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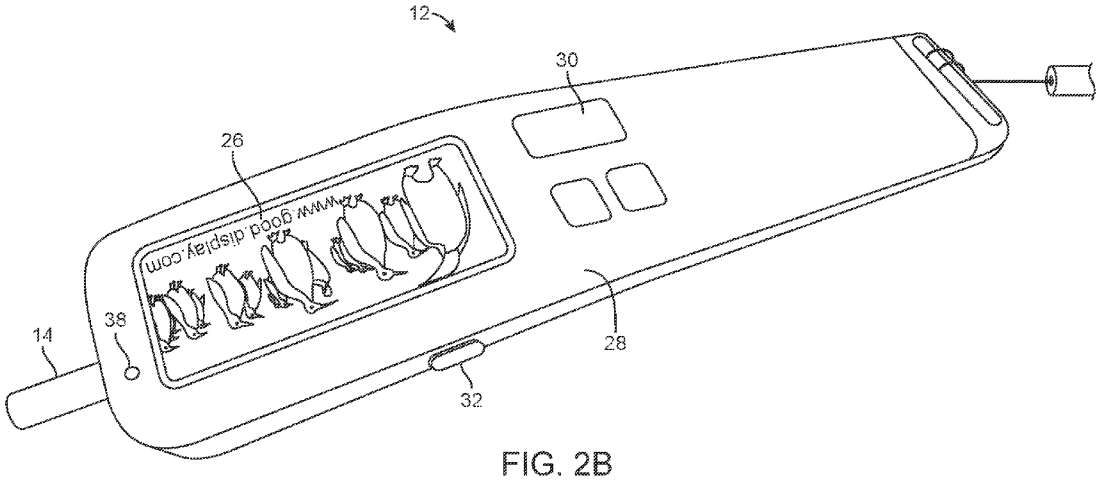


FIG. 2B

(57) Abstract: A method for using saliva to measure at least one substance or physiological parameter of a human or animal subject may involve inserting a first end of a sensor into a handheld saliva testing device. The method may also involve receiving saliva from the subject on a second end of the sensor, moving the saliva from the second end of the sensor to the first end, and processing the saliva with the handheld saliva testing device to provide initial saliva data related to the at least one substance or physiological parameter of the subject. In some embodiments, the sensor remains inserted in the handheld device while the subject deposits saliva on the opposite, free end of the sensor.

WO 2019/104165 A1

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SALIVA TESTING SYSTEM

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is being filed on 21 November 2018, as a PCT International patent application, and claims priority to U.S. Provisional Patent Application No. 62/589,028, filed November 21, 2017, entitled, "SALIVA TESTING SYSTEM." The disclosure of this priority application is hereby incorporated by reference in its entirety into the present application.

TECHNICAL FIELD

[0002] This application is directed to medical devices, systems and methods. More specifically, the application is directed to devices, systems and methods that use saliva to measure one or more physiological parameters.

BACKGROUND OF THE INVENTION

[0003] Appropriate hydration in the human body is vital for health and proper functioning of the body organs. Water is lost from the body during respiration, perspiration and urination. Fluid loss of just a few percent can negatively impact cardiovascular function, thermal dissipation, and exercise performance. Dehydration can cause headaches, light-headedness, dizziness, fainting and in extreme cases delirium, unconsciousness or death. Hyponatremia ("over-hydration") can also detrimentally affect the body's functioning, particularly during exercising, and can even lead to death in extreme cases.

[0004] Dehydration is considered an excessive loss of body fluid. In physiological terms, dehydration may entail a deficiency of fluid within an organism. Dehydration may be caused by losing too much fluid, not drinking enough water or fluids, or both. Vomiting, diarrhea, and excessive perspiration without sufficient liquid intake are other causes of dehydration, which may be particularly worrisome for athletes and people that work under hot and dry conditions. There are three main types of dehydration: hypotonic (primarily a loss of electrolytes, especially sodium), hypertonic (primarily a loss of water), and isotonic (equal loss of water and

electrolytes). While isotonic dehydration is the most common, distinction between the three types of dehydration may be important for administering proper treatment.

[0005] Relying on thirst as a feedback mechanism to trigger demand for fluid intake may not be adequate to maintain an optimal hydration level, since a sensation of thirst sufficient to cause a subject to drink is often not triggered until after the subject is already dehydrated. Unfortunately, there are currently no practical, affordable, non-invasive devices for measuring a person's hydration level. Measurement devices that use blood or urine to measure hydration are impractical, invasive, expensive or some combination thereof.

[0006] There are many other physiological parameters and levels of various substances in the human or animal body that are frequently tested or would be desirable to test for. Unfortunately, it is often necessary to sample blood, urine or other substances, such as cerebrospinal fluid, to measure a desired parameter. Or, even worse, some parameters may involve even more invasive or costly tests.

[0007] Therefore, it would be highly beneficial to have a practical, affordable, non-invasive system and method for measuring a person's hydration level. It would also be very desirable to have practical, affordable, non-invasive systems and methods for testing other parameters in the body.

BRIEF SUMMARY

[0008] Saliva may be an ideal bodily substance for use in measuring hydration and dehydration. Saliva is easily obtained with minimal invasiveness, but it is a complex fluid. Approximately 99% of saliva is water, and the remaining 1% consists of large organic molecules, such as proteins, small organic molecules, such as urea, and electrolytes, such as sodium and potassium. Whole saliva, considered as the total fluid content of the mouth, contains many other constituents, including serum components, blood cells, bacteria, bacterial products, epithelial cells, cell products, food debris and bronchial secretions. Thus, processing saliva to measure an individual's hydration level is challenging but likely highly beneficial if done effectively.

[0009] The present application describes systems, methods and devices for testing (or "measuring" or "analyzing") saliva, to measure a subject's hydration level. These

same systems, methods and devices, or variations thereon, may also be used to measure one or more other substances and/or physiological parameters in a human or animal subject. The details of these systems, methods and devices are described in further detail below.

[0010] In one aspect of the present disclosure, a method for using saliva to measure at least one substance or physiological parameter of a human or animal subject involves: inserting a first end of a sensor into a handheld saliva testing device; receiving saliva from the subject on a second end of the sensor; moving the saliva from the second end of the sensor to the first end; and processing the saliva with the handheld saliva testing device to provide initial saliva data related to the at least one substance or physiological parameter of the subject. In some cases, the saliva is received on the second end of the sensor while the first end of the sensor remains inserted within the handheld saliva testing device. For example, receiving the saliva may involve simply contacting the second end of the sensor with the subject's tongue, lips or mouth. In some embodiments, the method may also include: providing an audio and/or visual alert with the handheld saliva testing device when a sufficient amount of saliva is received on the sensor; and removing the second end of the sensor from the subject's tongue or mouth. Typically, the saliva is automatically processed with the processor after the alert is provided.

[0011] The method may further involve transmitting the initial saliva data from the handheld saliva testing device to a computer processor and processing the initial saliva data with the computer processor to provide final measurement data describing the at least one substance or physiological parameter. In some embodiments, the initial saliva data is transmitted wirelessly to the computer processor, which is located separately from the handheld saliva measurement device. For example, the computer processor may be an application on a mobile computing device. In some embodiments, the measured parameter is hydration, and the final measurement data includes a hydration score for the subject. Other examples of the substance or physiological parameter that may be measured include, but are not limited to, lactate level, ketones, glucose, glycerides, sodium, potassium, calcium, magnesium, chlorides, phosphates, caffeine, melatonin, c-reactive protein,

chemokines, cytokines, troponin, cortisol, creatinine kinase, insulin, beta hydroxyl butyrate, iron, ferritin, salivary amylase and oxalic acid.

[0012] Moving the saliva involves moving the saliva through at least one microfluidic channel in the sensor. Optionally, moving the saliva may also involve moving the saliva through a chemically functionalized mesh embedded in the sensor. The method may also include ejecting the sensor from the handheld saliva testing device, by pressing an eject button the handheld saliva testing device, after the saliva has been analyzed.

[0013] In another aspect of the present application, a method for using saliva to measure at least one substance or physiological parameter of a human or animal subject may involve: inserting a first end of a sensor into a handheld saliva testing device; contacting a second end of the sensor with the subject's tongue or mouth to collect the subject's saliva on the second end of the sensor; moving the saliva from the second end of the sensor to the first end; analyzing the saliva with the handheld saliva testing device to determine if there is a sufficient amount of the saliva to provide a measurement; providing an audio and/or visual alert with the handheld saliva testing device when the sufficient amount of saliva is received on the sensor; and analyzing the saliva with the handheld saliva testing device to measure the substance or physiological parameter.

[0014] In another aspect of the present disclosure, a system for testing saliva to measure at least one substance or physiological parameter of a human or animal subject may include: a handheld saliva testing device comprising a sensor slot and a display; a sensor comprising a first end configured for insertion into the sensor slot of the handheld saliva testing device and a second end configured for receiving saliva directly from the subject's mouth; and a computer processor coupled with the handheld saliva testing device to process initial data from the handheld saliva testing device to provide final measurement data describing the at least one substance or physiological parameter.

[0015] In some embodiments, the sensor is configured to receive the saliva on the second end of the sensor while the first end of the sensor remains inserted within the handheld saliva testing device. The computer processor may be located separately from, and may be wirelessly connectable to, the handheld saliva measurement

device. In some embodiments, the computer processor is an application on a mobile computing device. In some embodiments, the parameter is hydration, and the computer processor is configured to generate the final measurement data, including a hydration score for the subject. In various other embodiments, the substance or physiological parameter may include, but is not limited to, lactate level, ketones, glucose, glycerides, sodium, potassium, calcium, magnesium, chlorides, phosphates, caffeine, melatonin, c-reactive protein, chemokines, cytokines, troponin, cortisol, creatinine kinase, insulin, beta hydroxyl butyrate, iron, ferritin, salivary amylase and oxalic acid.

[0016] The sensor may include at least one microfluidic channel for directing saliva from the second end to the first end of the sensor and a chemically functionalized mesh embedded between a top layer and a bottom layer of the sensor, to facilitate movement of saliva along a length of the sensor. The system may include an additional computer processor embedded in the handheld saliva testing device for generating the initial data. The handheld saliva testing device may further include an on/off switch, a speaker for emitting an alert, and an eject button for ejecting the sensor out of the sensor slot.

[0017] In another aspect of the present application, a handheld device for testing saliva to measure at least one substance or physiological parameter of a human or animal subject may include: a housing; a sensor slot in the housing; a display on the housing; and a computer processor housed in the housing for generating initial data related to the substance or parameter from the saliva. The device may also include an eject button on the housing for ejecting a used sensor out of the sensor slot. The device may also include multiple buttons on the housing for controlling the handheld device. The device may also include a wireless transmitter for transmitting the initial data to an additional computer processor separate from the handheld device.

[0018] In another aspect of the present application, a saliva sensor for use with a saliva testing device to measure at least one substance or physiological parameter of a human or animal subject may include: a bottom layer; multiple electrodes applied to the bottom layer; a top layer; at least one microfluidic channel between the bottom layer and the top layer, for directing saliva from one end to an opposite end of the saliva sensor; and a chemically functionalized mesh embedded between the

bottom layer and the top layer to facilitate movement of saliva along a length of the saliva sensor. The saliva sensor may also include an insulating layer including a hydrophobic, dielectric material. In some embodiments, the saliva sensor may include multiple microfluidic channels, and the saliva sensor may thus be configured for measuring at least two substances or physiological parameters of the subject.

[0019] In yet another aspect of the present invention, a tangible computer readable medium may store instructions for performing a method for testing saliva to measure at least one substance or physiological parameter of a human or animal subject. The method may include receiving initial saliva data from a saliva testing device, the initial saliva data related to the at least one physiological parameter of the subject, and processing the initial saliva data to provide final measurement data describing the at least one substance or physiological parameter.

[0020] These and other aspects and embodiments are described in greater detail below, in relation to the attached drawing figures.

BRIEF DESCRIPTION OF THE DRAWINGS

[0021] FIG. 1A is a perspective view of a saliva measurement system, according to one embodiment;

[0022] FIG. 1B is a diagrammatic representation of a saliva measurement system provided in the form of a kit, according to one embodiment;

[0023] FIG. 2A is a diagrammatic representation of a handheld device and sensor of a saliva measurement system, according to one embodiment;

[0024] FIGS. 2B-2E are perspective, front, back and top/perspective views, respectively, of a handheld device and sensor of a saliva measurement system, according to one embodiment;

[0025] FIG. 3 is a block diagram of the internal components of a handheld device of a saliva measurement system, according to one embodiment;

[0026] FIG. 4 is a diagram of a portion of the electronics of a handheld device of a saliva measurement system, according to one embodiment;

[0027] FIGS. 5A-5C are additional diagrams of portions of the electronics of a handheld device of a saliva measurement system, according to one embodiment;

[0028] FIGS. 6A and 6B are perspective/exploded and assembled/side/top views, respectively, of a sensor of a saliva measurement system, according to one embodiment;

[0029] FIGS. 7A-7C are top views of various embodiments of sensor of a saliva measurement system;

[0030] FIG. 7D are side and top views of a portion of a sensor of a saliva measurement system, according to one embodiment;

[0031] FIG. 8 is a flow diagram illustrating movement of information between a handheld device and a computer application of a saliva measurement system, as well as the cloud, according to one embodiment;

[0032] FIGS. 9A-9I are diagrammatic representations illustrating a method of using a saliva measurement system, according to one embodiment; and

[0033] FIGS. 10A-10L are screen shots illustrating a method of using a computer application of a saliva measurement system, according to one embodiment.

DETAILED DESCRIPTION OF THE INVENTION

[0034] This application is generally directed to systems, devices and methods for testing saliva to measure levels of one or more substances and/or one or more physiological parameters in, or of, a human or animal subject. According to various embodiments, saliva may be used to test for any suitable substance or substances or any parameter or parameters. Although much of the following discussion focuses on testing for hydration of a human subject, the same or alternative embodiments may be used for any of a large number of other measurements. Just a few examples of such measurements include, but are not limited to, hydration, lactate level, ketones, glucose, glycerides, sodium, potassium, calcium, magnesium, chlorides, phosphates, caffeine, melatonin, c-reactive protein, chemokines, cytokines, troponin, cortisol, creatinine kinase, insulin, beta hydroxyl butyrate, iron, ferritin, salivary amylase and oxalic acid and the like. In some embodiments, the system and method may be used to measure multiple substances or parameters, such as any combination of the substances/parameters just listed. And although it will not be repeated continuously throughout, any embodiment described for use with a human subject may alternatively be used for an animal subject (e.g., veterinary medicine, research, etc.).

[0035] In general, the system described herein includes a saliva sensor, a handheld device, and a computer processor, which may take the form of a computer application on a medical device. Each of these three primary components may also be provided separately as a saliva testing device, and all three components will be described in detail below.

[0036] Referring now to FIG. 1A, in one embodiment, a saliva testing system 10 may include a handheld device 12, a sensor 14 (also referred to as a "strip" or "test strip") and a computer application 16, which may be located on a mobile computing device 18. In FIG. 1A, as in all figures provided in this application, features are not necessarily drawn to scale. For example, in this illustration, sensor 14 is disproportionately large, compared to handheld device 12 and mobile computing device 18. Furthermore, although computer application 16 will be referred to herein as an "application," this component of system 10 may include any computer software and/or hardware capable of receiving and processing data. In one form, computer application 16 is an application (or "app") that may be downloaded on any suitable mobile computing device 18, such as but not limited to a smart phone, tablet, or the like, or any other suitable computing devices, such as but not limited to a laptop computer, desktop computer, medical monitoring device or the like.

[0037] As will be described in greater detail below, one end of sensor 14 is configured to be inserted into a sensor slot on handheld device 12. A test subject 20 (or "user") then deposits saliva onto the opposite, free end of sensor 14, while sensor 14 is still inserted into handheld device 12. Sensor 14 moves the saliva across its surface via microfluidic channels and/or other mechanism(s) and measures at least one characteristic of the saliva. Handheld device 12 then reads data related to this measurement (or measurements) off of sensor 14. Handheld device 12 transmits data wirelessly or via wired connection to application 16 via mobile device 18. Test subject 20, physicians, coaches, family members and/or any other suitable people may then access the data via mobile device 18. For example, in one embodiment test subject 20 may be given a hydration score, which she can read off of mobile device 18. In some embodiments, mobile device 18 may also send data to the cloud 22 for storage and/or further processing. Each of these functions will be described in further detail below.

[0038] With reference to FIG. 1B, a diagrammatic illustration of saliva testing system 10, in the form of a kit, is provided. This illustration shows handheld device 12, a box 15 of sensors 14, a USB cable 24 and a representation of computer application 16. In some embodiments, system 10 may be provided as such a kit or as a similar kit containing the same or similar components, along with instructions for use.

[0039] Handheld device 12 stimulates and acquires signals from sensor 14, performs signal processing, and transmits the data to computer application 16, for example via Bluetooth low energy or via USB cable 24. Handheld device 12 may include a display 26, which may provide information to test subject 20. For example, display 26 and/or a speaker (not shown) on handheld device 12 may alert test subject 20 when a sensor 14 is properly and completely inserted into handheld device 12, when a saliva measurement has started, when a saliva measurement has been completed, when a sufficient amount of saliva has been collected and tested, and/or the like. Handheld device 12 may also be configured to recognize different types of sensors 14, for example sensors configured to test for different parameters, such as a hydration sensor 14 versus a potassium sensor. Similarly, handheld device 12 may include a lock-out function that senses whether a sensor is new/unused versus used or approved for use with system 10 versus a counterfeit or defective sensor. The identification and lock-out function prevents handheld device 12 from activating if a sensor is inserted that is used, counterfeit, broken, etc. Handheld device 12 may also be configured to receive software updates wirelessly. Handheld device 12 may be powered by rechargeable or disposable batteries, according to different embodiments, and it may also include a battery level indicator, which may be displayed on display 26 or separately.

[0040] FIG. 2A is a diagrammatic representation of handheld device 12 and sensor 14. In this embodiment, handheld device 12 includes a housing 28, LCD display 26, multiple buttons 30 for controlling various functionality, a power switch 32, a sensor ejection button 34, a speaker 36, an LED battery level indicator 38 and an LED Bluetooth status indicator 39. In one embodiment, sensor 14 may be inserted into a slot (not visible) on the top of housing 28. When a sensing and measuring process is completed, sensor 14 can be ejected from housing 28 using

sensor ejection button 34. In alternative embodiments, sensor 14 may be manually removed by the user after the test is complete. This is merely one embodiment of handheld device 12, and alternative embodiments may include fewer, different or additional features.

[0041] FIGS. 2B-2E are perspective, front, back and top/perspective views, respectively, of one embodiment of handheld device 12, shown with one embodiment of sensor 14 in FIG. 2B. This embodiment includes three buttons 30 on the front of housing 28, one of which is an up/down toggle switch. As shown in FIG. 2D, the back of housing 28 may include a battery cover 35, inside of which is a battery housing for holding one or more rechargeable or disposable batteries for powering handheld device 12. FIG. 2E shows a sensor slot 31 in housing 28, which was mentioned previously. In use, one end of sensor 14 is inserted into sensor slot 31, and saliva is collected on the opposite, "free" end of sensor 14 by contacting that free end with the subject's tongue, lips or any other part of the subject's mouth. This collection step may also be referred to as "depositing" saliva on sensor 14. In alternative embodiments, the saliva may be deposited indirectly, for example by collecting the saliva in a collection device and then depositing it on sensor 14. However, the direct collection method, where the free end of sensor 14 is contacted with the subject's tongue/mouth, may be advantageous for convenience, ease and speed of testing, reduction of contaminants in the saliva and/or other reasons.

[0042] Once the saliva is collected on the free end of sensor 14, it is transported at least partway across the length of sensor 14 via microfluidics on sensor 14. The saliva is then analyzed by handheld device 12, and sensor 14 is ejected from sensor slot 31 by pressing sensor ejection button 34 (FIGS. 2C and 2D). In an alternative embodiment, sensor 14 may simply be pulled out of sensor slot 31 manually after use, rather than ejected.

[0043] FIG. 3 is a diagrammatic representation of the internal components of handheld device 12. In this embodiment, handheld device 12 includes: a central processing unit (CPU) 40; a power management module 42 for managing power and charging handheld device 12; a clock module 48 including a crystal 50 and a real time clock 52; a Bluetooth module 44 including a transceiver module and antennas; a memory 46 for storage of code and the user's measurement data; an input/output

(I/O) management module 62 to control buttons 64, LEDs 66, LCDs 68 and a speaker 70 for interaction of the user with the device; a sensing circuit 54 that includes a signal generator 56, current sensing 58 and temperature sensing 60, and a sensor interface 72 that connects handheld device 12 and sensor 14.

[0044] In one embodiment, handheld device 12 is powered from single cell 1000mAh Li-on battery. A buck switching regulator may be included, to convert battery voltage to 3.3V, with a maximum current of 1A. A single on/off push button switch may be included, to turn on the system. The battery can be recharged on fast mode with up to 2A current. A lightning connector may be used in some embodiments. An integrated Bluetooth module 44 may be included, which may be fully compatible with Bluetooth 5. Handheld device 12 may further include integrated 1M flash ROM and 512kB RAM. The CPU may operate at 32 MHz. Some embodiments may include an external micro SD card storage for measurement storage. Clock module 48 may include a 32 MHz crystal 50. Real time clock 52 may be available for time stamp labelling of sensor measurement. LCD display 26 may be a touch screen LCD. Buttons 30 may be push buttons and may control any suitable functions of handheld device 12. Micro speaker 36 may be used to provide audible cues to indicate the start of a measurement, completion of a measurement an error during measurement and/or the like.

[0045] Referring to FIG. 4, sensor interface 72 may include a strip with seven connectors. In FIG. 4, R4, R5, R6, R7 are reference resistors. Q1 is an N type MOSFET, with maximum current greater than 1A. S1 and S2 are analog switches, with maximum current above 100mA. Sensing circuit 54 includes a sinusoidal signal generator 74 for hydration detection, with frequency up to 20 kHz and adjustable amplitude up to 200 mV. Sensing circuit may also include a square wave generator 76 for lactate and testosterone detection, with arbitrary on/off duty cycle and magnitude that varies from 50mV to 700mV. Sensing circuit 54 may be a three-electrode electrochemical circuit, which can be used for hydration and/or lactate/testosterone detection. The type of detection can be multiplex using analogue switching. Sensing circuit may also include on-board temperature sensor 60, as a reference for both electronic circuit performance and sensor strip temperature detection.

[0046] FIG. 5A is a more detailed hardware system diagram for handheld device 12, according to one embodiment. FIG. 5B is circuit diagram for a battery charger circuit for handheld device 12, according to one embodiment. FIG. 5C is a circuit diagram for a power on/off smart controller for handheld device 12, according to one embodiment.

[0047] Referring now to FIGS. 6A and 6B, sensor 14 is shown in more detail. In general, sensor 14 is the sensing component of system 10. It measures the osmolality and/or osmolarity of a user's saliva and includes a saliva collector, a fluidic channel to deliver saliva to a sensing area, and multiple electrodes. FIG. 6A, shows three sensors 14—the two on the left are assembled, and the one on the right is shown in exploded view. The exploded view illustrates that sensor 14 may include three layers—a bottom layer is the electrode layer 80 (T1 in the figure), a middle layer is the spacer layer 82 (T2 in the figure), and a top layer is the cover 84 (T3 in the figure). In this embodiment, electrode layer 80 includes a bottom layer of polyethylene terephthalate (PET) 86, a middle layer of silver 88 and a top layer of carbon 90. The bottom layer 86 can be constructed of a variety of materials, such as carbon, polystyrene, polycarbonate, polyvinyl chloride resin, and polyester. In the illustrated embodiment, the bottom layer 86 is constructed of PET. The same variations of materials may be used in any of the other layers described below as being made of PET. Spacer layer 82 includes a bottom layer of pressure sensitive adhesive 92, a middle layer of PET 94 and a top layer of pressure sensitive adhesive 96. Cover 84 is made simply of one layer of PET in this embodiment. Sensor 14 also includes an enzyme mesh insert 98, for facilitating fluid flow along sensor 14. In alternative embodiments, sensor may include multiple fluidic channels and multiple sets of electrodes, to measure multiple molecules of interest.

[0048] In the illustrated embodiment, sensor 14 includes three electrodes, all of which are made of silver—in other words, the middle silver layer 88 of the electrode layer 80. Thus, for purposes of the description of FIGS. 6A and 6B, "silver layer" and "silver electrodes" will both use the reference label 88. In this embodiment, sensor 14 has three silver electrodes 88, two of which are for electrochemical measurement and one of which is for fluid detection. Silver electrodes 88, in general, are used to electronically determine the presence and/or amount of a

substance (or "analyte") of interest present in a fluid sample. For example, electrodes 88 may be used to detect osmolarity of a saliva sample, which information may be used to determine hydration of a human or animal subject. Carbon layer 90 helps increase conductivity of silver electrodes 88.

[0049] In one embodiment, electrodes 88 are printed on bottom layer 86. In various alternative embodiments, Ag/AgCl, carbon inks (graphite), palladium, gold, platinum, iridium, doped indium tin oxide, stainless steel, and other suitable conducting materials may be used. Electrodes 88 may also be made of combinations of these materials. For example, one portion of an electrode 88 may be one material, and another portion of the same electrode 88 may be another material. Electrodes 88 may be arranged on bottom layer 86 in any desirable format.

[0050] FIG. 6B includes a top view of sensor 14 (bottom portion of figure), with layers removed to show detail of silver electrodes 88, a side view of sensor 14 (middle portion of figure), and a detailed side view of one end of sensor 14 (top magnified view). Dimensions for one embodiment are also labeled in this figure. As illustrated in the top view, sensor 14 may include a volume detection electrode 88a, a counter/reference electrode 88b and a working electrode 88c. Other embodiments and configurations are contemplated within the scope of the present disclosure.

[0051] Referring now to FIGS. 7A-7D, various alternative embodiments of a sensor are shown. FIG. 7A is a top view of a sensor 150 having multiple microfluidic channels and a split mesh. FIG. 7B is a top view of a sensor 160 having separated channels. FIG. 7C is a top view of sensor 170 having one channel. And FIG. 7D shows a side view (top panel) and top view (bottom panel) of a substrate 180 of a sensor, according to one embodiment.

[0052] Referring now to FIG. 8, computer application 16, which may be located on mobile computing device 18, communicates with handheld device 12 and the cloud 22. Data pertaining to test subject 20 (e.g., personal information and measurement results) may be stored in the cloud 22. Any of a number of different types of information may travel back and forth between handheld device 12 and computer application 16. For example, initial data regarding tested saliva may be sent from handheld device 12 to computer application 16 for further processing. Advertising and/or any other suitable data may also be sent from handheld device 12

to computer application 16. Computer application 16 may send a connection request to handheld device 12, and an accept message may be transmitted back to computer application 16, along with a confirmation code. Handheld device 12 and computer application 16 may work together to establish the connection between the two.

[0053] With reference now to FIGS. 9A-9I, a method for using saliva testing system 10, according to one embodiment, will now be described. Referring to FIG. 9A, in this embodiment, a trainer T tests saliva from six players P1-P6, although only Player 1's test will be described. In this embodiment, the trainer T uses an iPad mobile tablet computing device 18, with computer application 16 loaded onto it, along with handheld device 12 and multiple sensors 14. As mentioned above, system 10 may be provided in a kit form in some embodiments, and sensors 14 may be provided in a box, packet or other container.

[0054] As illustrated in FIG. 9B, the trainer T turns on handheld device 12, opens and logs onto computer application 16, and handheld device 12 and application 16 pair with one another. This may be done automatically, for example if an auto-connect function is enabled, or may be done manually by the trainer T. Each handheld device 12 may include a unique identifier, such as a Bluetooth low energy identifier, which may facilitate pairing and ensure security. The trainer T may also scan a QR code on the box of sensors, for example for security and quality control reasons. Referring to FIG. 9C, the trainer T may next type a name and/or other identifier of Player1 P1 on the computer application 16 on the mobile computing device 18. Computer application 16 may display an image of Player1 P1 with a MEASURE button. As shown in FIG. 9D, the trainer T may then activate the MEASURE button, at which point computer application 16 may transmit a signal to handheld device 12, telling the latter that Player1 P1 is being measured. Handheld device 12 may display the name and ID of Player1 P1 on the LCD display 26.

[0055] As shown in FIG. 9E, the trainer T then inserts a sensor 14 into handheld device 12, which detects that sensor 14 has been inserted. Display 26 may include an indicator 27 that shows when sensor 14 is ready for a measurement. Indicator 27 may change colors or simply appear on display 26 when sensor 14 is fully and properly inserted. If there is no player information when sensor 14 is inserted, handheld device 12 may alert the trainer T to look for the player information on

computer application 16 before proceeding. The alert may be via visual and/or audio display.

[0056] Referring next to FIG. 9F, the trainer T then places the free end of sensor 14 in Player1's mouth to collect a saliva sample. Handheld device 12 detects if there is a sufficient amount of saliva in sensor 14. If there is enough saliva, handheld device 12 performs the reading automatically (for example in 1-3 seconds). Handheld device 12 may play a beep sound 80 to let the trainer T know the measurement has started. Referring to FIG. 9G, upon hearing beep 80, the trainer T may remove sensor 14 from Player1's mouth and wait for approximately five seconds. After five seconds (or other appropriate period of time in alternative embodiments), handheld device 12 may display DONE and/or play a sound to indicate the measurement has finished. Handheld device 12 may at this point transmit initial data to computer application 16 on mobile computing device. Computer application 16 then processes the initial data and displays hydration status of Player1 P1. Finally, as illustrated in FIG. 9H, the trainer T ejects sensor 14 from handheld device 12. It is important that sensor 14 not be reused by Player 1 P1 or any other player. Referring to FIG. 8I, the steps outlined above may then be repeated by the trainer T for as many other players P2-P6 as desired.

[0057] Referring now to FIGS. 10A-10N, a series of screen shots of graphical user interfaces (GUIs) are shown, illustrating displays provided by computer application 16 to a user, according to one embodiment. These screen shots illustrate one method for progressing through computer application 16 during a saliva/hydration measurement of a player. This is only one exemplary method and series of interfaces, however, and should not be interpreted as limiting the scope of the present disclosure.

[0058] FIG. 10A shows a log-in screen 90, where a user can input a user name and password to log into computer application 16. FIG. 10B shows a player dashboard 92 screen, which provides information about a player. As illustrated on the left of the player dashboard 92, this screen allows a user to select from among a menu of multiple players. FIG. 10C shows a statistics page 94, which provides hydration statistics and information for multiple players. FIG. 10D shows an add-new-player page 96. FIG. 10E shows a staff page 98, and FIG. 10F shows a staff

setting page 100 indicating a connection with a connected device. FIG. 10G is a pair-new-device page 102, for pairing a new handheld device 12 with computer application 16.

[0059] FIG. 10H is a device details page 104, where details of the paired handheld device 12 are provided. FIG. 10I is an edit profile page 106. FIG. 10J is a first measurement page 108, which tells the user to insert sensor 14 into handheld device 12 and click "Measure." FIG. 10K is a fluid detection page 110. Finally, FIG. 10L is a measurement result page 112. As mentioned above, saliva testing system 10 may provide any suitable data to a user, according to various embodiments. For example, computer application may indicate whether the test subject is hydrated or dehydrated, to what extent the subject is hydrated or dehydrated, a hydration score or rating for the subject, and/or the like. Again, the GUIs illustrated in FIGS. 10A-10L are for exemplary purposes only and are not meant to limit the scope of the application.

[0060] The above description is intended to be a complete description of one embodiment of a system and method for measuring eye tracking for one or more diagnostic purposes. It is meant to be a description of examples only and is not intended to limit the scope of the invention.

CLAIMS

We claim:

1. A method for using saliva to measure at least one substance or physiological parameter of a human or animal subject, the method comprising:

inserting a first end of a sensor into a handheld saliva testing device;

receiving saliva from the subject on a second end of the sensor;

moving the saliva from the second end of the sensor to the first end; and

processing the saliva with the handheld saliva testing device to provide initial saliva data related to the at least one substance or physiological parameter of the subject.

2. The method of claim 1, wherein the saliva is received on the second end of the sensor while the first end of the sensor remains inserted within the handheld saliva testing device.

3. The method of claim 2, wherein receiving the saliva comprises contacting the second end of the sensor with the subject's tongue or mouth.

4. The method of claim 3, further comprising:

providing an alert with the handheld saliva testing device when a sufficient amount of saliva is received on the sensor, wherein the alert comprises at least one of an audio alert or a visual alert; and

removing the second end of the sensor from the subject's tongue or mouth.

5. The method of claim 4, wherein the saliva is automatically processed with the processor after the alert is provided.

6. The method of claim 1, further comprising:

transmitting the initial saliva data from the handheld saliva testing device to a computer processor; and

processing the initial saliva data with the computer processor to provide final measurement data describing the at least one substance or physiological parameter.

7. The method of claim 6, wherein the initial saliva data is transmitted wirelessly to the computer processor, which is located separately from the handheld saliva measurement device.

8. The method of claim 7, wherein the computer processor comprises an application on a mobile computing device.

9. The method of claim 6, wherein the at least one parameter comprises hydration, and wherein the final measurement data comprises a hydration score for the subject.

10. The method of claim 1, wherein the at least one substance or physiological parameter is selected from the group consisting of hydration, lactate level, ketones, glucose, glycerides, sodium, potassium, calcium, magnesium, chlorides, phosphates, caffeine, melatonin, c-reactive protein, chemokines, cytokines, troponin, cortisol, creatinine kinase, insulin, beta hydroxyl butyrate, iron, ferritin, salivary amylase and oxalic acid.

11. The method of claim 1, wherein moving the saliva comprises moving the saliva through at least one microfluidic channel in the sensor.

12. The method of claim 11, wherein moving the saliva further comprises moving the saliva through a chemically functionalized mesh embedded in the sensor.

13. The method of claim 1, further comprising ejecting the sensor from the handheld saliva testing device, by pressing an eject button the handheld saliva testing device.

14. A method for using saliva to measure at least one substance or physiological parameter of a human or animal subject, the method comprising:

inserting a first end of a sensor into a handheld saliva testing device;

contacting a second end of the sensor with the subject's tongue or mouth to collect the subject's saliva on the second end of the sensor;

moving the saliva from the second end of the sensor to the first end;

analyzing the saliva with the handheld saliva testing device to determine if there is a sufficient amount of the saliva to provide a measurement;

providing an alert with the handheld saliva testing device when the sufficient amount of saliva is received on the sensor, wherein the alert comprises at least one of an audio alert or a visual alert; and

analyzing the saliva with the handheld saliva testing device to measure the at least one substance or physiological parameter of the subject.

15. A system for testing saliva to measure at least one substance or physiological parameter of a human or animal subject, the system comprising:

a handheld saliva testing device comprising a sensor slot and a display;

a sensor comprising a first end configured for insertion into the sensor slot of the handheld saliva testing device and a second end configured for receiving saliva directly from the subject's mouth; and

a computer processor coupled with the handheld saliva testing device to process initial data from the handheld saliva testing device to provide final measurement data describing the at least one substance or physiological parameter.

16. The system of claim 15, wherein the sensor is configured to receive the saliva on the second end of the sensor while the first end of the sensor remains inserted within the handheld saliva testing device.

17. The system of claim 15, wherein the computer processor is located separately from, and is wirelessly connectable to, the handheld saliva measurement device.

18. The system of claim 15, wherein the computer processor comprises an application on a mobile computing device.

19. The system of claim 15, wherein the at least one parameter comprises hydration, and wherein the computer processor is configured to generate the final measurement data, including a hydration score for the subject.

20. The system of claim 15, wherein the at least one substance or physiological parameter selected from the group consisting of hydration, lactate level, ketones, glucose, glycerides, sodium, potassium, calcium, magnesium, chlorides, phosphates, caffeine, melatonin, c-reactive protein, chemokines, cytokines, troponin, cortisol, creatinine kinase, insulin, beta hydroxyl butyrate, iron, ferritin, salivary amylase and oxalic acid.

21. The system of claim 15, wherein the sensor comprises:

at least one microfluidic channel for directing saliva from the second end to the first end of the sensor; and

a chemically functionalized mesh embedded between a top layer and a bottom layer of the sensor, to facilitate movement of saliva along a length of the sensor.

22. The system of claim 15, further comprising an additional computer processor embedded in the handheld saliva testing device for generating the initial data.

23. The system of claim 15, wherein the handheld saliva testing device further comprises:

an on/off switch;

a speaker for emitting an alert; and

an eject button for ejecting the sensor out of the sensor slot.

24. A handheld device for testing saliva to measure at least one substance or physiological parameter of a human or animal subject, the handheld device comprising:

a housing;

a sensor slot in the housing;

a display on the housing; and

a computer processor housed in the housing for generating initial data related to the at least one substance or parameter from the saliva.

25. The device of claim 24, further comprising an eject button on the housing for ejecting a used sensor out of the sensor slot.

26. The device of claim 25, further comprising multiple buttons on the housing for controlling the handheld device.

27. The device of claim 24, further comprising a wireless transmitter for transmitting the initial data to an additional computer processor separate from the handheld device.

28. A saliva sensor for use with a saliva testing device to measure at least one substance or physiological parameter of a human or animal subject, the saliva sensor comprising:

a bottom layer;

multiple electrodes applied to the bottom layer;

a top layer;

at least one microfluidic channel between the bottom layer and the top layer, for directing saliva from one end to an opposite end of the saliva sensor; and

a chemically functionalized mesh embedded between the bottom layer and the top layer to facilitate movement of saliva along a length of the saliva sensor.

29. The saliva sensor of claim 28, further comprising an insulating layer comprising a hydrophobic, dielectric material.

30. The saliva sensor of claim 28, wherein the at least one microfluidic channel comprises multiple microfluidic channels, and wherein the saliva sensor is configured for measuring at least two substances or physiological parameters of the subject.

31. A tangible computer readable medium storing instructions for performing a method for testing saliva to measure at least one substance or physiological parameter of a human or animal subject, the method comprising:

receiving initial saliva data from a saliva testing device, the initial saliva data related to the at least one physiological parameter of the subject; and

processing the initial saliva data to provide final measurement data describing the at least one substance or physiological parameter.

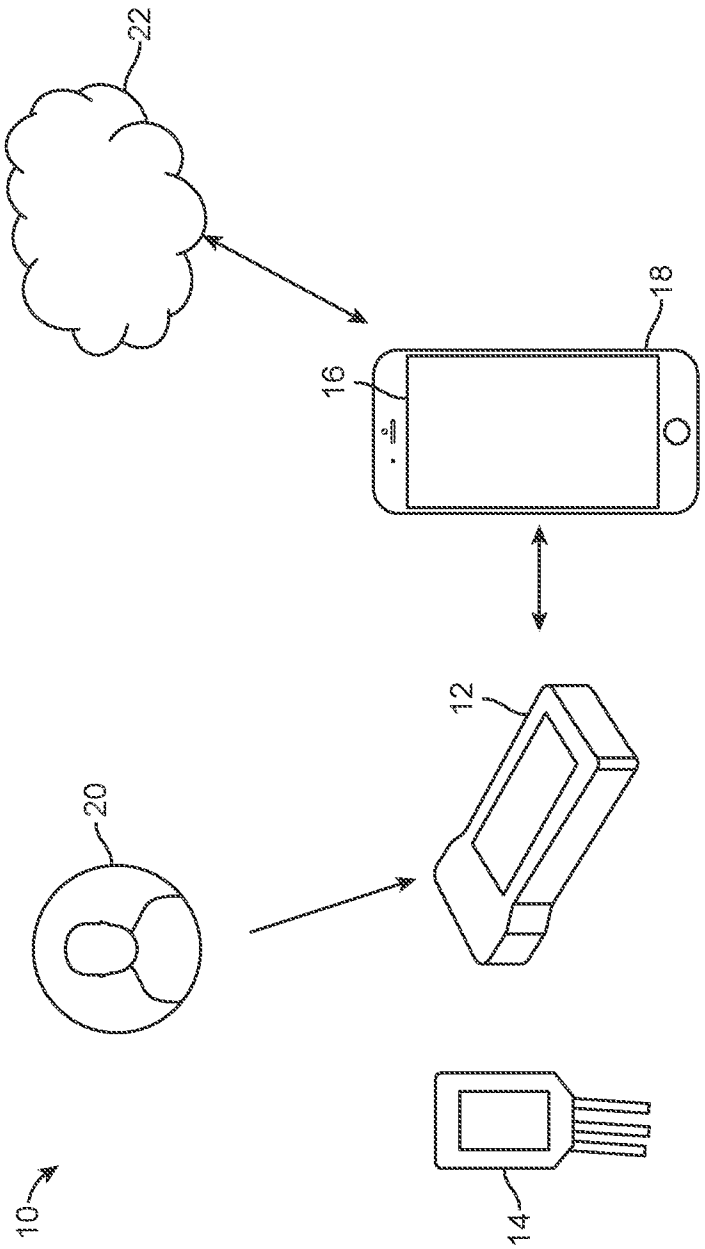


FIG. 1A

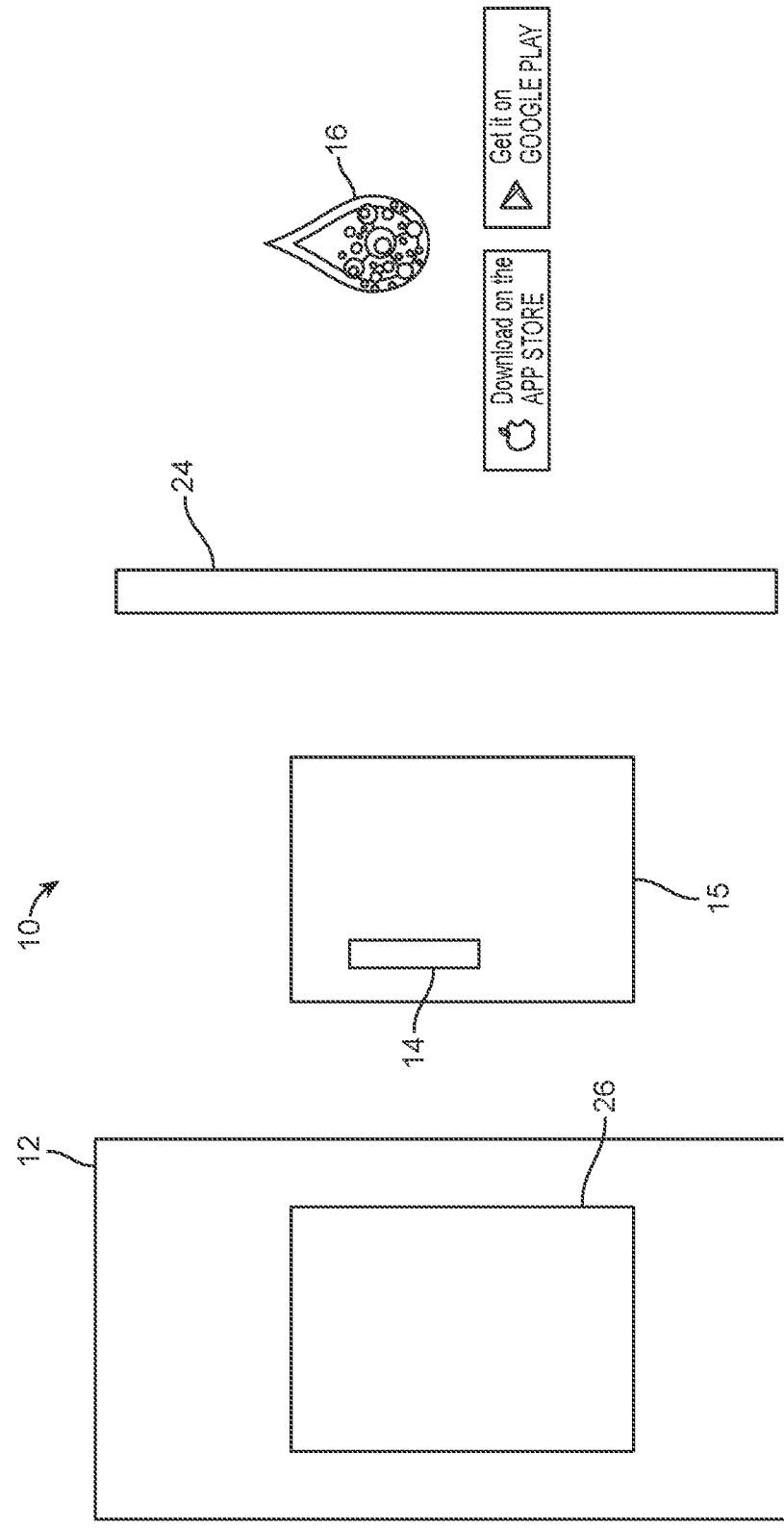

10
12
14
15
16
24
26
Download on the APP STORE
Get it on GOOGLE PLAY

FIG. 1B

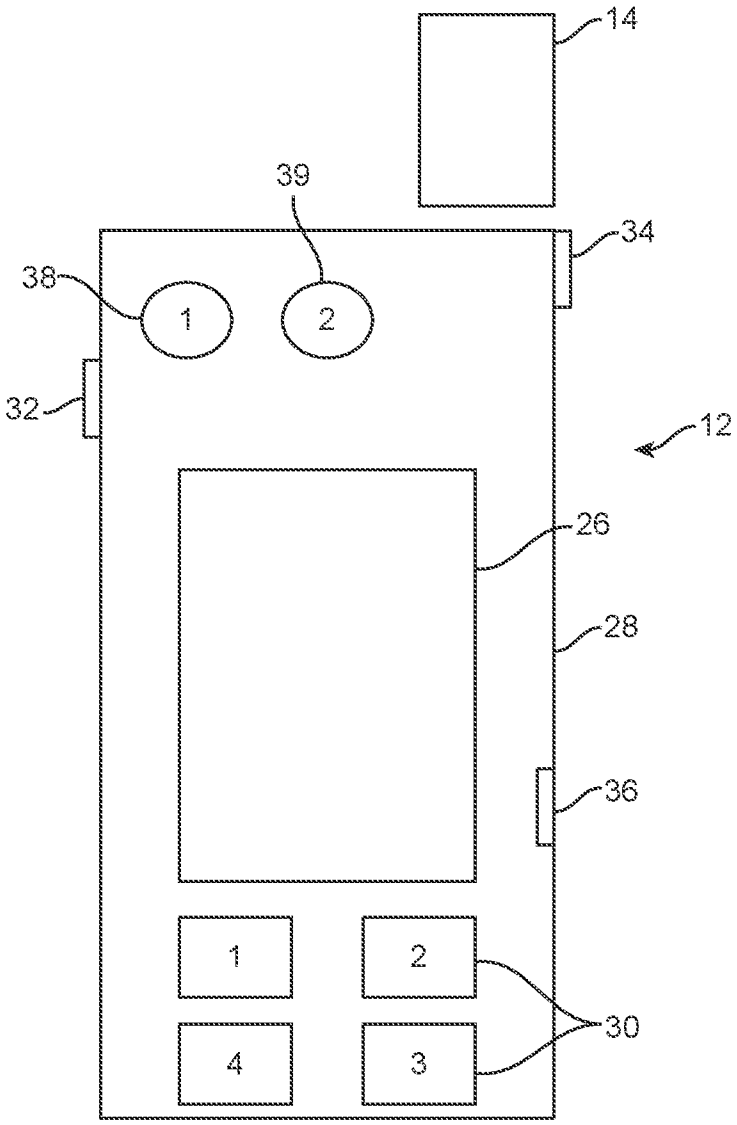


FIG. 2A

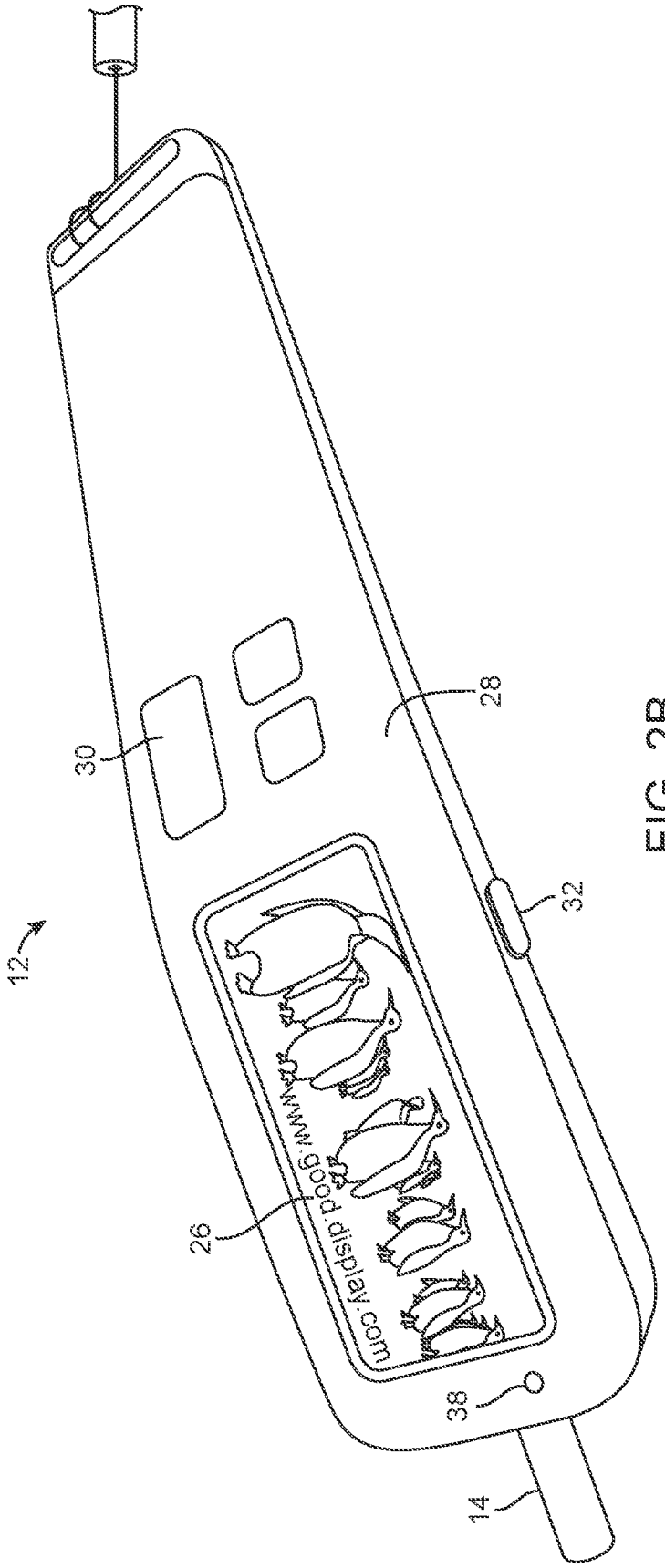


FIG. 2B

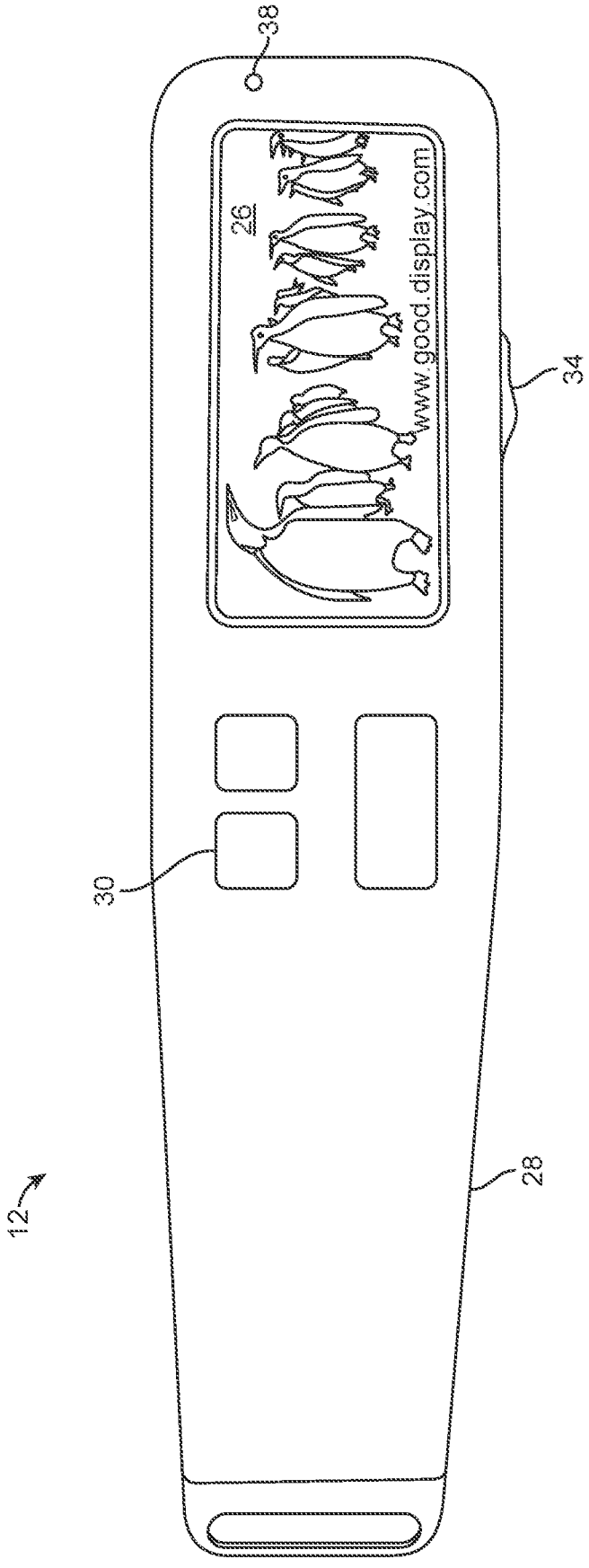


FIG. 2C

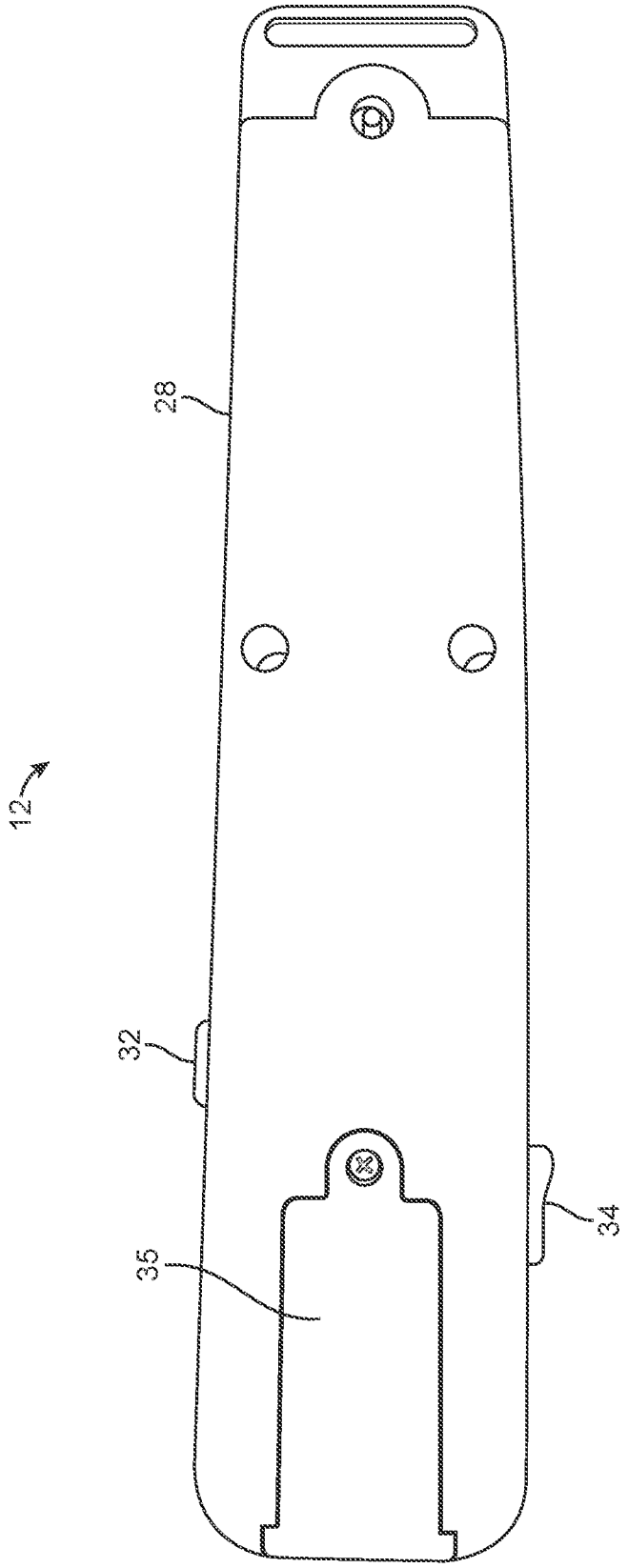


FIG. 2D

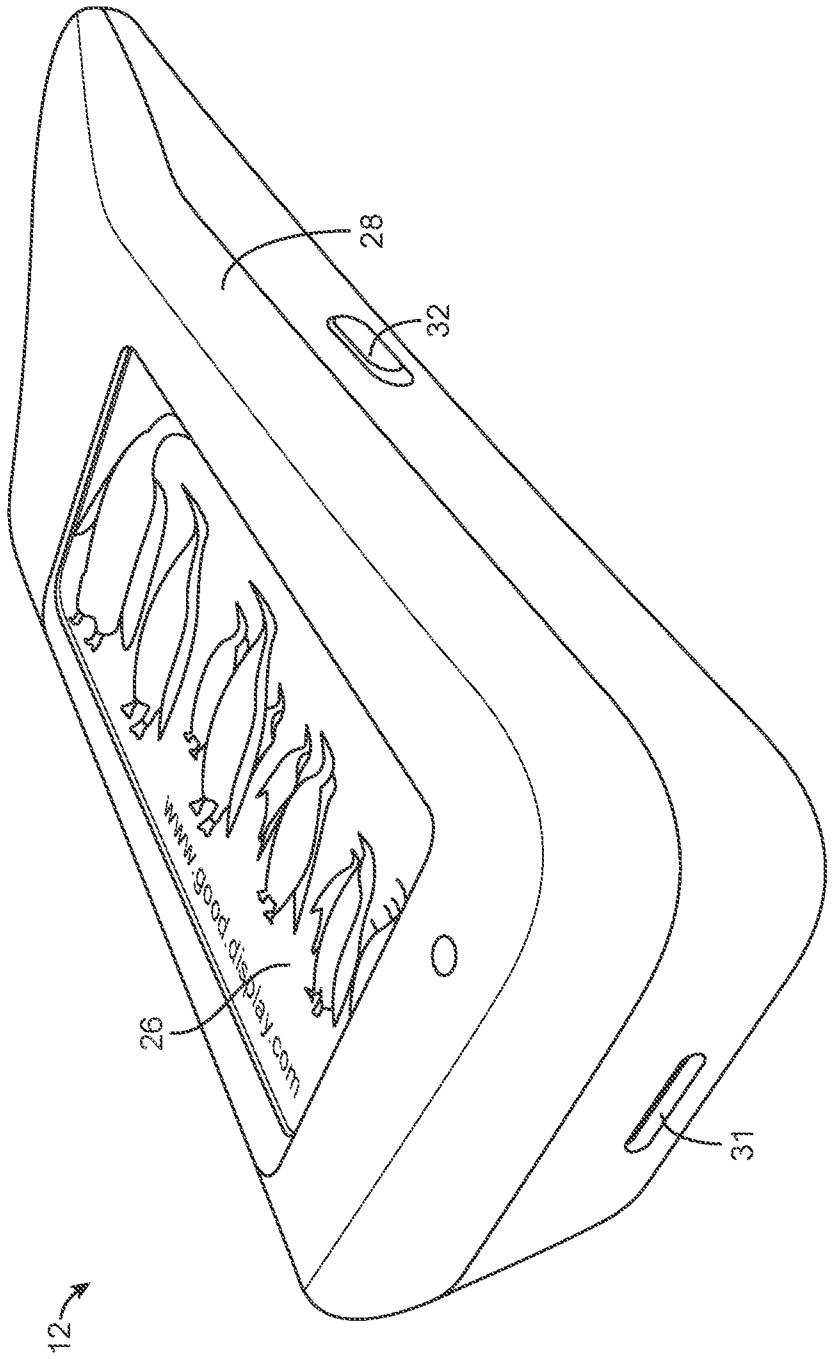


FIG. 2E

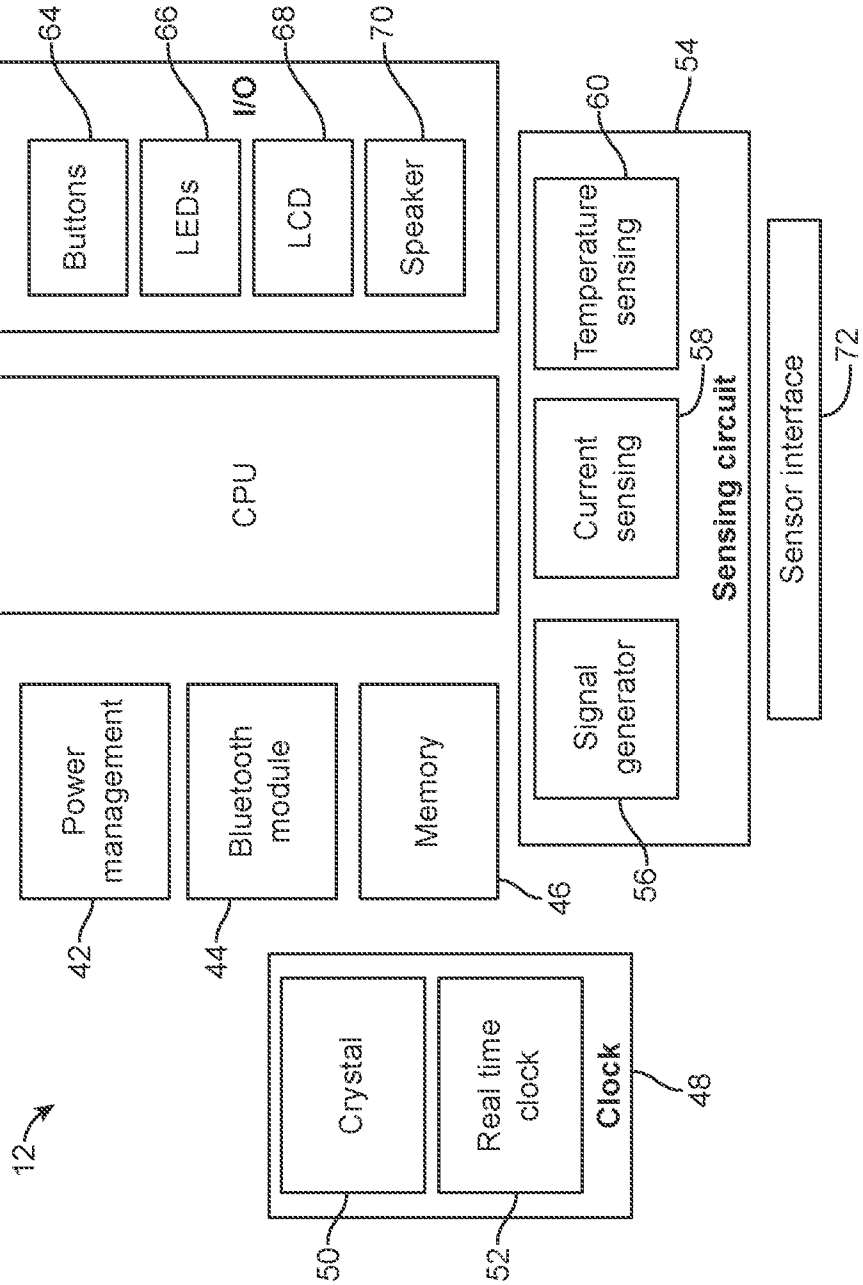

12
40
CPU
62
I/O
64
Buttons
66
LEDs
68
LCD
70
Speaker
42
Power management
44
Bluetooth module
46
Memory
48
Clock
50
Crystal
52
Real time clock
54
Sensing circuit
56
Signal generator
58
Current sensing
60
Temperature sensing
72
Sensor interface

FIG. 3

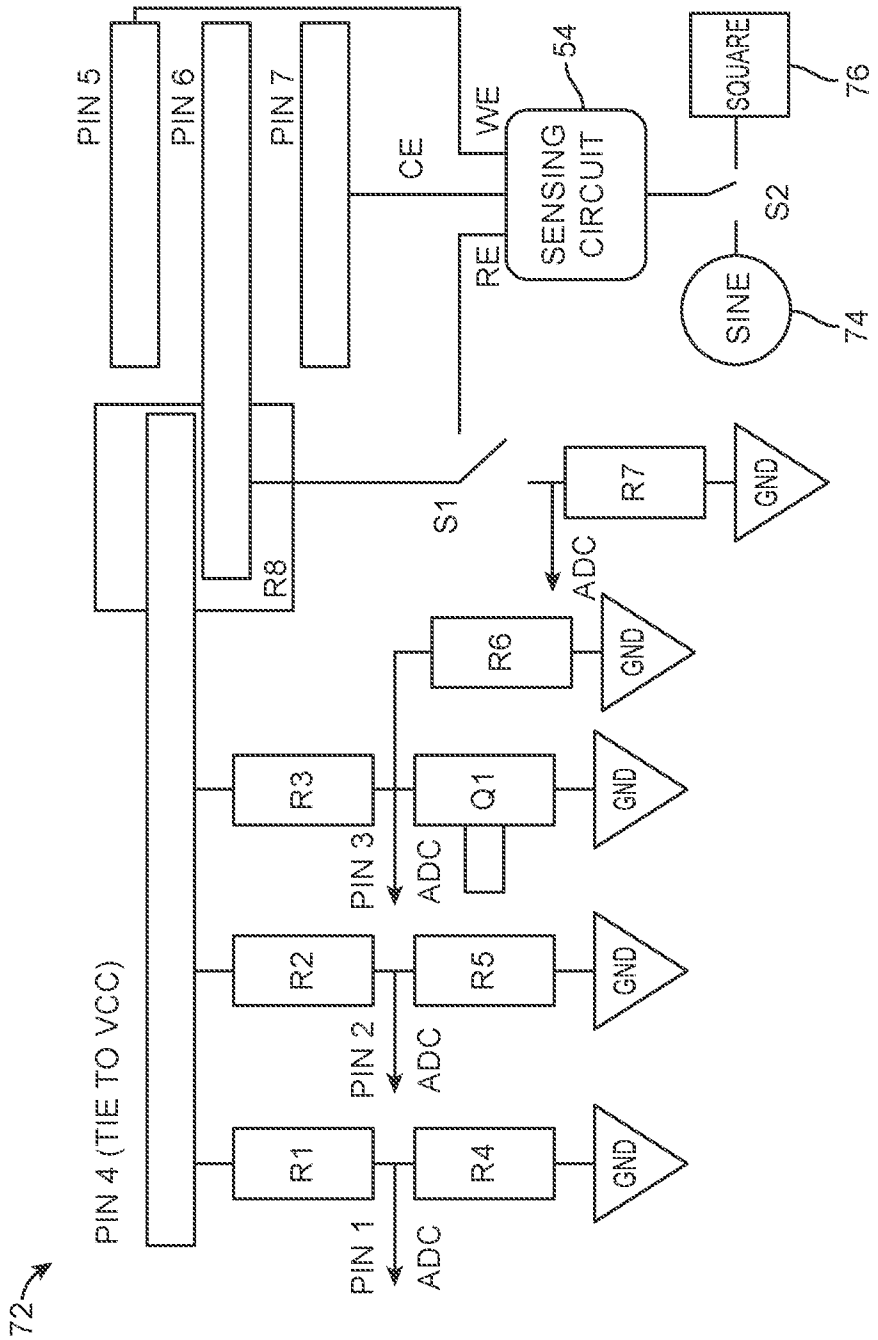

72
PIN 4 (TIE TO VCC)
PIN 5
PIN 6
PIN 7
CE
WE
RE
54
SENSING CIRCUIT
S1
S2
SQUARE
76
SINE
74
R8
R7
GND
ADC
R6
GND
R3
Q1
GND
PIN 3
ADC
R2
R5
GND
PIN 2
ADC
R1
R4
GND
PIN 1
ADC

FIG. 4

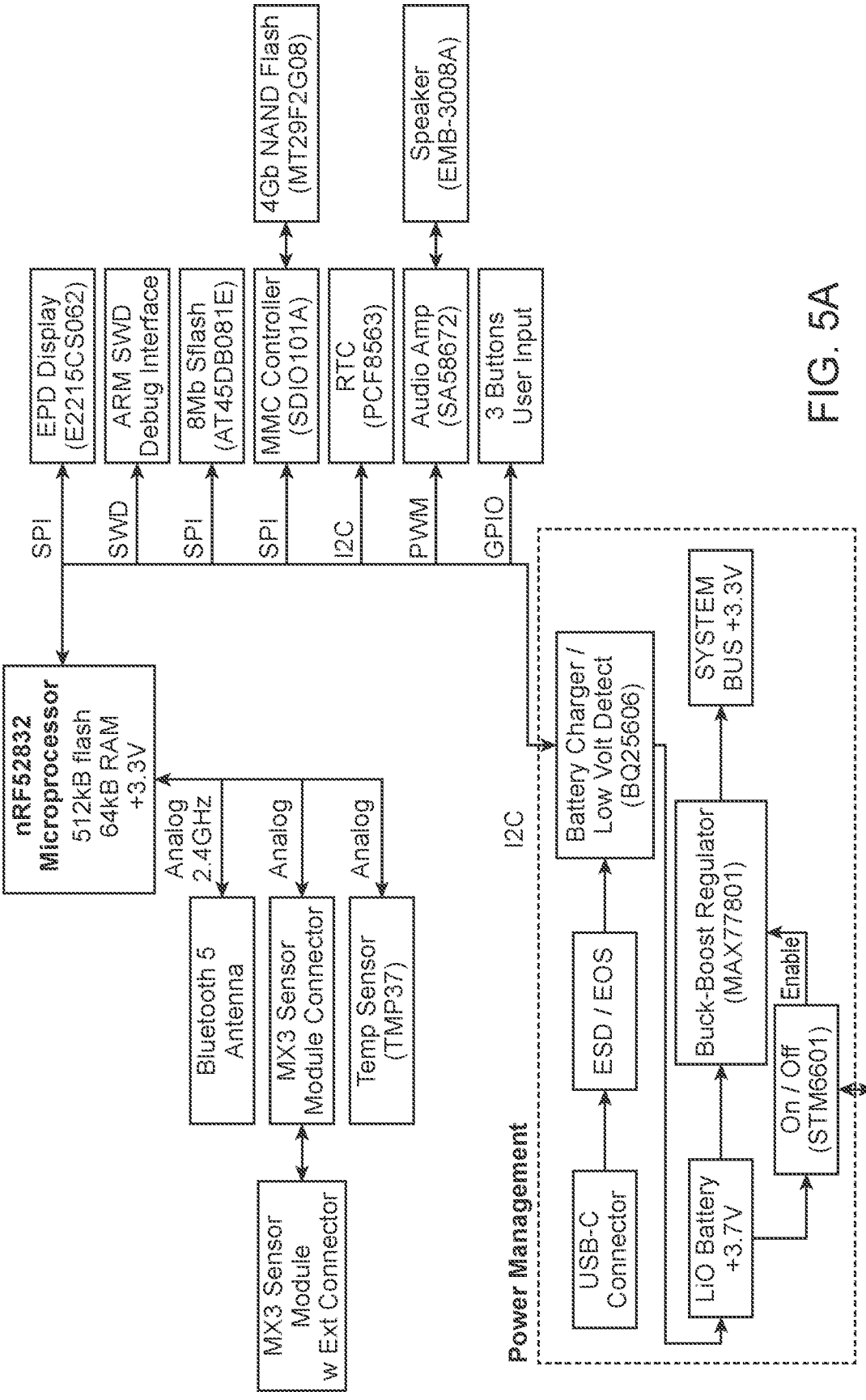

nRF52832
Microprocessor
512kB flash
64kB RAM
+3.3V
SPI
SWD
SPI
SPI
I2C
PWM
GPIO
EPD Display
(E2215CS062)
ARM SWD
Debug Interface
8Mb Sflash
(AT45DB081E)
MMC Controller
(SDIO101A)
RTC
(PCF8563)
Audio Amp
(SA58672)
3 Buttons
User Input
4Gb NAND Flash
(MT29F2G08)
Speaker
(EMB-3008A)
Analog
2.4GHz
Analog
Analog
Bluetooth 5
Antenna
MX3 Sensor
Module Connector
Temp Sensor
(TMP37)
MX3 Sensor
Module
w Ext Connector
I2C
Power Management
Battery Charger /
Low Volt Detect
(BQ25606)
ESD / EOS
USB-C
Connector
SYSTEM
BUS +3.3V
Buck-Boost Regulator
(MAX77801)
Enable
On / Off
(STM6601)
LiO Battery
+3.7V
1 Button
Power On/Off

FIG. 5A

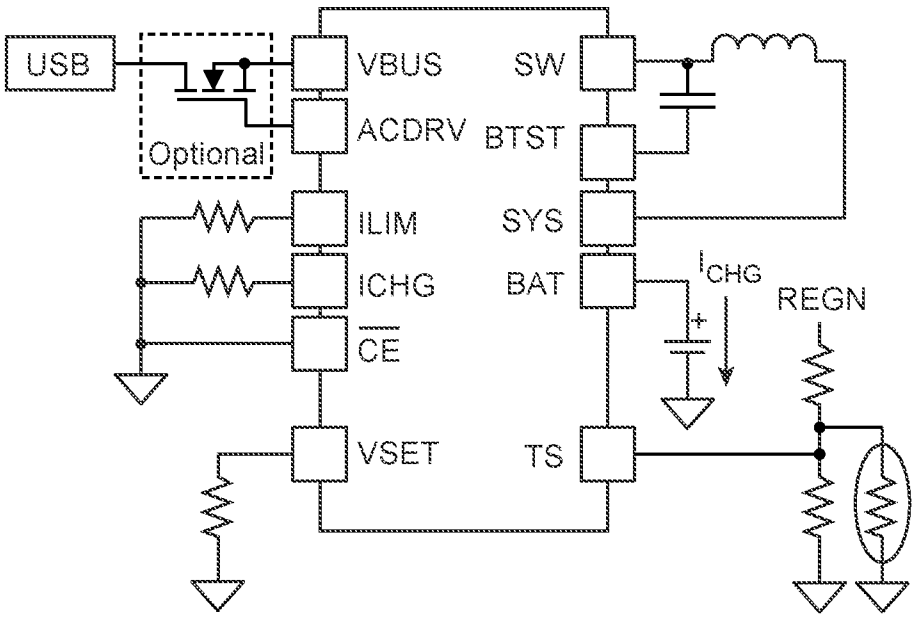

USB
Optional
VBUS
ACDRV
ILIM
ICHG
CE
VSET
SW
BTST
SYS
BAT
TS
ICHG
REGN

FIG. 5B

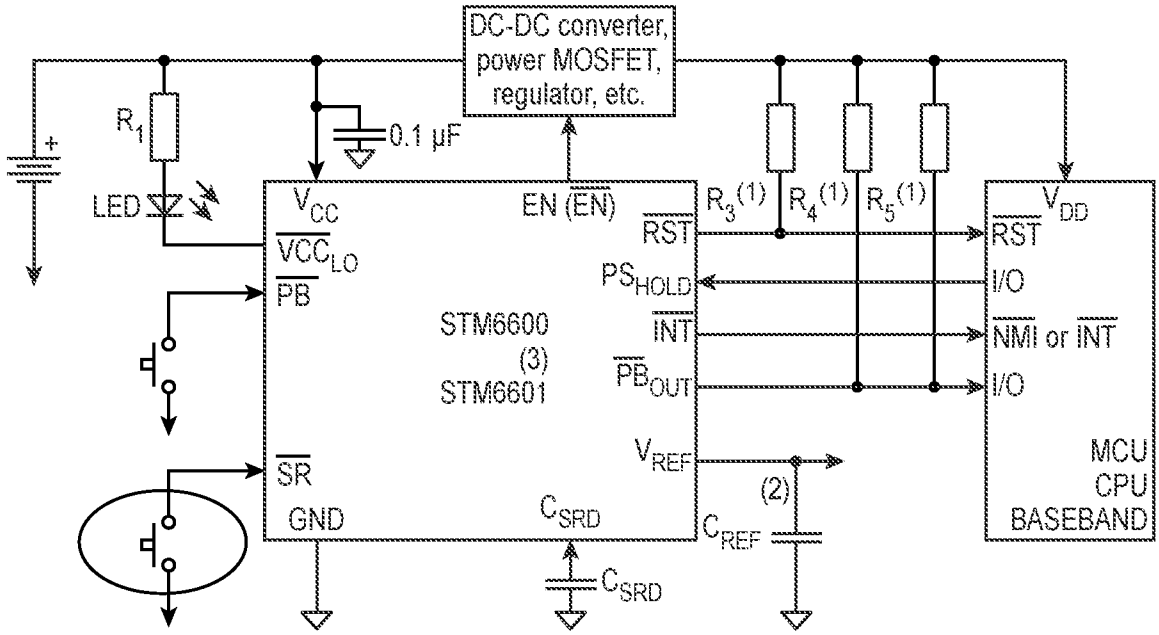

DC-DC converter, power MOSFET, regulator, etc.
R1
0.1 µF
LED
VCC
VCCLO
PB
EN (EN)
STM6600
(3)
STM6601
SR
GND
CSRD
RST
PSHOLD
INT
PBOUT
VREF
CREF
(2)
R3(1)
R4(1)
R5(1)
VDD
RST
I/O
NMI or INT
I/O
MCU
CPU
BASEBAND

FIG. 5C

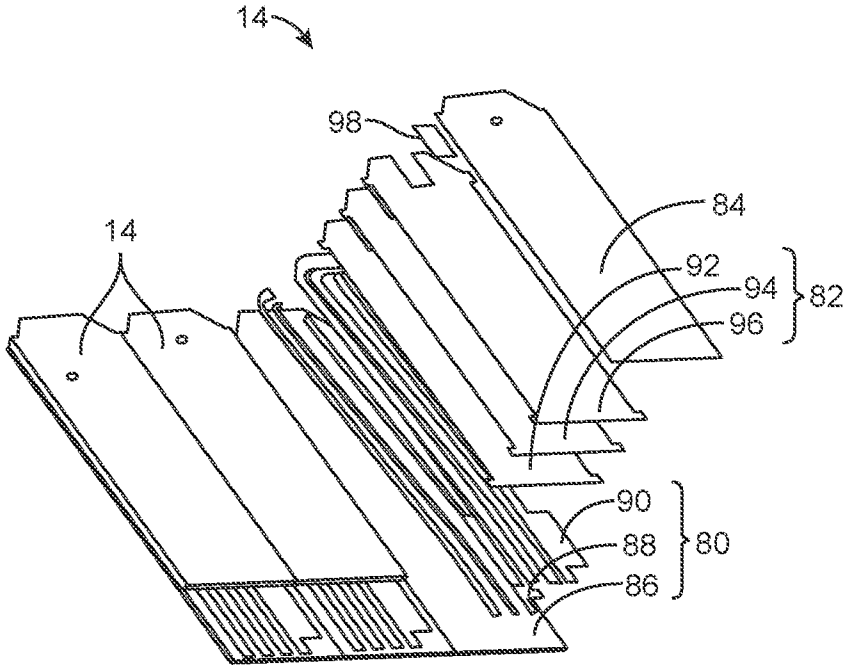


FIG. 6A

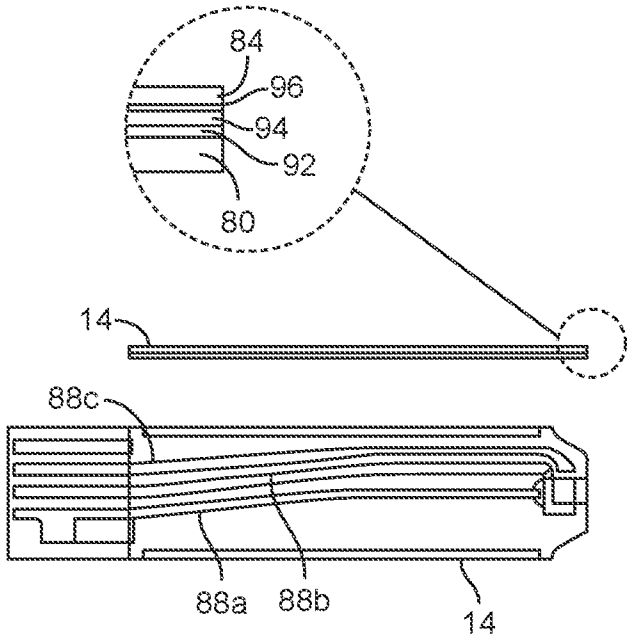


FIG. 6B



FIG. 7A



FIG. 7B



FIG. 7C

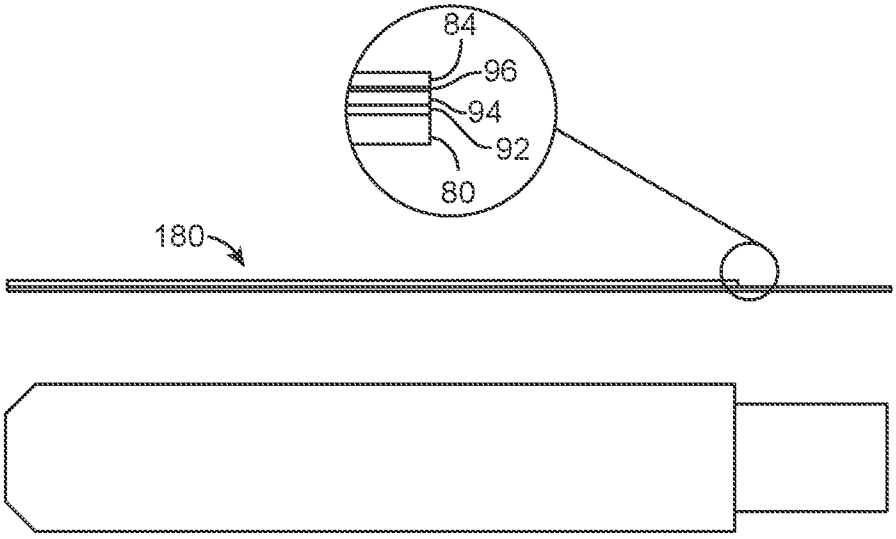


FIG. 7D

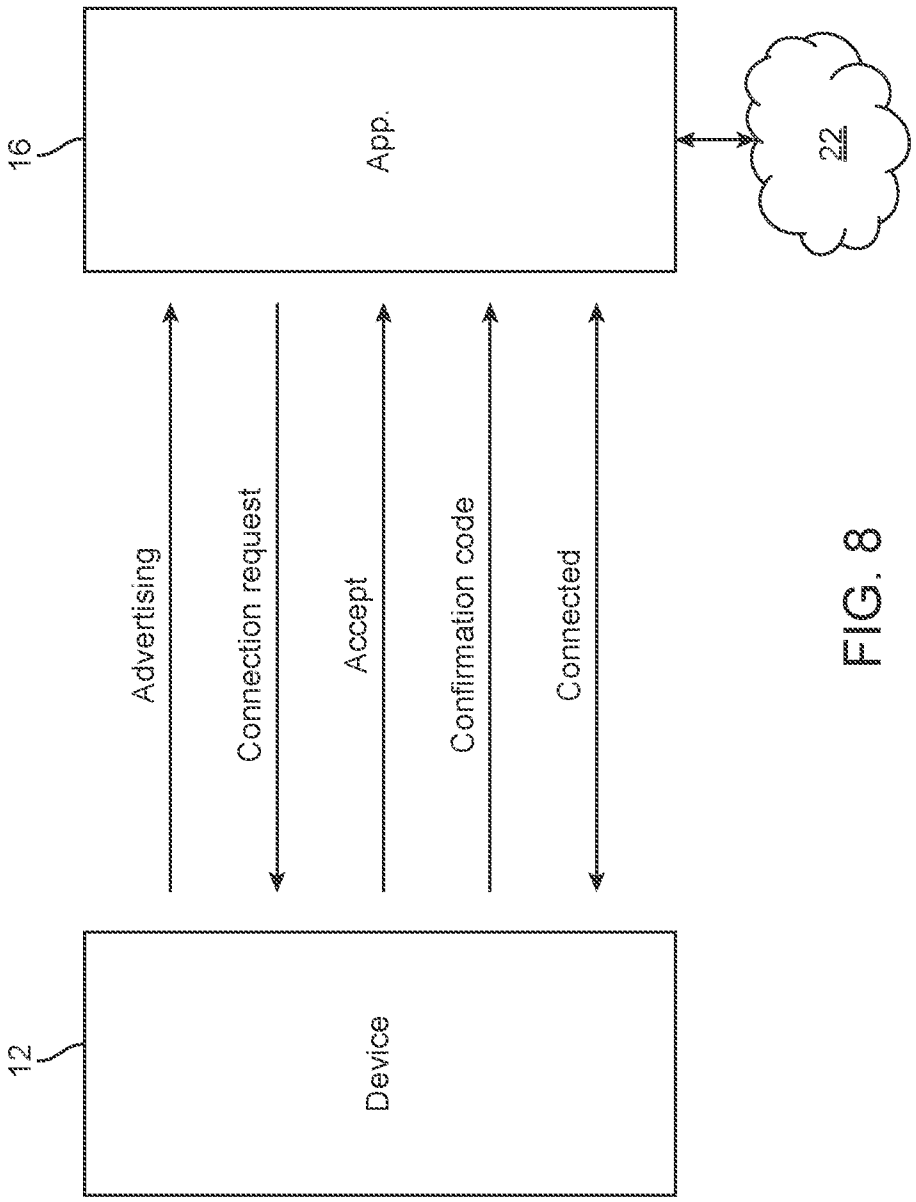

16
App.
22
Advertising
Connection request
Accept
Confirmation code
Connected
12
Device

FIG. 8

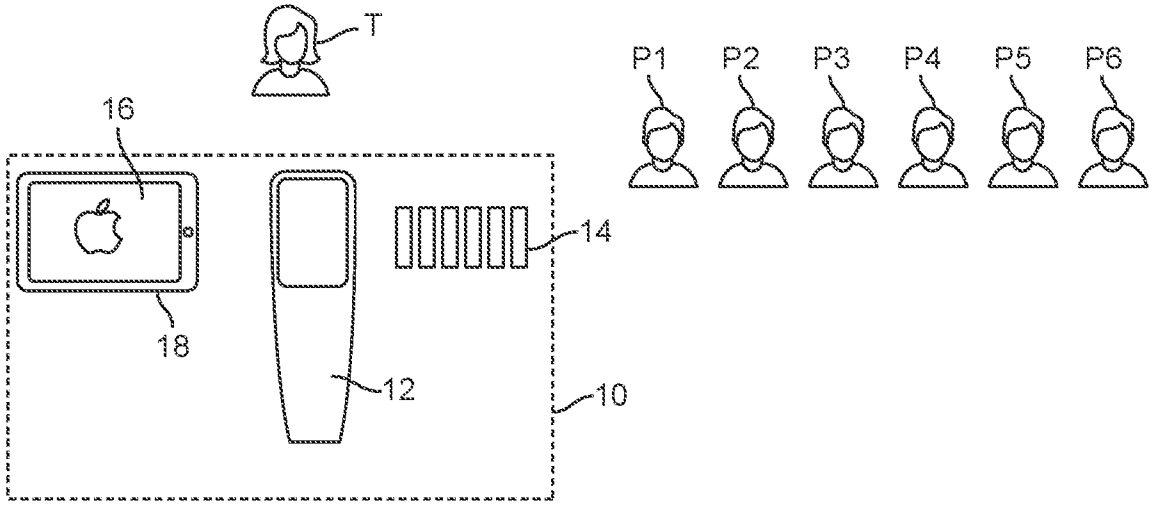


FIG. 9A

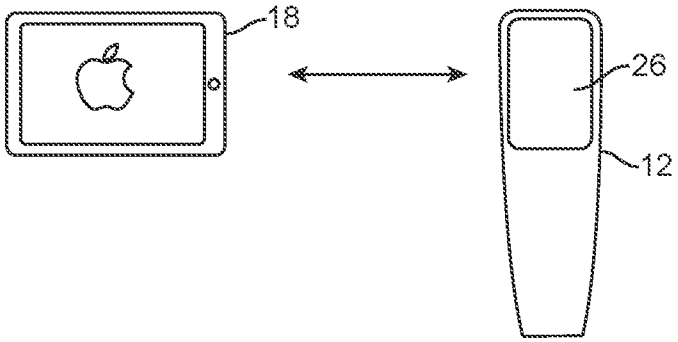


FIG. 9B

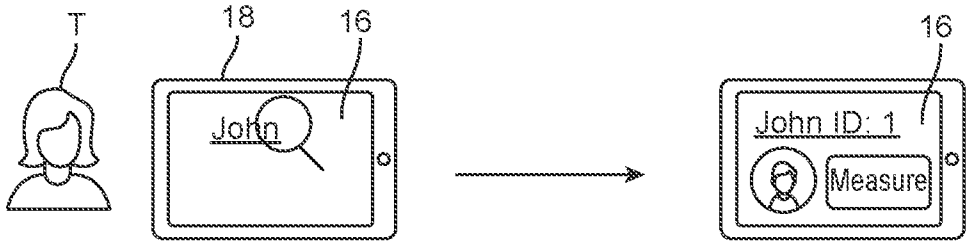


FIG. 9C

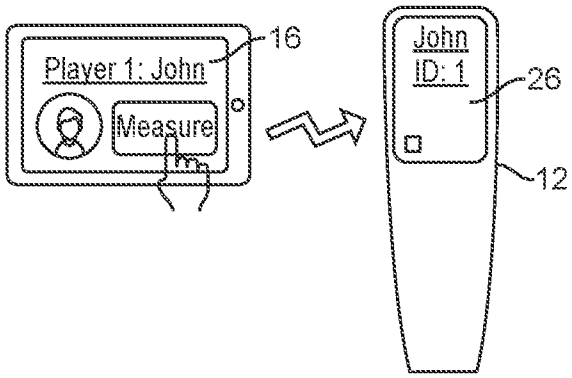


FIG. 9D

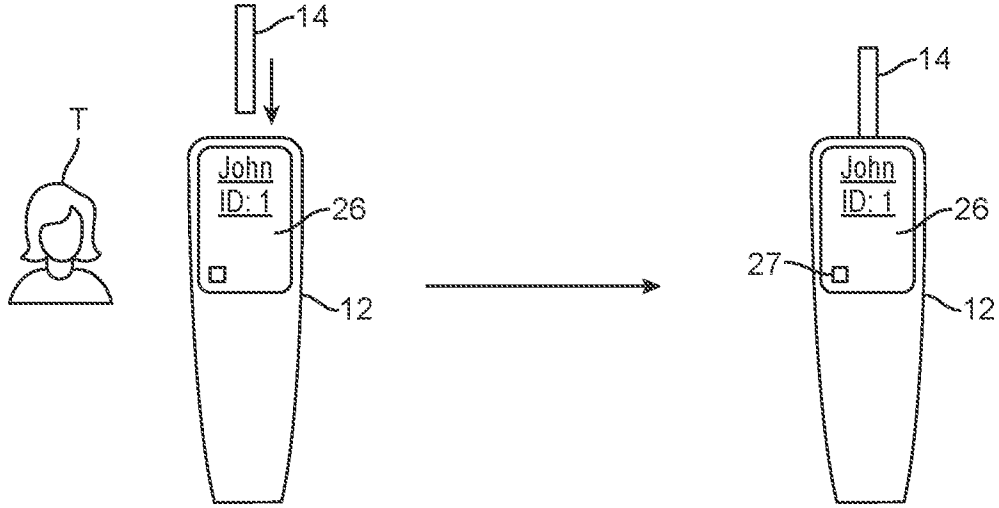


FIG. 9E

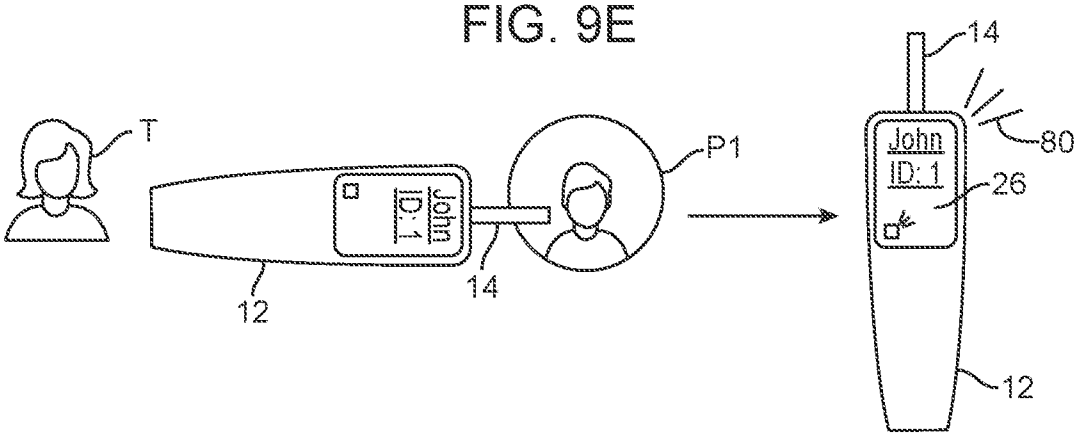


FIG. 9F

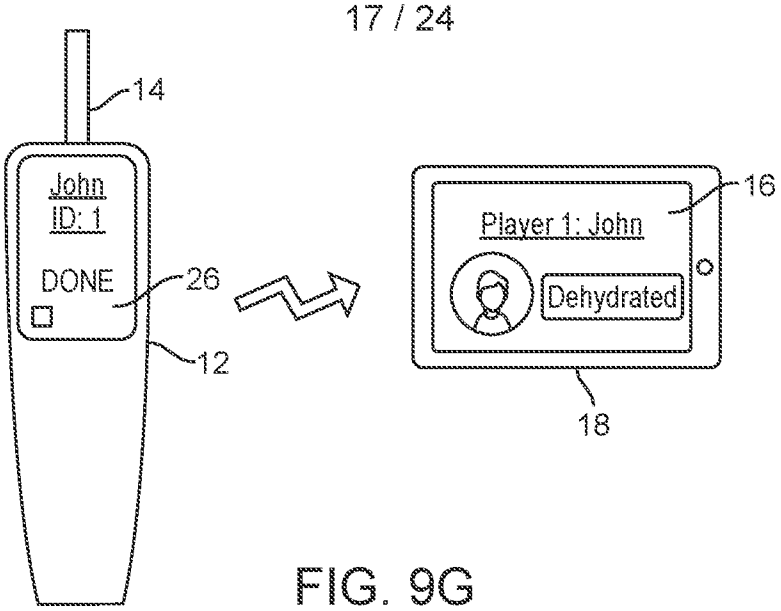


FIG. 9G

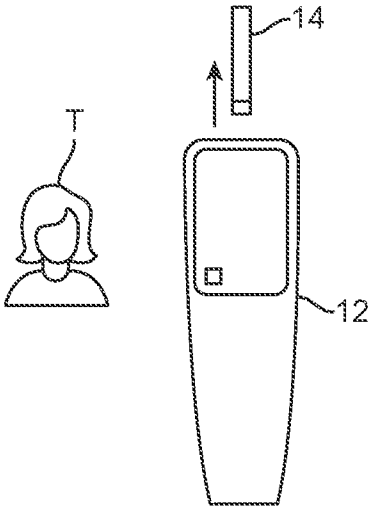


FIG. 9H

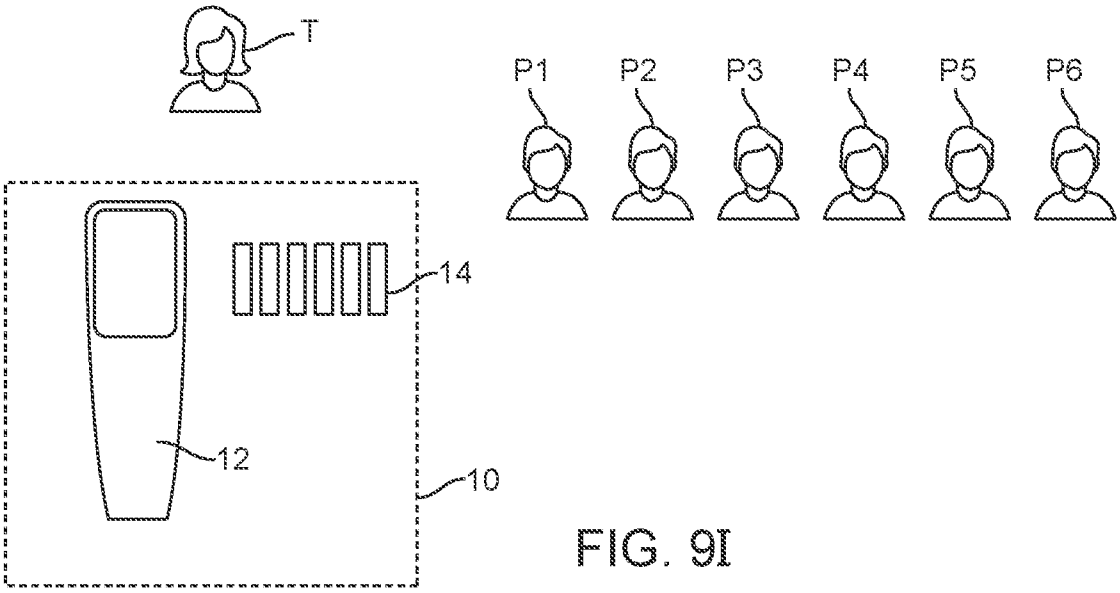


FIG. 9I

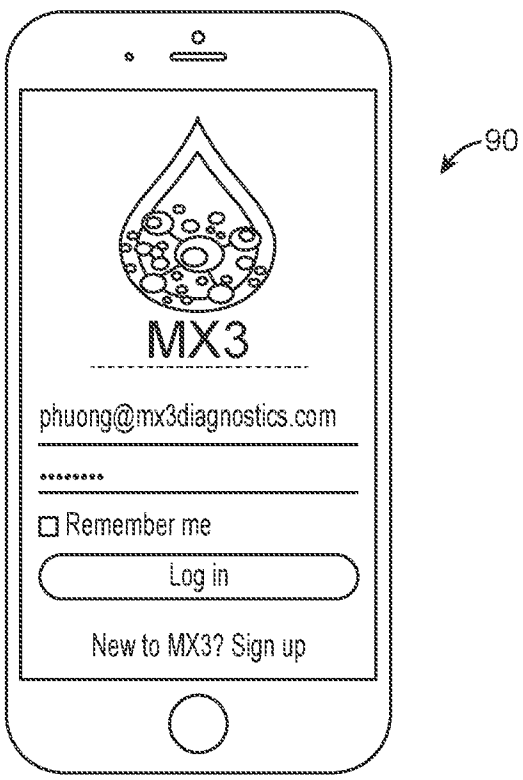


FIG. 10A

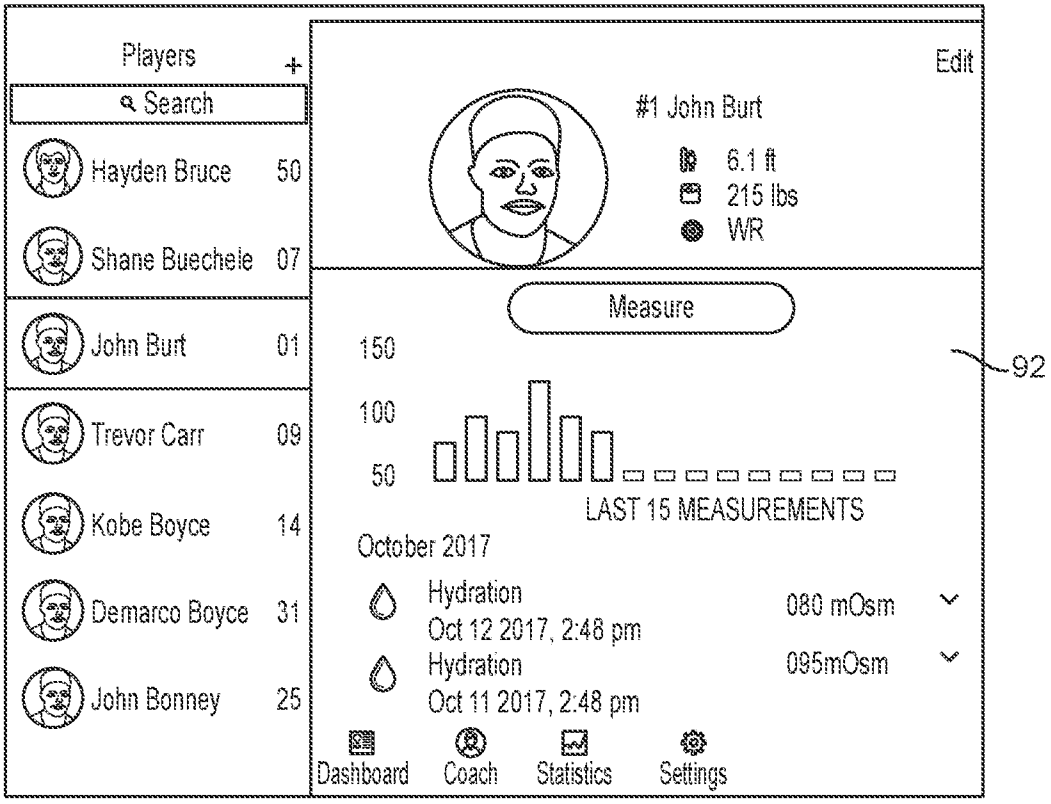


FIG. 10B

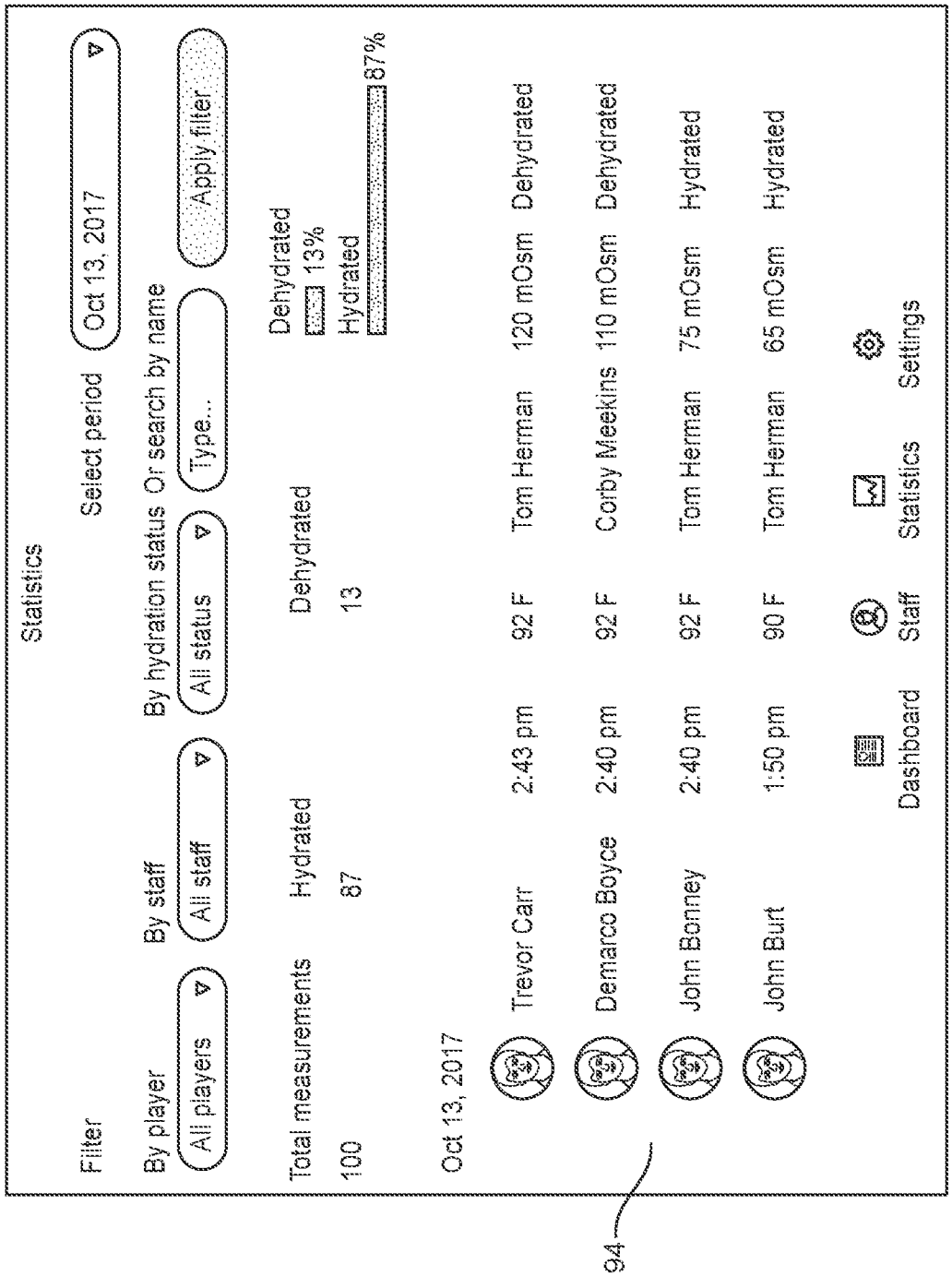

Statistics
Filter
Select period
Oct 13, 2017
By player
By staff
By hydration status
Or search by name
All players
All staff
All status
Type...
Apply filter
Total measurements
Hydrated
Dehydrated
Dehydrated
13%
Hydrated
87%
100
87
13
Oct 13, 2017
Trevor Carr
2:43 pm
92 F
Tom Herman
120 mOsm
Dehydrated
Demarco Boyce
2:40 pm
92 F
Corby Meekins
110 mOsm
Dehydrated
John Bonney
2:40 pm
92 F
Tom Herman
75 mOsm
Hydrated
John Burt
1:50 pm
90 F
Tom Herman
65 mOsm
Hydrated
Dashboard
Staff
Statistics
Settings
94

FIG. 10C

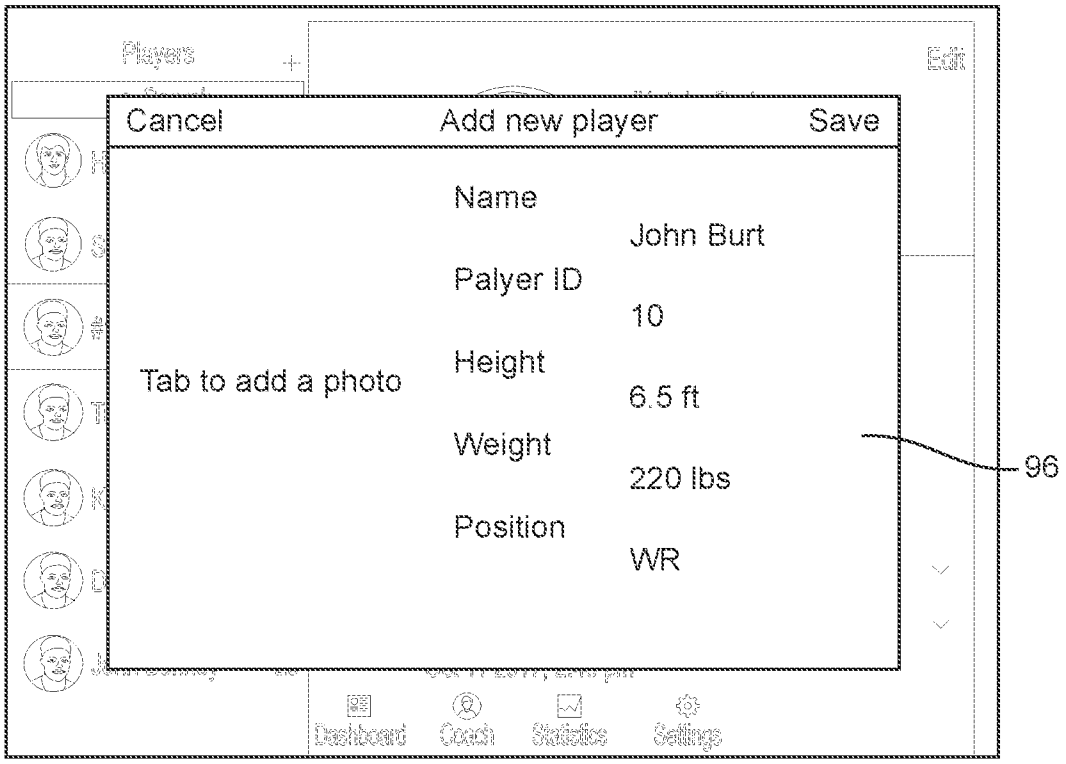


FIG. 10D

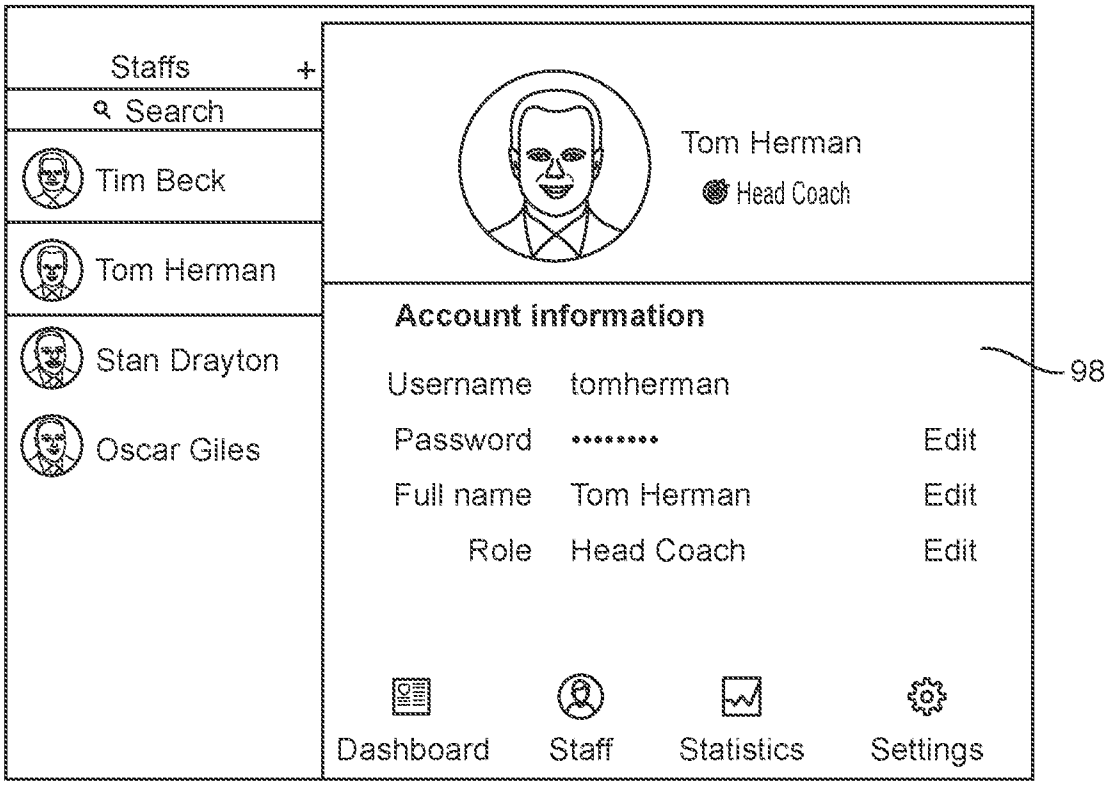


FIG. 10E

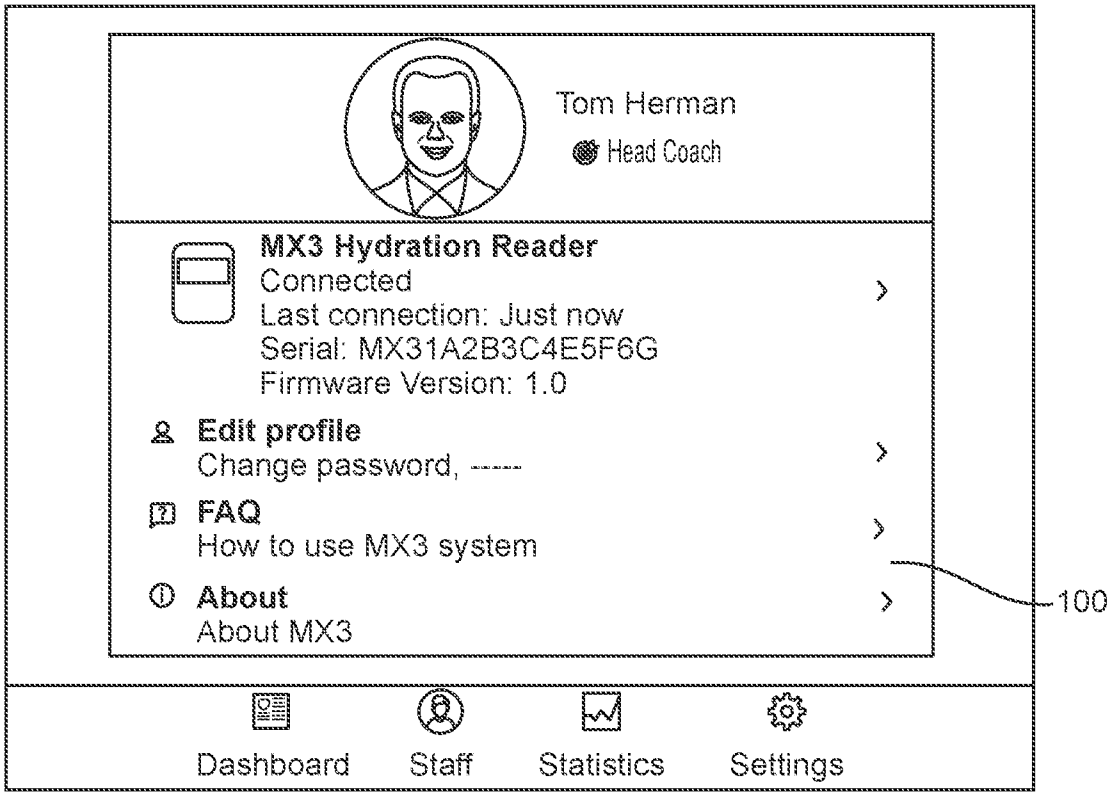


FIG. 10F

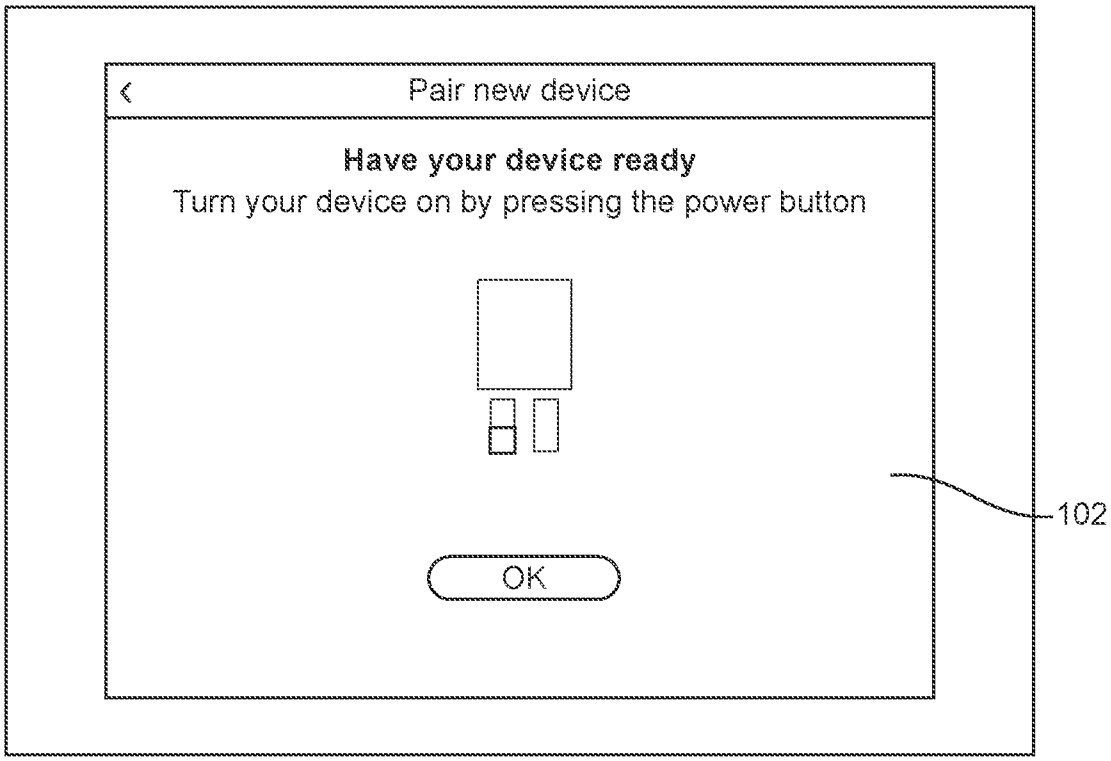


FIG. 10G

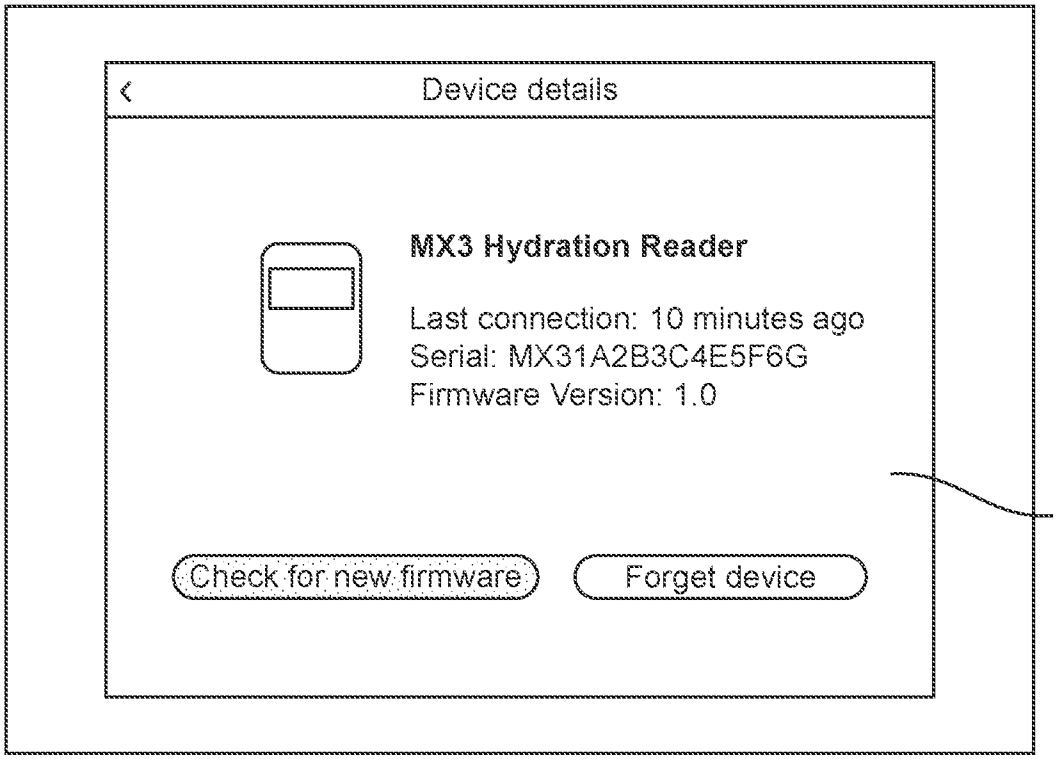


FIG. 10H

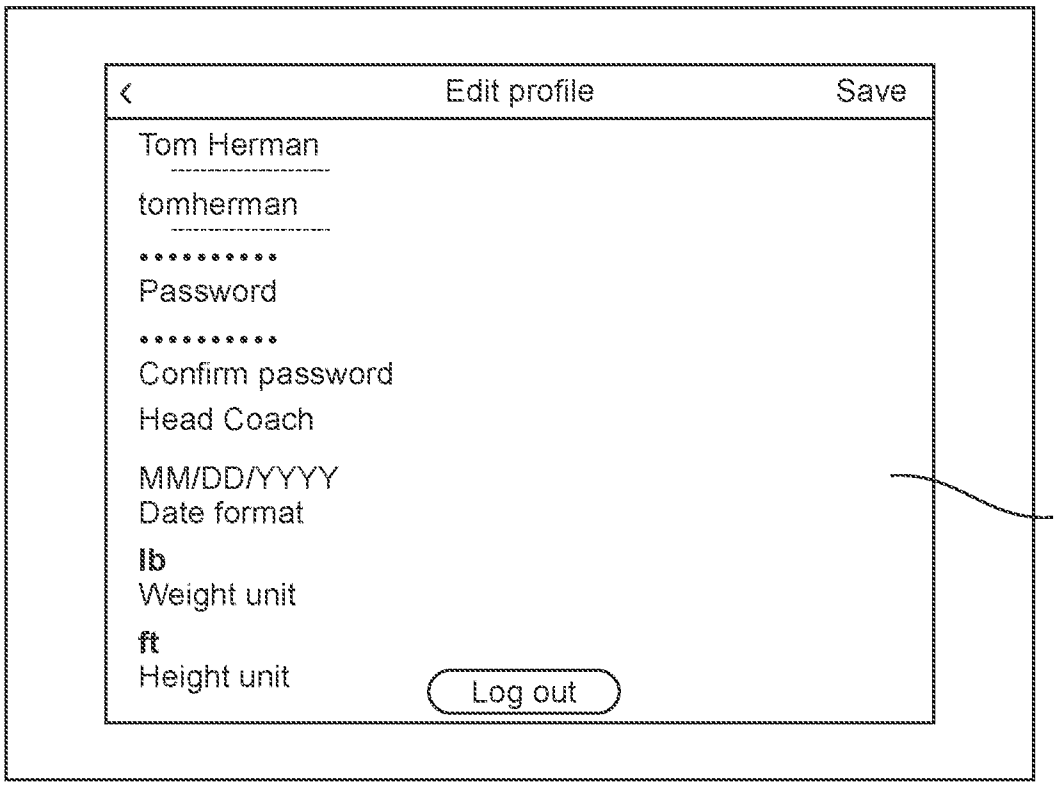


FIG. 10I

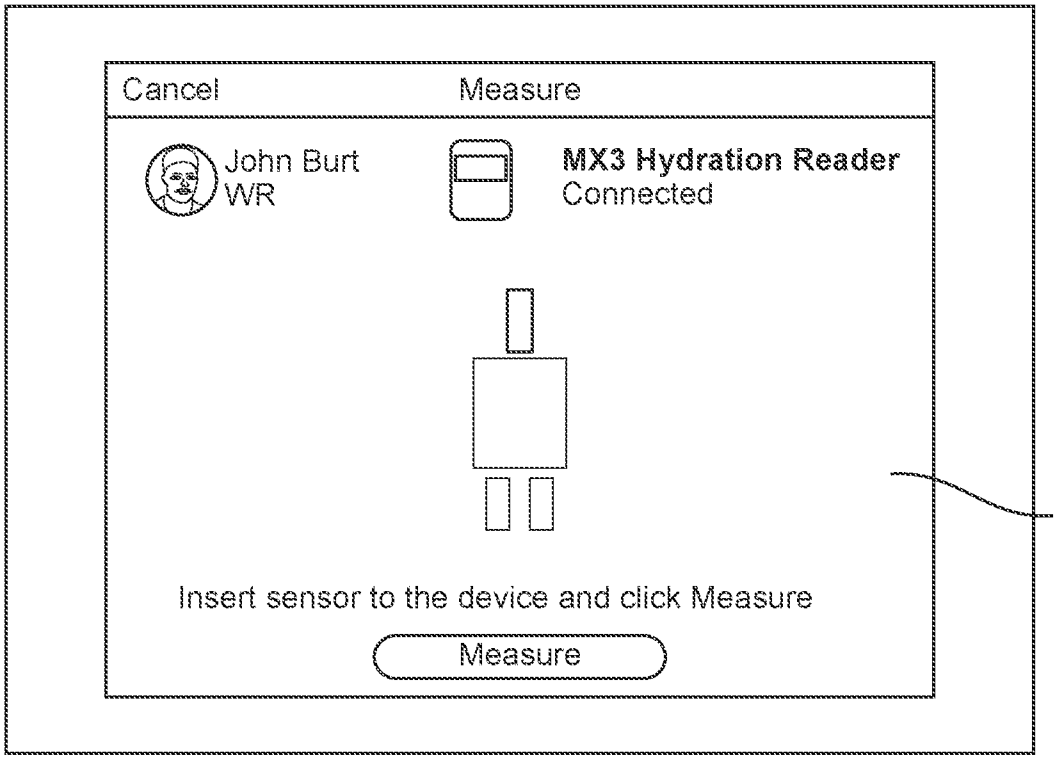


FIG. 10J

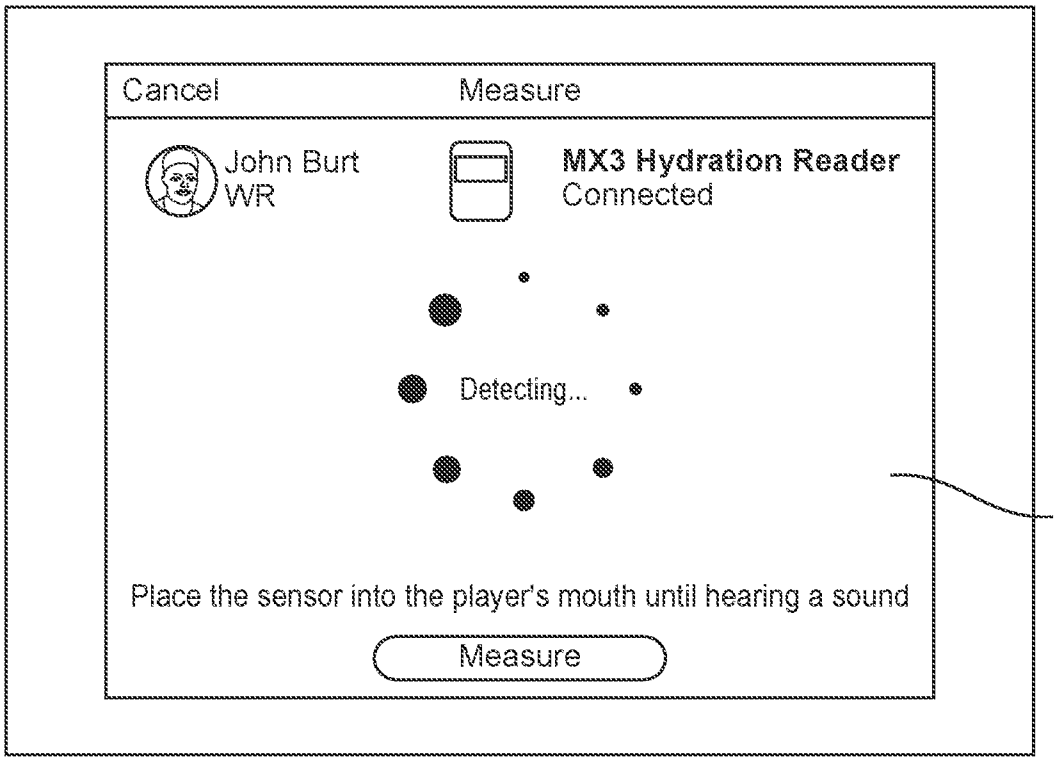


FIG. 10K

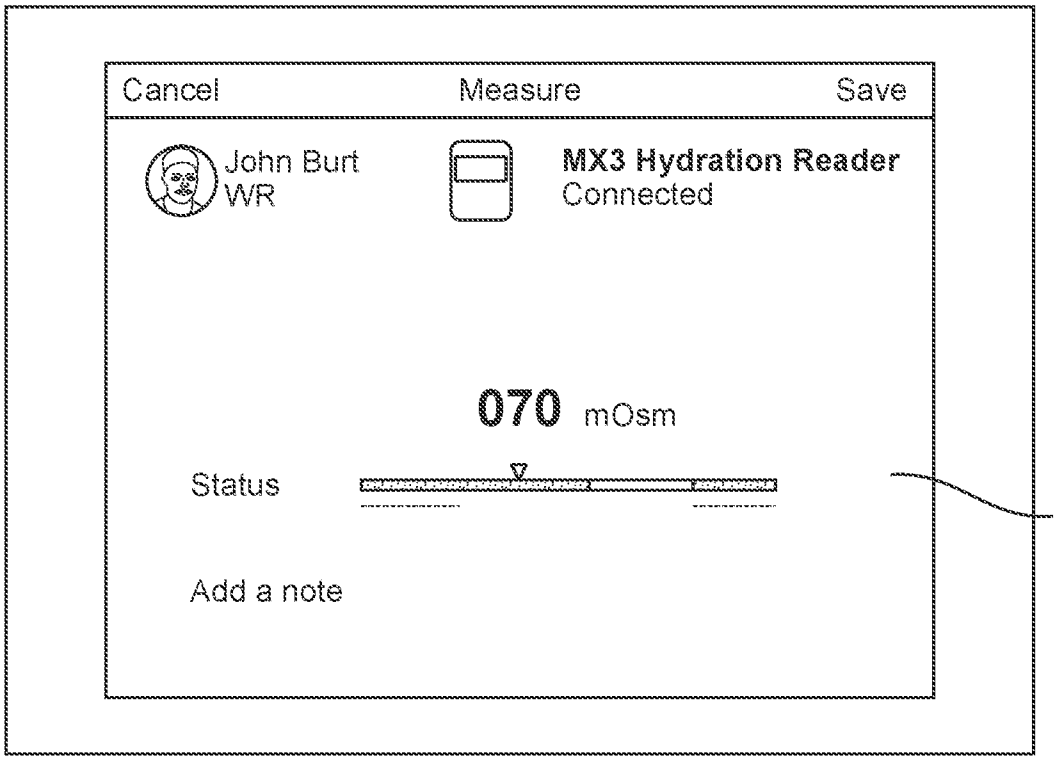

Cancel
Measure
Save
John Burt
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MX3 Hydration Reader
Connected
070 mOsm
Status
Add a note
112

FIG. 10L

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2018/062243

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B5/00 A61B5/145 G01N33/50
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B G01N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2015/226752 A1 (NAZARETH ALBERT R [US] ET AL) 13 August 2015 (2015-08-13) paragraphs [0045], [0046], [0057] - [0059], [0072], [0093]	1-27,31
X	WO 2014/176753 A1 (CHENGDU LINGYU BIOTECHNOLOGY CO LTD [CN]; MA YICAI [CN]) 6 November 2014 (2014-11-06) page 12 page 14, paragraphs 2,4 page 23, paragraph 6 page 24	1-27,31
X	US 2016/011178 A1 (HOENES JOACHIM [DE] ET AL) 14 January 2016 (2016-01-14) paragraphs [0013], [0084], [0113] - [0122], [0173]	1-27,31

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

[X] 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	Date of mailing of the international search report
1 February 2019	03/04/2019

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Knüpling, Moritz

1

Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2018/062243

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2017/138962 A1 (SOUTHERN SARKA O [US]) 18 May 2017 (2017-05-18) paragraphs [0093], [0113], [0202]	1,3,6,9, 10,15, 19,20
A	US 2012/165626 A1 (IRINA FINKELSHTEIN V [US] ET AL) 28 June 2012 (2012-06-28) paragraphs [0009], [0108]	1,4,14, 15
A	US 2008/118397 A1 (SLOWEY PAUL D [US] ET AL) 22 May 2008 (2008-05-22) paragraphs [0055], [0064], [0068], [0069]	1,4,14, 15
A	EP 1 710 565 A1 (HOFFMANN LA ROCHE [CH]; ROCHE DIAGNOSTICS GMBH [DE]) 11 October 2006 (2006-10-11) paragraphs [0033], [0047], [0048]	1,6,7, 14,15,17
A	VLAD ONCESCU ET AL: "Smartphone based health accessory for colorimetric detection of biomarkers in sweat and saliva", LAB ON A CHIP, vol. 13, no. 16, 1 January 2013 (2013-01-01), page 3232, XP055145187, ISSN: 1473-0197, DOI: 10.1039/c3lc50431j abstract page 3233, section "Smartphone application"	1,8,14, 15,18

1

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2018/062243

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

1-27, 31

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-27, 31

   Method, device and computer program for saliva testing comprising contacting mouth or tong

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2. claims: 28-30

   Sensor device comprising electrodes and functionalized mesh

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2018/062243

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2015226752 A1	13-08-2015	NONE	
WO 2014176753 A1	06-11-2014	CN 105393108 A	09-03-2016
		WO 2014176753 A1	06-11-2014
US 2016011178 A1	14-01-2016	CA 2897627 A1	25-09-2014
		CN 105164534 A	16-12-2015
		EP 2781919 A1	24-09-2014
		EP 2976643 A1	27-01-2016
		HK 1218778 A1	10-03-2017
		JP 2016514830 A	23-05-2016
		KR 20150119364 A	23-10-2015
		US 2016011178 A1	14-01-2016
		WO 2014147074 A1	25-09-2014
US 2017138962 A1	18-05-2017	US 2017138962 A1	18-05-2017
		US 2018246125 A1	30-08-2018
US 2012165626 A1	28-06-2012	AU 2010273741 A1	01-03-2012
		CA 2778773 A1	20-01-2011
		EP 2454587 A2	23-05-2012
		US 2012165626 A1	28-06-2012
		WO 2011008581 A2	20-01-2011
US 2008118397 A1	22-05-2008	US 2008118397 A1	22-05-2008
		US 2011268626 A1	03-11-2011
EP 1710565 A1	11-10-2006	EP 1710565 A1	11-10-2006
		WO 2006106084 A1	12-10-2006