Title: TEST ELEMENT HOLDING SYSTEM AND PERSONAL DIAGNOSTIC DEVICE COMPRISING THE SAME

Abstract: A test element holding system for a personal diagnostic device is provided comprising a test element holder and an analyte test element for inserting into the test element holder, characterized in that the test element holder comprises first and second major structures generally arranged in a parallel formation to each other, defining a horizontal passageway of predefined width generally corresponding to at least the thickness of the test element, wherein a first engagement means for allowing pivotal engagement with a first recess of the test element and a second engagement means for releasably engaging a second recess of the test element are provided at or adjacent to the first and/or second major structures of the test element holder to allow securing of the test element within the holder by a ‘hingelock’ mechanism. Visible indication is provided to a user that the test element has been correctly inserted into the test element holder. Also provided is a removable protective structure for the test element holding system of the personal diagnostic device.
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TEST ELEMENT HOLDING SYSTEM
AND PERSONAL DIAGNOSTIC DEVICE COMPRISING THE SAME

FIELD OF THE INVENTION

[0001] The invention relates to a test element holding system for use in chronic disease monitoring and management, and in particular to a system comprising a holder for receiving and engaging a test element for evaluation of analytes in physiological fluids. Further, the invention relates to a personal diagnostic device comprising the test element holding system and a method for using the same.

BACKGROUND OF THE INVENTION

[0002] The use of personal diagnostic devices (e.g. analytical meters) at the point of care has become increasingly common and prevalent over the last few years with the development of electronic miniaturization techniques, improved test element technology, and the increasing number of individuals eager to self-manage their diseases.

[0003] One disease which is becoming common in the western world is diabetes mellitus. Diabetes mellitus is a disease characterised by varying or persistent hyperglycemia, resulting either from inadequate secretion of the hormone insulin, an inadequate response of target cells to insulin, or a combination of these factors. In 2006, according to the World Health Organization, at least 171 million people worldwide suffer from diabetes. Its incidence is increasing rapidly, and it is estimated that by the year 2030, this number will approximately double.
[0004] Diabetes mellitus affects people of all ages and currently no known cure exists. People suffering from such a chronic disease are recommended by a Health Care Professional (HCP) to establish their blood glucose concentrations, often several times per day, to minimize the long term complications emanating from such a disease. For example, the impact of uncontrolled or erratic blood glucose levels can lead to a high risk of further complications occurring, such as kidney failure, sight impairment, and nerve damage.

[0005] Measuring the glucose concentration in samples of physiological fluid is a particularly common task. Generally, such a task is performed by means of a diagnostic kit. The kit may typically include a lancing device, lancets, a container containing test elements, and a portable diagnostic device.

[0006] Performing a diagnostic test usually involves a user removing a test element from a vial or container, inserting the test element into a holder of the portable diagnostic device, pricking of a finger with the lancing device, and subsequently applying a physiological sample fluid e.g. capillary blood, onto an application area of the test element. Evaluation of an analyte concentration is performed and the user is notified of the result after a few moments. Spent test elements are removed from the diagnostic device and appropriately disposed.

[0007] Critical to photometric measurement based devices is the correct placement of a test element into an associated holder, furthermore that the test element always takes a definitive position relative to a measuring optical system. The positioning of a test element into a corresponding holder is extremely important to obtain an accurate measurement. It is also essential that a test element remains in the correct position in a corresponding holder during an entire measurement cycle. Moreover, it is also of paramount importance that during handling and insertion of a test element into a corresponding holder the test element is not subjected to bending stresses.

[0008] However, patients are challenged in performing frequent measurements due to the dimensional limitations of both the test elements and corresponding holders of existing test systems. Of course, such problems are exasperated for sight impaired patients, an impairment being a particular consequence of diabetes mellitus.
[0009] Nevertheless, for those patients who do diligently and conscientiously adhere to HCP guidelines in blood glucose monitoring, efficient handling and insertion of test elements into an associated holder may be compromised by a complex handling procedure. Furthermore, such complicated handling procedures are compounded as a consequence of diabetes neuropathy.

[00010] Even so, frequent insertion of a test element into a respective test holder increases the risk of transferring environmental dirt such as dust into the holder. Such activities also increase the risk of transferring handling residue from a test element into the holder. Furthermore, the risk of blood entering the holder itself directly correlates to the frequency of tests performed by a user.

[00011] In many commercially available portable diagnostic devices, especially photometric measurement based devices the collection of residue (e.g. dust, blood etc.) in a test element holder can cause the diagnostic device to report an error function. Common to these error functions is the need for the user to interface with an instruction manual to understand the correct steps in cleaning a test element holder of a personal diagnostic device. In exceptional cases, the user may be of poor sight (e.g. as a consequence of diabetes mellitus) and/or may not be as dextrous as a non-diabetic patient thus making cleaning of the device or components thereof extremely challenging and difficult.

[00012] Indeed, parts of the holder may inherently be inaccessible as a consequence of designers having a 'one size fits all' design methodology. Unfortunately, standardisation of design and capability, in general, tends to approach a lowest common denominator e.g. small test elements and correspondingly small test holders. Accordingly, and as a consequence of these issues, the user maybe inconveniently forced to contact a support team to establish whether the portable diagnostic device is malfunctioning. In many instances, the distributor of such devices has to provide a replacement diagnostic device at no cost to the user.

[00013] Insertion of test elements into respective holders has long been considered an important area of research, and United States Patent 6,458,326 published to Modzelewski et al., discloses a test strip platform having a shroud
which defines a test strip track for positioning an inserted test strip over an optical aperture for making analytical determinations. However, such a platform relies on stabilizing members and at least one camming members to guide a leading edge of an inserted test strip into cooperative engagement with the stabilizing member. Moreover, manufacture of such platform is considered somewhat expensive.

[00014] United States Patent 5,424,035 published to Hönes et al., discloses an analysis apparatus with a test strip holding device and matching test strips. The test strip holding device serves to position the test strip in a defined position relative to a measuring unit. However, by its configuration the test strip is consequently subjected to a bending stress to ensure a particular distance of a test field from the measuring unit.

[00015] United States Patent 2004,057,878 published on 25 March 2004 to House et al., discloses a strip holder for use in a meter. However, the strip holder is readily removable by the user which could easily be lost during the cleaning process.

[00016] United States Patent 5,714,123 published on 3 February 1998 to Sohrab, discloses a protective shield secured to a strip, bounding at least three sides of the sample-receiving area, and covering a part of the meter that adjoins the slot when the strip is in position. Again, the user is presented with removal parts which, by the very nature of disease monitoring in discussion could again be lost or be troublesome during disassembly and/or re-assembly.

[00017] Another example apparatus that describes the difficulties of keeping a strip holder and an optical system clean and the requirement to present the test element in a correct perspective to the optics is described in United States Patent 5,515,170 and published to Matzinger et al., on 7th May 1996.

[00018] WO9640434 published on 19 December 1996 to Mackay et al., discloses a test element holder having an elongated hollow member having an open end and a closed end and a support configured to hold a test element within the elongated hollow member in a position spaced from inner walls of the elongated hollow member and at least one vent positioned between the open end and the closed end.
In summary, the test element holder devices described above are disadvantageous in that they are complicated in use, expensive in manufacture and/or provide an inaccurate positioning of the test element leading to inaccurate measurement results.

Thus, it is an object of the present invention to provide an analyte test element holding system which allows simplified insertion of a test element therein and which is simple in design and inexpensive to manufacture.

It is another object of the present invention to provide analyte test element holding system which retains an analyte test element in a correct position during an entire measurement cycle.

It is another object of the present invention to provide an analyte test element holding system which allows a user a visible indication of whether a test element is correctly positioned prior and during a measurement of an analyte.

SUMMARY OF THE INVENTION

The present invention provides a test element holding system for a personal diagnostic device comprising a test element holder and an analyte test element for inserting into the test element holder, characterized in that the test element holder comprises first and second major structures generally arranged in a parallel formation to each other, defining a horizontal passageway of predefined width generally corresponding to at least the thickness of the test element, wherein a first engagement means for allowing pivotal engagement with a first recess of a leading end of the test element and a second engagement means for releasably engaging a second recess at a longitudinal part of the test element are provided at or adjacent to the first and/or second major structures of the test element holder to allow securing of the test element within the holder by a ‘hinge-lock’ mechanism.

The test element holding system of the present invention allows simplified insertion of a test element therein and is simple in design and inexpensive to manufacture. Moreover the test element holding system of the present invention allows a user a visible indication of whether a test element is correctly
positioned prior and during a measurement of an analyte. The test element holding system of the present invention protects a measuring optical system and corresponding measurement area of a test element from ambient light. In addition, the inventive analyte test element holding system has no user removable parts and can be easily cleaned.

[00025] The present invention also provides a personal diagnostic device comprising the test element holding system described above and a method of using the inventive test element holding system of a personal diagnostic device. The method allows insertion of an analyte test element into a test element holder allowing a definitive position relative to a measuring optical system. The present invention also provides a removable protective structure for the test element holding system of the personal diagnostic device.

BRIEF DESCRIPTION OF DRAWINGS

[00026] A better understanding of the features and advantages of the present invention will be obtained by reference to the following detailed description that sets forth illustrative embodiments by way of example only, in which the principles of the invention are utilized, and the accompanying drawings of which:

[00027] Figure 1 shows a simplified front view of a test element holding system of the present invention comprising a test element holder and an analyte test element inserted into a personal diagnostic device according to an embodiment of the present invention;

[00028] Figure 2 shows a simplified perspective view of an embodiment of a test element holder removed from a personal diagnostic device and showing an area for receiving at least one light detector according to an embodiment of the present invention;

[00029] Figure 3 shows a simplified perspective view of a test element holder removed from a personal diagnostic device and showing an area for receiving light emitting diodes according to an embodiment of the present invention;
[00030] Figure 4 shows a simplified side view of a test element holder removed from a personal diagnostic device showing a passageway for receiving a test element;

[00031] Figure 5a shows a simplified frontal view of a personal diagnostic device showing first and second engagement means for cooperating with a test element according to an embodiment of the present invention;

[00032] Figure 5b shows a modified simplified frontal view of a personal diagnostic device according to an other embodiment of the present invention;

[00033] Figure 5c shows a modified simplified frontal view of a personal diagnostic device according to another embodiment of the present invention;

[00034] Figure 5d shows a modified simplified frontal view of a personal diagnostic device according to another embodiment of the present invention;

[00035] Figure 6 shows a simplified top view of a test element holder showing the elongated passageway for receiving a test element according to an embodiment of the present invention;

[00036] Figure 7a shows a schematic view of a test element for cooperating with a test element holder according to embodiments of the present invention;

[00037] Figure 7b shows a schematic view of a test element for cooperating with a test element holder according to embodiments of the present invention;

[00038] Figure 7c shows a schematic view of a test element for cooperating with a test element holder according to embodiments of the present invention;

[00039] Figures 8a-8c show schematically a series of representations of a test element being inserted into a test element holder according to the method of using the test element holding system of the present invention;

[00040] Figure 9 shows a schematic representation of a cleaning element for use with embodiments of the present invention.

[00041] Figure 10 shows a simplified perspective view of a protective structure for a test element holder according to an embodiment of the present invention;

[00042] Figure 11 shows simplified schematic bottom view of a protective structure according to an embodiment of the present invention; and
Figure 12 shows a schematic view of protective structure fitted onto personal diagnostic device according to embodiments of the present invention.

5 DETAILED DESCRIPTION OF THE INVENTION

Figure 1 shows a simplified frontal view of a test element holding system of the present invention, arranged with a personal diagnostic device 22. The test element holding system 1 comprises a test element holder 2 and an analyte test element 3 inserted into the test element holder 2. Further shown are first and second recesses 36, 38 in the test element 3 engaging first and second engagement means 10, 12 of the test element holder 2, as will be described later in detail.

Figure 2 shows a simplified perspective view of an exemplary embodiment of a test element holder 2, which is removed from a personal diagnostic device for the purposes of clarity. Test element holder 2 is generally defined as having a first major structure 4 and a second major structure 6 which are generally arranged in a parallel formation to each other. First and second major structures 4, 6 each have a distal end 4a, 6a and a proximal end 4b, 6b. Between first and second major structures 4, 6 a horizontal passageway 8 of predefined width X is provided. This width X generally corresponds to at least the thickness of a test element 3, as will be described later.

First and second major structures 4, 6 are generally configured to house, by means of a recess, printed circuit boards (not shown). Printed circuit board(s) may be positioned and fixed in place within the recessed housing by means of snap fitment and/or glue and/or screw fixings or a combination thereof. Optionally, PCB(s) may be populated with light emitting diodes and/or photo detectors and which may be connected to a further electronic circuit of an optional separate PCB. Optional separate PCB may be housed within a personal diagnostic device (not shown) and populated with a microprocessor, measurement circuit, storage circuit, a display running a specialized user interface, and so forth. Further, the test element holder 2 may include electrical contacts for engaging with corresponding electrical contacts.
of an electrochemical based test element 3. In this optional arrangement, electrical contacts of test element 3 may be connected to a measurement circuit of the personal diagnostic device.

[00047] Further, first and second major structures 4, 6 each have apertures 14, 16 that are aligned with the light emitting diodes and/or photo detectors. Apertures 14 of first major structure 4 are aligned mostly congruent with apertures 16 of second major structure 6 (shown in Figure 3) for allowing optical signals to be transferred from at least one LED optionally forming part of the second major structure 6 to at least one photo detector optionally forming part of the first major structure 4.

[00048] Of importance to users, especially those suffering from diabetes mellitus with prevalent eye problems, is the need for a palpable assurance that a test element is being and has been correctly inserted into holder 2. In particular it is imperative that a test element remains in place during a complete measurement cycle. Accordingly, and as further shown in Figure 2, a first and a second engagement means in the form of circumferential extending engagement pins 10, 12 are provided. The first circumferential extending engagement pin 10 is intended for pivotal cooperation with a first recess 36 that is arranged on an end of the test element 3 (as shown in Figure 1) during insertion into holder 2. The first pin 10 is also intended, as will be described later, to limit horizontal movement of a test element inserted within test holder 2.

[00049] In the current embodiment of Figure 2, first circumferential extending engagement pin 10 forms part of a distal end 6a of the second major structure 6. First engagement pin 10 is regulated to be vertically offset relative to horizontal passageway 8 according to dimensions of the test element 3 as will be shown later. Further, position of first engagement pin 10 is in addition regulated to be inwardly offset, that is to say, offset in the direction of the apertures forming part of first and/or second major structure 4, 6. Inward offset is regulated by dimensions of a test element as will be shown later. Whilst it is shown in Figure 2 that first engaging pin 10 forms part of second major structure 6, it would be obvious to those skilled in the art that pin 10 may be provided elsewhere about holder 2 as long as it is engaging with a different part (i.e. recess) of the test element 3 as second engagement means 12.
In a preferred embodiment, engaging pin 10 is of a contrasting color to the color of the first and/or second major structure 4, 6. This contrast in color is to aid a user in the correct placement of the test element 3 prior to performing an analyte measurement. For example, the first and second major structures 4, 6 may be black and first engagement pin 10 may be colored red. Preferably, the color of the first engagement pin 10 is coincident with a surrounding rim of the first recess 36 of test element 3 (shown later).

Second engagement means 12 in the form of a circumferential extending pin is provided in the current embodiment shown in Figure 2 on the proximal end of test element holder 2 and serves for rigidly cooperating with a second recess 38 that is arranged on a longitudinal part 44 of a test element 3. Second circumferential extending engagement pin 12 may be arranged to form part of first and/or second major structure 4, 6. Preferably however, second engagement pin 12 is arranged at the horizontal passageway 8 provided between first and second major structure 4, 6 and more preferably protrudes above its surface.

In a preferred embodiment, second engagement pin 12 may be of a contrasting color to first and/or second major structures 4, 6 to aid in the correct placement of a test element 3 into the holder 2 prior to performing a measurement. Preferably, color of second engagement pin 12 contrasts with color of first engagement pin 10, preferably such colors being coincident with surrounding rims of test element recesses 36, 38 as will be shown later.

Forming part of strip holder 2 is a switch 18 which serves to activate electronic circuit of PCB (not shown) after correct insertion of a test element 3 in test element holder 2. In particular, switch may be a mechanical type and may be arranged to slightly protrude above horizontal passageway 8 so that it contacts a test element 3 after full and correct insertion into test element holder 2. In an alternative configuration, switch 18 may be recessed about test element holder 2 with a corresponding protrusion provided on a test element 3. In yet another configuration, switch may form part of first and/or second major structure 4, 6 to allow triggering of an electronic circuit during insertion of test element 3 into holder 2, such a configuration may for example be pro-
vided to trigger an instruction screen displayed on a user interface (not shown) of the personal diagnostic device.

[00054] Test element holder 2 is preferably manufactured from a high strength material such as polypropylene or metal. High strength material allows test element holder 2 to be sufficiently rigid to retain its shape when manipulated by a user. Such manipulations can occur during insertion and removal of a test element 3 into/from test element holder 2 and optionally during removal of test element holder 2 from a personal diagnostic device (not shown). Test element holder 2 can be formed by a one-shot or two shot moulding process as would be known to persons skilled in the art. In particular test element holder 2 can be formed by injection molding.

[00055] Figure 3 shows a schematic view of a second side of the second major structure 6 of test element holder 2. Light emitting diodes are removed for the purposes of clarity exposing apertures 16. As will be described later, apertures 16 are generally arranged horizontally offset from horizontal passageway 8 such that they are aligned with at least one reaction site of a test element 3 during a measurement cycle. Additionally, generally downwardly extending part 5 is shown, which preferably includes at least one aperture 7 for allowing a screw to be inserted therethrough for rigidly connecting with the main housing of the personal diagnostic device.

[00056] Figure 4 shows a side view of the proximal end of the test element holder 2 showing the parallel arranged first and second major structures 4, 6 between which a horizontal passageway 8 is provided for accommodating an analyte test element 3. As can be seen at the proximal end of holder 2, second engagement pin 12 protrudes from a first surface of second major structure 6 and has a length generally greater than the width of the horizontal passageway 8. Whilst it is shown that second engagement pin 12 protrudes from second major structure 6, it would be obvious to those skilled in the art that in an alternative embodiment second engagement pin 12 may protrude and straddle across passageway between first and second major structures 4, 6.

[00057] Depicted at the distal end of the current figure, is first circumferential extending engagement pin 10. Again, first engagement pin 10 protrudes from at least one major structure 4, 6 in the general direction of the oppositely ar-
ranged major structure, allowing a corresponding recess of a test element 3 to engage thereon during interfacing of test element 3 into test element holder 2.

[00058] Further depicted in the current figure are chamfered edges 4c, 6c of first and second major structures. Edges 4c, 6c are chamfered for the purposes reducing the possibility of flexing and/or bending of a test element 3 during insertion into test element holder 2.

[00059] Figure 5a shows a schematic frontal view of a test element holder 2 arranged with a personal diagnostic device 22 and showing the first and second major vertical structures 4, 6. Holder 2 may be housed between an upper housing 23a and a lower housing 23b of the personal diagnostic device 22. In particular test element holder 2 is rigidly held within the housing of personal diagnostic device by means of snap fitment and/or gluing. Preferably however, test element holder 2 is rigidly held within housing of personal diagnostic device by means of fixing screws which interface with apertures 7 of downwardly extending part, thus allowing the upper part of test element holder 2 to be generally exposed to a user. In the embodiment shown in Figure 5a, second major structure 6 is dimensionally longer than length of first major structure 4. Test element holder 2 is arranged on a top part of the personal diagnostic device 22 and is centrally arranged along centre line Y-Y" thus easing the user experience during test element manipulation. Further, first major structure 4 is arranged equidistance from distal and proximal ends 6a, 6b of second major structure which serves to expose first and second engagement pins 10, 12.

[00060] First engagement pin 10, being exposed to a user, is horizontally offset from horizontal passageway 8 and arranged near an upper edge of second major structure 6. As mentioned previously, first engagement pin 10 serves to cooperate with a first recess 36 of test element 3 to aid insertion into test element holder 2 and protrudes a sufficient length to ensure that recessed part of test element remains on engagement pin 10 during test element manipulation. Second engagement pin 12 is additionally exposed due to the dimensional limitation of the first major structure 4. Second engaging pin 12, arranged on proximal end of test element holder 2, protrudes a sufficient length to ensure that a second recessed part 38 of a test element 3 engages and remains thereon during test element manipulation. In a preferred embodiment, length
of first engagement pin 10 and second engagement pin 12 is in the order of 5mm and having a diameter in the order of 4mm. Such dimensions, as would be known to persons skilled in the art, are not limited and can be changed without changing the scope of the present invention.

[00061] In addition, switch 18, shown here on a proximal end of holder 2, slightly protrudes above the passageway for ensuring that the personal diagnostic device is activated after full and correct insertion of test element 3 into holder 2.

[00062] Figure 5b shows a test element holder 2 of the same design as in Figure 5a. However, here proximal ends 4b, 6b of first and second major structures 4, 6 are generally coincident. In this configuration second engagement pin 12 is not directly exposed to the user, with horizontal passageway extending to proximal ends of the first and second major vertical structures. The second engagement pin fulfills the same function as the aforementioned engagement pin 12, that is to ensure that a test element inserted within holder 2 remains in a predefined position during a complete measurement cycle.

[00063] Figure 5c shows a test holder 2 of the same design as in Figure 5a. However, here distal ends 4a, 6a of the first and second major structures 4, 6 are generally coincident. Again, in this configuration first engagement pin 10 is not directly exposed to the user e.g. being only viewable from a top view. In this configuration, horizontal passageway 8 extends to distal ends of the first and second major structures. First engagement pin fulfills the same function as the aforementioned engagement pin 10.

[00064] Figure 5d shows a test element holding system of the same design as in Figure 5a. However, here proximal ends 4b, 6b of the first and second major structures 4, 6 are generally coincident. Further, distal ends 4a, 6a of the first and second major structures 4, 6 are additionally coincident. Again, in this configuration neither the first engagement pin 10 or the second engagement pin 12 are directly exposed to the user, the horizontal passageway extending from a distal end to a proximal end of the first and second major structures. First and second engagement pins 10, 12 of this configuration fulfill the same function as the aforementioned engagement pins.
Figure 6 shows a simplified top view of the test element holder 2 according to one embodiment of the present invention and which is fixed by means of screw fixing and/or snap fitment (not shown) within upper 23a and lower housing 23b of personal diagnostic device 22.

As can be seen in the current figure, parallel arranged first and second major structures 4, 6 are arranged so that a horizontal passageway 8 of a predetermined width X is provided. Predetermined width X preferably is in the order of 0.8 to 1.0 mm. Preferably, width X is about 0.9mm and is provided to be greater than a height of a test element 3 as will become clear later. It is further shown that in the present embodiment the first and second major structures 4, 6 have unequal lengths thus clearly exposing first and second engagement pins 10, 12.

In the embodiment shown in Figure 6, first major structure 4 is generally arranged between first and second engagement pins 10, 12 of second major structure 6. First major structure is of sufficient dimension to contain components e.g. opto electronics (not shown), in particular at least one photo detector and/or at least one light emitter. Indeed, first and second major structures 4, 6 are fully enclosed to reduce the likelihood Electrical Static Discharge issues commonly associated in personal diagnostic devices. Optionally, first and/or second major structures 4, 6 may house a sensor for sensing the temperature near holder 2. Further, first and/or second major structures 4, 6 may optionally house a heating element for the purpose of heating a test element during a measurement cycle.

Preferably, edges 4c, 6c of the first and second major structures 4, 6 which interface with a test element 3 on insertion are chamfered to reduce the likelihood of flexing during insertion into holder 2. Positioned near the second engagement pin 12 is switch 18. Switch 18 is arranged to contact an edge of a test element 3 after it has been fully inserted into holder. Switch 18 is provided to trigger an electronic circuit contained within housing of the personal diagnostic device and in particular to activate CPU of personal diagnostic device 22.

Figure 7a shows a schematic view of an analyte test element 3 useful in the test element holding system of the present invention. The test element 3
shown in Figure 7 represents an embodiment of the analyte test element according to European Patent 1,574,858 which is herein incorporated by reference and which is designed for use in test element holder 2 of the present invention. Briefly, test element 3 includes two major surfaces 32a, 32b of length of around 40mm, separated by a discontinuous intermediate layer (not shown) and having a sample application area 34 provided opposite a longitudinal part or edge 44. Height of test element i.e. combined height of two major surfaces 32a, 32b and intermediate layer is in the order of about 550 to 600μm, preferably of 590μm.

Test element 3, in addition, includes a first recess 36 located on a distal end thereof. In general, distal end 33a serves as a leading end representing the end that is initially inserted into the test element holder 2. Recess 36 is generally arcuate in form and serves to cooperate and engage with first engagement pin 10 of test element holder 2. Preferably, first recess 36 is horizontally offset from longitudinal part or edge 44 of element 3 by distance of for example 5mm and which distance corresponding to offset of first engagement pin 10 relative to horizontal passageway 8 defined by first and second major structures 4, 6. As will be shown later, first recess 36 of test element 3 cooperates with first engagement pin 10 allowing pivotal movement around a horizontal axis in a ‘hinge’-like mechanism. In a preferred embodiment, surrounding rim 37 of first recess 36 is colored, e.g. red, optionally corresponding to the color of the first engagement pin 10, to aid in the correct engagement of the test element 3 into test element holder 2.

Longitudinal part or edge 44 of test element 3 includes a recess 38.

Recess 38 forming part of longitudinal part or edge 44 of test element 3 is located at a proximal end 33b, and is for cooperating and engaging with a second engagement pin 12 of test element holder 2. Preferably, second recess 38 has a general arcuate shape to cooperate with second engagement pin 12 of test element holder 2. As will be shown later, recess 38 cooperates with second engagement pin 12 after test element 3 has been pivotally moved towards horizontal passageway 8 in a ‘lock’-like mechanism. Preferably, second recess 38 has a ‘hook’-like projection 39a which hooks second engagement pin 12 when recess 38 of test element 3 cooperates with second engagement pin 12.
Preferably, second recess 38 is positioned at a distance of for example approximately 24.5mm from distal or leading end 33a of test element or 14.5 mm from proximal end 33b of test element 3. Furthermore, second recess 38 of test element 3 is arranged perpendicular to first recess 38 of test element 3. Preferably, the proximal end 33b serves as the handling area of the test element 3 and can be considered as the trailing end. In an embodiment, the proximal end 33b of the test element 3 presents a distinguishing feature 35 indicating to the user that this end represents the handling area of the analyte test element. The distinguishing feature 35 is for example realized by printing a hand symbol onto the surface of proximal end 33b of element 3 or by contour milling a hand or other appropriate form at the proximal end 33b of test element 3.

In a preferred embodiment, surrounding rim of second recess 39 is colored, e.g. black, a contrasting color to first recess, e.g. red, and optionally corresponding to the color of the second engagement pin 12 to aid in the correct engagement of the test element 3 into test element holder 2.

Whilst second recess 38 is shown to be of general arcuate shape it would be obvious to those skilled in the art that second recess could be of varying shapes and sizes, such shapes and sizes being coincident with second engagement pin 12. For example, and as shown in Figures 7b, 7c, second recesses 38 of strip may be shaped as a square and/or triangle or a combination thereof. More importantly however, is that second recess 38 is sized to allow a good fit with second pin 12 to avoid bending of the test element 3 during insertion into test element holder 2. Moreover, preferably second recess 38 is dimensioned such that lateral movement of test element 3 when inserted into test element holder 2 is avoided, even when production tolerances are taken into account.

In a further embodiment, the test element 3 may include electrical contacts such as carbon, gold or any other noble metal and which are connected by means of electrical tracks to at least one reaction area of the test element. In this configuration the electrical contacts of the test element would engage with corresponding contact elements of the holder when the test element is correctly positioned within the holder.
OPERATIONAL SEQUENCE

[00076] Figures 8a-8c show a schematic representation of a test element 3 being inserted into a test element holder 2 of the present invention. Test elements are stored in a container 40 such as those disclosed in Co-pending Patent Application PCT/EP2007/000753 which is incorporated herein by reference.

[00077] In a first step, as shown in Figure 8a, the user removes a test element 3, by grabbing the test element 3 at its handling area 33b, from a resealable container 40 and inserts leading end 33a having first, optional colored recess 36 onto first, optionally correspondingly colored engagement pin 10 of test element holder 2.

[00078] Next, as shown in Figure 8b, user pivotally moves test element 3 in a general downward movement towards horizontal passageway 8 so that major surfaces of test element 3 are in a parallel formation with respect to first and second major vertical structures 4, 6.

[00079] Next, as shown in Figure 8c, the user manipulates the handling area of test element 3 so that second, optionally colored recess 38 of test element 3 engages with second optionally correspondingly colored engagement pin 12 of test element holder 2, optionally being of contrasting color to first engagement pin 10. Next, longitudinal part 44 of test element 3 contacts switch 18 so that personal diagnostic device 22 is activated, that is information (not shown) is displayed on a display device and that it is ready to perform a measurement. Accordingly, by such ‘hinge-lock’ mechanism described above, test element 3 is secured in place during a measurement cycle and further lateral movement of test element is prevented by means of first and second engagement pins 10, 12 interfacing with first and second recesses 36, 38 of the analyte test element 3.

[00080] Figure 9 shows a schematic representation of a cleaning element 50. Cleaning element 50 serves to allow a user to clean test element holder 2 of the present invention when instructed to do so e.g. by prompting by a user interface of personal diagnostic device 22 and/or when instructed to do so by a health care professional.
In general, cleaning element 50 has a general rectangular flexible substrate 52 having a first major surface 52a and a second major surface 52b. Although, cleaning element is depicted having a rectangular shape, it would be obvious to persons skilled in the art that cleaning element can be circular, triangular, square of a combination thereof. Length of substrate preferably is in the order of about 40mm and has a width of around 10mm. Each first and/or second surface is flocked serving to limit the possibility of scratching surfaces of the first and/or second major vertical structures of holder 2. To further reduce the possibility of damaging surfaces of holder 2, cleaning element 50 is supplied with alcohol moistened surfaces 52a, 52b. Cleaning element 50 is supplied in an enclosed sealed package which protects cleaning element 50 from deleterious effects of the environment such as dirt. Sealed package (not shown) also ensures that cleaning element 50 remains moist. Cleaning element 50 is supplied for example by ECS AG, Roosstrasse 53, Wollerau, Switzerland.

Cleaning test element holder by means of cleaning element 50 is an easy process and involves, in a first step, removing element 50 from sealed element and then, in a second step, inserting and manipulating element 50 between first and second major vertical structures 4, 6 of holder 2 until it is clean.

Figure 10 shows a schematic perspective view of a protective structure 60 for the test element holding system of personal diagnostic device 22. Protective structure 60 serves to protect test element holding system from dirt and or dust, and may be provided as a cap. In a preferred embodiment, protective structure 60 has opposing side walls 62, 64 and which are formed together with additional opposing side walls 72, 74 to form a body section of structure 60. One end 70 of the structure 60 is closed and an opposite end is open defining at least one hollow cavity 68 therein. Optionally, closed end 70 of protective structure is shaped to accommodate first and second major structures of device 22. Furthermore, protective structure 60 is dimensioned to follow the contour of housing of personal diagnostic device 22 when protective structure 60 is fitted over holder 2.
Figure 11 shows a view inside of structure 60 showing at least one hollow cavity area 68. Arranged within hollow cavity 68 is an internal wall 66 having a thickness which generally corresponds to the thickness of a test element. In particular, internal wall 66 has a planar surface that extends into horizontal passageway 8 when structure 60 is arranged over strip holder 2 of personal diagnostic device 22. Optionally, internal wall 66 of structure 60 has an optionally removable flocked surface to ensure that surfaces of first and second major structures are cleaned during fitting of structure 60 onto holder 2 of personal diagnostic device.

Figure 12 shows a schematic representation of protective structure 60 arranged over strip holder 2 of personal diagnostic device 22. Walls 62, 64, 72, 74 follow the contour of upper and lower housing 23a, 23b of personal diagnostic device when arranged thereon and thus provide a tight seal to exclude dust and dirt from entering the test element holding system.

Whilst the present invention may have particular applicability to personal glucose diagnostic devices, it is should be noted that the present invention is also applicable to other types of analytes e.g. cholesterol, alcohol, lactate and the like, and to sensors such as immunoassay sensors, coagulation sensors and the like. It should also be noted that the present invention is equally applicable to photometric measurement systems and electrochemical measurement systems.

Various embodiments of the invention have been described above. The descriptions are intended to be illustrative, not limitative. Thus, it will be apparent to one skilled in the art that certain modifications may be made to the invention as described without departing from the scope of the claims set out below.
CLAIMS

WHAT IS CLAIMED IS:

1. A test element holding system for a personal diagnostic device comprising a test element holder (2) and an analyte test element (3) for inserting into the test element holder (2), characterized in that the test element holder (2) comprises a first major structure (4) and a second major structure (6) generally arranged in a parallel formation to each other, wherein between first and second major structure (4, 6) a horizontal passageway (8) of predefined width generally corresponding to at least the thickness of the test element (3) is provided, and wherein a first engagement means (10) for allowing pivotal engagement with a first recess (36) of a leading end (33a) of test element (3), and a second engagement means (12) for releasably engaging a second recess (38) at a longitudinal part (44) of the test element (3) are provided at or adjacent to the first and/or second major structures (4, 6) of the test element holder (2).

2. A test element holding system according to claim 1, further characterised in that the first engagement means (10) is positioned at a distal end of the test element holder (2), and the second engagement means (12) is positioned at a proximal end of the test element holder (2).

3. A test element holding system according to claim 1 or claim 2, further characterised in that the first and second major structures (4, 6) of the test element holder (2) are of unequal length exposing first and/or second engagement means (10, 12) to a user.

4. A test element holding system according to any one of claims 1 to 3, further characterised in that the first and/or second engagement means (10, 12) of the test element holder (2) is/are vertically offset from the horizontal passageway (8) provided between first and second major structures (4, 6) of the test element holder (2).
5. A test element holding system according to any one of claims 1 to 4, further characterised in that the first engagement means (10) is arranged horizontally and/or inwardly offset from the distal end (4a, 6a) of first and/or second major structure (4, 6) of the test element holder (2).

6. A test element holding system according to any one of claims 1 to 5, further characterised in that the second engagement means (12) is arranged horizontally and/or inwardly offset from the proximal end (4b, 6b) of first and/or second major structure (4, 6) of the test element holder (2).

7. A test element holding system according to any one of the preceding claims, further characterised in that the first engagement means (10) is an arcuate shaped pin for engaging in a hinge-like mechanism into open-ended recess (33a) of test element (3).

8. A test element holding system according to any one of the preceding claims, further characterised in that the second engagement means (12) is an arcuate shaped pin.

9. A test element holding system according to any one of the preceding claims, further characterised in that first engagement means (10) is of a contrasting color to second engagement means (12).

10. A test element holding system according to claim 9, further characterised in that the different colors of first and second engagement means (10, 12) are coincident with surrounding rims (37, 39) of first and second recesses (36, 38) of test element (3).

11. A test element holding system according to any one of the preceding claims, further characterised in that first major structure (4) houses at least one light source and the second major structure (6) houses at least one light detector.
12. A test element holding system according to any one of the preceding claims, further characterised in that first major structure (4) and/or second major structure (6) houses an electrical connector.

13. A test element holding system according to any one of the preceding claims, further characterised in that the first major structure (4) and/or the second major structure (6) and/or the passageway (8) further comprises a microswitch (18) activating a personal diagnostic device.

14. A test element holding system according to claim 1, further characterised in that first recess (36) of test element (3) is arranged perpendicular to second recess (38) of test element (3).

15. A test element holding system according to claim 1, further characterised in that test element (3) comprises a distinguishing feature to indicate the handling area of test element (3).

16. A method of using a test element holding system of a personal diagnostic device according to any one of the preceding claims comprising the steps of:

   (i) removing a test element (3) from a container;

   (ii) engaging first arcuate shaped recess (36) of the test element (3) onto first engagement means (10) of holder (2);

   (iii) pivoting test element (3) downwards about first engagement means (10) towards second engagement means (12) of test element holder (2);

   (iv) engaging second arcuate shaped recess (38) of the test element (3) onto second engagement means (12) of test element holder (2); and optionally

   (v) activating a personal diagnostic device by pushing a microswitch with a part of the test element (3) when correctly positioned within test element holder (2).

17. A method of using a test element holding system of a personal diagnostic device according to claim 15, further comprising the steps of:

   (vi) inserting a cleaning element (50) into the passageway (8) defined between first and second major structures (4, 6) of test element holder (2),
(ii) manipulating cleaning element between first and second major structures until surfaces are clean.

18. A protective structure for a test element holding system according to any one of claims 1 to 15, further characterised in that the protective structure comprises a body section having an open end and an opposite closed end defining a hollow cavity (68) therein.

19. A protective structure for a test holding system according to claim 18, further characterised in that hollow cavity (68) comprises a wall (66) having dimensions which generally corresponds to the thickness of test element (3).

20. A protective structure for a test holding system according to claims 18 to 19, further characterised in that wall (66) extends into passageway (8) when protective structure (60) is arranged over test element holding system (1).

21. A personal diagnostic device comprising a test element holding system according to any one of claims 1 to 15.

22. A personal diagnostic device according to claim 21, wherein the diagnostic device is for measuring the glucose concentration in a blood sample.
INTERNATIONAL SEARCH REPORT

A. CLASSIFICATION OF SUBJECT MATTER

INV. G01N21/86  G01N33/487  G01N33/52

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)

G01N BO11

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, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

<table>
<thead>
<tr>
<th>Category*</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim No.</th>
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<tbody>
<tr>
<td>A</td>
<td>EP 1 574 858 A (STIENE MATTHIAS DR [DE]) EGOMEDICAL SWISS AG [CH]) 14 September 2005 (2005-09-14) cited in the application paragraphs [0085], [0086]; figure 12</td>
<td>1-22</td>
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<td>A</td>
<td>US 4 934 817 A (GASSENHUBER HELMUT [DE]) 19 June 1990 (1990-06-19) column 4, lines 18-35; figures 2,3</td>
<td>1-22</td>
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See patent family annex.

Date of the actual completion of the international search

14 July 2009

Date of mailing of the international search report

21/07/2009

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