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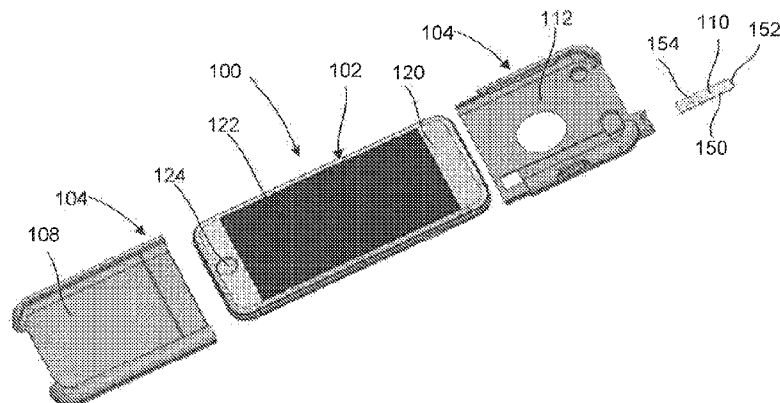
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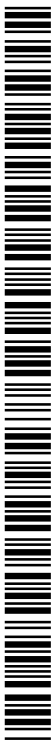
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- (54) Title: METHOD AND SYSTEM OF USING A MOBILE DEVICE FOR ANALYTE DETECTION

FIG. 1A



- (57) Abstract: A method and system for determining an analyte concentration in a fluid sample. A mobile device such as a smart phone includes a processor, a camera, and a memory. A carrying case is provided to hold the mobile device. The carrying case has a sensor housing to hold a test sensor having a reaction area for holding the fluid sample. When the carrying case is mated with the mobile device, the reaction area of the test sensor is aligned with the camera. A metering application is loaded on the mobile device. The application is executed by the processor to capture image data of the fluid sample from the camera and analyze the content of the fluid sample based on the image data.



## METHOD AND SYSTEM OF USING A MOBILE DEVICE FOR ANALYTE DETECTION

### CROSS-REFERENCE TO RELATED APPLICATION(S)

[0001] This application claims priority to U.S. Provisional Patent Application No. 62/234,382, filed September 29, 2015, which is hereby incorporated by reference herein in its entirety.

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### TECHNICAL FIELD

[0003] The present invention relates generally to a system for fluid analyte analysis (e.g., blood glucose) and more specifically a system that uses an existing mobile device in conjunction with a carrying case to provide fluid analyte determinations.

### BACKGROUND

[0004] The quantitative determination of analytes in body fluids is of great importance in the diagnoses and maintenance of certain physiological conditions. For example, persons with diabetes (PWDs) frequently check the glucose level in their bodily fluids. The results of such tests can be used to regulate the glucose intake in their diets and/or to determine whether insulin or other medication needs to be administered. A PWD typically uses a measurement device (e.g., a blood glucose meter) that calculates the glucose concentration in a fluid sample from the PWD, where the fluid sample is collected on a test sensor that is received by the measurement device. The failure to take corrective action may have serious medical implications for that person.

[0005] One method of monitoring a person's blood glucose level is with a portable testing device. The portable nature of these devices enables users to conveniently test their blood glucose levels at different locations. One type of device utilizes an electrochemical test sensor to harvest and analyze the blood sample. A user employs a lancet to obtain a blood sample for the test sensor. The electrochemical test sensor typically includes electrodes that,

when mated with the meter, electrically measures the reaction of the blood sample to determine an analyte concentration. A special meter device must therefore be carried by the user to determine the blood sample analysis.

**[0006]** Electromechanical sensor strips are relatively expensive to manufacture as they must use noble metal for fabricating the electrodes. An alternative is an optically-based test sensor stripe that relies on light being applied to the fluid test sample. The color of the sample is detected by a specialized meter and is used to analyze the content of the fluid sample. Although such sensors are relatively less expensive to manufacture, they still require a specialized meter to optically sense the fluid sample and analyze the data to determine the content of the sample.

**[0007]** Thus, there exists a need for a test sensor system that may use an already in use mobile device as a meter device eliminating the need for a separate meter. There is a further need for a system that uses an optically-based test sensor eliminating the need for an electrochemical test sensor. There is also a need for a metering application that may operate on a mobile device to provide content analysis of a fluid.

### **SUMMARY**

**[0008]** According to one example, a measurement system for determining an analyte concentration in a fluid sample is disclosed. The system includes a mobile device having a processor, a camera, and a memory. The system includes a carrying case having a sensor housing to hold a test sensor. The test sensor has a reaction area for holding the fluid sample. The carrying case is mateable with the mobile device to align the reaction area with the camera when the carrying case is mated with the mobile device. The processor operates to capture image data of the fluid sample from the camera and analyze the content of the fluid sample based on the image data.

**[0009]** Another example is a carrying case for allowing a mobile device to determine an analyte concentration in a fluid sample on a test sensor. The carrying case has a back plate including a pair of guides for holding the mobile device and a channel in the back plate for holding the test sensor with a reaction area for holding a fluid sample. The carrying case includes an aperture in the back plate in alignment with a camera on the mobile device. When the test sensor is inserted in the channel the reaction area is aligned with the aperture.

**[0010]** Another example is a method of determining an analyte concentration in a fluid sample by a mobile device mated with a carrying case. The mobile device includes a processor, a memory and a camera. An analyte concentration metering application is loaded

in the memory of the mobile device. A test sensor with a reaction area in a slot is received in the carrying case. The test sensor is received to align the reaction area in proximity to the camera. A fluid sample is collected in the reaction area of the test sensor. The camera is operated to take an image of the fluid sample. The color change from a reagent mixed with the fluid sample from the image of the fluid sample is analyzed to determine the analyte concentration of the fluid sample.

Another example is a method of using a mobile device having a processor, a memory and a camera to determine analyte concentration in a fluid sample. An analyte concentration metering application is loaded in the memory of the mobile device. A carrying case is mated with the mobile device. The carrying case has a slot to receive a test sensor with a reaction area. The test sensor is positioned by the carrying case to align the reaction area in proximity to the camera. A fluid sample is collected in the reaction area of the test sensor. The camera is operated to take an image of the fluid sample. The color change from a reagent mixed with the fluid sample from the image of the fluid sample is analyzed to determine the analyte concentration of the fluid sample.

**[0011]** Additional aspects of the invention will be apparent to those of ordinary skill in the art in view of the detailed description of various embodiments, which is made with reference to the drawings, a brief description of which is provided below.

#### **BRIEF DESCRIPTION OF THE DRAWINGS**

**[0012]** FIG. 1A is a exploded perspective view of a fluid analyte system using an existing mobile device and a specialized upper carrying case component according to one embodiment;

**[0013]** FIG. 1B is a exploded perspective view of the mobile device in FIG. 1A with a standard carrying case;

**[0014]** FIG. 2A is a front perspective view of the mobile device in FIG. 1 with an assembled carrying case according to one embodiment;

**[0015]** FIG. 2B is a back perspective view of the mobile device in FIG. 1 with the assembled carrying case;

**[0016]** FIG. 2C is a side view of the mobile device in FIG. 1 with the assembled carrying case;

**[0017]** FIG. 2D shows a back view of the mobile device in FIG. 1 with the assembled carrying case;

[0018] FIG. 3A is a close-up perspective view of the upper part of the carrying case in FIG. 1;

[0019] FIG. 3B is a close-up perspective view of the lower part of the carrying case in FIG. 1;

[0020] FIG. 4A is a diagram of the interface between the mobile device, the test sensor and the carrying case in FIG. 1 for taking a measurement of a fluid sample;

[0021] FIG. 4B is a diagram of an alternate interface between the mobile device, the test sensor and the carrying case in FIG. 1 for taking a measurement of a fluid sample;

[0022] FIG. 5 is block diagram of a mobile device that may be incorporated in the fluid analyte system in FIG. 1; and

[0023] FIG. 6 is a flow diagram of a fluid sample metering application that may be run on the mobile device in FIG. 1.

[0024] While the invention is susceptible to various modifications and alternative forms, specific embodiments have been shown by way of example in the drawings and will be described in detail herein. It should be understood, however, that the invention is not intended to be limited to the particular forms disclosed. Rather, the invention is to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the invention as defined by the appended claims.

### **DETAILED DESCRIPTION**

[0025] FIG. 1A shows a fluid analyte system 100 for the collection and analysis of a fluid sample such as determining the analyte concentration of the fluid sample. The system 100 includes a mobile device 102 that may be a mobile phone, a smart phone or other suitable device. The system 100 includes a carrying case 104 that is used to protect the mobile device 102. As will be explained above, the carrying case 104 has a specialized component that allows the positioning of an optically based test sensor 110 relative to the mobile device 102.

[0026] As shown in FIG. 1B, a two piece carrying case 105 for holding the mobile device 102 includes a standard upper protective case 106 and a lower protective case 108. The standard upper protective case 106 slides over the upper part of the mobile device 102 and the lower protective case 108 slides over the lower part of the mobile device 102 for a user to carry the mobile device 102 and to protect the mobile device 102 from blunt force impact or contaminant exposure. In FIG. 1A, an alternate upper protective case 112 to hold the test sensor 110 may be used instead of the standard upper protective case 106 in FIG. 1B to form the carrying case 104. The lower protective case 108 remains the same between the carrying

case 104 in FIG. 1A and the carrying case 105 in FIG. 1B. The test sensor 110 holds collected fluid from the user for testing and analysis by the mobile device 102. The upper protective cases 106, 112 and the lower protective case 108 may be constructed from plastic material such as polycarbonate. It is contemplated that the protective cases may be made from other polymeric or non-polymeric materials. A liner made of rubber may be provided for the sides of the carrying case 104 for additional shock protection of the mobile device 102.

[0027] The carrying case 104 holds the mobile device 102, thereby mating the upper protective case 112 with the lower protective case 108 as shown in FIGs. 2A-2D. The upper protective case 112 may be used instead of the upper protective case 106 to hold the test sensor 110 and allow the mobile device 102 to analyze a fluid sample on the test sensor 110. Thus, in normal circumstances, the standard upper protective case 106 is used with the lower protective case 108. As will be explained below, when a user desires to test a fluid sample, the user replaces the standard upper protective case 106 with the upper protective case 112. The upper protective case includes a test sensor housing 114 as shown in FIG. 2B-2D and thus allows a user to insert the test sensor 110 to receive a fluid sample for testing. Of course, the upper protective case 112 may be used during normal circumstances.

[0028] In this example, the mobile device 102 may be a smart phone, such as an iPhone 6® manufactured by Apple Corp., having a processor for running different applications, a camera and a light source but other smart phones or mobile devices such as an Android phone, a Galaxy phone, etc. with similar capabilities may be used. The mobile device 102 has a front surface 120 that includes a display screen 122 and a function button 124 that may be a home button as shown in FIG. 1A. As shown in FIG. 2A, the carrying case 104 is open in the front to allow a user to view the display screen 122 and operate the mobile device 102 through the function button 124 and touching the display screen 122. FIG. 2D shows a back view of the mobile device 102 with the upper protective case 112 installed. As shown in FIG. 2B, the carrying case largely covers back of the mobile device 102. As shown in FIG. 2D, the mobile device 102 has a rear surface 130 that includes a lens for a camera 132 and a light source 134. An optional infrared (IR) sensor 136 may be provided in this embodiment.

[0029] As shown in FIG. 1A, the test sensor 110 includes an elongated rectangular body 150 having a fluid-receiving end 152 and a reaction area 154 opposite the fluid-receiving end 152. In this example, the test sensor 110 includes a capillary channel on the elongated rectangular body 150 and a reagent layer for holding a reagent for reaction with a fluid sample that is introduced through the capillary channel to the reaction area 154.

**[0030]** As shown in FIG. 3A, the upper protective case 112 has a generally flat back plate 310 that includes two side guides 312 and 314 that each include interior tracks that mate with the sides of the mobile device 102. The side guides 312 and 314 include respective exterior rubber bumpers 316 and 318 that cushion the upper protective case 112 against shock. The back plate 310 includes a camera aperture 320 that is aligned with the lens of the camera 132 (FIG. 2D) and the light source 134 (FIG. 2D) when the upper protective case 112 is mated with the mobile device 102.

**[0031]** The test sensor housing 114 may include a sensor holder 330 that includes a slot 332 sized to receive the test sensor 110. The slot 332 leads to a rectangular channel 334 formed in the sensor holder 330 to hold the test sensor 110. The channel 334 is of sufficient length so the fluid-receiving end 152 extends out from the slot 332 while the reaction area 154 is aligned with the camera aperture 320 when the test sensor 110 is fully inserted in the channel 334. The sensor housing 330 includes a light guide 336 that extends between the flash light and the camera when the carrying case 104 is inserted on the mobile device 102. As shown, in FIG. 2D, the light guide 336 transmits light from the light source 134 to illuminate the camera 132.

**[0032]** The standard upper protective case 106 in FIG. 1B is similar in construction to the upper protective case 112 with the exception that the standard upper protective case 106 is not capable of holding the test sensor 110. As shown in FIG. 1B, the standard upper protective case 106 includes a back plate 160 with side guides 162 and 164 that hold the sides of the mobile device 102. The back plate 160 includes a camera aperture 170 that is aligned with the lens of the camera 132 when the standard upper protective case 106 is mated with the mobile device 102. The camera aperture 170 allows the user of the mobile device 102 to take pictures through the camera 132 when the mobile device 102 is inserted in the carrying case 104. The camera aperture 170 also is aligned with the light source 134 to allow the functioning of the flash from the light source 134.

**[0033]** As shown in FIG. 3B, the lower protective case 108 includes a back plate 350 that holds two side guides 352 and 354. The side guides 352 and 354 each have interior tracks that are mated with the sides of the mobile device 102. The side guides 352 and 354 each include respective exterior rubber bumpers 356 and 358 to further cushion the carrying case 104 from shock.

**[0034]** A specialized fluid metering application may be loaded in the mobile device 102 as will be explained below. When the test sensor 110 is inserted in the upper carrying case 112, it may be used to collect a fluid sample from the user in the reaction area 154. For example, a

user may employ a lancing device to pierce a finger or other area of the body to produce a blood sample at the skin surface. The user may then collect this blood sample by placing the fluid in the receiving end 152 of test sensor 110 that extends out from the upper carrying case 112. The fluid is wicked into the reaction area 154 of test sensor 110 via the capillary channel. The test sensor 110 contains a reagent which reacts with the sample to indicate the concentration of an analyte in the sample. As will be explained below, the reagent reaction changes the color of the sample. After filling the reaction area 154 with the blood sample, the test sensor 110 is inserted into the carrying case 104 as shown in FIGs. 2A-2D.

**[0035]** The user then runs the specialized fluid metering application on the mobile device 102. The specialized fluid metering application operates the light source 134 on the mobile device 102. The light from the light source 134 is guided by the light guide 336 on the upper protective case 112 to illuminate the camera 132. The camera 132 in the mobile device 102 is activated to take an image of the illuminated fluid sample. The image is stored by the mobile device 102 and the specialized fluid metering application performs analysis of the fluid sample via the image data. Of course, the mobile device 102 may send the data or analysis to another storage device such as cloud storage or a server via wireless communication as will be explained below.

**[0036]** Examples of the types of analytes that may be collected include glucose, lipid profiles (e.g., cholesterol, triglycerides, LDL and HDL), microalbumin, hemoglobin A<sub>1c</sub>, fructose, lactate, or bilirubin. It is contemplated that other analyte concentrations may also be determined. It is also contemplated that more than one analyte may be determined. The analytes may be in, for example, a whole blood sample, a blood serum sample, a blood plasma sample, other body fluids like ISF (interstitial fluid) and urine, and non-body fluids. As used within this application, the term “concentration” refers to an analyte concentration, activity (e.g., enzymes and electrolytes), titers (e.g., antibodies), or any other measure concentration used to measure the desired analyte.

**[0037]** Under the direction of the specialized fluid metering application, the mobile device 102 functions as a spectroscope using the camera 132 as an input device for measuring the analyte concentration in the fluid sample on the test sensor 110. For example, an indicator reagent system and an analyte in a sample of body fluid can be reacted to produce a chromatic reaction, as the reaction between the reagent and analyte causes the fluid sample to change color. The degree of color change is indicative of the analyte concentration in the body fluid. The color change of the sample can be evaluated to measure the absorbance level of a transmitted light such as from the light source 134. The camera 132 therefore captures a



raw optical signal based on the light absorbed by, and reflected from, the fluid sample on the test sensor 110.

**[0038]** In this example, the camera 132 is a charged coupled device (CCD) array that captures red blue green (RGB) subpixels of the image of the fluid sample. The specialized fluid metering application could interrogate red, green or blue pixel data from the CCD array separately to improve signal selectivity by resolving contributions from different wavelengths of the visible spectrum from the fluid sample. Alternatively, a light filter may be included in the test sensor 110 either to filter light from the light source 134 or covering the reaction area 154.

**[0039]** The change in optical properties may be compared to stored calibration data previously obtained by similarly testing a calibration sample of a known analyte concentration. Alternatively, the sensing capillary may not be coated with a reagent and the analyte concentration is determined by reading the amount of analyte directly at specific wavelengths.

**[0040]** In addition, the application may use the IR sensor 136 to make additional determinations on the fluid sample. The IR sensor 136 includes an IR light source and an IR light detector. The hematocrit level of whole blood affects the spectral response throughout the visible and near IR (“infrared”) light regions (e.g., 400 to 1100 nm). The light transmission varies with and is proportional to different hematocrit levels because of differences in the scattered light due to the number of red blood cells. The hematocrit transmission bias at near IR wavelengths is proportional to the hematocrit level of the blood. Thus, the IR light source could be activated and the reflected/transmitted IR light from the sample associated with the number of red blood cells could be measured to determine the hematocrit level.

**[0041]** The metering application may display the results of the reading on the display 122 of the mobile device 102. Other analysis functions such as providing instructions, providing reminders, and showing detailed analysis of results may be performed by the metering application. The data may be stored in the mobile device 102 and may be transmitted to health care providers, remote storage devices or other computing devices.

**[0042]** FIG. 4A is a block diagram shown the transmission of the optical signal from the test sensor 110 to the mobile device 102. As shown in FIG. 4A, the test sensor 110 is inserted into the upper protective case 112 so the reaction area 154 is in approximate alignment with the camera 132 and a corresponding lens 402 on the mobile device 102. A fluid sample 400 flows into the reaction area 154 of the test sensor 110. The upper protective

case 112 includes a collection lens 406 in alignment with a window 408 at the bottom of the reaction area 154.

**[0043]** The light guide 336 of the upper protective case 112 includes a collimation lens 410 that is aligned with the light source 134 of the mobile device 102. The light guide 336 transmits light from the collimation lens 410 to an output end 412 that is located near the sample 400. The light from the output end 412 is transmitted through the window 408 and through the sample 400. The sample 400 scatters the light to the collection lens 406. The collection lens 406 collects light that is scattered by the fluid sample 400 in the reaction area 154 to direct the light to the lens 402. In this manner, light from the light source 134 is transmitted to illuminate the sample 400 for the camera 132 to capture the optical data from the sample 400 for analyte analysis.

**[0044]** The IR sensor 136 is also shown in FIG. 4A. The IR sensor 136 is in proximity to the camera 132 and may be directed to detect infrared light transmitted through the sample 400. The infrared light reflected/transmitted through the sample 400 may be sensed by the infrared sensor 136 and the metering application may determine hematocrit content of the sample 400 based on the infrared light wavelength transmitted through the sample 400.

**[0045]** FIG. 4B is a block diagram of an alternate system 450 for analyte analysis that is based on reflection of light and therefore may not require a light guide. As may be seen in FIG. 4B, if the light source 134 is sufficiently close to the camera lens 402, light from the light source 134 is angled toward the sample 400, and reflected from the back surface of the upper protective case 112 and returned to the camera 132 as shown by the arrows in FIG. 4B. In this manner, the sample 400 may be illuminated and the image may be captured by the camera 132 through the window 408.

**[0046]** FIG. 5 is a block diagram of the components of a mobile user device such as the mobile user device 102 in FIG. 1. The mobile user device 102 includes an application processor 510, a power source 512, a baseband processor 516, and a CODEC 518. The display 122 is an LCD touch screen that allows the user to control the applications run by the application processor 510 via touch inputs as well as view graphics generated by the application processor 510. The display 122 is controlled by a touch screen controller 520. The application processor 510 may be coupled to various devices such as the camera 132, the flash light 134 and the IR sensor 136 and other interfaces such as a communication port, etc.

**[0047]** The baseband processor 516 receives signals from a network transmitter receiver 530 allowing communications with networks such as the Internet and a geo-referencing receiver 532 that allows the reception of positioning data to determine the location of the

mobile device 102. The baseband processor 516 processes in the signals and is coupled to the CODEC 518, which converts the signals for use by the application processor 510. The CODEC 518 also decodes audio signals received by a microphone 540 and encodes data signals for output by a speaker 542 for functions such as a telephone application run by the applications processor 510. Of course other audio devices such as a headset may be coupled through the CODEC 518.

**[0048]** The processors 510 and 516 may be conveniently implemented using one or more general purpose computer systems, microprocessors, digital signal processors, micro-controllers, application specific integrated circuits (ASIC), programmable logic devices (PLD), field programmable logic devices (FPLD), field programmable gate arrays (FPGA), and the like, programmed according to the teachings as described and illustrated herein, as will be appreciated by those skilled in the computer, software, and networking arts.

**[0049]** The operating system software and other applications are stored on read only memory (ROM) 550, random access memory (RAM) 552 and a memory storage device 554 for access by the applications processor 510. In this example, the memory storage device 554 is flash memory, but other memory devices may be used. The applications stored on the memory storage device 554 may include the fluid metering application. In this example, the fluid metering application may be preloaded on the mobile device 102 or may be offered as an application that may be downloaded to the mobile device 102 from a network server.

**[0050]** The memory storage device 554 includes a machine-readable medium on which is stored one or more sets of instructions (e.g., software) embodying any one or more of the methodologies or functions described herein. The instructions may also reside, completely or at least partially, within memory storage device 554, the ROM 550, the RAM 552, and/or within the processors 510 or 516 during execution thereof by the mobile device 102. The instructions may further be transmitted or received over a network via the network transmitter receiver 530. While the machine-readable medium is shown in an example to be a single medium, the term “machine-readable medium” should be taken to include a single medium or multiple media (e.g., a centralized or distributed database, and/or associated caches and servers) that store the one or more sets of instructions. The term “machine-readable medium” can also be taken to include any medium that is capable of storing, encoding, or carrying a set of instructions for execution by the machine and that cause the machine to perform any one or more of the methodologies of the various embodiments, or that is capable of storing, encoding, or carrying data structures utilized by or associated with such a set of instructions.

The term “machine-readable medium” can accordingly be taken to include, but not be limited to, solid-state memories, optical media, and magnetic media.

**[0051]** A variety of different types of memory storage devices, such as a random access memory (RAM) or a read only memory (ROM) in the system or a floppy disk, hard disk, CD ROM, DVD ROM, flash, or other computer readable medium that is read from and/or written to by a magnetic, optical, or other reading and/or writing system that is coupled to the processor, may be used for the memory or memories in the mobile device 102.

**[0052]** The operation of the metering application on the example mobile device 102 shown in FIGs. 1 and 5, will now be described with reference to FIGs. 1 and 5 in conjunction with the flow diagram shown in FIG. 6. The flow diagram in FIG. 6 is representative of example machine readable instructions for implementing the application to collect an image of a fluid sample and perform content analysis from the image. In this example, the machine readable instructions comprise an algorithm for execution by: (a) a processor, (b) a controller, and/or (c) one or more other suitable processing device(s). The algorithm may be embodied in software stored on tangible media such as, for example, a flash memory, a CD-ROM, a floppy disk, a hard drive, a digital video (versatile) disk (DVD), or other memory devices, but persons of ordinary skill in the art will readily appreciate that the entire algorithm and/or parts thereof could alternatively be executed by a device other than a processor and/or embodied in firmware or dedicated hardware in a well-known manner (e.g., it may be implemented by an application specific integrated circuit (ASIC), a programmable logic device (PLD), a field programmable logic device (FPLD), a field programmable gate array (FPGA), discrete logic, etc.). For example, any or all of the components of the interfaces could be implemented by software, hardware, and/or firmware. Also, some or all of the machine readable instructions represented by the flowchart of FIG. 6 may be implemented manually. Further, although the example algorithm is described with reference to the flowcharts illustrated in FIG. 6 persons of ordinary skill in the art will readily appreciate that many other methods of implementing the example machine readable instructions may alternatively be used. For example, the order of execution of the blocks may be changed, and/or some of the blocks described may be changed, eliminated, or combined.

**[0053]** The metering application receives an indication from the user that the test sensor 110 has been inserted in the upper protective case 112 as shown in FIG. 2A-2D and a fluid sample has been collected (600). The metering application then operates the light source 134 to cause a flash of light to illuminate the fluid sample through either transmittance through a

light guide as shown in FIG. 4A or via reflectance as shown in FIG. 4B (602). The metering application then operates the camera 132 to take an image of the illuminated sample (604).

**[0054]** The metering application then determines color data from the sample via the different color subpixels (606). The color data is correlated with the concentration of the analyte via a look up table, algorithm or other method (608). The results of the analysis are stored in memory (610). The results are then displayed on the display 122 (612).

**[0055]** One advantage of the system 100 is that “meter” in this case is a non-electronic, low-cost adapter in the form of an application running on the mobile device 102. While the system 100 requires a fluid metering application stored on the mobile device 102 that includes signal processing and analysis functionality, there is no separate hardware other than the mobile device 102. Thus, the application is easy to update and inexpensive to distribute to users that have already existing mobile devices such as smart phones and the like. The use of an optically based test strip such as the test sensor 110 does not utilize noble metals, reducing the cost of the test sensor.

**[0056]** Each of these embodiments and obvious variations thereof is contemplated as falling within the spirit and scope of the claimed invention, which is set forth in the following claims.

**CLAIMS**

What is claimed is:

1. A measurement system for determining an analyte concentration in a fluid sample comprising:
  - a mobile device including a processor, a camera, and a memory;
  - a carrying case having a sensor housing to hold a test sensor, the test sensor having a reaction area for holding the fluid sample, the carrying case being mateable with the mobile device to align the reaction area with the camera when the carrying case is mated with the mobile device, and
  - wherein the processor operates to capture image data of the fluid sample from the camera and analyze the content of the fluid sample based on the image data.
2. The measurement system of claim 1, wherein the carrying case includes an upper protective case and a lower protective case.
3. The measurement system of claim 1, wherein the mobile device includes a light source in proximity to the camera.
4. The measurement system of claim 3, wherein the test sensor includes a window allowing light transmission to the reaction area and wherein the carrying case includes a light guide having an input end and an output end, the input end being aligned with the light source and the output end being in proximity to the window when the carrying case with the test sensor is mated with the mobile device, the light guide guiding light from the light source to the fluid sample in the reaction area.
5. The measurement system of claim 3, wherein the carrying case includes a collimating lens generally aligned with the reaction area opposite the output end of the light conduit.
6. The measurement system of claim 3, wherein the test sensor includes a collection lens opposite the window.

7. The measurement system of claim 1, wherein the mobile device includes an infrared light emitter, and wherein the processor is operative to determine hematocrit content of the fluid sample via emitting an IR light and measuring the reflected IR light from the sample.
8. The measurement system of claim 2, wherein the upper protective case includes a back plate and two side guides to hold the mobile device, the upper protective case including the sensor housing.
9. The measurement system of claim 8, wherein the sensor housing includes a slot for insertion of the test sensor.
10. The measurement system of claim 1, wherein the test sensor includes a body having a fluid-receiving end, a capillary leading from the fluid-receiving end to the reaction area and a reagent layer.
11. A carrying case for allowing a mobile device to determine an analyte concentration in a fluid sample on a test sensor, the carrying case comprising:
  - a back plate including a pair of guides for holding the mobile device;
  - a channel in the back plate for holding the test sensor with a reaction area for holding a fluid sample; and
  - an aperture in the back plate in alignment with a camera on the mobile device,wherein when the test sensor is inserted in the channel, the reaction area is aligned with the aperture.
12. The carrying case of claim 11, further comprising a lower protective case, wherein the back plate forms an upper protective case.
13. The carrying case of claim 11, wherein the test sensor includes a window allowing light transmission to the reaction area and wherein the carrying case includes a light guide having an input end and an output end, the input end being aligned with a light source on the mobile device and the output end being in proximity to the window when the carrying case with the test sensor is mated with the mobile device, the light guide guiding light from the light source to the fluid sample in the reaction area.

14. The carrying case of claim 13, wherein the carrying case includes a collimating lens generally aligned with the reaction area opposite the output end of the light conduit.
15. The carrying case of claim 11, wherein the upper casing includes a back plate and two side guides to hold the mobile device, the upper casing including the sensor housing.
16. The carrying case of claim 15, wherein the sensor housing includes a slot for insertion of the test sensor.
17. A method of determining an analyte concentration in a fluid sample by a mobile device mated with a carrying case, the mobile device including a processor, a memory and a camera, the method comprising:
- loading an analyte concentration metering application in the memory of the mobile device;
  - receiving a test sensor with a reaction area in a slot in the carrying case, the test sensor being received to align the reaction area in proximity to the camera;
  - collecting a fluid sample in the reaction area of the test sensor;
  - operating the camera to take an image of the fluid sample; and
  - analyzing the color change from a reagent mixed with the fluid sample from the image of the fluid sample to determine the analyte concentration of the fluid sample.
18. A method of using a mobile device having a processor, a memory and a camera to determine analyte concentration in a fluid sample, the method comprising:
- loading an analyte concentration metering application in the memory of the mobile device;
  - mating a carrying case with the mobile device, the carrying case having a slot to receive a test sensor with a reaction area, wherein the test sensor is positioned by the carrying case to align the reaction area in proximity to the camera;
  - collecting a fluid sample in the reaction area of the test sensor;
  - operating the camera to take an image of the fluid sample; and
  - analyzing the color change from a reagent mixed with the fluid sample from the image of the fluid sample to determine the analyte concentration of the fluid sample.



FIG. 1A

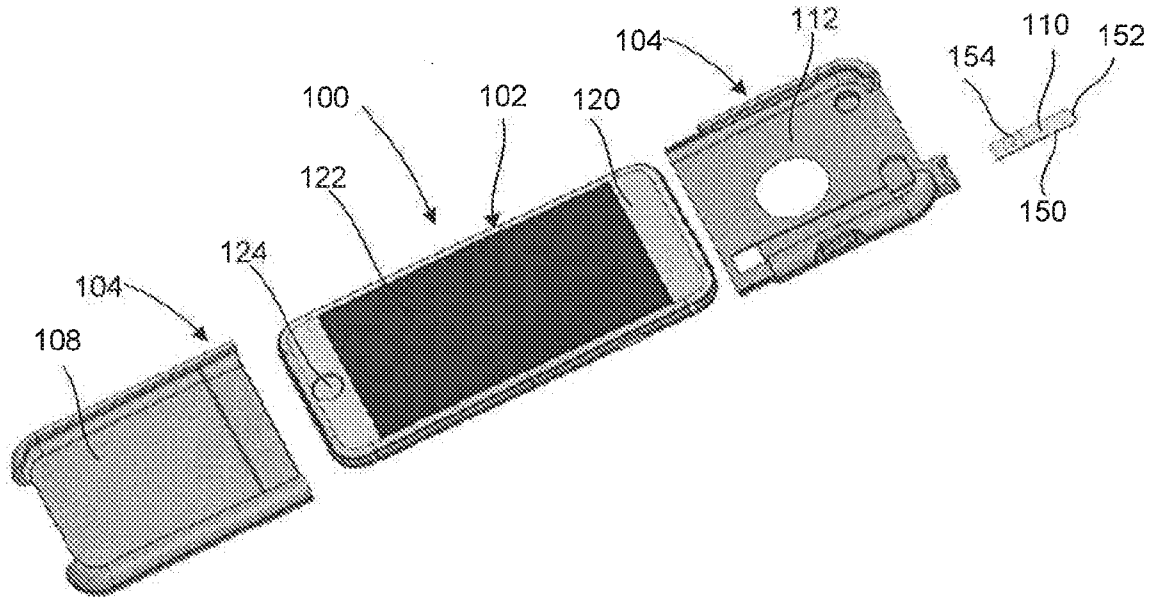


FIG. 1B

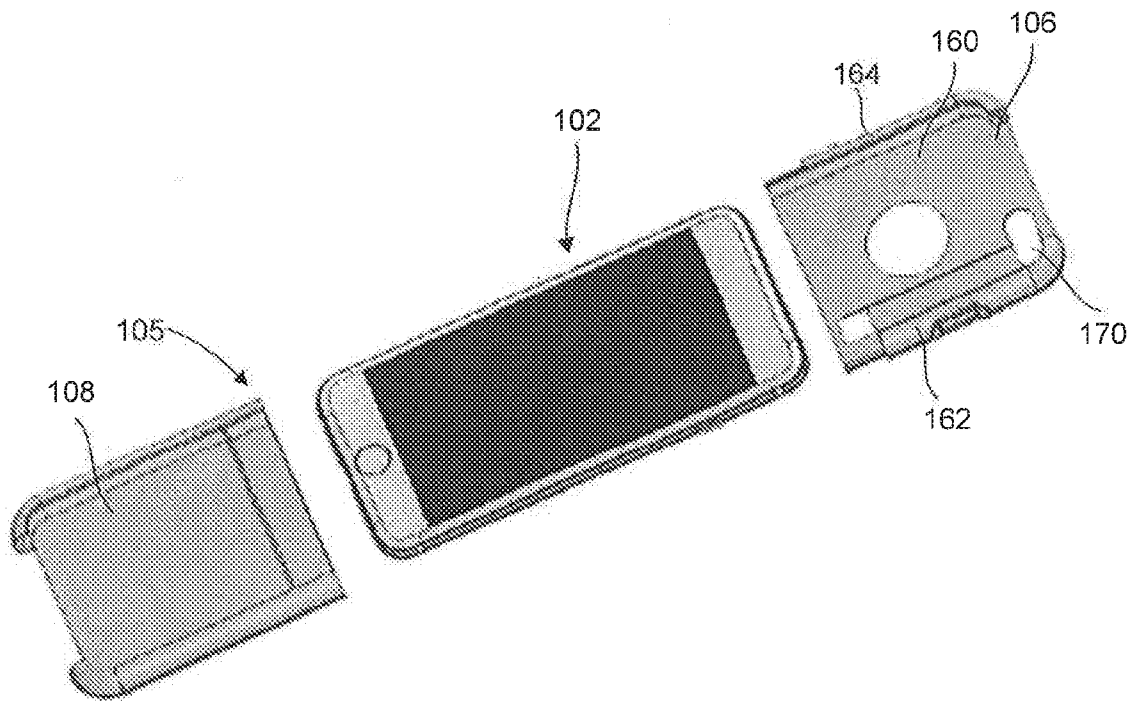


FIG. 2A

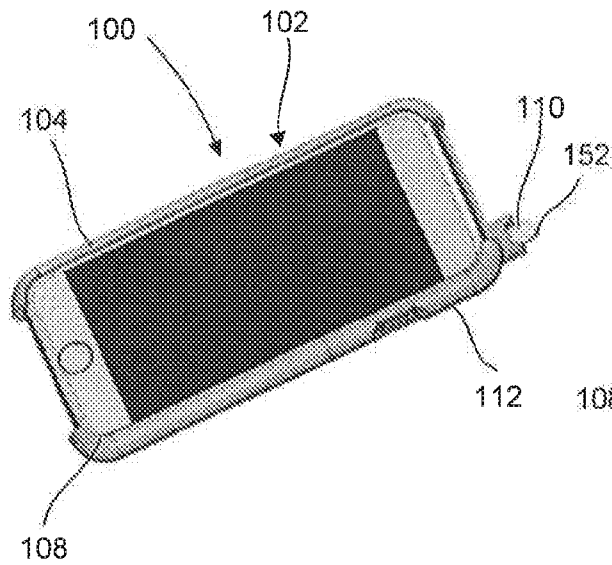


FIG. 2B

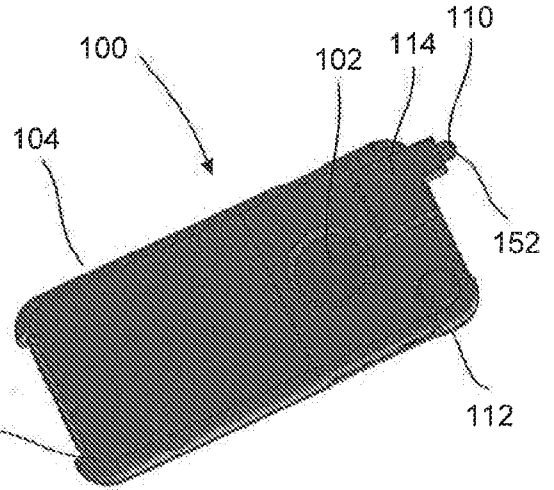


FIG. 2C

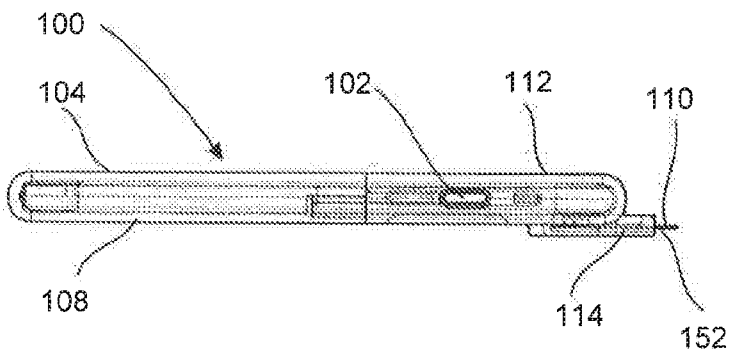


FIG. 2D

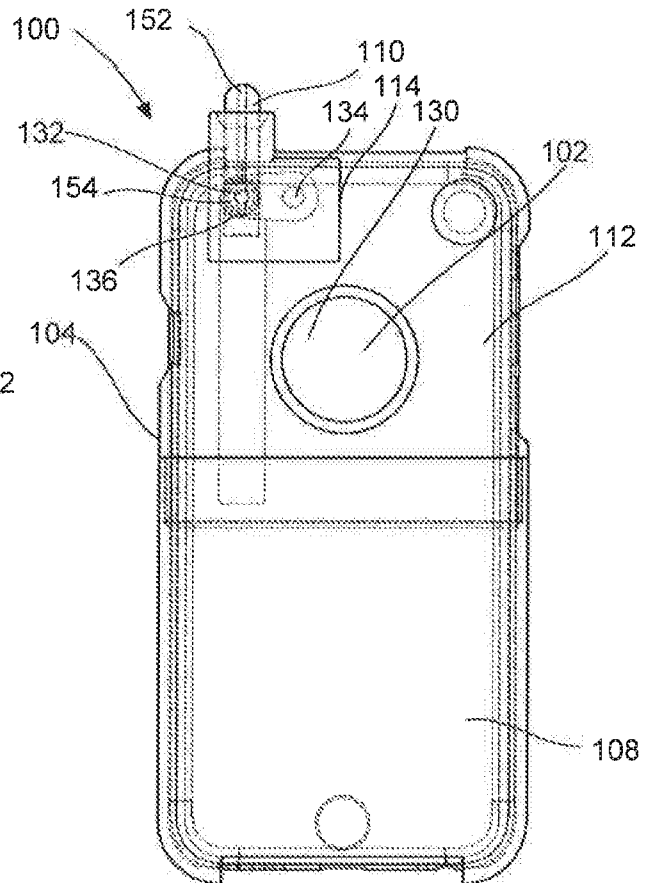


FIG. 3A

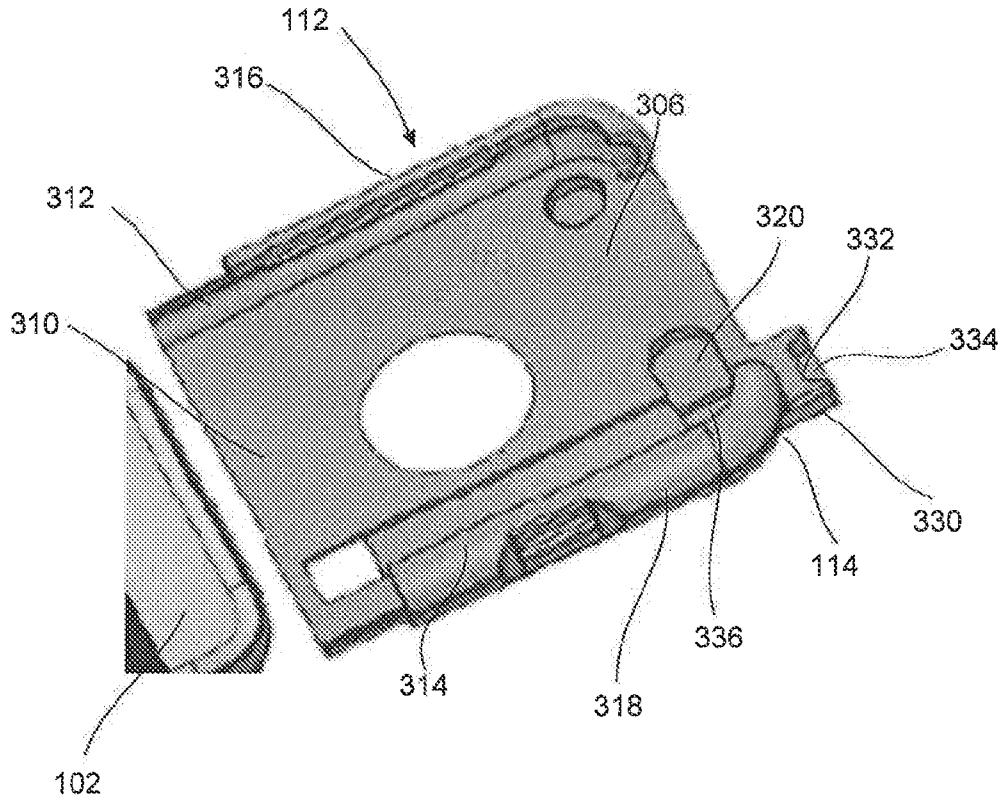


FIG. 3B

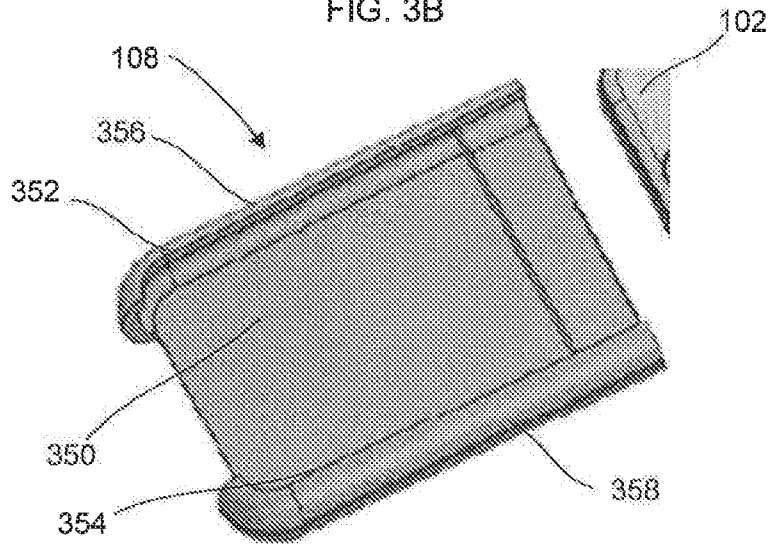


FIG. 4A

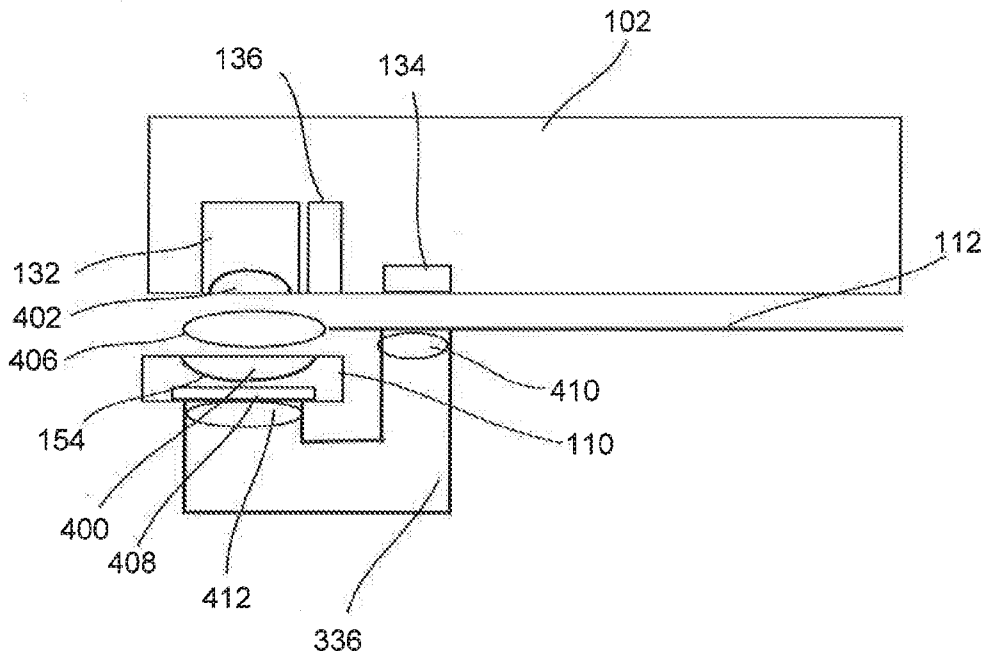


FIG. 4B

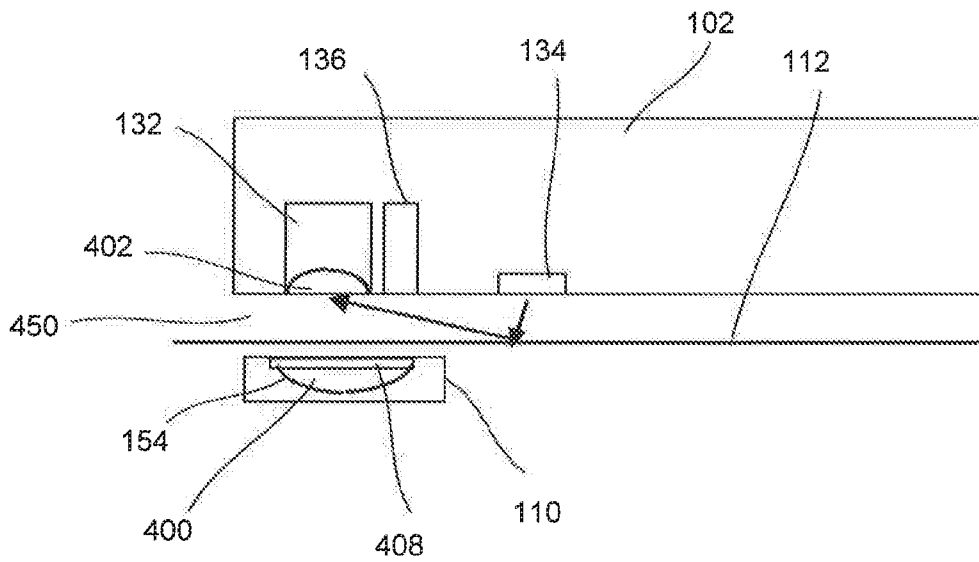
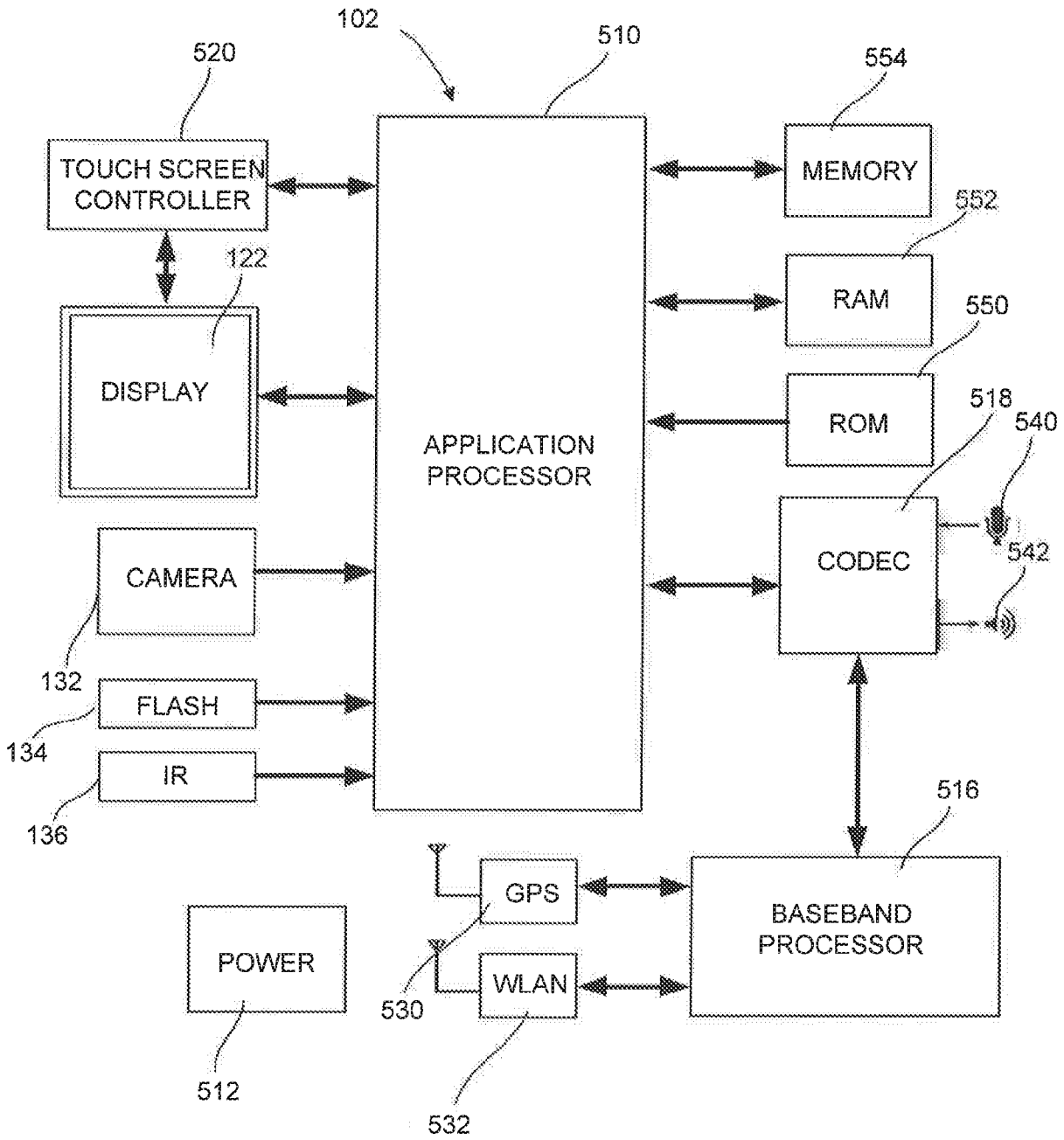
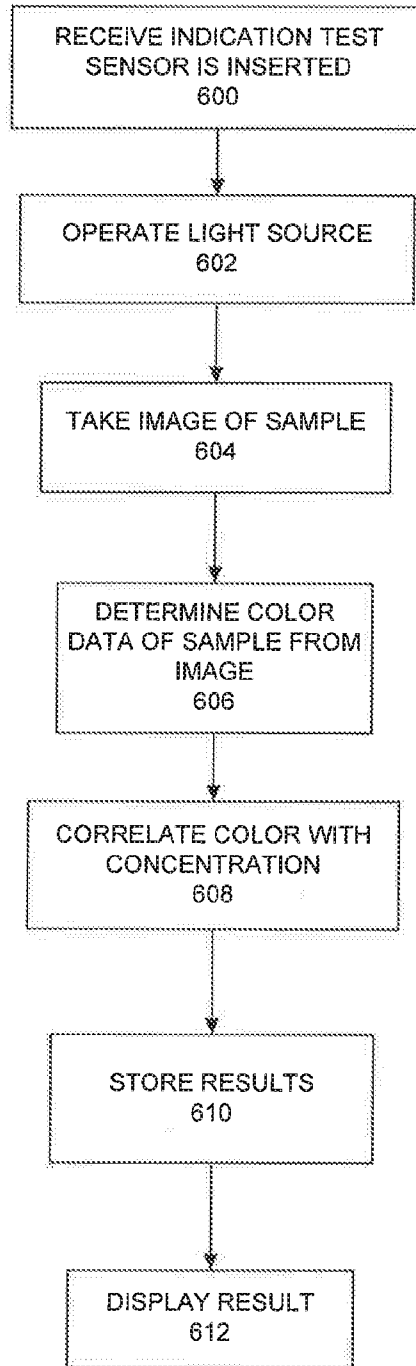


FIG. 5



6/6

FIG. 6



**INTERNATIONAL SEARCH REPORT**

International application No  
PCT/IB2016/055778

<b>A. CLASSIFICATION OF SUBJECT MATTER</b> INV. G01N21/84 ADD.		
According to International Patent Classification (IPC) or to both national classification and IPC		
<b>B. FIELDS SEARCHED</b>		
Minimum documentation searched (classification system followed by classification symbols) G01N		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) EPO-Internal, COMPENDEX, INSPEC, WPI Data		
<b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>		
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<input checked="" type="checkbox"/>	Further documents are listed in the continuation of Box C.	<input checked="" type="checkbox"/>
<input checked="" type="checkbox"/>	See patent family annex.	
* Special categories of cited documents :		
"A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier application or patent but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family	
Date of the actual completion of the international search <p align="center">23 November 2016</p>		Date of mailing of the international search report <p align="center">14/12/2016</p>
Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016		Authorized officer <p align="center">Koll, Hermann</p>

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