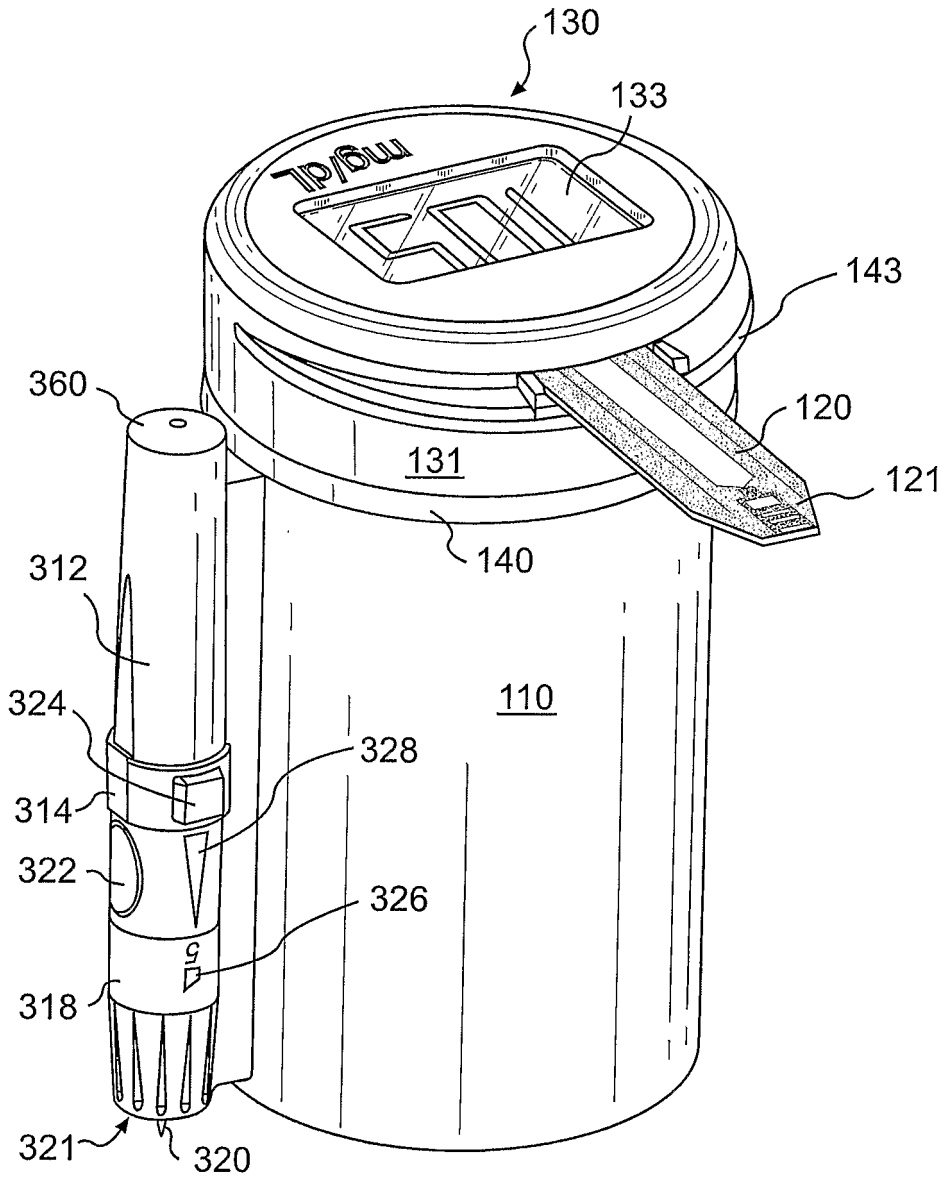


FIG. 2


130
133
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131
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140
312
110
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314
322
326
318
321
320

FIG. 3

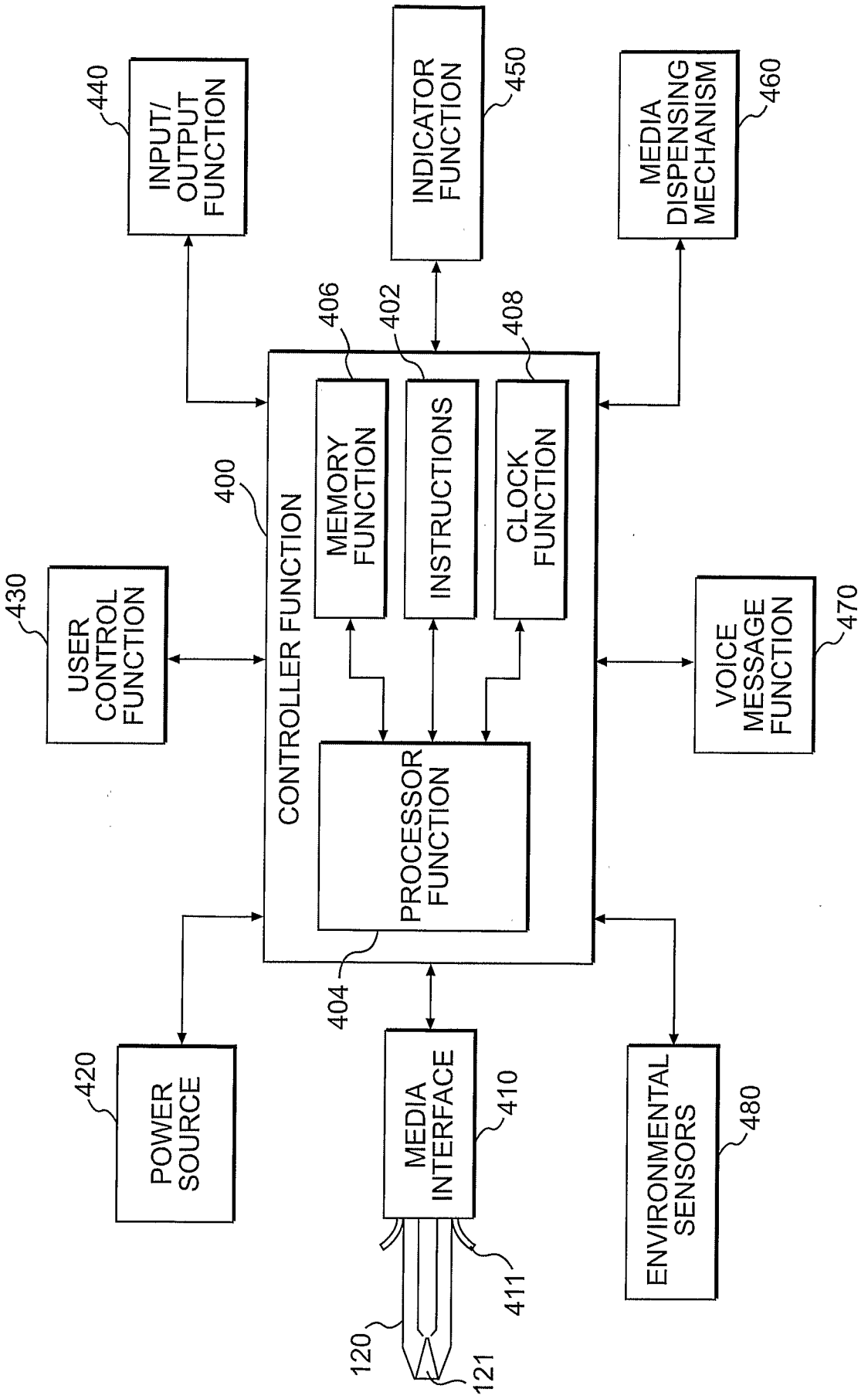
INPUT/ OUTPUT FUNCTION
440
INDICATOR FUNCTION
450
MEDIA DISPENSING MECHANISM
460
406
402
408
400
CONTROLLER FUNCTION
MEMORY FUNCTION
INSTRUCTIONS
CLOCK FUNCTION
430
USER CONTROL FUNCTION
VOICE MESSAGE FUNCTION
470
PROCESSOR FUNCTION
404
420
POWER SOURCE
MEDIA INTERFACE
410
ENVIRONMENTAL SENSORS
480
411
120
121

FIG. 4

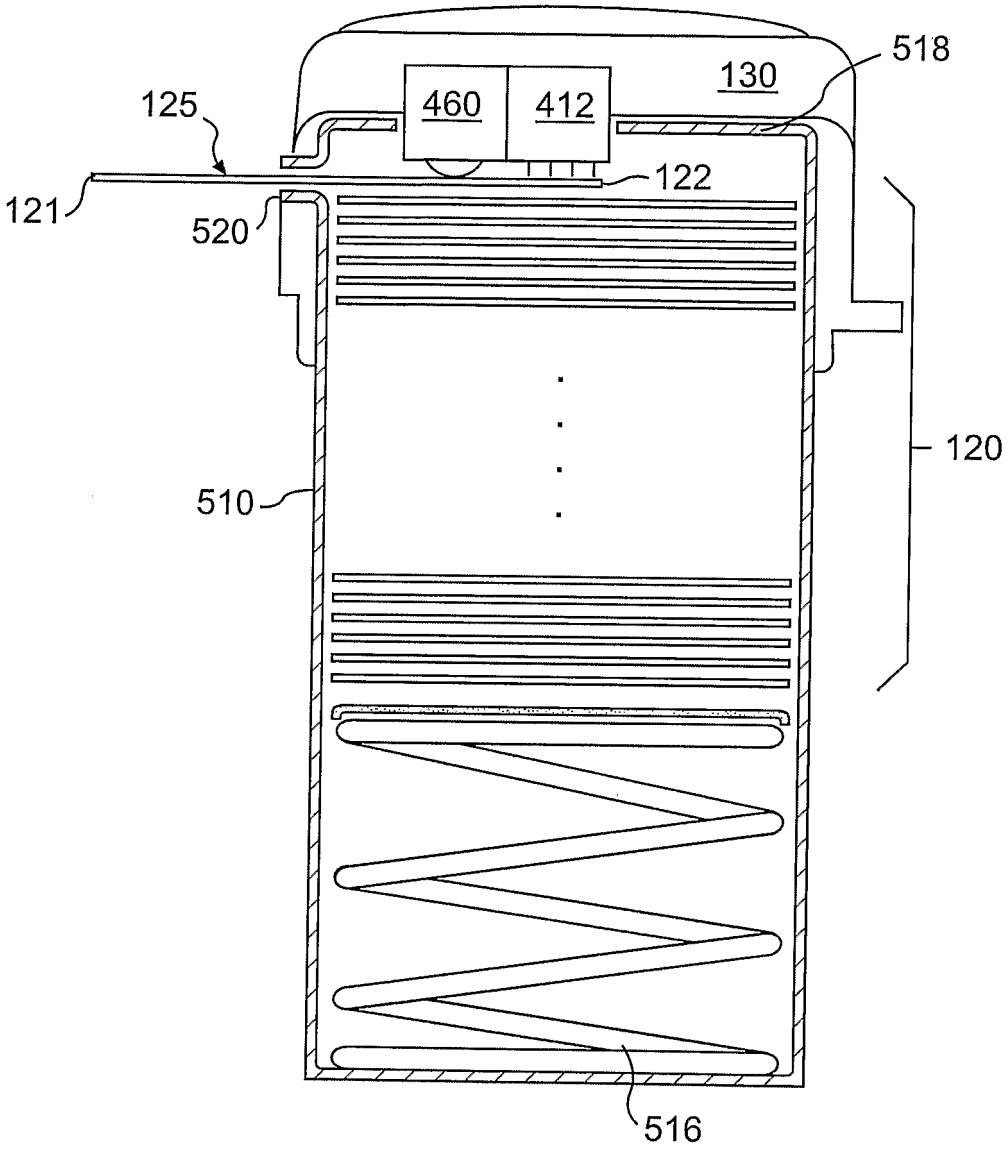

FIG. 5

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US2004/042724

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B5/00 A61B5/15 G01N33/487

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)
IPC 7 A61B G01N

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 practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 02/078533 A (INVERNESS MEDICAL LIMITED; MOERMAN, PIET; SHAANAN, GAD; MAINVILLE, PAT) 10 October 2002 (2002-10-10) page 12, line 31 - page 13, line 25 page 14, line 25 - page 19, line 27 page 30, line 10 - page 31, line 30; figures 1-4,5a-5c,6-8,29,30	1-80
X	US 2003/185705 A1 (OTAKE GARY) 2 October 2003 (2003-10-02) paragraphs '0032!, '0033!, '0063! - '0067!, '0069! - '0072!, '0076!, '0089!, '0105!; figures 3A,3B,4,5A-5C	1-9, 16-20, 38,39

-/--

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

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

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"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

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"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
7 April 2005	15/04/2005

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Pohjamo, T

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US2004/042724

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 03/042691 A (HYPOGUARD LIMITED) 22 May 2003 (2003-05-22) page 12, line 6 - page 14, line 21 page 15, line 26 - page 17, line 25; figures 1a-1d,2a-2d,4-6,11,18	1-9, 16-20, 38,39
A	EP 1 352 611 A (INVERNESS MEDICAL LIMITED) 15 October 2003 (2003-10-15) paragraphs '0057!, '0058!, '0074! - '0076!, '0079!; figure 2	1-80
A	US 2003/175155 A1 (CHARLTON STEVEN C) 18 September 2003 (2003-09-18) paragraphs '0023!, '0037!; figure 3	1-80

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/US2004/042724

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
WO 02078533 A	10-10-2002	CA	2410812 A1	10-10-2002
		CN	1501788 A	02-06-2004
		CZ	20023861 A3	17-09-2003
		EP	1328192 A2	23-07-2003
		WO	02078533 A2	10-10-2002
		JP	2004519302 T	02-07-2004
		MX	PA02011934 A	22-04-2003
		NO	20025699 A	20-01-2003
		US	2003191415 A1	09-10-2003
US 2003185705 A1	02-10-2003	CA	2422962 A1	02-10-2003
		CN	1448722 A	15-10-2003
		EP	1369686 A2	10-12-2003
		JP	2003337132 A	28-11-2003
WO 03042691 A	22-05-2003	EP	1444512 A1	11-08-2004
		WO	03042691 A1	22-05-2003
		US	2003089730 A1	15-05-2003
EP 1352611 A	15-10-2003	GB	2390602 A	14-01-2004
		AU	2003223067 A1	13-10-2003
		CA	2424197 A1	02-10-2003
		EP	1352611 A1	15-10-2003
		WO	03082092 A1	09-10-2003
		JP	2003344424 A	03-12-2003
		US	2004007585 A1	15-01-2004
US 2003175155 A1	18-09-2003	AU	2003200811 A1	09-10-2003
		CA	2419905 A1	18-09-2003
		EP	1347296 A2	24-09-2003
		JP	2004003990 A	08-01-2004

专利名称(译)	综合诊断测试系统		
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申请号	EP2004814860	申请日	2004-12-21
[标]申请(专利权)人(译)	家庭診斷法股份有限公司		
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当前申请(专利权)人(译)	HOME DIAGNOSTICS，INC.		
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CPC分类号	A61B5/14532 A61B5/14546 A61B5/1486 A61B5/150022 A61B5/150175 A61B5/150259 A61B5/150305 A61B5/150358 A61B5/150412 A61B5/150503 A61B5/150824 A61B5/15113 A61B5/15117 A61B5/1519 A61B5/157 A61B2560/0209 Y10T436/110833		
优先权	60/533557 2003-12-31 US 10/857917 2004-06-02 US		
其他公开文献	EP1706024B1		
外部链接	Espacenet		

摘要(译)

用于诊断测试的系统可以包括用于对施加到测试介质（120）的样品执行诊断测试的仪表（130）和被配置为包含与仪表兼容的测试介质的容器（110）。仪表可包括用于选择性地关闭容器开口的封闭部分（140）。该系统还可以提供可操作地连接到容器的采样装置（360），例如刺血针。该系统还可以提供禁用电源，仪表的自动开启功能，仪表的诊断测试功能或者当已经确定已经发生触发事件时仪表的其他功能的机制。触发事件可以是，例如，特定时间段的某个期满的到期，某个日期的通过，一定量的诊断测试的执行，或者使用一定量的测试媒体。