Abstract: A lancing device for drawing a body fluid sample from skin is disclosed. The device comprises a body portion and a lancet located within the body portion in a retracted position. The lancet is movable between a retracted position and an extended position and is adapted to puncture the skin in an extended position. At least a portion of at least one of the body portion and lancet has antimicrobial properties.
ANALYTE-TESTING INSTRUMENTS HAVING ANTIMICROBIAL PROPERTIES
AND METHODS OF USING THE SAME

FIELD OF THE INVENTION

[001] The present invention relates generally to analyte-testing instruments and, more particularly, to analyte-testing instruments having antimicrobial properties and methods of using the same.

BACKGROUND OF THE INVENTION

[002] The quantitative determination of analytes in body fluids is of great importance in the diagnoses and maintenance of certain physiological abnormalities. For example, lactate, cholesterol, and bilirubin should be monitored in certain individuals. In particular, determining glucose in body fluids is important to diabetic individuals who must frequently check the glucose level in their body fluids to regulate the glucose intake in their diets. The results of such tests can be used to determine what, if any, insulin or other medication needs to be administered. In one type of testing system, test sensors are used to test a fluid such as a sample of blood.

[003] One method of monitoring a person's blood glucose level is with a portable, handheld blood glucose testing device (e.g., a meter). To determine the blood glucose level with the meter, a lancet device, typically containing a needle lancet, pierces the skin tissue, allowing a whole blood sample to form on the skin's surface. Once the requisite amount of blood is produced on the skin's surface, the blood sample is transferred to a test sensor. The test sensor is generally placed within an opening in the body of the meter, where an electrical signal indicative of the blood glucose level being tested is supplied and transmitted to an electrical assembly within the meter.

[004] Bacteria and germs may be transmitted to and from analyte-testing instruments (e.g., meter, lancet device, test sensor) through the air or by physical contact. In addition, users often do not clean their hands or the testing instruments as often as is needed to maintain a low level of microorganisms. Because of this, microbes, bacteria, fungi, viral organisms, or combinations thereof often exist and grow on the testing instruments. This creates significant hygiene issues that may lead to illness, infection, and/or disease. The existence and growth of
microorganisms on the testing instruments are especially dangerous since the testing instruments are used to pierce the skin and are subsequently in close proximity to the site of the pierced skin.

[005] It would be desirable to have analyte-testing instruments that assist in addressing one or more of the above disadvantages.

**SUMMARY OF THE INVENTION**

[006] According to one embodiment of the present invention, a lancing device for drawing a body fluid sample from skin is disclosed. The device comprises a body portion and a lancet located within the body portion in a retracted position. The lancet is movable between a retracted position and an extended position and is adapted to puncture the skin in an extended position. At least a portion of at least one of the body portion and lancet has antimicrobial properties.

[007] According to another embodiment of the present invention, an instrument adapted to determine an analyte concentration of a fluid sample using a test sensor is disclosed. The instrument comprises a display, a user-interface mechanism, and a body portion. The display is adapted to display information to a user. The user-interface mechanism allows the user to interact with the instrument. The body portion includes at least one opening formed therein. The at least one opening is adapted to receive a test sensor. At least a portion of at least one of the display, user-interface mechanism, and body portion has antimicrobial properties.

[008] According to another embodiment of the present invention, a method of determining a concentration of at least one analyte in a body fluid sample drawn from skin is disclosed. The method comprises the acts of providing a lancing device, puncturing the skin, drawing a body fluid sample from the skin, contacting the body fluid sample with a test sensor, placing the test sensor within an opening adapted to receive the test sensor, and determining the concentration of the at least one analyte. The lancing device comprises a body portion and a lancet. The lancet is located within the body portion in a retracted position. The lancet is movable between a retracted and an extended position. The skin is punctured by actuating the lancet into the extended position. The opening adapted to receive a test sensor is located on an analyte-testing device. The analyte-testing device further comprises a display and a user-interface mechanism. The concentration of the at least one analyte is determined using the
analyte-testing device. At least a portion of at least one of the lancing device, test sensor, and analyte-testing device has antimicrobial properties.

[009] The above summary of the present invention is not intended to represent each embodiment or every aspect of the present invention. Additional features and benefits of the present invention are apparent from the detailed description and figures set forth below.

BRIEF DESCRIPTION OF THE DRAWINGS

[0010] FIG. 1a is a top view of a lancing device according to one embodiment.
[0011] FIG. 1b is a bottom view of the lancing device of FIG. 1a.
[0012] FIG. 2a is a test sensor including a lid according to one embodiment.
[0013] FIG. 2b is the test sensor of FIG. 2a without the lid.
[0014] FIG. 3 is a front view of a meter according to one embodiment.
[0015] FIG. 4 is a perspective view of a meter having an integrated lancet system according to another embodiment.

DESCRIPTION OF ILLUSTRATED EMBODIMENTS

[0016] The present invention is directed to analyte-testing instruments having antimicrobial properties and methods of using the same. It is contemplated that one or more components of the analyte-testing instruments may have antimicrobial properties to assist in destroying, preventing, or inhibiting the growth and/or spread of, for example, microbes, bacteria, fungi, viral organisms, or combinations thereof. It may be desirable to include antimicrobial properties on components of the testing instruments that a user frequently contacts and/or components that are typically in close proximity to an area of skin that has been pierced to obtain a fluid (e.g., blood) sample.

[0017] Analytes that may be measured using the analyte-testing instruments of the present invention include glucose, lipid profiles (e.g., cholesterol, triglycerides, LDL, and HDL), microalbumin, hemoglobin A1C, fructose, lactate, and/or bilirubin. The present invention is not limited, however, to these specific analytes, and it is contemplated that other analyte concentrations may be determined. The analytes may be in, for example, a whole blood sample, a blood serum sample, a blood plasma sample, or other body fluids like ISF (interstitial fluid)
and/or urine. One non-limiting example of the analyte-testing instalments’ use is to determine the glucose concentration in a user's blood or plasma.

[0018] To test the concentration of an analyte (e.g., glucose) in a body fluid (e.g., blood), a user typically places his or her finger or other area of the body up to a lancet or a lancing device to generate a whole blood sample. A non-limiting example of a lancing device used to obtain a fluid sample from a user is illustrated in FIGs. 1a,b. According to the embodiment of FIGs. 1a,b, a lancing device 100 has a body portion including a main housing 102 and a movable housing 114 that is movable relative to the main housing 102. An endcap support 116 is connected to the main housing 102 on the testing end of the lancing device 100. An endcap 118 may be removably attached to the endcap support 116. When attached, the endcap 118 is retained on the endcap support 116 by a pair of support arms 120a,b integrally formed with the endcap support 116. The lancing device 100 may be provided with a number of different endcaps 118, each having a different opening, diameter, and/or shape, to facilitate the formation of skin punctures of various depths. One example is an alternative site testing endcap, which may be substantially transparent and/or have a wider opening such that a deeper skin puncture may be achieved. Alternatively, the endcap 118 may include an adjustable dial 134 for allowing punctures of different depths to be performed utilizing a single endcap 118. One company employing such a lancet device is Bayer Healthcare LLC (Tarrytown, New York). An example of such a lancing device from Bayer includes the Ascencia® MICROLET® Adjustable Lancing Device.

[0019] To use the lancing device 100, a user grasps and pulls the movable housing 114 away from the main housing 102, thereby moving an internal lancet mechanism 129 to a cocked position. The user then places his or her finger against the endcap 118 so that the finger generally covers an aperture formed in the endcap 118. In the embodiment of FIGs. 1a,b, the user places his or her finger against the adjustable dial 134 so that the finger generally covers an aperture formed in the adjustable dial 134. The user then presses a pushbutton 130 to actuate the lancet mechanism 129 so that a sharp tip 131 of the lancet mechanism 129 is forced through the aperture in the endcap 118 and/or adjustable dial 134, thereby piercing the user’s skin.

[0020] According to the present invention, one or more components of the lancing device 100 include antimicrobial properties. It may be desirable to include antimicrobial properties on components of the lancing device 100 that have significant user contact. For example, according
to one embodiment of the present invention, the movable housing 114 has antimicrobial properties. As explained above, prior to testing, the user grasps and pulls the movable housing 114 away from the main housing 102 to cock the lancet mechanism 129. Any microorganisms located on the movable housing 114 may thus be transferred to the user, for example on the finger that is to be pierced. Thus, it may be beneficial for the movable housing 114 to have antimicrobial properties to inhibit or prevent the growth and/or spread of microorganisms.

[0021] Alternatively or additionally, the lancing device 100 may include an end cap 118 having antimicrobial properties, according to another embodiment of the present invention. As explained above, the user contacts the endcap 118 by placing his or her finger against the endcap 118 while the finger is being pierced. Thus, any microorganisms on the endcap 118 may be transferred to the user's finger near the site of the pierced skin. The microorganisms may then travel to and contact the site of the pierced skin, thereby potentially causing illness, infection, and/or disease.

[0022] Alternatively or in addition to the embodiments described above, other components of the lancing device 100 may have antimicrobial properties including, but not limited to, the main housing 102, the sharp tip 131 of the lancet mechanism 129, the adjustable dial 134, or combinations thereof. It is contemplated that the entire lancing device 100 may have antimicrobial properties. It is contemplated that other lancing devices besides the illustrated lancing device 100 may include the antimicrobial properties of the present invention.

[0023] Once the user has pierced his or her finger, the user contacts the whole blood sample that has formulated on his or her finger with a testing end of a test sensor. A portion of the blood is generally drawn into a capillary channel of the test sensor by capillary action. The test sensors are typically provided with a capillary channel extending from the front or testing end of the sensors to biosensing or reagent material disposed in the sensor. The biosensing or reagent material is designed to react with the desired analyte to be tested.

[0024] One non-limiting example of a test sensor is shown in FIGs. 2a,b. FIGs. 2a,b depict a test sensor 200 that includes a capillary channel 272, a lid 274, and a plurality of electrodes 276, 278, and 280. The plurality of electrodes includes a counter electrode 276, a detection electrode 278, and a working (measuring) electrode 280. As shown in FIG. 2b, the test sensor 200 includes a fluid-receiving area 282 that contains reagent. The operation of a fluid-receiving area with reagent and electrodes on test sensors is known to those skilled in the art and
will therefore not be described in further detail. Examples of electrochemical test sensors, including their operation, may be found at, for example, U.S. Patent Number 6,531,040 and EP 1152239. Other test sensors including, but not limited to, optical test sensors may also be used for analyte testing.

[0025] According to another embodiment of the present invention, one or more portions of a test sensor (e.g., test sensor 200 of FIGs. 2a,b) has antimicrobial properties. As explained above, the user contacts the test sensor 200 with his or her finger immediately after the finger has been pierced. Thus, microorganisms located on the test sensor 200 may be transferred from the test sensor 200 directly onto the pierced finger, thereby potentially causing illness, infection, and/or disease. Accordingly, it may be desirable for the test sensor 200 or components thereof (e.g., fluid-receiving area 282, lid 274) to have antimicrobial properties. It is further contemplated that other components or combination of components of the test sensor 200 may have antimicrobial properties. It is contemplated that other test sensors besides the test sensor 200 may include the antimicrobial properties of the present invention.

[0026] After a minimum amount of blood is drawn into the test sensor, the blood chemically reacts with the reagent material in the test sensor so that an electrical signal indicative of the blood glucose level of the sample being tested is supplied and subsequently transmitted to an electrical assembly. The electrical assembly is typically located within an analyte-testing instrument, or a meter.

[0027] FIG. 3 illustrates a meter 300 according to one embodiment. The meter 300 includes a display 312, a body portion 313 having a test sensor dispensing port 314 adapted to receive and/or hold a test sensor, and a user-interface mechanism. In the illustrated embodiment, the user-interface mechanism includes a plurality of buttons 316a-c. It is contemplated that the user-interface may include other mechanisms suitable for communicating with the meter including, but not limited to, a scroll wheel and/or a touch screen. One example of a display 312 that may be used in the meter 300 is a liquid-crystal display. The meter 300 typically shows information from a testing procedure and/or in response to signals input by the user-interface mechanism (e.g., buttons 316a-c) on the display 312 and then stores the information in memory. The result of the testing may also be announced audibly, by, for example, using a speaker, and stored in memory.
[0028] After the testing has been completed, the test sensor may be removed from the
test sensor dispensing port 314 by several methods. In one embodiment, the meter 300 may
include an eject mechanism 340 that ejects the used test sensor from the meter 300. In such an
embodiment, the test sensors are released forcefully. In a further embodiment, the test sensor
may be removed manually from the meter 300.

[0029] Turning next to FIG. 4, a front view of a meter 400 according to another
embodiment is shown. The meter 400 has generally the same structure as the meter 300 of FIG.
3. Additionally, the meter 400 includes an integrated lancet system 401. The integrated lancet
system 401 has a body portion 402 including a main housing 403 and a movable housing 405
that is movable relative to the main housing 403. An endcap 407 may be removably attached to
the main housing 403.

[0030] To use the integrated lancet system 401, a user performs substantially the same
acts as described above with respect to the lancing device 100 of FIGs. 1a,b. The user grasps
and pulls the movable housing 405 away from the main housing 403, thereby moving an internal
lancet mechanism 409 to a cocked position. The user then places his or her finger against the
endcap 407 so that the finger generally covers an aperture formed in the endcap 407. The user
then presses a pushbutton 411 to actuate the lancet mechanism 409 so that a sharp tip 413 of the
lancet mechanism 409 is forced through the aperture in the endcap 407, thereby piercing the
user's skin. The endcap may further include an adjustable dial (not shown) for allowing
punctures of different depths to be performed using a single endcap 407. It is contemplated that
other types of meters including integrated lancet systems may incorporate the antimicrobial
properties of the present invention.

[0031] Returning now to FIG. 3, in another embodiment of the present invention,
components of the meter 300 may have antimicrobial properties. Because the user generally
contacts the user-interface mechanism (e.g., buttons 316a-c) several times during the testing
procedure, it may be desirable for the user-interface mechanism to have antimicrobial properties.
Alternatively or additionally, because the user may contact the port 314 and/or the area of the
meter 300 surrounding the port 314 when removing the test sensor once the testing is completed,
it may be desirable for the port 314 and/or the area surrounding the port 314 to include
antimicrobial properties. It is contemplated that other components or combination of
components of the meter 300 may have antimicrobial properties including, but not limited to, parts of the body portion 313 where the meter 300 is generally held by the user.

[0032] In another embodiment of the present invention, the meter 400 of FIG. 4, or components thereof, includes antimicrobial properties. The components of the meter 400 having antimicrobial properties may correspond to those described above with respect to the meter 300 (e.g., user-interface mechanism 416, body portion 402, port 414). Alternatively or additionally, the integrated lancet system 401 or components thereof may have antimicrobial properties. For example, the movable housing 405, the pushbutton 411, the endcap 407, the sharp tip 413 of the lancet mechanism 409, or combinations thereof may have antimicrobial properties.

[0033] It is contemplated that other suitable mechanisms for providing antimicrobial properties to the embodiments of the present invention may be used. The antimicrobial properties may be achieved by incorporating antimicrobials, such as silver, chlorine dioxide, triclosan, allyl isothiocyanate, organic alternative products, or the like. Other antimicrobials may include natural oils such as cinnamon, peppermint, and spearmint. The antimicrobial may be in the form of an additive, a premix, a coating, or the like. One company marketing antimicrobial materials is Bayer MaterialScience (Pittsburgh, Pennsylvania). An example of such an antimicrobial material from Bayer includes Makrolon® 3108 polycarbonate material antimicrobial additive.

[0034] The components of the analyte-testing instruments having antimicrobial properties may be selected based on factors such as the amount of user contact, cost considerations, availability of antimicrobial materials, or the like. It is contemplated that other analyte-testing instruments including, but not limited to, test-sensor cartridges, lancets, syringes, or components thereof may incorporate the antimicrobial properties described above.

**ALTERNATIVE EMBODIMENT A**

[0035] A lancing device for drawing a body fluid sample from skin, the device comprising:

a body portion; and

a lancet located within the body portion in a retracted position, the lancet being movable between a retracted position and an extended position, and adapted to puncture the skin in an extended position,
wherein at least a portion of at least one of the body portion and lancet has antimicrobial properties.

**ALTERNATIVE EMBODIMENT B**

[0036] The lancing device of Alternative Embodiment A, wherein the body portion further comprises a main housing and a movable housing, the movable housing being movable relative to the main housing.

**ALTERNATIVE EMBODIMENT C**

[0037] The lancing device of Alternative Embodiment B, wherein at least a portion of the movable housing has antimicrobial properties.

**ALTERNATIVE EMBODIMENT D**

[0038] The lancing device of Alternative Embodiment B, wherein the main housing further comprises a pushbutton adapted to actuate the lancet, the pushbutton having antimicrobial properties.

**ALTERNATIVE EMBODIMENT E**

[0039] The lancing device of Alternative Embodiment A further comprising an endcap detachably coupled to the body portion, wherein the lancet is adapted to puncture the skin by extending through an opening formed in the endcap.

**ALTERNATIVE EMBODIMENT F**

[0040] The lancing device of Alternative Embodiment E, wherein at least a portion of the endcap has antimicrobial properties.

**ALTERNATIVE EMBODIMENT G**

[0041] The lancing device of Alternative Embodiment E, wherein the endcap further comprises an adjustable dial, wherein at least a portion of the adjustable dial has antimicrobial properties.

**ALTERNATIVE EMBODIMENT H**

[0042] The lancing device of Alternative Embodiment A, wherein at least a portion of the lancet has antimicrobial properties.

**ALTERNATIVE EMBODIMENT I**

[0043] An instrument adapted to determine an analyte concentration of a fluid sample using a test sensor, the instrument comprising:

- a display adapted to display information to a user;
a user-interface mechanism for allowing the user to interact with the instrument; and
a body portion including at least one opening formed therein, the at least one opening being adapted to receive a test sensor,
wherein at least a portion of at least one of the display, user-interface mechanism, and body portion has antimicrobial properties.

ALTERNATIVE EMBODIMENT J
[0044] The instrument of Alternative Embodiment I, wherein at least one portion of the user-interface mechanism has antimicrobial properties.

ALTERNATIVE EMBODIMENT K
[0045] The instrument of Alternative Embodiment I, wherein at least a portion of the body portion has antimicrobial properties.

ALTERNATIVE EMBODIMENT L
[0046] The instrument of Alternative Embodiment K, wherein the portion of the body portion having antimicrobial properties includes an area surrounding the at least one opening.

ALTERNATIVE EMBODIMENT M
[0047] The instrument of Alternative Embodiment I, wherein the body portion further includes an integrated lancing device.

ALTERNATIVE EMBODIMENT N
[0048] The instrument of Alternative Embodiment M, wherein at least a portion of the integrated lancing device has antimicrobial properties.

ALTERNATIVE PROCESS O
[0049] A method of determining a concentration of at least one analyte in a body fluid sample drawn from skin, the method comprising the acts of:

- providing a lancing device that comprises a body portion and a lancet, the lancet being located within the body portion in a retracted position, the lancet being movable between a retracted and an extended position;
- puncturing the skin by actuating the lancet into the extended position;
- drawing a body fluid sample from the skin;
- contacting the body fluid sample with a test sensor;
placing the test sensor within an opening adapted to receive the test sensor, the opening being located on an analyte-testing device, the analyte-testing device further comprising a display and a user-interface mechanism; and
determining the concentration of the at least one analyte using the analyte-testing device;
wherein at least a portion of at least one of the lancing device, test sensor, and analyte-
testing device has antimicrobial properties.

**ALTERNATIVEPROCESS P**

[0050] The method of Alternative Process O, wherein at least a portion of the lancing device has antimicrobial properties.

**ALTERNATIVEPROCESS O**

[0051] The method of Alternative Process O, wherein at least a portion of the test sensor has antimicrobial properties.

**ALTERNATIVEPROCESS R**

[0052] The method of Alternative Process O, wherein at least a portion of the analyte-
testing device has antimicrobial properties.

**ALTERNATIVEPROCESS S**

[0053] The method of Alternative Process O, wherein the lancing device further comprises an endcap detachably coupled to the body portion.

**ALTERNATIVEPROCESS T**

[0054] The method of Alternative Process S, wherein the lancet extends through an opening formed in the endcap during the act of puncturing the skin by actuating the lancet into an extended position.

[0055] While the invention is susceptible to various modifications and alternative forms, specific embodiments and methods thereof have been shown by way of example in the drawings and are described in detail herein. It should be understood, however, that it is not intended to limit the invention to the particular forms or methods disclosed, but, to the contrary, the intention is to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the invention as defined by the appended claims.
CLAIMS:

1. A lancing device for drawing a body fluid sample from skin, the device comprising:
   a body portion; and
   a lancet located within the body portion in a retracted position, the lancet being movable between a retracted position and an extended position, and adapted to puncture the skin in an extended position,
   wherein at least a portion of at least one of the body portion and lancet has antimicrobial properties.

2. The lancing device of claim 1, wherein the body portion further comprises a main housing and a movable housing, the movable housing being movable relative to the main housing.

3. The lancing device of claim 2, wherein at least a portion of the movable housing has antimicrobial properties.

4. The lancing device of claim 2, wherein the main housing further comprises a pushbutton adapted to actuate the lancet, the pushbutton having antimicrobial properties.

5. The lancing device of claim 1, further comprising an endcap detachably coupled to the body portion, wherein the lancet is adapted to puncture the skin by extending through an opening formed in the endcap.

6. The lancing device of claim 5, wherein at least a portion of the endcap has antimicrobial properties.

7. The lancing device of claim 5, wherein the endcap further comprises an adjustable dial, wherein at least a portion of the adjustable dial has antimicrobial properties.

8. The lancing device of claim 1, wherein at least a portion of the lancet has antimicrobial properties.

9. An instrument adapted to determine an analyte concentration of a fluid sample using a test sensor, the instrument comprising:
   a display adapted to display information to a user;
a user-interface mechanism for allowing the user to interact with the instrument; and

a body portion including at least one opening formed therein, the at least one opening being adapted to receive a test sensor,

wherein at least a portion of at least one of the display, user-interface mechanism, and body portion has antimicrobial properties.

10. The instrument of claim 9, wherein at least one portion of the user-interface mechanism has antimicrobial properties.

11. The instrument of claim 9, wherein at least a portion of the body portion has antimicrobial properties.

12. The instrument of claim 11, wherein the portion of the body portion having antimicrobial properties includes an area surrounding the at least one opening.

13. The instrument of claim 9, wherein the body portion further includes an integrated lancing device.

14. The instrument of claim 13, wherein at least a portion of the integrated lancing device has antimicrobial properties.

15. A method of determining a concentration of at least one analyte in a body fluid sample drawn from skin, the method comprising the acts of:

- providing a lancing device that comprises a body portion and a lancet, the lancet being located within the body portion in a retracted position, the lancet being movable between a retracted and an extended position;
- puncturing the skin by actuating the lancet into the extended position;
- drawing a body fluid sample from the skin;
- contacting the body fluid sample with a test sensor;
- placing the test sensor within an opening adapted to receive the test sensor, the opening being located on an analyte-testing device, the analyte-testing device further comprising a display and a user-interface mechanism; and
- determining the concentration of the at least one analyte using the analyte-testing device;

wherein at least a portion of at least one of the lancing device, test sensor, and analyte-testing device has antimicrobial properties.
16. The method of claim 15, wherein at least a portion of the lancing device has antimicrobial properties.

17. The method of claim 15, wherein at least a portion of the test sensor has antimicrobial properties.

18. The method of claim 15, wherein at least a portion of the analyte-testing device has antimicrobial properties.

19. The method of claim 15, wherein the lancing device further comprises an endcap detachably coupled to the body portion.

20. The method of claim 19, wherein the lancet extends through an opening formed in the endcap during the act of puncturing the skin by actuating the lancet into an extended position.
Fig. 4