

IMPROVEMENTS RELATING TO HAND HELD ANALYTICAL DEVICES**Field of the Invention**

[0001] The present invention relates to a hand held analytical device and, more particularly, to an electronic discharge cover for use in such a device.

Background of the Invention

[0002] Hand held meters that are used for analysis of body fluids, for example, blood, interstitial fluid, urine etc can be adversely affected by electrostatic discharge. Such meters, which are often based on the principles of electro-chemical or photometric detection, may make use of disposable test sensors in the form of test strips. Test sensors can be inserted through a small aperture in the case or housing of the meter in order to form a physical and electrical connection with the electronic measuring system of the meter. Such hand held meters can be used to detect analytes or other indicators such as glucose, HbA1c, ketones and hematocrit in body fluids such as blood, interstitial fluid or urine etc.

[0003] Typically such meters include a printed circuit board upon which electronic circuit components of the meter, and connections between these components, are provided as would be understood by someone skilled in the art. Usually a special connector called a strip port connector is mounted opposite the aperture in the meter for receipt of the disposable test sensor such as a test strip. Optionally a data port with a jack socket can be provided for uploading information to the meter controller, typically a central processing unit, or memory, or for downloading information from the CPU or memory of the meter. Occasionally, a simple hole in the case of the meter is provided to access one or more connection points on the PCB for uploading information to the meter memory or CPU, such as calibration information. Sometimes two or more holes can be so provided. A relatively rigid flexible sticker with adhesive backing is placed over the hole or holes to prevent mechanical or electrical access to the inside of the meter via the case once the information has been uploaded to the meter. Alternatively, a relatively rigid flexible panel is attached to the meter casing by separate adhesive to completely cover the hole or holes.

Such a sticker or flexible pad prevents access to the connection points on the PCB lying beneath the holes in the casing.

[0004] Nevertheless, such stickers or flexible pads are not permanently fixed to the case and these can become dislodged either partially or wholly in which case access to the PCB may become possible. This can be a particular problem in an excessively warm, cold, dry or humid environments. This is because such conditions can affect the effectiveness of the sticker adhesive or the adhesive used to fix the flexible pad to the meter casing.

[0005] Static electricity can build up in the body of a human particularly when, for example, walking on a nylon carpet or vinyl floor or sitting on a stool made of a manmade material. It is not uncommon for static charges exceeding 30kV to be developed depending upon the temperature and relative humidity of the environment. Static will discharge from a body when it approaches or contacts material of differing potentials. Often the material of differing potential is connected to ground. Static discharge will typically follow the easiest route to this differing potential such as ground. Thus, for example, lightning is conducted to ground through a pointed lightning conductor attached to a building in preference to discharging through the building itself.

[0006] As a general rule, static charge of 1kV will discharge across an air gap of 1mm thus a 30kV charge could potentially bridge a gap of 30mm. Thus, under certain circumstances, there is a risk that static will be discharged from the user to the hand held device through any openings in the hand held device. Discharge of static to a hand held analytical device such as a meter can occur if (a) a user who has developed a high static charge touches a meter which has been kept at a separate location e.g. such as a bag or cupboard, in other words, a meter at a different potential to the user; (b) the user hands a meter to a different individual, for example, a health care professional at a different potential charge; (c) the meter comes into contact with another object with differing potential and the gap between these items is reduced sufficiently for static discharge to occur. Thus the internal components of the analytical device are vulnerable to static discharge to them via any openings in the meter casing such as the aperture for inserting a disposable test sensor or data port or any holes in the casing for accessing the PCB.

[0007] Furthermore, discharge of static to the hand held device such as a meter through any openings in the casing can result in physical damage of the critical circuits and

components. The result of this can be a malfunction of the hand held device which could give erroneous results. There is, therefore, a need to alleviate such risks and as far as possible avoid them.

[0008] There are a number of methods currently in use to alleviate damaging effects of electrostatic discharge (ESD) on the sensitive circuits and components of a printed circuit board in hand held devices, these include the incorporation of surge protection devices, which are costly and relatively complex components. The use of such components, which are based on integrated circuit designs, adds an additional level of complexity to the circuitry into which they are incorporated. Thus, particularly for medical devices which are subject to a high level of regulation in many countries, there is a requirement for further additional testing to validate these additional components to the integrity of the PCB in addition to a number of additional manufacturing steps. Such additional validation and manufacturing steps increase the cost of such a device. Thus there is a need to develop alternative methods and means to alleviate the effects and risks of electrostatic discharge that can be more easily and cheaply incorporated into a hand held analytical device.

Summary of the Invention

[0009] According to one embodiment, the present invention is directed to a meter for the detection of glucose, the meter including a programmable chip, an external opening through the meter housing, a connector for programming the programmable chip, wherein the connector is accessible through the external opening, and an electrostatic discharge cover adapted to protect the meter from electrostatic discharge by covering the connector. The present invention may further include a meter wherein the connector includes a plurality of connector pins, the electrostatic discharge cover includes a plurality of protrusions including indentations, the protrusions being adapted to fit over the connector pins. The present invention may further include a meter wherein the cover is removable. The present invention may further include a meter wherein the programmable chip is an ASIC chip. The present invention may further include a meter wherein the programmable chip is a memory chip.

[0010] A further embodiment of the present invention is directed to a method of programming a meter for the detection of glucose, wherein the meter comprises a

programmable chip, an external opening through the meter housing, a connector for programming the programmable chip, and an electrostatic discharge cover adapted to protect the meter from electrostatic discharge by covering the connector. In this embodiment of the present invention, the method comprises the steps of assembling the meter such that the connector extends through the meter casing, covering the connector with the electrostatic discharge cover, completing assembly of the meter, removing the electrostatic discharge cover to expose the connector, connecting to the exposed connector, programming the meter through the connector, replacing the electrostatic discharge cover.

Brief Description of the Figures

- [0011] The invention will now be described, by way of example only, with reference to the following figures.
- [0012] Figure 1 is a perspective view of the front of a hand held meter for testing glucose according to the present invention.
- [0013] Figure 1A is a perspective views of the rear of a hand held meter for testing glucose according to the present invention.
- [0014] Figure 2 is a plan view of the rear of the meter of Figure 1 according to an exemplary embodiment of the present invention.
- [0015] Figure 3 is an elevation view of the rear half of the meter casing of the meter of Figures 1 and 2 along line A-A'.
- [0016] Figure 4 is a plan view of the rear face of an internal printed circuit board of the meter of Figures 1 and 2.
- [0017] Figure 5 is a plan view of an insert plug according to an exemplary embodiment of the present invention.
- [0018] Figure 6 is a cross section along line B-B' of the insert of Figure 5.
- [0019] Figure 7 is a plan view of a flexible second insert in the form of a flexible pad or sticker or label according to an exemplary embodiment of the present invention for use with the meter shown in Figures 1-3.
- [0020] Figure 8 is a flow diagram illustrating a method of assembling a meter according to the present invention.

Detailed Description of the Figures

- [0021] Figure 1 shows a meter 2 having an aperture 4 at an end 5 of meter 2 for receiving a test sensor such as a disposable test strip such as, for example, the One Touch Ultra test strip available from LifeScan Inc., Milpitas, California, USA. A number of sloping lands 6 help guide a test strip on its approach to the meter and onwards into aperture 4. A display 8 is provided to indicate the on/off status of the meter, the results of any test and test instructions. A button 10 can be used to control the calibration code or enter memory mode. The strip insertion/retraction automatically controls the on/off status of the meter. The meter casing is in two shaped halves 14 and 16 (as seen in Figure 3) which are snap fitted and/or ultrasonically welded together to provide a complete casing. Overlapping inter-engagement snapfit features are provided around the rim of first portion 14 of casing 12 along with corresponding features on the rim of second portion 16 of casing 12.
- [0022] Such a meter is typically used for testing for glucose in blood, for example. The user pricks their finger using a commercially available lancet such as the PenletPlus available from LifeScan Inc., Milpitas, California, USA. The user deposits a drop of blood on a disposable strip which has been pre-inserted into aperture 4, guided by lands 6, to make connection with meter electronics inside casing 12. The meter electronics then controls a test measurement of the blood on the strip to determine the concentration of glucose in the blood.
- [0023] Referring now to Figure 2, second or rear portion 16 of casing 12 can be seen. Figure 2 shows rear portion 16 in plan view and Figure 3 shows rear portion 16 in cross sectional view along line A-A'. Casing portions 14 and 16 are formed by injection molding or other methods as understood by those skilled in the art. These are made from grey colored dielectric resin or plastic such as ABS type material available from DuPont or such as cycolac available from General Electric, USA.
- [0024] In Figure 1A, a specially shaped clip 18 is made from the same material as portion 16 and is attached to casing 16. Clip 18 can either be manufactured separately or integral with casing half 16. Clip 18 has two large radius concave shaped edges 19 and one smaller radius convex shaped edge 21. Clip 18 is slightly resiliently mounted with respect to casing 16 so that when the clip is placed over material of a pocket, the material is securely gripped between clip 18 and meter 16. Indeed as can be seen in Figure 3, clip 18

abuts case half 16 near edge 21 so that clip 18 must be bent away from case 16 slightly when the fabric of a pocket is passed between clip 18 and casing half 16. This means that clip 18 is under tension and grips the fabric securely. The shaped edges 19 and 21 of clip 18 facilitate easy insertion of clip 18 over the fabric of a pocket. Such an arrangement facilitates the easy storage of the hand held analytical device about a person. The width of clip 18 is relatively large compared to the width of meter casing 16. At its widest point clip 18 is 24 mm, while at its narrowest point clip 18 may be 15 mm. Typically clip 18 is around 50 mm in length. Therefore, a relatively large region is provided in the centre of clip 18. This central region can be used for example for providing a label 23 with additional information for a user such as helpline number or an individual name tag to be written upon by a user.

[0025] A first relatively shallow four-sided rebate 20 is provided in rear portion 16 of meter casing 12. Rebate 20 can be seen clearly in Figures 2 and 3. The depth of rebate 20 is typically around 0.5 mm from the outline of the casing. Rebate 20 is shaped to correspond more or less with the outer edge of meter casing portion 16. A second rebate 25 is provided inwardly of rebate 20. Rebate 25 is a rectangular shape and is of relatively greater depth than the depth of rebate 20. Rebate 25 has a total depth of approximately 1 mm (typically 0.95 mm from the outline of the casing). A number of access holes 22, of diameter around 2mm, situated at the bottom of rebate 20, extend right through casing 12. Typically the casing and holes are 1.75mm in this region. While in this particular embodiment holes 22 are provided in the rear-casing portion 16 rather than the front casing portion 14, they may be provided in one or both portions. Ten holes are provided in this particular embodiment, although differing numbers such as one or more, two or more and so on or greater than 10 holes can be provided as would be understood by someone skilled in the art.

[0026] Referring now to Figure 4, a plan view of the inside of meter 2, as if casing portion 16 were removed, is shown. The rim of casing portion 14 can be seen. In addition, the rear 7 of one of lands 6 can be seen at end 5 of meter 2. A PCB 27 is also provided to which various components are attached as will be understood by those skilled in the art. A number of contact points 24 are provided on PCB 27 at locations to correspond with the locations of holes 22 in casing portion 16. A programmable chip 26, which, in one

embodiment of the present invention may be an ASIC (application specific integrated circuit), is provided with the meter control, electronics and programming. A battery 28 is situated on PCB 27. Typically, contact pads 24 are printed along with other similar components and contact pads for PCB 27 during the manufacture of the PCB. Thus, no additional processing steps are required at this stage. Pads 24 typically comprise a gold layer (10 to 100 μm thick) that is electroplated onto the copper track of the PCB, revealed by etching of the PCB layout that is printed on the PCB blank. Pads 24 are electrically connected to components on the PCB 27 via the PCB, such as the ASIC 26 or to a separate CPU or memory.

[0027] Referring now to Figure 5, an insert plug 30 can be seen. Typically insert plug 30 is made from rigid plastic material. It may be made of grey colored resin or polymer material such as ABS type material available from DuPont or such as cycolac from General Electric, USA. A number of spigots or upstanding protrusions or pegs 34 are provided in a layout to correspond to the layout of holes 22 in casing portion 16. Furthermore, the size and shape of pegs 34 are sized and shaped to closely fit within holes 22. The pegs 34 may be an interference fit with holes 22. While all holes 22 and pegs 34 are of the same size and shape in this embodiment, this needs not necessarily be the case. Indeed larger and/or smaller holes and/or holes of different shapes can be provided depending upon the requirements for electrical contact with PCB 27 via contact pads 24.

[0028] The size, shape and orientation of pegs 34 relative to rigid base panel 32 can be seen more clearly in Figure 6. In one possible alternative embodiment base 32 and/or pegs 34 may be made from an elastomeric material such as rubber or flexible plastic.

[0029] Referring now to Figure 7, flexible sticker pad 36 is provided. Sticker 36 is typically made from a dielectric plastic such as Mylar. It may be in the form of a stickable label containing information such as a manufacturers details or calibration codes etc. In this example embodiment, sticker 36 may have a pre-applied layer of adhesive on one side to facilitate adhesion of sticker 36 within rebate 20, although it may do in another example embodiment. The size and shape of edge 38 of pad 36 corresponds to the size and shape of rebate 20. Likewise the thickness of pad 36 is arranged to correspond to the thickness of the depth of rebate 20. Indeed pad 36 may be flexible or rigid and may be an interference fit in rebate 20. Similarly, the outer edge 33 of insert plug 30 is sized and

shaped to correspond closely to that of rebate 25. Indeed insert 30 may be an interference fit in rebate 25. Furthermore, the height of rigid base panel 32 is arranged to correspond to the depth of rebate 25. Such arrangements mean that when fully assembled the outer casing 16 is more or less flush with the outermost surface of flexible pad 36 and further the base of rebate 20 is substantially flat to receive sticker 36. Adhesive 29 is provided around the outer edge of rebate 25 to fix pad 36 to casing 16. The adhesive may be provided in a continuous or discrete manner on casing 16.

[0030] During assembly, components 26 and 28 plus any other additional components such as memory are mounted on a pre-prepared PCB 27 having contact pads 24. PCB 27 is fixed within casing portion 14 and casing portion 16 is snap fitted and/or stuck onto casing portion 14 for example by ultrasonic welding. Following this assembly insert plug 30 is optionally placed in rebate 25. In this arrangement pegs 34 pass through and effectively close holes 22. This minimizes the width of any air gap in holes 22. Thus, the possibility of electrostatic discharge via these holes is reduced.

[0031] If insert 30 is added to protect the meter from ESD during manufacture then prior to the following step it is removed. Contact is made to the PCB from outside the casing via pads 24 using electrical contact pins which access pads 24 via holes 22. Once uploading of information such as manufacturing parameters, and/or software and/or calibration information has taken place, insert 30 is replaced or added to casing portion 16. Thus, control software and/or calibration information and/or other information can be uploaded to the meter via holes 22 in casing 16. Insert 30 is placed in rebate 25, closing holes 22 in this example embodiment substantially entirely closing holes 22 so as to virtually eliminate an air gap. Optionally, insert 30 can be bonded to casing 16 by adhesive or otherwise. Optionally, insert 30 is removably attached to casing 16 for example using adhesive.

[0032] Next, adhesive is applied either to casing 16 such as at regions 29 and/or to the rear surface of flexible pad 36 if it is not already provided with adhesive. Next, flexible pad 36 is attached to meter casing 16 within rebate 20 completely covering insert 30, which itself completely covers holes 22. Removable insert 30 may optionally be fixed to casing 16 by adhesive or other means. Pad 36 may be removable by breaking adhesive 29 and either wholly or partially removing adhesive 29 and replacing it with further adhesive or using a

type of adhesive 29 that allows removal and replacement of pad 36 with no or little detriment to the adhesive effect between pad 36 and casing portion 16.

[0033] In this arrangement the chance of electrostatic discharge reaching PCB 27 is further reduced. Indeed, should pad 36 be wholly or partially dislodged for whatever reason, insert 30 provides a fallback arrangement to prevent ESD entering into the inside of meter casing 12. In other words, in one embodiment insert 30 virtually eliminates any air gaps by the provision of pegs 34 which correspond to holes 22 in size and shape. Furthermore, should there be any manufacturing difficulties such that a small air gap does exist around plug 30 and pegs 34 into meter facing 12, then flexible pad 36 provides additional protection increasing the length of the air gap and therefore the length of travel of any electrostatic discharge. Thus the risk of electrostatic discharge into the meter and damage to any meter components is virtually eliminated by the combination of removable insert 30 and pad 36.

[0034] It will be recognized that equivalent structures may be substituted for the structures illustrated and described herein and that the described embodiment of the invention is not the only structure that may be employed to implement the claimed invention. In addition, it should be understood that every structure described above has a function and such structure can be referred to as a means for performing that function.

[0035] While preferred embodiments of the present invention have been shown and described herein, it will be obvious to those skilled in the art that such embodiments are provided by way of example only. Numerous variations, changes, and substitutions will now occur to those skilled in the art without departing from the invention. It should be understood that various alternatives to the embodiments of the invention described herein may be employed in practicing the invention. It is intended that the following claims define the scope of the invention and that methods and structures within the scope of these claims and their equivalents be covered thereby.

WHAT IS CLAIMED IS:

1. A meter for the detection of glucose, wherein the meter comprises:
a programmable chip;
an external opening through said meter housing;
a connector for programming said programmable chip, wherein said connector is accessible through said external opening; and
an electrostatic discharge cover adapted to protect said meter from electrostatic discharge by covering said connector.
2. A meter according to Claim 1 wherein:
said connector comprises a plurality of connector pins;
said electrostatic discharge cover includes a plurality of protrusions including indentations, wherein said protrusions are adapted to fit over said connector pins.
3. A meter according to Claim 2, wherein said cover is removable.
4. A meter according to Claim 1, wherein said programmable chip is an ASIC chip.
5. A meter according to Claim 1, wherein said programmable chip is a memory chip.
6. A method of programming a meter wherein said meter comprises a programmable chip, an external opening through said meter housing, a connector for programming said programmable chip, and an electrostatic discharge cover adapted to protect said meter from electrostatic discharge by covering said connector, said method comprising the steps of:
assembling said meter such that said connector extends through said meter casing;
covering said connector with said electrostatic discharge cover;
completing assembly of said meter;
removing said electrostatic discharge cover to expose said connector;
connecting to said exposed connector;
programming said meter through said connector;
replacing said electrostatic discharge cover.